



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 models¹ 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, 5 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 5 years)	89.2%
—	Freedom from reoperation (at 5 years)	98.7%
12.2–14.8 (years 1–5)	Mean pressure gradient (mmHg)	10.2–11.5 (years 1–5)
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 2,989 pt-yrs of follow-up

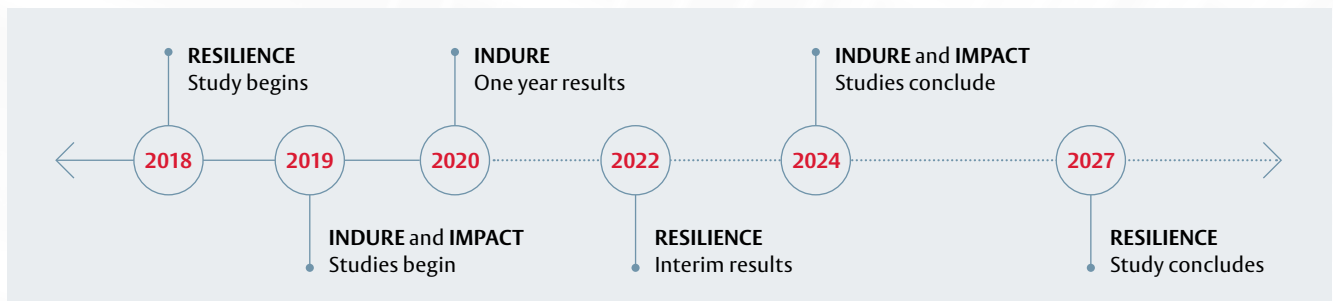
† No clinical data are available that evaluate the long-term impact of RESILIA tissue in patients.



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.

 <p>Study designed to establish long term durability of RESILIA tissue via innovative calcium scoring tests investigating time to valve failure.</p> <p>View for more details ▶</p>	 <p>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.</p> <p>View for more details ▶</p> <p><small>* Edwards-Investigator Collaborative Study</small></p>	 <p>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.</p> <p>View for more details ▶</p> <p><small>* Edwards-Investigator Collaborative Study</small></p>
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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. Bavaria JE, et al. Five-year Outcomes of the COMMENCE Trial Investigating Aortic Valve Replacement with RESILIA Tissue. *Ann Thorac Surg*. 2022.
4. Meuris, B, 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; 15:1-9.
5. Bakhtiary F, et al. Impact of pre-existing comorbidities on outcomes of patients undergoing surgical aortic valve replacement—rationale and design of the international IMPACT registry. *J of Cardiovasc Surg*, 2021; 16:1-8.

Important Safety Information: For Indications, contraindications and general warnings related to use of INSPIRIS RESILIA Aortic Valve, please refer to the detailed Instructions for Use

CAUTION: See Instructions for Use for full prescribing information.

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