TTE Screening

MitraClip®

Percutaneous Mitral Valve Repair

Transthoracic Echo Acquisition Guide

Settings and 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
- The following views represent key considerations for the MitraClip Therapy

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Indications

This material may be utilized for Clinical Site participants involved in Abbott Vascular sponsored trials or disclosed to a user facility for educational purposes.

Indications for Use

MitraClip Clip Delivery System

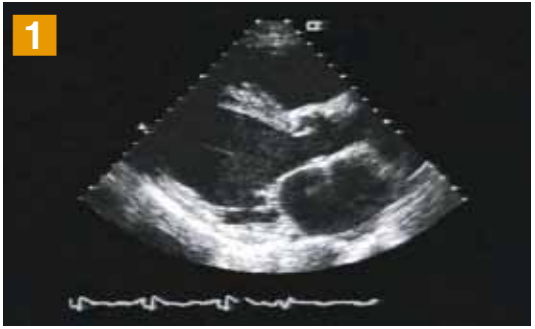
The MitraClip Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart 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.

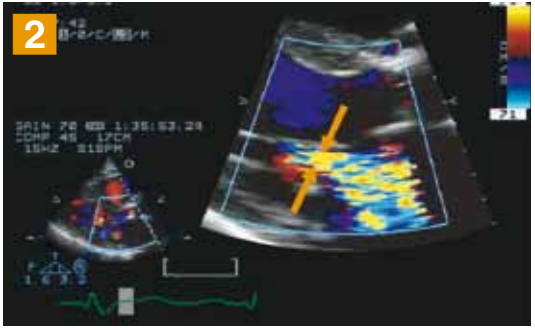
Steerable Guide Catheter

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

For Functional MR: Caution: Investigational device. Limited by Federal (US) law to investigational use only.

Parasternal Long Axis Views to Obtain





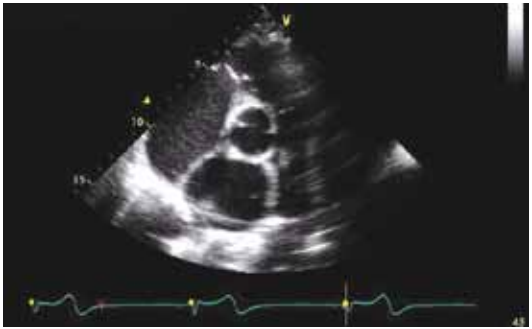
Parasternal Long Axis

- 2D with and without magnification of LVOT
- Color Doppler MV for vena contracta width in magnified mode
- M-mode of the LV

Key Elements

- Magnify the image of the LVOT and mitral valve — two separate views may be necessary
- Position magnified image sector to view part of IVS, aortic valve, and mitral leaflets
- Show coaptation of both leaflets clearly 1
- M-mode of LV perpendicular and just below tips of mitral valve leaflets
- Choose a scan plane that shows proximal flow convergence, vena contracta (magnify specifically at mitral valve), and jet 2

Parasternal Short Axis Views to Obtain

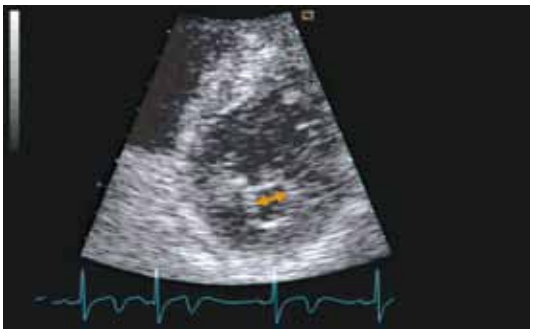


Aortic Valve Level

- 2D optimizing pulmonary valve annulus
- PW Doppler of pulmonary valve

Key Elements

- For PW Doppler of pulmonary valve, capture image with and without color
- Closing artifact of valve needs to be visible on screen—adjust Doppler gain to optimize spectral envelope

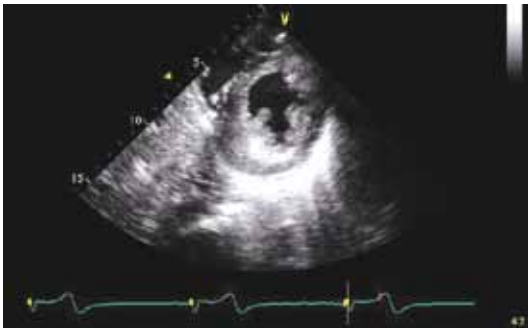


Mitral Valve Level

- 2D at tips of MV leaflets
- 2D at level of annulus
- Color Doppler of MV en face

Key Elements

- For color Doppler of MV, capture image with and without color
- Measure mitral valve area at leaflet tips
- Measure flail width (drop-in/drop-out)
- Determine jet origin



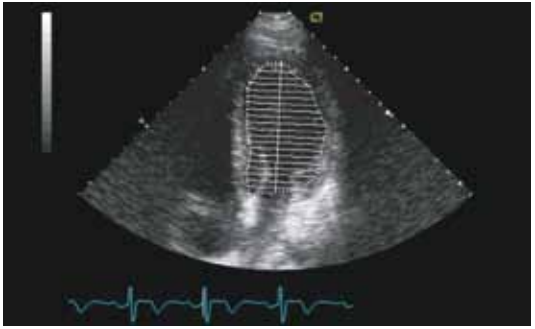
Mid-papillary Muscle Level

- 2D
- M-mode

Key Elements

- Obtain true cross section (non-oblique)

Apical 4-chamber Views to Obtain

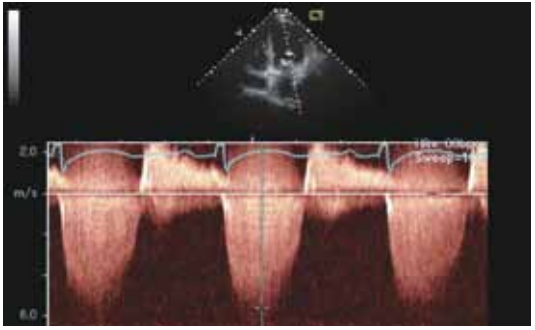


4-chamber

- 2D with and without magnification of mitral valve
- Color Doppler of MR jet at Nyquist limit of 0.5–0.7 m/sec

Key Elements

- Show endocardium without foreshortening, and analyze LV volumes by method of discs
- Use contrast as appropriate per your institutional guidelines—if endocardial border delineation is <80%, contrast is recommended at end of study

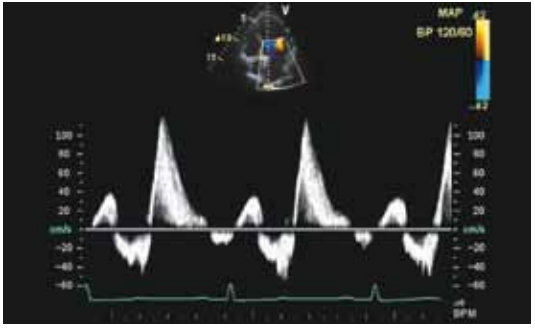


Spectral Doppler

- CW Doppler of MR jet
- CW Doppler of mitral inflow
- PW Doppler of mitral inflow at mitral annulus
- PW Doppler of mitral inflow at MV leaflet tips

Key Elements

- Sample volume should be at tip of mitral leaflets
- Adjust baseline and Doppler scale to visualize peak velocities (MR jet)
- MR peak velocity should be at least 5.0 m/sec
- Align cursor in direction of flow



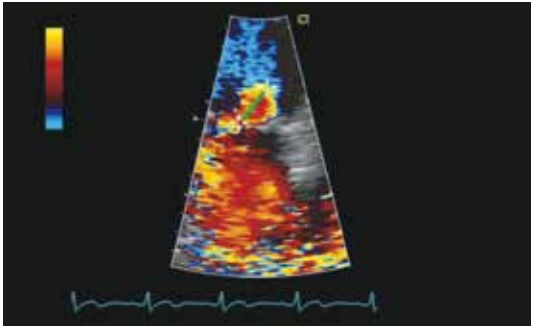
Pulmonary Vein Flow

- PW Doppler at right upper pulmonary vein

Key Elements

- Sampling position should be 1 cm within PV and not in LA
- Capture flow above and below the baseline—if unable to capture flow simultaneously, adjust baseline and capture flow individually

Apical 4-chamber Views to Obtain

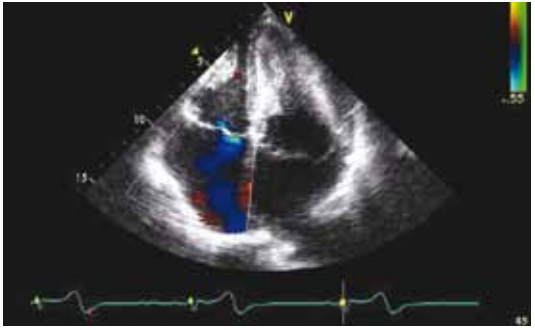


PISA

- Color Doppler of MR PISA in magnify mode

Key Elements

- For PISA, magnification is recommended and sample with and without color
- Ensure Nyquist limit of 0.3–0.4 m/sec
- Measure MR PISA radius in the direction of flow



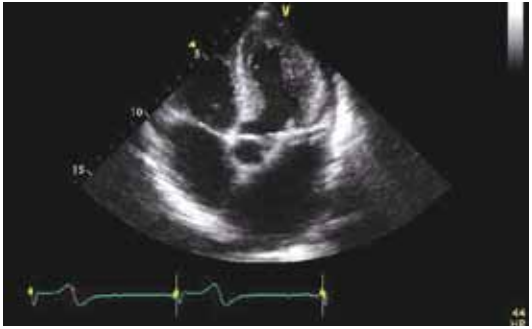
TR Jet

- Color Doppler of TR jet
- CW Doppler of TR jet

Key Elements

- If unable to get TR velocity measurement, consider agitated saline to enhance TR jet

Apical Views to Obtain

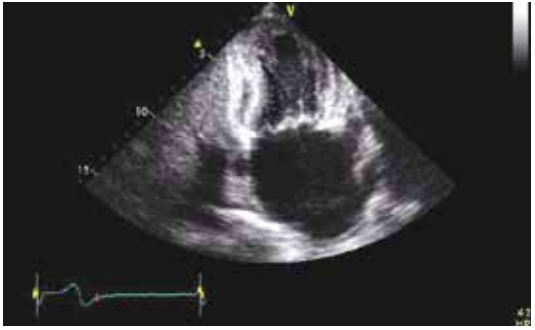


Apical 5-chamber

- 2D
- Color Doppler of aortic valve
- CW Doppler of aortic insufficiency, if present
- CW Doppler of aortic valve
- PW Doppler of LVOT

Key Elements

- Closing artifact of valve needs to be on screen—adjust Doppler gain to optimize spectral envelope
- Sample volume should be about 5 mm from the aortic valve

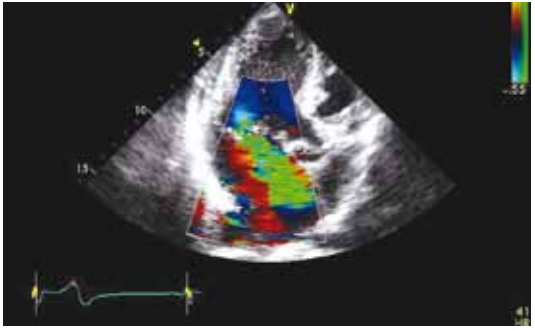


Apical 2-chamber

- 2D
- Color Doppler of the mitral regurgitant jet

Key Elements

- Image should not include right ventricle
- Show endocardium without foreshortening, and analyze LV volumes by method of discs
- Views of anterior and posterior valve leaflets



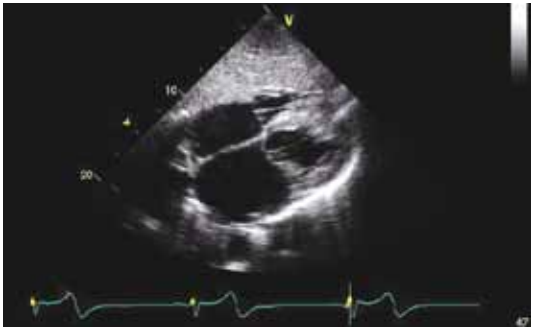
Apical 3-chamber

- 2D
- Color Doppler of aortic valve
- Color Doppler of mitral valve

Key Elements

- This view used to supplement parasternal long axis views and provide additional information on the mitral and aortic valves
- Acquire using standard technique

Subcostal Views to Obtain

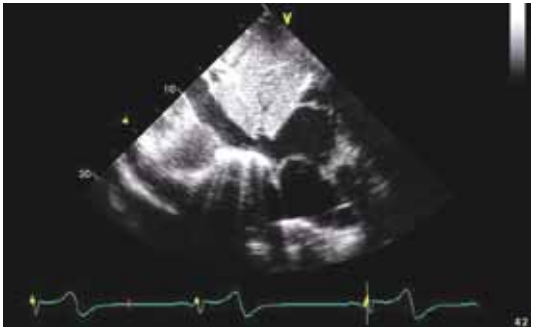


Subcostal Long Axis

- 2D of inferior vena cava collapsing (sniff test)
- Color Doppler of atrial septum to interrogate presence of ASD

Key Elements

- Acquire using standard technique



Subcostal Short Axis

- 2D of inferior vena cava collapsing (sniff test)

Key Elements

- Acquire using standard technique

MITRACLIP CLIP DELIVERY SYSTEM

Rx ONLY

INDICATION FOR USE

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.

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 ≤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 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 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
    - 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 > 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 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

STEERABLE GUIDE CATHETER

Rx ONLY

INDICATION FOR USE

The Steerable Guide Catheter is used for introducing various cardiovascular catheters into the left side of the heart through 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, warning and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps to avoid user injury.
- Use the Steerable Guide Catheter 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.
- The Steerable 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 Steerable 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 atrium.
  - 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 abscess.
  - Known or suspected left atrial myxoma could result in thromboembolism and tissue injury due to difficulty with device positioning.
  - Recent cerebrovascular event (CVA) may increase the procedural morbidity associated with a transcatheter intervention, such as recurrent stroke.

PRECAUTIONS

NOTE the "Use by" date specified on the package.

Inspect all product prior to use. Do not use if 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.
The outside surface of the inner pouch is NOT sterile.

Prior to use, please reference the Instructions for Use at www.abbottvascular.com/ifu for more information on indications, contraindications, warnings, precautions, and adverse events.

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This is material may be utilized for Clinical Site participants involved in Abbott Vascular sponsored trials or disclosed to a user facility for educational purposes.

CAUTION For Functional MR: This product is intended for use by or under the direction of a physician. Prior to use, it is important to read the package insert thoroughly for Instructions for Use, Warnings and Potential Complications associated with use of this device.

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www.AbbottVascular.com

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