

A man with a beard and mustache, wearing a bright green polo shirt and grey trousers, stands in profile looking out a large window. The view outside shows a well-maintained garden with a stone pond, several poinsettia plants in pots, and tall, thin evergreen trees. The scene is bright and clear, suggesting a sunny day.

LIVING WITH YOUR
CardioMEMS™ HF System



ST. JUDE MEDICAL®



YOUR GUIDE TO HEART FAILURE AND THE CardioMEMS™ HF System



Heart failure (HF) is a common condition that results from damage to the heart. This damage makes it difficult for the heart to pump enough blood to your body. Often heart failure is a progressive disease that gets worse over time.

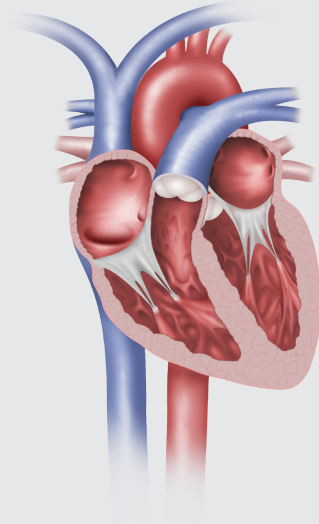
Historically, heart failure has been one of the most common reasons for hospitalizations in people over 70 years of age. If you're diagnosed with heart failure, your doctor may monitor your weight and blood pressure or prescribe several different medications and even recommend a cardiac resynchronization therapy device, or CRT. Now, there's a new tool that will help your heart failure team understand how your pulmonary artery pressures (which are reflective of your heart failure condition) are responding to different therapies, such as medications, lifestyle changes, or CRT. It's called the CardioMEMS™ HF System, and your doctor may recommend that you get and use this system.

The CardioMEMS HF System features a sensor that was designed to measure and record the pressures in your pulmonary artery (PA). Studies show that PA pressure is a good indicator of worsening heart failure, and patients whose clinicians used the CardioMEMS HF System actually had fewer hospitalizations than patients who did not.

This handbook will answer some of your questions, tell you how the system operates and what to expect during and after the implant of the sensor. If you have more questions after reading, please discuss them with your doctor.

How Your Heart Works

Your heart is a muscle that pumps blood throughout your body. It has four chambers. The upper chambers are called atria (left and right) and the lower chambers are called ventricles (left and right). The right side of the heart receives “used” blood coming back from the body and pumps the blood to the lungs, where it picks up oxygen. Blood then returns to the left side of the heart, which in turn pumps the blood to the rest of the body.



What Is Heart Failure?

The Centers for Disease Control (CDC) defines heart failure as “a condition in which the heart can’t pump enough blood to meet the body’s needs. In some cases, the heart can’t fill with enough blood. In other cases, the heart can’t pump blood to the rest of the body with enough force. Some people have both problems.”

HOW COMMON IS HEART FAILURE?

Heart failure affects about 5.1 million Americans, with 670,000 new cases diagnosed each year.

What Causes Heart Failure?

Heart failure has many underlying causes. Coronary artery disease (CAD) causes about half of all HF cases. CAD is a disease of the arteries that deliver blood to the heart muscle to keep it working and healthy. Another common cause is untreated high blood pressure (hypertension), which can make the heart work harder to do its job. Other root causes include persistent abnormal heart rhythms (such as atrial fibrillation), heart valve disease, congenital heart disease, diabetes and infections of the heart. In many cases, the cause is unknown.

Symptoms of Heart Failure

It's important to talk to your doctor when you experience any of the following symptoms. These can quickly lead to problems that require a hospital stay. But by being aware of these symptoms, you can help control your health:

Fatigue, Loss of Energy

You may find that you get very tired from very little effort, like walking up the stairs or doing your daily chores.

Shortness of Breath

You might have the sensation of “not getting enough air” or become more short of breath with exertion. You may awaken abruptly at night with a sensation of shortness of breath or feel the need to sit up to sleep. You may also experience a frequent, dry cough that is made worse when you lie down.

Weight Gain

Weight gain over several days in a row is a common sign that there is fluid buildup in the body. You may experience a weight gain of 3 pounds or more before you notice any swelling or shortness of breath.

Swelling

You may notice swelling of your feet, legs or abdomen. This is usually worse later in the day and in the lowest part of your body. Swelling occurs because the extra fluid seeps into the tissues from the small blood vessels. You may notice that your shoes, socks or pants are fitting more tightly by evening.

Loss of Appetite or Bloating Sensation

Many people with heart failure notice retention of fluid in the abdomen. When this happens, you may experience a distended or bloated sensation. You may also experience loss of appetite or even an upset stomach. When this is the case, medicines may not be absorbed as well and therefore will not work as effectively.

Decreased Urination During the Day, Increased Urination at Night

The heart works harder during the day than at night, when you are at rest. This leads to less urine production during the day. When you are sleeping the work of the heart is lessened, which allows the kidneys to make more urine.

Managing Your Heart Failure

By managing your heart failure, you can decrease the impact it has on your daily life. Making changes in your food selections and daily activities, taking the medications your doctor prescribes, and measuring your PA pressures can all make a major difference in how you feel.

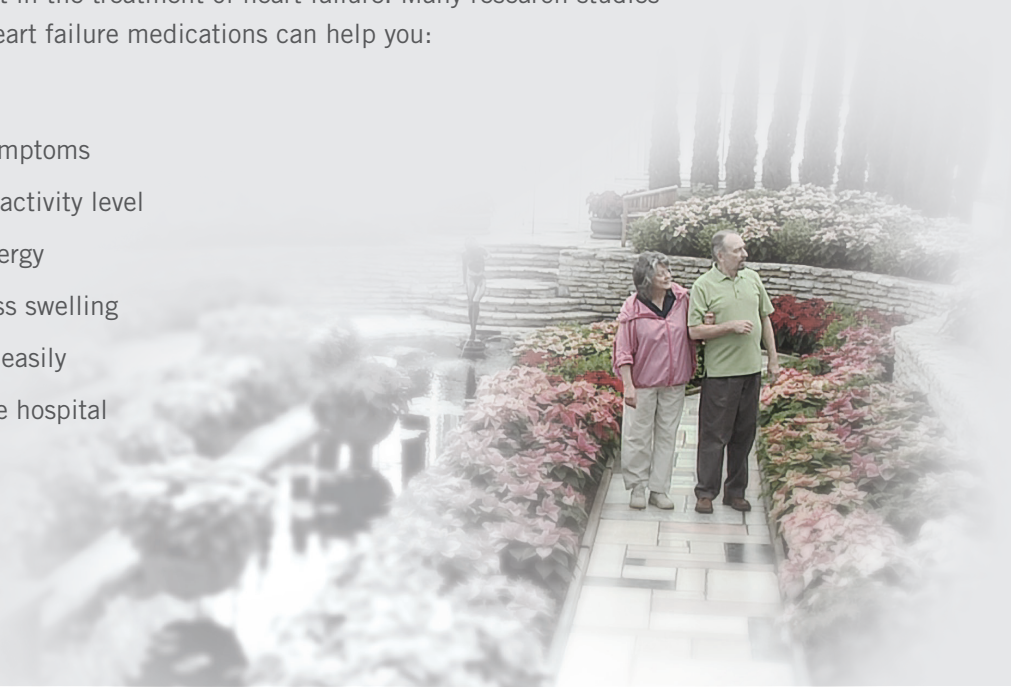
HOW CAN THE CARDIOMEMS™ HF SYSTEM HELP?

The pressures in the vessels around your heart change before you feel any of the symptoms of heart failure. The CardioMEMS™ PA Sensor detects these changes in PA pressure. Your doctor can use these pressures to adjust your medications and suggest different lifestyle choices. By keeping your pressures lower, your doctor can reduce your chances of developing new symptoms or going to the hospital.

Medications

Drugs are important in the treatment of heart failure. Many research studies have proven that heart failure medications can help you:

- Live longer
- Have fewer symptoms
- Increase your activity level
- Have more energy
- Experience less swelling
- Breathe more easily
- Stay out of the hospital



Where does the CardioMEMS™ HF System fit in?

By measuring your PA pressure on a regular basis, you're providing your doctor with the information he or she needs to adjust your medications and lifestyle choices before symptoms get in the way of your life or your health. The CardioMEMS™ HF System is a valuable tool that helps your physician personalize your care.

Lifestyle choices that can impact your heart health

Sodium

It's important to decrease the amount of sodium you eat because heart failure causes your body to hold onto extra sodium. This, in turn, causes extra fluid to build up and can lead to swelling of the ankles, feet or abdomen, shortness of breath or weight gain.

Alcohol

Alcohol decreases the strength of the heart's contractions. With a muscle that is already weak, such as in heart failure, this can negatively affect your heart. Limit alcohol to one drink or less per day.

Tobacco

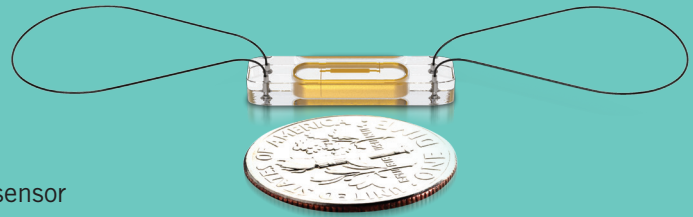
Tobacco products (cigarettes, chewing tobacco, etc.) contain nicotine, a chemical that causes blood vessels to become narrower. This raises blood pressure and pulse rate, making more work for your already weakened heart. Avoid tobacco products altogether.

Exercise

Your heart is a muscle and it benefits from exercise, just like any other muscle in your body. Activity can help you feel better, decrease your symptoms and improve your heart's function. Ask your doctor about a walking program that will help you build your tolerance for exercise.

Your Implant Procedure

The CardioMEMS™ PA Sensor is no bigger than the size of a dime, with two thin loops at each end. This sensor does not have any batteries or wires. The sensor will be placed in the pulmonary artery (the blood vessel that moves blood from your heart to your lungs), and it will send information through a bedside electronics unit directly to a secure website your doctor can access.



You may receive a mild sedative before and/or during the procedure, but you will be awake so you can follow instructions. A nurse will clean an area on your upper thigh and a local anesthetic will be injected at that site. An electrocardiogram (EKG) will constantly monitor your heart rate and rhythm.

Your doctor will make a small incision and insert a device called a catheter into your femoral vein. Using a fluoroscope (a type of x-ray), he or she will thread the catheter through your body to your heart and into your pulmonary artery. The doctor will check that the catheter is in the right position and release the sensor into your artery. The doctor will then hold an antenna to your back, chest or side to make sure that it can read the signals from the sensor.

The length of the procedure depends on your specific anatomy and the time it takes to locate a good position for the sensor. After it is complete, you may be asked to lie flat on your back for a few hours to prevent bleeding. You may feel some mild discomfort at the injection site as you recover. You should be able to return to normal activities soon after the procedure.

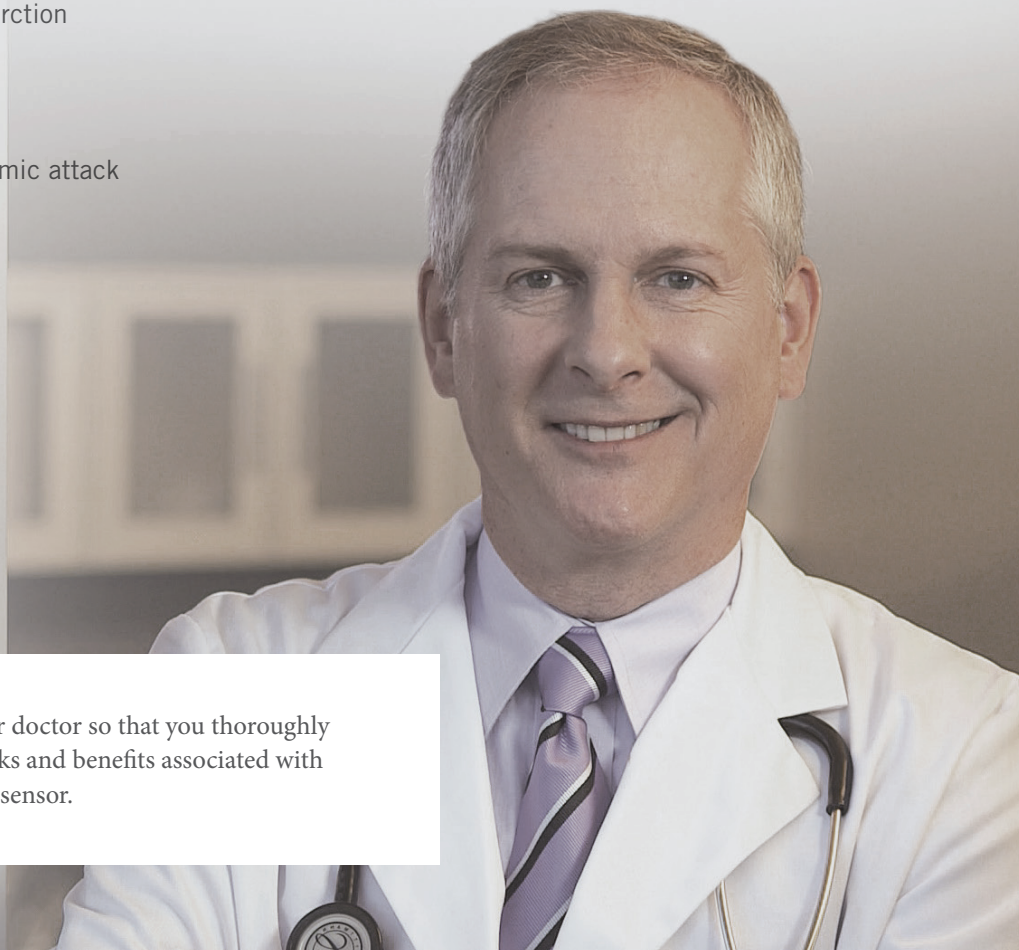
Your PA sensor is permanently implanted. You will not feel it, and it will not interfere with your daily activities. The sensor will not interfere with other devices you may have such as a pacemaker or defibrillator.

Implant Risks

As with any medical procedure, there are risks associated with the implantation of a sensor, although complications are very rare. Some of these risks include:

- Arrhythmias
- Bleeding
- Death
- Device embolization
- Hematoma
- Infection
- Myocardial infarction
- Stroke
- Thrombus
- Transient ischemic attack

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the implantation of this sensor.



After Your Implant Procedure

As you recover from your implant procedure, it is important that you follow your doctor's instructions, including:

- Report any redness, swelling or drainage from the insertion site.
- Walk, exercise, and bathe according to your doctor's instructions.
- Contact your doctor if you develop a fever that does not go away in two to three days.
- Ask your doctor any questions you have about your device, heart failure or your medication.

You will receive training about how to set up and take readings with your Patient Electronics System before you go home. A customer service representative will be available should you have any questions after you are home, or you can refer to the Patient Electronics System video.

Identification Information About Your Sensor

Your doctor or nurse will complete a temporary patient identification card before you leave the hospital. A permanent card will be mailed to you within a few weeks of discharge. This card provides information about the sensor to health care professionals so it can be identified correctly if you need a chest x-ray, CT scan, MRI or other testing.

The patient identification card will contain your name, your doctor's name and the serial number of your sensor. Always carry your patient identification card with you. It will alert medical and security personnel that you have an implanted sensor.

Your CardioMEMS™ At-Home System

Taking PA pressure readings should be part of your daily routine. It will take only a few minutes each morning. If you are having trouble obtaining a signal or it is taking longer than usual, please contact Technical Support.

Your Patient Electronics System is portable but most patients set it up in their bedroom for maximum efficiency. Electric blankets and waterbeds can cause interference with the system. If you have either an electric blanket or a waterbed, you may want to take your reading in another room.

Electromagnetic interference from theft detection systems, airport security systems, etc., could make it difficult to take sensor readings. However, it is highly unlikely that you would be taking a reading when you are close to these devices.



Antenna

The antenna is paddle-shaped and is placed inside a pillow to make it easier and more comfortable for you to take readings.

Patient Electronics Unit

The Patient Electronics Unit reads the pressure measurement from your sensor wirelessly. For instructions on setting up the system, refer to the CardioMEMS™ Patient Electronics System guide that was included with the system.

For technical support, call 1-877-696-3754.

To learn more about Heart Failure and the CardioMEMS™ HF System, please visit HeartFailureAnswers.com

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HeartFailureAnswers.com



Rx Only

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.

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