PRO 2
CORDELLA®
PROACTIVE-HF 2 Trial

Engage Patients & Achieve More

Remote HF Management that Reinforces Simple Patient Habits for Better Outcomes

Learn about the PROACTIVE-HF 2 clinical trial and how to manage HF patients using pulmonary artery (PA) pressure and vital sign data to improve HF outcomes.

ENDOTRONIX®

What is the PROACTIVE-HF 2 Trial?

The trial is designed to evaluate how pulmonary artery (PA) pressure and other vital sign data (e.g. blood pressure, heart rate, pulse ox, and weight) securely collected at home with Cordella can help you better manage NYHA class III heart failure patients with guideline-based care.

In addition, the trial is evaluating the use of Cordella to manage NYHA class II heart failure patients.

Who is Eligible to Participate?*

- **NYHA class II & III HFrEF and HFpEF patients ≥ 3 months***
- **On appropriate HF medical therapy ≥ 30 days***
- **Recent HF-related Hospitalization**
- **Glomerular filtration rate (GFR) ≥ 20 ml/min**

All study participants will have:

- **The Cordella PA Sensor implanted & receive a myCordella Patient Kit.**
- **Access to key health trends and daily measurements.+**
- **Regular communication and treatment guidance from the research HF team.+**

During the study, only the managing HF study team will have access to patient data via the Cordella Patient Management Portal (PMP).

* Reach out to the study PI for the complete inclusion/exclusion criteria
\+ Using a patient-provided tablet

Simple Habits. Strong Engagement.

The Cordella Advantage*

95%

of patients want to see their health information[1]

97%

of patients said the system is easy to use[2]

97%

of patients believe PA pressure monitoring & resulting care has a positive impact on their health[1]

80%

reduction in HF hospitalization rate pre/post Cordella[1]

* For NYHA class III HF patient

HF management with Cordella has demonstrated an improvement in patient quality of life metrics and low HF hospitalization rates.[2,3]

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

Meet Cordella®

PROACTIVE | COMPREHENSIVE | ENGAGING

Cordella® PA Sensor System
Wireless, implantable sensor for remote transmission of PA pressures

myCordella™ Patient Kit
At-home kit collects and securely transmits health data to the clinician

The comprehensive HF platform enables a streamlined review of key health data to remotely guide medical management and reduce congestion.

to submit a daily reading

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The potential risks of the Cordella PA sensor procedure are similar to other heart procedures. The most serious risks include, but are not limited to, death, serious damage to the arteries or valves, serious bleeding, pulmonary embolism/occlusion, allergic reactions, arrhythmias, renal issues, and worsening heart failure.

To find the nearest PROACTIVE-HF 2 trial site, visit myheart.com/pro2.

For questions about the trial or to refer a patient, please contact the study site principal investigator (PI) / research team.

As part of the trial, participants will be asked to provide informed consent, submit daily health data using the myCordella Patient Kit, and return for clinic visits at specific intervals.

Your Proactive-HF 2 Site Contact

Name _____

Email _____

Phone _____

INTENDED USE

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT) as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

For important safety information, please visit endotronix.com/safety. See the Instructions for Use for a complete listing of the indications, contraindications, warnings and precautions.

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.

The Cordella PA Sensor System is an investigational device in NYHA Class II patients and is not currently approved for clinical use in NYHA Class II patients in any geography, nor has it been proven safe or effective in NYHA Class II HF patients. CAUTION – Investigational Device. Limited by Federal (or United States) Law to Investigational Use. Exclusively for Clinical Investigation.

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For more information, please visit clinicaltrials.gov NCT05934487.

1 Guichard JL. Presented at THT 2023, Boston MA.

2 Sharif F et al. ESC Heart Fail. 2024 Apr;11(2):1133-1143.

3 Guichard JL et al. J Am Coll Cardiol HF. 2024 Aug 2:S2213-1779(24)00485-2.

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