

MitraClip
Transcatheter Mitral Valve Repair

BECOME AN EXPERT
IN MR TREATMENT



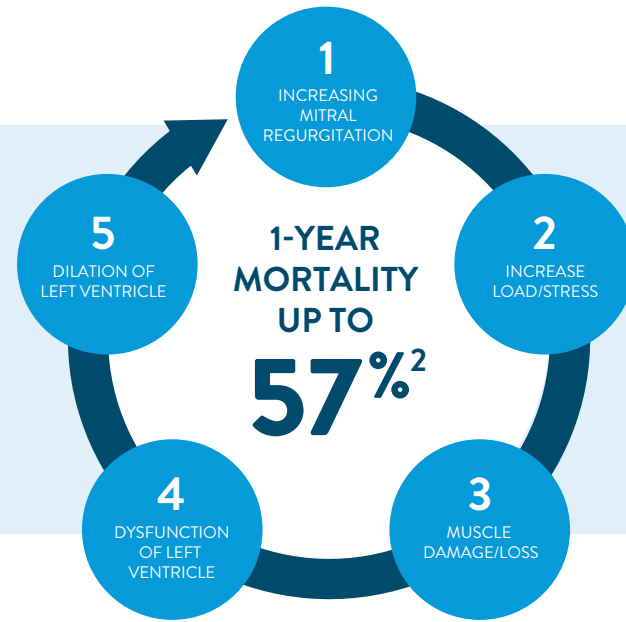
LIVING **V.S.** SURVIVING

Take action with MitraClip—do more for MR patients in need

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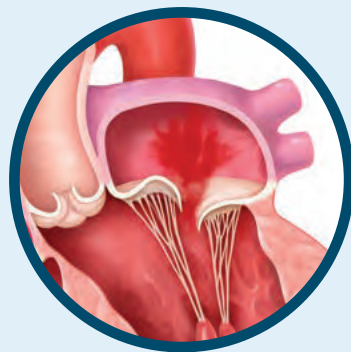
 **Abbott**

MR IS PREVALENT AND, IF LEFT UNTREATED, INITIATES A CASCADE OF EVENTS LEADING TO HEART FAILURE AND DEATH¹⁻³

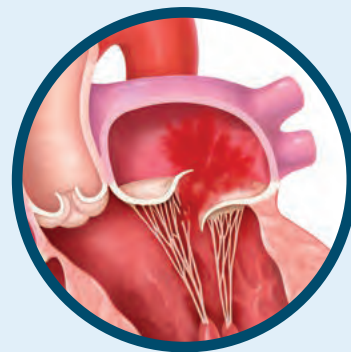


THERE ARE DIFFERENT TYPES OF MR^{4,5}

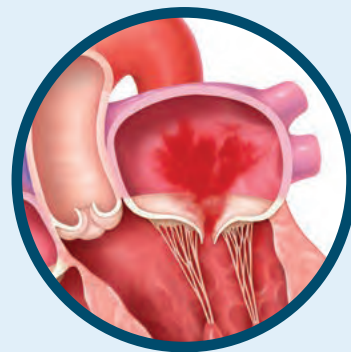
DEGENERATIVE MR: PROLAPSE



DEGENERATIVE MR: FLAIL



FUNCTIONAL MR

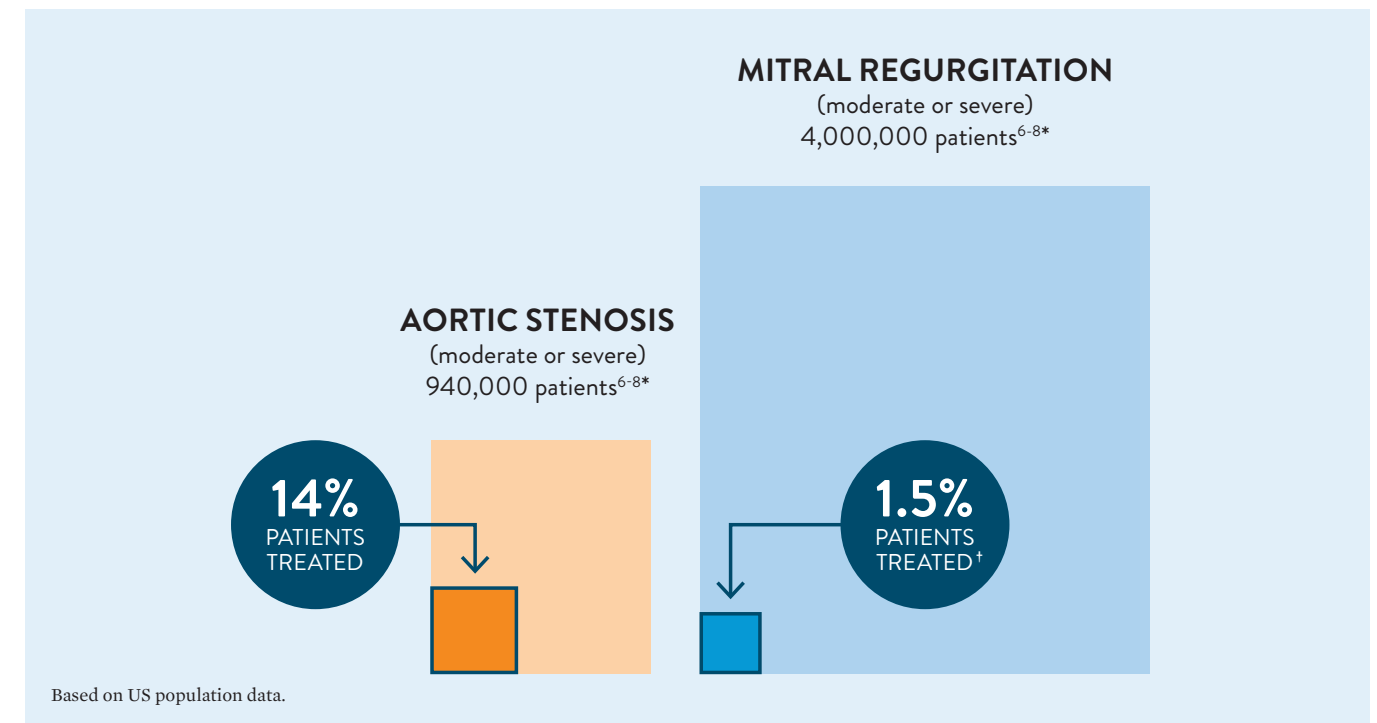


MR IS A PROGRESSIVE DISEASE AND OVER TIME CAUSES IRREVERSIBLE DAMAGE TO CARDIAC STRUCTURE AND FUNCTION¹⁻⁵

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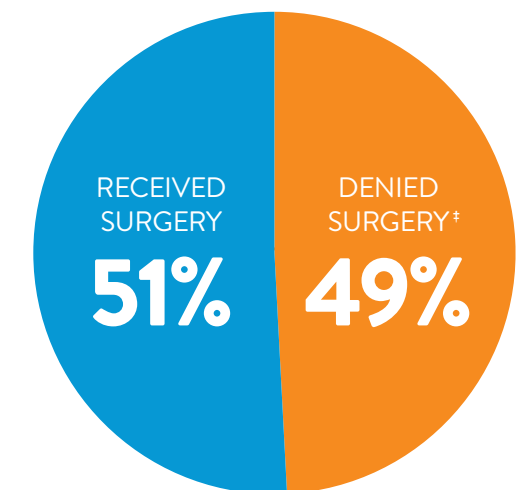
MORE LIVES ARE COMPROMISED BY MR THAN ANY OTHER VALVE DISEASE, BUT LESS THAN 1.5% ARE TREATED^{6-8*†}

SIGNIFICANT MR IS 4Xs MORE PREVALENT THAN SIGNIFICANT AORTIC STENOSIS^{6,7*}



APPROXIMATELY 50% OF MR PATIENTS ARE NOT CANDIDATES FOR SURGERY DUE TO UNDERLYING FACTORS^{9‡}

MR patients in most need of intervention are also the most likely to be denied for surgery due to impaired LV ejection fraction, high operative risk, multiple comorbidities, and advanced age.⁹



*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.

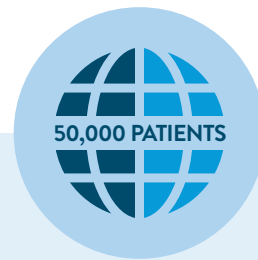
‡Based on a survey of severely symptomatic MR patients in NYHA Class III-IV (n = 396); 10% had surgery the following year. The remainder had no surgery; medical management only.

MITRACLIP: THE LEADER IN TRANSCATHETER MITRAL VALVE REPAIR (TMVr) TECHNOLOGY

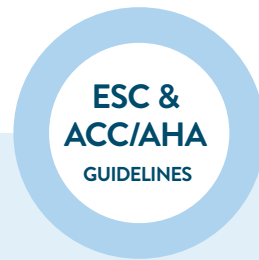
BACKED BY EXTENSIVE CLINICAL AND REAL-WORLD EXPERIENCE⁸



The most studied TMVr device with over 1,000 scientific papers published⁸



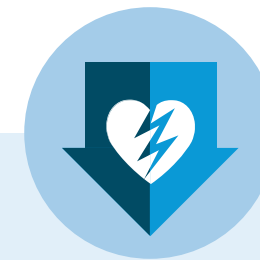
Over 50,000 patients have been treated worldwide⁸



The only TMVr therapy recommended by 2017 AHA/ACC, 2016 ESC/HF and 2017 ESC/EACTS Guidelines^{5,10,11}

MITRACLIP MAKES INTERVENTION POSSIBLE FOR YOUR PATIENTS WITH SIGNIFICANT MR

MITRACLIP OFFERS A UNIQUE BENEFIT-TO-RISK PROFILE^{12,13}



Low rate of major adverse events^{12,13}



Higher survival rate than predicted¹²

OPTIMIZE THE PATIENT CARE EXPERIENCE FROM START TO FINISH WITH MITRACLIP THERAPY



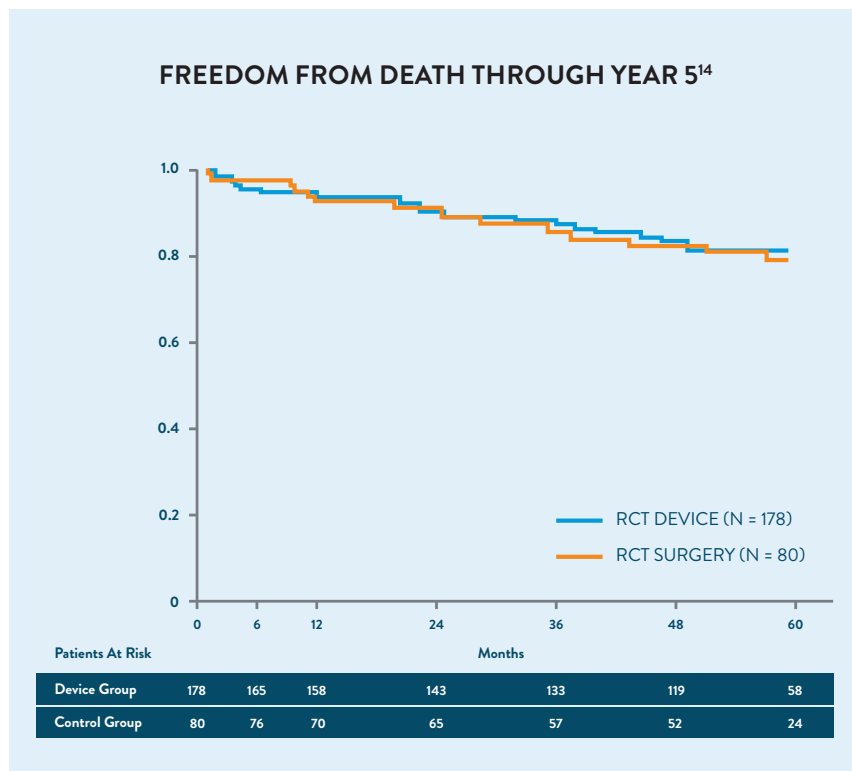
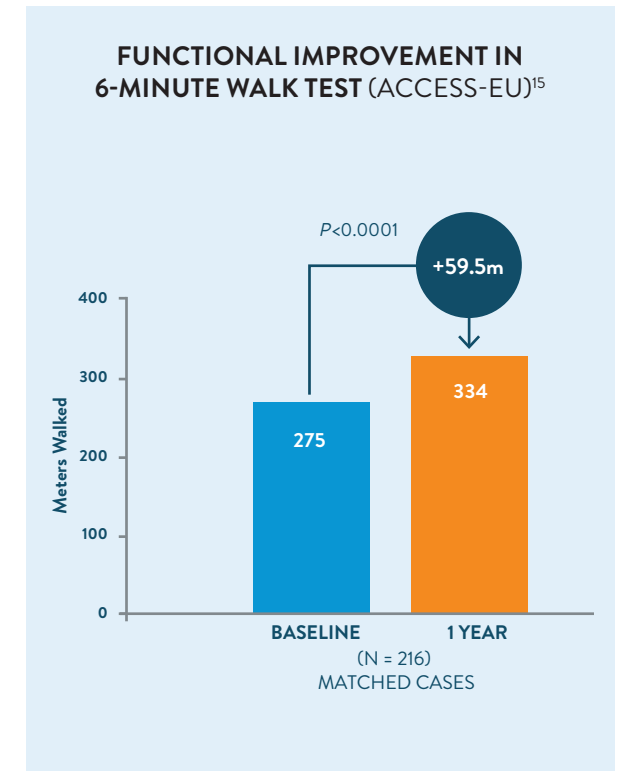
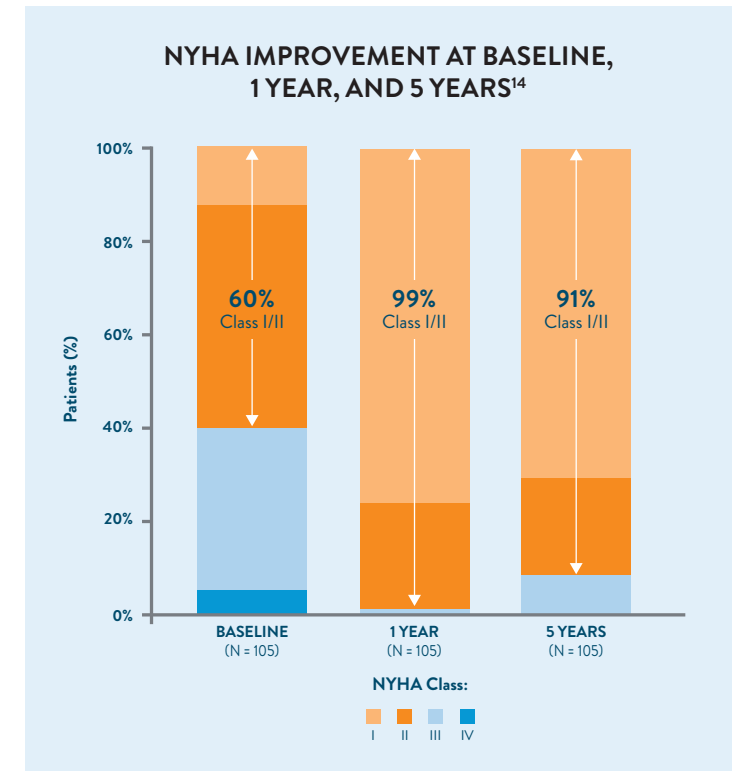
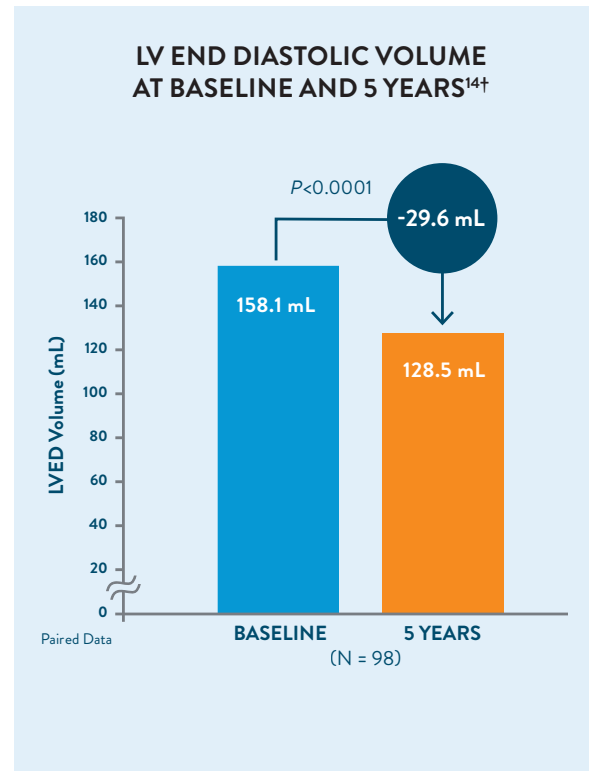
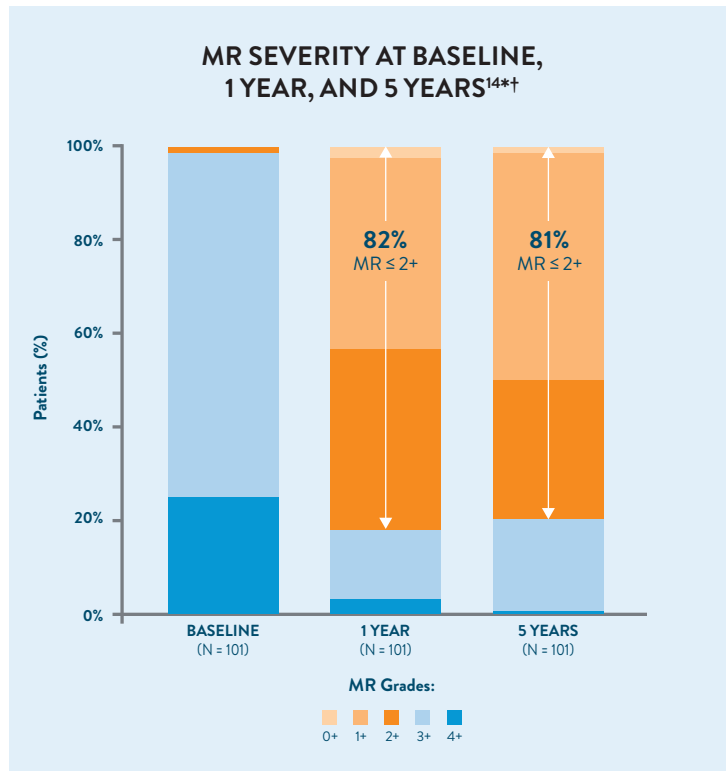
*Investigator sponsored studies.

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MITRACLIP: CLINICALLY MEANINGFUL AND DURABLE RESULTS

THE POWER TO IMPROVE CARDIAC FUNCTION AND ACHIEVE REVERSE REMODELING¹⁴

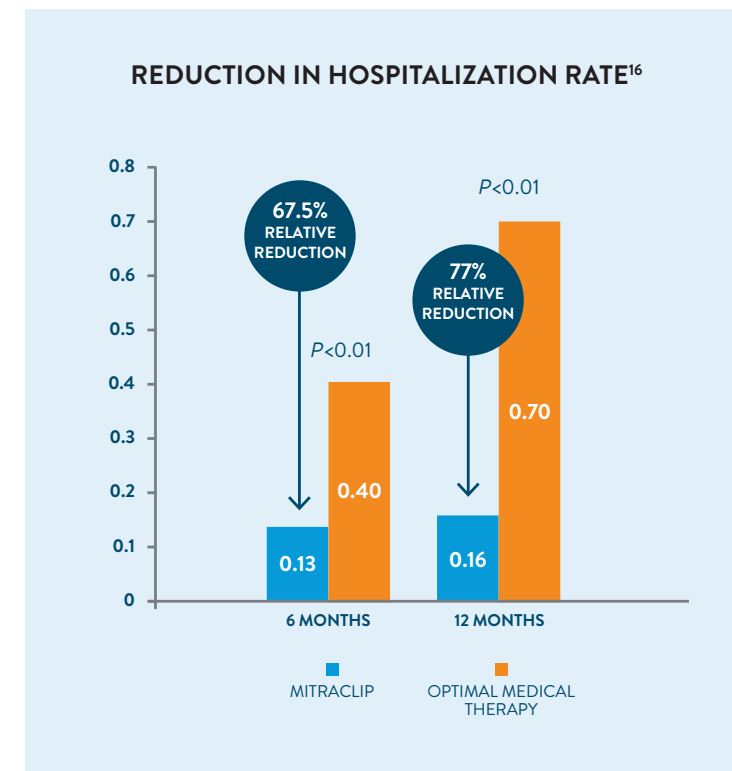
FAST RECOVERY WITH MEANINGFUL OUTCOMES THAT PATIENTS CAN FEEL¹⁴



REAL WORLD CONFIRMATION

- From ACCESS-EU (N=567): A substantial portion of patients experienced a reduction in MR grade irrespectively of etiology¹⁵
 - 79% of patients with FMR and 75% of patients with DMR who received MitraClip therapy had MR grade of ≤2+ after a year post-surgery¹⁵

[†]In surviving patients with paired data.
[‡]Everest RCT Conclusion: The final 5-year results of the EVEREST II trial supported the superiority of surgery in reducing MR but clearly supported the long-term safety of the MitraClip and the durability of MR reduction after percutaneous repair. **Beyond 1 year, worsening MR and surgery for MV dysfunction occurred rarely after either surgery or percutaneous repair.**



REAL WORLD CONFIRMATION

- From ACCESS-EU (N=567): 70% of patients with FMR and 81% of patients with DMR had an NYHA class of ≤2 after 1 year (P < 0.0001)¹⁷
- From TRAMI (N=749): Patients' self-rated health status at 1 year improved by 10 points with a significant proportion of patients regaining complete independence in self-care (74.0 vs. 58.6 at baseline, P = 0.005)¹³

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MITRACLIP: AN ONGOING COMMITMENT TO INNOVATION

THE MITRACLIP NT SYSTEM¹²

The MitraClip NT System performs **transcatheter mitral valve repair** by creating a vertical line of coaptation, forming a double-orifice valve.

- Beating heart procedure—no cardiopulmonary bypass
- Allows for real-time positioning and repositioning to optimize MR reduction
- Designed to fit coaxially to accurately position and reposition multiple implants with the use of 1 guide
- Femoral venous access

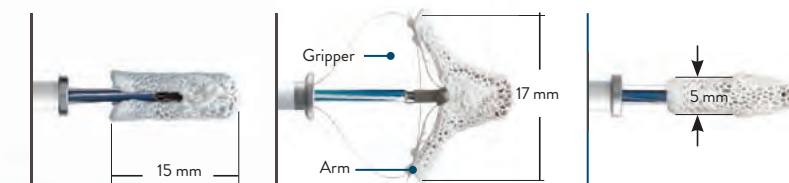
STEERABLE GUIDE CATHETER

- 24-French steerable catheter
- Percutaneous venous access
- Requires successful transseptal puncture



CLIP DELIVERY SYSTEM

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



MITRACLIP NT DEVICE (IMPLANT)

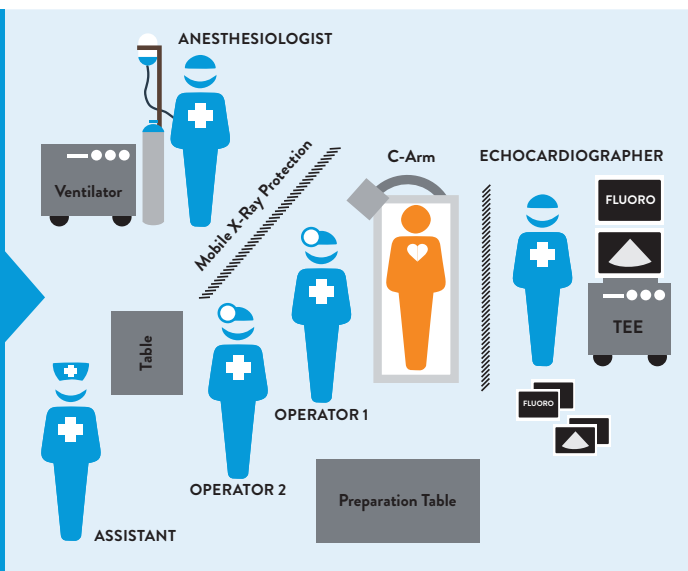
- Cobalt-Chromium and Nitinol Construction
- Polyester cover designed to promote tissue growth
- Static magnetic field of 1.5 or 3 Tesla*

*Static magnetic field of 1.5 or 3 Tesla; maximum spatial field gradient of 2500 Gauss/cm; maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode).

EQUIPMENT

The MitraClip NT 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 (SZR01ST)



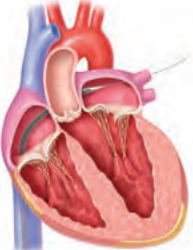
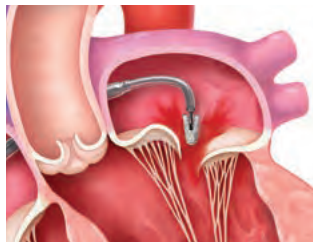
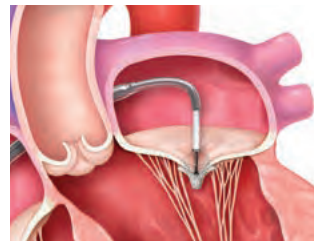
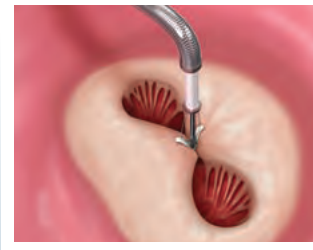
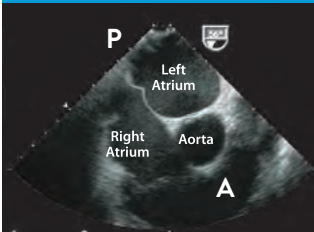
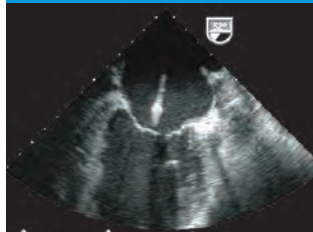
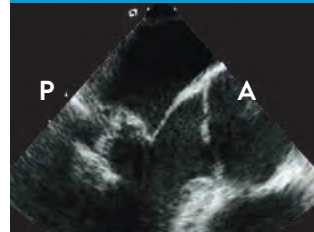
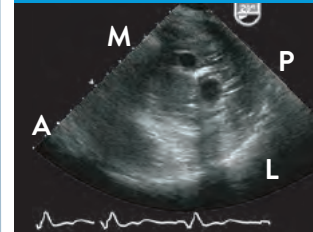

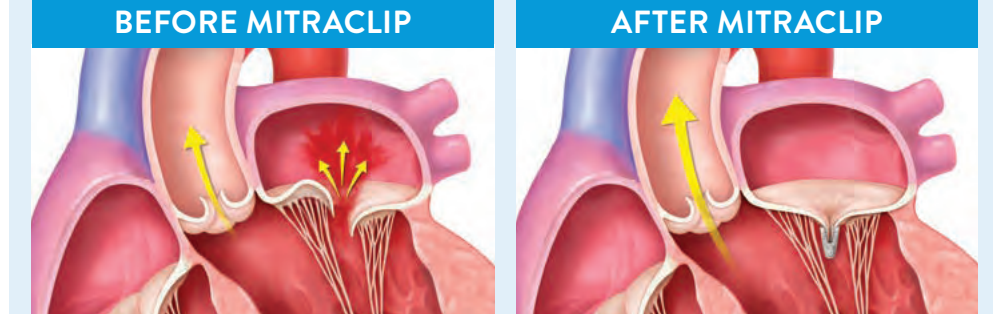
Support Plate (PLT01ST)



Lift (LFT01ST)

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MITRACLIP: A MINIMALLY INVASIVE PROCEDURE WITH CONSISTENT PROCEDURAL SUCCESS*

<p>TRANSSEPTAL CROSSING AND GUIDE INSERTION</p>	<p>CDS INSERTION AND STEERING IN THE LEFT ATRIUM</p>	<p>ADVANCING INTO LEFT VENTRICLE AND LEAFLET GRASPING</p>	<p>LEAFLET INSERTION ASSESSMENT AND HEMODYNAMIC MEASUREMENTS</p>
			
<p>IMAGING INVOLVED</p> 	<p>IMAGING INVOLVED</p> 	<p>IMAGING INVOLVED</p> 	<p>IMAGING INVOLVED</p> 
<ul style="list-style-type: none"> • Bicaval • Short axis at base (SAX) • 4-chamber • 3D echo • Fluoroscopy 	<ul style="list-style-type: none"> • SAX • Intercommissural—2-chamber • Left ventricular outflow tract (LVOT) • 3D echo • Transgastric short axis • Fluoroscopy 	<ul style="list-style-type: none"> • LVOT • Intercommissural • X-Plane (LVOT, Intercommissural) • 3D echo • Transgastric short axis • Fluoroscopy 	<ul style="list-style-type: none"> • LVOT • Intercommissural—2-chamber • 4-chamber • X-Plane • 3D echo • Transgastric short axis
<p>DEPLOYMENT AND SYSTEM REMOVAL</p>	<p>PRE- AND POST-MITRACLIP THERAPY</p>		
			
<ul style="list-style-type: none"> • Intercommissural • LVOT • SAX • Fluoroscopy 	<p>Baseline MR</p> <p>Visible MR reduction after Clip deployment</p>		

*The MitraClip device was implanted successfully in a majority (95.3%) of patients.¹²

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MITRACLIP HAS DEMONSTRATED HIGH AND PREDICTABLE SUCCESS RATES WITH POSITIVE POST PROCEDURE EXPERIENCE

 <p>97% SUCCESS</p>	 <p>2.6 DAYS</p>	 <p>89.3% DISCHARGED</p>
<p>High procedural success rate seen in real world experience¹³</p>	<p>Short average length of hospital stay^{8,18}</p>	<p>Patients undergoing the MitraClip procedure were discharged directly home¹³</p>

References: 1. Enriquez-Sarano M, Avierinos JF, Messika-Zeitoun D, et al. Quantitative determinants of the outcome of asymptomatic mitral regurgitation. *N Engl J Med.* 2005;352(9):875-883. 2. Cioffi G, Tarantini L, De Feo S, et al. Functional mitral regurgitation predicts 1-year mortality in elderly patients with systolic chronic heart failure. *Eur J Heart Fail.* 2005;7(7):1112-1117. 3. Grigioni F, Tribouilloy C, Avierinos JF, et al; MIDA Investigators. Outcomes in mitral regurgitation due to flail leaflets: a multicenter European study. *JACC Cardiovasc Imaging.* 2008;1(2):133-141. 4. Mayo Clinic Staff. Mitral valve regurgitation: symptoms and causes. The Mayo Clinic. <http://www.mayoclinic.org/diseases-conditions/mitral-valve-regurgitation/symptoms-causes/dxc-20121850>. Published May 24, 2017. Accessed July 5, 2017. 5. Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation.* 2017;136(9):1-123. DOI: 10.1161/CIR.0000000000000503. 6. Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M. Burden of valvular heart diseases: a population-based study. *Lancet.* 2006;368(9540):1005-1011. 7. United States Census Bureau, 2010. Age and sex composition. Issued May 2011:1-16. 8. Abbott data on file as of July 2017. 9. Mirabel M, Lung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? *Eur Heart J.* 2007;28(11):1358-1365. 10. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease: The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J.* 2017;00:1-53. 11. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. *Eur J Heart Fail.* 2016;18(8):891-975. 12. MitraClip NT Clip Delivery System Instructions for Use. 13. Puls M, Lubos E, Boekstegers P, et al. One-year outcomes and predictors of mortality after MitraClip therapy in contemporary clinical practice: results from the German transcatheter mitral valve interventions registry. *Eur Heart J.* 2016;37(8):703-712. 14. Feldman T, Kar S, Elmariah S, et al. Randomized comparison of percutaneous repair and surgery for mitral regurgitation: 5-year results of EVEREST II. *J Am Coll Cardiol.* 2015;66(25):2844-2854. 15. Maisano F, Franzen O, Baldus S, et al. Percutaneous mitral valve interventions in the real world: early and 1-year results from the ACCESS-EU, a prospective, multicenter, nonrandomized post-approval study of the MitraClip therapy in Europe. *J Am Coll Cardiol.* 2013;62(12):1052-1061. 16. Armeni P, Boscolo PR, Tarricone R, et al. Real-world cost effectiveness of MitraClip combined with medical therapy versus medical therapy alone in patients with moderate or severe mitral regurgitation. *Int J Cardiol.* 2016;209:153-160. 17. Butter C, Franzen O, Treede H, et al. Analysis of outcomes at 12 months by mitral regurgitation etiology in the ACCESS-EUROPE Phase I Study. Presented at EuroPCR. May 21-24, 2013. Paris, France. 18. Feldman T. Final results of the EVEREST II randomized controlled trial of percutaneous and surgical reduction of mitral regurgitation. Presented at: The American College of Cardiology (ACC) Scientific Sessions; March 29-31, 2014; Washington DC, USA.

MITRACLIP: TRANSFORMS YOUR INSTITUTION INTO A HEART VALVE CENTER OF EXCELLENCE



Safety and effectiveness of the MitraClip device have not been established in pediatric patients.

ABBOTT: A WORLD-CLASS PARTNERSHIP THAT OFFERS UNPRECEDENTED TRAINING, EDUCATION, AND SUPPORT

- 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

BECOME A 360° PROVIDER OF MITRAL VALVE SOLUTIONS AND ELEVATE YOUR INSTITUTION INTO A TRUE ADVANCED HEART CENTER

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