



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, anaesthesia, 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: 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 eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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