

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** 





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



to submit a daily reading

<sup>\*</sup> Includes PA pressure and vital sign data for blood pressure, heart rate, oxygen levels and weight.

<sup>+</sup> Using the patient-provided tablet











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



At-home kit collects and securely transmits health data to the clinician

The comprehensive platform enables regular review of key health metrics 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



† 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.

#### 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.<sup>3</sup>

## 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.

#### 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 pulmonary artery pressure data from NYHA Class II-III heart failure patients at home to clinicians for assessment and patient-centered heart failure management, with the goal of reducing heart failure hospitalizations.

For more information, please visit clinicaltrial.gov NCT05934487

- 1 Guichard JL, Presented at THT 2023, Boston MA.
- 2 Sharif F et al. ESC Heart Fail. 2022 Oct;9(5):2862-2872.
- 3 Heidenreich PA et al. Circulation. 2022;145:e895-e132.



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