RESILIA TISSUE SURGICAL VALVE PORTFOLIO

At the cutting edge of innovation

Advancing valve design and tissue technology to push performance forward

Edwards

Innovation built on a proven platform

Setting the bar on tissue valve durability with the PERIMOUNT valve platform

RESILIA tissue valves are built on the **Carpentier-Edwards PERIMOUNT valve** platform, whose performance is backed by **30 years** of durability data, including the largest long-term study of a bioprosthetic valve.

40+ years
of real-world experience

30+ years
span of published clinical data

Raising the bar with next-generation advancements

RESILIA tissue valves are enhanced with the **following features** to help you deliver exceptional patient care.

INSPIRIS RESILIA aortic valve

+ RESILIA tissue technology
+ **Novel VFit expansion technology** to facilitate future valve-in-valve (ViV) intervention*

MITRIS RESILIA mitral valve

+ RESILIA tissue technology
+ Designed for the mitral position
+ **Nitinol stents** fold down to 55 degrees, allowing for ease of implant; stents return to original position when valve is implanted

KONECT RESILIA aortic valved conduit

+ RESILIA tissue technology
+ First preassembled, ready-to-implant† valved conduit with RESILIA tissue
+ Versatile DualFit sewing ring

*Refer to device **Instructions for Use** for important warnings related to VFit technology. These features have not been evaluated in clinical studies to establish safety and effectiveness of the model 11500A for use in ViV procedures. VFit technology is available on sizes 19-25 mm.

†Consult instructions for use for device preparation instructions.

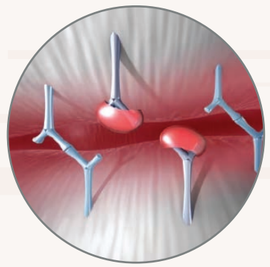
Innovation that transformed the tissue valve landscape

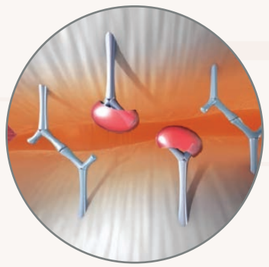
RESILIA tissue technology

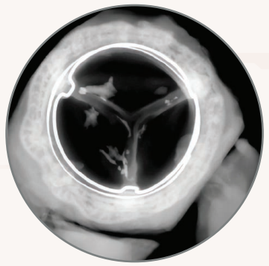
RESILIA tissue* builds on the trusted ThermaFix process and is treated with a **novel preservation technology** to **resist calcification more effectively** and allow for **dry storage**.[1]

+ Calcium-blocking technology
Stable-capping permanently blocks free aldehydes to prevent calcium binding within the tissue

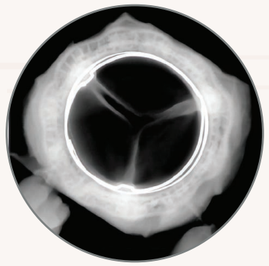
+ Glycerolization
Mitigates calcium-attracting glutaraldehyde residuals and **enables dry tissue storage for increased ease of use**







Control valve (6900P)



RESILIA tissue valve

72% less
calcium content
after 8 months†
(follow-up exceeded the 5-month duration required by regulatory agencies)

RESILIA tissue showed **significant improvement** in calcium-blocking properties[1]

*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.
†RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards in a juvenile sheep model. Flameng, et al. *J Thorac Cardiovasc Surg*. 2015;149:340-345.

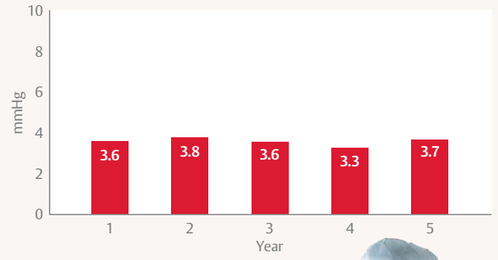
Taking performance and durability to new heights

The RESILIA tissue portfolio is backed by a strong, growing base of clinical evidence attesting to its hemodynamic performance and durability. RESILIA tissue treatment has been applied to INSPIRIS and MITRIS valves and the KONECT aortic valved conduit.

Clinically stable hemodynamics[2,3]

COMMENCE aortic trial
(echo-derived mean gradient, mmHg)

COMMENCE mitral trial
(echo-derived median gradient, mmHg)



Durability data[2,3]

COMMENCE aortic trial
99.3%
freedom
from SVD
through 7 years

COMMENCE mitral trial
98.7%
freedom
from SVD
through 5 years

- RESILIA tissue valves showed less SVD-related HVD vs conventional valves in a comparison of COMMENCE and PARTNER IIA trials[4]

AVC=aortic valved conduit; HVD=hemodynamic valve deterioration; SVD=structural valve deterioration.

Innovation that keeps future procedures in mind

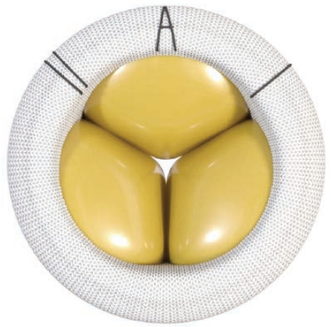
Expanding patient possibilities with VFit technology

The INSPIRIS valve is designed to enable valve-in-valve procedures in the future, at a time when patients are older and potentially at a higher risk for complications.

Only the INSPIRIS valve is designed with **VFit technology**, using a cobalt-chromium alloy band to deliver a controlled and predictable expansion during valve-in-valve deployment.*[5]

- Avoids high-pressure bioprosthetic valve fracture to expand the valve[6]

Largest opening area, with the lowest gradients



The MITRIS valve has the largest surgical valve opening post TMVR, and the lowest peak/mean gradients (data from a comparative preclinical study).[7]

*Based on bench data. Refer to device **Instructions for Use** for important warnings related to VFit technology. These features have not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedures. VFit technology is available on sizes 19–25 mm to fit a broad range of patients with varying annulus size.

TMVR=transcatheter mitral valve replacement.

Designed to prevent obstruction

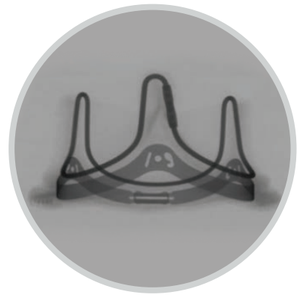
The INSPIRIS valve has biomechanically engineered, internally mounted leaflets. Coronary obstruction is less common in stented bioprostheses with internally mounted leaflets.

The MITRIS valve is designed with the lowest-profile stents that do not obstruct blood flow through the left ventricular outflow tract (LVOT).

Delivering the best visibility for future interventions

A comparative TMVR study showed MITRIS valve was the most fluoroscopically visible vs Epic valve and Mosaic valve.[7]

Chromium-cobalt bands on RESILIA tissue valves offer easy identification of the inflow and outflow edges.



Innovation today for a better tomorrow

Championing continuous improvements in patient care

The RESILIA tissue portfolio represents a landmark innovation attesting to our ongoing commitment to enhance quality of life and prepare for the future—affording patients increased opportunities for tomorrow.

Talk to your representative or visit edwards.com/RESILIA to find out more

References: 1. Flameng W, Hermans H, Verbeken E, et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg.* 2015;149(1):340-345. **2.** Beaver T, Bavaria J, Griffith B, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. *J Thorac Cardiovasc Surg.* 2023;x:1-11. **3.** Heimansohn DA, Baker C, Rodriguez E, et al. Mid-term outcomes of the COMMENCE trial investigating mitral valve replacement using a bioprosthesis with a novel tissue. *JTCVS Open.* 2023;15:151-163. **4.** Bartus K, Bavaria J, Thourani V, et al. Structural hemodynamic valve deterioration durability of RESILIA-tissue versus contemporary aortic bioprostheses. *J Comp Eff Res.* 2023;12(3):e220180. **5.** Saxon JT, Allen K, Cohen D, et al. Bioprosthetic valve fracture during valve-in-valve TAVR: bench to bedside. *Interv Cardiol.* 2018;13(1):20-26. **6.** Saxon JT, Allen K, Cohen D, et al. Complications of bioprosthetic valve fracture as an adjunct to valve-in-valve TAVR. *Structural Heart.* 2019;3(2):92-99. **7.** Wang DD, O'Neill B, Caranasos T, et al. Comparative differences of mitral valve-in-valve implantation: A new mitral bioprosthesis versus current mosaic and epic valves. *Catheter Cardiovasc Interv.* 2022;99(3):934-942.

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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