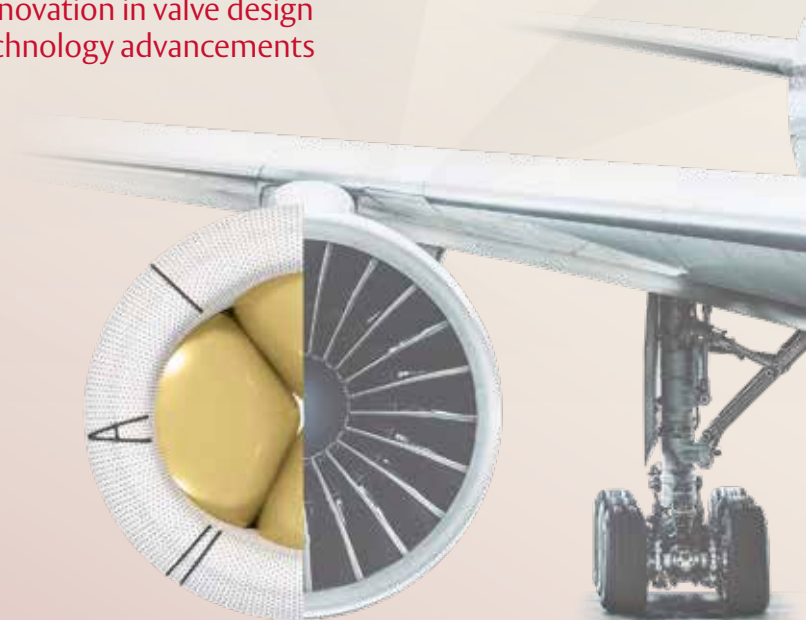


The MITRIS RESILIA valve

A legacy of innovation in valve design
and tissue technology advancements



*Performance and
durability, reimagined¹⁻⁶*



Edwards

Built on five generations of Edwards Lifesciences' mitral tissue valves



Edwards Lifesciences transitioned from developing porcine mitral valves to bovine pericardial valves in the mitral position, offering mitral patients a tissue better suited to withstand the higher pressures of the mitral valve.⁷⁻⁹

The MITRIS RESILIA valve, the latest generation of the PERIMOUNT platform, features an improved design, which enhances its haemodynamics, durability, and ease of use.^{5,6}

The MITRIS RESILIA valve is also built with potential future transcatheter interventions in mind, supporting **lifetime management** for your patients.

The MITRIS RESILIA valve is designed to handle the pressure of the mitral position

Valve design is not just important; it directly **dictates performance** and, therefore, patient outcomes.¹⁰



It is optimised for ease of use:^{11,12}

Lowest anterior profile height that does not obstruct blood flow through the left ventricular outflow tract (LVOT)

Atrialised cuff design to reduce ventricular projection and to minimise risk of LVOT obstruction and left ventricular (LV) wall injury

Asymmetrical saddle-shaped sewing cuff to mimic the native mitral annulus

Foldable, nitinol stent posts that minimise the potential occurrence of suture entrapment/looping

Holder design stops the user from over-torquing the dial which can lead to the breakage of the blue polymer thread during the stent folding process

Cobalt chromium bands that provide good visibility under fluoroscopy for easy identification of the landing zone for potential future transcatheter interventions

Black “A” markings to ensure optimal orientation with the anterior portion of the mitral annulus

A single-cut point for easy release

Haemodynamically, the MITRIS RESILIA valve outperforms porcine valves⁵

In a head-to-head comparison study with the Abbott Epic™ and Medtronic Mosaic™ porcine valves, the MITRIS RESILIA valve was shown to have the:⁵

**Largest internal frame
dimensions and valve
opening area**

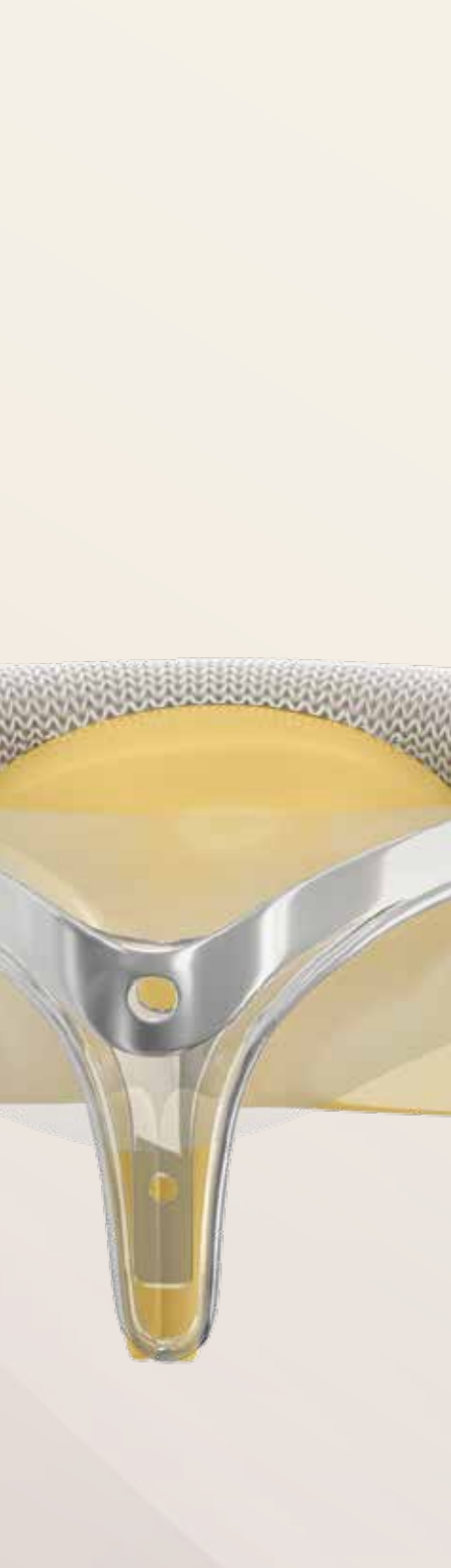


**Shortest and
narrowest struts**

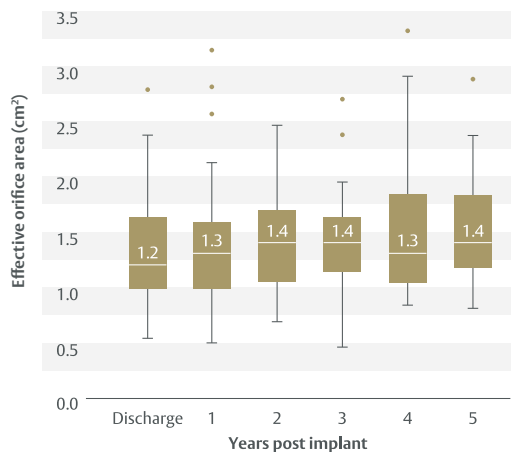
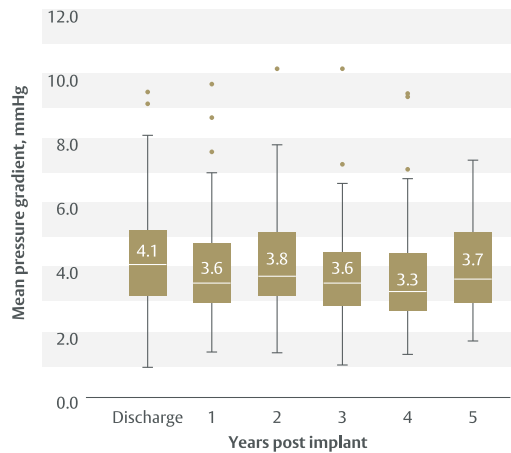


**Lowest peak/mean
mitral gradients**





The COMMENCE mitral trial also showed **clinically stable mean pressure gradients and effective orifice areas** through to 5-year follow-up after mitral valve replacement with the Carpentier-Edwards PERIMOUNT Magna Mitral Ease valve featuring **RESILIA tissue**.^{††13}



Box and whisker plots of median, interquartile ranges and outliers are shown.

Graphs adapted from Heimansohn DA, *et al.* 2023.¹³

RESILIA tissue
is now supported
by a strong and
growing body of
clinical evidence
in both the
aortic and mitral
positions^{2,13,14}



As life expectancies rise tissue valves must be increasingly durable,^{3,4} and so Edwards Lifesciences has incorporated its latest generation bovine pericardial tissue, RESILIA tissue, in the MITRIS RESILIA valve. Engineered with a special integrity preservation technology, **RESILIA tissue effectively eliminates free aldehydes, a key factor in tissue calcification, potentially allowing the valve to last longer.**⁶

As well as the results from COMMENCE mitral trial,¹³ the MOMENTIS trial demonstrated that **MITRIS RESILIA valves delivered 100% freedom from structural valve deterioration (SVD) at 1 year in the mitral position.**^{§15} The MOMENTIS trial will track patient outcomes for up to 10 years.

In the aortic position, RESILIA tissue has already shown a significant improvement in freedom from SVD at 8 years (99.3% vs 90.5% in non-RESILIA tissue valves; $P < 0.0001$), with a favourable safety profile.¹¹

Learn more about how the MITRIS RESILIA valve's design could impact your patients' lifetime management of mitral valve disease at our website using the QR code below:



*A head-to-head study evaluating three mitral bioprostheses of comparable measured internal diameters implanted in 12 Yorkshire pigs with similar-sized cardiac anatomy (27 mm Abbott Epic™ mitral valve [n=4]; 27 mm Medtronic Mosaic™ mitral valve [n=4]; 25 mm MITRIS RESILIA valve [n=4]) via thoracotomy on cardiopulmonary bypass (CPB). After CPB, epicardial echocardiographic measurements were performed to assess haemodynamic function, followed by post-operative gated contrast computed tomography (CT). To ensure comparable anatomical and haemodynamic study conditions, pigs with a >6% anatomical variation were excluded from the study.⁵

[†]Clinical data on surgical aortic valves with RESILIA tissue up to 7-year follow-up have been published, with additional follow-up to 10-years in progress.²

[‡]The COMMENCE mitral trial was a prospective, multicentre, single-arm study across 17 US and Canadian centres, evaluating the Carpentier-Edwards PERIMOUNT Magna Mitral Ease valve (Model 11000M) with RESILIA tissue. It enrolled 82 MVR patients (with/without coronary artery bypass graft), with 54 completing 5-year follow-up. Median patient age was 70 years (IQR 13), 41.5% male, 35% NYHA II, 42% NYHA III. Valve sizes 27 or 29 mm were implanted in 65.9%. The median (IQR) follow-up time was 5.1 (1.4) years, with a total of 374.2 patient-years in aggregate.¹³

[§]The MOMENTIS mitral study was designed to evaluate the safety and effectiveness of the MITRIS RESILIA valve in adults with a dysfunctional native or prosthetic mitral valve who required replacement.¹⁵

[¶]COMMENCE, a study evaluating 8-year outcomes in two propensity-matched cohorts, following aortic valve replacement. The RESILIA tissue valve cohort consisted of patients from the COMMENCE aortic trial (n=689). The non-RESILIA tissue valve cohort originated from the Carpentier-Edwards PERIMOUNT Magna Ease post-approval study (n=258).¹

Abbreviations

CPB, cardiopulmonary bypass; CT, computed tomography; IQR, interquartile range; LV, left ventricular; LVOT, left ventricular outflow tract; MVR, mitral valve replacement; NYHA, New York Heart Association; SVD, structural valve deterioration; US, United states.

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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 where applicable).

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