

# Clinical Summary:

## Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with a novel tissue bioprosthesis

Bavaria J, Griffith B, Heimansohn DA, et al. Presented at the Society of Thoracic Surgeons Annual Meeting, January 2021.

Inspiring  
Results

### Objective

The COMMENCE trial is a FDA pivotal trial designed to evaluate the safety and effectiveness of a bioprosthetic valve with the novel RESILIA tissue. In particular, as the follow up time in this study advances beyond the early period, direct and indirect measures of RESILIA durability will be highlighted.

### Key Points

- Through a median follow up of 5 years, results of the COMMENCE aortic trial indicate a favorable safety profile and stable hemodynamic performance of a bioprosthetic valve with RESILIA tissue
- No SVD through 5 years, stable gradients, and freedom from regurgitation all support durability over the observational period

### Methods

- Prospective, non-randomized, multicenter, single-arm Investigational Device Exemption (IDE) Trial
  - Study subjects were enrolled at 27 clinical sites in U.S. and Europe
  - All patients undergo annual follow up through 5 years; a subset will be followed through 10 years
- Safety endpoints
  - All potential safety endpoints adjudicated by an independent Clinical Events Committee
  - Structural valve deterioration (SVD) and other safety outcomes defined per “Guidelines for reporting morbidity and mortality after cardiac valve interventions” (Akins et al. 2008)
- Effectiveness endpoints
  - Hemodynamic performance evaluated by an Independent Echocardiographic Core Laboratory
  - NYHA Functional Class

### Patient Demographics

- 689 patients underwent surgical AVR with the Edwards Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
  - Mean age  $66.9 \pm 11.6$  years, with 140 patients (21%) under 60 years
  - 71.8% male
  - 26% NYHA Class III/IV
  - Mean STS PROM  $2.0 \pm 1.8\%$
  - 59% isolated AVR
- 2989 aggregate patient-years of follow up
  - Follow up:  $4.3 \pm 1.4$  yrs

### Results

- Safety endpoints, probability event-free at 5 years (shown in Fig. 1):
  - All-cause mortality, 89.2%
  - Major paravalvular leak, 99.5%
  - Endocarditis, 97.8%

- Improved hemodynamic performance compared to baseline was observed through 5 years
  - Mean gradient was  $10.2 \pm 4.6$  at 1 year,  $10.2 \pm 4.5$  at 2 years, and  $10.8 \pm 5.7$  at 3 years,  $11.1 \pm 5.7$  mmHg at 4 years, and  $11.5 \pm 6.0$  at 5 years (shown in Fig. 2)

Fig 1. Safety endpoints

Endpoint	Early ( $\leq 30$ POD) events (%)	Kaplan-Meier probability event-free at 5 yrs (%) (95% CI)
All-cause mortality	8 (1.2%)	89.2 (86.7 – 91.6)
Stroke	11 (1.6%)	94.5 (92.7 – 96.3)
Valve thrombosis	0 (0%)	100.0 (100.0 – 100.0)
Major bleeding	5 (0.7%)	94.3 (92.4 – 96.1)
Endocarditis	0 (0%)	97.8 (96.6 – 99.0)
Major PVL <sup>†</sup>	1 (0.1%)	99.5 (99.0 – 100.0)
NSVD (other than PVL)	0 (0%)	100.0 (100.0 – 100.0)
SVD*	0 (0%)	100.0 (100.0 – 100.0)
Reoperation	1 (0.1%)	98.7 (97.8 – 99.6)

<sup>†</sup> Major PVL is PVL of any grade requiring surgical intervention or considered an SAE.

\* 1 SVD diagnosed at POD 1848.

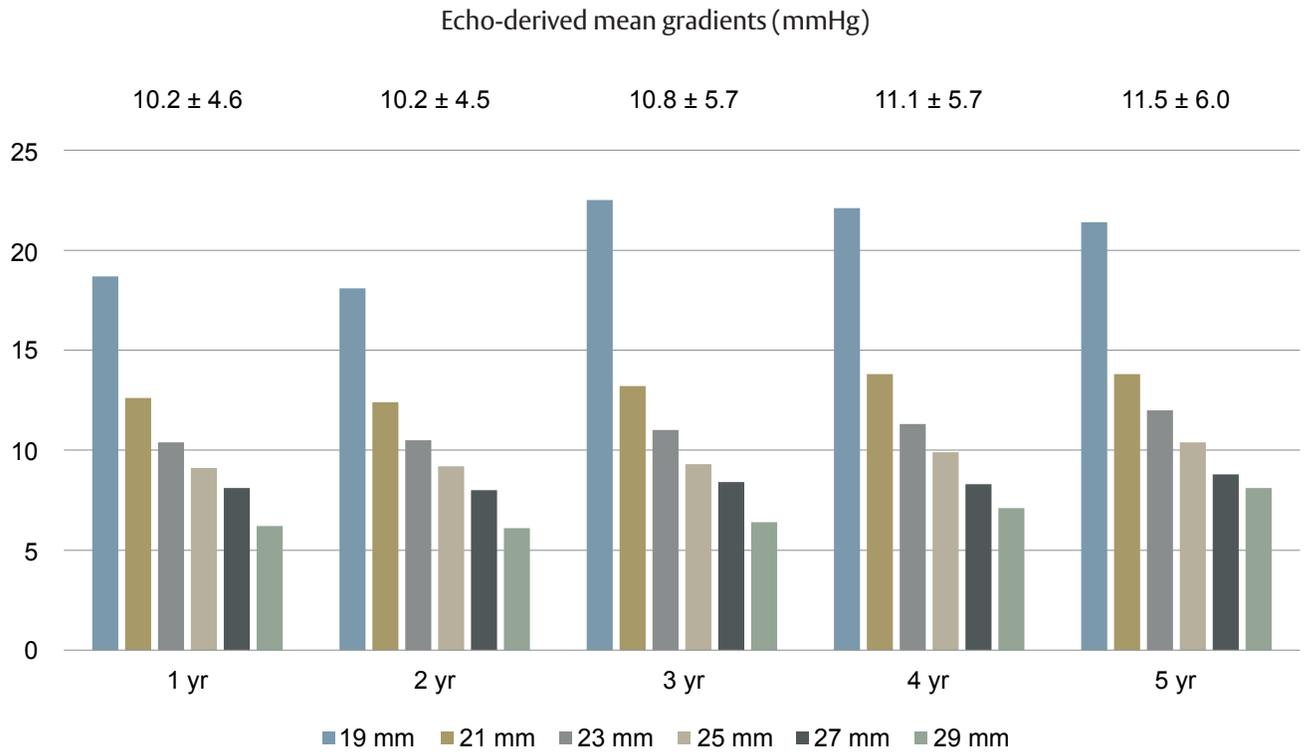
### Conclusions

- Favorable safety profile and stable hemodynamic performance of a bioprosthetic valve with RESILIA tissue
- No SVD through 5 years, stable gradients, and freedom from regurgitation all support durability over the observational period
- Ongoing follow-up continues to evaluate the long-term safety and effectiveness of this new tissue
  - Data from 10-year follow up in extended follow-up cohort and RESILIENCE trial with 11-year follow-up forthcoming



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**Fig 2. Hemodynamic performance**



**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 (United States) 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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