Comparison: 8-year outcomes of RESILIA tissue valves vs. Non-RESILIA tissue valves

Edwards

*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.

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 Sep;168(3):781-791*

In an 8-year, propensity-matched comparison between RESILIA tissue valves and non-RESILIA tissue valves, RESILIA tissue valves performed significantly better in:

Freedom from **SVD**	Freedom from **reoperation due to SVD**	Freedom from **all-cause reoperation**

The study represents the longest follow-up and first long-term propensity-matched analysis comparing outcomes from the novel calcification-resistant RESILIA tissue treatment versus a widely used contemporary bioprosthesis.

Study comparison

- Multicenter
- Single-arm
- Clinical events committee
- SVD Definition: Akins et al. (2008)

	RESILIA Tissue at 8 years†	Non-RESILIA Tissue at 8 years‡
Size	689 patients (239 reconsented)	258 patients
Mean age	66.9 years old	68.5 years old

†The RESILIA tissue valve cohort consisted of patients from the COMMENCE aortic trial (n=689)
‡The non-RESILIA tissue valve cohort originated from the Carpentier-Edwards PERIMOUNT Magna Ease post approval study (n=258)

RESILIA tissue valves demonstrated significantly improved freedom from SVD, reoperation due to SVD, and reoperation compared to the non-RESILIA tissue valves

Outcomes at 8 years (Kaplan-Meier analyses)

RESILIA tissue valves | Non-RESILIA tissue valves

Freedom from SVD

p<0.0001

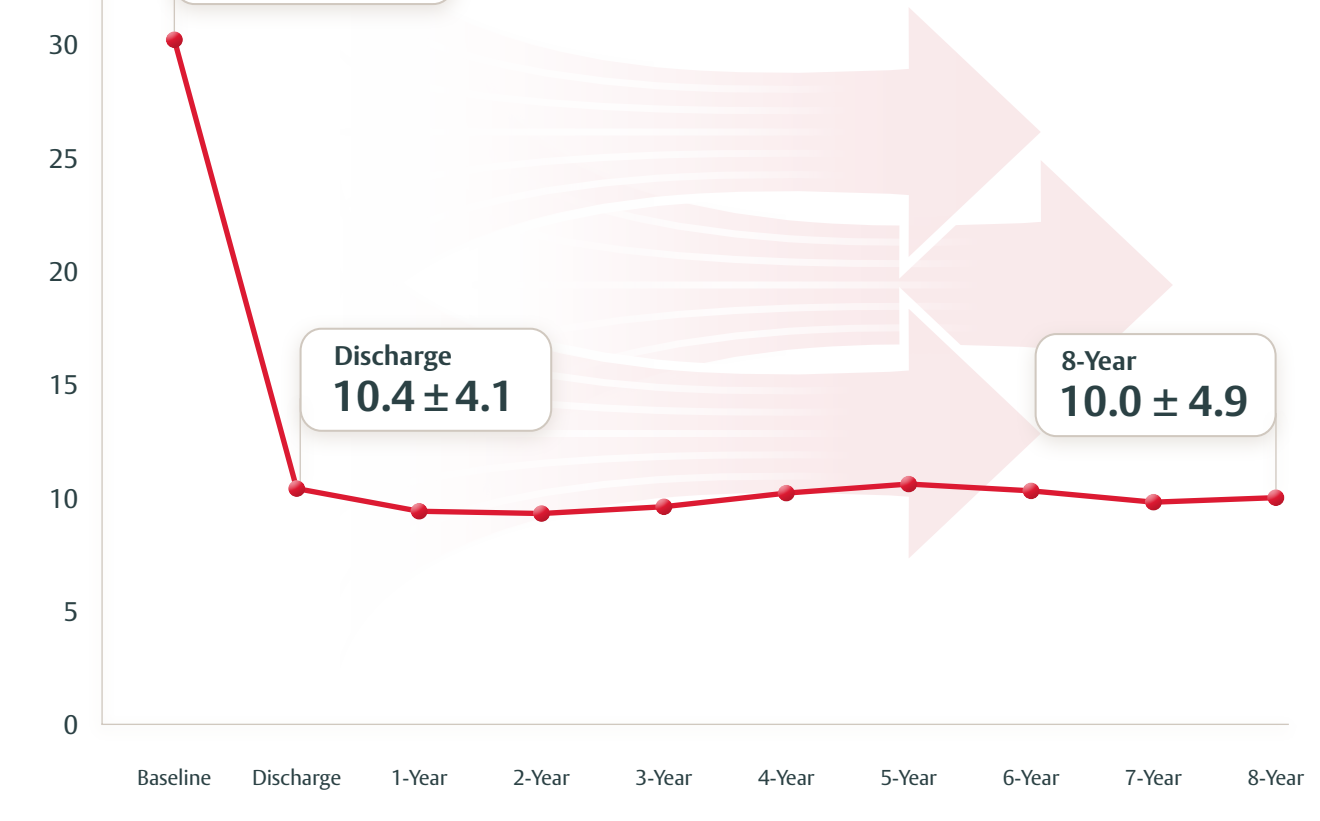
Freedom from reoperation due to SVD | **Freedom from reoperation**

p=0.0003 | p=0.0007

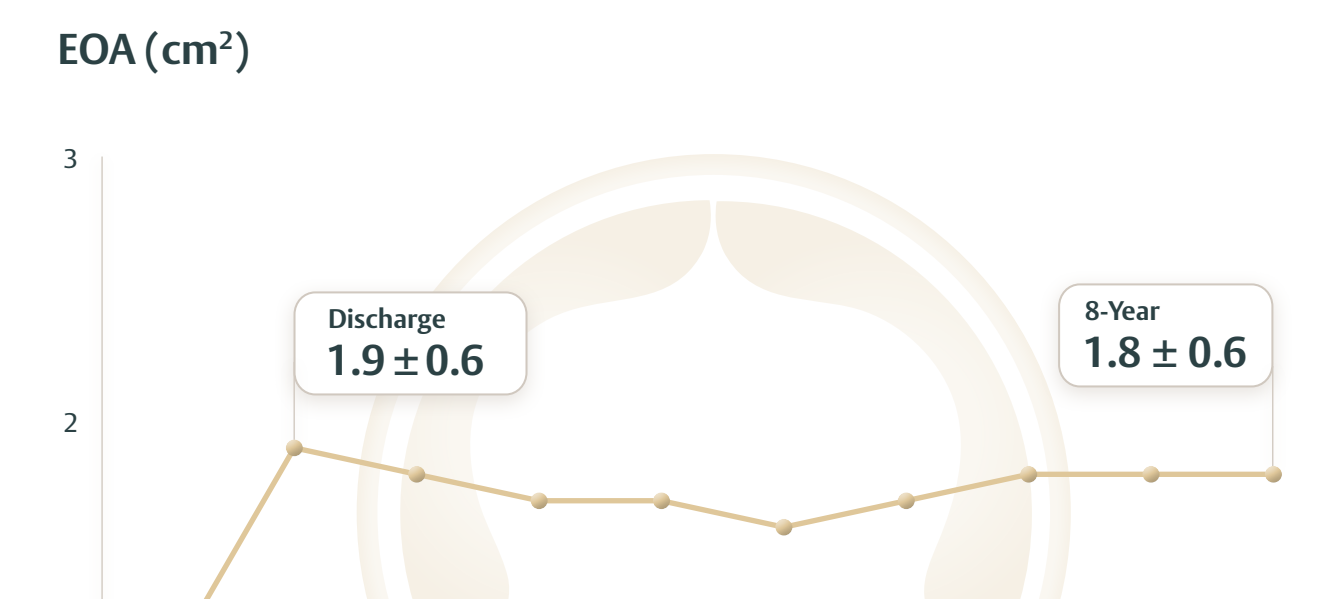
Note: Superiority Test Log-Rank P-Value

RESILIA tissue valves demonstrated clinically stable hemodynamics through 8 years

Mean Gradient (mmHg)



EOA (cm^2)



RESILIA tissue valves delivered a favorable safety profile through 8 years**

RESILIA tissue valves		Non-RESILIA tissue valves
16.7% All-cause mortality	vs.	18.7% All-cause mortality
4.1% Valve related mortality	vs.	4.3% Valve related mortality
0.9% Non-structural valve deterioration	vs.	2.1% Non-structural valve deterioration

**Data from Kaplan Meier analysis after Propensity Score Adjustment

This study supports the choice of RESILIA tissue valves over non-RESILIA tissue valves for SAVR in patients aiming to maximize life expectancy while minimizing cumulative risk

Interested in learning more?

Download the clinical summary

The INSPIRIS RESILIA aortic valve with RESILIA tissue technology

Leads the world as the most implanted surgical aortic tissue valve.

The INSPIRIS RESILIA valve incorporates novel VFit technology, designed to enable valve-in-valve procedures in the future, at a time when patients are older and potentially at a higher risk for complications.

Built on the Carpentier-Edwards PERIMOUNT valve platform, which is backed by over 40 years of real-world experience.

Explore the benefits at
Edwards.com/INSPIRIS

Important Safety Information

RESILIA Tissue Devices

Indications: INSPIRIS RESILIA Aortic Valve - For use in replacement of native or prosthetic aortic heart valves. **KONECT RESILIA Aortic Valved Conduit** - For use in replacement of native or prosthetic aortic heart valves and the associated repair or replacement of a damaged or diseased ascending aorta. **MITRIS RESILIA Mitral Valve** - For use in replacement of native or prosthetic mitral heart valves.

Contraindications: There are no known contraindications with the use of these RESILIA tissue heart valve devices.

Complications and Side Effects: INSPIRIS RESILIA Aortic Valve - Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valvedeterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead toreoperation, explantation, permanent disability, and death. Additional adverse events potentially associated with the use of polyester vascular grafts in the **KONECT RESILIA AVC** include hemorrhage, thrombosis, graft infection, embolism, aneurysm, pseudoaneurysm, seroma, occlusion (anastomotic intimal hyperplasia), immunological reaction tocollagen (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation. **MITRIS RESILIA Mitral Valve** - Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia,transient ischemic attack/stroke, congestive heart failure, myocardial infarction, ventricular perforation by stent posts, any of which could lead to reoperation, explantation,permanent disability, and death.

Warnings: INSPIRIS RESILIA Aortic Valve - DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO OR DURING IMPLANTATION OF THE SURGICAL VALVE. Theexpandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aorticincompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19 – 25 mm as this may expand the valvecausing aortic incompetence, coronary embolism or annular rupture. Valve-in-valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heartvalves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician. See Instructions for Use for full prescribing information.

Reference
1. Kaneko, T, Johnston D, Bavaria JE, et al. Propensity-matched 8-year Outcomes Following Surgical Aortic Valve Replacement With Novel Calcification-resistant Versus Contemporary Tissue Bioprostheses. Presented at the Heart Valve Society Annual Scientific Meeting, April 2025.

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