

Right for today.
Ready for tomorrow.



INSPIRIS
RESILIA Aortic Valve



Edwards

INSPIRIS RESILIA Aortic Valve

The right choice today.

Because today, your patients want an improved quality of life and the potential to expand their future options.

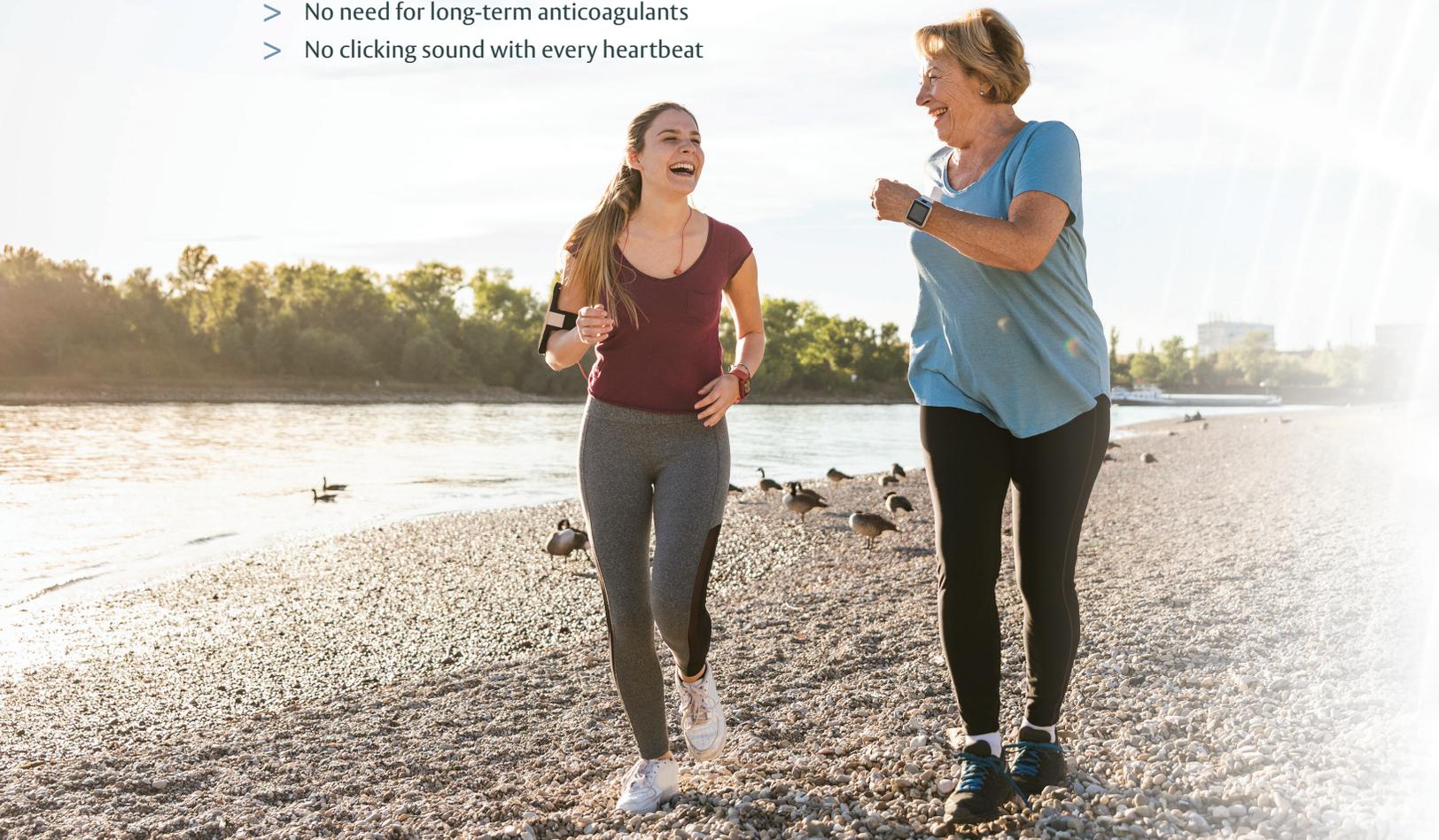
Feel confident with a design and features you can trust.

The INSPIRIS RESILIA aortic valve incorporates features of the trusted Edwards PERIMOUNT and Magna Ease aortic valve platforms to enhance ease of implant.^{1,2,3}

The INSPIRIS RESILIA valve delivers on the promise of better ongoing patient quality of life without the inconvenience of monitoring, dietary restrictions and reduction of participation in active lifestyles typically seen with a mechanical valve.^{4,5}

The INSPIRIS valve possesses many advantages over a mechanical valve:

- > Freedom to live a more active lifestyle
- > Fewer dietary restrictions
- > No need for long-term anticoagulants
- > No clicking sound with every heartbeat



Built with RESILIA tissue[†], the INSPIRIS valve is designed to offer enhanced tissue anti-calcification technology that will potentially allow the valve to last longer.⁶

- > RESILIA tissue is bovine pericardial tissue treated with a special integrity preservation technology that effectively eliminates free aldehydes, a key factor in tissue calcification, while protecting and preserving tissue.^{6,7}
- > RESILIA tissue is the result of a development program, involving more than 100 evaluations of safety and efficacy.

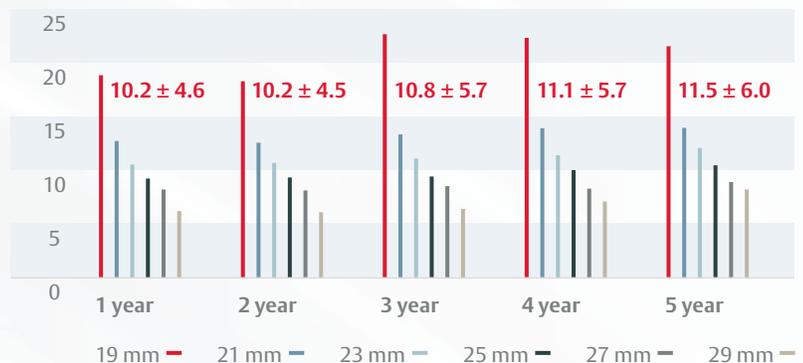
Backed by a strong and growing base of preclinical and clinical evidence supporting its ongoing study of durability and hemodynamic performance.^{6,8,9}

COMMENCE clinical trial (n=689)

Sustained hemodynamics and freedom from structural valve deterioration (SVD) through 5 years (an aggregate of over 2,989 patient years of follow-up).⁸



Stable gradients Mean gradient (mmHg)

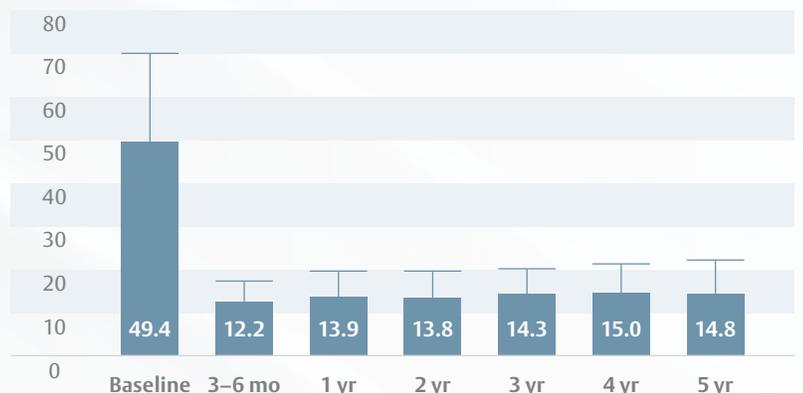


European feasibility trial (n=133)

Sustained hemodynamics and no observed SVD at 5-year follow-up (565 cumulative patient-years).⁹



Mean gradient (mmHg) Valve sizes 19–27 mm



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

†† 1 SVD diagnosed at POD 1848

Ready for tomorrow.

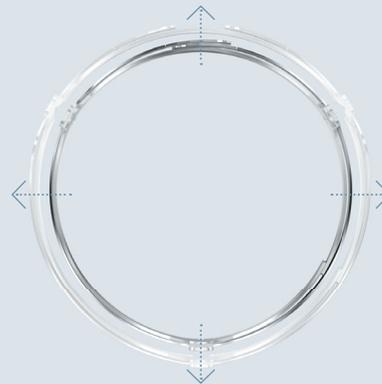
Help your patients meet the future confidently, with enhanced options for subsequent valve intervention.

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.

Unlike other valves, the INSPIRIS RESILIA valve is specifically designed to deliver a controlled and predictable expansion during valve-in-valve deployment.*¹⁰

Designed to deliver predictable and controlled expansion

The valve's cobalt-chromium alloy band enables a controlled expansion to fit a new transcatheter valve within the existing INSPIRIS RESILIA valve. The expansion feature is available on sizes 19–25 mm for a broad range of patients with varying annulus size.



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Patients undergoing a valve replacement are living long lives and remaining more active through their later years, increasing the need for advanced valve replacement technologies. The absence of structural valve deterioration in these patients is extremely encouraging and highlights the potential of valves containing RESILIA tissue for patients who may otherwise opt for a mechanical valve, which requires long-term use of blood thinning medications.”

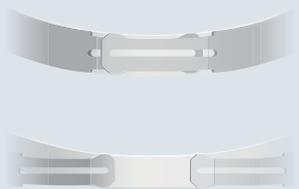
John D. Puskas, MD
Principal investigator for the COMMENCE study

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



How VFit technology enables a controlled expansion

— Valve expansion is activated by the radial force applied by the dilation of the new transcatheter valve within the existing INSPIRIS RESILIA valve, resulting in a uniform and controlled expansion around the INSPIRIS RESILIA valve's perimeter.



— The perforated polyester band is designed to expand at each of the 3 commissures during deployment of the new transcatheter valve, delivering controlled, predictable and uniform expansion of the valve's internal orifice.



— With the INSPIRIS RESILIA valve, to achieve area expansion, there is no need for a high-pressure bioprosthetic valve fracture (BVF) to expand the valve. BVF is associated with risk of stroke and other complications in valve-in-valve patients when used to crack a valve.¹¹

— VFit technology is available on sizes 19–25 mm to fit a broad range of patients with varying annulus size.





Expanding future possibilities for you and your patients starts today.

The INSPIRIS RESILIA valve is from Edwards Lifesciences, the company trusted by surgeons for more than 60 years to deliver safe, responsible structural heart disease innovation.

Talk to your rep or visit [edwards.com/inspiris](https://www.edwards.com/inspiris) to find out more.

References

1. Johnston DR, et al. Long-term durability of bioprosthetic aortic valves: implications from 12,569 implants. *Ann Thorac Surg.* 2015;99:1239–47.
2. Forcillo J, et al. Carpentier-Edwards pericardial valve in the aortic position: 25-years experience. *Ann Thorac Surg.* 2013;96:486–93.
3. Bourguignon T, et al. Very long-term outcomes of the Carpentier-Edwards PERIMOUNT valve in aortic position. *Ann Thorac Surg.* 2015;99:831–7.
4. Ruel M, et al. Long-term outcomes of valve replacement with modern prostheses in young adults. *Eur J Cardiothorac Surg.* 2005;27(3):425–433.
5. Kottmaier M, et al. Quality of Life and Anxiety in Younger Patients after Biological versus Mechanical Aortic Valve Replacement. *Thorac Cardiovasc Surg.* 2017;65(3):198–205.
6. 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.
7. Prieu A, et al. Glycerol decreases the volume and compressibility of protein interior. *Biochemistry.* 1996;35(7):2061–2066.
8. Bavaria, J. E. et al. Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with a novel tissue bioprosthesis. The Society of Thoracic Surgeons, 2021 Annual Meeting.
9. Bartus K, et al., Five-year Outcomes of Aortic Valve Replacement Using a Bioprosthetic Valve with the Novel RESILIA Tissue: Final Study Results. *Structural Heart*, 2019; vol3, no.51, 18
10. Saxon JT, et al. Bioprosthetic Valve Fracture During Valve-in-valve TAVR: Bench to Bedside. *Interv Cardiol.* 2018;13(1):20–26.
11. Saxon JT, et al. Complications of Bioprosthetic Valve Fracture as an Adjunct to Valve-in-Valve TAVR, *Structural Heart*, 2019;3:2, 92–99.

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 Effects:** 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: Federal (USA) law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information.

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