Cordella

Seated Pulmonary Artery Pressure Monitoring in Patients with Heart Failure (HF)

12-month PROACTIVE-HF Trial Outcomes[1]

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 visibility to health trends to encourage healthy lifestyle choices. 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
- 528 sensors implanted[2]
- 80% of cohort had previous HF hospitalizations (HFH) in the previous 12 months
- Highly diverse cohort (40% female, 24% non-white, 54% HFpEF)
- 115 unique implanters
- 52% implanted by HF physicians (48% by ICs)
- ~6 avg patient submissions/week
- ~2 avg days between clinician review
- Primary endpoints: safety & 6-month composite HFH/all-cause mortality rate[3]
- Secondary endpoints: patient quality of life (QoL) metrics, change in PA pressure, rate of HF hospitalizations and HF medication changes

6-month Results[4]

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

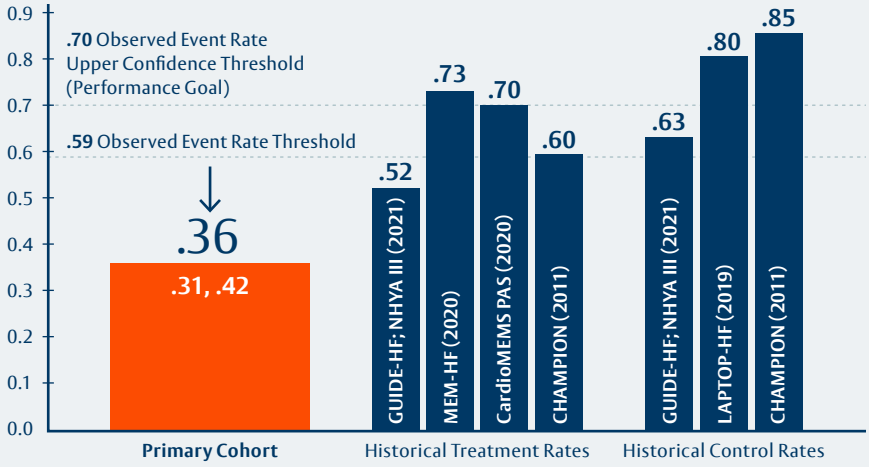
- Markedly low 6-month HFH/all-cause mortality rate (0.159 vs .43 events/pt/6-month).†
- 99.2% Freedom from device or system-related complications (DSRC), 99.8% freedom from PA sensor failure.

12-month Results[1]

The study maintained a lower HFH/all-cause mortality event rate than historical PA pressure studies.

12-month Incidence of HFH or All-Cause Mortality

73% reduction in HFH pre/post Cordella at 12 months.



For important safety information, please visit **endotronix.com/safety**.

Edwards

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

† Datapoints from the FDA Summary of Safety and Effectiveness Data (SSED) varied slightly due to a change in statistical analysis from published PROACTIVE-HF results (0.15 and 0.28).

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 (2.4%), 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)	6-Minute Walk Test	NT-proBNP
5.7-point clinical improvement	35 m improvement	268 pg/mL decrease

Conclusion

In NYHA class III HF patients at risk of congestion, the Cordella Sensor demonstrated sustained benefits at 12 months including a low complication rate, markedly reduced HF hospitalization rate, and improved the quality of life and functional capacity. **Learn more at endotronix.com.**

Read the 12-month results

1. Klein L et al. Seated Pulmonary Artery Pressure Management in Patients with heart Failure: 12-month outcomes in the PROACTIVE-HF Trial. Accepted in JACC-HF.
2. Includes 72 former control patients and 456 single-arm patients.
3. 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.
4. Guichard JL et al. J Am Coll Cardiol HF. 2024 Aug 2:S2213-1779(24)00485-2.

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.

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards