myCardioMEMS™ Application for the CardioMEMS™ HF System

PATIENT SELECTION TOOL

Patient selection is a key to success with the myCardioMEMS app. When considering patients for use of the app, use this assessment tool as a guide.

<table>
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<th>SELECTION CRITERIA</th>
<th>ASSESSMENT METHOD</th>
<th>SCORE</th>
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| 1. Patient or caregiver is a smartphone user, with a sufficient technical aptitude to install and utilize a mobile app. | • Smartphone (iPhone® or Android®)  
• Uses other mobile apps (e.g., MyChart, Fitbit) | High 3  
Med 2  
Low 0–1 |
| 2. Patient or caregiver has a cognitive ability to understand and acknowledge notifications and instructions delivered through the app. | • “Teach back” (patients able to successfully repeat back treatment instructions from clinician) | High 3  
Med 2  
Low 0–1 |
| 3. Patient or caregiver has demonstrated a willingness to be engaged in their own care and adhere to treatment instructions from the clinic. | • Patients compliant with instructions from clinic (medication changes, lifestyle instructions, phone calls) | High 3  
Med 2  
Low 0–1 |

Qualified patients: total score = 7+

We recommended that clinicians wait 30 days post-implant to activate the myCardioMEMS app, to allow time to get to know the patient and complete the assessment.
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.

Indications and Usage: The CardioMEMS™ HF System is indicated for wirelessly measuring and monitoring pulmonary artery (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.

Contraindications: The CardioMEMS HF System is contraindicated for patients with an inability to take dual antiplatelet or anticoagulants for one month post implant.

Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to the following: Infection, Arrhythmias, Bleeding, Hematoma, Thrombus, Myocardial infarction, Transient ischemic attack, Stroke, Death, and Device embolization.

Limitations: Patients must use their own Apple® or Android® mobile device to receive and transmit information to the myCardioMEMS™ mobile app. To do so the device must be powered on, app must be installed and data coverage (cellular or Wi-Fi®) available. The myCardioMEMS™ app can provide notification of medication adjustments and reminders, requests for lab work and acknowledgement that the PA pressure readings have been received. However there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of the notifications and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, clinic environment, schedule/configuration changes, or data processing.

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