The strategy for lifetime management

Edwards SAPIEN 3 platform

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What's your strategy for lifetime management?

With patients living longer and having high expectations for their quality of life, lifetime management is increasingly important.

The first valve choice matters. From outstanding outcomes and excellent durability* today to facilitating future interventions tomorrow, the SAPIEN platform is designed to deliver a TAVR experience an implanter can count on.

Life

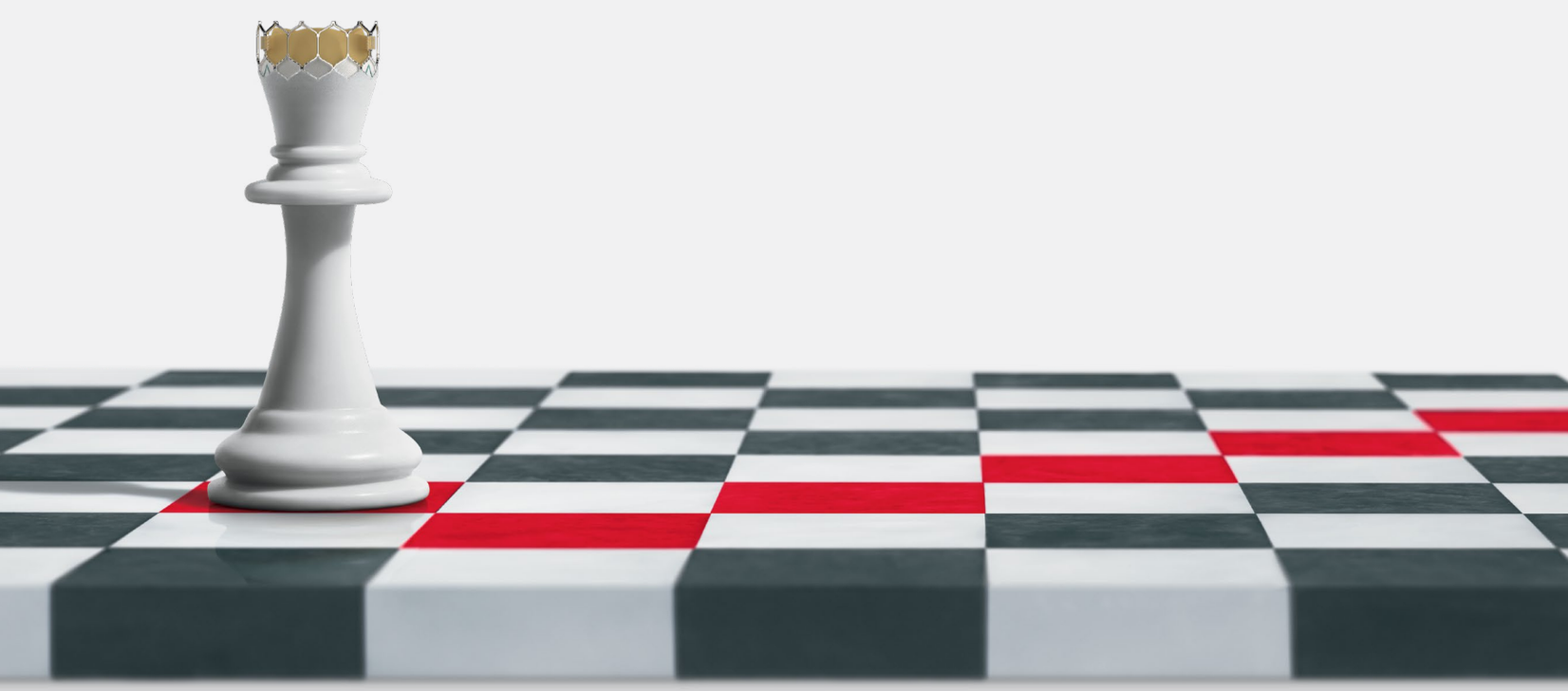
Consistently demonstrating the results you need for the outcomes that matter

Time

A comprehensive approach to durability that addresses the key drivers of reintervention

Management

Making future options possible



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

Life

Consistently demonstrating the results you need for the outcomes that matter

SAPIEN 3 transcatheter aortic valve replacement (TAVR) is proven superior* to surgery in low-risk patients at 1 year and proven equally effective at 5 years[1,2]

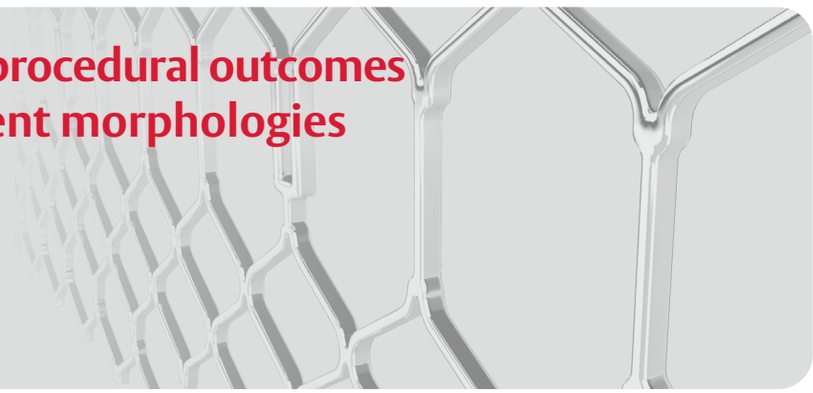
PARTNER 3 low-risk trial clinical events at 30 days, 1 year, and 5 years

	30 days		1 year			5 years		
	TAVR (n=496)	Surgery (n=454)	**TAVR (n=496)**	Surgery (n=454)	*P*-value	**TAVR (n=496)**	Surgery (n=454)	*P*-value
All-cause death	**0.4%**	1.1%	**1.0%**	2.5%	<0.09	**10.0%**	8.2%	0.35
All stroke	**0.6%**	2.4%	**1.2%**	3.1%	0.04	**5.8%**	6.4%	0.60
Rehospitalization*	**3.4%**	6.5%	**7.3%**	11.0%	0.046	**13.7%**	17.4%	0.09

Consistently strong procedural outcomes for a variety of patient morphologies

Excellent clinical outcomes in **low-risk bicuspid patients**.[3]

Consistently strong outcomes across indicated annular sizes.[4]



* The PARTNER 3 Trial, SAPIEN 3 transcatheter aortic valve replacement (TAVR) proven superior to surgery on the primary endpoint of all-cause death, all stroke, and rehospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low-risk patients.

PARTNER 3 Low-Risk Trial 5-Year Results - Low rates of cardiovascular mortality through five years (5.5% SAPIEN 3 system to 5.1% SAVR). Low rates of all-cause mortality through five years (10.0% SAPIEN 3 system vs. 8.2% with SAVR). Low rates of disabling stroke through five years (2.9% SAPIEN 3 system to 2.7% SAVR). Low rates of stroke through five years (5.8% SAPIEN 3 system vs. 6.4% SAVR). Lower rates of rehospitalization with the SAPIEN 3 system through five years (13.7% vs. 17.4%) in low-risk patients.

Time

SAPIEN valve technology is designed specifically to support valve durability

A unique design built for differentiated outcomes

Structural valve deterioration

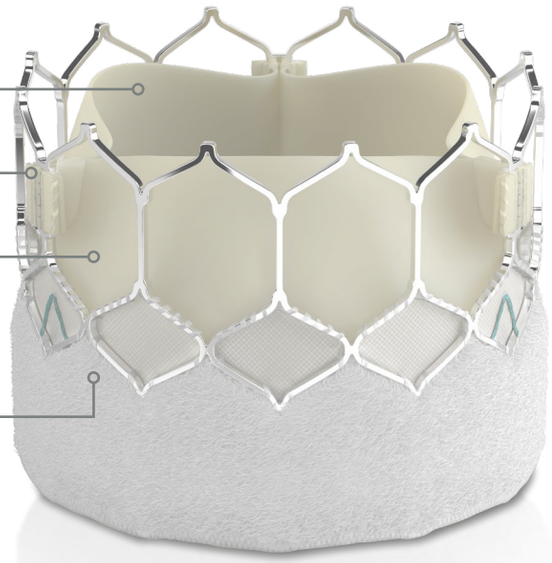
Bovine pericardium collagen structure that **reduces the potential for tissue tear**

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

Three independently matched leaflets for **thickness** and **elasticity**

Nonstructural valve dysfunction

40% taller*, textured outer skirt for low, real-world rates of paravalvular leak in a propensity-matched analysis[5]



SAPIEN 3 transcatheter aortic valve replacement has demonstrated excellent durability

5 years

The PARTNER II S3i intermediate-risk trial and PARTNER 3 low-risk trial demonstrated:

- SAPIEN 3 valve **durability similar to surgery** at 5 years[2,6]
- **Low rates of structural valve deterioration (SVD)** and **SVD-related bioprosthetic valve failure,** similar to surgery at 5 years[2,6]

Real-world data have demonstrated:

- Excellent 5-year SAPIEN valve **durability performance for small-annuli patients**[7]

*SAPIEN 3 Ultra valve, as compared to SAPIEN 3 valve.

Management

Facilitates coronary access, reducing obstacles to future therapy options[5,8]

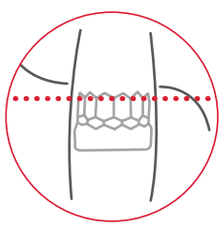
SAPIEN 3 transcatheter valve system technology is designed to minimize obstacles to future therapy

- Excellent real-world results for continued coronary access

100% (n=68/68) successful coronary access post-TAVR[8]

- The **only transcatheter heart valve** indicated for both TAV-in-TAV and TAV-in-SAV procedures*
  - A valve with excellent safety and procedural outcomes for surgical valve-in-valve procedures*[9]
  - Outcomes for TAV-in-TAV with the SAPIEN 3 valve are similar to native transcatheter aortic valve replacement[10]

Designed to host future valve interventions



Low risk plane

2.0% risk of future sinus sequestration†[11]

*For patients assessed at high risk for surgical replacement.

†Risk of sinus sequestration if (1) prior TAV commissure level was above sinotubular junction (STJ), and (2) the distance between TAV and STJ was <2.0 mm in each coronary sinus.

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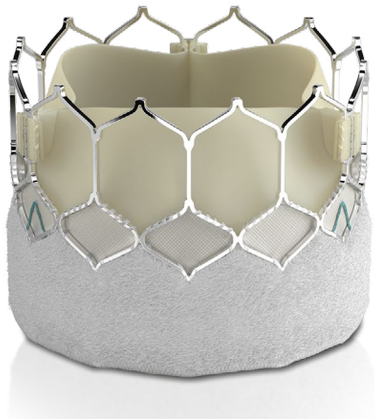
Built for now and what's next



See how the SAPIEN 3 platform works **as your strategy for success in comprehensive lifetime management** at heartvalves.com/ca

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.** Mack MJ, Leon MB, Thourani P, et al; PARTNER 3 investigators. Transcatheter aortic-valve replacement in low-risk patients at five years. *N Engl J Med*. 2023;389(21):1949-1960. **3.** 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. **4.** Eng MH, Abbas AE, Hahn RT, et al. Real world outcomes using 20 mm balloon expandable SAPIEN 3/ultra valves compared to larger valves (23, 26, and 29 mm) – a propensity matched analysis. *Catheter Cardiovasc Interv*. 2021;98(6):1185-1192. **5.** 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. *Circ Cardiovasc Interv*. 2021;14(9):e010543. **6.** 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. **7.** Okuno T, Tomii D, Lanz J, et al. 5-year outcomes with self-expanding vs balloon-expandable transcatheter aortic valve replacement in patients with small annuli. *JACC Cardiovasc Interv*. 2023;16(4):429-440. **8.** 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. **9.** Kaneko T, Makkar RR, Krishnaswami A, et al. Valve-in-surgical-valve with SAPIEN 3 for transcatheter aortic valve replacement based on Society of Thoracic Surgeons predicted risk of mortality [published correction appears in *Circ Cardiovasc Interv*. 2021;14(7):e000083]. *Circ Cardiovasc Interv*. 2021;14(5):e010288. **10.** Makkar RR, Kapadia S, Chakravarty T, et al. Outcomes of repeat transcatheter aortic valve replacement with balloon-expandable valves: a registry study. *Lancet*. 2023;402(10412):1529-1540. **11.** Ochiai T, Oakley L, Sekhon N, et al. Risk of coronary obstruction due to sinus sequestration in redo transcatheter aortic valve replacement. *JACC Cardiovasc Interv*. 2020;13(22):2617-2627.

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