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CARDIOMEMS™ HF SYSTEM
PATIENT CANDIDATE CONSIDERATIONS

THE CARDIOMEMS™ HF SYSTEM IS INDICATED FOR THESE PATIENTS:[1]

- ☑ NYHA Class III heart failure
- ☑ One heart failure hospitalization in the past 12 months

NOTE: A typical NYHA Class III heart failure patient has marked limitation of physical activity. Less than ordinary activity leads to symptoms (moderate CHF). Doctors commonly look at a Class III patient's heart failure symptoms in the last 30 days.

THE CARDIOMEMS HF SYSTEM IS CONTRAINDICATED FOR THESE PATIENTS

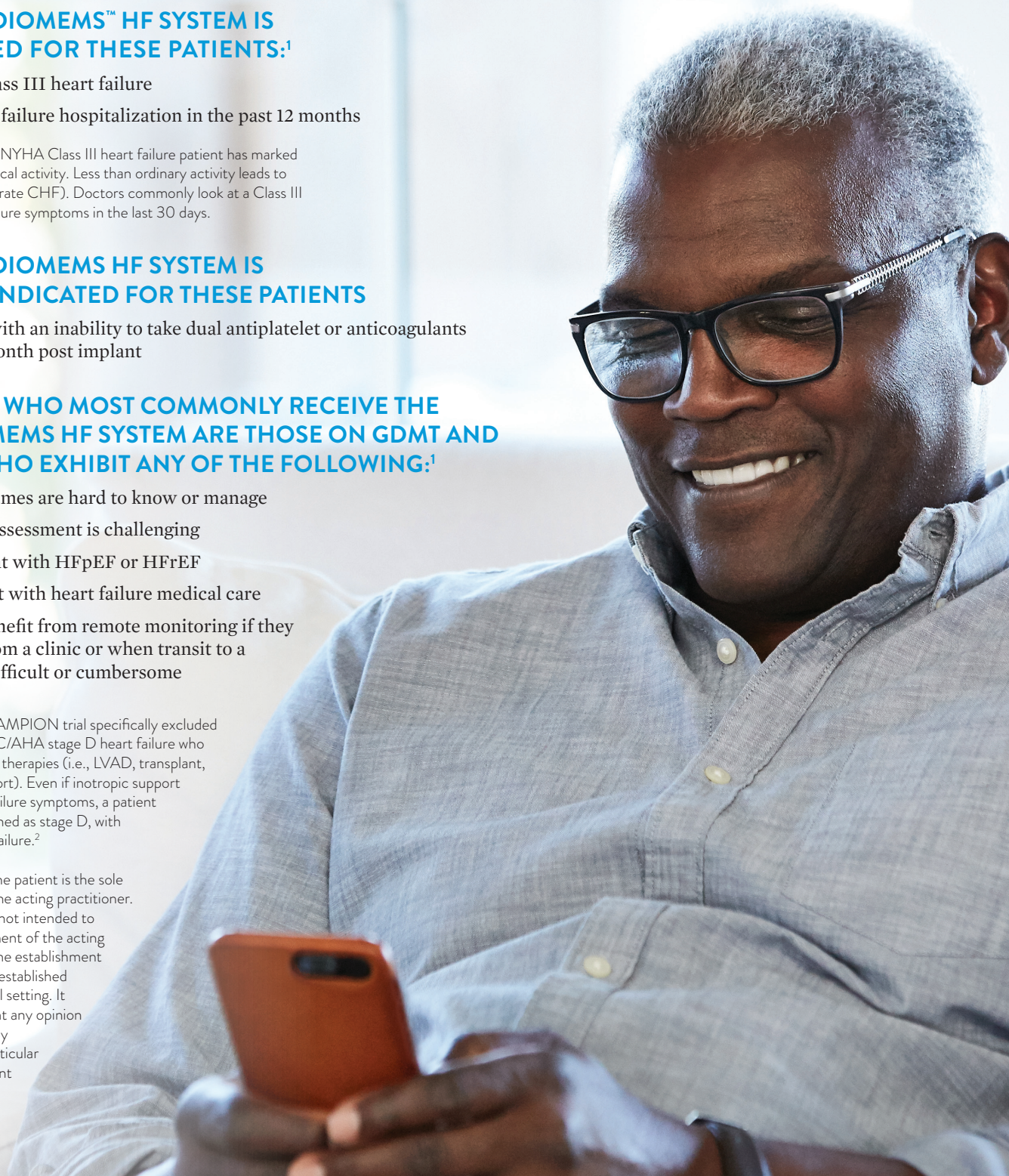
- ☐ Patients with an inability to take dual antiplatelet or anticoagulants for one month post implant

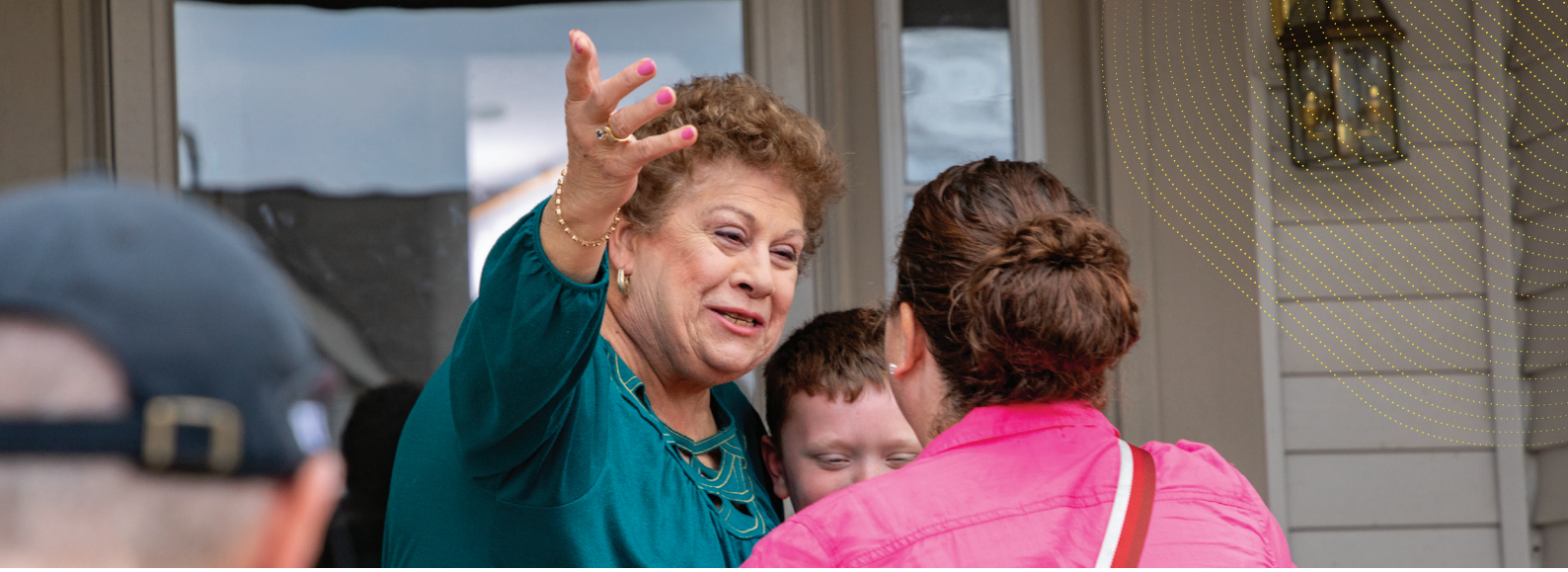
PATIENTS WHO MOST COMMONLY RECEIVE THE CARDIOMEMS HF SYSTEM ARE THOSE ON GDMT AND THOSE WHO EXHIBIT ANY OF THE FOLLOWING:[1]

- ☐ Fluid volumes are hard to know or manage
- ☐ Physical assessment is challenging
- ☐ Is a patient with HFpEF or HFrEF
- ☐ Compliant with heart failure medical care
- ☐ Would benefit from remote monitoring if they live far from a clinic or when transit to a clinic is difficult or cumbersome

NOTE: The CHAMPION trial specifically excluded patients with ACC/AHA stage D heart failure who needed advanced therapies (i.e., LVAD, transplant, or inotropic support). Even if inotropic support improved heart failure symptoms, a patient would still be defined as stage D, with refractory heart failure.[2]

Medical care of the patient is the sole responsibility of the acting practitioner. This document is not intended to replace the judgment of the acting practitioner nor the establishment of final protocols established within the hospital setting. It does not represent any opinion or endorsement by Abbott of any particular approach to patient management or treatment.





TAKE THE GUESSWORK OUT OF HEART FAILURE MANAGEMENT

PROACTIVELY MANAGE HEART FAILURE

Pulmonary artery pressure management allows proactive and personalized heart failure management for your patients, with pressure-guided medication intervention.

IMPROVE QUALITY OF LIFE (QOL)

Give your patients significant improvements in QOL, compared with standard of care heart failure management.

- Improved quality of life across all surveys (KCCQ, PHQ-9, EQ-5D-5L)[3]
- Improved exercise capacity[4]

REDUCE HEART FAILURE HOSPITALIZATIONS

The CardioMEMS™ HF System is more effective in reducing heart failure hospitalizations than signs/symptoms alone.[5]

- Heart failure hospitalizations ↓62% consistent in all predefined subgroups[3]
- All-cause 30-day readmissions ↓58%[6*]

HELP YOUR HFpEF PATIENTS

Provide your preserved EF patients with the CardioMEMS HF System, and significantly reduce their hospitalization risk.

- The CardioMEMS HF System is the first and only device that has shown improvement in this patient population.
- HFpEF heart failure hospitalizations ↓63%[3*]

*Retrospective analysis from the CHAMPION Trial.

1. Abraham WT, Adamson PB, Bourge RC, Aaron MF, Costanzo MR, Stevenson LW, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. The Lancet. 2011;377(9766):658-666.
2. Adapted from: CardioMEMS HF System Clinical Protocol Example, Philip B. Adamson, MD, MSc, FACC, Medical Director at St. Jude Medical, and former Director Heart Failure Institute at Oklahoma Heart Hospital, shares his experience with patient management of heart failure using PA Pressure.
3. https://pubmed.ncbi.nlm.nih.gov/32592227. Angermann CE, Assmus B, Anker SD, et al. Pulmonary artery pressure-guided therapy in ambula- tory patients with symptomatic heart failure: the CardioMEMS European Monitoring Study for Heart Failure (MEMSHF) [published online ahead of print, 2020 Jun 27]. Eur J Heart Fail. 2020;10.1002/ejhf.1943. doi:10.1002/ejhf.1943
4. Alam A, Jermyn R, Joseph M, Patel S, Jorde U, Saeed O. Improved quality of life scores and exercise capacity with remote pulmonary artery pressure monitoring in patients with chronic heart failure. Journal of the American College of Cardiology. 2016;67(13):1299.
5. Costanzo MR, Stevenson LW, Adamson PB, et al. Interventions linked to decreased heart failure hospitalizations during ambulatory pulmonary artery pressure monitoring. Journal of the American College of Cardiology: Heart Failure. 2016;4(5):333-344.
6. Adamson PB, Abraham WT, Stevenson LW, et al. Pulmonary artery pressure-guided heart failure management reduces 30-day readmissions. Circulation: Heart Failure. 2016;7:935-944

ABBOTT
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belgium
Tel: +32 2 774 68 11 | Cardiovascular.abbott

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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