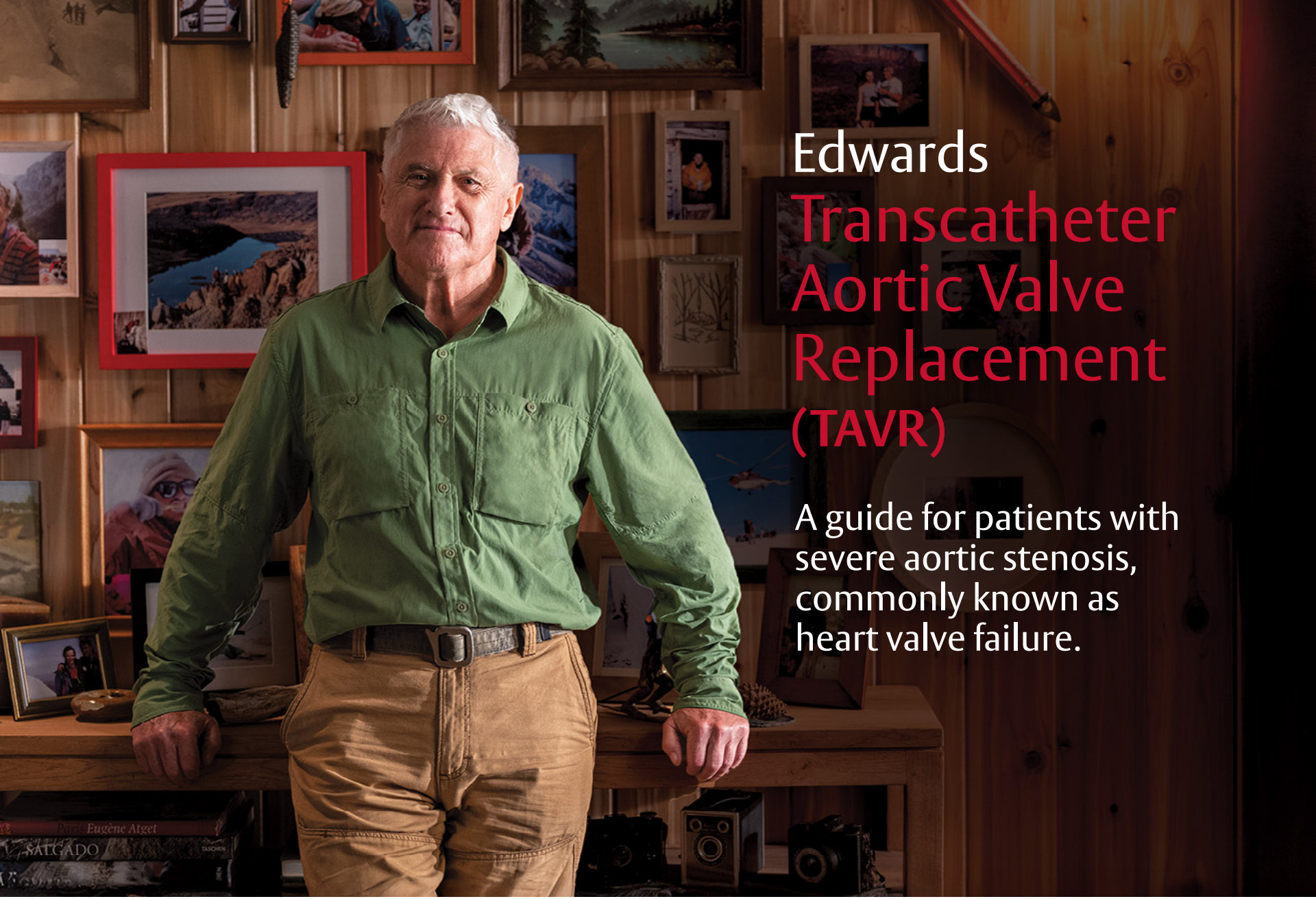


Edwards Transcatheter Aortic Valve Replacement (TAVR)

A guide for patients with severe aortic stenosis, commonly known as heart valve failure.

Transcatheter Aortic Valve Replacement (TAVR) with Edwards SAPIEN 3 Heart Valves

Edwards Lifesciences

This patient booklet is for those who are diagnosed with heart valve failure and need treatment.

This booklet will help you understand more about your disease and the importance of early treatment. It will also help you understand more about the minimally invasive procedure called transcatheter aortic valve replacement (TAVR).

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

Table of Contents

For more info visit TreatHeartValveFailure.com

This booklet is not intended to explain everything you need to know about your treatment options for heart valve failure or about the TAVR procedure. Please discuss any questions you have with your doctor.

Only a Heart Valve Team can decide which treatment option is right for you.

What Is Heart Valve Disease?

Your heart is a vital organ that depends on its four valves to help regulate blood flow throughout the body.

There are two problems that can occur in heart valves:

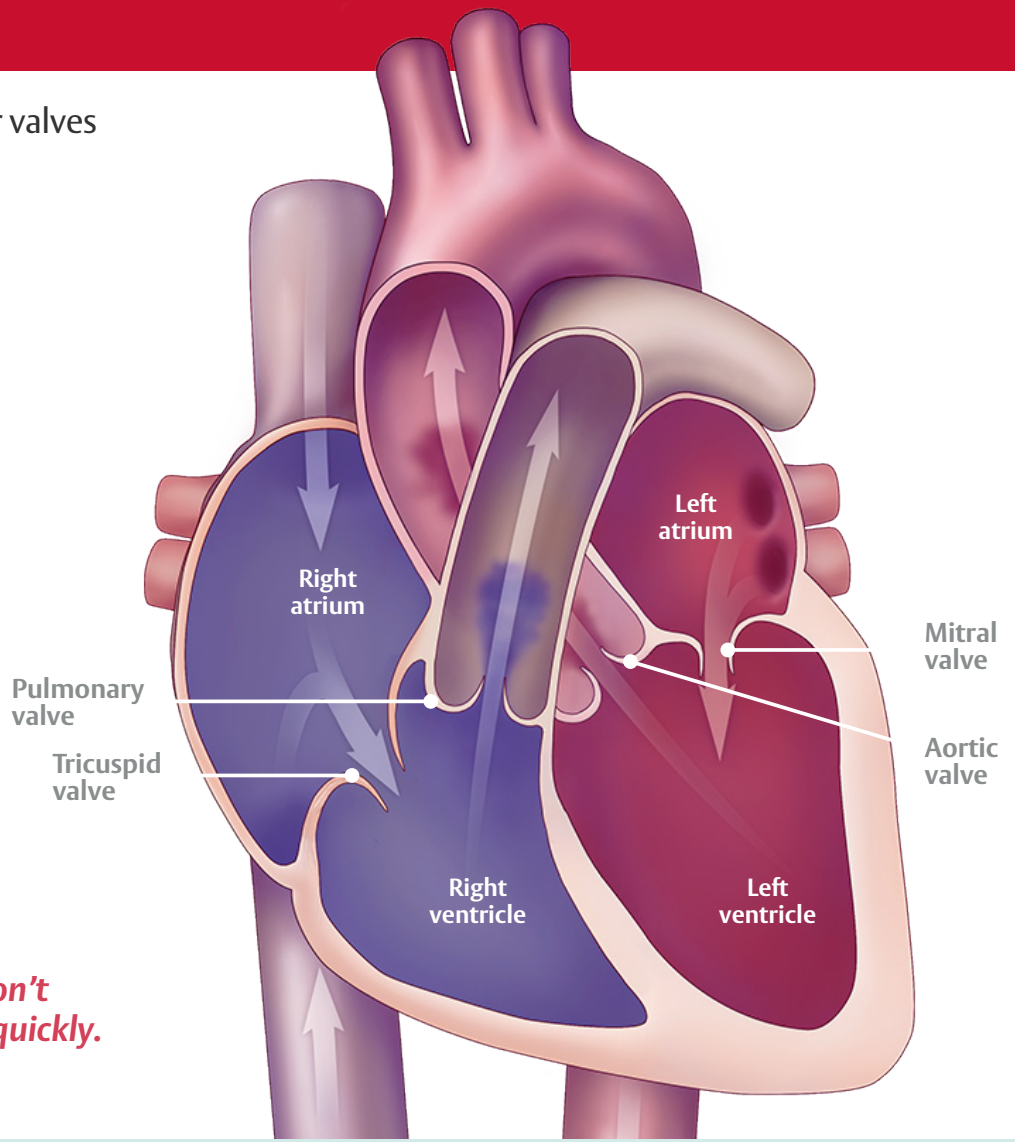
Stenosis: when your valve narrows and does not open completely

Regurgitation: when your valve does not close completely and blood can leak backwards

It is important that your valves are always working properly. 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

If your aortic valve stops working properly, it can contribute to damage in your heart. Even if you don't have symptoms, your quality of life could decline quickly.



Heart valve disease can affect any adult age 65 or older regardless of gender, race, or ZIP Code.

What Is Heart Valve Failure?

What is aortic stenosis?

Aortic stenosis is a type of heart valve disease that's common in people over 65.

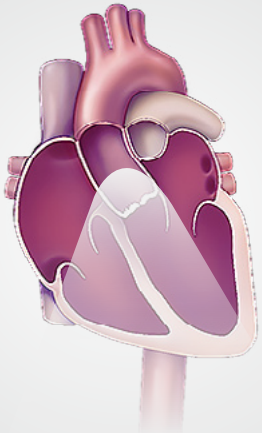
This disease occurs when the leaflets (or flaps) of the aortic valve become stiff due to calcium buildup over time, preventing them from properly opening and closing. When the leaflets don't fully open, your heart must work harder to push blood through the aortic valve to your body. Aortic stenosis is progressive, meaning it gets worse over time.

When aortic stenosis becomes severe, it is also known as heart valve failure.

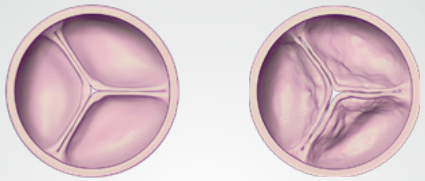
Heart valve failure is a dangerous and potentially deadly condition that doesn't always cause symptoms. Because it is progressive, it will get worse over time.

With heart valve failure, you may not experience symptoms. But if you do, they may include:

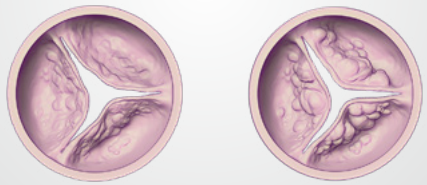
- Chest pain
- Rapid, fluttering heartbeat
- Fatigue
- Swollen ankles or feet
- Trouble breathing or feeling short of breath
- Feeling dizzy, lightheaded or even fainting
- Difficulty walking short distances
- Not doing activities you used to enjoy
- Difficulty sleeping or the need to sleep sitting up



Aortic stenosis is progressive. Calcium buildup makes leaflets in the valve become stiff over time.



Normal **Mild**



Moderate **Severe aortic stenosis** (heart valve failure)

If you have heart valve failure, talk to your doctor about treatment – *even if you don't have symptoms.*

Understanding Your Treatment Options

Medication

Medication will not cure heart valve failure. Your doctor may prescribe medication to control your symptoms. However, once symptoms appear, they will continue to get worse until you get your aortic valve replaced.

Transcatheter Aortic Valve Replacement (TAVR)

TAVR is a minimally invasive approach to aortic valve replacement compared to open heart surgery. With the TAVR 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 with a balloon and secured into place. It does not remove your old valve. It fits within the diseased valve.

Surgical Aortic Valve Replacement (SAVR)

Open heart surgery for aortic valve replacement 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 does the work of your heart and keeps the blood flowing throughout your body. Patients usually need to stay in the hospital for about a week before beginning a long period of recovery.

Even if you feel fine right now, **heart valve failure is a progressive disease.** That's why it's important to understand your options and get treatment before this condition has a chance to get worse.

TAVR Could Be the Right Treatment Option for You

Choosing the Best Treatment

Seeing a specialized doctor on a Heart Valve Team will make sure you will be checked 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

Only a Heart Valve Team can determine if TAVR is right for you.

What Are the Benefits of TAVR?

If you have heart valve failure, you will need to have your aortic valve replaced eventually. Experiencing symptoms? TAVR is a way to improve your quality of life. If you have heart valve failure without symptoms, TAVR is a way to prevent a rapid drop in your quality of life.

When compared to open heart surgery other benefits may include[*1]*:*

- ✓ Shorter hospital stay – most people go home the next day
- ✓ Minimally invasive, with minimal scarring
- ✓ Shorter recovery time to getting back to everyday activities
- ✓ Less pain and anxiety

Have questions about your treatment options?
Visit **TreatHeartValveFailure.com/Informed-Decision-Guide** to access the Informed Decision Guide to help you talk to your doctor about the best treatment option for you.

*The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and re-hospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.
PARTNER 3 Trial 5-Year Results in low-risk patients - Low rates of cardiovascular mortality through five years (5.5% SAPIEN 3 TAVR to 5.1% SAVR). Low rates of all-cause mortality through five years (10.1% SAPIEN 3 TAVR vs. 8.2% with SAVR). Low rates of disabling stroke through five years (2.9% SAPIEN 3 TAVR to 2.7% SAVR). Low rates of stroke through five years (5.8% SAPIEN 3 TAVR vs. 6.4% SAVR). Lower rates of rehospitalization with SAPIEN 3 TAVR through five years (13.7% vs. 17.4%).

1. PARTNER 3 Clinical Study Report SAPIEN 3 Low Risk (Study 2015-08). 2019.

The Edwards SAPIEN 3 Transcatheter Heart Valves*

For more than a decade, Edwards TAVR valves have been chosen by physicians for use in patients with heart valve failure who are experiencing symptoms. Edwards TAVR has been:

- Shown to have better outcomes than open heart surgery in low-risk patients after 1 year – and is equally effective after 5 years†
- Studied across patients of different ages, genders, and races
- Covered by Medicare for all eligible patients

Edwards TAVR is a safe and effective choice for all indicated patients. Over 1 million people worldwide have had TAVR with an Edwards valve, and this number continues to grow.

Hear from patients who have an Edwards TAVR valve.

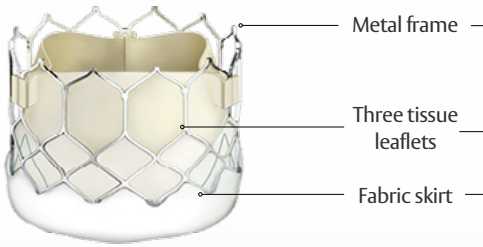
Visit TreatHeartValveFailure.com/PatientStories

*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.

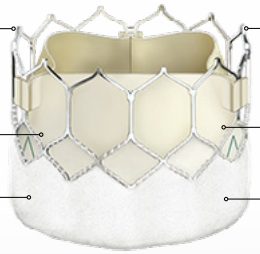
†The PARTNER 3 Trial, SAPIEN 3 TAVR proven superior to surgery on the primary endpoint of all-cause death, all stroke, and re-hospitalization (valve-related or procedure-related and including heart failure) at one year, and multiple pre-specified secondary endpoints in low risk patients.

PARTNER 3 Trial 5-Year Results in low-risk patients – Low rates of cardiovascular mortality through five years (5.5% SAPIEN 3 TAVR to 5.1% SAVR). Low rates of all-cause mortality through five years (10.1% SAPIEN 3 TAVR vs. 8.2% with SAVR). Low rates of disabling stroke through five years (2.9% SAPIEN 3 TAVR to 2.7% SAVR). Low rates of stroke through five years (5.8% SAPIEN 3 TAVR vs. 6.4% SAVR). Lower rates of rehospitalization with SAPIEN 3 TAVR through five years (13.7% vs. 17.4%).

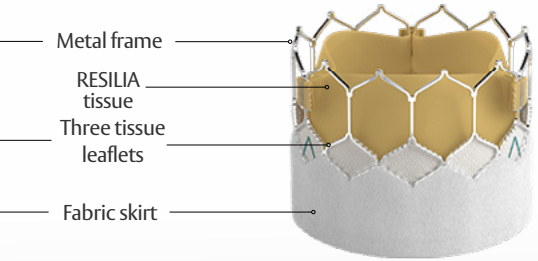
The Edwards SAPIEN 3 Valve



The Edwards SAPIEN 3 Ultra Valve



The Edwards SAPIEN 3 Ultra RESILIA Valve



The Edwards SAPIEN 3 Transcatheter Heart Valves

Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves are the latest TAVR valves from Edwards. They are made to work like the real aortic valve inside your body. The valve is inserted into your body through a small cut in your leg and expanded into place with the help of a balloon. It begins working as soon as it is implanted.

The SAPIEN 3 Ultra RESILIA valve is made of cow heart tissue that uses special technology to block calcium buildup.[1]

An outer sealing skirt surrounds the bottom of the valves to help stop any possible leakage.

Edwards TAVR valves are available in a wide range of sizes so that your doctor has the right size for your heart.

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

Long-term benefits in patients with symptoms who are at low risk may include:*

- Long-lasting durability of up to 5 years, similar to SAVR
- Excellent durability and performance in all types of people with both large and small valve sizes
- Low rates of needing to replace their valve a second time
- Low rates of stroke and high rates of survival comparable to SAVR

*PARTNER 3 Trial 5-Year Results in low-risk patients – Low rates of cardiovascular mortality through five years (5.5% SAPIEN 3 TAVR to 5.1% SAVR). Low rates of all-cause mortality through five years (10.1% SAPIEN 3 TAVR vs. 8.2% with SAVR). Low rates of disabling stroke through five years (2.9% SAPIEN 3 TAVR to 2.7% SAVR). Low rates of stroke through five years (5.8% SAPIEN 3 TAVR vs. 6.4% SAVR). Lower rates of rehospitalization with SAPIEN 3 TAVR through five years (13.7% vs. 17.4%).

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.

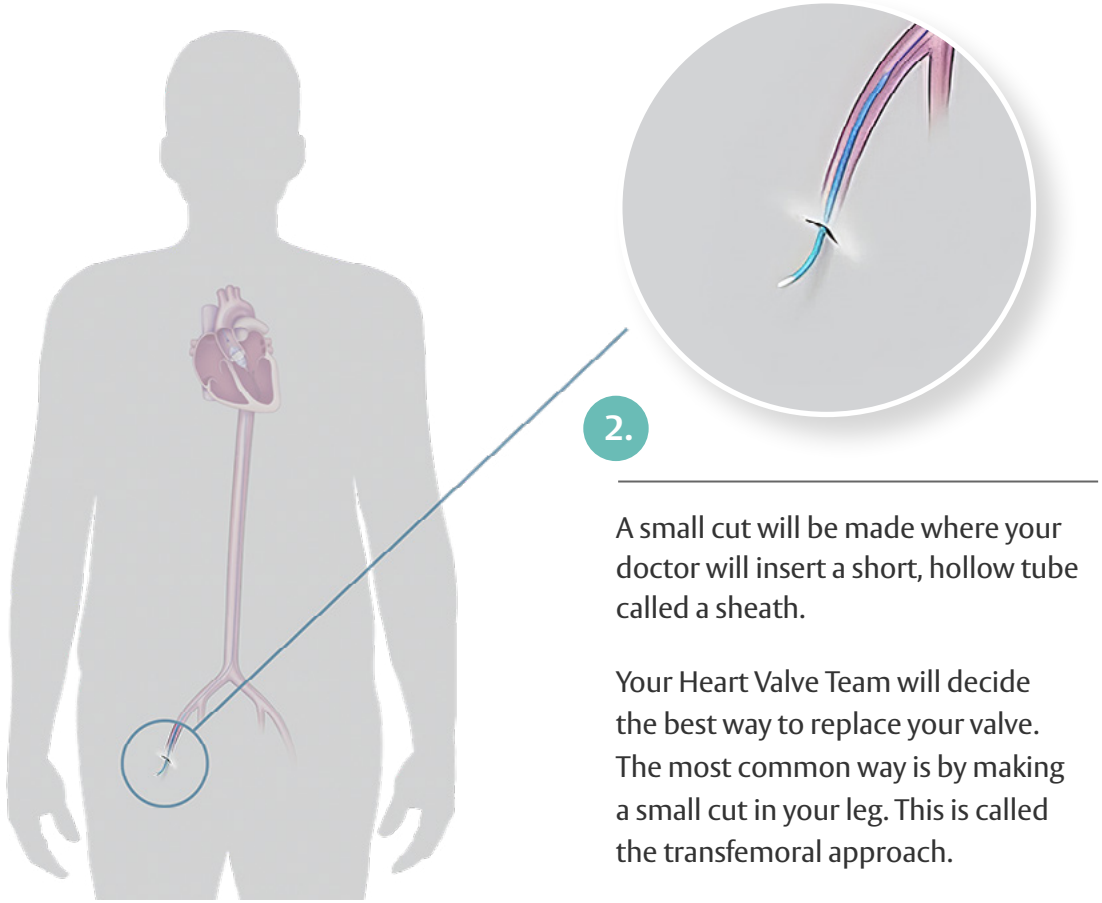
What to Expect With Your TAVR Procedure

What Do You Need to Do Before the Procedure?

Be sure to talk with your Heart Valve Team about any medication you may be taking. Your doctor may tell you to stop taking certain medications up to one week before the procedure. You should plan on getting a ride to and from the hospital, and arrange for help at home after the procedure.

Steps of the TAVR Procedure

TAVR allows a new valve to be inserted through a catheter.



1.

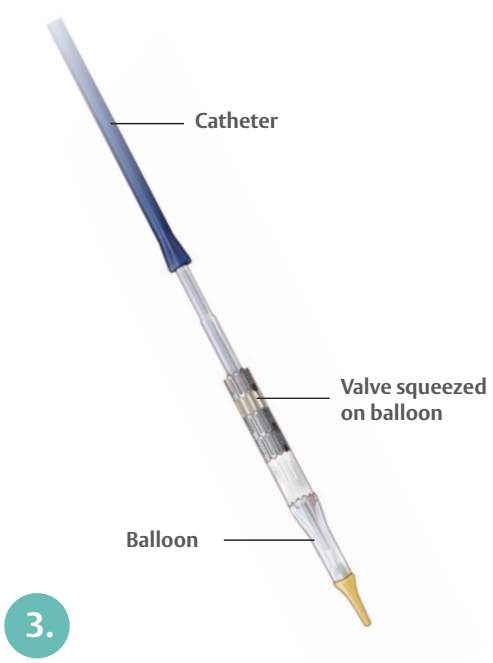
Before your procedure, you may be placed either under conscious sedation (medicine that helps you relax and block pain but you will remain awake) or general anesthesia (sleep medicine).

2.

A small cut will be made where your doctor will insert a short, hollow tube called a sheath.

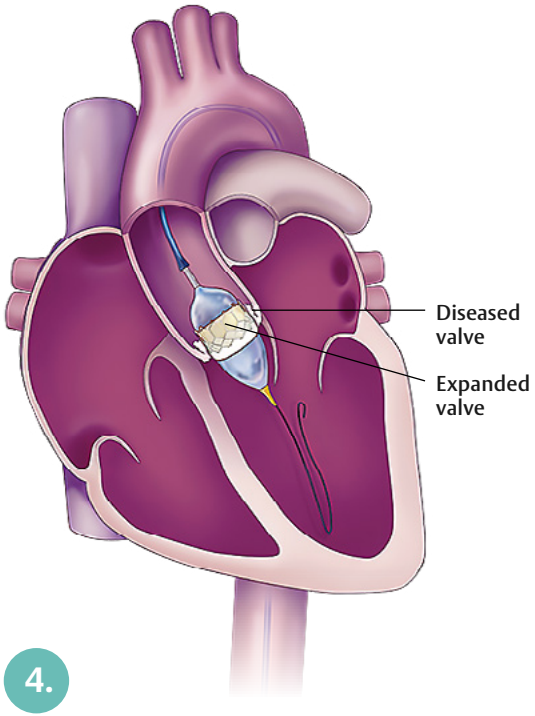
Your Heart Valve Team will decide the best way to replace your valve. The most common way is by making a small cut in your leg. This is called the transfemoral approach.

Watch this video and see a TAVR procedure.
Visit TreatHeartValveFailure.com/How-TAVR-Is-Performed



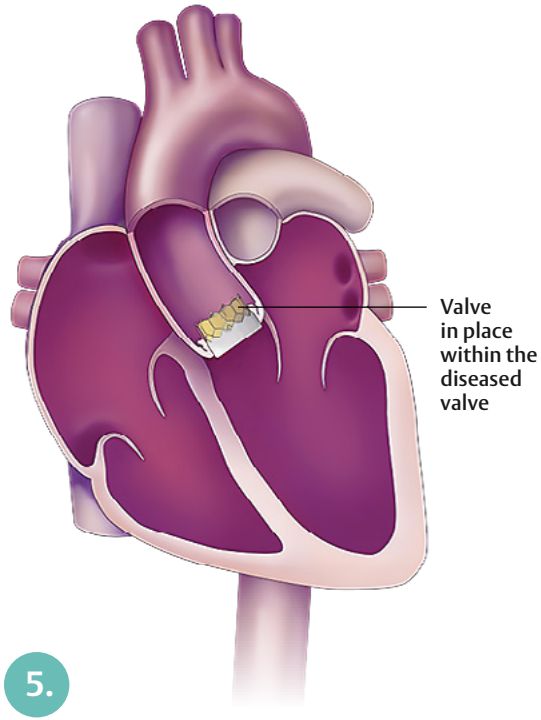
3.

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.

The balloon on the delivery system that carries the valve will be inflated, expanding the new valve within your diseased valve. The new valve will push the leaflets of your diseased valve aside. The frame of the new valve is strong and it will use the leaflets of your diseased valve to secure itself in place.



5.

Your doctor will make sure your new valve is working properly.

1 hour

On average, the TAVR procedure lasts about 1 hour, compared to 4 hours with open heart surgery.

What to Expect After Your TAVR Procedure

What Happens After the TAVR Procedure?

After your procedure, you may spend a day or two in the hospital. Every patient is different in how they recover. Most patients should begin walking very soon after their Edwards TAVR 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.

Be sure to follow your doctor's directions, especially if you need to take blood thinners.

TAVR Follow-Up Visits

Regular checkups with your doctor are very important. You will probably be asked to return to see your doctor for a 30-day checkup and every year for up to 10 years after your procedure.

Quality of Life Improvement

Quality of life means being able to do normal activities like taking care of yourself and doing things you like to do.

Patients who got Edwards TAVR before symptoms started avoided a large drop in quality of life compared to patients who waited to get TAVR.*

Patients who got Edwards TAVR after symptoms started had improvements in quality of life at 30 days compared to patients who had open heart surgery. At one year and continuing to 5 years there is no difference.

*In The EARLY TAVR Trial, receiving an Edwards TAVR valve before symptoms developed was superior to clinical surveillance for the primary outcome of death, stroke, or unplanned cardiovascular hospitalization (including aortic valve intervention/reintervention within 6 months), and for the secondary endpoints of favorable outcome.
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.

Most patients have a short recovery time and return home the next day.

Risks With the Edwards SAPIEN 3 THV and the TAVR Procedure

What Are the Risks of Edwards SAPIEN 3 TAVR?

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

The procedure's most serious risks are:

- Death
- Stroke
- Serious damage to the arteries
- Serious bleeding

The Edwards SAPIEN 3 TAVR Cannot Be Used in People Who:

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

If one of the Edwards SAPIEN 3 TAVR valves is used in the patients mentioned above, it will not work correctly, which could make you feel very sick or even cause death.

Additional potential risks associated with the procedure include:

- Heart attack
- Failure of your heart to pump enough blood to the body's organs
- Irregular heart rate
- Problems with the electrical pathway of your heart that requires a pacemaker
- 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
- Infection in your heart, blood, or other areas
- Injury to your blood vessels or heart that requires treatment
- Blocking, narrowing, or bulging of a blood vessel
- Blood clot, including a blood clot on the valve
- Trouble or inability to breathe
- Fluid buildup in your lungs
- Anemia
- Lab values that are not normal
- Abnormally high or low blood pressure
- Pain, inflammation, or fever
- Pain or changes at the incision site
- Problems with the valve (or accessories that do not allow it to work well) include, for example: wear, tear, or movement forward or backward from the normal position of the valve leaflets; calcium buildup on the leaflets; or a break in the frame
- Incorrect position of valve or valve movement
- Blood leak around the valve
- Additional cardiac surgery, vascular surgery, or intervention, including removal of the transcatheter heart valve

Risks (continued) and Warnings With the Edwards SAPIEN 3 THV and the TAVR Procedure

- Fainting or dizziness
- Weakness or trouble exercising
- Allergic reaction
- Inability to move (paralysis)
- Permanent disability
- Kidney failure
- Chest pain
- Damage to blood cells
- Repeat hospitalization
- Sudden or unexpected loss of heart function
- Injury to nerve
- Partial or complete blockage of coronary artery (artery supplying blood to the heart)
- Extra or unusual sound during heartbeat (heart murmur)

Warnings

- X-ray used during the procedure may cause radiation injury to the skin.
- 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 are allergic to any of the following: anesthesia, contrast media, chromium, nickel, molybdenum, manganese, copper, silicon, and plastics.

Precautions With the Edwards SAPIEN 3 THV and the TAVR Procedure

- TAVR patients should stay on blood-thinning medication 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).
- Patients who need a dental procedure should talk to their doctor about risk of infection and needing antibiotics.
- The safety of the transcatheter heart valve is not known for patients who have:
  - A heart that does not pump properly
  - An enlarged heart
- The Edwards TAVR valve has not been studied in patients:
  - Who have an aortic heart valve that has NO buildup of calcium
  - Who only have one leaflet (unicuspid) in their aortic valve
  - 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 have unusual ultrasound images of the heart that show possible irregularities, such as a blood clot
  - Who have allergies to blood-thinning medications
  - Who are allergic to dye that is injected during the procedure
  - Whose diseased aortic valve is too small or too big to fit the transcatheter heart valve
  - Who have diseased or abnormally shaped blood 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 to the heart

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 TAVR valves have been 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.

Edwards TAVR Clinical Data

This section shows the data from clinical trials of the Edwards TAVR valves. These trials included different types of patients to make sure that Edwards TAVR valves are effective and safe in those patients.

Your Heart Valve Team can help you understand which trial included the patients most like you.

Edwards TAVR Clinical Data for Patients Without Symptoms *(see page 17)*

The Edwards TAVR valves were studied in patients who had heart valve failure but did not have symptoms.

The rest of the trials included patients who had heart valve failure with symptoms.
These trials studied patients who had different levels of risk for undergoing open heart surgery.

Edwards TAVR Clinical Data for Low-Risk Patients *(see pages 18-19)*

Edwards TAVR valves were studied in patients at low risk for open heart surgery.

Edwards TAVR Clinical Data for Intermediate-Risk Patients *(see pages 20-21)*

Edwards TAVR valves were studied in patients at intermediate risk for open heart surgery.

Edwards TAVR Clinical Data for High-Risk and Inoperable Patients *(see page 22)*

Edwards TAVR valves were studied in patients who were either high-risk or too sick for open heart surgery.

Edwards TAVR Clinical Data for Bicuspid Patients *(see page 23)*

Edwards TAVR valves were also studied in patients who were born with a bicuspid aortic valve. This means their valve has two leaflets or flaps instead of the normal three.

Please see each trial description for more details about how the trial was done, and to see the results of the trial.

Edwards TAVR Clinical Data for Patients Without Symptoms

The EARLY TAVR Study

The risks with the procedure may depend on your overall health. If you have heart valve failure without symptoms, the clinical data shown in this chart could be what you would expect.

The SAPIEN 3 valve was studied in about 900 patients without symptoms, mostly in the U.S.

Patients were treated at random with either Edwards TAVR or clinical surveillance (monitoring by a doctor). With time, many of the clinical surveillance patients also received a valve.

These patients were checked at 1 year and 2 years. They will continue to be followed for 5 years for patients who had their valve replaced and 10 years for those who didn't.

EARLY TAVR Clinical Data		
	TAVR Before Symptoms Risk Within 2 Years	Clinical Surveillance Risk Within 2 Years
Death From Any Cause	4 out of 100	3 out of 100
Hospitalization From Heart Related Cause	17 out of 100	73 out of 100
Stroke	3 out of 100	4 out of 100
New Permanent Pacemaker	9 out of 100	8 out of 100

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

Early treatment with Edwards TAVR may prevent:

- Rapid drop in quality of life
- Start of heart valve failure symptoms
- Being hospitalized unexpectedly because of heart problems

Edwards TAVR Clinical Data for Low-Risk Patients

The PARTNER 3 Low-Risk Study

The risks with the procedure may depend on your overall health. If you have symptoms and are at low risk for open heart surgery, the clinical data shown in these charts could be what you would expect.

The SAPIEN 3 valve was studied in about 1,000 patients with symptoms, mostly in the U.S., who were at low risk for open heart surgery. Patients were treated at random with Edwards TAVR or open heart surgery (SAVR).

Patients were checked at 30 days, 1 year, and 5 years and will continue to be followed every year for 10 years.

Low-Risk Clinical Data – TAVR

TAVR Patients	Risk Within 30 Days	Risk Within 1 Year	Risk Within 5 Years
Death From Any Cause	1 out of 100	1 out of 100	11 out of 100
Death From Heart Related Cause	1 out of 100	1 out of 100	5 out of 100
Disabling Stroke	0 out of 100	1 out of 100	3 out of 100
New Permanent Pacemaker	7 out of 100	8 out of 100	N/A
Life-Threatening or Disabling Bleeding	2 out of 100	3 out of 100	N/A
Major Vascular Complications	3 out of 100	3 out of 100	N/A
Heart Attack (Myocardial Infarction)	1 out of 100	2 out of 100	N/A

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

TAVR Patients Treated With Small Valve Sizes

- 32 out of 100 TAVR patients were treated with the smallest valve sizes (20 & 23 mm).
- 77 out of 100 TAVR patients who received the smallest valve sizes were women.
- Death from any cause for the smallest valve sizes was 2 out of 100 TAVR patients at one year, and 9 out of 100 at 5 years.

Low-Risk Clinical Data – Open Heart Surgery			
SAVR Patients	Risk Within 30 Days	Risk Within 1 Year	Risk Within 5 Years
Death From Any Cause	2 out of 100	3 out of 100	9 out of 100
Death From Heart Related Cause	1 out of 100	2 out of 100	6 out of 100
Disabling Stroke	1 out of 100	2 out of 100	3 out of 100
New Permanent Pacemaker	4 out of 100	6 out of 100	N/A
Life-Threatening or Disabling Bleeding	12 out of 100	13 out of 100	N/A
Major Vascular Complications	2 out of 100	2 out of 100	N/A
Heart Attack (Myocardial Infarction)	2 out of 100	3 out of 100	N/A

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

SAVR Patients Treated With Small Valve Sizes

- 57 out of 100 SAVR patients were treated with the smallest valve sizes (19, 21 & 23 mm).
- 48 out of 100 SAVR patients who received the smallest valve sizes were women.
- Death from any cause for the smallest valve sizes was 3 out of 100 SAVR patients at one year and 11 out of 100 at 5 years.

Edwards TAVR Clinical Data for Intermediate-Risk Patients

The SAPIEN 3 Ultra Study

The risks with the procedure may depend on your overall health. If you have symptoms and are at intermediate risk for open heart surgery, the clinical data shown in these charts could be what you would expect.

The SAPIEN 3 Ultra valve was studied in about 100 patients with symptoms, mostly in the U.S., who were at intermediate risk for open heart surgery.

Intermediate-Risk Clinical Data			
SAPIEN 3 Ultra Valve Patients	Risk at Discharge From Hospital	Risk Within 30 Days	Risk Within 5 Years
Death From Any Cause	1 out of 100	1 out of 100	30 out of 100
Death From Heart Related Cause	0 out of 100	0 out of 100	15 out of 100
All Stroke	2 out of 100	3 out of 100	6 out of 100
New Permanent Pacemaker	10 out of 100	11 out of 100	17 out of 100
Major Vascular Complications	2 out of 100	2 out of 100	2 out of 100
Heart Attack (Myocardial Infarction)	0 out of 100	0 out of 100	6 out of 100

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

The PARTNER II Intermediate-Risk Study

The risks with the procedure may depend on your overall health. If you have symptoms and are at intermediate risk for open heart surgery, the clinical data shown in this chart could be what you would expect.

The SAPIEN 3 valve was studied in about 1,000 patients with symptoms, mostly in the U.S., who were at intermediate risk for open heart surgery.

Patients were checked at 30 days, 1 year, and 5 years. They will continue to be followed every year for 10 years.

Intermediate-Risk Clinical Data

SAPIEN 3 Valve Patients	TAVR			Open Heart Surgery		
	Risk Within 30 Days	Risk Within 1 Year	Risk Within 5 Years	Risk Within 30 Days	Risk Within 1 Year	Risk Within 5 Years
Death From Any Cause	2 out of 100	8 out of 100	42 out of 100	4 out of 100	13 out of 100	43 out of 100
Death From Heart Related Cause	1 out of 100	5 out of 100	26 out of 100	3 out of 100	8 out of 100	28 out of 100
Disabling Stroke	1 out of 100	3 out of 100	8 out of 100	5 out of 100	6 out of 100	10 out of 100
New Permanent Pacemaker	11 out of 100	N/A	N/A	8 out of 100	N/A	N/A
Life-Threatening or Disabling Bleeding	5 out of 100	N/A	N/A	47 out of 100	N/A	N/A
Major Vascular Complications	7 out of 100	N/A	N/A	6 out of 100	N/A	N/A
Heart Attack (Myocardial Infarction)	1 out of 100	N/A	N/A	2 out of 100	N/A	N/A

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

Edwards TAVR Clinical Data for High-Risk and Inoperable Patients

The PARTNER II High-Risk/Inoperable Study

The risks with the procedure may depend on your overall health. If you have symptoms and are at high risk or cannot have open heart surgery, the clinical data shown in this chart could be what you would expect.

The SAPIEN 3 valve was studied in approximately 600 U.S. patients with symptoms that were either high risk or too sick for open heart surgery. Patients were checked at 30 days, 1 year, and 5 years after the procedure.

High-Risk and Inoperable Clinical Data			
TAVR Patients	Risk Within 30 Days From TAVR	Risk Within 1 Year From TAVR	Risk Within 5 Years From TAVR
Death From Any Cause	2 out of 100	14 out of 100	62 out of 100
Death From Heart Related Cause	1 out of 100	8 out of 100	44 out of 100
All Stroke	2 out of 100	4 out of 100	15 out of 100
New Permanent Pacemaker	14 out of 100	17 out of 100	N/A
Life-Threatening or Disabling Bleeding	6 out of 100	N/A	N/A
Major Vascular Complications	6 out of 100	N/A	N/A
Heart Attack (Myocardial Infarction)	1 out of 100	3 out of 100	N/A

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

Edwards TAVR Clinical Data for Bicuspid Patients

Clinical Data for Bicuspid Patients

The risks with the procedure may depend on your overall health. If you have a bicuspid aortic valve (a valve with two leaflets), the clinical data shown in these charts could be what you would expect.

The SAPIEN 3 valve was studied in about 600 patients in the U.S. who had symptoms and were at low risk or above for open heart surgery. Patients were checked at 30 days and 1 year and will continue to be followed every year for 10 years.

Bicuspid Aortic Valve High-Risk and Inoperable Clinical Data

	Risk Within 30 Days From TAVR	Risk Within 1 Year From TAVR
Death From Any Cause	3 out of 100	11 out of 100
Death From Heart Related Cause	2 out of 100	3 out of 100
All Stroke	2 out of 100	3 out of 100
Aortic Valve Reintervention or Reoperation	1 out of 100	1 out of 100

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

Bicuspid Aortic Valve Low-Risk Clinical Data

	Risk Within 30 Days From TAVR	Risk Within 1 Year From TAVR
Death From Any Cause	0 out of 100	2 out of 100
Death From Heart Related Cause	0 out of 100	2 out of 100
All Stroke	3 out of 100	3 out of 100
Aortic Valve Reintervention or Reoperation	0 out of 100	0 out of 100

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

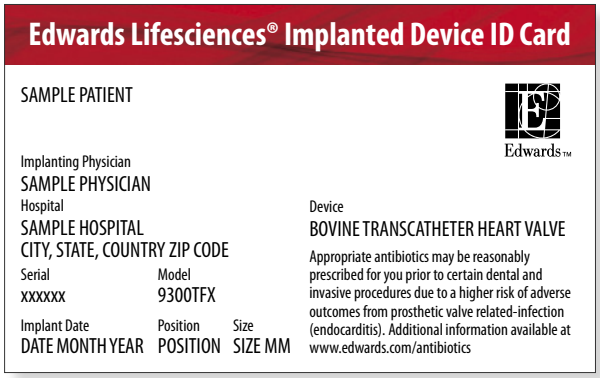
Your Implant Registry Card

Your Edwards TAVR 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 TAVR heart valve. Share this card with all members of your healthcare team, including your dentist. It is important to share information 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 TAVR heart valve.

Example:

Edwards SAPIEN 3 TAVR Valve Implant Card



For more information on your implant card, email the Patient Support Center at patient_support@edwards.com

Resources

Helpful resources just for you

Below you will find free resources that are available for you and your loved ones to better understand heart valve failure and the TAVR procedure.

General resources

For information on heart valve failure and TAVR, along with patient stories, go to **TreatHeartValveFailure.com/Resources**

Informed Decision Guide

Use the Informed Decision Guide questionnaire to help you prepare to talk with your doctor about your treatment options. Visit **TreatHeartValveFailure.com/Informed-Decision-Guide**

Caregiver resources

For caregiver support, visit the Family Caregiver Alliance at **caregiver.org**

Financial resources

If you need free professional assistance to help navigate insurance and reimbursement, visit **structuralheart.pafcareline.org** or call **(800) 532-5274**

Patient support line

Figuring out the next steps in treating heart valve failure may feel overwhelming. The Edwards Patient Team is here to support you. For more information, please call **(888) 713-1564**

Join Heart Valve Strong

Sign up to get tools and resources to help you speak up and take action.

TreatHeartValveFailure.com/Sign-Up

This guide is meant to help you better understand your disease and the minimally invasive procedure called transcatheter aortic valve replacement (TAVR). If you have been diagnosed with heart valve failure, TAVR may be an option for you.

Edwards TAVR:

- To date, more than 1 million people worldwide have had Edwards TAVR.
- On average, the TAVR procedure lasts about 1 hour, compared to 4 hours with open heart surgery.
- Most patients have a short recovery time and return home the next day.

Be sure to ask your Heart Valve Team to explain all of your treatment options and the possible risks and benefits of each. Only a Heart Valve Team can tell you if TAVR is right for you.

For More Information on Edwards SAPIEN 3 TAVR:

Call toll-free in the USA

(888) 713-1564

Email

TAVR_Education@edwards.com

Mail

Edwards Lifesciences
One Edwards Way
Irvine, California 92614

Online

TreatHeartValveFailure.com

Edwards.com

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • +1.949.250.2500 • +1.800.424.3278 • edwards.com

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