Edwards SAPIEN 3 Platform:

Sustained durability and valve performance



Outcomes from The PARTNER Trials:

SAPIEN 3 TAVI Demonstrates Excellent Long-Term Durability and Valve Performance Comparable to SAVR out to 7 and 10 Years[1,2]

Edwards

The PARTNER Trials: 20 Years of Advances in TAVI Evidence Generation and Care for Severe Aortic Stenosis Patients[1,2]

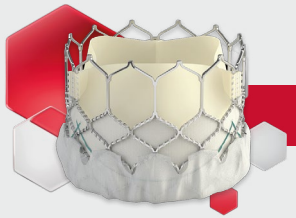
The PARTNER 3 Trial Design[1]

Randomized: N=1000

Allocated to TAVI n=503	Allocated to SAVR n=497
6 Withdrawals 1 Exclusion found	35 Withdrawals 8 Exclusions found
Procedure Initiated (AT) n=496	Procedure Initiated (AT) n=454
26 Withdrawals 1 Lost to follow-up 9 Missed visits	53 Withdrawals 3 Lost to follow-up 7 Missed visits
7-year follow-up n=460 (92.7%)	7-year follow-up n=391 (86.1%)

89.6% of patients available for primary endpoint analysis at 7 years*

Mortality follow-up with VSS n=471 (95.0%)	Mortality follow-up with VSS n=426 (93.8%)



10-year follow-up analysis planned

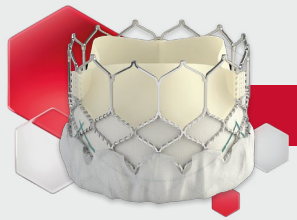
*Includes patients evaluable for the primary composite endpoint. Doxaes not include VSS data.[1]
AT=as treated; TA=transapical; TAo=transaortic; TF=transfemoral; VSS=vital status sweep.

The PARTNER 2A and S3i Study Designs[2]

Enrolled in P2S3i Registry: N=1078	Randomized to Surgery in P2A: N=1021
Valve Implant Population: n=1069	Valve Implant Population: n=936
TF TAVI n=943 / TA/TAo TAVI n=126	SAVR n=719 / SAVR n=217
5-year follow-up n=897 (83.9%)	5-year follow-up n=817 (87.3%)

Re-consent required for 10-year follow-up extension per FDA request

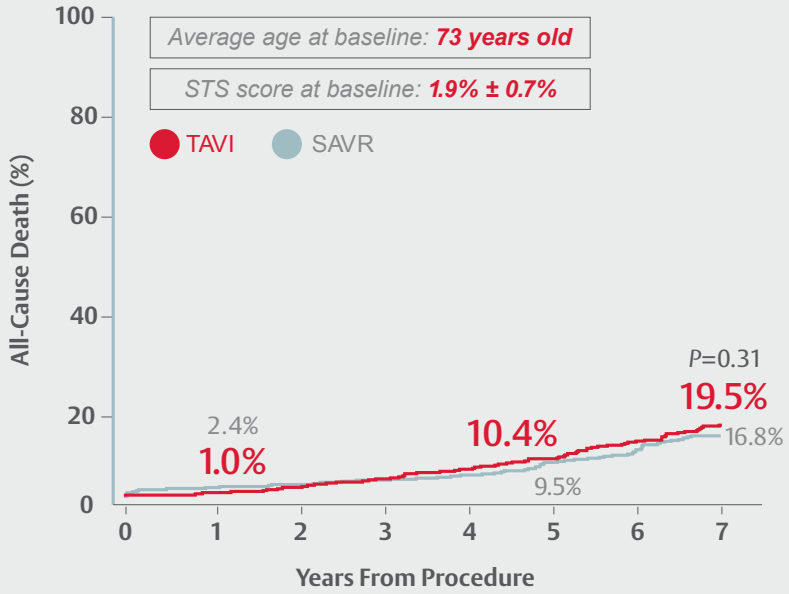
Did not re-consent (n=207)	Did not re-consent (n=270)
10-year follow-up n=647 (60.5%)	10-year follow-up n=506 (54.1%)
10-year follow-up with VSS n=959 (89.7%)	10-year follow-up with VSS n=838 (89.5%)



10-year follow-up analysis complete

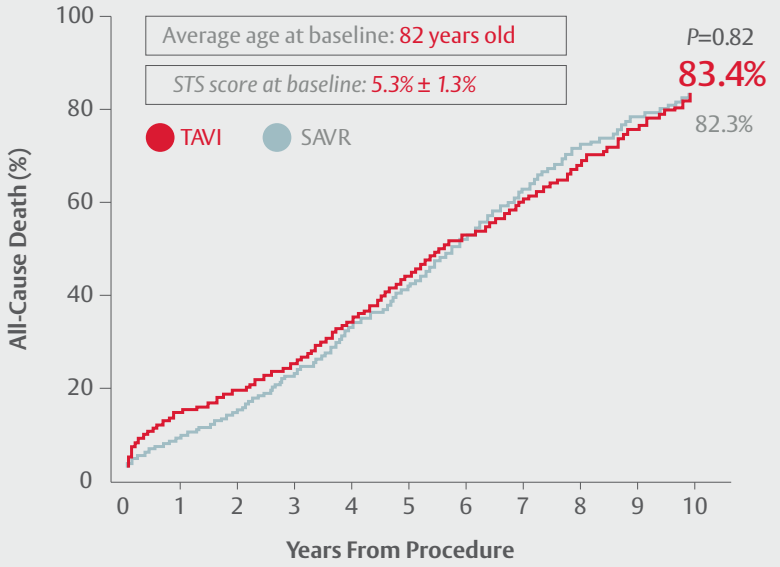
Mortality Outcomes With SAPIEN 3 TAVI Were Comparable to SAVR at 7 and 10 Years

The PARTNER 3 Low-Risk Trial: 7-Year Follow-Up*[1]



No. at Risk								
TAVI	496	490	481	468	449	433	405	377
SAVR	454	441	430	418	407	390	375	353

The PARTNER 2 S3i Intermediate-Risk Study: 10-Year Follow-Up*[2]



No. at Risk											
TAVI	783	726	671	605	515	443	352	276	206	151	80
SAVR	783	682	645	591	523	421	335	281	222	162	103

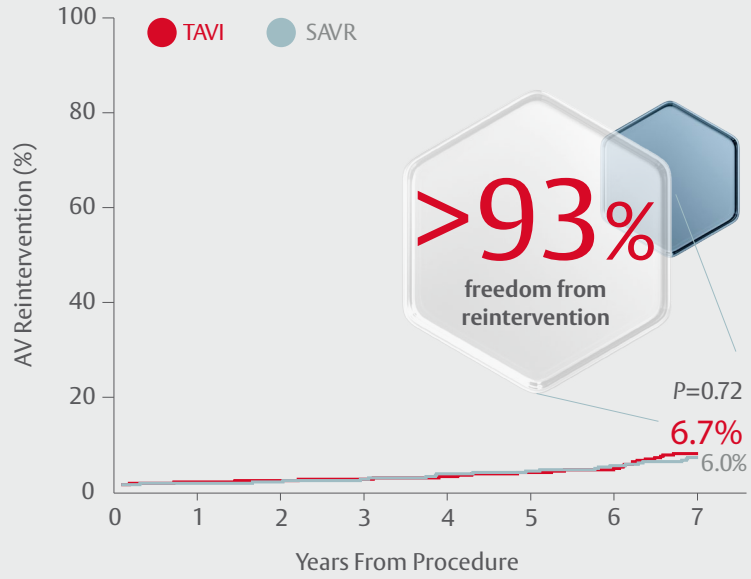
"In The PARTNER 3 Low-Risk Trial, we again see the early clinical benefit of TAVR with SAPIEN 3 over surgery, as well as excellent long-term valve performance and durability results for both therapies at 7 years, which should be reassuring to patients and their physicians."[3]

- Martin Leon, MD

*Includes VSS data. VSS was performed by sites on patients who withdrew, were lost to follow-up, did not re-consent, or missed a visit.[1,2,4]
STS=Society of Thoracic Surgeons.

SAPIEN 3 TAVI Demonstrated Excellent Long-Term Durability and Valve Performance at 7 and 10 Years

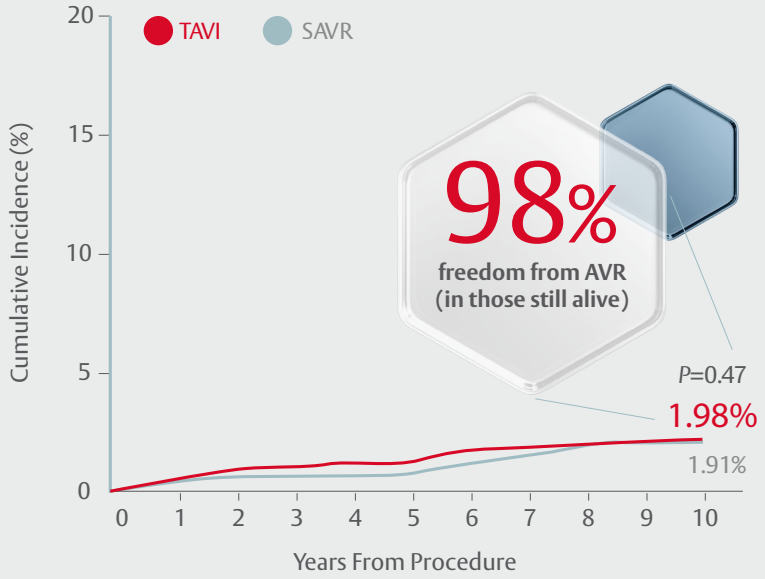
The PARTNER 3 Trial: AV Reintervention Rates at 7 Years[1]



No. at Risk

TAVI	496	488	477	461	437	413	378	333
SAVR	454	426	407	391	373	352	332	294

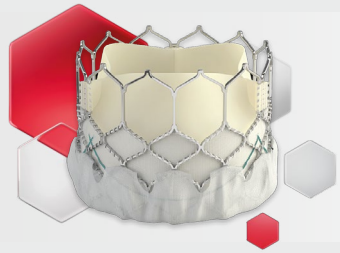
The PARTNER 2 S3i Study: AV Reintervention Rates at 10 Years[2]



No. at Risk

TAVI	783	712	647	566	458	310	165	125	101	75	32
SAVR	783	667	613	544	472	296	134	111	90	68	29

AV reintervention rates with the SAPIEN 3 valve were low and comparable to SAVR at both 7 and 10 years in both trials.[1,2] With this older generation valve, the leading causes of reintervention were stenosis and PV leak.[2,4]

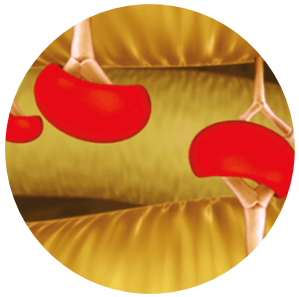


AV=aortic valve; PV=paravalvular.

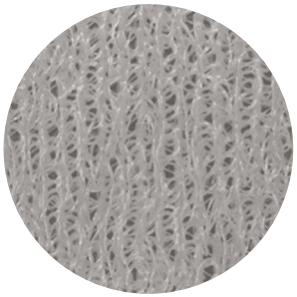
The SAPIEN 3 Ultra RESILIA Valve Is Designed to Further Elevate Long-Term Durability and Valve Performance[5,7]

Powered by RESILIA Tissue Technology

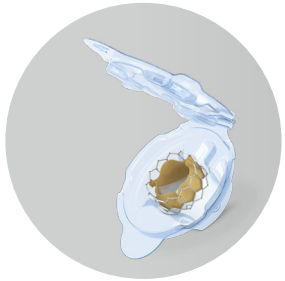




Advanced calcium-blocking tissue technology[6]



Taller,* textured outer skirt extended to 29 mm valve



The only transcatheter heart valve with dry tissue storage

*Compared to the SAPIEN 3 transcatheter valve.

See the long-term data at: **heartvalves.com/gb**

References: 1. Mack MJ, Leon MB. Seven-year outcomes of the PARTNER 3 low-risk trial. Presented at: TCT 2025; October 27, 2025; San Francisco, CA. **2.** Makkar R. Ten-year outcomes of the PARTNER 2 intermediate-risk studies: a propensity-matched analysis of P2S3i TAVR and P2A surgery. Presented at: TCT 2025; October 27, 2025; San Francisco, CA. **3.** Edwards SAPIEN 3 TAVR delivers proven long-term benefits and valve performance, new data presented at TCT 2025. Edwards Lifesciences. Published October 27, 2025. Accessed November 7, 2025. https://www.edwards.com/newsroom/news/2025-10-27-edwards-sapien-3-tavr-delivers-proven-long-term-be **4.** Leon MB, Mack MJ, Pibarot P, et al. Transcatheter or surgical aortic-valve replacement in low-risk patients at 7 years. *N Engl J Med.* Published on October 27, 2025. doi: 10.1056/NEJMoa2509766 **5.** Beaver T, Bavaria JE, Griffith B, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. *J Thorac Cardiovasc Surg.* 2024;168(3):781-791. **6.** De La Fuente AB, Wright GA, Olin JM, et al. Advanced integrity preservation technology reduces bioprosthesis calcification while preserving performance and safety. *J Heart Valve Dis.* 2015;24(1):101-109. **7.** Data on file

Clinical data on surgical valves with RESILIA tissue up to 7-year follow-up have been published, with additional follow-up to 10 years in progress.[5]

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, Edwards Lifesciences, the stylized E logo, Edwards SAPIEN, Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, PARTNER, PARTNER II, PARTNER 3, RESILIA, SAPIEN, SAPIEN 3, SAPIEN 3 Ultra and the PARTNER design logo are trademarks or service marks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

© 2026 Edwards Lifesciences Corporation. All rights reserved. PP--EU-11440 v3.0

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

Edwards