



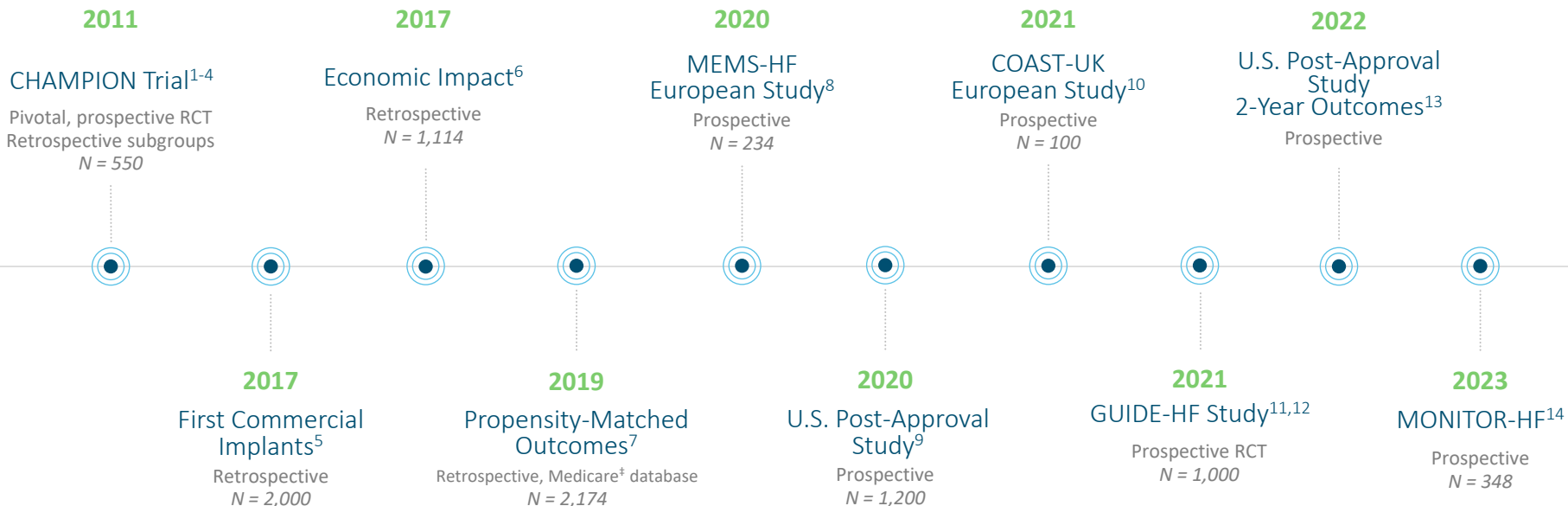
ABBOTT HEART FAILURE

CARDIOMEMS™ HF SYSTEM

Clinical data

Day | Month | YY

Key clinical studies



Key clinical outcomes



REDUCTION IN PA
PRESSURES^{1,2,5,8-13}



OUTSTANDING
SAFETY DATA^{1,8-11,13}



EXCELLENT PATIENT
ADHERENCE^{5,8-11}



REDUCTION IN
HEART FAILURE
HOSPITALIZATIONS^{1-3,6-14}



PROVEN SOLUTION FOR HFpEF
AND HFrEF PATIENTS^{1-3,8-12}



IMPROVED QOL^{1,8,11}



OPTIMIZED MEDICAL
MANAGEMENT^{1,2,4,8,9,13}



IMPROVED SURVIVAL^{4,7,15}

Supported by multiple study designs

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)



MONITOR-HF
(EUROPEAN)
(N = 348)

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
(EUROPEAN)
(N = 234)



COAST-HF
(UK COHORT)
(N = 100)

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)

HOW DO THE DATA

Come together?

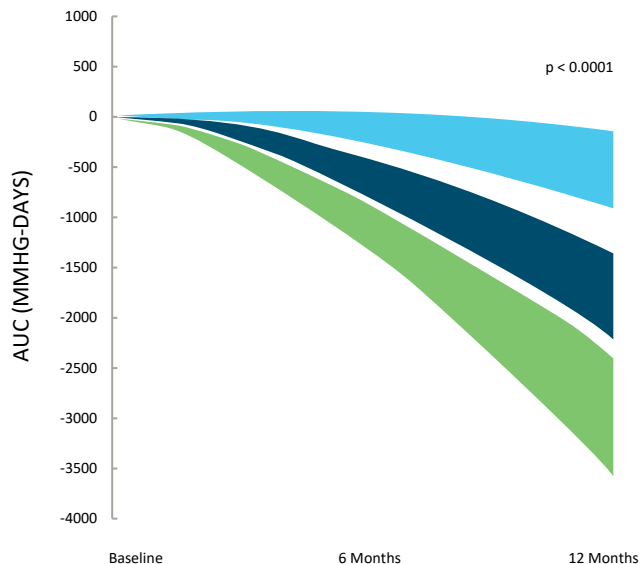


STUDY	DESIGN	N	Heart Failure Hospitalization	PA Pressure	HFpEF	Safety	QOL	Adherence	Elevated BNP*	Survival
CHAMPION Pivotal Study ²	RCT	550	✓	✓		✓	✓			
Proven Benefits in HFpEF Patients ³	RCT Subgroup	119	✓	✓	✓					
Synergistic Impact With GDMT ⁴	RCT Subgroup	456	✓							✓
First 2,000 Commercial Implants ⁵	Retrospective	2,000		✓	✓			✓		
COAST ¹⁰	OUS Single-Arm	100	✓	✓	✓	✓		✓		
Propensity-Matched Outcomes ⁷	Retrospective Database	2,174	✓							✓
MEMS-HF European Study ⁸	Single-Arm	234	✓	✓	✓	✓	✓	✓		
U.S. Post-Approval Study ⁹	Single-Arm	1,200	✓	✓	✓	✓		✓		
GUIDE-HF Study ¹¹	RCT	1,000	✓	✓	✓	✓		✓	✓	
MONITOR-HF ¹⁴	RCT	348	✓	✓	✓	✓	✓	✓	✓	
Meta-Analysis of GUIDE-HF, CHAMPION and LAPTOP ^{4,7,11,15}	Retrospective	1,350	✓							✓

PA pressure reduction

MEMS-HF European Study⁸

mPAP Change From Baseline



Baseline	N	AUC (mean)
mPAP < 35	82	-547.7
All Patients	176	-1,827.7
mPAP ≥ 35	87	-3,070.9

SUPPORTING STUDIES

PA PRESSURE REDUCTION

CHAMPION Study²



GUIDE-HF¹¹



MONITOR-HF¹⁴



MEMS-HF⁸



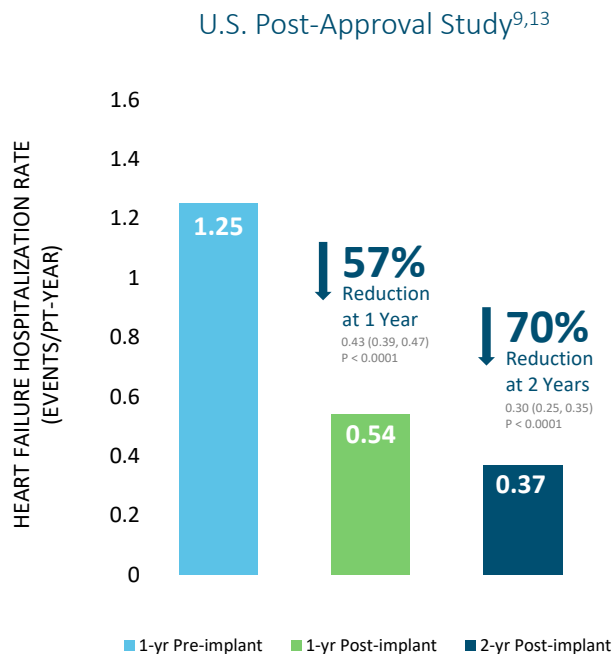
U.S. Post-Approval⁹



First 2,000 Implants⁵



Hospitalization reduction

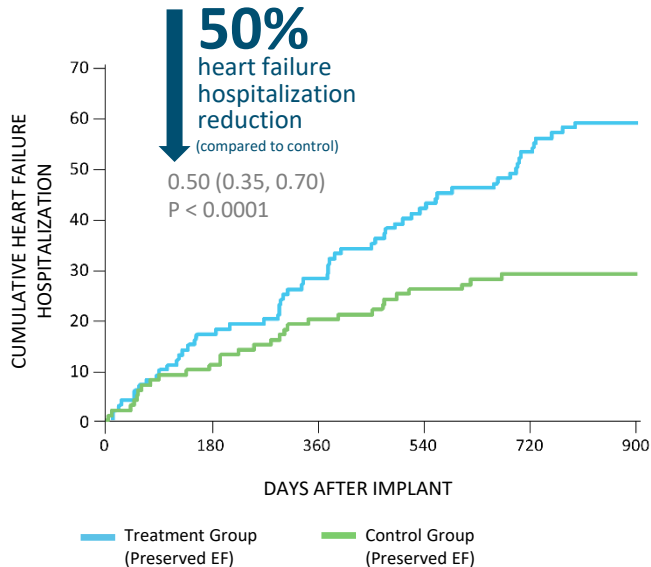


SUPPORTING STUDIES	HEART FAILURE HOSPITALIZATION REDUCTION	DESIGN
GUIDE-HF ¹¹	28%	RCT
MONITOR-HF ¹⁴	44%	RCT
U.S. Post-Approval ⁹	57%	Single-Arm
MEMS-HF ⁸	62%	Single-Arm
CHAMPION Study ²	33%	RCT
Economic Impact ⁵	34%	Retrospective Database
Synergistic Impact With GDMT ⁶	43%	Retrospective
Propensity-Matched Cohort ⁷	24%	Retrospective Database

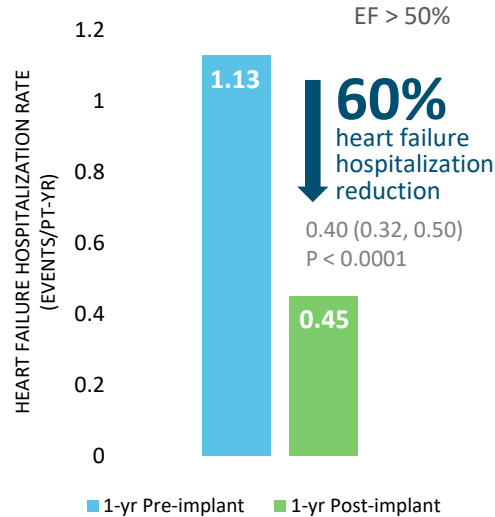
HFpEF outcomes

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

CHAMPION Subgroup³



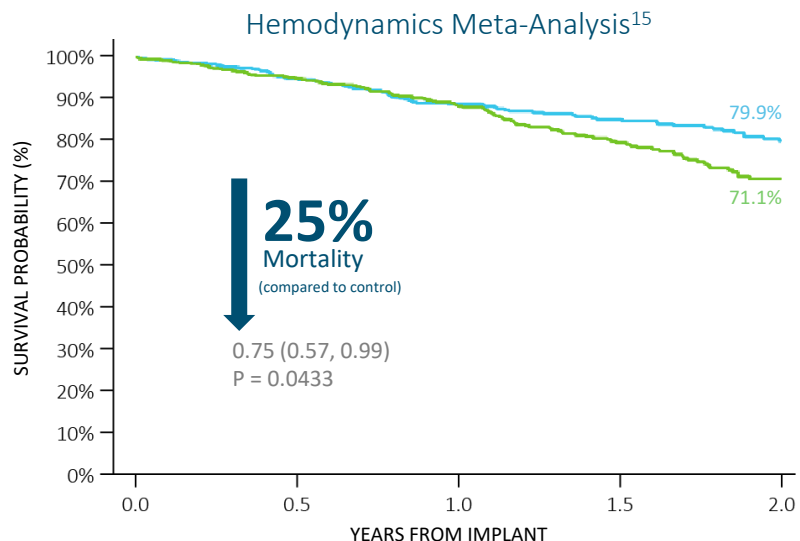
U.S. Post-Approval Study⁹



SUPPORTING STUDIES	BENEFIT TO HFpEF
GUIDE-HF ¹²	✓
CHAMPION ³	✓
COAST-UK ¹⁰	✓
U.S. Post-Approval ⁹	✓
MEMS-HF ⁸	✓
First 2,000 Implants ⁵	✓

Improved survival

Hemodynamic monitoring with the CardioMEMS™ HF System improves survival in heart failure patients^{4,7,15}



NUMBER AT RISK

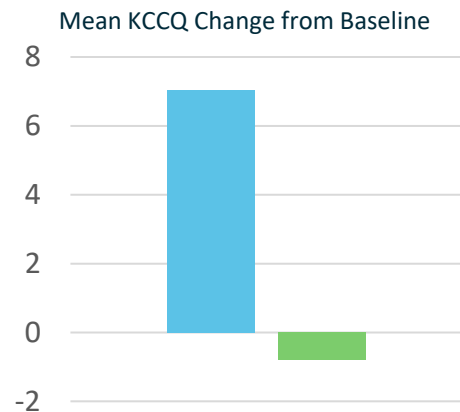
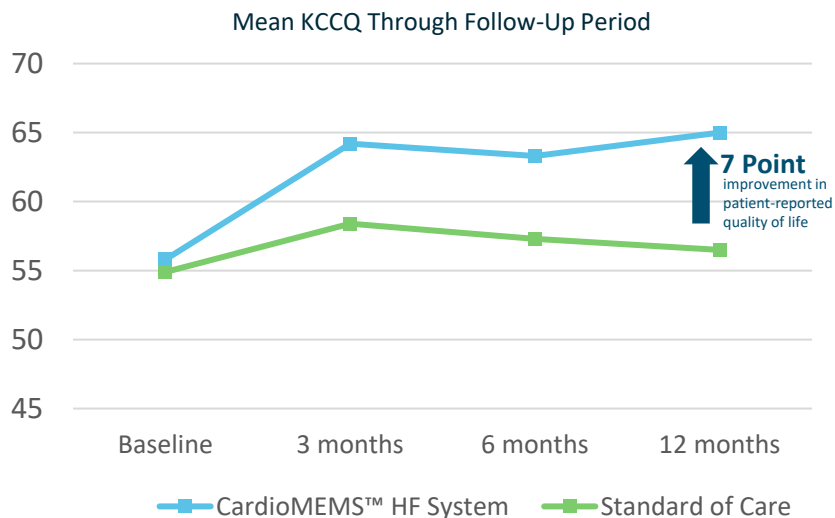
	0.0	0.5	1.0	1.5	2.0
Treatment Group	666	539	345	237	158
Control Group	684	556	355	213	115

SUPPORTING STUDIES	BENEFIT TO HFpEF
HFrEF Subgroup ⁴	✓
Propensity-Matched Analysis ⁷	✓
Hemodynamics Meta-Analysis ¹⁵	✓

Improved quality of life

Across all patient-reported outcomes

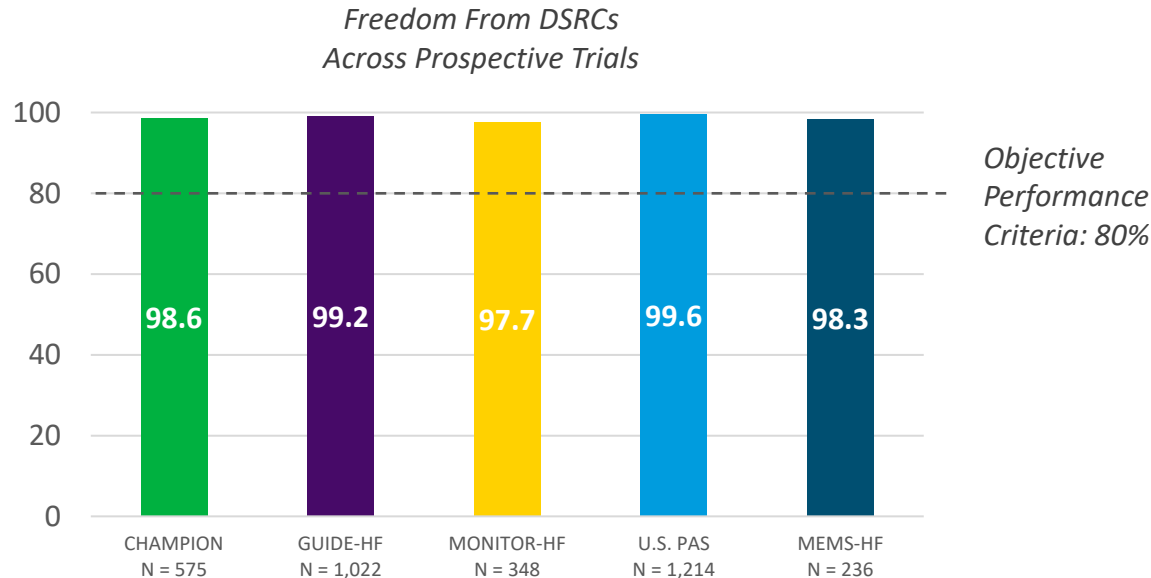
MONITOR-HF¹⁴



SUPPORTING STUDIES	IMPROVED QOL
CHAMPION Study ²	✓
MONITOR-HF ¹⁴	✓
MEMS-HF ⁸	✓

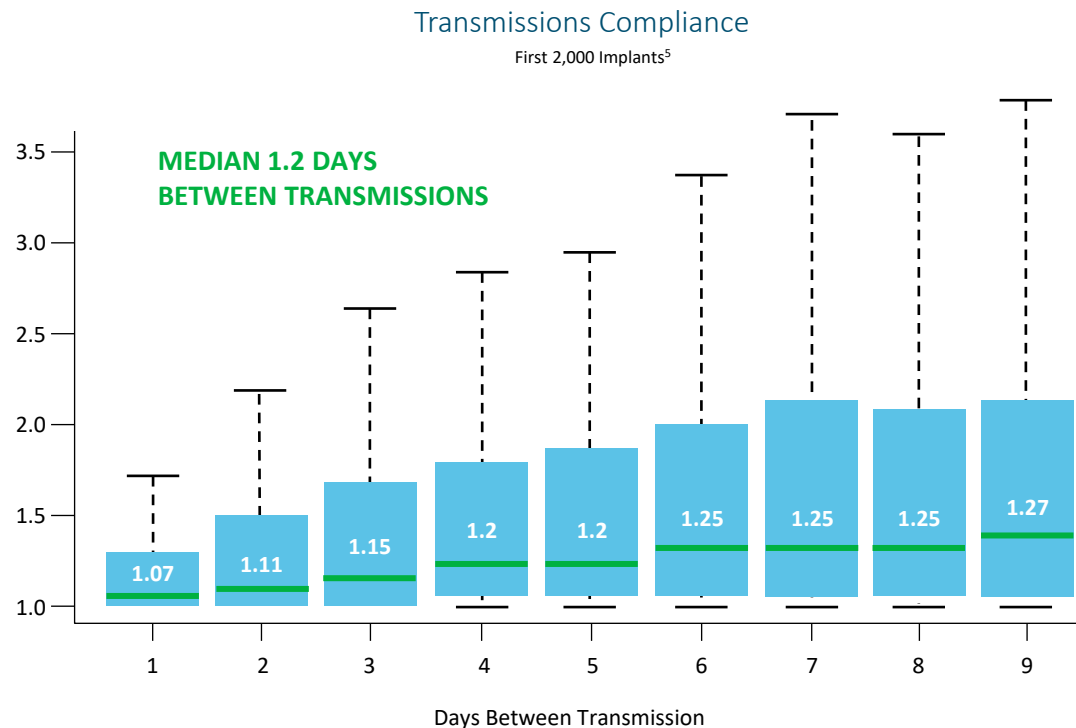
Outstanding safety performance

Over 3,300 patients in prospective trials demonstrating greater than 99% freedom from device complications



SUPPORTING STUDIES	FREEDOM FROM DSRC
CHAMPION Study ²	98.6%
GUIDE-HF ¹¹	99.2%
MONITOR-HF ¹⁴	97.7%
U.S. Post-Approval ⁹	99.6%
MEMS-HF ⁸	98.3%

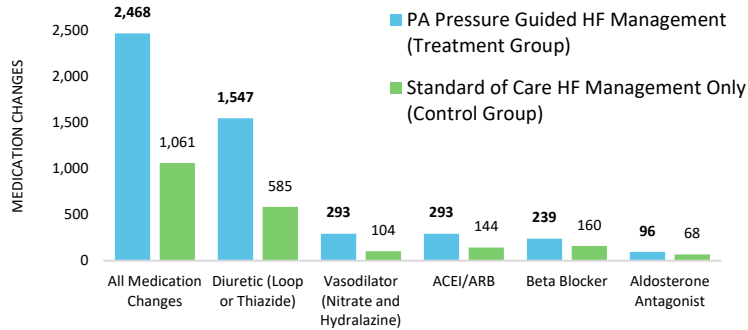
Excellent patient adherence



SUPPORTING STUDIES	MEAN WEEKLY TRANSMISSION
GUIDE-HF ¹¹	> 89%
MEMS-HF ⁸	89%
COAST-UK ¹⁰	94%
U.S. Post-Approval ⁹	93%
First 2,000 Implants ⁵	98%

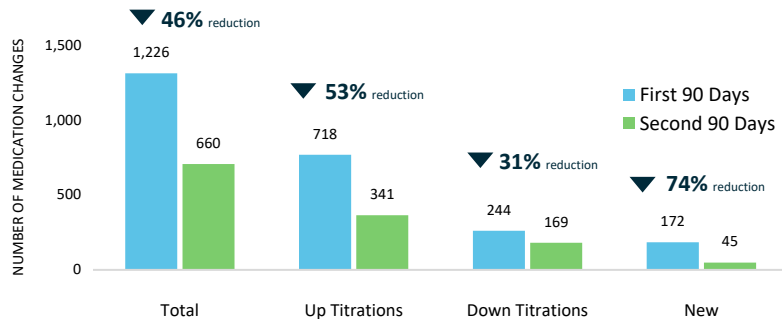
Optimizing medical management

Frequency of Medication Changes by Drug Class¹⁶



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

Medication Changes — First 90 Days vs. Second 90 Days¹⁷

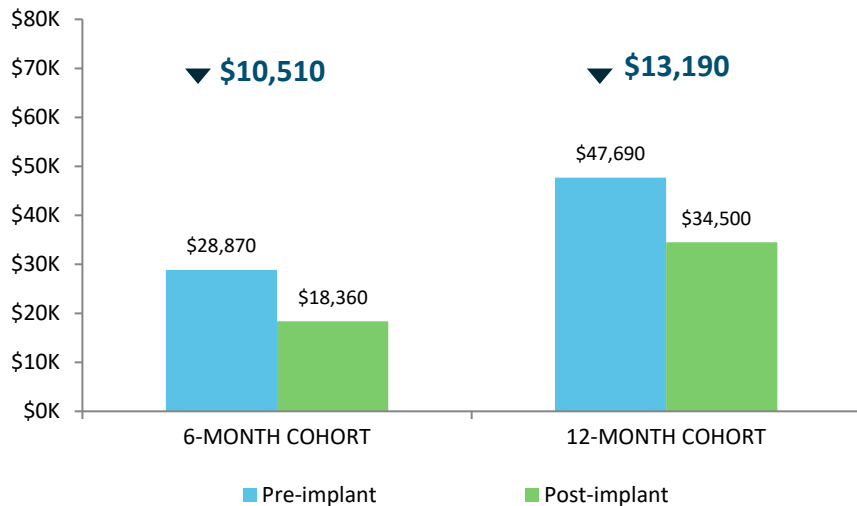


Medication changes decrease significantly after stabilization (~ 90 days)

SUPPORTING STUDIES	MEDICATION CHANGES
CHAMPION Study ^{1,2}	✓
MEMS-HF ⁸	✓
U.S. Post-Approval ⁹	✓
U.S. Post-Approval 2-Year Outcomes ¹³	✓
MONITOR-HF ¹⁴	✓

Cost-effective

Economic Impact⁶



Significant cost reductions at 6 and 12 months

SUPPORTING STUDIES	COST-EFFECTIVE
CHAMPION Study ^{1,2}	✓
Economic Impact ⁶	✓



ADDITIONAL COST-EFFECTIVENESS STUDIES

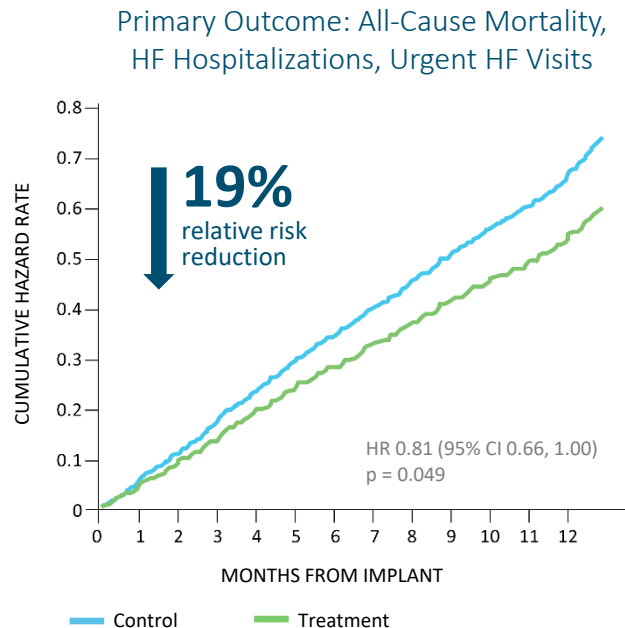
Kolominsky-Rabas, et al. *Telemedicine and e-Health*. 2016.¹⁸
 Martinson, et al. *European J Heart Failure*. 2017.¹⁹

Schmier, et al. *Clinical Cardiology*. 2017.²⁰
 Cowie, et al. *European J Heart Failure*. 2017.²¹

PRE-PANDEMIC ANALYSIS

GUIDE-HF randomized arm results¹¹

THE LARGEST CLINICAL TRIAL of the CardioMEMS™ HF System



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

Comparison of CardioMEMS™ HF system RCTs

Strong evidence across different endpoints, study designs and geographies²²

	CHAMPION²	GUIDE-HF¹¹	MONITOR-HF¹⁴
Patients	550	1,000	348
Study Design	Single-Blind RCT	Single-Blind RCT	Open Label RCT
Control Arm Received CardioMEMS HF System	Yes	Yes	No
Primary Endpoint	Composite of HF Events	HF Hospitalizations	Quality of Life (KCCQ)
Mean Follow-Up	17.6 Months	10.8 Months	21.4 Months
Published Date	2011	2021	2023
Sites # (Countries)	65 (USA)	65 (USA, Canada)	25 (Netherlands)

CardioMEMS™ HF system RCTs: reduction in HFH

	CHAMPION² N = 270	GUIDE-HF^{11*} N = 497	MONITOR-HF¹⁴ N = 176
Reduction in HFH HR (95% CI) P Value	0.67 (0.55, 0.80) P < 0.0001	0.72 (0.57, 0.92) P = 0.0072	0.56 (0.38, 0.84) P = 0.0053
% Reduction in HFH	33%	28%	44%

Consistent and improved outcomes in three prospective RCTs across Europe and North America, and independent of evolving and improving GDMT²²

*Pre-COVID-19 analysis.

HOW DO THE DATA

Come together?



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Proven Benefits in HFpEF Patients ³	RCT Subgroup	119	✓	✓	✓					
Synergistic Impact With GDMT ⁴	RCT Subgroup	456	✓							✓
First 2,000 Commercial Implants ⁵	Retrospective	2,000		✓	✓			✓		
COAST ¹⁰	OUS Single-Arm	100	✓	✓	✓	✓		✓		
Propensity-Matched Outcomes ⁷	Retrospective Database	2,174	✓							✓
MEMS-HF European Study ⁸	Single-Arm	234	✓	✓	✓	✓	✓	✓		
U.S. Post-Approval Study ⁹	Single-Arm	1,200	✓	✓	✓	✓		✓		
GUIDE-HF Study ¹¹	RCT	1,000	✓	✓	✓	✓		✓	✓	
MONITOR-HF ¹⁴	RCT	348	✓	✓	✓	✓	✓	✓	✓	
Meta-Analysis of GUIDE-HF, CHAMPION and LAPTOP ^{4,7,11,15}	Retrospective	1,350	✓							✓

Acronyms

ACEI	angiotensin-converting enzyme inhibitor	HFrEF	heart failure with reduced ejection fraction
ARB	angiotensin receptor blocker	HFpEF	heart failure with preserved ejection fraction
AUC	area under curve	HR	hazard ratio
BNP	B-type natriuretic peptide	KCCQ	Kansas City Cardiomyopathy Questionnaire
CI	confidence interval	mPAP	mean pulmonary artery pressure
DSRC	device-/system-related complication	OUS	outside the United States
EF	ejection fraction	PA	pulmonary artery
GDMT	guideline-directed medical therapy	QOL	quality of life
HF	heart failure	RCT	randomized controlled trial
HFH	heart failure hospitalizations		

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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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