

Edwards Transcatheter Heart Valve Replacement

*A guide for patients with a failing
bioprosthetic valve*



The Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System



Edwards



This patient booklet is for those who have a failing aortic or mitral bioprosthetic heart valve.

The information in this booklet will help you understand more about a less invasive procedure called transcatheter valve replacement.

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

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Edwards Lifesciences is the global leader in patient focused medical innovations for structural heart disease and has been helping critically ill patients for over 60 years. Driven by a passion to help patients, Edwards works to improve outcomes and enhance the lives of patients.

The Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter valves enable the treatment for patients whose bioprosthetic aortic or mitral valve has failed.

To learn more, go to

[NewHeartValv](#) .



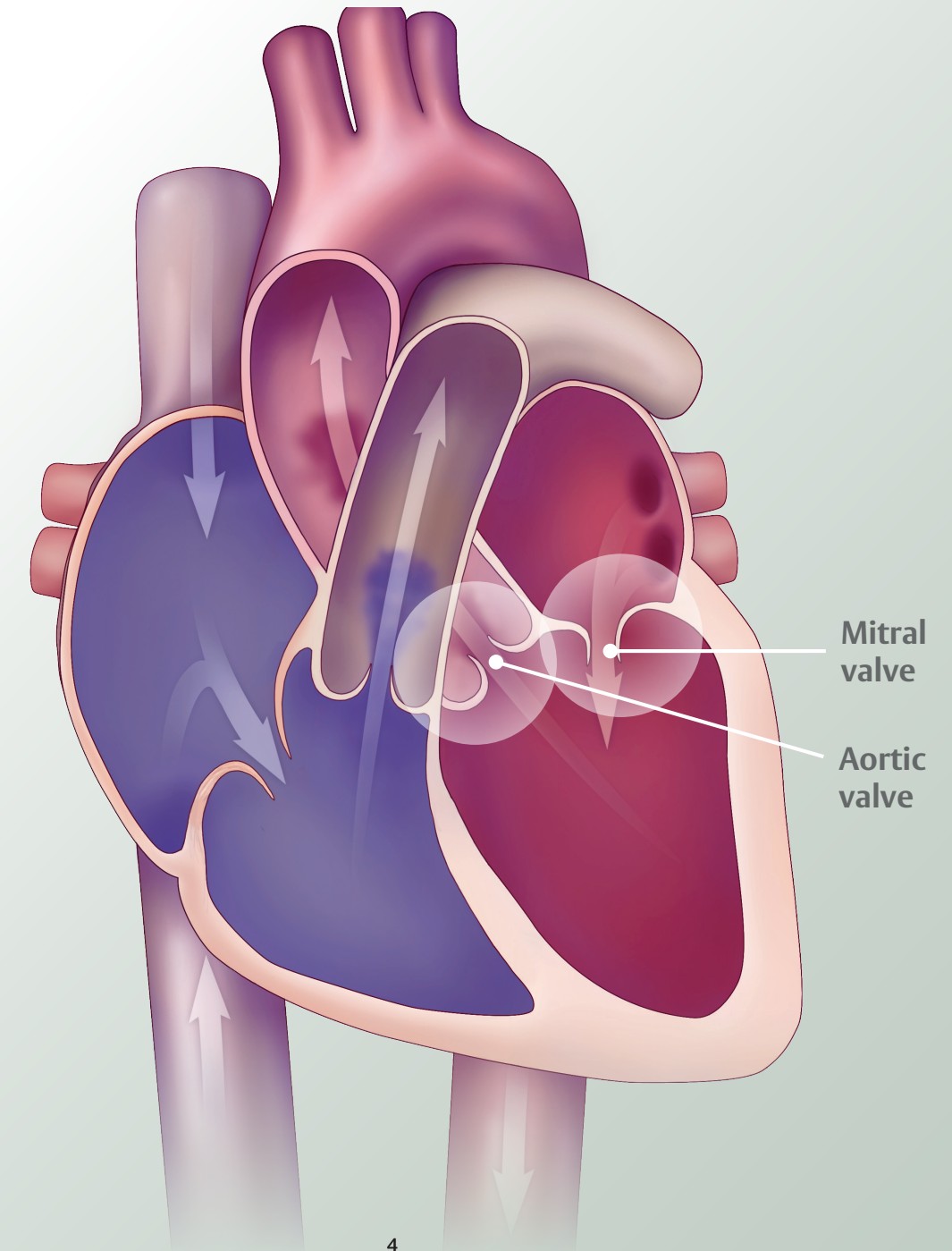
Why Your Surgical or Transcatheter Bioprosthetic Heart Valve May be Failing

If your native aortic or mitral heart valve has been replaced with a bioprosthetic heart valve, two common problems may occur over time:

- **Stenosis:** when your heart valve narrows and does not open completely
- **Regurgitation:** when your heart valve does not close completely and blood leaks backwards

It is important that your heart valves are always working properly. Your heart 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



Understanding Your Treatment Options

If you have a failing aortic or mitral bioprosthetic heart valve and your doctor has evaluated you as being at high or greater risk for open heart surgery, transcatheter valve replacement may be an option for you. Only a specialized Heart Team can determine which treatment option is best for you.

Medication

Your doctor may prescribe certain medications to help ease some of the symptoms of aortic stenosis; however, it will not cure or fix the valve.

Balloon Valvuloplasty (BAV)

Your doctor will inflate a balloon in your valve to help improve blood flow. This treatment will only provide temporary relief.

Surgical Valve Replacement

Open heart surgery for a failing bioprosthetic heart valve is where the doctor will open your chest and will completely remove the damaged valve and replace it with an artificial valve. You will be connected to a heart-lung machine that temporarily does the work of your heart and keeps the blood flowing throughout your body. Patients usually need to stay in the hospital for a week or more, before beginning a long period of recovery.

Transcatheter Valve Replacement

Transcatheter valve replacement for a failing bioprosthetic heart valve, sometimes referred to as “valve-in-valve,” is a less invasive approach to valve replacement compared to open heart surgery. In a transcatheter procedure, the doctor will make a small cut, usually in your groin. A thin, flexible tube is inserted into the artery to guide the heart valve up to your heart, and the valve is expanded into place. It does not remove your old failing bioprosthetic valve, it fits within the diseased valve.

What Is the Best Treatment Option for You?

Seeing a specialized doctor on a Heart Team will ensure you will be evaluated for all treatment options. They will consider all factors about your health to decide the best treatment option for you.

Your doctor will consider these factors:

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

Quality of Life Improvement:

Quality of life study with the Edwards SAPIEN 3 transcatheter heart valve showed patient health improvements within 30 days, including the ability to take care of themselves and participate in everyday activities.

What Are the Benefits of Transcatheter Valve Replacement?

If you have a failing bioprosthetic heart valve, transcatheter valve replacement may help your heart work better. Other benefits may include:

- Better clinical outcomes
- Less invasive, with minimal scarring
- Shorter hospital stay
- Shorter recovery time to getting back to everyday activities
- Less pain and anxiety
- Improved quality of life
- Relief of symptoms





Transcatheter Valve Replacement by Edwards Lifesciences

The Edwards SAPIEN transcatheter heart valve was the first of its kind to get FDA approval in the United States for patients who were too sick to undergo open heart surgery. Edwards first transcatheter heart valve was approved commercially in Europe in 2007 and in the United States in 2011 for replacement of native aortic valves with severe aortic stenosis.

To date, Edwards transcatheter heart valves have treated hundreds of thousands of patients in over 70 countries around the world.

The Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valves

Edwards Lifesciences transcatheter heart valves are designed to work like your native heart valve. The Edwards SAPIEN 3 and SAPIEN 3 Ultra valves are expanded into place with the help of a balloon and begin working immediately when they are implanted.

Transcatheter valve replacement is a less invasive procedure that uses a catheter for replacing your diseased valve. An interventional cardiologist (*specializes in catheter procedures*), along with a cardiothoracic surgeon (*specializes in surgical procedures of the heart*), will work together during the procedure to guide a new valve into the heart while it is still beating, using guidance from X-ray and echocardiography.

The Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valves

The Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves are part of the latest technology of valves from Edwards Lifesciences.

The SAPIEN 3 and SAPIEN 3 Ultra valves are bioprosthetic, balloon-expandable valves. The frame of the valves is made from cobalt chromium to help with strength and durability. The leaflets in the valves are made from the same bovine pericardial tissue (from a cow's heart) as

Edwards surgical valves. The SAPIEN 3 Ultra valve has a taller sealing skirt.

The SAPIEN 3 valve is available in four sizes (20, 23, 26, 29mm in diameter). The SAPIEN 3 Ultra valve is available in three sizes (20, 23, 26mm in diameter).

Your Heart Team will determine which valve is right for you.

The Edwards SAPIEN 3 Valve



The Edwards SAPIEN 3 Ultra Valve



Metal frame

Three tissue leaflets

Fabric skirt

Images are larger than actual valve size.

The Transcatheter Valve Replacement Procedure

This section describes what happens during transcatheter aortic/mitral valve replacement. It is intended as a general overview, and your experience may be different. Please talk to your doctor for more information about what you should expect.

Steps of the Transcatheter Valve Replacement Procedure

Your doctor will determine the best approach for replacing your aortic or mitral valve, but the most common technique involves a small cut made in your leg. This is called the transfemoral approach.

1. You will be placed under general anesthesia (sleep medicine) or conscious sedation (medicine that helps you relax and block pain but you will remain awake).
2. A small incision will be made where your doctor will insert a short, hollow tube called a sheath.
3. Your new valve will be placed on the delivery system tube and squeezed on the balloon to make it small enough to fit through the sheath.
4. Once the valve is in the intended location it will be inflated, expanding it within your diseased bioprosthetic valve. The new valve will push the leaflets of your diseased valve aside. The frame of the new valve will use the failed bioprosthetic valve to secure itself in place.
5. Your doctor will make sure your new valve is working properly.

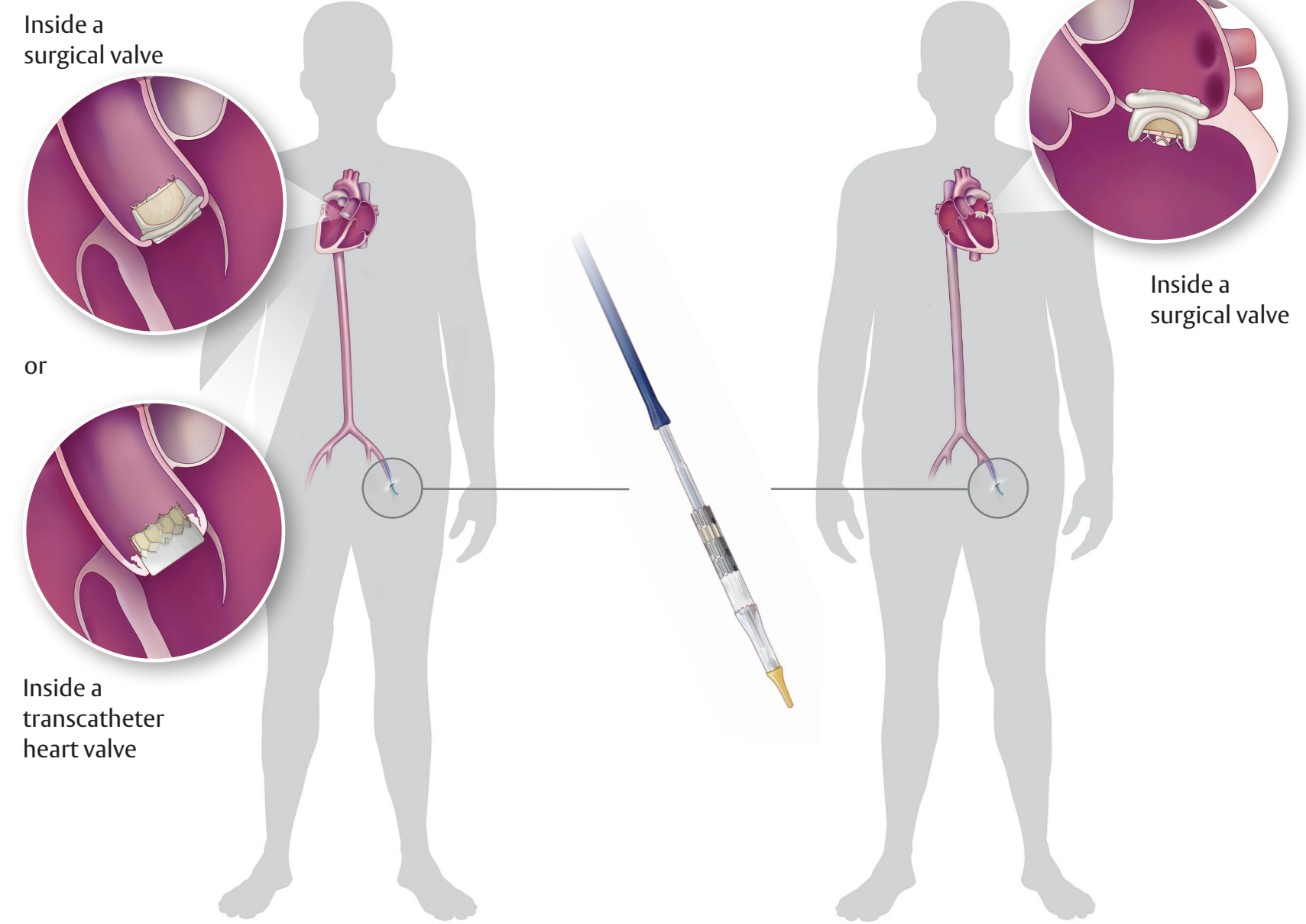


On average, the transcatheter procedure lasts about 1 2 hours.

Watch a video on the Edwards transcatheter procedure at [NewHeartValve.com/video](https://www.newheartvalve.com/video)



Aortic Replacement



Mitral Replacement

Average length of stay with this procedure:

5 days¹

compared to 7 days with open heart surgery

What Happens After the Transcatheter Valve Replacement Procedure?

After your procedure, you may spend a number of days in the hospital. Every patient is different in how they recover. Most patients should begin walking soon after their Edwards transcatheter valve procedure.

Before you leave the hospital, your doctor will discuss your aftercare plan with you. They will give you specific instructions to help you with your recovery. This may include a special diet, when to return to exercise, and any medicine you may need to take.

It is important to carefully follow your doctor's directions, especially if you need to take any blood thinning medication.

Transcatheter Valve Replacement Follow-Up Visits

Regular check-ups with your doctor are very important. You will probably be asked to return to your doctor to have your heart valve checked at 30 days and up to 10 years after your procedure.

However, call or see your doctor whenever you have questions or concerns about your health.

Your Edwards Lifesciences Implant Card

As you leave the hospital, your valve clinic coordinator or nurse should give you a temporary implant card.

A permanent card will be sent to you in approximately 6-8 weeks. This card has information about your Edwards heart valve. Share this card with all members of your healthcare team, including your dentist. It is important to share about your heart valve replacement before any medical, dental, or MRI (magnetic resonance imaging) procedures. If you need an MRI, tell your doctor that you have an Edwards heart valve.

Edwards Lifesciences® Implanted Device ID Card

SAMPLE PATIENT



Implanting Physician
SAMPLE PHYSICIAN
Hospital
SAMPLE HOSPITAL
CITY, STATE, COUNTRY ZIP CODE

Serial
xxxxxx

Model
9300TFX

Implant Date
DATE MONTH YEAR

Position
POSITION

Size
SIZE MM

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

For more information on your implant card, please go to Edwards.com

¹ Based on *The STS/ACC TVT Registry™



Clinical Data for Transcatheter-in-Surgical Valve Replacement

Edwards Transcatheter Replacement Clinical Data

The TVT Registry* collects safety and effectiveness data from hospitals in the US treating patients with transcatheter valve replacement.

Patients in the surgical valve replacement population received either a SAPIEN 3 valve or SAPIEN XT (an earlier generation) valve for heart disease associated with a failed surgical bioprosthetic aortic or mitral valve. They were determined to be at high or greater risk for open heart surgery.

There were 314 aortic valve in valve patients and 311 mitral valve in valve patients that were examined. If you are considering a transcatheter valve-in-surgical valve procedure, the data in the charts on this page could be what you would expect.

The frequency is shown as the number of patients out of every 100.

Transcatheter Valve in Aortic Surgical Valve Replacement		
	Discharge	Risk Within 30 Days
Death From Any Cause	3 out of 100	5 out of 100
Death From a Heart Related Cause	2 out of 100	3 out of 100
All Stroke	1 out of 100	1 out of 100
New Permanent Pacemaker	3 out of 100	3 out of 100
Major Vascular Complications	1 out of 100	1 out of 100
Heart Attack (Myocardial Infarction)	1 out of 100	1 out of 100

Transcatheter Valve in Mitral Surgical Valve Replacement		
	Discharge	Risk Within 30 Days
Death From Any Cause	6 out of 100	7 out of 100
Death From a Heart Related Cause	4 out of 100	5 out of 100
All Stroke	1 out of 100	1 out of 100
New Permanent Pacemaker	1 out of 100	1 out of 100
Major Vascular Complications	1 out of 100	1 out of 100
Heart Attack (Myocardial Infarction)	1 out of 100	1 out of 100

*The STS/ACC TVT Registry™ is the main repository for clinical data related to transcatheter aortic valve replacement (TAVR). The Registry, created by a collaboration between STS and the American College of Cardiology, monitors patient safety and real-world outcomes related to TAVR.

Clinical Data for Transcatheter-in-Transcatheter Aortic Valve Replacement

Transcatheter Valve in Transcatheter Aortic Valve Replacement		
	Risk Within 30 Days	Risk Within 1 Year
Death From Any Cause	6 out of 100	19 out of 100
Death From a Heart Related Cause	3 out of 100	6 out of 100
All Stroke	3 out of 100	3 out of 100
New Permanent Pacemaker	9 out of 100	11 out of 100
Major Vascular Complications	1 out of 100	1 out of 100
Heart Attack (Myocardial Infarction)	1 out of 100	4 out of 100

Patients in this data population received a SAPIEN 3 valve for heart disease associated with a failing transcatheter aortic valve. They were determined to be at high or greater risk for open heart surgery. There were 263 patients who underwent the transcatheter in transcatheter aortic valve (THV-in-THV) procedure. If you are considering a THV-in-THV procedure, the data in the chart above could be what you would expect.



What Are the Risks?

As with any medical procedure, there is a possibility of risks.

The most serious risks are:

- Death
- Stroke
- Serious damage to the arteries
- Serious bleeding
- Problems with the electrical pathway of your heart that requires a pacemaker

Edwards SAPIEN 3 and SAPIEN 3 Ultra Valves Cannot Be Used in People Who:

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

If the Edwards SAPIEN 3 or SAPIEN 3 Ultra valves are used in patients who cannot take blood thinners or have an active infection, it will not work correctly, which could make you feel very sick or even cause death.

Additional potential risks associated with the procedure include:

- Paralysis (loss of muscle function)
- Permanent disability
- Risks to your lungs
- Buildup or fluid in or around the lungs
- Risks to the heart:
 - Heart attack or heart failure
 - Heart that does not pump well
 - Irregular heartbeat possibly resulting in a permanent pacemaker
 - Severe bleeding in the heart or in the body that could require a transfusion or surgery
 - Injury to the heart, arteries, heart muscle or valves
 - Too much fluid around the heart
- Kidney function or failure
- Life-threatening infection
- Sudden loss of heart function

- Disruption or blockage of blood flow through the heart
- Formation of a blood clot
- Bleeding
- Emergency open heart surgery
- Mechanical failure of the delivery system and/or accessories
- Allergic reaction to anesthesia or dye
- Reoperation or additional open heart surgery
- False aneurysm
- Limited blood supply
- A decrease in red blood cells
- Abnormal lab values
- High or low blood pressure
- Valve movement after deployment requiring surgery
- Damage to the valve (e.g. wear, breakage, recurring aortic stenosis)
- Possible removal of valve
- Valve issues not related to structure (e.g. leakage, inappropriate sizing or positioning, blockage, excess tissue ingrowth, blood cell damage, etc.)
- Trouble breathing, fainting or dizziness
- Pain, infection or bleeding at incision site
- Weakness or inability to exercise
- Swelling
- Chest pain
- Heart murmur
- Fever



Warnings

- Younger patients, or patients with a disease that results in more calcium in their blood, may have early wear of their valve.
- Talk to your doctor if you have serious heart disease or are allergic to the materials used during the procedure: anesthesia, contrast media, chromium, nickel, molybdenum, manganese, copper, silicon, and plastics.
- X-ray used during the procedure may cause radiation injury to the skin.
- Transcatheter heart valve patients should stay on blood-thinning medicine and/or aspirin as recommended by their doctor. Patients who do not may be at increased risk of a stroke. Blood-thinning medication may increase the risk of bleeding in the brain (stroke).

How long your tissue valve will last depends on many patient factors and medical conditions. Follow all care instructions to ensure the best possible results. The Edwards SAPIEN 3 and SAPIEN 3 Ultra valves have been tested in a laboratory to mimic 5 years of use, without failure. Regular follow-ups will help your doctor know how your valve is working.

Precautions

- Patients who need a dental procedure should talk to their doctor about risk of infection and needing antibiotics
- Patients should be treated post-procedure for heart infection as a precaution

The safety and effectiveness of the transcatheter heart valve is not known for patients:

- Who have an aortic heart valve that has NO build-up of calcium
- Who have had previous heart valve replacement or repair
- Whose native mitral valve is calcified or leaking, or has Gorlin syndrome
- Who have a low white or red blood cell count, or other irregularities in the blood
- Who has an enlarged heart, with or without blockage
- Who have unusual ultrasound images of the heart that show possible irregularities, such as a blood clot
- Who have allergies to blood-thinning medications or the dye that is injected during the procedure
- Who have diseased or abnormally shaped vessels leading to the heart
- Whose femoral arteries in the legs are too diseased or too small for the delivery device
- Whose aortic valve leaflets have large pieces of calcium that may block the arteries that supply blood
- Whose previously implanted tissue valve is not securely in place or is damaged that could cause it to leak.
- Whose previously implanted valve could block a blood vessel caused from the leaflet partially detaching
- Your Heart Team will do tests to determine the exact size of the new valve you should receive and communicate what to expect

For More Information about the Edwards Transcatheter 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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