

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.



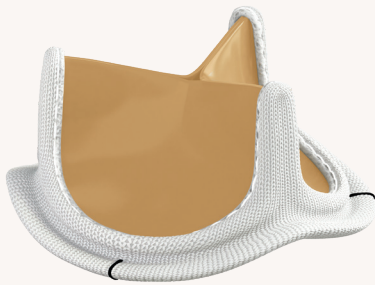
**40+ years**  
of real-world  
experience

**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 potential 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

\*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.

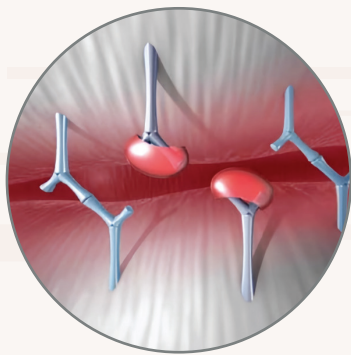
# Innovation that transformed the tissue valve landscape

## RESILIA tissue technology

RESILIA tissue\* builds on the trusted TheraFix process and is treated with a **novel preservation technology** to **resist calcification more effectively** and allow for **dry storage**.<sup>1</sup>

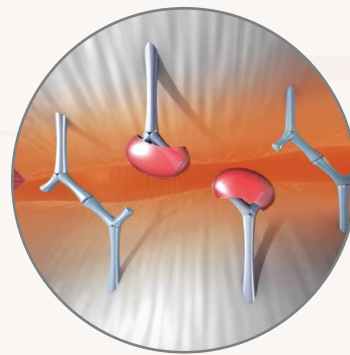
### + Calcium-blocking technology

Stable-capping permanently blocks free aldehydes to prevent calcium binding within the tissue

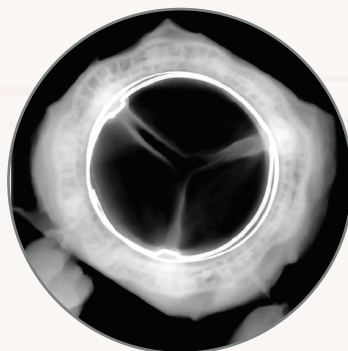


### + Glycerolization

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<sup>†</sup>

(follow-up exceeded the 5-month duration required by regulatory agencies)

RESILIA tissue showed **significant improvement** in calcium-blocking properties<sup>1</sup>

\*No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

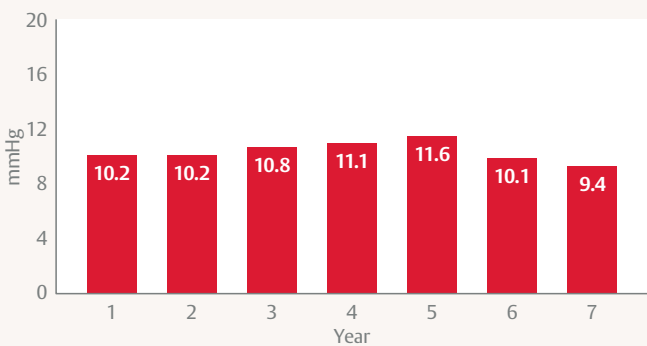
†RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards in a juvenile sheep model. Flameng, et al. *J Thorac Cardiovasc Surg.* 2015;149:340-345.

# Taking performance and durability to new heights

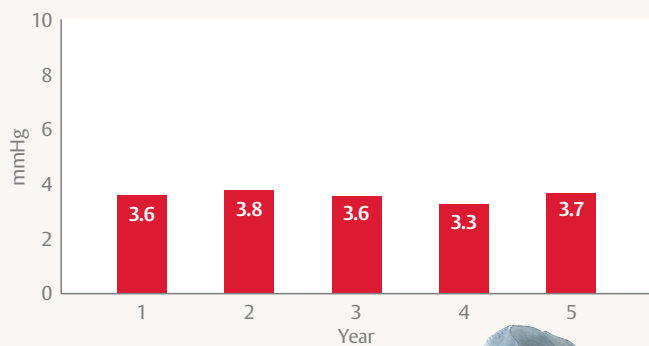
The RESILIA portfolio is backed by a robust, growing base of clinical evidence attesting to its hemodynamic performance and durability. RESILIA tissue treatment has been applied to INSPIRIS and MITRIS valves.

## Clinically stable hemodynamics<sup>2,3</sup>

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



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



## Durability data<sup>2,3</sup>

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<sup>4</sup>



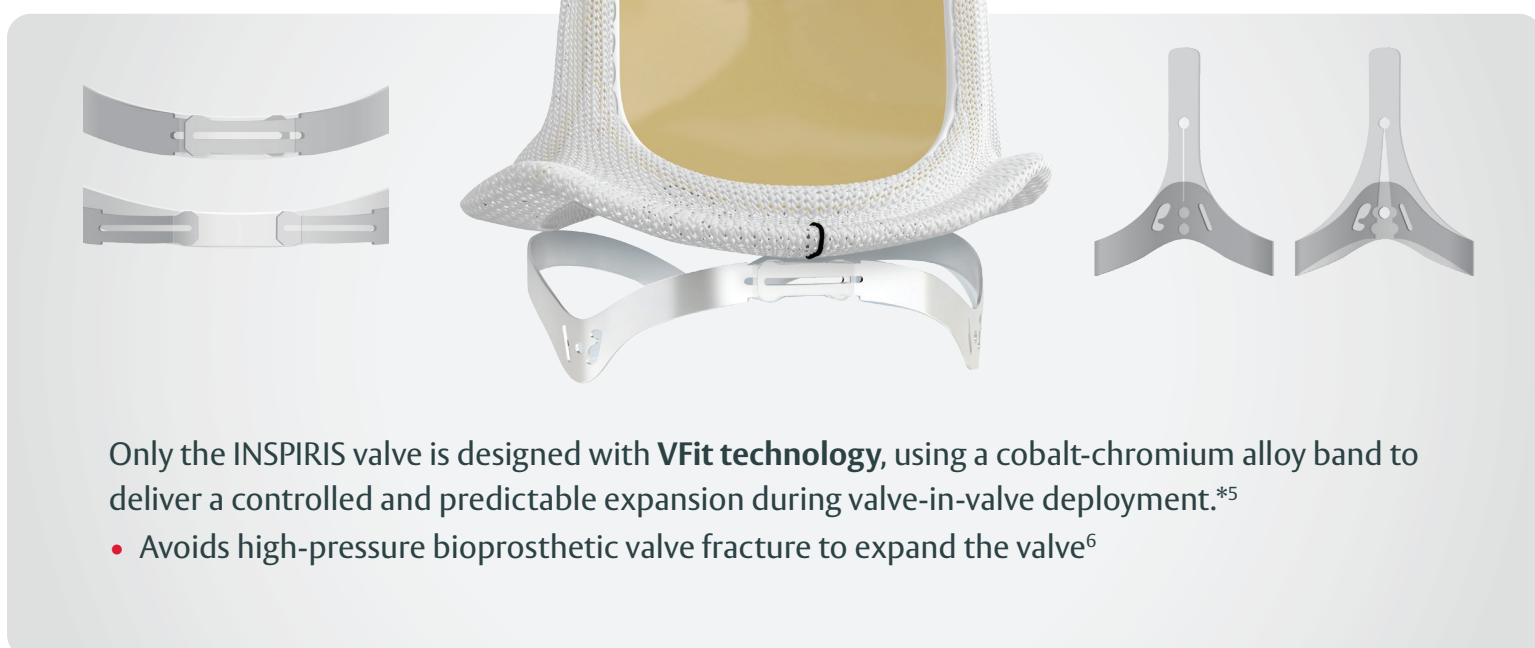
**Freedom**  
from SVD

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

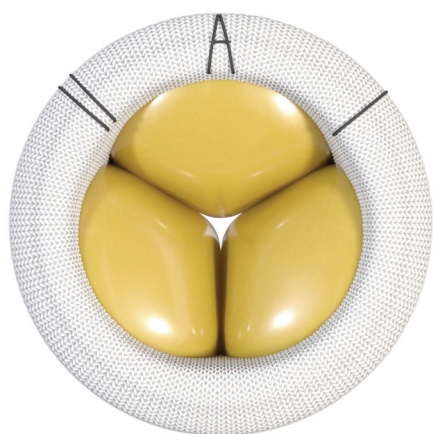
# Innovation that keeps future procedures in mind

## Expanding patient possibilities with VFit technology

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



## 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).<sup>7</sup>

\*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.

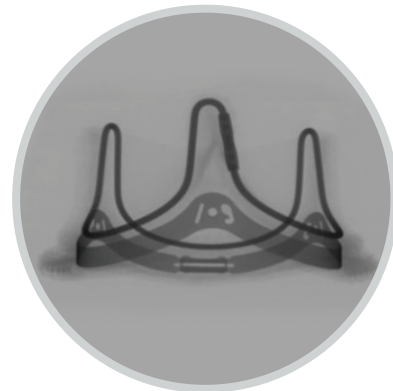


The MITRIS valve is designed with the lowest anterior profile stents that do not obstruct blood flow through the left ventricular outflow tract (LVOT).

## 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.<sup>7</sup>

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/gb/RESILIA](https://edwards.com/gb/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.

No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

**Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult [eifu.edwards.com](https://eifu.edwards.com) where applicable).**

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