ABBOTT

MitraClip™
Transcatheter Edge-to-Edge Repair



Five-year outcomes from the COAPT™ post-approval study

Insights from the TVT registry and CMS claims linkage[1]

Five-year outcomes from COAPT PAS demonstrated favorable long-term safety and effectiveness in real-world patients treated with M-TEER.

STS/ACC TVT registry

2396
patients with STS/ACC TVT registry – CMS linked data through 5 years

406
centers in the United States (in TVT registry)

Baseline characteristics

Older, clinically more complex population than COAPT RCT

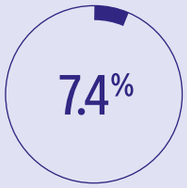
Characteristics	COAPT PAS	COAPT RCT[2]
Age (years)	76.1	71.7
STS replacement score	9.3%	7.8%
NYHA Class III/IV	85.1%	57.0%
Atrial fibrillation	65.4%	57.3%
Prior stroke or transient ischemic attack	11.7%	18.5%

For U.S. audience, see Important Safety Information referenced within. For audiences outside of the U.S., always check the regulatory status of the device in your region.

COAPT™ PAS 5-year outcomes[1]



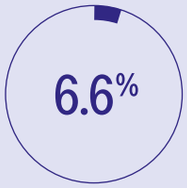
All-cause mortality



All-cause hospitalization



Freedom from stroke



Mitral valve reintervention

References:
1. M. Andrew Morse, Five-Year Outcomes from the COAPT Post-Approval Study Insights from the TVT Registry and CMS Claims Linkage. Data presented at TCT 2026.
2. Stone GW, Lindenfeld J, Abraham WT, et al. Transcatheter Mitral-Valve Repair in Patients with Heart Failure. N Engl J Med 2018; 379(24): 2307-18.

For U.S. Audiences Only
Rx Only
Important Safety Information
MITRACLIP™ CLIP DELIVERY SYSTEM

Indications for Use
The MitraClip™ G5 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™ G5 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™ G5 System is contraindicated for use in patients with the following conditions:
- Intolerance, including allergy or untreatable hypersensitivity, to procedural anticoagulation
- Untreatable hypersensitivity to Implant components (nickel- titanium alloy, cobalt-chromium alloy)
- Active endocarditis or other active infection of the mitral valve

Potential Complications and Adverse Events
The following events have been identified as possible complications of the MitraClip™ G5 procedure:
Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, device materials, and drug reactions to anticoagulation, or antiplatelet drugs, additional treatment/surgery from device-related complications, atrial septal defect, bleeding, blood disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)), Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias), Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, unstable angina, and stable angina), Cardiac perforation, Cardiac tamponade, chest pain, death, Dyspnea, Edema, Embolization (device or components of the device), Endocarditis, fever or hyperthermia, Fluoroscopy and Transesophageal echocardiogram (TEE) -related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation, Esophageal perforation, Gastrointestinal bleeding, Hypotension / hypertension; Infection including: Septicemia; Mitral valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single leaflet device attachment (SLDA), dislodgement of previously implanted devices, tissue damage, mitral valve stenosis, worsening, persistent or residual regurgitation, nausea or vomiting, pain, Pericardial effusion, stroke / cerebrovascular accident (CVA) and transient ischemic attack (TIA), system organ failure: cardio-respiratory arrest, worsening heart failure, Pulmonary congestion, Respiratory dysfunction or failure or atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic), Thrombosis, Vascular access complications which may require additional intervention, including: wound dehiscence, bleeding of the access site, Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation (rupture), vascular occlusion, Embolism (air, thrombus), Peripheral nerve injury, Venous thrombosis (including deep vein thrombosis) and thromboembolism (including pulmonary embolism).

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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 www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions, and Adverse Events. Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photo(s) on file at Abbott.

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