Abbott

HEALTH ECONOMICS & REIMBURSEMENT

# MitraClip™ Transcatheter Edge-to-Edge Repair (TEER)

## TEMPLATE FOR CLINICAL ASSESSMENT OF PROHIBITIVE RISK STATUS FOR MITRAL VALVE SURGERY

This guide is intended to facilitate a clinical determination of an individual patient's surgical risk status by the cardiac surgeon responsible for the patient evaluation. 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.

This guide is based on the MitraClip™ therapy FDA Instructions for Use, with certain modifications intended to facilitate a clinical assessment by a heart team of an individual patient's mitral valve surgical risk status. 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 MitraClip TEER. 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 or extensive calcification**
  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.]

_____

_____

_____

## Rx Only
## Important Safety Information

**MITRACLIP™ CLIP DELIVERY SYSTEM**
**Indications for Use**

- The MitraClip™ G4 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™ G4 System, when used with maximally tolerated guideline-directed medical therapy (GDMT), is indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR; MR ≥ Grade III per American Society of Echocardiography criteria) in patients with a left ventricular ejection fraction (LVEF) ≥ 20% and ≤ 50%, and a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease.

**Contraindications**
The MitraClip G4 System is contraindicated in patients with the following conditions: Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or post procedural anti-platelet regime; Patients with known hypersensitivity to clip components (nickel / titanium, cobalt, chromium, polyester), or with contrast sensitivity; Active endocarditis of the mitral valve; Rheumatic mitral valve disease; Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

**Potential Complications and Adverse Events**
The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip G4 procedure: Allergic reactions or hypersensitivity to latex, contrast agent, anesthesia, device materials (nickel / titanium, cobalt, chromium, polyester), and drug reactions to anticoagulation, or antiplatelet drugs, Vascular access complications which may require transfusion or vessel repair including: wound dehiscence, catheter site reactions, Bleeding (including ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage), Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, vascular occlusion, Emboli (air thrombotic material, implant, device component); Peripheral Nerve Injury; Lymphatic complications; Pericardial complications which may require additional intervention, including: Pericardial effuse on, Cardiac tamponade, Pericarditis; Cardiac complications which may require additional interventions or emergency cardiac surgery, including: Cardiac perforation, Atrial septal defect; Mitral valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single Leaflet Device Attachment (SLDA), Thrombosis, Dislodgement of previously implanted devices, Tissue damage, Mitral valve stenosis, Persistent or residual mitral regurgitation, Endocarditis; Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, and unstable / stable angina); Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post procedure pulmonary embolism); Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction / failure / atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Blood cell disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)); Hypotension / hypertension; Infection including: Urinary Tract Infection (UTI), Pneumonia, Septicemia; Nausea / vomiting; Chest pain; Dyspnea; Edema; Fever or hyperthermia; Pain; Death; Fluoroscopy, Transesophageal echocardiogram (TEE) and Transthoracic echocardiogram (TTE) -related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation; Esophageal perforation, Gastrointestinal bleeding

**CAUTION:** Product(s) intended for use by or under the direction of a physician. Prior to use, reference to the Instructions for Use, inside the product carton (when available) or at https://www.eifu.abbott/ for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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