**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.

**Can your patients benefit from MitraClip® Therapy?**

Connect with a TMVR Center.

**TMVR with MitraClip® Therapy is Transforming the Standard of Care**

Transcatheter mitral valve repair (TMVR) with MitraClip® therapy is an important, minimally invasive treatment option for significant, symptomatic, degenerative mitral regurgitation patients who are at prohibitive risk for surgery. TMVR can reduce MR and improve quality of life.1
Heart valve centers currently providing MitraClip® therapy in United States

Updated list as of August 2014.
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Valves repaired. Lives improved.
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
- Pneumatic 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 the procedure are outweighed by the associated 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 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 product 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 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 ST-segment advanced mortality risk index 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.
- FRAILLY (assessed by in-person cardiac surgeon consultation)
- Hostility chest
- Severe pulmonary disease (MOLD Score >12)
- Severe pulmonary hypertension (systolic pulmonary artery pressure >2/3 systemic pressure)
- Unusual extanting 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.
- Evaluate data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an UEF <20% or an UESD >60mm. 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 ≤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 and other important data 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.

Contraindications, contraindication, warnings, precautions, and adverse events.