



A Guide to Treating Your Mitral Regurgitation

MitraClip[™]

Transcatheter Edge-to-Edge Repair



Abbott

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Dear Patient,

Our mission at Abbott is to restore people’s health and improve their quality of life. We are delighted that you have taken the first steps toward treating your mitral regurgitation with transcatheter edge-to-edge repair (TEER).

This patient guide is for those who have significant mitral regurgitation (MR) due to abnormality of the mitral valve who are too sick for open-heart surgery, or have moderate-to-severe or worse MR due to underlying heart disease who continue to have symptoms despite being on heart failure medication.

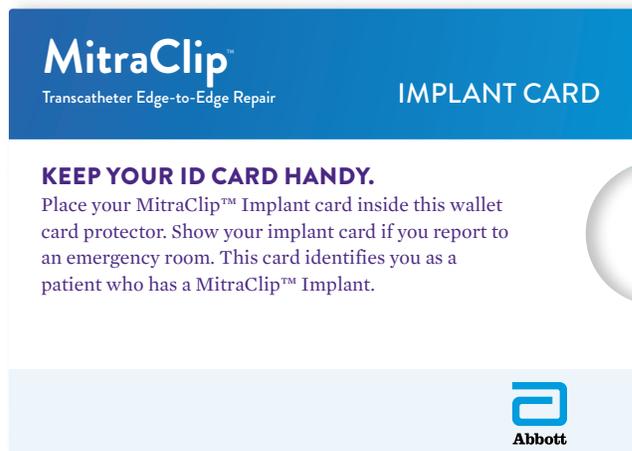
Please take the time to review the information found in this guide, as well as share it with your loved ones and friends. If you have any additional questions, please reach out to the healthcare professionals in your local Heart Team.

We wish you all the best and good health!



Lars Sondergaard,
Chief Medical Officer

YOUR IMPLANT CARD



APPOINTMENTS

MY MITRACLIP™ PROCEDURE IS SCHEDULED:

Date/time: _____

Location: _____

Arrival Time: _____

MY _____ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: _____

Location: _____

Arrival Time: _____

MY _____ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: _____

Location: _____

Arrival Time: _____

MY _____ FOLLOW-UP VISIT IS SCHEDULED:

Date/time: _____

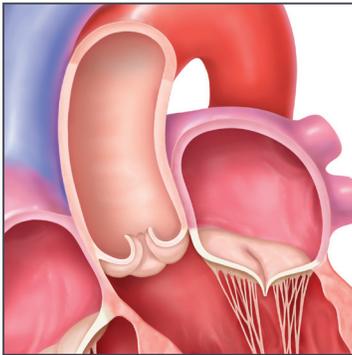
Location: _____

Arrival Time: _____

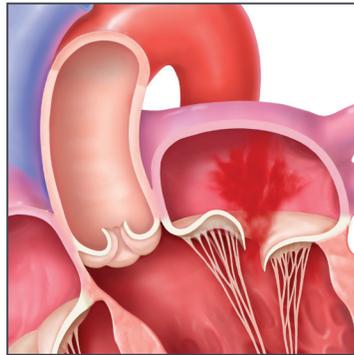
WHAT IS MITRAL REGURGITATION?

Mitral regurgitation (MR) is a condition affecting the mitral valve and occurs when the mitral valve fails to close completely and blood leaks backward inside your heart.

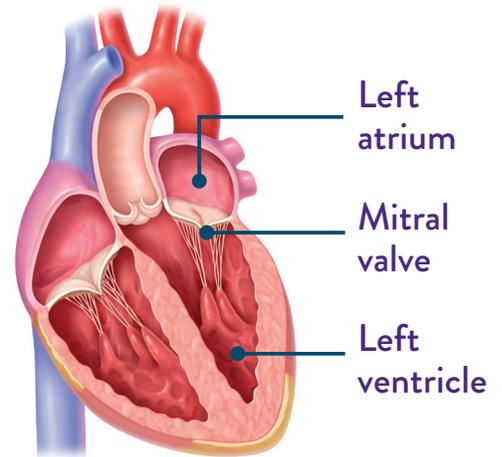
MR can get worse over time and really impact your quality of life. It weakens your ability to complete simple day-to-day tasks.



Normally functioning mitral valve



Mitral regurgitation



WHAT ARE THE SYMPTOMS?



FATIGUE



HEART PALPITATIONS



DRY, HACKING COUGH



SHORTNESS OF BREATH



FAINING



SWOLLEN ANKLES OR FEET

WHAT ARE THE TREATMENT OPTIONS?

Based on your level of risk, the outcomes from your diagnostic tests and lifestyle preferences, your doctor and Heart Team will recommend the best treatment option(s) for you. There are various treatment options available for mitral regurgitation, including medication, transcatheter edge-to-edge repair (TEER) and surgical mitral valve replacement and repair.



DISCUSS ALL TREATMENT OPTIONS WITH YOUR DOCTOR.

Your doctor can describe the risks and benefits and help you decide which option is right for you.



MEDICATION

There are a variety of medications available to potentially help manage your MR symptoms. Your doctor will work with you on developing the right regimen for your specific needs.



TRANSCATHETER EDGE-TO-EDGE REPAIR (TEER)

MitraClip™ Transcatheter Edge-to-Edge Repair (TEER) is a minimally invasive treatment to repair your leaking mitral valve using an implanted clip, delivered through a catheter (a tube-like device).



SURGICAL MITRAL VALVE REPLACEMENT AND REPAIR

If your mitral valve cannot be repaired, your doctor may recommend surgical valve repair or replacement with an artificial (prosthetic) valve. Two types of prosthetic mitral valves are available: mechanical or tissue. Each type of valve offers different benefits and risks, depending on your specific needs.



To learn more about MR, visit:
abbo.tt/MR_US

THE MITRACLIP™ SYSTEM

WHAT IS THE MITRACLIP™ SYSTEM AND HOW IS IT USED?

The MitraClip™ Implant is a small clip that is placed to help close the leaflets of your mitral valve. The Implant is inserted through a catheter and guided to your heart.

The MitraClip™ System treats mitral regurgitation by clipping the leaflets (the flaps) of the mitral valve. The valve continues to open and close on either side of the clip. This allows blood to flow on both sides of the clip into the left ventricle while reducing or preventing blood from flowing backward into the left atrium.

MitraClip™ Therapy is a safe, effective, and well-studied procedure. Highlights include:



**REDUCES MORTALITY
& HOSPITALIZATIONS**



**MINIMALLY
INVASIVE**



**SHORT
HOSPITAL STAY**



200K+

Patients treated worldwide



20+

Years of proven safety

MitraClip™

Transcatheter Edge-to-Edge Repair

MitraClip™ Therapy is a simple procedure to fix your mitral valve, without the need for open-heart surgery.



**The MitraClip™ Implant is
about the size of a dime.**

WHAT IS THE BEST TREATMENT FOR YOU?

A team of doctors will evaluate you for all treatment options. They will consider the following factors to decide the most appropriate treatment option for you:

- Your medical history, age, and current health status
- Your ability to undergo a surgical or transcatheter procedure and recover from it
- The overall condition of your heart

WHAT ARE THE BENEFITS OF THE MITRACLIP™ PROCEDURE?

Patients studied one year after the MitraClip™ Procedure continued to experience reduced mitral regurgitation, resulting in the following benefits*:

- **Improved heart function:** Reducing MR lessens the burden placed on the heart. This results in a reversal of heart enlargement and allowing the heart to pump blood more efficiently.
- **Reduced mortality:** After the MitraClip™ Procedure, patients have a lower risk of mortality.
- **Improvement in symptoms:** Patients experience significant improvement in how they feel during physical activity. This is measured by a system called the New York Heart Association (NYHA) functional classification, which places patients in 1 of 4 classes.
- **Fewer heart-failure-related hospitalizations:** Patients experience significantly fewer hospital stays for heart failure after the MitraClip™ Procedure compared to before.
- **Improved quality of life:** Patients experience meaningful improvements in physical and mental function, as measured by a standardized quality-of-life survey.



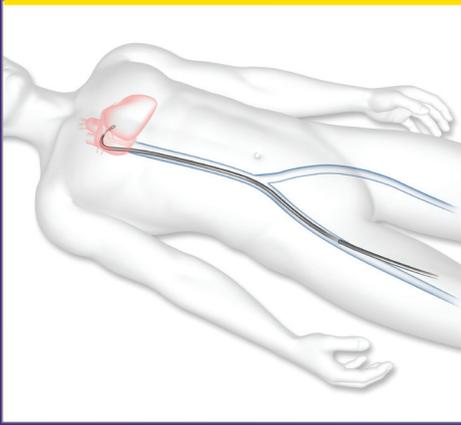
* The degree of improvement will depend on your medical status before undergoing the MitraClip™ Procedure.

WHAT HAPPENS DURING THE MITRACLIP™ PROCEDURE?

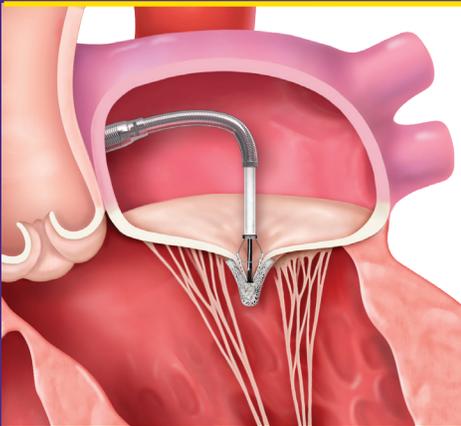
The following steps provide a general overview of the MitraClip™ Procedure —your experience may be different. Your doctor will explain the procedure to you and can provide you with specific details and answer any questions you may have.



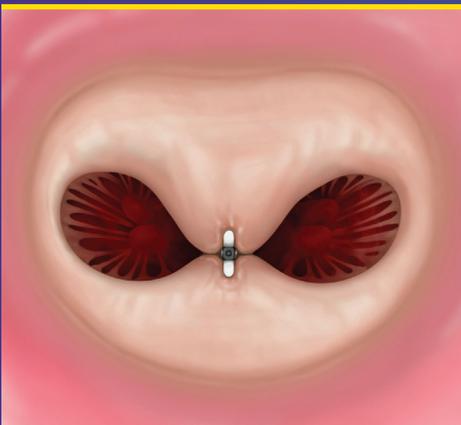
The implantation procedure typically lasts 1 to 3 hours.



- 1** Your doctor will make a small puncture in your groin to access your vein and insert a catheter to reach your heart.



- 2** The Implant will be advanced to the left atrium and positioned in the appropriate location to grasp the mitral valve leaflets. One or more Implants may be deployed.



- 3** The catheter will be removed and the MitraClip™ Implant will become a permanent part of your heart, allowing your mitral valve to close more tightly and reduce the backward flow of blood.

AFTER YOUR MITRACLIP™ PROCEDURE

WHAT HAPPENS AFTER THE MITRACLIP™ PROCEDURE?

Clinical data from patients who underwent the MitraClip™ Procedure demonstrate an immediate reduction of mitral regurgitation.

After your procedure, you may spend on average 1-2 days in the hospital.

Before you leave the hospital, your doctor will discuss next steps with you. They will give you specific instructions to help you with your recovery. It is important to carefully follow your doctor's directions, especially if you need to take any medications.

HOW LONG BEFORE I FEEL THE EFFECTS OF THE MITRACLIP™ PROCEDURE?

You should experience significant improvement in your symptoms of mitral regurgitation and quality of life soon after your procedure. It is important to discuss what to expect following the procedure with your Structural Heart Team.

FOLLOW-UP VISITS

Regular check-ups with your doctor are very important. You will be released to the care of your cardiologist or family doctor, and you may be asked to return for follow-up visits per your doctor's directions. It's important that you call or see your doctor whenever you have questions or concerns about your health.

YOUR ABBOTT IMPLANT CARD

As you leave the hospital, you will receive an Implant card, which has information about your MitraClip™ Implant. Please share your Implant card with all members of your healthcare team, and before any medical, dental, or MRI (magnetic resonance imaging) procedures.



MitraClip™ System
Patient Implant Card

Patient Name: _____

Implant Date: _____

Device LOT#: _____

Implanting Physician: _____

Physician Phone: _____

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(continued on reverse)

IT'S GOOD TO BE BACK HOME,
BUT REMEMBER TO TAKE TIME
TO RECOVER.



RECOVERING AFTER YOUR PROCEDURE

You should be back to your baseline activity at 1-2 weeks. Your doctor will provide more detailed instructions about when you can return to normal activities. For now, be sure that you are familiar with these important recovery tips.

TEND TO YOUR ACCESS SITE

Keep your access site dry for the first 24 hours

- Avoid soaking the area, you are likely able to take a shower
- Avoid perfumes, lotions, etc.

If bruising around the access site suddenly gets bigger or harder:

- Call your doctor immediately
- If any bleeding occurs, or if symptoms worsen, you may need to seek emergency medical treatment.



**Call for help if you experience any of the below symptoms.
Contact your doctor or emergency services.**

- 1 You experience an increase in shortness of breath or sudden chest pain that doesn't go away with rest or medication**
- 2 You feel dizzy, very tired or faint, or have a fever**
- 3 You have weight gain greater than 2lbs overnight**
- 4 You cannot keep taking your medications because of side effects, such as rash, bleeding, or upset stomach**
- 5 The access site is bleeding, becomes swollen, red, painful or has yellow or green discharge**

PRE-PROCEDURE TESTS

Your doctor may order some of the tests below.

<input checked="" type="checkbox"/> Ordered	TEST	PURPOSE/EXPLANATION	<input checked="" type="checkbox"/> Completed
<input type="checkbox"/>	Transthoracic Echocardiogram (TTE)	An ultrasound of your heart which shows how your heart and valves are functioning	<input type="checkbox"/>
<input type="checkbox"/>	Transesophageal Echocardiogram (TEE)	An ultrasound of your heart, performed with sedation, which shows how your heart and valves are functioning. The probe is placed in your throat for closer images of your mitral valve	<input type="checkbox"/>
<input type="checkbox"/>	Cardiac Assessment	Your physician may order an invasive or non-invasive test to evaluate your heart anatomy and measure pressures within the heart	<input type="checkbox"/>
<input type="checkbox"/>	Electrocardiogram (EKG/ECG)	Evaluates the electrical rhythm of your heart	<input type="checkbox"/>
<input type="checkbox"/>	6-Minute Walk Test	Timed walk test done during the office visit to assess balance, mobility, and exercise capacity	<input type="checkbox"/>
<input type="checkbox"/>	Kansas City Cardiomyopathy Questionnaire (KCCQ)	A questionnaire to measure your quality of life	<input type="checkbox"/>
<input type="checkbox"/>	Laboratory Tests	Baseline blood work prior to procedure	<input type="checkbox"/>
<input type="checkbox"/>	Chest X-Ray	Non-invasive imaging to review any lung abnormalities	<input type="checkbox"/>
<input type="checkbox"/>	Other		<input type="checkbox"/>

CONVERSATIONS WITH YOUR CLINICIAN

The following are some suggested questions as you discuss your treatment plan. Be sure to write down any questions you have and bring them to your scheduled appointments.

1. What are the benefits and risks of MitraClip™ vs. surgery?

2. Is there any type of access site care that will need to be managed?

3. What type of sedation will be used for the procedure?

4. How long will I be in the hospital? Will I go home or into rehab?

Will someone need to drive me home?

5. After the procedure, are there medications that I need to take or will there be a change in my medications? What are my recovery instructions?

6. What type of support should I arrange in advance for after I am discharged?

7. When can I return to work/normal activities?

CLINICAL DATA

CLINICAL DATA FOR PATIENTS WITH PRIMARY MITRAL REGURGITATION TREATED WITH MITRACLIP™ THERAPY

The safety and effectiveness of MitraClip™ Therapy were studied in 127 patients with primary mitral regurgitation (PMR). These patients were considered to be too sick for open heart surgery due to age, advanced heart failure, or other serious medical conditions.

The following is a summary of the risks observed within 30 days and 1 year of the MitraClip™ Procedure in patients with PMR. These patients were elderly and had high incidence of one or more serious diseases. This data supported the approval for the MitraClip™ System to be used in this select patient population.

RISKS WITHIN 30 DAYS AND 1 YEAR AFTER THE MITRACLIP™ PROCEDURE FOR PMR		
	30 DAYS	1 YEAR
Death (from any cause)	7 out of 100 patients	24 out of 100 patients
Stroke	3 out of 100 patients	3 out of 100 patients
Myocardial infarction (heart attack)	1 out of 100 patients	1 out of 100 patients
Re-operation for failed surgical repair	0 out of 100 patients	0 out of 100 patients
Heart surgery required for complications	1 out of 100 patients	1 out of 100 patients
Kidney failure	2 out of 100 patients	4 out of 100 patients
Deep wound infection	0 out of 100 patients	0 out of 100 patients
Ventilation longer than 48 hours	4 out of 100 patients	5 out of 100 patients
Gastrointestinal complication requiring surgery	1 out of 100 patients	3 out of 100 patients
New onset of permanent atrial fibrillation (fast, irregular heart rhythm)	0 out of 100 patients	0 out of 100 patients
Septicemia (serious blood infection)	0 out of 100 patients	5 out of 100 patients
Bleeding event (transfusion of 2 or more units of blood)	13 out of 100 patients	20 out of 100 patients
Major vascular complications	6 out of 100 patients	8 out of 100 patients

CLINICAL DATA FOR PATIENTS WITH SECONDARY MITRAL REGURGITATION TREATED WITH MITRACLIP™ THERAPY

The safety and efficacy of MitraClip™ Therapy were studied in 614 patients with heart failure and secondary mitral regurgitation (SMR). Of the 614 patients, half were randomly (like flipping a coin) assigned to Device group (MitraClip™ plus medication) and the other half were assigned to the Control group (medication). The study showed that patients in the Device group had reduced MR, higher survival, reduced hospitalizations and improved quality-of-life after 1 year.

The following table is a summary of the risks observed within 30 days and 1 year of the MitraClip™ Procedure. This data supported the approval for the MitraClip™ System to be used in this select patient population.

RISKS WITHIN 30 DAYS AND 1 YEAR AFTER THE MITRACLIP™ PROCEDURE FOR SMR		
	30 DAYS	1 YEAR
Death (from any cause)	3 out of 100 patients	20 out of 100 patients
Stroke	1 out of 100 patients	3 out of 100 patients
SLDA (Single leaflet device attachment)	1 out of 100 patients	1 out of 100 patients
Device embolization (movement of device from implantation site)	1 out of 100 patients	1 out of 100 patients
LVAD implant (mechanical heart pump)	0 out of 100 patients	1 out of 100 patients
Heart transplant	0 out of 100 patients	1 out of 100 patients
Mitral valve stenosis (mitral valve is narrowed) requiring surgery	0 out of 100 patients	0 out of 100 patients
Device related complications requiring non-elective cardiovascular surgery	1 out of 100 patients	1 out of 100 patients
Myocardial infarction (heart attack)	1 out of 100 patients	4 out of 100 patients



PRECAUTIONS

- If you have a diseased valve, your doctor will carefully assess if MitraClip™ Therapy is appropriate for you.
- Patients who have had a MitraClip™ Procedure should receive antibiotic medication before any medical or dental procedure to lessen the chance of infection.
- The MitraClip™ System has not been tested in pregnant or lactating women, children or infants.

WHO SHOULD NOT HAVE THE PROCEDURE

The MitraClip™ System cannot be used in people who:

- Have an active infection in the heart
- Have an untreatable allergy to nickel-titanium or cobalt-chromium alloys or blood thinning medications

RISKS

As with any medical procedure, there is a possibility of complications. The most serious risks of the MitraClip™ Procedure include:

- **Death**
- **Stroke:** A condition in which decreased blood flow to the brain can result in brain damage and may cause severe disability
- **Transient ischemic attack:** Stroke symptoms that last only a few minutes
- **Major vascular complications:** Damage to a major blood vessel that may require surgery
- **Life threatening bleeding event:** a major bleeding event that requires a blood transfusion

Additional potential risks associated with the procedure include:

- Heart attack
- Worsening heart failure
- Failure of your heart to pump enough blood to the body organs
- Foreign particles (air, blood clot, or device material) floating in the bloodstream or attached to a blood vessel, that may cause blockage in blood flow
- Infection in your heart, blood, or other areas
- Injury to your blood vessels or heart which may require additional surgery or other intervention
- Blocking, tightening, narrowing, or bulging of a blood vessel
- Trouble or inability to breathe
- Swelling caused by fluid build-up
- Irregular heartbeat
- Abnormally high or low blood pressure
- Pain
- A wound that does not close or heal properly
- Fever
- Incorrect positioning, inability to implant, or movement of the MitraClip™ Implant
- Continuing mitral regurgitation through the mitral valve
- Blocking, narrowing, or injury to the mitral valve
- Additional treatment or surgery
- Nausea or vomiting
- Chest pain
- Throat irritation
- Injury or narrowing of the throat
- Worsening kidney function or kidney failure
- Blood disorders
- Skin injury or tissue changes due to exposure to radiation
- Allergic reactions
- Lung failure
- Nerve damage

RESOURCES FOR CAREGIVERS

As a caregiver, you have an important role to play in supporting the recovery of the patient. Below are things you should be considering both before and after the procedure.

1

Accompany the patient to their doctor's visits.

If possible, join the patient on their visit to help ensure they bring their list of questions for the heart team, and that those questions are answered and written down. Bring your own list of questions, as well. A list of suggested questions is provided in the back of this guide.

2

Check that the patient has prepared their legal documents.

If needed, work with the patient to make sure their legal documents are organized and ready before the procedure.

3

Help the patient pack for their hospital stay.

It can be easy to forget a needed item—Prepare a packing list to help ensure everything is there for the patient to have a more comfortable stay.

4

Go over the discharge plan ahead of time.

Once the patient is home, they may need additional support in many ways. They may need assistance taking their medicines and getting to follow-up doctor visits. They may also need help with their routine care and chores or errands around the home.

5

Watch over the patient's physical activity after their procedure.

Make sure they are following the heart team's instructions.

6

Help the patient develop and maintain healthy eating habits.

It's important to understand dietary changes recommended for the patient, and to help them create and stick to a well-balanced diet.

CONTACT INFORMATION

**FOR MORE INFORMATION ON THE MITRACLIP™ PROCEDURE,
PLEASE CONTACT ABBOTT:**

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Mail: Abbott
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St. Paul, MN 55117

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