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

Study Introduction & Key Points

The MOMENTIS mitral study was designed to evaluate the safety and effectiveness of the MITRIS RESILIA mitral 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

Real-world patients

- Promising outcomes in real-world mitral patients with a mean STS risk score of 3.4

Outcomes

- High rates of freedom from valve-related reintervention and freedom from structural valve deterioration (SVD) through 1 year

Safety and effectiveness

- Favorable safety profile
- Stable hemodynamic performance

Study Methods & Patient Demographics

Methods

Trial methodology

- **Prospective, observational, post-market, single-arm, real-world evidence study**
- **Up to 45 sites** across the US, Canada, and Europe
- **Key inclusion criteria:** 18 years or older; had dysfunctional native or prosthetic mitral valve and required mitral valve replacement surgery
- **Key exclusion criteria:** Active endocarditis 3 months prior to the procedure; 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%; <2-year life expectancy due to non-cardiovascular, life-threatening disease; stage 4 renal disease or requiring dialysis

Safety endpoints

- **Adjudicated by a Clinical Events Committee**
- **Primary endpoints** included 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

Key primary effectiveness endpoints

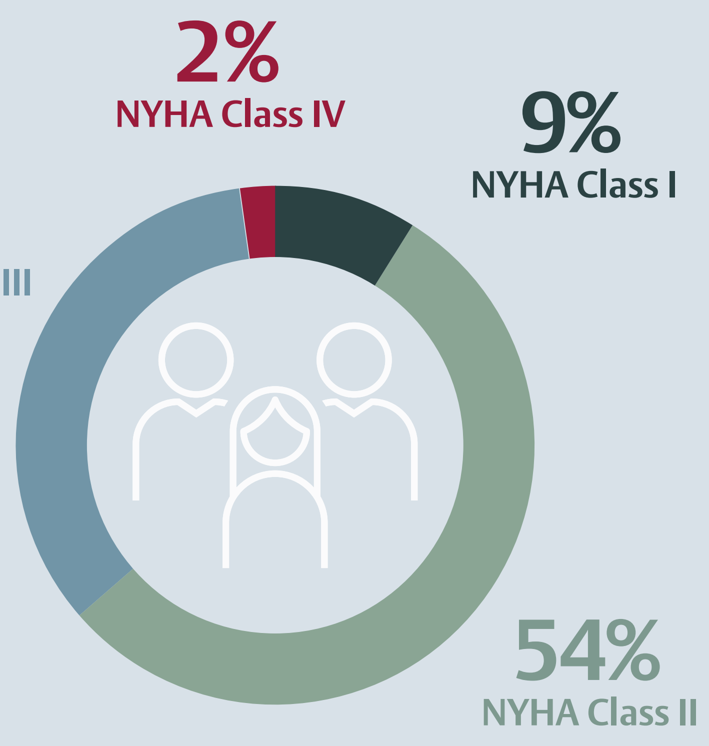
- **Hemodynamic performance evaluated by independent echo core lab, including mean gradient, peak gradient, transvalvular regurgitation, and paravalvular leak**

Patient Demographics

351
North American patients underwent valve implantation

68.9
± 10.0 years mean age

3.4
± 2.12 mean STS risk score



Results

Summary of safety events

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.

Outcomes @ 1 year

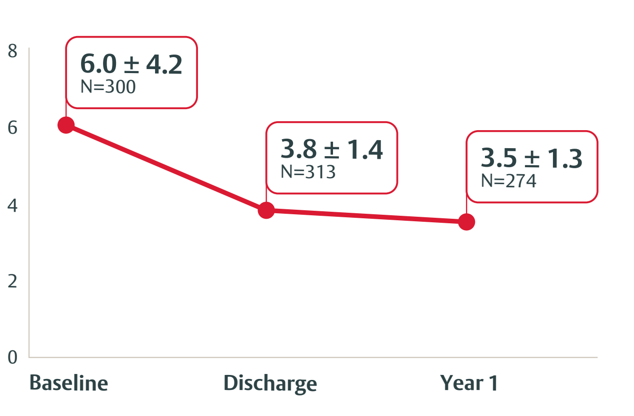
99.7% Freedom from valve-related death

99.7% Freedom from valve-related reintervention

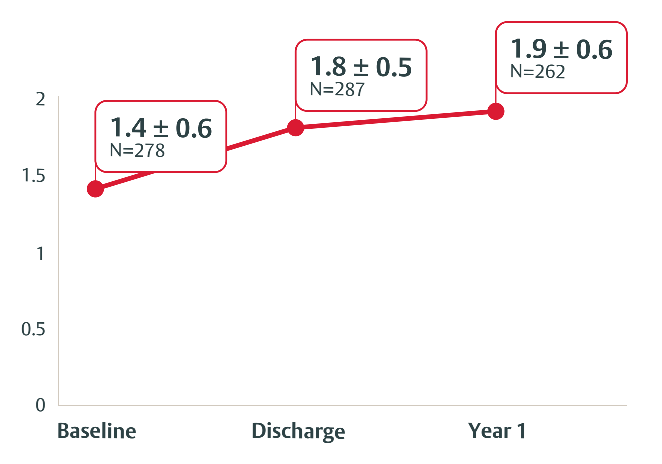
100% Freedom from SVD

Hemodynamics through 1 year

Stable hemodynamics: Mean gradient (mmHg)



Hemodynamic performance: Mean EOA (cm^2)



Performance @ 1 year

92% Had no/trace transvalvular regurgitation

95.3% Patients were in NYHA Class I or II

Conclusions

Outcomes in real-world mitral patients

- At one year of follow-up, the MOMENTIS study demonstrated promising results for mitral valve patients with the MITRIS RESILIA mitral valve

Ongoing, long-term follow-up

- Projected follow-up through 10 years will continue to evaluate long-term safety and effectiveness

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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