

Tendyne™ Transcatheter Mitral Valve System

Patient Guide



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Introduction

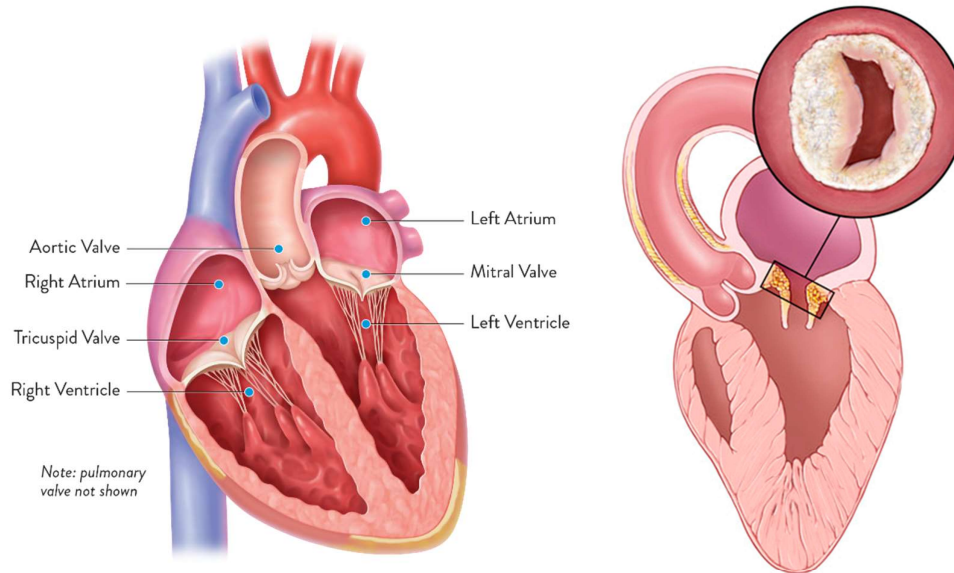
This guide gives general information about treating mitral valve problems caused by mitral annular calcification (MAC) with transcatheter mitral valve replacement. It does not give medical advice. Ask your doctor to explain all treatment options and their risks and benefits.



What is Mitral Annular Calcification (MAC)?

The mitral valve is between the heart's two left chambers, the atrium and ventricle. It has two flaps called leaflets that open and close to let blood flow in one direction.

MAC is a condition where the ring supporting the leaflets, gets hard with calcium. This can cause problems by narrowing the valve opening or stopping the valve from closing, which makes the valve leak.



Symptoms of Mitral Valve Dysfunction/Problems

Symptoms depend on the type and how severe the problem is. They may include:

- Chest pain
- Loss of appetite
- Dry cough
- Needing to urinate often
- Fainting
- Feeling tired
- Fast heartbeat
- Cannot exercise
- Feeling dizzy
- Hard to breathe
- Swollen feet or ankles

Treatment Options

What are the treatment options?

Right now, there are limited treatments for patients with severe mitral valve disease caused by MAC:

- Medications can help with symptoms, but they do not fix the disease.
- Surgery is often not recommended because it is very complex and carries higher risks.
- Transcatheter edge-to-edge repair is a less invasive option, but it usually doesn't work well for patients with MAC. The calcium can block the valve opening, making it harder for blood to flow.

What should patients do?

Each treatment has its own benefits and risks. It's important to talk with your doctor about all the options. Together, you can choose the one that best fits your health needs and lifestyle.

Transcatheter Mitral Valve Replacement

Mitral valve replacement with the Tendyne system, is an option that does not require open-heart surgery. When implanting the Tendyne system, doctors make a small cut in the chest to reach the heart and replace the mitral valve with an artificial valve.



Choosing the Right Treatment

Your doctor is your best person to help you choose the treatment options. Talk to your doctor and follow their advice.

Eligibility for Transcatheter Mitral Valve Replacement

Patients with mitral valve problems due to severe MAC who cannot have surgery can be screened for transcatheter mitral valve replacement.



Who Should Not Receive Transcatheter Mitral Valve Replacement?

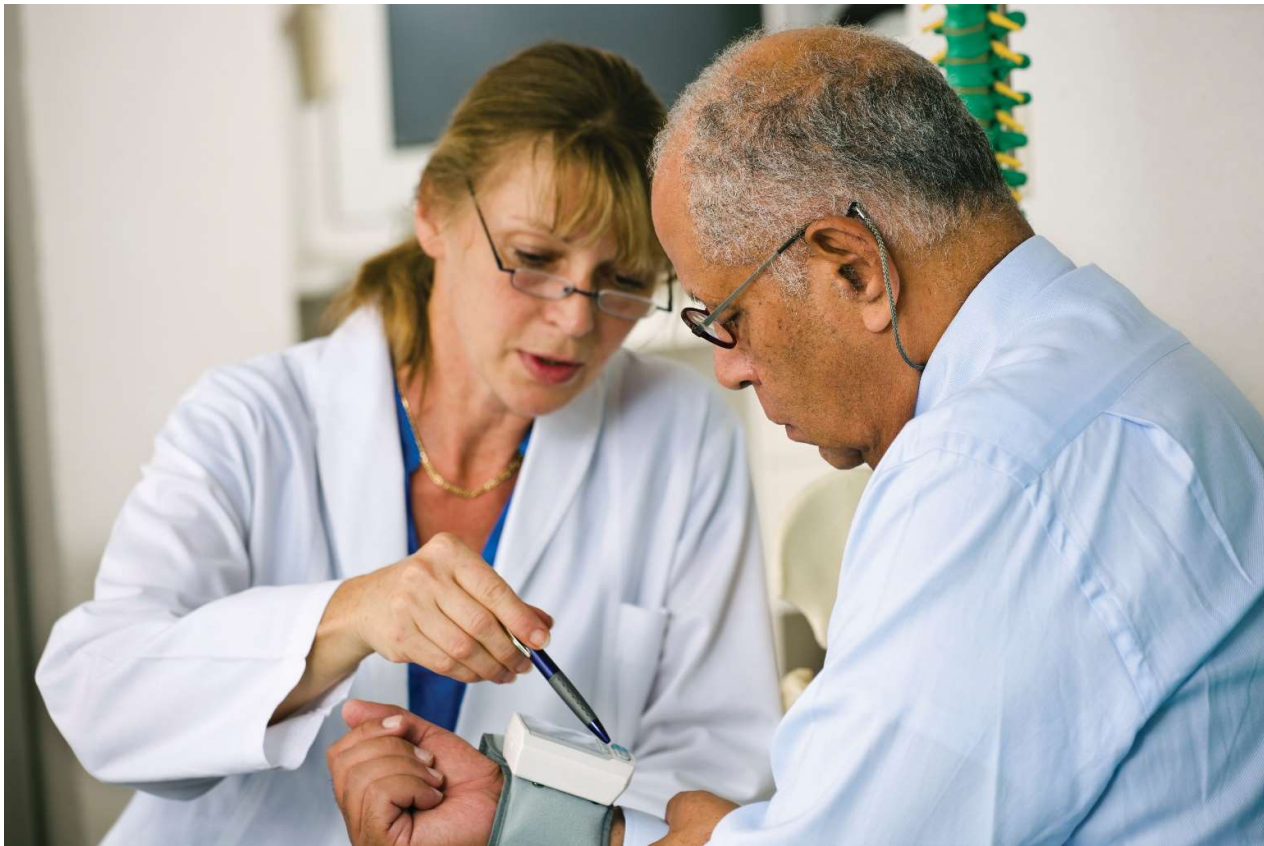
The Tendyne system should not be used for patients who:

- Cannot take blood thinning medicine
- Have serious infections
- Have a blood clot in the heart
- Have a weak bottom tip of the heart
- Have allergies to nickel or titanium

CAUTION: Tell your doctor if you have allergies or are sensitive to aldehyde, silicone, polymeric materials or contrast.

The Tendyne system has not been studied in these patients:

- People with serious coronary artery disease that needs treatment
- People with severe tricuspid regurgitation or tricuspid valve disease that needs surgery
- People with severe right heart problems
- People with very thick heart muscle
- Pregnant or nursing women
- Those under 18 years old



Risks Associated with the Tendyne System

All medical procedures have risks. Risks with the Tendyne System include:

- Death
- Reaction to a foreign object
- Reaction to anesthesia
- Allergic reaction
- Anemia (not enough healthy red blood cells)
- Tear in the mitral valve ring
- Aortic valve problems
- Heart injury
- Hole between the heart chambers
- Valve not working properly
- Bleeding problems
- Blood loss needing a transfusion
- Heart stops beating
- Irregular heartbeat
- Puncture wound in the heart
- Problems with the heart's electrical system, that may or may not require a pacemaker
- Damage to heart tissue or structures

- Decreased heart function
- Valve escapes into the bloodstream and cause blockage
- Valve rubs against the heart and cause tissue damage
- Valve slips out of position
- Valve placed in wrong position
- Blood clot on the valve
- Blockage caused by release of air, blood clot, tissue into the bloodstream
- Heart infection
- Injury to the esophagus (the tube that connects the mouth to the stomach)
- Fever
- Heart failure
- Collection of blood under tissue
- Rupture of red blood cells
- Low blood pressure
- Infection
- Rupture of valve or heart tissue
- Liver failure
- Mitral valve injury
- Floppy leaflets or narrowing of the valve opening
- Heart attack
- Blocked blood flow
- Pain
- Leak around the valve
- Fluid build-up around the heart that can cause compression of the heart
- Fluid build-up between the lungs and chest wall
- Blood clot blocking an artery in the lungs
- Increased lung pressure
- Kidney problems
- Lung failure
- Stroke
- Device damage
- Problems during valve or monitoring equipment insertion
- Worsening valve leak

Tendyne System Clinical Trial Data

The Tendyne system was studied in 103 patients with mitral valve dysfunction due to severe MAC in the SUMMIT clinical trial. The trial evaluated the safety and effectiveness of the Tendyne system. Here are some risks that might happen within 30 days of your procedure.

Event	Approximate Rate
Death	7 out of 100
Heart Failure Hospitalization	14 out of 100
Fatal bleeding	3 out of 100
Life-threatening bleeding	7 out of 100
New atrial fibrillation	14 out of 100
Worsening atrial fibrillation	13 out of 100
Acute kidney injury	12 out of 100
Stroke	3 out of 100
Another mitral valve procedure	2 out of 100

Before the Procedure

Before your procedure:

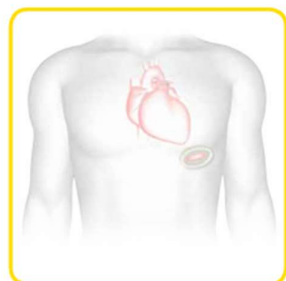
- Follow your doctor's instructions for medications
- Tell your doctor about other medications you take
- Tell your doctor about any allergies
- Follow all instructions from your doctor or nurse

During the Procedure

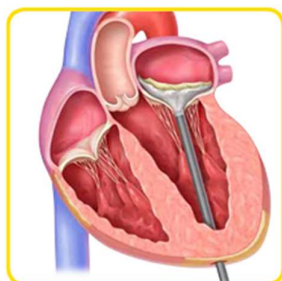
You will be under general anesthesia to put you in deep sleep (your heart will not be stopped) and a ventilator will help you breathe. The procedure usually takes 1-2 hours, but can vary.

Steps of the Tendyne™ system implant procedure:

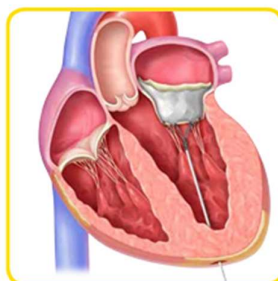
1. A small cut is made between the ribs on the left side of the chest
2. The Tendyne valve is placed into the heart with a catheter. Ultrasound images make sure the valve is placed correctly
3. The catheter is removed
4. A cord attached to the valve is connected to a pad at the bottom of your heart to keep the valve in place. The valve, cord, and pad stay in your heart permanently.



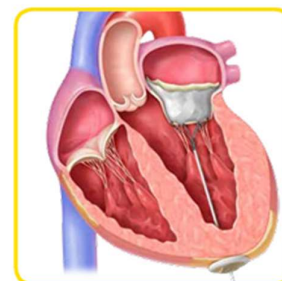
- 1** A physician guides the Tendyne Mitral Valve System through a small incision made between the ribs on the left side of the chest, between 4-6 cm.



- 2** The Tendyne valve is placed into the heart with a catheter. Ultrasound images of the heart are used to ensure the valve is correctly placed.



- 3** After the valve has been implanted, the catheter is removed.



- 4** A cord attached to the valve (called the "valve tether") is then connected to a small pad at the bottom of your heart, which secures the valve in place.

The valve, tether, and pad become a permanent implant in your heart, reducing mitral regurgitation and improving blood flow through your heart.

After the Procedure

Your hospital stay may last several days. You should feel better as you recover.

During recovery, you will be watched closely. Your doctor will do tests to check your heart. You will likely be given blood-thinning medication. Follow your doctor's instructions on medications and care for your incision site.

You will return to your doctor for follow-up visits. It is important that you attend all follow-up appointments and follow your doctor's instructions.

After Discharge

After leaving the hospital:

- Limit physical activities for at least 30 days
- Keep the cut site clean
- Follow your doctor's instructions on medications, especially prescribed medication that thins the blood
- Call your doctor if you have side effects from medications
- Notify your doctor before any medical or dental procedure

WARNING: If you do not carefully follow your doctor's instructions, you have a higher chance of problems. If you feel any pain, have problems related to your procedure, or your symptoms come back, contact your doctor right away.



Symptoms of Worsening Mitral Valve Problems

If you experience symptoms of worsening mitral valve problems or heart failure, seek medical help immediately.

Patient Identification Card

After your procedure, you will receive a Patient Identification Card. Carry it at all times.

If you have questions about your Patient Identification Card contact your primary care doctor.

IMPORTANT: Show your Patient Identification Card if you go to a hospital emergency room or before any medical or dental procedure. This card shows that you have a Tendyne Valve and Apical Pad.

Medical Equipment Interference

Most medical equipment will not affect the device. Inform hospital staff about your implant before any procedure. MRI scans are generally acceptable. If an MRI is needed, inform the MRI staff about the implant. The device's instructions for use will have information about MRI and your device.





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Mitral Valve

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Apical Pad and **Delivery System**

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