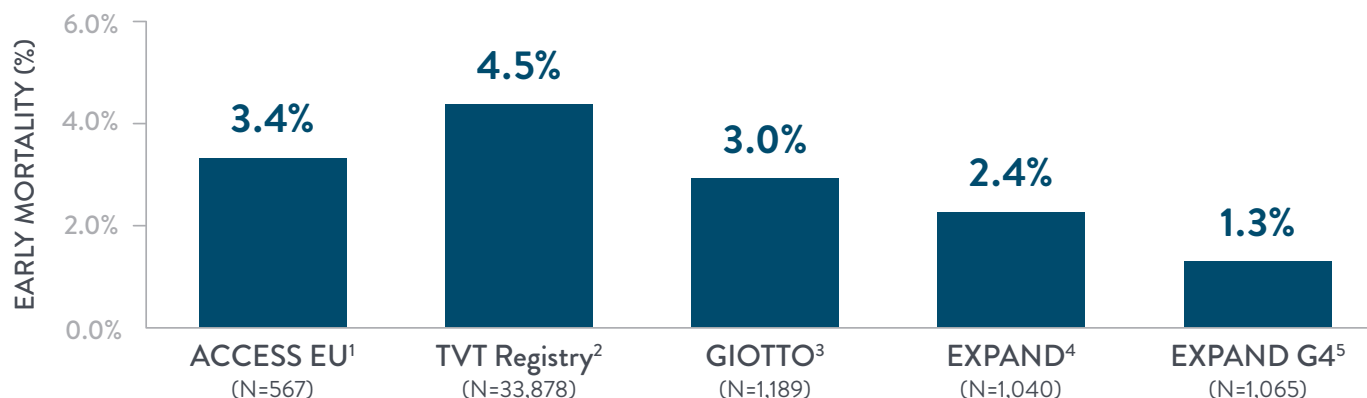


LOW PROCEDURAL RISKS. CONSISTENT SAFETY OUTCOMES.



MitraClip™ TEER has demonstrated low early complication rates and high procedural success in a real world population. Safety outcomes are consistent across trials and post-approval studies, including in elderly and high risk patients.

LOW 30-DAY MORTALITY RATE REPORTED IN REAL-WORLD STUDIES WITH MITRACLIP TEER



SUSTAINED PATIENT SAFETY OUTCOMES



FREEDOM FROM
DEVICE-SPECIFIC
COMPLICATIONS
AT 5 YEARS⁶

CONTEMPORARY EXPAND AND EXPAND G4 STUDIES FURTHER CONFIRM MITRACLIP TEER SAFETY PROFILE

KEY MEASURES OF DEVICE SAFETY	EXPAND⁷,¹⁰	EXPAND G4⁵,⁸,⁹
LEAFLET ADVERSE EVENTS (LAE)		
• Single Leaflet Attachment (SLDA)	1.7% (30-Days) 1.7% (1-Year)	1.1% (30-Days) 1.6% (1-Year) 1.7% (2-Years)
• Leaflet injury (leaflet tear or perforation)	0.4% (30-Days) 0.4% (1-Year)	0.2% (30-Days) 0.2% (1-Year) N/A (2-Years)
MITRAL VALVE SURGICAL REINTERVENTION		
	N/A (30-Days) 1.9% (1-Year)	0.9% (30-Days) 1.9% (1-Year) <2.8% (2-Years)

N/A = Not Available

NOTE: Data not from head-to-head studies. Data differences depicted between these trials may not be directly comparable, statistically significant, or clinically meaningful due to differences in trial protocols, endpoints, and/or patient populations. Data provided for informational purposes only.

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.

E N G I N E E R E D F O R L I F E

HIGH PROCEDURAL SUCCESS RATE AND PREDICTABLE EXPERIENCE

97%

ACUTE
PROCEDURAL
SUCCESS⁹

98%

IMPLANT RATE⁷

77
mins

MEDIAN
PROCEDURE
TIME⁹

REFERENCES:

1. Maisano F, et al. Percutaneous mitral valve interventions in the real world: early and 1-year results from the ACCESS-EU, a prospective, multicenter, nonrandomized post-approval study of the MitraClip therapy in Europe. *Journal of the American College of Cardiology*. 2013;62(12):1052–1061.
2. Sorajja P, et al. Outcomes With Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. *J Am Coll Cardiol*. 2017;70:2315–2327.
3. Bedogni F, et al. Real World Safety and Efficacy of Transcatheter Mitral Valve Repair With MitraClip: Thirty Day Results From the Italian Society of Interventional Cardiology (GISe) Registry Of Transcatheter Treatment of Mitral Valve RegurgitaTiOn (GIOTTO). *Cardiovascular Revascularization Medicine*. 2020;21(9):1057–1062.
4. Lim Scott D. Contemporary Outcomes with MitraClip™ (NTR/ XTR) System in Primary Mitral Regurgitation: Results from the Global EXPAND Study. Data presented at ACC 2020.
5. von Bardeleben RS, et al. Real-World Outcomes of Fourth Generation Mitral Transcatheter Repair: 30-Day Results from EXPAND G4. *JACC Cardiovasc Interv*. 2023 Jun 26; 16(12): 1463-73.
6. Stone GW, et al. Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation. *N Engl J Med*. March 5, 2023. DOI: 10.1056/NEJMOA2300213.
7. Kar S, von Bardeleben R, Rottbauer W, et al. Contemporary Outcomes Following Transcatheter Edge-to-Edge Repair: 1-Year Results From the EXPAND Study. *J Am Coll Cardiol Interv*. 2023 Mar, 16 (5) 589–602.
8. von Bardeleben RS, et al. 1-Year Outcomes With Fourth-Generation Mitral Valve Transcatheter Edge-to-Edge Repair from the EXPAND G4 Study. *JACC Cardiovasc Interv*. 2023, DOI: 10.1016/j. cin.2023.09.029.
9. De Marco F. Two-Year Outcomes with the MitraClip G4 System: Results from the EXPAND G4 Study. Data presented PCR London Valves 2025.
10. Asch FM, et al. Incidence and standardised definitions of mitral valve leaflet adverse events after transcatheter mitral valve repair: the EXPAND study. *EuroInterv*. 2021;17:e932-941.

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)

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.

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.

Abbott

3200 Lakeside Dr., Santa Clara, CA 95054 USA

™ Indicates a trademark of the Abbott group of companies

www.structuralheart.abbott

©2026 Abbott. All rights reserved. MAT-2676326 v1.0 | Item approved for Global use.

