PRO 2

CORDELLA®

PROACTIVE-HF 2 Trial

Take Control of Heart Failure

Discover the PROACTIVE-HF 2 trial and how Cordella® helps you stay engaged to improve outcomes.[1]

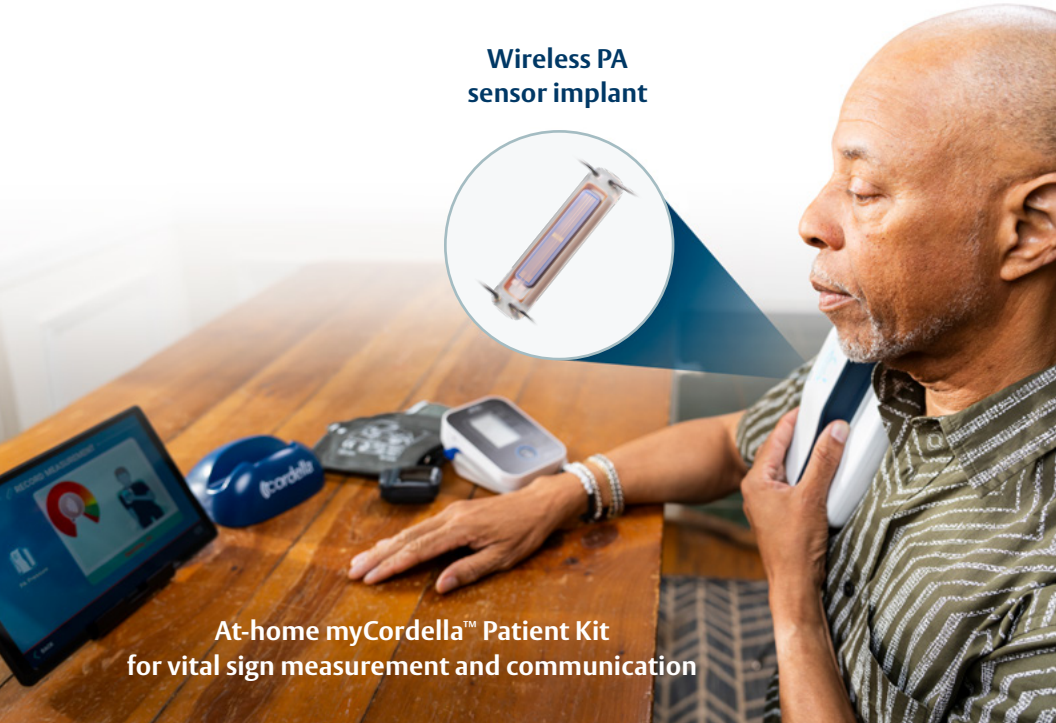
Edwards

What is the PROACTIVE-HF 2 Trial?

The PROACTIVE-HF 2 trial is a clinical study for people living with NYHA Class II and Class III heart failure (HF). It is designed to evaluate how daily health data—like pulmonary artery (PA) pressure and vital signs—collected at home using the Cordella® PA Sensor and HF System, can support better heart failure management.

By securely sharing this information with your care team, the trial aims to understand how early insights, treatment adjustments, and patient engagement may improve patient outcomes.

cordella



Frequently Asked Questions

Q: Why is PA pressure important to managing heart failure?

A: Rising PA pressure is an early sign of worsening heart failure, often before symptoms appear. Combining this information with key vital sign data allows your care team to intervene earlier to reduce congestion with remote medication adjustments.[5]

Q: How long does the Cordella PA Sensor procedure take, and is it safe?

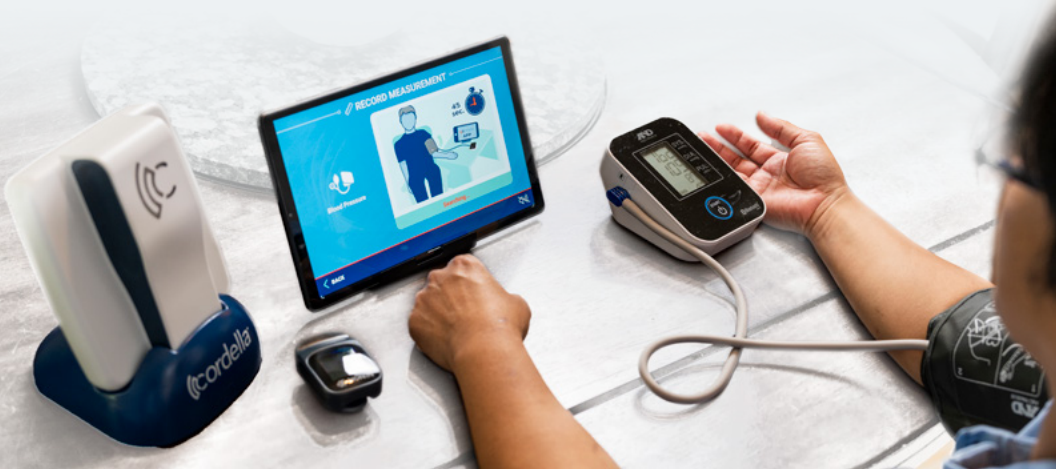
A: The minimally invasive procedure usually takes an hour, and most patients go home the same day. The sensor has been studied in clinical trials, showing a low complication rate.[1,3] The Cordella Sensor is FDA approved for NYHA class III HF patients.

Q. Where in the body is the sensor placed?

A: The sensor is permanently implanted in your right pulmonary artery during a minimally invasive procedure.

Q: How do I send my measurements to my care team?

A: Each day, you will use a handheld reader to capture your PA pressure and the myCordella Patient Kit to measure your vital signs. It takes less than 5 minutes, and your data is securely sent to your care team through the tablet.[2]



HF Care with a Real Connection

- Monitor and securely share your heart health data from home
- Stay connected between clinic visits
- Receive personalized treatment and medication adjustments
- Take a more active role in managing your HF

5 min

Under 5 minute daily routine[2]

97%

of Cordella patients said the system is easy to use[3]

97%

of Cordella patients believe PA pressure monitoring and care has a positive health impact[4]

Clinically Proven to Help You Stay Ahead of HF

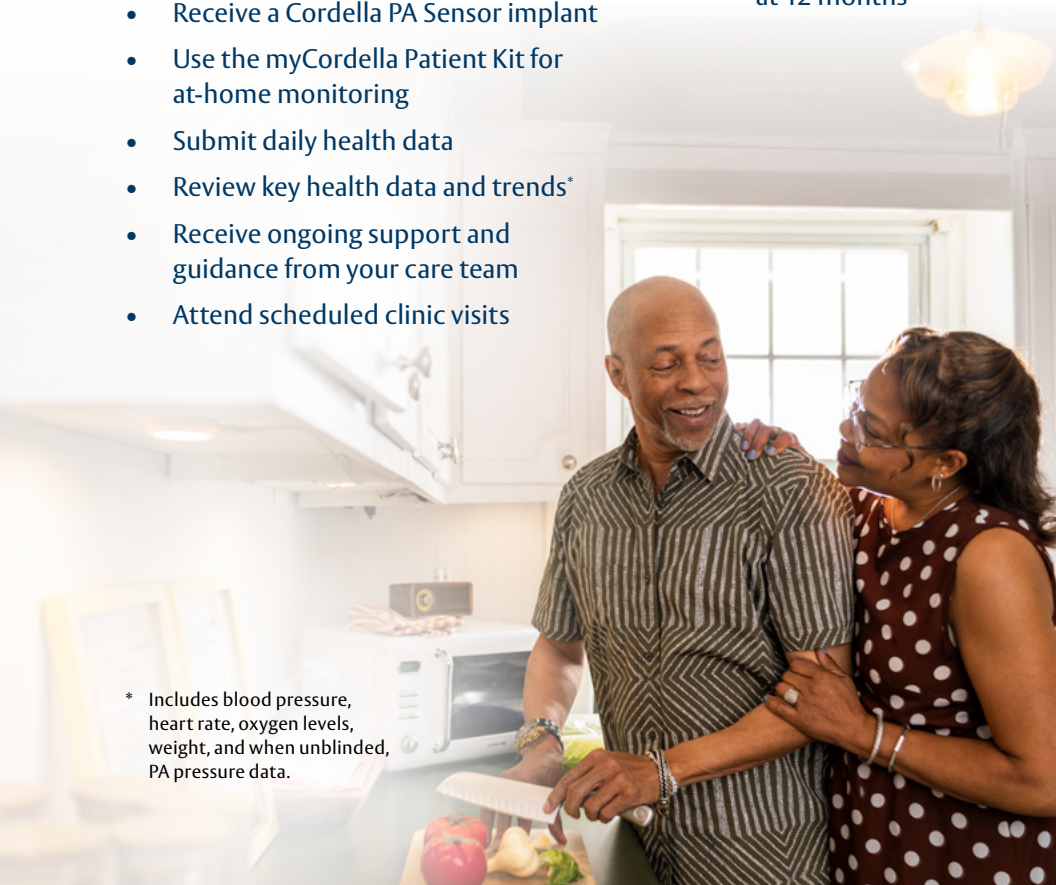
Cordella enables better HF management in NYHA class III patients and has a proven safety profile with a low complication rate.[1]

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

As part of this study, you will:

- Provide informed consent
- Receive a Cordella PA Sensor implant
- Use the myCordella Patient Kit for at-home monitoring
- Submit daily health data
- Review key health data and trends*
- Receive ongoing support and guidance from your care team
- Attend scheduled clinic visits

Reduction in HF hospitalization (HFH) rate pre/post Cordella at 12 months[1]



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

During the informed consent process, the care team will explain the study, review risks and benefits, and answer your questions.

Learn more at **myheart.com/pro2**.

References

1 Klein L et al. Seated Pulmonary Artery Pressure Management in Patients with Heart Failure: 12-Month Outcomes in the PROACTIVE-HF Trial. Accepted in JACC-HF.

2 Data on file.

3 Sharif et al. ESC Heart Fail.2024 APR;77(2):7733-7743.

4 Guichard JL et al. Presented at THT 2023, Boston MA.

5 Heidenreich PA et al. Circulation. 2022;145:e895-e132.

For more information, please visit clinicaltrials.gov (NCT05934487).

NYHA Class III patients: In the US, 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.

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

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.

See instructions for use for full prescribing information. As with any medical procedure, there is a possibility of risks. The most serious risks of the Cordella PA Sensor 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. For important risk information, visit. endotronix.com/risks.

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