



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

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www.structuralheart.abbott

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A Guide to Treating Your Mitral Regurgitation

MitraClip™

Transcatheter Edge-to-Edge Repair





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).

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!



Nadim Geloo
Senior Director, Medical Affairs



YOUR IMPLANT CARD

Following your procedure, you will receive an Implant Identification Card. This card is filled out by your doctor. You must carry it with you at all times.

See Important Safety Information referenced within.

THIS BELONGS TO:

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: _____

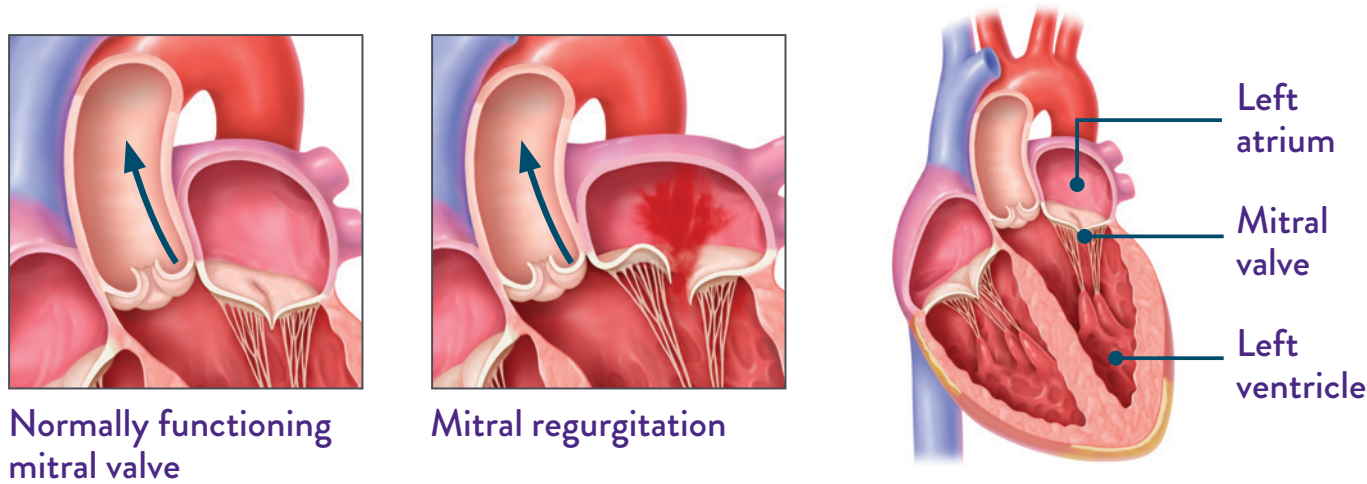


DISCUSS ALL TREATMENT OPTIONS WITH YOUR DOCTOR.

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


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.




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.




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 mitral valve repair (TEER) is a minimally invasive treatment to repair your leaking mitral valve using an implanted clip.




SURGICAL MITRAL VALVE REPLACEMENT AND REPAIR

If your mitral valve cannot be repaired, your doctor may recommend valve 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.


WHAT ARE THE SYMPTOMS?¹




FATIGUE




HEART PALPITATIONS




DRY, HACKING COUGH



SHORTNESS OF BREATH



FAINTING



SWOLLEN ANKLES OR FEET



To learn more about your mitral valve and mitral regurgitation visit: structuralheart.abbott/patients/mitral-regurgitation-treatment

1. Mayo Clinic. Mitral Valve Regurgitation. Accessed March 15, 2023.

WHAT IS MITRACLIP™ THERAPY?

MitraClip therapy is a simple procedure to fix your mitral valve. During the procedure, doctors access the mitral valve with a thin tube (called a catheter) that is guided through a vein in your leg to reach your heart.

A small implanted clip is attached to your mitral valve to help it close more completely. This helps to restore normal blood flow through your heart.



PROVEN CLINICAL OUTCOMES

MitraClip™ therapy is a safe, effective, and well-studied procedure.

Highlights include:



MINIMALLY INVASIVE

This procedure does not require opening the chest or temporarily stopping the heart.



QUICK PROCEDURE

The implantation procedure typically lasts 1 to 3 hours.¹



SHORT HOSPITAL STAY

Patients are out of the hospital within one day² (US median), significantly less time compared to surgery.



47%

Reduced risk of heart failure hospitalizations³

2.5X

More likely to experience a large improvement in health-related quality of life⁴



PROVEN SAFE AND EFFECTIVE



20+

Years of proven safety

200K+

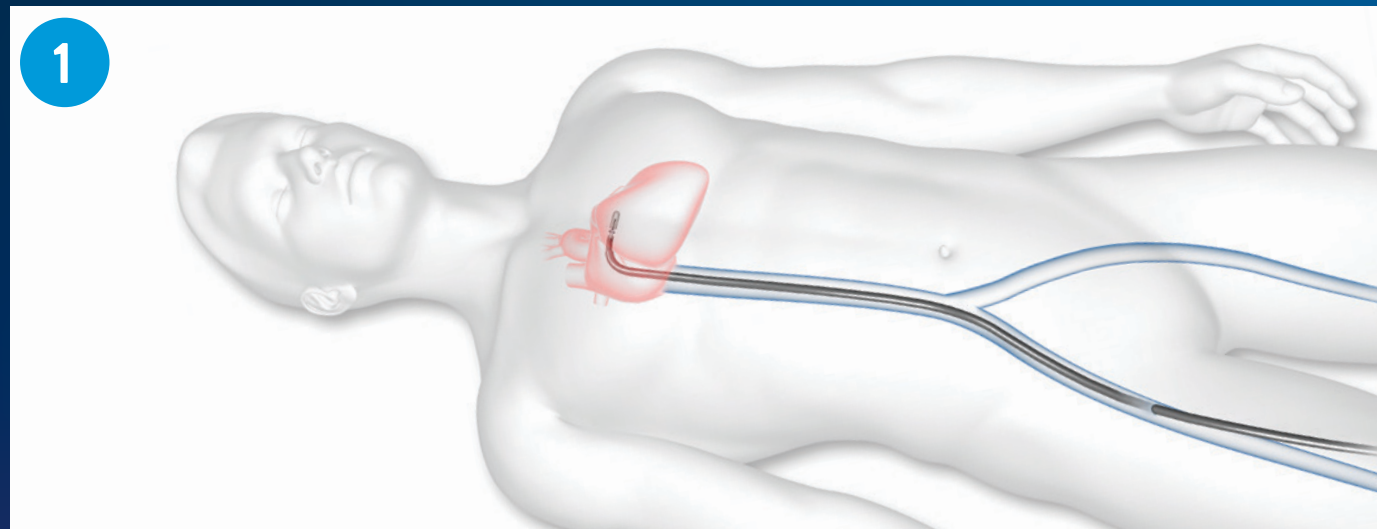
Patients treated worldwide⁵



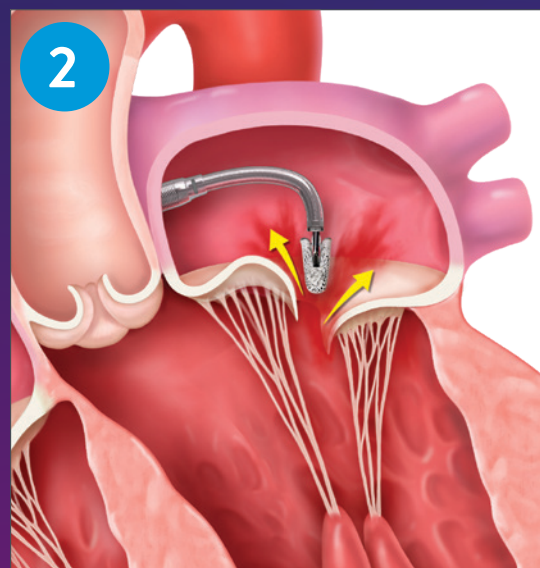
1. Bardeleben, et al. Contemporary Clinical and Echocardiographic Outcomes of 1000+ Patients Treated with MitraClip™ G4: Results from the EXPAND G4 Post Approval Study presented at TCT 2022. 2. Kar S, von Bardeleben R, Rottbauer W, et al. Contemporary Outcomes Following Transcatheter Edge-to-Edge Repair: 1-Year Results From the EXPAND Study. *J Am Coll Cardiol Interv*. 2023 Mar, 16 (5) 589–602. 3. Mack, M., et al. COAPT: Three-year outcomes from a randomized trial of transcatheter mitral valve leaflet approximation in patients with heart failure and secondary mitral regurgitation. Presented at TCT 2019. 4. Arnold, SV., et al. Health status after transcatheter mitral valve repair in heart failure and secondary mitral regurgitation. *JACC* Mar 2019, 25951; DOI: 10.1016/j.jacc.2019.02.010. 5. Data on file at Abbott.

WHAT WILL HAPPEN DURING THE PROCEDURE?

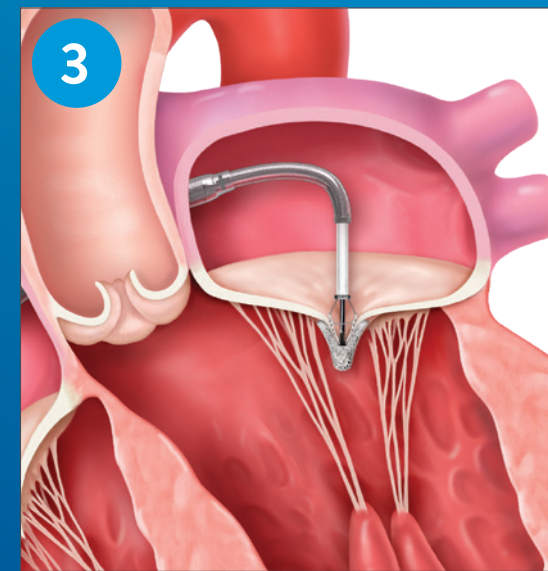
The following steps provide a general overview of the MitraClip™ procedure—your experience may be different. Your doctor will explain the procedure to you and can provide you with specific details and answer any questions you may have.



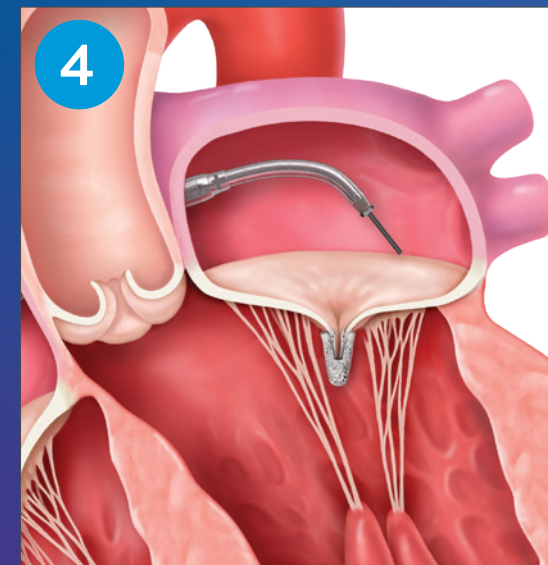
Your doctor will introduce the system through a vein in the groin area and it will be advanced to reach the heart.



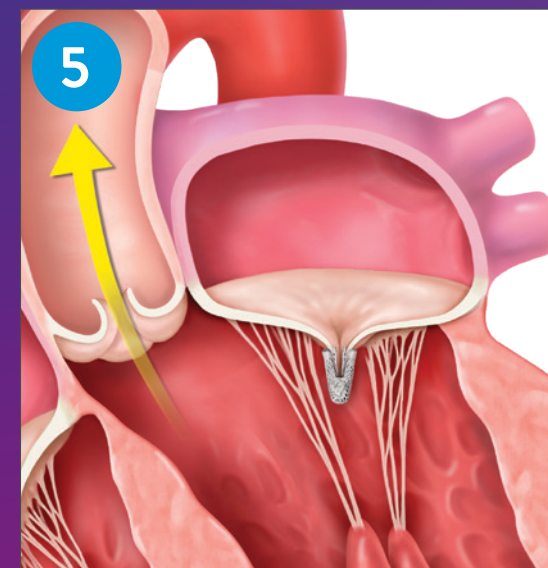
The MitraClip implant will be guided from the right atrium to the left atrium and then ultimately to your mitral valve through the catheter.



Your doctor will implant MitraClip at the appropriate position on your mitral valve. The MitraClip implant will grasp the mitral valve leaflets to close the center of the mitral valve and reduce mitral regurgitation.



Once the implant is in place and working properly, the Clip Delivery System and the Steerable Guide Catheter will then be removed from your body.



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.

PREPARING FOR YOUR MITRACLIP™ PROCEDURE



PRE-PROCEDURE TESTS

Your doctor may order some of the tests below.

<div><input checked="" type="checkbox"/></div> Ordered	TEST	PURPOSE/EXPLANATION	<div><input checked="" type="checkbox"/></div> Completed
<input type="radio"/>	Transthoracic Echocardiogram (TTE)	An ultrasound of your heart which shows how your heart and valves are functioning	<input type="radio"/>
<input type="radio"/>	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 esophagus for closer images of your mitral valve	<input type="radio"/>
<input type="radio"/>	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="radio"/>
<input type="radio"/>	Electrocardiogram (EKG)	Evaluates the electrical rhythm of your heart	<input type="radio"/>
<input type="radio"/>	6-Minute Walk Test	Timed walk test done during the office visit to assess balance, mobility, activity tolerance, frailty and surgical risk	<input type="radio"/>
<input type="radio"/>	Kansas City Cardiomyopathy Questionnaire (KCCQ)	A questionnaire to measure your quality of life	<input type="radio"/>
<input type="radio"/>	Laboratory Tests	Baseline blood work prior to procedure	<input type="radio"/>
<input type="radio"/>	Chest X-Ray	Non-invasive imaging to review any lung abnormalities	<input type="radio"/>
<input type="radio"/>	Other		<input type="radio"/>

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?

PREPARING FOR YOUR PROCEDURE DAY

In the days before your procedure, it is important that you:

- 1

Make sure all of your lab work is complete
- 2

Gather any images you need to bring with you
- 3

Ensure you have prepared your legal documents and your caregiver knows where they are located
- 4

Make sure you have made all arrangements for after you are discharged from the hospital
- 5

Take all your prescribed medications as directed by your doctor in the days before your procedure
- 6

Tell your doctor if you are taking any other medications
- 7

Make sure your doctor knows of any allergies you have
- 8

Follow all instructions given to you by your doctor or nurse

WHAT WILL HAPPEN ON THE DAY OF YOUR PROCEDURE?

Most patients will check in for their procedure on the morning it is scheduled. Occasionally, a patient may be checked in the evening before.

Once you are checked in, you will be prepped and taken in for the procedure. Your caregiver will be directed to a waiting room.

After the procedure is complete, someone from your care team will let your caregiver know how the procedure went and how you are doing. Depending on your hospital’s policy, your caregiver may be able to visit you in recovery, or they may be directed to meet you in your inpatient room.

Once your heart team is comfortable with your recovery, you will be moved into your patient room. Your caregiver will be able to bring the belongings you packed into the room for you.

PACKING FOR YOUR HOSPITAL STAY

Check with your hospital ahead of time.

Below is a handy list to help you pack for your hospital stay:

<input type="radio"/>	Toiletries (toothbrush/toothpaste, comb or brush, shampoo, etc.)
<input type="radio"/>	Slippers (with nonslip soles)
<input type="radio"/>	Glasses
<input type="radio"/>	Denture case
<input type="radio"/>	Hearing aids
<input type="radio"/>	List of your current medications
<input type="radio"/>	Contact information for key family members and friends
<input type="radio"/>	Entertainment items (books, phone/charger, tablet/charger)
<input type="radio"/>	Pajamas
<input type="radio"/>	Comfortable clothes to go home in

It is recommended that you do not bring cash or valuables to the hospital.

LIFE AFTER THE PROCEDURE:

A TIMELINE FOR RECOVERY

YOUR HOSPITAL STAY



As you recover in the hospital, your team will work with you on discharge planning. They will evaluate your medications and make any recommended changes. They may also perform follow-up tests to evaluate your recovery.

THE FIRST FEW WEEKS



Don't stress yourself. That means no strenuous exercise and no lifting heavy objects (nothing heavier than a gallon of milk). Have someone drive you to appointments. Walk only short distances on level ground.

30-DAY CHECK-UP



You will need to see your doctor 30 days after your procedure. There you will have repeat imaging to see how your valve is working with the MitraClip™ device in place.

HEART HEALTHY LIFESTYLE



As you recover from your procedure, it is important you focus on creating a healthy lifestyle that will support the activities you wish to pursue. That includes focusing on diet, exercise, and maintaining a healthy mindset.

YOUR ONE-YEAR EXAM



Similar to your 30-day exam, you will be asked to return at one year to have your heart valve checked. Repeat imaging will be conducted to see how your heart valve is working.

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 depending on the severity of your symptoms, 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 Before any medical or dental procedure;** you may need to be prescribed antibiotics to avoid potential infection
- 6 The access site is bleeding, becomes swollen, red, painful or has yellow or green discharge**

DEVELOPING A HEART HEALTHY DIET

After your procedure, it is a good idea to develop a heart-healthy diet. Below are some tips on healthy eating from the American Heart Association (AHA):



DEVELOP A BALANCED APPROACH TO YOUR DIET:

Tailor healthy eating to meet your personal and cultural food preferences



PLAN YOUR GROCERY TRIPS WITH HEALTH IN MIND:

Developing and sticking to a list makes it easier to avoid mindlessly grabbing tempting foods from the shelves



INCORPORATE MORE OF THE FOLLOWING INTO YOUR DIET:

Fresh fruits and vegetables, whole grains, healthy protein sources, and lower sodium food options



WORK TO MINIMIZE YOUR CONSUMPTION OF:

Processed foods, added sugars and salt, and alcohol



FOR MORE RESOURCES, VISIT THE AHA'S HEALTHY EATING WEBSITE:

<https://www.heart.org/en/healthy-living/healthy-eating>

SCAN ME



EXERCISE, DIET, AND PHYSICAL ACTIVITY

DURING YOUR RECOVERY

Getting and staying active can help you take care of your heart health. Your doctor will let you know when you can return to normal activities. Be sure to check with your doctor to see when you can start exercising as well. Until then, use this time to make a plan for after your recovery period.

BEGIN THESE AFTER YOU HAVE BEEN CLEARED TO START PHYSICAL ACTIVITIES



SIT-TO-STAND
Rising from a chair uses some of the largest and most important muscles in your body. Using a firm chair, try doing 12 sit-to-stands without using your hands.
Work up to doing 12 sit-to-stands 2 to 3 times a day.



WALKING
Try to walk for 5 minutes every day. Then, slowly increase how far and how fast you walk over time.
Take someone with you the first few times you walk, and wear comfortable clothes and shoes.



LONG-TERM ACTIVITY GOALS

Developing a long-term strategy to stay physically active is a great way to help keep your heart healthy. Below are things that can help you build that plan:

FIND THINGS YOU ENJOY DOING

Being physically active doesn't have to mean driving to and from a gym. Gardening, walking, golfing or bowling with friends—these are all physical activities, too!

MAKE A PLAN

We stand a better chance of doing most things in life when we make a plan and stick to it. Put your activities on your calendar. It's important to make time to take care of yourself.

PARTNER UP

If you are exercising, look for an accountability partner. Join a walking club or other league. Including friends and family in your plan helps you stick to it, and is also more enjoyable.

DEVELOPING A HEALTHY MINDSET

Developing a healthy mindset can do wonders for your physical health. It is also very normal for patients to experience stress and anxiety following a health event. Below are actions you can take to focus on your mental health.



DEVELOP POSITIVE GOALS AS YOU RECOVER

What do you want to do? Be sure to celebrate the positive steps you are taking in your recovery.



CONNECT WITH FELLOW PATIENTS WHO ARE NAVIGATING HEART CONDITIONS

Your hospital may have local recommendations, or you could join national organizations like Mended Hearts[†] that are building a community of support for patients like you.



INFORM YOUR CARE TEAM IF YOU ARE EXPERIENCING ANY SADNESS, DEPRESSION, OR ANXIETY FOLLOWING YOUR PROCEDURE

It's very normal to experience these types of feelings after a cardiac health event. They may recommend talking to a mental health professional or joining a support group at your hospital.



CONSIDER DEVELOPING A MINDFULNESS PRACTICE

Meditation, tai chi, yoga, and even breathing exercises have been shown to decrease stress and promote a positive mindset.



SCAN ME

FOR MORE RESOURCES AND SUPPORT, VISIT THE MENDED HEARTS[†] PROGRAM WEBSITE:

<https://mendedhearts.org/about-us/>



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—earlier in this patient guide you will find 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.

FREQUENTLY ASKED QUESTIONS

HOW DOES MY DOCTOR DETERMINE IF I HAVE MITRAL REGURGITATION?

To determine if you have mitral regurgitation and to assess the function and condition of your heart and mitral valve, your cardiologist may perform diagnostic evaluations including:

- Taking a chest x-ray to see the size and shape of your heart and evaluate your lungs
- Evaluating you for symptoms of congestive heart failure (such as shortness of breath or fatigue) or other related heart conditions

HOW WILL MY DOCTORS DECIDE IF I AM A CANDIDATE FOR THE MITRACLIP™ PROCEDURE?

You will be evaluated by a specially trained heart team at a MitraClip treating center, including a cardiac surgeon and a cardiologist, who will review your medical history and perform a variety of tests. There are several factors they will take into consideration when deciding whether or not you are too sick for heart surgery, and therefore a possible candidate for MitraClip therapy, such as your age, frailty, and the condition of your heart.

WHAT IS THE MITRACLIP DEVICE MADE OF?

The MitraClip device is a small metal clip covered with a polyester fabric that is implanted on your mitral valve. The clip is inserted through a catheter, without the need to temporarily stop your heart. There can be up to 4 different clip sizes used to tailor your clip size to your valve.

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

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

WILL I BE ABLE TO FEEL THE MITRACLIP IMPLANT IN MY HEART?

No, you will not be able to feel the implant.

WILL I BE PRESCRIBED ANY MEDICATIONS FOLLOWING THE MITRACLIP™ PROCEDURE?

Your doctor or nurse will give you instructions about your medications before you leave the hospital.

WHO SHOULD NOT HAVE THE MITRACLIP PROCEDURE?

Your doctor may decide that the MitraClip procedure is not appropriate for you if you:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming
- Have an active infection or inflammation of the mitral valve
- Have mitral valve disease as a result of rheumatic fever
- Have a blood clot in your heart or in the vessels that carry blood from the lower body to the heart
- Your doctor should discuss with you if you have any of these issues that would prevent you from having the MitraClip procedure. An evaluation of your heart will also confirm if your heart valve anatomy would allow for successful placement of the device.

NOTES

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[illegible]

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IMPORTANT SAFETY INFORMATION

MitraClip™ Transcatheter Mitral Valve Repair

What is MitraClip™ Therapy approved for?

Available by prescription only.

MitraClip Therapy is a minimally invasive procedure approved for treating patients with clinically significant mitral regurgitation due to either (a) a deteriorated mitral valve in patients who are deemed to be at prohibitive risk for surgery, or (b) mitral valve in patients who have heart failure and an enlarged heart who remain symptomatic on maximally tolerated medications to treat their heart failure.

Patients should work with their doctor and a multidisciplinary heart team, which should include a heart surgeon and cardiologist with experience treating heart failure, to confirm their surgical risk or optimal medications. The heart team will determine if the patient meets the indications for the MitraClip Procedure.

Who should not have the MitraClip Procedure?

Patients that have any of the following conditions should not have the MitraClip Procedure: inability to tolerate or are allergic or hypersensitive to anti-coagulants, anti-platelet therapies, nickel, titanium, cobalt, chromium, polyester, or contrast dye; have inflammation or rheumatic disease of the valve; have blood clots inside the heart or blood vessels (inferior vena cava, femoral vein) , or have mitral valve anatomy which is deemed not suitable for repair with MitraClip.

What can happen to me during the MitraClip Procedure?

As with most medical procedures, MitraClip Implant placement has risks, including inappropriate device placement, device movement from its implanted site, and failed or difficult delivery or retrieval of the device once implanted. Your physician will determine if you fall within the labeled indication for the MitraClip Procedure.

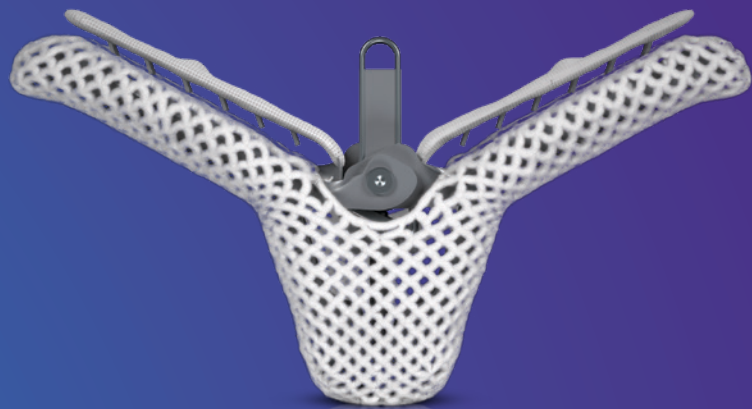
Who is more at risk during the MitraClip Procedure?

Even though MitraClip Therapy is a minimally invasive medical procedure, it carries risks, and some patients may be at a higher risk than others. If you have either a weak heart that may need support during the procedure or a rotated heart from prior heart surgery, talk to your doctor to weigh the additional risks to the benefits of the MitraClip Procedure as the safety and effectiveness has not been tested in these patients.

What are the possible complications associated with the MitraClip Procedure?

The MitraClip Procedure carries risks which include, but are not limited to: Allergic reactions to the implant materials or medications used during or after the procedure; Tissue damage at the puncture (entry) site such as wound reopening, reaction to the catheter, bleeding, air bubbles, tissue or nerve injury; Inflammation, buildup of fluid or blood in the sac surrounding the heart, and complications that may require more interventions or heart surgery; Mitral valve complications including device dislodgement, entanglement with chords, narrowing of the mitral valve, continuing backflow of blood through the mitral valve during heart contraction, and inflammation; Abnormal heart rhythm, stroke (resulting from blood clot or burst vessel in the brain) or transient stroke, high or low blood pressure; Multiple organ failure, death, pain; Complications related to the echocardiographic imaging such as irritation or perforation of the throat.

Talk to your doctor to learn more about the risks associated with MitraClip Therapy, and ask for the detailed Important Safety Information if you'd like to review the full list of complications.



MitraClip™
Transcatheter Edge-to-Edge Repair