TRIFORMIS RESILIA Tricuspid Valve

No longer the forgotten valve

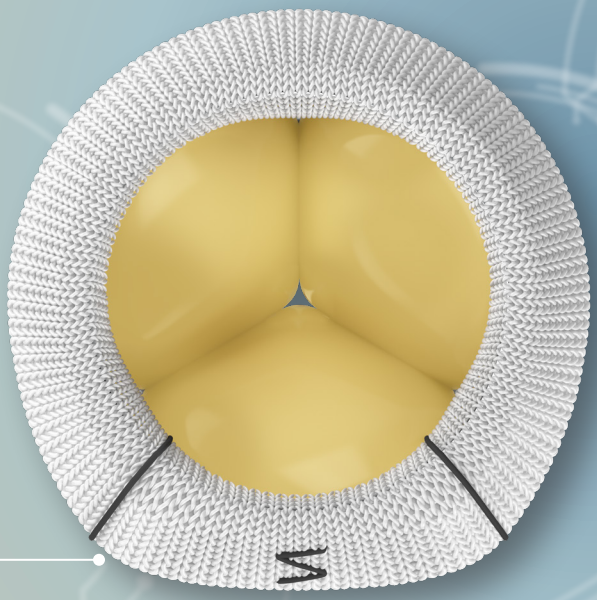
The first and only surgical valve designed specifically for the tricuspid position

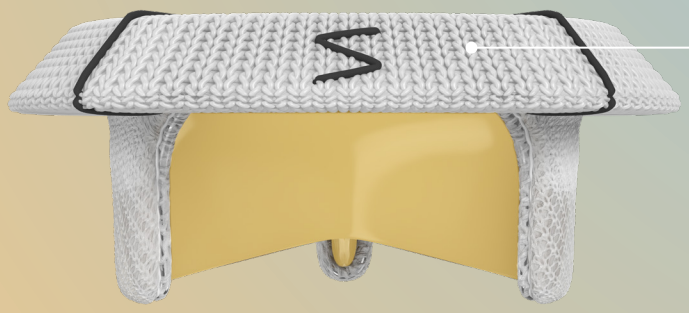
Edwards

Once forgotten, now at the forefront.

Take advantage of tricuspid-specific design.

The valve's unique sewing ring shape with a flat section along the septal region is designed to avoid AV node disruption.





The sewing ring has a flat profile that mimics the tricuspid annulus and is specifically designed for optimal seating.

Innovation with purpose

The TRIFORMIS RESILIA tricuspid valve is designed to address unmet patient needs.

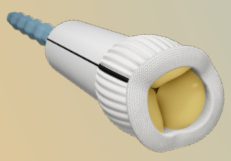
Historically, surgery for isolated tricuspid regurgitation is rarely performed because of perceptions of high mortality.

A new analysis of STS outcomes shows that the risk is lower than previously observed[1], providing a new benchmark for current and future isolated tricuspid valve interventions.

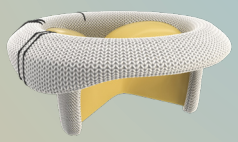
The latest addition to the RESILIA tissue surgical valve portfolio, all specifically designed to conform to native valve anatomy.

INSPIRIS RESILIA
aortic valve

KONECT RESILIA
aortic valved conduit

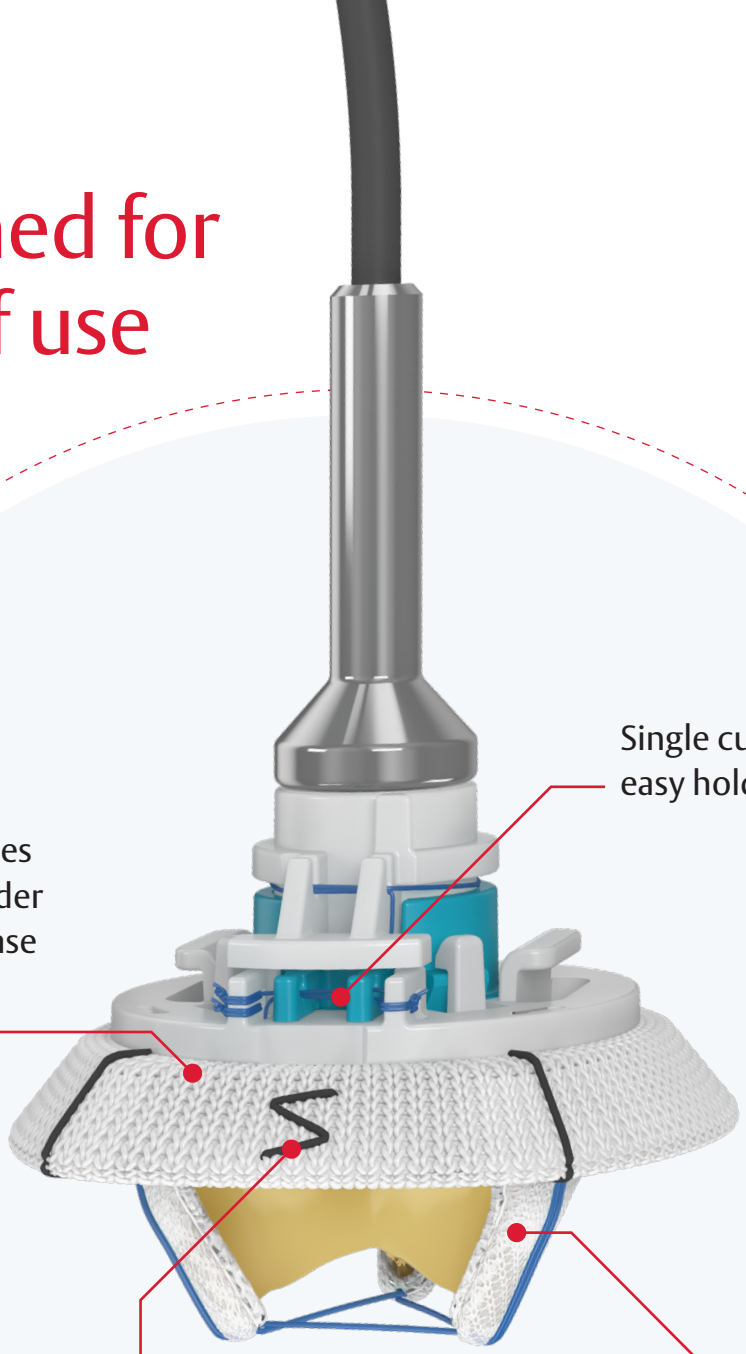


MITRIS RESILIA
mitral valve



TRIFORMIS RESILIA
tricuspid valve

Designed for ease of use



Single cut point for easy holder release

CoCr band provides good visibility under fluoroscopy for ease of landing zone identification

Clear commissure and septal region markers aid in orientation and positioning

Nitinol stent posts fold to 55 degrees for ease of implantation and to avoid suture looping

Tackling the leading causes of SVD

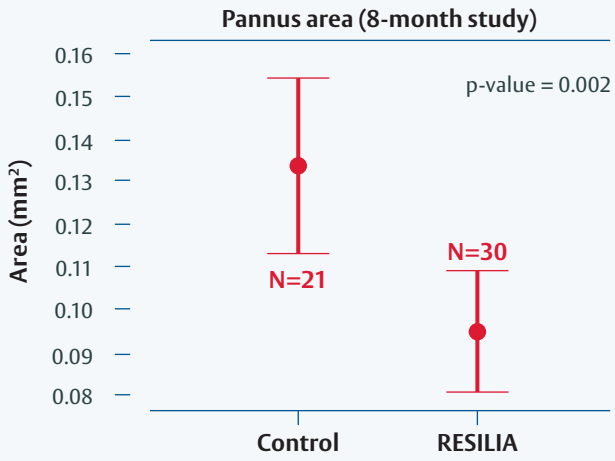
RESILIA tissue,*[2] created through a novel preservation technology applied to bovine pericardium, has been shown in pre-clinical studies to significantly reduce both calcification and pannus.[3,4]

These pre-clinical and clinical studies are part of a growing base of evidence supporting the durability and hemodynamic performance of RESILIA tissue valves.[2,3,4,5]

To learn more about the latest RESILIA tissue durability evidence, visit Edwards.com/RESILIAdata

Pannus formation pre-clinical study shows significantly less pannus growth at 8 months on RESILIA tissue valves[3]

Compared to XenoLogiX treatment control valves[3]
N= number of leaflets



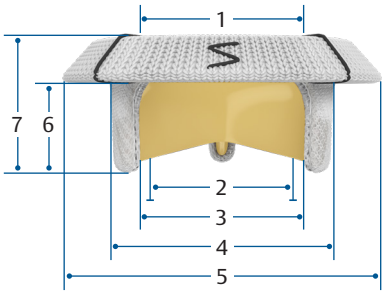
Pre-clinical study performance of the TRIFORMIS RESILIA valve in the tricuspid position demonstrated:

- Good leaflet mobility
- Good hemodynamic performance
- No significant conduction abnormalities
- Optimal seating

* Clinical data on valves with RESILIA tissue up to 7-year follow-up have been published, with additional follow-up of up to 10 years in process.

Model 11300T

Valve Size	25 mm	27 mm	29 mm	31 mm	33 mm
1. Inflow orifice diameter (mm)	23.0	25.0	27.0	29.0	29.0
2. Effective orifice diameter (mm)	19.5	21.0	23.0	25.0	25.0
3. Stent diameter (wireform, mm)	25.0	27.0	29.0	31.0	31.0
4. Valve housing external diameter (mm)	27.5	29.5	31.5	33.5	33.5
5. External sewing ring diameter (mm)	37.5	40.0	42.5	44.5	46.0
6. Effective profile height (mm)	10.0	11.0	11.5	12.0	12.0
7. Total profile height (mm)	15.0	16.0	17.0	18.0	18.0



Accessories

Model	Description
1173B	Individual barrel sizer
SET1173	Tray only

Handle

Model	Description
1140M	Nitinol handle
1141M	Stainless steel handle

See how the TRIFORMIS RESILIA tricuspid valve addresses unmet patient needs.

Visit **Edwards.com/TRIFORMIS** or scan the QR code to learn more.

Important Safety Information: TRIFORMIS RESILIA Tricuspid Valve

Indications: For use in replacement of native or prosthetic tricuspid heart valves. **Contraindications:** The TRIFORMIS RESILIA tricuspid valve is contraindicated in patients who have untreatable hypersensitivity to nitinol alloys (nickel and titanium). **Complications and Side Effects:** 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.

CAUTION: US law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information.

References
1. Thourani VH, Bonnell L, Wyler von Ballmoos MC, et al. Outcomes of isolated tricuspid valve surgery: a Society of Thoracic Surgeons analysis and risk model. *Ann Thorac Surg*. 2024;118:873-881. doi: 10.1016/j.athoracsur.2024.04.014
2. Beaver T, Bavaria J, Griffith B, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. *J Thorac Cardiovasc Surg*. 2023;x:1-11. doi: 10.1016/j.jtcvs.2023.09.047
3. Tod TJ, Gohres RA, Torky M et al. Influence of tissue technology on pannus formation on bioprosthetic heart valves. *Cardiovasc Eng Technol*. 2021; 12: 418-25. doi: 10.1007/s13239-021-00530-1
4. Flameng W, Hermans H, Verbeken E, et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg*. 2015;149(1):340-345. doi: 10.1016/j.jtcvs.2014.09.062
5. Heimansohn DA, Baker C, Rodriguez E, et al. Mid-term outcomes of the COMMENCE trial investigating mitral valve replacement using a bioprosthesis with a novel tissue. *JTCVS Open*. 2023;15:151-163. doi: 10.1016/j.xjon.2023.05.008

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