PROACTIVE-HF
CORDELLA®

Manage your Heart Failure from Home

with the Cordella® Heart Failure System

A guide to learn more about
the PROACTIVE-HF clinical trial

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What is the PROACTIVE-HF Trial?

The PROACTIVE-HF trial is designed to evaluate a new medical device for management of heart failure called the **Cordella® Pulmonary Artery (PA) Pressure Sensor***. The trial will assess the benefits of remote management using daily pulmonary artery pressure readings, a leading indicator of worsening heart failure symptoms.

- **All patients will receive physician-directed therapy**[1]
- **All patients will be implanted with the Cordella® Sensor**
- **All patients will recieve the myCordella™ Patient Kit**

As part of the trial you will be asked to:

- Provide informed consent
- Return for clinic visits at specific intervals
- Submit your daily health data using the myCordella Patient Kit

to submit a daily reading

Frequently Asked Questions

Q: Why is Pulmonary Artery Pressure important to managing my heart failure?

A: Changes in PA pressure often indicate worsening heart failure 2–4 weeks before an urgent intervention is required.[2,3,4]

Q: How long will the Cordella 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 Sensor implanted in my body?

A: Using a minimally invasive procedure your doctor will place the 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 and heart rate. The information is collected in less than 5 minutes and securely shared with your doctor.

The Cordella® Heart Failure System

87% of patients believe their health is better with the Cordella HF System[5]

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

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

The system is designed to make remote management of your heart failure easy for you and your doctor.

- **Provides comprehensive daily health status**
- **Allows review of key health trends**
- **Supports proactive medication adjustments**
- **Enhances communication with your doctor**

Prior to enrollment, the clinical staff will fully review the study risks and benefits to address any questions you may have. This process is referred to as informed consent.

Indications

The Cordella® Heart Failure System is intended to electronically transfer communications and data from a set of medical devices in a heart failure patient's home to a database for storage, retrieval and display to healthcare providers.

The Cordella® PA Sensor System is intended to measure, record, and transmit PA pressure data from NYHA Class III heart failure patients at home to clinicians for assessment and patient-centered heart failure management.

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1 For more information, please visit clinicaltrial.gov (NCT04089059).

2 Abraham WT, et al. Wireless pulmonary artery hemodynamic monitoring in chronic heart failure: a randomized control study. Lancet. 2011 Feb 19;377(9766):658-66.

3 Abraham WT, Adamson PB, et al. (2015, March). Pulmonary artery pressure management in heart failure patients with reduced ejection fraction significantly reduces heart failure hospitalizations and mortality above and beyond background guideline-directed medical therapy. Abstract 902-04 presented at ACC 2015, San Diego, CA.

4 Adamson, PB, Curr Heart Fail Reports 2009; 6:267.

5 Data based on survey of Cordella HF System patients without the Cordella PA Pressure sensor. Data on file at Endotronix, Inc.

* CAUTION—Investigational Device. Limited by Federal (or United States) Law to Investigational Use. The Cordella® PA Pressure Sensor System is an investigational device and is not currently approved for clinical use in any geography.

The Cordella® Heart Failure System is commercially available in the U.S. and E.U.

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