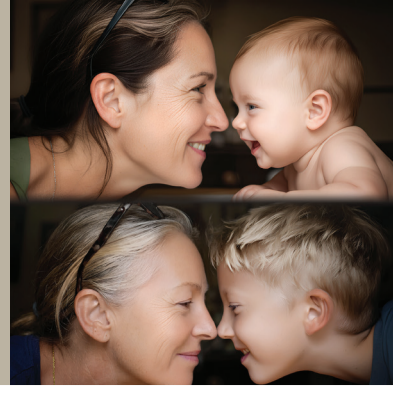


10 years later. From one heart to over 500,000 lives touched.



## COMMENCE Aortic Trial 10-Year Outcomes

### Study Introduction & Key Points<sup>1</sup>

The COMMENCE aortic trial is an FDA-approved pivotal trial designed to evaluate the safety and effectiveness of a bioprosthesis with RESILIA tissue used in surgical aortic valve replacement (SAVR). As the follow-up time in this study has reached the 10-year mark, direct and indirect measures of valve durability with RESILIA tissue will be highlighted.

#### Key points<sup>1</sup>



##### Ten-year milestone for RESILIA tissue valves

- The innovation that advanced the tissue valve landscape continues to demonstrate favorable safety outcomes and durable performance at 10 years



##### Sustained hemodynamic performance

- Clinically stable hemodynamic performance through 10 years



##### Tissue designed to last: Promising durability through 10 years

- The first reported long-term data demonstrating excellent results through 10 years with RESILIA tissue valves
- High rates of freedom from reintervention and structural valve deterioration (SVD)

### Results<sup>1</sup>

#### Outcomes at 10 years



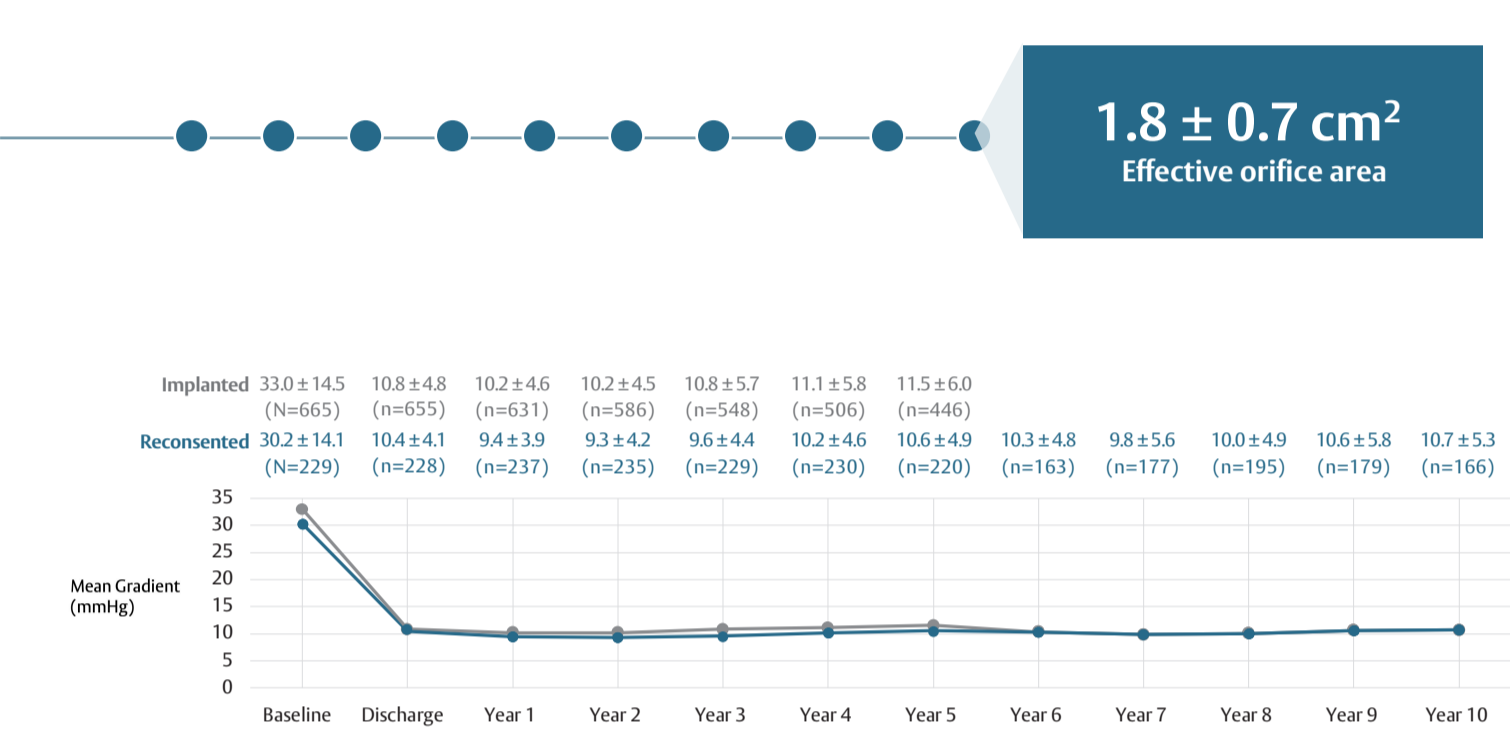
**97.9%**  
Freedom from SVD

**97.8%**  
Freedom from reoperation due to SVD

**94.3%**  
Freedom from valve-related mortality

**98.6%**  
Freedom from NSVD

#### Clinically stable hemodynamics through 10 years<sup>1</sup>



\*Publication details to come.

#### Favorable safety outcomes and sustained hemodynamic performance at 10 years



### Study Methods & Patient Demographics<sup>1</sup>

#### Methods

##### Trial methodology

- Between January 2013 and March 2016, 689 patients in the full cohort underwent SAVR with the Edwards Lifesciences Pericardial Aortic Bioprosthesis with RESILIA tissue (model 11000A)
- A large, prospective, non-randomized, multicenter, single-arm, IDE trial exploring the outcomes of SAVR with a bioprosthesis utilizing RESILIA tissue
- Study subjects were initially enrolled at 27 clinical sites in the US and Europe
- At 5 years, patient re-consent was performed across 10 centers for longer-term follow-up to 10 years

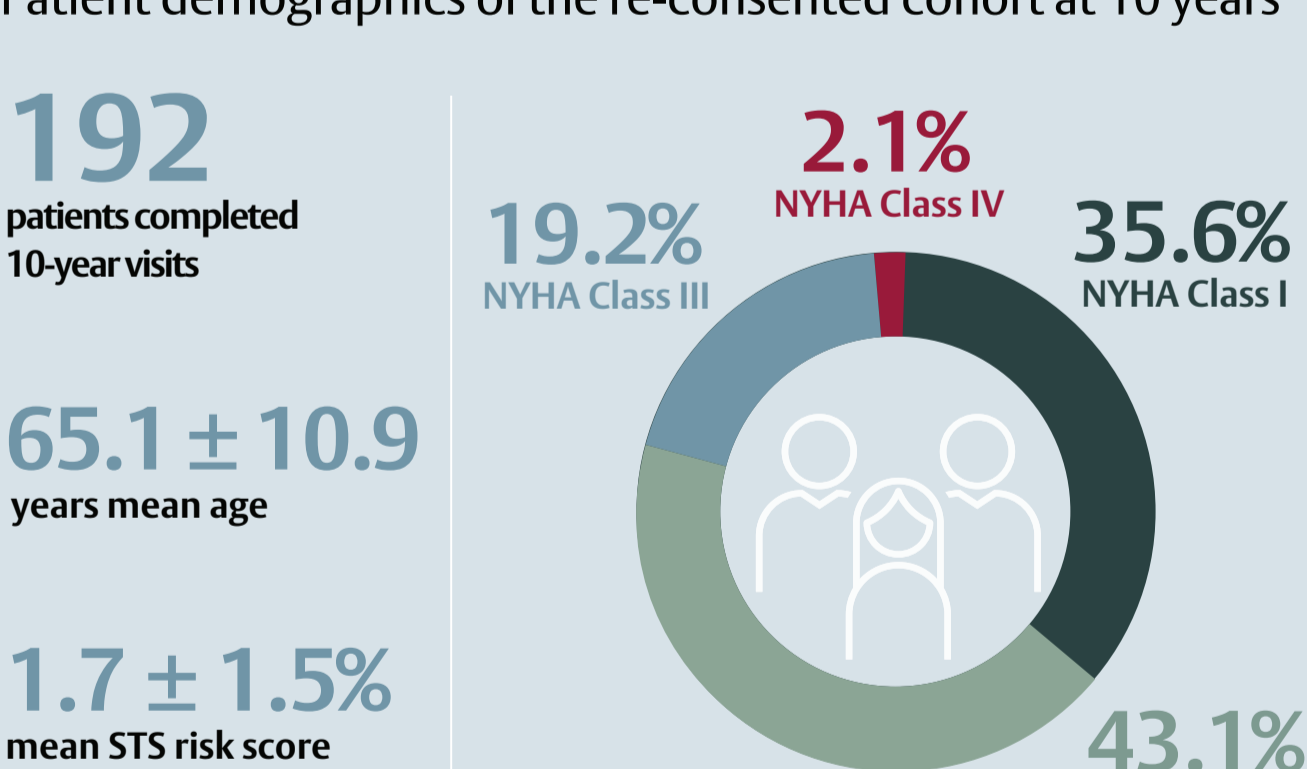
##### Safety endpoints

- All potential safety endpoints were adjudicated by an independent Clinical Events Committee
- SVD and other safety outcomes were defined per Akins et al. 2008<sup>2</sup>

##### Key primary effectiveness endpoints

- Hemodynamic performance was evaluated by an independent echocardiographic core laboratory
- NYHA Class improvement

#### Patient demographics of the re-consented cohort at 10 years



### Summary of Safety Events<sup>1,3,4</sup>

Endpoint	Cumulative events at 10 years	Freedom from events, (%) (95% CI)		
		At 5 years	At 7 years	At 10 years
SVD	5	100.0 (100.0–100.0)	99.3 (98.3–100.0)	97.9 (96.0–99.8)
Valve-related mortality	25	96.8 (95.4–98.2)	N/A	94.3 (91.8–96.8)
Reoperation	18	98.7 (97.8–99.6)	97.2 (95.5–99.0)	94.5 (91.8–97.2)
Reoperation due to SVD	5	N/A	N/A	97.8 (95.8–99.7)
Study valve explant	10	99.0 (98.2–99.8)	N/A	97.5 (95.8–99.2)
Stroke	39	94.5 (92.7–96.3)	94.0 (92.1–95.9)	93.1 (90.9–95.4)
Valve thrombosis	2	100.0 (100.0–100.0)	99.4 (98.6–100.0)	99.5 (98.7–100.0)
Endocarditis	15	97.8 (96.6–99.0)	97.3 (95.8–98.7)	97.3 (95.9–98.7)
All-cause mortality	97	89.2 (86.7–91.6)	85.4 (82.2–88.7)	78.3 (74.1–82.6)

Freedom from event: Survival estimate (lower confidence limit, upper confidence limit). Event counts, survival estimates, and CI based on Kaplan-Meier analysis of time to first occurrence (early or late).

N/A, not applicable.

### Conclusions<sup>1</sup>

#### Ten years of data

- The 10-year data from the COMMENCE aortic trial represents the longest follow-up after SAVR with RESILIA tissue

#### Stable, durable performance

- The low incidence of SVD and valve-related reintervention at 10 years demonstrate sustained long-term durability

References: 1. Svensson L, Blackstone E, Bavaria J, et al. Long-term outcomes following aortic valve replacement with a novel tissue bioprosthesis: 10-year results from the COMMENCE trial. Presented at the American Association for Thoracic Surgery, May 2026. 2. Akins CW, Miller DC, Turina MJ, et al. Guidelines for reporting mortality and morbidity after cardiac valve interventions. Ann Thorac Surg. 2008;85(4):1490-1495. doi:10.1016/j.athoracsur.2007.12.082 3. Bavaria JE, Griffith B, Helmssohn DA, et al. Five-year outcomes of the COMMENCE trial investigating aortic valve replacement with RESILIA tissue. Ann Thorac Surg. 2023;115(6):1429-1436. doi:10.1016/j.athoracsur.2021.12.05 4. Beaver T, Bavaria JE, Griffith B, et al. Seven-year outcomes following aortic valve replacement with a novel tissue bioprosthesis. J Thorac Cardiovasc Surg. 2024;168(3):781-791. doi:10.1016/j.jtcvs.2023.09.047

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