

# 2020 Investor Conference

December 10, 2020



Edwards

# 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



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



# Patient-Focused Innovation Strategy

## Focus

Singular focus on the large unmet needs of structural heart and critically ill patients

## Leadership

Lead groundbreaking standards of care through trusted relationships



## Innovation

Pioneer breakthrough technologies with compelling evidence

# Edwards' patient-focused innovation strategy has produced sustained underlying sales growth

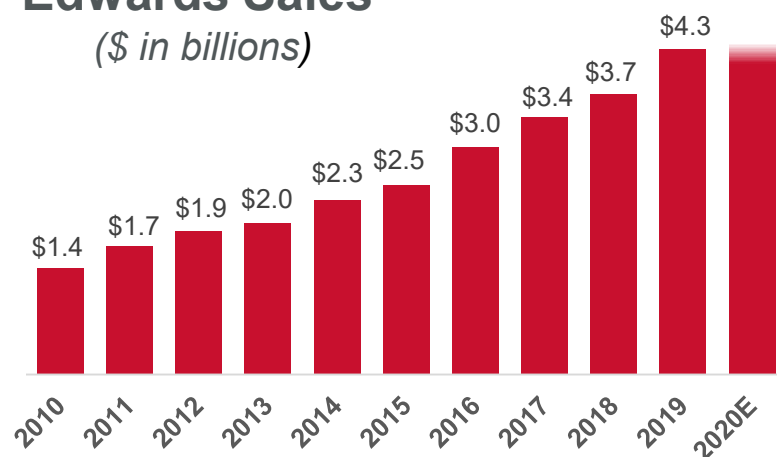
## Global Transcatheter Opportunity

**\$10B+** by 2025

Focused on opportunities where patient demand is very large



## Edwards Sales (*\$ in billions*)



**Long-term investments** have yielded high-value, organic growth

### Track record of **triple wins**:

- Improved outcomes
- Enhanced quality of life
- Cost effectiveness

# Edwards 2021 and Beyond



Edwards



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

## 2021 Expectations

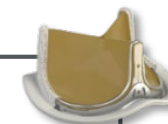
**Mid-teens**  
Underlying net  
sales growth

**\$2.00 - \$2.20**  
Adjusted  
EPS



### TAVR

- Therapy expansion
- Technology advances
- Geographic expansion



### Surgical

- Surgeon partnership
- Leading pipeline
- Growth segment focus



### TMVT

- Differentiated portfolio
- Clinical evidence
- Real-world outcomes



### Critical Care

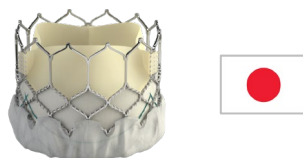
- HemoSphere growth
- Smart technologies
- Portfolio expansion



# 2021 Product Group Milestones



EARLY TAVR Asymptomatic Enrollment Completion



Japan TAVR Low Risk Approval



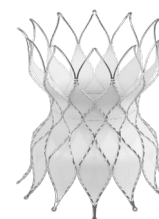
INSPIRIS China Launch



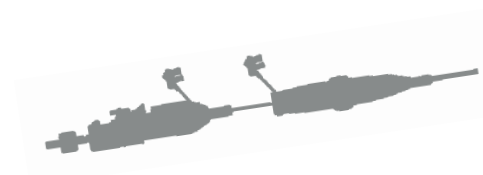
MITRIS US and Japan Launch



Critical Care Viewfinder Connectivity Solution



Alterra Adaptive Prestent



Next Generation PASCAL Delivery System Initial Clinical Experience



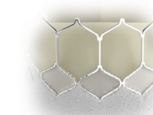
Expanded Launch of KONECT



Launching Moderate AS Trial



Next Generation EVOQUE Mitral System Initial Clinical Experience



SAPIEN X4 Clinical Trial Launch

# 2020 Investor Conference Agenda

**Transcatheter Aortic Valve Replacement**

Larry Wood and Huimin Wang, M.D.

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**Surgical Structural Heart**

Daveen Chopra

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**Advanced Technologies**

Todd Brinton, M.D.

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**Transcatheter Mitral and Tricuspid Therapies**

Bernard Zovighian and Jean-Luc Lemercier

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**Critical Care**

Katie Szyman

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**Financial Outlook**

Scott Ullem

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**Closing Remarks**

Mike Mussallem

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**Question and Answer Session**

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# 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

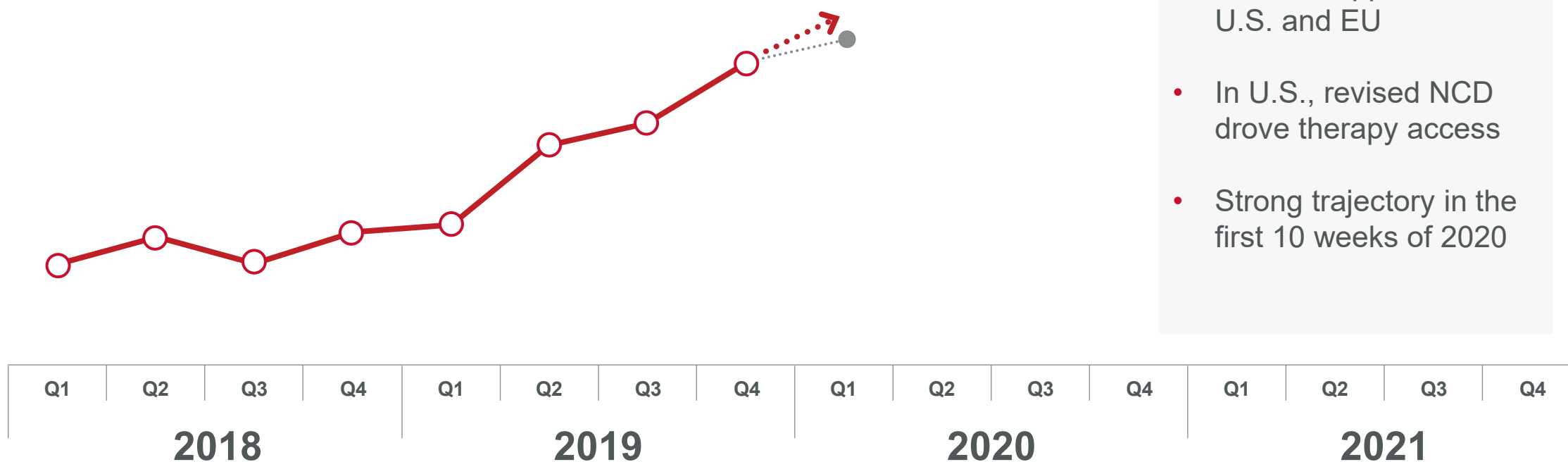
Transcatheter Aortic Heart Valves



Edwards

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

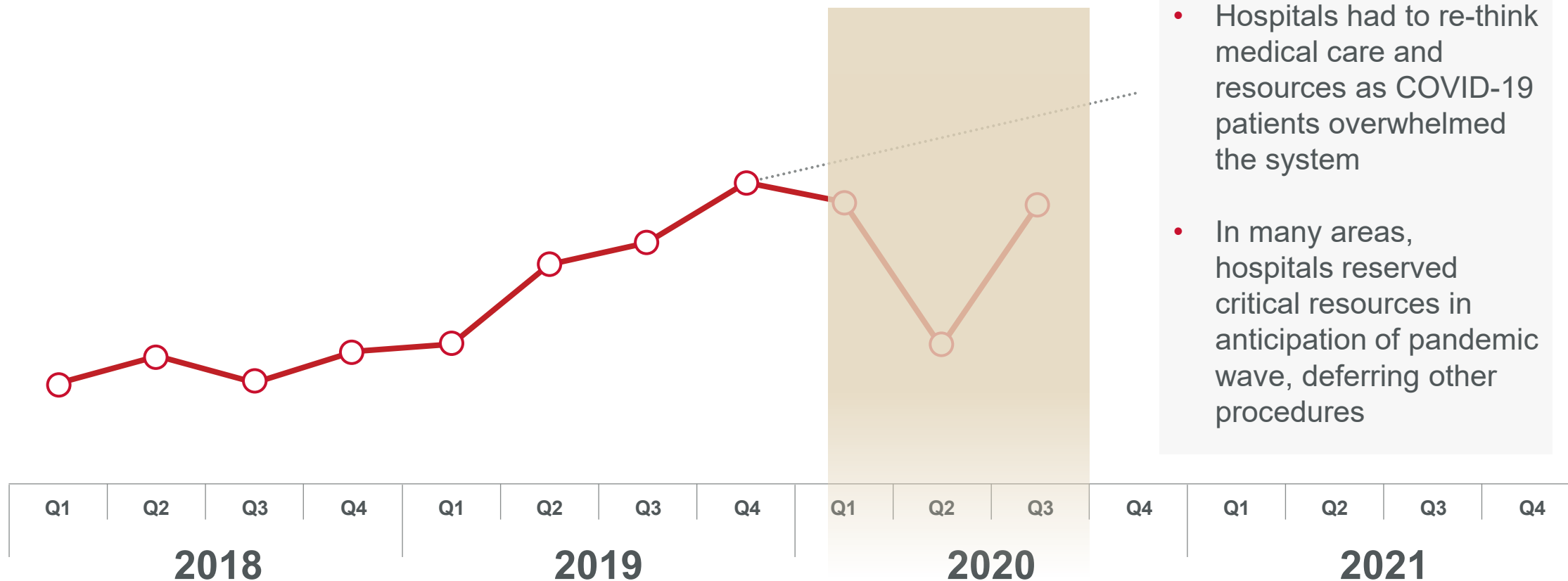
EW Global TAVR Sales (\$M)



- 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

## ...then the pandemic hit

EW Global TAVR Sales (\$M)



- 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

EW Global TAVR Sales (\$M)



We remain laser focused on patient care and clinical partnership

# Bicuspid precaution removed

*Provides further confidence for low risk, younger patients*

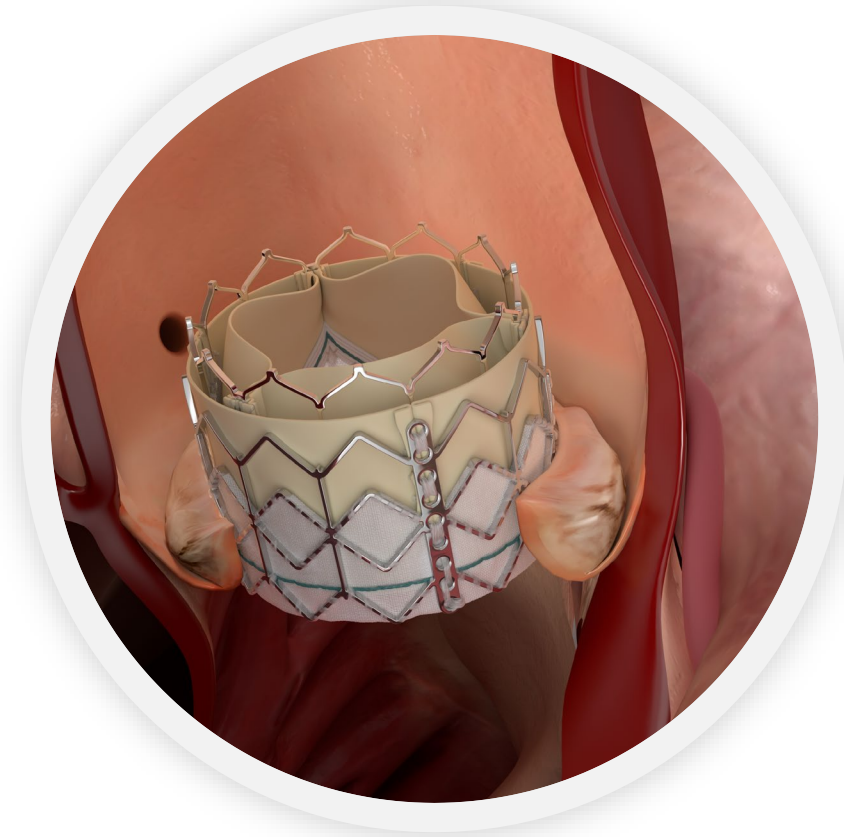
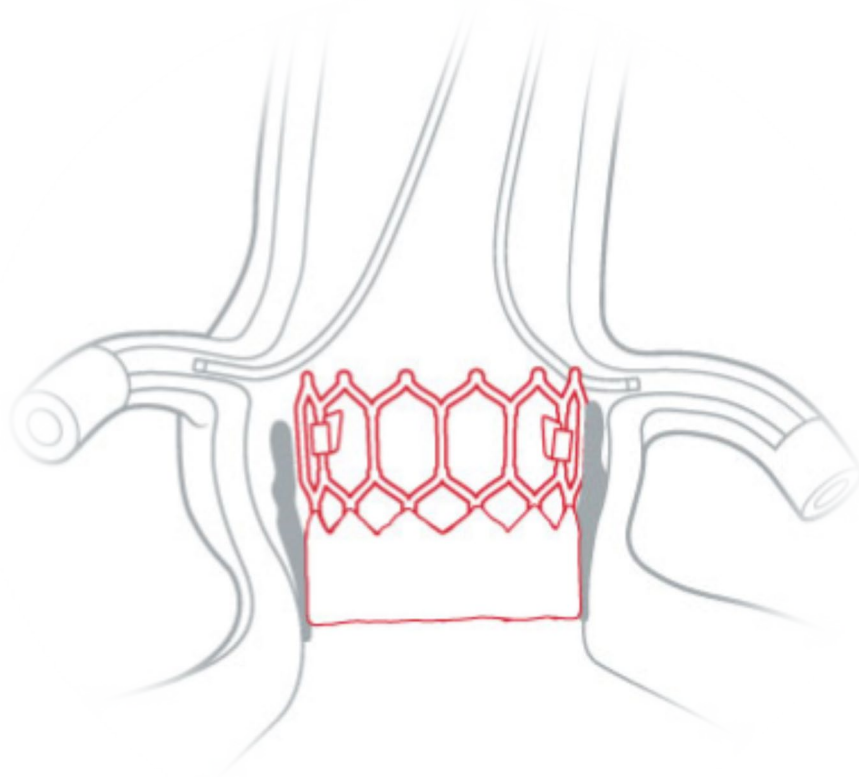


## Low rates of complications that matter most to bicuspid patients<sup>1</sup>

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 22<sup>nd</sup> 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

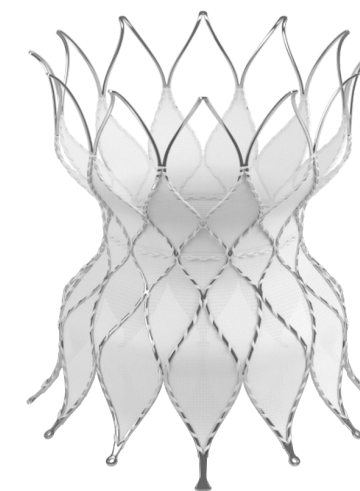
# Expanding Options for Congenital Pulmonic Heart Disease Patients

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



**SAPIEN 3 Valve**

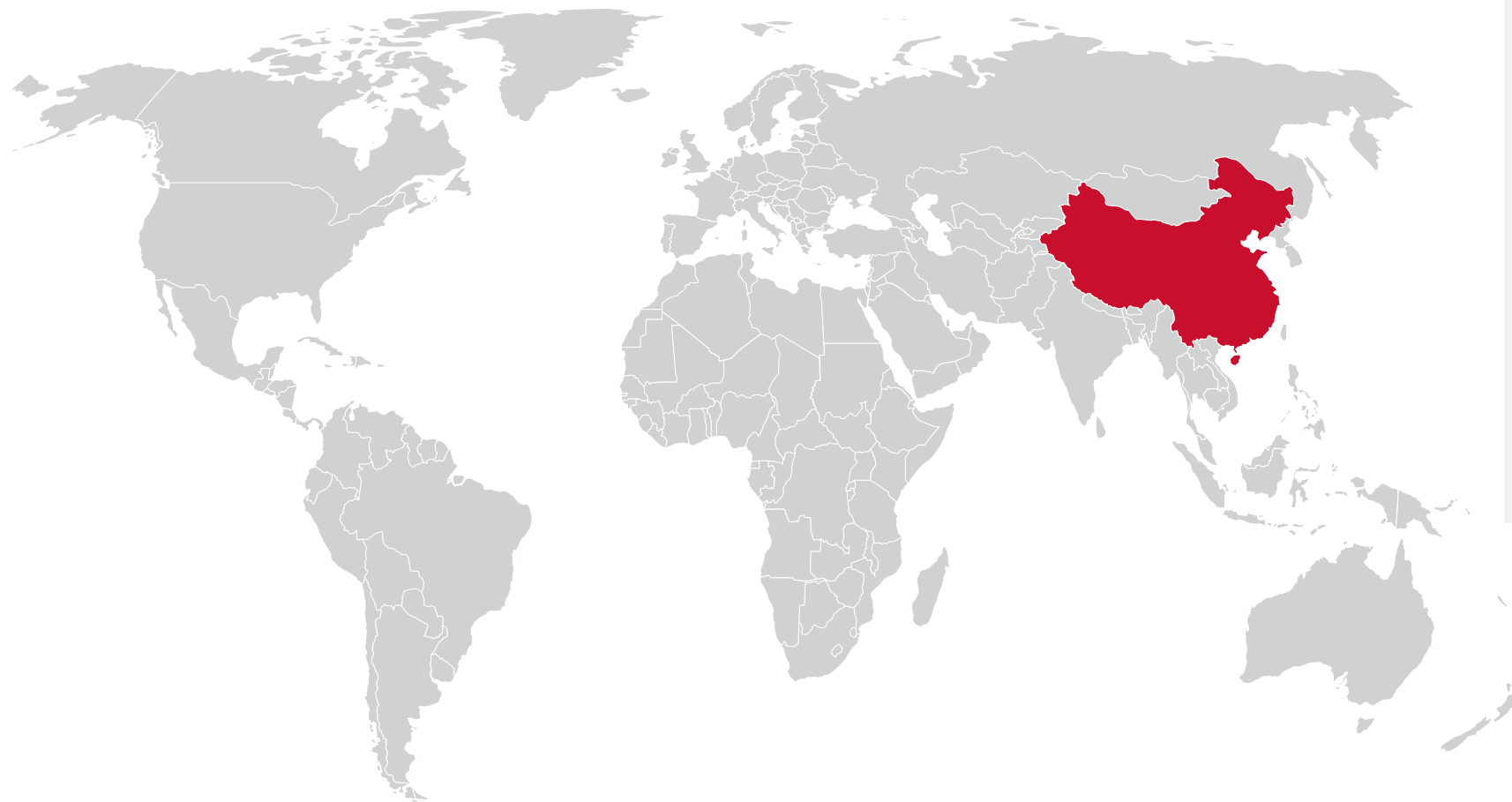
+



**Alterra Adaptive  
Presept**

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.

10%



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.

1 in 5



## 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

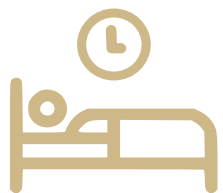


**Low  
pacemaker  
rates**

**Low rates  
of PVL**



# Edwards' TAVR allows hospitals to treat patients with confidence



Low  
complication  
rates



Short  
length-of-stay



Patients  
discharged  
home

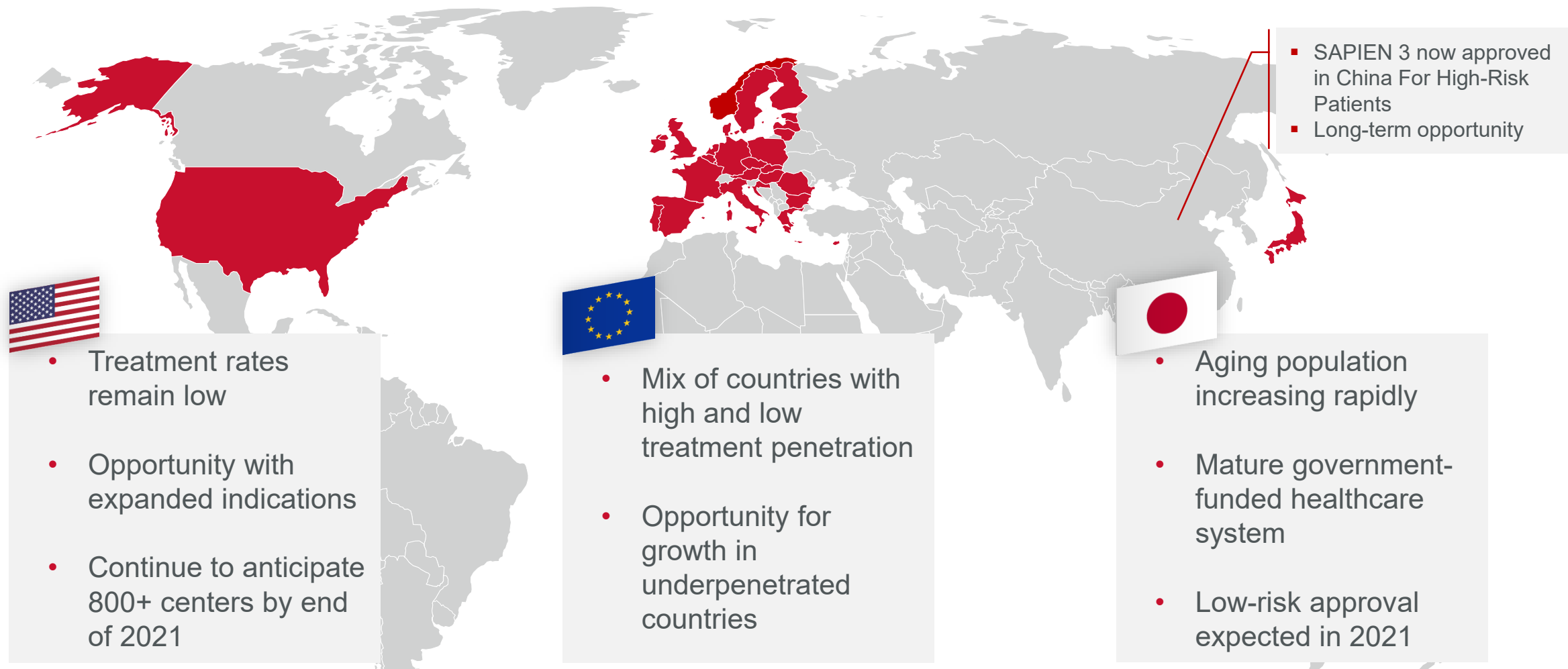


Low  
re-hospitalization  
rates



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

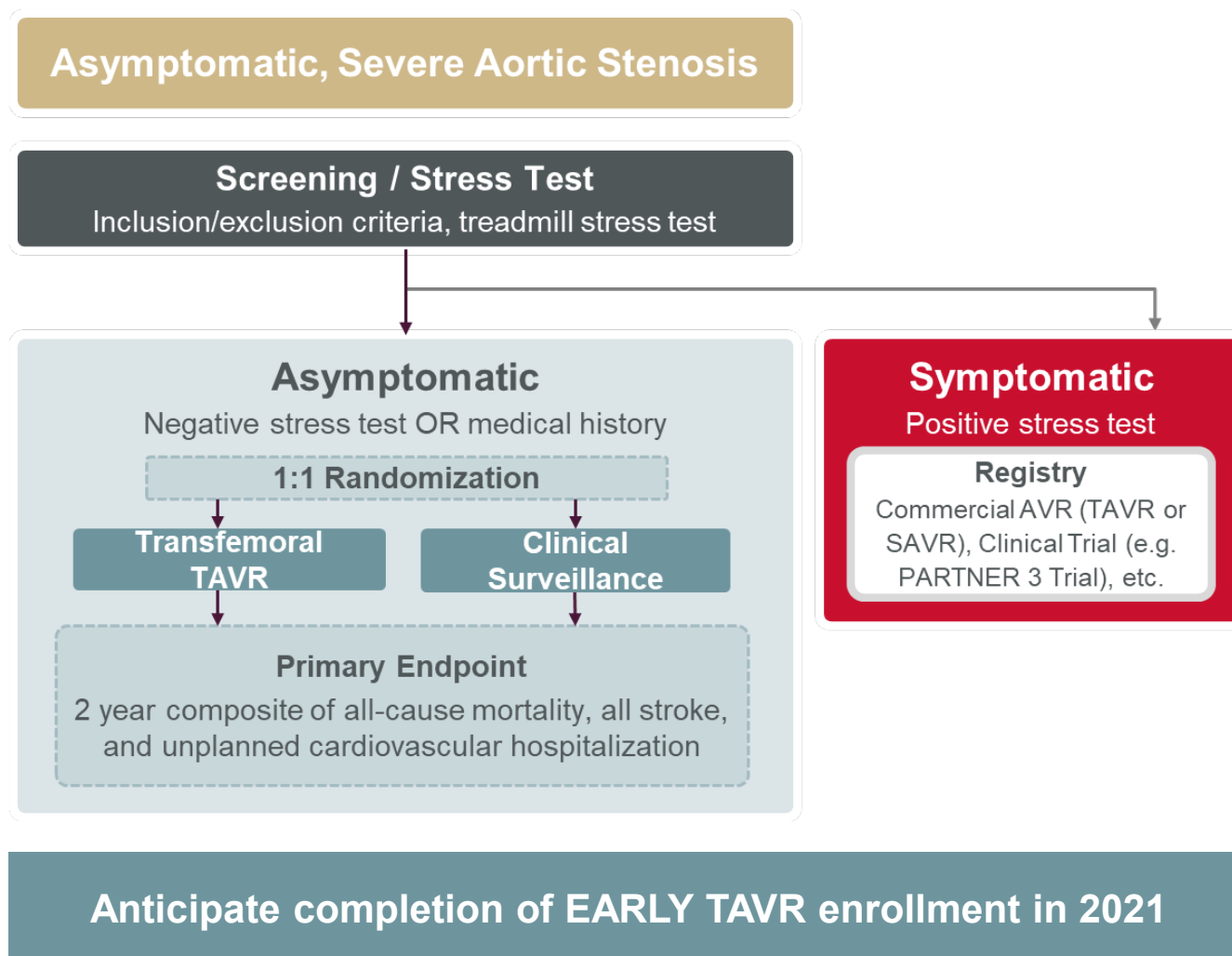
# TAVR fundamentals remain strong in developed markets around the world



**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 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

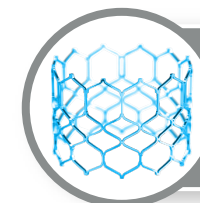


**Next-Generation**



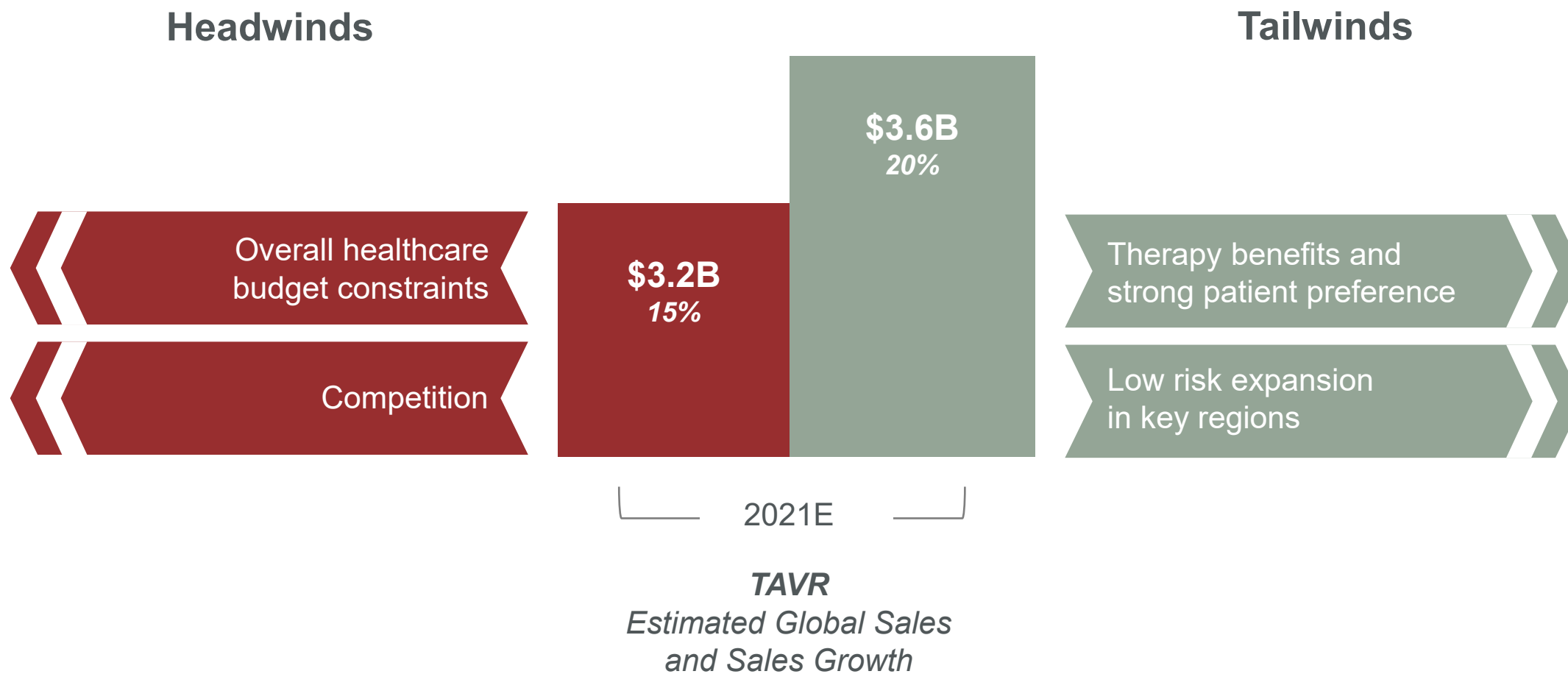
**SAPIEN X4**

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



**Revolutionary  
platform**

# 2021 Global Sales Outlook



# 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

**CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**

### **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  $\geq 8\%$  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. Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established. Glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Safety Data Sheet available from Edwards Lifesciences. 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; 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; 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. For Left axillary approach, a left subclavian takeoff angle  $\sim \geq 90^\circ$  from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage. Ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor PA pressure in homolateral radial artery. 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; thoracic bleeding; embolization including air, calcific valve material, or thrombus; infection including septicemia and endocarditis; heart failure; myocardial infarction; renal insufficiency or renal failure; conduction system defect which may require a permanent pacemaker; arrhythmia; retroperitoneal bleed; arteriovenous (AV) fistula or pseudoaneurysm; reoperation; ischemia or nerve injury or brachial plexus injury; restenosis; pulmonary edema; pleural effusion; bleeding; anemia; abnormal lab values (including electrolyte imbalance); hypertension or hypotension; allergic reaction to anesthesia, contrast media, or device materials; hematoma; syncope; pain or changes at the access site; exercise intolerance or weakness; inflammation; angina; heart murmur; and fever.



Additional potential risks associated with the use of the valve, delivery system, and/or accessories include: cardiac arrest; cardiogenic shock; emergency cardiac surgery; cardiac failure or low cardiac output; coronary flow obstruction/transvalvular flow disturbance; device thrombosis requiring intervention; valve thrombosis; device embolization; device migration or malposition requiring intervention; left ventricular outflow tract obstruction; valve deployment in unintended location; valve stenosis; structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis); device degeneration; paravalvular or transvalvular leak; valve regurgitation; hemolysis; device explants; nonstructural dysfunction; mechanical failure of delivery system and/or accessories; and non-emergent reoperation.

### **Edwards 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 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.

**Edwards Lifesciences 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.**

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



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Helping Patients is Our Life's Work, and

*life is now*

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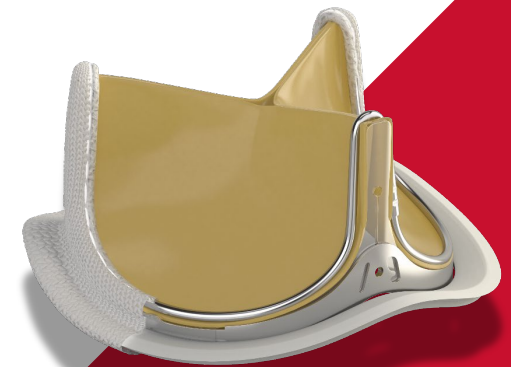
Surgical Structural Heart



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



# Adult cardiac surgery continues to grow mid-single digits driven by awareness and an aging population

## Surgical Aortic Valve Replacement

Growth in emerging regions equally offset decline in developed regions

## Surgical Mitral Valve Replacement and Repair

Continued global mid-single digit growth

Developed Regions

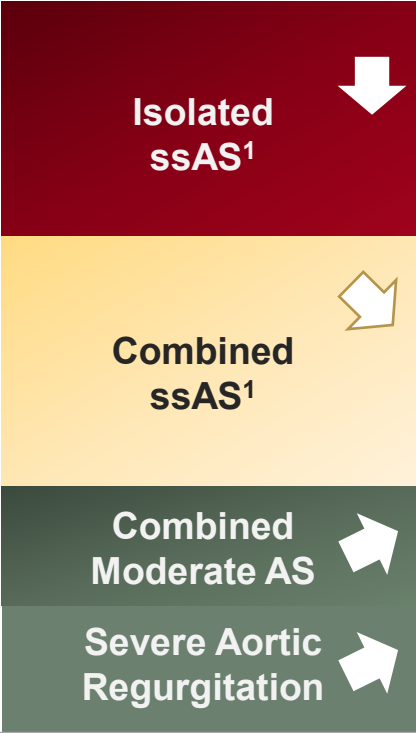
Emerging Regions



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

## Surgical Aortic Procedures (U.S. & EU)

Growth (20-26)



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

<sup>1</sup> 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)

Functional MR



Degenerative MR



Rheumatic, Endocarditis, Other MR



2020E

## Mitral Patients Best Treated Surgically



**Surgical low risk degenerative patients** where surgery remains the gold standard



**Patients with complex disease** who require combined procedures

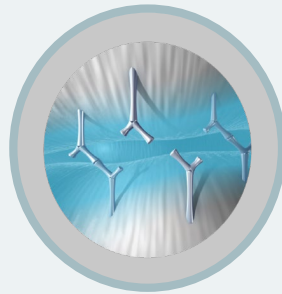


**Patients with rheumatic or endocarditis diseases** who require a surgical approach

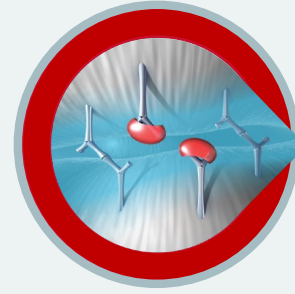
# We continue to generate robust clinical evidence for our leading RESILIA tissue technology

## RESILIA Tissue Technology

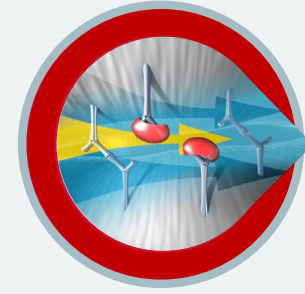
### Anti-calcification to improve tissue durability



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

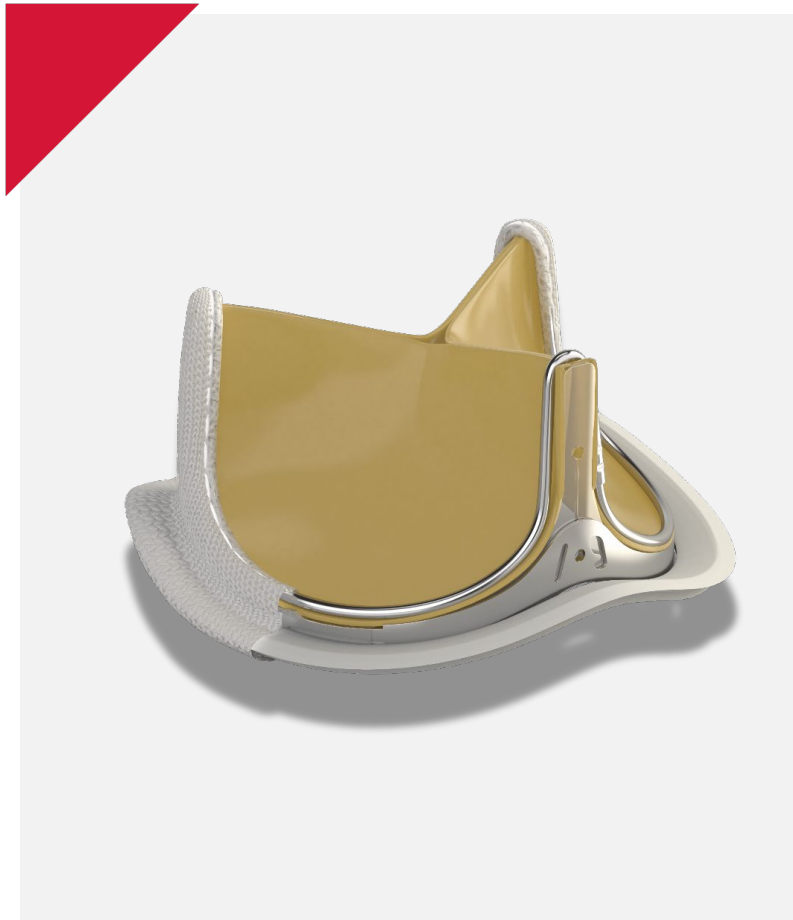
### RESILIENCE

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

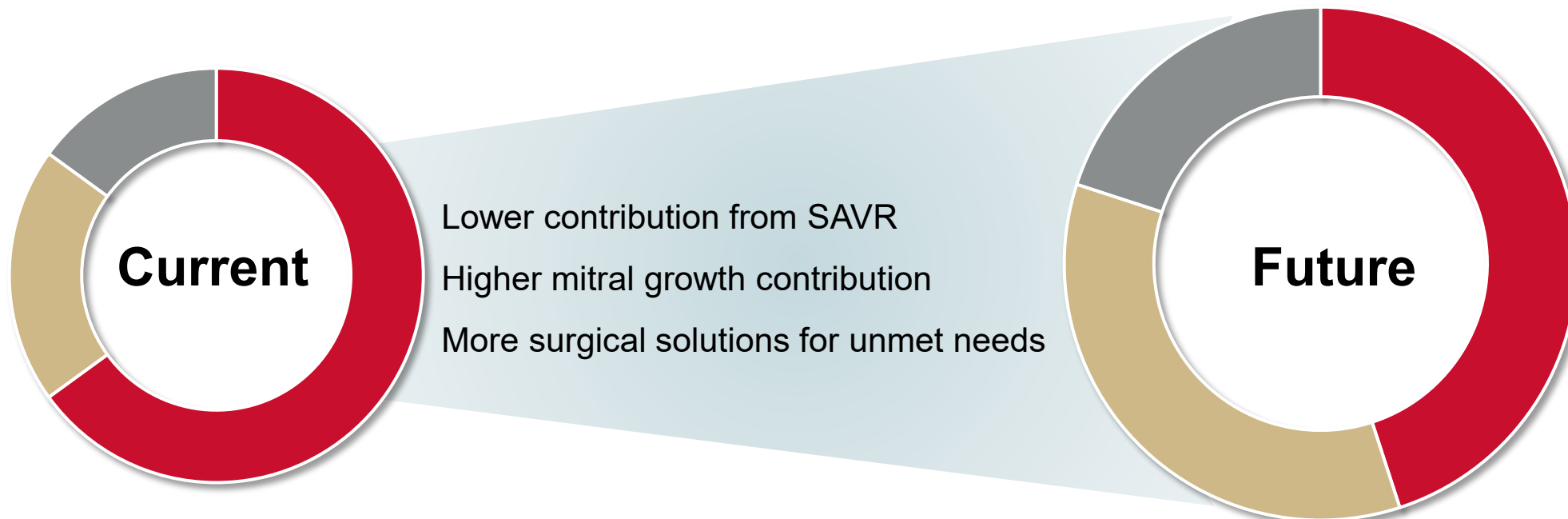


- Standardizing mitral repair with an **echo-guided, beating-heart procedure**
- **Launched in 2020** with potential to convert ~20k surgical repair patients across the U.S., Europe, and Japan
- **Started the RESTORE U.S. pivotal trial**, a unique, non-randomized study with a one-year endpoint

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

## Surgical Structural Heart Revenue by Segment

- Aortic
- Mitral
- Other



# 2021 Global Sales Outlook

## Headwinds

Continued TAVR conversion in U.S. & EU

Overall healthcare budget constraints

\$800M

\$900M

## Tailwinds

Adoption of RESILIA products

Accelerated mech-to-tissue conversion

2021E

***Surgical Structural Heart***  
*Estimated Global Sales*

# 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

**Important Safety Information:****INSPIRIS RESILIA Aortic Valve**

Indications: For use in replacement of native or prosthetic aortic heart valves.

Contraindications: There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve.

Complications and Side Effects: Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death.

Warnings: DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO/OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON

THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

**CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information. KONECT RESILIA Aortic Valved Conduit**

Indications: For use in replacement of native or prosthetic aortic heart valves and the associated repair or replacement of a damaged or diseased ascending aorta.

Contraindications: There are no known contraindications with the use of the KONECT RESILIA Aortic Valved Conduit.

Complications and Side Effects: Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explanation, permanent disability, and death. Adverse events potentially associated with the use of polyester vascular grafts include hemorrhage, thrombosis, graft infection, embolism, aneurysm, pseudoaneurysm, seroma, occlusion (anastomotic intimal hyperplasia), immunological reaction to collagen (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation.

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Helping Patients is Our Life's Work, and

*life is now*

# 2020 Investor Conference

Transcatheter Mitral and  
Tricuspid Therapies



Edwards

# TMTT is guided by our vision to lead and transform treatment for patients with mitral and tricuspid valve disease

Today, patients with **Mitral and Tricuspid regurgitation** remain **undertreated** and suffer poor quality of life and high mortality

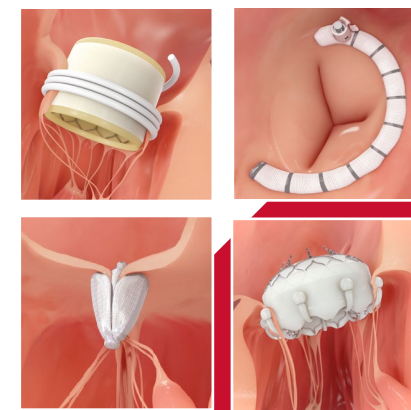
TMTT is delivering a **portfolio of therapies** – including leaflet repair, annular reduction, and valve replacement – to **address the diversity and complexity of Mitral and Tricuspid disease**

*To achieve this vision, TMTT is focused on 3 key value drivers*

- 1 Our **portfolio of differentiated therapies**
- 2 **Positive** results from our **pivotal trials**
- 3 **Favorable real-world outcomes**

## **TMTT will double revenue in 2021**

Ongoing innovation & clinical evidence will support the development of a **\$3B MR/TR opportunity in 2025**, with significant growth beyond 2025



# TMTT is innovating a broad transcatheter portfolio

## TRICUSPID

## MITRAL

Leaflet Repair



PASCAL



PASCAL Ace



PASCAL



PASCAL Ace

Annular Reduction



Cardioband



Cardioband

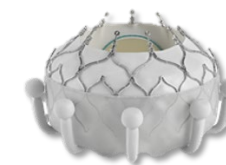
Valve Replacement



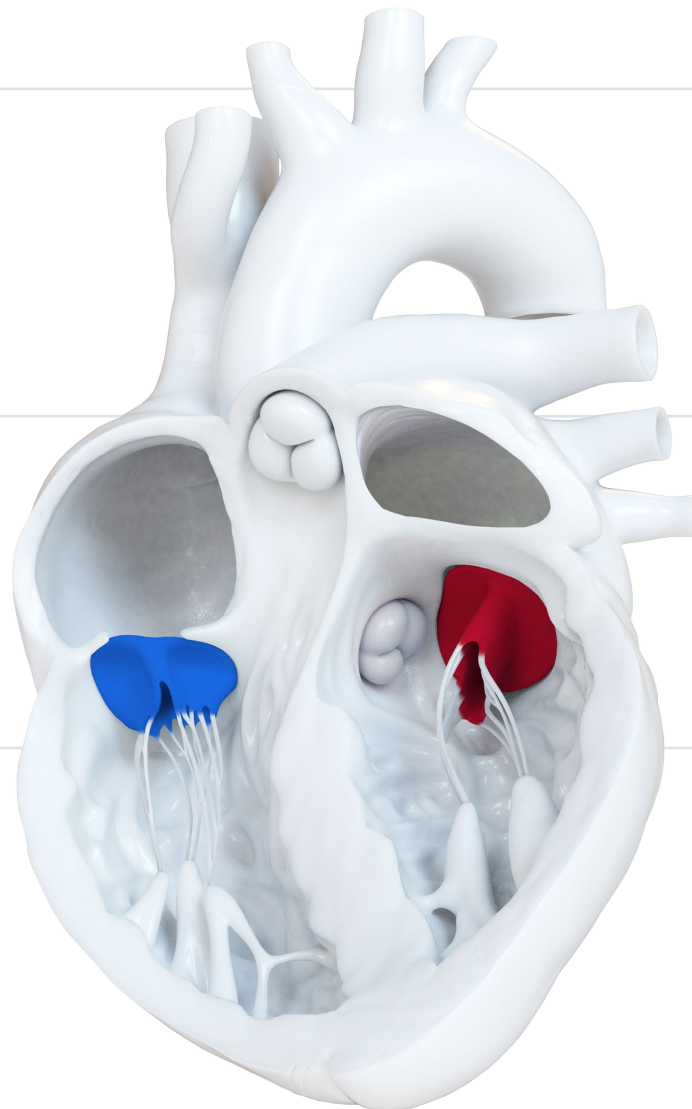
EVOQUE



SAPIEN M3



EVOQUE



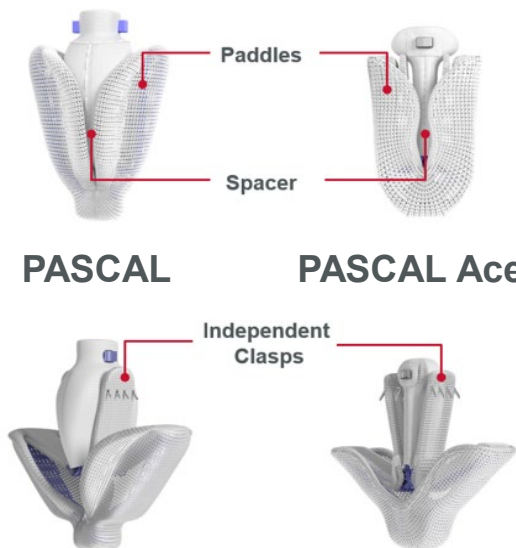
# Mitral Innovations: PASCAL for Leaflet Repair



## 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

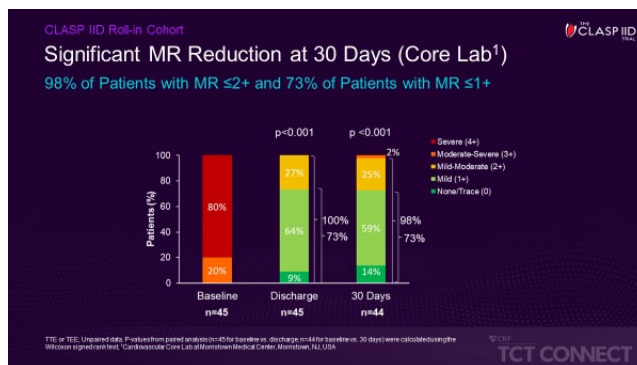
Bringing a consistent cadence of advancements to the PASCAL platform, including a next-gen delivery system in 2021

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

## CLASP IID Roll-In Data

**73%**

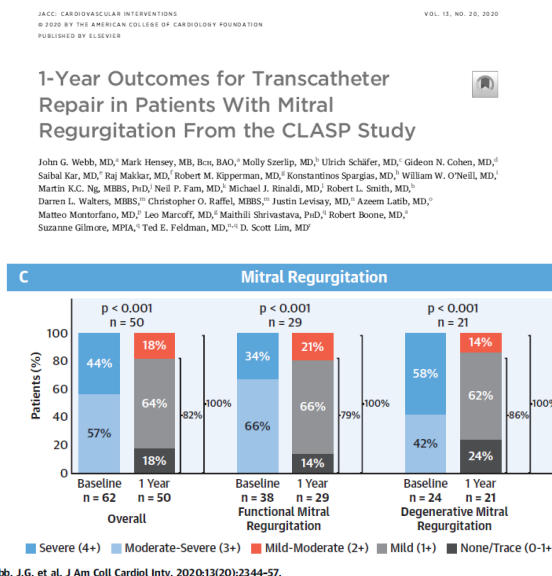
Percentage of patients with MR ≤0/1+ at 30 days<sup>1</sup>



## CLASP CE Mark Study

**82%**

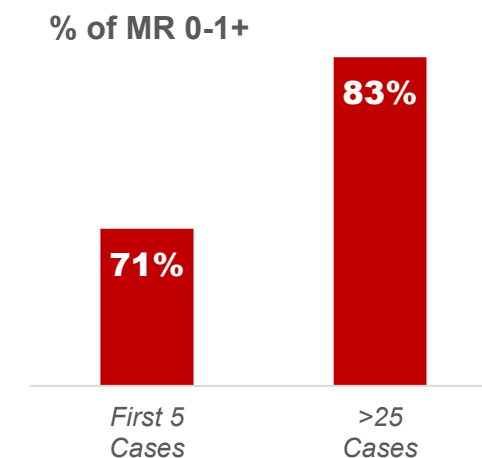
Percentage of patients with MR ≤0/1+ at 1 year<sup>2</sup>



## Real-World Experience

**83%**

Percentage of patients with MR ≤0/1+ at discharge<sup>3</sup> after 25 case experience



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

# 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



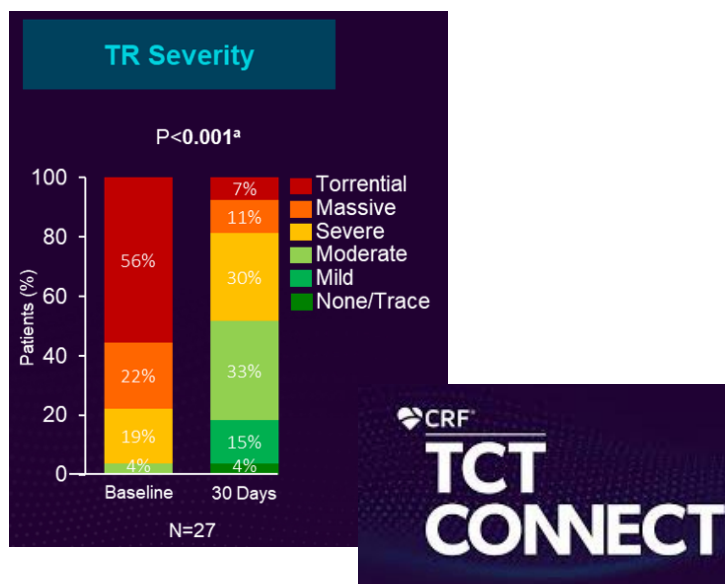
## Cardioband

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

### PASCAL: CLASP TR EFS Study

# 70%

Percentage of patients with  $\geq 2$  TR grade reduction<sup>1</sup>



### Cardioband: Tri-Repair CE Mark Study

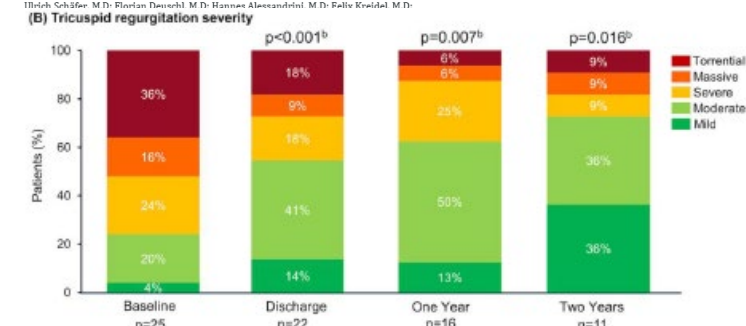
# 72%

Percentage of patients with TR  $\leq$  moderate at 30 days<sup>2</sup>



Title: Two-year Outcomes with the Cardioband Tricuspid System from the Multicentre, Prospective TRI REPAIR Study.

Authors: Georg Nickenig, M.D.; Marcel Weber, M.D.; Robert Schuler, M.D.; Jörg Hausleiter, M.D.; Michael Nabauer, M.D.; Ralph S. von Bardeleben, M.D.; Efthymios Sotiriou, M.D.; Ilina A. Galina, M.D.; Florian Tanschel, M.D.; Hannes Altesobrunt, M.D.; Felix Kraljic, M.D.



Experience with next generation PASCAL expected next year

# Innovations & Evidence In Tricuspid Valve Replacement

## EVOQUE

Tricuspid platform with three valve sizes to address diverse tricuspid anatomy



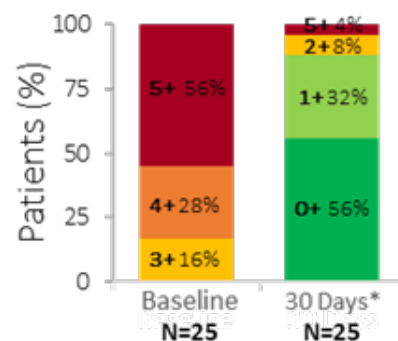
All three valves use the same **<30F** transfemoral delivery system

*EVOQUE Compassionate Use*

# 88%

Percentage of patients with TR  $\leq 0/1+$  at 30 days<sup>1</sup>

### TR severity



Average procedure time of ~1 hour



\*Mean TV gradient:  $3.2 \pm 0.6$  mmHg

*“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

# 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

# 2021 Global Sales Outlook

## Headwinds

Slower adoption of novel TMTT therapies

Competition for clinical trial enrollment

Doubling  
2020 to  
~\$80M

2021E

**TMTT**  
*Estimated Global Sales*

## Tailwinds

PASCAL differentiation driving faster site activation in Europe

Rapid enrollment in CLASP IID trial

# 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

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# 2020 Investor Conference

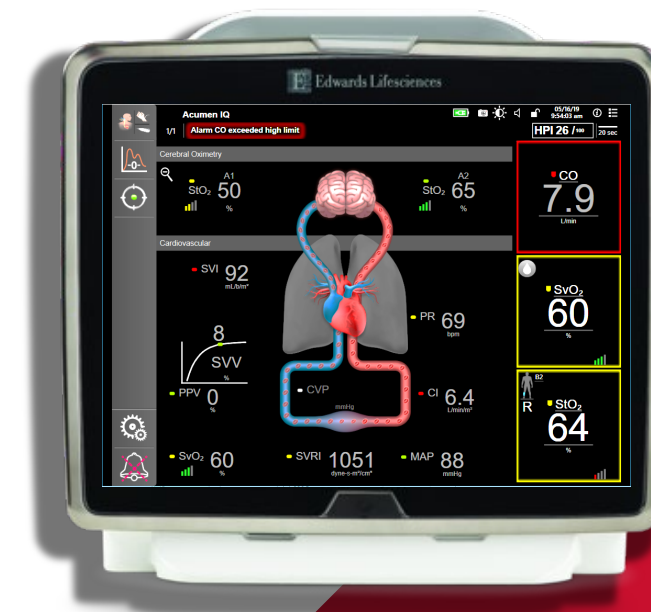
Critical Care



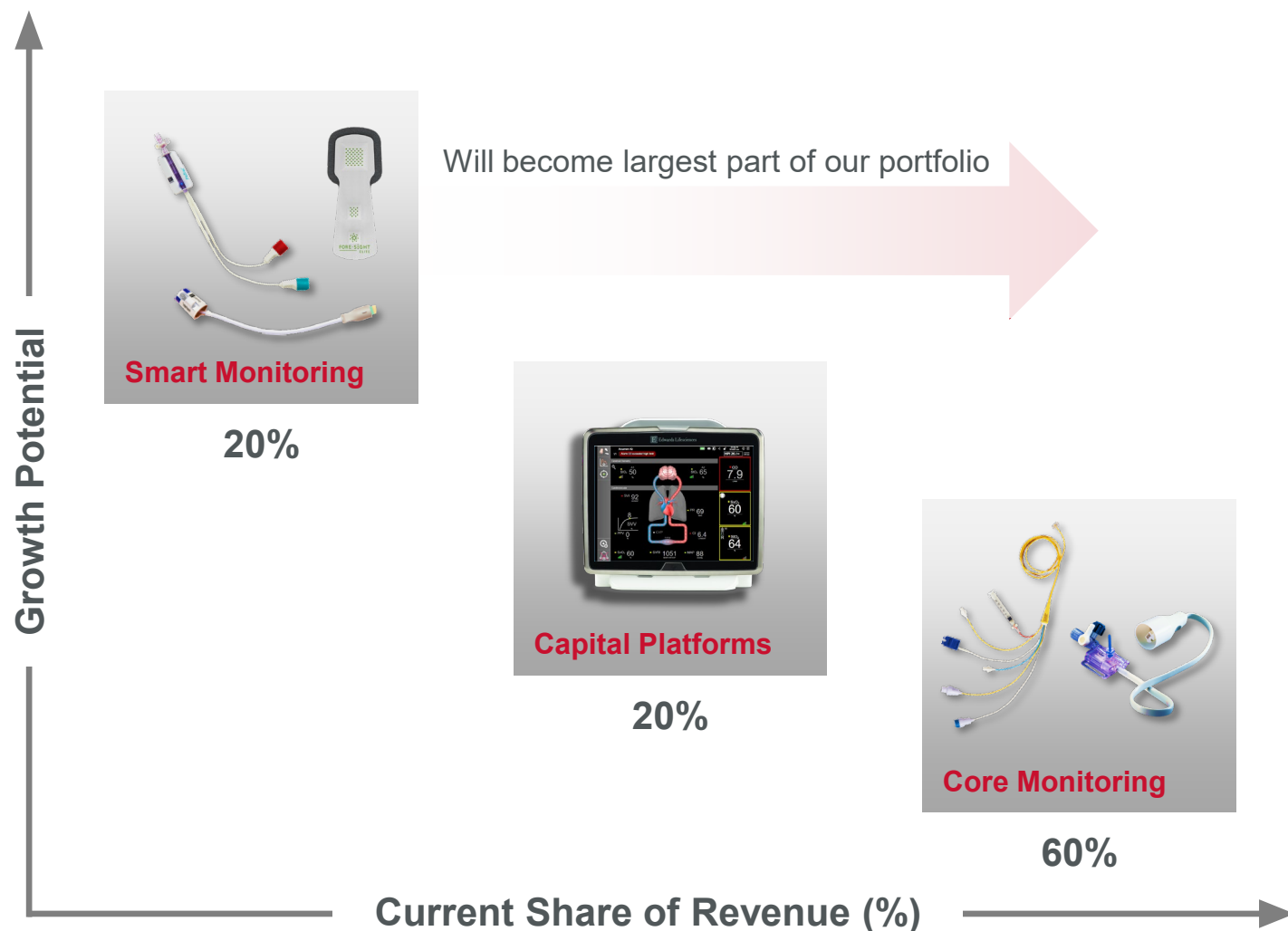
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# Critical Care improving the quality of care for patients

- 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

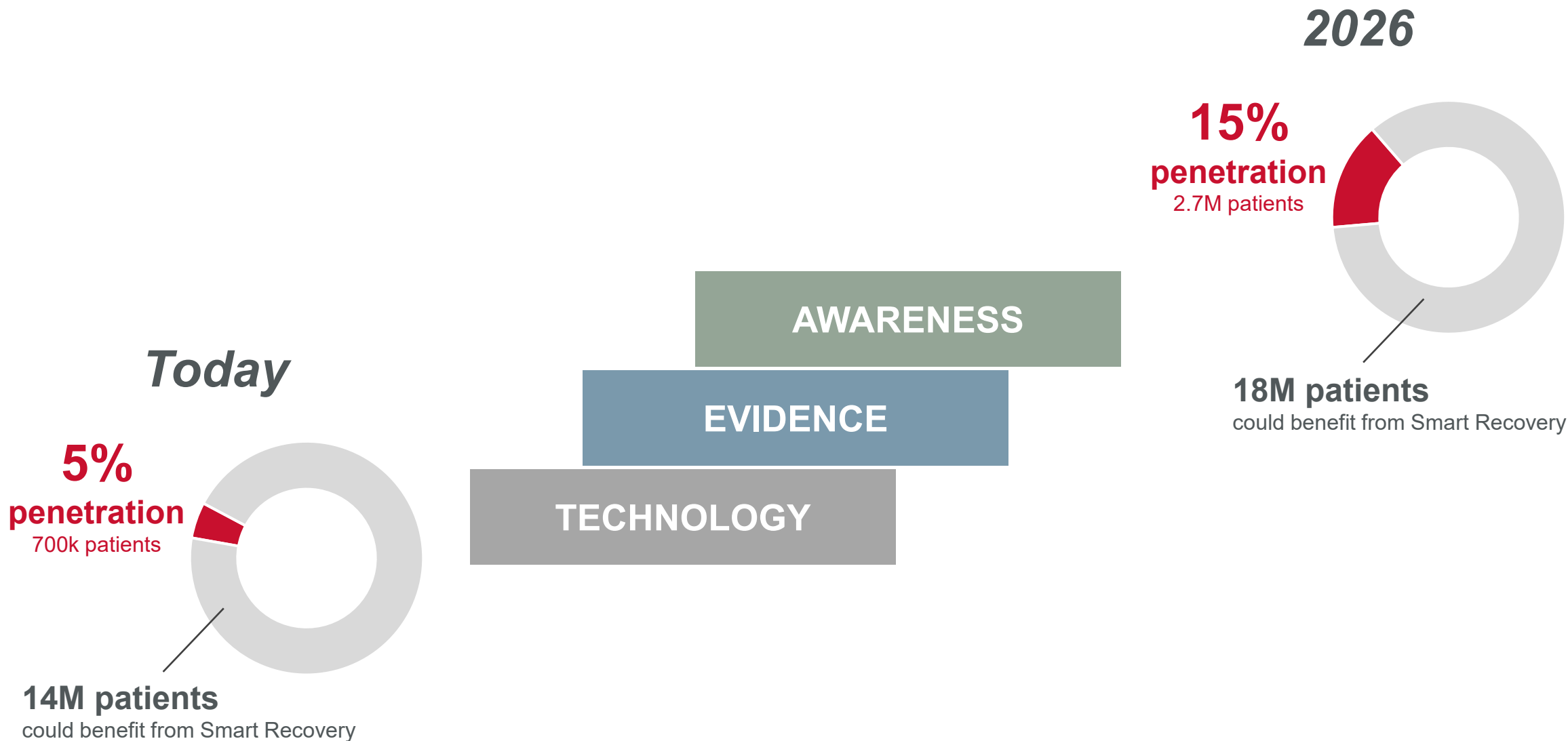


# We are shifting focus of business to Smart Recovery



- 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

# Three Key Building Blocks for Smart Recovery

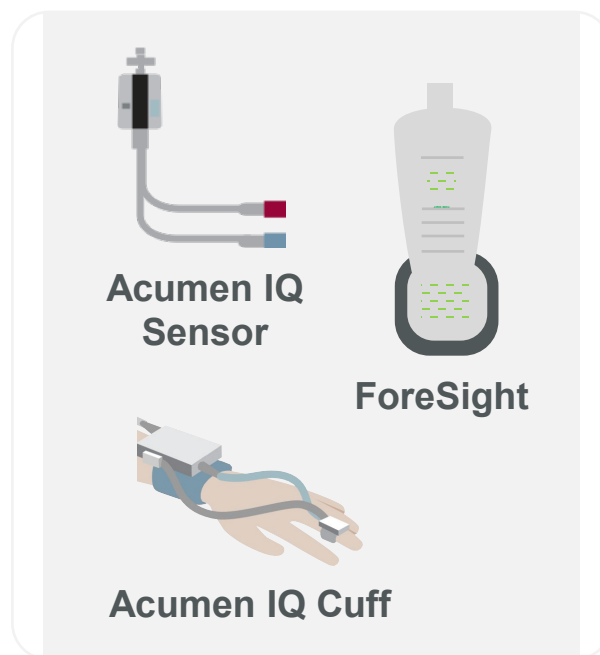


# Having the Right Technologies Deployed in Hospitals

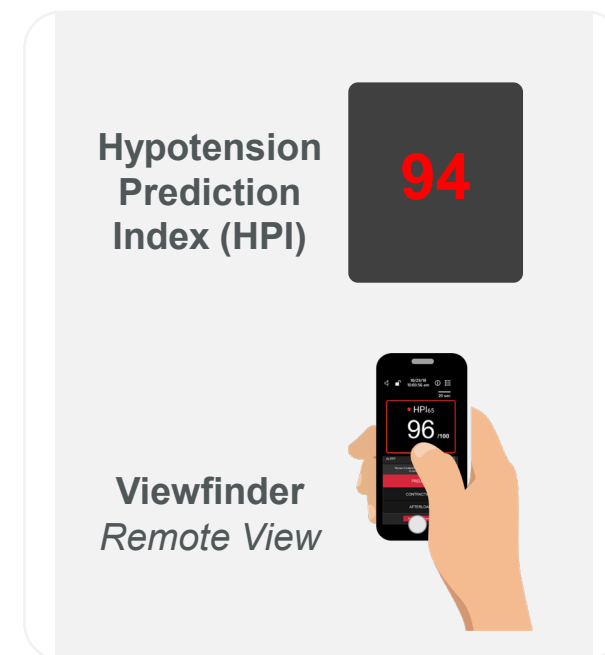
## CAPITAL PLATFORM



## SENSORS



## SOFTWARE



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<sup>1,\*</sup>, T. H. Kappen<sup>1</sup>, H. M. Torn<sup>1</sup>, A. J. C. Slooter<sup>2</sup> and W. A. van Klei<sup>1</sup>

<sup>1</sup>Department of Anesthesiology, Utrecht, The Netherlands and <sup>2</sup>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

■ without Acumen HPI software ■ with Acumen HPI software

HYPE Trial

**76%**  
Decrease in IOH

33 mins

8 mins

Edwards Trial

**65%**  
Decrease in IOH

25 mins

9 mins

# 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**



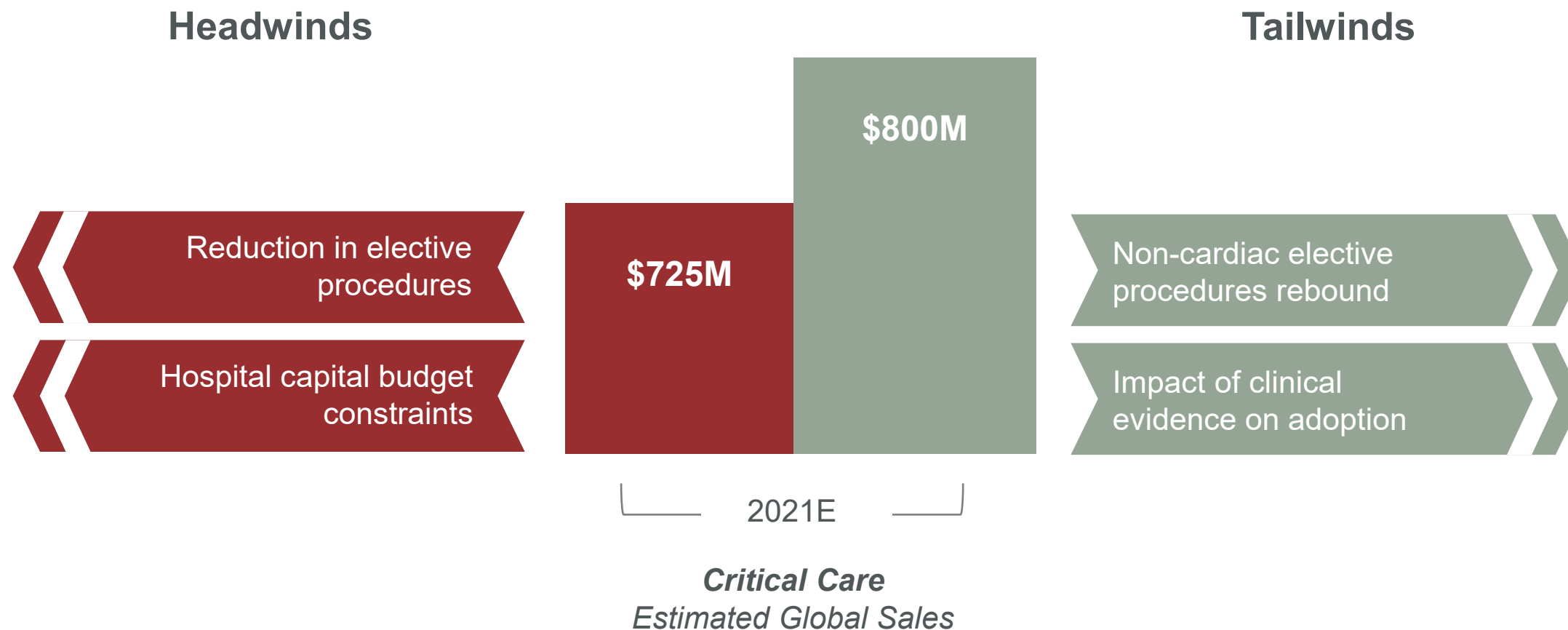
*“My doctor said to me, ‘I can do anesthesia in a special way using Acumen HPI.’ Now, thank God, I can walk again.”*

– **Juan Gil Garcia, HPI Patient**



We believe the increased evidence around hypotension will drive awareness

# 2021 Global Sales Outlook





# Executive Summary

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

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# Financial Outlook

Scott Ullem  
Chief Financial Officer



Edwards

# Edwards has delivered strong financial performance



# Edwards Financial Objectives



## **STRONG SALES GROWTH EXCEEDING MEDTECH SECTOR**

- Sales growth fueled by successful long-term investments in R&D and advancements of breakthrough innovations
- Sustained leadership position supported by strong evidence base of value to patients and clinicians
- Addressing large, growing unmet patient needs

# COVID significantly impacted 2020 financial performance

*(Excludes special items; \$ in millions except earnings per share)*

Adjusted Item	2019 Investor Conference	October Guidance
Sales	\$4,500-5,000	Year-over-year growth below plan
FX Impact on Sales	~\$(40) (~1% downside to sales)	Neutral impact
Gross Profit Margin	76-77%	Year-to-date Q3: 75.6%
Earnings Per Share	\$2.02-2.10 (adjusted for 3-for-1 split)	\$1.85-1.95
Free Cash Flow	\$1,000-1,100	Below plan

# 2020 Sales Guidance Comparison

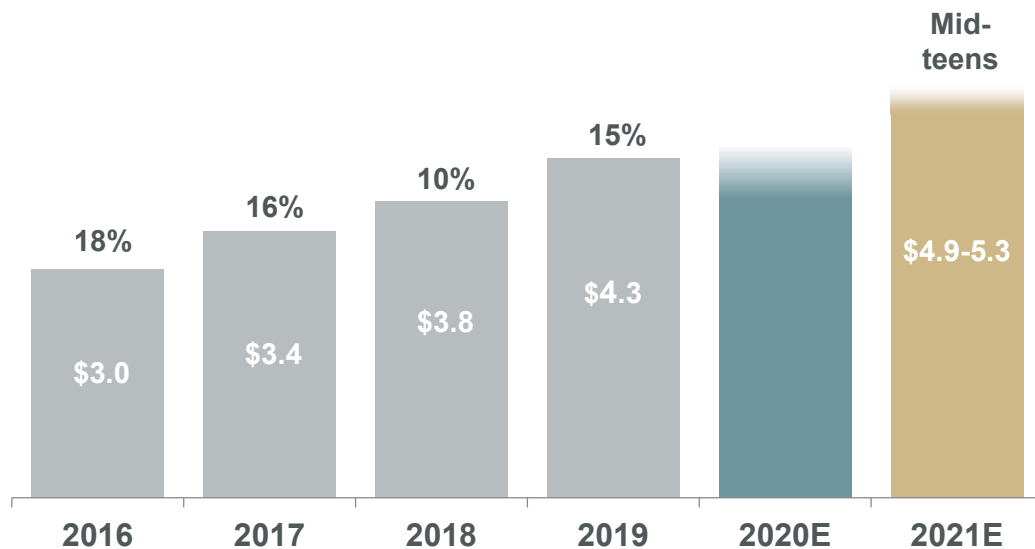
*Total company year-over-year Q4 growth rate trending lower than Q3 due to COVID*

	2019 Investor Conference	Current Guidance
<b>Transcatheter Aortic Valve Replacement</b>	12-15%	Higher End (5%)-5%
<b>Transcatheter Mitral &amp; Tricuspid Therapies</b>	\$50-\$70M	Around \$40M
<b>Surgical Structural Heart</b>	0-3%	(15%)-(5%)
<b>Critical Care</b>	6-9%	(5%)-0%
<b>Total Edwards</b>	10-12%	Q3 YTD: ~1%



# Mid-teens sales growth expected in 2021

(Adjusted sales \$ in billions; underlying growth rates)



## 2021 EXPECTATIONS

- Hospitals continue to face headwinds from COVID
- Growth in all regions with expectations for interruptions due to COVID
- FX impact expected to be approximately 1% favorable in 2021 at current rates
- Expect high variability in quarterly growth rates

# 2021 Sales Guidance – Product Group

*(\$ in millions at current exchange rates)*

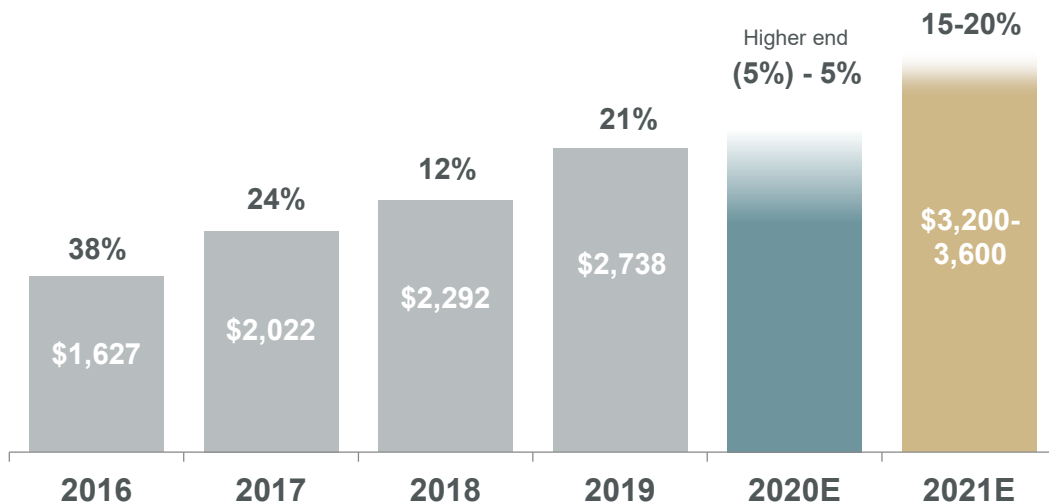
	<b>Underlying Sales</b>
<b>Transcatheter Aortic Valve Replacement</b>	\$3,200-3,600 (Underlying growth 15-20%)
<b>Transcatheter Mitral &amp; Tricuspid Therapies</b>	~\$80 (Approximately 2x 2020)
<b>Surgical Structural Heart</b>	\$800-900
<b>Critical Care</b>	\$725-800
<b>Total Edwards</b>	\$4,900-5,300 (Mid-teens underlying growth)

## 2021 Guidance Assumptions

- COVID continues to stress the global healthcare system
- COVID impact lessens after winter flu season
- Effective vaccine becomes widely available by mid-2021
- Hospitals continue to improve ability to treat structural heart patients

# TAVR to return to double-digit sales growth in 2021

(Adjusted sales \$ in millions; underlying growth rates)

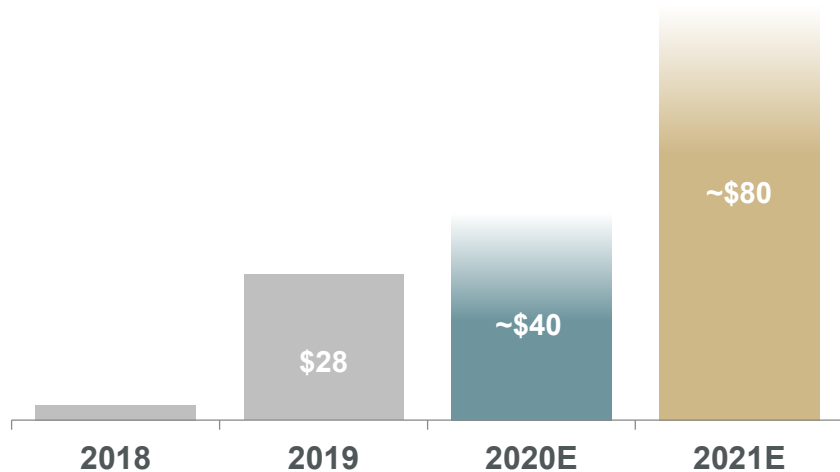


## 2021 HIGHLIGHTS

- Procedure growth driven by improved TAVR adoption
- EARLY TAVR enrollment complete
- FDA approval to start Moderate AS pivotal trial
- Japan low-risk approval late 2021
- Alterra approval
- SAPIEN X4 clinical trial initiated

# TMTT has strong momentum going into 2021

(Adjusted sales \$ in millions)

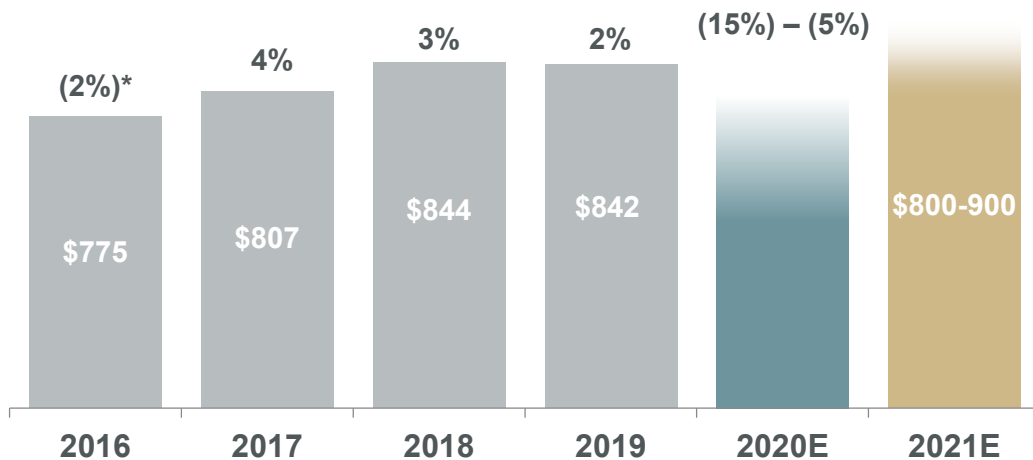


## 2021 HIGHLIGHTS

- Doubling 2020 global revenue led by PASCAL and PASCAL Ace for both mitral and tricuspid patients
- Enrolling 5 pivotal studies: SAPIEN M3 (ENCIRCLE); EVOQUE TR (TRISCEND II); and PASCAL (CLASP IID, IID, and IITR)
- 1<sup>st</sup> clinical experience with next generation PASCAL delivery system
- 1<sup>st</sup> clinical experience with next generation EVOQUE MR

# Surgical Structural Heart brings leading innovation

(Adjusted sales \$ in millions; underlying growth rates)

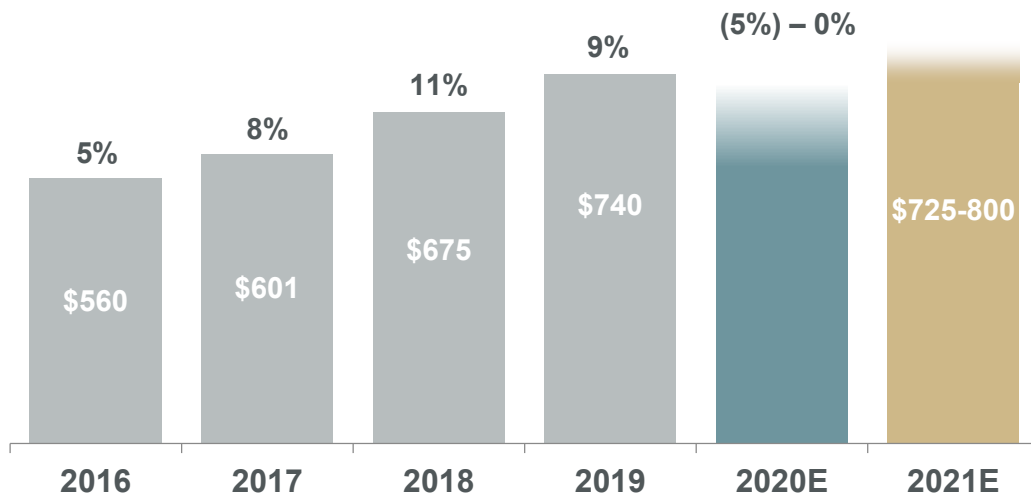


## 2021 HIGHLIGHTS

- Drive adoption of our RESILIA products, INSPIRIS and KONECT
- INSPIRIS China launch
- MITRIS US and Japan launch
- HARPOON U.S. pivotal trial enrolling (RESTORE)

# Critical Care shifting focus to Smart Recovery

(Adjusted sales \$ in millions; underlying growth rates)



## 2021 HIGHLIGHTS

- Drive growth with capital equipment and Smart Recovery products
- Focus on advancing Smart Recovery and improving quality of care with the expansion of HPI technology
- Viewfinder connectivity solution available in 2021

# 2021 Product Group Milestones

## TAVR

- Procedure growth driven by improved TAVR adoption
- EARLY TAVR enrollment complete
- FDA approval to start Moderate AS pivotal trail
- Japan low-risk approval in late 2021
- Alterra approval H2 2021
- SAPIEN X4 clinical trial initiated

## TMTT

- Double 2020 global revenue led by PASCAL and PASCAL Ace for both mitral and tricuspid patients
- Enrolling 5 pivotal studies
- Initial clinical experience with the next-generation PASCAL delivery system
- Initial clinical experience with the next-generation EVOQUE mitral system

## Surgical Structural Heart

- RESILIA product adoption (INSPIRIS and KONECT)
- INSPIRIS China launch
- MITRIS US and Japan launch
- HARPOON U.S. pivotal trial enrolling (RESTORE)

## Critical Care

- Global expansion of HPI technology
- Viewfinder connectivity solution available
- Increased clinical evidence to drive adoption



# Edwards Financial Objectives



## HEALTHY PROFITABILITY

- Generating strong gross profit and operating margins
- Funding growing field organization and strengthening global supply chain
- Investing aggressively for profitable organic growth
- Maintaining efficient tax structure

# 2021 Gross Profit Margin Outlook

Year-over-Year

Sales Mix	+	<p>Mix benefit from TAVR growth</p> <p>Some lower-volume new product margins below the corporate average</p> <p>Modest price compression driven by volume discounts</p>
Optimizing Global Supply Chain	+/-	<p>Creating business continuity across our global manufacturing network</p> <p>Increasing capacity and improving efficiency</p> <p>Upgrading manufacturing systems across plant network</p> <p>Enhancing supplier network</p>
Foreign Exchange	-	<p>At current FX rates, expect modest negative impact</p>
Net Impact	=	<p><b>Adjusted Gross Margin forecast to be 76-77%</b></p>

# Plan to invest aggressively in 2021 for future growth despite expected COVID disruptions



## R&D

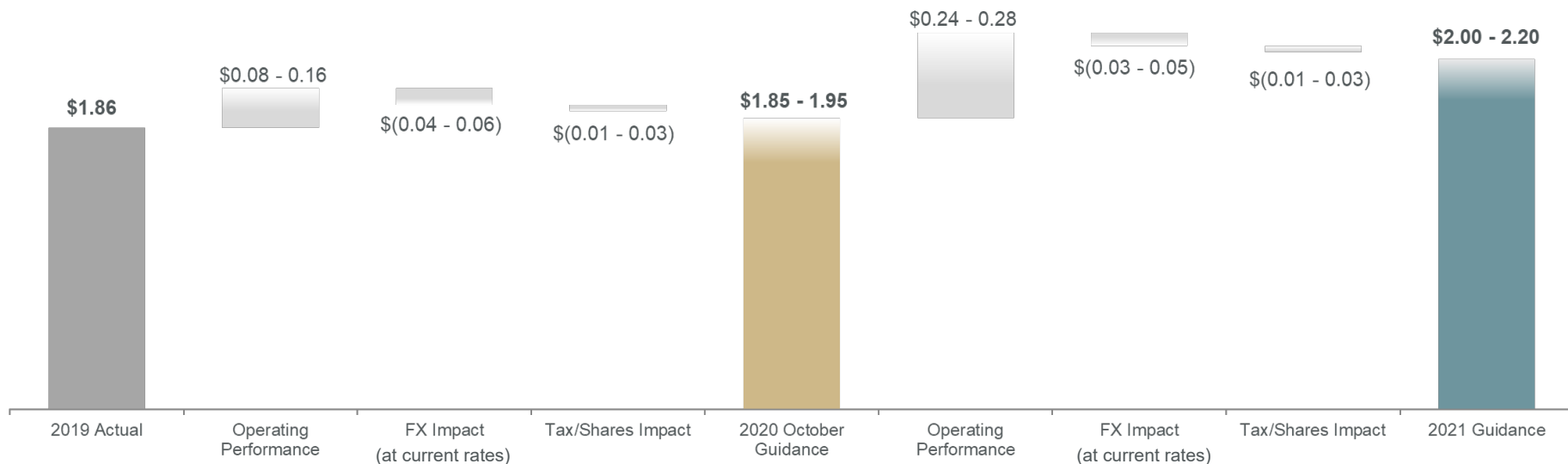
- TAVR and TMTT investments focused on developing new technologies and generating evidence to expand indications
- Enrolling 7 pivotal trials
- Approximately 1/3 of R&D investment is allocated to clinical evidence generation
- Targeted investments to grow core businesses



## SG&A

- Continuing to support high-touch model for U.S. TAVR
- Ongoing build-out of commercial and clinical teams to support TMTT
- Travel resumes as COVID permits

# 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

# Cash Flows and Capital Deployment

2016 - 2019

Nearly  
**\$4B**  
of cash generated  
from operations



**\$2.5B**

Share Repurchases

**\$0.8B**

CAPEX

**\$0.3B**

Upfront Acquisition  
Payments

## 2021 HIGHLIGHTS

- Continued growth results in significant cash flows that fund future internal and external opportunities
- 2021 capital expenditures expected around \$350 million as capacity expansion continues
- EPS model assumes flat diluted shares outstanding of 630 million

# 2021 Guidance Summary

*(Excludes special items; \$ and shares in millions except earnings per share)*

Adjusted Item	FY 2021	Adjusted Item	FY 2021
Sales	\$4,900-5,300	Operating Margin	29-30%
Underlying growth	Mid-teens	Tax rate	11-15% (~5pp ETB benefit)
FX Impact on Sales	~\$35 (1% upside to sales)	Earnings Per Share	\$2.00-\$2.20
Gross Profit Margin	76-77%	CAPEX	~\$350M
SG&A % of Sales	Similar to pre-COVID	Shares Outstanding	Modeled to be flat with 2020 levels of 630 million
R&D % of Sales			

# Longer-Term Guidance

<b>Underlying Sales Growth</b>	Innovation expected to drive organic growth that exceeds medtech sector
<b>Gross Margin</b>	Mix and efficiencies expected to benefit longer-term margin
<b>R&amp;D % of Sales</b>	Significant investments in clinical trials to expand indications and develop new technologies
<b>SG&amp;A % of Sales</b>	Disciplined focus on leveraging our scale and controlling G&A expenses, partially offset by investments to support growth initiatives
<b>Operating Margin</b>	Investing to gradually expand margin over time
<b>Tax Rate %</b>	Upward pressure and less predictability due to stock option accounting
<b>Outstanding Shares</b>	Routine share repurchases to offset dilution from employee shares Opportunistically reduce net shares outstanding



# Edwards Financial Objectives





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Helping Patients is Our Life's Work, and

*life is now*

# Closing Remarks

Michael A. Mussallem  
Chairman and CEO



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# Patient-Focused Innovation Strategy

## Focus

Singular focus on the large unmet needs of structural heart and critically ill patients

## Leadership

Lead groundbreaking standards of care through trusted relationships



## Innovation

Pioneer breakthrough technologies with compelling evidence

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

## 2021 Expectations

**Mid-teens**  
Underlying net  
sales growth

**\$2.00 - \$2.20**  
Adjusted  
EPS



### TAVR

- Therapy expansion
- Technology advances
- Geographic expansion



### Surgical

- Surgeon partnership
- Leading pipeline
- Growth segment focus



### TMVT

- 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



2019 Constituent MSCI ESG Leaders Indexes



**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 is poised for long-term value creation

**Patient-Focused Culture**  
motivates and guides our global team

**Sustainable Growth**  
organic revenue



**Large Populations**  
of under-served  
patients

**Credibility and Trust**  
with clinicians, regulators,  
payors and patients

**Innovative R&D**  
produces breakthrough  
therapies and drives  
shareholder returns



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# 2020 Investor Conference

Forward-looking statements and  
disclaimers



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# Cautionary Statement

This video presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements can sometimes be identified by the use of words such as “may,” “will,” “should,” “anticipate,” “believe,” “plan,” “project,” “estimate,” “potential,” “predict,” “unstoppable,” “early clinician feedback,” “expect,” “intend,” “guidance,” “outlook,” “optimistic,” “aspire,” “confident” or other forms of these words or similar expressions and include, but are not limited to, the company’s financial goals or expectations for 2020, 2021 and beyond (including sales, underlying growth, foreign exchange impact on sales, gross profit, earnings per share and its key components, free cash flow, SG&A, R&D, tax rate, operating margin, diluted shares outstanding, and other financial expectations, such as several of these measures expressed as percentages); expectations for our products (including, headwinds and tailwinds, growth drivers, expected global opportunity, the timing and results of clinical trials, regulatory approvals, and reimbursement coverage); industry growth projections, the ability to extend leadership positions; forecasted trends in patient treatment and demographics; strategies for the company’s new and existing products; and continued development of future innovations.

Statements of past performance, efforts, or results about which inferences or assumptions may be made can also be forward-looking statements and are not indicative of future performance or results. Forward-looking statements are based on estimates and assumptions made by management of the company and are believed to be reasonable, though they are inherently uncertain, difficult to predict, and may be outside of the company’s control. The company’s forward-looking statements speak only as of the date on which they are made and the company does not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of the statement. If the company does update or correct one or more of these statements, investors and others should not conclude that the company will make additional updates or corrections.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Factors that could cause actual results to differ from that expressed or implied by the forward-looking statements are detailed in the Company’s periodic reports filed with the Securities and Exchange Commission.

The opinions expressed by our guest clinicians are their own and do not necessarily reflect the views of Edwards Lifesciences.

# Use of Non-GAAP Financial Measures

- Unless otherwise indicated, all figures are GAAP financial measures
- The Company uses the term "adjusted sales" or "underlying growth rate" when referring to non-GAAP sales information, which excludes foreign exchange rate fluctuations, the conversion to a consignment inventory system for surgical structural heart, the positive impact of transcatheter aortic valve replacement ("TAVR") stocking sales in Germany and the negative impact of de-stocking, sales return reserves associated with TAVR product upgrades, and includes the prior year proforma sales results of a business acquisition. The Company uses the term "adjusted" to also exclude intellectual property litigation income and expenses, amortization of intangible assets, fair value adjustments to contingent consideration liabilities arising from acquisitions, impairments of long-lived assets, and the purchase of intellectual property.
- A reconciliation of non-GAAP historical financial measures to the most comparable GAAP measure is available on the "Investors" page at [www.edwards.com](http://www.edwards.com)
- Guidance for sales and sales growth rates is provided on an "underlying basis," and projections for diluted earnings per share, net income and growth, gross profit margin, taxes, and free cash flow are also provided on a non-GAAP basis as adjusted for the items identified above due to the inherent difficulty in forecasting such items. The Company is not able to provide a reconciliation of the non-GAAP guidance to comparable GAAP measures due to the unknown effect, timing, and potential significance of special charges or gains, and management's inability to forecast charges associated with future transactions and initiatives.



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*life is now*

## EDWARDS LIFESCIENCES CORPORATION

### Non-GAAP Financial Information

To supplement the consolidated financial results prepared in accordance with Generally Accepted Accounting Principles ("GAAP"), the Company uses non-GAAP historical financial measures. Management makes adjustments to the GAAP measures for items (both charges and gains) that (a) do not reflect the core operational activities of the Company, (b) are commonly adjusted within the Company's industry to enhance comparability of the Company's financial results with those of its peer group, or (c) are inconsistent in amount or frequency between periods (albeit such items are monitored and controlled with equal diligence relative to core operations). The Company uses the term "adjusted sales" or "underlying growth rate" when referring to non-GAAP sales information, which excludes foreign exchange rate fluctuations, the conversion to a consignment inventory system for surgical structural heart ("Surgical"), the positive impact of transcatheter aortic valve replacement ("TAVR") stocking sales in Germany and the negative impact of de-stocking, sales return reserves associated with TAVR product upgrades, and includes the prior year proforma sales results of a business acquisition. The Company uses the term "adjusted" to also exclude intellectual property litigation income and expenses, amortization of intangible assets, fair value adjustments to contingent consideration liabilities arising from acquisitions, impairments of long-lived assets, and the purchase of intellectual property.

Management uses non-GAAP financial measures internally for strategic decision making, forecasting future results, and evaluating current performance. These non-GAAP financial measures are used in addition to, and in conjunction with, results presented in accordance with GAAP and reflect an additional way of viewing aspects of the Company's operations by investors that, when viewed with its GAAP results, provide a more complete understanding of factors and trends affecting the Company's business and facilitate comparability to historical periods.

Non-GAAP financial measures are not prepared in accordance with GAAP; therefore, the information is not necessarily comparable to other companies and should be considered as a supplement to, and not as a substitute for, or superior to, the corresponding measures calculated in accordance with GAAP. A reconciliation of non-GAAP historical financial measures to the most comparable GAAP measure is provided in the tables below.

Fluctuations in exchange rates impact the comparative results and sales growth rates of the Company's underlying business. Management believes that excluding the impact of foreign exchange rate fluctuations from its sales growth provides investors a more useful comparison to historical financial results.

Guidance for sales and sales growth rates is provided on an "underlying basis," and projections for diluted earnings per share, net income and growth, gross profit margin, taxes, and free cash flow are also provided on a non-GAAP basis as adjusted for the items identified above due to the inherent difficulty in forecasting such items. The Company is not able to provide a reconciliation of the non-GAAP guidance to comparable GAAP measures due to the unknown effect, timing, and potential significance of special charges or gains, and management's inability to forecast charges associated with future transactions and initiatives.

Management considers free cash flow to be a liquidity measure which provides useful information to management and investors about the amount of cash generated by business operations, after deducting payments for capital expenditures, which can then be used for strategic opportunities or other business purposes including, among others, investing in the Company's business, making strategic acquisitions, strengthening the balance sheet, and repurchasing stock.

#### **The items described below are adjustments to the GAAP financial results in the reconciliations that follow:**

**TAVR Inventory Write Off** - The Company recorded a \$73.1 million charge in 2019 primarily comprised of the write off of inventory in response to strategic decisions regarding its TAVR portfolio.

**Intellectual Property Litigation (Income) Expenses, net** - In 2019, the Company incurred intellectual property litigation expenses of \$33.4 million.

**Change in Fair Value of Contingent Consideration Liabilities** - In 2019, the Company recorded a net gain of \$6.1 million related to changes in the fair value of its contingent consideration liabilities arising from acquisitions.

**Amortization of Intellectual Property** - In 2019, the Company recorded amortization expense of \$4.6 million related to developed technology, patents and trademarks.

**Impairment of Long-lived Assets** - The Company recorded a \$40.6 million charge in 2019 related to the other-than-temporary impairment of certain in-process research and development assets acquired as part of the acquisition of Valtech Cardio Ltd.

**Purchase of Intellectual Property** - The Company recorded a \$24.0 million charge in 2019 related to the acquisition of early-stage transcatheter intellectual property and associated clinical and regulatory experience.

**Adjusted Free Cash Flow** - The Company defines free cash flow as cash flows from operating activities less capital expenditures. During 2019, the Company excluded from its calculation payments related to a litigation settlement, net of the associated tax benefit. During 2018, the Company excluded from its calculation payments related to tax audit settlements and the repatriation tax resulting from U.S. tax law changes. During 2017, the Company excluded from its calculation a receipt of a litigation payment and the amount of an escrow deposit related to the purchase of a building.



## Unaudited Reconciliation of GAAP to Non-GAAP Financial Information

Twelve months ended December 31 (in millions, except per share and percentage data)

### **RECONCILIATION OF GAAP TO ADJUSTED NET INCOME**

	<u>2019</u>
<b>GAAP Net Income</b>	\$1,046.9
<b>Non-GAAP adjustments:</b>	
TAVR inventory write-off	73.1
Intellectual property litigation expenses, net	33.4
Change in fair value of contingent consideration liabilities, net	(6.1)
Amortization of intangible assets	4.6
Impairment of long-lived assets	40.6
Purchased in-process research and development	24.0
Provision for income taxes:	
Tax effect on non-GAAP adjustments	(33.6)
<b>Adjusted Net Income</b>	<u>\$1,182.9</u>

### **RECONCILIATION OF GAAP TO ADJUSTED DILUTED EARNINGS PER SHARE**

<b>GAAP Diluted Earnings Per Share</b>	\$ 1.64
<b>Non-GAAP adjustments:</b>	
TAVR inventory write-off	0.09
Intellectual property litigation expenses, net	0.04
Change in fair value of contingent consideration liabilities, net	(0.01)
Amortization of intangible assets	0.01
Impairment of long-lived assets	0.06
Purchased in-process research and development	0.03
<b>Adjusted Diluted Earnings Per Share</b>	<u>\$ 1.86</u>

Note: Numbers may not calculate due to rounding

**EDWARDS LIFESCIENCES CORPORATION**  
**Reconciliation of GAAP to Non-GAAP Financial Information**  
**Adjusted Free Cash Flow \***

(in millions)	Year Ended			
	2019	2018	2017	2016
<b>Net cash provided by operating activities</b>	\$1,179.4	\$926.8	\$1,000.7	\$704.4
Capital expenditures	(254.4)	(238.7)	(168.1)	(176.1)
Litigation settlements	138.3	-	(112.5)	-
Tax audit settlements	-	56.7	-	-
Repatriation tax payments	-	41.0	-	-
Deposit of cash in escrow	-	-	(25.0)	-
<b>Adjusted Free Cash Flow</b>	<b>\$ 1,063.3</b>	<b>\$ 785.8</b>	<b>\$ 695.1</b>	<b>\$ 528.3</b>

\* See description of "Adjusted Free Cash Flow" on the Non-GAAP Financial Information page.

**EDWARDS LIFESCIENCES CORPORATION**

**Unaudited Reconciliation of Sales by Product Group and Region**

(\$ in millions)

Sales by Product Group (YTD)	2019	2018	Change	GAAP Growth Rate*	2019 Adjusted	2018 Adjusted					
					2019 Adjusted Sales	CASMED Acquisition	Surgical Consignment Conversion	Germany Stocking	FX Impact	2018 Adjusted Sales	Underlying Growth Rate *
Transcatheter Aortic Valve Replacement	\$ 2,737.9	\$ 2,283.8	\$ 454.1	19.9%	\$ 2,737.9	\$ -	\$ -	\$ 8.0	\$ (32.7)	\$ 2,259.1	21.2%
Transcatheter Mitral and Tricuspid Therapies	28.2	2.9	25.3	NM	28.2	-	-	-	(0.1)	2.8	NM
Surgical Structural Heart	841.7	761.6	80.1	10.5%	841.7	-	82.5	-	(14.5)	829.6	1.5%
Critical Care	740.2	674.5	65.7	9.7%	740.2	15.3	-	-	(9.1)	680.7	8.8%
<b>Total Sales</b>	<b>\$ 4,348.0</b>	<b>\$ 3,722.8</b>	<b>\$ 625.2</b>	<b>16.8%</b>	<b>\$ 4,348.0</b>	<b>\$ 15.3</b>	<b>\$ 82.5</b>	<b>\$ 8.0</b>	<b>\$ (56.4)</b>	<b>\$ 3,772.2</b>	<b>15.3%</b>

\* Numbers may not calculate due to rounding.

**EDWARDS LIFESCIENCES CORPORATION**

**Unaudited Reconciliation of Sales by Product Group and Region**

(\$ in millions)

Sales by Product Group (YTD)	2018	2017	Change	GAAP Growth Rate*	2018 Adjusted			2017 Adjusted			Underlying Growth Rate *
					Surgical Consignment Conversion	Germany Stocking	2018 Adjusted Sales	Germany Stocking	FX Impact	2017 Adjusted Sales	
Transcatheter Aortic Valve Replacement	\$ 2,283.8	\$ 2,023.8	\$ 260.0	12.8%	\$ -	\$ 8.0	\$ 2,291.8	\$ (1.4)	\$ 20.0	\$ 2,042.4	12.2%
Transcatheter Mitral and Tricuspid Therapies	2.9	3.4	(0.5)	(14.7%)	-	-	2.9	-	-	3.4	(14.7%)
Surgical Structural Heart	761.6	807.1	(45.5)	(5.6%)	82.5	-	844.1	-	9.2	816.3	3.4%
Critical Care	674.5	601.0	73.5	12.2%	-	-	674.5	-	5.1	606.1	11.3%
<b>Total Sales</b>	<b>\$ 3,722.8</b>	<b>\$ 3,435.3</b>	<b>\$ 287.5</b>	<b>8.4%</b>	<b>\$ 82.5</b>	<b>\$ 8.0</b>	<b>\$ 3,813.3</b>	<b>\$ (1.4)</b>	<b>\$ 34.3</b>	<b>\$ 3,468.2</b>	<b>10.0%</b>

\* Numbers may not calculate due to rounding.

**EDWARDS LIFESCIENCES CORPORATION**

**Unaudited Reconciliation of Sales by Product Group and Region**

(\$ in millions)

<b>Sales by Product Group (YTD)</b>	<b>2017</b>	<b>2016</b>	<b>Change</b>	<b>GAAP Growth Rate*</b>
Transcatheter Aortic Valve Replacement	\$ 2,023.8	\$ 1,628.2	\$ 395.6	24.3%
Transcatheter Mitral and Tricuspid Therapies	3.4	0.3	3.1	NM
Surgical Structural Heart	807.1	774.9	32.2	4.2%
Critical Care	601.0	560.3	40.7	7.2%
<b>Total Sales</b>	<b>\$ 3,435.3</b>	<b>\$ 2,963.7</b>	<b>\$ 471.6</b>	<b>15.9%</b>

<b>2017 Adjusted</b>	
<b>Germany Stocking</b>	<b>2017 Adjusted Sales</b>
\$ (1.4)	\$ 2,022.4
-	3.4
-	807.1
-	601.0
<b>\$ (1.4)</b>	<b>\$ 3,433.9</b>

<b>2016 Adjusted</b>			
<b>Sales Return Reserve</b>	<b>FX Impact</b>	<b>2016 Adjusted Sales</b>	<b>Underlying Growth Rate *</b>
\$ (1.7)	\$ 5.2	\$ 1,631.7	24.1%
-	-	0.3	NM
-	0.8	775.7	4.0%
-	(1.0)	559.3	7.5%
<b>\$ (1.7)</b>	<b>\$ 5.0</b>	<b>\$ 2,967.0</b>	<b>15.7%</b>

\* Numbers may not calculate due to rounding.

**EDWARDS LIFESCIENCES CORPORATION**  
**Unaudited Reconciliation of Sales by Product Group**  
(\$ in millions)

<b>Sales by Product Group (YTD)</b>	<b>2016</b>	<b>2015</b>	<b>Change</b>	<b>GAAP Growth Rate*</b>
<b>Transcatheter Aortic Valve Replacement</b>	\$ 1,628.2	\$ 1,180.1	\$ 448.1	38.0%
<b>Transcatheter Mitral and Tricuspid Therapies</b>	0.3	0.2	0.1	NM
<b>Surgical Structural Heart</b>	774.9	785.0	(10.1)	(1.3%)
<b>Critical Care</b>	560.3	528.4	31.9	6.0%
<b>Total Sales</b>	<b>\$ 2,963.7</b>	<b>\$ 2,493.7</b>	<b>\$ 470.0</b>	<b>18.8%</b>

<b>2016 Adjusted</b>		<b>2015 Adjusted</b>			<b>Underlying Growth Rate *</b>
<b>Sales Returns Reserve</b>	<b>2016 Adjusted Sales</b>	<b>Sales Returns Reserve</b>	<b>FX Impact</b>	<b>2015 Adjusted Sales</b>	
\$ (1.7)	\$ 1,626.5	\$ 1.7	\$ (2.5)	\$ 1,179.3	37.9%
-	0.3	-	-	0.2	45.0%
-	774.9	-	2.2	787.2	(1.6%)
-	560.3	-	5.0	533.4	5.0%
<b>\$ (1.7)</b>	<b>\$ 2,962.0</b>	<b>\$ 1.7</b>	<b>\$ 4.7</b>	<b>\$ 2,500.1</b>	<b>18.5%</b>

\* Numbers may not calculate due to rounding.