Manage your Heart Failure from Home

with the Cordella® Heart Failure System

A guide to learn more about the PROACTIVE-HF clinical trial
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
- All patients will be implanted with the Cordella® Sensor
- All patients will receive 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

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

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

87% of patients believe their health is better with the Cordella HF System\(^5\)
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.

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


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.

©2022 Endotronix, Inc. All rights reserved. Endotronix, myCordella and Cordella are trademarks of Endotronix, Inc.

The A&D marks are owned by A&D Engineering, Inc. and are used by Endotronix with permission of A&D Engineering, Inc.

The Nonin marks are owned by Nonin Medical, Inc. and are used by Endotronix with permission of Nonin Medical, Inc.

ML1356 Rev 3