

MitraClip™
Transcatheter Mitral Valve Repair



**ADVANCING MITRAL THERAPY
FOR YOUR PATIENTS**

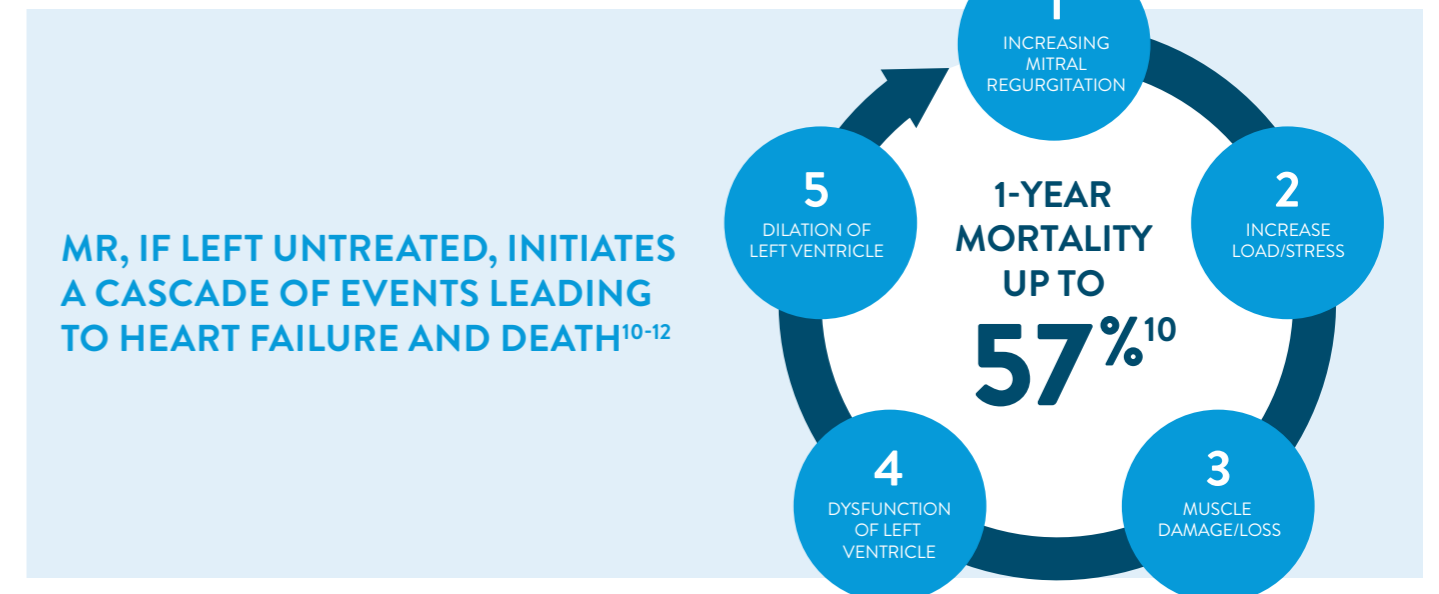
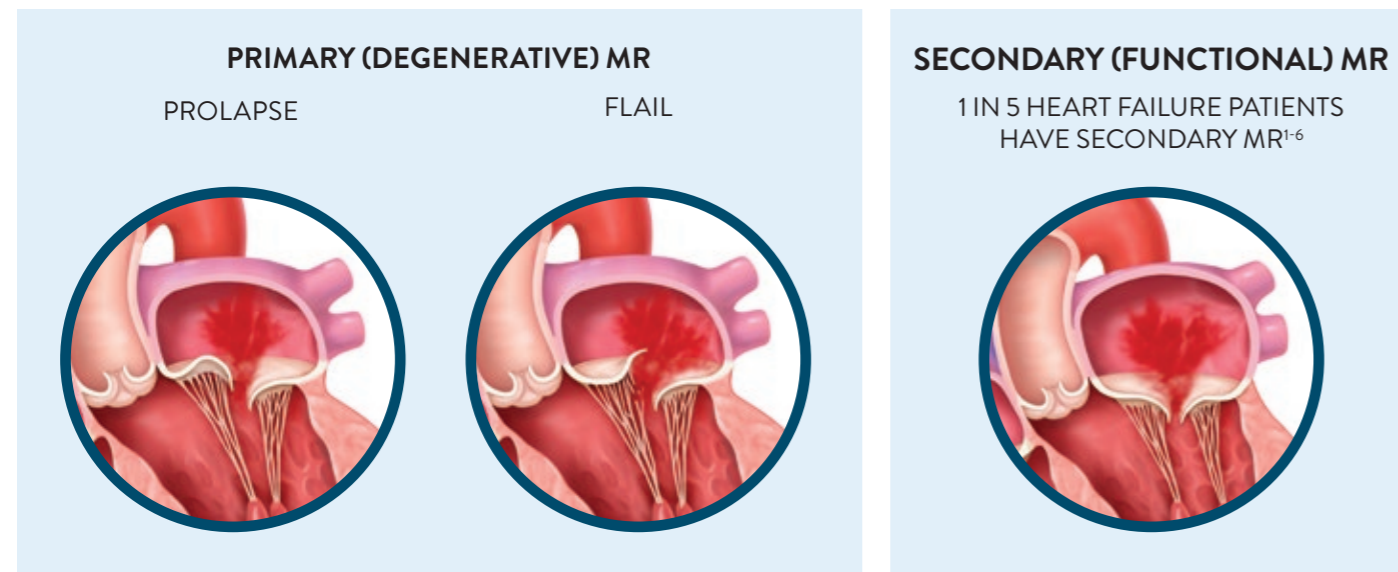
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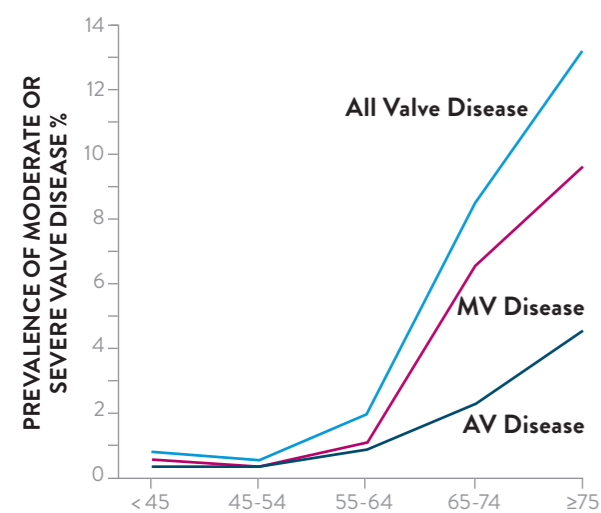
MITRAL VALVE DISEASE: HIGHLY PREVALENT AND UNDERTREATED

UNTREATED, MITRAL REGURGITATION KILLS

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

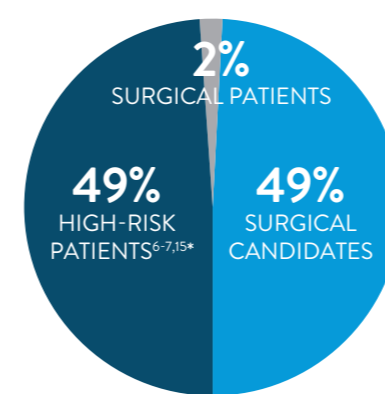


MORE LIVES ARE COMPROMISED BY MR THAN ANY OTHER VALVE DISEASE, BUT LESS THAN 1.5% ARE TREATED^{7-9*†}



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.

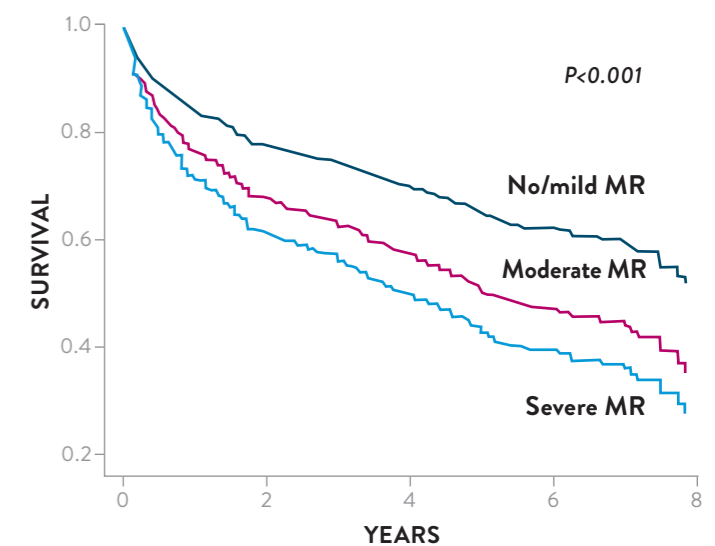
APPROXIMATELY 50% OF PRIMARY MR PATIENTS ARE NOT CANDIDATES FOR SURGERY DUE TO UNDERLYING FACTORS¹³⁻¹⁴



Factors prohibiting surgery include¹⁶:

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

SEVERE SECONDARY MR IS AN INDEPENDENT PREDICTOR OF MORTALITY¹⁷



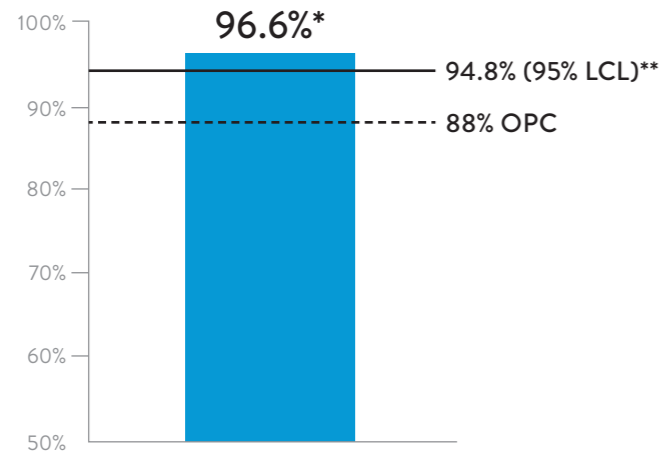
Symptoms and MR may persist in Secondary MR patients, despite maximally-tolerated GDMT.

*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: DURABILITY AND FREEDOM FROM COMPLICATIONS

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



96.6%

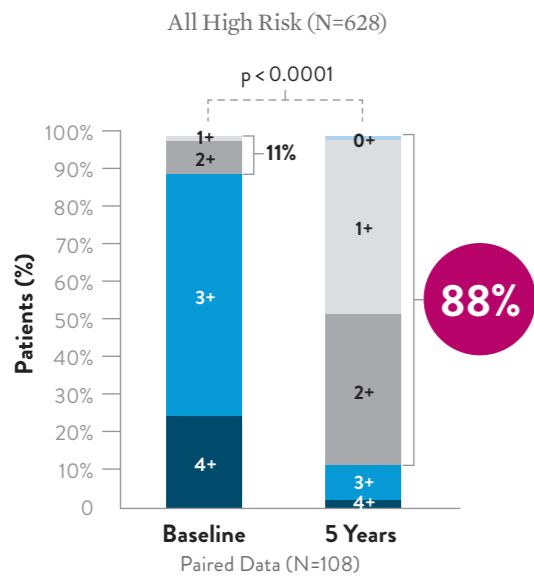
**FREEDOM FROM
DEVICE-RELATED
COMPLICATIONS AT
12 MONTHS¹⁸**

*KM estimate.

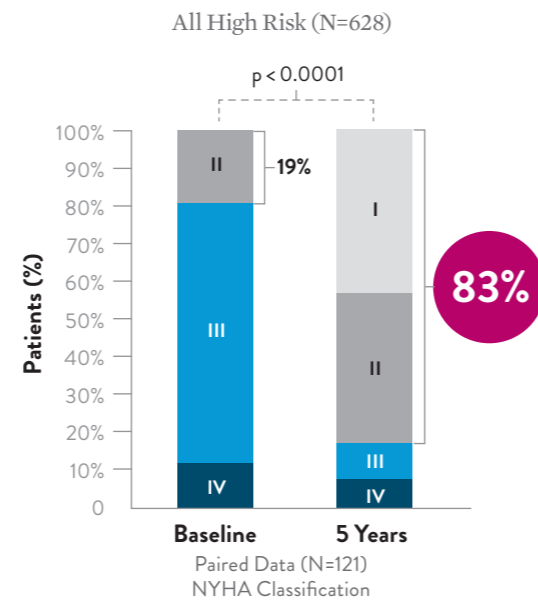
**Calculated from Z test with Greenwood's method of estimated variance against a pre-specified objective performance goal of 88%.

THE ONLY TMV DEVICE WITH PROVEN DURABLE OUTCOMES OUT TO 5 YEARS^{19§}

SUSTAINED REDUCTION IN MR SEVERITY AT 5 YEARS

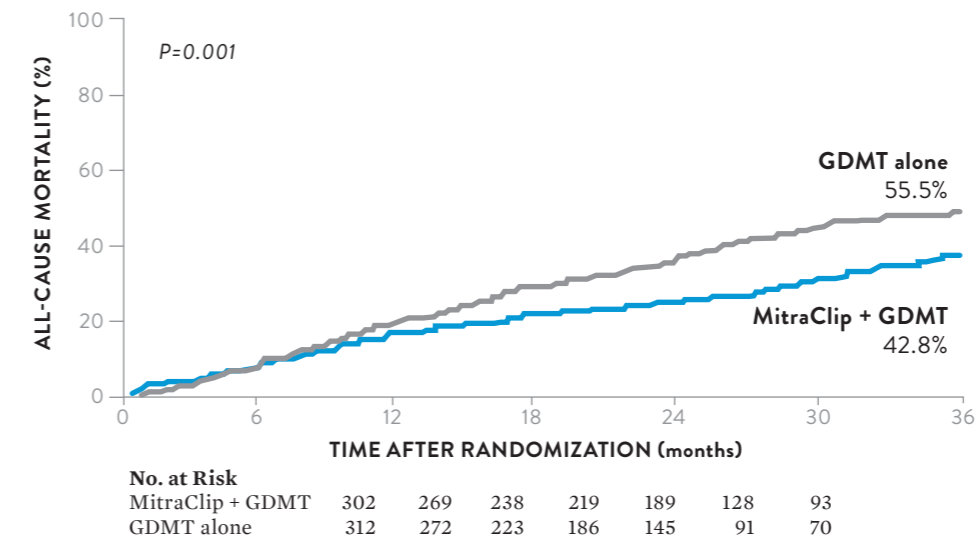


SUSTAINED IMPROVEMENTS IN HEART FAILURE SYMPTOMS AT 5 YEARS



MITRACLIP CONTINUES TO IMPROVE SURVIVAL AT 3 YEARS²⁰

ALL-CAUSE MORTALITY



33%

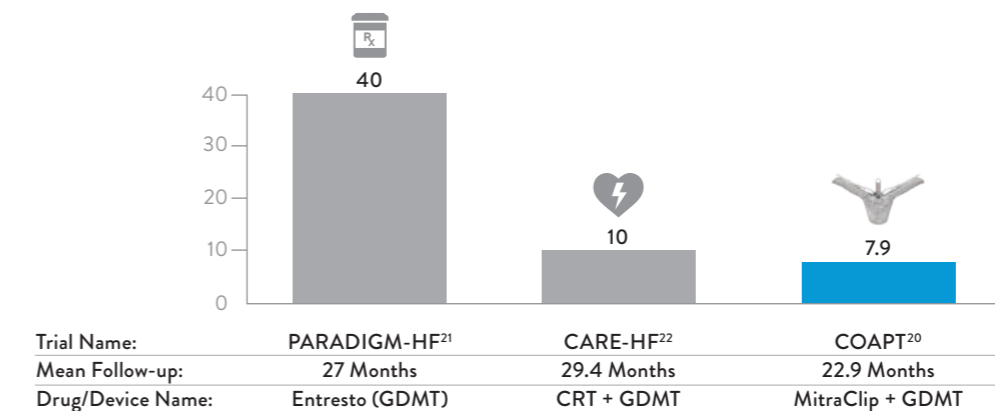
RELATIVE RISK REDUCTION
IN MORTALITY

7.9

NUMBER NEEDED TO TREAT
TO PREVENT ONE DEATH*

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.

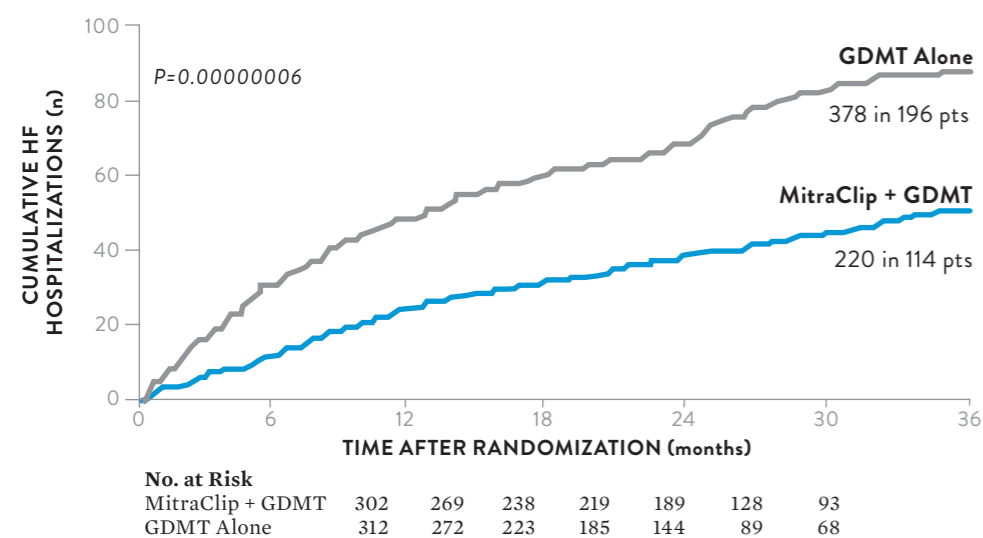
Data on file at Abbott.

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

MITRACLIP: REDUCES MR

MITRACLIP CONTINUES TO REDUCE HF HOSPITALIZATIONS AT 3 YEARS²⁰

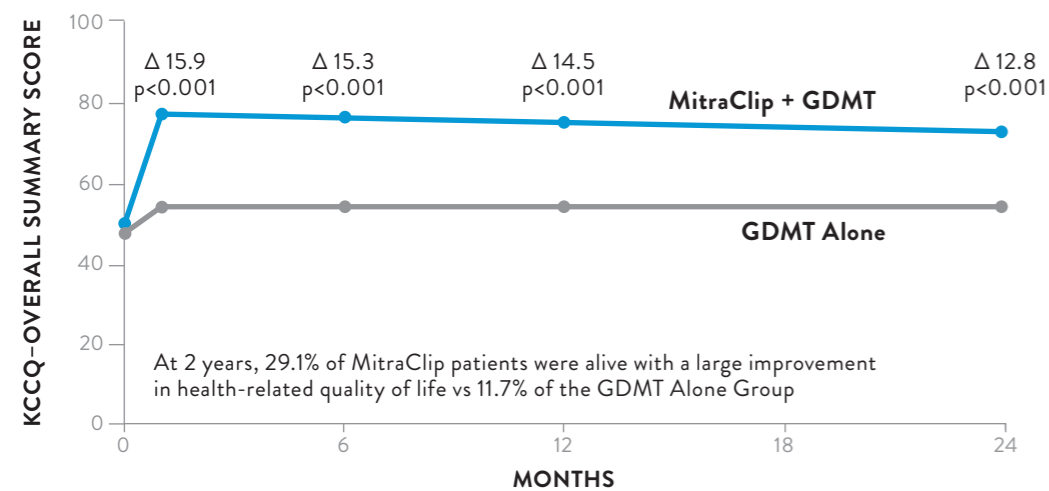
REDUCES HOSPITALIZATIONS FOR HF



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 LIFE²³

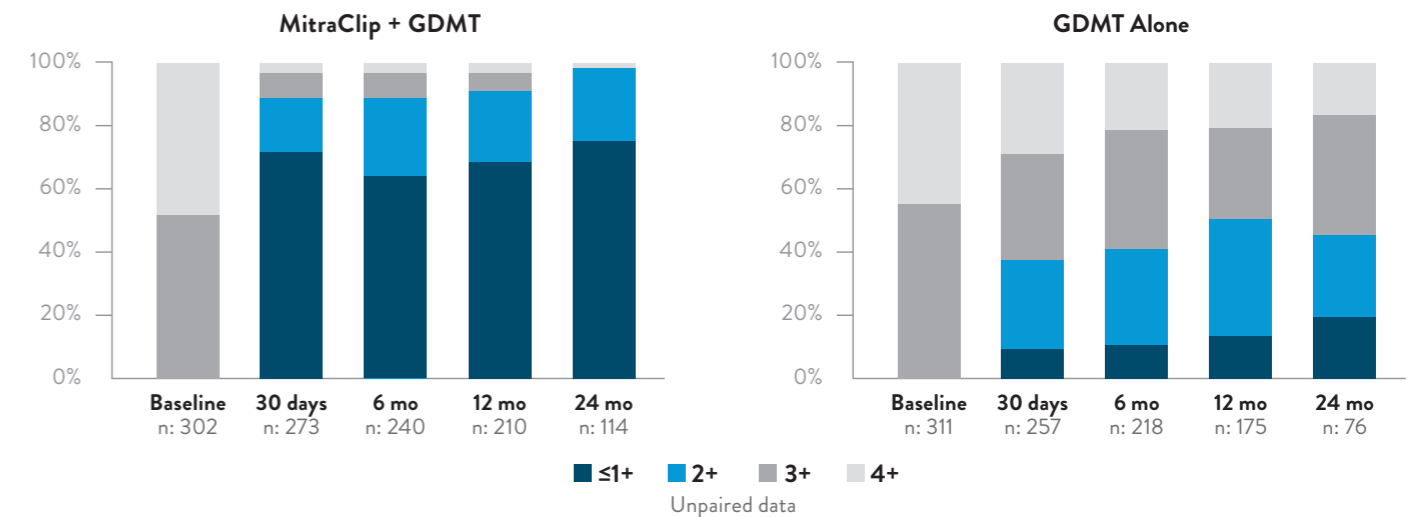


2.5X
MORE LIKELY TO EXPERIENCE A LARGE IMPROVEMENT IN QUALITY OF LIFE WITH MITRACLIP

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 ≥ 20 Points in KCCQ from Baseline; quality of life is assessed only in surviving patients

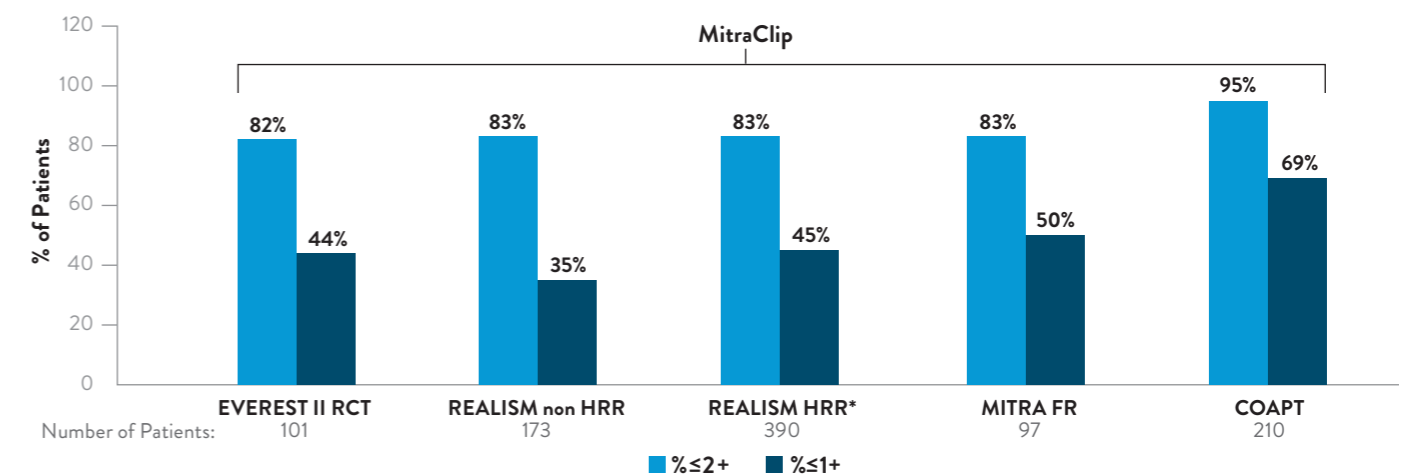
MITRACLIP™ REDUCES SECONDARY MR SEVERITY¹⁸

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



MR REDUCTION DEMONSTRATED OVER MULTIPLE CLINICAL STUDIES^{19,24-26}

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%

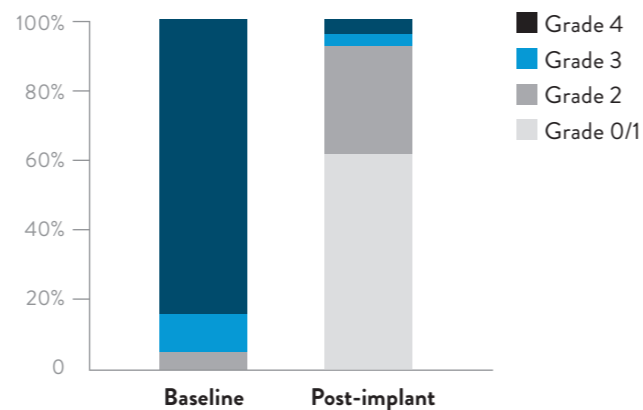
REAL WORLD EVIDENCE AND EXPERIENCE SUPPORTS PROVEN OUTCOMES

PROVEN SAFETY AND EFFECTIVENESS DATA FROM TVT REGISTRY²⁷ 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

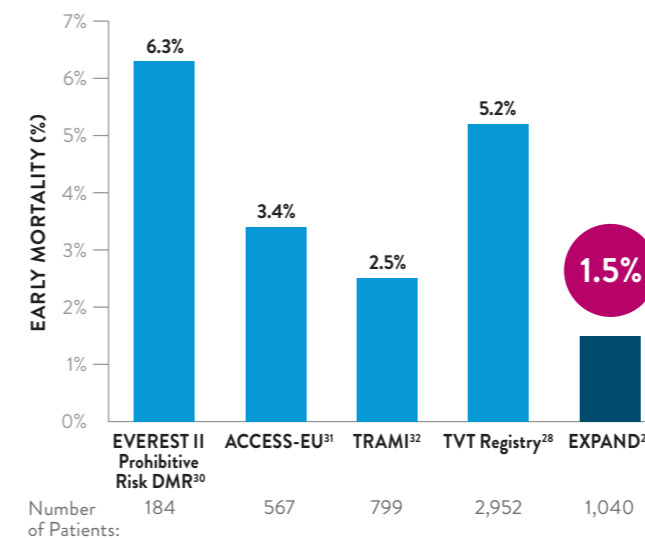
**85.9%
DISCHARGED**

PATIENTS UNDERGOING THE
MITRACLIP PROCEDURE WERE
DISCHARGED DIRECTLY HOME

THE EXPAND STUDY WITH MITRACLIP NTR/XTR²⁸ IN AN ALL COMER, REAL WORLD STUDY N=1041 PATIENTS (60 centers from the US and Europe)

LOWEST 30-DAY MORTALITY²⁹

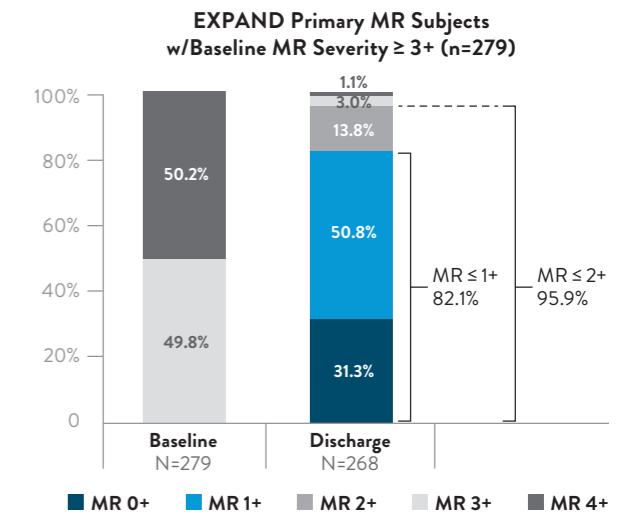
Reported to date in large scale studies



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

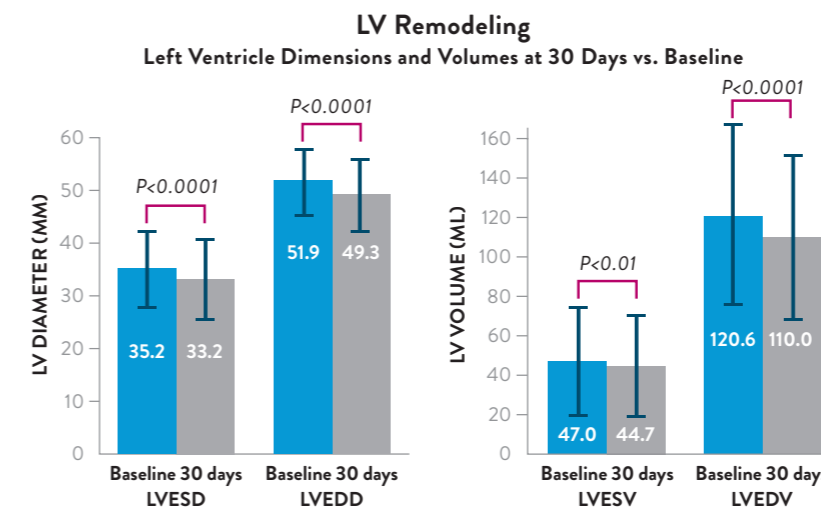
OPERATORS ARE ACHIEVING MR ≤1+ TODAY WITH NTR AND XTR

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

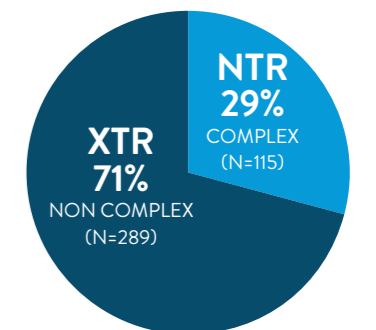


Early evidence of reduction in left ventricular dimensions and volumes; Larger, more clinically significant changes may be evident at longer term follow-up

MORE COMPLEX ANATOMIES BEING TREATED IN REAL WORLD

With NTR and XTR Systems

Complexity of MV Anatomy (N=404)



WITH GREATER MR REDUCTION ACHIEVED USING XTR

MITRACLIP WITH GDMT IS A COST EFFECTIVE TREATMENT IN HEART FAILURE PATIENTS WITH SECONDARY MR³³

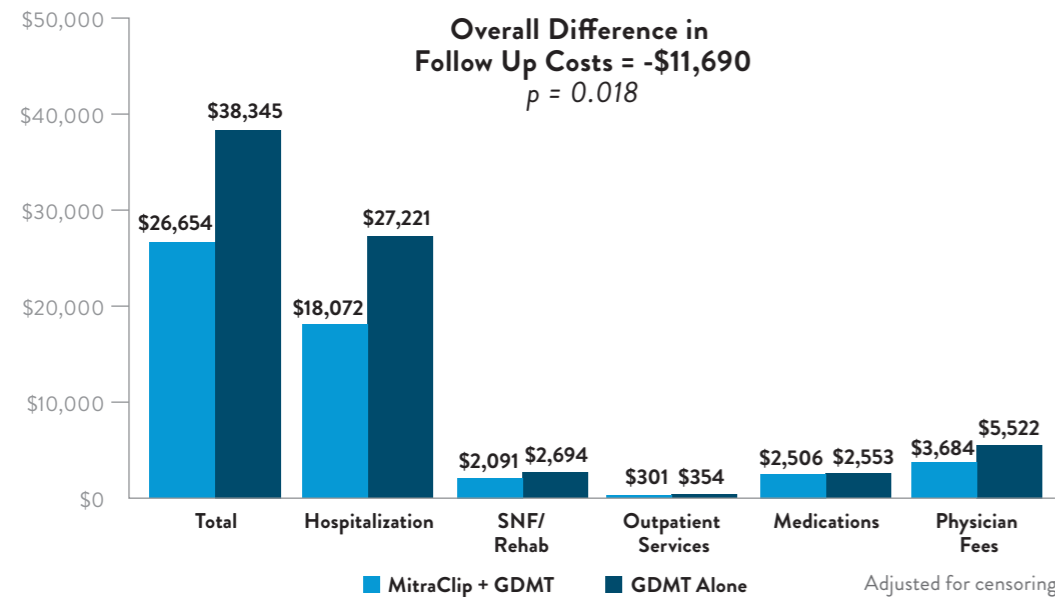
MITRACLIP PROCEDURE KEY STEPS

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

Step	Imaging Involved	Key Imaging Views
TRANSEPTAL CROSSING AND GUIDE INSERTION 	IMAGING INVOLVED <ul style="list-style-type: none"> Bicaval Short axis at base (SAX) 4-chamber 3D echo Fluoroscopy 	P, Left Atrium, Right Atrium, Aorta, A
CDS INSERTION AND STEERING IN THE LEFT ATRIUM 	IMAGING INVOLVED <ul style="list-style-type: none"> SAX Intercommissural-2-chamber Left ventricular outflow tract (LVOT) 3D echo Transgastric short axis Fluoroscopy 	M, P, A, L
ADVANCING INTO LEFT VENTRICLE AND LEAFLET GRASPING 	IMAGING INVOLVED <ul style="list-style-type: none"> LVOT Intercommissural X-Plane (LVOT, Intercommissural) 3D echo Transgastric short axis Fluoroscopy 	P, A, L
LEAFLET INSERTION ASSESSMENT AND HEMODYNAMIC MEASUREMENTS 	IMAGING INVOLVED <ul style="list-style-type: none"> LVOT Intercommissural-2-chamber 4-chamber X-Plane 3D echo Transgastric short axis 	M, P, A, L
DEPLOYMENT AND SYSTEM REMOVAL 	<ul style="list-style-type: none"> Intercommissural LVOT SAX Fluoroscopy 	
PRE- AND POST-MITRACLIP THERAPY		
BEFORE MITRACLIP 	AFTER MITRACLIP 	Baseline MR vs Visible MR reduction after Clip deployment

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

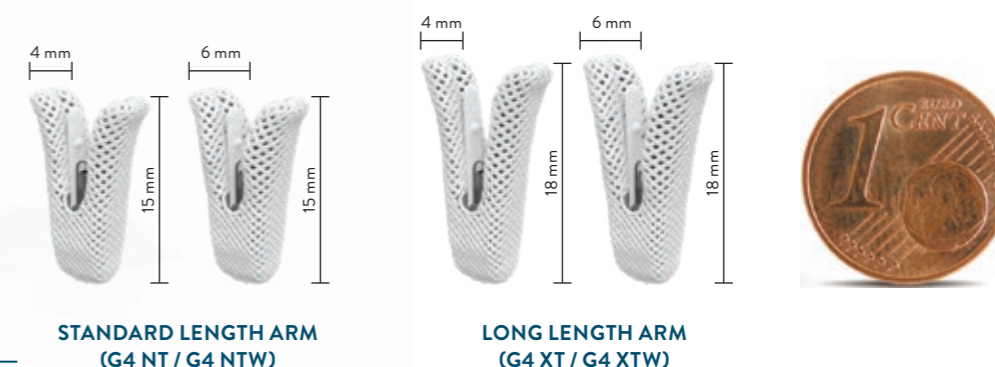


CLIP DELIVERY SYSTEM

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

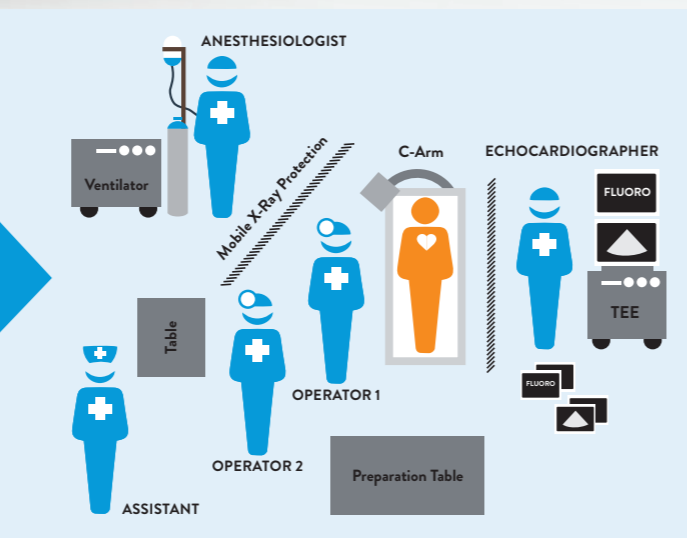


- Cobalt-Chromium and Nitinol Construction
- Polyester cover designed to promote tissue growth
- All implants are safe under labeled MRI scanning conditions*

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_r THERAPY



OVER 16 YEARS
OF CLINICAL EXPERIENCE



OVER 100K PATIENTS
TREATED WORLDWIDE



OVER 2050
PUBLICATIONS



OVER 30,000
PATIENTS STUDIED



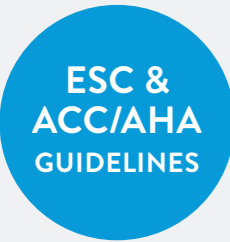
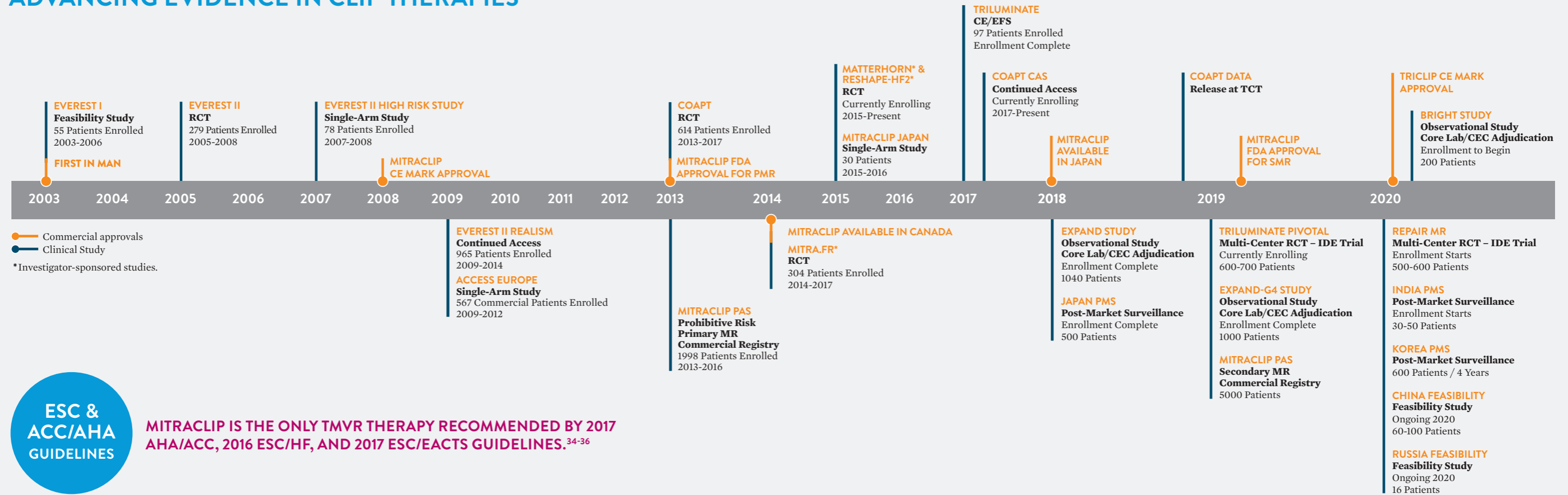
3 RCTS DEMONSTRATING
SAFETY AND EFFICACY
IN PMR AND SMR



OVER \$250 MILLION
INVESTED IN EVIDENCE

Data on File at Abbott

ADVANCING EVIDENCE IN CLIP THERAPIES



MITRACLIP IS THE ONLY TMV_r THERAPY RECOMMENDED BY 2017 AHA/ACC, 2016 ESC/HF, AND 2017 ESC/EACTS GUIDELINES.³⁴⁻³⁶

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

TO LEARN MORE, CONTACT YOUR LOCAL ABBOTT THERAPY SPECIALIST

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