

Learn about the PROACTIVE-HF 2 clinical trial and how to take an active role in your HF management.



What is the PROACTIVE-HF 2 Trial?

The PROACTIVE-HF 2 trial is designed to evaluate how pulmonary artery (PA) pressure and additional vital sign data, securely collected with Cordella, can help you better manage your heart failure from home under the guidance of a clinician.

The trial is intended to assess the benefits of remote PA pressure management in NYHA class II and III heart failure patients.

PROACTIVE COMPREHENSIVE

ENGAGING





As part of this study, you will:

- Provide informed consent
- Be implanted with the Cordella PA Sensor
- Receive a myCordella Patient Kit for at-home monitoring
- Submit daily health data⁺
- Have access to key health trends and daily measurements**
- Have regular communication and treatment guidance from your care team[†]
- · Return for clinic visits at specific intervals



to submit a daily reading

⁺ Using the patient-provided tablet

^{*} Includes blood pressure, heart rate, oxygen levels and weight and when unblinded, PA pressure data.











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

Cordella is clinically proven to enable better heart failure mangement^{3,**} with regular review of key health data to help guide your medical management from home.

- Proactive care with medication adjustments
- Comprehensive daily health status
- Engage with your health data
- Connect with your care team



For important risk information, please visit endotronix.com/risks.

As with any medical procedure, there is a possibility of risks. The most serious risks of the Cordella PA Sensor procedure 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.

Frequently Asked Questions

- Q: Why is PA pressure important to managing my heart failure?
- **A:** Changes in PA pressure often indicate worsening heart failure before an urgent intervention is required.⁴
- Q: How long will the Cordella PA Sensor implant procedure take?
- **A:** The minimally invasive procedure typically takes around an hour and most patients go home the same day.

- Q: Where is the Cordella PA Sensor implanted in my body?
- **A:** Using a minimally invasive procedure your doctor will place the permanent wireless implant in your right pulmonary artery.
- Q: How do I send my PA pressure readings to my doctor?
- A: Each day you will place a handheld reader over the location of your sensor for less than 30 seconds. In addition, you will collect other health data, such as weight, blood pressure, heart rate, blood oxygen, and answer health questions. The information is collected in less than 5 minutes and securely transmitted via your tablet to your doctor to foster a strong connection.

Prior to enrollment, the clinical staff will fully review the study, including risks and benefits, and address any questions you may have. This process is referred to as informed consent. Learn more at **myheart.com/pro2**.

INTENDED USE

The Cordella Pulmonary Artery Sensor is designed to measure and send pulmonary artery pressure (PAP) data for patients with Class III heart failure who are receiving medical treatment and have been stable for 30 days.

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

For more information, please visit clinicaltrials.gov NCT05934487.

In the U.S., the Cordella $^{\text{TM}}$ 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.

- 1 Sharif F et al. ESC Heart Fail. 2024 Apr;11(2):1133-1143
- 2 Guichard JL. Presented at THT 2023, Boston MA
- 3 Guichard JL et al. J Am Coll Cardiol HF. 2024 Aug 2:S2213-1779(24)00485-2.
- 4 Heidenreich PA et al. Circulation. 2022;145:e895-e132.



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