

The image shows a modern, multi-story building with a glass facade. In the foreground, there is a landscaped area with a central feature that looks like a water wall or a decorative wall with the company name. The sky is clear and blue.

# 2021 Investor Conference

*Edwards Lifesciences*

# 2021 Investor Conference

Mark Wilterding  
VP, IR and Treasurer



Edwards

## Cautionary Statement

Presentations and comments made today by management of Edwards Lifesciences Corporation (the “Company”) will include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 2021, 2022 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); 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 Company’s rate of penetration in individual and global markets; 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 U.S. Securities and Exchange Commission.

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

## 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.





Edwards

Helping Patients is Our Life's Work, and

*life is now*

# Opening Remarks

Michael A. Mussallem  
Chairman and CEO



Edwards

## Our Credo

A photograph showing a close-up of a doctor's face on the left, wearing a blue and white checkered shirt and a red stethoscope. He is looking towards a young child on the right. The child is smiling broadly and looking upwards. The background is slightly blurred, showing what appears to be an outdoor setting with a fence.

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

**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.

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Helping patients is our life's work, and

*life is now*

# Our Aspirations

Edwards is a global leader dedicated to...

Transforming patient lives with **breakthrough** medical technologies



Delivering exceptional **shareholder value**



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



**Passionate engagement** that strengthens our communities



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



# Edwards Lifesciences at a Glance



**600K+**  
Patients Treated with  
Transcatheter Therapies


**15,000+**  
Global Employees



**50%+**  
Millennials and Generation Z



**~2,000**  
Engineers



Investment in R&D  
**17-18%**  
of 2021E sales



**80%+**  
Charitable employee  
engagement



**7**  
Manufacturing Facilities  
Around the World



Resilient Supply  
Chain



**95%+**  
Sales from Products with  
#1 Global Market Share

# Patient-Focused Innovation Strategy



## Innovation

Pioneer breakthrough technologies with compelling evidence



## Leadership

Lead groundbreaking standards of care through trusted relationships



## Focus

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

**Create Meaningful Value by Transforming Patient Care**

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



Focused on opportunities where **patient demand** is very large



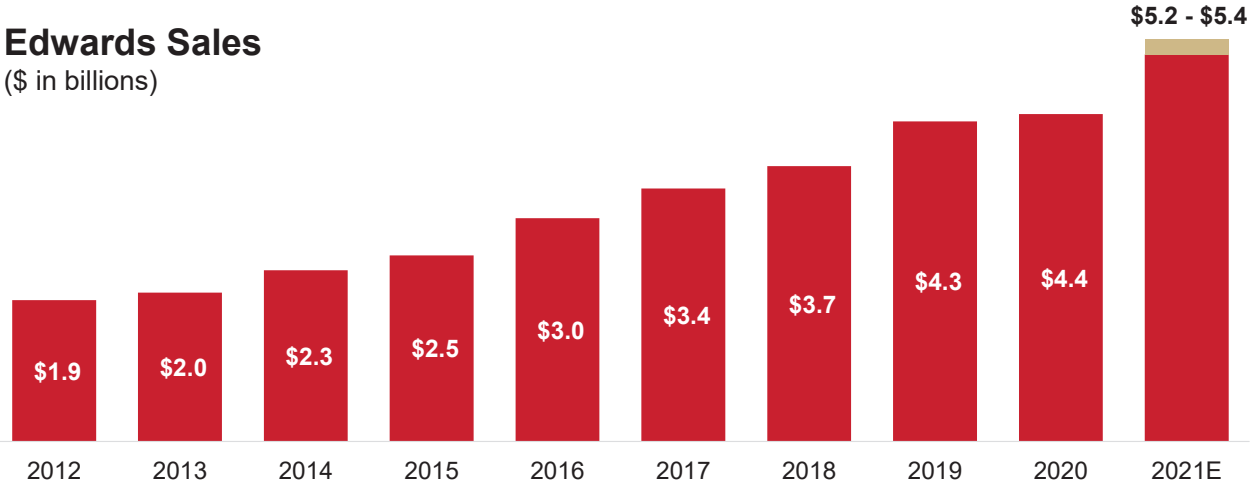
Track record of **triple wins:**

- Improved outcomes
- Enhanced quality of life
- Cost effectiveness

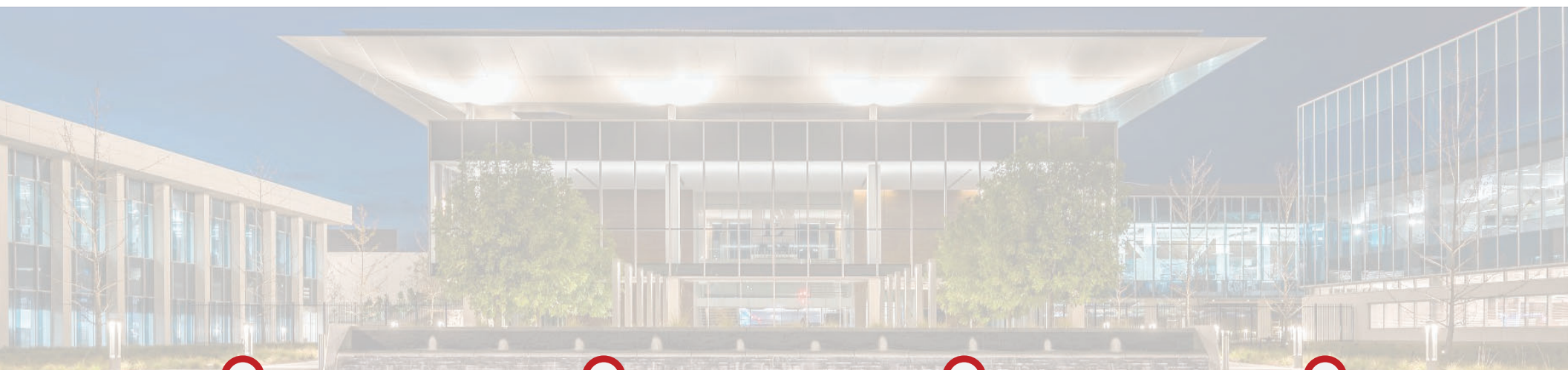


**Long-term investments** have yielded high-value, organic growth

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



## Conference Highlights



Delivering results in **2021** while investing to create future value

**2022** expected to be a year of significant milestone achievements

Long-term **global market opportunity** is expanding

Highly **strategic** and experienced leadership team



# 2021 Delivering Results to Drive Value

## Strengthening Positions Despite COVID

- TAVR therapy and geographic expansion
- Surgical driving adoption of premium technologies
- Critical Care exceeding growth expectations
- TMTT implementing bold agenda

## Achieving Clinical and R&D Milestones

- Gaining patient experience in multiple breakthrough therapies
- R&D 17-18% of 2021E sales
- Advancing portfolio of catheter-based solutions

## Delivering Results while Investing to Create Future Value

- Strong earnings growth while aggressively investing in R&D and infrastructure
- Resilient global supply chain



Estimated 2021  
Sales Growth:  
**High-Teens**

Estimated Adjusted  
EPS growth:  
**21-23%**

**October Guidance  
Unchanged**

# 2022 expected to be a year of significant milestone achievements and investment in our future



## TAVR

Moderate AS trial enrollment  
SAPIEN X4 trial enrollment



## TMTT

PASCAL - DMR approval in the U.S.  
EVOQUE TR approval in Europe



## SURGICAL

MITRIS approval in the U.S.  
Continued adoption of RESILIA



## CRITICAL CARE

HemoSphere with Viewfinder  
Smart BP enrollment

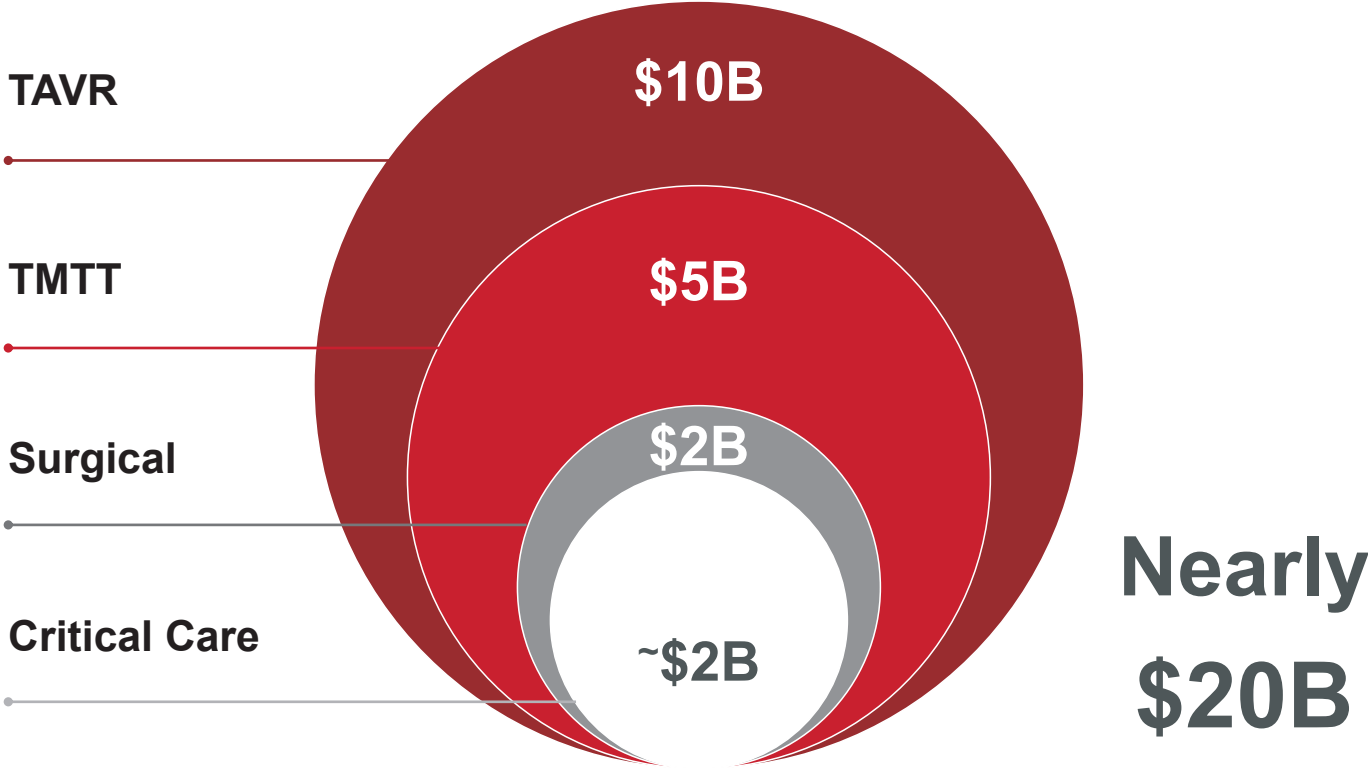
**Low double-digits**  
Underlying sales growth

**2022**  
**EXPECTATIONS**

**\$2.50 - \$2.65**  
Adjusted EPS

# Global Market Opportunity by 2028

Currently around \$10 billion



We are just getting started

# 2021 Investor Conference Agenda



## **Transcatheter Aortic Valve Replacement**

Larry Wood

## **Surgical Structural Heart**

Daveen Chopra

## **Transcatheter Mitral and Tricuspid Therapies**

Bernard Zovighian

## **Critical Care**

Katie Szyman

## **Financial Outlook**

Scott Ullem

## **Closing Remarks**

Mike Mussallem

## **Q&A Session**



# Edwards' Executive Leadership Team



**Mike Mussallem**  
Chairman & CEO



**Daveen Chopra**  
Surgical Structural Heart



**Christine McCauley**  
Human Resources



**Gary Sorsher**  
Quality, Regulatory, Clinical



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



**Don Bobo, Jr.**  
Strategy & Corporate Development



**Dirksen Lehman**  
Public Affairs



**Joe Nuzzolese**  
Global Supply Chain



**Katie Szyman**  
Critical Care



**Larry Wood**  
Transcatheter Aortic Valve Replacement



**Todd Brinton, M.D.**  
Chief Scientific Officer



**Jean-Luc Lemercier**  
EMEA, Canada and Latin America



**Arnold Pinkston**  
General Counsel



**Scott Ullem**  
Chief Financial Officer



**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*

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# Transcatheter Aortic Valve Replacement

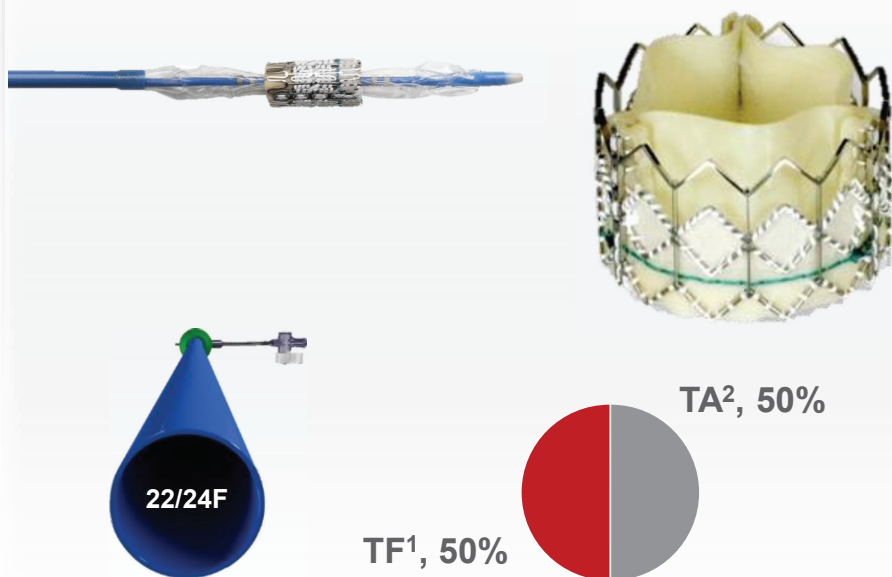
Larry L. Wood  
Corporate Vice President  
Transcatheter Aortic Valve Replacement



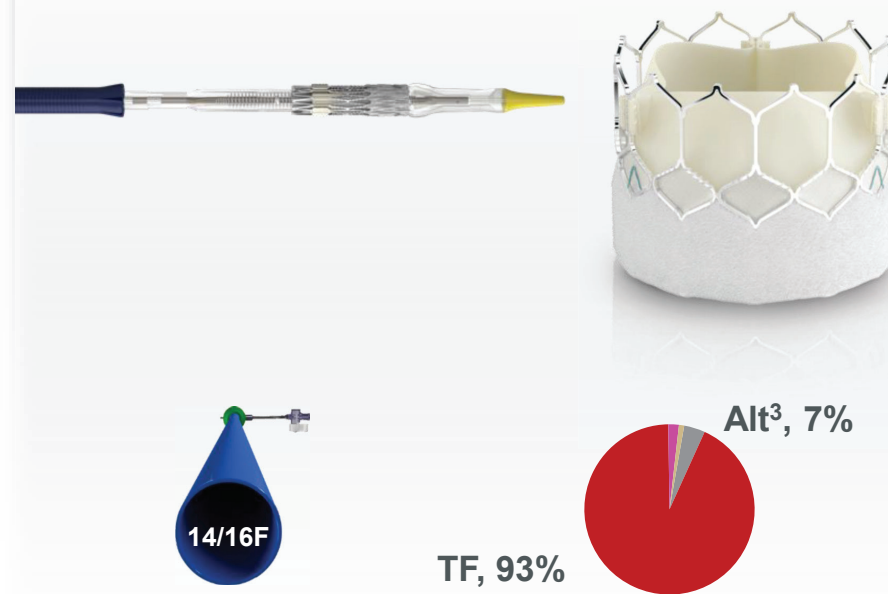
Edwards

# Over a decade ago, we set out to establish new frontiers in heart valve therapy

Original SAPIEN System used in PARTNER Study



SAPIEN 3 Ultra System



Over 600,000 patients treated with SAPIEN platform

1. TF = Transfemoral; 2. TA = Transapical; 3. Alt = Alternative Access



## Where we are today



All-cause Death

3.4%

1%

All-Stroke

5.5%

1.2%

Major Vascular  
Complications

11%

2%

Index  
Hospitalization

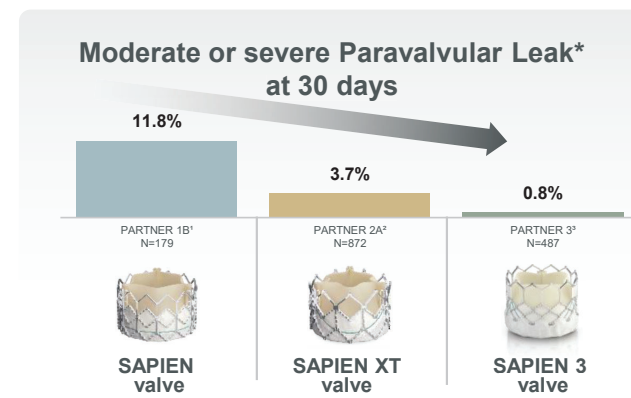
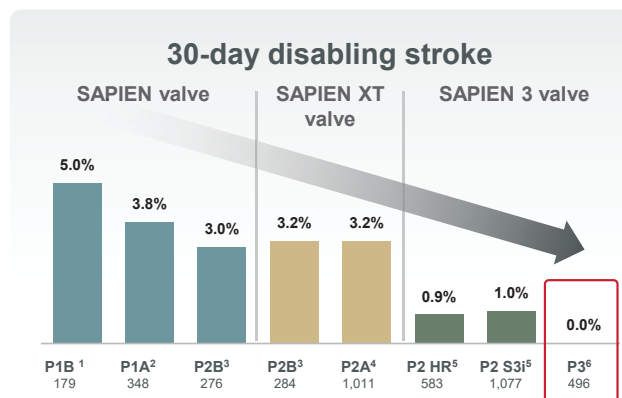
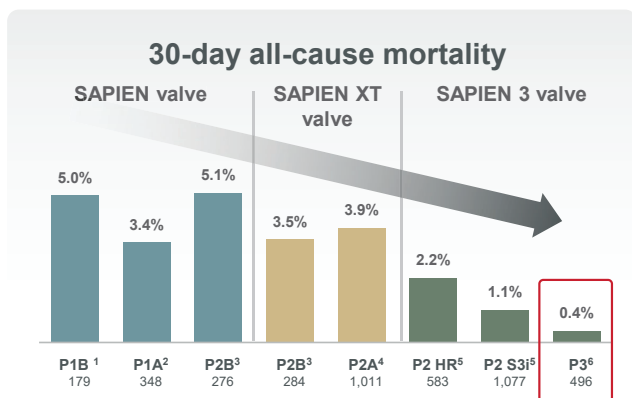
8 days

3 days

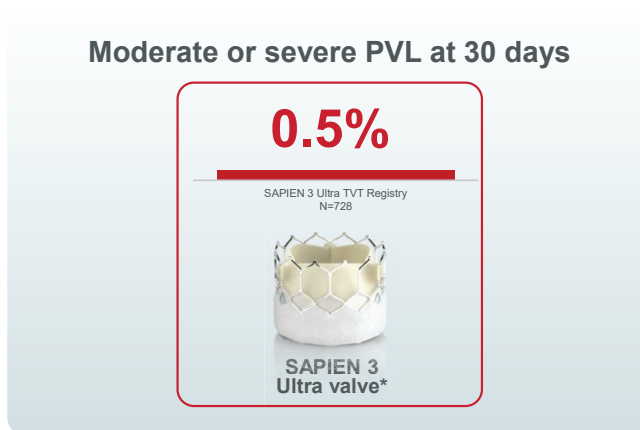
At 30-days

At 1-year

# We have made significant progress



**SAPIEN 3 Ultra** has further elevated the benchmark of SAPIEN Platform

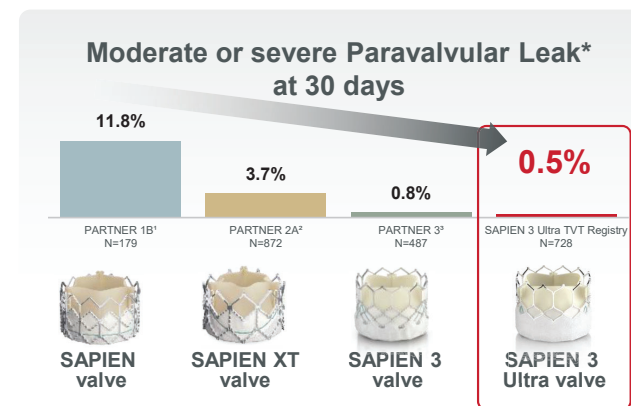
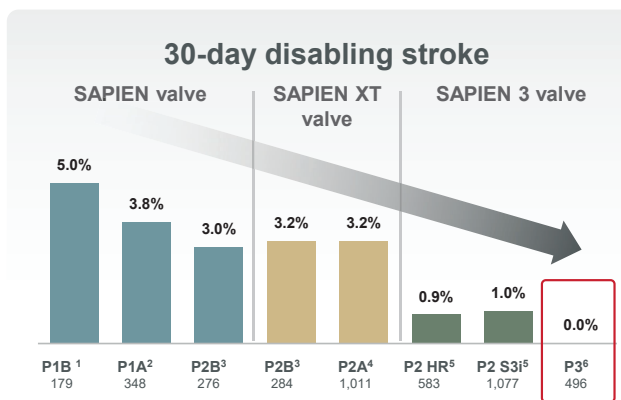
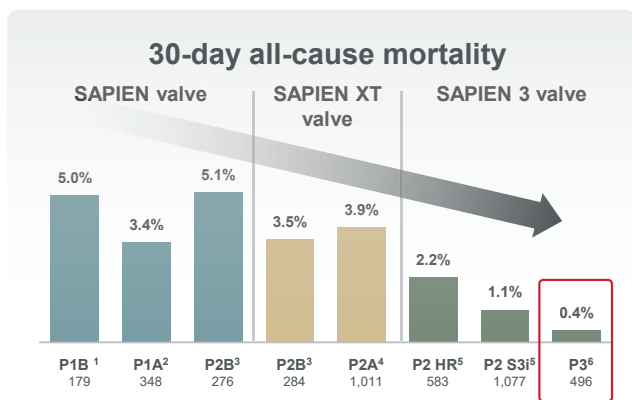


SAPIEN 3 Ultra now accounts for **92%** of global sales

For references 1 through 6, see supplemental slides

\* Nazif T, Daniels D, McCabe J, Chehab B, et al. Real-world experience with the SAPIEN 3 Ultra TAVI: A propensity matched analysis from the United States. Presented virtually at TVT Connect 2020.

# We have made significant progress



**45**  
minutes

Median procedure time<sup>7</sup>

**80%**

Next day discharge rate<sup>7</sup>

**96%**

Discharged home<sup>8</sup>

For references 1 through 6, see supplemental slides

7. Wood, D.A.; Lauck, S.B.; Cairns, J.A. et al. The Vancouver 3M (Multidisciplinary, Multimodality, But Minimalist) Clinical Pathway Facilitates Safe Next-Day Discharge Home at Low-, Medium-, and High-volume Transfemoral Transcatheter Aortic Valve Replacement Centers: The 3M TAVI Study. J Am Coll Cardiol Intv. 2019.

8. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. N Engl J Med. 2019.

Improvement reflects a disciplined approach of advancing the technology, procedural techniques and partnership with regulators

# TAVR has transformed patient care for the Severe Symptomatic AS patient

Median Survival Years for All SAS Patients



# SAPIEN 3 economically dominant compared to SAVR in low-risk patients

## Economic Outcomes of TAVR vs. SAVR for Low-Risk Patients: Results from the PARTNER 3 Trial

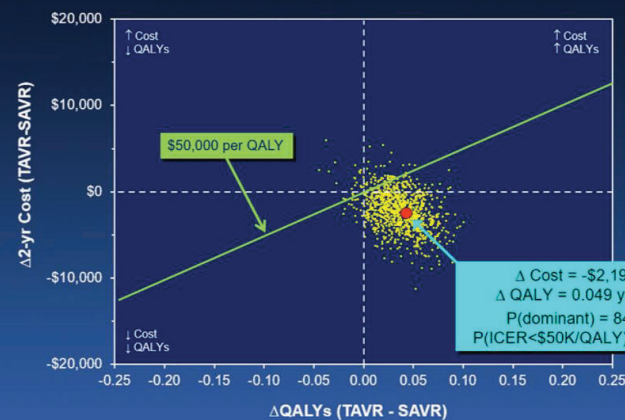
David J. Cohen, MD, MSc  
on behalf of the PARTNER 3 Trial Investigators

Cardiovascular Research Foundation, New York, NY USA  
St. Francis Hospital and Heart Center, Roslyn, NY USA



TCT 2021 | Orlando, FL | November 5, 2021

## Cost-Effectiveness– Base Case



### Base Case Assumptions

- No difference in survival or costs beyond 2 years
- All costs and effects discounted at 3%/yr

- SAPIEN 3 resulted in **cost savings of >\$2,000 per patient** through the 2-year study period
- Driven by **reductions in LOS and substantially lower follow-up costs**
- **SAPIEN 3 had small but significant improvement in quality-adjusted life expectancy**, driven by improved early quality of life and survival



## Next generation valve platforms are focused on future needs of AS patients



**Optimizing valve sizing in complex anatomy**



**Enhanced durability for patients with longer life expectancy**



**Continue to raise benchmark and eliminate mild PV leak**



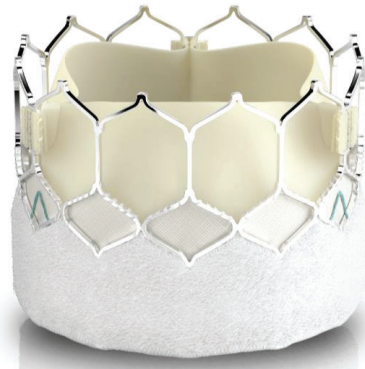
**Further enhance future Coronary access**

**We are just getting started...**

# We will continue to advance our portfolio



**SAPIEN 3**



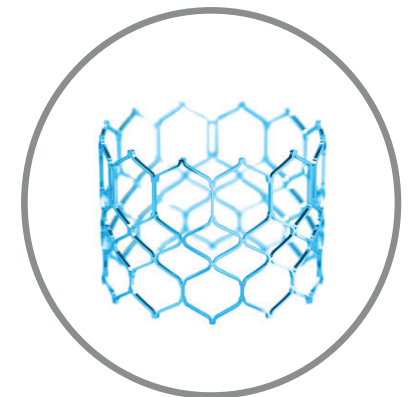
**SAPIEN 3 Ultra**

US and EU launches  
Evolutionary advancements



**SAPIEN X4**

ALLIANCE U.S. IDE approval  
expected by end of 2021



**Future Platform**

## The treatment of other progressive diseases focuses on early detection and intervention – cancer is an example

### Progression of Cancer



**Early intervention prevents the disease from progressing further and causing additional damage to the body**

# Aortic stenosis is a progressive disease but the treatment paradigm is to wait until symptoms

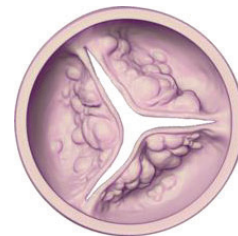
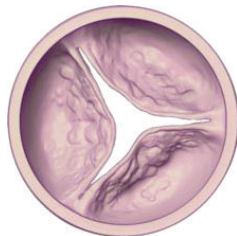
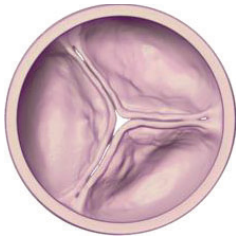
## Progression of Aortic Stenosis

Mild

Moderate

Severe Asymptomatic

Severe Symptomatic

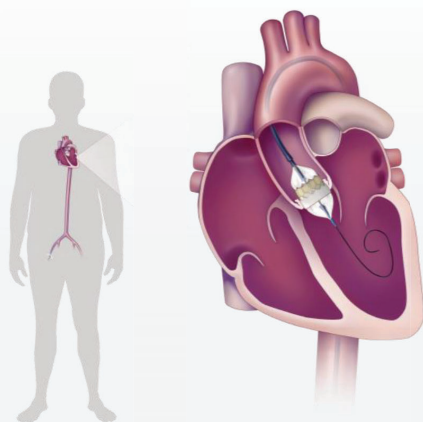


For 20 Years, We Have Been Focused on This



- **PARTNER 1:** Inoperable/ High-risk
- **PARTNER 2:** Intermediate risk
- **PARTNER 3:** Low risk

# With TAVR as a treatment option to treat progressive AS disease, we believe the current paradigm needs a deeper look



**TAVR - Minimally Invasive Therapy**

99%

Freedom from death<sup>1</sup>

99%

Freedom from disabling stroke<sup>1</sup>

80%

Next day Discharge<sup>2</sup>

96%

Discharged home<sup>1</sup>

**Superior Patient Outcomes and Benefits**



**TAVR-in-TAVR Indication**

1. Mack M, Leon M, Thourani R, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med* 2019;380:1695-705.  
 2. Wood, D.A.; Lauck, S.B.; Cairns, J.A. et al. The Vancouver 3M (Multidisciplinary, Multimodality, But Minimalist) Clinical Pathway Facilitates Safe Next-Day Discharge Home at Low-, Medium-, and High-volume Transfemoral Transcatheter Aortic Valve Replacement Centers: The 3M TAVI Study. *J Am Coll Cardiol Intv.* 2019

# The first step is understanding if intervention should occur before symptoms develop

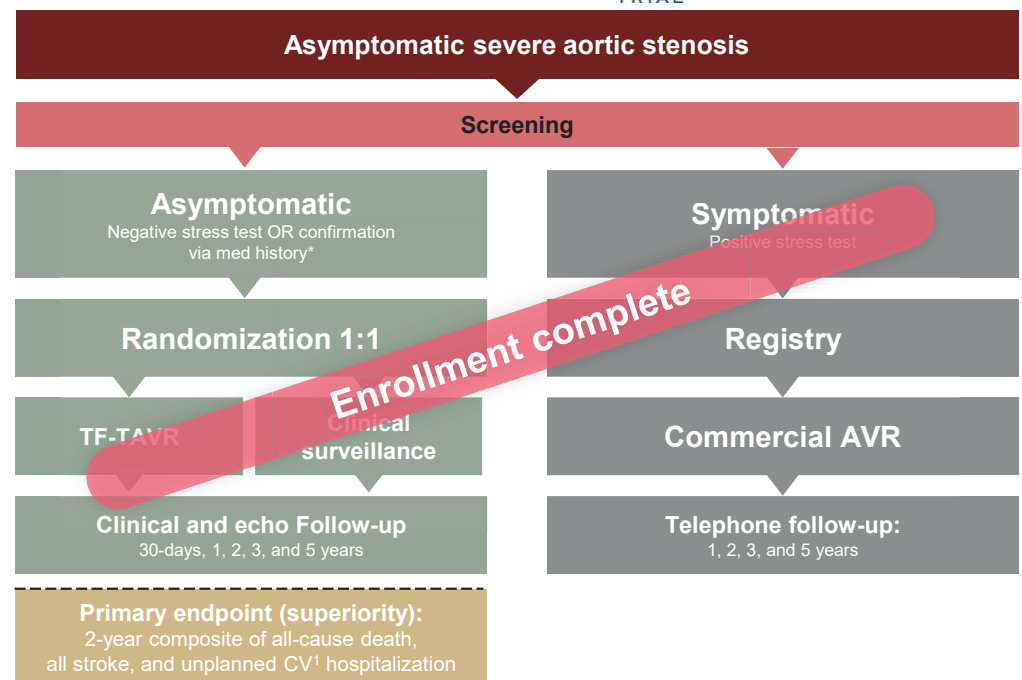


## Key questions

What percentage of patients are truly asymptomatic?

How fast do asymptomatic patients progress to symptomatic?

Does treating patients earlier prevent damage to the heart?



(1) CV = Cardiovascular

\* In patients who cannot perform stress test



# With EARLY TAVR, we are still only addressing Severe AS patients

For 20 Years, We Have Only Been Focused on This

Progression of Aortic Stenosis

Mild

Moderate

Severe Asymptomatic

Severe Symptomatic



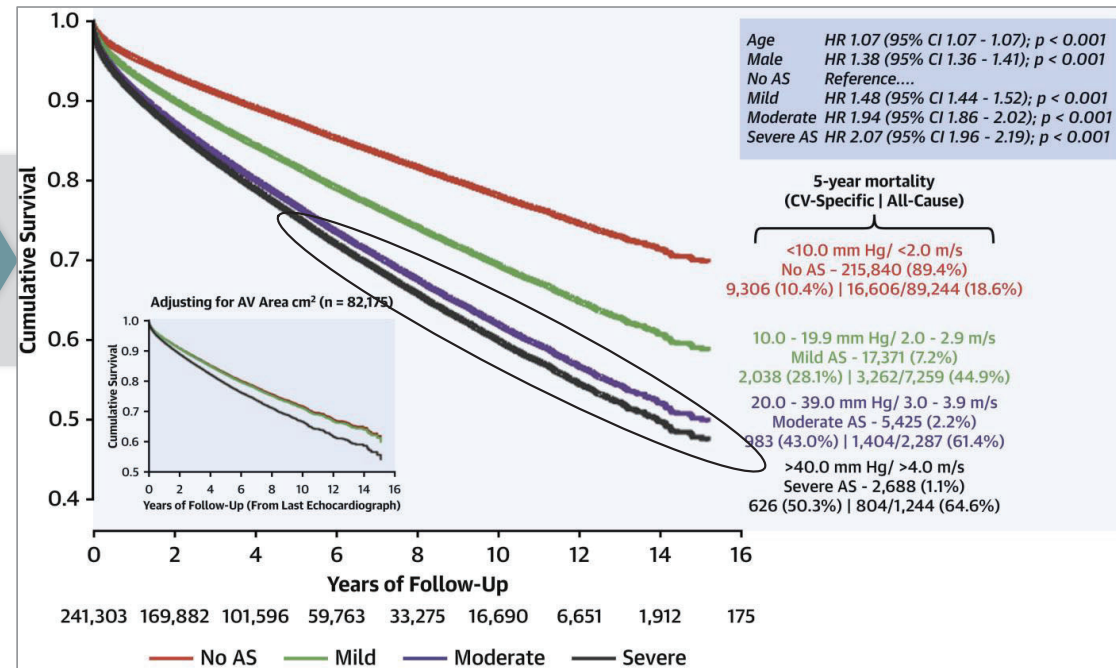
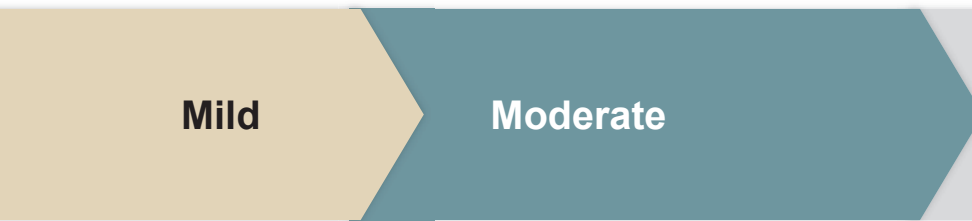
- **Asymptomatic** patients who still have **severe AS**
- Currently **enrolling**



- **PARTNER 1:** Inoperable/ High-risk
- **PARTNER 2:** Intermediate risk
- **PARTNER 3:** Low risk

# Studies have suggested that Moderate AS disease may have a similarly poor prognosis

## Progression of Aortic Stenosis



Geoff Strange et al. J Am Coll Cardiol 2019; 74:1851-1863.

We believe that Moderate AS patients may benefit from early intervention

## We are also embarking on understanding the true impact of Moderate AS



### Key questions

How fast do people progress from moderate to severe AS?

Do all patients progress at the same rate?



Moderate, calcific AS and appropriate anatomy for transfemoral TAVR

1:1 Randomization (n = 750)

TAVR  
(SAPIEN 3/ SAPIEN 3 Ultra)

Enrollment has begun

Clinical surveillance

Potential delayed-AVR<sup>1</sup>

Primary endpoint  
Death, stroke and unplanned CV2 rehospitalization at 2 years

Follow-up  
Annually through 10 years

(1) AVR = Aortic Valve Replacement

(2) CV = Cardiovascular

## We have an opportunity to increase our understanding of AS disease progression and timing of intervention with the PROGRESS Trial

For 20 Years, We Have Only  
Been Focused on This

### Progression of Aortic Stenosis

Mild

Moderate

Severe Asymptomatic

Severe Symptomatic



- Patients with moderate AS who have **not yet progressed to severe**
- Enrollment has begun



- **Asymptomatic** patients who still have **severe AS**
- Currently **enrolling**



- **PARTNER 1:** Inoperable/ High-risk
- **PARTNER 2:** Intermediate risk
- **PARTNER 3:** Low risk

**Early intervention may prevent the disease from progressing further and causing additional damage to the heart**

# We believe the moderate AS patient cohort is significantly larger than the severe AS cohort



In 2021, I-ENHANCED-AS1, **retrospective study, examined 240K+ patients Echo database**

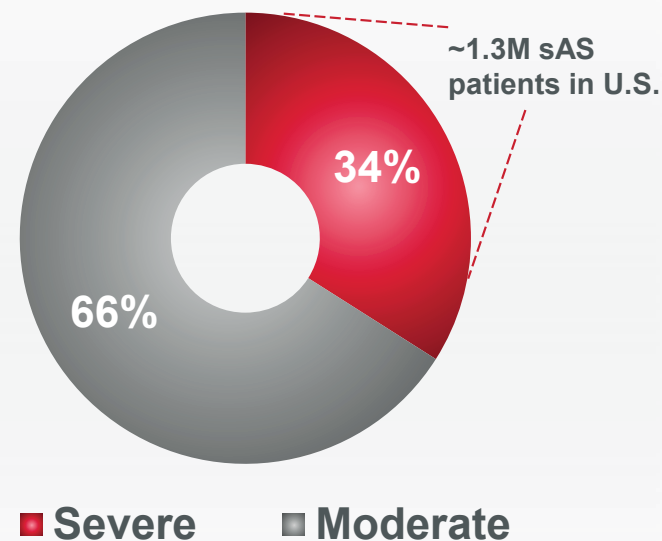


**Over 210K echos from Australia<sup>2</sup> and over 30K echos from U.S.<sup>3</sup> met study inclusion criteria** ( $\geq 65$  years age with native aortic valve on the last echo)



Moderate : Severe AS patients identified 11,987:5658  
**Ratio mAS:sAS  $\approx$  2:1**

**Ratio of moderate to severe AS patients**



1. The International ENHancing the ANalysis of Clinical Events & Death in Aortic Stenosis (I-ENHANCED-AS) study, presented by Dr. Jordan Strom, MD MSc, Harvard Medical School, 2021 European Society of Cardiology Congress, August 27-30, 2021
2. NEDA database Australia
3. Beth Israel Deaconess Medical Center + Harvard Medical School database; Largest single-center Echo dataset linked to complete Medicare Claims

# Despite continued COVID challenges, we delivered on the key milestones we set out in the last year



Low-risk Approval  
in Japan



EARLY TAVR Enrollment Complete



Moderate AS Trial FDA  
Approved



Expecting Approval of  
SAPIEN X4 IDE by  
Year End



ALTEGRA Adaptive  
Pre-stent FDA Approval  
On Track for Year End



## Bringing patients off the sidelines was challenging even before COVID

- Despite progressive nature and poor prognosis of AS, the rate of people “knowing and being concerned” about AS is still very low<sup>1</sup>
- 2019 Survey of ~13,000 people aged ≥60 years old across 11 European Countries showed:
  - 34% of people were “most concerned” with cancer vs **only 5%** for Heart Valve Disease (HVD)
  - **Only 6%** were able to correctly describe Aortic stenosis

**COVID has exacerbated the challenges of getting patients off the sidelines**

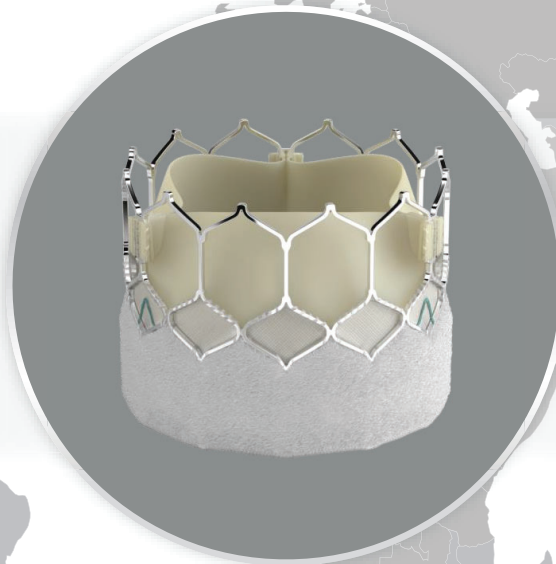
## We have launched a nationwide TV ad campaign to drive awareness of patients to TAVR therapy



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



We expect the global TAVR market to double and reach **\$10B by 2028**



Growth drivers beyond the plan horizon remain strong

# 2022 Underlying Global Sales Growth Outlook

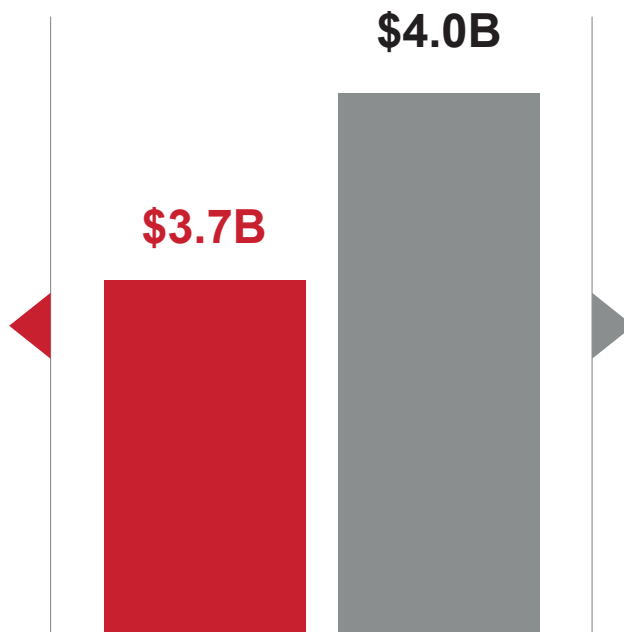
## Headwinds



Overall healthcare spending pressures



COVID recovery



## Tailwinds

Benefits of TAVR therapy and strong patient preference



Low risk expansion in key regions



2022E

Underlying **Global TAVR** Estimated Sales Growth  
12-15%

**Edwards SAPIEN 3 and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System**

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

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

**Contraindications:** 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, or who have significant annuloplasty ring dehiscence.

**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. 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. 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 prostheses 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. Do not perform stand-alone balloon aortic valvuloplasty procedures in the INSPIRIS RESILIA aortic valve for the sizes 19-25 mm. This may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial annuloplasty ring dehiscence due to high risk of PVL. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of partial (incomplete) annuloplasty rings in the absence of annular calcium due to increased risk of valve embolization. Transcatheter valve replacement in mitral annuloplasty rings is not recommended in cases of rigid annuloplasty rings due to increased risk of PVL or THV deformation.

**Precautions:** 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. If a significant increase in resistance occurs when advancing the catheter through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications. 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 in the atrial septum preventing safe transseptal access. Special care must be exercised in mitral valve replacement 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 the tricuspid 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 prosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireframe frame fracture, annuloplasty ring dehiscence); 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. For left/right axillary approach, ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery. Residual mean gradient may be higher in a “THV-in-failing prosthesis” 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 prosthesis 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 (e.g., wound infection, hematoma, and other wound care complications) 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 Crimper**

**Indications:** The Edwards Crimper is indicated for use in preparing the Edwards SAPIEN 3 transcatheter heart valve for implantation.

**Contraindications:** There are no known contraindications.

**Warnings:** The device is designed, intended, and distributed for single use only. Do not resterilize or reuse the device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing. Do not mishandle the device. Do not use the device if the packaging or any components are not sterile, have been opened or are damaged, or the expiration date has elapsed.

**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 SAPIEN 3 and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System**

**INVESTIGATIONAL DEVICES. CAUTION:** The Edwards SAPIEN 3 transcatheter heart valve is an investigational device when used in asymptomatic patients. Limited by Federal (USA) law to investigational use only. These devices are not available for marketing or commercial sale in the United States for asymptomatic patients. See Instructions for Use for full information, including indications, contraindications, warnings, precautions, and adverse events.

**SAPIEN M3 Transcatheter Heart Valve System**

**INVESTIGATIONAL DEVICES. CAUTION:** The SAPIEN M3 System consists of investigational devices, limited by Federal (United States) law to investigational use. These devices are not available for marketing or commercial sale. See instructions for use for full information, including indications, contraindications, warnings, precautions, and adverse events.

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Edwards



Edwards

Helping Patients is Our Life's Work, and

*life is now*

# Surgical Structural Heart

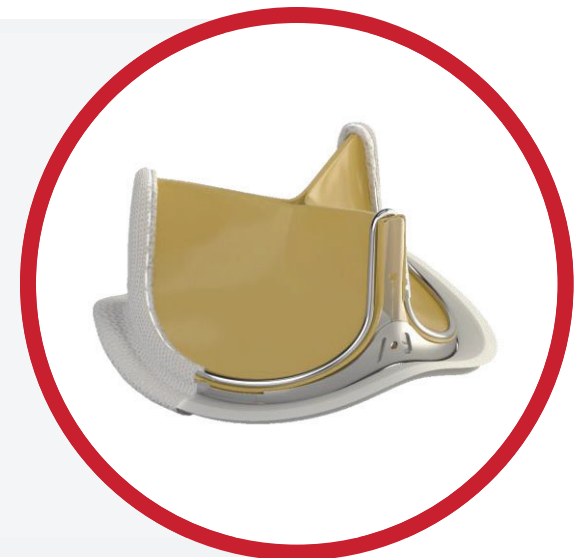
Daveen Chopra  
Corporate Vice President  
Surgical Structural Heart



Edwards

## Surgical Structural Heart is transforming patients' lives by solving critical unmet needs in cardiac surgery

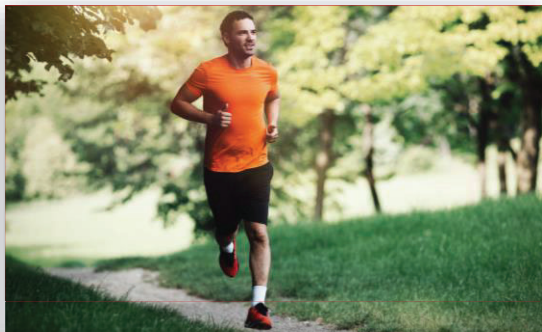
- The surgical structural heart market will **continue to grow mid-single digits to \$2B** by 2028
- We closely partner with surgeons to **understand and address unsolved challenges** in surgery
- We are **pioneering life-saving technologies** for patients best treated surgically



Leading Innovator for Patients | Partner of Choice for Cardiac Surgeons

## The surgical structural heart market continues to grow

- **Cardiac surgery remained a high priority** throughout the COVID pandemic
- **Improved awareness and diagnosis of structural heart disease** is contributing to the growth of the global structural heart market
- As more patients are diagnosed, **referrals to Heart Teams are increasing** and many patients continue to be best treated surgically



Younger, active patients



Patients whose **anatomical complexity** requires a surgical approach



Patients with **heterogenous disease**, requiring **combined procedures**

# Edwards Surgical continues to bring leading innovation

## Our Patient Focus

Pioneering more resilient surgical therapies that **help patients live longer and better**

## Through Transformative Innovation

**Redefining tissue durability standards** with robust clinical evidence on RESILIA tissue

## Impacts Lives Globally

**Increasing global patient access and adoption** of superior therapies

# RESILIA tissue improves durability through its novel anti-calcification properties

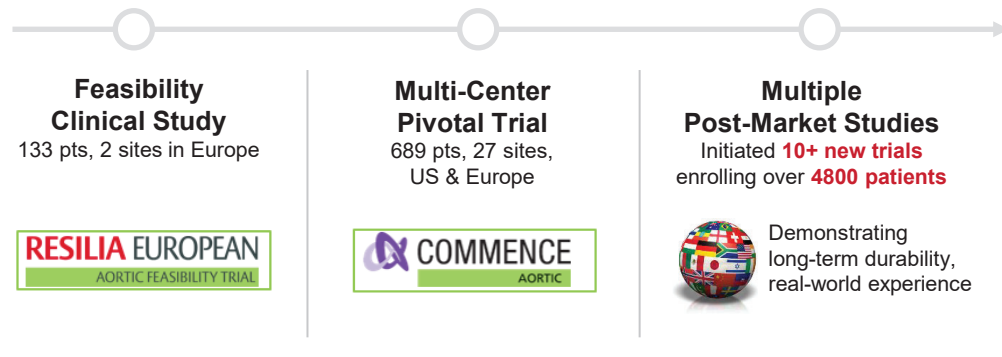
## Clinical Need

The primary mode of failure for tissue valves is **calcification**



We believe **RESILIA's novel capping technology significantly slows calcification formation pathways** to potentially increase tissue durability

## Investing in long-term, real-world evidence on durability

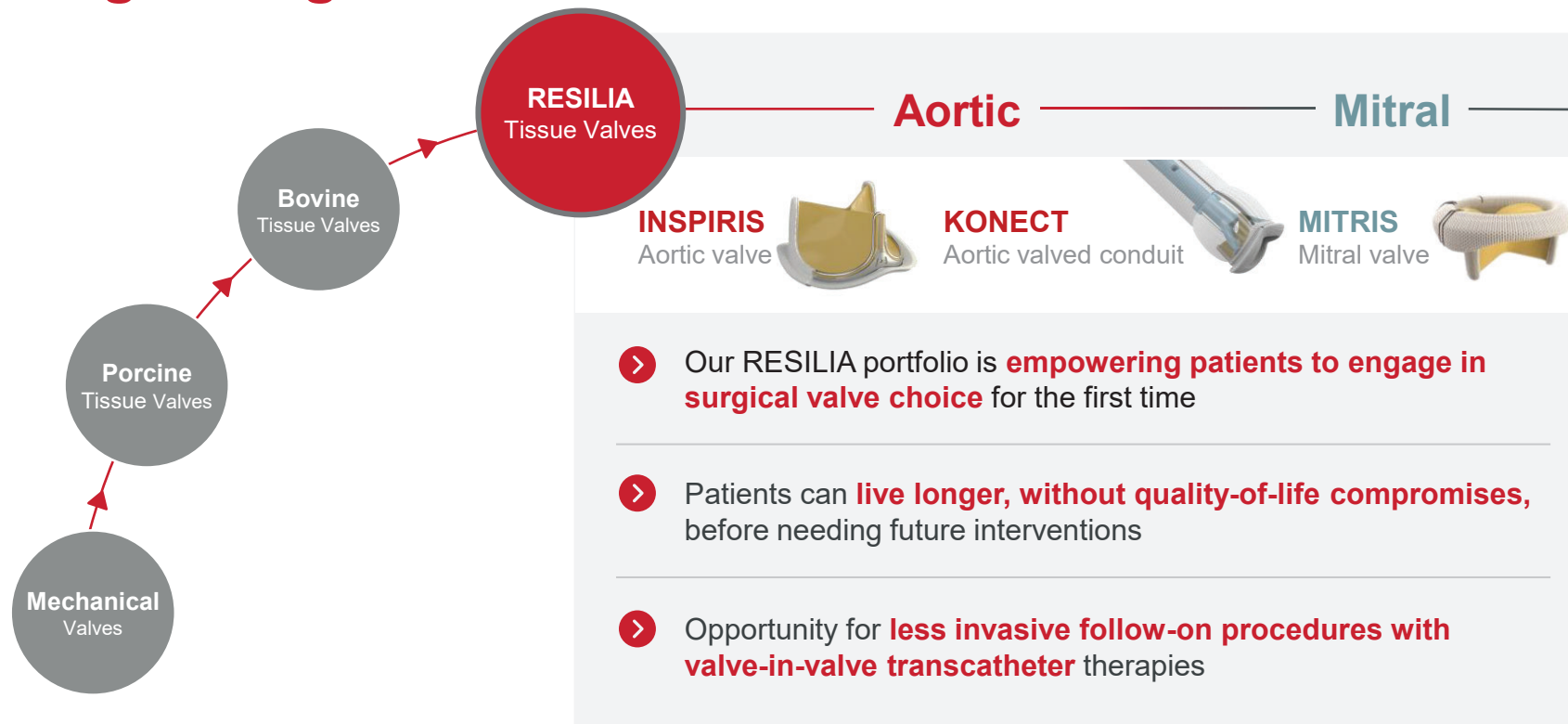


Latest 5-year COMMENCE data provides increasing confidence in RESILIA tissue:

**0% structural valve deterioration at 5-yr follow-up<sup>1</sup>**

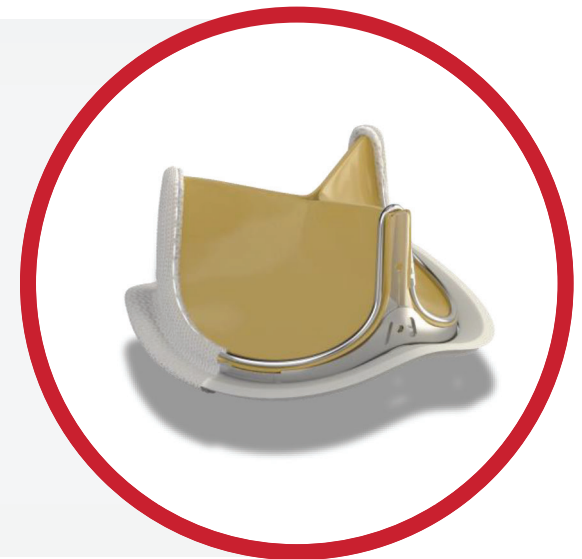


# Increasing global adoption of RESILIA accelerates long-term growth



## INSPIRIS is the leading surgical aortic valve in the world

- Designed with expandable VFit technology, enabling potential **future valve-in-valve procedures**
- More than 5 years of **promising clinical data** on RESILIA
- **Driving global access** to accelerate conversion to premium tissue valves



## KONECT is a ready-to-implant tissue conduit for complex aortic patients

- **Only device on market that simplifies** difficult, combined aortic valve and root surgeries
- This segment, best addressed surgically, is forecasted for **double-digit growth** in the US
- **Rapidly increasing adoption** of this specialized, high premium innovation



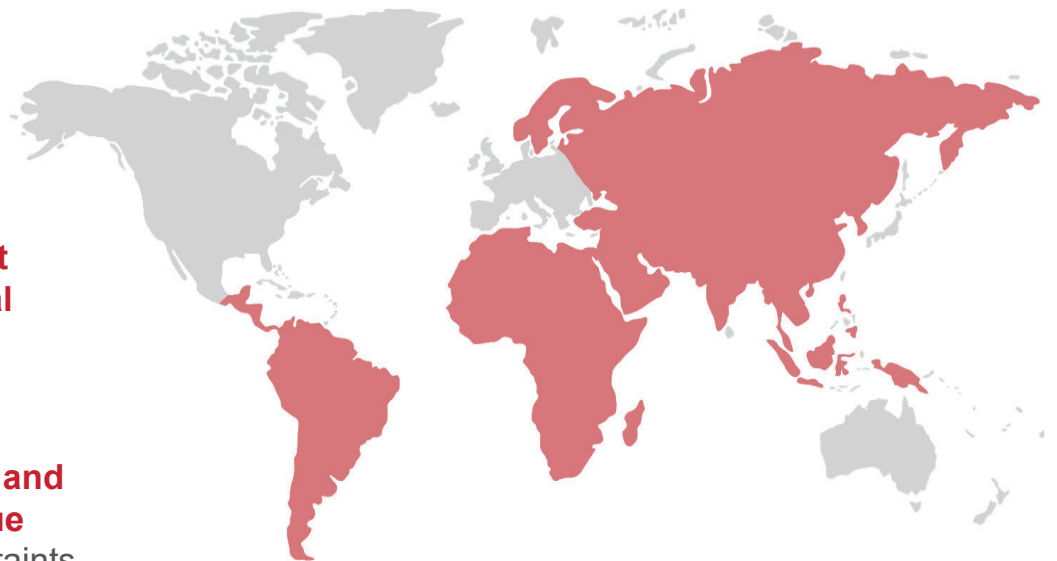
## MITRIS is designed to improve durability by withstanding higher pressures in the mitral valve

- **Enhanced ease-of-use for implantation** and valve-in-valve compatibility
- Leading mitral valve in Japan six months post-launch; **US launch planned for 2022**
- **Long-term growth opportunity** as 60% of global mitral valve replacement patients receive a mechanical valve



## Significant opportunity to grow and accelerate patient impact in emerging markets

- **Adult cardiac surgery continues to grow quickly** in emerging regions due to increased awareness, diagnosis, and wealth
- **Surgery remains the predominant treatment option**, and most patients **receive mechanical valves** that require quality-of-life compromises
- Our strategy is to **expand patient awareness and accelerate conversion to our premium tissue valves** that allow patients to live without constraints



# Two opportunities for innovation in a growing surgical mitral repair market

When performed well, surgical mitral repair is the **most durable treatment option** and restores patients to their normal life expectancy curve

However, repair is complex with **high variability in techniques and patient outcomes**

Even at top US centers, ~11% of patients have recurrent moderate or severe MR within two weeks of surgical mitral repair.<sup>1</sup>

## Innovating Premium Surgical Repair Therapies

*Helping surgeons achieve excellent, consistent procedural outcomes*

### HARPOON

Beating-heart repair for degenerative patients with leaflet prolapse



### Mitral Adjustable Repair System

On-and-off pump implant adjustability for degenerative MR



(1) Johnston et al., Ann Thorac Surg, 2010

# 2022 Underlying Global Sales Growth Outlook

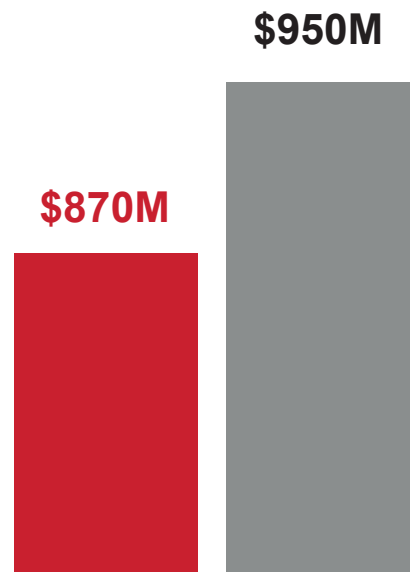
## Headwinds



Continued TAVR conversion in developed markets



COVID recovery



## Tailwinds

Adoption of RESILIA products



Accelerated mechanical-to-tissue valve conversion



2022E

Underlying **Global Surgical** Estimated Sales Growth  
Mid single-digits



## In Summary

- The **Surgical Structural Heart market is anticipated to grow** mid-single digits, including growth in surgical aortic valve replacement
- **2022 growth driven by the adoption of our RESILIA platform**, becoming the new standard of care for surgical patients
- We will continue to **extend patient reach** globally and **solve critical unmet needs** to enable **sustained, long-term growth**

**Important Safety Information: RESILIA Tissue Devices**

**Indications: INSPIRIS RESILIA Aortic Valve** - For use in replacement of native or prosthetic aortic heart valves. **KONECT RESILIA Aortic Valved Conduit** - 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 these RESILIA tissue heart valve devices.

**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. Additional adverse events potentially associated with the use of polyester vascular grafts in the **KONECT RESILIA AVC** 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.

**Warnings: INSPIRIS RESILIA Aortic Valve** - 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 these devices to sale by or on the order of a physician. See instructions for use for full prescribing information.**

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**MITRIS RESILIA mitral valve and HARPOON Beating Heart Mitral Valve Repair System**

**INVESTIGATIONAL DEVICES. CAUTION: Limited to investigational use. These devices are not available for marketing or commercial sale. See instructions for use full information, including indications, contraindications, warnings, precautions and adverse events.**

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Edwards

Helping Patients is Our Life's Work, and

*life is now*

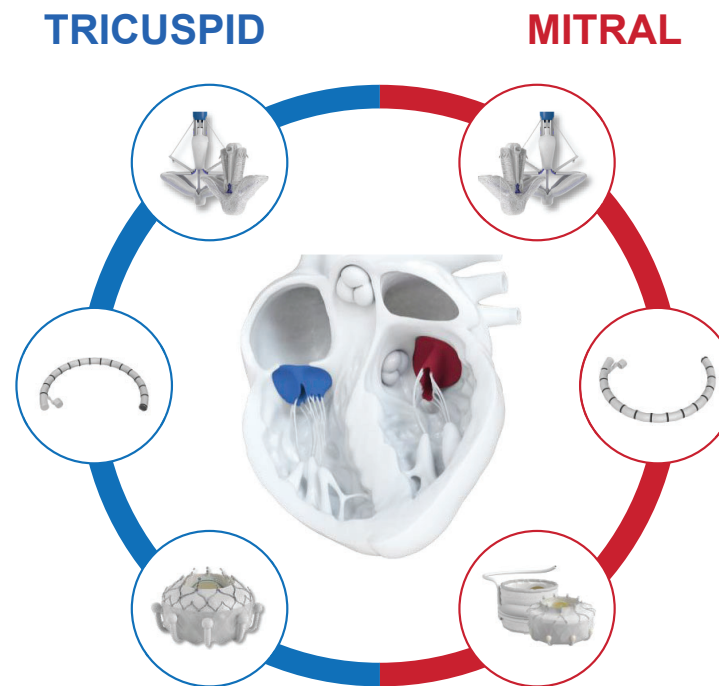
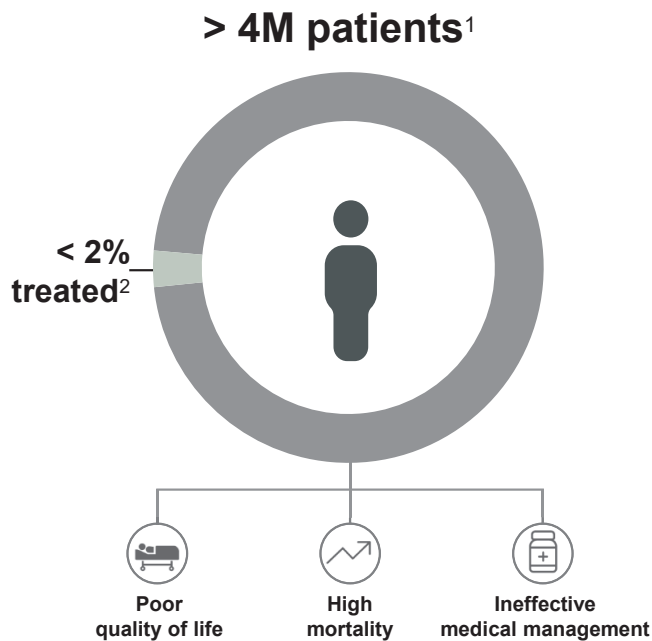
# Transcatheter Mitral and Tricuspid Therapies

Bernard J. Zovighian  
Corporate Vice President  
Transcatheter Mitral and Tricuspid Therapies



Edwards

# TMTT has a bold vision to transform care for the many patients with Mitral and Tricuspid valve disease...



**Global Transcatheter Mitral and Tricuspid Market**  
 expected to grow from ~\$1B in 2021 to

**\$5B**  
 by 2028

and continue strong growth beyond 2028

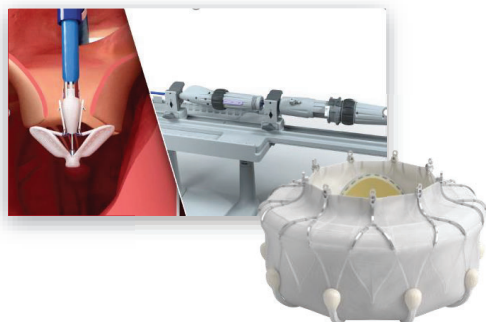
...a comprehensive portfolio uniquely positions TMTT to realize this vision, and lead this rapidly growing opportunity

1. U.S. prevalence of patients with ≥ moderate or greater Mitral / Tricuspid regurgitation 2. Excluding medical management, including surgical and transcatheter treatment  
 Caution: Investigational Devices. Limited to investigational use only.

# TMTT overcame numerous obstacles to achieve our ambitious milestones in 2021...

## Differentiated Portfolio

- Initial clinical experience with next-gen PASCAL Precision System
- Initial clinical experience with next-gen TMVR (EVOQUE Eos)



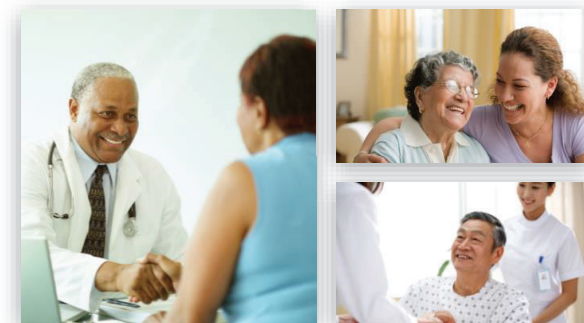
## Robust Clinical Evidence

- Continued pivotal enrollment
- Meaningful data publication



## Real-World / Commercial Outcomes

- Enroll CLASP IID trial by year-end supporting late 2022 PASCAL DMR U.S. approval
- Enrolled TRISCEND study supporting late 2022 EVOQUE TR EU approval
- 2x Revenue



...establishing a strong foundation for 2022 and beyond

# PASCAL's adoption is driven by an increasingly large and compelling body of Mitral evidence and experience



**>4,500**  
total patients treated  
with PASCAL Mitral<sup>1</sup>

**>3,800**  
patients with  
reported data<sup>2</sup>

**>450** study patients  
@ 1-year follow-up<sup>3</sup>



## Pivotal Trials



1. Total cumulative commercial and clinical patients treated with PASCAL Mitral 2. Including clinical and commercial reported patient data 3. Number of patients having completed follow-up; a subset of which has been externally reported

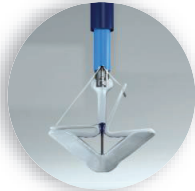


# TMTT is delivering a rapid cadence of innovation in transcatheter edge-to-edge repair (TEER)

**PASCAL is designed to address meaningful patient needs...**



**Versatile implant**  
to safely navigate even challenging anatomies



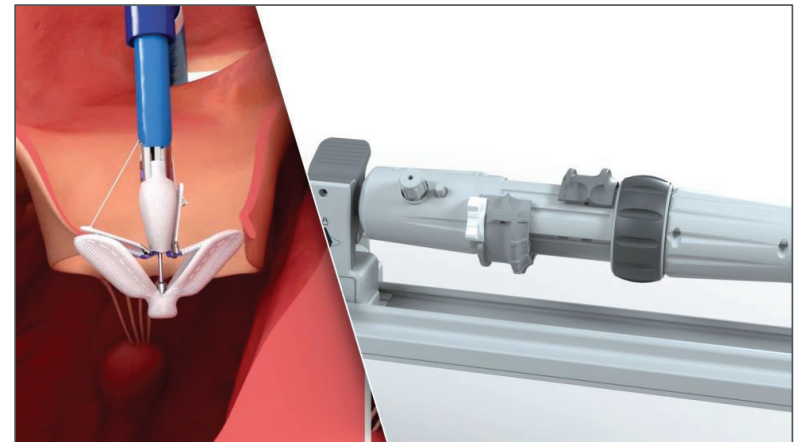
**Atraumatic clasp control**  
to optimize patient outcomes



**Compliant implant**  
designed to respect native anatomy



**...and the new PASCAL Precision System extends this differentiated performance**



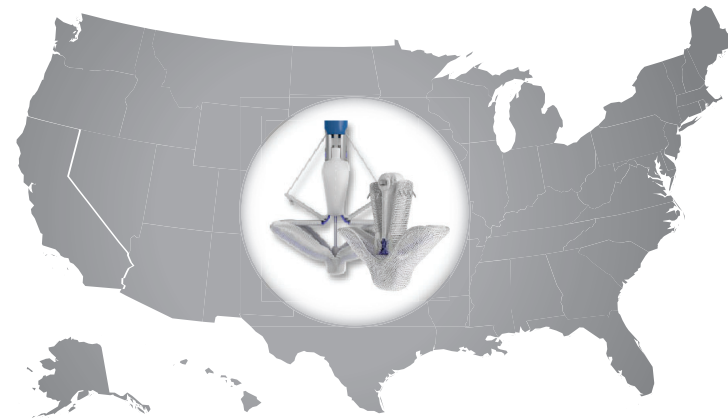
Engineered for  
**intuitive user experience**

Optimized catheters  
**enhance navigation**

**Impressive performance**  
in clinical use

**TMTT's innovation continues with a novel next-generation PASCAL device, initiating first clinical use in 2022**

# TMTT expects FDA approval of PASCAL Precision for DMR in late 2022



Controlled launch planned in the U.S. with a **dedicated field team** deploying our **high-touch clinical support model**



**Support patient screening**



**Comprehensive physician training**



**100% case support**

# Transfemoral replacement is expected to significantly expand the Mitral opportunity in the mid-term

## Addressing patients' needs with product design



**Eliminating residual MR** offers significant patient benefits

**<30F**  
Transfemoral delivery systems

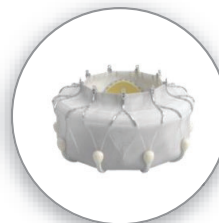
enhance ease-of-use and aim to match TEER<sup>1</sup> safety

## Two-platform strategy positions TMTT for leadership



### SAPIEN M3

- On-track to be the first commercially available sub-30F TMVR<sup>2</sup>
- Leverages the proven SAPIEN valve
- Actively enrolling ENCIRCLE pivotal trial



### EVOQUE Eos

- Designed specifically for Mitral valve replacement and sub-30F
- Fully repositionable to enhance patient safety
- Clinical experience in the MISCEND early feasibility study is encouraging



1. Transcatheter edge-to-edge repair

2. Transfemoral mitral valve replacement. Caution: Investigational Devices. Limited to investigational use only.

## TMTT is well positioned to achieve critical Mitral milestones in 2022, setting up a strong 2023

### Differentiated Portfolio

- Initial clinical experience with novel next-generation PASCAL System
- Expanded clinical experience with EVOQUE Eos

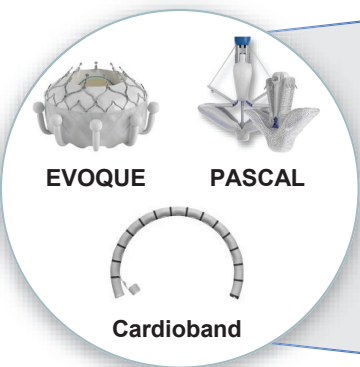
### Robust Clinical Evidence

- FDA submission with CLASP IID: mid-year 2022
- CLASP IID presentation: 2H 2022 and prior to approval
- Continued enrollment in CLASP IIF & ENCIRCLE pivotal trials
- Presentation and publication of significant clinical data

### Favorable real-world / commercial outcomes

- PASCAL Precision DMR approval in US: Late 2022
- PASCAL Precision approval in EU: Late 2022

# Early tricuspid clinical evidence is promising, and demonstrates the diversity of patients' needs...



**>1,500**

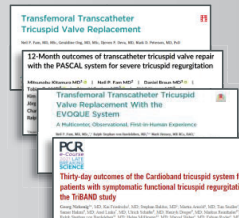
*total patients treated with TMTT's Tricuspid Portfolio<sup>1</sup>*

**~500**

*patients with reported data<sup>2</sup>*

**>150**

*study patients @ 1-year follow-up<sup>3</sup>*



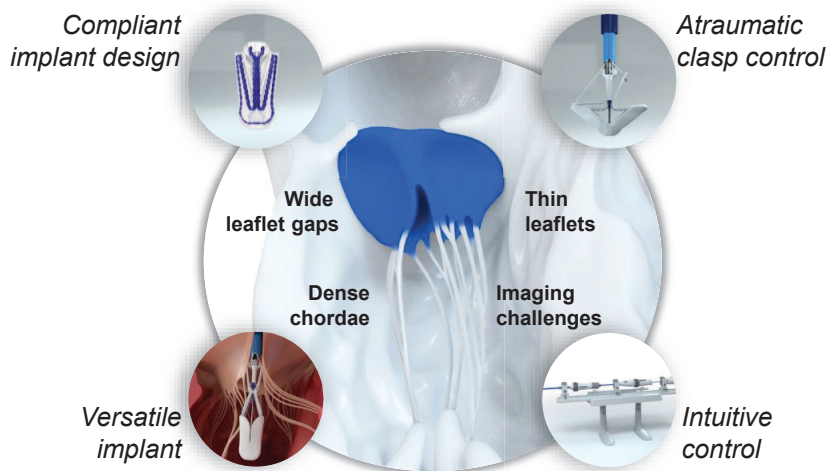
## Pivotal Trials



1. Total cumulative commercial and clinical patients treated with PASCAL Tricuspid 2. Including clinical and commercial reported patient data  
3. Number of patients having completed follow-up; a subset of which has been externally reported; Caution: Investigational Devices. Limited to investigational use only.

# ...which TMTT's Tricuspid portfolio is designed to treat, with safety, efficacy, and ease-of use

## Tricuspid Repair: PASCAL Precision System



**PASCAL's differentiated features are highly applicable to Tricuspid Valve anatomy**

## Tricuspid Replacement: EVOQUE



### 3 Valve Sizes

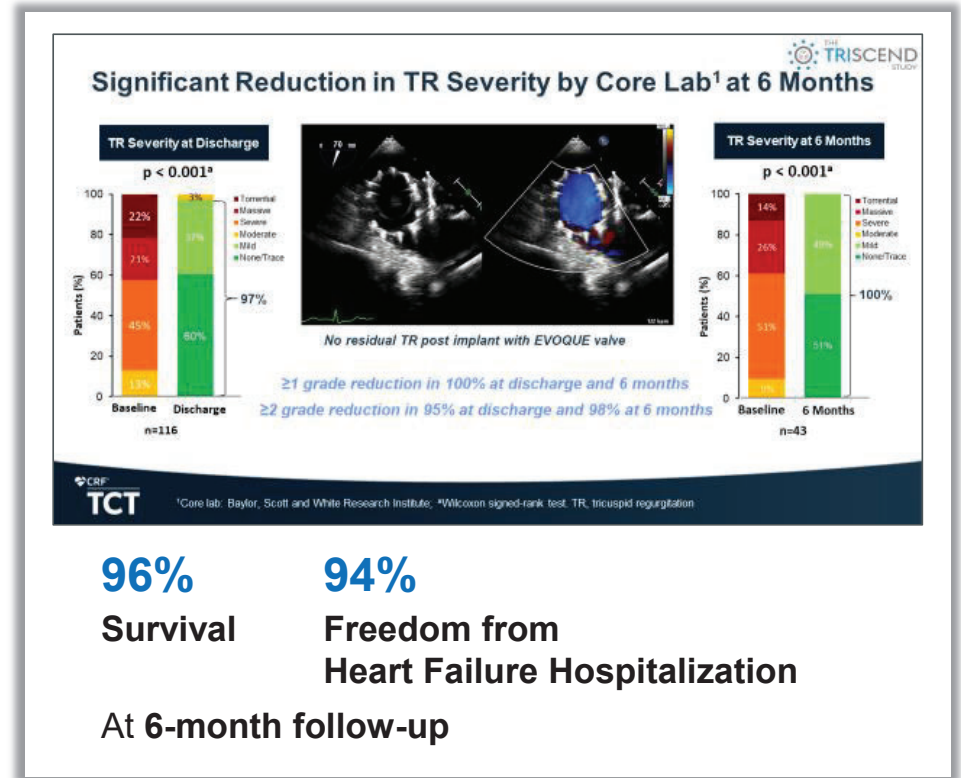
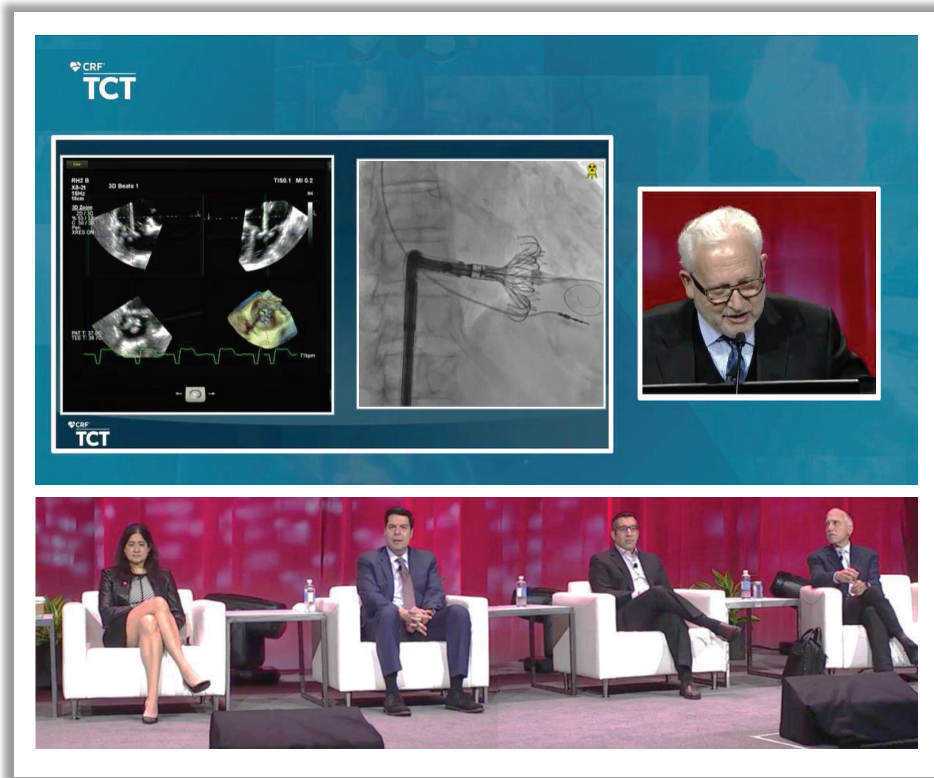
Enable treatment in a **wide range of patient anatomies**



### <30F

Delivery system designed for **safety and ease-of-use**

# Excitement is building for EVOQUE, which kicked off TCT 2021 with a live case, and presented 6-month late breaking trial data





# TMTT's understanding of Tricuspid clinical needs drives an ability to achieve significant milestones in 2022

## Differentiated Portfolio

- Initial clinical experience with novel next-generation PASCAL system
- Initial clinical experience with the next-generation Cardioband system

## Robust Clinical Evidence

- Continued enrollment of TRISCEND II and CLASP II TR pivotal trials
- Presentation and publication of significant clinical data

## Favorable real-world / commercial outcomes

- EVOQUE approval in Europe  
Late 2022

# 2022 Global Sales Outlook

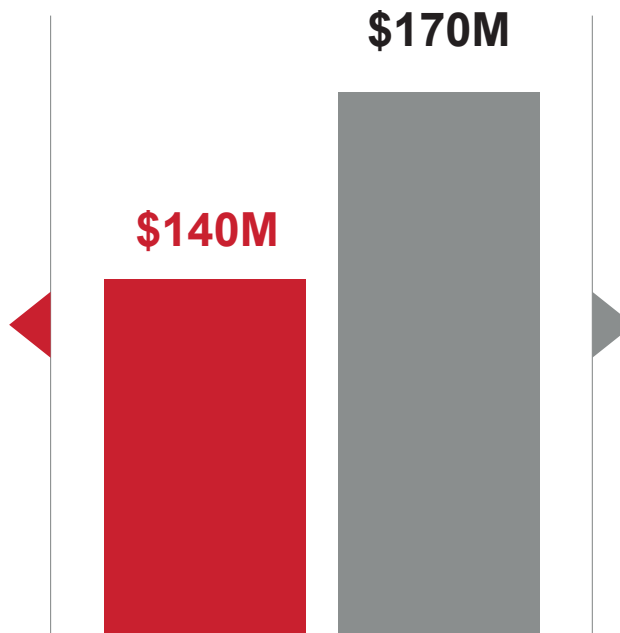
## Headwinds



The new European regulatory system



COVID recovery



## Tailwinds

European Mitral market returns more quickly to higher growth



High quality evidence across the TMTT portfolio



2022E

**Global TMTT  
Estimated Sales**

## TMTT is committed to continue delivering on our vision in 2022, with significant sales growth and major product approvals...



- PASCAL Precision DMR approval in U.S.:  
Late 2022
- PASCAL Precision approval in EU:  
Late 2022
- EVOQUE approval in EU:  
Late 2022
- >6,000 patients treated in 2022
- Revenue of \$140-\$170M

...setting the stage for **2023 and beyond**

## IMPORTANT SAFETY INFORMATION

### SAPIEN M3 Transcatheter Heart Valve System

**INVESTIGATIONAL DEVICES. CAUTION:** The SAPIEN M3 System consists of investigational devices, limited by Federal (United States) law to investigational use. These devices are not available for marketing or commercial sale. See instructions for use for full information, including indications, contraindications, warnings, precautions, and adverse events.

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### The Edwards EVOQUE System and EVOQUE Eos System, the Edwards Cardioband System, and the Edwards Pascal and Pascal Precision Systems

**INVESTIGATIONAL DEVICES. CAUTION:** Limited to investigational use. These devices are not available for marketing or commercial sale. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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### Edwards Pascal System

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Edwards

Helping Patients is Our Life's Work, and

*life is now*

# Critical Care

Katie M. Szyman  
Corporate Vice President, Critical Care



Edwards

# Our vision is to improve the quality of care for millions



Leading Smart Recovery with  
**AI enabled technologies**

---



Reaching more patients with  
compelling **clinical evidence**

---

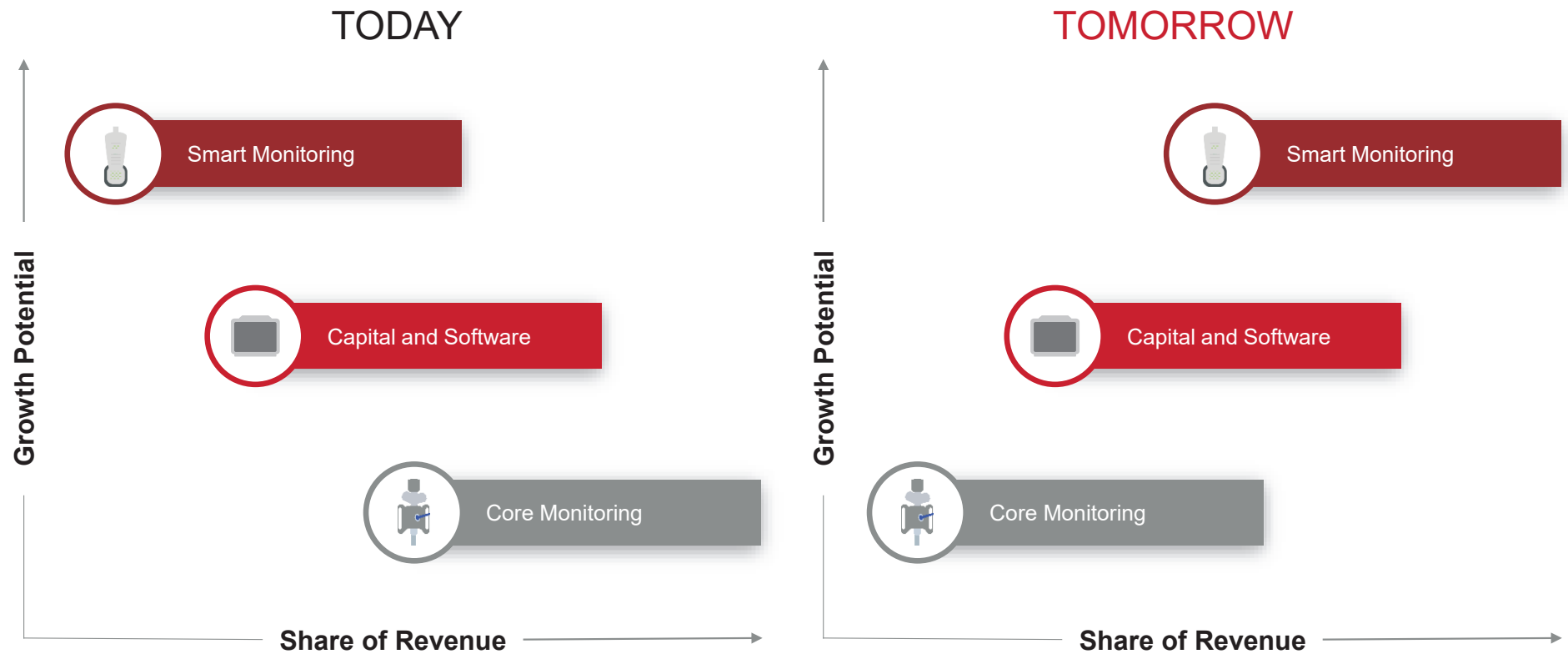


Improving patient care with  
**adoption** of innovative solutions





# We continue to shift mix towards Smart Recovery



Smart Monitoring



Faster Recovery



Smart Recovery



# Building blocks for Smart Recovery acceleration



## Technology

Deploying the Right  
Technologies



## Evidence

Generating Compelling  
Clinical Evidence



## Adoption

Creating Solutions that  
Drive Adoption

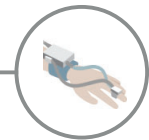
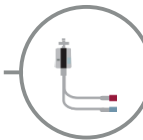
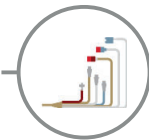
# Smart Recovery Begins WITH TECHNOLOGY



CONNECTIVITY

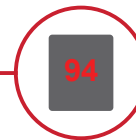
## SENSORS

Connects patient and monitor



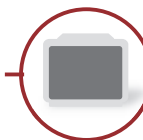
## ALGORITHMS

Enables smarter patient care



## SMART MONITORING PLATFORM

HemoSphere builds the foundation




# HemoSphere platform builds foundation for growth

## Two HemoSphere Offerings






HemoSphere

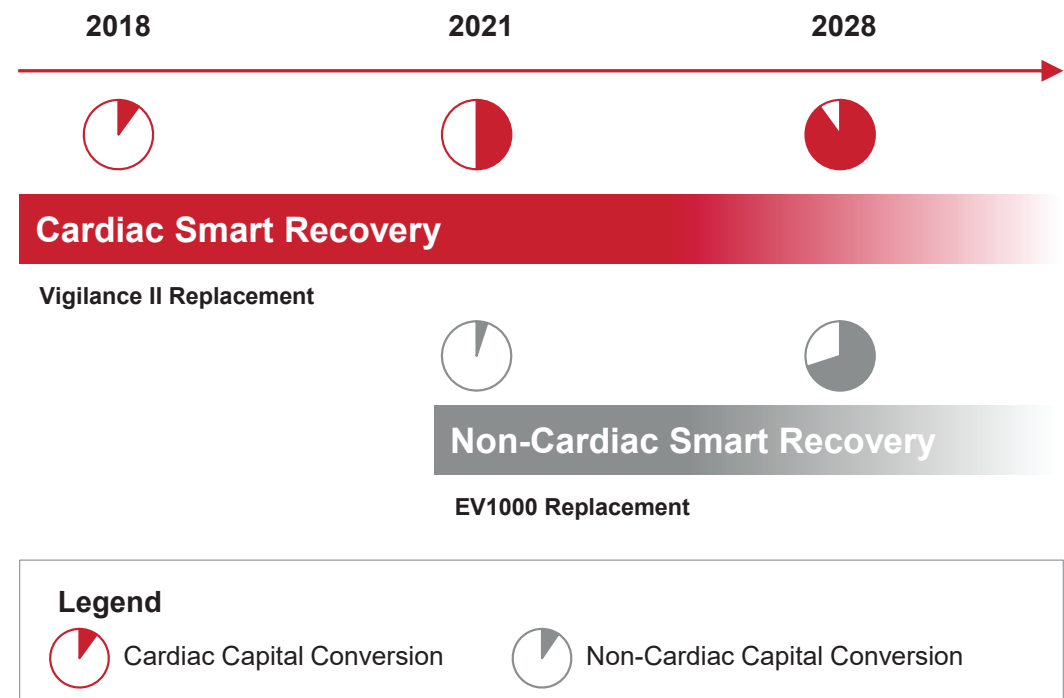
### Cardiac

-  Swan-Ganz
-  Acumen IQ Sensor & HPI
-  ForeSight

### Non-Cardiac

-  Acumen IQ Sensor & HPI
-  ForeSight
-  Acumen IQ Cuff & HPI

## Phased rollout to replace legacy platforms



# “Smartify” to improve patient care

## Legacy...

### SENSORS



FLOTTRAC



CLEARLIGHT



SWAN-GANZ

### DESCRIPTIVE ALGORITHM



CO



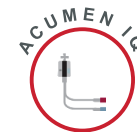
BP



SV

## ...Today and Beyond

### SMART SENSORS



SENSOR  
2018



CUFF  
2021



CATHETER

### SMART ALGORITHM



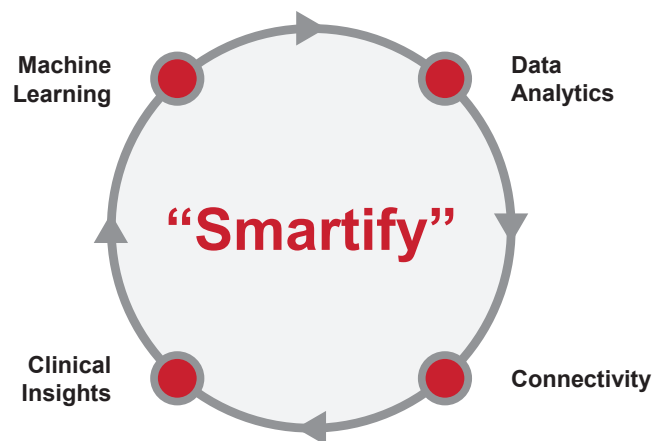
HPI  
2018



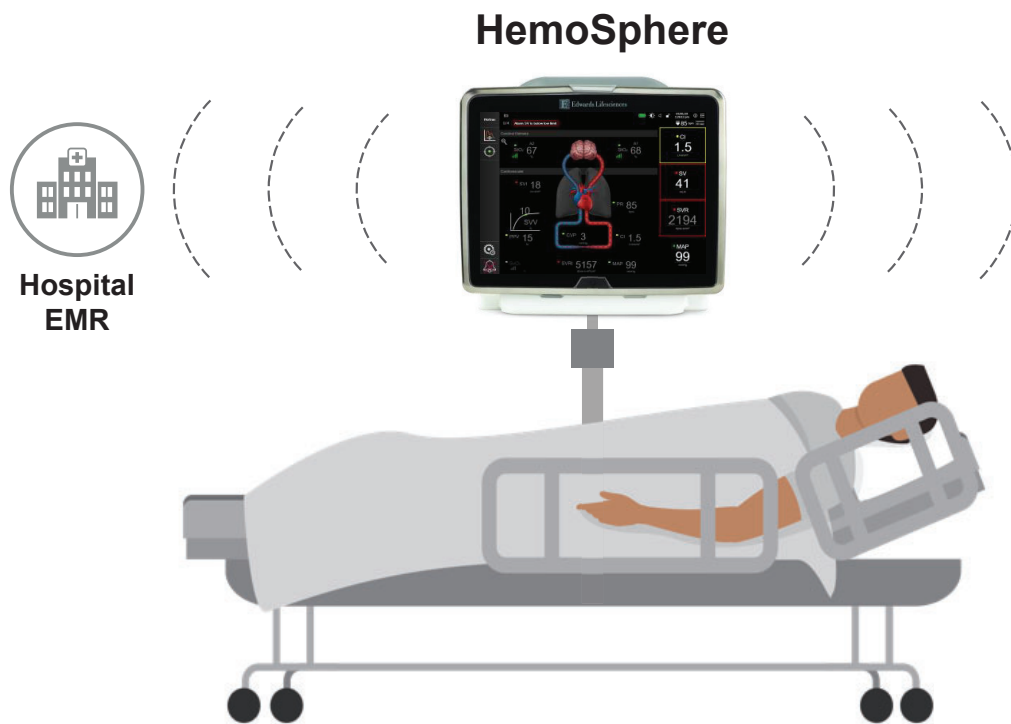
AFM  
2022



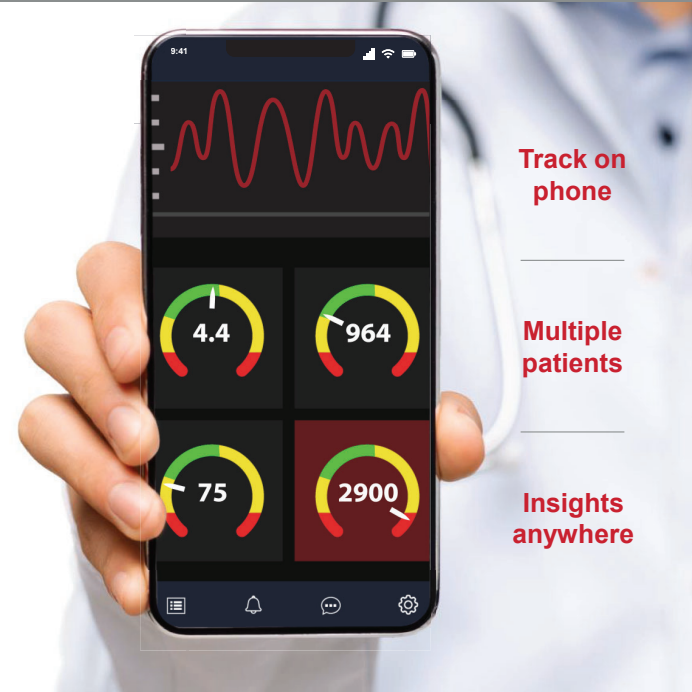
Future Algorithms



# Connectivity solution enables remote patient care



**Viewfinder Remote App**  
FDA clearance received 2021



Track on phone

Multiple patients

Insights anywhere

**The Viewfinder Remote App enables remote patient supervision and earlier intervention**





# Smart Recovery Advances

WITH EVIDENCE

## Hypotension Prediction Index (HPI) Data On Label

Mean Minutes of Hypotension

28 mins

12 mins



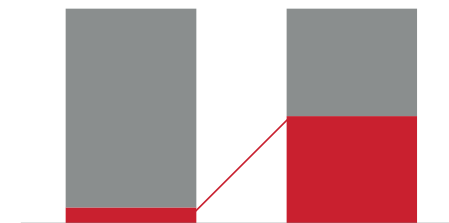
**58%**

**Decrease in IOH**

Edwards MPOG Study<sup>1</sup>

## Acumen IQ mix increasing

■ Acumen IQ Sensor    ■ FloTrac Classic



2021

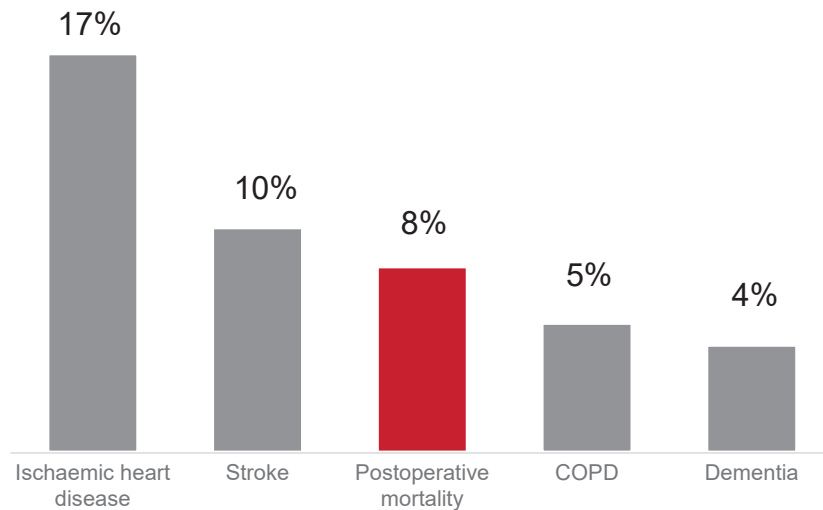
Future

**HPI software proven to reduce hypotension**

1. Edwards MPOG Study – HPI treatment arm (n=485) vs. historical control group (N=22,109), evaluating procedures ≥3 hours and ASA scores ≥3

# Hypotension can be prevented

**Top 5 Global Causes of Death<sup>1</sup>**  
(percent of total)



Hypotension is associated with increased risk of postoperative mortality<sup>2</sup>

**88%** of surgical patients experience hypotension<sup>3</sup>

“*Intraoperative hypotension seems to be a threat to patient safety that is hiding in plain sight.*”

– Daniel Cole, MD Anesthesiology, UCLA

**Postoperative mortality is the third leading cause of death**

# New study evaluating HPI's impact on outcomes

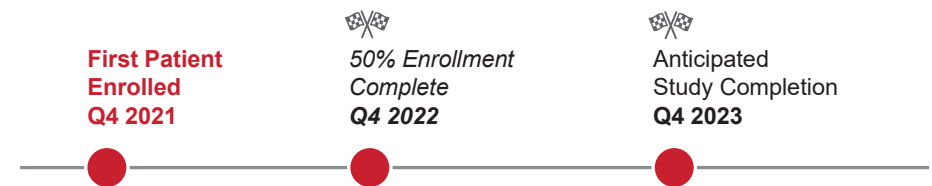
## HPI SMART BP

U.S. Adaptive multi-center RCT

### Objectives

- Generate clinical outcomes linking HPI software to clinical benefit for intraoperative arterial-line patients

## Timeline



**SMART BP RCT (~1500 Patients)**

## Study Endpoints

### Primary Endpoint: Composite Complications

- MINS, stroke, 30-Day mortality
- Acute kidney injury
- Deep wound & surgical site infections

### Exploratory Endpoints

- Reduction of ICU length of stay
- Reduction in cost of care

**Smart, predictive and easier to use**



# Smart Recovery Expands

WITH ADOPTION



## Hypotension Quality Measure



Intraoperative Hypotension (IOH) quality measure approved by CMS



Measure endorsed by ASA with initial target to reach ~200k patients



## Real World Evidence



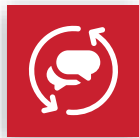
Leverage data registries to demonstrate IOH association with increased risk



Quality improvement projects using Smart Monitoring to improve outcomes

# 2022 Underlying Global Sales Growth Outlook

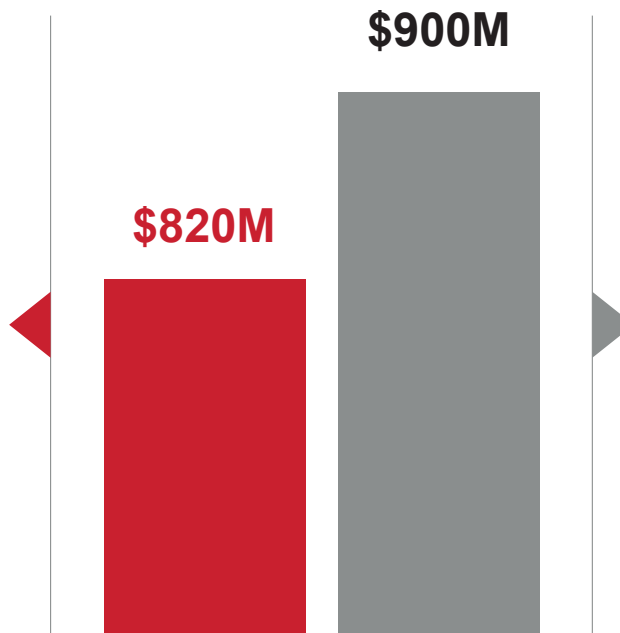
## Headwinds



Long conversion cycles



Discontinuing non-strategic products



## Tailwinds

Rebound in hospital capital budgets



Impact of clinical evidence on adoption



2022E

Underlying **Global Critical Care** Estimated Sales Growth  
Mid single-digits

# Executive Summary



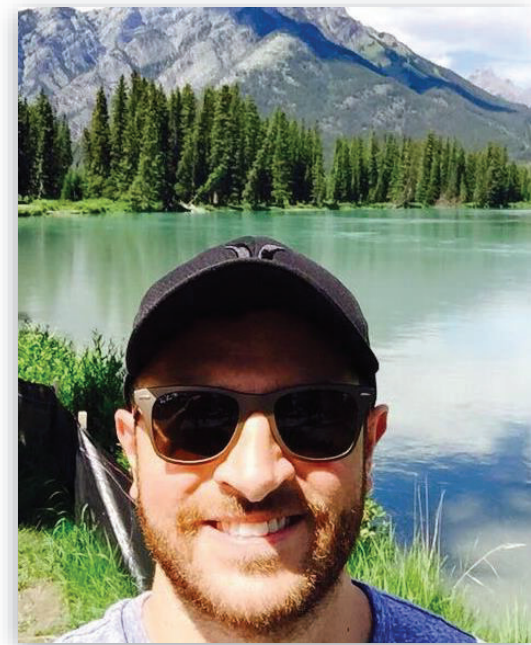
Leading Smart Recovery with  
**AI enabled technologies**



Reaching more patients with  
compelling **clinical evidence**



Improving patient care with  
**adoption** of innovative solutions



**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, including indications, contraindications, warnings, precautions and adverse events.**

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Helping Patients is Our Life's Work, and

*life is now*

# Financial Outlook

Scott Ullem  
Chief Financial Officer



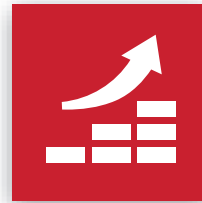
Edwards

## Edwards has delivered strong financial performance



### Sales Growth

Strong sales growth exceeding medtech sector



### Profitability

Healthy gross profit and operating margins



### Capital Allocation

Balance sheet management and disciplined capital deployment

## Long-Term Shareholder Returns

# Edwards Financial Objectives



## Sales Growth

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

- Sales growth fueled by successful long-term investments in R&D and advancements of focused breakthrough therapies

---

- Sustained leadership position supported by strong evidence-based value to patients and clinicians and healthcare system

---

- Addressing large, growing unmet patient needs

## Delivering strong 2021 performance despite COVID impact

(\$ in millions except earnings per share)

	2020 Investor Conference	October Guidance (Unchanged)
<b>Sales</b>	\$4,900 - 5,300	\$5,200 - 5,400
<b>FX Impact on Sales</b>	~\$35 (~1% upside to sales)	~\$70 (~1.5% upside to sales)
<b>Adjusted Gross Profit Margin</b>	76-77%	76-77%
<b>Adjusted Earnings Per Share</b>	\$2.00 - \$2.20	High-end of the range \$2.07 - \$2.27

## 2021 Sales Guidance – Product Group

(\$ in millions)

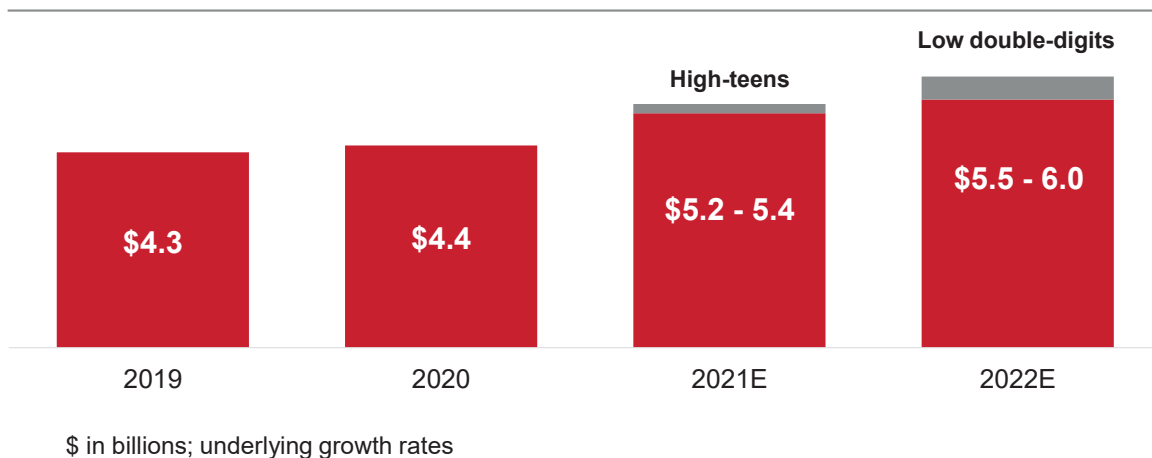
	2020 Investor Conference	October Guidance (Unchanged)
<b>Transcatheter Aortic Valve Replacement</b>	\$3,200 - 3,600	\$3,400 - 3,600
<b>Transcatheter Mitral &amp; Tricuspid Therapies</b>	~\$80	\$80 - 100
<b>Surgical Structural Heart</b>	\$800 - 900	\$875 - 925
<b>Critical Care</b>	\$725 - 800	\$800 - 850
<b>Total Edwards</b>	\$4,900 - 5,300	\$5,200 - 5,400

## Low double-digit sales growth expected in 2022



2022  
Expectations

- Gradual COVID recovery and assumes no significant impact from new variants
- Growth across all major regions
- FX impact expected to be approximately \$120 million or 2% downside to reported sales at current rates
- Expect high variability in year-over-year growth rates by quarter

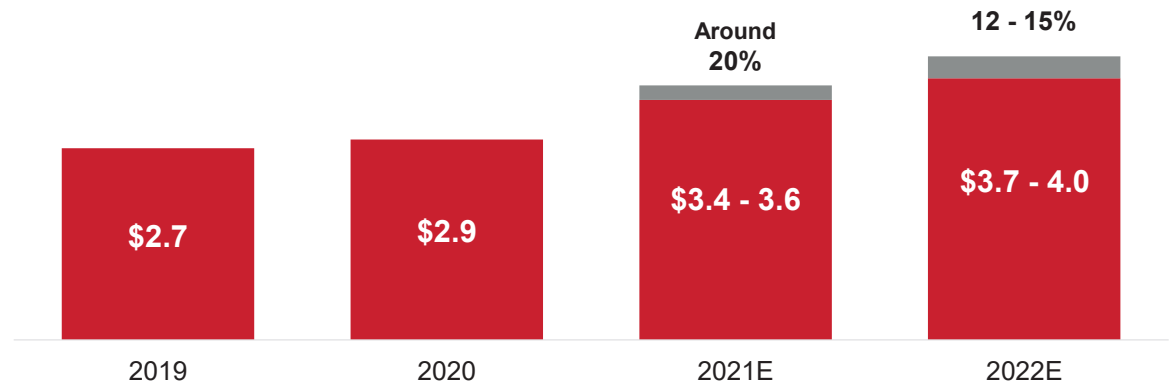


## TAVR sustains double-digit sales growth in 2022



2022  
Expectations

- Double-digit growth across all major regions
- Anticipated stable ASP and share position
- Q2 expiration of ~\$40M annual royalty revenue



\$ in billions; underlying growth rates

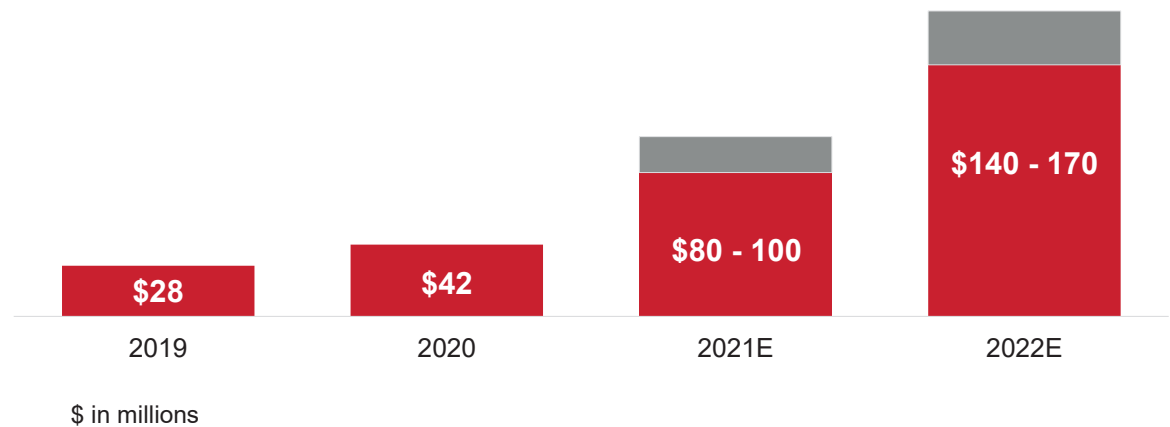


## TMTT continues strong momentum



2022  
Expectations

- Remain focused on excellent patient outcomes
- PASCAL expansion in Europe drives growth
- PASCAL in the U.S. and EVOQUE TR in Europe approved late 2022 with negligible impact on 2022 sales
- Build enrollment in ENCIRCLE, TRISCEND II, and MISCEND trials

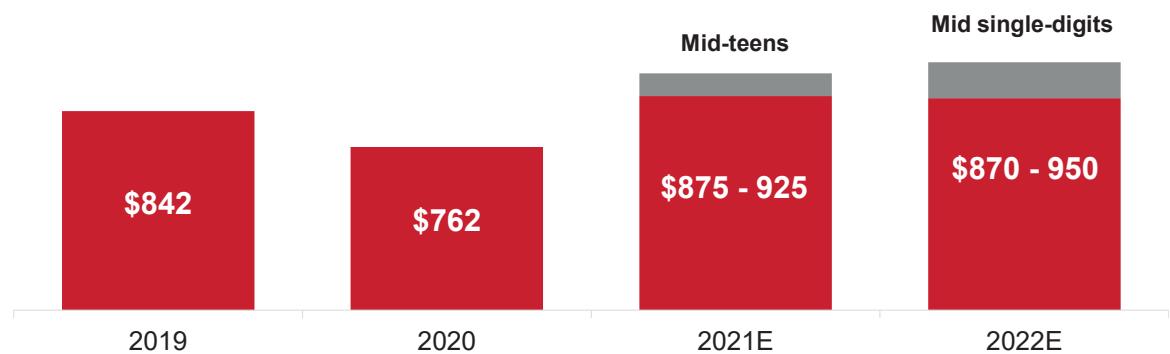


# Surgical Structural Heart brings leading innovations



2022  
Expectations

- Increased adoption of RESILIA products drives growth
- MITRIS U.S. launch
- Ongoing mechanical to tissue valve conversion



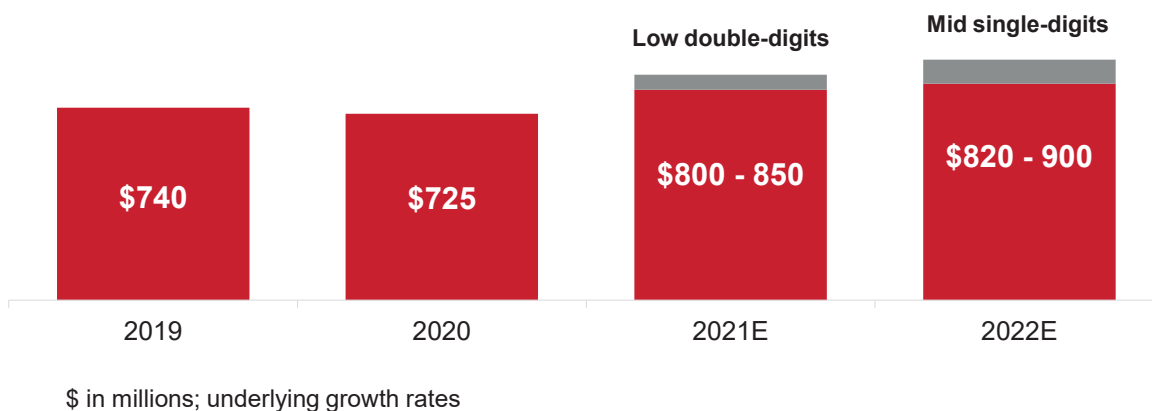
\$ in millions; underlying growth rates

## Critical Care shifting focus to Smart Recovery



2022  
Expectations

- Accelerated adoption of Smart Recovery and the expansion of HPI technology
- Launch Viewfinder connectivity solution
- Advance Smart BP enrollment

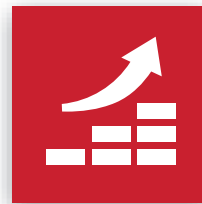


## Edwards has delivered strong financial performance



### Sales Growth

Strong sales growth  
exceeding medtech sector



### Profitability

Healthy gross profit and  
operating margins



### Capital Allocation

Balance sheet management and  
disciplined capital deployment

## Long-Term Shareholder Returns

# Edwards Financial Objectives



Profitability

## HEALTHY PROFITABILITY

- Generating strong gross profit

---

- Funding growing field organization and strengthening global supply chain

---

- Investing aggressively in innovation for profitable organic growth

---

- Maintaining efficient tax structure

## 2022 Gross Profit margin favorably impacted by FX



### GROSS PROFIT MARGIN

Between 78 - 79%



- FX impact
- Operational efficiencies
- Product mix



- Investments in manufacturing capacity
- Expiration of TAVR royalty

# 2022 Operating Expenses



## OPEX

SG&A: 28 - 30%; R&D: 17 - 18%



- FX impact
- Leveraging scale
- Nominal impact from inflation



- TMTT U.S. launch
- Investments in clinical trials and product development
- Normalization of pre-COVID activities

# Expanding Operating Margin in 2022



2022  
Expectations



## Gross Profit Margin

Adjusted Gross Profit margin forecast 78 - 79%, lifted primarily by foreign exchange



## Selling General and Administrative

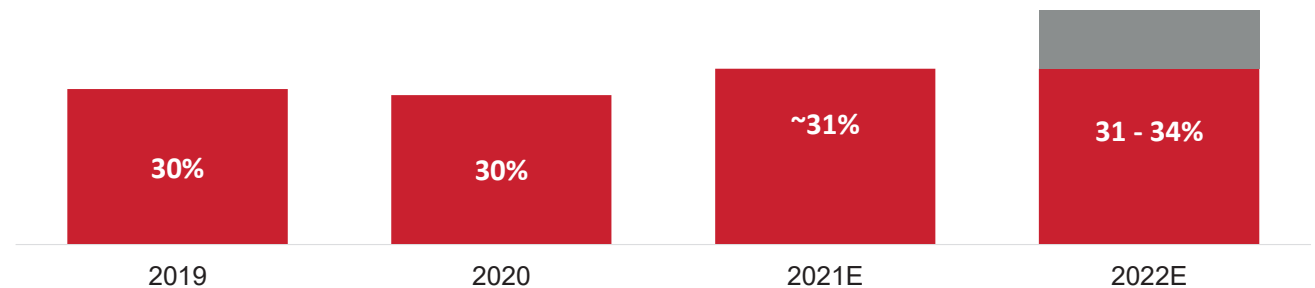
Continuing to support high-touch model for TAVR and ongoing build-out of TMTT commercial and clinical teams



## Research & Development

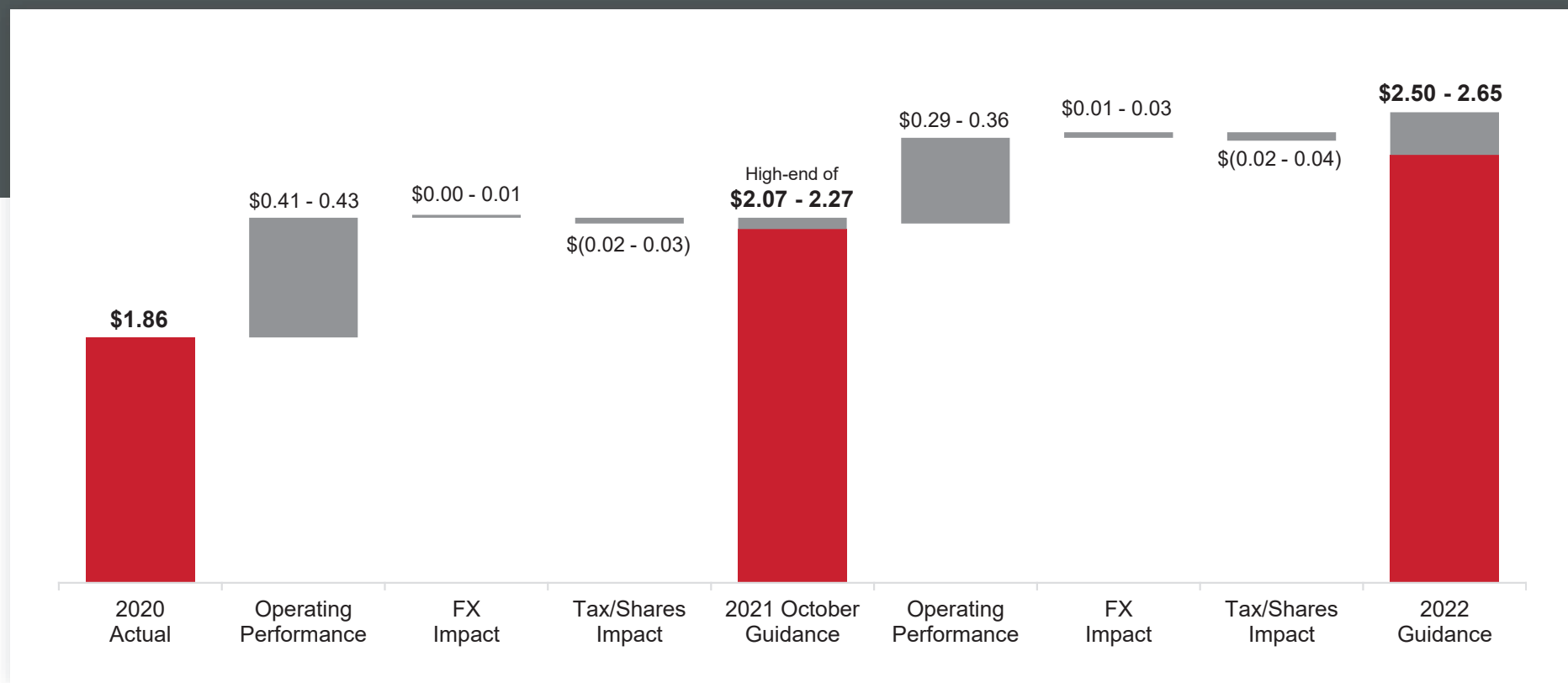
Targeted investments to continue profitable organic growth

### Adjusted Operating Margin





## Operating performance drives Adjusted EPS growth

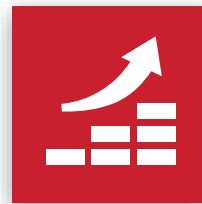


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## Long-Term Shareholder Returns

# Edwards Financial Objectives



## Capital Allocation

### ROBUST CASH FLOW AND DISCIPLINED CAPITAL DEPLOYMENT

- Supports global capacity expansion

---

- Strategic acquisitions to support and supplement R&D initiatives

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- Returning capital to shareholders through opportunistic share repurchases

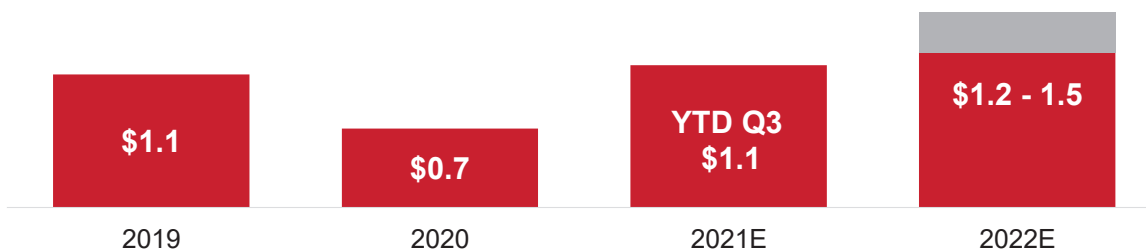
## Cash Flow and Capital Deployment



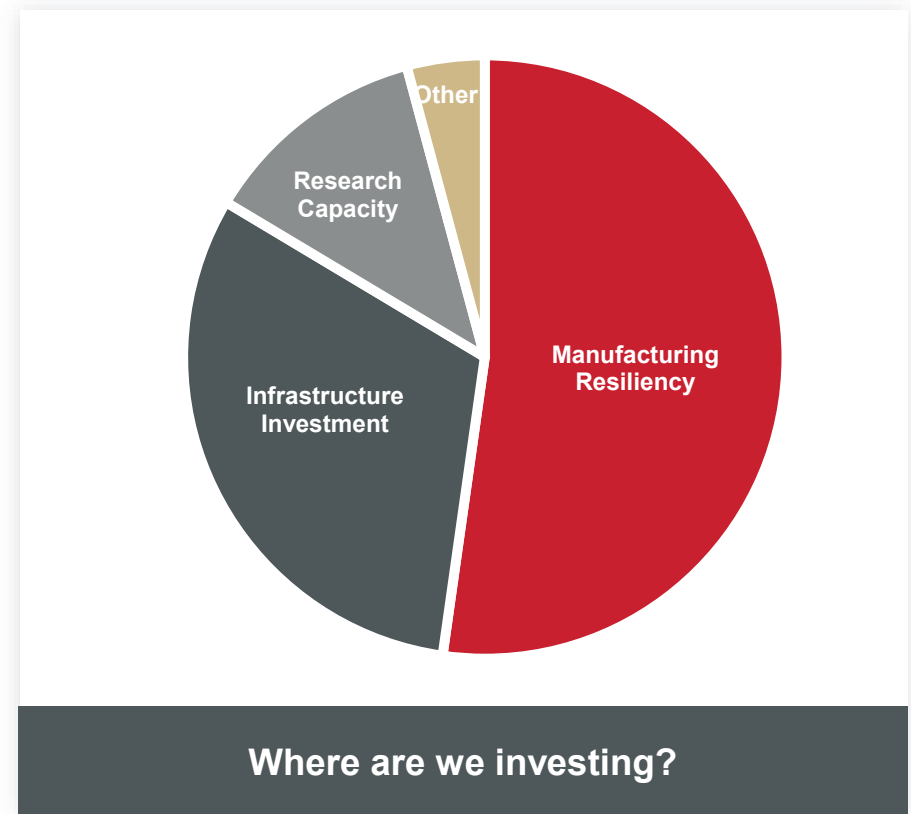
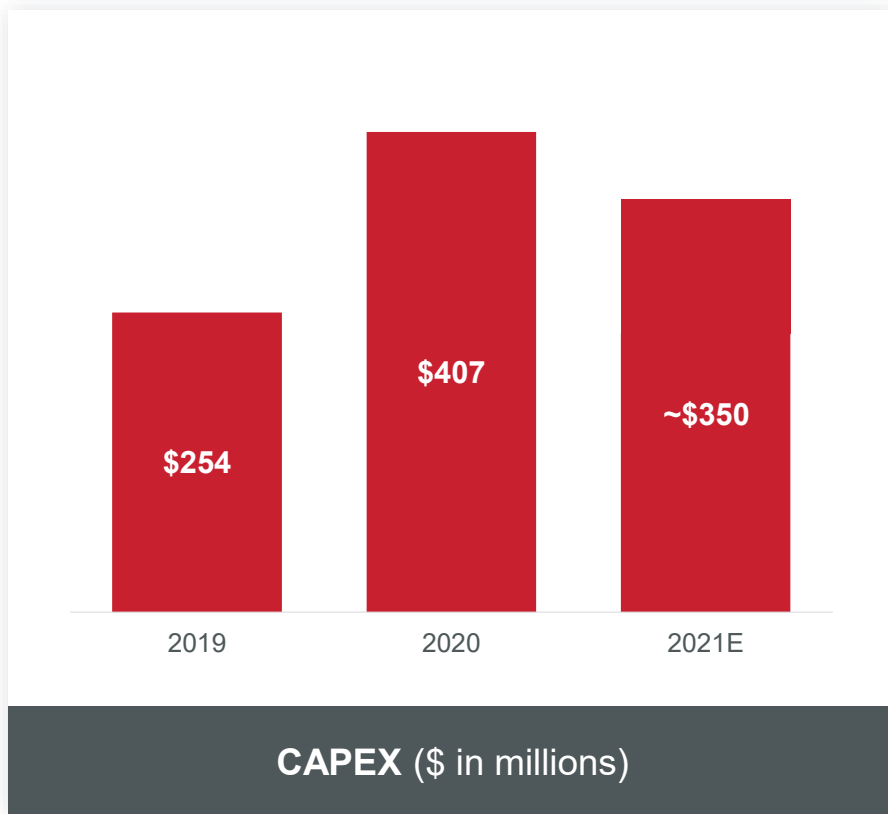
2022  
Expectations

- Continued growth results in significant cash flows that fund future internal and external opportunities
- EPS model expects diluted shares outstanding between 630 and 635 million
- Includes ~\$200M of accelerated tax payments starting in 2022 due to change in tax treatment of R&D

### Adjusted Free Cash Flow (\$ in billions)

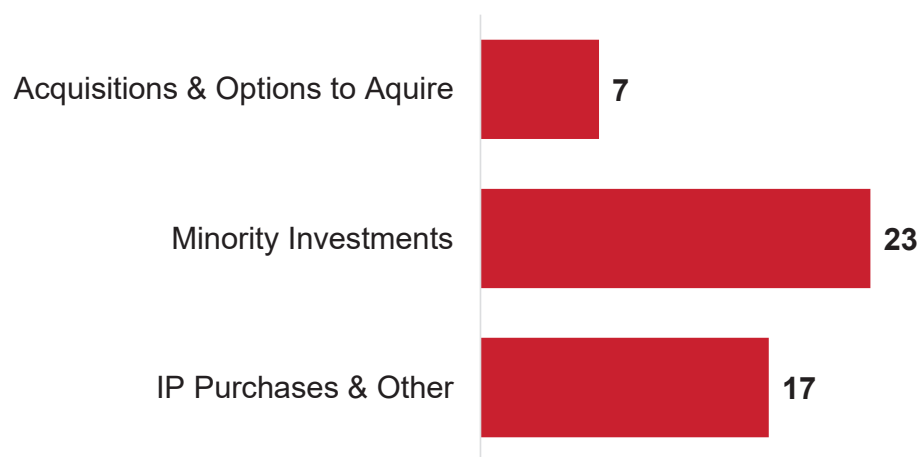


# Investing Capital for the Future



# Acquisitions & Divestitures

## CLOSED TRANSACTIONS SINCE 2016



## FOCUS

- Structural heart
- Smaller tuck-ins
- Early-stage, pre-revenue companies
- Strategic fit



## EXIT

- Non-strategic products
- Low growth potential

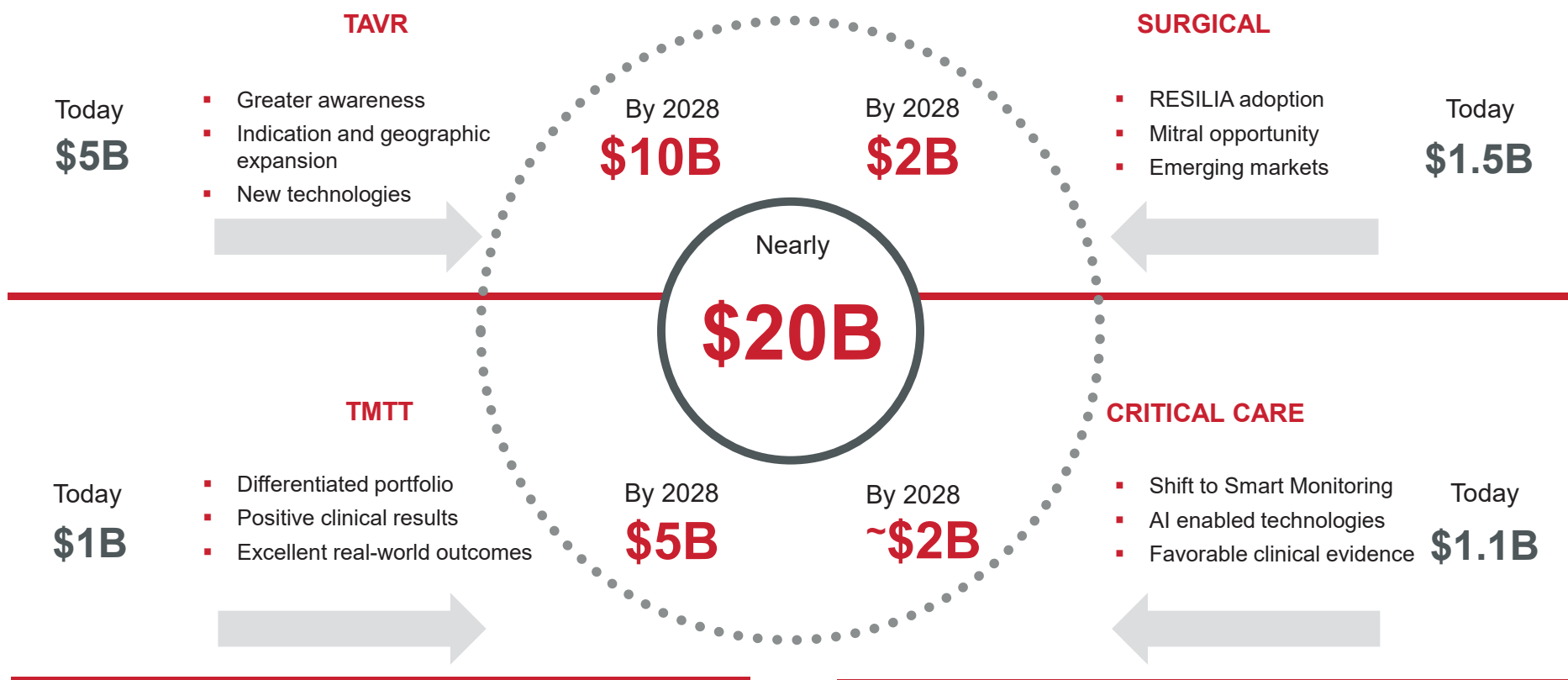
# 2022 Guidance Summary

*(\$ and shares in millions except earnings per share)*

<b>Sales</b>	\$5,500 - 6,000
<b>Underlying growth</b>	Low double-digits
<b>FX Impact on Sales</b>	~(\$120) (2% downside to sales)
<b>Gross Profit Margin*</b>	78 - 79%
<b>SG&amp;A % of Sales</b>	28 - 30%
<b>R&amp;D % of Sales</b>	17 - 18%

<b>Operating Margin*</b>	Expansion to 31 - 34%
<b>Tax rate*</b>	11 - 15% (~3pp ETB benefit)
<b>Earnings Per Share*</b>	\$2.50 - 2.65
<b>Shares Outstanding</b>	630 - 635
<b>Free Cash Flow*</b>	\$1,200 - 1,500

# Global Market Opportunity





# Longer-Term Guidance



## SALES GROWTH

### Underlying Sales Growth

- Innovation expected to drive organic growth that exceeds medtech sector

### Global Market Opportunity

Nearly  
**\$20B**  
 By 2028



## OPERATING EFFICIENCY

### Gross Profit Margin

- Mix and efficiencies expected to benefit longer-term margin

### SG&A

- Disciplined focus on leveraging scale and controlling G&A expenses, partially offset by investments to support growth initiatives

### R&D

- Significant investments in clinical trials to expand indications and develop new technologies



## EARNINGS

### Tax Rate

- Upward pressure

### Earnings Per Share

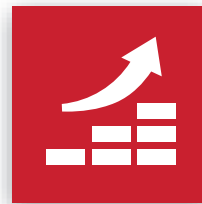
- Routine share repurchases to offset dilution from employee shares
- Opportunistically reduce net shares outstanding
- FX volatility mitigated by consistent hedging strategy

## Edwards' plan generates strong financial performance



### Sales Growth

Strong sales growth exceeding medtech sector



### Profitability

Healthy gross profit and operating margins



### Capital Allocation

Balance sheet management and disciplined capital deployment

## Long-Term Shareholder Returns



Edwards

Helping Patients is Our Life's Work, and

*life is now*

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# Closing Remarks

Michael A. Mussallem  
Chairman and CEO



Edwards

# Patient-Focused Innovation Strategy



## Innovation

Pioneer breakthrough technologies with compelling evidence

## Leadership

Lead groundbreaking standards of care through trusted relationships

## Focus

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

**Create Meaningful Value by Transforming Patient Care**

# 2022 expected to be a year of significant milestone achievements and investment in our future



## TAVR

Moderate AS trial enrollment  
SAPIEN X4 trial enrollment



## TMVT

PASCAL - DMR approval in the U.S.  
EVOQUE TR approval in Europe



## SURGICAL

MITRIS approval in the U.S.  
Continued adoption of RESILIA



## CRITICAL CARE

HemoSphere with Viewfinder  
Smart BP enrollment

**Low double-digits**  
Underlying sales growth

**2022**  
**EXPECTATIONS**

**\$2.50 - \$2.65**  
Adjusted EPS

# Edwards' Board is accomplished and engaged



**Leading governance practices**



**Highly experienced leaders**



**Oversees compensation program based on performance:**

- Financial performance
- Key operating drivers
- Shareholder value creation



# Sustainability is integrated into our culture and strategy





# Edwards is committed to giving back

Foundation supporting 250+ global charities in 2021



## Every Heartbeat Matters

Improve the lives of **2.5M** additional underserved structural heart and critical care patients by the end of 2025



## Strengthening Our Communities

Meet basic community needs where we live and work; **>80%** employee involvement towards our 100% aspiration

# Edwards is poised for long-term value creation

**Large Populations**  
of patients with unmet needs



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



**Sustainable**  
organic long-term sales growth



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



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



**We are just getting started**



Edwards

Helping Patients is Our Life's Work, and

*life is now*