Edwards

Transcatheter Mitral Valve Replacement

A guide for patients with mitral valve disease

The SAPIEN M3 Mitral Valve Replacement System

Edwards

This patient guide is for those who are suffering from mitral heart valve disease and need treatment.

The information in this guide will help you and your loved ones understand more about your heart and your disease.

A less invasive procedure called transcatheter mitral valve replacement (TMVR) may be an option for you.

This guide is not intended to explain everything you need to know about your treatment options for mitral valve disease or about the TMVR procedure.

Please discuss any questions you have with your doctor.

Be sure to ask your Heart Team to explain all your treatment options and the possible risks and benefits of each.

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Edwards Lifesciences is the global leader in new medical technology for heart disease and has been helping patients for over 60 years. Driven by a passion to help patients, Edwards works to deliver better outcomes to improve the lives of patients.

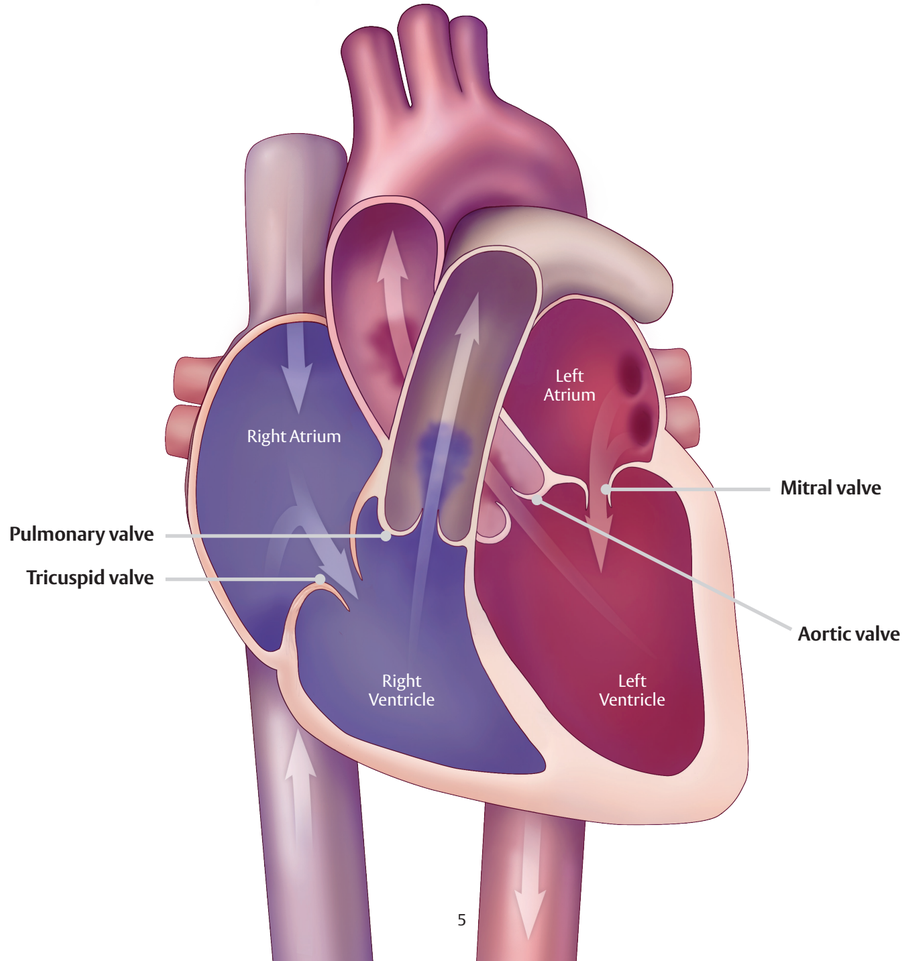
The SAPIEN M3 transcatheter mitral valve replacement system is designed to replace your diseased mitral valve without surgery.

How the Heart Works

The heart is a powerful muscle located in your chest between your lungs. Blood flows from your body to the right side of your heart which sends it to the lungs to pick up oxygen. Once this occurs, the blood moves to the left side of the heart, which then pumps out to the rest of your body.

As blood cycles through your heart, there are four valves that open and close to help blood flow in one direction. Your valves should:

- Be properly formed and flexible
- Open all the way so that the right amount of blood can pass through
- Close tightly so that no blood leaks back into the chamber



There are two main types of problems that can cause your mitral valve not to work properly.

Mitral valve regurgitation (MR)

When your valve does not close completely and blood can leak backwards

Mitral valve stenosis (MS)

When your valve narrows and does not open completely

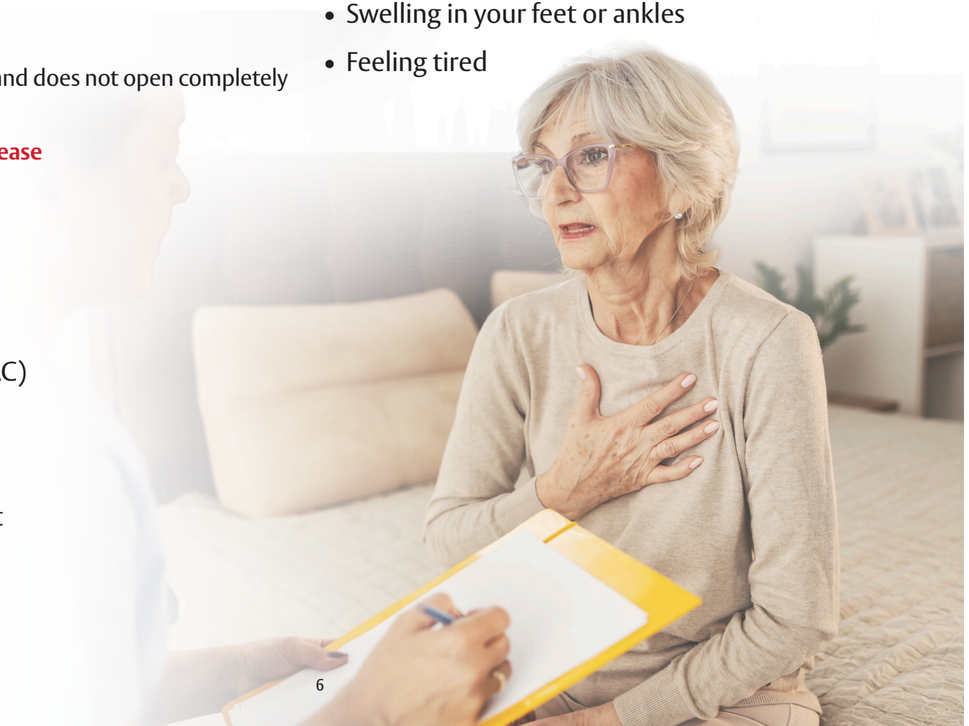
Causes of Mitral Valve Disease

- Age
- Heart expansion
- Heart damage
- Calcium buildup (MAC)
- Rheumatic fever
- Radiation therapy
- Infection of the heart

Signs and Symptoms

With these conditions, it is difficult for your heart to move blood through the rest of your body efficiently and you may experience symptoms like:

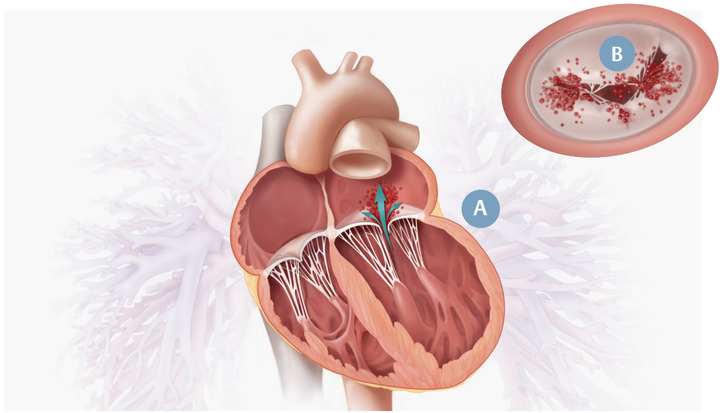
- Shortness of breath
- Swelling in your feet or ankles
- Feeling tired



Heart with Mitral Regurgitation

A Leaflets do not close properly and blood flows backward through the valve

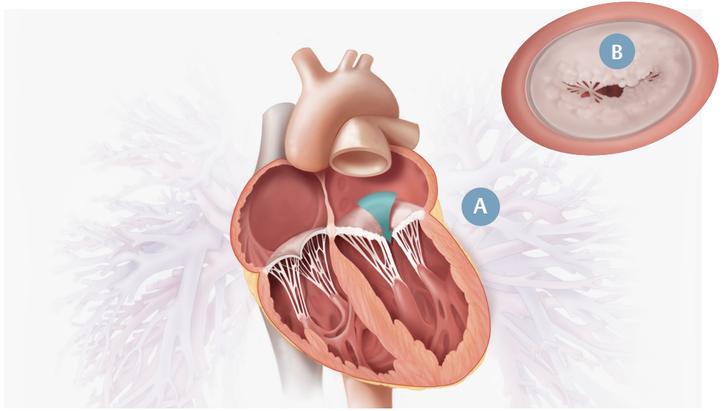
B Top view of leaflets showing blood escaping through the valve during closure



Heart with Mitral Stenosis

A Narrowing of the valve prevents valve from opening properly

B Top view of leaflets



Understanding your treatment options:

There are different options to treat mitral valve disease:

- Medical therapy
- Surgery
- Mitral valvuloplasty
- Transcatheter edge to edge repair (TEER)
- Transcatheter mitral valve replacement (TMVR)

Only a specialized Heart Team can determine which treatment option is appropriate for you.

Medical therapy:

Your doctor may prescribe certain medications to help some symptoms. However, it will not cure or fix the valve.

Surgical valve repair or replacement:

If surgery is right for you, the doctor will open your chest to repair or replace your valve.

Mitral Valvuloplasty:

This treatment is a less invasive method performed through a small incision in the leg. During the procedure, a thin tube called a balloon catheter is inserted into your body and advanced to your mitral valve. Once positioned, the balloon is inflated to widen the narrowed mitral valve, deflated, and then removed.

Transcatheter Edge to Edge Repair:

This treatment is also a less invasive option performed through a small incision in the leg. Using several catheters, the doctor places a small implant to repair your own mitral valve.

Transcatheter Valve Replacement:

This is another less invasive option similar to transcatheter valve repair. However, during this procedure, the doctor places an artificial valve inside your old valve to replace it instead of trying to repair it.

What are the benefits of Transcatheter Mitral Valve Replacement?

If you have severe mitral valve disease and need your valve replaced, transcatheter mitral valve replacement may help your heart work better.

Other benefits may include:

- Reduced MR
- Improved quality of life
- Relief of symptoms
- Improved exercise capacity

What is the best treatment option for you?

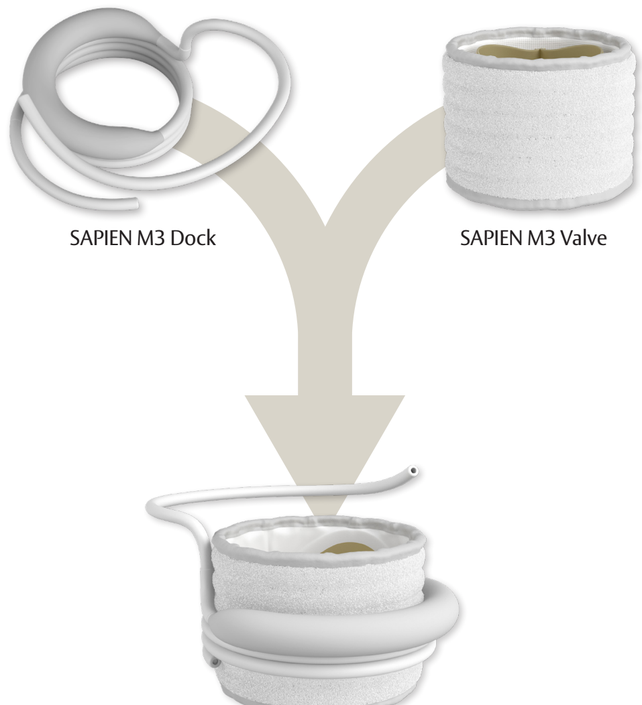
A specialized doctor on a Heart Team will evaluate you for treatment options. They will consider factors about your health to decide the most appropriate treatment option for you.

Your doctor will consider these factors:

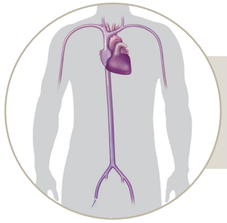
- Your medical history
- Your age
- Your current health status
- Your anatomy
- Your ability to undergo the procedure and recover from it
- The overall condition of your heart

The SAPIEN M3 Mitral Valve Replacement System

The SAPIEN M3 system contains 2 parts: The artificial heart valve and the dock that holds it in place. Together it is used to replace your mitral valve. It is put into place using a minimally invasive delivery system through a small puncture in your groin. The SAPIEN M3 dock allows the SAPIEN M3 valve to stay secured and prevent possible leakage around the valve. The leaflets in the SAPIEN M3 valve are made from cow heart tissue, which is the same material used in Edwards' surgical and transcatheter aortic valves.



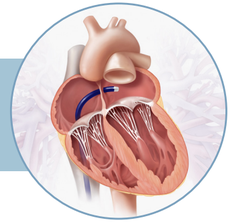
The Transcatheter Mitral Valve Replacement Procedure



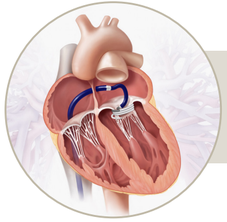
Step 1

The procedure is performed by inserting a narrow tube (called a catheter) through a small incision in the leg and navigated to your heart

Step 2



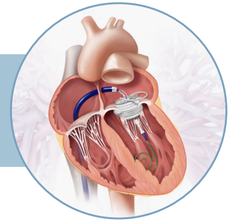
The catheter crosses the septum, a heart wall tissue, to access your mitral valve



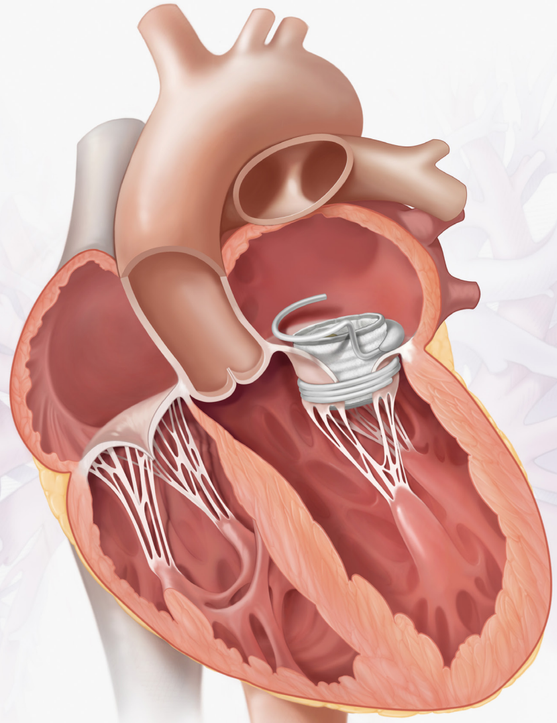
Step 3

The SAPIEN M3 dock is deployed into position, encircling the leaflets of your mitral valve.

Step 4



The SAPIEN M3 valve is deployed into the dock (with your native valve leaflets in between) to replace your mitral valve



Placement of the SAPIEN M3 system

What Happens After the Transcatheter Mitral Valve Replacement Procedure?

On average, you can expect to spend 3 days in the hospital. However, every patient's recovery is different. Before you leave the hospital, your doctor will talk to you about recovery plan. Carefully follow your doctor's directions, including taking medications.

Transcatheter Heart Valve Replacement Follow Up Visits

Regular check-ups with your doctor are very important. You may be asked to return to your doctor to have your heart valve checked at 30 days and annually up to 5 years after your procedure. However, you should call or see your doctor whenever you have questions or concerns about your health.

Your Edwards Implant Cards

As you leave the hospital, your valve clinic coordinator or nurse should give you 2 implant cards. These cards have information about your Edwards SAPIEN M3 heart valve replacement implants (1 for the dock, 1 for the valve). It is important to inform all members of your healthcare team about your heart valve replacement. Show these cards before any future medical or dental procedures. If you need an MRI (magnetic resonance imaging), tell your doctor you have a SAPIEN M3 implant.

Edwards Lifesciences® Implanted Device ID Card

SAMPLE PATIENT

Edwards™

Implanting Physician
SAMPLE PHYSICIAN

Hospital
SAMPLE HOSPITAL
CITY, STATE, COUNTRY ZIP CODE

Device
BOVINE TRANSCATHETER HEART VALVE

Appropriate antibiotics may be reasonably prescribed for you prior to certain dental and invasive procedures due to a higher risk of adverse outcomes from prosthetic valve related-infection (endocarditis). Additional information available at www.edwards.com/antibiotics

Serial	Model		
xxxxxx	9300TFX		
Implant Date	**Position**	**Size**	
DATE MONTH YEAR	POSITION	SIZE MM	

The ENCIRCLE Study

The risks of the procedure may depend on your overall health. If you undergo a TMVR procedure with the SAPIEN M3 system, the clinical data shown in these charts could be what you would expect.

As part of the ENCIRCLE study, the SAPIEN M3 valve was studied in 300 patients with symptoms of moderate to severe or severe MR (Main cohort) and in 100 patients with symptoms of moderate to severe or severe MR, severe MS or moderate MR with moderate MS with MAC (MAC cohort), mostly in the United States

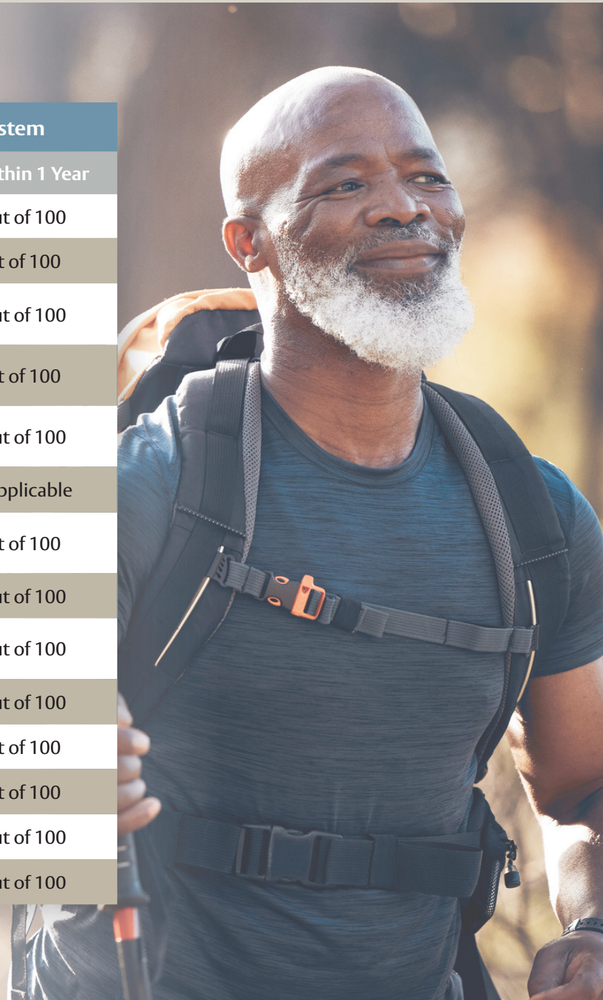
Patients were examined at 30 days and 1 year after the procedure and will continue to be followed every year for up to 5 years.

Main Cohort Data

Transcatheter Mitral Valve Replacement with the SAPIEN M3 System		
Major Complications	**Risk Within 30 Days**	**Risk Within 1 Year**
Death from any cause	1 out of 100	14 out of 100
Stroke	3 out of 100	10 out of 100
Serious damage to the heart structures	3 out of 100	3 out of 100
Serious damage to the blood vessels	1 out of 100	1 out of 100
Hospitalization for heart failure	4 out of 100	17 out of 100
Kidney failure	3 out of 100	Not Applicable
Blood clot, including a blood clot on the valve	3 out of 100	7 out of 100
Serious bleeding	4 out of 100	8 out of 100
Red blood cell breakdown needing additional treatment	5 out of 100	8 out of 100
Repeat mitral valve procedure	3 out of 100	7 out of 100
Heart attack	1 out of 100	2 out of 100
Endocarditis	0 out of 100	2 out of 100
New permanent pacemaker	3 out of 100	6 out of 100
New abnormal heartbeat	8 out of 100	12 out of 100

MAC Cohort Data

Transcatheter Mitral Valve Replacement with the SAPIEN M3 System		
Major Complications	**Risk Within 30 Days**	**Risk Within 1 Year**
Death from any cause	6 out of 100	22 out of 100
Stroke	1 out of 100	8 out of 100
Serious damage to the heart structures	7 out of 100	10 out of 100
Serious damage to the blood vessels	2 out of 100	2 out of 100
Hospitalization for heart failure	6 out of 100	20 out of 100
Kidney failure	1 out of 100	Not Applicable
Blood clot, including a blood clot on the valve	1 out of 100	3 out of 100
Serious bleeding	9 out of 100	16 out of 100
Red blood cell breakdown needing additional treatment	10 out of 100	10 out of 100
Repeat mitral valve procedure	4 out of 100	12 out of 100
Heart attack	3 out of 100	5 out of 100
Endocarditis	2 out of 100	2 out of 100
New permanent pacemaker	7 out of 100	12 out of 100
New abnormal heartbeat	13 out of 100	22 out of 100



What Are the Risks?

As with any medical procedure, there is a possibility of risks. The most serious risks are:

- Death
- Stroke
- Serious bleeding
- Serious damage to the blood vessels

The SAPIEN M3 System Cannot Be Used in People Who:

- Cannot take blood thinning medications
- Have an active infection in the heart or elsewhere

If the SAPIEN M3 valve is used, it will not work correctly. It could make you feel very sick, and even cause death.

Additional Potential Risks Associated With the Procedure Include:

- Heart attack
- Kidney failure
- Failure of your heart to pump enough blood to the body's organs
- Sudden or unexpected loss of heart function
- Collection of fluid or blood around your heart
- Having an abnormal particle (air or blood clots) floating in the bloodstream or attached to an object, including the valve
- Irregular heart rate
- Abnormally high or low blood pressure
- Blood leak around the valve
- Damage to blood cells
- Blood clot, including a blood clot on the valve
- Trouble or inability to breathe
- Problems with the valve or accessories that do not allow it to work well, including but not limited to, wear, tear, or movement forward (prolapse) or backward (retraction) from the normal position of the valve leaflets, calcium buildup on the leaflets, or a break in the frame
- Additional cardiac surgery, vascular surgery, or intervention, including removal of the transcatheter heart valve
- Fluid buildup in your lungs
- Blocked pathway of blood in the lower left chamber
- Incorrect position of valve or valve movement
- Infection in your heart, blood, or other areas
- Allergic reaction
- Hole in the heart's wall
- Fainting or dizziness
- Problems with the electrical pathway of your heart that requires a pacemaker
- Skin burn, injury or tissue changes due to x-ray exposure
- Abnormal lab results
- Chest pain/partial or complete blockage of coronary artery (artery supplying blood to the heart)
- Anemia
- Pain, inflammation, or fever
- Pain or changes at the incision site

Warnings

- X-rays used during the procedure may cause radiation injury to the skin
- Talk to your doctor if you are allergic to any of the following materials:
  - Anesthesia
  - Contrast media
  - Chromium
  - Nickel
  - Titanium
  - Molybdenum
  - Manganese
  - Copper
  - Silicon
  - Plastics

Precautions

- Blood thinning medication will be necessary after valve replacement. If blood thinning medication is not taken, you may be at an increased risk of having a stroke. Blood thinning medications may also increase the risk of bleeding in the brain
- Patients who need a dental procedure should talk to their doctor about the risk of infection and needing antibiotics
- Long-term durability has not been established for the SAPIEN M3 valve and regular medical follow-up is advised

The safety and effectiveness of the valve have not been proven for patients with certain conditions, including:

- Severe right heart dysfunction
- History of heart transplant
- Severe high blood pressure in the lungs
- Low white or red blood cell count, or other irregularities in the blood

For More Information about the Edwards Transcatheter Mitral Valve Replacement Procedure

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CAUTION: Federal (United States) law restricts these devices to sale by or on the order of a physician. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

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