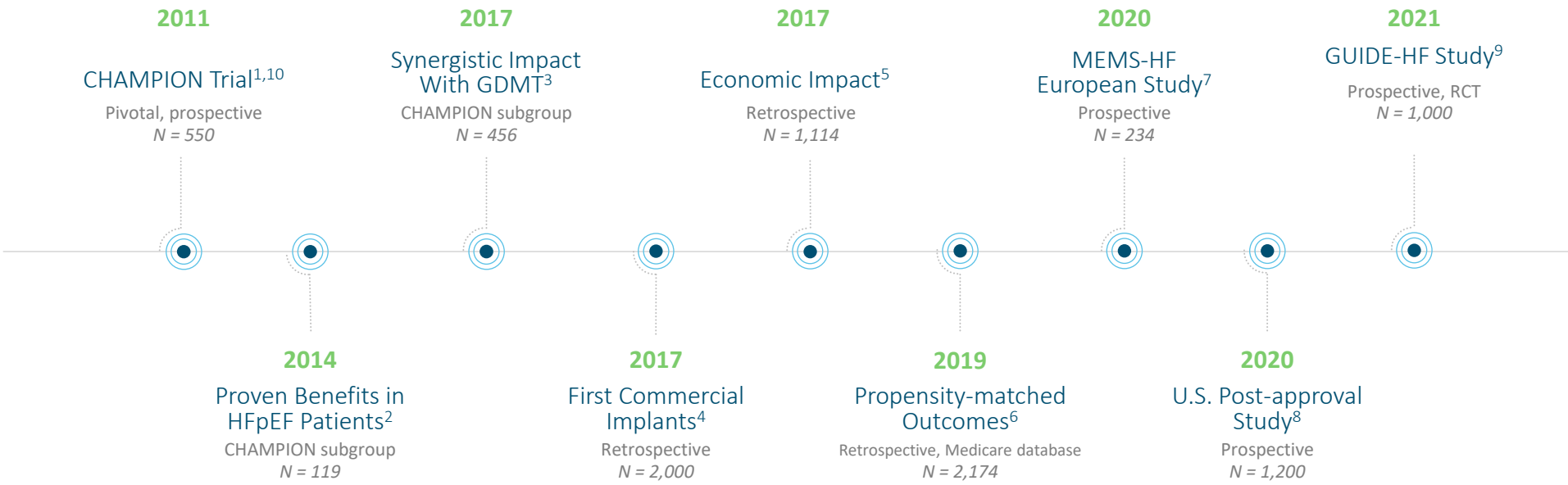
Abbott

CARDIOMEMS™ HF SYSTEM

Clinical Data

Day | Month | YY

Key clinical studies



Key clinical outcomes

REDUCTION IN PA PRESSURES[1,4,7,9]

OUTSTANDING SAFETY DATA[1,7-9]

EXCELLENT PATIENT ADHERENCE[4,7,8]

REDUCTION IN HEART FAILURE HOSPITALIZATIONS[1-3,5-9]

THE NUMBER ONE PROVEN SOLUTION FOR HFpEF AND HFrEF PATIENTS[2,4,7-9]

IMPROVED QOL[1,7]

OPTIMIZED MEDICAL MANAGEMENT[1,2,7,8]

Supported by multiple study designs

SINGLE-ARM

The patient's pre-implant history serves as the comparator to what the patient experiences prospectively after implant.

U.S. POST-APPROVAL
(N = 1,200)

MEMS-HF
(N = 234)

PROPENSITY-MATCHED

Retrospective analysis comparing similar baseline patients over the same time period. Those who were not implanted serve as the "control."

ABRAHAM MEDICARE
(N = 2,174)

RANDOMIZED CONTROLLED

The "gold standard" of clinical trials. All patients are implanted and followed prospectively. Patients are blinded to group assignment. Treatment is compared to control.

CHAMPION
(N = 550)

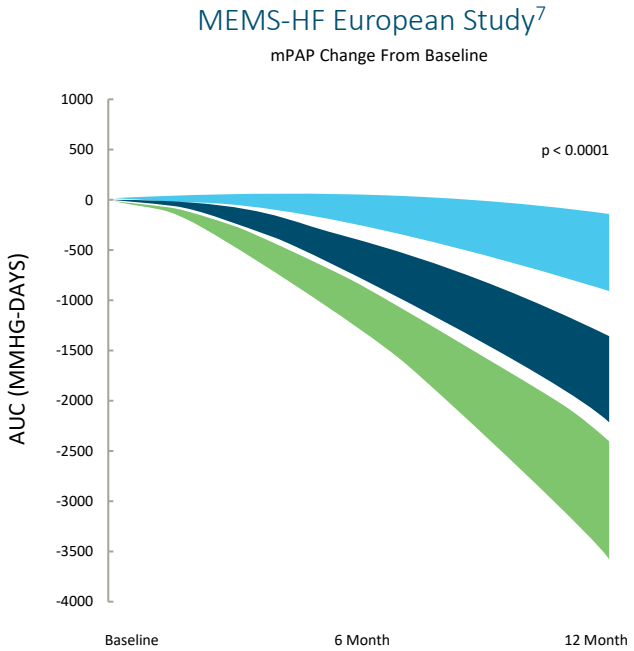
GUIDE-HF
(N = 1,000)

HOW DO THE DATA

Come together?

STUDY	DESIGN	N	Heart Failure Hospitalization	PA Pressure	HFpEF	Safety	QOL	Adherence	NYHA Class III	Elevated BNP	NYHA Class II
CHAMPION Pivotal Study[1] WT Abraham	RCT	550	✓	✓	✓	✓	✓		✓		
Proven Benefits in HFpEF Patients[2] Adamson	RCT Subgroup	119	✓	✓	✓				✓		
Synergistic Impact With GDMT[3] Givertz	Retrospective	456	✓						✓		
First 2,000 Commercial Implants[4] Heywood	Retrospective	2,000		✓	✓			✓	✓		
Economic Impact[5] Desai	Retrospective Database	1,114	✓						✓		
Propensity-matched Outcomes[6] J Abraham	Retrospective Database	2,174	✓						✓		
MEMS-HF European Study[7] Angermann	Single-arm	234	✓	✓	✓	✓	✓	✓	✓		
U.S. Post-approval Study[8] Shavelle	Single-arm	1,200	✓	✓	✓	✓		✓	✓		
GUIDE-HF Study[9] Lindenfeld	RCT	1,000	✓	✓	✓	✓		✓	✓	✓	✓

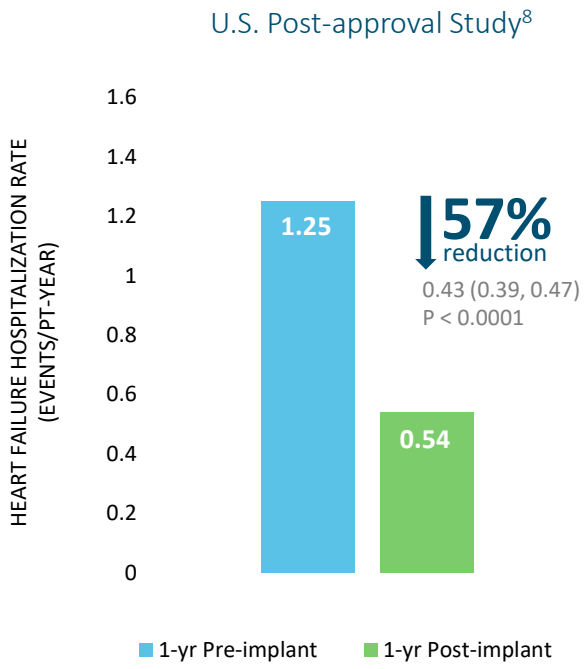
PA pressure reduction



Baseline	N	AUC (mean)
mPAP < 35	82	-547.7
All Patients	176	-1827.7
mPAP ≥ 35	87	-3070.9

SUPPORTING STUDIES	PA PRESSURE REDUCTION
GUIDE-HF[9]	✓
MEMS-HF[7]	✓
U.S. Post-approval[8]	✓
CHAMPION Study[1]	✓
First 2,000 Implants[4]	✓

Hospitalization reduction

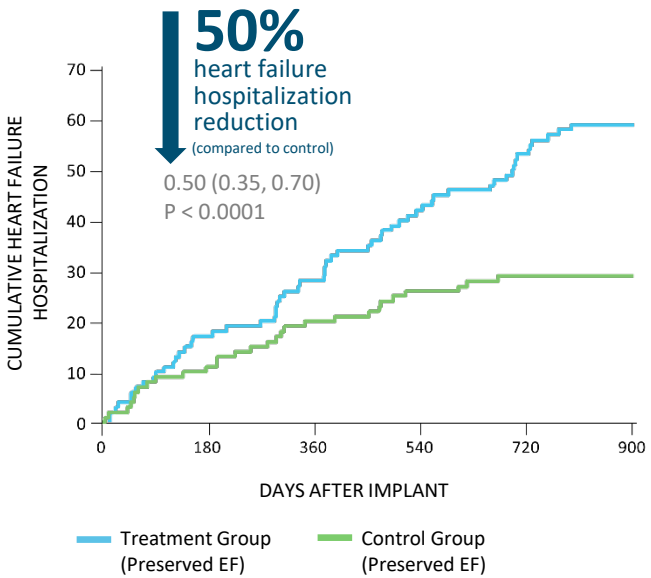


SUPPORTING STUDIES	HEART FAILURE HOSPITALIZATION REDUCTION	DESIGN
GUIDE-HF[9]	**28%**	**RCT**
U.S. Post-approval[8]	**57%**	**Single-arm**
MEMS-HF[7]	**62%**	**Single-arm**
CHAMPION Study[1]	**33%**	**RCT**
Economic Impact[5]	**34%**	**Retrospective Database**
Synergistic Impact With GDMT[3]	**43%**	**Retrospective**
Propensity-matched Cohort[6]	**24%**	**Retrospective Database**

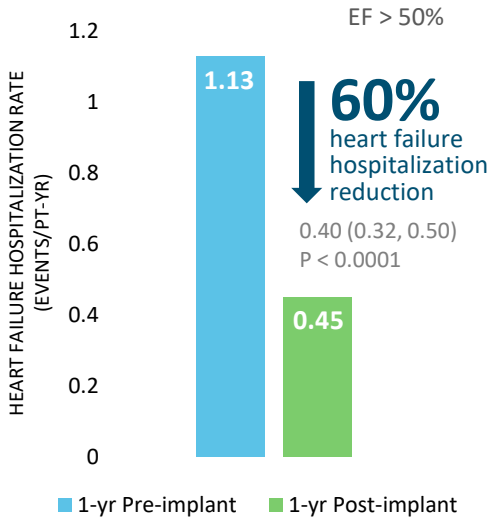
HFpEF outcomes

The number one proven therapy to reduce heart failure hospitalizations in HFpEF patients

Proven Benefits in HFpEF Patients[2]



U.S. Post-approval Study[8]

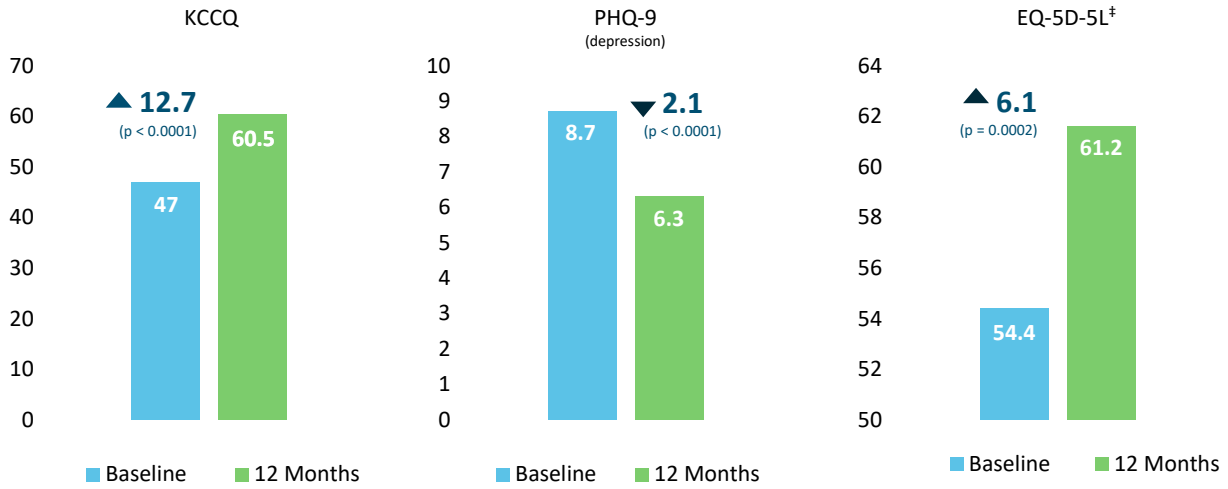


SUPPORTING STUDIES	BENEFIT TO HFpEF
GUIDE-HF[9]	✓
Proven Benefits in HFpEF Patients[2]	✓
First 2,000 Implants[4]	✓
U.S. Post-approval[8]	✓
MEMS-HF[7]	✓

Improved QOL

Across all patient-reported outcomes

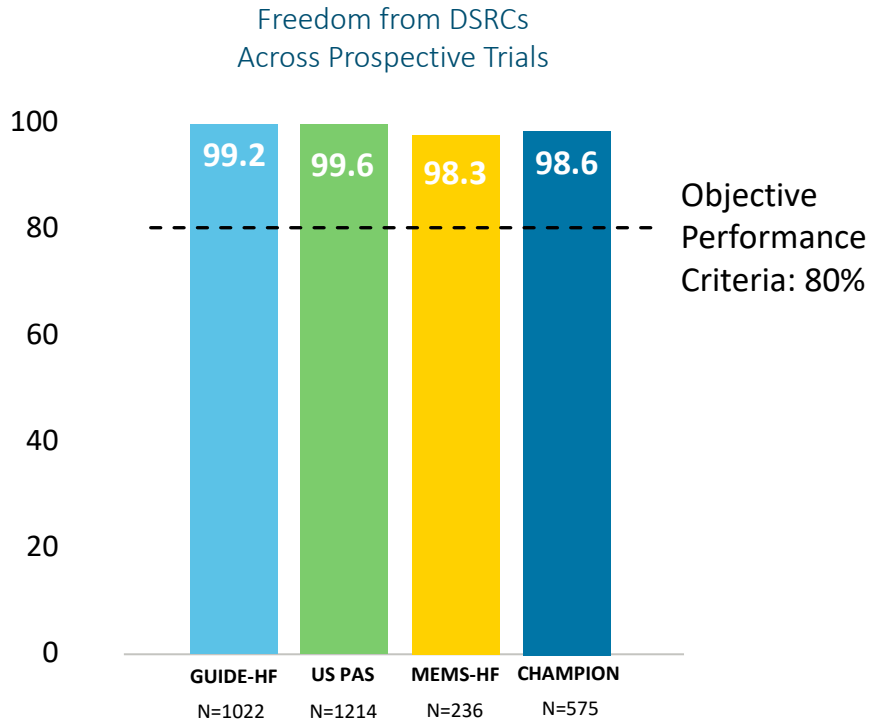
MEMS-HF European Study[7]



SUPPORTING STUDIES	IMPROVED QOL
CHAMPION Study[1]	✓
MEMS-HF[7]	✓

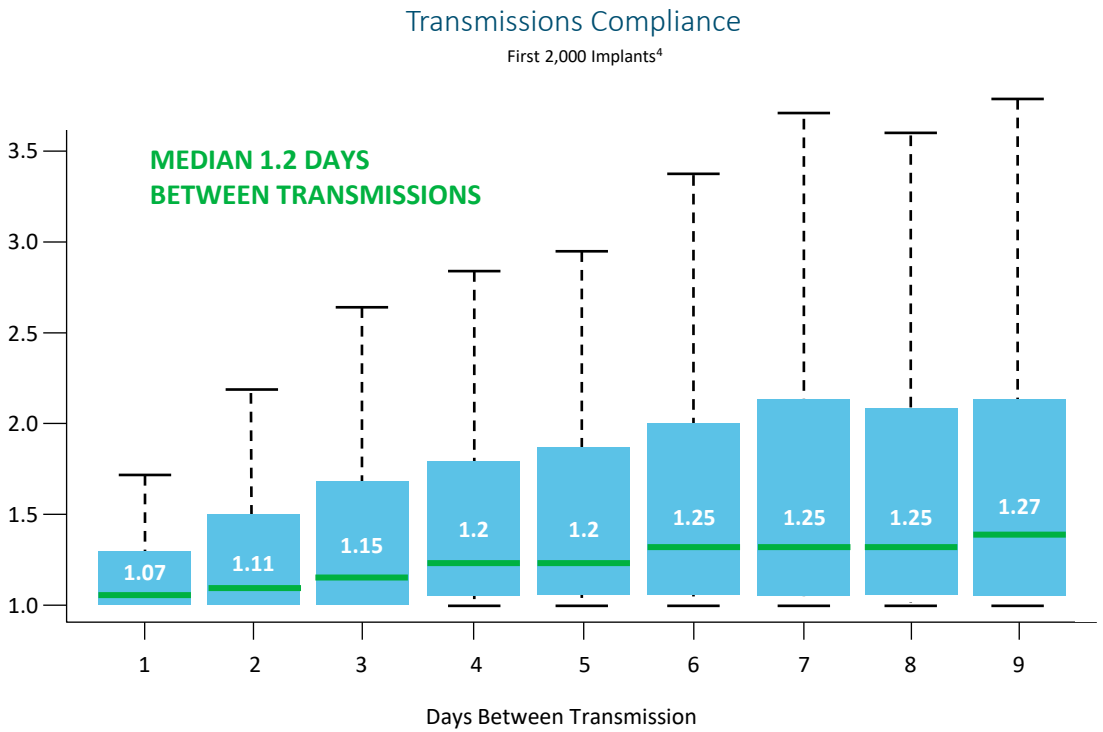
Outstanding safety performance

Over 3,000 patients in prospective trials demonstrating greater than 99% freedom from device complications



SUPPORTING STUDIES	FREEDOM FROM DSRC
GUIDE-HF[9]	**99.2%**
CHAMPION Study[1]	**98.6%**
U.S. Post-approval[8]	**99.6%**
MEMS-HF[7]	**98.3%**

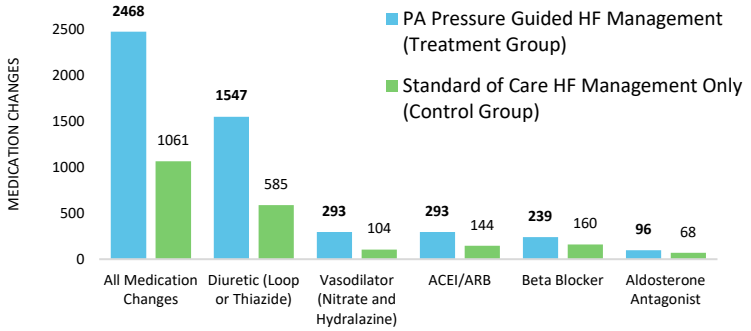
Excellent patient adherence



SUPPORTING STUDIES	MEAN WEEKLY TRANSMISSION
GUIDE-HF[9]	> 89%
First 2,000 Implants[4]	98%
MEMS-HF[7]	89%
U.S. Post-approval[8]	93%

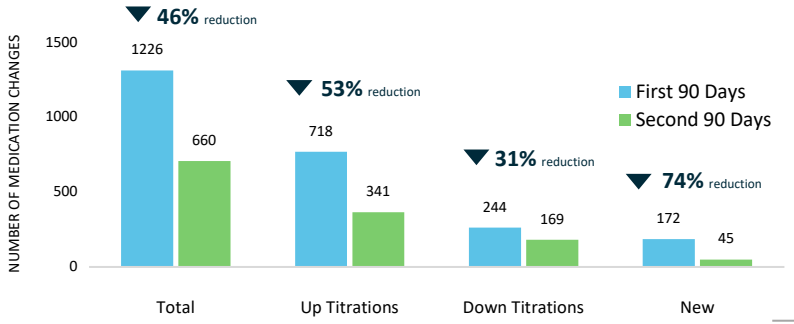
Optimizing medical management

Frequency of Medication Changes by Drug Class[11]



Initial frequency in medication changes increases based on PA pressure for optimization

Medication Changes — First 90 Days vs. Second 90 Days[12]

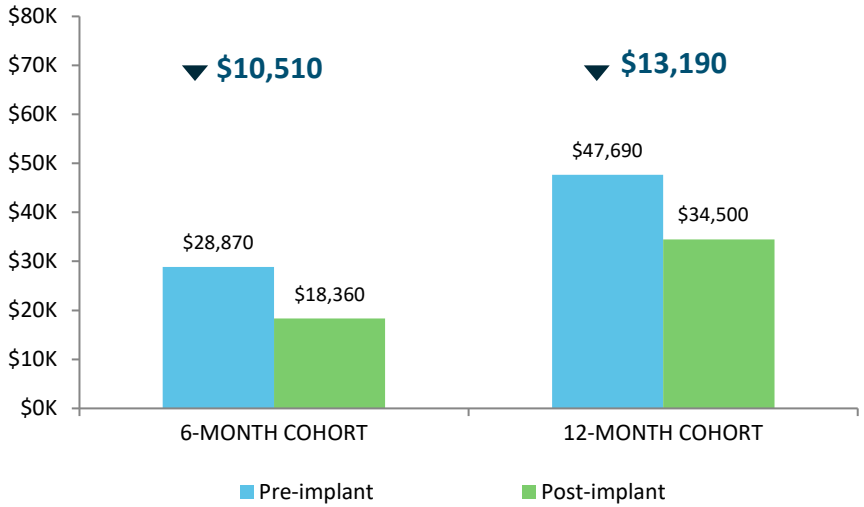


Medication changes decrease significantly after stabilization (~ 90 days)

SUPPORTING STUDIES	MEDICATION CHANGES
CHAMPION Study[1]	✓
Proven Benefits in HFpEF Patients[2]	✓
MEMS-HF[7]	✓
U.S. Post-approval[8]	✓

Cost-effective

Economic Impact[5]



Significant cost reductions at 6 and 12 months

SUPPORTING STUDIES	COST-EFFECTIVE
CHAMPION Study[1]	✓
Economic Impact[5]	✓

ADDITIONAL COST-EFFECTIVENESS STUDIES

Kolominsky-Rabas, et al. *Telemedicine and e-Health*. 2016.[13]

Martinson, et al. *European J Heart Failure*. 2017.[14]

Schmier, et al. *Clinical Cardiology*. 2017.[15]

Cowie, et al. *European J Heart Failure*. 2017.[16]

GUIDE-HF randomized arm

THE LARGEST CLINICAL TRIAL of the CardioMEMS™ HF System designed to evaluate management in a **WIDER POPULATION** and including a **BROADER RANGE OF ENDPOINT EVENTS**

ENROLLED 1,000 PATIENTS

- NYHA Class II, III or ambulatory IV patients
- Either a recent heart failure hospitalization or elevated natriuretic peptides

GUIDE-HF PRIMARY ENDPOINT

CHAMPION Primary Endpoint

URGENT HEART FAILURE VISITS (ED/OUTPATIENT)

HEART FAILURE HOSPITALIZATIONS

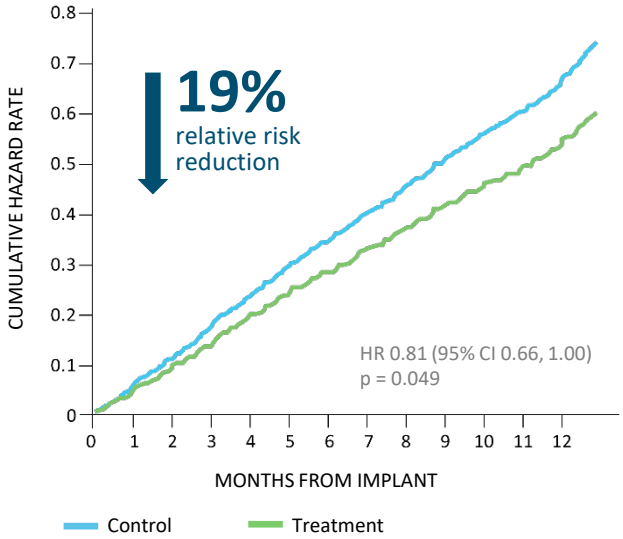
ALL-CAUSE MORTALITY

PRE-PANDEMIC ANALYSIS

GUIDE-HF randomized arm results

THE LARGEST CLINICAL TRIAL of the CardioMEMS™ HF System

Primary Outcome: All-cause Mortality, HF Hospitalizations, Urgent HF Visits



RESULT HIGHLIGHTS

- 28% heart failure hospitalization reduction
- Significantly greater PA pressure reduction in the treatment group versus the control group
- Similar benefit for patients enrolled with previous heart failure hospitalization versus elevated BNP alone
- 99.2% freedom from DSRC

GUIDE-HF **reaffirmed** all previous studies of the CardioMEMS HF System and demonstrated an extended benefit in **earlier** and **less severe** stages of heart failure

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Come together?

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Synergistic Impact With GDMT[3] Givertz	Retrospective	456	✓						✓		
First 2,000 Commercial Implants[4] Heywood	Retrospective	2,000		✓	✓			✓	✓		
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MEMS-HF European Study[7] Angermann	Single-arm	234	✓	✓	✓	✓	✓	✓	✓		
U.S. Post-approval Study[8] Shavelle	Single-arm	1,200	✓	✓	✓	✓		✓	✓		
GUIDE-HF Study[9] Lindenfeld	RCT	1,000	✓	✓	✓	✓		✓	✓	✓	✓

Acronyms

AUC	area under curve
BNP	B-type natriuretic peptide
DSRC	device-/system-related complication
ED	emergency department
EF	ejection fraction
HFpEF	heart failure with preserved ejection fraction
KCCQ	Kansas City Cardiomyopathy Questionnaire
mPAP	mean pulmonary artery pressure
NYHA	New York Heart Association
PA	pulmonary artery
PHQ-9	Patient Health Questionnaire-9
QOL	quality of life
RCT	randomized controlled trial

References

1. Abraham WT, Stevenson LW, Bourge RC, et al. Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: Complete follow-up results from the CHAMPION randomised trial. *Lancet*. 2016;387(10017):453-461.
2. Adamson, et al. Wireless Pulmonary Artery Pressure Monitoring Guides Management to Reduce Decompensation in Heart Failure With Preserved Ejection Fraction. *Circulation: Heart Failure*. 2014;7:935-944.
3. Givertz MM, Stevenson LW, Costanzo MR, et al., on behalf of the CHAMPION Trial Investigators. Pulmonary artery pressure–guided management of patients with heart failure and reduced ejection fraction. *J Am Coll Cardiol*. 2017;70:1875-86.
4. Heywood JT, Jermyn R, Shavelle D, et al. Impact of practice-based management of PA pressures in 2000 patients implanted with the CardioMEMS sensor. *Circulation*. 2017;135:1509-17.
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15. Schmier JK, Ong KL, Fonarow GC. Cost-Effectiveness of Remote Cardiac Monitoring with the CardioMEMS Heart Failure System. *Clinical Cardiology*. 2017;40:430-436.
16. Cowie MR, Simon M, Klein L, Thokala P. The cost-effectiveness of real-time pulmonary artery pressure monitoring in heart failure patients: a European perspective. *European Journal of Heart Failure*. 2017;19:661-669.

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Cardiovascular.Abbott/CardioMEMS

Rx Only
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.

CardioMEMS™ HF System Indications and Usage: The CardioMEMS HF System is indicated for wirelessly measuring and monitoring pulmonary artery pressure and heart rate in NYHA Class II or III heart failure patients who either have been hospitalized for heart failure in the previous year and/or have elevated natriuretic peptides. The hemodynamic data are used by physicians for heart failure management with the goal of controlling pulmonary artery pressures and reducing heart failure hospitalizations.

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

CardioMEMS™ HF System Potential Adverse Events: Potential adverse events associated with the implantation procedure include, but are not limited to, the following: air embolism, allergic reaction, infection, delayed wound healing, arrhythmias, bleeding, hemoptysis, hematoma, nausea, cerebrovascular accident, thrombus, cardiovascular injury, myocardial infarction, death, embolization, thermal burn, cardiac perforation, pneumothorax, thoracic duct injury and hemothorax.

myCardioMEMS™ Mobile App 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™ Mobile 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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