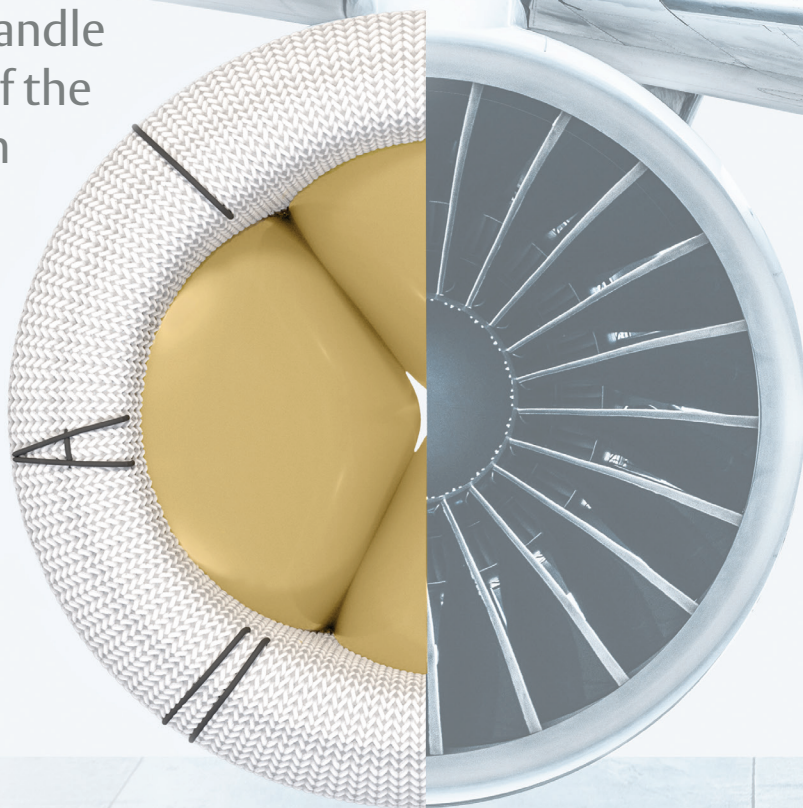


# MITRIS RESILIA Mitral Valve

Designed to handle  
the pressure of the  
mitral position



Edwards

Enhanced delivery experience.

Built on the **Carpentier-Edwards PERIMOUNT valve platform** – a platform with over 20 years of published clinical durability<sup>3</sup>

Nitinol stents fold down to 55 degrees allowing for **ease of implant**; stents return to original position when valve is implanted.

A posteromedial commissure mark (single black line), an anterolateral commissure mark (double black line), and an anterior segment mark (“A” mark). The black commissure markers **facilitate the orientation of the valve** and help avoid obstruction of the left ventricular outflow tract by stent posts.

## We designed the MITRIS RESILIA mitral valve:

- > To be conformable and seat well on the mitral annulus
- > To be a replacement option similar to the native valve
- > To handle the pressure of the mitral position

**Learn what the MITRIS valve can do for you and your patients.**



# When replacement is the best choice, what if you had an option designed to be **similar to the native valve?**

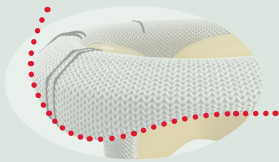
When your patient's disease may be too complex, and mitral valve repair is not feasible, Edwards Lifesciences brings you the MITRIS RESILIA mitral valve.

As your trusted partner in cardiac surgery innovation, Edwards has developed the MITRIS RESILIA mitral valve to help meet the specialized needs of your patients. We understand the mitral valve and that the skill required to repair or replace it commands your respect. That's why we designed a replacement valve built for the mitral position.



## How the MITRIS valve handles the pressure of the mitral position:

A **saddle-shaped** sewing cuff that mimics the native mitral annulus. This asymmetrical design is specifically tailored to the contours of the native annulus.



**RESILIA tissue\*** is designed to offer enhanced<sup>†</sup> tissue anti-calcification technology and the promise of increased durability.<sup>1</sup>

RESILIA tissue is bovine pericardial tissue treated with a special integrity preservation technology that effectively eliminates free aldehydes, a key factor in tissue calcification, while protecting and preserving tissue.<sup>1,2</sup>



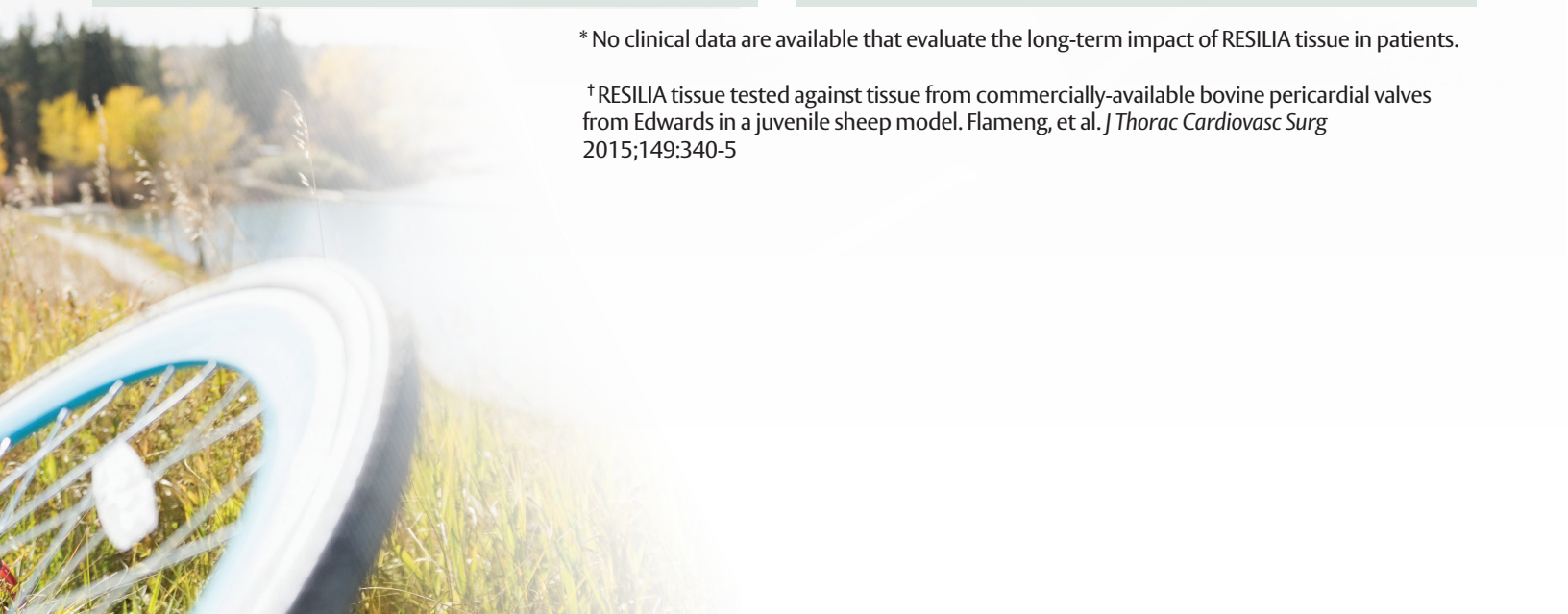
**Good visibility under fluoroscopy** for easy identification of the landing zone for potential future transcatheter interventions.

**Lowest profile stents** do not obstruct blood flow through the left ventricular outflow tract (LVOT).

Dry storage to **eliminate the need for rinsing.**

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

<sup>†</sup> 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;149:340-5



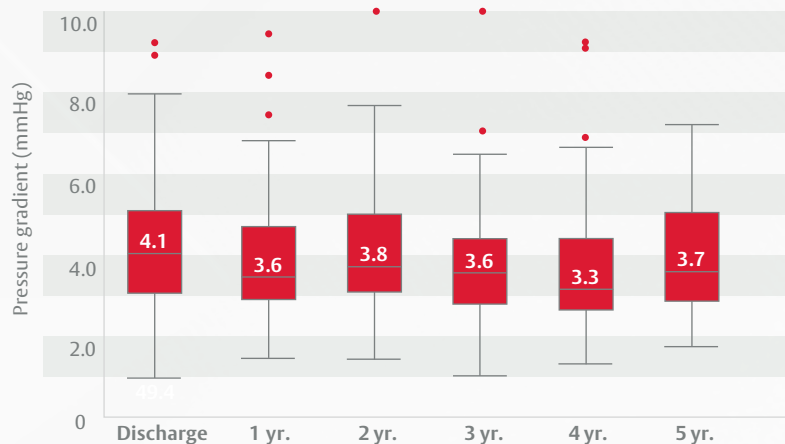
Backed by a strong and growing body of clinical evidence supported by RESILIA tissue's ongoing study of durability and hemodynamic performance <sup>1,4,5,6</sup>

### COMMENCE Mitral clinical trial

Clinically stable hemodynamics and one incident of structural valve deterioration (SVD) through 5 years.

**98.7%** Actuarial freedom from SVD through 5 years

Stable gradient Median gradient (mmHg)

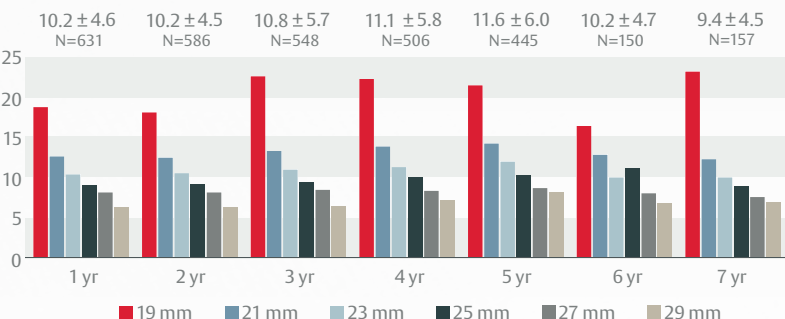


### COMMENCE Aortic clinical trial

Clinically stable hemodynamics and two incidents of SVD through 7 years.

**99.3%** Actuarial freedom from SVD through 7 years

Stable gradients Mean gradient (mmHg)

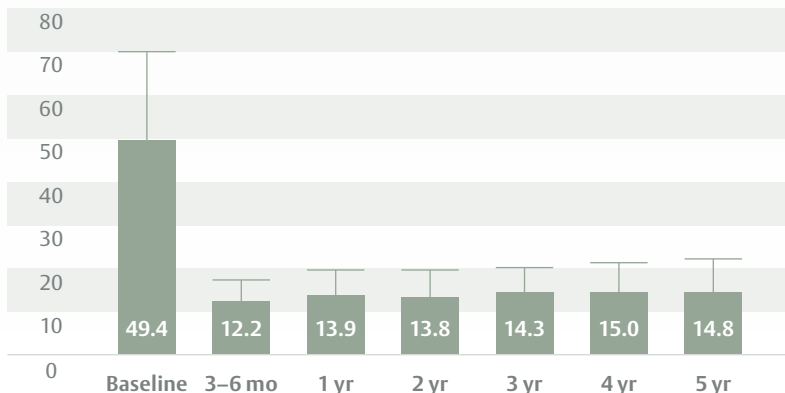


### European Aortic clinical trial

Clinically stable hemodynamics and zero SVD through 5 years in 133 patients.

**100%** Actuarial freedom from SVD through 5 years

Mean gradient (mmHg) Valve sizes 19–27 mm





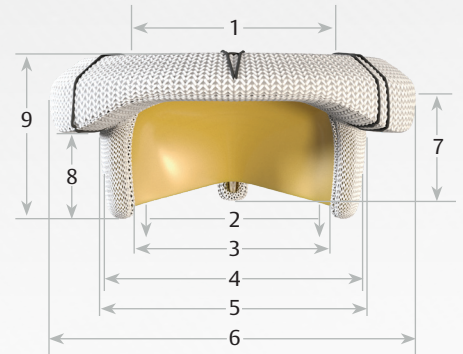
Built on the trusted Carpentier-Edwards PERIMOUNT valve platform, and made with RESILIA tissue for decreased calcification\*, this is the mitral valve developed with your patient's quality of life in mind.

Here you have a valve choice designed to handle the pressure of the mitral position.

Talk to your rep or visit [Edwards.com/MITRIS](https://www.edwards.com/MITRIS) to find out more.

## Model 11400M

| 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  |



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

| Models available in odd sizes 25–33mm                    | Accessories - Sizers   | Handle   |
|--|--|--|
| 11400M25    11400M31<br>11400M27    11400M33<br>11400M29 | Individual barrel sizers 1173B<br>Complete barrel set SET1173B<br>Individual replica sizers 1173R<br>Complete replica set SET1173R | 1140M Nitinol handle<br>1141M Stainless steel handle |

### 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 (USA) law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information.**

### 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; 149:340–5.
2. Prieve A, Almagor A, Yedgar S, et al. Glycerol decreases the volume and compressibility of protein interior. *Biochemistry.* 1996;35(7):2061–2066.
3. Bourguignon T, Bouquiaux-Stablo A, Loardi C, et al. Very long-term outcomes for mitral valve replacement with the Carpentier-Edwards pericardial bioprosthesis: 25-year follow-up of 450 implantations. *J Cardiothorac Surg.* 2014;148(5):2004-11.
4. Beaver T, Bavaria JE, Griffith B, Svensson LG, Pibarot P, Borger MA, Sharaf OM, Heimansohn DA, Thourani VH, Blackstone EH, Puskas JD; COMMENCE Trial Investigators. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. *J Thorac Cardiovasc Surg.* 2023 Sep 29;S0022-5223(23)00873-5. doi: 10.1016/j.jtcvs.2023.09.047. Epub ahead of print. PMID: 37778503.
5. Bartus K, Litwinowicz R, Bilewska A, et al. Final 5-year outcomes following aortic valve replacement with a RESILIA tissue bioprosthesis. *Eur J Cardiothorac Surg.* 2021;59(2):434-41.
6. 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.

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