

Transcatheter Mitral Valve Repair (TMVr) with MitraClip® Guide for Clinical Assessment of Prohibitive Risk Status for Mitral Valve Surgery

Indication: The MitraClip® NT 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.

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.

This guide is intended to facilitate a clinical determination of an individual patient's surgical risk status. Such a determination should be based on the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease.

Note, this guide is limited to the clinical assessment of a patient's prohibitive risk status and does not address other aspects of patient selection for TMVr with MitraClip®. Please refer to MitraClip® *Instructions for Use* for additional details regarding patient selection considerations.

Presence of one or more following documented surgical risk factors [Check and complete all that apply]:

- Patient's 30-day STS predicted operative mortality risk score: _____ [Attach patient-specific printout from web-based STS tool]

Check one of the following that apply to this patient:

- Patient likely to undergo mitral valve replacement [Above STS score must be ≥8%]
- Patient likely to undergo mitral valve repair [Above STS score must be ≥6%]

- Porcelain aorta

As determined by [Describe imaging or other diagnostic work-up(s), as well as physician responsible for this determination; include relevant attachments as appropriate]

- Extensively calcified ascending aorta

As determined by [Describe imaging or other diagnostic work-up(s), as well as physician responsible for this determination; include relevant attachments as appropriate]

- Frailty as assessed by two or more indices at an in-person consultation by a cardiac surgeon

Summarize cardiac surgeon consultation, as well as frailty indices utilized [Include physician who conducted consultation, indices and the date thereof]

- Hostile chest [Describe rationale(s) for this determination, as well as physician responsible for this determination; include relevant attachments as appropriate]

- Severe liver disease / cirrhosis

- Patient's MELD Score: _____ [MELD Score must be >12]
- Other patient-specific hepatic issues / diagnoses:

- Severe pulmonary hypertension [complete below]

- Systolic pulmonary artery pressure: _____
- Systemic pressure: _____ [Systolic pulmonary artery pressure must be >2/3 of systemic pressure]

- Unusual extenuating circumstance [check all that apply and describe below]
 - 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
 - Other unusual extenuating circumstances [Because this criterion is vague, describe below these "other unusual extenuating circumstances;" address why they are truly extenuating and why the patient is at prohibitive risk. Include a summary from the consulting cardiologist that supports this determination.]
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Disclaimer: This guide is based on the FDA *Instructions for Use* for MitraClip®, with certain modifications intended to facilitate a clinical assessment by a heart team of an individual patient's mitral valve surgical risk status.

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INDICATION FOR USE

The MitraClip® NT 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® NT 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® NT 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® NT is intended to reduce mitral regurgitation. The MitraClip® NT 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® NT. 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® NT may not occur.
- The MitraClip® NT 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® NT System to avoid user injury.
- Use of the MitraClip® NT should be restricted to those physicians trained to perform invasive endovascular and transeptal 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

- 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® NT should be used only when criteria for clip suitability for DMR have been met.
 - The major clinical benefits of MitraClip® NT 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® NT 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.
- Note the “Use by” date specified on the package.
- Inspect all product prior to use. Do not use if the package is open or damaged, or if product is damaged.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip® NT 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; Chordal entanglement/rupture; Coagulopathy; Conversion to standard valve surgery; Death; Deep venous thrombus (DVT); Dislodgement of previously implanted devices; Dizziness; Drug reaction to anti-platelet/ anticoagulation agents/contrast media; Dyskinesia; Dyspnea; Edema; Emboli (air, thrombus, MitraClip® NT Device); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip® NT to the intended site; Failure to retrieve MitraClip® NT System components; Fever or hyperthermia; Gastrointestinal bleeding or infarct; Hematoma; Hemolysis; Hemorrhage requiring transfusion; Hypotension/hypertension; Infection; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; MitraClip® NT erosion, migration or malposition; MitraClip® NT Device thrombosis; MitraClip® NT System component(s) embolization; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea/ vomiting; Pain; Peripheral ischemia; Prolonged angina; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal insufficiency or failure; Respiratory failure/atelectasis/pneumonia; Septicemia; Shock, Anaphylactic or Cardiogenic; 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



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 transeptal 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.

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.

CAUTION: This product 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 ifu.abbottvascular.com or at manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions, and Adverse Events.