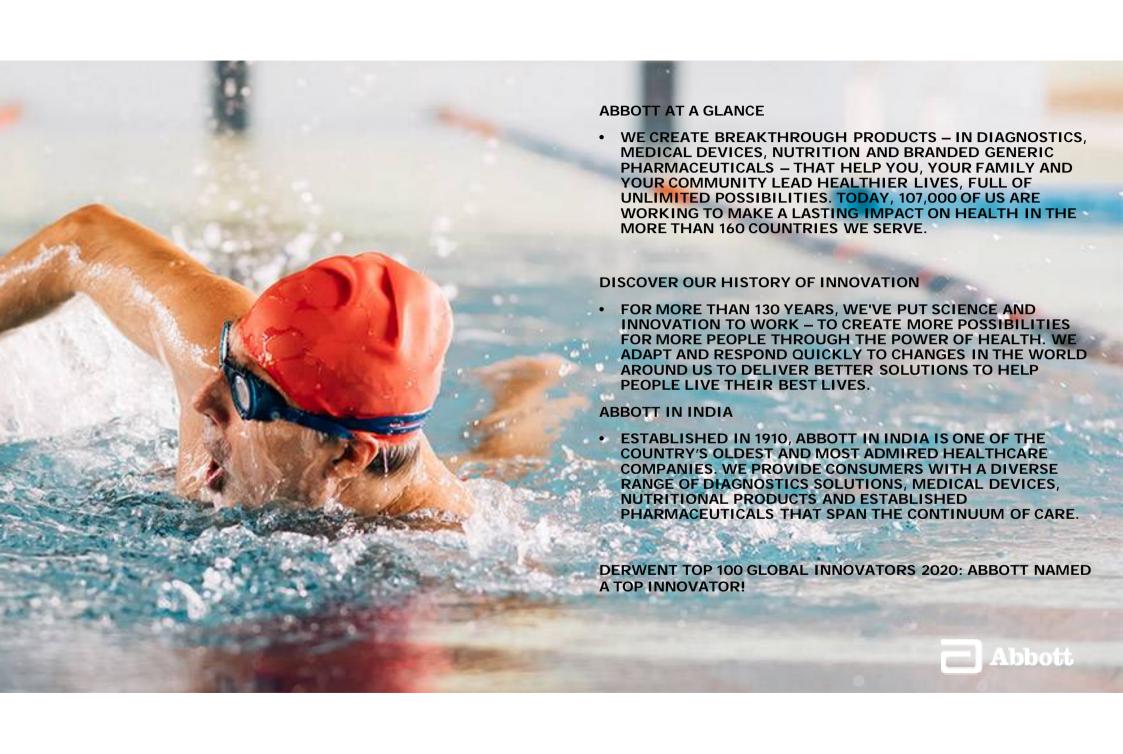


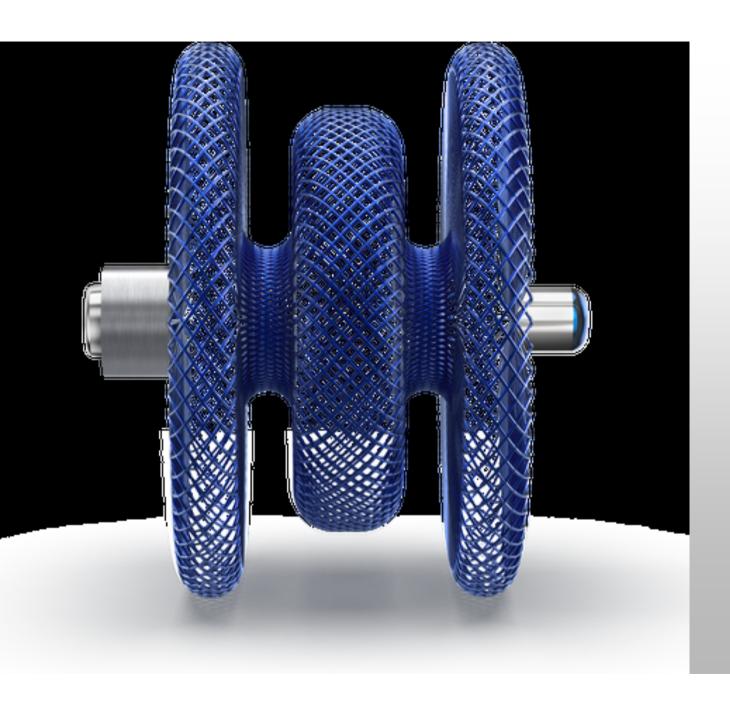
New Medical Device Technologies in Cardiac Disease Management





# MITRACLIP™ TRANSCATHETER MITRAL VALVE REPAIR

- BREAKTHROUGH THERAPY FOR SELECT PATIENTS WITH MITRAL REGURGITATION
- MITRACLIP IS THE WORLD'S FIRST TRANSCATHETER MITRAL VALVE REPAIR (TMVR) THERAPY THAT DELIVERS A TREATMENT OPTION FOR SELECT PATIENTS WITH PRIMARY OR SECONDARY MITRAL REGURGITATION WHO WOULD OTHERWISE GO UNTREATED.
- USED IN OVER 80,000 PATIENTS
   WORLDWIDE, MITRACLIP IS A WELLESTABLISHED PROCEDURE WITH A
   GROWING BODY OF CLINICAL AND REALWORLD EXPERIENCE.
- NOW APPROVED IN THE U.S. FOR TREATMENT OF SECONDARY MR IN SELECT HEART FAILURE PATIENTS WHO REMAIN SYMPTOMATIC DESPITE GDMT



# **AMPLATZER™ PICCOLO**

- THE WORLD'S FIRST DEVICE THAT CAN CLOSE A HOLE IN EVEN THE TINIEST OF HEARTS.
- CLOSING A HOLE IN THE MOST FRAGILE OF HEARTS
- EVERY BABY IS BORN WITH A HOLE IN THEIR HEART. THIS BLOOD V ESSEL, CALLED THE DUCTUS ARTERIOSUS, ALLOWS THEM TO RECEI VE OXYGENRICH BLOOD FROM THEIR MOTHER WHILE IN THE WO MB. AFTER BIRTH, THE HOLE SHOULD NATURALLY CLOSE OVER THE FIRST FEW DAYS OF LIFE, LETTING THE LUNGS AND HEART TAKE O VER. BUT FOR THOUSANDS OF BABIES EACH YEAR, THE HOLE DOES N'T CLOSE PROPERLY —

KNOWN AS A PDA (PATENT DUCTUS ARTERIOSUS). WHEN THAT H APPENS, IT CAN THREATEN THEIR ALREADY FRAGILE LIFE AND BECO ME A HOUSE OF CARDS.

- A PDA IS PRESENT IN APPROXIMATELY1 IN 2,000 BIRTHS
- PDA RISK IS CONSIDERABLY HIGHER 20-60 % IN PRETERM BABIES
- BREAKTHROUGHS, THAT'S ALSO ONE OF THE SMALLEST
- SOMETIMES SOLVING THE BIGGEST CHALLENGES MEANS THINKIN G SMALL – VERY SMALL.
- AT NO BIGGER THAN A PEA, OUR AMPLATZER ™ PICCOLO IS ONE
  OF THE SMALLEST HEART DEVICES EVER. MOST IMPORTANTLY, PICC
  OLO IS THE FIRST U.S. APPROVED DEVICE SMALL ENOUGH TO CLO
  SE A HOLE IN THE HEART OF A PREMATURE INFANT WEIGHING AS
  LITTLE AS 700 GRAMS (ABOUT 1.5 POUNDS). AND BECAUSE PICCO
  LO IS A MINIMALLY-
  - Invasive device, it can eliminate the need for riskier surger y.
- A BREAKTHROUGH THAT FOR THOUSANDS OF FUTURE NEWBORN LIVES, WILL KEEP OPEN A LIFETIME OF POSSIBILITY.

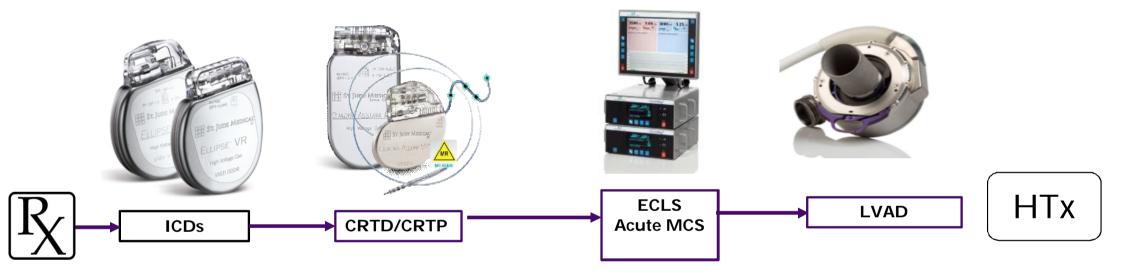


# PERCUTANEOUS TRANSCATHETER OCCLUSION OF THE LEFT ATRIAL APPENDAGE (LAAO)

- REAL-WORLD STUDY RESULTS SUPPORT USE OF ABBOTT'S AMPLATZER™ AMULET™ TO REDUCE STROKE IN PATIENTS SUFFERING FROM ATRIAL FIBRILLATION WITHOUT THE NEED FOR LIFETIME BLOOD THINNERS
- STUDY CONFIRMS SAFETY OF TREATMENT WITH AMPLATZER AMULET DEVICE AND REDUCTION IN STROKE RISK BY NEARLY 60 PERCENT
- - POST-IMPLANT, AMPLATZER AMULET SUCCESSFULLY SEALED LEFT ATRIAL APPENDAGE IN 99 PERCENT OF PATIENTS
- - IN PATIENT POPULATION AT HIGH RISK FOR STROKE - AND MAJOR BLEEDING - NEED FOR BLOOD-THINNING MEDICATION REDUCED

# **Comprehensive HF Solutions**

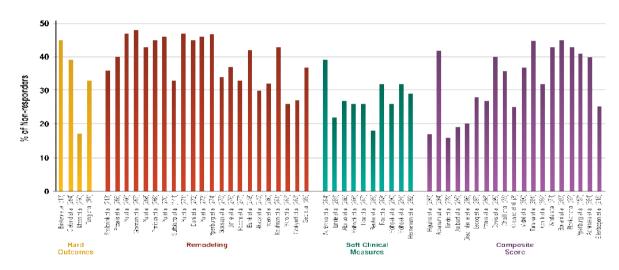
A continuum of care from asymptomatic to refractory.



- Pioneering and establishing standards.
- Developing Internal protocols to manage HF patients
- Mining insights to get ahead of adverse events.
- Reducing hospitalizations, lowering cost.

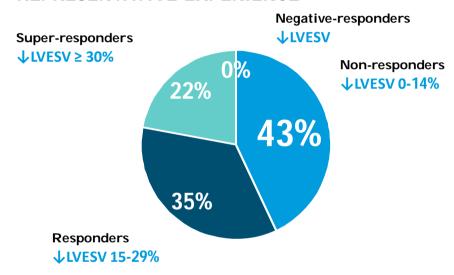
# **Challenge: CRT-Response**

### RESPONSE TO CRT IS INADEQUATE AND UNPREDICTABLE<sup>1</sup>



### 1. Daubert, J.C., Saxon, L., Adamson, P.B., Auricchio, A., Berger, ... Torp-Pedersen, C.T. (2012). 2012 EHRA/HRS expert consensus statement on cardiac resynchronization therapy in heartfailure: implant and follow-up recommendations and management. Europace, 14(9):1236-86.

### REPRESENTATIVE EXPERIENCE<sup>2</sup>



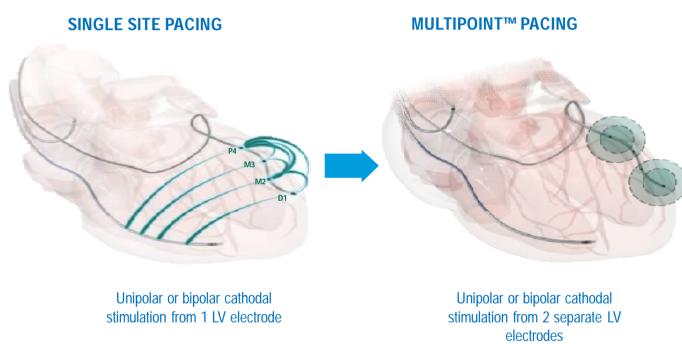
43% of CRT patients classified as non-responders or negative-responders by LVESV after 6 months (N = 303)

23003-SJM-MLP-0516-0061(1) | Item approved for U.S. use only.

<sup>2.</sup> Ypenburg, C., Bommel, R. J., Borleffs, C. J., Bleeker, G. B., Boersma, E., Schalij, M. J., & Bax, J. J. (2009). Long-Term Prognosis After Cardiac Resynchronization Therapy Is Related to the Extent of Left Ventricular Reverse Remodeling at Midterm Follow-Up. Journal of the American College of Cardiology, 53(6), 483-490. doi:10.1016/j.jacz.2008.10.032.

# From multisite to Multi-Point Pacing (MPP)

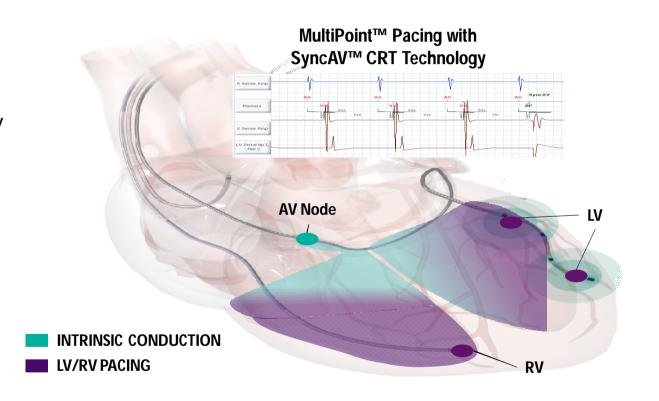
- Faster depolarization along longitudinal direction of myocardial fibers
- Capture a larger area of myocardium
- Capture more tissue around areas of scar
- Better resynchronization
- Better hemodynamics
- Better remodelling
- Better response



# SyncAV™ CRT Dynamically Tailored to the Patient's Beat¹

- New dynamic timing feature for quadripolar CRT devices
- Individualize and dynamically adjust timing (AV Delays) based on intrinsic patient rhythm
- Drive fusion with intrinsic rhythm for improved electrical synchrony and narrower QRS<sup>1</sup>
- Can complement Multipoint<sup>™</sup> Pacing

Wisnoskey BJ, Cranke G, Cantillon DJ, and Varma N. (2016). Feasibility of Device-Based Electrical Optimization via Application of the Negative AV Hysteresis Algorithm during Cardiac Resynchronization Therapy (CRT).



# Merlin.net Clinical Benefits



# Remote monitoring is now recognised as the standard of care<sup>1</sup>

The 2015 HRS EXPERT CONSENSUS STATEMENT ON RC recommendations were that remote monitoring represents the new standard of care for patients with ICDs, with alert-driven patient visits replacing most routine office interrogations.

HRS Remote Monitoring Consensus Statement Recommendations					
Device Follow-Up Paradigm	Class of Recommendation	Level of Evidence			
A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	I	А			
All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	I	A			
RM should be performed for surveillance of lead function and battery conservation.	I *	Α			
RM is useful to reduce the incidence of inappropriate ICD shocks.	I	B-R			
RM is useful for the early detection and quantification of atrial fibrillation.	I	Α			

<sup>1.</sup> Slotwiener, D. et al, HRS Expert Consensus Statement on remote interrogation & monitoring for cardiovascular implantable electronic devices, Heart Rhythm Society, May 13 2015

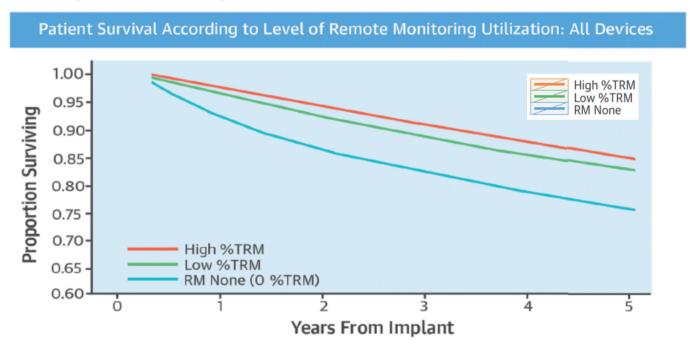


<sup>\*</sup> B-R = level of evidence B indicates a moderate level from randomised trials

# Merlin.net Clinical Benefits

# **2.1x greater survival** probability for patients utilising remote monitoring vs. those without monitoring<sup>2</sup>

Survival rates shown from the 269,471 patient study were all from using the **SJM Merlin.net Patient Care Network** with RF telemetry for SJM CRTs, ICDs and PPMs. The degree of adherence to remote management correlated strikingly with the magnitude of survival gain with weekly adherence to remote monitoring of >75% exhibiting the best survival.



<sup>2.</sup> The Relationship Between Level of Adherence to Automatic Wireless Remote Monitoring and Survival in Pacemaker and Defibrillator Patients, Varma N. et al, J Am Coll Cardiol. 2015;65(24):2601-2610. doi:10.1016/j.jacc.2015.04.033

Proprietary and confidential — do not distribute

# ABBOTT INTRODUCES NEXT-GENERATION HEART RHYTHM MANAGEMENT DEVICES IN EUROPE, FEATURING STATE-OF-THE-ART PATIENT APP AND BLUETOOTH CONNECTIVITY

New Gallant™ high voltage devices offer patients and their doctors a smartphone app and Bluetooth connectivity designed to help doctors tailor therapy to a patient's unique clinical needs

Gallant ICD and CRT-D devices feature a more comfortable design, preferred by patients without compromising on battery longevity or high-voltage output, which remain among the highest in the industry



# ADVISOR™ HD GRID MAPPING CATHETER, SENSOR ENABLED™

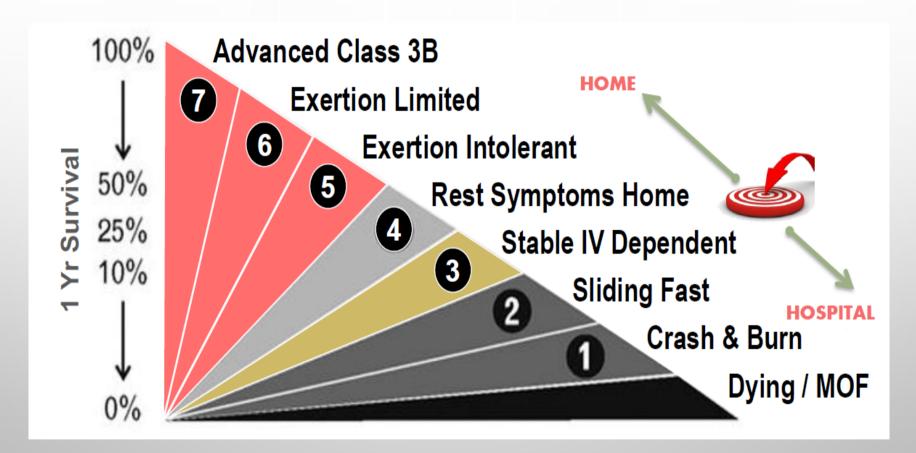


## SEE THINGS DIFFERENTLY.

The Advisor™ HD Grid Mapping
Catheter, Sensor Enabled,™ is a
steerable, flexible, insulated
electrophysiology catheter designed to
capture information often missed with
traditional 10-pole mapping catheters.
Offering a first-of-its kind electrode
configuration for high density mapping,
the Advisor HD Grid Mapping Catheter,
Sensor Enabled pairs with the EnSite
Precision™ Cardiac Mapping System for
additional display and data options.

Proprietary and confidential — do not distribute

# **INTERMACS - CLASSIFICATION**



# **Evolution : Technology**

HeartMate II: Axial flow pump



- Tested over 1,300 patient clinical trial (BTT & DT) and extensive post-market study experience with highly challenging patient populations.
- Only device approved for both BTT & DT by USFDA
- Proven over 25,000 patients implanted

> 600 published, peer-reviewed articlesPatient are living with this technology for over a decade

# HeartMate 3: Full MagLev Technology



- Implanted in over 10000 Patients Gloally
- Designed for haemocompatibility with the goal of minimizing complications
- Full support (flow) up to 10L/minute at lower pump speeds
- Return of pulsatility into continuous flow profile
- Compact size for less invasive surgical approaches

# THE LOWEST HEMOCOMPATIBILITY-RELATED ADVERSE EVENT (HRAE) RATES FOR ANY LVAD\*\*\*\*

HRAE refers to the constellation of bleeding, stroke and thrombosis events that often aggregate together in the same individual.

10% STROKE

MOMENT	MOMENTUM 3 2019' ENDURA		NCE 2017 <sup>2</sup>	
HeartMate 3™ LVAD	HeartMate II™ LVAD	HVAD <sup>†</sup> LVAD	HeartMate II LVAD	
(n = 516)	(n = 512)	(n = 297)	(n = 148)	
9.9% / 0.08	<b>19.4% / 0.18</b>	<b>29.7% / 0.29</b>	<b>12.1% / 0.09</b>	
(% / EPPY)	(% / EPPY)	(% / EPPY)	(% / EPPY)	

EPPY = Events per patient-year.

1%
THROMBOSIS<sup>1</sup>

MOMENTUM 3 20191		ENDURA	ENDURANCE 2017 <sup>2</sup>	
HeartMate 3 LVAD (n = 516)	HeartMate II LVAD (n = 512)	HVAD LVAD (n = 297)	HeartMate II LVAD (n = 148)	
1.0%5	11.1%⁵	6.4% 55	10.7%55	

Based on published data from multicenter experience and separate studies, which may involve different patient populations and other variables. Not a head-to-head comparison. Data presented for informational purposes only.



# Confirm Rx: Smart Heart Monitoring via Smartphone

**DELIVER**CONVENIENTLY

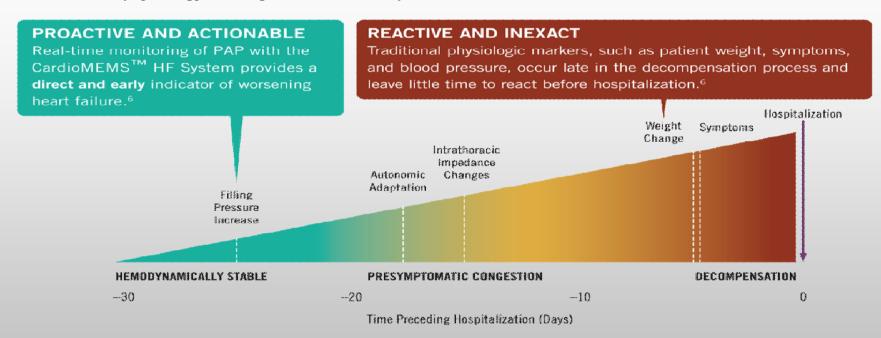
**DETECT** ACCURATELY **DECIDE**CONFIDENTLY



- SMALL DEVICE (~1.4 CC); 2 YEAR BATTERY LONGEVITY; MR CONDITIONAL
- SIMPLE INSERTION PROCEDURE
- INTUITIVE ONE-TOUCH INDICATION BASED PROGRAMMING VIA TRADITIONAL MERLIN
- AUTOMATIC WIRELESS CONNECTIVITY BETWEEN DEVICE, PATIENT SMARTPHONE AND MERLIN.NET

# The CardioMEMS™ HF System takes the guesswork out of Heart Failure Management

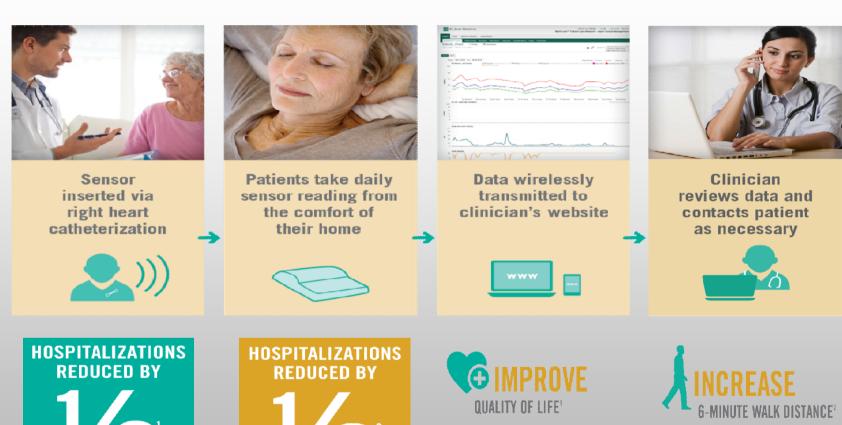
Pathophysiology of Congestion and Decompensation



# For heart failure patients, avoiding hospitalization is crucial

- After hospitalization, the heart failure prognosis worsens dramatically<sup>7</sup>
  - Mortality has been shown to be 37% 1 year after discharge, 79% at 5 years8

# CardioMEMS™ HF System implantation and usage is simple, quick, and secure



HOSPITALIZATIONS
REDUCED BY

18 MONTHS
(p < 0.0001)







# Thank you