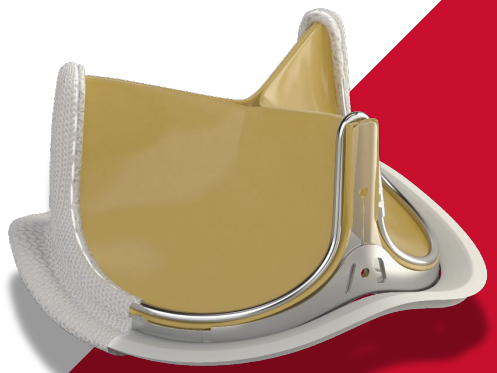
# 2020 Investor Conference

## Surgical Structural Heart

Edwards

# Surgical Structural Heart brings leading innovation

- Current $1.8B surgical structural heart market expected to grow **mid-single digits through 2026**
- **We extended our leadership** as the partner of choice for cardiac surgeons with three product launches in 2020
- **We continue to bring life-saving surgical innovation** to patients best-treated surgically



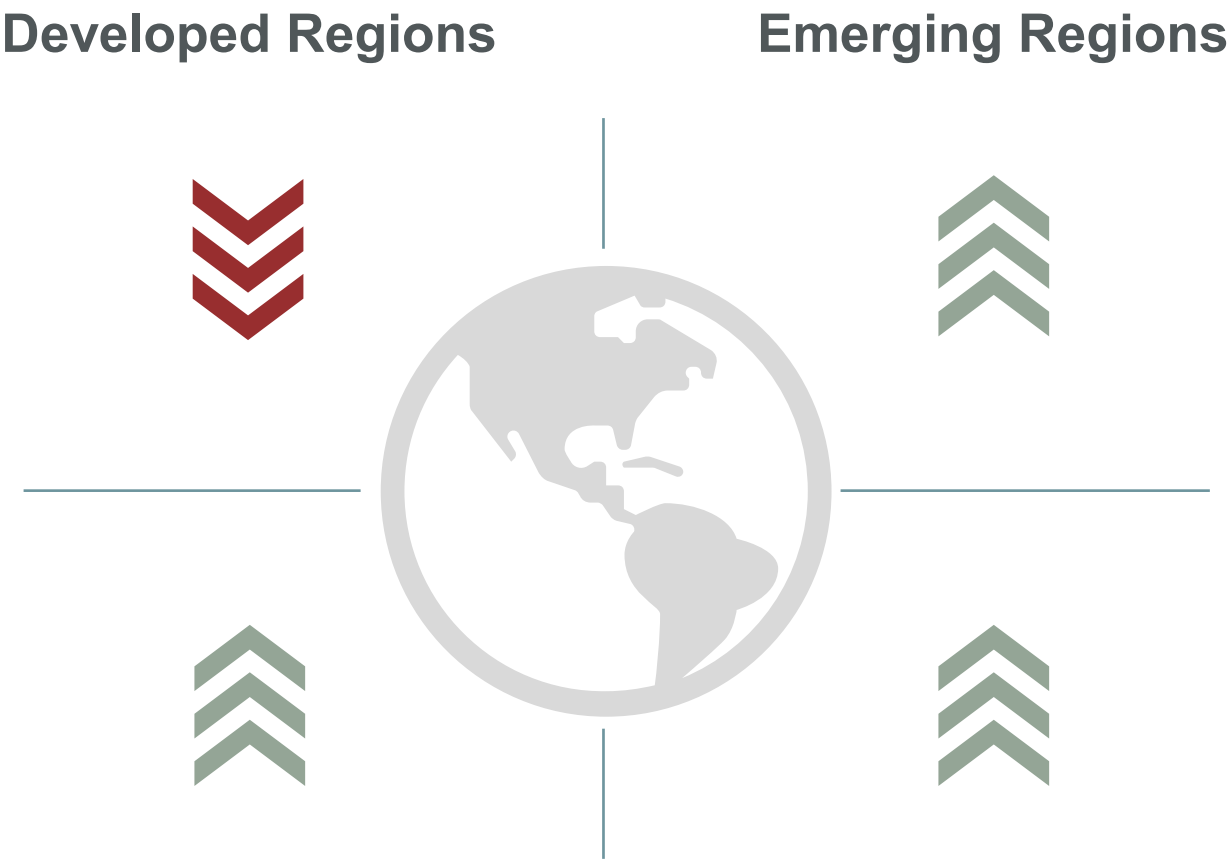
# Adult cardiac surgery continues to grow mid-single digits driven by awareness and an aging population

**Surgical Aortic Valve Replacement**

Growth in emerging regions equally offset decline in developed regions

**Surgical Mitral Valve Replacement and Repair**

Continued global mid-single digit growth



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

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

*Growth (20-26)*

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

**2020E**

## Aortic Patients Best Treated Surgically

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

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

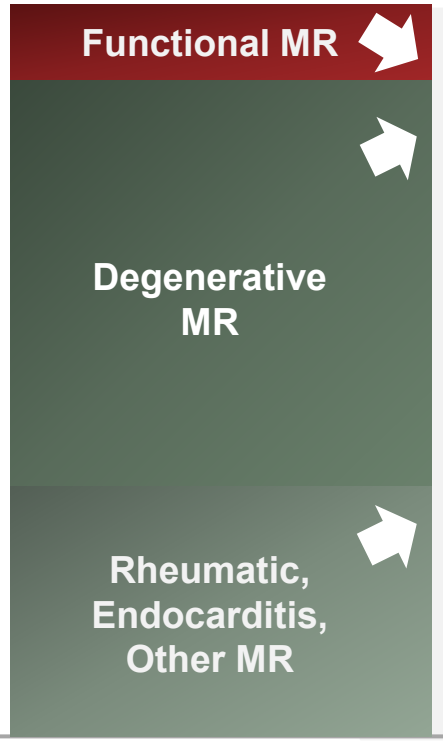
**Patients with aortic regurgitation** who require a surgical approach

[1] Severe Symptomatic Aortic Stenosis

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

**Surgical Mitral Procedures (U.S. & EU)**

*Growth (20-26)*




## Mitral Patients Best Treated Surgically

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

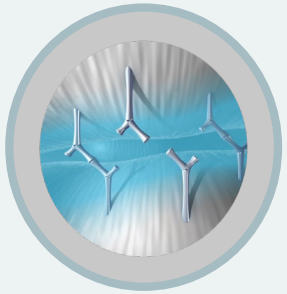
**Patients with complex disease** who require combined procedures

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

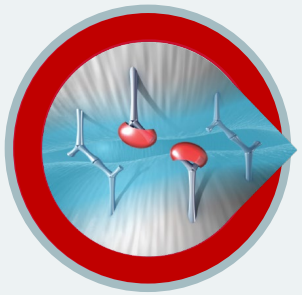
# We continue to generate robust clinical evidence for our leading RESILIA tissue technology

**RESILIA Tissue Technology**

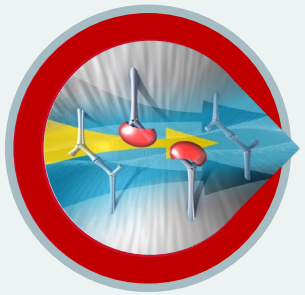
## Anti-calcification to improve tissue durability



Residual aldehydes on tissue attract calcium



RESILIA permanently caps residual aldehydes



Capped aldehydes block calcium

**Long-Term RESILIA Tissue Clinical Evidence**

### EU Feasibility Study

133 patients across 2 centers in Poland

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

### COMMENCE Aortic

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

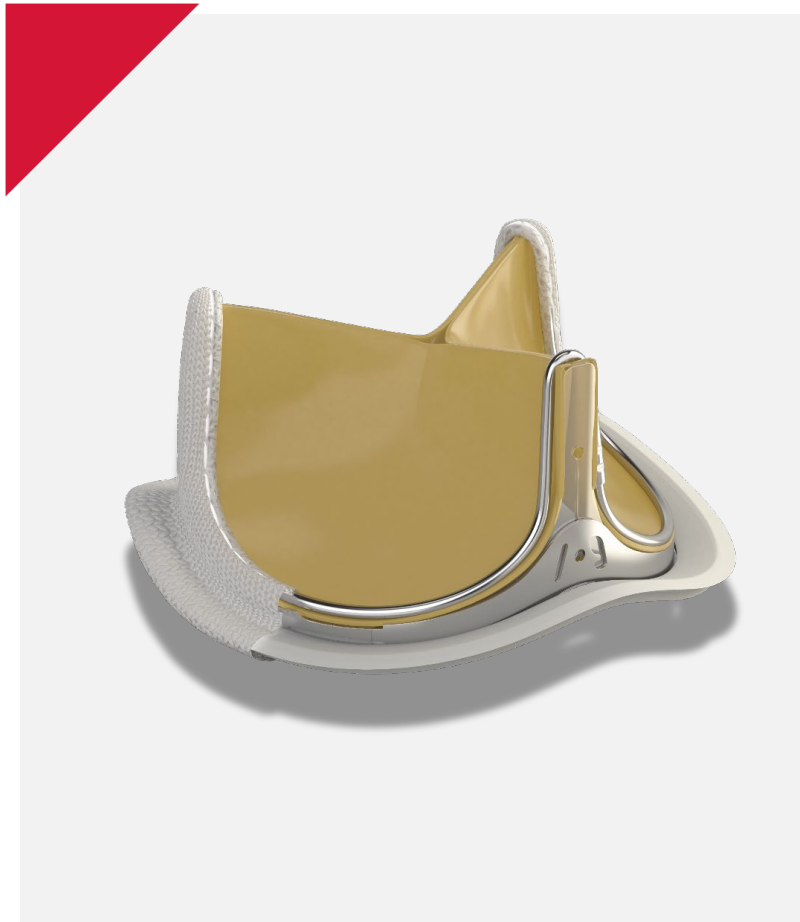
**4yr follow-up showed 0% SVD 5yr outcomes in early 2021**

### RESILIENCE

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

**Follow-up through 11yrs**

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



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

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

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

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

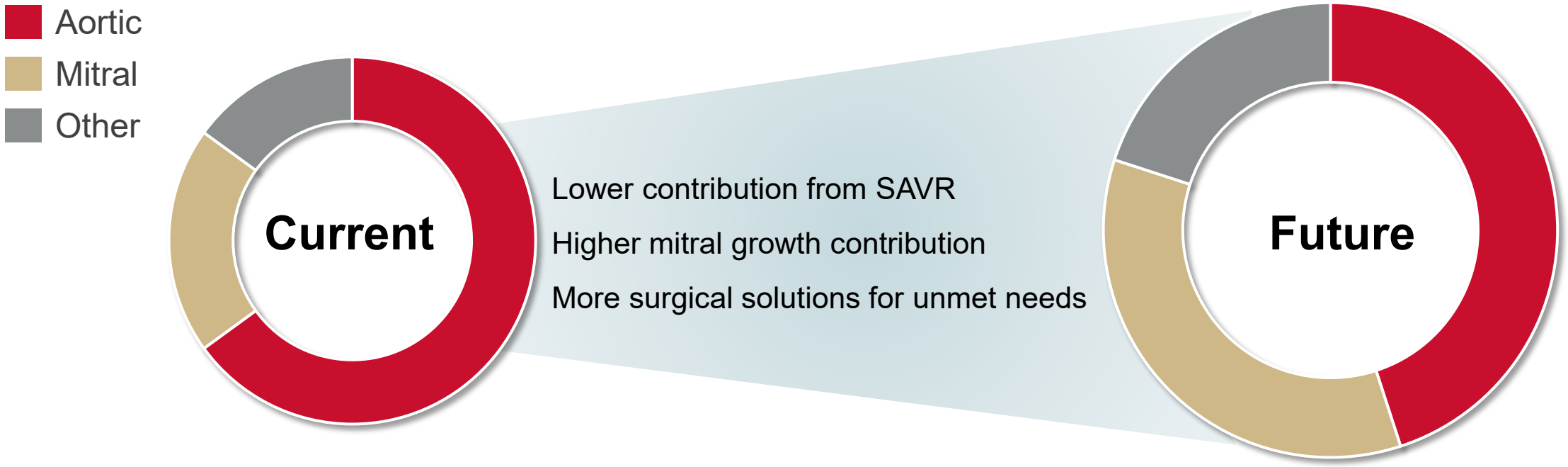
- **Differentiating RESILIA tissue, ease-of-use enhancements**, and valve-in-valve compatibility
- **Growth opportunity** as 60% of global mitral valve replacement patients receive a mechanical valve
- **Launching in the U.S. and Japan in 2021**

# HARPOON transforms surgery for many patients with degenerative mitral regurgitation


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

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

## Surgical Structural Heart Revenue by Segment



# 2021 Global Sales Outlook

## Headwinds

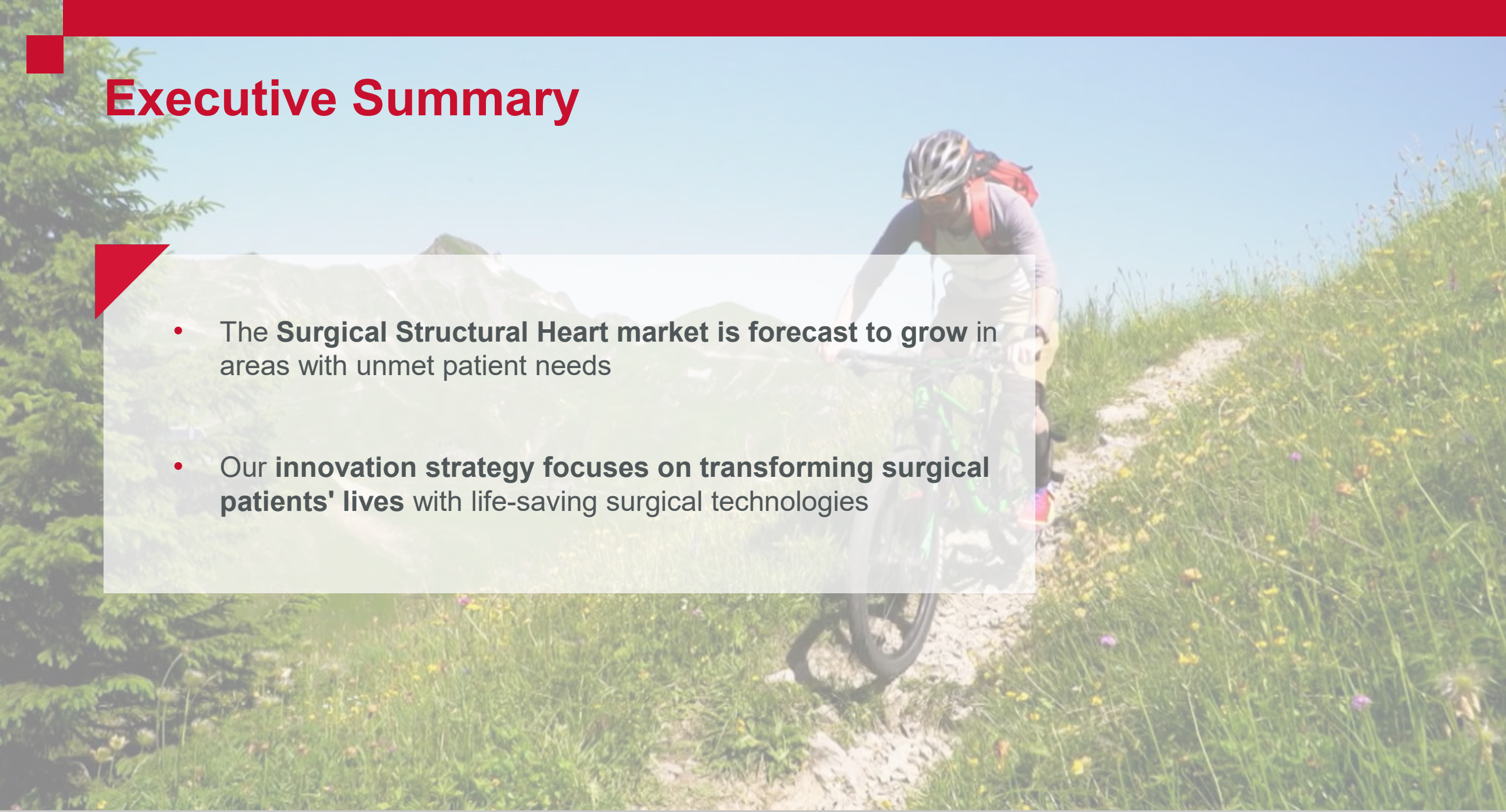
- Continued TAVR conversion in U.S. & EU
- Overall healthcare budget constraints


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

## Tailwinds

- Adoption of RESILIA products
- Accelerated mech-to-tissue conversion

# Executive Summary



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

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

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

Indications: For use in replacement of native or prosthetic aortic heart valves.
Contraindications: There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve.

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

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

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

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

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

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

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

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

Edwards devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity. Edwards Mitris Valve.

INVESTIGATIONAL DEVICES. CAUTION: Limited to investigational use. These devices are not available for marketing or commercial sale.

See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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