MitraClip®

Percutaneous Mitral Valve Repair

Important Safety Information

MITRACLIP® CLIP DELIVERY SYSTEM

INDICATION FOR USE

MitraClip is intended to reduce 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 Delivery System is contraindicated in DM patients with the following conditions:

- Patients who cannot tolerate procedural anticoagulation or antiplatelet 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 DM 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 maximally 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 Device should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transesophageal [TEE] 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 exposure.
- 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, 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
    - Posterolateral or extensively calcified ascending aorta
- Fruity (assessed by in-person cardiac surgeon consultation)
- Hostile chest
- Severe liver disease / cirrhosis (MELD Score >12)
- Severe pulmonary hypertension (systolic pulmonary artery pressure >25 mmHg systemic pressure)
- Unfavorable anatomic circumstances, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapeutic for malignancy, major bleeding diathesis, active infection, multi-system organ failure, right atrial or internal mammary artery (IMA) at high risk of injury, etc.
- Evaluate data regarding safety or effectiveness is not available for prohibitive risk DM patients with an LVEF ≤ 20% or an LVEDD > 60mm. MitraClip should be used only when criteria for clip suitability for DM 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.
- For reasonable assurance of device effectiveness, pre-procedural evaluation of the mitral valve and underlying pathologic anatomy and procedural echocardiographic assessment are essential.
- Theinside of the outer porch is not a sterile barrier. The inner pouch within the outer pouch is the sterile barrier. Only the outside 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.

- Access site complications (e.g., bleeds, skin laceration), device misplacement or device retrieval
- MitraClip device attach failure
- MitraClip device fractures
- MitraClip component(s) embolization
- Coagulopathy
- Conversion to standard valve surgery; Death; Deep venous thrombosis (DVT)
- Dislodgement of previously implanted devices; Drug reaction to anti-platelet/anticoagulation agents/contra- trium media; Dyspnea; Edema; Embolism (air, thrombus, MitraClip Device Event); Endocarditis; Esophageal perforation; Excessive pressure; Infection and pain at insertion site; Infection and pain at incision site; Injury to mitral valve repairing or preventing later surgical repair
- MitraClip System complications: 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

STEREABLE GUIDE CATHETER

INDICATION FOR USE

The Stereable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart via the interatrial septum.

CONTRAINDICATIONS

Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS

- 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 Stereable Guide Catheter.
- Use the Stereable Guide Catheter with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transesophageal [TEE] in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- The Stereable Guide Catheter is 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.
- Patients with the following considerations in whom the Stereable Guide Catheter is used may have an increased risk of having a serious adverse event which may be avoided with preoperative evaluation and proper device usage:
  - Previous interatrial septal patch or prosthetic atrial septal defect (ASD) closure device which could result in significant difficulty in visualization or technical challenges during transseptal puncture and/or introducing the SGC into the left atrial appendage
  - Known or suspected unstable angina or myocardial infarction within the last 12 weeks could increase the procedural morbidity and mortality due to increased hemodynamic stress secondary to general anesthesia
  - Patients with active infection have an increased risk of developing an intraoperative and/or postoperative infection, such as sepsis or soft tissue abscesses
  - Known or suspected left atrial myxoma could result in thromboembolism and tissue injury due to difficulty with device positioning.
  - Recent coronavascular event (CVA) may increase the procedural morbidity associated with a transcatheter intervention, such as recurrent stroke.

PRECAUTIONS

- Use the “Use by” date specified on the package. Inspect all product prior to use. Do not use if the package is opened or damaged.
- 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.
- Prior to use, please reference the Instructions for Use at www.AbbottVascular.com/ifs for more information on indications, contraindications, warnings, precautions, and adverse events.