



Preparing for Your Transcatheter Mitral Valve Repair Procedure

What you should know
about MitraClip® therapy

About the Transcatheter Mitral Valve Repair Procedure



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 a new, 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.

The MitraClip® device (or “clip”) is smaller than the size of a dime.



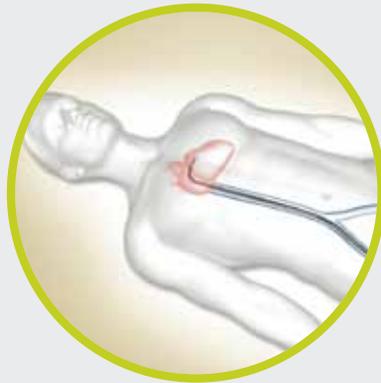
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What will happen during your procedure (continued)

The following steps provide a general overview of the TMVR procedure with the MitraClip® device (or “clip”)—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.

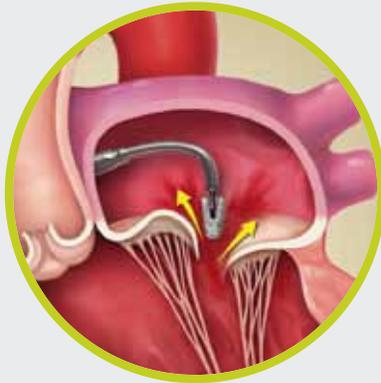
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Your doctor will make a small incision in your upper leg, where a guide catheter (a hollow, flexible tube slightly larger than the diameter of a pencil) will be inserted through a vein to reach your heart.



2

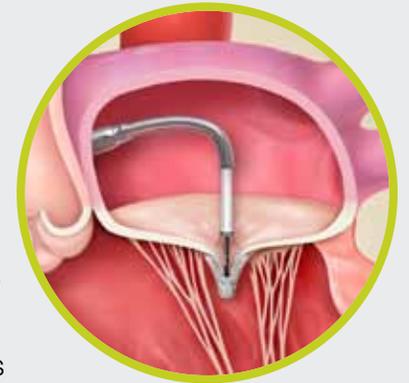
The clip, which is attached to the end of a clip delivery system, will be guided to your mitral valve through the catheter. Your doctor will use imaging equipment to guide the placement of the clip.



3

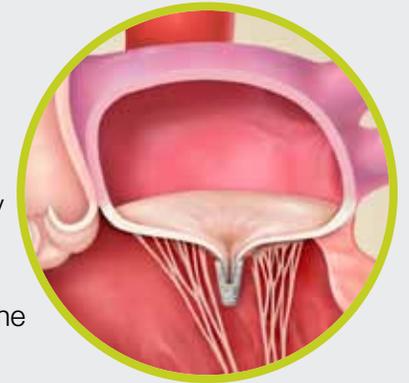
Your doctor will implant the clip at the appropriate position on your mitral valve. The clip will grasp the mitral valve leaflets to close the center of the mitral valve and reduce mitral regurgitation.

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.



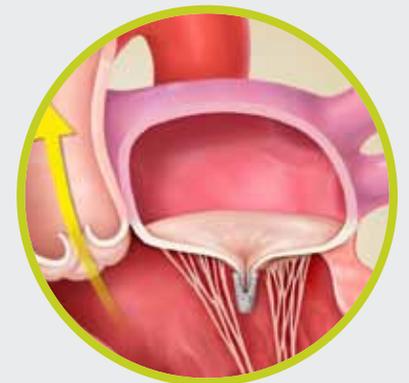
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Once the clip is in place and working properly, it will be disconnected from the clip delivery system. The clip delivery system and the guide catheter will then be removed from your body and the incision in your leg will be closed.



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



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® device 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.

Warnings

- **MitraClip® therapy should only be used in patients with significant, symptomatic, degenerative mitral regurgitation who are too sick for mitral valve surgery.**
- MitraClip® therapy is intended to reduce mitral regurgitation. If mitral regurgitation is not reduced enough, you may not get the full treatment benefits of reduced hospitalizations and improvement in heart failure symptoms and quality of life expected from MitraClip® therapy.

Precautions

- MitraClip® therapy should only be used in patients considered to be too sick for surgery. This 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, based on the presence of one or more surgical risk factors.
- The major clinical benefits of MitraClip® therapy are reduction of mitral regurgitation, resulting in reduced hospitalizations and improvement in heart failure symptoms and quality of life. **No benefit on how long a patient survives following MitraClip® therapy has been demonstrated.**
- How long the MitraClip® device will last is unknown at this time. The first MitraClip® device was implanted in 2003 and laboratory testing supports durability of the device over a period of 15 years. Regular medical follow-up is essential to evaluate how the MitraClip® device is performing. Notify your doctor immediately if you experience the return of any symptoms related to mitral regurgitation.
- Patients who have undergone MitraClip® therapy should receive prophylactic antibiotic therapy before any medical or dental procedure to minimize the possibility of infection.
- **The safety and effectiveness of MitraClip® therapy have not been established in patients who have functional (also called secondary) mitral regurgitation.**
- The safety and effectiveness of MitraClip® therapy have not been established in patients who have specific mitral valve anatomy that may interfere with proper placement and positioning of the MitraClip® device:
 - A mitral valve opening that is too small
 - Calcified mitral valve leaflets
 - A cleft of the mitral valve leaflet
 - A leaflet flail width or leaflet flail gap that is too large
- MitraClip® therapy has not been tested in pregnant women or children or infants, and the device may not work for these patients.

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.

	Implant Identification Card Evalue, Inc. MitraClip® Device
Patient Name: _____	
Implant Date: _____	
Device Serial #: _____	
Implanting Physician: _____	
Physician Phone: _____	
ENGLISH (continued on reverse)	Evalue, Inc. +1 (650) 833-1600 4045 Campbell Ave., Menlo Park, CA 94025

IMPORTANT: Show your Implant Identification 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 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.

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