

Edwards Transcatheter Heart Valve Replacement

A guide for patients with a failing bioprosthetic valve or a failing native mitral valve with prosthetic ring

The Edwards SAPIEN 3 Transcatheter Heart Valves

Edwards

This patient booklet is for those who have a failing aortic or mitral bioprosthetic heart valve, or have a failing native mitral valve with a prosthetic ring.

The information in this booklet will help you understand more about a less invasive procedure called transcatheter valve replacement (also known as TAVR) and TAVR valves.

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



Table of Contents

Understanding The Heart.....3-4

Valve Replacement Options.....5

Deciding on the Right Treatment Option For You.....6

The Edwards SAPIEN 3 TAVR Valves.....7-8

The Edwards SAPIEN 3 TAVR Procedure.....9-10

After Your Edwards SAPIEN 3 TAVR Procedure.....11

Edwards TAVR Clinical Data.....12-14

Risks of the Edwards SAPIEN 3 TAVR Procedure.....15-16

Warnings and Precautions.....17-18

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 transcatheter valves enable treatment for patients whose bioprosthetic aortic or mitral valve is failing, or native mitral valve with a mitral prosthetic ring that
is failing.

To learn more, go to

NewHeartValve.com



Why You May Need Treatment To Help Heal Your Heart

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

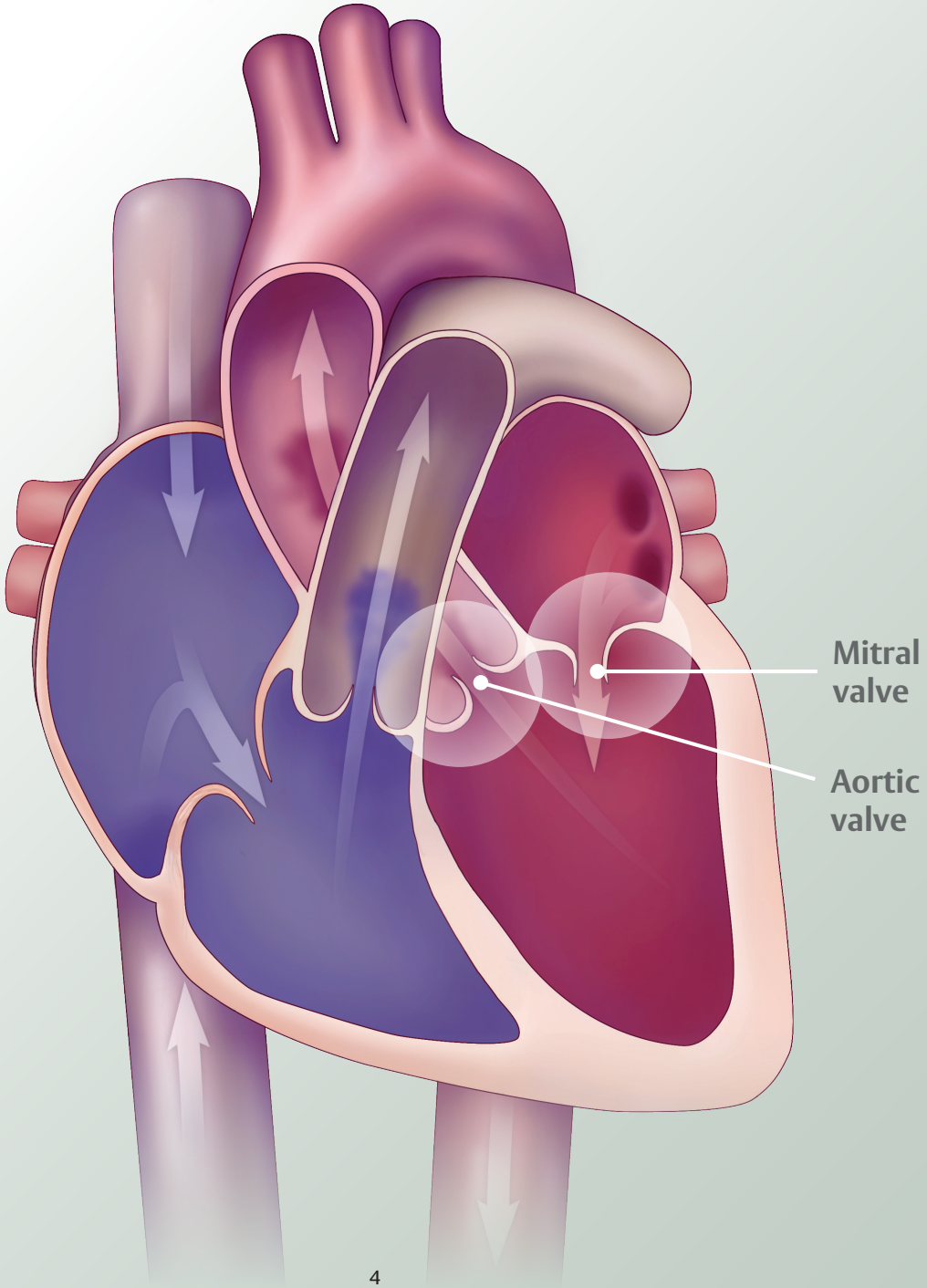
- **Stenosis**: when your heart valve narrows and does not open completely

  and/or

- **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


Mitral valve
Aortic valve

Understanding Your Treatment Options

If you have a **failing aortic bioprosthetic heart valve or a failing native mitral valve with a prosthetic ring** 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.

If you have a **failing mitral bioprosthetic heart valve** and your doctor has evaluated you as being at intermediate 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 or mitral stenosis, or regurgitation, 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, or a failing native mitral valve with a prosthetic ring, is where the doctor will open your chest and will completely remove the damaged valve or ring, then replace it with an artificial valve. The doctor may also choose to repair your valve or ring instead of removing the valve or ring. 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 or a failing native mitral valve with a prosthetic ring, sometimes referred to as “valve-in-valve” or “valve in ring,” is a less invasive approach for 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 a blood vessel to guide the heart valve up to your heart, and the valve is expanded into place. It does not remove your old failing prosthesis (valve or ring), but 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

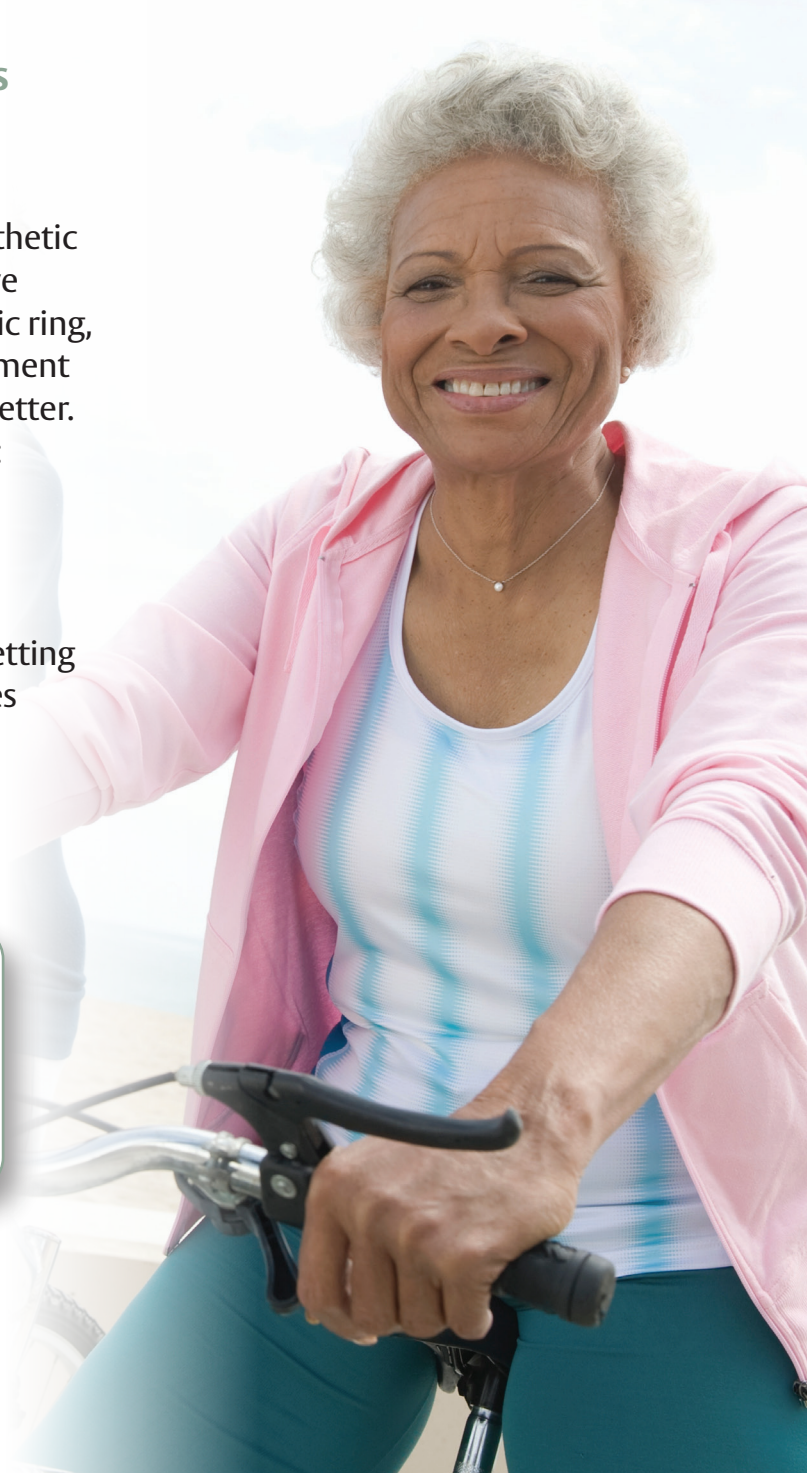
What Are the Benefits of Transcatheter Valve Replacement?

If you have a failing bioprosthetic heart valve, or a failing native mitral valve with a prosthetic ring, transcatheter valve replacement may help your heart work better. Other benefits may include:

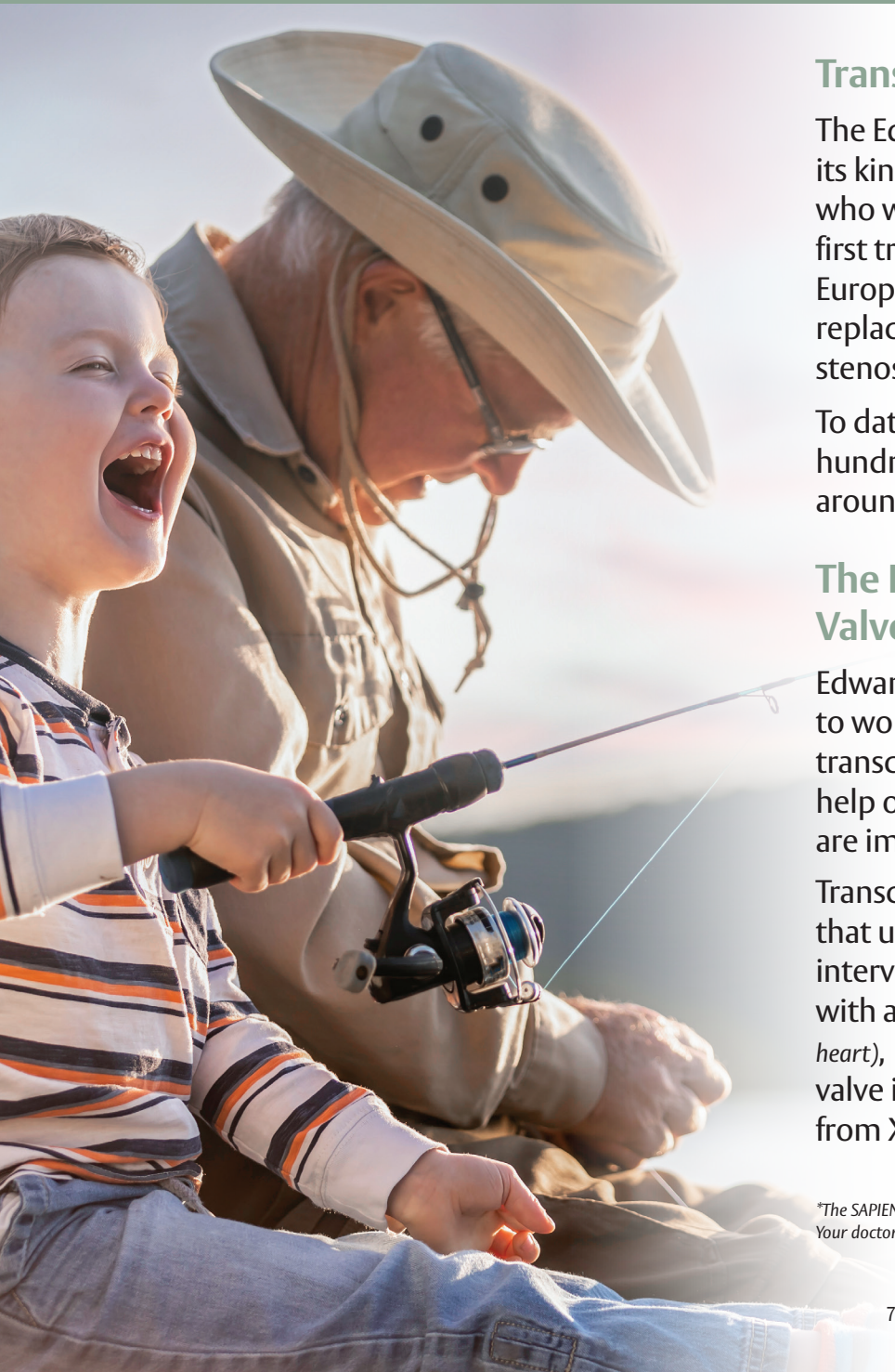
- Minimally invasive with minimal scarring
- Short hospital stay
- Short recovery time to getting back to everyday activities
- Relief of symptoms

Quality of Life Improvement:

Quality of life studies with the Edwards SAPIEN 3 TAVR* have shown patient health improvements within 30 days, including the ability to take care of themselves and participate in everyday activities.



**The SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA valves are commercially available in the United States. Your doctor will tell you which valve you will receive*



Transcatheter Valve Replacement

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 Transcatheter Heart Valves

Edwards Lifesciences transcatheter heart valves are designed to work like your native heart valve. The Edwards SAPIEN 3 transcatheter heart 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 SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA valves are commercially available in the United States. Your doctor will tell you which valve you will receive*

The Edwards SAPIEN 3 Transcatheter Heart Valves

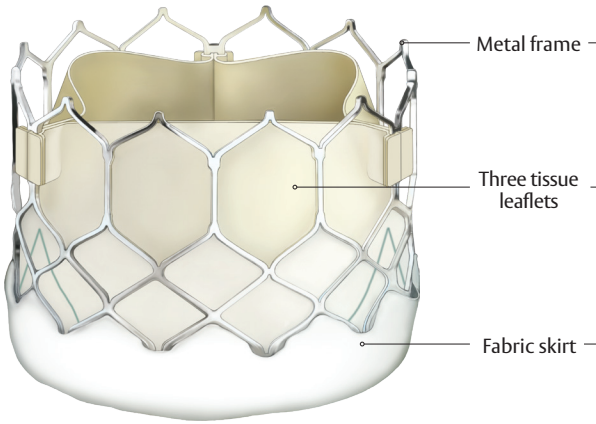
Edwards SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA transcatheter heart valves are a part of the latest technology of TAVR valves from Edwards Lifesciences.

The SAPIEN 3, SAPIEN 3 Ultra and SAPIEN 3 Ultra RESILIA 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 Edwards SAPIEN 3 Ultra RESILIA valve is made of RESILIA tissue. It is a bovine (cow) heart tissue that has been preserved with a special Edwards technology to reduce calcium build-up on the valve tissue. The special technology used on the SAPIEN 3 Ultra RESILIA valve blocks the calcium from depositing on the tissue. The RESILIA tissue has been shown in animal studies to significantly reduce calcium build-up over traditional valve tissues.[1]* Less calcium build-up could potentially allow the valve to last longer. An outer sealing skirt surrounds the bottom of all three valves, to help stop any possible leakage around the valve.

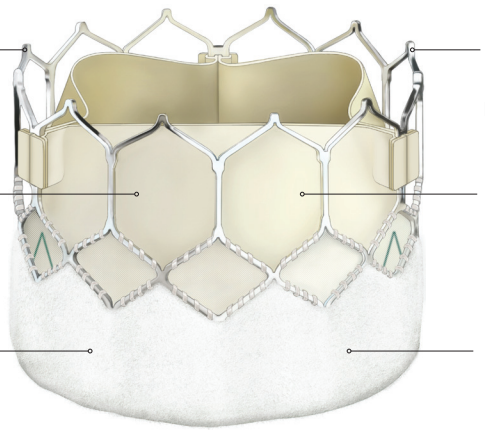
The valves are available in four sizes: 20, 23, 26, and 29 mm in diameter.

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

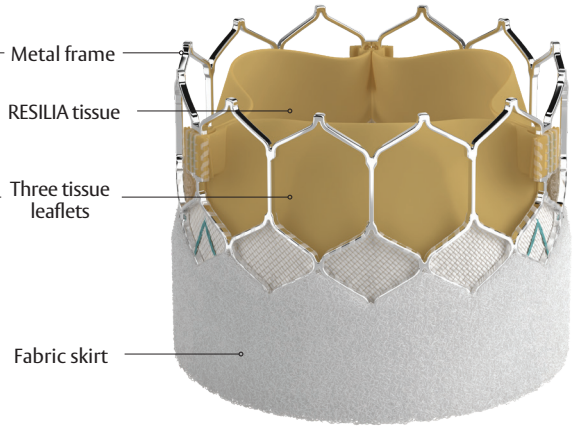
The Edwards SAPIEN 3 Valve



The Edwards SAPIEN 3 Ultra Valve



The Edwards SAPIEN 3 Ultra RESILIA Valve



Images are larger than actual valve size.

1. Flameng et al. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. J Thorac Cardiovasc Surg. 2015;149:340–5.
**RESILIA tissue has not been studied for long-term results in patients.*

The Transcatheter Valve Replacement Procedure

This section describes what happens during the 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 valve. The frame of the new valve will use the failing bioprosthetic valve or mitral prosthetic ring to secure itself in place.
5. Your doctor will make sure your new valve is working properly.

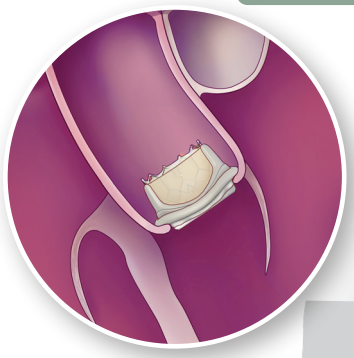


On average, the transcatheter procedure lasts about 1-2.5 hours.

Watch a video on the Edwards transcatheter procedure at NewHeartValve.com/video

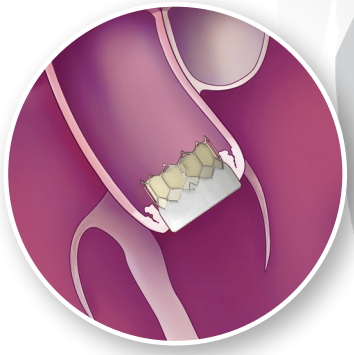
NewHeartValve.com

Aortic Replacement



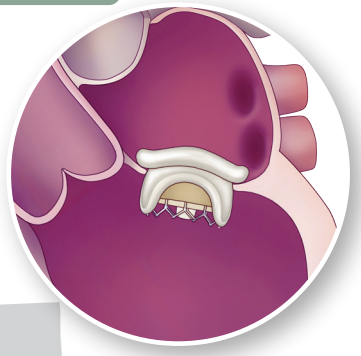
Inside a
surgical valve

or



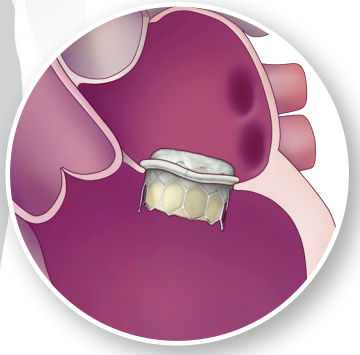
Inside a
transcatheter
heart valve

Mitral Replacement

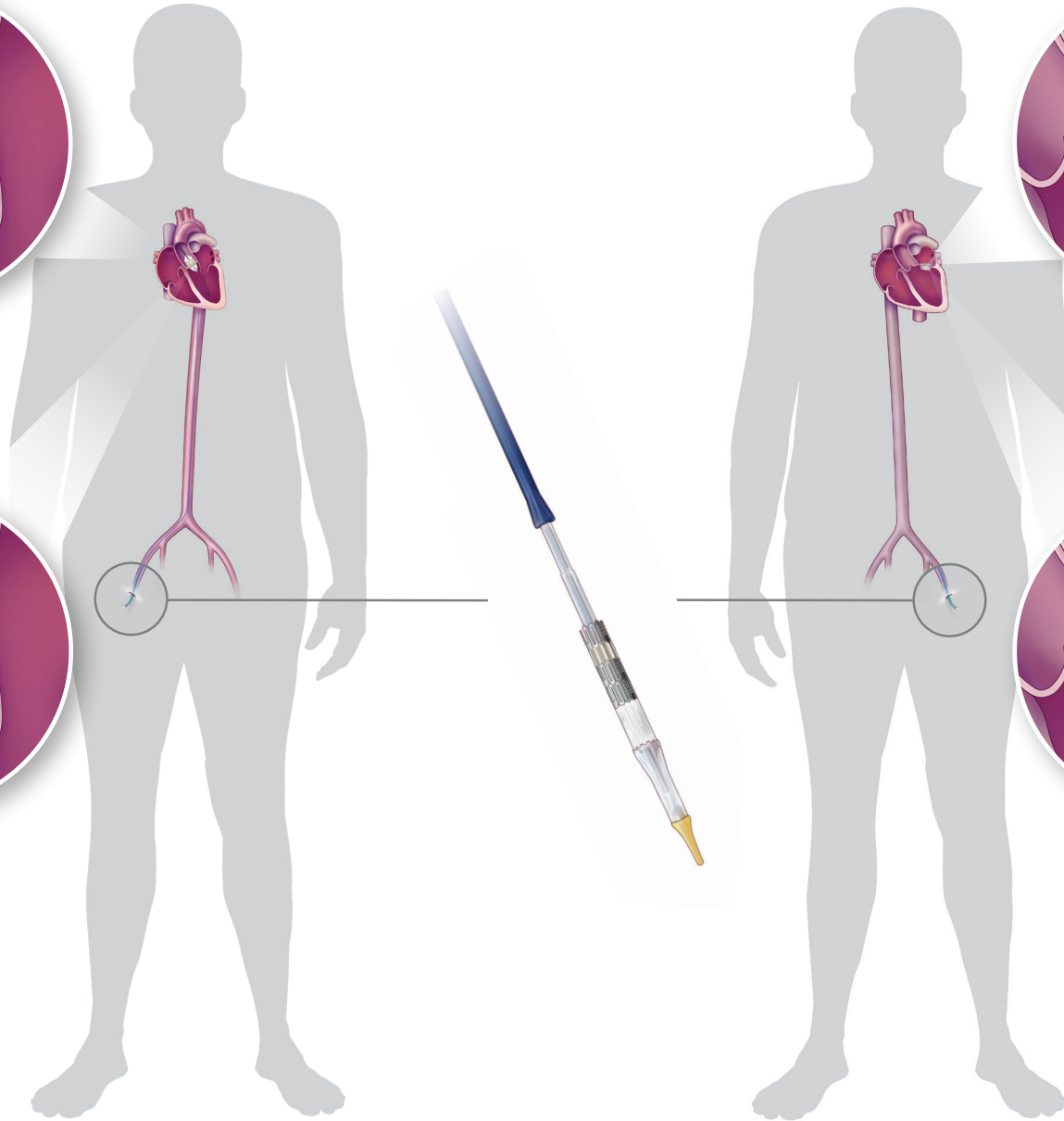


Inside a
surgical valve

or



Inside a
mitral ring



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 very soon after their 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.

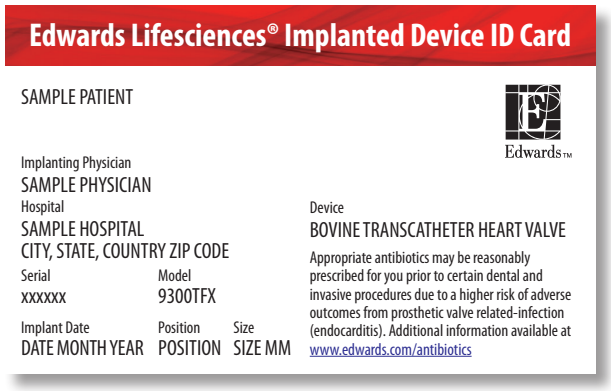
However, call or see your doctor whenever you have questions or concerns about your health.

Your Edwards Valve 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.

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

Example:
Edwards TAVR Valve Implant Card



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 – High Risk		
	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

Edwards Transcatheter Replacement Clinical Data

If you were to undergo replacement of your diseased aortic or mitral surgical valves, transcatheter aortic valve, or native mitral valve with a prosthetic ring, the risks you could expect are shown in the following tables. These risks were based on clinical data recorded in a national registry that collects data from hospitals treating patients with transcatheter heart valves and in a physician-led clinical study (for patients with a prosthetic mitral ring only).

Clinical Data



Transcatheter Valve in Transcatheter Aortic Valve Replacement

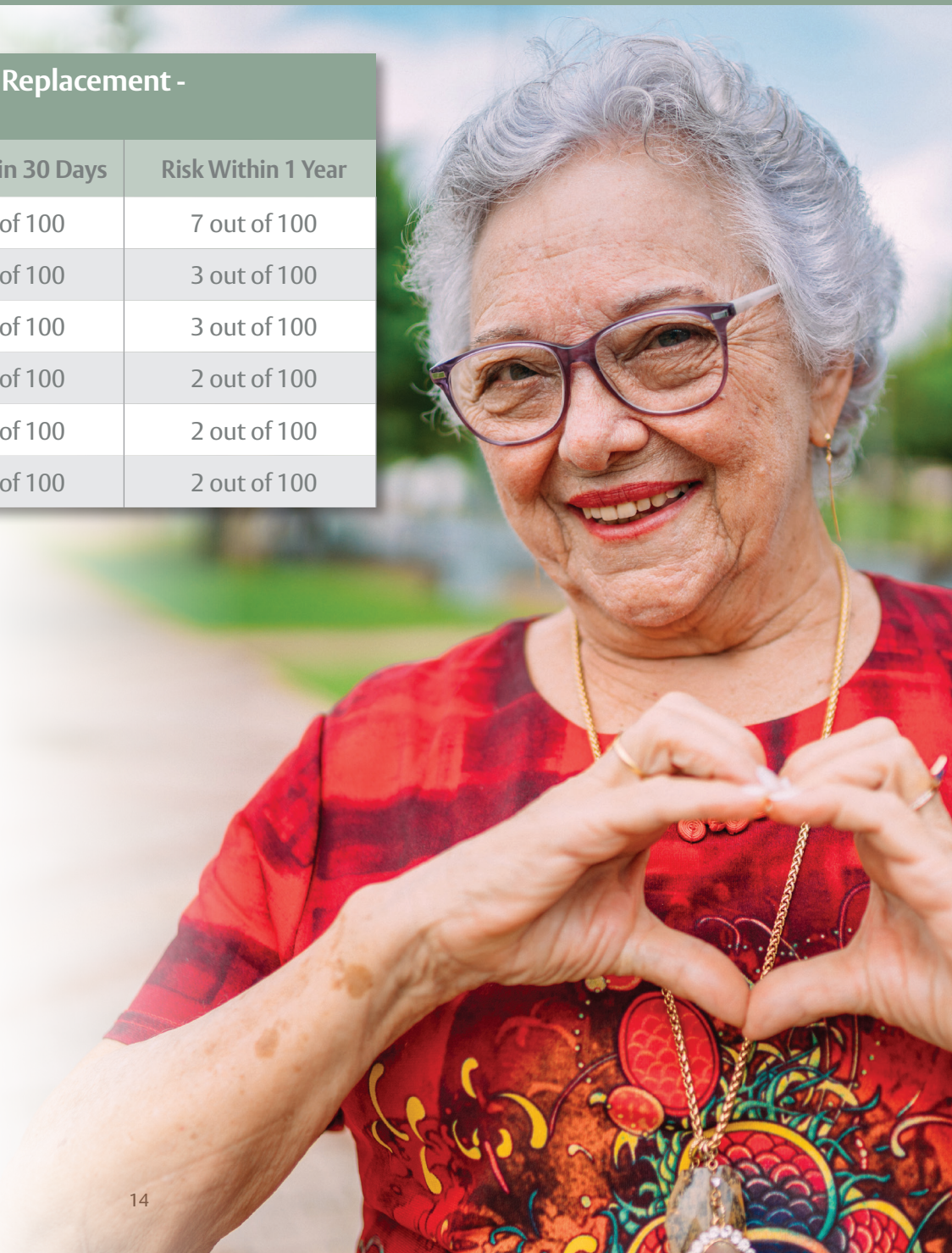
	Risk Within 30 Days	Risk Within 1 Year
Death From Any Cause	6 out of 100	19 out of 100
Death From a Heart Related Cause	3 out of 100	6 out of 100
All Stroke	3 out of 100	3 out of 100
New Permanent Pacemaker	9 out of 100	11 out of 100
Major Vascular Complications	1 out of 100	1 out of 100
Heart Attack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

Transcatheter Valve in Mitral Ring Replacement

	Risk Within 30 Days	Risk Within 1 Year
Death From Any Cause	11 out of 100	29 out of 100
Death From a Heart Related Cause	6 out of 100	10 out of 100
All Stroke	2 out of 100	2 out of 100
New Permanent Pacemaker	1 out of 100	3 out of 100
Major Vascular Complications	3 out of 100	3 out of 100
Heart Attack (Myocardial Infarction)	1 out of 100	2 out of 100

Clinical Data

Transcatheter Valve in Mitral Surgical Valve Replacement - Intermediate Risk		
	Risk within 30 Days	Risk Within 1 Year
Death From Any Cause	2 out of 100	7 out of 100
Death From a Heart Related Cause	1 out of 100	3 out of 100
All Stroke	1 out of 100	3 out of 100
New Permanent Pacemaker	1 out of 100	2 out of 100
Major Vascular Complications	2 out of 100	2 out of 100
Heart Attack (Myocardial Infarction)	1 out of 100	2 out of 100



Risks of the Transcatheter Valve Procedure

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

The Edwards SAPIEN 3 TAVR Family of Valves Cannot Be Used for People Who

- Cannot take blood thinning medications
- Have an active infection in the heart or elsewhere
- Have a mitral ring that is damaged and can no longer support the valve

If one of the Edwards SAPIEN 3 TAVR valve is used in patients who cannot take blood thinners, have an active infection, or have a mitral ring that is damaged and can no longer support the valve, 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 permeant 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 and Precautions



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 artificial 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 TAVR 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.

Your Heart Team will do tests to determine the exact size of the new valve you should receive and communicate what to expect.

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 of the transcatheter heart valve is not known for patients:

- Who have an aortic heart valve that has NO build-up of calcium
- Whose native mitral valve is calcified or leaking, or has Gorlin syndrome
- Who have a prosthetic ring in the tricuspid position
- 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 artificial valve or ring is not securely in place or is damaged that could cause it to leak
- Whose previously implanted valve or ring could block a blood vessel caused from the leaflet partially detaching

For More Information about the Edwards Transcatheter Valve Replacement Procedure:

Toll-free phone in the USA:
888-713-1564

Email address:
TAVR_Education@Edwards.com

Online:
www.NewHeartValve.com
www.TAVRbyEdwards.com
www.Edwards.com

Mail:
Edwards Lifesciences
One Edwards Way
Irvine, California 92614

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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