WHAT IS THE CHAMPION CLINICAL TRIAL?
The CHAMPION (“CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Patients”) Trial, sponsored by CardioMEMS, was designed to study the safety and effectiveness of the CardioMEMS™ HF System. The trial studied patients with class III heart failure (HF), per the New York Heart Association (NYHA) Function Classification System, who had been hospitalized for HF in the previous 12 months.

NYHA class III HF includes patients with cardiac disease resulting in marked limitation of physical activity. They may be comfortable at rest, but less than ordinary activity causes fatigue, shortness of breath and chest pain.

The first patient enrolled in the trial was implanted with the CardioMEMS HF System in 2006, during the feasibility phase of the clinical trial. Early results from the feasibility phase were reviewed by the U.S. Food and Drug Administration (FDA) and the trial was expanded to a randomized, controlled, pivotal study in July 2007.

All 550 participants in the study were implanted with the CardioMEMS sensor and all patients took a daily reading. During the first phase of the trial, participants in the investigational group were treated by their physician based on pulmonary artery (PA) pressure data, captured by the CardioMEMS HF System. Participants randomized to the control group had the device implanted and took daily readings; however, data from the device was not made available for treatment decisions. During the second phase of the trial, physicians were then able to access data readings from all participants, including those in the control group.

RESULTS OF THE CHAMPION CLINICAL TRIAL
The primary endpoint was the rate of HF hospitalization, secondary endpoints included change in PA pressure, number of patients admitted to the hospital for HF, days alive outside of the hospital and quality of life as measured by the Minnesota Living with Heart Failure Questionnaire.

With approximately 1,200 patient years of data, results showed that over time, compared to the control group, patients managed with PA pressure monitoring had:

- Significantly fewer HF-related hospitalizations
  - 28 percent reduction at six months
  - 37 percent reduction at 15 months
- Significant improvement in quality of life
- Persistently lower mean PA pressures over the treatment period
- More medication changes

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.