Heart Failure
Fact Sheet

WHAT IS HEART FAILURE?
Heart failure (HF) occurs when, for any number of reasons, the heart is unable to pump enough blood to meet the body’s demands. When this occurs, blood pressure within the heart and lung blood vessels increase eventually leading to congestive symptoms and commonly to shortness of breath.

Approximately 90 percent of patients admitted to a hospital for HF have pulmonary congestion (excess fluid). Episodes of pulmonary congestion can lead to a downward spiral of progressive cardiac deterioration and mortality.

WHAT IS THE IMPACT OF HEART FAILURE ON AMERICANS?
An estimated 5 million Americans suffer from HF. 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.

Over half of HF costs are due to hospitalization and there are more than 1 million HF admissions each year. By 2030, every U.S. taxpayer could pay $244 each year for HF expenses.

FAST FACT
The estimated U.S. heart failure cost in 2012 was $31 billion and is estimated to swell to $70 billion in 2030.

WHAT HAPPENS WHEN YOU HAVE HEART FAILURE?
Heart failure occurs when the heart is not pumping as well as it should be and therefore the weakened heart cannot supply cells with enough blood. This results in:

- shortness of breath
- trouble breathing
- fatigue
- swelling

Patients with HF are frequently hospitalized, have a reduced quality of life and face a higher risk of death.

WHAT CAUSES HEART FAILURE?
There are many underlying causes of HF. In the U.S., about 50 percent of HF is caused by coronary artery disease. Other causes include high blood pressure, persistent cardiac arrhythmias (such as atrial fibrillation), heart valve disease, congenital heart disease, diabetes, and infections and diseases of the heart muscle itself.
HOW IS HEART FAILURE TYPICALLY TREATED?

Heart failure typically is treated first with changes in lifestyle and a combination of drugs, which tend to be more effective when the disease is in its earlier stages. When these treatments are no longer able to effectively manage HF, other procedures are required. These procedures range from minimally invasive procedures to highly invasive surgery.

- **Pharmacology** — Medications that are proven to reduce mortality in HF patients include angiotensin converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs) and beta-blockers.

- **Stenting, balloon angioplasty and bypass surgery** — When coronary artery disease is the cause of the heart failure, balloon angioplasty, stenting and bypass surgery can treat the underlying problem and sometimes relieve HF symptoms.

- **Device therapy** — Some patients can be treated using cardiac resynchronization therapy (CRT). CRT involves pacing in three chambers of the heart (rather than one or two chambers). A CRT device paces the right atrium (RA) and right ventricle (RV), plus the left ventricle (LV). The goal of CRT is to synchronize the two ventricles (RV and LV) for optimal contraction. CRT can be provided through either a pacemaker or an implantable cardioverter defibrillator (ICD) — which offers an additional measure of safety to the patient should he or she be at risk for sudden cardiac arrest.

- **Heart transplant** — Heart transplants can cure HF, but are only performed in about 1 percent of patients with advanced HF, due to the scarcity of donor organs, invasiveness of the procedure, and the high cost of the procedure. As a result, while waiting for a transplant, some patients receive a left ventricular assist device (LVAD), which is a mechanical pump that assists the heart.

HOW HAS HEART FAILURE TYPICALLY BEEN MONITORED?

There are several ways to monitor HF in patients, including:

- Directly measuring pulmonary artery (PA) pressure via a right-heart catheterization procedure, which is the standard of care for managing worsening HF in hospitalized patients.

- 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.

Despite advances in medical therapy, measuring HF status with daily self-monitoring is unsuccessful, showing:

- 25% of HF patients are readmitted to the hospital within 30 days, and

- 50% of HF patients are readmitted to the hospital within six months.

In several clinical trials, health care 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 and added economic burden on the health care system.

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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 a 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 HELP CLINICIANS TO BETTER MANAGE HEART FAILURE?

Clinicians can directly measure pulmonary artery (PA) pressure from inside the body with the CardioMEMSTM HF System. 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 and the pressure readings are then wirelessly transmitted to a secure website. Clinicians use that data to stabilize PA pressures by proactively managing medications and other treatment options while also providing an early indication of worsening HF.

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.

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.

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