

Leading Innovation in Transcatheter Mitral Valve Therapy

Meeting an unmet clinical need with first-of-its kind technology.

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Mitral regurgitation (MR) is not just a clinical challenge; it is also a quality and economic concern for hospitals as untreated MR can lead to heart failure, one of the 30-day readmissions measures in Hospital Readmissions Reduction Program and an outcome measure in Value-Based Purchasing Program by the Centers for Medicare and Medicaid Services (CMS). The national average readmissions rate due to heart failure (HF) remains higher than other indicators at 24.6%,¹ according to CMS Hospital Compare data. As hospitals continue to improve on ways to manage readmissions and quality outcomes, treating conditions that cause HF may have substantial quality and economic impact. The clinical challenge to treating MR, however, is that patients with severe, symptomatic MR who demonstrate HF symptoms are often overlooked as candidates for mitral valve repair due to age and/or comorbidity.² Adding to the challenge is the prevalence of mitral valve disease (the most frequent form of valvular heart disease) in an aging U.S. population.³

Transcatheter mitral valve therapy is one option to treat MR and manage HF. In 2014, the American Heart Association and American College of Cardiology's Guideline for the Management of Patients with Valvular Heart Disease addressed the complexity of MR treatment, especially for high-surgical-risk patients, and included transcatheter mitral valve repair as an option for intervention. The importance of treating complex MR patients through safe, minimally invasive procedures is evident in the emergence of technologies being developed to percutaneously treat MR. Leading the transcatheter mitral valve therapy movement is MitraClip therapy—the first-of-its-kind, minimally invasive option for mitral valve repair indicated for select patients with significant, symptomatic degenerative MR who cannot undergo conventional surgical repair. MitraClip therapy is not only the world's first-in-class transcatheter mitral valve therapy, but also one with proven safety and efficacy. With the use of MitraClip, patients experienced clinically meaningful improvement in NYHA functional class, the proportion of patients in NYHA Class III/IV reduced from 87% to 13% one year after implantation.⁴ “A typical MitraClip patient would be ... somebody who is at high risk for conventional open surgical repair,” said Paul Sorajja, MD, Director of Valve and Structural Heart Disease at Minneapolis Heart Institute. “[MitraClip] is a very efficacious procedure with relatively low risk.”

MitraClip supports hospitals in their readmissions and quality improvement efforts by reducing HF-related hospitalizations. In a clinical trial setting, patients who received MitraClip experienced on average a 73% reduction in HF hospitalization rate⁴ in the year following the procedure, which may potentially lead to economic savings from minimizing the volume of high-cost HF treatment and avoiding penalties. Having MitraClip also helps complete a hospital's armamentarium of treatment options for valvular heart disease and become a truly comprehensive heart center. The distinction demonstrates a commitment to the community by treating a previously unmet clinical need. “The addition of transcatheter mitral valve therapy to our current portfolio of valvular disease treatment enables our center to care for a previously underserved patient population, reduce the rate of HF-related readmission, and be a center of choice for complex MR,” said Kevin DiLallo, Chief Executive Officer at Manatee Memorial Hospital. More importantly, MitraClip offers patient-focused benefits that may significantly impact patients' quality of life. In addition to patients experiencing improved physical function, the average hospital stay for the procedure is less than 3 days,⁴ and the majority of patients are discharged to home instead of a skilled nursing facility or rehabilitation center.⁵

With over 25,000 patients treated worldwide, MitraClip therapy delivers a growing body of clinical and real-world experience. Abbott is committed to our vision for focused innovations by pioneering breakthrough therapies, such as MitraClip and meeting unmet clinical needs. As with MitraClip, Abbott is prepared to continue its forward momentum in driving future innovations with a focus on proven safety and support for our hospital partners. ■

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1. Boccuti C, Casillas G. Aiming for fewer hospital U-turns (issue brief). <http://files.kff.org/attachment/issue-brief-aiming-for-fewer-hospital-u-turns-the-medicare-hospital-readmission-reduction-program>. 2015. Accessed September 16, 2015.

2. Mirabel M, Iung B, Baron G, et al. What are the characteristics of patients with severe, symptomatic, mitral regurgitation who are denied surgery? *Eur Heart J*. 2007;28:1358-1365.

3. Nkomo VT, Gardin JM, Skelton TN, et al. Burden of valvular heart diseases: a population-based study. *Lancet*. 2006;368:1005-1011.

4. Lim DS, Reynolds MR, Feldman T, et al. Improved functional status and quality of life in prohibitive surgical risk patients with degenerative mitral regurgitation after transcatheter mitral valve repair. *J Am Coll Cardiol*. 2014;64:182-192.

5. MitraClip Clip Delivery System Instructions for Use.

INDICATION FOR USE The MitraClip® Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR $\geq 3+$ due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

CONTRAINDICATIONS The MitraClip Clip Delivery System is contraindicated in DMR patients with the following conditions:

- Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS

- DO NOT use MitraClip outside of the labeled indication. Treatment of non-prohibitive risk DMR patients should be conducted in accordance with standard hospital practices for surgical repair and replacement.
- MitraClip is intended to reduce mitral regurgitation. The MitraClip procedure is recommended to be performed when an experienced heart team has determined that reduction of MR to $\leq 2+$ is reasonably expected following the MitraClip. If MR reduction to $\leq 2+$ is not achieved, the benefits of reduced symptoms and hospitalizations, improved quality of life, and reverse LV remodeling expected from MitraClip may not occur.
- The MitraClip Device should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling the MitraClip System to avoid user injury.
- Use of the MitraClip should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and/or reuse may result in infections, malfunction of the device or other serious injury or death. Inspect all products prior to use. DO NOT use if the package is opened or damaged.

PRECAUTIONS Patient Selection:

• Prohibitive risk is determined by the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, due to the presence of one or more of the following documented surgical risk factors:

- 30-day STS predicted operative mortality risk score of $\geq 8\%$ for patients deemed likely to undergo mitral valve replacement or $\geq 6\%$ for patients deemed likely to undergo mitral valve repair
- Porcelain aorta or extensively calcified ascending aorta.
- Frailty (assessed by in-person cardiac surgeon consultation)
- Hostile chest
- Severe liver disease / cirrhosis (MELD Score > 12)
- Severe pulmonary hypertension (systolic pulmonary artery pressure $> 2/3$ systemic pressure)
- Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, internal mammary artery (IMA) at high risk of injury, etc.
- Evaluable data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF $< 20\%$ or an LVESD $> 60\text{mm}$. MitraClip should be used only when criteria for clip suitability for DMR have been met.
- The major clinical benefits of MitraClip are reduction of MR to $\leq 2+$ resulting in reduced hospitalizations, improved quality of life, reverse LV remodeling and symptomatic relief in patients who have no other therapeutic option. No mortality benefit following MitraClip therapy has been demonstrated.
- The heart team should include a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and may also include appropriate physicians to assess the adequacy of heart failure treatment and valvular anatomy.
- The heart team may determine an in-person surgical consult is needed to complete the assessment of prohibitive risk. The experienced mitral valve surgeon and heart team should take into account the outcome of this surgical consult when making the final determination of patient risk status.
- For reasonable assurance of device effectiveness, pre-procedural evaluation of the mitral valve and underlying pathologic anatomy and procedural echocardiographic assessment are essential.
- The inside of the outer pouch is not a sterile barrier. The inner pouch within the outer pouch is the sterile barrier. Only the contents of the inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.
- Note the "Use by" date specified on the package.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip procedure. Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex); Aneurysm or pseudo-aneurysm; Arrhythmias; Atrial fibrillation; Atrial septal defect requiring intervention; Arterio-venous fistula; Bleeding; Cardiac arrest; Cardiac perforation; Cardiac tamponade/Pericardial Effusion; MitraClip erosion, migration or malposition; MitraClip Device thrombosis; MitraClip System component(s) embolization; Coagulopathy; Conversion to standard valve surgery; Death; Deep venous thrombus (DVT); Dislodgement of previously implanted devices; Drug reaction to anti-platelet/anticoagulation agents/contrast media; Dyspnea; Edema; Emboli (air, thrombus, MitraClip Device); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip to the intended site; Failure to retrieve MitraClip System components; Fever or hyperthermia; Gastrointestinal bleeding or infarct; Hematoma; Hemolysis; Hemorrhage requiring transfusion; Hypotension/hypertension; Infection and

pain at insertion site; Infection and pain at incision site; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea/vomiting; Peripheral ischemia; Prolonged angina; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal insufficiency or failure; Respiratory failure/atelectasis/pneumonia; Septicemia; Single leaflet device attachment (SLDA); Skin injury or tissue changes due to exposure to ionizing radiation; Stroke or transient ischemic attack (TIA); Urinary tract infection; Vascular trauma, dissection or occlusion; Vessel spasm; Vessel perforation or laceration; Worsening heart failure; Worsening mitral regurgitation; Wound dehiscence

Caution: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available) or at www.abbottvascular.com/ifu/ for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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