Device gives early warning on heart failure

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Joe Jones has been hospitalized half a dozen times for heart failure.

Most recently, he was discharged from the hospital on his birthday, Dec. 30. But Jones, 56, knew from experience that it wouldn't be long before he felt that familiar shortness of breath again and would have to go back to the emergency room.

He decided not to wait for another emergency. Instead, he went in for a 30-minute procedure last week to get a new diagnostic device called CardioMEMS permanently threaded into the pulmonary artery near his heart, becoming the first patient in the Twin Cities to get the device following a lengthy approval process from the U.S. Food and Drug Administration.

The tiny batteryless gadget, made by St. Jude Medical, can detect signs of impending heart failure events before they devolve into stressful and costly emergencies.

"It might keep me out of the hospital," Jones said hopefully from his bed.

CardioMEMS was held up for years at the FDA, as experts debated the safety of implanting the device and whether the underlying clinical trial was biased. The rate of complications from implantation was eventually judged to be minimal, and the FDA cleared the device last May.

Now St. Jude is hoping that thousands of patients - many thousands, in

fact - will follow in Jones' lead.

"Our hope and belief is that this will become standard of care," said Dr. Mark Carlson, chief medical officer for St. Jude. "We believe that this device and the therapeutic approach associated with this device will transform the care of heart failure."

At least 5.5 million Americans have heart failure, and 500,000 new cases are diagnosed each year. Heart failure is a common condition that occurs when the heart doesn't pump as much blood as it should, creating shortness of breath and fatigue. Although most patients are hospitalized after they feel physical symptoms, clinical studies found that CardioMEMS can accurately detect small changes in blood pressure between the heart and lungs that predict an impending crisis.

By adjusting prescription-drug intake and diet based on same-day readings, patients with CardioMEMS were 37 percent less likely to be hospitalized than those who had a device implanted but didn't have active monitoring of their data, a company-sponsored study found. The reduction was much steeper when looking only at patients over age 65, which is relevant to hospitals facing steep penalties when too many Medicare patients are readmitted for heart failure symptoms.

"Those numbers catch the attention of hospital administrators, as well they should," Carlson said.

St. Jude is projecting $70 million in revenue this year from the device, and Wells Fargo analyst Dr. David Y. Brill said sales could hit $192 million by 2017. The company is not commenting on reports that each device costs roughly $20,000, though it celebrated the news last August that Medicare had bumped up funding to pay for it. Jones said his private insurance plan covered his device.

When analyst Mike Matson at Needham & Co. summarized St. Jude's sales prospects for 2015, he called CardioMEMS "clearly the biggest potential growth driver" for the company. He estimated sales this year would hit $90 million, based on the fact that St. Jude had 90 sales contracts already from a pool of 325 heart failure clinics around the country targeted for sales.

CardioMEMS is a first-of-its-kind device on the market, according to the FDA, although Medtronic has a similarly small implantable diagnostic device called the Reveal Linq that measures cardiac rhythm in patients with unexplained fainting. Analysts see Linq as a near-term revenue-driver at Medtronic as well.

The St. Jude device was developed by an Atlanta-based company called CardioMEMS, which St. Jude acquired last year for $375 million just after the FDA approved the device. St. Jude had already invested $60 million for the exclusive right to buy the company following FDA approval.

The device itself is just slightly larger than a standard USB port on a computer, and it includes two nickel-titanium wires that protrude like moth wings to secure the device in a patient's pulmonary artery until it gets covered with tissue that permanently embeds it in the body. It has no battery. Rather, the energy to trigger a reading from the device comes from a "wand" embedded in a special mat that a CardioMEMS patient lies on at home. The readings are sent to a company website, where doctors can view it in real time.

"The wand has the radio-frequency energy in it, and that excites the sensor to generate the wave form" that contains the blood-pressure reading, said Dr. Steven Goldsmith, of the hospital where Jones' procedure was performed. "So, no moving parts, nothing to wear out."

Brian Anderson said that's good news to him.

Anderson, 54, has been hospitalized for heart failure at least five times, including twice in January and once this month. His heart pumps at about 30 percent capacity today, after a major heart attack last July.

"When I call 911, they come to me real quick," he quipped just before he became one of three patients to get CardioMEMS last week, along with Jones. "If it will keep me out of the hospital, I'm all for it."

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