



MITRAL REGURGITATION

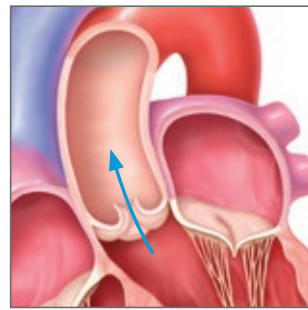
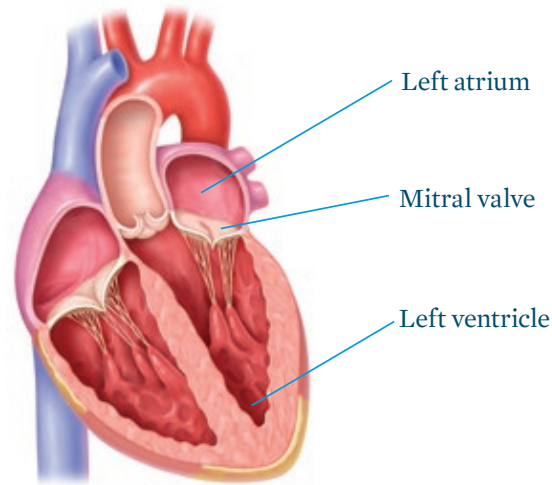
**DON'T WAIT TO DO SOMETHING –
THERE ARE OPTIONS.**



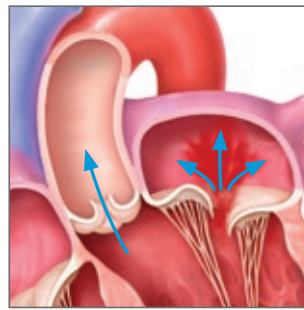
WHAT IS MITRAL REGURGITATION?

Mitral regurgitation (MR) is a condition affecting the mitral valve. The mitral valve is located between your heart's two left chambers and has two flaps of tissue that open and close to ensure that blood flows in only one direction.

Mitral regurgitation occurs when the mitral valve fails to close completely and blood leaks backward inside your heart.



Normally functioning mitral valve



Mitral regurgitation

Mitral regurgitation can get worse over time and really impact your quality of life. It weakens your ability to complete simple day-to-day tasks.

WHAT ARE THE SYMPTOMS?

Over time, MR may lead to heart failure. Heart failure means that the heart is unable to pump enough blood to meet the body's demands. In some cases, patients with MR may never experience symptoms. Others may develop symptoms of heart failure, such as:¹⁻³

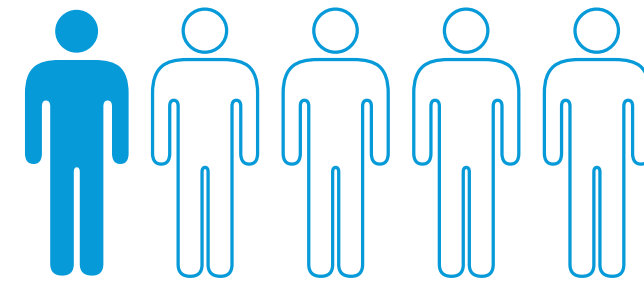
- Fatigue
- Inability to exercise
- Decrease in appetite
- Dry, hacking cough (often worse when lying down)
- Shortness of breath (especially at night)
- Fainting
- Weight gain from retaining fluid
- Accumulation of fluid in feet, ankles, and lungs (edema)

If you are experiencing any of these symptoms, talk to your doctor to receive a thorough examination and diagnosis. You should also seek treatment if you notice that your symptoms are getting worse.

WHAT ARE THE RISK FACTORS?

Several factors can increase your risk of MR, including:⁴

- History of valve disease
- Heart attack
- Certain forms of heart disease
- Infections such as endocarditis (inner heart lining is inflamed) or rheumatic fever (inflammatory disease caused by complications from strep throat)
- Age—by middle age, many people have some MR



ABOUT 1 IN 5 PEOPLE AGE 75 AND OLDER HAVE MR⁵⁻¹⁰

WHAT IS THE IMPACT?

Patients with MR may experience a poorer quality of life, and without treatment, MR can lead to irreversible heart damage with serious consequences.

- MR places an extra burden on your heart and lungs
- Over time, some people may develop an enlarged heart, as the heart must work harder to pump blood through the body
- If it is not treated, MR can cause other, more serious problems to your heart, such as heart failure and death

WHAT ARE MY TREATMENT OPTIONS?

Treatment depends on how bad your condition is, and if it's getting worse. Consult with your doctor to discuss all treatment options, risks, and benefits. Only your doctor can help you decide which option is right for you.



MEDICATIONS

Your doctor may prescribe medications to manage your symptoms. However, these will only treat MR symptoms and cannot eliminate the root causes.¹¹



SURGERY

Depending on the root cause of the MR, severity, and symptoms, your physician may recommend open-heart surgery to have the mitral valve repaired or replaced.



CARDIAC RESYNCHRONIZATION THERAPY (CRT)

CRT is a potential treatment option for patients that helps improve the heart rhythm and increases blood flow to help treat heart failure symptoms.



TRANSCATHETER MITRAL VALVE REPAIR

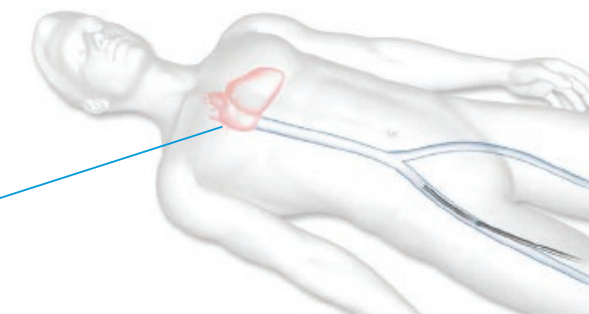
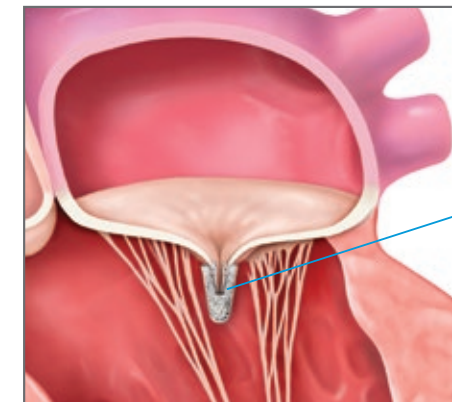
If you meet certain criteria, your physician may recommend a procedure which is less invasive compared to open-heart surgery: transcatheter mitral valve repair.



WHAT ARE THE BENEFITS OF A MINIMALLY INVASIVE TREATMENT OPTION?



Transcatheter mitral valve repair is an approved, minimally invasive treatment to repair your leaking mitral valve using an implanted clip.



The entire system is introduced through a vein in the groin area and advanced to the heart.



MINIMALLY INVASIVE BEATING HEART PROCEDURE

Less invasive than traditional open-heart surgery, the device is implanted via a small tube, or catheter, inserted through an incision in your upper leg.



IMPROVED QUALITY OF LIFE

Most patients experience improvement in symptoms and quality of life after the procedure.¹⁵



PROVEN THERAPY

Included in the medical guidelines for treating mitral regurgitation, and proven safe and effective with over 15 years of use, reaching 100,000 patients treated, and more than 1,000 scientific publications.¹²



SHORT HOSPITAL STAY

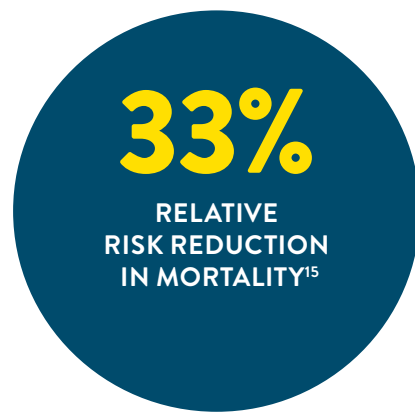
Patients are usually released from the hospital within 2 to 3 days, significantly less time compared to surgery.¹³

CLINICAL RESULTS FROM A LANDMARK TRIAL SHOW DRAMATIC IMPROVEMENT IN QUALITY OF LIFE.

SPEAK WITH YOUR DOCTOR ABOUT THE NEW CLINICAL TRIAL RESULTS FOR COAPT™ AND MITRACLIP™.

In a published landmark clinical trial called COAPT, selected heart failure patients with MR who were treated with MitraClip with guideline-directed medical therapy had a dramatic improvement in survival, had fewer hospitalizations for heart failure, and experienced improved quality of life compared to patients who were treated with guideline-directed medical therapy alone.¹⁴

SAVES LIVES



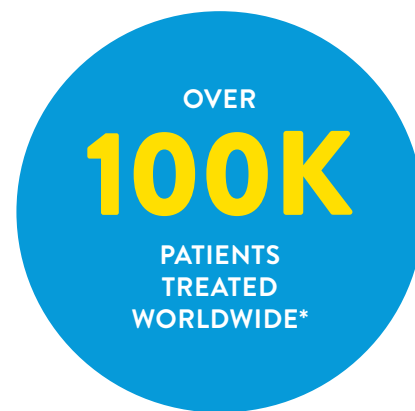
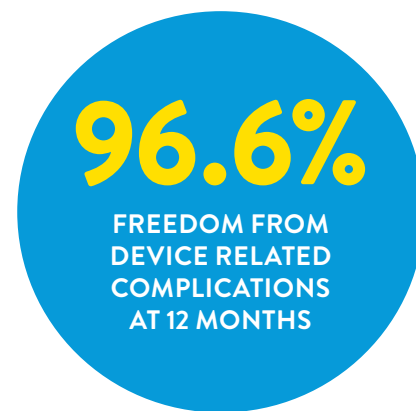
FEWER HOSPITALIZATIONS FOR HEART FAILURE



FEEL BETTER



PROVEN SAFE AND EFFECTIVE



A NEW OPTION FOR HEART FAILURE PATIENTS.

Transcatheter mitral valve repair has made a difference for thousands of patients worldwide, providing new quality of life and the opportunity for a new story.*

“I can do anything a normal person can. There are times I forget that I had the procedure done.”

– THE FIRST MITRACLIP PATIENT WHO RECEIVED MITRACLIP IN 2003



“It’s all about solving that problem, trying to make the patient feel better and give them the life they want to live.”

– PHYSICIAN



“I immediately saw a difference. I saw her come alive again...A real quality of life again...”

– CAREGIVER

If you or a loved one would like more information about Transcatheter Mitral Valve Repair, talk to your doctor, or visit MitraClip.com.**

*This testimonial relates an account of an individual’s response to the treatment. The testimonial is genuine; however, it does not provide any indication, guide, warranty or guarantee as to the response other persons may have to the treatment. Responses to the treatment discussed can and do vary and are specific to the individual’s account.

**The information contained in this website is in no way a substitute for professional medical advice. If you have any questions about treatment options, contact your doctor.

MitraClip™

Transcatheter Mitral Valve Repair

Rx ONLY MITRACLIP CLIP DELIVERY SYSTEMS

INDICATIONS FOR USE

- The MitraClip™ NTR/XTR Clip Delivery 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™ NTR/XTR Clip Delivery 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™ NTR/XTR Clip Delivery System is contraindicated in patients with the following conditions:

- Patients who cannot tolerate procedural anticoagulation or post procedural antiplatelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS

- DO NOT use MitraClip™ outside of the labeled indication.
- The MitraClip™ Implant should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transeophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling the MitraClip™ System to avoid user injury.

REFERENCES

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See Important Safety Information Referenced Within.

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

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- Use of the MitraClip™ should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and/or reuse may result in infections, malfunction of the device or other serious injury or death.
- Use caution when treating patients with hemodynamic instability requiring inotropic support or mechanical heart assistance due to the increased risk of mortality in this patient population. The safety and effectiveness of MitraClip™ in these patients has not been evaluated.

PRECAUTIONS

- Note the product “Use by” date specified on the package.
- Inspect all product prior to use. Do not use if the package is open or damaged, or if product is damaged.
- Prohibitive Risk Primary (or degenerative) Mitral Regurgitation
 - Prohibitive risk is determined by the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, due to the presence of one or more of the following documented surgical risk factors:
 - 30-day STS predicted operative mortality risk score of
 - ≥8% for patients deemed likely to undergo mitral valve replacement or
 - ≥6% for patients deemed likely to undergo mitral valve repair
 - Porcelain aorta or extensively calcified ascending aorta.
 - Frailty (assessed by in-person cardiac surgeon consultation)
 - Hostile chest
 - Severe liver disease/cirrhosis (MELD Score > 12)
 - Severe pulmonary hypertension (systolic pulmonary artery pressure > 2/3 systemic pressure)
 - Unusual extenuating circumstance, such as 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, etc.
 - Evaluable data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60 mm. MitraClip™ should be used only when criteria for clip suitability for DMR have been met.

- The heart team should include a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and may also include appropriate physicians to assess the adequacy of heart failure treatment and valvular anatomy.
- Secondary Mitral Regurgitation
 - Evaluable data regarding safety or effectiveness is not available for secondary MR patients with an LVEF < 20% or an LVESD > 70 mm.
 - The multidisciplinary heart team should be experienced in the evaluation and treatment of heart failure and mitral valve disease and determine that symptoms and MR severity persist despite maximally tolerated GDMT.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip™ procedure.

Death; Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex); Aneurysm or pseudo-aneurysm; Arrhythmias; Atrial fibrillation; Atrial septal defect requiring intervention; Arterio-venous fistula; Bleeding; Cardiac arrest; Cardiac perforation; Cardiac tamponade/ Pericardial Effusion; Chordal entanglement/rupture; Coagulopathy; Conversion to standard valve surgery; Deep venous thrombus (DVT); Dislodgement of previously implanted devices; Dizziness; Drug reaction to anti-platelet/anticoagulation agents/contrast media; Dyskinesia; Dyspnea; Edema; Emboli (air, thrombus, MitraClip™ Implant); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip™ to the intended site; Failure to retrieve MitraClip™ System components; Fever or hyperthermia; Gastrointestinal bleeding or infarct; Hematoma; Hemolysis; Hemorrhage requiring transfusion; Hypotension/hypertension; Infection; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; MitraClip™ Implant erosion, migration or malposition; MitraClip™ Implant thrombosis; MitraClip™ System component(s) embolization; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea/vomiting; Pain; Peripheral ischemia; Prolonged angina; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal insufficiency or failure; Respiratory failure/atelectasis/pneumonia; Septicemia; Shock. Anaphylactic or Cardiogenic; Single leaflet device attachment (SLDA); Skin injury or tissue changes due to exposure to ionizing radiation; Stroke or transient ischemic attack (TIA); Urinary tract infection; Vascular trauma, dissection or occlusion; Vessel spasm; Vessel perforation or laceration; Worsening heart failure; Worsening mitral regurgitation; Wound dehiscence

