

# MitraClip™

Transcatheter Mitral Valve Repair



## ADVANCING MITRAL THERAPY FOR YOUR PATIENTS

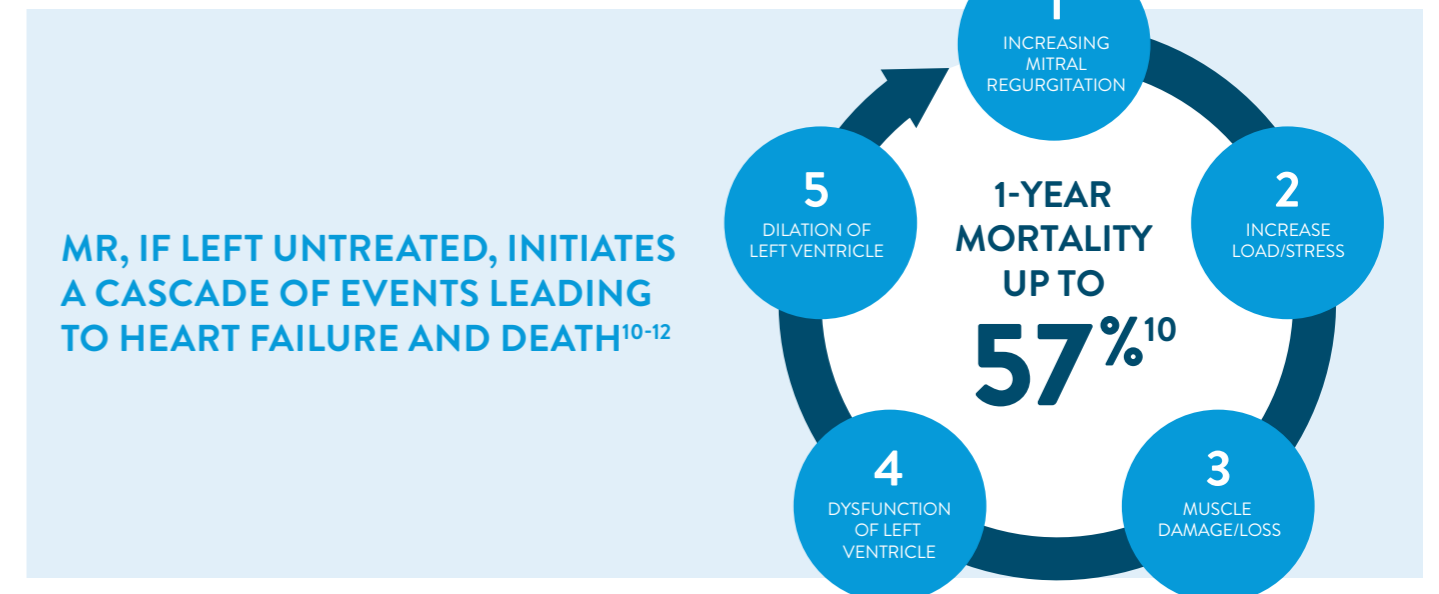
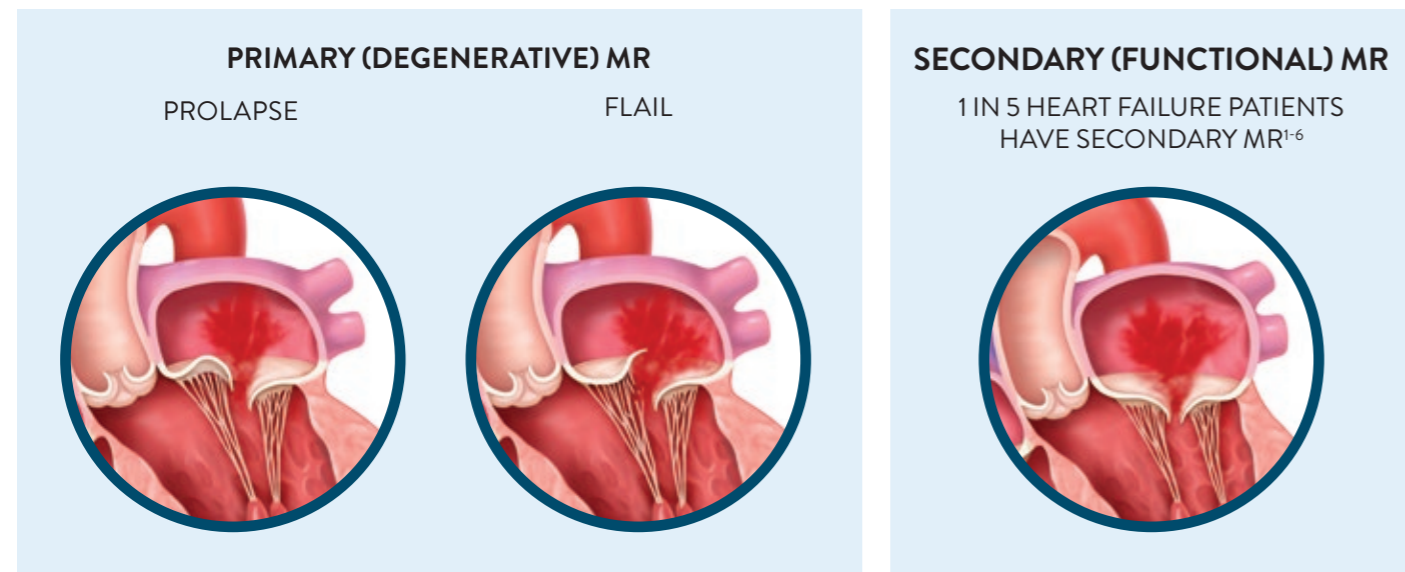
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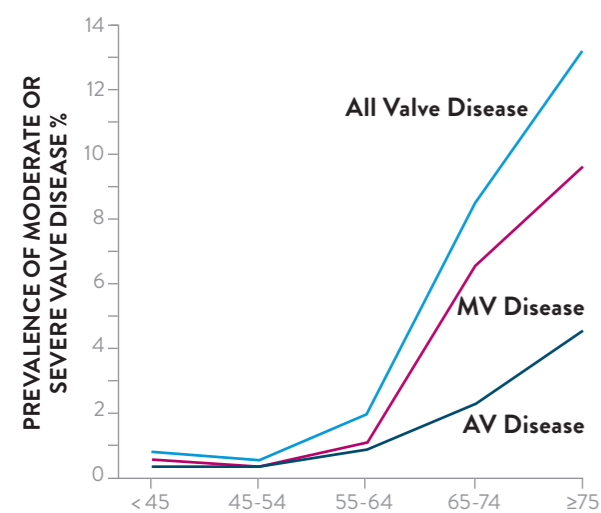
# MITRAL VALVE DISEASE: HIGHLY PREVALENT AND UNDERTREATED

# UNTREATED, MITRAL REGURGITATION KILLS

MITRACLIP™ IS INDICATED TO TREAT BOTH PRIMARY MITRAL REGURGITATION (MR) AND SEVERE SECONDARY MR

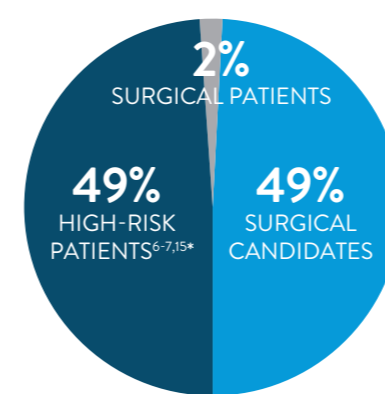


MORE LIVES ARE COMPROMISED BY MR THAN ANY OTHER VALVE DISEASE, BUT LESS THAN 1.5% ARE TREATED<sup>7-9\*†</sup>



SIGNIFICANT MR IS 4X MORE PREVALENT THAN SIGNIFICANT AORTIC STENOSIS, WITH OVER 4 MILLION PATIENTS SUFFERING FROM IMMEDIATE OR SEVERE MR IN THE U.S. ALONE.

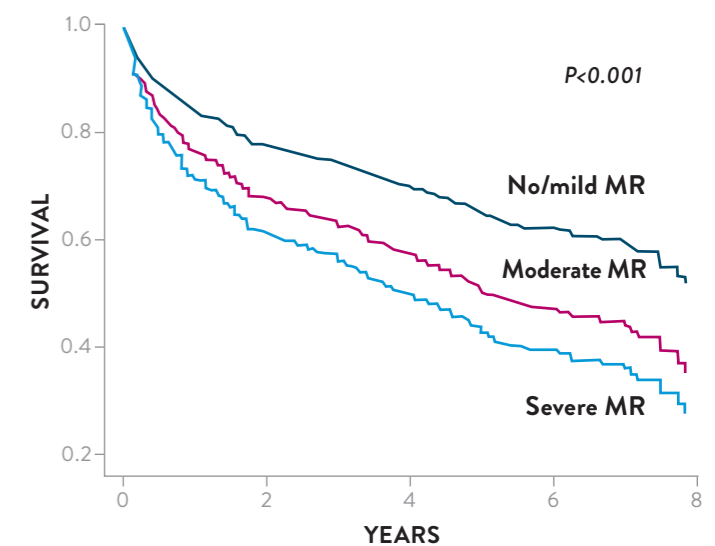
APPROXIMATELY 50% OF PRIMARY MR PATIENTS ARE NOT CANDIDATES FOR SURGERY DUE TO UNDERLYING FACTORS<sup>13-14</sup>



Factors prohibiting surgery include<sup>16</sup>:

- Impaired LVEF
- High operative risk
- Multiple comorbidities
- Advanced age

SEVERE SECONDARY MR IS AN INDEPENDENT PREDICTOR OF MORTALITY<sup>17</sup>



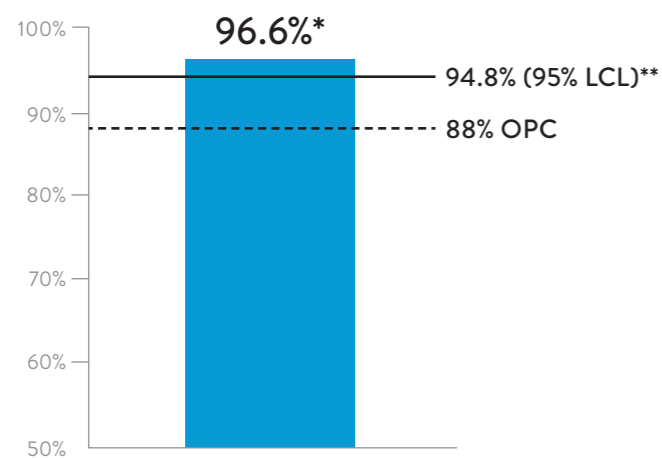
Symptoms and MR may persist in Secondary MR patients, despite maximally-tolerated GDMT.

\*Calculations are approximations made based on data from Mills J, Furlong C. CANACCORD: Biomedical Devices and Services. Nov 8, 2016 and Millennium Research Group. US Markets for Heart Valve Devices 2014. 2013; RPUS12HV13:92; and data from Abbott (LRP 20161130; based on LBE4) and Millennium Research Group. US Markets for Heart Valve Devices 2014. 2013; RPUS12HV13:94,153.

†Patients treated defined as undergoing surgery or transcatheter procedure.

# MITRACLIP: PROVEN SAFETY AND DURABILITY

# THE ONLY MV DEVICE SHOWN TO IMPROVE SURVIVAL IN HF PATIENTS WITH SECONDARY MR



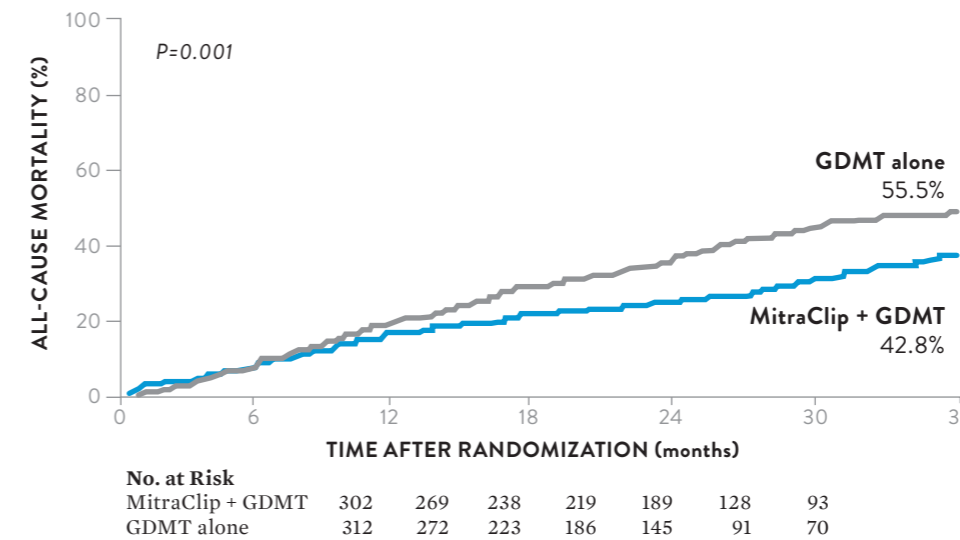
**96.6%**

**FREEDOM FROM  
DEVICE-RELATED  
COMPLICATIONS AT  
12 MONTHS<sup>18</sup>**

\*KM estimate.  
\*\*Calculated from Z test with Greenwood's method of estimated variance against a pre-specified objective performance goal of 88%.

## MITRACLIP CONTINUES TO IMPROVE SURVIVAL AT 3 YEARS<sup>20</sup>

### ALL-CAUSE MORTALITY



**33%**

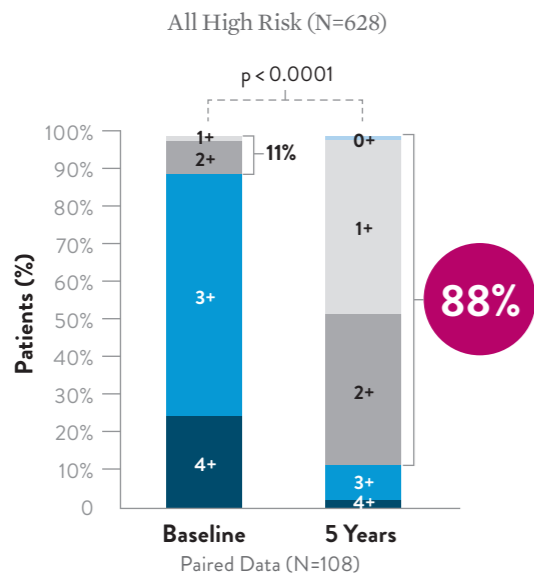
RELATIVE RISK REDUCTION  
IN MORTALITY

**7.9**

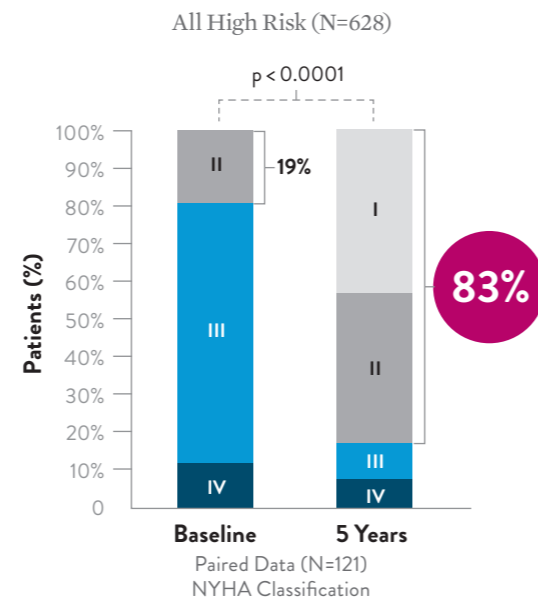
NUMBER NEEDED TO TREAT  
TO PREVENT ONE DEATH\*

## THE ONLY TMV DEVICE WITH PROVEN DURABLE OUTCOMES OUT TO 5 YEARS<sup>19</sup>

### SUSTAINED REDUCTION IN MR SEVERITY AT 5 YEARS

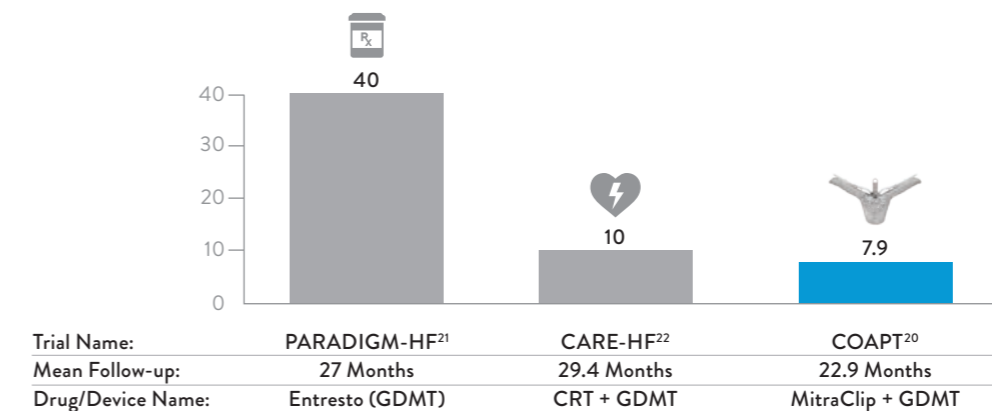


### SUSTAINED IMPROVEMENTS IN HEART FAILURE SYMPTOMS AT 5 YEARS



## MITRACLIP SETS A NEW STANDARD WITH NNT OF 7.9

### NUMBER NEEDED TO TREAT (NNT) TO PREVENT ONE DEATH FROM ANY CAUSE\*\*



**MITRACLIP WITH  
GDMT WAS PROVEN  
MORE EFFECTIVE  
THAN GDMT ALONE**

\* Includes crossover patients (GDMT only patients that were allowed to crossover to MitraClip after 24 mths).

\*\*Data from different trials with similar follow up periods; incremental benefits due to test drug/device above background therapy.

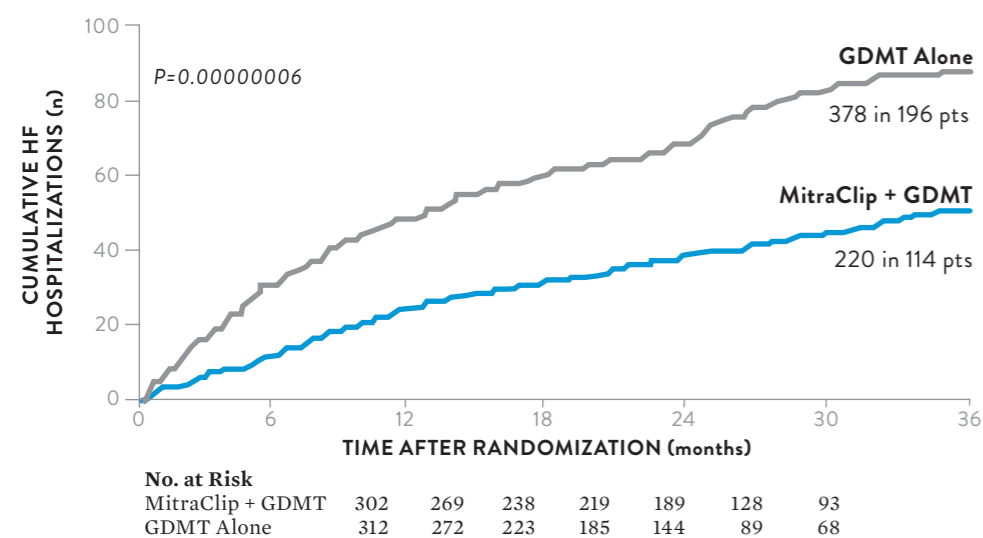
NOTE: Results from clinical trials are not directly comparable. Information provided for educational purposes only.

# COAPT™ TRIAL: LANDMARK STUDY IN THE MANAGEMENT OF HEART FAILURE

# MITRACLIP: PROVEN TO REDUCE MR

## MITRACLIP CONTINUES TO REDUCE HF HOSPITALIZATIONS AT 3 YEARS<sup>20</sup>

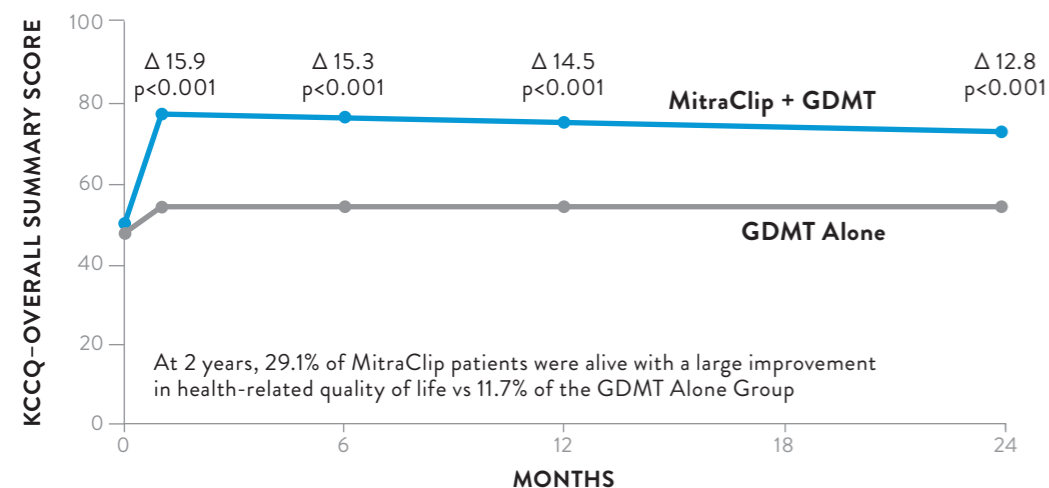
REDUCES HOSPITALIZATIONS FOR HF



**51%**  
RELATIVE RISK REDUCTION IN HEART FAILURE HOSPITALIZATIONS

**3.0**  
NUMBER NEEDED TO TREAT TO PREVENT ONE HEART FAILURE HOSPITALIZATION\*

## DRAMATIC IMPROVEMENT IN QUALITY OF LIFE<sup>23</sup>

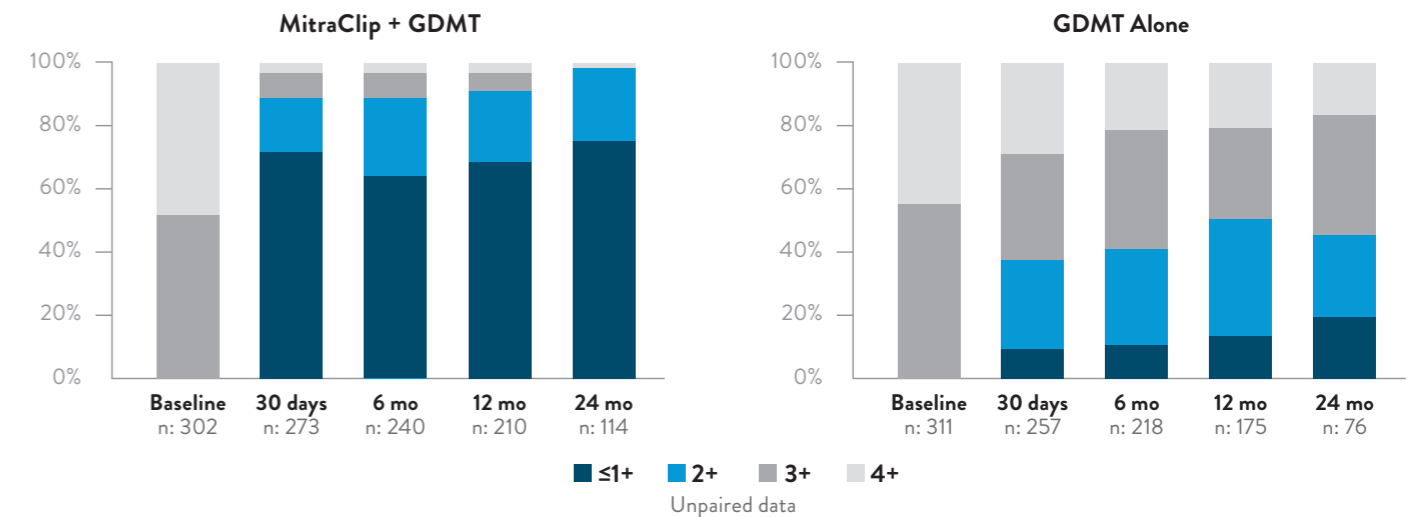


**2.5X**  
MORE LIKELY TO EXPERIENCE A LARGE IMPROVEMENT IN QUALITY OF LIFE WITH MITRACLIP

Includes crossover patients (GDMT only patients that were allowed to crossover to MitraClip after 24 mths).  
Note: KCCQ Minimum for Clinically Important Difference (MCID)= 5 points; Large Improvement Defined as  $\geq 20$  Points in KCCQ from Baseline; quality of life is assessed only in surviving patients

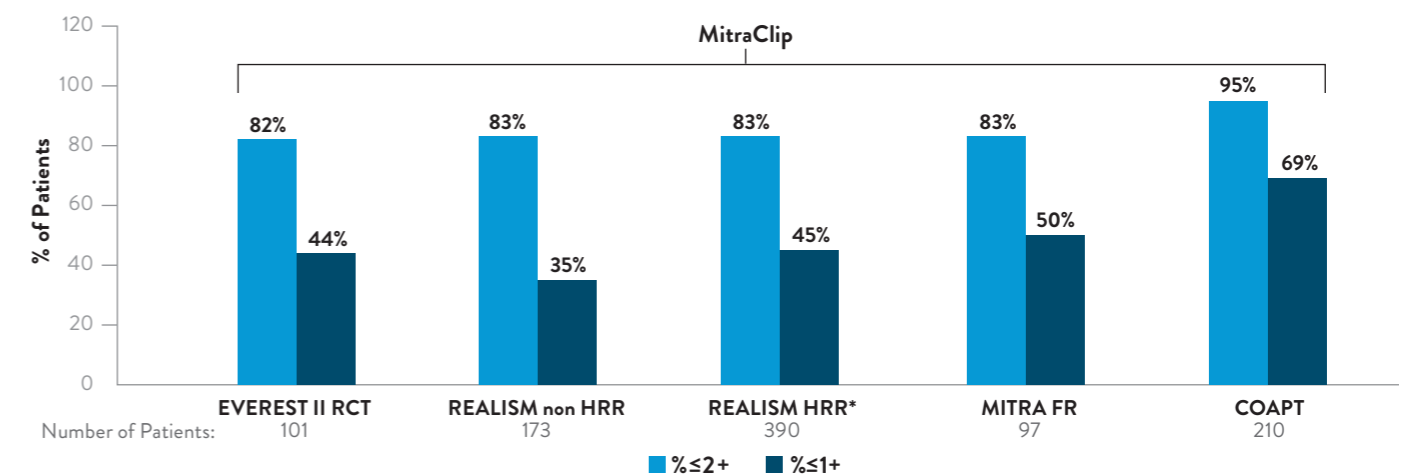
## MITRACLIP™ REDUCES SECONDARY MR SEVERITY<sup>18</sup>

99.1% OF MITRACLIP PATIENTS HAD MR  $\leq 2+$  AT 24 MONTHS



## MR REDUCTION DEMONSTRATED OVER MULTIPLE CLINICAL STUDIES<sup>19,24-26</sup>

MITRAL REGURGITATION SEVERITY AT 12 MONTHS



\*FMR patient cohort; DMR patient cohort N=108; % of patients with MR  $\leq 2+$ : 83%; % of patients with MR  $\leq 1+$ : 43%

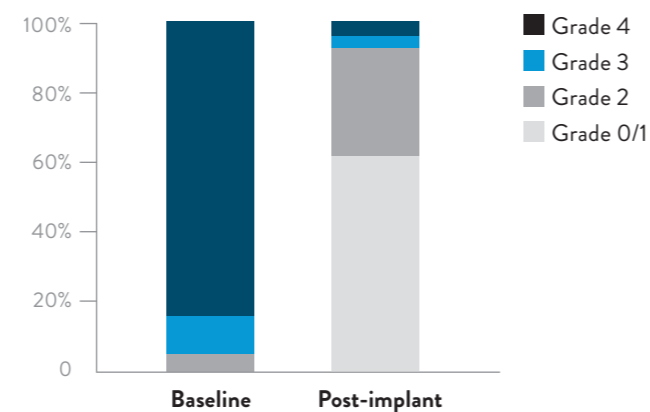
# REAL WORLD EVIDENCE AND EXPERIENCE SUPPORTS PROVEN OUTCOMES

## PROVEN SAFETY AND EFFECTIVENESS DATA FROM TVT REGISTRY<sup>27</sup> N=2,952 PATIENTS



30 day and 1 year events from linked CMS claims data

### ACUTE PROCEDURAL OUTCOMES



**93%**

POST-PROCEDURAL  
MR < 2+

**2.7%**

IN-HOSPITAL  
MORTALITY

**92%  
SUCCESS**

ACUTE PROCEDURAL  
SUCCESS

**2  
DAYS**

MEDIAN LENGTH  
OF STAY

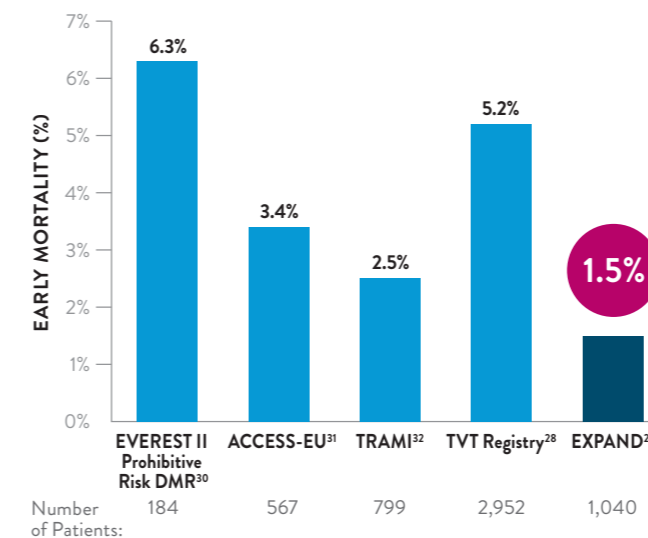
**85.9%  
DISCHARGED**

PATIENTS UNDERGOING THE  
MITRACLIP PROCEDURE WERE  
DISCHARGED DIRECTLY HOME

## THE EXPAND STUDY WITH MITRACLIP NTR/XTR<sup>28</sup> IN AN ALL COMER, REAL WORLD STUDY N=1041 PATIENTS (60 centers from the US and Europe)

### LOWEST 30-DAY MORTALITY<sup>29</sup>

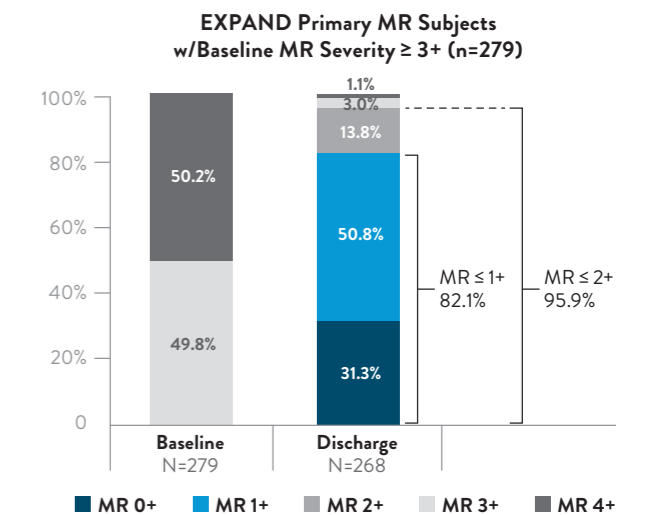
Reported to date in large scale studies



NOTE: Results from clinical trials are not directly comparable. Information provided for educational purposes only.

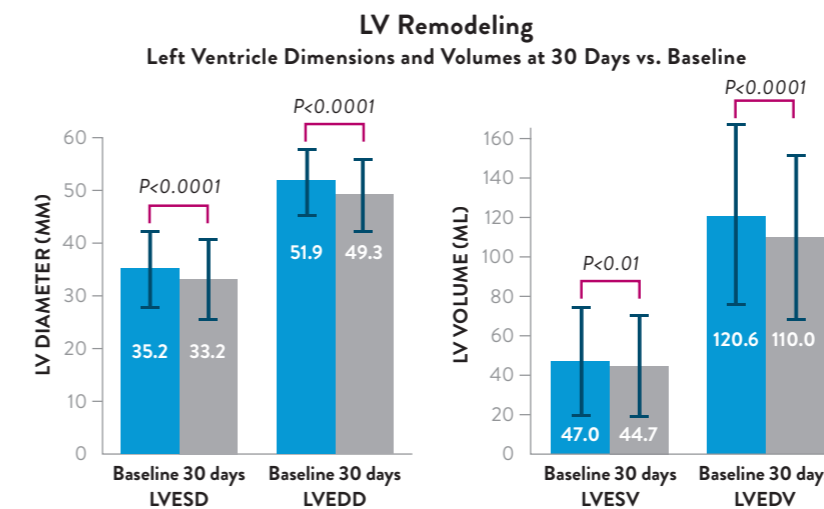
### OPERATORS ARE ACHIEVING MR ≤1+ TODAY WITH NTR AND XTR

More often than previously observed in EVEREST II and other trials



### SIGNIFICANT INCREMENTAL REDUCTION IN THE LEFT VENTRICULAR VOLUME AND DIMENSIONS

MitraClip remodels the LV within 30 days of treatment



Early evidence of reduction in left ventricular dimensions and volumes; Larger, more clinically significant changes may be evident at longer term follow-up



# MITRACLIP WITH GDMT IS A COST EFFECTIVE TREATMENT IN HEART FAILURE PATIENTS WITH SECONDARY MR<sup>33</sup>

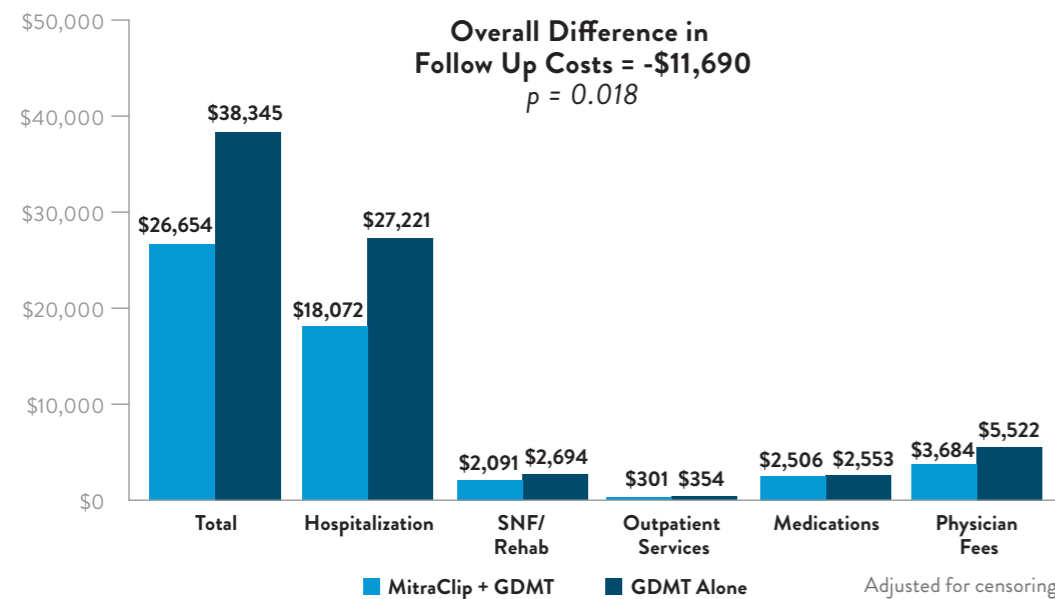
# MITRACLIP PROCEDURE KEY STEPS

## THE FIRST RCT-BASED COST EFFECTIVENESS STUDY COMPARING TRANSCATHETER MITRAL VALVE DEVICE VS MEDICAL THERAPY ALONE



**MITRACLIP IS AN INTERMEDIATE-HIGH VALUE THERAPY**

## 2-YEAR FOLLOW UP COSTS



**MITRACLIP REDUCES 2-YEAR FOLLOW-UP COSTS COMPARED TO GDMT ALONE**

**TRANSEPTAL CROSSING AND GUIDE INSERTION**

**IMAGING INVOLVED**

- Bicaval
- Short axis at base (SAX)
- 4-chamber
- 3D echo
- Fluoroscopy

**CDS INSERTION AND STEERING IN THE LEFT ATRIUM**

**IMAGING INVOLVED**

- SAX
- Intercommissural—2-chamber
- Left ventricular outflow tract (LVOT)
- 3D echo
- Transgastric short axis
- Fluoroscopy

**ADVANCING INTO LEFT VENTRICLE AND LEAFLET GRASPING**

**IMAGING INVOLVED**

- LVOT
- Intercommissural
- X-Plane (LVOT, Intercommissural)
- 3D echo
- Transgastric short axis
- Fluoroscopy

**LEAFLET INSERTION ASSESSMENT AND HEMODYNAMIC MEASUREMENTS**

**IMAGING INVOLVED**

- LVOT
- Intercommissural—2-chamber
- 4-chamber
- X-Plane
- 3D echo
- Transgastric short axis

**DEPLOYMENT AND SYSTEM REMOVAL**

- Intercommissural
- LVOT
- SAX
- Fluoroscopy

**PRE- AND POST-MITRACLIP THERAPY**

**BEFORE MITRACLIP**

Baseline MR

**AFTER MITRACLIP**

Visible MR reduction after Clip deployment

Images courtesy of Dr. Paul Sorajja at Abbott Northwestern.

# MITRACLIP: AN ONGOING COMMITMENT TO INNOVATION

## THE MITRACLIP SYSTEM

The MitraClip System performs **transcatheter mitral valve repair** by reestablishing leaflet coaptation, forming a double or multiple orifice valve.

- Transcatheter beating heart procedure – no cardiopulmonary bypass
- Allows for real-time positioning and repositioning to optimise MR reduction
- Femoral venous access requiring successful transseptal puncture
- Can be used in a standard cath lab or hybrid room

### STEERABLE GUIDE CATHETER

- A25-French steerable catheter



### CLIP DELIVERY SYSTEM

Contains the implant, attached to a highly maneuverable delivery catheter, with all controls at the proximal end.

### MITRACLIP DEVICE (IMPLANT)

Multiple clip sizes for tailored repair



STANDARD LENGTH ARM  
(G4 NT / G4 NTW)

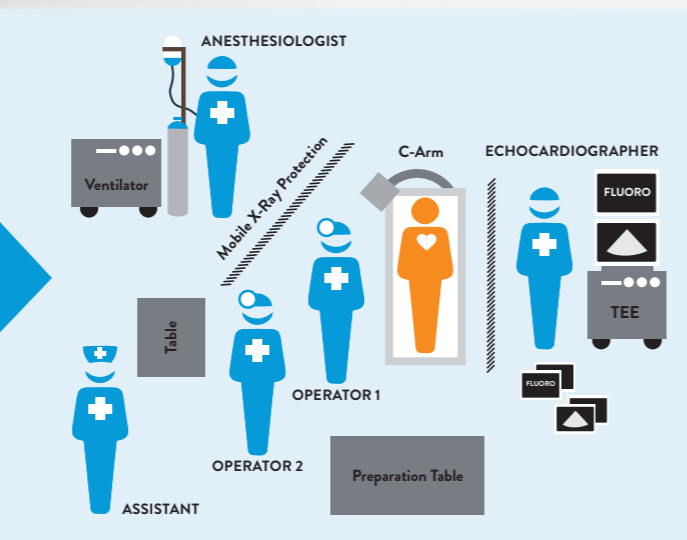
LONG LENGTH ARM  
(G4 XT / G4 XTW)

- Cobalt-Chromium and Nitinol Construction
- Polyester cover designed to promote tissue growth
- All implants are safe under labeled MRI scanning conditions\*

### EQUIPMENT

The MitraClip G4 System can be used in a standard cath lab or hybrid room. Equipment required includes:

- Fluoroscopy
- Slave monitors (one for echocardiography, one for fluoroscopy)
- General anesthesia
- Echocardiography machine equipped with transesophageal echo (TEE) probe
- Sterile system-preparation station



### REUSABLE ACCESSORIES



STABILIZER



SUPPORT PLATE



LIFT

\*Non-clinical testing has demonstrated that the MitraClip implants are MR conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3.0 T)

Maximum spatial field gradient of 4,000 Gauss/cm (40 T/m)

Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2W/kg (normal Operating Mode)

# MITRACLIP: FIRST & FOREMOST

# THE ONLY PROVEN TMV<sub>r</sub> THERAPY



OVER 16 YEARS  
OF CLINICAL EXPERIENCE



OVER 100K PATIENTS  
TREATED WORLDWIDE



OVER 2050  
PUBLICATIONS



OVER 30,000  
PATIENTS STUDIED



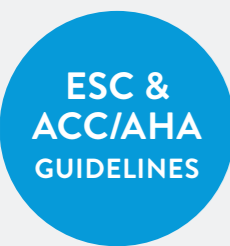
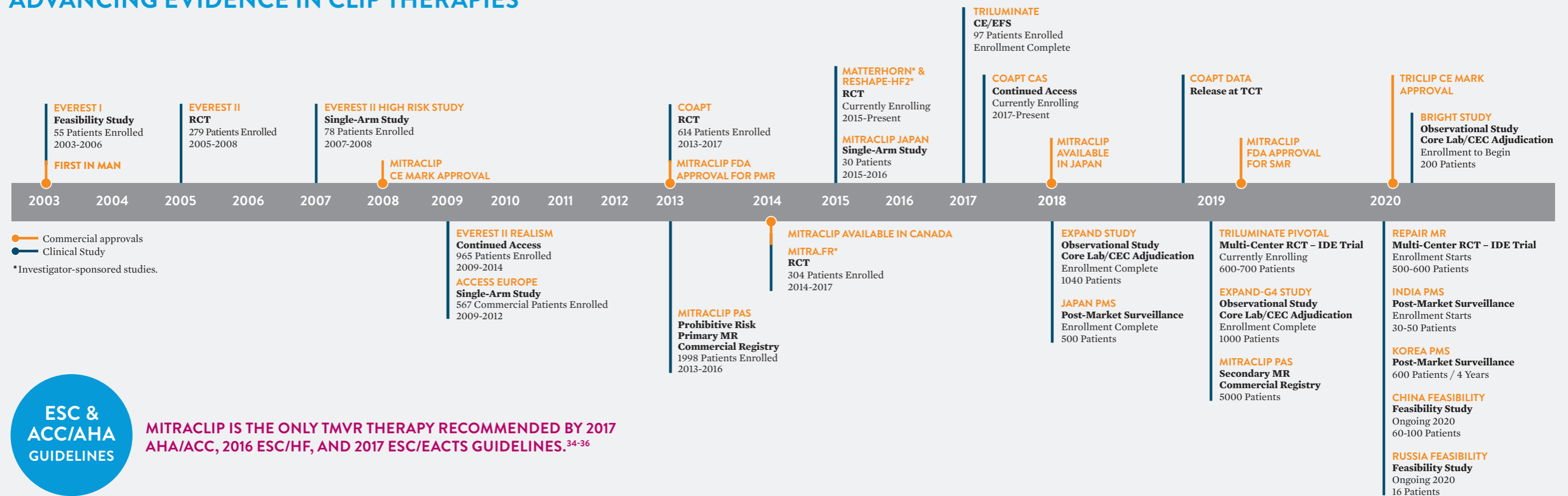
3 RCTS DEMONSTRATING  
SAFETY AND EFFICACY  
IN PMR AND SMR



OVER \$250 MILLION  
INVESTED IN EVIDENCE

Data on File at Abbott

## ADVANCING EVIDENCE IN CLIP THERAPIES



MITRACLIP IS THE ONLY TMV<sub>r</sub> THERAPY RECOMMENDED BY 2017 AHA/ACC, 2016 ESC/HF, AND 2017 ESC/EACTS GUIDELINES.<sup>34-36</sup>



# FROM THE FIRST PATIENT...

# TO OVER

# 100K



“I can do anything a normal person can. There are times I forget that I had the procedure done.”

– THE FIRST MITRACLIP PATIENT WHO RECEIVED MITRACLIP IN 2003

PATIENTS TREATED  
WORLDWIDE\*

\*Data on File.

This testimonial relates an account of an individual's response to the treatment. The testimonial is genuine; however, it does not provide any indication, guide, warranty or guarantee as to the response other persons may have to the treatment. Responses to the treatment discussed can and do vary and are specific to the individual's account options, contact your doctor.

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- Access digital tools and resources for your practice and patients
- Receive guidance on hospital resource optimization
- Expand access to life-changing MR therapy to patients in need within your community

LEARN MORE AT [ADVANCEDHEARTTHERAPIES.COM](https://ADVANCEDHEARTTHERAPIES.COM)

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