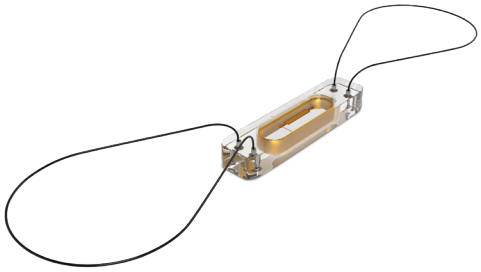
HEART FAILURE MONITORING SYSTEM

CardioMEMS™ HF System

PA Sensor and Delivery System



Product Highlights

- The CardioMEMS™ HF System is the first and only FDA and CE Mark approved heart failure (HF) monitor proven to significantly reduce HF hospital admissions and improve quality of life in NYHA Class III patients. When used by clinicians to manage HF, the CardioMEMS HF System is:
  - **Safe and reliable** — demonstrates 98.6% freedom from device or system complications[1]
  - **Clinically proven** — reduced HF admissions by 62%[2]
  - **Proactive and personalized** — patient management through direct monitoring of PA pressure and titration of medications
- The CardioMEMS HF System provides direct pulmonary artery (PA) pressure monitoring using the sensor, patient electronics system and the Merlin.net™ PCN website to manage patient data. Patient-initiated sensor readings are wirelessly transmitted to an electronics unit and stored in a secure website for clinicians to access and review
- The reliable radiopaque sensor is implanted in the pulmonary artery using a delivery system via a safe and proven right-heart catheterization procedure[1]
- In a clinical study with 1167 patient years of experience,[3] no sensor failures (inability to obtain readings) were reported, indicating reliable PA pressure monitoring[1]
- The sensor endothelializes, occupying on average ~10% of cross-sectional lumen for low risk of infection, thrombus or occlusion[3]
- PA sensor pressure measurements (n = 85) showed agreement within 1,0 ± 4,7 (mean difference +/- sd) mmHg with a pulmonary artery catheter during follow-up measurements performed after an average follow-up of 265 ± 169 days post implantation without interim re-calibration[4]
- The sensor is calibrated during manufacturing and the mean pressure baseline is matched to the pulmonary artery catheter mean pressure during the implant procedure. The sensor does not contain a battery or other components which would limit its usable life

Ordering Information

Contents: PA Sensor and Delivery System

MODEL NUMBER	DESCRIPTION
CM2000	PA Sensor and Delivery System

1. Abraham, W. T., Adamson, P. B., Bourge, R. C., Aaron, M. F., Costanzo, M. R., Stevenson, L. W.,...Yaday, J. S., (2011). Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. *The Lancet, 377*(9766), 658-666. doi:10.1016/S0140-6736(11)60101-3.
2. Angermann C., Abmus B., et al. Pulmonary Artery Pressure Guided Therapy in Ambulatory Patients with Symptomatic Heart Failure The CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF).European J of Heart Failure. 2020.10.1002/ejhf.1943
3. Abbott Data on File. G060187, September 2006. PMA P100045, December 2010. G060187/S031, August 2008.
4. Abbott Data on File. The CardioMEMS Champion™ HF Monitoring System for Patients with NYHA Class III Heart Failure: Draft Briefing Document for the Circulatory Systems Device Panel Advisory Committee, December 8, 2011. P100045.

CardioMEMS™ HF System

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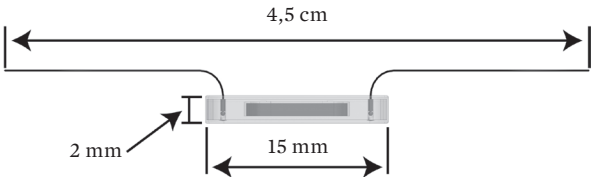
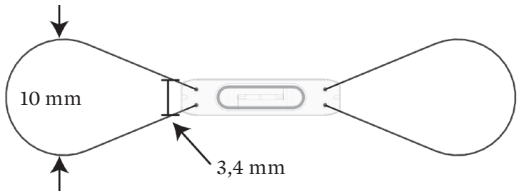
Product Specifications

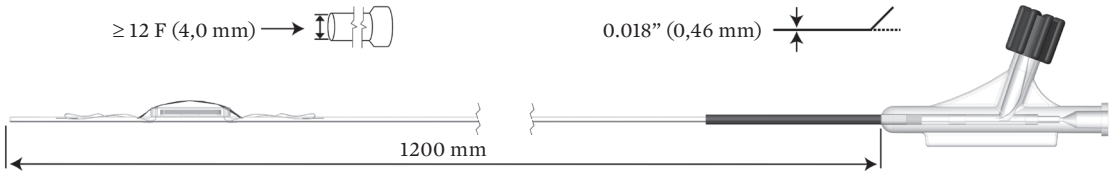
Model **CardioMEMS™ PA Sensor**	**CM2000**
Sensor Body Dimensions (H x W x D, mm)	2 x 3,4 x 1540
Wire Loop Expanded Diameter (mm)	10
Total Length (including wire loops (mm)	45
Longevity	Permanent implant
Power	
Power Source	Externally powered by radiofrequency energy





CardioMEMS™ PA Sensor Delivery System

Model **Electronics Unit**	**CM2000**
Delivery System Usable Length (mm)	1200
Guidewire Lumen Compatibility	0,018" (0,46 mm) OD Guidewires
Min. Introducer Sheath ID	12 F sheaths



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Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (PA) pressure and heart rate in New York Heart Association (NYHA) Class III heart failure patients who have been hospitalized for heart failure in the previous year. The hemodynamic data are used by physicians for heart failure management and with the goal of reducing heart failure hospitalizations.

Contraindications: The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: Infection, Arrhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death, and Device embolization.

Limitations: Patients must use their own Apple‡ or Android‡ mobile device to receive and transmit information to the myCardioMEMS™ mobile app. To do so the device must be powered on, app must be installed and data coverage (cellular or Wi-Fi‡) available. The myCardioMEMS™ app can provide notification of medication adjustments and reminders, requests for lab work and acknowledgement that the PA pressure readings have been received. However there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of the notifications and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, clinic environment, schedule/configuration changes, or data processing.

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