

# Life<sup>R</sup>

Life to the power of RESILIA

Edwards Lifesciences  
RESILIA tissue portfolio



Edwards

# A promise of freedom. That's the power of RESILIA tissue.<sup>†\*</sup>

Edwards Lifesciences is advancing the future of cardiac surgery with a growing portfolio of valves designed with RESILIA tissue. The reason is simple: because RESILIA tissue is different.

## For surgeons, a difference that offers more options

For patients referred for surgical valve replacement, there are now three options: mechanical valves, conventional tissue valves or RESILIA tissue valves. RESILIA tissue gives surgeons the freedom to offer a resilient tissue alternative that brings the quality-of-life benefits of tissue valves to patients.

A key challenge with pericardial tissue is structural valve deterioration (SVD) due to calcium buildup. RESILIA tissue is transformed to resist calcification differently.

## Several generations of tissue valve leadership

Since 1981 with the Carpentier-Edwards PERIMOUNT valve, Edwards Lifesciences has been pioneering the development of advanced pericardial tissue technologies.

Edwards Lifesciences innovations include the first:

- Bioengineered tissue valve
- Bioengineered mitral valve
- Transcatheter aortic valve

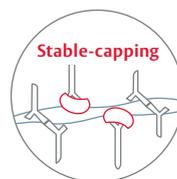
*“From my perspective the prospect of enhanced tissue durability is the most important aspect.”*

**Patrick Klein, MD**

## Tissue with a difference



Proprietary tissue integrity preservation technology mitigates residual aldehydes. This enables dry storage that simplifies handling.



RESILIA tissue offers enhanced anti-calcification technology that will potentially allow the valve to last longer than conventional bioprosthetic valves.\*



RESILIA tissue offers the possibility of avoiding costly surgical re-intervention later in life, when risks may be higher.

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

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

## Evidence of RESILIA tissue performance

### COMMENCE aortic clinical trial

Clinically stable hemodynamics and zero structural valve deterioration (SVD) through 5 years (in 689 patients).

# Zero SVD

through 5 years\*

### Preclinical juvenile sheep model study

Significant improvement of anti-calcification properties in test valves compared to control.<sup>1</sup>

# 72% less calcium content

after 8 months\*\*

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

\* 1 SVD diagnosed at Post-operative Day 1848.

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## For patients, a different way forward

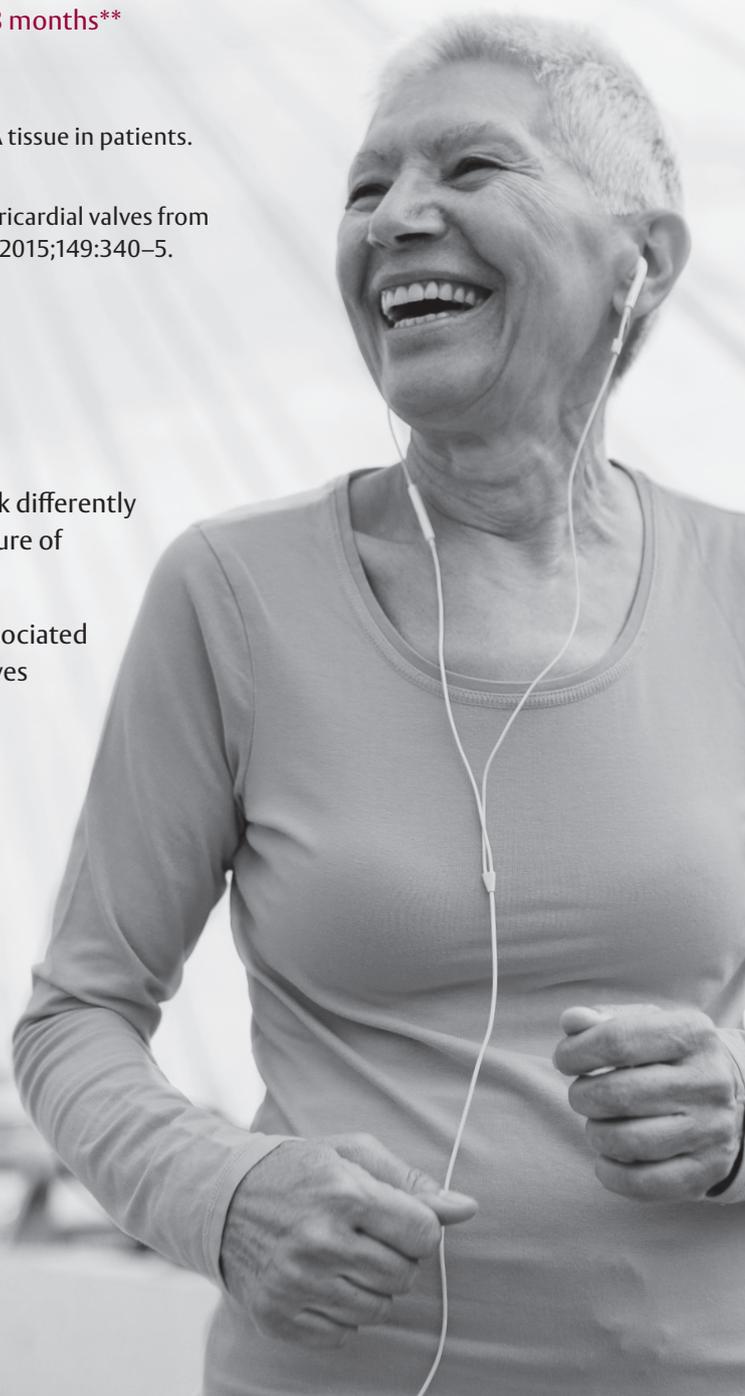
Surgical heart valves with RESILIA tissue offer patients a way to think differently about life after surgery. Choosing a RESILIA tissue valve means a future of possibility: an active life.

- A life that's free from ongoing anticoagulant therapy and the associated dietary and lifestyle restrictions that come with mechanical valves
- A life with the potential to avoid future open heart surgery
- A life of confidence in what's to come

*"The procedure gave me a newfound appreciation of how precious my time is. Being able to watch my children and grandchildren continue to grow, develop and flourish is a tremendous gift."<sup>2</sup>*

### Bill Holder

One of the first recipients of an Edwards INSPIRIS RESILIA aortic valve



# Together, charting the future of surgical valves

Today's RESILIA tissue portfolio represents the best of creative scientific minds coming together to address unmet needs and satisfy patient demands for better surgical options.

With RESILIA tissue, patients and surgeons alike gain the freedom that comes with peace of mind.

Edwards Lifesciences has a proven commitment to ongoing innovation in surgical structural heart solutions, to advance the state of the art and put better outcomes within reach.

To learn more about RESILIA tissue, visit [edwards.com/therapies/resilia](https://www.edwards.com/therapies/resilia)



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#### 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. **Contraindications:** There are no known contraindications with the use of these RESILIA tissue heart valve devices. **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. 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 to collagen (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation. **Warnings:** **INSPIRIS RESILIA Aortic Valve** - 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 these devices to sale by or on the order of a physician. See instructions for use for full prescribing information.

#### References

1. 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
2. "A daughter's job and a dad's heart". *Irvine Standard*, August 2, 2020. <https://www.irvinestandard.com/2020/a-daughters-job-and-a-dads-heart/>

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