



WHAT YOU NEED TO KNOW
ABOUT MITRACLIP™ THERAPY

Preparing for Your Transcatheter Mitral Valve Repair Procedure





ABOUT THE PROCEDURE TRANSCATHETER MITRAL VALVE REPAIR

This pamphlet is for patients like you who have been evaluated by a team of heart doctors and selected for transcatheter mitral valve repair (or “TMVr”) with MitraClip™ therapy. MitraClip™ therapy is an approved treatment to repair your leaking mitral valve using an implanted Clip. Your team of heart doctors has determined that you would benefit from having this procedure.

HOW SHOULD YOU PREPARE FOR YOUR PROCEDURE?

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

- Take all your prescribed medications
- 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

WHAT WILL HAPPEN DURING YOUR PROCEDURE?

Your procedure will most likely be performed in a specialized room at the hospital called a “cath lab.” During the procedure, you will be placed under general anesthesia to put you in a deep sleep, and a ventilator will be used to help you breathe. Your doctor will use fluoroscopy (a type of X-ray that delivers radiation to you) and echocardiography (a type of ultrasound) during the procedure to visualize your heart. On average, the time required to perform the TMVr procedure is between 3 to 4 hours. However, the length of the procedure can vary due to differences in anatomy.

MITRACLIP™ IMPLANT

MitraClip™ is available in 2 different sizes to help personalize your care for optimal results. The Clip is small, made of metal, and covered with a polyester fabric to **PROMOTE HEALING.**¹

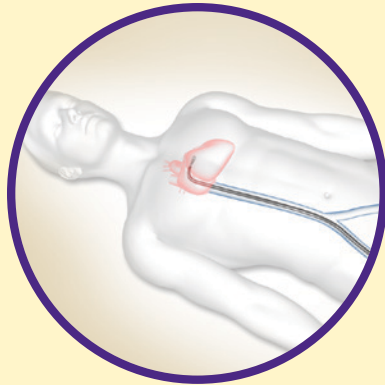


MitraClip™ NTR/XTR

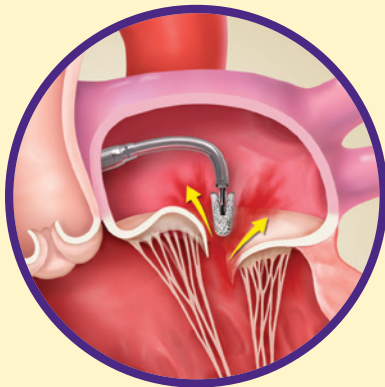
WHAT WILL HAPPEN DURING YOUR PROCEDURE (CONTINUED)

The following steps provide a general overview of the TMVr procedure with the MitraClip™ system—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.

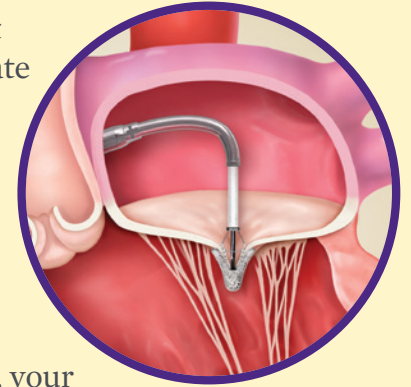
- 1** Your doctor will make a small incision in your upper leg, where a Steerable Guide Catheter (a hollow, flexible tube slightly larger than the diameter of a pencil) will be inserted through a vein to reach your heart.



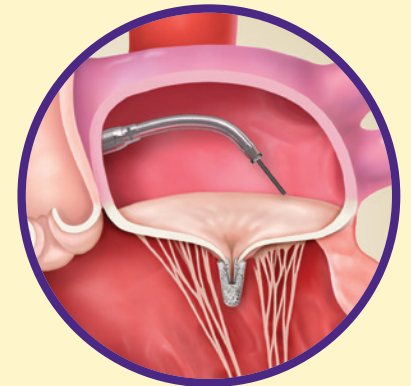
- 2** The MitraClip™ Implant, which is attached to the end of a Clip Delivery System, will be guided to your mitral valve through the catheter. Your doctor will use imaging equipment to guide the placement of the Clip.



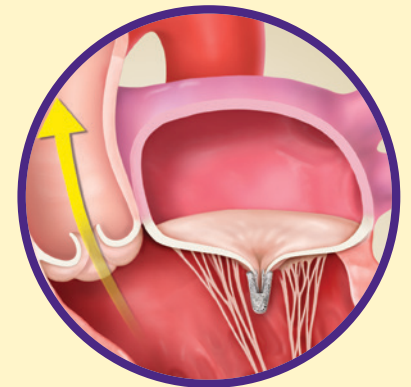
- 3** Your doctor will implant the Clip at the appropriate position on your mitral valve. The Clip will grasp the mitral valve leaflets to close the center of the mitral valve and reduce mitral regurgitation. Your doctor will then perform tests to confirm that the Clip is working properly. In some cases, your doctor may implant a second Clip for further reduction of mitral regurgitation.



- 4** Once the Clip is in place and working properly, it will be disconnected from the Clip Delivery System. The Clip Delivery System and the Steerable Guide Catheter will then be removed from your body and the incision in your leg will be closed.



- 5** 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.





WHAT WILL HAPPEN AFTER YOUR PROCEDURE?

Your hospital stay following the procedure will likely range from one to five days, depending on your recovery and overall health. You should experience relief from your symptoms of mitral regurgitation soon after your procedure. Most patients will not need special assistance at home following discharge from the hospital, outside of ongoing needs for any unrelated health conditions.

While in the hospital, you will be closely monitored and your doctor will perform various tests to evaluate your heart function. You may be prescribed blood-thinning medications to help reduce the risk of developing a dangerous blood clot after the procedure. Your doctor or nurse will give you instructions about your medications before you leave the hospital.

You will be discharged to the care of your cardiologist or family doctor, who will ask you to return for follow-up visits. It is important that you keep all appointments for follow-up care and follow your doctor's instructions.

AFTER BEING DISCHARGED FROM THE HOSPITAL, IT IS IMPORTANT THAT YOU:

- Limit strenuous physical activity (such as jogging or activities that cause breath-holding, grunting, or straining such as lifting heavy objects) for at least 30 days, or longer if your doctor thinks it is necessary
- Carefully follow your doctor's instructions regarding medications you need to take, especially if blood-thinning drugs are prescribed
- Call your doctor if you cannot keep taking your medications because of side effects, such as rash, bleeding, or upset stomach
- Notify your doctor before any medical or dental procedure; you may need to be prescribed antibiotics to avoid potential infection

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., 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. 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.
- Use of the MitraClip™ should be restricted to those physicians trained to perform invasive endovascular and transeptal 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

Potential adverse events that may occur during or after a procedure placing this device include, but are not limited to:

- 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
 - $\geq 8\%$ 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 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.



Failure to follow these instructions will increase your risk for complications and may result in the return of your mitral regurgitation or cause the MitraClip™ Implant to not work properly. Notify your doctor immediately if you experience any pain or other problems that may be related to your procedure or the return of any symptoms related to mitral regurgitation.

YOUR IMPLANT IDENTIFICATION CARD

Following your procedure, you will receive an Implant Identification Card, which your doctor will fill out and which you must carry with you at all times.

IMPORTANT:

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

REFERENCES: 1. Ladich, E, Michaels, M, Jones, R, et al. Pathological Healing Response of Explanted MitraClips. *Circ.* 2011;123:1418-1427

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

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