SAPIEN 3 Ultra
RESILIA system

Designed for Lifetime Management Strategy

Edwards

Life

SAPIEN 3 Ultra RESILIA valve - designed for Lifetime management

Built on the legacy of SAPIEN 3 Ultra valve and INSPIRIS RESILIA valve

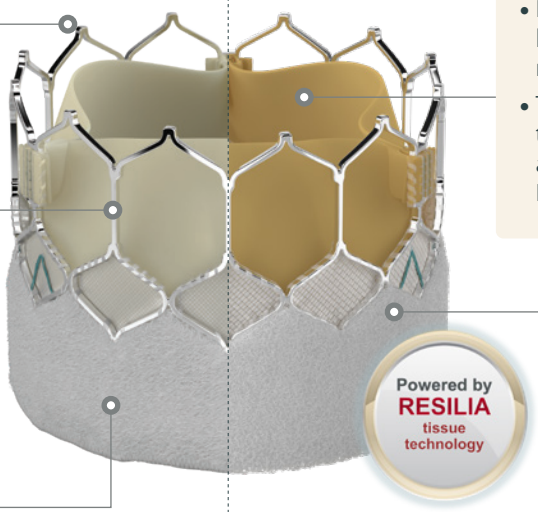
SAPIEN 3 platform legacy

Short frame height and open cell geometry
- Enables 100% Coronary access[6]

Cobalt Chromium frame with high radial strength
- Provides circularity
- Optimal leaflet coaptation

Textured outer skirt
- Mitigates PVL

SAPIEN 3 Ultra RESILIA valve



Advanced calcium-blocking tissue technology[1,2]
- Potential to improve valve longevity and reduce risk of reintervention.
- The same tissue technology of the most implanted surgical aortic tissue valve in the world, INSPIRIS RESILIA valve.[3]

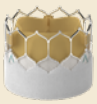
Taller*, textured outer skirt extended to 29mm valve[1]
- Delivering the PVL results you demand impacting immediate and long-term outcomes[4,5]

Only THV with dry tissue storage[1]
Mitigates calcium-attracting glutaraldehyde residuals

PVL, paravalvular leak
* Compared to the SAPIEN 3 transcatheter valve.

SAPIEN 3 Ultra RESILIA valve delivers excellent performance[7]

Equally excellent outcomes when compared with SAPIEN 3/SAPIEN 3 Ultra valves

1-year clinical outcomes (propensity matched)	All-cause mortality	Stroke	Life-threatening bleeding	Permanent pacemaker implantation	AKI Stage 4	
 SAPIEN 3 / SAPIEN 3 Ultra THV (n=4,598)	9.7% (356)	3.2% (130)	2.7% (110)	9.6% (384)	0.6% (23)	0.4% (16)
 SAPIEN 3 Ultra RESILIA THV (n=4,598)	7.6% (261)	2.7% (108)	2.0% (78)	10.6% (419)	0.6% (25)	0.6 % (22)

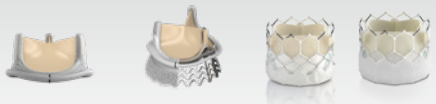
Most implanted Transcatheter Heart Valve in United States

THV, transcatheter heart valve.

Time

RESILIA tissue technology to mitigate leaflets calcification[8]

ThermaFix process



PERIMOUNT Magna Ease valve

EDWARDS INTUITY Elite valve

SAPIEN 3 valve/ SAPIEN 3 Ultra valve

RESILIA tissue technology*

INSPIRIS RESILIA aortic valve

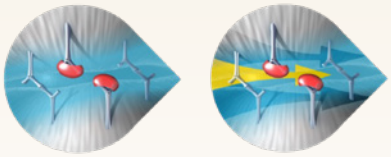
MITRIS RESILIA mitral valve

SAPIEN 3 Ultra RESILIA valve

Glutaraldehyde stabilization

Free Aldehydes

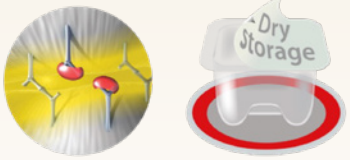
Advanced calcium-blocking technology



Stable-Capping
Permanently blocks free aldehydes

Glycerolization
Glycerol displaces water in the tissue and preserves tissue integrity, which enables dry storage

RESILIA tissue



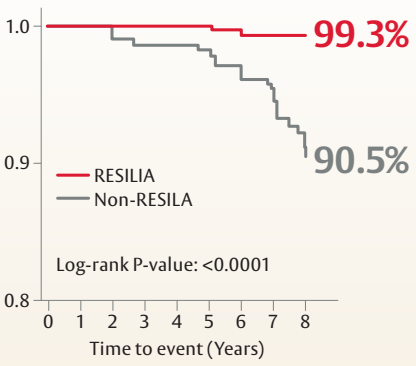
Glycerolized Tissue

Stable Storage
Long-term viability

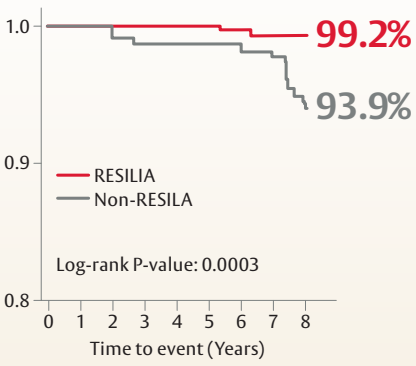
* No clinical data are available to evaluate the long-term impact of RESILIA tissue in patients. Additional clinical data for up to 10 years of follow-up are being collected to monitor the long-term safety and performance of RESILIA tissue.

Eight-years clinical data from a surgical propensity-score matching confirms RESILIA tissue technology's excellent long-term performance[9]

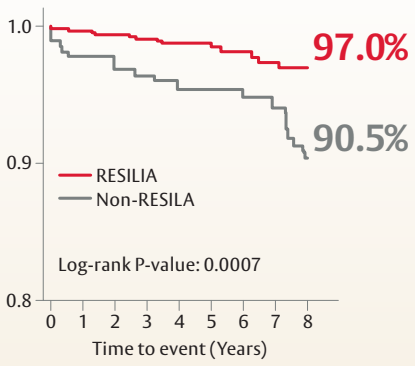
Freedom from SVD*



Freedom from Reoperation due to SVD*



Freedom from Reoperation



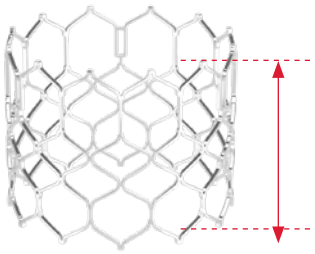
Age (years), Mean ± SD (n)	
RESILIA	Non-RESILIA
66 ± 11.61 (689)	68.5 ± 8.83 (258)

RESILIA tissue surgical valves had significantly improved freedom from reoperation due to SVD* compared to Non-RESILIA valves

* Standardized definition of SVD was utilized (Akins et. al 2008)

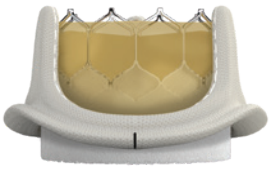
Management

How do we enable future procedures and coronary access?

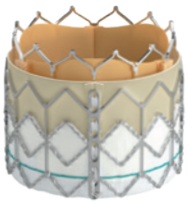


100% Coronary access[6] **thanks to:**
- Low frame design
- Open cell geometry

Aortic



THV-in-SAV*



Aortic THV-in-THV*

The only one approved for Aortic THV-in-THV

Mitral

THV-in-Surgical Mitral valve*

The only one approved for THV-in-Surgical Mitral valve

Approved for both THV in SAVR and THV in THV

THV, transcatheter heart valve; SAV, surgical aortic valve; SAVR, surgical aortic valve replacement.

RESILIA tissue technology – Results from economic analyses based on assumptions informed by surgical data

Reintervention reduction may result in significant savings at 8 years

Incidence of reoperation due to SVD† at 8 years**

0.8%
RESILIA tissue
(COMMENCE trial n=689)

6.1%
Non-RESILIA tissue
(Magna Ease n=258)

Country	Potential reintervention cost* TAVI Low risk	Potential reintervention cost with RESILIA per patient	Potential reinter-vention cost with non-RESILIA per patient	Potential cost savings with RESILIA valves per patient (Δ)
Norway	NOK 378 148[11]	NOK 3 025	NOK 23 067	NOK 20 042
France	€ 26 130[12]	€ 209	€ 1 594	€ 1 385
Italy	€ 36 945[13]	€ 296	€ 2 254	€ 1 958
Spain	€ 30 058[14]	€ 240	€ 1 834	€ 1 593
Germany	€ 30 051[15]	€ 240	€ 1 833	€ 1 593
Belgium	€ 32 962[16]	€ 264	€ 2 011	€ 1 747
Netherlands	€ 43 163[17]	€ 345	€ 2 633	€ 2 288
Switzerland	CHF 52 953[18]	CHF 424	CHF 3 230	CHF 2 807
Sweden	SEK 337 188[19]	SEK 2 698	SEK 20 568	SEK 17 871
UK	£ 33 084[20]	£ 265	£ 2 018	£ 1 753

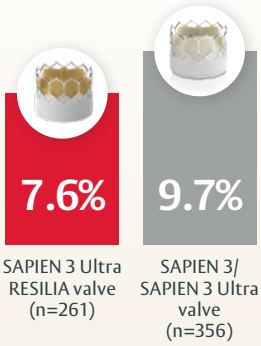
† Standardized definition of SVD was utilized (Akins et. al 2008)

*Costs were based on cost information from published literature, and adjusted for inflation to 2024 when necessary unless otherwise stated.

** Financial savings were calculated based on Kaneko et al. (presented at HVS 2025).
Assumptions: As no additional risk of reintervention with SAPIEN 3 vs. SAVR from PARTNER 2 SAPIEN 3i[21] and PARTNER 3[22] was observed using same VARC 3 definitions of BVD and SVD at 5 years, SAPIEN 3 Ultra RESILIA valve is expected to have similar durability to SAVR.

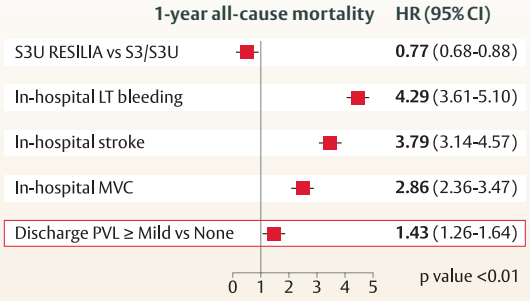
The SAPIEN 3 Ultra RESILIA valve benefits are mainly driven by lower rates of complications and PVL[7]

All-cause mortality at 1 year

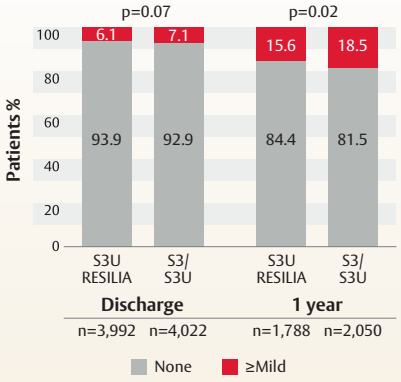


PVL is independently associated with mortality

Multivariable analysis of covariates associated with 1-year mortality



Lower PVL rates for SAPIEN 3 Ultra RESILIA valve contribute to the lower mortality rate



Building on the performance of the SAPIEN 3 Ultra valve, SAPIEN 3 Ultra RESILIA valve offers lower gradient, consistent across all valve sizes

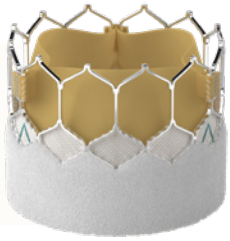
CI, confidence interval; HR, hazard ratio; LT, life threatening; MVC, major vascular complication; PVL, paravalvular leak; S3, SAPIEN 3 valve; S3U, SAPIEN 3 Ultra valve; S3UR, SAPIEN 3 Ultra RESILIA valve.

Permanent pacemaker and stroke with SAPIEN 3 Ultra RESILIA valve at 30 days[10]

8.3% PPI
at 30 days

(n= 10,312)

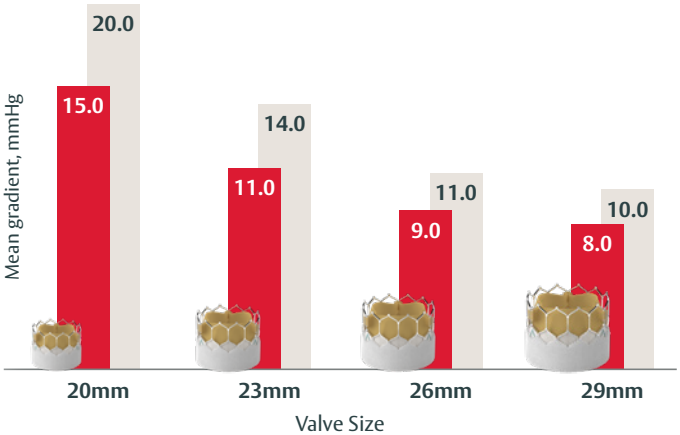
1.8% Stroke
at 30 days



PPI, Permanent Pacemaker Implantation

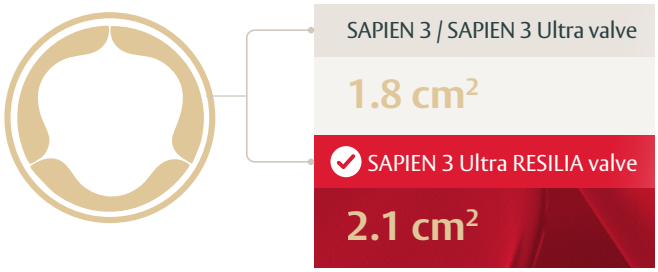
Consistently excellent 1-year clinical outcomes[7]

Significantly lower echo-derived mean gradients and larger EOAs across all valve sizes



	20mm	23mm	26mm	29mm
SAPIEN 3 Ultra RESILIA valve	n=61	n=608	n=857	n=415
SAPIEN 3 & SAPIEN 3 Ultra valves	n=83	n=702	n=920	n=487

Larger EOA measurements across all valve sizes*



* Compared to SAPIEN 3 and SAPIEN 3 Ultra valves | EOA, effective orifice area

References:

1. Data on file
2. De la Fuente et al. Advanced Integrity Preservation Technology Reduces Bioprosthesis Calcification While Preserving Performance and Safety. Journal of Heart Valve Disease. 2015.
3. Data on file
4. 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
5. Makkar R et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. N Engl J Med. 2020
6. Tarantini et al. Coronary Access After Transcatheter Aortic Valve Replacement With Commissural Alignment: The ALIGN-ACCESS Study - Circ Cardiovasc Interv 2022 Feb;15(2):e011045. Epub 2022 Feb 15.
7. Kini AS et al. JACC Cardiovasc Interv. 2024; doi: 10.1016/j.jcin.2024.11.015
8. De la Fuente AB, Wright GA, Olin JM, et al. Advanced Integrity Preservation Technology Reduces Bioprosthesis Calcification While Preserving Performance and Safety. Journal of Heart Valve Disease. 2015.
9. Kaneko, T, Johnston D, Bavaria JE, et al. Propensity-matched 8-year Outcomes Following Surgical Aortic Valve Replacement with ith Novel Calcification-resistant Versus Contemporary Tissue Bioprostheses. Presented at the Heart Valve Society Annual Scientific Meeting, April 2025.
10. Stinis CT et al. JACC Cardiovasc Interv. 2024; 17: 1032–44
11. Norwegian Institute of Public Health (NIPH). Transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement (SAVR) for patients with severe aortic stenosis and low surgical risk and across surgical risk groups: a health technology assessment 2021 [Available from: https://www.fhi.no/en/publ/2021/TAVI-vs-SAVR-for-patients-with-severe-aortic-stenosis-and-low-surgical-risk-and-across-surgical-risk-groups/].
12. Gilard M, Eltchaninoff H, Iung B, et al. Cost-effectiveness analysis of SAPIEN 3 TAVI procedure compared with surgery in patients with severe aortic stenosis at low risk of surgical mortality in France. Value Health 2022;25:605–13.
13. Mennini FS, Meucci F, Pesarini G, et al. Cost-effectiveness of transcatheter aortic valve implantation versus surgical aortic valve replacement in low surgical risk aortic stenosis patients. Int J Cardiol 2022;357:26–32.
14. Vázquez Rodríguez JM, Bermúdez EP, Zamorano JL, et al. Cost-effectiveness of SAPIEN 3 transcatheter aortic valve implantation in low surgical mortality risk patients in Spain. REC Interv Cardiol 2023:38–45.
15. Kuck KH, Leidl R, Frankenstein L, et al. Cost-Effectiveness of SAPIEN 3 Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in German Severe Aortic Stenosis Patients at Low Surgical Mortality Risk. Adv Ther 2023;40:1031–46.
16. Dubois C, Adriaenssens T, Annemans L, et al. Transcatheter aortic valve implantation versus surgical aortic valve replacement in severe aortic stenosis patients at low surgical mortality risk: a cost-effectiveness analysis in Belgium. Acta Cardiol 2024;79:46–57.
17. Eerdekens R, Kats S, Grutters JP, et al. Cost-utility analysis of TAVI compared with surgery in patients with severe aortic stenosis at low risk of surgical mortality in the Netherlands. Cost Eff Resour Alloc 2024;22:24.
18. Wyss CA, Corti R, Nestelberger T, et al. Transcatheter aortic valve implantation with SAPIEN 3 versus surgical aortic valve replacement in patients with symptomatic severe aortic stenosis at low risk of surgical mortality: a cost-utility analysis for Switzerland. Swiss Med Wkly [Internet] 2024;154:3558.
19. Nilsson K, James S, Angerås O, et al. Cost-effectiveness analysis of transcatheter aortic valve implantation versus surgical aortic valve replacement in patients with severe aortic stenosis at low risk of surgical mortality in Sweden. Upsala J Med Sci 2024;129:e10741.
20. Candolfi P, MacCarthy P, Blackman DJ T, Clinton TL, Aetesam-Ur-Rahman M, Bromilow T, Sellitto V, Curzen N. Cost-utility analysis of TAVI vs surgery in low-risk patients with severe aortic stenosis in the UK. Open Heart [submitted].
21. Madhavan MV, et al. Outcomes of SAPIEN 3 Transcatheter Aortic Valve Replacement Compared With Surgical Valve Replacement in Intermediate-Risk Patients. J Am Coll Cardiol. 2023.
22. Mack MJ, et al. PARTNER 3 Investigators. Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years. N Engl J Med. 2023.

Abreviations:

CI, confidence interval

EOA, effective orifice area

HR, hazard ratio

LT, life threatening

MVC, major vascular complication

PPI, Permanent Pacemaker Implantation

PVL, paravalvular leak

SAV, surgical aortic valve

SAVR, surgical aortic valve replacement

S3, SAPIEN 3 valve

S3U, SAPIEN 3 Ultra valve

S3UR, SAPIEN 3 Ultra RESILIA valve.

THV, transcatheter heart valve

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

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).

Edwards Lifesciences Sàrl • Route de l'Etraz 70, 1260 Nyon, Switzerland • edwards.com

Edwards