

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.

1. Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC focused update of the 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017;136(9):1-123. DOI: 10.1161/CIR.0000000000000503. 2. Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease: The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2017;00:1-53. 3. Ponikowski P, Voors AA, Anker SD, et al. 2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure of the European Society of Cardiology (ESC). Developed with the special contribution of the Heart Failure Association (HFA) of the ESC. *Eur J Heart Fail*. 2016;18(8):891-975. 4. Mayo Clinic. Mitral valve regurgitation. <https://www.mayoclinic.org/diseases-conditions/mitral-valve-regurgitation/symptoms-causes/syc-20350178>. Accessed 22 October, 2018. 5. Benjamin EJ, Blaha MJ, Chiuve SE et al. Heart disease and stroke statistics—2017 update: A report from the American Heart Association. *Circulation*. 2017 Mar 7;135(10):e146-e603. doi: 10.1161/CIR.0000000000000485. Epub 2017 Jan 25. 6. Cioffi G, et al. *Eur J Heart Fail*. 2005;7(7):1112-1117. 7. Stone GW, et al. *N Engl J Med*. 2018;379(24):2307-2318. 8. Samad Z, et al. *Eur Heart J*. 2015;36(40):2733-2741. 9. Abbott data on file as of Nov 2019. 10. Mack M. 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. 11. Sorajja P, Vemulapali S, Feldman T, et al. Outcomes with transcatheter mitral valve repair in the United States: An STS/ACC TVT registry report. *J Am Coll Cardiol*. 2017;70(19):2315-2327. 12. Stone GW, Lindenfeld JA, Abraham WT et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med*. 2018; DOI: 10.1056/NEJMoa1806640. 13. 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.

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A guide for people with Mitral Regurgitation.

MitraClip™
Transcatheter Mitral Valve Repair





Dear Patient,

Our mission at Abbott Structural Heart is to restore people’s health and improve their quality of life. As a company, we are delighted that you have taken the first steps along the journey for the treatment of your Mitral Regurgitation with our minimally invasive, MitraClip™ Transcatheter Mitral Valve Repair System. This is a proven therapy that holds true to our core mission and which can improve the quality of your life.

Please take your time to review the information found in this guide with your loved ones and friends. Please reach out to the health care professionals in your local Heart Team with any additional questions.

We wish you all the best and good health!



Dr. Neil Moat
Chief Medical Officer, Abbott Structural Heart

Name:

Your MitraClip™ procedure is scheduled:

For (date/time):

At (location):

Please arrive at (time):



CONTENTS

PRE-PROCEDURAL GUIDE

Understanding the disease	1
Benefits of MitraClip™ therapy.....	3
What will happen during the procedure?	5
Preparing for the procedure.....	7
Real patient testimonials	9

POST-PROCEDURAL GUIDE

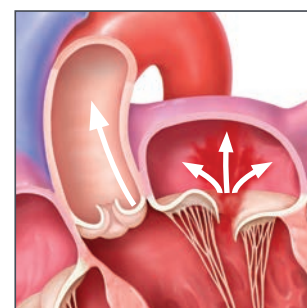
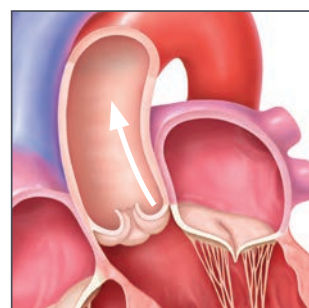
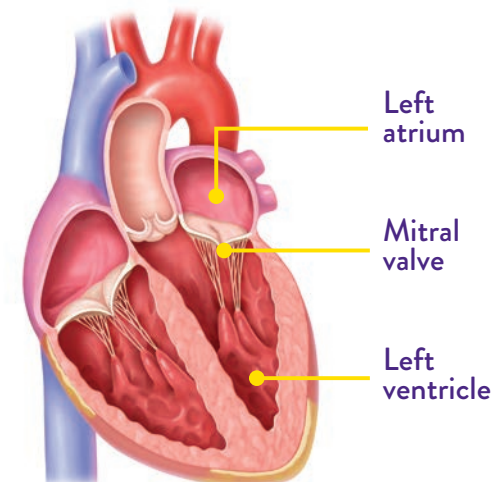
Recovering after your procedure	14
A timeline for recovery	15
Exercise, diet & state of mind	17
Helpful websites.....	19

UNDERSTANDING THE DISEASE

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.



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



Shortness of breath



Fatigue



Dry, hacking cough



Excessive urination



Fainting



Swollen feet or ankles



Inability to exercise

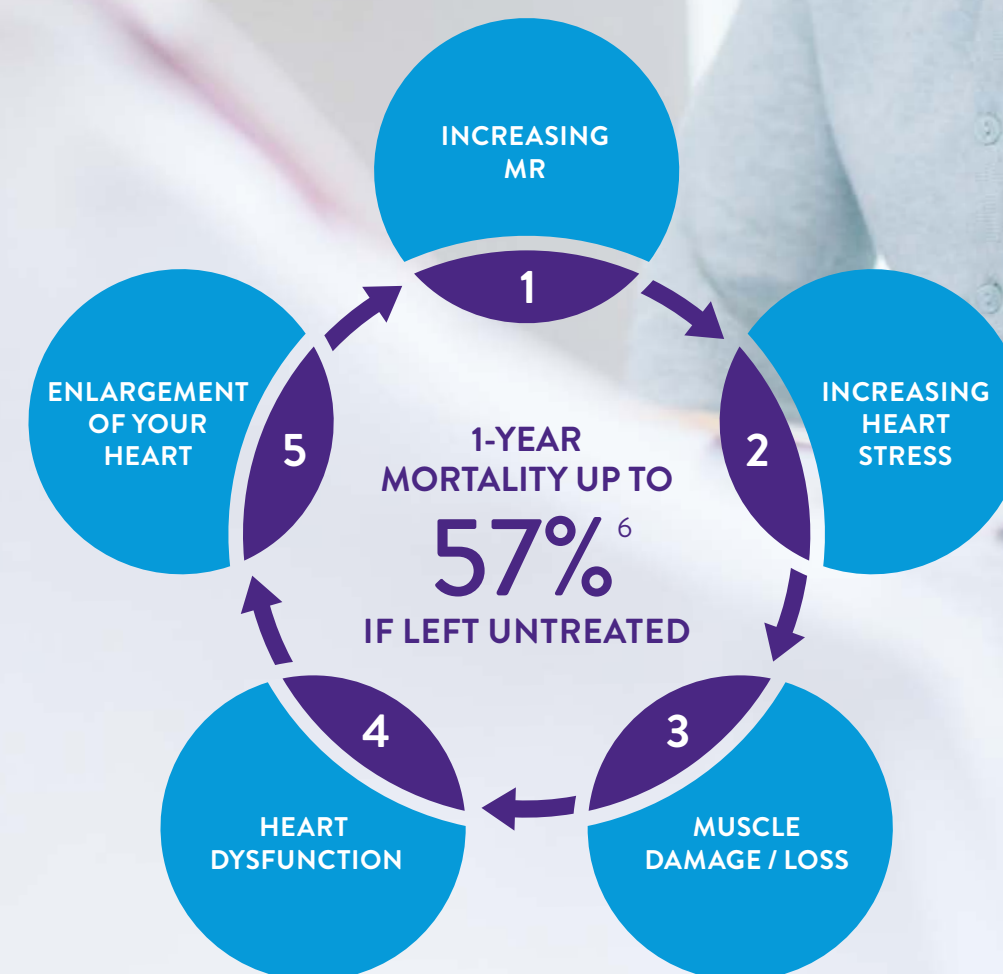


Decrease in appetite

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?

If left untreated, up to 57% of MR patients may experience mortality at 1 year due to a cascade of adverse events listed below.⁶⁻⁸



For many people with MR, optimized prescription drugs may not be enough.



In many cases, surgery is also not a viable option for people with MR.



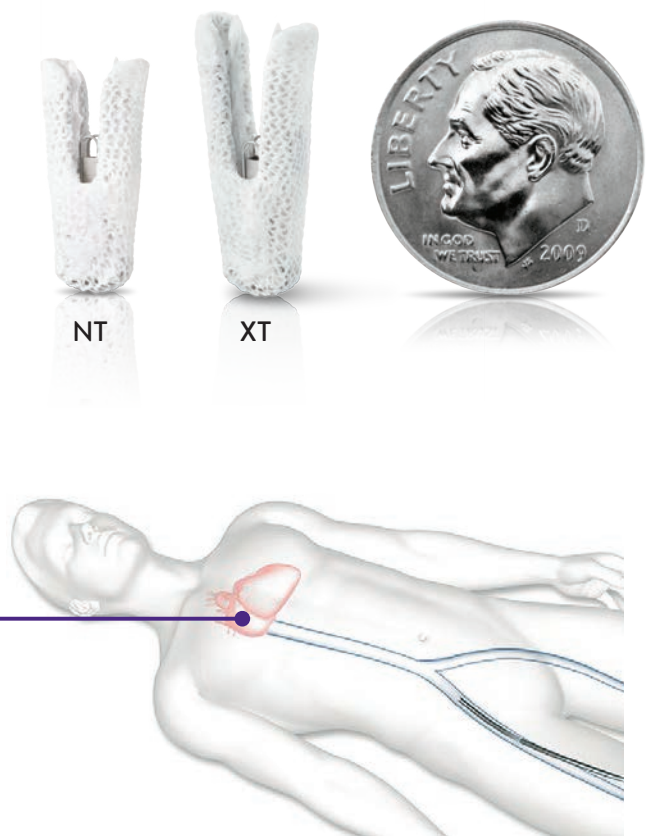
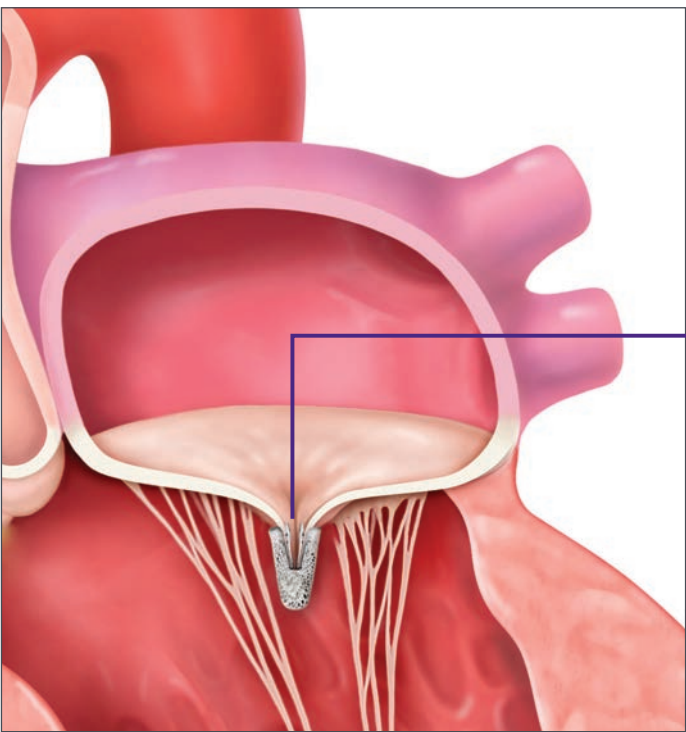
SCAN ME

To watch a short video about your Mitral Valve and Mitral Regurgitation visit: mitraclip.com/what-is-mitral-regurgitation

BENEFITS OF MITRACLIP™ THERAPY

MINIMALLY INVASIVE, CATHETER BASED PROCEDURE

Transcatheter mitral valve repair is a U.S. 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.



PROVEN CLINICAL OUTCOMES



SPEAK WITH YOUR DOCTOR ABOUT THE RESULTS FROM A LANDMARK TRIAL CALLED COAPT™^{10,13}

In a clinical trial called COAPT™, published in the New England Journal of Medicine, heart failure patients with secondary MR who were treated with MitraClip™ Therapy and optimized prescription medication experienced:

- Dramatic improvement in survival
- Fewer hospitalizations for heart failure
- Improved quality of life

When compared to patients who were treated with optimized prescription medication alone.



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.*



SHORT HOSPITAL STAY

Patients are usually released from the hospital within 1 to 3 days*, significantly less time compared to surgery.



51%

REDUCED RISK OF HEART FAILURE HOSPITALIZATIONS¹⁰

2.5X

MORE LIKELY TO EXPERIENCE A LARGE IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE¹³



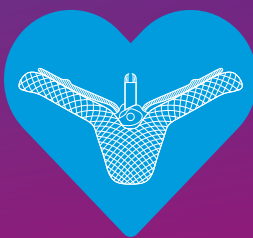
PROVEN SAFE AND EFFECTIVE

16+

YEARS OF USE

100K+

PATIENTS TREATED WORLDWIDE**

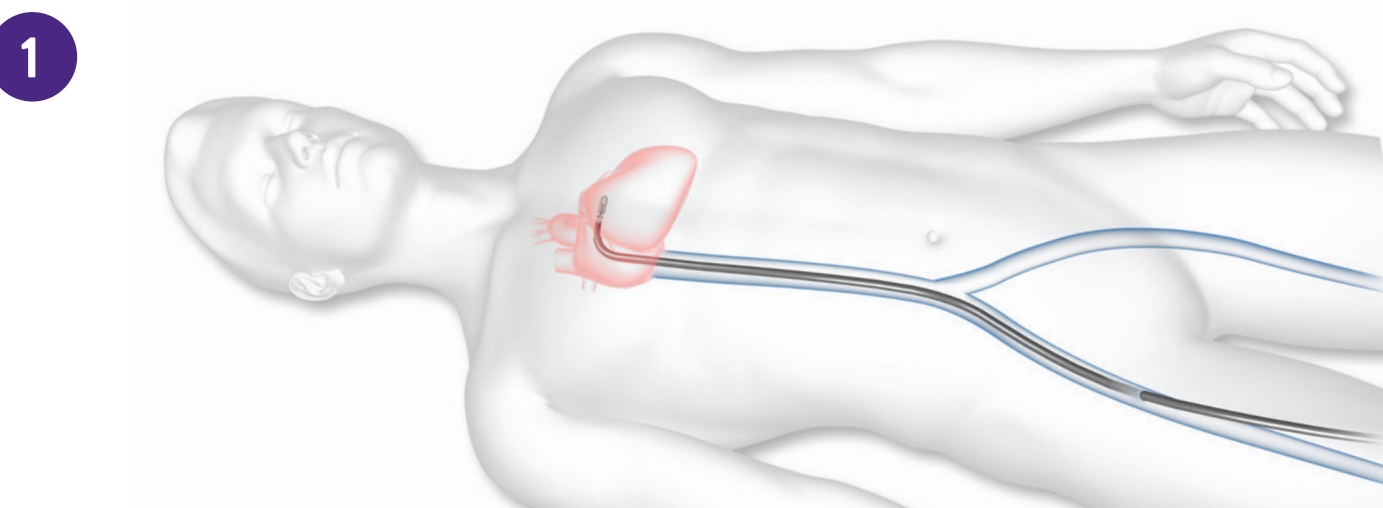


* Lim DS et al. Contemporary Outcomes with MitraClip (NTRXTR) System In Primary Mitral Regurgitation Results From The Global EXPAND, ACC 2020.

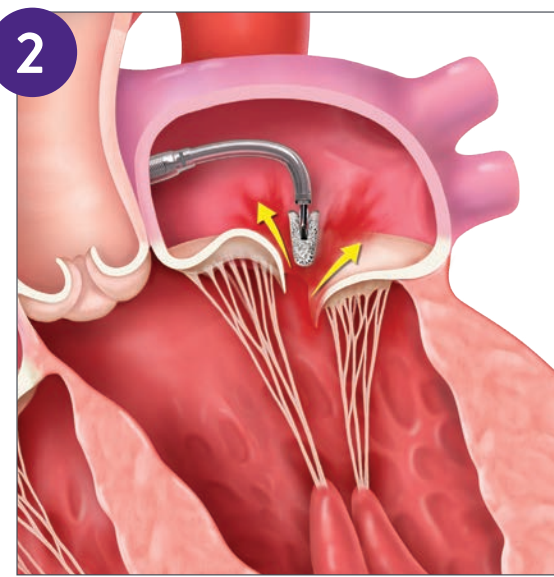
** Data on File at Abbott.

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.

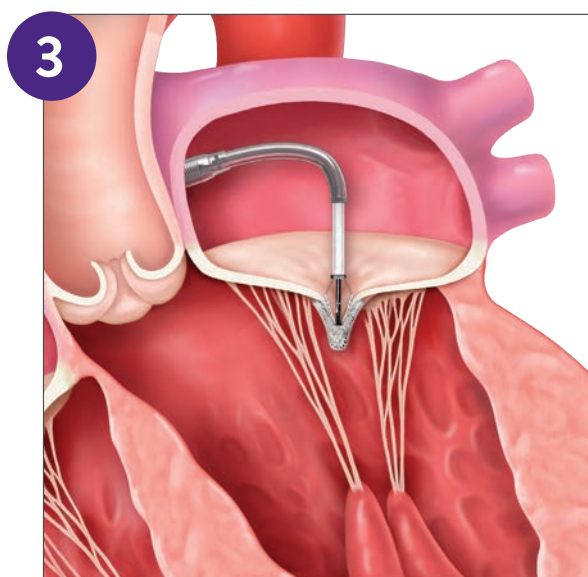


The MitraClip™ implant will be guided from the right atrium to the left atrium and then ultimately to your mitral valve through the catheter.

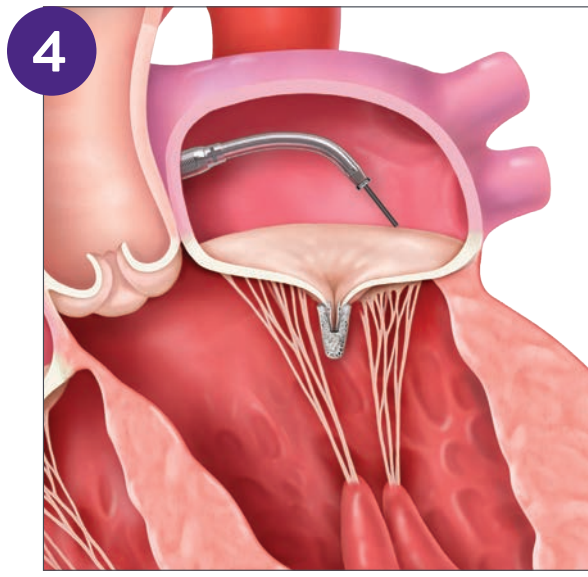


To watch a short video animation of the MitraClip™ procedure, visit <https://mitraclip.com/mitraclip-procedure/>

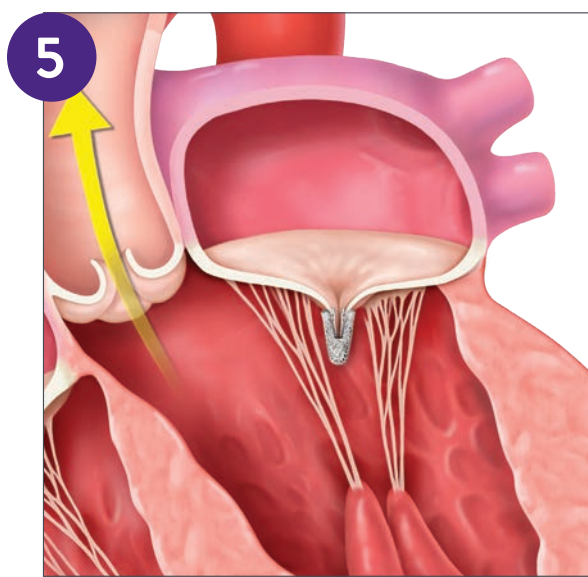
SCAN ME



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



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



The implanted Clip 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 PROCEDURE

BEFORE THE PROCEDURE

- 

Take all your medications as instructed by your healthcare provider.
- 

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

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

Follow all instructions given to you by your doctor or nurse.

DURING THE PROCEDURE

- 

The procedure will likely be performed in a specialized room called a “cath lab.”
- 

You will be placed under general anesthesia to put you in a deep sleep.
- 

Your doctor will use x-ray and echocardiography to visualize your heart.
- 

On average, the procedure will take between 1 to 3 hours.*

AFTER THE PROCEDURE

- 

Your hospital stay after the procedure will likely range from 1 to 3 days.*
- 

Your physician might prescribe cardiac rehab to improve your recovery time.
- 

Your medications may change slightly after your procedure. Follow the instructions of your healthcare provider.
- 

You will be discharged to the care of your cardiologist or family doctor.

* Lim DS et al. Contemporary Outcomes with MitraClip (NTRXTR) System In Primary Mitral Regurgitation Results From The Global EXPAND, ACC 2020.

REAL PATIENT TESTIMONIALS

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.”
- Octalina Mendoza, The First MitraClip™ Patient



SCAN ME

Watch the video:
<https://abbo.tt/MitraClipOctalina>



“ I’m doing anything and everything I want; I’m back to living again.”
- Betty Vaughn, MitraClip™ Patient



SCAN ME

Watch the video:
<https://abbo.tt/MitraClipBetty>



“ It’s been years since I’ve felt like this.”
- Bill Sterling, MitraClip™ Patient



SCAN ME

Watch the video:
<https://abbo.tt/MitraClipBill>



A guide for living life to the fullest after your procedure.

These testimonials relate accounts of an individual’s response to the treatment. These patient’s accounts are genuine, typical and documented. However, they do 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 patient.



ON THE ROAD TO RECOVERY

Now that your procedure is over, it's time to move on to your recovery. As you recover, it may be helpful to use the materials in this kit, including:

- **IMPLANT ID CARD HOLDER** to protect your MitraClip™ identification card
- **MEDICATION TRACKER** to keep track of your medical information
- **NUTRITION GUIDE** to help you plan heart-healthy grocery shopping

MITRACLIP™ THERAPY

During your procedure, your doctor implanted the MitraClip™ device at the appropriate position on your mitral valve. The implanted clip will become a permanent part of your heart, allowing your mitral valve to close more tightly and reduce the backward flow of blood.

WORK WITH YOUR HEALTH TEAM

Your team of healthcare professionals is there to help you. Work closely and communicate clearly with them. If you have questions or concerns, let them know—and listen to their professional guidance.

TAKE TIME TO RECOVER

Be patient, rest, and take it easy. Over the next few days, avoid physically straining yourself in any way. Remember that rushing your recovery can set you back and might even put you at serious risk.

When your doctor says you are ready to exercise again, develop a fitness plan together to keep your heart healthy.

VISIT THE WEBSITE

Visit www.mitraclip.com to learn more about the MitraClip™ device you received. This site also has useful information about mitral regurgitation and healthy living, as well as resources that can help you stay on track. Also sign up to receive email updates.

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

Recovery from your procedure usually takes about a week. 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.

RECOVERING AFTER YOUR PROCEDURE

TAKE IT EASY—it's important not to strain yourself as you recover.

- 1 **Avoid lifting heavy objects and doing strenuous exercise** until your doctor says it's safe. You can walk a short distance on level ground, but nothing more challenging than that
- 2 **Do not go up and down the stairs** more than 2 times per day—at least for the first 2 to 3 days
- 3 **Avoid driving** until your doctor says it's safe
- 4 **Eat heart-healthy foods**, including fruits, vegetables, and low-fat options

TEND TO YOUR WOUND—take care of the area where the catheter was inserted.

Keep your wound dry for the first 24 hours

- If you take a shower, avoid getting water on the wound
- Do not take a bath or go swimming for at least 1 week

If bruising around the wound suddenly gets bigger or harder:

- Call your doctor immediately
- Lie down and apply pressure to the area just above the wound for 15 minutes (this should stop the bleeding) For safety, lie down for 2 or more hours

CALL FOR HELP IF—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 wound site is bleeding, becomes swollen, red, painful or has yellow or green discharge**

LIFE AFTER THE PROCEDURE:

A TIMELINE FOR RECOVERY

THE FIRST
24 HOURS:



From the time you arrive at home, keep activity to a minimum—no more than walking around your home. Make sure the area where the catheter was inserted is clean, dry and bandaged. Contact your physician if you notice extensive swelling, bleeding or discharge at the site.

WITHIN
2-3 DAYS:



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. Avoid going up and down stairs more than twice a day.

1 WEEK
LATER:



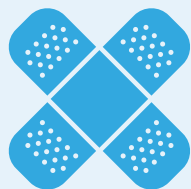
Check with your doctor if you're concerned about the physical requirements of your job. You may experience minor chest pain—this is normal.

7-10 DAYS
LATER:



Keep your workouts light. Slowly increase the intensity over the next few weeks. It is critical you keep your follow-up doctor appointments. Ask for a cardiac rehab referral at your follow-up appointment to help with cardiac remodeling.

EXERCISE, DIET & STATE OF MIND



PHYSICAL RECOVERY

As you recover, pay attention to any pain you are feeling. Continue to rest and help your body heal. Full recovery can take a few weeks.

CHEST DISCOMFORT

The tissue in your artery can get injured. This can lead to muscle spasms, which may cause some pain. If you experience discomfort, let your doctor know right away. Your doctor can determine if this pain is related to your procedure.

WOUND HEALING

The area where your catheter was inserted may be black and blue, sore, or tender for several days. You may also notice swelling or a small, hard lump at this site.

- If your wound is in the groin, do not strain yourself while going to the bathroom for the first 3 to 4 days after your procedure



EXERCISE & ACTIVITY

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.

YOU CAN INCLUDE THESE LIGHT EXERCISES IN YOUR PLAN:

Sit-To-Stand

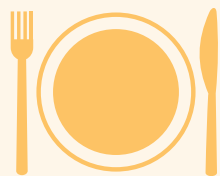
Rising from a chair uses some of the largest and most important muscles in your body. Using a firm chair, try doing 12 sit-to-stands without using your hands.

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.



HEART-HEALTHY DIET

After your procedure, it's a good idea to eat foods that promote your heart health. Start your heart-healthy diet by working some of these foods into your meals each day:

GREENS like spinach, arugula, broccoli, collard greens, and mustard greens have a protective effect on the heart

WALNUTS contain antioxidants and fatty acids that help lower cholesterol

FISH with high levels of omega-3 fatty acids—like salmon, mackerel, anchovies, and herring—may help arteries from narrowing

COCOA contains an antioxidant that may improve artery health

BERRIES are packed with antioxidants and fiber to help reduce your heart disease risks

RED WINE is thought to prevent plaque buildup in the arteries

OLIVE OIL has been proven to reduce heart disease risks, and can be used to replace other fats in your diet

LIMIT THESE FOOD ITEMS IN YOUR DIET:

- Fats
- Processed meats
- Refined carbohydrate
- Sugary drinks
- Sodium



STATE OF MIND

A positive attitude can do wonders for your recovery and your health. If you're feeling positive right now, that's great! If not, it's okay. Try these tips to find your balance again:

GET BACK INTO THE SWING OF THINGS

Continue doing the things you love. Just take it slowly, or do things a little differently while you heal. Your doctor will let you know when you can fully return to your normal activities.

START A HEALTHY ROUTINE

Look up healthy recipes, go for a walk, meditate—do anything that makes you feel good from the inside out. Always check with your doctor before beginning any new exercise or nutrition plan.

KEEP A JOURNAL

Writing is a great way to get in touch with your feelings. If your day did not go as planned, go back and read about a good day.

SET GOALS

Set positive goals for after you recover. In the meantime, celebrate your progress along the way. Take it a day at a time, and remember: you control your outlook.



QUESTION FOR THE DOCTOR:
How long will it be before I feel like myself again?



QUESTION FOR THE DOCTOR:
Can you suggest an exercise plan that is right for me?



QUESTION FOR THE DOCTOR:
Do I have a fluid restriction after my MitraClip™ procedure?



QUESTION FOR THE DOCTOR:
What do most people do to adjust after their procedure?

HELPFUL WEBSITES

Taking control of your mitral valve repair recovery means taking advantage of the many resources available to help you live a healthier life. Here are a variety of helpful websites that may provide additional information on potential symptoms of mitral regurgitation and treatment of mitral valve repair as well as support services.

ABBOTT RESOURCES



SCAN ME

www.mitraclip.com

- What is MR
- MR symptoms
- Treatment options
- MitraClip™ procedure
- FAQ
- MitraClip™ procedure video
- MitraClip™ device benefits





SCAN ME

www.structuralheartsolutions.com/us

- About Structural Heart
- Conditions
- Products & solutions
- Tools & resources
- Patient education videos
- MR patient quote/video testimonial



OTHER RESOURCES


Online support and resources

- Alliance for Aging Research** | www.agingresearch.org
- American Heart Association (AHA)** | www.heart.org/heartvalves
- CardioSmart** | www.CardioSmart.org/HeartValveDisease
- Women Heart** | www.womenheart.org
- Caregiver resource**
- Family Caregiver Alliance** | www.caregiver.org
- Community support**
- Mended Hearts** | www.mendedhearts.org
- Financial resource**
- The Centers for Medicare & Medicaid Services (CMS)** | www.cms.gov



YOUR MITRACLIP™ DEVICE IMPLANT CARD GOES INSIDE THIS WALLET PROTECTOR


Following your procedure, you will receive a MitraClip™ device implant card which your doctor will fill out and which you must carry with you at all times. Place your MitraClip™ device implant card inside this wallet card protector. Carrying this wallet card protector with your MitraClip™ device implant card will let others know in an emergency situation that you take antiplatelet (anti-clotting) medications.



DEVICE IMPLANT CARD

KEEP YOUR ID CARD HANDY.

Place your MitraClip™ device implant card inside this wallet card protector. Show your identification card if you report to an emergency room. This card identifies you as a patient who has had a MitraClip™ device implanted and will let others know in an emergency situation that you take antiplatelet (anti-clotting) medications.



IMPORTANT: Show your MitraClip™ device implant card if you report to an emergency room. This card identifies you as a patient who has had a MitraClip™ device implanted. If you require a magnetic resonance imaging (MRI) scan, tell your doctor or MRI technician that you have had a MitraClip™ device implanted. Test results indicate that patients with the MitraClip™ device can safely undergo MRI scans under certain conditions described on the card.

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

[illegible]

WARNINGS

- **DO NOT use MitraClip™ outside of the labeled indication.**
- The MitraClip™ G4 Implant should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Use universal precautions for biohazards and sharps while handling the MitraClip™ G4 System to avoid user injury. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury, including:
 - MitraClip™ G4 Implant erosion, migration or malposition
 - Failure to deliver MitraClip™ G4 Implant to the intended site
 - Difficulty or failure to retrieve MitraClip™ G4 system components
- 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.
- Patients with a rotated heart due to prior cardiac surgery in whom the System is used may have a potential risk of experiencing adverse events such as atrial perforation, cardiac tamponade, tissue damage, and embolism which may be avoided with preoperative evaluation and proper device usage.
- For the Steerable Guide Catheter and Delivery Catheter only:
 - The Guide Catheter: the distal 65 cm of the Steerable Guide Catheter with the exception of the distal soft tip, is coated with a hydrophilic coating.
 - The Delivery Catheter: coated with a hydrophilic coating for a length of approximately 131 cm.
 - Failure to prepare the device as stated in these instructions and failure to handle the device with care could lead to additional intervention or serious adverse event.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and / or re-use may result in infections, malfunction of the device and other serious injury or death.
- 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.

PRECAUTIONS

- 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
 - ▶ $\geq 8\%$ for patients deemed likely to undergo mitral valve replacement or
 - ▶ $\geq 6\%$ 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 primary patients with an LVEF $< 20\%$ or an LVESD > 60 mm. MitraClip™ should be used only when criteria for clip suitability for primary 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.

- This patient has been implanted with a metal implant attached to the leaflets of the mitral valve.
- Patients scheduled to undergo procedures which are likely to result in bacteremia should be treated with prophylactic antibiotics. Such procedures include dental work, sigmoidoscopy, proctoscopy, cystoscopy, etc.
- Non-clinical testing has demonstrated that the MitraClip™ Implants are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:
 - Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3.0 T)
 - Maximum field gradient of 4,000 Gauss/cm (40T/m)
 - Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).
- Under the scan conditions defined above, MitraClip™ Implants are expected to produce a maximum temperature rise of less than or equal to 3.1°C after 15 minutes of continuous scanning.
- In non-clinical testing, the image artifact caused by a pair of MitraClip™ Implants extends approximately 40 mm beyond the MitraClip™ Implants when imaged with a spin echo or gradient echo pulse sequence in a 3 T magnetic resonance imaging system. The presence of additional implants in a patient’s valve may increase the image artifact size when imaged in an MRI system.

