**CARDIOMEMS TECHNOLOGY**

**Fact Sheet**

**WHAT IS HEART FAILURE?**
When the heart is unable to pump enough blood to meet the body’s demands, blood pressure within the heart is elevated, leading to heart failure (HF). Significant HF progression over a period of days is known as acute decompensation and leads to hospitalization. According to the American Heart Association, the estimated direct and indirect cost of HF in the U.S. for 2012 was $31 billion and that number is expected to more than double by 2030.

**HOW CAN HEART FAILURE BE MONITORED?**
Directly measuring pulmonary artery pressure (PA) pressure via a procedure called a right-heart catheterization is a standard-of-care practice for managing worsening HF in patients who have been hospitalized. However, since HF is a chronic disease, most days are spent outside the hospital. Therefore, clinicians use a number of indirect markers to monitor HF, including:

- Patient self-monitoring with equipment such as blood pressure cuffs and electronic scales.
- In-clinic devices used by health care providers during frequent office visits.
- Implantable devices that alert patients when they detect impedance changes across the thoracic cavity that may be indicative of fluid accumulation in the chest.

In recent years health professionals have found that self and in-clinic monitoring, which are limited by poor sensitivity to detecting subtle HF changes, have resulted in increased admissions to the hospital. In 2013, the Centers for Medicare & Medicaid Services (CMS) began penalizing hospitals in an effort to eliminate unnecessary readmissions and other events following a HF patient’s discharge. CMS is also incentivizing hospitals that are able to provide care that avoids complications following an HF discharge, which ultimately results in a lower cost per patient. Still, further changes are on the horizon for physicians’ individual treatment of HF patients. These outcomes may directly impact physician fees paid by the Medicare program as early as 2015. Thus, there has been a rapidly expanding need for emerging sensing technologies designed to broaden the standard of care for outpatient HF monitoring.

**HOW DOES THE CARDIOMEMS TECHNOLOGY WORK?**
The CardioMEMS™ HF System uses a miniaturized, wireless monitoring sensor that is implanted in the pulmonary artery during a minimally invasive procedure to directly measure PA pressure. The system allows patients to transmit PA pressure data from their homes to their health care providers allowing for personalized and proactive management to reduce the likelihood of hospitalization.

The implantable sensor is a completely sealed capsule that uses microelectromechanical systems (MEMS) technology, which allows the creation of sensors with measurement stability and energy efficiency. All of the sensor components are made of materials that have been chosen for their durability, robustness, biocompatibility, and insensitivity to changes in body chemistry or biology. The sensor is powered by radio frequency (RF) energy. It is implanted into the pulmonary artery using minimally invasive techniques via a catheter and is designed to last the lifetime of the patient.
The sensor does not have a battery or leads and is very small. Once implanted, the sensor wirelessly sends pressure readings to the external patient electronic system. There is no pain or sensation for the patient during the readings. The electronics transmit the readings to a secure website where it can be seen by the patient’s clinician.

**The external measurement system** wirelessly tracks frequency and uses it to determine the pressure in the pulmonary artery.

At home, HF patients use a portable electronic unit and a special pillow containing an antenna to take daily sensor readings. This is a simple process that takes only a few minutes. The patient’s electronic unit is turned on and the patient lies on the pillow. The electronic unit uses audible signals telling the patient to press the button to initiate a reading. The pressure readings are then wirelessly transmitted to a secure website.

Clinicians access patients’ pressure readings and trending data transmissions using the patient management website, providing valuable clinical insight for guiding treatment decisions. Automated alerts will be sent to health care providers if pressure readings fall outside of prespecified ranges.

The CardioMEMS HF System is a game-changing technology that creates a major opportunity for improving outcomes in chronic HF disease management. The system has several advantages including measuring a direct marker of HF progression, the ability to monitor daily HF status without the need to be in the clinic, and the capability to automatically transmit important data to the clinician’s office.

**WHAT IS THE POTENTIAL IMPACT OF THE CARDIOMEMS HF SYSTEM?**

The CardioMEMS HF System is the first and only FDA-approved HF monitoring device that has been proven to significantly reduce hospital admissions when used by physicians to manage heart failure, and improve quality of life in NYHA class III HF patients who have been hospitalized in the previous 12 months. More than 5 million Americans have HF with 670,000 new cases diagnosed each year. Roughly 1.4 million patients in the U.S. have NYHA Class III HF, and historically these patients account for nearly half of all HF hospitalizations.

**WHAT IS THE LABELED INDICATION FOR THE CARDIOMEMS HF SYSTEM?**

The CardioMEMS HF System is indicated for wirelessly measuring and monitoring 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.

The CardioMEMS HF System is used by the physician in the hospital or office setting to obtain and review PA pressure measurements. The CardioMEMS HF System is used by the patient in the home or other remote location to wirelessly obtain and send hemodynamic and PA pressure measurements to a secure database for review and evaluation by the patient’s physician.

**HOW IS THE CARDIOMEMS TECHNOLOGY UNIQUE?**

St. Jude Medical is at the forefront of developing transformative medical solutions that are changing the way medicine is practiced around the world. The CardioMEMS HF System includes a miniature wireless sensor that is implanted into the pulmonary artery using catheter-based procedure. The sensor transmits blood pressure and heart rate data from inside the
body. The CardioMEMS system allows clinicians to stabilize PA pressures by proactively managing medications and other treatment options while also providing an early indication of worsening HF.

St. Jude Medical has a 19 percent ownership of CardioMEMS and intends to exercise its exclusive option to purchase the remaining portion of the company.