

Transcatheter Mitral Valve Repair With MitraClip™ Therapy

What You and Your Family Should Know About This Minimally Invasive Procedure





This guide provides you and your family with information about your heart and mitral regurgitation (MR). MR is a condition where the mitral valve does not close fully. Blood leaks backwards inside the heart.

Patients with this problem who cannot have open-heart surgery can learn about a less-invasive treatment option called transcatheter mitral valve repair (TMVr) with MitraClip therapy.

You can read an overview of the steps involved in TMVr and expectations for patients before, during, and after the procedure. It is important that you discuss your treatment options with your doctor, to determine if this treatment is right for you.

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Understanding Your Heart

How Your Heart Works

Your heart beats thousands of times per day, pumping dozens of gallons of blood each hour. It pumps blood through your lungs to replenish it with oxygen and then pumps the oxygen-rich blood back out to the rest of your body.

The heart has four chambers; the upper two chambers are called atria (each one

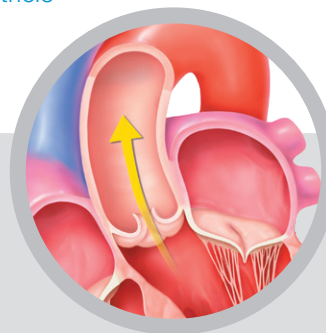
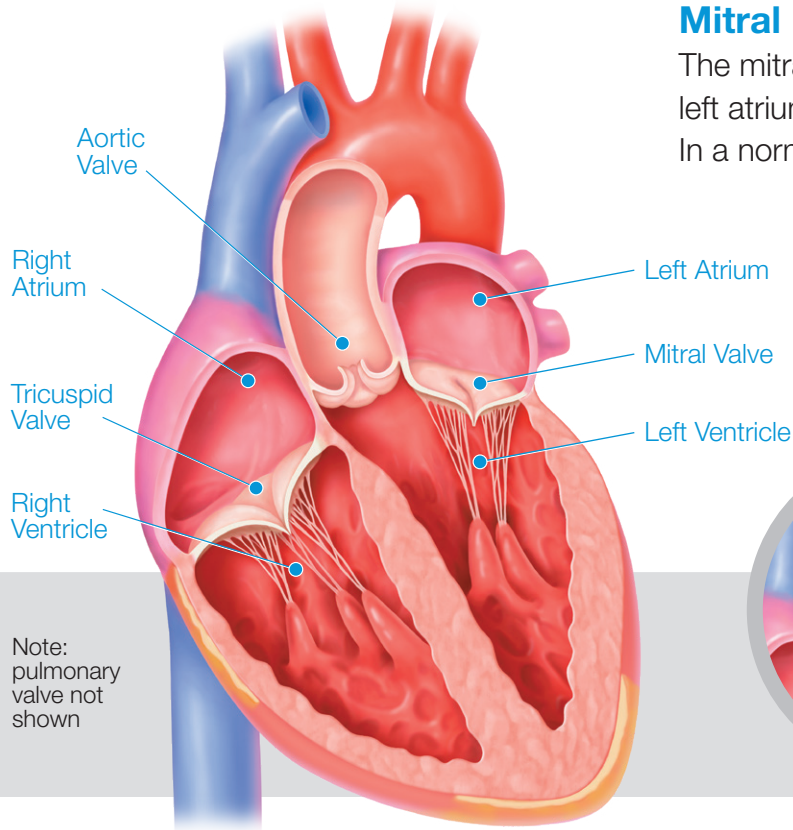
is an atrium), and the lower two are called ventricles. There are four valves that function as the doorways between these chambers (see figure below). Each valve is made of thin but strong flaps of tissue called leaflets. The valves open in one direction to let blood pass from one chamber to the next, closing quickly between heart beats so blood does not flow backward.

The Mitral Valve and Mitral Regurgitation

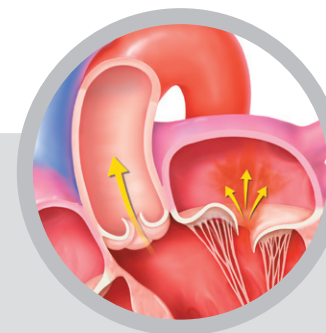
The mitral valve is the valve between the left atrium and left ventricle of your heart. In a normally working mitral valve, blood

flows in a single direction between the left atrium and left ventricle. However, when your mitral valve's two leaflets (or flaps) do not close properly, some blood flows backward. This is called mitral regurgitation.

To make up for the backflow of blood, your left ventricle must pump harder to keep blood flowing through your body. This can enlarge and weaken your heart. Over time, the extra burden on your heart and lungs may lead to congestive heart failure, a condition that occurs when your heart can't pump enough blood to meet the needs of your body. This may cause you to have shortness of breath, fatigue, an irregular heartbeat, or a constant cough.



Normally functioning mitral valve



Improperly functioning mitral valve allowing blood to flow back into left atrium (mitral regurgitation)

Types of Mitral Regurgitation



Mitral regurgitation is common, affecting nearly 1 in 10 Americans aged 75 and above. It is a condition that worsens over time. It can severely impact quality of life and lead to heart failure if left untreated.

There are two types of Mitral Regurgitation (MR):

- Primary Mitral Regurgitation
- Secondary Mitral Regurgitation

Primary Mitral Regurgitation

One type of MR is called primary MR (also called degenerative or organic MR). It can be related to age, a birth defect, or an underlying heart disease.

Secondary Mitral Regurgitation

Another type of MR is called secondary MR (also called functional MR). It can occur due to underlying heart disease related to congestive heart failure. With the progression of heart failure, the ventricle of the heart can widen causing the mitral valve leaflets not to close properly.

To determine if you have MR and to assess the function and condition of your heart and mitral valve, your doctor may perform diagnostic tests, including:

- Listening to your heart with a stethoscope
- Using an ultrasound to get a close look at your heart and mitral valve
- Taking a chest X-ray to see your heart and evaluate your lungs
- Evaluating you for symptoms of heart failure (such as shortness of breath or fatigue) or other related heart conditions

Moderate or severe MR means you have a very large amount of blood flowing in the wrong direction through your mitral valve. Significant or symptomatic MR may mean that you have congestive heart failure or other related heart conditions.

Treatment Options for Mitral Regurgitation

Treatment for your mitral regurgitation (MR) depends on how bad it is, how sick you are, and what type of MR you have.

Primary MR itself can only be treated in two ways: mitral valve surgery or transcatheter mitral valve repair. Mitral valve surgery is the preferred treatment for primary MR. While open-heart surgery is an effective treatment for primary MR, your doctor may suggest another treatment due to your age, advanced heart failure, or other serious medical conditions. Patients who are too sick for open-heart surgery (also referred to as being at “high surgical risk”) may be candidates for transcatheter mitral valve repair, a less-invasive treatment option.

Secondary MR can be treated in two ways: medication or transcatheter mitral valve repair. Medication is the preferred treatment for secondary MR. If your MR gets worse after taking medication, transcatheter mitral valve repair may be an option to treat your symptoms and disease.

Patients who are ideal for less invasive procedure TMVr are those who are too sick for open-heart surgery. Or those who have symptoms despite taking medications for heart failure.



Transcatheter Mitral Valve Repair

Transcatheter mitral valve repair (TMVr) is a minimally invasive procedure.

Doctors place a thin tube (called a catheter) into a large vein in your leg to reach your heart. A clip is then placed onto the center of your mitral valve. The valve continues to open and close, allowing blood to flow through while reducing MR.

To determine the right treatment option, you will be evaluated by a Heart Team.

The TMVr procedure is not right for everyone. In some cases, the risks of the procedure may be higher than the benefits. See pages 14-15 to review the risks of the TMVr procedure.

About the Transcatheter Mitral Valve Repair Procedure



Your doctor should discuss with you if you have any issues that would prevent you from having the MitraClip procedure. An assessment of your heart will also confirm if your heart valve anatomy would allow for successful placement of the implant.

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 is the MitraClip System and How is it Used?

The MitraClip implant is a small clip (see figure below) that is placed to help close the leaflets of your mitral valve. The clip is inserted through a catheter (a thin tube), without the need for open-heart surgery.

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.

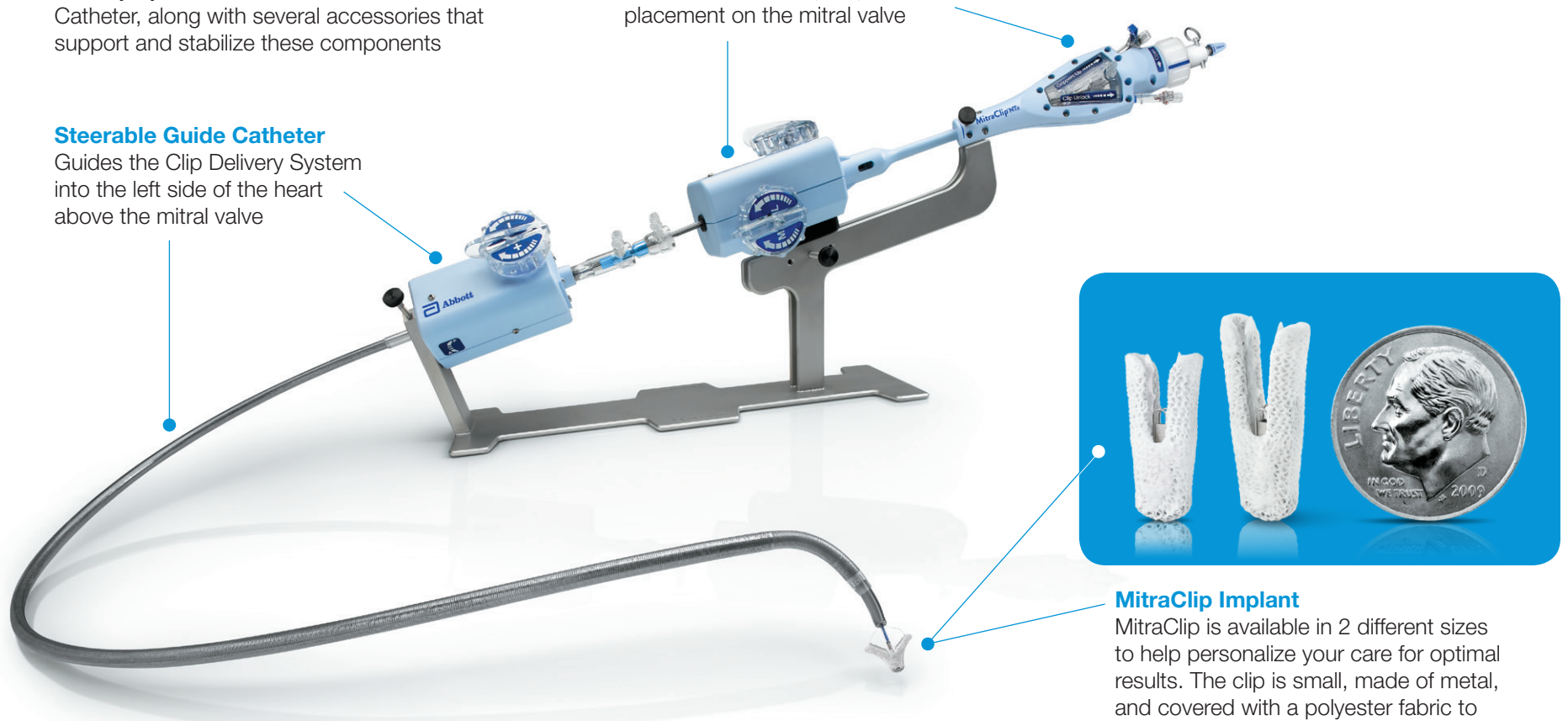
The **MitraClip System** consists of the Clip Delivery System and the Steerable Guide Catheter, along with several accessories that support and stabilize these components

Clip Delivery System

Delivers the MitraClip implant for placement on the mitral valve

Steerable Guide Catheter

Guides the Clip Delivery System into the left side of the heart above the mitral valve



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.

The MitraClip system depicted here is the MitraClip NTR.

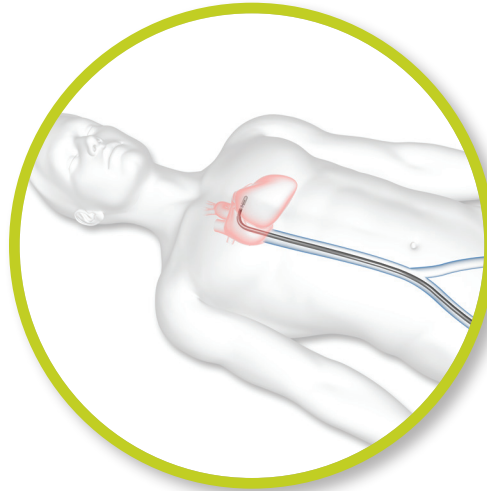
About the Transcatheter Mitral Valve Repair Procedure *(continued)*

What Will Happen During Your Procedure?

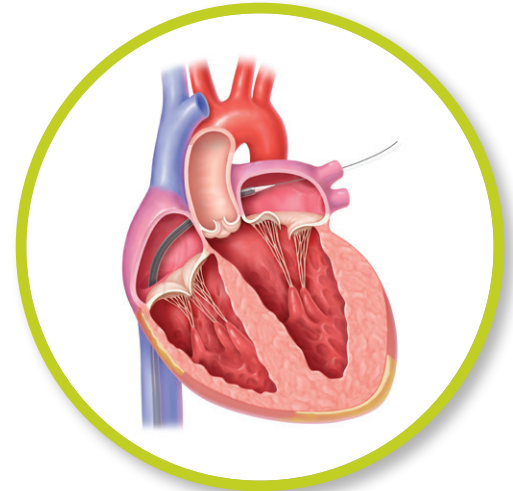
During the procedure, you will be placed under general anesthesia to put you in a deep sleep. A ventilator will be used to help you breathe. Your doctor will use fluoroscopy (a type of Xray) and echocardiography (a type of ultrasound) during the procedure to visualize your heart.

On average, the time required to perform the procedure is between 3 and 4 hours. However, the length of the procedure can vary due to differences in anatomy.

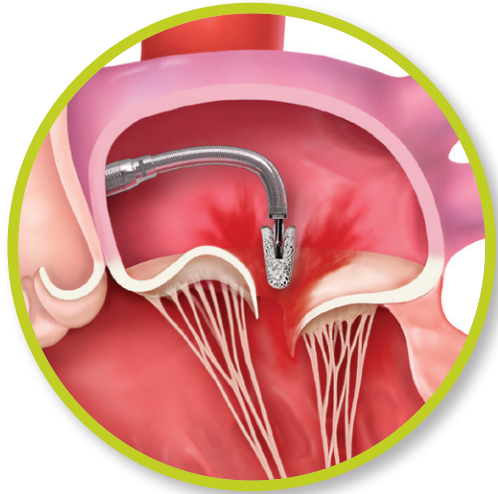
The following steps provide a general overview of the MitraClip procedure. Experiences may vary. Your doctor will explain the procedure, provide you with specific details, and answer any questions you may have.



1 Your doctor will make a small cut in your upper leg. A guide catheter (a thin tube) will be inserted through a vein to reach your heart.

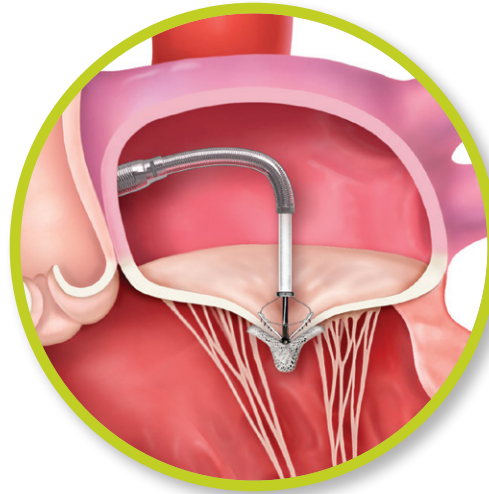


2 The MitraClip implant, which is attached to the end of a clip delivery system, will be guided to your mitral valve through the catheter. Your cardiologist will use imaging equipment to guide the placement of the clip.

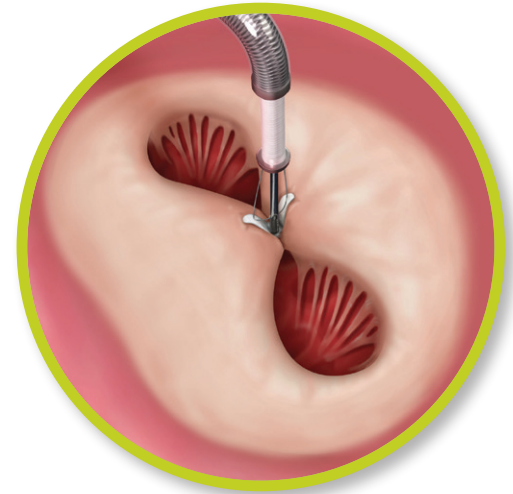


3 Your cardiologist will implant the clip at the appropriate position on your mitral valve. The clip will grasp the mitral valve leaflets to close the center of the mitral valve and reduce mitral regurgitation.

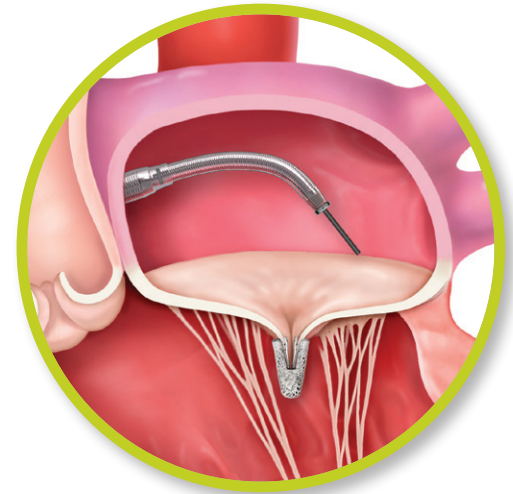
Your cardiologist will perform tests to confirm that the clip is working properly. In some cases, your cardiologist may implant a second clip for further reduction of mitral regurgitation.



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



About the Transcatheter Mitral Valve Repair Procedure *(continued)*

What Will Happen After Your Procedure?

Your hospital stay after the procedure may range from 1 to 5 days. This will depend on your recovery and overall health. You should feel better from your MR symptoms soon after your procedure. Most patients will not need special assistance at home due to this procedure.

While in the hospital, you will be closely monitored. Your doctor will perform various tests to assess your heart function. You may be prescribed medication that thins the blood. This will help lower the chance of dangerous blood clots after the procedure. Your doctor or nurse will give you instructions about your medications before you leave the hospital.

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

If you do not carefully follow your doctor's instructions, you will have a higher chance of complications and your MR may possibly return. **If you feel any pain or have other problems related to your procedure or your symptoms have returned, contact your doctor immediately.**

After being released from the hospital, it is important that you:

- Limit physical activities that are tiring for at least 30 days, or longer if your doctor thinks it is needed
- Carefully follow your doctor's instructions on your medications, especially prescribed medications that thin the blood
- Call your doctor if you cannot continue your medications due to side effects
- Notify your doctor before any medical or dental procedure. You may need to be given medication to avoid possible infection.

MitraClip therapy has more than 15 years of clinical experience. More than 4,000 patients in the U.S. have been treated with MitraClip therapy in several clinical studies. Over 70,000 patients have been treated with MitraClip therapy worldwide.



Clinical Information on Benefits and Risks

Benefits

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.
- **Improvement in symptoms:** Patients experience significant improvement in how they feel during physical activity. This is measured a system called the New York Heart Association (NYHA), 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





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 when blood stops flowing in the brain, which may cause severe disability
- Transient ischemic attack: a stroke that lasts only a few minutes
- Major vascular complications: a large blood clot under the skin, which may require another surgery
- Life threatening bleeding event: a bleeding event that requires a blood transfusion

Additional potential risks associated with the procedure include:

- Heart attack or worsening heart failure
- Failure of your heart to pump enough blood to the body organs
- Having an abnormal particle (air, blood clot, or piece of device) floating in the blood stream or attached to an object, including the valve
- Infection in your heart, blood or other areas
- Injury to your blood vessels or heart that requires treatment
- Blocking, tightening, narrowing or bulging of a blood vessel
- Trouble or inability to breathe
- Fluid build-up
- Irregular heart rate
- Abnormally high or low blood pressure
- Pain, inflammation and/or fever
- Pain or changes at the incision site
- Incorrect positioning, inability to implant, or movement of the MitraClip
- Continuing blood leak through the mitral valve
- Blocking, narrowing, or injury of your mitral valve
- If your heart failure worsens, you may need a new heart (transplant) or heart pump (left ventricular assist device)
- Additional cardiac surgery, vascular or intervention
- Nausea or vomiting
- Chest pain
- Throat irritation
- Worsening kidney function or kidney failure
- Dizziness
- Blood disorders
- Movement disorders
- Reaction to radiation
- Allergic reactions
- Ischemia (lack of oxygen to parts of your body)

Clinical Information on Benefits and Risks *(continued)*

Clinical Data for Patients with Primary Mitral Regurgitation Treated with MitraClip

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.

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

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.

Risks Within 30 Days and 1 Year After the MitraClip Procedure for SMR		
	30 Days	1 Year
Death (from any cause)	2 out of 100 patients	19 out of 100 patients
Stroke	1 out of 100 patients	4 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	2 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

Precautions

- The device should only be used in patients with:
 - Primary mitral regurgitation (PMR) in patients who are too sick for surgery
 - Secondary mitral regurgitation (SMR) in patients who still remain sick after medication and are not offered surgery
- Patients who have had MitraClip therapy should receive antibiotic medication before any medical or dental procedure to lessen the chance of infection
- MitraClip therapy has not been established in patients who have specific mitral valve anatomy that may hinder proper placement and positioning of the MitraClip implant:
 - 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

Who Should Not Have the Procedure

The MitraClip device should not be used in patients who:

- Cannot tolerate medication that thins the blood or prevents blood clots from forming
- Have an active infection in the heart
- Have mitral valve disease due to inflammation
- Have evidence of clots in veins within the heart or whose access to femoral vein is restricted due to blood clot



Your Implant Identification Card

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

IMPORTANT: Show your Implant Identification Card if you go to an emergency room. This card shows that you have a MitraClip implant. If you require a MRI (magnetic resonance imaging) scan, tell your doctor or MRI technician that you have a MitraClip implant. Test results show that patients with the MitraClip implant can safely have MRI scans under certain conditions described on the card.

Contact Information

For more information on the MitraClip procedure, please contact Abbott:

Toll-free phone in the USA:

1-800-227-9902

Email Address:

av.customercare@av.abbott.com

Mail:

Abbott
3200 Lakeside Dr.
Santa Clara, CA 95054

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