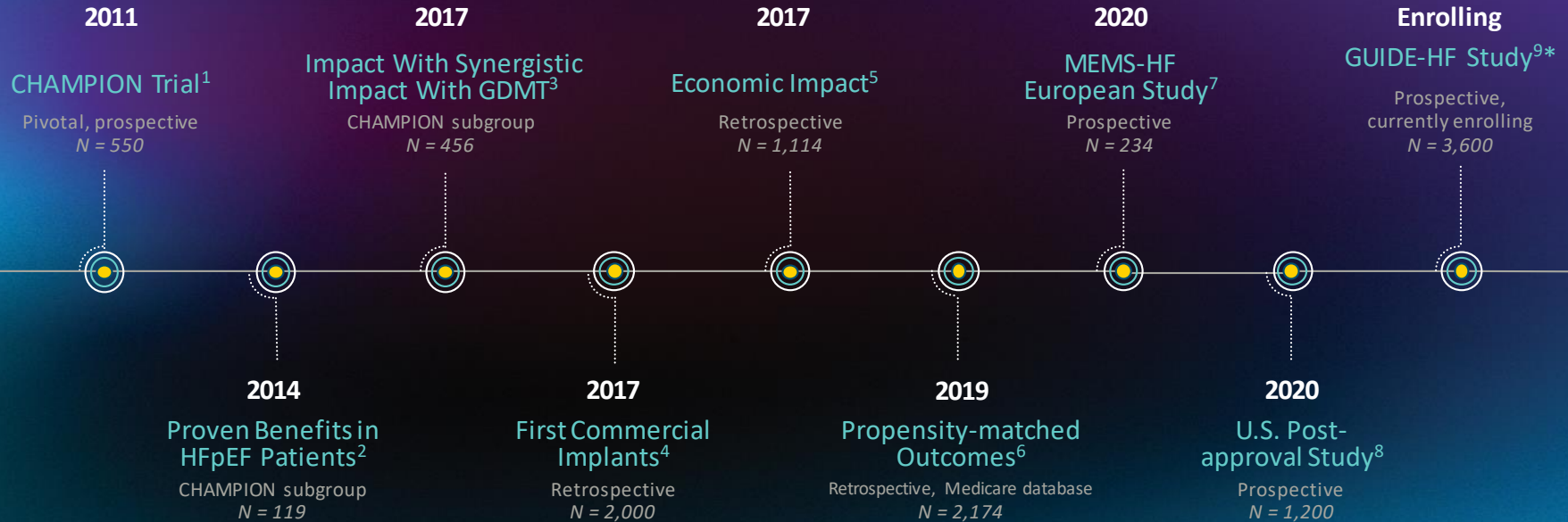




# THE CARDIOMEMS™ HF SYSTEM

## CLINICAL DATA

# KEY CLINICAL STUDIES



\*Unpublished.

1. Abraham WT, et al. *Lancet*. 2016.
2. Adamson, et al. *Circ HF*. 2014.
3. Givertz, et al. *J Am Coll Cardio*. 2017.
4. Heywood, et al. *Circulation*. 2017.
5. Desai, et al. *J Am Coll Card*. 2017.

6. Abraham J, et al. *JAMA Card*. 2019.
7. Angermann, et al. *Euro J Heart Fail*. 2020.
8. Shavelle, et al. *Circ HF*. 2020.
9. Lindenfeld, et al. *Am Heart J*. 2019.

# KEY CLINICAL OUTCOMES



Reduction in PA pressures<sup>1,4,7</sup>



Increased survival<sup>3,6</sup>



Outstanding safety data<sup>1,7,8</sup>



Excellent patient adherence<sup>4,7,8</sup>



Reduction in heart failure hospitalizations<sup>1-3, 5-8</sup>



The ONLY proven solution in HFpEF patients<sup>2,4,7,8</sup>



Improved QOL<sup>1,7</sup>



Optimized medical management<sup>1,2,7,8</sup>

1. Abraham WT, et al. *Lancet*. 2016.

2. Adamson, et al. *Circ HF*. 2014.

3. Givertz, et al. *J Am Coll Cardiol*. 2017.

4. Heywood, et al. *Circulation*. 2017.

5. Desai, et al. *J Am Coll Card*. 2017.

6. Abraham J, et al. *JAMA Card*. 2019.

7. Angermann, et al. *Euro J Heart Fail*. 2020.

8. Shavelle, et al. *Circ HF*. 2020.

## HOW DO THE DATA

# COME TOGETHER?



STUDY	AUTHOR	N	Heart Failure Hospitalization	PA Pressure	↑ Survival	HFpEF	QOL	Cost Benefit	Safety	Adherence	Medication Change
CHAMPION Pivotal Study <sup>1</sup>	WT Abraham	550	✓	✓			✓	✓	✓		✓
Proven Benefits in HFpEF Patients <sup>2</sup>	Adamson	119	✓			✓					✓
Synergistic Impact With GDMT <sup>3</sup>	Givertz	456	✓		✓						
First 2,000 Commercial Implants <sup>4</sup>	Heywood	2,000		✓		✓				✓	
Economic Impact <sup>5</sup>	Desai	1,114	✓					✓			
Propensity-matched Outcomes <sup>6</sup>	J Abraham	2,174	✓		✓						
MEMS-HF European Study <sup>7</sup>	Angermann	234	✓	✓		✓	✓		✓	✓	✓
U.S. Post-approval Study <sup>8</sup>	Shavelle	1,200	✓			✓			✓	✓	✓

1. Abraham WT, et al. *Lancet*. 2016.

2. Adamson, et al. *Circ HF*. 2014.

MAT-2007440 v3.0 | Item approved for U.S. use only.

3. Givertz, et al. *J Am Coll Cardiol*. 2017.

4. Heywood, et al. *Circulation*. 2017.

5. Desai, et al. *J Am Coll Card*. 2017.

6. Abraham J, et al. *JAMA Card*. 2019.

7. Angermann, et al. *Euro J Heart Fail*. 2020.

8. Shavelle, et al. *Circ HF*. 2020.

## HOW DO THE DATA

# COME TOGETHER?



STUDY	AUTHOR	N	Heart Failure Hospitalization	PA Pressure	↑ Survival	HFpEF	QOL	Cost Benefit	Safety	Adherence	Medication Change
CHAMPION Pivotal Study <sup>1</sup>	WT Abraham	550	33%	✓			✓	✓	✓		✓
Proven Benefits in HFpEF Patients <sup>2</sup>	Adamson	119	50%			✓					✓
Synergistic Impact With GDMT <sup>3</sup>	Givertz	456	43%		✓						
First 2,000 Commercial Implants <sup>4</sup>	Heywood	2,000		✓		✓				✓	
Economic Impact <sup>5</sup>	Desai	1,114	34%					✓			
Propensity-matched Outcomes <sup>6</sup>	J Abraham	2,174	24%		✓						
MEMS-HF European Study <sup>7</sup>	Angermann	234	62%	✓		✓	✓		✓	✓	✓
U.S. Post-approval Study <sup>8</sup>	Shavelle	1,200	57%			✓			✓	✓	✓

1. Abraham WT, et al. *Lancet*. 2016.

2. Adamson, et al. *Circ HF*. 2014.

MAT-2007440 v3.0 | Item approved for U.S. use only.

3. Givertz, et al. *J Am Coll Cardiol*. 2017.

4. Heywood, et al. *Circulation*. 2017.

5. Desai, et al. *J Am Coll Card*. 2017.

6. Abraham J, et al. *JAMA Card*. 2019.

7. Angermann, et al. *Euro J Heart Fail*. 2020.

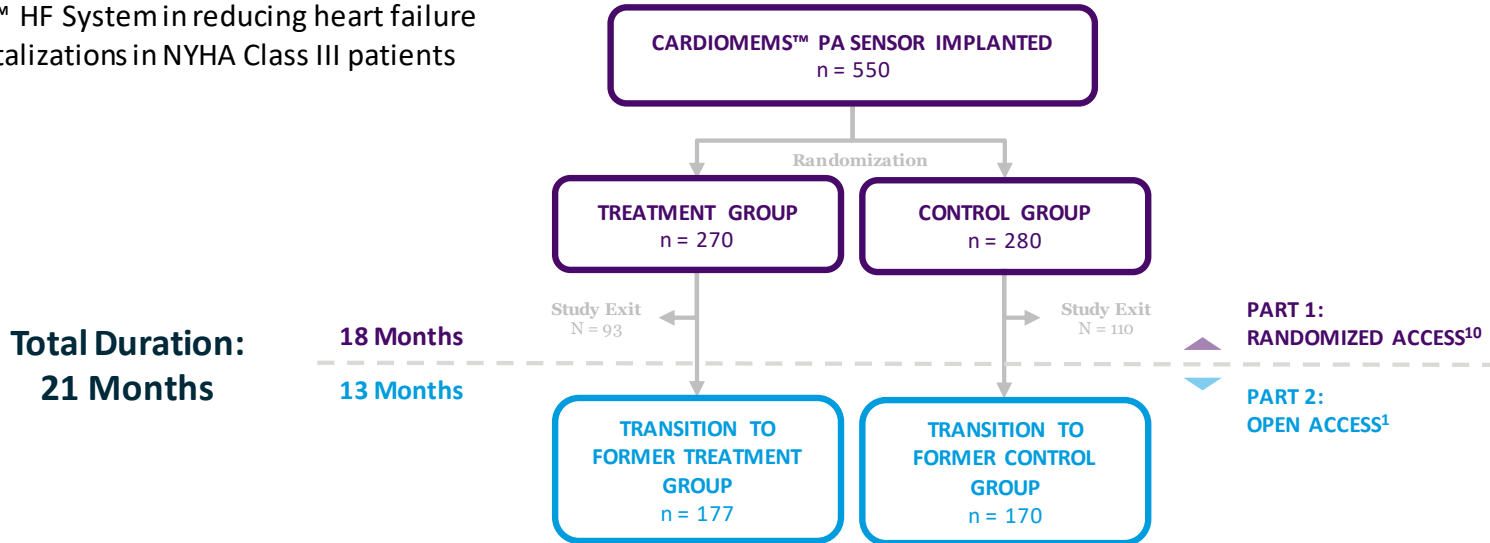
8. Shavelle, et al. *Circ HF*. 2020.

# PIVOTAL CHAMPION TRIAL

## TRIAL PURPOSE

Evaluate the safety and efficacy of the CardioMEMS™ HF System in reducing heart failure related hospitalizations in NYHA Class III patients

## TRIAL DESIGN








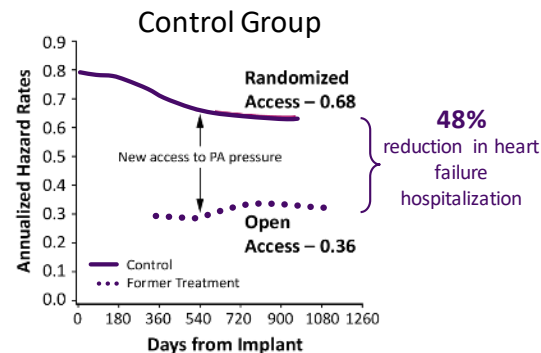
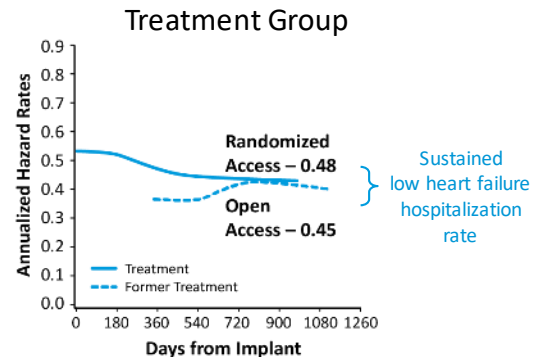
1. Abraham WT, et al. *Lancet*. 2016.

10. Abraham WT, et al. *Lancet*. 2011.

# PIVOTAL CHAMPION TRIAL: RESULTS

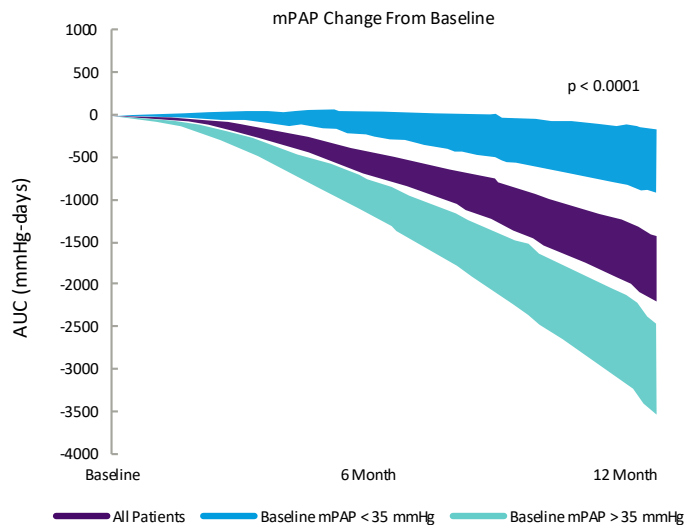
GENERALIZABLE OUTSIDE RIGOROUS CLINICAL TRIAL

Endpoint	Result		P Value
	Treatment	Control	
 <b>Reduction in PA mean pressure from baseline</b> (mean AUC [mmHg x days])	-156	33	0.008
 <b>Reduction in heart failure hospitalizations</b>	33%		< 0.0001
 <b>Improvement in HFpEF heart failure hospitalizations</b> (Treatment HFpEF vs. Control HFpEF)	50%		< 0.0001
 <b>Improved QOL</b> (Minnesota Living with Heart Failure Questionnaire, mean)	45 ± 26	51 ± 25	0.02
 <b>Excellent safety data</b> (Freedom from DSRC)	98.6%		



# PA PRESSURE REDUCTION

## MEMS-HF European Study<sup>7</sup>



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

### Supporting Studies PA Pressure Reduction

MEMS-HF<sup>7</sup>



U.S. Post-approval<sup>8</sup>



CHAMPION Study<sup>1</sup>



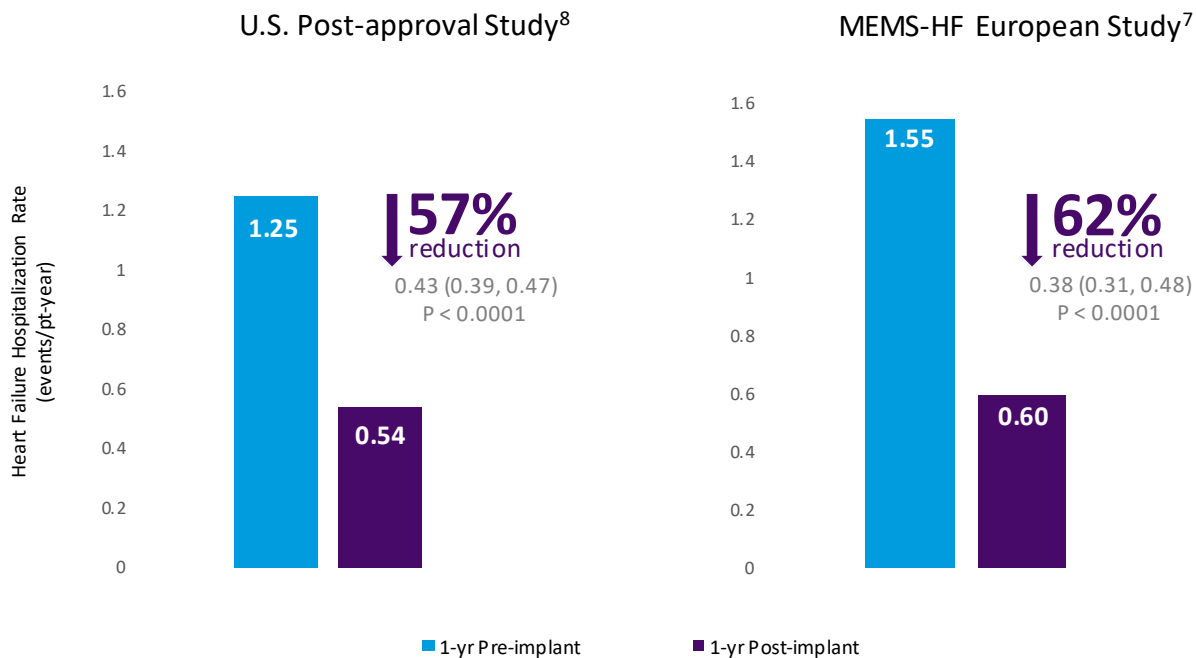
First 2,000 Implants<sup>4</sup>



1. Abraham WT, et al. *Lancet*. 2016.  
 4. Heywood, et al. *Circulation*. 2017.  
 7. Angermann, et al. *Euro J Heart Fail*. 2020.  
 8. Shavelle, et al. *Circ HF*. 2020.



# HEART FAILURE HOSPITALIZATION REDUCTION

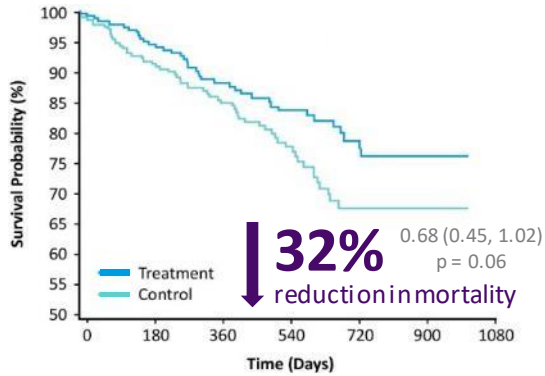


Supporting Studies	Heart Failure Hospitalization Reduction
U.S. Post-approval <sup>8</sup>	57%
MEMS-HF <sup>7</sup>	62%
CHAMPION Study <sup>1</sup>	33%
Economic Impact <sup>5</sup>	34%
Synergistic Impact With GDMT <sup>3</sup>	43%
Propensity-matched Cohort <sup>6</sup>	24%

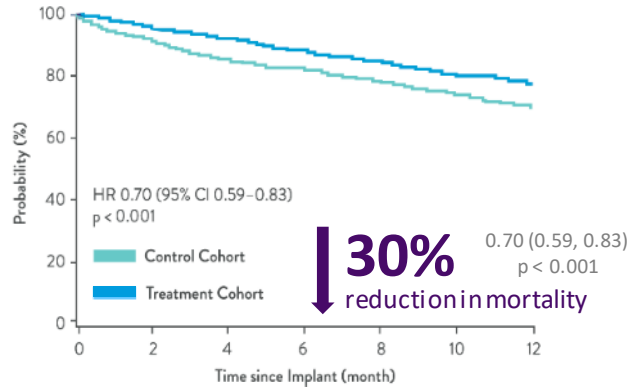
1. Abraham WT, et al. *Lancet*. 2016.  
 3. Givertz, et al. *J Am Coll Cardio*. 2017.  
 5. Desai, et al. *J Am Coll Card*. 2017.  
 6. Abraham J, et al. *JAMA Card*. 2019.  
 7. Angermann, et al. *Euro J Heart Fail*. 2020.  
 8. Shavelle, et al. *Circ HF*. 2020.

# INCREASED SURVIVAL

Synergistic Impact With GDMT<sup>3</sup>  
(CHAMPION subgroup)



Propensity-matched Cohort<sup>6</sup>  
(Medicare database)



Supporting  
Studies

Increased  
Survival

Synergistic Impact  
With GDMT<sup>3</sup>



Propensity-  
matched Cohort<sup>6</sup>

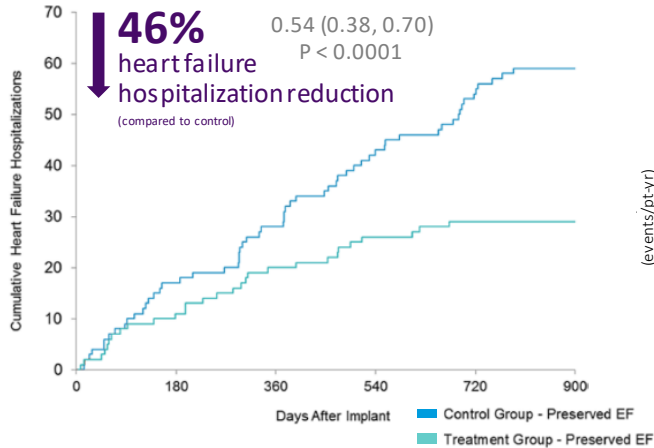


3. Givertz, et al. *J Am Coll Cardio*. 2017.  
6. Abraham J, et al. *JAMA Card*. 2019.

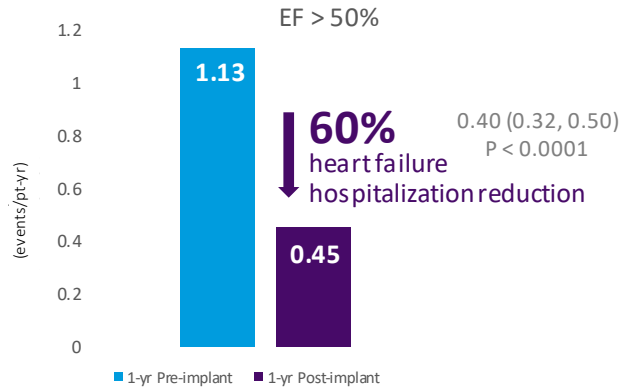
# HFpEF OUTCOMES

THE **ONLY** PROVEN THERAPY TO REDUCE HEART FAILURE HOSPITALIZATIONS IN HFpEF PATIENTS

## Proven Benefits in HFpEF Patients<sup>2</sup>



## U.S Post-approval Study<sup>8</sup>



### Supporting Studies

### Benefit to HFpEF

Proven Benefits in HFpEF Patients<sup>2</sup>



First 2,000 Implants<sup>4</sup>



U.S Post-approval<sup>8</sup>



MEMS-HF<sup>7</sup>



2. Adamson, et al. *Circ HF*. 2014.

4. Heywood, et al. *Circulation*. 2017.

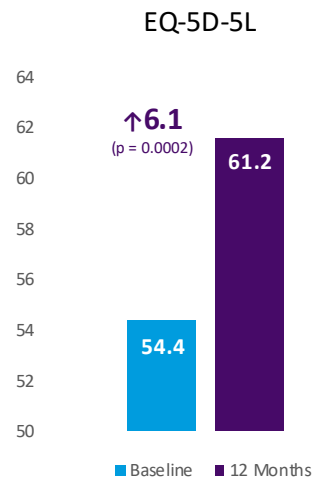
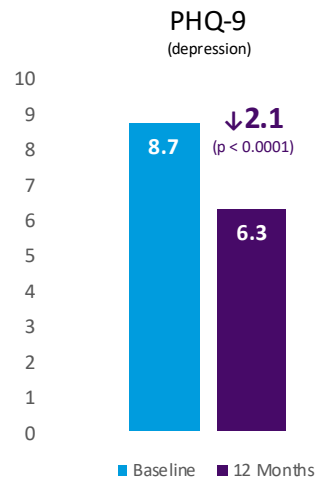
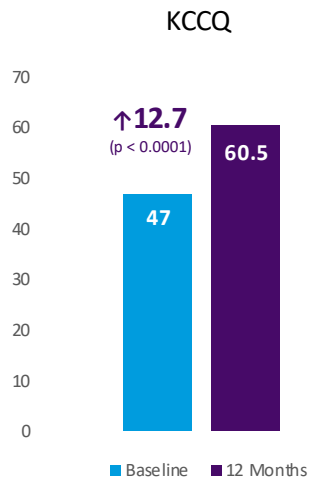
7. Angermann, et al. *Euro J Heart Fail*. 2020.

8. Shavelle, et al. *Circ HF*. 2020.

# IMPROVED QOL

ACROSS ALL PATIENT-REPORTED OUTCOMES

## MEMS-HF European Study<sup>7</sup>



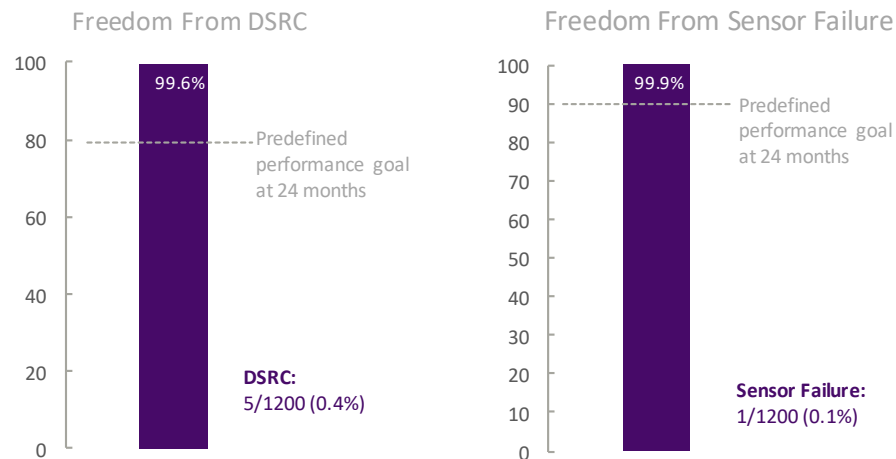
Supporting Studies	Improved QOL
CHAMPION Study <sup>1</sup>	✓
MEMS-HF <sup>7</sup>	✓

1. Abraham WT, et al. *Lancet*. 2016.  
7. Angermann, et al. *Euro J Heart Fail*. 2020.

# OUTSTANDING SAFETY PERFORMANCE

## U.S. Post-approval Study<sup>8</sup>

(1-year follow-up results)



Supporting Studies	Freedom From DSRC
--------------------	-------------------

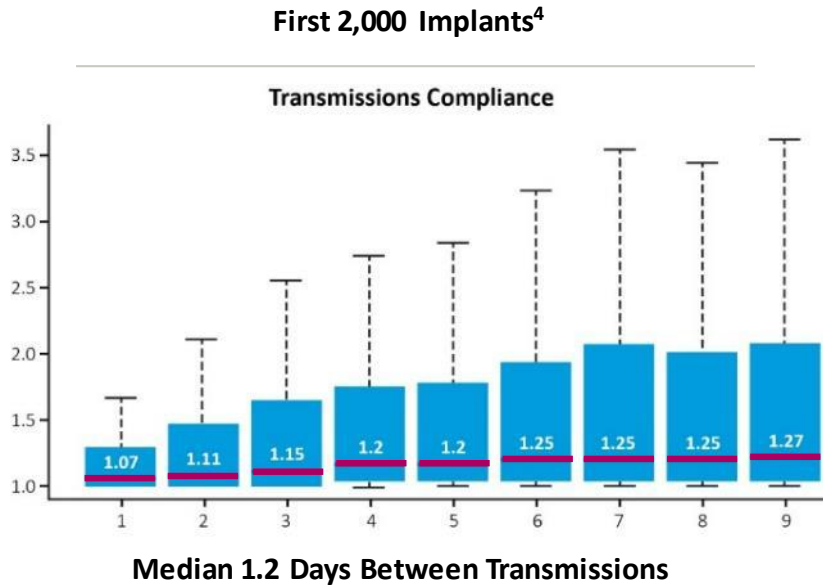
CHAMPION Study <sup>1</sup>	98.6%
-----------------------------	-------

U.S Post-approval <sup>8</sup>	99.6%
--------------------------------	-------

MEMS-HF <sup>7</sup>	98.3%
----------------------	-------

1. Abraham WT, et al. *Lancet*. 2016.  
7. Angermann, et al. *Euro J Heart Fail*. 2020.  
8. Shavelle, et al. *Circ HF*. 2020.

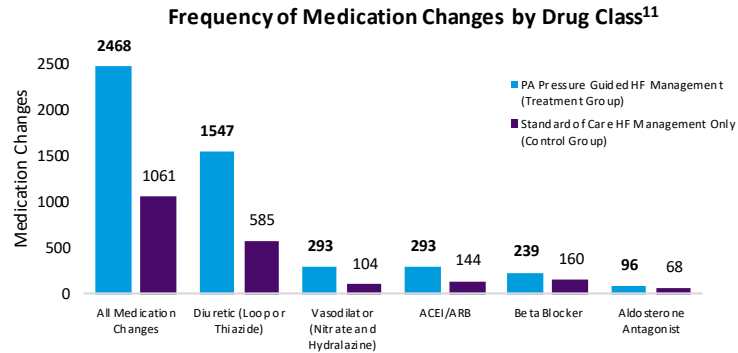
# EXCELLENT PATIENT ADHERENCE



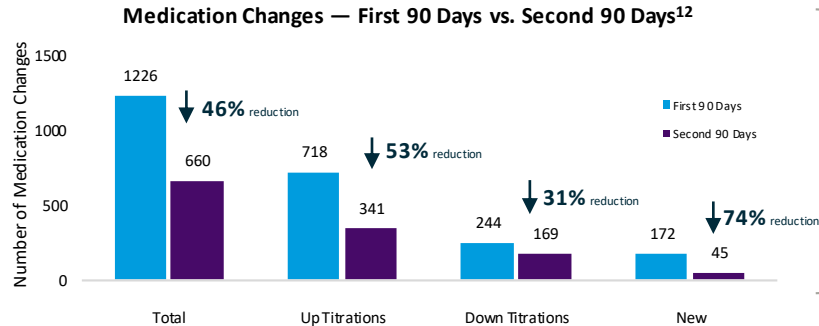
Supporting Studies	Mean Weekly Transmission
First 2,000 Implants <sup>4</sup>	98%
MEMS-HF <sup>7</sup>	89%
U.S. Post-Approval <sup>8</sup>	93%

4. Heywood, et al. *Circulation*. 2017.  
7. Angermann, et al. *Euro J Heart Fail*. 2020.  
8. Shavelle, et al. *Circ HF*. 2020.

# OPTIMIZING MEDICAL MANAGEMENT



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



Medication changes decrease significantly after stabilization (~ 90 days)

Supporting Studies

Medication Changes

CHAMPION Study<sup>1</sup>



Proven Benefits in HFpEF Patients<sup>2</sup>



MEMS-HF<sup>7</sup>



U.S Post-approval<sup>8</sup>



1. Abraham WT, et al. *Lancet*. 2016.

2. Adamson, et al. *Circ HF*. 2014.

7. Angermann, et al. *Euro J Heart Fail*. 2010.

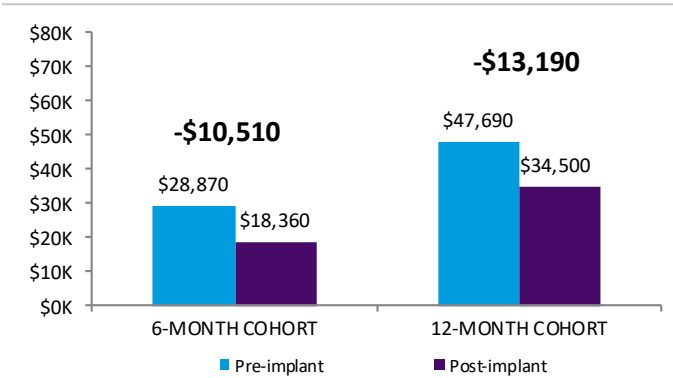
8. Shavelle, et al. *Circ HF*. 2020.

11. Costanzo, et al. *J Am Coll Cardio*. 2016.

12. Raval, et al. Presented at: HFSA. 2017.

# COST-EFFECTIVE

## Economic Impact<sup>5</sup>



### Additional Cost-effectiveness Studies

Kolominsky-Rabas, et al. *Telemedicine and e-Health*. 2016.<sup>13</sup>

Martinson, et al. *European J Heart Failure*. 2017.<sup>14</sup>

Schmier, et al. *Clinical Cardiology*. 2017.<sup>15</sup>

Cowie, et al. *European J Heart Failure*. 2017.<sup>16</sup>

**Significant cost reductions  
at 6 and 12 months**

Supporting  
Studies

Cost-  
effective

CHAMPION Study<sup>1</sup>



Economic Impact<sup>5</sup>



1. Abraham WT, et al. *Lancet*. 2016.  
5. Desai, et al. *J Am Coll Card*. 2017.



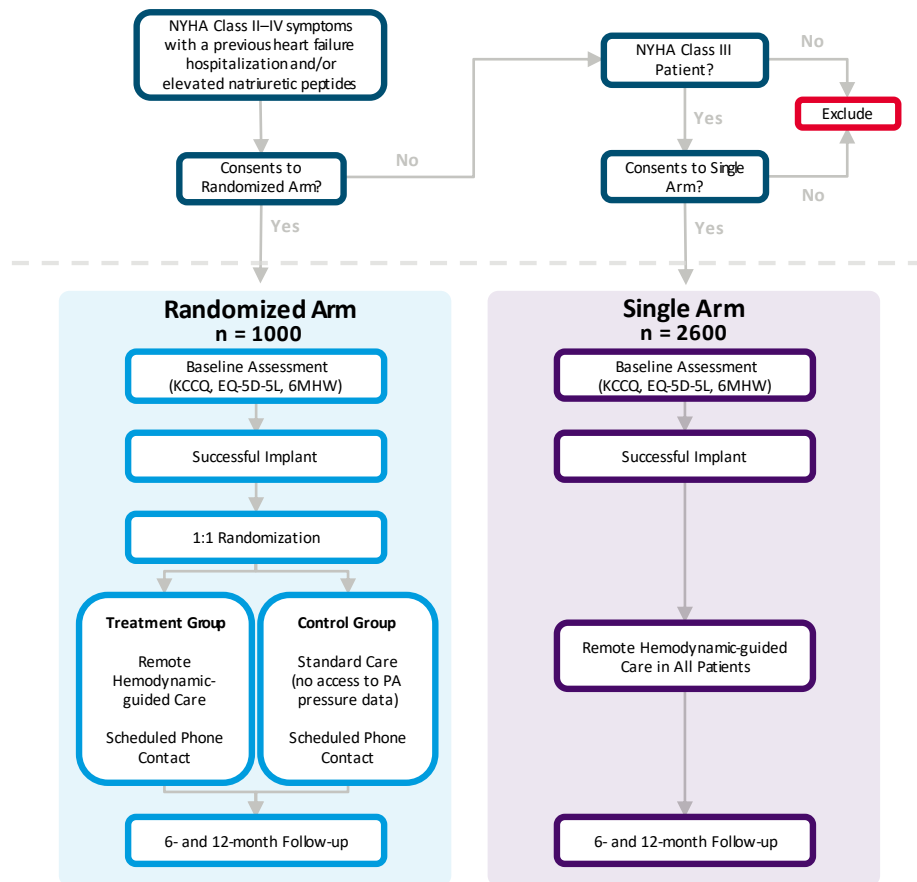
# GUIDE-HF<sup>9\*</sup>

## DESIGN AND GOALS

THE LARGEST CLINICAL TRIAL OF THE  
CARDIOMEMS™ HF SYSTEM

### GOALS OF THE STUDY

- 3,600 patients
- Expand indications to NYHA Class II–IV
- Establish elevated BNP/NT-proBNP OR prior heart failure hospitalization as selection criteria
- Establish mortality benefit
- Provide foundation for entry into ACC/AHA Heart Failure Guidelines
- Obtain National Coverage Determination



\*Trial in progress.

9. Lindenfeld, et al. *Am Heart J.* 2019.

## HOW DO THE DATA

# COME TOGETHER?



STUDY	AUTHOR	N	Heart Failure Hospitalization	PA Pressure	↑ Survival	HFpEF	QOL	Cost Benefit	Safety	Adherence	Medication Change
CHAMPION Pivotal Study <sup>1</sup>	WT Abraham	550	✓	✓			✓	✓	✓		✓
Proven Benefits in HFpEF Patients <sup>2</sup>	Adamson	119	✓			✓					✓
Synergistic Impact With GDMT <sup>3</sup>	Givertz	456	✓		✓						
First 2,000 Commercial Implants <sup>4</sup>	Heywood	2,000		✓		✓				✓	
Economic Impact <sup>5</sup>	Desai	1,114	✓					✓			
Propensity-matched Outcomes <sup>6</sup>	J Abraham	2,174	✓		✓						
MEMS-HF European Study <sup>7</sup>	Angermann	234	✓	✓		✓	✓		✓	✓	✓
U.S. Post-approval Study <sup>8</sup>	Shavelle	1,200	✓	✓		✓			✓	✓	✓

1. Abraham WT, et al. *Lancet*. 2016.

2. Adamson, et al. *Circ HF*. 2014.

MAT-2007440 v3.0 | Item approved for U.S. use only.

3. Givertz, et al. *J Am Coll Cardiol*. 2017.

4. Heywood, et al. *Circulation*. 2017.

5. Desai, et al. *J Am Coll Card*. 2017.

6. Abraham J, et al. *JAMA Card*. 2019.

7. Angermann, et al. *Euro J Heart Fail*. 2020.

8. Shavelle, et al. *Circ HF*. 2020.

# ACRONYMS

6MHW	six-minute hall walk
ACC	American College of Cardiology
AHA	American Heart Association
AUC	area under curve
BNP	B-type natriuretic peptide
DSRC	device-/system-related complication
EF	ejection fraction
HFpEF	heart failure with preserved ejection fraction
KCCQ	Kansas City Cardiomyopathy Questionnaire
mPAP	mean pulmonary artery pressure
NT-proBNP	N-terminal pro b-type natriuretic peptide
NYHA	New York Heart Association
PA	pulmonary artery
PHQ-9	Patient Health Questionnaire-9
QOL	quality of life

# 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.
5. Desai AS, et al. Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in "Real-World" Clinical Practice. *J Am Coll Cardiol*. 2017;69(19):2357-65.
6. Abraham J, et al. Association of Ambulatory Hemodynamic Monitoring with Clinical Outcomes in a Concurrent Matched Cohort Analysis. *JAMA Cardiology*. 2019;4(6):556-563.
7. Angermann C, Assmus B, et al. Pulmonary-Artery-Pressure-Guided Therapy in Ambulatory Patients with Symptomatic Heart Failure: The CardioMEMS European Monitoring Study for Heart Failure (MEMS-HF). *European J of Heart Failure*. 2020. 10.1002/ejhf.1943.
8. Shavelle D, Desai A, Abraham W, et al. Lower rates of heart failure and all-cause hospitalizations during pulmonary artery pressure-guided therapy for ambulatory heart failure. *Circulation: Heart Failure*. Published online 2020. <https://doi.org/10.1161/CIRCHEARTFAILURE.119.006863>.
9. Lindenfeld J, et al. Hemodynamic-GUIDEd management of Heart Failure (GUIDE-HF). *Am Heart J*. 2019;214:18-27.
10. Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomized controlled trial. *The Lancet*. 2011;377(9766):658-666.
11. Costanzo MR, Stevenson LW, Adamson PB, et al. Interventions Linked to Decreased Heart Failure Hospitalizations During Ambulatory Pulmonary Artery Pressure Monitoring. *J Am Coll Cardiol Heart Fail*. 2016.
12. Raval NY, et al. Significant Reductions in Heart Failure Hospitalizations with the Pulmonary Artery Pressure Guided HF System: Preliminary Observations From the CardioMEMS Post Approval Study. Abstracts presented at: HFSA 2017 21st Annual Meeting. *Journal of Cardiac Failure*. August 2017;23(8). Supplement:S27.
13. Kolominsky-Rabas PL, et al. Health economic impact of a pulmonary artery pressure sensor for heart failure telemonitoring: A dynamic simulation. *Telemedicine and e-Health*. 2016;22:798- 808.
14. Martinson M, Bharmi R, Dalal N, Abraham WT, Adamson PB. Pulmonary artery pressure-guided heart failure management: US cost-effectiveness analyses using the results of the CHAMPION clinical trial. *European Journal Heart Failure*. 2017. doi:10.1002/ejhf.642.
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.

## Abbott

One St. Jude Medical Dr., St. Paul, MN 55117 USA, Tel: 1 651 756 2000  
Cardiovascular.Abbott

## 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 (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.

**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: infection, arrhythmias, bleeding, hematoma, thrombus, myocardial infarction, transient ischemic attack, stroke, death, and device embolization.

™ Indicates a trademark of the Abbott group of companies.

‡ Indicates a third party trademark, which is property of its respective owner.

© 2020 Abbott. All Rights Reserved.

MAT-2007440 v3.0 | Item approved for U.S. use only.



**Abbott**