**Indication for Use**

The MitraClip System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary MR. Echocardiography of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heat 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 antithrombotic regimens
- 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 designed to reduce mitral regurgitation. The MitraClip procedure is recommended to be performed when an experienced heart team has determined that the patient is at prohibitive risk for mitral valve surgery. 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 surgery may not be realized.

- The MitraClip Implant 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 sharpsh and wash hands while handling the MitraClip System to avoid 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**

- 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, as well as the presence of comorbidities.

- At least 30 day STS predicted operative mortality risk score of 10% for patients deemed likely to undergo mitral valve replacement or surgery for MR ≥ 2+ for patients deemed likely to undergo mitral valve repair

- Porcelain aorta or extensively calcified ascending aorta.

- Failed (assessed by in-person cardiac surgeon consultation)

- Hostile chest

- Severe liver disease / cirrhosis (MELD Score > 12)

- Severe pulmonary hypertension (PH) due to primary pulmonary hypertension or secondary PH due to left heart disease or systemic disease; and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

**Quick Reference to Transcatheter Mitral Valve Repair**

- The MitraClip System 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 the product carton (when available) or at eifu.abbottvascular.com or at eifu.abbottvascular.com.

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The following transthoracic echo (TTE) views represent key considerations for MitraClip therapy. Adherence to this systematic protocol is recommended to ensure efficient analysis of the mitral valve and to assess anatomic eligibility for the MitraClip procedure.

**GENERAL COMMENTS**
- Digital archived images should include three (3) or more cardiac cycles—unless patient has atrial fibrillation, then five (5) cardiac cycles are recommended.
- Ensure color Doppler Nyquist limits range from 0.5–0.7 m/sec—unless specified for PISA.
- Adjust gain and depth to enhance and maximize the image for measurements.
- Perform all spectral Doppler and M-mode recordings at a sweep speed of 100 mm/sec.
- Use of color compare setting is strongly recommended.
- Ensure that peak spectral velocities are fully visible on screen.
- Confirm that EKG signal is clearly visible on all frames.
- All calibration lines should be clearly visible.
- Use of a customized echocardiography bed is strongly recommended.
- Use 3D images to supplement and confirm initial diagnosis.
- Ensure that all cardiac structures are analyzed per institution guidelines.

*MitraClip therapy in the US is not indicated for functional mitral regurgitation.*

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### TTE ASSESSMENT CHECKLIST

1. **Color flow jet**
   - None
   - Mild
   - Moderate
   - Moderate-to-severe
   - Severe

2. **Pulmonary vein flow**
   - Normal pulmonary vein flow
   - Codominant pulmonary vein flow
   - Diastolic dominant pulmonary vein flow
   - Systolic pulmonary vein flow reversal

3. **Vena contracta width (cm)**

4. **Regurgitant volume (mL/beat)**

5. **Regurgitant fraction (%)**

6. **Regurgitant orifice area (cm²)**

7. **Mitral valve orifice area (cm²)**

8. **LV ejection fraction (%)**

9. **LV end systolic dimension (LVSDs) (cm)**

10. **Presence of mitral annular calcifications**
    - None
    - Mild/moderate
    - Severe

11. **Origin of primary regurgitant jet**

12. **Presence of a second clinically significant jet**

13. **MR etiology**
    - Functional*
    - Degenerative
    - Mixed

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### PARASTERNAL LONG AXIS VIEW

**In this view, assess:**
- LV size and function
- LA size
- MR etiology
- MR severity
- Pulmonary vein flow
- Calcification in mitral valve area (if any/severity)
- Vena contracta width

### PARASTERNAL SHORT AXIS VIEW: AORTIC VALVE LEVEL

**In this view, assess:**
- For ASDs, VSDs, and shunts by interrogating the intra-atrial septum

### PARASTERNAL SHORT AXIS VIEW: MITRAL VALVE LEVEL

**In this view, assess:**
- Calcification in mitral valve area (if any/severity)
- Jet origin with color Doppler applied
- Size of mitral valve area by planimetry

### PARASTERNAL SHORT AXIS VIEW: AORTIC VALVE LEVEL

**In this view, assess:**
- Jet origin with color Doppler applied
- Size of mitral valve area by planimetry

### APICAL 4-CHAMBER VIEW

**In this view, assess:**
- LV size and function
- LA size
- MR etiology
- MR severity
- Pulmonary vein flow
- Calcification in mitral valve area (if any/severity)
- Vena contracta width

### APICAL 3-CHAMBER VIEW

**In this view, assess:**
- LV size and function
- LA size
- MR etiology
- Calcification in mitral valve area (if any/severity)

### SUBCOSTAL SHORT AXIS VIEW

**In this view, assess:**
- Color Doppler of atrial septum to interrogate presence of ASD

### APICAL 5-CHAMBER VIEW

**In this view, assess:**
- LV size and function
- LA size
- MR etiology
- MR severity
- Pulmonary vein flow
- Interrogate aortic valve using standard technique

### SUBCOSTAL LONG AXIS VIEW

**In this view, assess:**
- 2D of inferior vena cava collapsing (sniff test)