

# 2022 Investor Conference



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 2022, 2023 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 “underlying or organic or constant currency 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.

# Opening Remarks

**Michael A. Mussallem**  
Chairman and CEO



Edwards

## Our Credo

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**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.

Helping patients is our life's work, and

*life is now*

# Edwards Lifesciences at a Glance



## 800K+

Patients Treated With  
Transcatheter Therapies



## ~95%

Sales from Products with  
#1 Global Position

## 2,000+

Engineers



Investment in R&D  
**17-18%**  
of 2022E sales



## 17,000+

Global Employees



## 60%+

Millennials and Generation Z



Resilient Supply  
Chain



## 7

Manufacturing Locations  
Around the World



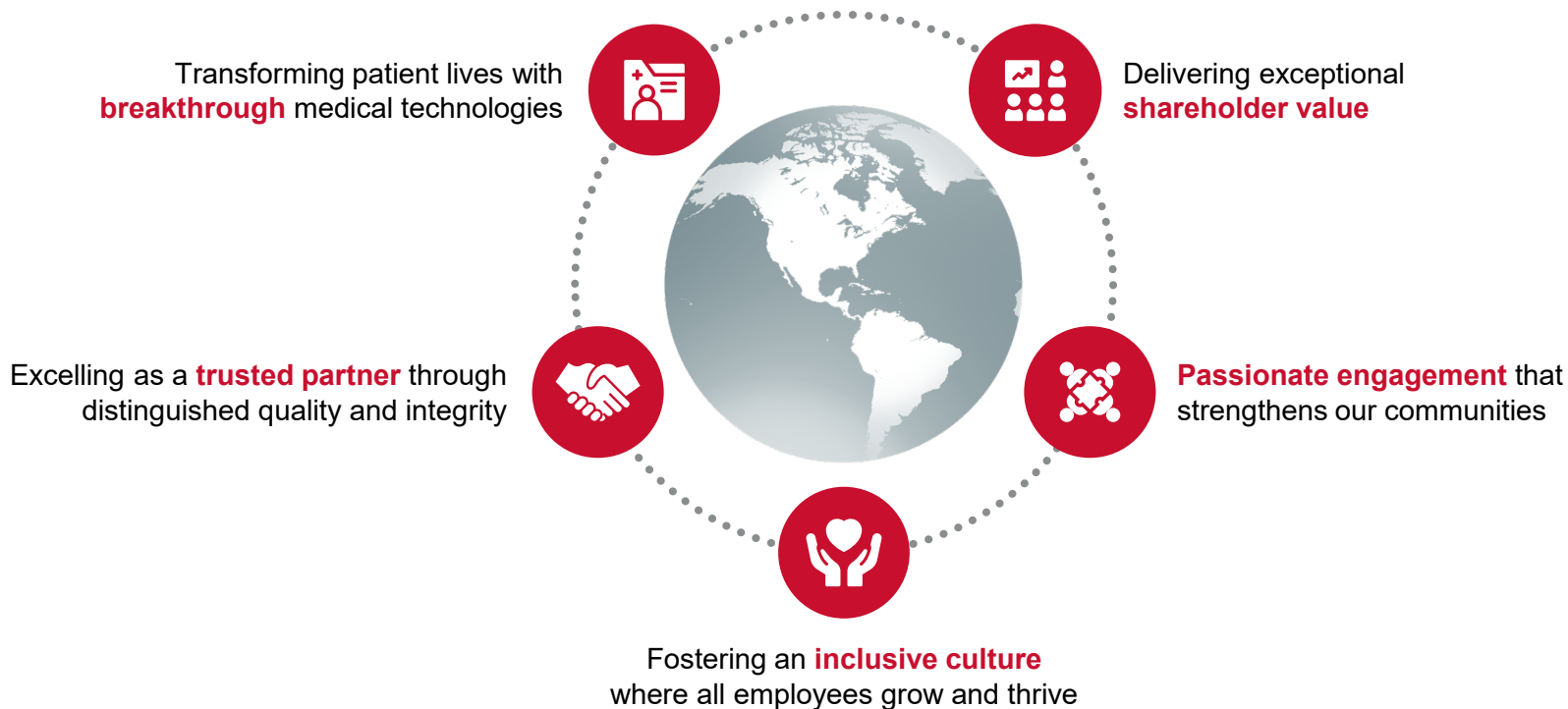
## 85%+

Charitable employee  
engagement



# Our Aspirations

Edwards is a global leader dedicated to...



# 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 Sales Growth



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



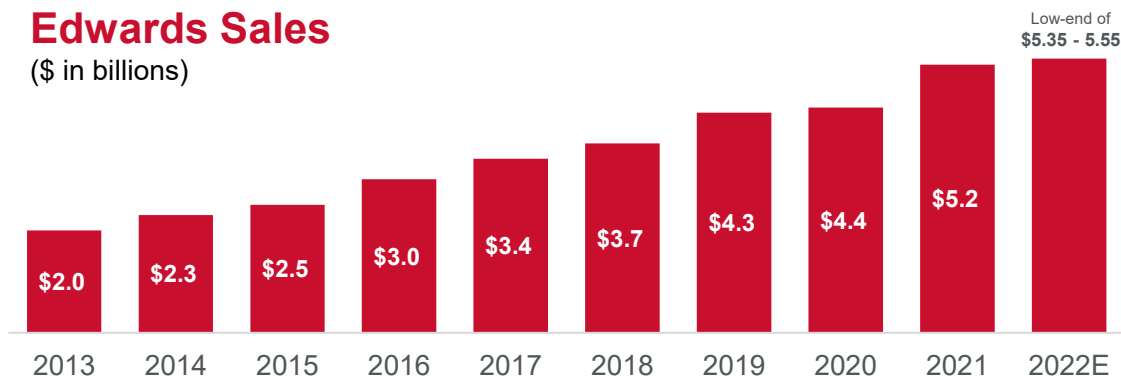
Track record of **triple wins**:

- Improved outcomes
- Enhanced quality of life
- Cost effectiveness



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

## Edwards Sales (\$ in billions)



# Conference Highlights



Grew during challenging environment in **2022** while investing to create future value



**2023** expected **9-12%** sales growth and achieving innovation milestones



Opportunity to double the already large **global addressable market**



Highly **strategic** and experienced leadership team

# Growing in 2022 while investing to create future value



## Obtained Important Regulatory Approvals

- SAPIEN 3 Ultra RESILIA U.S. and Japan
- PASCAL U.S. DMR approval
- PASCAL Precision CE Mark
- MITRIS RESILIA U.S.

## Achieving Clinical and R&D Milestones

- Continued enrollment in Moderate AS trial
- CLASP IID trial met primary safety and effectiveness endpoints
- Initiated ALLIANCE trial for SAPIEN X4
- TRISCEND study demonstrated favorable clinical outcomes at 1 year

## Investing to Create Future Value

- Sustained investment in R&D and infrastructure
- Resilient global supply chain

Low-end of  
**\$5,350 - 5,550**  
 Estimated 2022 Sales

**October Guidance  
 Unchanged**

**\$2.40 - 2.50**  
 Estimated 2022  
 Adjusted EPS

# COVID triggered global healthcare staffing challenges

## Forbes

### What It Takes To Curb The Healthcare Staffing Shortage

Nov 3, 2022, 07:30am EDT

In a letter addressed to the U.S. House of Representatives Energy and Commerce Committee, the [American Hospital Association \(AHA\)](#) declared the shortages “a national emergency.” It is estimated that for nurses alone, the deficit will reach 1.1 million by the end of 2022.

THE WALL STREET JOURNAL  
WSJ

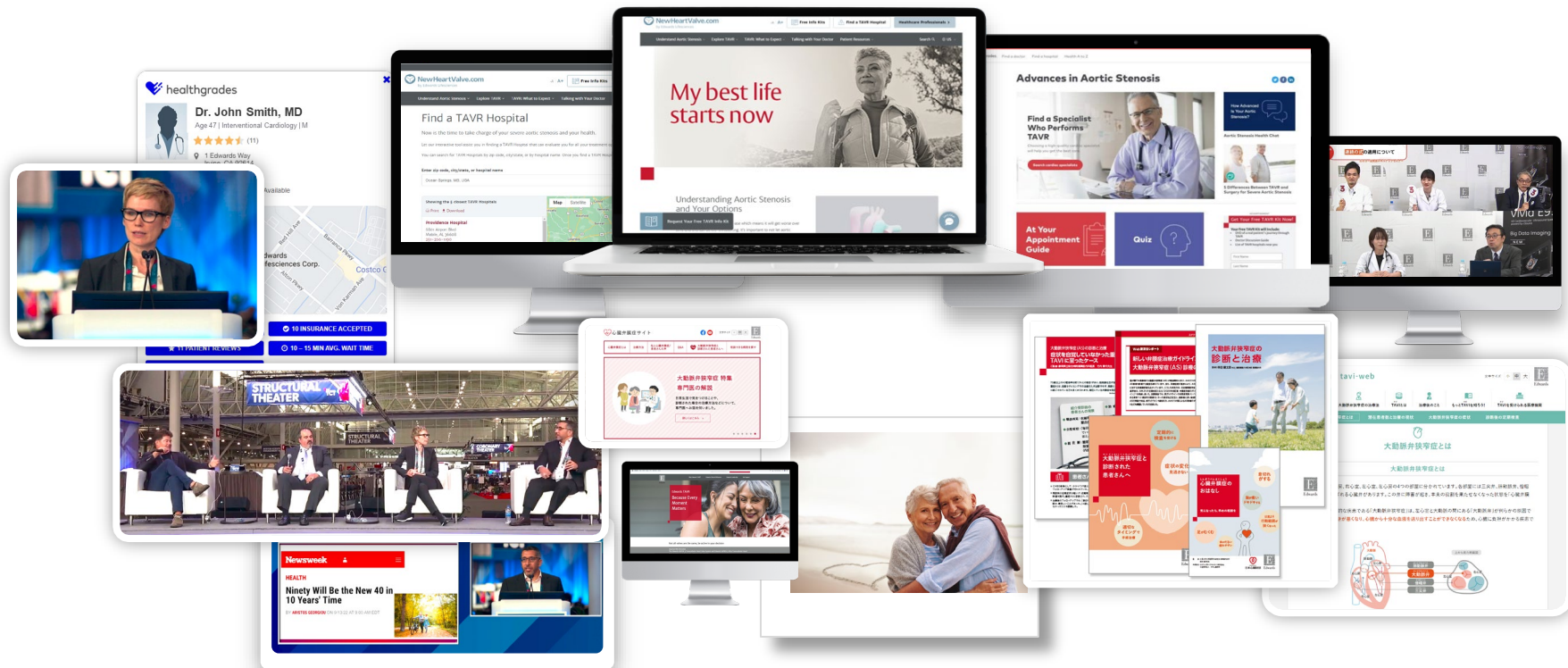
### Covid's Drag on the Workforce Proves Persistent. 'It Sets Us Back.

Nov. 7, 2022 9:39 am ET

Virus still keeping millions out of work while reducing productivity and hours of millions more, disrupting business operations and raising costs

“In the average month this year, **nearly 630,000 more workers missed at least a week of work** because of illness than in the years before the pandemic, according to Labor Department data.”

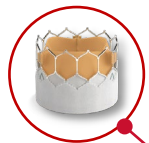
# Prioritizing widespread initiatives to improve near-term patient access



# 2023 expected to be a year of strong growth and investment in our future

## TAVR

- > SAPIEN 3 Ultra RESILIA launch
- > Moderate AS trial enrollment
- > SAPIEN X4 trial enrollment

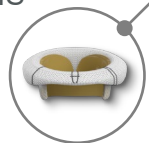


## TMTT

- > Present CLASP IID full cohort 1-yr data
- > ENCIRCLE trial complete enrollment
- > Receive CE Mark for EVOQUE TR
- > TRISCEND II complete enrollment

## SURGICAL

- > Continued global adoption of INSPIRIS
- > MITRIS U.S. penetration
- > Present RESILIA 7-year data



## CRITICAL CARE

- > Continued Acumen IQ conversion
- > HemoSphere expansion
- > Ongoing adoption of ForeSight

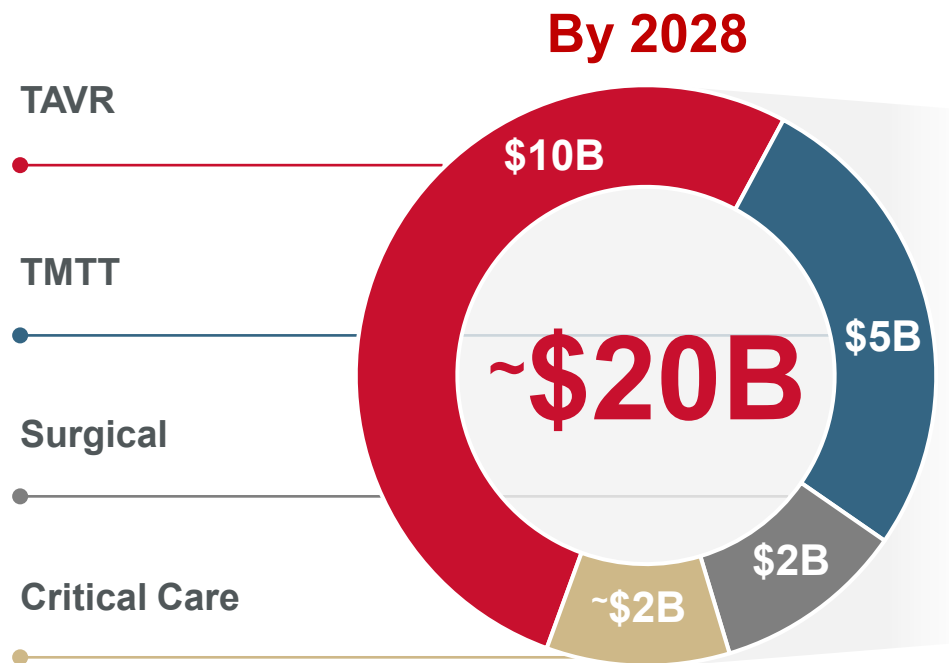
**9 – 12%**  
Underlying sales growth

**2023**

**\$2.45 - 2.60**  
Adjusted EPS

# Significant Global Market Opportunity

Currently around \$10B



## Beyond

Significant opportunity to increase with:

- Moderate AS indication
- Global TMTT valve replacement expansion
- Interventional heart failure innovations

Entering a New Era of Structural Heart Innovation

# 2022 Investor Conference Agenda



## Transcatheter Aortic Valve Replacement

Larry Wood



## Transcatheter Mitral and Tricuspid Therapies

Bernard Zovighian



## Surgical Structural Heart

Daveen Chopra



## Critical Care

Katie Szyman



## Financial Outlook

Scott Ullem



## Closing Remarks

Mike Mussallem



## Q&A Session



# Edwards' Executive Leadership Team



**Mike  
Mussallem**  
Chairman & CEO



**Don 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, Latin  
America and JAPAC



**Christine  
McCauley**  
Human Resources



**Joe  
Nuzzolese**  
Global Supply Chain



**Arnold  
Pinkston**  
General Counsel



**Gary Sorsher**  
Quality & Regulatory  
Compliance



**Katie Szyman**  
Critical Care



**Scott Ullem**  
Chief Financial Officer



**Larry Wood**  
Transcatheter Aortic  
Valve Replacement



**Bernard  
Zovighian**  
Transcatheter Mitral  
& Tricuspid Therapies

Long-tenured expert  
healthcare executives

Rigorous succession  
planning

Incentives aligned  
with shareholders



Edwards

Helping Patients is Our Life's Work, and

*life is now*

# Transcatheter Aortic Valve Replacement

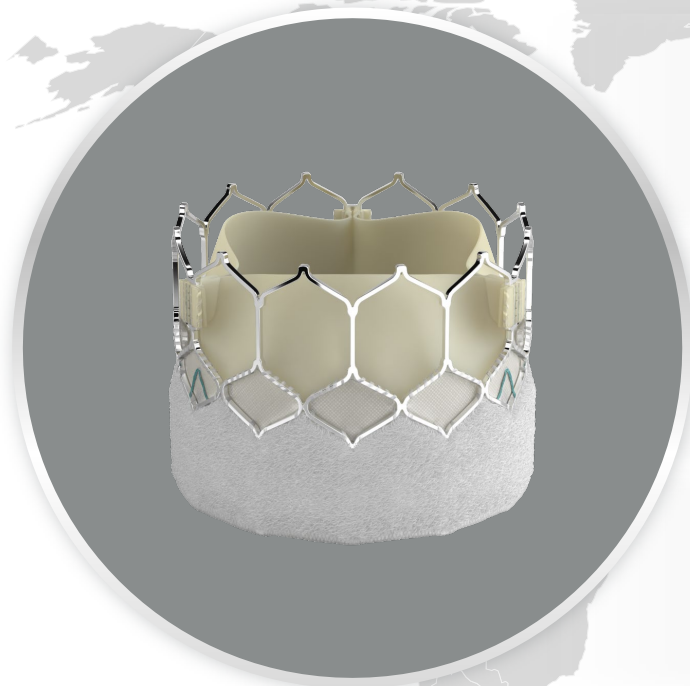
Larry L. Wood  
Corporate Vice President  
Transcatheter Aortic Valve Replacement



Edwards

# Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

## Key Pillars of Our Strategy



**Increase Therapy Adoption  
in Growing AS Opportunity**

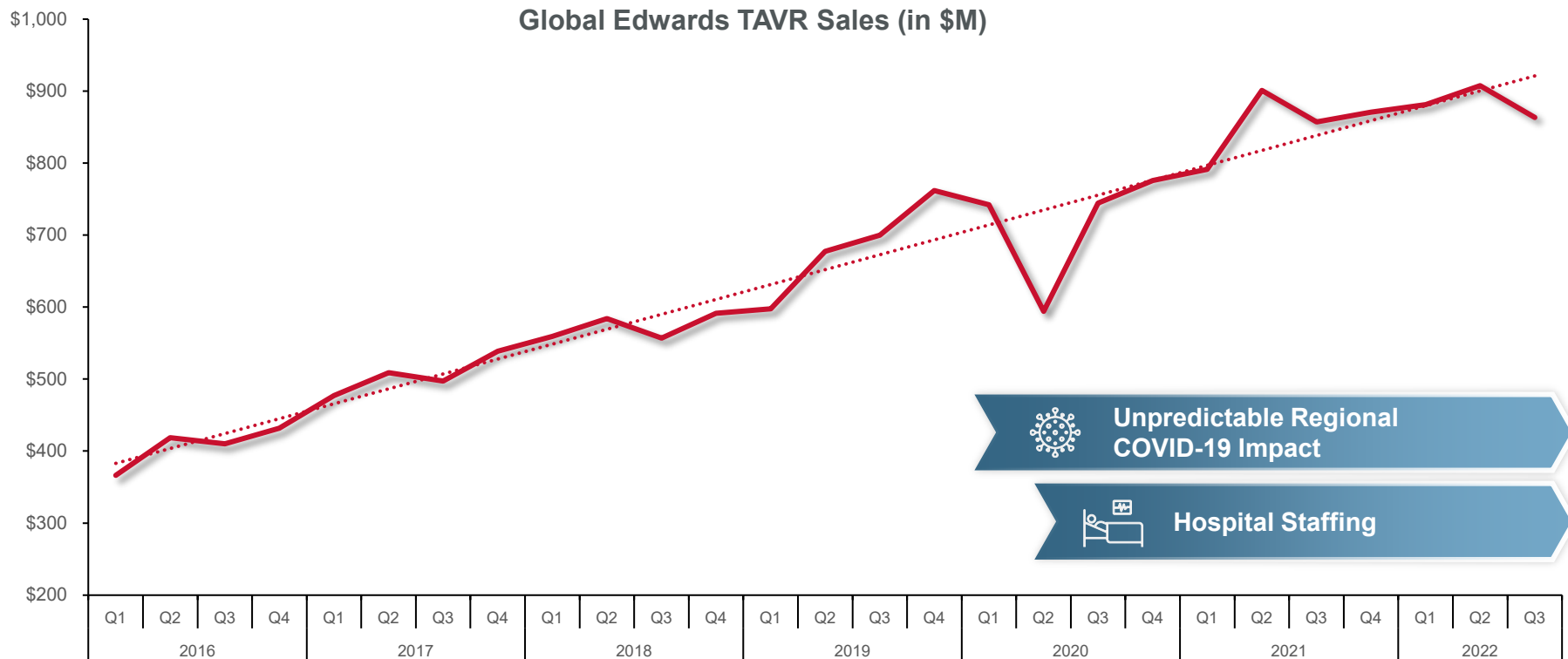


**Expand Indications**

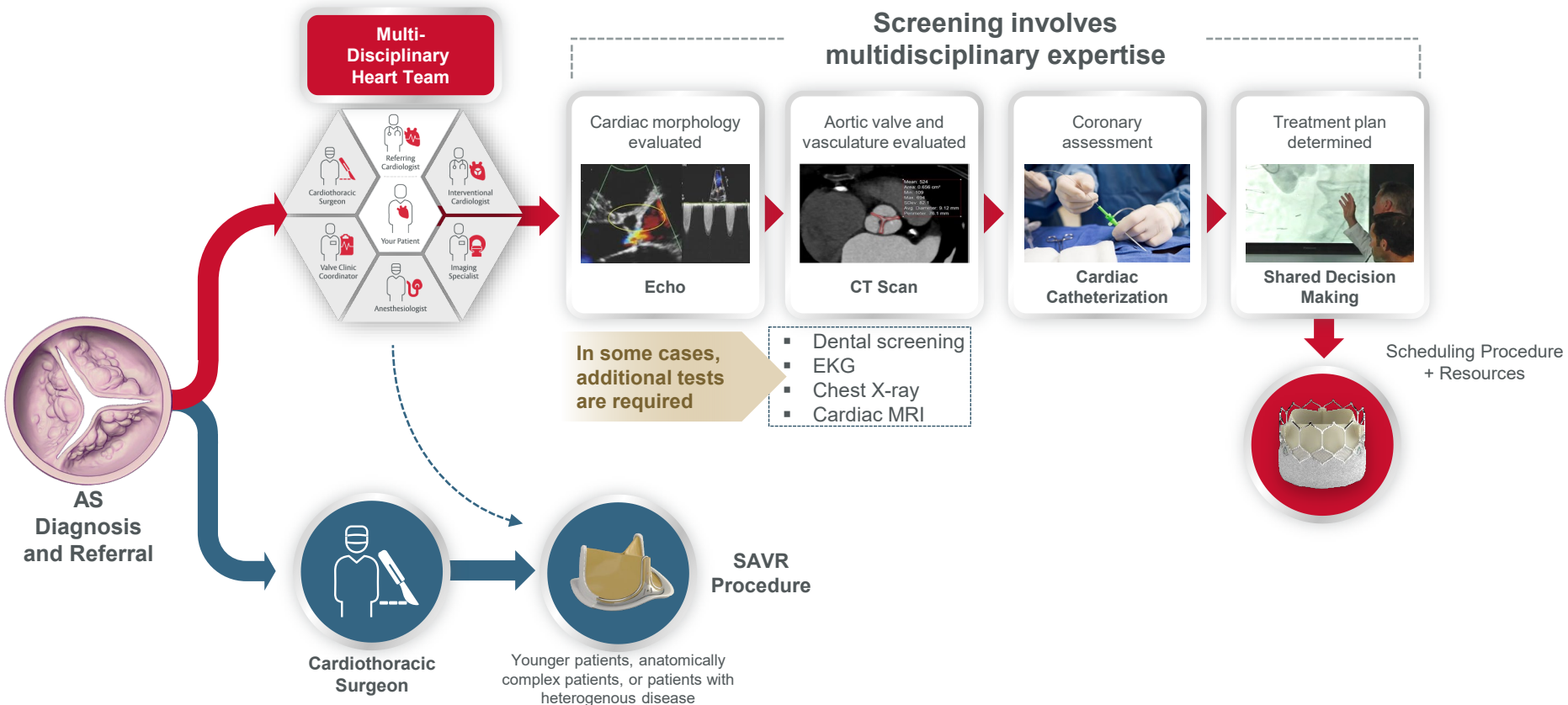


**Deliver Strong  
Portfolio Innovation**

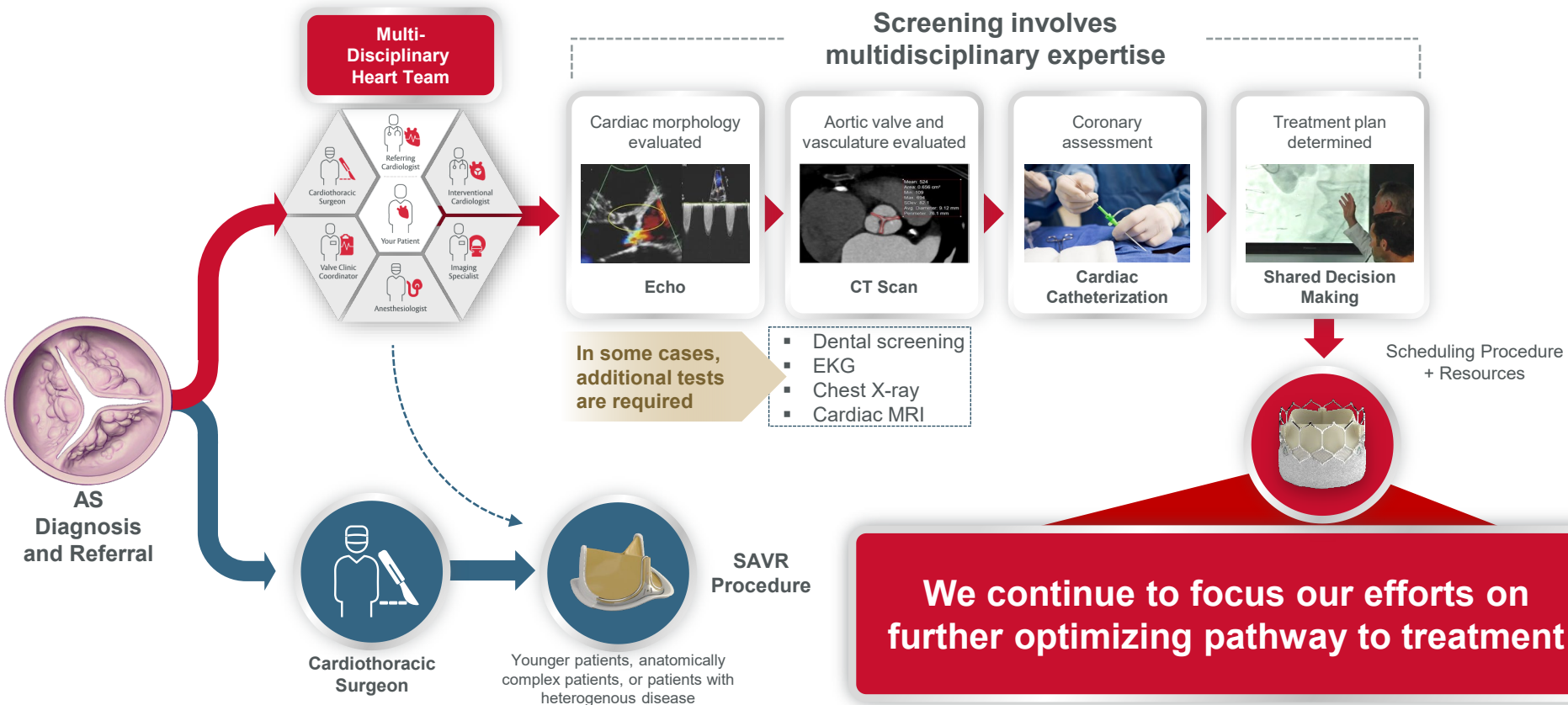
# Despite challenges, global EW TAVR has delivered double-digit growth over the past six years



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



# Over the years, we have improved TAVR efficiencies

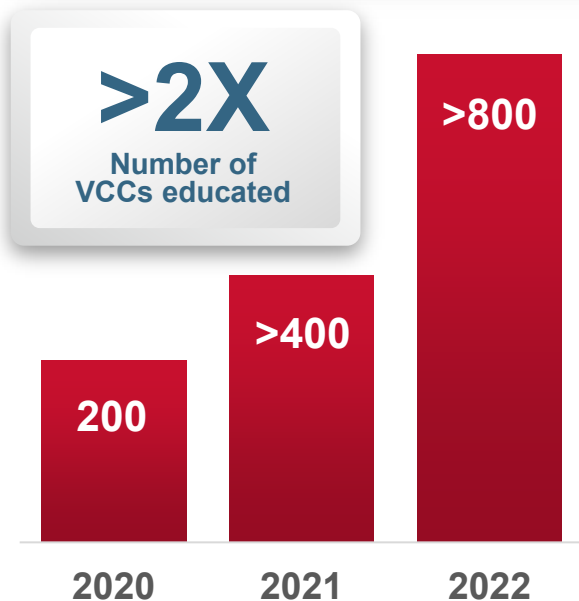




# We Remain Focused on Supporting Hospitals as Trusted Partners

## Valve Clinic Coordinator Education Programs

## Provider Education Programs



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

### Edwards Facilitated Peer-to-Peer Education Programs:

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



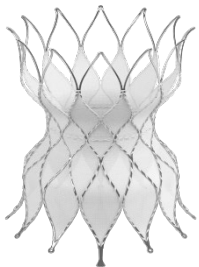
**300+**  
fellows expected to complete programs in FY22<sup>1</sup>

**225+**  
HCPs<sup>2</sup> completed programs this year





# We Continue to Deliver On Our Long-Term Growth Drivers



## ALTErra

Pulmonic Adaptive  
PreStent launched

Commercial



## SAPIEN 3 Ultra RESILIA

Approved in the  
U.S. and JPN



## SAPIEN X4 System

ALLIANCE Trial  
enrollment started

Technology



## EARLY TAVR Trial

Enrollment complete;  
in follow-up

Indication Expansion

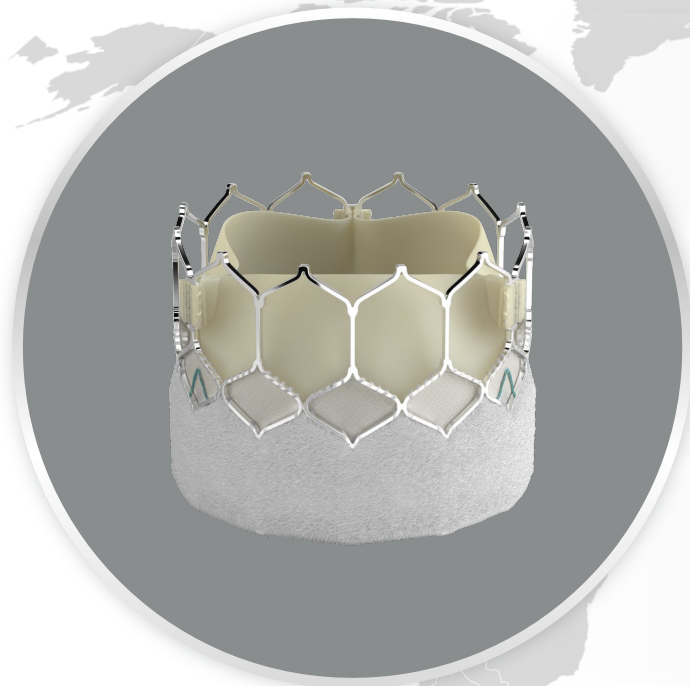


## PROGRESS Trial

Enrolling for  
moderate AS

# Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

## Key Pillars of Our Strategy



**Increase Therapy Adoption  
in Growing AS Opportunity**



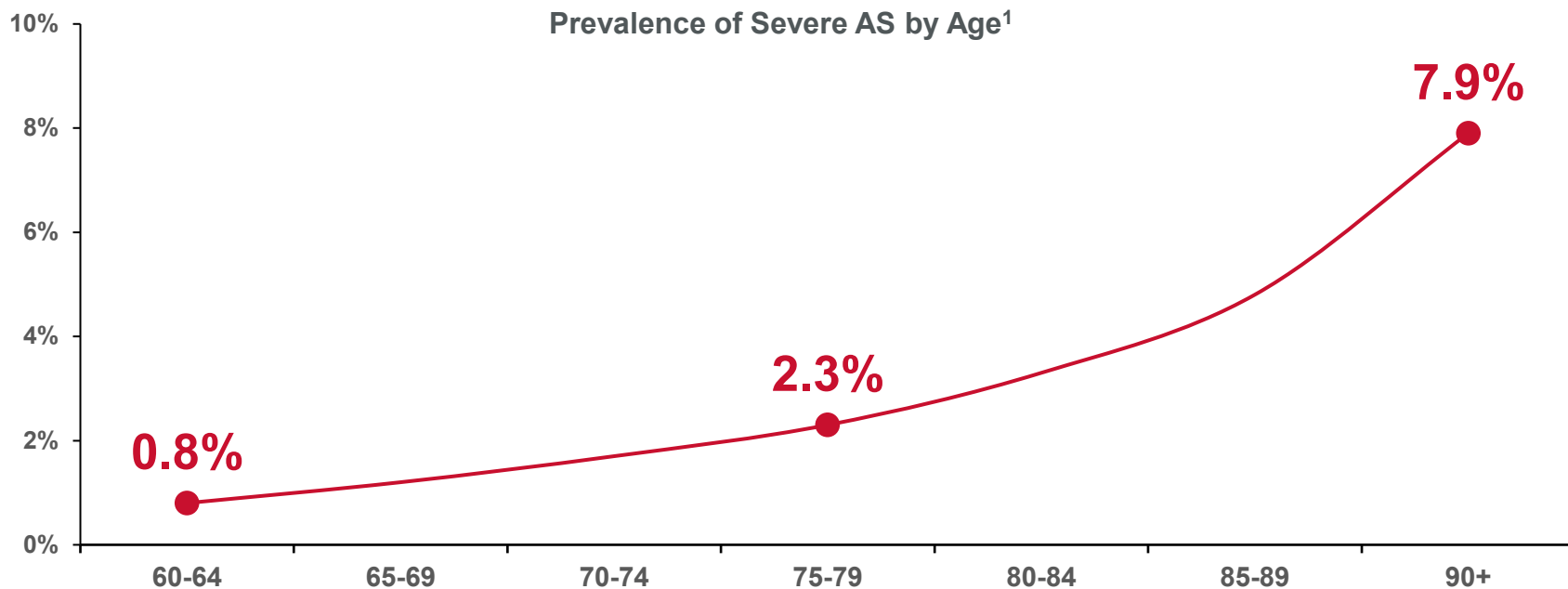
**Expand Indications**



**Deliver Strong  
Portfolio Innovation**

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

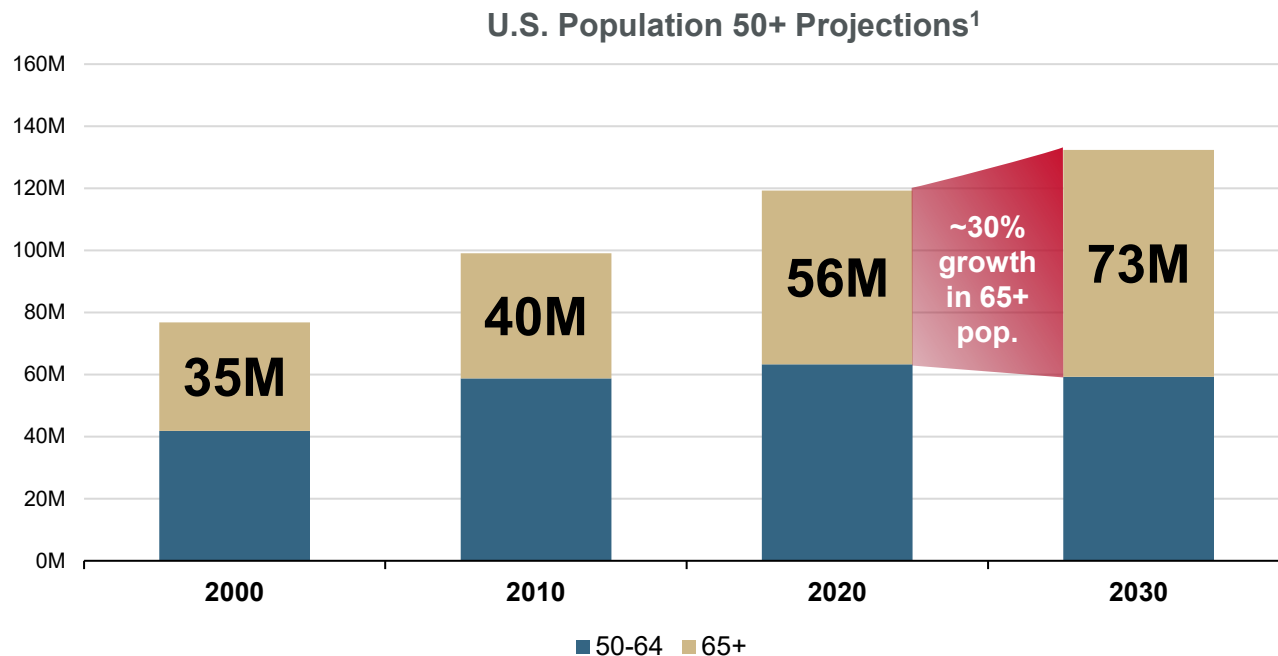
Clinical research papers reaffirm higher Severe Aortic Stenosis prevalence in the elderly





# Rapidly growing aging population increases the burden of severe AS

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



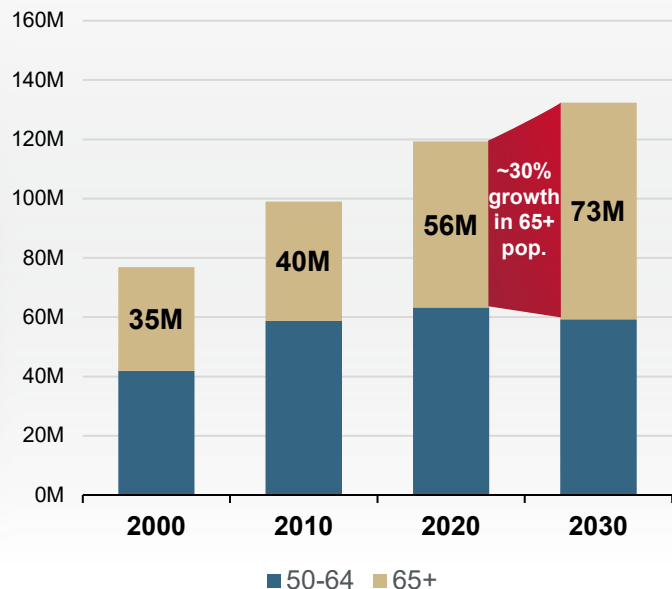
**~10,000**  
People turn 65  
years every day<sup>2</sup>

**All Baby Boomers**  
will be 65 or  
older by 2030<sup>2</sup>



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

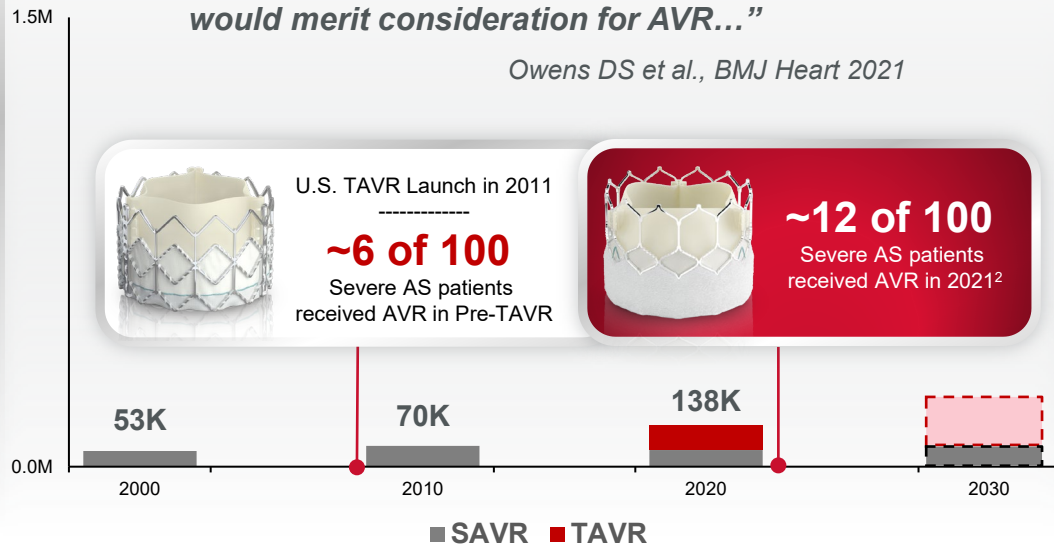
## U.S. Population 50+ Projections<sup>1</sup>



## Growth in AVR Treatment<sup>2</sup>

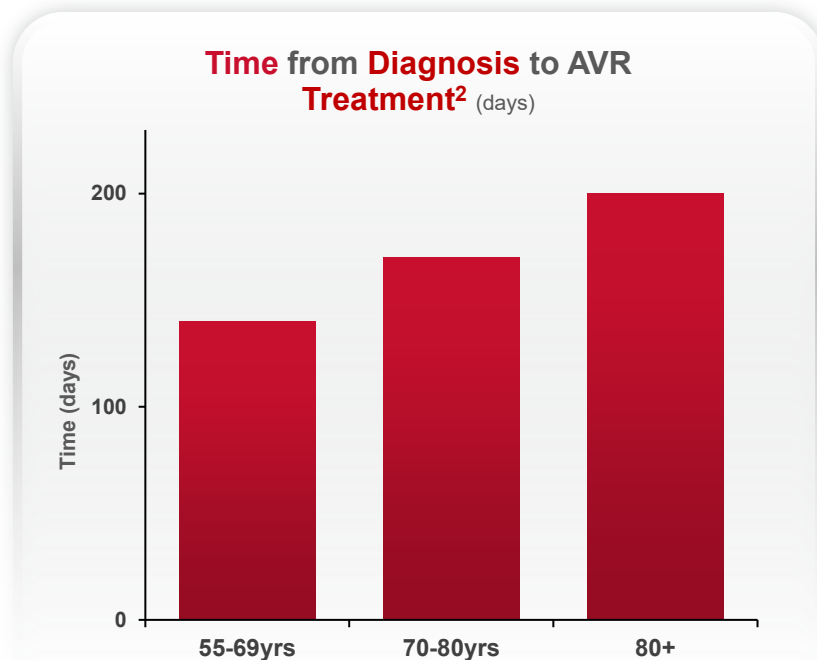
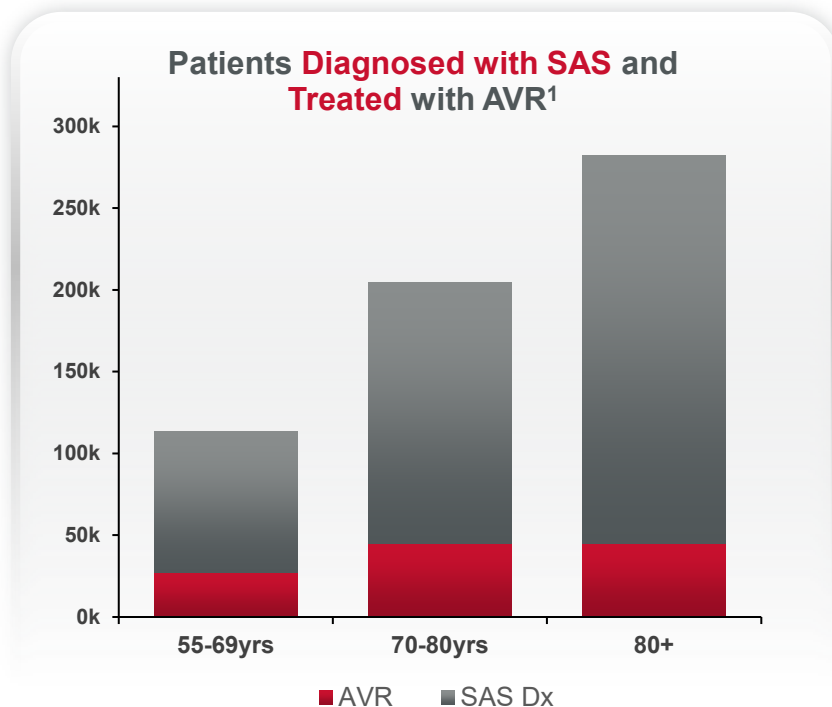
“... currently ~1.3 to 1.6 million Americans would merit consideration for AVR...”

Owens DS et al., *BMJ Heart* 2021





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



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

Freedom From  
All-cause Death  
at 30 Days

Freedom From  
Stroke at  
30 Days

Freedom From  
Death or Stroke  
at 30 Days

**80 – 89 yrs**  
n = 59,470

**97.9%**

**98.1%**

**96.3%**

**70 – 79 yrs**  
n = 56,025

**98.6%**

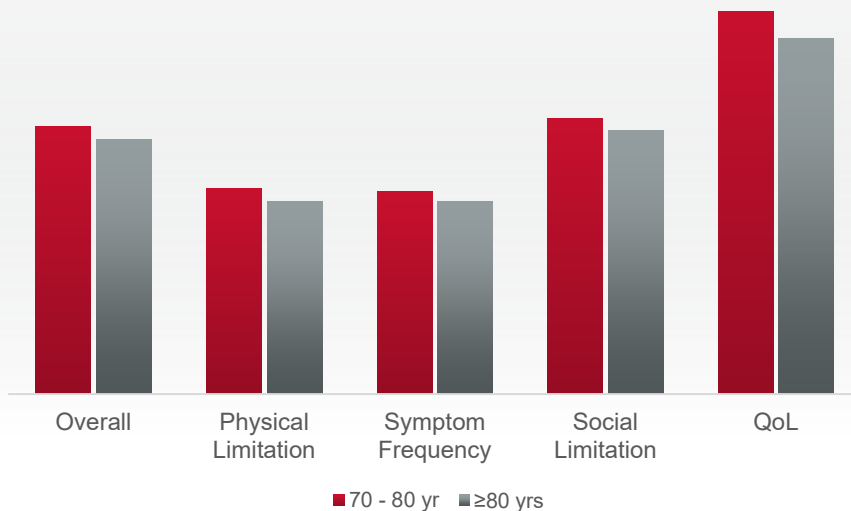
**98.5%**

**97.2%**

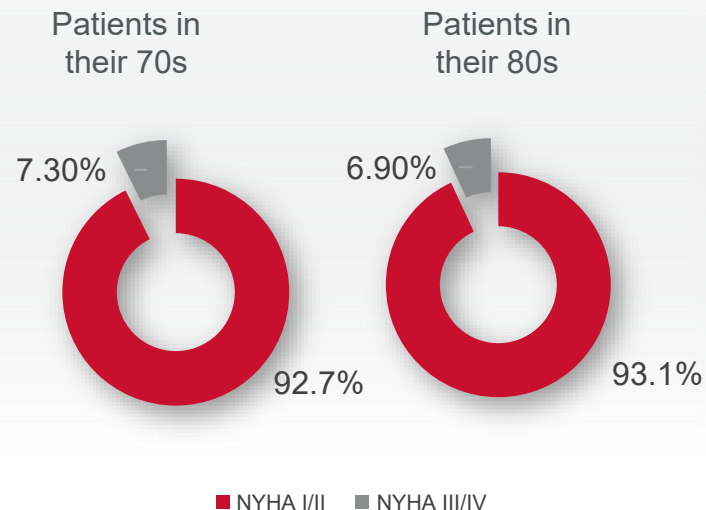


# After TAVR, QoL in 80+ year old patients improves as much as QoL of patients in their 70s

## Change in KCCQ (Baseline to 1 Year)

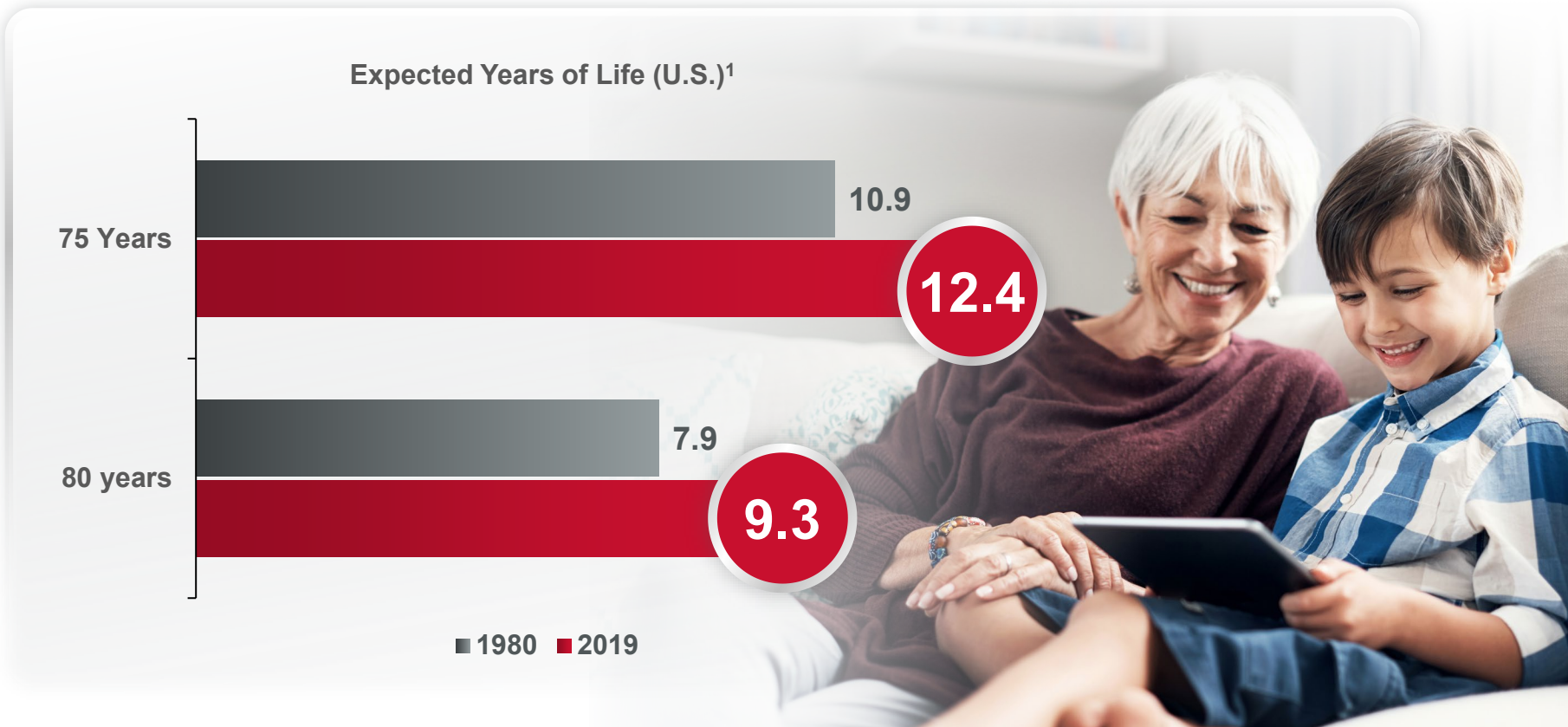


## NYHA Class at 1 Year



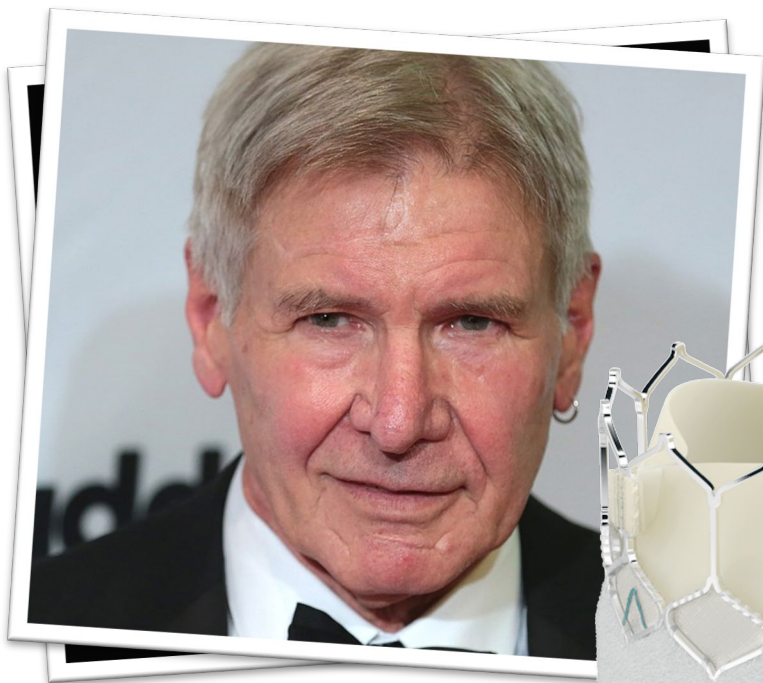


# Elderly patients are living longer



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

# This is What 80 Looks Like...



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

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

BY JONATHAN FUGE  
PUBLISHED 5 DAYS AGO



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



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



**healthgrades**

**Dr. Jenny Smith, MD**  
Age 47 | Interventional Cardiology | F

★★★★★ (11)

1 Edwards Way  
Irvine, CA 92614

Accepting New Patients

(800) 867-5309

Telehealth Services Available

Edwards Lifesciences Corp.

GET DIRECTIONS

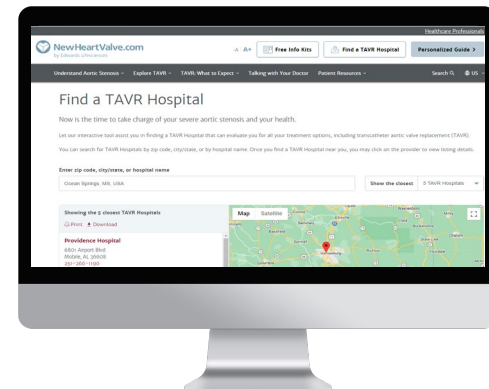
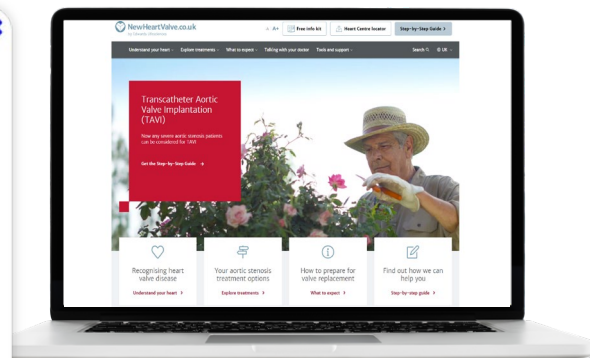
10 INSURANCE ACCEPTED

11 PATIENT REVIEWS

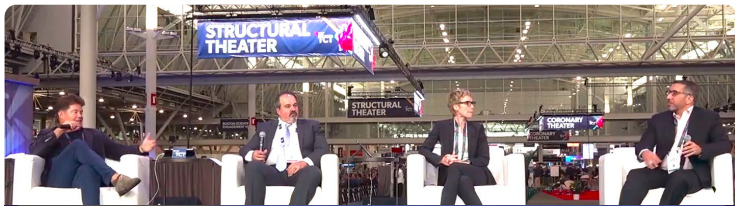
10 - 15 MIN AVG. WAIT TIME

2 BOARD CERTIFICATIONS

View the full profile on healthgrades.com



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



Original Broadcast: September 18, 2022

## Treatment of Aortic Stenosis by age in the US: Evidence of institutional ageism

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



American Heart Association.

## Target: Aortic Stenosis™

### Aortic Stenosis Resources

Whether you've only begun experiencing symptoms or you're preparing for a valve replacement, find the information you need to take control of your health.



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

Patients in their 80's have as favorable TAVR outcomes as those in their 70's

	Freedom from all cause death at 30 days	Freedom from stroke at 30 days	Freedom from death or stroke at 30 days
<b>80 – 89 yrs</b> n = 59,470	97.9%	98.1%	96.3%
<b>70 – 79 yrs</b> n = 56,025	98.6%	98.5%	97.2%



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

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

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



American Heart Association.

Target: Aortic Stenosis™

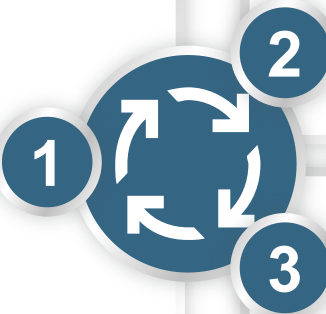
**80**

**hospitals  
in next  
3 years**



## Hospital Systems

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



## HCPs

Professional education



## Patients

Awareness & engagement



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

Website: [www.heart.org/TargetAS](http://www.heart.org/TargetAS)

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

The collage features several key elements:

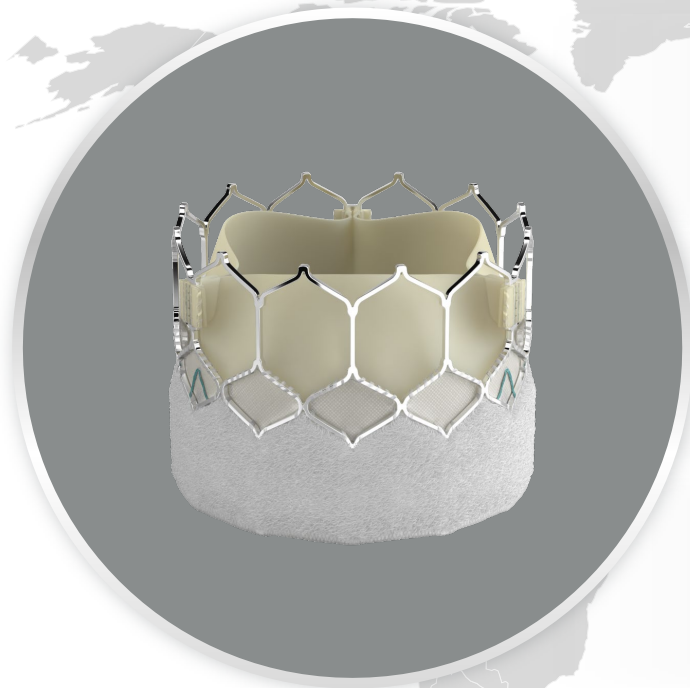
- Top Row:** A laptop displaying the NewHeartValve.com website with the headline "My best life starts now" and a woman's portrait. To its right, a tablet shows "Advances in Aortic Stenosis" with a doctor's image and a "Find a Specialist Who Performs TAVR" button. Further right, a monitor displays a Japanese medical conference with speakers and a "VIVID" logo.
- Left Side:** A tablet shows a Healthgrades profile for Dr. Jenny Smith, MD, an Interventional Cardiologist at Edwards Way. Below it is a photo of a woman speaking at a podium.
- Center:** A laptop displays the "Find a TAVR Hospital" page on NewHeartValve.com, including a map and hospital details.
- Bottom Row:** A monitor shows a Japanese website for "大動脈弁狭窄症" (Aortic Stenosis) with a "診断と治療" (Diagnosis and Treatment) section. To its right is a photo of an elderly couple embracing. Further right, a monitor displays a Japanese medical poster with a heart diagram and text about "大動脈弁狭窄症とは" (What is Aortic Stenosis).
- Bottom Left:** A monitor shows a "Newsweek" article titled "Ninety Will Be the New 40 in 10 Years' Time".
- Bottom Center:** A monitor shows a photo of a woman and a child.

Three prominent red callout boxes are overlaid on the collage, each with a white icon and text:

- Hospital Systems:** Represented by a building icon.
- Patients:** Represented by a person icon with a heart.
- HCPs:** Represented by a doctor icon with a stethoscope.

# Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

## Key Pillars of Our Strategy



Increase Therapy Adoption  
in Growing AS Opportunity



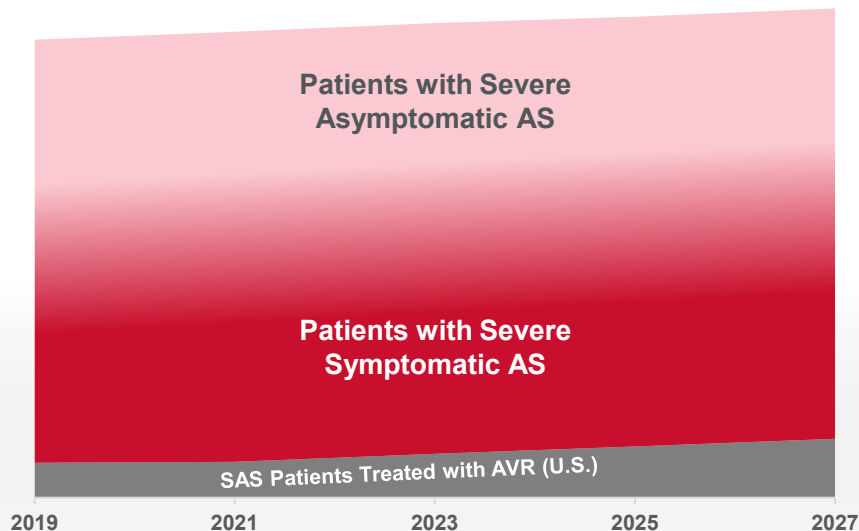
Expand Indications



Deliver Strong  
Portfolio Innovation

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

## Severe AS Opportunity in U.S.

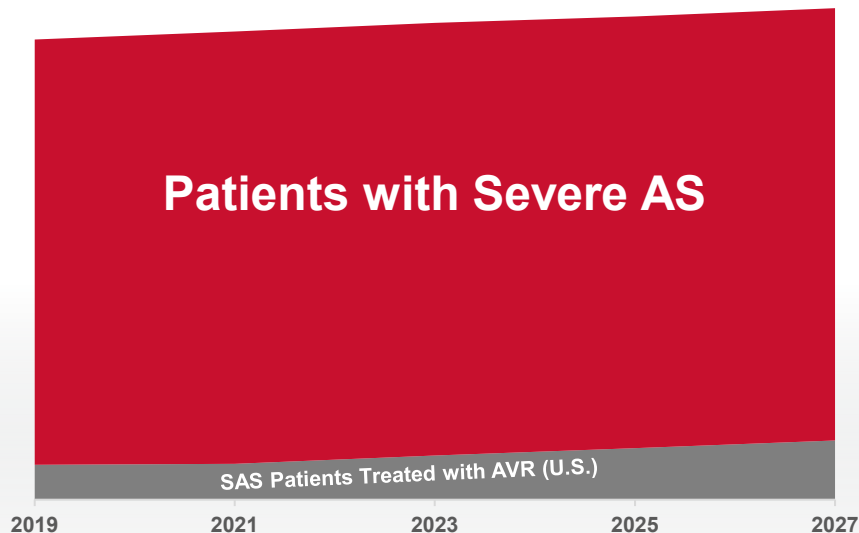


- Significant number of severe AS patients are **perceived** asymptomatic
- Symptoms are unnoticed, ignored, or associated with general aging
- Providers fail to elicit symptoms in patients during office visit



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

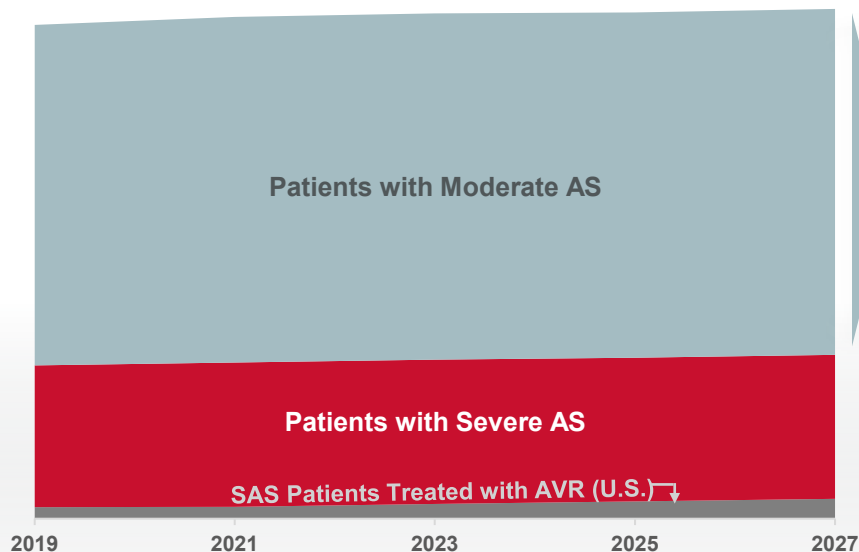
### Severe AS Opportunity in U.S.



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

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

## Moderate-to-Severe AS Opportunity in U.S.



**2:1**

Ratio of  
Moderate to  
Severe AS  
patients<sup>1</sup>



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

# PROGRESS Trial Design



Moderate, calcific AS and appropriate anatomy for transfemoral TAVR

1:1 Randomization (n = 750)

**TAVR**  
(SAPIEN 3/ SAPIEN 3 Ultra System)

Clinical surveillance

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

**Primary endpoint**  
Death, stroke and unplanned CV<sup>2</sup> rehospitalization at 2 years

**Follow-up**  
Annually through 10 years

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



Moderate, calcific AS and appropriate anatomy for transfemoral TAVR

1:1 Randomization (n = 750)

TAVR  
(SAPIEN 3/ SAPIEN 3 Ultra System)

Clinical surveillance

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

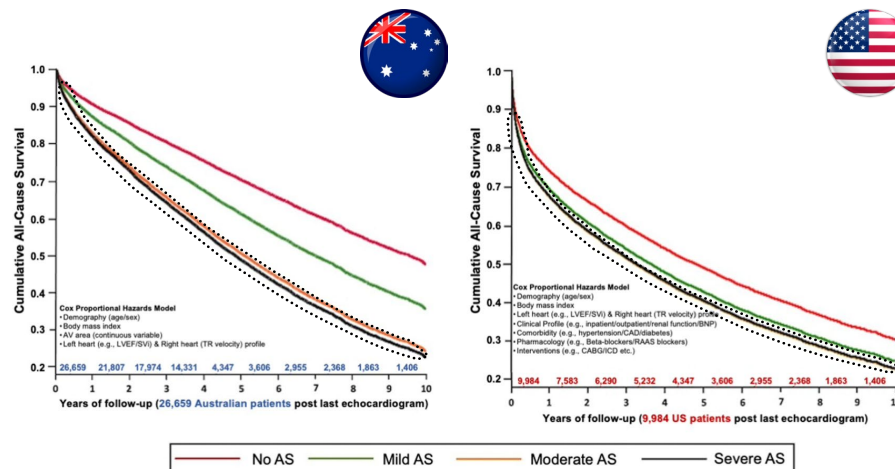
Primary endpoint

Death, stroke and unplanned CV<sup>2</sup> rehospitalization at 2 years

Follow-up

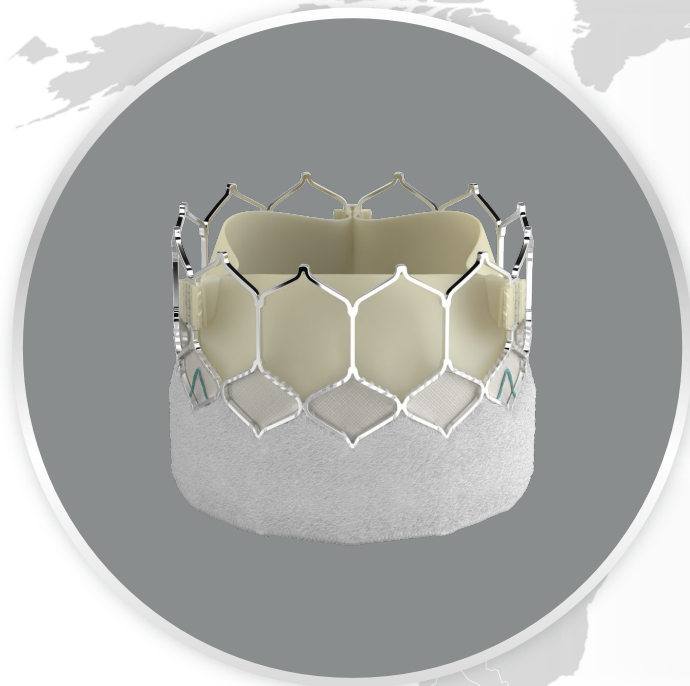
Annually through 10 years

Fully adjusted all-cause mortality according to AS stage<sup>3</sup>



# Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

## Key Pillars of Our Strategy



Increase Therapy Adoption  
in Growing AS Opportunity



Expand Indications



Deliver Strong  
Portfolio Innovation

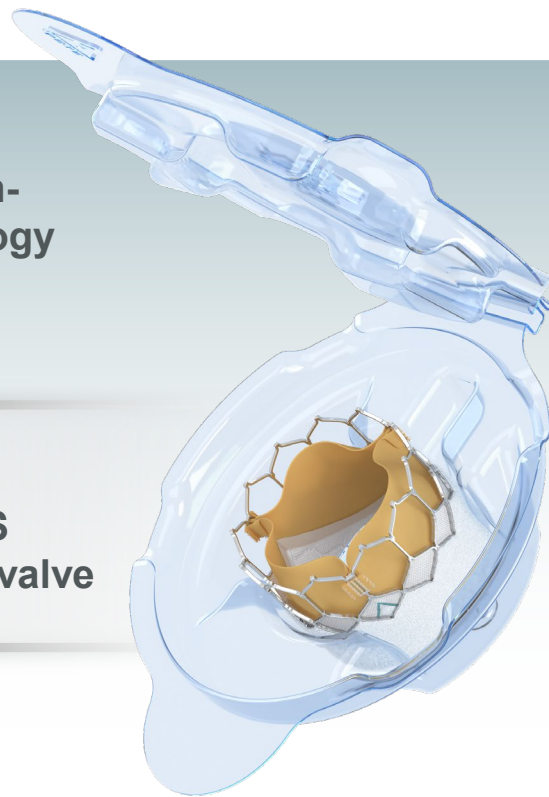
# Our future portfolio further elevates TAVR and the benchmark of lifetime management



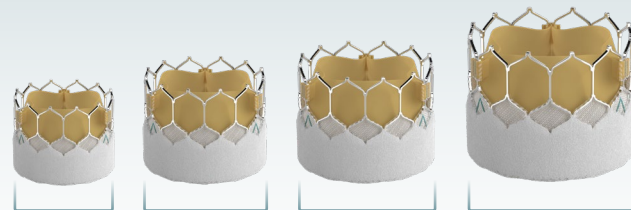
# The first step in further elevating the TAVR therapy is the launch of SAPIEN 3 Ultra RESILIA system

Advanced **calcium-blocking technology**

**RESILIA Tissue:**  
Same as INSPIRIS  
RESILIA surgical valve



The only THV with  
**dry tissue storage**



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

# Our Next Generation Technology: SAPIEN X4 Transcatheter Heart Valve System

Novel Frame and  
Leaflet Design to Enable  
Adjustable Sizing

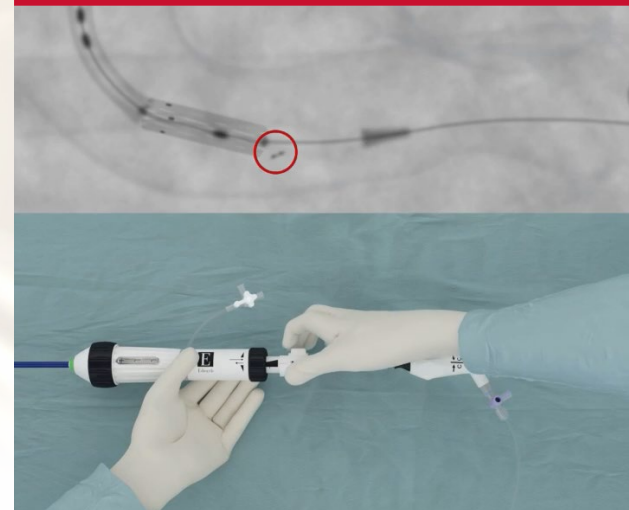
Frame Design to Facilitate  
Future Coronary Access

Advanced PET Outer  
Skirt Technology

RESILIA Tissue



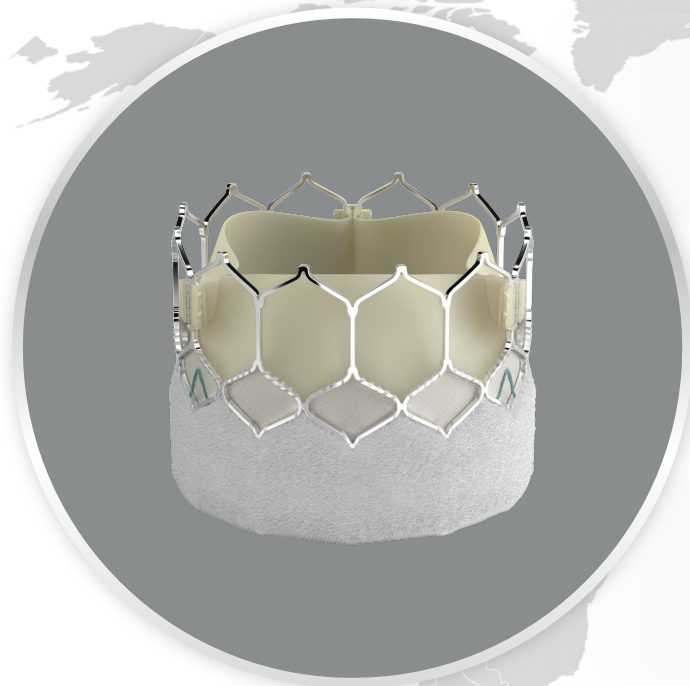
Advanced Delivery System  
Technology Offers  
Commissural Alignment





# Immediate Challenges are Transient; TAVR Fundamentals Remain Strong

## Key Pillars of Our Strategy



**Increase Therapy Adoption  
in Growing AS Opportunity**



**Expand Indications**



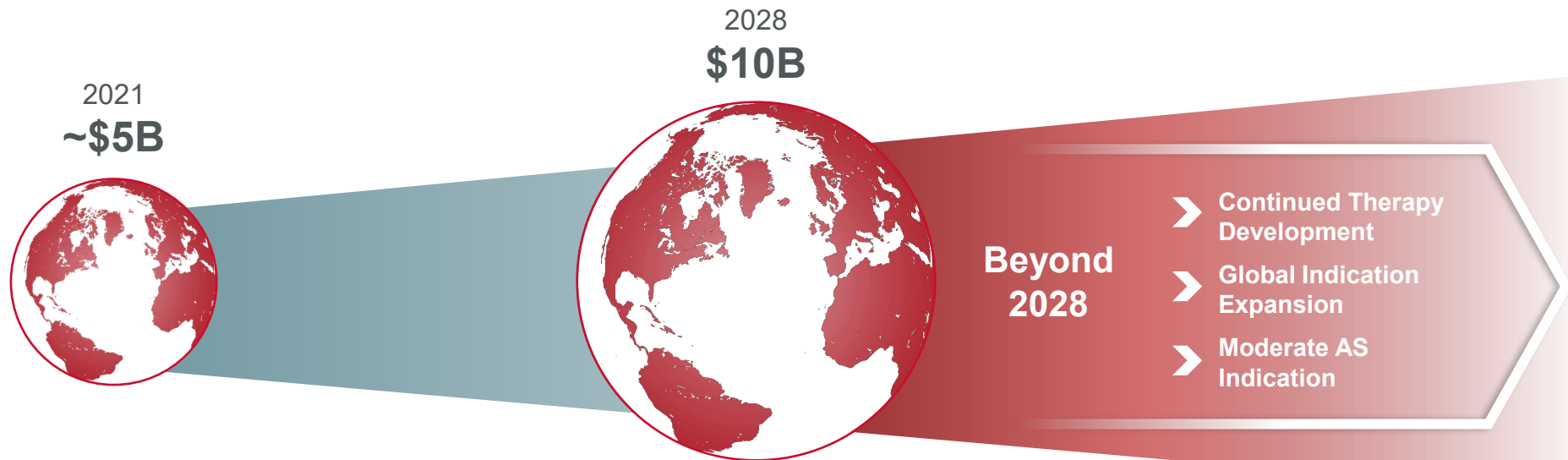
**Deliver Strong  
Portfolio Innovation**

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



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

## And growth drivers beyond the plan horizon remain strong



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

# 2023 Underlying Global Sales Growth Outlook

## Headwinds



Ongoing healthcare staffing recovery



COVID uncertainties

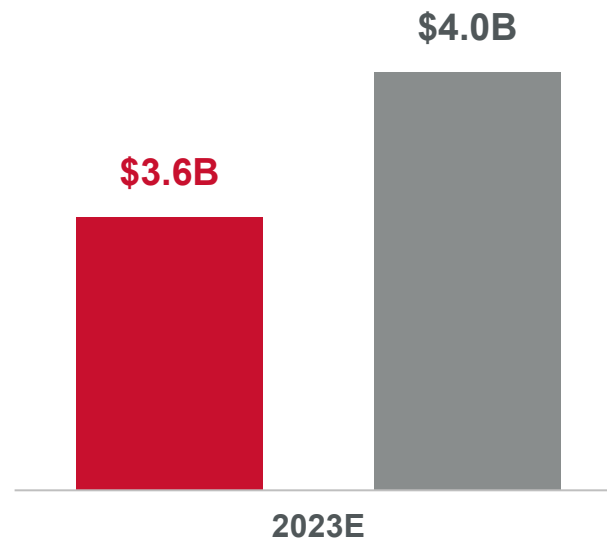
## Tailwinds



Increasing therapy adoption in a rapidly growing elderly population



Potential patient backlog



Underlying **Global TAVR** Estimated Sales Growth **9 – 12%**

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

**Indications:** The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve system is indicated for relief of aortic stenosis in 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, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA 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 or the storage solution does not completely cover the valve (SAPIEN 3 and SAPIEN 3 Ultra only), 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 (SAPIEN 3 and SAPIEN 3 Ultra only), 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. As compared to SAPIEN 3, system advancement force may be higher with the use of SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA THV in tortuous/challenging vessel anatomies. 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 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; access characteristics that would preclude safe placement of the Edwards sheath, such as severe obstructive calcification or severe tortuosity; 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 SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestant**

**Indications:** The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestant is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation as measured by echocardiography who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for pulmonary valve replacement.

**Contraindications:** The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestant is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

**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. The physician must verify correct orientation of the valve prior to its implantation; the inflow (outer skirt end) of the valve should be oriented towards the proximal end (handle) of the delivery system to prevent the risk of severe patient harm. 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. 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 the expiration date has elapsed. Do not add or apply antibiotics to the storage solution, rinse solutions or to the valve.

**Precautions:** Long-term durability has not been established for the device. Regular medical follow-up is advised to evaluate device performance. Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials may have an allergic reaction to these materials. Accelerated deterioration of the valve may occur in patients with an altered calcium metabolism. Assessment for coronary compression risk prior to implantation is recommended. Patient venous anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device. 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. Fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. Patient radiation dose should be monitored during the procedure. 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 Material Safety Data Sheet available from Edwards Lifesciences. Patient should be heparinized to maintain the ACT at  $\geq 250$  sec prior to introduction of the delivery system in order to prevent thrombosis. To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon. Device 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 antiplatelet therapy. It is recommended that all device recipients be prophylactically treated for endocarditis to minimize the possibility of prosthetic valve infection. Correct sizing of the prestant into the RVOT is essential to minimize risks such as paravalvular leak, migration, embolization, and/or RVOT rupture. If a prestant fracture is detected with significant loss in valve functionality, reintervention should be considered. Safety and effectiveness have not been established for patients with the following characteristics/comorbidities: blood dyscrasias defined as: leukopenia, acute anemia, thrombocytopenia, or history of bleeding diathesis or coagulopathy; a known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated; positive urine or serum pregnancy test in female patients of childbearing potential.

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

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

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#### **Edwards SAPIEN 4 Transcatheter Heart Valve System**

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

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

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Edwards





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

# Mitral / Tricuspid disease is common, complex, and undertreated

## Transcatheter therapies can revolutionize patient care

# 4 Million+

U.S. patients with  $\geq$  moderate-to-severe Mitral / Tricuspid Disease

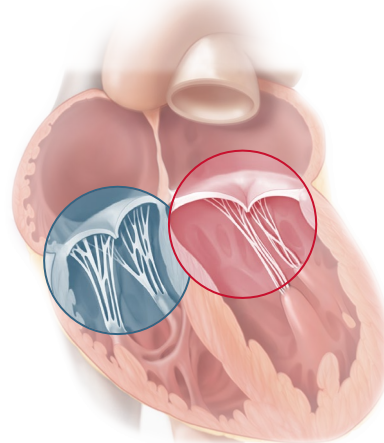
### TRICUSPID

**30 – 45%**

MORTALITY  
of moderate or severe  
TR at 1 year<sup>2</sup>

**<1%**

INTERVENTION<sup>1</sup>



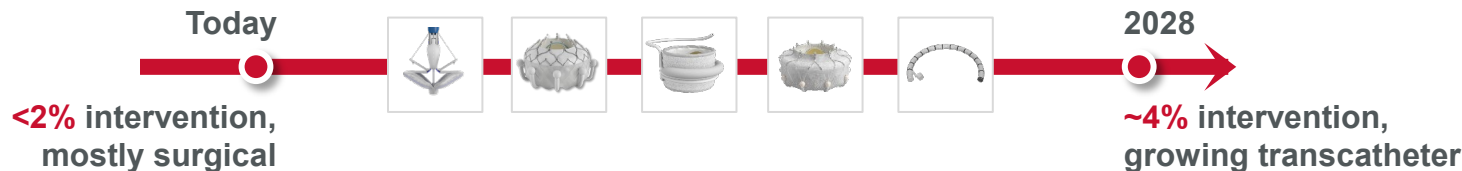
### MITRAL

**~20%**

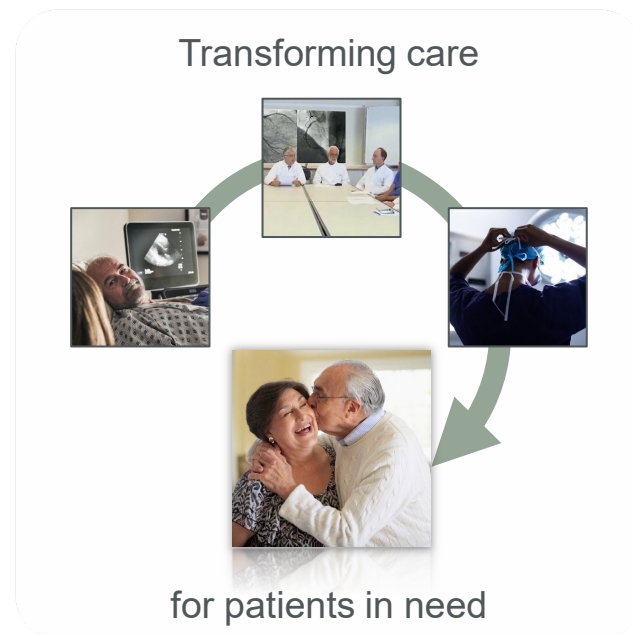
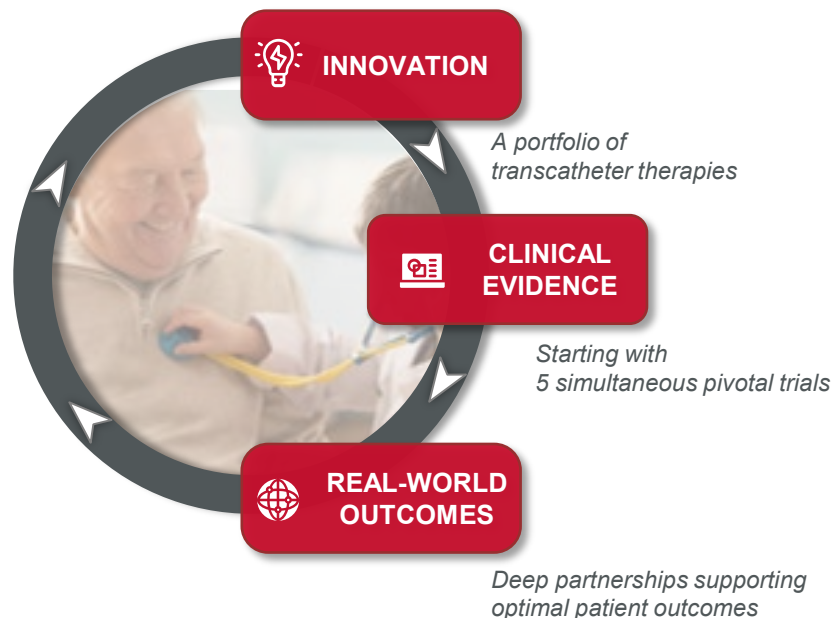
MORTALITY  
of  $\geq$  moderate-to-severe  
MR at 1 year<sup>3</sup>

**<3%**

INTERVENTION<sup>1</sup>

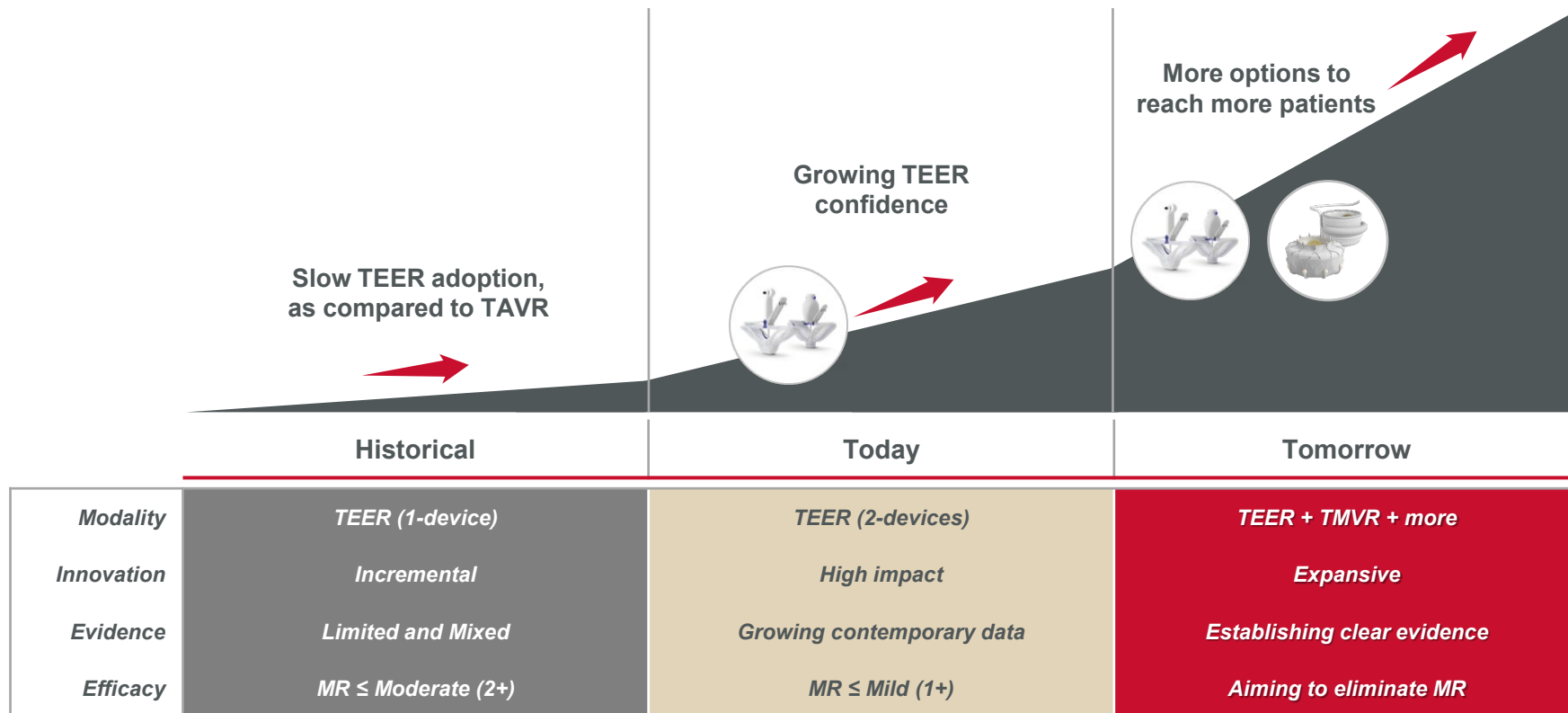


# Our bold vision to transform patient care is enabled by three key value drivers



Growing adoption drives a projected  
\$5B Global Transcatheter Mitral and Tricuspid Market by 2028

# Advancements in transcatheter therapies are driving a paradigm shift in the treatment of mitral disease



# PASCAL Precision system delivers new Mitral treatment options

## Committed to ongoing innovation to further elevate TEER

Early commercial experience with PASCAL Precision system suggests:



Faster procedures



Enhanced patient outcomes

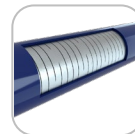
Atraumatic  
Clasp & Closure



Versatile Implant  
Configuration



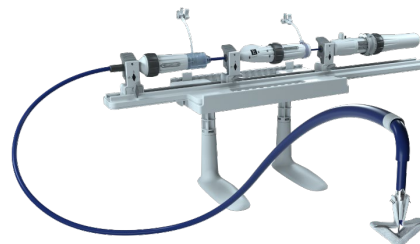
Accurate,  
Intuitive Control



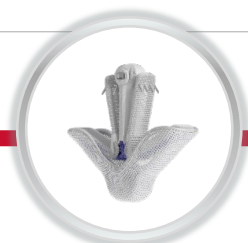
PMA Approval



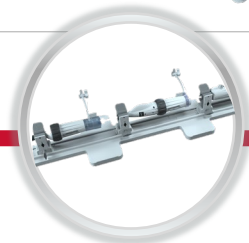
CE Mark



PASCAL  
System  
2018



PASCAL Ace  
Implant  
2020

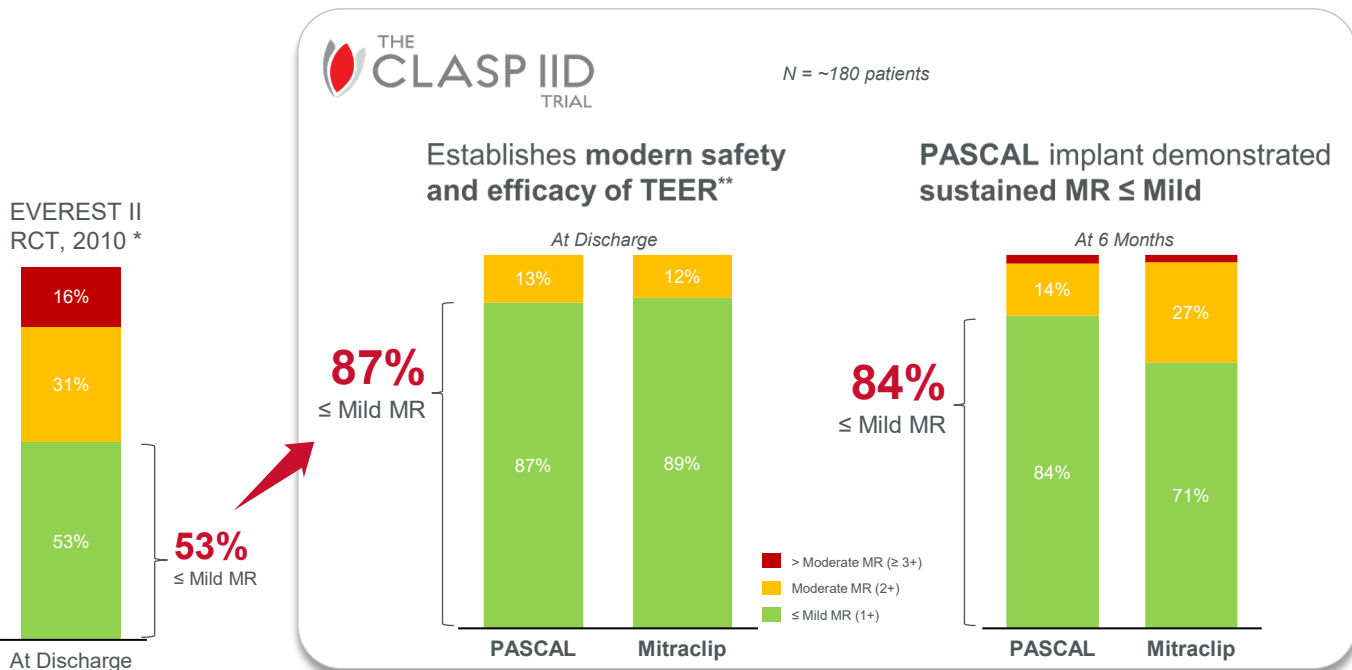


PASCAL Precision  
System  
2022



PASCAL System  
*Next Generation*

# TMTT is advancing Mitral TEER therapy with positive randomized clinical data on patients with degenerative disease



**THE CLASP IID TRIAL** | **THE CLASP IIF TRIAL**

**Ongoing commitment to evidence**

**2023  
Milestone**

**Present CLASP IID trial full 300 patient cohort with 1-year follow-up in 2023**

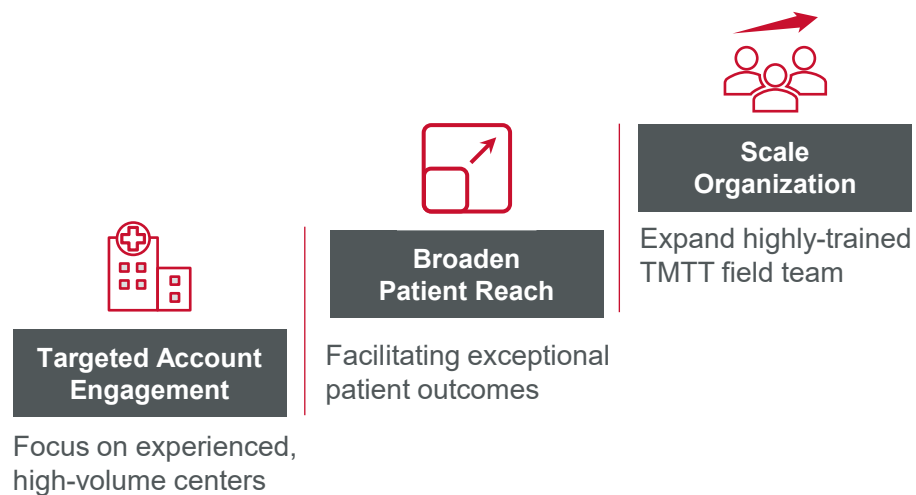
# The U.S. launch of PASCAL Precision system focuses on achieving exceptional patient outcomes with TMTT's high-touch model

## High-Touch Model



**Establishes TMTT as trusted partners and promotes consistently positive patient outcomes**

## Expanding U.S. Launch



2023  
Milestone

**Anticipate growing our presence in large centers, with positive patient outcomes and premium pricing, throughout 2023**



# Anticipate safe and effective Transfemoral Mitral Valve Replacement to complement TEER, expand mitral treatment options

Transcatheter mitral replacement offers distinct potential advantages

➤ Elimination of Mitral Regurgitation

➤ Consistent Outcomes

➤ Expanded Treatable Population

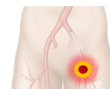
Not all transcatheter systems are equal...

**Access Site Matters**



Transapical

- Surgical procedure



Transfemoral

+ Less bleeding  
+ Less impact to sick left ventricles  
+ Faster recovery

And not all transfemoral systems are equal...

**Transfemoral Sheath Size Matters**

>30 Fr  
Large Profile

- Surgical cutdown  
- Could damage atrial septum

<30 Fr  
Low Profile\*

+ Percutaneous  
+ Less need for septal closure  
+ Fewer vascular complications

**Transfemoral, low-profile delivery is key to the growth of TMVR**

# Edwards is committed to leading Mitral Replacement, currently advancing 2 transfemoral, <30 Fr systems

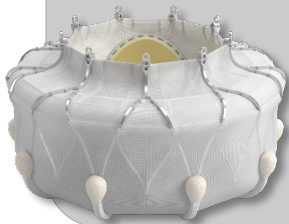
## SAPIEN M3 Device

- Leverages proven SAPIEN 3 platform
- Recapturable, repositionable dock



## EVOQUE Eos Device

- Designed specifically for the Mitral position
- Recapturable, repositionable valve



Patients with Symptomatic,  $\geq 3+$  MR deemed unsuitable for commercial treatment options

Main Cohort  
(n= up to 300)

Failed TEER Registry  
(n = up to 100)

MAC Registry  
(n= up to 100)

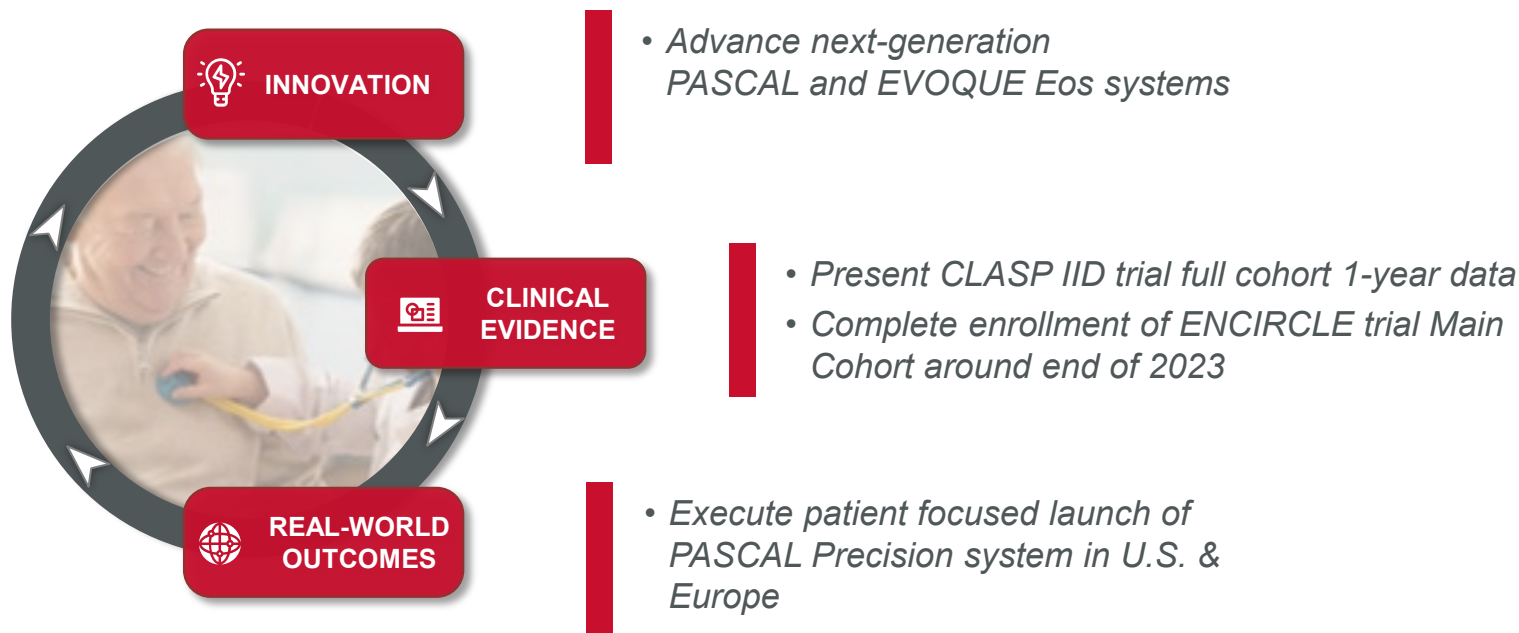
Primary Endpoint:  
Death & HF Re-hospitalization at 1-year

Follow-up: discharge, 30 days, 6 months, 1 year and annually through 5 years

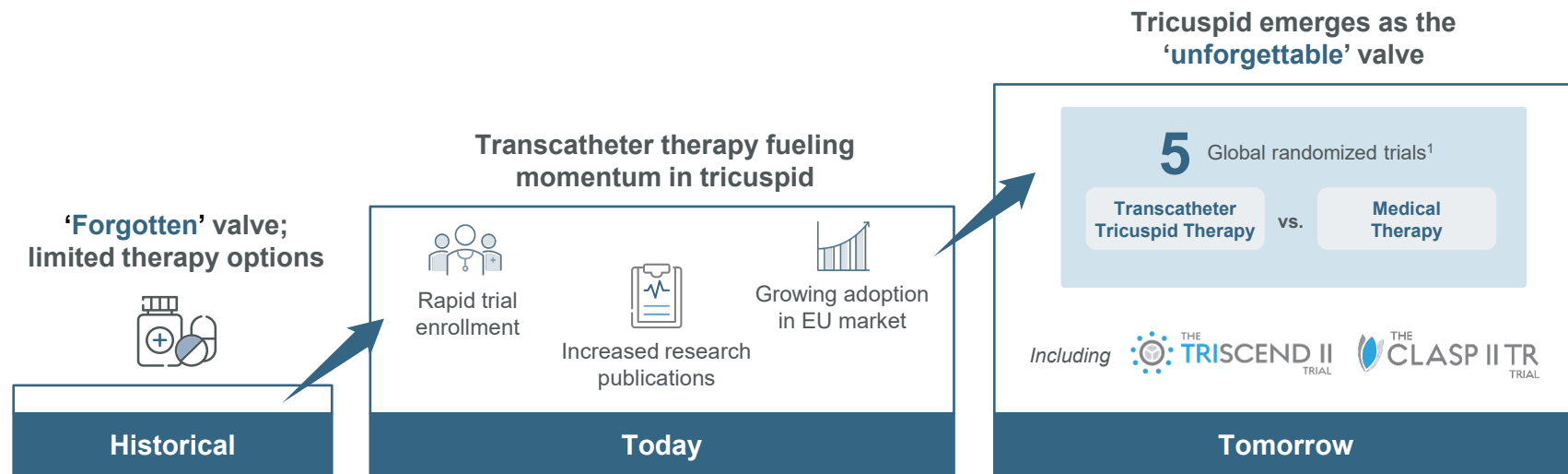
2023  
Milestone

Complete enrollment of ENCIRCLE trial  
Main Cohort around end of 2023

# Near-term milestones extend transcatheter therapy to more Mitral patients in 2023 and beyond



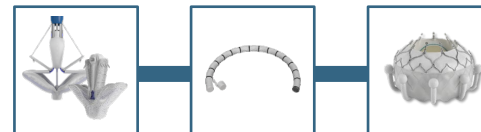
# Growing experience reinforces that Tricuspid Regurgitation is a significant patient need, addressable with transcatheter therapies



Edwards is poised to lead with largest breadth of experience...

# 3,000+

patients treated across TMTT's Tricuspid Portfolio



...and most comprehensive portfolio

# PASCAL Precision system enables clinicians to treat TR patients with confidence

THE  
TriCLASP  
STUDY

THE  
CLASP TR  
STUDY

THE  
CLASP II TR  
TRIAL

2022  
PCR  
london valves

Positive outcomes in **real-world study** of 177 patients with 6-months follow-up <sup>1</sup>

**99%**

Successful  
Implant rate

**4%**

Major Adverse  
Events at  
6-months

**High procedural success  
and low complication rates**



Reduced  
symptoms



Improved daily  
function

**Patients returning home  
with improved quality-of-life**

**Versatility of PASCAL Precision system  
enables tailored therapy in tricuspid anatomy**

*Preserve Integrity*  
of Thin Leaflets

*Spacer bridges*  
Large Coaptation  
Gaps

*Navigate*  
Dense Chordae

# Early EVOQUE device outcomes are setting the standard for Transcatheter Tricuspid Replacement



Excellent survival and symptom improvement at 1-year <sup>1</sup>



**90%**

Survival at 1-year

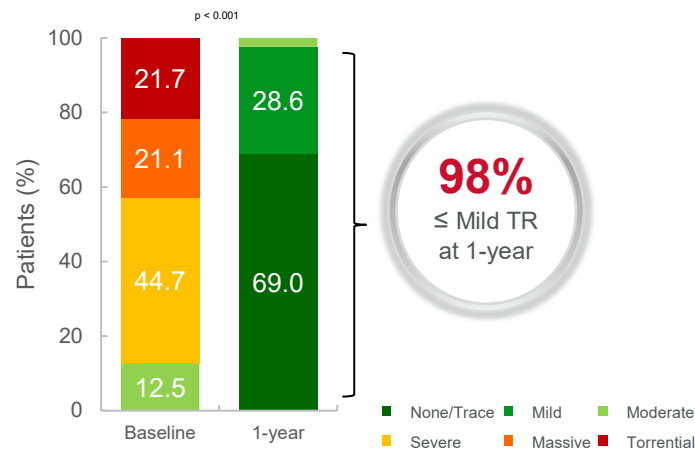
**91%**

Discharged Home

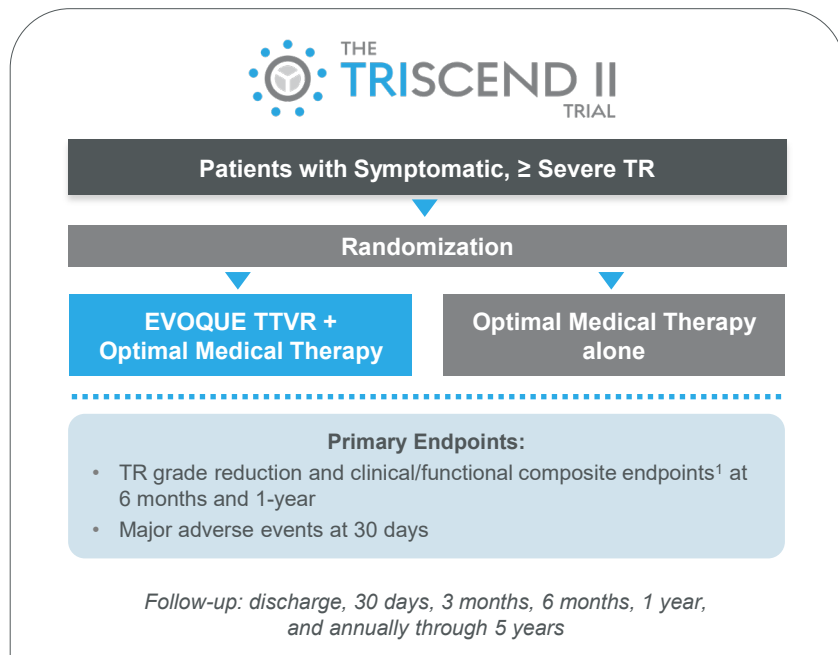
**93%**

NYHA I/II at 1-year

Substantial TR reduction <sup>1</sup>

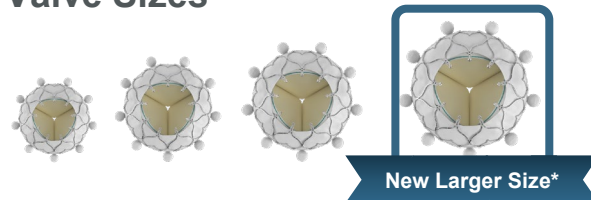


# TRISCEND II trial continues enrolling well, putting the EVOQUE system on track for a U.S. approval around the end of 2024

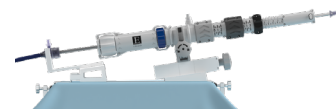


EVOQUE system builds on 60+ years of Edwards innovation in tissue technology and valve design

## 4 Valve Sizes



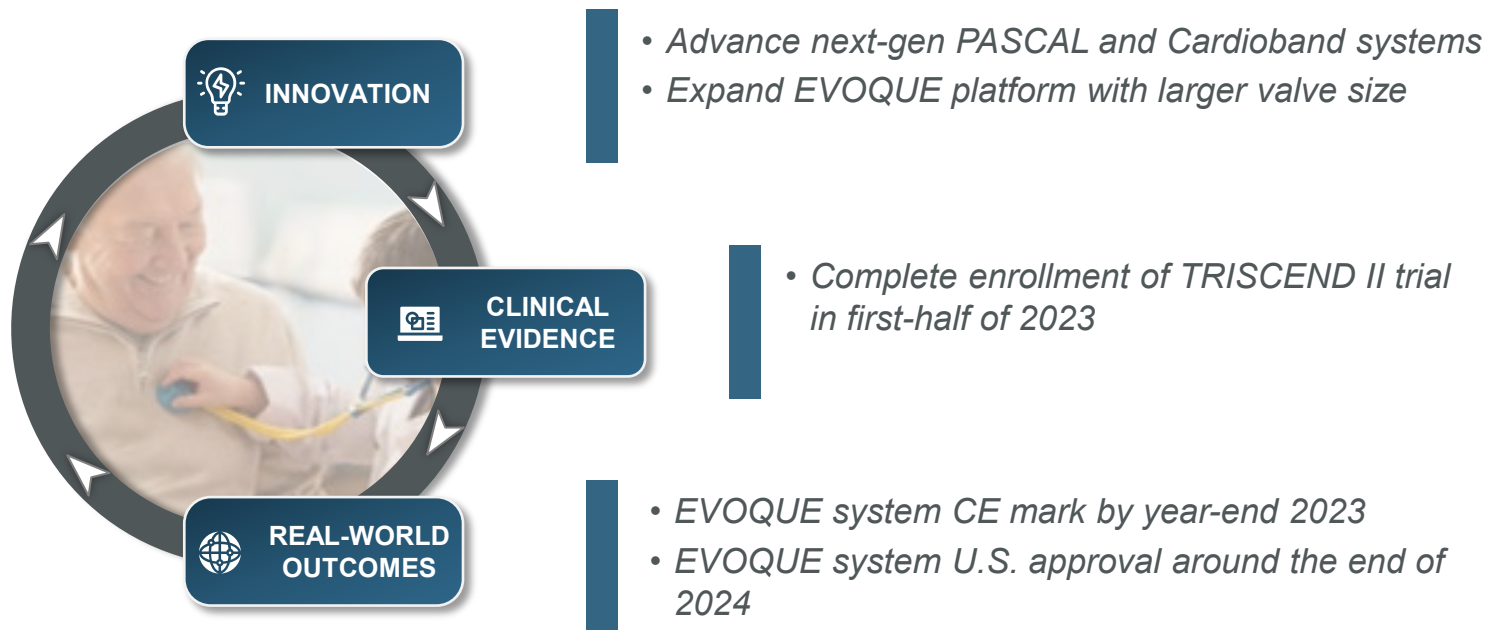
<30Fr transfemoral delivery system



2023 / 2024  
Milestones

- Complete enrollment of TRISCEND II trial in first-half of 2023
- EVOQUE system CE Mark by year-end 2023 and U.S. approval around end of 2024

# TMTT continues to extend transcatheter therapy to more patients with Tricuspid valve disease in 2023 and beyond





# 2023 Global Sales Outlook

## Headwinds



Evolving EU regulatory environment



Hospital staffing recovery and COVID uncertainty

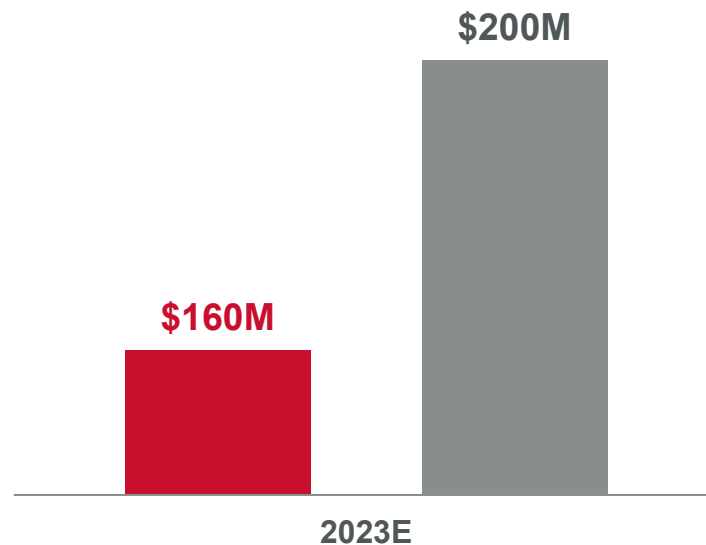
## Tailwinds



Robust evidence across the TMTT portfolio, driving accelerated therapy adoption



Stronger recovery of Mitral market growth



# Near-term milestones advance TMTT's vision of transforming Mitral and Tricuspid patient care



## INNOVATION

- Advance next-generation of PASCAL & Cardioband systems
- Expand the EVOQUE platform with larger valve size
- Increase clinical experience with EVOQUE Eos system



## CLINICAL EVIDENCE

- Present CLASP IID trial full cohort data: *2023*
- Complete enrollment of TRISCEND II trial: *First-half 2023*
- Complete enrollment of ENCIRCLE trial main cohort: *Around the end of 2023*



## REAL-WORLD OUTCOMES

- Execute patient focused launch of PASCAL Precision system
- EVOQUE system CE Mark: *By year-end 2023*
- EVOQUE system U.S. approval: *Around the end of 2024*

**4 Million+**

US patients with significant Mitral / Tricuspid Disease

Today

**<2% intervention,  
mostly surgical**

2028

**~4% intervention,  
growing transcatheter**

**Important Safety Information: Edwards PASCAL Precision Transcatheter Valve Repair System**

**Indications:** The PASCAL Precision Transcatheter Valve Repair System (the PASCAL Precision system) is indicated for the percutaneous reduction of significant, symptomatic mitral regurgitation (MR  $\geq 3+$ ) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR.

**Contraindications:** The PASCAL Precision system is contraindicated in patients with the following conditions: patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen; untreatable hypersensitivity or contraindication to nitinol alloys (nickel and titanium) or contrast media; active endocarditis of the mitral valve; rheumatic etiology for mitral regurgitation; evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.

**Warnings:** The devices are designed, intended, and distributed for single use only. There are no data to support the sterility, non-pyrogenicity, and functionality of the devices after reprocessing. Devices should be handled using standard sterile technique to prevent infection. Do not expose any of the devices to any solutions, chemicals, etc., except for the sterile physiological and/or heparinized saline solution. Irreparable damage to the device, which may not be apparent under visual inspection, may result. Do not use any of the devices in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants. Do not use the devices if the expiration date has elapsed. Do not use if the packaging seal is broken or if the packaging is damaged for sterile devices. Do not use if any of the devices were dropped, damaged or mishandled in any way. Standard flushing and de-airing technique should be used during preparation and throughout procedure to prevent air embolism.

As with any implanted medical device, there is a potential for an adverse immunological response. Serious adverse events, sometimes leading to surgical intervention and/or death, may be associated with the use of this system ("Potential Adverse Events"). A full explanation of the benefits and risks should be given to each prospective patient before use. Careful and continuous medical follow-up is advised so that implant-related complications can be diagnosed and properly managed. Anticoagulation therapy must be determined by the physician per institutional guidelines.

**Precautions:** Prior to use, patient selection should be performed by a heart team to assess patient risk and anatomical suitability. After use, short-term anticoagulation therapy may be necessary after valve repair with the PASCAL Precision system. Prescribe anticoagulation and other medical therapy per institutional guidelines.

**Potential Adverse Events:** Below is a list of the potential adverse effects (e.g., complications) associated with the use of the PASCAL Precision system: death, abnormal lab values; allergic reaction to anesthetic, contrast, heparin, Nitinol; anemia or decreased hemoglobin (may require transfusion); aneurysm or pseudoaneurysm; angina or chest pain; anaphylactic shock; arrhythmias - atrial (i.e. atrial fibrillation, Supraventricular tachycardia); arrhythmias - ventricular (i.e. ventricular tachycardia, ventricular fibrillation); arterio-venous fistula; atrial septal injury requiring intervention; bleeding; cardiac arrest; cardiac failure; cardiac injury, including perforation; cardiac tamponade/pericardial effusion; cardiogenic shock; chordal entanglement or rupture that may require intervention; coagulopathy, coagulation disorder, bleeding diathesis; conduction system injury which may require permanent pacemaker; deep vein thrombosis (DVT); deterioration of native valve (e.g. leaflet tearing, retraction, thickening); dislodgement of previously deployed implant; dyspnea; edema; electrolyte imbalance; emboli/embolization including air, particulate, calcific material, or thrombus; endocarditis; esophageal perforation or stricture; exercise intolerance or weakness; failure to retrieve any PASCAL Precision system components; fever; gastrointestinal bleeding or infarct; heart failure; hematoma; hemodynamic compromise; hemolysis; hemorrhage requiring transfusion or intervention; hypertension; hypotension; implant deterioration (wear, tear, fracture, or other); implant embolization; implant malposition or failure to deliver to intended site; implant migration; implant thrombosis; infection; inflammation; LVOT obstruction; mesenteric ischemia; multi-system organ failure; myocardial infarction; native valve injury; native valve stenosis; nausea and/or vomiting; need for open surgery (conversion, emergent or nonemergent reoperation, explant), nerve injury neurological symptoms, including dyskinesia, without diagnosis of TIA or stroke; non-neurological thromboembolic events; pain; papillary muscle damage; paralysis; PASCAL Precision system component(s) embolization; peripheral ischemia; pleural effusion; pulmonary edema; pulmonary embolism; reaction to anti-platelet or anticoagulation agents; renal insufficiency; respiratory compromise, respiratory failure, atelectasis, pneumonia - may require prolonged ventilation; retroperitoneal bleed; septal damage or perforation; septicemia, sepsis; skin burn, injury or tissue changes due to exposure to ionizing radiation; single leaflet device attachment (SLDA); stroke; syncope; transient ischemic attack (TIA); urinary tract infection; and/or bleeding; valvular regurgitation; vascular injury or trauma, including dissection or occlusion; vessel spasm; ventricular wall damage or perforation; worsening native valve regurgitation / valvular insufficiency; worsening of heart failure; wound dehiscence, delayed or incomplete healing.

**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.**

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

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#### **SAPIEN M3 Transcatheter Heart Valve System**

**CAUTION – Investigational Device. 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.**

--

#### **The Edwards EVOQUE Eos System, and the Edwards Cardioband System**

**CAUTION – Investigational Device. Limited by Federal (United States) law to investigational use. These devices are not available for marketing or commercial sale.**

--

#### **Edwards PASCAL Precision Transcatheter Valve Repair System**

**CAUTION – Investigational Device. Limited by Federal (USA) law to investigational use. The device is not available for marketing or commercial sale for the treatment of tricuspid regurgitation.**

Edwards, Edwards Lifesciences, the stylized E logo, Cardioband, CLASP, ENCIRCLE, the ENCIRCLE logo, EVOQUE, EVOQUE Eos, PASCAL, PASCAL Ace, PASCAL Precision, SAPIEN M3, SAPIEN 3, TRISCEND, and the TRISCEND logo are trademarks of Edwards Lifesciences Corporation or its affiliates. All other trademarks are the property of their respective owners.

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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

# Edwards Surgical Structural Heart is growing by identifying and solving for increasing critical unmet needs in cardiac surgery

- The surgical structural heart market is expected to **grow by mid-single digits to over \$2B** by 2028

---

- As structural heart disease therapy expands, **many patients are best treated surgically**

---

- **Patients requiring cardiac surgery are being prioritized** to receive life-saving interventions



# The surgical structural heart market is growing due to several dynamics around the world

## Macro Trends

- Aging global population
- Growing access and wealth in emerging markets
- New structural heart innovations



**Greater  
Awareness**

**Increased  
Diagnosis**

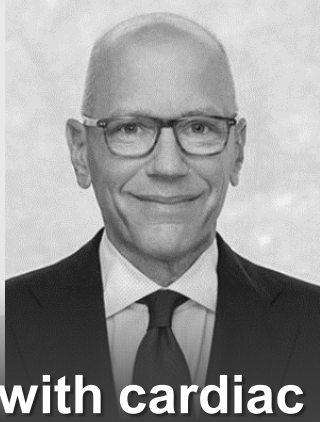
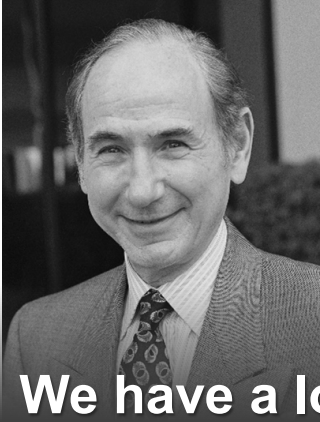
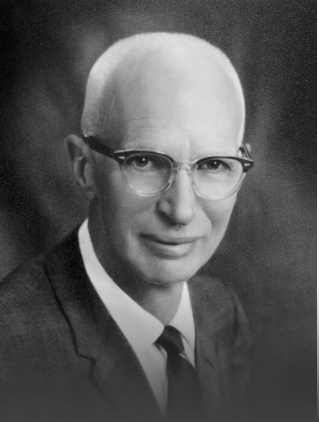


**More Heart  
Team Referrals**

**Growth in  
Surgery**



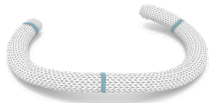




**We have a long history of partnering with cardiac surgeons to drive leading surgical therapies**



**Introduced**  
the First Successful  
Artificial Valve



**Pioneered** Mitral  
& Tricuspid  
Repair



**Led** Bovine  
Pericardial Valve  
Innovation



**Launched** the  
RESILIA Tissue  
Aortic Valve



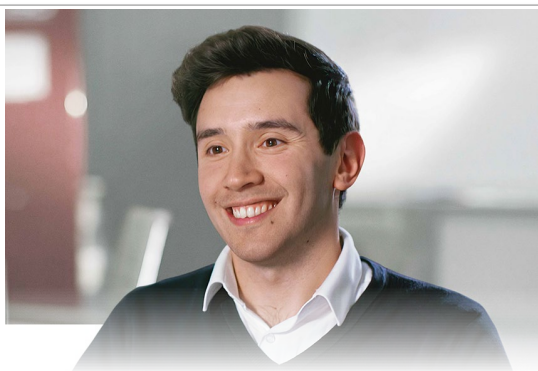
**Developed** the Only  
Pre-Assembled Tissue  
Valved Conduit



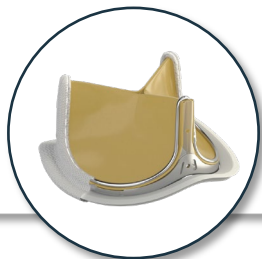
**Expanded** RESILIA  
Tissue to the  
Mitral Valve

**50% of Revenue from Products Launched within the Past Five Years**

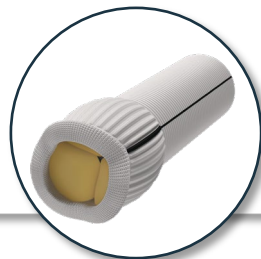
# Our vision is to transform patients' lives through surgical structural heart innovations that address their unmet needs



**Extended Durability & Lifetime Management**



**Solutions for Complex & Concomitant Cases**



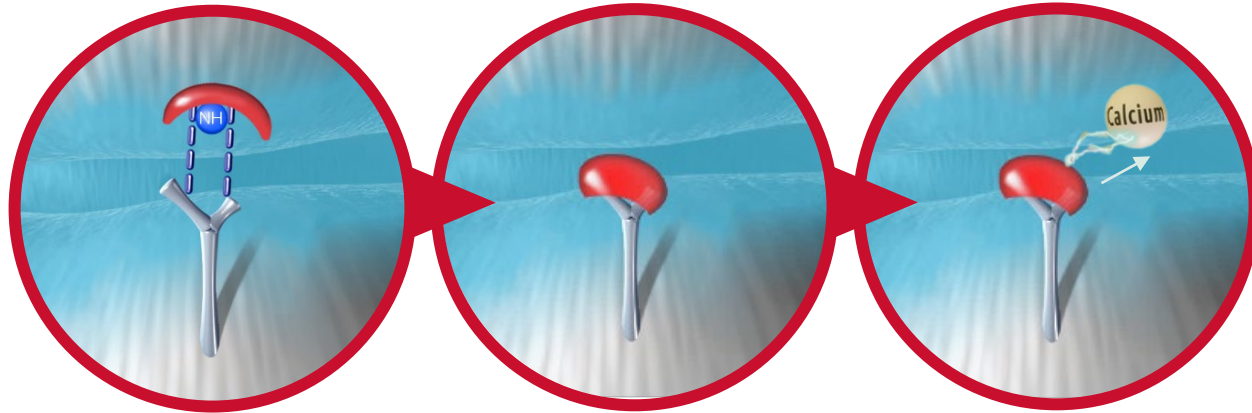
**Global Access to Best-in-Class Innovations**



# Our innovative RESILIA tissue technology is meeting patients' needs for extended valve durability

## Clinical Need

The primary mode of long-term failure for tissue valves is **calcification**



RESILIA tissue's novel capping technology effectively **stops specific calcification formation pathways** to significantly increase valve durability

# Our robust evidence is proving the clear value proposition of RESILIA tissue technology for patients

“

*Having a fully functional valve for the first time in my life has felt amazing. I can't believe the difference it has made.*

”

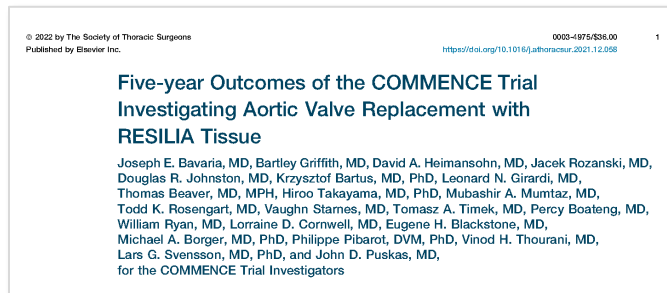


**Daniel Colgan**

INSPIRIS RESILIA Aortic Valve Patient



**Zero cases of structural valve deterioration (SVD)** in pre-market studies of 822 patients at 5-year follow-up



*COMMENCE Aortic Trial Results, Published in the Annals of Thoracic Surgery, 2022*



Generating real-world evidence in **14 post-market studies in over 6,400 patients** with RESILIA tissue around the world

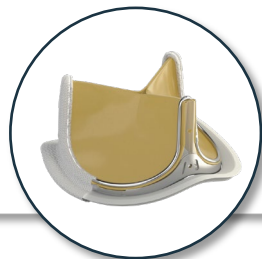
# In 2023, we will achieve two new meaningful RESILIA tissue technology clinical evidence milestones



*Foundational Clinical Evidence on  
RESILIA Tissue Technology*

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**Pivotal 7-Year Data to Be  
Presented in Mid-2023**



*MITRIS valve Global Post-Market Study  
of 500 Patients, 10-Year Follow-Up*

---

**Patient Enrollment to  
Start in Early 2023**



# INSPIRIS valve improves durability and lifetime management for surgical aortic valve replacement (SAVR) patients

- **The leading SAVR valve in the world**, continuing to outpace surgical market growth

---

- Features **RESILIA tissue technology** for extended durability and VFit expandability for TAVR valve-in-valve

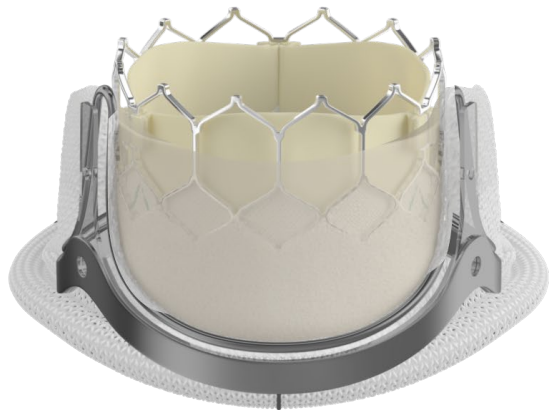
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- INSPIRIS valve is **driving sustained growth** through increasing adoption around the world



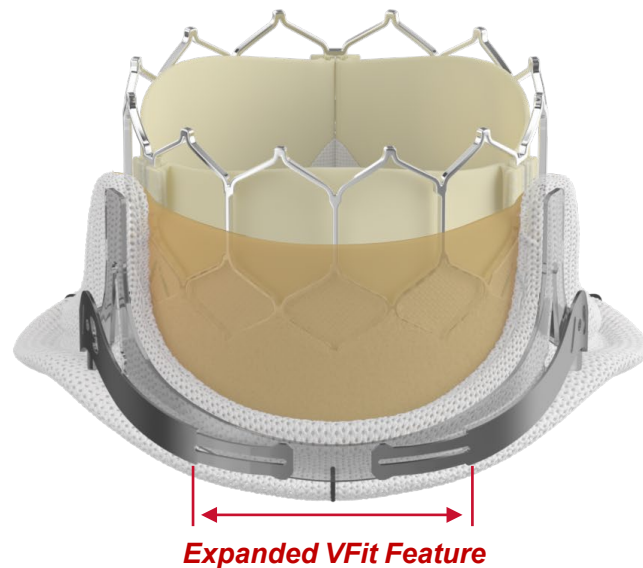
# With the VFit feature, INSPIRIS valve expands for larger TAVR valve-in-valve, leading to better clinical outcomes

Without VFit



**20mm** SAPIEN 3 Platform in a  
21mm Traditional Valve

With VFit



**26mm** SAPIEN 3 Platform in a  
21mm INSPIRIS Valve

# KONECT valved conduit streamlines difficult, complex aortic procedures for both surgeons and patients

- The **leading tissue valved conduit** for cases where the aortic valve, root and ascending aorta are replaced

---

- **RESILIA tissue technology with a pre-assembled design** increases surgeon confidence over alternative solutions

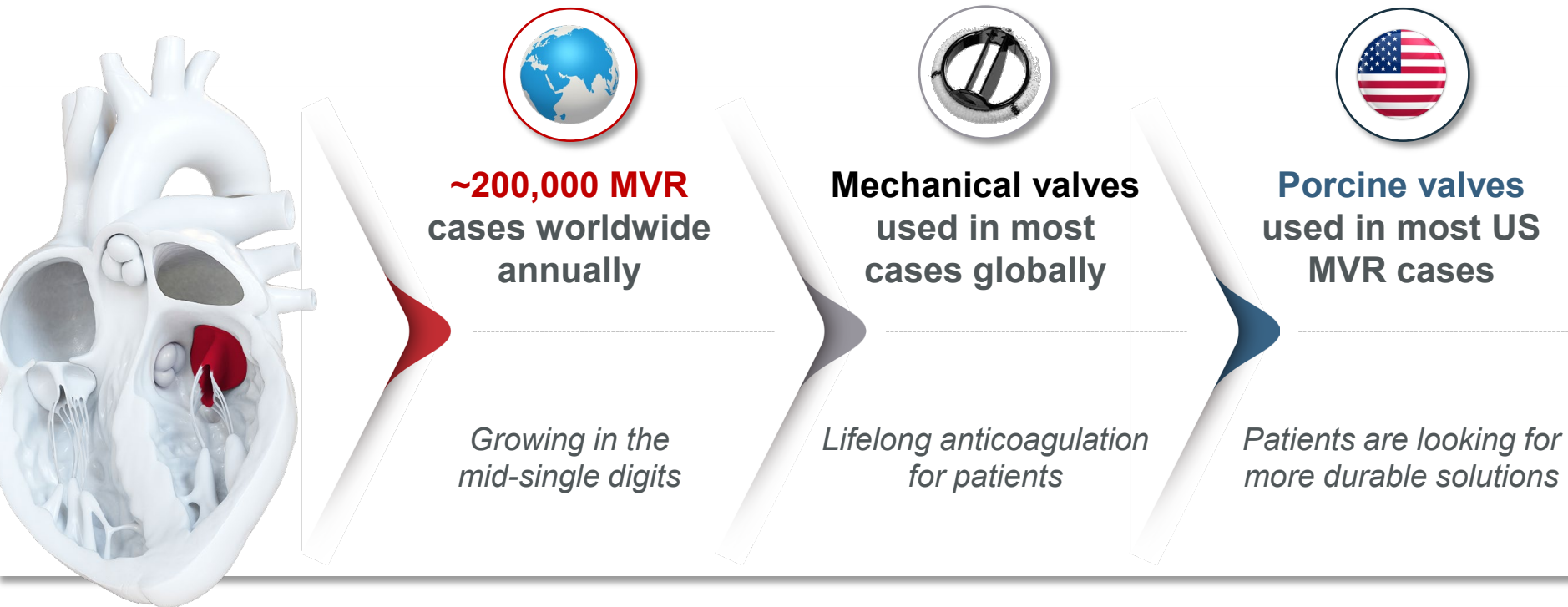
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- The KONECT valved conduit is **outperforming high-single digit market** growth for complex aortic procedures in the US





# Patients in need of mitral valve replacement (MVR) are seeking better options



# MITRIS valve is designed to deliver better outcomes for surgical MVR patients around the world

- Our newest premium valve, the MITRIS valve is **specifically designed for the mitral position** and its higher pressures

---

- Features **RESILIA tissue technology** for extended durability with key ease of use and lifetime management features

---

- Launched in the US in mid-2022 with strong adoption, **anticipating MVR market leadership in 2023**



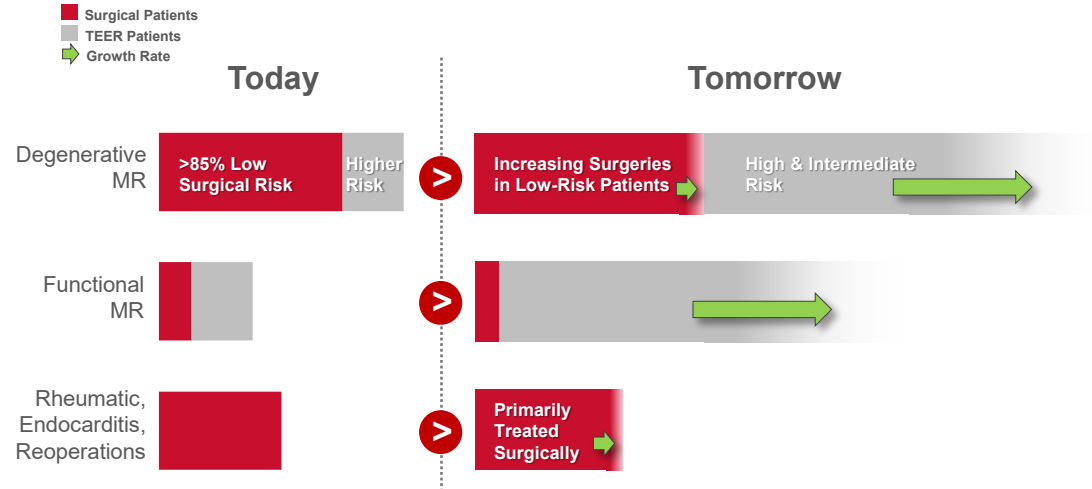
# Mitral regurgitation (MR) is largely under-treated but growing; surgical repair indicated for low-risk degenerative MR patients

<3% of patients with MR receive treatment in the US



As overall treatment increases, a significant portion of patients will continue to be treated surgically

## US Surgical Mitral and TEER Market Volume by Disease



<sup>1</sup> US prevalence of patients with moderate mitral regurgitation

# Consistent, optimal results can be challenging to achieve with mitral repair; we are innovating to improve surgical outcomes

When performed well, surgical repair can restore patients to their normal life expectancy curve

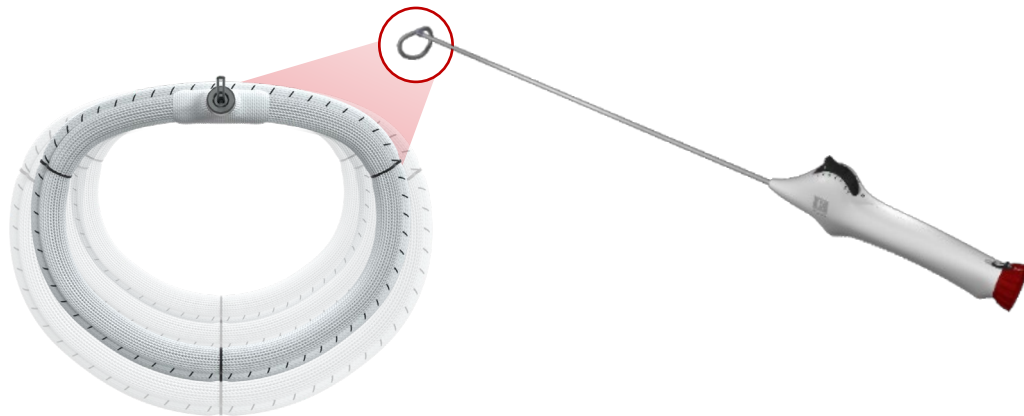
— *However* —

**16%**

of patients can present with sub-optimal results at 2 years (≥moderate MR or reoperation)

## Mitral Adjustable Repair System Program

Enables **beating-heart adjustability of implant size** during the procedure to eliminate any remaining regurgitation



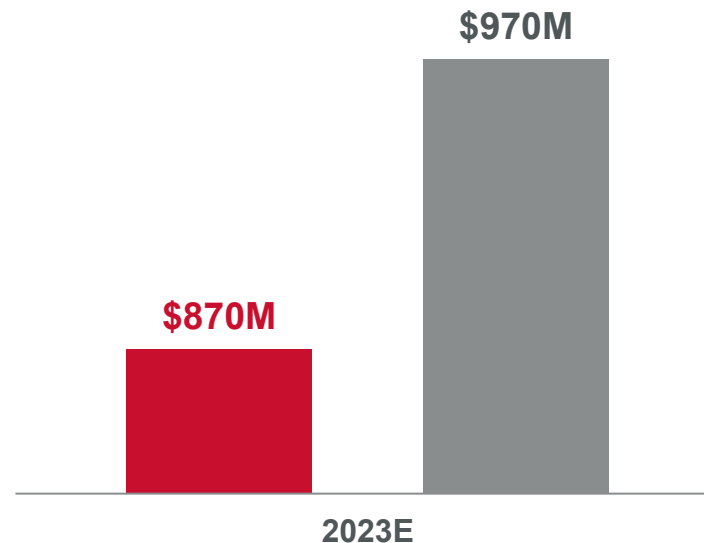
# 2023 Underlying Global Sales Growth Outlook

## Headwinds

- Additional TAVR conversion in developed markets
- Overall healthcare spending pressure

## Tailwinds

- Adoption of our premium RESILIA innovations
- Accelerated mechanical-to-tissue valve conversion



Underlying **Global Surgical Structural Heart** Estimated Sales Growth Mid-Single Digits

## In Summary

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**The surgical market is growing**, especially in patients who require complex and concomitant procedures

**Edwards Surgical is outpacing market growth** with our premium RESILIA tissue aortic and mitral innovations

There continue to be many unmet needs within surgery and **significant growth opportunities ahead**



**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. **MITRIS RESILIA Mitral Valve** - For use in replacement of native or prosthetic mitral heart valves.

**Contraindications:** There are no known contraindications with the use of these RESILIA tissue heart valve devices.

**Complications and Side Effects: INSPIRIS RESILIA Aortic Valve** - 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. **MITRIS RESILIA Mitral Valve** - Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

**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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Edwards



Edwards

Helping Patients is Our Life's Work, and

*life is now*




# Critical Care

**Katie Szyman**  
**Corporate Vice President**  
**Critical Care**



Edwards



**Our vision is  
to improve the  
quality of care  
for millions of  
patients**

---



Drive Smart Recovery with  
leading predictive **technology**

---



Reach more patients with  
compelling clinical **evidence**

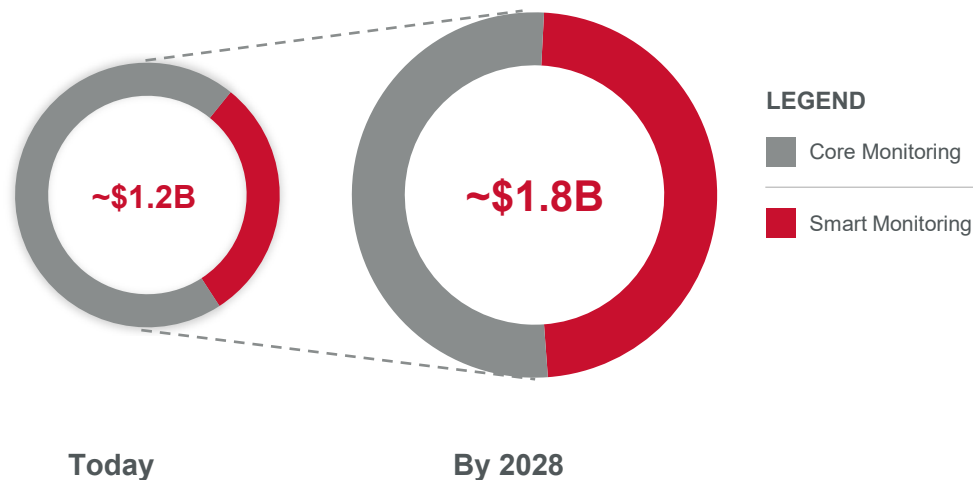
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Increase awareness to drive  
**adoption** of innovative solutions

# Evolving our portfolio toward Smart Monitoring

## Hemodynamic Monitoring Market<sup>1</sup>



**Core Monitoring is highly penetrated and is a large portion of the overall hemodynamic segment**

**Smart Monitoring represents an under penetrated growth opportunity with greater clinical value**

1. Includes capital and tissue oximetry

Smart Monitoring

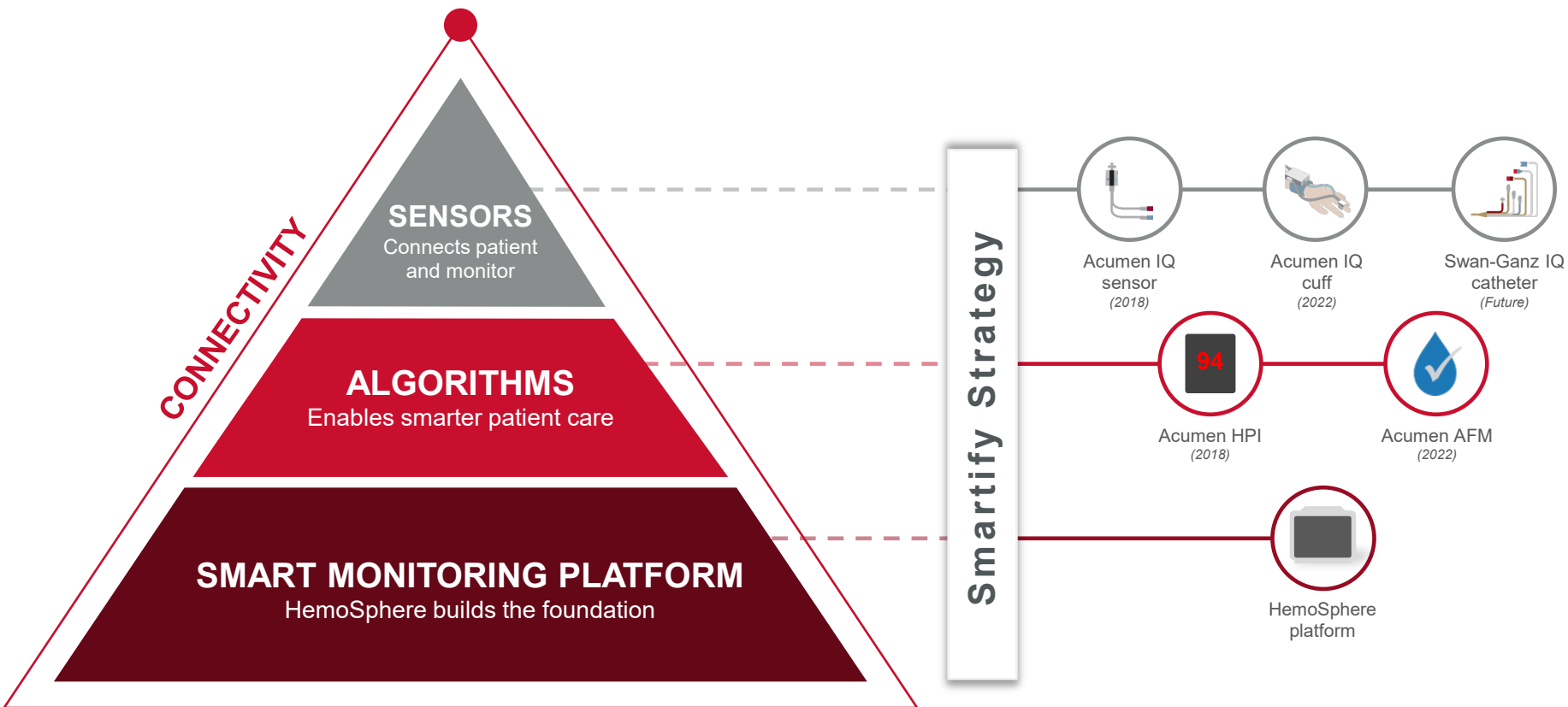


Faster Recovery

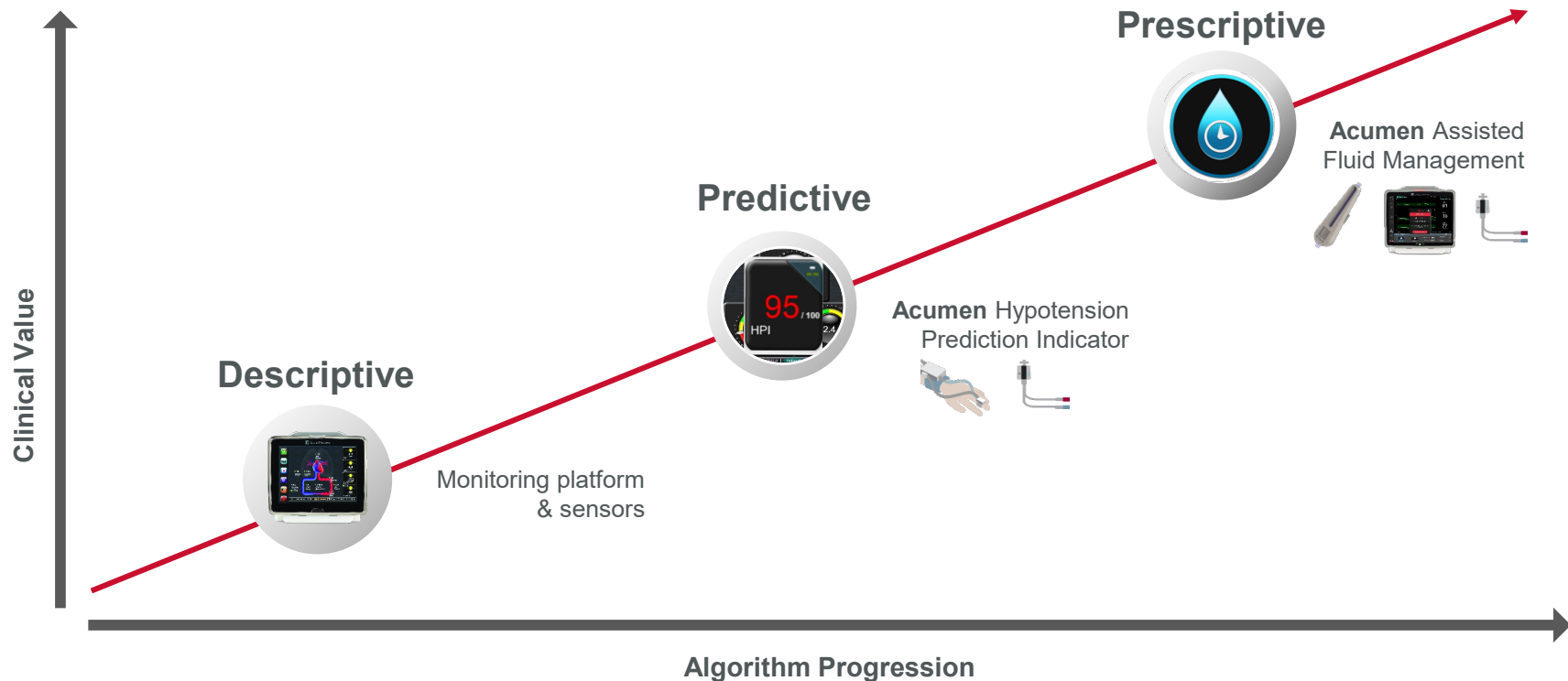


Smart Recovery

# Smart Recovery begins with technology



# Algorithms advance predictive and prescriptive technologies



# Continued success with HemoSphere conversion and expansion

## HemoSphere Platform



**HemoSphere**  
with Viewfinder Remote app

### Supports portfolio of sensors



Acumen IQ  
sensor & HPI



Acumen IQ  
cuff & HPI



Swan-Ganz  
catheter



ForeSight  
sensor

## Conversions surpassing 50% of installed base



2018



2023



2028

Expansion

+

Conversion (Every ~7-9 years)

### Legend



% Capital conversion of legacy units



Capital expansion units

# HemoSphere Smart Recovery product introductions drive growth

## 2022 Product Introductions



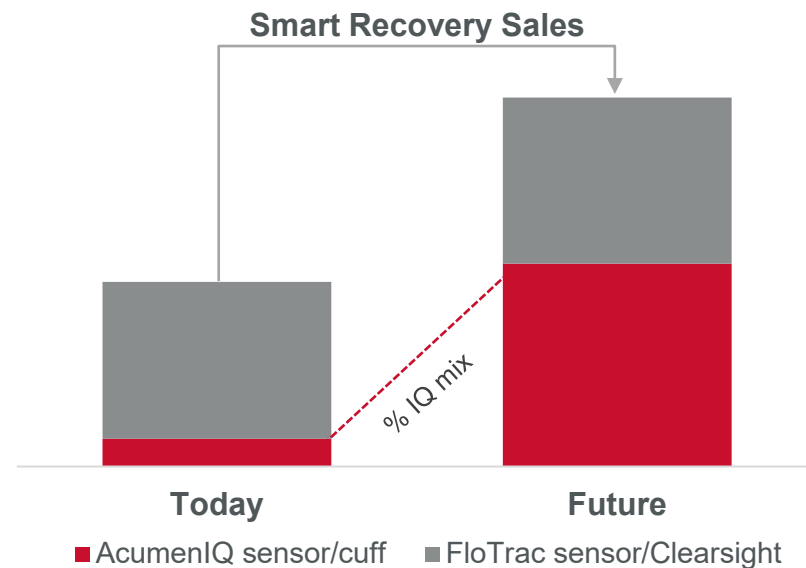
**HemoSphere**  
with Viewfinder Remote app  
Version 7

**MultiTech Monitoring**  
(Acumen IQ and Swan-Ganz)

**HPI software Smart Trends** <sup>IQ</sup>  
**Assisted Fluid Management** <sup>IQ</sup>



## Accelerating Acumen IQ Conversion



# Growing clinical evidence proves value of Smart Recovery

## Proved ability to reduce hypotension

Mean Minutes of Hypotension

28 mins



12 mins

**58%**

**Decrease in IOH**

Edwards MPOG Study



**HPI Data On Label**

## Ongoing studies advance hemodynamic learnings



### Multi-center Prospective Registry

*Observe patient hypotension using Acumen HPI*



### Multi-center Open Randomized Trial

*Evaluate cardiac output guided fluid therapy*



### Multi-center RCT

*Evaluate cardiac output guided fluid therapy*



### Multi-center Hospital Quality Project

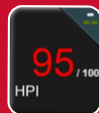
*Leveraging Acumen HPI to improve cardiac care*



# Edwards HPI shown to reduce ICU stay in cardiac patients

## Real world data

Analysis before and after implementation of Acumen HPI guided hemodynamic management



**~1400**  
cardiac patients



**3**  
hospital partners

## Key Results



Mean ICU length of stay decrease of ~7 hours



34% reduction in total initial ventilation time



Decrease in post-op renal failure in all centers



Presented at American Association for Thoracic Surgery (May 2022)

# Increase awareness through multiple avenues to drive adoption



## Hypotension Awareness

### Public Awareness

Recognizing hypotension as top harm<sup>1</sup>



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
OFFICE OF INSPECTOR GENERAL

### Real World Evidence

Key groups demonstrating prevalence of hypotension



### Hypotension Quality Measure

Setting a standard for improved quality of care



# 2023 Underlying Global Sales Growth Outlook

## Headwinds



Recession impacts capital budgets



Semiconductor supply chain risk

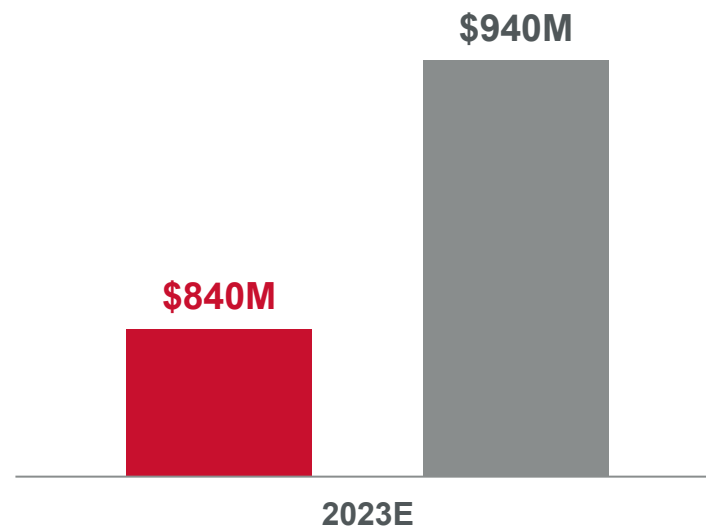
## Tailwinds



Accelerated adoption of IQ technologies



Impact of real-world data on adoption



Underlying **Global Critical Care** Estimated Sales Growth Mid Single-Digits

# Executive Summary



We are leading Smart Recovery with AI Enabled **Technology**

---



We are reaching more patients with clinical **Evidence**

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We are gaining **Adoption** to get patients home to their families faster

**The Best Is Yet To Come**



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Helping Patients is Our Life's Work, and

*life is now*

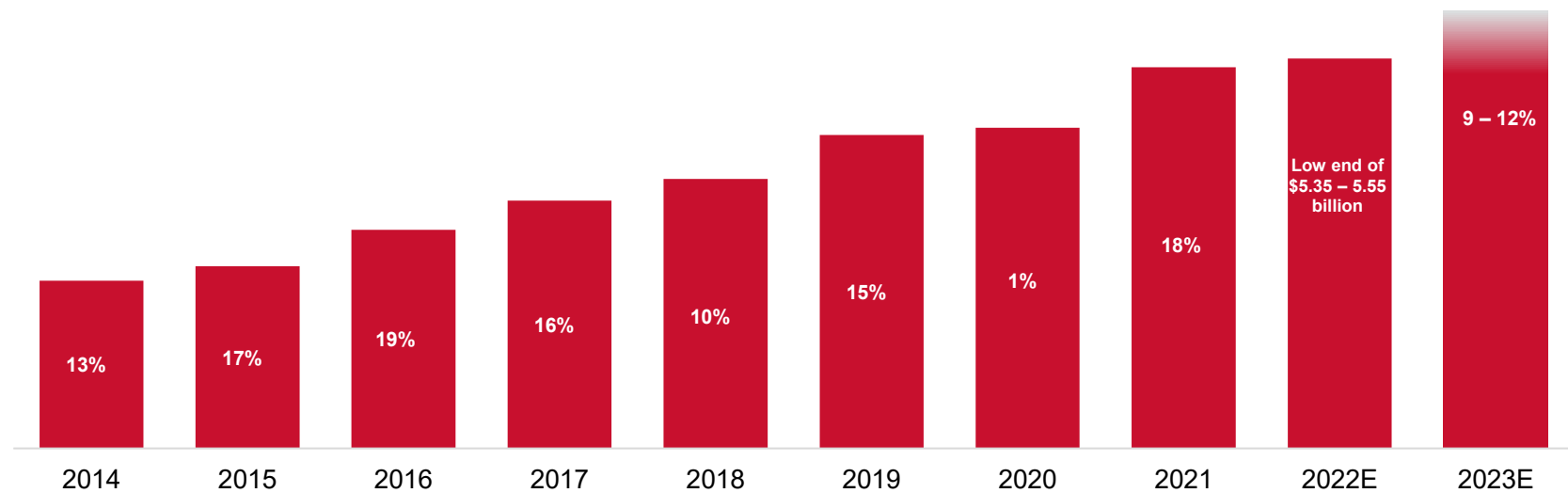
# Financial Outlook

**Scott Ullem**  
Chief Financial Officer



Edwards

# Edwards expects a return to double-digit constant currency sales growth in 2023, lifted by TAVR





# Edwards expects to generate durable organic growth



## Sales Growth

Constant currency sales growth  
in the low double-digits



## Profitability

Continued healthy gross profit  
and operating margins  
(significant FX impact in 2023)



## Capital Allocation

Strategic balance sheet  
management and capital  
deployment

Long-Term Shareholder Returns

# Edwards Financial Objectives

## Strong Organic Sales Growth



Addressing large and growing patient populations



Global sales growth fueled by successful long-term R&D investments to drive breakthrough therapies



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

# 2022 sales and growth impacted by TAVR and FX

(\$ in millions except earnings per share)

	2021 Investor Conference Guidance	October Guidance (Unchanged)
<b>Sales</b> <i>(Constant Currency Growth)</i>	\$5,500 - 6,000 <i>(Low double-digit)</i>	Low-end of \$5,350 - 5,550
<b>FX Impact on Sales</b>	~(\$120) ~2pp downside to sales	~(\$270) ~5pp downside to sales
<b>Adjusted Gross Profit Margin</b>	78 - 79%	Approximately 80%
<b>Adjusted Earnings Per Share</b>	\$2.50 - 2.65	\$2.40 - 2.50

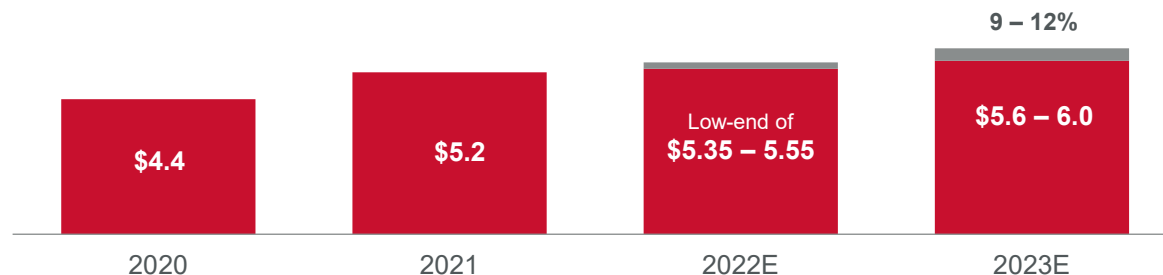
# Expecting 9 – 12% total company sales growth

(Constant currency growth, \$ in billions)



2023  
Expectations

- Assumes gradual recovery of hospital staffing and improving procedure volumes
- Growth across all major regions
- At current rates, negative FX impact expected to be approximately \$100 million, or 1.5%, compared to 2022
- Accelerating quarterly sales growth resulting in low double-digits for the year



# Expecting fewer staffing disruptions, enabling 9 – 12% sales growth in TAVR

(Constant currency growth, \$ in billions)



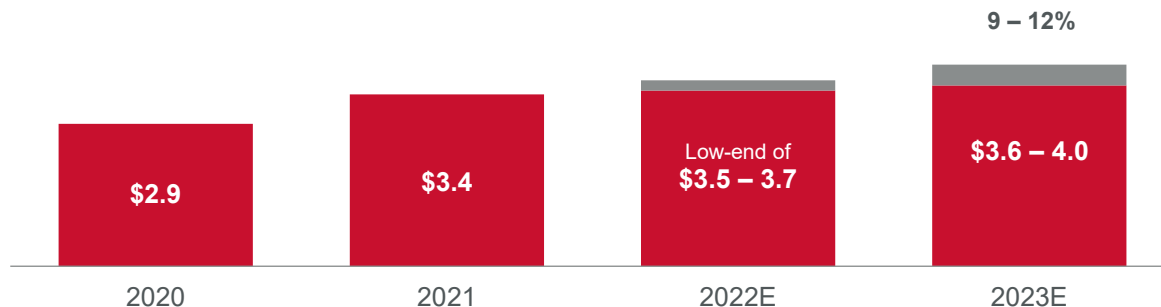
Expectations

## 2023

- Strong growth across all major regions including the U.S.
- Launch of SAPIEN 3 Ultra RESILIA in the U.S. and Japan
- Anticipated stable ASP and share position

## LONG - TERM

- Growing patient population
- Investing in mitigating staffing disruptions
- Focusing on increasing treatment rates
- \$10 billion sales opportunity by 2028



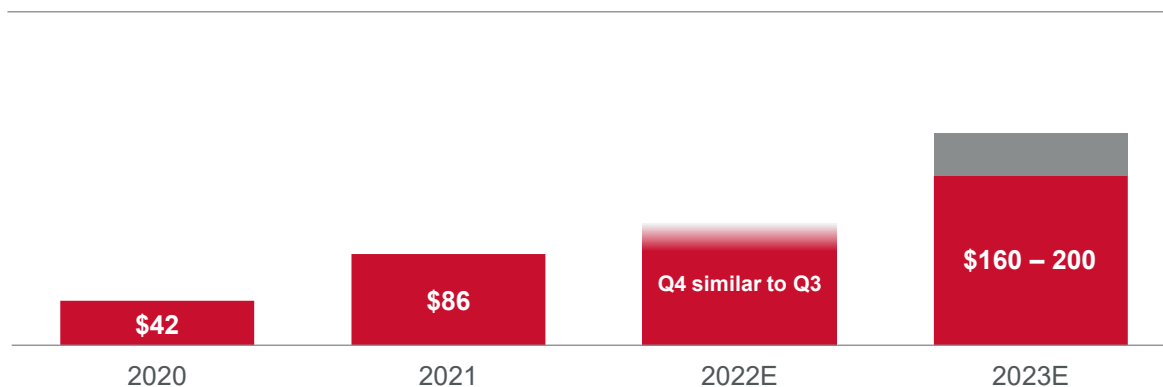
# TMTT sustains strong momentum

(\$ in millions)



2023  
Expectations

- Remain focused on excellent patient outcomes
- PASCAL launch in the U.S. and continued expansion in Europe drives growth
- Expect EVOQUE TR Europe approval in late 2023 with reimbursement in 2024
- Complete enrollment in ENCIRCLE for SAPIEN M3, and advance ongoing pivotal trials



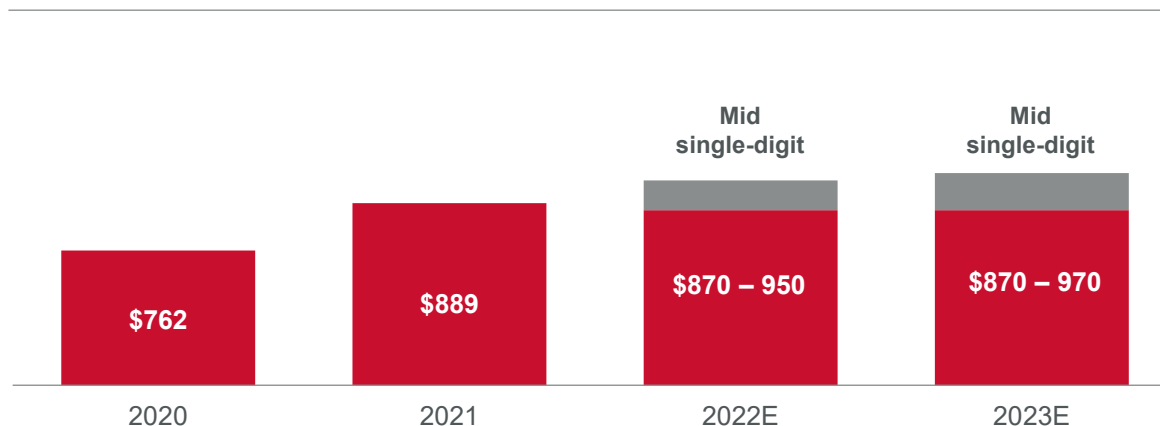
# Surgical Structural Heart continues to grow

(Constant currency growth, \$ in millions)



2023  
Expectations

- Increased adoption of premium technologies drives growth
- Continue generating meaningful RESILIA clinical evidence
- Continue launch of MITRIS RESILIA valve in the U.S.



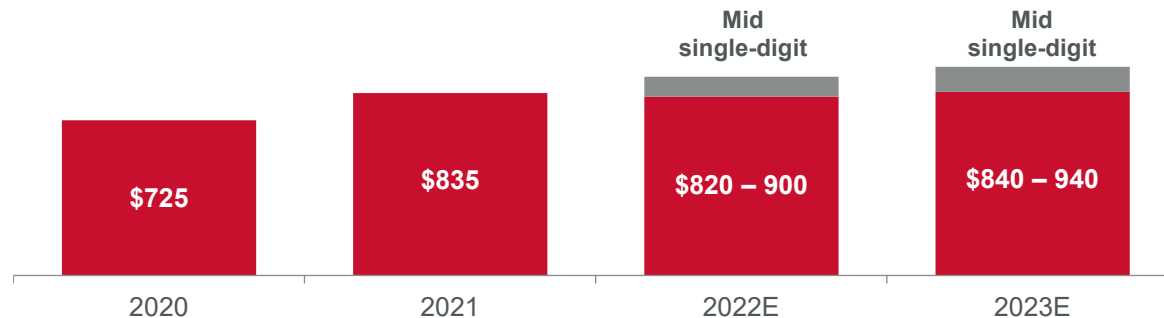
# Critical Care accelerates shift to Smart Recovery

(Constant currency growth, \$ in millions)



2023  
Expectations

- Drive Smart Recovery with leading predictive technology
- Generate compelling clinical evidence
- Increase awareness to drive adoption





# Edwards Financial Objectives

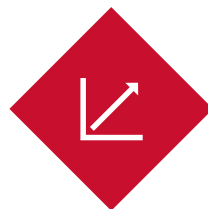
## Healthy Profitability



Generating strong  
gross profit



Funding growing field  
organization and  
strengthening global  
supply chain



Investing aggressively in  
innovation for profitable  
organic growth

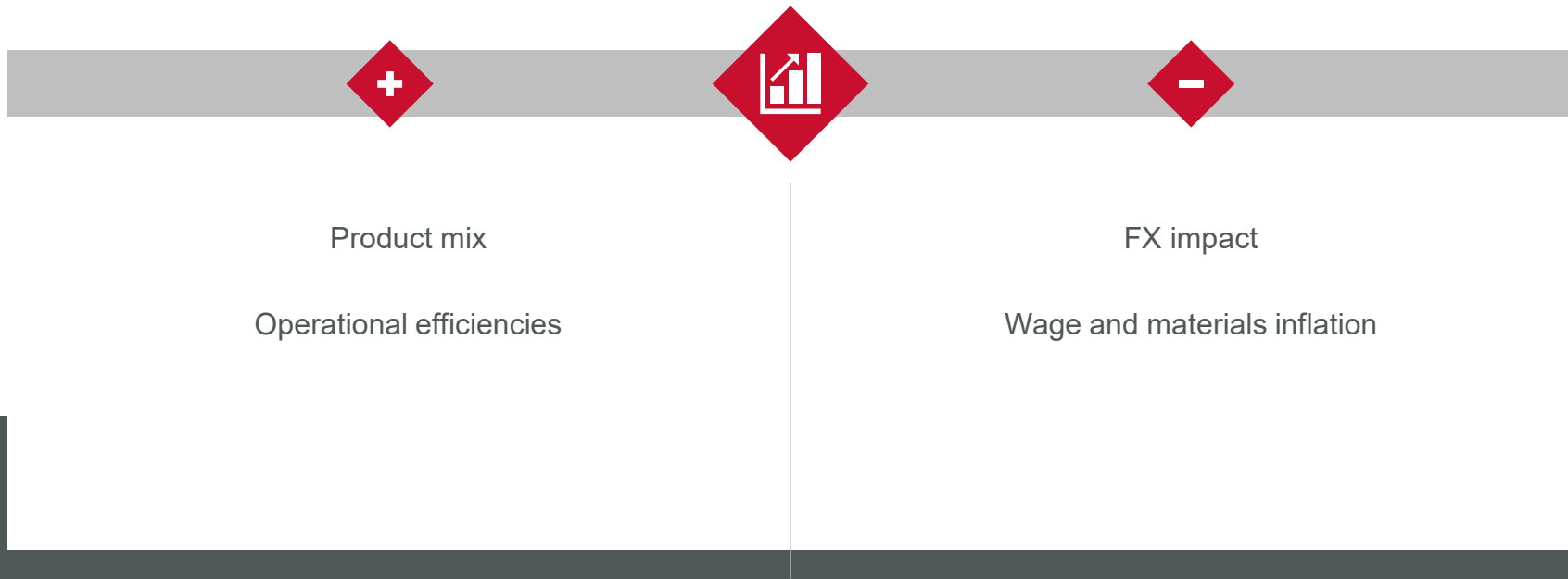


Maintaining efficient  
tax structure

# 2023 gross profit margin unfavorably impacted by FX

## Gross Profit Margin

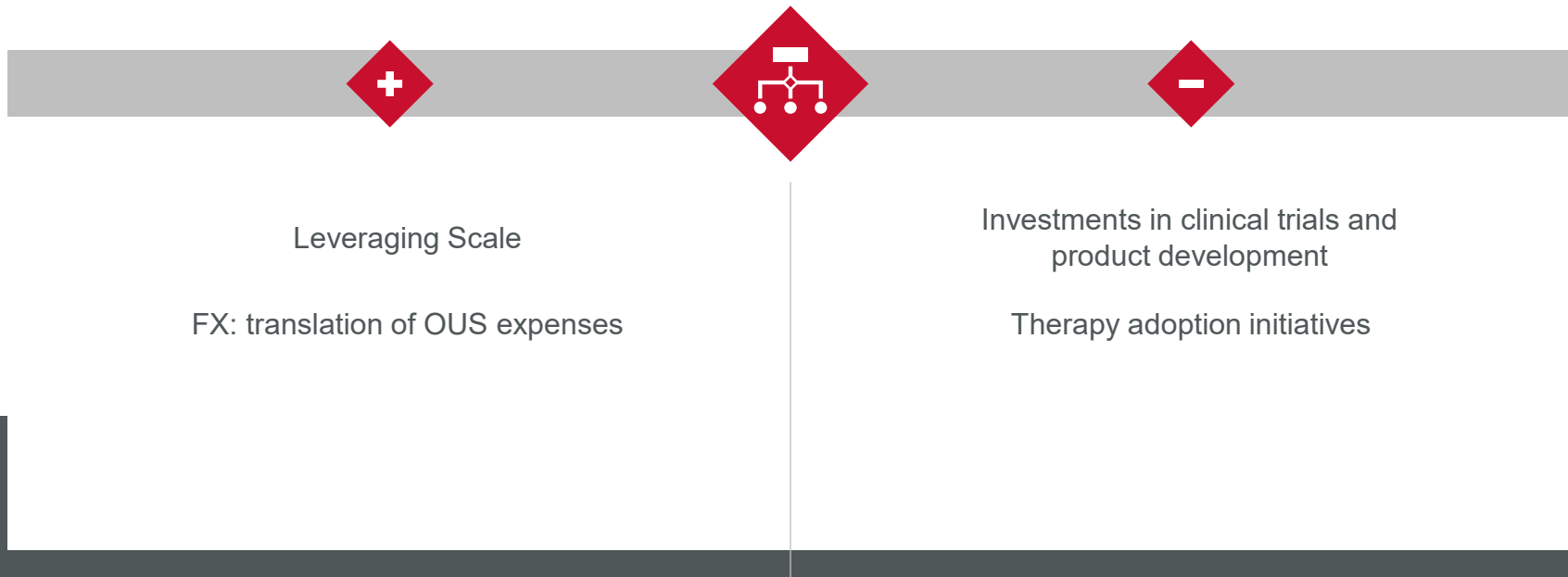
Between 76 - 78%



# 2023 Operating Expenses

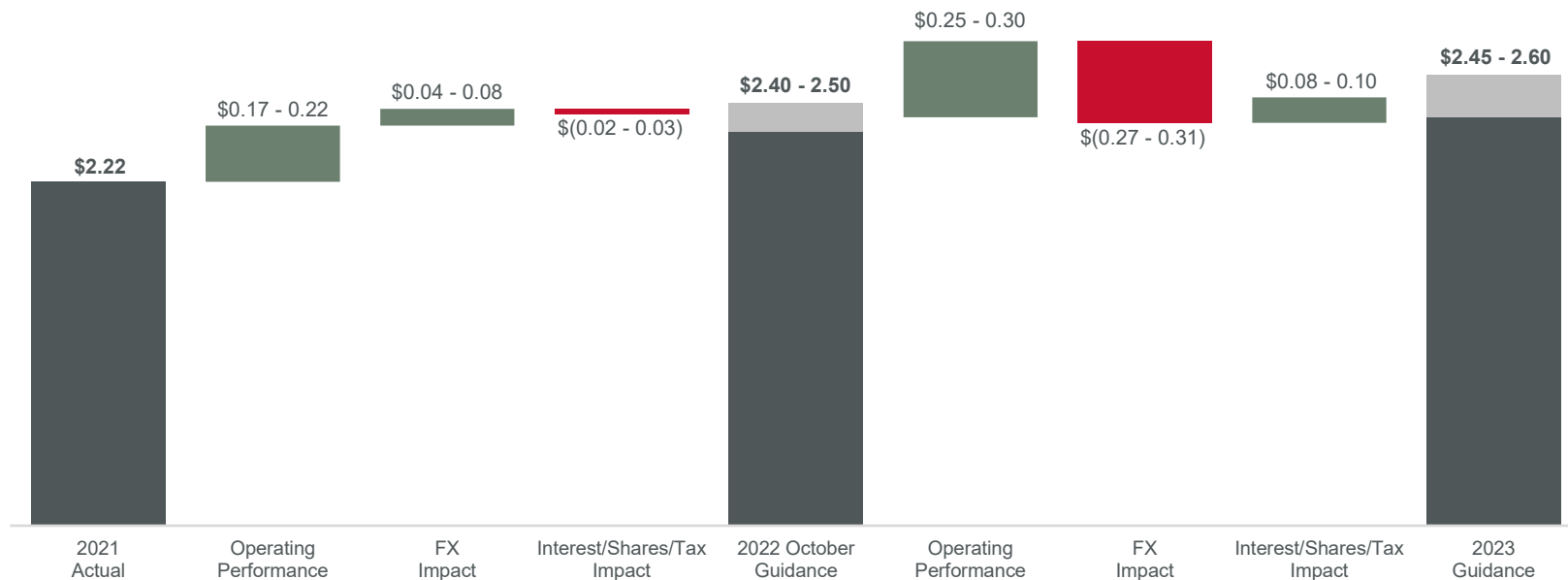
## OPEX

SG&A: 29 - 30%; R&D: 17 - 18%



# Negative FX impact forecasted to outweigh profit growth from operations

*(Adjusted earnings per share)*

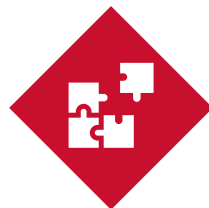


# Edwards Financial Objectives

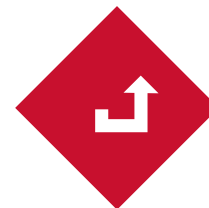
## Robust Cash Flow and Strategic Capital Deployment



Supports global capacity expansion



Strategic acquisitions to support and supplement R&D initiatives



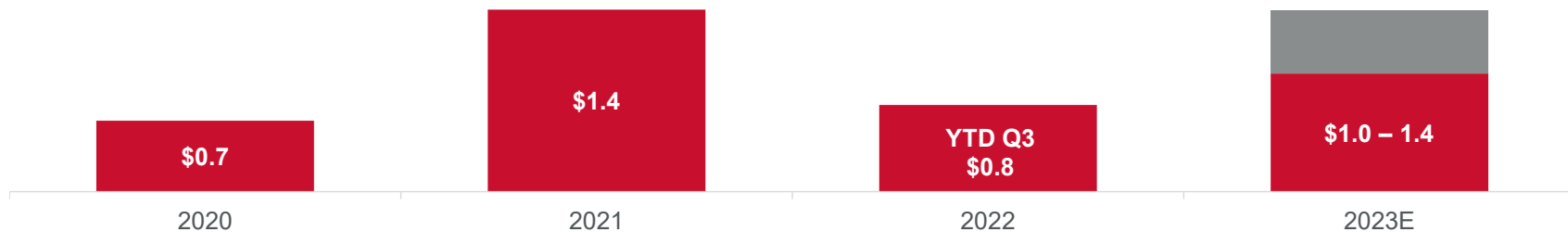
Returning capital to shareholders through opportunistic share repurchases

# Cash Flow and Capital Deployment

## 2023 Expectations

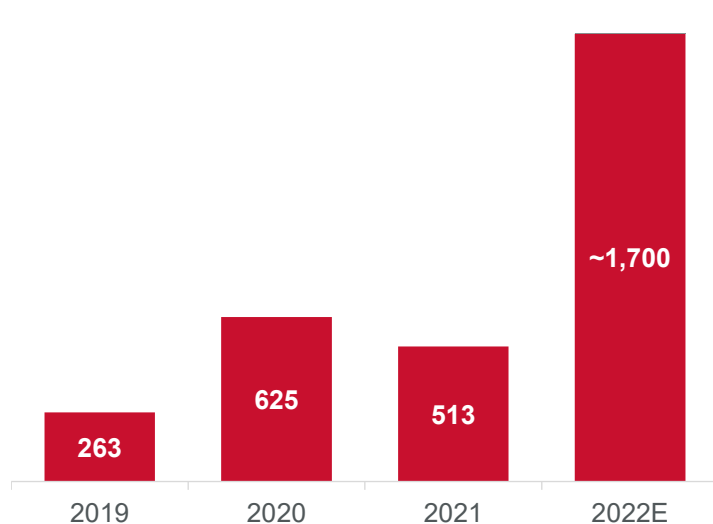
- Continued growth results in significant cash flows that fund future internal and external opportunities
- Diluted shares outstanding estimated between 610 and 615 million

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

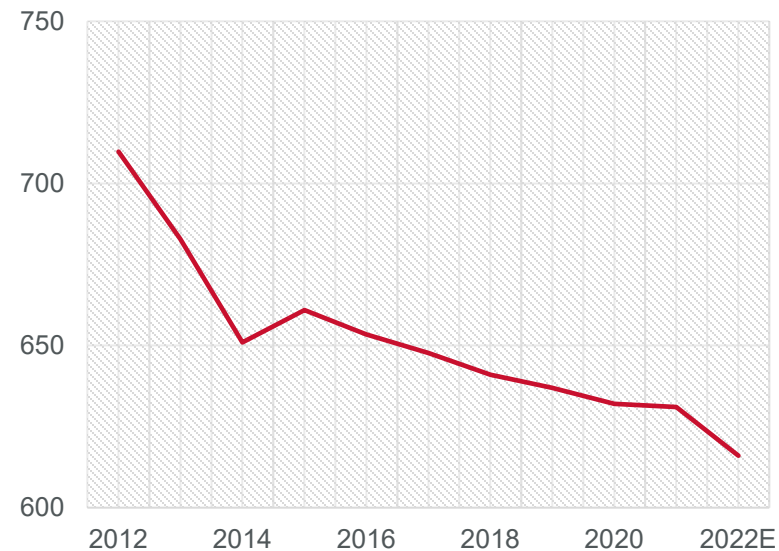


# Share Buyback Activity

## Share Repurchases (\$ millions)

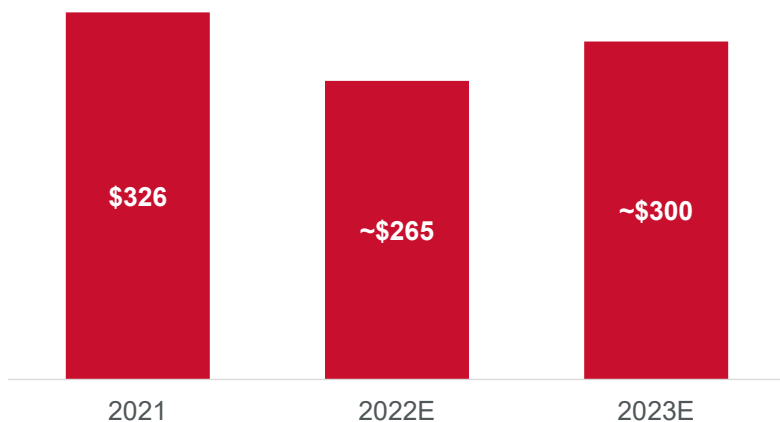


## Shares Outstanding (millions)

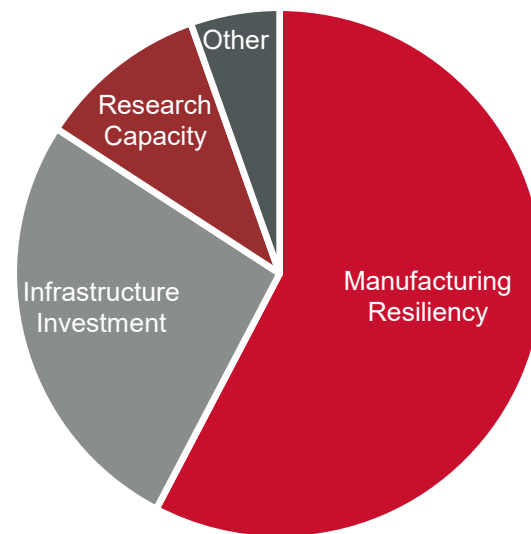


# Investing Capital for the Future

CAPEX (\$ in millions)



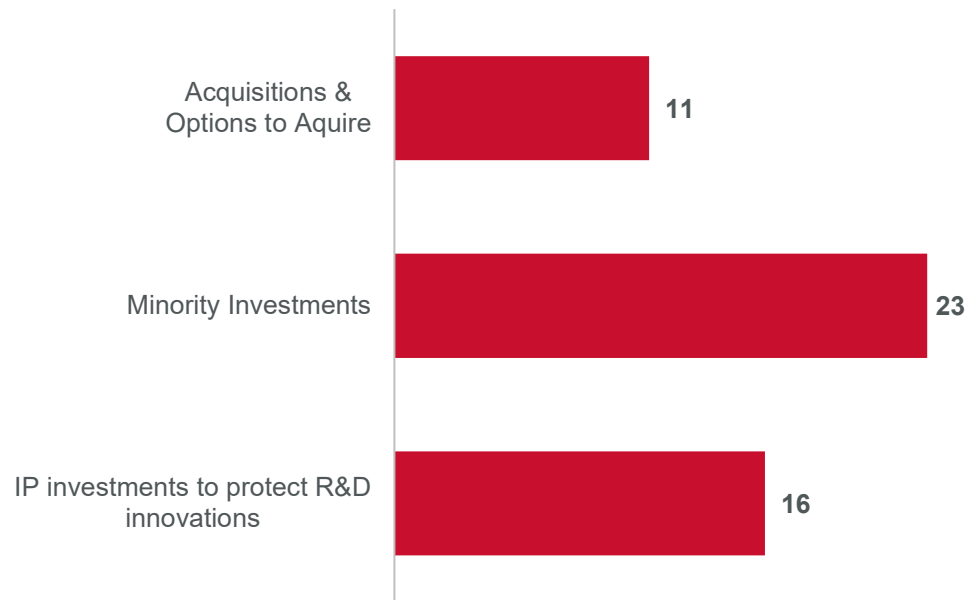
Where are we investing?





# Active Portfolio Management

## Closed Transactions Since 2017



## FOCUSED ADDITIONS

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

## EXITS

- Non-strategic products
- Low growth potential

# 2023 Guidance Summary

(\$ in millions except earnings per share)

<b>Sales</b>	\$5,600 - 6,000	<b>Operating Margin</b>	~30%
<b>Underlying growth</b>	9 - 12%	<b>Tax rate</b>	13 - 17%
<b>FX Impact on Sales</b> <i>At current rates</i>	~(\$100) <i>(1.5pp downside to growth)</i>	<b>Earnings Per Share</b>	\$2.45 - 2.60
<b>Gross Profit Margin</b>	76 - 78%	<b>Diluted Shares</b>	610 - 615
<b>SG&amp;A % of Sales</b>	29 - 30%	<b>CAPEX</b>	~\$300
<b>R&amp;D % of Sales</b>	17 - 18%	<b>Free Cash Flow</b>	\$1,000 - 1,400

# Longer-Term Outlook



## Constant Currency Sales Growth

Organic sales growth in the low double-digits

Global Market Opportunity

**~\$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

Neutral to 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 expects to generate durable organic growth



## Sales Growth

Constant currency sales growth  
in the low double-digits



## Profitability

Continued healthy gross profit  
and operating margins  
(significant FX impact in 2023)



## Capital Allocation

Strategic balance sheet  
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Long-Term Shareholder Returns



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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

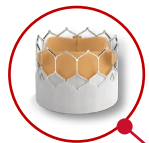
Singular focus on the large unmet needs of structural heart and critically ill patients

**Create Meaningful Value by Transforming Patient Care**

# 2023 expected to be a year of strong growth and investment in our future

## TAVR

- > SAPIEN 3 Ultra RESILIA launch
- > Moderate AS trial enrollment
- > SAPIEN X4 trial enrollment

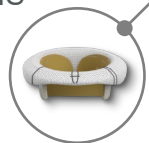


## TMTT

- > Present CLASP IID full cohort 1-yr data
- > ENCIRCLE trial complete enrollment
- > Receive CE Mark for EVOQUE TR
- > TRISCEND II complete enrollment

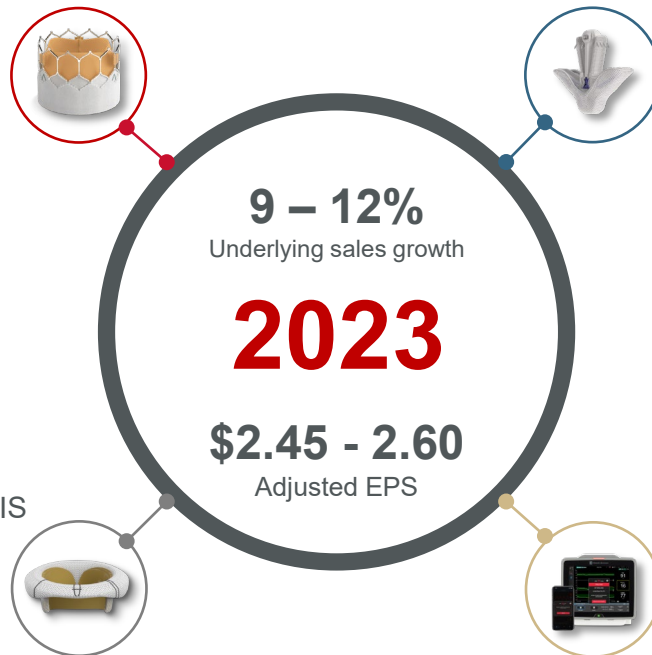
## SURGICAL

- > Continued global adoption of INSPIRIS
- > MITRIS U.S. penetration
- > Present RESILIA 7-year data



## CRITICAL CARE

- > Continued Acumen IQ conversion
- > HemoSphere expansion
- > Ongoing adoption of ForeSight





# 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



FTSE4Good



Member of  
**Dow Jones  
Sustainability Indices**

Powered by the S&P Global CSA



# Edwards is Committed to Giving Back

Foundation supporting nearly 50 countries in 2022



## Every Heartbeat Matters

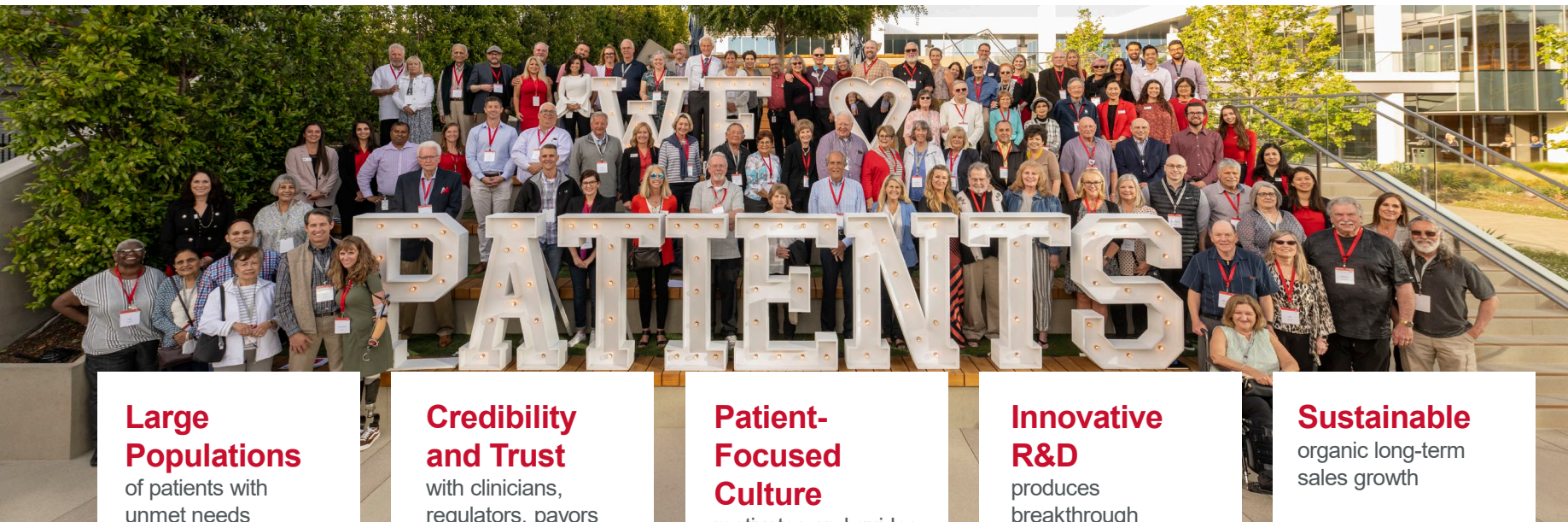
Improve the lives of **2.5M** additional underserved structural heart and critical care patients by the end of 2025



## Strengthening Our Communities

Aspire for **100%** employee involvement in charitable activity; focused on underserved and underrepresented communities

# Edwards is poised for long-term value creation



## Large Populations

of patients with unmet needs

## Credibility and Trust

with clinicians, regulators, payors and patients

## Patient-Focused Culture

motivates and guides our global team

## Innovative R&D

produces breakthrough therapies and drives shareholder returns

## Sustainable

organic long-term sales growth

## Entering a New Era of Structural Heart Innovation



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Helping Patients is Our Life's Work, and

*life is now*

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