CLINICAL EVIDENCE IS THE FOUNDATION FOR GUIDELINES AND RECOMMENDATIONS FOR VALVULAR HEART DISEASE AND HEART FAILURE TREATMENT

Robust evidence from MitraClip™ and TriClip™ TEER trials has created **DEFINING MOMENTS** in the management of valvular heart disease. The pivotal studies, demonstrating significant improvements in patient symptoms and quality of life, are associated with the guidelines upgrades for the management of mitral and tricuspid regurgitation with TEER therapy.

2011
- **EVEREST II**
  1Y RESULTS

2012
- **EVEREST II HRR**
  1Y RESULTS

2014
- **2014 AHA/ACC VHD GUIDELINE**
  Class IIb recommendation for primary MR (PMR)

2015
- **EVEREST II**
  5Y RESULTS

2017
- **STS/ACC TVT**
  Registry report
- **2017 FOCUSED UPDATE**
  No change to TMVr recommendation

2018
- **COAPT™**
  2Y RESULTS
- **MITRA-FR***
  1Y RESULTS

2020
- **2020 ACC/AHA VHD GUIDELINE**
  Upgrade to Class IIa for PMR and new Class IIa for SMR

2021
- **2021 HFA/ESC VHD GUIDELINES**
  Upgrade to Class IIa and IIb for select SMR patients and Class IIb for select PMR patients
- **2021 APSC CONSENSUS**
  MitraClip TEER drives recommendation in Asia-Pacific region for treatment of MR

2022
- **2022 AHA/ACC/HFSA HF GUIDELINE**
  Upgrade to Class IIa for select SMR

2023
- **COAPT™**
  5Y RESULTS

2024
- **RESHAPE-HF2***
  2Y RESULTS
- **MATTERHORN TRIAL***
  1Y RESULTS
- **bRIGHT**
  1Y RESULTS
- **TRILUMINATE™ PIVOTAL**
  1Y RESULTS
- **TRI.FR***
  1Y RESULTS

2025
- **2025 ESC/EACTS VHD GUIDELINES**
  Upgrade to Class I for severe ventricular SMR, Class IIa for severe PMR and a new Class IIb for severe atrial SMR. Upgrade to Class IIa for transcatheter tricuspid valve intervention.
- **TRILUMINATE™ PIVOTAL**
  2Y RESULTS
- **bRIGHT STUDY**
  2Y RESULTS

2026
- **TRI.FR***
  2Y RESULTS

FUTURE
- New clinical evidence from Abbott will continue to drive guidelines forward

*Investigator sponsored studies

REFERENCES:

1. Praz F, Borger MA, Lanz J, et al; ESC/EACTS Scientific Document Group. 2025 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2025;00:1-102. Doi:10.1093/eurheartj/ehaf194.
2. Heidenreich PA, et al. "2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association. Joint Committee on Clinical Practice Guidelines." J Am Coll Cardiol. Apr 01, 2022. Epublished DOI: 10.1016/j.jacc.2021.12.012.
3. Otto C, et al. "2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines." J Am Coll Cardiol. Dec 17, 2020. Epublished DOI: 10.1016/j.jacc.2020.11.018.

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Rx Only. Important Safety Information

MITRACLIP™ CLIP DELIVERY SYSTEM
TRICLIP™ CLIP DELIVERY SYSTEM

MitraClip™ G5 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.

TriClip™ G5 System Indications for Use

The TriClip™ G5 System is indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, who are at intermediate or greater risk for surgery and in whom transcatheter edge-to-edge valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team.

MitraClip™ G5 and TriClip™ G5 Systems Contraindications

Both the MitraClip™ G5 System and the TriClip™ G5 System are 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 or tricuspid valve.

MitraClip™ G5 Systems and TriClip™ G5 Systems Potential Complications and Adverse Events

The following events have been identified as possible complications for both the MitraClip™ G5 and TriClip™ G5 procedures (except as noted): 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 (in MitraClip only), 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 and Tricuspid 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.

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TRANSCATHETER TREATMENT OF MITRAL AND TRICUSPID REGURGITATION

VALVULAR HEART DISEASE GUIDELINES AND RECOMMENDATIONS

MitraClip™ & TriClip™
Transcatheter Edge-to-Edge Repair

ENGINEERED **FOR LIFE**

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2025 ESC/EACTS GUIDELINES[1]

In 2025, The European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) Guidelines for the management of valvular heart disease support transcatheter edge-to-edge repair (TEER) for patients with the following recommendations:[1]

MITRAL REGURGITATION (MR)

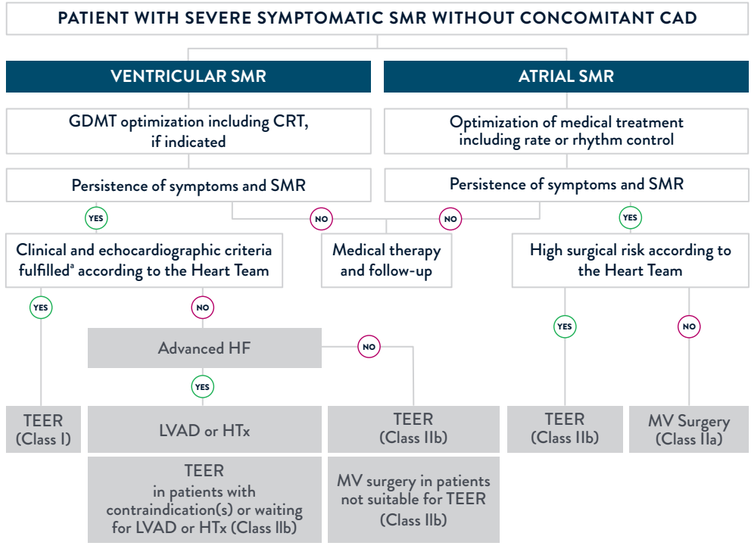
		PREVIOUS	2025
REV. **SEVERE PRIMARY MR**	TEER should be considered in symptomatic patients with severe PMR who are anatomically suitable and at high surgical risk according to the Heart Team.	Class IIb (B)	Class IIa (B)
NEW **SEVERE VENTRICULAR SECONDARY MR WITHOUT CONCOMITANT CORONARY ARTERY DESEASE** This upgrade in the Class of Recommendation firmly establishes **M-TEER as the standard of care** for patients with ventricular SMR.	TEER is recommended to reduce HF hospitalizations and improve quality of life in haemodynamically stable, symptomatic patients with impaired LVEF (< 50%) and persistent severe ventricular SMR, despite optimized GDMT and CRT (if indicated), fulfilling specific clinical and echocardiographic criteria.	Class IIa (B)	Class I (A)
	TEER may be considered for symptom improvement in selected symptomatic patients with severe ventricular SMR not fulfilling the specific clinical and echocardiographic criteria after careful evaluation of LVAD or HTx.		Class IIb (B)
NEW **SEVERE ATRIAL SECONDARY MR** The guidelines place significant emphasis on the distinction between atrial and ventricular pathologies, indicating that this distinction has clear prognostic and management implications.	TEER may be considered in symptomatic patients with severe atrial SMR not eligible for surgery after optimization of medical therapy including rhythm control, when appropriate.		Class IIb (B)

NEW TRICUSPID REGURGITATION (TR)

Careful evaluation of TR etiology, stage of the disease (i.e. degree of TR severity, RV and LV dysfunction, and PH), patient operative risk, and likelihood of recovery by a multidisciplinary Heart Team is recommended in patients with severe TR prior to intervention.	Transcatheter TV treatment should be considered to improve quality of life and RV remodelling in high-risk patients, with symptomatic severe TR despite optimal medical therapy, in the absence of severe RV dysfunction or pre-capillary PH.	Class IIb (C)	Class IIa (A)

For US 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.

TREATMENT OF SEVERE SECONDARY MITRAL REGURGITATION WITHOUT CONCOMITANT CORONARY ARTERY DISEASE



CHARACTERISTICS DISTINGUISHING BETWEEN ATRIAL AND VENTRICULAR SMR

ATRIAL SMR	KEY CRITERIA	VENTRICULAR SMR
	LVEF ≥ 50% without regional wall motion abnormalities	LVEF < 50% with or without regional wall motion abnormalities
	No or mildly dilated LV cavity without leaflet tethering	Restrictive leaflet motion with tethering
	Mitral annulus dilatation (AP > 35 mm)	Normal leaflet morphology
	Enlarged LA (LAVI > 34 mL/m^2)	Central or eccentric jet
	ADDITIONAL ECHOCARDIOGRAPHIC CRITERIA	
	Normal leaflet motion	Dilated LV
	Normal leaflet morphology	Dilated LA
	Usually central jet	Dilated MV annulus
	ADDITIONAL CLINICAL CRITERIA	
	Atrial fibrillation	Ischaemic heart disease
	HFpEF	Dilated cardiomyopathy

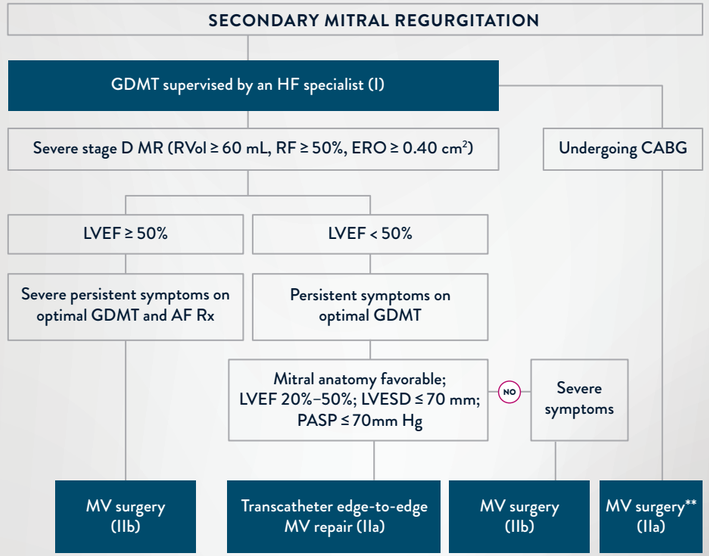
Adapted from Praz F, et al. 2025 ESC/EACTS Guidelines for the Management of Valvular Heart Disease

2022 ACC/AHA/HFSA GUIDELINE[2]

In 2022, the American Heart Association (AHA), American College of Cardiology (ACC) and Heart Failure Society of America (HFSA) formally updated their clinical practice guideline for the management of patients with heart failure.

TEER had been strengthened to a Class IIa recommendation for COAPT-like* Secondary MR Patients, reinforcing the 2020 Valvular Heart Disease Guideline.

TREATMENT APPROACH FOR SECONDARY MITRAL REGURGITATION[3]



Adapted from Otto C, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease

2020 ACC/AHA GUIDELINE[3]

PRIMARY MR

Class IIa, LoE B-NR: In severely symptomatic patients (NYHA class III or IV) with primary severe MR and **high or prohibitive surgical risk, TEER is reasonable** if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least one year.

*COAPT-like: NYHA II-IV; severe secondary MR; suitable anatomy; LVEF 20%-50%; LVESD ≤ 70 mm; PASP ≤ 70 mm Hg.
**Chordal-sparing MV replacement may be reasonable to choose over downsized annuloplasty repair.