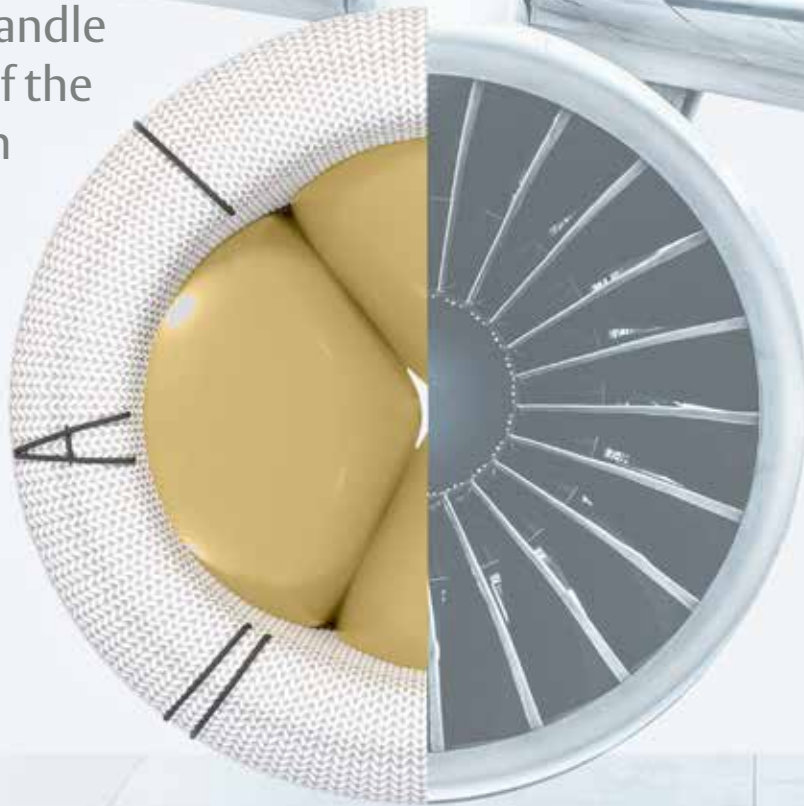


MITRIS RESILIA Mitral Valve

Designed to handle
the pressure of the
mitral position



Edwards

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

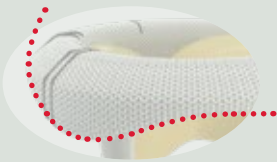
When your patient's disease may be too complex, and mitral valve repair is not feasible, Edwards Lifesciences brings you the MITRIS RESILIA mitral valve.

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.



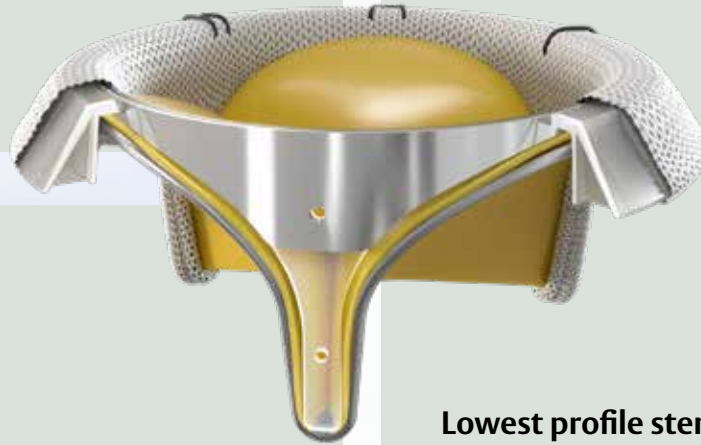
How the MITRIS valve handles the pressure of the mitral position:

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 tissue anti-calcification technology and the promise of increased durability.¹

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.^{1,2}



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 need** for rinsing.

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



Enhanced delivery experience.

Built on the **Carpentier-Edwards PERIMOUNT valve platform** – a platform with over 20 years of published clinical durability³.

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.

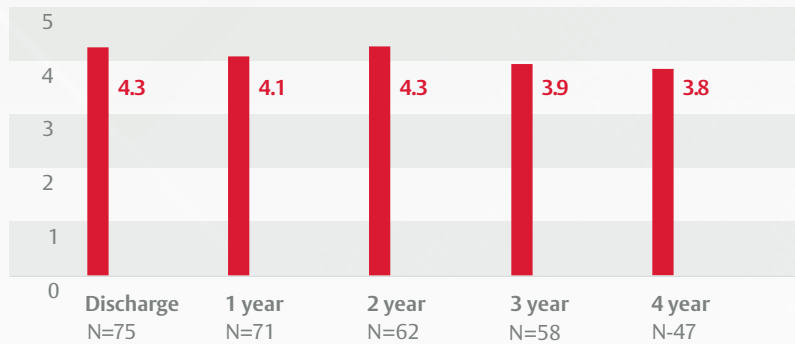
Backed by a strong and growing body of clinical evidence supporting RESILIA tissue's ongoing study of durability and hemodynamic performance ^{1,4,5,6}

COMMENCE Mitral clinical trial

Clinically stable hemodynamics and one incident of structural valve deterioration (SVD) through 4 years in 82 patients.

98.7% Actuarial freedom from SVD through 4 years

Stable gradients Mean gradient (mmHg)

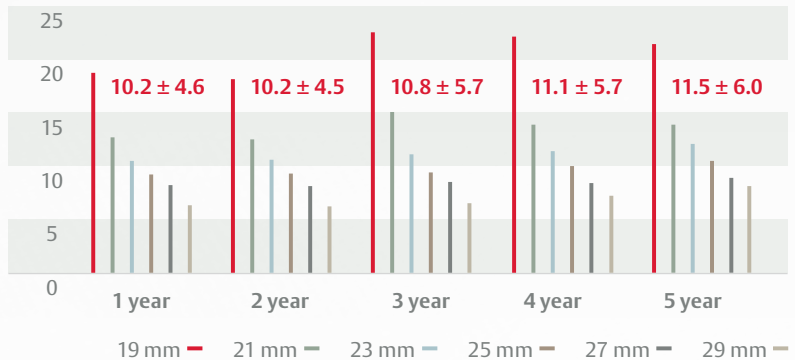


COMMENCE Aortic clinical trial

Clinically stable hemodynamics and zero SVD through 5 years in 689 patients.*

100% Actuarial freedom from SVD through 5 years*

Stable gradients Mean gradient (mmHg)



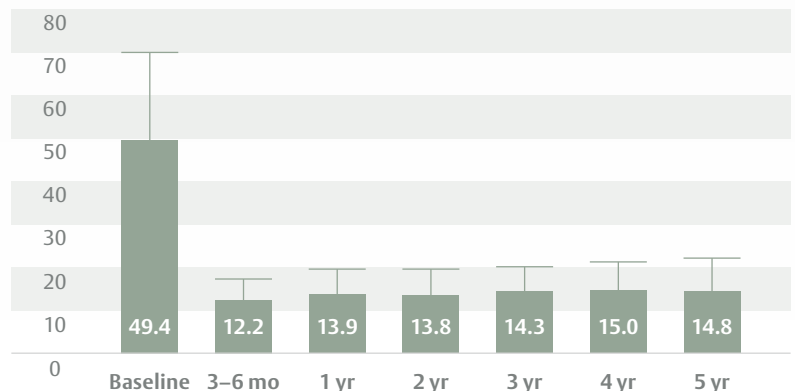
*1 SVD diagnosed at post-operative day 1848

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.

* 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	Individual barrel sizers 1173B	Reusable Handle 1140M
11400M27	11400M33	Complete barrel set SET1173B	
11400M29		Individual replica sizers 1173R	
		Complete replica set SET1173R	

References:

1. Flameng W, 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. Prieu A, et al. Glycerol decreases the volume and compressibility of protein interior. Biochemistry. 1996;35(7):2061–2066.
3. Bourguignon T, 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. Bavaria, et al. Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with a novel tissue bioprosthesis. Society of Thoracic Surgery, 2021 Annual Meeting.
5. Bartus K, 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 D, et al. Mitral Valve Replacement using a Pericardial Valve with RESILIA Tissue. American Association of Thoracic Surgery, 2021 Annual Meeting.

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.

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