

LEARNING ABOUT THE CARDIOMEMS™ HF SYSTEM

FREQUENTLY ASKED QUESTIONS

WHAT IS THE CARDIOMEMS HF SYSTEM?

The CardioMEMS™ HF System is the first and only FDA-approved heart failure monitor proven to significantly reduce heart failure hospital admissions and improve quality of life.¹ In the clinical trial, it was demonstrated that use of the device helped to reduce heart failure hospitalizations by 33%.¹

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.

HOW DOES THE CARDIOMEMS HF SYSTEM HELP A HEART FAILURE PATIENT?

Changes in PA pressures are an early indicator of worsening heart failure, even before the patient notices symptoms such as shortness of breath or weight gain.

The CardioMEMS HF System comes with an electronics unit used at home to take daily measurements of PA pressures. These PA pressure readings are sent wirelessly to a secure website for the clinician to review. This allows adjustment of medications without the need for a hospital or clinic visit.

IS THE CARDIOMEMS HF SYSTEM FDA APPROVED?

Yes, the CardioMEMS HF System is the first and only FDA-approved wireless heart failure monitor.

WHO CAN GET THE CARDIOMEMS HF SYSTEM?

Patients who have NYHA Class III heart failure and have had a heart failure hospitalization in the last 12 months are eligible for the CardioMEMS HF System.

WHO CANNOT GET THE CARDIOMEMS HF SYSTEM?

The CardioMEMS HF System is not indicated for patients who are unable to take dual antiplatelet or anticoagulants for one month after the implantation of the PA sensor.

WHAT RISKS ARE ASSOCIATED WITH THE CARDIOMEMS HF SYSTEM?

Although complications are very rare, risks associated with the implantation of a PA sensor include arrhythmias, bleeding, death, device embolization, hematoma, infection, myocardial infarction, stroke, thrombus and transient ischemic attack.

HOW IS THE CARDIOMEMS™ PA SENSOR IMPLANTED?

The CardioMEMS™ PA Sensor is inserted into the PA during a right heart catheterization procedure.

The doctor will make a small incision and insert a device called a catheter into the femoral vein. Using a fluoroscope (a type of X-ray) to visually guide the placement of the device, the doctor will thread the catheter through the body to the heart and into the PA. Once the catheter is in the right position, the sensor is released into the artery, where it remains permanently. Patients may feel some mild discomfort at the access site during recovery, but should be able to return to normal activities soon after the procedure.

IS THE CARDIOMEMS HF SYSTEM COMPLICATED TO USE?

The system is easy to use and patients will be trained to use the system before they are released from the hospital. The system also comes with an instructional DVD and a user's guide.

HOW BIG IS THE CARDIOMEMS PA SENSOR?

The PA sensor is shorter than the width of a dime and has two thin wire loops at each end.

HOW LONG DOES THE CARDIOMEMS PA SENSOR LAST?

The PA sensor does not need a battery or replaceable parts and is intended to last the lifetime of the patient.

CAN A MAGNETIC RESONANCE IMAGING (MRI) SCAN BE DONE WITH THE PA SENSOR?

Patients can have an MRI scan under certain conditions. Talk with the doctor ordering the MRI scan to ensure that he or she knows that you have a CardioMEMS PA Sensor.

WILL THE PA SENSOR INTERFERE WITH A PACEMAKER OR AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD)?

No, the PA sensor will not interfere with a pacemaker or an ICD, even when a reading is being taken.

CAN PATIENTS TRAVEL WITH THE CARDIOMEMS HF SYSTEM?

Yes, patients can travel with the CardioMEMS HF System. The home electronics system can be packed in its carrying case and checked as luggage. The PA sensor should not alert airport security when a patient passes through the security checkpoint. A travel letter is available to address any concerns that may arise with TSA, when traveling with your home electronics system.



WHERE CAN A POTENTIAL PATIENT FIND OUT WHAT IT IS LIKE FOR PEOPLE TO LIVE WITH THE CARDIOMEMS™ HF SYSTEM FROM PEOPLE WHO HAVE BEEN IMPLANTED?

Many patients have shared their stories about how the CardioMEMS™ HF System has impacted their lives. You can view these by visiting www.StayAheadofHF.com.

WHERE CAN A POTENTIAL PATIENT GET THE CARDIOMEMS HF SYSTEM?

There are many centers nationwide that are implanting the CardioMEMS HF System. For a list of centers, visit www.StayAheadofHF.com.

IS THE PROCEDURE COVERED BY HEALTH INSURANCE OR MEDICARE?

The procedure may be covered by health insurance or Medicare. When you speak to the medical center, after they determine you are a candidate, they can help explain your coverage options.

HEART FAILURE

WHAT IS HEART FAILURE?

Heart failure is a widespread, serious and progressive disease that develops when the heart muscle is unable to pump a sufficient amount of blood throughout the body. Left untreated, the inadequate blood flow causes the organs to progressively fail. This results in numerous medical complications which reduces quality of life and often leads to death.

HOW COMMON IS HEART FAILURE?

Heart failure is very common. According to the Heart Failure Society of America, nearly 6.5 million Americans over the age of 20 have heart failure. One major study estimates there are 960,000 new heart failure cases annually.²

IS THERE A CURE FOR HEART FAILURE?

No. Heart failure is a chronic disease needing lifelong management. However, with treatment, signs and symptoms of heart failure can improve.³

WHAT ARE THE TREATMENT OPTIONS FOR HEART FAILURE?

Depending on the severity of heart failure, there may be many treatment choices that can help patients live longer and feel better. In the early stages, a healthy lifestyle and medicines can be enough to control the symptoms of heart failure. If heart failure has progressed to advanced stages, this approach may not be enough. The next steps for treatment may include cardiac resynchronization therapy, PA pressure monitoring, heart transplantation and/or a heart pump called a left ventricular assist device to help your heart pump blood.

WHERE CAN ONE GO TO FIND OUT MORE INFORMATION ON HEART FAILURE?

Visit www.StayAheadofHF.com for more information on heart failure.

1. Abraham WT, Stevenson L, Bourge RC, Lindenfeld J, Bauman J, Adamson PB. Sustained efficacy of pulmonary artery pressure to guide to adjustment of chronic heart failure therapy: Complete follow-up results from the CHAMPION randomized trial. *The Lancet*. 2016;387(10017):453-461. [https://doi.org/10.1016/S0140-6736\(15\)00723-0](https://doi.org/10.1016/S0140-6736(15)00723-0).
2. How Common is heart failure? Heart Failure Society of America Web site. <https://www.hfsa.org/patient/learn/>. Accessed on October 31, 2018.
3. Heart failure Diagnosis and Treatment. Mayo Clinic Web site. <https://www.mayoclinic.org/diseases-conditions/heart-failure/diagnosis-treatment/drc-20373148>. Accessed on October 22, 2018.

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St. Jude Medical is now Abbott.

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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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