

SEATED PULMONARY ARTERY PRESSURE MONITORING IN PATIENTS WITH HEART FAILURE (HF)

12-month PROACTIVE-HF Trial Outcomes¹

Cordella is the first remote HF platform for NYHA class III patients that offers comprehensive management with pulmonary artery (PA) pressure and vital sign* data. It enables effective remote HF management by engaging patients with access to their health data. The prospective, open-label, single-arm PROACTIVE-HF trial was designed to study the safety and effectiveness of the Cordella PA Sensor.

Demographics & Methods Overview

- 75 U.S. & E.U. sites
- mITT population: 456 patients; 395 completed 12-month follow-up
- 80% of the cohort had heart failure hospitalization (HFH) in the last 12 months
- Highly diverse cohort: 39.4% female; 24.0% non-white; and 44.1% HFpEF
- Sensor implanted by IC or HF specialist
- Primary endpoints: safety & 6-month composite HFH/all-cause mortality rate[†]
- Key secondary endpoints: HFH at 12 months post-implant compared to 12 months pre-implant, quality of life, patient and site compliance

High patient and clinician compliance at 12 months

- 5.9 average patient submissions per week
- 2.4 average days from submission to clinician review

For important safety information, please visit cordella.com.

IC, interventional cardiologist; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; mITT, modified intent-to-treat; NT-proBNP, N-terminal pro-B-type natriuretic peptide; PA, pulmonary artery.

*Including blood pressure, heart rate, pulse oxygen level, and weight.

[†]As compared to a pre-determined performance goal of 0.43 at 6 months and 0.70 at 12 months. The performance goal and expected event rates were within observed event rates in the treatment arms and lower than observed event rates in the control arms of CardioMEMS studies.



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6-month Results²

Primary Endpoints: PROACTIVE-HF met primary efficacy and safety endpoints.

- Markedly low HFH/all-cause mortality rate of 0.15 (events / pt / 6-months)*
- 99.2% Freedom from device or system-related complications (DSRC), 99.8% freedom from PA sensor failure



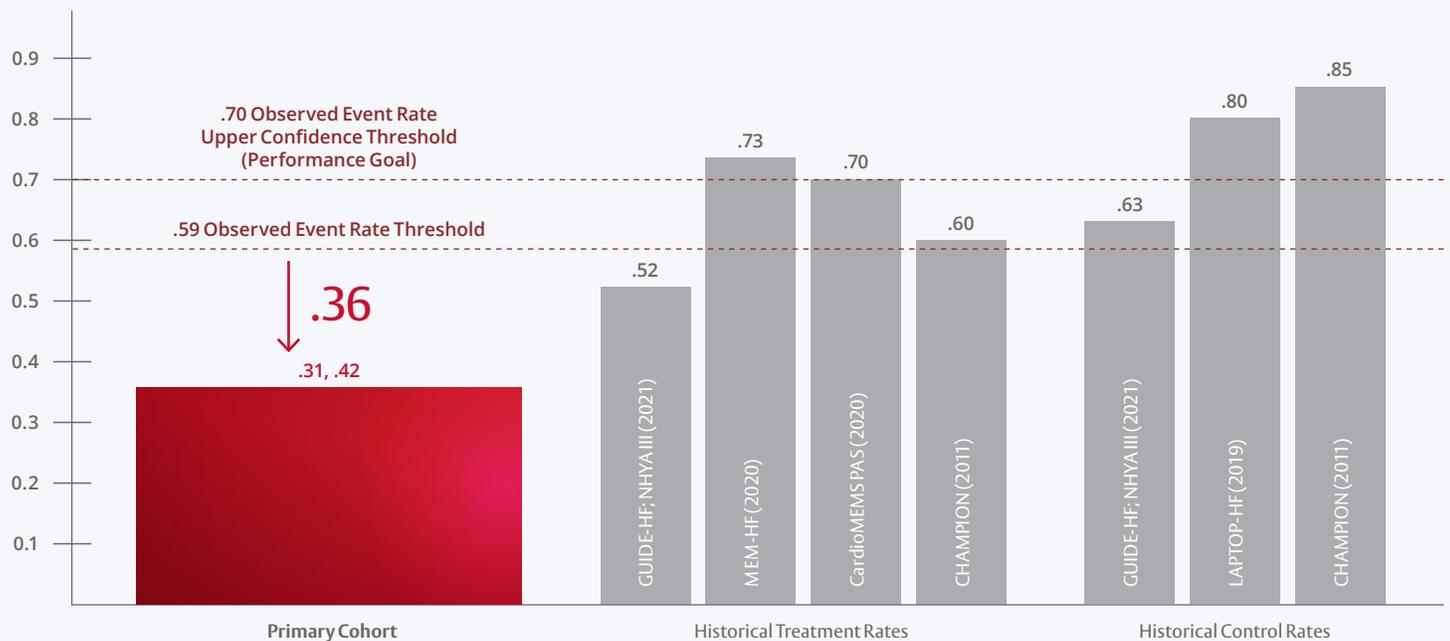
*Significantly lower than performance goal of 0.43 (P<.0001). Performance goal based on prior MEMS trials and adjusted for SGLT2 inhibitors

12-month Results¹

The study maintained a low HFH/all-cause mortality rate of 0.36 (events / pt / 12-months)*

73%

REDUCTION IN HFH PRE/POST CORDELLA AT 12 MONTHS.



12-month Incidence of HFH or All-Cause Mortality

*Significantly lower than performance goal of 0.70 (P<.0001). Performance goal based on prior MEMS trials and adjusted for SGLT2 inhibitors

Secondary Safety Endpoint

At 12 months, PROACTIVE-HF demonstrated a low complication rate with a proven safety profile.

- No additional primary safety events after 6 months
- Low incidence of serious adverse events
Acute kidney injury (2.6%), pulmonary embolism (1.0%), bleeding (0.6%), myocardial infarction (0.4%), arrhythmia (10.1%), hemoptysis (3.0%)

Key Secondary Findings

At 12 months, PROACTIVE-HF demonstrated sustained significant improvements in patient QoL and clinical metrics.



Kansas City Cardiomyopathy Questionnaire (KCCQ)

5.7-point clinical improvement
($P < .0001$)



6-Minute Walk Test

34.6 m improvement
($P = .0004$)



NT-proBNP

268 pg/mL decrease
($P = .006$)

Conclusion

Remote management using seated mPAP and vital signs in NYHA Class III HF patients is safe and results in a low rate of HF hospitalizations and mortality over 12 months. These results support the use of seated mPAP monitoring and extend the growing body of evidence that PAP-guided management improves outcomes in HF. Learn more at cordella.com.



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1. Data on file. Edwards Lifesciences, 2026.
2. Guichard JL, Bonno EL, Nassif ME, et al. Seated pulmonary artery pressure monitoring in patients with heart failure: results of the PROACTIVE-HF trial. JACC Heart Fail. 2024;12(11):1879-1893. doi:10.1016/j.jchf.2024.05.017

In the U.S., the Cordella PA Sensor System is Rx Only. CAUTION: Federal law restricts this device to sale by or on the order of a physician. In Europe, the Cordella PA Sensor System is Exclusively for Clinical Investigation.

See [instructions for use](#) for full prescribing information. As with any medical procedure, there is a possibility of risks. The most serious risks of the Cordella PA Sensor are similar to other heart procedures and include death, serious damage to the arteries, serious bleeding, breathing problems, renal (kidney issues), and worsening heart failure.

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