Premarket Approval (PMA)

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

Device	Edwards SAPIEN 3, Ultra 3 Transcatheter Heart Valve
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered
Applicant	EDWARDS LIFESCIENCES, LLC. One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S102
Date Received	11/18/2019
Decision Date	04/10/2020
Product Code	NPT[24]
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track No User Fee
Supplement Reason	Location Change - Manufacturer/Sterilizer/Packager/Supplier
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval for a manufacturing site located at Edwards Lifesciences (Singapore) Pte. Ltd, 35 Changi North Crescent, Singapore 499641 SG, to receive and process bovine pericardial tissue sacs into treated tissue heart valve leaflets.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases

6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfpma/pma.cfm
23. /scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P140031&SupplementType=NONE
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&ProductCode=NPT

Page Last Updated: 07/19/2021

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/

February 22 is Heart Valve Disease Awareness Day. Take control of your severe aortic stenosis, the most common type of HVD, by using this Informed Discussion Guide.

Edwards TAVR

I'm Just Getting Started. Nothing Will

We know you want to be informed, empowered, and in control when making important decisions about treating your severe aortic stenosis. When it comes to choosing transcatheter aortic valve replacement (TAVR), or other treatment options, that means knowing which treatment option is best for you.

Put yourself in the driver's seat of your health. Talk to your doctor about your valve options today.



Don't Settle for Just Any Valve. Know the Differences

TAVR is available to more people than ever before. Learn about the features unique to Edwards TAVR and why having an Edwards valve matters.[1]

Explore Edwards Valves



Your Second Act Is Waiting. Edwards TAVR Can Help You Get There

Without aortic valve replacement, severe aortic stenosis is fatal. Luckily, you can experience a quicker recovery, a shorter hospital stay, and a faster return to activities with an Edwards TAVR valve, when compared to open heart surgery. Freedom from severe aortic stenosis means freedom to do more of what you love. Find out how an Edwards TAVR valve can help you get back to life quicker than open heart surgery.[2]

> Understand the Edwards Clinical Difference



Get Support and Resources to Live Your Best Life

From an interactive discussion guide and helpful websites to TAVR brochures and procedure videos—there are many resources available to help you throughout your TAVR treatment journey. Discover the many resources available to you as you embrace the next act in life.

View Edwards Resources

Next Page: Explore Edwards TAVR Valves

Explore Edwards TAVR valves and learn why they lead to better outcomes for patients.

Go to the Explore Edwards TAVR Valves page

References

1. The SAPIEN 3 and SAPIEN 3 Ultra valve are both commercially available in the United States. Your doctor will tell you which valve you will receive.

2. PARTNER 3 trial, low-risk cohort unadjusted clinical event rates, AT population.

COOKIE PREFERENCES

Important Risk Information

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

Potential risks associated with the procedure include:

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

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

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

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

© 2022 Edwards Lifesciences Corporation. All rights reserved.

Edwards

2020 Investor Conference

December 10, 2020



Opening Remarks

Michael A. Mussallem
Chairman and CEO

Edwards

Our Credo

Through our actions, we will become trusted partners with customers, colleagues, and patients – creating a community unified in its mission to improve the quality of life around the world. Our results will benefit customers, patients, employees and shareholders.

We will celebrate our successes, thrive on discovery, and continually expand our boundaries. We will act boldly, decisively, and with determination on behalf of people fighting cardiovascular disease.



At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease.

Helping Patients is Our Life's Work, and *life is now*

Our Aspirations



Edwards is a global leader dedicated to…

Fostering an **inclusive culture** where all employees grow and thrive

Transforming patient lives with **breakthrough** medical technologies

Excelling as a **trusted partner** through distinguished quality and integrity

Passionate engagement that strengthens our communities

Delivering exceptional **shareholder value**

Helping Patients Around the World



*Source: 2020 engagement survey results of global professional employees

Edwards
2021 and Beyond



2021 expected to be a year of significant growth and investment in our future

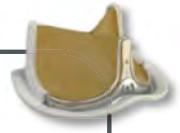
2021 Expectations

Mid-teens	**$2.00 - $2.20**
Underlying net sales growth	Adjusted EPS



TAVR

- Therapy expansion
- Technology advances
- Geographic expansion



Surgical

- Surgeon partnership
- Leading pipeline
- Growth segment focus



TMTT

- Differentiated portfolio
- Clinical evidence
- Real-world outcomes



Critical Care

- HemoSphere growth
- Smart technologies
- Portfolio expansion

2021 Product Group Milestones

THE EARLY TAVR TRIAL

EARLY TAVR Asymptomatic
Enrollment Completion



Japan TAVR
Low Risk Approval





INSPIRIS
China Launch



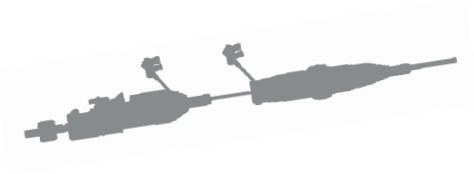
MITRIS
US and Japan Launch



Critical Care
Viewfinder
Connectivity
Solution



Alterra
Adaptive Prestent



Next Generation
PASCAL Delivery System
Initial Clinical Experience



Expanded
Launch
of KONECT



Launching
Moderate AS Trial



Next Generation
EVOQUE Mitral System
Initial Clinical Experience



SAPIEN X4
Clinical Trial Launch

Edwards' Executive Leadership Team



Michael Mussallem
Chairman & CEO



Donald Bobo, Jr.
Strategy & Corporate Development



Todd Brinton, M.D.
Chief Scientific Officer



Daveen Chopra
Surgical Structural Heart



Dirksen Lehman
Public Affairs



Jean-Luc Lemercier
EMEA, Canada and Latin America



Christine McCauley
Human Resources



Gary Sorsher
Quality, Regulatory, Clinical



Joseph Nuzzolese
Global Supply Chain



Arnold Pinkston
General Counsel



Katie Szyman
Critical Care



Scott Ullem
Chief Financial Officer



Huimin Wang, M.D.
Japan, Asia and Pacific



Larry Wood
Transcatheter Aortic Valve Replacement



Bernard Zovighian
Transcatheter Mitral & Tricuspid Therapies

Long-tenured expert healthcare executives

Highly strategic and collaborative team

Incentives aligned with shareholders



Edwards

Helping Patients is Our Life's Work, and *life is now*

2020 Investor Conference

Transcatheter Aortic Heart Valves

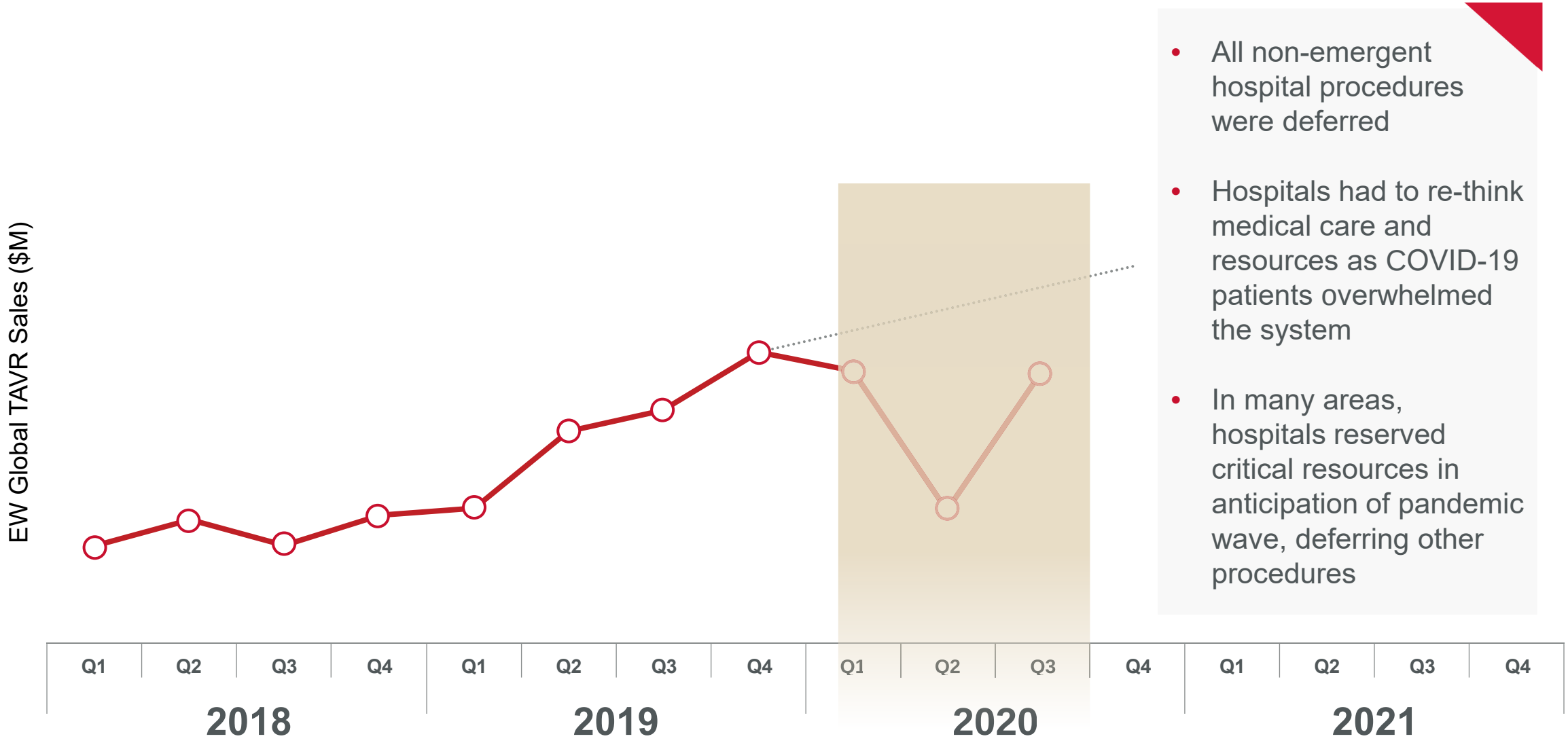
Edwards

We entered 2020 with strong momentum on a path to exceed our goals…



- PARTNER 3 results demonstrated SAPIEN 3 is the only valve superior to surgery
- Low-risk approval in U.S. and EU
- In U.S., revised NCD drove therapy access
- Strong trajectory in the first 10 weeks of 2020

t.. hen the pandemic hit



- All non-emergent hospital procedures were deferred
- Hospitals had to re-think medical care and resources as COVID-19 patients overwhelmed the system
- In many areas, hospitals reserved critical resources in anticipation of pandemic wave, deferring other procedures

But we did not stop…

Severe Aortic Stenosis is a deadly disease

Severe AS patients' mortality rates increase drastically as patients wait for treatment

Helping patients remains our top priority



We remain laser focused on patient care and clinical partnership

Edwards data on file; 2020 Q4 and 2021 internal range estimates. Forecast is an illustration and not to scale.

Bicuspid precaution removed

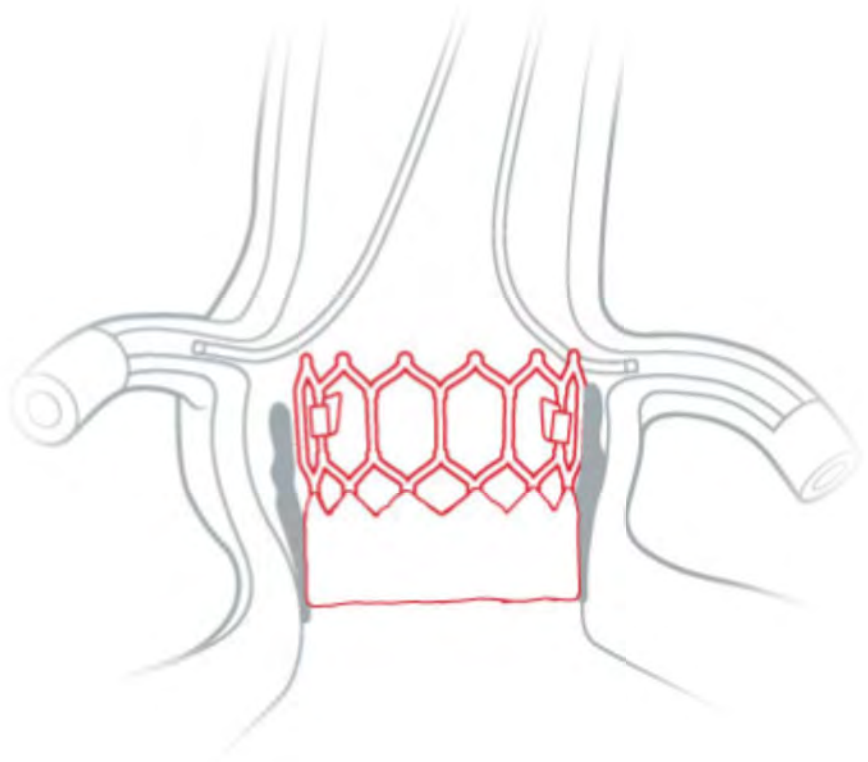
Provides further confidence for low risk, younger patients

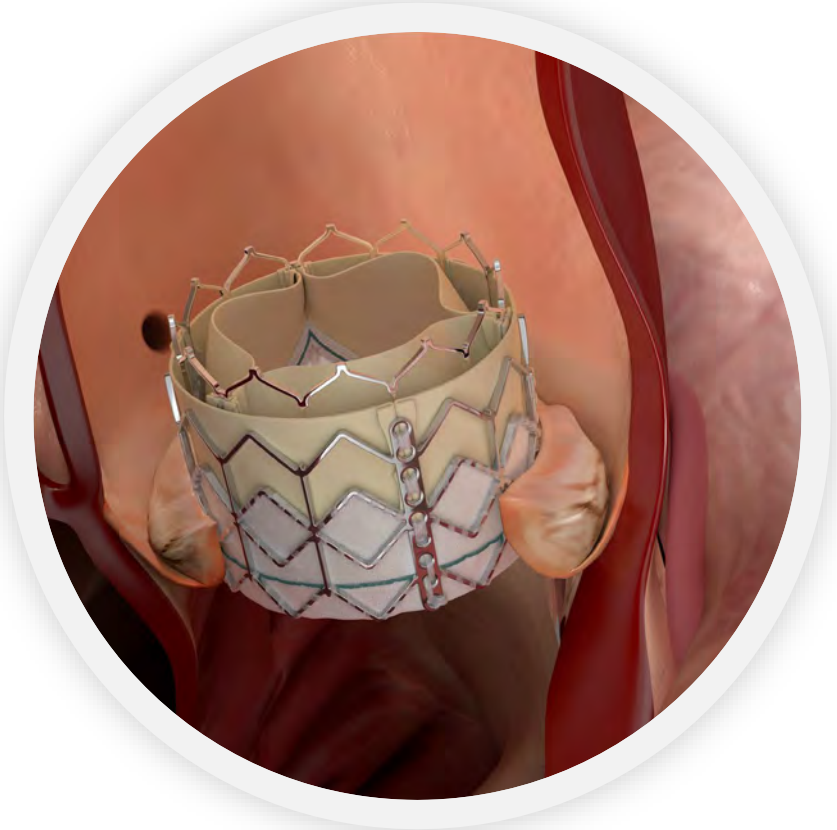


Low rates of complications that matter most to bicuspid patients[1]		
CEC-adjudicated Event	30 Days (n=71)	1 Year (n=71)
All-cause mortality	0%	1.4%
All stroke	2.8%	2.8%
Disabling stroke	0%	0%
New permanent pacemaker	9.9%	11.3%
Moderate/severe PVL	1.4%	0%

1. PARTNER 3 bicuspid nested registry analysis
2. FDA precaution removal letter dated 22nd July 2020

Edwards SAPIEN 3 TAVR Now Approved for TAVR-in-TAVR Indication





Provides long-term treatment option for patients with AS and reflects our dedication to long-term care

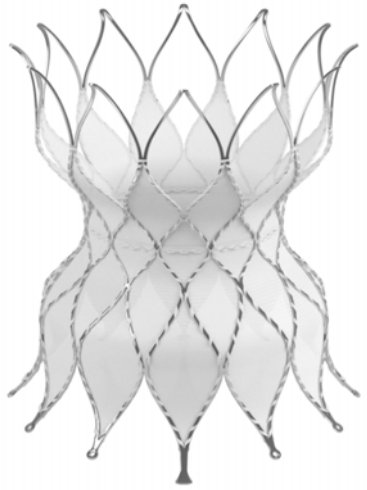
Expanding Options for Congenital Pulmonic Heart Disease Patients

- SAPIEN 3 now approved for pulmonic patients (direct valve replacement)
- Alterra Adaptive Prestent and SAPIEN 3 Pulmonic System expands therapy
- Alterra U.S. Approval anticipated in 2H 2021



SAPIEN 3 Valve

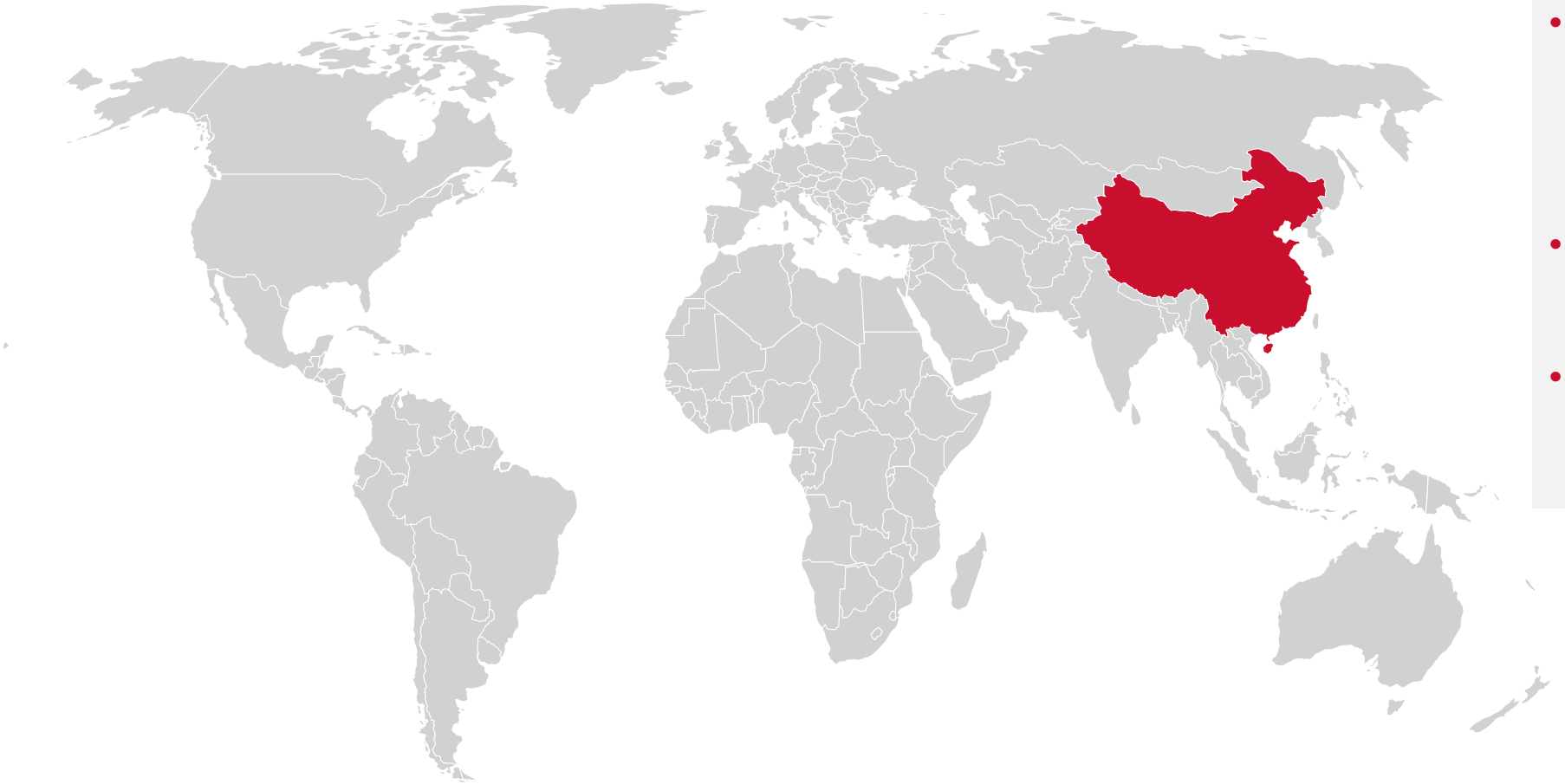
+



Alterra Adaptive Prestent

Congenital Pulmonary Valve disease is a serious issue, and these patients have unique challenges

SAPIEN 3 Now Approved in China For High Risk Patients



- Focused on establishing strong relationships to become the trusted clinical partner
- Patient outcomes remain the priority
- Contributor to long-term growth



The COVID-19 experience helped to inform our future



- Patients with Aortic Stenosis don't wait well, and TAVR is an essential procedure
- High-touch model remains valued
- We expect hospitals to adapt to local outbreaks and prioritize structural heart procedures until the pandemic subsides
- TAVR outcomes and efficiencies will continue to be highly valued

Data from New York City and Switzerland demonstrate risks of waiting

In the first study from New York City, 10% of patients awaiting aortic valve replacement at a busy structural heart program ended up undergoing urgent TAVR or died during in the first 30 days after elective procedures were halted. By 3 months, more than one-third of patients affected by the ban on elective procedures required an urgent intervention or died, the vast majority sent for TAVR because of worsening symptoms.



Across the pond, Swiss researchers reported that nearly one in five patients scheduled for aortic valve replacement who had the procedure delayed reported to hospital with valve-related symptoms or worsening heart failure. Thomas Pilgrim, MD (Bern University Hospital), senior researcher of the prospective Aortic Stenosis Defer (AS-DEFER) study, said elective procedures were halted in Switzerland on March 20, 2020, but they knew they'd have to take on selected patients given their risk.



"TAVR Delays During Pandemic's Peak Led to Hospitalizations, Deaths", www.tctmd.com, Sept 30, 2020

PARTNER 3 Best-in-Class Outcomes

99%
Freedom from death and disabling stroke at 1 year

96%
of patients discharged home

90%
did not need to be rehospitalized within 2 years

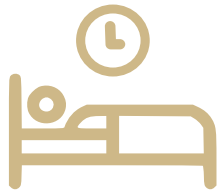


Low pacemaker rates

Low rates of PVL

PVL: Paravalvular Leak

Edwards' TAVR allows hospitals to treat patients with confidence



Low complication rates



Short length-of-stay



Patients discharged home

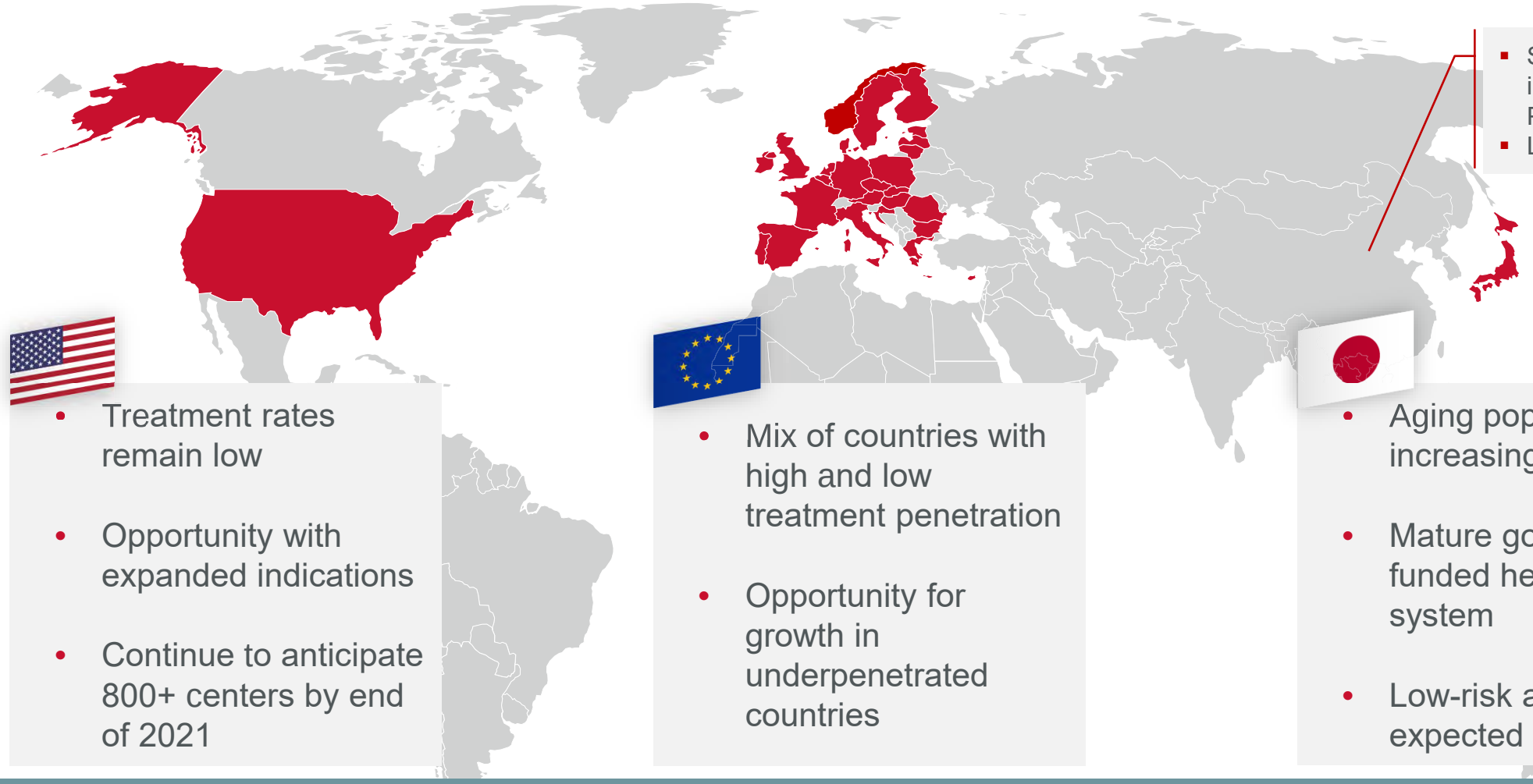


Low re-hospitalization rates



TAVR has become a healthcare priority and Edwards' TAVR advantage is now stronger than ever

TAVR fundamentals remain strong in developed markets around the world



- SAPIEN 3 now approved in China For High-Risk Patients
- Long-term opportunity

- Treatment rates remain low
- Opportunity with expanded indications
- Continue to anticipate 800+ centers by end of 2021

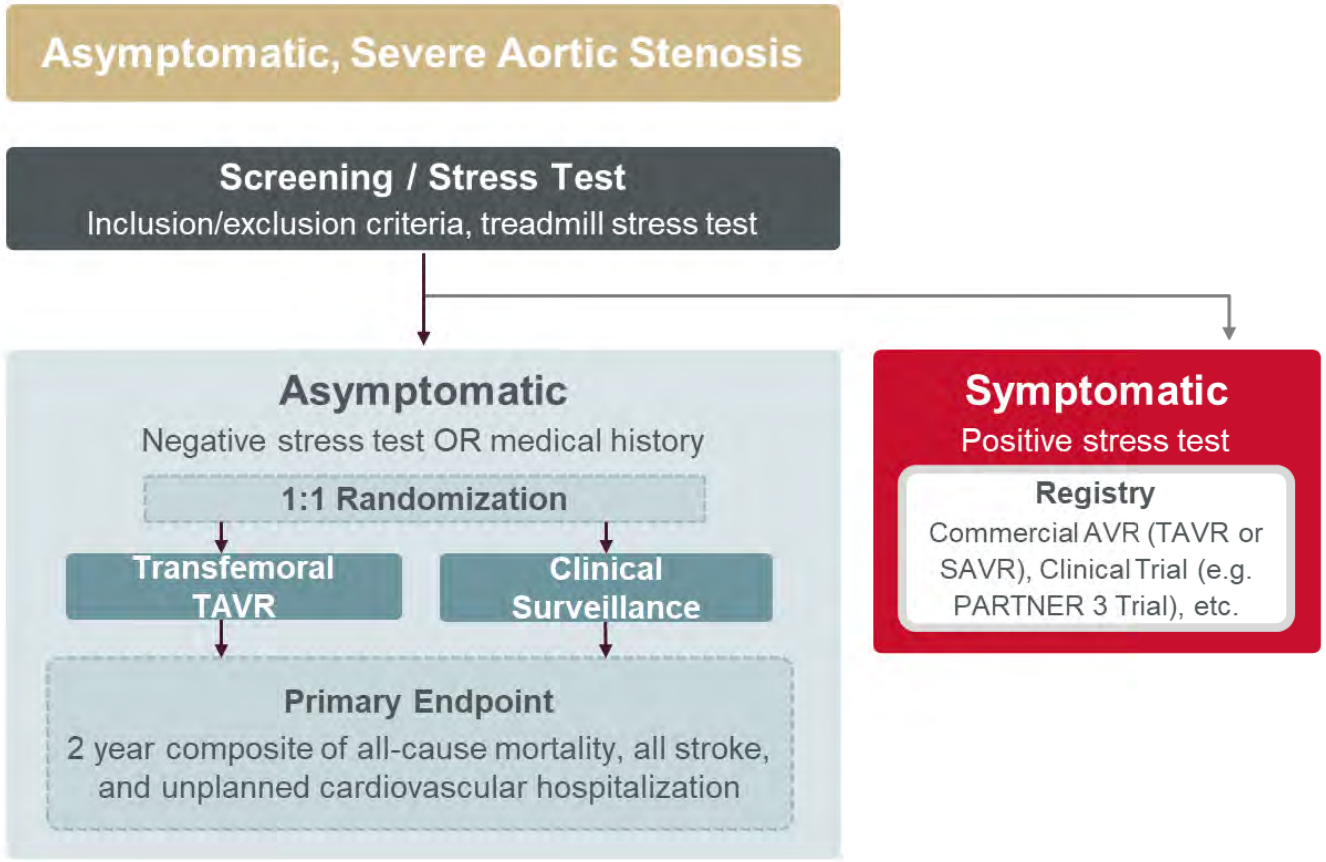
- Mix of countries with high and low treatment penetration
- Opportunity for growth in underpenetrated countries

- Aging population increasing rapidly
- Mature government-funded healthcare system
- Low-risk approval expected in 2021

We Continue to Expect the Global TAVR Market Opportunity to Exceed $7B by 2024

Asymptomatic and Moderate Risk Clinical Trials

Expected to add significant growth beyond 2024



- Beyond Severe Aortic stenosis, we believe our TAVR therapy may benefit patients with Moderate Aortic Stenosis
- Currently working closely with KOLs on a pivotal trial design

Anticipate completion of EARLY TAVR enrollment in 2021

Anticipate FDA approval to start the Moderate AS trial in 2021

Our portfolio is constantly evolving



SAPIEN 3



SAPIEN 3 Ultra

U.S. and EU launches evolutionary advancements

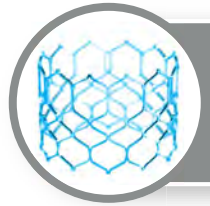


Next-Generation



SAPIEN X4

Clinical work expected to begin in U.S. in 2021



Revolutionary platform

Executive Summary

- **Aortic Stenosis is a deadly disease** and timely treatment is paramount
- Globally, **diagnosis and treatment rates of AS remain low** providing opportunity for low-double digit TAVR growth long-term
- We have **learned from the pandemic** and Edwards' TAVR therapy **fundamentals remain strong**
- Continued **investment in groundbreaking trials** beyond severe symptomatic aortic stenosis and transformational technologies to treat patients



Edwards

Helping Patients is Our Life's Work, and *life is now*

2020 Investor Conference

Surgical Structural Heart

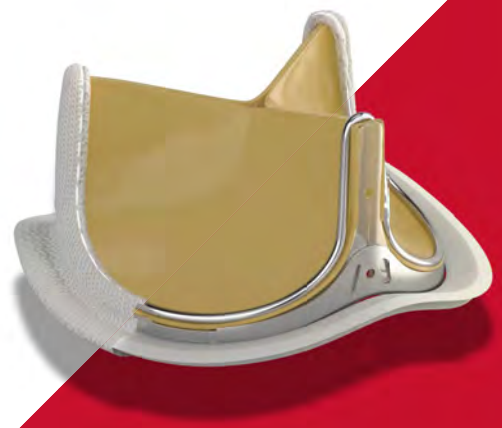
Edwards

Surgical Structural Heart brings leading innovation

- Current $1.8B surgical structural heart market expected to grow **mid-single digits through 2026**

- **We extended our leadership** as the partner of choice for cardiac surgeons with three product launches in 2020

- **We continue to bring life-saving surgical innovation** to patients best-treated surgically



Surgical aortic cases continue to grow in segments and emerging regions with less TAVR impact

Surgical Aortic Procedures (U.S. & EU)

Growth (20-26)

- **Isolated ssAS[1]** ↓
- **Combined ssAS[1]** ↘
- **Combined Moderate AS** →
- **Severe Aortic Regurgitation** →

2020E

Aortic Patients Best Treated Surgically



Younger, active patients who do not want the burden of anticoagulation



Patients with complex disease who require combined procedures



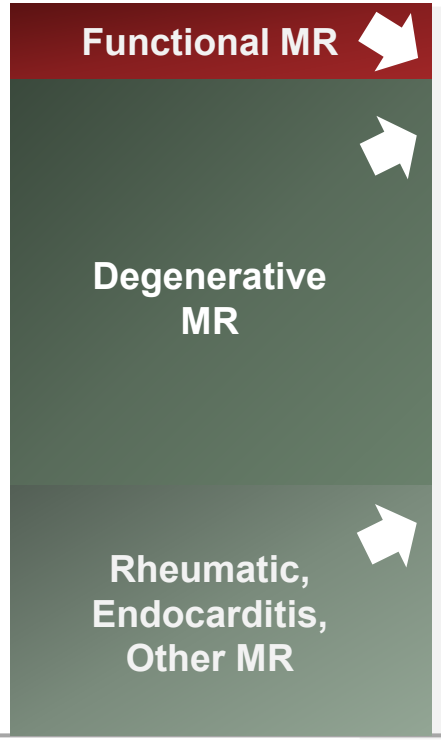
Patients with aortic regurgitation who require a surgical approach

[1] Severe Symptomatic Aortic Stenosis

Less than 2% of mitral valve disease patients are treated today, with minimal transcatheter cannibalization

Surgical Mitral Procedures (U.S. & EU)

Growth (20-26)



Mitral Patients Best Treated Surgically



Surgical low risk degenerative patients where surgery remains the gold standard



Patients with complex disease who require combined procedures



Patients with rheumatic or endocarditis diseases who require a surgical approach

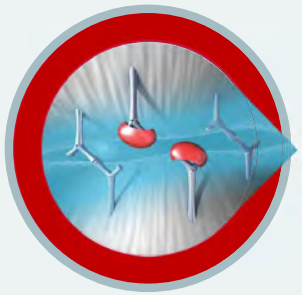
We continue to generate robust clinical evidence for our leading RESILIA tissue technology

RESILIA Tissue Technology

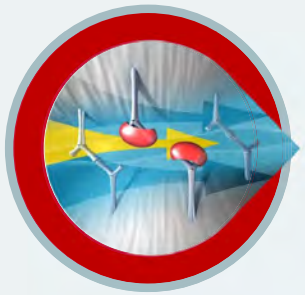
Anti-calcification to improve tissue durability



Residual aldehydes on tissue attract calcium



RESILIA permanently caps residual aldehydes



Capped aldehydes block calcium

Long-Term RESILIA Tissue Clinical Evidence

EU Feasibility Study

133 patients across 2 centers in Poland

5yr follow-up showed 0% structural valve deterioration (SVD)

COMMENCE Aortic

694 patients across 27 centers in U.S. & Poland

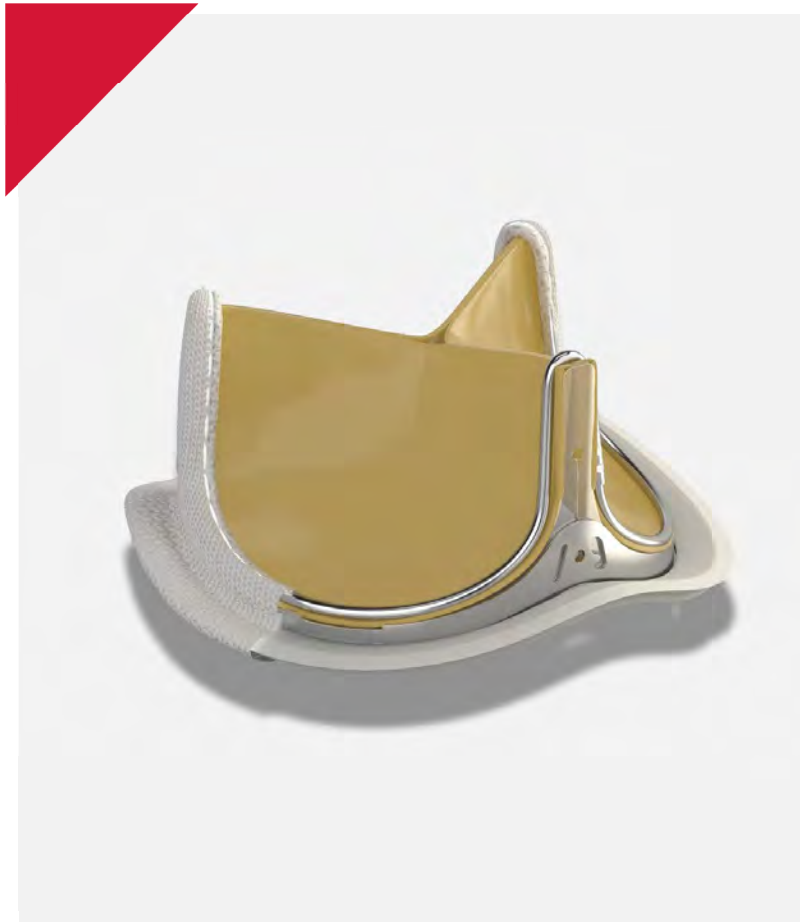
4yr follow-up showed 0% SVD 5yr outcomes in early 2021

RESILIENCE

Long term follow up in <65 year old COMMENCE aortic patients

Follow-up through 11yrs

INSPIRIS is now the leading aortic surgical valve in the world



- **Provides RESILIA tissue and VFit technology** for potential future valve-in-valve procedures
- **#1 implanted aortic surgical valve** in the U.S. and Japan, **launching in China in 2021**
- **Continuing adoption** across U.S. and Europe

KONECT addresses key unmet needs of patients and drives growth in 2021



- **Launched in the U.S. in June 2020** as the first pre-assembled, ready-to-implant tissue conduit
- Designed for **complex aortic valve patients with combined aortic root disease**
- **Impacts ~7,500 surgical procedures annually in the U.S.**, growing in the high single-digits

MITRIS is designed for active mitral patients who might otherwise receive a mechanical valve



- **Differentiating RESILIA tissue, ease-of-use enhancements**, and valve-in-valve compatibility
- **Growth opportunity** as 60% of global mitral valve replacement patients receive a mechanical valve
- **Launching in the U.S. and Japan in 2021**

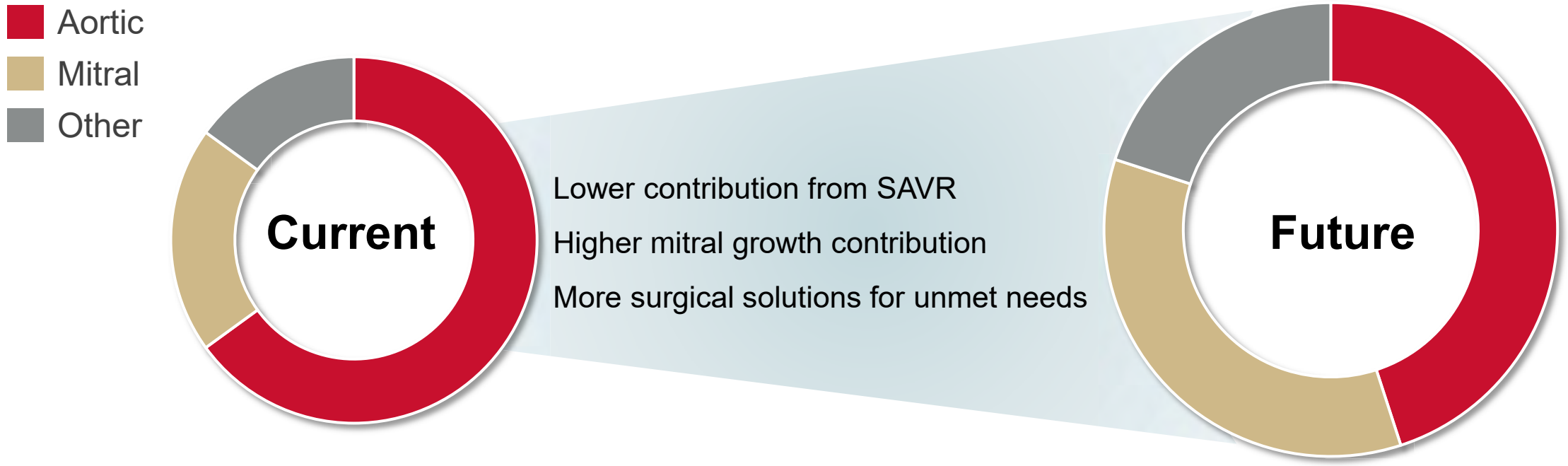
HARPOON transforms surgery for many patients with degenerative mitral regurgitation



- Standardizing mitral repair with an **echo-guided, beating-heart procedure**
- **Launched in 2020** with potential to convert ~20k surgical repair patients across the U.S., Europe, and Japan
- **Started the RESTORE U.S. pivotal trial,** a unique, non-randomized study with a one-year endpoint

Our strategy will provide a balanced portfolio and will extend patient impact

Surgical Structural Heart Revenue by Segment



Executive Summary



- The **Surgical Structural Heart market is forecast to grow** in areas with unmet patient needs

- Our **innovation strategy focuses on transforming surgical patients' lives** with life-saving surgical technologies



Edwards

Helping Patients is Our Life's Work, and *life is now*

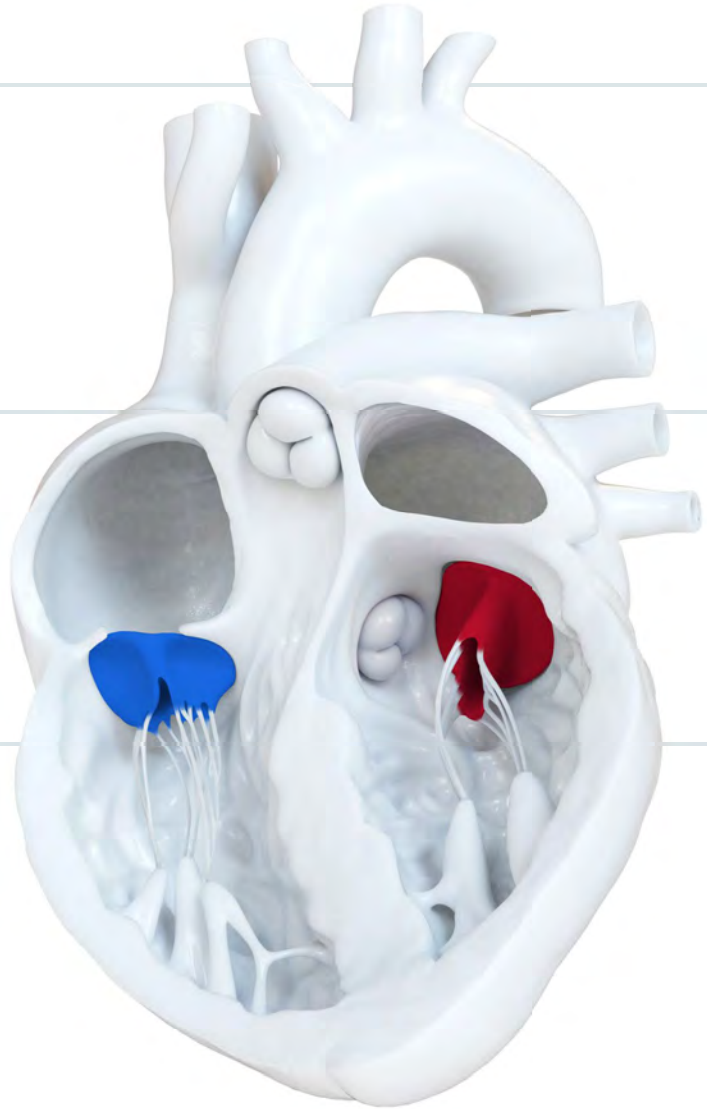
2020 Investor Conference

Transcatheter Mitral and Tricuspid Therapies

Edwards

TMTT is innovating a broad transcatheter portfolio

	TRICUSPID		MITRAL	
Leaflet Repair	 PASCAL	 PASCAL Ace	 PASCAL	 PASCAL Ace
Annular Reduction	 Cardioband			 Cardioband
Valve Replacement	 EVOQUE		 SAPIEN M3	 EVOQUE



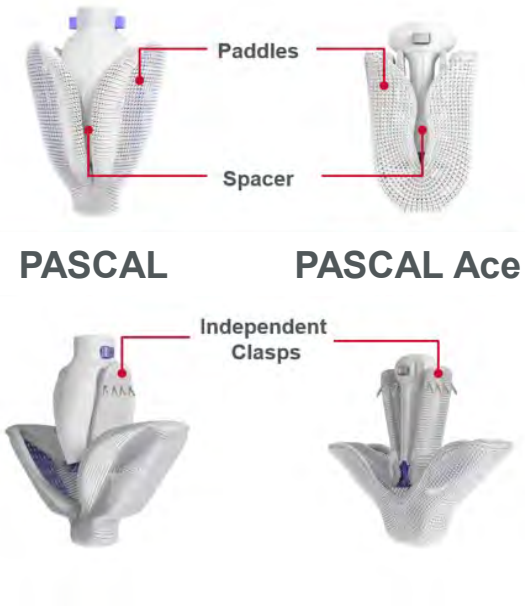
Mitral Innovations: PASCAL for Leaflet Repair



PASCAL Ace

CE Marked in 2020

New implant with **narrower profile** and spacer to achieve optimal outcomes for more patients



PASCAL & PASCAL Ace share **differentiated features**

A **nitinol design** to allow strong and yet flexible closure

A **central spacer** to bridge the coaptation gap and prevent backflow across the valve

The **ability to elongate** the device to navigate dense chords

Independent clasps, which can be used without restriction, to optimize MR reduction

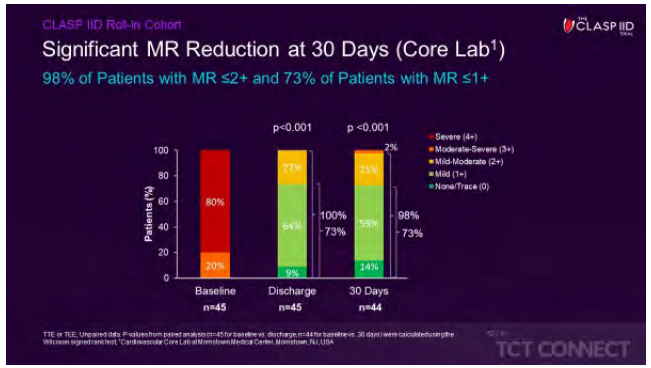
Bringing a consistent cadence of advancements to the PASCAL platform, including a next-gen delivery system in 2021

High rates of MR reduction are achieved with PASCAL, starting from physicians' earliest experience

CLASP IID Roll-In Data

73%

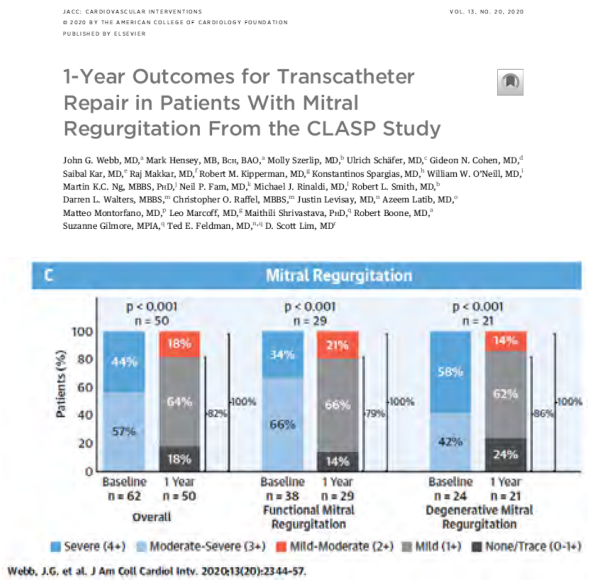
Percentage of patients with ... ≤0/1+ at 30 days [1]



CLASP CE Mark Study

82%

Percentage of patients with MR ≤0/1+ at 1 year[2]


JACC: CARDIOVASCULAR INTERVENTIONS VOL. 13, NO. 20, 2020
© 2020 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER

1-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study

John G. Webb, MD,[a] Mark Hensey, MB, BCh, BAO,[a] Molly Szerlip, MD,[b] Ulrich Schäfer, MD,[c] Gideon N. Cohen, MD,[d] Saibal Kar, MD,[e] Raj Makkar, MD,[f] Robert M. Kipperman, MD,[g] Konstantinos Spargias, MD,[h] William W. O'Neill, MD,[i] Martin K.C. Ng, MBBS, PhD,[j] Neil P. Fam, MD,[k] Michael J. Rinaldi, MD,[l] Robert L. Smith, MD,[b] Darren L. Walters, MBBS,[m] Christopher O. Raffel, MBBS,[m] Justin Levisay, MD,[n] Azeem Latib, MD,[o] Matteo Montorfano, MD,[p] Leo Marcoff, MD,[q] Maithili Shrivastava, PhD,[r] Robert Boone, MD,[s] Suzanne Gilmore, MPIA,[t] Ted E. Feldman, MD,[u,v] D. Scott Lim, MD[t]

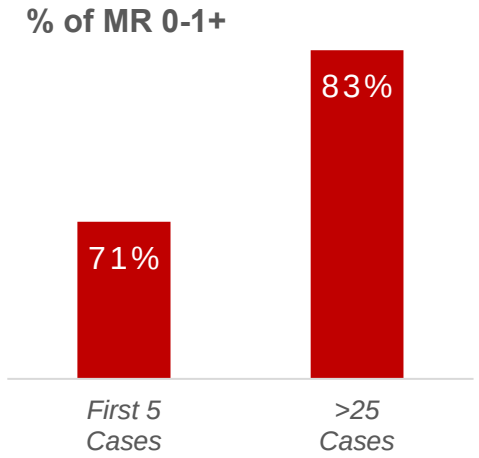
Webb, J.G. et al. J Am Coll Cardiol Intv. 2020;13(20):2344-57.

Real-World Experience

83%

Percentage of patients with MR ≤0/1+ at discharge[3]

after 25 case experience



Expect a steady cadence of evidence from CLASP, CLASP IID/IIF, and post market studies

1. Lim, TCT Connect, 2020; 2. Webb, JACC: Cardiovascular Interventions, 2020 3. Edwards data on file

Mitral Innovations: Two-platform strategy positions TMTT for transfemoral replacement leadership



SAPIEN M3

Leverages the **proven SAPIEN valve**, coupled with a novel docking system



EVOQUE

Delivers a **dedicated mitral valve replacement** therapy

Both transfemoral delivery systems are

<30F

ensuring **safety and ease-of-use** during femoral puncture and septal crossing

"The **strength of the Edwards mitral program is the diverse portfolio**…
to be able to treat a wide range of patients percutaneously and be able to discharge them as soon as the next day."

Dr. Raj Makkar
Cedars-Sinai Medical Center



We have initiated the ENCIRCLE pivotal study for SAPIEN M3, and will begin clinical experience with our next generation EVOQUE mitral system early next year

Innovations & Evidence In Tricuspid Repair



PASCAL

Differentiated leaflet repair leverages mitral platform



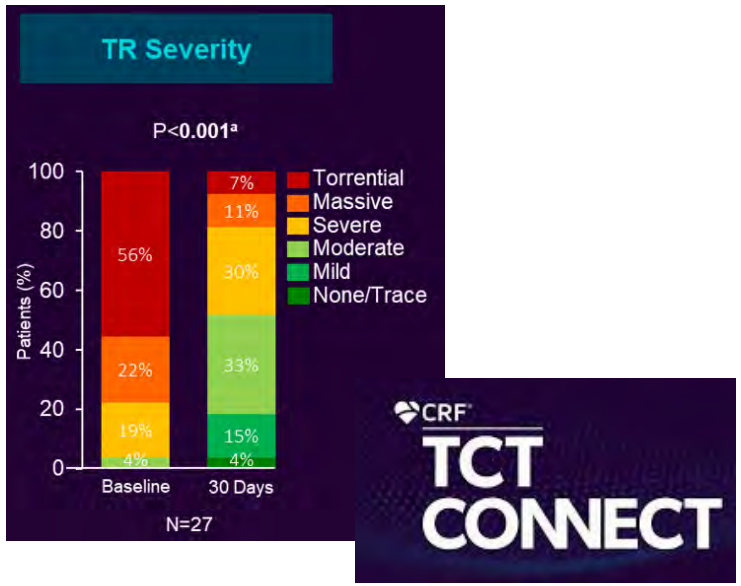
Cardioband

Strong and durable results to 2 years; investing in next generation system

PASCAL: CLASP TR EFS Study

70%

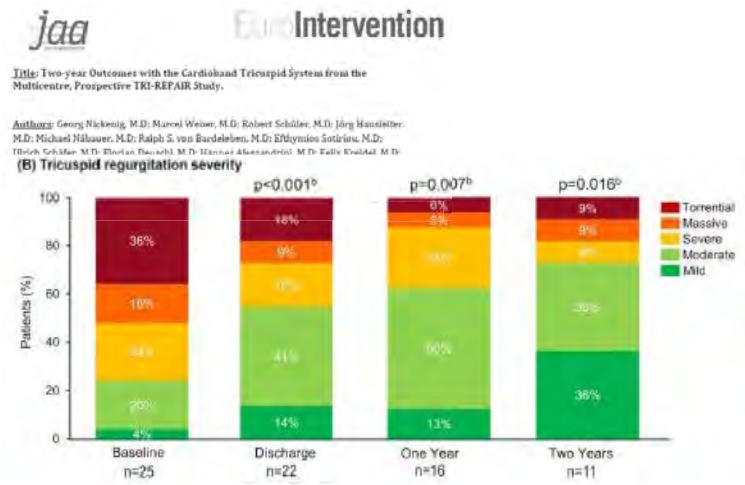
Percentage of patients with ≥ 2 TR grade reduction[1]



Cardioband: Tri-Repair CE Mark Study

72%

Percentage of patients with TR ≤ moderate at 30 days[2]



Experience with next generation PASCAL expected next year

1. Davidson, TCT Connect, 2020; 2. Nickenig, EuroIntervention, 2020

Innovations & Evidence In Tricuspid Valve Replacement



EVOQUE

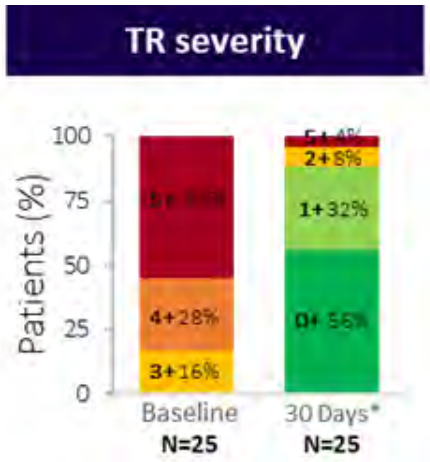
Tricuspid platform with three valve sizes to address diverse tricuspid anatomy

All three valves use the same <30F **transfemoral delivery** system

EVOQUE Compassionate Use

88%

Percentage of patients with TR ≤0/1+ at 30 days[1]



*Mean TV gradient: 3.2 ± 0.6 mmHg

Average procedure time of ~1 hour

2020 PCR e-Course

*"Having **all of these options** simultaneously in your toolbox **expands dramatically the number of patients you are able to treat."***

Dr. Stephan vonBardeleben

Heart Valve Center, Mainz Germany



Initiating the TRISCEND II randomized pivotal study based on the FDA's breakthrough designation pathway

1. Fam, Euro PCR, 2020

A dedicated team of talented people executing our high touch model to deliver outstanding patient outcomes

The TMTT high touch model

- Commitment to initial and ongoing physician training
- Highly trained clinical specialists providing full case coverage and support



Transforming treatment for patients with mitral and tricuspid valve disease to change standard of care

What to expect from TMTT in 2021

Additional Innovations

Continued innovations on each platform

Initial clinical experience with our:

- Next generation EVOQUE Mitral System
- Next generation PASCAL Delivery System

Clinical Evidence

Expanding our body of **clinical evidence**, including:

- Continued enrollment in our 5 pivotal trials
- Meaningful follow-up data publications and presentations across the portfolio

TMTT Revenue

Doubling TMTT revenue led by PASCAL and PASCAL Ace for both mitral and tricuspid patients

And in late 2022 – expect U.S. approval for PASCAL DMR and EU approval for EVOQUE Tricuspid

Executive Summary



- Patients with Mitral and Tricuspid regurgitation **remain undertreated** and suffer from poor quality of life
- TMTT is delivering a **portfolio of therapies, backed by clinical evidence**, to address the diversity and complexity of Mitral and Tricuspid disease
- **Doubling revenue** in 2021



Edwards

Helping Patients is Our Life's Work, and *life is now*

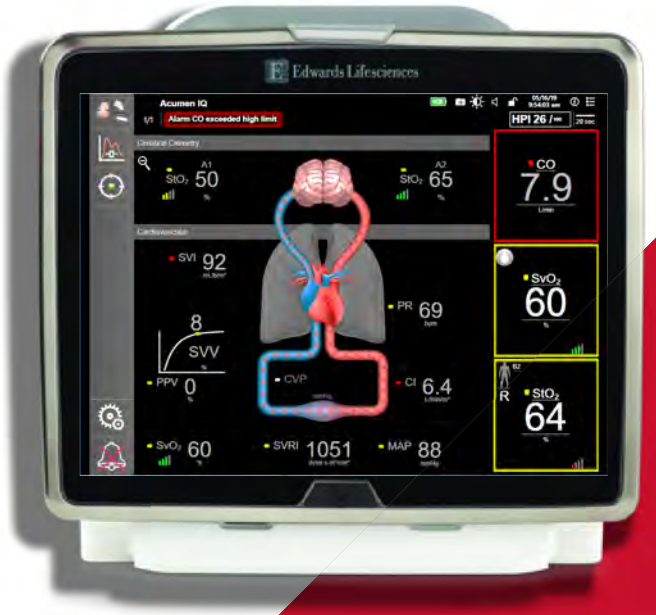
2020 Investor Conference

Critical Care

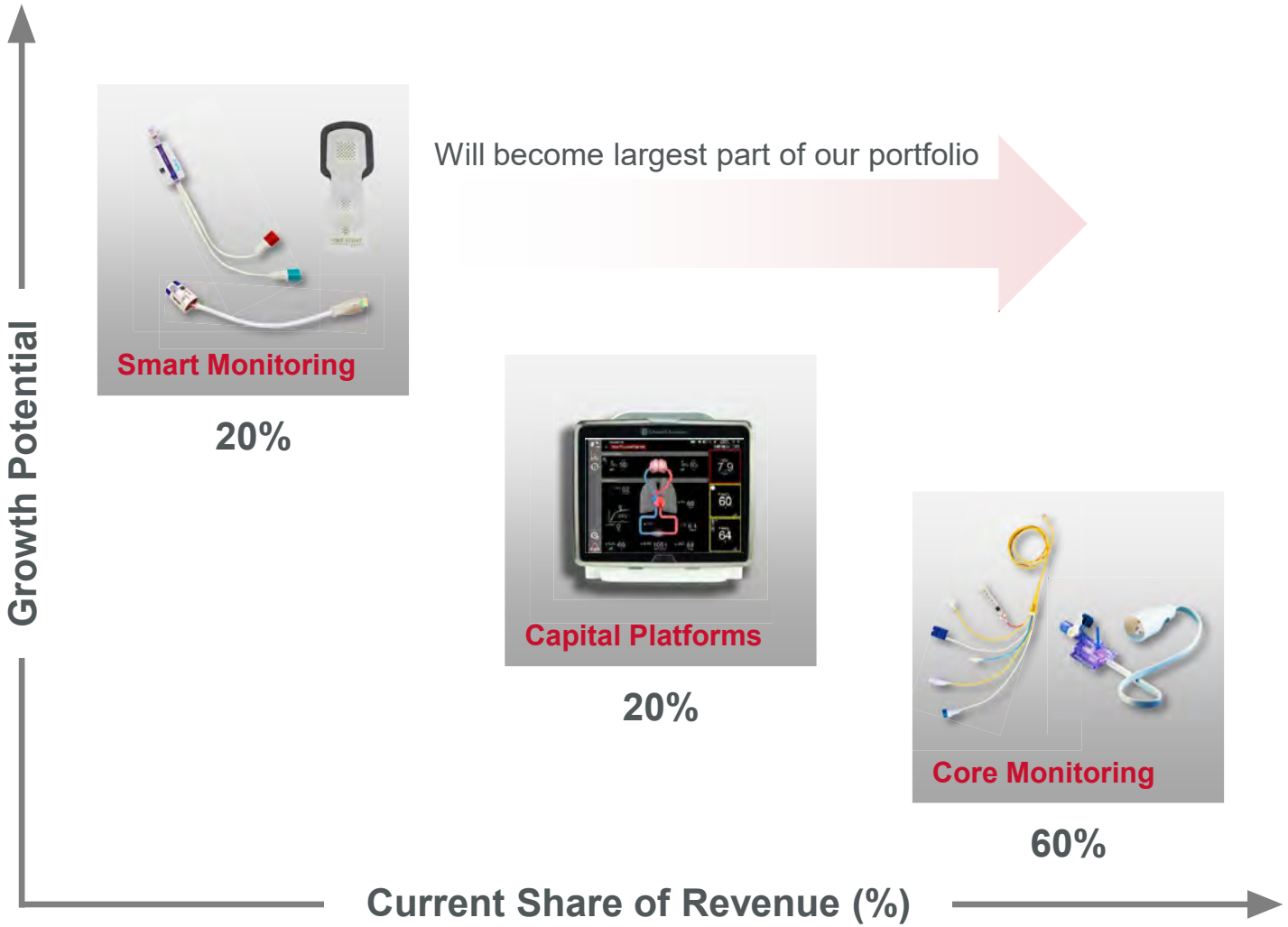
Edwards

Critical Care improving the quality of care for patients

- Continuing to **shift product mix** towards Smart Recovery, which has **highest growth** potential of our product groups
- Focusing on three **key building blocks** to advance Smart Recovery patient penetration from **5% to 15% by 2026**
- Deploying **right technologies**, generating **clinical evidence** and creating **product awareness** to drive us towards our goal



We are shifting focus of business to Smart Recovery



- Will **shift mix towards Smart Recovery**, which has highest growth potential
- This will lead to Smart Recovery becoming **largest part of our portfolio**
- **Core monitoring** largest contributor to overall revenue
- Core monitoring products support clinical efforts in fight against COVID

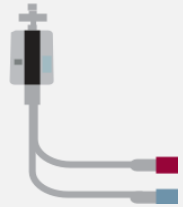
Having the Right Technologies Deployed in Hospitals

CAPITAL PLATFORM



HemoSphere

SENSORS



Acumen IQ Sensor



ForeSight



Acumen IQ Cuff

SOFTWARE

Hypotension Prediction Index (HPI)



Viewfinder
Remote View



Long-term growth can only be accomplished if we have our advanced monitoring platform in place

Generating Compelling Clinical Evidence

Intraoperative Hypotension (IOH) Matters

Both studies demonstrate IOH linked to:

Acute kidney injury	Myocardial injury	30-day mortality

Intraoperative hypotension and the risk of postoperative adverse outcomes: a systematic review

E. M. Wesselink[1,*], T. H. Kappen[1], H. M. Torn[1], A. J. C. Slooter[2] and W. A. van Klei[1]

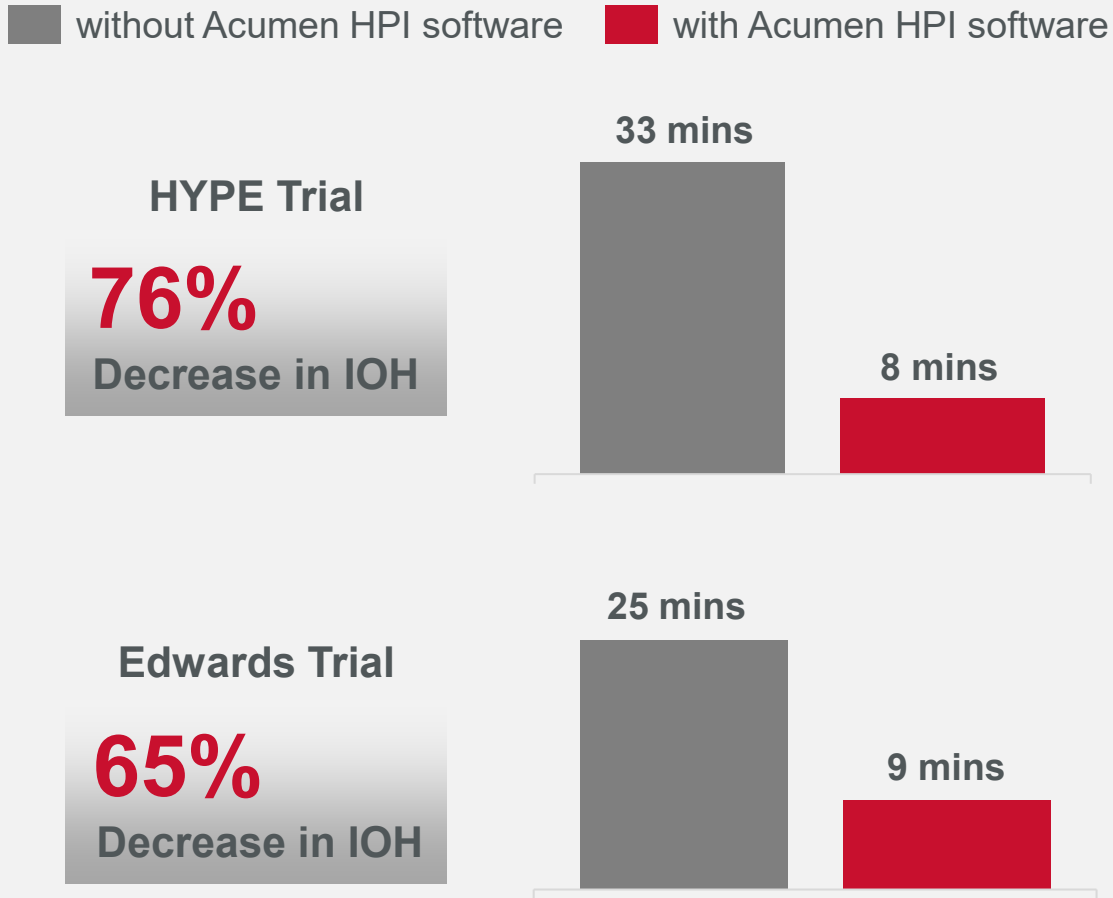
[1]Department of Anesthesiology, Utrecht, The Netherlands and [2]Department of Intensive Care Medicine, University Medical Center Utrecht, Utrecht University, Utrecht, The Netherlands

ORIGINAL CLINICAL RESEARCH REPORT

Intraoperative Hypotension Is Associated With Adverse Clinical Outcomes After Noncardiac Surgery

Anne Gregory, MD, MSc, FRCPC,* Wolf H. Stapelfeldt, MD,† Ashish K. Khanna, MD, FCCP, FCCM,‡§ Nathan J. Smischney, MD, MSc,‖ Isabel J. Boero, MD, MS,¶ Qinyu Chen, MS,¶ Mitali Stevens, PharmD, BCPS,# and Andrew D. Shaw, MB, FRCPC*,**

Edwards HPI Software Can Reduce IOH



Creating Awareness for our Products Through Evidence



"HPI was high…and 10 minutes later there was hypotension. I didn't see it coming at all."

– Simon Davies, MD MBChB FRCA



"We were able to decrease the rate of hypotension by about 50%, which is quite impressive I think."

– Michael Sander, MD, PhD



"My doctor said to me, 'I can do anesthesia in a special way using Acumen HPI.' Now, thank God, I can walk again."

– Juan Gil Garcia, HPI Patient



We believe the increased evidence around hypotension will drive awareness

Executive Summary

- Shift product mix towards **higher growth Smart Recovery**
- Advance Smart Recovery **penetration from 5% to 15%**
- Implement building blocks: **technology, evidence, awareness**



Edwards

Helping Patients is Our Life's Work, and *life is now*

Financial Outlook

Scott Ullem
Chief Financial Officer

Edwards

Edwards has delivered strong financial performance



Operating performance drives adjusted EPS growth



Edwards Financial Objectives



ROBUST CASH FLOW AND DISCIPLINED CAPITAL DEPLOYMENT

- Enables aggressive R&D investments
- Internal growth supplemented by smaller strategic acquisitions
- Investing in expanding global capacity
- Commitment to returning capital to shareholders through opportunistic share repurchase

Edwards Financial Objectives





Edwards

Helping Patients is Our Life's Work, and *life is now*

Closing Remarks

Michael A. Mussallem
Chairman and CEO

Edwards

2021 expected to be a year of significant growth and investment in our future

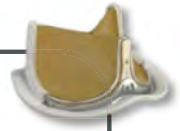
2021 Expectations

Mid-teens	$2.00 - $2.20
Underlying net sales growth	Adjusted EPS



TAVR

- Therapy expansion
- Technology advances
- Geographic expansion



Surgical

- Surgeon partnership
- Leading pipeline
- Growth segment focus



TMTT

- Differentiated portfolio
- Clinical evidence
- Real-world outcomes



Critical Care

- HemoSphere growth
- Smart technologies
- Portfolio expansion

Edwards' Board is diverse and accomplished


Michael A. Mussallem


Kieran T. Gallahue


Leslie S. Heisz


Paul A. LaViolette


William J. Link Ph.D.


Steven R. Loranger


Martha H. Marsh


Ramona Sequeira


Nicholas J. Valeriani

- **Leading governance** practices
- Proactive shareholder **engagement**
- **Performance-based compensation** philosophy based on:
  - Financial performance
  - Key operating drivers
  - Shareholder value creation

Edwards is committed to good corporate citizenship

Forbes | JUST Capital
2021 America's Most JUST Companies

Barron's Most Sustainable Companies 2020

2020 America's Most Responsible Companies

2020 World's Most Ethical Companies

Investor's Business Daily
50 Best ESG Companies in 2020, 2019

America's Best Large Employers 2019

2019 Management Top 250

2019 Best Performing CEOs in the World

MEMBER OF
Dow Jones Sustainability Indices
In Collaboration with RobecoSAM

- DJSI World
- DJSI North America

MSCI 2019 Constituent MSCI ESG Leaders Indexes

FTSE4Good
FTSE4Good Index Series Constituent

ISS E&S Disclosure QualityScore
Pillar Score of 1 in Environmental and Social Disclosure

Edwards is committed to giving back



EVERY HEARTBEAT MATTERS

Launched new goal to improve lives of **2.5M** additional underserved structural heart and critically ill patients by the end of 2025



COVID-19 RESPONSE

Edwards Lifesciences Foundation issued emergency grants to more than **20** partner organizations around the world



Edwards

Helping Patients is Our Life's Work, and *life is now*

2020 Investor Conference

Forward-looking statements and disclaimers

Edwards



Edwards

Helping Patients is Our Life's Work, and *life is now*

Edwards Lifesciences

39th Annual J.P. Morgan Healthcare Conference

January 11, 2021



Our Credo

Through our actions, we will become trusted partners with customers, colleagues, and patients – creating a community unified in its mission to improve the quality of life around the world. Our results will benefit customers, patients, employees and shareholders.

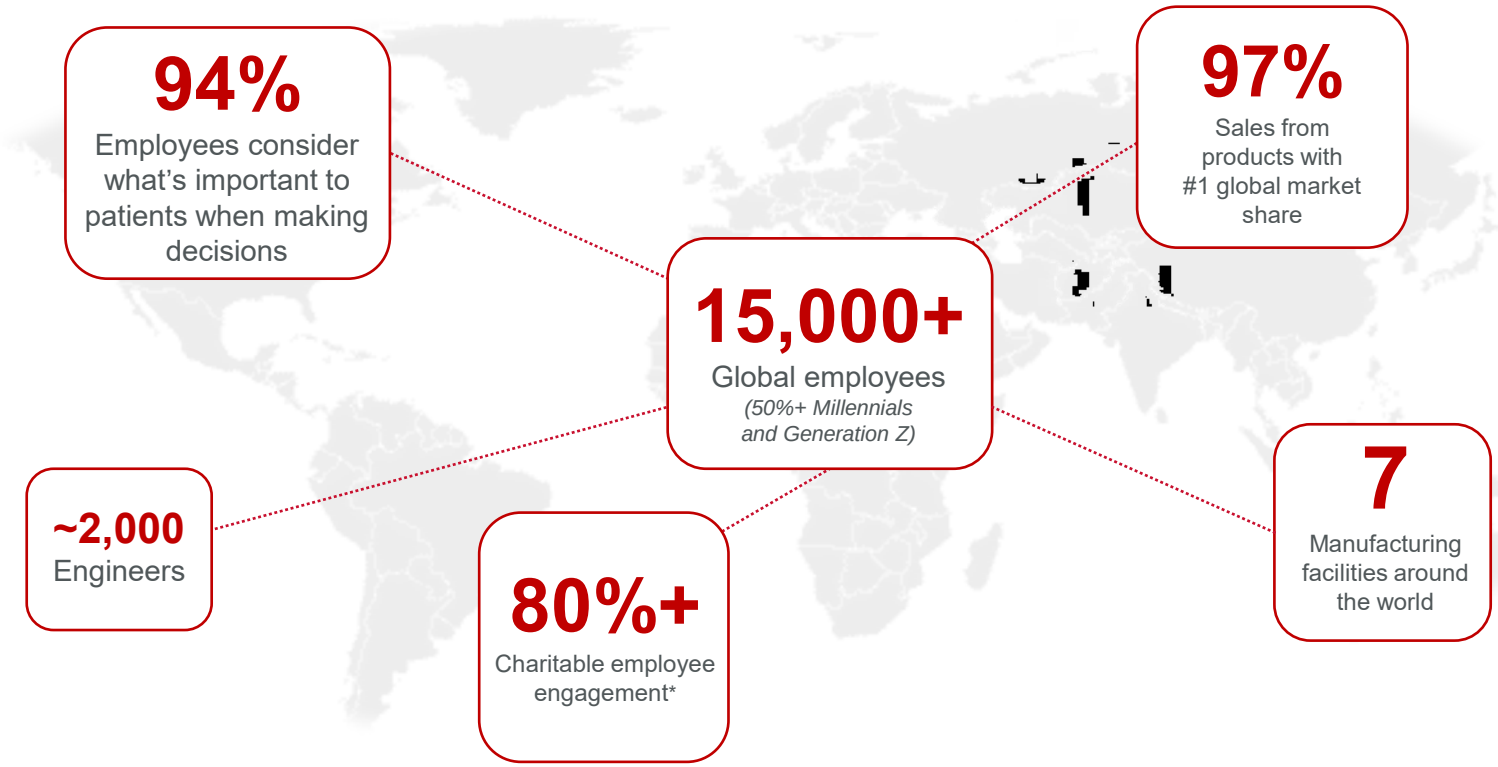
We will celebrate our successes, thrive on discovery, and continually expand our boundaries. We will act boldly, decisively, and with determination on behalf of people fighting cardiovascular disease.



At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease.

Helping Patients is Our Life's Work, and *life is now*

Helping Patients Around the World



*Source: 2020 engagement survey results of global professional employees

Business Overview

Strong Leadership Positions and
Significant Growth Opportunities

Edwards

Leader in $4B+ Global Transcatheter Aortic Valve Replacement Market

Primary global growth drivers: **indication expansion**, **therapy awareness**, and **technology advances**

Globally, **diagnosis and treatment rates of AS remain low** providing opportunity for low-double digit TAVR growth long-term

Continued **investment in groundbreaking trials** beyond severe symptomatic aortic stenosis and transformational technologies to treat patients



$7B+ Estimated Global TAVR Opportunity by 2024

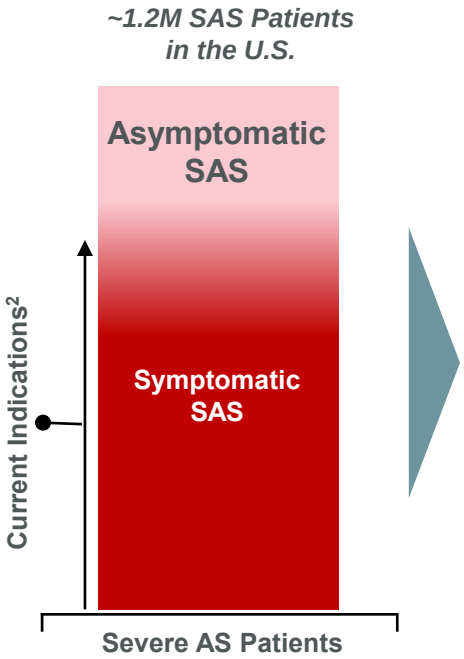
- **Indication Expansion**
- **Increasing Awareness**
- **Technology**



We anticipate the global TAVR opportunity to grow at low double-digit CAGR through 2024

Asymptomatic and Moderate Risk Clinical Trials

Expected to add significant growth beyond 2024



- **Treating severe AS before symptoms may:[1]**
  - Prevent irreversible myocardial damage
  - Reduce risk of sudden death
  - Early treatment may lead to better outcomes

- Beyond Severe Aortic stenosis, we believe our TAVR therapy may benefit patients with Moderate Aortic Stenosis
- Currently working closely with KOLs on a pivotal trial design

Anticipate completion of EARLY TAVR enrollment in 2021

Anticipate FDA approval to start the Moderate AS trial in 2021

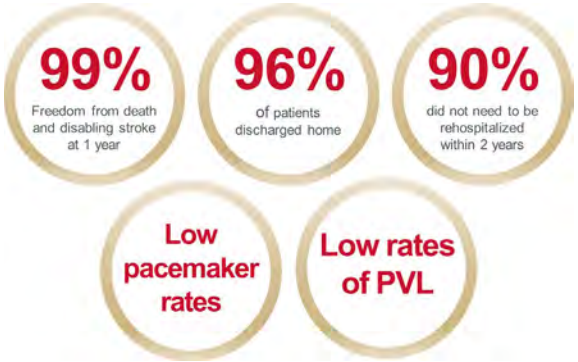
[1] Genereux P. Natural history, diagnostic approaches and therapeutic strategies for patients with asymptomatic severe AS. JACC 2016: 2263-88.
[2] Including low-risk indication.

Our portfolio is constantly evolving

SAPIEN 3 Ultra System

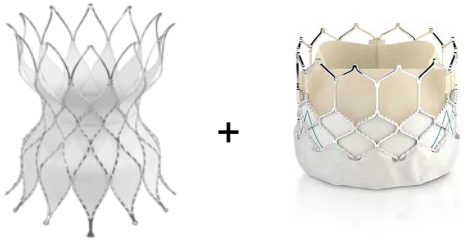
Further elevates the performance benchmark of SAPIEN 3





SAPIEN 3 Pulmonic + Alterra

Pulmonic platform expands therapy for Congenital Heart Disease patients



- Alterra Adaptive Prestent and SAPIEN 3 Pulmonic System expands therapy
- Alterra U.S. Approval anticipated in 2H 2021

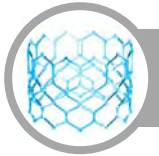
Next Generation TAVR



SAPIEN X4

Clinical work expected to begin in U.S. in 2021

- Enhanced control and precision
- Enables best-in-class safety and efficacy outcomes



Revolutionary Platform

TMTT focused on leading and transforming treatment for patients with mitral and tricuspid valve disease

Three key value drivers: a portfolio of differentiated therapies, positive results from pivotal clinical trials and favorable real-world clinical outcomes

Patients with Mitral and Tricuspid regurgitation remain **undertreated** and suffer from poor quality of life

TMTT is delivering a **portfolio of therapies**, backed by clinical evidence, to address the diversity and complexity of Mitral and Tricuspid disease

$3B global opportunity by 2025 with significant longer-term growth



Diverse and complex patients need better treatment options

DIVERSE

Mitral and tricuspid regurgitation are complex diseases

No two patients are alike

PREVALENT

10+%

people in the U.S. over 65 **suffer from moderate or severe MR/TR**



DEADLY

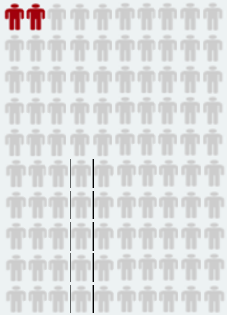
Untreated patients have **poor quality of life** and **high mortality rates**



UNDERTREATED

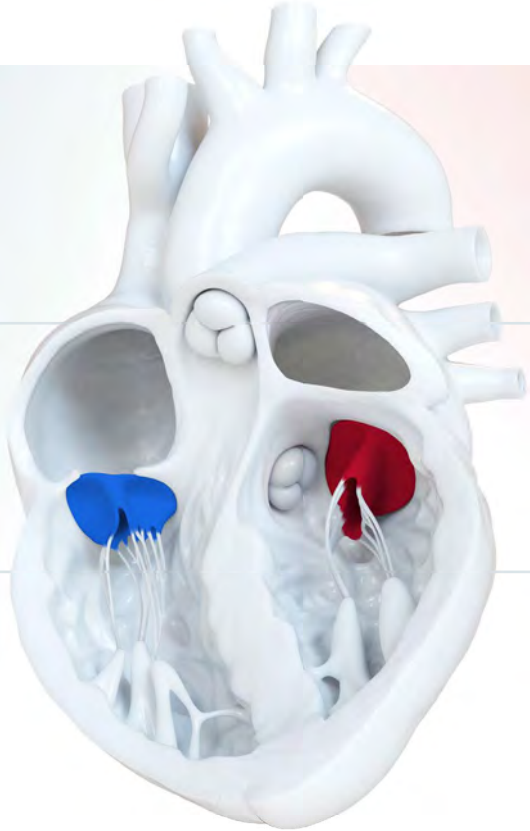
<2%

patients receive an intervention today



TMTT is innovating a broad transcatheter portfolio

	TRICUSPID		MITRAL	
Leaflet Repair	 PASCAL	 PASCAL Ace	 PASCAL	 PASCAL Ace
Annular Reduction	 Cardioband			 Cardioband
Valve Replacement	 EVOQUE		 SAPIEN M3	 EVOQUE



Building clinical evidence to transform standard of care

5 Pivotal Studies



THE CLASP IID TRIAL



PASCAL
Degenerative MR

THE CLASP IIF TRIAL



PASCAL
Functional MR

THE CLASP II TR TRIAL



PASCAL
Tricuspid

THE ENCIRCLE TRIAL



SAPIEN M3
Mitral

THE TRISCEND II PIVOTAL TRIAL



EVOQUE
Tricuspid

Strong evidence is central to expanding patient treatment

Surgical Structural Heart brings leading innovation

Current surgical structural heart market expected to **grow mid-single digits through 2026**

Extending our leadership as the partner of choice for cardiac surgeons with three product launches in 2020

Continuing to bring **life-saving surgical innovation** to patients best-treated surgically

Extend leadership in $1.8B global surgical opportunity



INSPIRIS is the world's leading aortic surgical valve

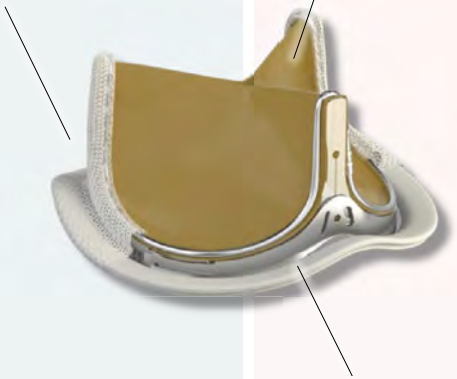
Trusted Platform

Magna Ease
Proven PERIMOUNT Platform

Active patients can avoid anticoagulation required with mechanical valves

Resilient Valve Class

RESILIA
Resilient Tissue Technology



VFit technology
Designed for potential future valve-in-valve procedures

- **#1 implanted aortic surgical valve** in the U.S. and Japan, **China launch in 2021**
- **Continuing adoption** across U.S. and Europe
- Provides **RESILIA tissue and VFit technology** for potential future valve-in-valve procedures

Our surgical portfolio strategy enables sustained growth through innovation

KONECT RESILIA
Aortic Valved Conduit



- First pre-assembled, ready-to-implant tissue conduit
- For complex aortic valve patients with combined aortic root disease
- Impacts ~7,500 surgical procedures annually in the U.S., growing in the high single-digits

MITRIS RESILIA
Surgical Mitral Valve



- Differentiating RESILIA tissue, ease-of-use enhancements, and valve-in-valve compatibility
- 60% of global mitral valve replacement patients currently receive a mechanical valve
- U.S. and Japan launch in 2021

HARPOON
Mitral Valve Repair System



- Standardizing mitral repair
- Launched in 2020 with potential to convert ~20,000 surgical repair patients across the U.S., Europe, and Japan
- RESTORE pivotal trial underway

Critical Care improving the quality of care for patients

Continuing to **shift product mix** towards Smart Recovery, which has highest growth potential of our product groups

Focusing on **three key building blocks** to advance Smart Recovery patient penetration from 5% to 15% by 2026

Deploying **right technologies**, generating **clinical evidence** and creating **product awareness** to drive us towards our goal

Critical Care products benefit millions of patients every year



We are the global leader in hemodynamic monitoring impacting more than 14 million patients per year[1]

[1] Incudes pulmonary artery catheters and pressure monitoring products, excludes capital.

Three Key Building Blocks for Smart Recovery

TECHNOLOGY

CAPITAL PLATFORM



HemoSphere

+

SENSORS



Acumen IQ Sensor



ForeSight



Acumen IQ Cuff

+

SOFTWARE

Hypotension Prediction Index (HPI)

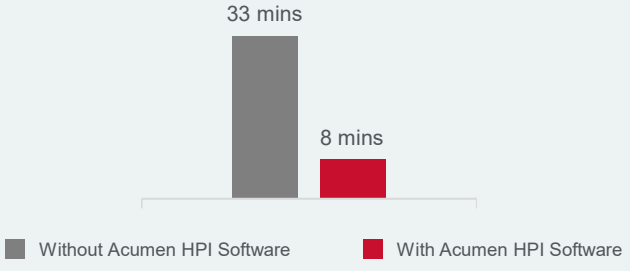
94

Viewfinder
Remote View



EVIDENCE

Edwards HPI Software Can Reduce Intraoperative Hypotension – HYPE TRIAL



AWARENESS



"HPI was high and 10 minutes later there was hypotension. I didn't see it coming at all."

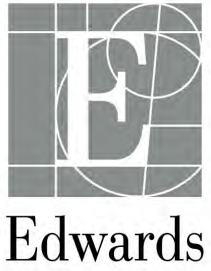
– Simon Davies, MD MBChB FRCA



"We were able to decrease the rate of hypotension by about 50%, which is quite impressive I think."

– Michael Sander, MD, PhD

Financial Outlook



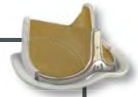
2021 expected to be a year of significant growth and investment in our future

2021 Expectations

Mid-teens	$2.00 - $2.20
Underlying net sales growth	Adjusted EPS



TAVR
- Therapy expansion
- Technology advances
- Geographic expansion



Surgical
- Surgeon partnership
- Leading pipeline
- Growth segment focus



TMTT
- Differentiated portfolio
- Clinical evidence
- Real-world outcomes



Critical Care
- HemoSphere growth
- Smart technologies
- Portfolio expansion



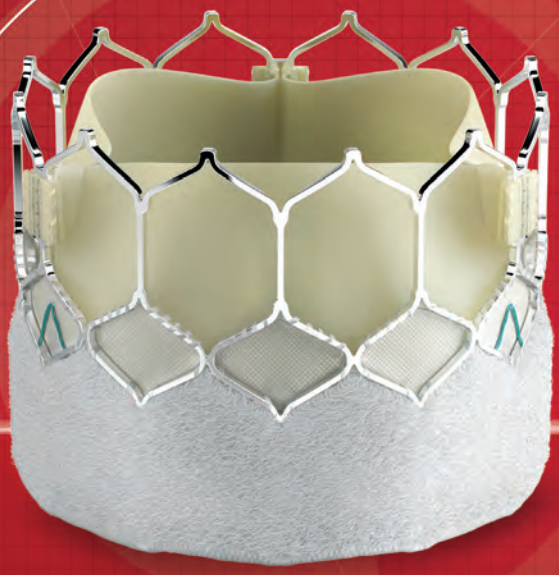
Edwards

Helping Patients is Our Life's Work, and *life is now*

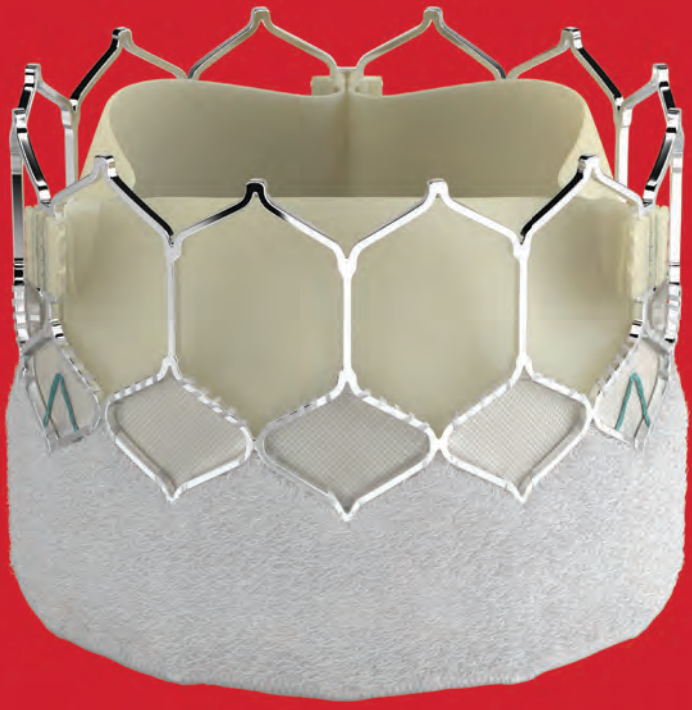
Introducing the

SAPIEN 3 Ultra valve

Edwards Engineering for Tomorrow's TAVI



Edwards



An evolution of the valve you know and trust

Edwards Lifesciences' commitment to innovation continues with the SAPIEN 3 Ultra valve.

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

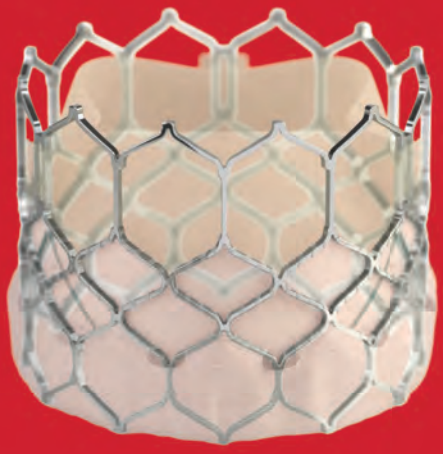


Sealing skirt technology

SAPIEN 3 Ultra valve features an approximately 40% taller*, textured PET outer skirt

Enhanced frame design

Frame geometry designed for high radial strength; short frame height facilitates future coronary access[2]





Valve tissue

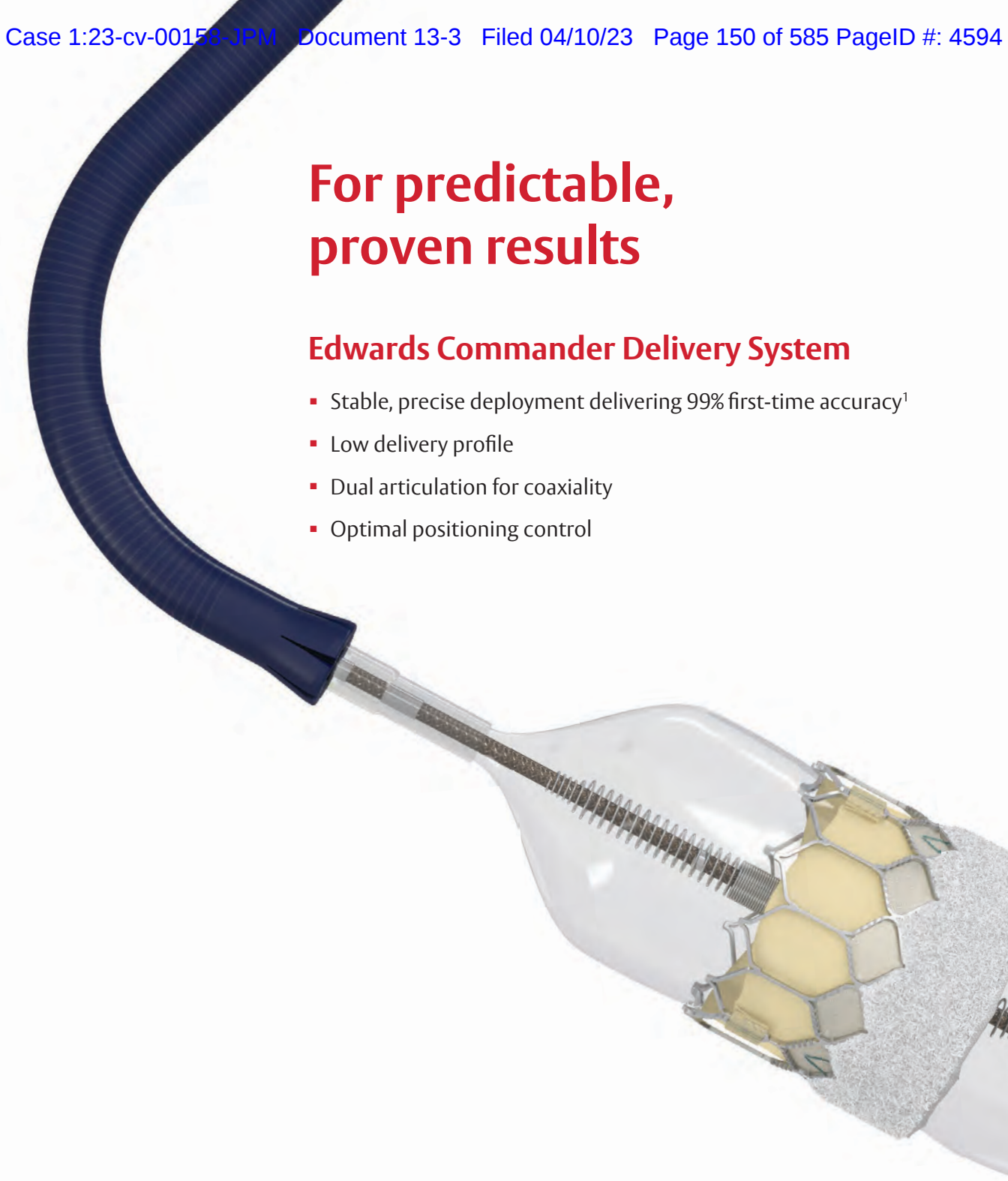
Uses same bovine pericardium tissue and process as the SAPIEN 3 valve

*Compared with the Edwards SAPIEN 3 valve. Available in 20, 23 and 26mm sizes.

For predictable, proven results

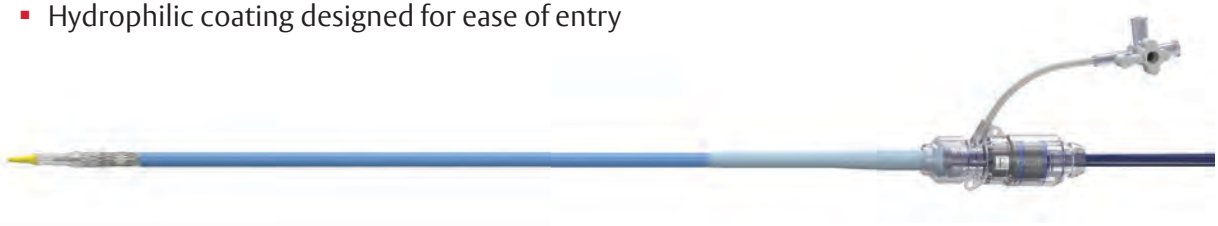
Edwards Commander Delivery System

- Stable, precise deployment delivering 99% first-time accuracy[1]
- Low delivery profile
- Dual articulation for coaxiality
- Optimal positioning control



Edwards eSheath Introducer Set

- 14F compatibility
- Dynamic Expansion Mechanism (DEM) for low-profile access
- Hydrophilic coating designed for ease of entry



The SAPIEN 3 Ultra valve is available with the Edwards Commander delivery system and Edwards eSheath Introducer helping you achieve consistent performance and controlled deployment.



Tomorrow's TAVI is here today.

- Future TAVI patients need systems designed for performance. Choose SAPIEN 3 Ultra TAVI for your patients and their severe aortic stenosis.

References:

1. The PARTNER II Trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1077).
2. Tarantini G, Fovino LN, Leprince P, et al. Predictors, feasibility and outcomes of coronary intervention up to 3 years after TAVI with a balloon-expandable valve: results from a large European multicenter registry. Presented at: ESC Congress 2019; September 2019; Paris, France.

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (*consult eifu.edwards.com where applicable*). Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

Edwards, Edwards Lifesciences, the stylized E logo, Edwards Commander, Edwards eSheath, eSheath, PARTNER, PARTNER II, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, SAPIEN, SAPIEN 3, and SAPIEN 3 Ultra are trademarks or service marks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2020 Edwards Lifesciences Corporation. All rights reserved. PP--EU-0118 v1.0

Edwards Lifesciences • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

Edwards

Edwards

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System

SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve SAPIEN 3 Ultra Delivery System

Instructions for Use

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

Implantation of the transcatheter heart valve should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in balloon aortic valvuloplasty.

Please verify that you have the latest version of the instructions for use prior to using the device by visiting http://THVIFU.edwards.com or by calling 1.800.822.9837. In order to access the instructions for use, an IFU Code will be required.

STERILE: The valve is supplied sterilized with glutaraldehyde solution. The delivery system, Sheath, and crimper are supplied sterilized with ethylene oxide gas.

Edwards, Edwards Lifesciences, the stylized E logo, Carpentier-Edwards, Certitude, Edwards eSheath, Edwards SAPIEN, Edwards SAPIEN XT, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, eSheath, PARTNER, PARTNER II, PARTNER 3, Qualcrimp, SAPIEN, SAPIEN XT, SAPIEN 3, SAPIEN 3 Ultra, and ThermaFix are trademarks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

1.0 Device Description

Edwards SAPIEN 3 Ultra Transcatheter Heart Valve (THV) System

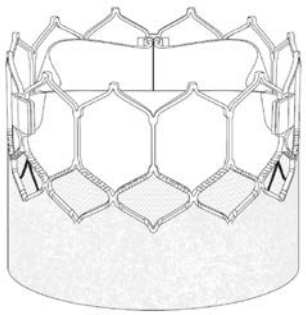
The Edwards SAPIEN 3 Ultra Transcatheter Heart Valve system consists of the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves and delivery systems.

- **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.

- **Edwards SAPIEN 3 Transcatheter Heart Valve – (Figure 2)**

The Edwards SAPIEN 3 transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. 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



9600TFX

Figure 2. Edwards SAPIEN 3 Transcatheter Heart Valve

Table 2

Valve Size	Valve Height
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm
29 mm	22.5 mm

- **Edwards SAPIEN 3 Ultra Delivery System (Figure 3)**

The Edwards SAPIEN 3 Ultra delivery system facilitates the placement of the bioprosthesis. The delivery system consists of a Flex Catheter to aid in tracking and valve positioning. The delivery system includes a tapered tip to facilitate crossing of the valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter and Fine Adjustment Wheel to facilitate valve positioning within the target location. A stylet is included within the guidewire lumen of the delivery system. A radiopaque Positioning Marker in the balloon is provided to assist with valve positioning. The inflation parameters for valve deployment are:

Table 5

Model	Nominal Balloon Diameter	Nominal Inflation Volume	Rated Burst Pressure (RBP)
9630TF20	20 mm	11 mL	7 atm
9630TF23	23 mm	17 mL	7 atm
9630TF26	26 mm	23 mL	7 atm
9630TF29	29 mm	33 mL	7 atm

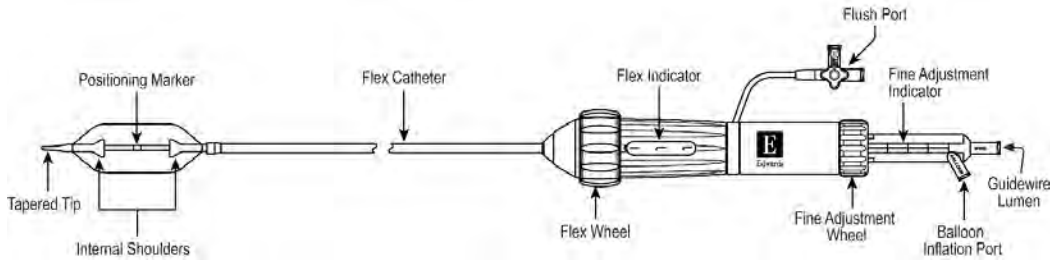


Figure 3. Edwards SAPIEN 3 Ultra Delivery System

Additional Accessories

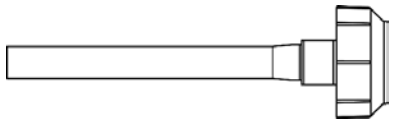


Figure 4. Loader



Figure 5. Qualcrimp Crimping Accessory

- **Edwards Sheath**

Refer to the provided Edwards sheath instructions for use for device description.

- **Edwards Crimper**

Refer to the Edwards Crimper instructions for use for device description.



Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System

SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve Edwards Certitude Delivery System

Instructions for Use

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

Implantation of the transcatheter heart valve should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in balloon aortic valvuloplasty.

Please verify that you have the latest version of the instructions for use prior to using the device by visiting http://THVIFU.edwards.com or by calling 1.800.822.9837. In order to access the instructions for use, an IFU Code will be required.

STERILE: The valve is supplied sterilized with glutaraldehyde solution. The delivery system, introducer sheath set, and crimper are supplied sterilized with ethylene oxide gas.

Edwards, Edwards Lifesciences, the stylized E logo, Carpentier-Edwards, Certitude, Edwards SAPIEN, Edwards SAPIEN XT, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, PARTNER, PARTNER II, PARTNER 3, Qualcrimp, SAPIEN, SAPIEN XT, SAPIEN 3, SAPIEN 3 Ultra, and ThermaFix are trademarks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

1.0 Device Description

Edwards SAPIEN 3 Ultra Trancatheter Heart Valve (THV) system

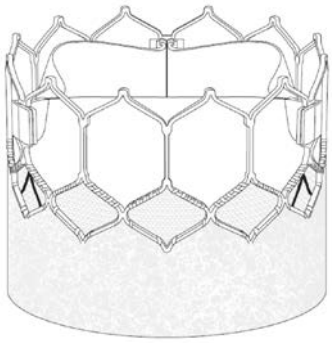
The Edwards SAPIEN 3 Ultra Transcatheter Heart Valve system consists of the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves and delivery systems.

- **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.

- **Edwards SAPIEN 3 Transcatheter Heart Valve – (Figure 2)**

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

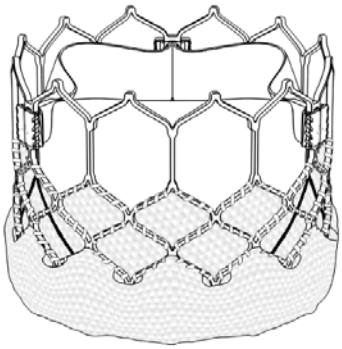


9750TFX

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



9600TFX

Figure 2. Edwards SAPIEN 3 Transcatheter Heart Valve

Table 2

Valve Size	Valve Height
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm
29 mm	22.5 mm

- **Edwards Certitude Delivery System (Figure 3)**

The Edwards Certitude delivery system facilitates the placement of the bioprosthesis. The delivery system consists of a Flex Catheter to aid in tracking and valve positioning. The delivery system includes a tapered tip to facilitate crossing of the valve. The handle contains a Flex Wheel to control flexing of the balloon catheter. A stylet is included within the guidewire lumen of the delivery system. A radiopaque Center Marker in the balloon is provided to assist with valve positioning. The inflation parameters for valve deployment are:

Table 5

Model	Nominal Balloon Diameter	Nominal Inflation Volume	Rated Burst Pressure (RBP)
9630TA20 9600SDS20	20 mm	12 mL	7 atm
9630TA23 9600SDS23	23 mm	17 mL	7 atm
9630TA26 9600SDS26	26 mm	23 mL	7 atm
9630TA29 9600SDS29	29 mm	30 mL	7 atm

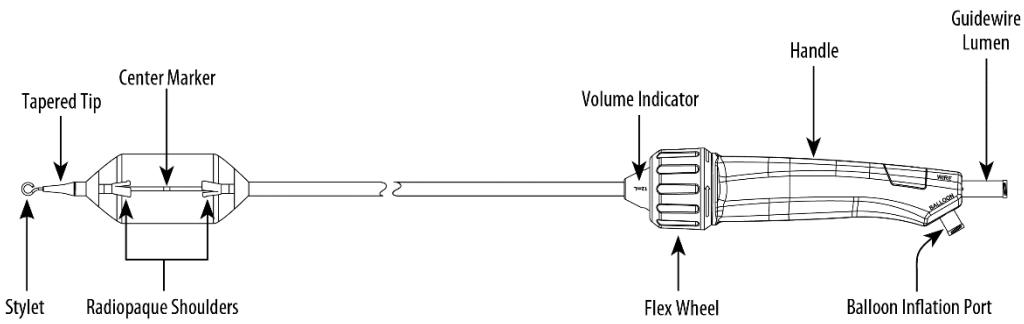


Figure 3. Edwards Certitude Delivery System

Additional Accessories

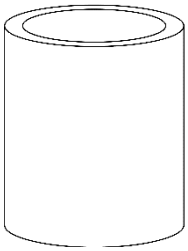


Figure 4. Qualcrimp Crimping Accessory

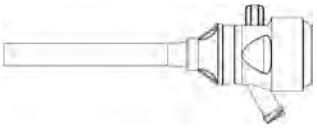


Figure 5. Loader

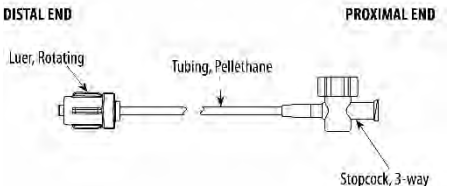


Figure 6. Extension Tubing

- **Edwards Certitude Introducer Sheath Set (Figure 7)**

The Edwards Certitude introducer sheath set facilitates the introduction and removal of devices utilized with the SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves. The sheath has a radiopaque marker for visualization of the sheath tip and non-radiopaque depth markings on the distal end of the body of the sheath. The proximal end of the sheath includes a flush tube and three hemostasis valves. An introducer is supplied with the sheath. The entire introducer is radiopaque.

1. Housing
2. Flush Tube with Stopcock
3. Sheath
4. Radiopaque Marker
5. Non-Radiopaque Depth Markers
6. Introducer

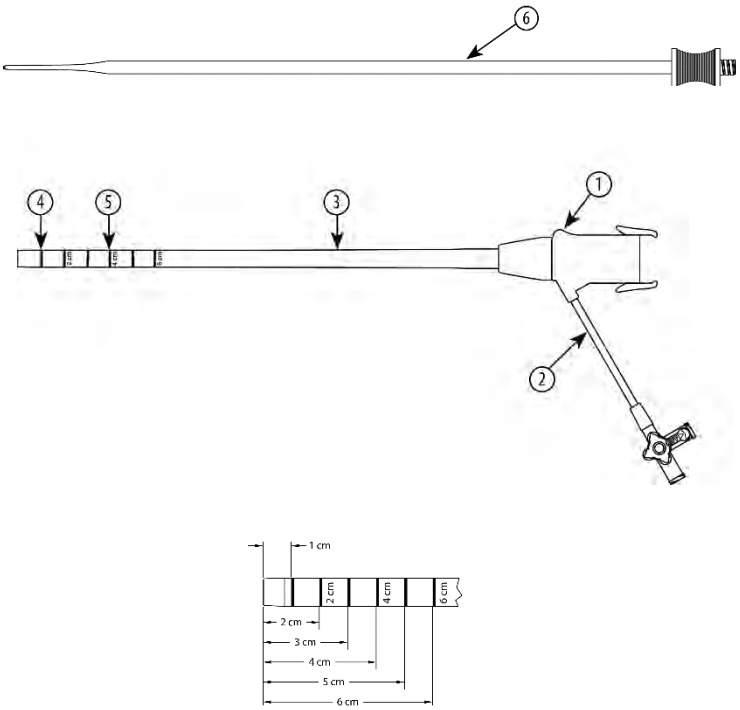
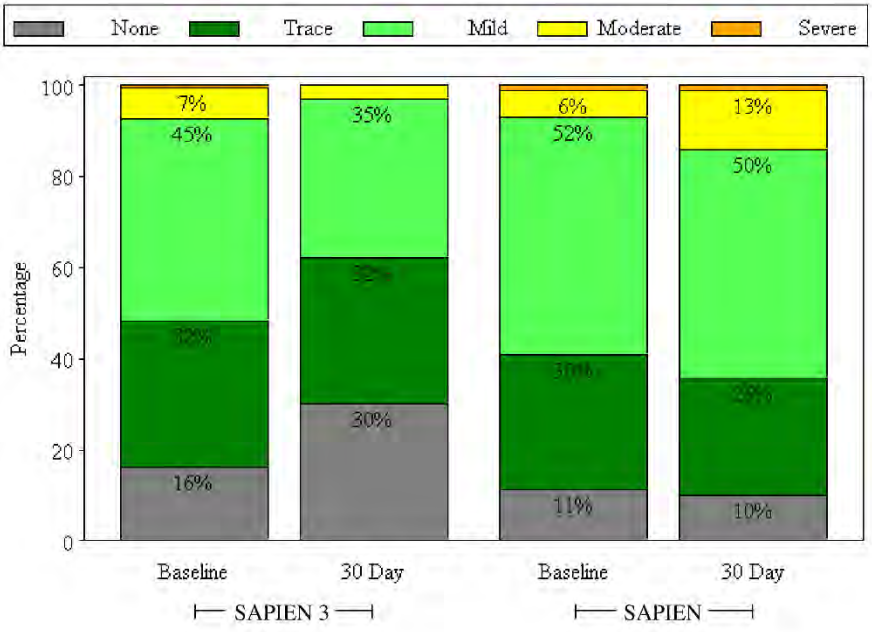


Figure 7. Edwards Certitude Introducer Sheath Set

Secondary Endpoints

Aortic insufficiency by visit is provided in Figure 8.

Figure 8:
Aortic Insufficiency by Visit –
SAPIEN 3 Valve (PIIS3HR VI Population) vs. SAPIEN Valve



The proportion of patients with AI ≥ moderate at 30 days was 3.0% in the SAPIEN 3 cohort and 14.3% in the SAPIEN cohort, which were found to be statistically significantly different (p=0.0051; Table 12).

Table 12:
Aortic Insufficiency at 30 Days
(SAPIEN 3 Valve vs. SAPIEN Valve VI Population)

Event at 30 Days	SAPIEN 3 Valve (N = 583)	SAPIEN Valve (N = 326)	Weighted Proportion Difference in Average Treatment Effect on the Treated (ATT)	P-value
AI ≥ Moderate, n/Total no. (%) [95% CI]	16/532 (3.0%) [1.7%, 4.8%][1]	40/280 (14.3%) [10.4%, 18.9%][1]	-13.1% [-22.2%, -3.9%][2]	0.0051

[1] 95% Clopper-Pearson Exact confidence interval.
[2] The Wald-type two-sided 90% confidence interval using weighted mean and SD is provided.

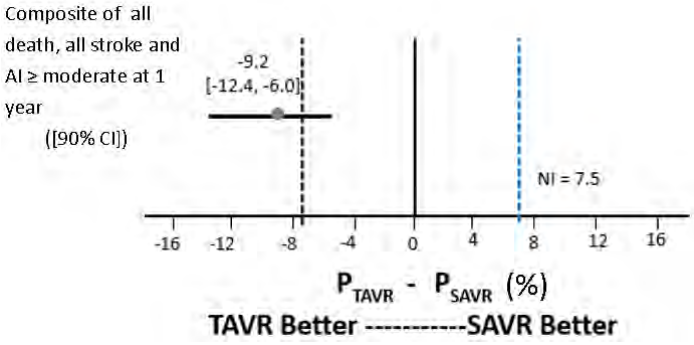
The rate of major vascular complications at 30 days post implantation is shown in Figure 9. The rate was 5.0% for the SAPIEN 3 cohort and 10.1% for the SAPIEN cohort, which were found to be not statistically significantly different (p=0.0578; Table 13).

Table 21:
Primary Endpoint Non-Inferiority Test
(VI Population)

	Observed Event rate		Propensity Score Quintile Pooled Proportion Difference (ATT Method*) [90% CI]†	Margin	Conclusion for Non-Inferiority Test
	SAPIEN 3 (N = 1069)	PIIA-SAVR (N = 936)			
Composite of all-cause death, all stroke, and aortic insufficiency (AI) ≥ moderate at 1 year	13.0%	23.2%	-9.2% [-12.4%, -6.0%]	7.5%	Pass

* ATT: average treatment effect on the treated
† Two-sided 90% Wald-type confidence interval

Figure 24:
Forest Plot – Composite of All Death, All Stroke and AI ≥ Moderate
(VI Population)



The Kaplan-Meier (KM) estimates for all-cause death and all stroke at 1 year for the PIIS3i cohort and the PIIA-SAVR cohort are provided in Table 22, as well as Figures 25 and 26, respectively.

Table 22:
All-Cause Death and All Stroke at 1 Year
(VI Population)

	SAPIEN 3 Valve (N = 1069)			PIIA-SAVR (N = 936)			Propensity Score Quintile Pooled Proportion Difference (ATT Method†)
Endpoints	Observed Event Rate	Kaplan-Meier Event Rate*		Observed Event Rate	Kaplan-Meier Event Rate*		
		Point Estimate	Standard Error		Point Estimate	Standard Error	
All-cause death at 1 year	7.0%	7.1%	0.79%	12.4%	12.6%	1.09%	-5.2%
All stroke at 1 year	4.5%	4.6%	0.65%	7.9%	8.1%	0.91%	-3.5%

* Kaplan-Meier estimates were calculated at 365 days and included only the first event for each patient. Events occurring after 365 days were not included in this analysis.
† ATT: average treatment effect on the treated

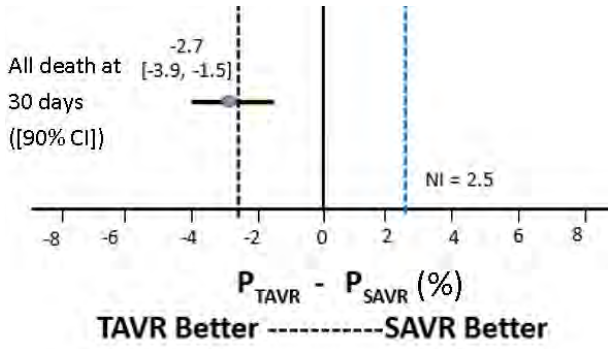
Figure 25:
All-Cause Death through 1 Year
(VI Population)

Pre-Specified Order for Gatekeeping/ Hierarchical Method	Endpoints	Observed Event Rate		Weighted Proportion Difference in Average Treatment Effect on the Treated [90% CI]†	Margin	Conclusion for Non-Inferiority Test
		SAPIEN 3 Valve (N = 1069)	PIIA-SAVR (N = 936)			
No. 5	All stroke through 30 days	2.6%	6.1%	-3.2% [-4.7%, -1.6%]	2.5%	Pass

† Two-sided 90% Wald-type confidence interval.

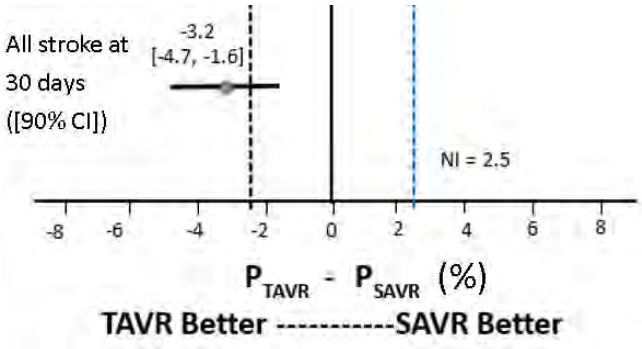
The forest plots for all-cause death and all stroke at 30 days are provided in Figures 27 and 28, respectively.

Figure 27:
Forest Plot – All-Cause Death at 30 Days
(VI Population)



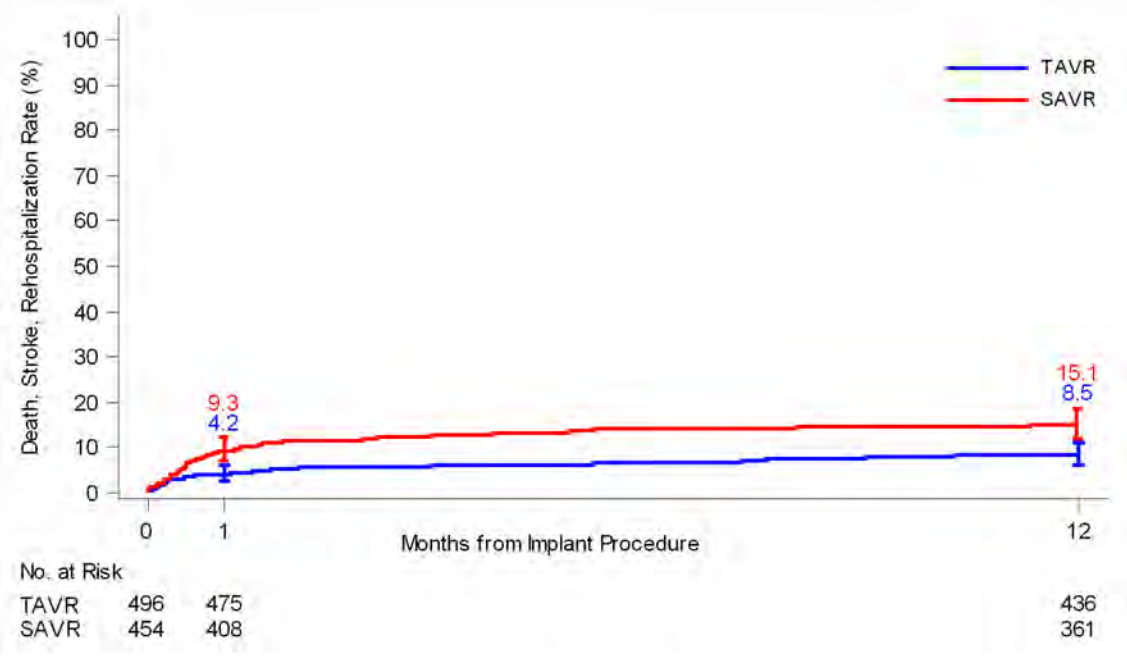
Note: As part of a pre-specified hierarchy, the hypothesis for this endpoint was tested using a hierarchical gatekeeping approach. The confidence interval shown here was not adjusted for multiplicity per the gatekeeping approach.

Figure 28:
Forest Plot – All Stroke at 30 Days (VI Population)



Note: As part of a pre-specified hierarchy, the hypothesis for this endpoint was tested using a hierarchical gatekeeping approach. The confidence interval shown here was not adjusted for multiplicity per the gatekeeping approach.

Figure 39: All-Cause Death, All Stroke, and Rehospitalization through 1 Year (AT Population)



Note: The confidence intervals were calculated without multiplicity adjustment. The adjusted confidence intervals could be wider than presented here. As such, confidence intervals are provided to illustrate the variability only and should not be used to draw any statistical conclusion.

Safety and Effectiveness Results

Aortic Valve-in-Valve

Safety Endpoints

The mortality rates at discharge and 30 days and the Kaplan-Meier curve for all-cause mortality for the aortic valve-in-valve cohort are shown in Table 58 and Figure 57, respectively. There were a total of 12 deaths reported at 30 days.

Table 58:
Death Rate - Aortic Valve-in-Valve (Attempted Implant Population)

	Discharge*	30 Days†
All-cause death	2.5% (8)	4.5% (12)
Cardiac death	1.3% (4)	2.2% (6)

*Observed rate - % (n)
†Kaplan-Meier estimate - % (n)

Figure 57:
All-Cause Death Rate - Aortic Valve-in-Valve
(Attempted Implant Population)

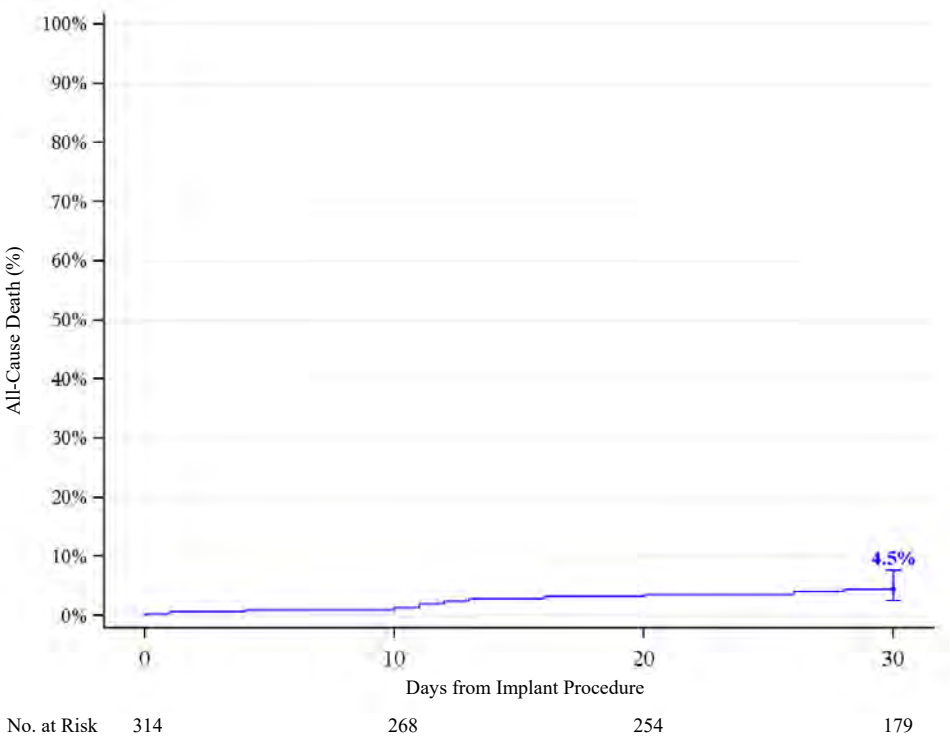
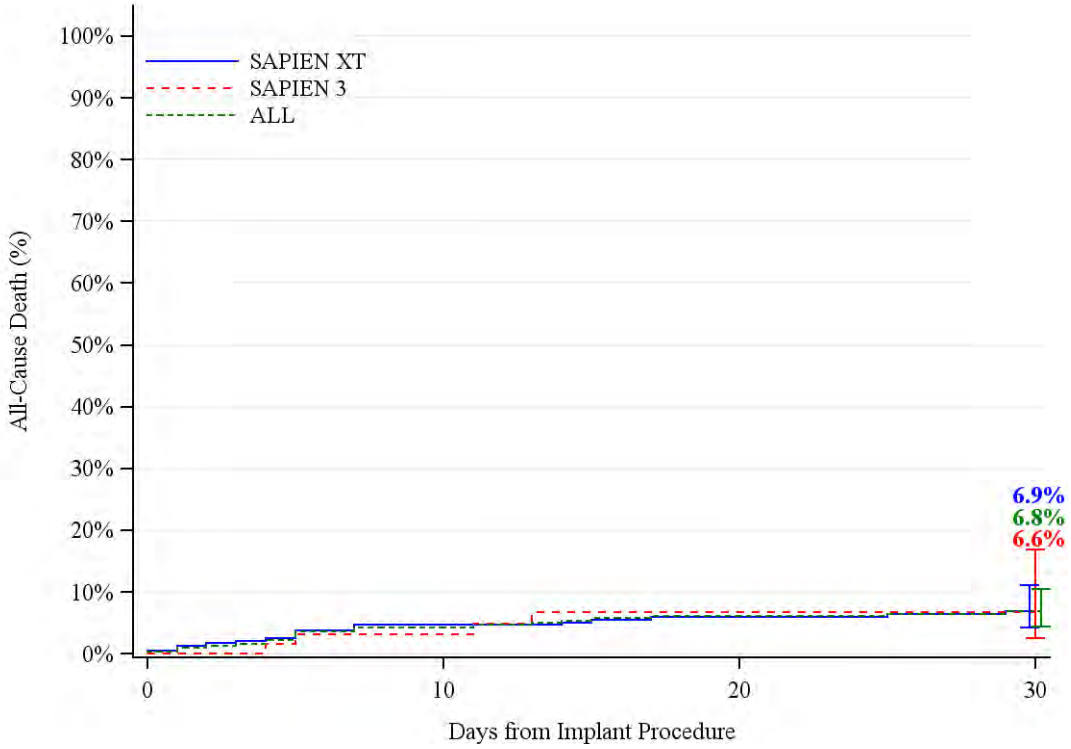


Figure 63:
All-Cause Death Rate - Mitral Valve-in-Valve
(Attempted Implant Population)



No. at Risk				
SAPIEN XT	241	216	209	186
SAPIEN 3	70	56	52	45
ALL	311	272	261	231

The DCRI-adjudicated events, including all strokes/TIAs, heart failure readmissions, and mitral valve reinterventions at discharge and 30 days, for the mitral valve-in-valve cohort are shown in Table 66.

Table 66:
Duke Clinical Research Institute Adjudicated Events - Mitral Valve-in-Valve
(Attempted Implant Population)

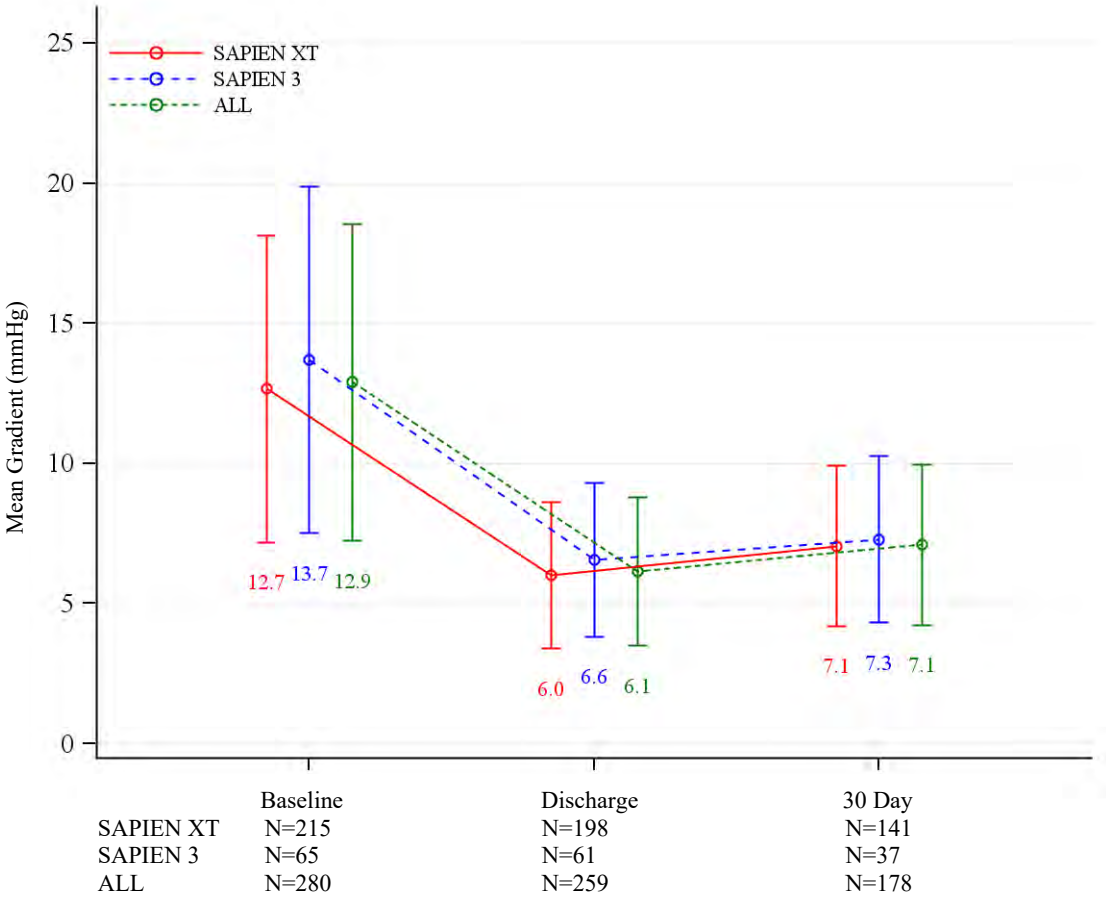
Events	Discharge*			30 Day†		
	SAPIEN XT	SAPIEN 3	All	SAPIEN XT	SAPIEN 3	All
All stroke	0.4% (1, 1)	1.4% (1, 1)	0.6% (2, 2)	0.4% (1, 1)	1.5% (1, 1)	0.7% (2, 2)
Ischemic stroke	0.4% (1, 1)	1.4% (1, 1)	0.6% (2, 2)	0.4% (1, 1)	1.5% (1, 1)	0.7% (2, 2)
Hemorrhagic stroke	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)
Transient ischemic attack (TIA)	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)
Readmission - heart failure	N/A	N/A	N/A	1.0% (2, 2)	0.0% (0, 0)	0.8% (2, 2)
Mitral valve reintervention	0.0% (0, 0)	0.0% (0, 0)	0.0% (0, 0)	0.5% (1, 1)	0.0% (0, 0)	0.4% (1, 1)

*Observed rate - % (no. of events, no. of subjects with the event)
†Kaplan-Meier estimate - % (no. of events, no. of subjects with the event)

Site Reported Adverse Events

The site reported adverse events at discharge and 30 days for the mitral valve-in-valve cohort are shown in Table 67.

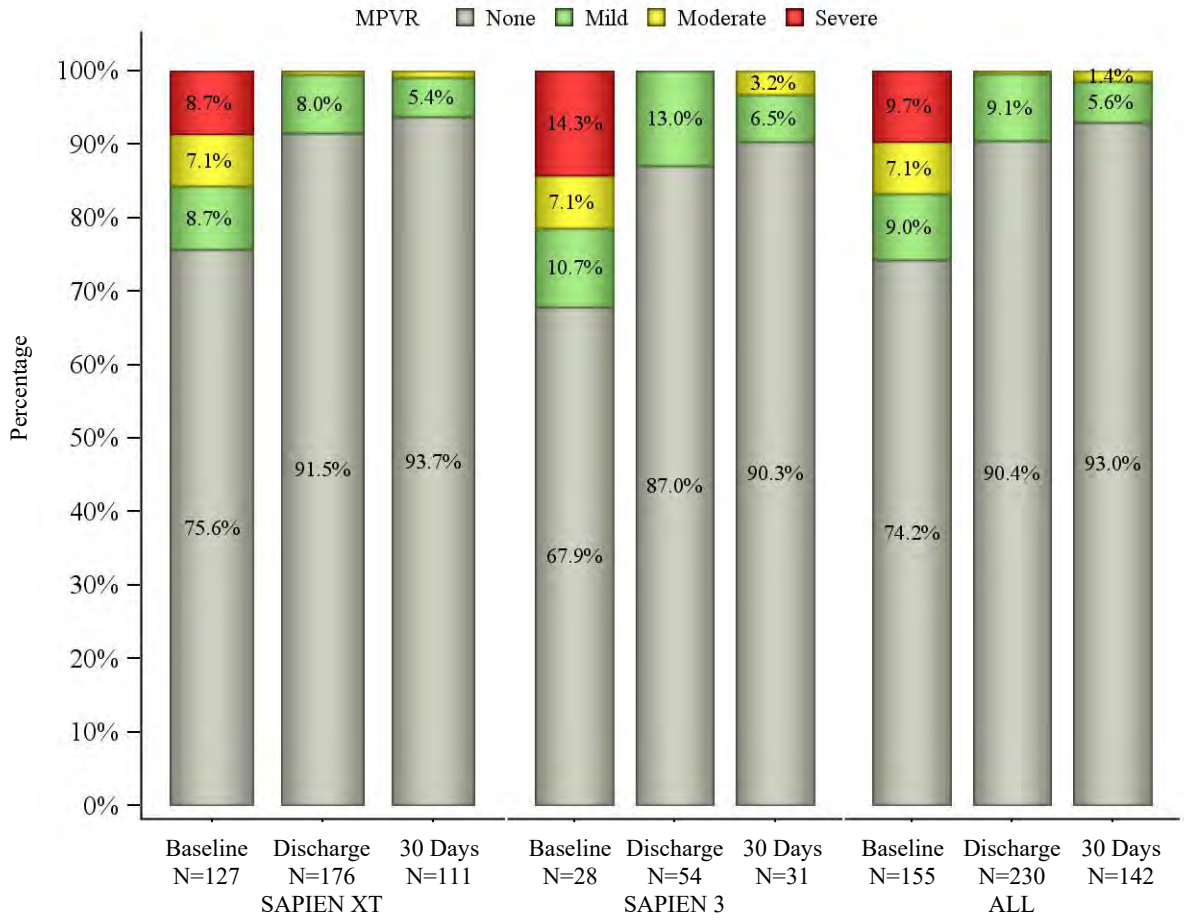
Figure 64:
Mean Gradient by Visit - Mitral Valve-in-Valve
(Valve Implant Population)



	Baseline	Discharge	30 Day
SAPIEN XT	N=215	N=198	N=141
SAPIEN 3	N=65	N=61	N=37
ALL	N=280	N=259	N=178

Note: Line plot with mean and standard deviation. The total number of patients at each time point only counted the patients with valid values.

Figure 66:
Paravalvular Regurgitation by Visit - Mitral Valve-in-Valve
(Valve Implant Population)

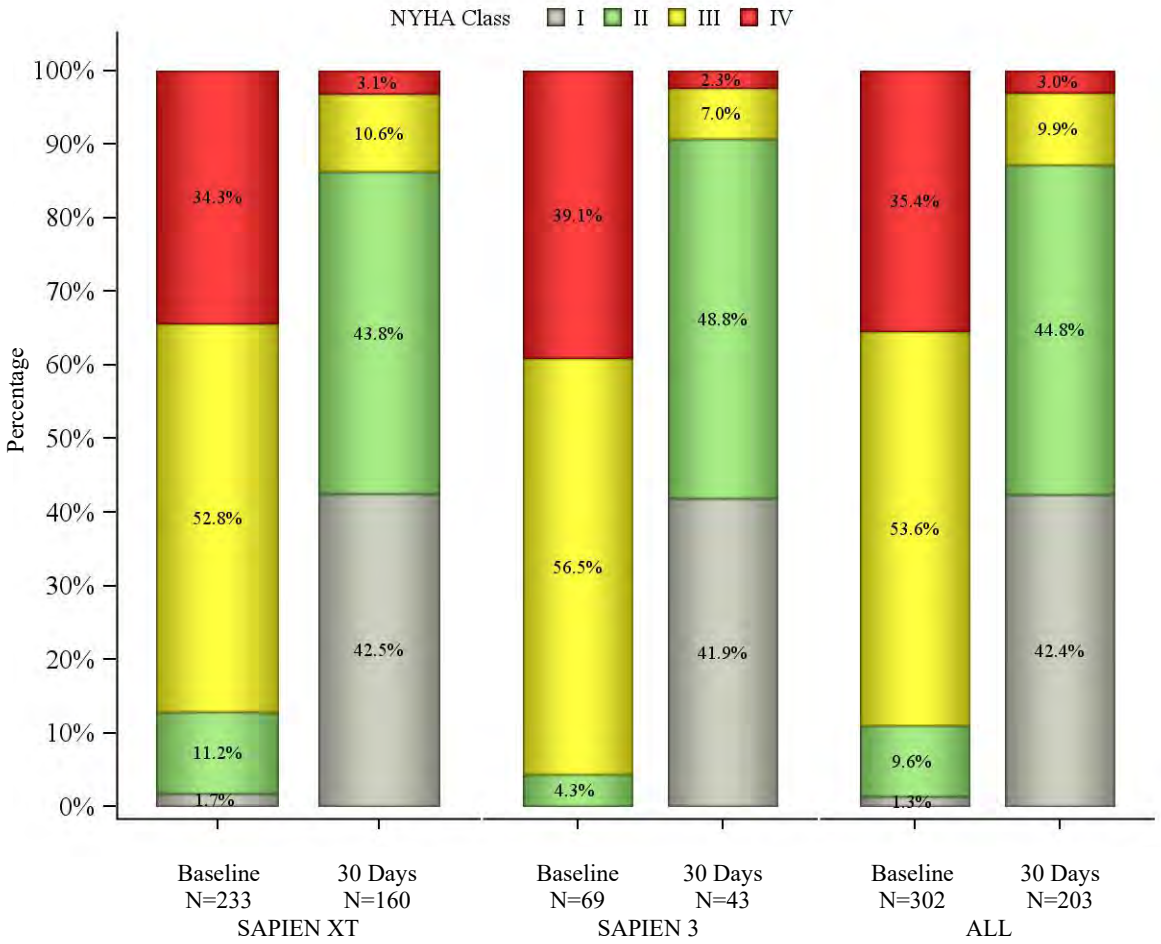


Note: Values that are < 1.0% are not labeled in the bar chart. The total number of patients at each time point only counted the patients with valid values.

NYHA Class

The NYHA class distributions at baseline and the 30-day visit and the NYHA class changes from baseline to the 30-day visit are shown in Figure 67 and Table 68, respectively. The majority (85.6%) of the patients had an improved NYHA class at the 30-day visit.

Figure 67:
NYHA Functional Class - Mitral Valve-in-Valve
(Valve Implant Population)



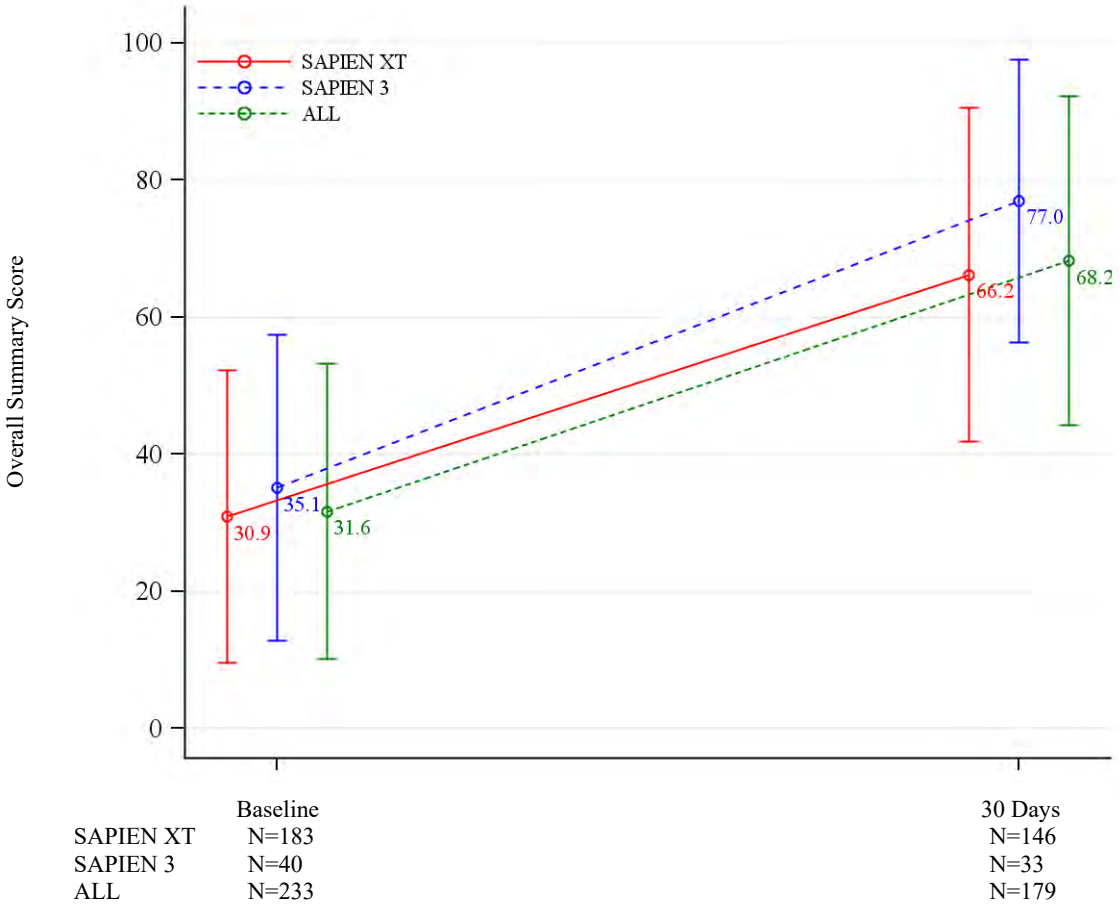
Note: The total number of patients at each time point only counted the patients with valid values.

Table 68:
NYHA Class Change - Mitral Valve-in-Valve
(Valve Implant Population)

		NYHA Class Change*		
		Improved	**Same**	**Worsened**
Baseline to 30-day visit	SAPIEN XT	133/159 (83.6%)	24/159 (15.1%)	2/159 (1.3%)
	SAPIEN 3	40/43 (93.0%)	3/43 (7.0%)	0/43 (0.0%)
	All	173/202 (85.6%)	27/202 (13.4%)	2/202 (1.0%)

*n/Total no. (%); the total no. only counted the patients with valid values.

Figure 68:
KCCQ Overall Summary Score - Mitral Valve-in-Valve (Valve Implant Population)



Note: Line plot with mean and standard deviation. The total number of patients at each time point only counted the patients with valid values.

Procedural Information

The procedure information is presented in Table 71. The most common delivery approach for the mitral valve-in-valve implantation was the transapical approach, which was used in 65.3% (203 of 311) of cases, followed by the transseptal approach in 27.0% (84 of 311) of cases, the transfemoral approach in 6.1% (19/311) of cases, and other alternative approaches in 1.6% (5 of 311) of cases. The procedures were considered elective in 71.0% (220/310) of cases, urgent in 27.7% (86/310) of cases, and emergent or salvage in 1.3% (4/310) of cases. Two (2) cases were aborted and 5 were converted to open heart surgery. Overall, the device was implanted successfully in 97.4% (303/311) of the cases, which was defined as correct positioning of a single prosthetic heart valve in the proper anatomical location.



08/2019
© Copyright 2019, Edwards Lifesciences LLC
All rights reserved.

Manufacturer
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

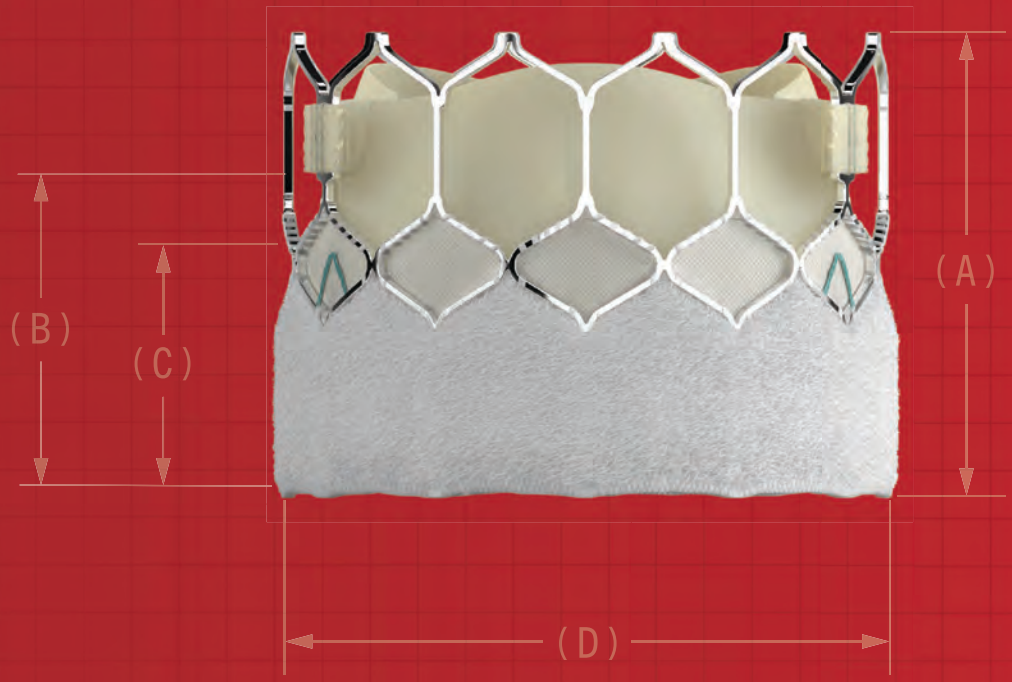
Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU
10033860001 A

Introducing the

SAPIEN 3 Ultra valve

The next generation of Edwards SAPIEN 3 TAVR



Edwards



An evolution of the valve you know and trust

Edwards Lifesciences' commitment to innovation continues with the SAPIEN 3 Ultra valve.

Built upon the proven SAPIEN platform, the SAPIEN 3 Ultra transcatheter heart valve was designed with your patients' needs in mind.



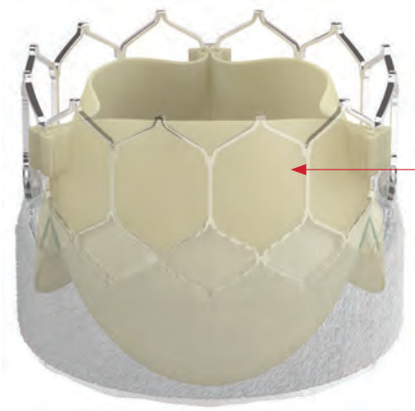
Sealing skirt technology

Built on the SAPIEN 3 valve designed to minimize paravalvular leak (PVL), the SAPIEN 3 Ultra valve now features a ~40% taller, textured polyethylene terephthalate (PET) outer skirt

Iconic geometric frame

Short frame height and open cell geometry facilitate coronary access





Valve tissue

Uses same trusted bovine pericardium tissue and process as the SAPIEN 3 valve

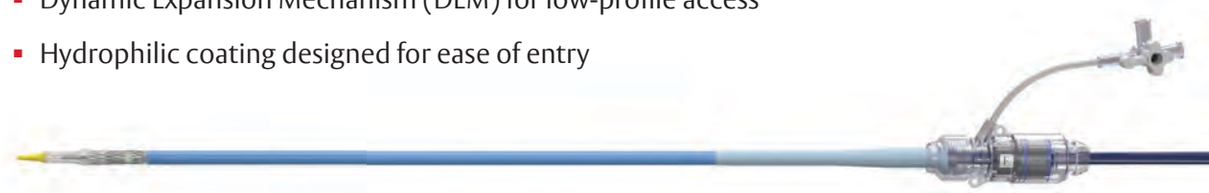
For predictable, proven results

Edwards Commander Delivery System

- Stable, precise deployment delivering 99% first-time accuracy[1]
- Low delivery profile
- Dual articulation for coaxiality
- Optimal positioning control

Edwards eSheath Introducer Set

- 14F & 16F low-profile access leads to significant reduction in major vascular complications
- Dynamic Expansion Mechanism (DEM) for low-profile access
- Hydrophilic coating designed for ease of entry

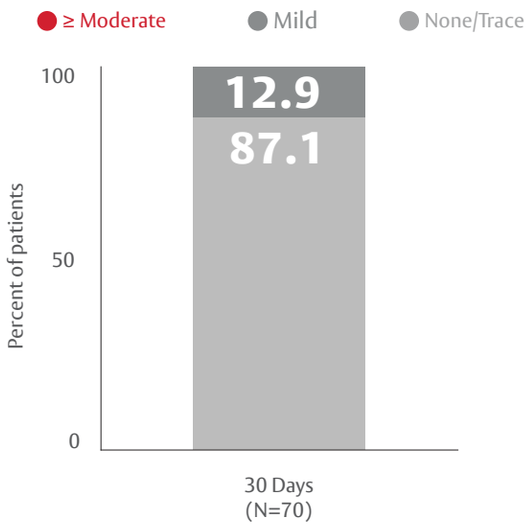




The SAPIEN 3 Ultra valve is available with the Edwards Commander Delivery System and Edwards eSheath– helping you to achieve consistent performance and controlled deployment.

Engineered for your patient's long-term future

- **Percentage of patients experiencing paravalvular leak at 30 Days[2]**

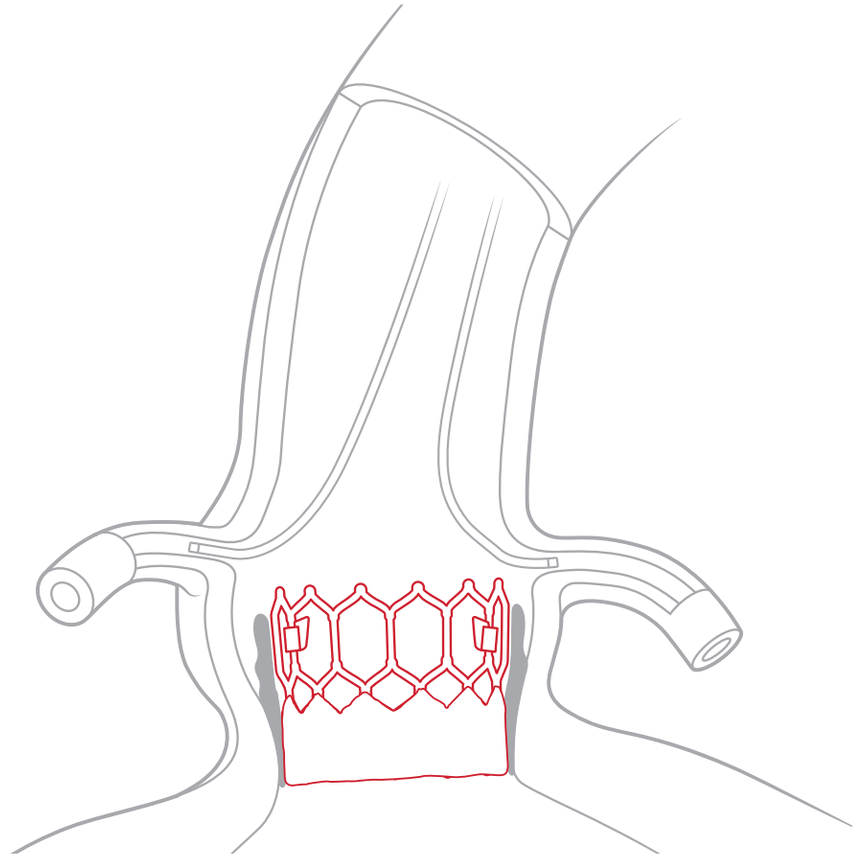


SAPIEN 3 Ultra Study

30-day findings were core lab adjudicated.

Edwards SAPIEN 3 Ultra features uniform sealing designed to minimize PVL.

- The SAPIEN 3 Ultra valve was designed with low frame height and large cell design to easily **facilitate future coronary access** should your patient require a procedure post-TAVR.





Access to the coronary arteries post-TAVR with the SAPIEN 3 Ultra valve was successful in 100% of cases (in 61 out of 61 patients).[3]

Important Safety Information

Edwards SAPIEN 3 THV System and Edwards SAPIEN 3 Ultra THV System

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

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

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

Warnings: Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation. There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients. Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch), and/or annular rupture. Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism. Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve. Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease. Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment. Do not use the valve if the tamper-evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed. Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g., kinked or stretched), or if the expiration date has elapsed. Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored. Patient injury could occur if the delivery system is not un-flexed prior to removal. Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials. The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting. Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without anticoagulation. Do not add or apply antibiotics to the storage solution, rinse solution, or to the valve. Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets. Failure to use slow, controlled inflation and prescribed nominal inflation volumes may result in balloon rupture, and lead to patient death or serious injuries associated with difficulty retrieving the delivery system and surgical intervention.

Precautions: Safety, effectiveness, and durability have not been established for THV-in-THV procedures. Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis. Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, the presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; and the presence of an Atrial Septal Occluder Device or calcium or abnormalities in the atrial septum preventing safe transseptal access. Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation to avoid entrapment of the subvalvular apparatus. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: non-calcified aortic annulus; severe ventricular dysfunction with ejection fraction < 20%; congenital unicuspid aortic valve; congenital bicuspid aortic valve in low surgical risk patients; mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation > 3+); pre-existing prosthetic ring in any position; severe mitral annular calcification (MAC); severe (> 3+) mitral insufficiency, or Gorlin syndrome; blood dyscrasias defined as leukopenia (WBC < 3000 cells/mL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/mL), or history of bleeding diathesis or coagulopathy; hypertrophic cardiomyopathy with or without obstruction (HOCM); echocardiographic evidence of intracardiac mass, thrombus, or vegetation; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid), or clopidogrel (Plavix), or sensitivity to contrast media, which cannot be adequately premedicated; significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater, marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta; access characteristics that would preclude safe placement of the 14F or 16F Edwards eSheath introducer set or the 14F Axela sheath, such as severe obstructive calcification, severe tortuosity, or diameter less than 5.5 mm (14F Axela or 14F eSheath introducer set) or 6 mm (16F eSheath introducer set or 14F Axela in subclavian access); excessive calcification at access site; bulky calcified aortic valve leaflets in close proximity to coronary ostia; a concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture); or a partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium. Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

Potential Adverse Events: Potential risks associated with the overall procedure, including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography: death; stroke/transient ischemic attack, clusters, or neurological deficit; paralysis; permanent disability; respiratory insufficiency or respiratory

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

Edwards Axela Sheath

Indications: The Edwards Axela sheath is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 Ultra delivery system.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm as it may preclude safe placement of the 14F Edwards Axela sheath. For subclavian/axillary vessels with the 29 mm Edwards SAPIEN 3 Ultra delivery system, caution should be used in vessels that have diameters less than 6.0 mm as it may preclude safe placement of the 14F Edwards Axela sheath. Use caution in tortuous or calcified vessels that would prevent safe entry of the sheath. Do not use the Edwards Axela sheath if the packaging sterile barriers and any components have been opened or damaged or the expiration date has elapsed. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards eSheath

Indications: The Edwards eSheath introducer set is indicated for the introduction and removal of devices used with the Edwards SAPIEN 3 and the Edwards SAPIEN 3 Ultra transcatheter heart valves.

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There is no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing. The Edwards eSheath introducer set must be used with a compatible 0.035" (0.89 mm) guidewire to prevent vessel injury.

Precautions: Caution should be used in vessels that have diameters less than 5.5 mm or 6 mm as it may preclude safe placement of the 14F and 16F Edwards eSheath introducer set respectively. Use caution in tortuous or calcified vessels that would prevent safe entry of the introducer set. Do not use the Edwards eSheath introducer set if the packaging sterile barriers and any components have been opened or damaged. When inserting, manipulating or withdrawing a device through the sheath, always maintain sheath position. When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.

Potential Adverse Events: Complications associated with standard catheterization and use of angiography include, but are not limited to, injury including perforation or dissection of vessels, thrombosis and/or plaque dislodgement which may result in emboli formation, distal vessel obstruction, hemorrhage, infection, and/or death.

Edwards Crimper

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

Contraindications: There are no known contraindications.

Warnings: The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.

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

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

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

Edwards, Edwards Lifesciences, the stylized E logo, Axela, Edwards eSheath, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, eSheath, SAPIEN, SAPIEN 3, and SAPIEN 3 Ultra are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2019 Edwards Lifesciences Corporation. All rights reserved. PP--US-4028 v2.0

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards

Experience the difference with the SAPIEN 3 Ultra valve

Learn more at **SAPIEN3Ultra.com.**

References:

1. The PARTNER II Trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVR with the SAPIEN 3 valve, AT population (n=1077).
2. Webb, John. A prospective multicenter study of the SAPIEN 3 Ultra system in intermediate-risk patients with severe aortic stenosis. Presented at: PCR London Valves 2019; November 2019; London, UK.
3. Tarantini G, Fovino LN, Leprince P, et al. Predictors, feasibility and outcomes of coronary intervention up to 3 years after TAVI with a balloon-expandable valve: results from a large European multicenter registry. Presented at: ESC Congress 2019; September 2019; Paris, France.

See enclosed Important Safety Information.

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

SAPIEN 3 and SAPIEN 3 Ultra involve serious risks, including death, stroke, major bleeding, and major vascular complications.

Edwards, Edwards Lifesciences, the stylized E logo, Axela, Commander, Edwards Commander, Edwards eSheath, eSheath, PARTNER II, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, SAPIEN, SAPIEN 3, and SAPIEN 3 Ultra are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2020 Edwards Lifesciences Corporation. All rights reserved. PP--US-4496 v1.0

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards

SAPIEN 3 Ultra Valve First-In-Human Experience

Dr Martyn Thomas
VP of Medical Affairs
Edwards Lifesciences



Edwards

Time Between Regional Approvals is Narrowing



SAPIEN valve



SAPIEN XT valve



SAPIEN 3 valve



SAPIEN 3 Ultra valve



September 2007

4 Years

November 2011



March 2010

4 Years

June 2014

January 2014

1.5 Years

June 2015

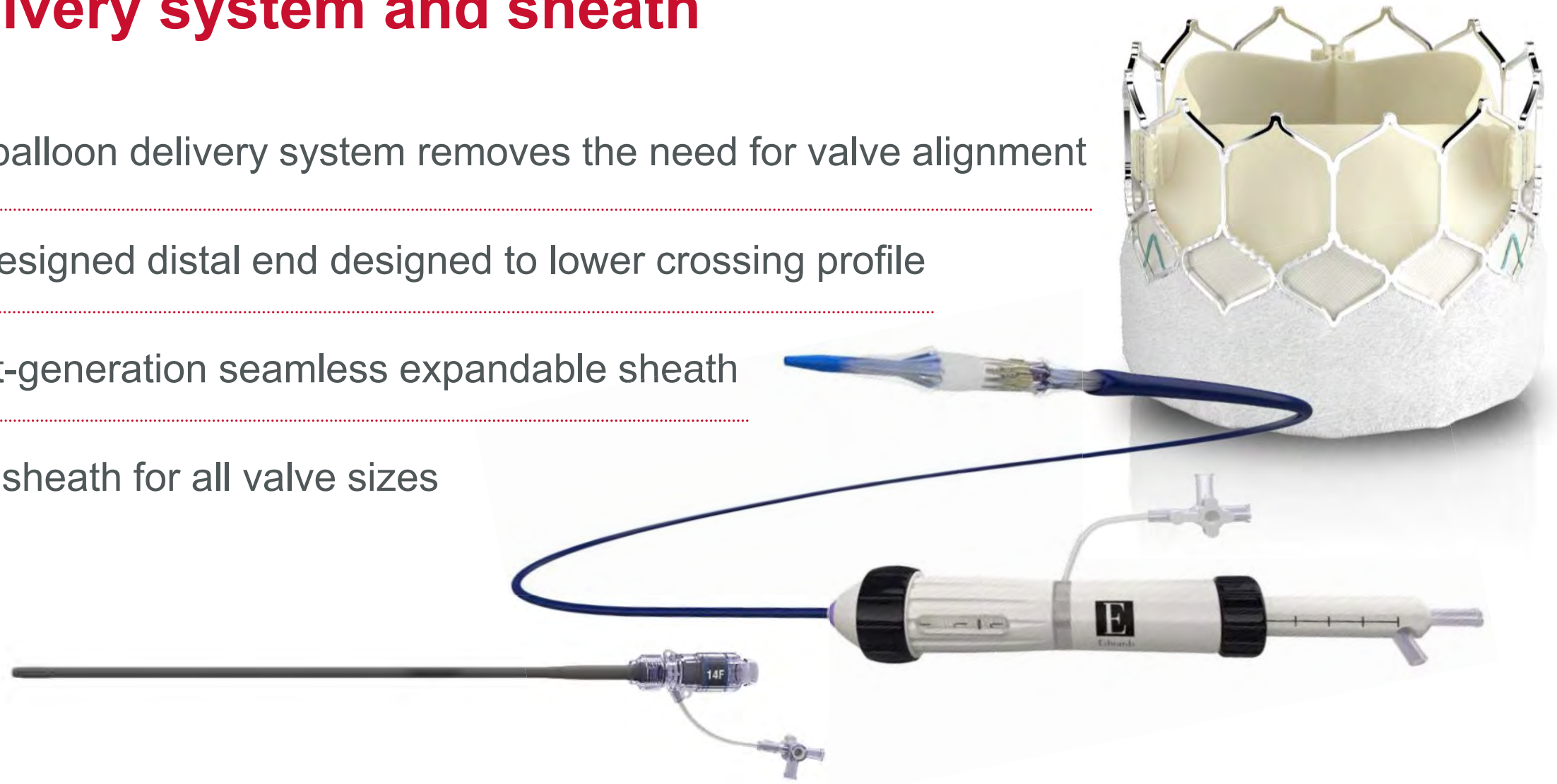
November 2018

1 Month

December 2018

The Edwards SAPIEN 3 Ultra System Delivery system and sheath

- On-balloon delivery system removes the need for valve alignment
- Redesigned distal end designed to lower crossing profile
- Next-generation seamless expandable sheath
- 14F sheath for all valve sizes

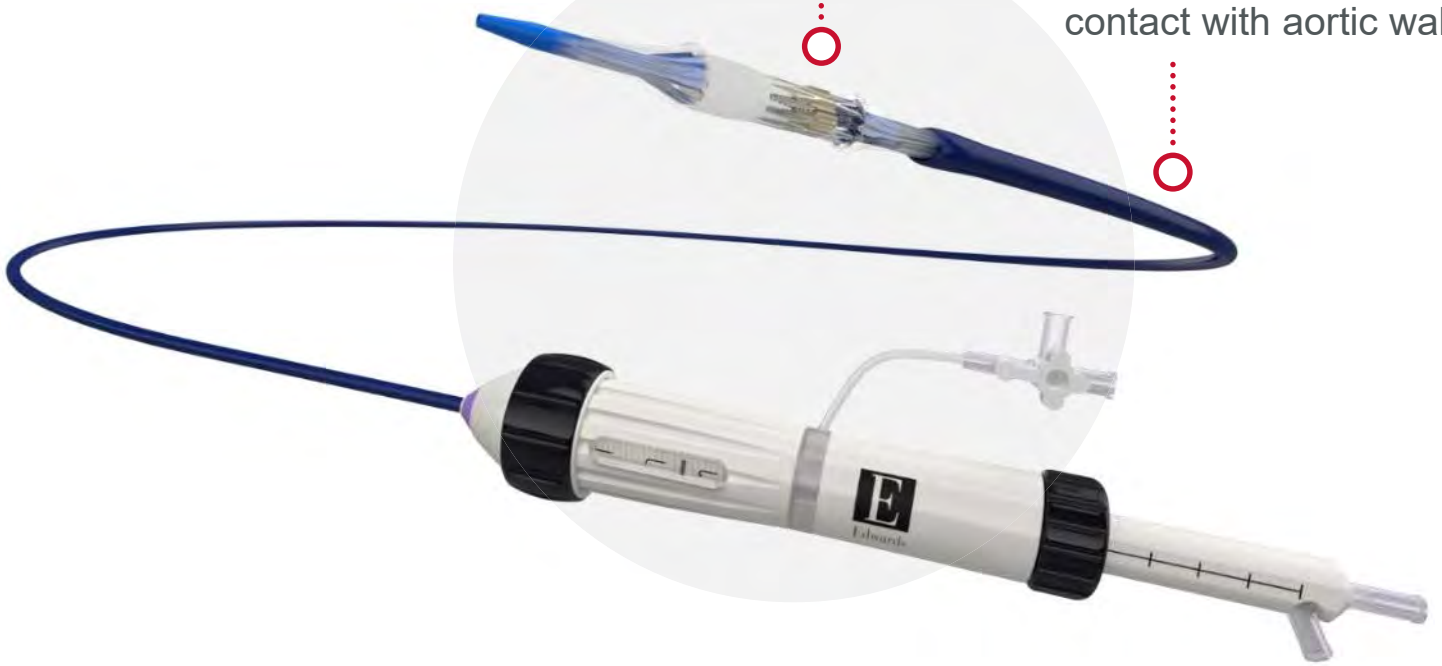


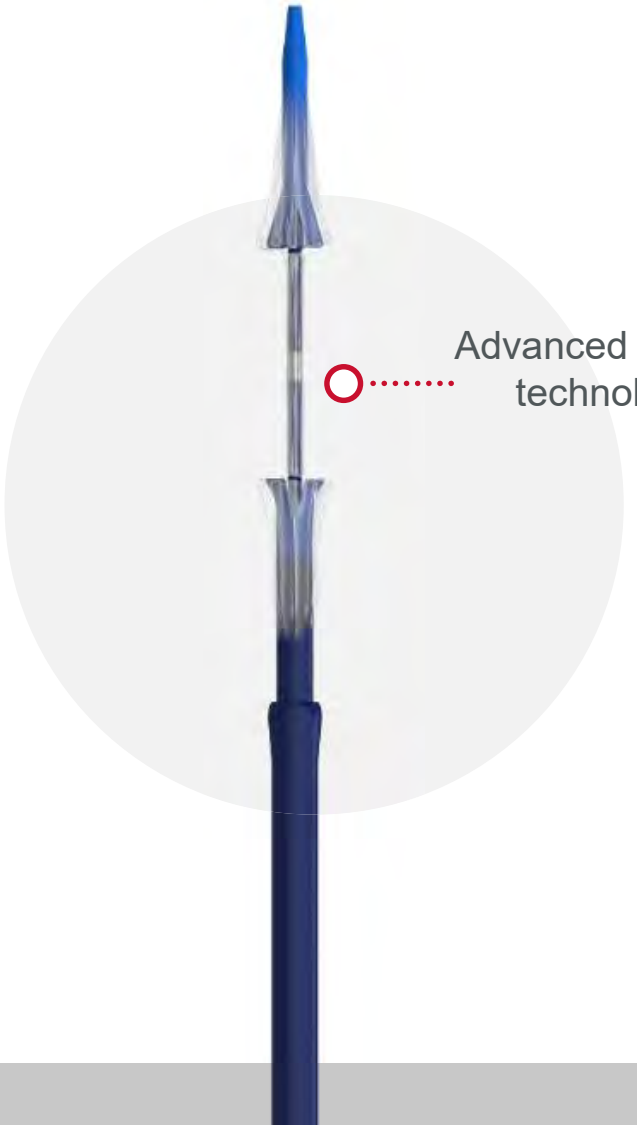
The Edwards SAPIEN 3 Ultra System

Redesigned distal end for improved crossability

On-balloon delivery system removes the need for valve alignment

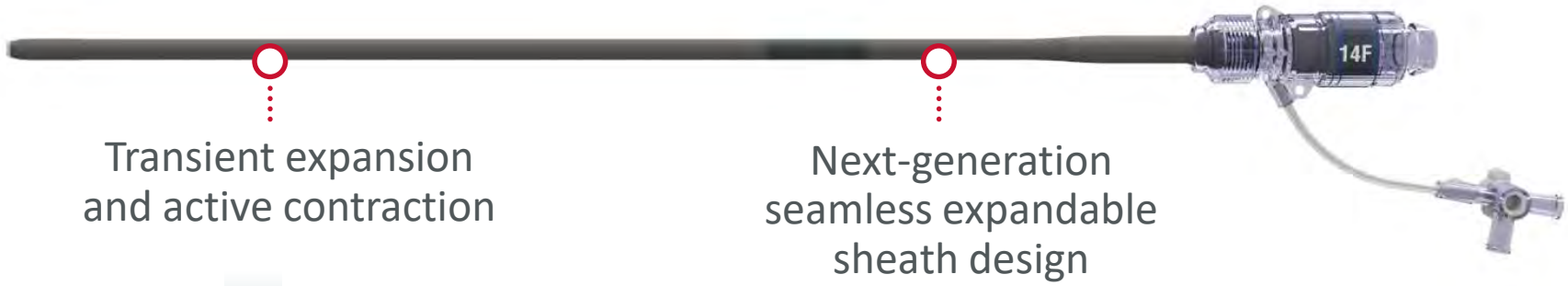
Responsive articulation avoids contact with aortic wall





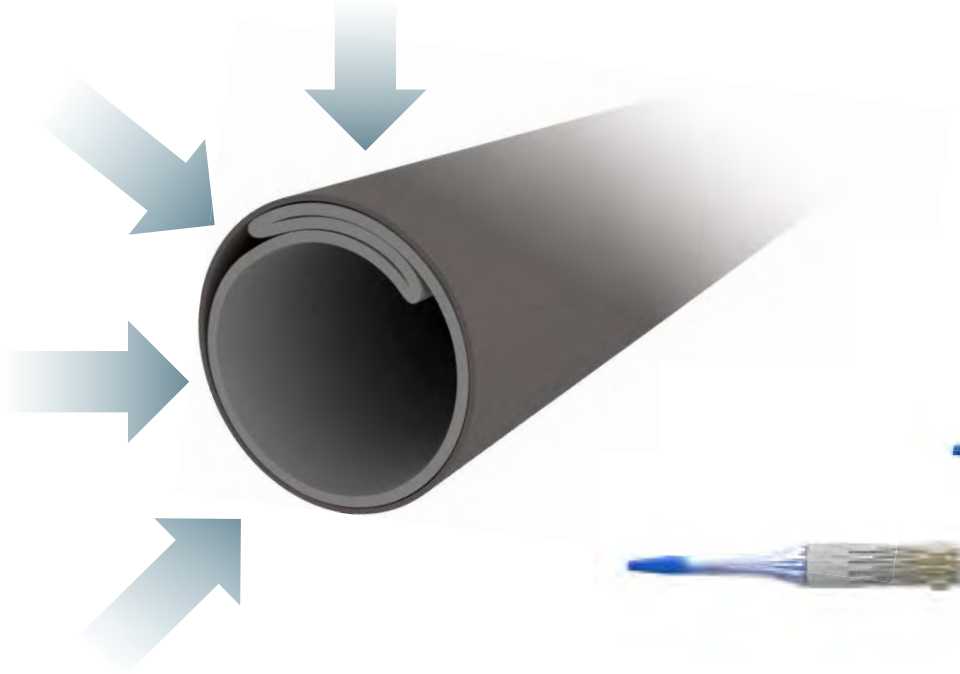
Advanced balloon technology

The Edwards SAPIEN 3 Ultra System: Axela Sheath



Transient expansion and active contraction

Next-generation seamless expandable sheath design

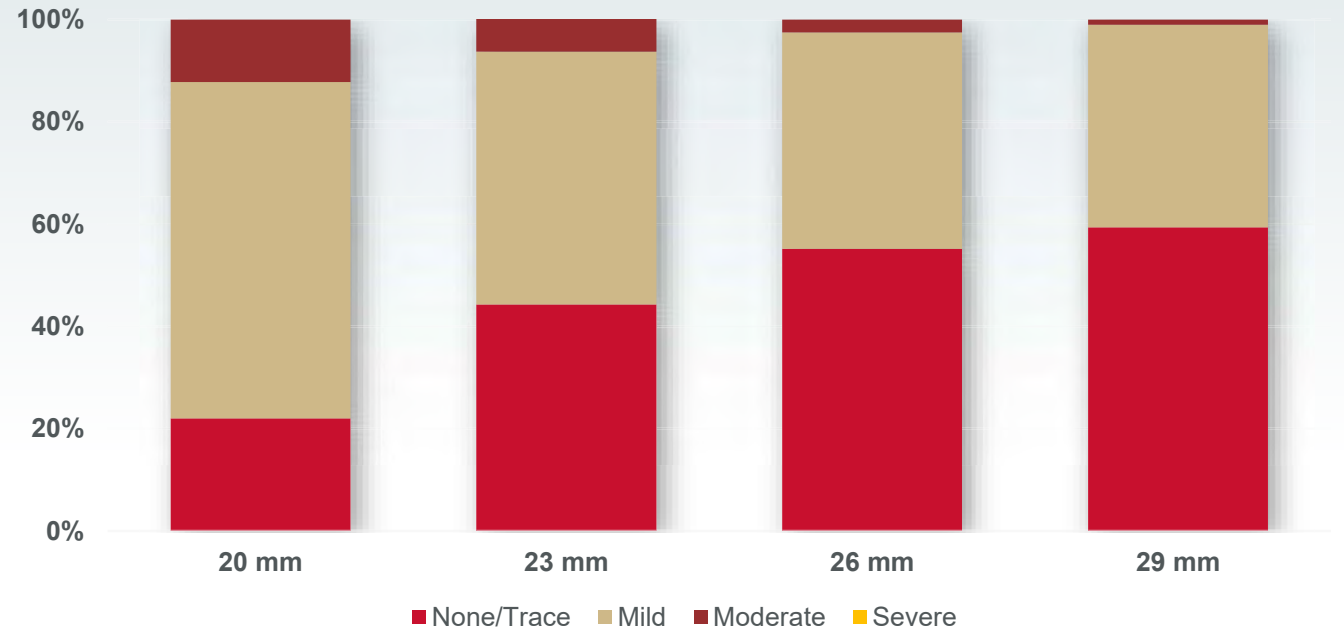


Valve Size	Sheath Size
20 mm	14F
23 mm	14F
26 mm	14F
29 mm	14F

The SAPIEN 3 Ultra Valve
Inspired by the 29mm SAPIEN 3 Valve

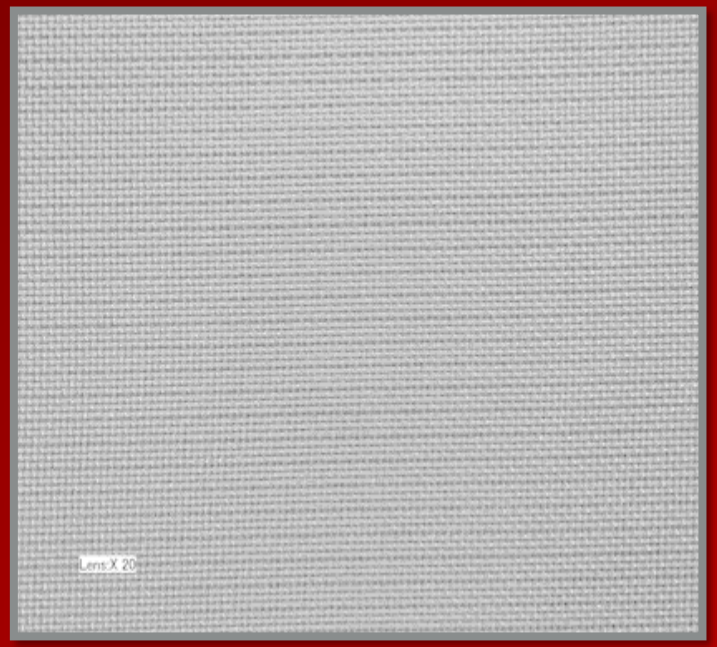


PARTNER IIA S3i PVL by Valve Size at 30 days

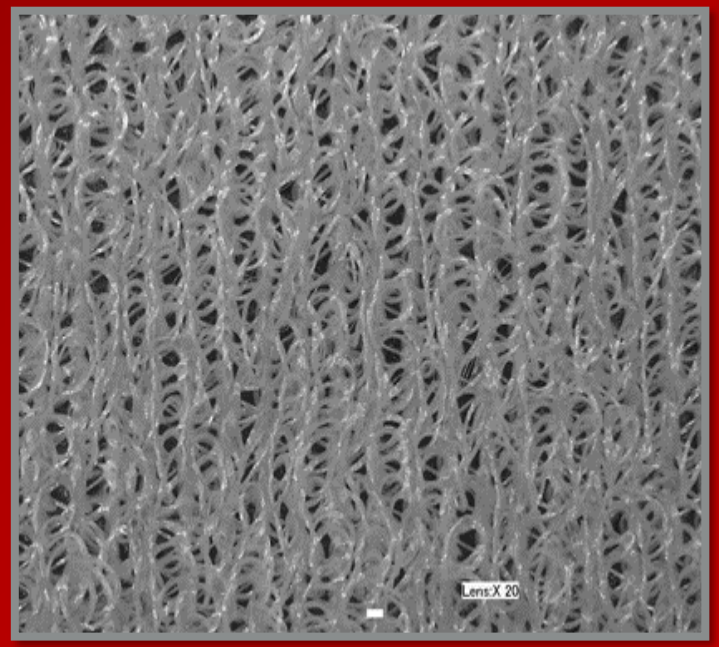


* Source: Clinical Study Report: The Placement of Aortic Transcatheter Valves (PARTNER) II Trial (Study 2012-12-US) -- SAPIEN 3, Feb 2016

Fabric Skirt



SAPIEN 3
Flat woven



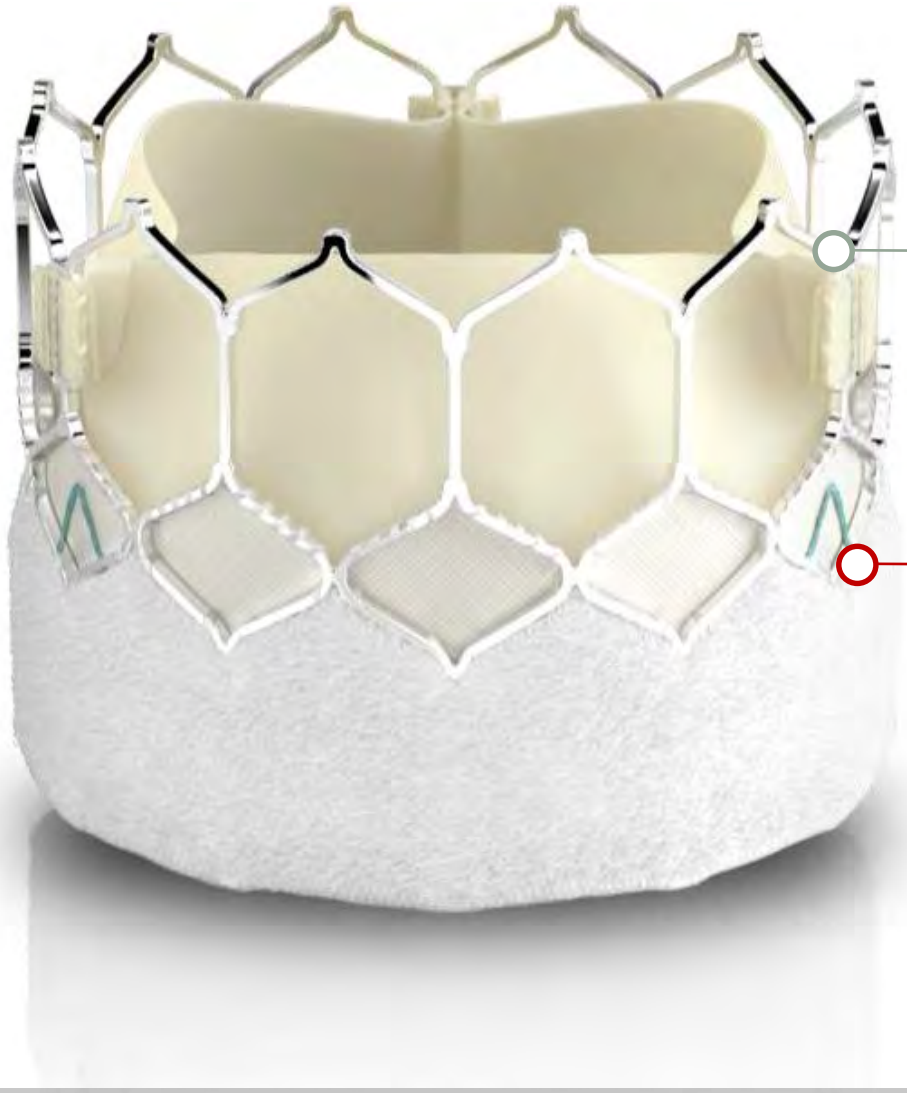
SAPIEN 3 Ultra
Textured



Proven PET Skirt Material

- Same biocompatible material as SAPIEN 3 valve
- Knitted, textured PET material

Edwards SAPIEN 3 Ultra Valve



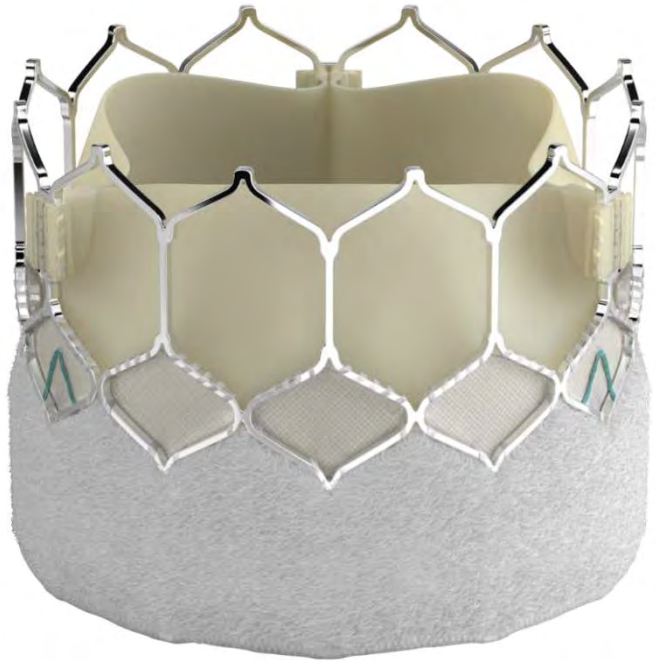
Frame and Leaflet Design

- Proven SAPIEN 3 leaflet and frame design

Outer Skirt

- Textured 3-dimensional PET skirt design
- 40% taller skirt - up to 50% more contact surface area with native anatomy
- 14F sheath compatible

THE SAPIEN 3 ULTRA TRIAL



SAPIEN 3 Ultra Trial

Up to 4 Sites and a minimum of 20 Patients

Severe, Calcific Aortic Stenosis

Intermediate Risk Assessment by Heart Team and STS ≥ 3 to < 8

Enrollment

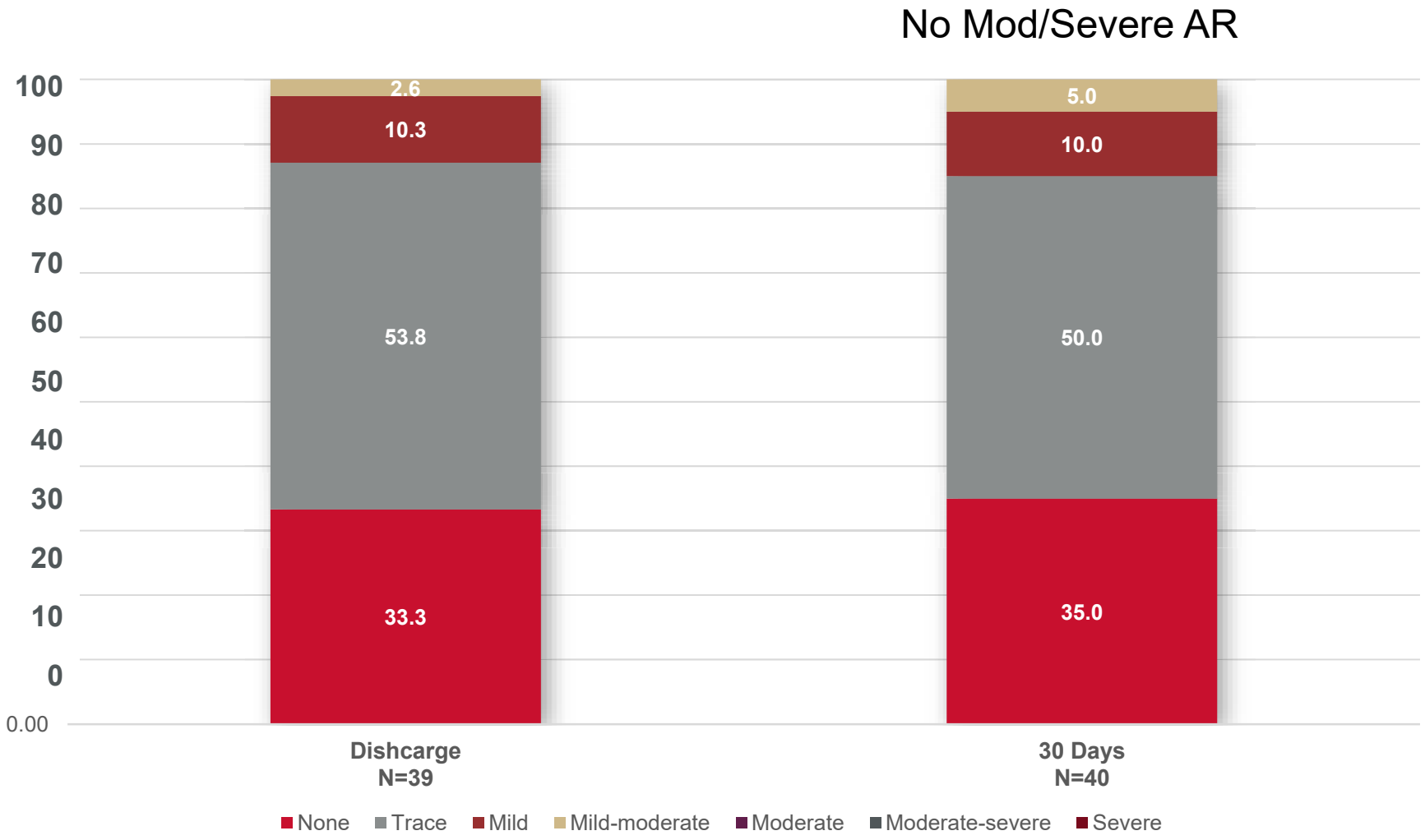
TAVR
(SAPIEN 3 Ultra THV and Delivery System)

Follow-up: Discharge, 30 days, 6 months, and annually through 5 years

Primary Endpoint: freedom from all of the following at exit from the procedure room:

- Mortality
- Conversion to surgery
- Moderate or severe paravalvular regurgitation

SAPIEN 3 Ultra Trial: Total Aortic Regurgitation



LinkedIn Join now Sign in

Dale Murdoch

Dale Murdoch
Interventional Cardiologist at The Prince Charles Hospital and St Vincent's Northside
7mo

First Australian SAPIEN 3 ULTRA case today at TPCH .. Congrats to all the team. Borderline annulus sizing at 540mm2 - 26mm nominal with no PVL - with **Karl Poon**



322 · 23 Comments

Like Comment Share

Michael Vallely 7mo
Well done. Great for Australian patients. Sapien 3 Ultra is a game changer when it comes to paravalvular leak - need the 29 (& a 31!).
Like Reply | 8 Likes

Gilbert Tang, MD, MSc, MBA, FRCSC, FACC 7mo
Great job Karl and team. 540mm2 we definitely go 26 S3 Ultra and depending on Ca severity may to +1cc. We've used it to treat area up to 580mm2 going +2cc with trivial PVL only. Bicuspid we can go up to 590mm2!
Like Reply | 1 Like

Belinda Shearer 7mo
Congrats team!
Like Reply | 2 Likes

Dr Anthony French 7mo
Legend leading legends.... karl poon
Like Reply

Maria Fernanda R. 7mo ···

Inspiring
Like Reply

Rogerio Zeimert 7mo ···
beautiful!
Like Reply

Nick Aroney 7mo ···
Great to hear Dale! I've had a great experience with them over here thus far.
Like Reply

Nicholas Dangerfield 6mo ···
Congrats Dale,Karl and team
Like Reply

John Kearney 7mo ···
Well done Murdoch!!!
Like Reply

Kannan Natarajan 7mo ···
Inspiring Dale, Karl, Chris & team.
Like Reply

See more comments

To view or add a comment, **sign in**



962 followers

6 Posts · 0 Articles

View Profile + Follow

Accessibility
User Agreement
Privacy Policy
Cookie Policy
Copyright Policy
Brand Policy
Guest Controls
Community Guidelines
Language

Premarket Approval (PMA)

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

Device	Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve
Generic Name	Aortic Valve, Prosthesis, Percutaneously Delivered
Applicant	EDWARDS LIFESCIENCES, LLC. One Edwards Way Irvine, CA 92614
PMA Number	P140031
Supplement Number	S141
Date Received	05/02/2022
Decision Date	07/28/2022
Product Code	NPT[24]
Advisory Committee	Cardiovascular
Supplement Type	Normal 180 Day Track
Supplement Reason	Change Design/Components/Specifications/Material
Expedited Review Granted?	No
Combination Product	No

Approval Order Statement

Approval For The Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve.

Post-Approval Study Show Report Schedule And Study Progress[25]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

11. /scripts/cdrh/cfdocs/cfRES/res.cfm
12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfpma/pma.cfm
23. /scripts/cdrh/cfdocs/cfpma/pma.cfm?start_search=1&PMANumber=P140031&SupplementType=NONE
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&ProductCode=NPT
25. /scripts/cdrh/cfdocs/cfpma/pma_pas.cfm?tid=762598

Page Last Updated: 02/06/2023

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of Health & Human Services

Links on this page:

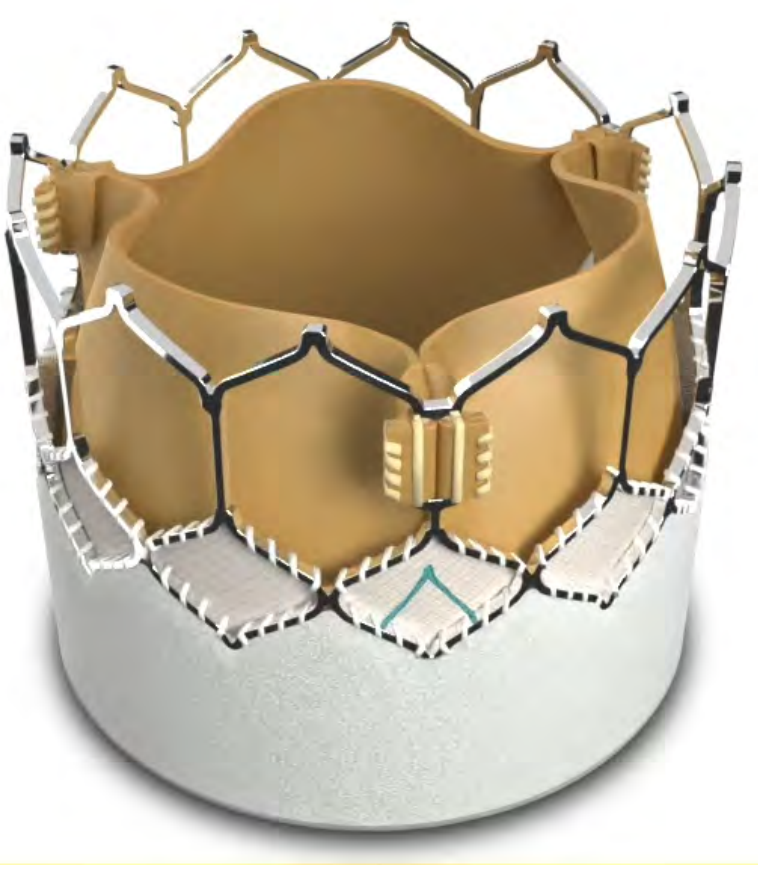
1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. https://www.fda.gov/Medical-Devices
5. https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
6. /scripts/cdrh/devicesatfda/index.cfm

Edwards

The SAPIEN 3 Ultra Valve, Now Powered By RESILIA Tissue

Building on the benefits of the SAPIEN 3 platform, now with RESILIA tissue's calcium-blocking technology*[2]

Calcification is a leading cause of structural valve deterioration (SVD) in aortic tissue valves.[1] RESILIA tissue effectively addresses calcification with advanced calcium-blocking.*[2]





Stable capping blocks calcium from binding to tissue*

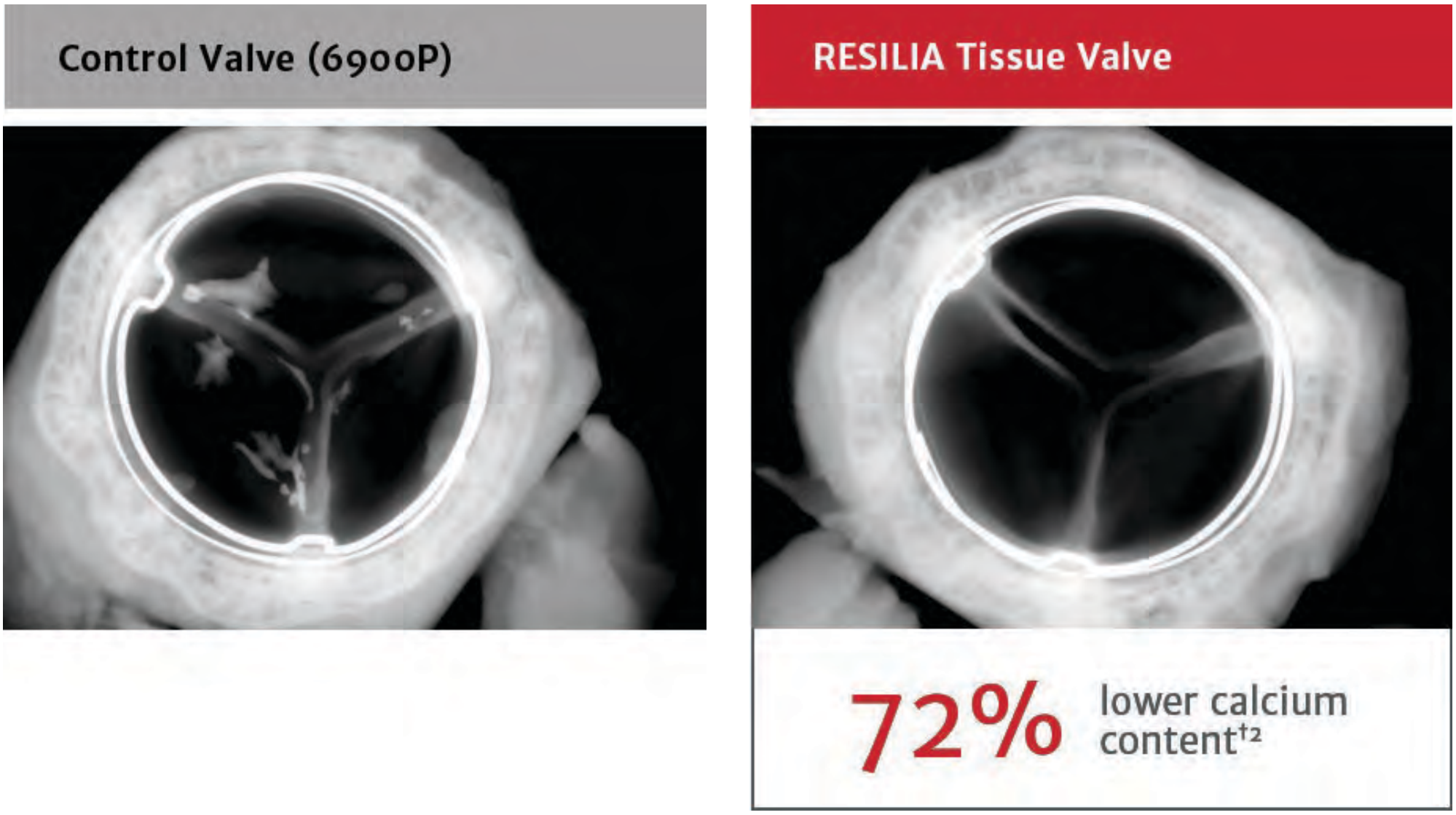
*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

See the difference

Important Safety Information

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

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



RESILIA tissue features the same tissue technology used in the #1 implanted surgical valve in the U.S.

Delivering the potential to improve valve longevity and reduce reintervention*†

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

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



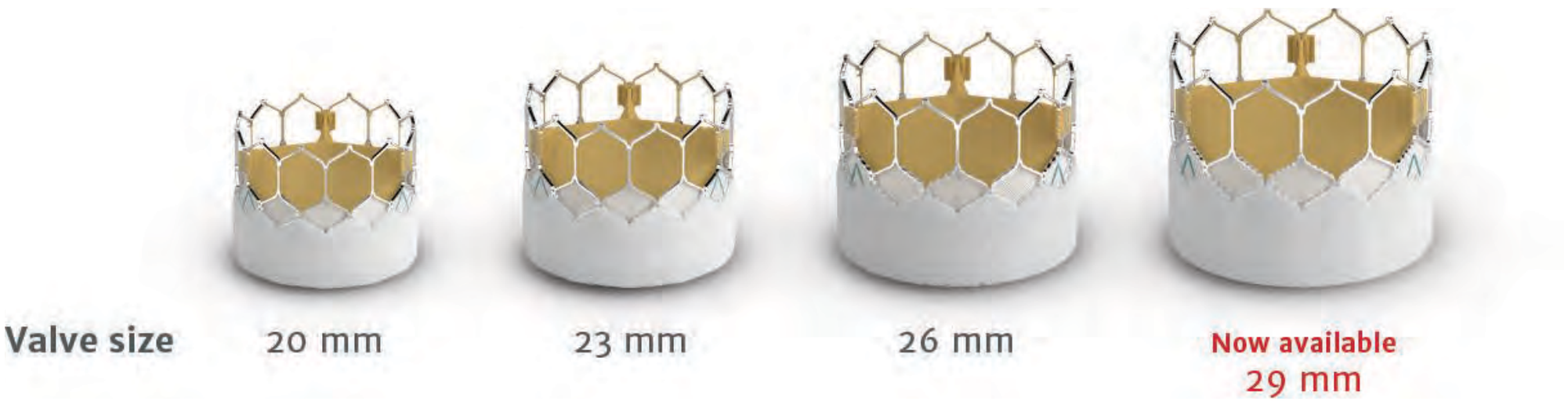
The only transcatheter heart valve (THV) with dry tissue storage

Important Safety Information

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

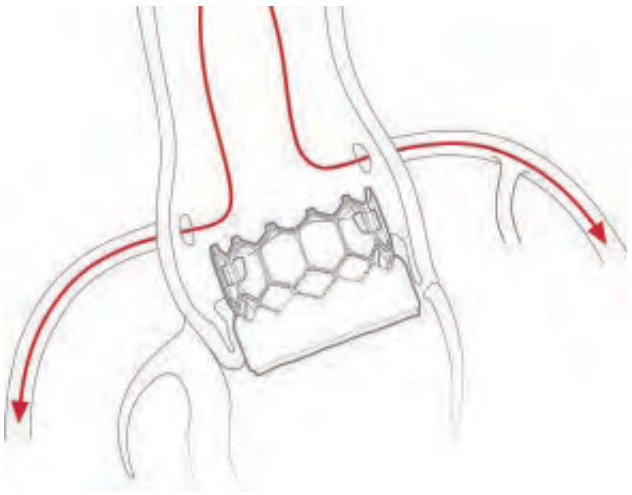
Indications: The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in

SAPIEN 3 Ultra valve taller* paravalvular leak (PVL) skirt now available in the 29 mm size



*Compared to SAPIEN 3 valve

The SAPIEN 3 TAVR fully addresses the vital considerations for lifetime management



Superior outcomes‡4

1% death and disabling stroke at one year[4]

90.9% none/trace PVL at discharge[5]

6.5% new pacemaker rate at 30 days[4]

Future treatment options

100% successful post-TAVR coronary access rate (68/68 patients)[6]



The only transcatheter heart valve with a **THV-in-THV** indication

†In the PARTNER 3 trial, SAPIEN 3 TAVR was proven superior to surgery on the primary endpoint of all-cause death, all stroke, and reshospitilization (valve-related or procedure-related, and including due to heart failure) at one year and multiple prespecified secondary endpoints in low risk patients.

Click a hot spot to learn more

Important Safety Information

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

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

technology*

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

In a robust clinical trial, surgical valves with RESILIA tissue demonstrated 0% structural valve deterioration (SVD) at 5 years.*[3]

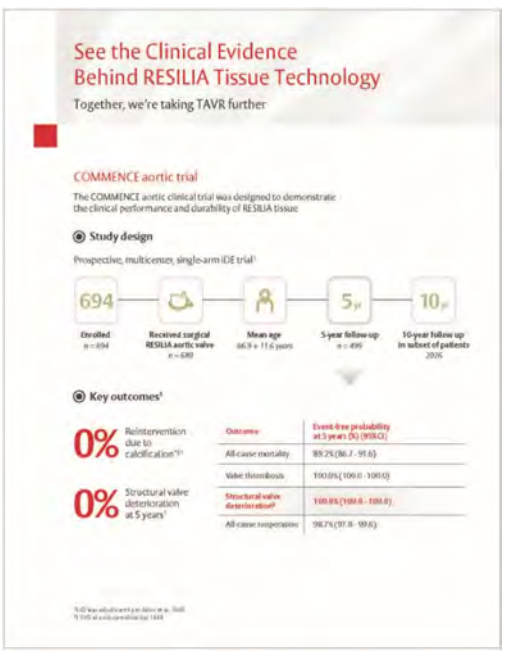
0%

SVD at 5 years*

0%

reintervention due to calcification

*SVD measured per surgical guidelines as any reintervention



Download Clinical Data

See the clinical evidence behind RESILIA tissue technology.

Download now

Important Safety Information

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

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

Register for updates →

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

References: **1.** Schoen F, et al. Calcification of Tissue Heart Valve Substitutes: Progress Towards Understanding and Prevention. *Ann Thorac Surgery* 2005 79;1072-80 **2.** Flameng W, Hermans H, Verbeken E, et al: Randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg*. 2015;149(1):340-345. **3.** Bavaria JE, Griffith B, Heimansohn DA, et al. Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with RESILIA tissue [published online ahead of print, 2022 Jan 20]. *Ann Thorac Surg*. 2022;S0003-4975(22)00063-7. doi:10.1016/j.athoracsur.2021.12.058. **4.** Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *NEJM*. 2019; 380:1695-1705. doi:10.1056/NEJMoa1814052. **5.** Nazif TM, Cahill TJ, Daniels D, et al. Real-world experience with the SAPIEN 3 Ultra transcatheter heart valve: a propensity-matched analysis from the United States. *Circ Cardiovasc Interv*. 2021;14:e010543. doi:10.1161/CIRCINTERVENTIONS.121.010543. **6.** Tarantini G, Nai Fovino L, Le Prince P, et al. Coronary access and percutaneous coronary intervention up to 3 years after transcatheter aortic valve implantation with a balloon-expandable valve. *Circ Cardiovasc Interv*. 2020;13:e008972. doi:10.1161/CIRCINTERVENTIONS.120.008972.

COOKIE PREFERENCES

Important Safety Information

Site Map

Legal Terms

Privacy Policy

Do Not Sell my Information

© 2022 Edwards Lifesciences Corporation. All rights reserved.

Important Safety Information

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

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

February 22 is Heart Valve Disease Awareness Day. Take control of your severe aortic stenosis, the most common type of HVD, by using this Informed Discussion Guide.

Find a TAVR Hospital

For Healthcare Professionals

Talking With Your Doctor

Edwards



Understand why your first valve choice matters

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

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

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

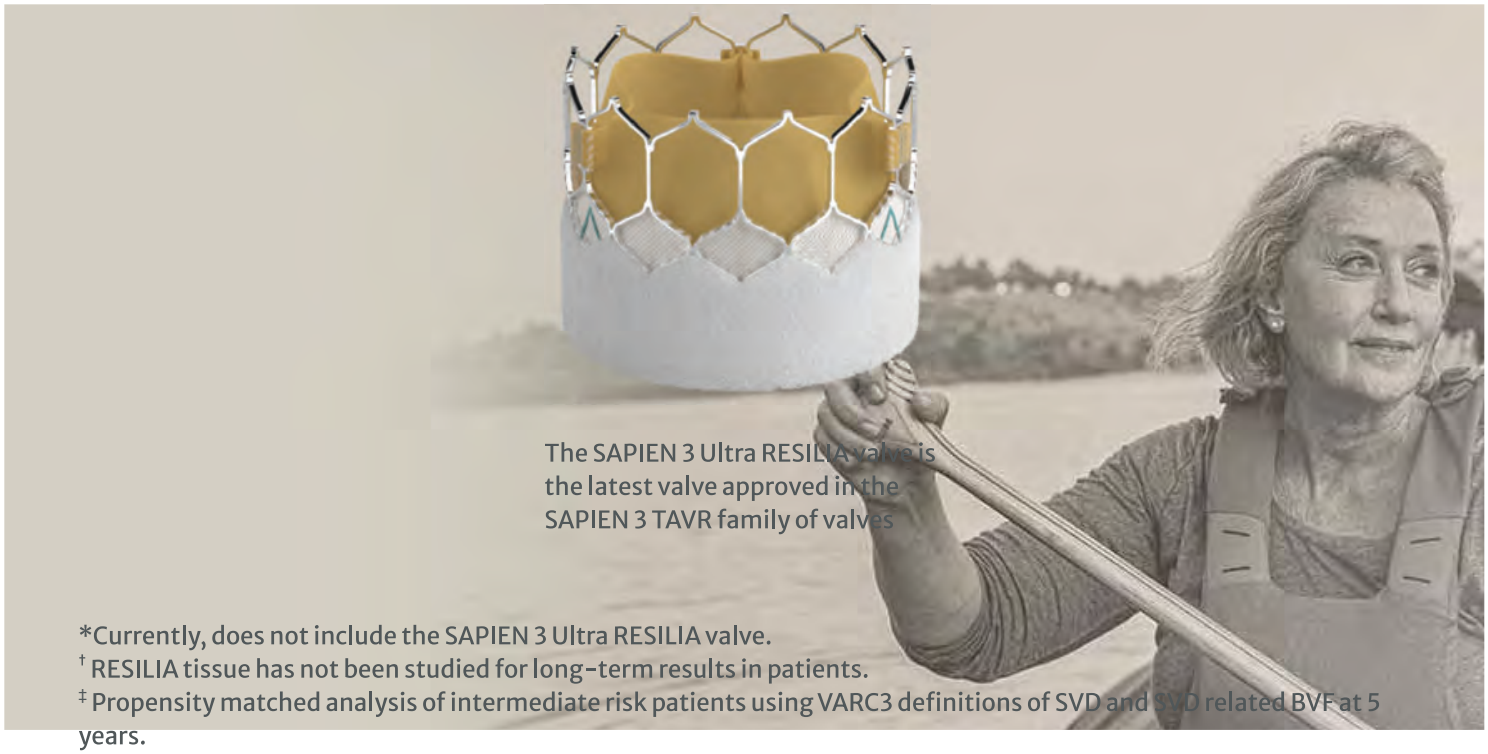
TAVR with the SAPIEN 3, has similar durability to that of the leading surgical valves at 5 years.[†‡1,2]

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

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

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

Important Risk Information



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

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

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

Designed like your heart

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

Designed to last

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

Important Risk Information

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

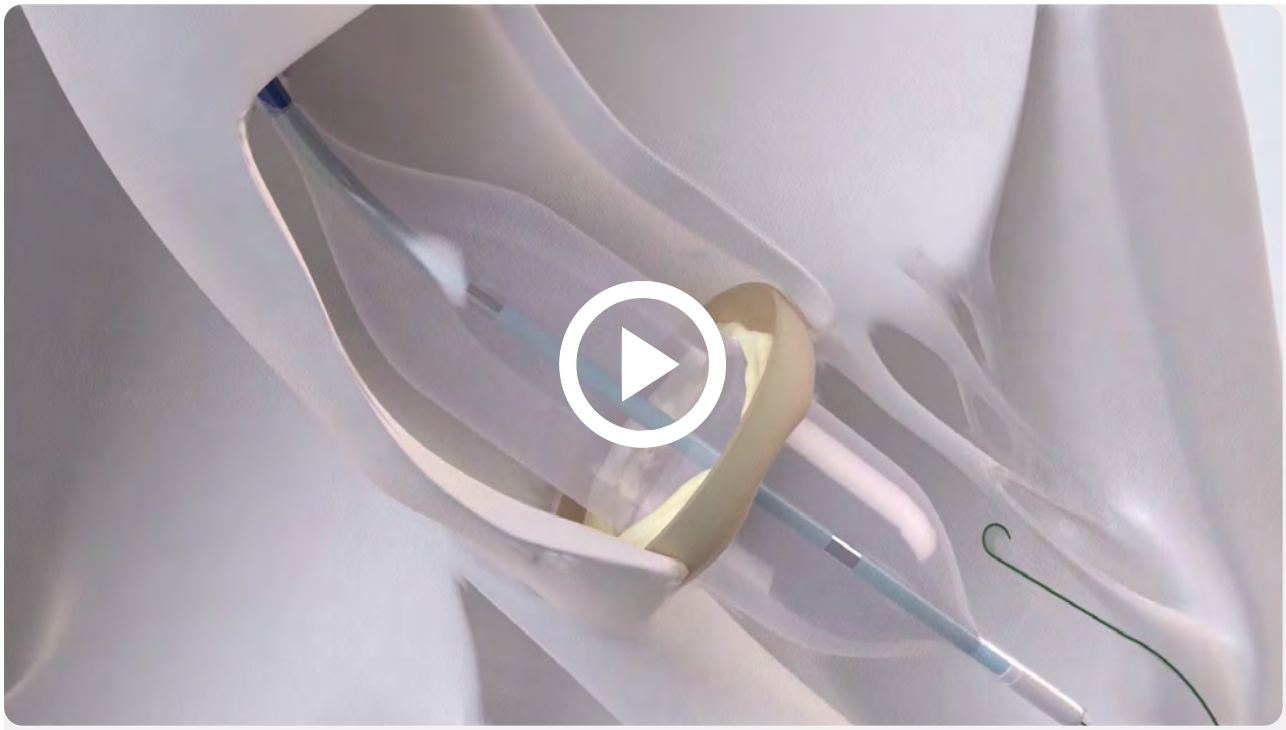


Designed for your future

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

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

TAVR procedure animation



Watch this animation to learn more about SAPIEN 3 TAVR valves and ask your doctor about which TAVR valve is right for you.

Watch the TAVR Procedure Animation

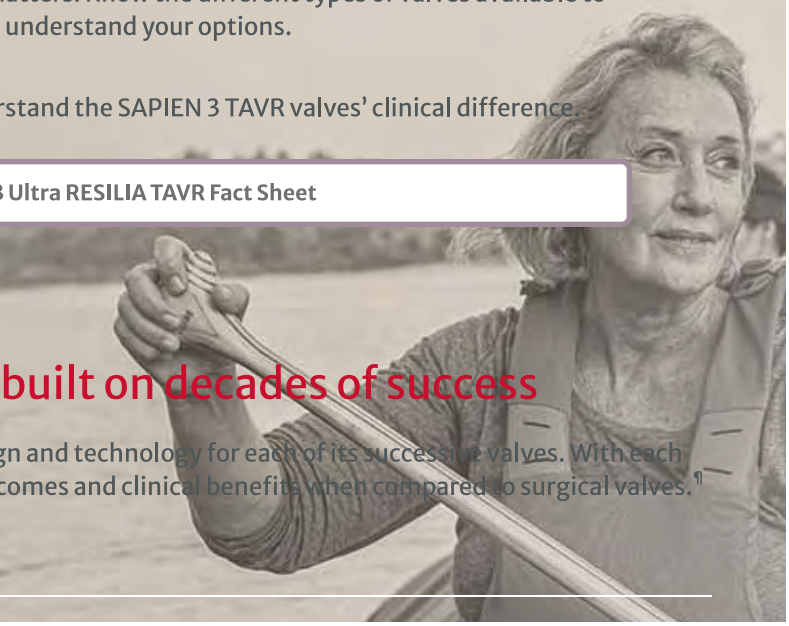
Important Risk Information

Ask which TAVR valve you are getting today

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

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

Download the SAPIEN 3 Ultra RESILIA TAVR Fact Sheet



Edwards SAPIEN 3 TAVR valves built on decades of success

Edwards continues to build upon its best-in-class design and technology for each of its successive valves. With each generation of Edwards valves comes better patient outcomes and clinical benefits when compared to surgical valves.[1]



FDA Approved 2022

Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve

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

Edwards' commitment to technology continues with the SAPIEN 3 Ultra RESILIA

FDA Approved 2018

Edwards SAPIEN 3 ULTRA Transcatheter Heart Valve

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

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

FDA Approved 2015

Edwards SAPIEN 3 Transcatheter Heart Valve

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

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

Important Risk Information

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



Next page: know the clinical difference

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

Go to the Clinical Difference Page

References

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

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

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

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

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

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

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

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

© 2022 Edwards Lifesciences Corporation. All rights reserved.

Important Risk Information

Transcatheter Aortic Valve Replacement

Larry L. Wood
Corporate Vice President
Transcatheter Aortic Valve Replacement

Edwards

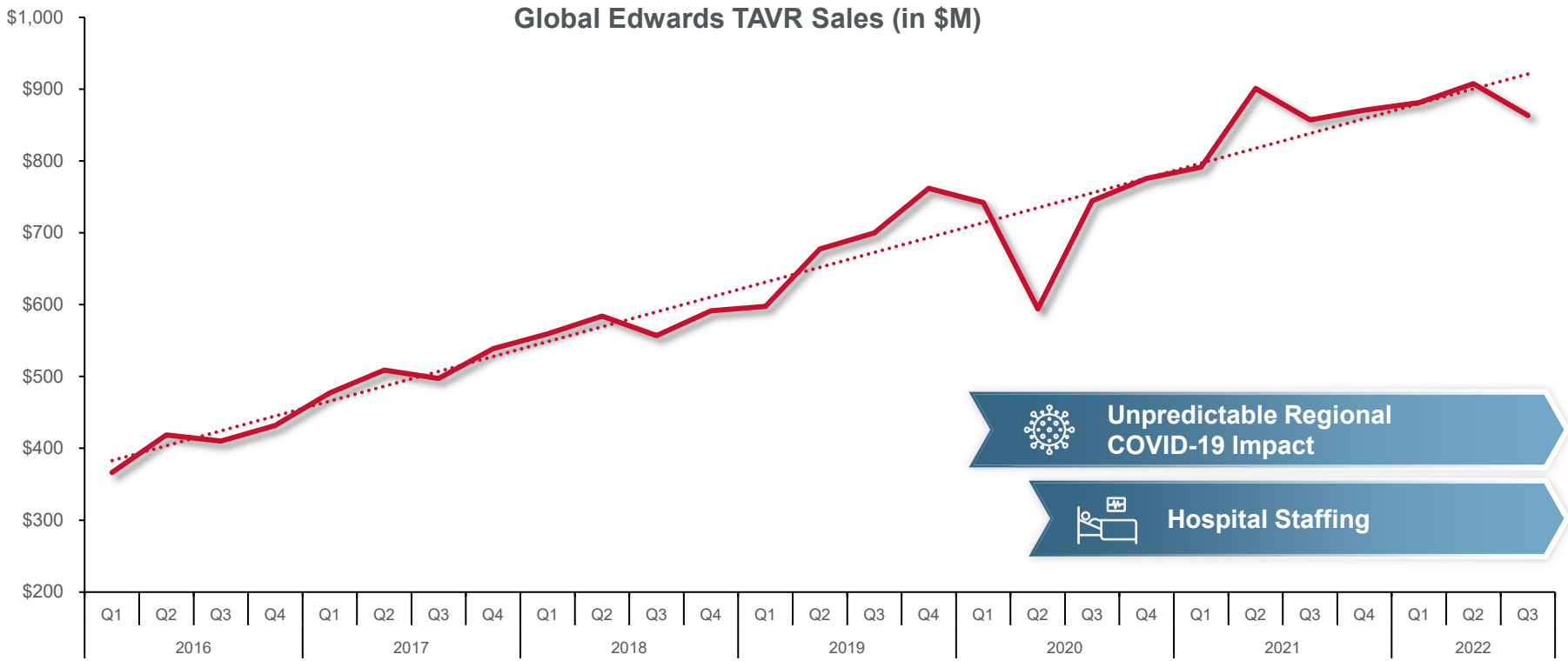
Immediate Challenges are Transient; TAVR Fundamentals Remain Strong



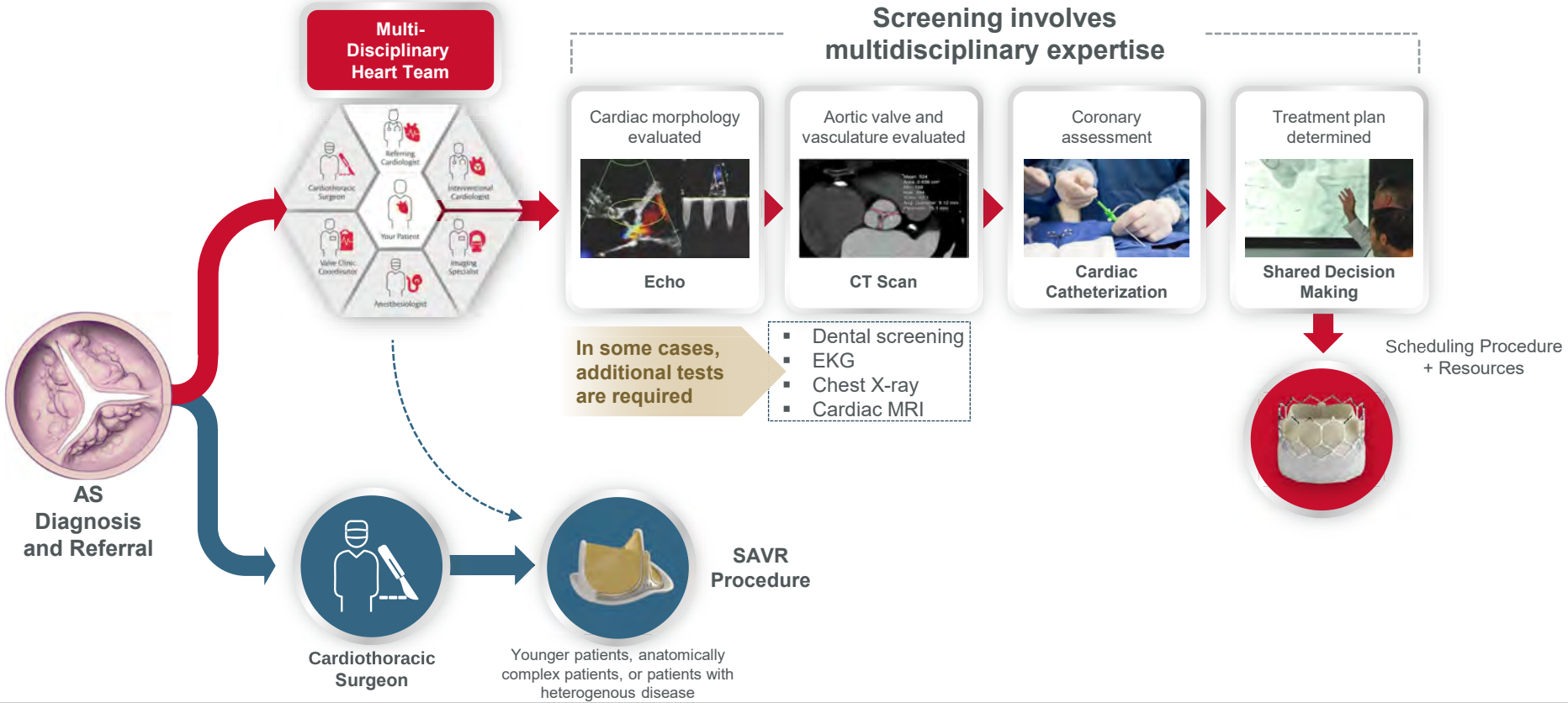
Key Pillars of Our Strategy

- Increase Therapy Adoption in Growing AS Opportunity
- Expand Indications
- Deliver Strong Portfolio Innovation

Despite challenges, global EW TAVR has delivered double-digit growth over the past six years



Administrative requirements before TAVR are higher than other service lines, and staffing shortages impact TAVR patients



Over the years, we have improved TAVR efficiencies

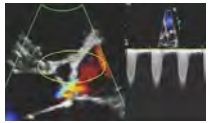
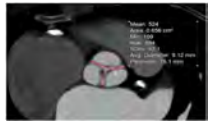


AS Diagnosis and Referral

Multi-Disciplinary Heart Team



Screening involves multidisciplinary expertise

Cardiac morphology evaluated	Aortic valve and vasculature evaluated	Coronary assessment	Treatment plan determined
			
Echo	**CT Scan**	**Cardiac Catheterization**	**Shared Decision Making**

In some cases, additional tests are required

- Dental screening
- EKG
- Chest X-ray
- Cardiac MRI

Scheduling Procedure + Resources



Cardiothoracic Surgeon



Younger patients, anatomically complex patients, or patients with heterogenous disease

SAVR Procedure

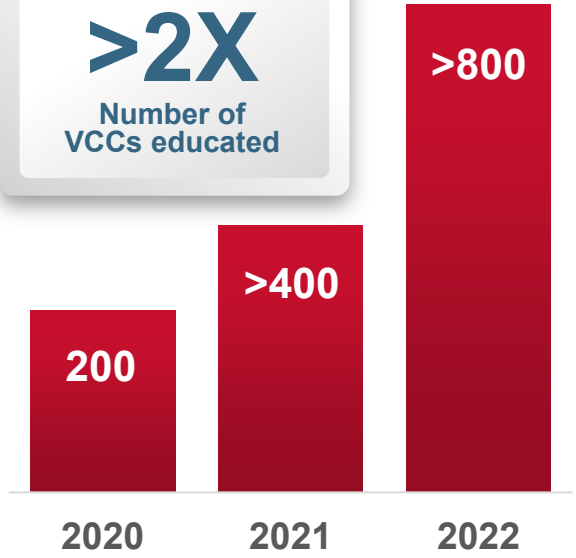
We continue to focus our efforts on further optimizing pathway to treatment

(1) LOS – Length of Stay (2) Carroll JD et al, 2021, STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement

We Remain Focused on Supporting Hospitals as Trusted Partners

Valve Clinic Coordinator Education Programs

>2X
Number of VCCs educated



VCCs are typically trained nurses who support patients from referral through post-TAVR procedure follow-up

Edwards Facilitated Peer-to-Peer Education Programs:

- **Quickstart** – first 30-60 days foundational program
- **Level 1** – for new VCCs to support TAVR program development
- **Level 2** – for experienced VCCs to support TAVR program optimization

Provider Education Programs



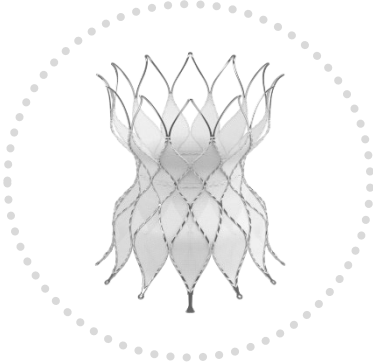
300+
fellows expected to complete programs in FY22[1]

225+
HCPs[2] completed programs this year



(1) FY22 - Jul 2021 to Jun 2022 (2) HCP - Healthcare Personnel

We Continue to Deliver On Our Long-Term Growth Drivers







THE EARLY TAVR TRIAL

THE PROGRESS TRIAL

ALTERRA

Pulmonic Adaptive Prestent launched

SAPIEN 3 Ultra RESILIA

Approved in the U.S. and JPN

SAPIEN X4 System

ALLIANCE Trial enrollment started

EARLY TAVR Trial

Enrollment complete; in follow-up

PROGRESS Trial

Enrolling for moderate AS

Commercial | **Technology** | **Indication Expansion**

Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

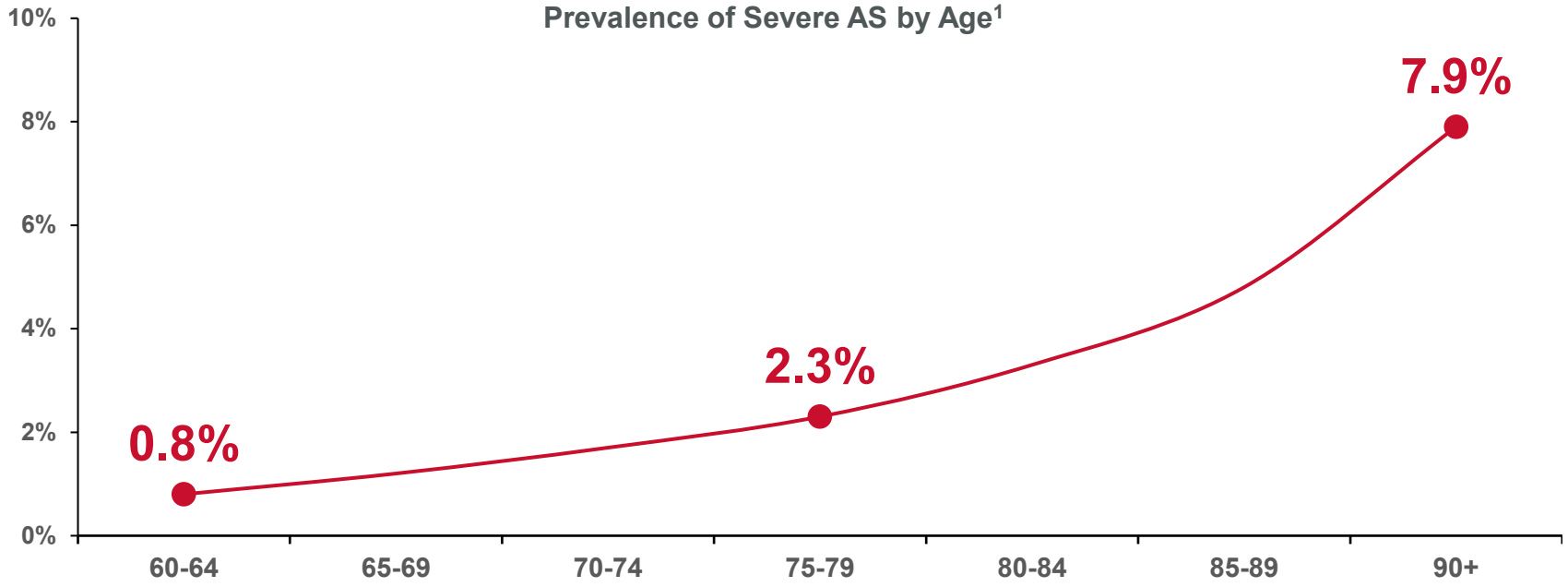


Key Pillars of Our Strategy

- Increase Therapy Adoption in Growing AS Opportunity
- Expand Indications
- Deliver Strong Portfolio Innovation

Severe aortic stenosis is a disease of the elderly: Prevalence increasing with age

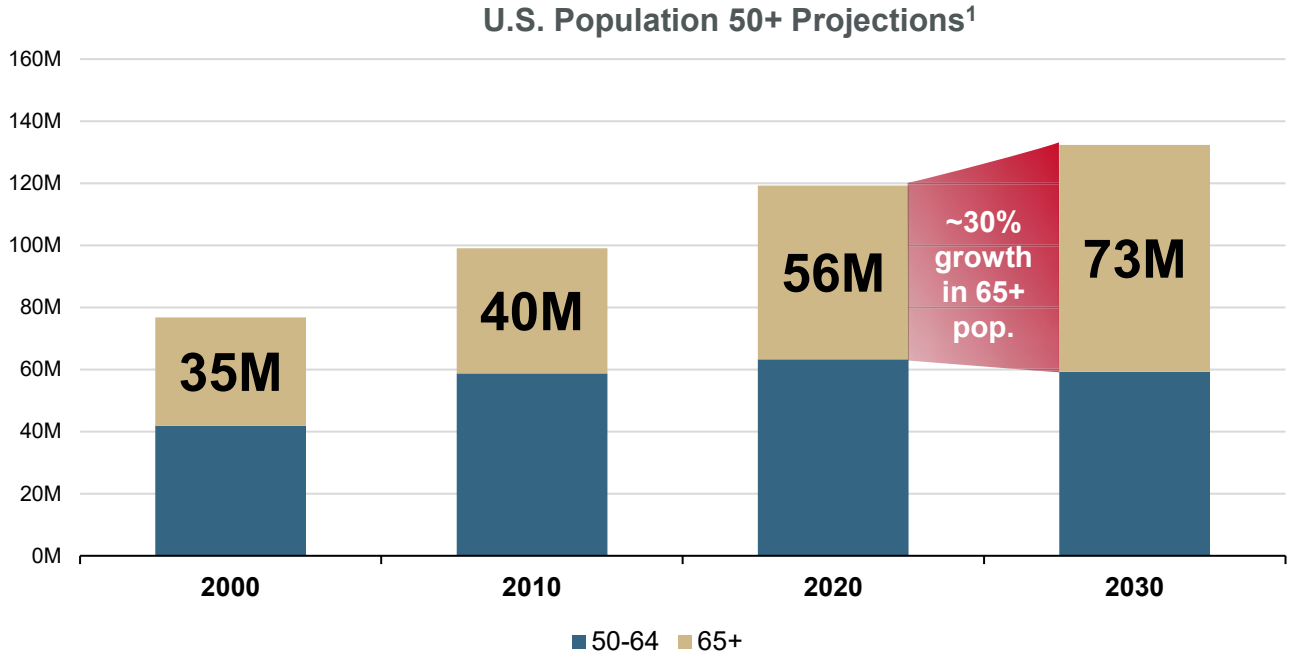
Clinical research papers reaffirm higher Severe Aortic Stenosis prevalence in the elderly



(1) EW estimate; drawn from: Lindroos 1993, Stewart 1997, Nkomo 2006, Vaes 2011, Danielsen 2014, Osnabrugge 2013

Rapidly growing aging population increases the burden of severe AS

By 2030, we expect to see significant growth in the 65+ population



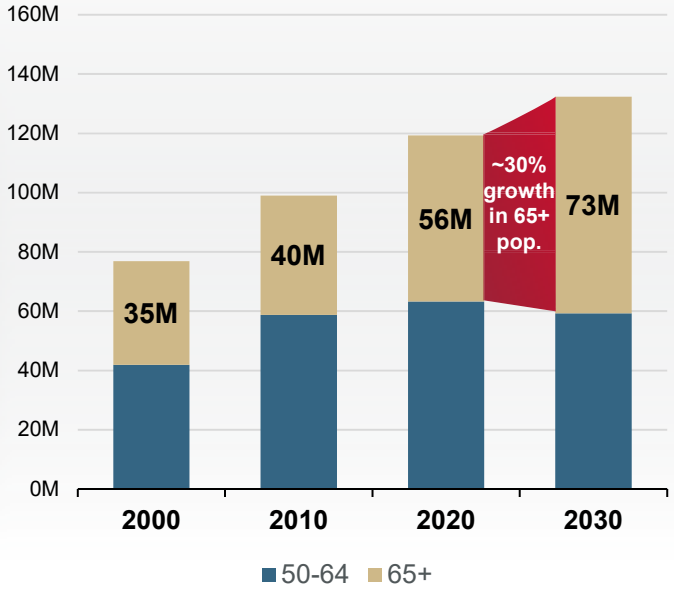
~10,000
People turn 65 years every day[2]

All Baby Boomers
will be 65 or older by 2030[2]

(1) U.S. Census data: 2017 National Population Projections Tables (2) https://www.census.gov/library/stories/2019/12/by-2030-all-baby-boomers-will-be-age-65-or-older.html

While the AVR treatment growth has accelerated since the advent of TAVR, treatment utilization remains low

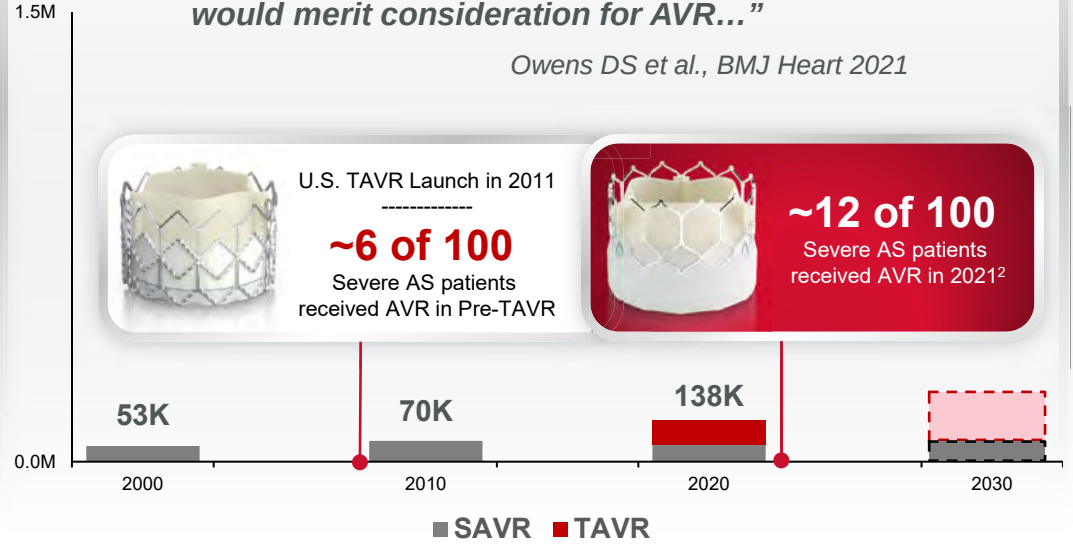
U.S. Population 50+ Projections[1]



Growth in AVR Treatment[2]

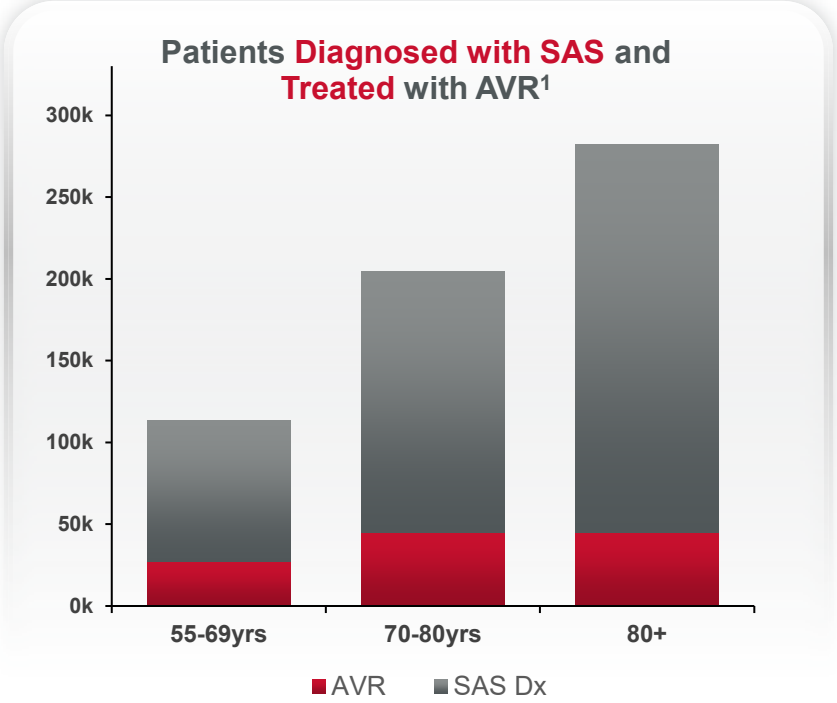
" … currently ~1.3 to 1.6 million Americans would merit consideration for AVR…"

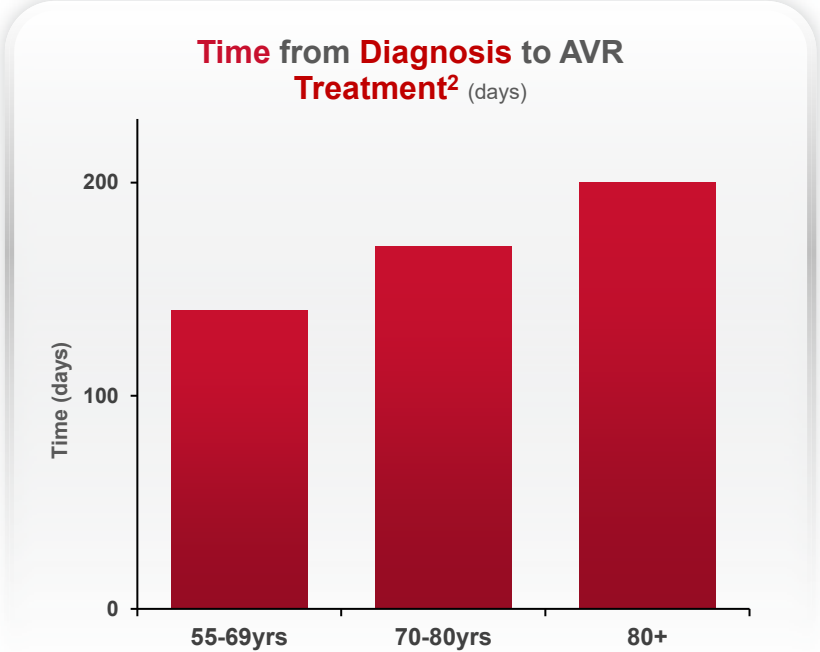
Owens DS et al., BMJ Heart 2021



(1) U.S. Census data: 2017 National Population Projections Tables (2) EW Internal Estimates of U.S. AVR Volume. Therapy penetration of ~12% calculated based off the 1.3M Severe AS patients; Ref: Cumulative burden of clinically significant aortic stenosis in community-dwelling older adults; Owens et al. 2021

Undertreatment is exacerbated in elderly patients, who also have longer time to treatment





(1) Data as presented by Dr. Elmariah in 2022 TCT Symposium: Treatment of Aortic Stenosis by age in the U.S.: Evidence of institutional ageism (2) EW Internal Estimates from Claims data

Patients in their 80s have as favorable TAVR outcomes with Edwards TAVR as patients in their 70s

	Freedom From All-cause Death at 30 Days	Freedom From Stroke at 30 Days	Freedom From Death or Stroke at 30 Days
80 – 89 yrs n = 59,470	97.9%	98.1%	96.3%
70 – 79 yrs n = 56,025	98.6%	98.5%	97.2%





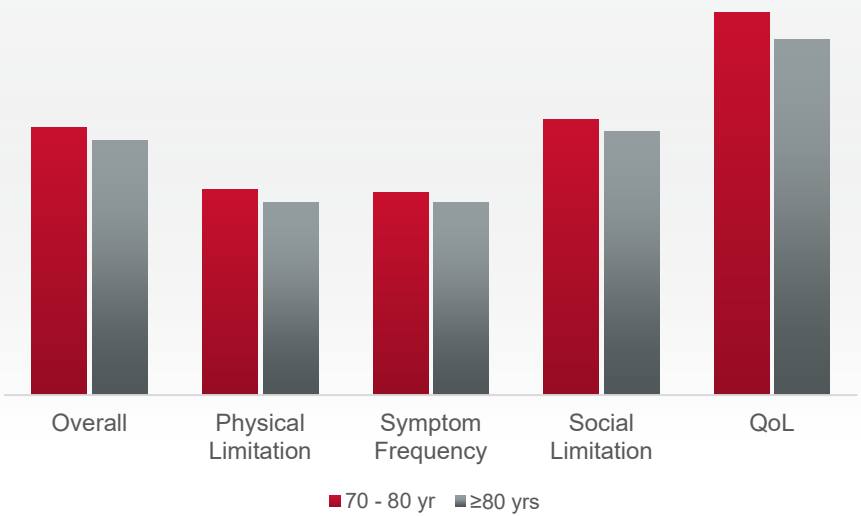


Data from TVT Registry 1/2019 – 12/2021; Unadjusted analysis; As presented by Dr. Megan Coylewright, 2022 TCT Symposium: Results and benefits of transcatheter aortic valve intervention in the U.S. by age

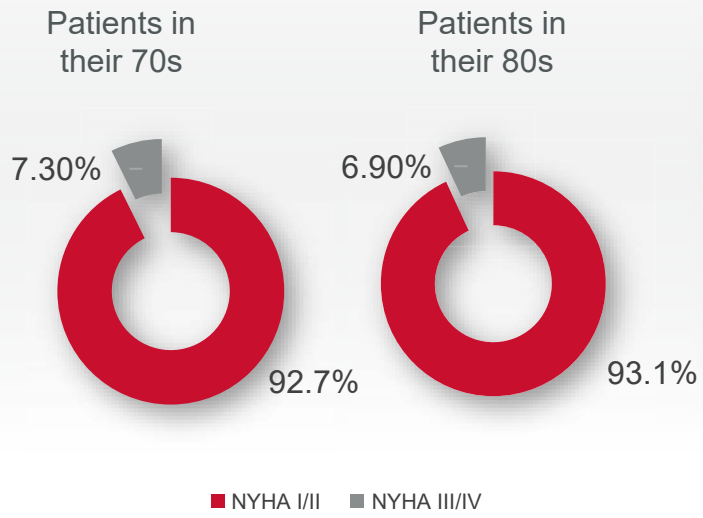
After TAVR, QoL in 80+ year old patients improves as much as QoL of patients in their 70s

Change in KCCQ

(Baseline to 1 Year)

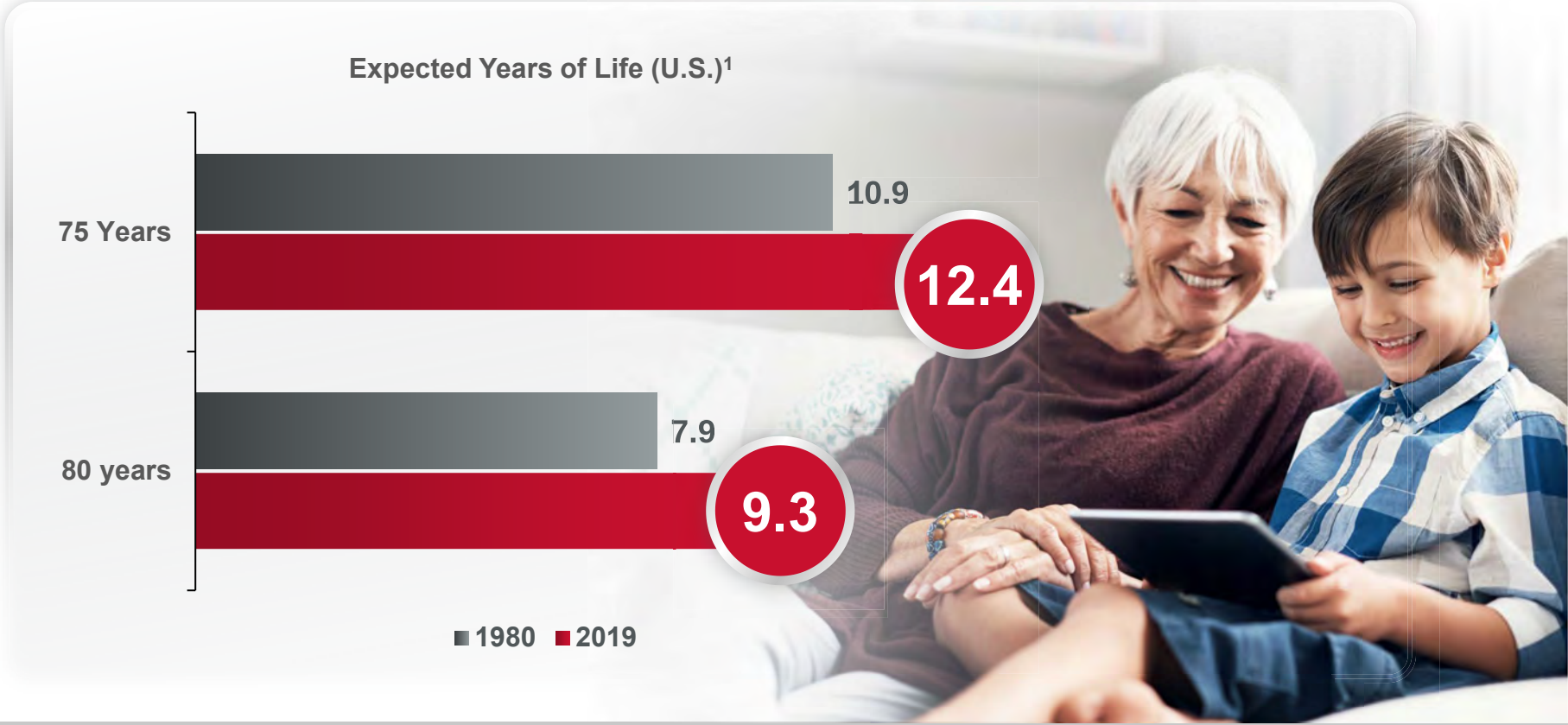


NYHA Class at 1 Year



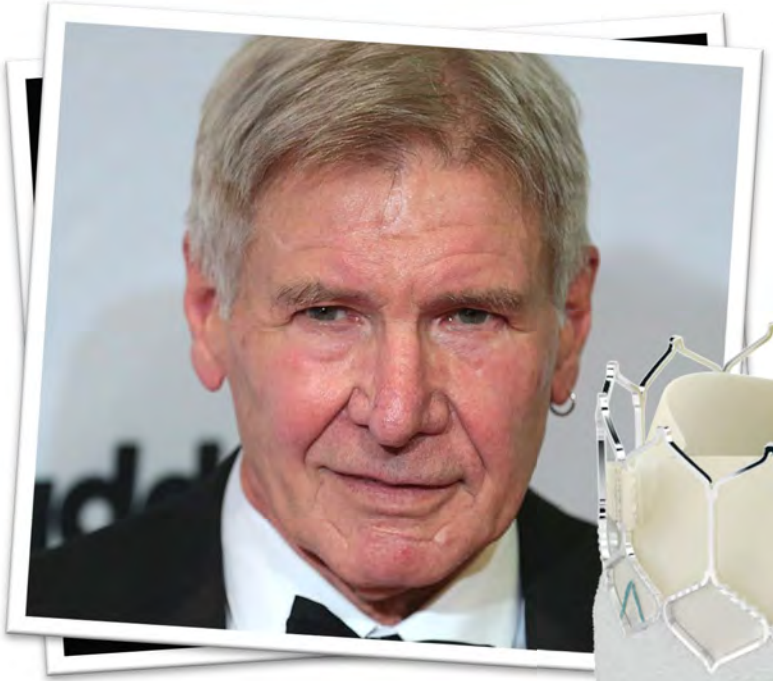
Data from TVT Registry 1/2019 – 12/2021; Unadjusted analysis; As presented by Dr. Megan Coylewright, 2022 TCT Symposium: Results and benefits of transcatheter aortic valve intervention in the U.S. by age
QoL – Quality of Life; KCCQ - Kansas City Cardiomyopathy Questionnaire; NYHA - New York Heart Association

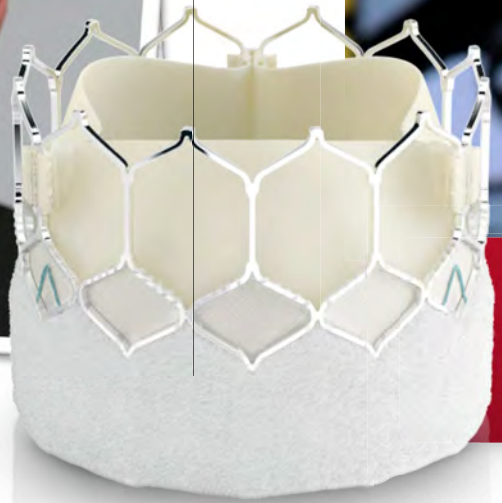
Elderly patients are living longer



(1) https://www.cdc.gov/nchs/products/life_tables.htm for 1980 and 2019 Life Tables; As presented by Dr. Elmariah in 2022 TCT Symposium: Treatment of Aortic Stenosis by age in the U.S.: Evidence of institutional ageism

This is What 80 Looks Like…

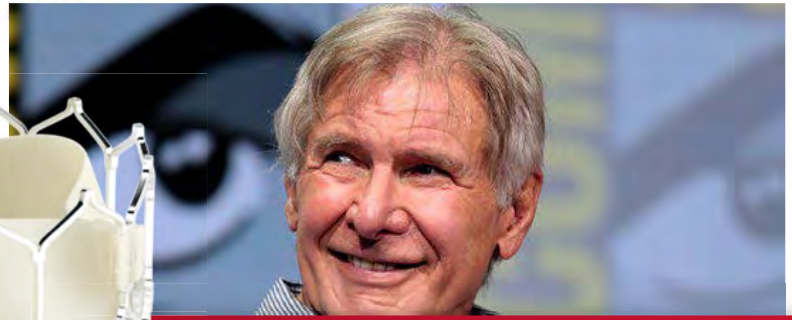




Indiana Jones 5 Star Left in Awe of Harrison Ford: 'Age Ain't Nothing But a Number to This Man'

Indiana Jones 5 star Boyd Holbrook heaps praise on Harrison Ford.

BY JONATHAN FUGE
PUBLISHED 5 DAYS AGO



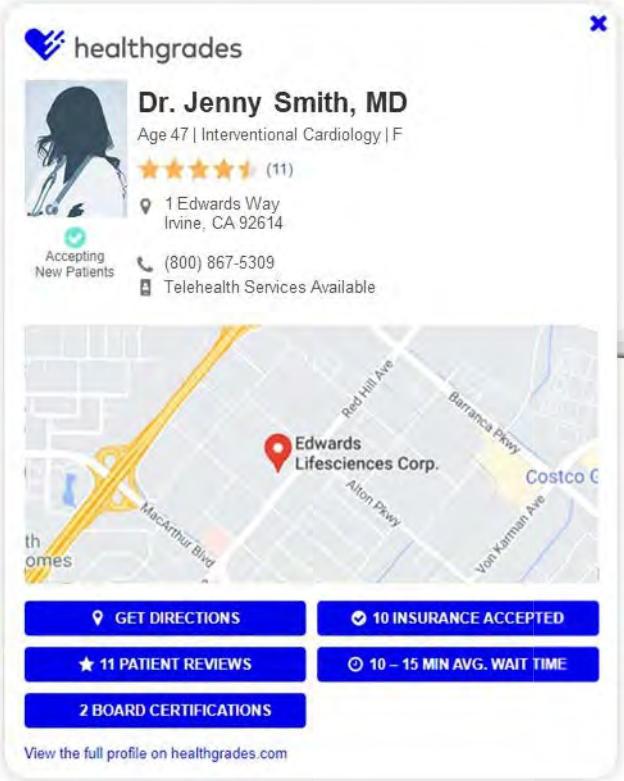
If Indiana Jones were diagnosed with Severe AS,
he would deserve a TAVR!

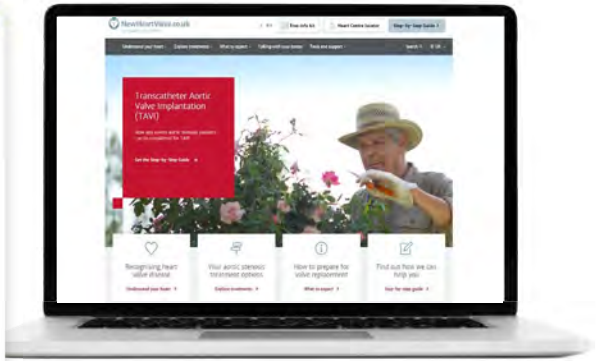
© 2022 Harrison Ford by Gage Skidmore is licensed under CC BY 4.0

Our immediate focus: Improve therapy penetration in 80+ cohort by engaging patients and referrers through our global digital and media strategy







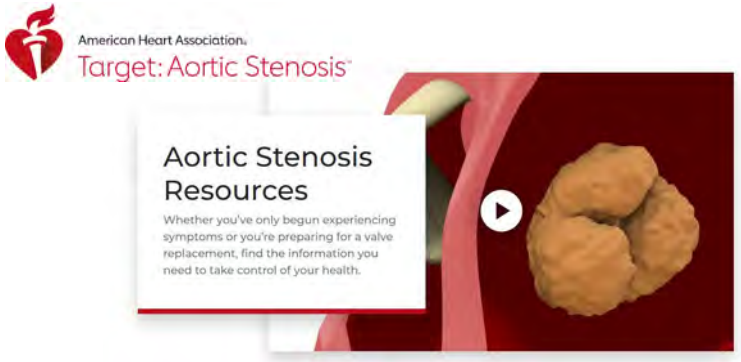




Our immediate focus: Engage with the clinical community through scientific education to address undertreatment head-on

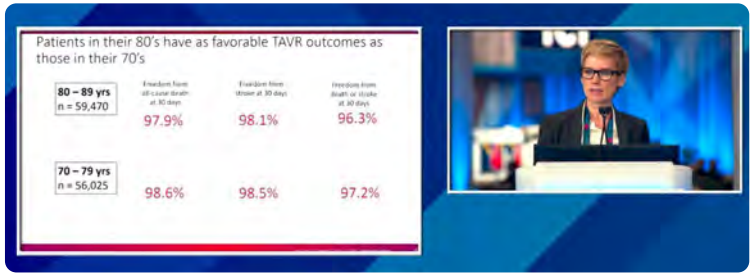


2022 TCT Symposium Moderated by David A. Wood;
Faculty: Evelio Rodriguez, Megan Coylewright, Sammy Elmariah





Dr. Sammy Elmariah, 2022 TCT Symposium: Treatment of Aortic Stenosis by age in the U.S.: Evidence of institutional ageism



Dr. Megan Coylewright, 2022 TCT Symposium: Results and benefits of transcatheter aortic valve intervention in the U.S. by age

Edwards is supporting a quality-of-care initiative led by AHA

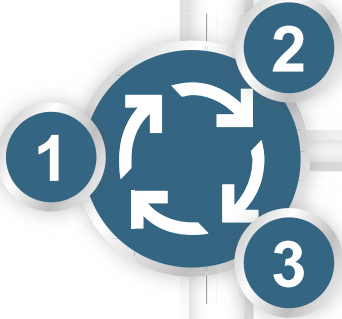
The **American Heart Association and Edwards have a shared goal** of lowering cardiovascular mortality, specifically by "establishing and advancing a new standard of care in structural heart disease"

American Heart Association.
Target: Aortic Stenosis™

80
hospitals in next 3 years

Hospital Systems

Implement **quality measures** to ensure patients are treated in accordance to guidelines in a timely manner



HCPs

Professional education

Patients

Awareness & engagement

Edwards Lifesciences is the national sponsor of American Heart Association's Target: Aortic Stenosis

Website: www.heart.org/TargetAS

We believe that a combination of all of these activities will have a meaningful impact on immediate challenges and therapy adoption



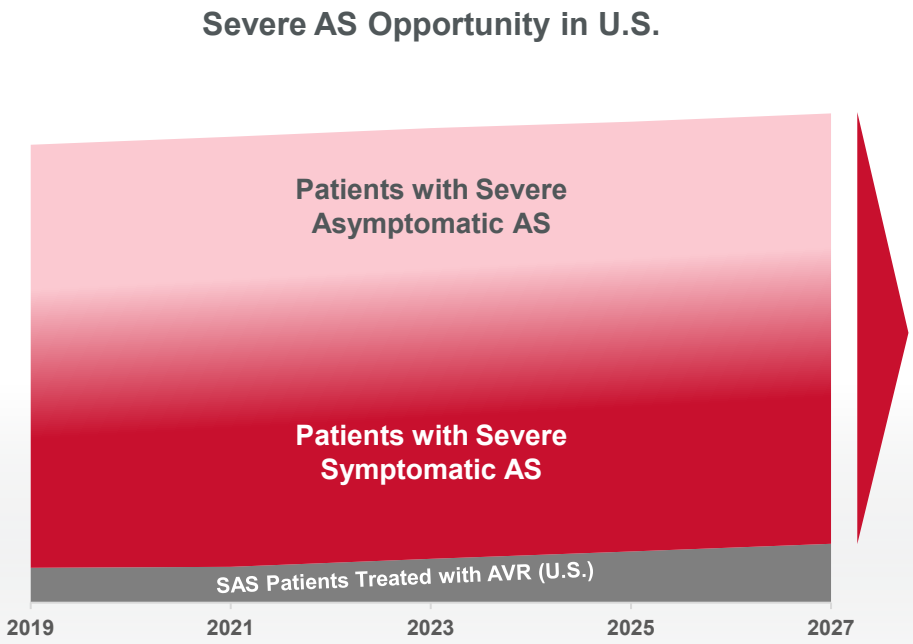
Immediate Challenges are Transient; TAVR Fundamentals Remain Strong



Key Pillars of Our Strategy

- Increase Therapy Adoption in Growing AS Opportunity
- Expand Indications
- Deliver Strong Portfolio Innovation

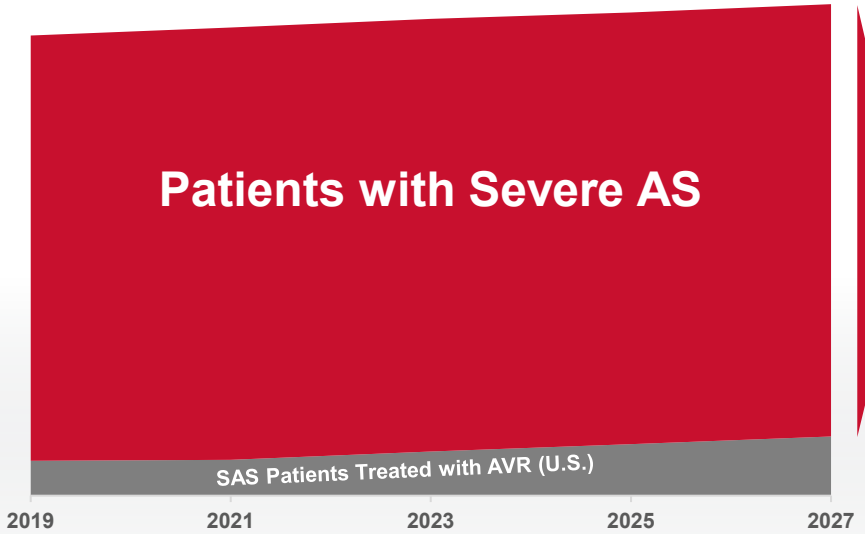
Long term, we continue to build evidence to further expand our leadership within the severe AS opportunity



- Significant number of severe AS patients are **perceived** asymptomatic
- Symptoms are unnoticed, ignored, or associated with general aging
- Providers fail to elicit symptoms in patients during office visit

With EARLY TAVR, we are still only addressing severe AS patients

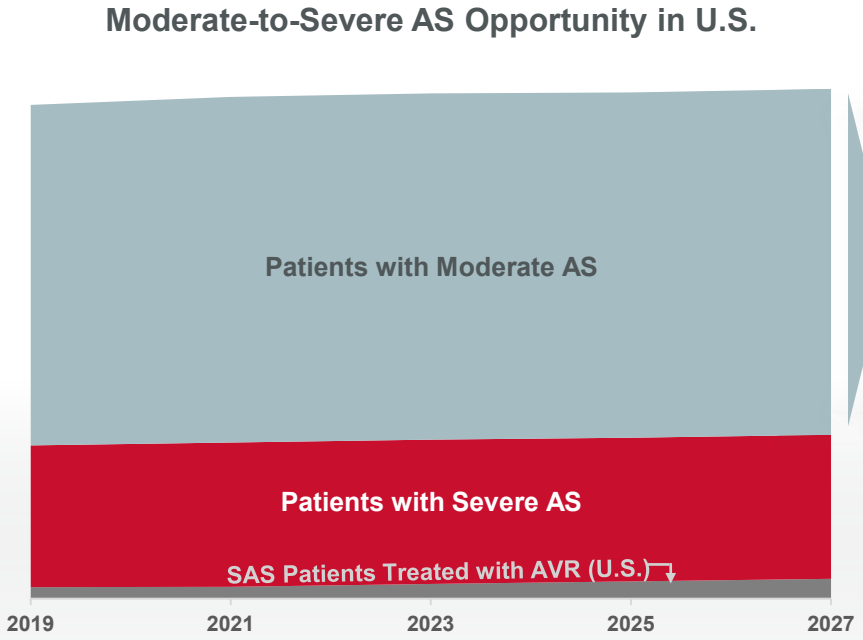
Severe AS Opportunity in U.S.



THE EARLY TAVR TRIAL

- EARLY TAVR trial will help us understand if intervention should occur before symptoms develop
- Enrollment completed in 2021
- Currently, in follow-up (2-year primary endpoint)

While the severe AS opportunity is significant, moderate AS adds new frontier for growth



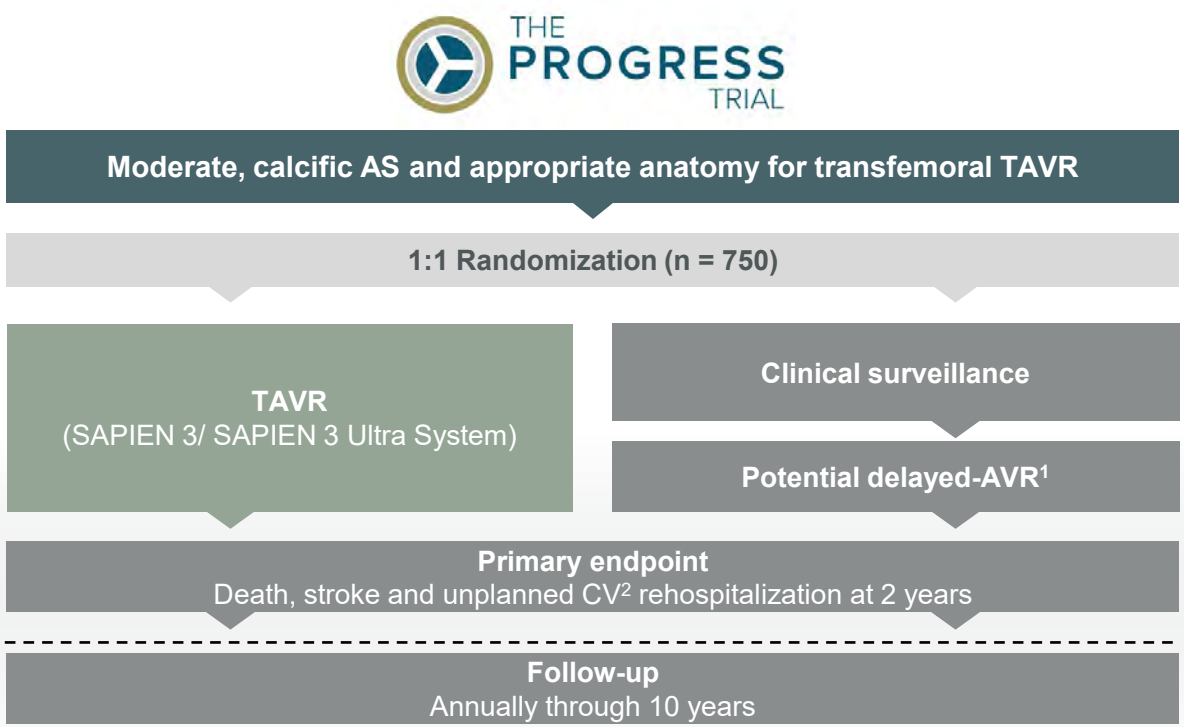
2:1

Ratio of Moderate to Severe AS patients[1]

THE PROGRESS TRIAL

- The PROGRESS Trial will help us understand the true impact of Moderate AS and the optimal time of intervention before damage to the heart occurs
- Currently enrolling

PROGRESS Trial Design



(1) AVR - Aortic Valve Replacement **(2)** CV - Cardiovascular

Contemporary data shows moderate AS patients have similarly poor prognoses as severe AS patients

THE PROGRESS TRIAL

Moderate, calcific AS and appropriate anatomy for transfemoral TAVR

1:1 Randomization (n = 750)

TAVR
(SAPIEN 3/ SAPIEN 3 Ultra System)

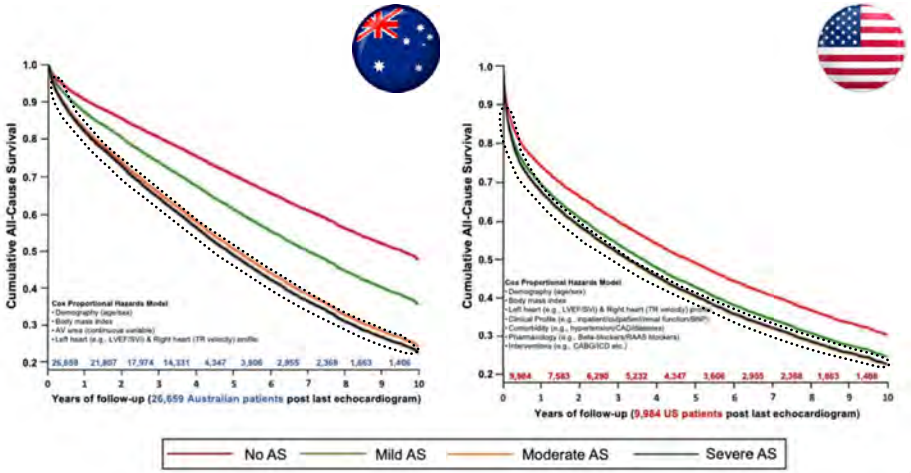
Clinical surveillance

Potential delayed-AVR[1]

Primary endpoint
Death, stroke and unplanned CV[2] rehospitalization at 2 years

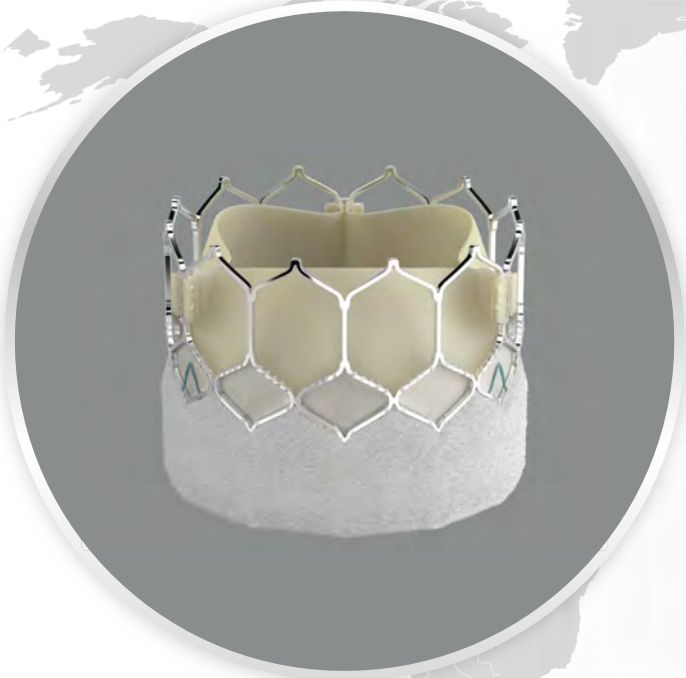
Follow-up
Annually through 10 years

Fully adjusted all-cause mortality according to AS stage[3]



(1) AVR - Aortic Valve Replacement **(2)** CV - Cardiovascular **(3)** Strom JB, Playford D, Stewart S, Li S, Shen C, et al. (2022) Increasing risk of mortality across the spectrum of aortic stenosis is independent of comorbidity & treatment: An international, parallel cohort study of 248,464 patients

Immediate Challenges are Transient; TAVR Fundamentals Remain Strong



Key Pillars of Our Strategy

- Increase Therapy Adoption in Growing AS Opportunity
- Expand Indications
- Deliver Strong Portfolio Innovation

Our future portfolio further elevates TAVR and the benchmark of lifetime management



SAPIEN SAPIEN XT SAPIEN 3 SAPIEN 3 Ultra



SAPIEN 3 Ultra RESILIA



SAPIEN X4

Future Platforms

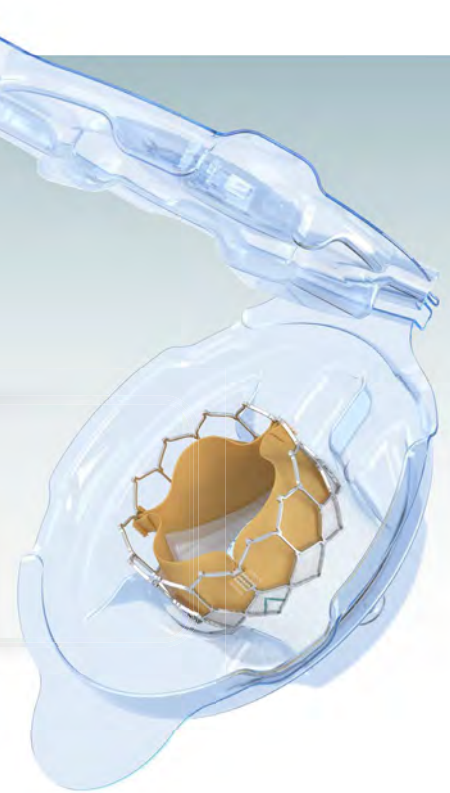
2011 2014 2015 2019 2022 Future

SAPIEN Valves shown above are part of the Edwards SAPIEN Transcatheter Heart Valve System

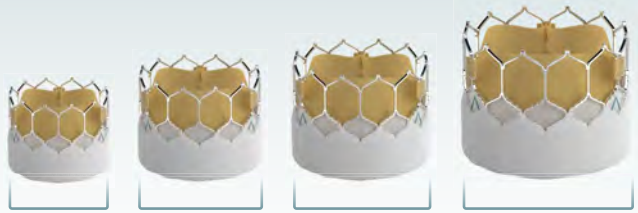
The first step in further elevating the TAVR therapy is the launch of SAPIEN 3 Ultra RESILIA system

Advanced **calcium-blocking technology**

RESILIA Tissue:
Same as INSPIRIS RESILIA surgical valve



The only THV with **dry tissue storage**



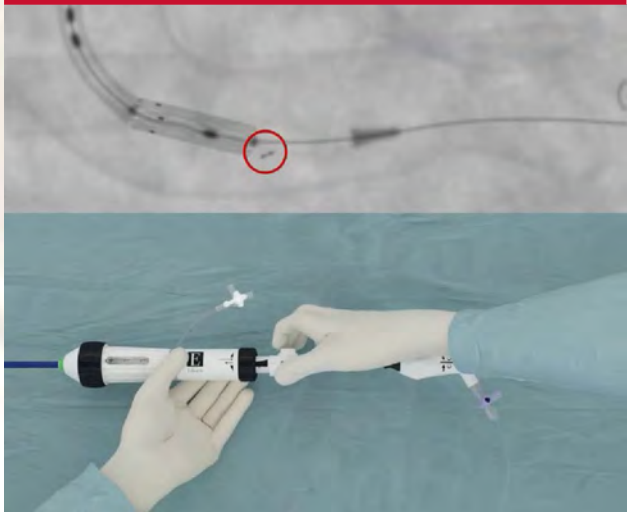
Enhanced PVL skirt for all valve sizes (including 29mm)

Our Next Generation Technology: SAPIEN X4 Transcatheter Heart Valve System

- Novel Frame and Leaflet Design to Enable Adjustable Sizing
- Frame Design to Facilitate Future Coronary Access
- Advanced PET Outer Skirt Technology
- RESILIA Tissue



Advanced Delivery System Technology Offers Commissural Alignment



Immediate Challenges are Transient; TAVR Fundamentals Remain Strong



Key Pillars of Our Strategy

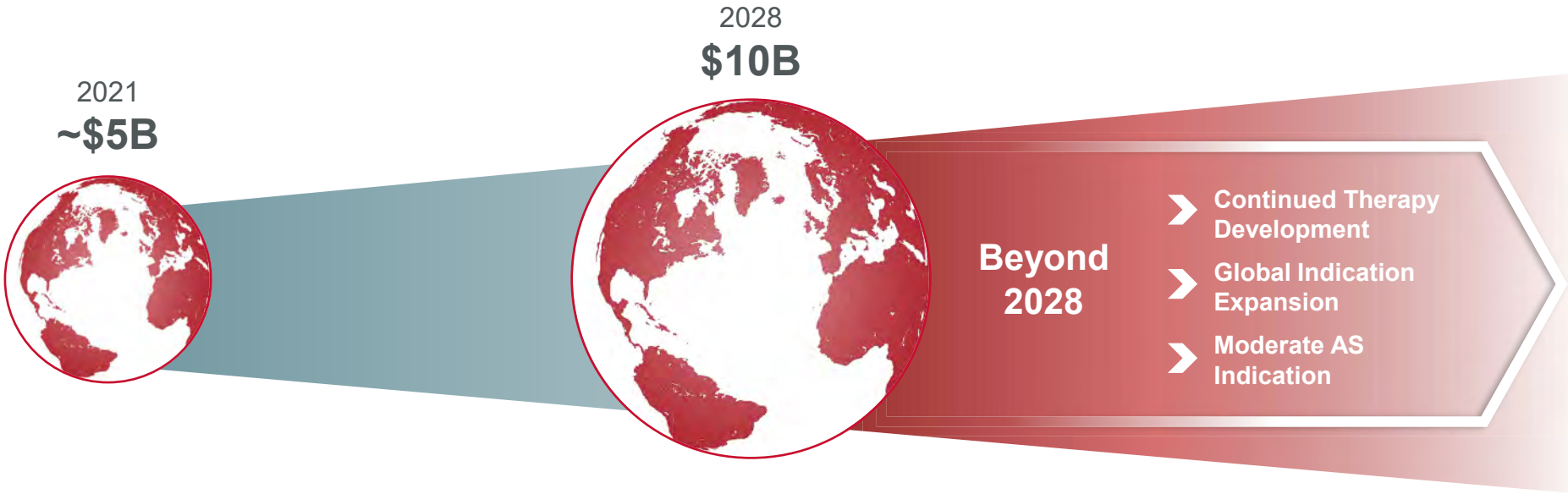
- Increase Therapy Adoption in Growing AS Opportunity
- Expand Indications
- Deliver Strong Portfolio Innovation

We remain confident in our view that the global TAVR opportunity will double by 2028



The fundamentals of TAVR remain strong and the opportunity ahead is significant

And growth drivers beyond the plan horizon remain strong



The fundamentals of TAVR remain strong and the opportunity ahead is significant

Potential Adverse Events: Potential risks associated with the anesthesia, interventional procedure, and imaging include but are not limited to death; stroke/transient ischemic attack; respiratory insufficiency or respiratory failure; cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium, or valvular structures, including rupture of the RVOT that may require intervention; pericardial effusion/cardiac tamponade; cardiac failure; embolic event: air, calcific material, thrombus, device fragments; infection, including incisional site infection, septicemia, and endocarditis; myocardial infarction; renal insufficiency or renal failure; conduction system injury; arrhythmia; deep vein thrombosis; arteriovenous (AV) fistula; systemic or peripheral nerve injury; systemic or peripheral ischemia; pulmonary edema; pneumothorax; pleural effusion; dyspnea; atelectasis; dislodgement of previously implanted devices (i.e. pacing lead); blood loss requiring transfusion; anemia; radiation injury; electrolyte imbalance; hypertension or hypotension; allergic reaction to anesthesia, contrast media, antithrombotic therapy, device materials; hematoma or ecchymosis; syncope; pain; exercise intolerance or weakness; inflammation; angina; fever. Potential risks, that may or may not require intervention, associated with the valve, prestent, delivery system, and/or accessories include, but may not be limited to, the following: cardiac arrest; cardiogenic shock; coronary flow obstruction/transvalvular flow disturbance; device thrombosis; injury to tricuspid valve; device fracture; device embolization; device acute migration or malposition; endocarditis; chest pain/discomfort; hemolysis/ hemolytic anemia; device penetration/perforation into surrounding vasculature; device dysfunction (regurgitation and/or stenosis); aortic root distortion; embolic events: device fragments; mechanical failure of delivery system, and/or accessories.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information.

--

Edwards SAPIEN 4 Transcatheter Heart Valve System

CAUTION – Investigational Device. Limited by Federal (United States) law to investigational use.
This device is not available for marketing or commercial sale.

Edwards, Edwards Lifesciences, the stylized E logo, ALLIANCE, Alterra, EARLY TAVR, INSPIRIS, INSPIRIS RESILIA, PROGRESS, RESILIA, SAPIEN, SAPIEN XT, SAPIEN X4, SAPIEN 3, SAPIEN 3 Ultra, and the EARLY TAVR Trial logo are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

© 2022 Edwards Lifesciences Corporation. All rights reserved.

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards



Edwards

Helping Patients is Our Life's Work, and *life is now*

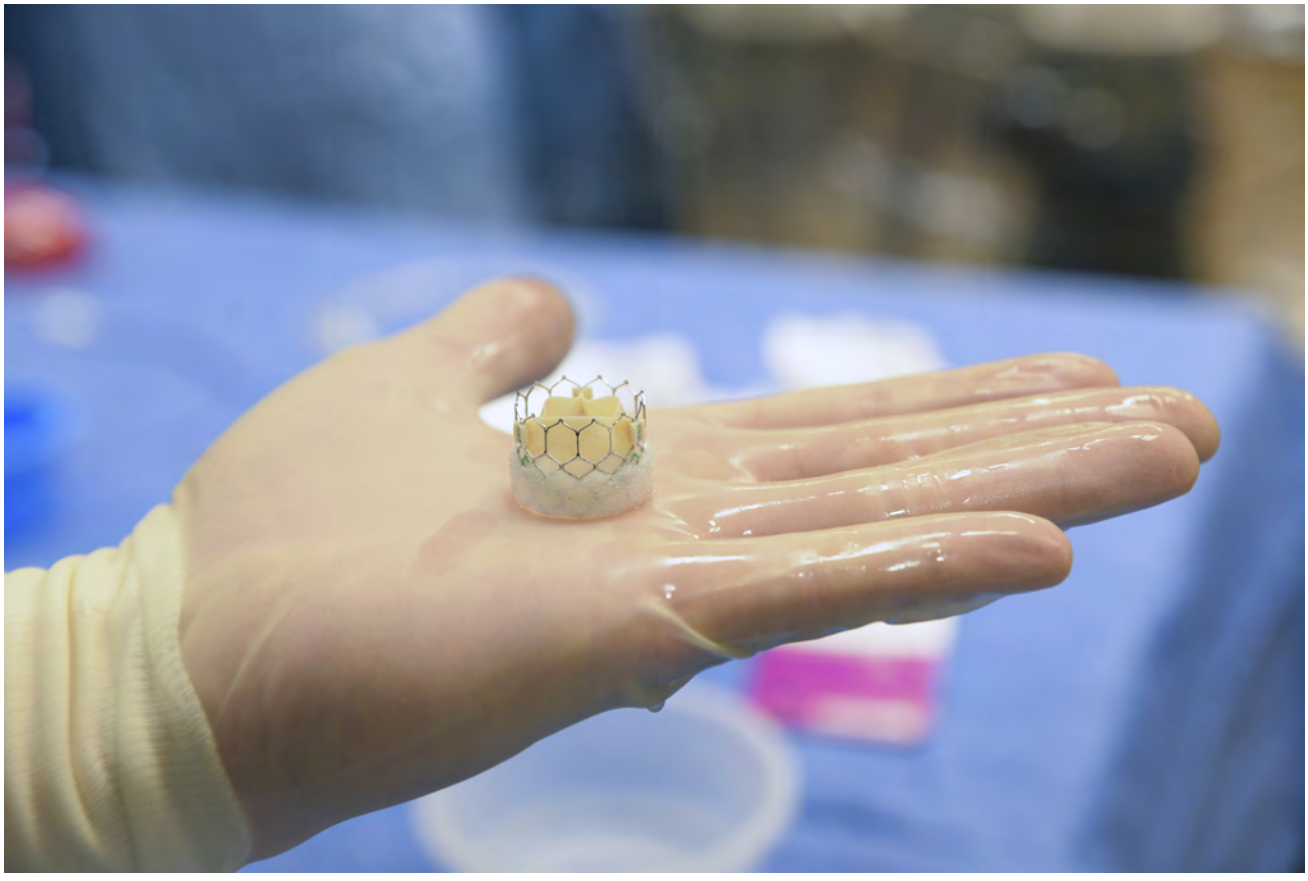
Skip the wait and schedule your appointments **online (https://findadoctor.slhn.org/?theme=dir_sluhn&scheduleOnline=true)** or through **MyChart (https://www.slhn.org/mychart/information?utm_content=global-alert-header)**.

Create Account (https://mychart.slhn.org/mychart/) | Sign in to MyChart (https://mychart.slhn.org) SEARCH

NEWS

New Non-Surgery Heart Valve

September 28, 2020



Luis Delarosa enjoys doing physically demanding outdoors projects at home in Slatington, sometimes working from sunrise to sunset in the fresh air. Having been a landscaper for his entire adult life, the 76-year-old

Slatington man figured the fatigue and shortness of breath came with his

Case 1:23-cv-00158-JPM Document 13-4 Filed 04/10/23 Page 64 of 112 PageID #: 5093

Edwards

Edwards SAPIEN 3 Ultra valve

Built on proven technology

Advancing valve design

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



Valve tissue

Uses same trusted bovine pericardium leaflet and ThermaFix anticalcification process as the Edwards SAPIEN 3 valve.





Enhanced geometric frame

Low profile and open cell geometry facilitate coronary access.[1]

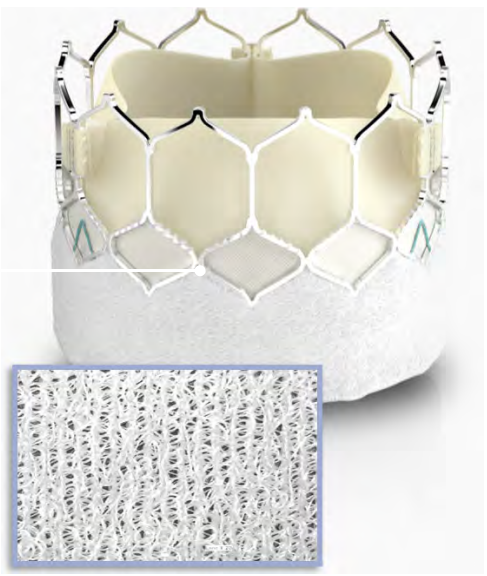
Case 1:23-cv-00158-JPM Document 134 Filed 04/10/23 Page 65 of 112 PageID #: 5094

Sealing skirt technology

Features a ~40% taller, textured polyethylene terephthalate (PET) outer skirt.*

*Compared to the Edwards SAPIEN 3 valve

Minimising paravalvular leak[2]



Textured fabric

Important reductions in paravalvular leak (PVL)

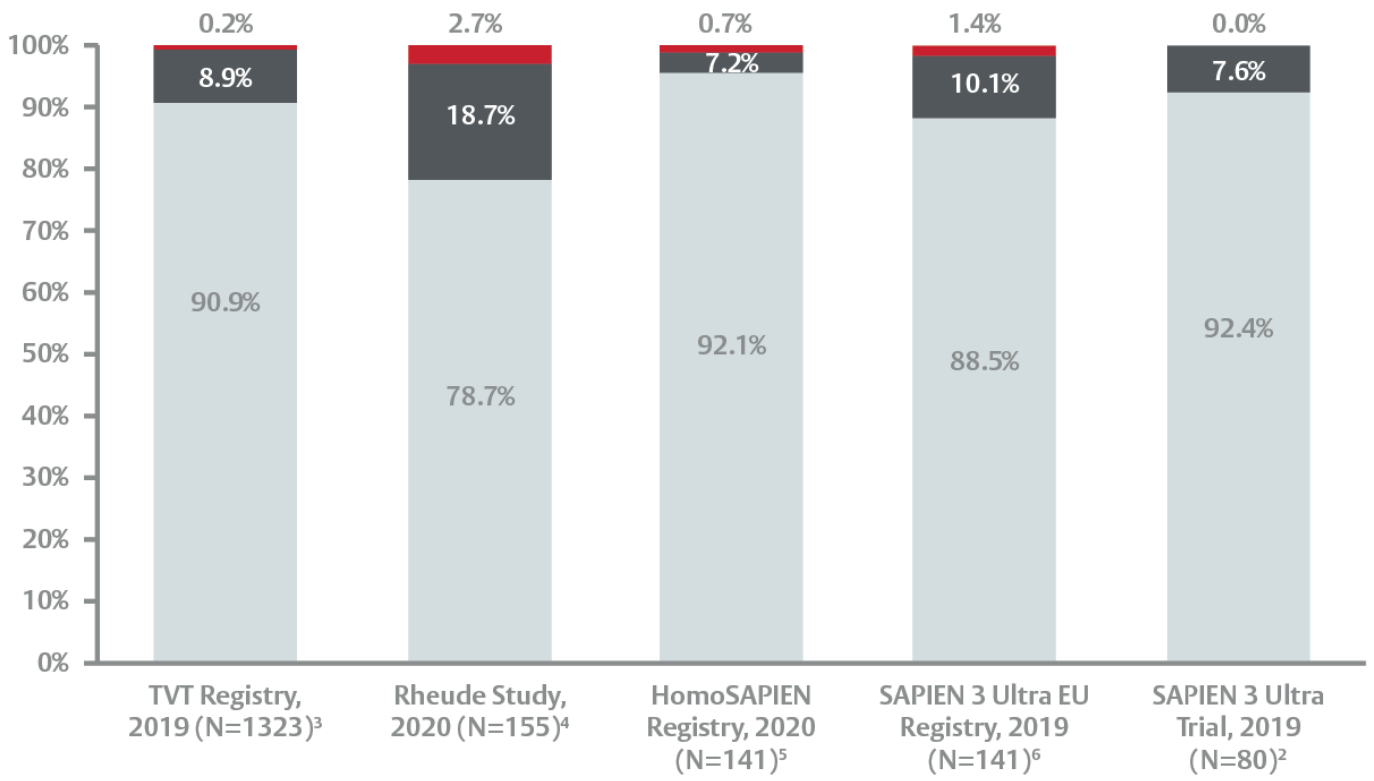
Edwards SAPIEN 3 Ultra valve engineered to further reduce PVL

In the TVT Registry in over 1300 procedures:

- Edwards SAPIEN 3 Ultra valve eliminated severe PVL and produced close to zero levels of moderate PVL[3]
- Consistently low levels of mild PVL across the studies[2-6]

Moderate and severe PVL are independent predictors of 5-year all-cause mortality in multivariable analysis.[7]

Consistently low paravalvular leak rates at discharge[3*]

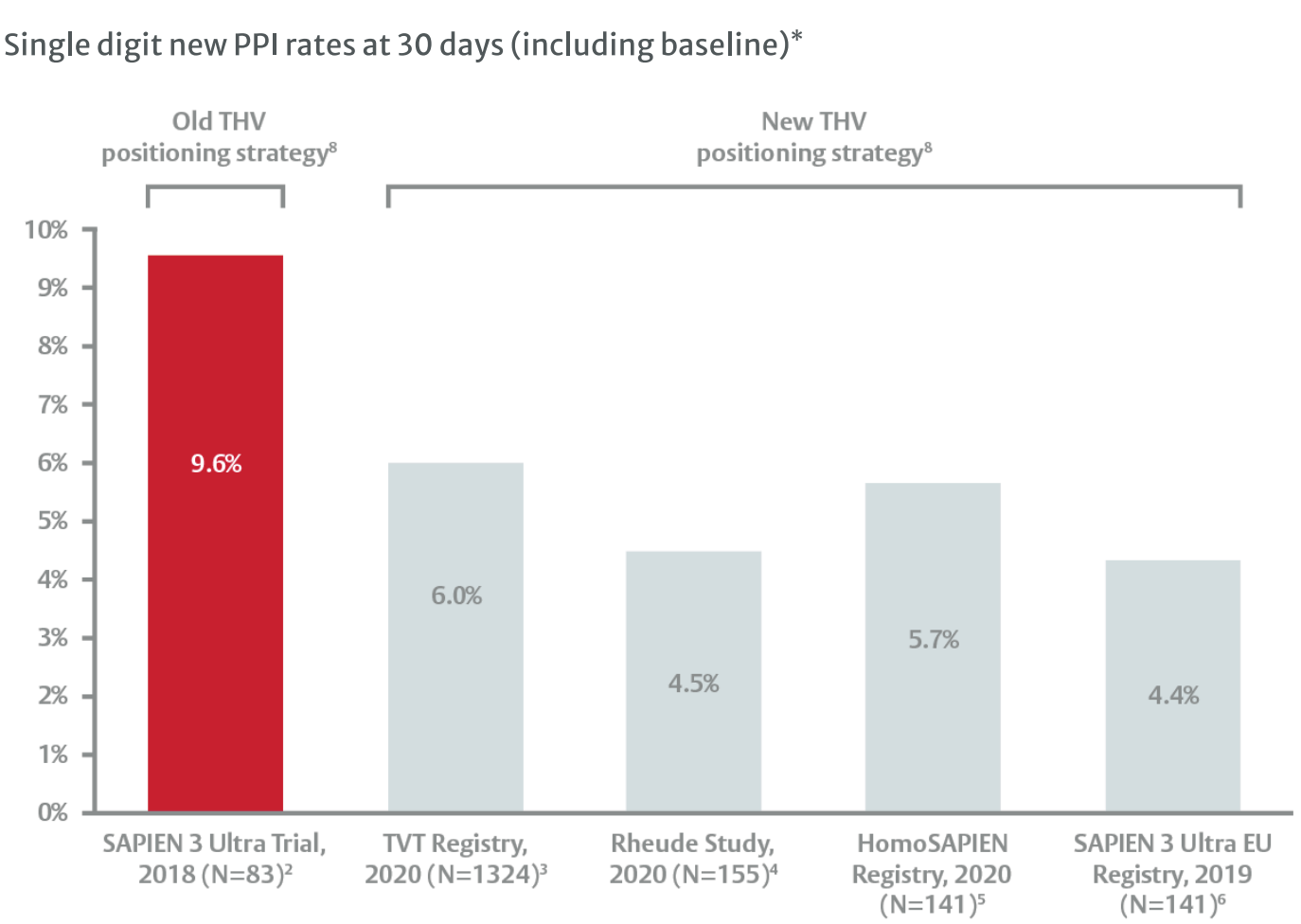


Single digit new permanent pacemaker rates

Low rates of new permanent pacemaker implantation (PPI) achieved with a high valve positioning strategy[8]

- New PPI is an independent predictor of mortality at 1 year[9]

Case 1:23-cv-00158-JPM Document 13-4 Filed 04/10/23 Page 66 of 112 PageID #: 5095

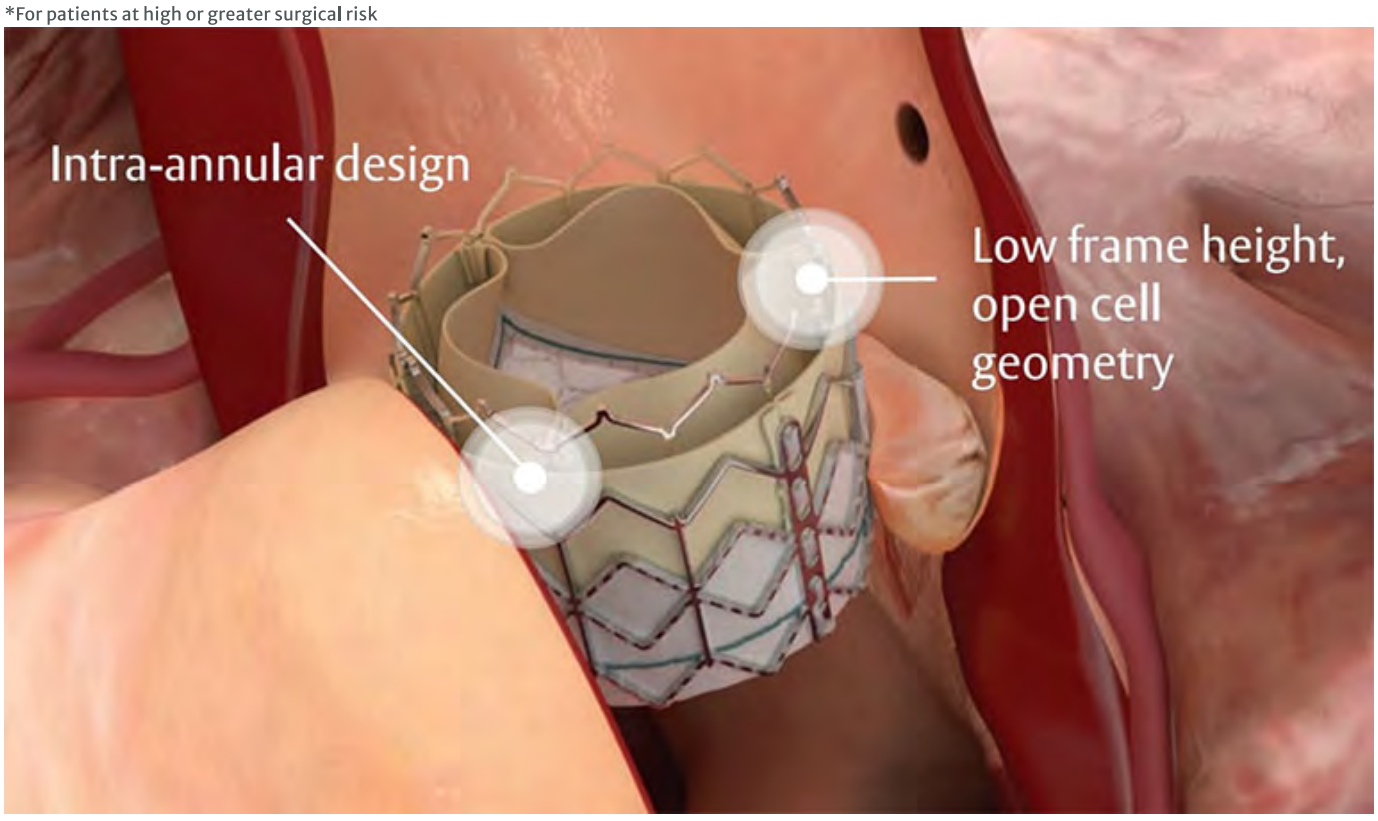


Today's transcatheter heart valve (THV) solution designed for lifetime patient management

Edwards SAPIEN 3 transcatheter aortic valve implantation (TAVI) is indicated for use in aortic and mitral redo procedures (including THV-in-THV)*

A lifesaving reintervention when TAVI is a preferred treatment option.

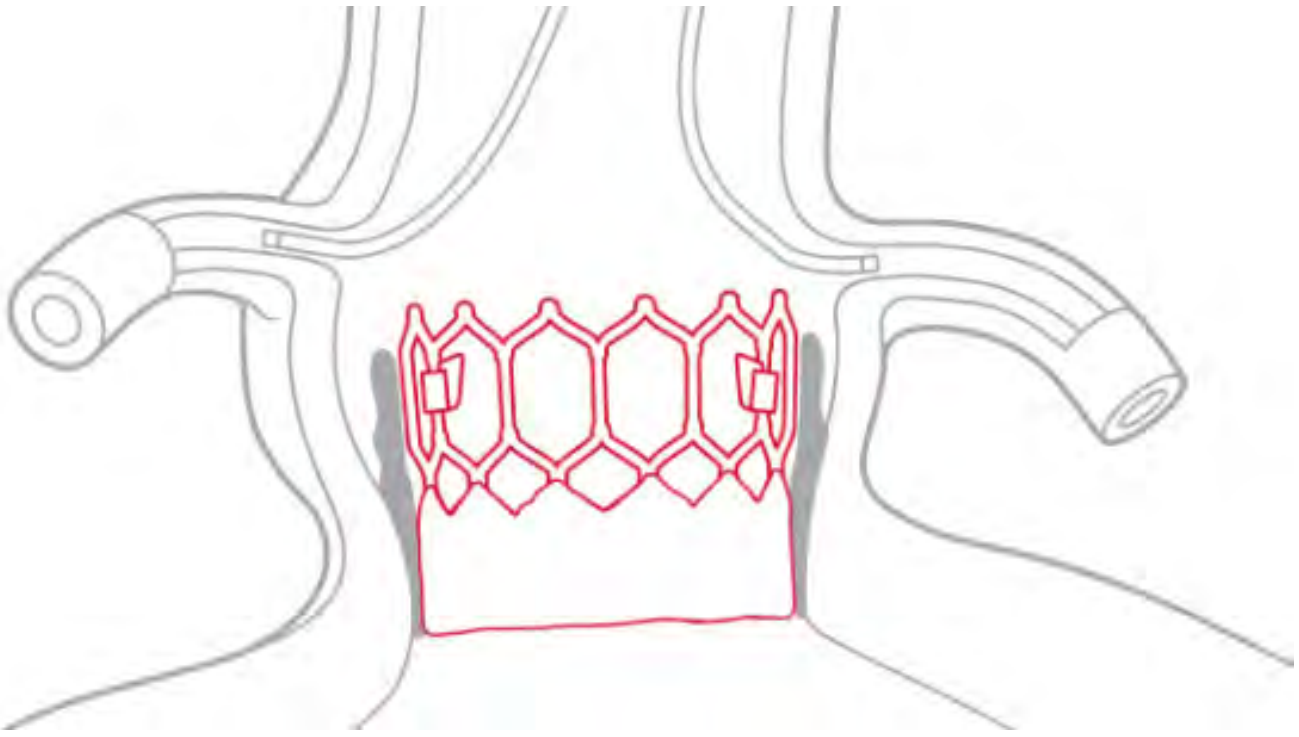
*For patients at high or greater surgical risk

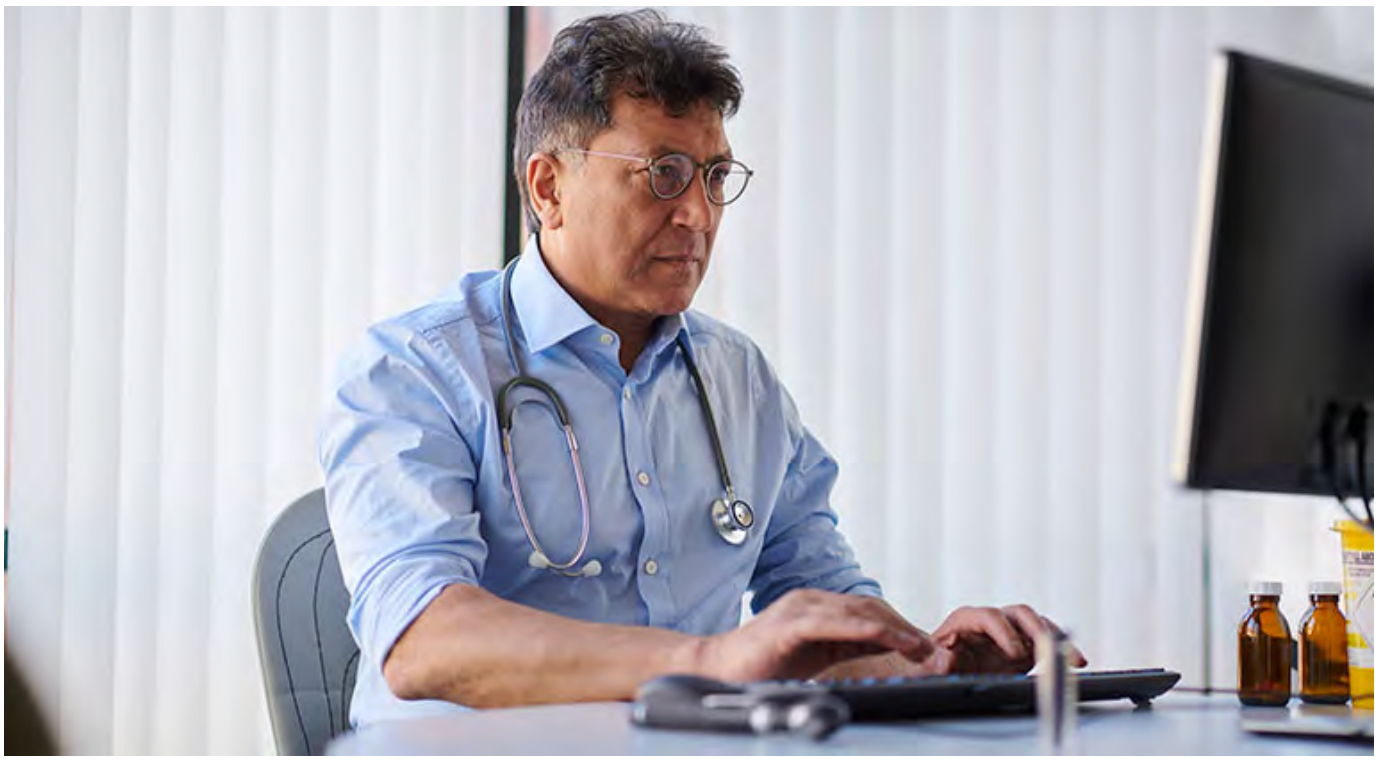


Designed for future coronary access

Low profile frame design and open geometry facilitates future coronary access.[1]

Registry data from SOURCE 3 showed 100% successful coronary access (n=61) post-TAVI.[10]





Edwards SAPIEN 3 Ultra valve Instructions for Use

See the Operator's Manual for all Edwards Lifesciences products.

Visit Instructions for Use website

The Edwards COMMANDER delivery system

Designed to streamline the TAVI procedure and reduce complications with an ultra-low delivery profile, optimal positioning control and predictable deployment.

For predictable, proven results

Features of the Edwards COMMANDER delivery system:

- Stable, precise deployment delivering 99% first-time accuracy[11†]
- Low delivery profile
- Dual articulation for coaxiality
- Optimal positioning control

†The PARTNER II Trial intermediate-risk cohort 30-day unadjusted clinical event rates for TAVI with the Edwards SAPIEN 3 valve, as-treated population (n=1078).[11]



You refuse to compromise.

We couldn't agree more.

Find out more →

3D Sizing and Delivery System Guide

Edwards SAPIEN 3 Ultra valve is available in 3 sizes for maximum flexibility and optimal fitting.

Edwards SAPIEN 3 valve is also available in a 29mm size for larger annular diameters.

Edwards SAPIEN 3 Ultra valve size (mm)	3-D Area-derived Diameter (mm)	3-D Annular Area (mm^2)	Delivery System COMMANDER
20	18.6-21.0	273-345	14F e-Sheath
23	20.7-23.4	338-430	14F e-Sheath
26	23.4-26.4	430-546	14F e-Sheath

Edwards Lifesciences SAPIEN 3 Ultra TAVI procedural videos

Procedural guides on transfemoral access and Edwards SAPIEN 3 Ultra TAVI procedures:

01:53

Prendergast testimonial on valve design and coronary access (01:52)

Coronary access live action procedural demonstration.

02:20

balloon-expandable technology (02:19)

Transfemoral access procedure from insertion to deployment.

01:07

Edwards SAPIEN 3 Ultra valve — built for coronary access (01:06)

Edwards SAPIEN 3 Ultra valve coronary access and deployment procedure in detail.

Contact your Edwards Lifesciences Sales Representative for more information.

Stay informed with our newsletter

* **Your email**

Your email address

* **Country**

United Kingdom

* **Hospital**

Hospital

* **Occupation**

Select...

Terms and Conditions

Submit

References:

1. Yudi MB, et al. Coronary angiography and percutaneous coronary intervention after transcatheter aortic valve replacement. J Am Coll Cardiol. 2018;71(12):1360-1378.
2. Webb, J. A prospective multicenter study of the SAPIEN 3 Ultra system in intermediate-risk patients with severe aortic stenosis. Presented at PCR London Valves 2019 (Nov 2019).
3. Nazif et al. Real-World Experience with the SAPIEN 3 Ultra TAVR: A Propensity Matched Analysis from the United States, TVT Connect 2020.
4. Rheude. Transcatheter Aortic Valve Replacement With Balloon-Expandable Valves Comparison of SAPIEN 3 Ultra Versus SAPIEN 3. JACC: Cardiovasc Interv. 2020;13(22)2631-2638.
5. Moriyama N. et al. Hemodynamic comparison of TAVR with the SAPIEN 3 Ultra versus SAPIEN 3: The HomoSAPIEN registry. Catheter Cardiovasc Interv. 2021;97(7):E982-E991.
6. Saia F et al. SAPIEN 3 Ultra balloon-expandable transcatheter aortic valve: in-hospital and 30-day results from the multicentre S3U registry. EuroIntervention. 2020;15(14):1240-1247.
7. Giuliano Costa MD et al., Long-term outcomes of self-expanding versus balloon-expandable transcatheter aortic valves: Insights from the OBSERVANT study. Valvular and Structural Heart Diseases. First published: 13 April 2021. https://doi.org/10.1002/ccd.29701
8. Sammour Y. et al. Systematic Approach to High Implantation of SAPIEN-3 Valve Achieves a Lower Rate of Conduction Abnormalities Including Pacemaker Implantation. Circulation: Cardiovascular Interventions 2021, 14:e009407.
9. Glaser N, et al., JAMA Network Open. 2021;4(7):e2116564. doi:10.1001/jamanetworkopen.2021.16564.
10. Tarantini G, Fovino LN, Le Prince P, et al. Coronary access and percutaneous coronary intervention up to 3 years after transcatheter aortic valve implantation with a balloon-expandable valve. Circ Cardiovasc Interv. 2020;13(7):e008972.
11. Thourani VH et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet 2016; 387: 2218–2225.

For professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

PP--EU-3361 v1.0

COOKIE PREFERENCES

Legal terms

Privacy policy

© 2023 Edwards Lifesciences Corporation. All rights reserved.