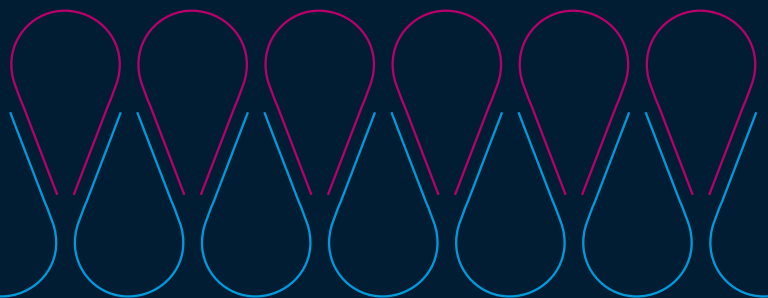
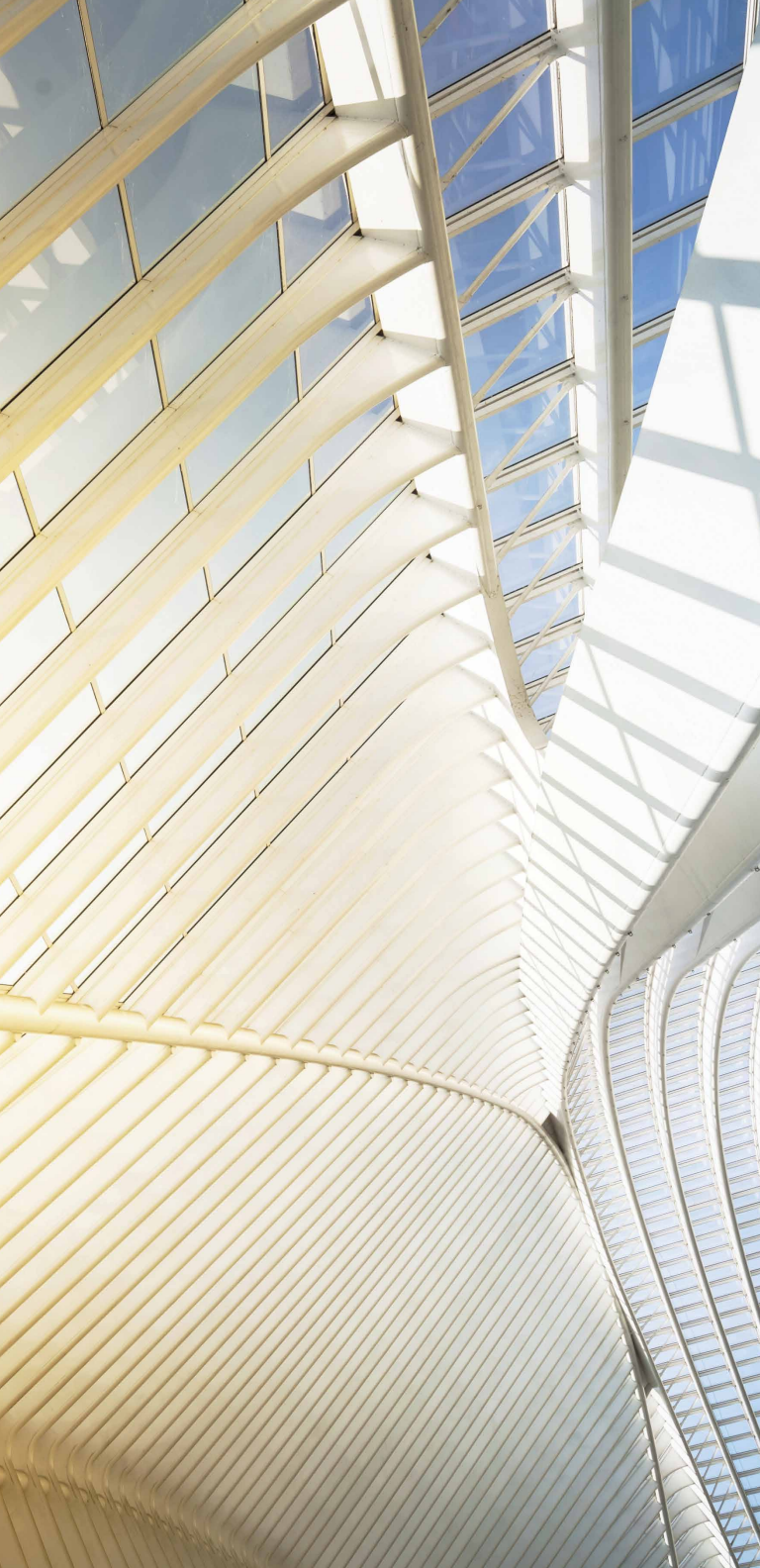




CARDIOMEMS™ HF SYSTEM

HOW TO STAY ABOVE
HEART FAILURE:
**TALKING TO YOUR
PATIENT ABOUT THE
CARDIOMEMS™ HF SYSTEM**





This overview of clinical workflow best practices and patient talking points

is based on in-depth research and feedback¹ on the behaviors and attitudes from more than 160 heart failure clinicians currently managing heart failure patients on the CardioMEMS™ HF System at over 125 facilities in the U.S., as well as the clinical practices² of Philip B. Adamson, M.D., MSc, FACC, a CHAMPION trial³ principal investigator.

Medical care of the patient is the sole responsibility of the acting practitioner.

This document is not intended to replace the judgment of the acting practitioner nor the establishment of final protocols within the hospital setting. It does not represent any opinion or endorsement by Abbott of any particular approach to patient management or treatment.

TIPS FOR STAFF WHEN DISCUSSING THE CARDIOMEMS™ HF SYSTEM

- Remind heart failure patients of the gravity of their heart failure prognosis and the importance of carefully managing their health to stay above heart failure.
- Using the CardioMEMS™ HF System, along with guideline-directed medical therapy (GDMT), can help optimize patients' quality of life and help them stay out of the hospital.
- Patient education is a critical part of the patient consent process. Soon after a heart failure hospitalization (within a week), schedule at least an hour in clinic with your heart failure patient and the main caregiver for comprehensive patient education about the CardioMEMS HF System.

PATIENT CANDIDATE CONSIDERATIONS

THE CARDIOMEMS™ HF SYSTEM IS INDICATED FOR THESE PATIENTS³:

- NYHA Class III heart failure
- One heart failure hospitalization in the past 12 months

Note: A typical NYHA Class III heart failure patient has marked limitation of physical activity. Less than ordinary activity leads to symptoms (moderate congestive heart failure). Doctors commonly look at what the patient's heart failure symptoms have predominantly been in the last 30 days.

THE CARDIOMEMS HF SYSTEM IS CONTRAINDICATED FOR THESE PATIENTS:

- Patients with an inability to take dual antiplatelet or anticoagulants for one month post implant

PATIENTS WHO MOST COMMONLY RECEIVE THE CARDIOMEMS HF SYSTEM ARE THOSE ON GDMT AND THOSE WHO EXHIBIT ANY OF THE FOLLOWING³:

- Fluid volumes are hard to know or manage
- Physical assessment is challenging
- Is a patient with HFpEF or HFrEF
- Compliant with heart failure medical care
- Would benefit from remote monitoring if they live far from a clinic

Note: The CHAMPION trial specifically excluded patients with American College of Cardiology/American Heart Association stage D heart failure who needed advanced therapies (i.e., left ventricular assist device, transplant or inotropic support). Even if inotropic support improved heart failure symptoms, a patient would still be defined as stage D, with refractory heart failure.³

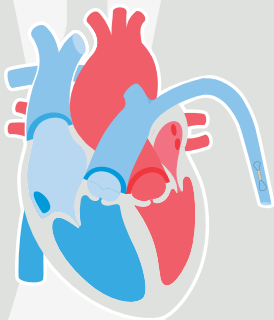
INTRODUCING PA PRESSURE MANAGEMENT WITH THE CARDIOMEMS™ HF SYSTEM

- It is best to introduce the CardioMEMS™ HF System to a patient while they are still in the hospital.
- At their first clinic follow-up after a heart failure hospitalization, discuss the CardioMEMS HF System in depth with the patient and their main caregiver.
- Having the main caregiver present can help patients better understand the information, and support them as they make their decision.
- It is important to focus on how the CardioMEMS HF System works to help reduce future hospitalizations and reduce clinic visits.
- Use this first clinic visit after a heart failure hospitalization to explain the following:
 - That the CardioMEMS HF System monitors the pressures inside their heart and lungs
 - How increased pressure in the heart's pulmonary artery (PA) typically indicates that:
 - Fluids are rising
 - Heart failure will soon get worse
 - Another hospitalization is likely soon
 - Further damage may occur to their heart
 - With the CardioMEMS HF System and Merlin.net™ Patient Care Network, clinicians can see when a patient's PA pressures change so that they can adjust medications before their heart failure worsens — sometimes even before a patient notices symptoms.

DESCRIBING THE CARDIOMEMS™ HF SYSTEM

□ Consider using the following descriptions of the system when talking to your patients¹:

- Implanting the CardioMEMS™ PA Sensor is a short, low-risk procedure. The sensor is secured in the patient's PA with a catheter accessed through a vein in their groin area. This approach is very similar to other heart procedures.
- The sensor is small and self-contained – about the size of a paper clip. There are no batteries or wires. The patient should not feel the sensor inside their body. This is a good time to show the sensor demo to the patient.
- The patient will take a wireless reading from their PA sensor once a day from the comfort of their home. Daily data transmissions are also easily done while traveling in the United States.
- Pressure data from this daily wireless reading is transmitted to a secure website for the physician and clinical team to review.
- Pacemakers, implantable cardioverter defibrillators and ventricular assist devices can work in conjunction with the PA sensor and will not affect the performance of the system.
- If a patient decides they do not want to continue, or cannot continue, transmitting data, they can stop. However, the sensor will remain in their PA with no risk to the patient.



1. Abbott. Data on File. 90305907 Rev. A. The CardioMEMS™ HF System Workflow Research. May 2017.
2. Abbott. Data on File. Adapted from: “CardioMEMS HF System Clinical Protocol Example, Philip B. Adamson, MD, MSc, FACC, Medical Director at Abbott, and former Director Heart Failure Institute at Oklahoma Heart Hospital, shares his experience with patient management of heart failure using PA Pressure.”
3. Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial. *The Lancet*. 2011;377(9766):658-666.

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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.

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