Edwards SAPIEN 3 Ultra valve

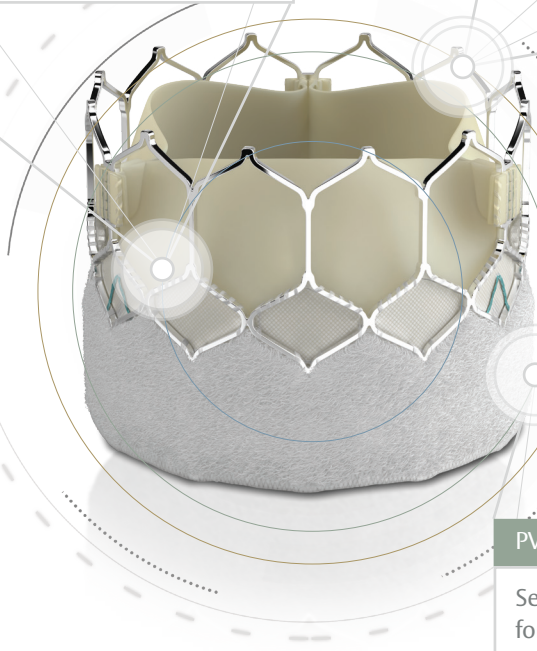
Now approved for low-risk severe aortic stenosis

Low rates of pacemaker implantation[1]

Predictable positioning and low frame height while demonstrating low rates of permanent pacemaker implantation[1,2]

Future coronary access

Short frame height and open cell geometry facilitates future coronary access[3]



PVL performance

Sealing skirt designed for paravalvular leak (PVL) performance

Low-risk patients deserve the lowest-risk procedure

Give your patients SAPIEN 3 Ultra TAVI

Edwards

Low-risk patients deserve the lowest-risk procedure

SAPIEN 3 Ultra demonstrates low rates of death and stroke at 30 days.[1]

Your valve choice today can impact your patients' future

Coronary access

- Post-TAVI patients are at risk of developing coronary artery disease (CAD) following implantation[4]

Paravalvular leak

- Paravalvular leak (PVL) has been associated with long-term patient cardiovascular mortality after TAVI[5]

Conduction disturbances

- Long-term complications from pacemaker implantation negatively impact patient quality of life and mortality[6]

References:

1. STS/ACC TVT Registry, Data on File at Edwards Lifesciences.
2. Webb J, Gerosa G, Lefèvre T, Leipsic J, Spence M, Thomas M, et al. Multicenter evaluation of a next-generation balloon-expandable transcatheter aortic valve. J Am Coll Cardiol. 2014;64(21):2235–43.
3. Tarantini G, Fovino LN, Leprince P, et al. Predictors, feasibility and outcomes of coronary intervention up to 3 years after TAVI with a balloon-expandable valve: results from a large European multicenter registry. Presented at: ESC Congress 2019; September 2019; Paris, France.
4. Yudi MB, et al. Coronary Angiography and percutaneous coronary intervention after transcatheter aortic valve replacement. *JACC* Vol 71, No 12, 2018.
5. Kapadia-, S. et al. (2015). 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial. *The Lancet*. 385 (9986), 2485-91.
6. Fujita B, et al. Impact of new pacemaker implantation following surgical and transcatheter aortic valve replacement on 1-year outcome. *Eur J Cardiothorac Surg* 2019.

Available in 20, 23, and 26 mm sizes.
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Your patients are resilient.

Their valves should be too.

Discover how RESILIA tissue is enabling the latest class of resilient heart valves

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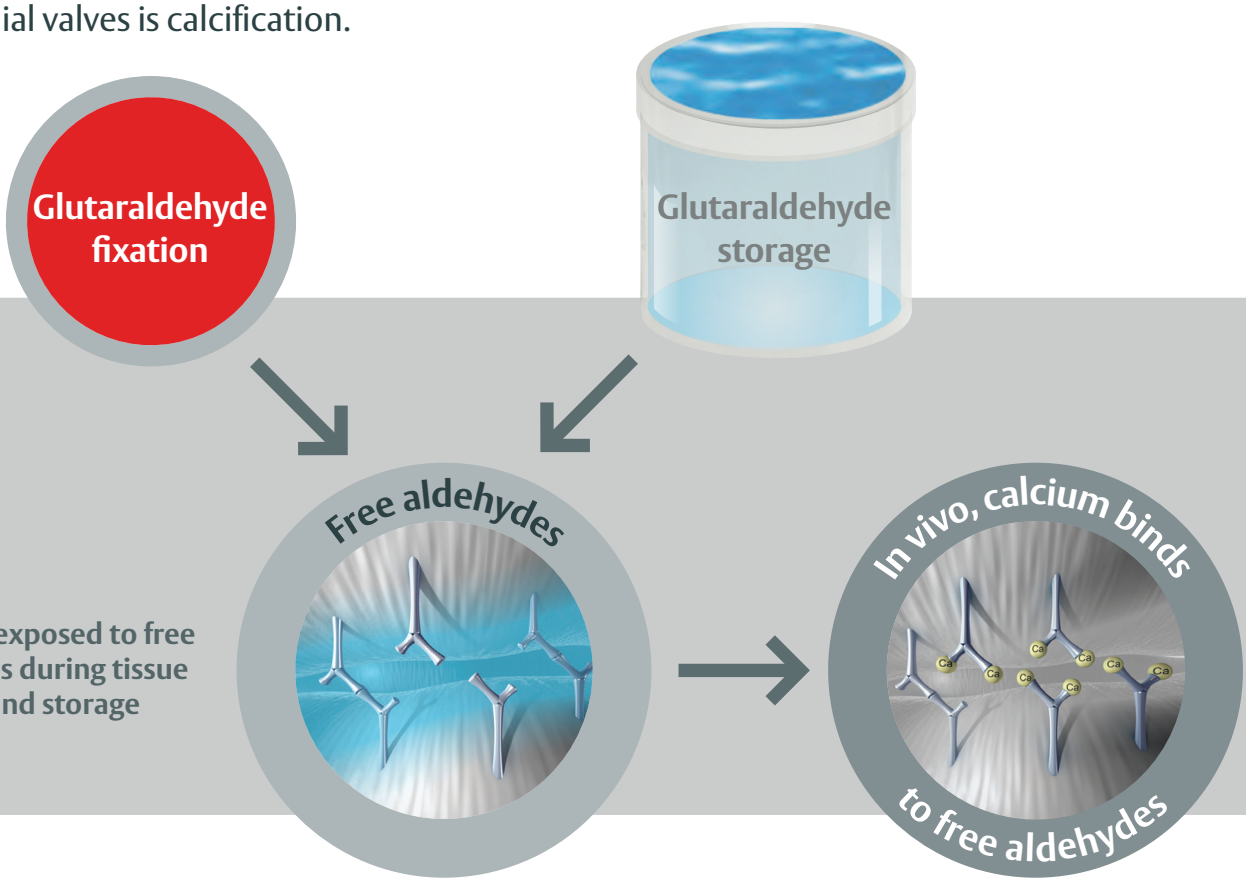
Today's patient:
Needs and expectations

Your patients are living longer than ever before – and they want to live their longer lives to the fullest, continuing to enjoy their active lifestyles.

Current technology:
Inherent limitations

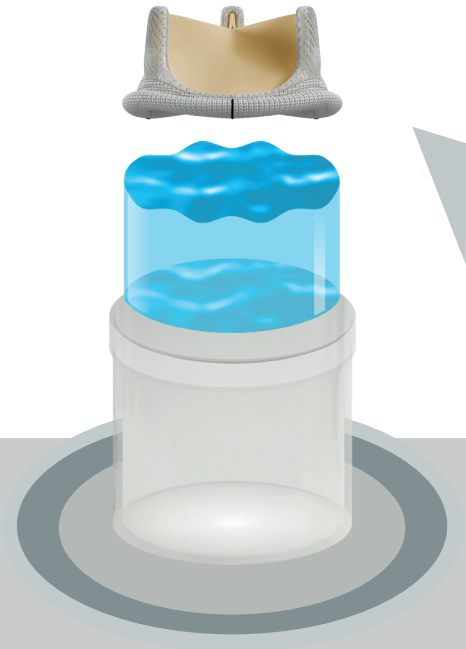
The primary mode of failure for bovine pericardial valves is calcification.

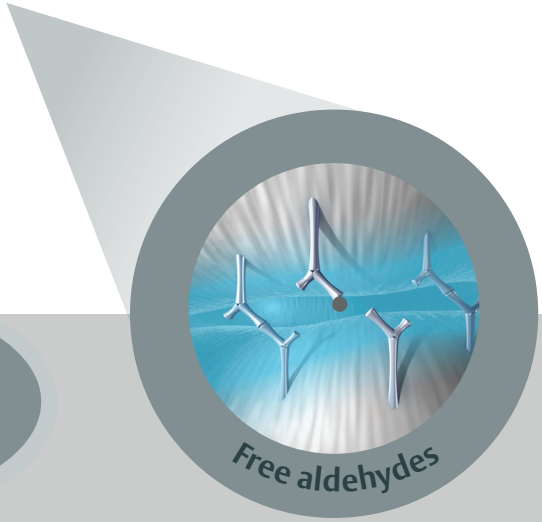


Patients in the future may need a more resilient tissue solution

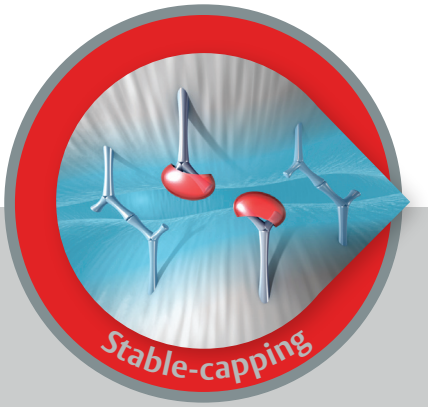
Making tissue more resilient:
Introducing RESILIA tissue

RESILIA tissue is bovine pericardial tissue transformed by the addition of a novel **integrity preservation technology**, which incorporates two proprietary features.



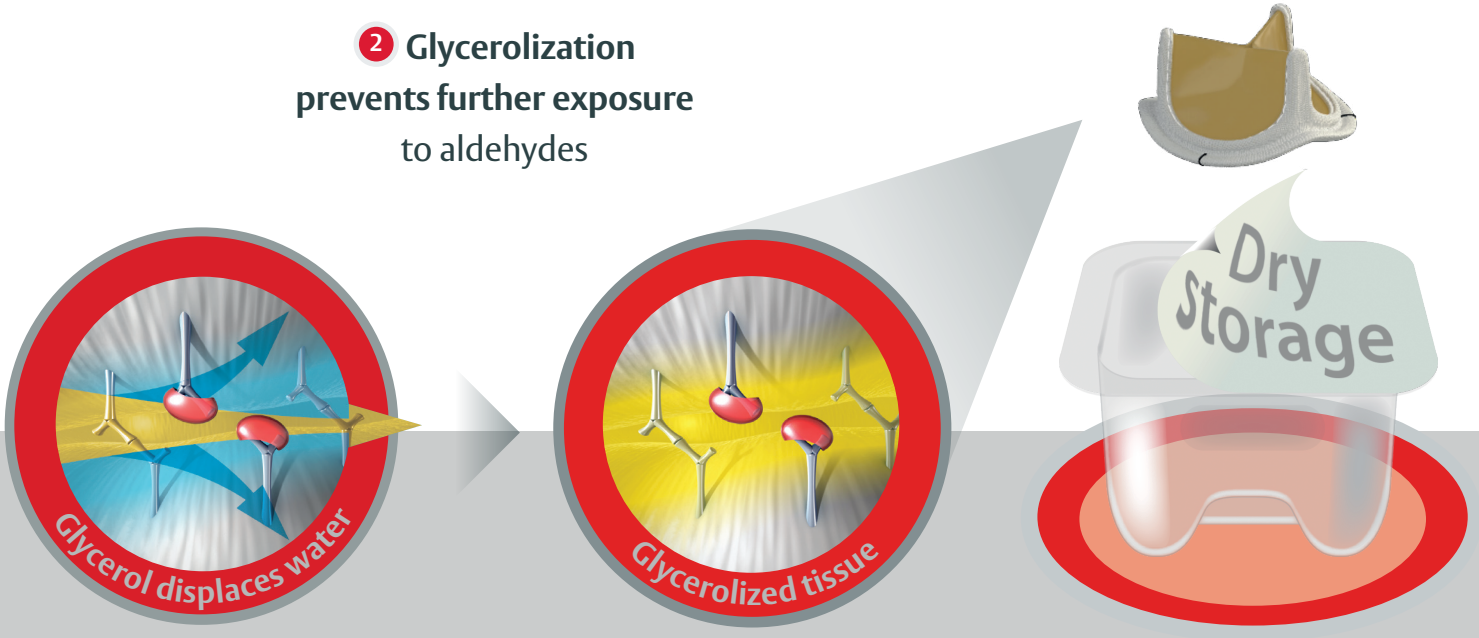


1 Stable-capping permanently blocks free aldehydes



Integrity preservation technology
virtually eliminates free aldehydes while protecting and preserving the tissue

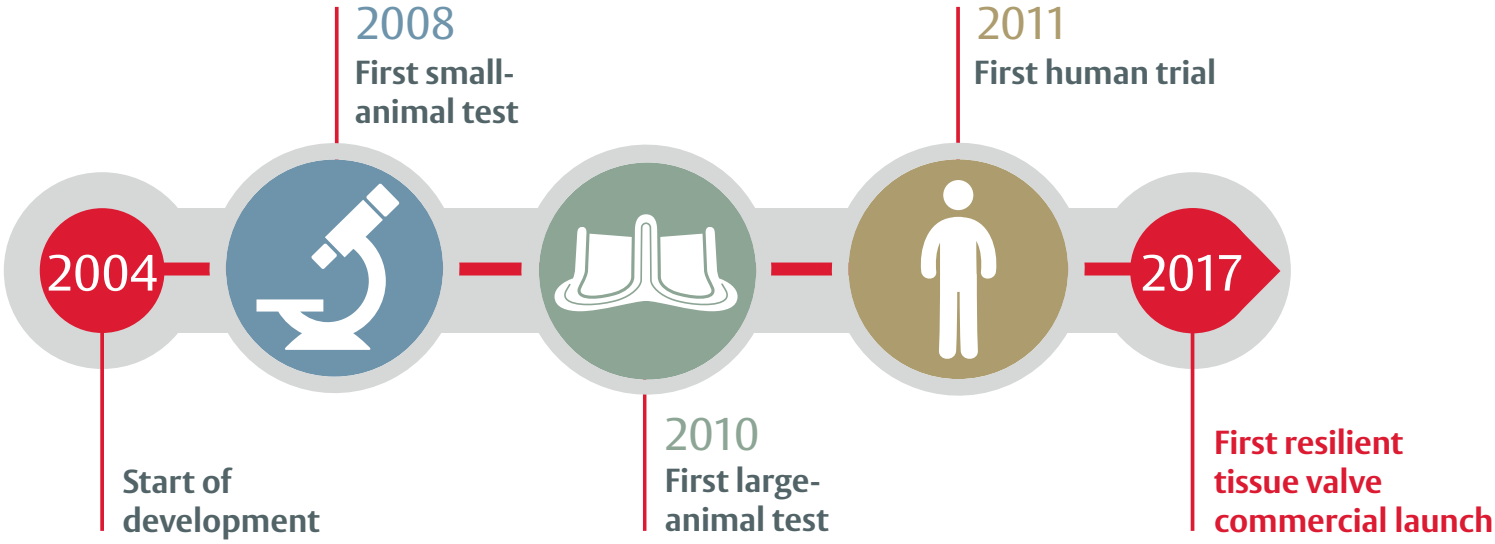
2 Glycerolization prevents further exposure
to aldehydes



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

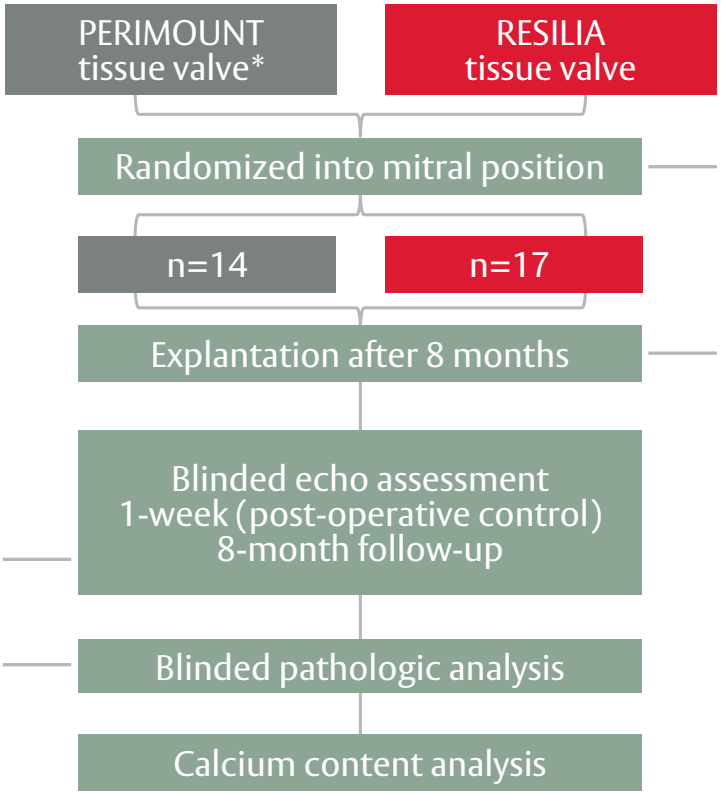
The path to the latest class of tissue valves:
A rigorous 13-year development program

RESILIA tissue has been subjected to **over 100 evaluations of safety and efficacy**.



Preclinical evaluation:
Valves with RESILIA tissue

Valves with RESILIA tissue were compared against PERIMOUNT valves in a large, first-of-its-kind juvenile sheep study.[2]



Mitral valve is **worst case for calcification** in sheep

Maximum duration before sheep outgrow valve, and **more than the 5-month duration required by regulatory agencies**

Blinded assessment & analysis – **reduced risk of bias**

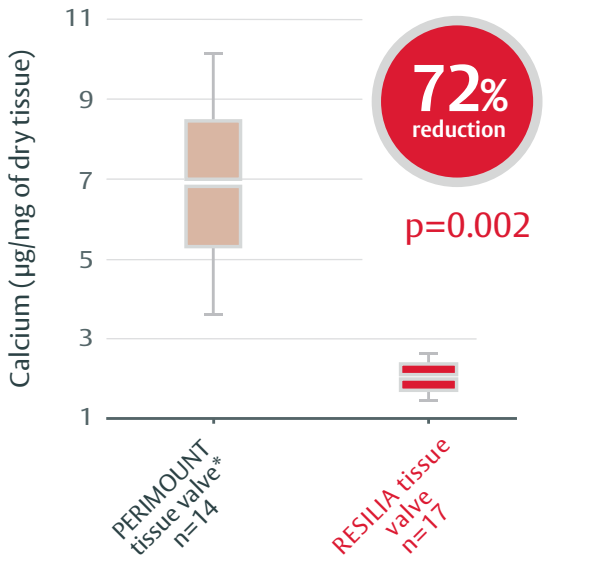
This model mirrors the accelerated calcification that is often seen in younger humans.[2]

* Carpentier-Edwards PERIMOUNT Plus pericardial mitral bioprosthesis, model 6900P.
No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

Preclinical evaluation:
Valves with RESILIA tissue

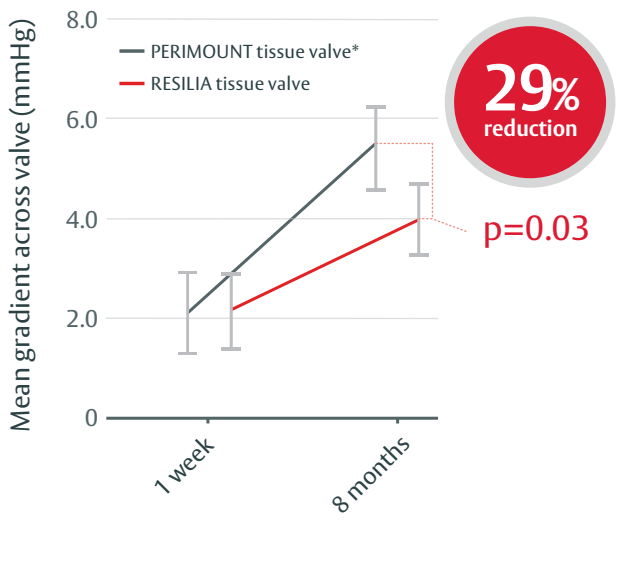
Significant reduction in leaflet calcification and improved sustained hemodynamic performance.

Calcium content[2]



Horizontal lines represent mean; boxes represent mean ± standard error; whiskers represent mean ± 0.95 confidence interval

Mean gradient[2]

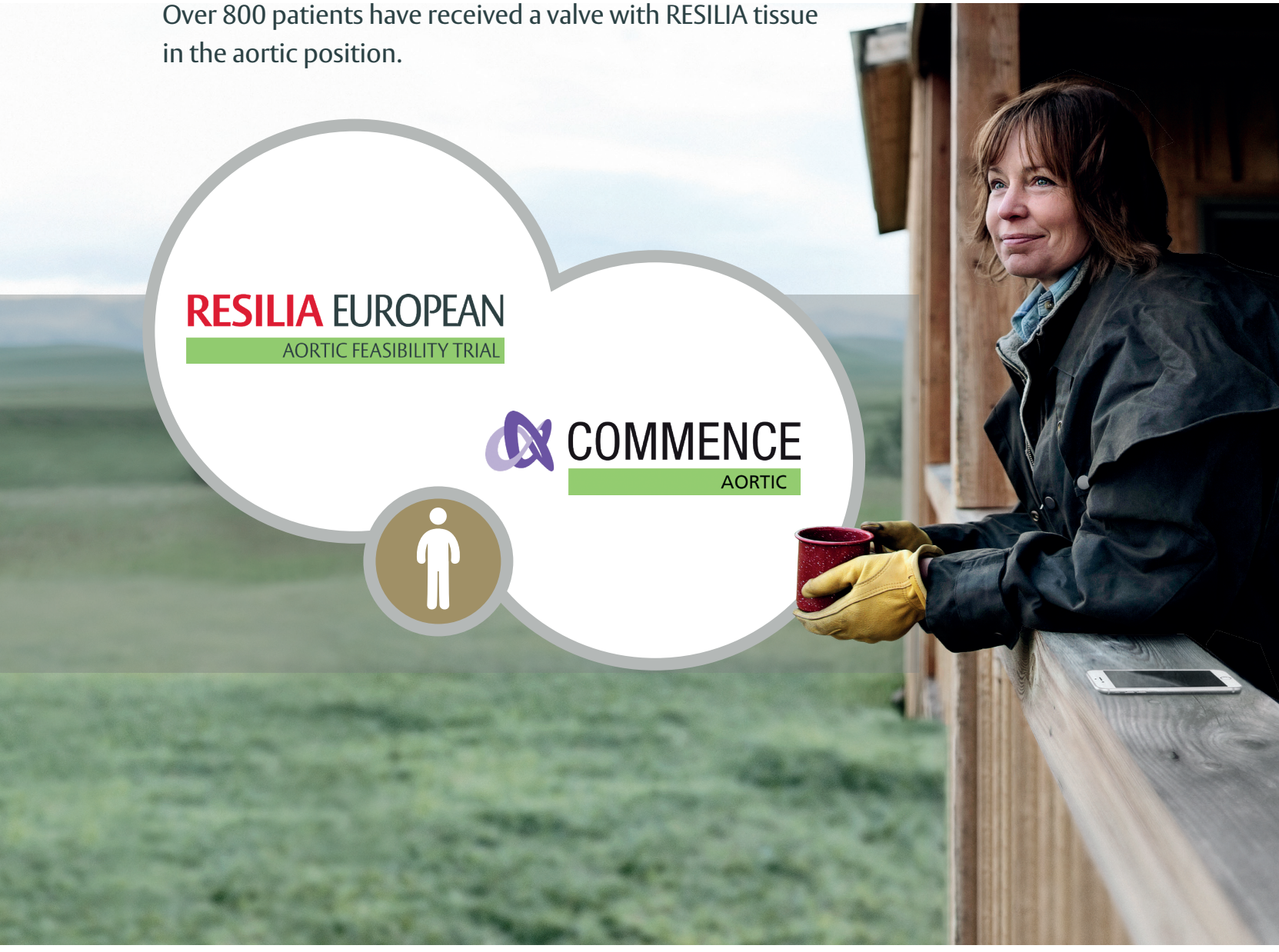


Whiskers represent mean ± standard error of the mean

* Carpentier-Edwards PERIMOUNT Plus pericardial mitral bioprosthesis, model 6900P.
No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

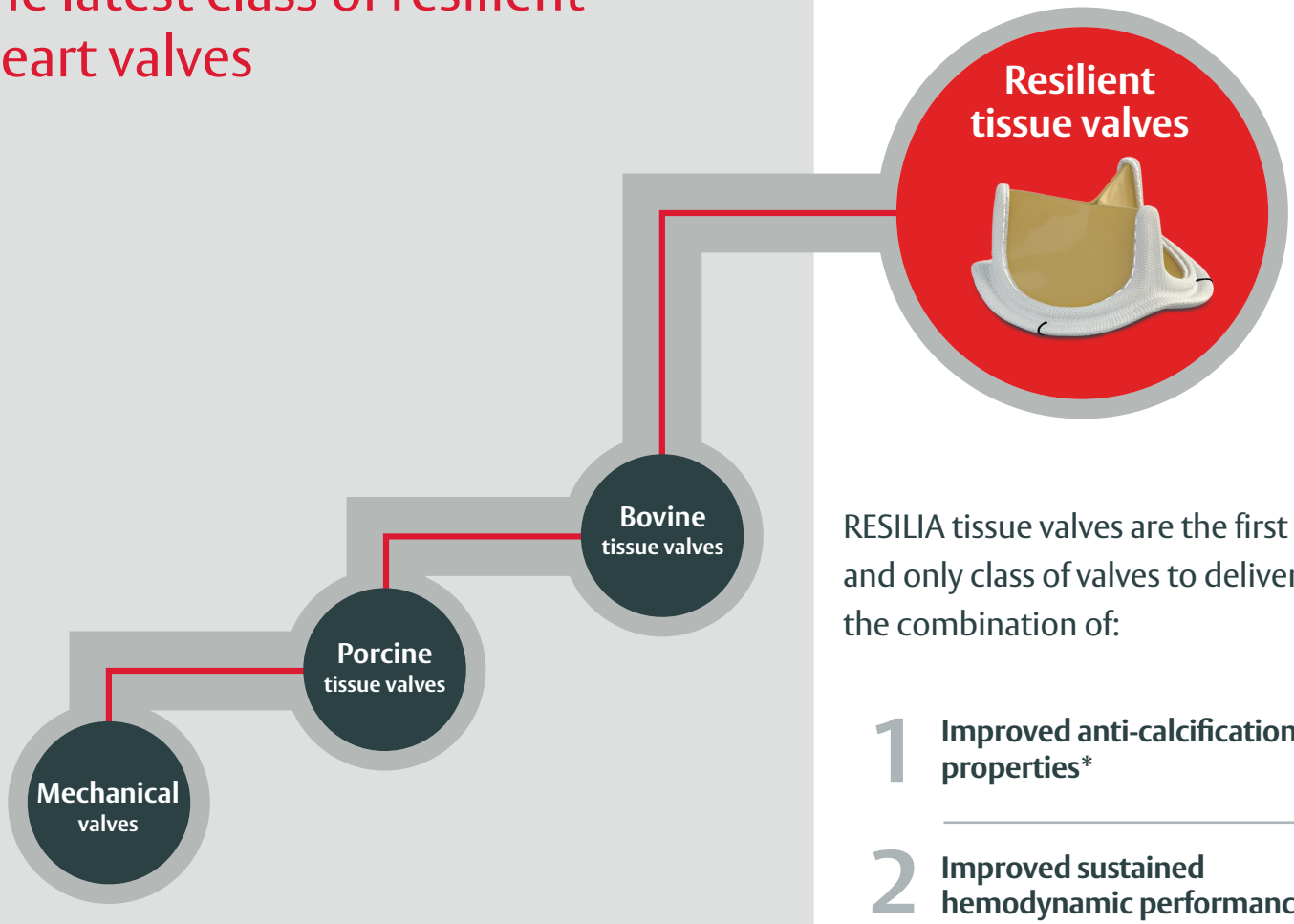
Clinical evaluation:
Valves with RESILIA tissue

Over 800 patients have received a valve with RESILIA tissue in the aortic position.



Refer to clinicaltrials.gov for additional information: 1. Aortic: NCT01757665 2. Aortic: NCT01651052
Device using RESILIA tissue is commercially available in the EU for the aortic position only.

RESILIA tissue is enabling the latest class of resilient heart valves



RESILIA tissue valves are the first and only class of valves to deliver the combination of:

1. **Improved anti-calcification properties***
2. **Improved sustained hemodynamic performance***
3. **Unique preservation for dry storage**

* RESILIA tissue tested against commercially-available bovine pericardial tissue from Edwards in a juvenile sheep model.[2]

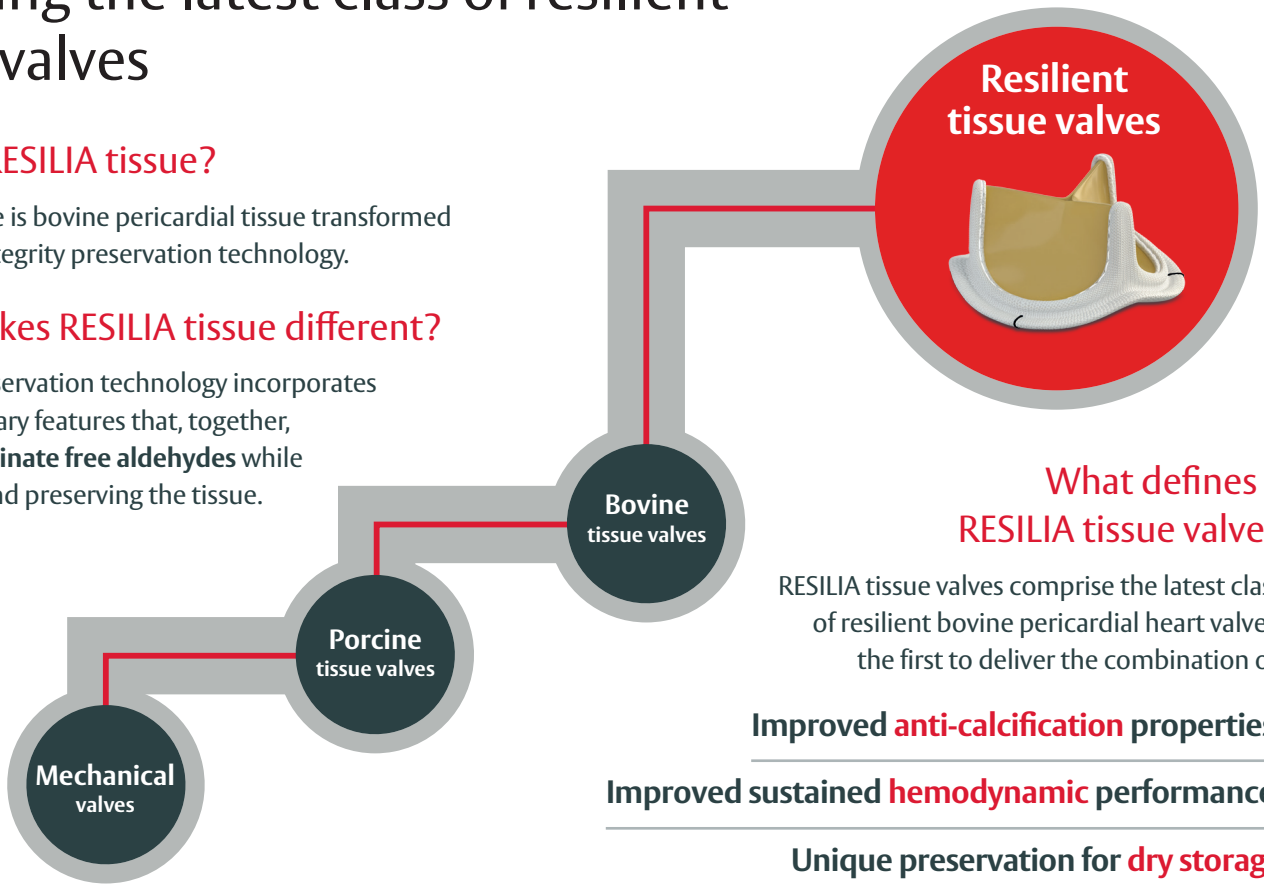
Discover how RESILIA tissue is enabling the latest class of resilient heart valves

What is RESILIA tissue?

RESILIA tissue is bovine pericardial tissue transformed by a novel integrity preservation technology.

What makes RESILIA tissue different?

Integrity preservation technology incorporates two proprietary features that, together, virtually **eliminate free aldehydes** while protecting and preserving the tissue.



What defines a RESILIA tissue valve?

RESILIA tissue valves comprise the latest class of resilient bovine pericardial heart valves, the first to deliver the combination of:

Improved anti-calcification properties*

Improved sustained hemodynamic performance*

Unique preservation for dry storage

* RESILIA tissue tested against commercially-available bovine pericardial tissue from Edwards in a juvenile sheep model.[2] No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

Reference

1. World Health Organization. World Health Statistics 2014. Geneva, Switzerland: WHO; 2014. WHO/HIS/HSI/14.1.
2. 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.

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Important Safety Information pertaining to valves manufactured with RESILIA tissue is available on the device-specific brochure.

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Introducing the Edwards PASCAL Transcatheter Valve Repair System

Empowering and effective MR reduction that respects the native anatomy

Empowering

Effective

Safe

Driven by a passion to help patients.

With over 60 years of experience in creating new therapies and procedures that elevate care in meaningful ways, Edwards Lifesciences is the global leader in patient-focused medical innovations.

For more information, please visit **www.Edwards.com/PASCAL**
or contact us at **pascal_info@edwards.com**

References

1. Nkomo VT, Gardin JM, Skelton TN, et al. Burden of valvular heart diseases: a population-based study. *Lancet*. 2006;368:1005-1011.
2. Goel SS, Bajaj N, Aggarwal B, et al. Prevalence and outcomes of unoperated patients with severe symptomatic mitral regurgitation and heart failure: comprehensive analysis to determine the potential role of MitraClip for this unmet need. *J Am Coll Cardiol*. 2014;63:185-186.
3. Praz F, Spargias K, Chrissoheris M et al. Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicentre, prospective, observational, first-in-man study. *Lancet.* 2017;390(10096):773-780.

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Edwards

Empowering. Effective. Safe.

Transform the way you see mitral valve repair

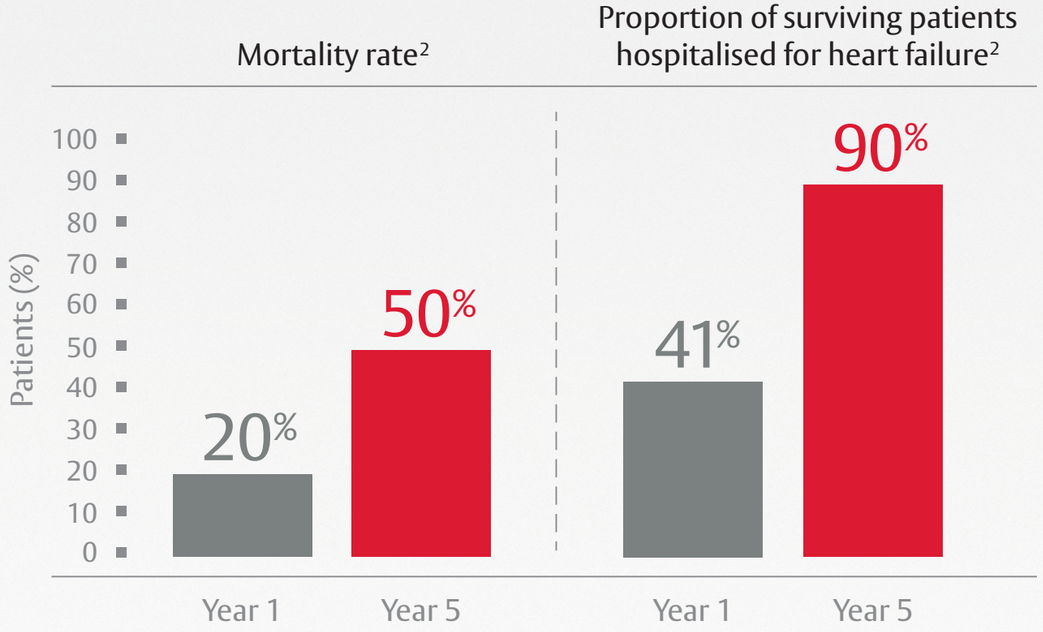
Introducing the CE Mark approved Edwards PASCAL Transcatheter Valve Repair System

Edwards

Mitral regurgitation: complex disease with limited options

Mitral regurgitation (MR) occurs in approximately 2% of the population, with up to 10% of people over 75 years old affected[1]

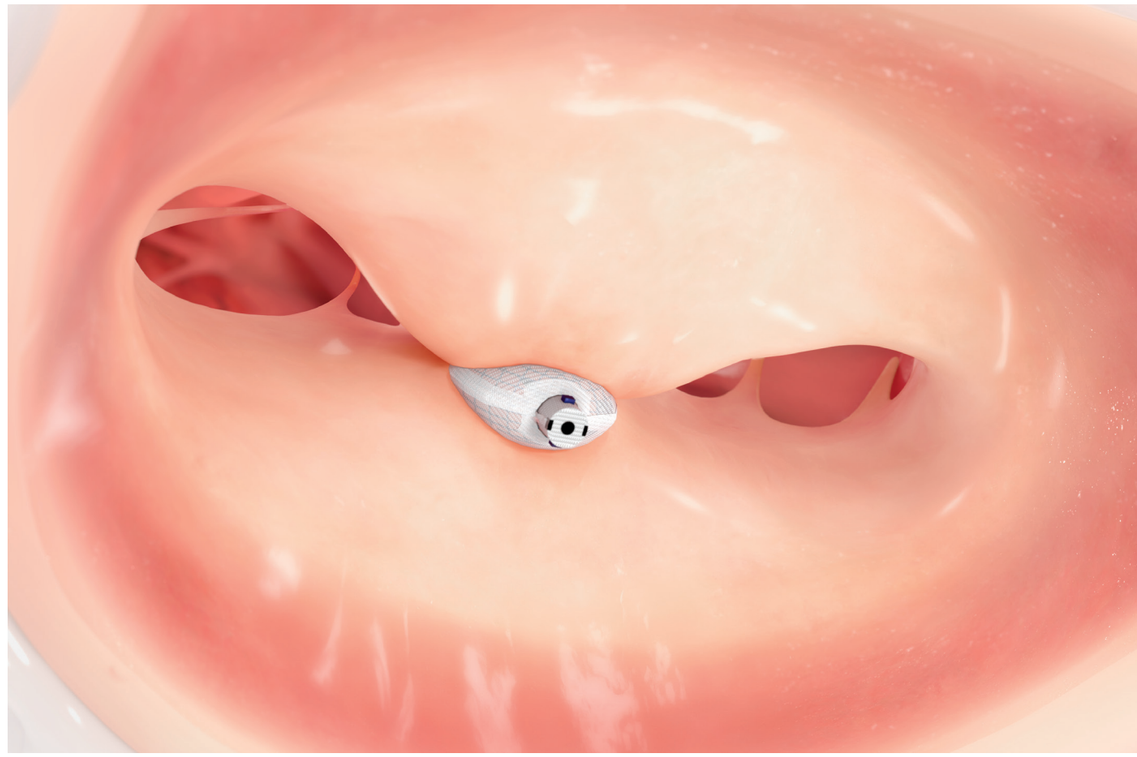
Medically managed patients with severe MR have poor outcomes[2]:

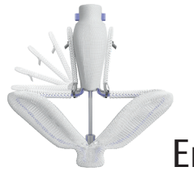


Introducing the PASCAL Repair System

An empowering transcatheter mitral valve repair system that effectively reduces MR while respecting the native anatomy

- Enables optimised leaflet capture
- Designed for effective MR reduction[3]
- Helps promote procedural safety

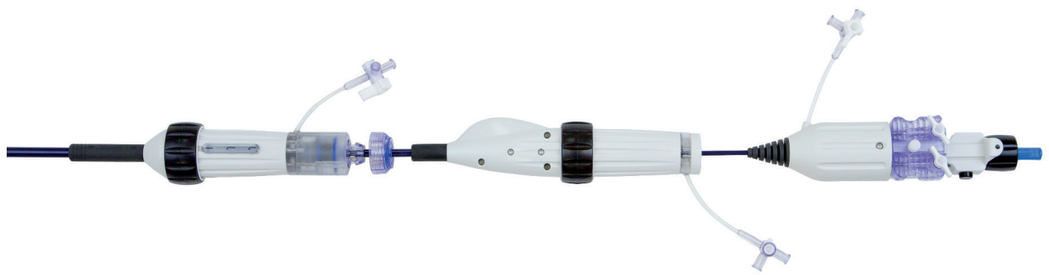




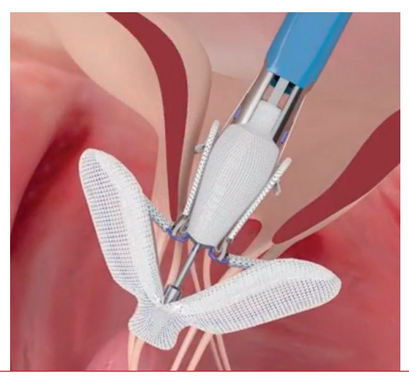
Empowering

Optimised leaflet capture

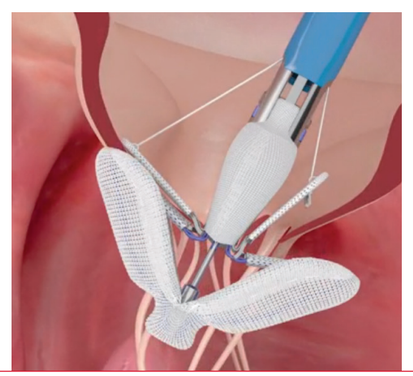
Empowering Edwards delivery system with direct manoeuvring in three planes to improve procedural efficiency



Broad paddles create a wide capture area for simplified leaflet capture



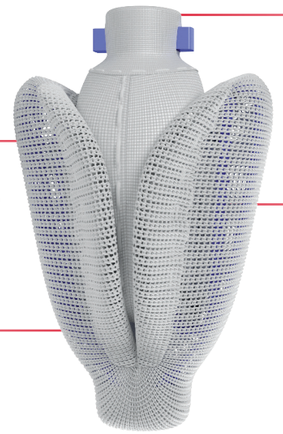
Independent leaflet capture supports gentle interaction and enables operators to capture leaflets in difficult pathologies



Effective

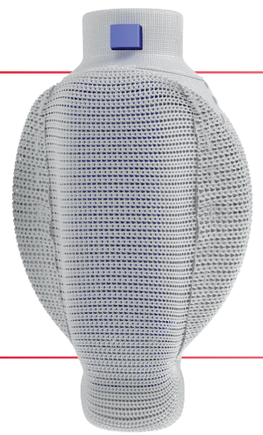
Designed for effective mitral regurgitation reduction[3]

Helps deliver the desired outcomes while respecting the native anatomy



Central spacer fills the regurgitant orifice area

Contoured paddles designed to reduce stress on leaflets



Broad paddles designed to maximise leaflet coaptation

Safe

Excellent safety profile

Contoured paddles and a unique central spacer are designed to reduce leaflet stress while implant elongation helps promote safe subvalvular manoeuvring

Contoured paddles

Unique central spacer

Implant elongation