



CORDELLA

Know what matters

The next-generation pulmonary artery pressure sensor system for heart failure care

CORDELLA IS INDICATED
FOR PATIENTS WITH NYHA
CLASS III HEART FAILURE¹

CORDELLA IS COVERED BY
CMS NATIONAL COVERAGE
DETERMINATION²

For important safety information, please visit cordella.com.
For US Healthcare Professionals.



Edwards

The relentless rise of heart failure

8.7M

Americans projected to live with HF by 2030 (prevalence)³

1.2M

Primary HF hospitalizations in 2021 (increasing since 2014)³

HF=heart failure; HFH=heart failure hospitalization; PA=pulmonary artery

For important safety information, please visit [cordella.com](https://www.cordella.com).

Each hospitalization compounds the risk

~30%

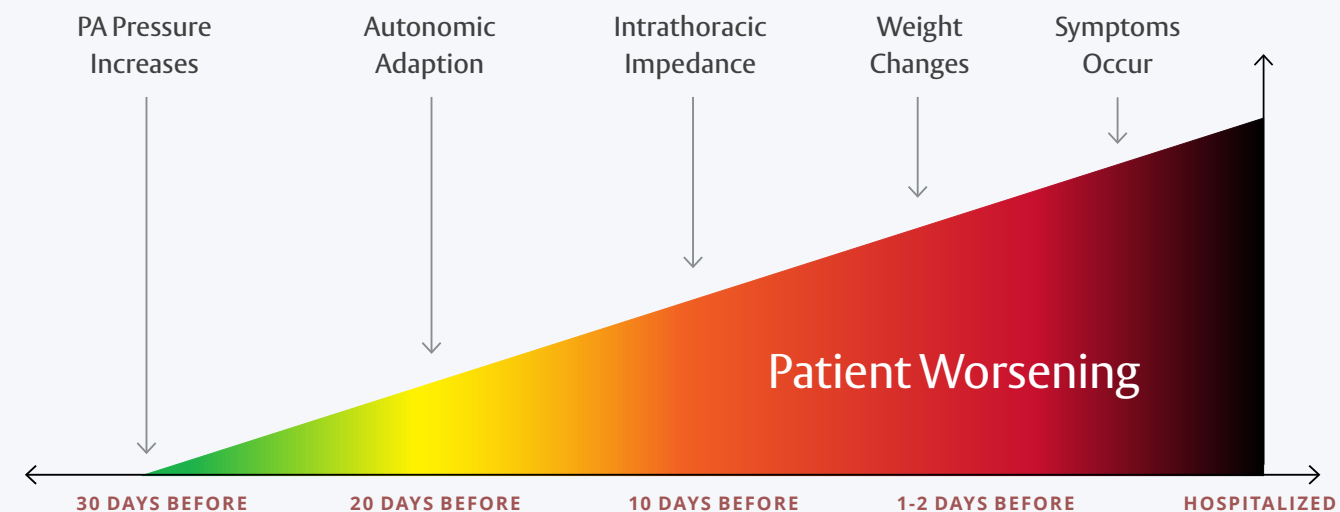
OF PATIENTS READMITTED
WITHIN 90 DAYS⁴

2.4 years

AVERAGE MORTALITY AFTER FIRST HFH, WITH
SIGNIFICANT INCREASE AFTER EACH ADDITIONAL HFH*⁵

PA Pressure allows for intervention sooner

Pathophysiology of congestion⁶



Adapted from Adamson P

Additional vitals signs provide a more complete picture

2022 AHA/ACC/HFSA Guideline Class I Recommendation: Vital signs and clinical congestion should be assessed at each encounter to guide overall management.⁷

*Median survival times after the first, second, third, and fourth hospitalization were 2.4 (95% CI 2.3-2.5), 1.4 (95% CI 1.2-1.5), 1.0 (95% CI 0.9-1.1), and 0.6 (95% CI 0.5-0.9) years



The future of heart failure care, is here

The first and only implantable sensor system to combine seated pulmonary artery pressure monitoring with daily vitals, **Cordella reveals what matters when it matters most.**

Cordella provides a more complete clinical picture



PA Pressure (mmHg)



Weight (lb/kg)



Blood pressure (mmHg)



Emotional well-being



Heart rate (bpm)



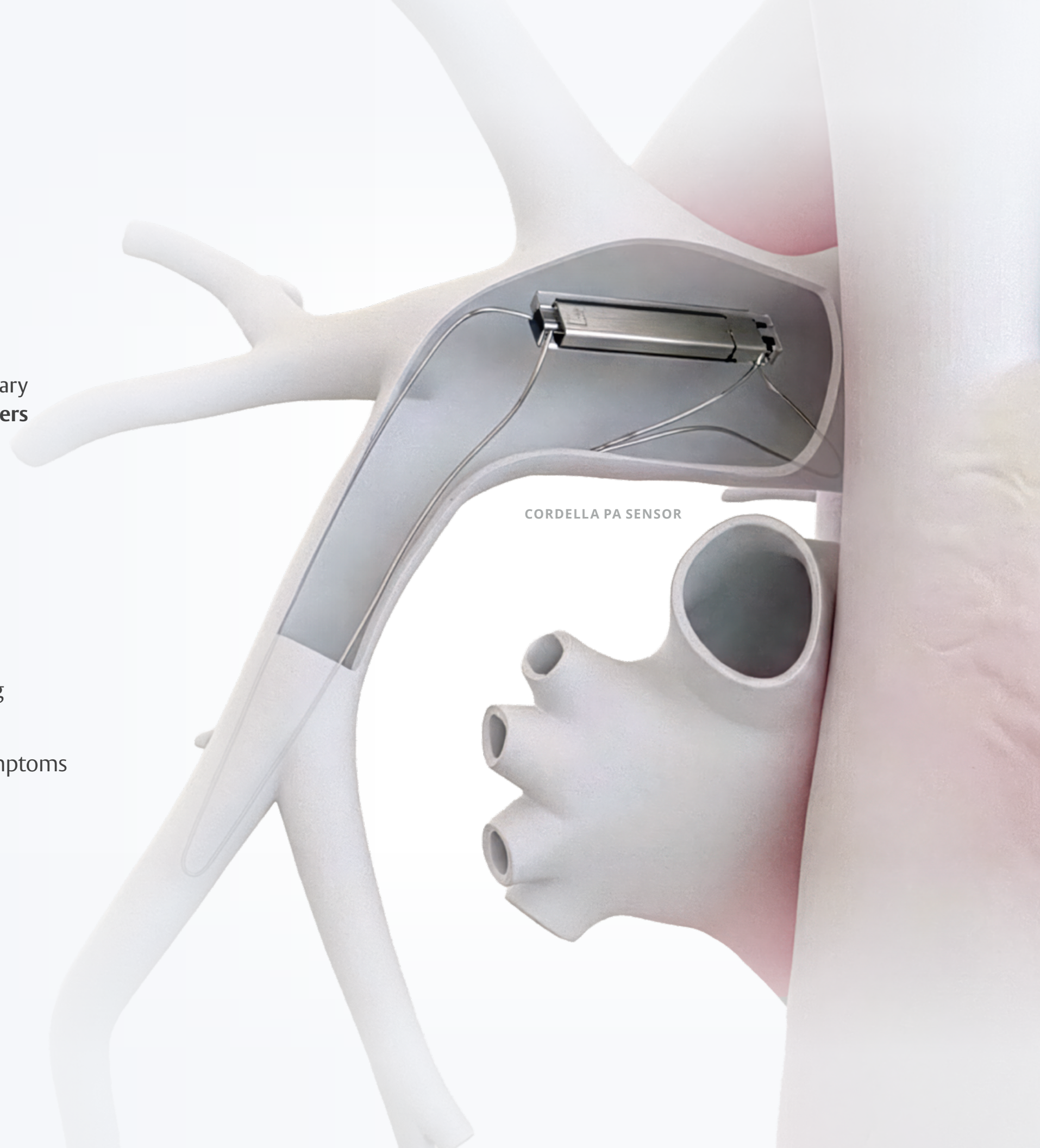
Patient-reported symptoms



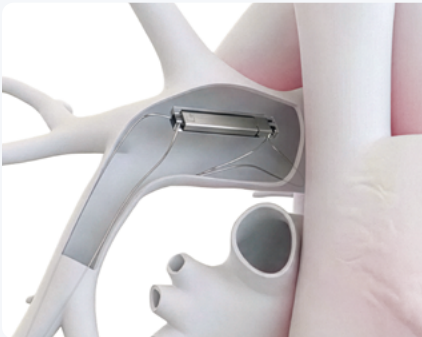
SpO₂ (%)

PA=pulmonary artery; SpO₂=peripheral oxygen saturation

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Platform for heart failure care



Cordella PA Sensor

Small implant that resides permanently in the right pulmonary artery⁸

- Wireless, battery-free design
- Implanted with minimally invasive right heart catheterization



Delivery System

Implants sensor during right heart catheterization via venous (IJ/TF) access⁸

- Allows control of sensor rotational angle
- Stability sheath allows calibration without extra catheter exchange

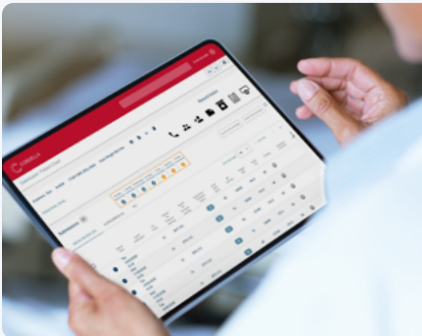


Calibration Equipment (CalEQ)

Hospital equipment to support procedure⁸

- Enables calibration using a simultaneous line-in reference pressure*

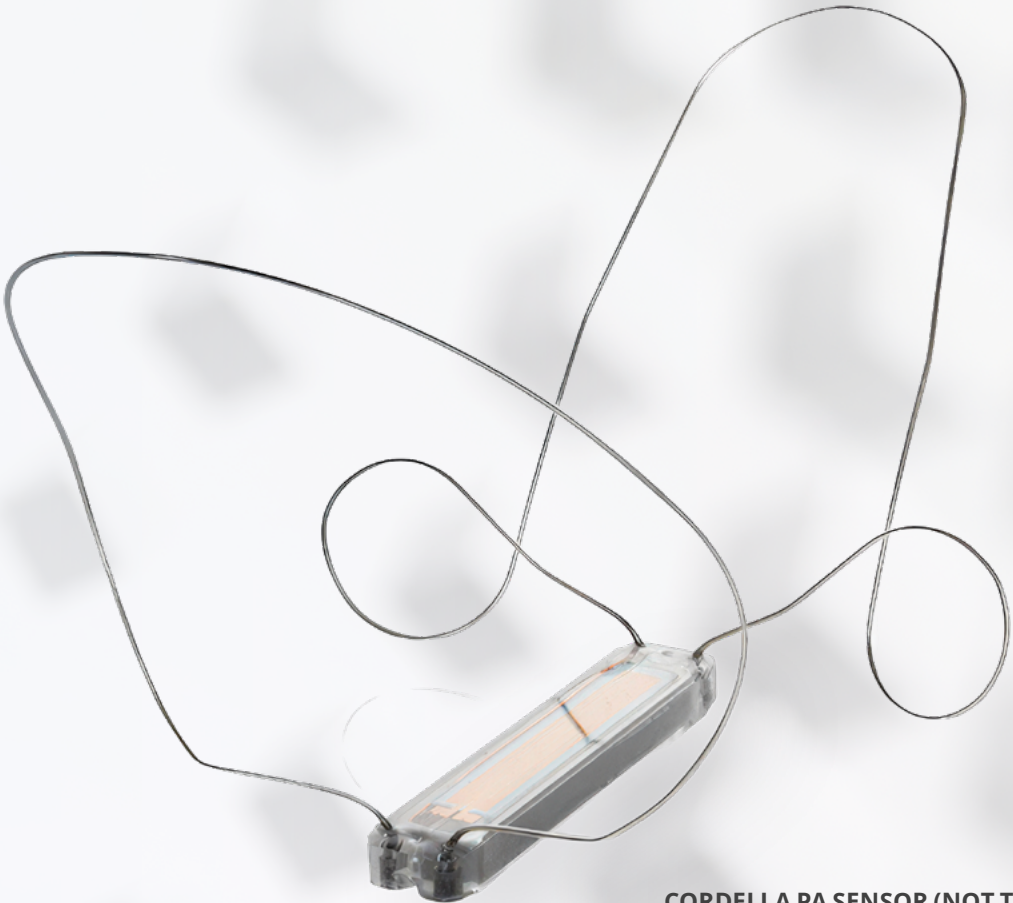
*compatible models only.



myCordella Patient Management Portal

Web based app displays patient data and enables HF care⁸

- Customizable platform that integrates PA pressure, vitals and patient symptoms for efficient decision making



CORDELLA PA SENSOR (NOT TO SCALE)

Actionable information enabled by a safe and accurate platform

At 12 months, there was good agreement between the Cordella PA Sensor System and RHC, with the average difference for mean PAP being 2.9 ± 7.3 mmHg (N=70)⁹

99.8%
FREEDOM FROM
PRESSURE SENSOR
FAILURE*¹⁰
(95% CI: 98.6%-100%)

99.2%
FREEDOM FROM DEVICE
OR SYSTEM-RELATED
COMPLICATIONS*¹⁰
(95% CI: 97.9%-99.7%)

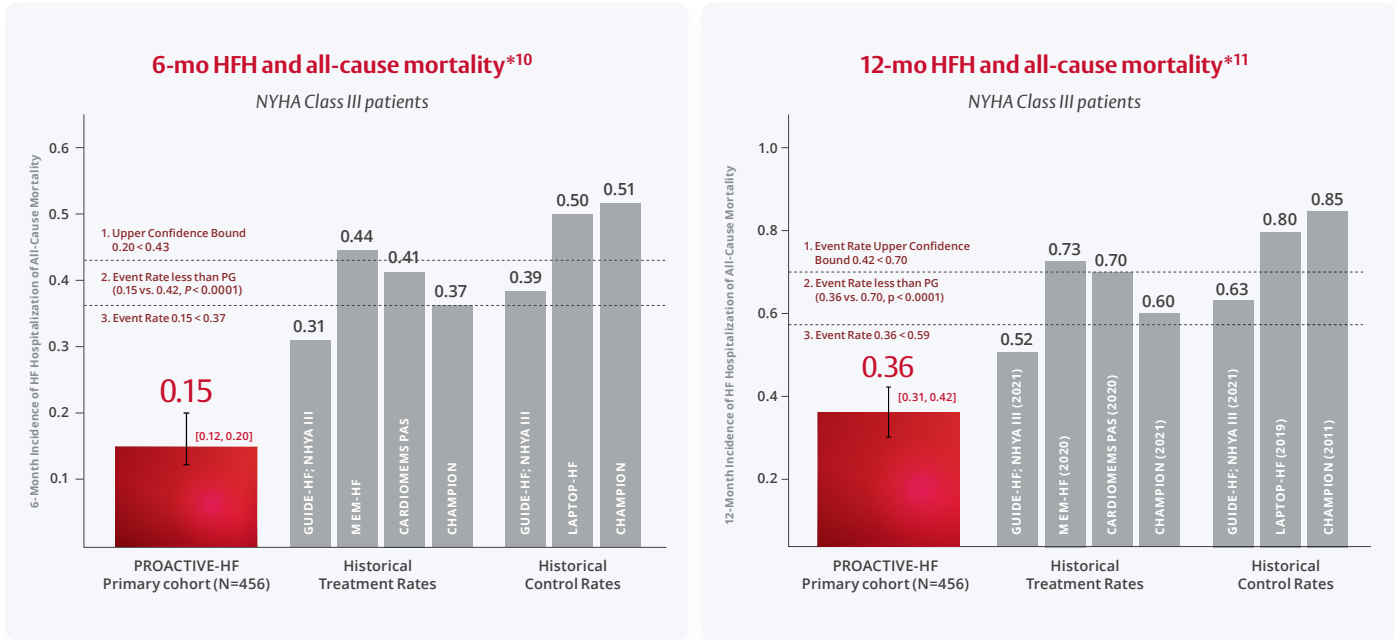
1st
REPORT ON LONG TERM
PRE-SPECIFIED ACCURACY
OF PA SENSOR**⁹

*PROACTIVE-HF (n=456) at 6-months.
**Long-term defined as > 90 days

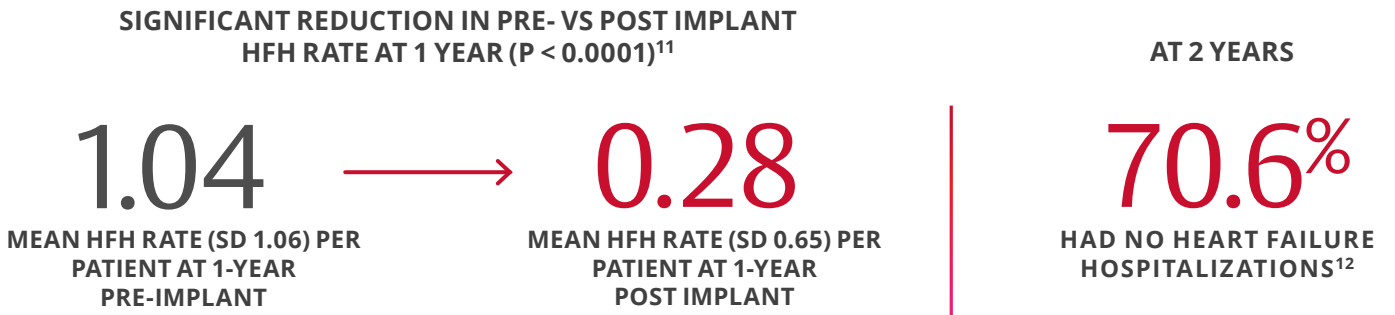
Smarter decisions, sooner

Cordella showed significantly lower HFH and all-cause mortality rate compared to objective performance goal (P < 0.0001)*

Results from PROACTIVE-HF (N=456; NYHA class III patients with recent HFH or elevated natriuretic peptides)



Low event rate is sustained at 2 years and PROACTIVE-HF is the only pivotal trial in PA Pressure guided HF management to report 2-year outcomes across EF.¹²



*Performance goal was based on prior hemodynamic guided HF trials

HFH=heart failure hospitalization; NYHA=New York Heart Association; KCCQ=Kansas City Cardiomyopathy Questionnaire; HFpEF= Heart failure with preserved ejection fraction

Enabling a better quality of life

Improvements at 2-year follow-up with Cordella (PROACTIVE-HF)

Quality of life¹²
KCCQ score improved by 5.1 points (P < 0.0001)

Functional capacity¹²
Higher 6-minute walk test scores in HFpEF patients (P = 0.0053)

Symptom severity¹²
Significant NYHA class improvement (P < 0.0001)



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Innovation designed ...

myCordella Patient Reader

Lightweight, handheld reader designed for comfort and control

- The first platform with seated PA Pressure readings
- Reflects upright physiology – how patients spend most of the day

84%
PREFER PAP READINGS IN THE SEATED POSITION VS LYING FLAT*¹³

>5x/week
PATIENTS SUBMITTED AN AVERAGE OF 5.8 READINGS PER WEEK AT 2 YEARS**¹²

*Results from SIRONA-2 trial (n=37).
**PROACTIVE-HF (n=456) at 24-months.
***Other parts of the myCordella patient kit include Carrying Case, Stylus, myCordella Patient Manual, myCordella Quick Start Guide.
§PROACTIVE-HF former control group (n=40).

PAP=pulmonary artery pressure

... with patients in mind

myCordella Patient Kit

Tools for a more complete picture

- The first platform that combines PA Pressure monitoring with vitals
- Includes myCordella Tablet, BP Monitor (connected), Pulse Oximeter, Weight Scale***

97%
OF PATIENTS REPORT THE SYSTEM IS EASY TO USE*¹³

<5 min
TO SUBMIT DAILY PAP + VITAL READINGS



myCordella Tablet

Intuitive, user-friendly display screen that assists patients with obtaining daily measurements

- Real-time visibility into daily readings keeps patients engaged
- Empowers patients to become true participants in their care

84%
HAD A FAVORABLE RESPONSE TO THE IMPACT OF PAP READINGS AND CLINICIAN CARE ON THEIR HEALTH^{§14}

78%
REPORTED MAKING LIFESTYLE CHANGES BASED ON THEIR PAP TRENDS^{§14}





Vital intelligence transforming the future of heart failure care

Smarter decisions, sooner

PA Pressure and vitals in one unified ecosystem enable GDMT optimization to help reduce hospitalizations^{10,11}

Patient-centered experience

Seated PA Pressure readings with visibility into their pressures and vitals data supports long-term patient engagement¹²

Empowered heart failure care

Reduces urgent and total office visits, designed for scalable care as HF populations grow^{3,15}

Which of your NYHA class III patients could benefit from earlier intervention?

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PAP=pulmonary artery pressure; HF=heart failure

References: 1. US Food and Drug Administration. Approval order: Cordella Pulmonary Artery Sensor System (CorPASS), P230040. Published June 20, 2024. Accessed April 16, 2026. https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230040A.pdf 2. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD): implantable pulmonary artery pressure sensors for heart failure management (20.36). Effective January 13, 2025. Accessed April 16, 2026. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=3783> 3. Writing Committee Members. HF STATS 2025: Heart failure epidemiology and outcomes statistics in an updated 2025 report from the Heart Failure Society of America. *J Card Fail.* 2026;32(2):439–498. doi:10.1016/j.cardfail.2025.07.007 4. Khan MS, Sreenivasan J, Lateef N, et al. Trends in 30- and 90-day readmission rates for heart failure. *Circ Heart Fail.* 2021;14:e008335. doi:10.1161/CIRCHEARTFAILURE.121.008335 5. Setoguchi S, Stevenson LW, Schneeweiss S. Repeated hospitalizations predict mortality in the community population with heart failure. *Am Heart J.* 2007;154(2):260–266. doi:10.1016/j.ahj.2007.01.041 6. Adamson PB. Pathophysiology of the transition from chronic compensated and acute decompensated heart failure: new insights from continuous monitoring devices. *Curr Heart Fail Rep.* 2009;6(4):287–292. doi:10.1007/s11897-009-0039-z 7. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18):e895–e1032. doi:10.1161/CIR.0000000000001063 8. Endotronix, Inc. *Cordella Pulmonary Artery Sensor System: Instructions for Use.* Rev D. 2024. Accessed April 16, 2026. 9. Shariff F, Rosenkranz S, Bartunek J, et al. Twelve-month follow-up results from the SIRONA 2 clinical trial. *ESC Heart Fail.* 2024;11(2):1133–1143. doi:10.1002/ehf2.14657 10. Guichard JL, Bonno EL, Nassif ME, et al. Seated pulmonary artery pressure monitoring in patients with heart failure: Results of the PROACTIVE-HF trial. *JACC Heart Fail.* 2024;12(11):1879–1893. doi:10.1016/j.jchf.2024.05.017 11. Guichard JL, Bonno EL, Nassif ME, et al. Seated pulmonary artery pressure management in patients with heart failure: 12-month outcomes of the PROACTIVE-HF trial. *JACC Heart Fail.* 2026;102847. doi:10.1016/j.jchf.2025.102847 12. Guichard JL, Bonno EL, Nassif ME, et al. Two-year results of the PROACTIVE-HF trial stratified by LVEF. *Journal of Cardiac Failure.* 2026. doi.org/10.1016/j.cardfail.2026.01.023 13. Shariff F, Rosenkranz S, Bartunek J, et al. Safety and efficacy of a wireless pulmonary artery pressure sensor: primary endpoint results of the SIRONA 2 clinical trial. *ESC Heart Fail.* 2022;9(5):2862–2872. doi:10.1002/ehf2.14006 14. Cowger J, Guichard J, Miranda, D, et al. Engaging patients and clinicians with remote pulmonary artery pressures monitoring improves care: the PROACTIVE-HF clinical trial. *J Am Coll Cardiol HF.* null2026, 0 (0). <https://doi.org/10.1016/j.jchf.2026.103008> 15. Craig W, Ohlmann S. The benefits of using active remote patient management for enhanced heart failure outcomes in rural cardiology practice: single-site retrospective cohort study. *J Med Internet Res.* 2024;26:e49710. doi: 10.2196/49710.

In the U.S., 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.

Indications for use: The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT) as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.

Contraindications: The Cordella Pulmonary Artery Sensor System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

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.

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