INSPIRIS RESILIA Aortic Valve
Right for today. Ready for tomorrow.

Spotlight: Growing evidence for the INSPIRIS RESILIA valve

Encouraging study results give cardiac surgeons the data-driven confidence they're looking for today, in a valve that's ready for tomorrow.

The base of evidence supporting the benefits of INSPIRIS RESILIA valve technology is strong and growing†. Initial studies have highlighted the safety, performance and durability of the INSPIRIS valve's core tissue technology using the proven PERIMOUNT valve platform. Additional independent studies are examining the INSPIRIS valve itself.

Highlighting safety, performance and durability

Following successful testing in juvenile sheep models[1] that showed 72% less calcification, RESILIA tissue achieved excellent five-year results in human feasibility testing. Study findings to date show consistently excellent results after data collection encompassing thousands of patient-years, especially in two areas that the INSPIRIS RESILIA valve is designed to address: valve durability and sustained hemodynamic performance.

> "The absence of structural valve deterioration* in these patients is extremely encouraging and highlights the potential of valves containing RESILIA tissue..."
>
> **John D. Puskas, MD**
> Principal investigator for the COMMENCE study

* Through intermediate-term follow-up.

RESILIA tissue studies focusing on intermediate-term durability and performance

EU Feasibility Study[2] Prospective, single arm N=133, 5 years of follow-up	Key findings	COMMENCE trial[3] Prospective, multicenter, single-arm N=689, 4 years of follow-up (a subset to 10 years)
0.0%	Structural valve deterioration (/ late pt-yr)	0.0%
0.0%	Major paravalvular leak (/ late pt-yr)	0.1%
0.2%	Valve thrombosis (/ late pt-yr)	0.0%
–	Freedom from all-cause mortality (at 4 years)	91.9%
–	Freedom from reoperation (at 4 years)	98.6%
12.2–14.8 (years 1–5)	Mean pressure gradient (mmHg)	10.2–11.0 (years 1–4)
43.6% of study valves were sizes 19 or 21 mm		22.2% of study valves were sizes 19 or 21 mm
Data reported through 565 pt-yrs of follow-up		Data reported through 2,533 pt-yrs of follow-up
View the latest data ▶		View the latest data ▶

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

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Broadening the evidence base

In addition to the ongoing COMMENCE clinical study, three additional studies that include the RESILIA tissue and INSPIRIS RESILIA valve are underway.

RESILIENCE

Study designed to establish long term durability of RESILIA tissue via **innovative calcium scoring tests** investigating time to valve failure.

View for more details ▸

INDURE[4,*]

Designed to assess clinical outcomes for **INSPIRIS RESILIA valve in 400 patients under 60 y.o.** undergoing AVR **in 20 EU sites.** Target follow-up: 5 years.

View for more details ▸

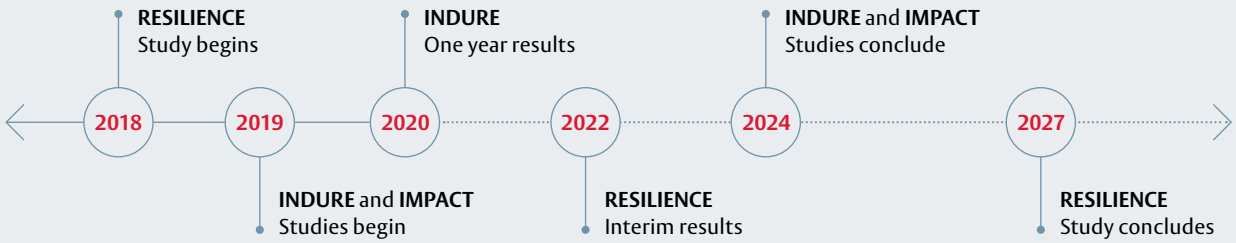
* Edwards-Investigator Collaborative Study

IMPACT*

Designed to **assess the impact of comorbidities** on all-cause mortality in **500 patients** with the INSPIRIS RESILIA valve in **25 EU sites (DACH & NL).** Target follow-up: 5 years.

View for more details ▸

* Edwards-Investigator Collaborative Study



There's more to explore

> To learn more about how the INSPIRIS RESILIA valve can benefit you and your patients, speak with your Edwards Lifesciences representative or visit **www.edwards.com/inspiris.**

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. 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.S1, 18
3. Johnston DR, et al. Intermediate-term outcomes of aortic valve replacement using a bioprosthesis with a novel tissue. *J Thorac Cardiovasc Surg.* 2020.
4. Meuris, et al. Durability of bioprosthetic aortic valves in patients under the age of 60 years – rationale and design of the international INDURE registry. *J of Cardiovasc Surg*. 2020

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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