IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

AORTIC INNOVATIONS' DISCLOSURE OF ASSERTED CLAIMS AND INFRINGEMENT CONTENTIONS

Plaintiff Aortic Innovations LLC ("Aortic") makes the following infringement disclosures under the Western District of Tennessee Local Patent Rules, LPR 3-1 and 3-2 and the Scheduling Order in this matter. D.I. 21. Aortic makes these disclosures with respect to 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").

Aortic's investigation is ongoing and discovery is in its preliminary stages. Accordingly, these disclosures are based on information available to Aortic at this time. Aortic reserves the right to supplement this disclosure after further discovery from Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc. (collectively, "Edwards") and non-parties. Aortic also reserves the right to assert additional claims of the Patents-in-Suit, accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards' products.

Edwards v. Aortic Innovations
U.S. Patent 11,337,834
Edwards Ex. 1123

I. DISCLOSURE OF ASSERTED CLAIMS AND PRELIMINARY INFRINGEMENT CONTENTIONS PURSUANT TO LPR 3-1

A. Asserted Claims

Edwards has infringed and continues to infringe at least the following claims of the Patents-in-Suit:

- '834 Patent: claims 1-6, 8-11, 13-18
- '310 Patent: claims 1, 3, 5, 8, 11, 13
- '033 Patent: claims 1, 5
- '364 Patent: claims 1-7, 9
- '918 Patent: claims 1, 4-10, 16-17, 20-22, 26

Aortic reserves the right to seek leave of court to amend this list of asserted claims if merited by further discovery, the Court's claim construction, or other circumstances. Aortic incorporates by reference the allegations and evidence contained and referenced in Aortic's Second Amended Complaint and any amendments or supplements thereto.

B. Accused Instrumentalities

The accused instrumentalities for all Patents-in-Suit are: all models, versions and sizes of Edwards' Sapien 3 Ultra (with both Resilia and non-Resilia leaflets) the same and similar to those identified in the claim charts attached as Exhibits A-E ("Accused Instrumentalities"). Discovery is ongoing and Aortic reserves the right to amend the identified Accused Instrumentalities to the extent that additional relevant information is obtained during discovery, or if merited by the Court's claim construction or other circumstances.

C. Claim Charts

Claim charts mapping each claim element of the asserted claims to the Accused Instrumentalities are attached as Exhibits A-E. Aortic reserves the right to amend these claim

charts, as well as other information contained in this document and the exhibits hereto to incorporate new information learned during the course of discovery, including, but not limited to, information that is not publicly available or readily discernible without discovery. In an effort to focus the issues, Aortic identifies exemplary evidence for each claim limitation. The evidence cited for a particular claim element should be considered in light of the additional evidence cited for the other claim elements. Aortic reserves the right to rely on evidence cited for any particular element of an asserted claim for any other elements of the asserted claims. Aortic also incorporates by reference the evidence and allegations contained in Aortic's Second Amended Complaint.

Edwards makes, has made, uses, has used, imports, has imported, exports, has exported, offers to sell, has offered to sell, sells and/or has sold the Accused Instrumentalities and has directly infringed and continues to directly infringe each of the asserted claims as specified in Exhibits A-E ('834, '310, '033, '364, and '918 Patents). On information and belief, Edwards' employees, consultants and agents (including any physicians retained as employees or consultants) use the Sapien 3 Ultra TAVR as part of design and development activities, testing, customer support, training, sales, marketing, in preparation for TAVR procedures and/or are otherwise. On information and belief, Edwards' employees and consultants use the claimed TAVRs as part of their demonstration to and instruction of other physicians on how to use and deploy the Sapien 3 Ultra device. On further information and belief, Edwards uses the claimed TAVRs when it uses and tests the Sapien 3 Ultra in animals and/or cadavers as part of its development, optimization, quality control, adverse event testing and/or for other reasons. Edwards directly infringes the asserted '834, '310, '033, '364, and '918 Patent claims when it performs the aforementioned activities in the United States.

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the Asserted Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, offers for sale, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See* https://ir.edwards.com/events-presentations/;

https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths.

Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the Accused Instrumentalities for testing, instruction, demonstration or otherwise. *See, e.g.*, https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences.").

In addition, the '834, '310, '033, '364, and '918 asserted claims are infringed when Edwards offers for sale and sells the Accused Instrumentalities. Edwards offers for sale and promotes the 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 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.

Edwards is also a direct infringer under 35 U.S.C. § 271(a) of the '834, '310, '033, '364, and '918 Patents because Edwards controls and/or directs third parties, including Edwards' customers, consultants, proctors, physicians, hospitals, and others, to use the claimed assemblies and apparatuses. Edwards conditions use and receipt of the benefit of the claimed assemblies and apparatuses on use of the Accused Instrumentalities in an infringing manner, and Edwards establishes the manner and/or timing of doing so, by way of the foregoing conduct, thus further establishing Edwards as a direct infringer under 35 U.S.C. § 271(a). *See, e.g.*, Edwards' consignment, use, and/or other agreements with hospitals.

Edwards indirectly infringes the '834, '310, '033, '364, and '918 Patents, as provided in 35 U.S.C. § 271(b), including by inducing infringement by others, such as Edwards' customers, end-users, doctors, hospitals, medical professionals, and/or other Edwards entities in this district and elsewhere in the United States. For example, Edwards' customers, end-users, doctors, hospitals, medical professionals, and other Edwards entities directly infringe through their use of the inventions claimed in the '834, '310, '033, '364, and '918 Patents. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, and providing direction, instruction, documentation, and other information to Edwards' customers, end-users, doctors, hospitals,

medical professionals, and other Edwards entities suggesting they use the Accused Instrumentalities in an infringing manner, including instructions for use, technical and training support (e.g., though clinical specialists, physicians, and sales personnel), instructional seminars and classes, online technical support, marketing, product manuals, advertisements, online documentation, marketing materials, technical specifications, data sheets, web pages on its website, press releases, user manuals, scientific publications, and online videos, including all of the Edwards documentation cited in Aortic's Second Amended Complaint, herein and in the exhibits attached as exemplary evidence of infringement. By way of example, Edwards' instructions, documentation, and videos cited herein and in the exhibits instruct, promote, and encourage the use of the Accused Instrumentalities in an infringing manner, as provided in more detail in the attached claim charts and as explained in the Second Amended Complaint. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a "watchful eye" over doctors and other medical staff before and during such procedures. *See, e.g.*, Edwards' consignment, use, and/or other agreements with hospitals. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. *See* Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards' inducement, Edwards' customers, end-users, doctors, hospitals, medical professionals, and other Edwards entities use the Accused Instrumentalities in the way Edwards intends and directly infringe the '834, '310, '033, '364, and '918 Patents. Edwards performs these affirmative acts with knowledge or willful blindness of the '834, '310, '033, '364, and '918 Patents and with the intent, or willful

blindness, that the induced acts directly infringe the ‘834, ’310, ‘033, ‘364, and ‘918 Patents. Edwards has had knowledge and notice of the ‘834, ’310, ‘033, ‘364, and ‘918 Patents at least from Aortic’s notice correspondence discussed further herein and in the Second Amended Complaint and also from the filing of the Second Amended Complaint. On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to doctors, patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement# Edwards performs these affirmative acts with knowledge or willful blindness of the ‘834, ’310, ‘033, ‘364, and ‘918 Patents and with the intent, or willful blindness, that the actions of affiliates and others referenced above directly infringe the ‘834, ’310, ‘033, ‘364, and ‘918 Patents. Edwards has had knowledge and notice of the ‘834, ’310, ‘033, ‘364, and ‘918 Patents at least from Aortic’s notice correspondence and before discussed further herein and in the Second Amended Complaint.

Edwards also indirectly infringes the ‘834, ’310, ‘033, ‘364, and ‘918 Patents, as provided in 35 U.S.C. § 271(c), including by contributing to the infringement by others, such as Edwards’ customers, end-users, doctors, hospitals, medical professionals, and/or other Edwards entities, in this district and elsewhere in the United States. For example, Edwards’ affirmative acts of selling and offering to sell, in this District and elsewhere in the United States, the Accused Instrumentalities and/or components thereof and causing the Accused Instrumentalities to be made, used, sold, and offered for sale, contribute to Edwards’ customers’, doctors’, hospital personnel’s, other end-users’, and other Edwards entities’ direct infringement of the ‘834, ’310, ‘033, ‘364, and ‘918 Patents. The Accused Instrumentalities and accused components within the Accused Instrumentalities, including but not limited to the fiber sealing skirt, the inner skirt, and/or other components and features and related components provided by Edwards, are material to the

inventions of the ‘834, ’310, ‘033, ‘364, and ‘918 Patents, 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, ’310, ‘033, ‘364, and ‘918 Patents. For example, Edwards’ Accused Instrumentalities and components thereof when used and assembled are designed and advertised to be de delivered endovascularly and to prevent paravalvular leaks. *See, e.g.*, D.I. 1, Ex. 47 (“Textured 3-dimensional PET skirt design … 40% taller skirt – up to 50% more contact surface area with native anatomy … 14F sheath compatible”); D.I. 1, Ex. 46 (“Edwards Sapien 3 Ultra features uniform sealing designed to minimize PVL.”); *Id*. (“14F … low profile access leads to significant reduction in major vascular complications”); D.I. 1, Ex. 45 (“knitted outer skirt featuring a velour texture on one side”); D.I 1, Ex. 43; D.I. 1, Ex. 39 (“Less pain, fewer days in the hospital, and shorter recovery time … Open heart surgery can take months to heal from, but with Edwards TAVR, you can get back to your life sooner.”); D.I. 1, Ex. 33 (“Edwards SAPIEN 3 Ultra is engineered for your patient’s future … 0% ≥ moderate PVL at 30 days … In severe AS, moderate PVL is associated with increased mortality and rehospitalization.”); D.I. 1, Ex. 37 (video demonstrating transfemoral delivery); D.I. 1, Ex. 44 (Sapien 3 Ultra Instructions for Use). Edwards contributes to this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities and components thereof, and providing instruction, documentation, and other information and materials to customers, end-users, doctors, hospitals, medical professionals, and/or other Edwards entities suggesting they assemble and use the Accused Instrumentalities in an infringing manner, including instructions for use, technical and training support (e.g., though clinical specialists, physicians, and sales personnel), instructional seminars and classes, online technical support, marketing, product manuals, advertisements, online documentation, marketing

materials, technical specifications, data sheets, web pages on its website, press releases, scientific publications, user manuals, and online videos, including all of the Edwards documentation cited herein and in the exhibits attached as exemplary evidence of infringement. As a result of Edwards' actions, Edwards' customers, end-users, doctors, hospitals, medical professionals, and/or other Edwards entities assemble and use the Accused Instrumentalities and components thereof in the way Edwards intends and directly infringe the '834, '310, '033, '364, and '918 Patents. Edwards performs these affirmative acts with knowledge or willful blindness of the '834, '310, '033, '364, and '918 Patents and with the intent, or willful blindness, that the actions of affiliates and others referenced above directly infringe the '834, '310, '033, '364, and '918 Patents. Edwards has had knowledge and notice of the '834, '310, '033, '364, and '918 Patents at least from Aortic's notice correspondence and before as discussed further herein and in the Second Amended Complaint.

Edwards is also liable for infringement under 35 U.S.C. § 271(f), when 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 and infringes the '834, '310, '033, '364, and '918 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, in whole or in part, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

Edwards performs the foregoing affirmative acts with knowledge or willful blindness of the '834, '310, '033, '364, and '918 Patents and with the intent, or willful blindness, that the actions of affiliates and others referenced above directly infringe the '834, '310, '033, '364, and '918 Patents. Edwards has had knowledge and notice of the '834, '310, '033, '364, and '918 Patents at

least from Aortic's notice correspondence and before as discussed further herein and in the Second Amended Complaint.

D. Literal Infringement and Doctrine of Equivalents

With any exceptions noted in the claim charts, Aortic asserts that, under the proper construction of the asserted claims and their claim terms, the elements of the asserted claims of the Patents-in-Suit are literally present in the Accused Instrumentalities or acts accused of infringing the claims, as set forth in the claim charts attached hereto as Exhibits A-E. Aortic identifies claim elements which it contends, based on current knowledge, are satisfied under the Doctrine of Equivalents. *See* Exhibits A-E. Aortic contends that any and all elements found not to be literally infringed are infringed under the doctrine of equivalents because the differences between the claimed inventions and the accused instrumentalities, if any, are insubstantial.

Aortic's contention is that each claim element literally met, necessarily also would be met under the doctrine of equivalents because there are no substantial differences between the Accused Instrumentalities and the claims, in function, way, or result. As such, Aortic's current description of the function, way, and result for each element would correspond to the claim language itself. If Edwards attempts to argue that there is no infringement literally and also no infringement under doctrine of equivalents and attempts to draw any distinction between a claim element and the Accused Instrumentalities, then Aortic reserves its right to rebut the alleged distinction as a matter of literal infringement and/or as to whether any such distinction is substantial under the doctrine of equivalents.

Aortic reserves the right to amend or supplement its Infringement Contentions as to literal infringement or infringement under the doctrine of equivalents in light of new information learned during the course of discovery and the Court's claim construction, or other circumstances meriting amendment or supplementation. Further, Aortic reserves the right to rely on its doctrine of

equivalents disclosures in the attached exhibits for similar claim elements in the same and/or in other asserted patents.

E. Priority Dates to Earlier Applications

’834 Patent

The ’834 Patent was filed as U.S. Patent Application No. 17/327,673 on May 22, 2021, which is a continuation of U.S. Patent Application No. 17/213,251, which was filed on Mar. 26, 2021, which is a continuation of U.S. Patent Application No 17/096,253, 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 No. 17/060,557 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 No. 16/910,189 filed on Jun. 24, 2020 and issued as U.S. Pat. No. 10,857,011 on Dec. 8, 2020, which is a continuation of U.S. Patent Application No. 16/808,137 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 No. 16/736,879 filed on Jan. 8, 2020 and issued as U.S. Pat. No. 10,842,655 on Nov. 24, 2020, which is a continuation of U.S. Patent Application No. 16/042,286 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 No. 14/614,628 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 No. 14/569,306 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 No. 13/706,896 filed on Dec. 6, 2012 and issued as U.S. Pat. No. 8,940,040 on Jan. 27, 2015, which claims priority to U.S. Provisional Application No. 61/567,458 filed on Dec. 6, 2011 and to U.S. Provisional Application No. 61/723,446 filed on Nov. 7, 2012. All asserted claims of the ’834 Patent are entitled to a priority date of no later than Nov. 7, 2012.

’310 Patent

The ’310 Patent was filed as U.S. Patent Application No. 16/941,117 on Jul. 28, 2020, which is a continuation of U.S. Patent Application No. 16/935,261, which was filed on Jul. 22, 2020, which is a continuation of U.S. Patent Application No. 16/808,137 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 No. 16/736,879 filed on Jan. 8, 2020 and issued as U.S. Pat. No. 10,842,655 on Nov. 24, 2020, which is a continuation of U.S. Patent Application No. 16/042,286 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 No. 14/614,628 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 No. 14/569,306 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 No. 13/706,896 filed on Dec. 6, 2012 and issued as U.S. Pat. No. 8,940,040 on Jan. 27, 2015, which claims priority to U.S. Provisional Application No. 61/567,458 filed on Dec. 6, 2011 and to U.S. Provisional Application No. 61/723,446 filed on Nov. 7, 2012. All asserted claims of the ’310 Patent are entitled to a priority date of no later than Nov. 7, 2012.

’033 Patent

The ’033 Patent was filed as U.S. Patent Application No. 17/719,160 on April 12, 2022, which is a continuation of U.S. Patent Application No. 17/213,251, which was filed on Mar. 26, 2021, which is a continuation of U.S. Patent Application No 17/096,253, 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 No. 17/060,557 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 No. 16/910,189 filed on Jun. 24, 2020 and issued as U.S. Pat. No. 10,857,011 on Dec. 8, 2020, which is a continuation of U.S. Patent Application No. 16/808,137 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 No. 16/736,879 filed on Jan. 8, 2020 and issued as U.S. Pat. No. 10,842,655 on Nov. 24, 2020, which is a continuation of U.S. Patent Application No. 16/042,286 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 No. 14/614,628 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 No. 14/569,306 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 No. 13/706,896 filed on Dec. 6, 2012 and issued as U.S. Pat. No. 8,940,040 on Jan. 27, 2015, which claims priority to U.S. Provisional Application No. 61/567,458 filed on Dec. 6, 2011 and to U.S. Provisional Application No. 61/723,446 filed on Nov. 7, 2012. All asserted claims of the ’033 Patent are entitled to a priority date of no later than Nov. 7, 2012.

’634 Patent

The ’634 Patent was filed as U.S. Patent Application No. 17/469,391 on Sept. 8, 2021, which is a continuation of U.S. Patent Application No. 17/213,251, which was filed on Mar. 26, 2021, which is a continuation of U.S. Patent Application No 17/096,253, 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 No. 17/060,557 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 No. 16/910,189 filed on Jun. 24, 2020 and issued as U.S. Pat. No. 10,857,011 on Dec. 8, 2020, which is a continuation of U.S. Patent Application No. 16/808,137 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 No. 16/736,879 filed on Jan. 8, 2020 and issued as U.S. Pat. No. 10,842,655 on Nov. 24, 2020, which is a continuation of U.S. Patent Application No. 16/042,286 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 No. 14/614,628 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 No. 14/569,306 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 No. 13/706,896 filed on Dec. 6, 2012 and issued as U.S. Pat. No. 8,940,040 on Jan. 27, 2015, which claims priority to U.S. Provisional Application No. 61/567,458 filed on Dec. 6, 2011 and to U.S. Provisional Application No. 61/723,446 filed on Nov. 7, 2012. All asserted claims of the ’634 Patent are entitled to a priority date of no later than Nov. 7, 2012.

’918 Patent

The ’918 Patent was filed as U.S. Patent Application No. 17/213,251 on Mar. 26, 2021, which is a continuation of U.S. Patent Application No 17/096,253, 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 No. 17/060,557 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 No. 16/910,189 filed on Jun. 24, 2020 and issued as U.S. Pat. No. 10,857,011 on Dec. 8, 2020, which is a continuation of U.S. Patent Application No. 16/808,137 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 No. 16/736,879 filed on Jan. 8, 2020 and issued as U.S. Pat. No. 10,842,655 on Nov. 24, 2020, which is a continuation of U.S. Patent Application No. 16/042,286 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 No. 14/614,628 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 No. 14/569,306 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 No. 13/706,896 filed on Dec.

6, 2012 and issued as U.S. Pat. No. 8,940,040 on Jan. 27, 2015, which claims priority to U.S. Provisional Application No. 61/567,458 filed on Dec. 6, 2011 and to U.S. Provisional Application No. 61/723,446 filed on Nov. 7, 2012. All asserted claims of the ’918 Patent are entitled to a priority date of no later than Nov. 7, 2012.

F. Edwards’ Willful Infringement

Aortic contends that Edwards’ infringement of each the ‘834, ’310, ‘033, ‘364, and ‘918 Patents is and has been willful. Aortic’s willfulness allegations are set forth its Complaint and/or any amendments thereto which is incorporated herein in its entirety. D.I. 1. As detailed in the Aortic’s Complaint, Edwards has been aware of Aortic’s patent applications directed towards a TAVR design with outwardly extending fibers since at least as early as November, 2014 and has had direct dealings with Dr. Shahriari regarding his inventions since at least April 2017.

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 radially 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.

Further, prior to filing suit, Aortic 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. Don Bobo and Keith Newburry (Edwards’ Vice President, Chief Intellectual Property Counsel) expressly informing them of Edwards’ practice of the Aortic portfolio including the ’846, ’538, ’236 Patents and related patents and patent publications 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. D.I. 1, Ex. 22.

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." D.I. 1, Ex. 49. On information and belief, after receiving notice and performing its investigation, Edwards has not ceased its practice of the '846, '538, and '236 Patents.

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. D.I. 1, Ex. 50.

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.

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 who 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." D.I. 1, Ex. 51.

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

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. D.I. 1, Ex. 22.

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 in litigation for years.

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.

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.").

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. Each of Aortic's '834, '310, '033, '634, and '918 patents include claims without an "inner frame" limitation. On information and belief, the foregoing reflects that Edwards has followed the prosecution and issuance of Aortic's '834, '310, '033, '634, and '918 patents and their claims and has been aware and on notice of its infringement of one or more claims in those patents since around the time of their issuance. 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.

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 on or around the dates of their issuance on May 24, 2022, July 19, 2022, Nov. 8, 2022, Nov. 15, 2022, and Dec. 13, 2022, respectively.

Further, on February 15, 2023 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. D.I. 1, 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.*, D.I. 1, Exs. 76-80.

In light of Edwards' knowledge and notice of Dr. Shahriari's inventions, the '834, '310, '033, '634, and '918 Patents, its continued infringement, and its lack of good faith in the potential licensing discussions, Edwards' conduct has been egregious. As demonstrated by the foregoing, Edwards' infringement of the '834, '310, '033, '634, and '918 Patents has been, and continues to be, without permission, consent, authorization, or license. As a result, Edwards' conduct was and is willful and egregious.

II. PRODUCTION OF DOCUMENTS PURSUANT TO LPR 3-2

Aortic is producing or making available for inspection documents that are in Aortic's possession, custody or control as set forth in Western District of Tennessee Local Patent Rules, LPR 3-2. A Production Index identifying these documents is below.

This preliminary identification of documents is for convenience and is not an admission that each document falls within any exemplary categories in the Western District of Tennessee Local Patent Rules, or that any identified document suggests, evidences or qualifies as prior art or necessarily reflects or relates to an embodying product of any of the Patents-in-Suit. Aortic's investigation is ongoing and Aortic reserves its right to add to, delete from, or otherwise modify its disclosures in this section as its investigation proceeds. Any document identified within one particular category may be relevant to other categories and/or used by Aortic for purposes of showing conception and/or reduction to practice.

AORTIC'S PRODUCTION INDEX

LPR 3-2(a):

Bates Begin:	**Bates End:**
N/A	N/A

LPR 3-2(b):

Bates Begin:	**Bates End:**
AORTIC00000001	AORTIC00000049
See also LPR 3-2(c) documents	

LPR 3-2(c):

Bates Begin:	Bates End:
AORTIC00000050	AORTIC00000472
AORTIC00000489	AORTIC00010186
AORTIC00023134	AORTIC00023300
AORTIC00023310	AORTIC00023847
AORTIC00023851	AORTIC00024494
AORTIC00024498	AORTIC00028647

LPR 3-2(d):

Bates Begin:	Bates End:
AORTIC00000473	AORTIC00000488
AORTIC00023301	AORTIC0023309
AORTIC00023848	AORTIC00023850
AORTIC00024495	AORTIC00024497

Dated: June 5, 2023

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ATTORNEYS FOR PLAINTIFF
AORTIC INNOVATIONS LLC

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing document has been served on all counsel of record via email on June 5, 2023.

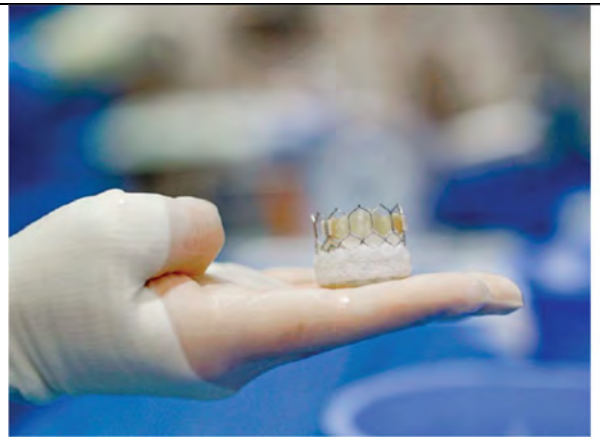
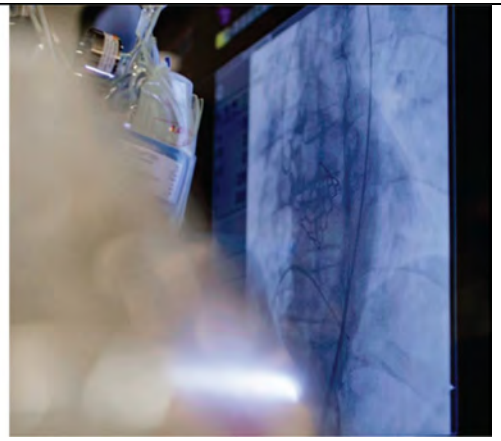
/s/ *Adam W. Poff*
Adam W. Poff

Exhibit A - Edwards' Infringement of U.S. Patent No. 11,337,834

Claim	Exemplary Infringement Evidence[1]
1. An endovascular prosthetic heart valve for use in a patient, comprising:	To the extent the preamble is limiting, the '834 patent Accused Instrumentalities[2] satisfy this element. For example, the '834 patent Accused Instrumentalities are endovascular prosthetic heart valves for use in a patient. The '834 patent Accused Instrumentalities are designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems.

[1] The exemplary evidence and infringement assertions cited herein may also be used to support any other claim element where appropriate. Aortic Innovation LLC's ("Aortic") investigation is ongoing and discovery is in its preliminary stages. Aortic hereby incorporates by reference the cover pleading to which this claim chart is attached. Aortic reserves the right to amend or supplement these contentions after further investigation and discovery from Edwards and non-parties and in accordance with the rules and schedule. Such supplemental information may include, but is not limited to, FDA submissions and correspondence, data sheets, design specifications, deposition testimony, testing information, reference designs, implementation and utilization information, and/or schematics. Aortic also reserves the right to assert additional claims of the Aortic patents-in-suit, accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products. Under the proper construction of the asserted claims and their claim terms, each element of the asserted claims is literally present in the accused products or acts accused of infringing the claim. Any and all elements found not to be literally infringed are infringed under the doctrine of equivalents because the differences between the claimed inventions and the Accused Instrumentalities, if any, are insubstantial. Aortic further reserves the right to accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products, based on further investigation and discovery, the claim construction process, the Court's rules, and/or other circumstances so meriting.

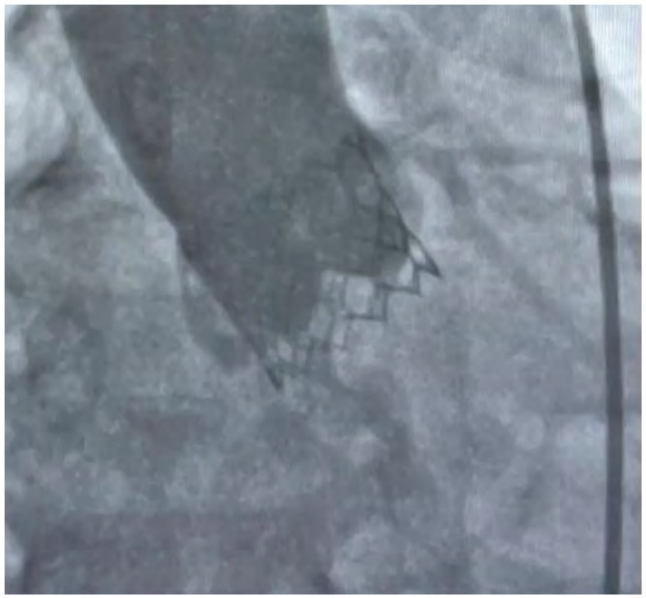
[2] "Accused Instrumentalities" refers to all models, versions, and sizes of Edwards's Sapien 3 Ultra devices, including, but not limited to Edwards Sapien 3 Ultra valves with non-Resilia valve leaflets and Edwards Sapien 3 Ultra Resilia valves, which Aortic understands to be the same as the Sapien 3 Ultra, but with Edwards' Resilia valve leaflet tissue which Aortic understands uses "a bovine (cow) heart tissue that has been treated with Edwards' technology to block calcium build-up on the valve." Discovery is ongoing and Aortic reserves the right to amend or supplement the identified Accused Instrumentalities to the extent that additional relevant information is obtained during discovery.

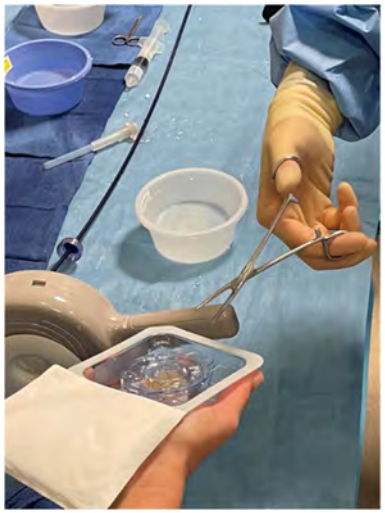
	  https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



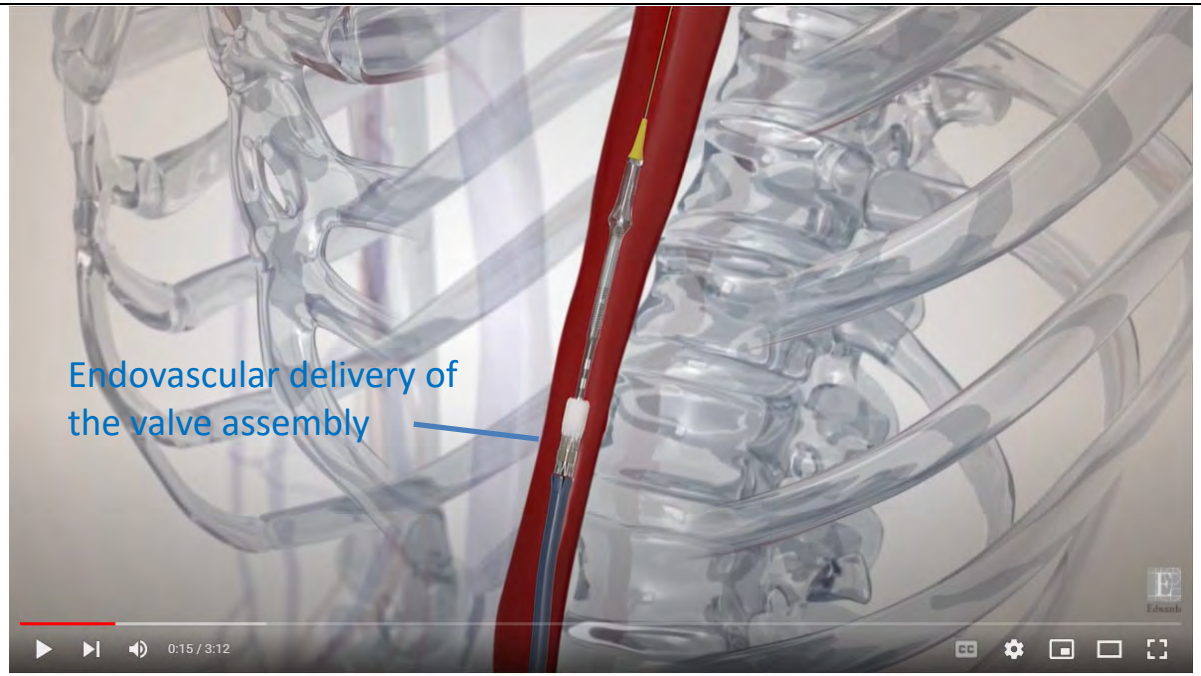


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra[3] is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[3] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.



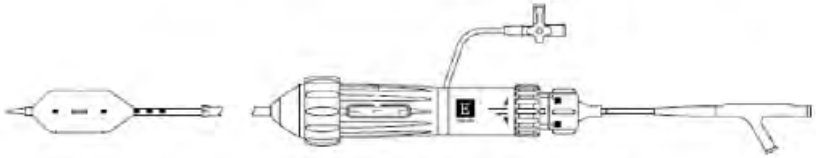
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



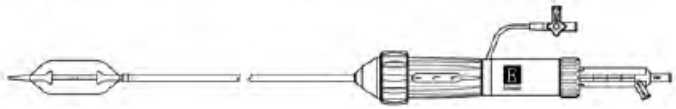
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

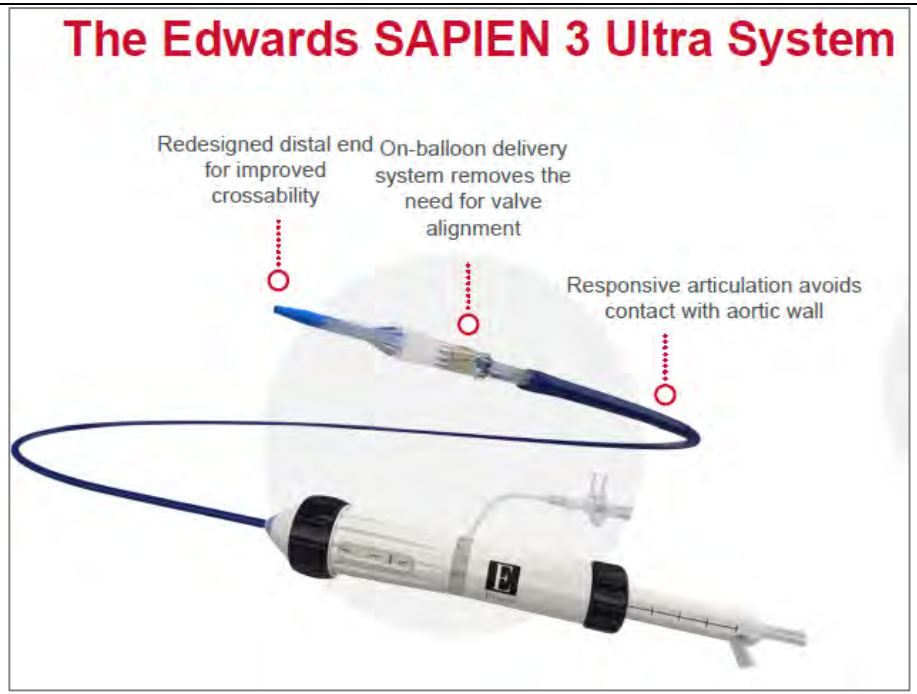
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

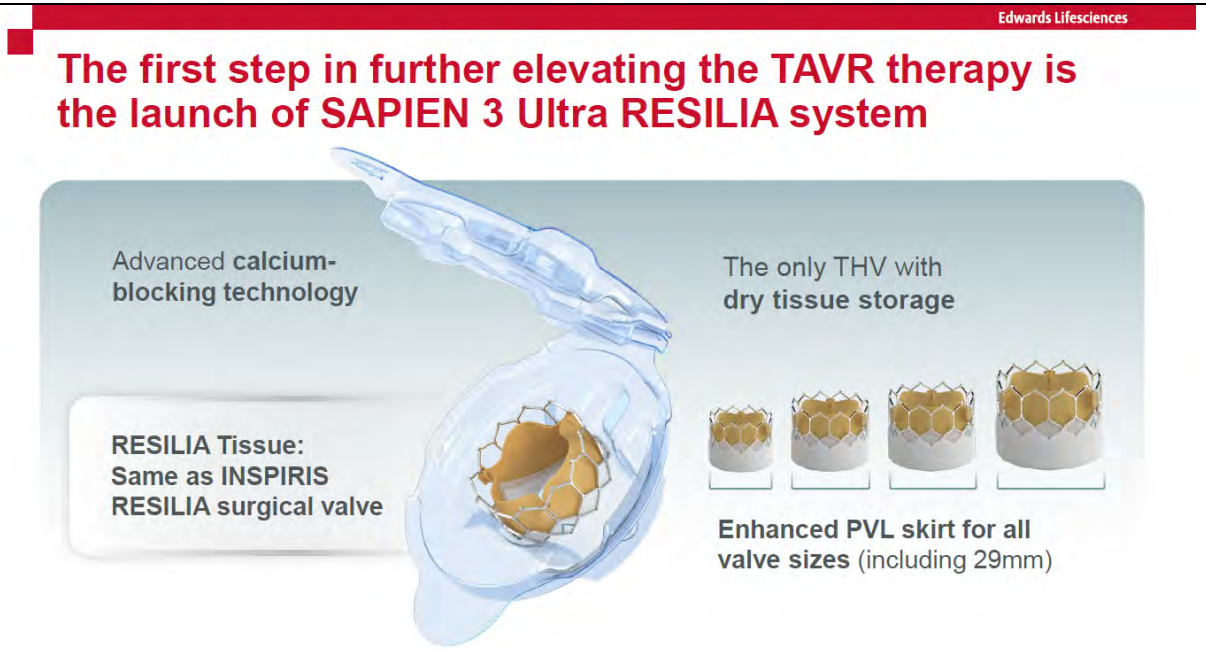
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

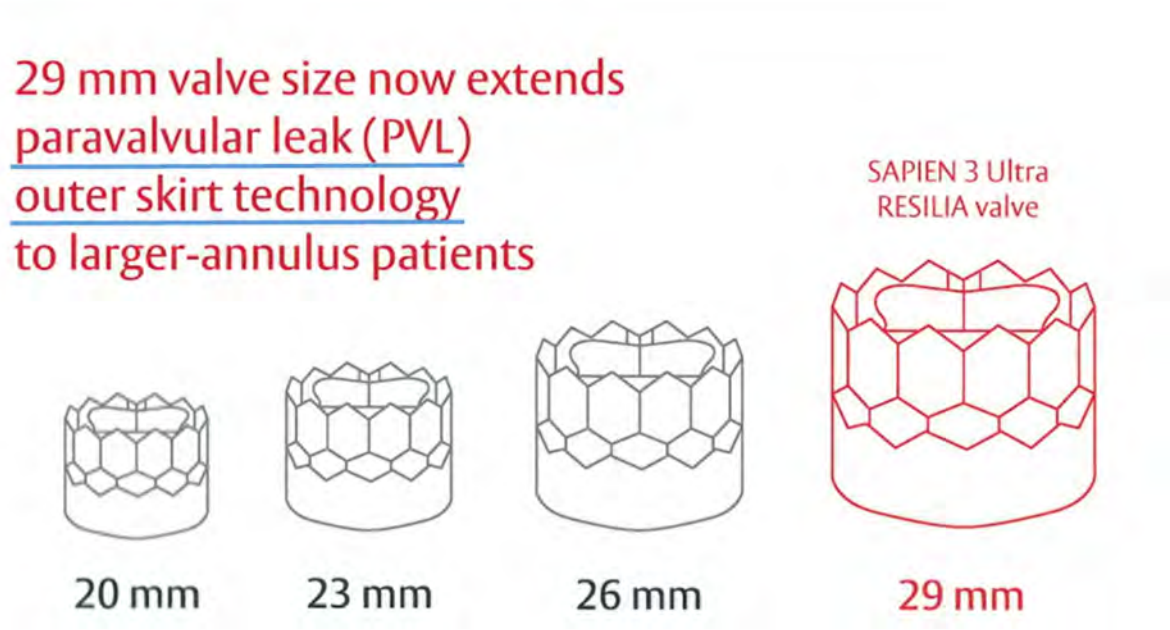
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

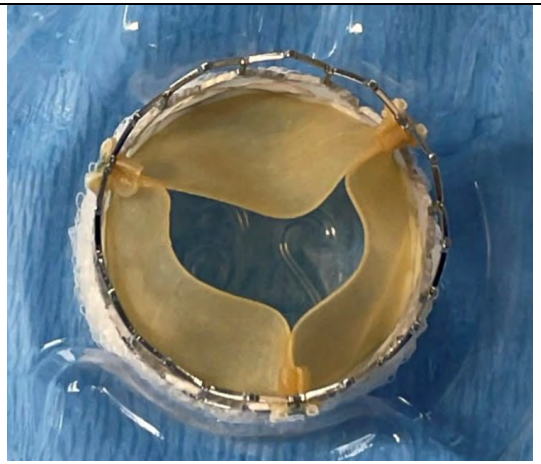
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’834 patent Accused Instrumentalities and infringes the ’834 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



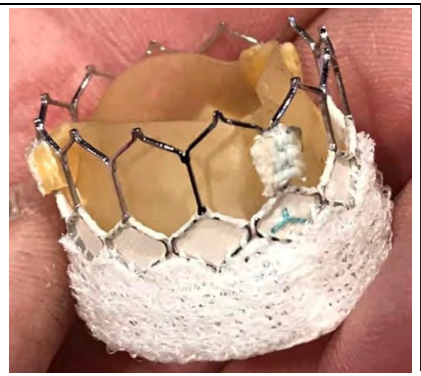
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



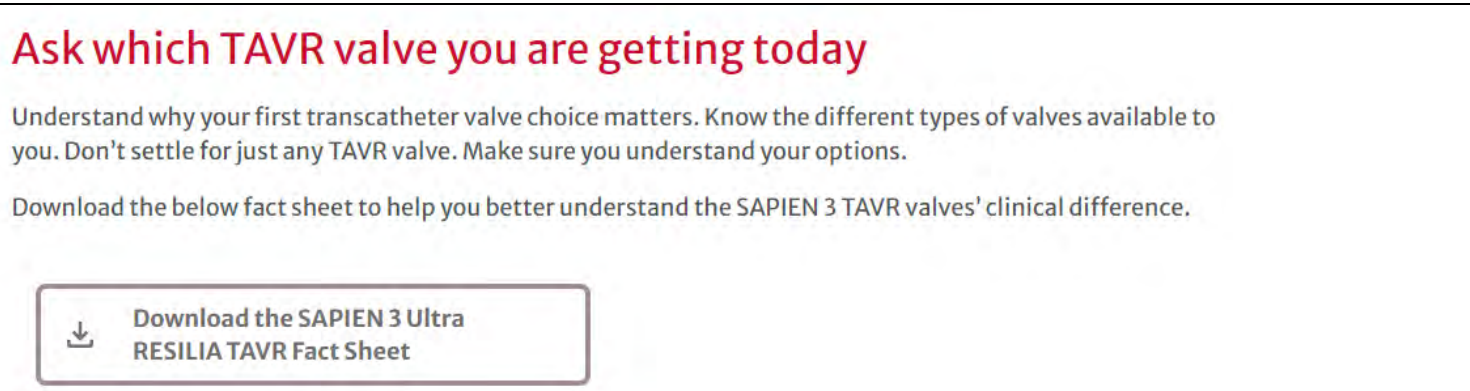

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the '834 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See* https://ir.edwards.com/events-presentations/;

	https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '834 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '834 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '834 asserted claims are infringed when Edwards offers for sale and sells the '834 patent Accused Instrumentalities. Edwards offers for sale and promotes the '834 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 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. 

	 https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

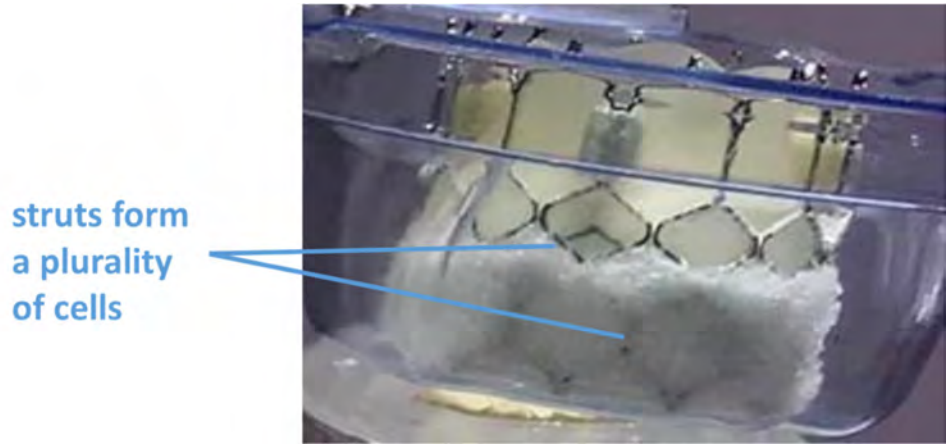


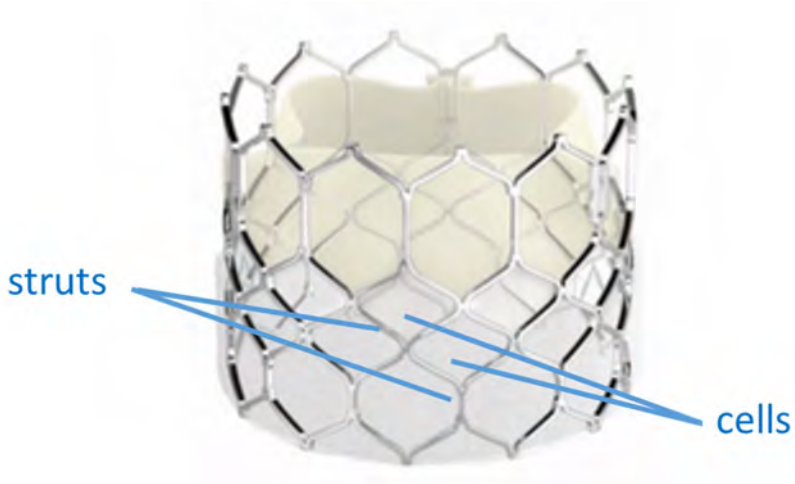
https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61).

On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement#

Further, the '834 patent asserted claims 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 in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the '834 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards' direct and induced infringement. For further example, on information and belief, Edwards's affiliated hospitals and doctors directly infringe the asserted '834 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a "watchful eye" over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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. 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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards's affirmative acts of marketing, selling and offering to

	sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' combination and use of the Accused Instrumentalities, such that the '834 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards' knowledge of Aortic's inventions, the patents-in-suit (including the '834 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
a frame formed of a plurality of struts that cooperate to form a plurality of cells,	The '834 patent Accused Instrumentalities satisfy this element. The '834 patent Accused Instrumentalities comprise a frame formed of a plurality of struts that cooperate to form a plurality of cells. For example, the Sapien 3 Ultra frame is formed of struts that together form a plurality of cells.  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).

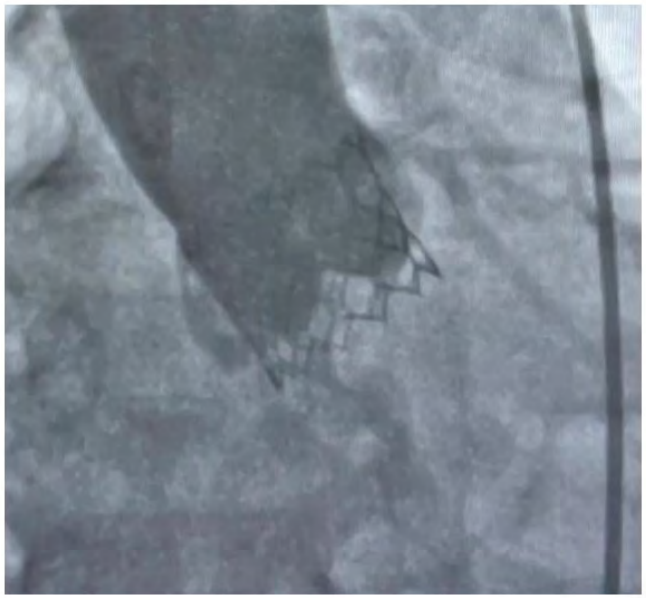


https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33).

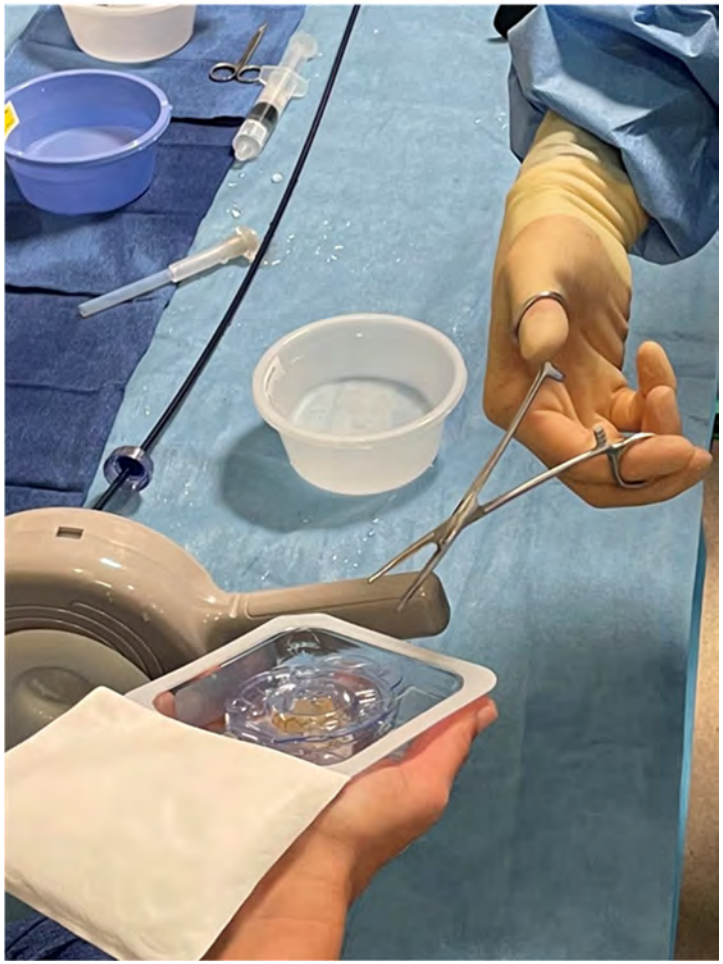
See also, evidence for preceding elements above.

With respect to the phrase, "a frame formed of a plurality of struts that cooperate to form a plurality of cells", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with struts and cells with the capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of providing a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a

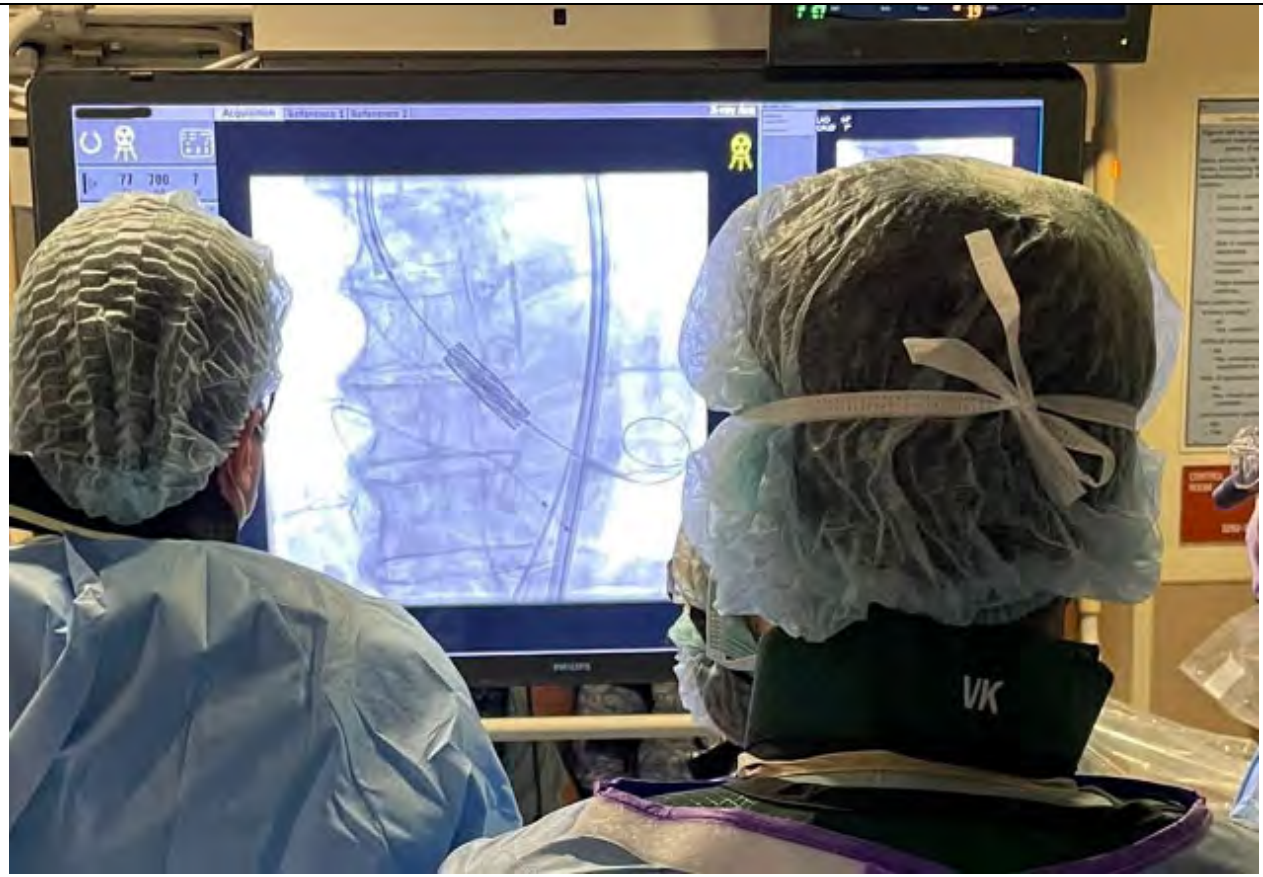
	patients' anatomy. Further, whether the frame with a plurality of struts that cooperate to form a plurality of cells is laser cut from a single piece of material or made otherwise is the same or, at most, an insubstantial difference.
wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation	The '834 patent Accused Instrumentalities satisfy this element. The '834 patent Accused Instrumentalities comprise a frame that is radially expandable from a radially compressed orientation to a radially expanded orientation. For example, the Sapien 3 Ultra is packaged and provided by Edwards in a radially expanded configuration. The Sapien 3 Ultra is designed by Edwards to be crimped onto an Edwards' balloon delivery system in a radially compressed orientation. The Sapien 3 Ultra is also designed to be expanded using an Edwards' balloon delivery system in the aorta of a patient into a radially expanded orientation.  Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

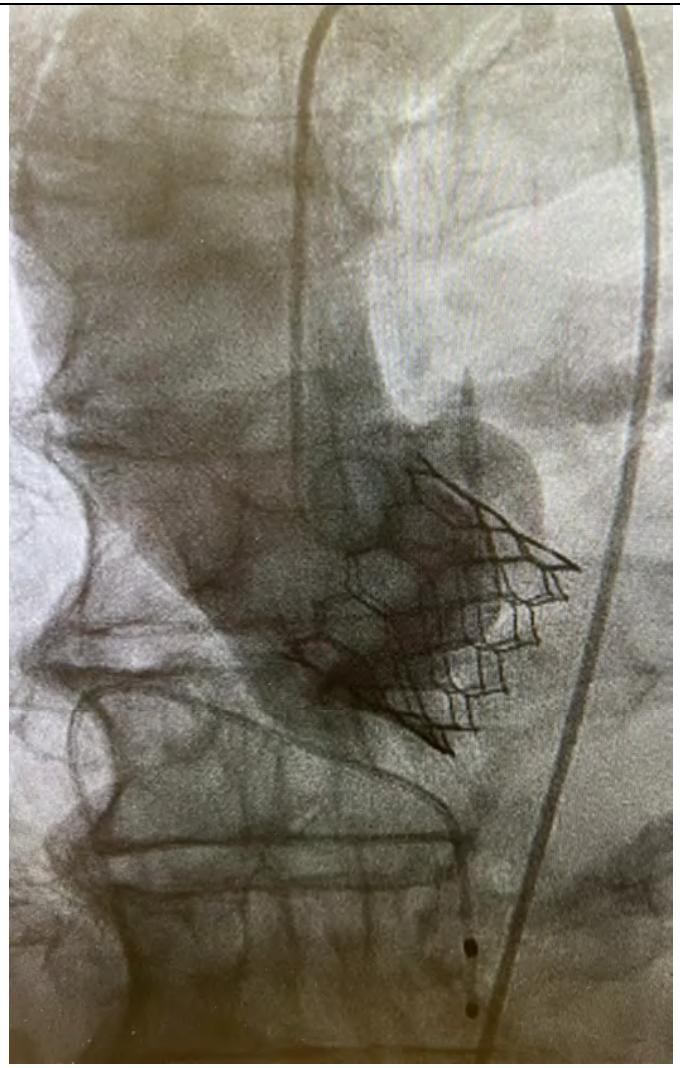
	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



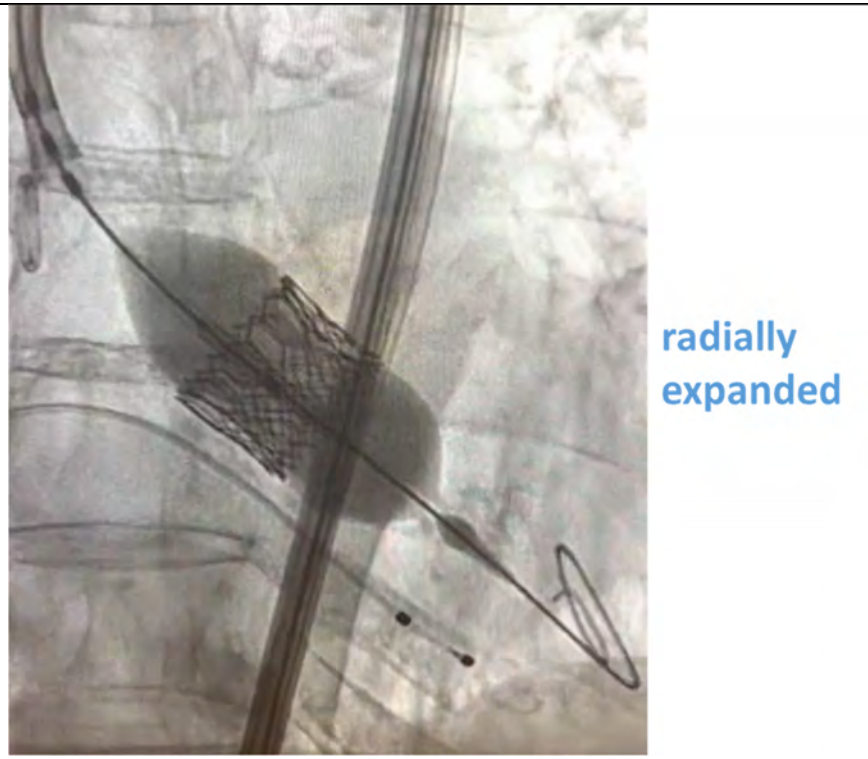
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

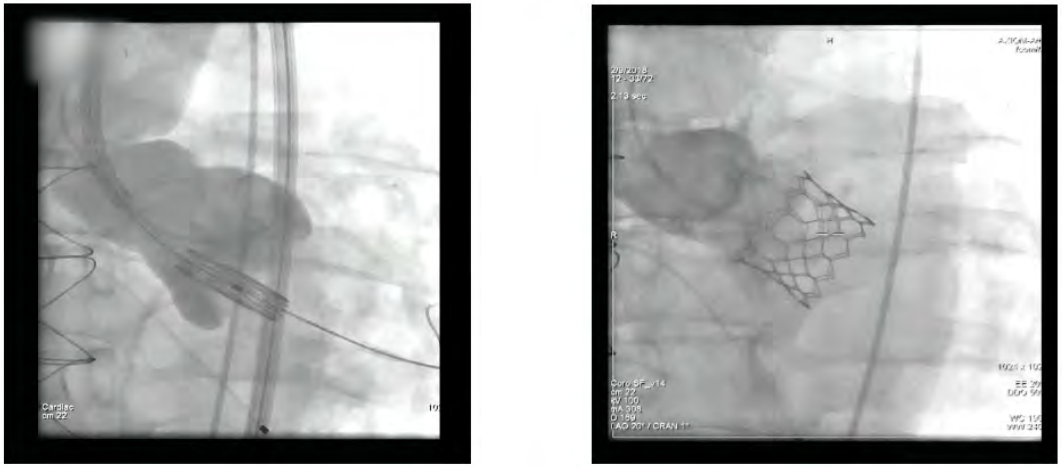


https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=7vNdYaSyfo8PlVNSNv2WDQ



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

SAPIEN 3 Ultra System Case Example



Edwards Presentation entitled “SAPIEN 3 Ultra Valve First-In-Human Experience” at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

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.



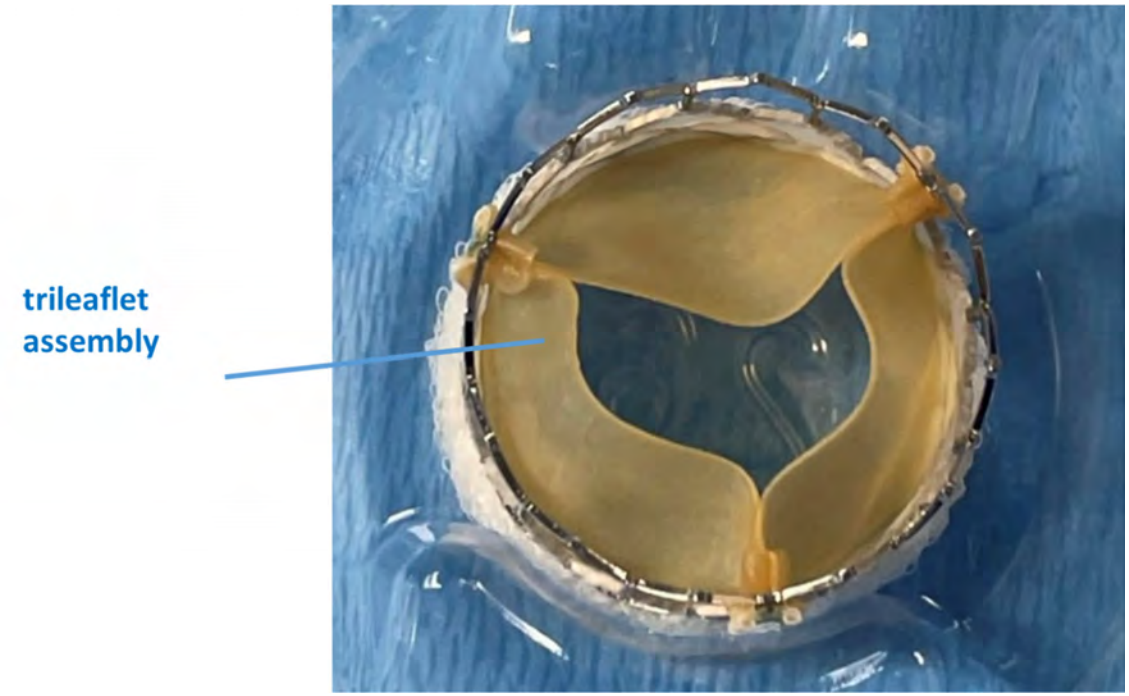
9750TFX

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 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a leaflet assembly within the frame;	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities comprise a leaflet assembly within the frame. For example, the Sapien 3 Ultra devices comprise a bovine pericardial tissue trileaflet assembly and/or Resilia tissue trileaflet assembly.  https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).

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.



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Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
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;	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities comprise 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. For example, the Edwards Sapien 3 Ultra has a polymer covering made from PET attached to the leaflet assembly. Further, the Sapien 3 Ultra polymer covering is positioned radially inward of the frame and radially outward of the leaflet assembly.  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added) (showing polymer covering radially inward of the frame and outward of the leaflet assembly) (D.I. 1, Ex. 33).

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.

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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.



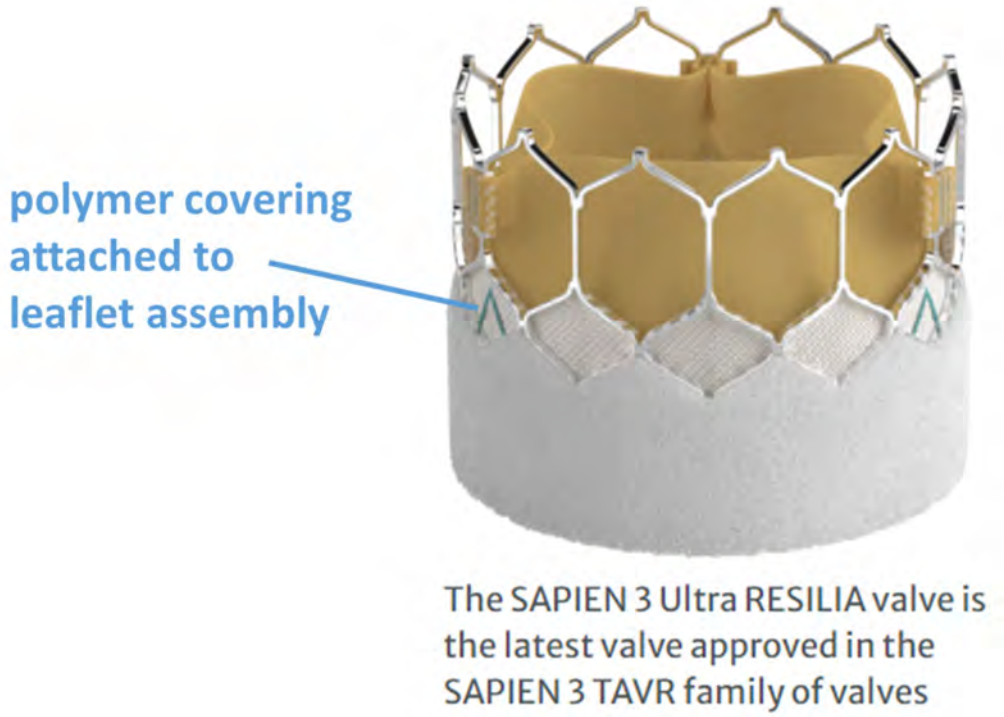
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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

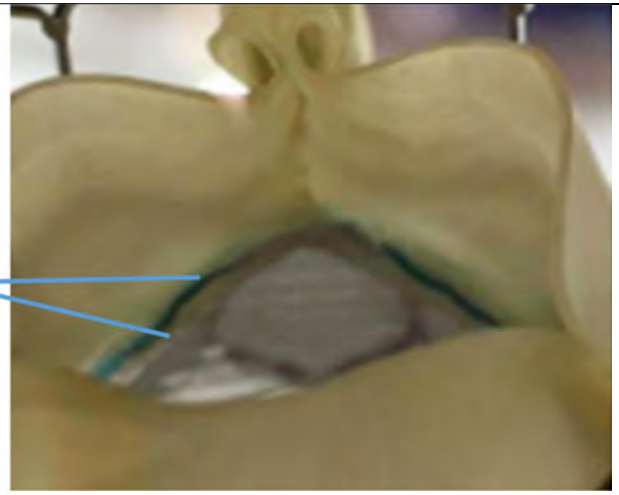
Table 1

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 (D.I. 1, Ex. 44).

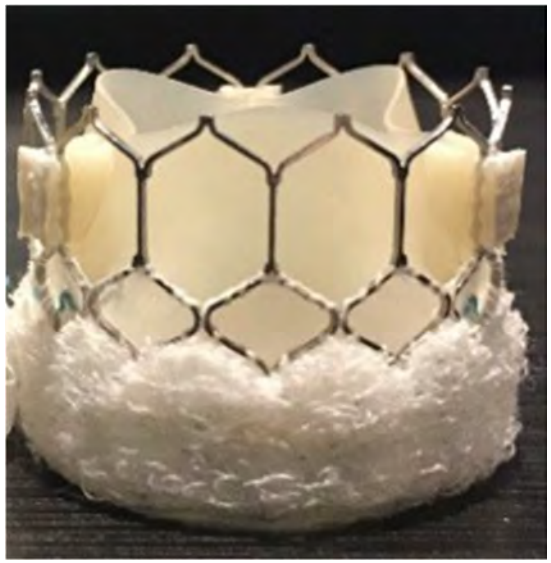


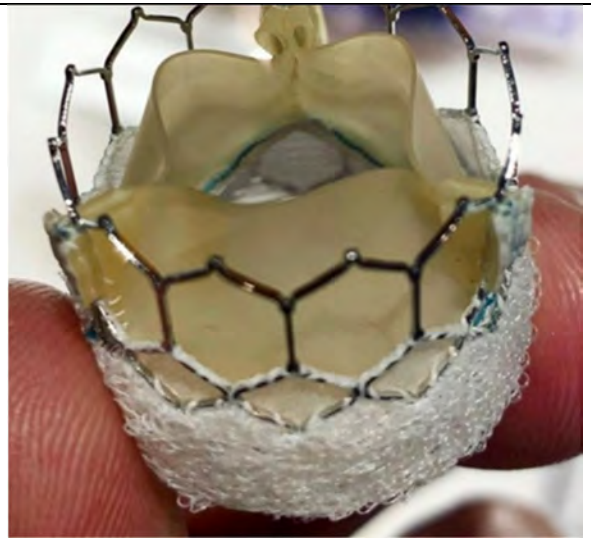
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

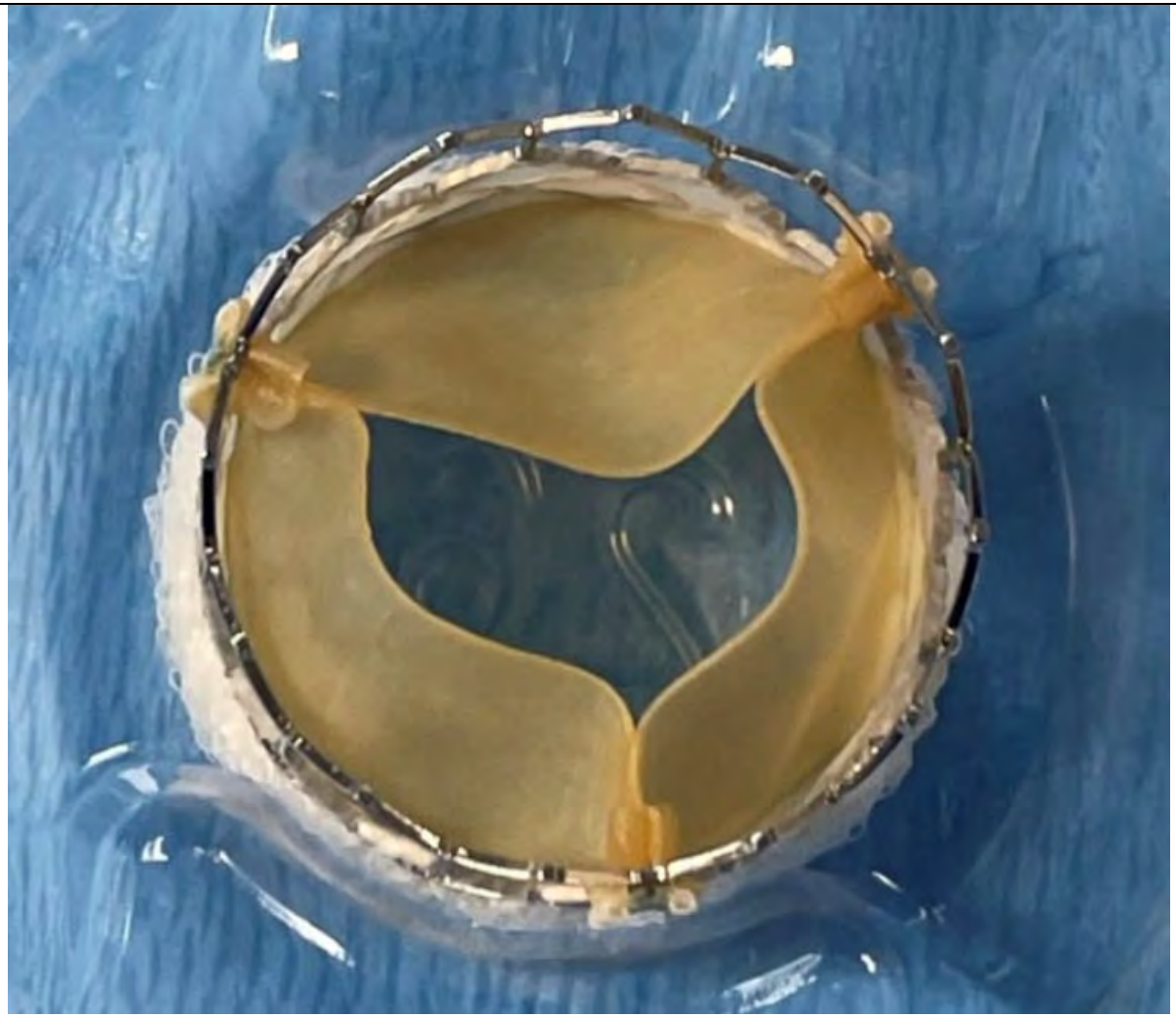


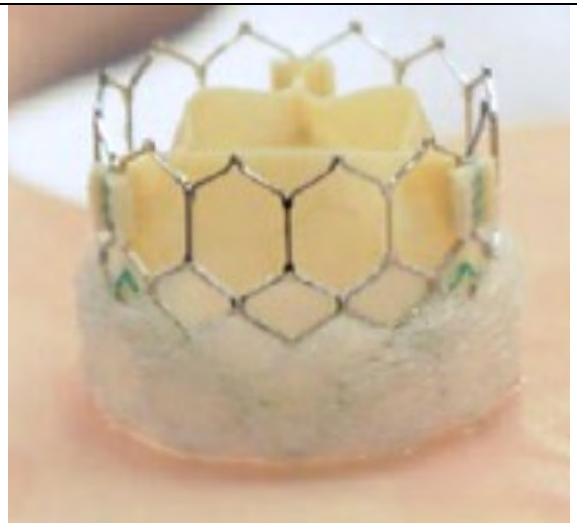
https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a polymer covering positioned radially inwardly of the frame and radially outwardly of the leaflet assembly, the identified polymer coverings are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused polymer covering performs the same or substantially the same function as the claim phrase by covering portions of the leaflet assembly and providing sealing thereto, in the same or substantially the same way as the claim phase through including a polymer covering that is positioned at least partially radially outward of the leaflet assembly and radially inward of the frame and by being attached to the leaflet assembly, to achieve the same or substantially the same result of a polymer covering configured to cover and/or seal or partially cover and/or seal the leaflet assembly.

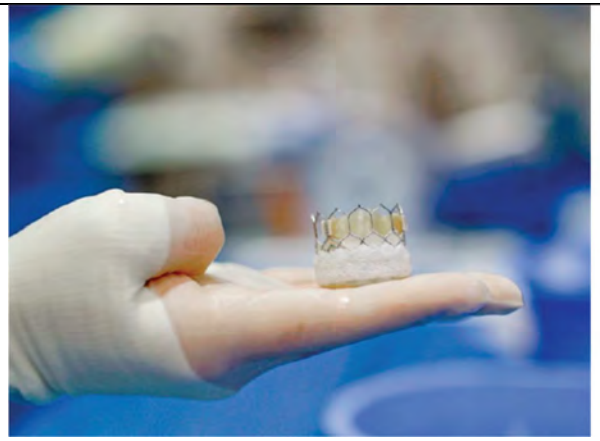
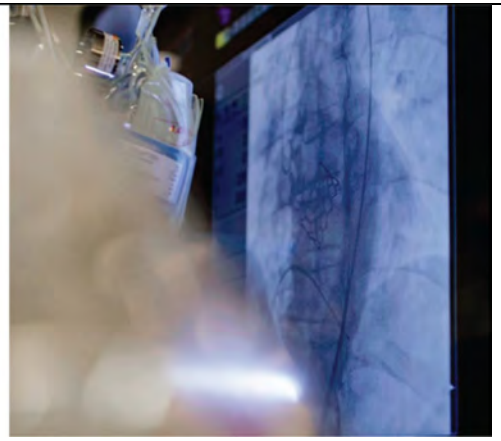
a first plurality of fibers that extend away from the frame, wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 Accused Instrumentalities comprise a first plurality of fibers that extend away from the frame, wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of fibers that extend away from the frame.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 29).

	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 64).

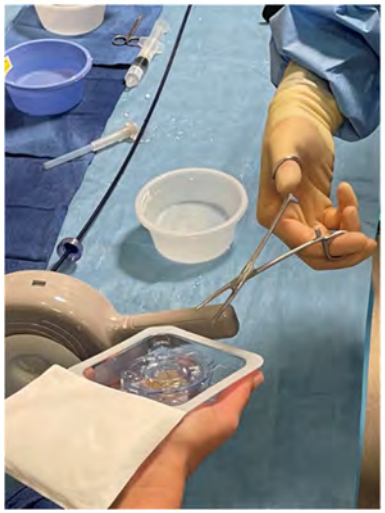
	 https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65) (showing plurality of fibers extending away from frame).

	 Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 3). Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through the femoral artery using Edwards' balloon catheter delivery systems.

	  https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg





https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

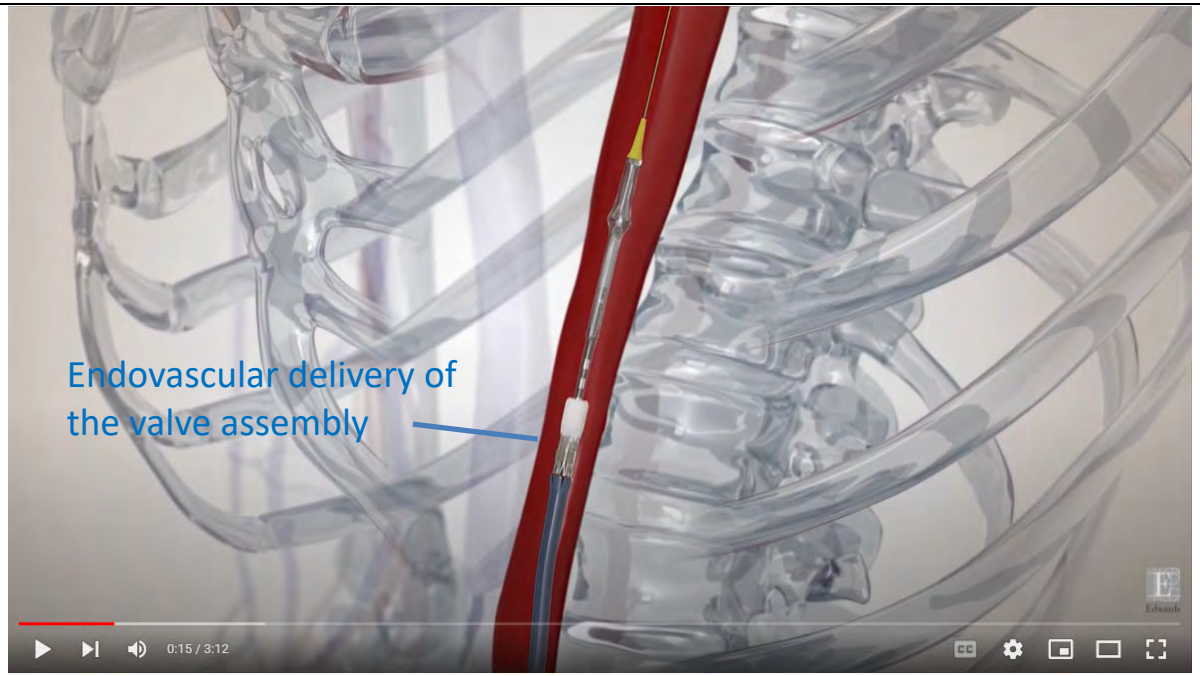


https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.

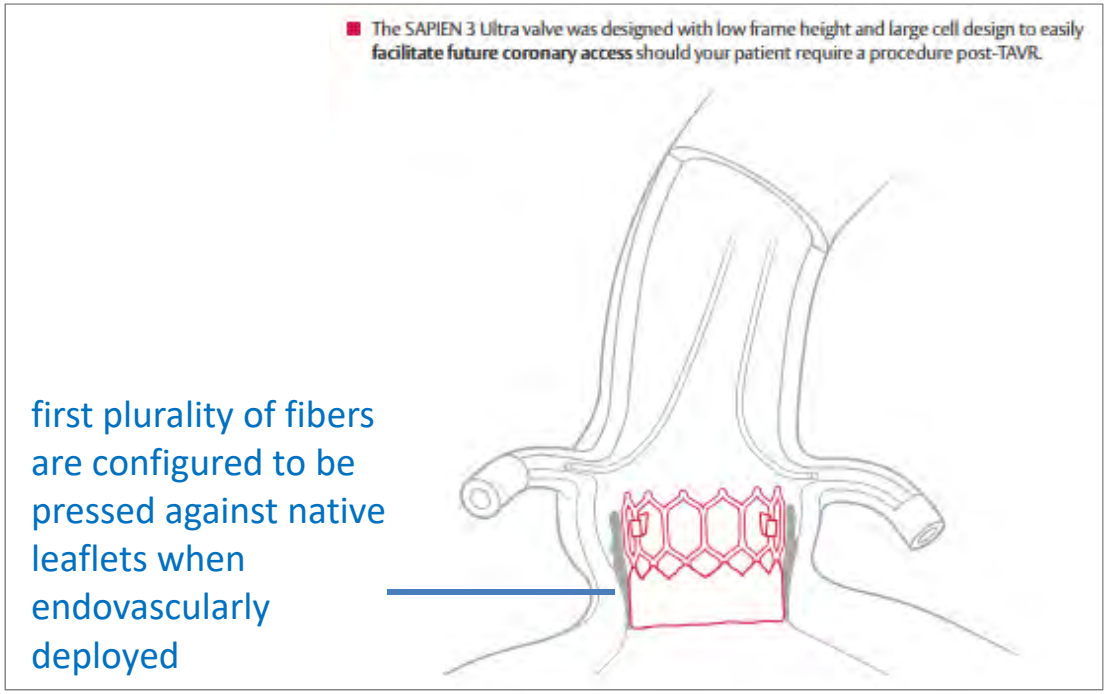


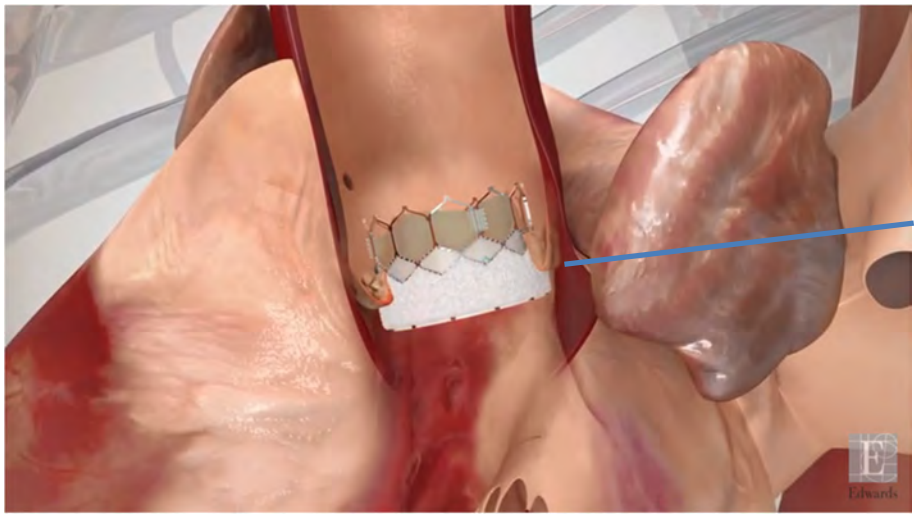
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

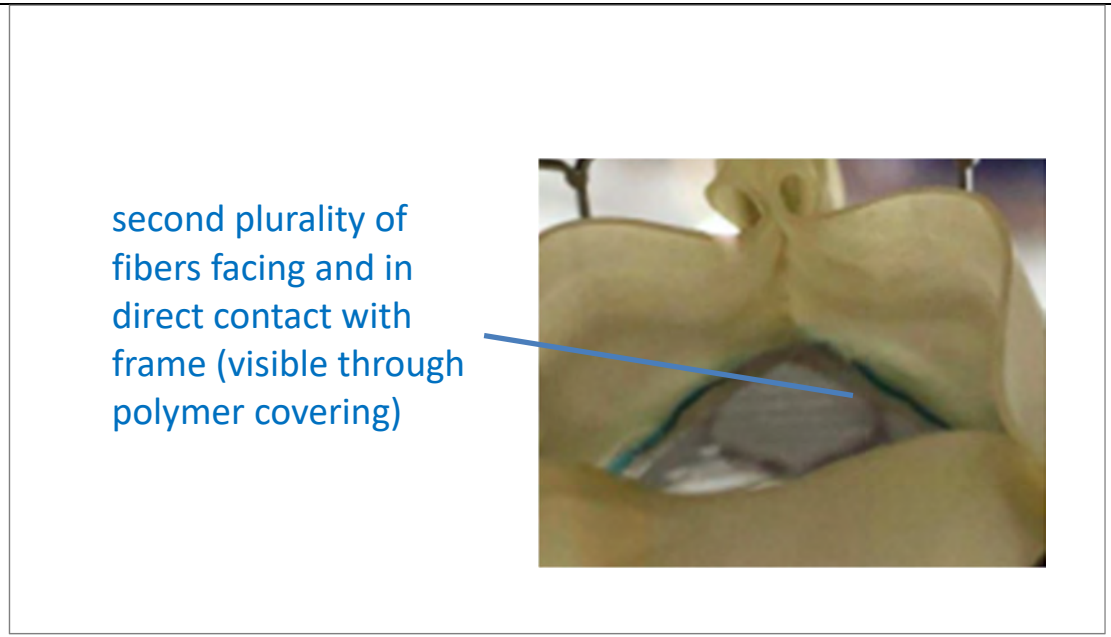


SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

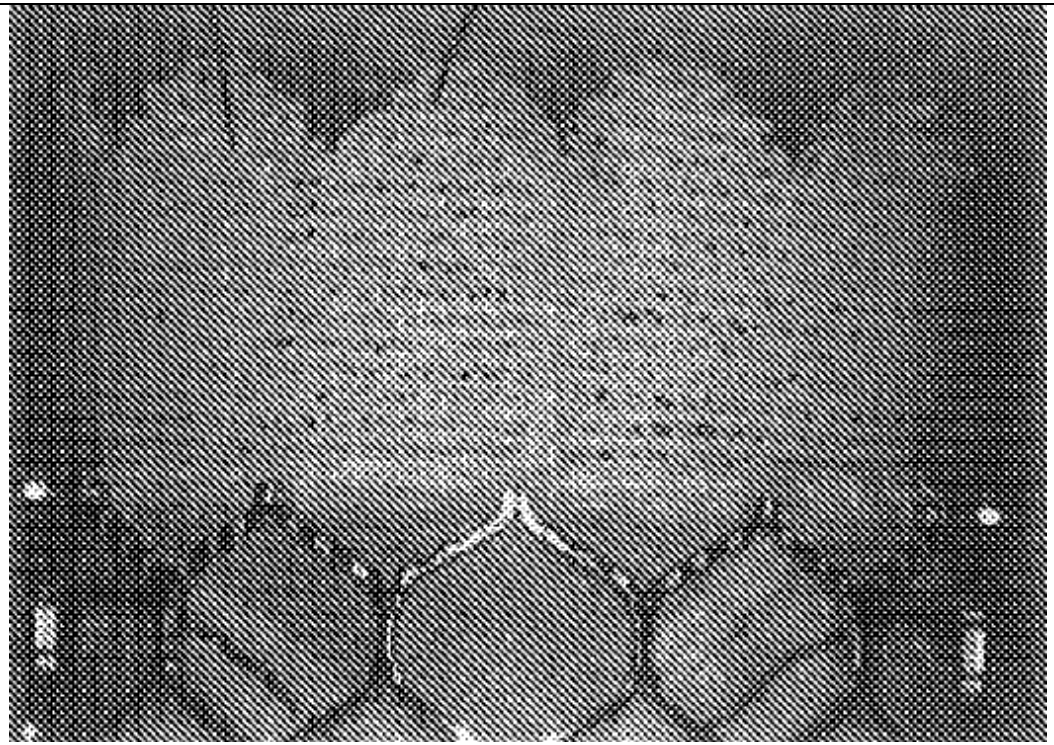
With respect to the phrase, "a first plurality of fibers that extend away from the frame" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a first plurality of fibers that extend away from the frame, the identified a first plurality of fibers that extend away from the frame of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused first portion of fibers perform the same or substantially the same function as the claim phrase by providing low profile sealing against the native leaflets of the aorta and spacings between fibers, in the same or substantially the same way as the claim phase by extending generally away from the frame and pressing against the native leaflets of the aorta of

	the patient and filing in spacings when the valve is expanded, to achieve the same or substantially the same result of a first plurality of fibers that generally extend away from the frame configured to provide sealing between the native annulus and the valve assembly.
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;	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities’ first plurality of fibers are 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. For example, the Sapien 3 Ultra fibers on the sealing skirt are configured to be pressed against native leaflets when endovascularly deployed and radially expanded within the native heart annulus of a patient. 

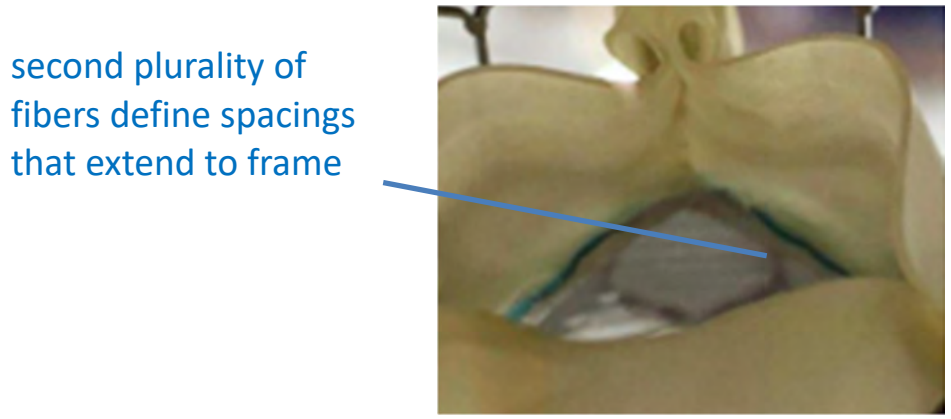
	Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).  "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
a second plurality 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.	The '834 patent Accused Instrumentalities satisfy this element. For example, the '834 patent Accused Instrumentalities comprise a second plurality of fibers positioned radially inwardly from the first plurality of fibers, wherein the second plurality of fibers is in direct contact with the frame. For example, the Sapien 3 Ultra sealing skirt includes fibers facing the frame that are in direct contact with the frame. The sealing skirt in the Sapien 3 Ultra is sewn to the frame and has a backside (internal facing portion) with a second plurality of fibers that directly contact the frame.



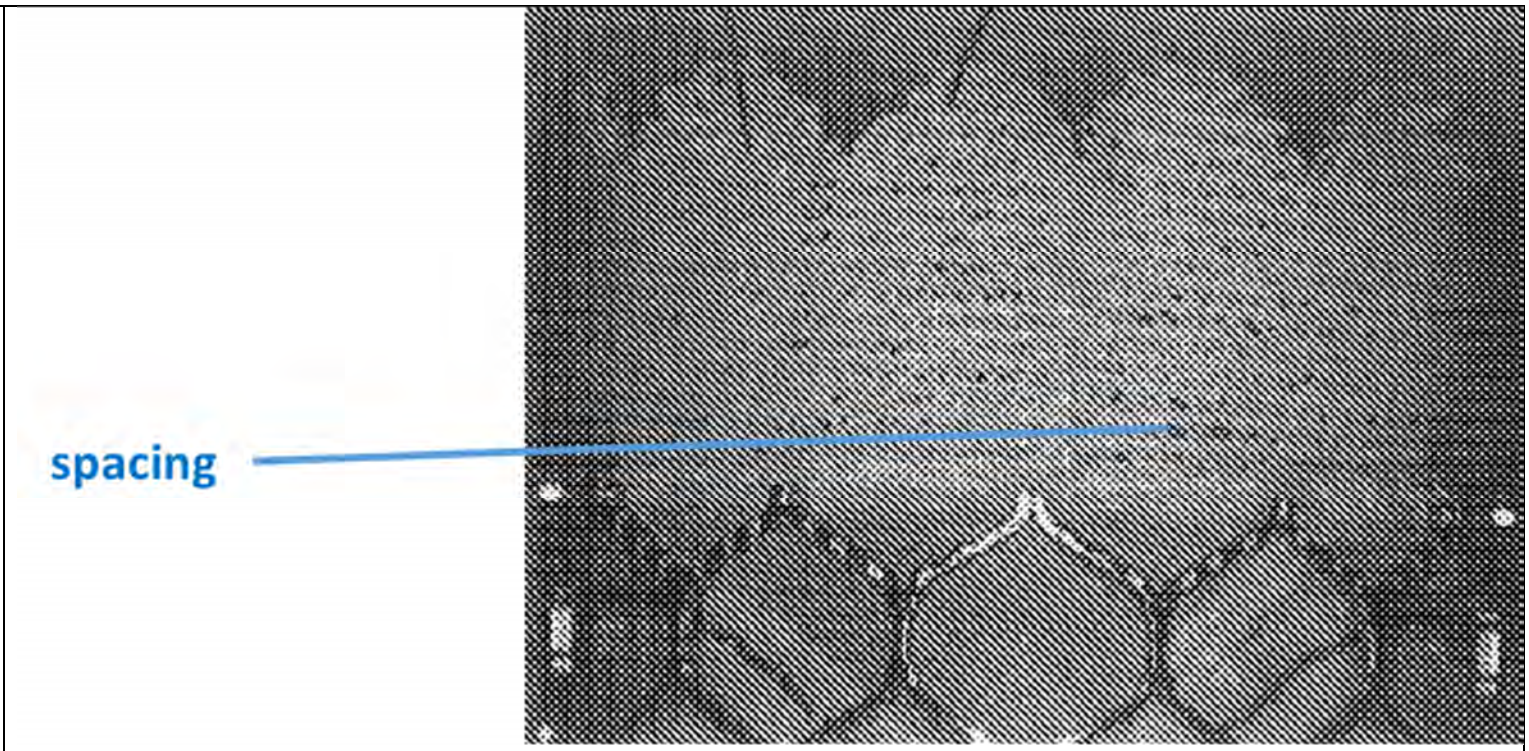
Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

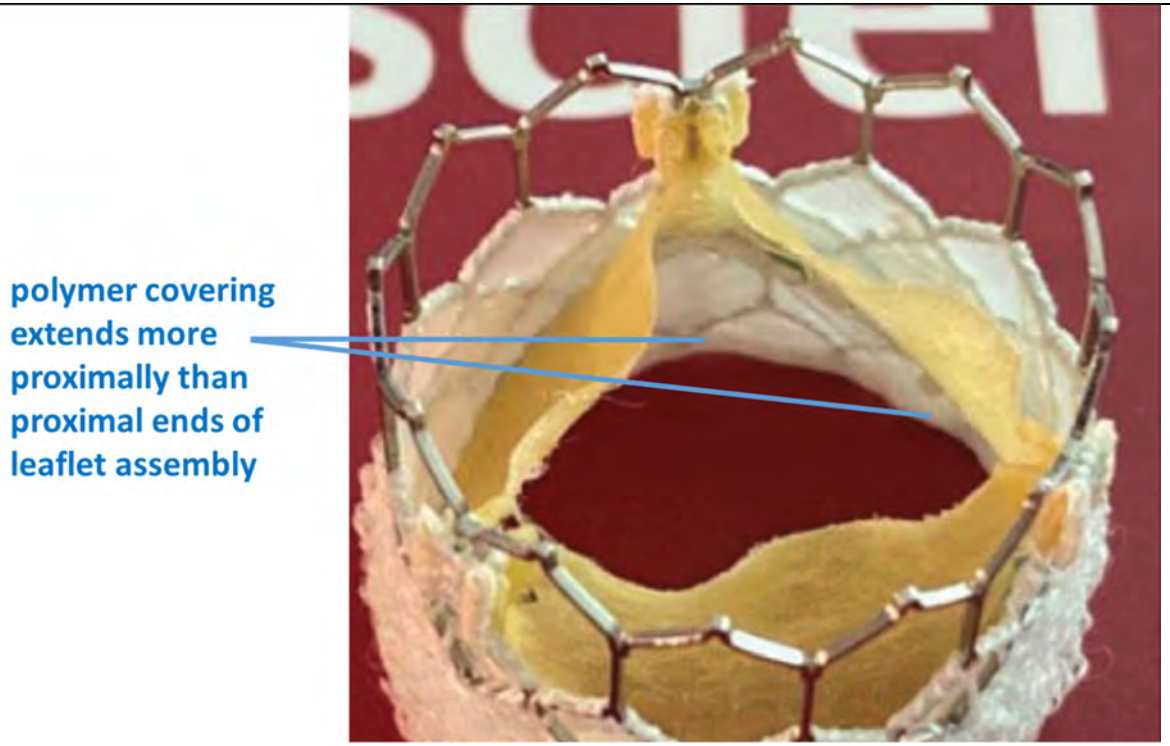
	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing fibers on flipped up backside of sealing skirt). With respect to the phrase, "a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers, the identified second plurality of fibers that is positioned radially inwardly from the first plurality of fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused second plurality of

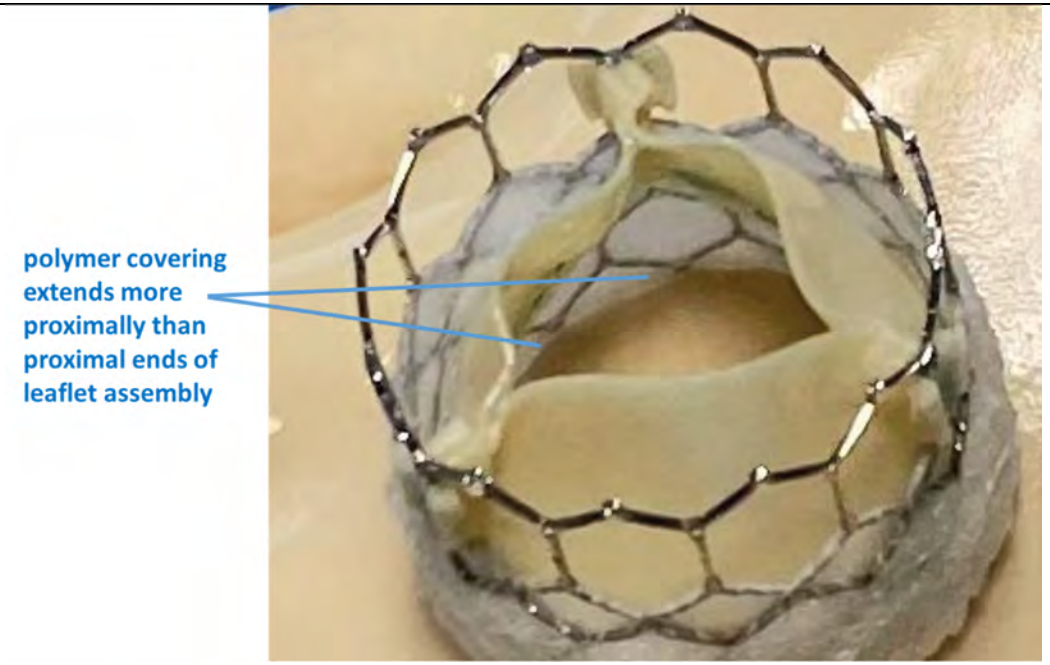
	fibers perform the same or substantially the same function as the claim phrase by helping provide low profile sealing against the frame when expanded, in the same or substantially the same way as the claim phase by being attached to and pressing against the frame, to achieve the same or substantially the same result of a second plurality of fibers configured to provide sealing against the frame of the valve assembly. With respect to the phrase, "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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by having a second plurality of fibers in direct contact with the frame, in the same or substantially the same way as the claim phase through including a plurality of fibers at least generally radially inwardly from the first plurality of fibers in direct or partially direct contact with the frame, to achieve the same or substantially the same result a second plurality of fibers configured to be in direct contact or generally 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.	The '834 patent Accused Instrumentalities satisfy this element. For example, the '834 patent Accused Instrumentalities comprise a 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 For example, the Sapien 3 Ultra sealing skirt includes fibers carried by the frame facing the frame. The Sapien 3 Ultra fibers are knitted together to form spacings between adjacent fibers that extend at least to the frame.

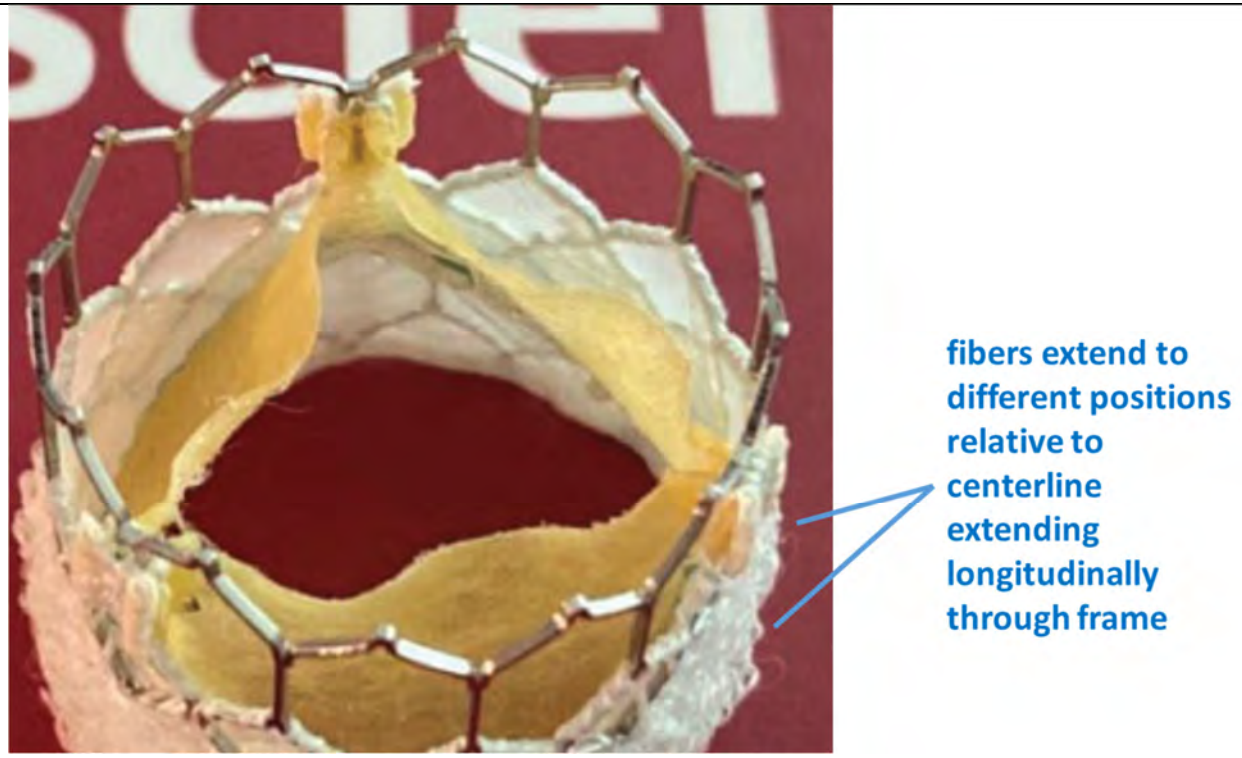


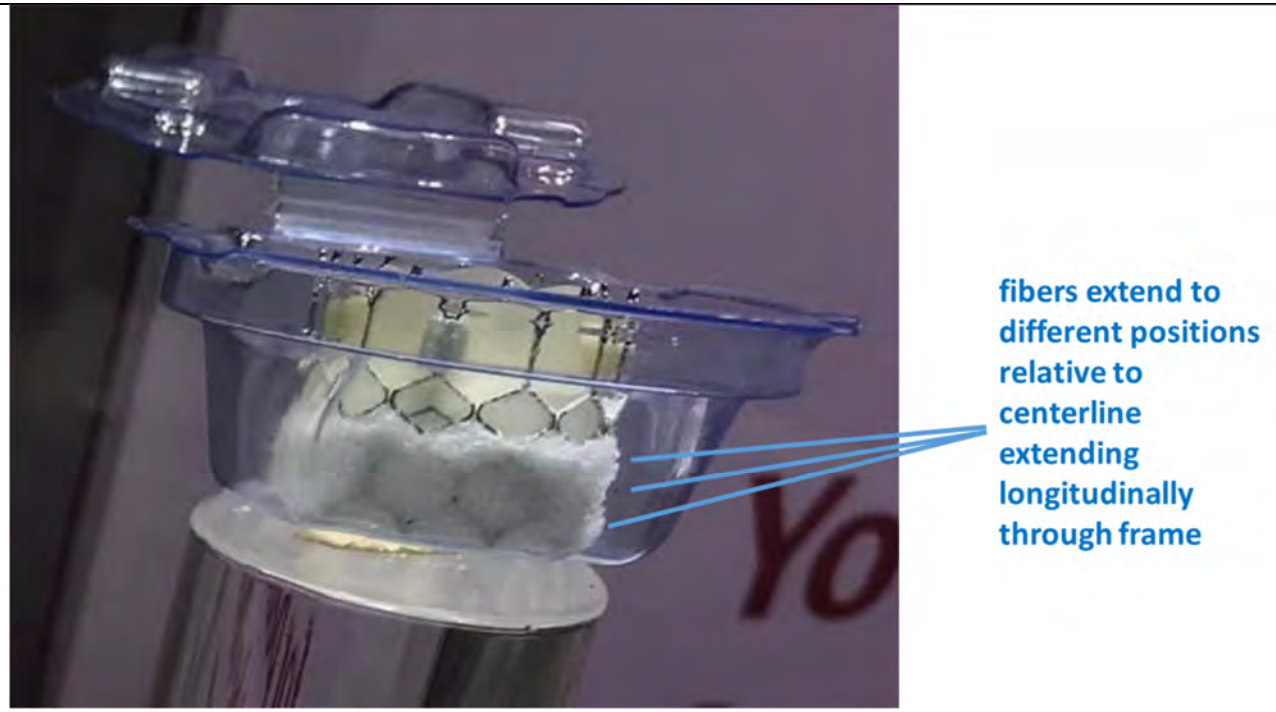
Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1-2 at 15).

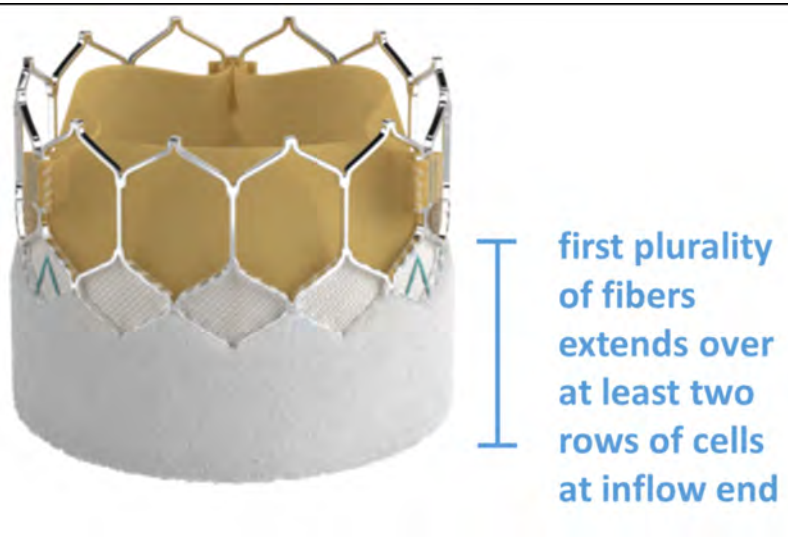
	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing spacings on flipped up backside of sealing skirt). *See also*, claim 1.
3. The prosthetic heart valve of claim 1, wherein the polymer covering extends proximally further than a proximal	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities’ polymer covering extends proximally further than a proximal end of the leaflet assembly. For example, the Sapien 3 Ultra inner skirt extend proximally further than a proximal end of the leaflet assembly.

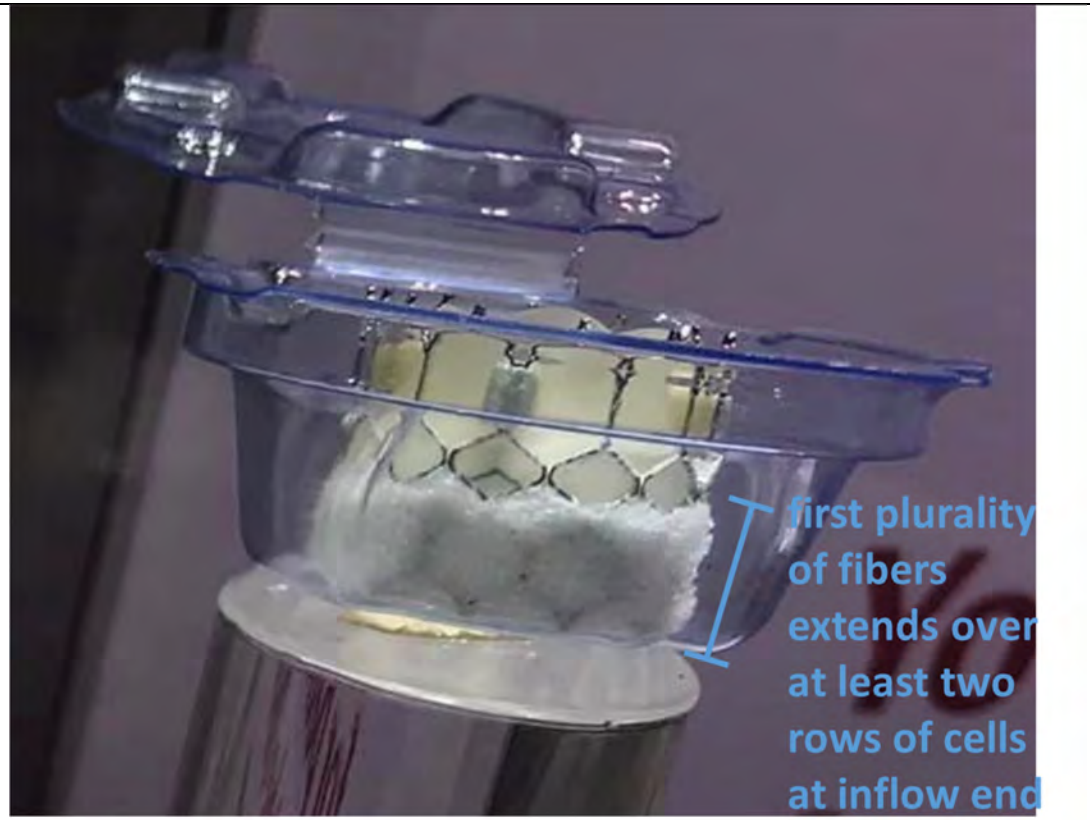
end of the leaflet assembly.	 Eduardo Saadi LinkedIn posts and image (C.V. 1-21-cv-01377, D.I. 106, Ex. K).

	 Quentin Landolff Twitter posts and images (C.V. 1-21-cv-01377, D.I. 106, Ex. T). *See also*, claim 1.
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	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ first plurality of fibers extend from a centerline extending longitudinally through the frame varies along a length of the centerline. For example, the Sapien 3 Ultra sealing skirt fibers extend variably from a centerline extending longitudinally though the frame along the length of the centerline.

varies along a length of the centerline.	 Eduardo Saadi LinkedIn posts and image (C.V. 1-21-cv-01377, D.I. 106, Ex. K).

	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3). *See also*, claim 1.
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	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ include 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. For example, the Sapien 3 Ultra frame includes at least two rows of cells at the inflow end with fibers extending thereover.

plurality of fibers extends over each of the at least two rows of cells.	 https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

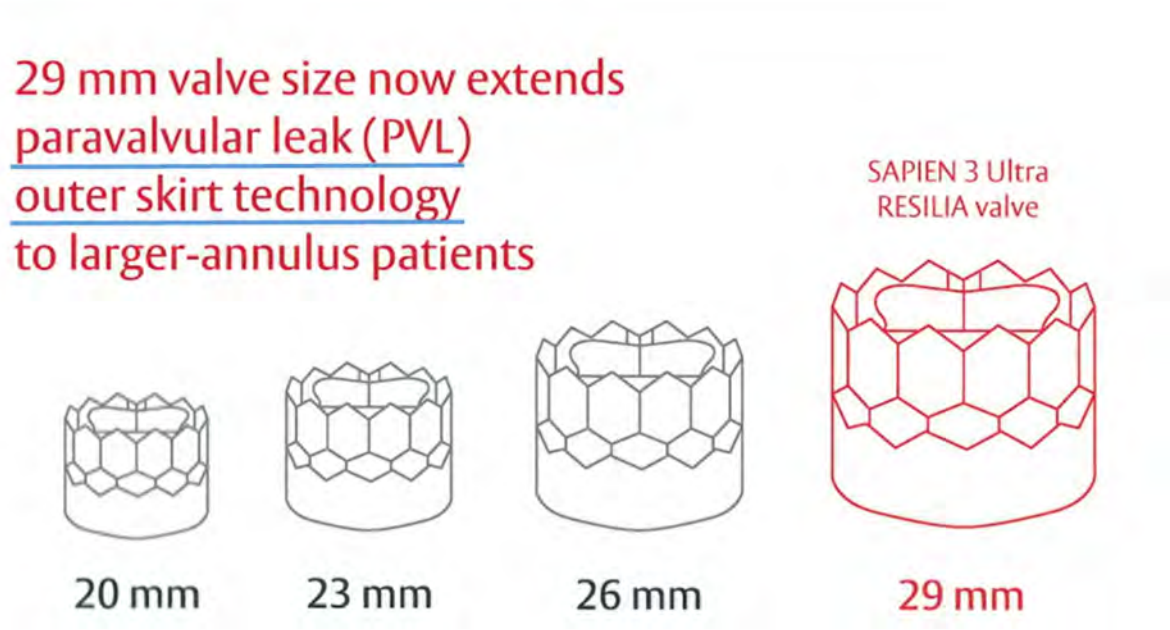


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

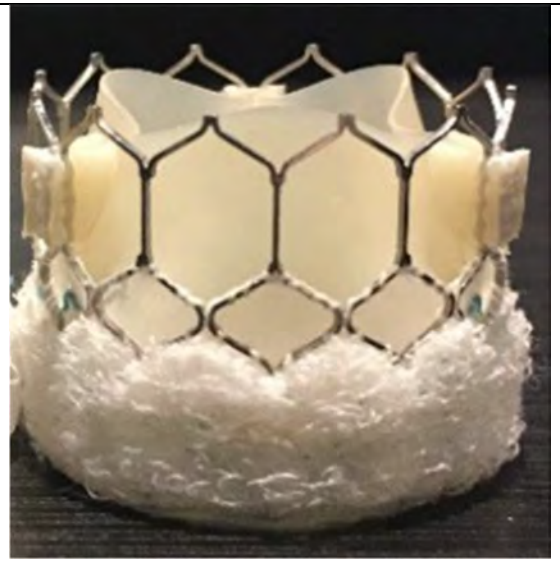
See also, claim 1.

With respect to the phrase, "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," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least

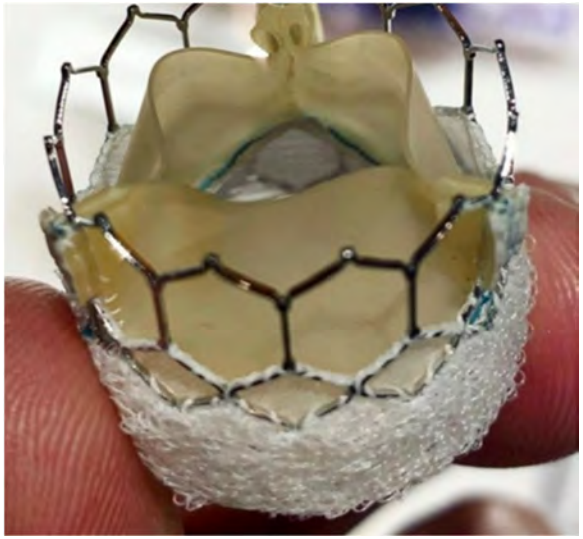
	substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused plurality of cells defines at least two rows of cells perform the same or substantially the same function as the claim phrase by allowing the frame to be compressed to a low profile and expanded, in the same or substantially the same way as the claim phase by being constructed of metal struts forming cells of the same or similar shapes and sizes, to achieve the same or substantially the same result of a plurality of cells defining at least two rows of cells at an inflow end of the frame.
6. The prosthetic heart valve of claim 1, wherein the first plurality of fibers and the second plurality of fibers are non-metallic.	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ first plurality of fibers and the second plurality of fibers are non-metallic. For example, the first and second plurality of fibers are made from PET which is non-metallic. **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. Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

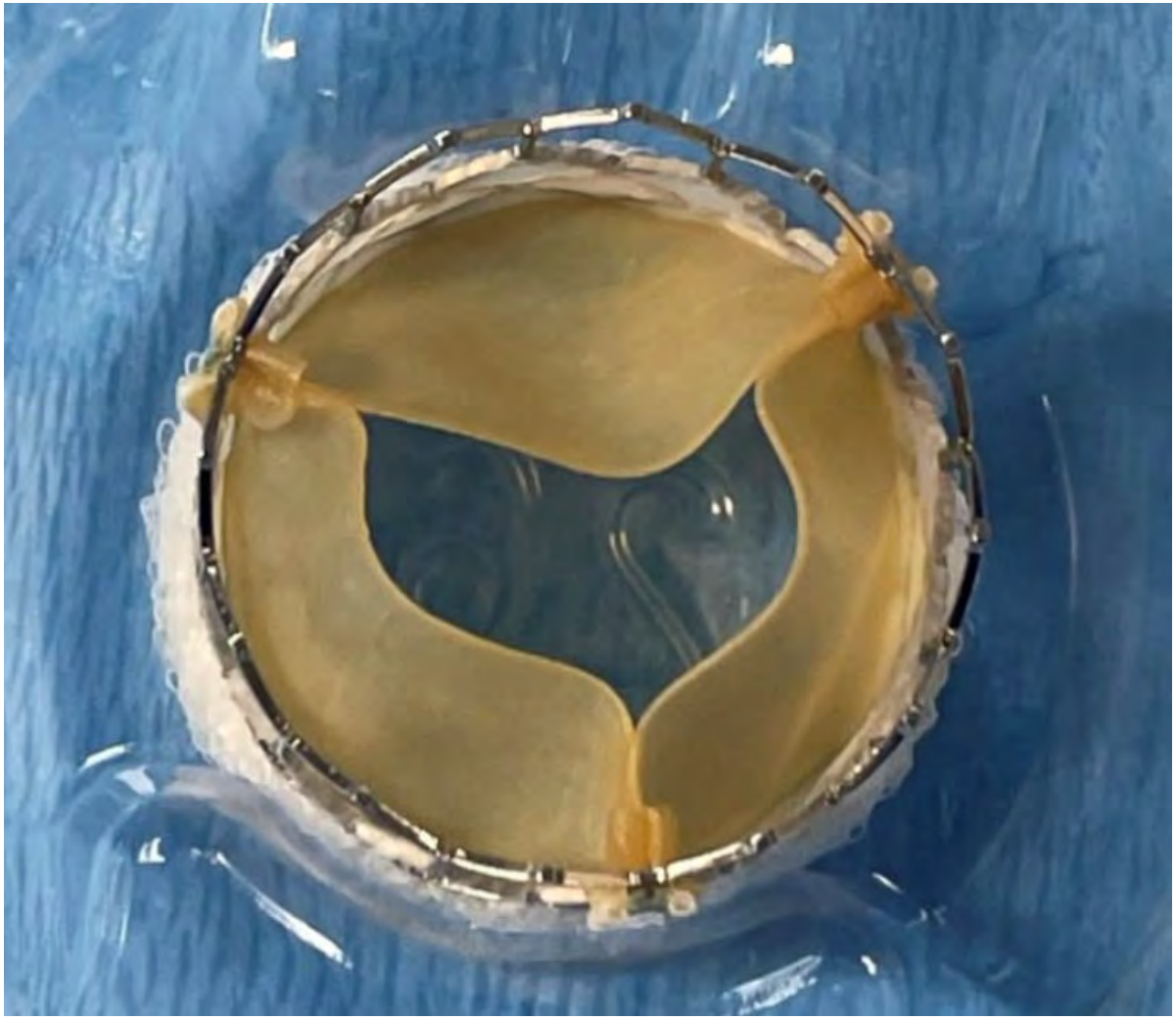


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



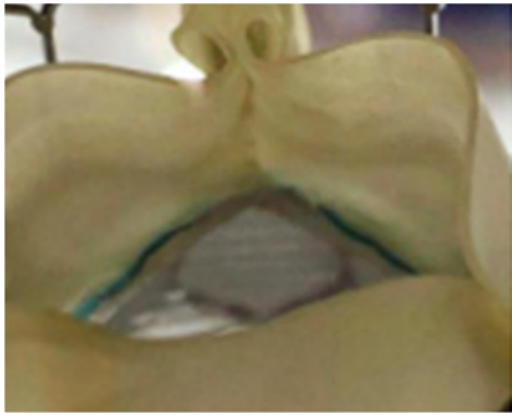
Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

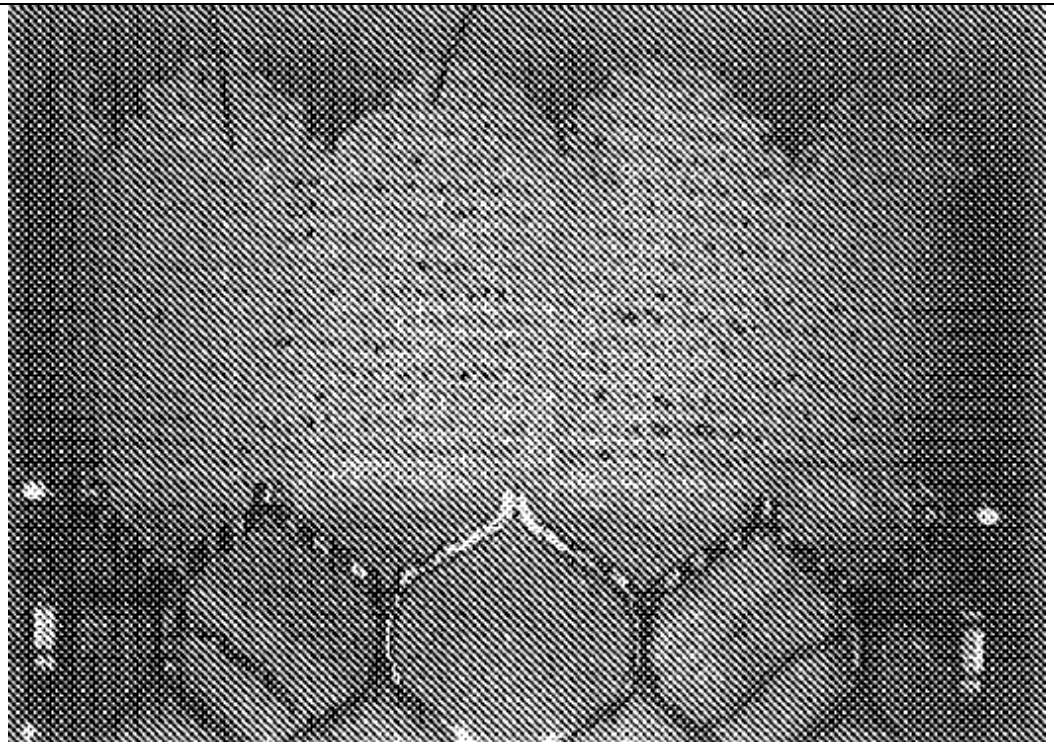


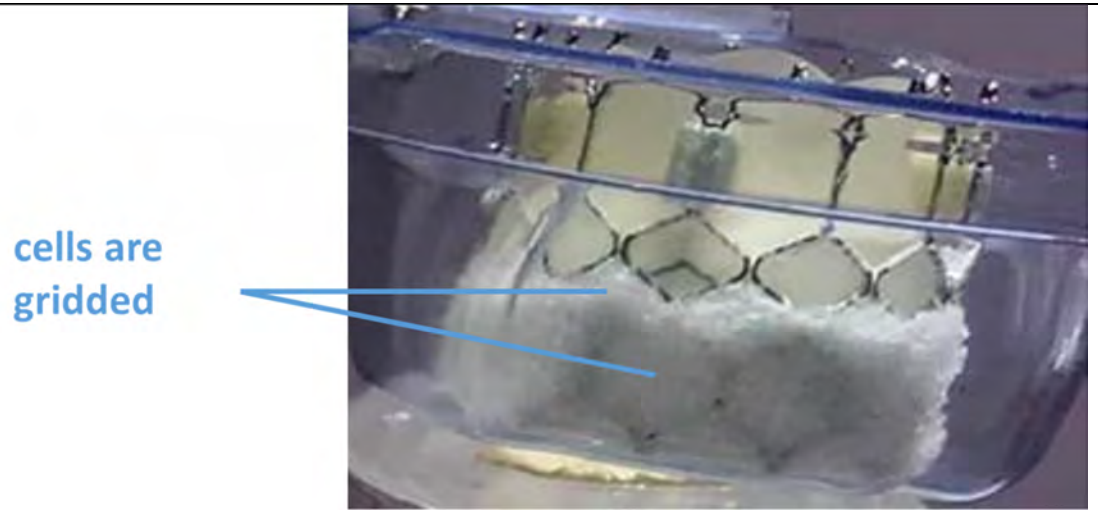
	https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 29). 

	https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 64).  https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65) (showing plurality of fibers extending away from frame).

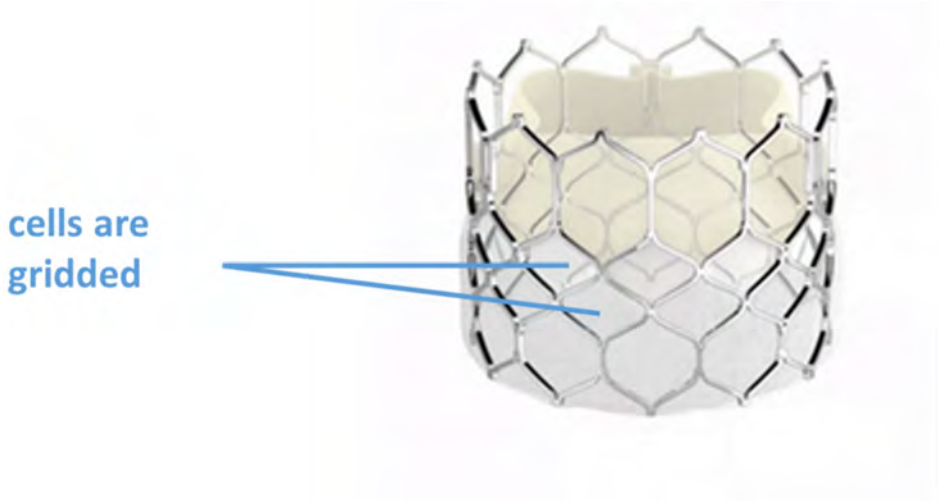
	 Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 3).

	second plurality of fibers (visible through polymer covering)  Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30. *See also*, claim 1.
8. The prosthetic heart valve of claim 1, wherein the cells formed in the frame are gridded.	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ include cells formed in the frame that are gridded. For example, the cells of the frame are in the form of a grid.

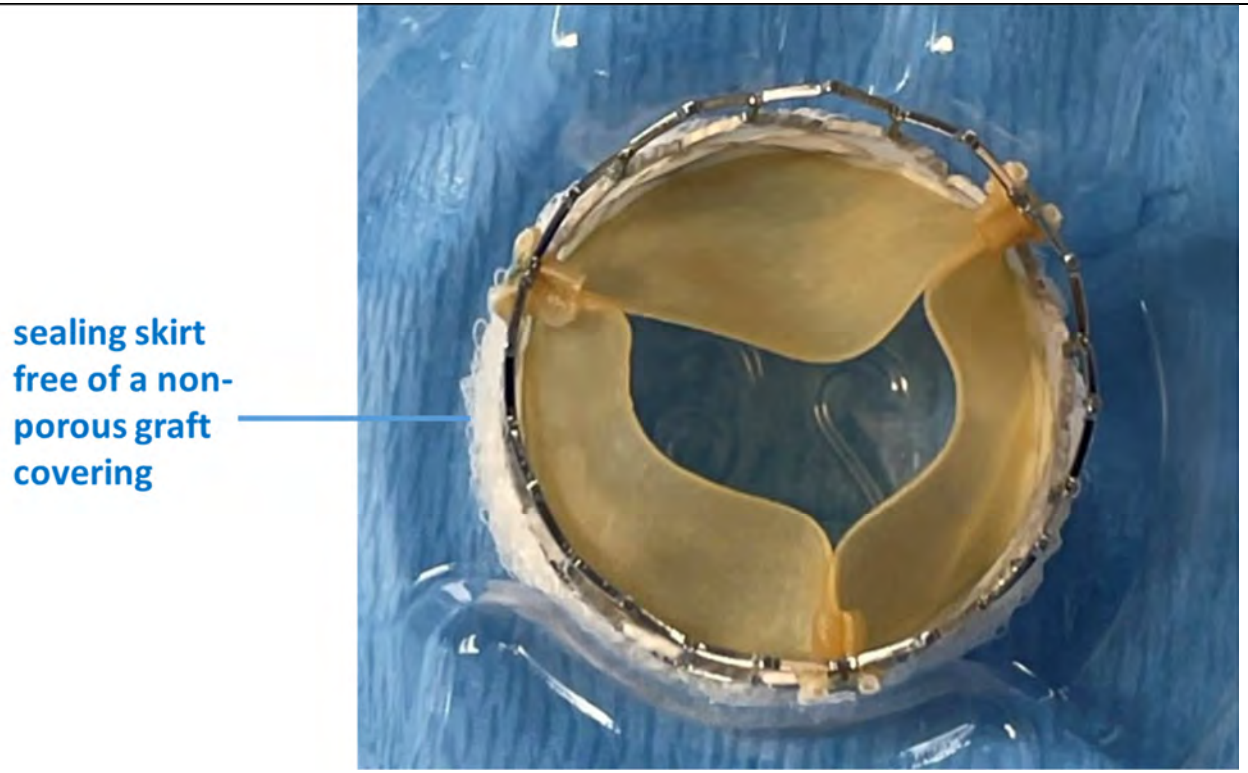


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).

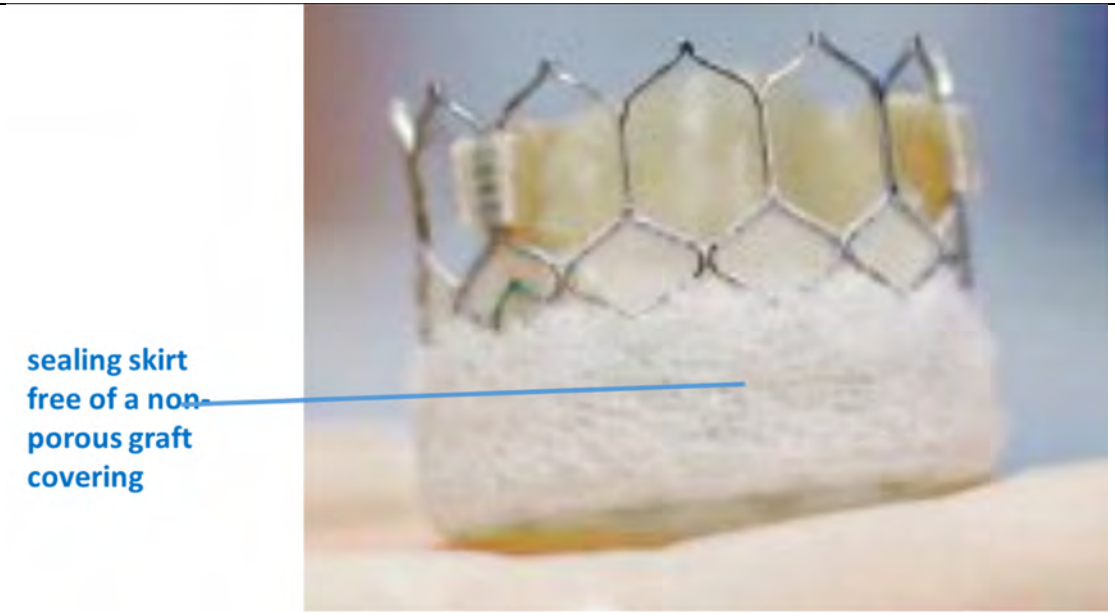


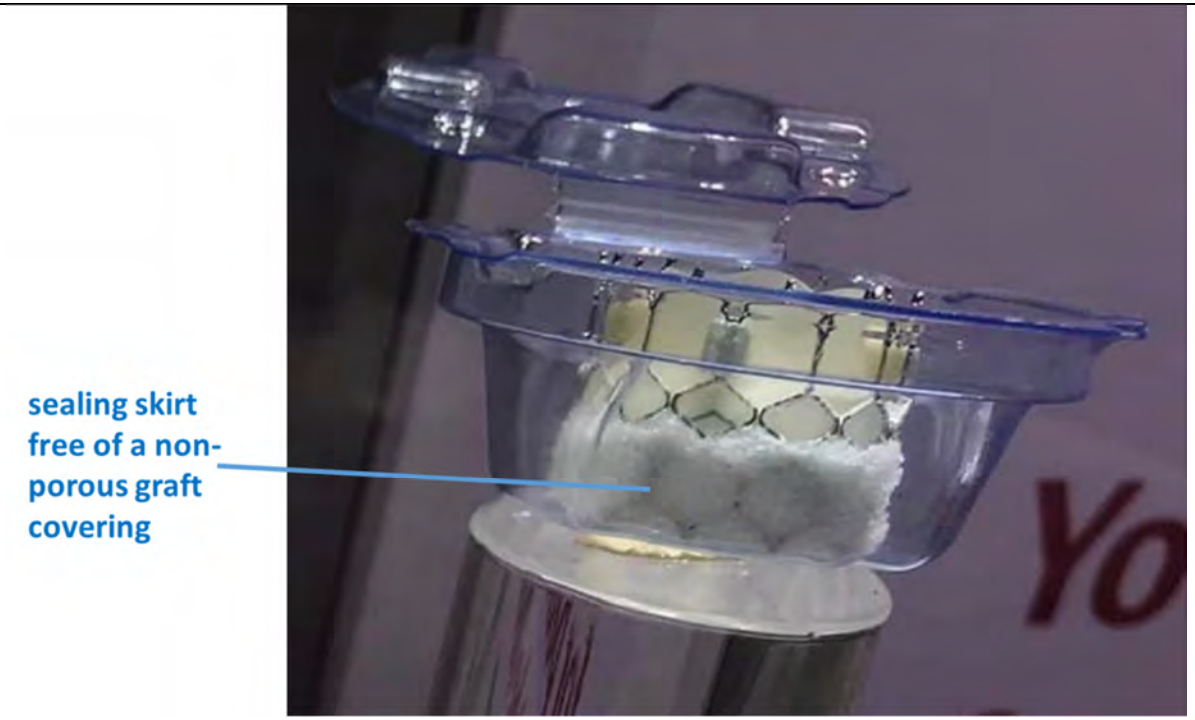
https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33).

	See also, claim 1. With respect to the phrase, "wherein the cells formed in the frame are gridded," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused gridded cells perform the same or substantially the same function as the claim phrase by allowing the frame to be compressed to a low profile and expanded, in the same or substantially the same way as the claim phase by being constructed of metal struts forming cells of the same or similar shapes and sizes, to achieve the same or substantially the same result of a frame with cells that are gridded and/or of a grid-like design.
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.	The '834 patent Accused Instrumentalities satisfy this element. The '834 patent Accused Instrumentalities' 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. For example, the Edwards Sapien 3 Ultra sealing skirt does not include a non-porous graft covering between the first plurality of fibers and the frame and the second plurality of fibers and the frame. Indeed, Edwards' FDA submissions, marketing materials, and related technical publications make no mention of the Sapien 3 Ultra having an sealing skirt with a non-porous graft covering.

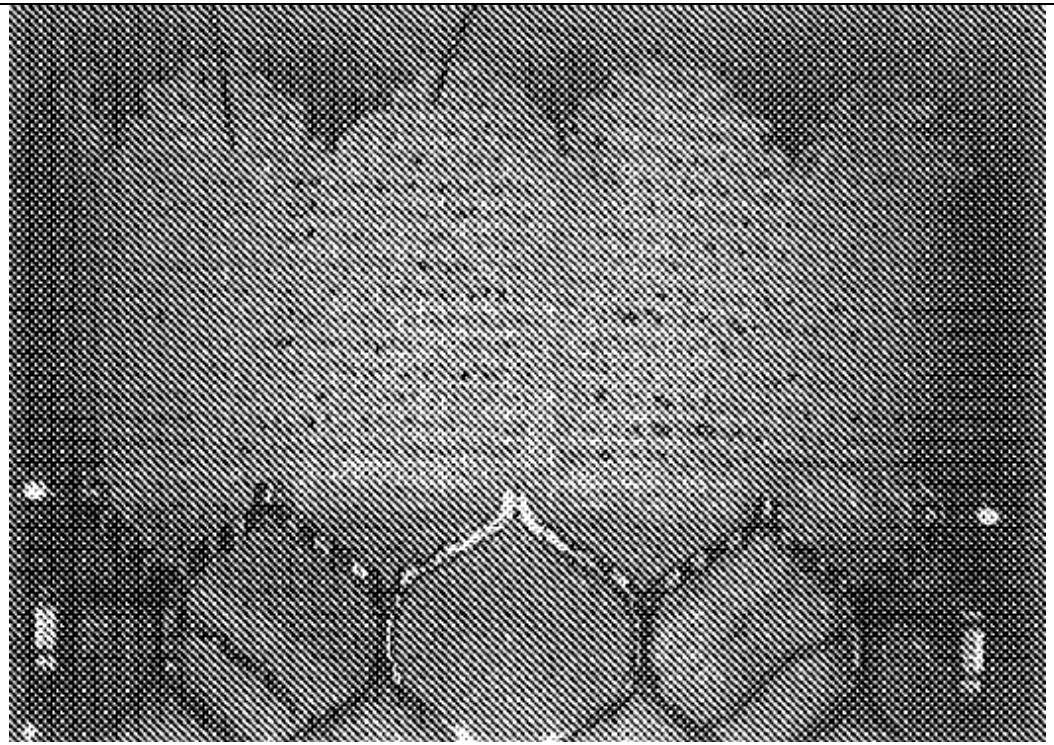


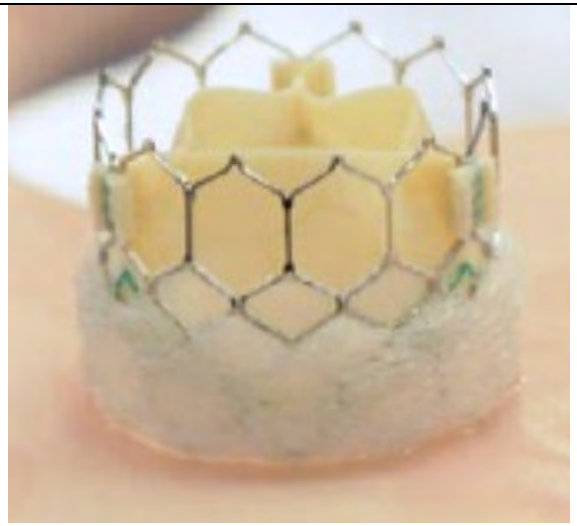
https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).

	 https://twitter.com/RajTayalMD/status/1587518463127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

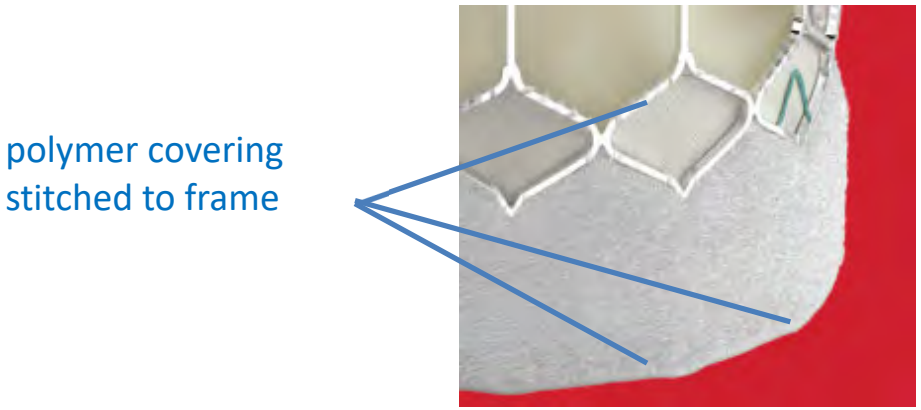


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

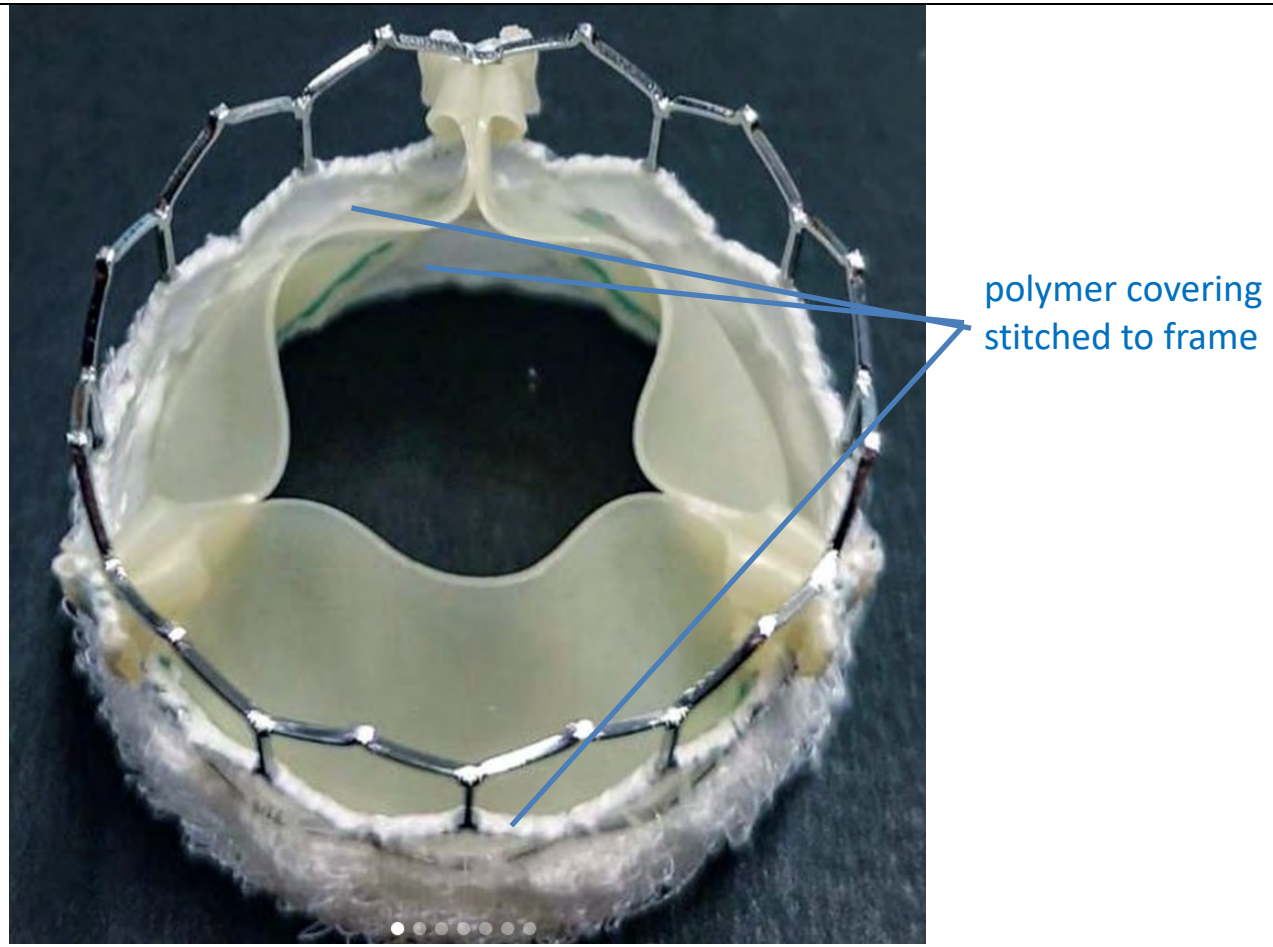
	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing free of a non-porous graft covering)

	 https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65).

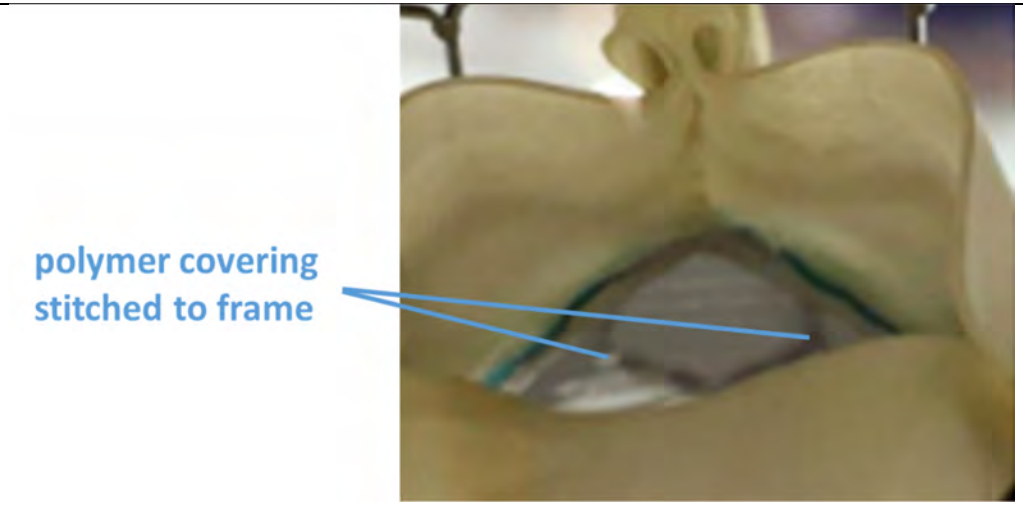
	 Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (D.I. 1, Ex. 3). *See also,* claim 1.
10. The prosthetic heart valve of claim 1, wherein the polymer covering is stitched to the frame.	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ polymer covering is stitched to the frame. For example, the Edwards Sapien 3 Ultra has a polymer covering made from PET that is stitched to the frame.

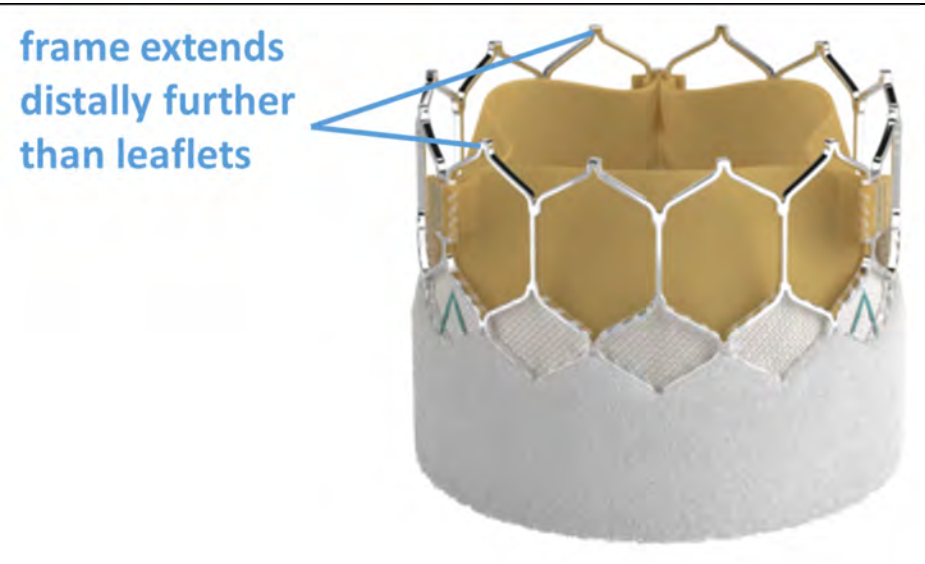


Introducing the SAPIEN 3 Ultra valve at 2 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

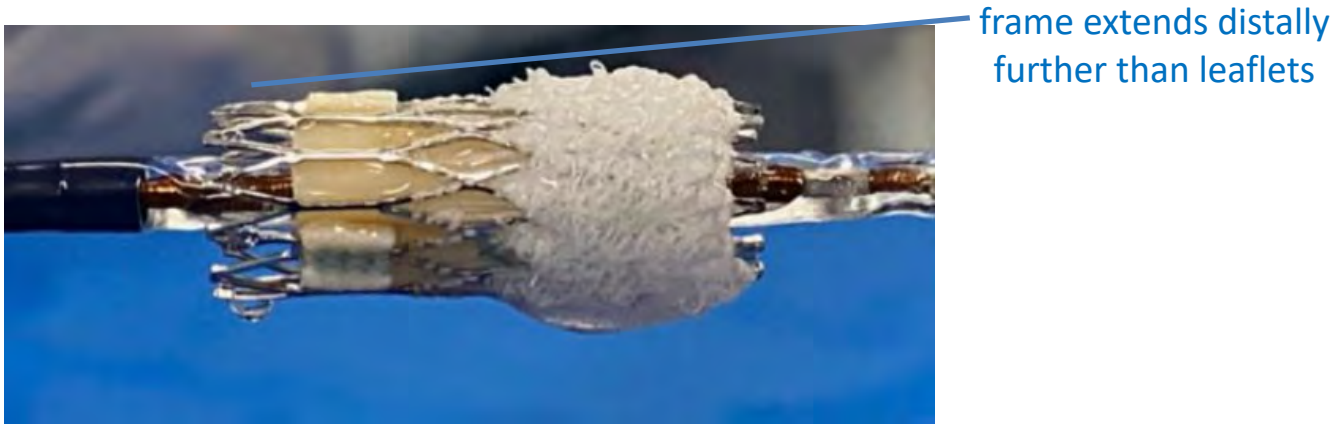


Julian Calain Twitter

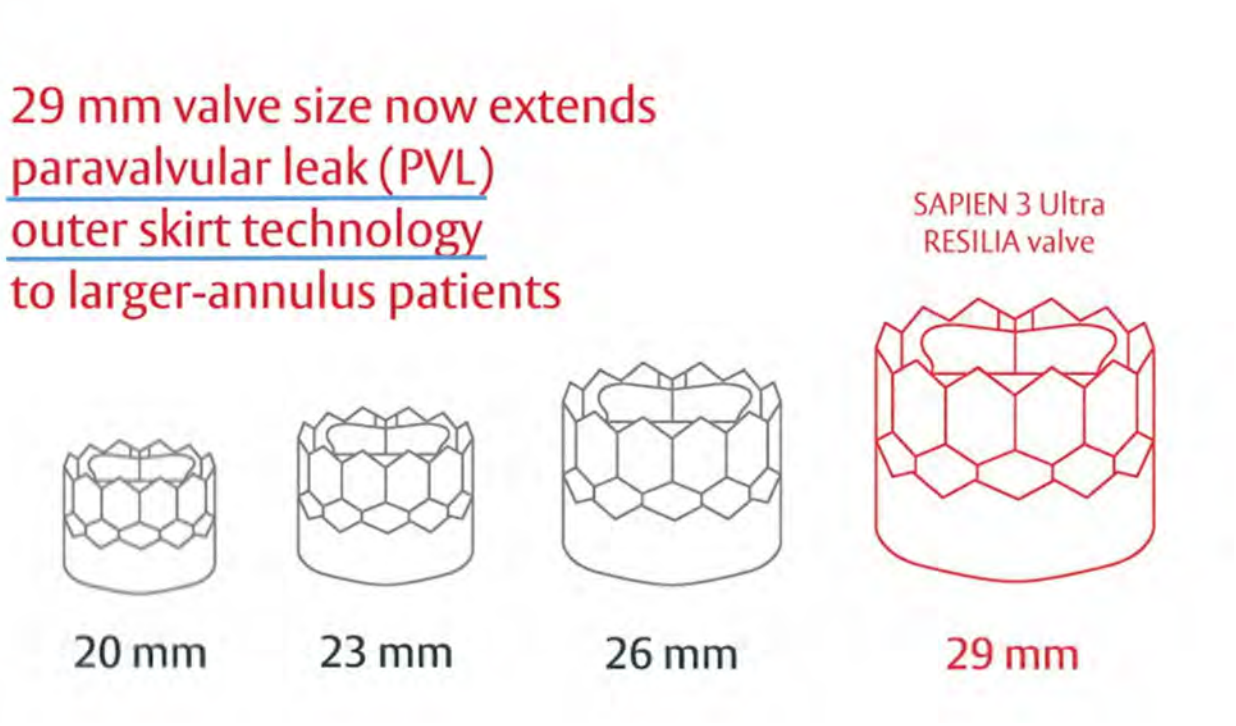
	 https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29). *See also*, claim 1.
11. The prosthetic heart valve of claim 1, wherein the frame extends distally further than the leaflet assembly.	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ frame extends distally further than the leaflet assembly. For example, this occurs when the heart valve is in compressed, expanded, and partial configurations. For example, the Sapien 3 Ultra frame extends distally further than the leaflet assembly.

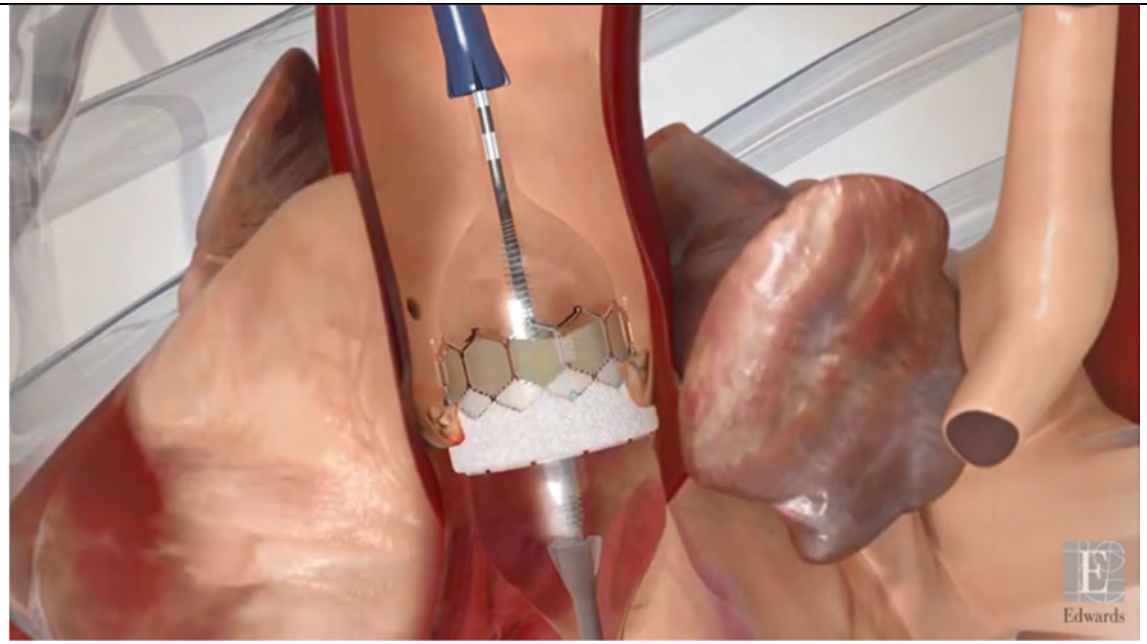


https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



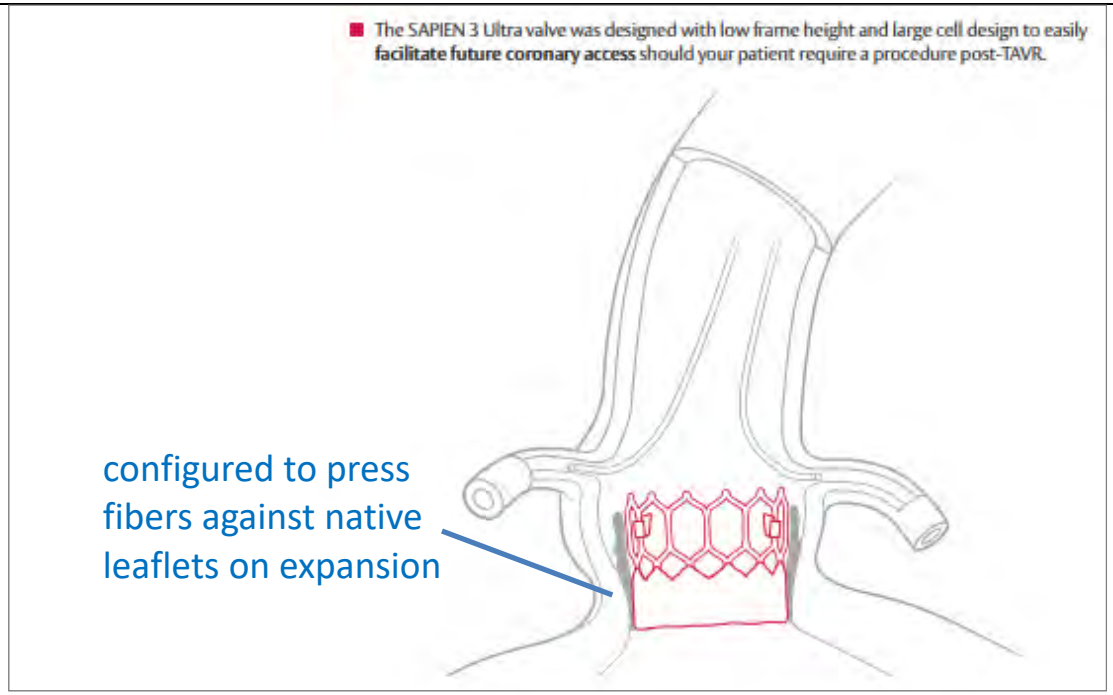
Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	See also, claim 1.
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.	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities are balloon expandable where expansion is configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient. For example, the Sapien 3 Ultra is deisgned and configured to be balloon expandable where expansion is configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient.  https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



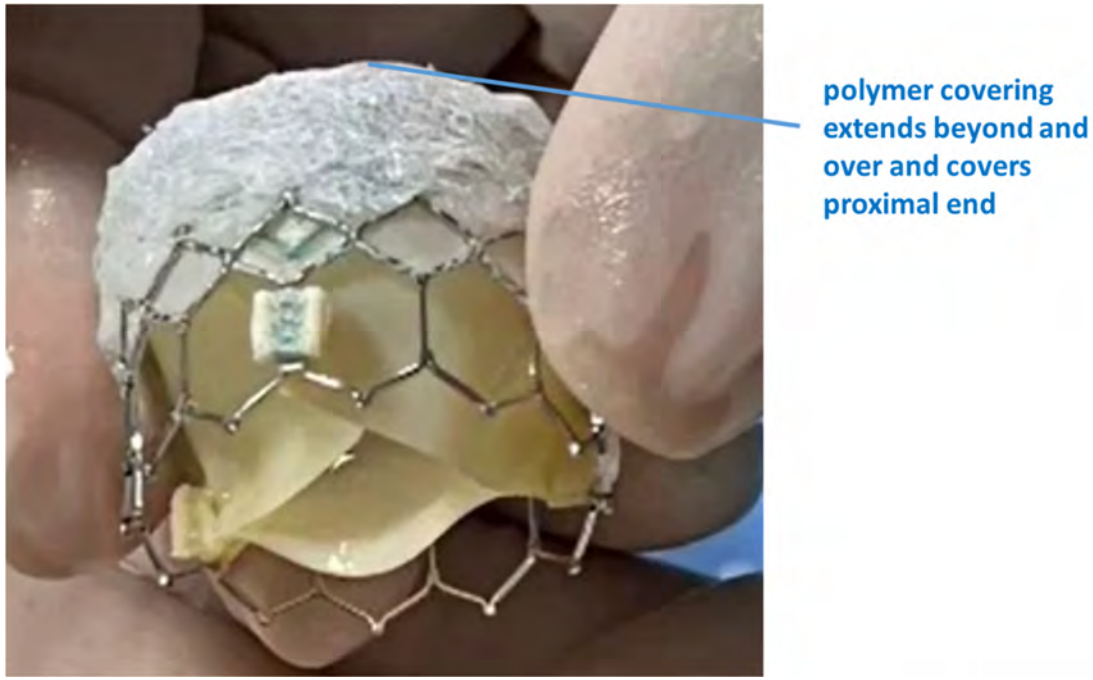
Ex.37, “TAVR Procedural Animation Using the SAPIEN 3 Ultra System,” available at https://youtu.be/o3whx7CdM3I.

	 https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

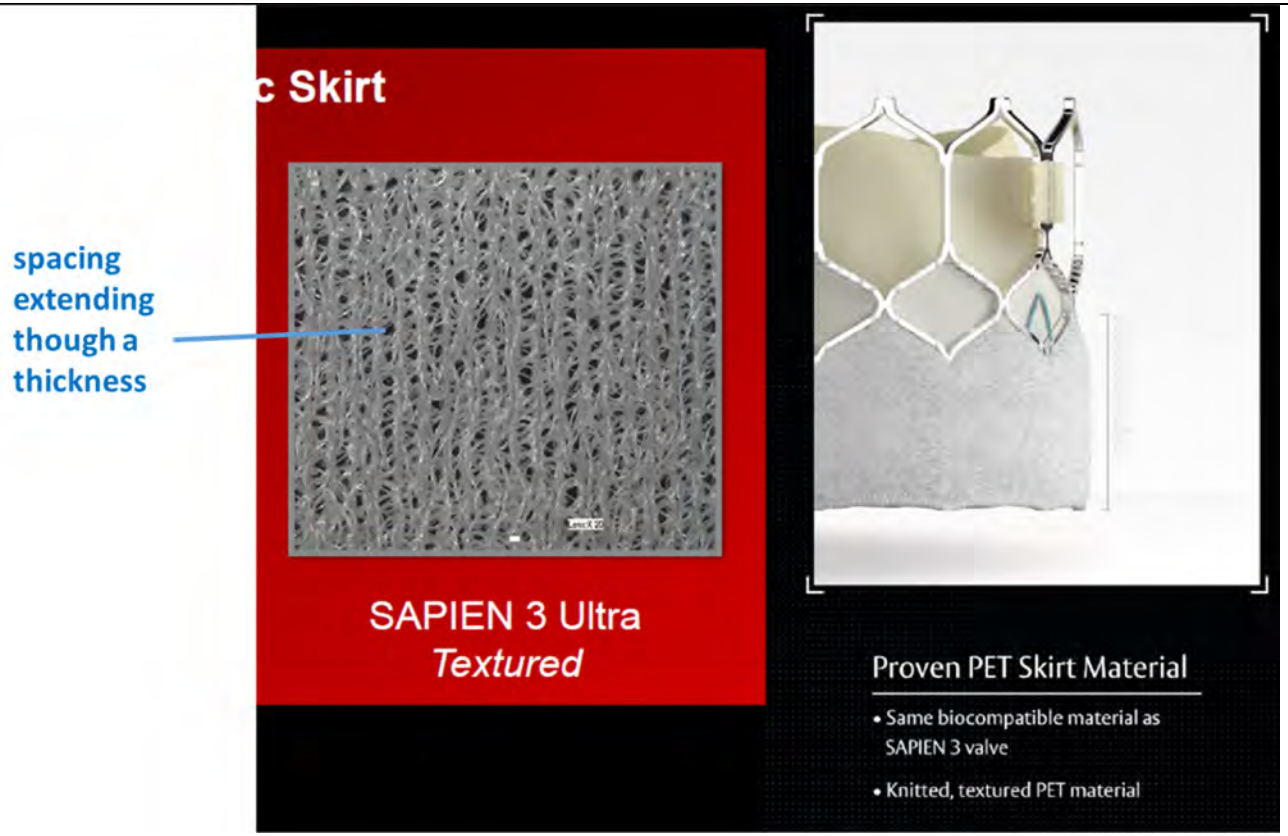


Introducing the Sapien 3 Ultra, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

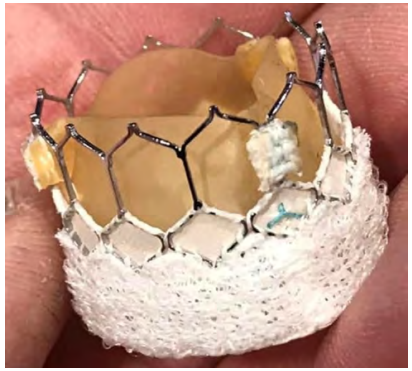
With respect to the phrase, "wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first plurality of fibers against native leaflets of an aorta of the patient", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by being capable of pressing at least some fibers against the leaflets in the aorta of the patient, in the same or substantially the same way as the claim phase through being balloon

	expandable and a first plurality of fibers to press at least some fibers against native leaflets, to achieve the same or substantially the same result of a balloon expandable heart valve configured to press some of the fibers against the leaflets of the aorta of the patient. *See also*, claim 1.
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.	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame. The Sapien 3 Ultra polymer covering, at least in some portions, extends beyond a proximal end of the frame and over the proximal ends to cover and/or partially cover at least portions of the proximal ends of the frame. 

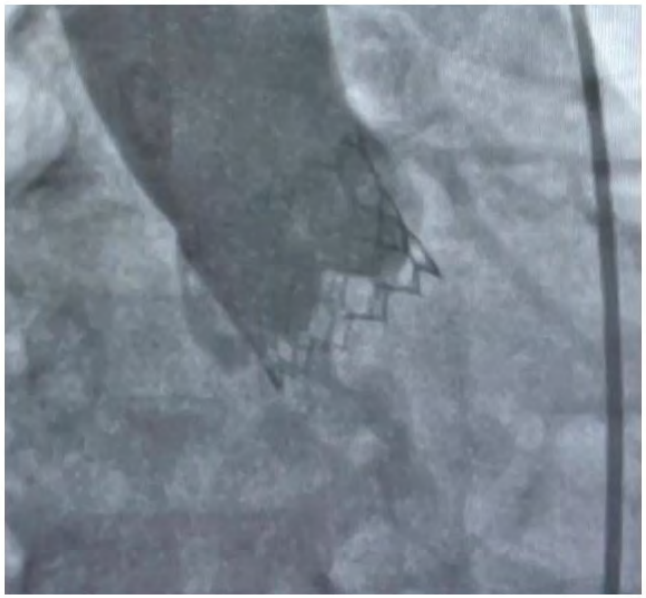
	Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74). *See also*, claim 1.
15. The prosthetic heart valve of claim 1, wherein the first plurality of fibers defines a spacing that extends through a thickness thereof that is created by a distance between adjacent fibers thereof.	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ first plurality of fibers defines a spacing that extends through a thickness thereof that is created by a distance between adjacent fibers thereof. The Sapien 3 Ultra first plurality of fibers include spacings created by distances between adjacent fibers that extend though a thickness thereof.

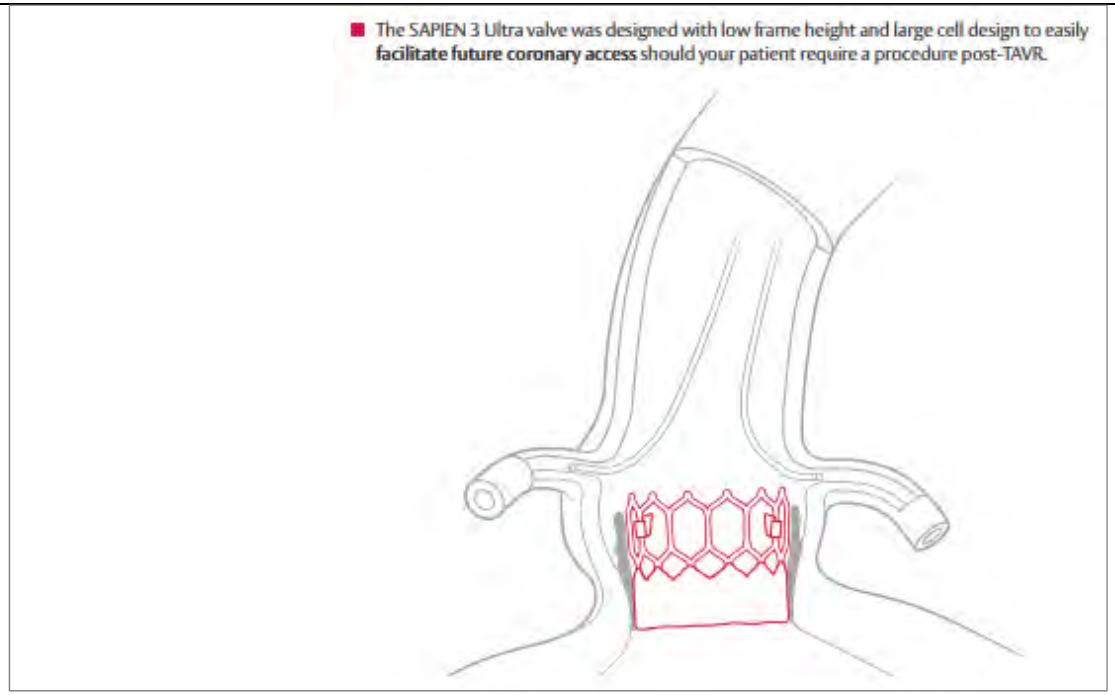


Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

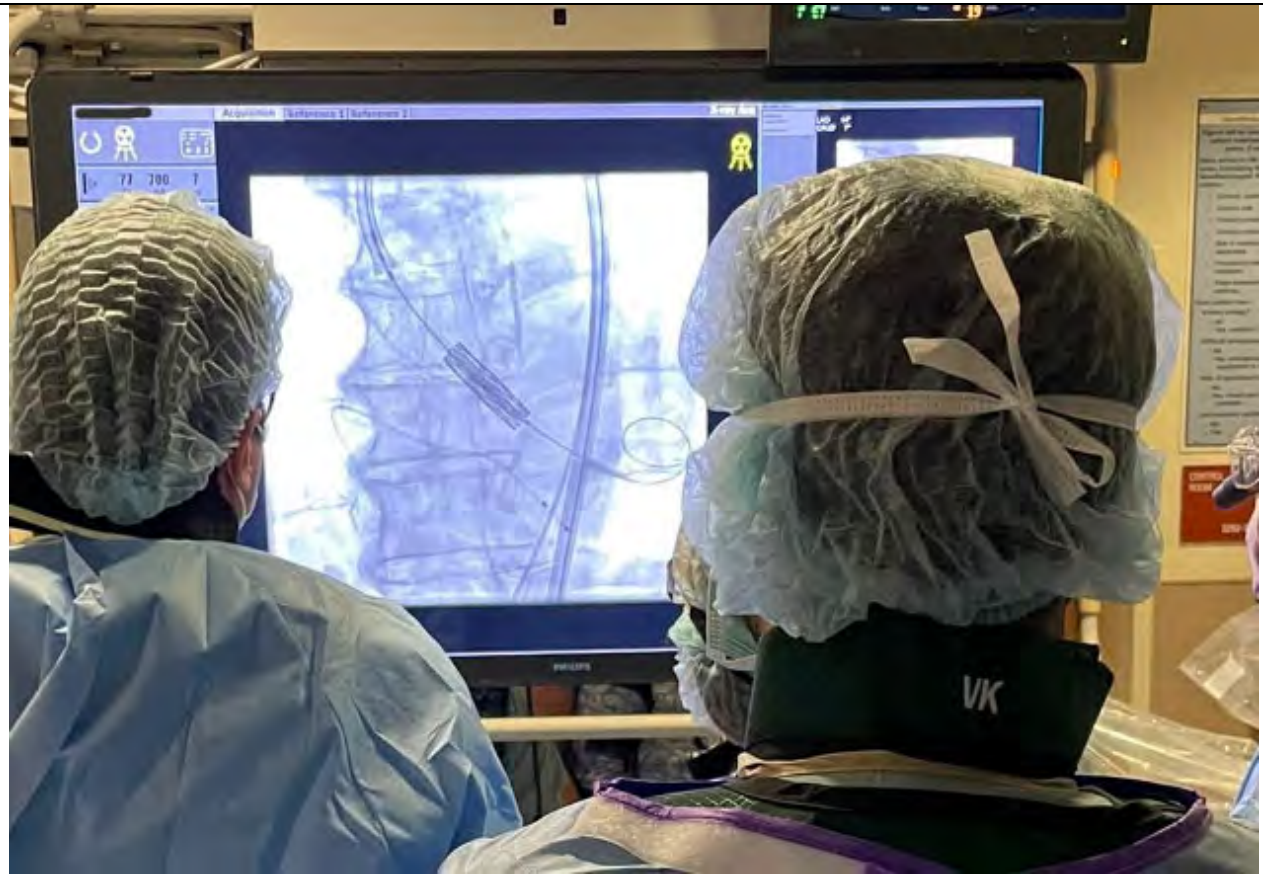
	  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3). *See also*, claim 1.
16. The prosthetic heart valve of claim 1, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ 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. The Sapien 3 Ultra is radially expandable from the radially compressed orientation along the length of the frame from the proximal to the distal end. The Sapien 3 Ultra is also designed to be expanded using an Edwards balloon delivery system in the aorta of a patient into a radially expanded orientation.

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

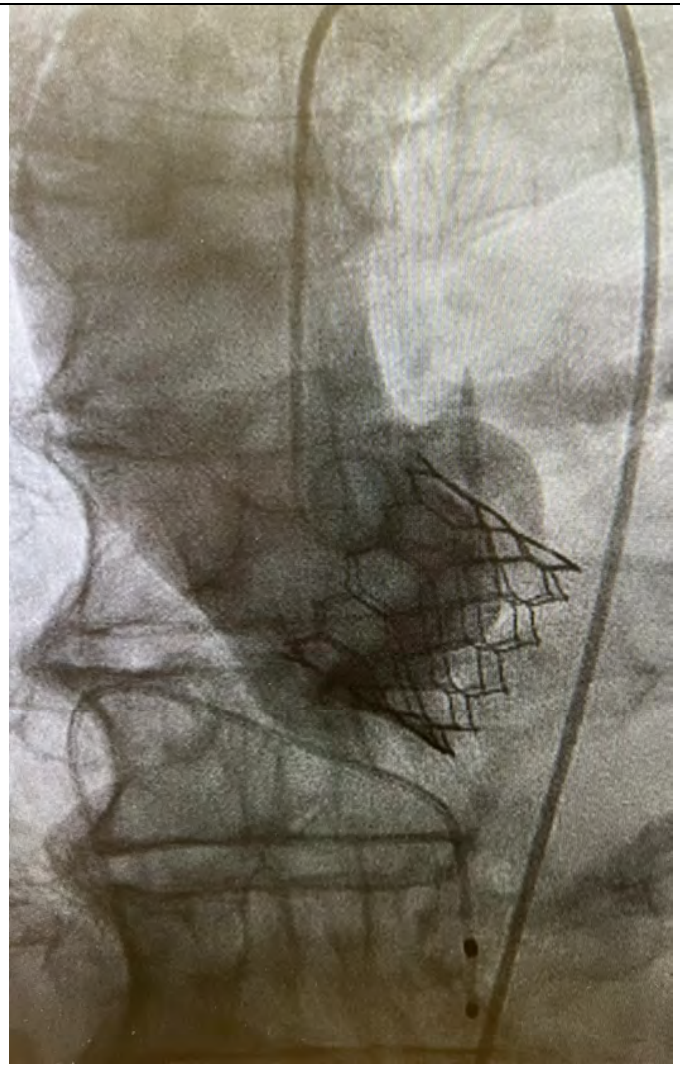
	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



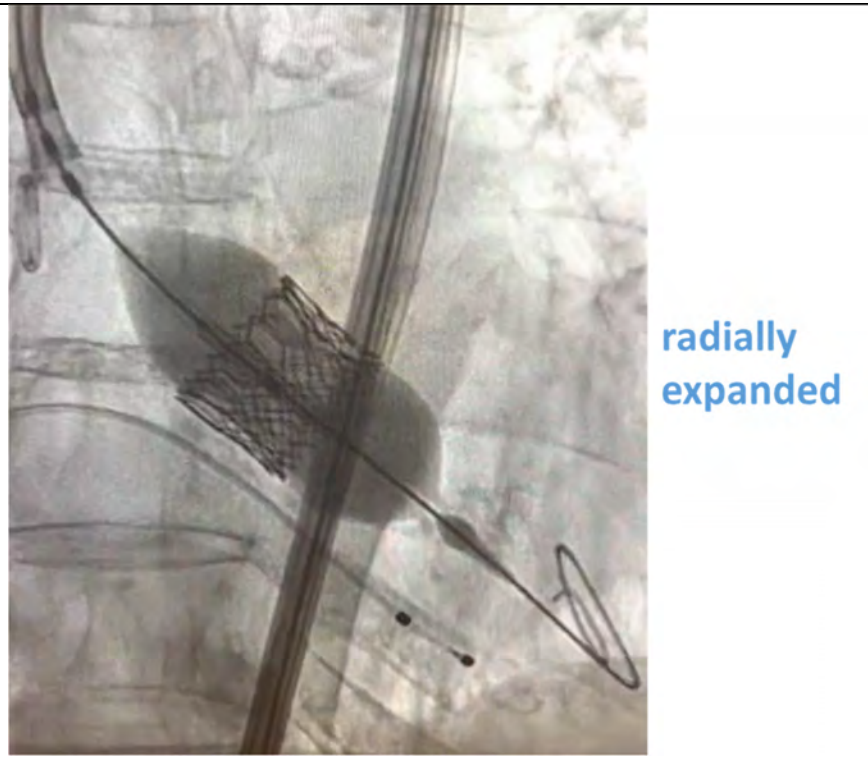
Introducing the Sapien 3 Ultra, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



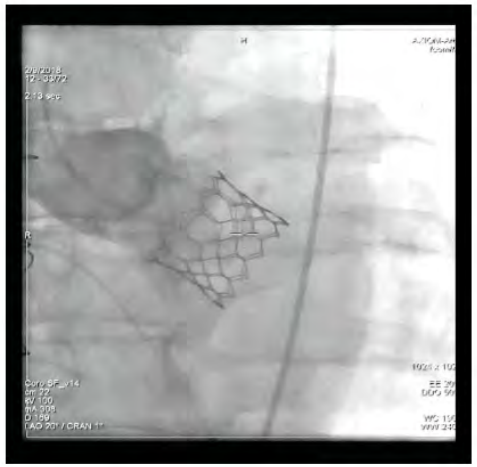
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

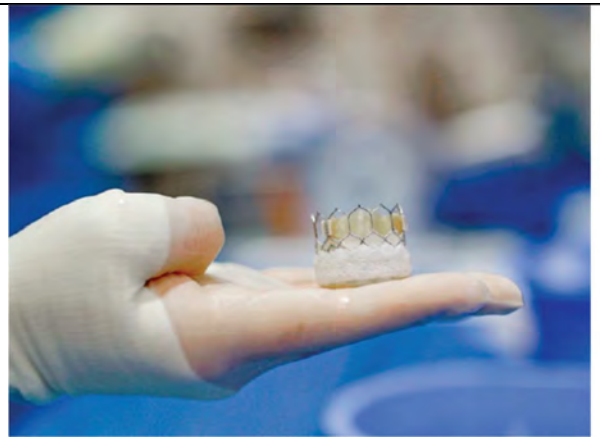
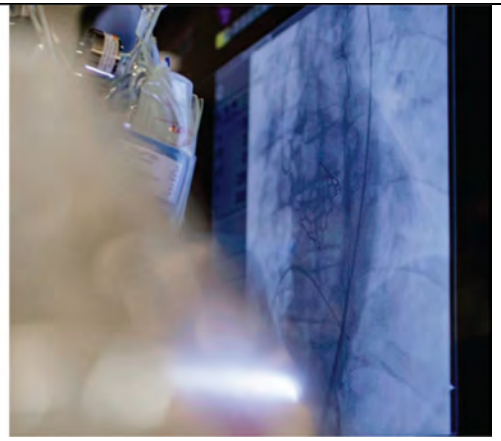
	 https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

	 https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=7vNdYaSyfo8PlVNSNv2WDQ



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

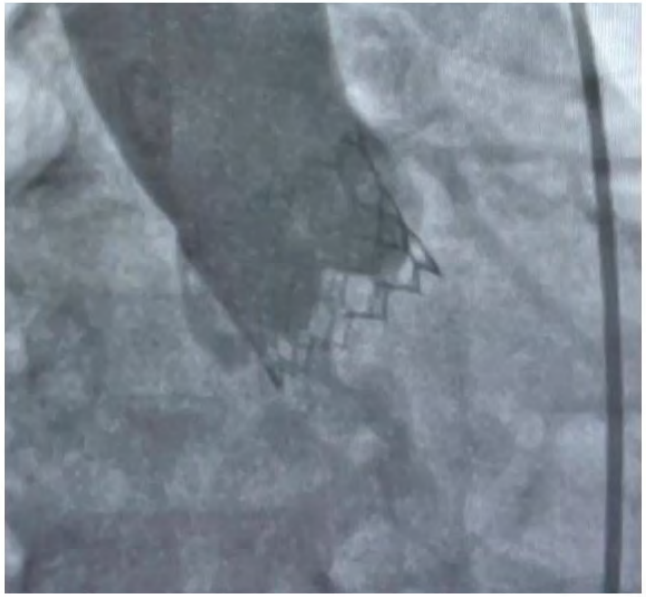
	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47). *See also*, claim 1.
17. An endovascular prosthetic heart valve for use in a patient, comprising:	To the extent the preamble is limiting, the '834 patent Accused Instrumentalities satisfy this element. For example, the '834 patent Accused Instrumentalities are endovascular prosthetic heart valves for use in a patient. The '834 patent Accused Instrumentalities are designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems.

https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

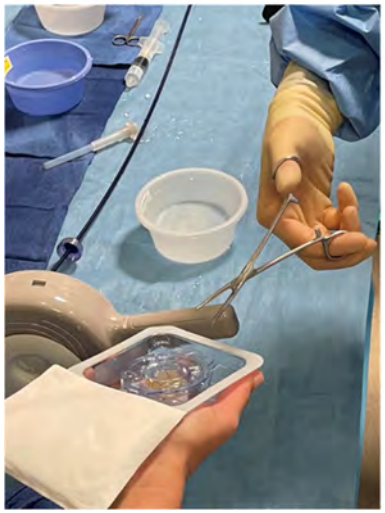


Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg



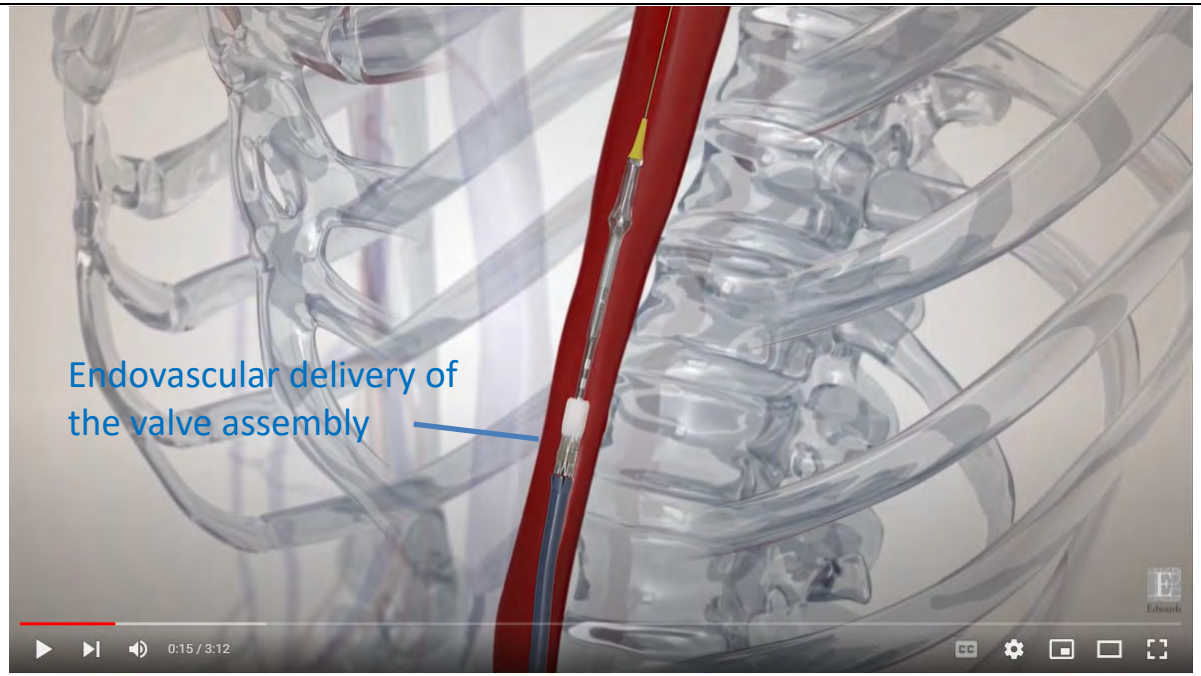


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra[4] is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[4] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.



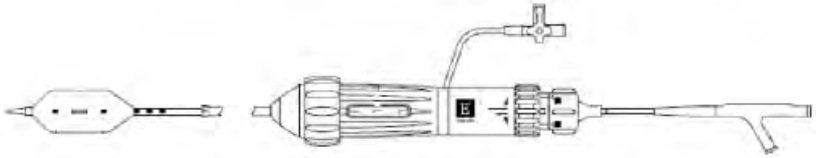
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



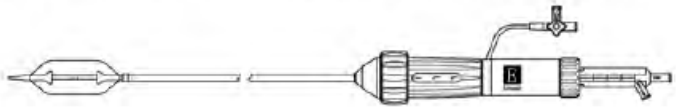
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

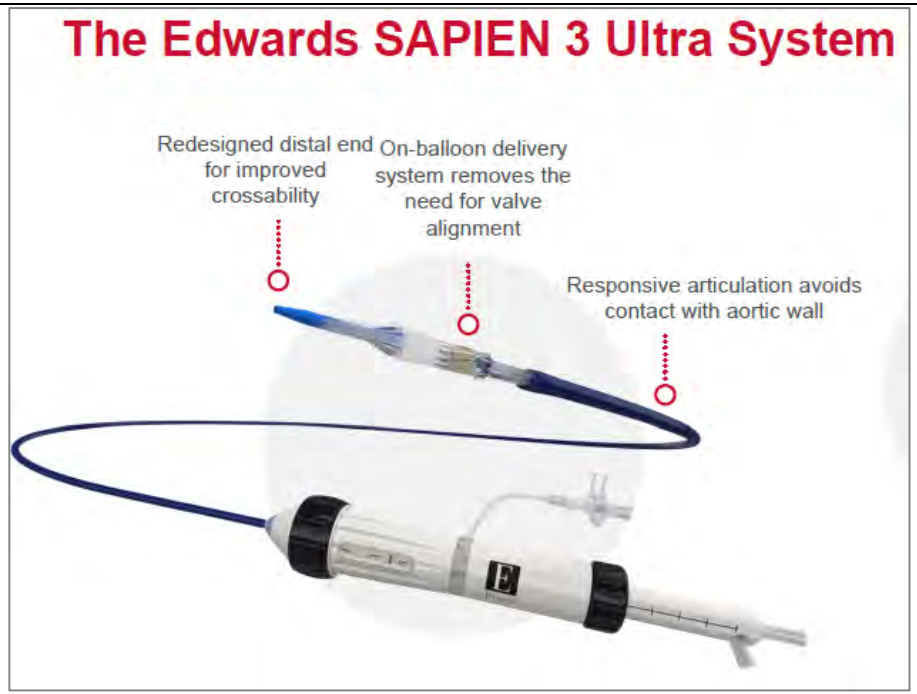
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

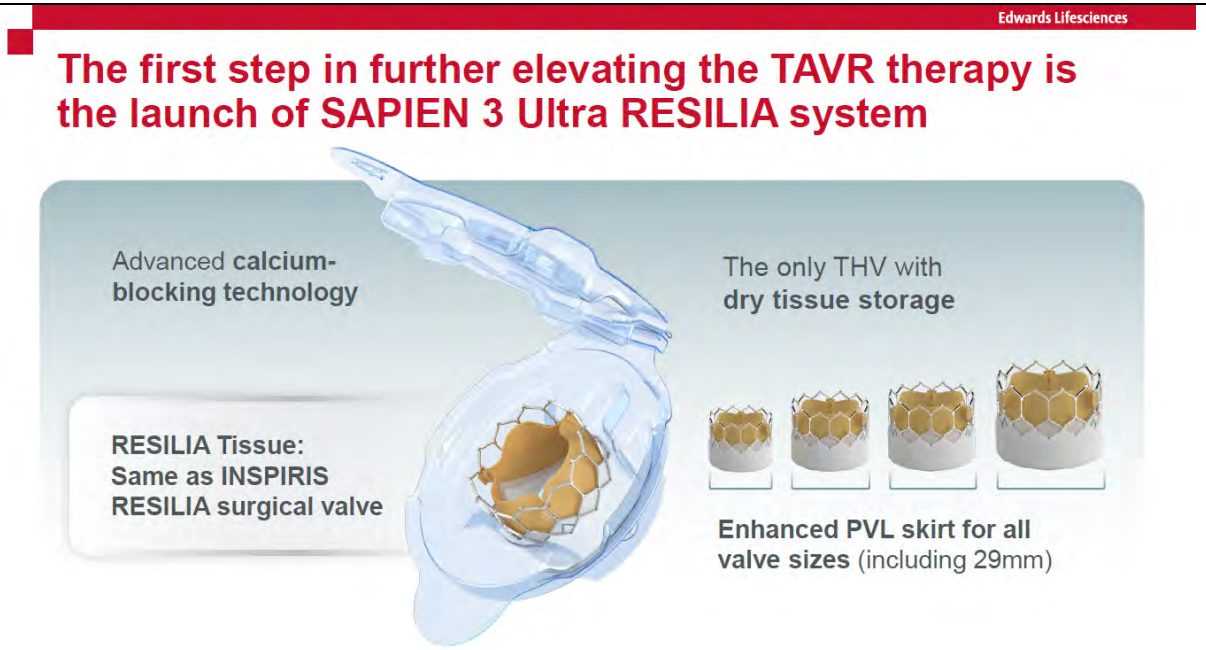
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

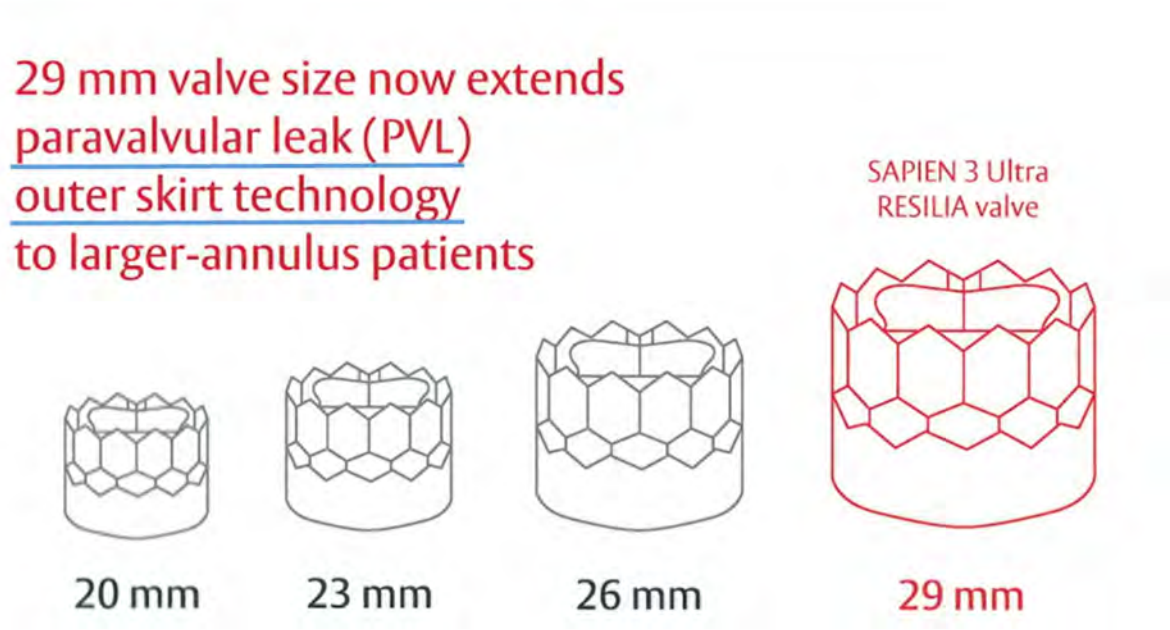
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

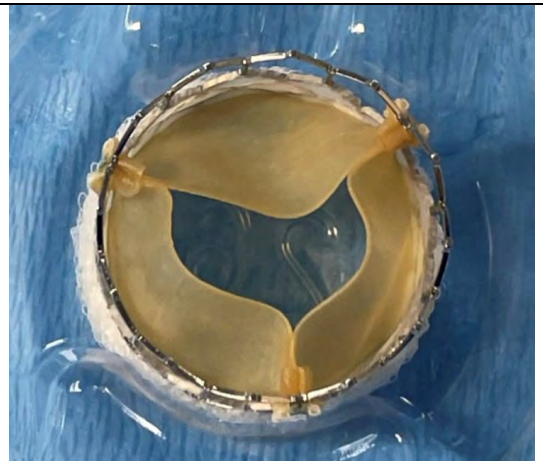
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’834 patent Accused Instrumentalities and infringes the ’834 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



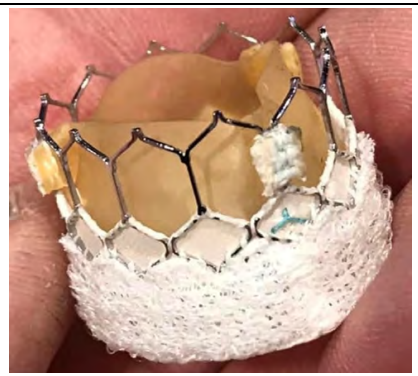
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



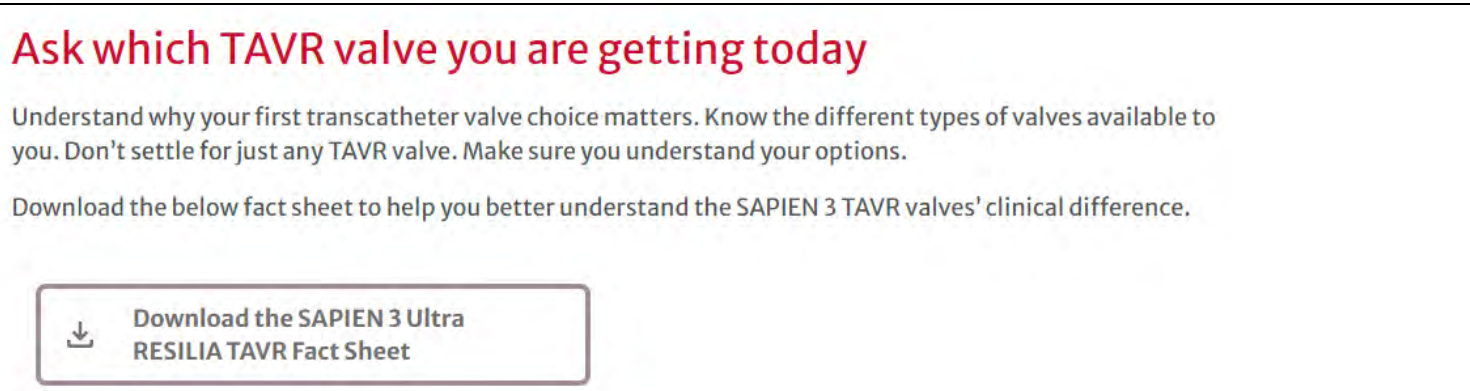

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the '834 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See* https://ir.edwards.com/events-presentations/;

	https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '834 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '834 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '834 asserted claims are infringed when Edwards offers for sale and sells the '834 patent Accused Instrumentalities. Edwards offers for sale and promotes the '834 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 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. 

	 https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

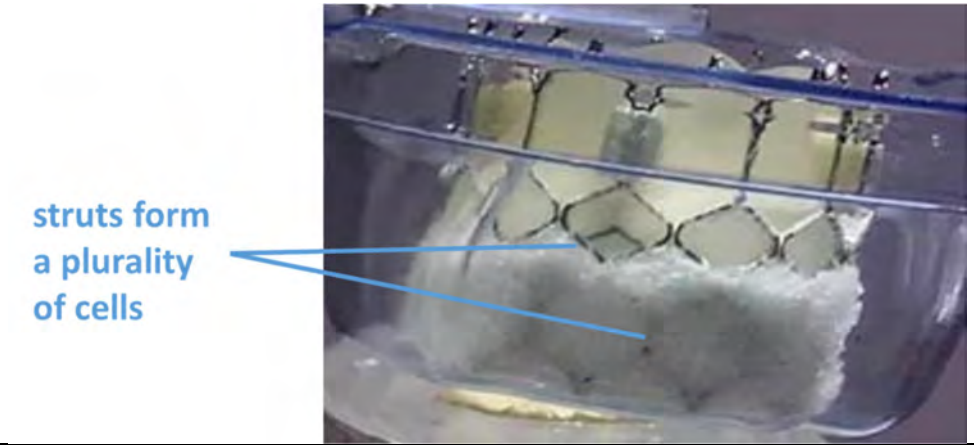


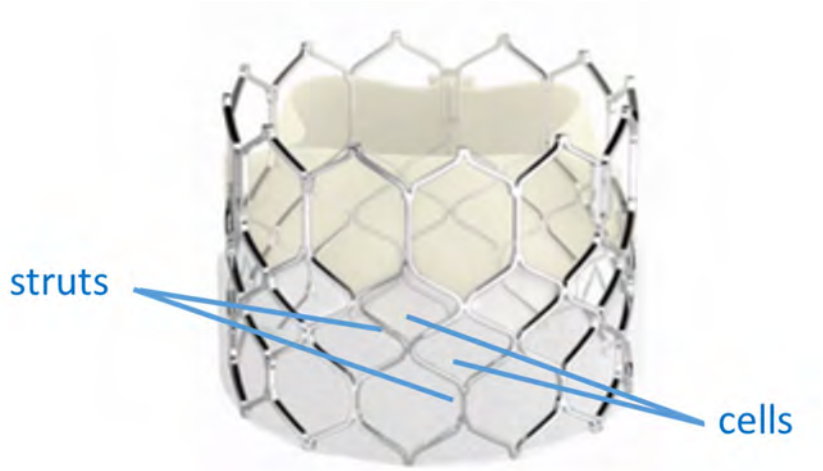
https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61).

On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement#

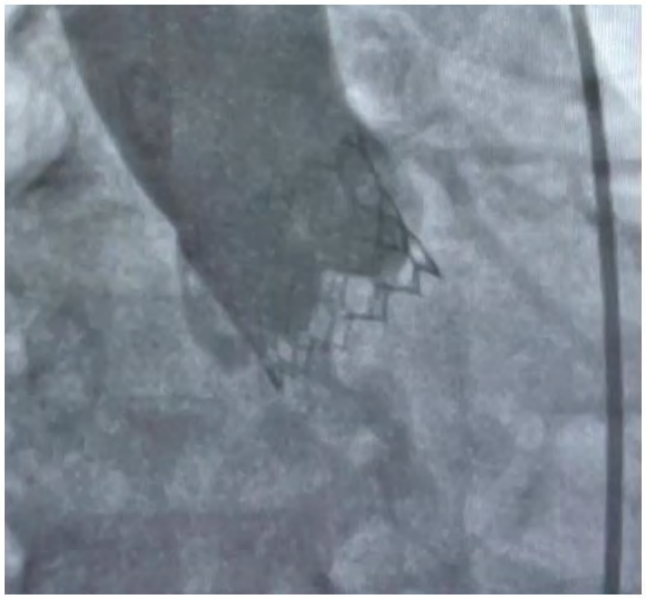
Further, the '834 patent asserted claims are directly infringed when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the '834 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards' direct and induced infringement. For further example, on information and belief, Edwards's affiliated hospitals and doctors directly infringe the asserted '834 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a "watchful eye" over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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. 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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards's affirmative acts of marketing, selling and offering to

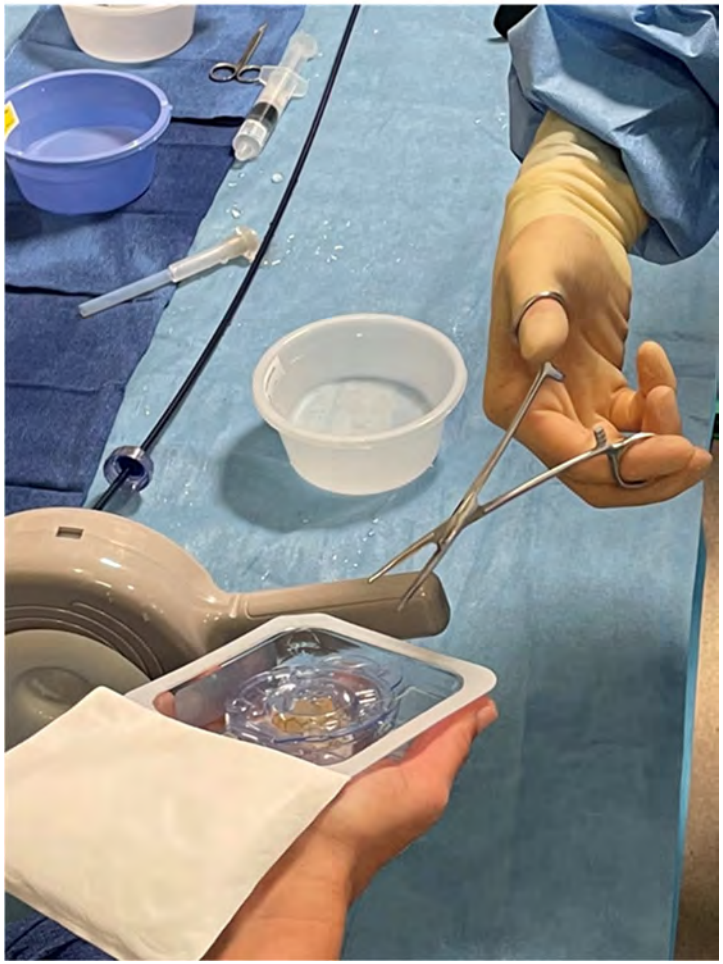
	sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' combination and use of the Accused Instrumentalities, such that the '834 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards' knowledge of Aortic's inventions, the patents-in-suit (including the '834 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
a frame formed of a plurality of struts that cooperate to form a plurality of cells,	The '834 patent Accused Instrumentalities satisfy this element. The '834 patent Accused Instrumentalities comprise a frame formed of a plurality of struts that cooperate to form a plurality of cells. For example, the Sapien 3 Ultra frame is formed of struts that cooperate to form a plurality of cells. 

	Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). *See also*, evidence for preceding elements above. With respect to the phrase, "a frame formed of a plurality of struts that cooperate to form a plurality of cells", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with the capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of providing a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy. Further,

	whether the frame formed of a plurality of struts that cooperate to form a plurality of cells is laser cut from a single piece of material or made otherwise is the same or, at most, an insubstantial difference.
wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities comprise a frame that is radially expandable from a radially compressed orientation to a radially expanded orientation. For example, the Sapien 3 Ultra is packaged and provided by Edwards in a radially expanded configuration. The Sapien 3 Ultra is designed by Edwards to be crimped onto an Edwards’ balloon delivery system in a radially compressed orientation. The Sapien 3 Ultra is also designed to be expanded using an Edwards’ balloon delivery system in the aorta of a patient into a radially expanded orientation.  Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

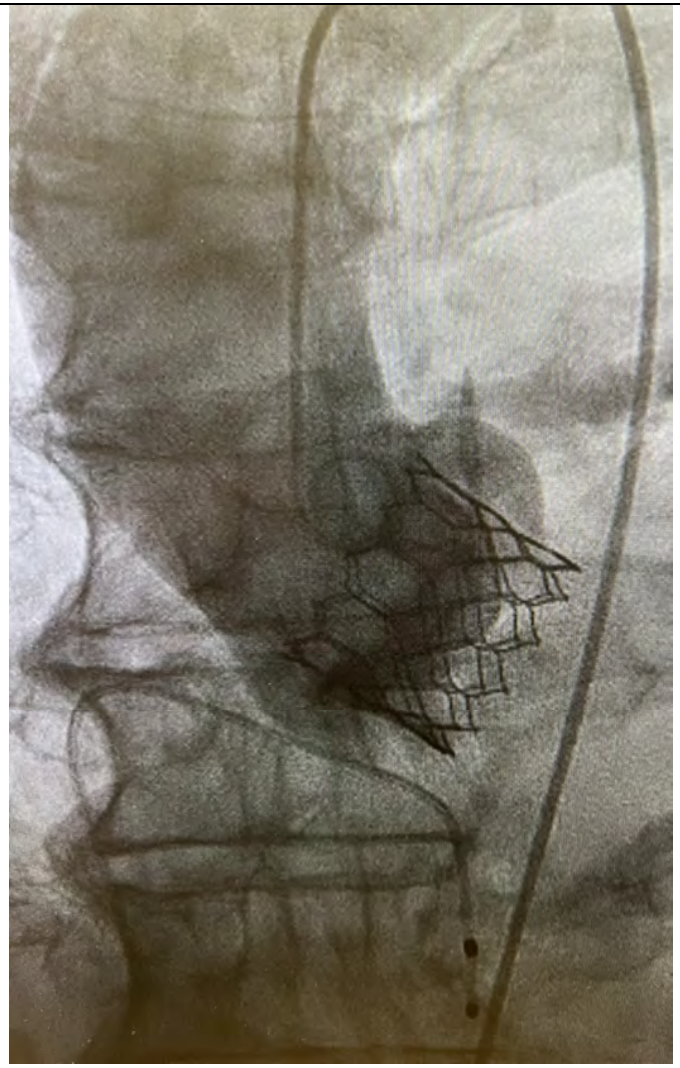
	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



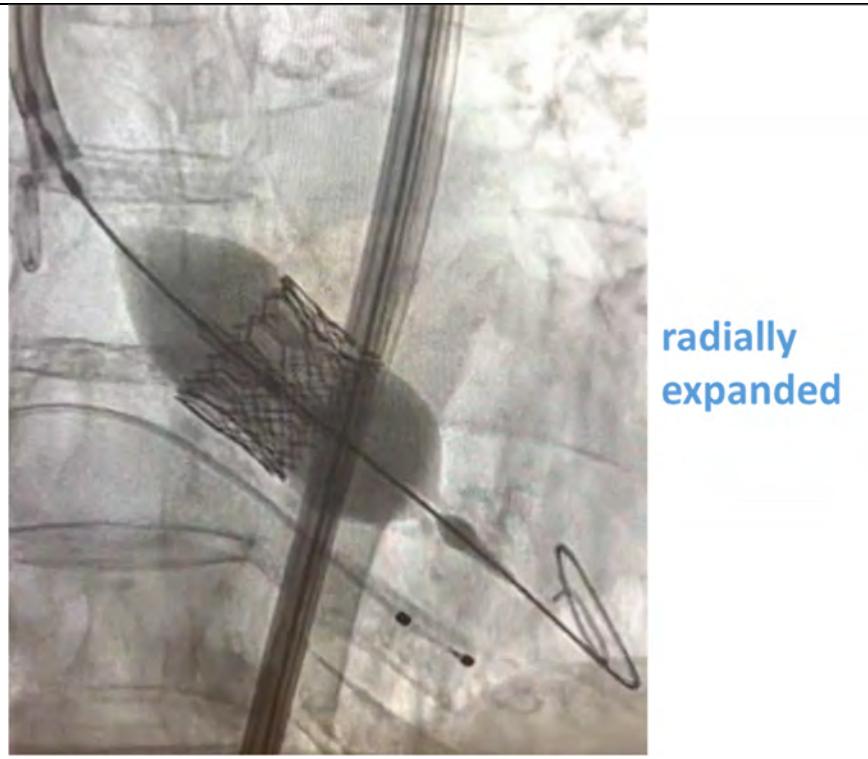
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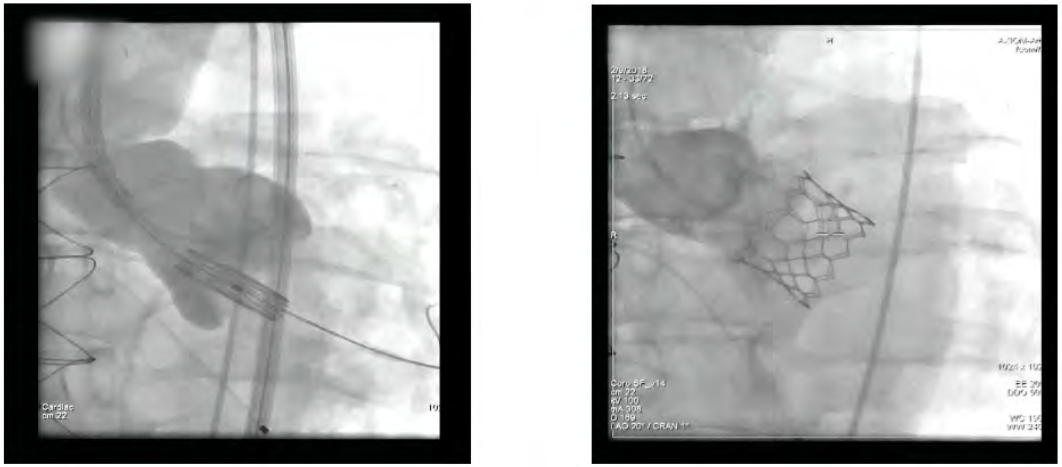
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https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=7vNdYaSyfo8PlVNSNv2WDQ



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

	SAPIEN 3 Ultra System Case Example  Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

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.



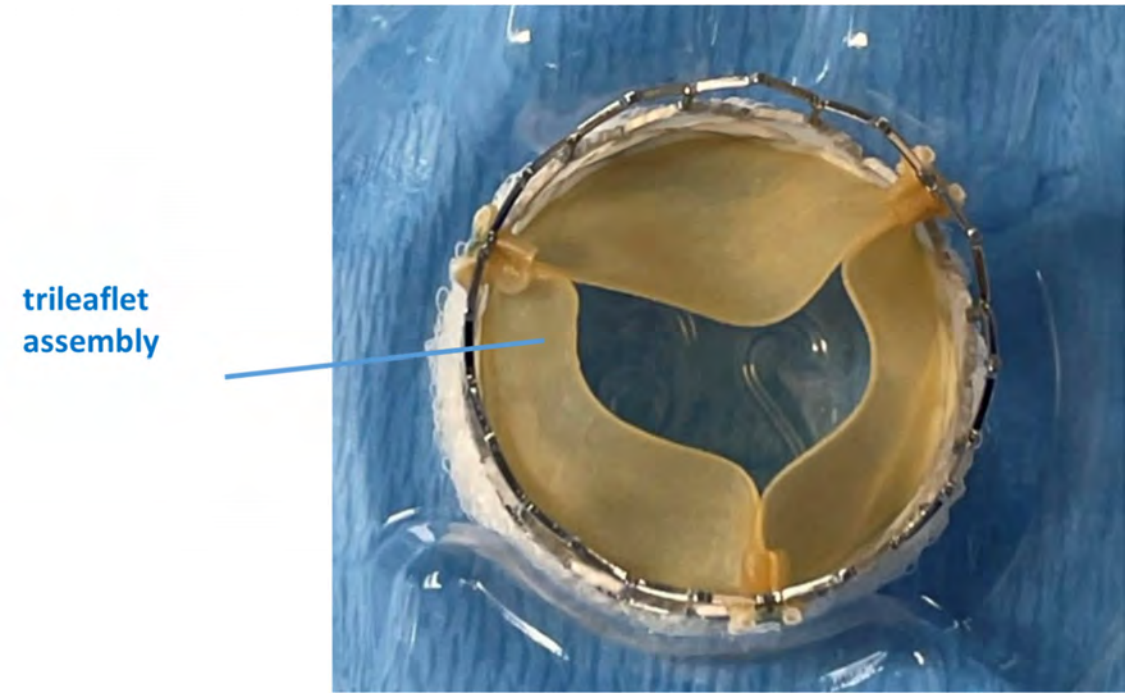
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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

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 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a leaflet assembly within the frame;	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities comprise a leaflet assembly within the frame. For example, the Sapien 3 Ultra devices comprise a bovine pericardial tissue trileaflet assembly and/or Resilia tissue trileaflet assembly housed within the frame.  https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).

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.

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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.



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23 mm	18 mm
26 mm	20 mm

Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities comprise a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly. For example, the Edwards Sapien 3 Ultra has a polymer covering made from PET that carries the leaflet assembly. Further, the Sapien 3 Ultra polymer covering is positioned radially inward of the frame and radially outward of the leaflet assembly.  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added) (showing polymer covering radially inward of the frame and outward of the leaflet assembly) (D.I. 1, Ex. 33).

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.

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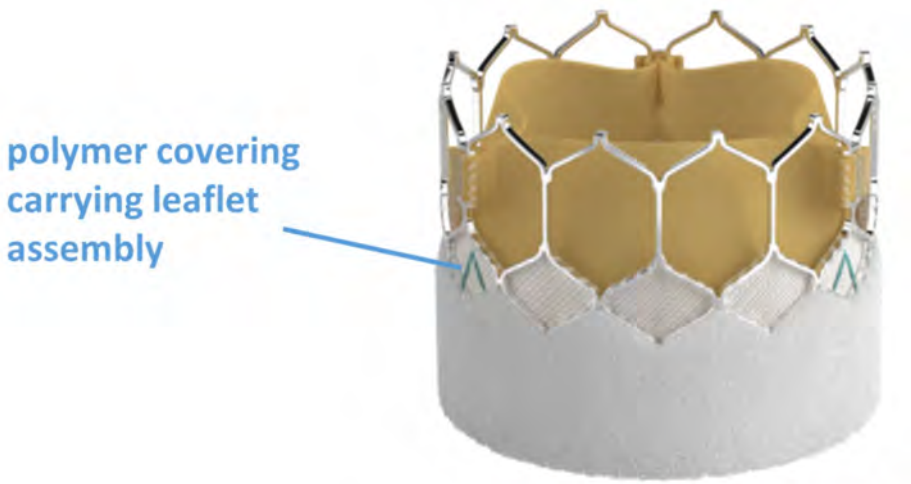
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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

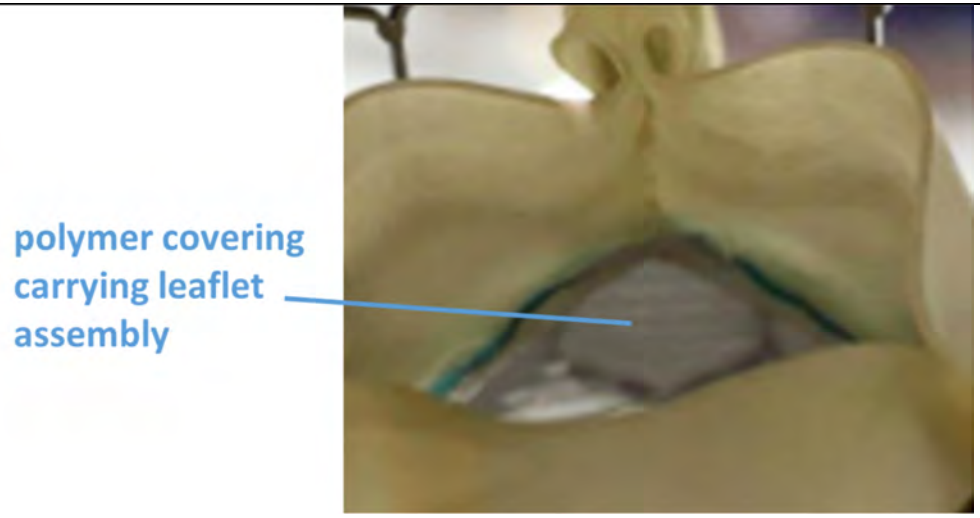
Table 1

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 (D.I. 1, Ex. 44).

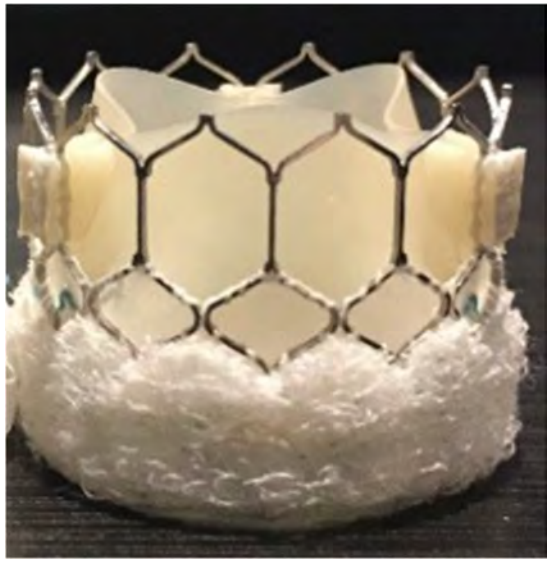


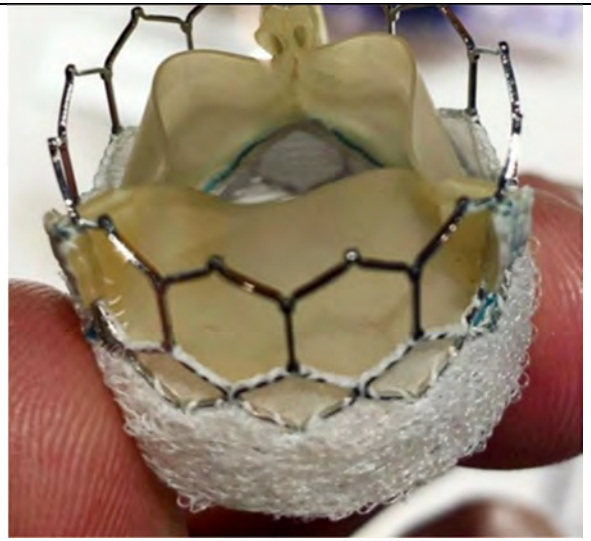
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

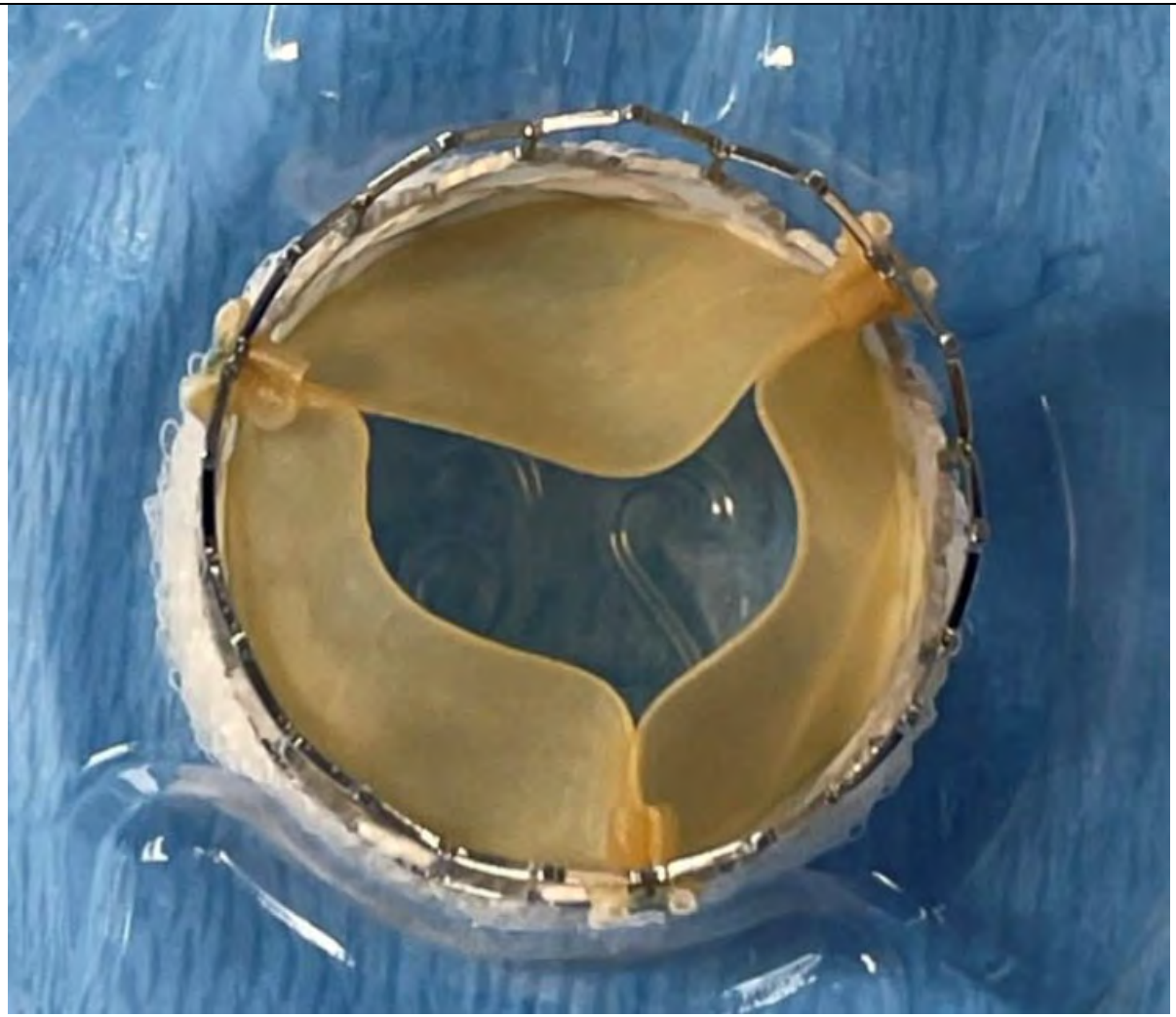


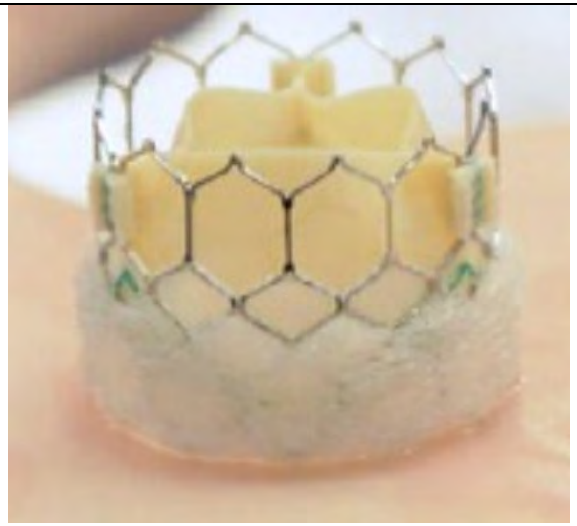
https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a polymer covering positioned radially inwardly of the frame and radially outwardly of the leaflet assembly, the identified polymer coverings are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused polymer covering performs the same or substantially the same function as the claim phrase by covering and carrying the leaflet assembly or portions thereof, in the same or substantially the same way as the claim phase through including a polymer covering that is positioned at least partially radially outward of the leaflet assembly and radially inward of the frame and by being attached to the leaflet assembly, to achieve the same or substantially the same result of a polymer covering configured to cover and/or carry or partially cover and/or carry the leaflet assembly.

a first plurality of fibers that extend away from the frame,	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 Accused Instrumentalities comprise a first plurality of fibers that extend away from the frame. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of fibers that extend away from the frame.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 29).

	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 64).

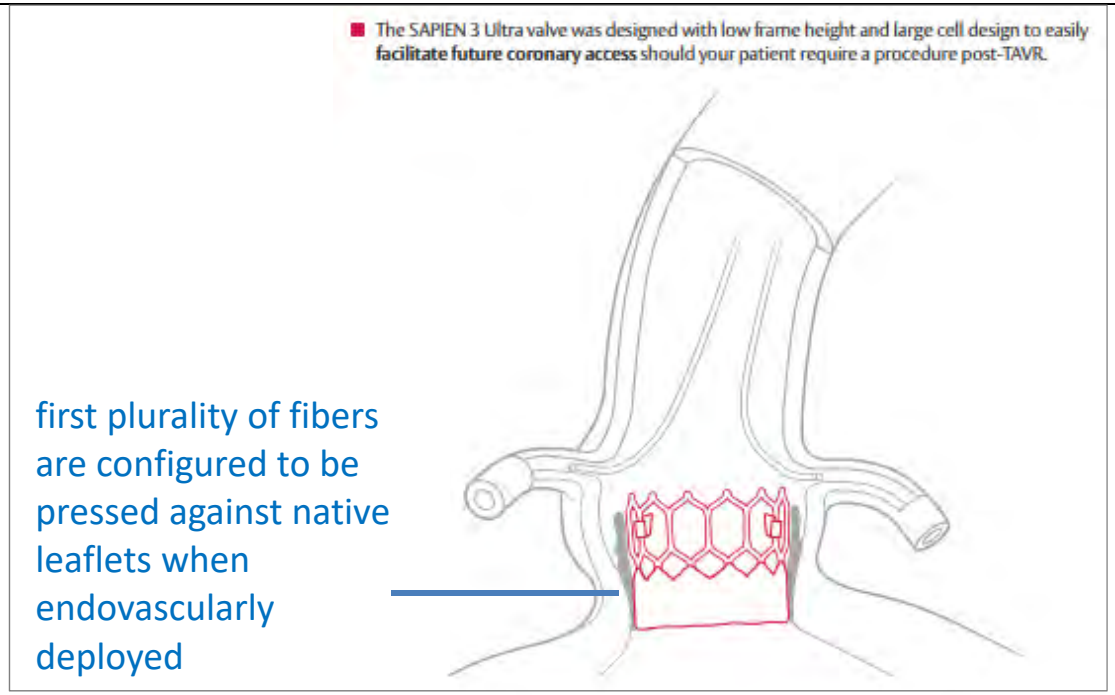
	 https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65) (showing plurality of fibers extending away from frame).



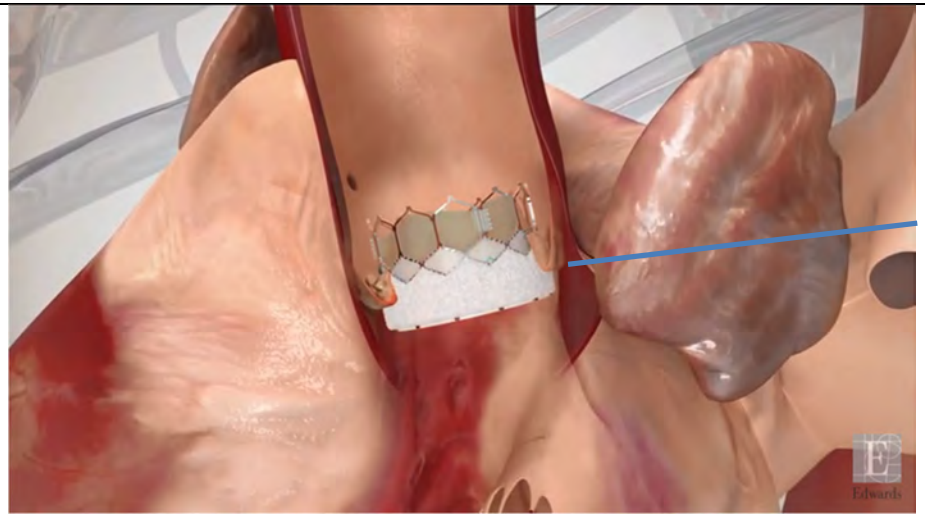
Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 3).

With respect to the phrase, "a first plurality of fibers that extend away from the frame" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a first plurality of fibers that extend away from the frame, the identified a first plurality of fibers that extend away from the frame of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused first portion of fibers perform the same or substantially the same function as the claim phrase by providing low profile sealing against the native leaflets of the aorta and spacings between fibers, in the same or substantially the same way

	as the claim phase by extending generally away from the frame and pressing against the native leaflets of the aorta of the patient and filing in spacings when the valve is expanded, to achieve the same or substantially the same result of a first plurality of fibers that generally extend away from the frame configured to provide sealing between the native annulus and the valve assembly.
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	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities’ first plurality of fibers are 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. For example, the Sapien 3 Ultra sealing skirt fibers are configured to be pressed against the native leaflets of the patient when endovascularly deployed and expanded.

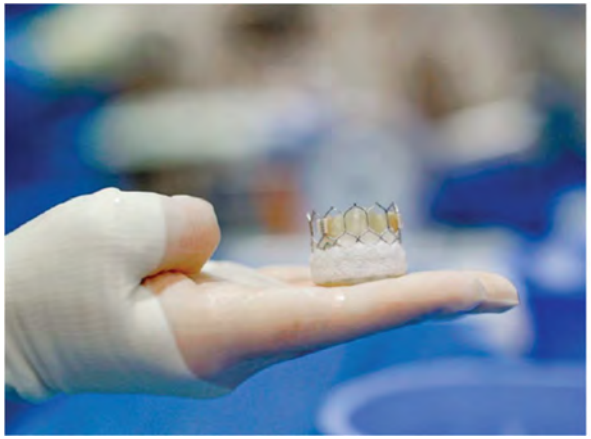


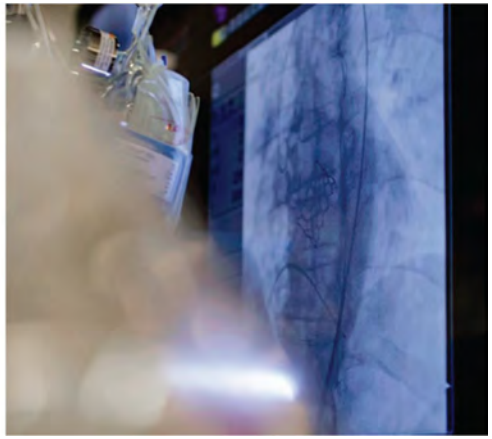
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



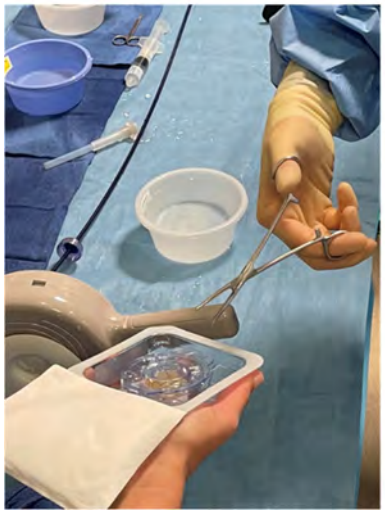
"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through the femoral artery using Edwards' balloon catheter delivery systems.





	https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).  https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg





https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

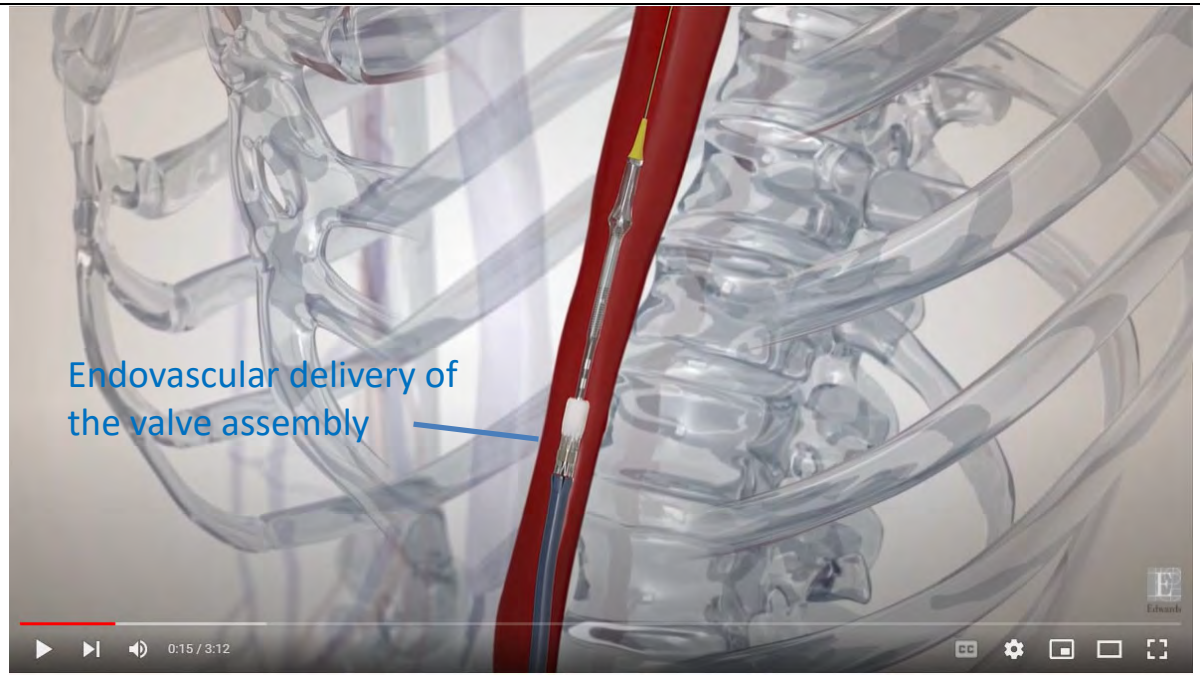


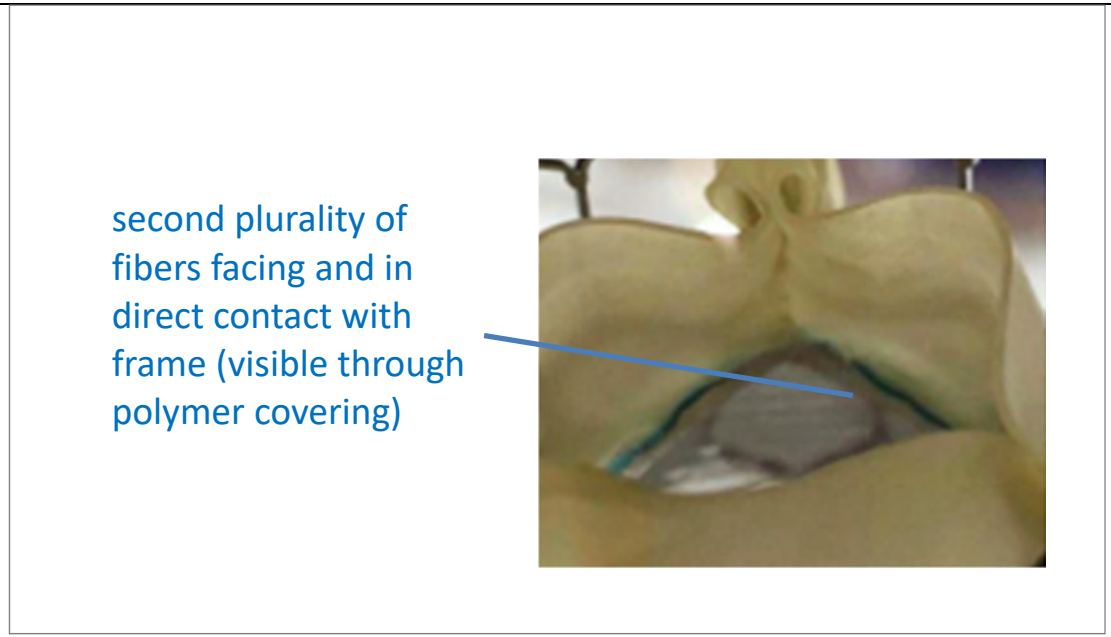
https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.

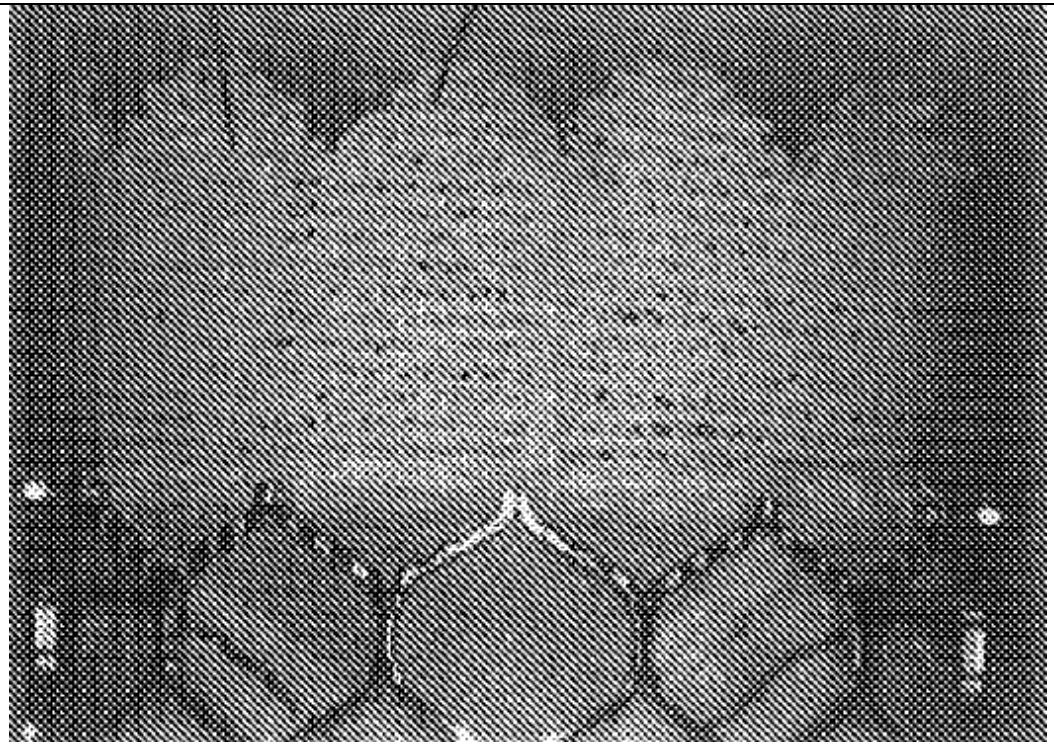


SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
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,	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities comprise a second plurality of fibers positioned radially inwardly from the first plurality of fibers, wherein the second plurality of fibers is in direct contact with the frame. For example, the Sapien 3 Ultra sealing skirt includes fibers facing the frame that are in direct contact with the frame. The sealing skirt in the Sapien 3 Ultra is sewn to the frame and has a backside (internal facing portion) with a second plurality of fibers that directly contact the frame.



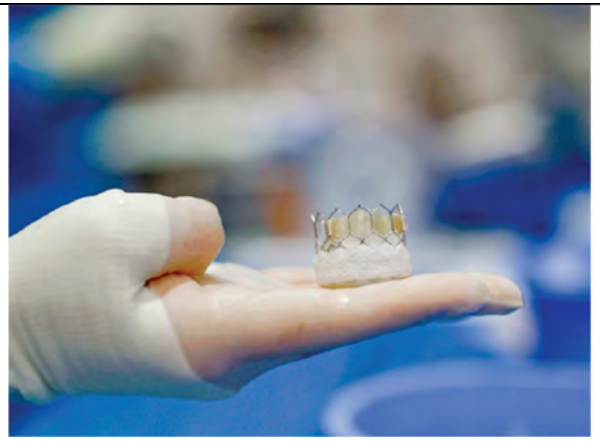
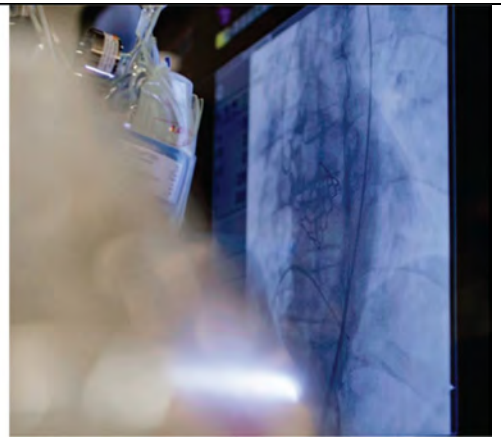
Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).



U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing fibers on flipped up backside of sealing skirt).

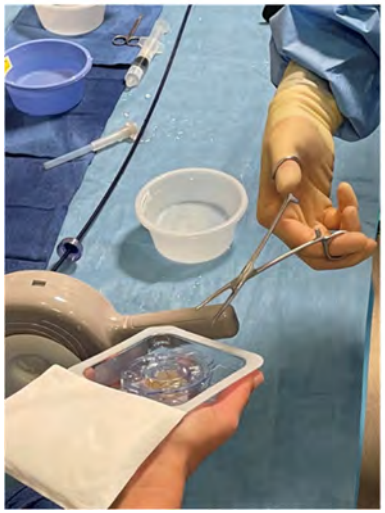
With respect to the phrase, "a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a second plurality of fibers that is positioned radially inwardly from the first plurality of fibers, the identified second plurality of fibers that is positioned radially inwardly from the first plurality of fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused second plurality of

	fibers perform the same or substantially the same function as the claim phrase by helping provide low profile sealing against the frame when expanded, in the same or substantially the same way as the claim phase by being attached to and pressing against the frame, to achieve the same or substantially the same result a second plurality of fibers configured to provide sealing against the frame of the valve assembly. With respect to the phrase, "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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by having a second plurality of fibers in direct contact with the frame, in the same or substantially the same way as the claim phase through including a plurality of fibers at least generally radially inwardly from the first plurality of fibers in direct or partially direct contact with the frame, to achieve the same or substantially the same result a second plurality of fibers configured to be in direct contact or generally in direct contact with the frame.
wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,	The '834 patent Accused Instrumentalities satisfy this element. For example, the '834 patent Accused Instrumentalities are designed, configured and deployable though a femoral artery of a patient. Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through the femoral artery using Edwards' balloon catheter delivery systems.

	  https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

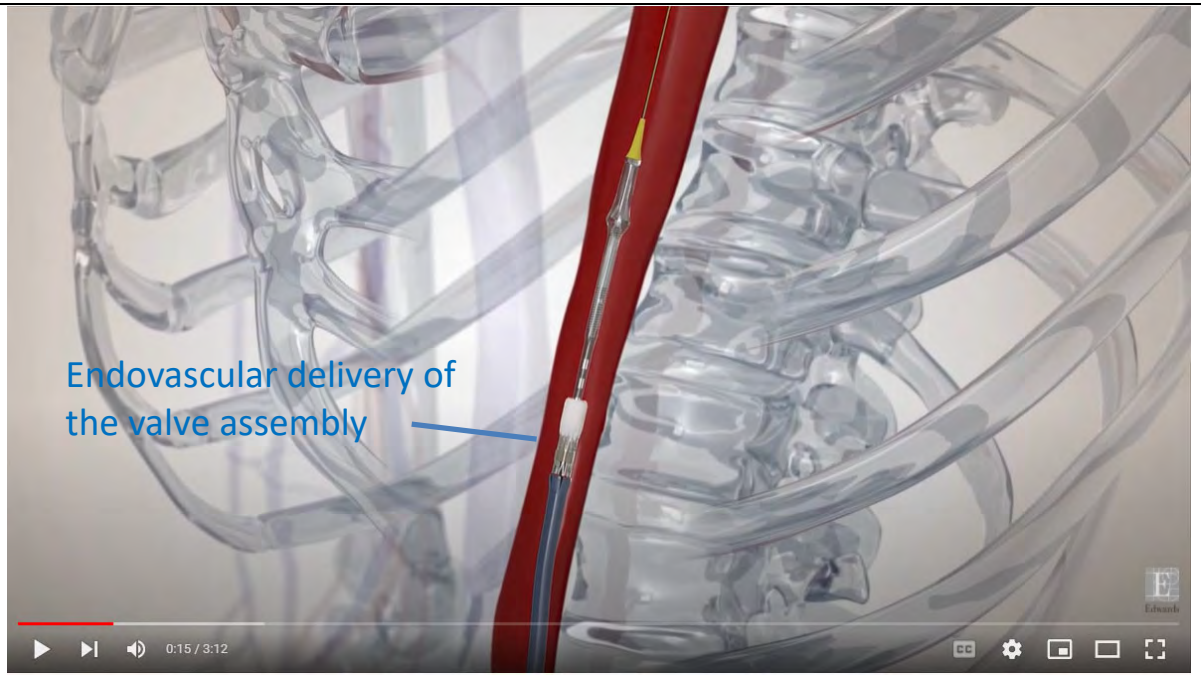


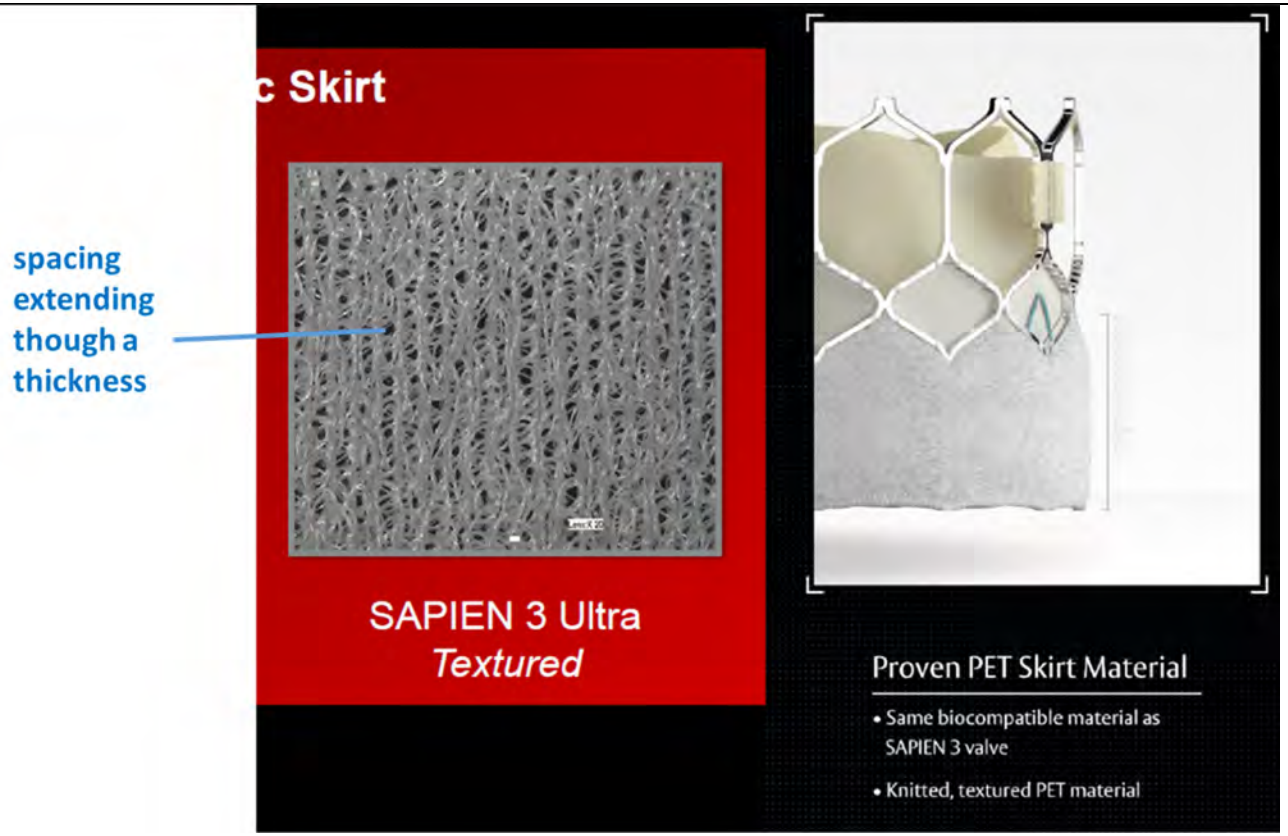


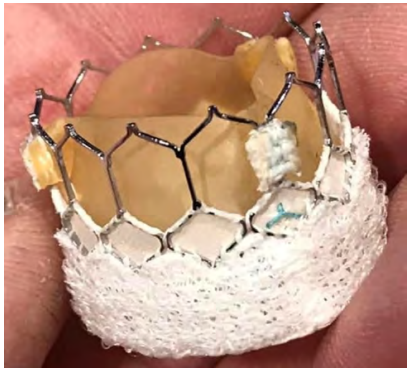
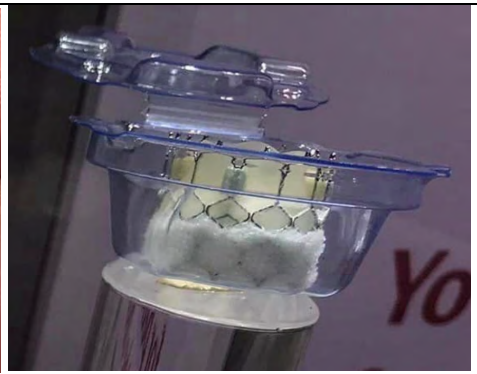
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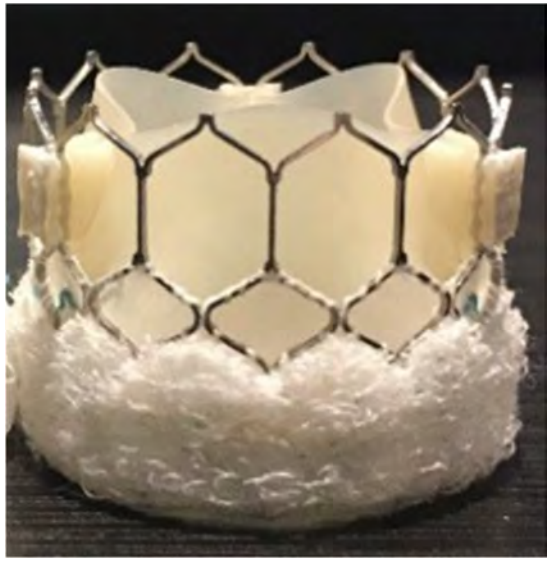
	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
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	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities comprise a 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 The Sapien 3 Ultra first plurality of fibers include spacings created by distances between adjacent fibers that extend though a thickness thereof.

thickness of the second plurality of fibers created by a distance between adjacent fibers thereof, and through the plurality of cells of the frame,	 Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

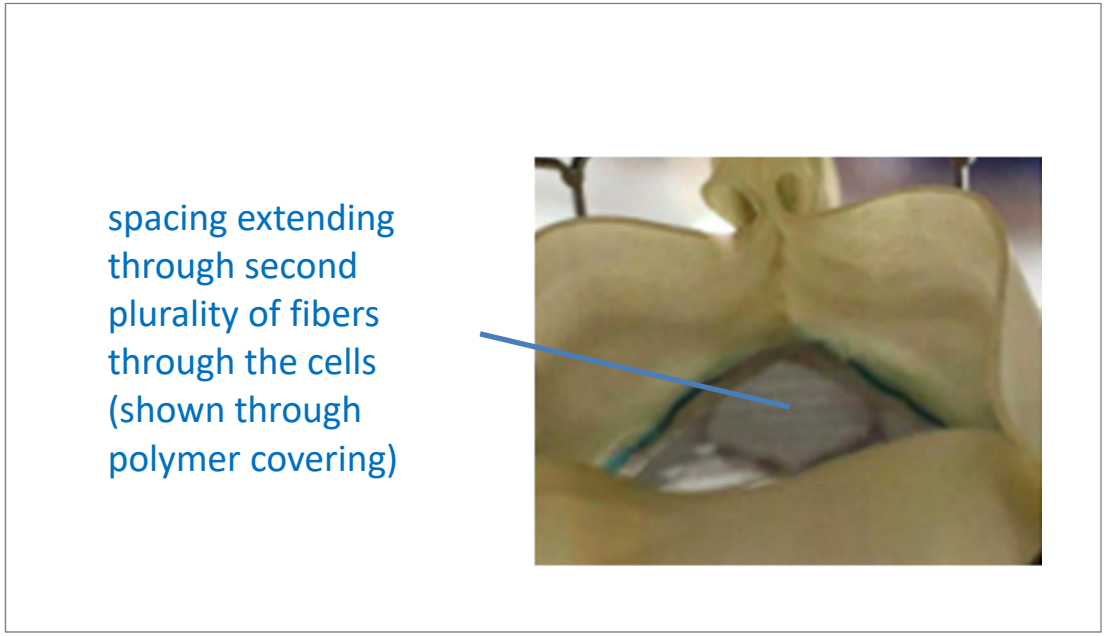



Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

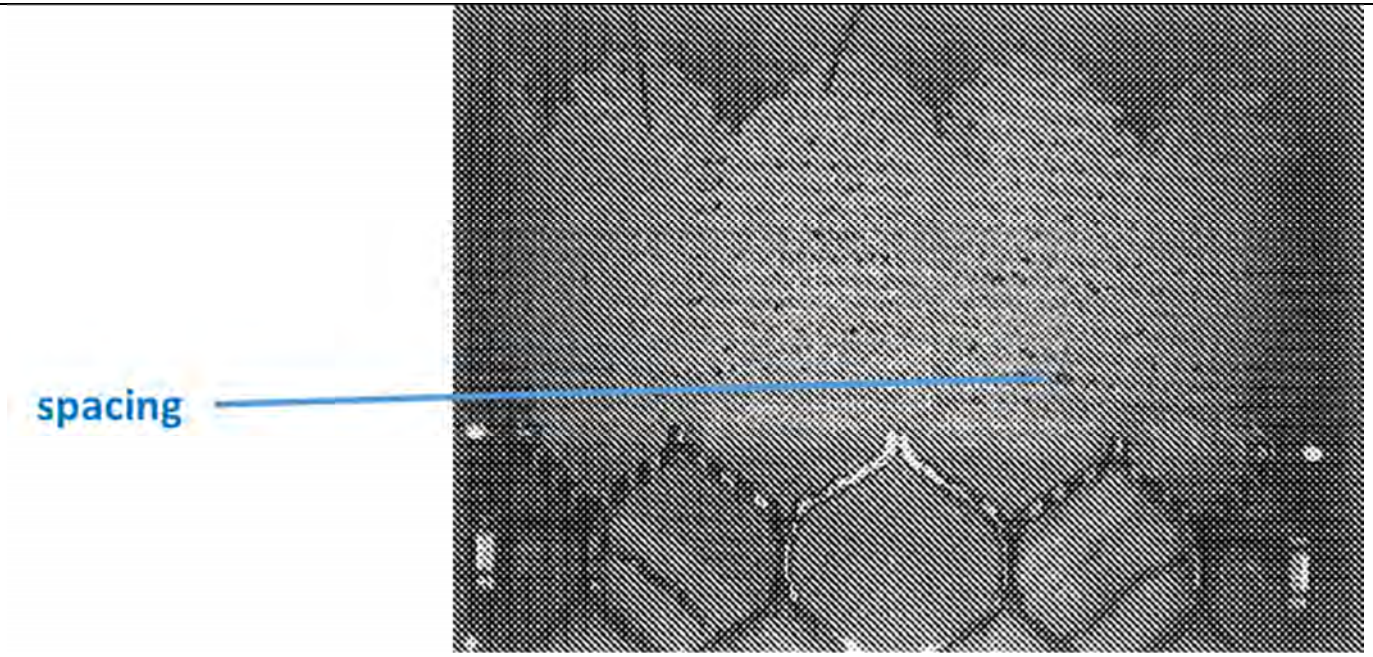


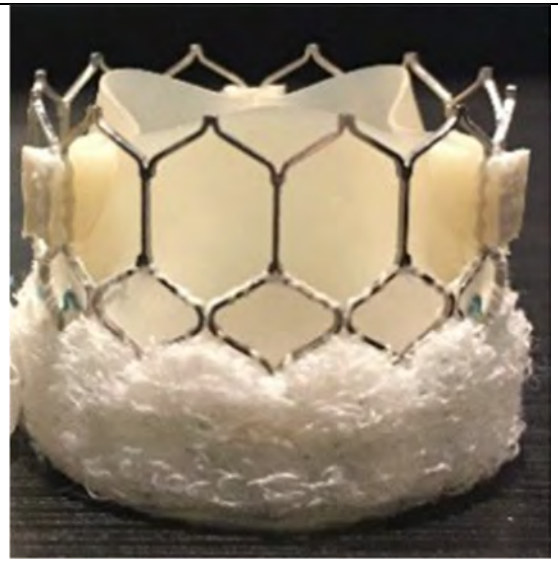
Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

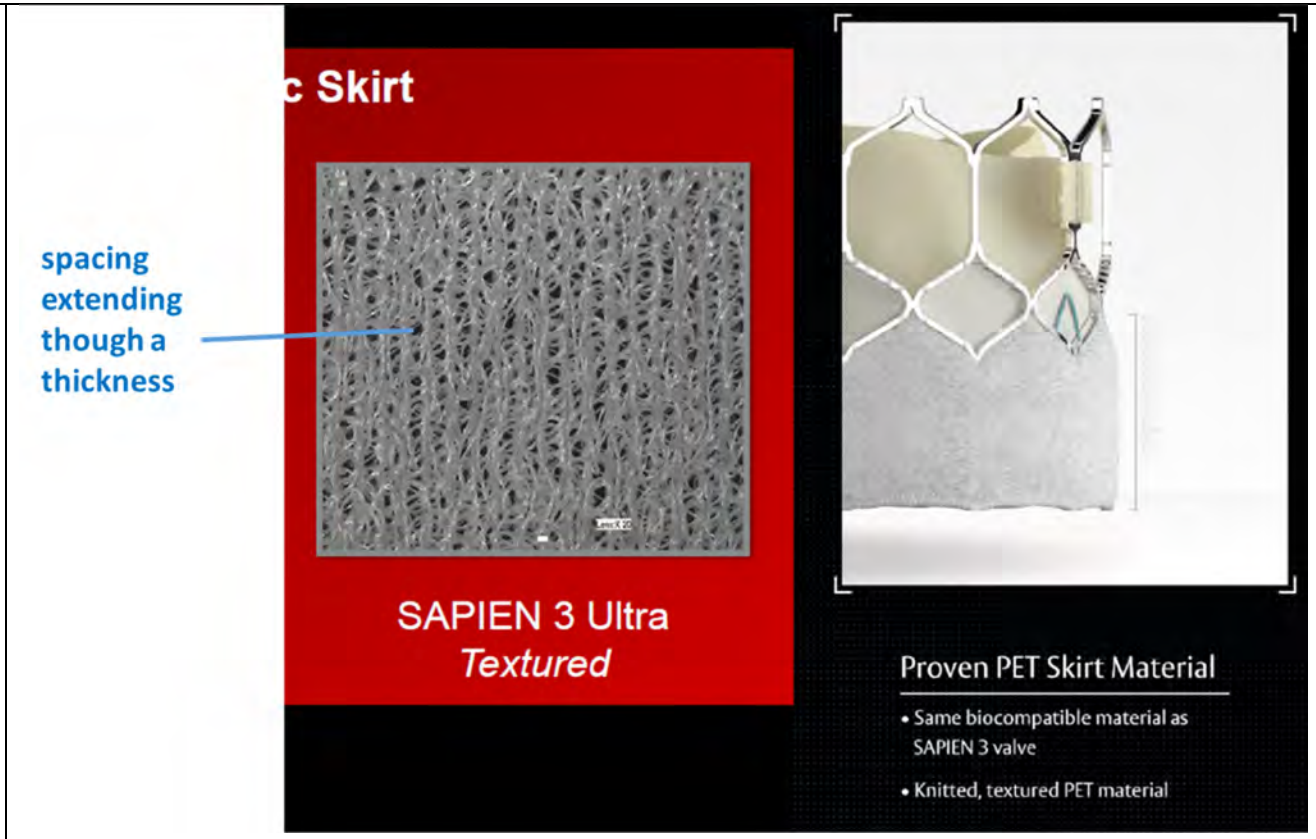
Further, the Sapien 3 Ultra sealing skirt includes fibers carried by the frame facing the frame. The spacings further extend though those adjacent fibers and though the cells of the frame.



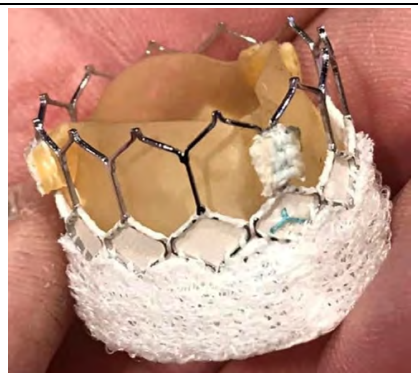
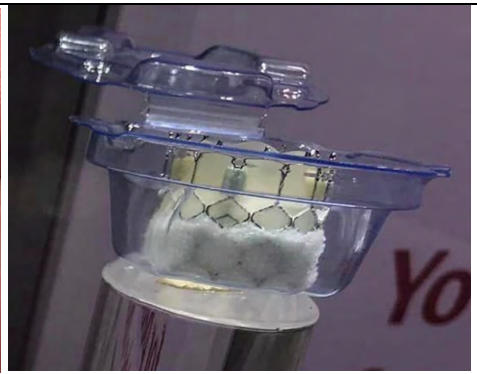
Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1-2 at 15).

	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing spacings on flipped up backside of sealing skirt).
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	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities are designed and configured such that 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. For example, the Sapien 3 Ultra is designed using knitted PET with compressible fibers such that when compressed in response to expansion of the heart valve in the aorta, the first plurality of fibers are compressed together with the second plurality of fibers relative to the spacings providing for sealing to help prevent paravalvular leakage.

of fibers relative to the spacing to create a seal thereabout.	 Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).



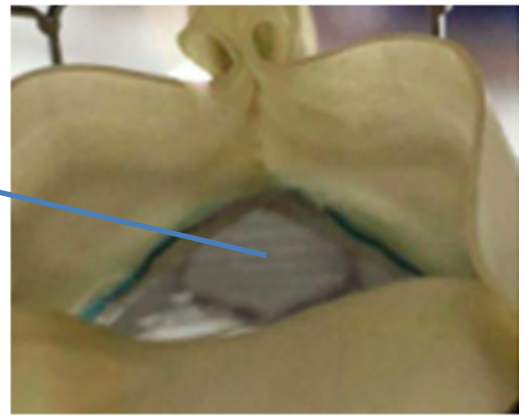
Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

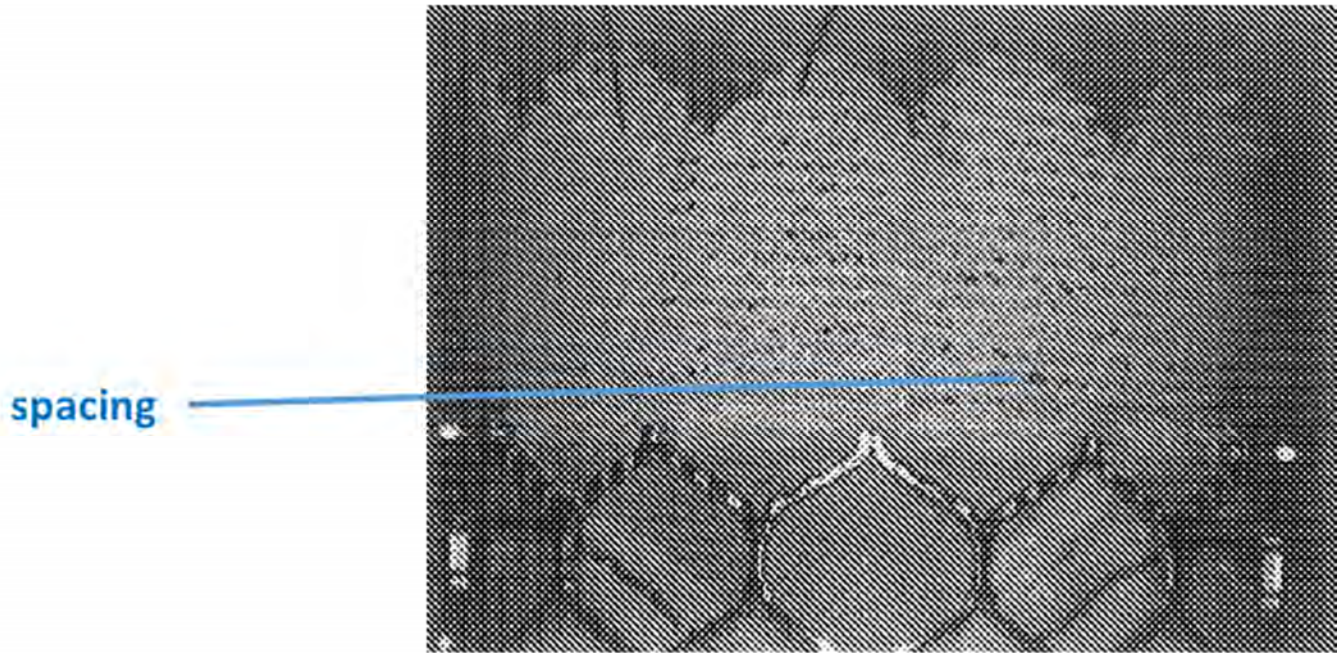



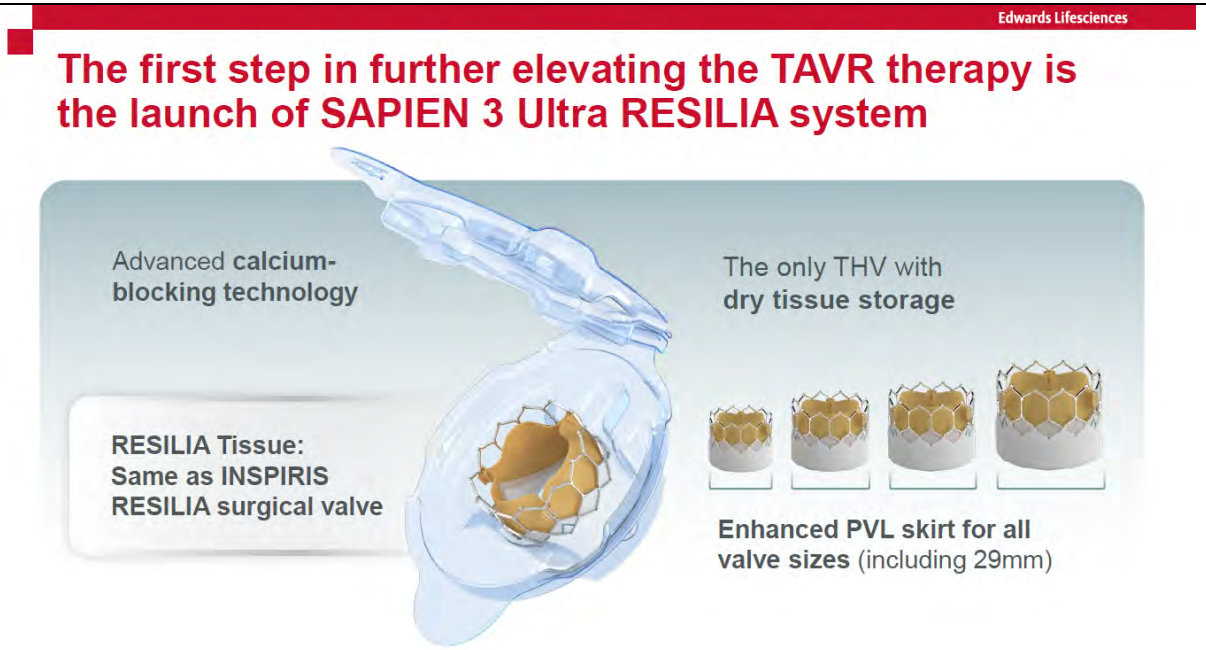
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

Further, the Sapien 3 Ultra sealing skirt includes fibers carried by the frame facing the frame. The spacings further extend though those adjacent fibers and though the cells of the frame.

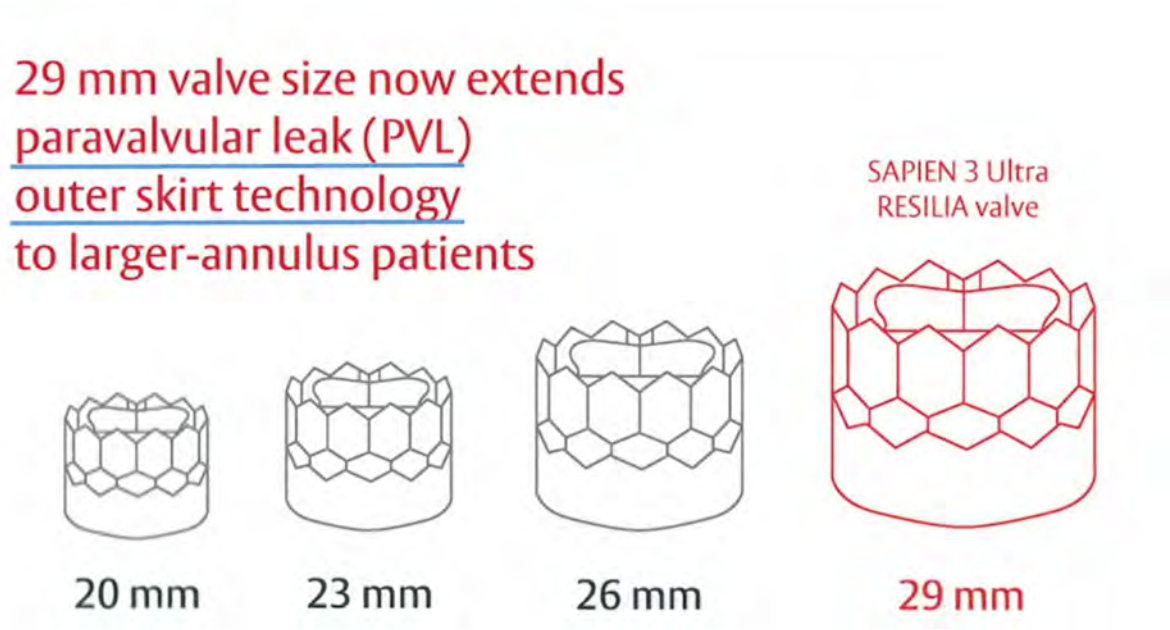
spacing extending through second plurality of fibers through the cells (shown through polymer covering)



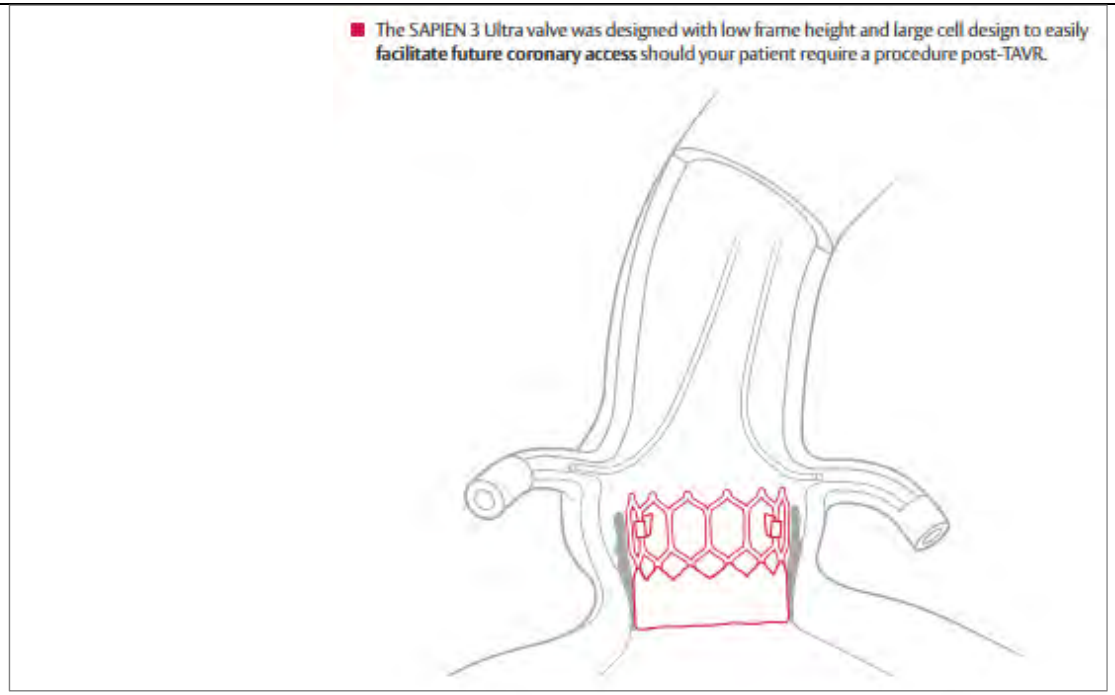
	Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1-2 at 15).  U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing spacings on flipped up backside of sealing skirt).



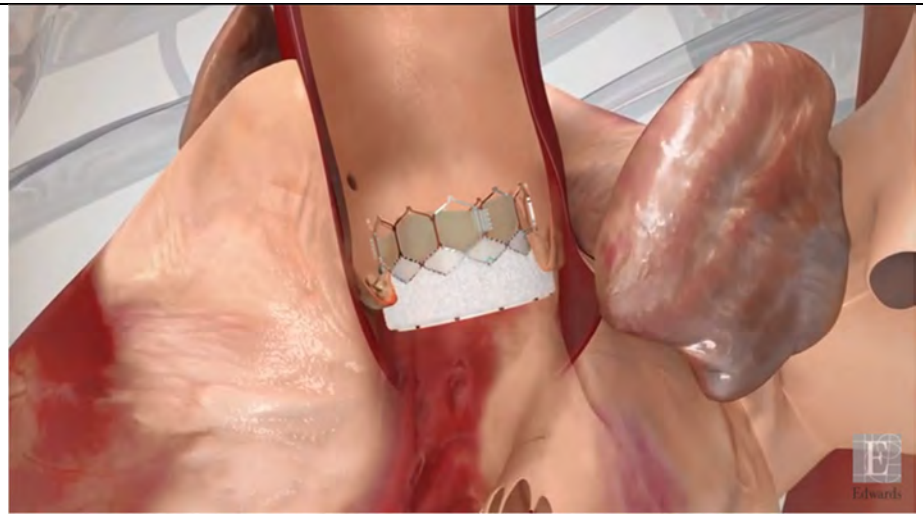
https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).

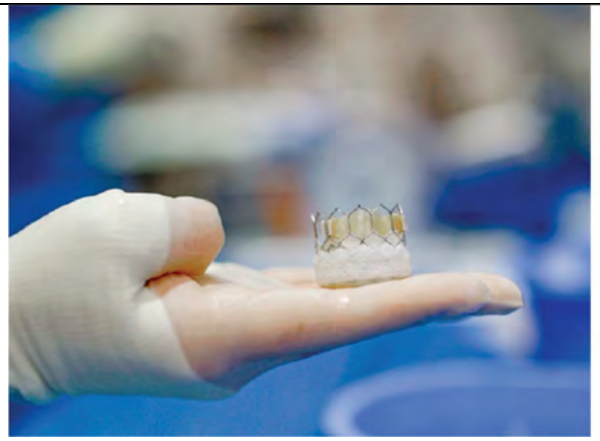
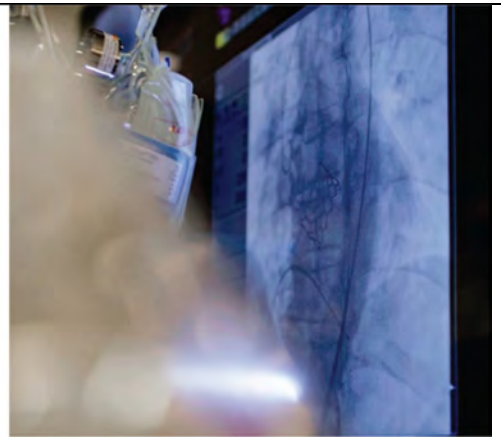


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

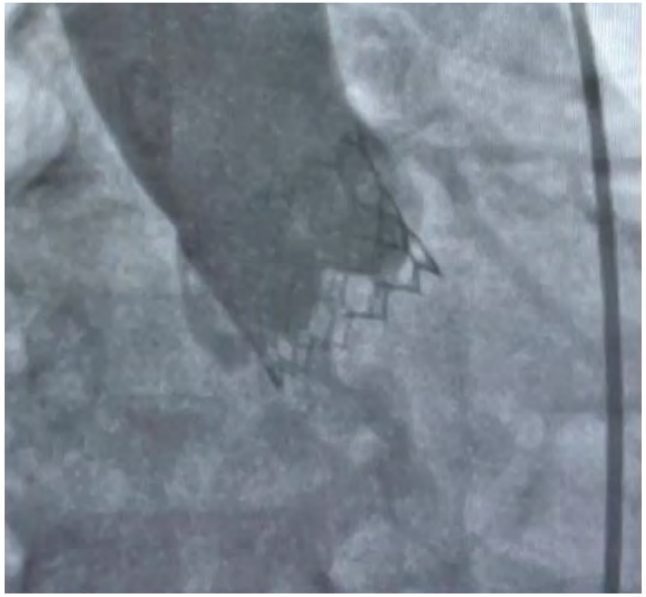
	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
18. An endovascular prosthetic heart valve for use in a patient, comprising:	To the extent the preamble is limiting, the '834 patent Accused Instrumentalities satisfy this element. For example, the '834 patent Accused Instrumentalities are endovascular prosthetic heart valves for use in a patient. The '834 patent Accused Instrumentalities are designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems.

https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

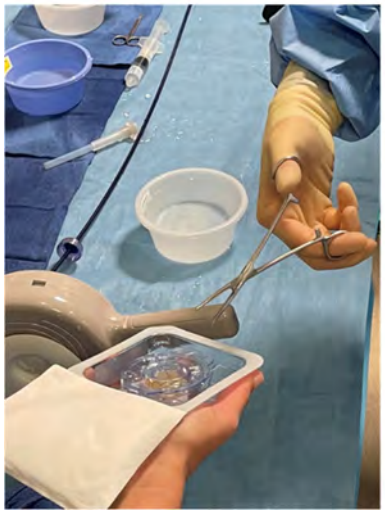


Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg



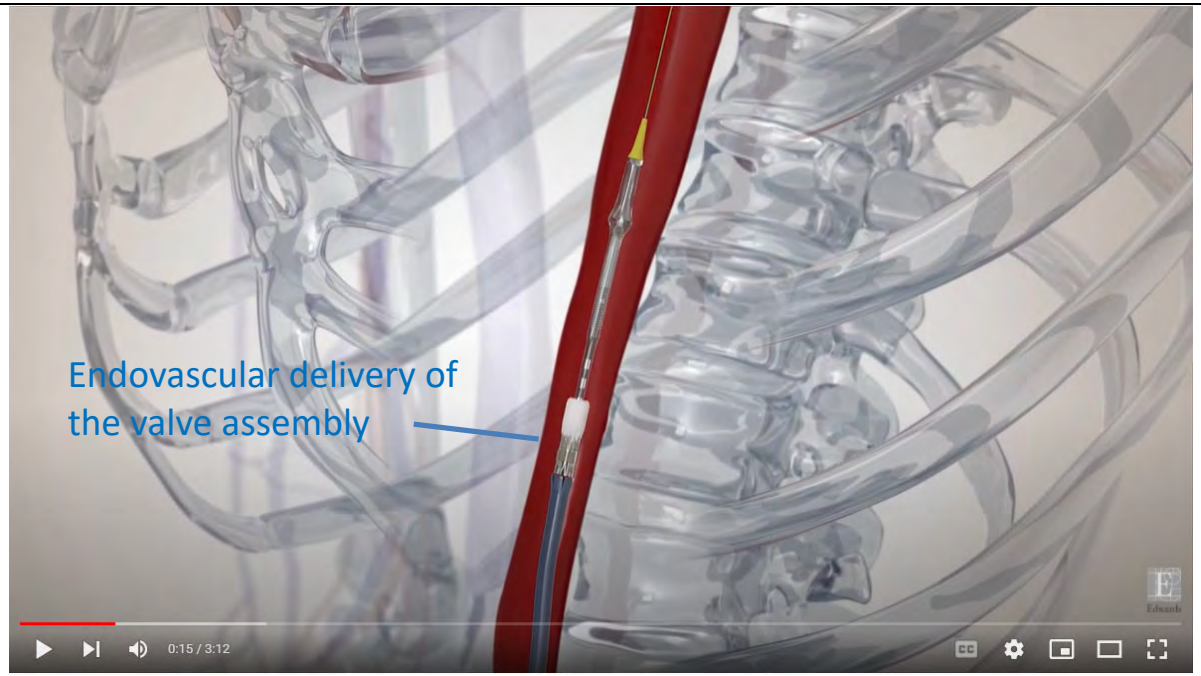


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra[5] is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[5] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.



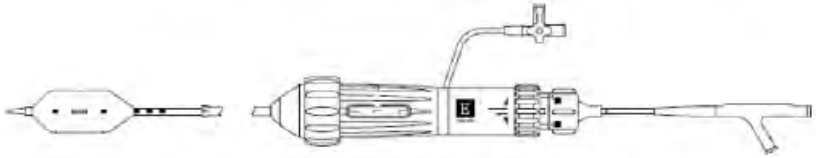
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



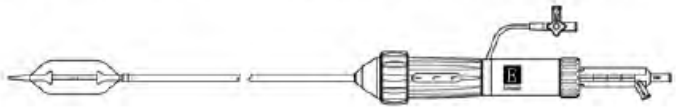
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

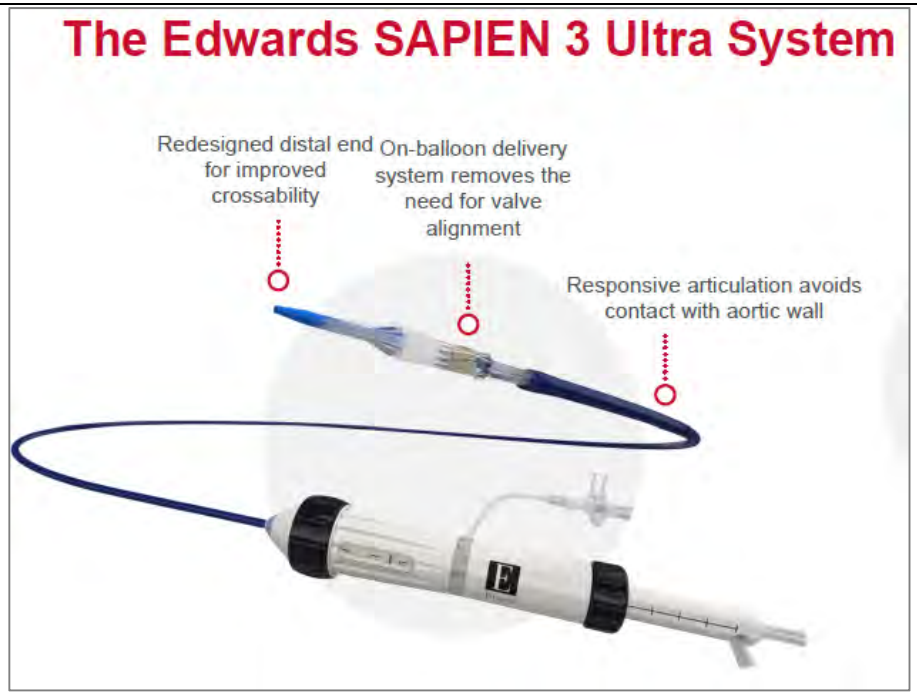
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

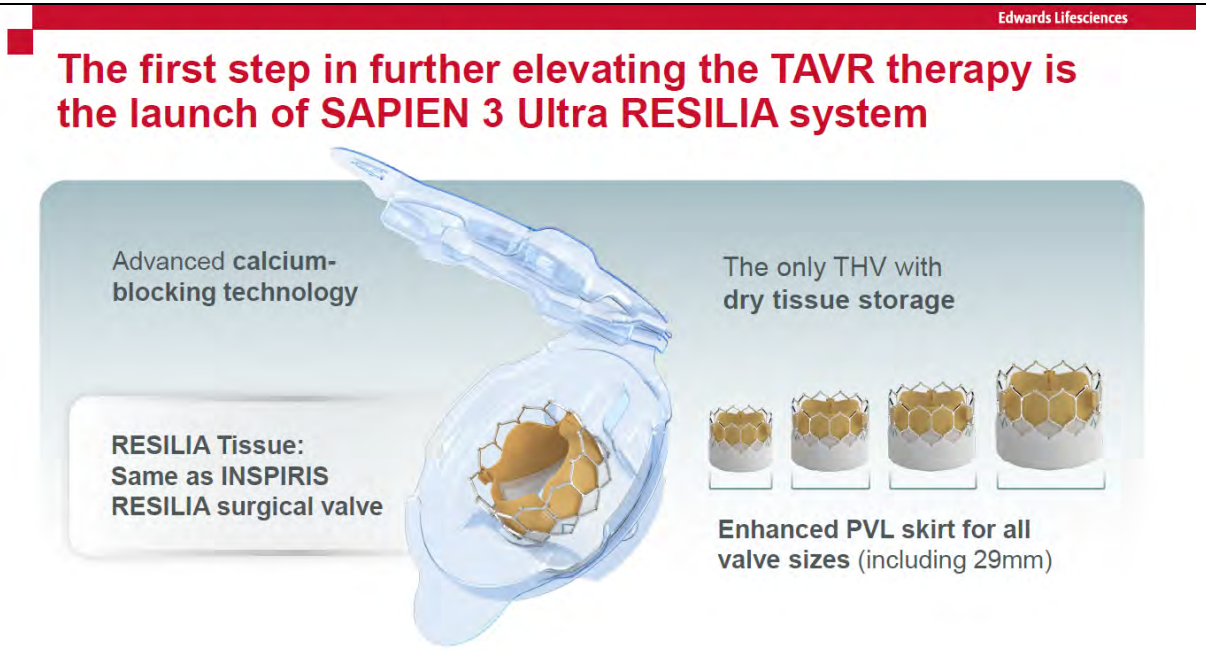
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

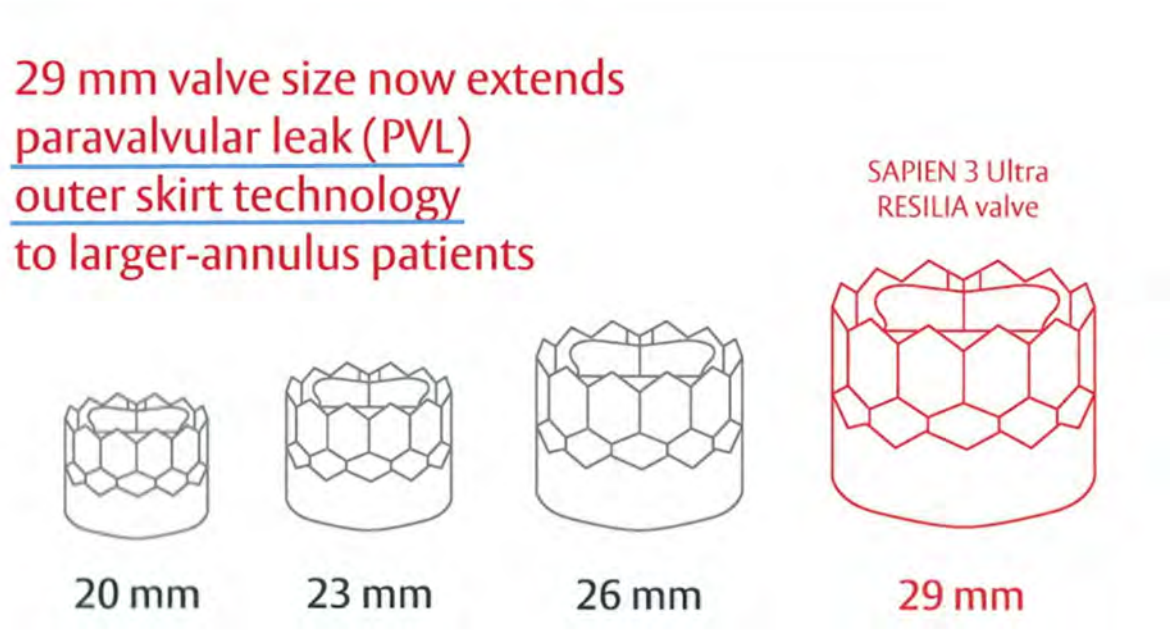
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

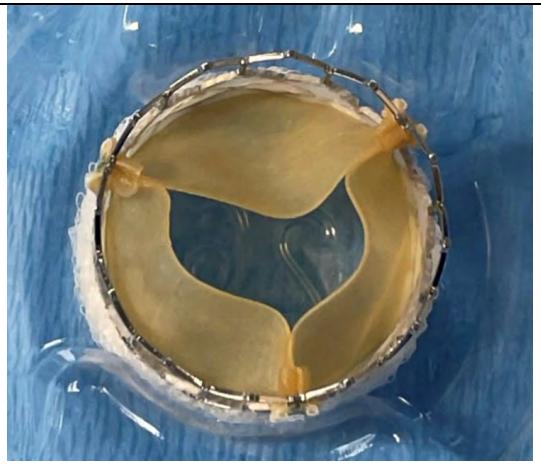
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’834 patent Accused Instrumentalities and infringes the ’834 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



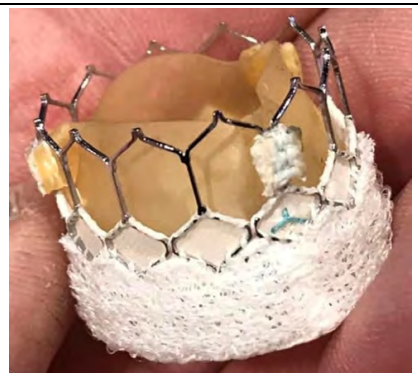
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



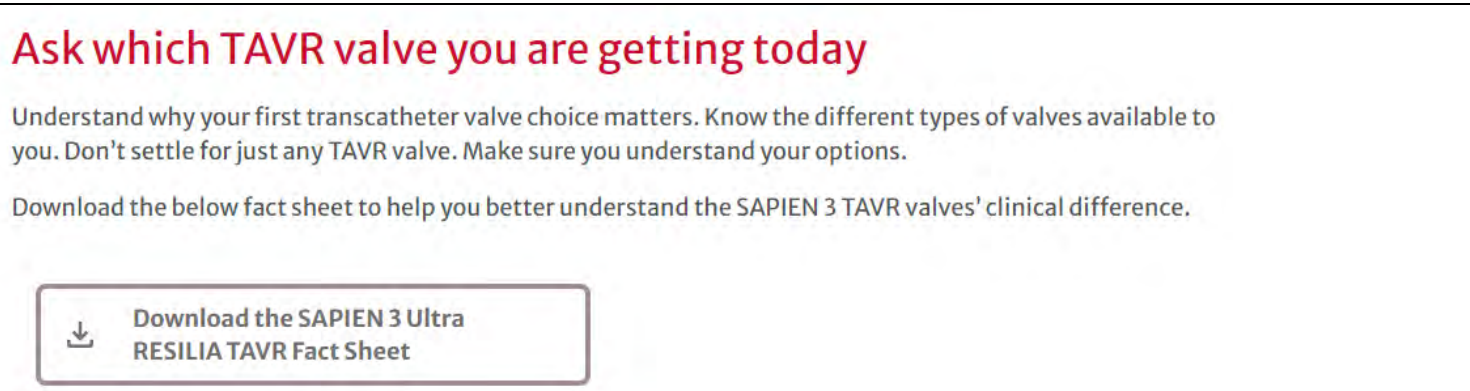

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

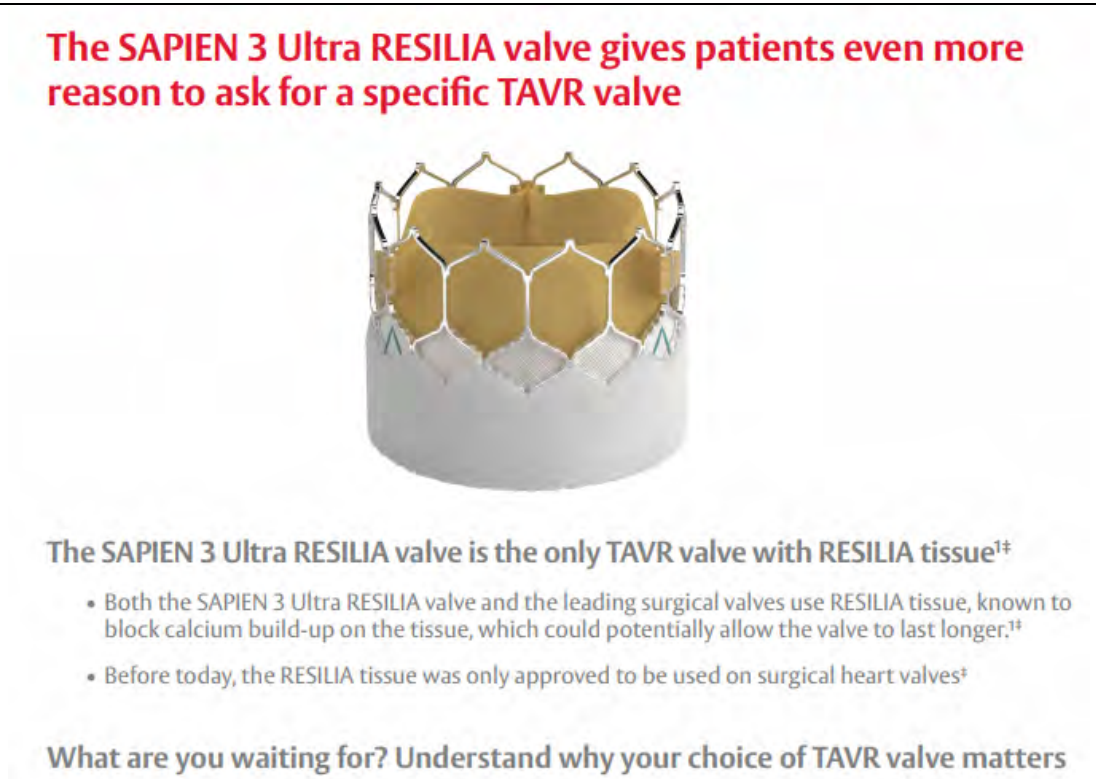
On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the '834 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

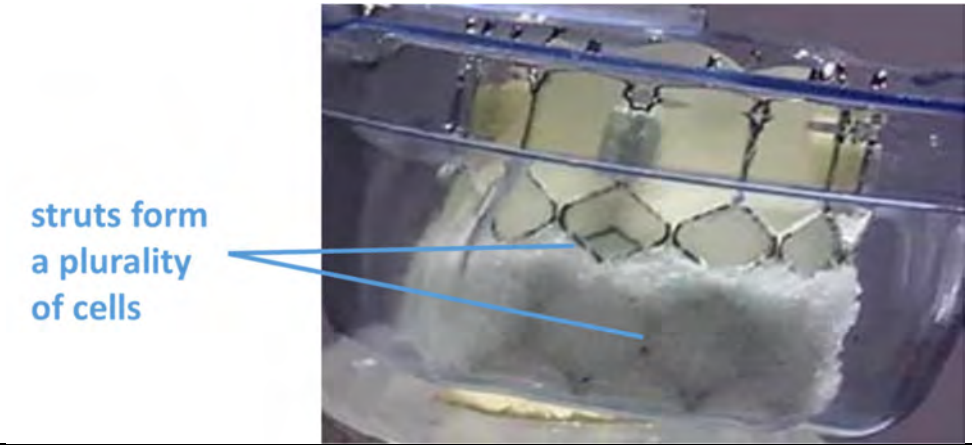
On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See* https://ir.edwards.com/events-presentations/;

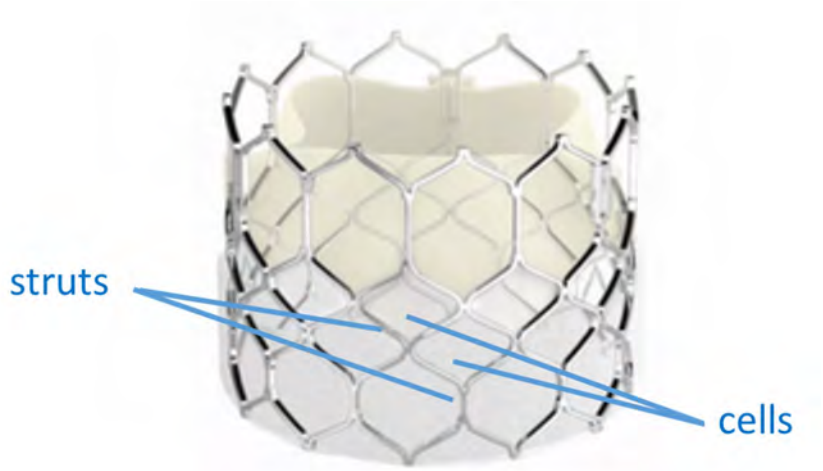
	https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '834 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '834 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '834 asserted claims are infringed when Edwards offers for sale and sells the '834 patent Accused Instrumentalities. Edwards offers for sale and promotes the '834 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 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. 

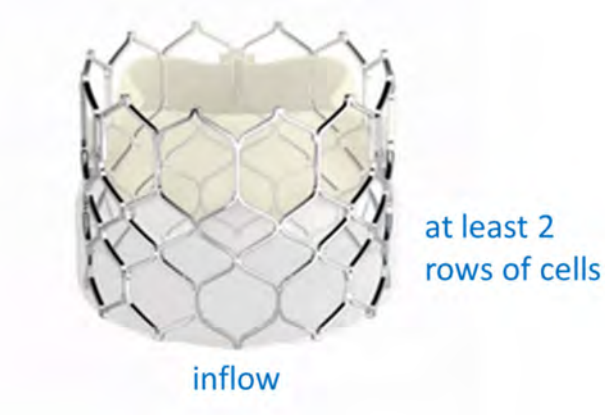
	 https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

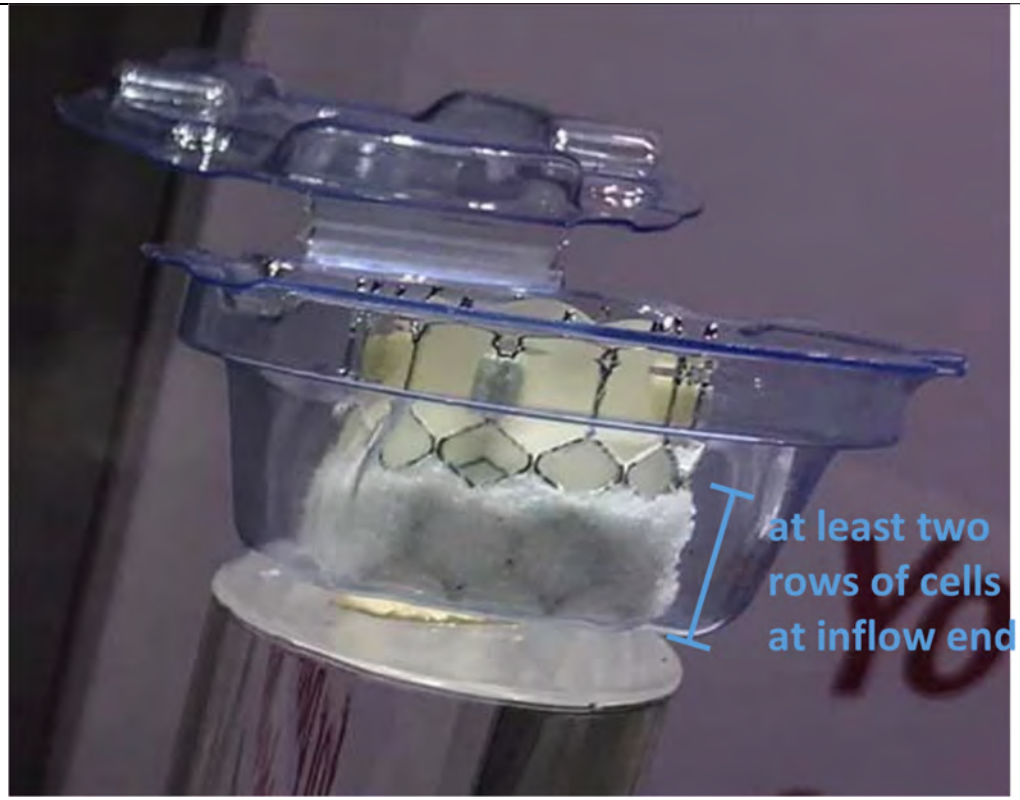
	 https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61). On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement# Further, the '834 patent asserted claims 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 in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the '834 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards' direct and induced infringement. For further example, on information and belief, Edwards's affiliated hospitals and doctors directly infringe the asserted '834 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a "watchful eye" over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards's inducement, Edwards's affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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. 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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards's affirmative acts of marketing, selling and offering to

	sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards's customers' and end users' combination and use of the Accused Instrumentalities, such that the '834 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards' knowledge of Aortic's inventions, the patents-in-suit (including the '834 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
a frame formed of a plurality of struts that cooperate to form a plurality of cells,	The '834 patent Accused Instrumentalities satisfy this element. The '834 patent Accused Instrumentalities comprise a frame formed of a plurality of struts that cooperate to form a plurality of cells. For example, the Sapien 3 Ultra frame is formed of struts that together form a plurality of cells. 

	Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). *See also*, evidence for preceding elements above. With respect to the phrase, "a frame formed of a plurality of struts that cooperate to form a plurality of cells", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with the capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of providing a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy. Further,

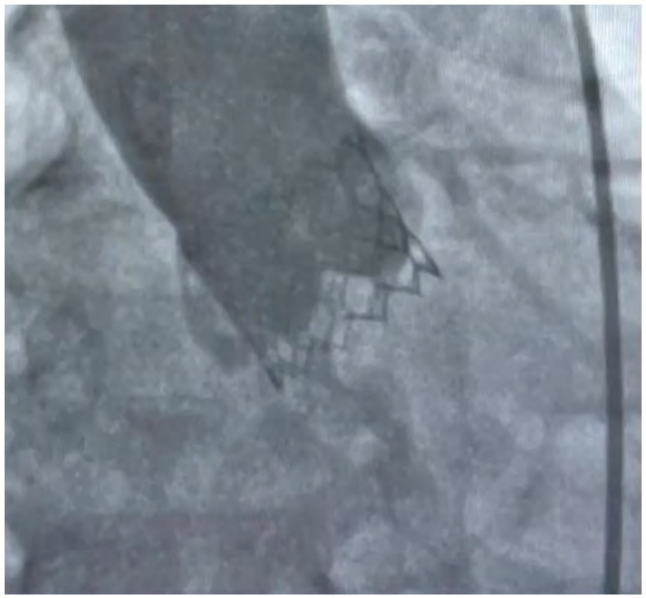
	whether the frame formed of a plurality of struts that cooperate to form a plurality of cells is laser cut from a single piece of material or made otherwise is the same or, at most, an insubstantial difference.
wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities’ plurality of cells defines at least two rows of cells at an inflow end of the frame. For example, the Sapien 3 Ultra frame includes at least two rows of cells at an inflow end of the frame.  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added) (showing polymer covering radially inward of the frame and outward of the leaflet assembly) (D.I. 1, Ex. 33).



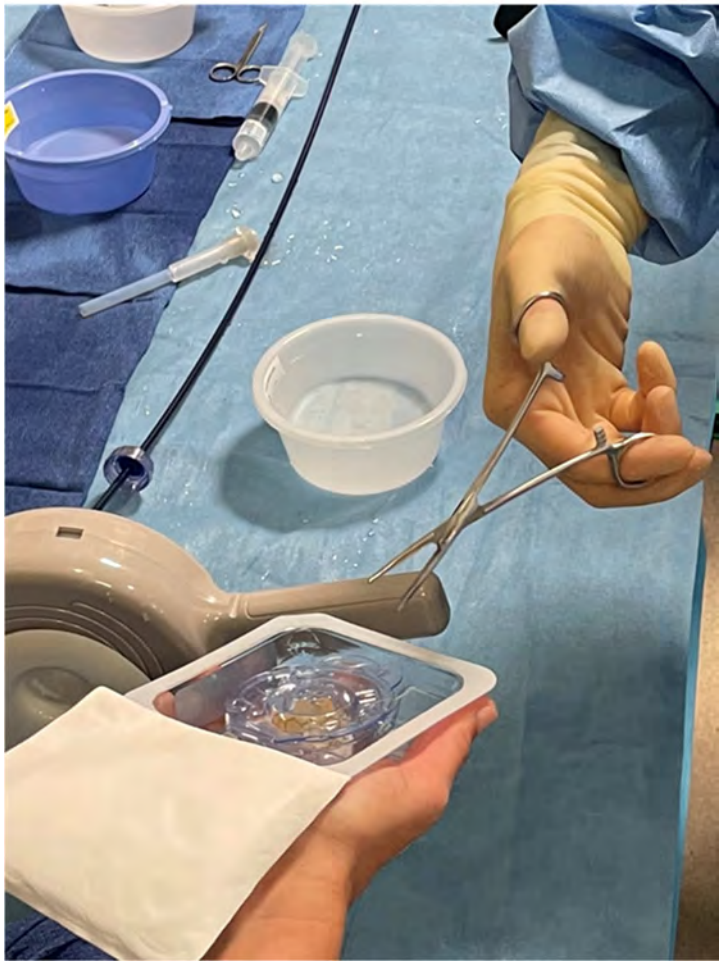
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).

With respect to the phrase, "wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused plurality of cells defines at least two rows of cells perform the same or substantially the same function as the claim phrase by allowing

	the frame to be compressed to a low profile and expanded, in the same or substantially the same way as the claim phase by being constructed of metal struts forming cells of the same or similar shapes and sizes, to achieve the same or substantially the same result of a plurality of cells defining 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;	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities comprise a frame that is radially expandable from a radially compressed orientation to a radially expanded orientation. For example, the Sapien 3 Ultra is packaged and provided by Edwards in a radially expanded configuration. The Sapien 3 Ultra is designed by Edwards to be crimped onto an Edwards’ balloon delivery system in a radially compressed orientation. The Sapien 3 Ultra is also designed to be expanded using an Edwards’ balloon delivery system in the aorta of a patient into a radially expanded orientation.  Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

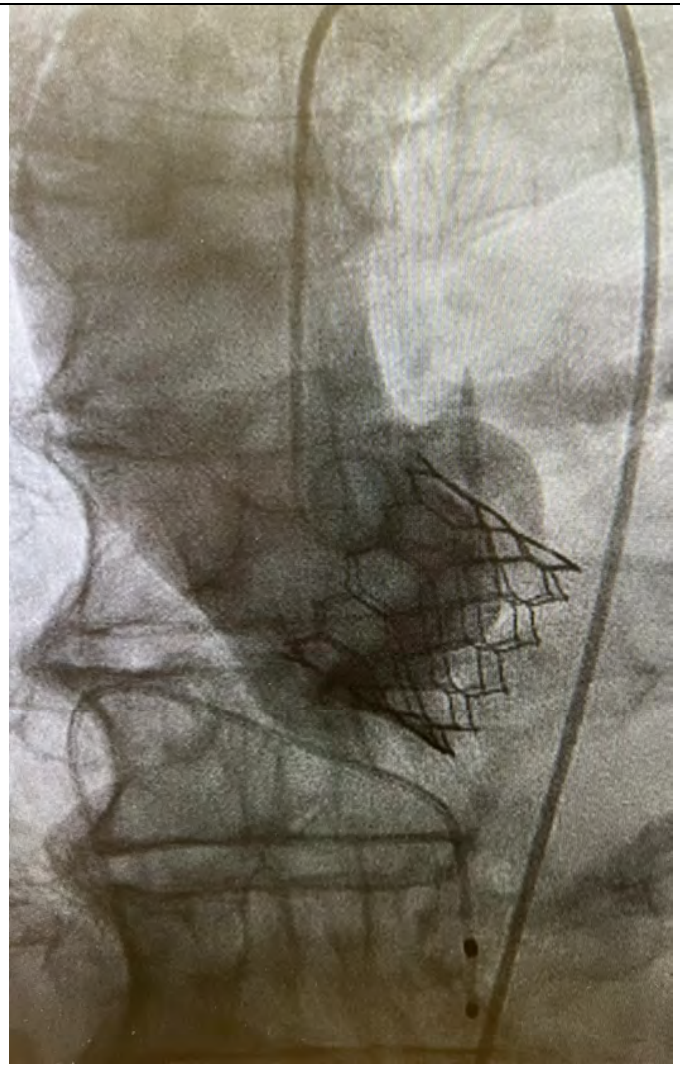
	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



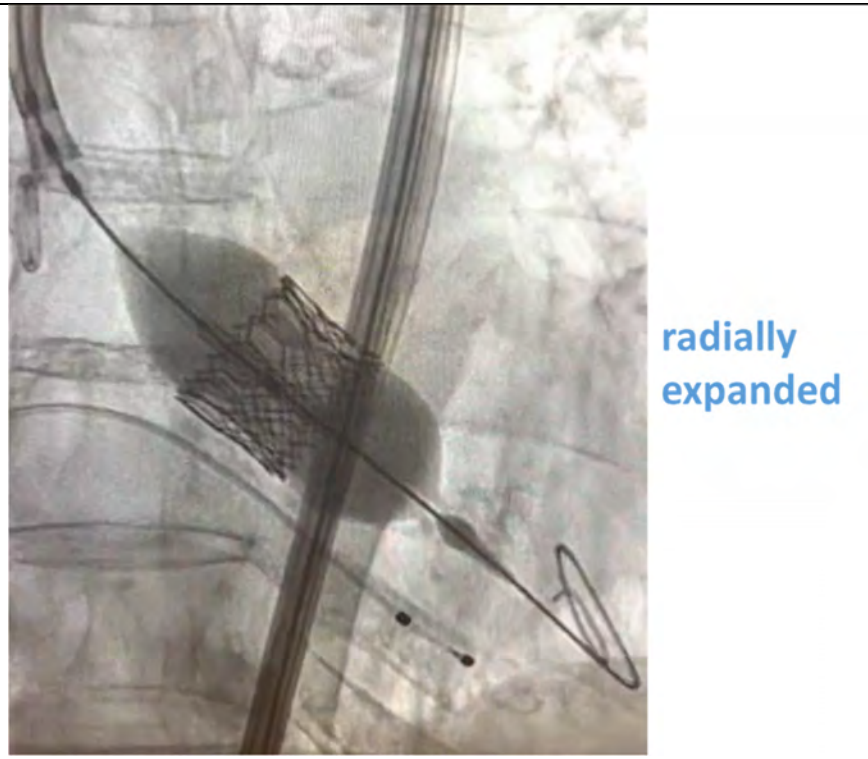
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=7vNdYaSyfo8PlVNSNv2WDQ



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

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.



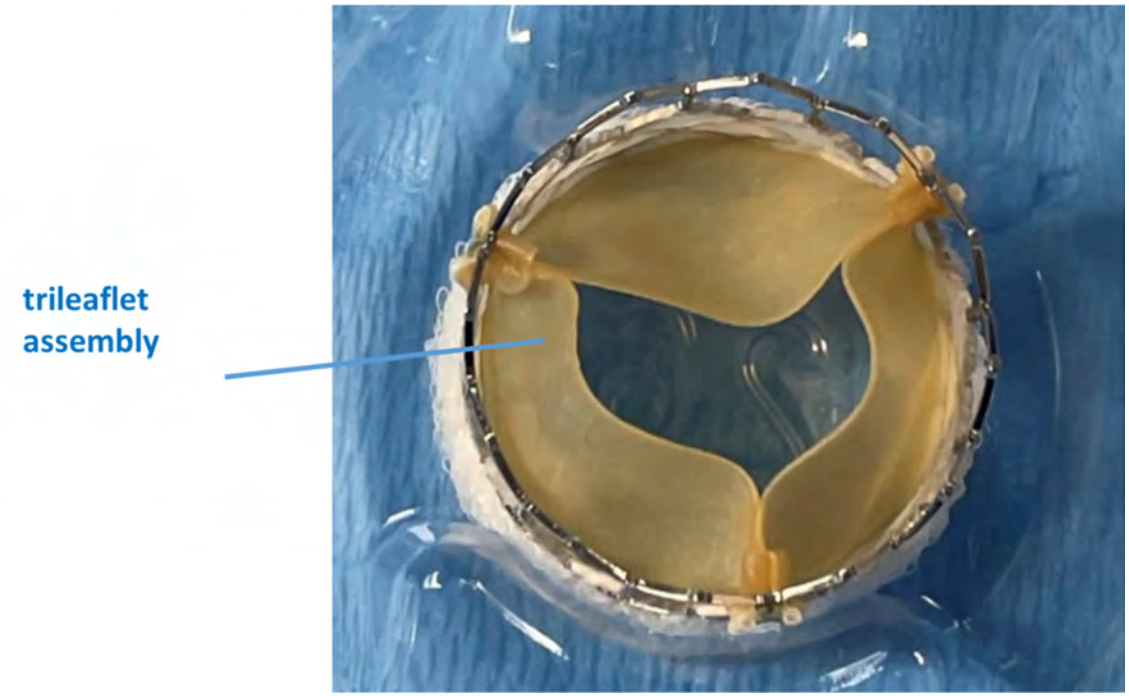
9750TFX

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 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a leaflet assembly within the frame;	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities comprise a leaflet assembly within the frame. For example, the Sapien 3 Ultra devices comprise a bovine pericardial tissue trileaflet assembly and/or Resilia tissue trileaflet assembly housed within the frame.  https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).

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.

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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 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly; and	The ’834 patent Accused Instrumentalities satisfy this element. The ’834 patent Accused Instrumentalities comprise a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly. For example, the Edwards Sapien 3 Ultra has a polymer covering made from PET that carries the leaflet assembly. Further, the Sapien 3 Ultra polymer covering is positioned radially inward of the frame and radially outward of the leaflet assembly.  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added) (showing polymer covering radially inward of the frame and outward of the leaflet assembly) (D.I. 1, Ex. 33).

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.



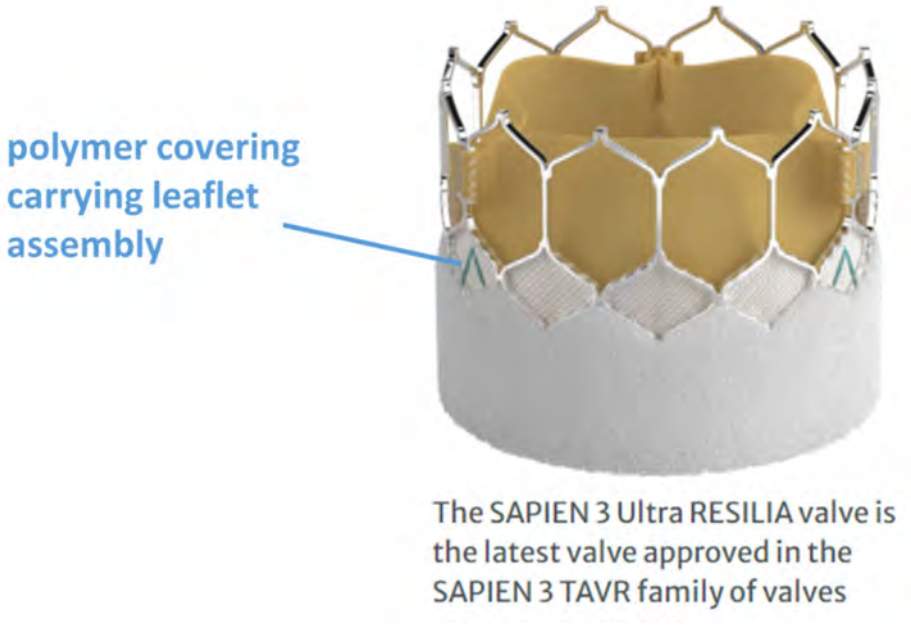
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

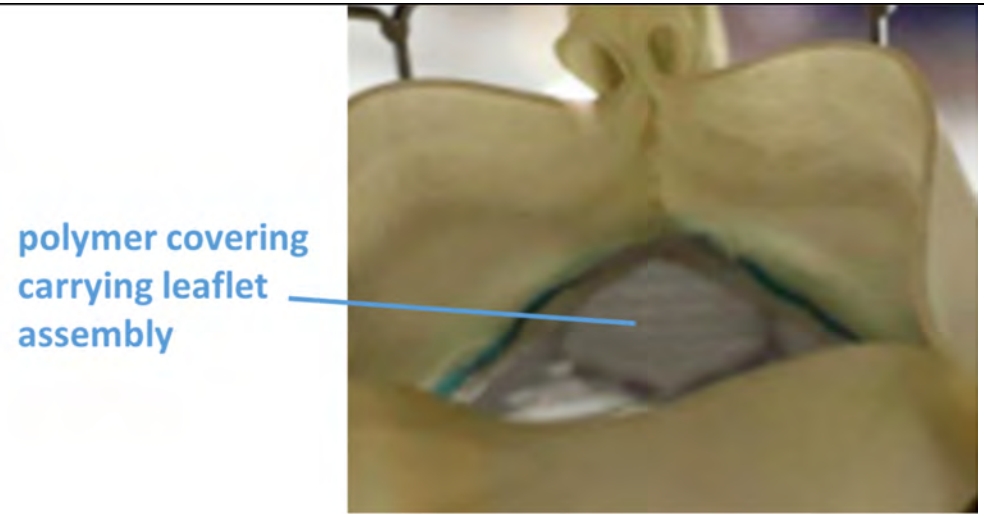
Table 1

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 (D.I. 1, Ex. 44).

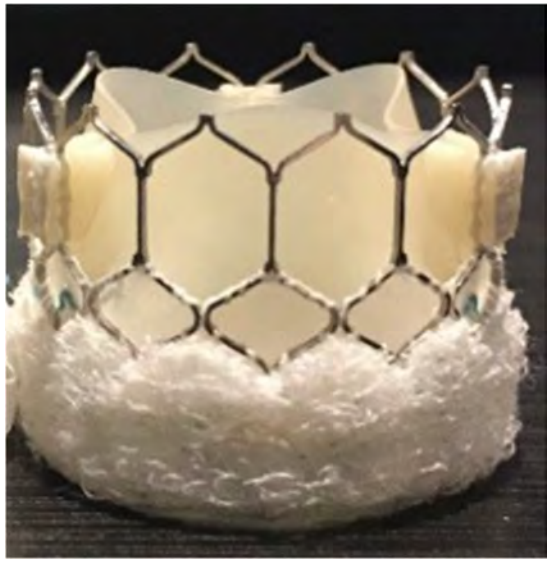


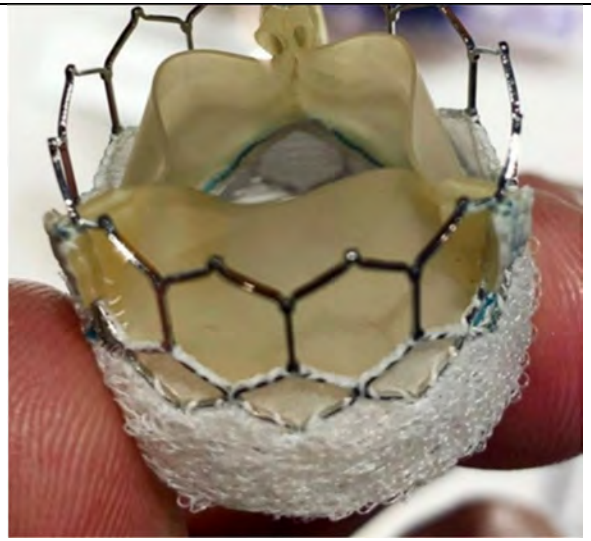
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

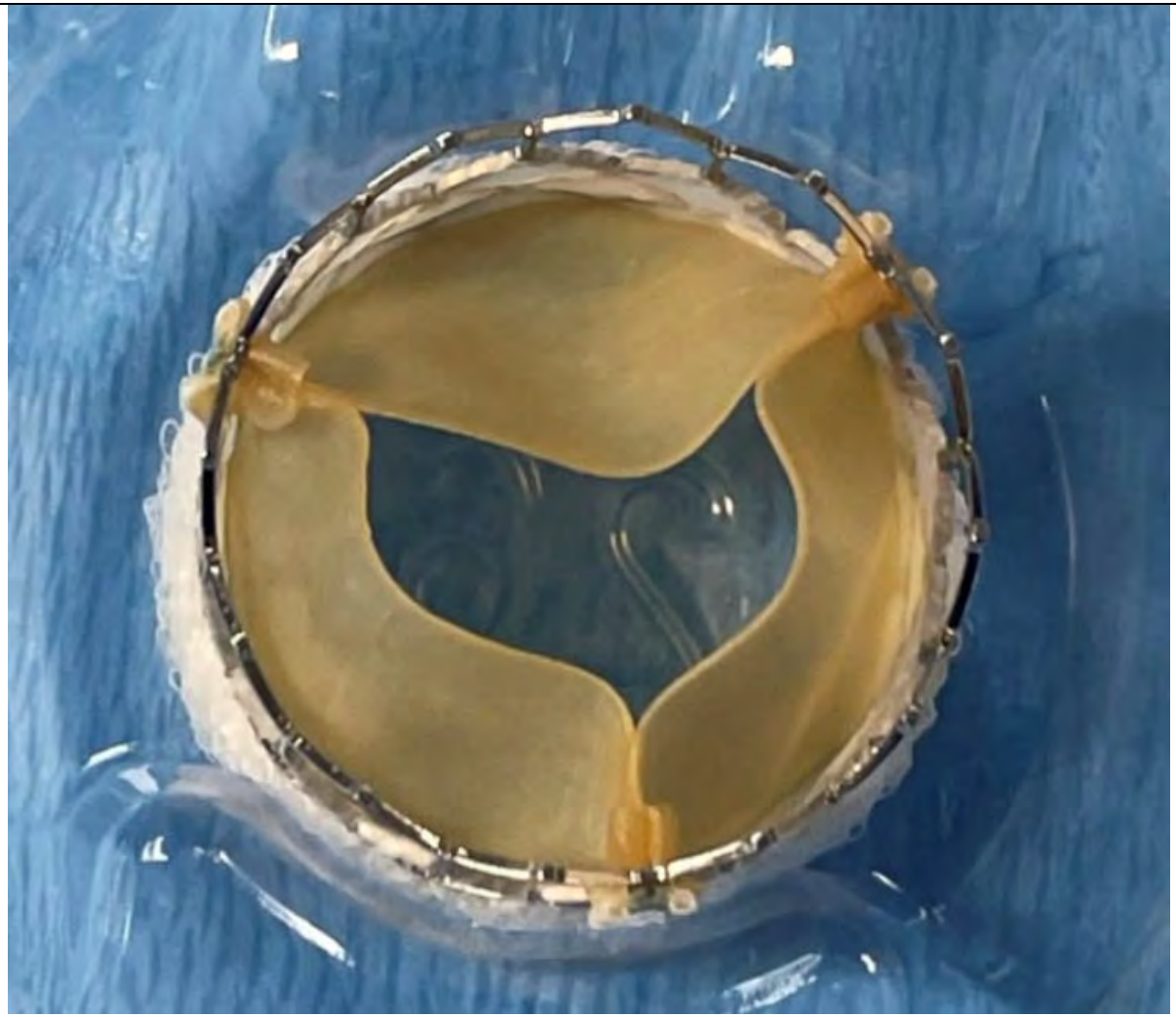


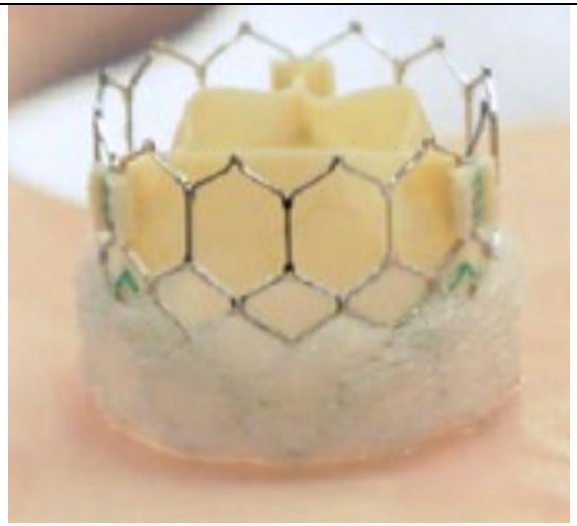
https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a polymer covering positioned radially inwardly of the frame and radially outwardly of the leaflet assembly, the identified polymer coverings are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused polymer covering performs the same or substantially the same function as the claim phrase by covering and carrying portions of the leaflet assembly, in the same or substantially the same way as the claim phase through including a polymer covering that is positioned at least partially radially outward of the leaflet assembly and radially inward of the frame and by being attached to the leaflet assembly, to achieve the same or substantially the same result of a polymer covering configured to cover and/or carry or partially cover and/or carry the leaflet assembly.

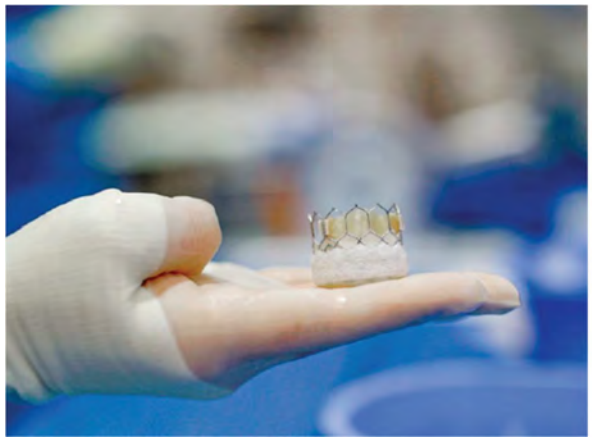
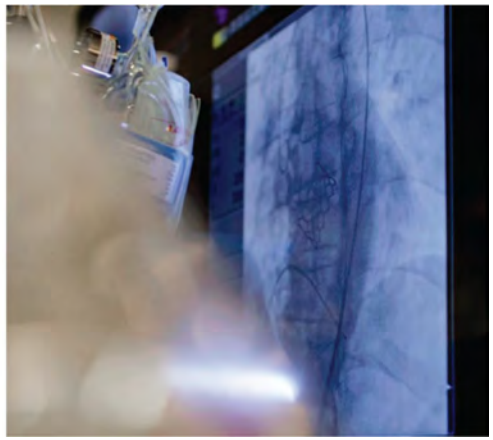
a plurality of fibers that extend away from the frame,	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 Accused Instrumentalities comprise a first plurality of fibers that extend away from the frame. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of fibers that extend away from the frame.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 29).

	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 64).

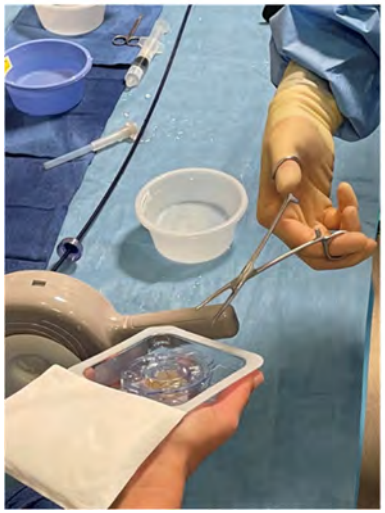
	 https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65) (showing plurality of fibers extending away from frame).

	 Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 3). With respect to the phrase, "a first plurality of fibers that extend away from the frame" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a first plurality of fibers that extend away from the frame, the identified a first plurality of fibers that extend away from the frame of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused first portion of fibers perform the same or substantially the same function as the claim phrase by providing low profile sealing against the native leaflets of the aorta and spacings between fibers, in the same or substantially the same way

	as the claim phase by extending generally away from the frame and pressing against the native leaflets of the aorta of the patient and filing in spacings when the valve is expanded, to achieve the same or substantially the same result of a first plurality of fibers that extend generally away from the frame that are configured to provide for sealing between the native annulus and the valve assembly.
wherein the prosthetic heart valve is endovascularly deployed through a femoral artery of the patient,	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities are designed, configured and deployable though a femoral artery of a patient. Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through the femoral artery using Edwards’ balloon catheter delivery systems.   https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

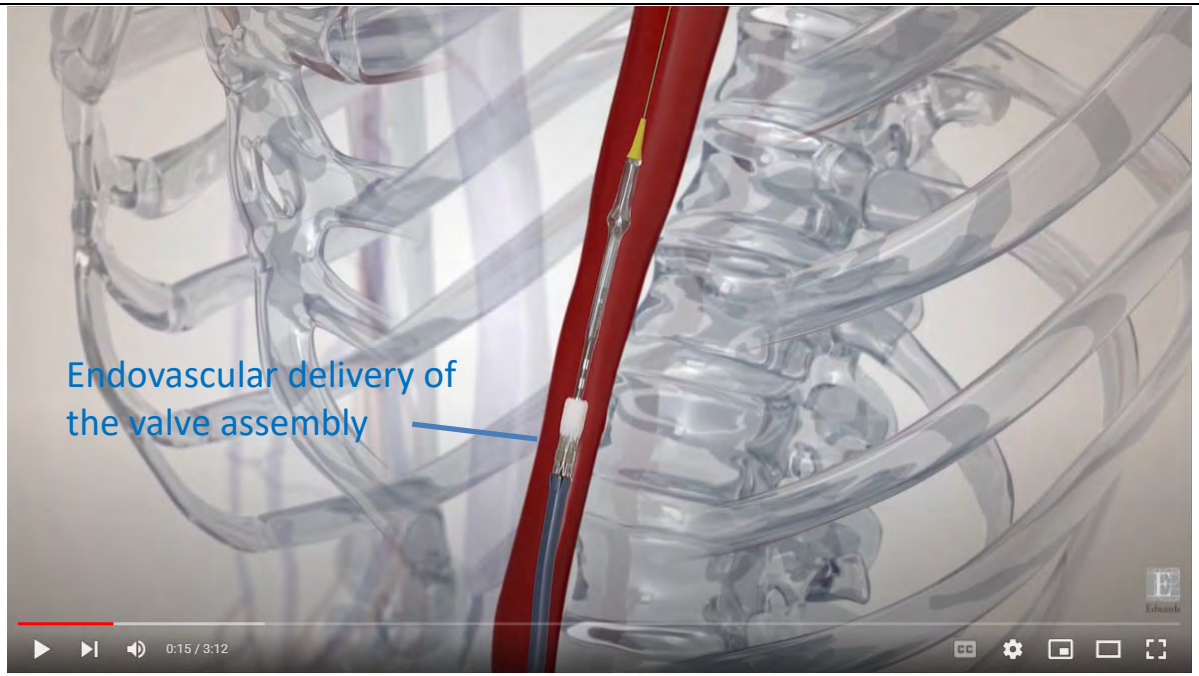


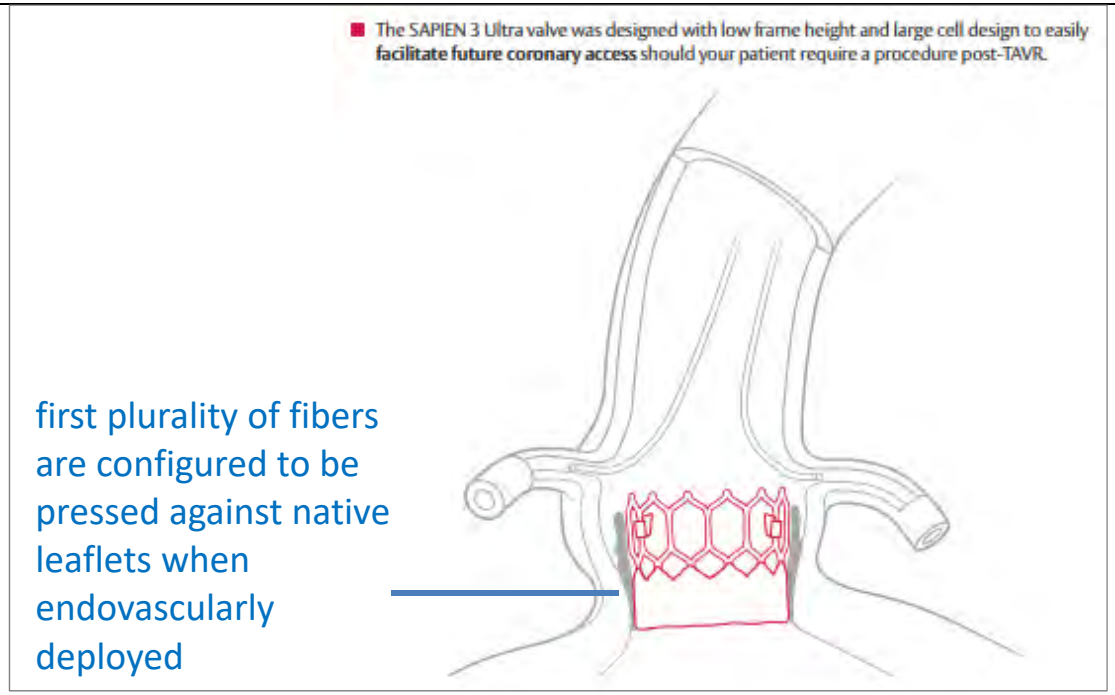


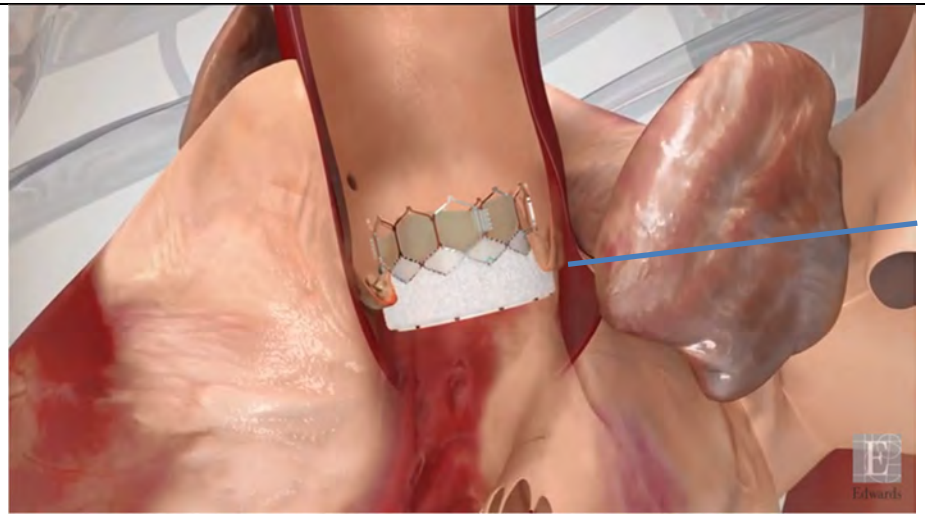
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

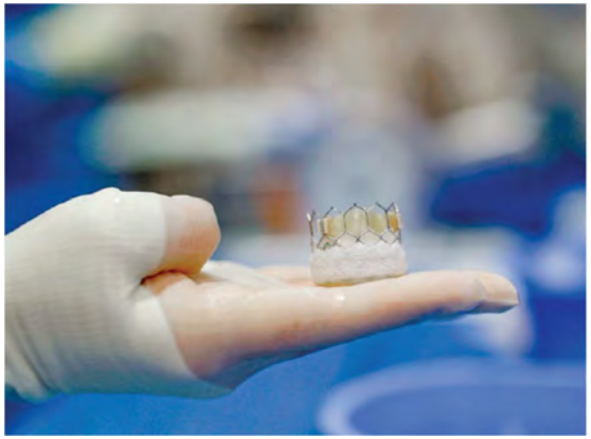
	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
wherein the plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities’ first plurality of fibers are 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. For example, the Sapien 3 Ultra sealing skirt fibers are configured to be pressed against the native leaflets of the patient when endovascularly deployed and expanded.

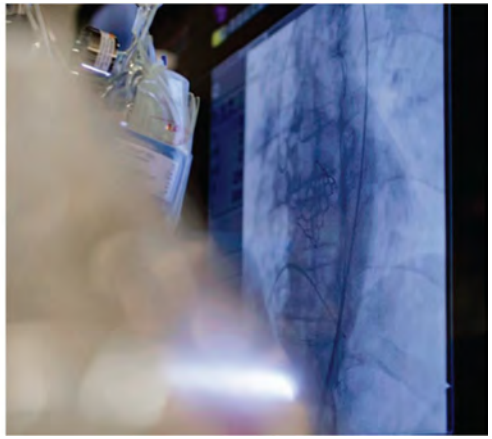
orientation within a native heart valve annulus of the patient,	 Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



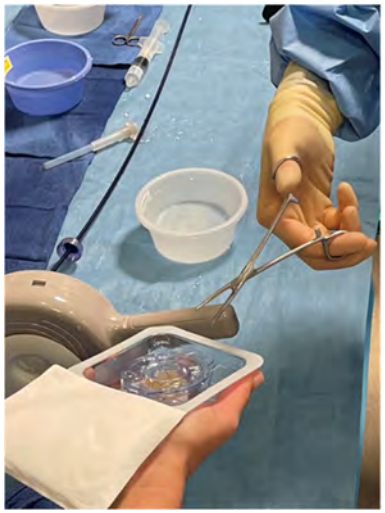
"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through the femoral artery using Edwards' balloon catheter delivery systems.





	https://twitter.com/RajTayalMD/status/1587518343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).  https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

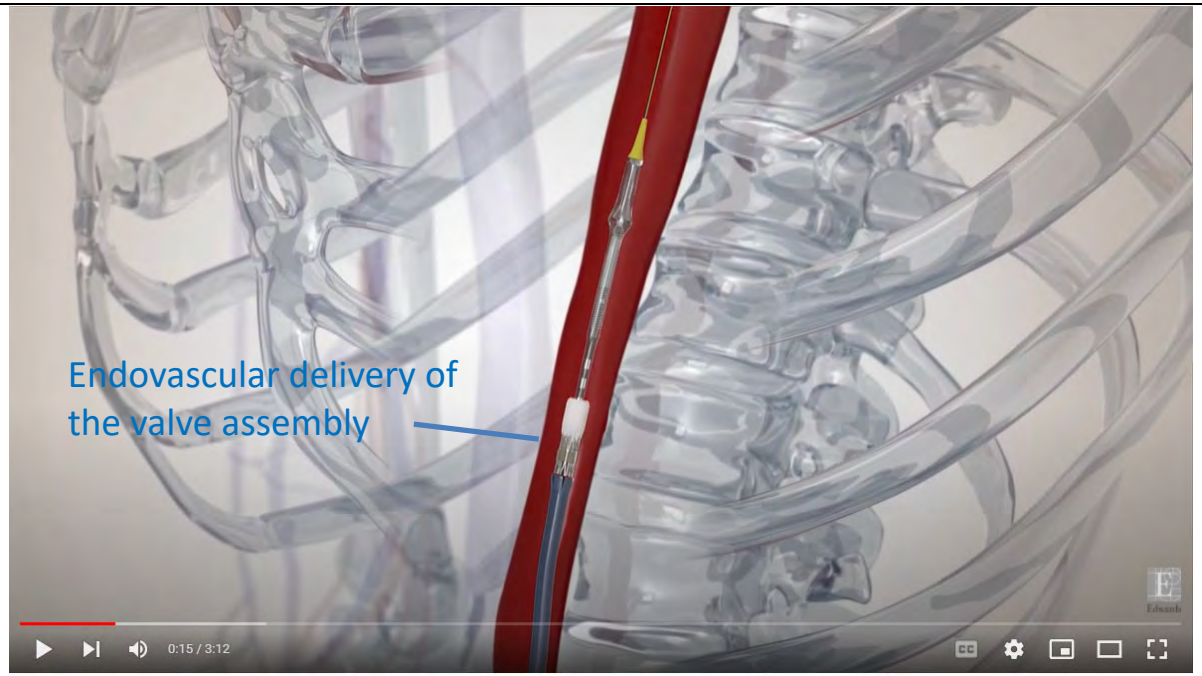


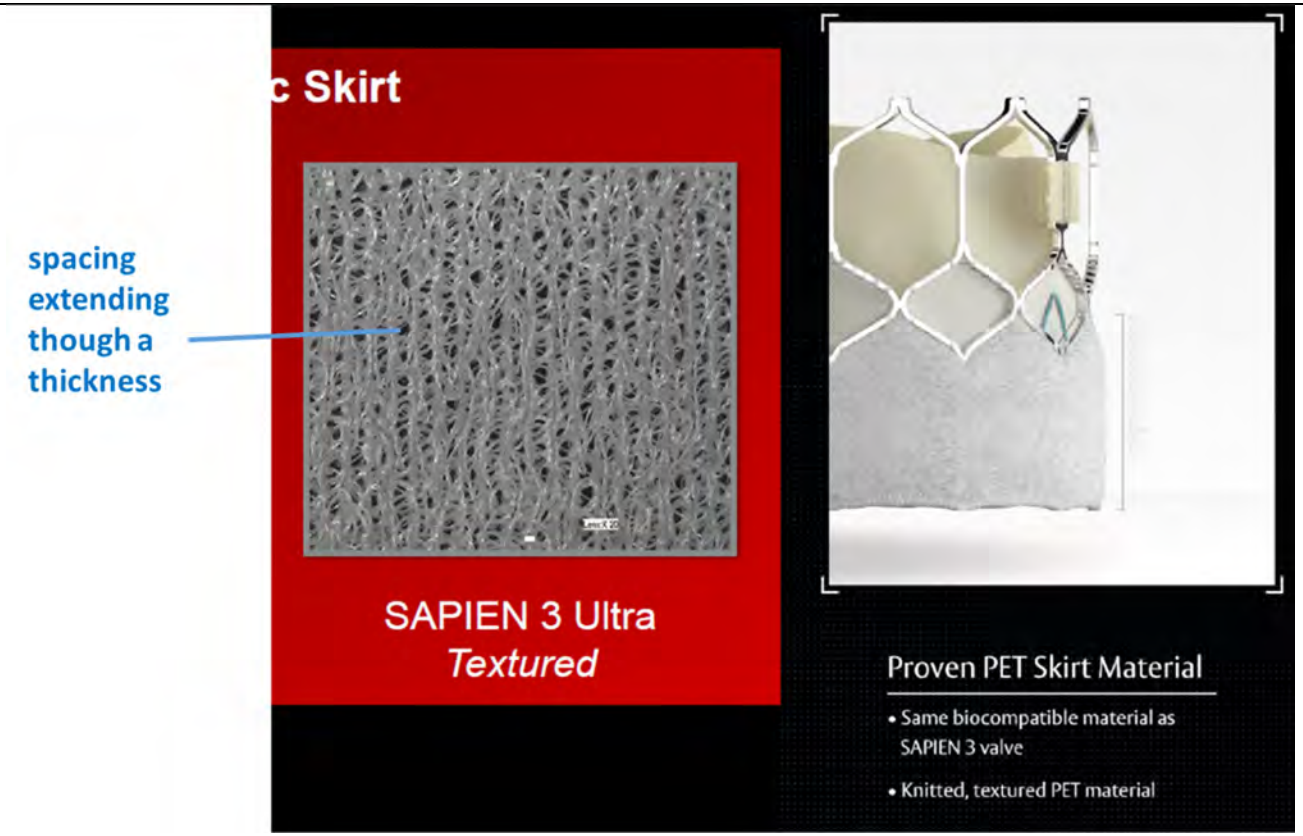


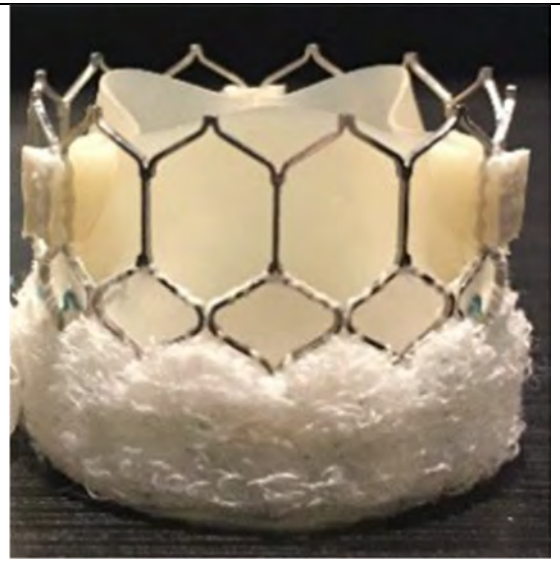
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



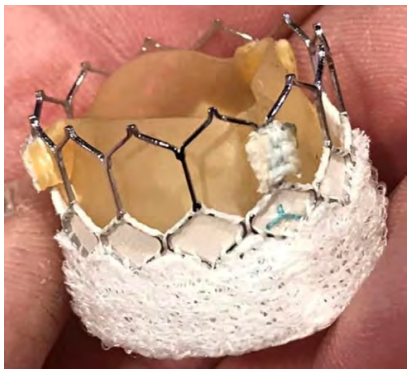
	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
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	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities define 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. The Sapien 3 Ultra fibers include spacings created by distances between adjacent fibers of the sealing skirt that extend though the cells of the frame.

plurality of cells of the frame,	 Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

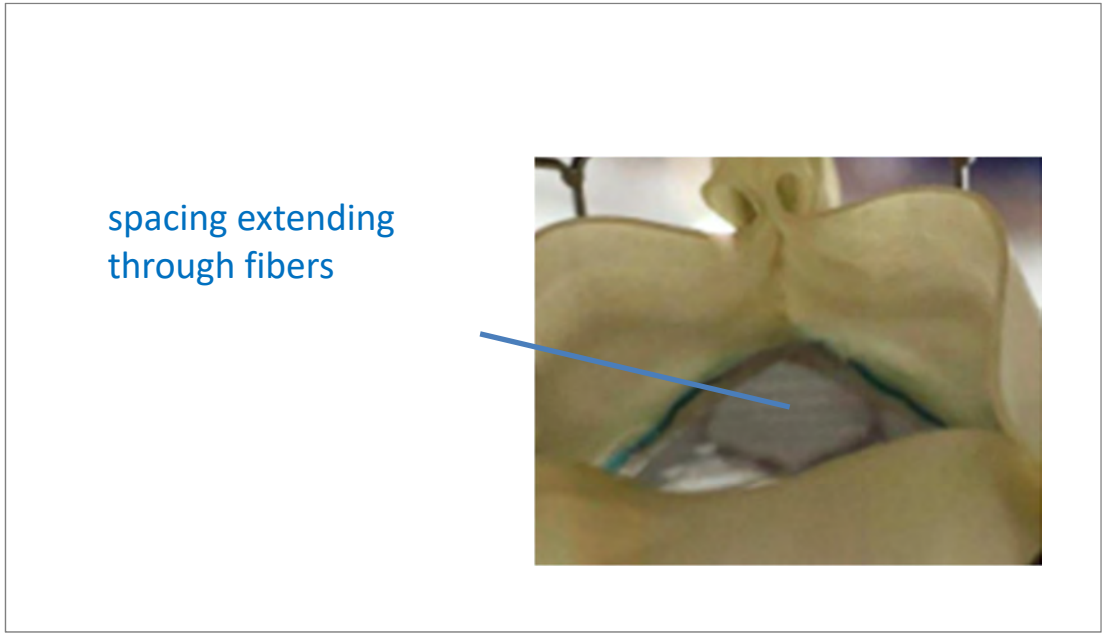


Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

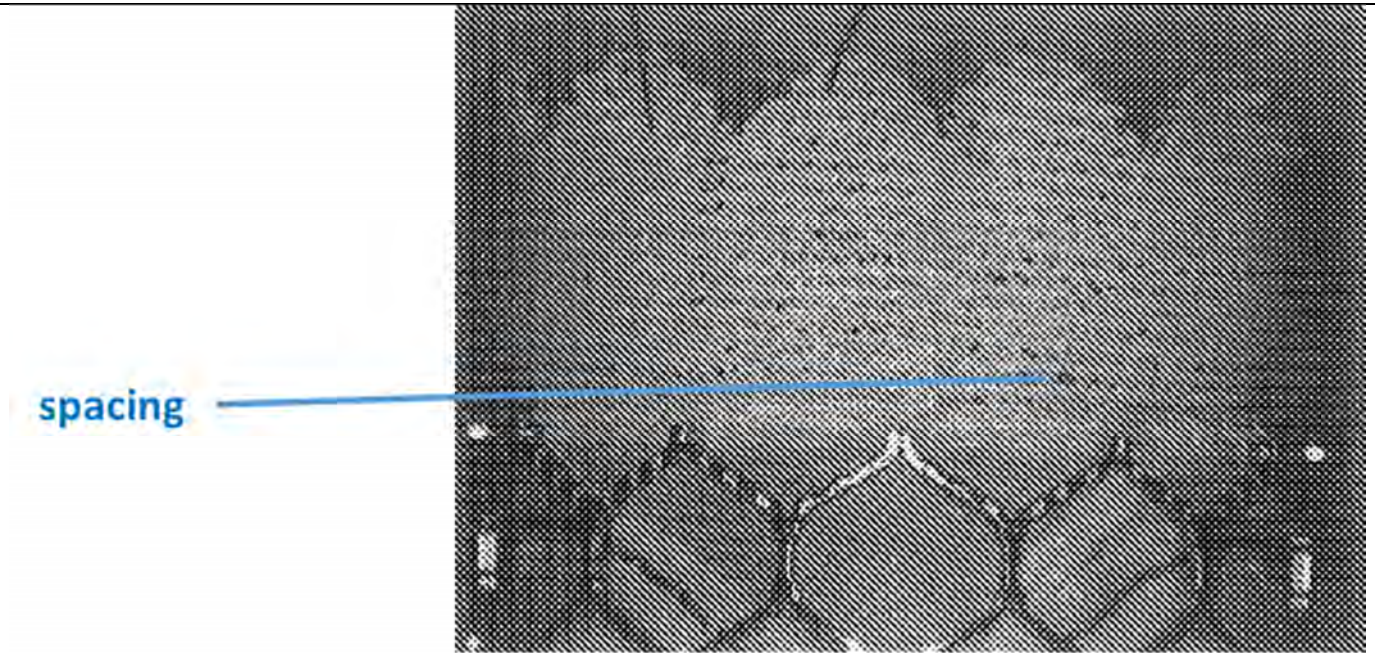


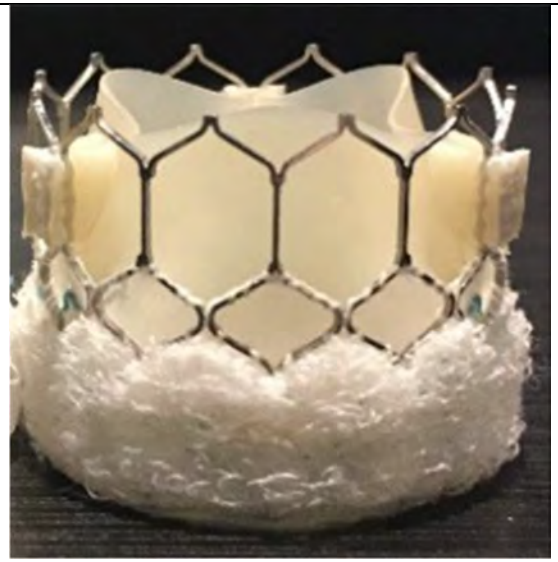

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

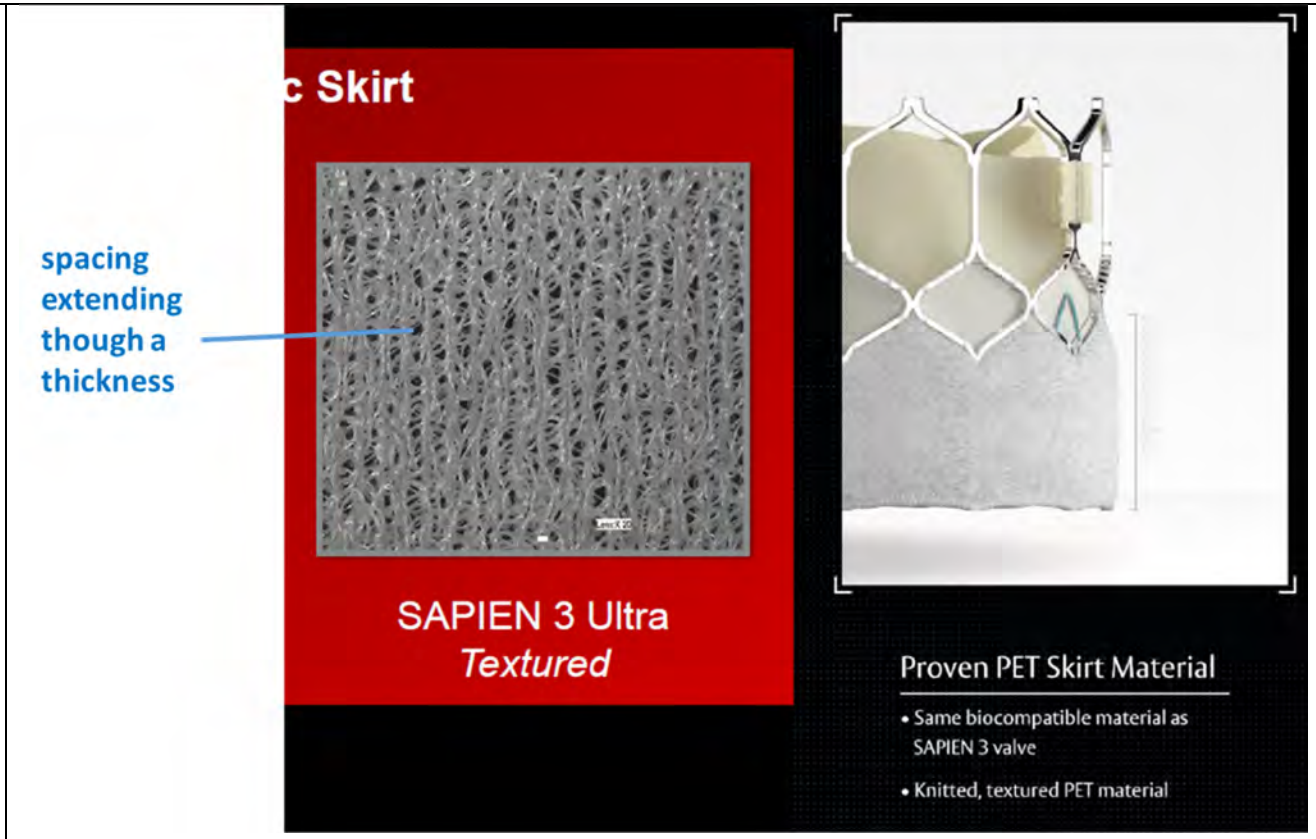
Further, the Sapien 3 Ultra sealing skirt includes fibers carried by the frame facing the frame. The spacings further extend though those adjacent fibers.



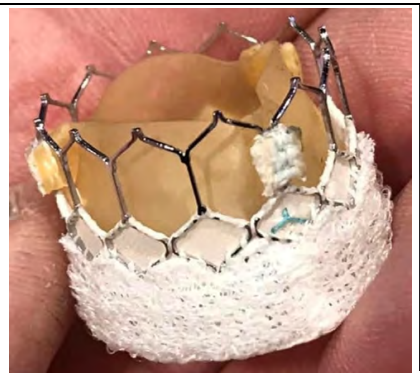
Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1-2 at 15).

	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing spacings on flipped up backside of sealing skirt).
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	The ’834 patent Accused Instrumentalities satisfy this element. For example, the ’834 patent Accused Instrumentalities are 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. For example, the Sapien 3 Ultra is designed using knitted PET with compressible fibers such that when compressed in response to expansion of the heart valve in the aorta, the fibers are compressed together relative to the spacings providing for sealing to help prevent paravalvular leakage.

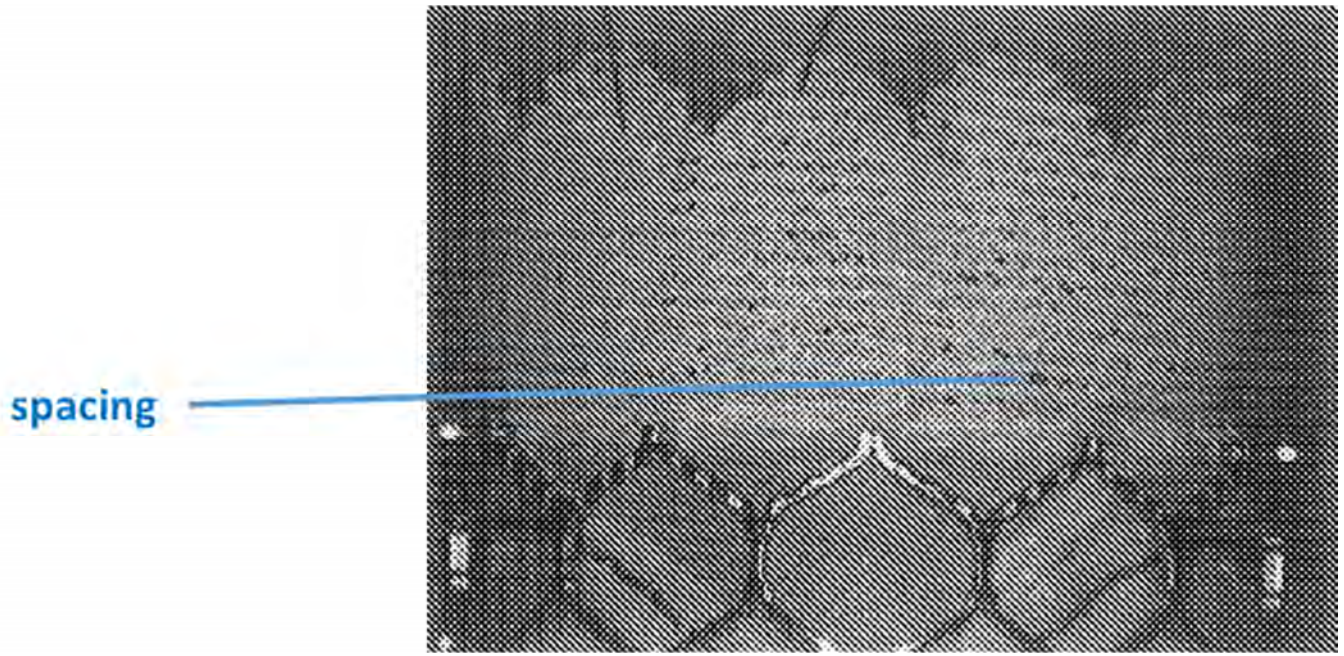
create a seal thereabout,	 Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

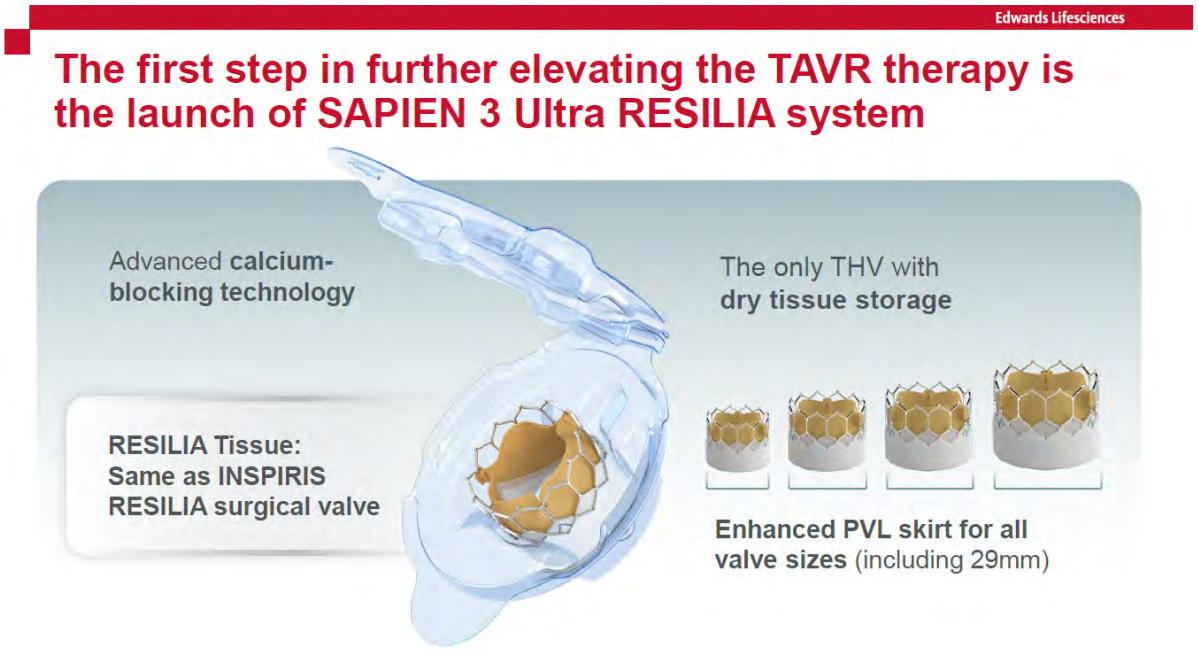


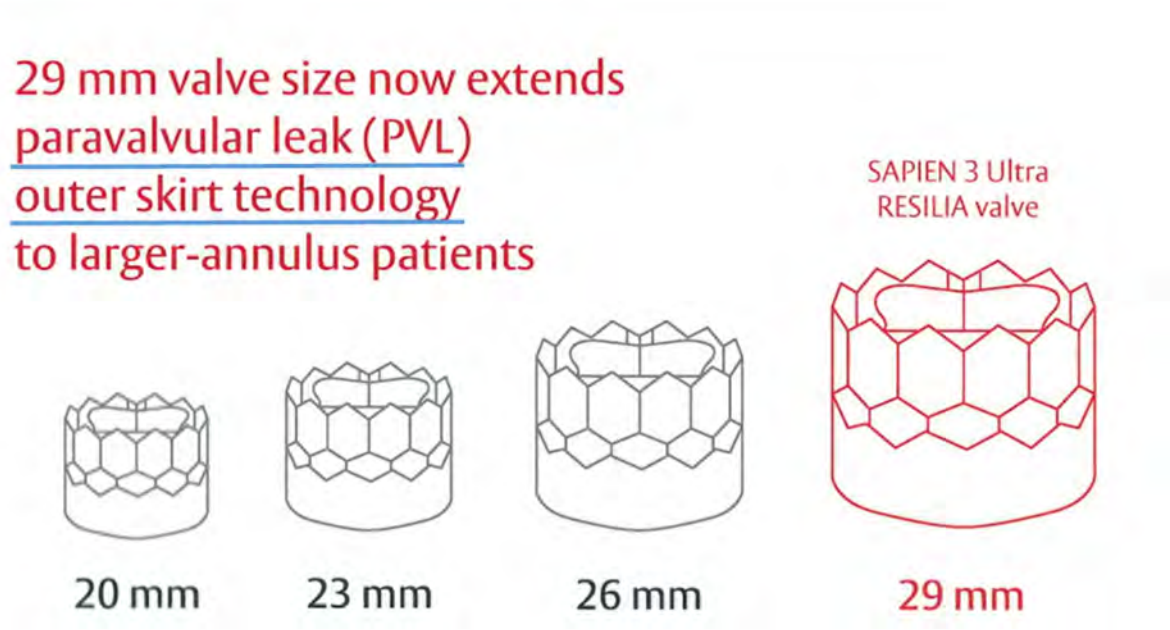
Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).



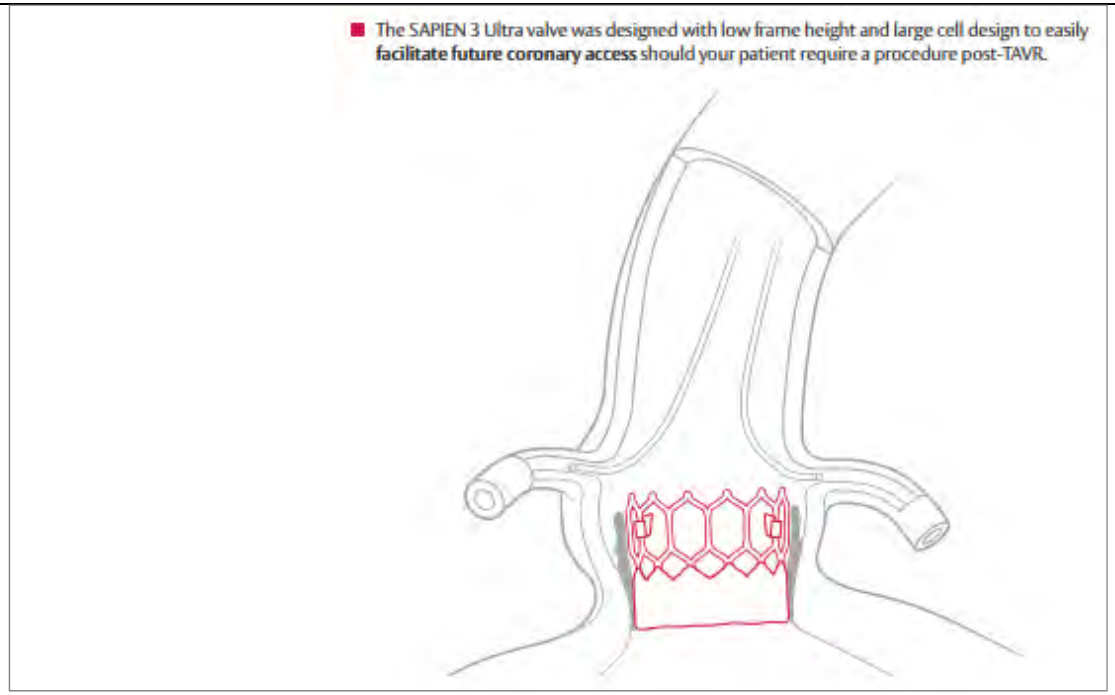

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).



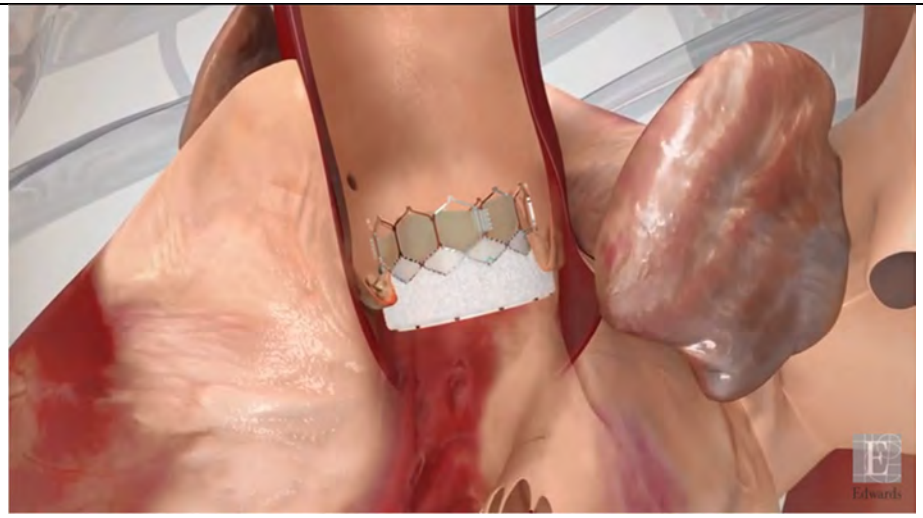
	U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing spacings on flipped up backside of sealing skirt).  https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).

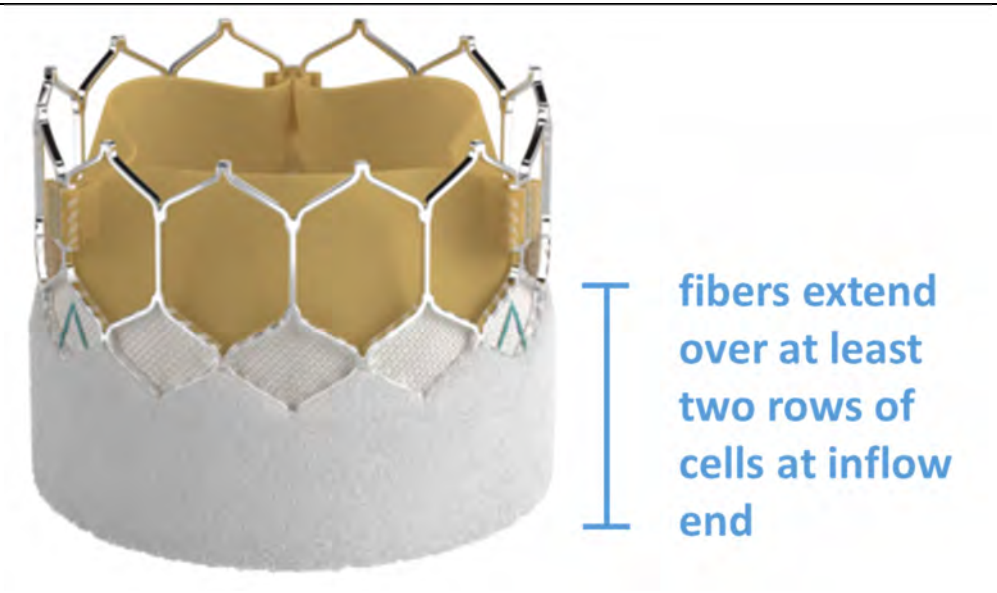


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

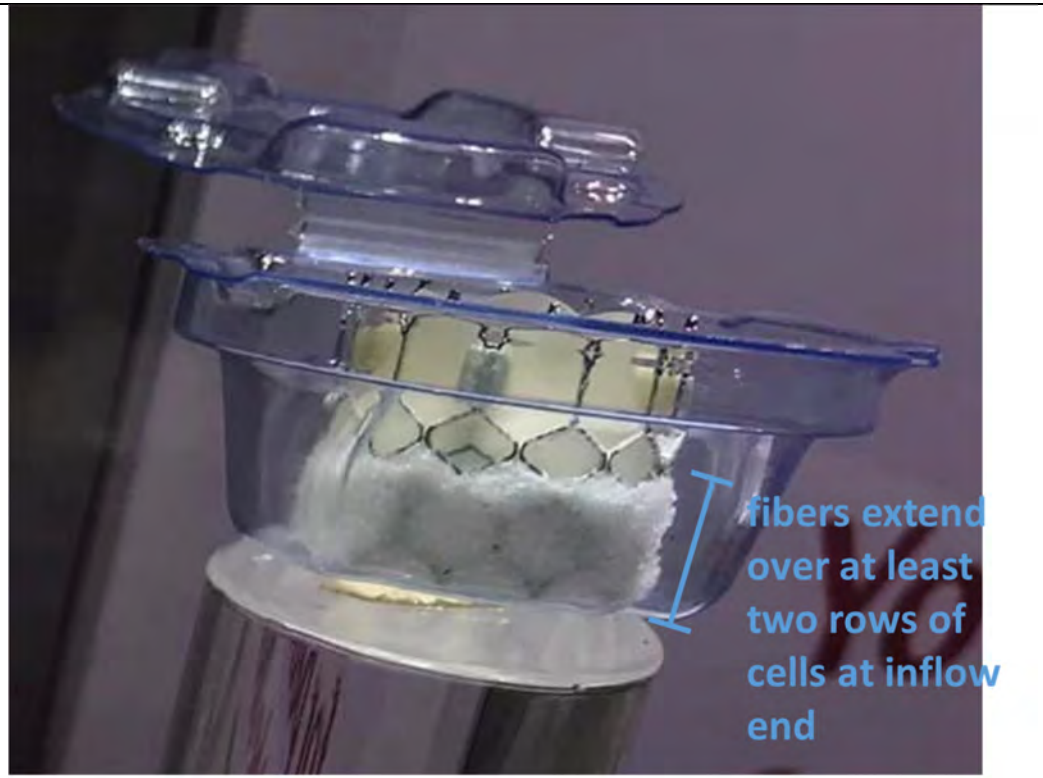


Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
wherein the plurality of fibers extends over each of the at least two rows of cells.	The '834 patent Accused Instrumentalities satisfy this element. The '834 patent Accused Instrumentalities' plurality of fibers extends over each of the at least two rows of cells. For example, the Sapien 3 Ultra sealing skirt has fibers that extend over a least two rows of cells at the inflow end.



https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



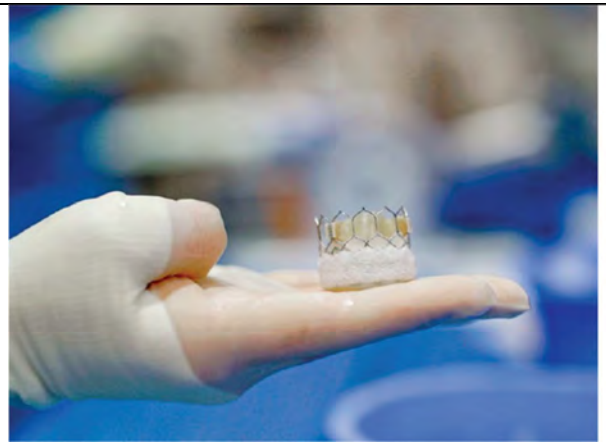
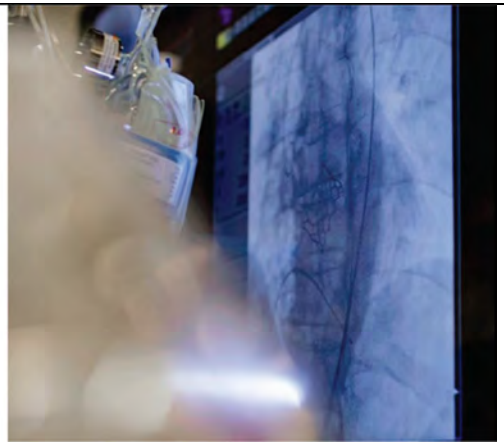
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

Exhibit B - Edwards' Infringement of U.S. Patent No. 11,389,310

Claim	Exemplary Infringement Evidence[1]
1. A transcatheter heart valve assembly comprising:	To the extent the preamble is limiting, the '310 patent Accused Instrumentalities[2] satisfy this element. For example, the '310 patent Accused Instrumentalities are transcatheter heart valve assemblies. The '310 patent Accused Instrumentalities are transcatheter heart valve assemblies designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems.

[1] The exemplary evidence and infringement assertions cited herein may also be used to support any other claim element where appropriate. Aortic Innovation LLC's ("Aortic") investigation is ongoing and discovery is in its preliminary stages. Aortic hereby incorporates by reference the cover pleading to which this claim chart is attached. Aortic reserves the right to amend or supplement these contentions after further investigation and discovery from Edwards and non-parties and in accordance with the rules and schedule. Such supplemental information may include, but is not limited to, FDA submissions and correspondence, data sheets, design specifications, deposition testimony, testing information, reference designs, implementation and utilization information, and/or schematics. Aortic also reserves the right to assert additional claims of the Aortic patents-in-suit, accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products. Under the proper construction of the asserted claims and their claim terms, each element of the asserted claims is literally present in the accused products or acts accused of infringing the claim. Any and all elements found not to be literally infringed are infringed under the doctrine of equivalents because the differences between the claimed inventions and the Accused Instrumentalities, if any, are insubstantial. Aortic further reserves the right to accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products, based on further investigation and discovery, the claim construction process, the Court's rules, and/or other circumstances so meriting.

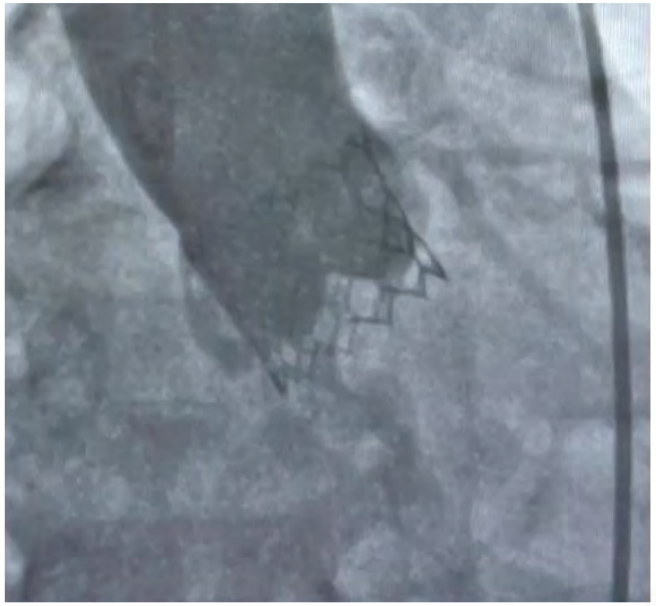
[2] "Accused Instrumentalities" refers to all models, versions, and sizes of Edwards's Sapien 3 Ultra devices, including, but not limited to Edwards Sapien 3 Ultra valves with non-Resilia valve leaflets and Edwards Sapien 3 Ultra Resilia valves, which Aortic understands to be the same as the Sapien 3 Ultra, but with Edwards' Resilia valve leaflet tissue which Aortic understands uses "a bovine (cow) heart tissue that has been treated with Edwards' technology to block calcium build-up on the valve." Discovery is ongoing and Aortic reserves the right to amend or supplement the identified Accused Instrumentalities to the extent that additional relevant information is obtained during discovery.

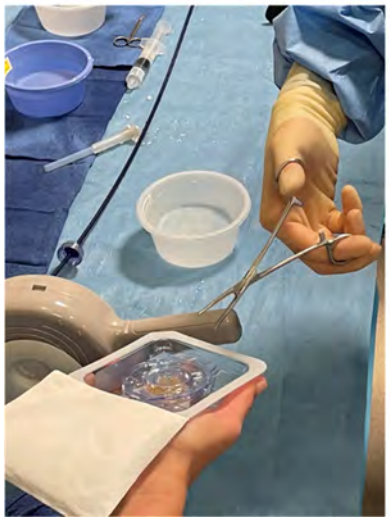
	  https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

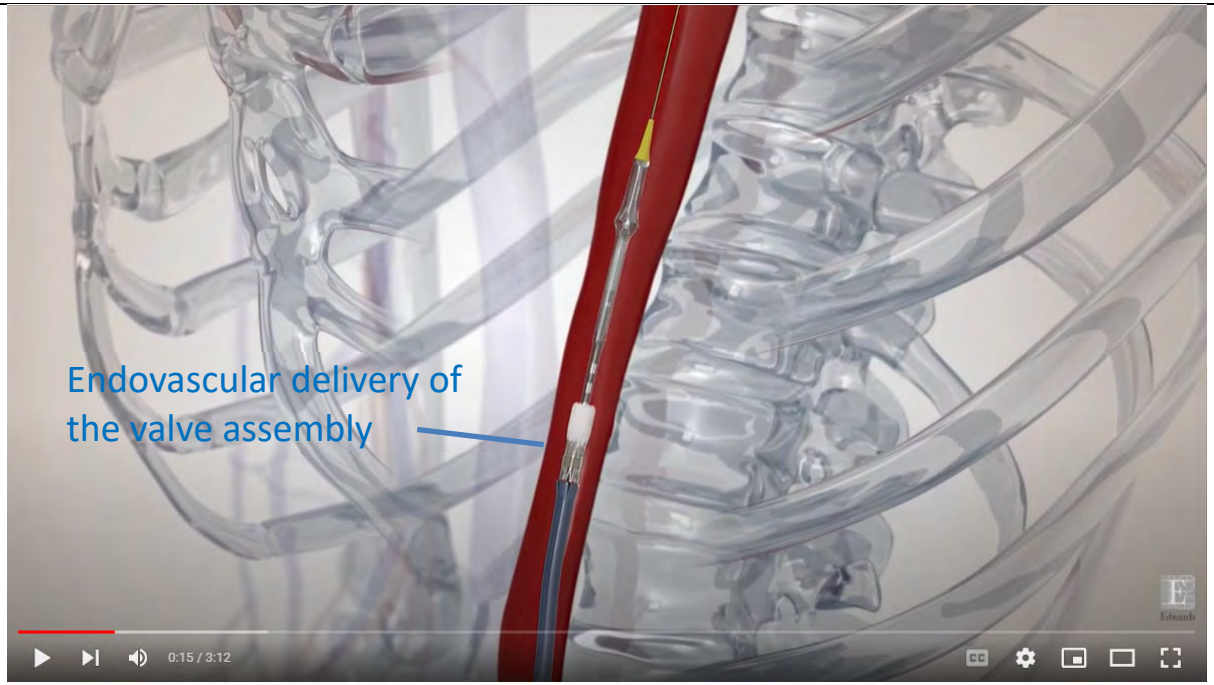




https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).



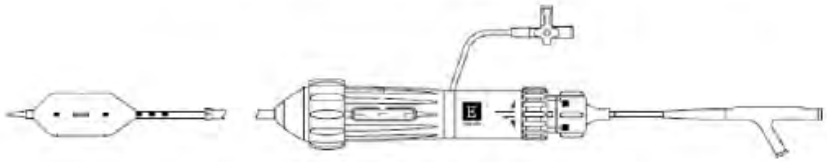
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



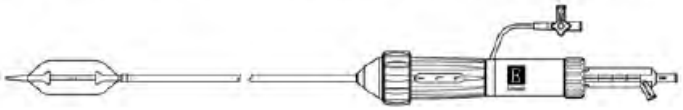
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

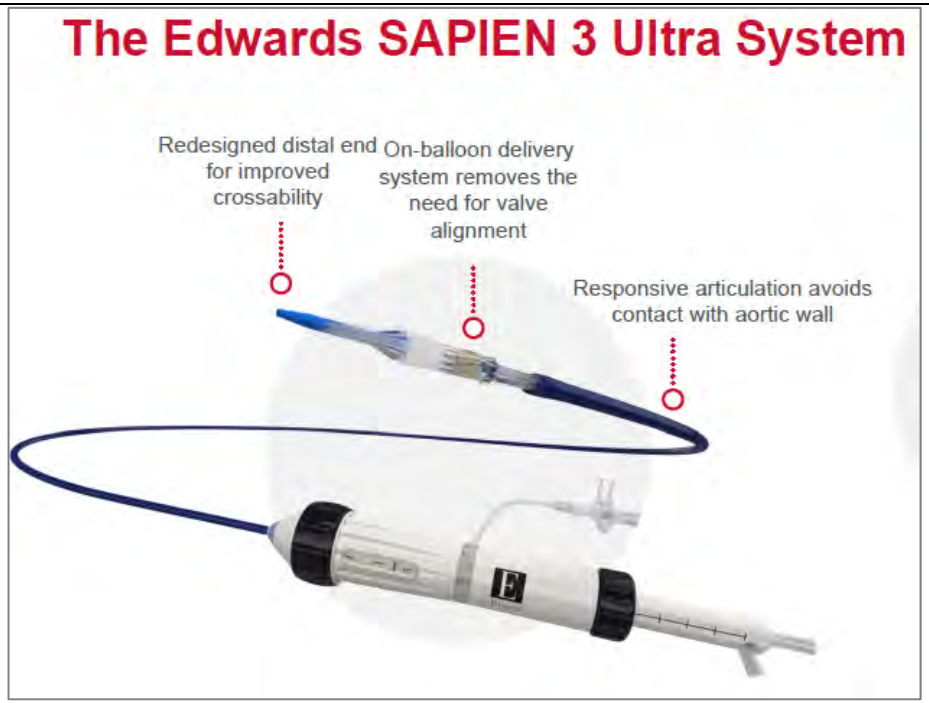
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

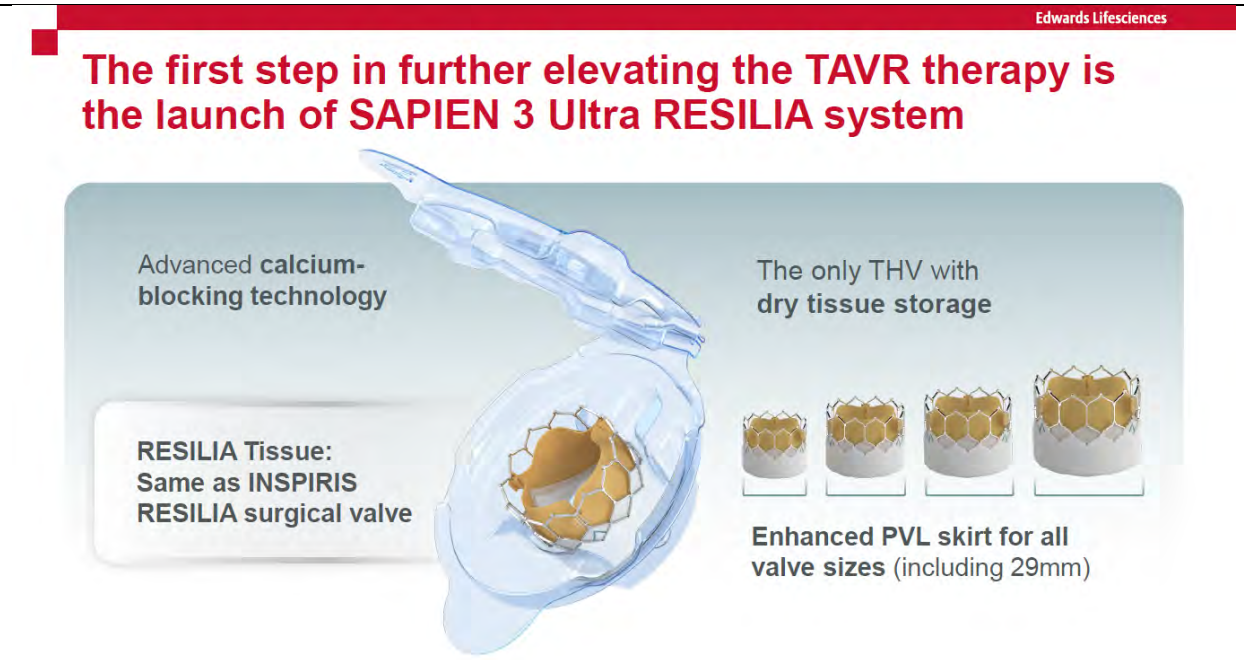
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

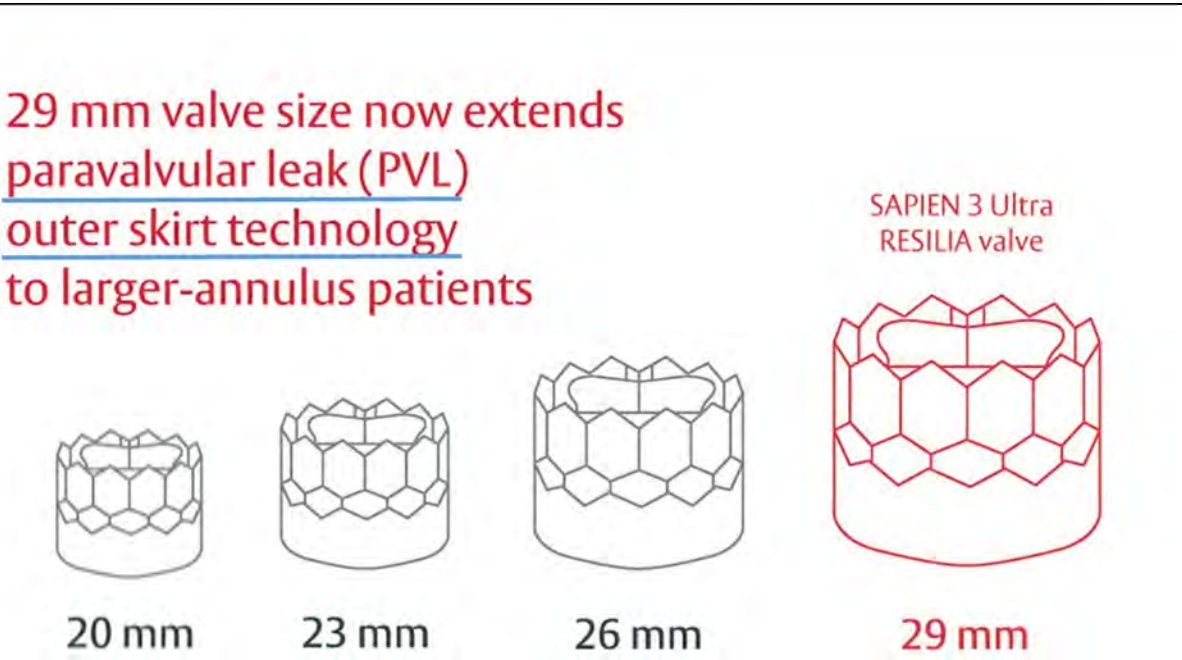
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

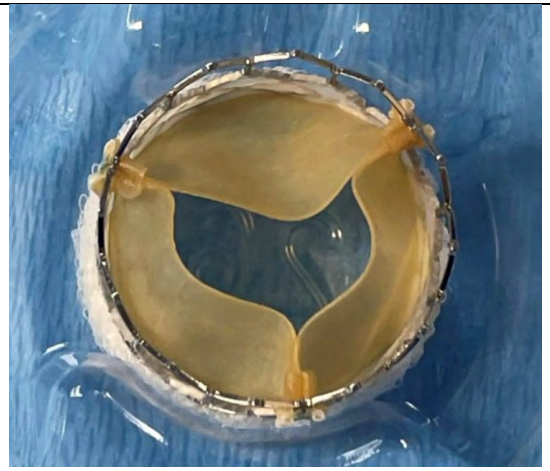
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’310 patent Accused Instrumentalities and infringes the ’310 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



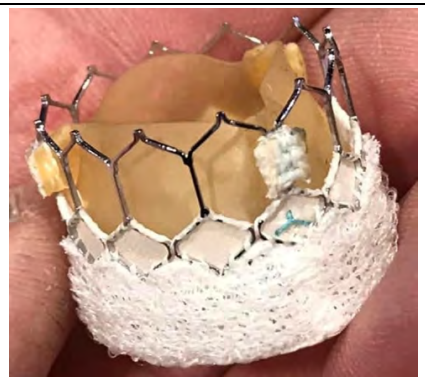
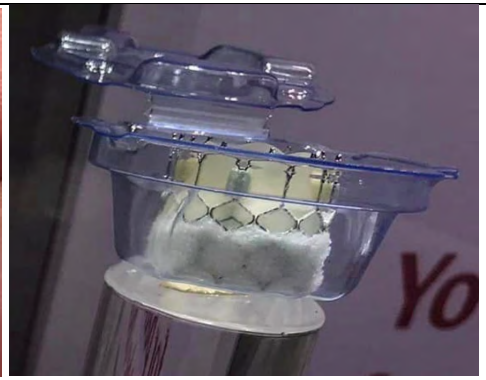
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

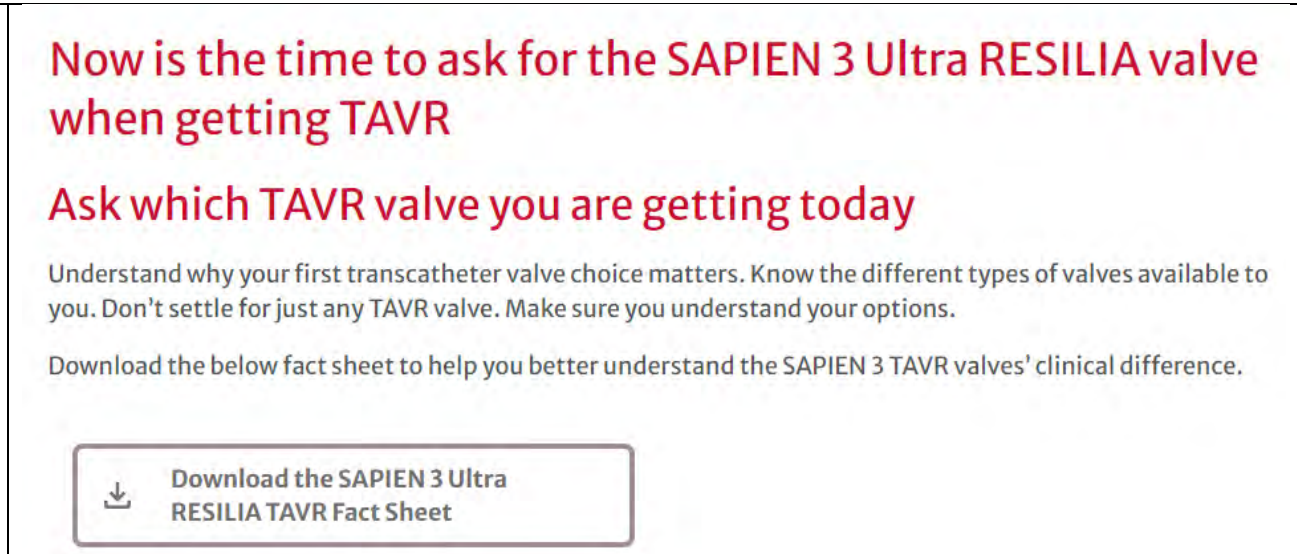
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the '310 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's

	recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See* https://ir.edwards.com/events-presentations/; https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '310 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '310 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '310 asserted claims are infringed when Edwards offers for sale and sells the '310 patent Accused Instrumentalities. Edwards offers for sale and promotes the '310 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 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.



https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61).

On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement#

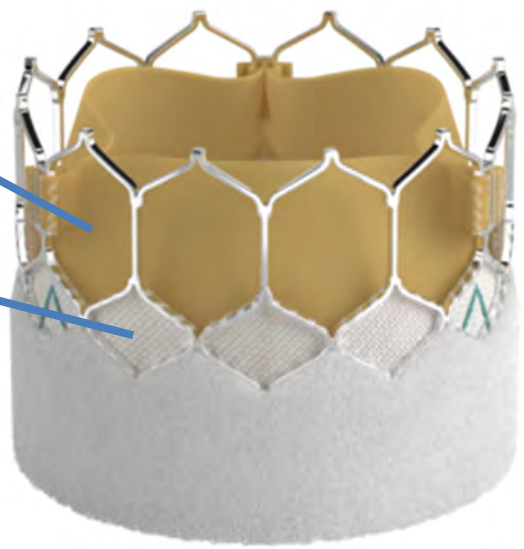
Further, the '310 patent asserted claims are directly infringed when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or tested by Edwards.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

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the ’310 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards’ direct and induced infringement. For further example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe the asserted ’310 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a “watchful eye” over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards’s inducement, Edwards’s affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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.

	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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards’s affirmative acts of marketing, selling and offering to sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ combination and use of the Accused Instrumentalities, such that the ’310 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards’ knowledge of Aortic’s inventions, the patents-in-suit (including the ’310 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
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;	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities comprise 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. For example, the Edwards Sapien 3 Ultra graft covering houses and extends about and provides sealing to the prosthetic heart valve leaflets.

heart valve having prosthetic leaflets

graft covering



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

https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

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.



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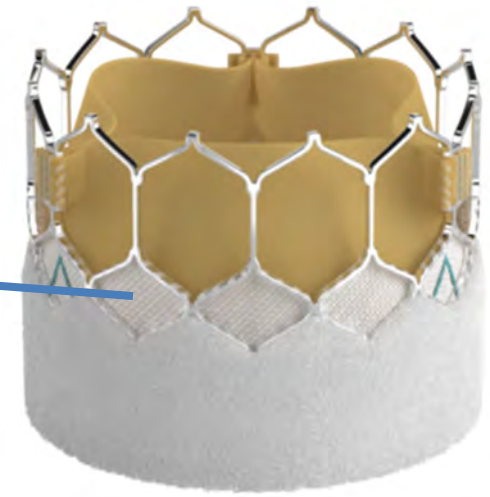
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

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

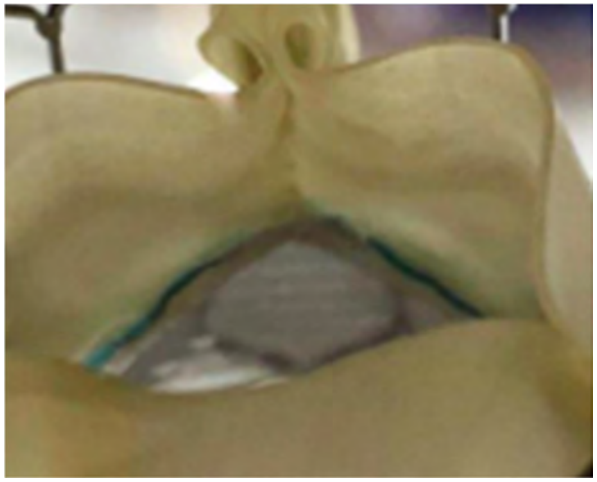
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

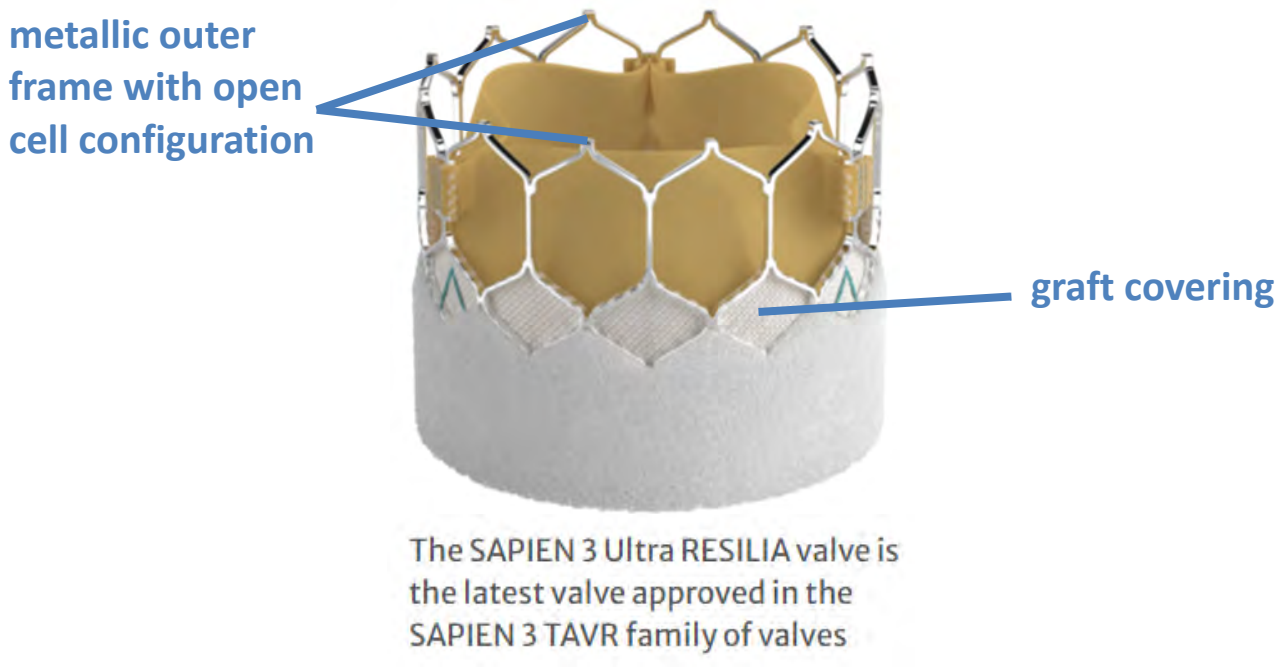
graft covering housing, extending around, and providing sealing to leaflets



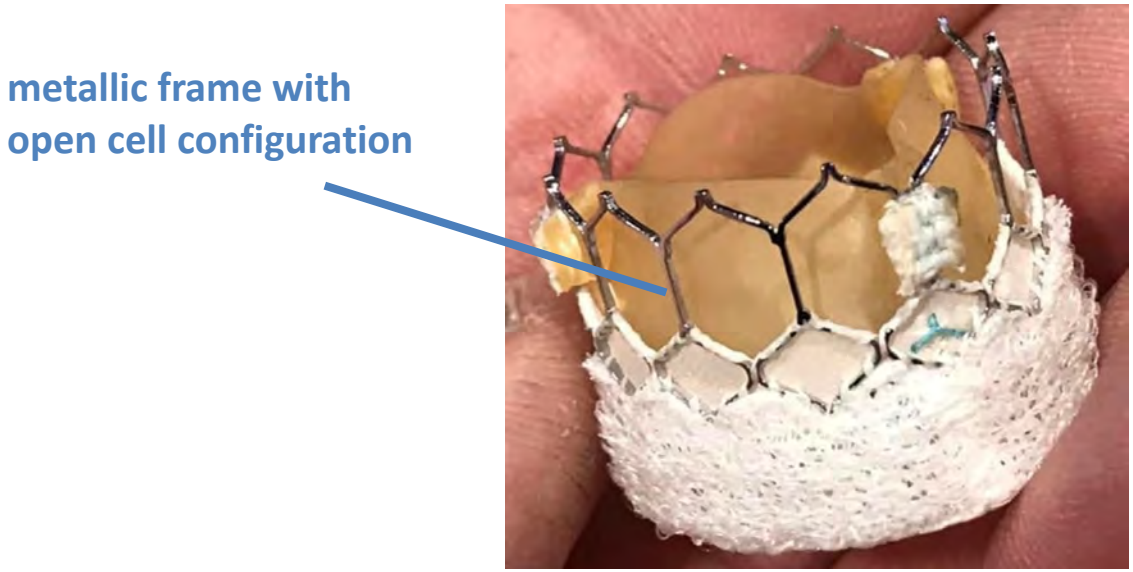
The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves

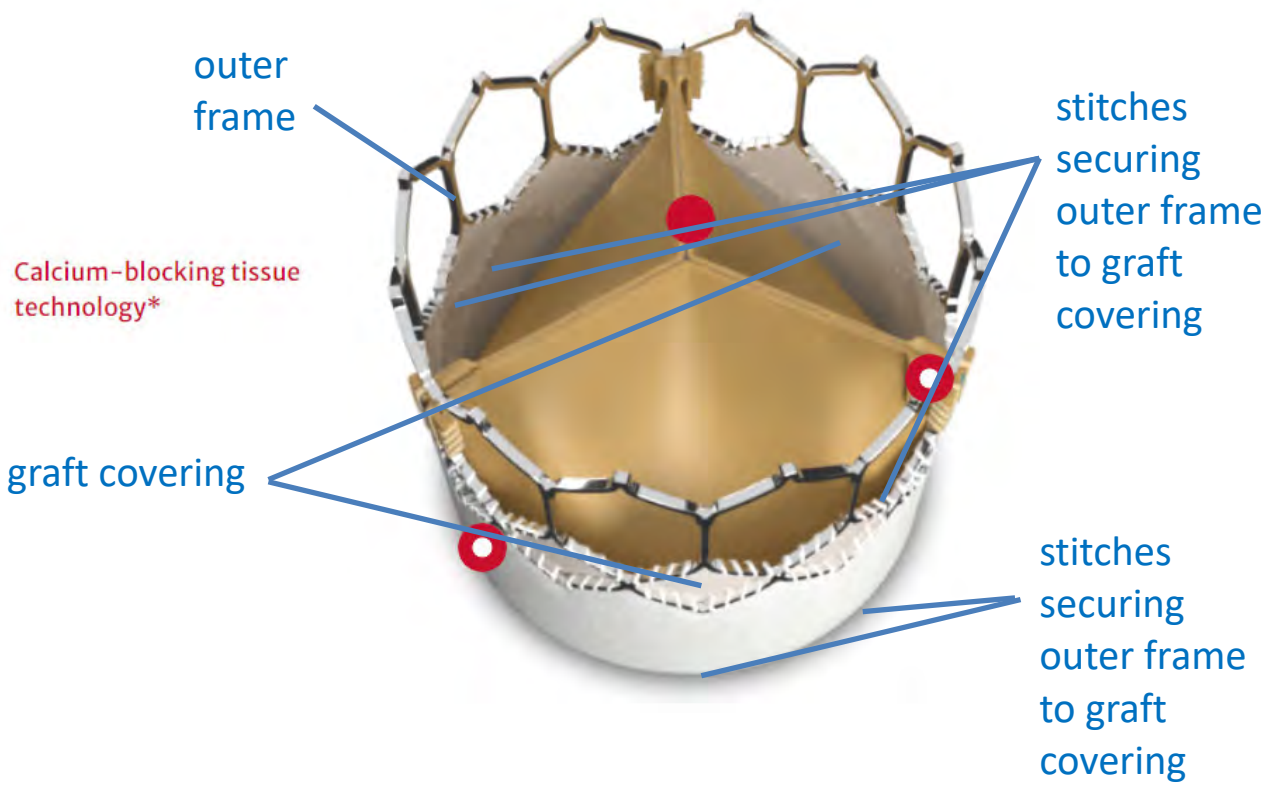
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	 https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29). With respect to the phrase, “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”, Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include 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, even taking into account any alleged “differences” identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering performs the same or substantially the same function as the claim phrase by partially and/or fully housing, extending around and providing sealing to the prosthetic heart valve leaflets, in the same or substantially the same way as the claim phase by fully or partially housing and extending around the prosthetic heart valve leaflets, to

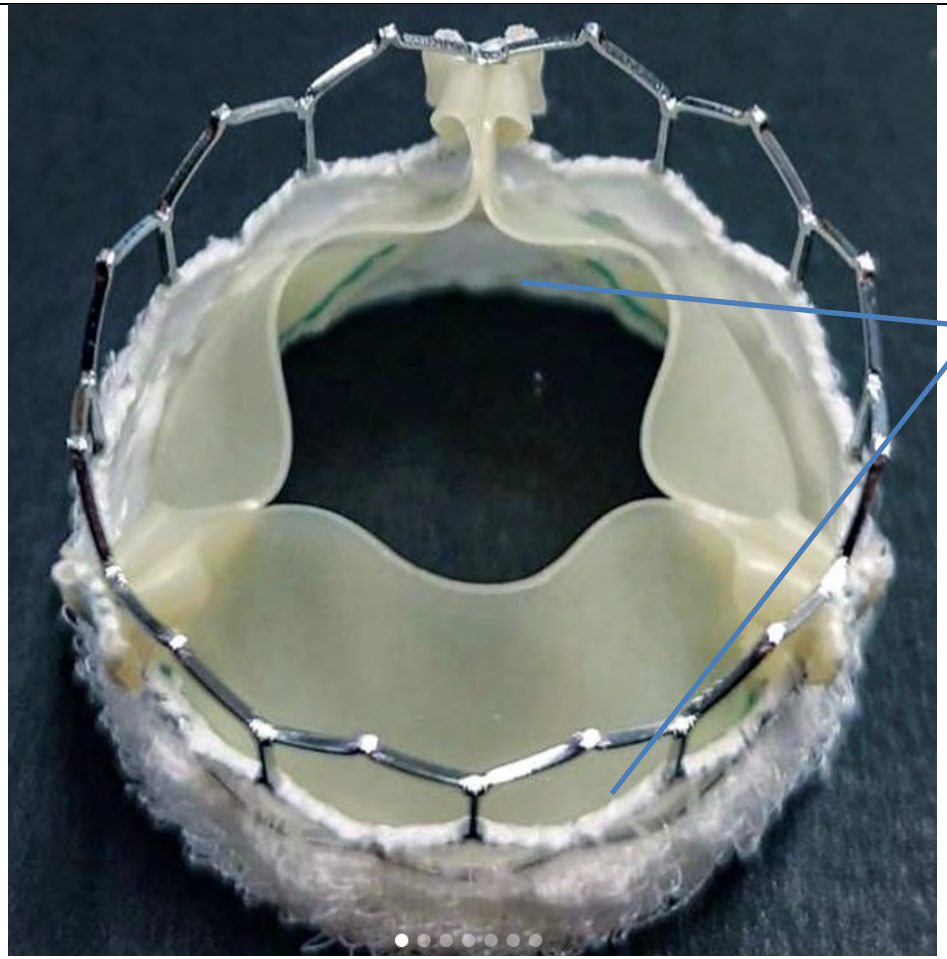
	achieve the same or substantially the same result a graft covering configured to provide sealing or partial sealing to the prosthetic heart valve leaflets.
an outer frame formed from a metallic material and defining an open cell configuration, and being secured to the graft covering; and	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities comprise an outer frame[3] formed from a metallic material and defining an open cell configuration, and being secured to the graft covering. For example, the Edwards Sapien 3 Ultra outer frame is formed from a cobalt-chromium metallic alloy and in an open cell configuration. 

[3] Aortic has filed a Motion for Clarification in the *Aortic I* matter regarding the “outer frame” term in the ’846, ’538, and ’236 patents and plans to appeal the “outer frame” construction on the ’735 patent.

	https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. For example, the Sapien 3 Ultra outer frame is secured to the graft covering by stitching.



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

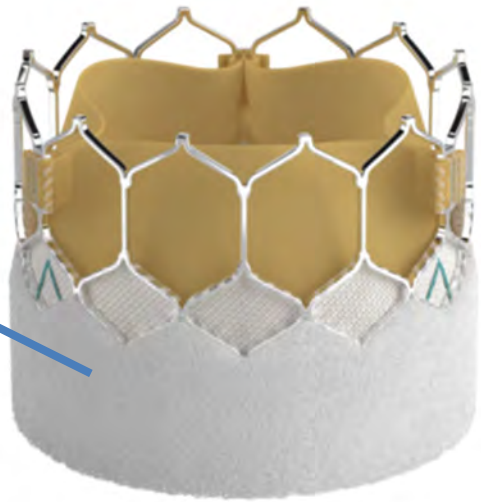


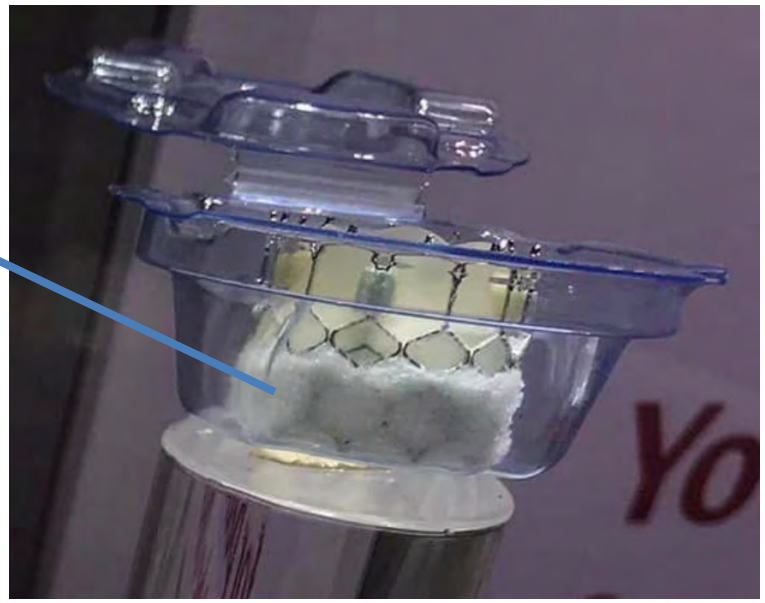
Julian Calain Twitter (D.I. 1, Ex. 30).

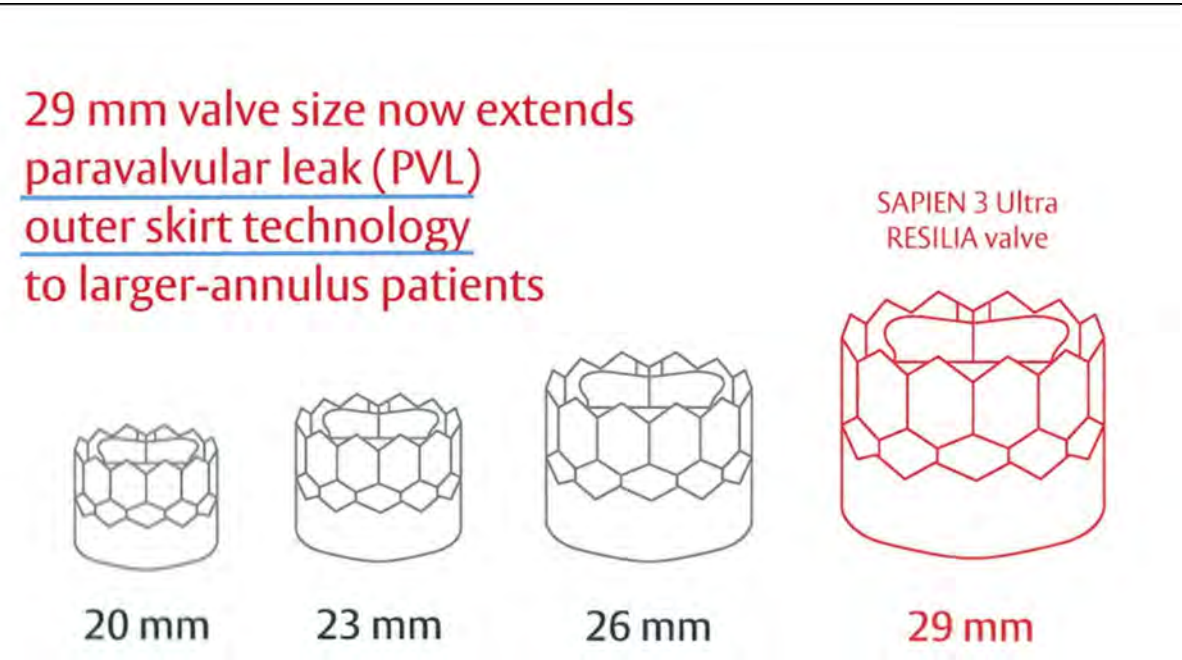
See also, element above.

With respect to the phrase, "an outer frame formed from a metallic material and defining an open cell configuration, and being secured to the graft covering", Aortic asserts that this element is literally present

	in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused outer frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with cells with the capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of providing a low profile collapsible and expandable outer frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy.
a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall to prevent paravalvular leaks,	The '310 patent Accused Instrumentalities satisfy this element. The '310 patent Accused Instrumentalities comprise 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 . For example, the Edwards Sapien 3 Ultra includes a sealing skirt for providing sealing between the outer frame and the patient's anatomical wall for preventing paravalvular leaks.

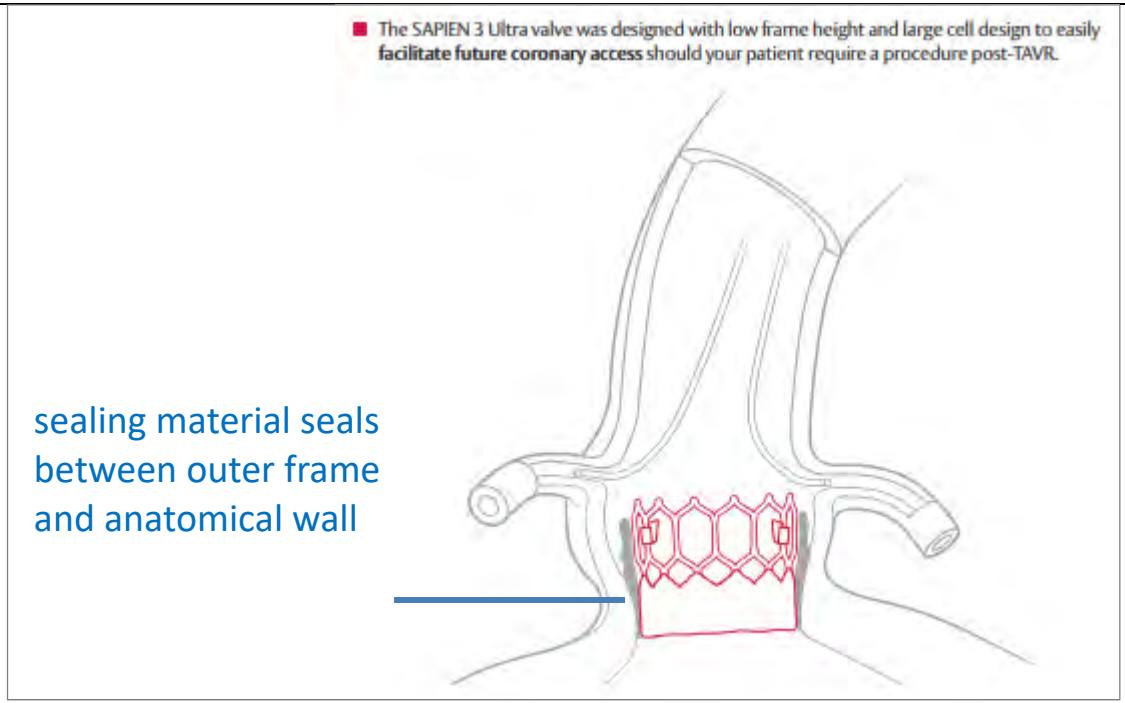
	sealing material external to outer frame for preventing paravalvular leaks  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	sealing material external to outer frame for preventing paravalvular leaks  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

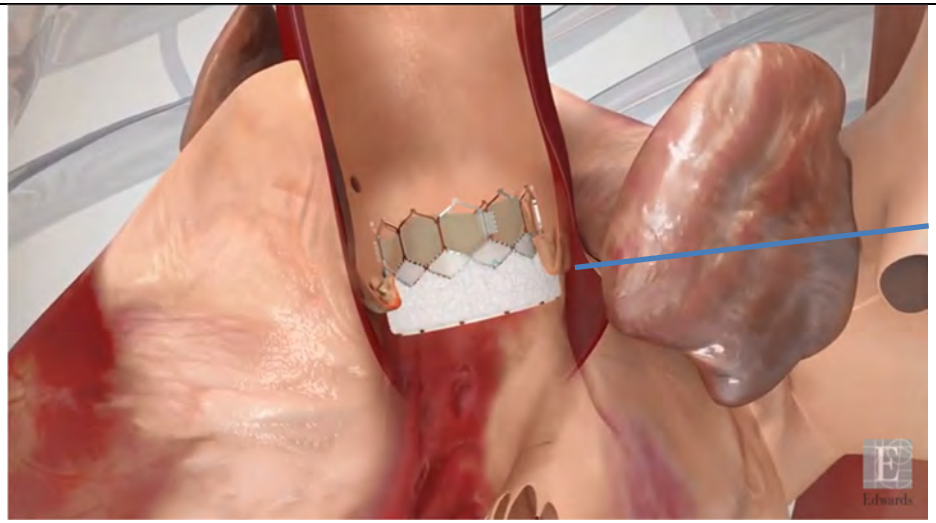


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

For example, the Sapien 3 Ultra sealing skirt provides for sealing between the outer frame and the patient's anatomical wall to help prevent PVL.

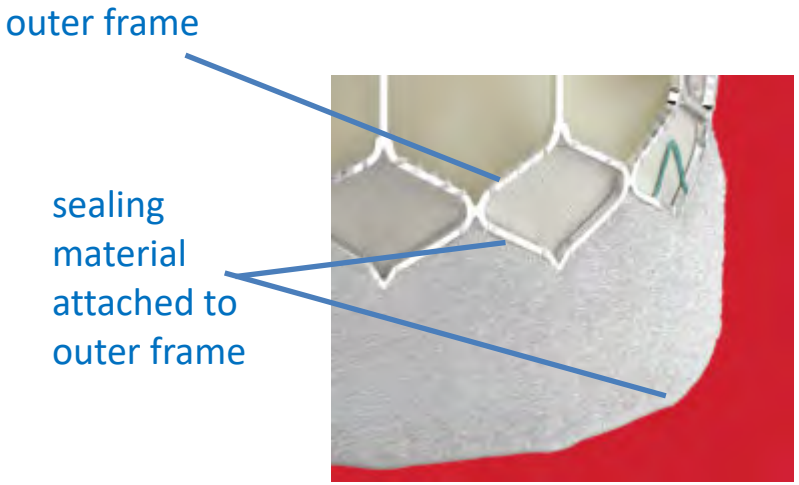


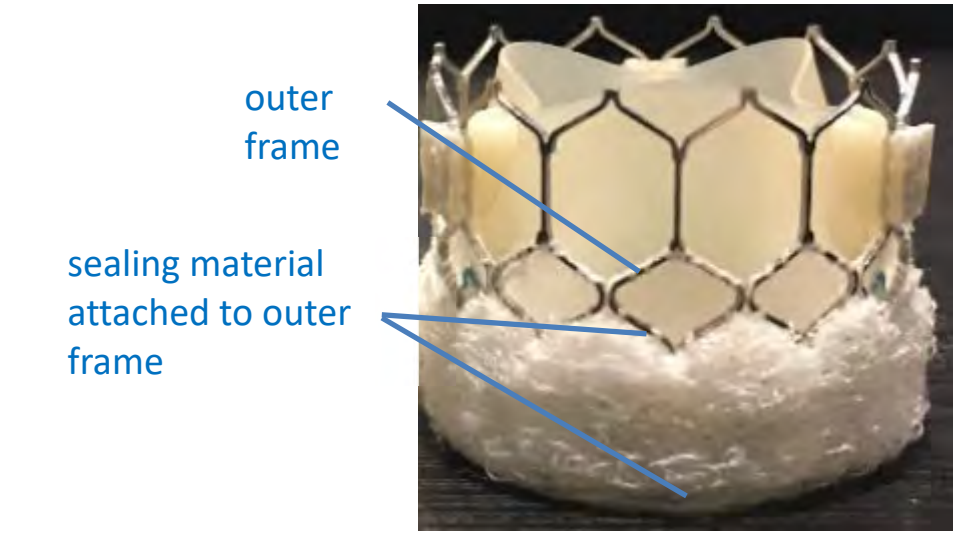
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



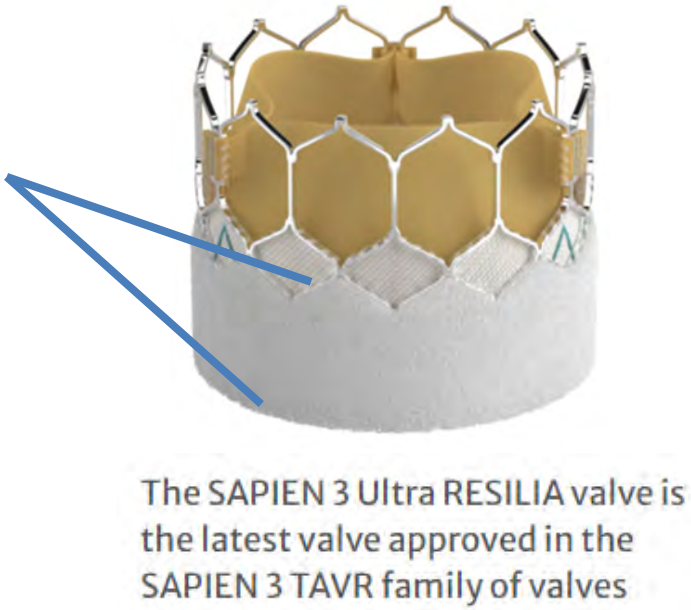
"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

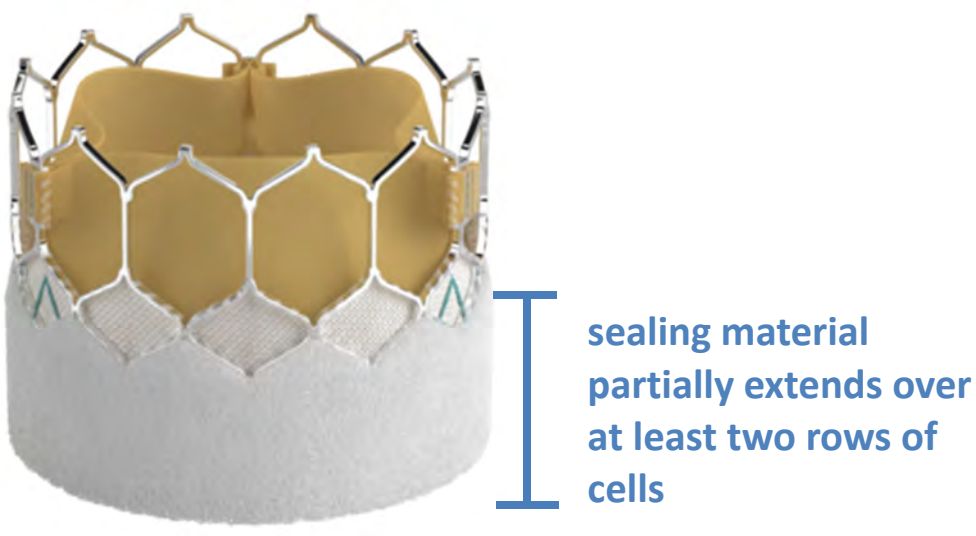
Further, with respect to the phrase, " a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall to prevent paravalvular leaks" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the sealing material does not allow visibility of the frame or that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing material of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused sealing material performs the same or substantially the same function as the claim phrase by providing for low profile sealing material capable of providing sealing between the anatomical wall and the outer frame, in the same or substantially the same way as the claim phase by using a low profile biocompatible polymeric sealing material configured to press against and providing sealing between the patient's anatomical wall and the outer frame, to achieve the same or substantially the same

	result of a sealing material configured to form a biocompatible seal between the anatomical wall and the frame for reduced paravalvular leakage.
wherein the sealing material is attached to the outer frame,	The ’310 patent Accused Instrumentalities satisfy this element. For example, the ’310 patent Accused Instrumentalities comprise a sealing material that is attached to the outer frame. For example, the sealing material is attached to the frame using stitching.  Introducing the SAPIEN 3 Ultra valve at 2, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

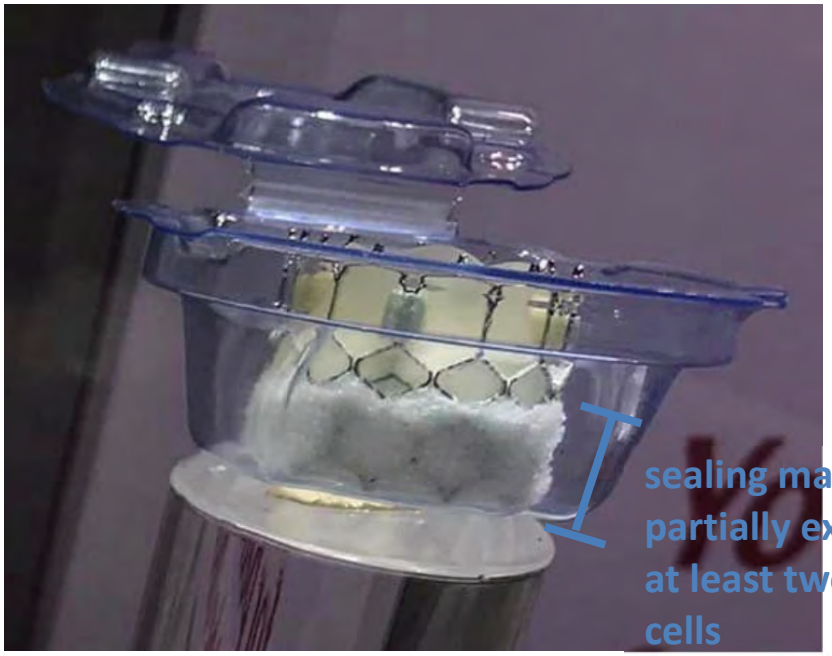


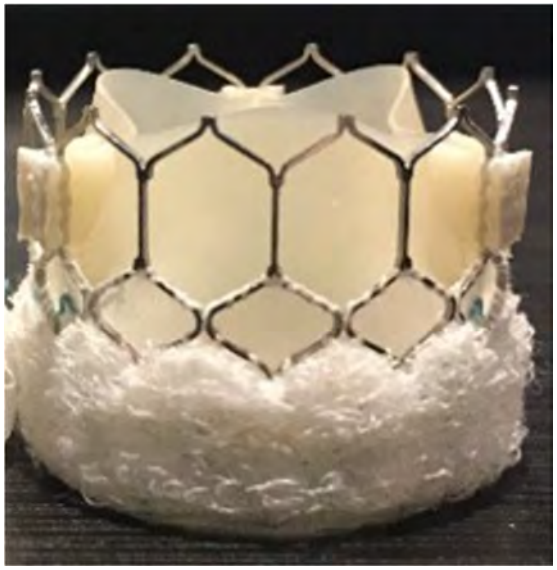
Sapien 3 Ultra image by William Suh, MD (annotated), https://twitter.com/willsuh76/status/1280708440734617600/photo/1 (D.I. 1, Ex. 7).

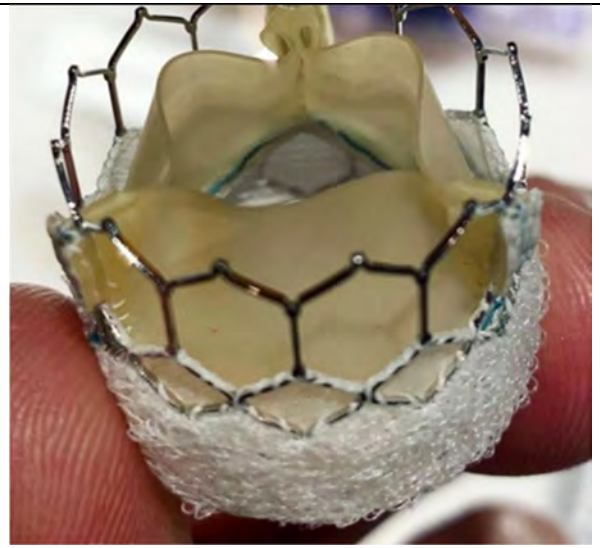
	 https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).
wherein the sealing material defines a height that partially extends over at least a first two rows of cells in the outer frame,	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ sealing material defines a height that partially extends over at least a first two rows of cells in the outer frame. For example, the Sapien 3 Ultra sealing skirt partially extends over a least two rows of cells in the frame.

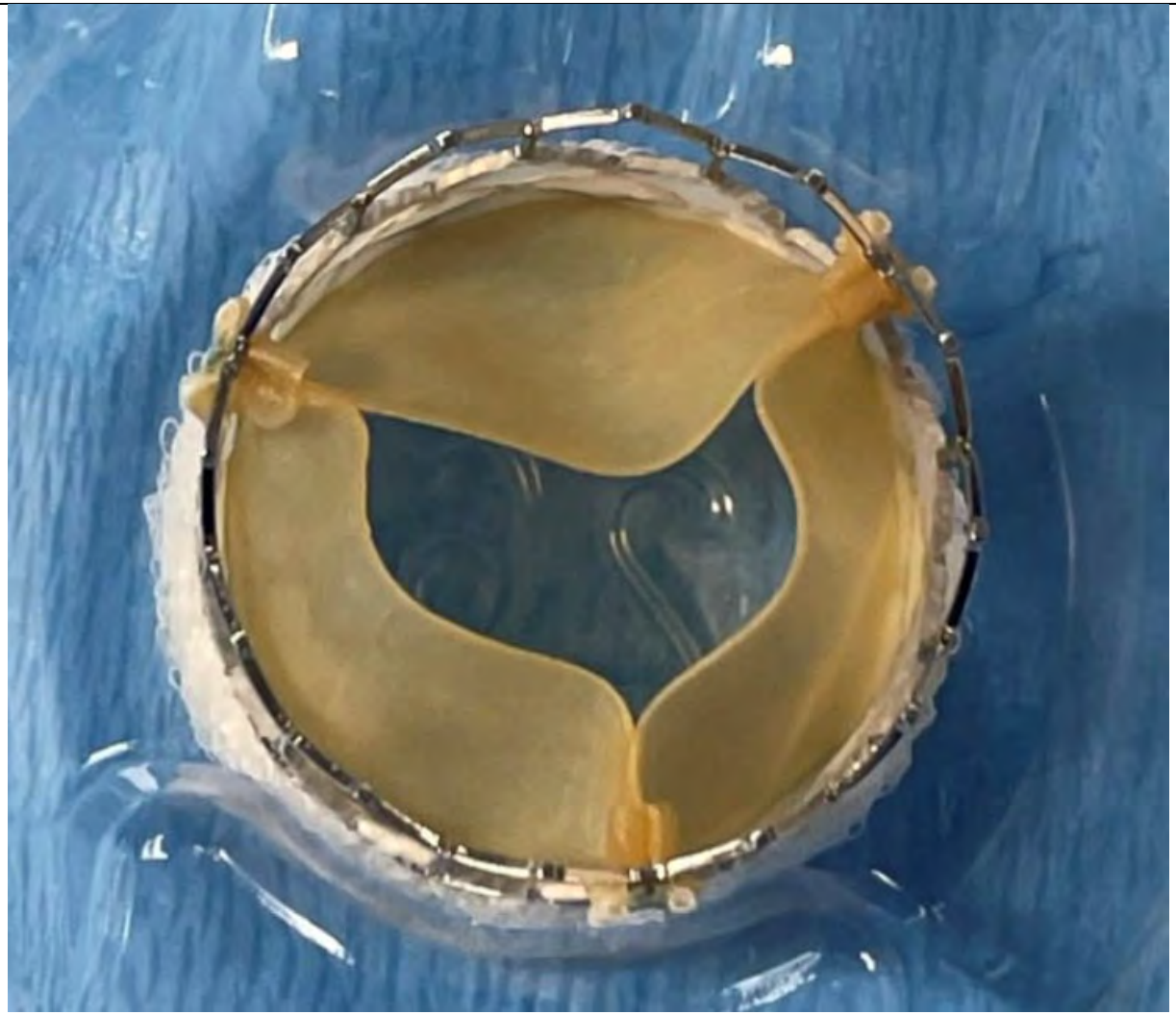


https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3). With respect to the phrase, "wherein the sealing material defines a height that partially extends over at least a first two rows of cells in the outer frame," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, at least two rows of cells perform the same or substantially the same function as the claim phrase by providing a collapsible and expandable structure for the sealing material to extend over, in the same or substantially the same way

	as the claim phase by being constructed of metal forming cells of the same or equivalent shapes and sizes, to achieve the same or substantially the same result of providing least two rows of cells for the sealing material to at least partially extend over.
wherein the sealing material includes a plurality of radially extending, arcuate fibers that extend outwardly of the outer frame;	The ’310 patent Accused Instrumentalities satisfy this element. For example, the ’310 Accused Instrumentalities’ sealing material includes a plurality of radially extending, arcuate fibers that extend outwardly of the outer frame. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the outer frame.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of outwardly extending arcuate fibers extending outwardly from outer frame) (D.I. 1, Ex. 29).

	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of outwardly extending arcuate fibers extending outwardly from outer frame) (D.I. 1, Ex. 64).

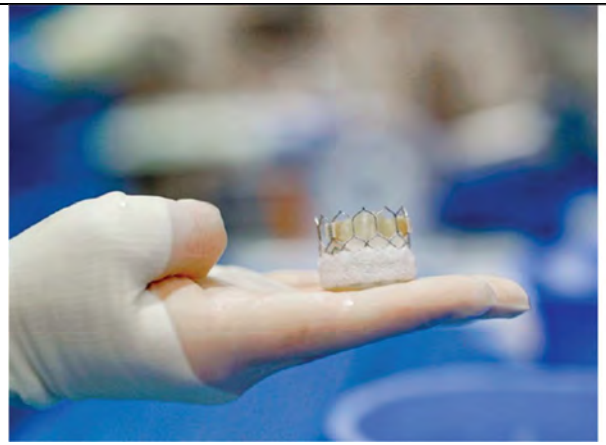
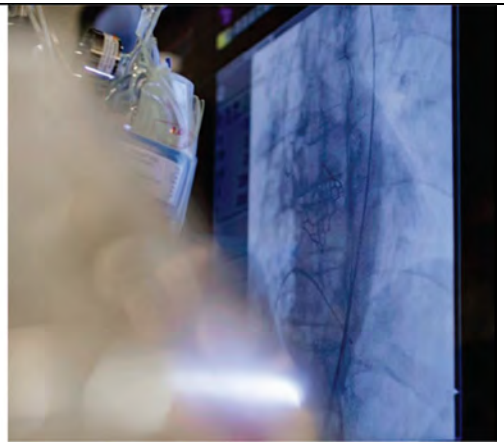


Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of outwardly extending arcuate fibers extending outwardly from outer frame) (D.I. 1, Ex. 3).

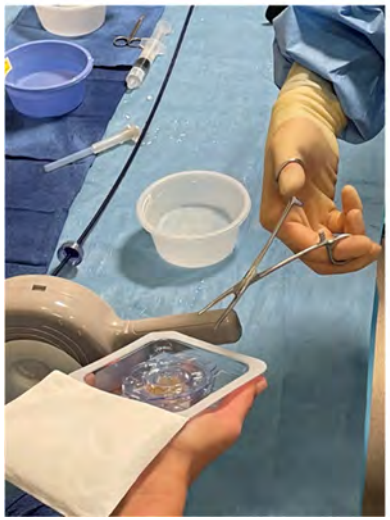
Further, with respect to the phrase, "wherein the sealing material includes a plurality of radially extending, arcuate fibers that extend outwardly of the outer frame" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing material including a plurality of outwardly extending fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused sealing

	material including a plurality of outwardly extending arcuate fibers performs the same or substantially the same function as the claim phrase by providing for low profile sealing material capable of sealing against the native leaflets, in the same or substantially the same way as the claim phase by including low profile biocompatible polymeric arcuate fibers with "tips" extending generally outwardly that are configured to press against the native leaflets of the aorta of the patient when the valve is expanded, to achieve the same or substantially the same result of sealing material configured to form a biocompatible seal between the native annulus/leaflets and frame and reduced paravalvular leakage.
wherein the graft covering is made of polyester, polytetrafluoroethylene, expanded polytetrafluoroethylene, or a polymer,	The '310 patent Accused Instrumentalities satisfy this element. The '310 patent Accused Instrumentalities' graft covering is made of a polyester polymer. For example, the Edwards Sapien 3 Ultra inner skirt is made of PET which is a polyester polymer. **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 (D.I. 1, Ex. 44).
wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient,	The ’310 patent Accused Instrumentalities satisfy this element. For example, the ’310 patent Accused Instrumentalities are configured to be deployed endovascularly through a femoral artery of the patient. Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through the femoral artery using Edwards’ balloon catheter delivery systems.

	  https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

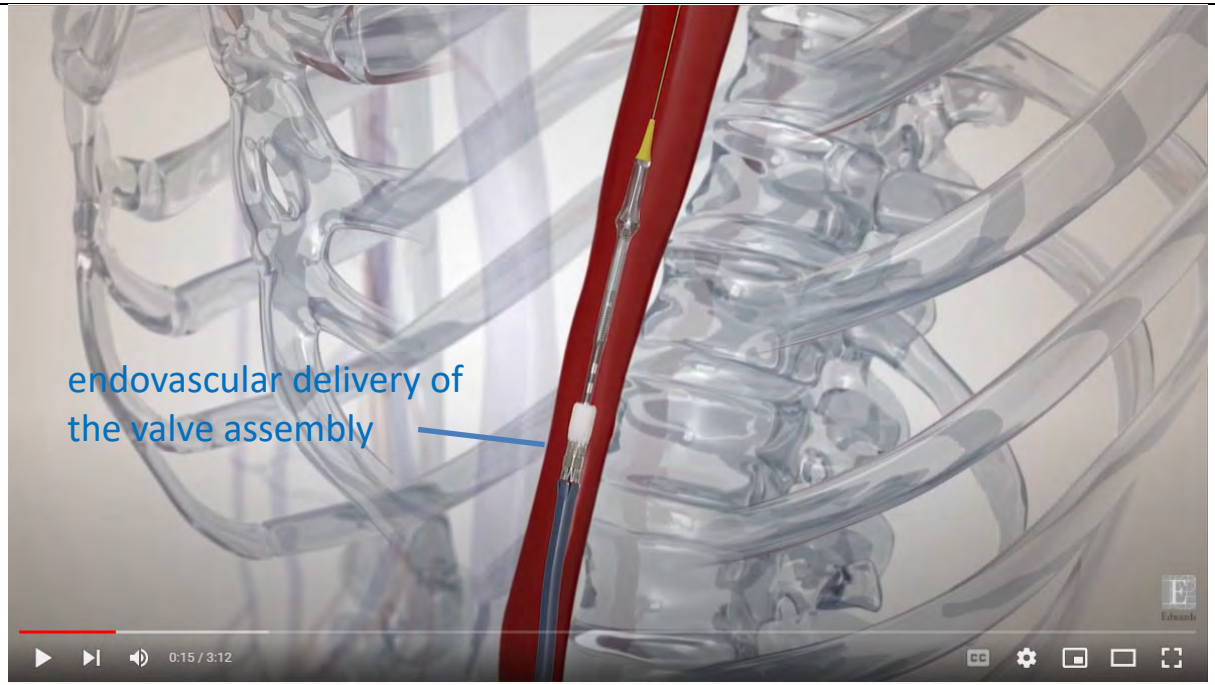




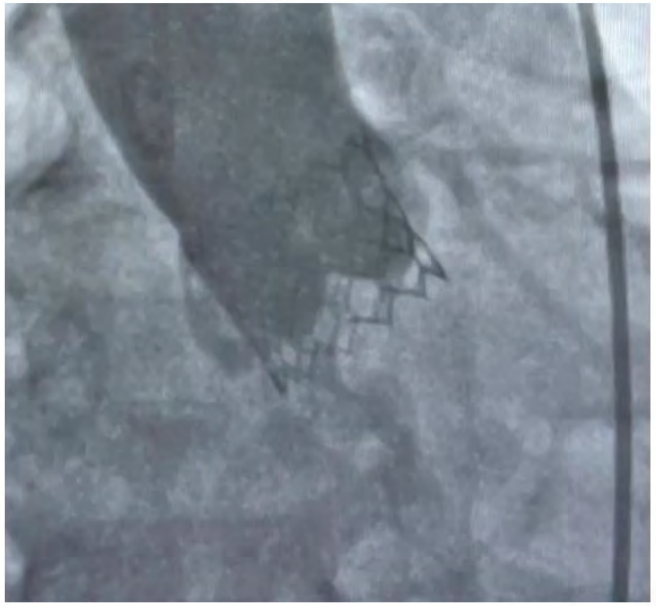
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

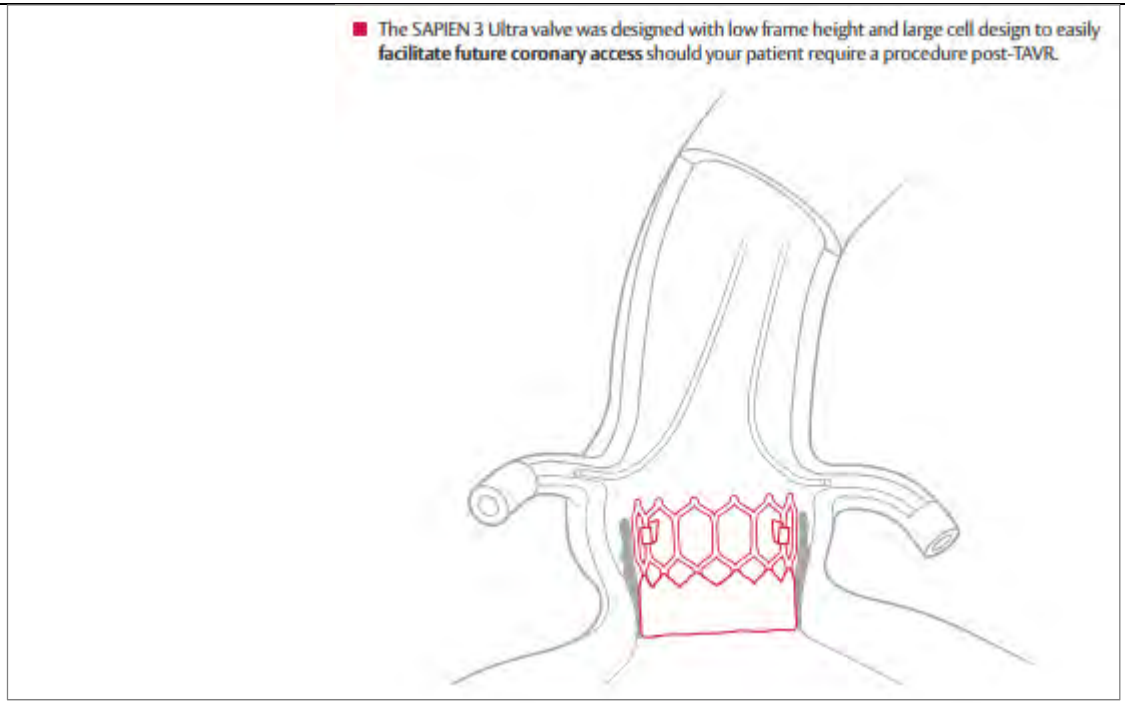


	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
wherein the heart valve assembly has a radially compressed and a radially expanded orientation,	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities have a radially compressed orientation and a radially expanded orientation. The Sapien 3 Ultra designed and configured to be expandable using an Edwards’ balloon delivery system in the aorta of a patient from a radially compressed orientation into a radially expanded orientation.

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

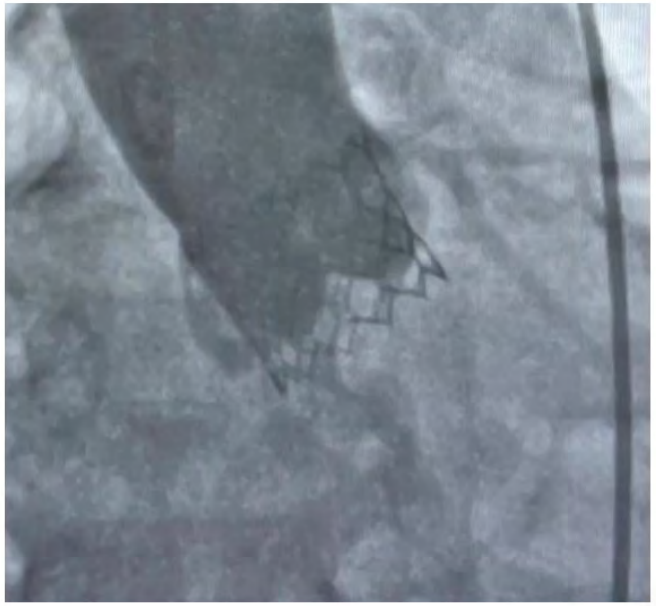
	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

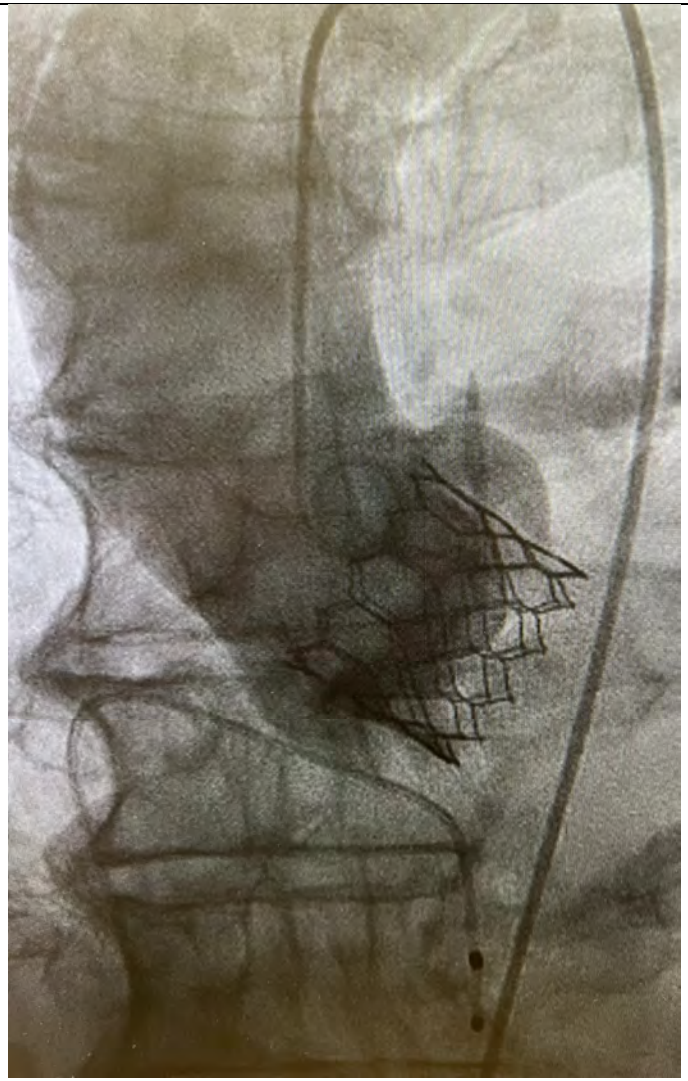


Introducing the Sapien 3 Ultra, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

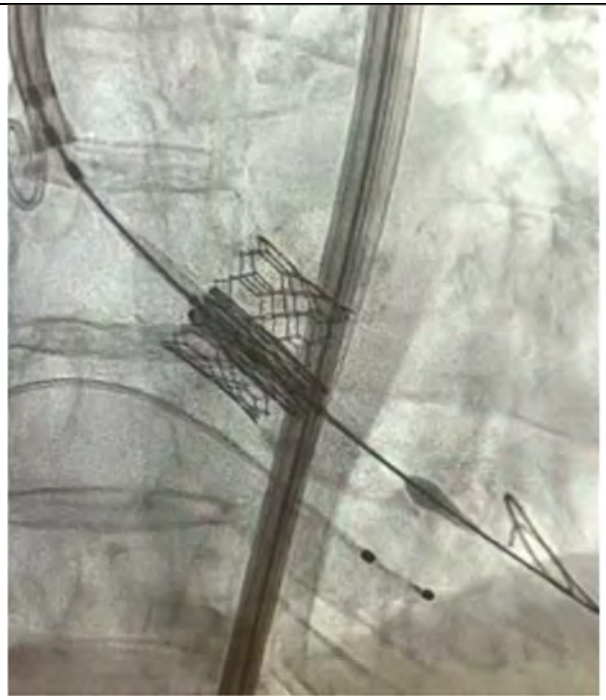


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



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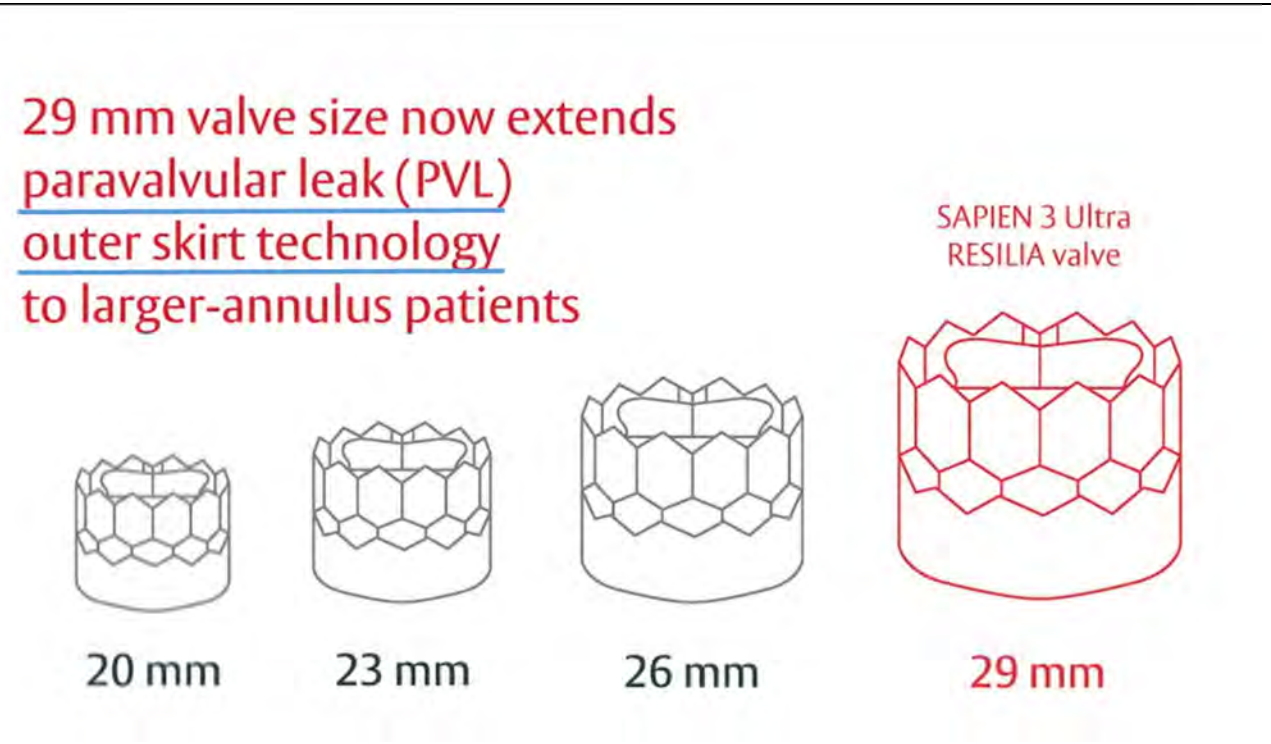
60



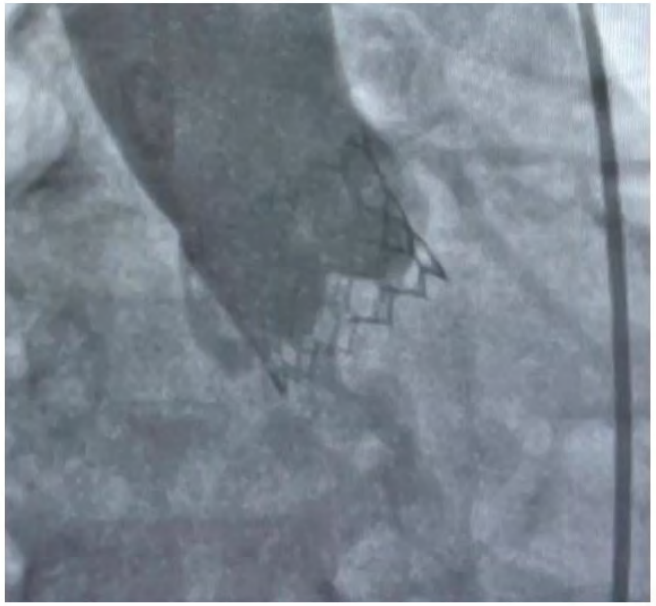
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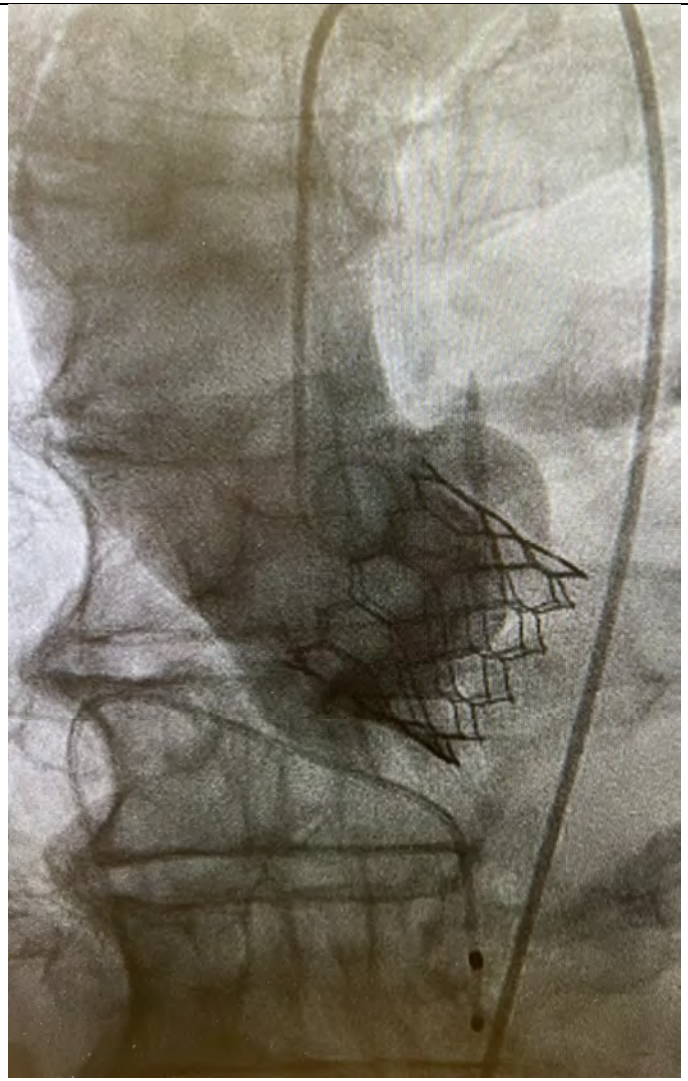
61

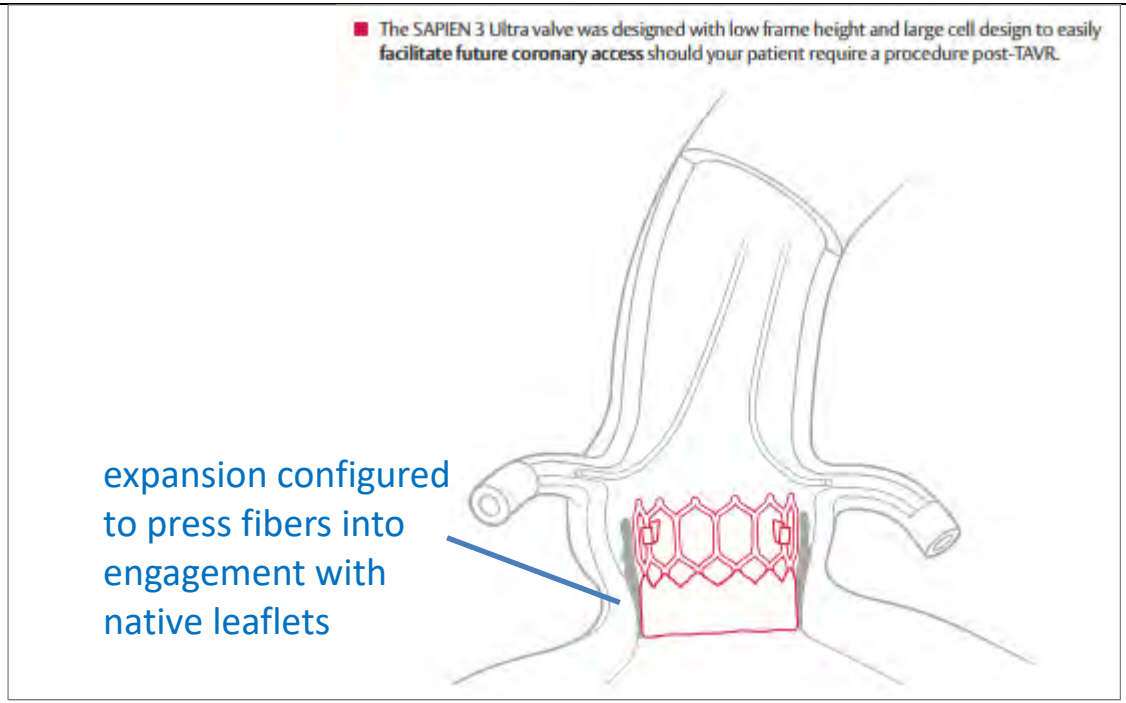
	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).
wherein expansion 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,	The '310 patent Accused Instrumentalities satisfy this element. The '310 patent Accused Instrumentalities are configured such that 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. The Sapien 3 Ultra is configured when deployed and expanded so that radially extending fibers are pressed into engagement with native leaflets of the aorta of the patient.



https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

	 https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



Introducing the Sapien 3 Ultra, including, but not limited to the Sapien 3 Ultra Resilia valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

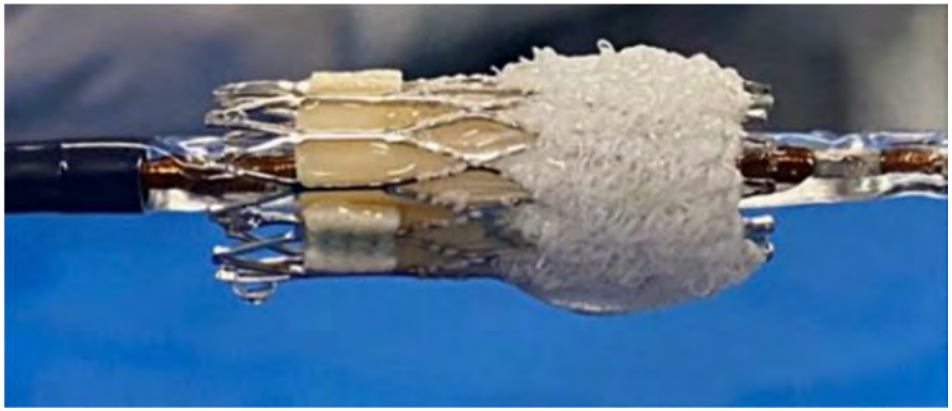
SAPIEN 3 Ultra System Case Example



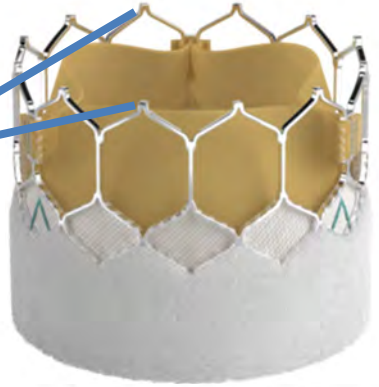


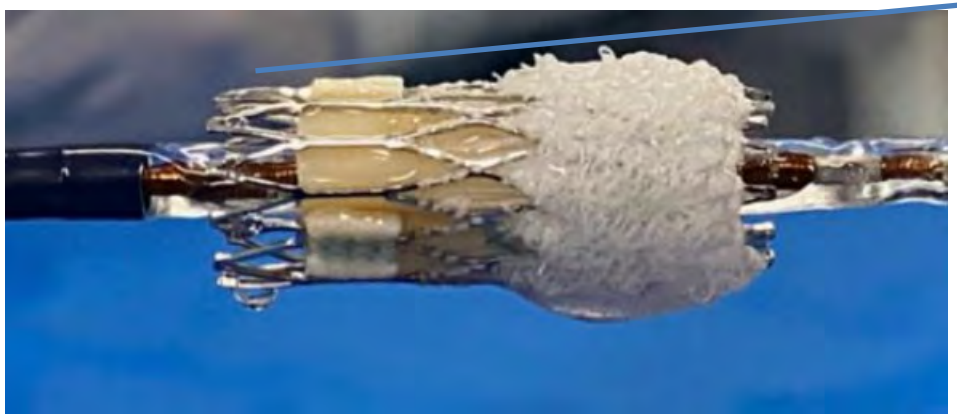
Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

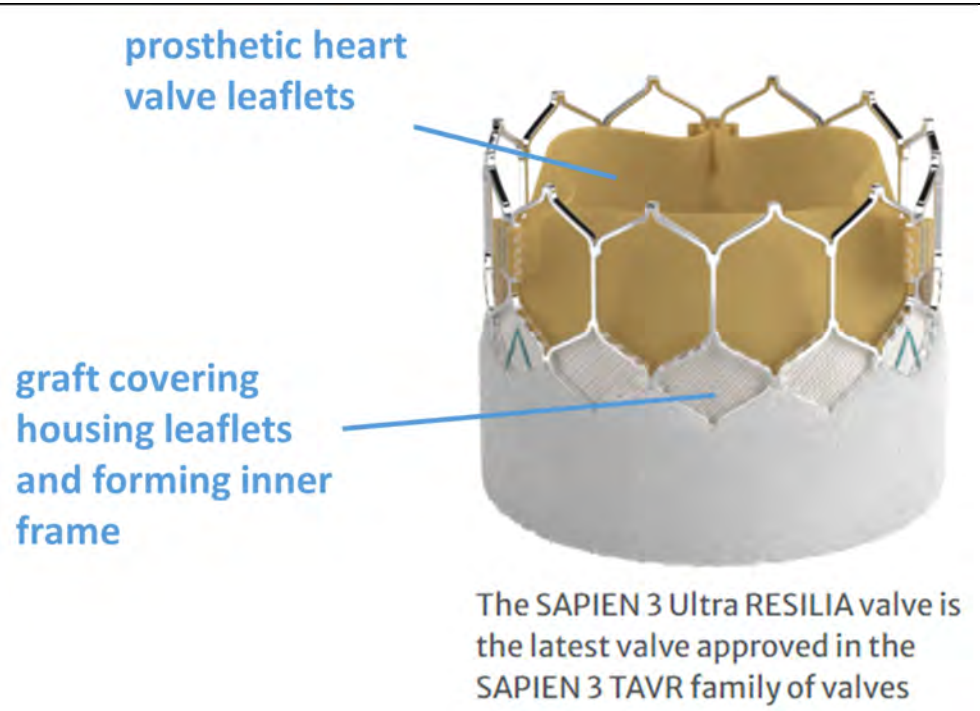
With respect to the phrase, "wherein expansion of the heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the radially extending fibers into engagement with native leaflets of the aorta of the patient", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by being capable of pressing at least some radially extending fibers against the leaflets in the aorta of the patient, in the

	same or substantially the same way as the claim phase through including sealing material with radially extending fibers, to achieve the same or substantially the same result of being configured to press radially extending fibers into engagement with the native leaflets 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,	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ 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. The Sapien 3 Ultra is configured such that 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.  Ex. 48, https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (showing plurality of fibers in contact with outer frame in compressed orientaiton).

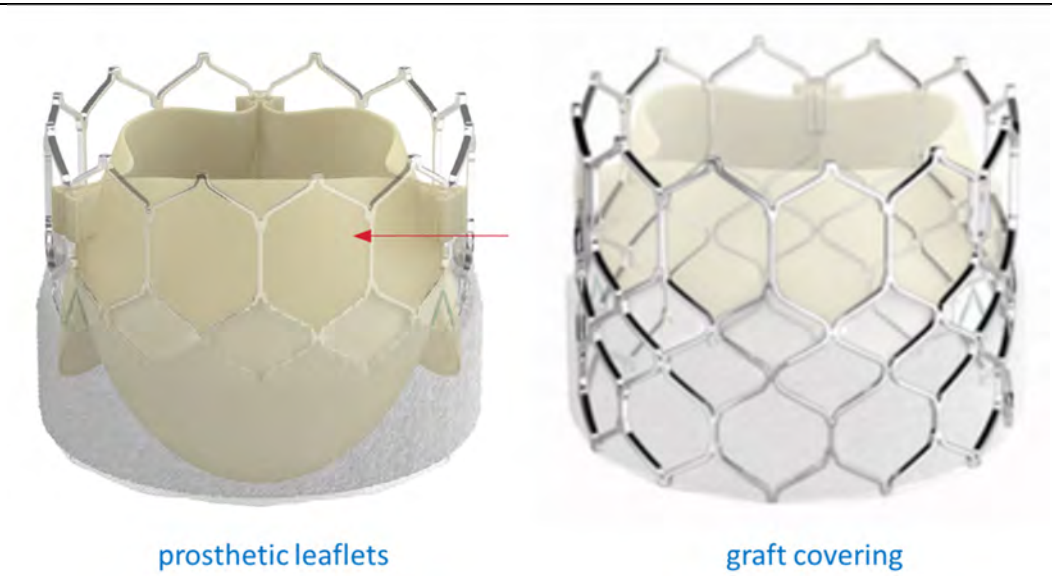
	 Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (showing plurality of fibers in contact with outer frame in expanded orientaiton). With respect to the phrase, "wherein the plurality of fibers is in contact with the outer frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by having fibers in contact with the outer frame along the height of the sealing material in the radially compressed and expanded orientations, in the same or substantially the same way as the claim phase through including low profile sealing material with radially extending fibers attached to the outer frame, to achieve the same or substantially the same result of fibers configured to be at least generally in contact with the outer frame along the height of the sealing material in the radially compressed and expanded orientations.

wherein the outer frame extends distally further than the prosthetic heart valve leaflets.	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ outer frame extends distally further than the prosthetic heart valve leaflets. For example, the Sapien 3 Ultra frame extends distally further than the prosthetic valve leaflets. **outer frame extends distally further than leaflets**  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).
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.	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve. For example, the Edwards Sapien 3 Ultra graft covering extends around and houses the prosthetic heart valve and provides support directly and indirectly to the prosthetic heart valve forming an inner frame. For example, the graft covering houses the valve leaflets and is secured to the valve leaflets and the outer frame. To the extent required, the inner frame is balloon expandable.

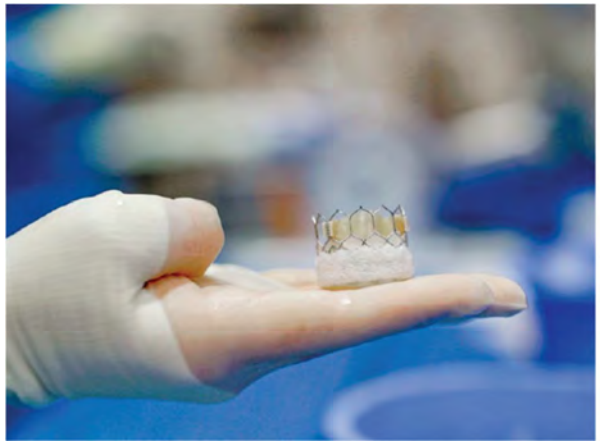
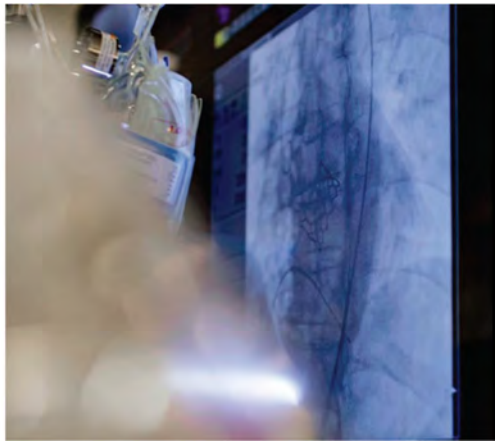


https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



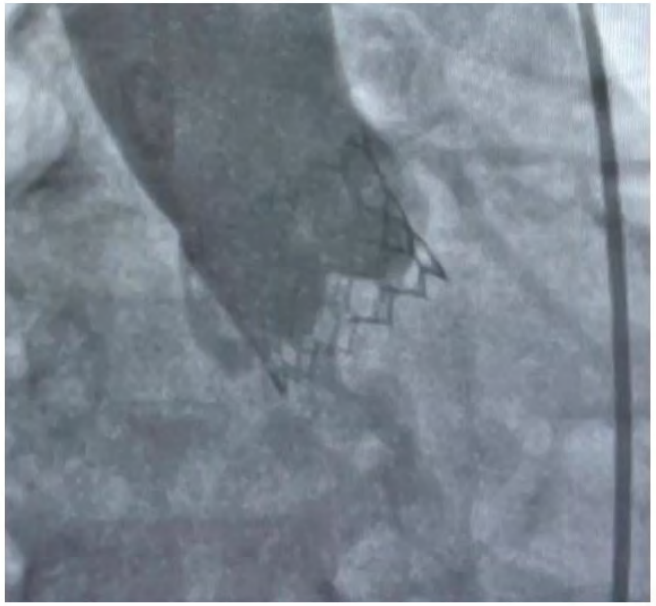
https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).

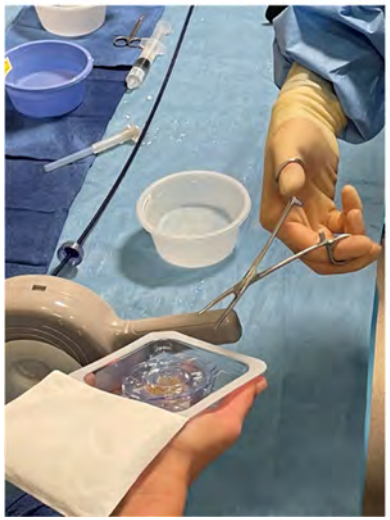
With respect to the phrase, "wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a graft covering inner frame that is balloon-expandable and/or that provides support and resist collapse, the identified graft covering that forms an inner frame for supporting the prosthetic heart valve, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering that forms an inner frame performs the same or substantially the same function as the claim phrase by being collapsible and expandable, as well as framing and providing support to the prosthetic heart valve, in the same or substantially the same way as the claim phase through a collapsible

	and expandable cylindrically extending graft covering inner frame secured by stitching to the outer frame extending at least partially around and housing and providing sealing to the prosthetic heart valve, to achieve the same or substantially the same result of a collapsible and expandable graft covering inner frame in a TAVR valve that is configured to frame, house, support (directly and/or indirectly), and/or provide sealing to the prosthetic heart valve. *See also*, claim 1.
5. A transcatheter heart valve assembly comprising:	To the extent the preamble is limiting, the '310 patent Accused Instrumentalities satisfy this element. For example, the '310 patent Accused Instrumentalities are transcatheter heart valve assemblies. The '310 patent Accused Instrumentalities are transcatheter heart valve assemblies designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems.   https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

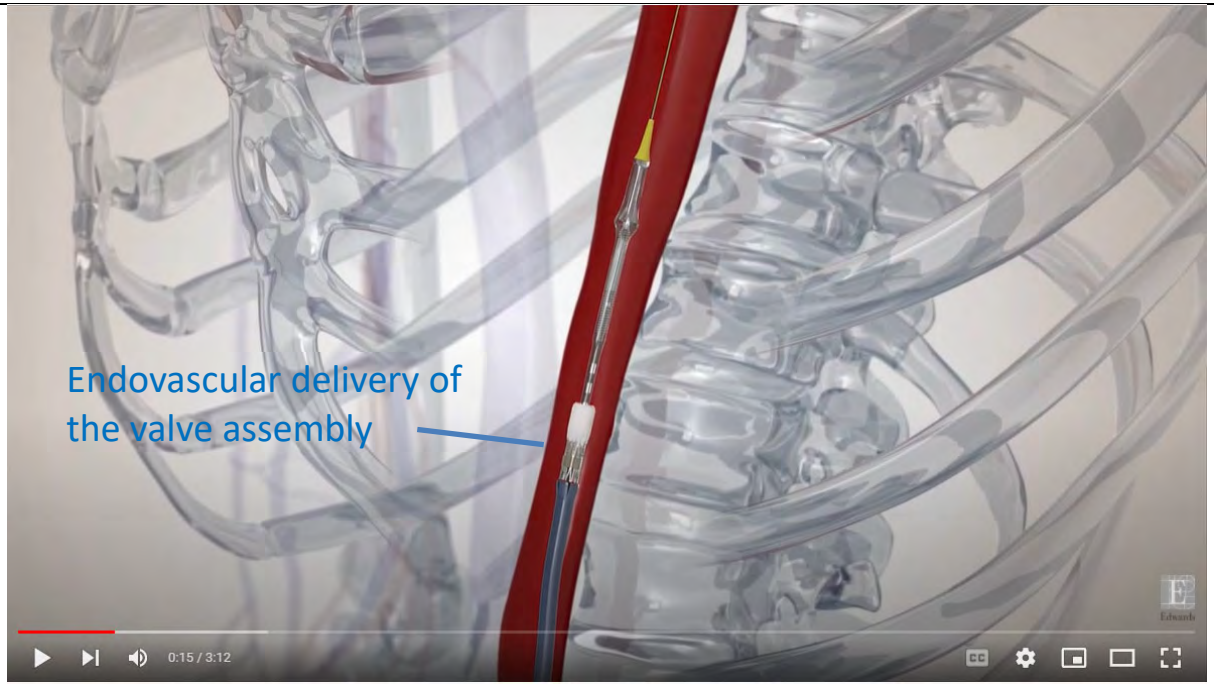




https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).



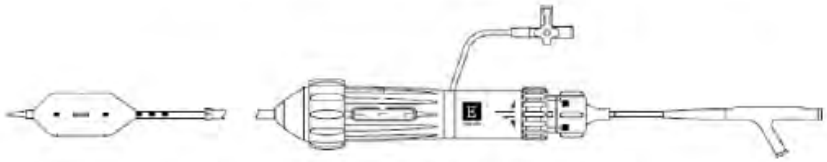
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



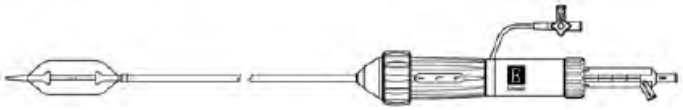
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

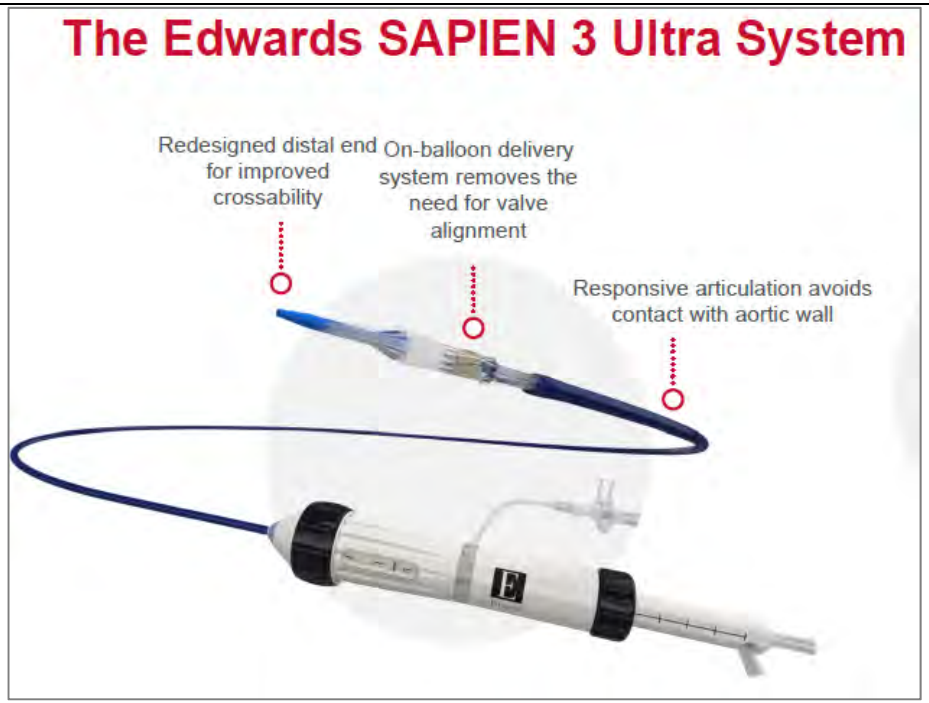
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

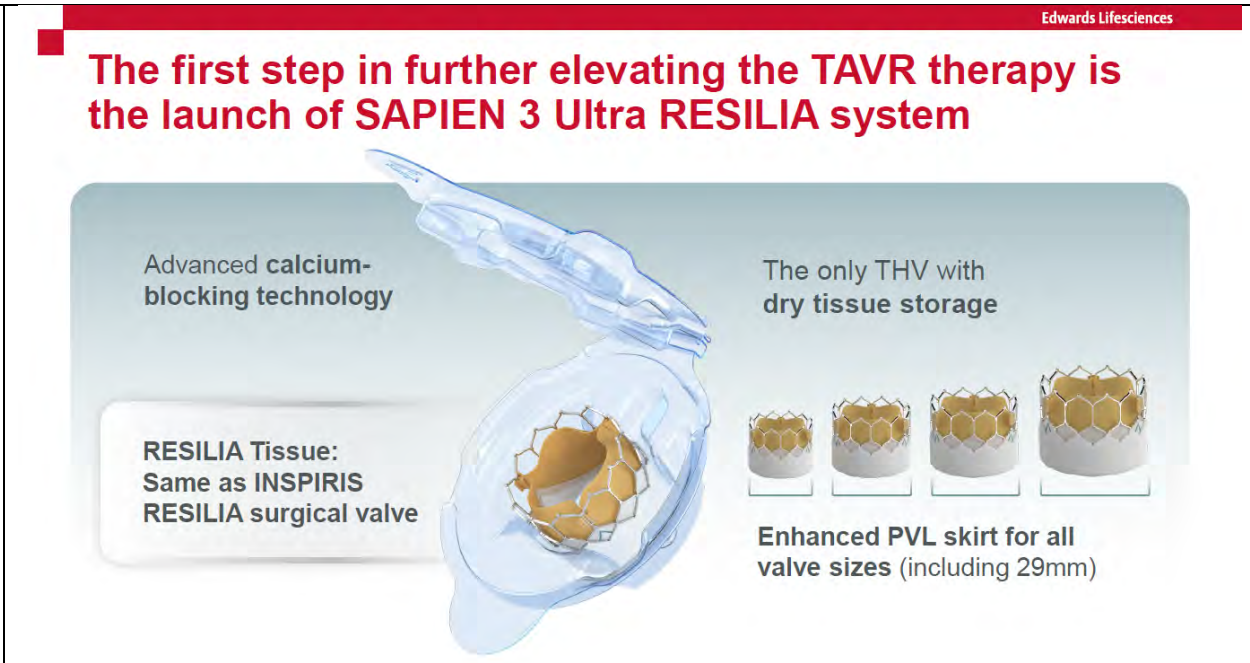
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

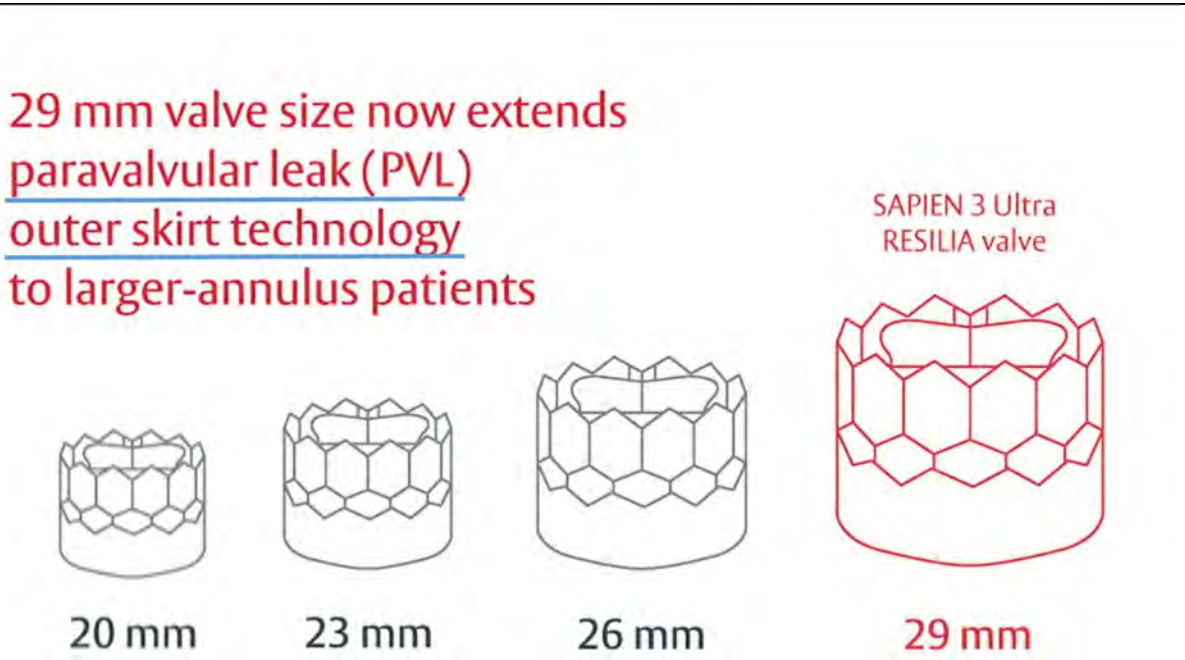
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

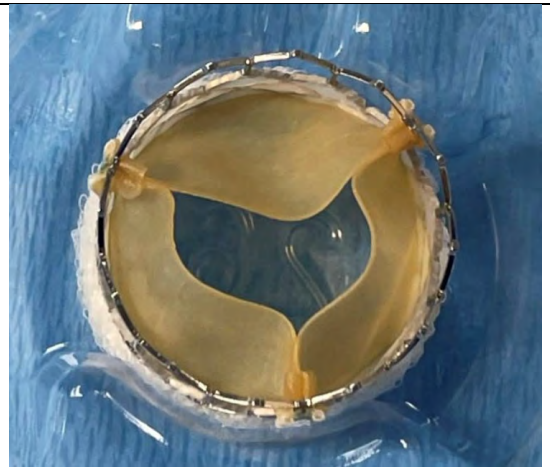
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’310 patent Accused Instrumentalities and infringes the ’310 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



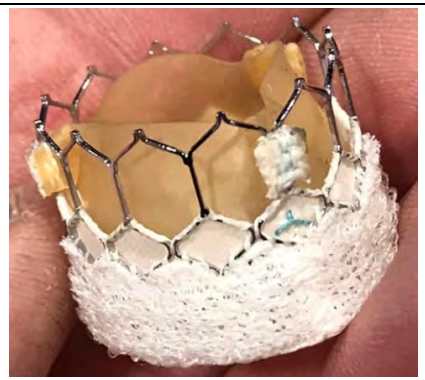
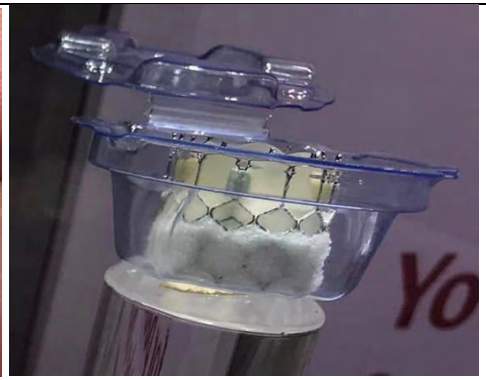
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

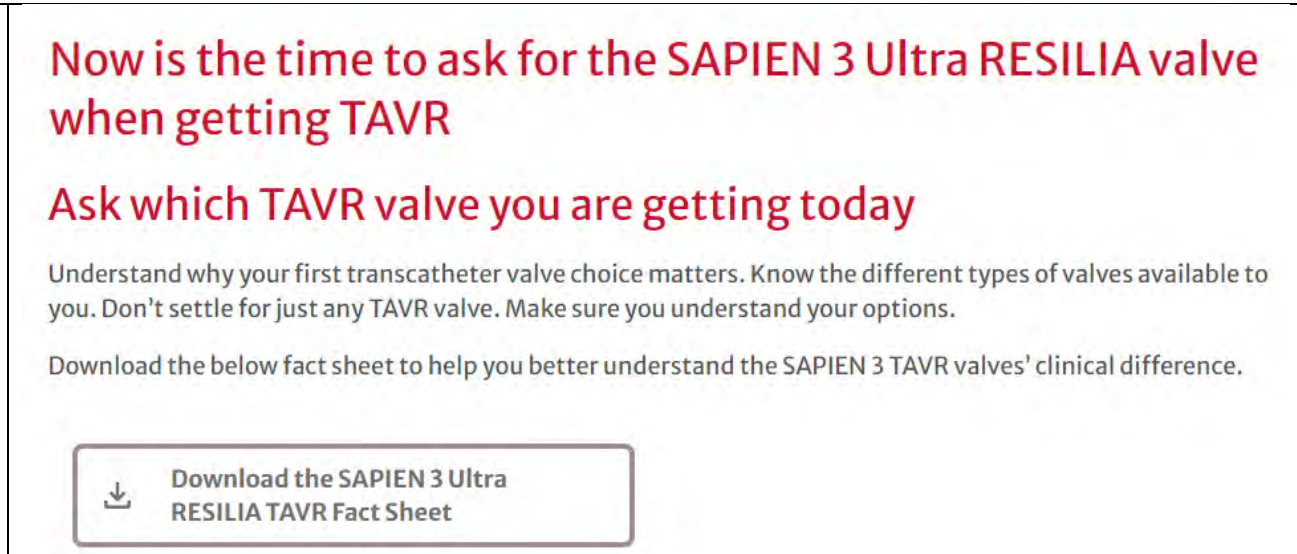
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the '310 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's

	recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See* https://ir.edwards.com/events-presentations/; https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '310 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '310 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '310 asserted claims are infringed when Edwards offers for sale and sells the '310 patent Accused Instrumentalities. Edwards offers for sale and promotes the '310 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 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.

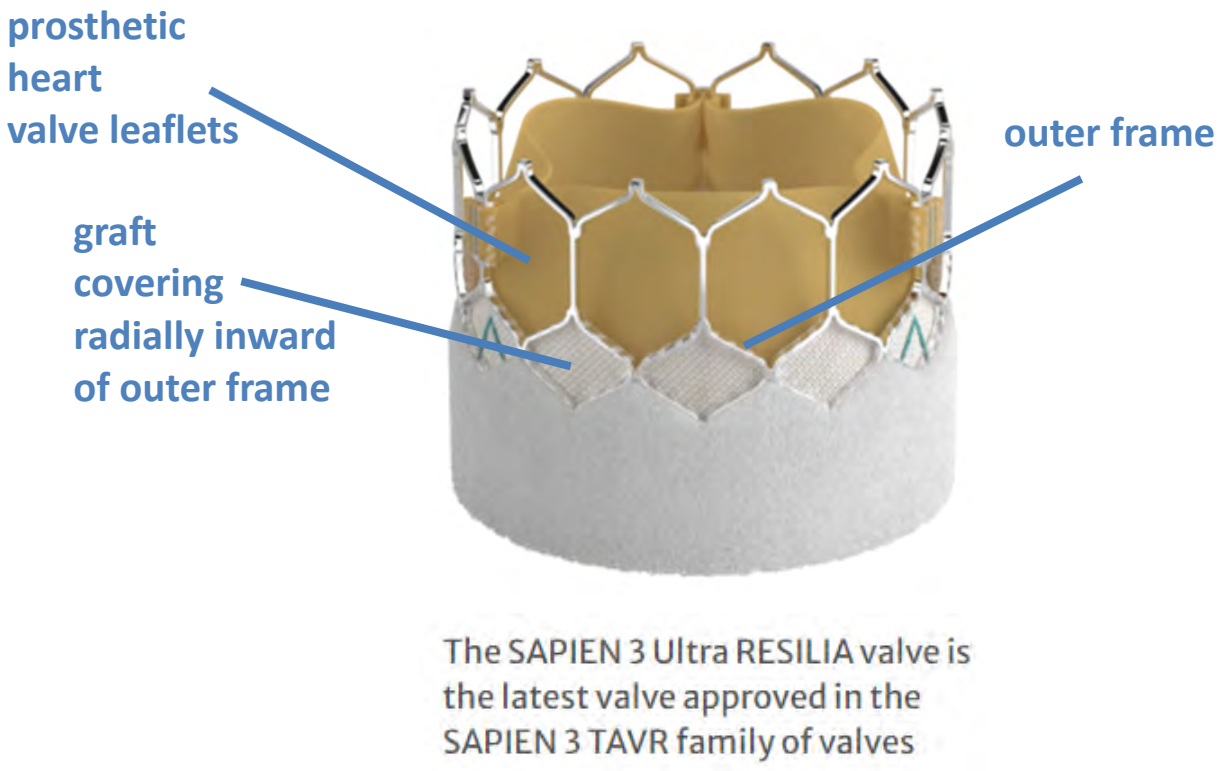


https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	 https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61). On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement# Further, the '310 patent asserted claims 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 in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the ’310 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards’ direct and induced infringement. For further example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe the asserted ’310 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a “watchful eye” over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards’s inducement, Edwards’s affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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.

	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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards’s affirmative acts of marketing, selling and offering to sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ combination and use of the Accused Instrumentalities, such that the ’310 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards’ knowledge of Aortic’s inventions, the patents-in-suit (including the ’310 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
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;	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities comprise 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. For example, the Edwards Sapien 3 Ultra graft covering houses and extends radially outwardly around the heart valve leaflets and radially inward of an outer frame and provides sealing to the prosthetic heart valve leaflets.



https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

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

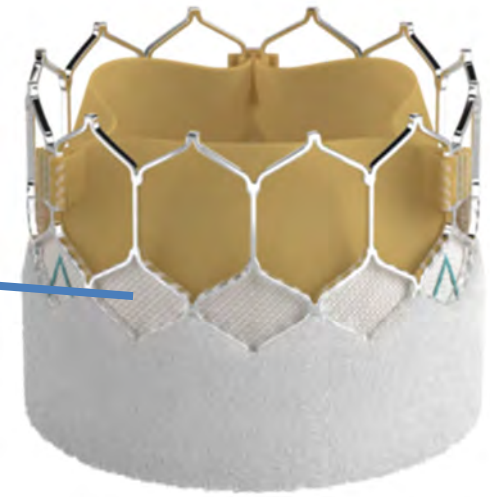
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

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

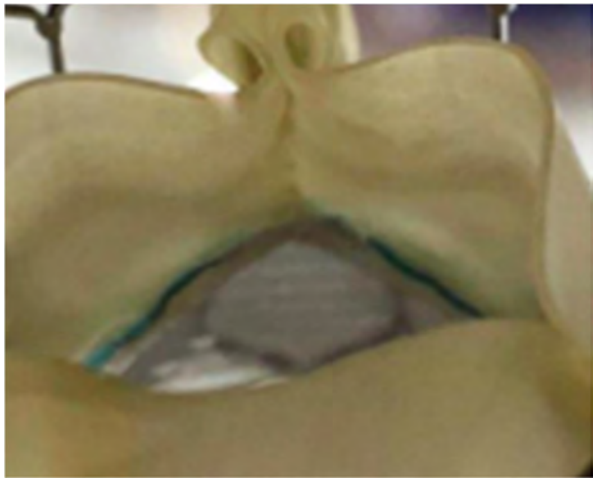
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

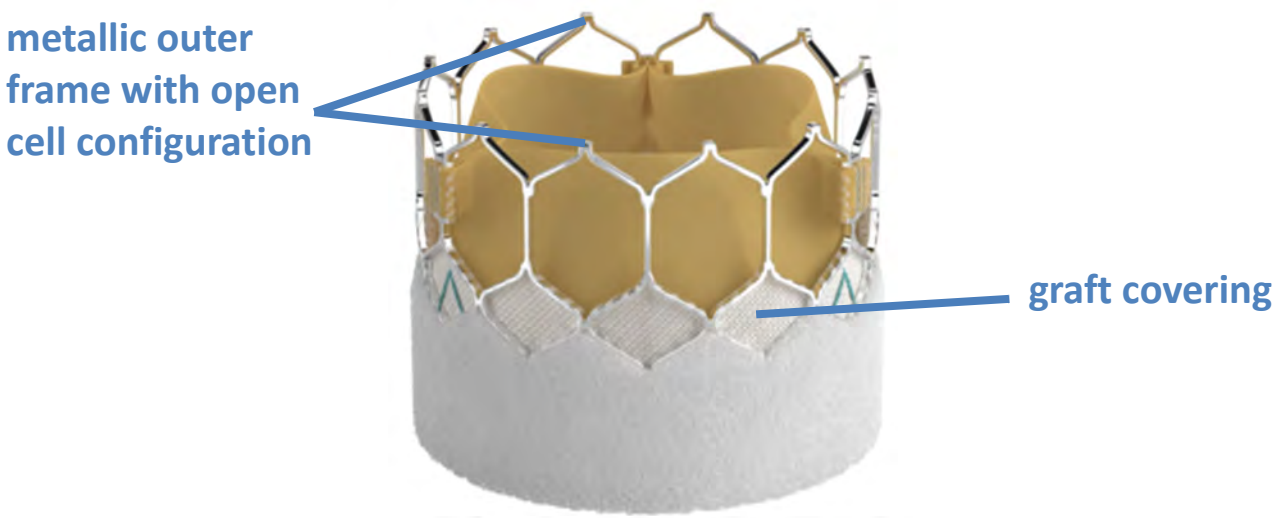
graft covering housing, extending radially outwardly around, and providing sealing to leaflets

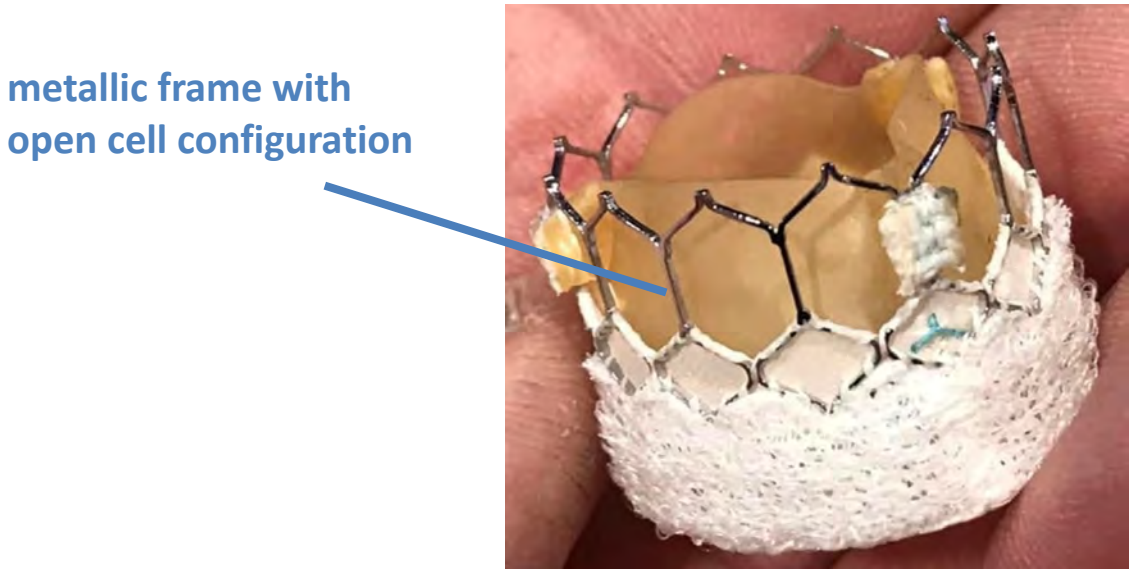


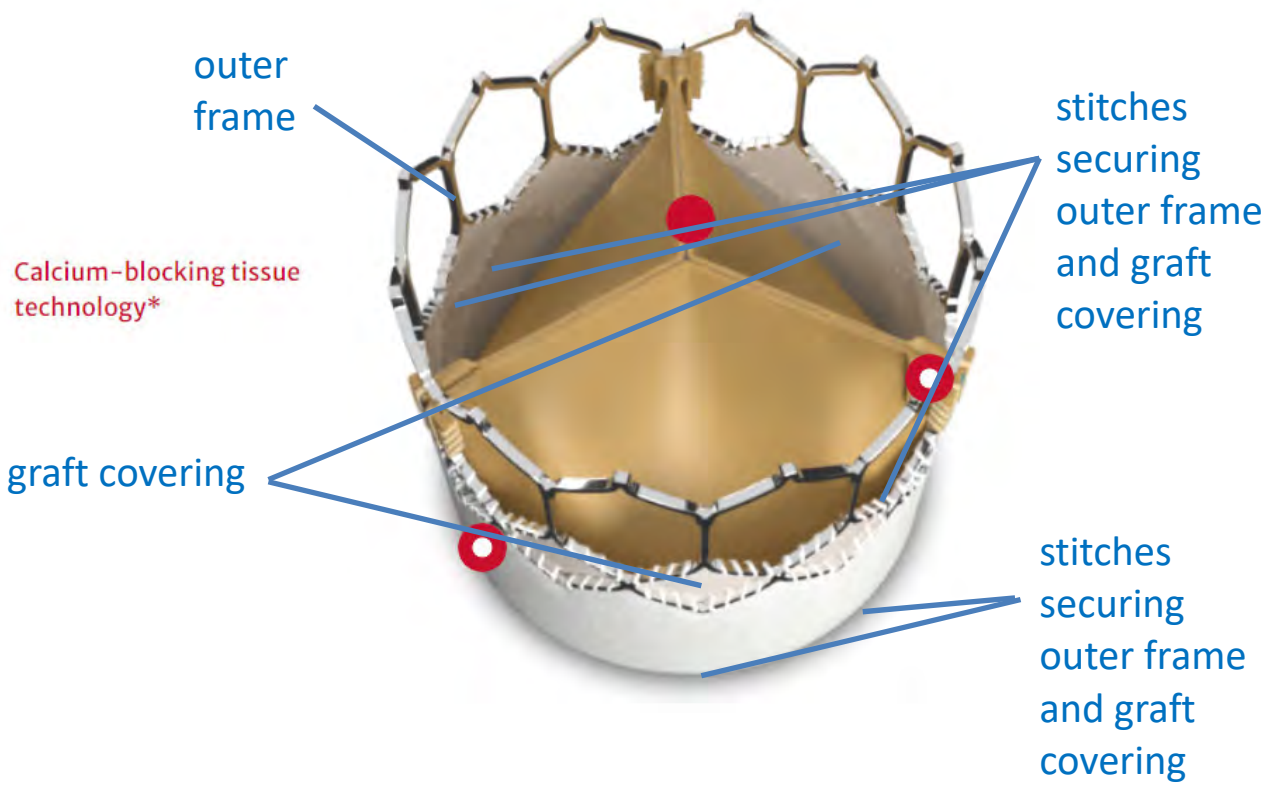
The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves

https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

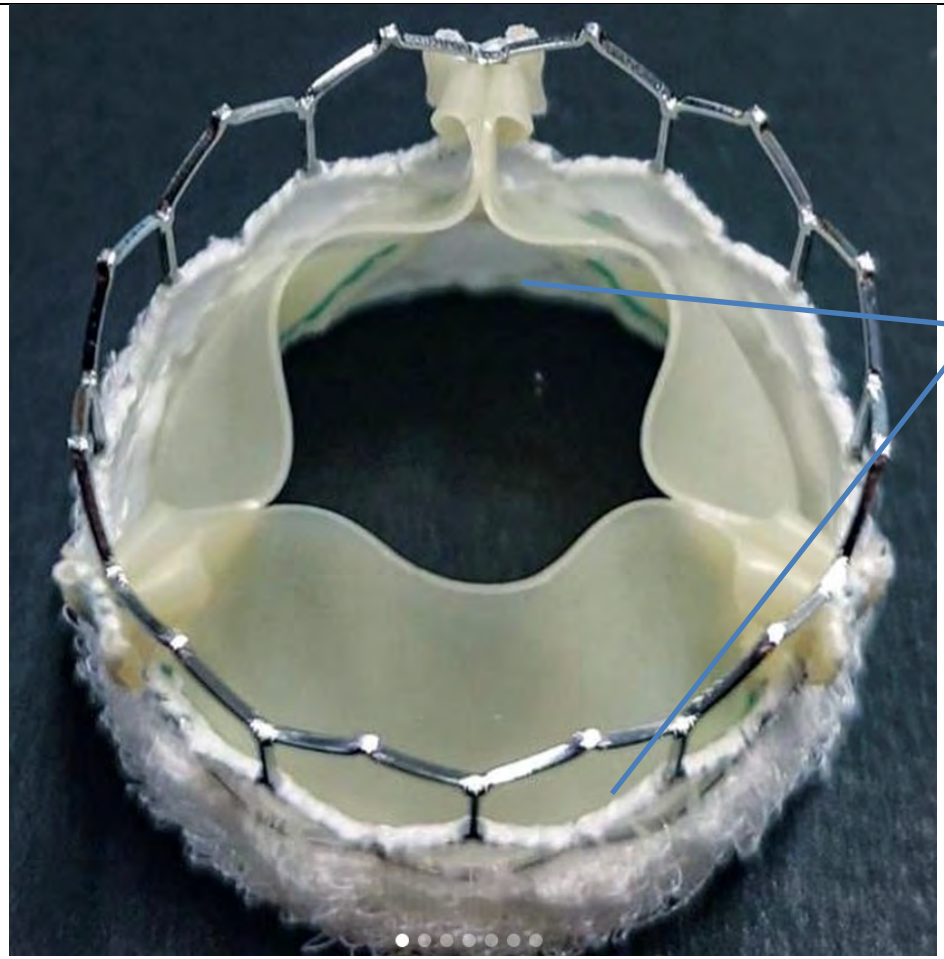
	 https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29). With respect to the phrase, “a graft covering housing prosthetic heart valve leaflets, wherein the graft covering extends radially outwardly around the prosthetic heart valve leaflets and radially inwardly of an outer frame for providing sealing to the prosthetic heart valve leaflets”, Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include 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, even taking into account any alleged “differences” identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering performs the same or substantially the same function as the claim phrase by partially and/or fully housing, extending radially outwardly around and providing sealing to the prosthetic heart valve leaflets

	while extending radially inwardly of an outer frame, in the same or substantially the same way as the claim phase by extending fully or partially housing and extending radially outwardly around the prosthetic heart valve leaflets and radially inwardly of an outer frame, to achieve the same or substantially the same result of a graft covering that is configured to provide for sealing or partial sealing of 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	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities comprise an outer frame formed from a metallic material that defines an open cell configuration, and is secured to the graft covering. For example, the Edwards Sapien 3 Ultra outer frame is formed from a cobalt-chromium metallic alloy and is in an open cell configuration.  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves

	https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. For example, the Sapien 3 Ultra outer frame is secured to the graft covering by stitching.



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

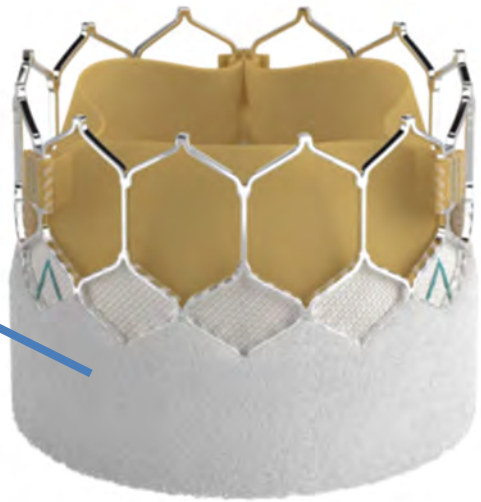


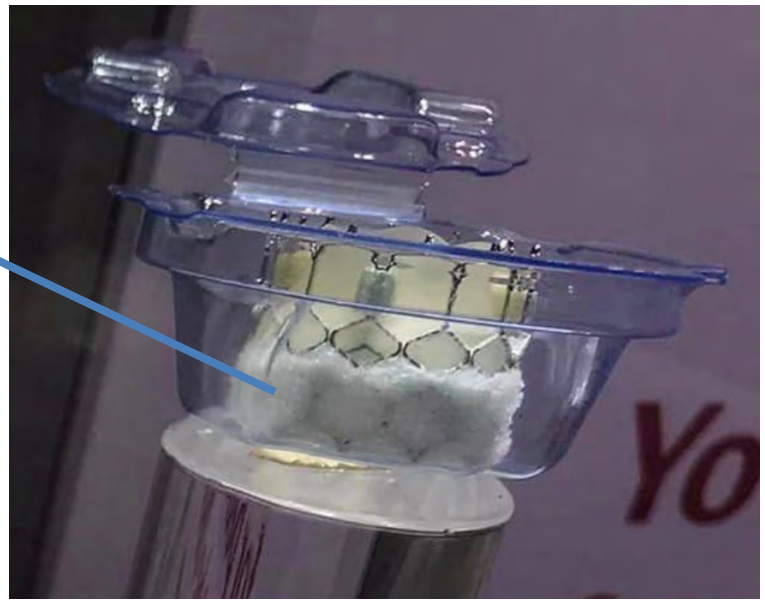
Julian Calain Twitter (D.I. 1, Ex. 30).

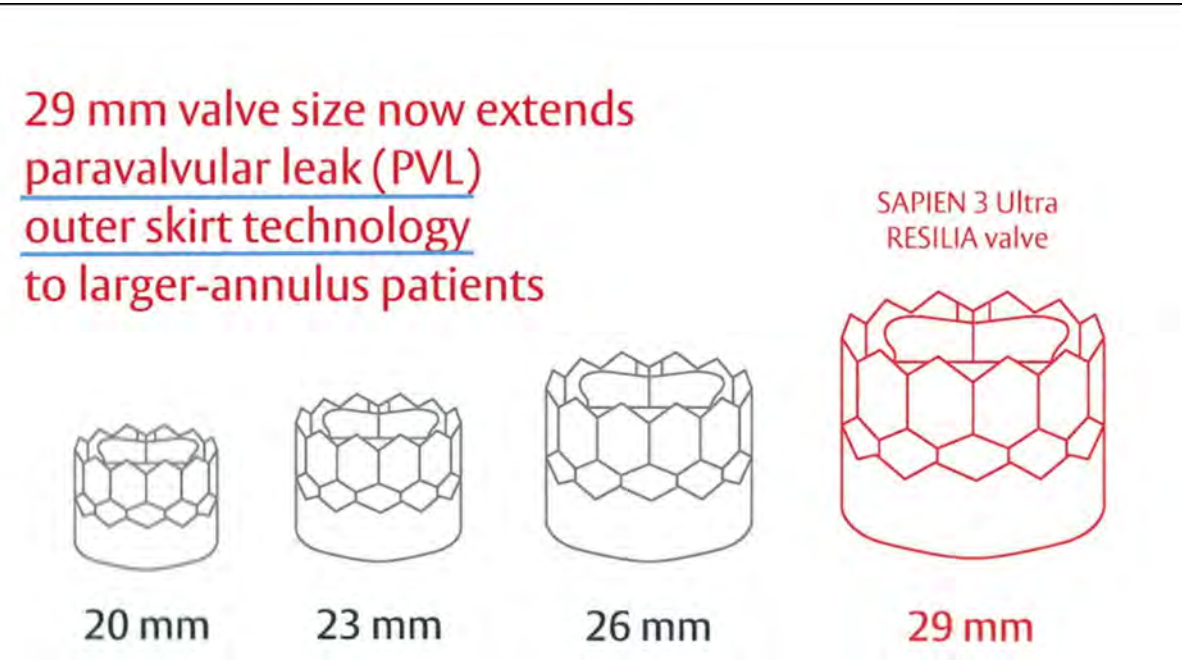
See also, element above.

With respect to the phrase, “wherein the outer frame is formed from a metallic material and defines an open cell configuration, and being secured to the graft covering”, Aortic asserts that this element is

	literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused outer frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with cells with the capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of providing a low profile collapsible and expandable outer frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy.
a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall to prevent paravalvular leaks,	The '310 patent Accused Instrumentalities satisfy this element. The '310 patent Accused Instrumentalities comprise 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. For example, the Edwards Sapien 3 Ultra includes a sealing skirt for providing sealing between the outer frame and the patient's anatomical wall for preventing paravalvular leaks.

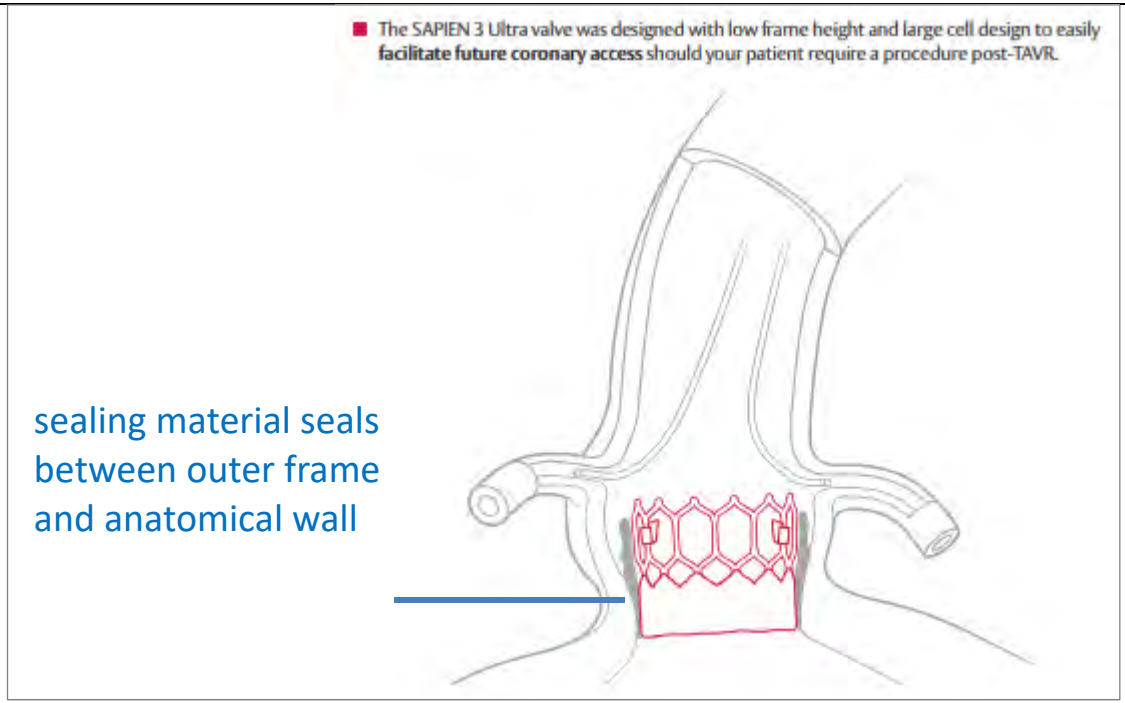
	sealing material external to outer frame for preventing paravalvular leaks  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	sealing material external to outer frame for preventing paravalvular leaks  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

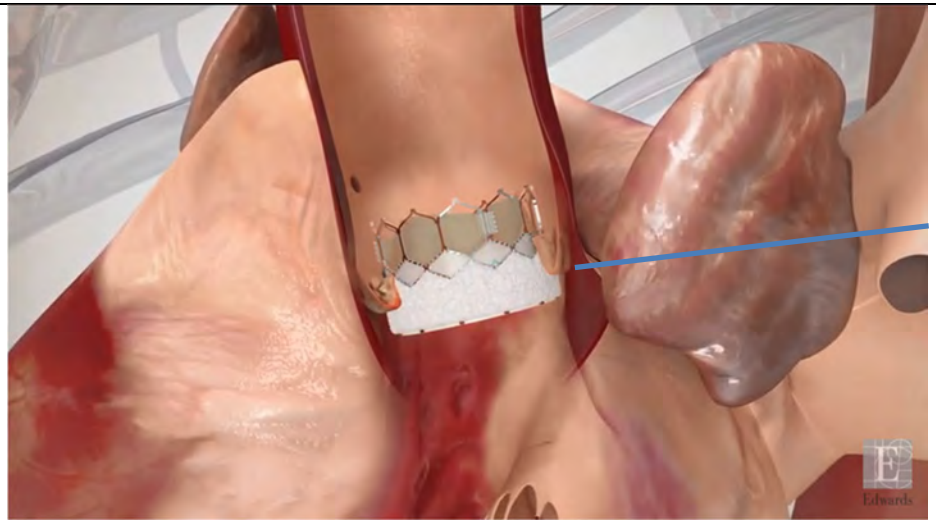


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

For example, the Sapien 3 Ultra sealing skirt provides for sealing between the outer frame and the patient's anatomical wall to help prevent PVL.

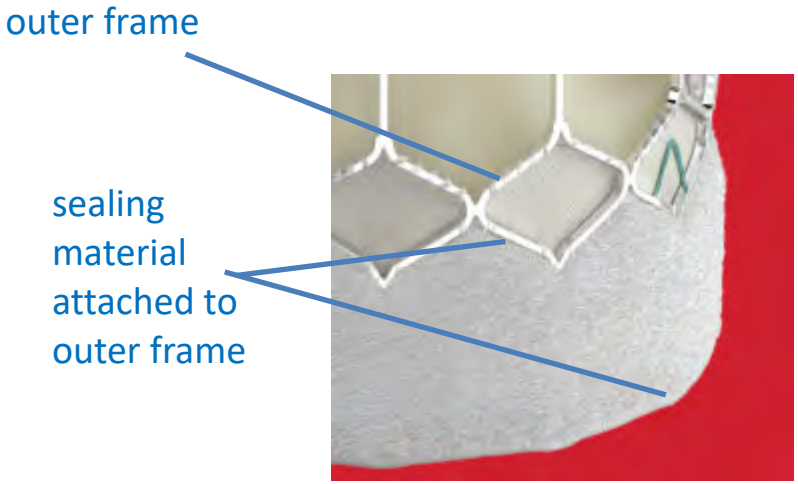


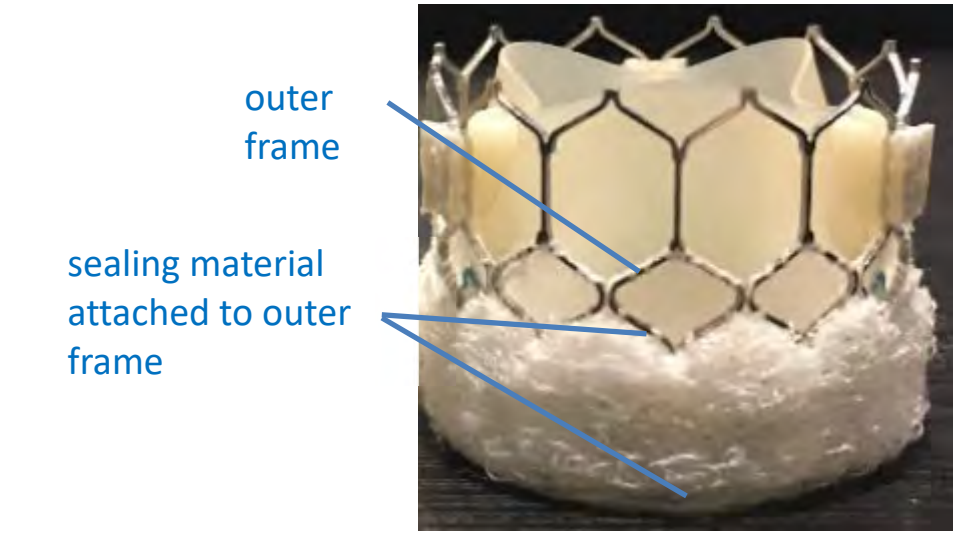
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



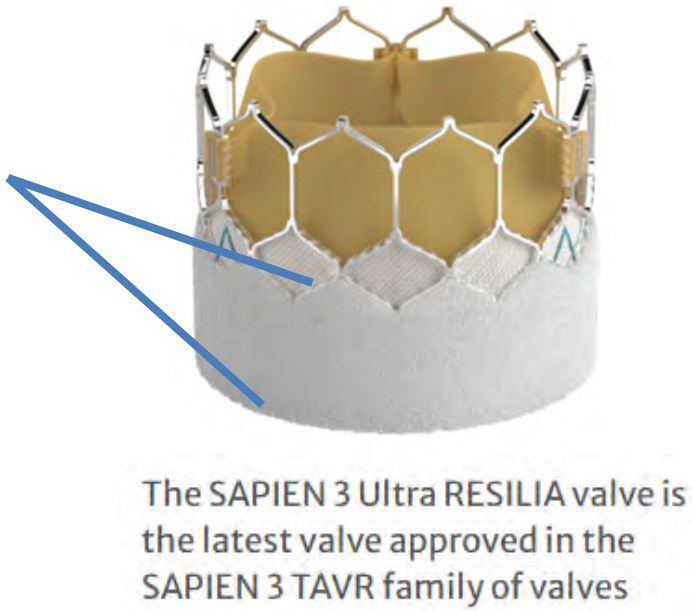
"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

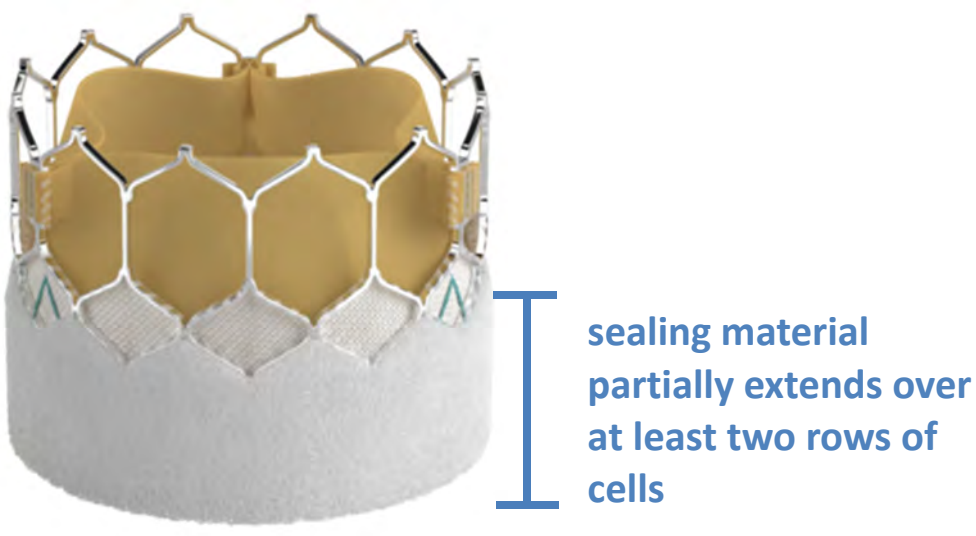
Further, with respect to the phrase, "a sealing material positioned externally to the outer frame for providing sealing between the outer frame and a patient's anatomical wall to prevent paravalvular leaks" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the sealing material does not allow visibility of the frame or that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing material of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused sealing material performs the same or substantially the same function as the claim phrase by providing for low profile sealing material capable of providing sealing between the anatomical wall and the outer frame, in the same or substantially the same way as the claim phase by using a low profile biocompatible polymeric sealing material configured to press against and providing sealing between the patient's anatomical wall and the outer frame, to achieve the same or substantially the same

	result of a sealing material configured to form a biocompatible seal between the anatomical wall and the frame for reduced paravalvular leakage.
wherein the sealing material is attached to the outer frame,	The ’310 patent Accused Instrumentalities satisfy this element. For example, the ’310 patent Accused Instrumentalities comprise a sealing material that is attached to the outer frame. For example, the sealing material is attached to the frame using stitching.  Introducing the SAPIEN 3 Ultra valve at 2, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

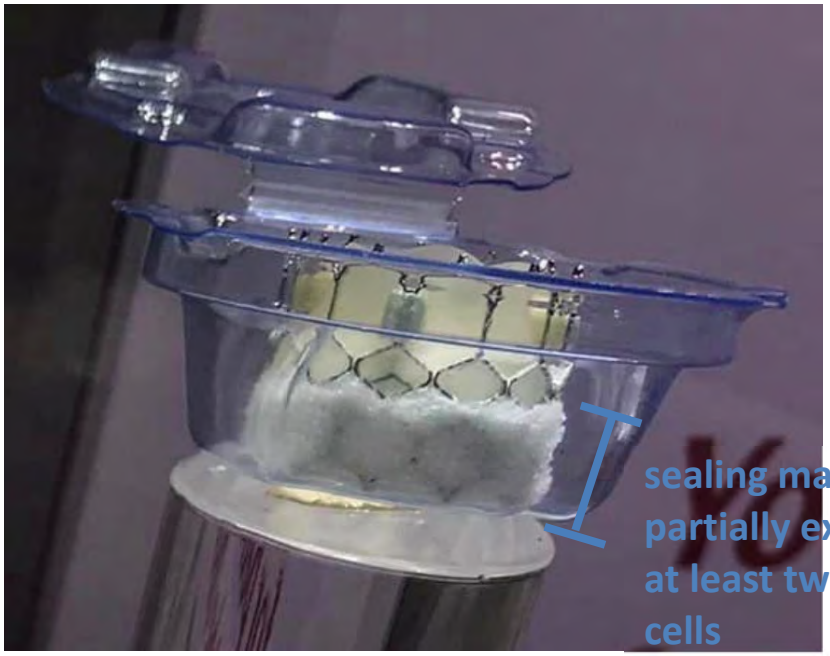


Sapien 3 Ultra image by William Suh, MD (annotated), https://twitter.com/willsuh76/status/1280708440734617600/photo/1 (D.I. 1, Ex. 7).

	 https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).
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,	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ sealing material defines a height that partially extends over at least a first two proximal circumferentially extending rows of cells in the outer frame. For example, the Sapien 3 Ultra sealing skirt partially extends over a least two rows of cells in the frame.

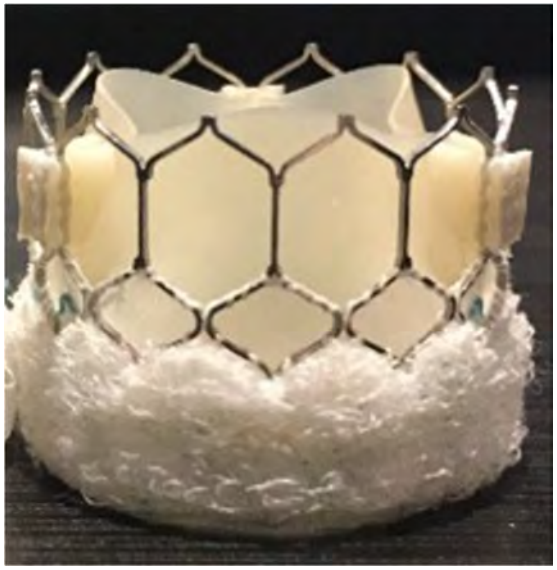


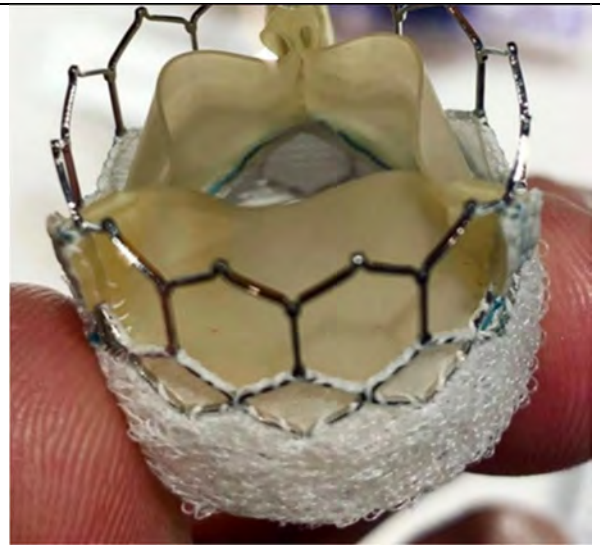
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

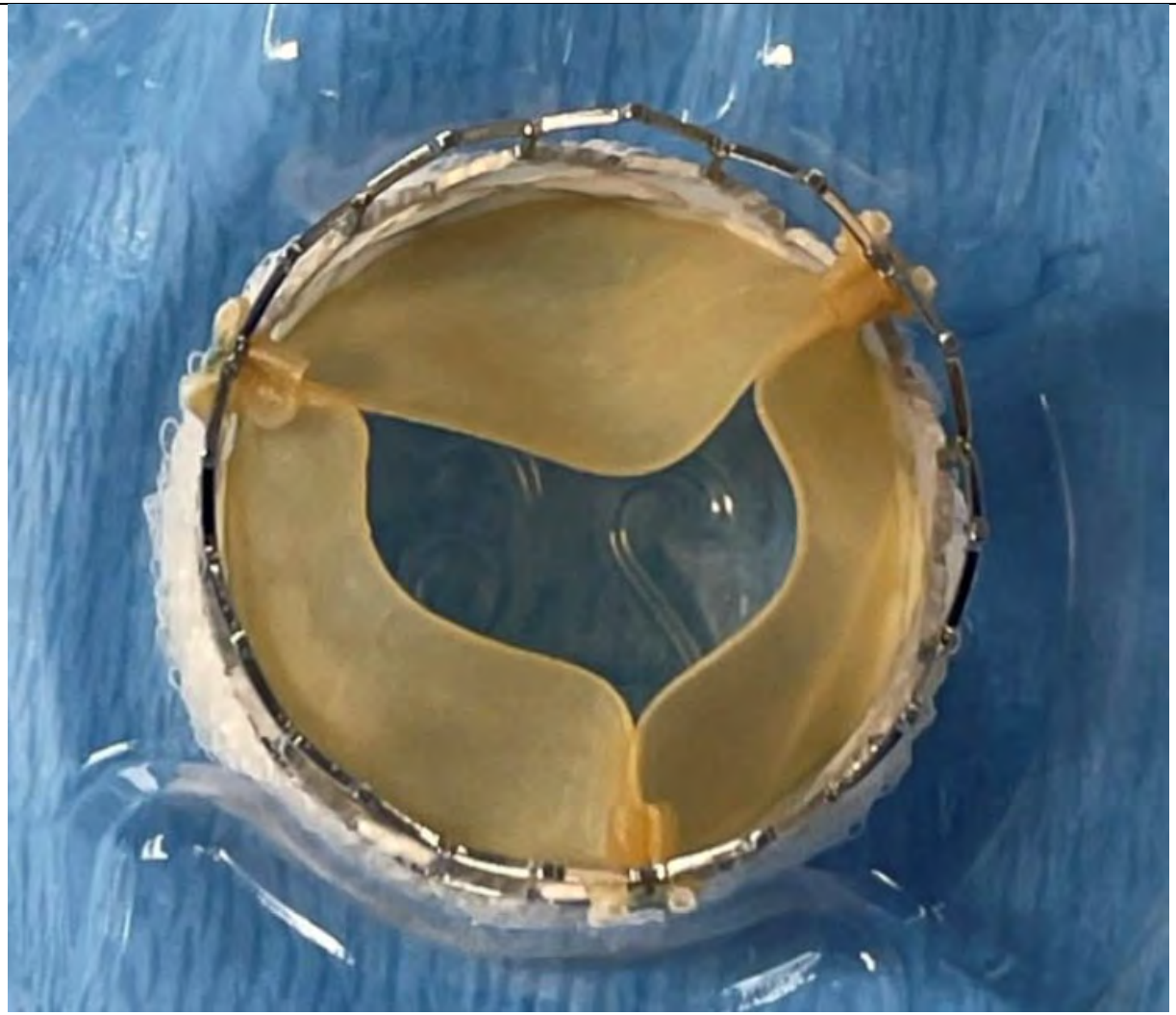


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

With respect to the phrase, "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," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, at least two rows of cells perform the same or substantially the same function as the claim phrase by providing a collapsible and expandable structure for the sealing material to extend over, in

	the same or substantially the same way as the claim phase by being constructed of metal forming cells of the same or equivalent shapes and sizes, to achieve the same or substantially the same result of providing least two rows of cells for the sealing material to at least partially extend over.
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,	The ’310 patent Accused Instrumentalities satisfy this element. For example, the ’310 Accused Instrumentalities’ sealing material includes a plurality of radially extending fibers that extend outwardly of the outer frame, wherein the radially extending fibers are arcuate. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the outer frame.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of outwardly extending arcuate fibers extending outwardly from outer frame) (D.I. 1, Ex. 29).



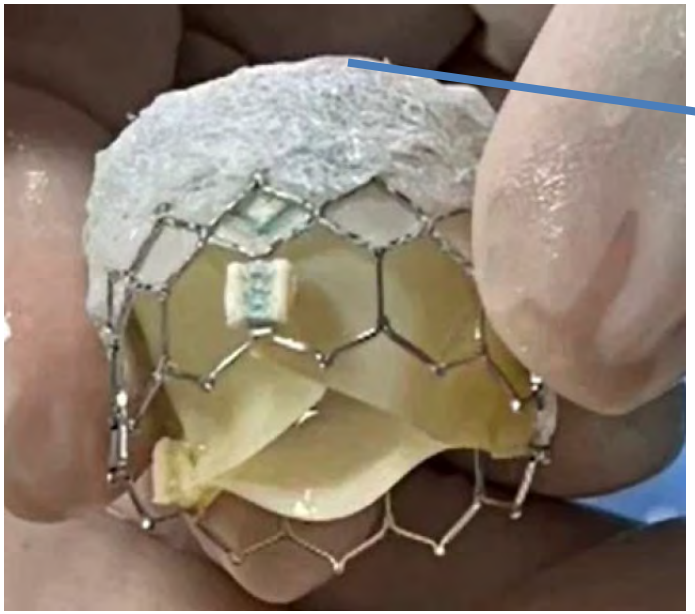
https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of outwardly extending arcuate fibers extending outwardly from outer frame) (D.I. 1, Ex. 64).



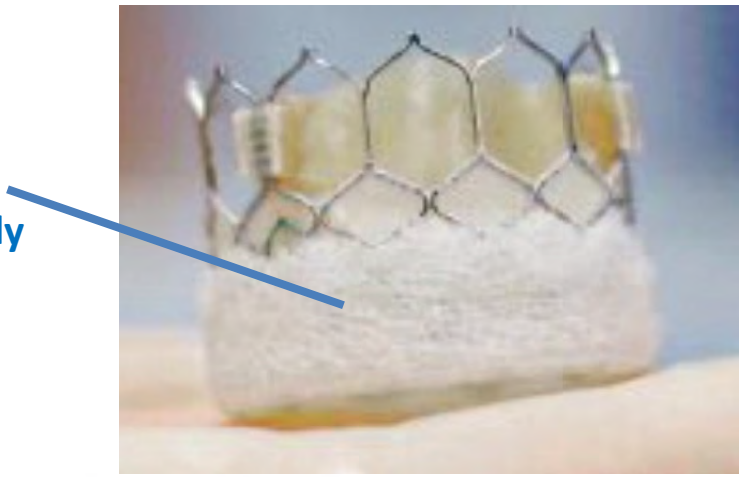
Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of outwardly extending arcuate fibers extending outwardly from outer frame) (D.I. 1, Ex. 3).

Further, with respect to the phrase, "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" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing material including a plurality of outwardly extending fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve

	substantially the same result. For example, the accused sealing material including a plurality of outwardly extending arcuate fibers performs the same or substantially the same function as the claim phrase by providing for low profile sealing material capable of sealing against the native leaflets, in the same or substantially the same way as the claim phase by including low profile biocompatible polymeric arcuate fibers with "tips" extending generally outwardly that are configured to press against the native leaflets of the aorta of the patient when the valve is expanded, to achieve the same or substantially the same result of providing a sealing material configured to form a biocompatible seal between the native annulus/leaflets and frame and reduced paravalvular leakage.
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,	The '310 patent Accused Instrumentalities satisfy this element. The '310 patent Accused Instrumentalities' 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. The Sapien 3 Ultra graft covering, at least in some portions, extends beyond a proximal end of the frame and over the proximal ends to cover and/or partially cover at least portions of the proximal ends of the frame.

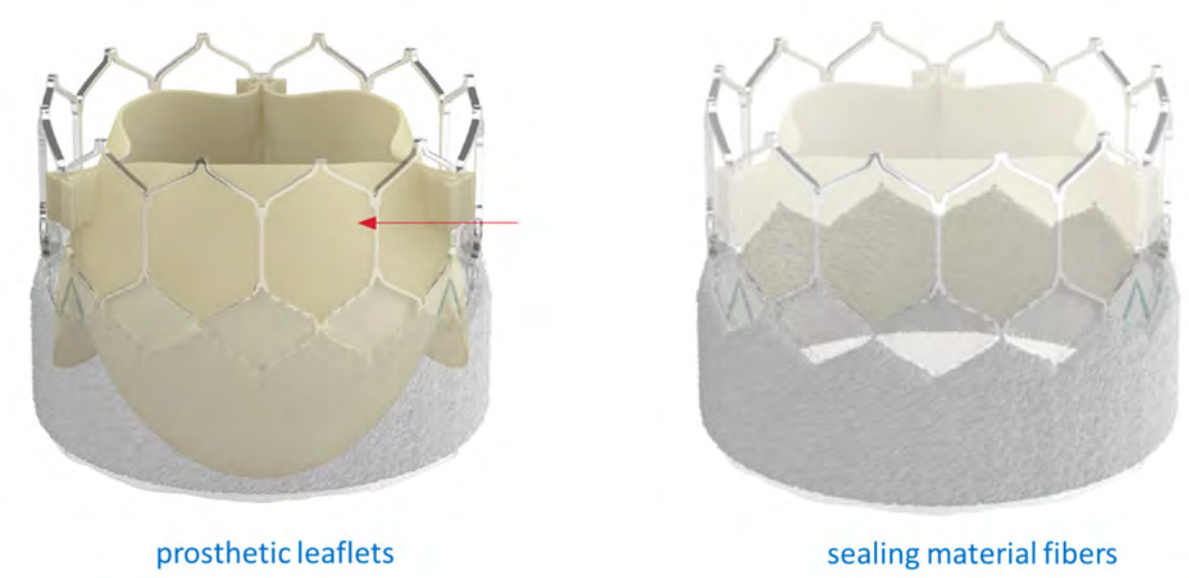
	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74). *See also*, claim 1.
wherein the plurality of radially extending fibers form a circumferential surface that extends outwardly of the outer frame;	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities plurality of radially extending fibers form a circumferential surface that extends outwardly of the outer frame. For example, the Sapien 3 Ultra is designed and configured such that the plurality of radially extending fibers form a circumferential surface that extends outwardly of the outer frame.

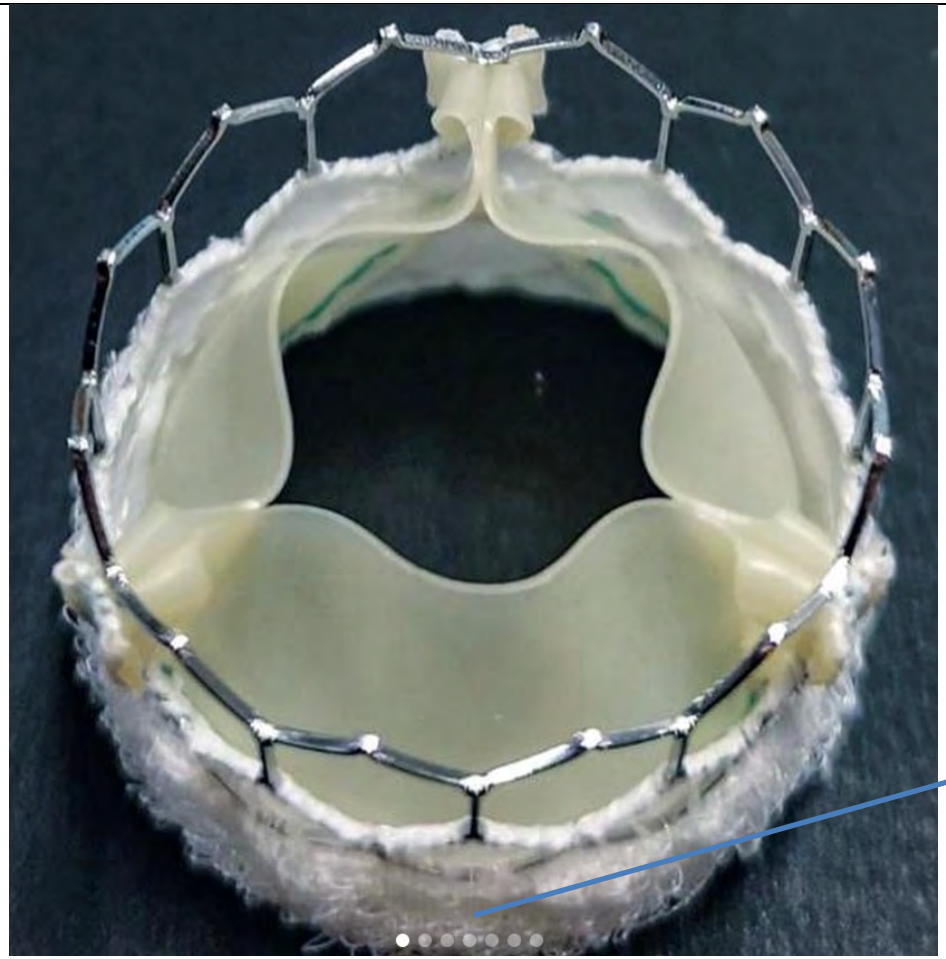
https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).





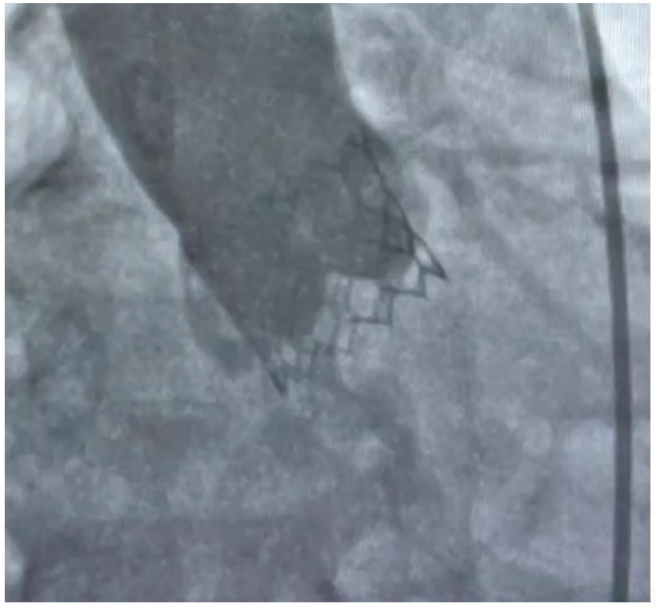
https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).

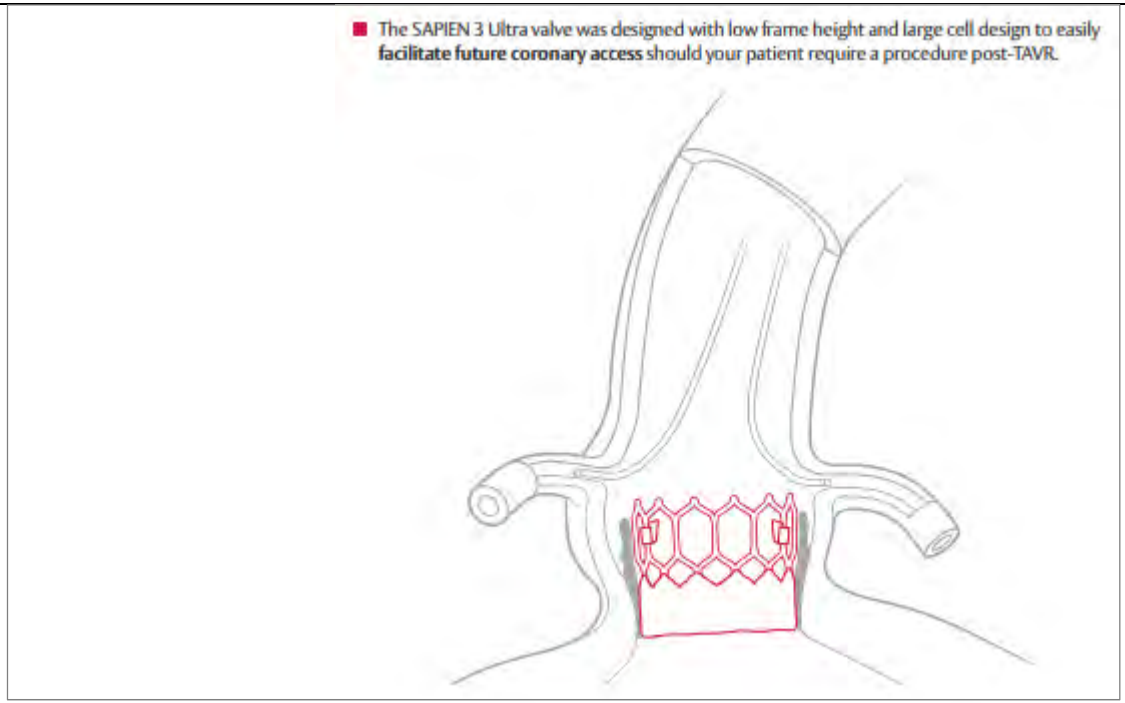
	See also, "sealing material" element above.
wherein the fibers radially overlap with the prosthetic heart valve leaflets,	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities' fibers radially overlap with the prosthetic heart valve leaflets. For example, the Sapien 3 Ultra is designed and configured such that at least some of the fibers of the sealing skirt radially overlap with at least portions of the prosthetic heart valve leaflets.  https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).

	 Julian Calain Twitter (D.I. 1-2 at 18).
wherein the graft covering is made of polyester, polytetrafluoroethylene	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ graft covering is made of a polyester polymer. For example, the Edwards Sapien 3 Ultra inner skirt is made of PET which is a polyester polymer.

, expanded polytetrafluoroethylene , or a polymer,	**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 (D.I. 1, Ex. 44).

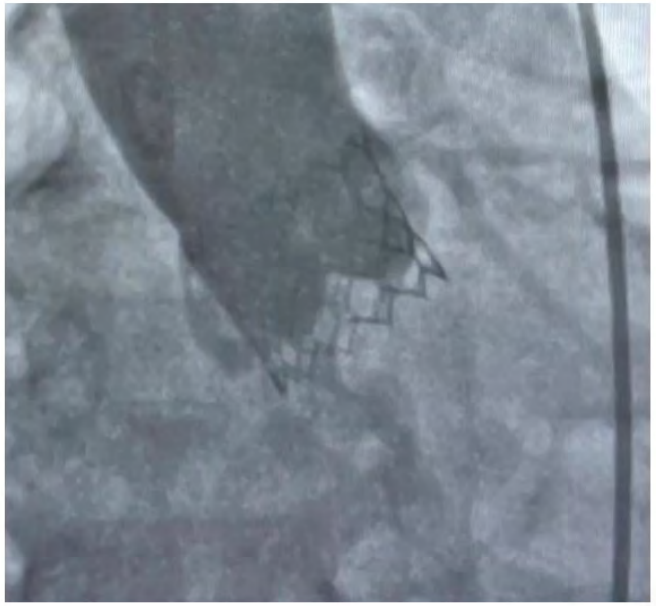
wherein the valve assembly is expandable during endovascular deployment,	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities are expandable during endovascular deployment. The Sapien 3 Ultra designed and configured to be expandable using an Edwards’ balloon delivery system in the aorta of a patient during endovascular deployment.  Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

	 Introducing the Sapien 3 Ultra, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

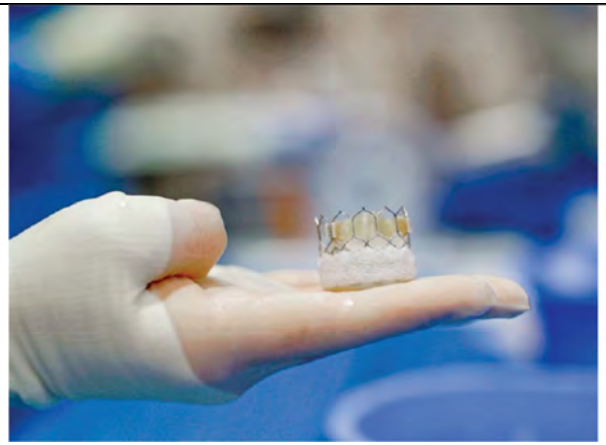
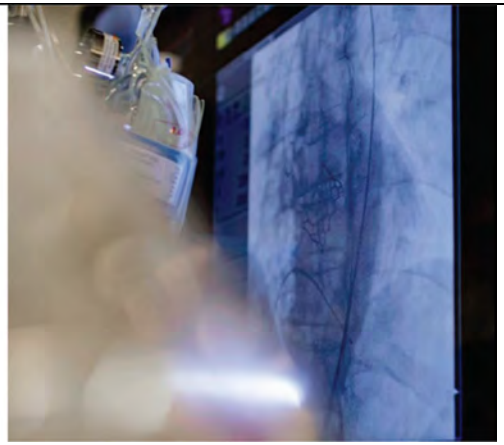


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

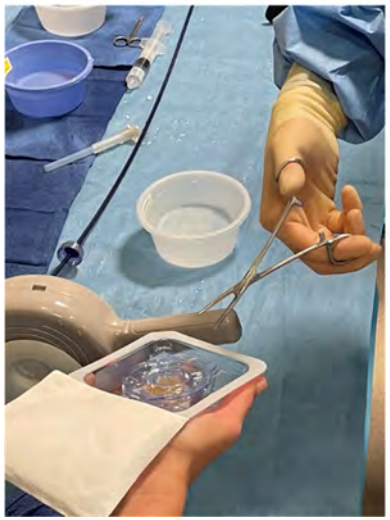
	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

	 https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).
wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient,	The '310 patent Accused Instrumentalities satisfy this element. For example, the '310 patent Accused Instrumentalities are configured to be deployed endovascularly through a femoral artery of the patient. Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through the femoral artery using Edwards' balloon catheter delivery systems.

	  https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

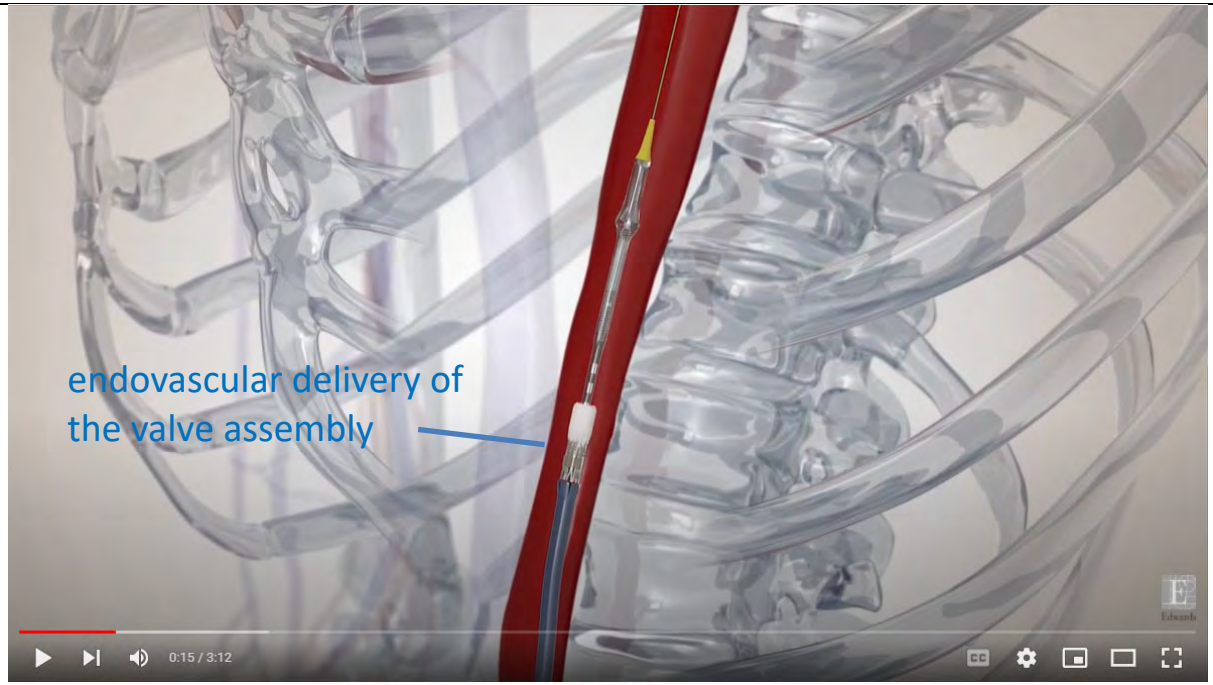


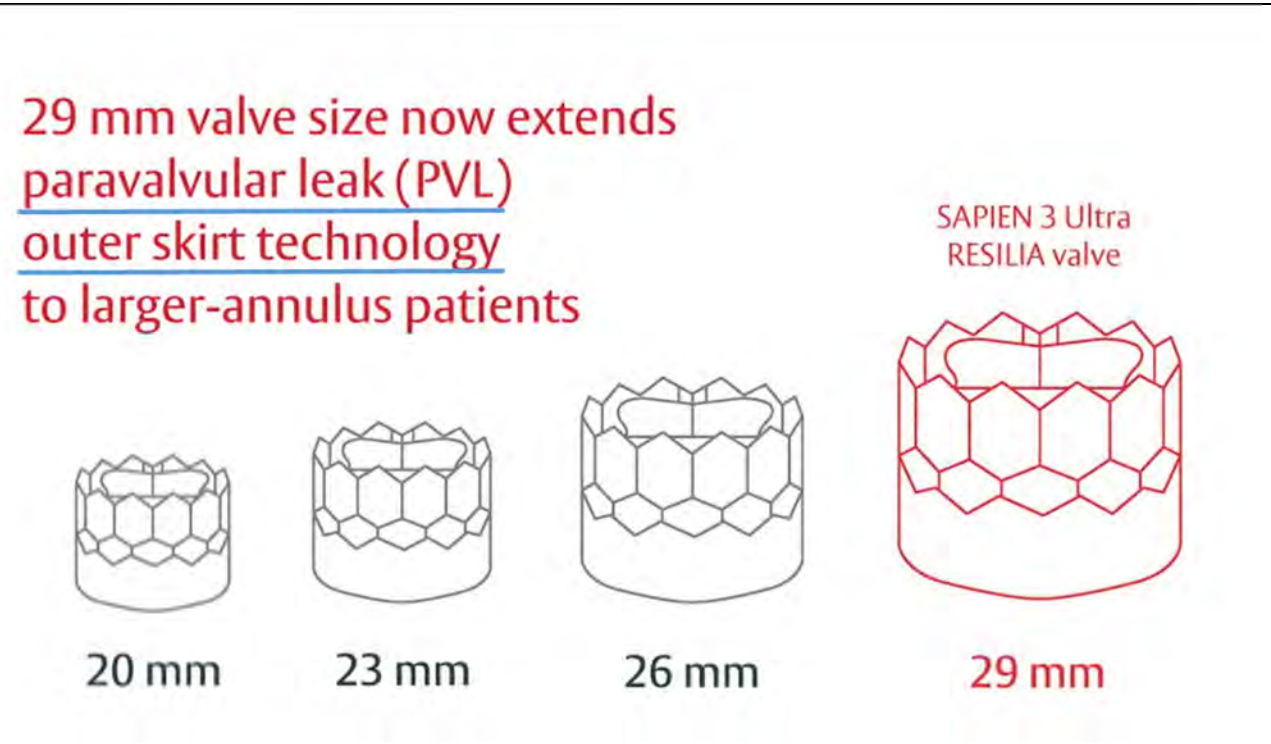


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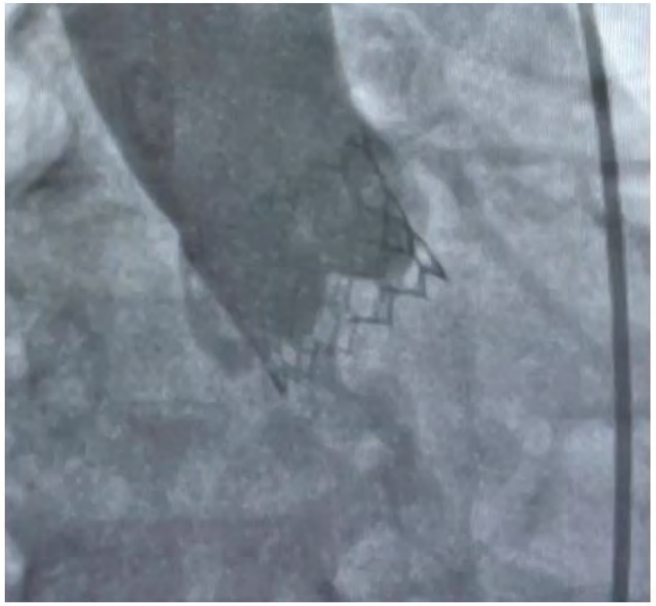


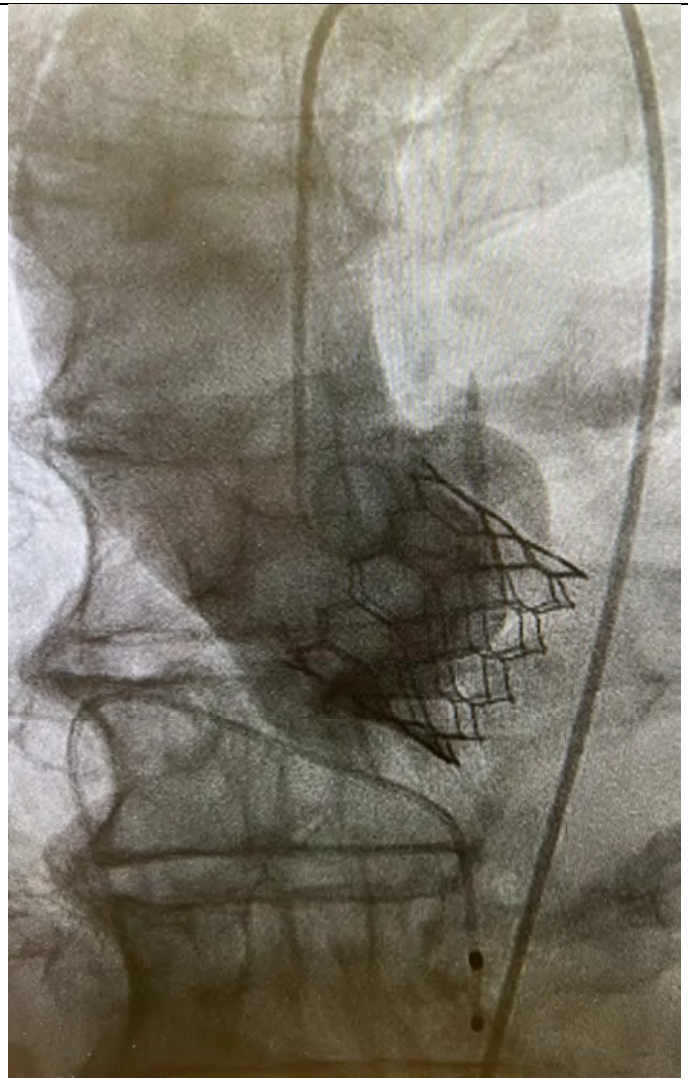
	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

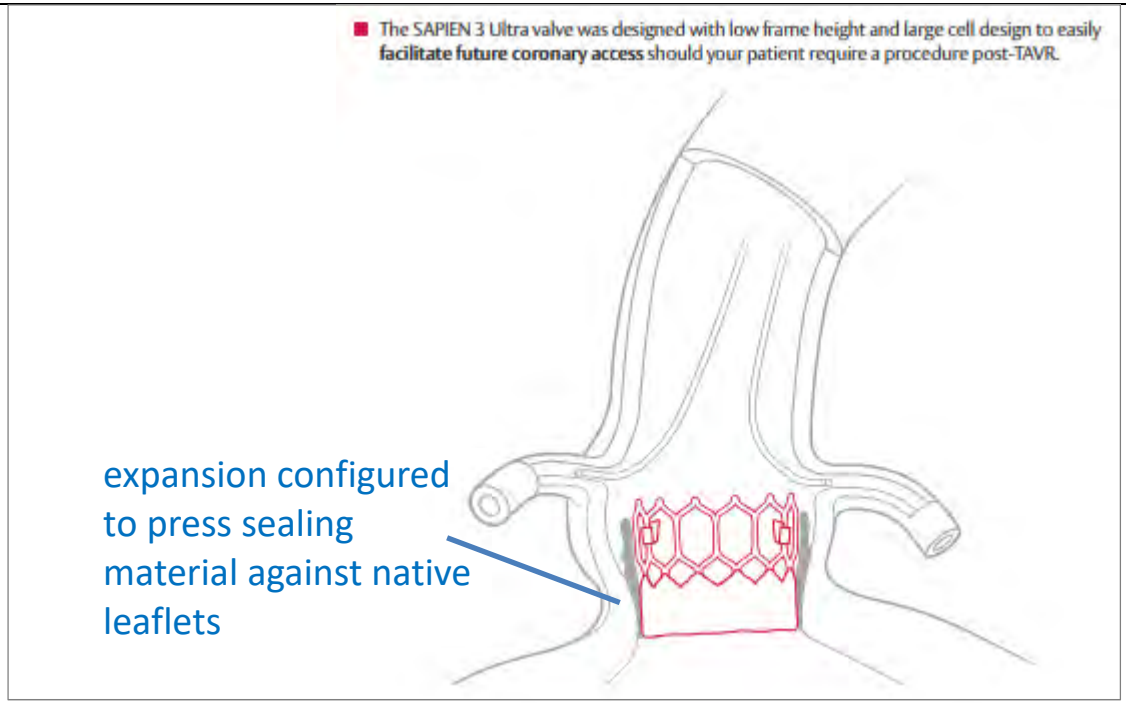
	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
wherein expansion of the heart valve assembly is configured to press the sealing material against native valve leaflets of an aorta of the patient,	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities are configured such that expansion of the heart valve assembly is configured to press the sealing material against native valve leaflets of an aorta of the patient. The Sapien 3 Ultra is configured so that expansion of the heart valve assembly is configured to press the sealing material against native valve leaflets of an aorta of the patient .



https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

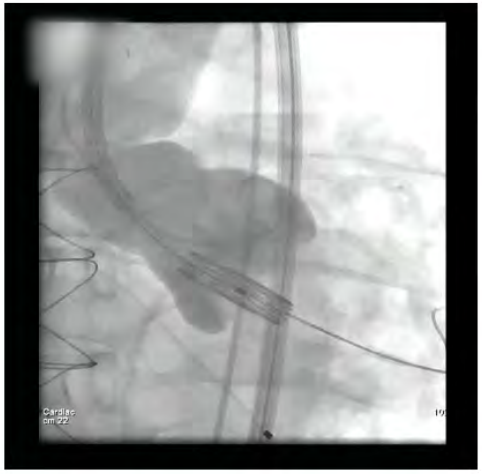
	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

	 https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



Introducing the Sapien 3 Ultra, including, but not limited to the Sapien 3 Ultra Resilia valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

SAPIEN 3 Ultra System Case Example



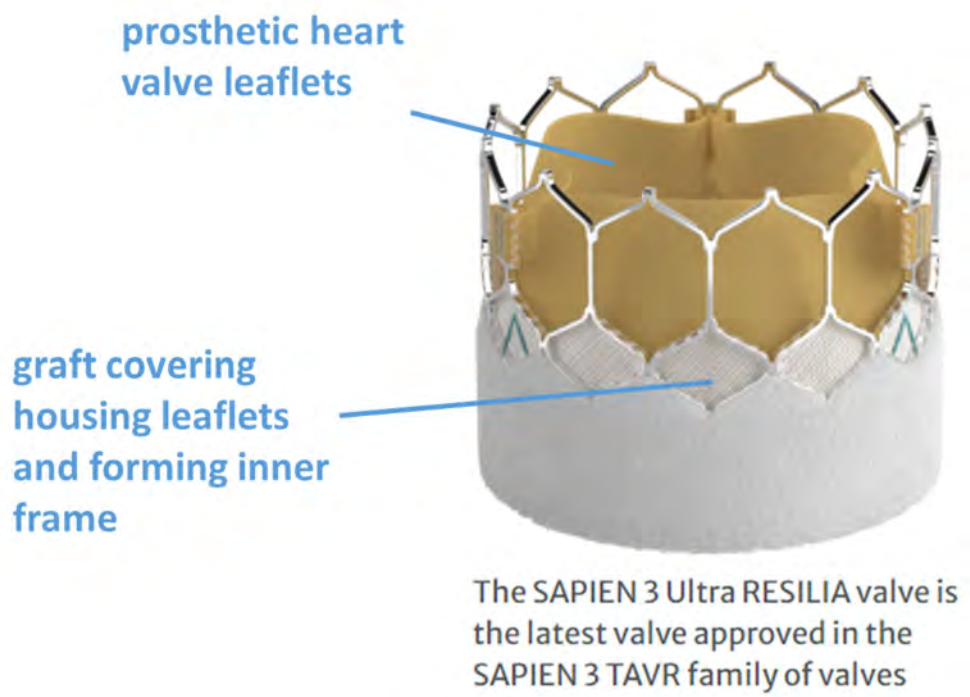


Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

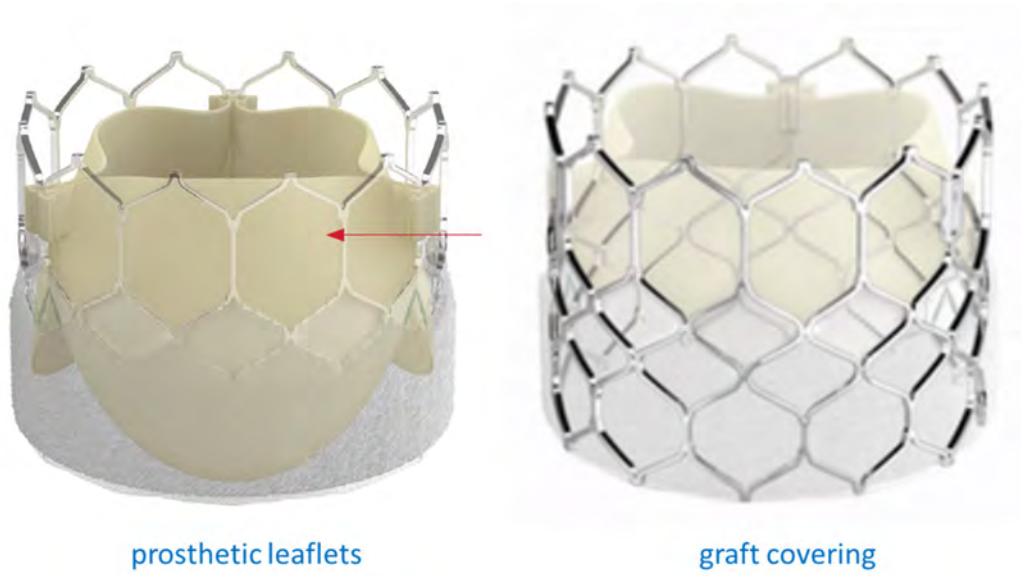
With respect to the phrase, "wherein expansion of the heart valve assembly is configured to press the sealing material against native valve leaflets of an aorta of the patient," Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by being capable of pressing at least some sealing material against the leaflets in the aorta of the patient, in the same or substantially the same way as the claim phase through including sealing material with outwardly

	extending arcuate fibers, to achieve the same or substantially the same result of a heart valve assembly configured to press at least some outwardly extending arcuate fibers into engagement with the native leaflets 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.	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ 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. The Sapien 3 Ultra is configured such that the plurality of fibers is in contact with 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.  Ex. 48, https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (showing plurality of fibers in contact with at least a first two proximal rows of cells of outer frame in compressed orientaiton).

	 Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (showing plurality of fibers in contact with at least a first two proximal rows of cells of outer frame in expanded orientaiton). With respect to the phrase, "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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by having fibers in contact with at least a first two proximal rows of cells of outer frame along the height of the sealing material in the radially compressed and expanded orientations, in the same or substantially the same way as the claim phase through including low profile sealing material with radially extending arcuate fibers attached to the frame, to achieve the same or substantially the same result of

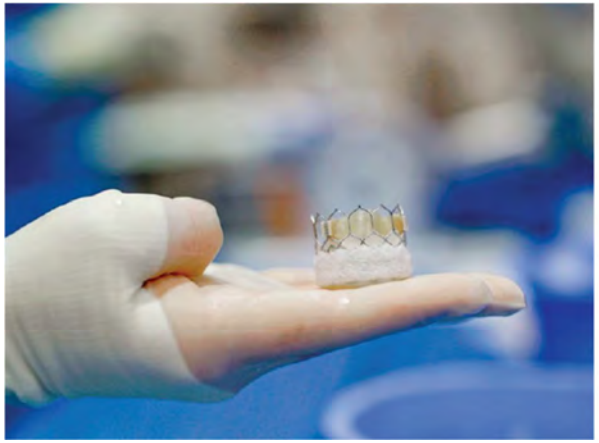
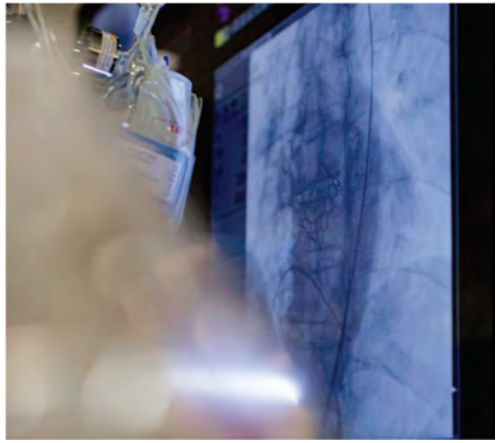
	fibers configured to at least generally contact at least a first two proximal rows of cells of outer frame along the height of the sealing material in the radially compressed and expanded orientations.
8. The valve assembly of claim 5, wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve.	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve. For example, the Edwards Sapien 3 Ultra graft covering extends around and houses the prosthetic heart valve and provides support directly and indirectly to the prosthetic heart valve forming an inner frame. For example, the graft covering houses the valve leaflets and is secured to the valve leaflets and the outer frame. To the extent required, the inner frame is balloon expandable.  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves

https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



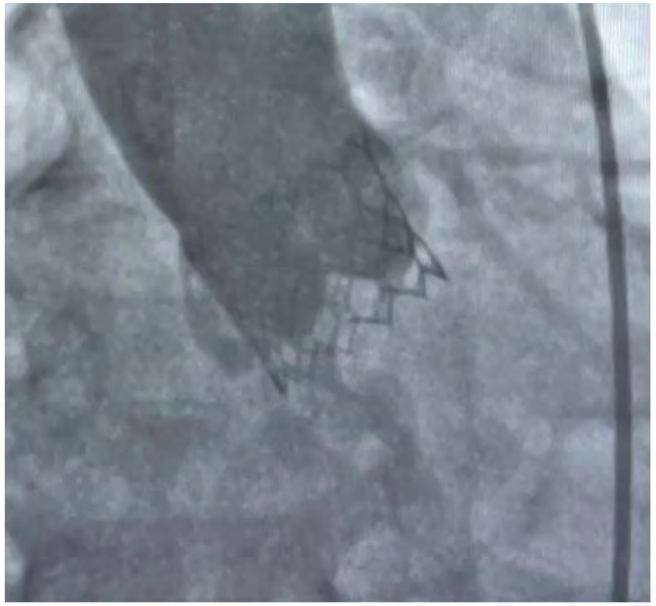
https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).

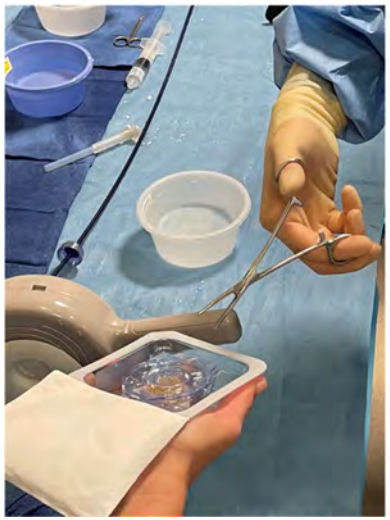
With respect to the phrase, "wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a graft covering inner frame that is balloon-expandable and/or that provides support and resist collapse, the identified graft covering that forms an inner frame for supporting the prosthetic heart valve, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering that forms an inner frame performs the same or substantially the same function as

	the claim phrase by being collapsible and expandable, as well as framing and providing support to the prosthetic heart valve, in the same or substantially the same way as the claim phase through a collapsible and expandable cylindrically extending graft covering inner frame secured by stitching to the outer frame extending at least partially around and housing and providing sealing to the prosthetic heart valve, to achieve the same or substantially the same result of a collapsible and expandable graft covering inner frame in a TAVR valve that is configured to frame, house, support (directly and/or indirectly), and/or provide sealing to the prosthetic heart valve. *See also,* claim 5.
11. A transcatheter aortic heart valve assembly comprising:	To the extent the preamble is limiting, the '310 patent Accused Instrumentalities satisfy this element. For example, the '310 patent Accused Instrumentalities are transcatheter aortic heart valve assemblies for use in a patient. The '310 patent Accused Instrumentalities are transcatheter aortic heart valve assemblies designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems.   https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



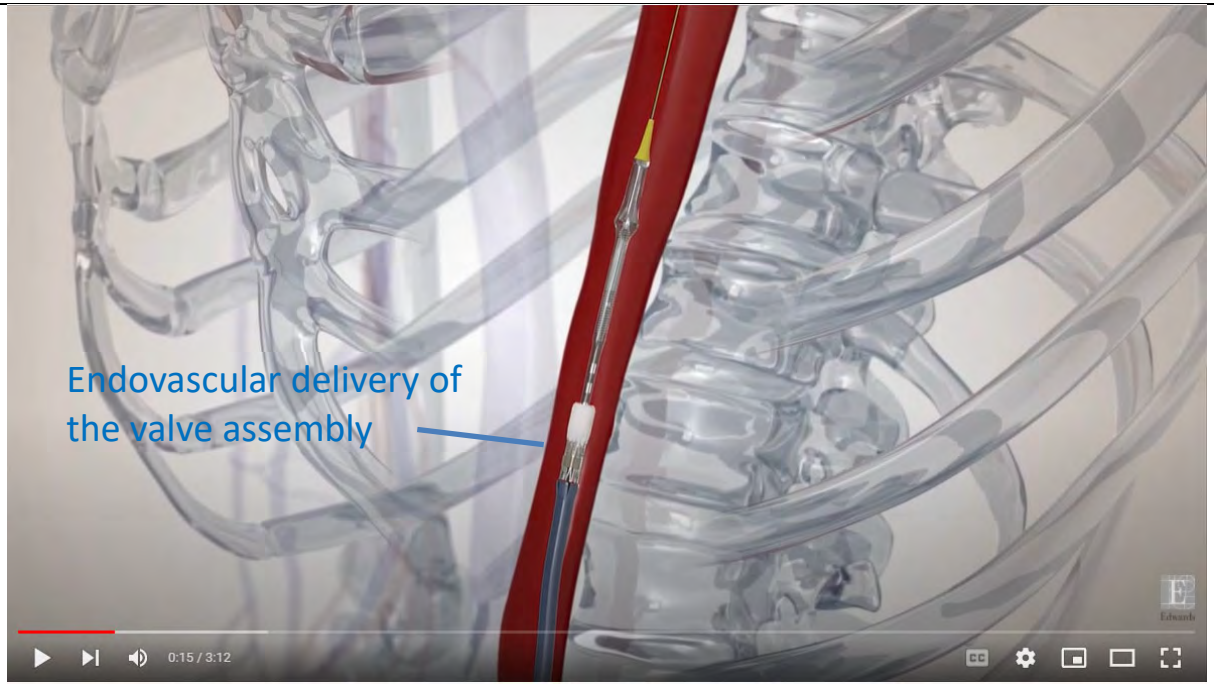


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra[4] is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[4] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.



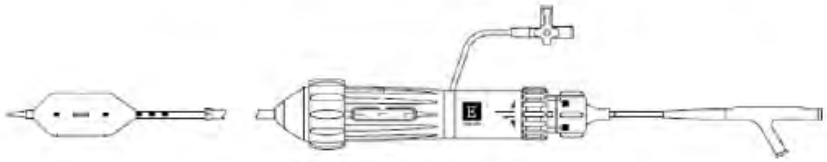
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



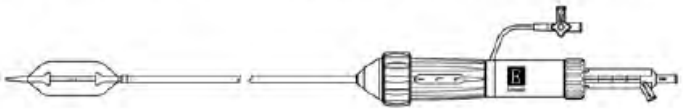
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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.



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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

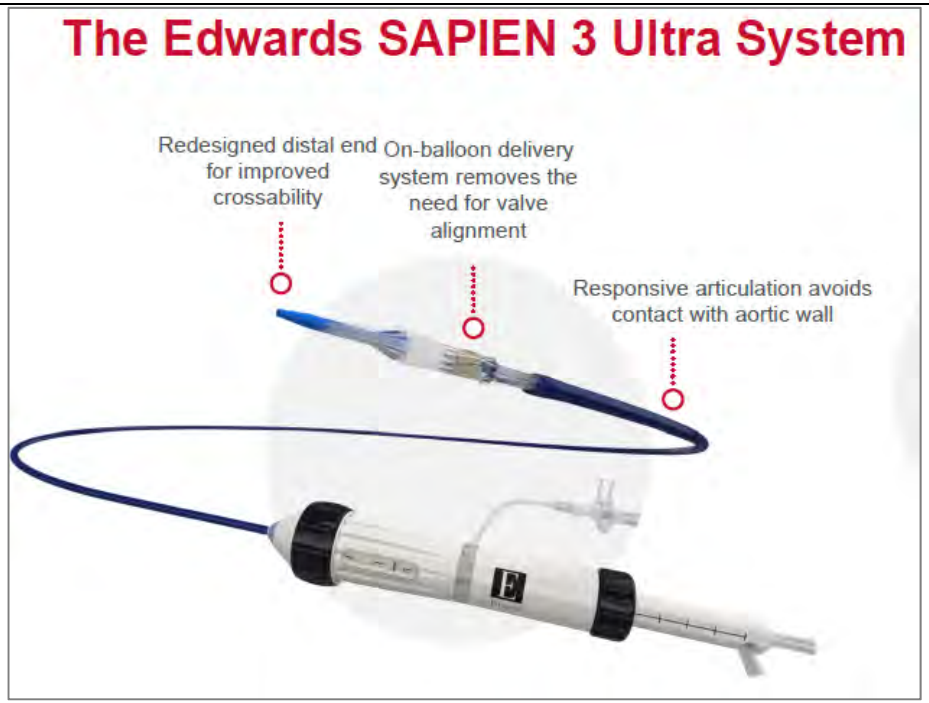
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

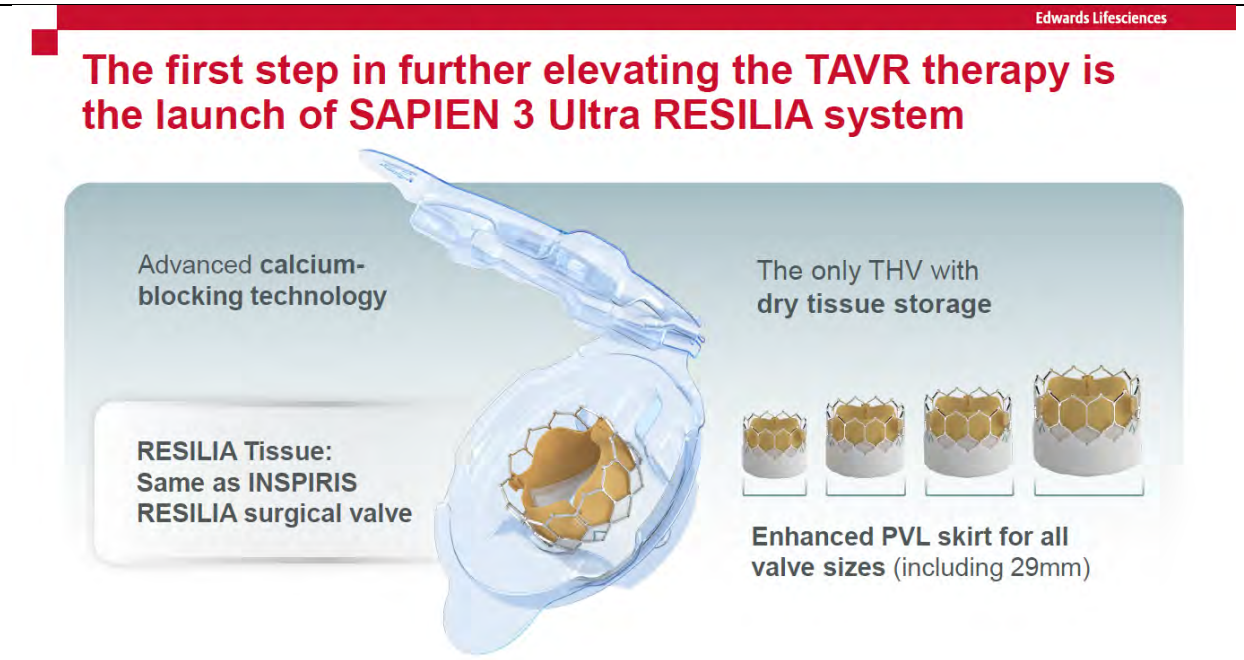
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

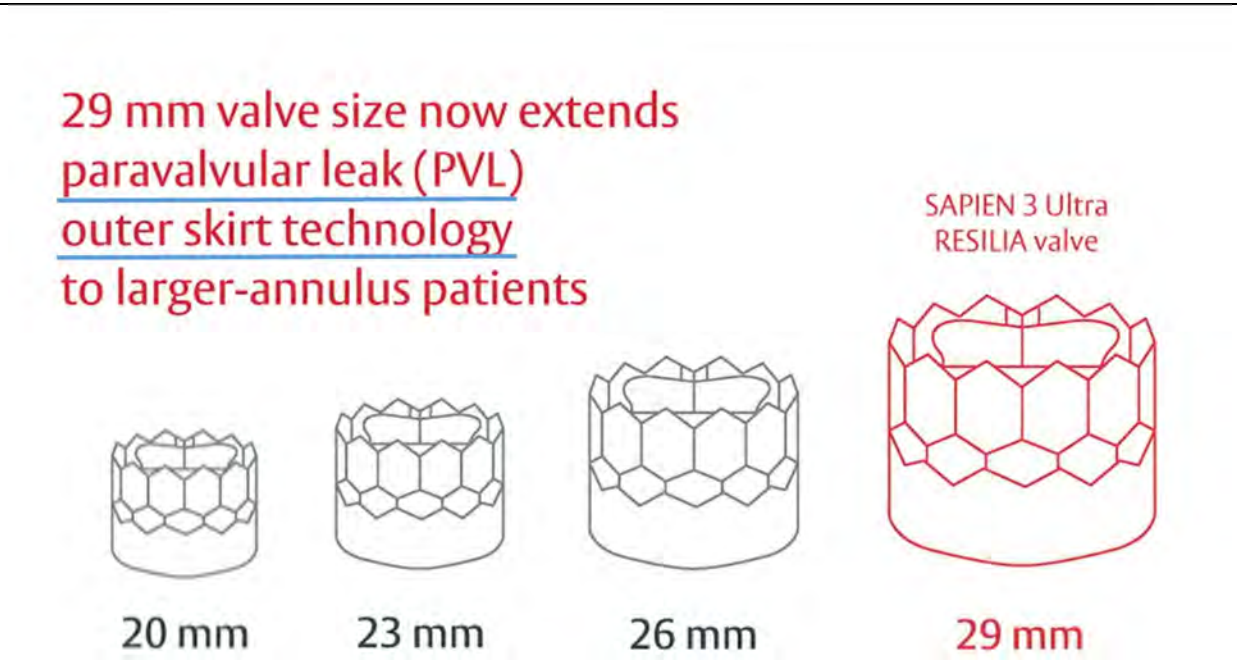
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

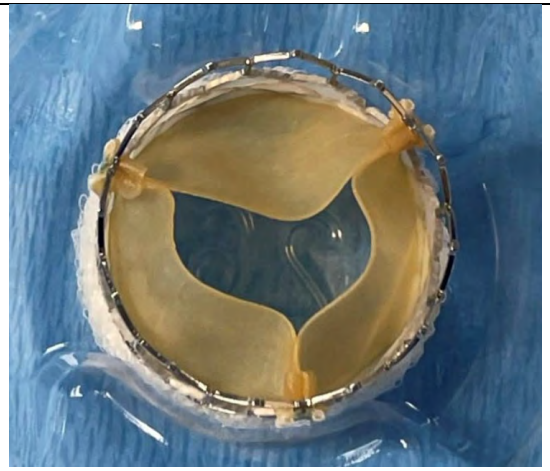
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’310 patent Accused Instrumentalities and infringes the ’310 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



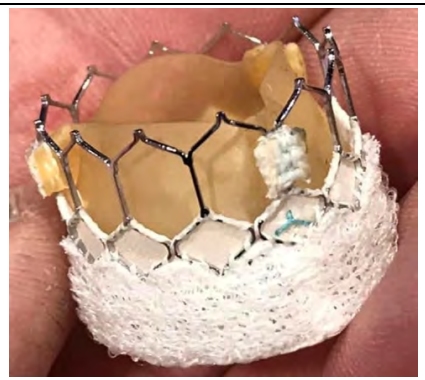
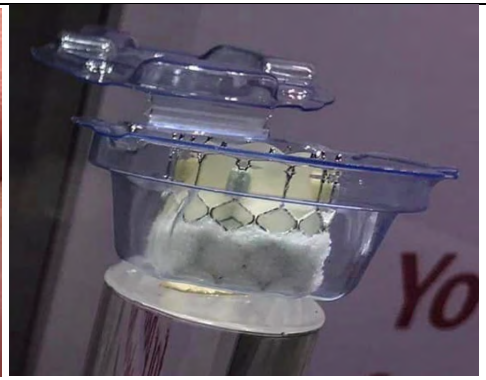
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

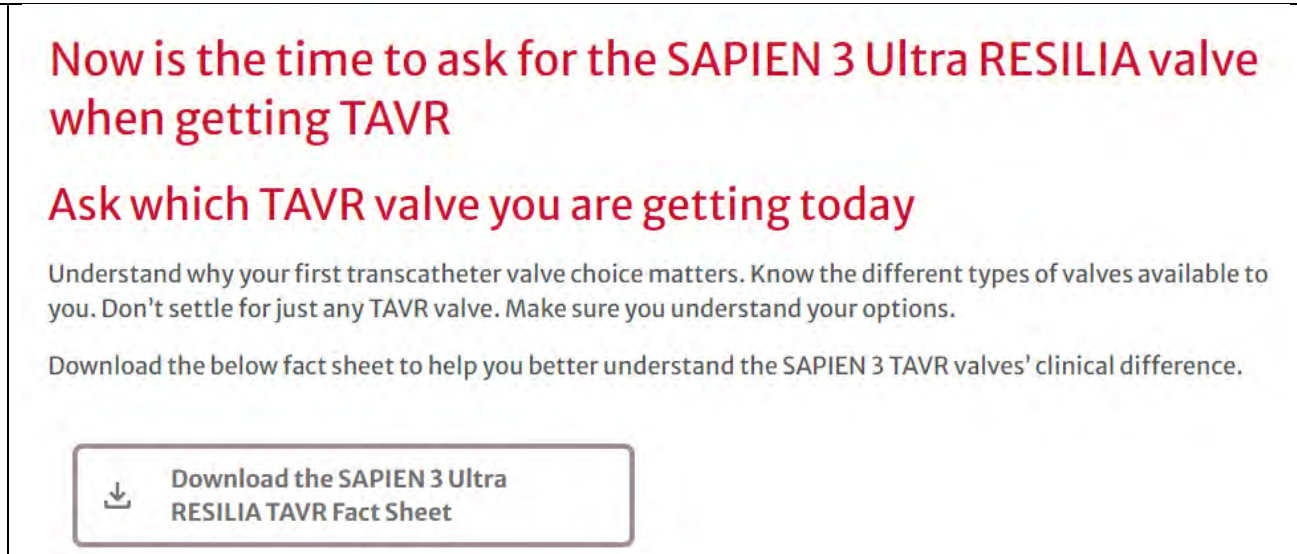
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the '310 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's

	recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See* https://ir.edwards.com/events-presentations/; https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '310 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '310 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '310 asserted claims are infringed when Edwards offers for sale and sells the '310 patent Accused Instrumentalities. Edwards offers for sale and promotes the '310 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 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.

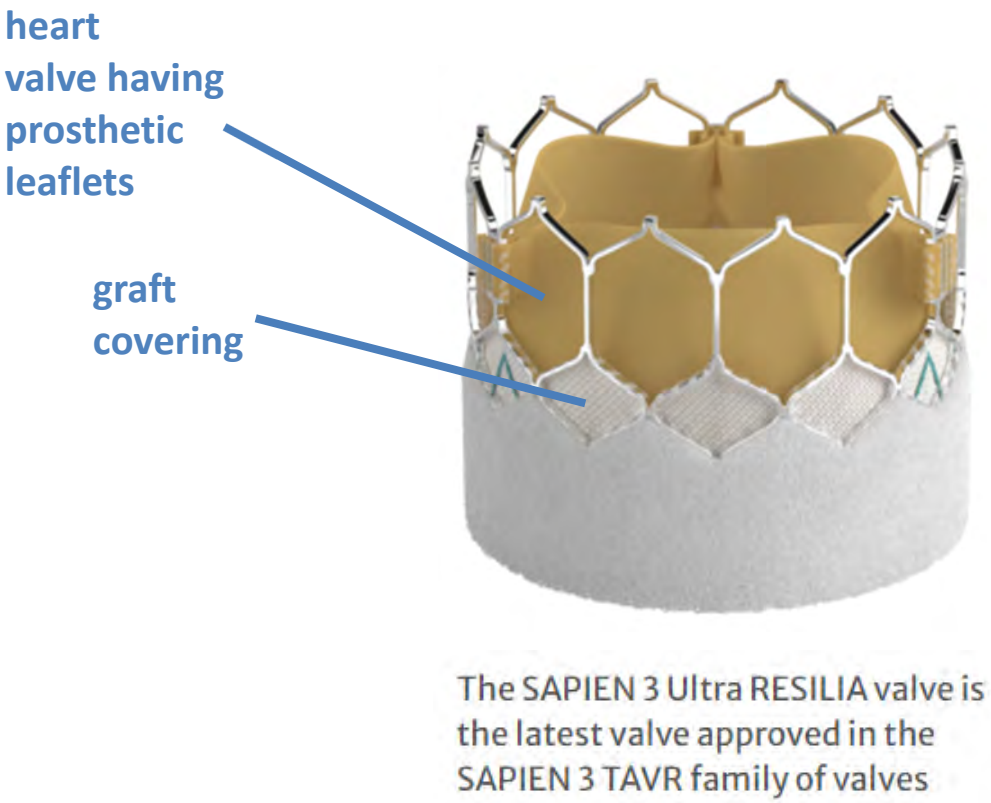


https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	The SAPIEN 3 Ultra RESILIA valve gives patients even more reason to ask for a specific TAVR valve  **The SAPIEN 3 Ultra RESILIA valve is the only TAVR valve with RESILIA tissue[1‡]** • Both the SAPIEN 3 Ultra RESILIA valve and the leading surgical valves use RESILIA tissue, known to block calcium build-up on the tissue, which could potentially allow the valve to last longer.[1‡] • Before today, the RESILIA tissue was only approved to be used on surgical heart valves[‡] **What are you waiting for? Understand why your choice of TAVR valve matters** https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61). On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement# Further, the '310 patent asserted claims 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 in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the ’310 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards’ direct and induced infringement. For further example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe the asserted ’310 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a “watchful eye” over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards’s inducement, Edwards’s affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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.

	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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards’s affirmative acts of marketing, selling and offering to sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ combination and use of the Accused Instrumentalities, such that the ’310 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards’ knowledge of Aortic’s inventions, the patents-in-suit (including the ’310 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
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;	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities comprise 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. For example, the Edwards Sapien 3 Ultra graft covering that engages and extends around and provides sealing to prosthetic heart valve leaflets.



https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

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

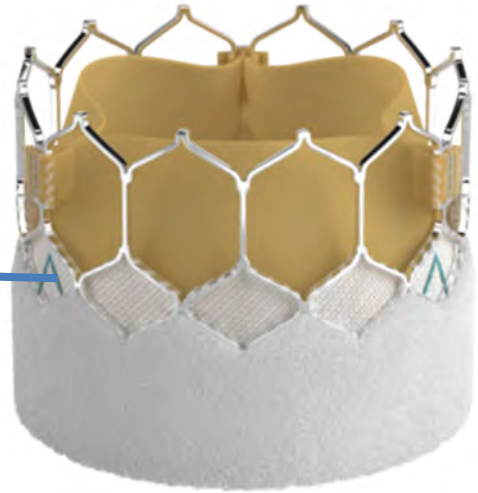
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

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

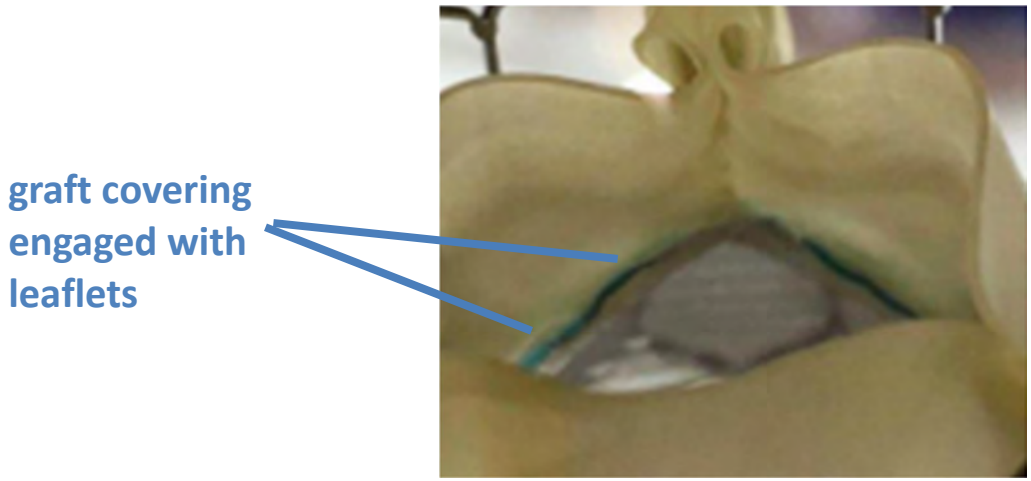
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

graft covering engaged with leaflets



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

https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	 https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29). With respect to the phrase, "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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include 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, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering performs the same or substantially the same function as the claim phrase by partially and/or fully providing sealing to the prosthetic heart valve leaflets, in the same or substantially the same way as the claim phase by engaging and/or being affixed to and extending fully or partially around the prosthetic

	heart valve leaflets, to achieve the same or substantially the same result of a graft covering configured to provide sealing or partial 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	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities comprise a frame formed from a metallic material and defining an open cell configuration, and being secured to the graft covering. For example, the Edwards Sapien 3 Ultra frame is made of a cobalt-chromium metallic alloy in an open cell configuration. **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.



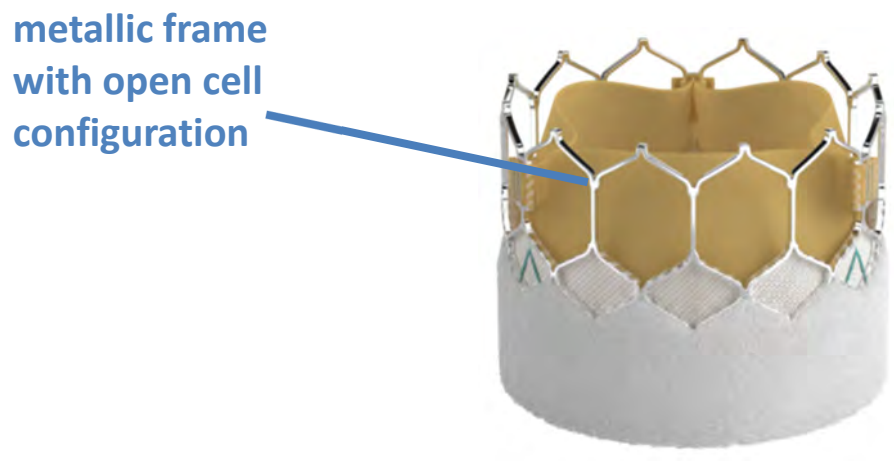
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

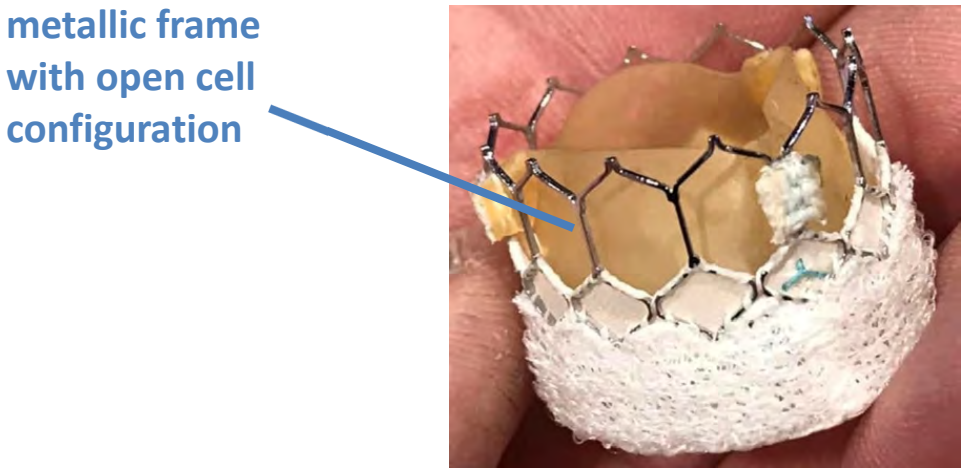
Table 1

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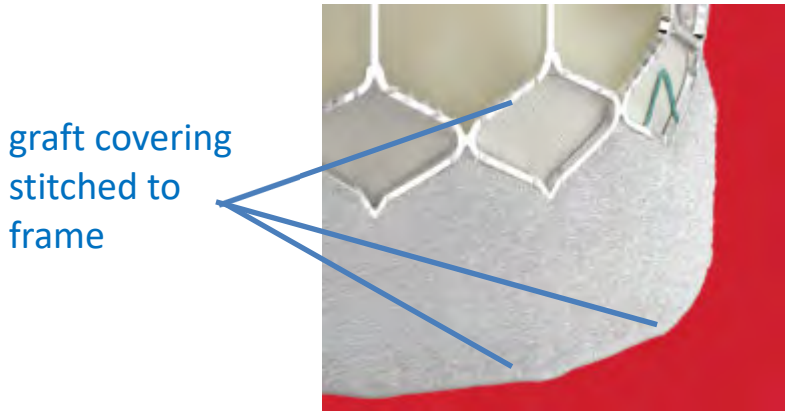
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

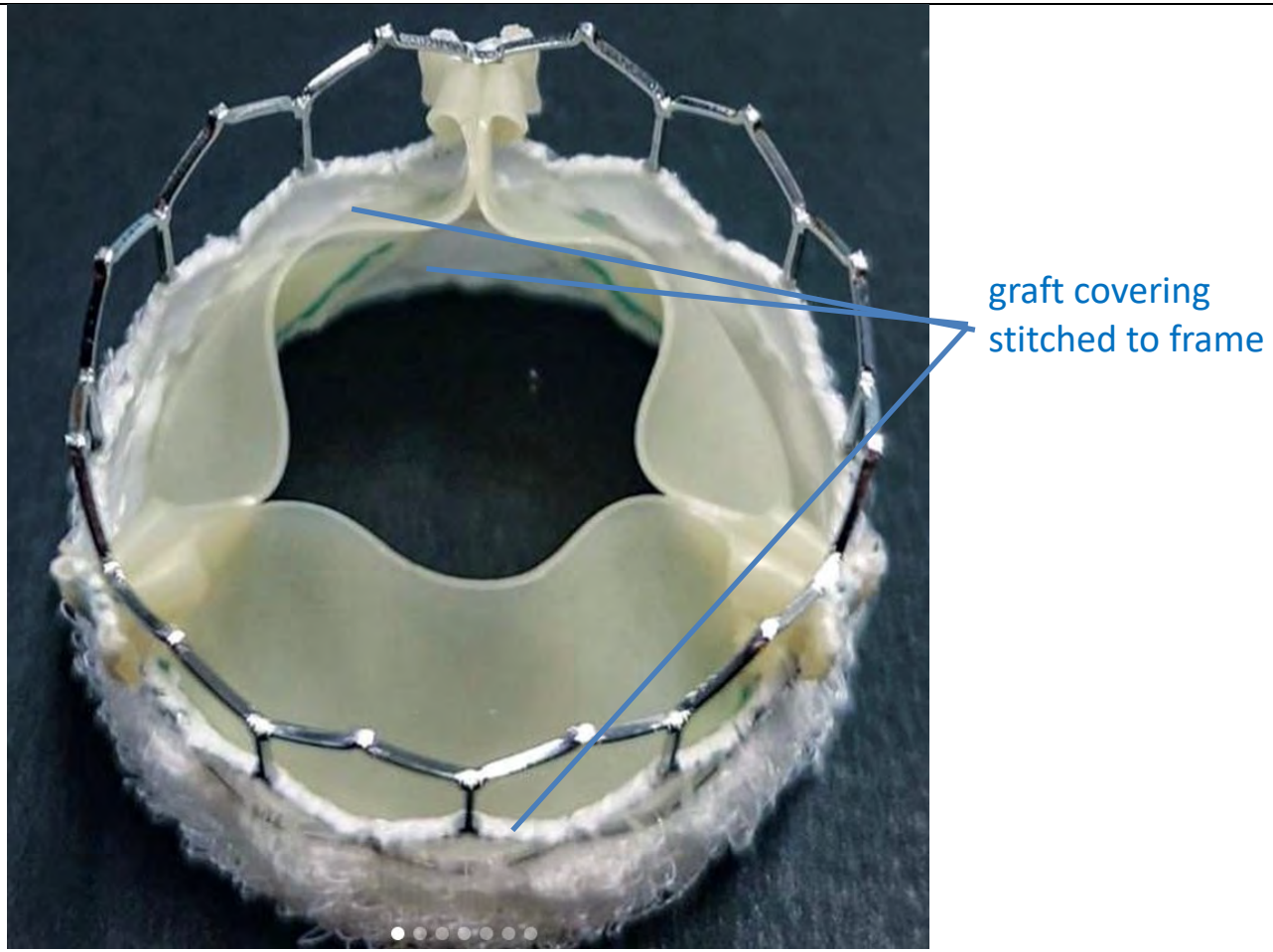


https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

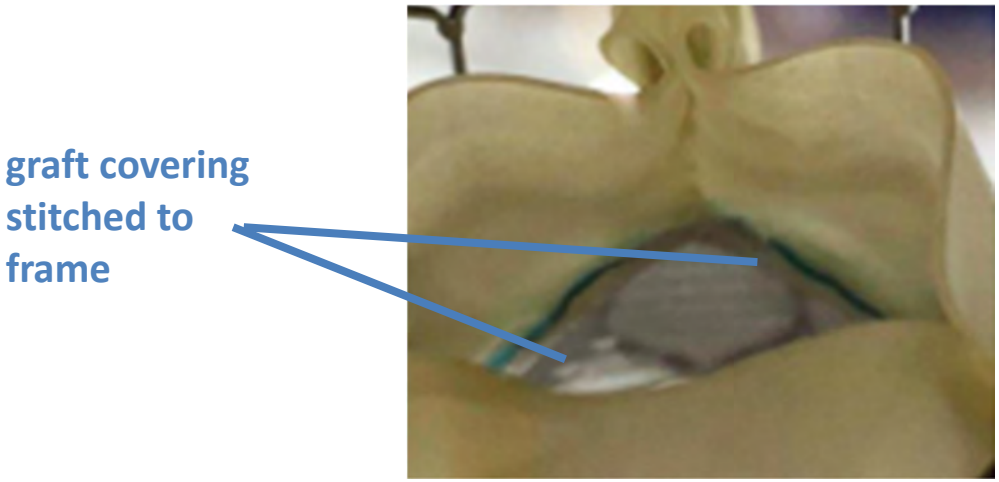


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

	For example, the Edwards Sapien 3 Ultra graft covering is stitched to the frame.  Introducing the SAPIEN 3 Ultra valve at 2 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

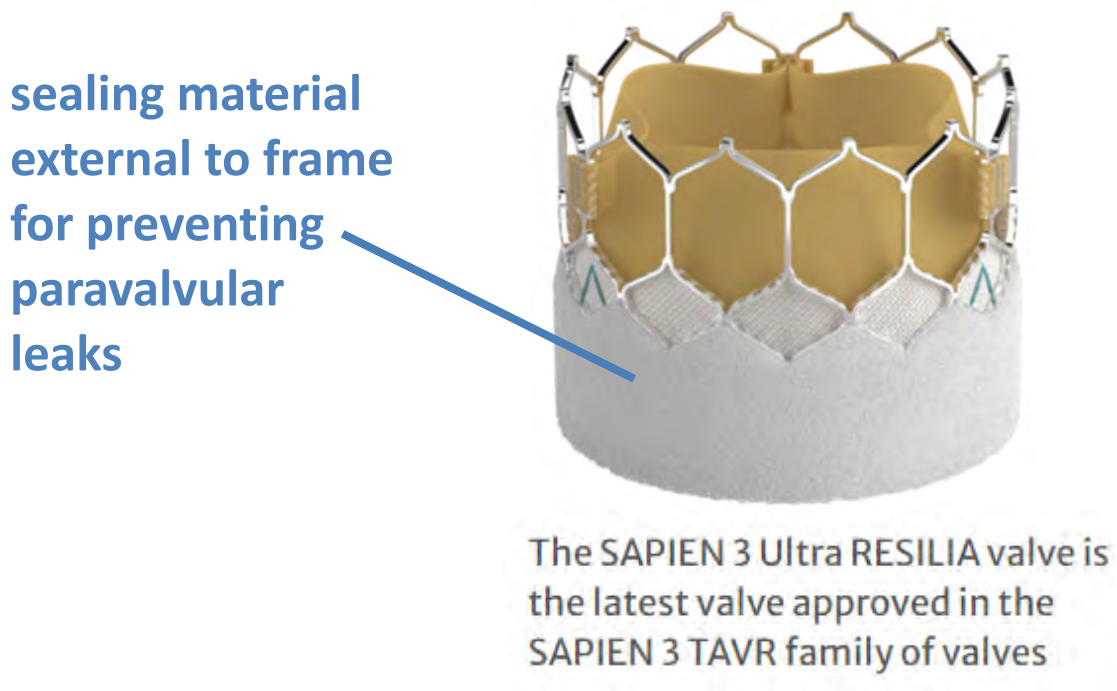


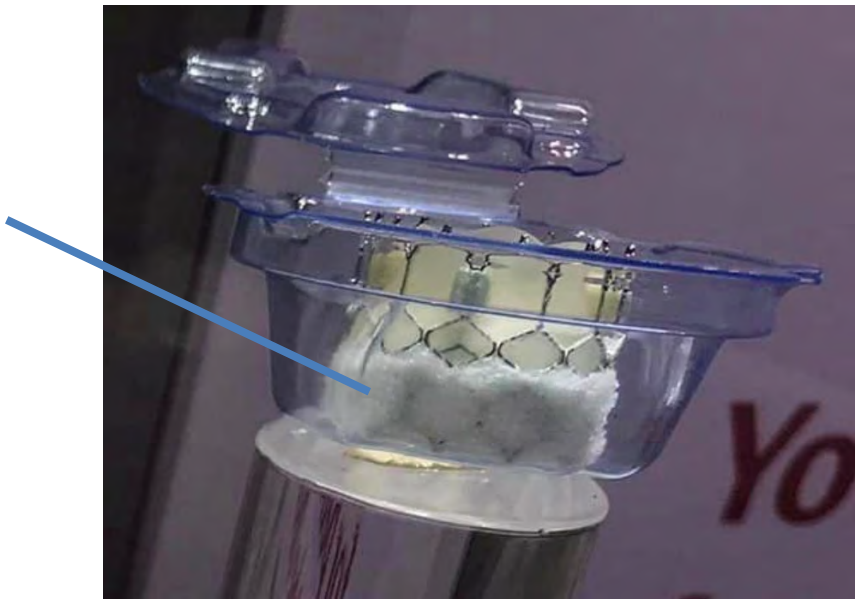
Julian Calain Twitter (D.I. 1, Ex. 30).

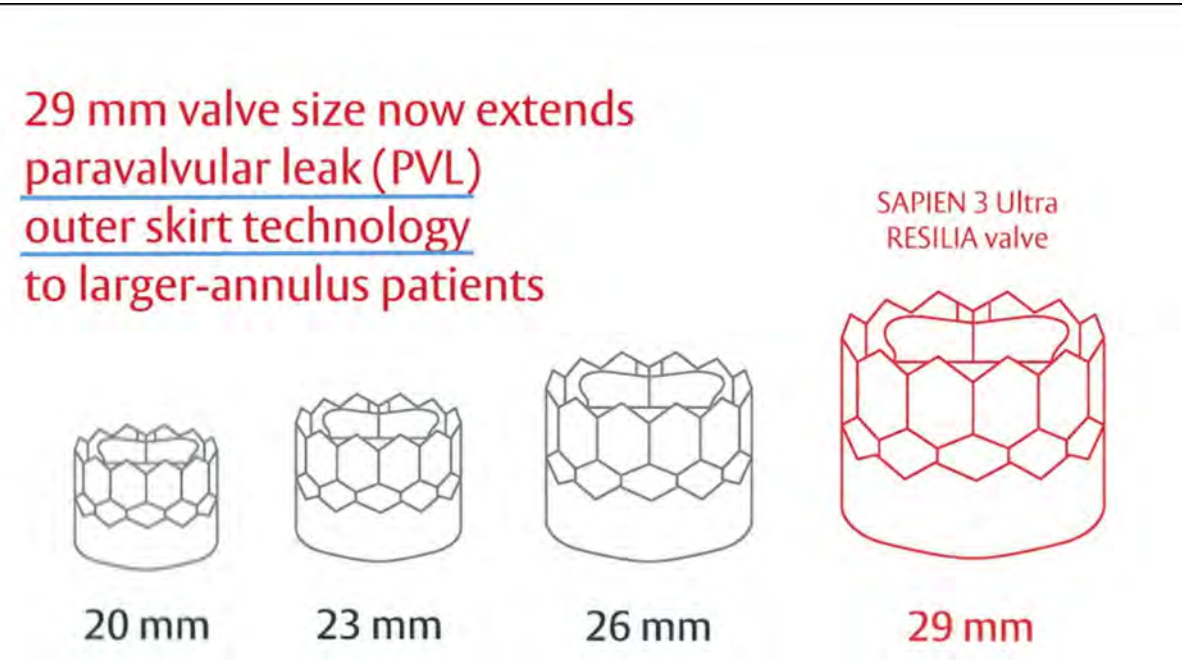


https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "a frame formed from a metallic material and defining an open cell configuration, and being secured to the graft covering", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with the capability to be expanded and collapsed to a low profile, to achieve the

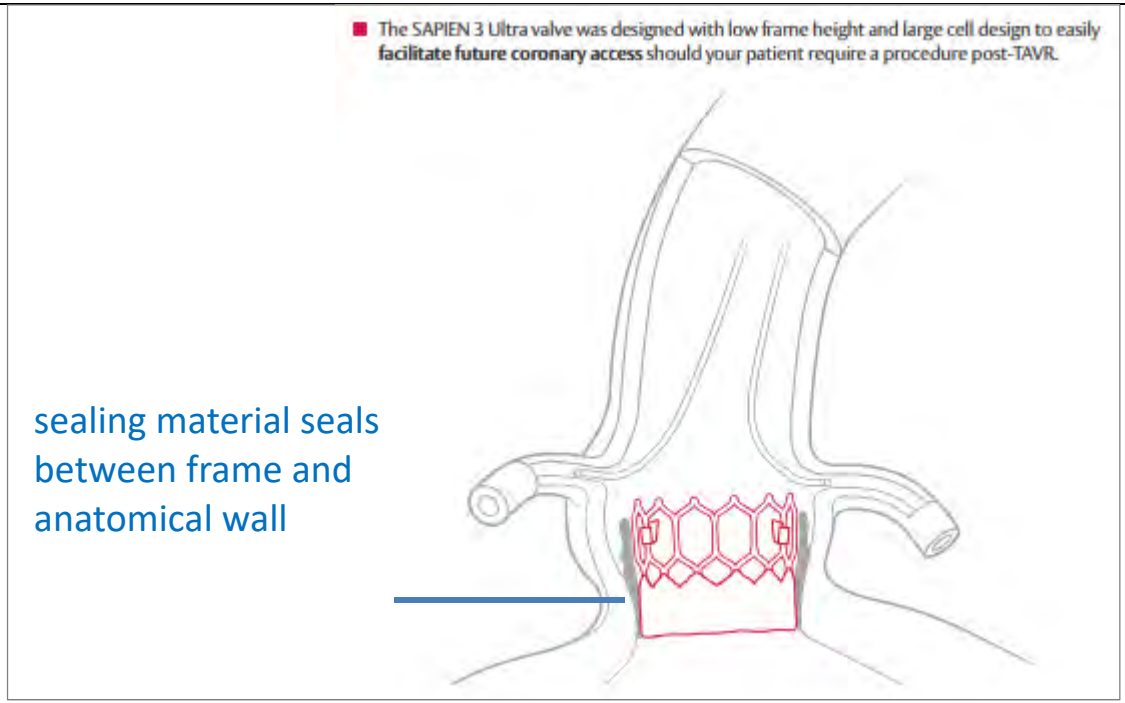
	same or substantially the same result of providing a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy.
a sealing material positioned externally to the frame for providing sealing between the frame and a patient's anatomical wall to prevent paravalvular leaks,	The '310 patent Accused Instrumentalities satisfy this element. The '310 patent Accused Instrumentalities comprise a sealing material positioned externally to the frame for providing sealing between the frame and a patient's anatomical wall to prevent paravalvular leaks. For example, the Edwards Sapien 3 Ultra includes a sealing skirt for providing sealing between the frame and the patient's anatomical wall for preventing paravalvular leaks.  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

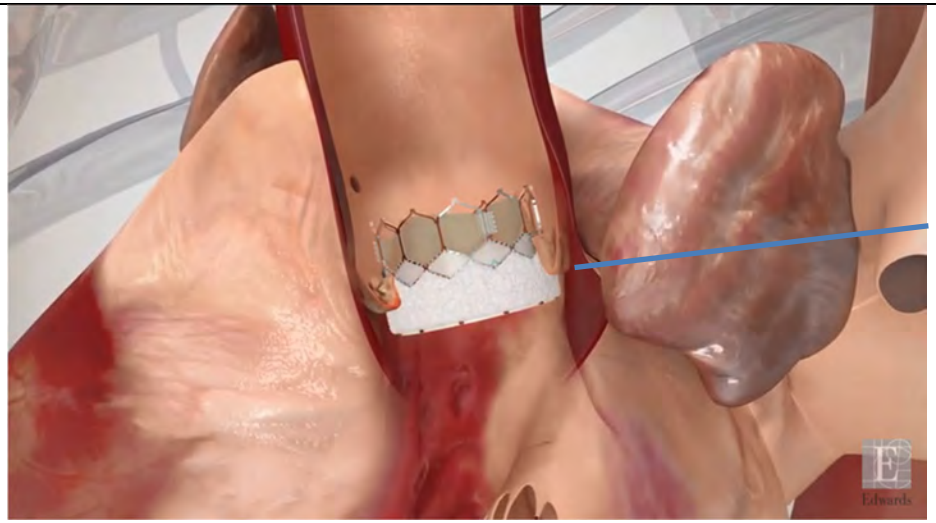


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

For example, the Sapien 3 Ultra sealing skirt provides for sealing between the frame and the patient's anatomical wall to help prevent PVL.

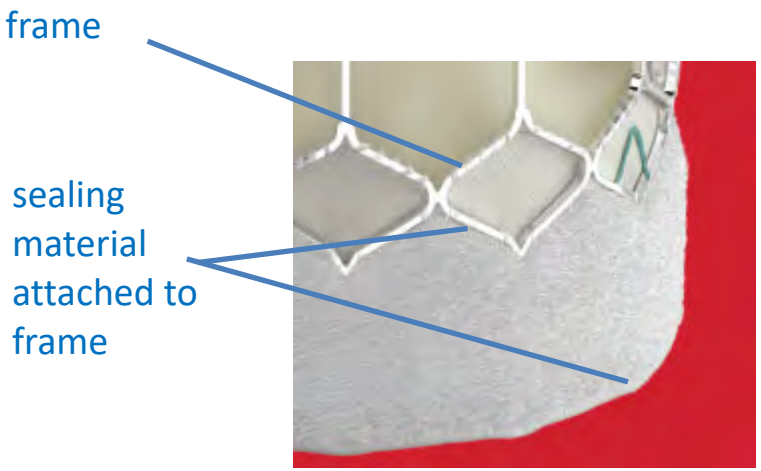


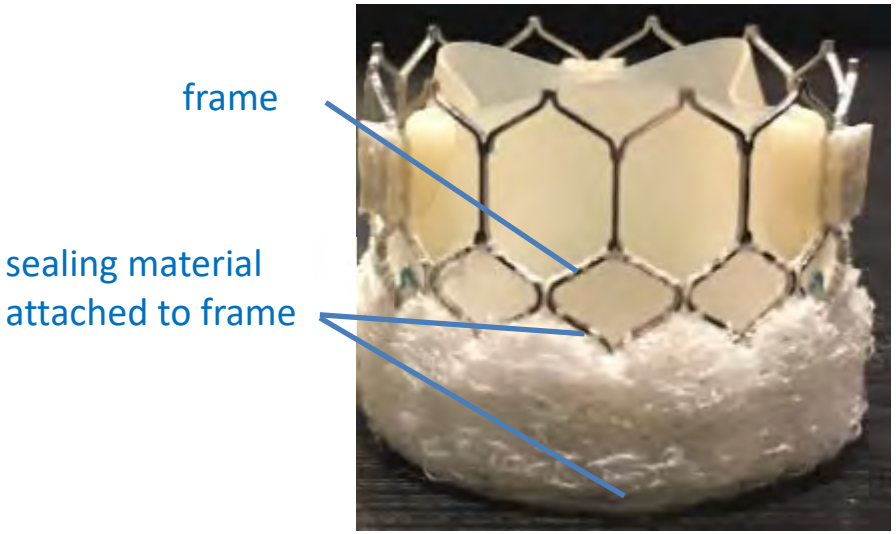
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



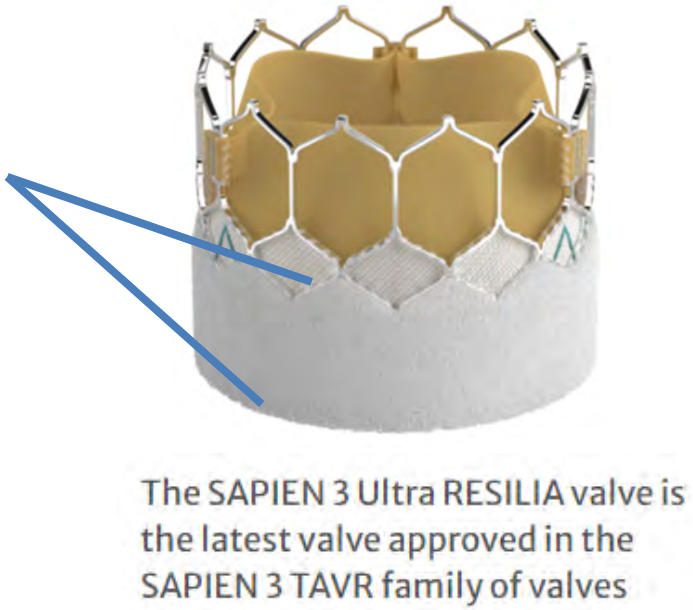
"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

Further, with respect to the phrase, "a sealing material positioned externally to the frame for providing sealing between the frame and a patient's anatomical wall to prevent paravalvular leaks" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the sealing material does not allow visibility of the frame or that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing material formed of outwardly extending fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused sealing material performs the same or substantially the same function as the claim phrase by providing for low profile sealing material capable of providing sealing between the anatomical wall and the frame, in the same or substantially the same way as the claim phase by using a biocompatible polymeric sealing material configured to press against and providing sealing between the patient's anatomical wall and the

	frame, to achieve the same or substantially the same result of a sealing material configured to form a biocompatible seal between the anatomical wall and the frame for reduced paravalvular leakage.
wherein the sealing material is attached to the frame,	The ’310 patent Accused Instrumentalities satisfy this element. For example, the ’310 patent Accused Instrumentalities comprise a sealing material wherein the sealing material is attached to the frame. For example, the sealing material is attached to the frame using stitching.  Introducing the SAPIEN 3 Ultra valve at 2, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

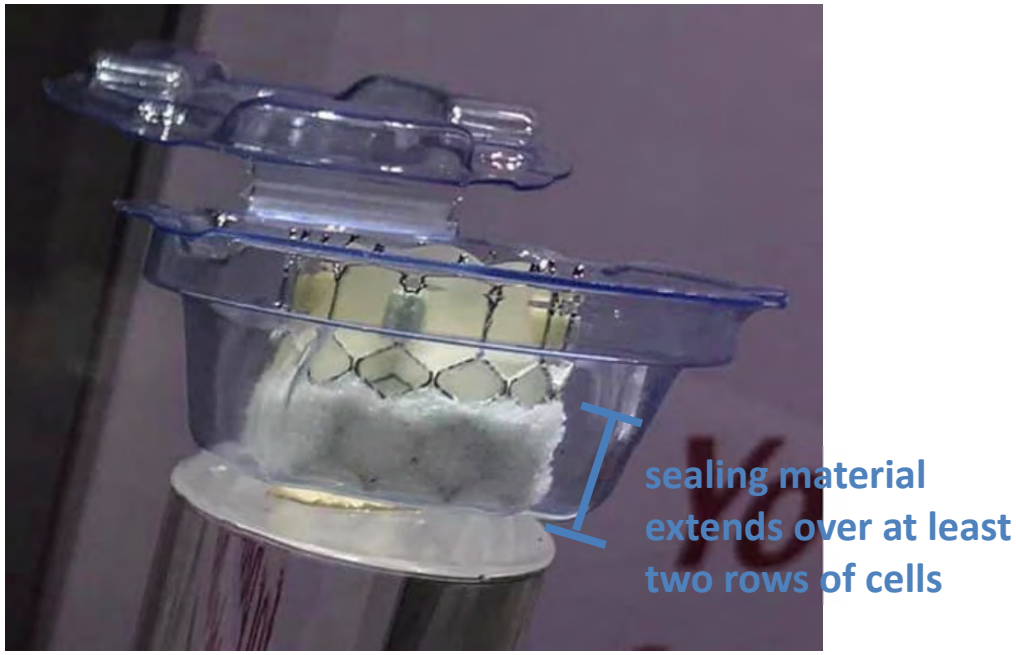


Sapien 3 Ultra image by William Suh, MD (annotated), https://twitter.com/willsuh76/status/1280708440734617600/photo/1 (D.I. 1, Ex. 7).

	 https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).
wherein the sealing material defines a height that extends over at least a first two rows of cells in the frame,	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ sealing material defines a height that extends over at least a first two rows of cells in the frame. For example, the Sapien 3 Ultra sealing skirt extends over a least two rows of cells in the frame.

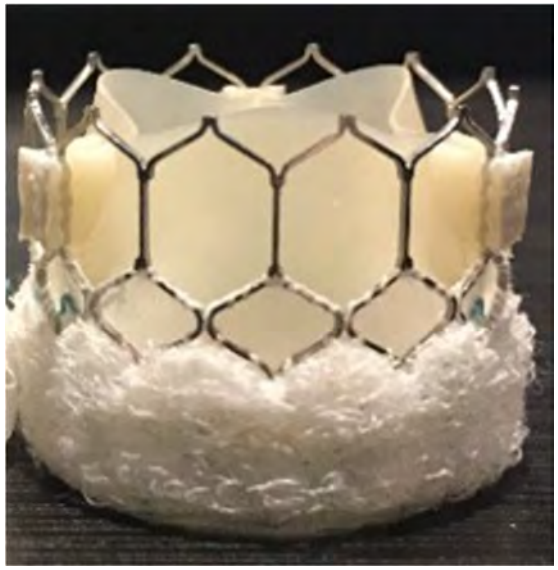


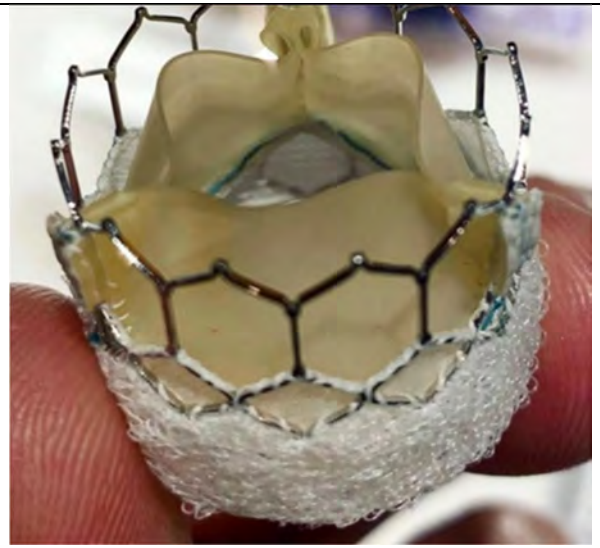
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

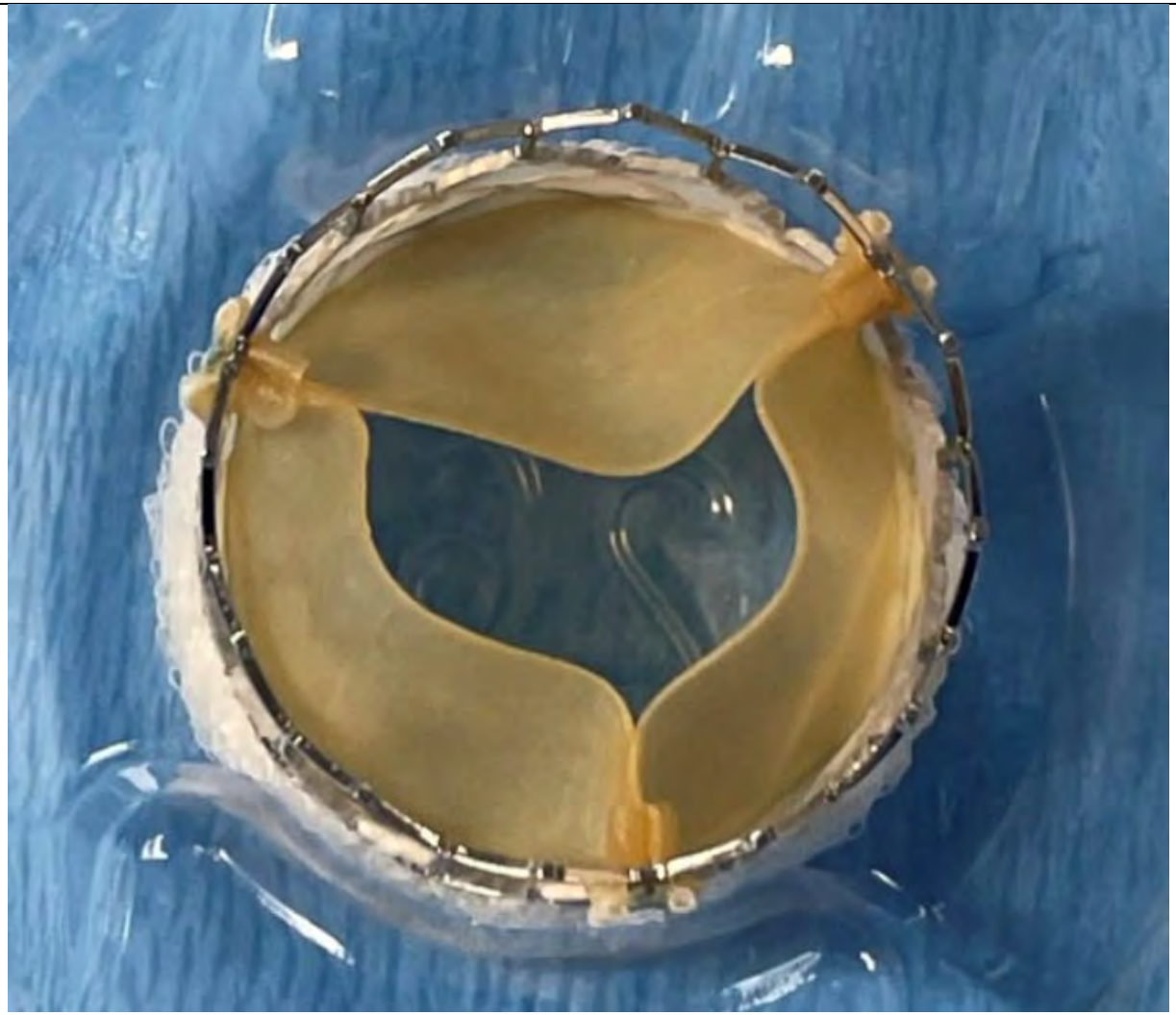


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

With respect to the phrase, "wherein the sealing material defines a height that extends over at least a first two rows of cells in the frame," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, at least two rows of cells perform the same or substantially the same function as the claim phrase by providing a collapsible and expandable structure for the sealing material to extend over, in the same or substantially the same way as the claim phase by being constructed of metal forming cells of the same or equivalent shapes and sizes, to achieve

	the same or substantially the same result of providing least two rows of cells for the sealing material to at least partially extend over.
wherein the sealing material includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame;	The ’310 patent Accused Instrumentalities satisfy this element. For example, the ’310 Accused Instrumentalities’ sealing material includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

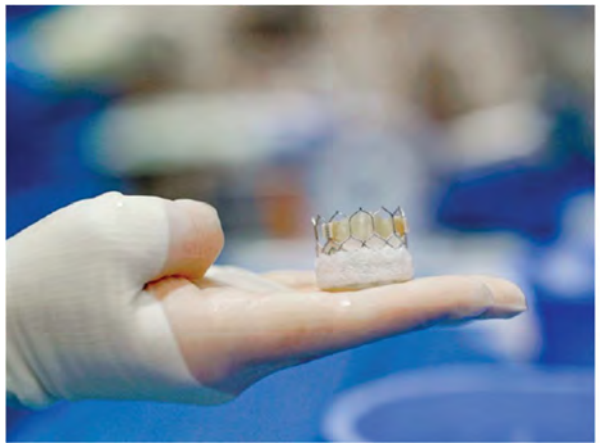
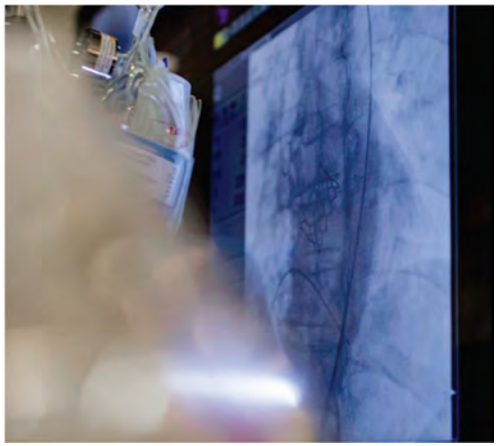
	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of outwardly extending arcuate fibers extending outwardly from frame) (D.I. 1, Ex. 29).

	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of outwardly extending arcuate fibers extending outwardly from frame) (D.I. 1, Ex. 64).

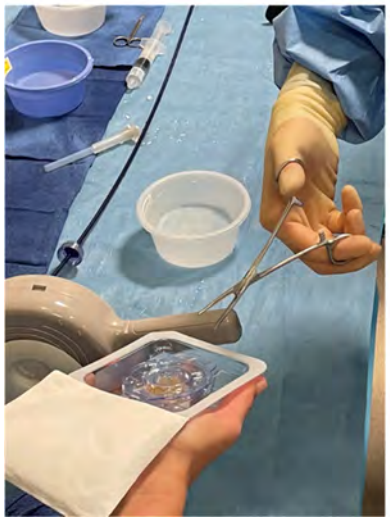


Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of outwardly extending arcuate fibers extending outwardly from frame) (D.I. 1, Ex. 3).

Further, with respect to the phrase, "wherein the sealing material includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing material including a plurality of outwardly extending fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the

	accused sealing material including a plurality of outwardly extending arcuate fibers performs the same or substantially the same function as the claim phrase by providing for low profile sealing material capable of sealing against the native leaflets, in the same or substantially the same way as the claim phase by including biocompatible polymeric arcuate fibers with “tips” extending generally outwardly that are configured to press against the native leaflets of the aorta of the patient when the valve is expanded, to achieve the same or substantially the same result of providing a sealing material configured to form a biocompatible seal between the native annulus/leaflets and frame and reduced paravalvular leakage.
wherein the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient,	The ’310 patent Accused Instrumentalities satisfy this element. For example, the ’310 patent Accused Instrumentalities are configured to be deployed endovascularly through a femoral artery of the patient. Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through the femoral artery using Edwards’ balloon catheter delivery systems.   https://twitter.com/RajTayalMD/status/1587513103127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

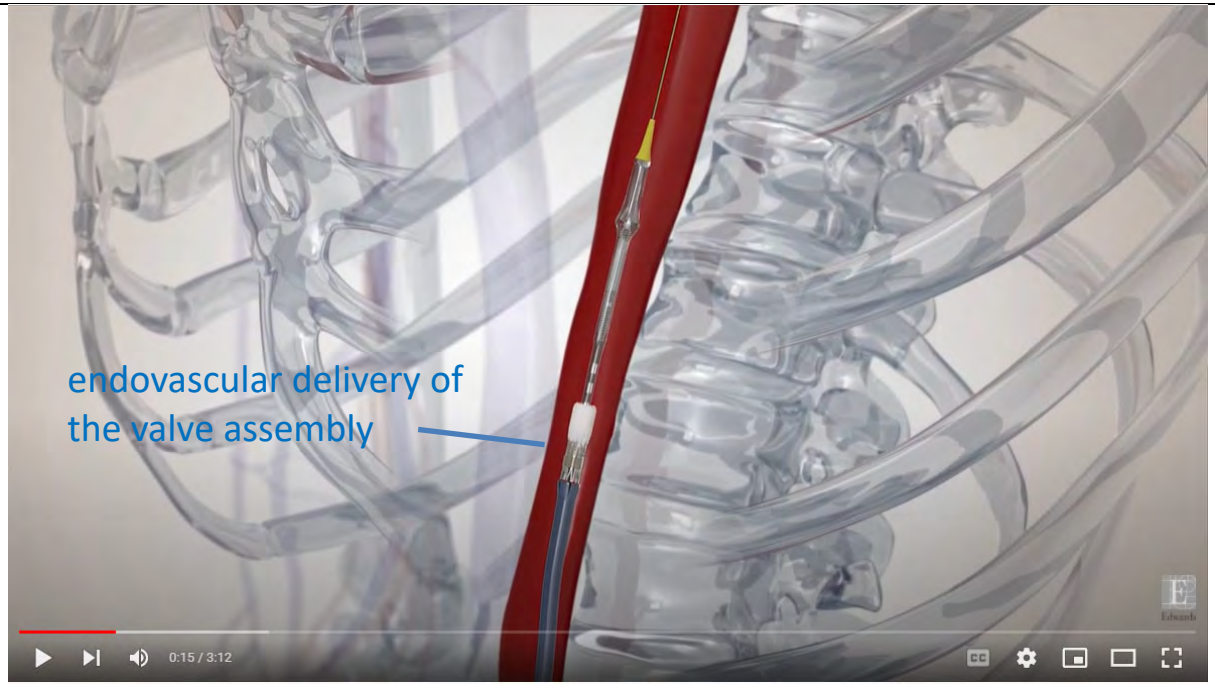




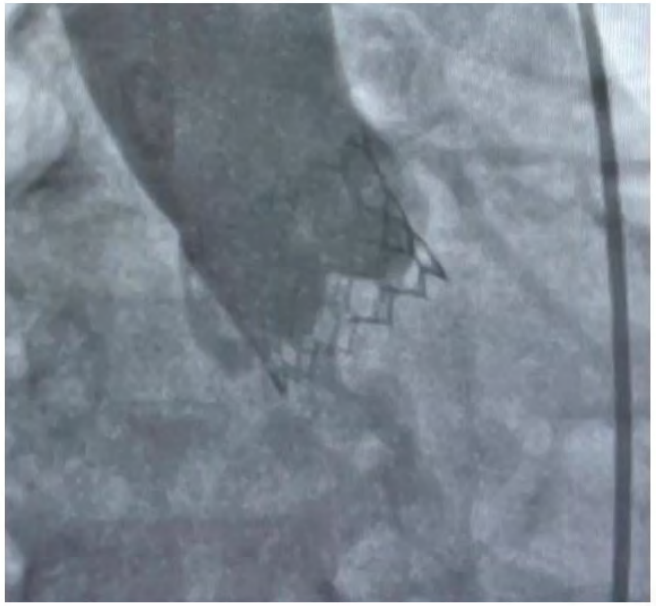
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

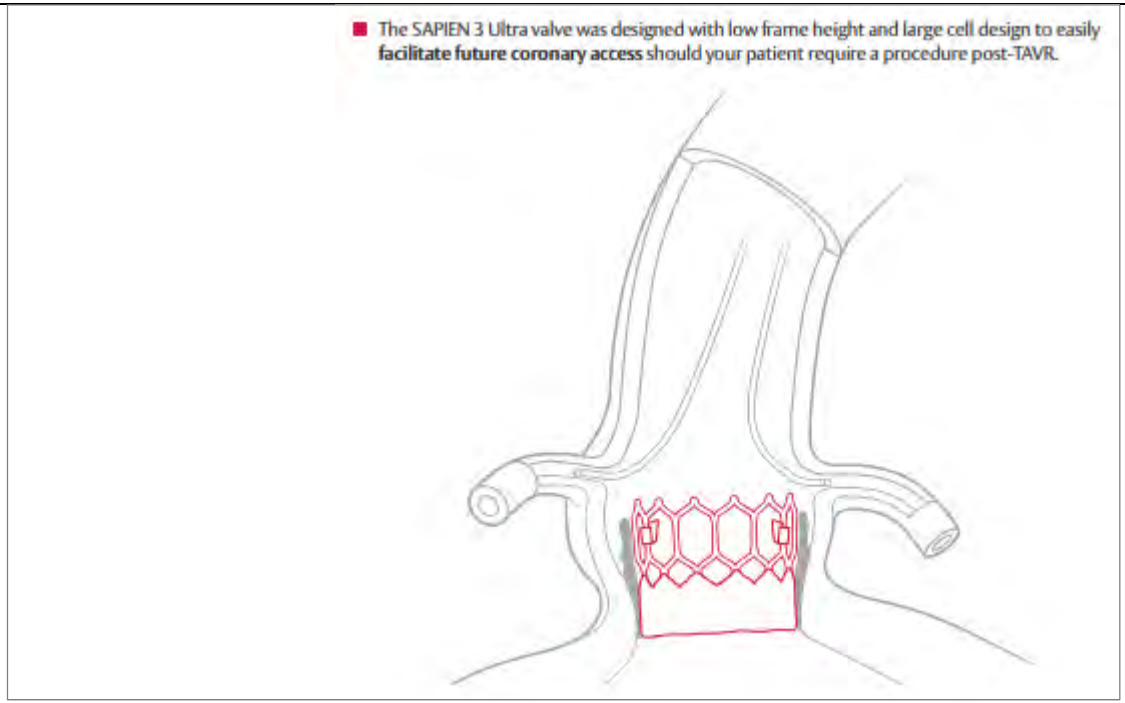


	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
wherein the heart valve assembly has a radially compressed orientation and a radially expanded orientation,	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities have a radially compressed orientation and a radially expanded orientation. The Sapien 3 Ultra designed and configured to be expandable using an Edwards’ balloon delivery system in the aorta of a patient from a radially compressed orientation into a radially expanded orientation.

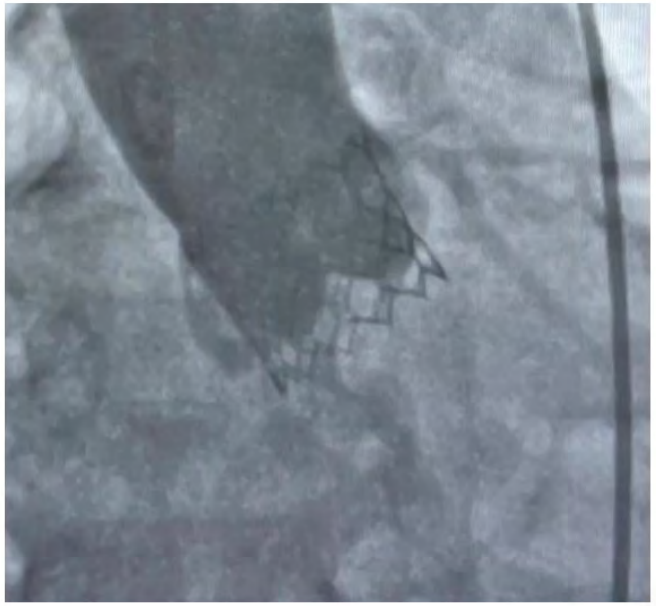
	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

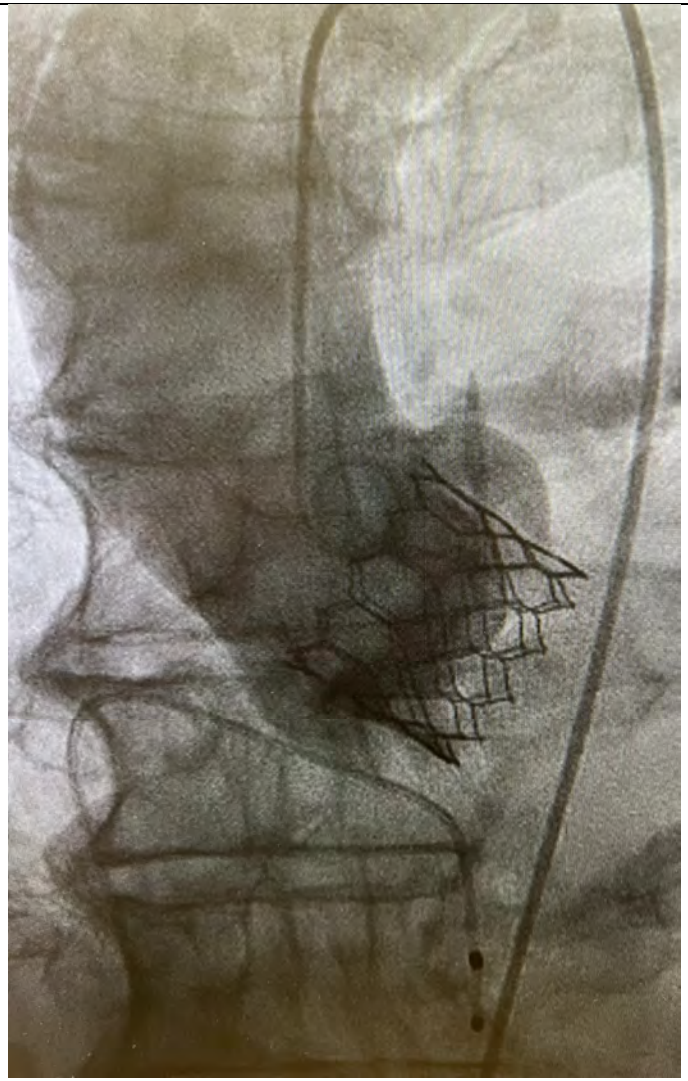
	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

	 Introducing the Sapien 3 Ultra, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

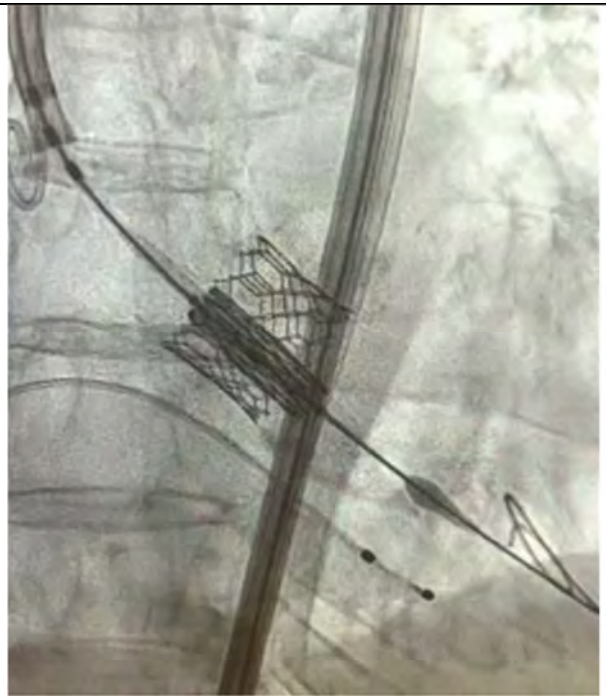


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil.(D.I. 1, Ex. 74).

	 https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

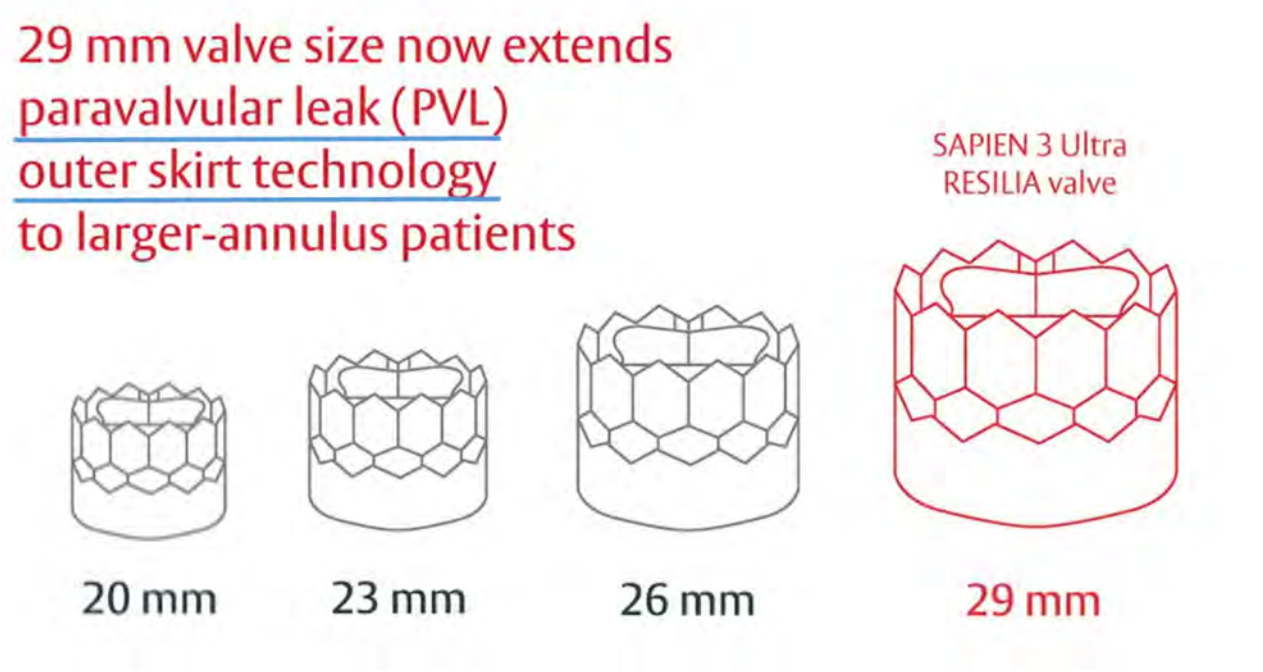
202

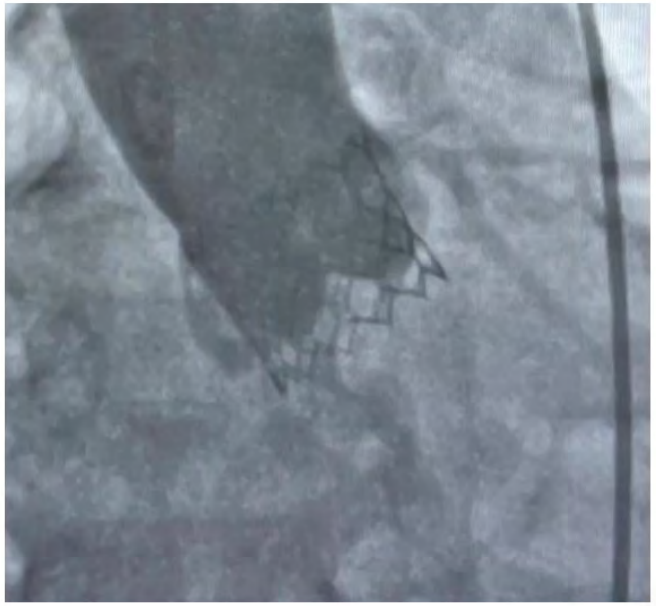
	 https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=7vNdYaSyfo8PlVNSNv2WDQ

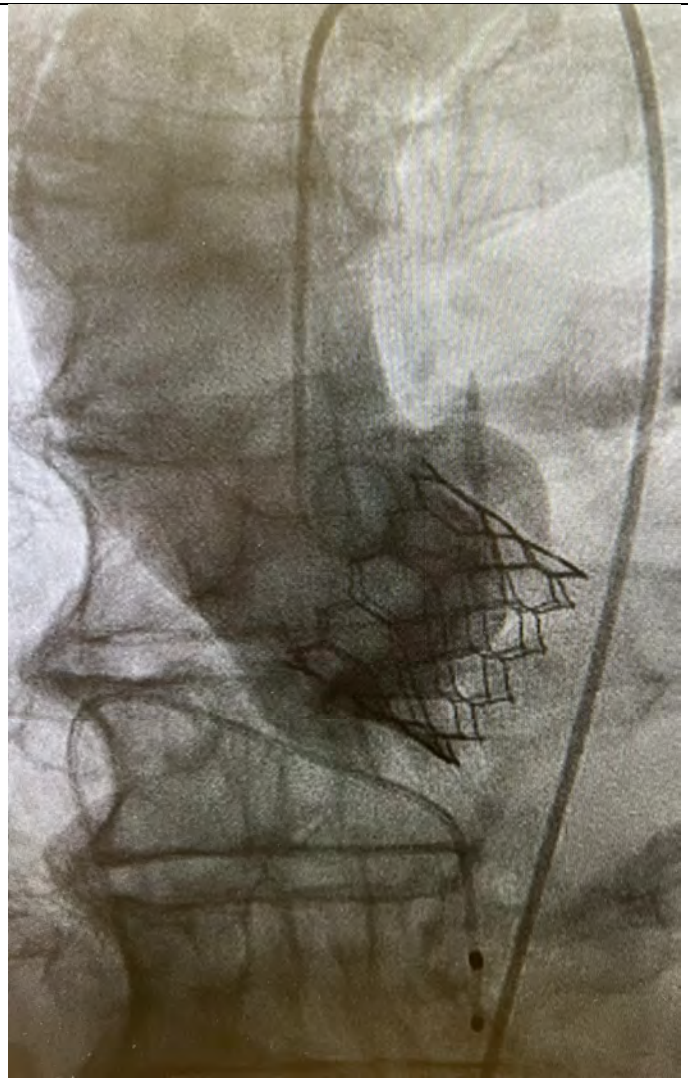


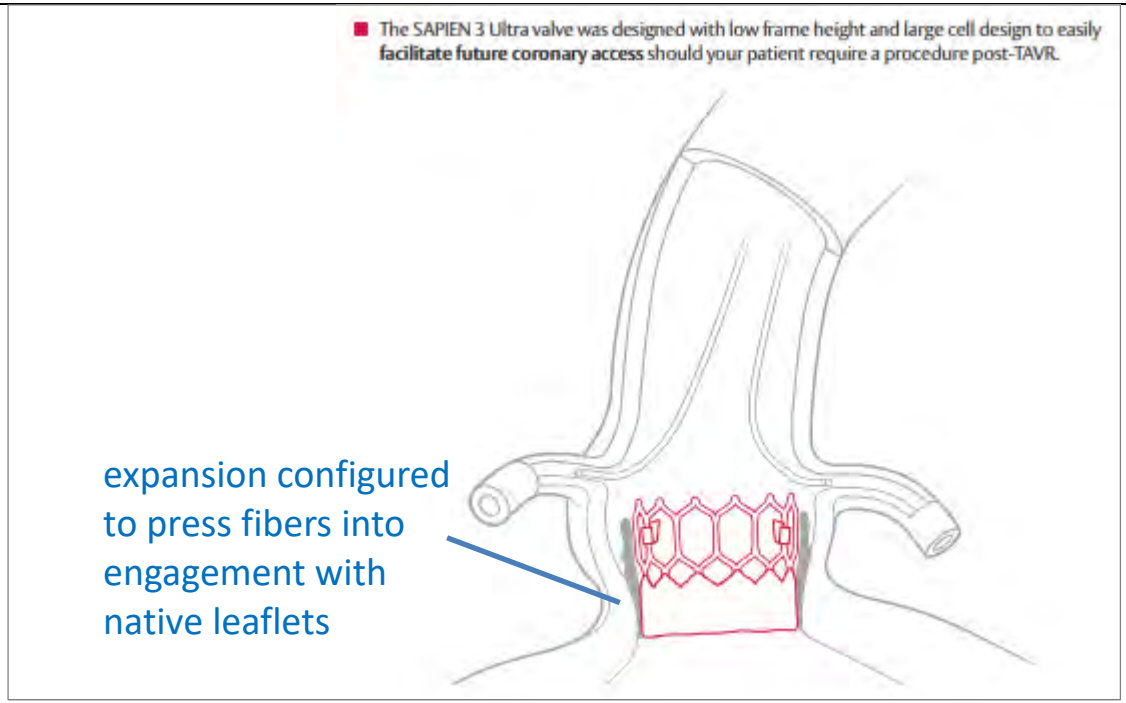
https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).
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,	The '310 patent Accused Instrumentalities satisfy this element. The '310 patent Accused Instrumentalities are configured such that 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. The Sapien 3 Ultra is configured when deployed and expanded so that outwardly extending fibers are pressed into engagement with native leaflets of the aorta of the patient.

	 https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

	 https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



Introducing the Sapien 3 Ultra, including, but not limited to the Sapien 3 Ultra Resilia valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

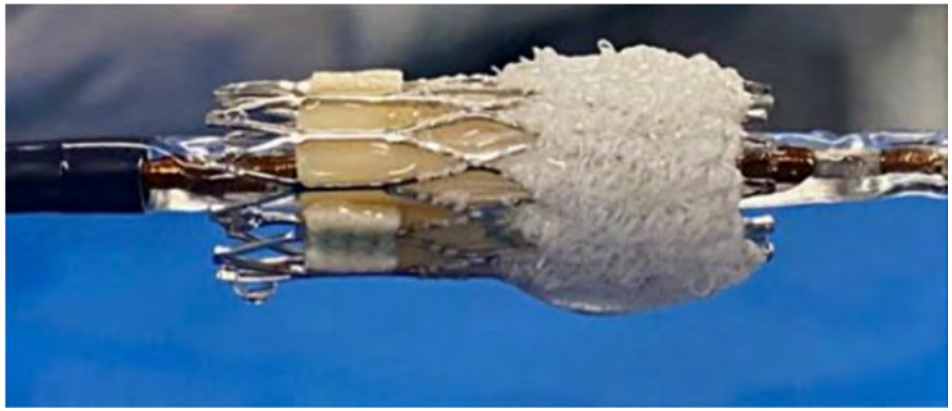
SAPIEN 3 Ultra System Case Example



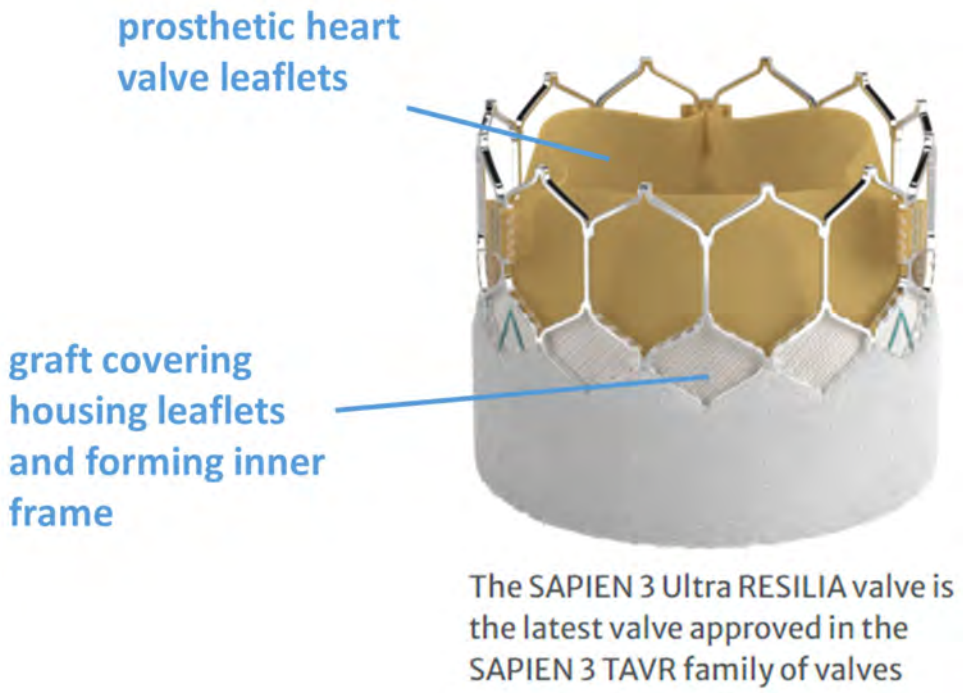


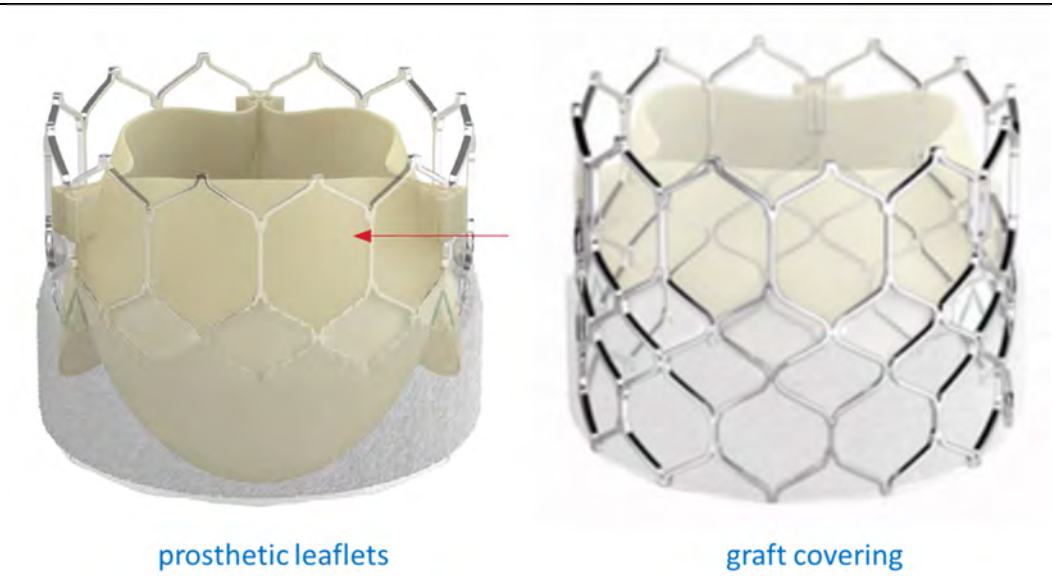
Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

With respect to the phrase, "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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by being capable of pressing at least some outwardly extending fibers against the leaflets in the aorta of the patient, in the

	same or substantially the same way as the claim phase through including sealing material with outwardly extending fibers, to achieve the same or substantially the same result of a heart valve assembly configured to press outwardly extending fibers into engagement with the native leaflets 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.	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ plurality of fibers are 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. The Sapien 3 Ultra is configured such that 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.  Ex. 48, https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (showing plurality of fibers in contact with frame in compressed orientaiton).

	 Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (showing plurality of fibers in contact with frame in expanded orientaiton). With respect to the phrase, "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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by having fibers with the frame along the height of the sealing material in the radially compressed and expanded orientations, in the same or substantially the same way as the claim phase through including low profile sealing material with radially extending arcuate fibers attached to at least a portion of the frame, to achieve the same or substantially the same result of fibers configured to be at least generally in contact with at least a portion of the frame along the height of the sealing material in the radially compressed and expanded orientations.

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.	The ’310 patent Accused Instrumentalities satisfy this element. The ’310 patent Accused Instrumentalities’ graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve. For example, the Edwards Sapien 3 Ultra graft covering extends around and houses the prosthetic heart valve and provides support directly and indirectly to the prosthetic heart valve forming an inner frame. For example, the graft covering houses the valve leaflets and is secured to the valve leaflets and the frame. To the extent required, the inner frame is balloon expandable.  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).

With respect to the phrase, "wherein the graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a graft covering inner frame that is balloon-expandable and/or that provides support and resist collapse, the identified graft covering that forms an inner frame for supporting the prosthetic heart valve, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering that forms an inner frame performs the same or substantially the same function as the claim phrase by being collapsible and expandable, as well as framing and providing support to the prosthetic heart valve, in the same or substantially the same way as the claim phase through a collapsible

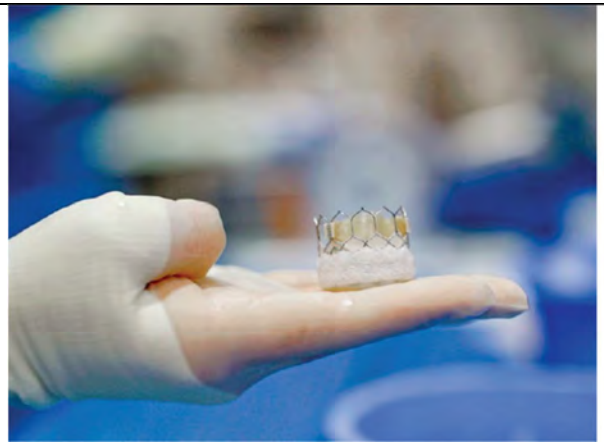
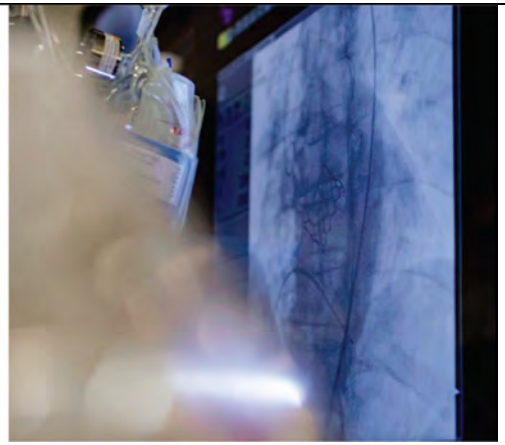
	and expandable cylindrically extending graft covering inner frame secured by stitching to the frame extending at least partially around and housing and providing sealing to the prosthetic heart valve, to achieve the same or substantially the same result of a collapsible and expandable graft covering inner frame in a TAVR valve that frames, houses, supports (directly and/or indirectly), and provides sealing to the prosthetic heart valve. *See also*, claim 11.

Exhibit C - Edwards' Infringement of U.S. Patent No. 11,491,033

Claim	Exemplary Infringement Evidence[1]
1. An endovascular prosthetic heart valve assembly having improved sealing for addressing paravalvular leakage for use in a patient, comprising:	To the extent the preamble is limiting, the '033 patent Accused Instrumentalities[2] satisfy this element. For example, the '033 patent Accused Instrumentalities are endovascular prosthetic heart valve assemblies having improved sealing for addressing paravalvular leakage for use in a patient. The '033 patent Accused Instrumentalities are designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems. Further, the '033 patent Accused Instrumentalities are designed, promoted, and configured to provide improved sealing for addressing paravalvular leakage.

[1] The exemplary evidence and infringement assertions cited herein may also be used to support any other claim element where appropriate. Aortic Innovation LLC's ("Aortic") investigation is ongoing and discovery is in its preliminary stages. Aortic hereby incorporates by reference the cover pleading to which this claim chart is attached. Aortic reserves the right to amend or supplement these contentions after further investigation and discovery from Edwards and non-parties and in accordance with the rules and schedule. Such supplemental information may include, but is not limited to, FDA submissions and correspondence, data sheets, design specifications, deposition testimony, testing information, reference designs, implementation and utilization information, and/or schematics. Aortic also reserves the right to assert additional claims of the Aortic patents-in-suit, accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products. Under the proper construction of the asserted claims and their claim terms, each element of the asserted claims is literally present in the accused products or acts accused of infringing the claim. Any and all elements found not to be literally infringed are infringed under the doctrine of equivalents because the differences between the claimed inventions and the Accused Instrumentalities, if any, are insubstantial. Aortic further reserves the right to accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products, based on further investigation and discovery, the claim construction process, the Court's rules, and/or other circumstances so meriting.

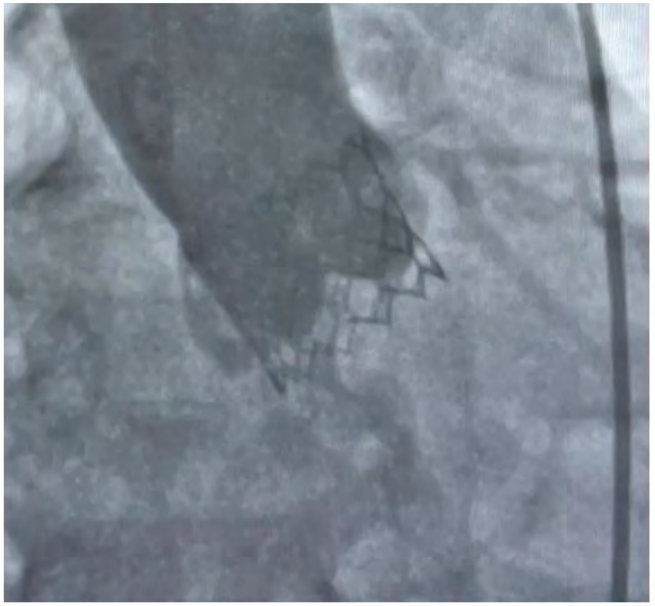
[2] "Accused Instrumentalities" refers to all models, versions, and sizes of Edwards's Sapien 3 Ultra devices, including, but not limited to Edwards Sapien 3 Ultra valves with non-Resilia valve leaflets and Edwards Sapien 3 Ultra Resilia valves, which Aortic understands to be the same as the Sapien 3 Ultra, but with Edwards' Resilia valve leaflet tissue which Aortic understands uses "a bovine (cow) heart tissue that has been treated with Edwards' technology to block calcium build-up on the valve." Discovery is ongoing and Aortic reserves the right to amend or supplement the identified Accused Instrumentalities to the extent that additional relevant information is obtained during discovery.

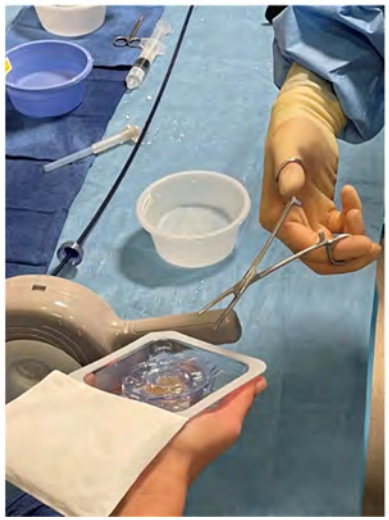
	  https://twitter.com/RajTayalMD/status/1587510333127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

3

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil.



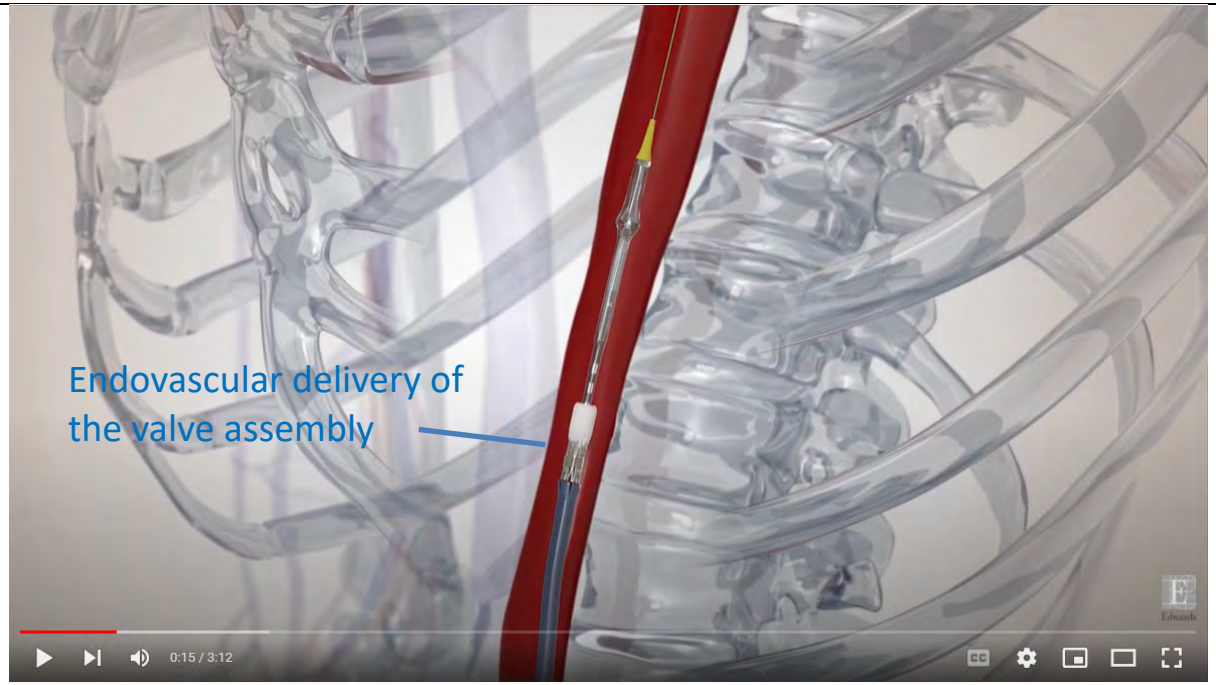


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra[3] is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[3] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.



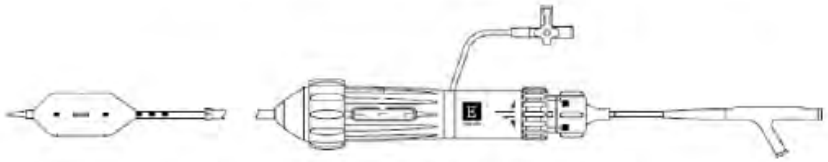
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



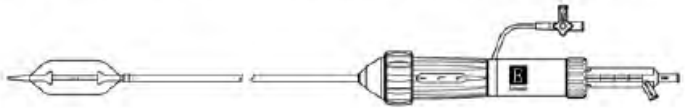
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

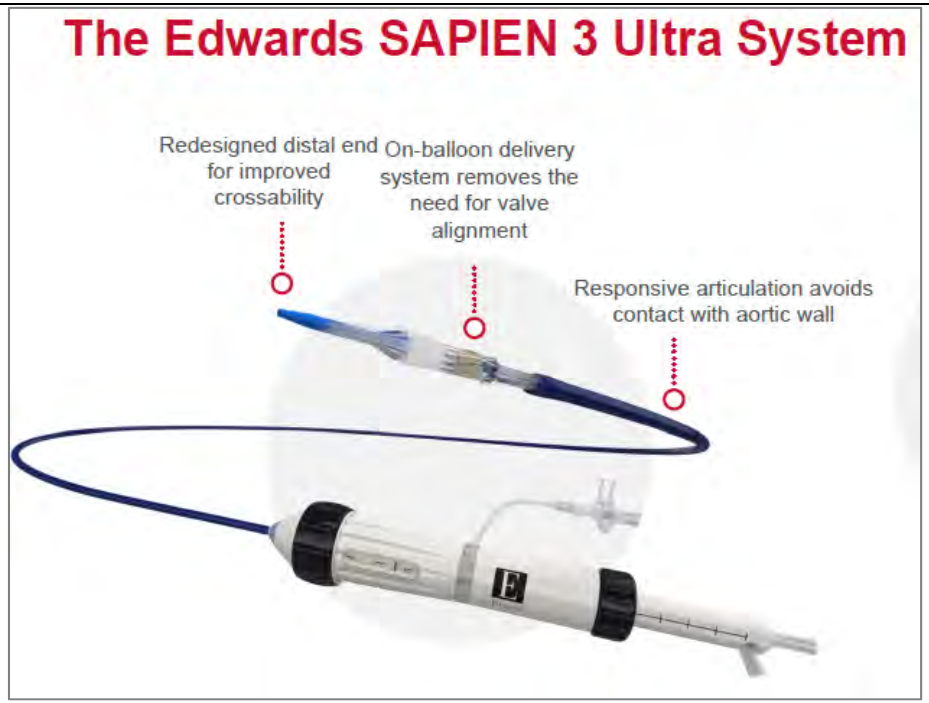
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

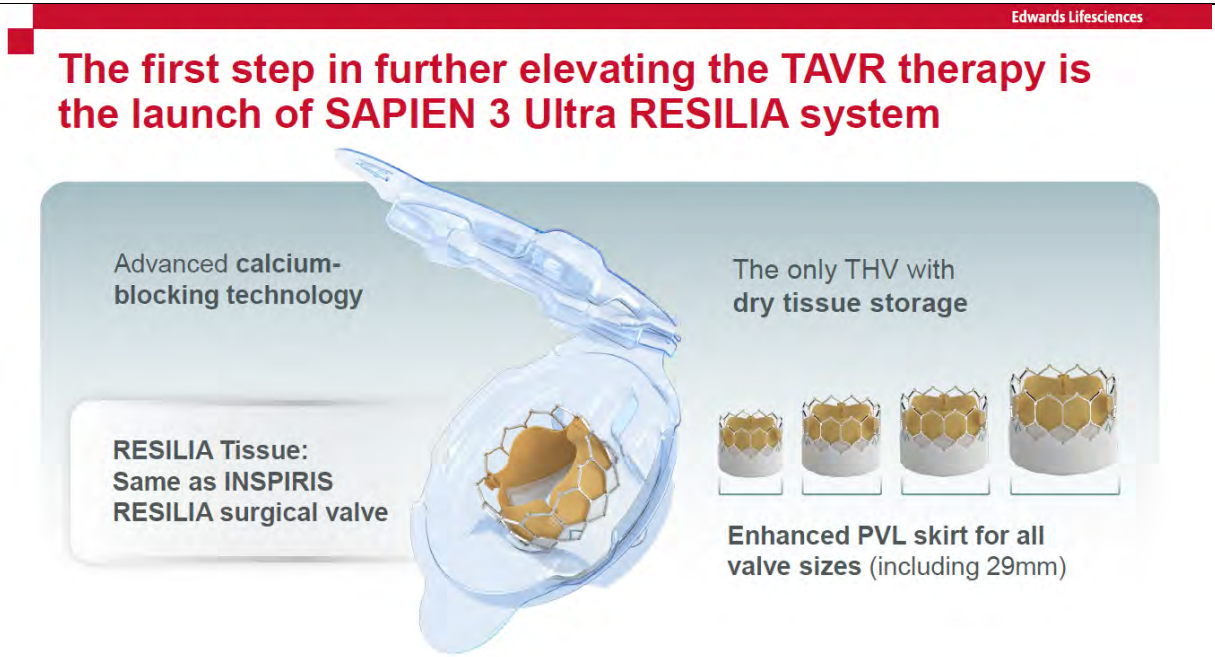
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

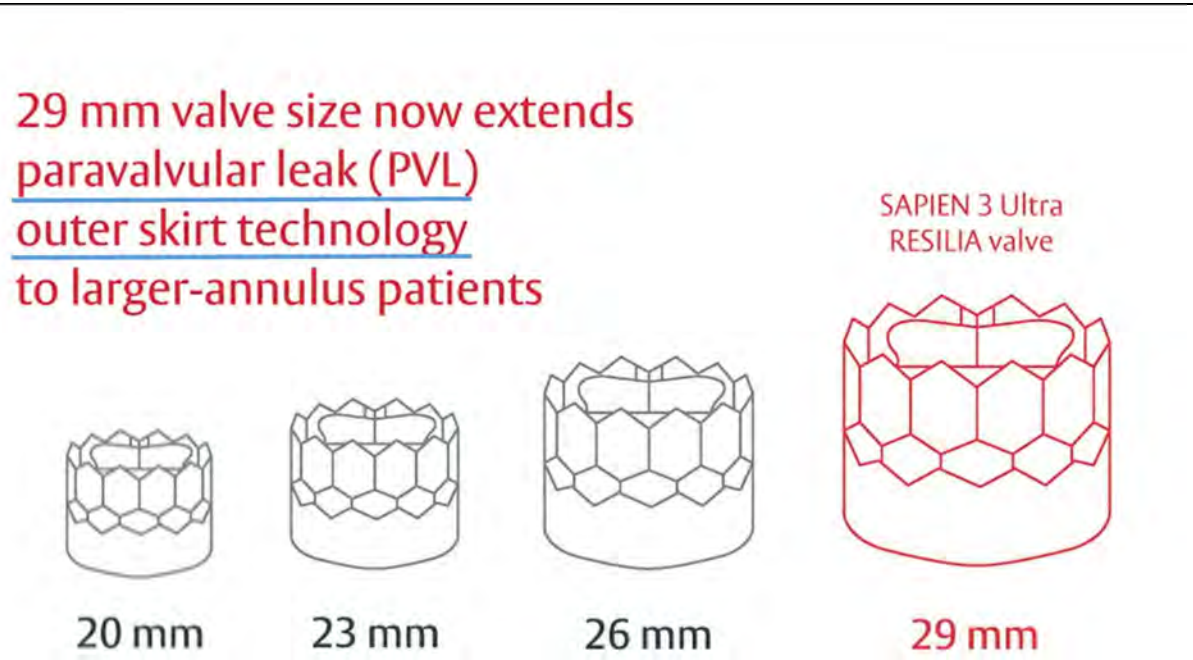
Additional Equipment:

- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

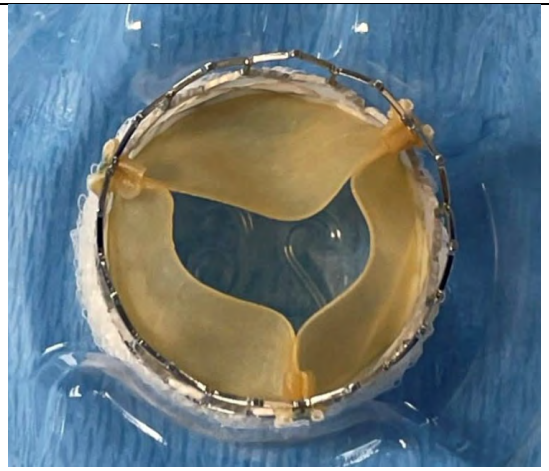
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’033 patent Accused Instrumentalities and infringes the ’033 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).

	 https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



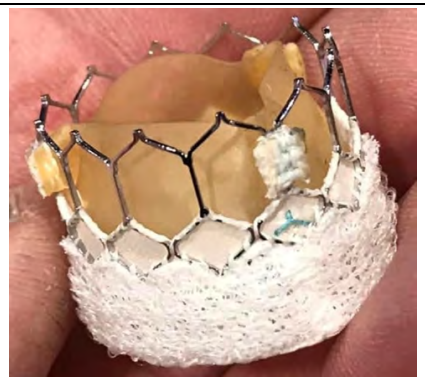
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587510333127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



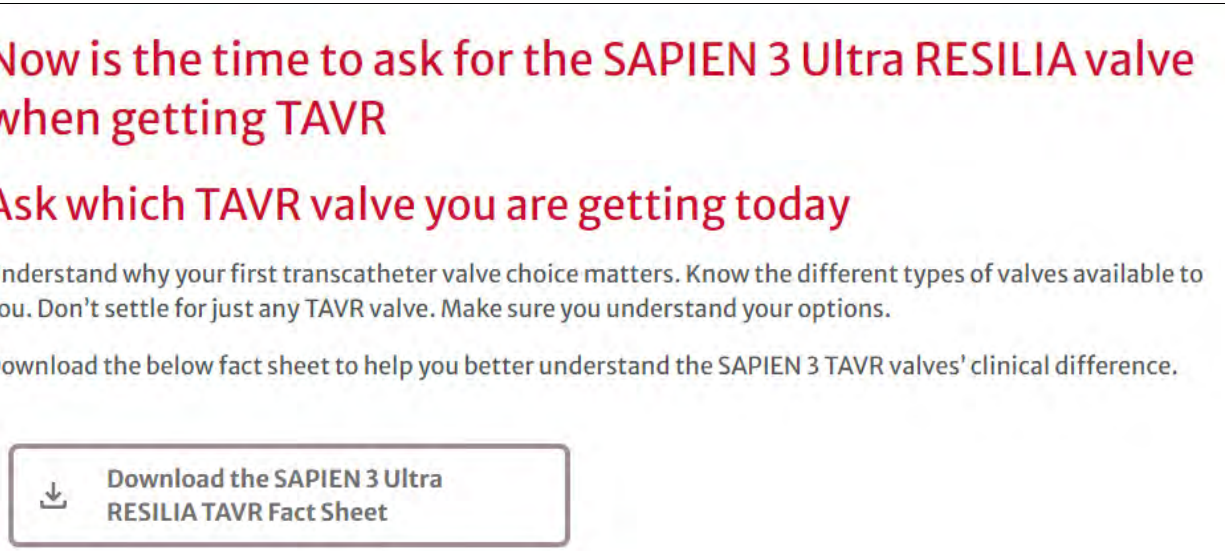

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the '033 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also

	include repeated mentions of the Sapien 3 Ultra product. *See* https://ir.edwards.com/events-presentations/; https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '033 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '033 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '033 asserted claims are infringed when Edwards offers for sale and sells the '033 patent Accused Instrumentalities. Edwards offers for sale and promotes the '033 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 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.



https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	The SAPIEN 3 Ultra RESILIA valve gives patients even more reason to ask for a specific TAVR valve  **The SAPIEN 3 Ultra RESILIA valve is the only TAVR valve with RESILIA tissue[1‡]** • Both the SAPIEN 3 Ultra RESILIA valve and the leading surgical valves use RESILIA tissue, known to block calcium build-up on the tissue, which could potentially allow the valve to last longer.[1‡] • Before today, the RESILIA tissue was only approved to be used on surgical heart valves[‡] **What are you waiting for? Understand why your choice of TAVR valve matters** https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61). On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement# Further, the '033 patent asserted claims 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 in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the ’033 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards’ direct and induced infringement. For further example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe the asserted ’033 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a “watchful eye” over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards’s inducement, Edwards’s affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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.

	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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards’s affirmative acts of marketing, selling and offering to sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ combination and use of the Accused Instrumentalities, such that the ’033 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards’ knowledge of Aortic’s inventions, the patents-in-suit (including the ’033 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
a frame formed of a plurality of cells,	The ’033 patent Accused Instrumentalities satisfy this element. The ’033 patent Accused Instrumentalities comprise a frame formed of a plurality of cells. For example, the Sapien 3 Ultra frame is formed of a plurality of cells.

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.



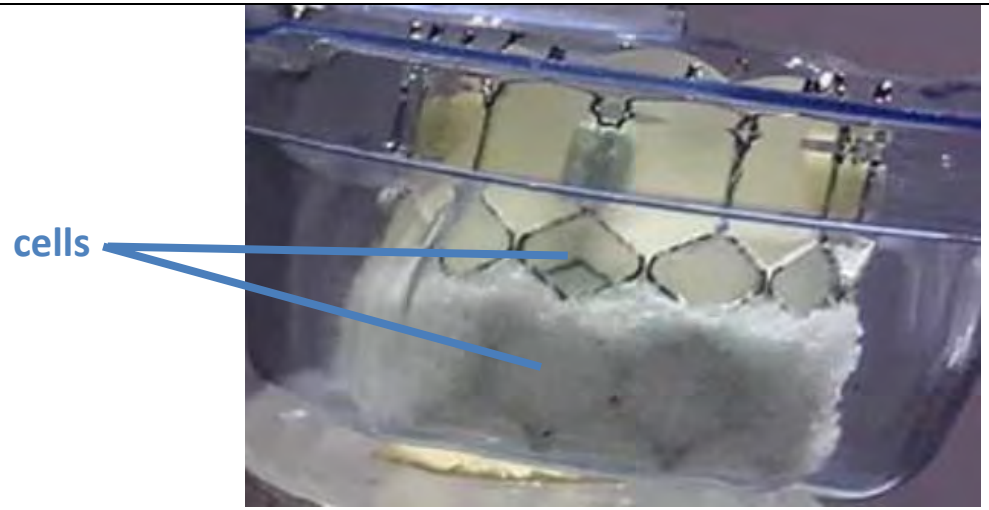
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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

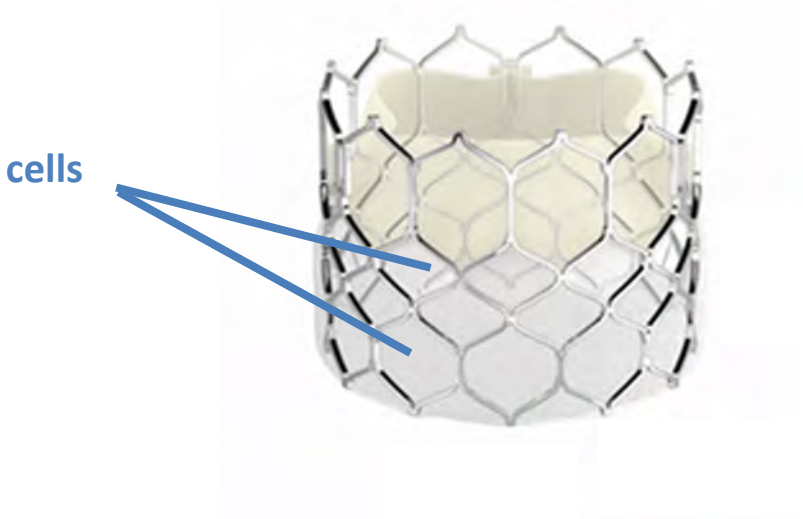
Table 1

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 (D.I. 1, Ex. 44).



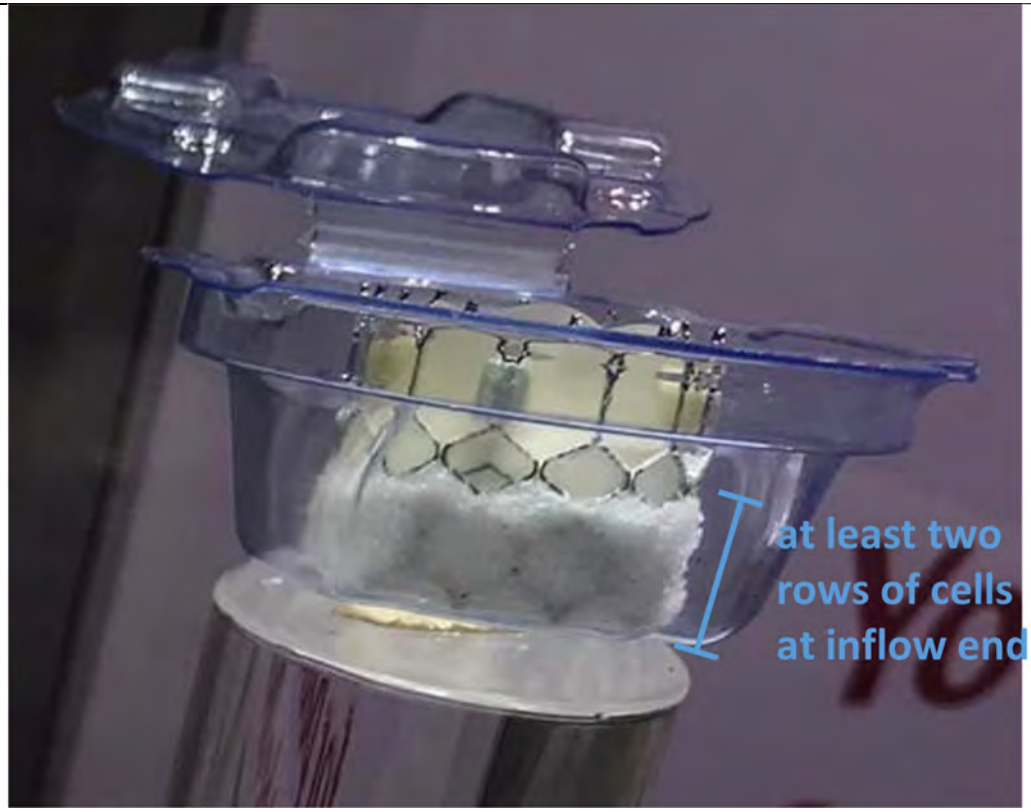
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).



	https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). *See also*, evidence for preceding elements above. With respect to the phrase, "a frame formed of a plurality of cells", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material formed in an open cell configuration with an equivalent frame shape with cells with the capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy.
wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,	The '033 patent Accused Instrumentalities satisfy this element. The '033 patent Accused Instrumentalities' plurality of cells defines at least two rows of cells at an inflow end of the frame. For example, the Sapien 3 Ultra frame includes at least two rows of cells at an inflow end of the frame.



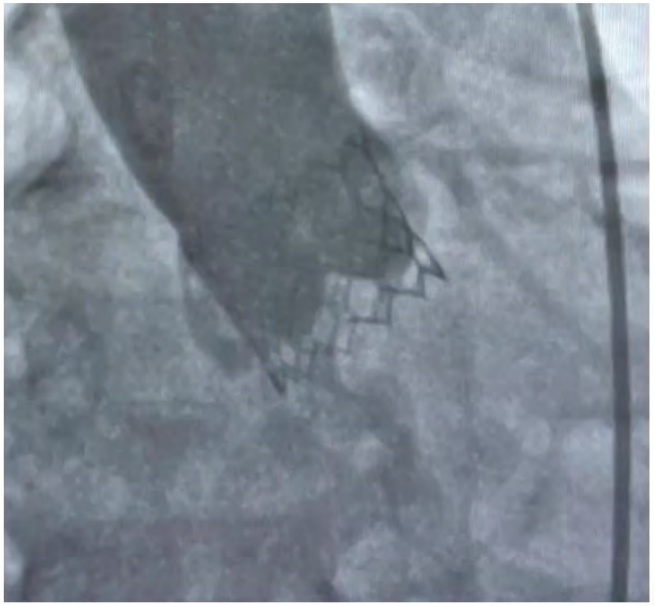
https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (D.I. 1, Ex. 33).



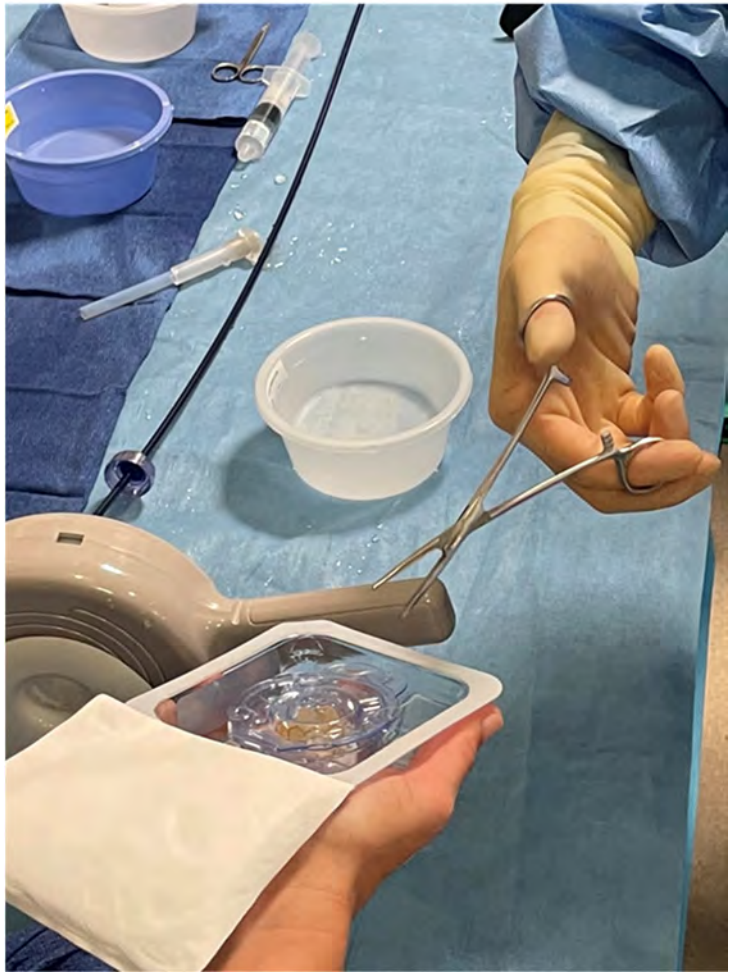
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).

With respect to the phrase, "wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused plurality of cells defines at least two rows of cells

	perform the same or substantially the same function as the claim phrase by allowing the frame to be compressed to a low profile and expanded, in the same or substantially the same way as the claim phase by being constructed of metal struts forming cells of the same or similar shapes and sizes, to achieve the same or substantially the same result of a plurality of cells defining 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;	The ’033 patent Accused Instrumentalities satisfy this element. The ’033 patent Accused Instrumentalities comprise a frame that is radially expandable from a radially compressed orientation to a radially expanded orientation. For example, the Sapien 3 Ultra is packaged and provided by Edwards in a radially expanded configuration. The Sapien 3 Ultra is designed by Edwards to be crimped onto an Edwards’ balloon delivery system in a radially compressed orientation. The Sapien 3 Ultra is also designed to be expanded using an Edwards’ balloon delivery system in the aorta of a patient into a radially expanded orientation.  Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil.

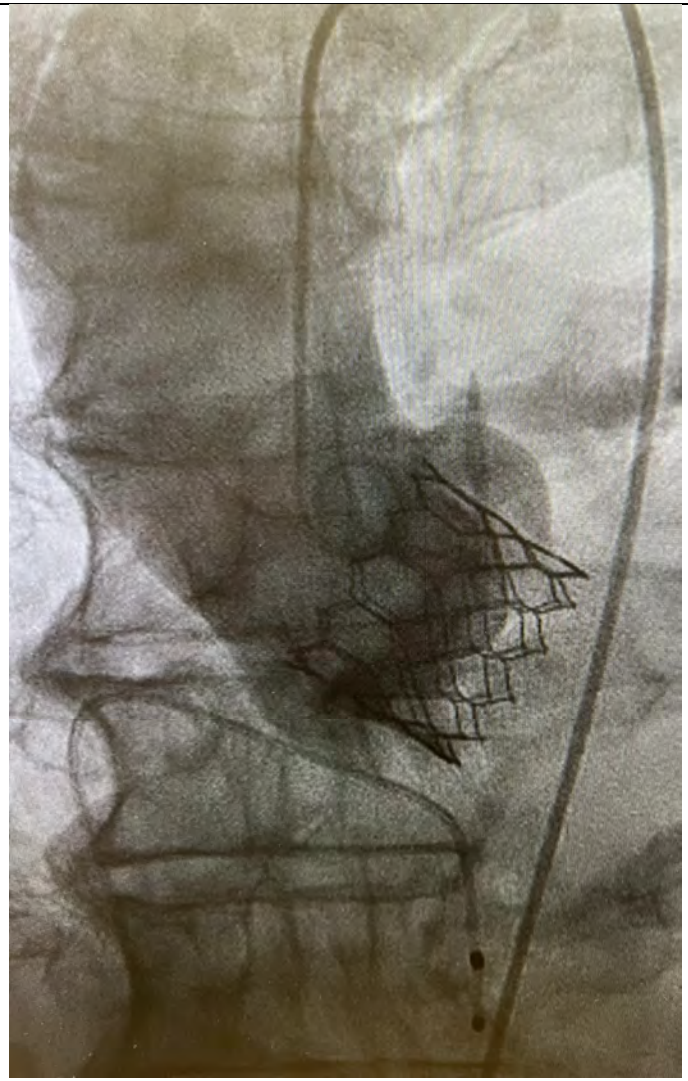
	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

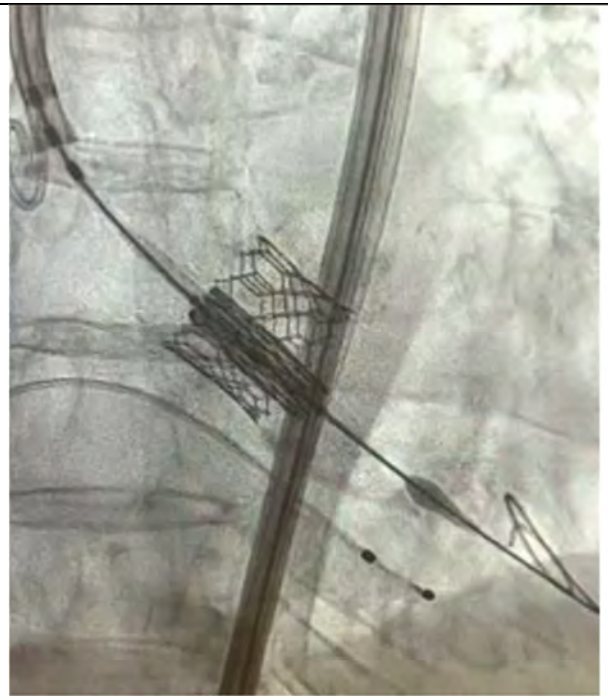


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

34



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=7vNdYaSyfo8PlVNSNv2WDQ

35



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

SAPIEN 3 Ultra System Case Example





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

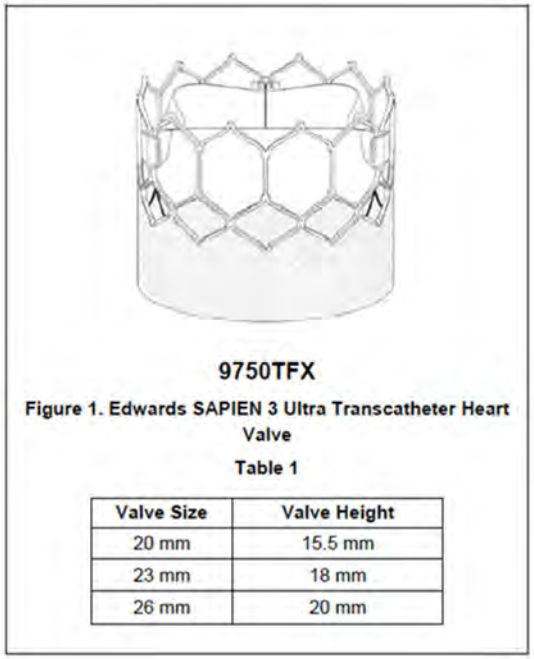
1.0 Device Description

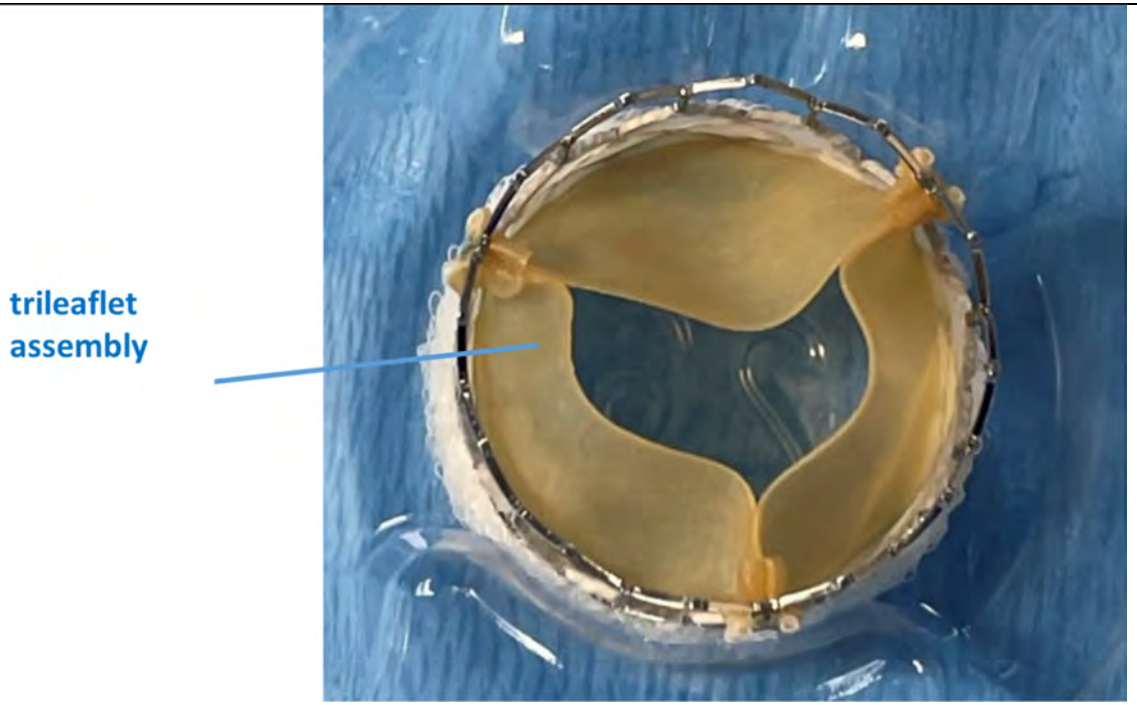
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve (THV) System

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 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a leaflet assembly within the frame;	The ’033 patent Accused Instrumentalities satisfy this element. The ’033 patent Accused Instrumentalities comprise a leaflet assembly within the frame. For example, the Sapien 3 Ultra devices comprise a bovine pericardial tissue trileaflet assembly and/or Resilia tissue trileaflet assembly within the frame.



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).

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 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
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	The ’033 patent Accused Instrumentalities satisfy this element. The ’033 patent Accused Instrumentalities comprise 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. For example, the Edwards Sapien 3 Ultra has a polymer covering made from PET that is inward of the frame and engaged with the leaflet assembly. Further, the Sapien 3 Ultra polymer covering is positioned radially inward of the frame and helps provide for sealing against paravalvular leakage as discussed further below.  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (annotations added) (showing polymer covering radially inward of the frame engaged with the leaflet assembly) (D.I. 1, Ex. 33).

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.



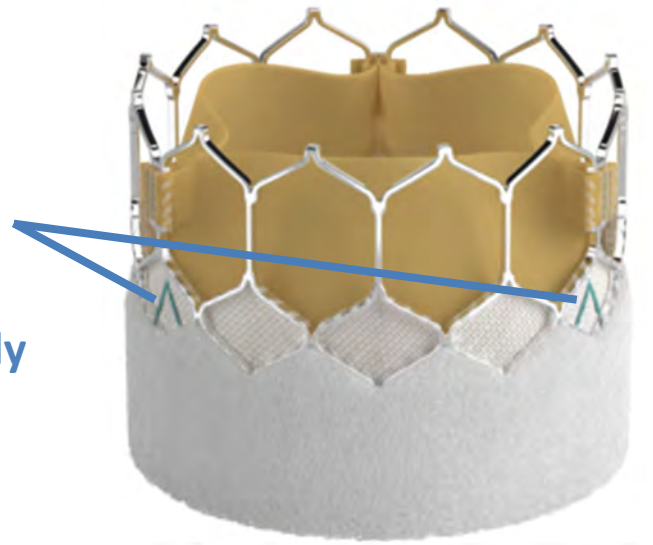
9750TFX

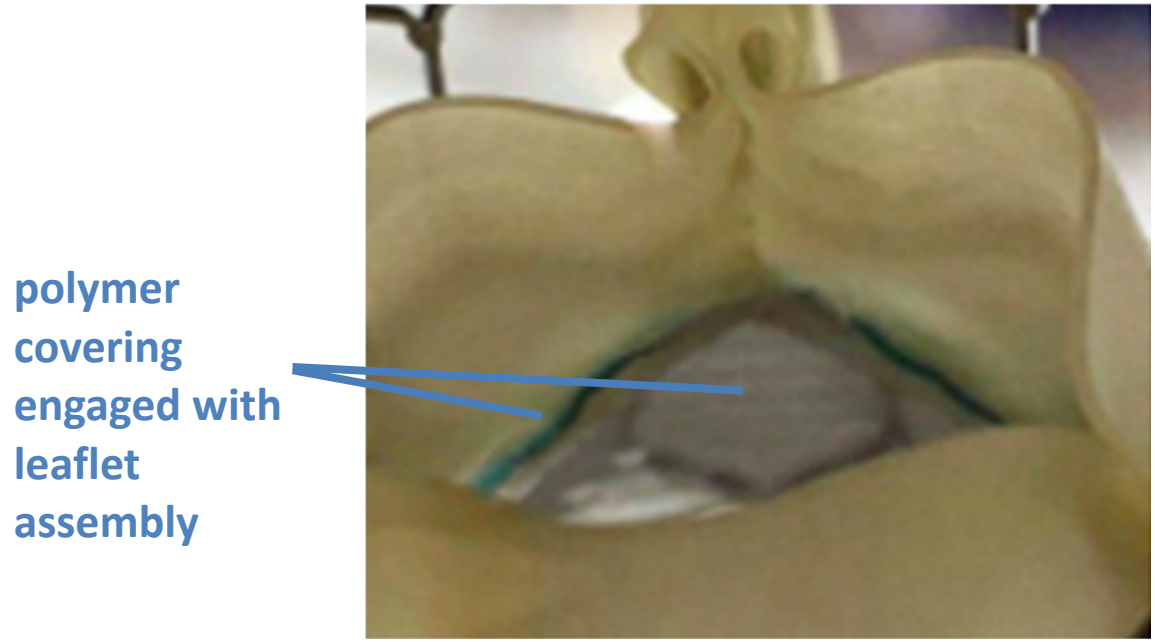
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

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

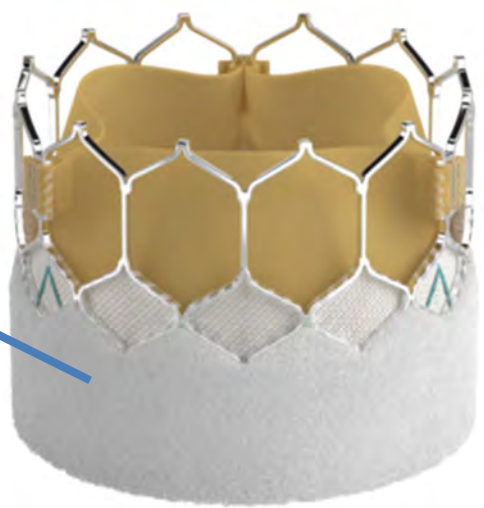
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

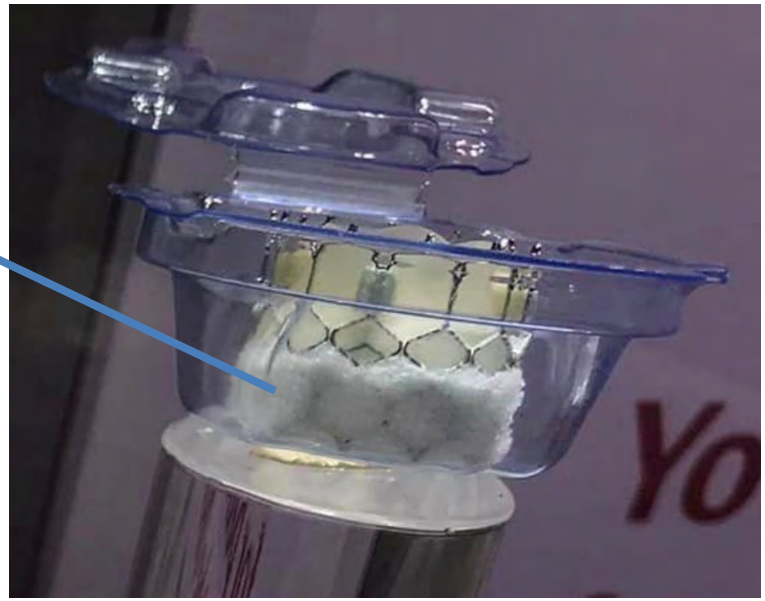
	 The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

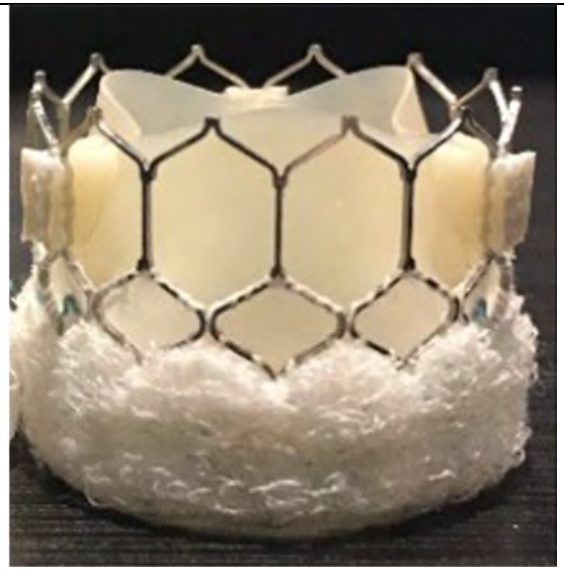


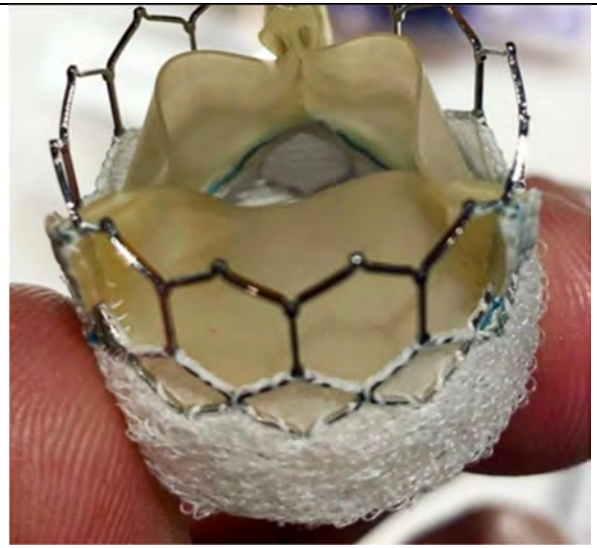
https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

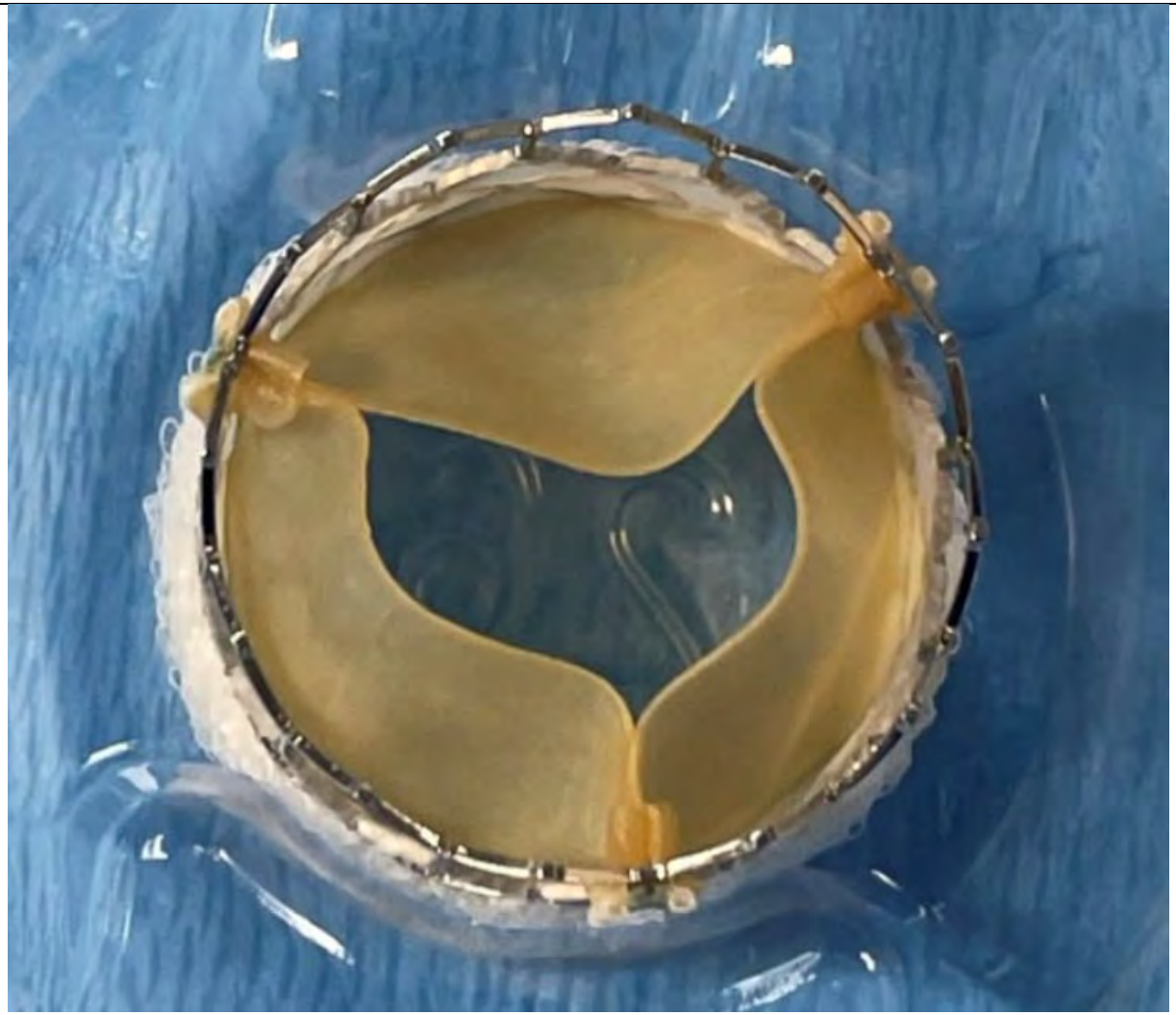
With respect to the phrase, "a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a polymer covering positioned radially inwardly of the frame and radially outwardly of the leaflet assembly, the identified polymer coverings are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused polymer covering performs the same or substantially the same function as the claim phrase by covering at least portions of the leaflet assembly and providing sealing thereto, in the same or substantially the same way as

	the claim phase through including a polymer covering that is positioned at least partially radially outward of the leaflet assembly and radially inward of the frame and by being attached to the leaflet assembly, to achieve the same or substantially the same result of a polymer covering configured to cover and/or seal or partially cover and/or seal the leaflet assembly.
a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage,	The ’033 patent Accused Instrumentalities satisfy this element. The ’033 patent Accused Instrumentalities comprise a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage. For example, the Edwards Sapien 3 Ultra includes a sealing skirt that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage. **sealing assembly that includes arcuate fibers extending from frame for preventing paravalvular leaks**  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves

	https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61). sealing assembly that includes arcuate fibers extending from frame for preventing paravalvular leaks  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3). For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame.

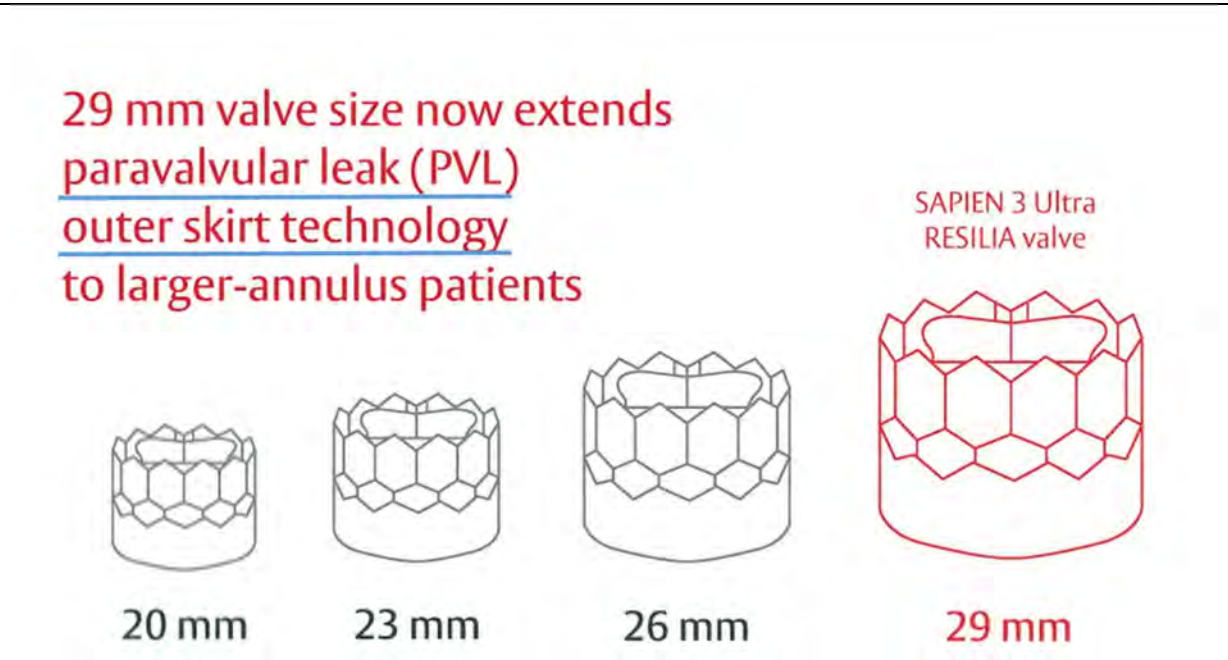
	 Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).	

	 https://www.instagram.com/p/BysjboFBLiG/ (showing sealing material with arcuate fibers extending away from frame) (D.I. 1, Ex. 29).

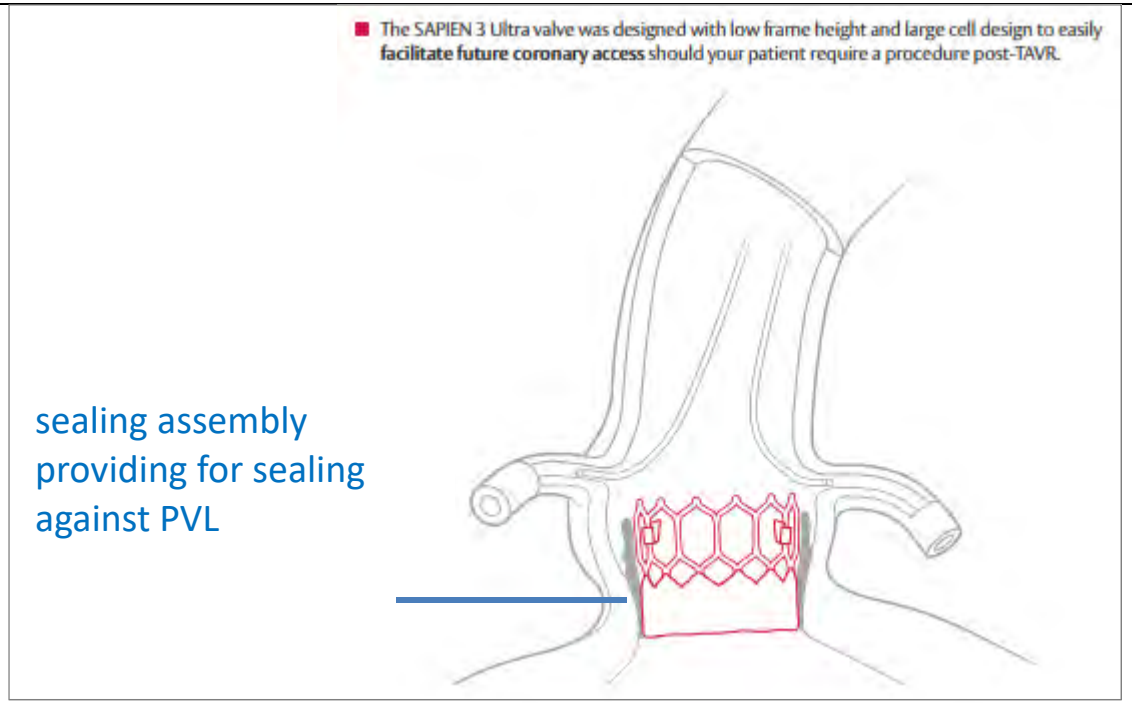


https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing sealing material with arcuate fibers extending away from frame) (D.I. 1, Ex. 64).

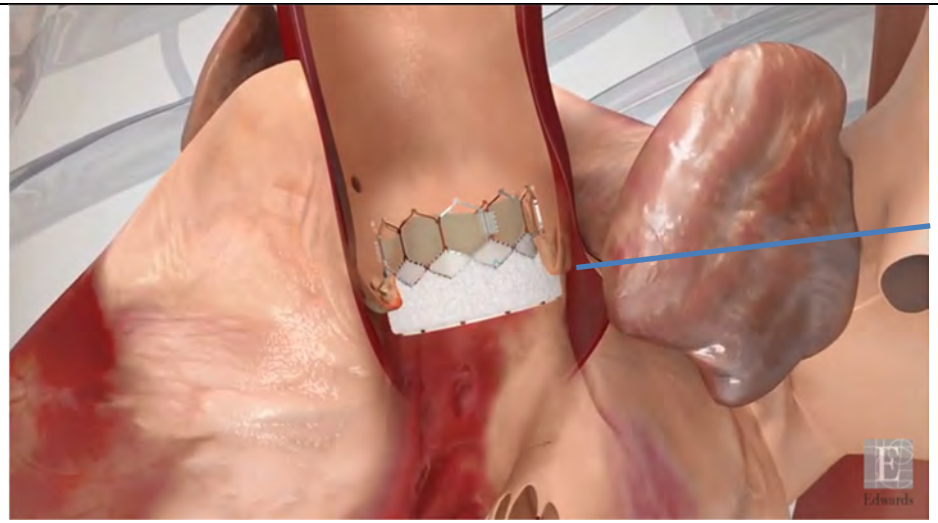
	 Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing sealing material with arcuate fibers extending away from frame) (D.I. 1, Ex. 3).



https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



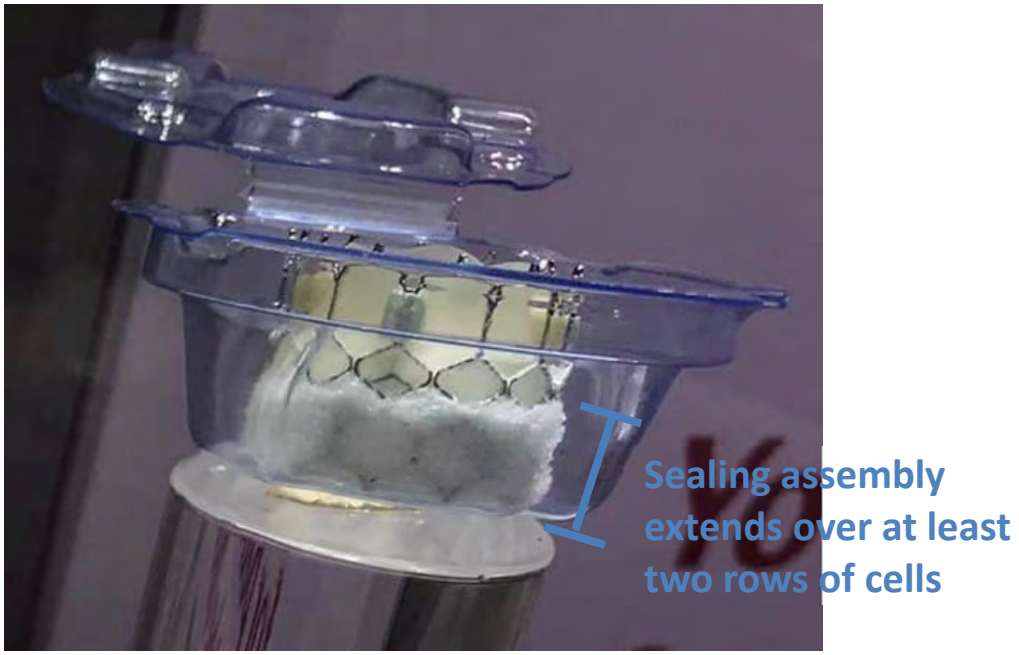
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

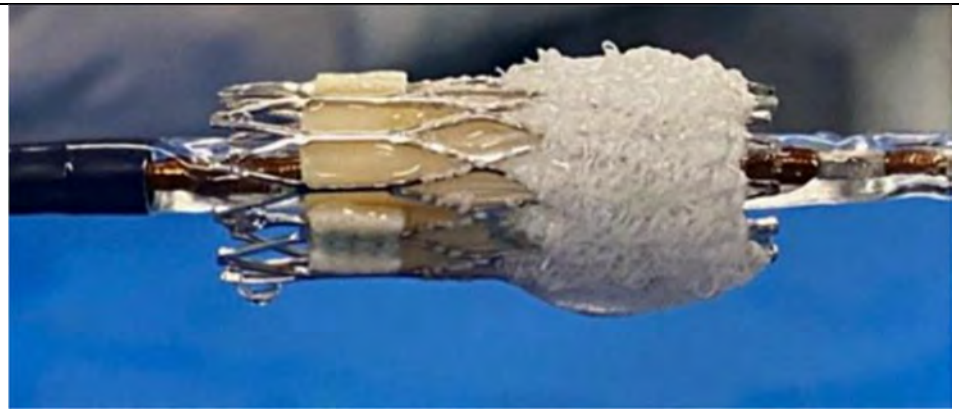


"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

Further, with respect to the phrase, "a sealing assembly that includes a plurality of arcuate fibers that extend away from the frame for providing sealing against paravalvular leakage" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the sealing assembly does not allow visibility of the frame or that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing assembly formed of outwardly extending fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused sealing assembly performs the same or substantially the same function as the claim phrase by providing for low profile sealing assembly capable of providing sealing between the anatomical wall and the frame, in the same or substantially the same way as the claim phase by using a biocompatible polymeric sealing assembly with arcuate fibers extending from the frame that are configured to press against and providing sealing between the patient's anatomical wall and the frame, to achieve the

	same or substantially the same result of a sealing assembly configured to form a biocompatible seal between the anatomical wall, frame, and graft covering for reduced paravalvular leakage.
wherein the sealing assembly extends over each of the at least two rows of cells,	The ’033 patent Accused Instrumentalities satisfy this element. The ’033 patent Accused Instrumentalities’ sealing assembly extends over each of the at least two rows of cells. For example, the Sapien 3 Ultra sealing skirt extends over a least two rows of cells in the frame.  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3). *See also*, "at least two rows of cells" element.
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,	The '033 patent Accused Instrumentalities satisfy this element. The '033 patent Accused Instrumentalities' sealing assembly lays against the frame when the prosthetic heart valve assembly is in the radially compressed orientation and the radially expanded orientation. The Sapien 3 Ultra is configured such that the sealing assembly lays against the frame when the prosthetic heart valve assembly is in the radially compressed orientation and the radially expanded orientation.



https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48) (showing sealing assembly laying against the frame in compressed orientation).

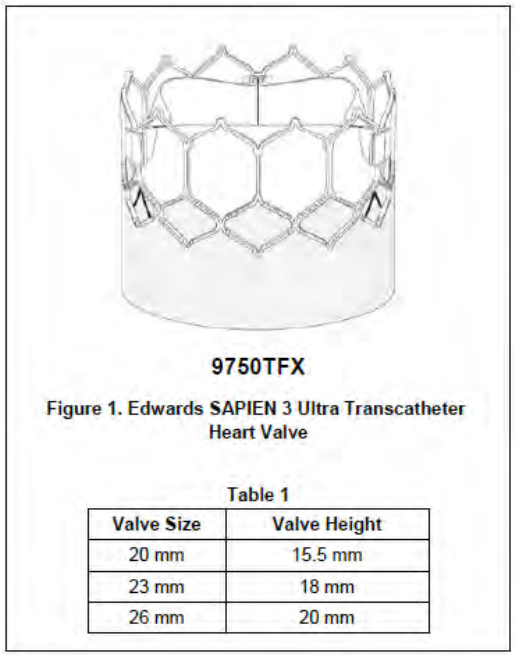


https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65) (showing sealing assembly laying against the frame in expanded orientation).



Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3) (showing sealing assembly laying against the frame in expanded orientation).

With respect to the phrase, "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," Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim

	phrase by having the sealing assembly laying against the frame in the radially compressed and expanded orientations, in the same or substantially the same way as the claim phase through including low profile sealing assembly attached to and contacting the frame, to achieve the same or substantially the same result of a sealing assembly configured to at least generally lay against the frame in the radially compressed and expanded orientations.
wherein the prosthetic heart valve assembly is sized and shaped to be endovascularly deployed through a femoral artery of the patient,	The ’033 patent Accused Instrumentalities satisfy this element. For example, the ’033 patent Accused Instrumentalities are sized and shaped to be endovascularly deployed through a femoral artery of the patient. Further, the Sapien 3 Ultra is designed, developed, promoted, sized, shaped, configured to be deployable and is deployable endovascularly through the femoral artery of a patient using Edwards’ balloon catheter delivery systems.  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 (D.I. 1, Ex. 44).

7.0 Directions for Use

7.1 System Compatibility

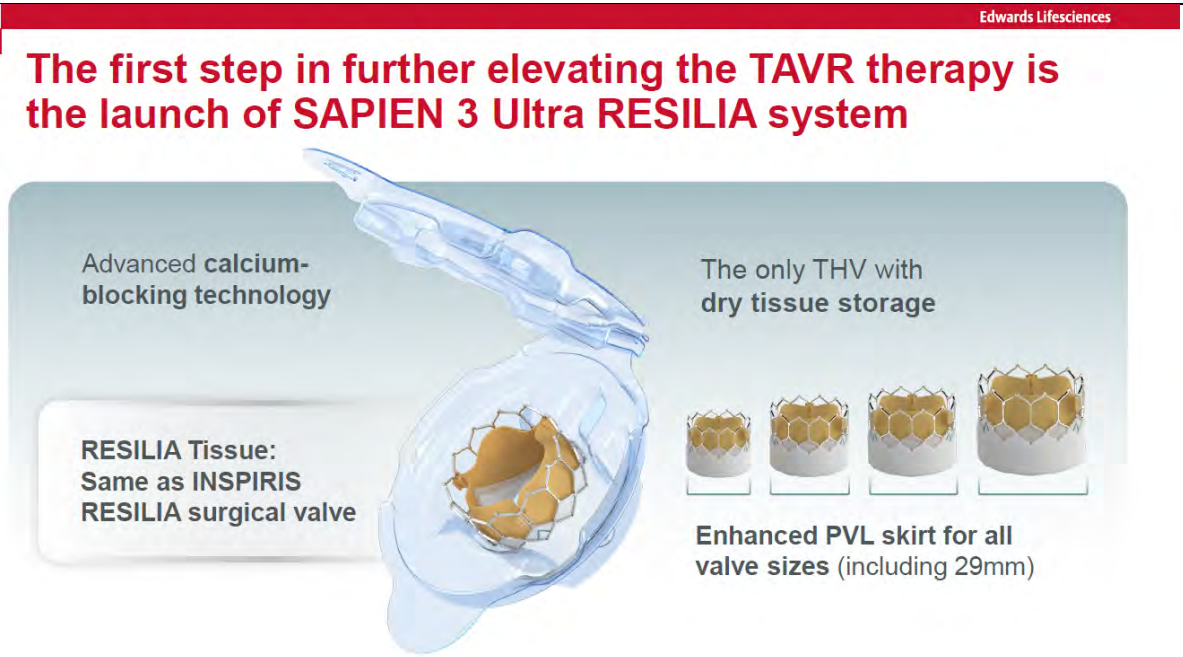
Table 6

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

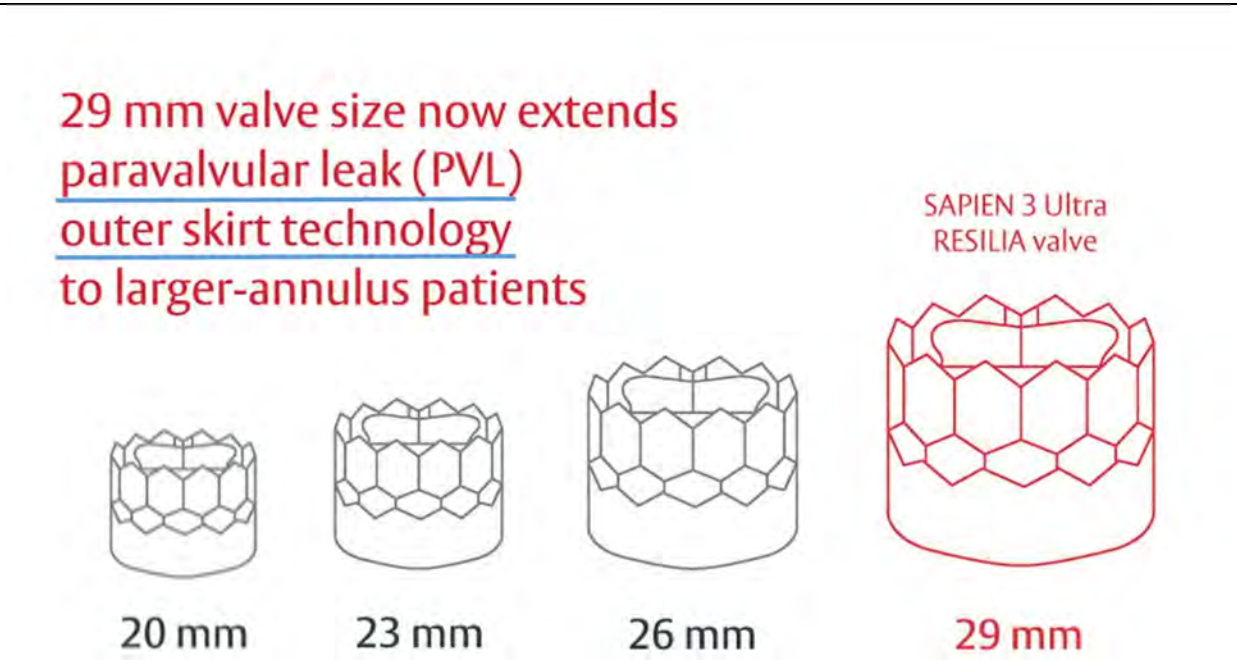
Additional Equipment:

- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

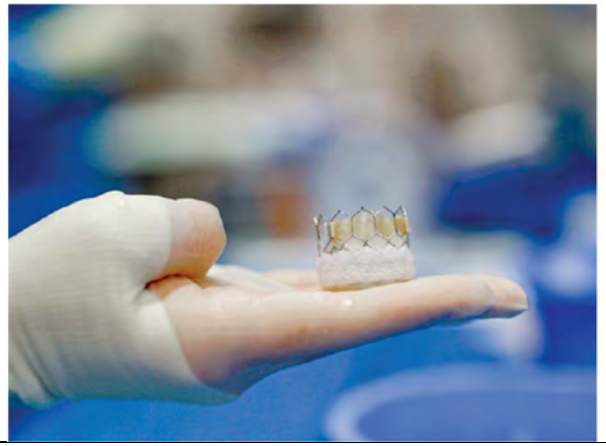
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

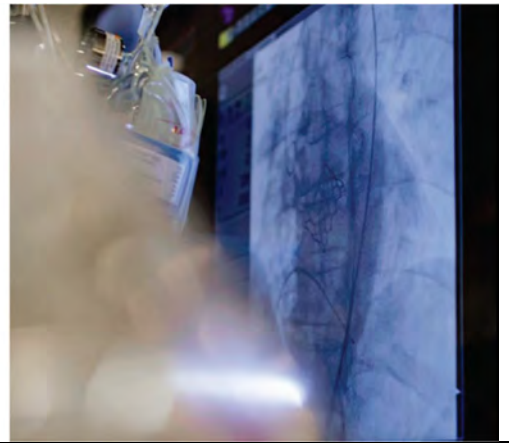


https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

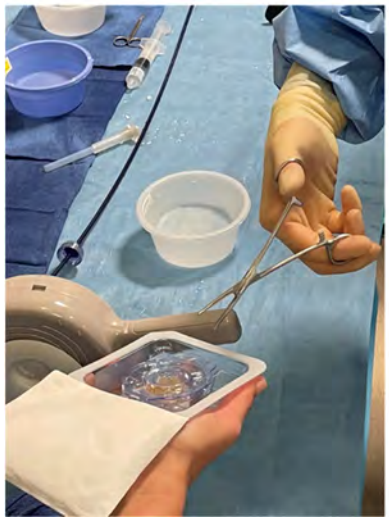




https://twitter.com/RajTayalMD/status/1587510333127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



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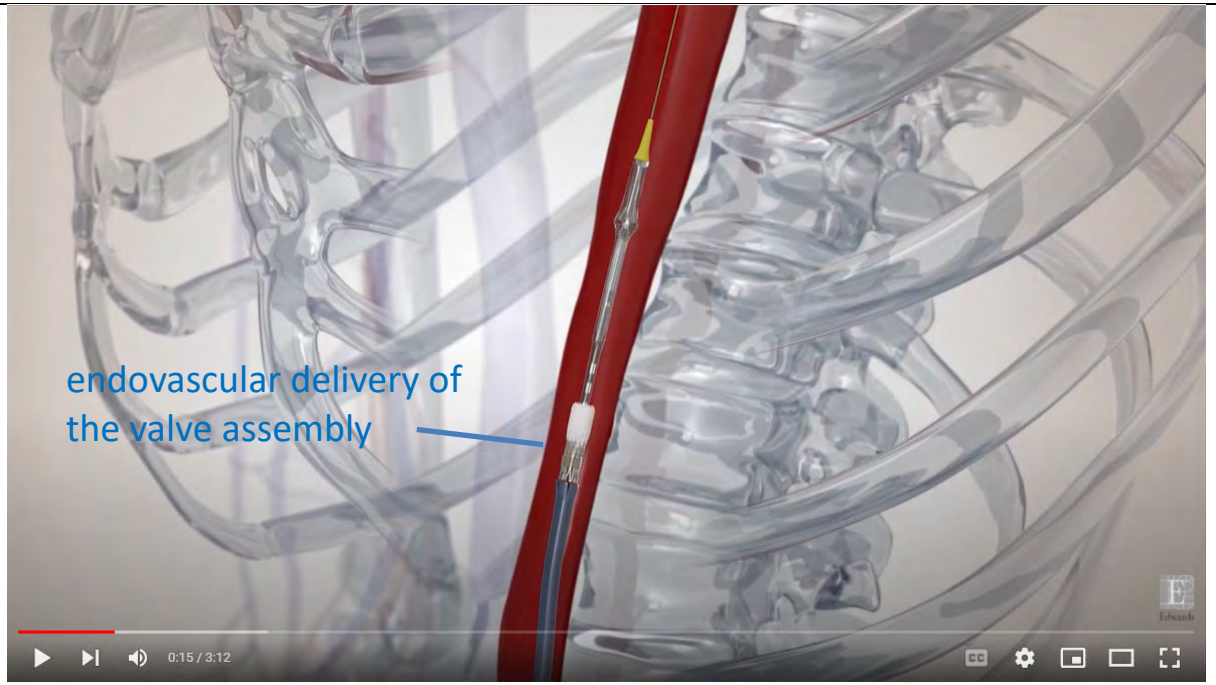


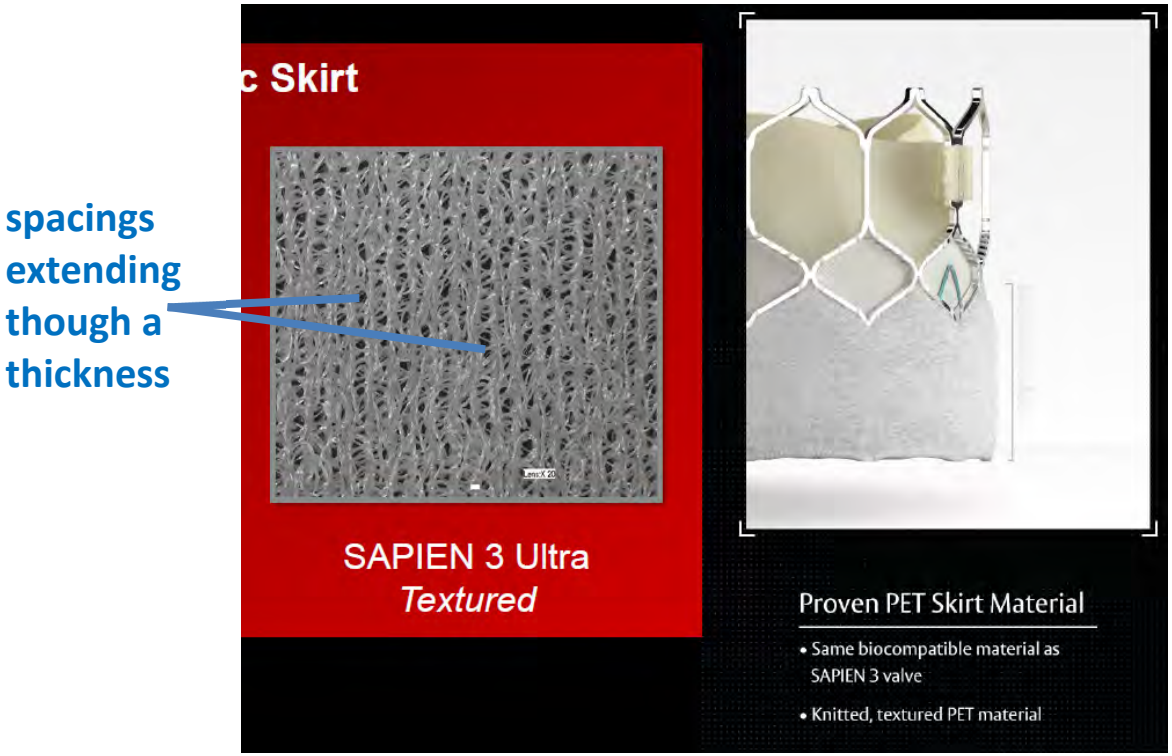


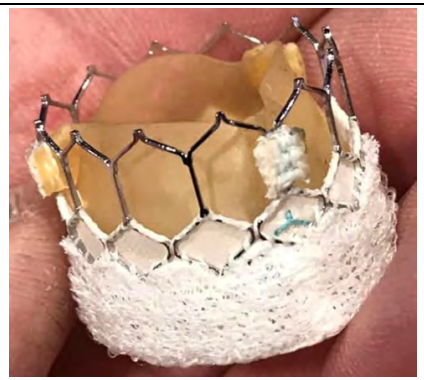
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



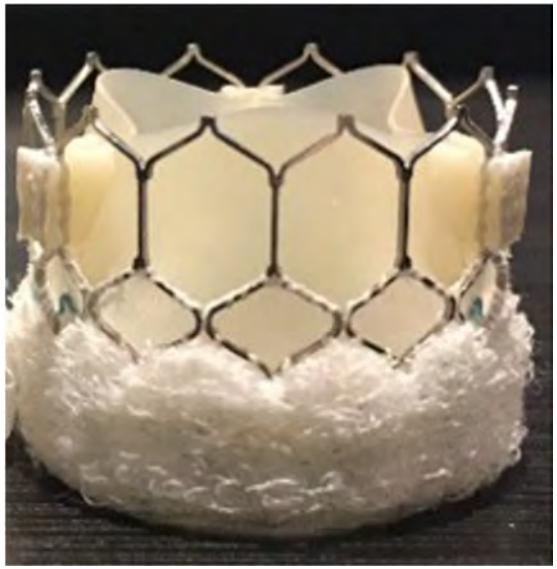
	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
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	The ’033 patent Accused Instrumentalities satisfy this element. For example, the ’033 patent Accused Instrumentalities define 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. The Sapien 3 Ultra defines spacings that extend though the sealing assembly that allow fluid to pass through when the valve assembly is undeployed.

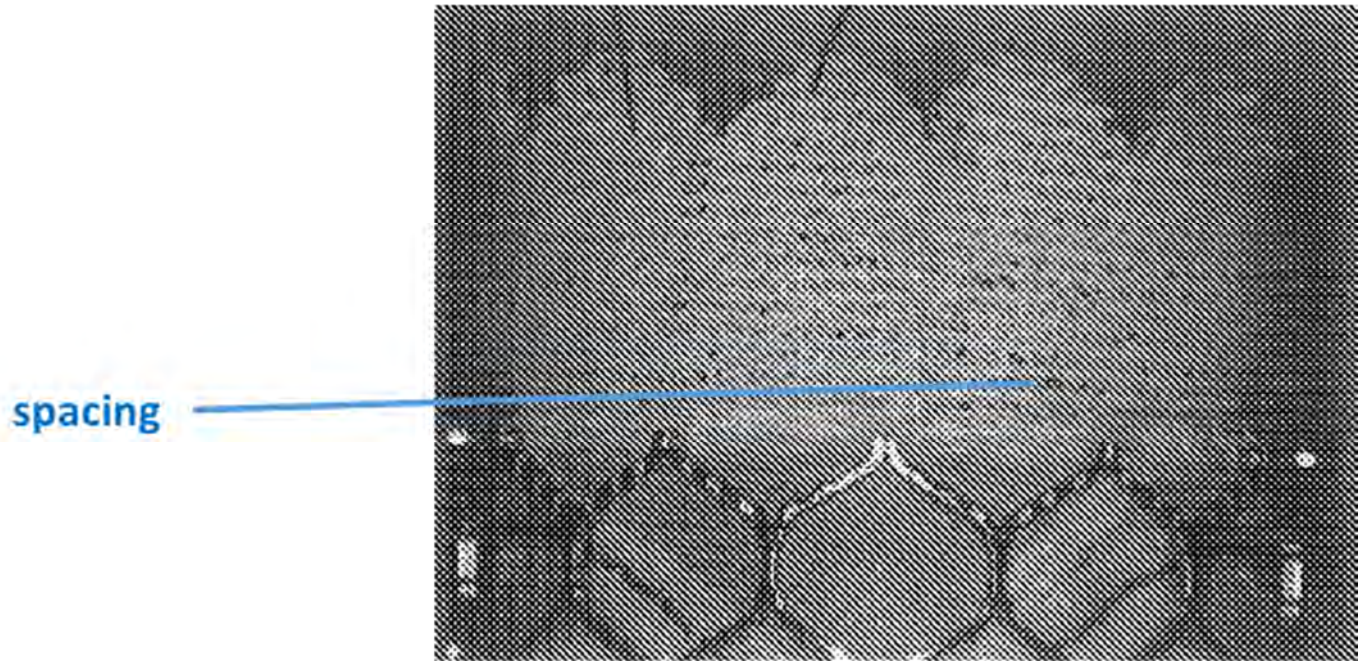
is in an undeployed state,	 Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

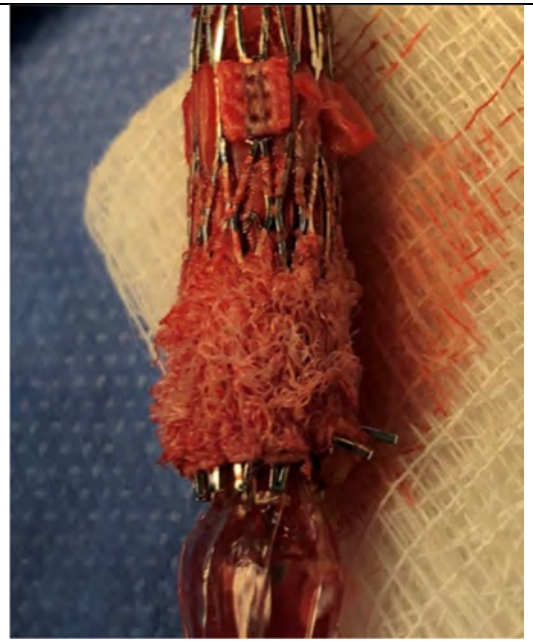


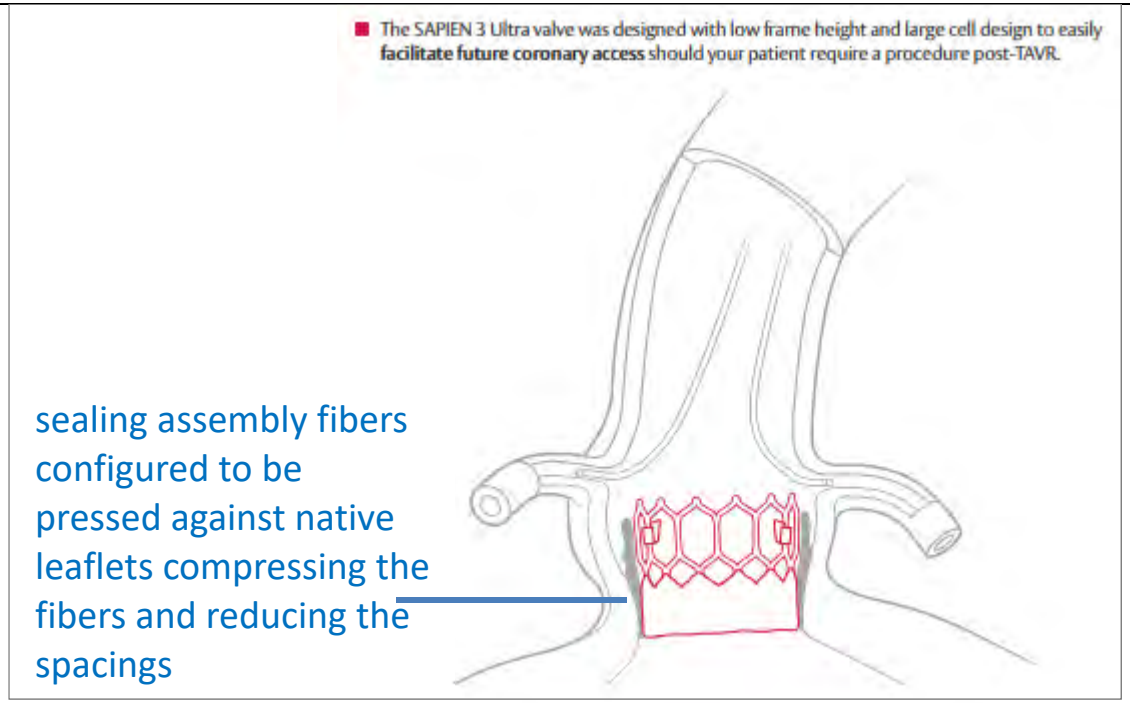

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

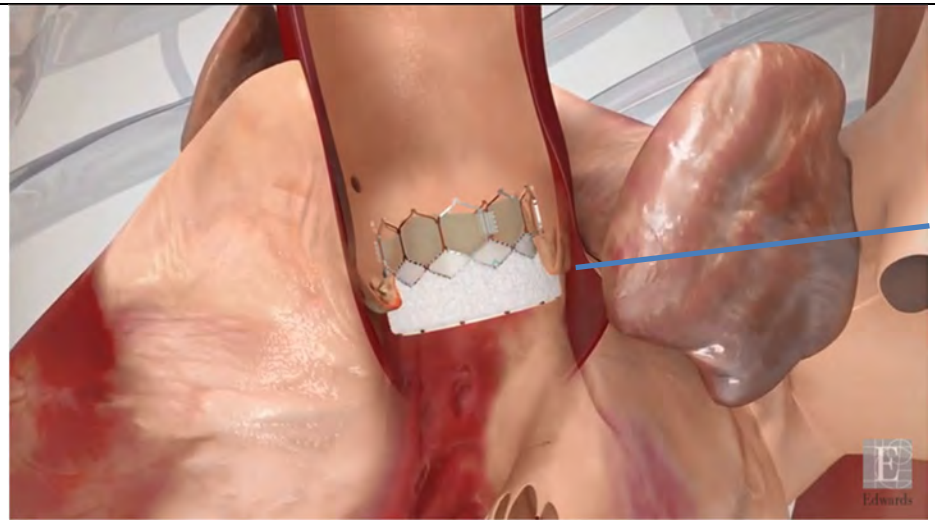


Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

	For example, the Sapien 3 Ultra sealing skirt spacings extend to and/or through the backside thereof allowing blood to pass through when undeployed.  U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing spacings on flipped up backside of sealing skirt).

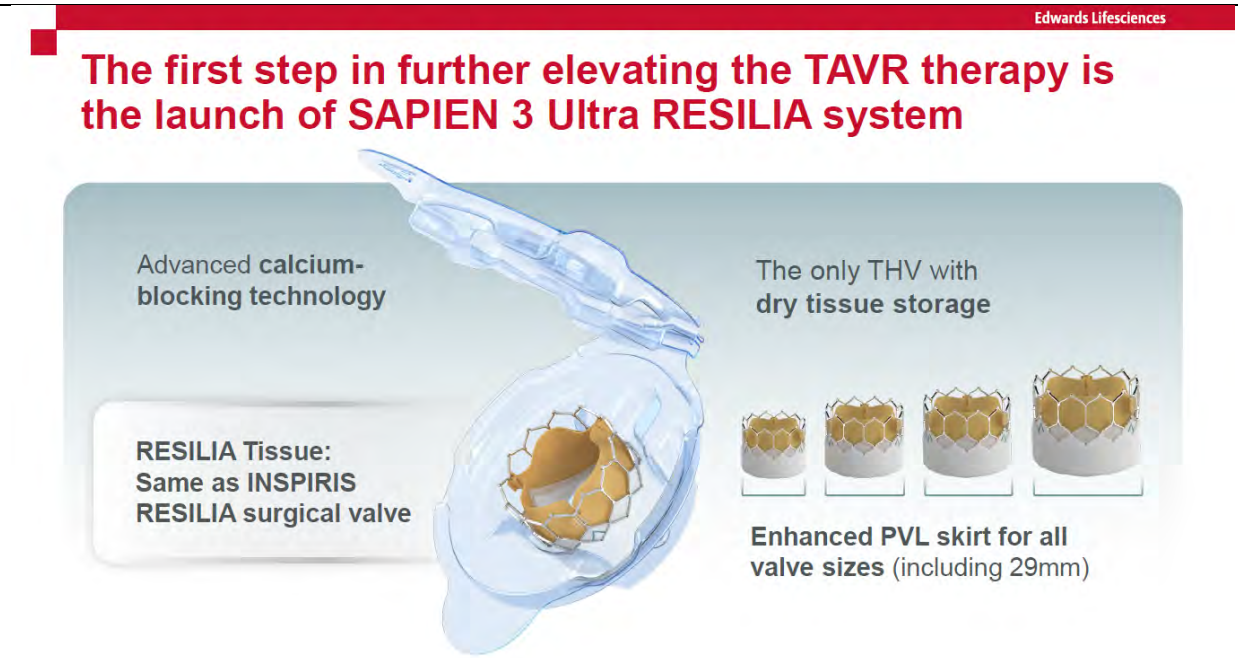
	 Twitter image of crimped Sapien 3 Ultra with blood.
wherein, in operation, expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state: presses the sealing assembly against the native leaflets of the aorta to impart compression of the sealing assembly	The ’033 patent Accused Instrumentalities satisfy this element. For example, the ’033 patent Accused Instrumentalities are designed and configured such tha, 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. For example, the Sapien 3 Ultra is designed and configured so that when expanded in a deployed state the sealing assembly is pressed against the native leaflets of the aortic compressing the fibers of the sealing assembly relative to the spacings reducing the spacings.

that compresses the plurality of fibers relative to the spacings thereby reducing the spacings; and expands the polymer covering radially outwardly,	 Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

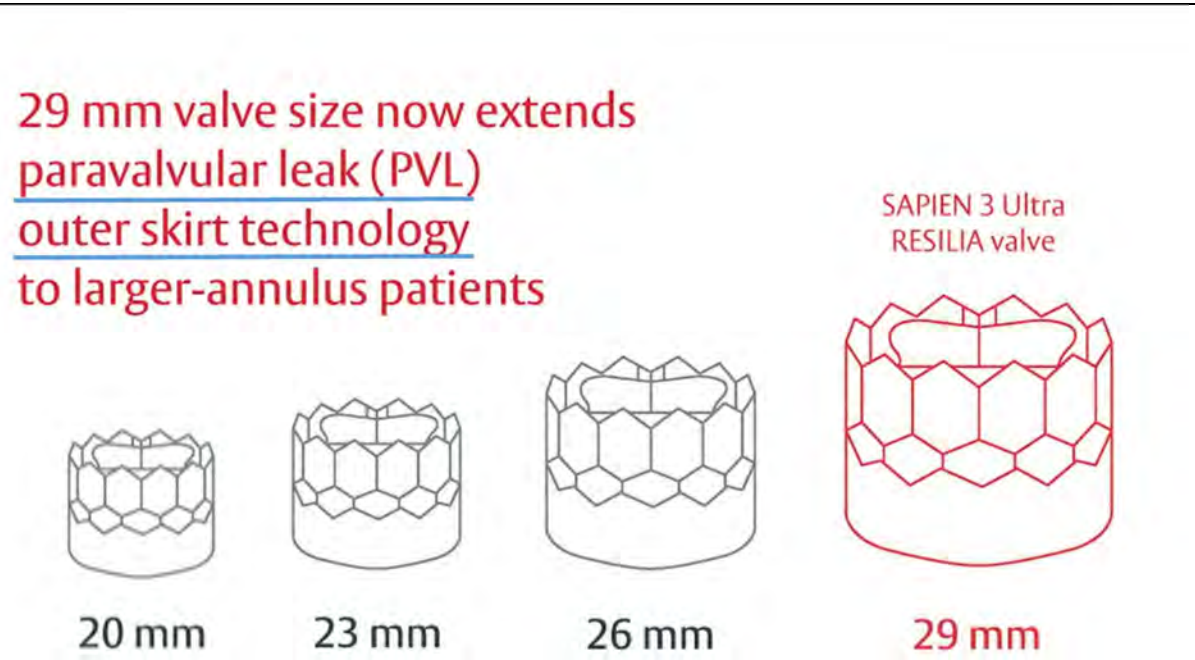


"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

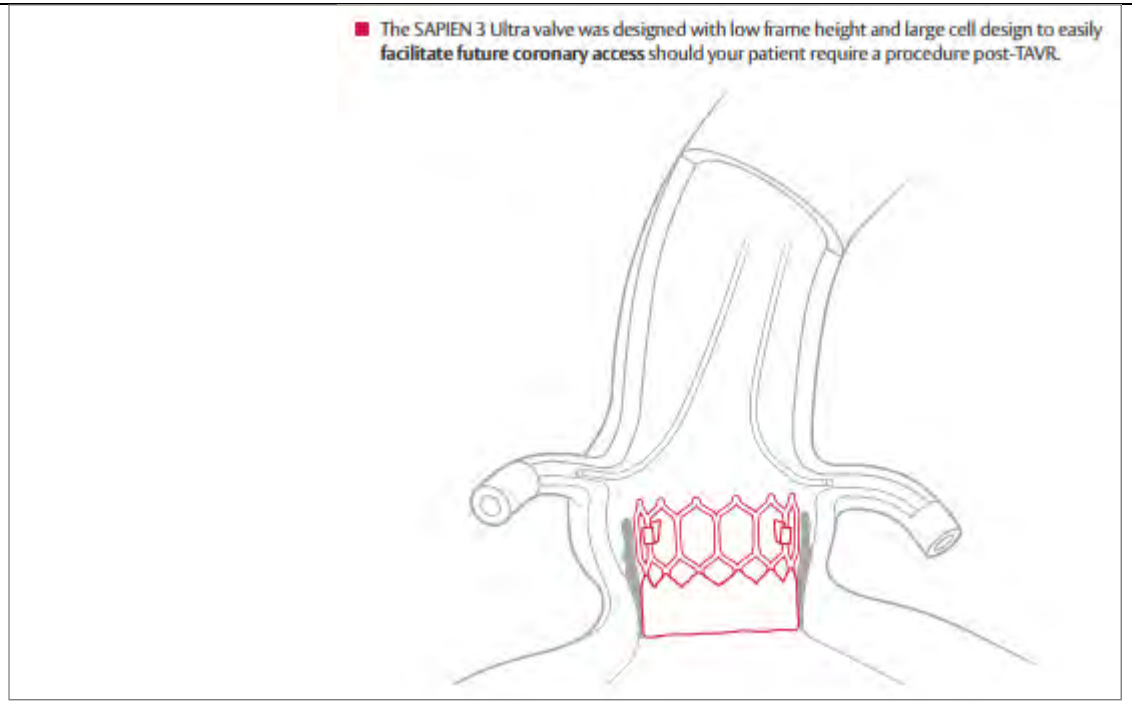
For example, the Sapien 3 Ultra is designed using knitted PET with compressible fibers such that when compressed in response to deployment and expansion of the heart valve in the aorta, the fibers are compressed together relative to the spacings providing for sealing to help prevent paravalvular leakage.



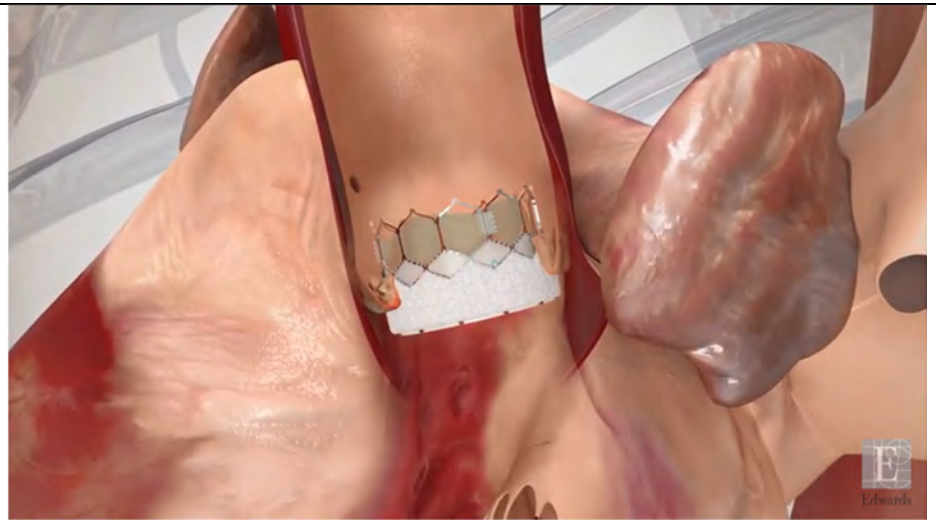
https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

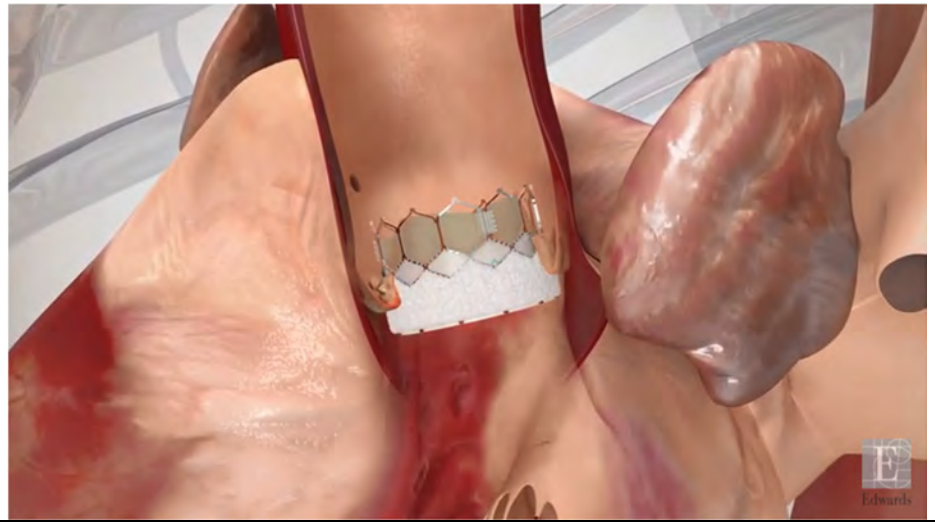


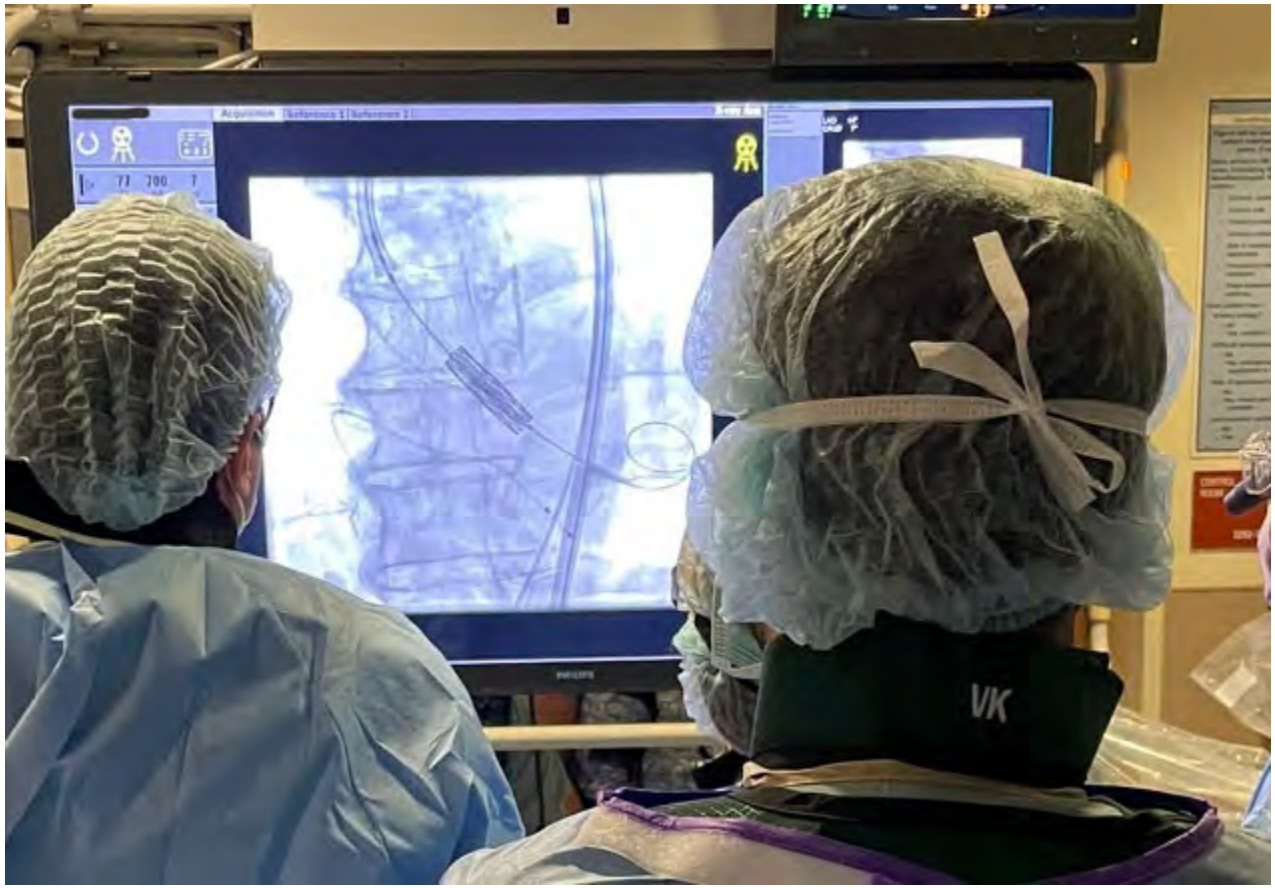
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

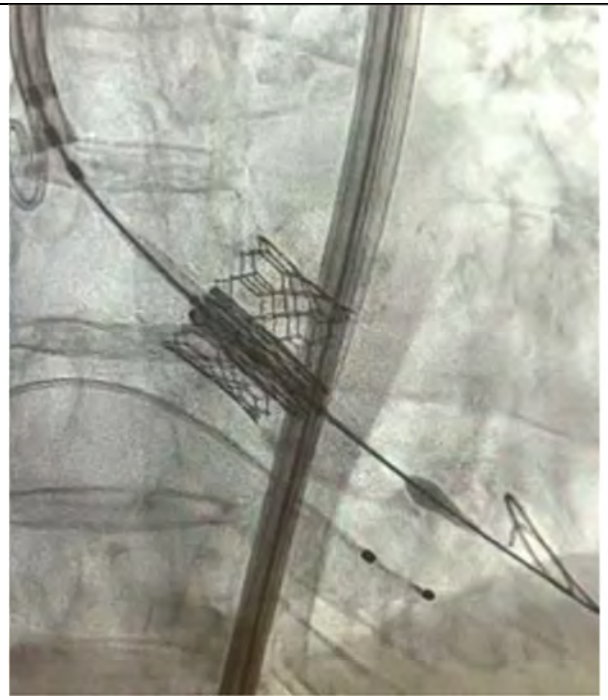
	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37). For further example, the Sapien 3 Ultra is designed and configured such that expansion of the prosthetic heart valve assembly to the radially expanded orientation in a deployed state expands the polymer covering radially outwardly.



Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (showing polymer covering in compressed state)



	"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37) (showing polymer covering in expanded state).  https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

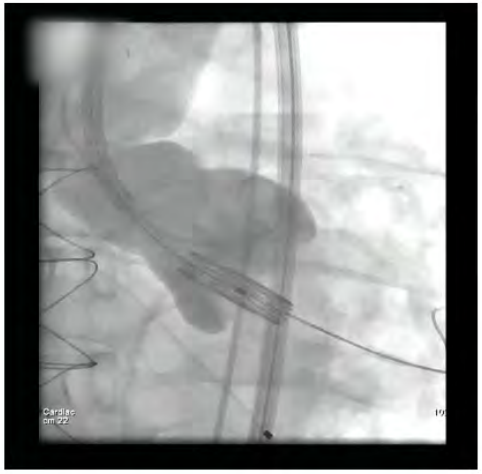


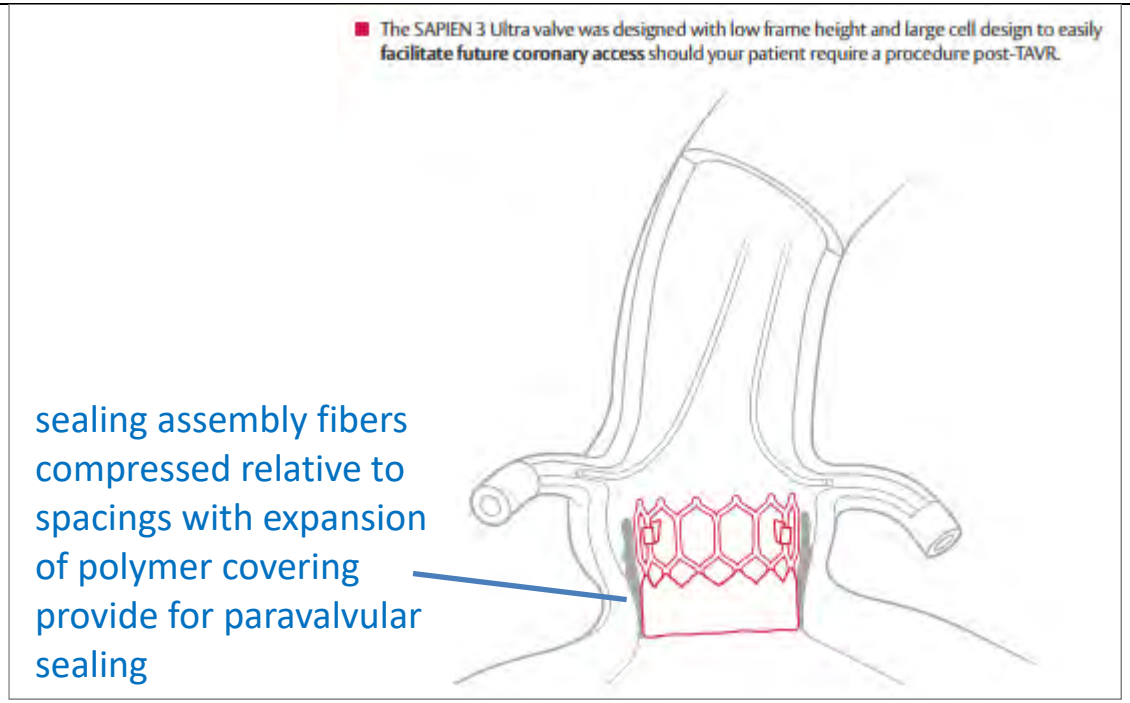
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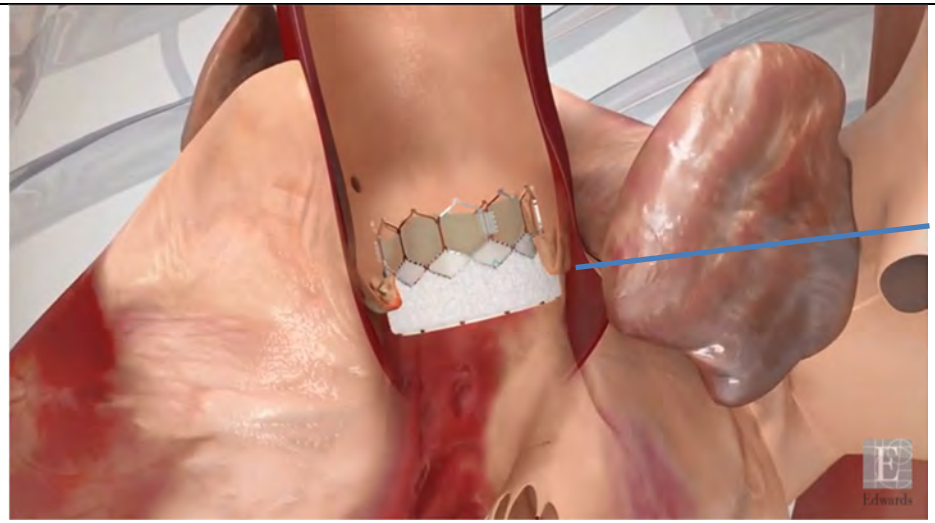
78



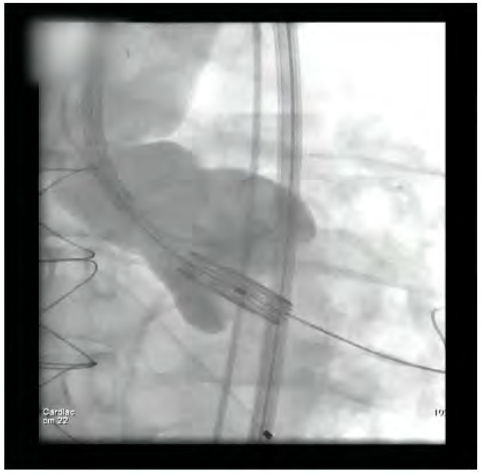
https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

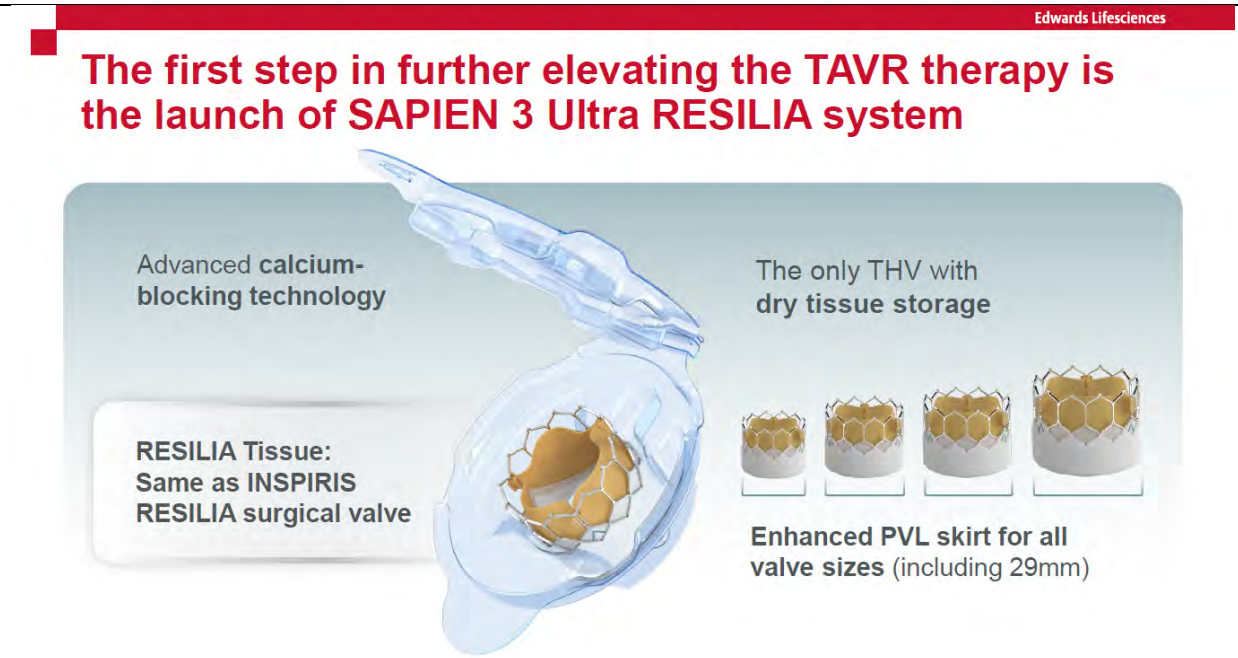
	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).
wherein the compression 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	The '033 patent Accused Instrumentalities satisfy this element. For example, the '033 patent Accused Instrumentalities are designed and configured such that 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. For example, the Sapien 3 Ultra is designed using knitted PET with compressible fibers such that when compressed in response to expansion of the heart valve in the aorta, the plurality of fibers are compressed relative to the spacings and the polymer covering is expanded cooperating to provide for paravalvular sealing about the frame and the native leaflets by reducing spaces in the sealing assembly.

in the sealing assembly.	 Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

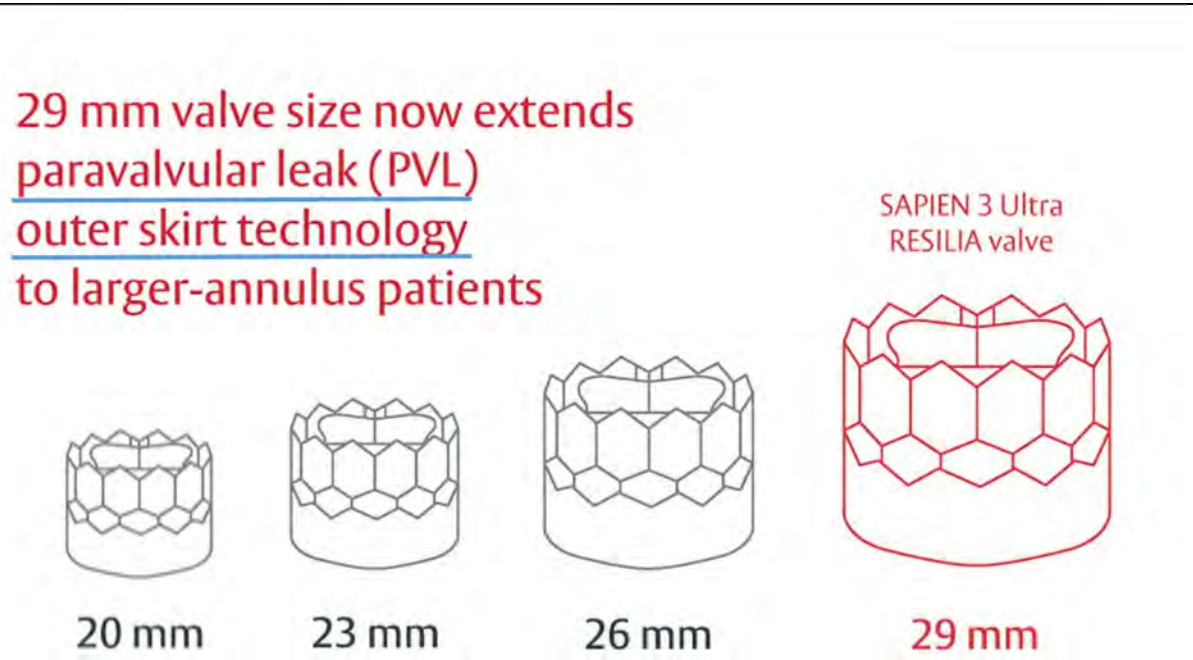


"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).

	 https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA
5. The prosthetic heart valve assembly of claim 1, wherein the frame is integrally formed.	The ’033 patent Accused Instrumentalities satisfy this element. For example, the ’033 patent Accused Instrumentalities’ frame is integrally formed. For example, the Edwards Sapien 3 Ultra frame is made of a cobalt-chromium metallic alloy in an integral form.

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.



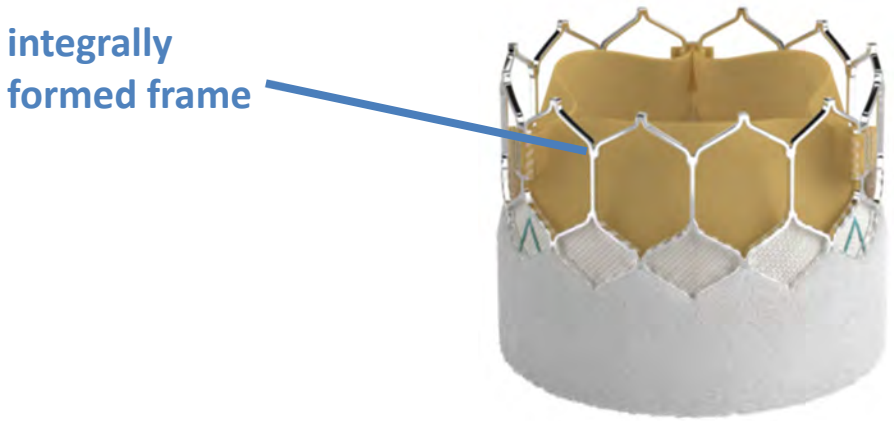
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

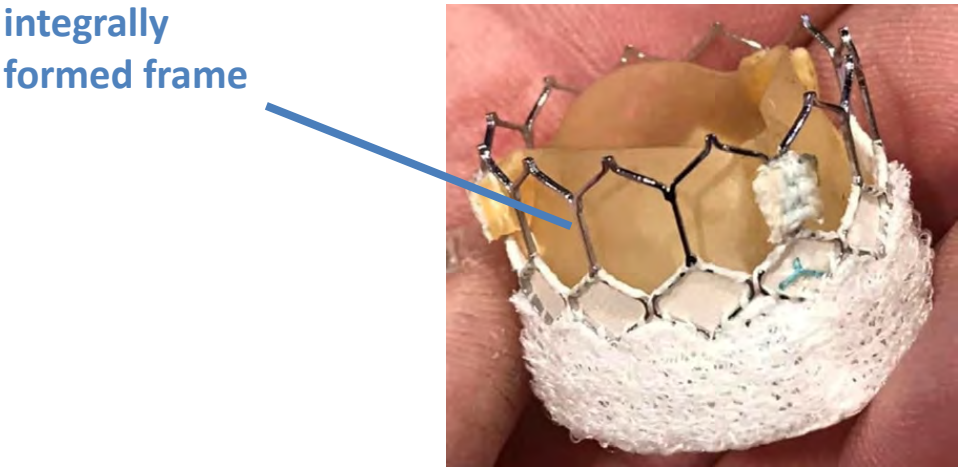
Table 1

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 (D.I. 1, Ex. 44).



https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

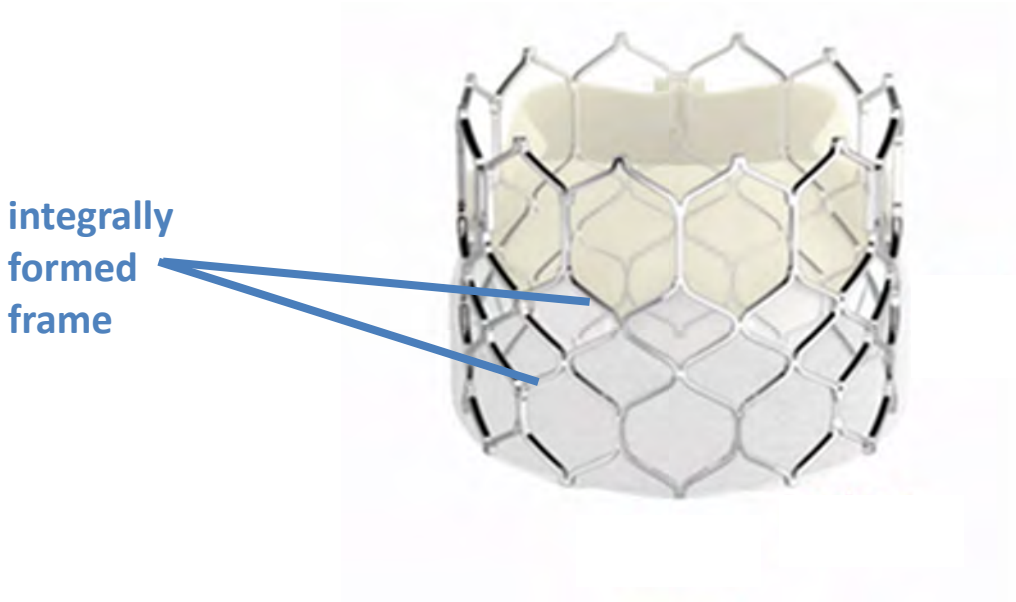
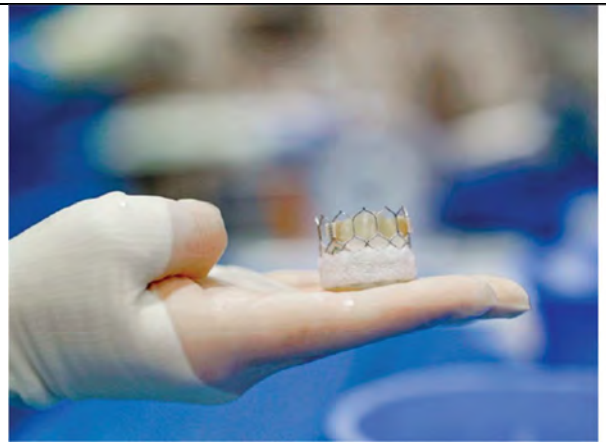
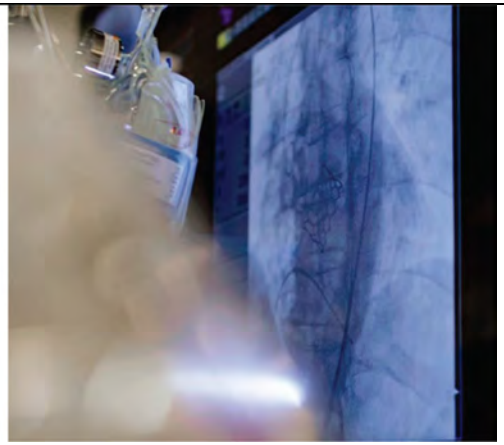
	 https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). *See also*, claim 1.

Exhibit D - Edwards' Infringement of U.S. Patent No. 11,497,634

Claim	Exemplary Infringement Evidence[1]
1. A transcatheter aortic heart valve assembly comprising:	To the extent the preamble is limiting, the '634 patent Accused Instrumentalities[2] satisfy this element. For example, the '634 patent Accused Instrumentalities are transcatheter aortic heart valve assemblies. The '634 patent Accused Instrumentalities are transcatheter aortic heart valve assemblies designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems.

[1] The exemplary evidence and infringement assertions cited herein may also be used to support any other claim element where appropriate. Aortic Innovation LLC's ("Aortic") investigation is ongoing and discovery is in its preliminary stages. Aortic hereby incorporates by reference the cover pleading to which this claim chart is attached. Aortic reserves the right to amend or supplement these contentions after further investigation and discovery from Edwards and non-parties and in accordance with the rules and schedule. Such supplemental information may include, but is not limited to, FDA submissions and correspondence, data sheets, design specifications, deposition testimony, testing information, reference designs, implementation and utilization information, and/or schematics. Aortic also reserves the right to assert additional claims of the Aortic patents-in-suit, accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products. Under the proper construction of the asserted claims and their claim terms, each element of the asserted claims is literally present in the accused products or acts accused of infringing the claim. Any and all elements found not to be literally infringed are infringed under the doctrine of equivalents because the differences between the claimed inventions and the Accused Instrumentalities, if any, are insubstantial. Aortic further reserves the right to accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products, based on further investigation and discovery, the claim construction process, the Court's rules, and/or other circumstances so meriting.

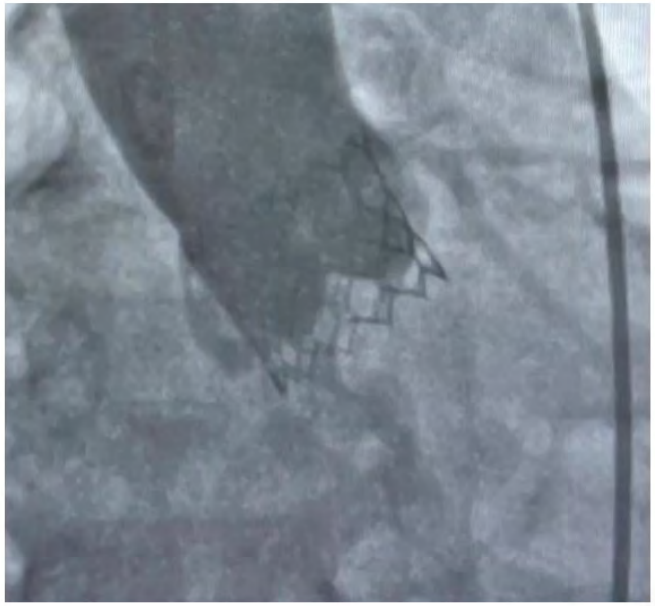
[2] "Accused Instrumentalities" refers to all models, versions, and sizes of Edwards's Sapien 3 Ultra devices, including, but not limited to Edwards Sapien 3 Ultra valves with non-Resilia valve leaflets and Edwards Sapien 3 Ultra Resilia valves, which Aortic understands to be the same as the Sapien 3 Ultra, but with Edwards' Resilia valve leaflet tissue which Aortic understands uses "a bovine (cow) heart tissue that has been treated with Edwards' technology to block calcium build-up on the valve." Discovery is ongoing and Aortic reserves the right to amend or supplement the identified Accused Instrumentalities to the extent that additional relevant information is obtained during discovery.

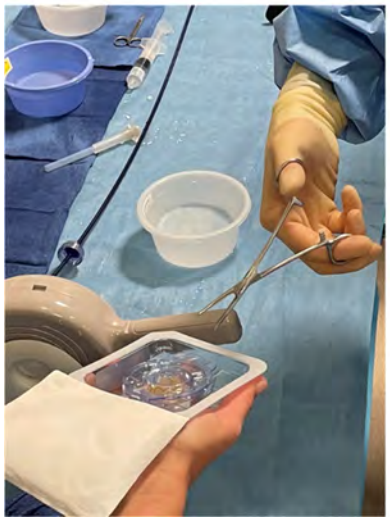
	  https://twitter.com/RajTayalMD/status/1587516343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

	 Instagram posts and images of Terapeutica Transcatheter Cardiovascular of Brazil. (D.I. 1, Ex. 74).





https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



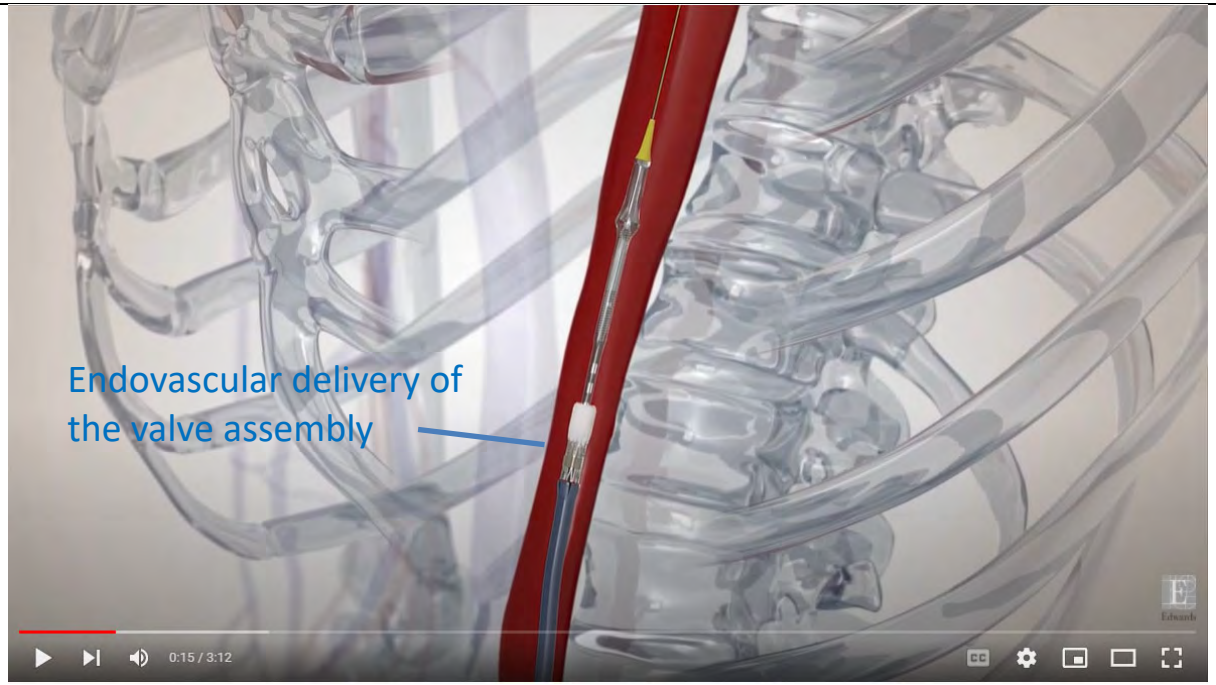
https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

The Sapien 3 Ultra[3] is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.



SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[3] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.



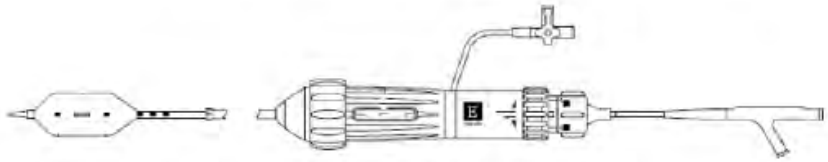
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



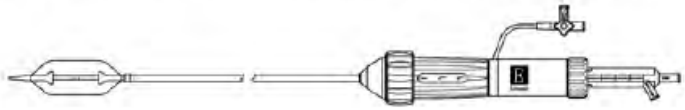
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

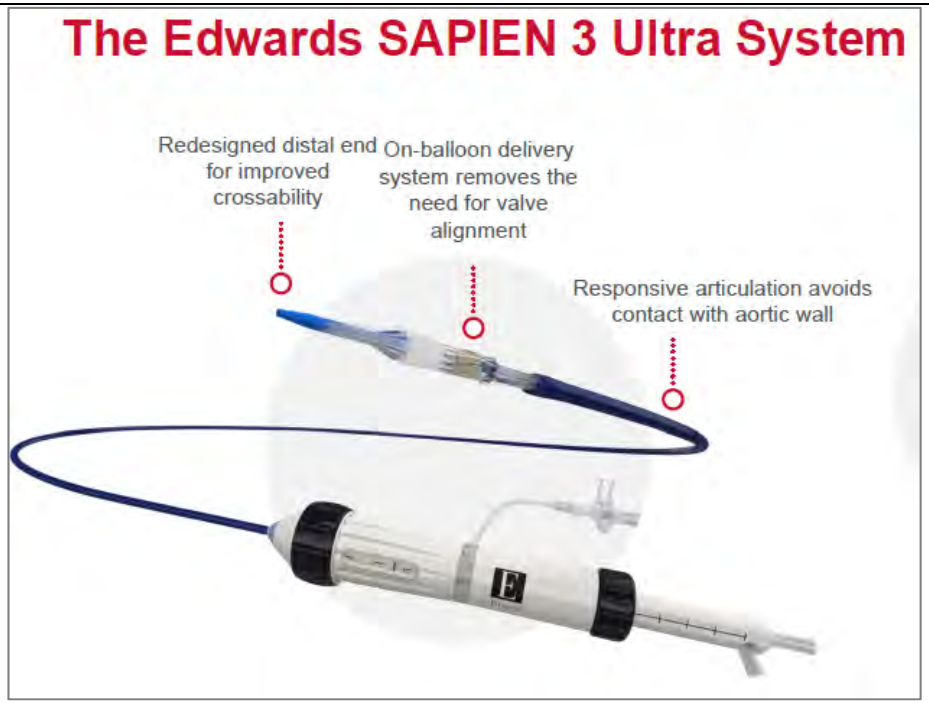
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

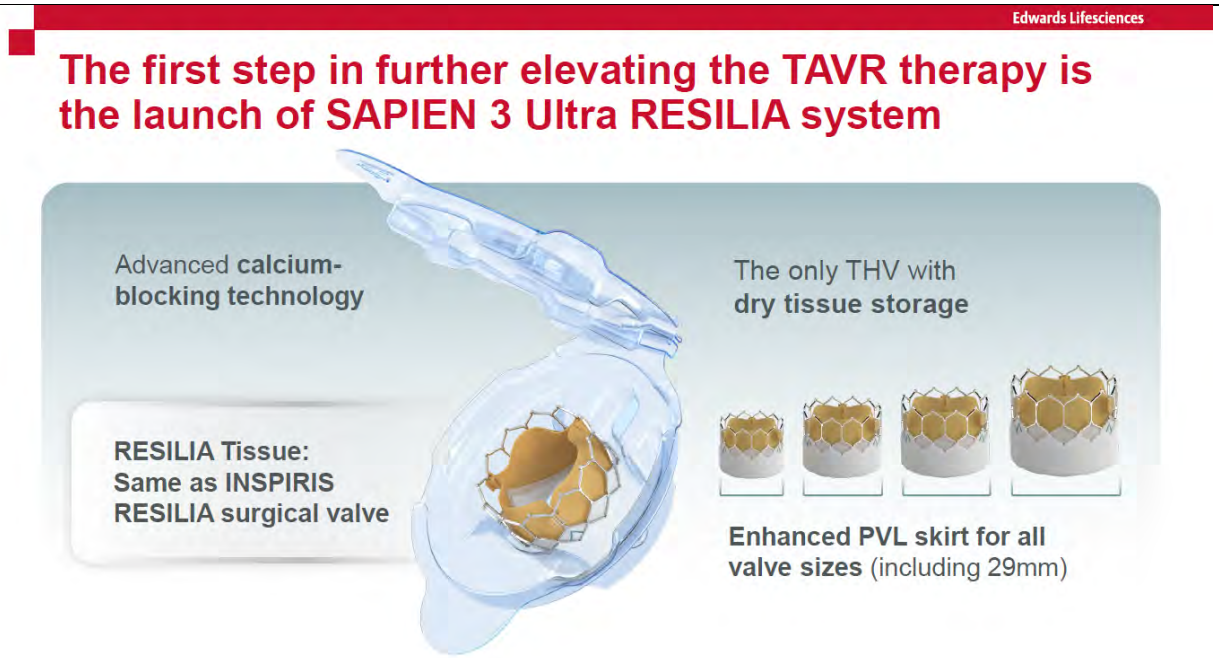
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

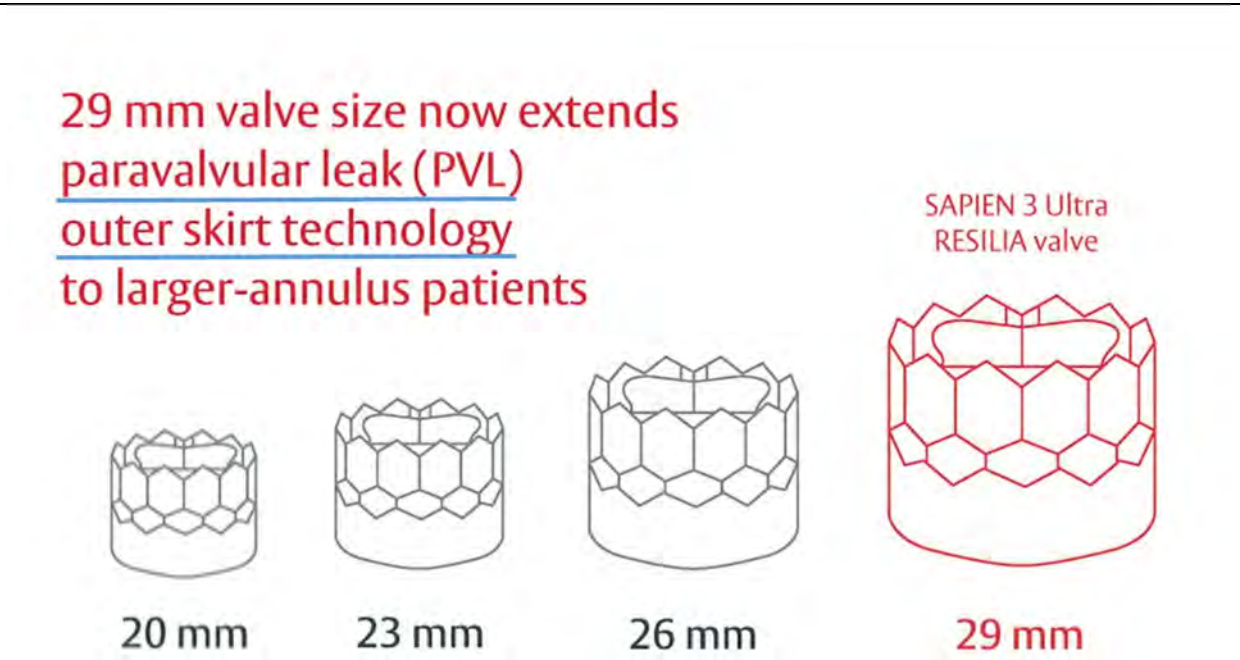
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

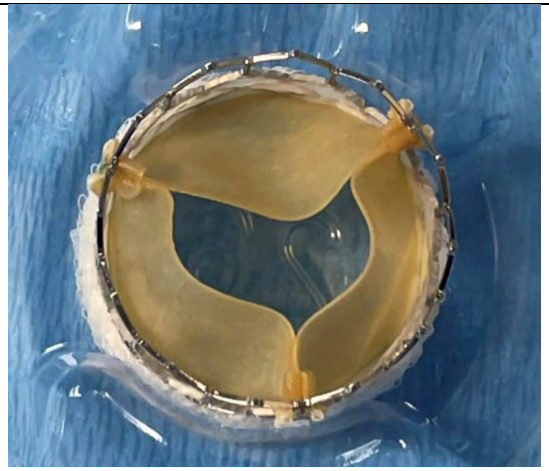
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’634 patent Accused Instrumentalities and infringes the ’634 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



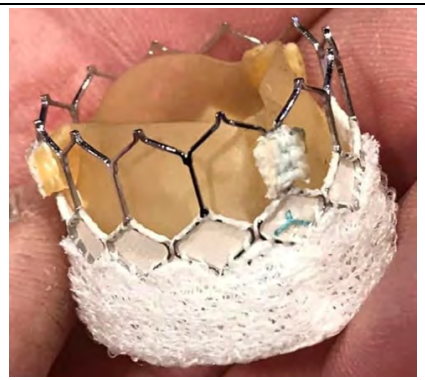
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587516343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



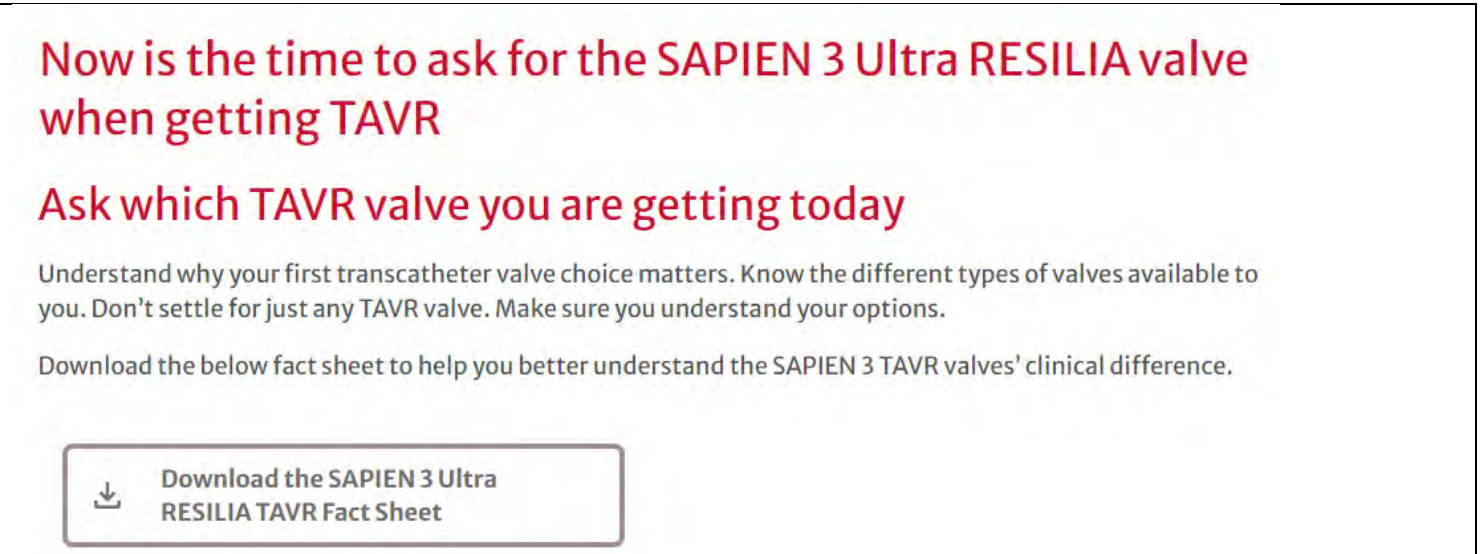

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

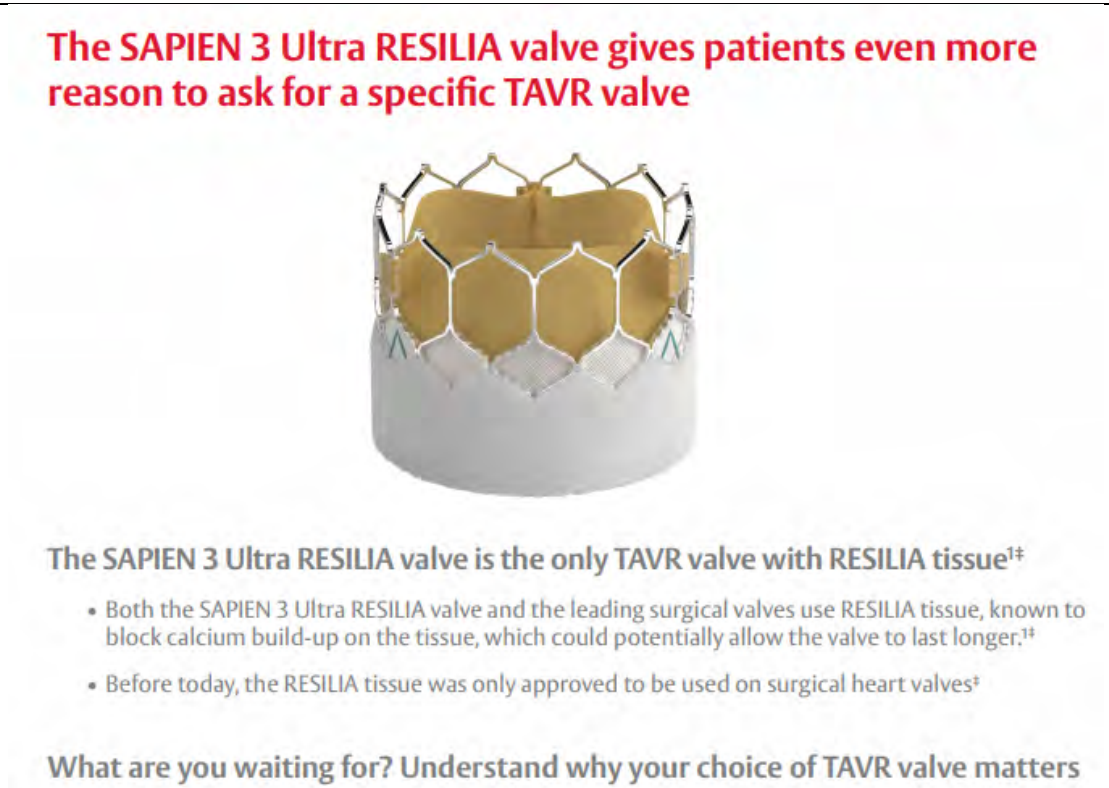
On information and belief, Edwards supplies in and/or from the United States some or all of the components of the Sapien 3 Ultra in such a manner that such components will be combined outside of the United States to form the Sapien 3 Ultra and infringes the '634 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See*

	https://ir.edwards.com/events-presentations/; https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '634 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '634 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpglobalearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpglobalearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '634 asserted claims are infringed when Edwards offers for sale and sells the '634 patent Accused Instrumentalities. Edwards offers for sale and promotes the '634 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 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.



https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61).

On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement#

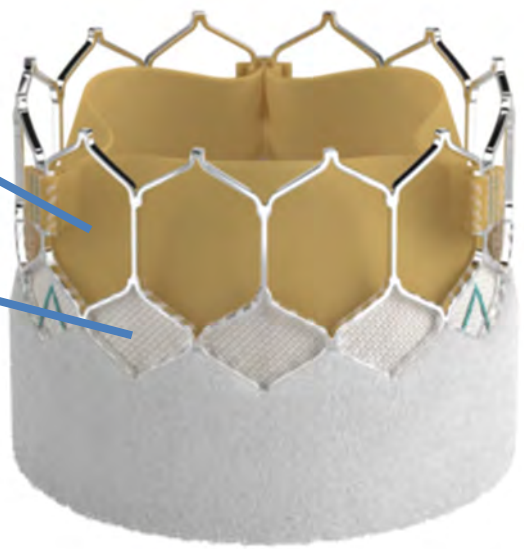
Further, the '634 patent asserted claims are directly infringed when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the ’634 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards’ direct and induced infringement. For further example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe the asserted ’634 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a “watchful eye” over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards’s inducement, Edwards’s affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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.

	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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards’s affirmative acts of marketing, selling and offering to sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ combination and use of the Accused Instrumentalities, such that the ’634 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards’ knowledge of Aortic’s inventions, the patents-in-suit (including the ’634 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
a graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto;	The ’634 patent Accused Instrumentalities satisfy this element. The ’634 patent Accused Instrumentalities comprise a graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto For example, the Edwards Sapien 3 Ultra graft covering that engages and extends about and provides sealing to prosthetic heart valve leaflets.

heart valve having prosthetic leaflets

graft covering



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

https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

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.



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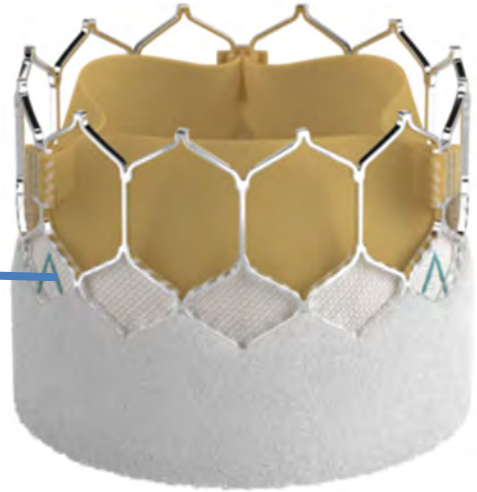
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

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

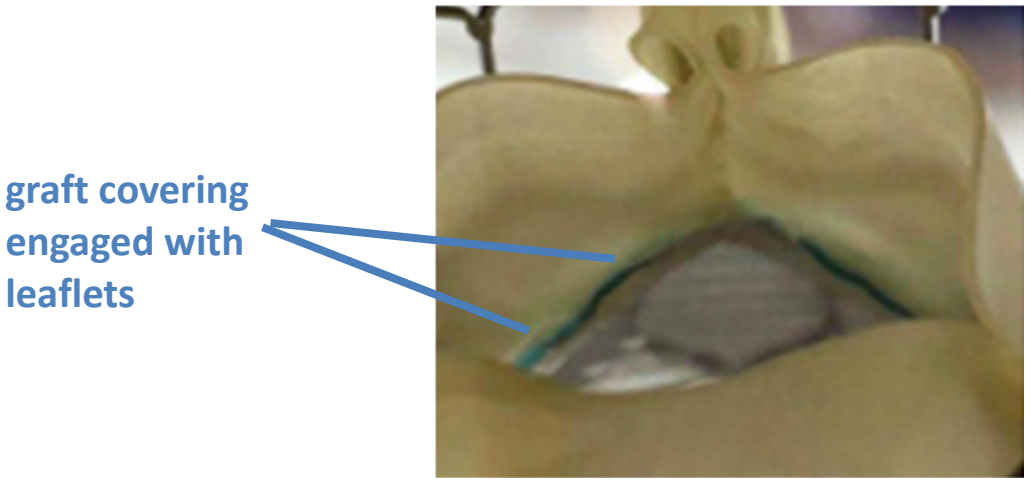
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

graft covering engaged with leaflets



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

https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "a graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a graft covering engaged with prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing to the leaflets, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering performs the same or substantially the same function as the claim phrase by partially and/or fully providing sealing to the prosthetic heart valve leaflets, in the same or substantially the same way as the claim phase by engaging and/or being affixed to and extending fully or partially about the prosthetic heart valve leaflets, to achieve the same or substantially the same result of a graft covering configured to provide sealing or partial sealing to the prosthetic heart valve leaflets.

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,	The ’634 patent Accused Instrumentalities satisfy this element. The ’634 patent Accused Instrumentalities comprise 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. For example, the Edwards Sapien 3 Ultra frame is made of a cobalt-chromium metallic alloy with continuously extending struts that extend through a circumference of the frame with the struts adjoining each other at an inflow end of the frame to form apices where the struts form an open cell configuration. **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.



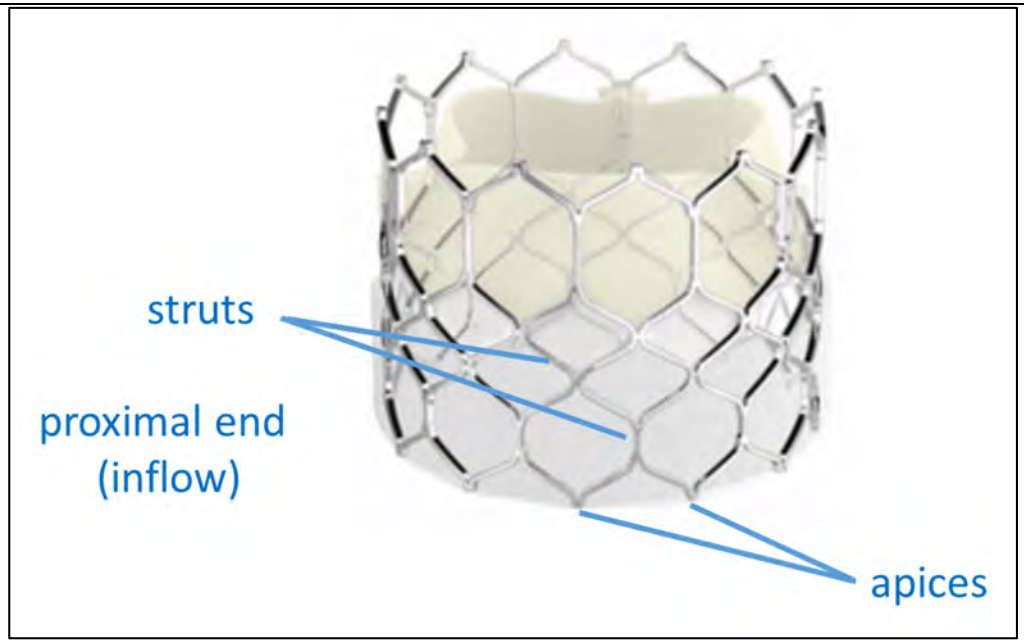
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

Valve Size	Valve Height
20 mm	15.5 mm
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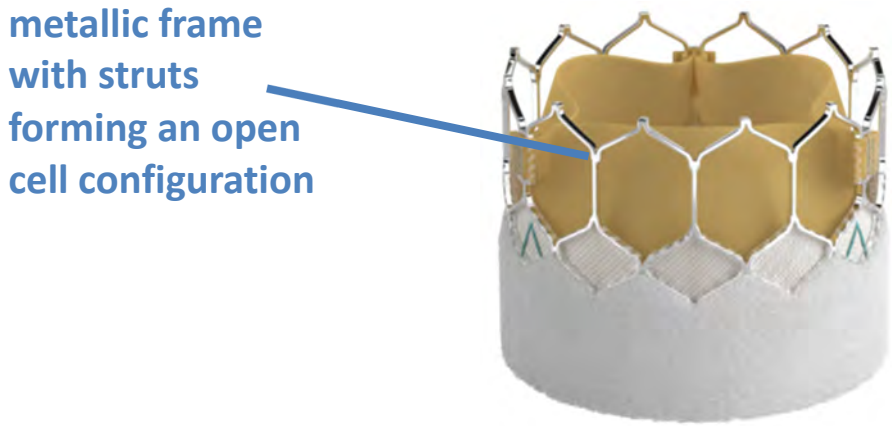
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

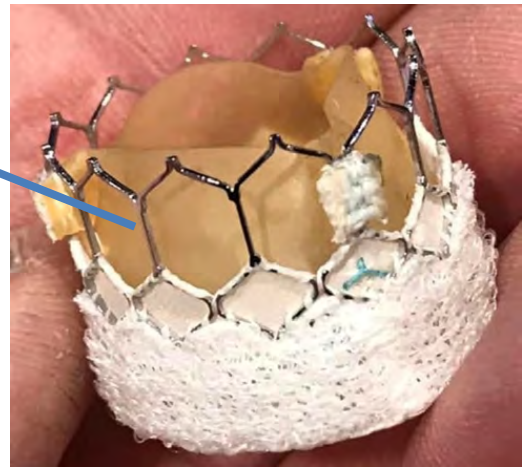


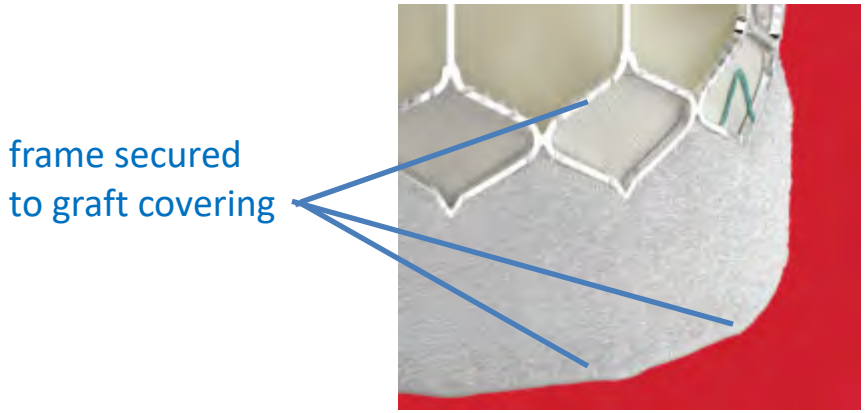
https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).

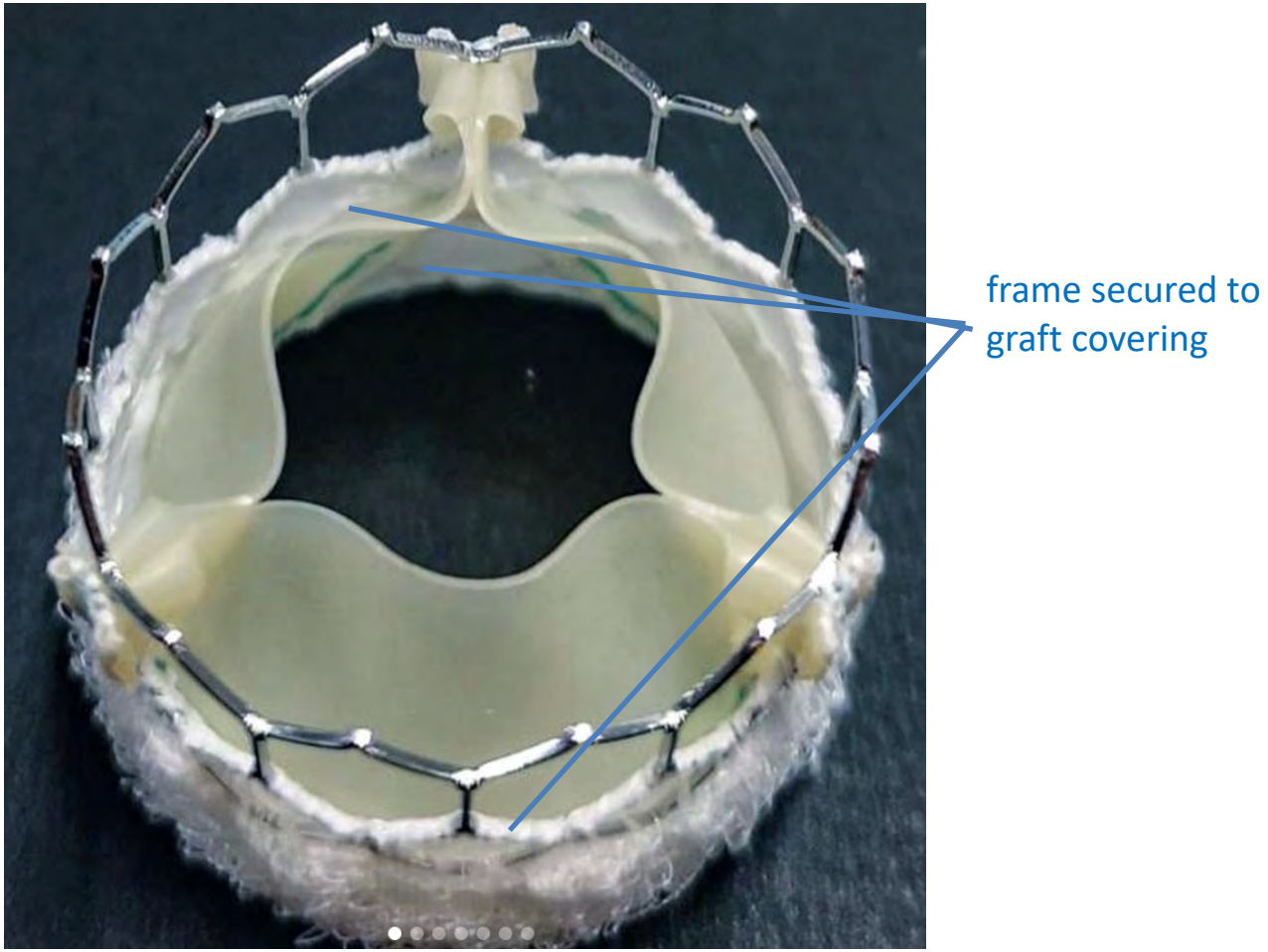


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

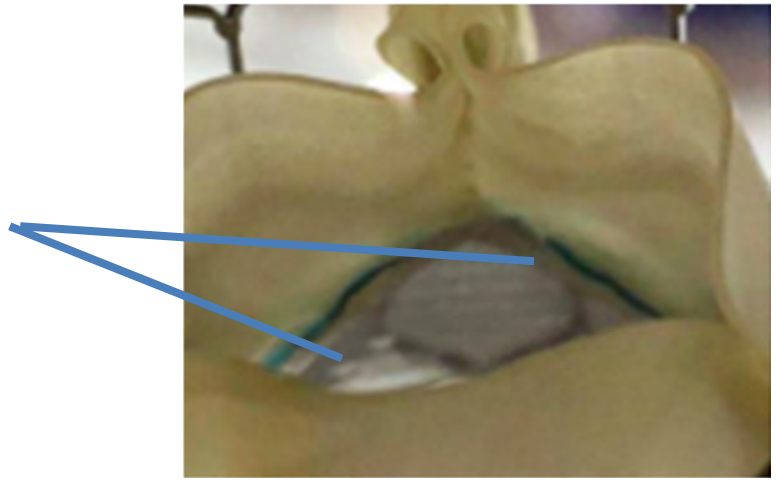


	https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3). With respect to the phrase, "a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through 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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with the

	capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy. Further, the frame formed from a metallic material and defining a plurality of continuously extending struts is laser cut from a single piece of material or made otherwise is the same or, at most, an insubstantial difference.
wherein the frame is secured to the graft covering,	The '634 patent Accused Instrumentalities satisfy this element. The '634 patent Accused Instrumentalities comprise a frame secured to the graft covering. For example, the Edwards Sapien 3 Ultra frame is secured to the graft covering.  Introducing the SAPIEN 3 Ultra valve at 2 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



Julian Calain Twitter (D.I. 1, Ex. 30).

	 https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).
wherein the graft covering is made of a polymer; and	The ’634 patent Accused Instrumentalities satisfy this element. The ’634 patent Accused Instrumentalities’ graft covering is made of a polymer. For example, the Edwards Sapien 3 Ultra graft covering is made of PET which is a polymer.

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.



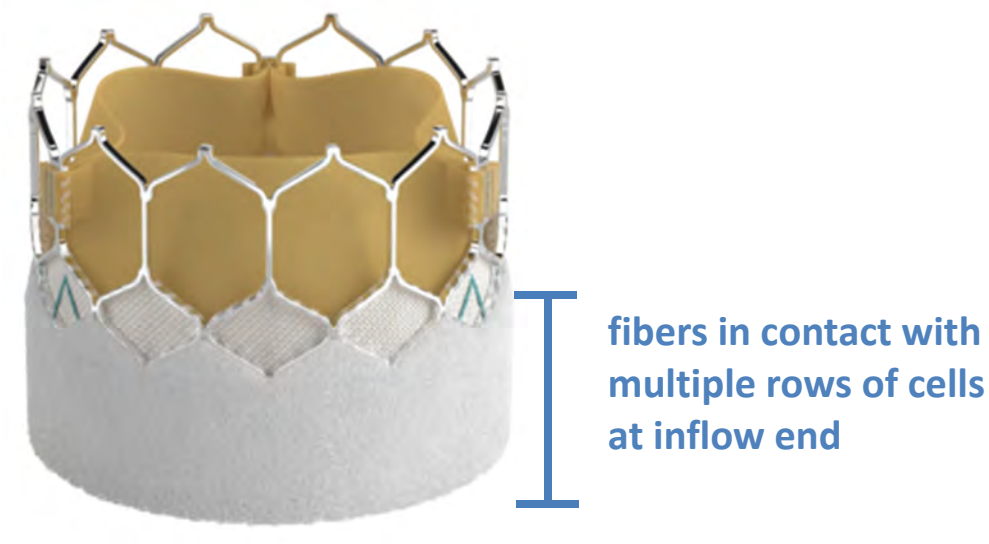
9750TFX

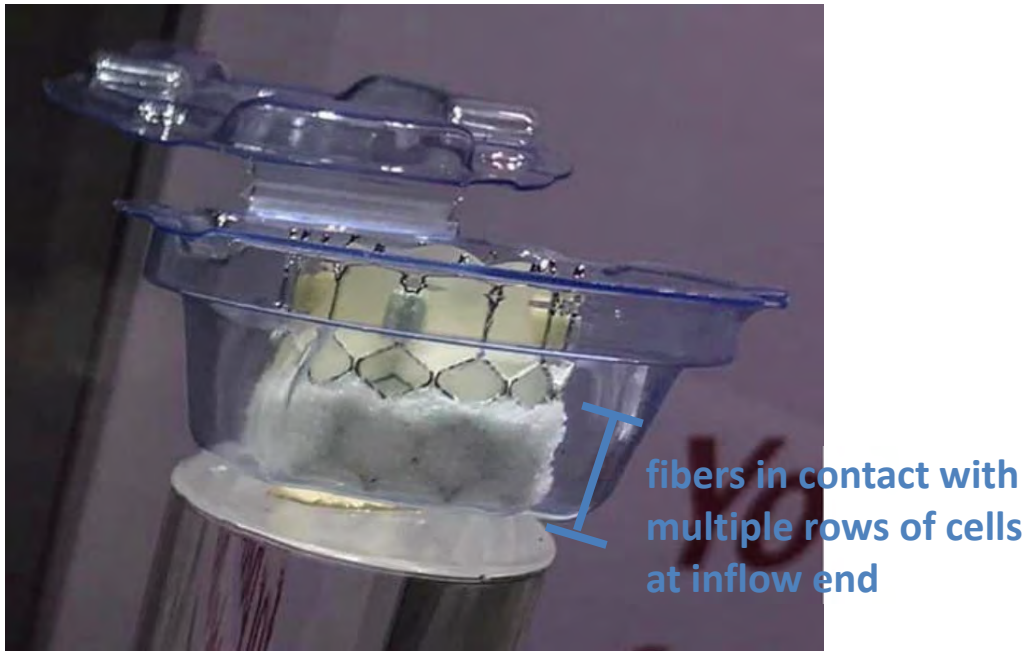
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

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

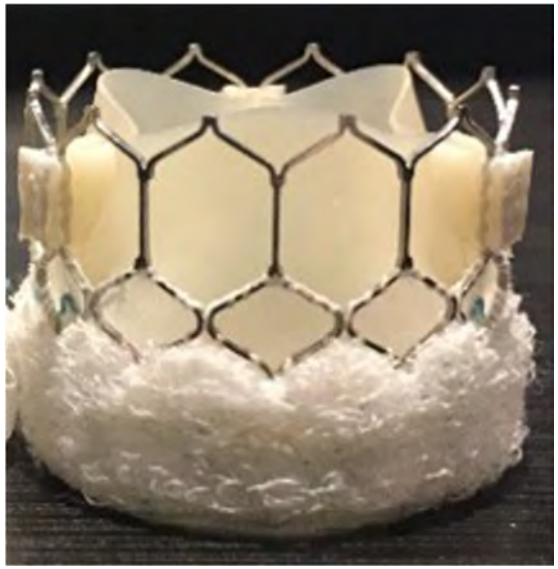
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

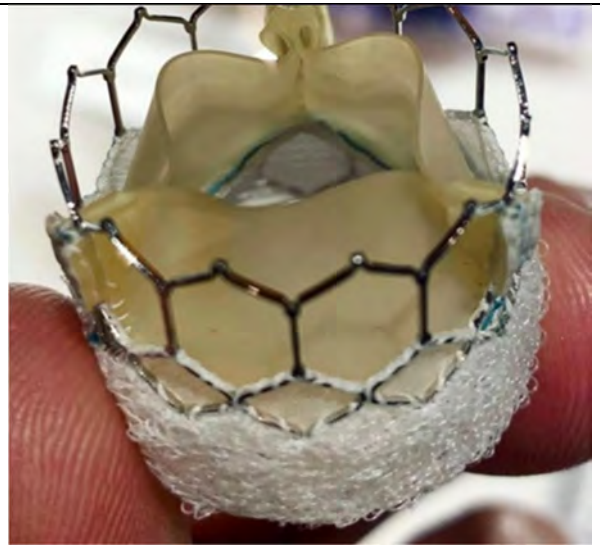
a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame,	The ’634 patent Accused Instrumentalities satisfy this element. The ’634 patent Accused Instrumentalities comprise a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame. For example, the Sapien 3 Ultra sealing skirt includes a plurality of fibers in contact with multiple rows of open cells at the inflow end of the frame. For example, the backside of the fibers are in contact with rows of open cells at the inflow end of the frame.  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

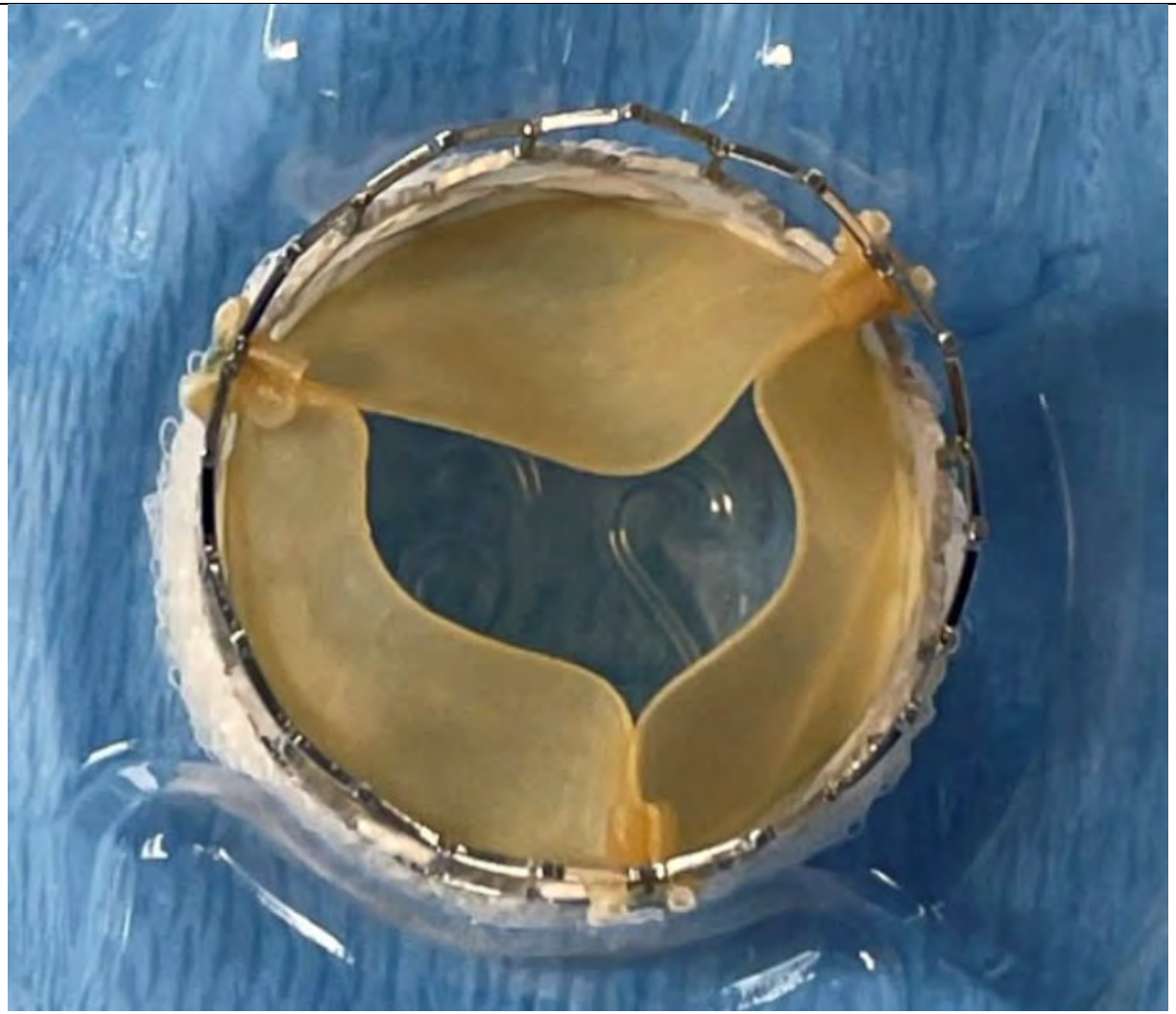


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

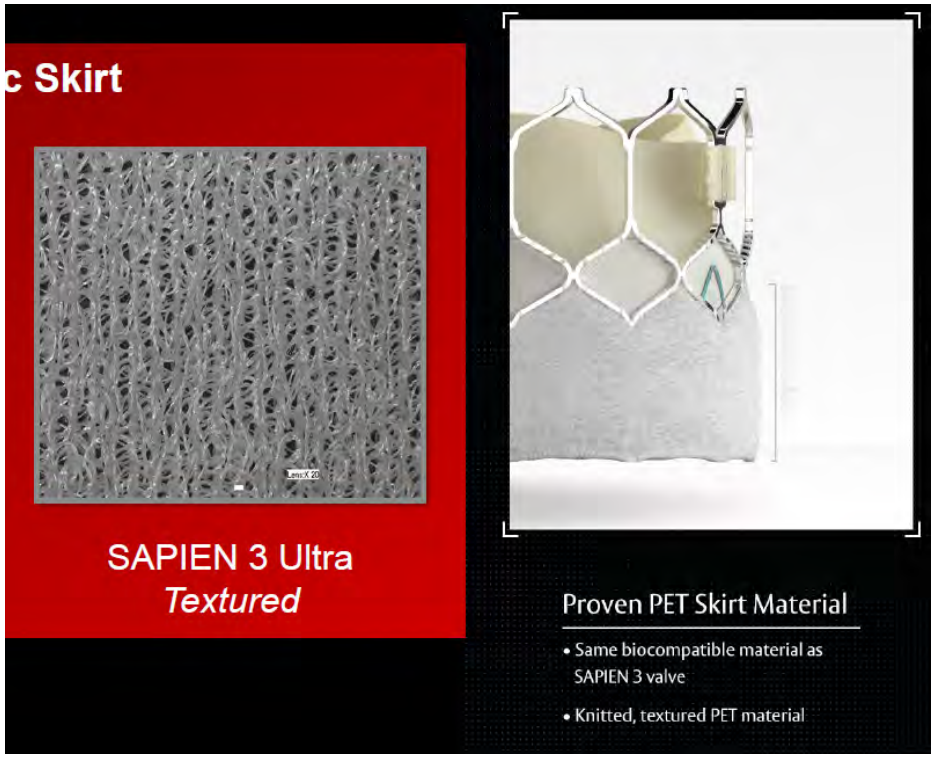
With respect to the phrase, "a plurality of fibers in contact with a plurality of rows of open cells at the inflow end of the frame," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the rows of open cells in contact with the plurality of fibers perform the same or substantially the same function as the claim phrase by providing a collapsible and expandable structure with openings for the fibers to at least partially contact, in the same or substantially the same way as the claim phase by being constructed of metal forming a frame structure with open cells at the inflow end of the same or equivalent shapes and sizes, to

	achieve the same or substantially the same result of rows of open cells that the fibers at least partially extend over and/or contact at the inflow end of the frame.
wherein the fibers are arcuate, spaced-apart, and outwardly extending,	The ’634 patent Accused Instrumentalities satisfy this element. The ’634 patent Accused Instrumentalities comprise fibers that are arcuate, spaced-apart, and outwardly extending. For example, the Edwards Sapien 3 Ultra includes a sealing skirt that includes a plurality of fibers that are arcuate, spaced-apart, and outwardly extending.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7) (showing arcuate, spaced apart, outwardly extending fibers).

	 https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29) (showing arcuate, spaced apart, outwardly extending fibers).

	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing arcuate, spaced apart, outwardly extending fibers) (D.I. 1, Ex. 64).

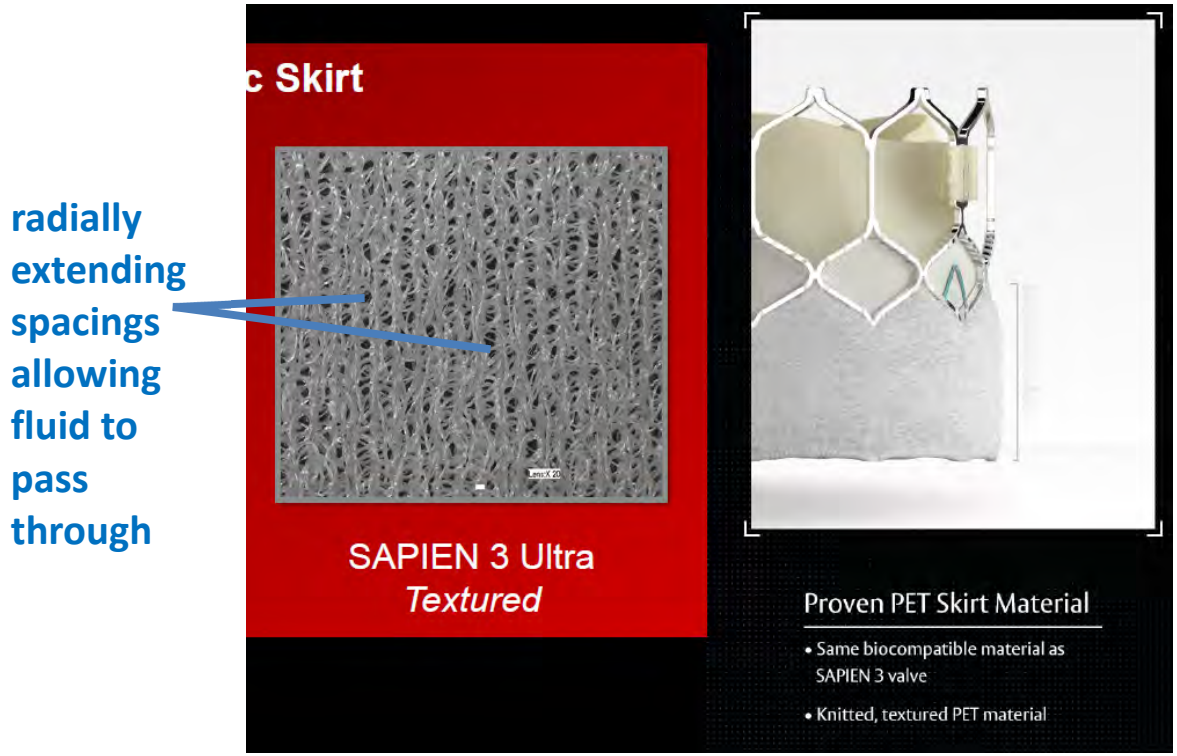
	 Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing arcuate, spaced apart, outwardly extending fibers) (D.I. 1, Ex. 3).



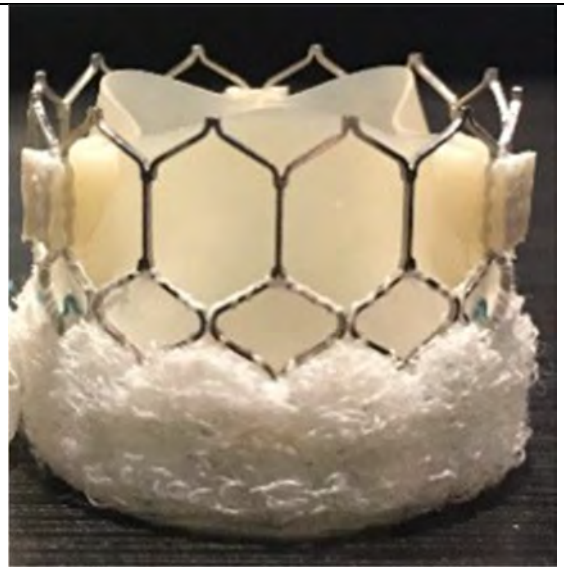
Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47) (showing arcuate, spaced apart, outwardly extending fibers).

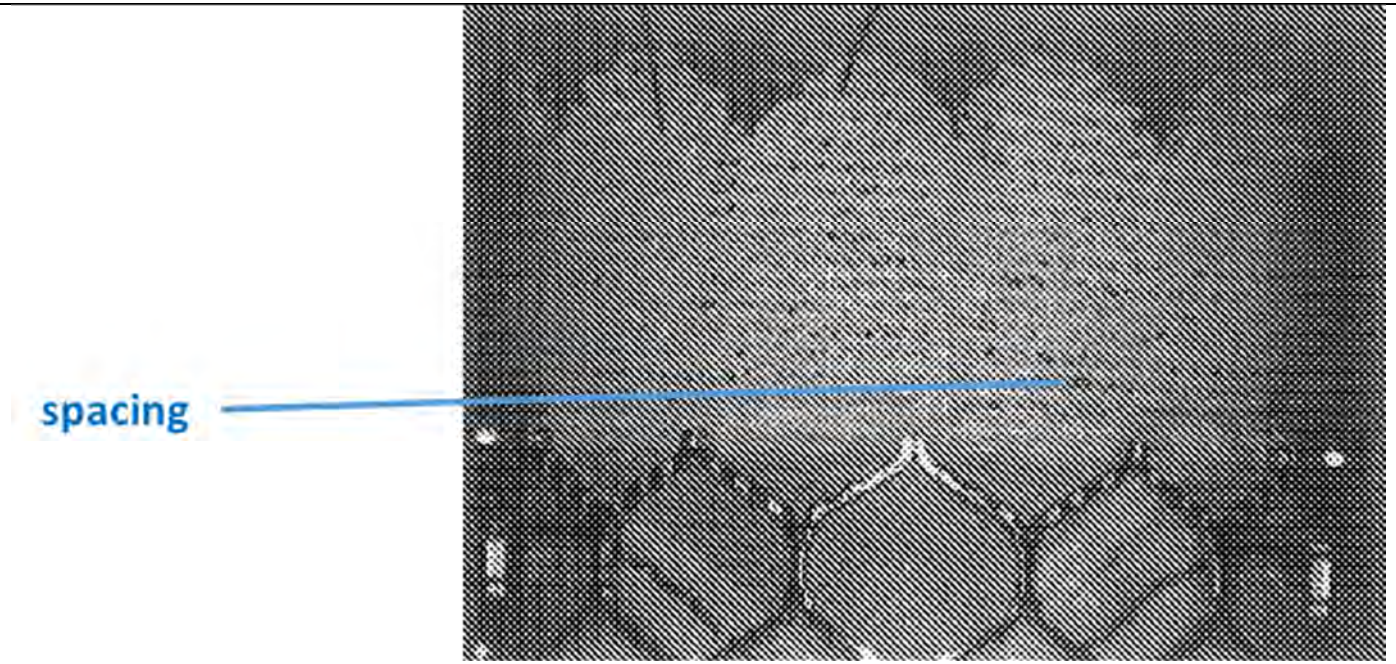
Further, with respect to the phrase, "wherein the fibers are arcuate, spaced-apart, and outwardly extending" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the sealing assembly does not allow visibility of the frame or that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing assembly formed of outwardly extending fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe

	at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused sealing assembly performs the same or substantially the same function as the claim phrase by providing for low profile sealing assembly capable of providing sealing between the anatomical wall and the frame, in the same or substantially the same way as the claim phase by using a biocompatible polymeric sealing assembly with arcuate fibers extending from the frame that are configured to press against and providing sealing between the patient's anatomical wall and the frame, to achieve the same or substantially the same result of providing outwardly extending, spaced apart, arcuate fibers configured to form a biocompatible seal between the anatomical wall, frame, and graft covering for reduced paravalvular leakage.
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,	The '634 patent Accused Instrumentalities satisfy this element. For example, the '634 patent Accused Instrumentalities' 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. For example, 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.



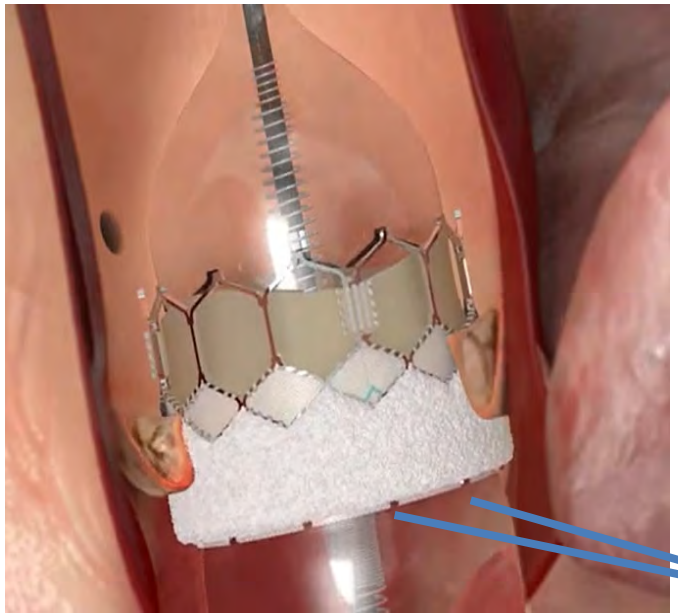
Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

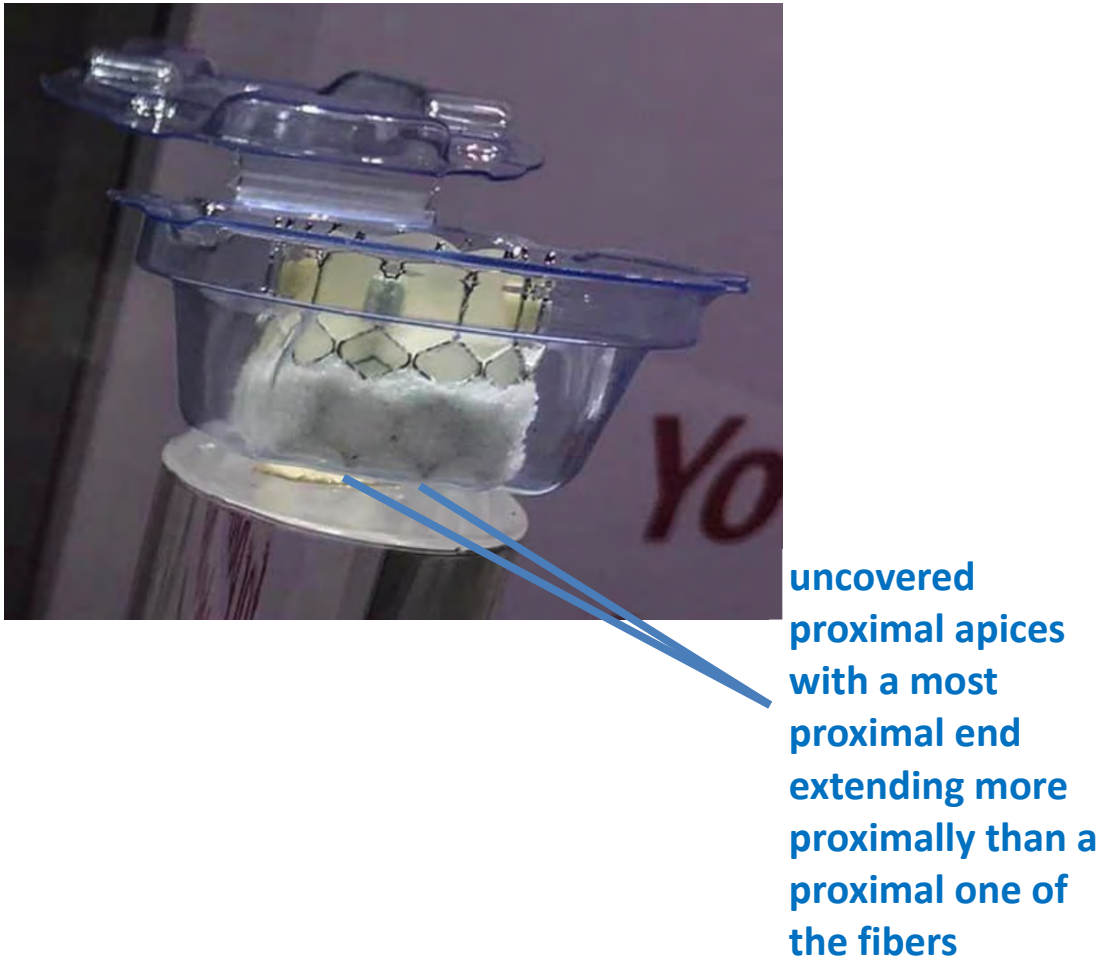
	 Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7). Further, the Sapien 3 Ultra sealing skirt spacings extend to the frame outer surface thereof allowing fluid to pass through when undeployed.



U.S. Provisional Patent Application No. 62/513,348, Fig. 30.

	 Twitter image of crimped Sapien 3 Ultra with blood.
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	The ’634 patent Accused Instrumentalities satisfy this element. The ’634 patent Accused Instrumentalities comprise 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. For example, the Sapien 3 Ultra is designed, manufactured, and tested by Edwards to ensure that ends of the most proximal apices of the frame are uncovered by the fibers and graft covering so that when crimped they extend into a low profile configuration. For further example, the Sapien 3 Ultra includes a frame where an end of the most proximal apices of the frame extends more proximally than a proximal one of the fibers.

proximal one of the plurality of fibers,	 **uncovered proximal apices with a most proximal end extending more proximally than a proximal one of the fibers** "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).



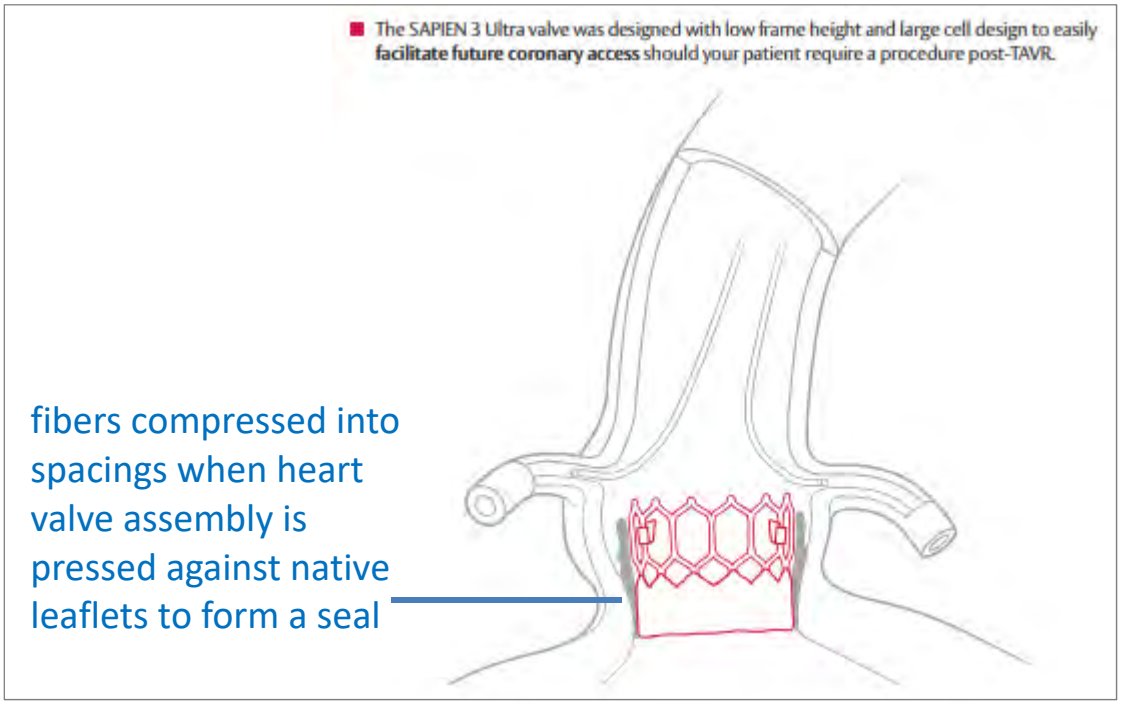
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth.

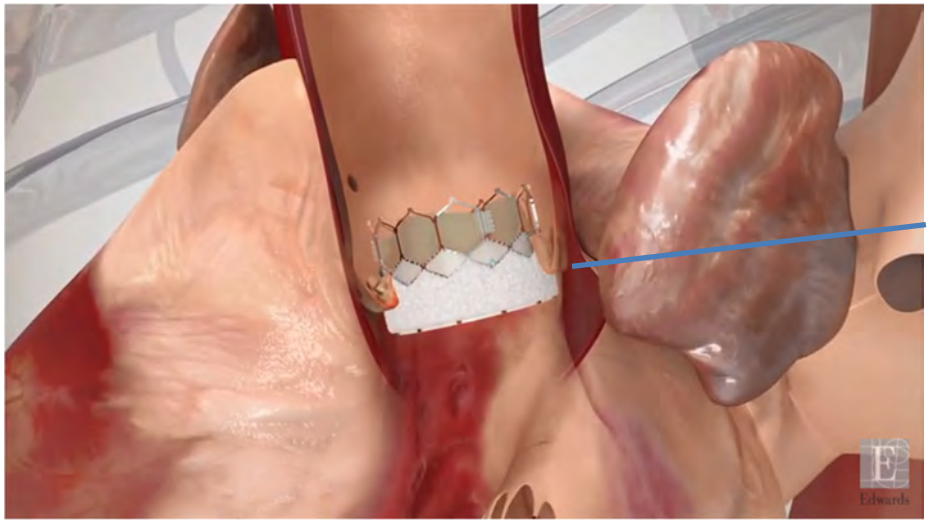


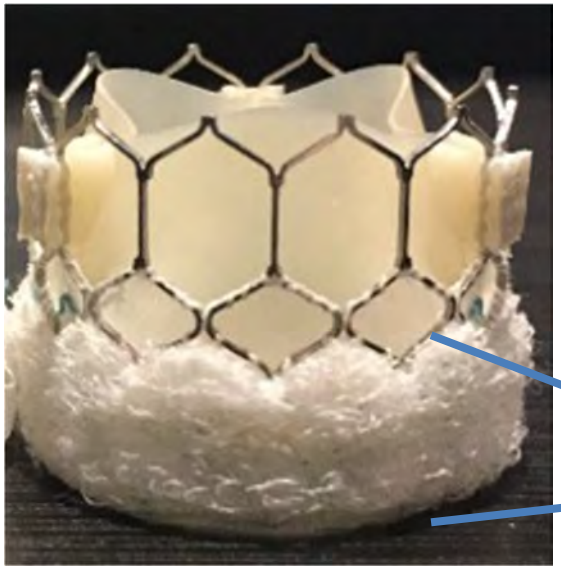
Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

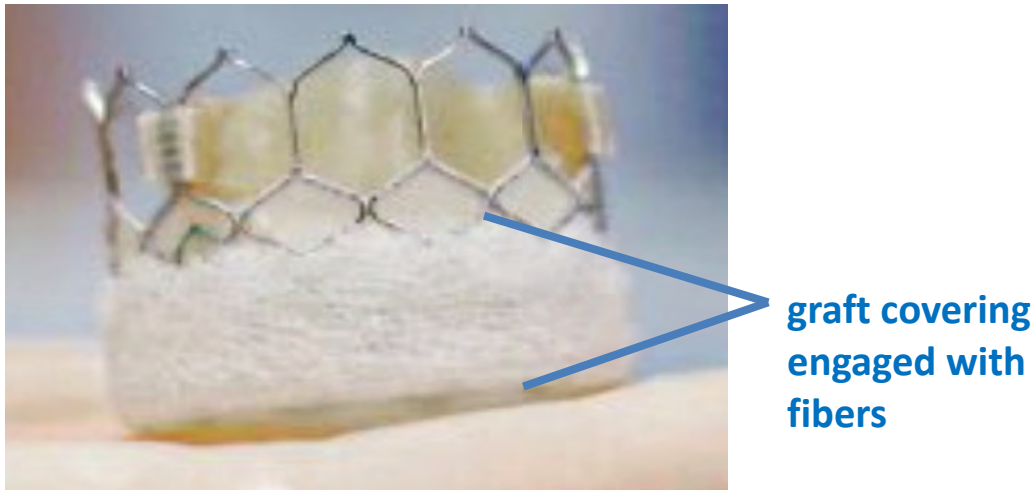
For example, the Sapien 3 Ultra includes a frame where an end of the most proximal apices of the frame extends more proximally than a proximal one of the fibers. The Sapien 3 Ultra is designed, manufactured, and tested by Edwards to ensure that an end(s) of the most proximal apices of the frame is uncovered and with a most proximal end extending more proximally than a proximal one of the fibers so that when crimped the valve assembly can extend into a low profile configuration.

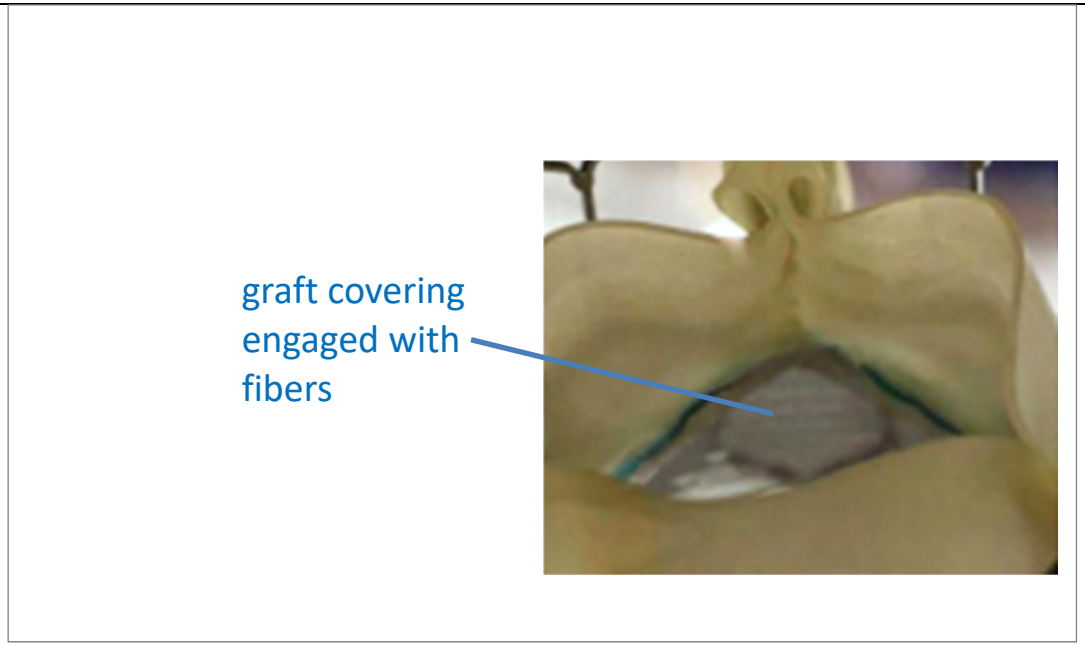
With respect to the phrase, "wherein an end of the apices of the frame that are most proximal are uncovered by the fibers and the graft covering such that an end of the most proximal apices of the frame extends more proximally than a most proximal one of the plurality of fibers," Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the end of the most proximal apices do not appear to be uncovered by the fibers and graft covering and/or to extend more proximally than a proximal one of the fibers in all images and configurations, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused end of the apices of the frame that are most proximal performs the same

	or substantially the same function as the claim phrase by being designed to permit the TAVR valve to achieve a low profile when in a collapsed/crimped state, in the same or substantially the same way as the claim phase by ensuring that the fibers and graft covering minimize interference with the ends of the most proximal apices of the frame and/or permits their further passage there through when the TAVR valve is in a collapsed/crimped state, to achieve the same or substantially the same result of a TAVR valve with an outwardly extending fibers that is capable of being collapsed/crimped to achieve a low profile for endovascular delivery.
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,	The ’634 patent Accused Instrumentalities satisfy this element. For example, the ’634 patent Accused Instrumentalities are 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. For example, the Sapien 3 Ultra is designed and configured so that when expanded the fibers are compressed into the radially extending spacings when heart valve assembly is pressed against native leaflets to form a seal. 

	Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).  "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
wherein the graft covering is engaged with fibers of the plurality of fibers,	The '634 patent Accused Instrumentalities satisfy this element. For example, the '634 patent Accused Instrumentalities' graft covering is engaged with fibers of the plurality of fibers. For example, the Sapien 3 Ultra graft covering is engaged at multiple places with the fibers of the sealing skirt. For further example, the graft covering and/or sealing material may protrude though the open cells in the frame an engage one another.

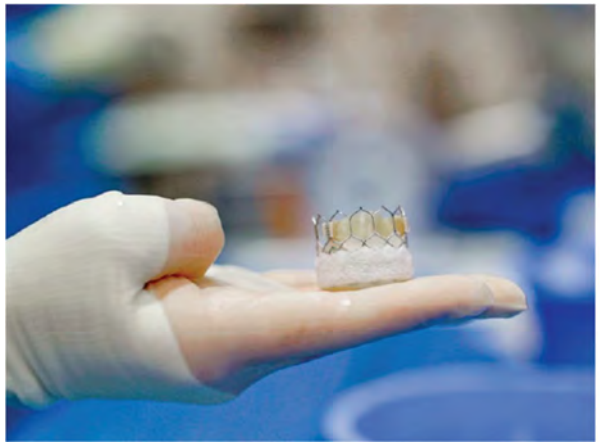
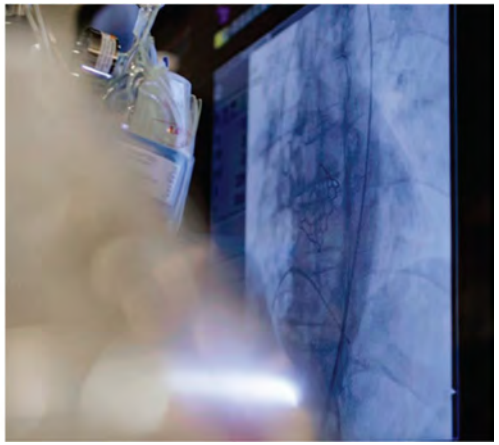
	 graft covering engaged with fibers

	Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).  R. Taj Twitter post (D.I. 1, 62)



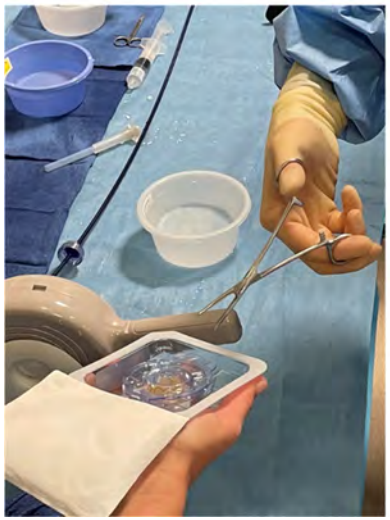
Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29)

With respect to the phrase, "wherein the graft covering is engaged with fibers of the plurality of fibers," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused plurality of graft covering is engaged with fibers perform the same or substantially the same function as the claim phrase by having a graft covering engaged with the fibers, in the same or substantially the same way as the claim phase by having a graft covering and sealing material fibers at least partially radially aligned and/or attached to one another directly or indirectly via an open cell frame, to achieve the same or substantially the same result of a graft covering that is configured to engage and/or partially engage 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.	The ’634 patent Accused Instrumentalities satisfy this element. For example, the ’634 patent Accused Instrumentalities in operation is configured to be deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery patient. Further, the Sapien 3 Ultra is designed, developed, promoted, configured to be deployable and is deployable endovascularly through a femoral artery of a patient after obtaining access thereto using Edwards’ balloon catheter delivery systems.   https://twitter.com/RajTayalMD/status/1587516343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg





https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

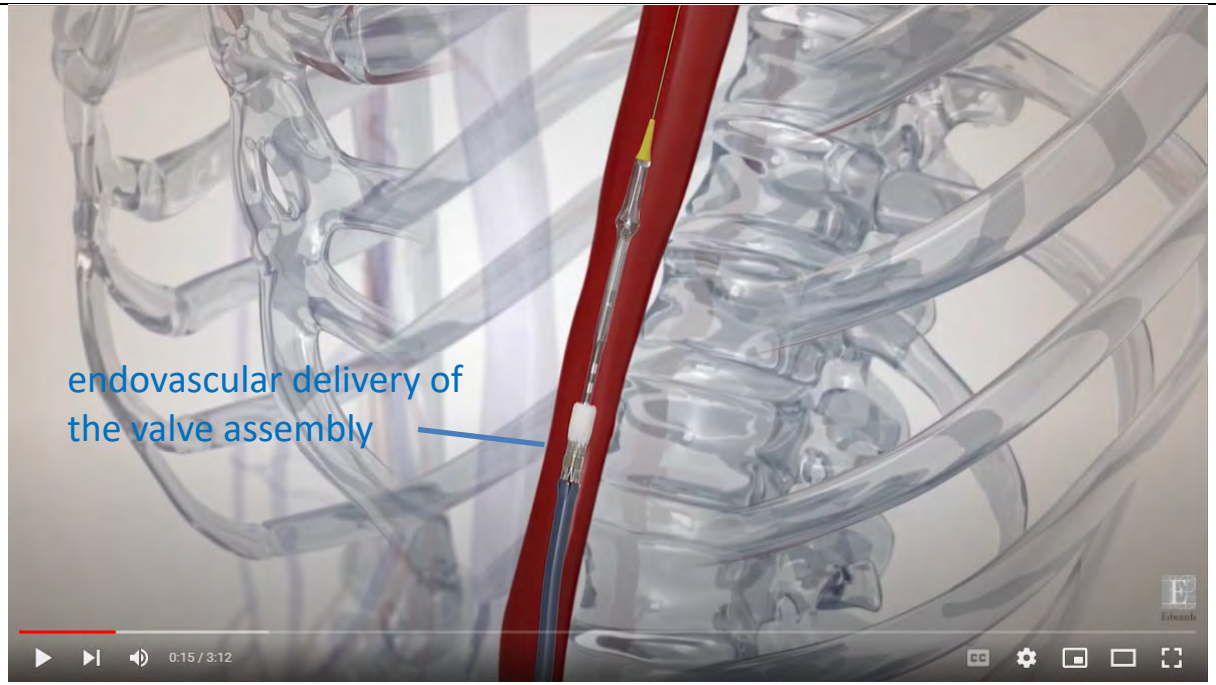


https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

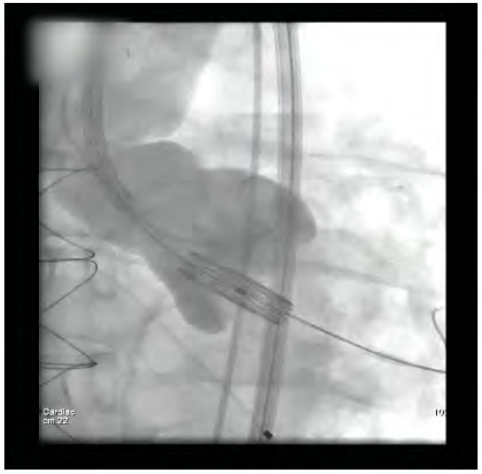
The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.

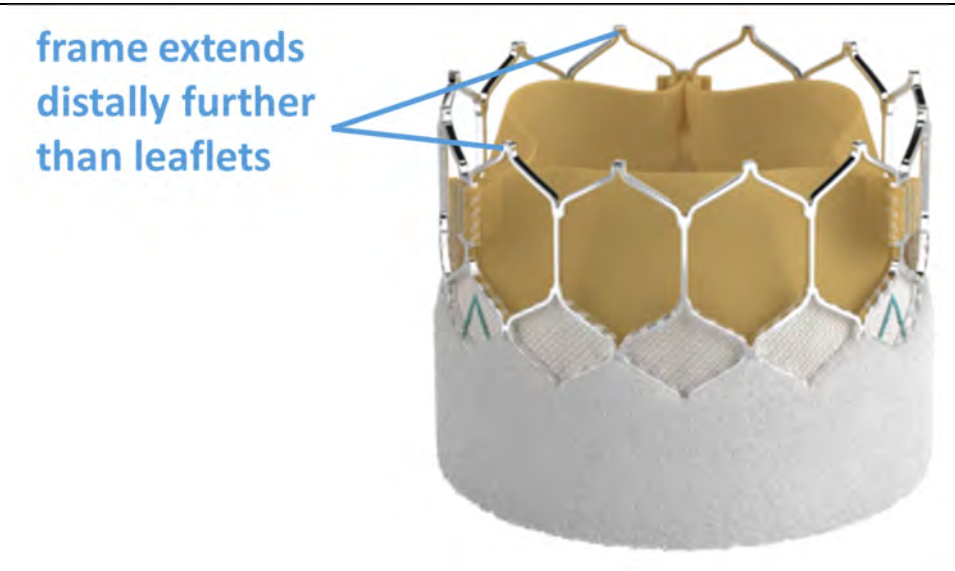


SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

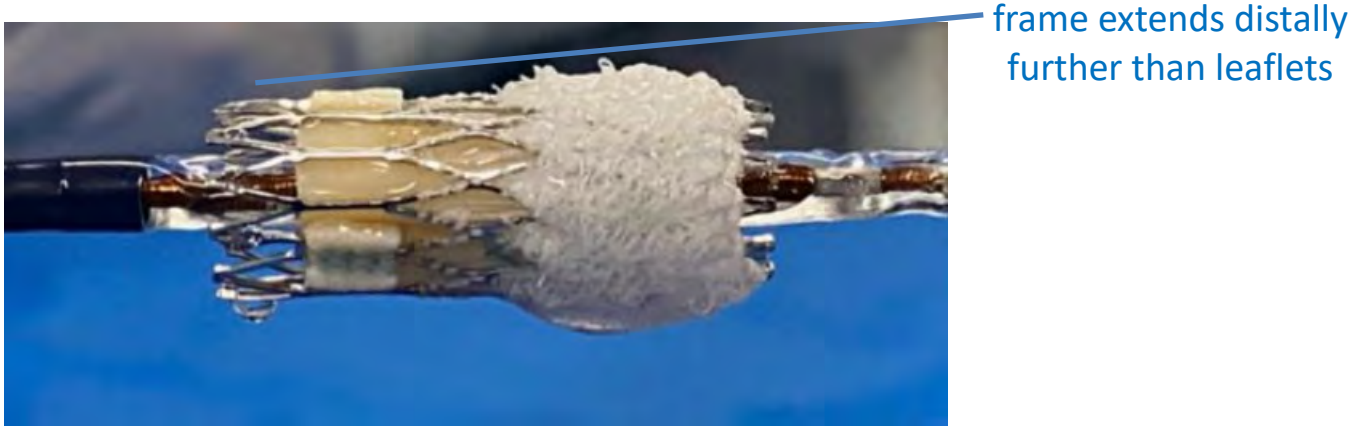


SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).
2. The valve assembly of claim 1, wherein the frame extends distally further than the prosthetic heart valve leaflets.	The '634 patent Accused Instrumentalities satisfy this element. The '634 patent Accused Instrumentalities' frame extends distally further than the prosthetic heart valve leaflets. For example, this occurs when the heart valve is in compressed, expanded, and partial configurations. For example, the Sapien 3 Ultra frame extends distally further than the prosthetic valve leaflets.

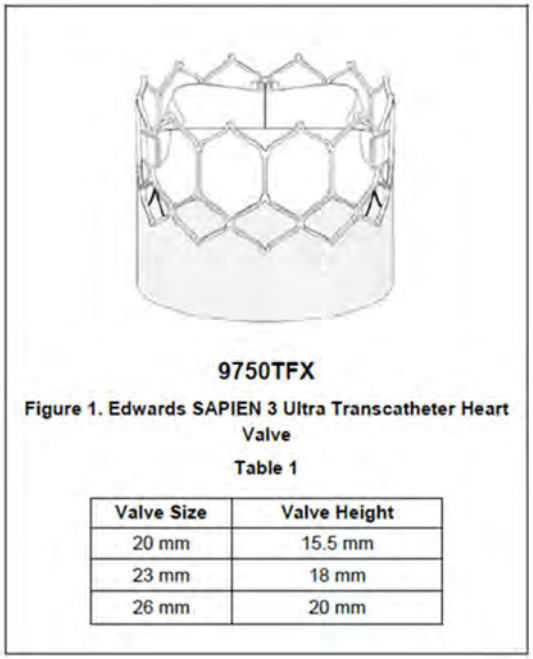


https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

	See also, claim 1.
3. The valve assembly of claim 1, wherein the frame is a singular, integral component.	The ’634 patent Accused Instrumentalities satisfy this element. For example, the ’634 patent Accused Instrumentalities’ frame is a singular, integral component. For example, the Edwards Sapien 3 Ultra frame is made of a cobalt-chromium metallic alloy as a singular, integral component. **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.



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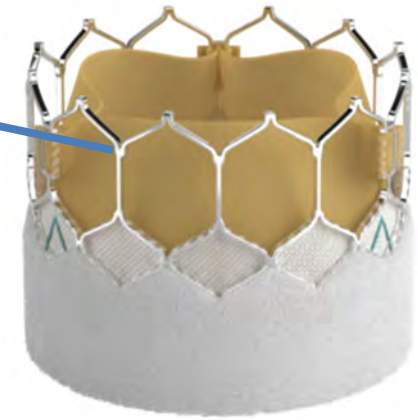
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

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

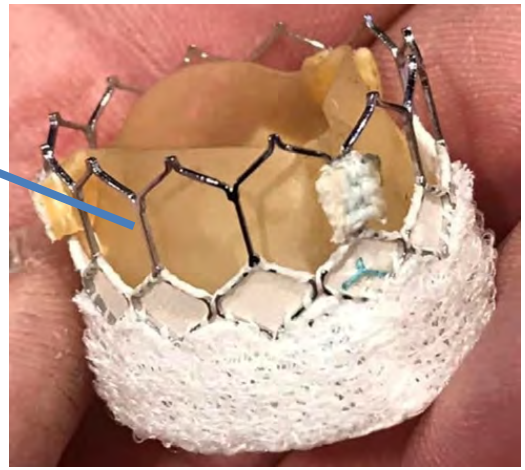
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

singular integral frame

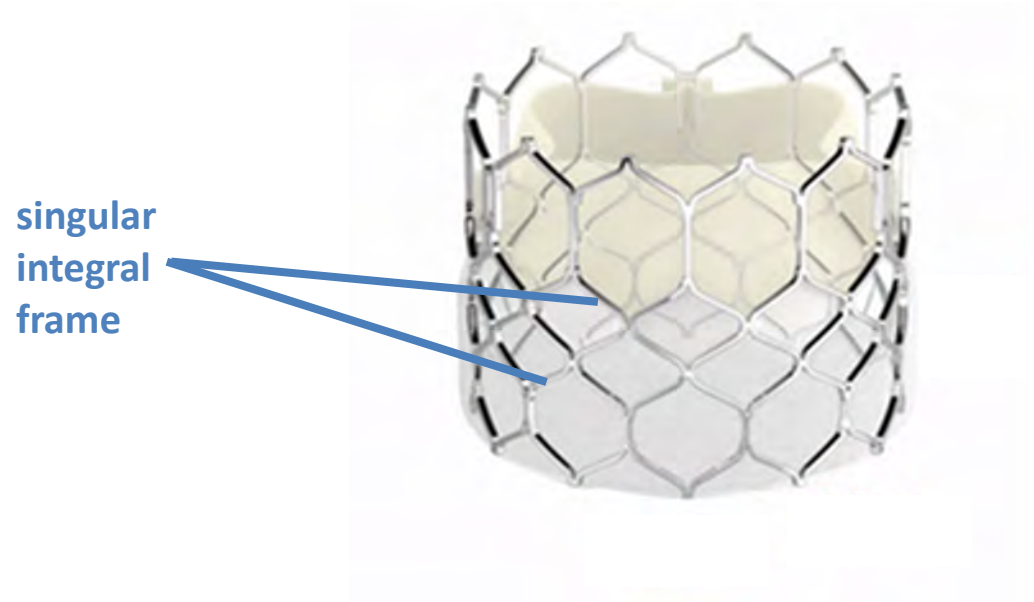


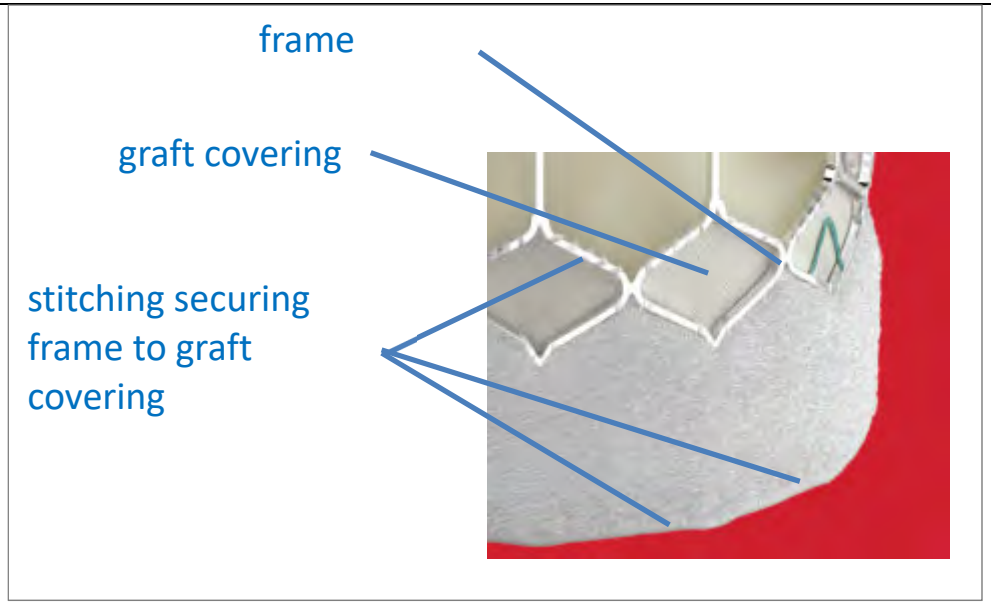
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

singular integral frame

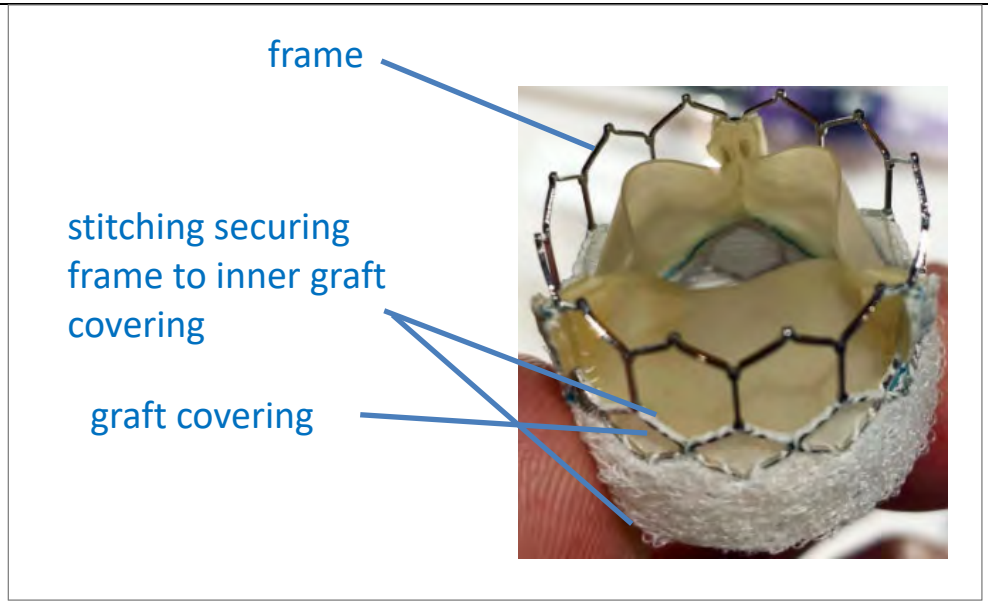


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

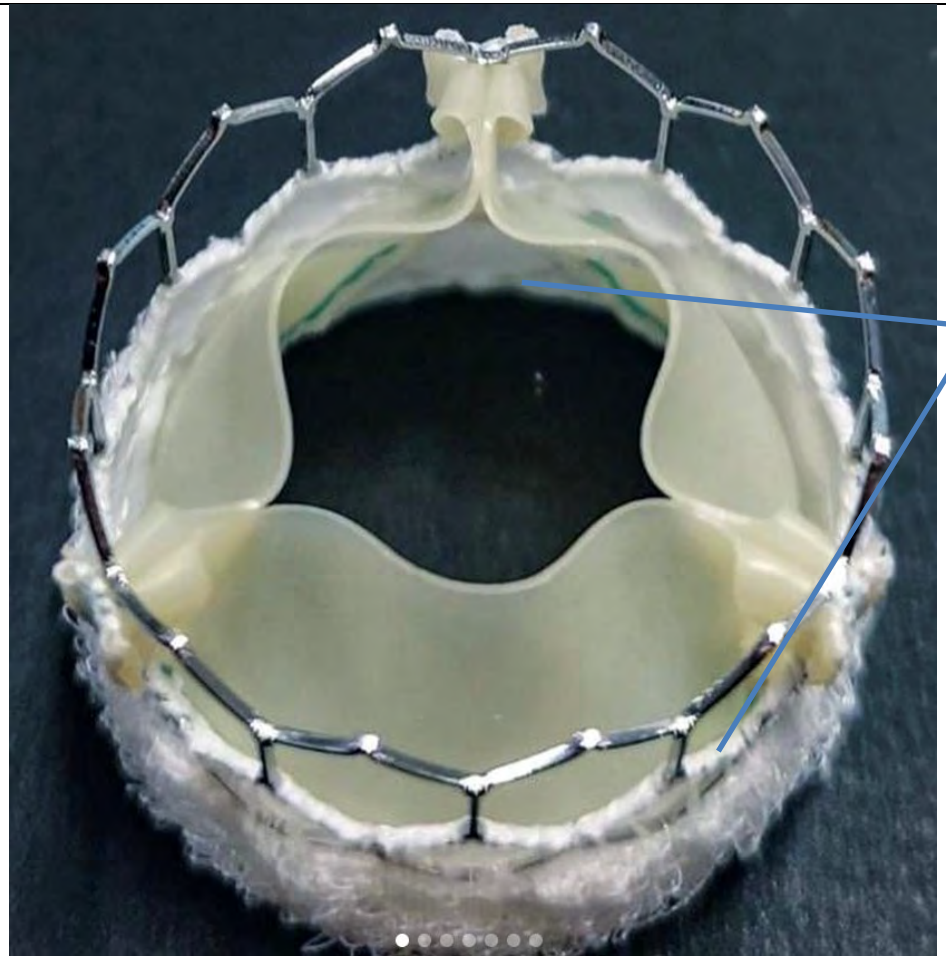
	 https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). *See also*, claim 1.
4. The valve assembly of claim 1, wherein the frame and the graft covering are attached by stitching at a top and bottom portion of the graft covering.	The ’634 patent Accused Instrumentalities satisfy this element. For example, the ’634 patent Accused Instrumentalities’ frame and the graft covering are attached by stitching at a top and bottom portion of the graft covering. For example, the Sapien 3 Ultra frame and graft covering are attached by stitching at the top and bottom portions of the graft covering.

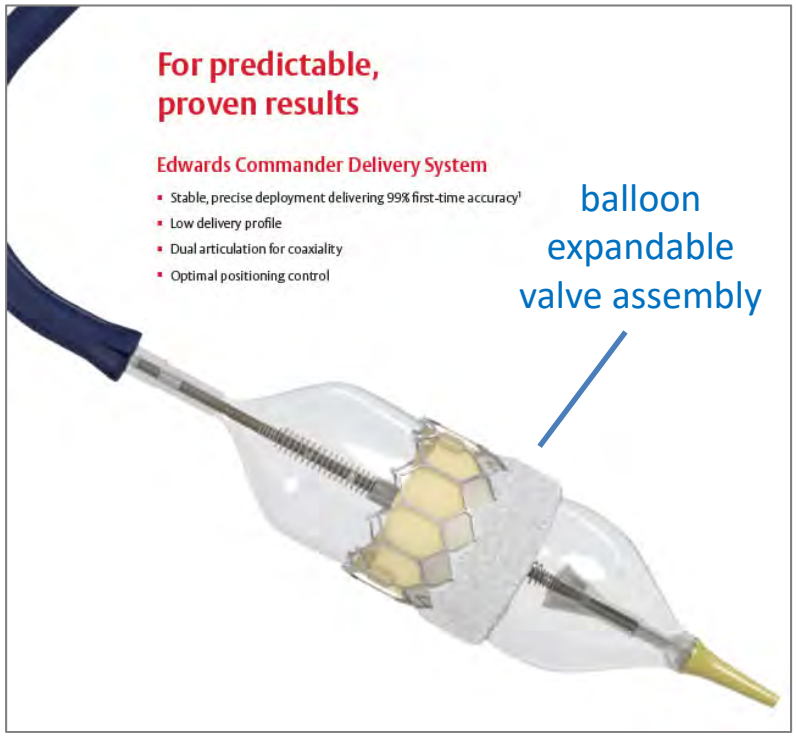


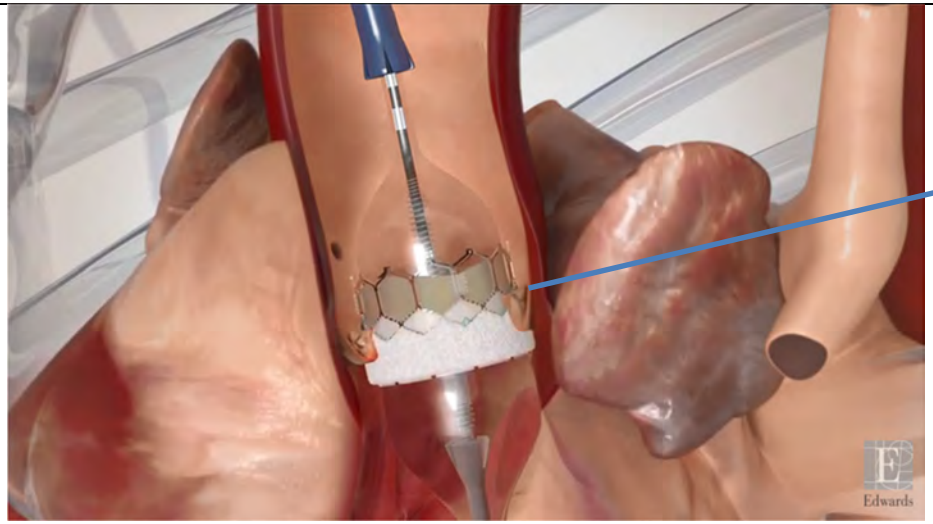
Introducing the SAPIEN 3 Ultra valve at 2 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

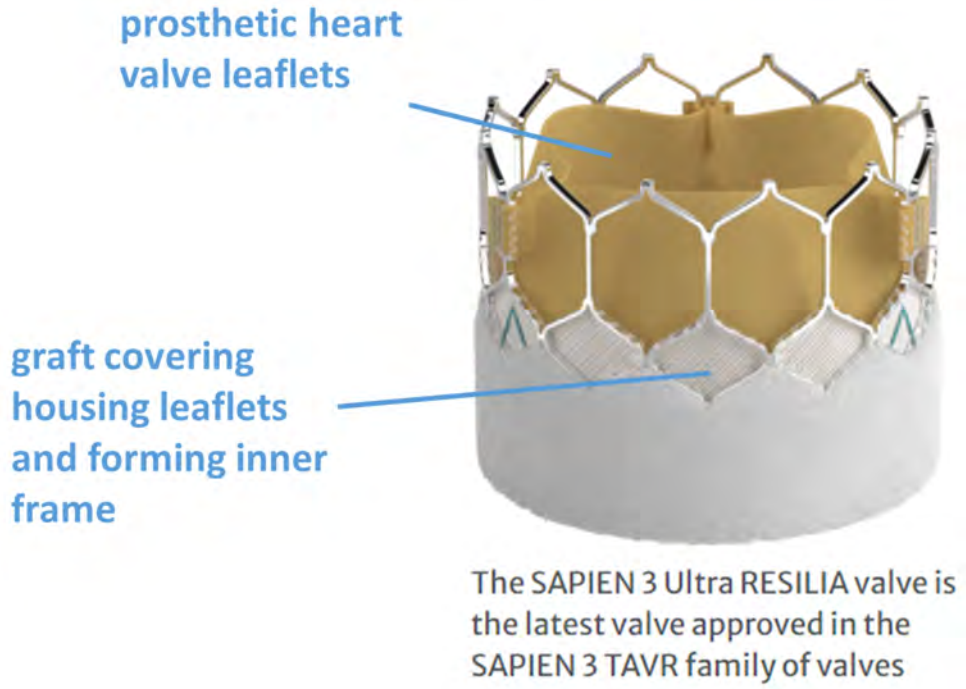


Sapien 3 Ultra image available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

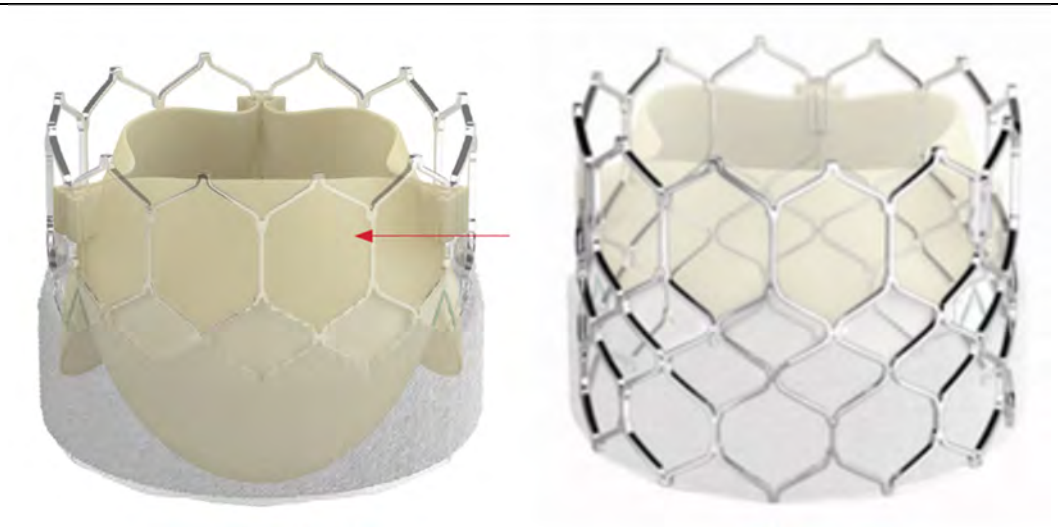
	 Julian Calain Twitter (D.I. 1, Ex. 30). *See also*, claim 1.
5. The valve assembly of claim 1,	The ’634 patent Accused Instrumentalities satisfy this element. For example, the ’634 patent Accused Instrumentalities comprise a valve assembly that is balloon expandable.

wherein the valve assembly is balloon expandable.	For example, the Edwards Sapien 3 Ultra is deployed and expanded using a balloon delivery system.  Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).

	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37). *See also*, claim 1.
6. The valve assembly of claim 1, wherein the graft covering forms an inner frame for housing the prosthetic heart valve leaflets.	The '634 patent Accused Instrumentalities satisfy this element. The '634 patent Accused Instrumentalities' graft covering housing a prosthetic heart valve forms an inner frame for supporting the prosthetic heart valve. For example, the Edwards Sapien 3 Ultra graft covering forms an inner frame that houses the prosthetic heart valve leaflets. To the extent required, the inner frame is balloon expandable.

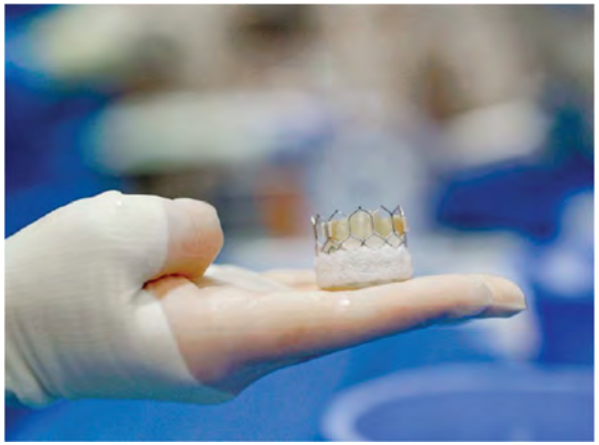
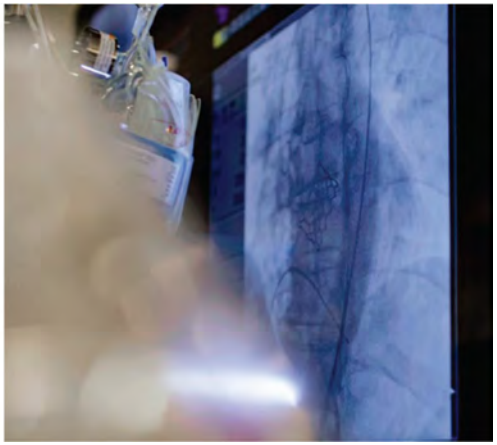


https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



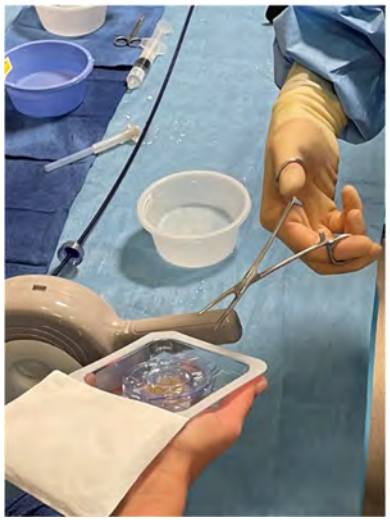
https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).

With respect to the phrase, "wherein the graft covering forms an inner frame for housing the prosthetic heart valve leaflets", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a graft covering inner frame that is balloon-expandable and/or that provides support and resist collapse, the identified graft covering, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering performs the same or substantially the same function as the claim phrase by being collapsible and expandable, as well as housing and framing the prosthetic heart valve, in the same or substantially the same way as the claim phase through a collapsible and expandable graft covering inner frame that extends around the prosthetic valve leaflets and is secured by stitching to the frame and housing and providing sealing to the prosthetic heart valve and/or valve

	leaflets, to achieve the same or substantially the same result of a collapsible and expandable graft covering inner frame in a TAVR valve that is configured to frame, house, support (directly and/or indirectly), and/or provide sealing to the prosthetic heart valve and/or valve leaflets. *See also*, claim 1.
7. The valve assembly of claim 1, wherein the valve assembly is configured for being received within a catheter that is delivered through the femoral artery of the patient.	The ’634 patent Accused Instrumentalities satisfy this element. For example, the ’634 patent Accused Instrumentalities are configured to be received within a catheter that is delivered through the femoral artery of the patient. For example, the Sapien 3 Ultra is designed, developed, promoted, and configured to be received within a catheter that is delivered through the femoral artery of the patient.   https://twitter.com/RajTayalMD/status/1587516343127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

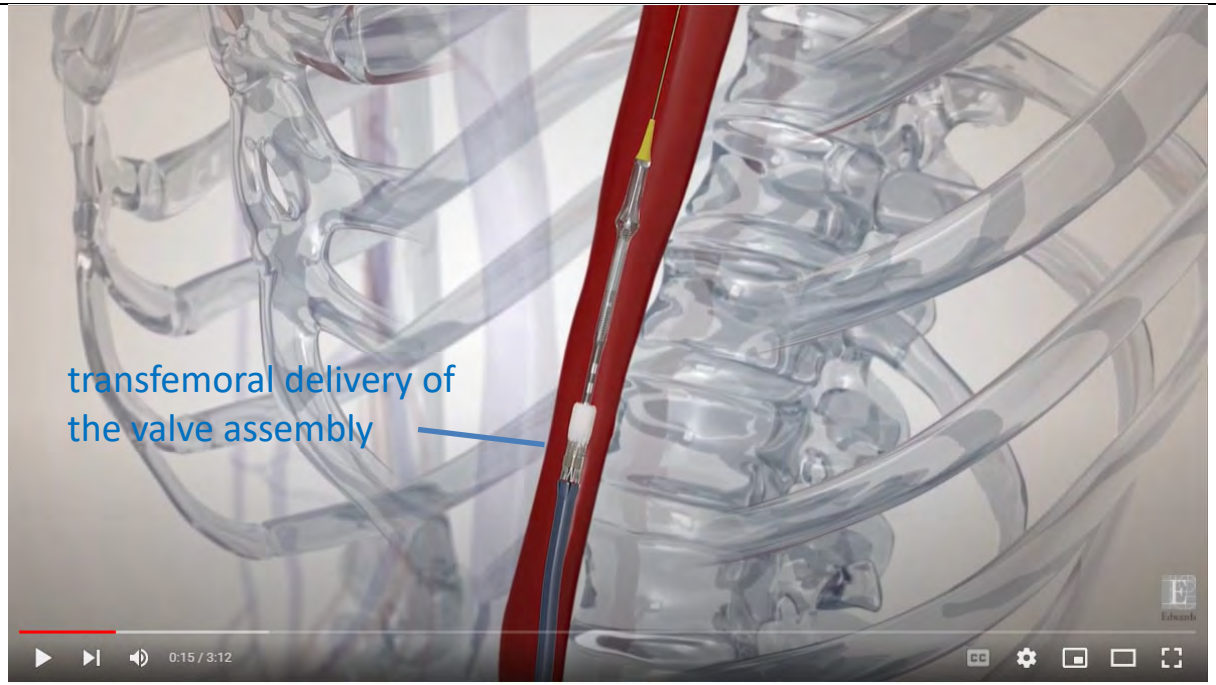




https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).



SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

SAPIEN 3 Ultra System Case Example





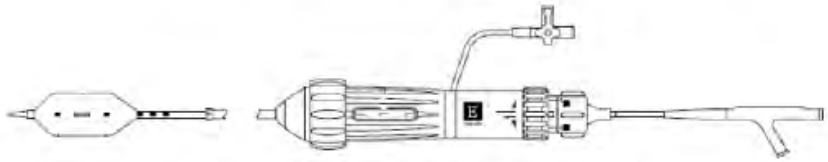
Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



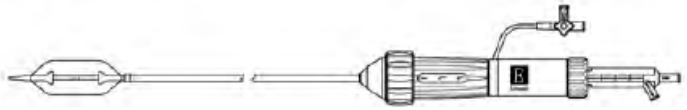
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

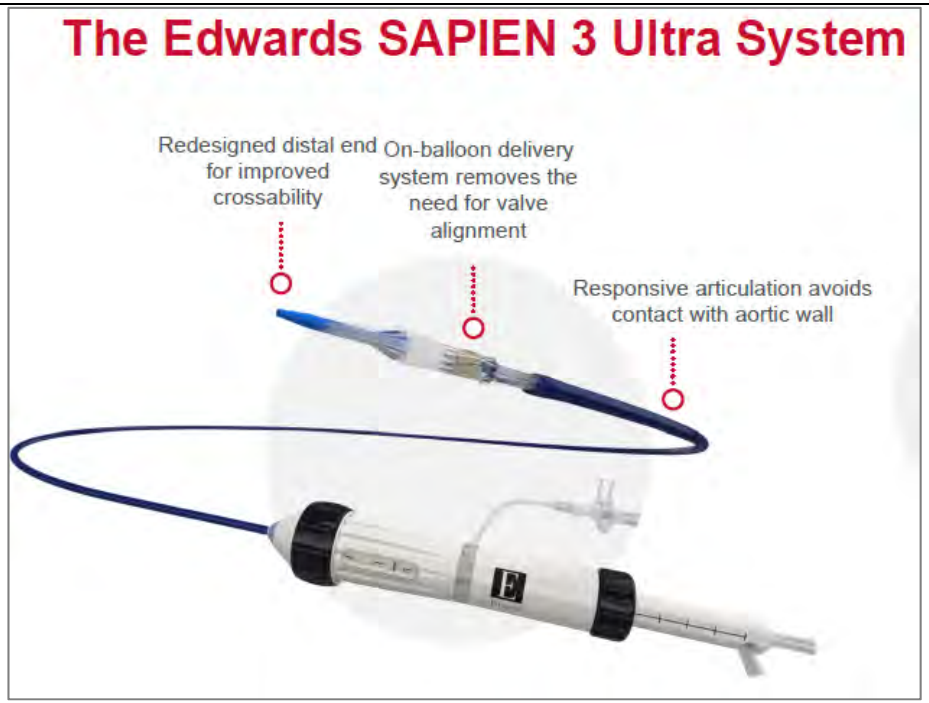
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

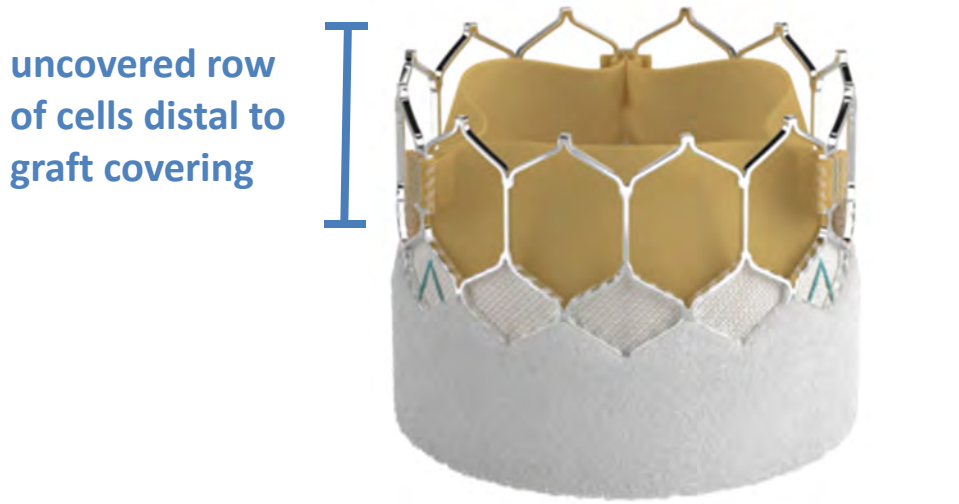
Table 6

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

	See also, claim 1.
9. The valve assembly of claim 1, wherein a row of cells distal to the graft covering is uncovered by the graft covering and the fibers.	The ’634 patent Accused Instrumentalities satisfy this element. For example, the ’634 patent Accused Instrumentalities include a row of cells distal to the graft covering that is uncovered by the graft covering and the fibers. For example, the Edwards Sapien 3 Ultra includes a row of cells distal to the graft covering is uncovered by the graft covering and the fibers.  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

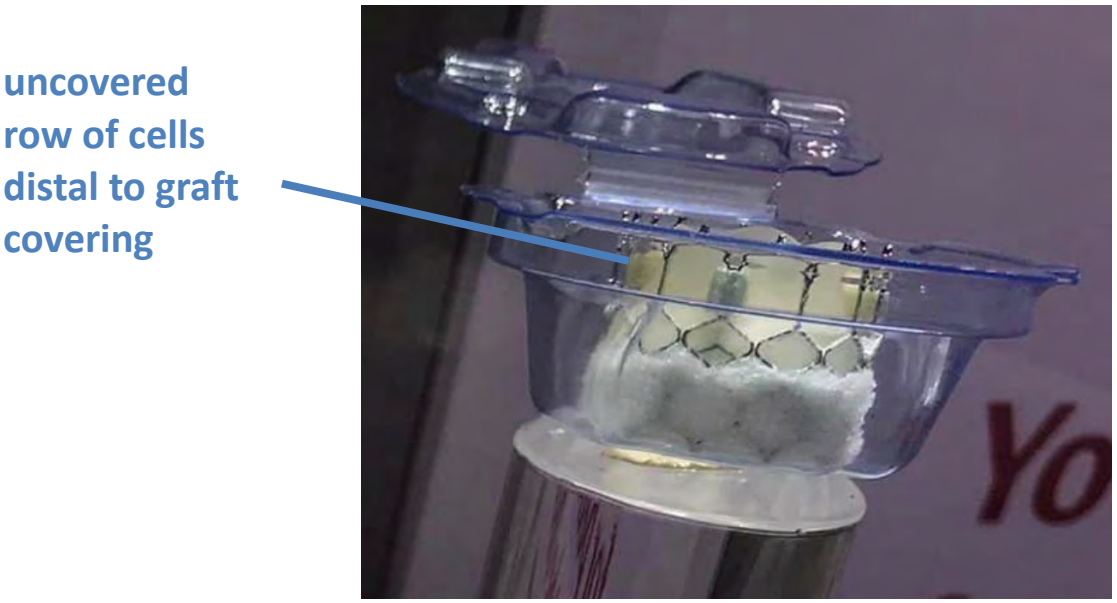
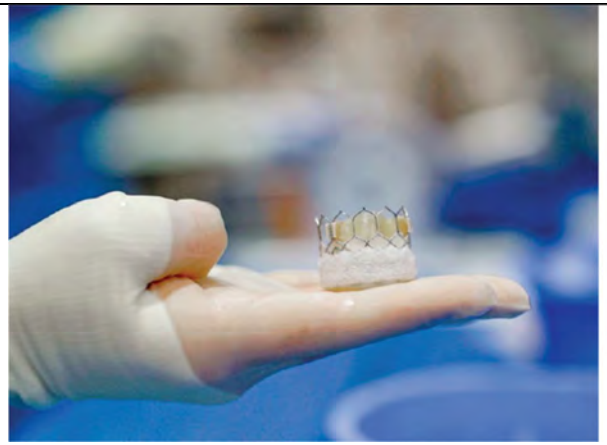
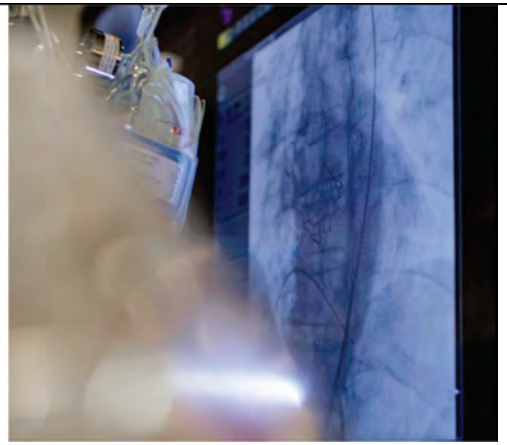
	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3). *See also*, claim 1.

Exhibit E - Edwards' Infringement of U.S. Patent No. 11,523,918

Claim	Exemplary Infringement Evidence[1]
1. An endovascularly deployed heart valve assembly comprising:	To the extent the preamble is limiting, the '918 patent Accused Instrumentalities[2] satisfy this element. For example, the '918 patent Accused Instrumentalities are endovascularly deployed heart valve assemblies. The '918 patent Accused Instrumentalities are endovascular aortic heart valve assemblies designed, promoted, configured to be deployable, and are deployable endovascularly using Edwards' balloon delivery systems.

[1] The exemplary evidence and infringement assertions cited herein may also be used to support any other claim element where appropriate. Aortic Innovation LLC's ("Aortic") investigation is ongoing and discovery is in its preliminary stages. Aortic hereby incorporates by reference the cover pleading to which this claim chart is attached. Aortic reserves the right to amend or supplement these contentions after further investigation and discovery from Edwards and non-parties and in accordance with the rules and schedule. Such supplemental information may include, but is not limited to, FDA submissions and correspondence, data sheets, design specifications, deposition testimony, testing information, reference designs, implementation and utilization information, and/or schematics. Aortic also reserves the right to assert additional claims of the Aortic patents-in-suit, accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products. Under the proper construction of the asserted claims and their claim terms, each element of the asserted claims is literally present in the accused products or acts accused of infringing the claim. Any and all elements found not to be literally infringed are infringed under the doctrine of equivalents because the differences between the claimed inventions and the Accused Instrumentalities, if any, are insubstantial. Aortic further reserves the right to accuse different products, or find alternative literal and/or equivalent infringing elements in Edwards's products, based on further investigation and discovery, the claim construction process, the Court's rules, and/or other circumstances so meriting.

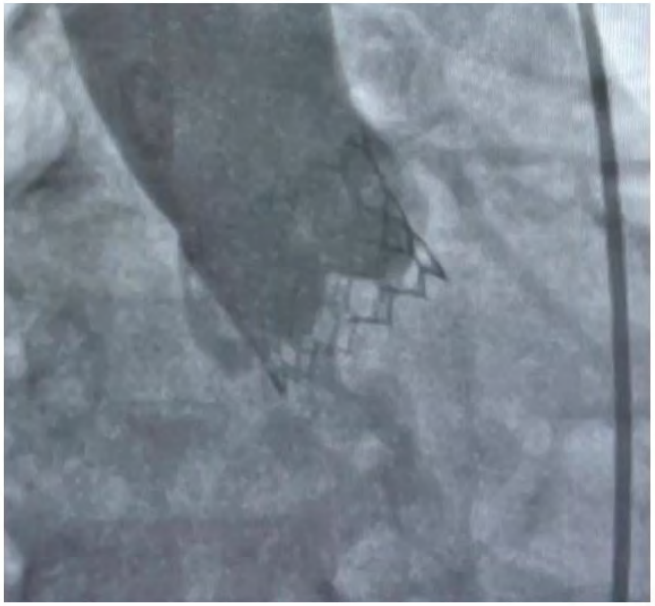
[2] "Accused Instrumentalities" refers to all models, versions, and sizes of Edwards's Sapien 3 Ultra devices, including, but not limited to Edwards Sapien 3 Ultra valves with non-Resilia valve leaflets and Edwards Sapien 3 Ultra Resilia valves, which Aortic understands to be the same as the Sapien 3 Ultra, but with Edwards' Resilia valve leaflet tissue which Aortic understands uses "a bovine (cow) heart tissue that has been treated with Edwards' technology to block calcium build-up on the valve." Discovery is ongoing and Aortic reserves the right to amend or supplement the identified Accused Instrumentalities to the extent that additional relevant information is obtained during discovery.

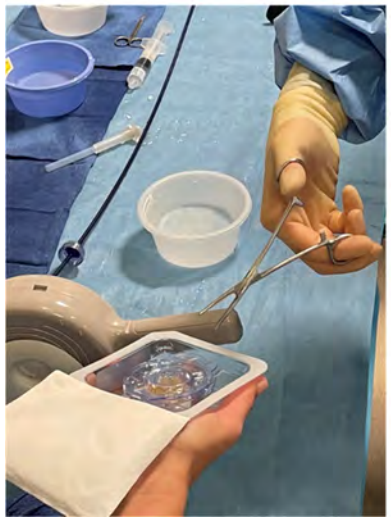
	  https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 54).

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



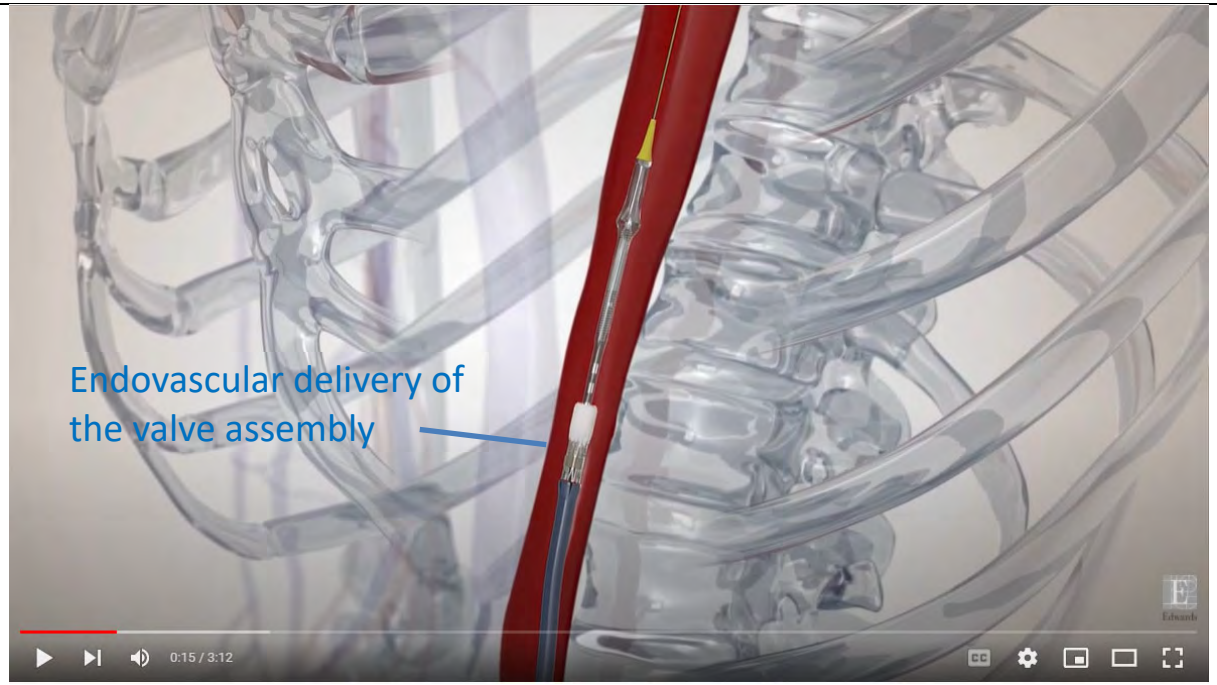


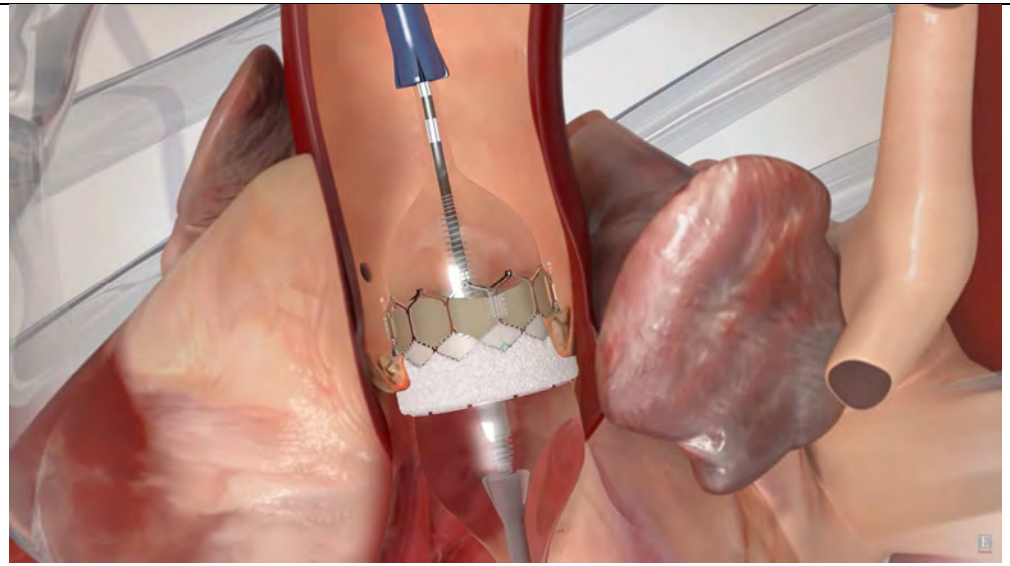
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra[3] is designed, manufactured, promoted, and sold by Edwards for endovascular deployment.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[3] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.


Endovascular delivery of
the valve assembly
0:15 / 3:12



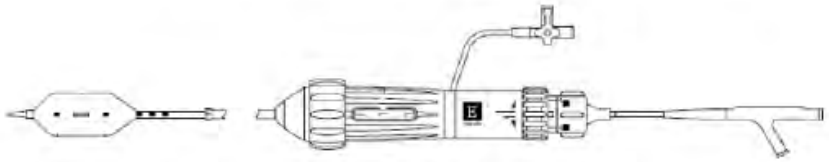
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8 (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



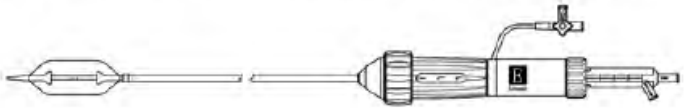
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

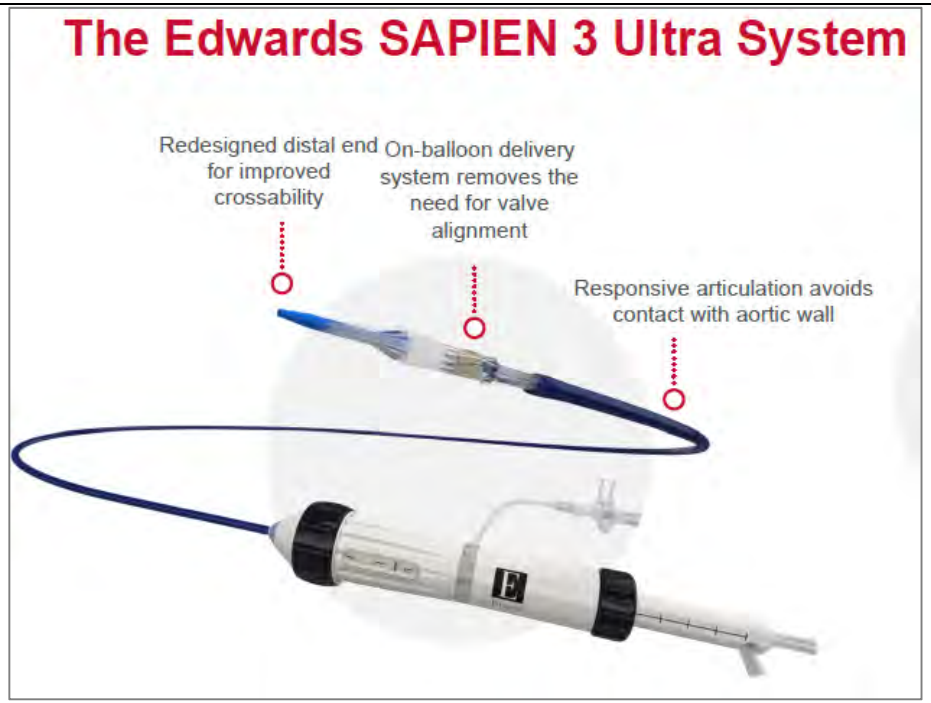
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

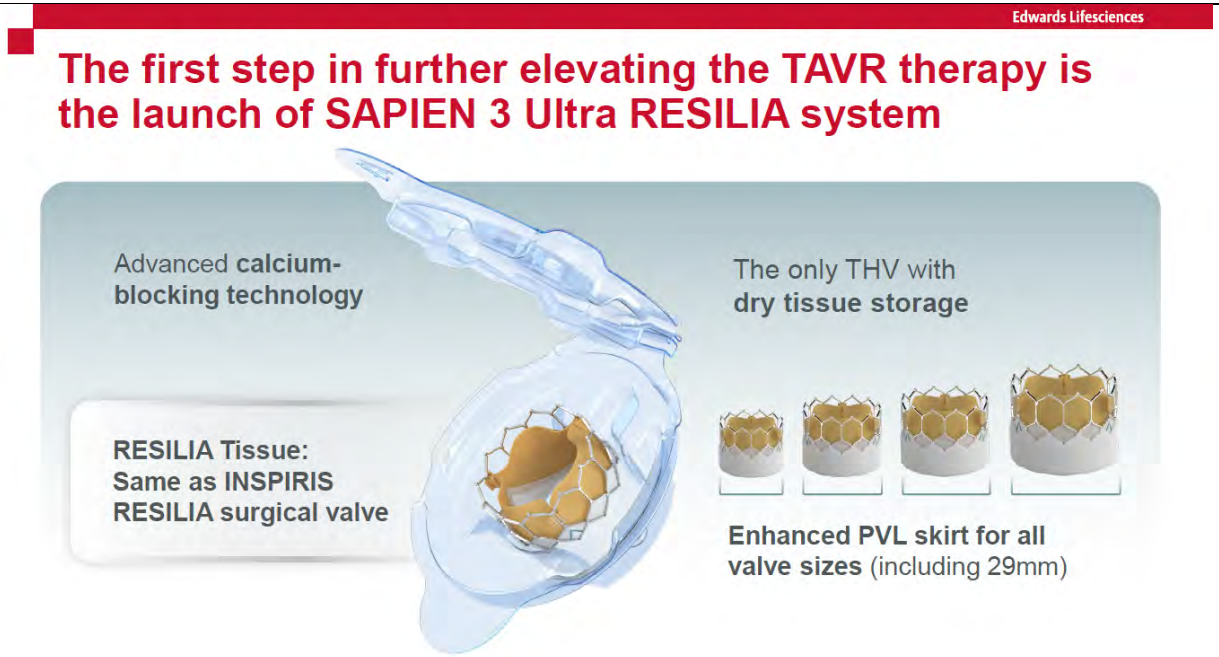
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

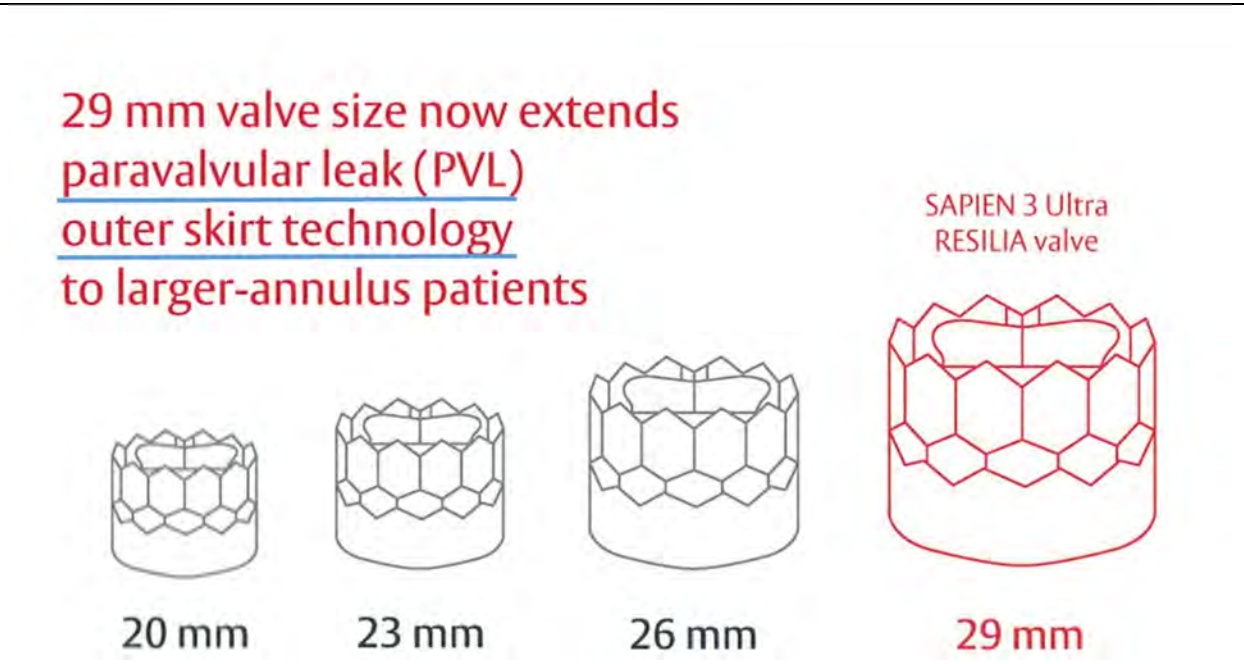
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

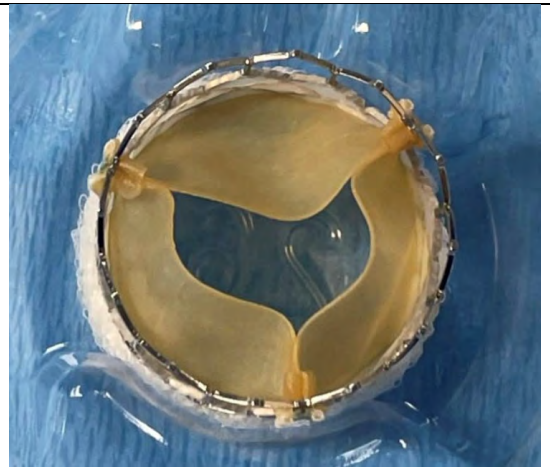
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’918 patent Accused Instrumentalities and infringes the ’918 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



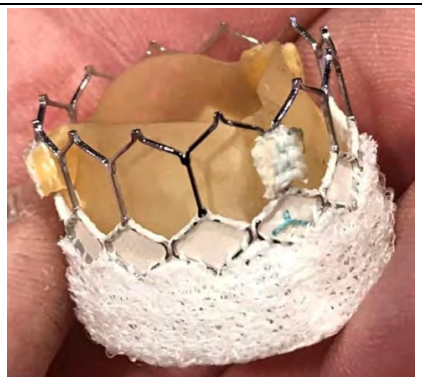
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



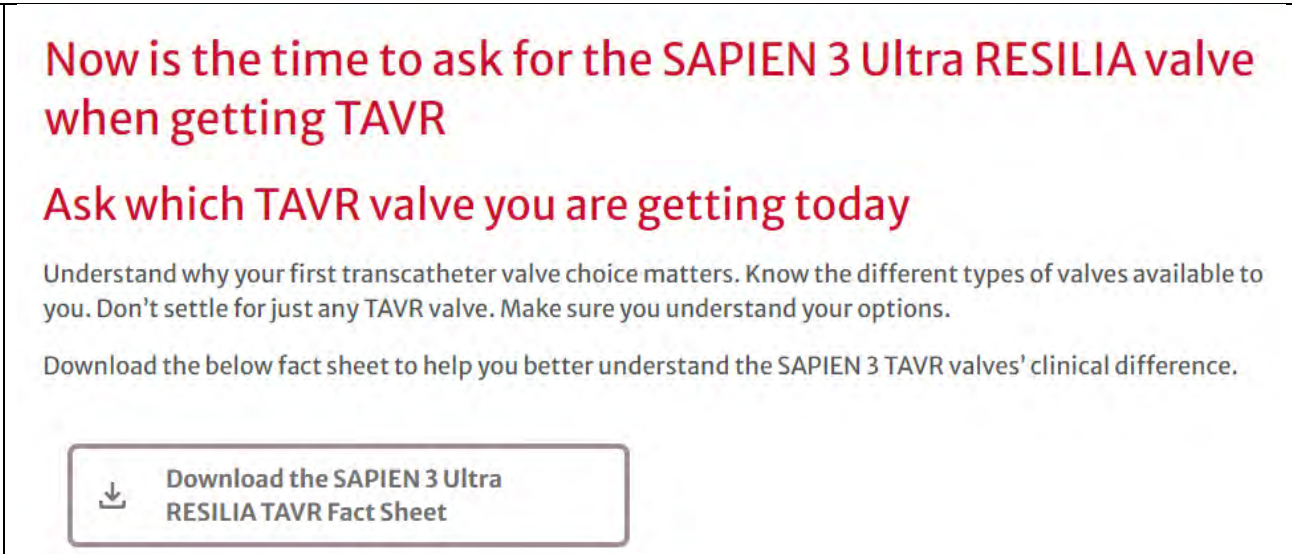

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

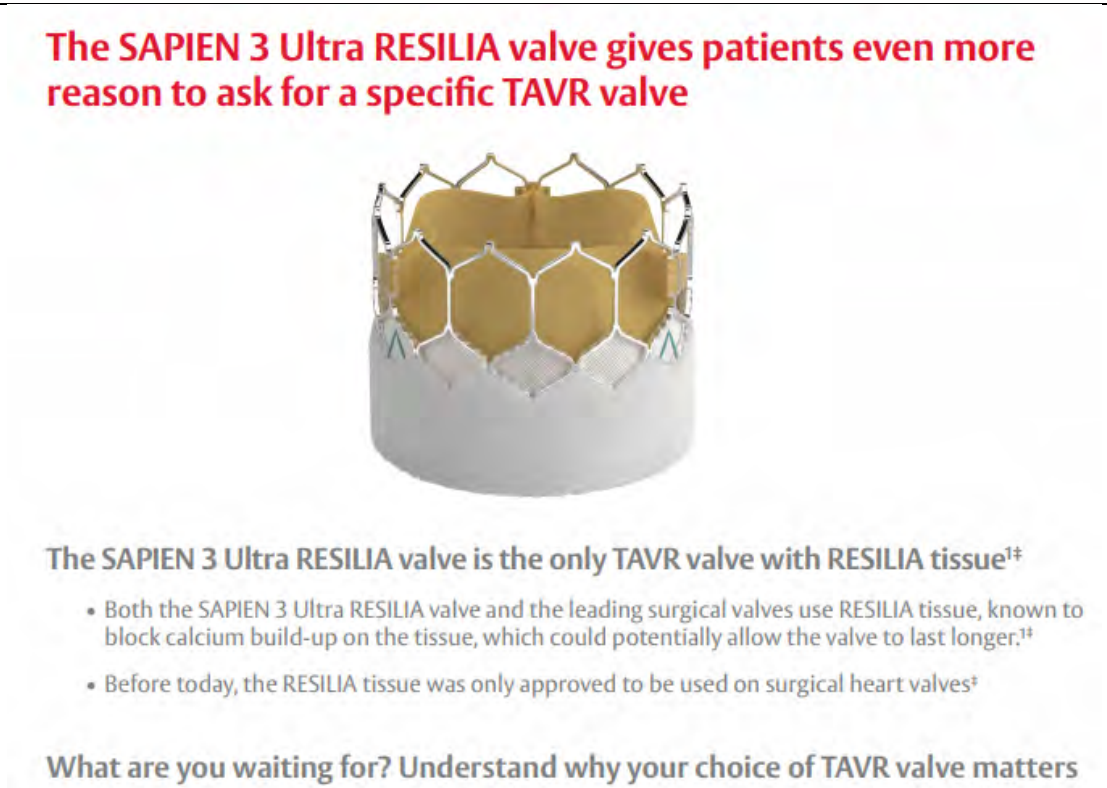
On information and belief, Edwards supplies in and/or from the United States some or all of the components of the Sapien 3 Ultra in such a manner that such components will be combined outside of the United States to form the Sapien 3 Ultra and infringes the '918 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See*

	https://ir.edwards.com/events-presentations/; https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '918 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '918 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpglobalearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpglobalearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '918 asserted claims are infringed when Edwards offers for sale and sells the '918 patent Accused Instrumentalities. Edwards offers for sale and promotes the '918 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 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.



https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



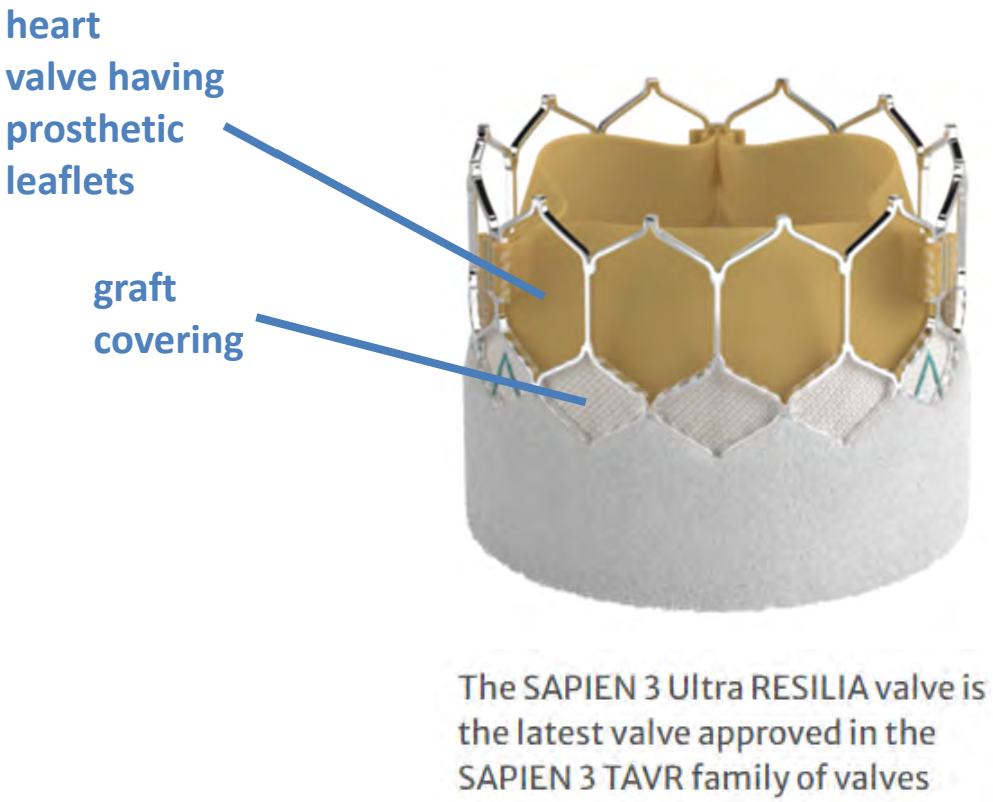
https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61).

On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement#

Further, the '918 patent asserted claims 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 in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the ’918 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards’ direct and induced infringement. For further example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe the asserted ’918 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a “watchful eye” over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards’s inducement, Edwards’s affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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.

	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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards’s affirmative acts of marketing, selling and offering to sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ combination and use of the Accused Instrumentalities, such that the ’918 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards’ knowledge of Aortic’s inventions, the patents-in-suit (including the ’918 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
a graft covering for engaging prosthetic heart valve leaflets, wherein the graft covering engages the prosthetic heart valve leaflets for providing sealing thereto;	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise a graft covering for engaging prosthetic heart valve leaflets, wherein the graft covering engages the prosthetic heart valve leaflets for providing sealing to the prosthetic heart valve leaflets. For example, the Edwards Sapien 3 Ultra graft covering that engages and extends around and provides sealing to prosthetic heart valve leaflets.



https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

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.



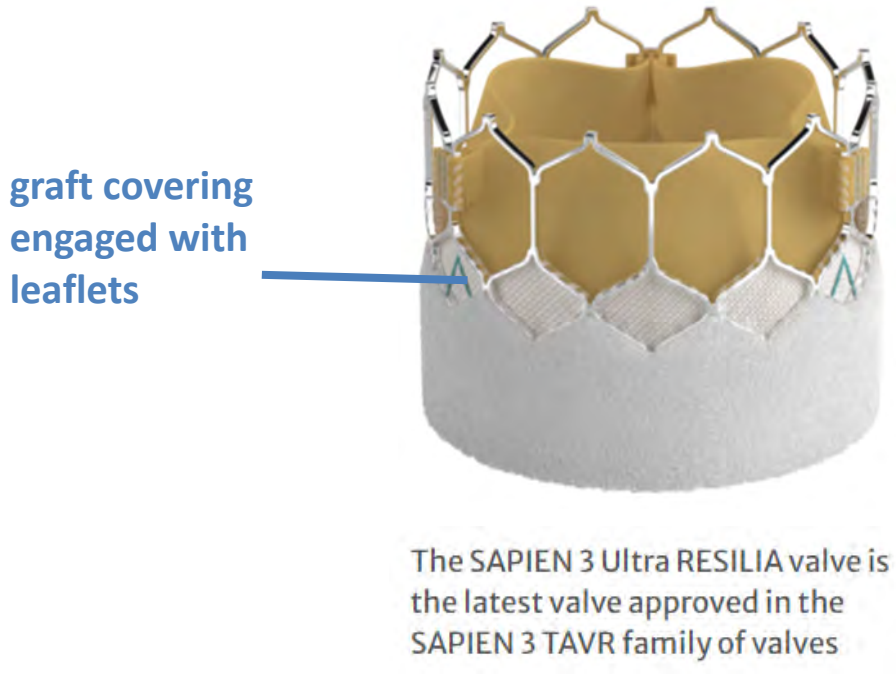
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

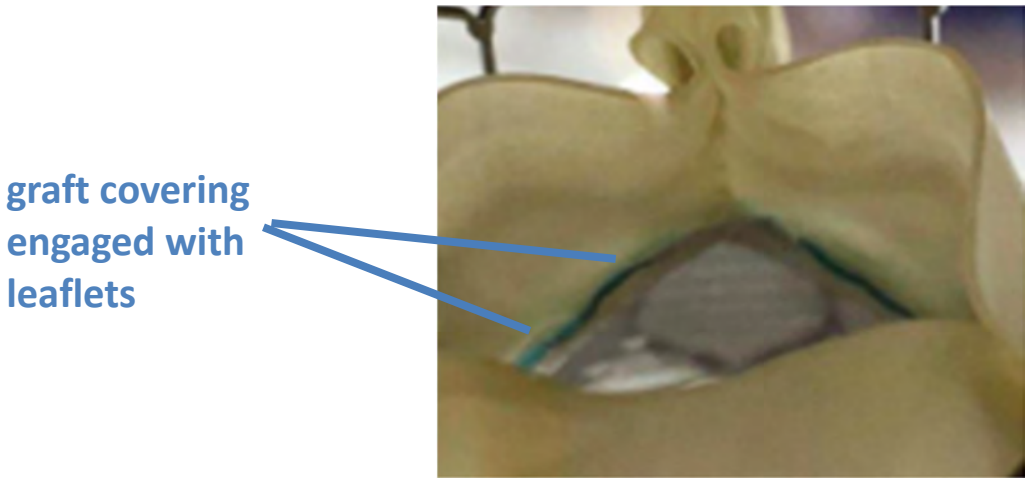
Table 1

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 (D.I. 1, Ex. 44).



https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "a graft covering for engaging prosthetic heart valve leaflets, wherein the graft covering engages the prosthetic heart valve leaflets for providing sealing thereto", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a graft covering for engaging prosthetic heart valve leaflets, wherein the graft covering engages the prosthetic heart valve leaflets for providing sealing thereto , even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering performs the same or substantially the same function as the claim phrase by partially and/or fully engaging and providing sealing to the prosthetic heart valve leaflets, in the same or substantially the same way as the claim phase by engaging and providing sealing the prosthetic heart valve leaflets, to achieve the same or substantially the same result of

	a graft covering configured to provide sealing or partial sealing to the prosthetic heart valve leaflets in the valve assembly.
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	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise 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. For example, the Edwards’ Sapien 3 Ultra frame is made of a cobalt-chromium metallic alloy in an open cell configuration with inflow and outflow end portions. Further, the Edwards Sapien 3 Ultra frame is secured to the graft covering. **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.



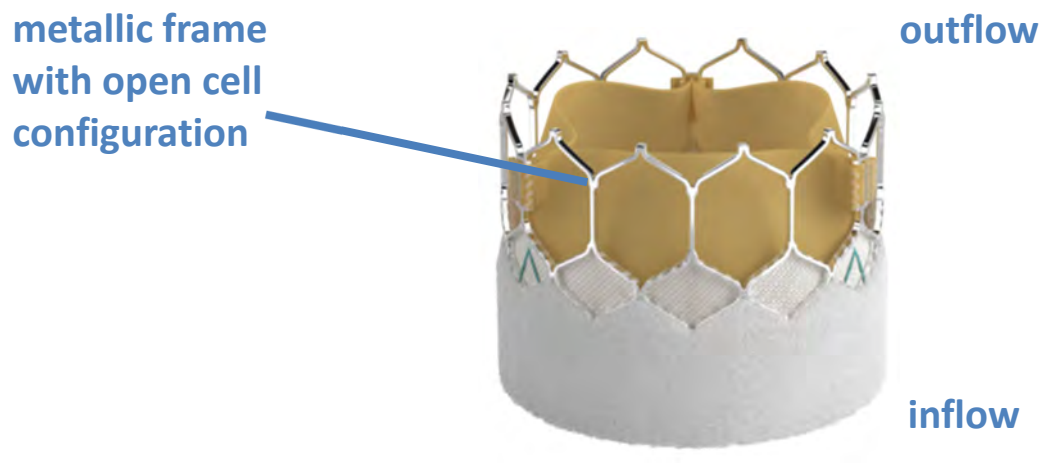
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

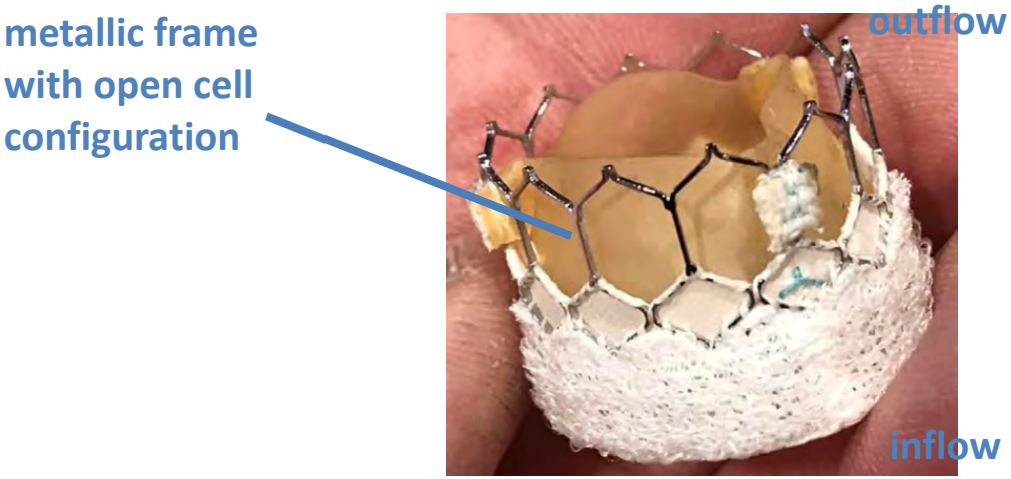
Table 1

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

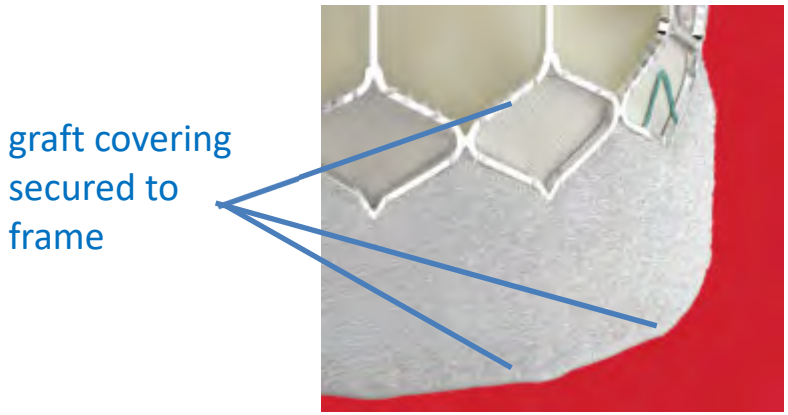
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

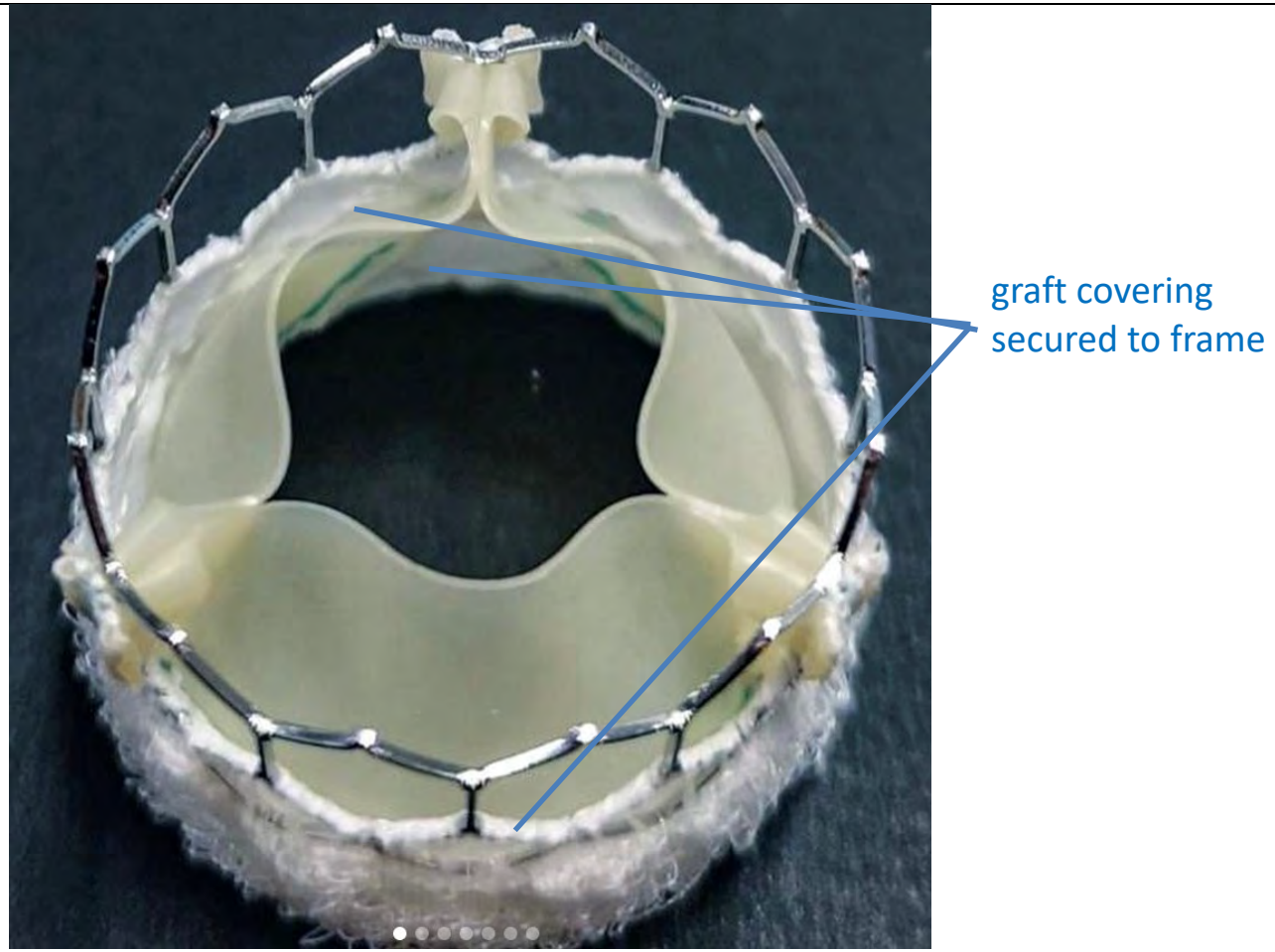


https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

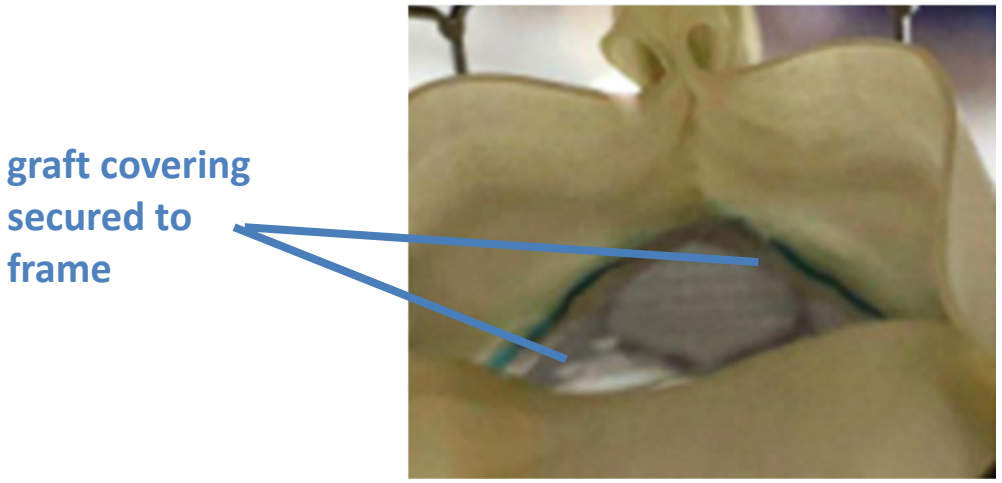


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

	For example, the Edwards Sapien 3 Ultra graft covering is secured to the frame.  Introducing the SAPIEN 3 Ultra valve at 2 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 43).

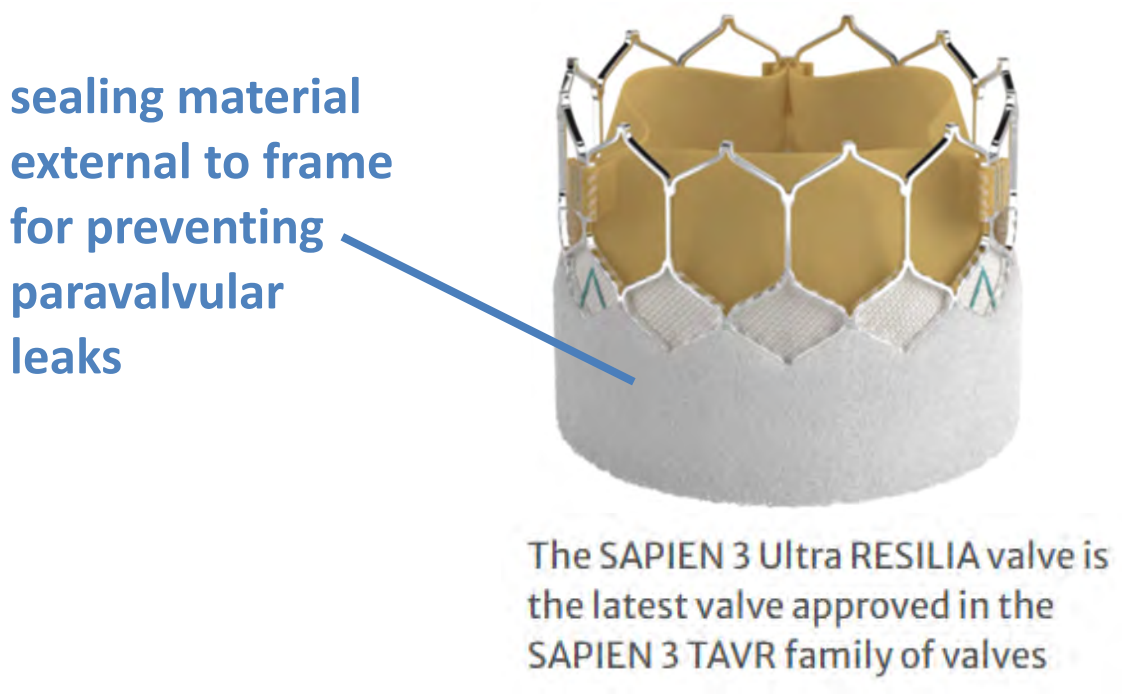


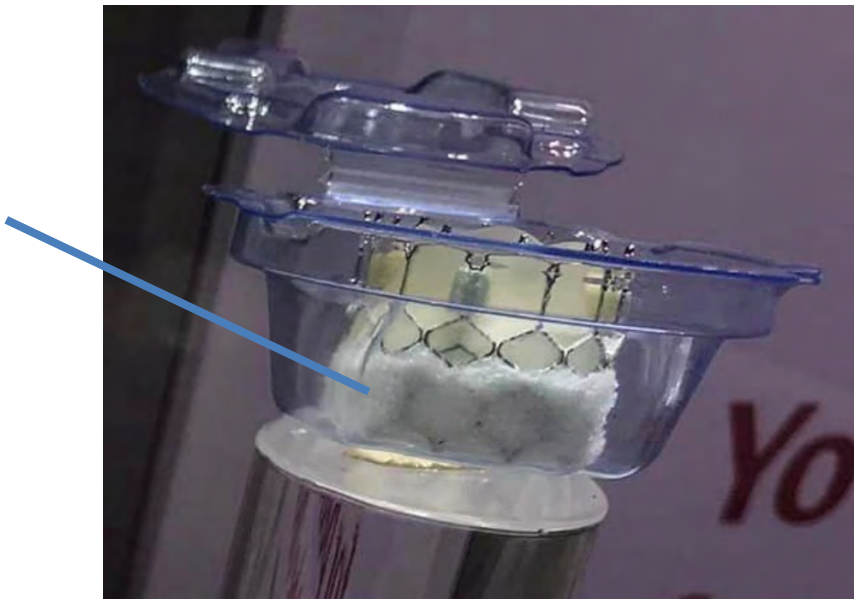
Julian Calain Twitter (D.I. 1, Ex. 64).

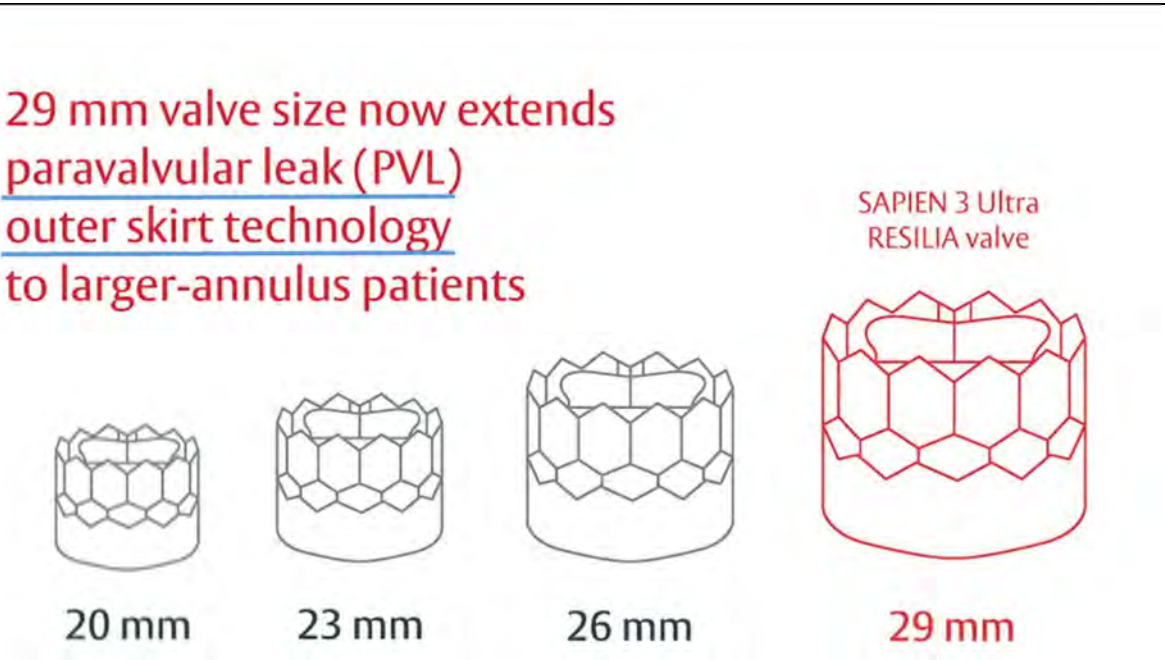


https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "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", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular deployment, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with a same or equivalent frame shape with the capability to be expanded and collapsed to a low profile, to achieve the same or

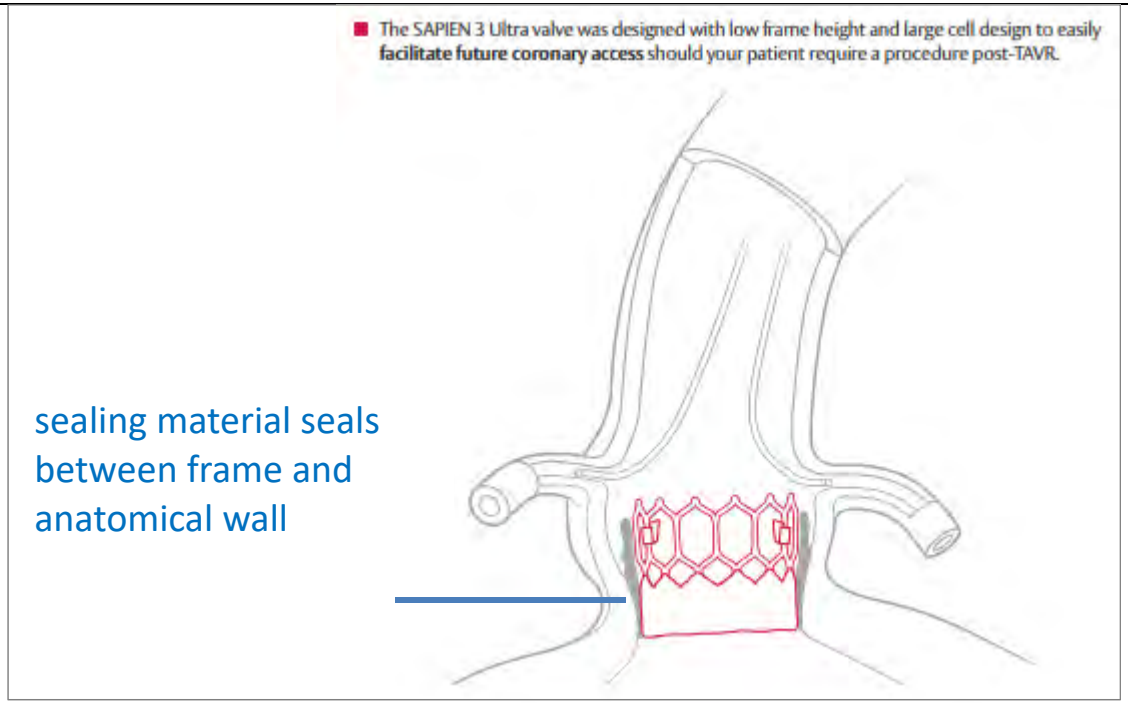
	substantially the same result a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular deployment and expansion to interface with a patients' anatomy.
a sealing material positioned externally to the frame for providing sealing between the frame and a patient's anatomical wall of the aorta to prevent paravalvular leaks,	The '918 patent Accused Instrumentalities satisfy this element. The '918 patent Accused Instrumentalities comprise 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 . For example, the Edwards Sapien 3 Ultra includes a sealing skirt for providing sealing between the frame and the patient's anatomical aortic wall for preventing paravalvular leaks.  The SAPIEN 3 Ultra RESILIA valve is the latest valve approved in the SAPIEN 3 TAVR family of valves https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

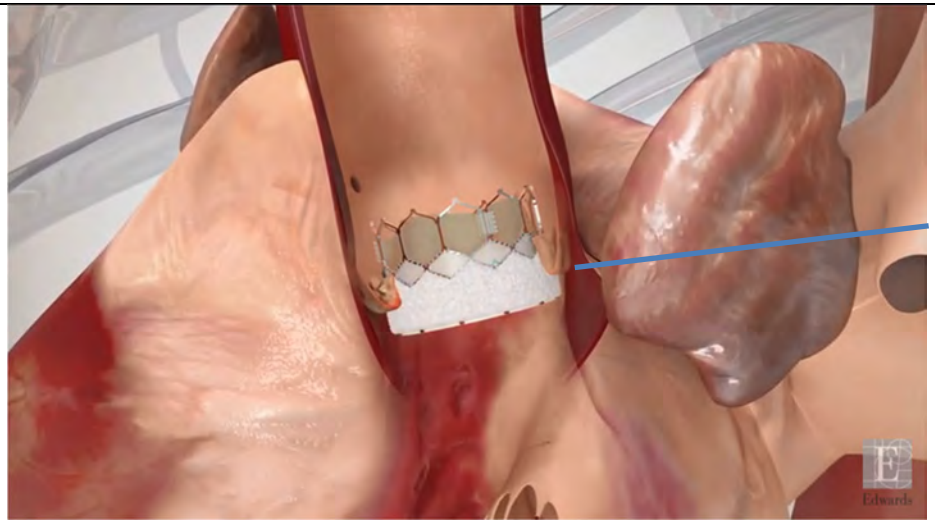


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

For example, the Sapien 3 Ultra sealing skirt provides for sealing between the frame and the patient's anatomical wall to help prevent PVL.

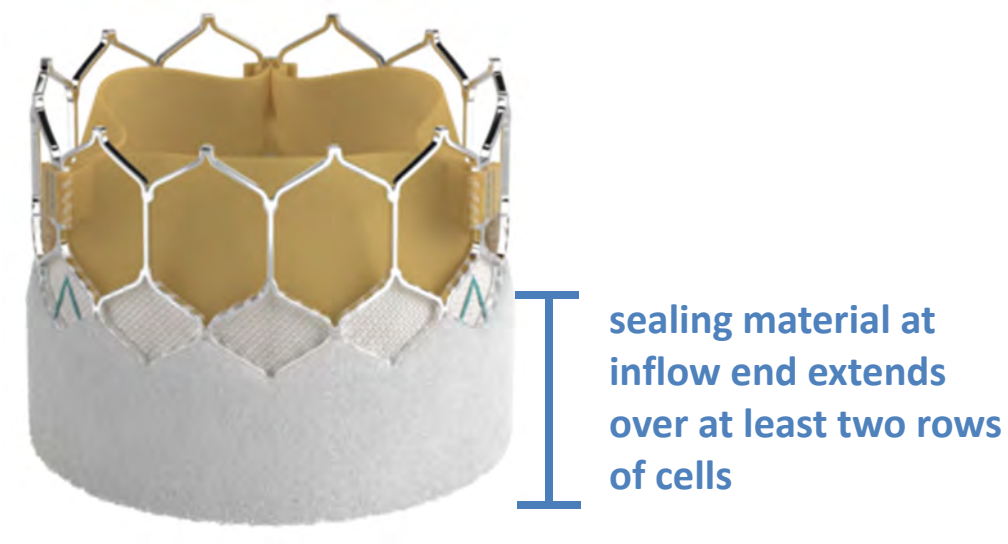


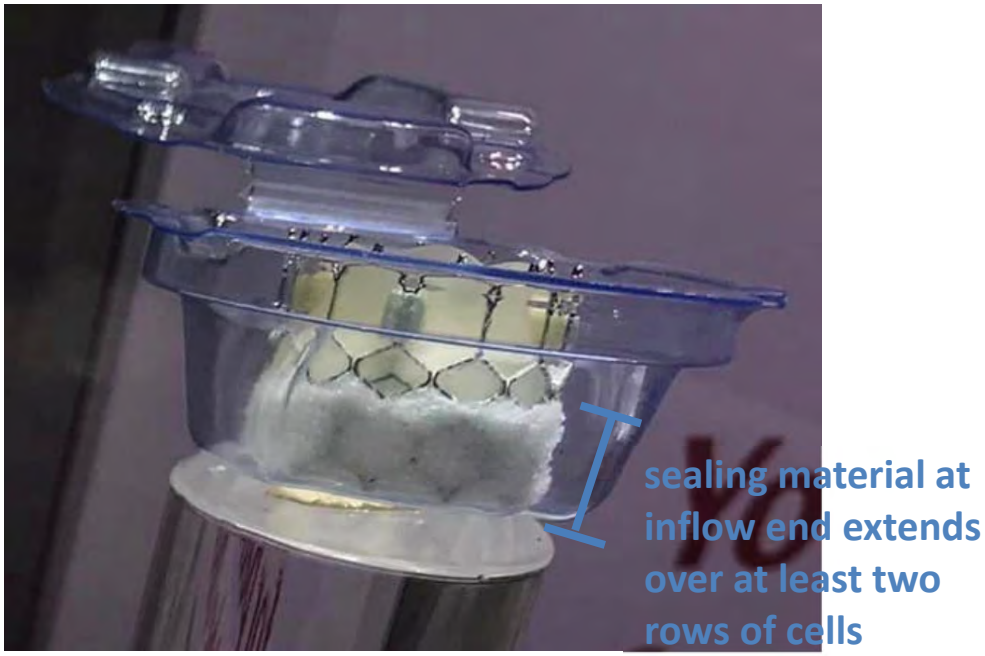
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



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

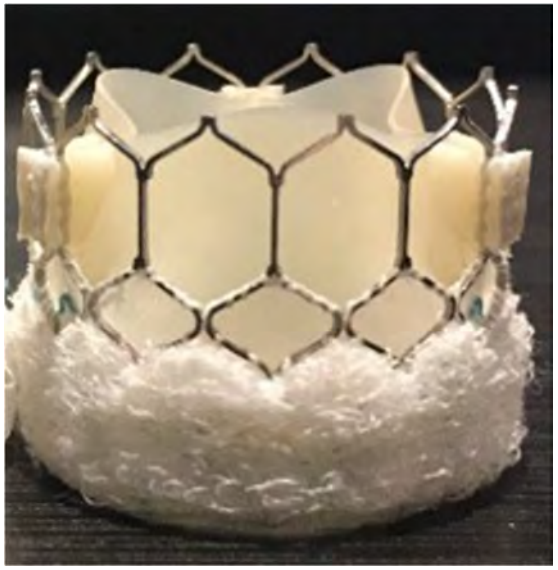
Further, with respect to the phrase, "a sealing material positioned externally to the frame for providing sealing between the frame and a patient's anatomical wall of the aorta to prevent paravalvular leaks" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the sealing material does not allow visibility of the frame or that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing material formed of outwardly extending fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused sealing material performs the same or substantially the same function as the claim phrase by providing for low profile sealing material capable of providing sealing between the anatomical wall and the frame, in the same or substantially the same way as the claim phase by using a biocompatible polymeric sealing material configured to press against and providing sealing between the patient's anatomical

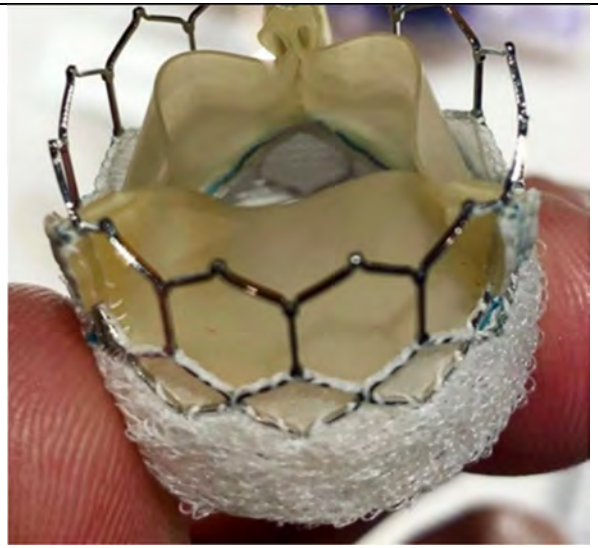
	wall and the frame, to achieve the same or substantially the same result of a sealing material configured to form a biocompatible seal between the anatomical wall and the frame for reduced paravalvular leakage.
wherein the sealing material begins at the inflow end portion of the frame and extends over at least two rows of cells formed in the open cell configuration of the frame,	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities’ 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. For example, the Sapien 3 Ultra sealing skirt beings at an inflow end and extends over a least two rows of cells in the open cell configuration in the frame.  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

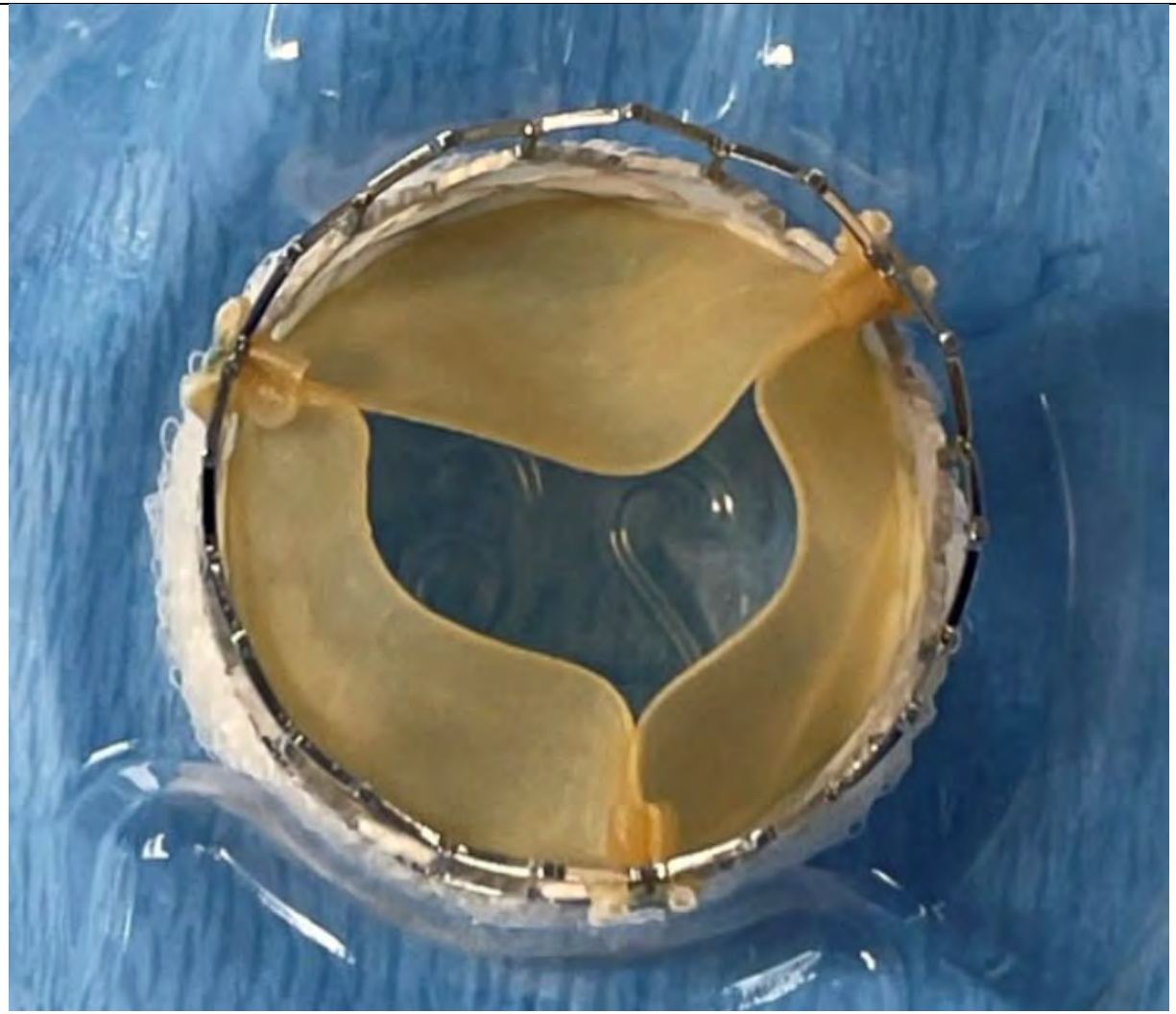


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

With respect to the phrase, "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," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, in whole or in part, the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused at least two rows of cells over which the sealing material extends performs the same or substantially the same function as the claim phrase by having at least two rows of cells at the inflow portion of the frame that the

	sealing material extends over, in the same or substantially the same way as the claim phase by utilizing and expandable and collapsible open cell frame structure with the same or similar shapes and sizes for the sealing material to extend over, to achieve the same or substantially the same result of the sealing material configured to extend over at least two rows of cells at the inflow portion 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,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 Accused Instrumentalities’ sealing material includes a plurality of outwardly extending fibers that extend outwardly of the frame, wherein the fibers are arcuate. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

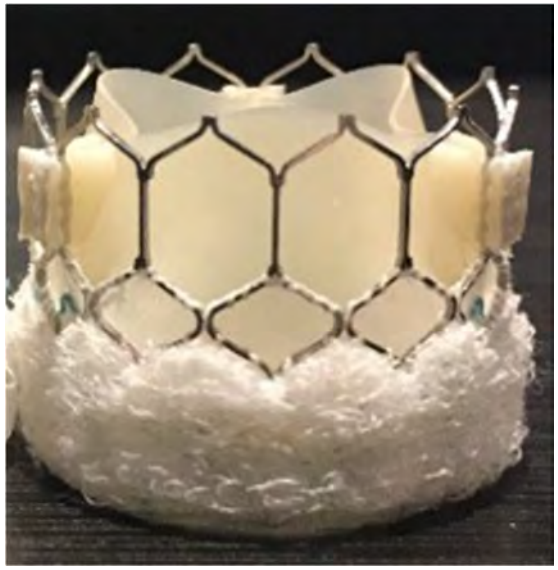
	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of outwardly extending arcuate fibers extending outwardly from frame) (D.I. 1, Ex. 29).

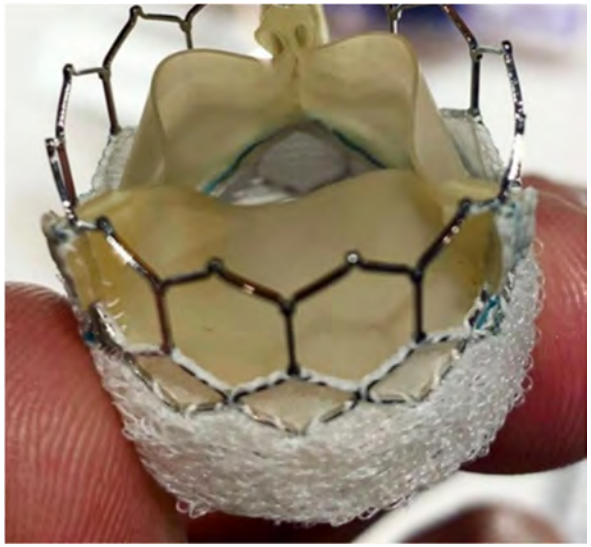
	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of outwardly extending arcuate fibers extending outwardly from frame) (D.I. 1, Ex. 64).

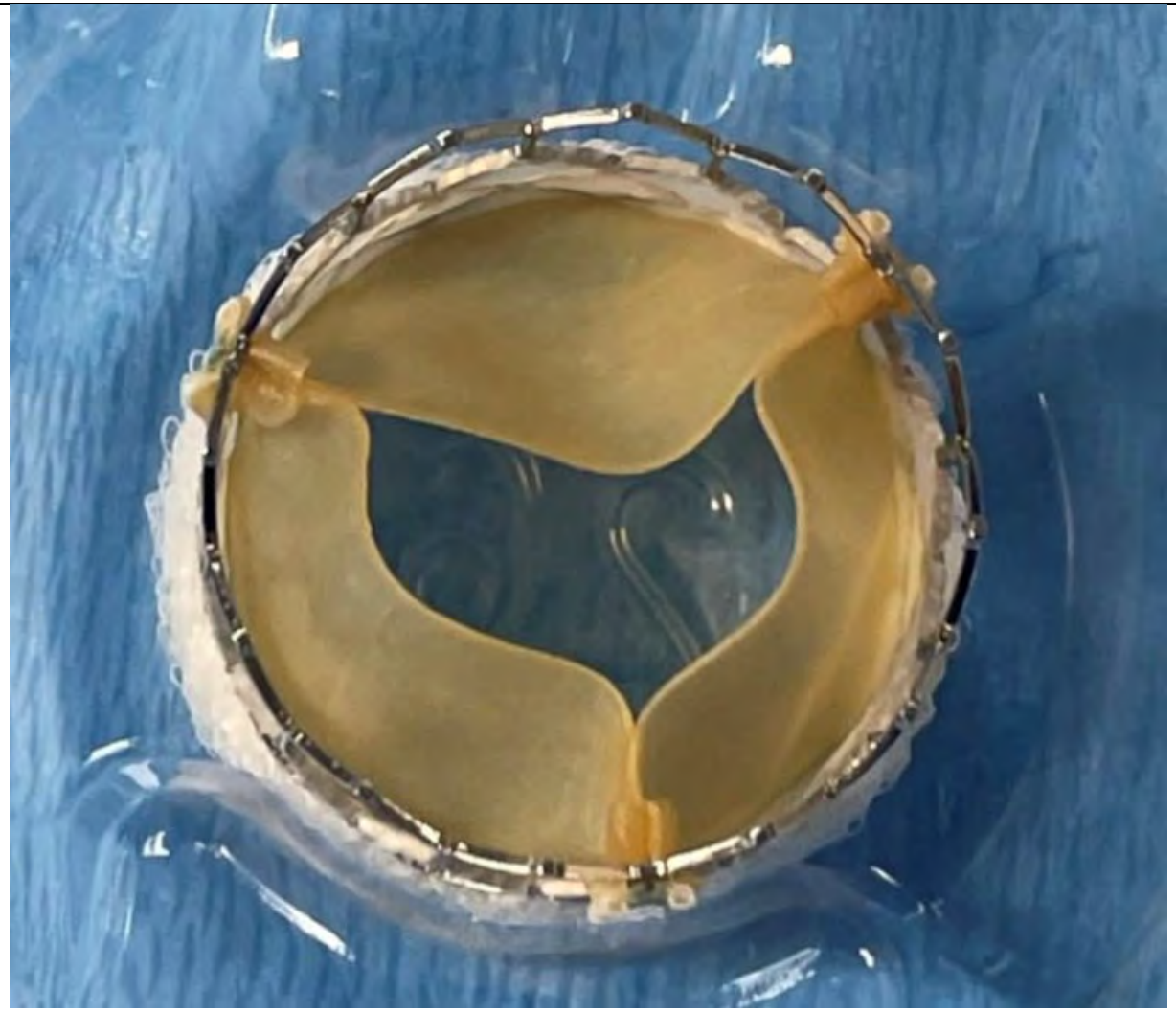


Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of outwardly extending arcuate fibers extending outwardly from frame) (D.I. 1, Ex. 3).

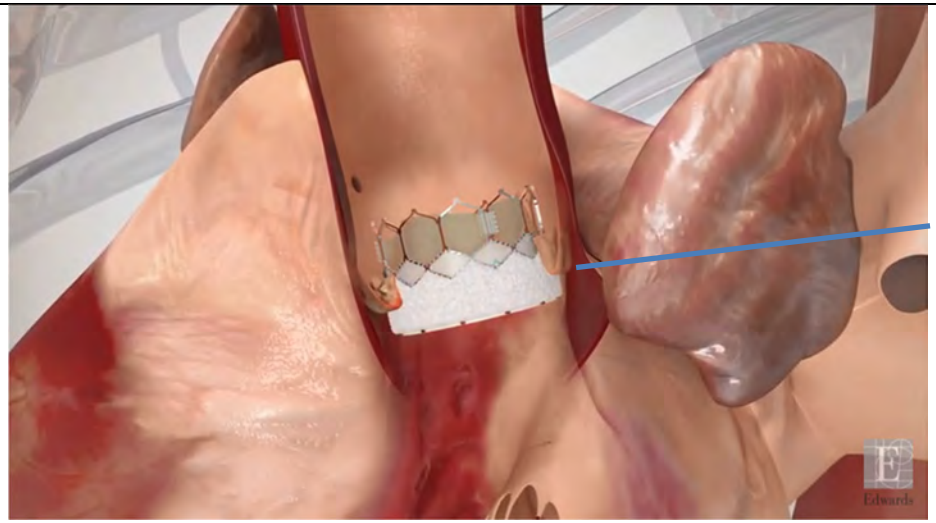
Further, with respect to the phrase, "wherein the sealing material includes a plurality of outwardly extending fibers that extend outwardly of the frame, wherein the fibers are arcuate" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging that the fibers are not discrete bundles of collagen fibers with outwardly extending "tips", the identified sealing material including a plurality of outwardly extending fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused sealing material including a

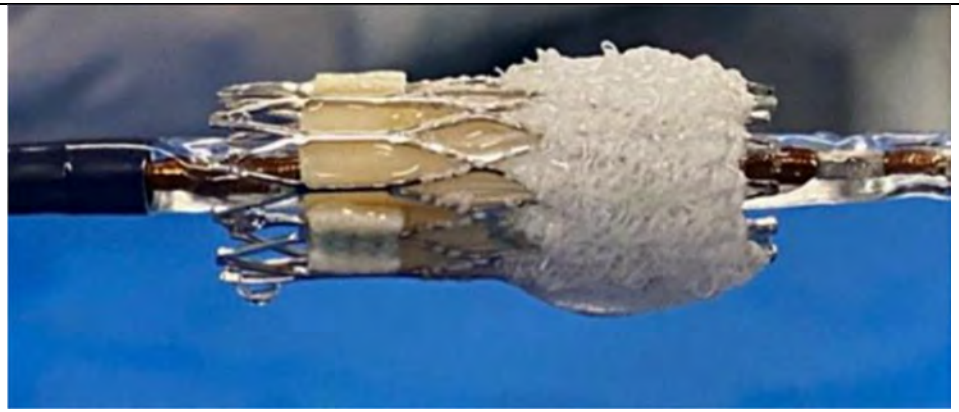
	plurality of outwardly extending arcuate fibers performs the same or substantially the same function as the claim phrase by providing for low profile sealing material capable of sealing against the native leaflets, in the same or substantially the same way as the claim phase by including biocompatible polymeric arcuate fibers with “tips” extending generally outwardly that are configured to press against the native leaflets of the aorta of the patient when the valve is expanded, to achieve the same or substantially the same result of sealing material configured to form a biocompatible seal between the native annulus/leaflets and frame and reduced paravalvular leakage.
wherein the fibers are flexible such that compression of the fibers imparts movement thereto,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 Accused Instrumentalities’ fibers are flexible such that compression of the fibers imparts movement thereto sealing material includes a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of thin flexible fibers made from PET that are designed and configured to move when compressed.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

	 https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

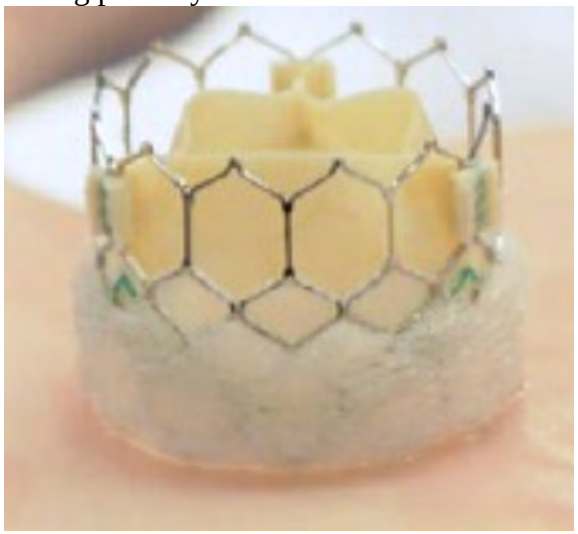
	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).

	 Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
wherein the fibers are in contact with the frame along a height of the sealing material,	The '918 patent Accused Instrumentalities satisfy this element. The '918 patent Accused Instrumentalities' fibers are in contact with the frame along a height of the sealing material. The Sapien 3 Ultra is configured such that the fibers are 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.



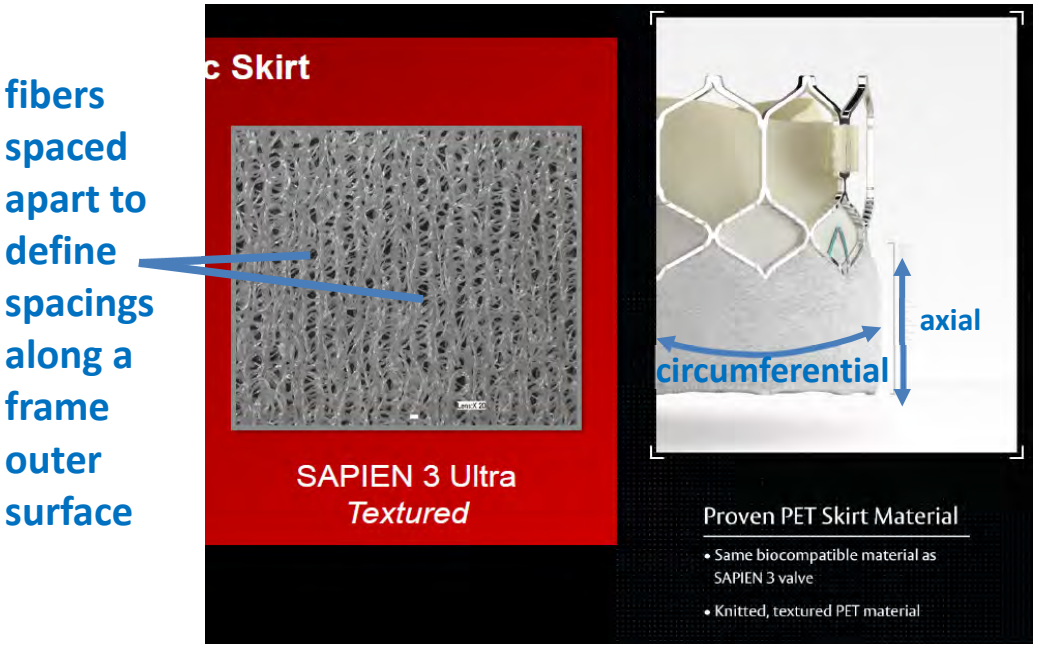
Ex. 48, https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (showing plurality of fibers in contact with frame in compressed orientaiton).

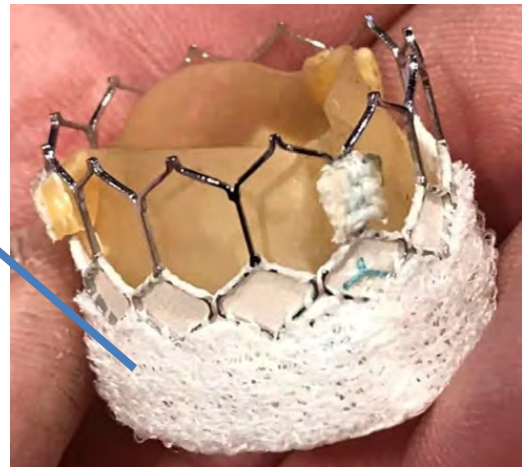


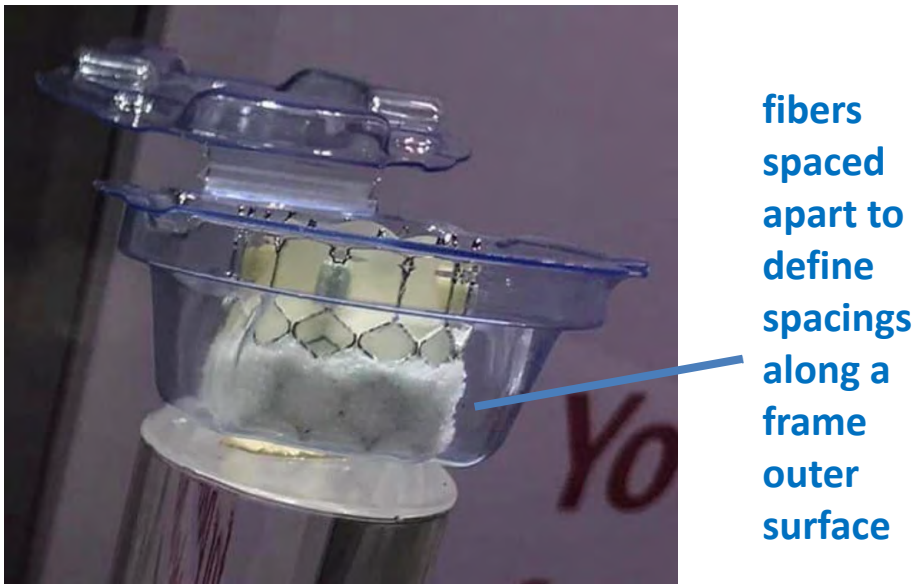
Ex. 65, https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (showing plurality of fibers in contact with frame in expanded orientaiton).

With respect to the phrase, "wherein the fibers are in contact with the frame along a height of the sealing material", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused

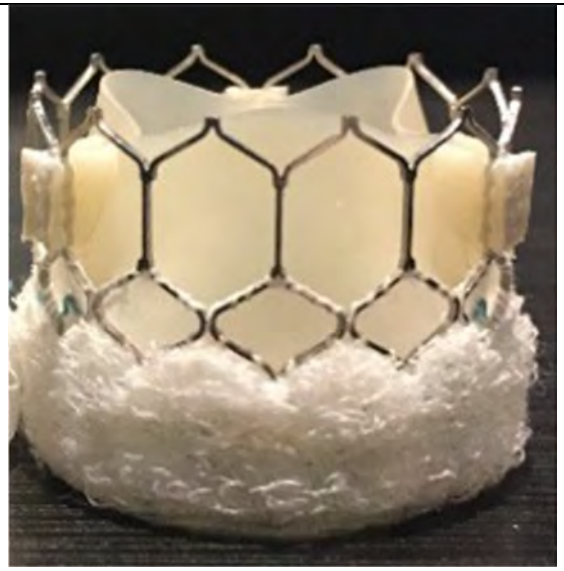
	Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused valve assembly performs the same or substantially the same function as the claim phrase by having fibers with the frame along the height of the sealing material in the radially compressed and/or expanded orientations, in the same or substantially the same way as the claim phase through including low profile sealing material with radially extending arcuate fibers attached to at least a portion of the frame, to achieve the same or substantially the same result of fibers configured to be at least generally in contact with at least a portion of the frame along the 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,	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities' fibers are spaced-apart to define spacings in a circumferentially extending direction and an axially extending direction along an outer surface of the frame. For example, 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.

	 Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

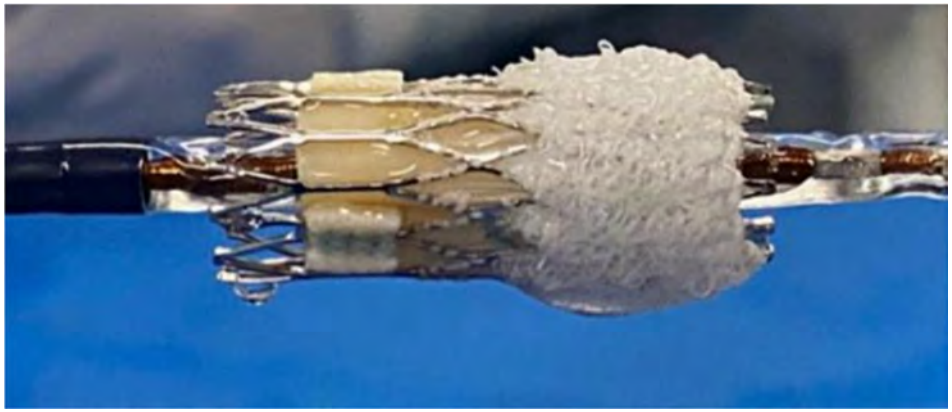
	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).



Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

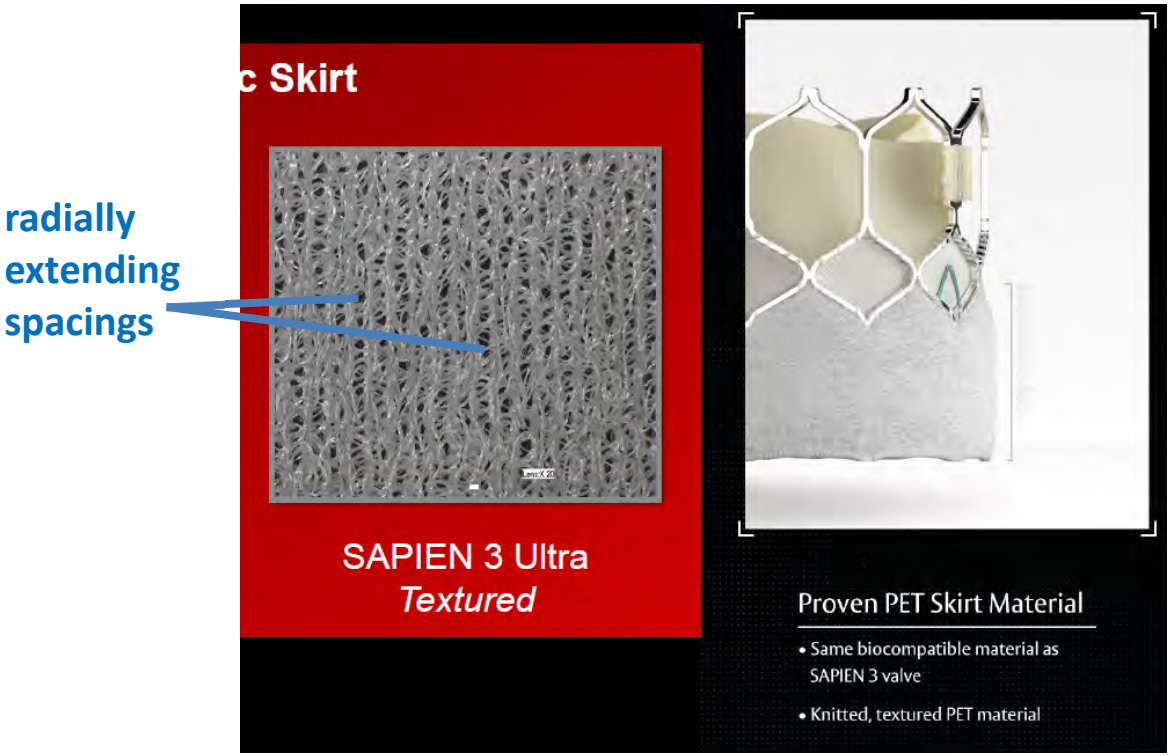


Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

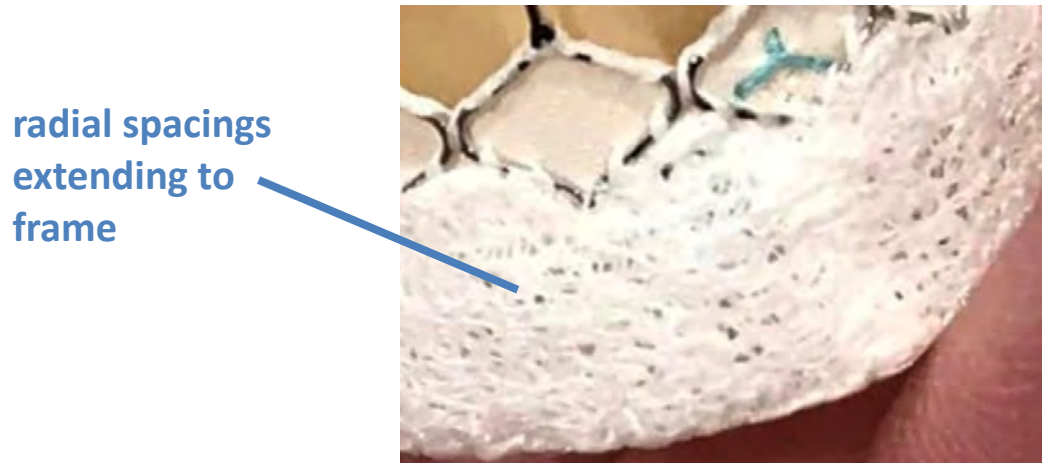


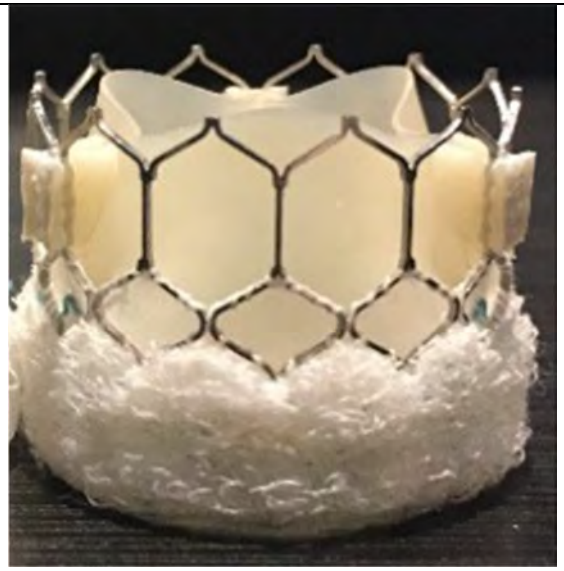
https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).

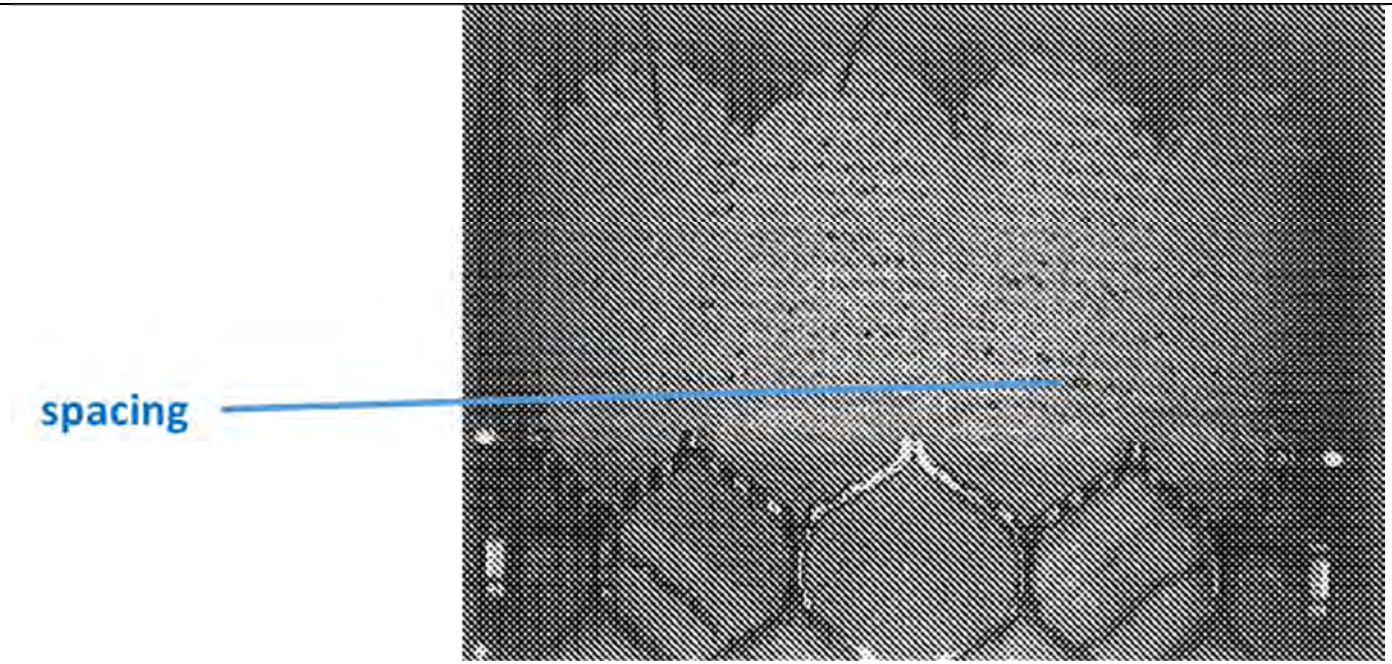
	 Instagram page for ttchemodinamica (D.I. 1, Ex. 74).
wherein the spacings extend radially through a thickness of the sealing material beginning at an outermost portion of the fibers and extending to the frame,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities’ spacings extend radially through a thickness of the sealing material beginning at an outermost portion of the fibers and extending to the frame. For example, the Sapien 3 Ultra has spacings that extend radially through a thickness of the sealing skirt material from the outermost portion of the fibers to the frame.



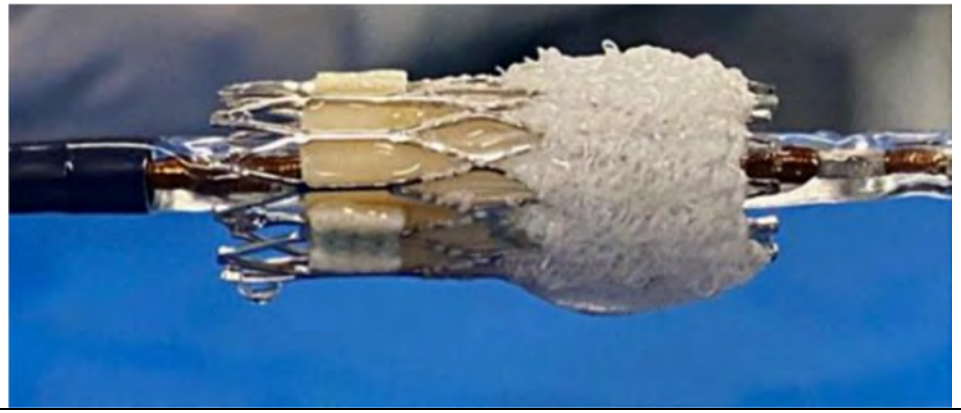
Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

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



U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (spacings extend to frame (see above showing spacings on flipped up backside of sealing skirt).

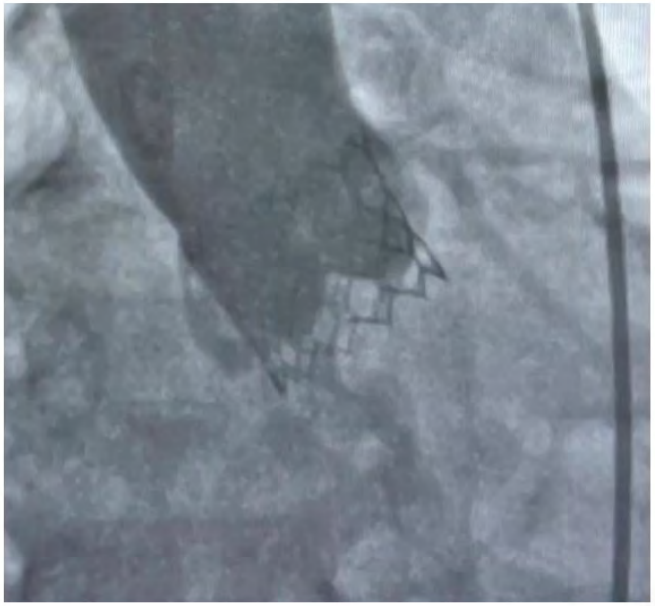


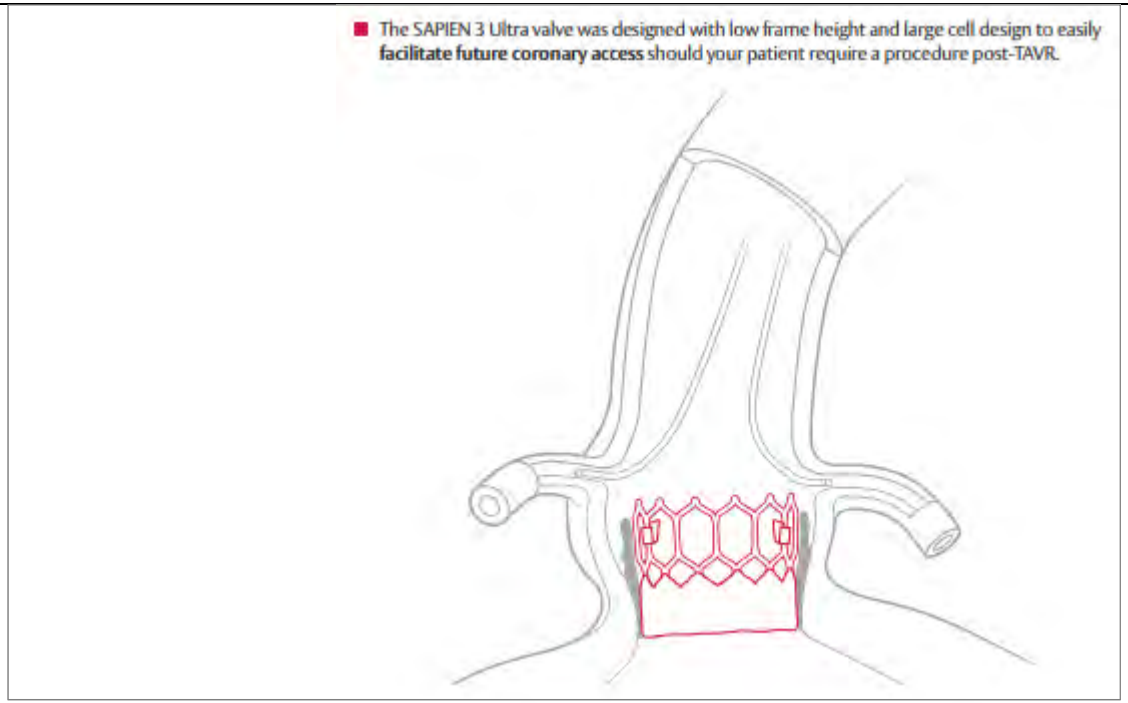
61

	https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1, Ex. 48).  Instagram page for ttchemodinamica (D.I. 1, Ex. 74).
wherein the heart valve assembly has a radially compressed orientation and a radially expanded orientation,	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities have a radially compressed orientation and a radially expanded orientation. The Sapien 3 Ultra is designed and configured have a radially compressed orientation and a radially expanded orientation. The Sapien 3 Ultra is designed and configured to be crimpable onto a balloon delivery system for deployment and expandable using an Edwards’ balloon delivery system in the aorta of a patient from a radially compressed orientation into a radially expanded orientation.

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

63

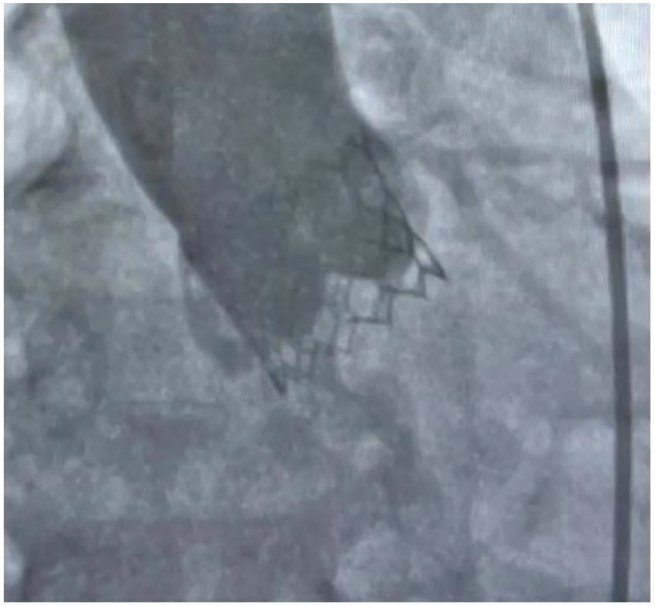
	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil.

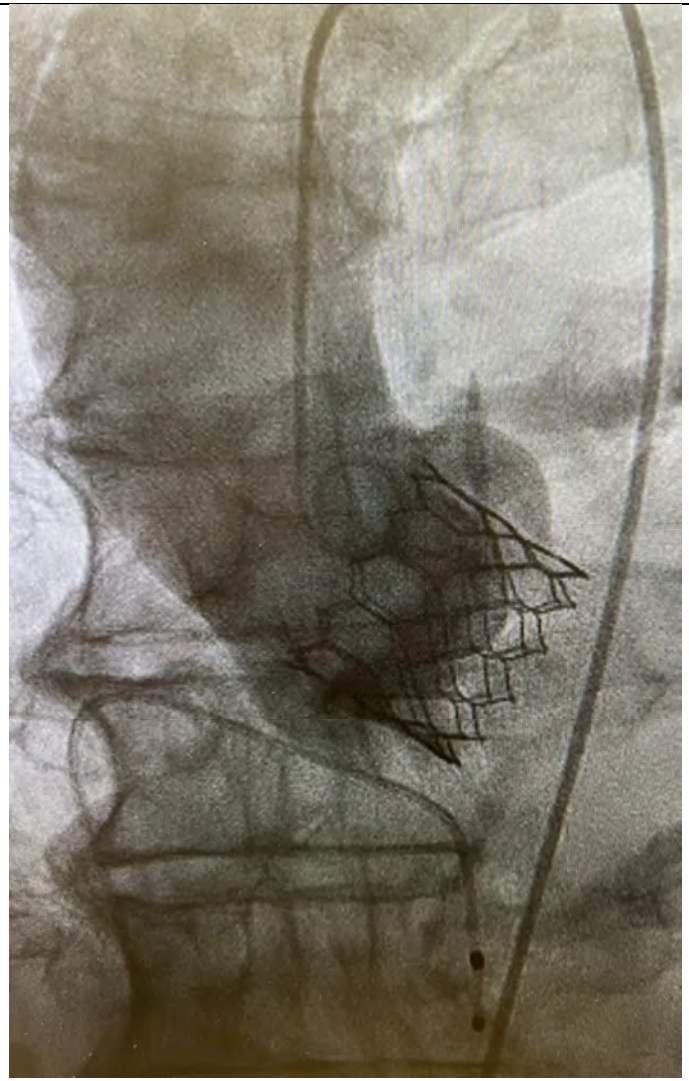


Introducing the Sapien 3 Ultra, available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

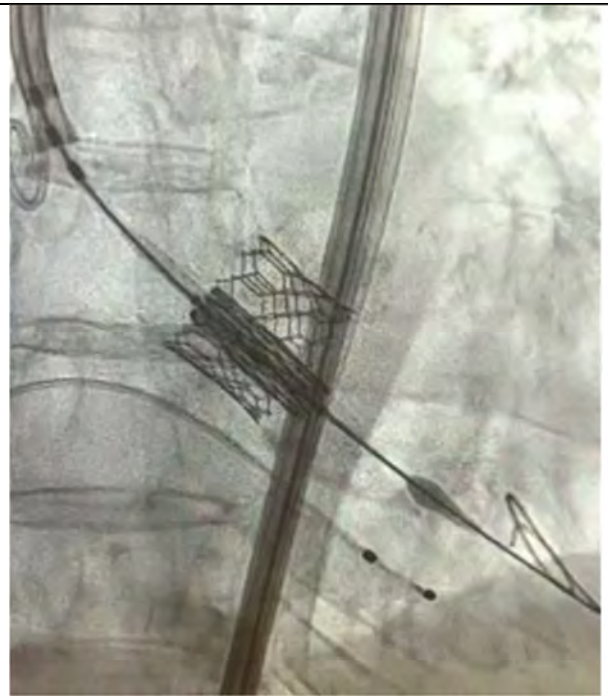


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil.



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

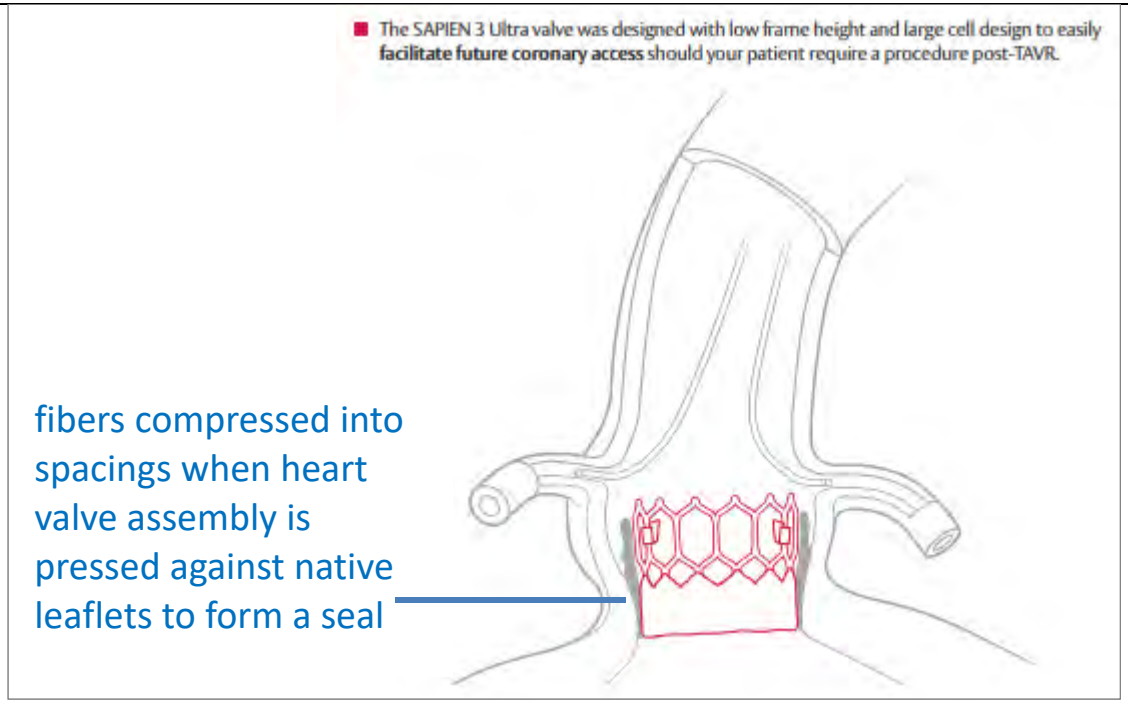


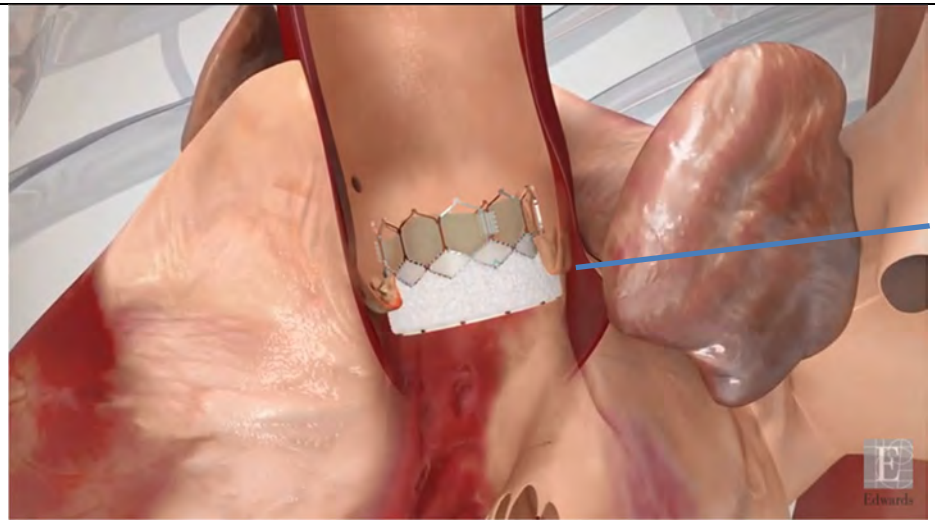
https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=7vNdYaSyfo8PlVNSNv2WDQ



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

	SAPIEN 3 Ultra System Case Example   Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).
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	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities are designed and configured such that 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,. For example, the Sapien 3 Ultra is designed and configured so that when expanded the fibers are compressed into the spacings when the sealing material is pressed against native leaflets reducing the spacings and forming a seal.

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,	 Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
wherein the heart valve assembly is sized and shaped for being delivered endovascularly through a femoral artery of a patient.	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities are sized and shaped for being delivered endovascularly through a femoral artery of a patient. Further, the Sapien 3 Ultra is designed, developed, promoted, sized, shaped, configured to be delivered and is deliverable endovascularly through the femoral artery of a patient using Edwards' balloon catheter delivery systems.



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 (D.I. 1, Ex. 44).

7.0 Directions for Use

7.1 System Compatibility

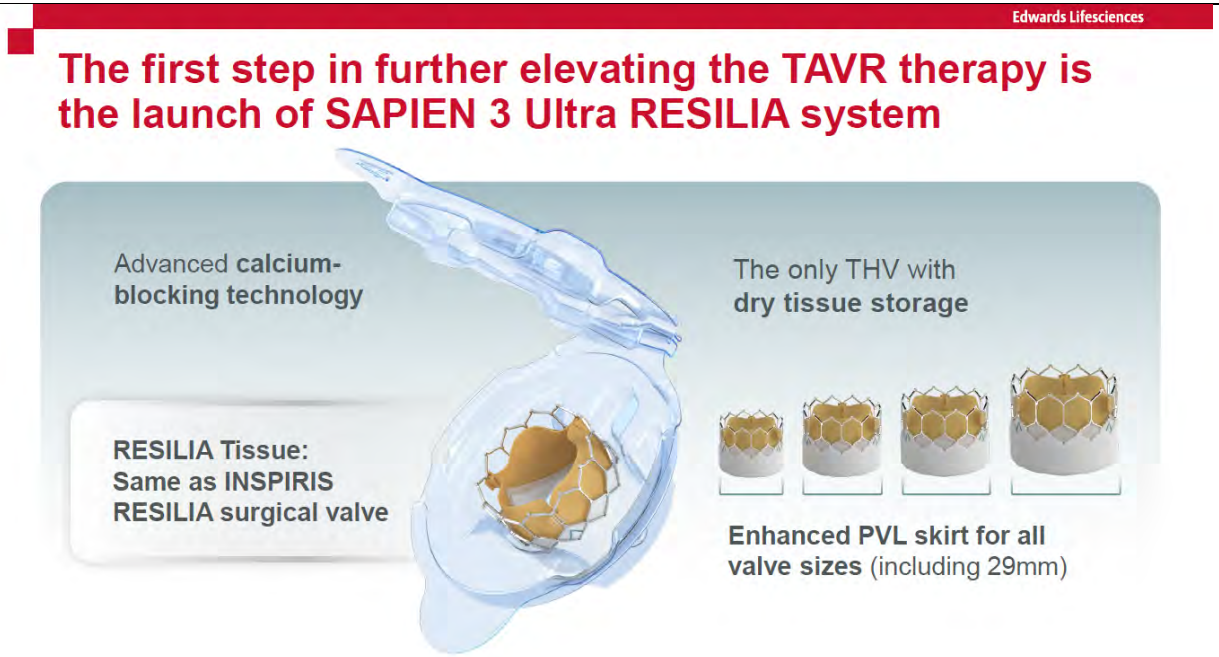
Table 6

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

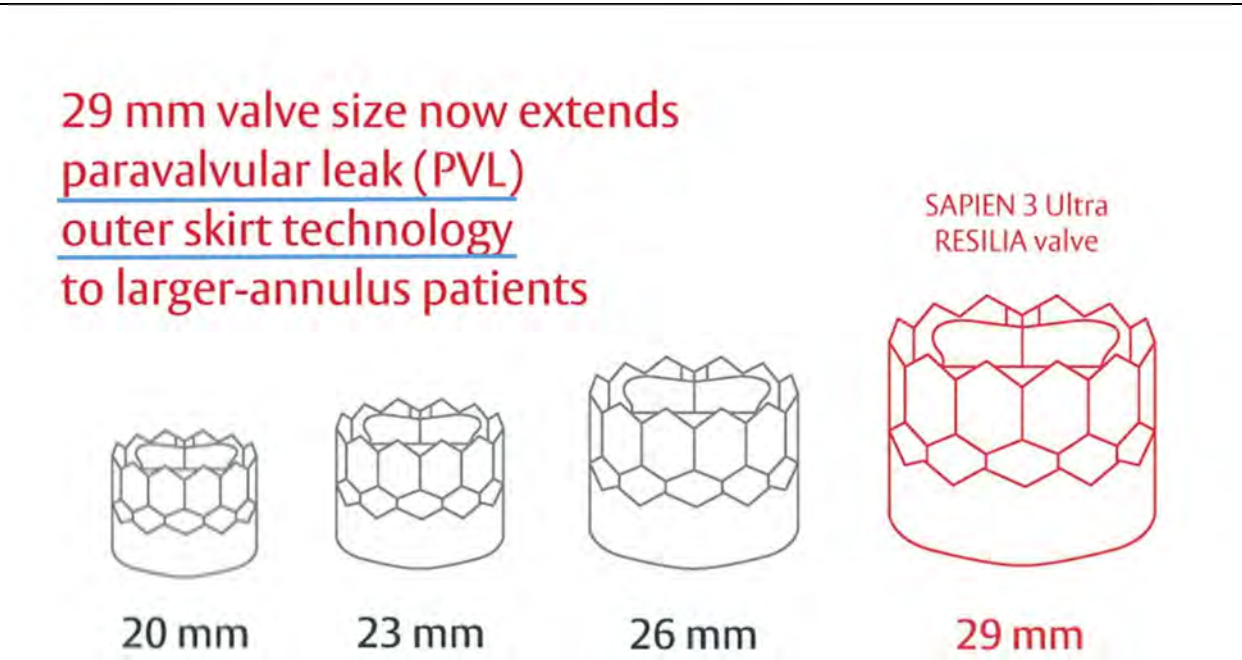
Additional Equipment:

- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

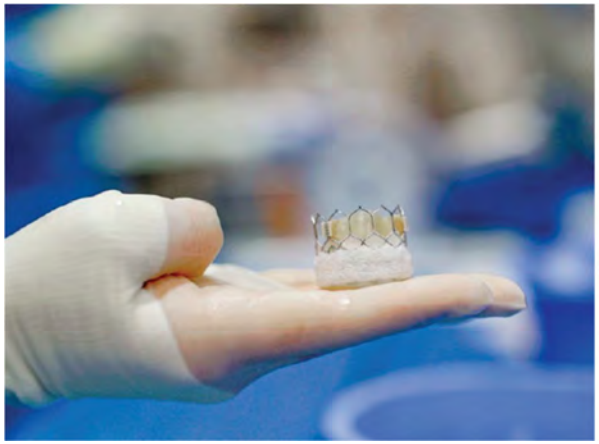
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

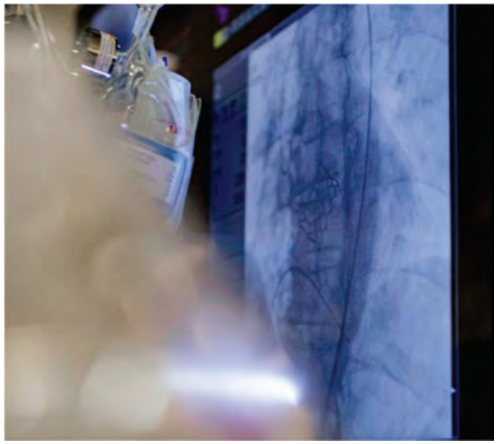


https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).

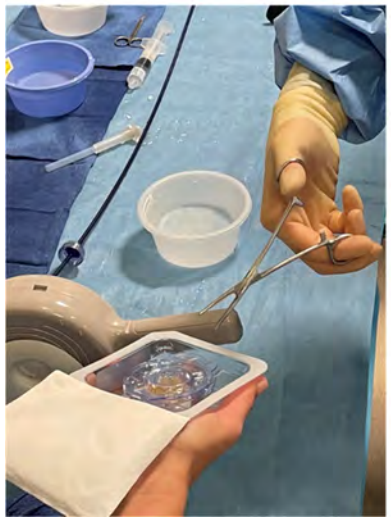


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA





	https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).  https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

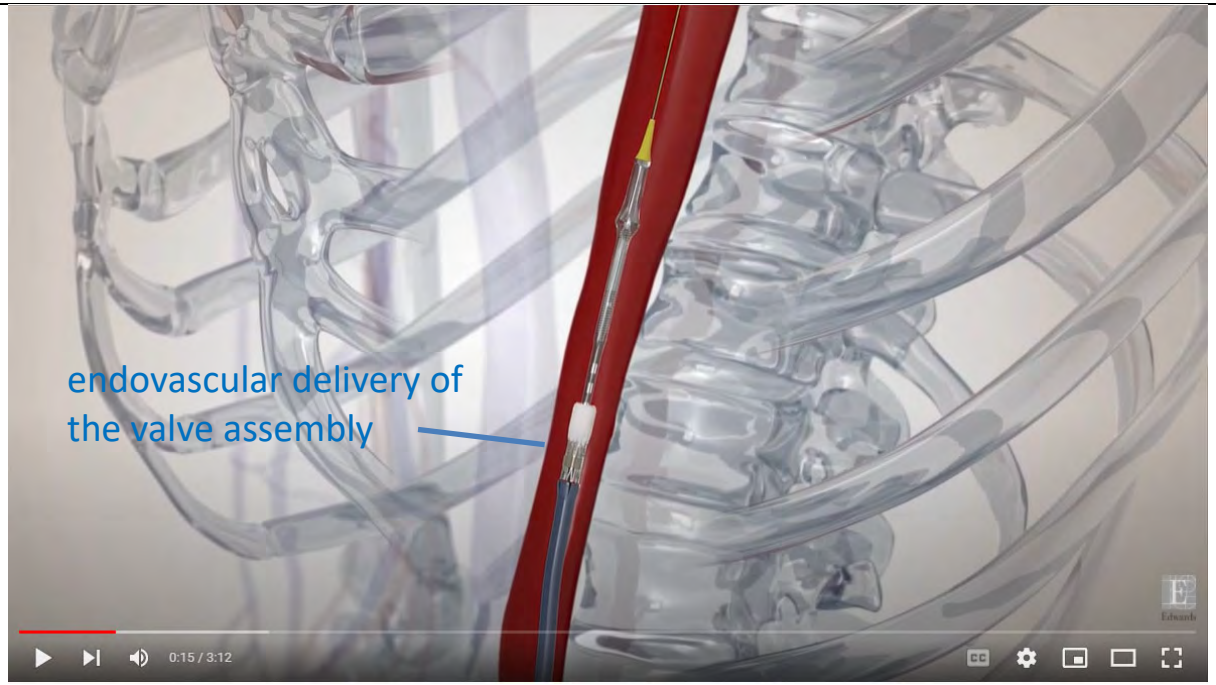




https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

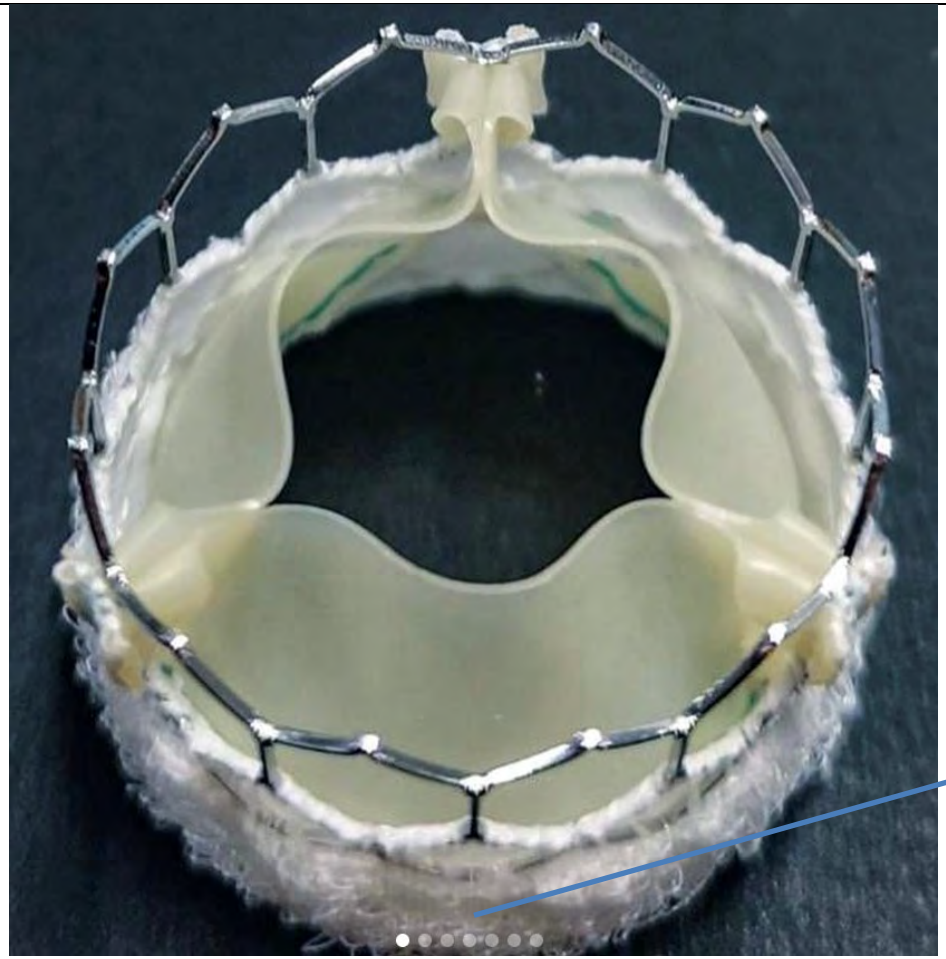


	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
4. The endovascularly deployed heart valve assembly of claim 1, wherein the graft covering, prosthetic leaflets, and the sealing material are radially overlapping.	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities include a graft covering, prosthetic leaflets, and sealing material that are radially overlapping. For example, the Sapien 3 Ultra is designed and configured such that at least some of the graft covering, prosthetic leaflets and the sealing material are radially overlapping. For example, the series of images below from Edwards demonstrate the radial overlapping alignment of the prosthetic leaflets, graft covering, and sealing material.



https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).

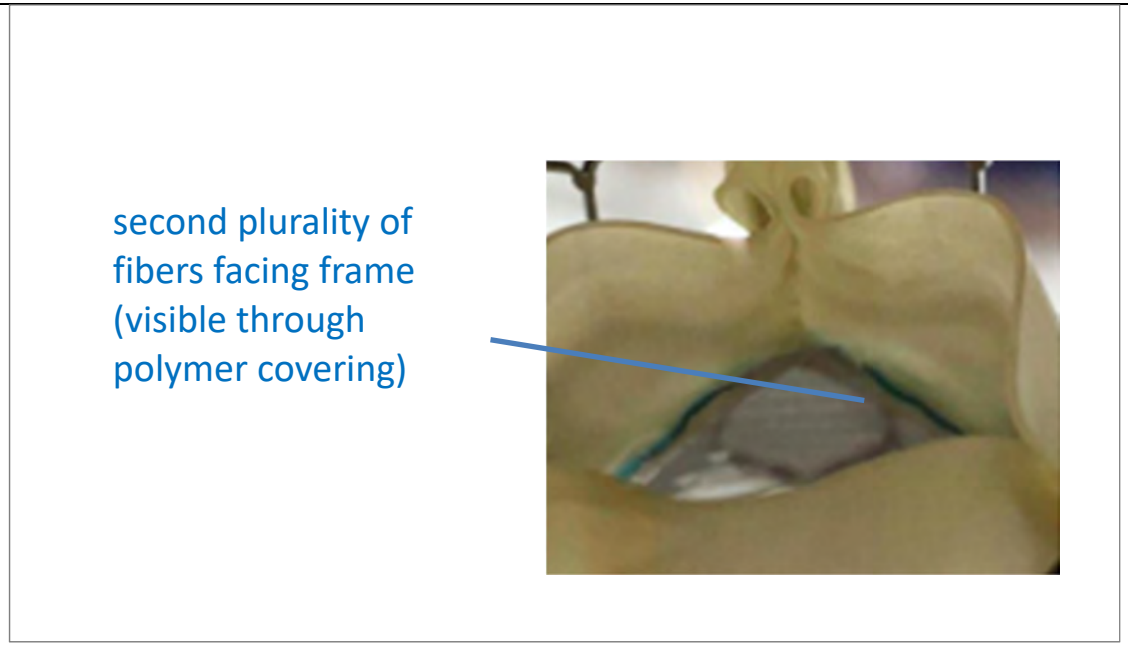


Julian Calain Twitter (D.I. 1-2 at 18).

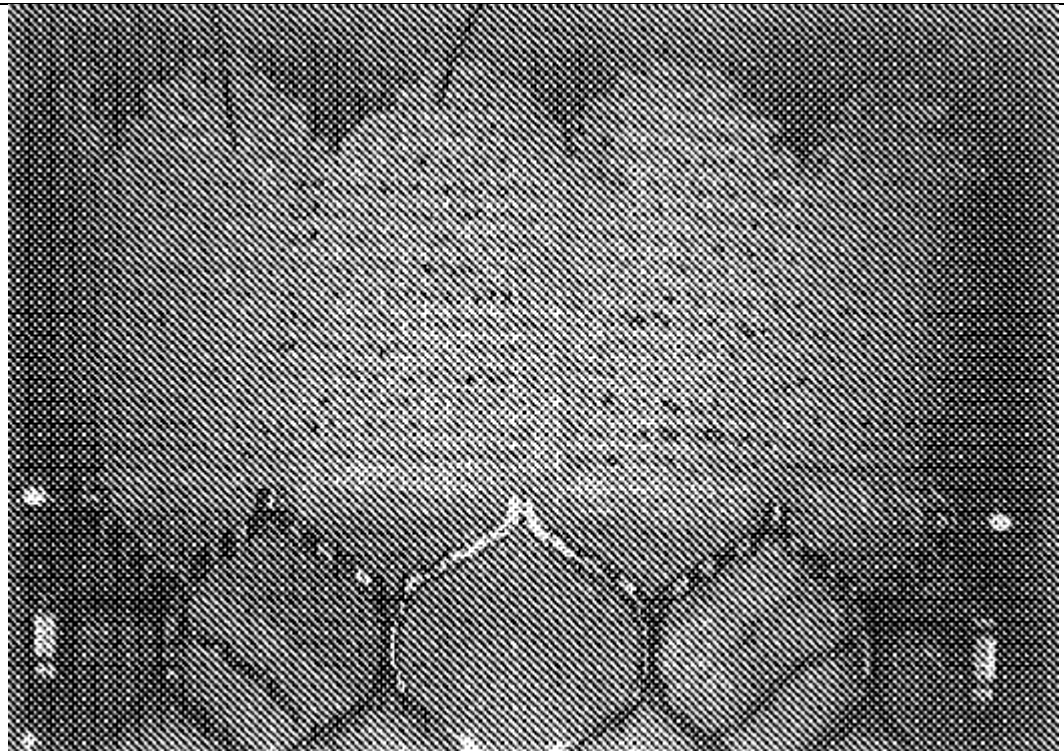
See also, claim 1.

With respect to the phrase, "wherein the graft covering, prosthetic leaflets, and the sealing material are radially overlapping", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in

	this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, they are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering, prosthetic leaflets, and the sealing material performs the same or substantially the same function as the claim phrase by being at least partially radially overlapping in portions of the valve assembly, in the same or substantially the same way as the claim phase through being designed and configured to be at least partially radially overlapping, to achieve the same or substantially the same result of a valve assembly configured to have at least partially radially overlapping graft covering, prosthetic leaflets, and sealing material.
5. The endovascularly deployed heart valve assembly of claim 1, further comprising a second plurality of fibers, the second plurality of fibers being spaced-radially inwardly of the plurality of fibers,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities comprise a second plurality of fibers, the second plurality of fibers being spaced-radially inwardly of the plurality of fibers. For example, the Sapien 3 Ultra sealing skirt includes fibers facing the frame.The sealing skirt in the Sapien 3 Ultra is sewn to the frame and has a backside (internal facing portion) that incudes a second plurality of fibers that are radially inward of the plurality of fibers on the front side.



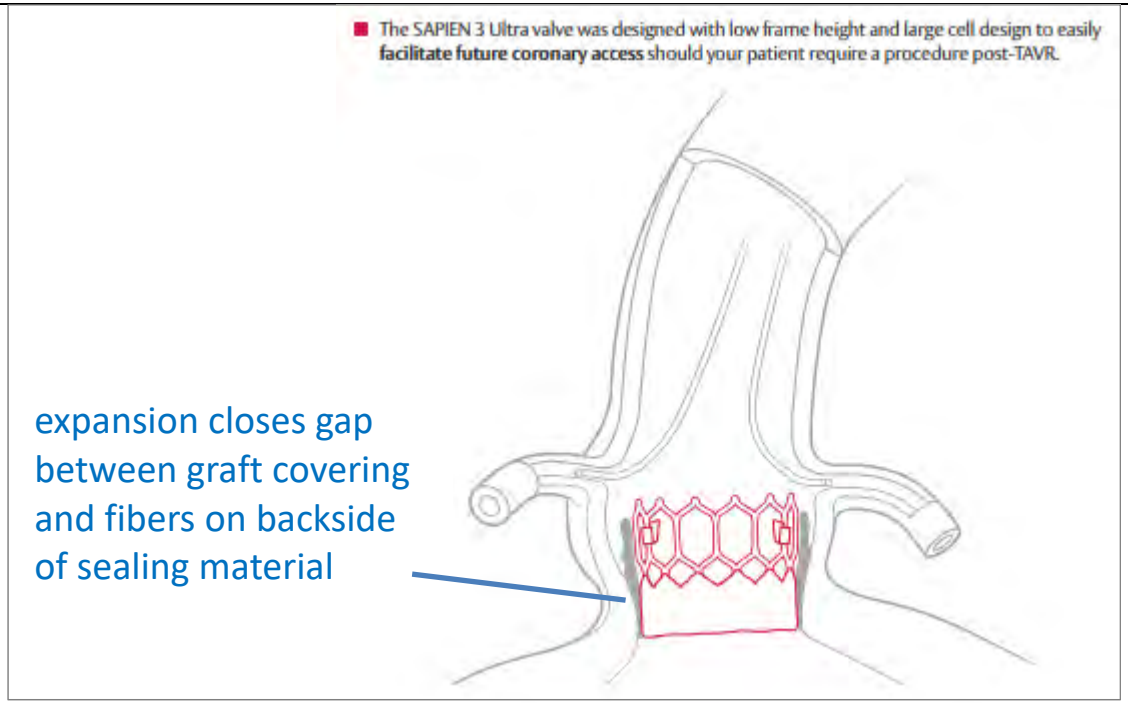
Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).



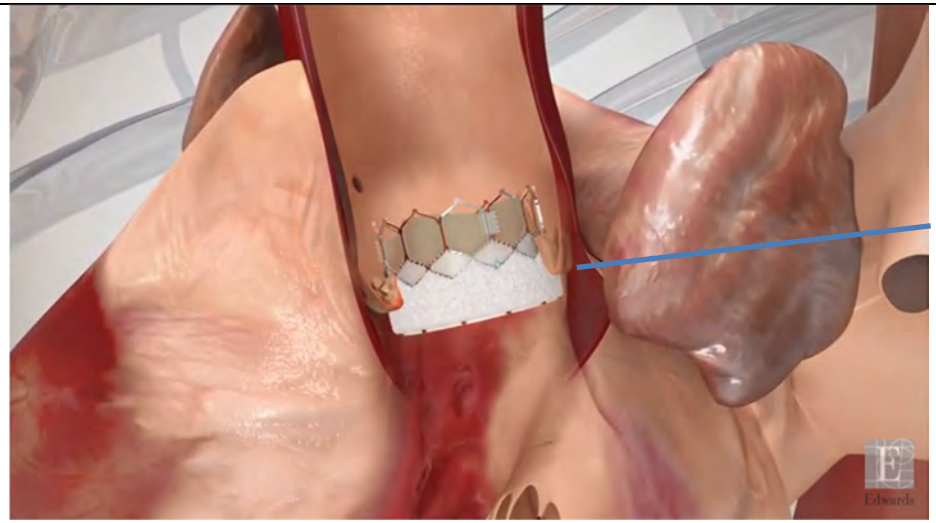
U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing fibers on flipped up backside of sealing skirt).

With respect to the phrase, "a second plurality of fibers, the second plurality of fibers being spaced-radially inwardly of the plurality of fibers" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a second plurality of fibers, the second plurality of fibers being spaced-radially inwardly of the plurality of fibers, the identified second plurality of fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform

	substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused second plurality of fibers perform the same or substantially the same function as the claim phrase by helping provide low profile sealing by closing the gap between the graft covering and the second plurality of fibers when expanded, in the same or substantially the same way as the claim phase by being configured on expansion to close the gap between the graft covering and fibers, to achieve the same or substantially the same result of a second plurality of fibers designed and configured to provide sealing between the graft covering and sealing material second plurality of fibers of the valve assembly. *See also,* claim 1.
wherein, expansion of the graft covering closes a gap between the graft covering and the second plurality of fibers to thereby create a seal therebetween.	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities are designed and configured such that expansion of the graft covering closes a gap between the graft covering and the second plurality of fibers to thereby create a seal therebetween. For example, the Sapien 3 Ultra is designed and configured such that when the valve is expanded (such as in the aorta of a patient) expansion closes a gap between the graft covering and second plurality of fibers on the backside of the sealing skirt to provide sealing therebetween.

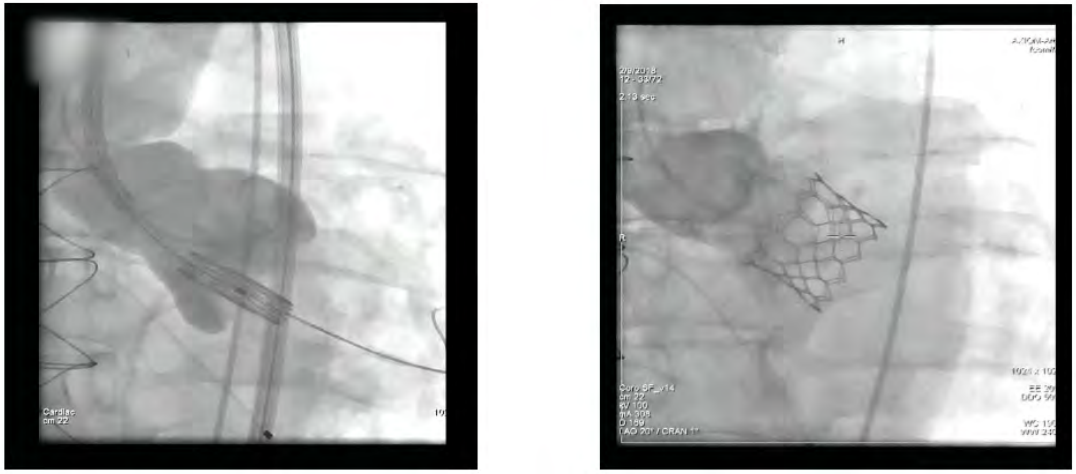


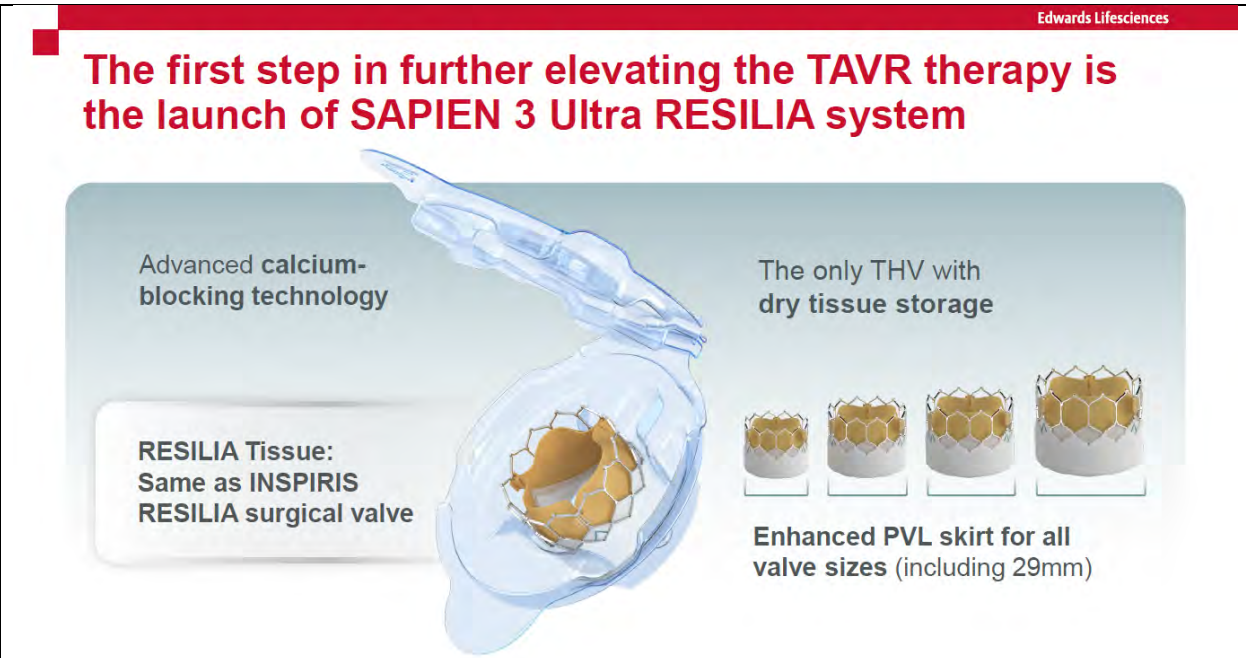
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



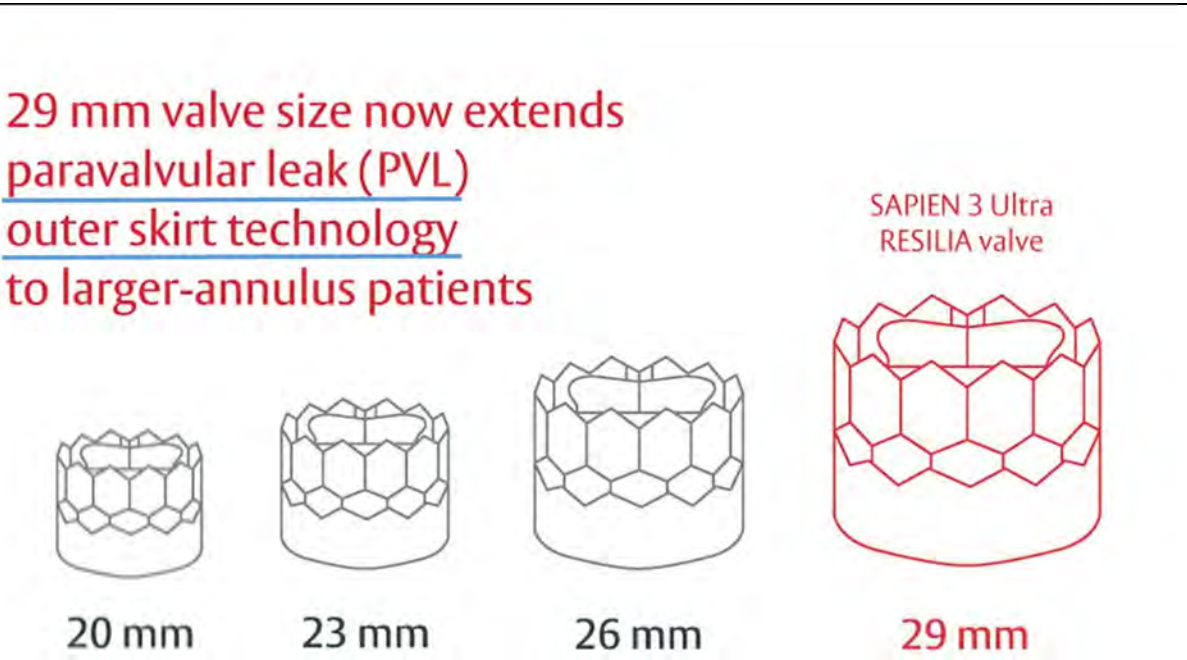
"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

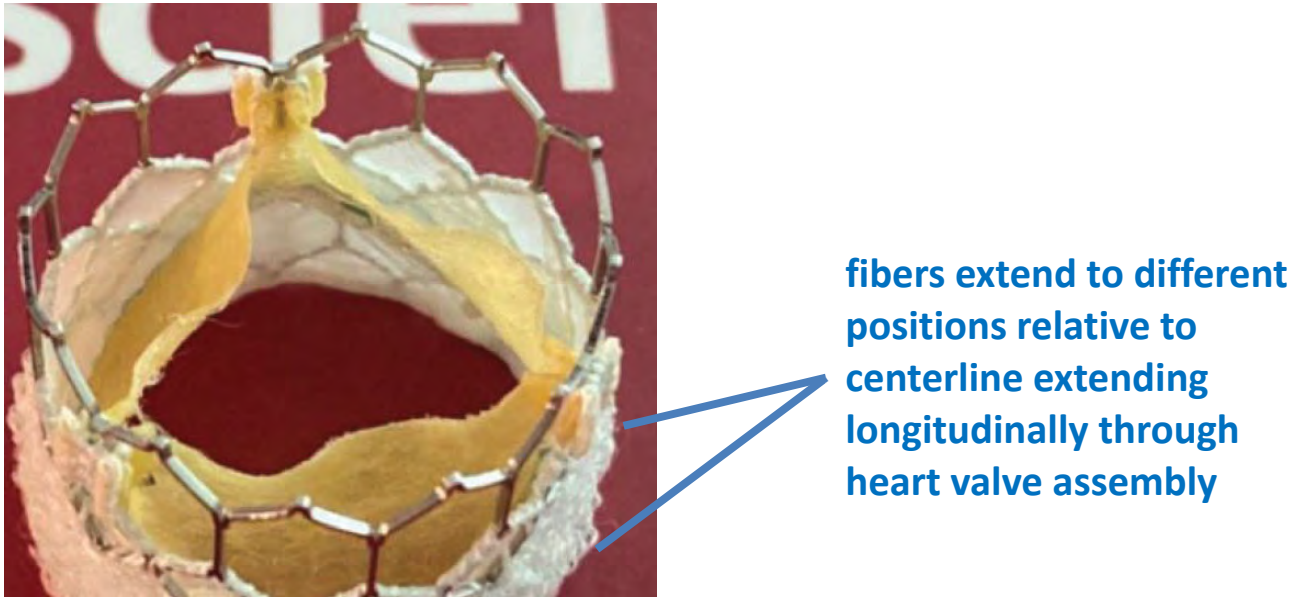
89

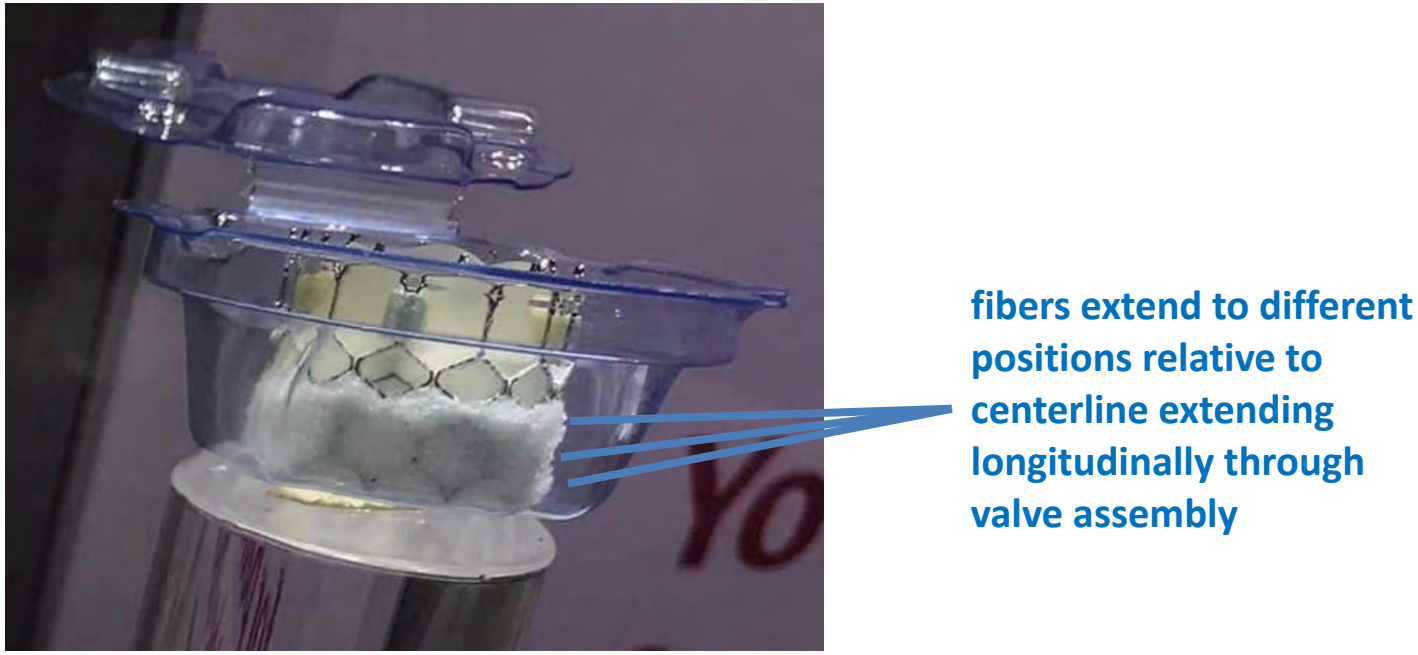
	SAPIEN 3 Ultra System Case Example  Edwards Presentation entitled "SAPIEN 3 Ultra Valve First-In-Human Experience" at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).



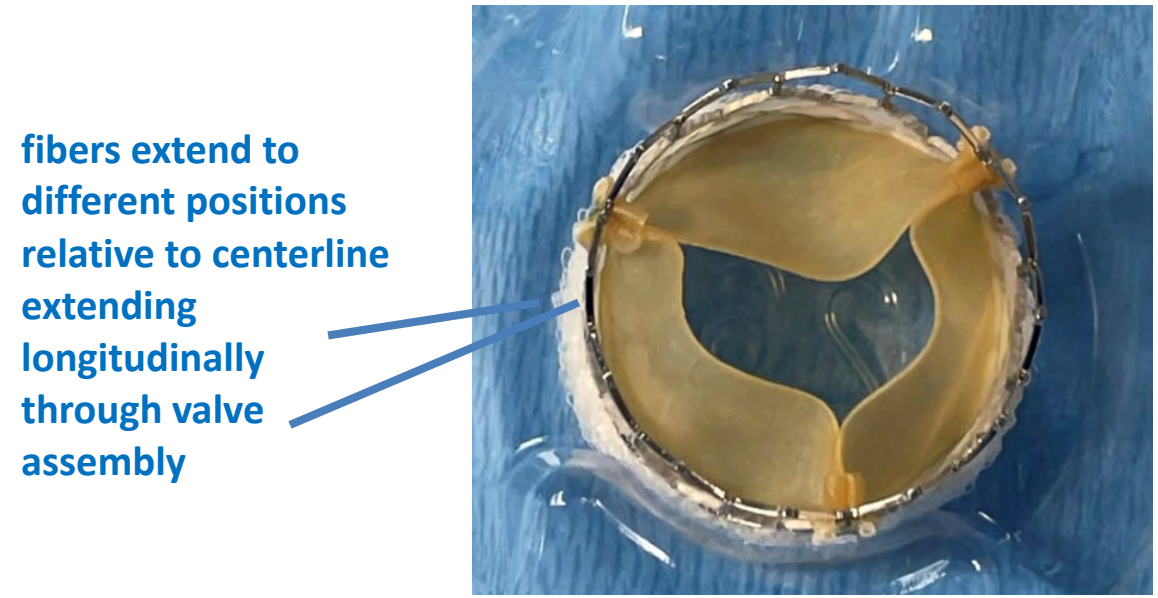
https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).

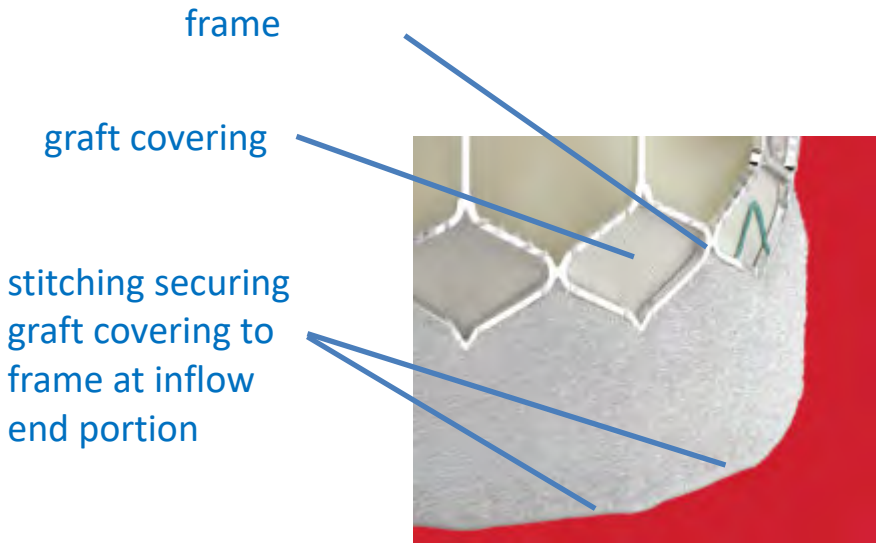
	 https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA *See also*, element above and claim 1.
6. The endovascularly deployed heart valve assembly of claim 1, wherein the fibers extend outwardly to different positions relative to a centerline run	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities’ fibers extend outwardly to different positions relative to a centerline run through a longitudinal of the heart valve assembly For example, the Sapien 3 Ultra sealing skirt fibers extend outwardly to different positions from a centerline extending longitudinally though the heart valve assembly.

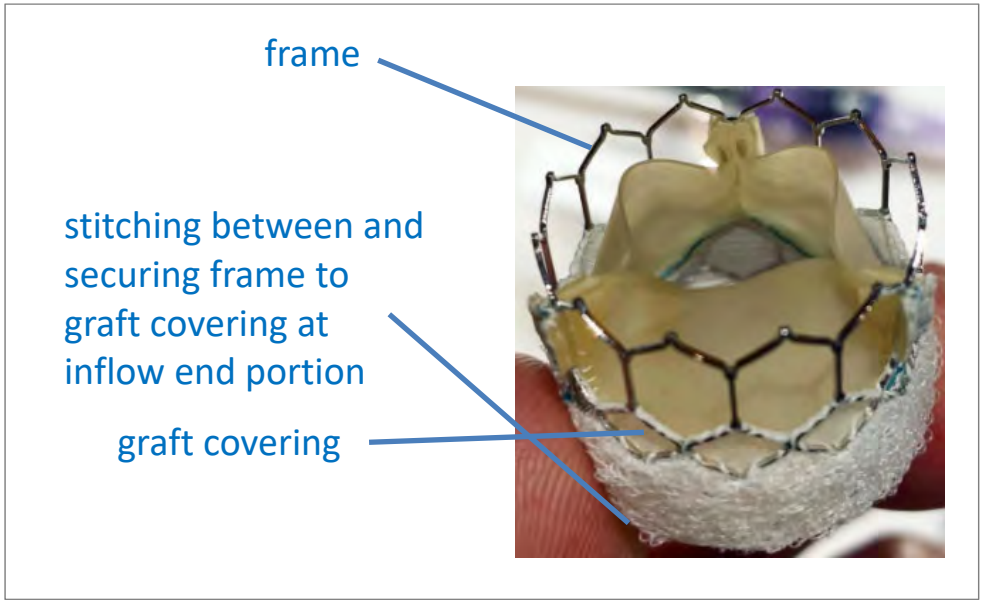
through a longitudinal of the heart valve assembly.	 Eduardo Saadi LinkedIn posts and image (C.V. 1-21-cv-01377) (D.I. 106, Ex. K).



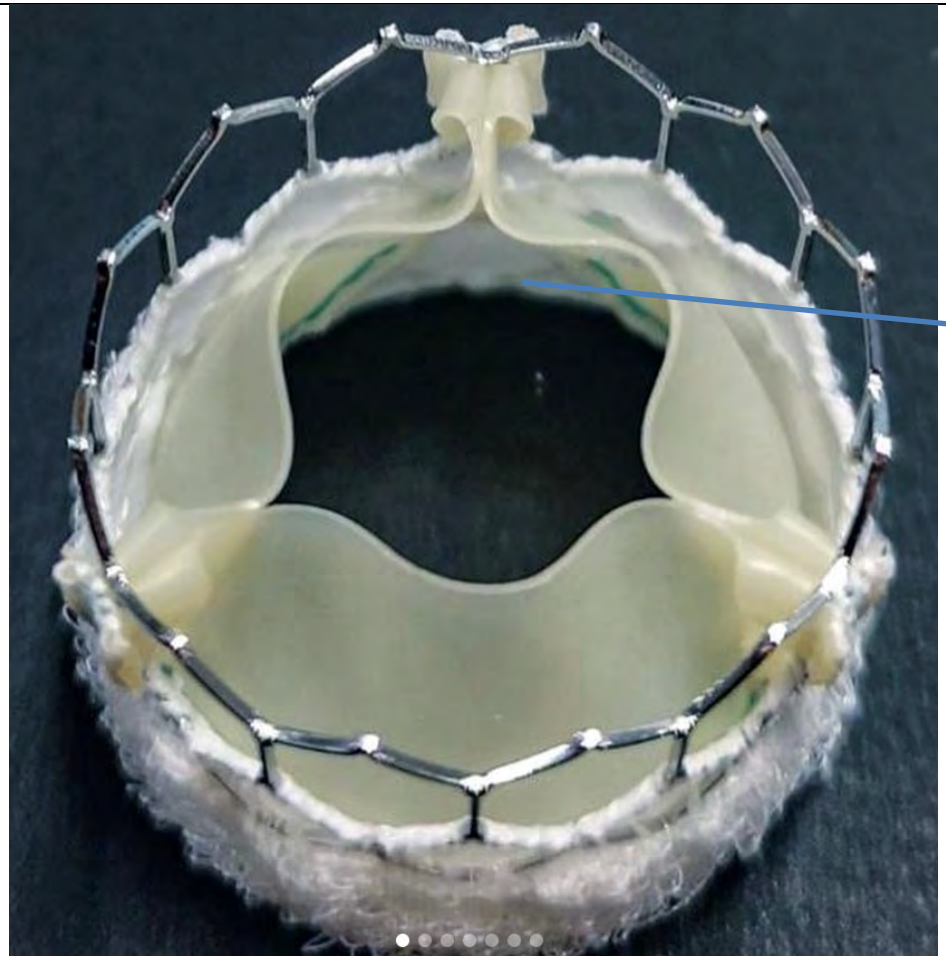
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64). *See also*, claim 1.
7. The endovascularly deployed heart valve assembly of claim 1, wherein the graft covering extends to the inflow end portion of the frame, wherein,	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities' graft covering extends to the inflow end portion of the frame, wherein, stitching extending between the graft covering and through the frame secures the graft covering to the inflow end portion of the frame. For example, the Sapien 3 Ultra graft covering extends to the inflow end of the frame and has stitching that extends between the graft covering and through the frame securing the graft covering to the inflow end portion of the frame.

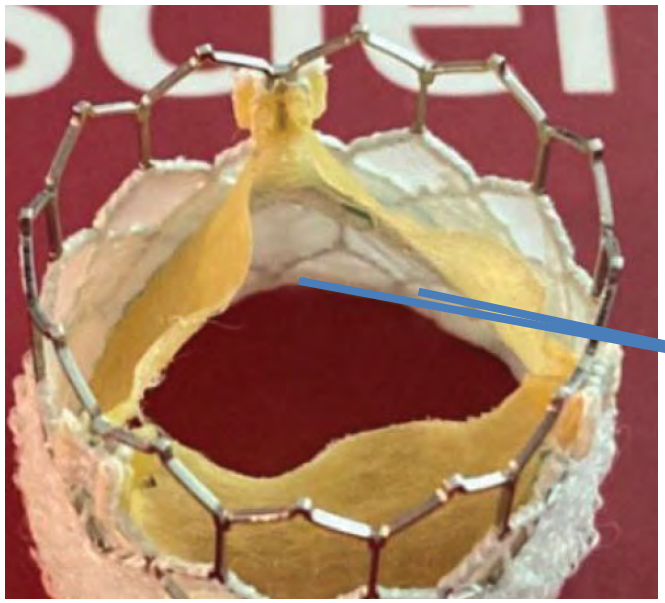
stitching extending between the graft covering and through the frame secures the graft covering to the inflow end portion of the frame.	 https://www.edwards.com/devices/heart-valves/transcatheter-Sapien-3-Ultra (D.I. 1, Ex. 33).  Introducing the SAPIEN 3 Ultra valve at 2 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

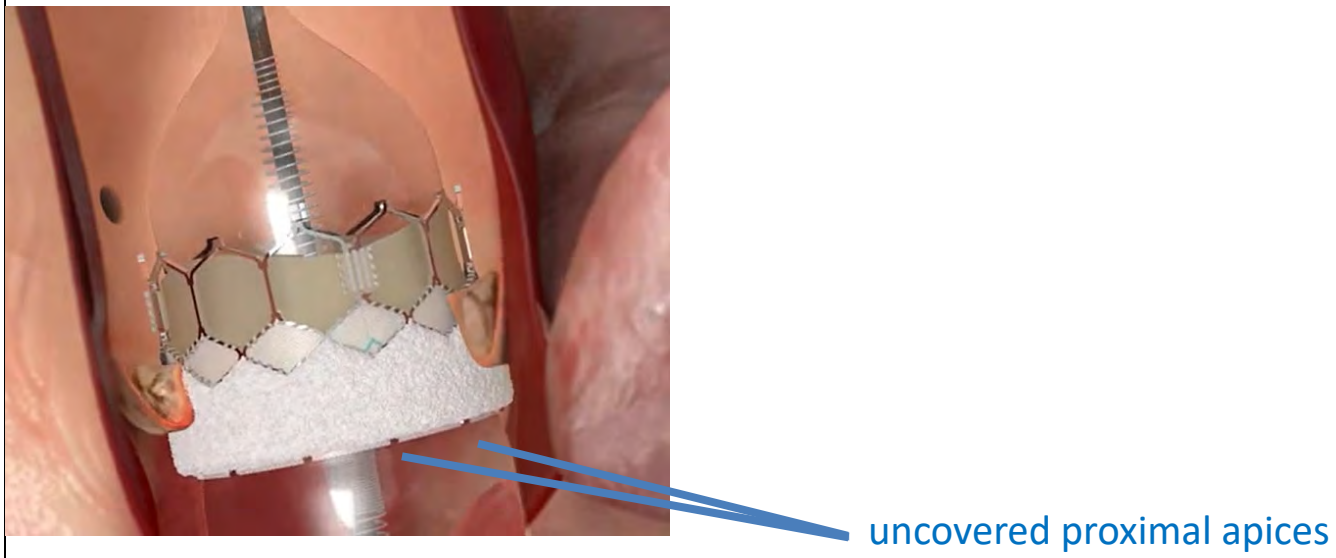


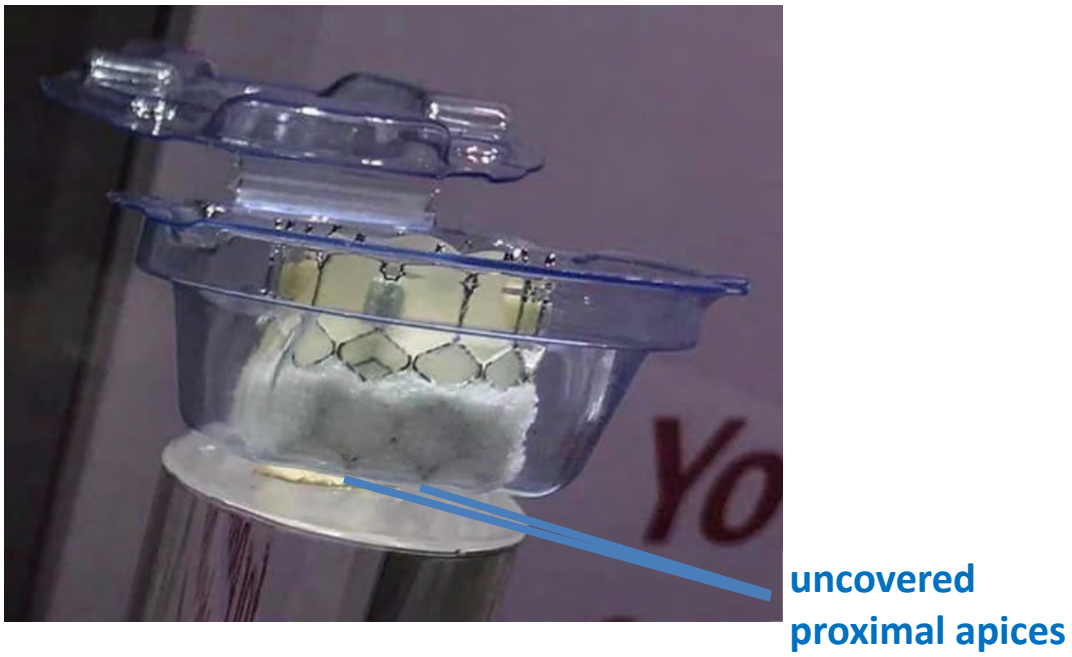
Sapien 3 Ultra image available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).



Julian Calain Twitter (D.I. 1, Ex. 30).

	 Eduardo Saadi LinkedIn posts and image (C.V. 1-21-cv-01377) (D.I. 106, Ex. K). *See also*, claim 1.
8. The endovascularly deployed heart valve assembly of claim 1, wherein an end of the most proximal apices of the frame are uncovered by sealing material	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise an end of the apices of the frame that are most proximal are uncovered by the sealing material and the graft covering. For example, the Sapien 3 Ultra is designed, manufactured, and tested by Edwards to ensure that ends of the most proximal apices of the frame are uncovered by the sealing material and graft covering so that when crimped they extend into a low profile configuration without being hindered.

and the graft covering,	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

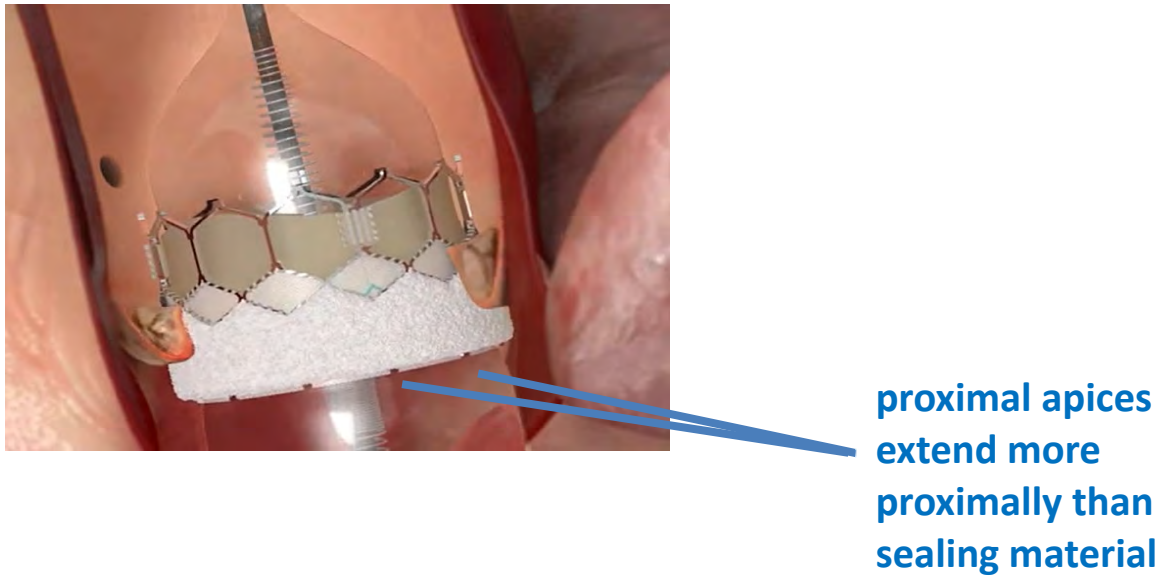


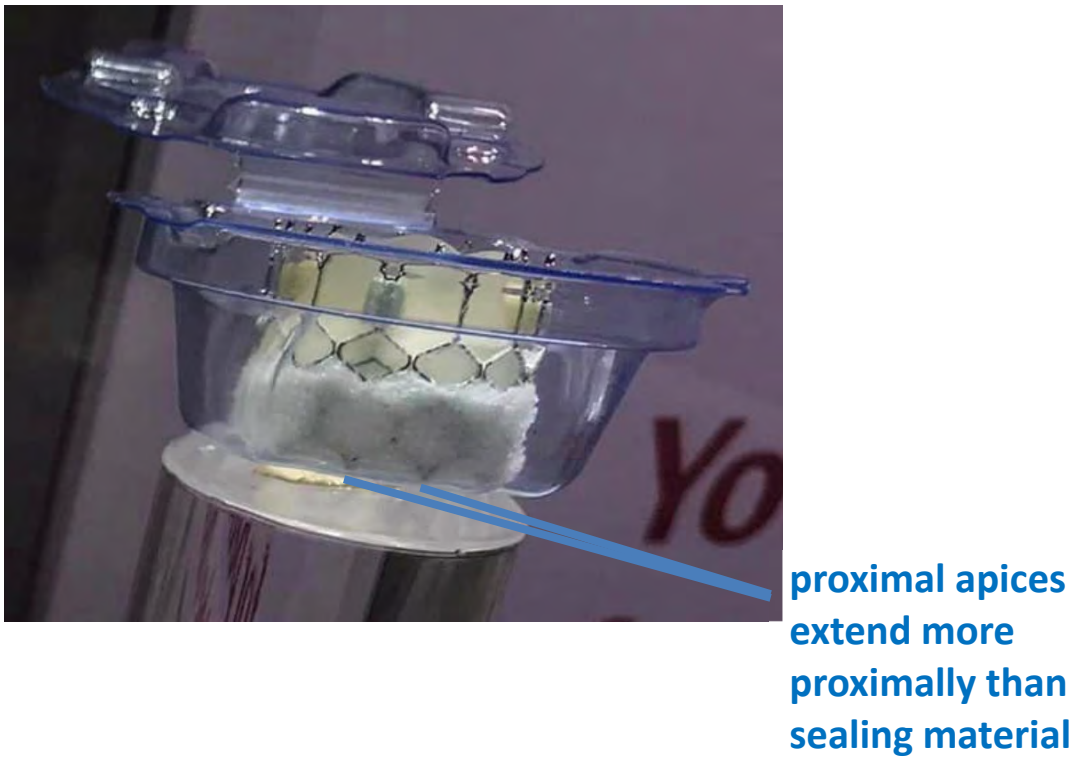
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth.



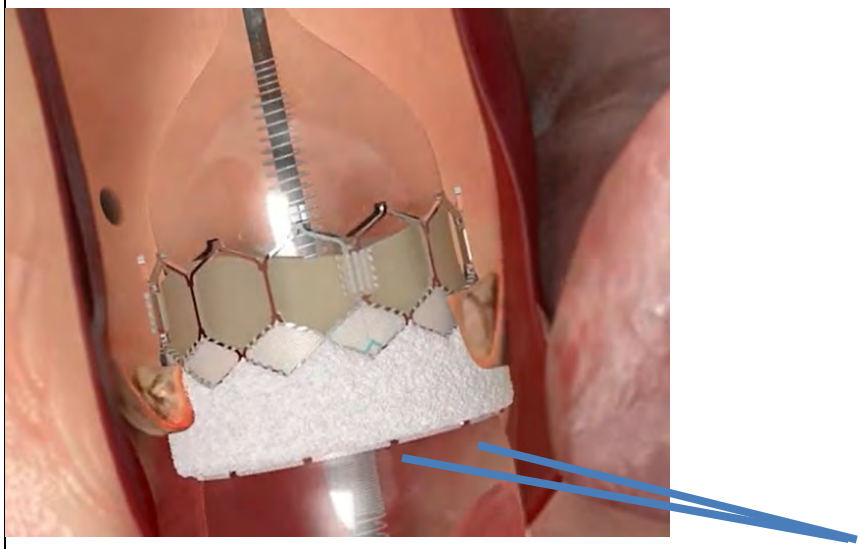
Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1-3 at 339).

With respect to the phrase, "wherein an end of the most proximal apices of the frame are uncovered by sealing material and the graft covering," Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the end of the most proximal apices do not appear to be uncovered in all images and configurations, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused end of the apices of the frame that are most proximal performs the same or substantially the same function as the claim phrase by permitting the TAVR valve to achieve a low profile when in a collapsed/crimped state, in the same or substantially the same way as the claim phase by ensuring that the sealing material and graft covering minimize interference with the ends of the most proximal apices of the frame and/or permits their further passage there through when the TAVR valve is collapsed/crimped state, to achieve the same or substantially the same result of a TAVR valve with an sealing material and a graft covering that is configured and capable of being collapsed/crimped to achieve a low profile for endovascular delivery.

	See also, claim 1.
wherein the end of the most proximal apices of the frame extends more proximally than a proximal end of the sealing material.	For example, the Sapien 3 Ultra includes a frame where the most proximal apices of the frame extends more proximally than a proximal end of the sealing material.  "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

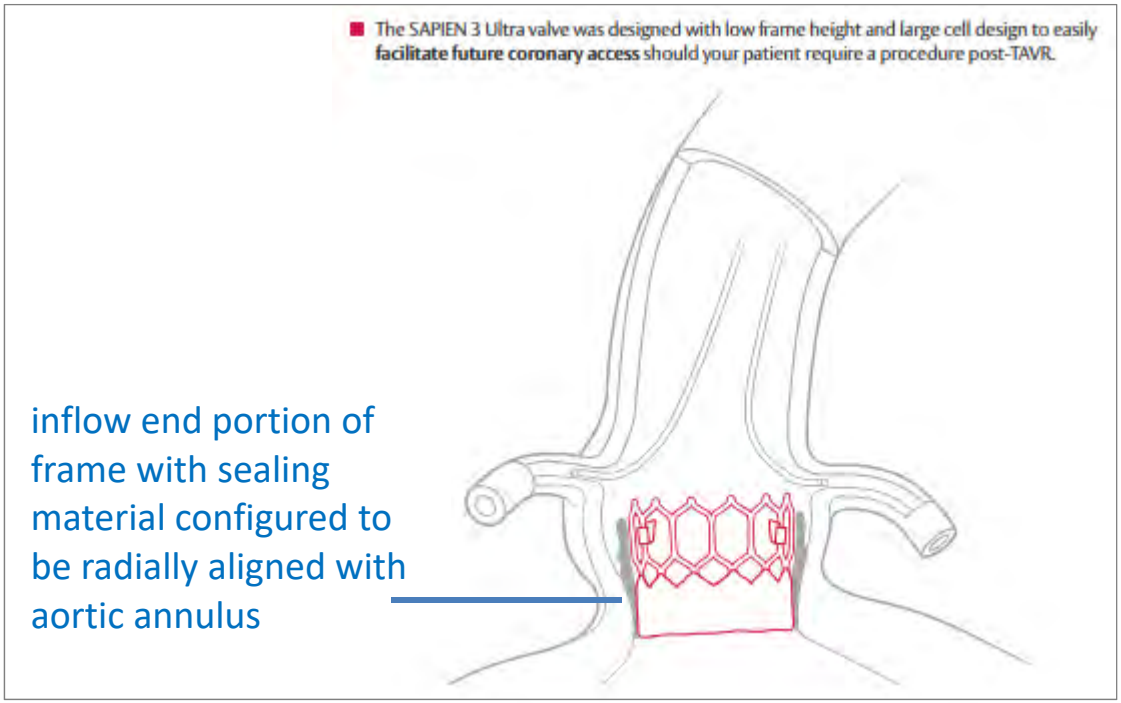


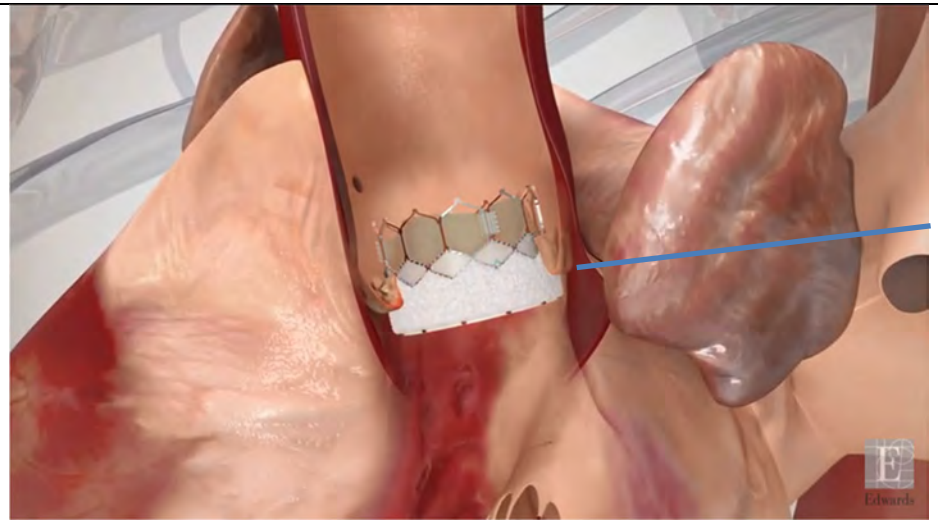
Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth.

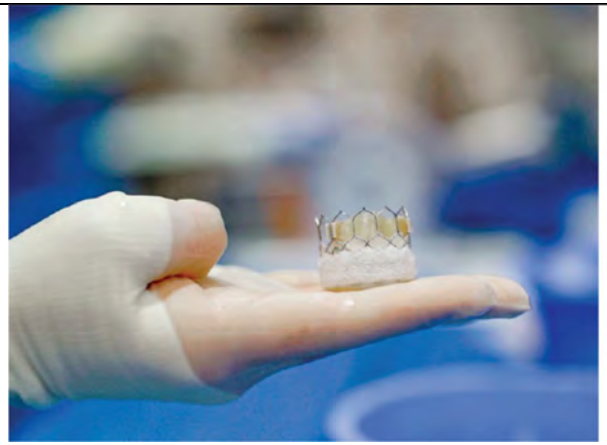
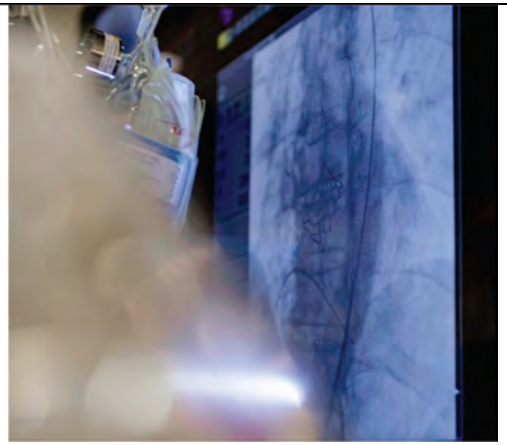


"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU (D.I. 1-3 at 339). With respect to the phrase, "wherein the end of the most proximal apices of the frame extends more proximally than a proximal end of the sealing material" Aortic also asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this element is not satisfied by the Accused Instrumentalities, for example, by alleging the end of the most proximal apices do not appear to extend more proximally than the proximal end of the sealing material in all images and configurations, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitations and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused end of the most proximal apices of the frame performs the same or substantially the same function as the claim phrase by being configured to permit the TAVR valve to achieve a low profile when in a collapsed/crimped state, in the same or substantially the same way as the claim phase by ensuring that the sealing material minimizes interference with the ends of the most proximal apices of the frame and/or permits their further passage there through when the TAVR valve is in a collapsed/crimped state, to achieve the same or substantially the same result of a TAVR valve with sealing material that is capable of being collapsed/crimped to achieve a low profile for endovascular delivery.

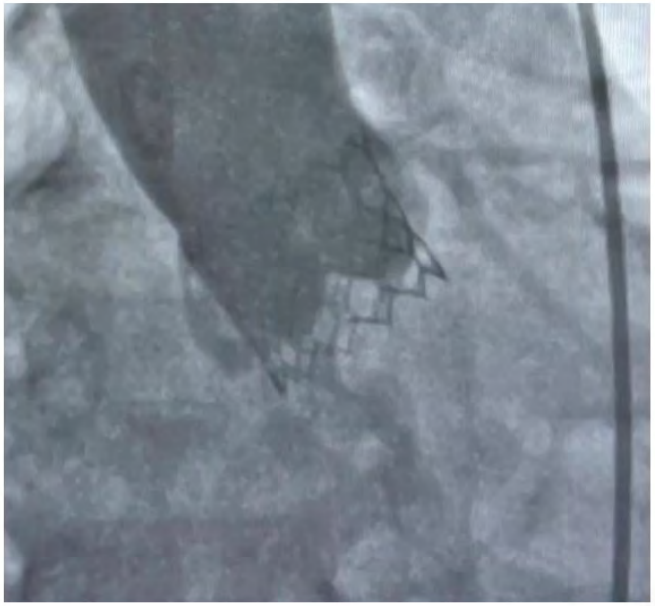
	See also, claim 1.
9. The endovascularly deployed heart valve assembly of claim 1, wherein the end of the frame in which sealing material begins at the inflow end portion of the frame is configured for being radially aligned with the aortic annulus when the valve assembly is deployed.	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities are designed and configured such that the end of the frame in which sealing material begins at the inflow end portion of the frame is configured for being radially aligned with the aortic annulus when the valve assembly is deployed. For example, the Sapien 3 Ultra is designed and configured such that end of the frame with the sealing materials is configured for being radially aligned with the aortic annulus when the valve assembly is deployed.  Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

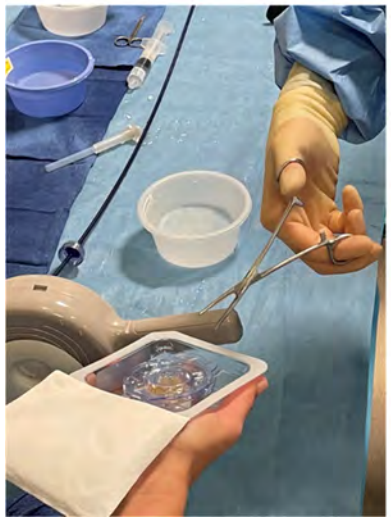
	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37). *See also*, claim 1.
10. An endovascular prosthetic heart valve assembly for use in a patient, comprising:	To the extent the preamble is limiting, the '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities are endovascular prosthetic heart valves for use in a patient. The '918 patent Accused Instrumentalities are designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards' balloon catheter delivery systems.

	  https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).

	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



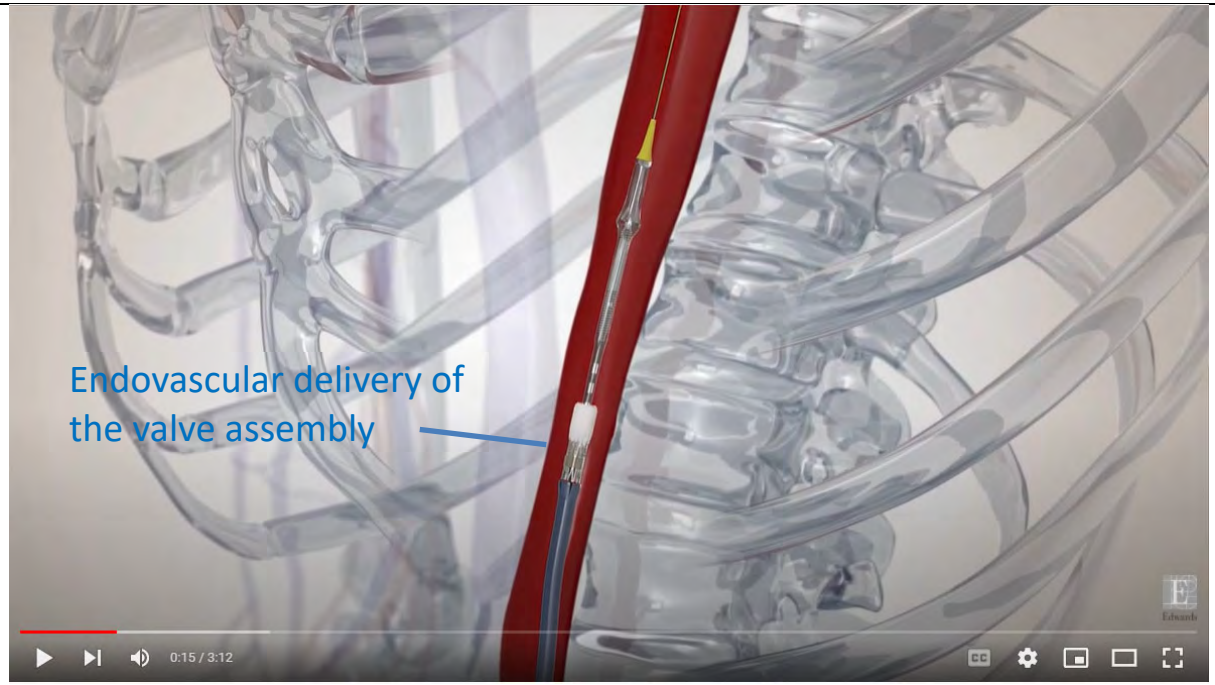


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra[4] is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[4] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.



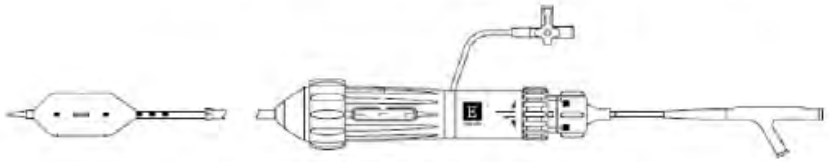
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



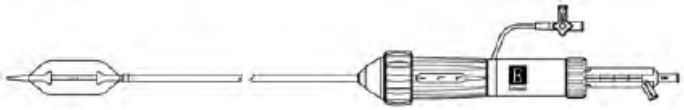
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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

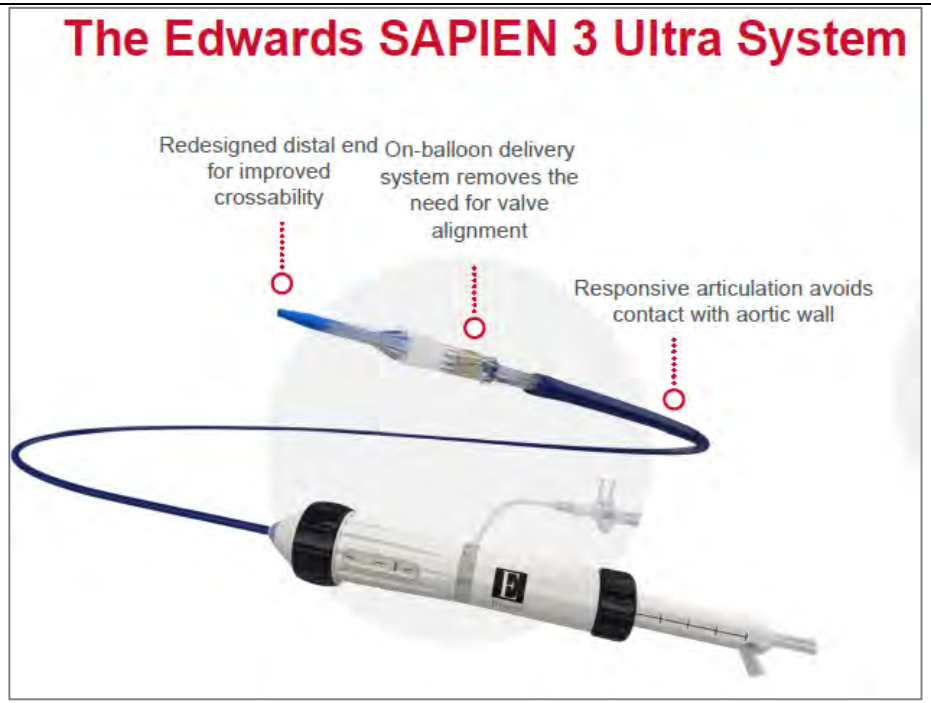
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

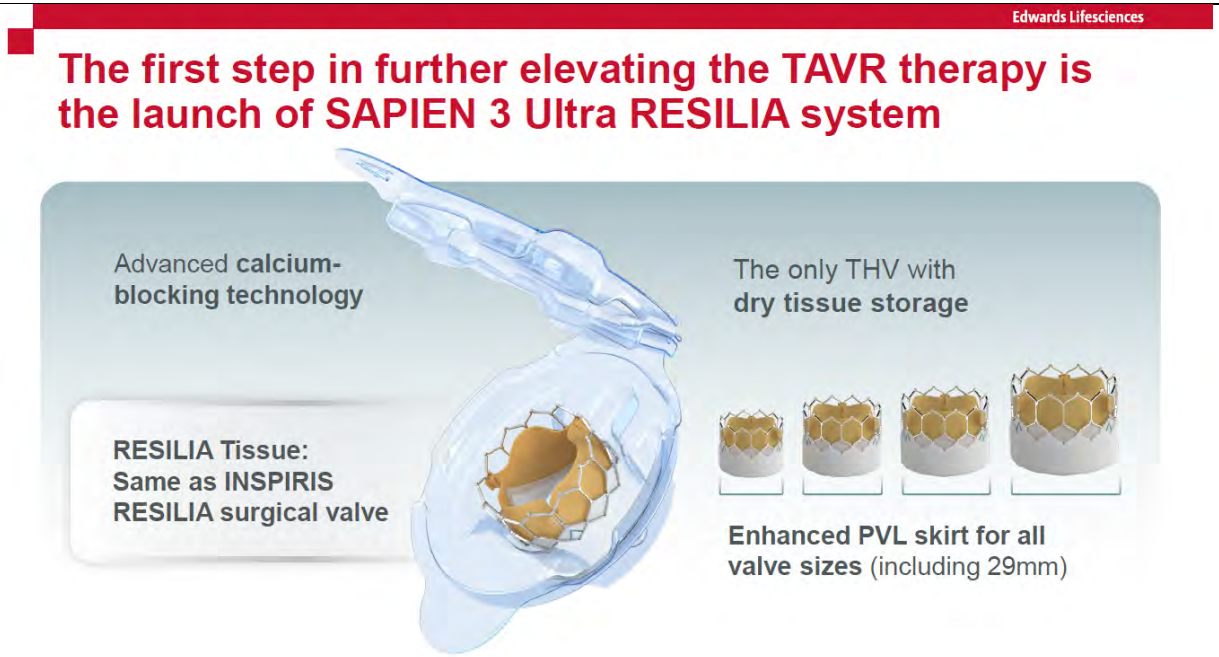
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

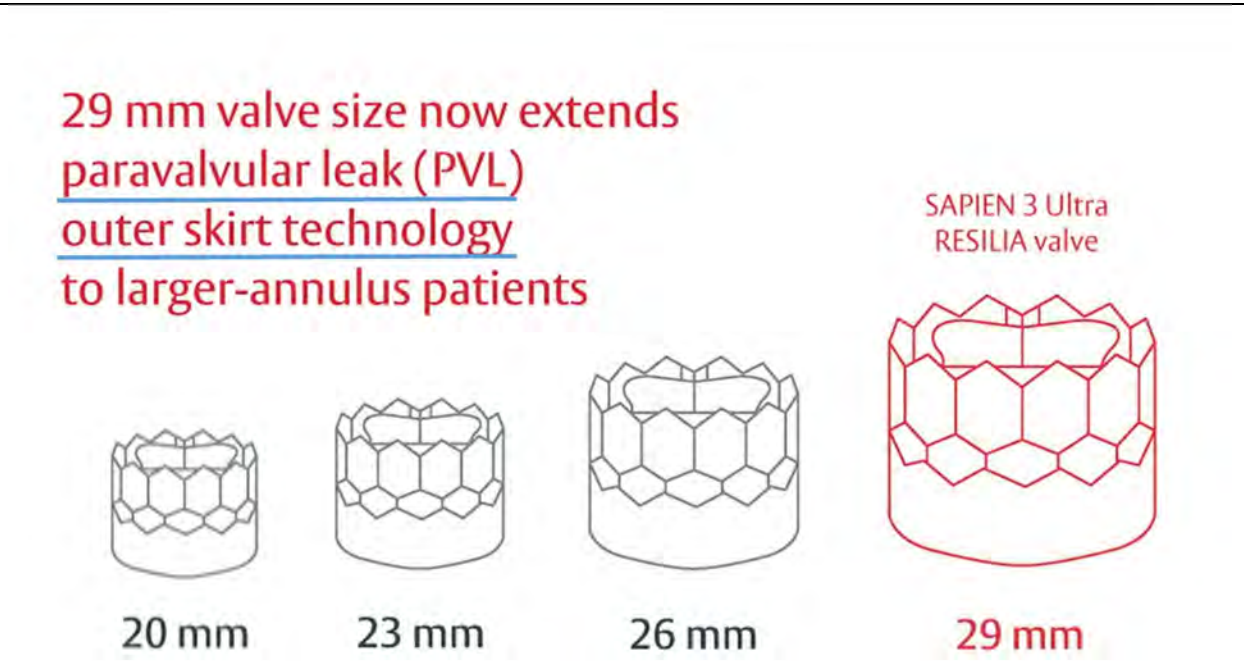
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

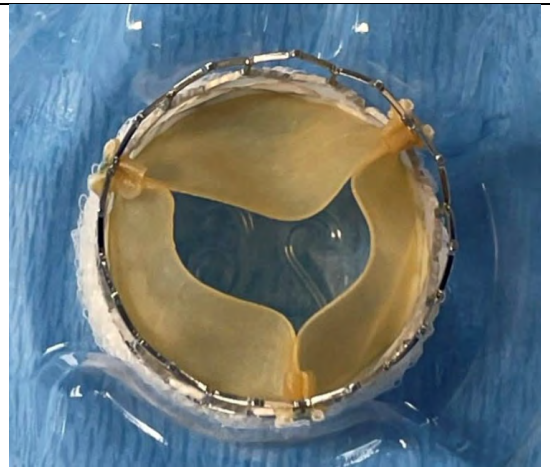
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’918 patent Accused Instrumentalities and infringes the ’918 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



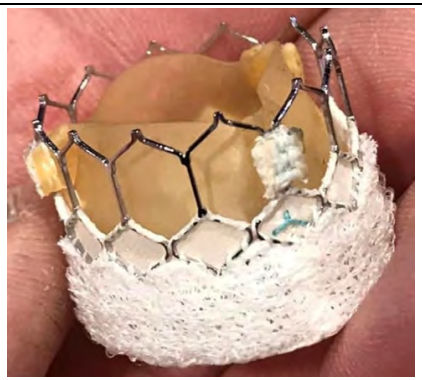
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



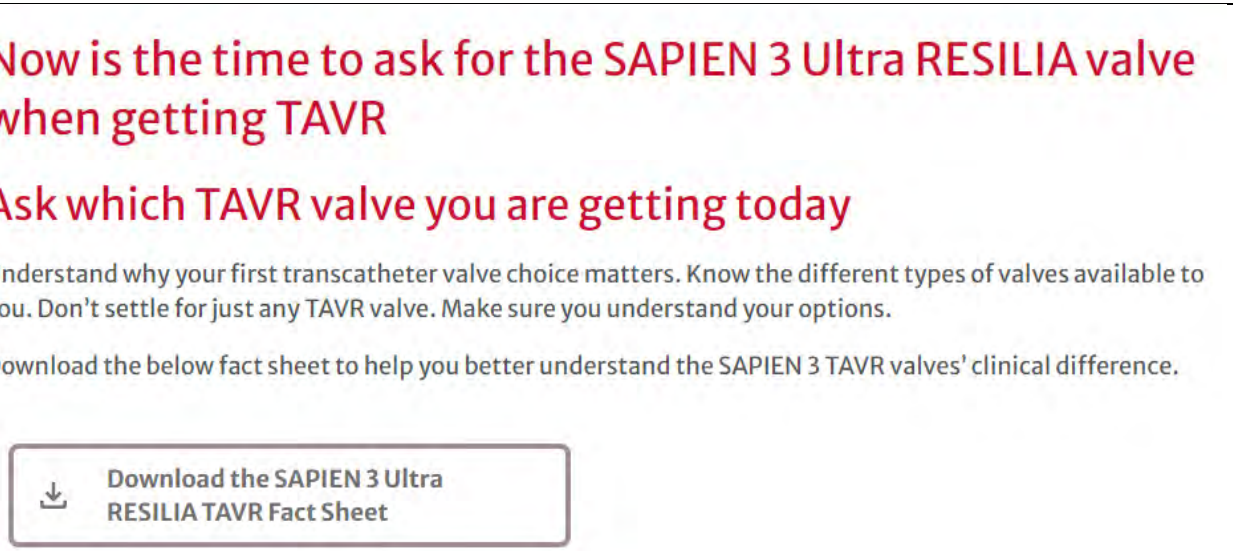

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

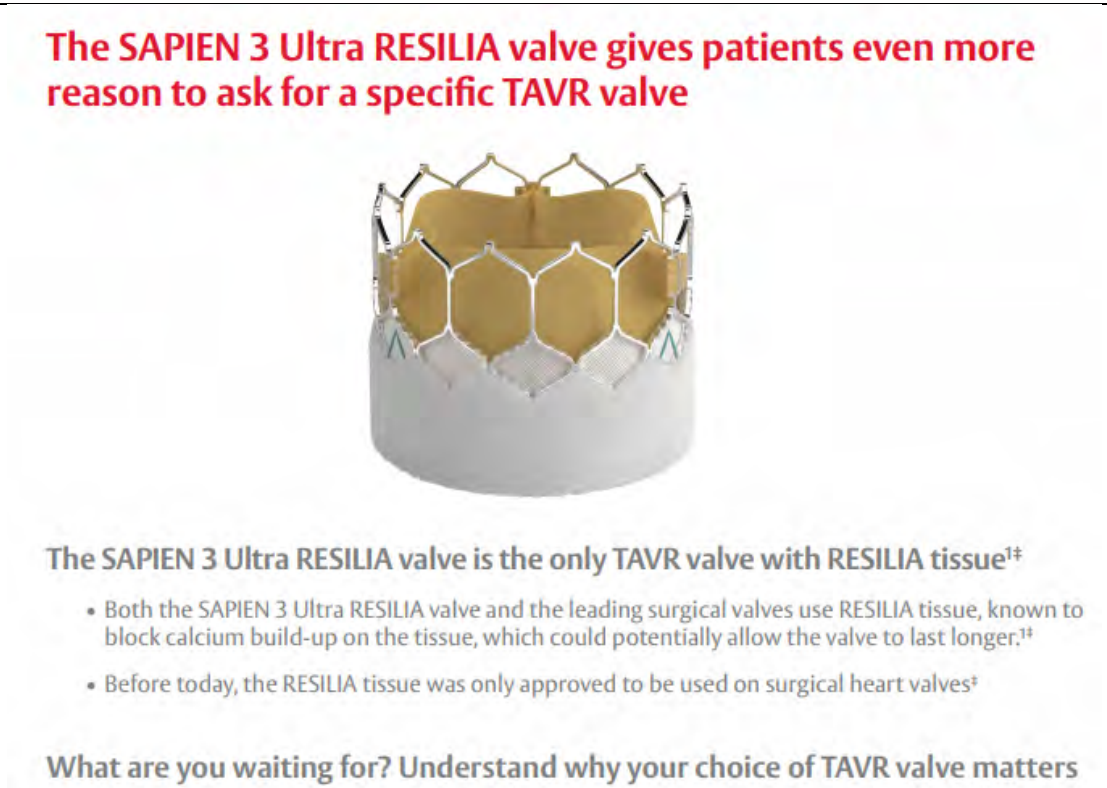
On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

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 and infringes the '918 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See*

	https://ir.edwards.com/events-presentations/; https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '918 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '918 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '918 asserted claims are infringed when Edwards offers for sale and sells the '918 patent Accused Instrumentalities. Edwards offers for sale and promotes the '918 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 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.

	 https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



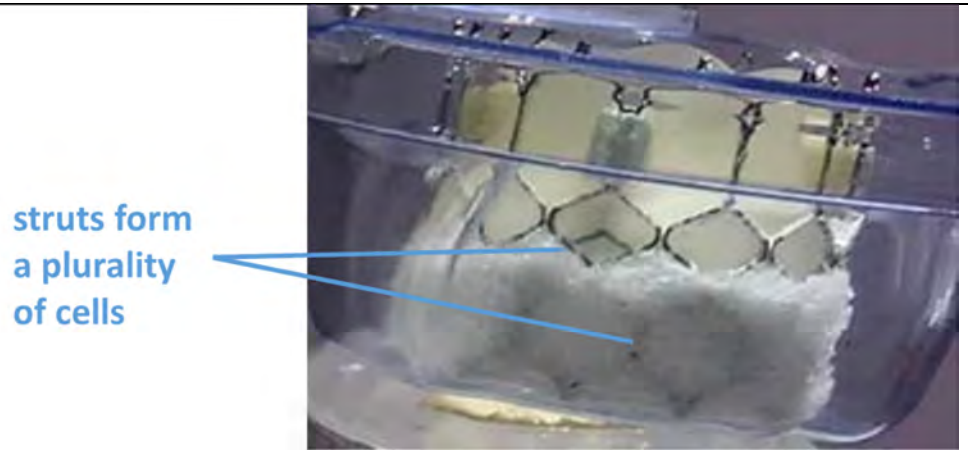
https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61).

On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement#

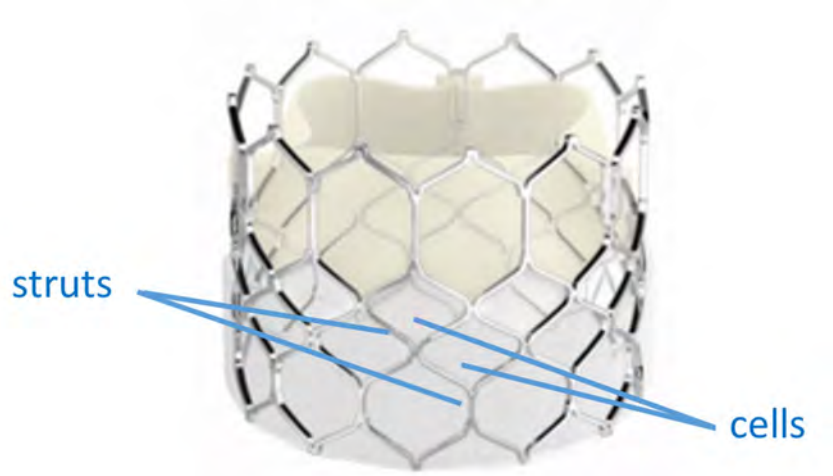
Further, the '918 patent asserted claims are directly infringed when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the ’918 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards’ direct and induced infringement. For further example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe the asserted ’918 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a “watchful eye” over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards’s inducement, Edwards’s affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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.

	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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards’s affirmative acts of marketing, selling and offering to sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ combination and use of the Accused Instrumentalities, such that the ’918 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards’ knowledge of Aortic’s inventions, the patents-in-suit (including the ’918 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
a frame formed of a plurality of struts that cooperate to form a plurality of cells,	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise a frame formed of a plurality of struts that cooperate to form a plurality of cells. For example, the Sapien 3 Ultra frame is formed of struts that together form a plurality of cells.



Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).

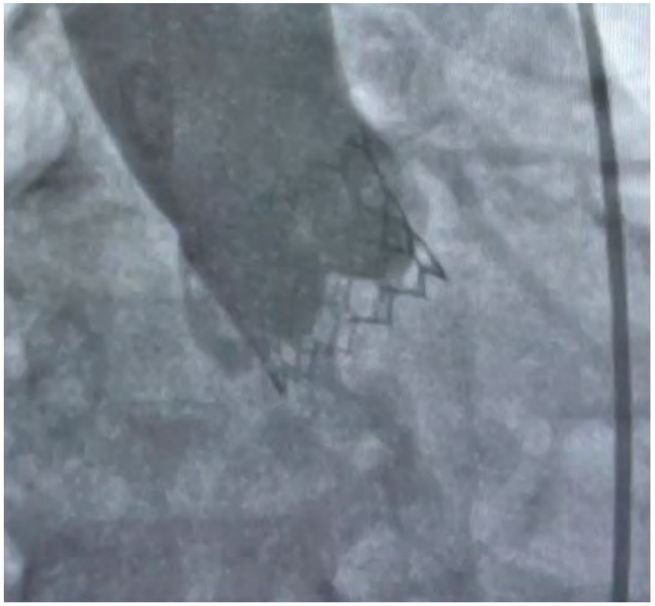


https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33).

See also, evidence for preceding elements above.

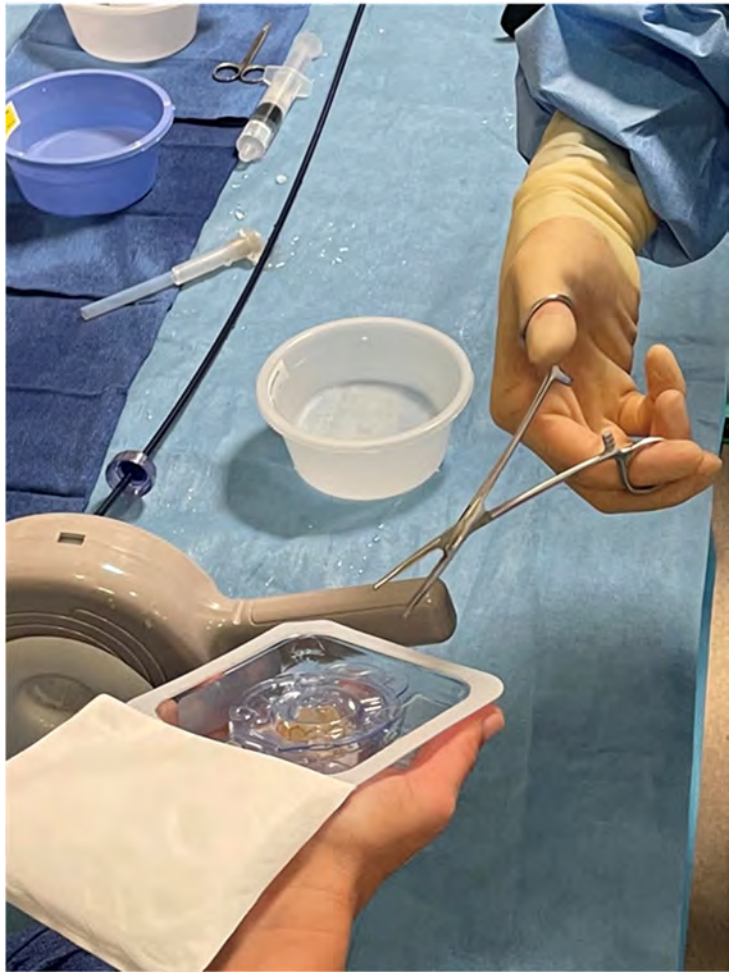
	With respect to the phrase, "a frame formed of a plurality of struts that cooperate to form a plurality of cells", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with struts and cells with the capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy. Further, whether the frame with a plurality of struts that cooperate to form a plurality of cells is laser cut from a single piece of material or made otherwise is the same or, at most, an insubstantial difference.
wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;	The '918 patent Accused Instrumentalities satisfy this element. The '918 patent Accused Instrumentalities comprise a frame that is radially expandable from a radially compressed orientation to a radially expanded orientation. For example, the Sapien 3 Ultra is packaged and provided by Edwards in a radially expanded configuration. The Sapien 3 Ultra is designed by Edwards to be crimpable onto an Edwards' balloon delivery system in a radially compressed orientation. The Sapien 3 Ultra is also designed to be expanded using an Edwards' balloon delivery system in the aorta of a patient into a radially expanded orientation.

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



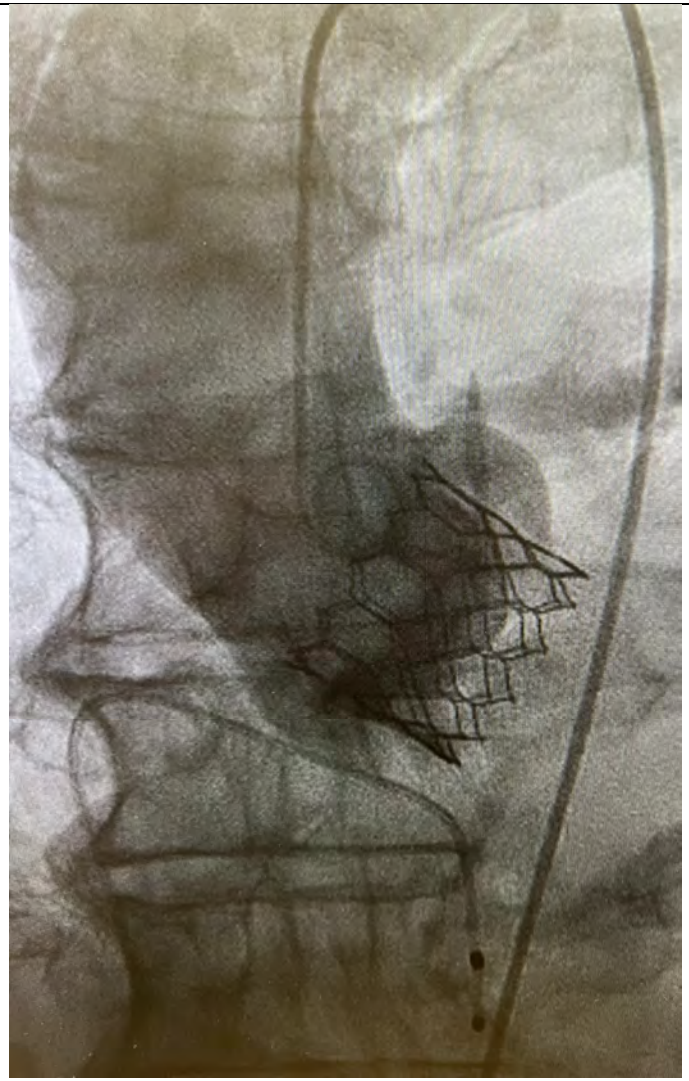
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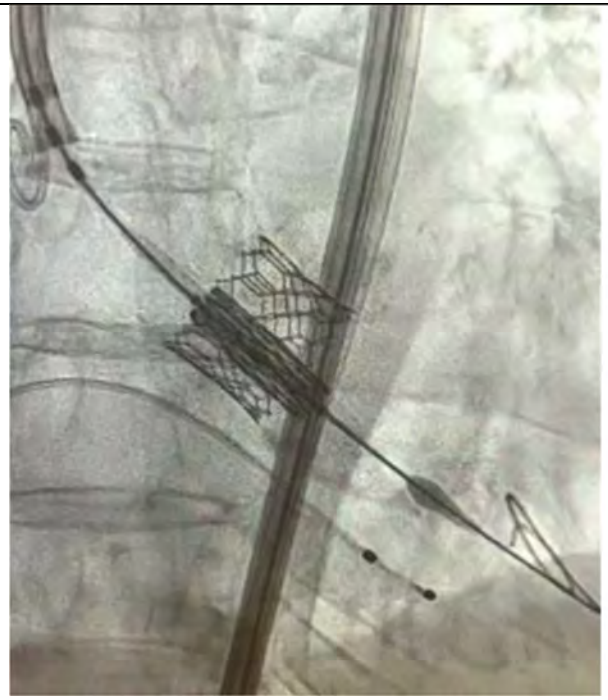
https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA

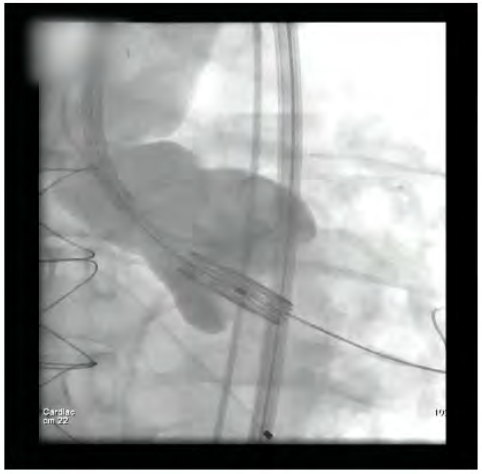


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https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

SAPIEN 3 Ultra System Case Example





Edwards Presentation entitled “SAPIEN 3 Ultra Valve First-In-Human Experience” at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

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.



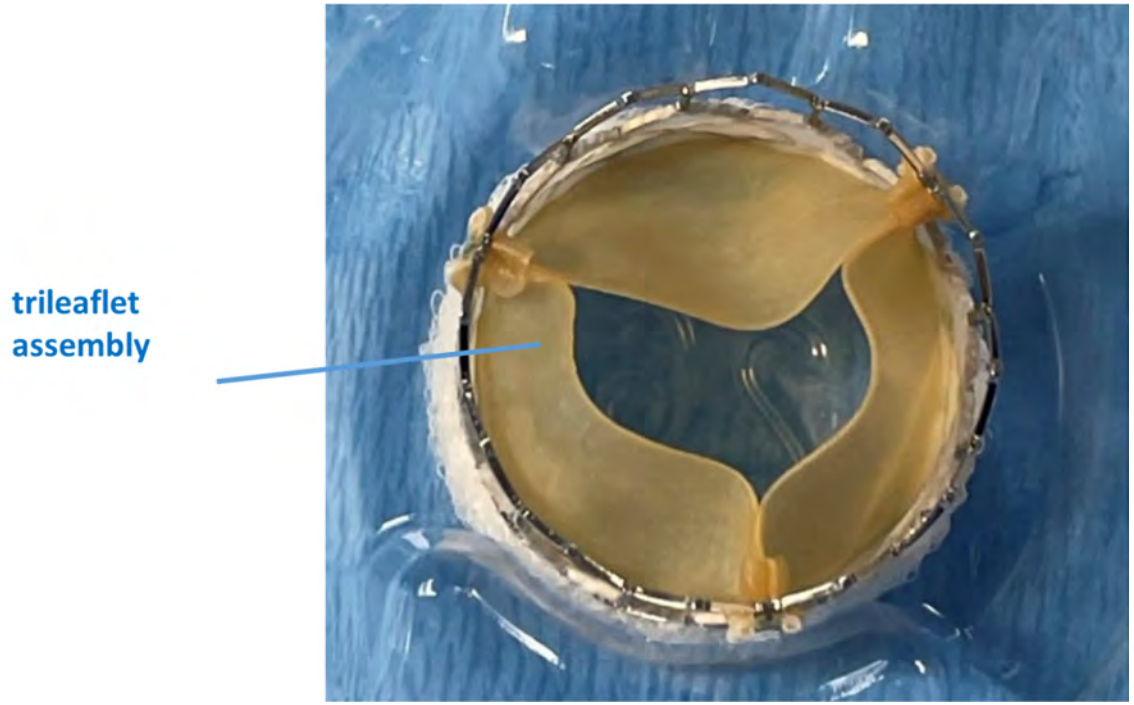
9750TFX

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 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a leaflet assembly within the frame;	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise a leaflet assembly within the frame. For example, the Sapien 3 Ultra devices comprise a bovine pericardial tissue trileaflet assembly and/or Resilia tissue trileaflet assembly within the frame.  https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).

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.

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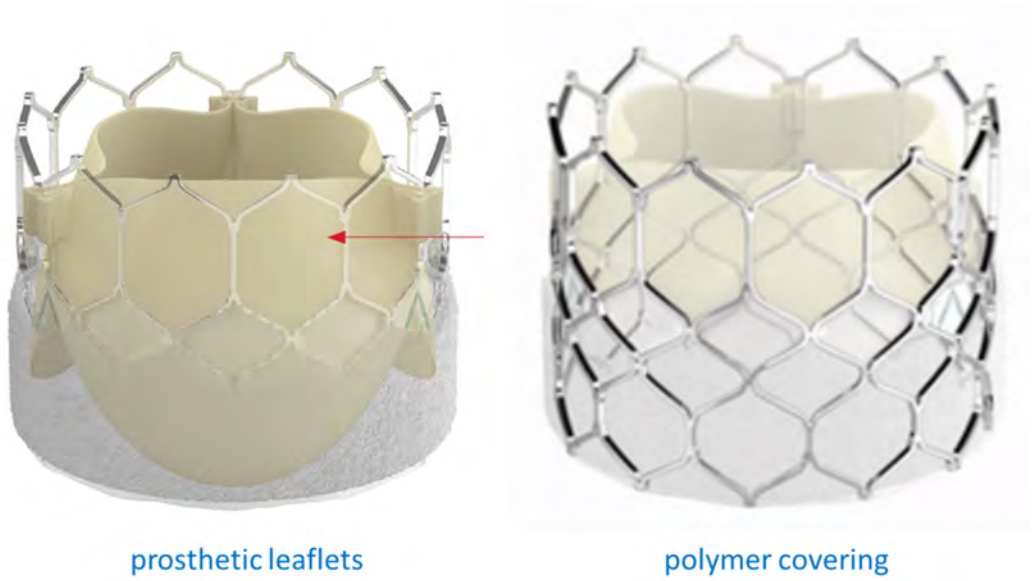
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

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Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly;	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise a polymer covering, carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly. For example, the Edwards Sapien 3 Ultra has a polymer covering made from PET attached to and touching the leaflet assembly. Further, the Sapien 3 Ultra polymer covering is positioned radially inward of the frame.  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (showing polymer covering radially inward of the frame carrying and engaging the leaflet assembly) (D.I. 1, Ex. 33).

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.



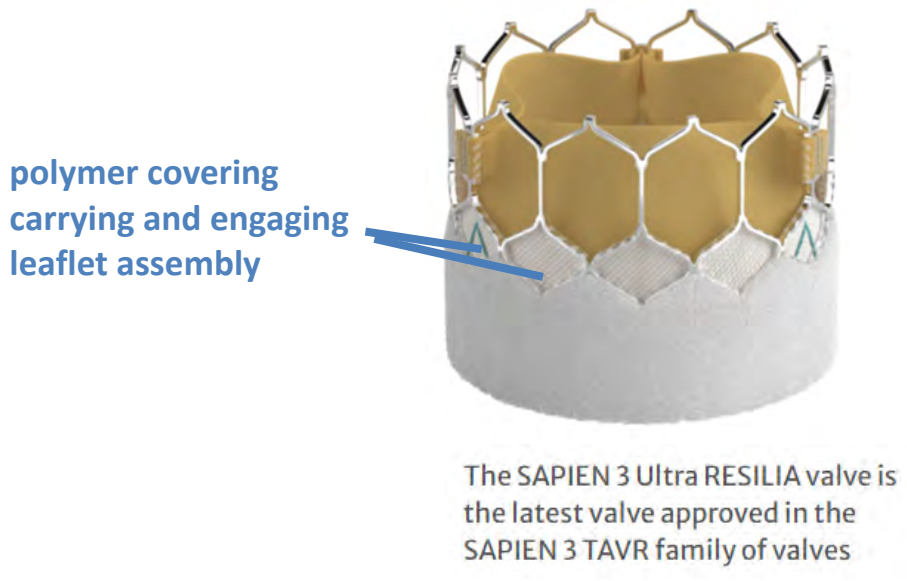
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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

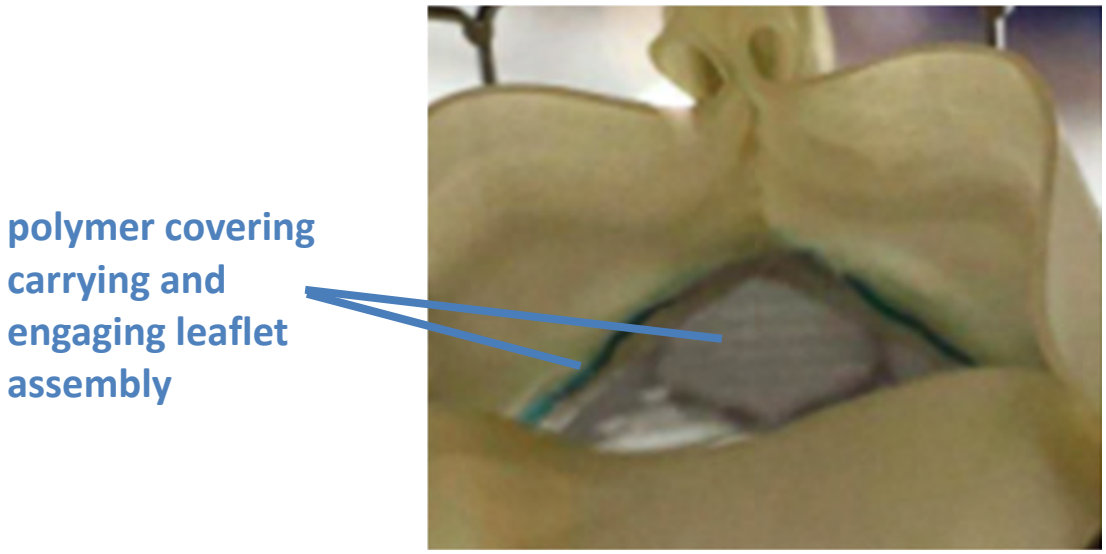
Table 1

Valve Size	Valve Height
20 mm	15.5 mm
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26 mm	20 mm

Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

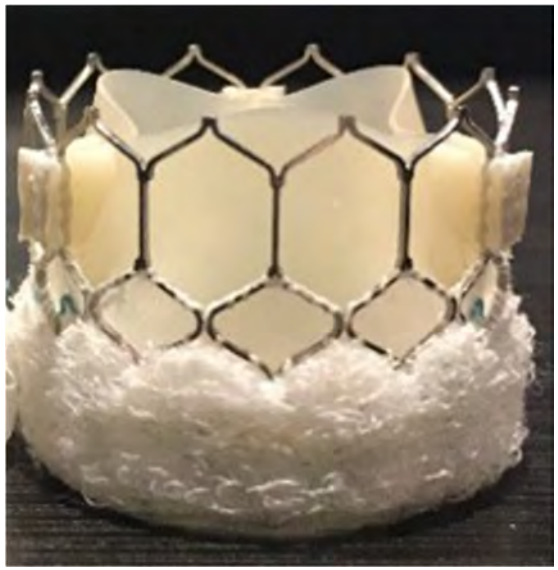


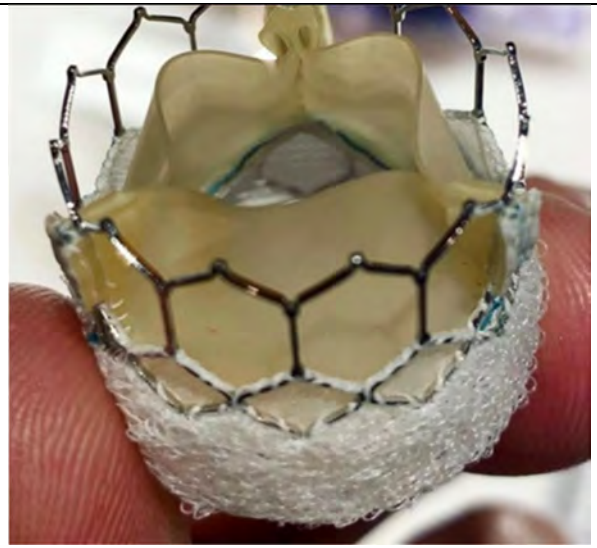
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

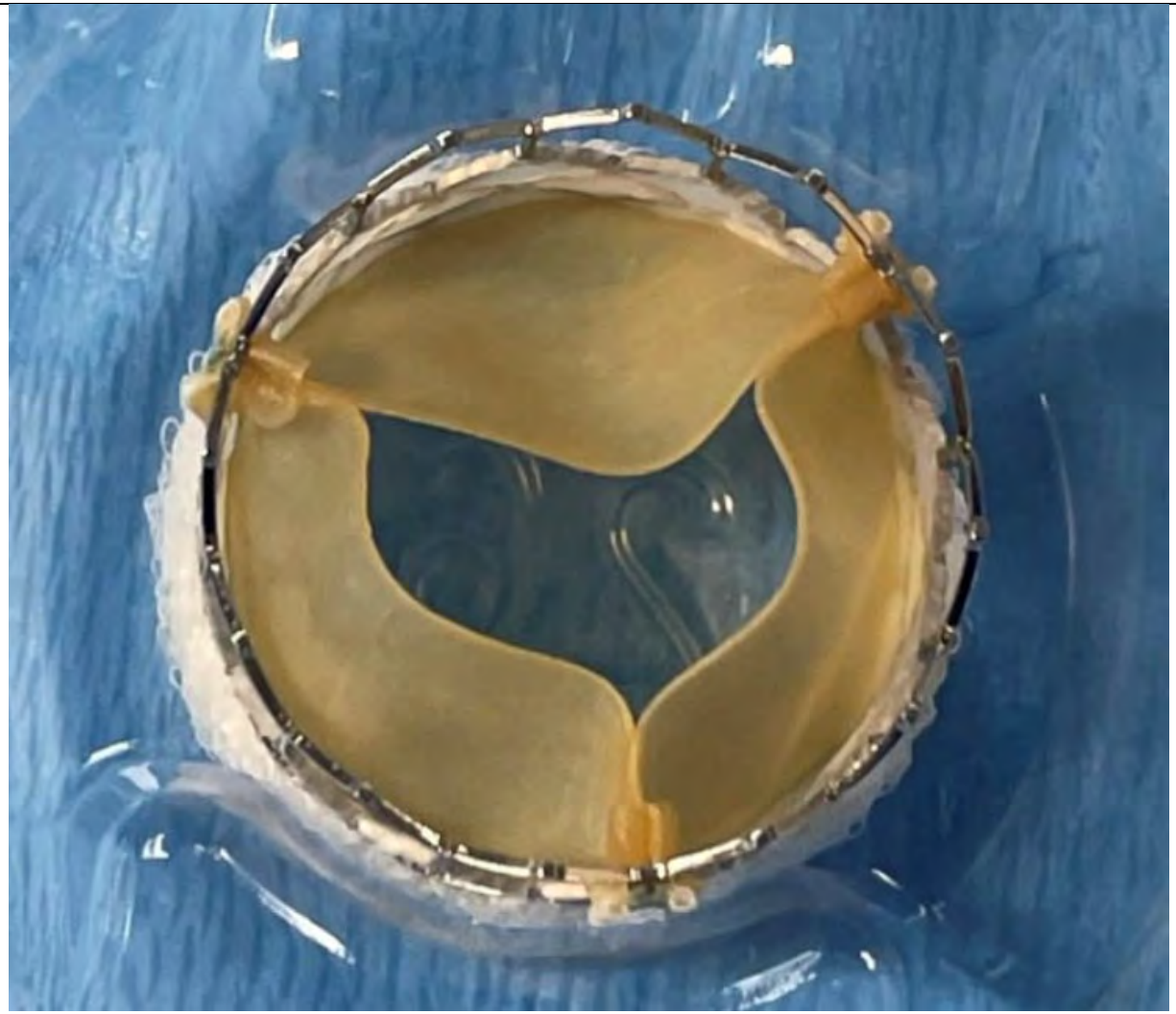


https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly , the identified polymer coverings are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused polymer covering performs the same or substantially the same function as the claim phrase by at least covering portions of the leaflet assembly and providing sealing thereto, in the same or substantially the same way as the claim phase through including a polymer covering that is positioned at least partially radially inward of the frame that at least partially carries and engages the leaflet

	assembly, to achieve the same or substantially the same result of a polymer covering configured to cover, carry, and/or engage or partially cover, carry, and/or engage the leaflet assembly.
a first plurality of fibers that extend away from the frame,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 Accused Instrumentalities comprise a first plurality of fibers that extend away from the frame. For example, the Sapien 3 Ultra has an sealing skirt that includes a plurality of fibers that extend away from the frame.  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 29).

	 https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 64).

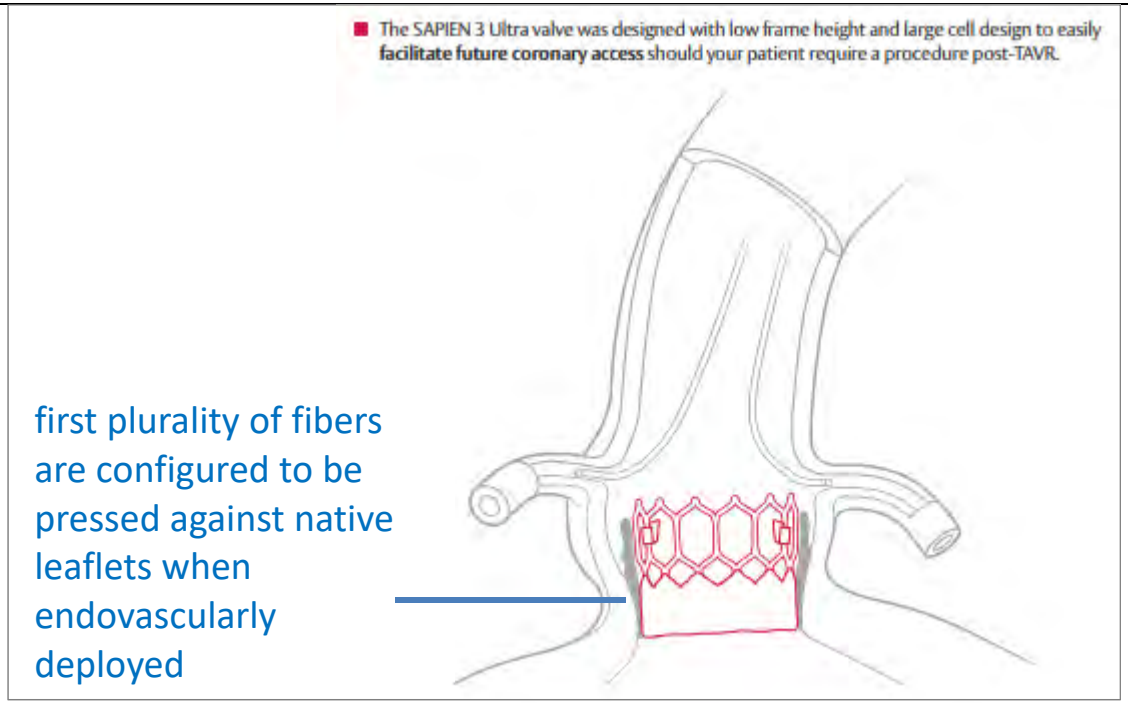
	 https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65) (showing plurality of fibers extending away from frame).



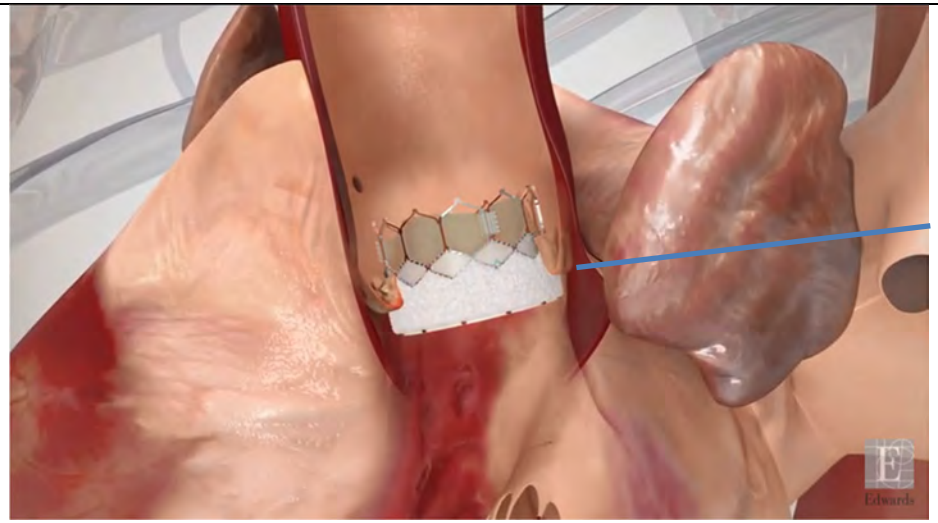
Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 3).

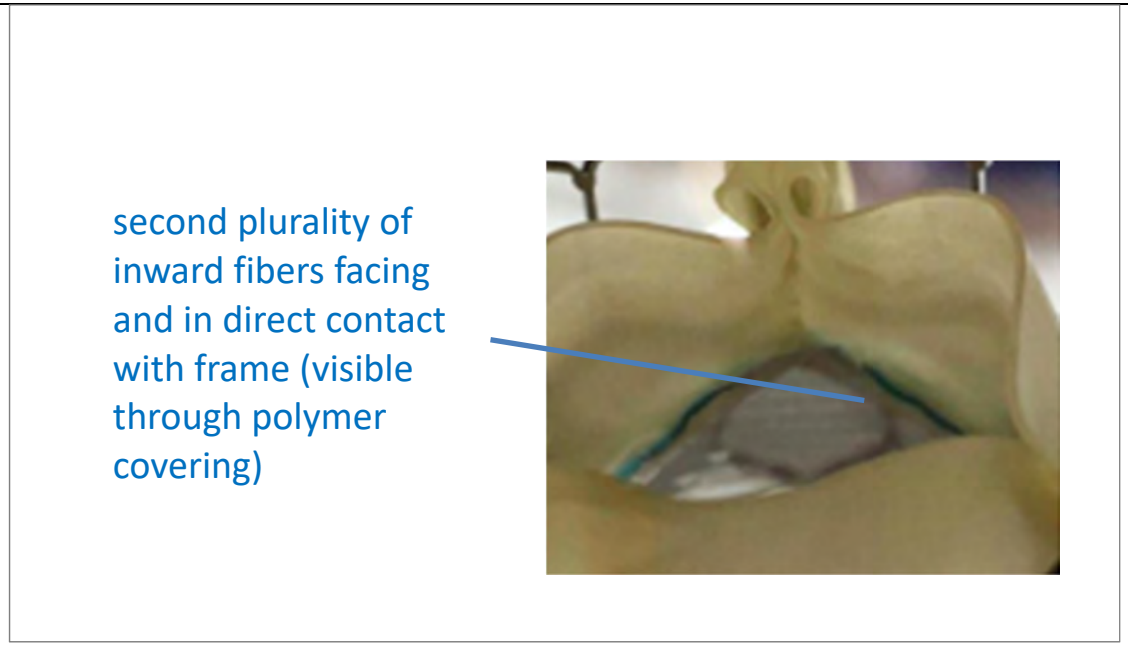
With respect to the phrase, “a first plurality of fibers that extend away from the frame” Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a first plurality of fibers that extend away from the frame, the identified a first plurality of fibers that extend away from the frame of the Accused Instrumentalities, even taking into account any alleged “differences” identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused first portion of fibers perform the same or substantially the same function as the claim phrase by providing low profile sealing against the native leaflets of the aorta and

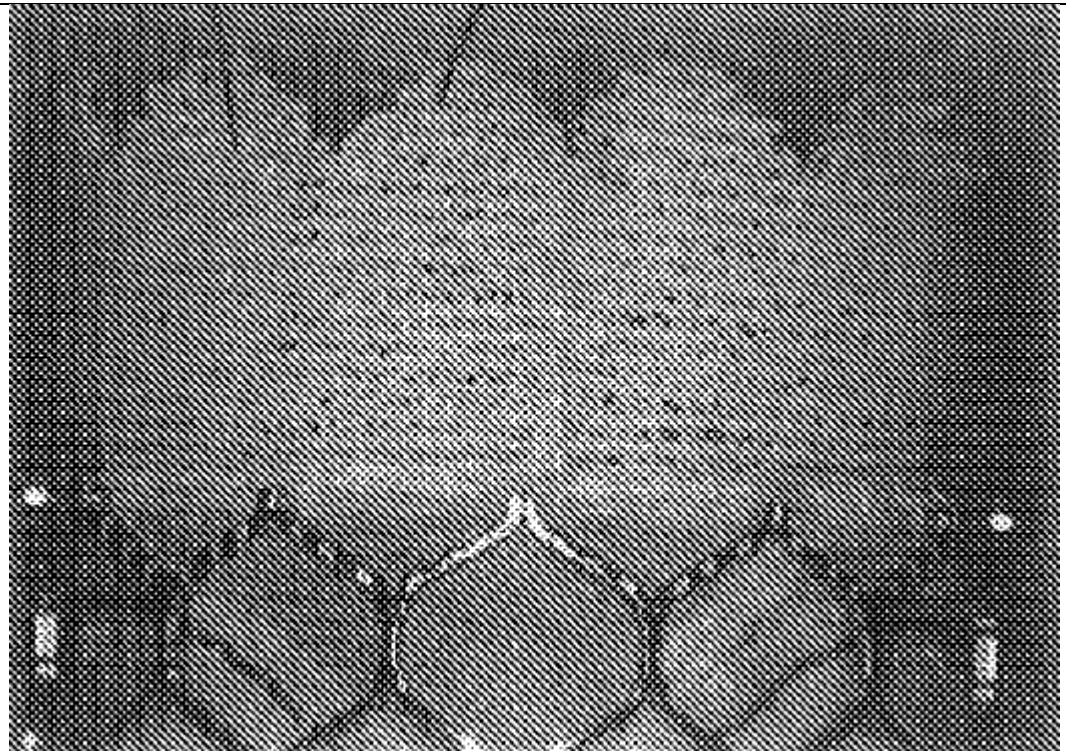
	spacings between fibers, in the same or substantially the same way as the claim phase by extending generally way from the frame and pressing against the native leaflets of the aorta of the patient and filing in the spacings when the valve is expanded and the fibers are compressed, to achieve the same or substantially the same result of a first plurality of fibers that extend generally way from the frame that are configured to provide for sealing between the native annulus and the valve assembly.
wherein the first plurality of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native aortic heart valve annulus of the patient; and	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities’ first plurality of fibers are 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. For example, the Sapien 3 Ultra fibers on the sealing skirt are configured to be pressed against native leaflets when endovascularly deployed and radially expanded within the native heart annulus of a patient.



Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

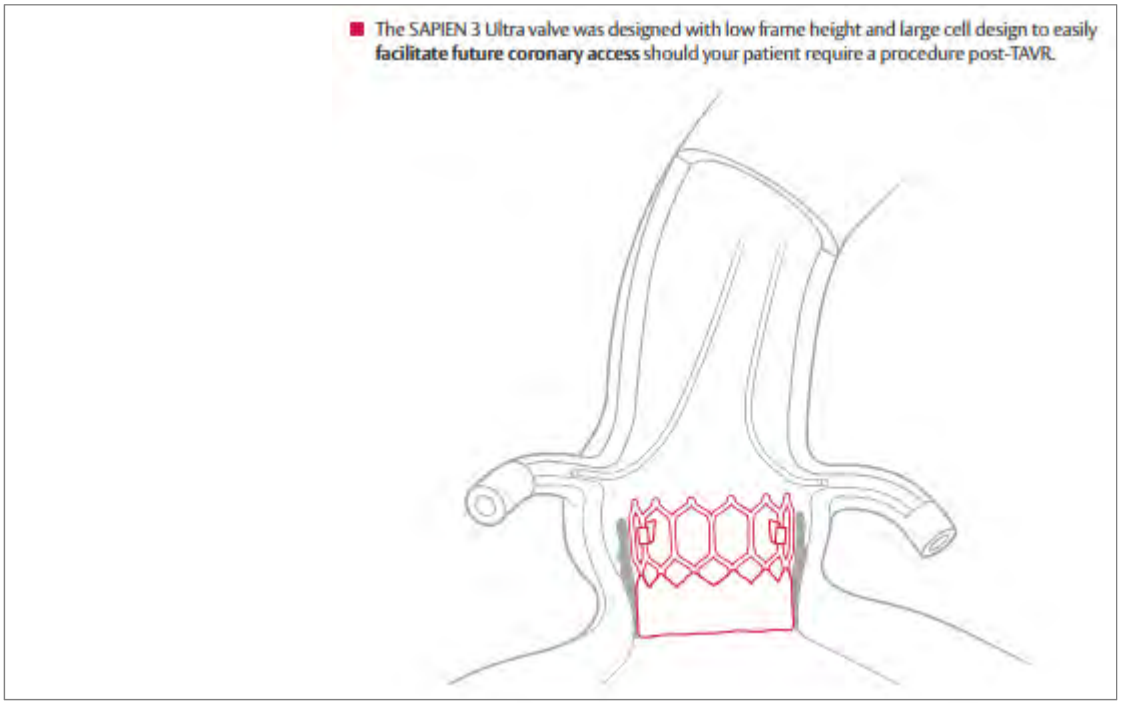
	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
a second plurality of fibers that is positioned inwardly from the first plurality of fibers, wherein the second plurality of fibers is in direct contact with the frame,	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities comprise a second plurality of fibers positioned inwardly from the first plurality of fibers, wherein the second plurality of fibers is in direct contact with the frame. For example, the Sapien 3 Ultra sealing skirt includes fibers facing the frame that are in direct contact with the frame. The sealing skirt in the Sapien 3 Ultra is sewn to the frame and has a backside (internal facing portion) with a second plurality of fibers that directly contact the frame that is inward from the first plurality of fibers.

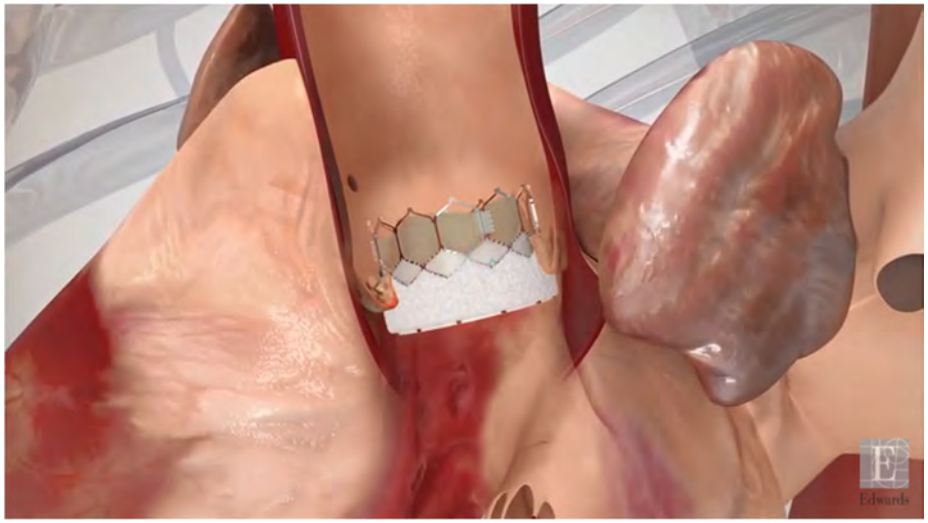
	 Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).	



U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing fibers on flipped up backside of sealing skirt).

With respect to the phrase, "a second plurality of fibers that is positioned inwardly from the first plurality of fibers, wherein the second plurality of fibers is in direct contact with the frame," Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, the identified second plurality of fibers that is positioned radially inwardly from the first plurality of fibers of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the

	same way, to achieve substantially the same result. For example, the accused second plurality of fibers perform the same or substantially the same function as the claim phrase by helping provide low profile sealing against the frame when expanded, in the same or substantially the same way as the claim phase by being configured to be in direct contact with at least portions of the frame, to achieve the same or substantially the same result of a second plurality of fibers configured to provide at least some sealing against the frame of the valve assembly upon compression in the native annulus.
wherein the first plurality of fibers radially overlap the second plurality of fibers to cooperatively cover the frame,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities’ first plurality of fibers radially overlap the second plurality of fibers to cooperatively cover the frame. For example, the Sapien 3 Ultra outer skirt first and second plurality of fibers cooperate to cover the frame when in an expanded deployed configuration. 

	Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).  "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37). With respect to the phrase, "wherein the first plurality of fibers radially overlap the second plurality of fibers to cooperatively cover the frame" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a first plurality of fibers that radially overlap the second plurality of fibers to cooperatively cover the frame , even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused first and second plurality of fibers perform the same or substantially the same function as the claim phrase by helping cover and provide low profile sealing against the frame when deployed, in the same or substantially the same way as the claim phase by radially overlapping and being configured to cooperate when deployed to at cover and provide sealing the frame, to achieve the same or

<table>
<tr><td></td><td>substantially the same result of a first plurality of fibers configured to provide at least some sealing against the frame of the valve assembly when deployed.</td></tr>
<tr><td>wherein the heart valve assembly is sized and shaped for being delivered endovascularly through a femoral artery of a patient into the aorta,</td><td>The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities are sized and shaped to be endovascularly deployed through a femoral artery of the patient.

For example, the Sapien 3 Ultra is designed, developed, promoted, sized, shaped, configured to be deployable and is deployable endovascularly through the femoral artery of a patient using Edwards’ balloon delivery systems.

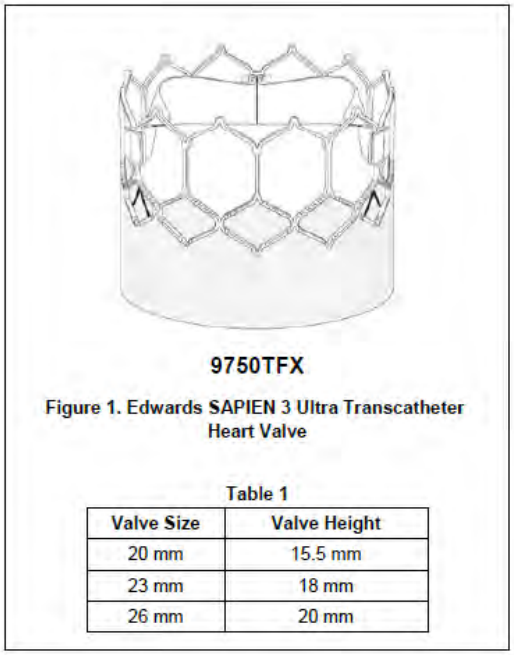
 
9750TFX
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1
<table><tr><th>Valve Size</th><th>Valve Height</th></tr><tr><td>20 mm</td><td>15.5 mm</td></tr><tr><td>23 mm</td><td>18 mm</td></tr><tr><td>26 mm</td><td>20 mm</td></tr></table>
Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).</td></tr>
</table>

7.0 Directions for Use

7.1 System Compatibility

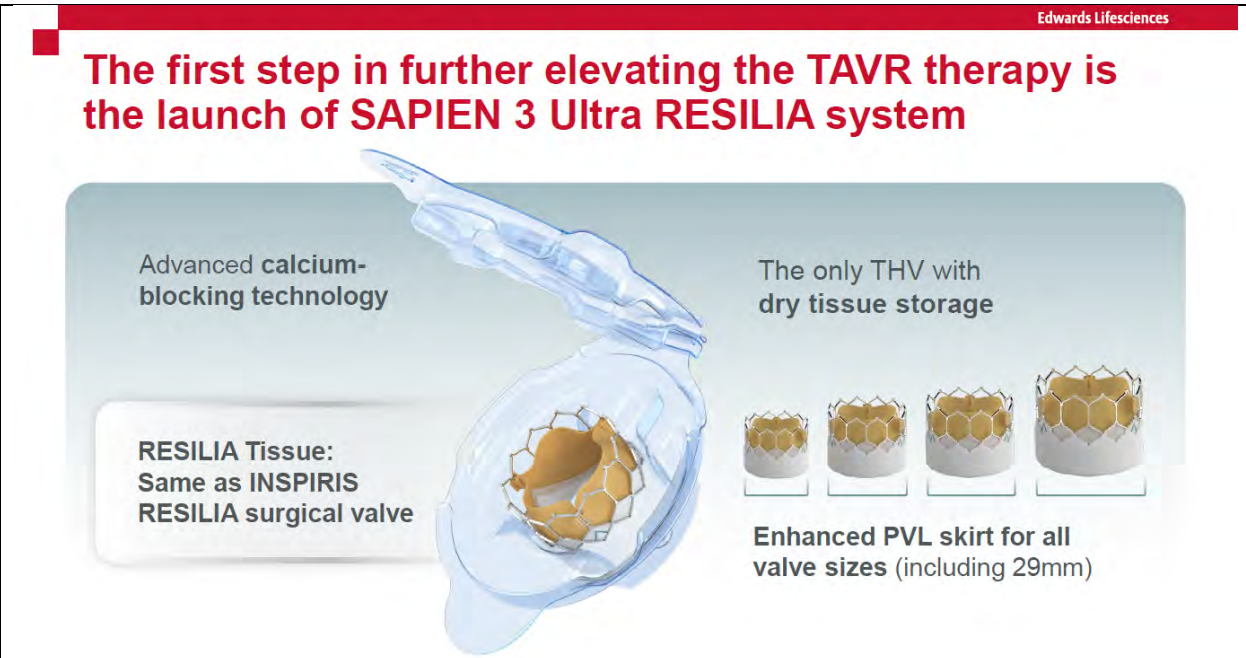
Table 6

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

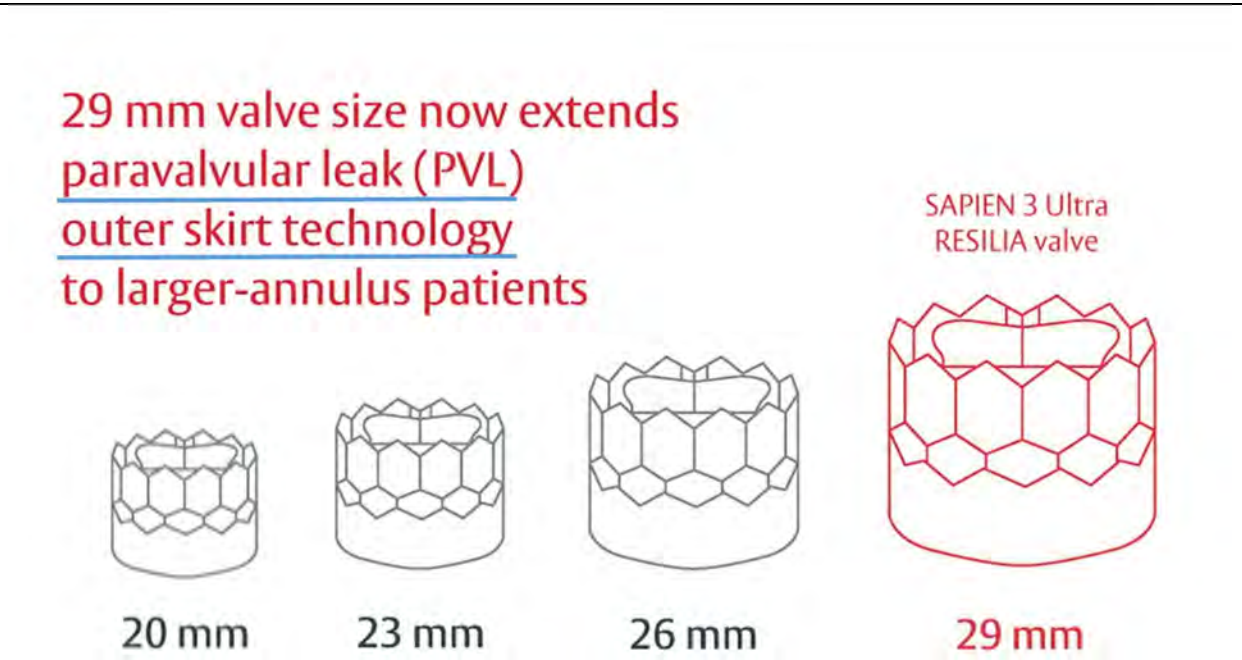
Additional Equipment:

- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

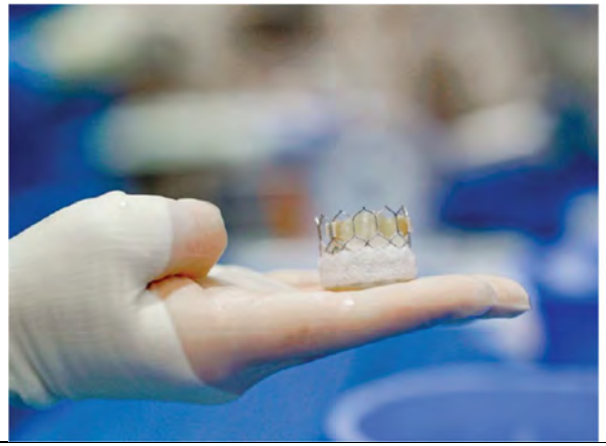
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

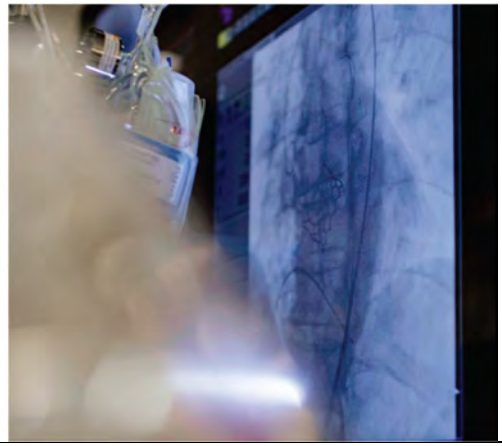


https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA

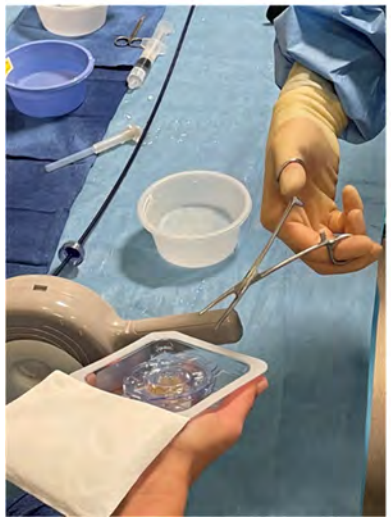
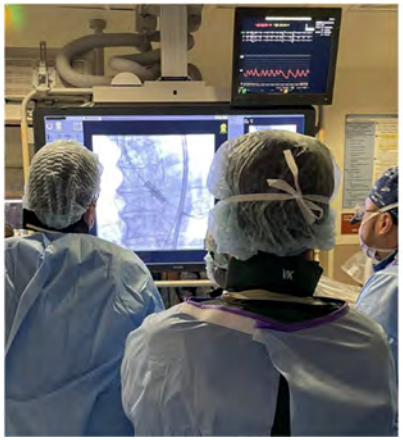




https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



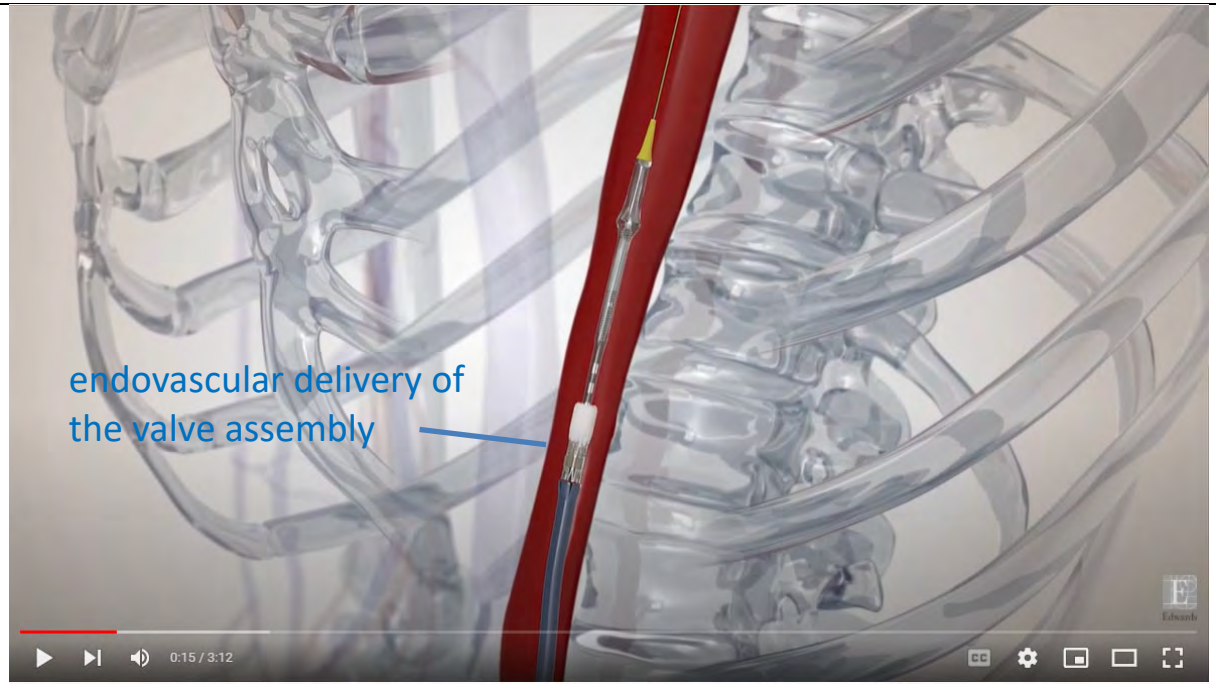
https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

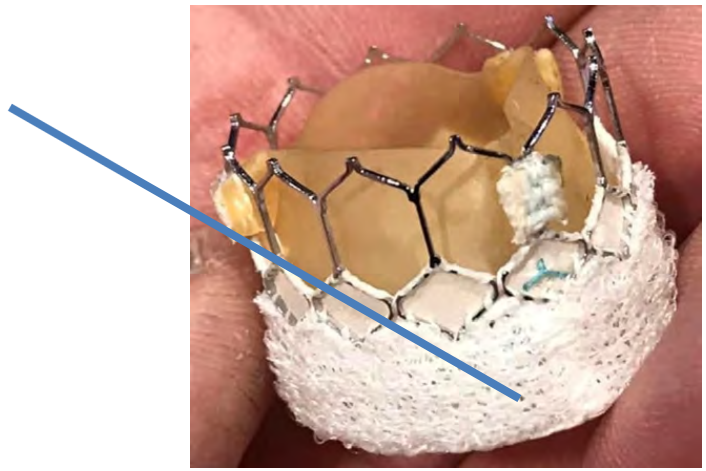

https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
wherein the prosthetic heart valve defines a spacing extending through a thickness of the first plurality of fibers that is created by a distance between fibers thereof and through a	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities define spacings extending through a thickness of the first plurality of fibers that is created by a distance between fibers thereof and through a thickness of the second plurality of fibers created by a distance between fibers thereof. The Sapien 3 Ultra first and second plurality of fibers include spacings created by distances between fibers that extend though thicknesses thereof.

thickness of the second plurality of fibers created by a distance between fibers thereof	 Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47).

	 Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

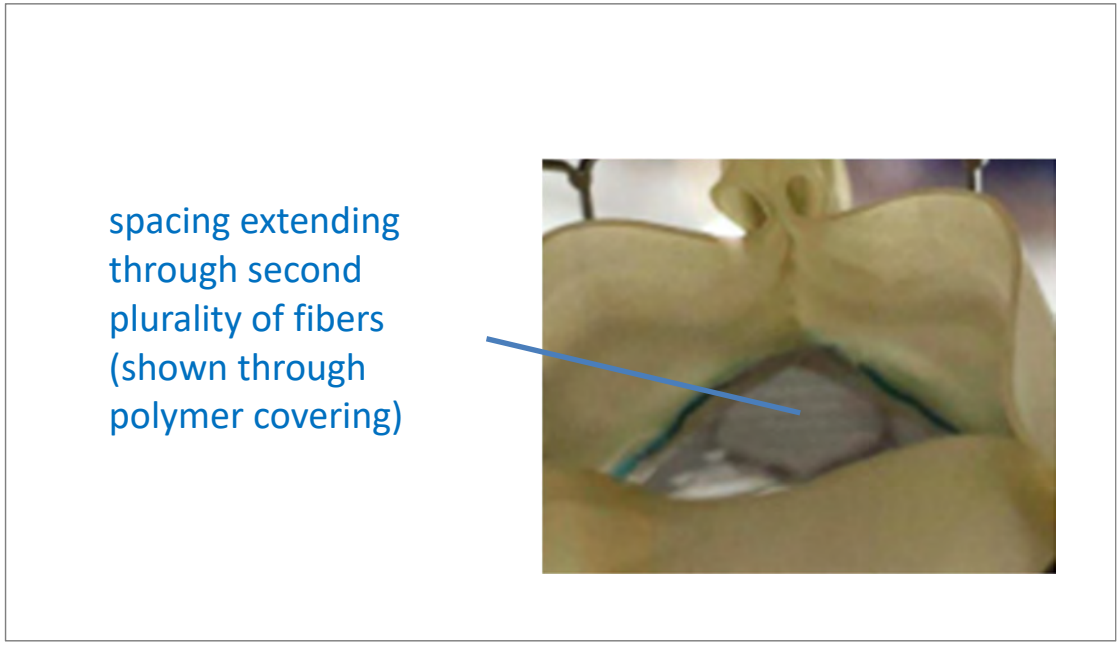


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

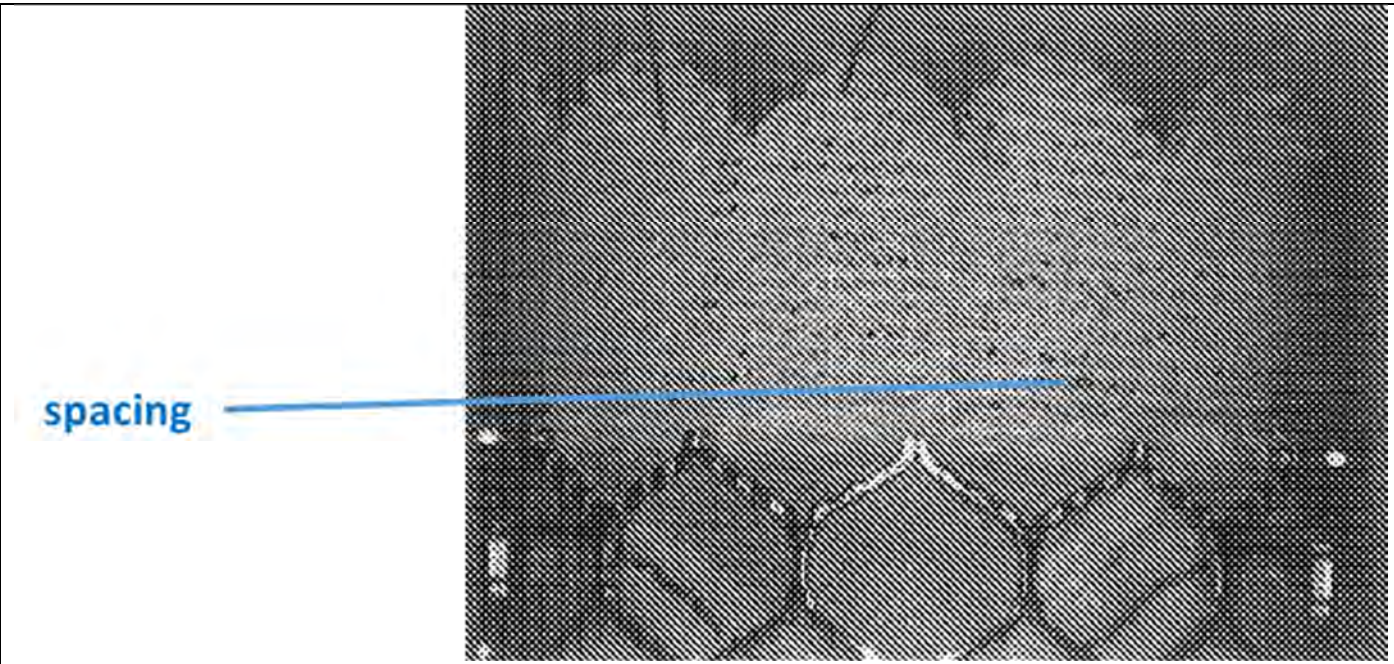


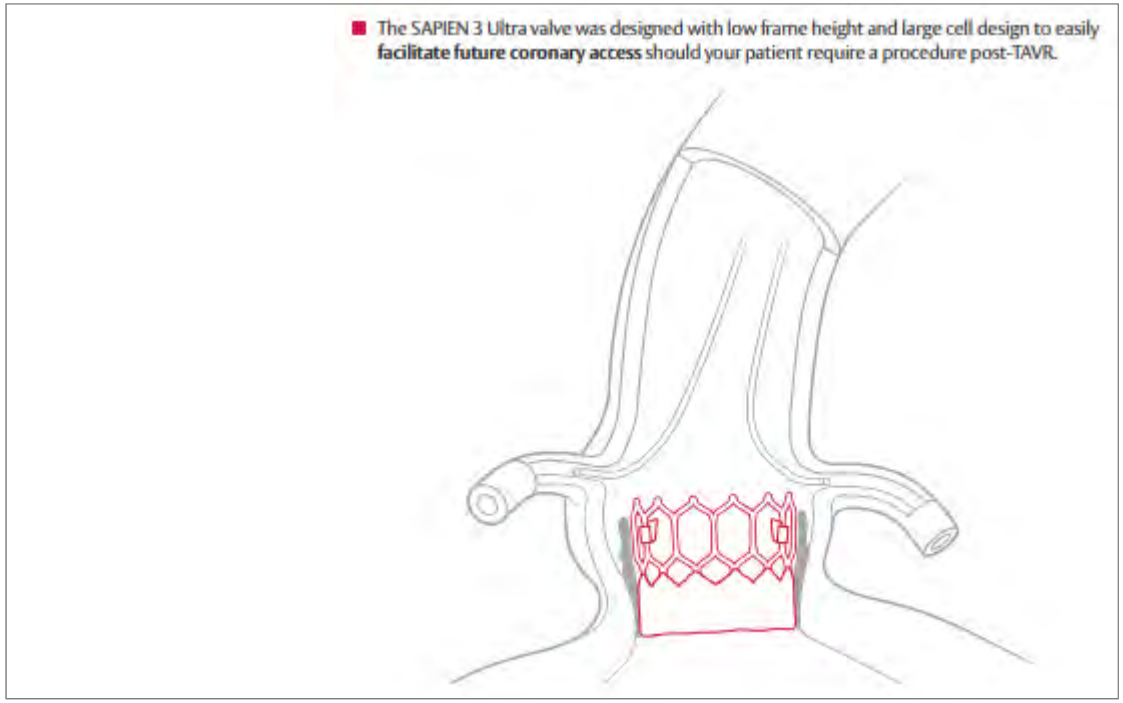
Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

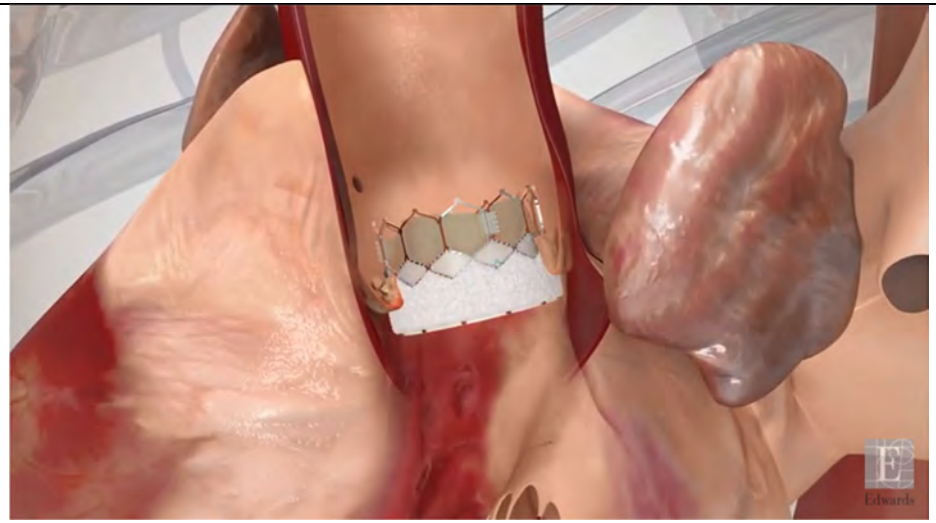
Further, the Sapien 3 Ultra sealing skirt includes fibers carried by the frame facing the frame. The spacings further extend though fibers of the second plurality of fibers.



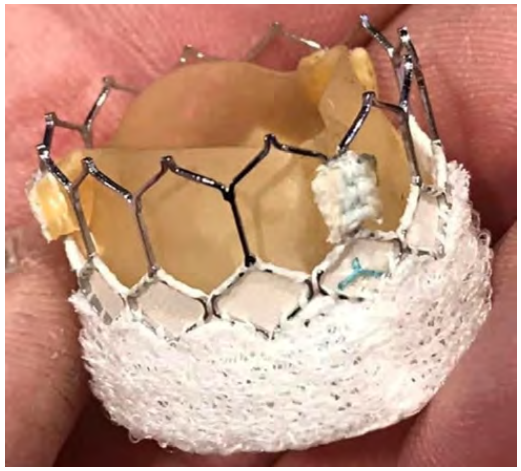
Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

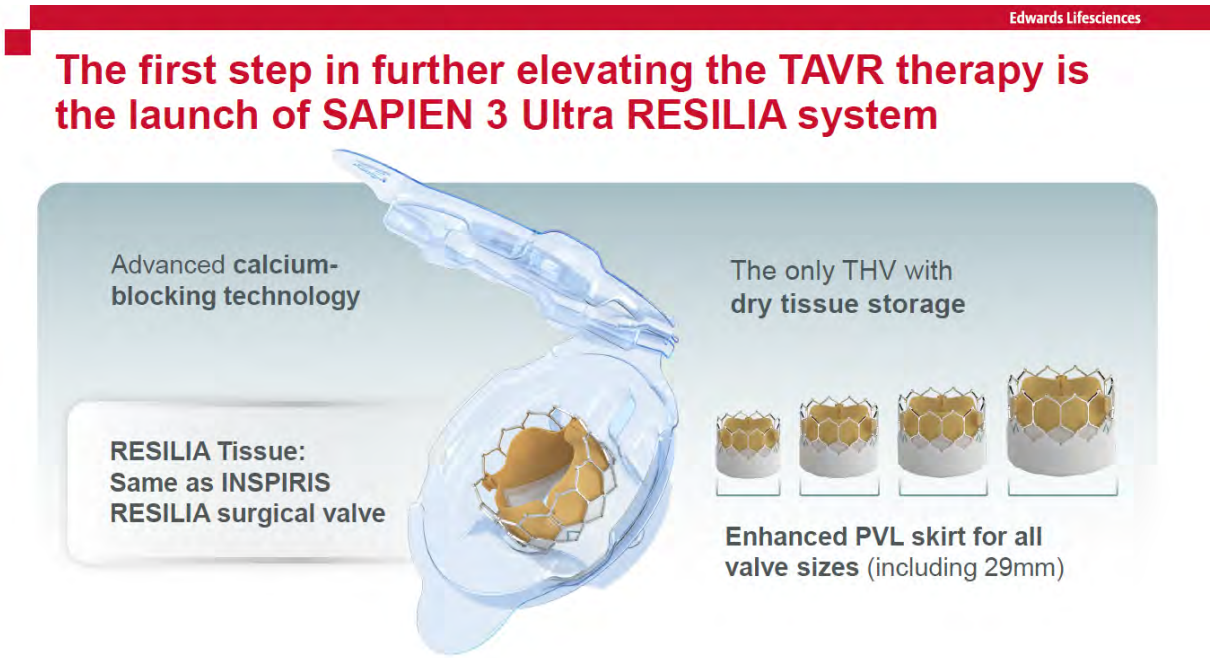
	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing spacings on flipped up backside of sealing skirt). *See also*, "first and second plurality of fibers" elements.
wherein, compression of the first plurality of fibers and the second plurality of fibers in response to expansion of the prosthetic heart	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities are designed and configured such that 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. For example, the Sapien 3 Ultra is designed using knitted PET with compressible fibers such that when compressed in response to expansion of the heart valve in the aorta, the first plurality of fibers are compressed together with the second plurality of fibers relative to the spacings providing for sealing thereabout to help prevent paravalvular leakage.

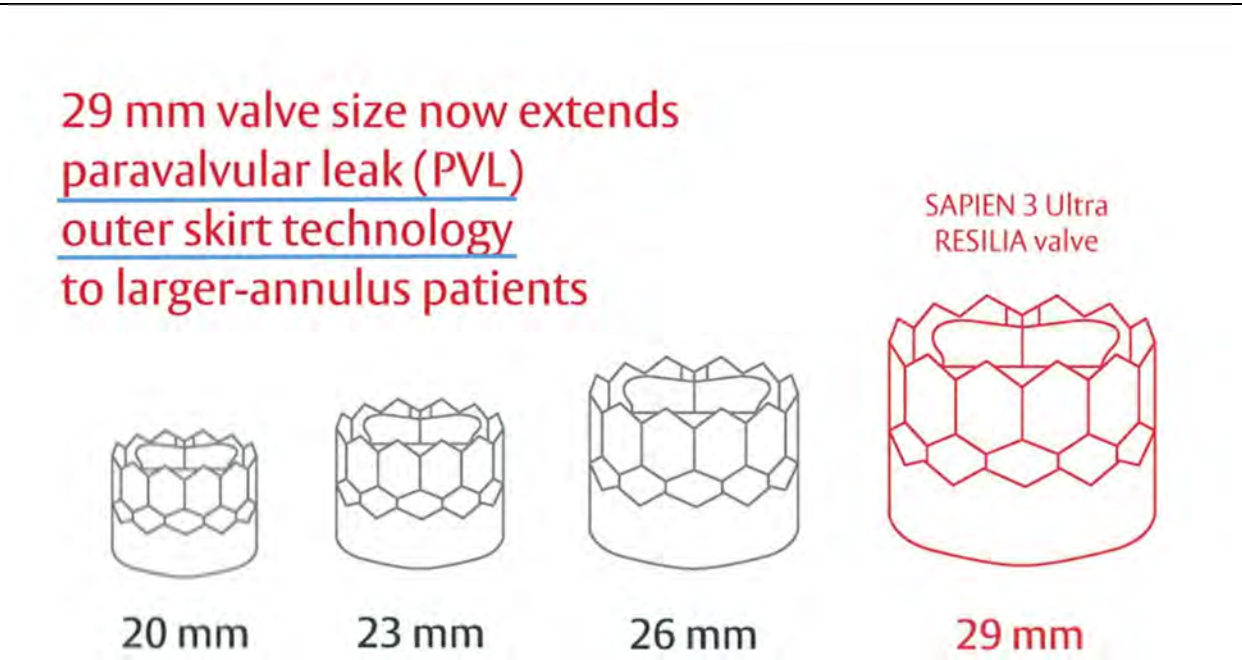
valve compresses the first plurality of fibers and the second plurality of fibers relative to the spacing to create a seal thereabout.	 Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).



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



	Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).  https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).

	 https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA
16. The endovascularly deployed heart valve assembly of claim 1, wherein the frame is integrally formed.	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities’ frame is integrally formed. For example, the Edwards Sapien 3 Ultra frame is made of a cobalt-chromium metallic alloy in an integral form.

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.



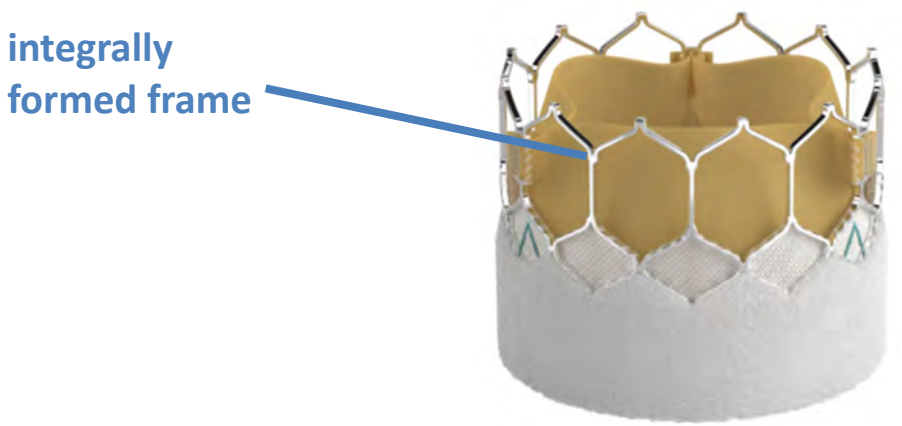
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

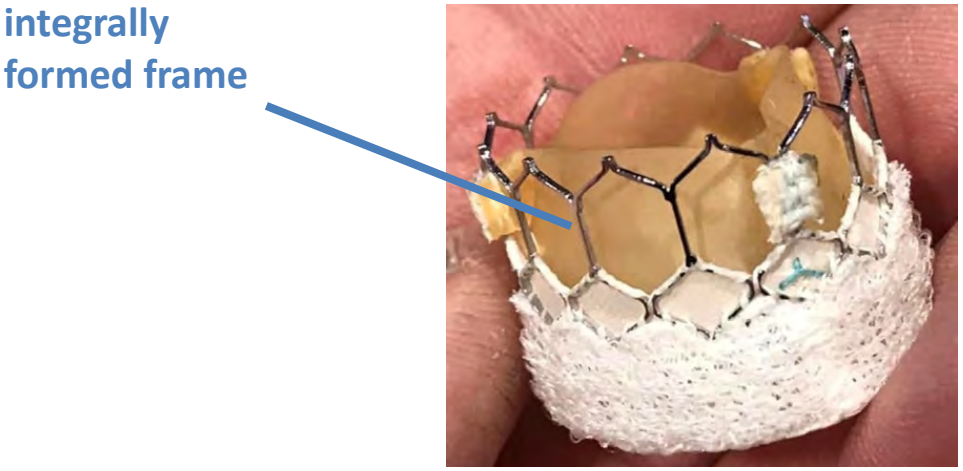
Table 1

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

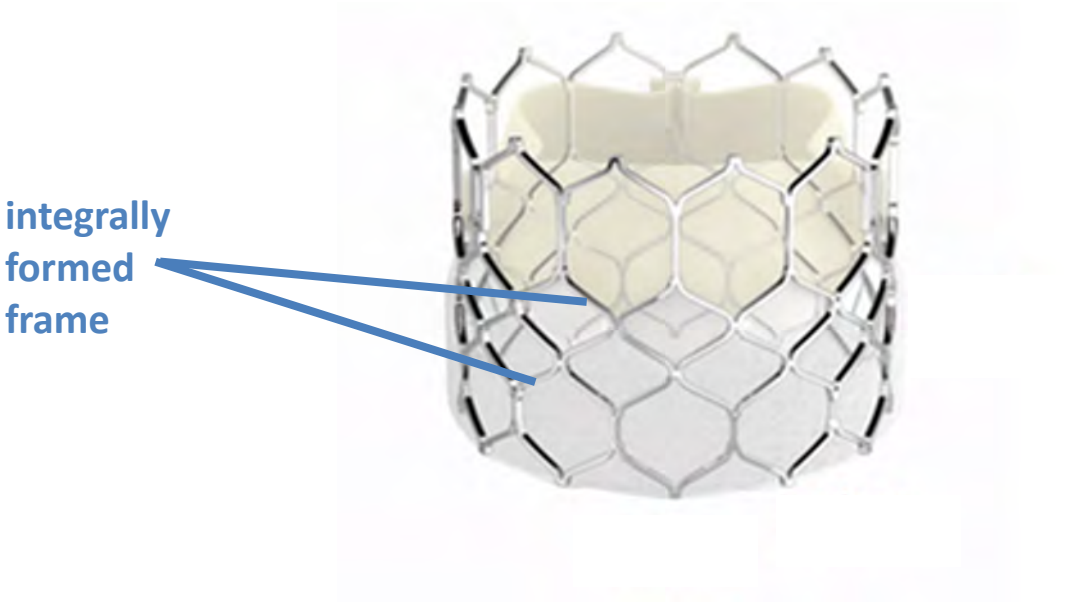
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).



https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

	 https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). *See also*, claim 1.
17. The valve assembly of claim 10, wherein the frame is integrally formed.	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities’ frame is integrally formed. For example, the Edwards Sapien 3 Ultra frame is made of a cobalt-chromium metallic alloy in an integral form.

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.



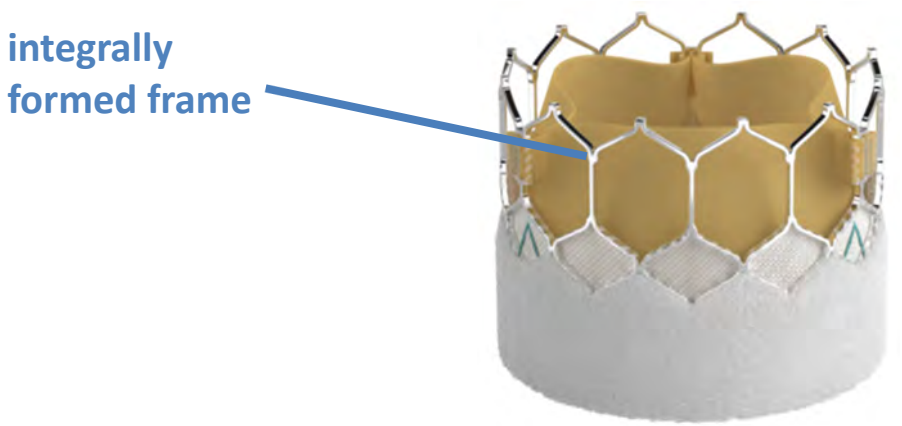
9750TFX

Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

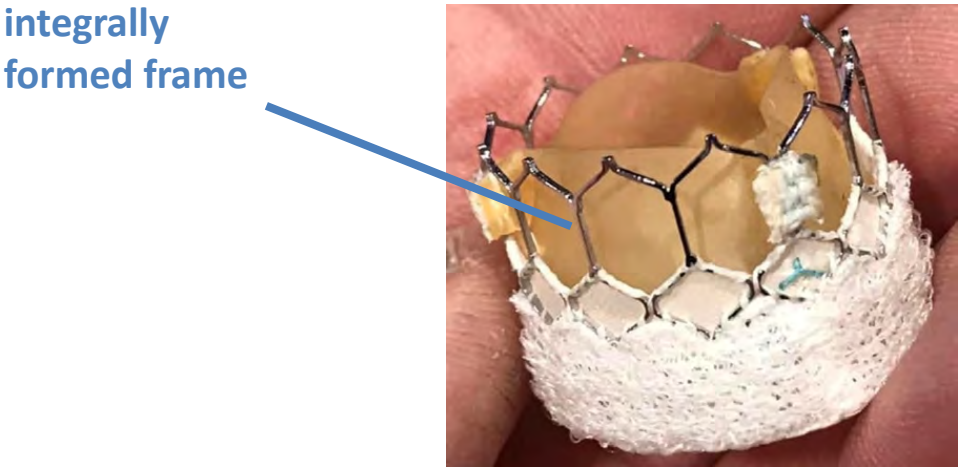
Table 1

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

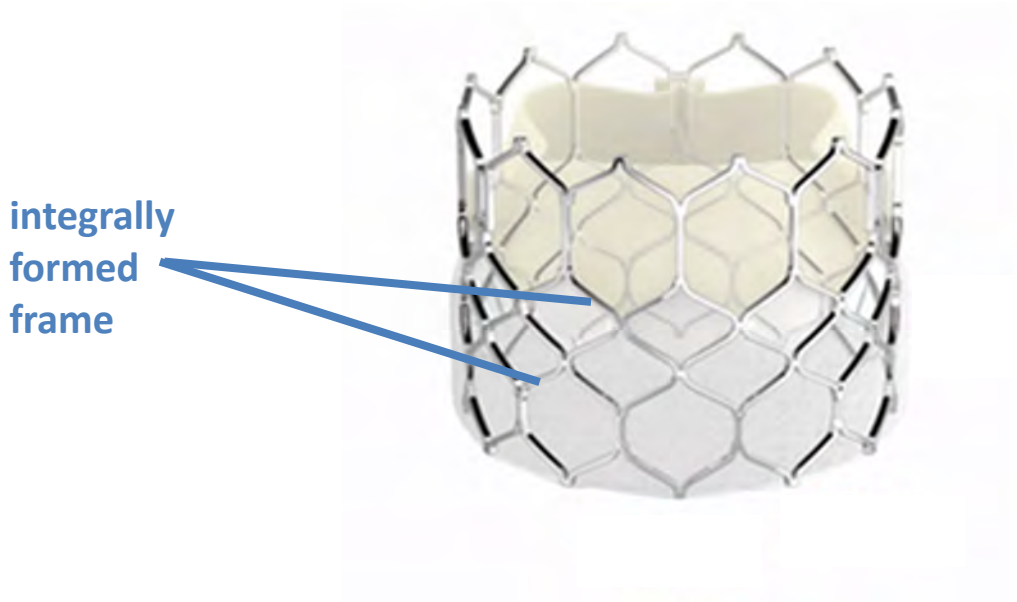
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

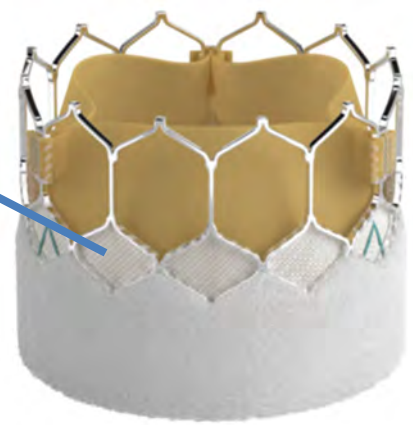
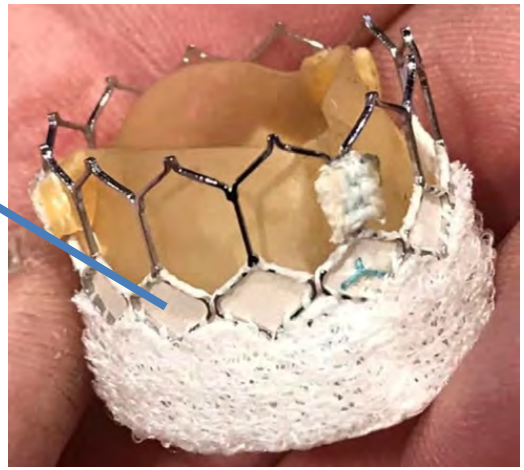


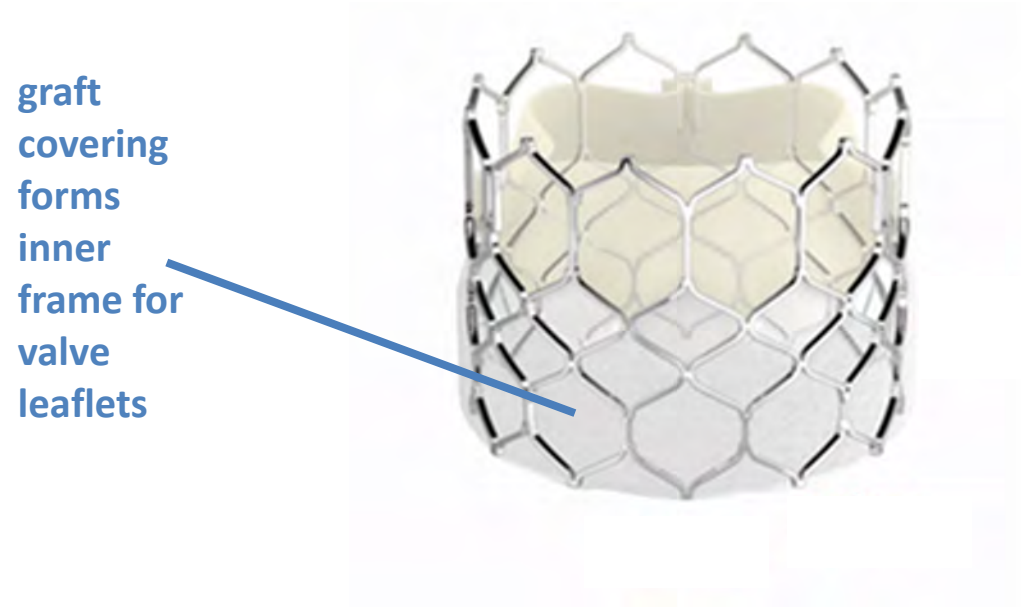
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

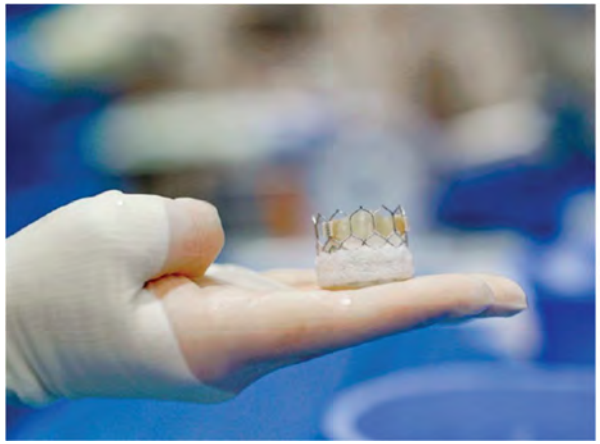
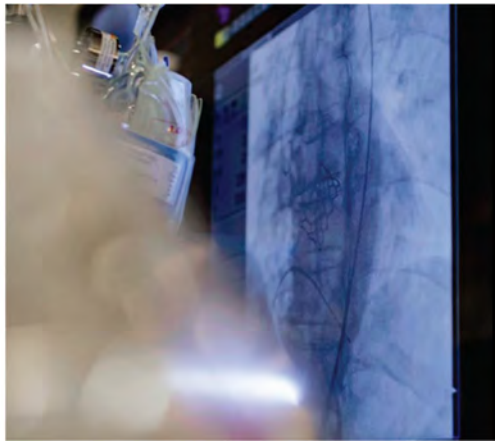


Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

	 https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). *See also*, claim 10.
20. The endovascularly deployed heart valve assembly of claim 1, wherein the graft covering forms an inner frame for supporting the	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities’ graft covering forms an inner frame for supporting the prosthetic heart valve leaflets. For example, the Edwards Sapien 3 Ultra graft covering provides an inner frame on the interior of the valve assembly that is attached to the prosthetic heart valve leaflets and provides support directly and/or indirectly thereto. To the extent required, the inner frame is balloon expandable.

prosthetic heart valve leaflets.	graft covering forms inner frame for valve leaflets  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61). graft covering forms inner frame for valve leaflets  Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

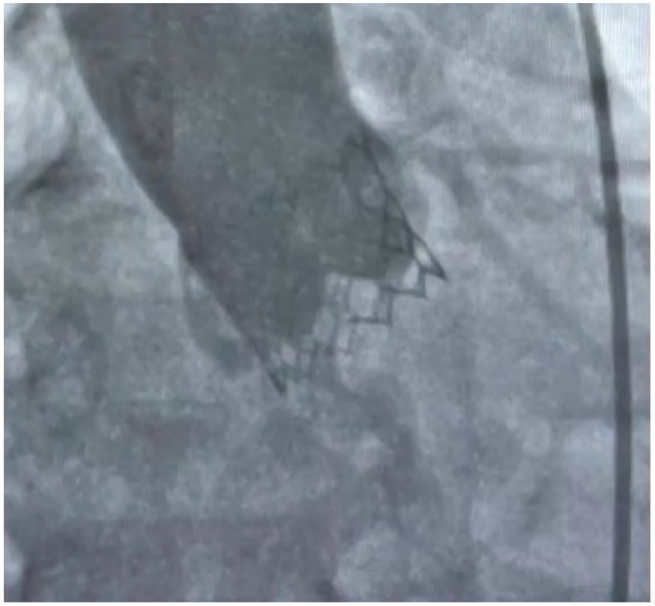
	 https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). With respect to the phrase, "wherein the graft covering forms an inner frame for supporting the prosthetic heart valve leaflets", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a graft covering inner frame that is balloon-expandable and/or that provides support and resist collapse, the identified graft covering that forms an inner frame for supporting the prosthetic heart valve, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused graft covering that forms an inner frame performs the same or substantially the same function as the claim phrase by being collapsible and expandable, as well as framing and providing support to the prosthetic heart valve leaflets, in the same or substantially the same way as the claim

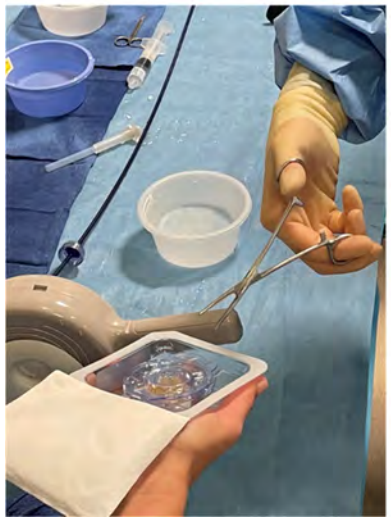
	phase through a collapsible and expandable cylindrically extending graft covering inner frame secured by stitching to the frame extending at least partially around and engaging and providing sealing to the prosthetic heart valve leaflets, to achieve the same or substantially the same result of a collapsible and expandable graft covering inner frame in a TAVR valve that is configured to frame, engage, support (directly and/or indirectly), and/or provide sealing to the prosthetic heart valve. *See also*, claim 1.
21. An endovascular prosthetic heart valve assembly for use in a patient, comprising:	To the extent the preamble is limiting, the ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities are endovascular prosthetic heart valve assemblies for use in a patient. The ’918 patent Accused Instrumentalities are designed, promoted, configured to be delivered, and are deliverable endovascularly using Edwards’ balloon delivery systems.   https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).



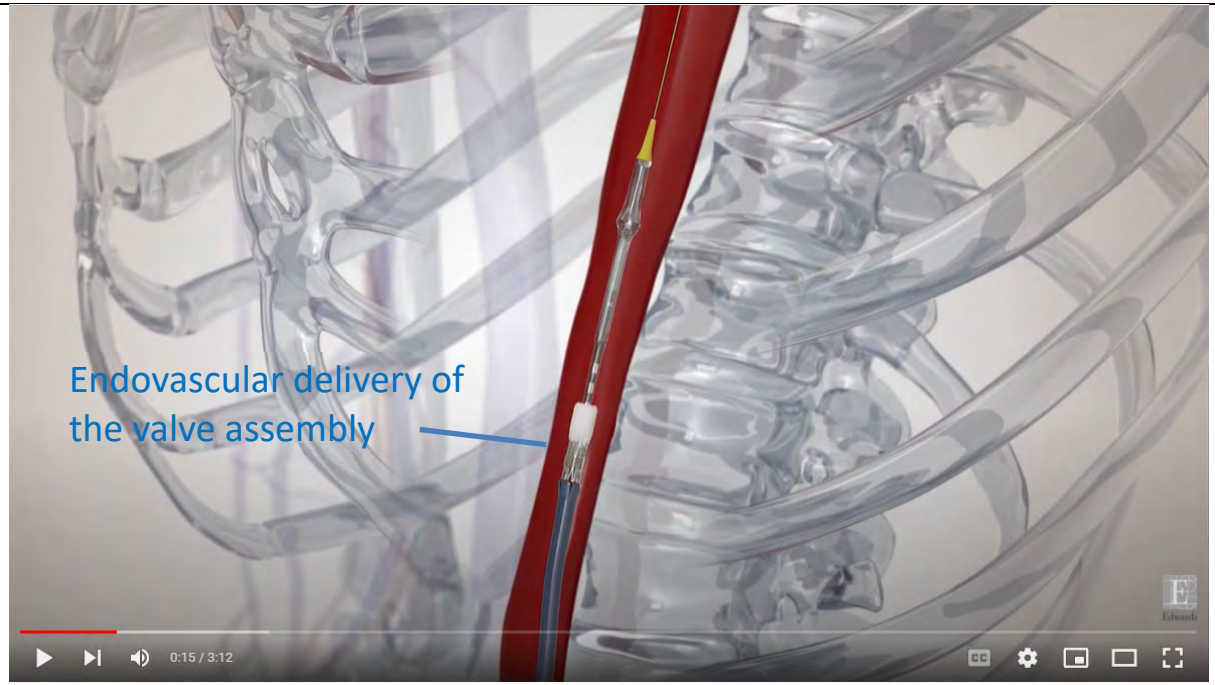


https://twitter.com/DrAFrangieh/status/1570644194859061248?s=20&t=cd_2oJkHFQhsG9DDfqhRZA



	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra[5] is designed, manufactured, promoted, and sold by Edwards for endovascular delivery.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

[5] As used herein, Sapien 3 Ultra refers to all models, versions, and sizes of the Sapien 3 Ultra, including, but not limited to all models, versions, and sizes of the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets.



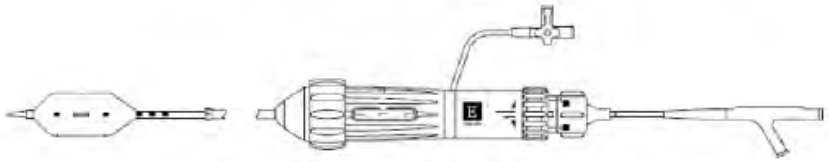
SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

Figure 2: SAPIEN 3 Ultra Transcatheter Heart Valve



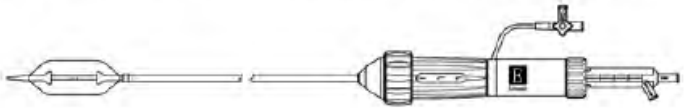
The Edwards Commander Delivery System (models 9600LDS20, 9600LDS23, 9600LDS26, and 9600LDS29), as shown in Figure 3, includes a handle that provides a flex wheel for articulation of the flex catheter, a tapered tip at the distal end of the delivery system, a balloon catheter for deployment of the THV, and radiopaque markers. It is used when a long access route is planned.

Figure 3: Edwards Commander Delivery System



The Edwards SAPIEN 3 Ultra Delivery System (models 9630TF20, 9630TF23, 9630TF26, and 9630TF29), as shown in Figure 4, includes a handle that provides a flex wheel to control flexing of the flex catheter, a fine adjustment wheel to facilitate THV positioning, a tapered tip at the distal end, and a radiopaque positioning marker in the balloon. It is also used when a long access route is planned.

Figure 4: Edwards SAPIEN 3 Ultra Delivery System



Edwards Sapien 3 Ultra Summary of Safety and Effectiveness Data ("SSED") at 3 (D.I. 1, Ex. 45), https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S112B.pdf.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter 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.



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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

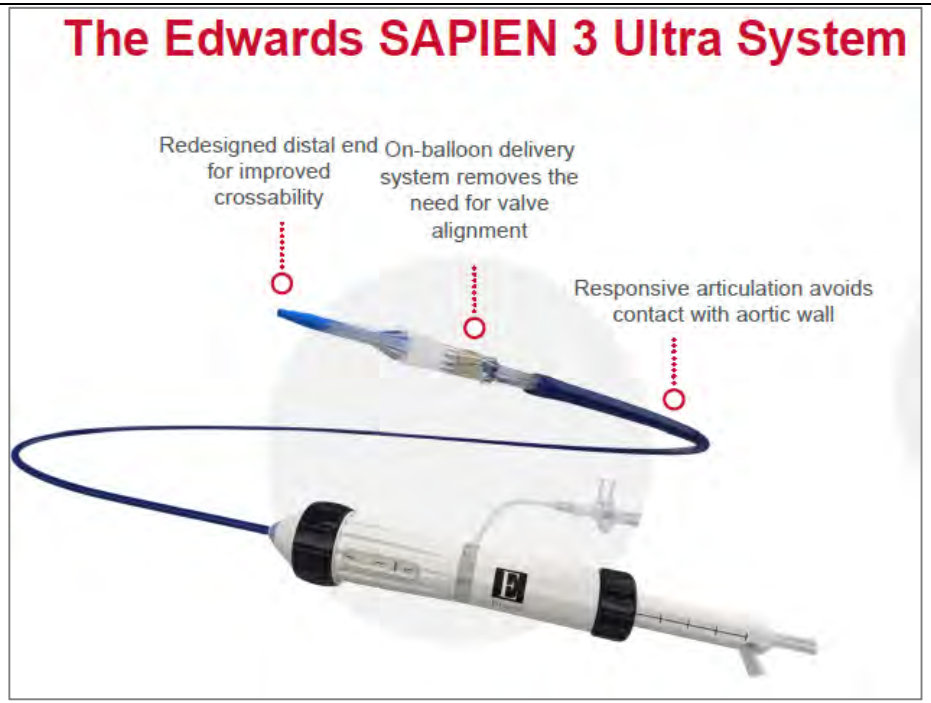
Table 1

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

Sapien 3 Ultra Instructions for Use (D.I. 1, Ex. 44).



Edwards Brochure entitled “Introducing the Sapien 3 Ultra valve” at 1 (D.I. 1, Ex. 46).



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

7.0 Directions for Use

7.1 System Compatibility

Table 6

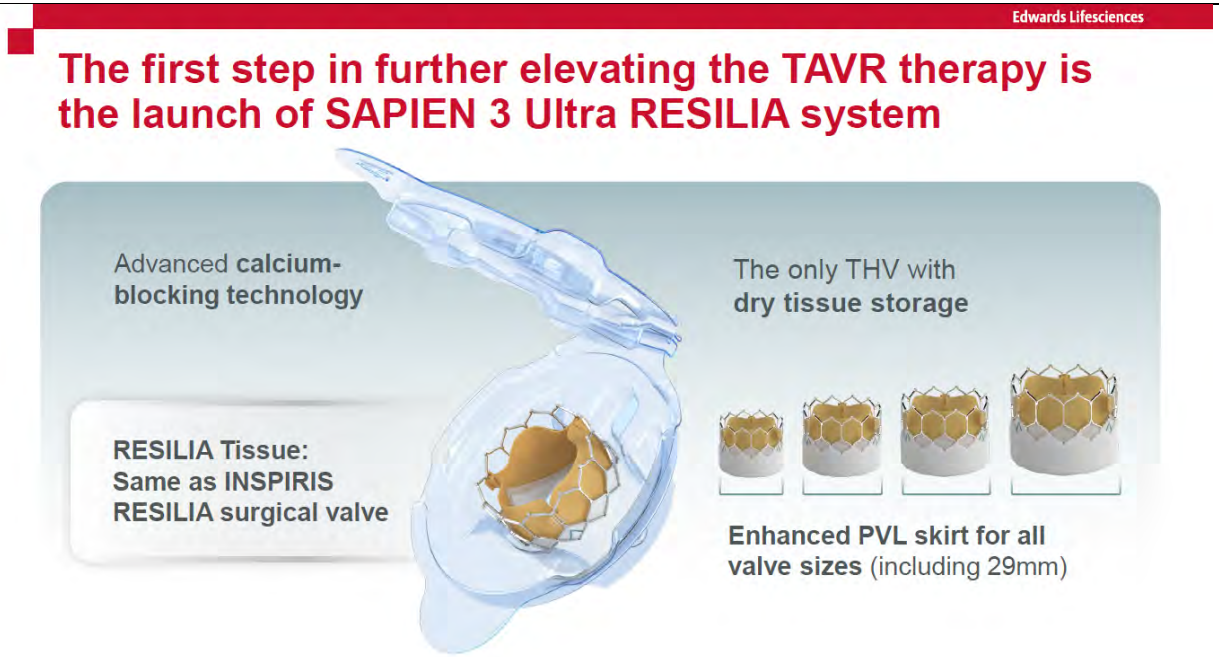
Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

Additional Equipment:

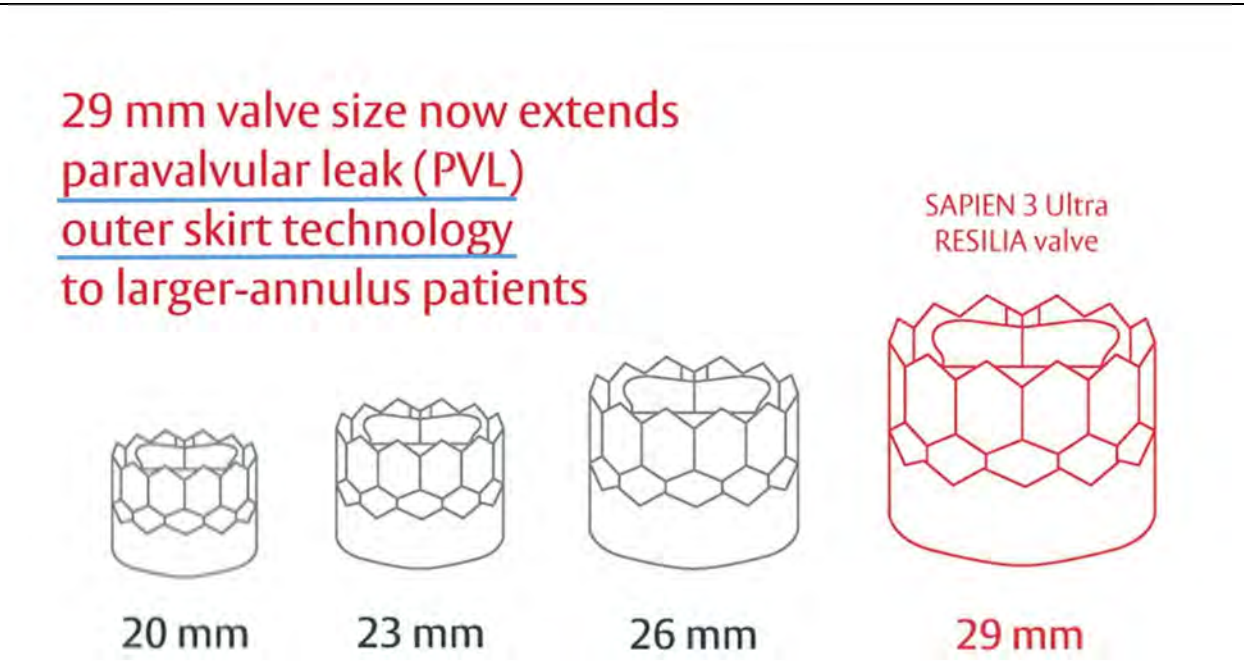
- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

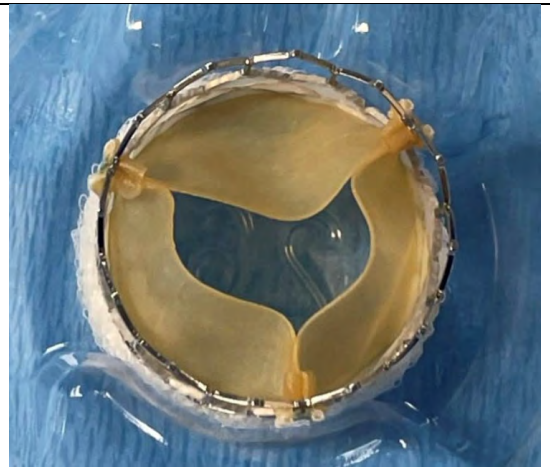
	Edwards makes, uses, offers for sale, sells, imports and/or exports the ’918 patent Accused Instrumentalities and infringes the ’918 Patent claims under 35 U.S.C. § 271(a). For example, on information and belief, Edwards manufactures, imports, tests, uses, offers for sale, and sells TAVR devices called Sapien 3 Ultra, including but not limited to the Sapien 3 Ultra Resilia and Sapien 3 Ultra with non-Resilia leaflets. Images of the Sapien 3 Ultra TAVR devices are shown below:  https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 76).



https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).



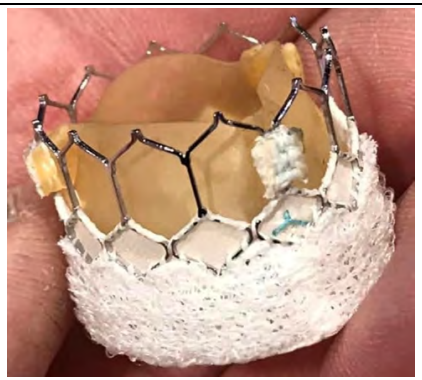
https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA



https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).



https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).



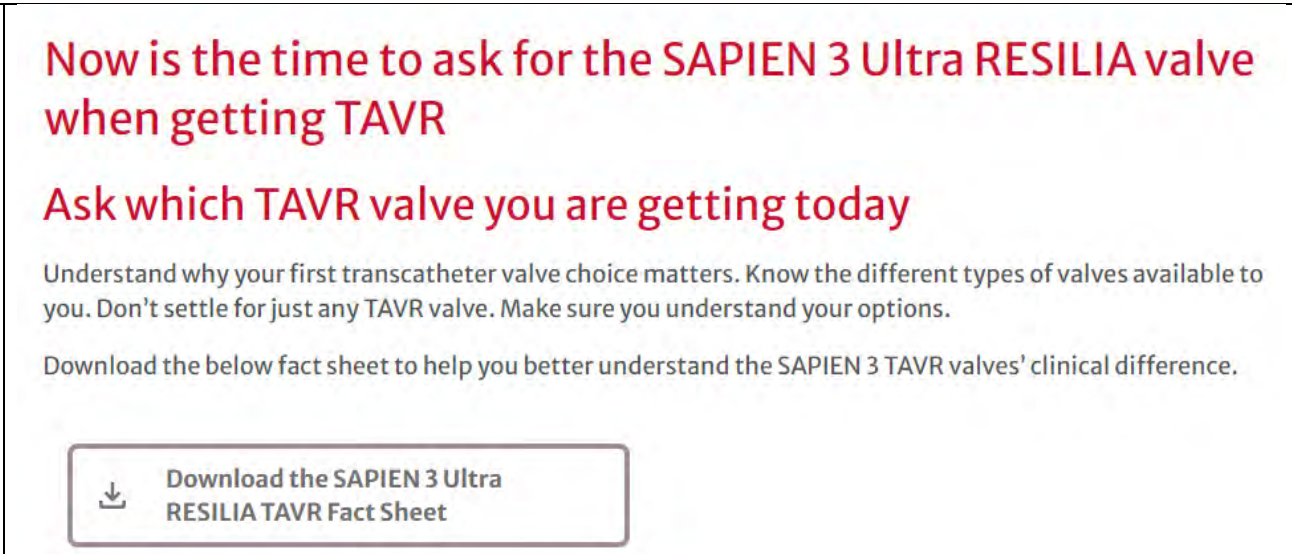

Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

On information and belief, Edwards manufacturers, assembles, sterilizes, and/or packages (in whole or in part) the Sapien 3 Ultra (and components thereof) in the United States, Costa Rica, Singapore and/or Ireland (and is approved by the FDA and other regulatory agencies to do so).

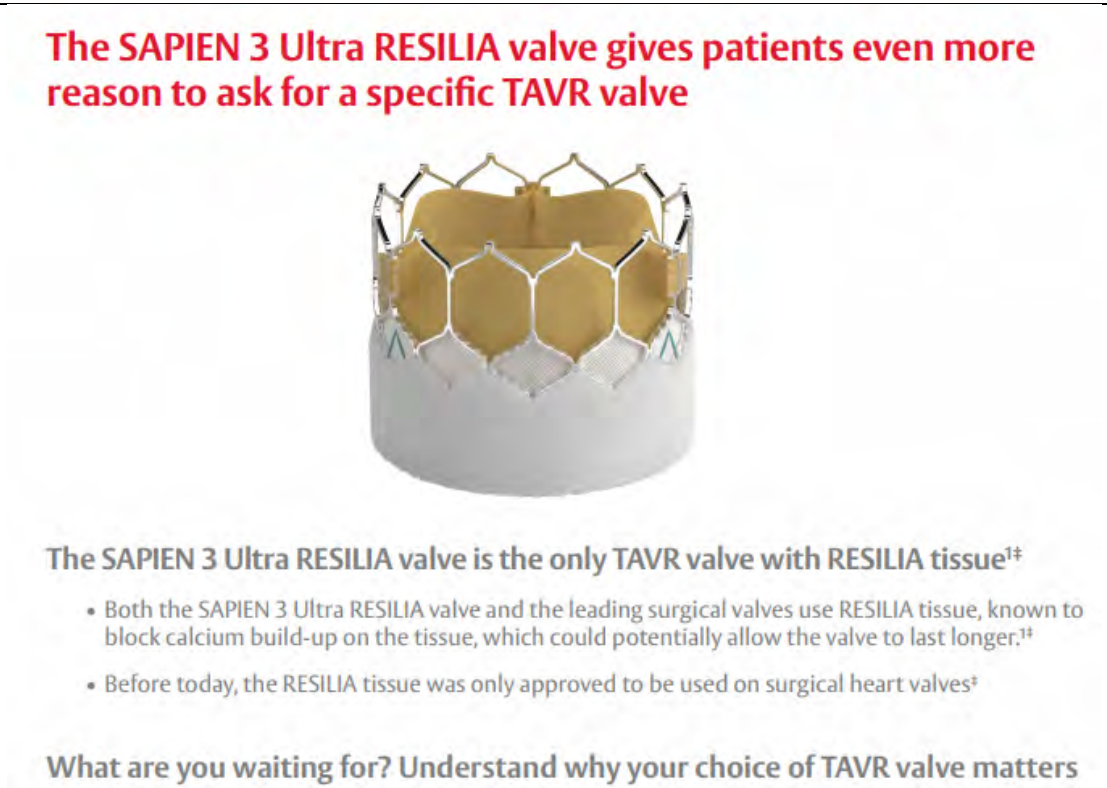
On information and belief, Edwards supplies in and/or from the United States some or all of the components of the Sapien 3 Ultra in such a manner that such components will be combined outside of the United States to form the Sapien 3 Ultra and infringes the '918 Patent claims under 35 U.S.C. § 271(f). Upon information and belief, such components are combined by Edwards, and/or its associated companies and affiliates, at manufacturing sites in the United States, Costa Rica and at other non-U.S. locations.

On information and belief, Edwards markets, sells, and/or provides Sapien 3 Ultra to patients (indirectly), hospitals, medical centers, clinics, surgeons, and other medical professionals in the United States and elsewhere directly, and/or through sales representatives or distributors, and provides information and documentation promoting the use of the Sapien 3 Ultra. For example, Edwards advertises and promotes its Sapien 3 Ultra products on public webpages registered to Edwards and provides information, images and videos branded and/or sponsored by Edwards. *See, e.g.*, 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. Edwards Lifesciences Corporation's recent investor conference meeting also include repeated mentions of the Sapien 3 Ultra product. *See*

	https://ir.edwards.com/events-presentations/; https://s27.q4cdn.com/788244549/files/doc_presentations/2022/12/Full-Presentation-Final-Website.pdf; https://s27.q4cdn.com/788244549/files/doc_events/12/2022-Investor-Conference-Final-Transcript.pdf. On information and belief, advertising and brochures from Edwards, available from at least the foregoing websites are directed by Edwards towards selling the Sapien 3 Ultra. Also, on information belief Edwards promotes the Sapien 3 Ultra at U.S. and international medical conferences at booths. Edwards commits acts of direct infringement, including, with respect to the asserted claims, including when Edwards prepares, assists with procedures, demonstrates, instructs, tests, or otherwise uses the '918 patent Accused Instrumentalities. Edwards further performs acts of direct infringement when it employs doctors who use the '918 patent Accused Instrumentalities for testing, instruction, demonstration or otherwise. See, e.g., https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing one doctor as "a paid proctor for Edwards Lifesciences", another doctor as "a paid proctor and consultant with Edwards Lifesciences" and a third doctor as "receiv[ing] institutional research grants from … Edwards Lifesciences."); *see also* https://www.hmpgloballearningnetwork.com/site/jic/original-contribution/comparison-26-mm-evolut-and-23-mm-sapien-3-valves-tavr-small-aortic (referencing a doctor as a "consultant and proctor for Edwards Lifesciences."). In addition, the '918 asserted claims are infringed when Edwards offers for sale and sells the '918 patent Accused Instrumentalities. Edwards offers for sale and promotes the '918 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 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.



https://www.tavrbyedwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).



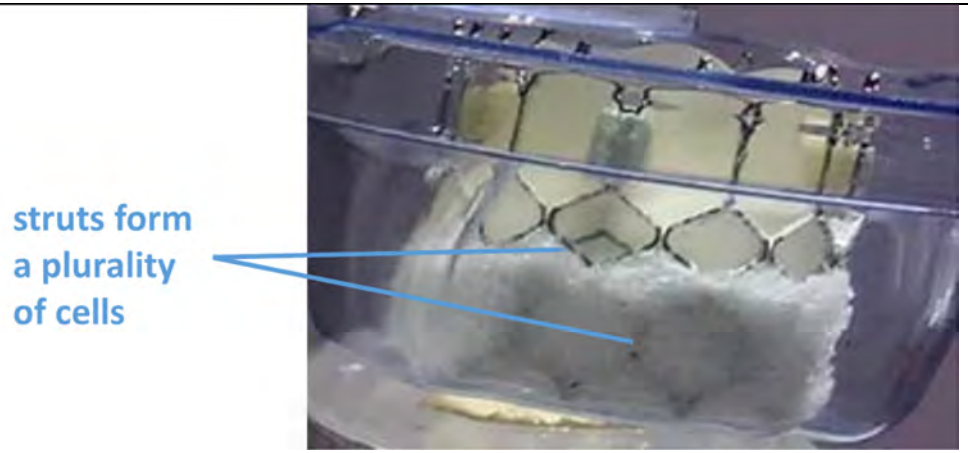
https://tavrbyedwards.edwards.com/wp-content/uploads/2022/09/SAPIEN-3-Ultra-RESILIA-Product-Sheet.pdf (D.I. 1, Ex. 61).

On information and belief, Edwards further provides incentives and reimbursements in connection with its offers for sale and sale of the Sapien 3 Ultra to patients and others through sales representatives and online. https://www.edwards.com/education/reimbursement#

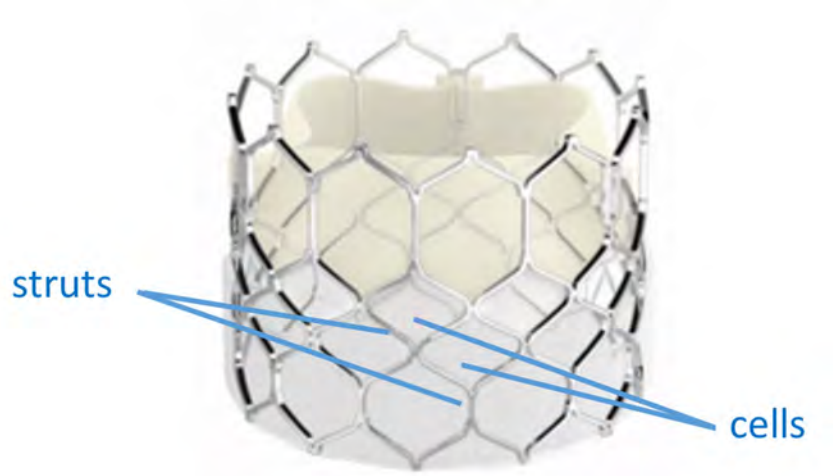
Further, the '918 patent asserted claims are directly infringed when the Sapien 3 Ultra is used as part of design, development, compliance, testing (e.g. interoperability, certification, reliability, comparability, PVL, clinical, and quality control testing), and/or otherwise used and/or tested by Edwards. Further, Edwards performs these infringing acts through its agents and consults where it sponsors in whole or in part such activities and testing.

	Edward further commits acts of direct infringement when Edwards, hospitals 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 devices according to the claims. When the Sapien 3 Ultra are used, prepared, 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 participation in the TAVR procedure or receiving a benefit therefrom and establishing the manner or timing of the performance thereof. 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, contracting with hospital and doctors, and participating in and supporting the Sapien 3 Ultra in TAVR procedures. Edwards infringes the claims of the ’918 Patent, as provided in 35 U.S.C. § 271(b), by inducing infringement by others, such as hospitals, doctors, medical professionals, distributors, customers, and end users. Aortic incorporates its discussion above regarding Edwards’ direct and induced infringement. For further example, on information and belief, Edwards’s affiliated hospitals and doctors directly infringe the asserted ’918 patent claims through their use and deployment of the Sapien 3 Ultra. Edwards induces this direct infringement through its affirmative acts of manufacturing, selling, distributing, and/or otherwise making available the Accused Instrumentalities, its agreements with doctors and hospitals, and providing instructions for use, documentation, study information, online technical support and videos, marketing, product manuals, advertisements, and other information and assistance to customers and end users directing use of the Accused Instrumentalities in an infringing manner. Further, on information and belief, Edwards sends its employees, consultants, and paid physicians to hospitals to provide product and instructional materials, educates doctors on the installation and use of the Sapien 3 Ultra, helps select patients for Sapien 3 Ultra TAVR procedures, performs and assists in the Sapien 3 Ultra TAVR procedures, and maintains a “watchful eye” over doctors and other medical staff before and during such procedures. Further, Edwards contracts with hospitals and doctors and maintains a consignment of Sapien 3 Ultra valves at affiliated hospitals for use. See Ex. 4 to Second Amended Complaint, Oh Declaration and attachments. As a result of Edwards’s inducement, Edwards’s affiliated hospitals, doctors, medical professionals, customers and end users use the Accused Instrumentalities 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.

	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 hospitals, doctors, medical professionals, distributors, patients, customers, and end users. On information and belief, Edwards’s affirmative acts of marketing, selling and offering to sell, the Accused Instrumentalities and causing the Accused Instrumentalities to be manufactured, used, sold, and offered for sale, contribute to Edwards’s customers’ and end users’ combination and use of the Accused Instrumentalities, such that the ’918 Patent is directly infringed. The Accused Instrumentalities and/or accused components within the Accused Instrumentalities, such as the Sapien 3 Ultra itself, the sealing skirt, the inner skirt, and/or other components and features are material to the inventions 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 the 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. Aortic incorporates by reference paragraphs 26-115 from the Second Amended Complaint and the willful infringement discussion in the Infringement Contention Cover Pleading, regarding Edwards’ knowledge of Aortic’s inventions, the patents-in-suit (including the ’918 patent), and its infringement in connection with the Sapien 3 Ultra TAVR.
a frame formed of a plurality of struts that cooperate to form a plurality of cells,	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise a frame formed of a plurality of struts that cooperate to form a plurality of cells. For example, the Sapien 3 Ultra frame is formed of struts that cooperate to form a plurality of cells.



Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth. (D.I. 1, Ex. 3).

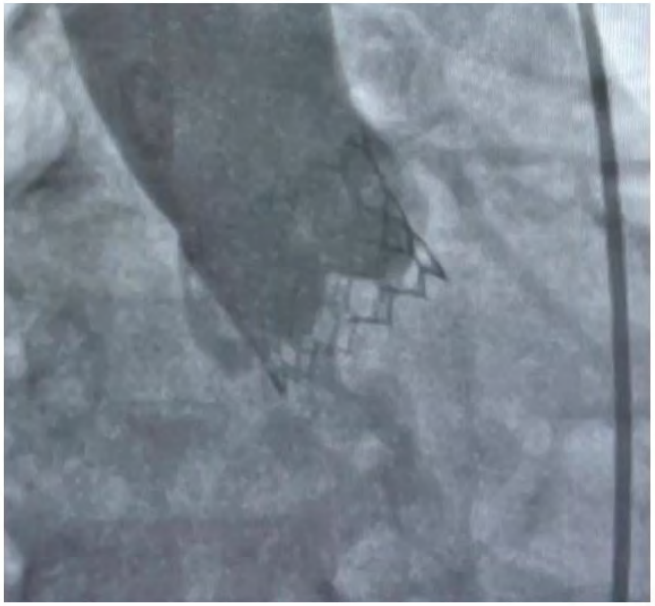


https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33).

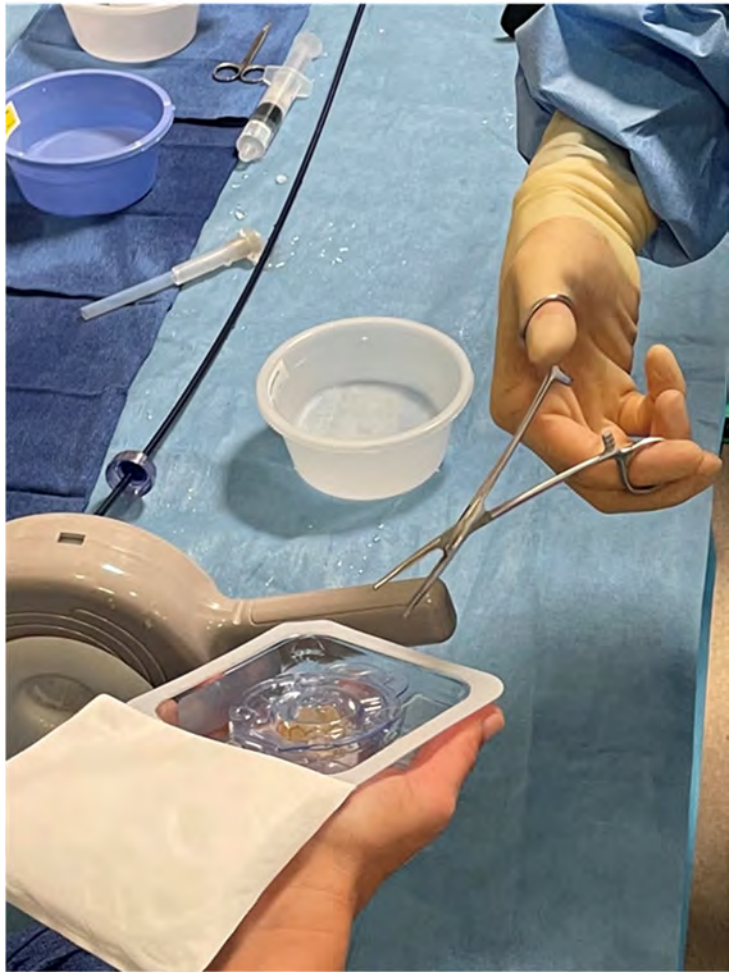
See also, evidence for preceding elements above.

	With respect to the phrase, "a frame formed of a plurality of struts that cooperate to form a plurality of cells", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, the Accused Instrumentalities are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused frame performs the same or substantially the same function as the claim phrase by framing and providing support for the prosthetic heart valve leaflets and other valve components and is collapsible to a low profile and expandable allowing for endovascular delivery, in the same or substantially the same way as the claim phase through being constructed of a metallic material in an open cell configuration with an equivalent frame shape with struts and cells with the capability to be expanded and collapsed to a low profile, to achieve the same or substantially the same result of a low profile collapsible and expandable frame in a TAVR valve that is capable of endovascular delivery and expansion to interface with a patients' anatomy. Further, whether the frame with a plurality of struts that cooperate to form a plurality of cells is laser cut from a single piece of material or made otherwise is the same or, at most, an insubstantial difference.
wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;	The '918 patent Accused Instrumentalities satisfy this element. The '918 patent Accused Instrumentalities comprise a frame that is radially expandable from a radially compressed orientation to a radially expanded orientation. For example, the Sapien 3 Ultra is packaged and provided by Edwards in a radially expanded configuration. The Sapien 3 Ultra is designed by Edwards to be crimped onto an Edwards' balloon delivery system in a radially compressed orientation. The Sapien 3 Ultra is also designed to be expanded using an Edwards' balloon delivery system in the aorta of a patient into a radially expanded orientation.

	 Dale Murdoch LinkedIn post, available at https://www.linkedin.com/posts/drdalemurdoch_first-australian-sapien-3-ultra-case-today-activity-6774632374585102336-y0EU

	 Instagram posts and images of Terapeutica Transcateter Cardiovascular of Brazil. (D.I. 1, Ex. 74).

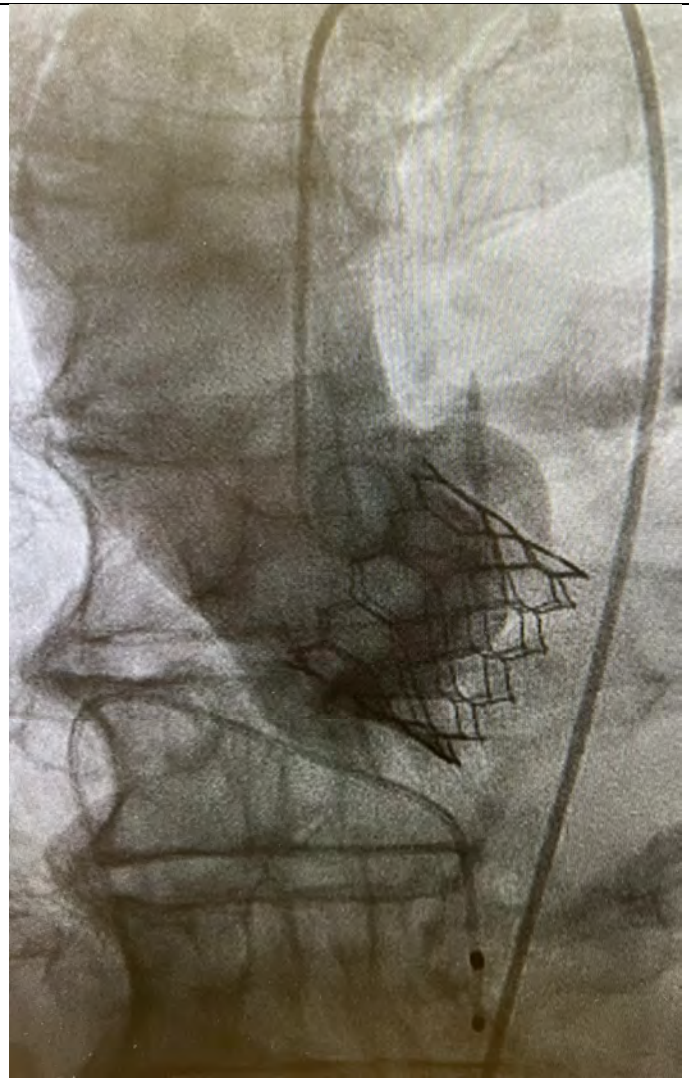
	 https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg



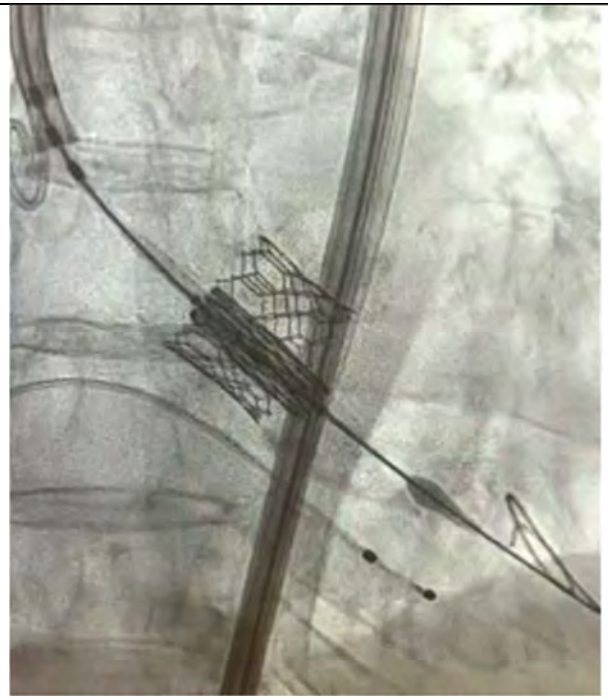
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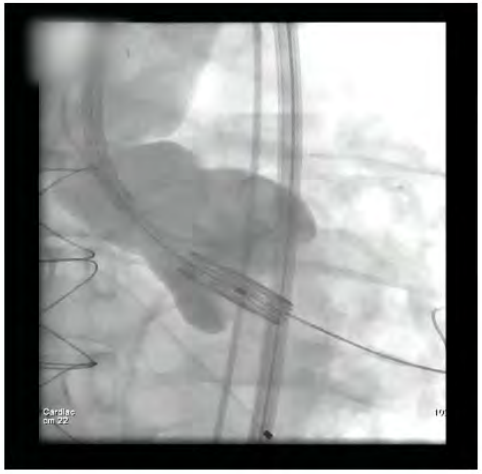


https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=7vNdYaSyfo8PlVNSNv2WDQ



https://twitter.com/UCI_Cardiology/status/1595633528959488001?s=20&t=oAv9Ck6VU-hcm9iUeZON9A

SAPIEN 3 Ultra System Case Example





Edwards Presentation entitled “SAPIEN 3 Ultra Valve First-In-Human Experience” at 5 (annotation added), http://www.crtonline.org/Assets/5b3e93b5-6b68-482c-9483-bb4bfe689bc5/636874631931730000/27e46c88-1e66-48a1-a04e-d13b1f9556ae-pdf (D.I. 1, Ex. 47).

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.



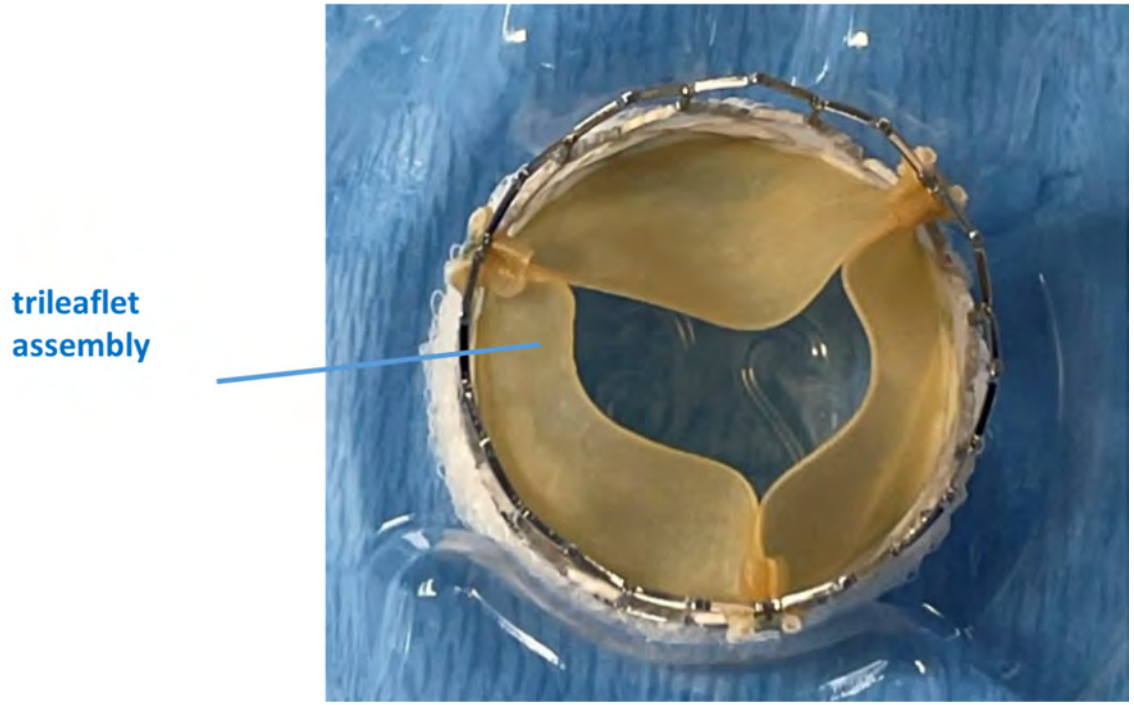
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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

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 (D.I. 1, 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 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a leaflet assembly within the frame;	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise a leaflet assembly within the frame. For example, the Sapien 3 Ultra devices comprise a bovine pericardial tissue trileaflet assembly and/or Resilia tissue trileaflet assembly within the frame.  https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (D.I. 1, Ex. 64).

1.0 Device Description

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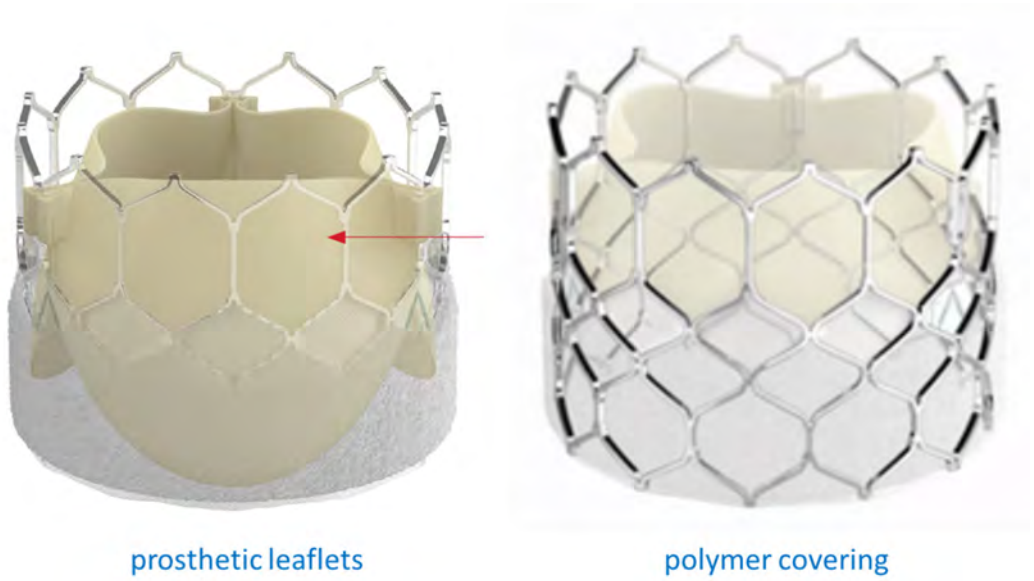
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Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44). https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf; *see also* Sapien 3 Ultra (PMA

	P140031/S085) FDA Summary of Safety and Effectiveness Data at 2-3 (D.I. 1, Ex. 45) https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085B.pdf.
a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly;	The ’918 patent Accused Instrumentalities satisfy this element. The ’918 patent Accused Instrumentalities comprise a polymer covering, carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly. For example, the Edwards Sapien 3 Ultra has a polymer covering made from PET attached to and touching the leaflet assembly. Further, the Sapien 3 Ultra polymer covering is positioned radially inward of the frame.  https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra (showing polymer covering radially inward of the frame carrying and engaging the leaflet assembly) (D.I. 1, Ex. 33).

1.0 Device Description

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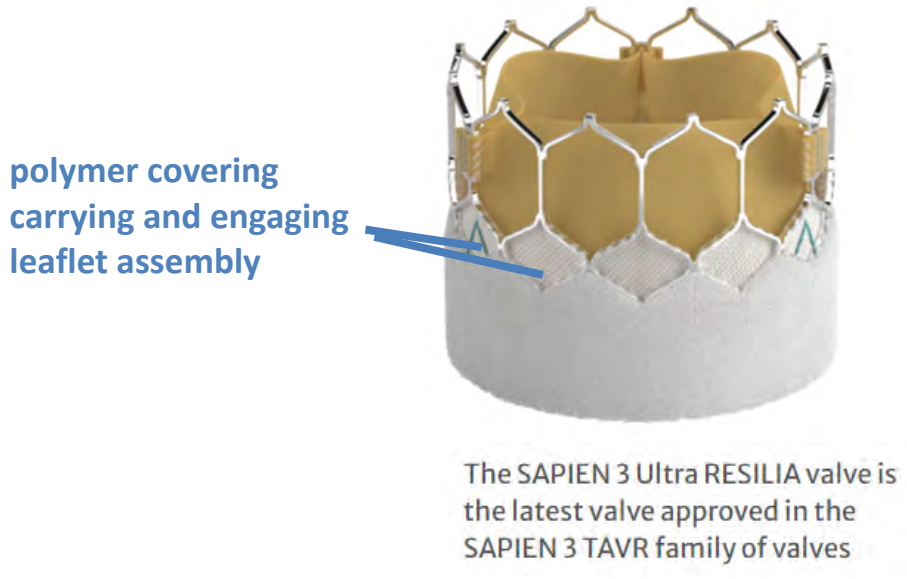
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Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

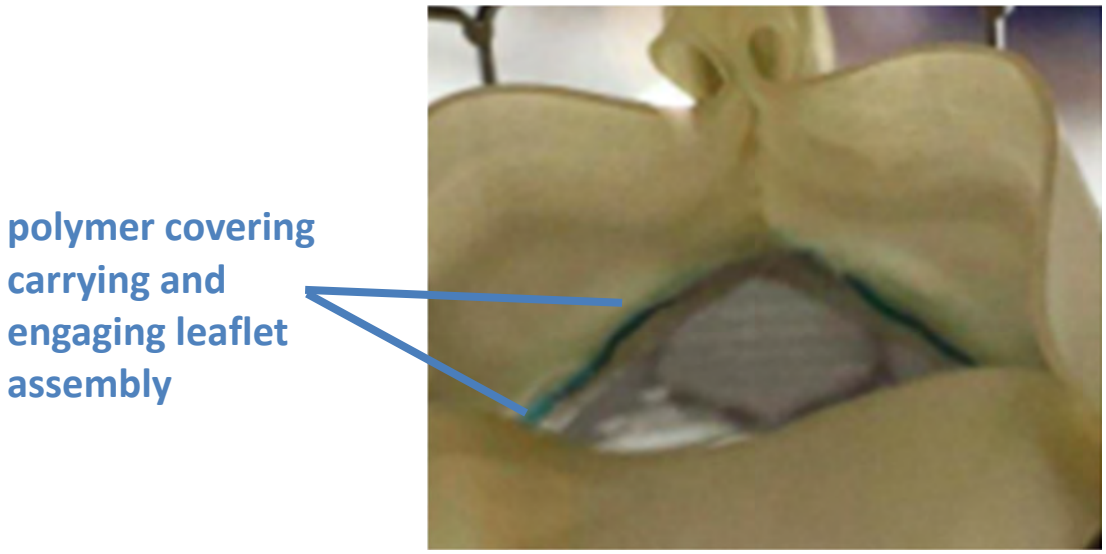
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Valve Size	Valve Height
20 mm	15.5 mm
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Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

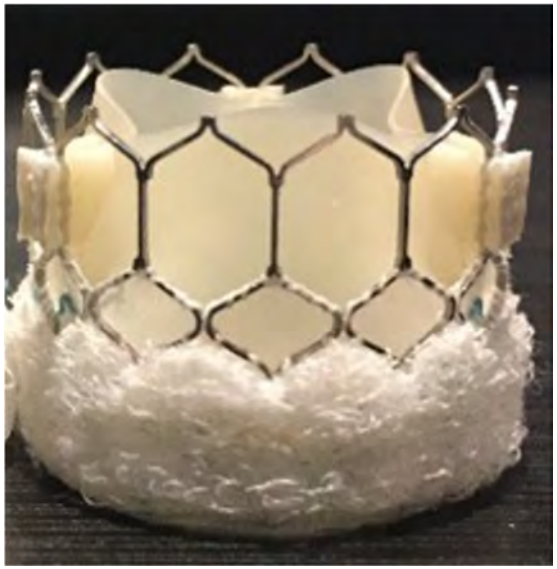


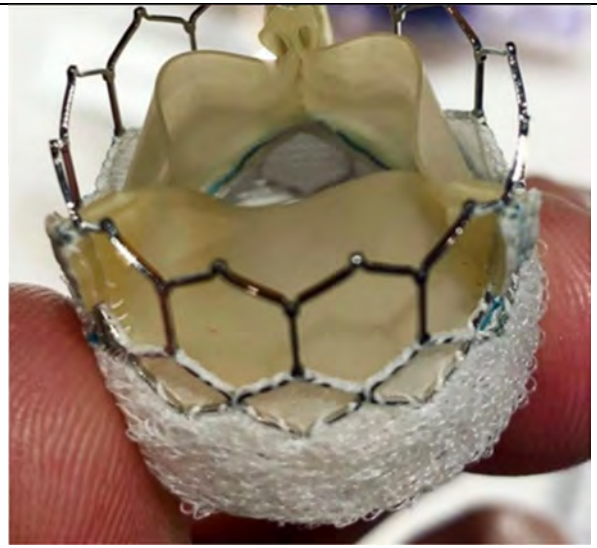
https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

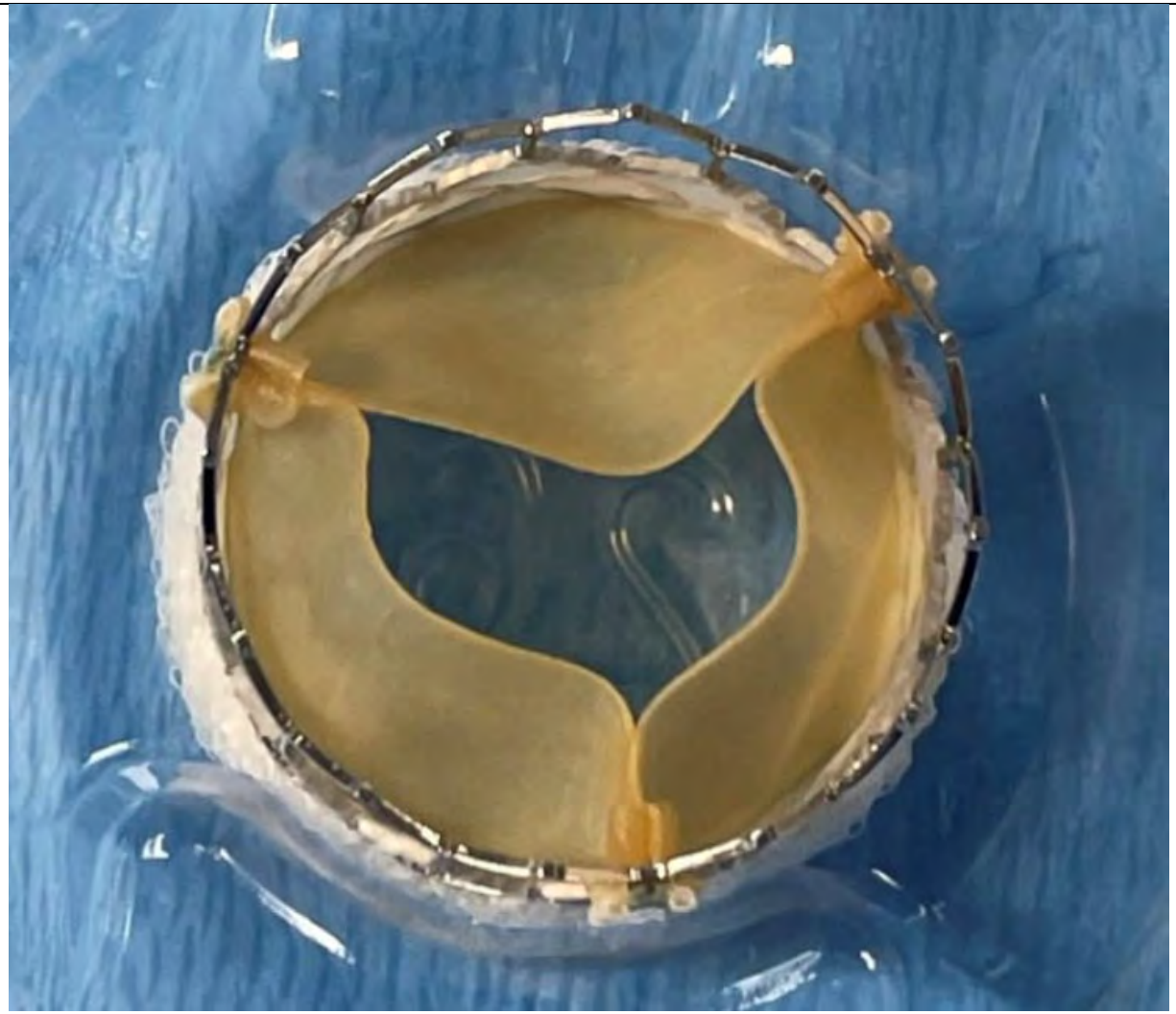


https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

With respect to the phrase, "a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly", Aortic asserts that this element is literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants argue that this phrase, or portions thereof, are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and engaging the leaflet assembly , the identified polymer coverings are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrases. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused polymer covering performs the same or substantially the same function as the claim phrase by at least covering portions of the leaflet assembly and providing sealing thereto, in the same or substantially the same way as the claim phase through including a polymer covering that is positioned at least partially radially inward of the frame that at least partially carries and engages the leaflet

	assembly, to achieve the same or substantially the same result of polymer covering configured to cover, carry, and/or engage or partially cover, carry, and/or engage the leaflet assembly.
a first layer for forming a seal upon compression,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 Accused Instrumentalities comprise a first layer for forming a seal upon compression. For example, the Sapien 3 Ultra has an sealing skirt that includes a first layer on the outside that forms a seal upon being compressed (e.g., when the valve assembly is expanded in the aorta of a patient).  Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7).

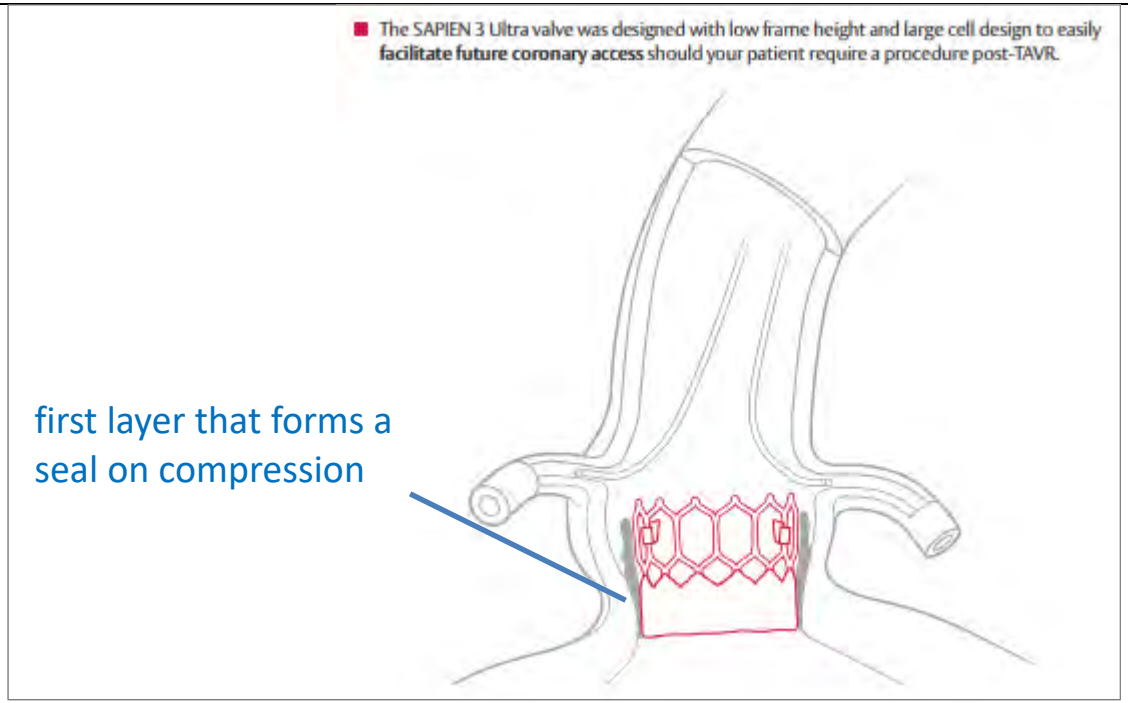
	 https://www.instagram.com/p/BysjboFBLiG/ (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 29).



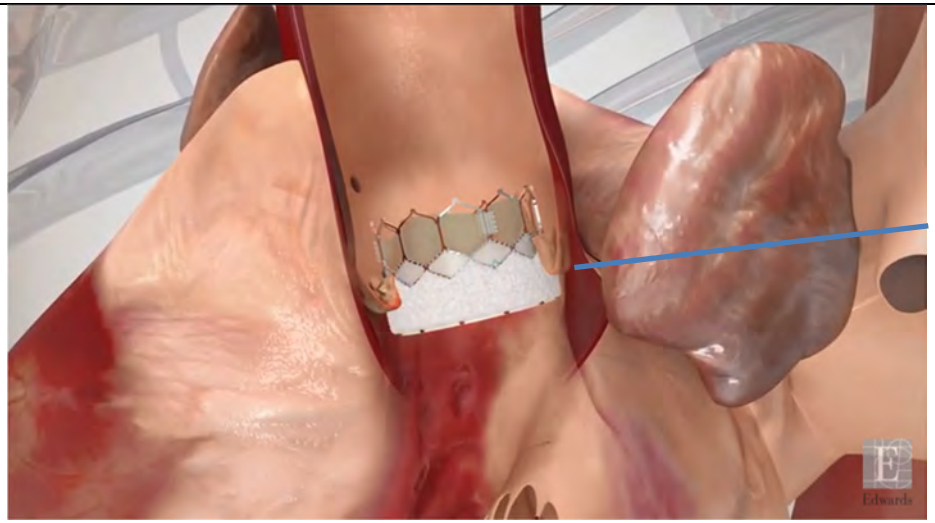
https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing plurality of fibers extending away from frame) (D.I. 1, Ex. 64).

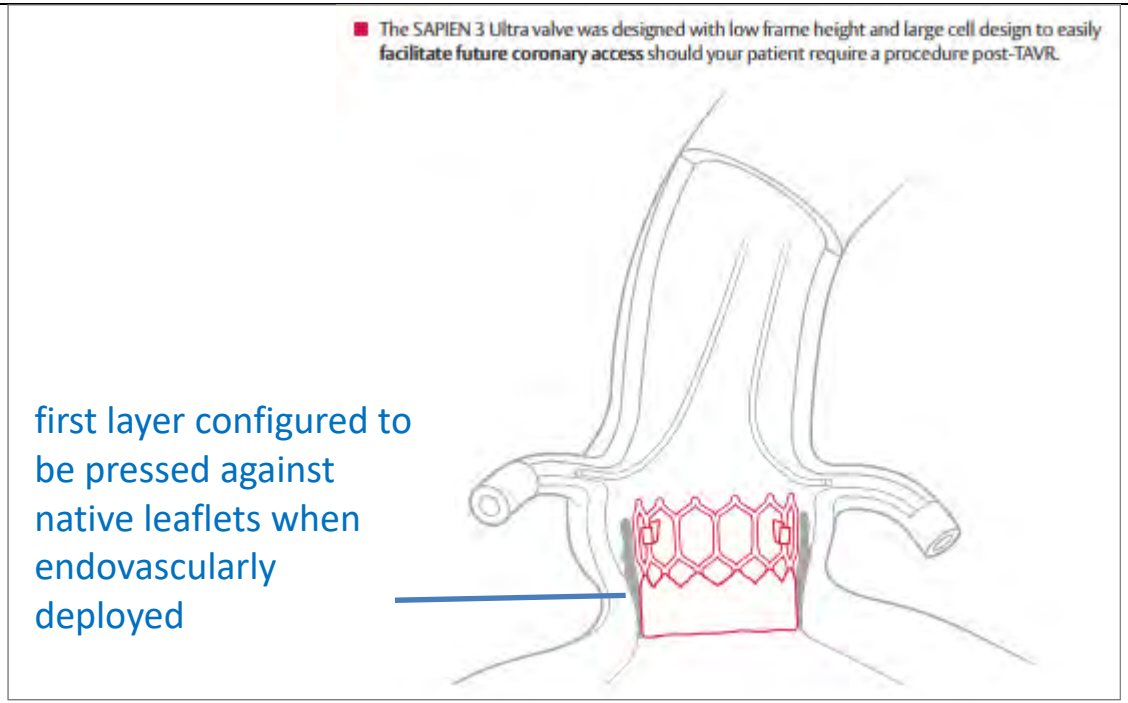
	 https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65).

	 Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

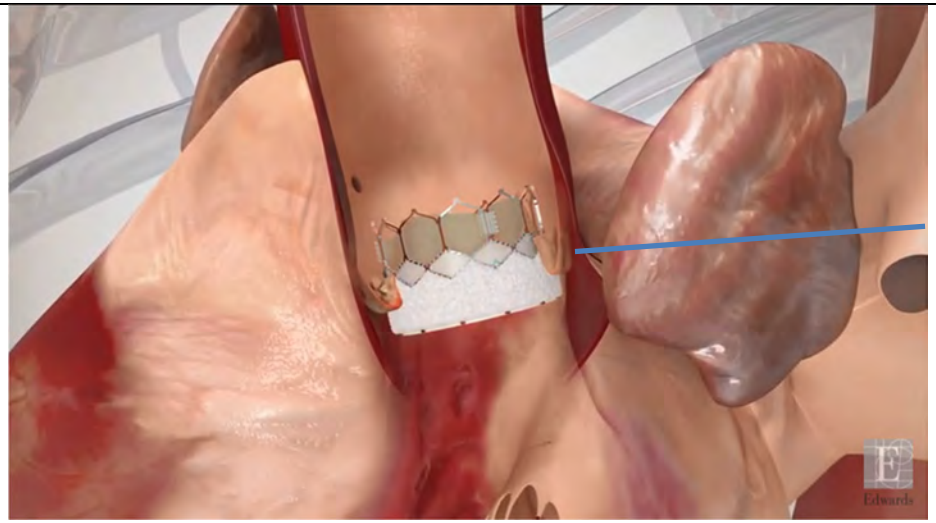


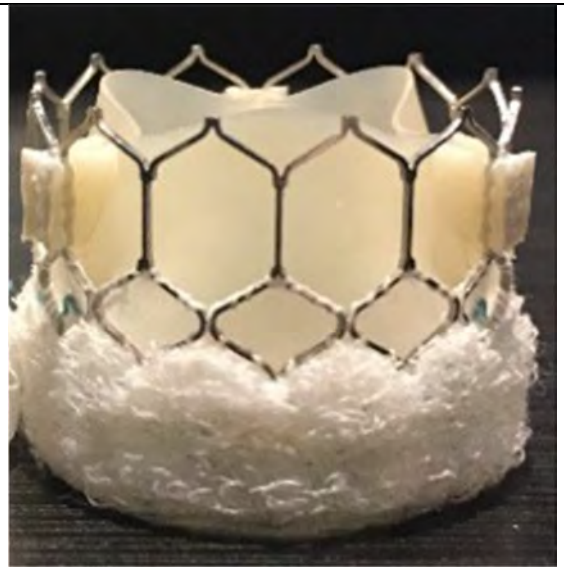
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
the first layer configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native aortic heart valve annulus of the patient,	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities' first layer is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native aortic heart valve annulus of the patient. For example, the Sapien 3 Ultra first layer on the outside of the sealing skirt is configured to be pressed against native leaflets when endovascularly deployed and radially expanded within the native heart annulus of a patient.

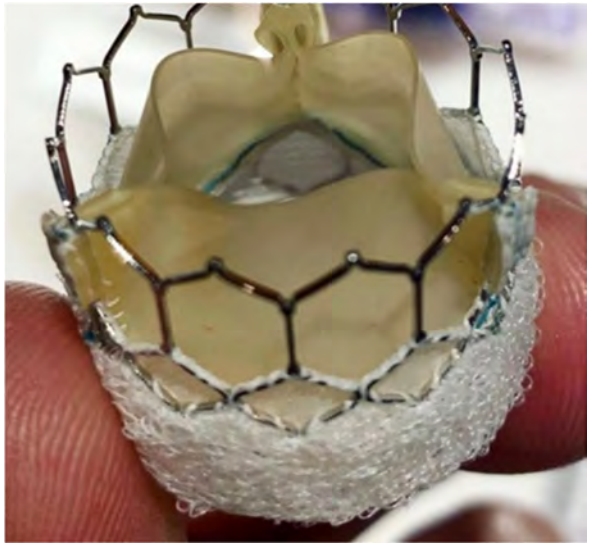


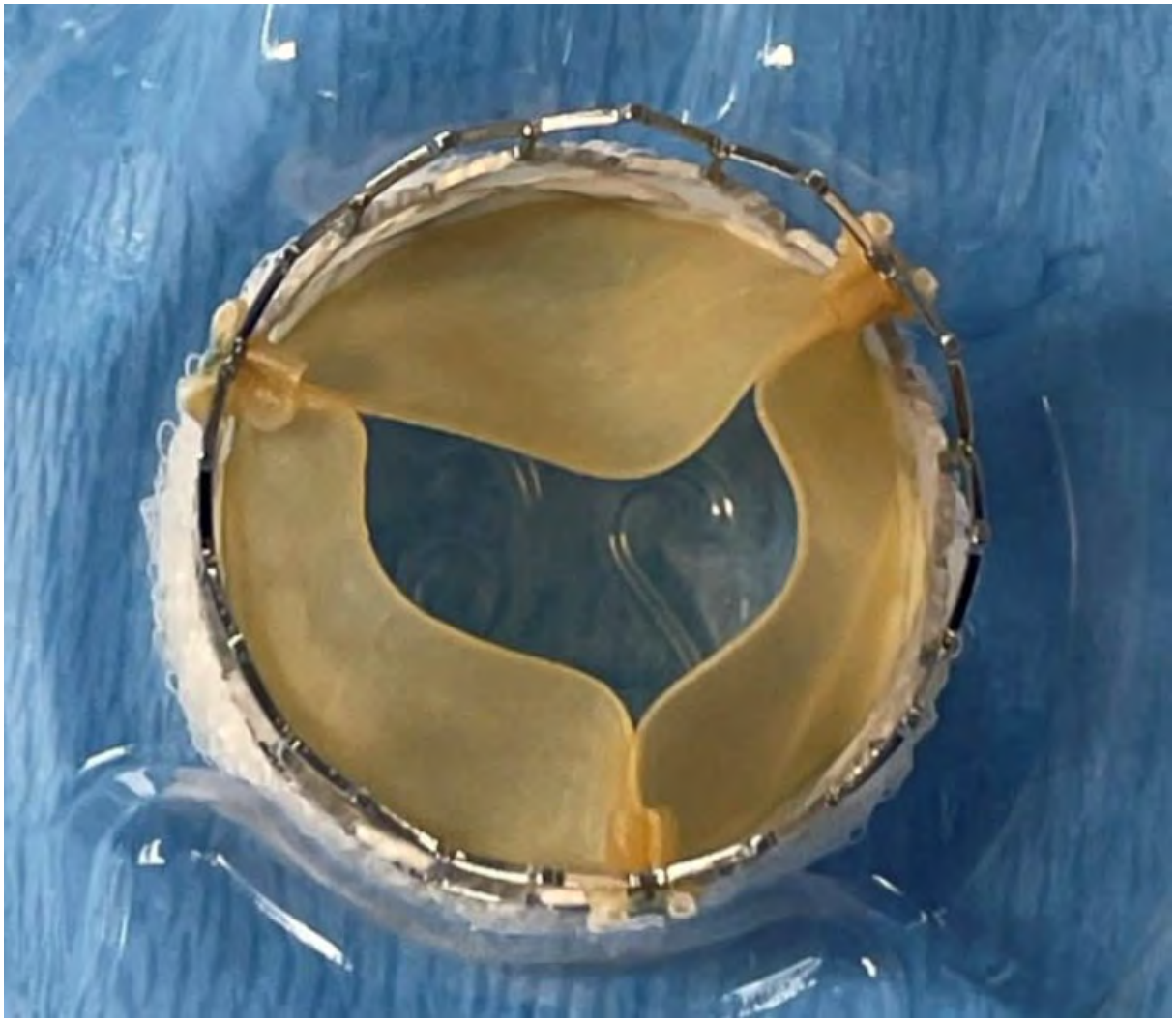
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

	 "TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).
wherein the first layer comprises a plurality of fibers that extend away from the frame, wherein the plurality of fibers is compressed against the native aortic heart valve annulus of the patient; and	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities' first layer comprises a plurality of fibers that extend away from the frame, wherein the plurality of fibers is compressed against the native aortic heart valve annulus of the patient. For example, the Sapien 3 Ultra sealing skirt first layer includes a plurality of fibers that extend away from the frame and are compressible against the native aortic heart valve annulus of the patient when the Sapien 3 Ultra is expanded.



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



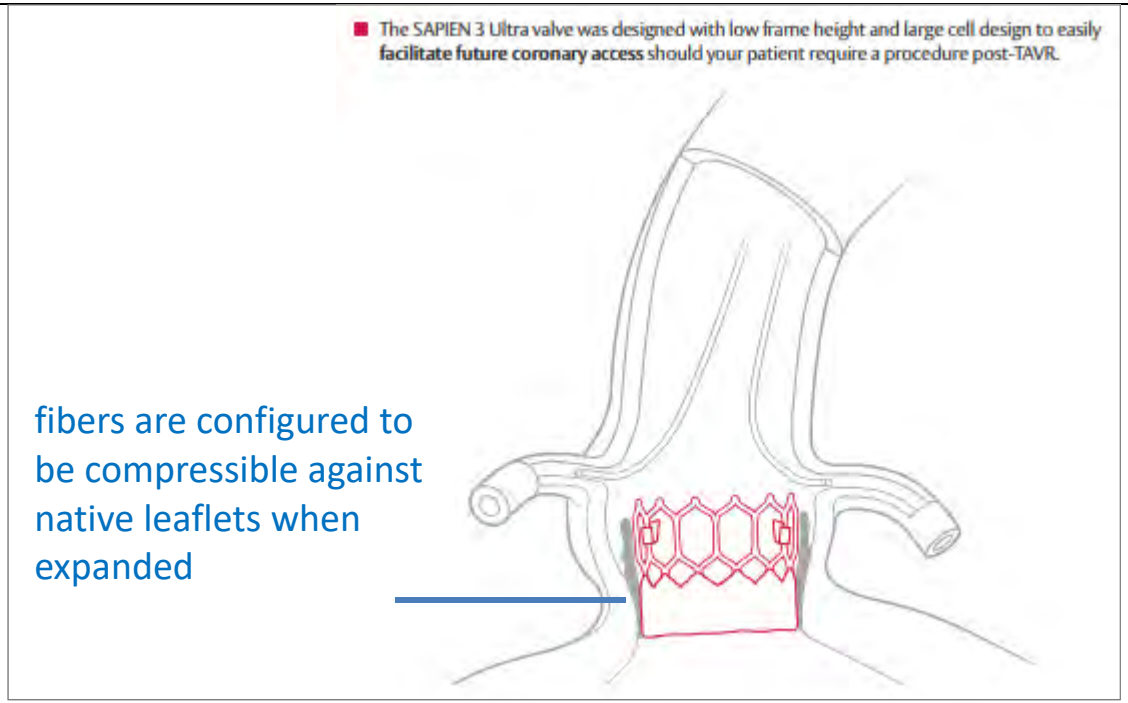
	https://www.instagram.com/p/BysjboFBLiG/ (showing fibers extending away from frame) (D.I. 1, Ex. 29). 

	https://twitter.com/jlevismd/status/1580673483138564096?s=20&t=GMt06qfjl4PI-lapFDHCNw (showing fibers extending away from frame) (D.I. 1, Ex. 64).  https://www.slhn.org/blog/2020/new-non-surgery-heart-valve (D.I. 1, Ex. 65) (showing fibers extending away from frame).

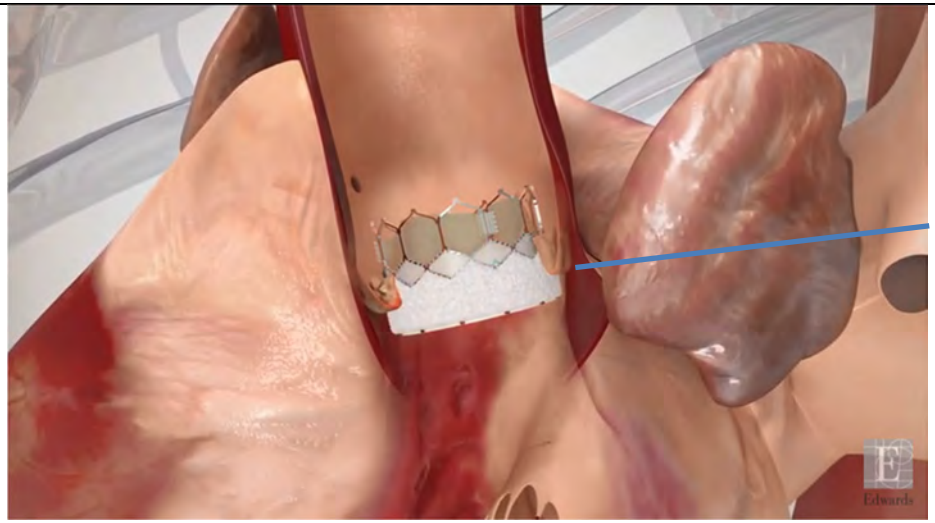


Cardiovascular Business LinkedIn Post of Edwards AHA 2022 Booth (showing fibers extending away from frame) (D.I. 1, Ex. 3).

For example, the Sapien 3 Ultra sealing skirt first layer fibers that extend away from the frame and are compressible against the native aortic heart valve annulus of the patient when the Sapien 3 Ultra is expanded.

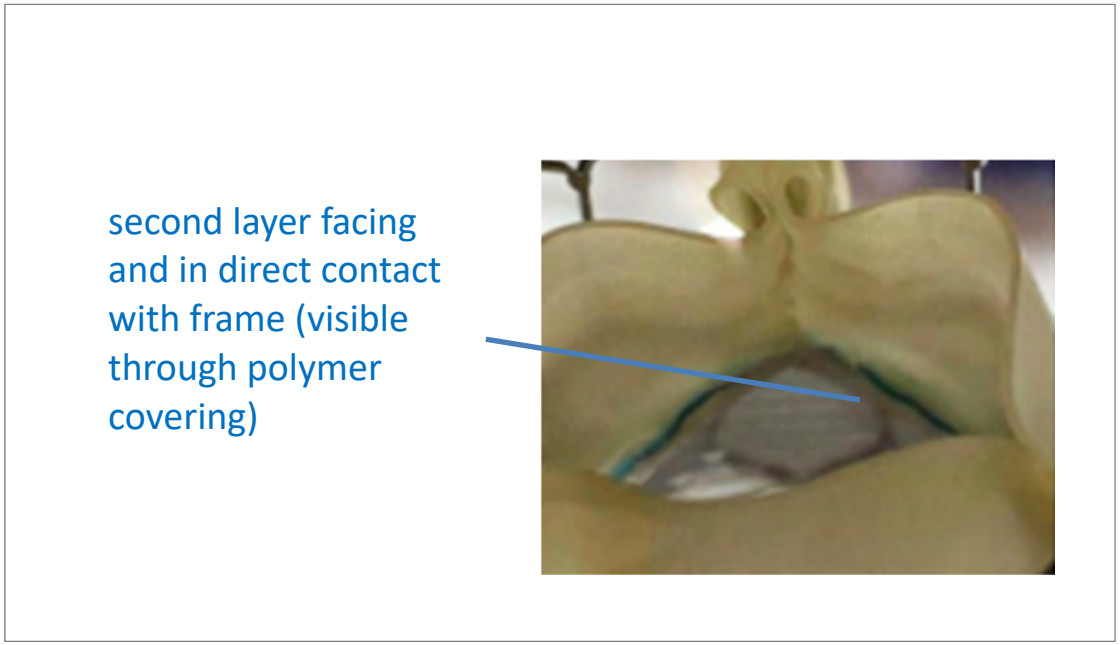


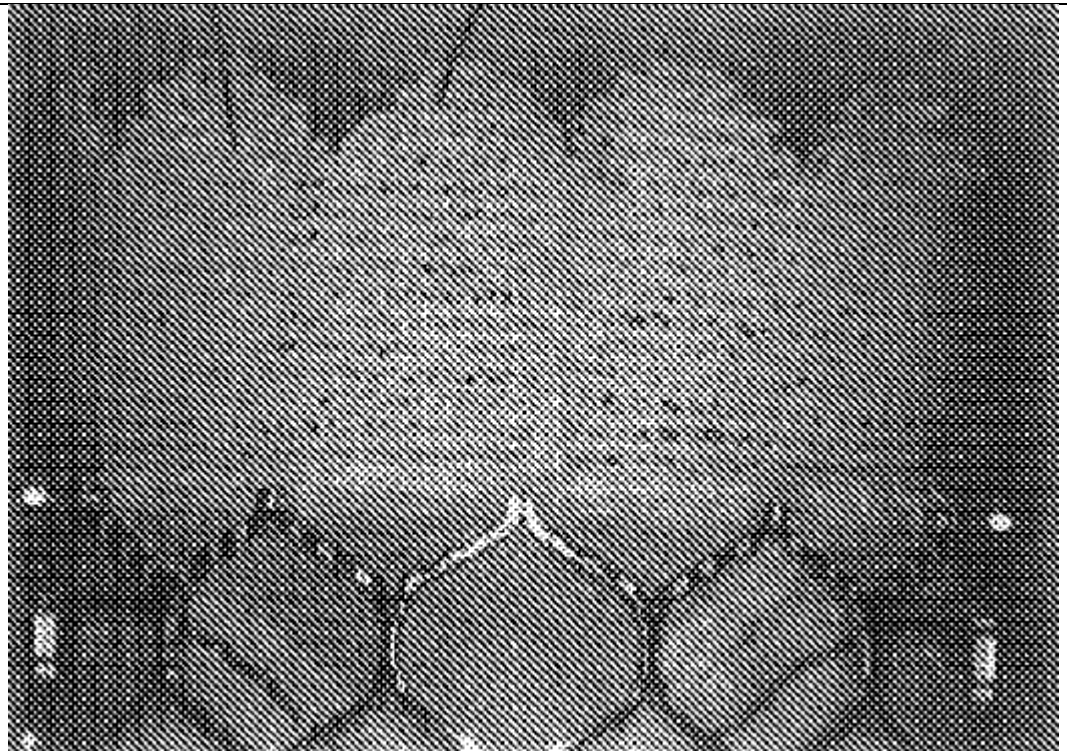
Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

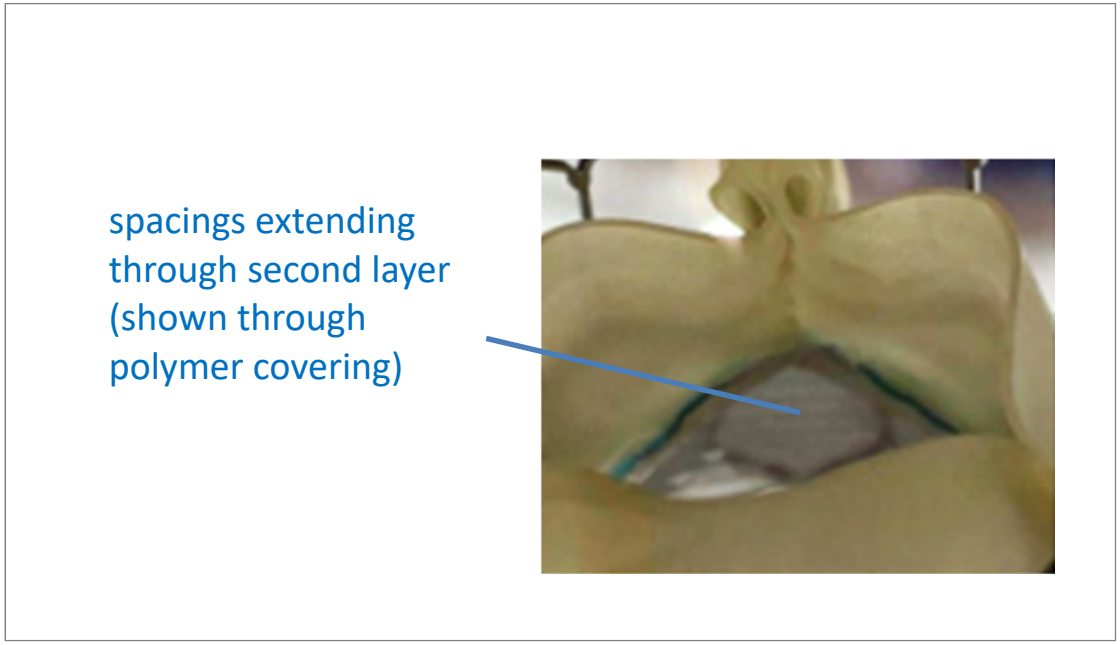


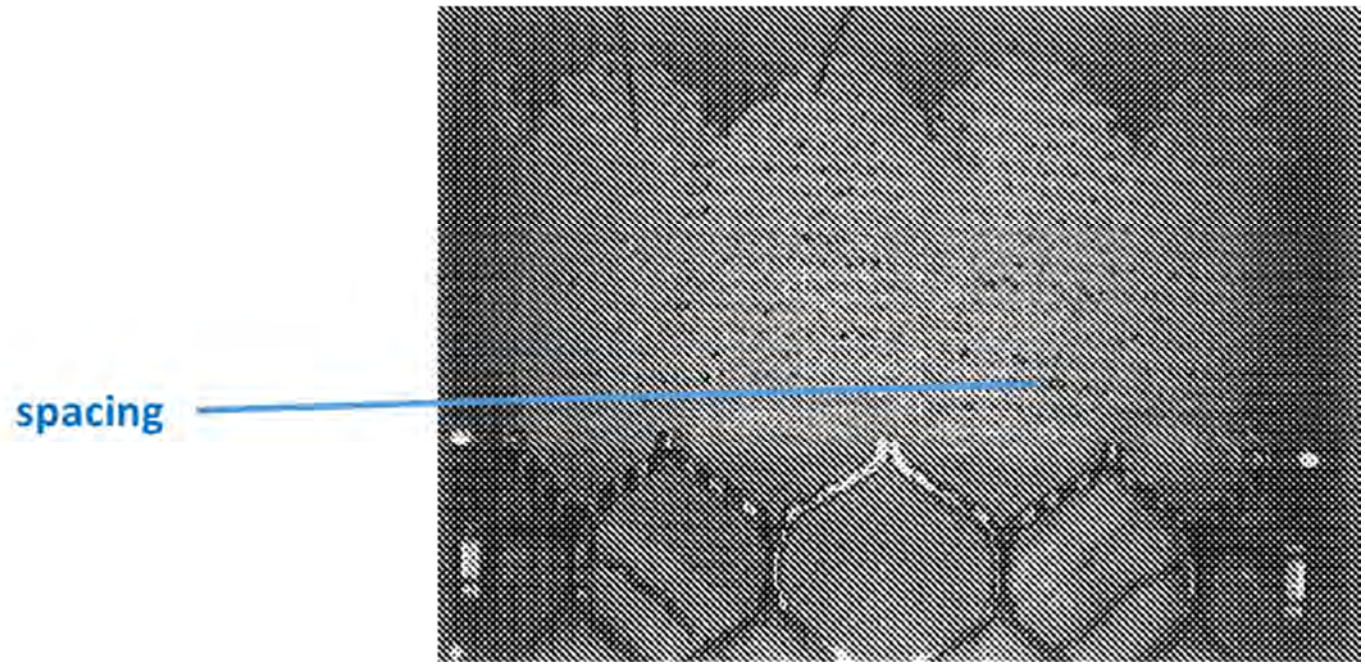
"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

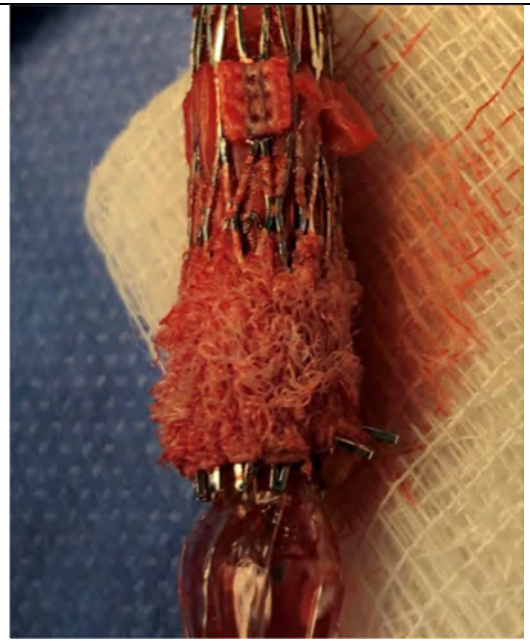
With respect to the phrase, "first layer comprises a plurality of fibers that extend away from the frame" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a plurality of fibers that extend away from the frame, the identified plurality of fibers that extend away from the frame of the Accused Instrumentalities, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused first layer comprising a plurality of fibers that extend away from the frame perform the same or substantially the same function as the claim phrase by providing low profile sealing against the native leaflets of the aorta and spacings, in the same or substantially the same way as the claim phase by comprising fibers generally extending away from the frame and pressing against the native leaflets of the aorta of the patient and filing in spacings when the valve is expanded and the layers are compressed together, to achieve the same or substantially the same result of a first layer with a plurality of fibers that

	extend generally away from the frame configured to provide sealing between the native annulus and the valve assembly.
a second layer for forming a seal upon compression, wherein the second layer is positioned radially inwardly from the first layer, wherein the second layer is in direct contact with the frame,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities comprise a second layer for forming a seal upon compression, wherein the second layer is positioned radially inwardly from the first layer, wherein the second layer is in direct contact with the frame. For example, the Sapien 3 Ultra sealing skirt includes a second layer facing the frame that is in direct contact with the frame. The sealing skirt in the Sapien 3 Ultra is radially inward from the first layer and has a backside (internal facing portion) with a second mesh type layer that directly contacts the frame.  Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1, Ex. 29).

	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing fibers on flipped up backside of sealing skirt). With respect to the phrase, "a second layer for forming a seal upon compression, wherein the second layer is positioned radially inwardly from the first layer, wherein the second layer is in direct contact with the frame" Aortic asserts that these elements are literally present in the Accused Instrumentalities as set forth in this exhibit. If Defendants later argue that these phrases are not satisfied by the Accused Instrumentalities, for example, by alleging they do not include a second layer for forming a seal upon compression, wherein the second layer is positioned radially inwardly from the first layer, wherein the second layer is in direct contact with the frame, even taking into account any alleged "differences" identified by Defendants, are at least substantially similar to the claim limitation and infringe at least under the Doctrine of Equivalents—i.e., there are no substantial differences between the Accused Instrumentalities and the claim phrase. Further, the

	pertinent features of the Accused Instrumentalities would at a minimum perform substantially the same function in substantially the same way, to achieve substantially the same result. For example, the accused second layer performs the same or substantially the same function as the claim phrase by helping provide low profile sealing against the frame when deployed, in the same or substantially the same way as the claim phase by being in direct contact with at least portions of the frame and interacting with first layer, to achieve the same or substantially the same result of a second layer designed and configured to help seal against the frame upon compression against the native annulus.
wherein the second layer defines a spacing extending through a thickness of the second layer for passage of fluid therethrough prior to forming a seal upon compression,	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities second layer defines a spacing extending through a thickness of the second layer for passage of fluid therethrough prior to forming a seal upon compression. Further, the Sapien 3 Ultra sealing skirt second layer has spacings extending through a thickenss of the second layer for passage of fluid therethrough prior to forming a seal upon compression. 

	Sapien 3 Ultra image (annotated), available at https://www.instagram.com/p/BysjboFBLiG/ (D.I. 1-2 at 15).  U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing spacings extending though second layer on backside of sealing skirt prior to compression).

	 Twitter image of crimped Sapien 3 Ultra with blood (allows passage of blood though spacings in mesh-like layer prior to deployment). *See also*, "second layer" element above.
wherein the heart valve assembly is sized and shaped for being delivered endovascularly through a femoral artery of a patient into the aorta,	The '918 patent Accused Instrumentalities satisfy this element. For example, the '918 patent Accused Instrumentalities are sized and shaped for being delivered endovascularly through a femoral artery of a patient into the aorta. For example, the Sapien 3 Ultra is designed, developed, promoted, sized, shaped, configured to be delivered and is delivered endovascularly through the femoral artery of a patient using Edwards' balloon delivery systems.



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 (D.I. 1, Ex. 44).

7.0 Directions for Use

7.1 System Compatibility

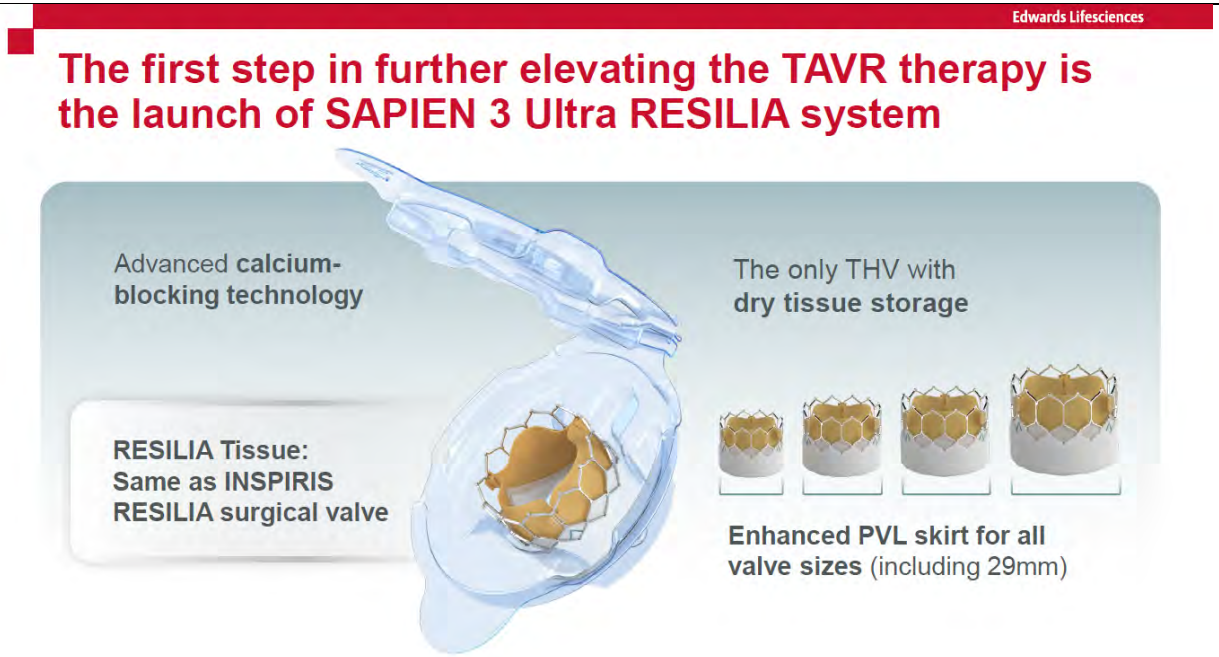
Table 6

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX20	9750TFX23	9750TFX26	
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX20	9600TFX23	9600TFX26	9600TFX29
Edwards SAPIEN 3 Ultra Delivery System	9630TF20	9630TF23	9630TF26	9630TF29
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			

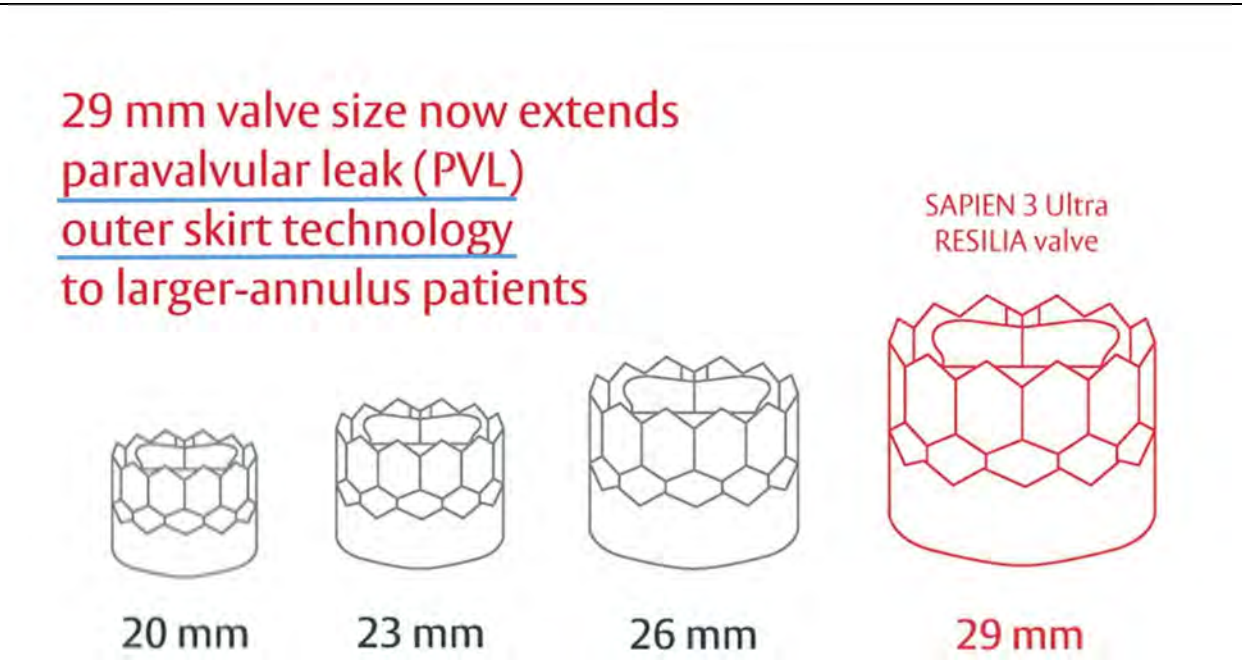
Additional Equipment:

- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

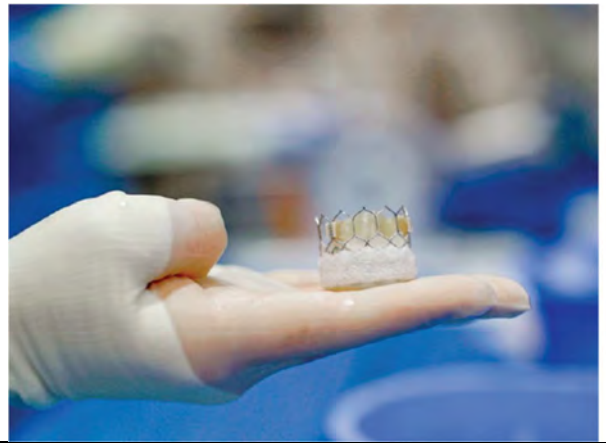
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System Instructions for Use ("IFU") at 9, available at https://www.accessdata.fda.gov/cdrh_docs/pdf14/P140031S085d.pdf (D.I. 1, Ex. 44).

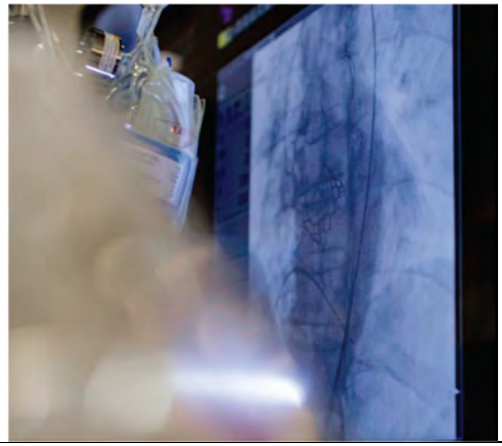


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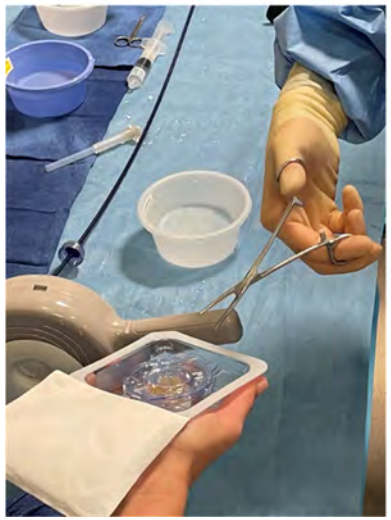
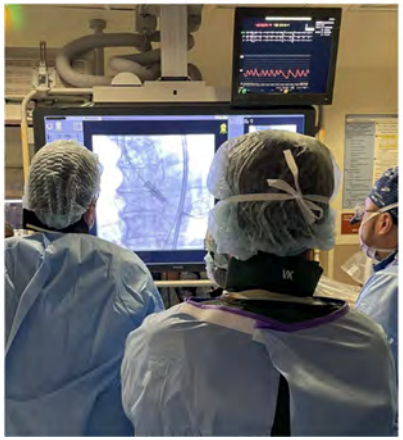


https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA





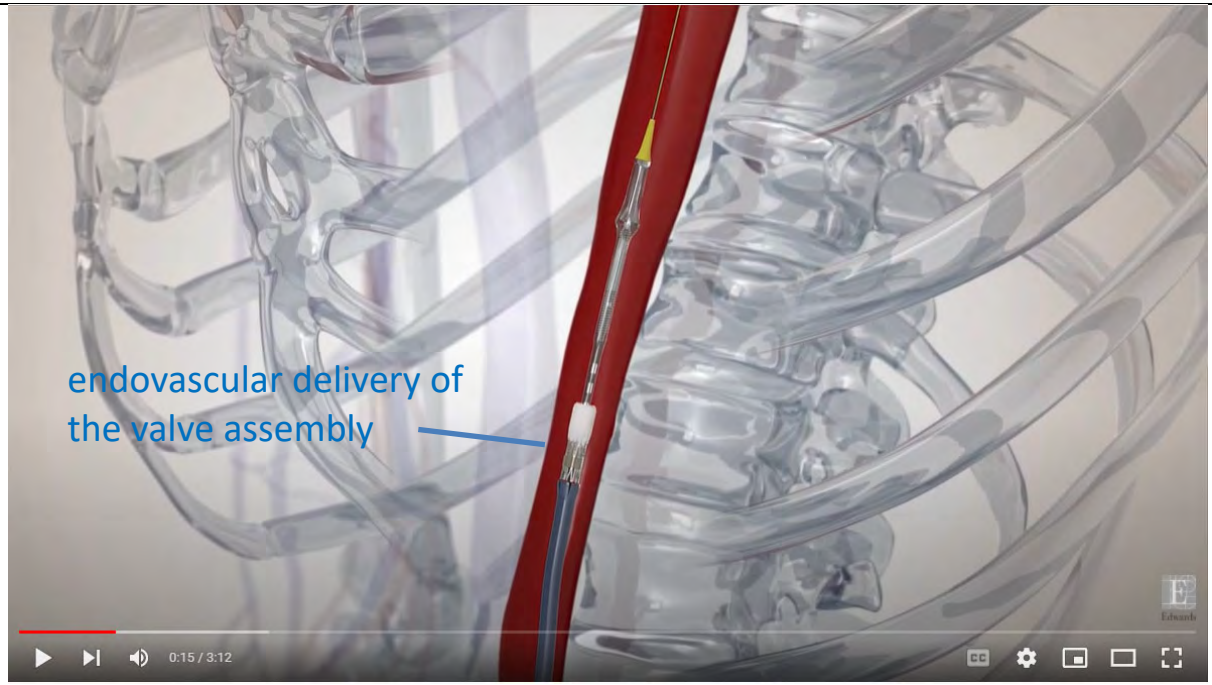
	https://twitter.com/RajTayalMD/status/1587519183127568391?s=20&t=HpBiZcnd67meRYwfqnqQKg (D.I. 1, Ex. 62).  https://twitter.com/jamiemccabeMD/status/1569506198902419456?s=20&t=WS5W9rg0LTQTaQtzHUr3Mg

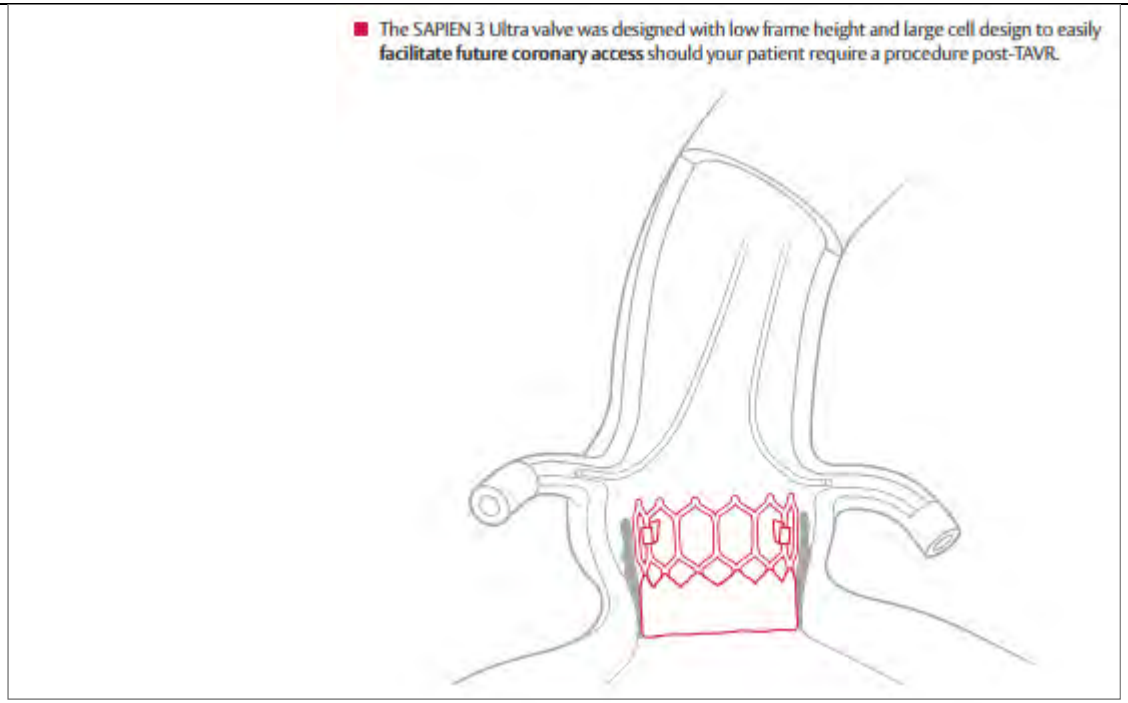



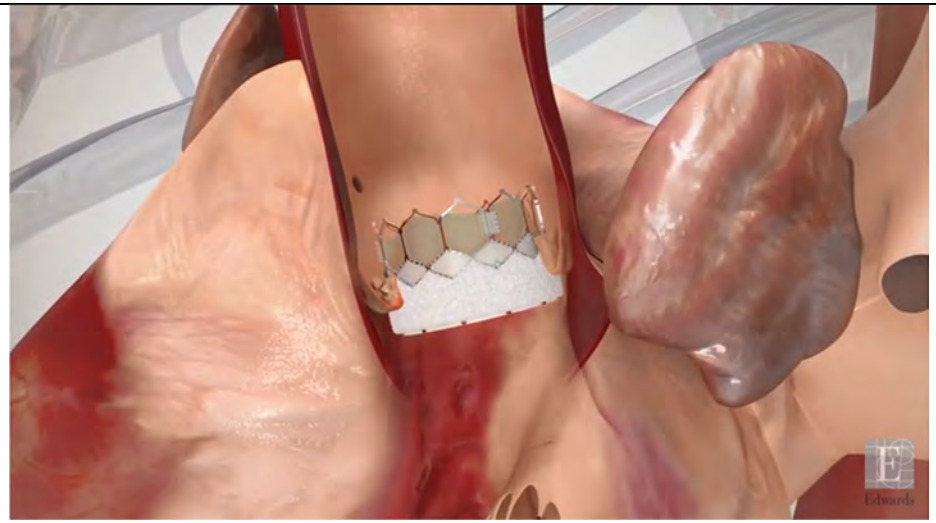

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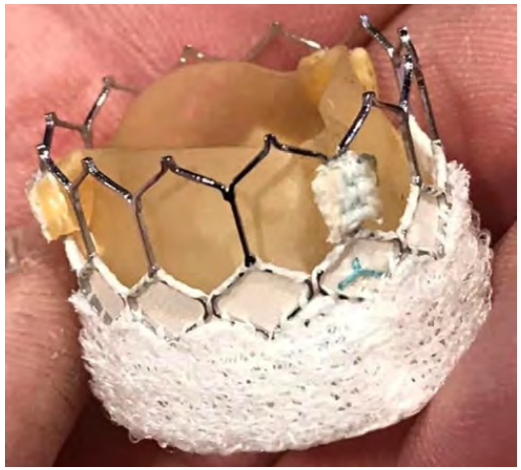
	https://twitter.com/UCI_Cardiology/status/1601719146432974848?s=20&t=oAv9Ck6VU-hcm9iUeZON9A The Sapien 3 Ultra is designed, manufactured, promoted, and sold by Edwards for endovascular delivery transfemorally.  SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).

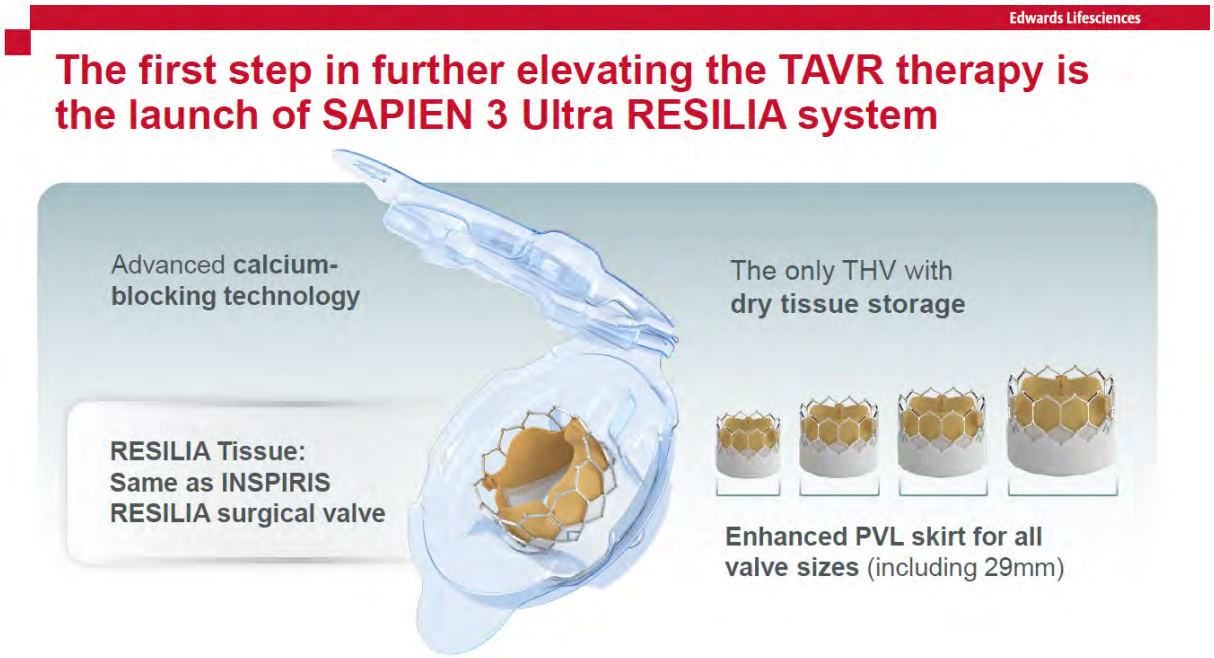
	 SAPIEN 3 Ultra + Commander Transfemoral Procedural Animation (annotated), https://www.youtube.com/watch?v=BoEiO9z6Wb8&t=6s (D.I. 1, Ex. 37).
wherein, compression of the first layer and the second layer in response to expansion of the prosthetic heart valve compresses the fibers of the first layer relative to the spacing to	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities are designed and configured such that compression of the first layer and the second layer in response to expansion of the prosthetic heart valve compresses the fibers of the first layer relative to the spacing to create a paravalvular seal. For example, the Sapien 3 Ultra is designed using knitted PET with compressible fibers such that when compressed in response to expansion of the heart valve in the aorta, the fibers of the first layer are compressed together with the second layer relative to the spacings to help create a paravalvular seal.

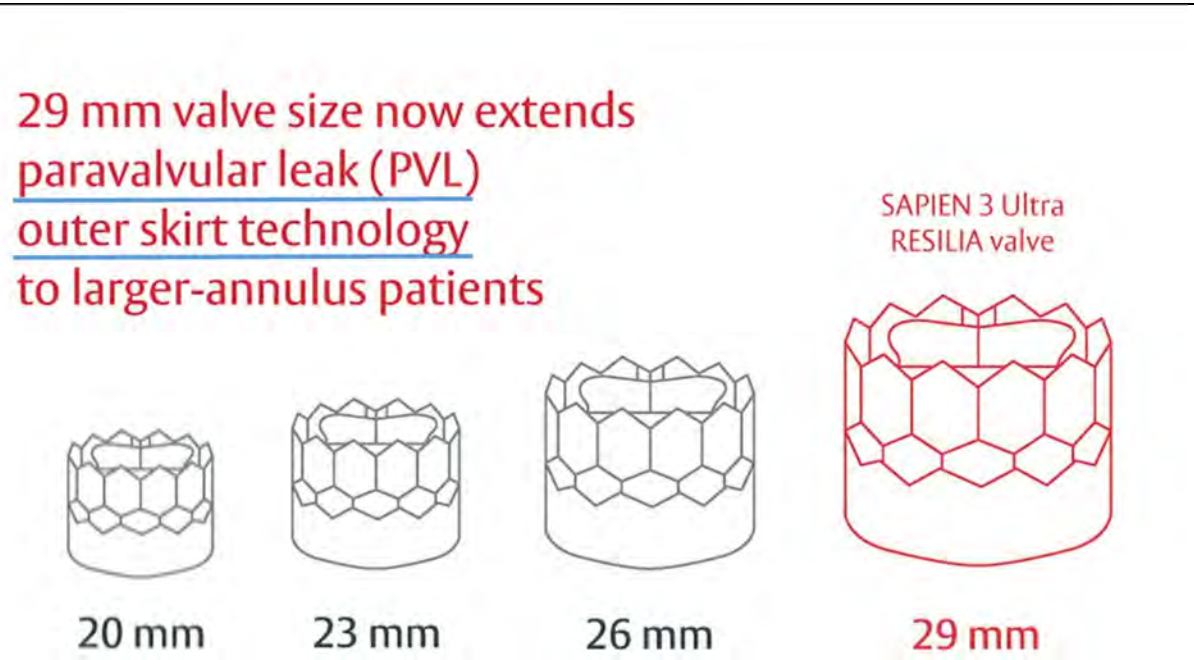
create a paravalvular seal.	 Introducing the SAPIEN 3 Ultra valve at 4 (annotated), available at https://scai-prod-public.s3.amazonaws.com/static/exhibit/20ex/down3ex17.pdf (D.I. 1, Ex. 46).

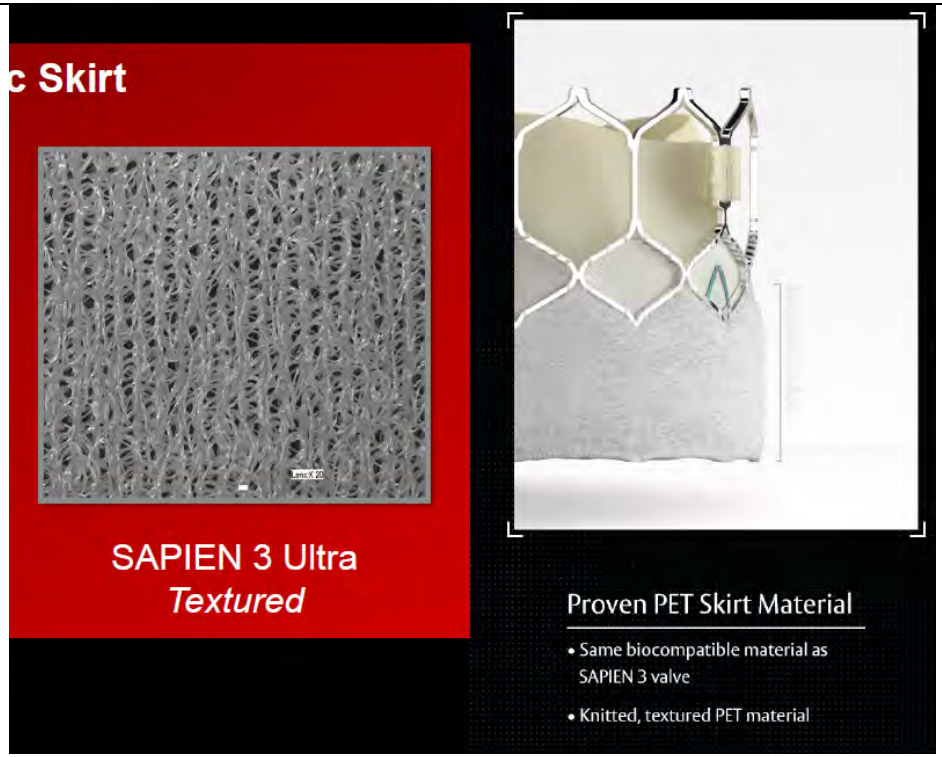


"TAVR Procedural Animation Using the SAPIEN 3 Ultra System," available at https://youtu.be/o3whx7CdM3I (D.I. 1, Ex. 37).

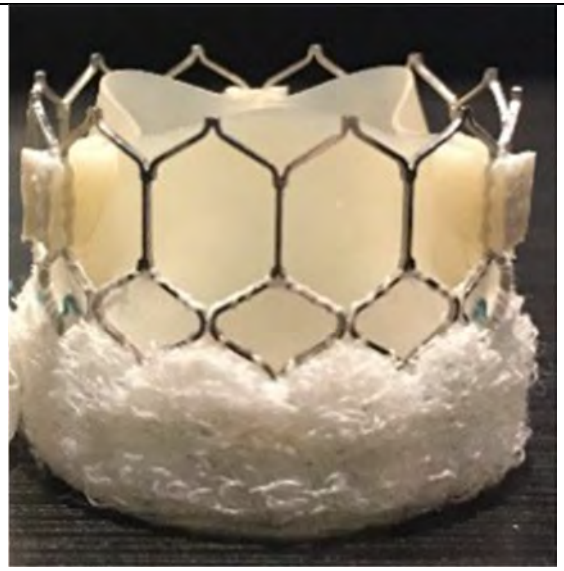


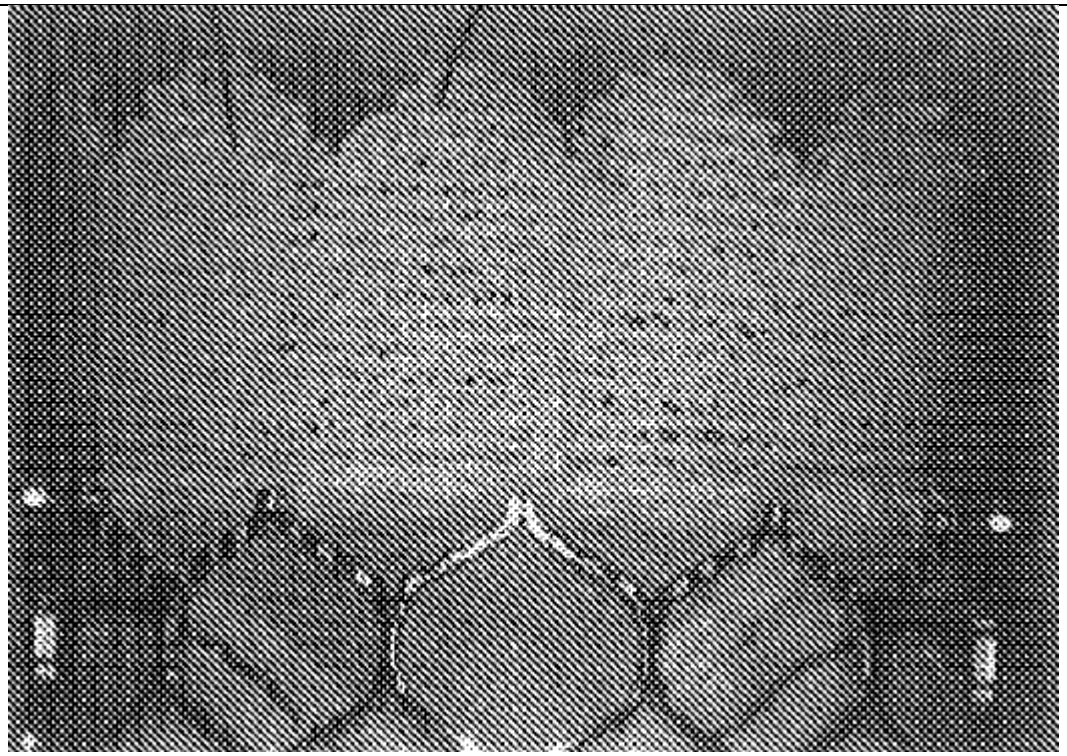
	Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).  https://s27.q4cdn.com/788244549/files/doc_downloads/2022/12/FORWARD-LOOKING-STATEMENTS-AND-DISCLAIMERS.pdf (D.I. 1, Ex. 63).

	 https://twitter.com/Edwards_TAVR/status/1605235347465576449?s=20&t=Jdnp88GteUKjcWvtm_OWcA
22. The valve assembly of claim 21, wherein the first layer and the second layer are distinct layers.	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities’ first layer and the second layer are distinct layers. For example, the Sapien 3 Ultra second layer is a mesh-like layer and the first layer described by Edwards as a textured/velour like layer.



Sapien 3 Ultra Valve First in Human Experience (D.I. 1, Ex. 47) (showing textured velour like layer)

	 Sapien 3 Ultra image by William Suh, MD at https://twitter.com/willsuh76/status/1280708440734617600/photo/1. (D.I. 1, Ex. 7) (showing textured velour like layer)	

	 U.S. Provisional Patent Application No. 62/513,348, Fig. 30 (showing mesh like layer on backside of sealing skirt). *See also*, claim 21.
26. The valve assembly of claim 21, wherein the frame is integrally formed.	The ’918 patent Accused Instrumentalities satisfy this element. For example, the ’918 patent Accused Instrumentalities’ frame is integrally formed. For example, the Edwards Sapien 3 Ultra frame is made of a cobalt-chromium metallic alloy in an integral form.

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.



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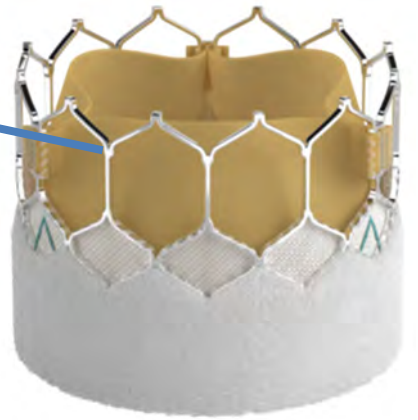
Figure 1. Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

Table 1

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

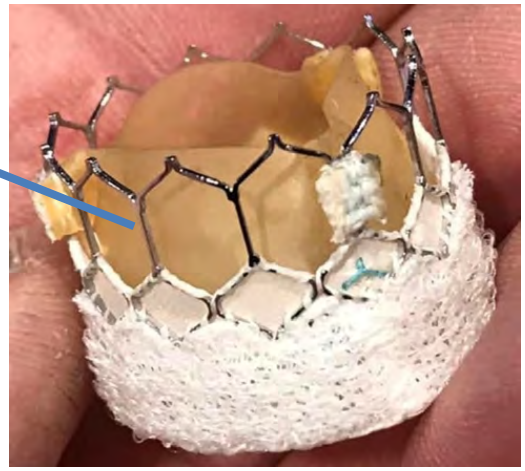
Sapien 3 Ultra Instructions for Use at 2 (D.I. 1, Ex. 44).

integrally formed frame

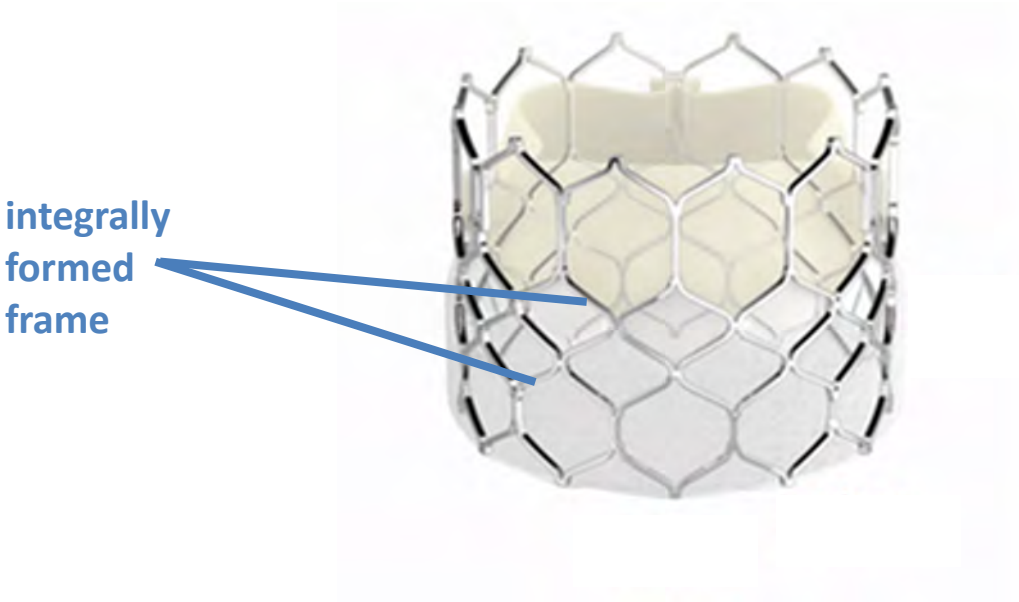


https://tavrbyedwards.edwards.com/why-edwards-tavr/ (D.I. 1, Ex. 61).

integrally formed frame



Cardiovascular Business LinkedIn Post Image of Edwards AHA 2022 Booth (D.I. 1, Ex. 3).

	 https://www.edwards.com/devices/heart-valves/transcatheter-SAPIEN-3-Ultra. (D.I. 1, Ex. 33). *See also*, claim 21.