**Transesophageal Echo Acquisition Guide**

**Suggested Settings**

- Each view should be performed with and without color flow Doppler using color compare when appropriate
  - Ensure capture of the MR jet at the valve
  - Visualize the entire jet within the LA
- Multiple cardiac cycles should be captured
- Color flow Doppler Nyquist limits = Range 0.5-0.7 m/sec
- Implement 3D imaging when appropriate but not to the exclusion of traditional 2D image acquisition
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.
**0° Views to Obtain**

**Superior**
5-chamber view with A1/P1 of the mitral valve (MV) clearly visualized.
This view is obtained at the mid-esophageal level. The aortic valve and left ventricular outflow tract are clearly visualized. The LV is foreshortened.

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**Central**
4-chamber view with A2/P2 clearly visualized.
Advanced probe 1–3 cm. The LV cavity is more completely visualized. For functional MR, vertical coaptation length should be measured. For degenerative MR, flail gap should be measured, if present.

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**Inferior**
4-chamber view with A3/P3 clearly visualized.
The probe is further advanced 1–3 cm. The coronary sinus and tricuspid valve may be seen.
60–90° Views to Obtain

**Anterior**
This view is obtained at the anterior side of the valve to visualize A1, A2, and A3 scallops.

The anterior leaflet can be isolated by torquing/rotating the probe clockwise from the midline.

**Midline**
This view is obtained at the midline of the valve to visualize P1, A2, and P3 scallops.

**Posterior**
This view is obtained at the posterior side of the valve to visualize P1, P2, and P3 scallops.

The posterior leaflet can be isolated by torquing/rotating the probe counterclockwise from midline.
110–130° Views to Obtain

**Lateral**
This view is obtained at the lateral side of the valve to visualize A1 and P1 scallops.

The lateral aspect can be isolated by torquing/rotating the probe counterclockwise from central.

**Central**
This view is of the central aspect of the valve with A2 and P2 scallops clearly visualized.

For degenerative MR, flail gap should be measured, if present.

**Medial**
This view is obtained at the medial side of the valve to visualize A3 and P3 scallops.

The medial aspect can be isolated by torquing/rotating the probe clockwise from central.
Left Upper Pulmonary Vein (0–30°)
Use color flow and PW Doppler. Place PW Doppler sample volume 1–2 cm into PV.

Right Upper Pulmonary Vein (90–120°)
Use color flow and PW Doppler. Place PW Doppler sample volume 1–2 cm into PV.

Bicaval (80–110°)
SVC and IVC should be visible along with atrial septum.
Additional Views to Obtain

**Short Axis at Base (15–45°)**
This procedural view demonstrates a cross-section of the aorta, atrial septum, and right and left atria.

**Transgastric Short Axis (0–20°)**
Adjust angle to optimize SAX with both anterior and posterior leaflets clearly visible. Measure flail width if present. Use color flow Doppler to demonstrate jet origin.

**3D En Face**
3D images should be used to supplement and confirm the initial diagnosis. 3D data may be useful when available.
Anatomic Measurements | Degenerative Mitral Regurgitation (DMR)

**DMR Flail Gap**
This should be taken in the view (LVOT or 4 chamber) where the flail gap is largest.

**DMR Flail Width**
This measurement should be taken in the transgastric short axis view where the flail width is largest.
**FMR Vertical Coaptation Length**

The measurement should be taken in the 4-chamber view where the vertical coaptation length is shortest.
MITRACLIP CLIP DELIVERY SYSTEM

INDICATION FOR USE
The MitraClip Device 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 ≥38% for patients deemed likely to undergo mitral valve replacement or ≥26% 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.
  - Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus
  - Rheumatic mitral valve disease
  - Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
  - Patients who can not tolerate the expected benefit from reduction of the mitral regurgitation

WARNINGs
- Repeat 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 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.
- Use 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 preparative evaluation and proper device usage.
- Previous interstitial 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 the package is opened or damaged.

The inside of the outer pouch is not a sterile barrier. The inner pouch should be considered sterile. The outside surface of the inner pouch is NOT sterile.

PATENTIAL 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 anticoagulation agents/contact material; Myocardial infarction; Myocardial ischemia; Necrosis; Nerve injury; Nausea/ Vomiting;
Pericardial effusion; Pericardial tamponade;
Polyethylene catheter rupture or obstruction; Pulmonary complications; Remodeling; Right atrial effusion; Right ventricular dysfunction;
Sepsis; Severe hyperkalemia; Stroke or transient ischemic attack (TIA); Urinary tract infection; Vascular trauma, dissection or occlusion; Vessel spasm; Vessel perforation or laceration; Worsening mitral regurgitation; Wound dehiscence.

STEERABLE GUIDE CAThETER

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, 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 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 preparative evaluation and proper device usage.
- Previous interstitial 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.
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PRECAUTIONS
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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.