



Built for now and what's next

Edwards SAPIEN 3 platform:
The strategy for lifetime management



The Edwards SAPIEN 3 platform: Built for now and what's next

With people living longer and having higher expectations for their health and quality of life, lifetime management is increasingly important.

That's why the first valve choice matters, and the Edwards SAPIEN 3 platform delivers:

Life

Consistent outcomes that matter, starting with the index procedure¹

Time

A comprehensive approach to a durable therapy that offers proven, long-term patient outcomes*⁵

Management

Making future options possible⁶



¹Propensity-matched analysis of intermediate-risk patients using VARC-3 definitions of structural valve deterioration (SVD) and SVD-related bioprosthetic valve failure at 5 years.

Building on a legacy of superior* outcomes¹

Consistently demonstrating the results you need for the outcomes that matter

At 1 year (n = 496), the SAPIEN 3 platform delivers excellent outcomes your patients need¹

1.0% all-cause mortality

0.2% disabling stroke

0.6% moderate or severe paravalvular regurgitation

7.3% permanent pacemaker implantation[‡]



Strong outcomes allow patients to stay out of the hospital

92.7% of patients did not require rehospitalization within 1 year.¹

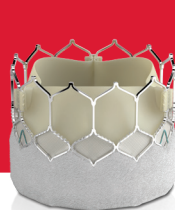
SAPIEN 3 transcatheter aortic valve implantation offers consistently outstanding and reliable outcomes

Across a variety of patient morphologies (n = 296), including low-risk bicuspid patients²

Across all valve sizes, small to large³



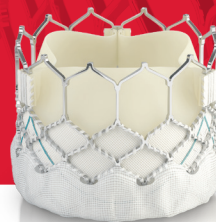
20 mm



23 mm



26 mm



29 mm[§]

*PARTNER 3 Trial proved SAPIEN 3 transcatheter aortic valve implantation is superior to surgery on the primary endpoint (all-cause death, all stroke, and rehospitalization¹) and multiple, prespecified secondary endpoints.

[‡]Rehospitalization (valve related or procedure related and including heart failure).

[#]Includes patients who had PPIs at baseline.

[§]29 mm available for SAPIEN 3 valve only.

SAPIEN 3 valve technology takes a comprehensive approach to durability

Addressing the structural and nonstructural drivers of reintervention

Structural valve deterioration⁷

Bovine pericardium collagen structure that **reduces the potential for tissue wear and tear**⁸

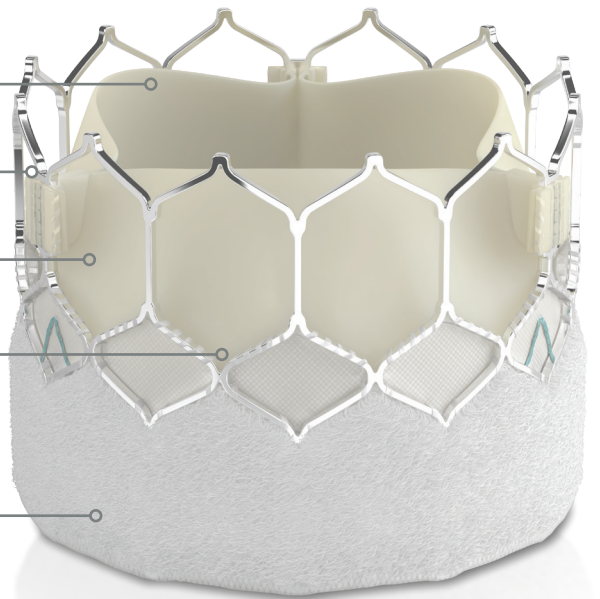
Circularity for **high radial strength** and **optimal hemodynamics**

Three independently matched leaflets for **thickness** and **elasticity to address leaflet disruption and flail**

Edwards anti-calcification technology to address a leading cause of **tissue valve failure**

Nonstructural valve dysfunction

40% taller,* textured outer skirt for **low real-world rates of paravalvular leak**⁹



The SAPIEN 3 platform has proven durability at 5 years^{†5}

The PARTNER II S3i trial demonstrated:

5
years

- SAPIEN 3 transcatheter aortic valve implantation **durability** similar to surgery⁵
- **Low rates of structural valve deterioration (SVD) (0.68%; n = 283) and SVD-related bioprosthetic valve failure (0.29%; n = 290), similar to surgery⁵**

*Compared to SAPIEN 3 transcatheter heart valve.

†Propensity-matched analysis of intermediate-risk patients using VARC-3 definitions of structural valve deterioration (SVD) and SVD-related bioprosthetic valve failure at 5 years.

Management

Ready for the next intervention and beyond

SAPIEN 3 Ultra valve system is designed to minimize obstacles, making future options possible

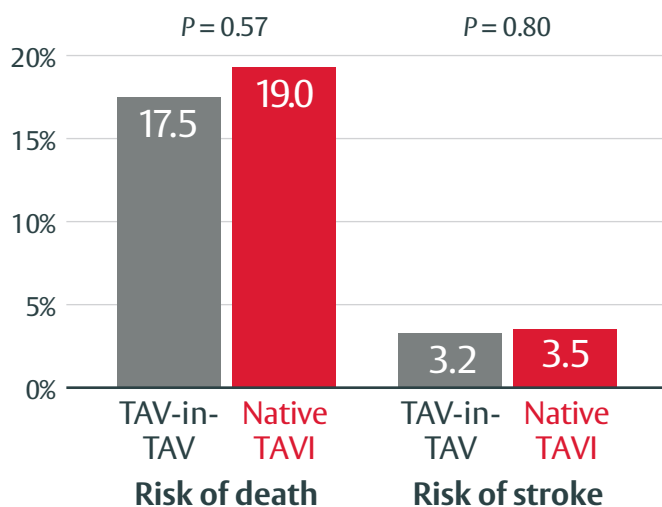
- Designed to facilitate coronary access

100% successful coronary access post transcatheter aortic valve implantation (68/68)⁶

- Currently the **only platform** approved and indicated for both TAV-in-TAV and TAV-in-SAV procedures
 - **Delivers similar outcomes and experience** as native transcatheter aortic valve implantation*¹⁰
 - Low risk plane ensures **favorable coronary access** in TAV-in-TAV procedures⁴

Outcomes similar for both TAV-in-TAV and native transcatheter aortic valve implantation (TAVI)

Patients at risk of death or stroke at 1 year (n = 1320)



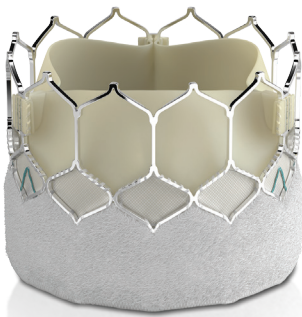
*Excellent safety and procedural outcomes for surgical valve-in-valve procedures.



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Choose the Edwards SAPIEN 3 platform as your strategy for success in lifetime management



See what makes the SAPIEN 3 platform the ideal choice for lifetime management at heartvalves.com

1. Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019;380(18):1695-1705. 2. Williams MR, Jilaihawi H, Makkar R, et al. The PARTNER 3 Bicuspid Registry for transcatheter aortic valve replacement in low-surgical-risk patients. *JACC Cardiovasc Interv.* 2022;15(5):523-532. 3. Nazif T, Daniels D, McCabe J, et al. Real-world experience with the SAPIEN 3 Ultra TAVI: A propensity matched analysis from the United States. Presented virtually at: TVT Connect 2020; June 18-28, 2020. 4. Makkar RR, Kapadia S, Chakravarty T, et al. Outcomes of repeat transcatheter aortic valve replacement with balloon-expandable valves: a registry study. *Lancet.* Published online August 31, 2023. 5. Pibarot P, Ternacle J, Jaber WA, et al. Structural deterioration of transcatheter versus surgical aortic valve bioprostheses in the PARTNER-2 trial. *J Am Coll Cardiol.* 2020;76(16):1830-1843. 6. Tarantini G, Nai Fovino L, Le Prince P, et al. Coronary access and percutaneous coronary intervention up to 3 years after transcatheter aortic valve implantation with a balloon-expandable valve. *Circ Cardiovasc Interv.* 2020;13(7):e008972. 7. Data on file. Edwards Lifesciences Corporation. 2022. 8. Kazerooni NA, Tkatchouk E. Porcine vs bovine pericardium assessment as leaflet in aortic valves. Presented at: Heart Valve Society (HVS) 2022; March 2-5, 2022; Miami, FL. 9. Nazif TM, Cahill TJ, Daniels D, et al. Real-world experience with the SAPIEN 3 Ultra transcatheter heart valve: a propensity-matched analysis from the United States. *Cir Cardiovasc Interv.* 2021;14(9):e010543. 10. De Backer O, Landes U, Fuchs A, et al. Coronary access after TAVR-in-TAVR as evaluated by multidetector computed tomography. *JACC Cardiovasc Interv.* 2020;13(21):2528-2538. doi:10.1016/j.jcin.2020.06.016

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