Clinical Summary:

Final 5-year outcomes following aortic valve replacement with a RESILIA tissue bioprosthesis

Bartus K, Litwinowicz R, Bilewska A, *et al*.
Eur J Cardiothorac Surg 2021;59:434–41.

Inspiring Results

Objective

Report the outcomes through 5 year follow-up of the EU feasibility study, investigating the safety and performance in AVR patients of a bioprosthesis with RESILIA tissue.

Key Points

- These findings represent the longest follow up of AVR patients with RESILIA tissue, and demonstrate excellent hemodynamic performance and safety outcomes at the final five year follow up.
- Absence of structural valve deterioration (SVD) and stable transvalvular gradients were observed through 5 years.

Methods

- Prospective, multicenter, single-arm, trial conducted at two sites
- 133 patients underwent surgical AVR with an Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue
  - 19 or 21 mm valve implanted in 43.6% of patients
  - Mean age 65.3 ± 13.5 years, with (26%) ≤ 60 years
- Mean follow up = 4.2 ± 1.5 years

Results

- Safety events at 5 years (shown in Fig. 1 and 2):
  - 100% freedom from SVD or major paravalvular leak
  - 83.4% freedom from all cause mortality
  - 99.2% freedom from valve thrombosis
  - 99.2% freedom from endocarditis
- Stable hemodynamic performance observed at 5 years
  - Mean gradient was 14.8 ± 7.6 mmHg (shown in Fig. 3)
  - Average EOA was 1.4 ± 0.5 cm^2

Conclusions

Through 5 years of follow-up, an aortic valve with RESILIA tissue exhibited good hemodynamics and zero SVD events.

Fig 1. Kaplan-Meier survival rates at 5 years of various safety events

	Patients at risk at 5 years	Cumulative events	Probability event free (95% CI)
Mortality	65	21	83.4% (76.8–89.9%)
Reoperation on study valve	65	1	99.2% (97.7–100%)
Explant	65	1	99.2% (97.7–100%)
Thromboembolism	65	5	95.9% (92.3–99.5%)
Valve thrombosis	65	1	99.2% (97.6–100%)
Major paravalvular leak	65	0	100% (100–100%)
Endocarditis	65	1	99.2% (97.7–100%)
Haemolysis	65	0	100% (100–100%)
Non-structural valve dysfunction	64	1	99.1% (97.4–100%)
Structural valve deterioration	65	0	100% (100–100%)

CI: confidence interval

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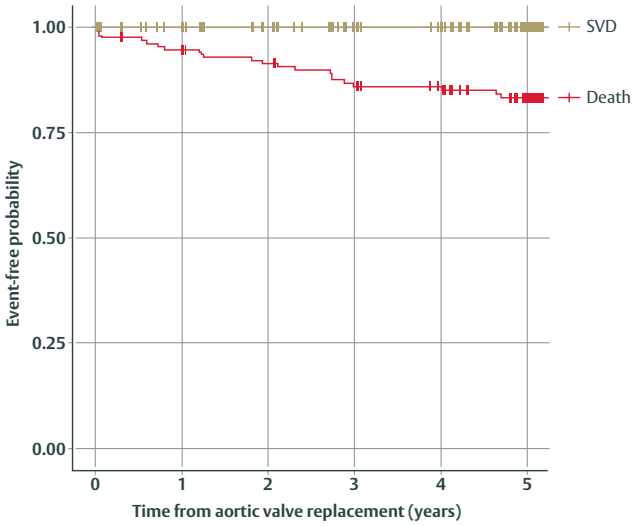
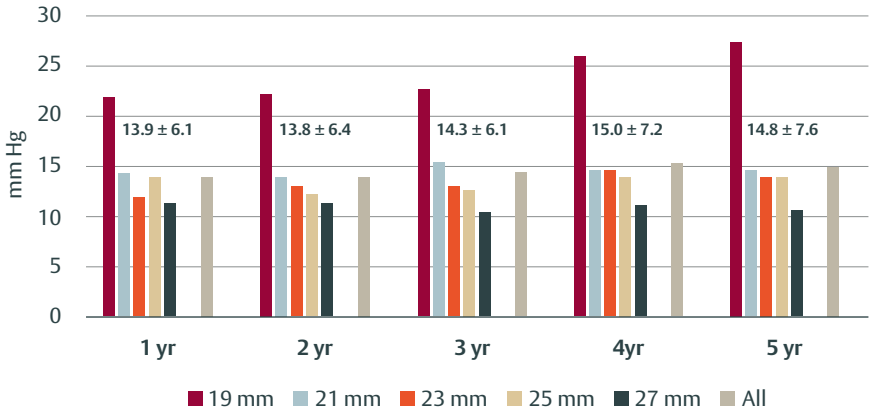
Fig 2. Kaplan-Meier curve



Patients at risk	133	124	117	109	104	65
Prob. (Freedom from death)	100%	95%	92%	86%	86%	83%
Freedom from SVD	100%	100%	100%	100%	100%	100%

Fig 3. Mean gradient



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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.

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