The MOMENTIS Study: One-Year Outcomes With the MITRIS RESILIA Mitral Valve in a North American Cohort

A summary of the results, patient demographics, study methods, and key points

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Clinical Summary:

One-year outcomes following MITRIS RESILIA mitral valve in the MOMENTIS real-world observational study

Ailawadi G, Heimansohn D, Accola K, et al. One-year safety and performance of a novel bovine pericardial mitral valve with advanced anti-calcification treatment. Presented at the 2026 Society of Thoracic Surgeons Annual Meeting. January 29, 2026.

Objective

The MOMENTIS mitral study was designed to evaluate the safety and effectiveness of the MITRIS RESILIA valve in adults with a dysfunctional native or prosthetic mitral valve who required replacement. The study is projected to continue for 10 years. The results from the North American cohort after 1 year are presented here.

Key Points

- Data from the MOMENTIS study demonstrate promising outcomes in real-world mitral patients with a mean STS risk score of 3.4
- The MITRIS RESILIA mitral valve showed high rates of freedom from valve-related reintervention and freedom from structural valve deterioration through 1 year
- Results from the MOMENTIS study through 1 year indicate a favorable safety profile and stable hemodynamic performance

Methods

- The MOMENTIS study is an ongoing prospective, observational, post-market, single-arm, real-world evidence study
  - Patients were enrolled at up to 45 sites across the US, Canada, and Europe
  - Inclusion criteria: 18 years or older; had dysfunctional native or prosthetic mitral valve and required mitral valve replacement surgery; provided written informed consent; willing to follow protocol requirements
  - Exclusion criteria: Active endocarditis 3 months prior to the procedure; stage 4 renal disease or requiring dialysis; <2-year life expectancy due to non-cardiovascular, life-threatening disease; high predicted risk of mortality prior to the procedure, as determined by STS predicted risk of mortality score of >8% or surgeon estimated risk of mortality >8%
- Safety endpoints
  - Adjudicated by a Clinical Events Committee
  - Primary endpoints were freedom from valve-related death or valve-related reintervention. Additional safety endpoints included thromboembolism, valve thrombosis, major bleeding, nonstructural valve dysfunction (NSVD), structural valve deterioration (SVD), endocarditis, valve-related reintervention, valve-related death, and all-cause mortality

Methods (*cont'd*)

- Key primary effectiveness endpoints
  - Hemodynamic performance evaluated by independent echo core lab, including mean gradient, peak gradient, transvalvular regurgitation, and paravalvular leak

Patient Demographics

- From January 2023 through December 2025, 351 North American patients underwent valve implantation with the Edwards MITRIS RESILIA mitral valve (model 11400M)
  - Mean age: 68.9 ± 10.0 years
  - Female: 57.3%
  - Mean STS risk score: 3.4 ± 2.12
  - New York Heart Association (NYHA) Class I, II, III, IV were 9%, 54%, 34%, and 2%, respectively
- A total of 294 patients completed the 1-year follow-up

Results

- Safety endpoints (shown in Table 1), probability event rate at 1 year:
  - 99.7% freedom from valve-related death
  - 99.7% freedom from valve-related reintervention
  - 100% freedom from structural valve deterioration
- Clinically stable hemodynamics at 1 year
  - Mean gradient was 3.5 ± 1.3 mmHg
  - Mean EOA was 1.9 ± 0.6 cm^2
- A majority of patients (92%) had no/trace transvalvular regurgitation at 1 year
- 95.3% of patients were in NYHA Class I or II at 1 year

Conclusions

- At the 1-year follow-up, the MOMENTIS study demonstrated promising results for mitral valve patients with the MITRIS RESILIA mitral valve
- Projected follow-up through 10 years will continue to evaluate long-term safety and effectiveness

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Figure 1. Mean gradients (mmHg)

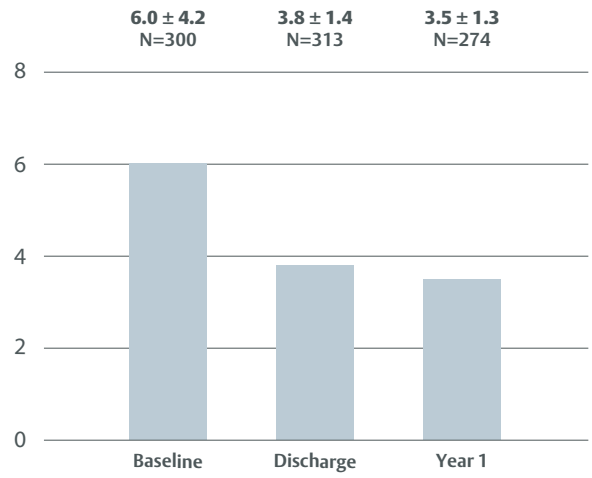

Figure 2. Mean EOA (cm^2)

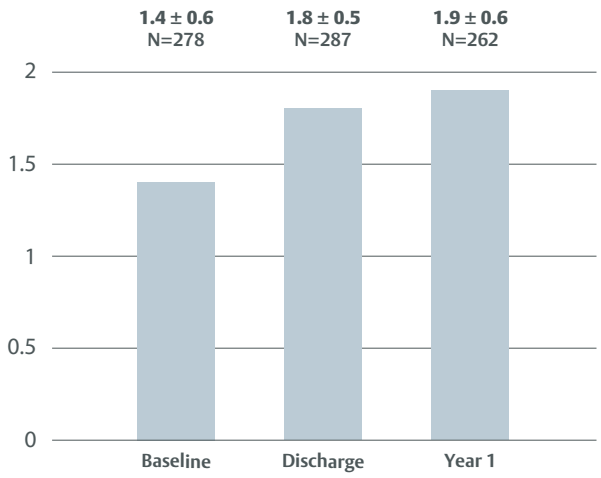

Table 1. Safety endpoints

Endpoint	30-day events %(n)* (N=351)	1-year events %(n)** (N=325)
Valve-related death***	0% (0)	0.3% (1)
Valve-related reintervention***	0.3% (1)	0.3% (1)
All-cause mortality	3.4% (12)	7.7% (25)
Thromboembolism	2.8% (10)	6.2% (20)
Stroke	2.3% (8)	4.3% (14)
Transient ischemic attack	0.3% (1)	2.2% (7)
Valve thrombosis	0.6% (2)	1.2% (4)
Nonstructural valve dysfunction	0.3% (1)	0.3% (1)
Structural valve deterioration	0% (0)	0% (0)
Endocarditis	0% (0)	0.3% (1)
Major bleeding†	10.5% (37)	13.8% (45)

*Event rate ≤30 day is calculated as number of patients with event divided by total number of patients.

**Event rate at 1 year is calculated as number of patients with event divided by patients with at least one CEC-confirmed event or at least 365 days of study follow-up.

***Primary safety endpoint is freedom from valve-related death or valve-related reintervention at 1 year.

†Per Akins, major bleeding is any episode of major internal or external bleeding that causes death, hospitalization, or permanent injury, requires pericardiocentesis or surgical intervention/reintervention, or necessitates transfusion of 3 or more red blood cell units.

Important Safety Information: MITRIS RESILIA Mitral Valve

Indications: For use in replacement of native or prosthetic mitral heart valves. **Contraindications:** There are no known contraindications with the use of the MITRIS RESILIA mitral 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, ventricular perforation by stent posts, any of which could lead to reoperation, explantation, permanent disability, and death.

CAUTION: US law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information.

Reference: Ailawadi G, Heimansohn D, Accola K, et al. One-year safety and performance of a novel bovine pericardial mitral valve with advanced anti-calcification treatment. Presented at the 2026 Society of Thoracic Surgeons Annual Meeting. January 29, 2026.

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