

Surgical Structural Heart

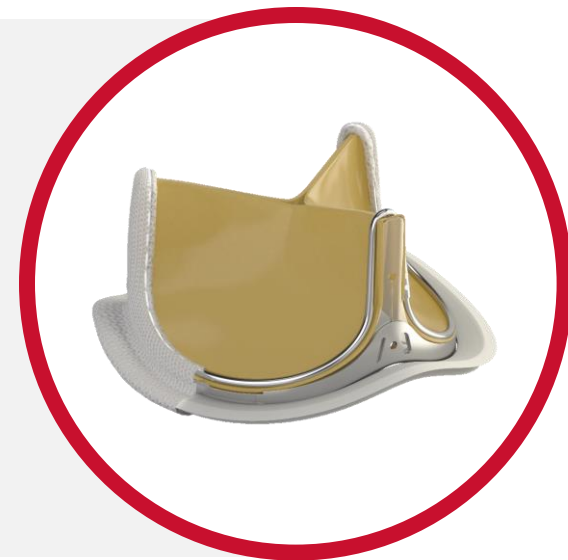
Daveen Chopra
Corporate Vice President
Surgical Structural Heart



Edwards

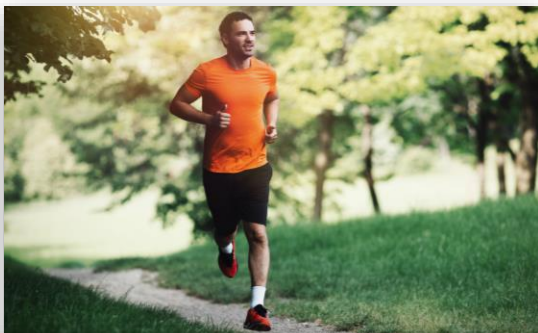
Surgical Structural Heart is transforming patients' lives by solving critical unmet needs in cardiac surgery

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

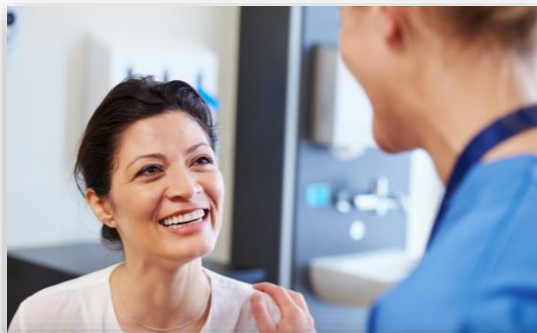


The surgical structural heart market continues to grow

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



Younger, active patients



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



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

Edwards Surgical continues to bring leading innovation

Our Patient Focus

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

Through Transformative Innovation

Redefining tissue durability standards with robust clinical evidence on RESILIA tissue

Impacts Lives Globally

Increasing global patient access and adoption of superior therapies

RESILIA tissue improves durability through its novel anti-calcification properties

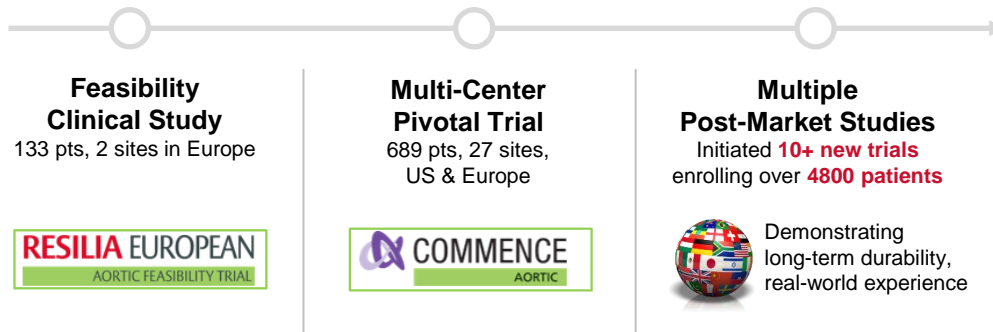
Clinical Need

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



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

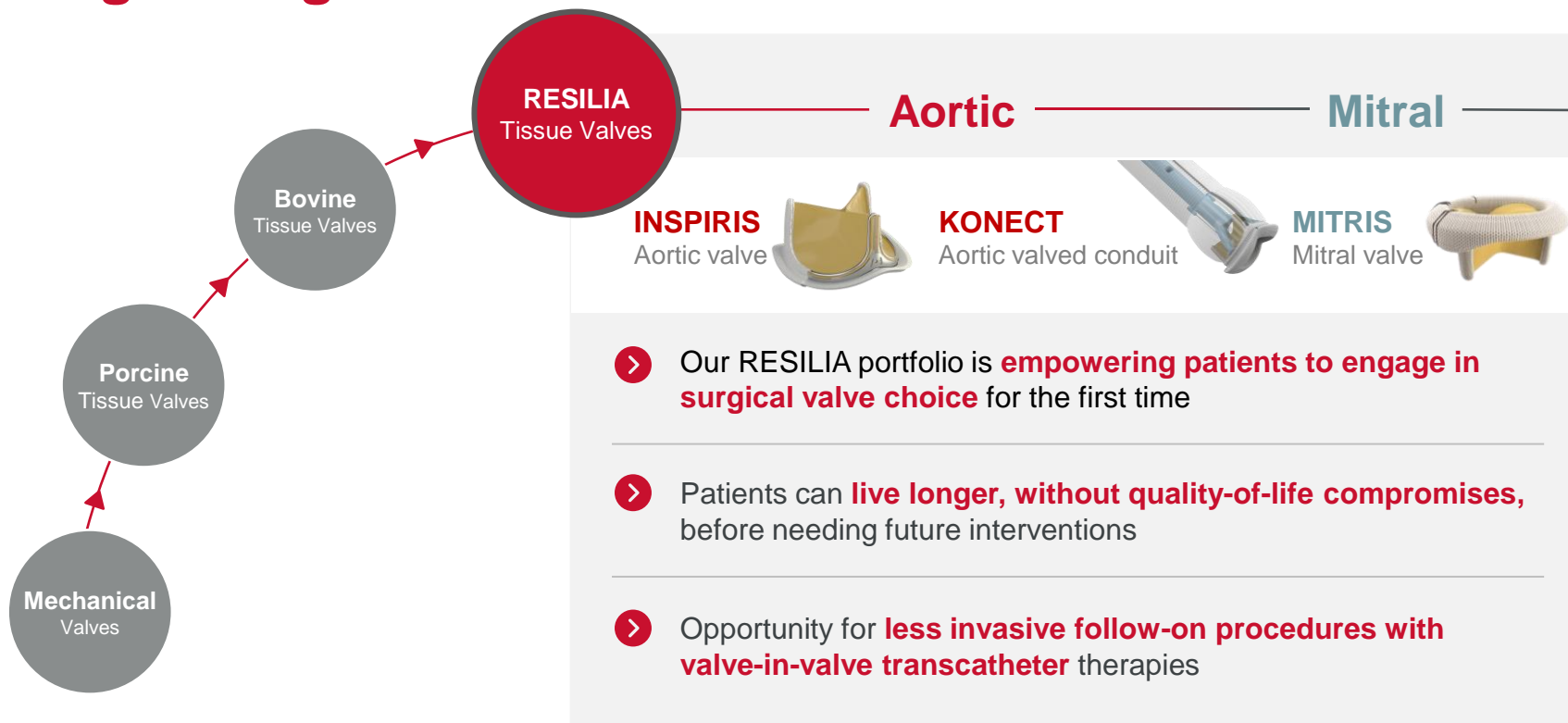
Investing in long-term, real-world evidence on durability



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

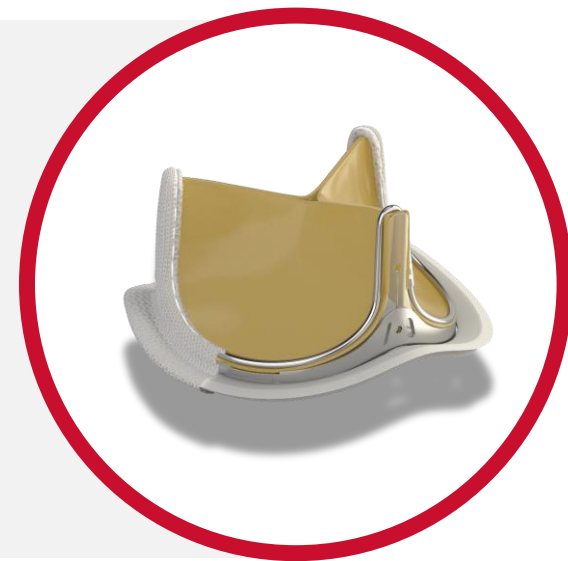
0% structural valve deterioration at 5-yr follow-up¹

Increasing global adoption of RESILIA accelerates long-term growth



INSPIRIS is the leading surgical aortic valve in the world

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



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

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



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

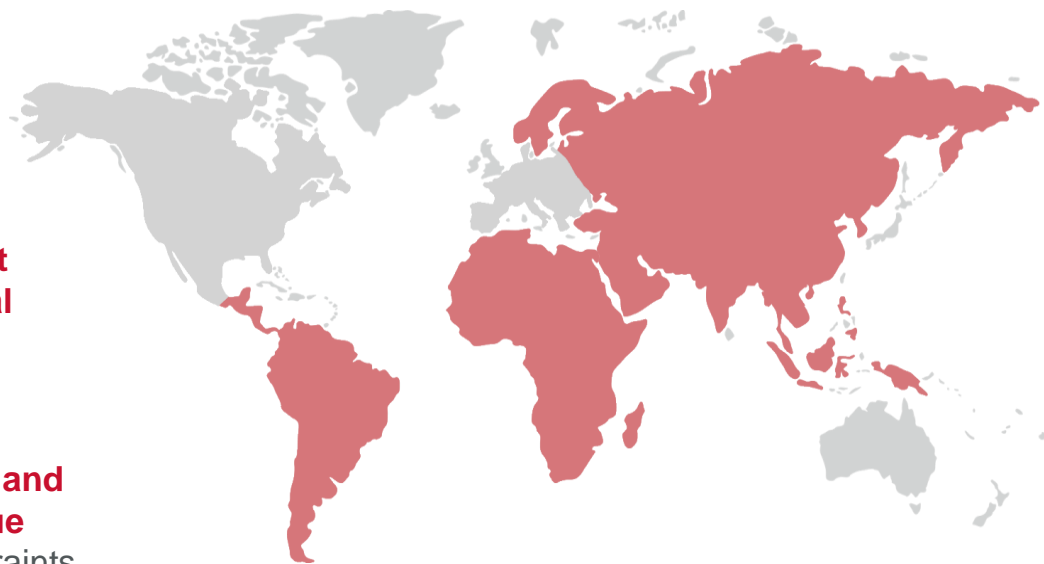
- **Enhanced ease-of-use for implantation** and valve-in-valve compatibility
- Leading mitral valve in Japan six months post-launch; **US launch planned for 2022**
- **Long-term growth opportunity** as 60% of global mitral valve replacement patients receive a mechanical valve



*Not approved in the US

Significant opportunity to grow and accelerate patient impact in emerging markets

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



Two opportunities for innovation in a growing surgical mitral repair market

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

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

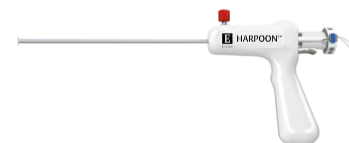
Even at top US centers, ~11% of patients have recurrent moderate or severe MR within two weeks of surgical mitral repair.¹

Innovating Premium Surgical Repair Therapies

Helping surgeons achieve excellent, consistent procedural outcomes

HARPOON

Beating-heart repair for degenerative patients with leaflet prolapse



Mitral Adjustable Repair System

On-and-off pump implant adjustability for degenerative MR



2022 Underlying Global Sales Growth Outlook

Headwinds



Continued TAVR conversion
in developed markets



COVID recovery

\$950M

\$870M

Tailwinds

Adoption of
RESILIA products



Accelerated
mechanical-to-tissue valve
conversion



2022E

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

In Summary

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



Important Safety Information: RESILIA Tissue Devices

Indications: INSPIRIS RESILIA Aortic Valve - For use in replacement of native or prosthetic aortic heart valves. **KONECT RESILIA Aortic Valved Conduit** - For use in replacement of native or prosthetic aortic heart valves and the associated repair or replacement of a damaged or diseased ascending aorta.

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

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

Warnings: INSPIRIS RESILIA Aortic Valve - DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

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

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

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

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