

Controlling for the future

You're always thinking ahead. We can get behind that.



The future of your bicuspid patients starts with their first TAVI

Congenital bicuspid aortic valve disease is more prevalent in younger patients requiring aortic valve replacement.¹ Planning for the lifetime well-being of these patients is crucial and begins with your choice for first-time TAVI.

Edwards SAPIEN 3 valve platform supports you with:



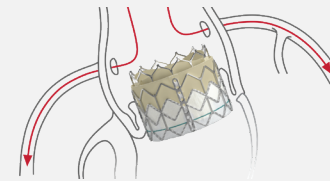
Careful therapy selection by the Heart Team

Insights from more than 4000 unique bicuspid patients treated with the SAPIEN 3 valve platform²



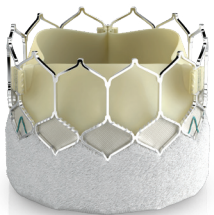
Excellent outcomes in challenging anatomies

Outstanding paravalvular leak (PVL) outcomes and low rates of mortality and stroke, independent of surgical risk^{3,4}



Controlling for the future of patients with longer life expectancies

Leaving future treatment options open for both valve-in-valve and coronary access procedures⁵



Edwards SAPIEN 3 Ultra TAVI

Take control for the future of your bicuspid patients with Edwards SAPIEN 3 Ultra TAVI by addressing what matters most.

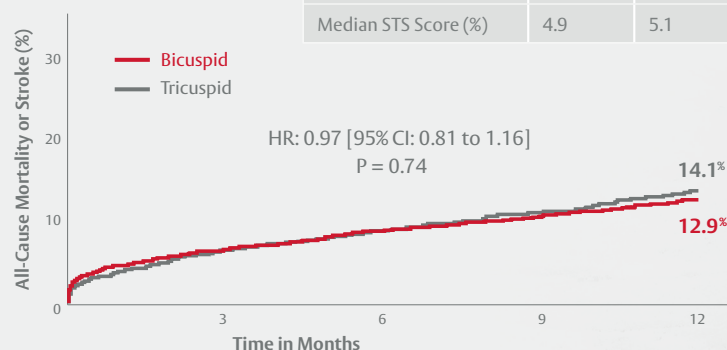


Deliver the outcomes you demand for your bicuspid patients

Real-world data shows SAPIEN 3 TAVI achieves outcomes similar to tricuspid patients in selected bicuspid patients.³

TVT registry data
Matched cohort

	Bicuspid	Tricuspid
Median Age (years)	74	74
Median STS Score (%)	4.9	5.1



Number at Risk

	0	3	6	9	12
Bicuspid	2,691	1,234	1,196	1,135	910
Tricuspid	2,691	1,341	1,296	1,226	952

Early experience with the SAPIEN 3 valve in low surgical risk bicuspid patients also shows excellent outcomes.⁴

Low rates of complications that matter to patients

CEC-adjudicated Event	30 Days		1 Year
	Registry (n=71)	Continued Access patients (n=98)	Registry (n=71)
Median Age (years)	68.5	71.7	68.5
Mean STS Score (%)	1.4	1.5	1.4
All-cause mortality (%)	0	0	1.4
All stroke (%)	2.8	0	2.8
Disabling stroke (%)	0	0	0
New PPI (%)	9.9	5.1	11.3

No patients experienced annular rupture or aortic dissection.

Choose SAPIEN 3 TAVI for the lifetime management of your bicuspid patients and achieve your Higher Standard. Learn more at [YourHigherStandard.com](https://www.edwards.com/YourHigherStandard)

1. Roberts WC. et al. Frequency of congenitally bicuspid aortic valves in patients ≥ 80 years of age undergoing aortic valve replacement for aortic stenosis (with or without aortic regurgitation) and implications for transcatheter aortic valve implantation. Am J Cardiol. 2012 Jun 1;109(11):1632-6.
2. STS/ACC TVT Registry, Data on File at Edwards Lifesciences.
3. Makkar RR. et al. Association Between Transcatheter Aortic Valve Replacement for Bicuspid vs Tricuspid Aortic Stenosis and Mortality or Stroke. JAMA. 2019 Jun 11;321(22):2193-2202.
4. Williams M. et al. The PARTNER 3 Bicuspid Registry for SAPIEN 3 TAVR in Low Surgical Risk Patients; Presented at TCT 2020; October 2020, [tctconnect.com](https://www.tctconnect.com)
5. Tarantini G. 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 Jul;13(7):e008972..

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