Right for today.
Ready for tomorrow.

INSPIRIS
RESILIA Aortic Valve
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 of over 10 years, 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

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

COMMENCE clinical trial
Sustained hemodynamics and freedom from structural valve deterioration (SVD) through 4 years (an aggregate of over 2,500 patient years of follow-up).8

European feasibility trial
Sustained hemodynamics and no observed SVD at 5-year follow-up (565 cumulative patient-years).6

† No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.
**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. 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 lifestyle typically seen with a mechanical valve. 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

**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.*

*Based on bench data. Refer to device instructions for use for important warnings related to VFit technology. These devices have not been approved in clinical studies to establish the safety and effectiveness of the novel INSPIRIS valve-in-valve procedures.

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

**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 valve is specifically designed to deliver a controlled and predictable expansion during valve-in-valve deployment.*

*Based on bench data. Refer to device instructions for use for important warnings related to VFit technology. These devices have not been approved in clinical studies to establish the safety and effectiveness of the novel INSPIRIS valve-in-valve procedures.

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 valve is specifically designed to deliver a controlled and predictable expansion during valve-in-valve deployment.*

*Based on bench data. Refer to device instructions for use for important warnings related to VFit technology. These devices have not been approved in clinical studies to establish the safety and effectiveness of the novel INSPIRIS valve-in-valve procedures.
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 successful structural heart disease innovation.

Talk to your rep or visit edwards.com/inspiris to find out more.

References

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/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 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.

Edwards, Edwards Lifesciences, the stylized E logo, Carpentier-Edwards, COMMENCE, INSPIRIS, INSPIRIS RESILIA, Magna, Magna Ease, PERIMOUNT, PERIMOUNT Magna, RESILIA, and VFit are trademarks or service marks of Edwards Lifesciences Corporation. All other trademarks are property of their respective owners.

© 2020 Edwards Lifesciences Corporation. All rights reserved. PP--US-5071 v1.0

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com