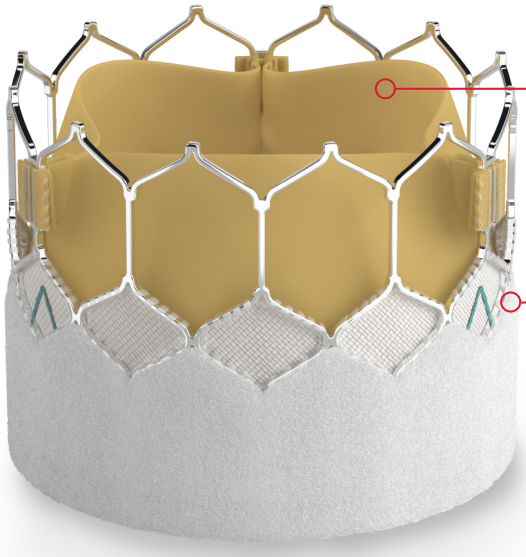
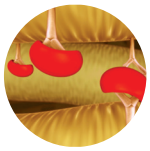
Edwards SAPIEN 3 Ultra RESILIA valve

The move for lifetime management

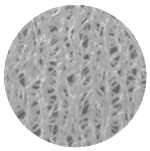
Building on the benefits of the Edwards SAPIEN platform: the valve system built for now and what's next





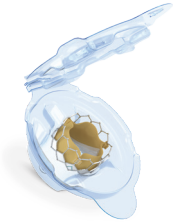
Advanced calcium-blocking tissue technology*[1]

Potential to improve valve longevity and reduce risk of reintervention



Taller, textured outer skirt extended to 29mm valve[5]**

Delivering the PVL results you demand impacting immediate and long-term outcomes[3,4]



Only THV with dry tissue storage[5]

Mitigates calcium-attracting glutaraldehyde residuals

Powered by RESILIA tissue technology

The **ultimate** lifetime management **solution** for all eligible patients

RESILIA tissue features proprietary, advanced anti-calcification technology*[1]

Stable capping

Blocks calcium from binding to tissue*[1]

Proprietary tissue integrity preservation technology

Enables dry tissue storage

RESILIA tissue technology blocks the receptors that enable calcium to bind to tissue*[1]

* No clinical data are available to evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

** Compared to the SAPIEN 3 valve

† RESILIA tissue tested against tissue from commercially available bovine pericardial valves from Edwards Lifesciences in a juvenile sheep model.[1]

RESILIA tissue is the product of nearly 20 years of research and development

2004 — Start of development

2008-2010 — Animal studies

2011 — First patient receives a valve with RESILIA tissue
—
EU human feasibility study

2012 — COMMENCE IDE trial begins

2017 — INSPIRIS RESILIA aortic valve

2020 — KONECT RESILIA aortic valved conduit

2022 — MITRIS RESILIA mitral valve
—
SAPIEN 3 Ultra RESILIA transcatheter heart valve

2026 — COMMENCE trial 10-year follow-up planned

Excellent clinical outcomes through 7 years, as demonstrated in the COMMENCE surgical trial*[2]

99.3%

freedom from structural valve deterioration

Outcome	Event-free probability at 7 years (%) (95% CI)
All-cause mortality	85.4 (82.2–88.7)
Valve thrombosis	99.4 (98.6–100.0)
Structural valve deterioration	99.3 (98.3–100.0)
Reoperation	97.2 (95.5–99.0)

*Prospective, multicenter, single-arm IDE trial, now in its postapproval phase, featuring a surgical bioprosthesis with RESILIA tissue (n = 195 at 7-year follow-up).

Learn more about RESILIA tissue technology and evidence at heartvalves.com/ca

All event definitions per CW Akins et al. *J Thorac Cardiovasc Surg.* 2008;135(4):732-738.

References: 1. Flameng W, Hermans H, Verbeken E, Meuris B. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg.* 2015;149(1):340-345. **2.** Beaver T, Bavaria J, Griffith B, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. Presented at: the American Association for Thoracic Surgery (AATS) 103rd Annual Meeting; May 6-9, 2023; Los Angeles, CA. **3.** Kodali S et al. Paravalvular regurgitation after transcatheter aortic valve replacement with the Edwards SAPIEN valve in the PARTNER trial: characterizing patients and impact on outcomes. Eur Heart J. 2015. **4.** Makkar R et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. N Engl J Med. 2020. **5.** Data on file.

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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