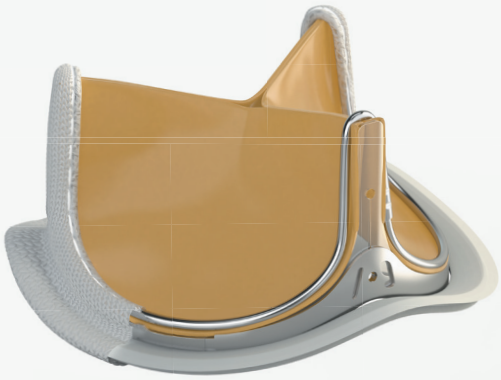
INSPIRIS RESILIA

Aortic Valve



For

Aortic valve replacement

When

You need a surgical valve replacement and want options for minimally invasive future interventions, ask if an INSPIRIS RESILIA is right for you.

Why

RESILIA tissue* is designed to offer enhanced† anti-calcification technology that will potentially allow the valve to last longer

RESILIA tissue

- Significant improvement of anti-calcification properties in test valves compared to control†
- Sustained hemodynamic performance across 5 years[1]

VFit technology‡

- Enables a controlled expansion during valve-in-valve deployment
- Expansion feature available on valve sizes 19–25 mm

Proven valve platform

- Built on the proven performance of the Carpentier-Edwards PERIMOUNT valve design – a valve design with published clinical durability of over 20 years[2–4]
- Incorporates features of the trusted PERIMOUNT valve platform to enhance ease of implant

* No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.

† RESILIA tissue tested against commercially available bovine pericardial tissue from Edwards in a juvenile sheep model. Flameng, et al. *J Thorac Cardiovasc Surg* 2015;149:340–5.

‡ Based on bench data. Refer to device **Instructions for Use** for important warnings related to VFit technology. These features have not been observed in clinical studies to establish the safety and effectiveness of the model 11500A for use in valve-in-valve procedures.

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Important Safety Information: INSPIRIS RESILIA Aortic Valve

Indications: For use in replacement of native or prosthetic aortic heart valves. **Contraindications:** There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve. **Complications and Side Eff ects:** Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death. **Warnings:** DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable 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 aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19–25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves.
Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

CAUTION: For professional use only. The Edwards Inspiris RESILIA Tissue Heart Valve is a Class III medical device and indicated for use in patients with a dysfunctional Aortic Valve. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

References

1. Bavaria JE, et al. Five-year Outcomes of Aortic Valve Replacement with a Bioprosthetic Valve with a Novel Tissue. The Society of Thoracic Surgeons, 2021 Annual Meeting.
2. Bourguignon T, et al. Very long-term outcomes of the Carpentier-Edwards PERIMOUNT valve in aortic position. *Ann Thorac Surg*. 2015;99:831–7.
3. Johnston DR, et al. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. *Ann Thorac Surg*. 2015;99:1239–47.
4. Forcillo J, et al. Carpentier-Edwards pericardial valve in the aortic position: 25-years experience. *Ann Thorac Surg*. 2013;96:486–93.
5. Flameng W, et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg*. 2015;149:340–5.

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