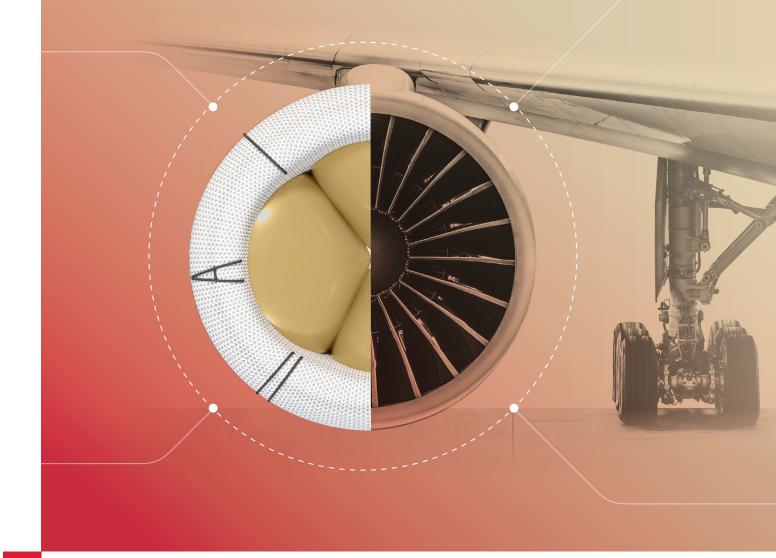
**MITRIS RESILIA Mitral Valve** 

# Designed to handle the pressure of the mitral position





# The tissue valve specifically built for the mitral position



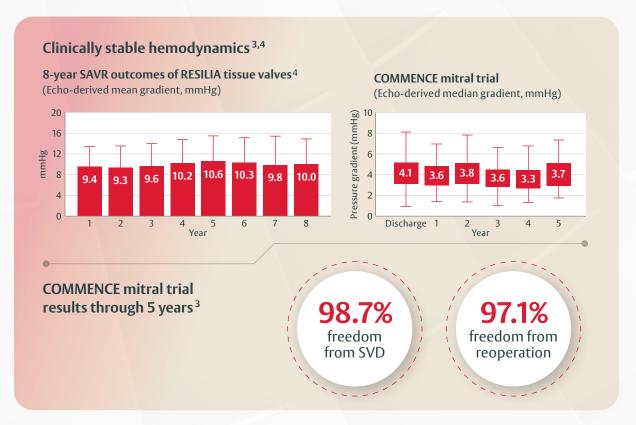
### MITRIS RESILIA valve combines advanced features with proven design

- + Saddle-shaped sewing cuff mimics the native mitral annulus with an atrialized cuff design to reduce ventricular protrusion
- + Lowest profile stents that do not obstruct blood flow through the LVOT
- + Largest surgical valve opening and lowest gradients compared to commercially available valves in a pre-clinical study 1
- + RESILIA tissue\* preservation technology, designed to enhance durability<sup>2</sup>
- + Built on the trusted PERIMOUNT valve platform

<sup>\*</sup> Clinical data on valves with RESILIA tissue up to 7-year follow-up have been published, with additional follow-up of up to 10 years in process.

#### What sets the MITRIS RESILIA valve apart? Data.

Since 2004, RESILIA tissue has been extensively studied. The growing body of clinical evidence supports RESILIA tissue valves' hemodynamic performance and resistance to structural valve deterioration in the mitral position.



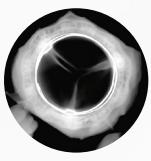
### Juvenile sheep study – mitral position

Reduced calcification after 8 months, exceeding the 5-month reporting requirement<sup>5</sup>

72% reduction in calcification





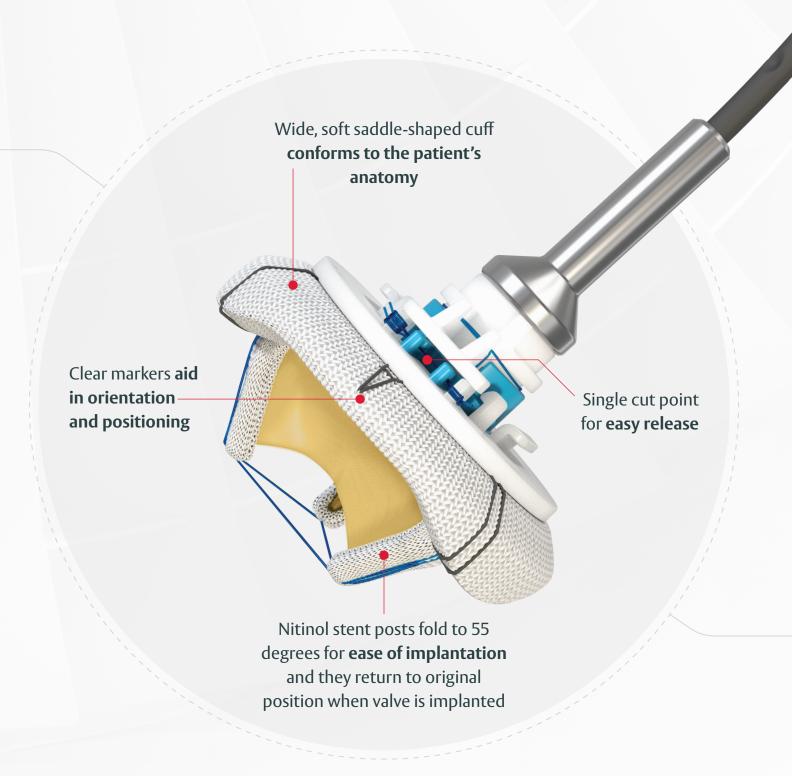


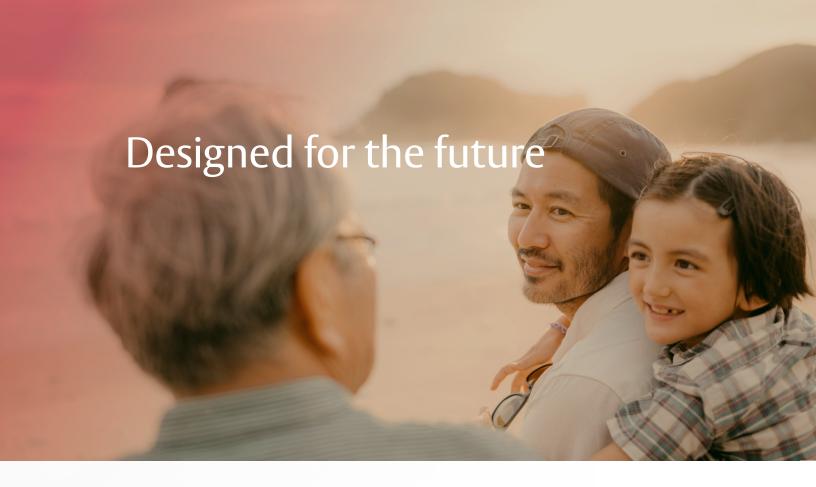
**RESILIA tissue valve** 

Ongoing real-world clinical outcomes study<sup>6</sup>
Global study of up to **500 patients** implanted with the MITRIS RESILIA valve



## Optimized for ease of use





## The MITRIS RESILIA valve is ideal for potential future transcatheter ViV interventions \*7



CoCr band provides better visibility under fluoroscopy compared to competing valves<sup>7</sup> for ease of landing zone identification



Compared to commercially available valves in a pre-clinical study, the MITRIS valve has:

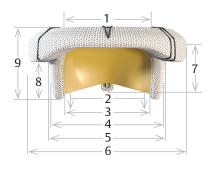
- + the columnar shape design that enables more uniformity in transcatheter heart valve (THV) expansion\*7
- + the least deformation of the THV frame for TMVR ViV\*7
- + the greatest THV leaflet opening area and lowest peak/ mean trans-mitral gradient for TMVR ViV\*7



<sup>\*</sup> While the SAPIEN 3 valve is approved for ViV procedures in the mitral position for patients who are at intermediate or greater risk for open surgical therapy, these individual surgical valves are not indicated for ViV. The safety and effectiveness of ViV in these surgical valves has not been established.

#### Model 11400M

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Valve Size (mm)	25 mm	27 mm	29 mm	31 mm	33 mm
1. Inflow orifice diameter (mm)	23.0	25.0	27.0	29.0	29.0
2. Effective orifice diameter (mm)*	19.5	21.0	23.0	25.0	25.0
3. Stent diameter (wireform, mm)	25.0	27.0	29.0	31.0	31.0
4. External stent post diameter (tip, mm)	27.0	29.0	30.0	33.0	33.0
5. Valve housing external diameter (mm)	27.5	29.5	31.5	33.5	33.5
6. External sewing ring diameter (mm)	36.5	38.5	41.0	42.5	44.5
7. Effective profile posterior (mm)	10.0	10.5	11.0	11.5	11.5
8. Effective profile anterior (mm)	7.0	7.5	8.0	8.5	8.5
9. Total profile height (mm)	15.0	16.0	17.0	18.0	18.0



\*Effective orifice diameter (ID-effective): a diameter derived from hydrodynamic performance data measured with a standard validated procedure. ID-effective is an indicator of hemodynamic performance.

#### Accessories

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Model	Description	
1173B	Individual barrel sizer	
1173R	Individual replica sizer	
SET1173	Sizer tray only	

#### Handle

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1140M Nitinol handle	
1141M Stainless steel handle	

## See the difference MITRIS RESILIA valve can make Visit Edwards.com/MITRIS or scan the QR code to learn more.



#### References

- 1. Wang DD, Caranasos TG, O'Neill BP, et al. Comparison of a new bioprosthetic mitral valve to other commercially available devices under controlled conditions in a porcine model. *J Card Surg*. 2021 Dec;36(12):4654–4662. doi: 10.1111/jocs.16021.
- 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;15:15–163.
- 4. Kaneko, T, Johnston D, Bavaria JE, et al. Propensity-matched 8-year Outcomes Following Surgical Aortic Valve Replacement With Novel Calcificationresistant Versus Contemporary Tissue Bioprostheses. Presented at the Heart Valve Society Annual Scientific Meeting, April 2025.
- 5. 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.
- 6. Real-world Clinical Outcomes of the MITRIS RESILIA Mitral Valve (MOMENTIS). Currently recruiting. https://clinicaltrials.gov/study/NCT05526560.
- 7. Wang DD, O'Neill BP, Caranasos TG, 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. doi: 10.1002/ccd.30011.

#### Important Safety Information: MITRIS RESILIA Mitral Valve

Indications: For use in replacement of native or prosthetic mitral heart valves. Contraindications: There are no known contraindications with the use of the MITRIS RESILIA mitral 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, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

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