Patient Screening Fact Sheet

Patient eligibility for transcatheter mitral valve repair (TMVr) with MitraClip therapy is determined by the following criteria:

<table>
<thead>
<tr>
<th>Degenerative MR</th>
<th>✓</th>
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<tbody>
<tr>
<td>Significant mitral regurgitation (MR ≥3+)</td>
<td>✓</td>
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<tr>
<td>Symptomatic (NYHA functional class III or IV)</td>
<td>✓</td>
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</table>
| Prohibitive risk criteria, including any of the following:  
  • 30-day STS predicted operative mortality risk score of ≥8% (mitral valve replacement)  
  • ≥6% (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 at high risk of injury, etc. | ✓ |
| Existing comorbidities do not preclude expected benefit of MR reduction | ✓ |

TMVr is contraindicated for degenerative MR patients with the following conditions:

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

For optimal results, the following anatomic patient characteristics should be considered:

| The primary regurgitant jet is non-commissural. If a secondary jet exists, it must be considered clinically insignificant | ✓ |
| Mitral valve area ≥4.0cm² | ✓ |
| Minimal calcification in the grasping area | ✓ |
| No leaflet cleft in the grasping area | ✓ |
| Flail width <15 mm and flail gap <10 mm | ✓ |
| LVEF >20% or LVESD <60mm | ✓ |

Do you have significant, symptomatic, degenerative MR patients who are at prohibitive-risk for surgery, and could benefit from this important treatment option?

Nearly 1 in 10 people age 75 and older have moderate-to-severe or severe mitral regurgitation¹

Connect with your nearest MitraClip therapy center, at http://www.mitraclip.com/hcp/locate_tmvr_heart_center

For a complete list of patient eligibility criteria, please refer to the MitraClip Clip Delivery System Instructions for Use.


Source: MitraClip Clip Delivery System Instructions for Use.

Indication: The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥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.

See Important Safety Information Referenced Within.
INDICATION FOR USE
The MitraClip System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 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 System is contraindicated in DMR patients with the following conditions:
• Patients who cannot tolerate procedural anticoagulation or post procedural antplatelet 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 ≤ 2+ is reasonably expected following the MitraClip. If MR reduction to ≤ 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 Implant should be implanted with sterile techniques using fluoroscopy and transseptal procedures and those trained in the handling the MitraClip System to avoid user injury. 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.

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
      • ≥ 8% for patients deemed likely to undergo mitral valve replacement or
      • ≥ 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.
  • Evaluative data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60 mm. MitraClip should be used only when criteria for clip suitability for DMR have been met.
  • The major clinical benefits of the MitraClip Implant are a reduction of MR to ≤ 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.
  • Note the product “Use by” date specified on the package.
  • Inspect all product prior to use. Do not use if the package is open or damaged, or if product is damaged.

SPECIAL PATIENT POPULATIONS
• Mitral Valve Etiology: Safety and effectiveness of the MitraClip device has not been established in patients with MR due to underlying ventricular pathology (functional mitral regurgitation or FMR).
• Pregnancy: The MitraClip device has not been tested in pregnant women. Effects on the developing fetus have not been studied. The risks and reproductive effects are unknown at this time.
• Gender: No safety or effectiveness related gender differences were observed in clinical studies.
• Ethnicity: Insufficient subject numbers prevent ethnicity-related analyses on the clinical safety and effectiveness.
• Pediatrics: Safety and effectiveness of the MitraClip device has not been established in pediatric patients.
• Anatomic Considerations: For optimal results, the following anatomic patient characteristics should be considered. The safety and effectiveness of the MitraClip outside of these conditions has not been established. Use outside these conditions may interfere with placement of the MitraClip Implant or mitral valve leaflet insertion.

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; Chordal entanglement / rupture; Coagulopathy; Conversion to standard valve surgery; Death; Deep venous thrombus (DVT); Dislodgement of previously implanted devices; Dizziness; Drug reaction to anti-platelet / anticoagulation agents / contrast media; Dyskinetic Dyspnea; Edema; Emboli (air, thrombus, MitraClip Implant); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip to the intended site; Foreign body reaction; Frailty; Femoral thrombus; Gastrointestinal bleeding or infarct; Hematoma; Hemolysis; Herniation requiring transfusion; Hypotension / hypervolemia; Infection; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; MitraClip Implanteronion, migration or malposition; MitraClip Implant thrombosis; MitraClip System component(s) embolization; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea / vomiting; Pain; Peripheral ischemia; Prolonged angina; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal insufficiency or failure; Respiratory failure / atelectasis / pneumonia; Septicemia; Shock, Anaphylactic or Cardiogenic; 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

WARNING: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. Illustrations are artist’s representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

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