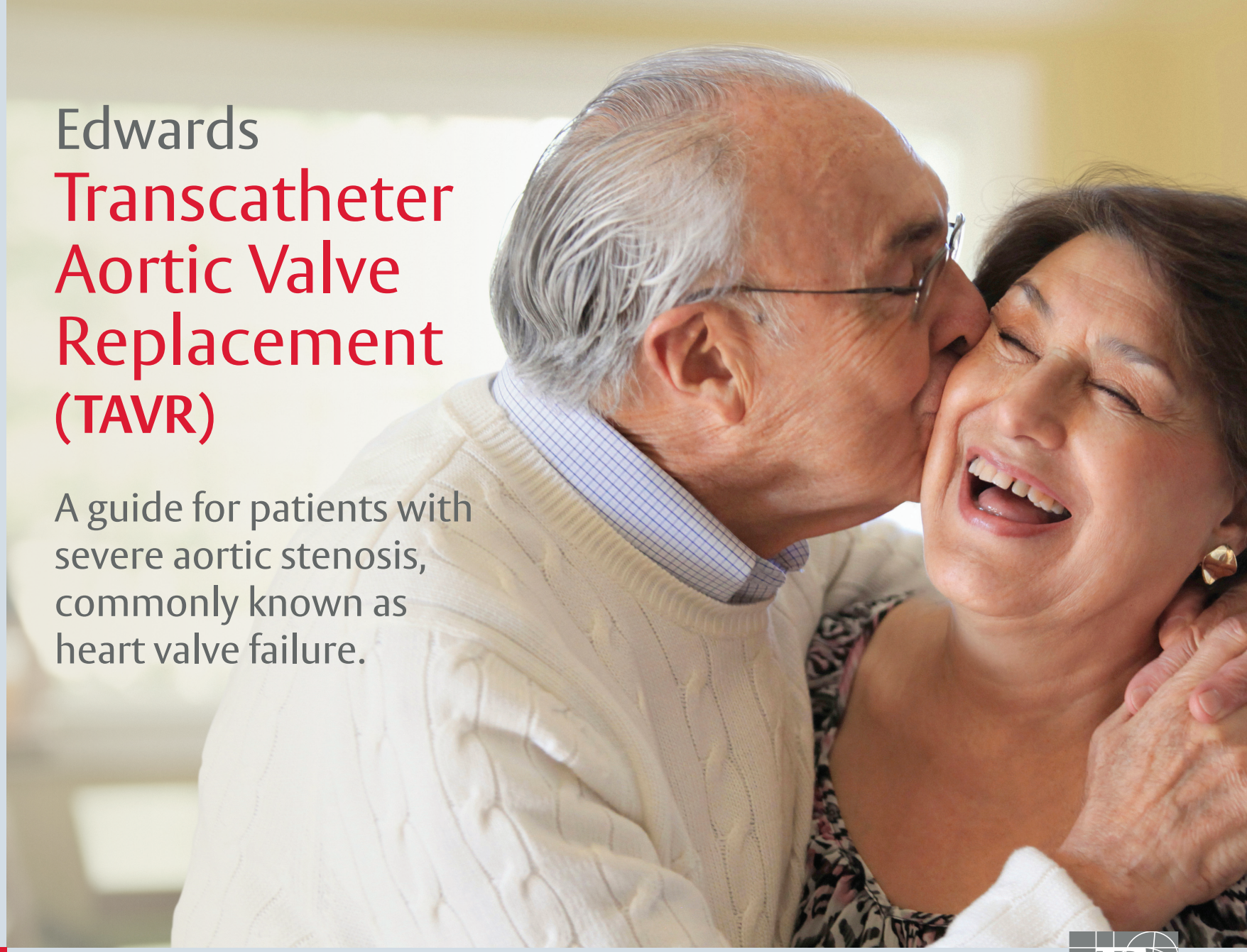


Edwards Transcatheter Aortic Valve Replacement (TAVR)

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

The Edwards SAPIEN 3 Transcatheter Heart Valves

Edwards

This patient booklet is for those who are suffering from severe aortic stenosis (heart valve failure) and need treatment.

The information in this booklet will help you understand more about your diagnosis, your disease, and a less invasive procedure called transcatheter aortic valve replacement (TAVR).

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

Table of Contents

This booklet is not intended to explain everything you need to know about your treatment options for aortic stenosis or about the TAVR procedure.

Please discuss any questions you have with your doctor.

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

Understanding The Heart

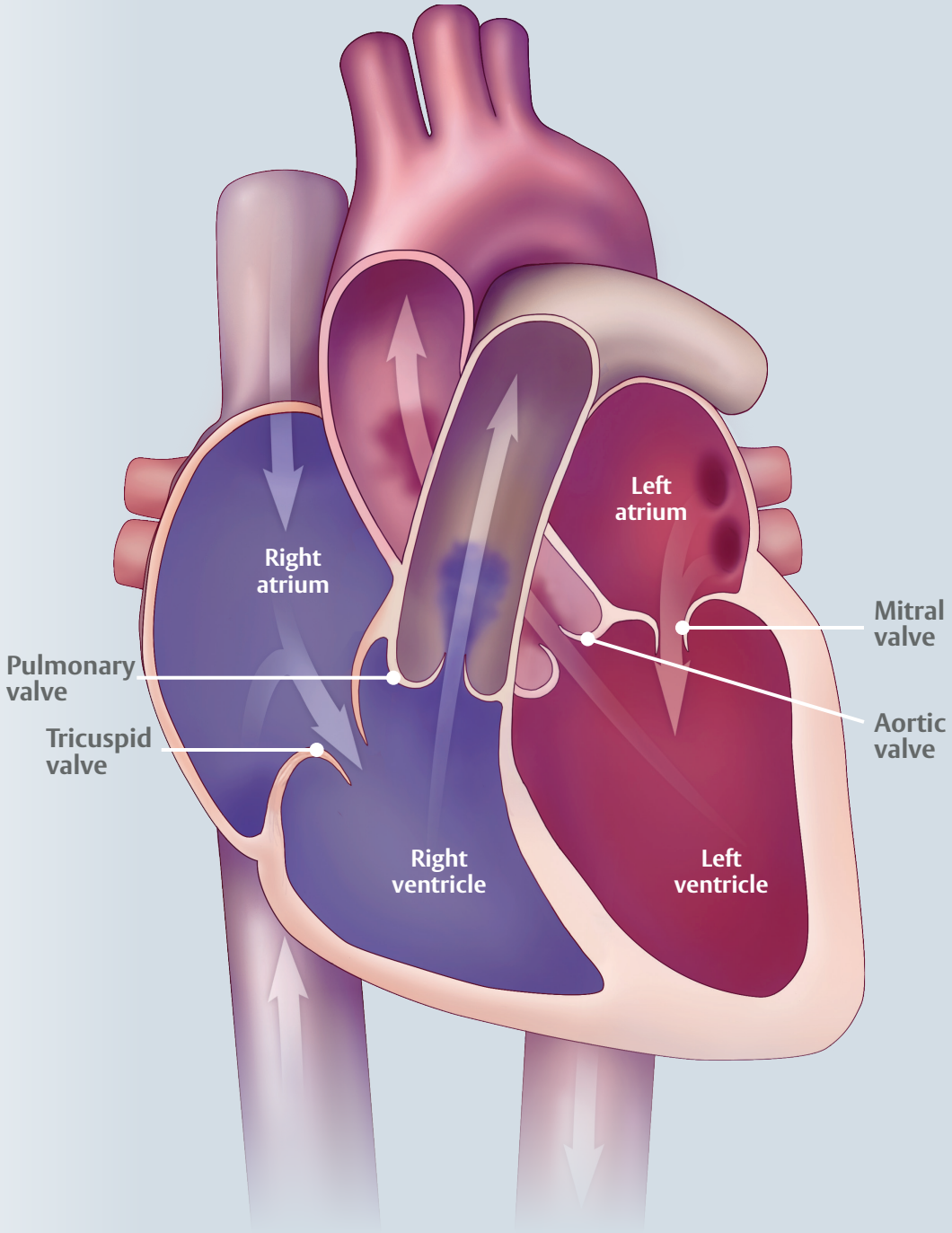
There are two problems that can occur in heart valves:

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:

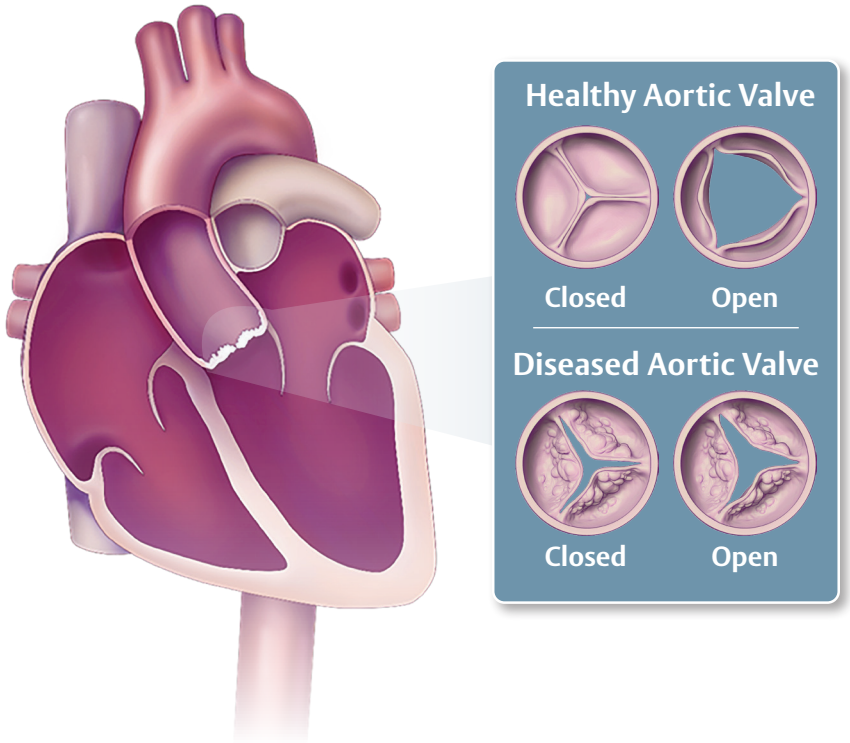
- Be properly formed and flexible
- Open all the way so that the right amount of blood can pass through
- Close tightly so that no blood leaks back into the chamber



What is aortic stenosis?

Aortic stenosis is a type of heart valve disease. It is progressive, meaning that over time, the leaflets become stiff. This reduces their ability to fully open and close. When the leaflets don't fully open, your heart must work harder to push blood through the aortic valve to your body. As a result, less oxygen-rich blood flows from the lungs to the brain and the rest of the body, which may cause symptoms.

The symptoms of heart valve disease are commonly misunderstood by patients as "normal" signs of aging.



Causes:

- Age
- Calcium build-up
- Radiation therapy
- Infection of the heart
- Birth defects
- Rheumatic fever

Symptoms:

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

It is important to know that heart valve disease and heart valve failure both may occur with no outward symptoms.

Understanding Your Treatment Options

If you have been diagnosed with severe aortic stenosis, also known as heart valve failure, and are experiencing symptoms, TAVR is an option for you. Only a Heart Team can tell you if TAVR is right for you.

Medication

Your doctor may prescribe certain medications to help ease some of the symptoms of your heart valve failure; however it will not cure or fix the 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 a week or more, before beginning a long period of recovery.

Transcatheter Aortic Valve Replacement (TAVR)

TAVR is a less 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.

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 compared to open heart surgery. At 1 year and continuing out to 5 years, there was no difference between TAVR and open heart surgery.

* *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.*

What Is the Best Treatment Option for You?

Seeing a specialized doctor on a TAVR 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 Aortic Valve Replacement?

If you have heart valve failure and have symptoms and need your valve replaced, transcatheter valve replacement may help your heart to work better and relieve symptoms.

When compared to open-heart surgery other benefits may include:

- Better clinical outcomes after 1-year in low-risk patients*
- Less invasive, with minimal scarring
- Shorter hospital stay
- Shorter recovery time to getting back to everyday activities
- Less pain and anxiety

*Long-term benefits in low risk patients** 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

* *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 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.

Your doctor may refer to your TAVR heart valve by a few different names including SAPIEN 3, SAPIEN 3 Ultra, or SAPIEN 3 Ultra RESILIA. Your doctor can help you decide which Edwards TAVR heart valve is right for you.

TAVR is a less invasive, technique that uses a catheter to replace your diseased aortic 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. They will guide a new valve into the heart while the heart is still beating, using guidance from X-ray and echocardiography.

TAVR by Edwards Lifesciences

TAVR by Edwards is a safe and effective choice for all indicated patients. Edwards' valves are the most rigorously studied in TAVR clinical trials. Over 26,000 patients have been studied in clinical trials worldwide, with follow-up out to 9 years. Edwards TAVR valves are studied in patients of varying ages, sexes, and ethnicities across multiple clinical trials.

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.

*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 is made from cobalt chromium to help with strength and durability. The leaflets are made from the same bovine pericardial tissue (from a cow's heart) as Edwards surgical valves.

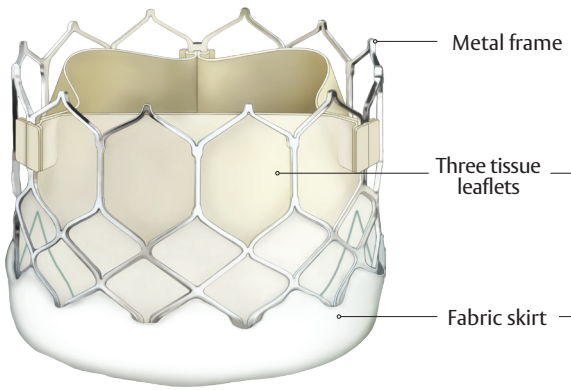
The Edwards SAPIEN 3 Ultra RESILIA valve is made of RESILIA tissue. The tissue from the cow's heart has been preserved with unique Edwards Technology to reduce calcium build-up on the valve tissue. The technology used on this latest valve blocks calcium from depositing on the tissue. The RESILIA tissue has been shown in animal studies to significantly reduce calcium build-up over traditional valve tissue.[1]* Less calcium build-up could potentially allow the valve to last longer.

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

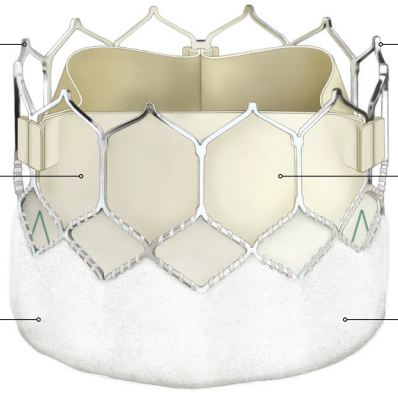
Edwards valves are available in four sizes to fit patients with unique anatomy including those with smaller or larger valve size needs: 20, 23, 26, and 29 mm in diameter.

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

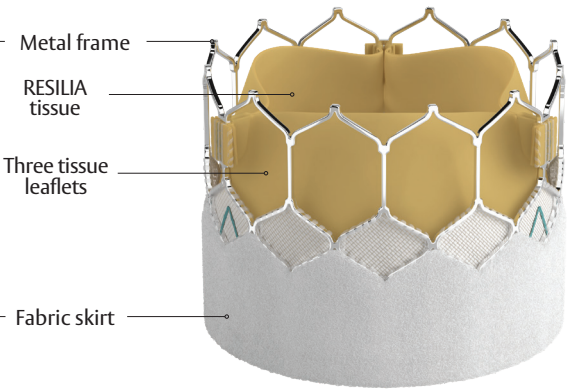
The Edwards SAPIEN 3 Valve



The Edwards SAPIEN 3 Ultra Valve



The Edwards SAPIEN 3 Ultra RESILIA Valve



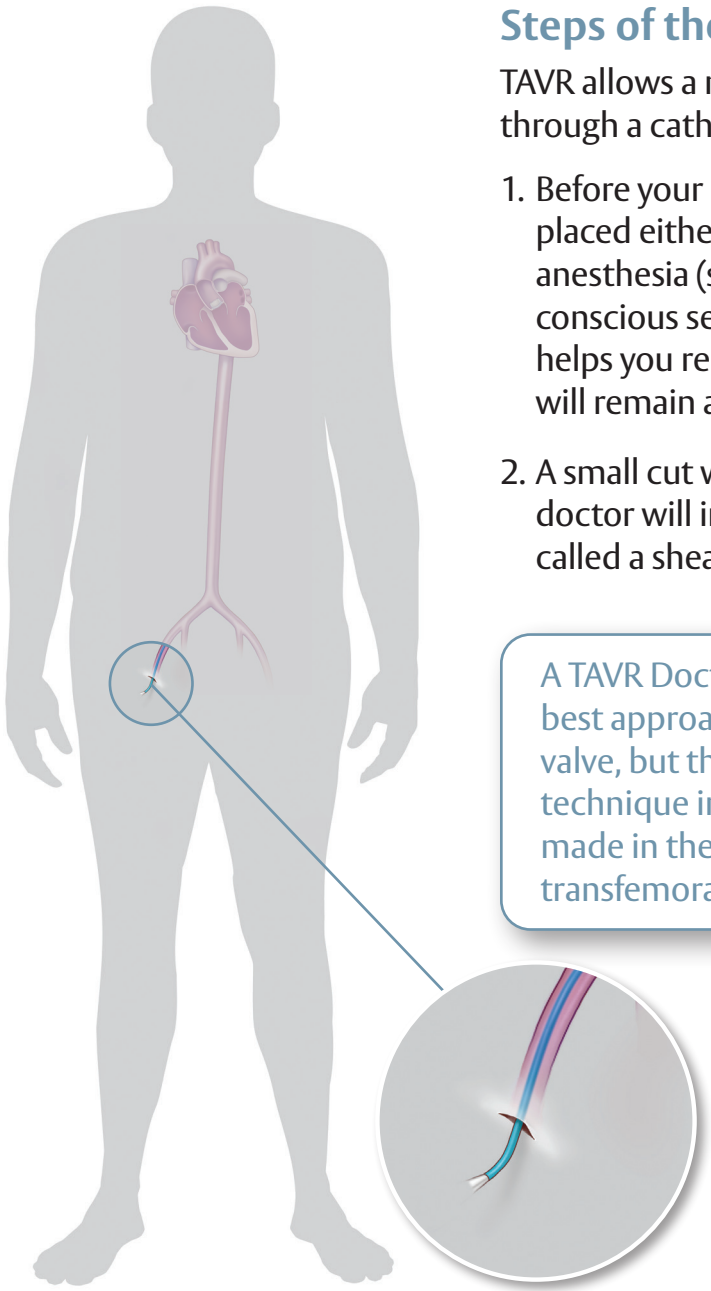
Images are larger than actual valve size.

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.

What Do You Need to Do Before the Procedure?

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

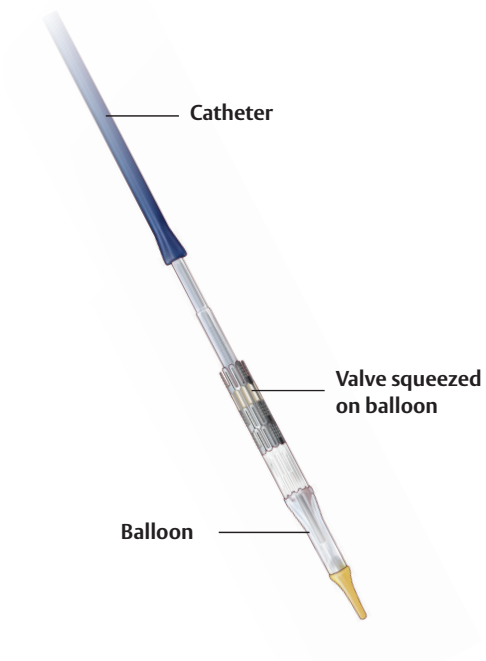


Steps of the TAVR Procedure

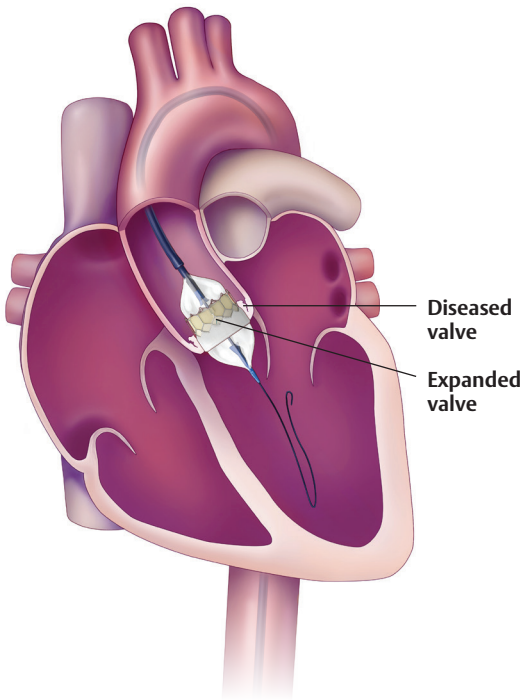
TAVR allows a new valve to be inserted through a catheter.

1. Before your procedure, you may be placed either under general anesthesia (sleep medicine) or conscious sedation (medicine that helps you relax and block pain but you will remain awake).
2. A small cut will be made where your doctor will insert a short, hollow tube called a sheath.

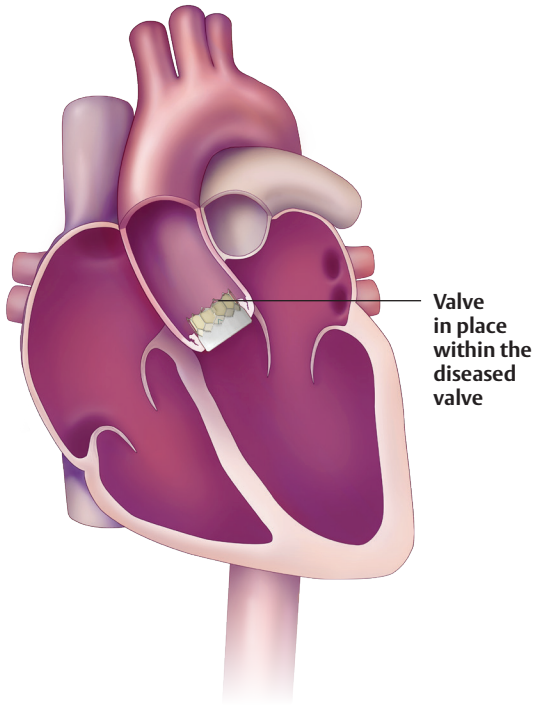
A TAVR Doctor will determine the best approach for replacing your valve, but the most common technique involves a small cut made in the leg. This is called the transfemoral approach.



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 delivery system carrying 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.

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

Average length of stay with the TAVR procedure:

3 days[1]

compared to 7 days with open heart surgery

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.

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

TAVR Follow-Up Visits

Regular check-ups with your doctor are very important. You will probably be asked to return to see your TAVR doctor to have your heart valve checked at 30 days and annually for up to 10 years after your procedure. However, call or see your doctor whenever you have questions or concerns about your health.

1. Based on PARTNER 3 Low Risk Trial Outcomes

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 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

Edwards Lifesciences® Implanted Device ID Card

SAMPLE PATIENT

Edwards™

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

Risks of the Edwards SAPIEN 3 TAVR Procedure

What Are the Risks of Edwards SAPIEN 3 TAVR?

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

The Edwards TAVR procedure's most serious risks are:

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

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

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

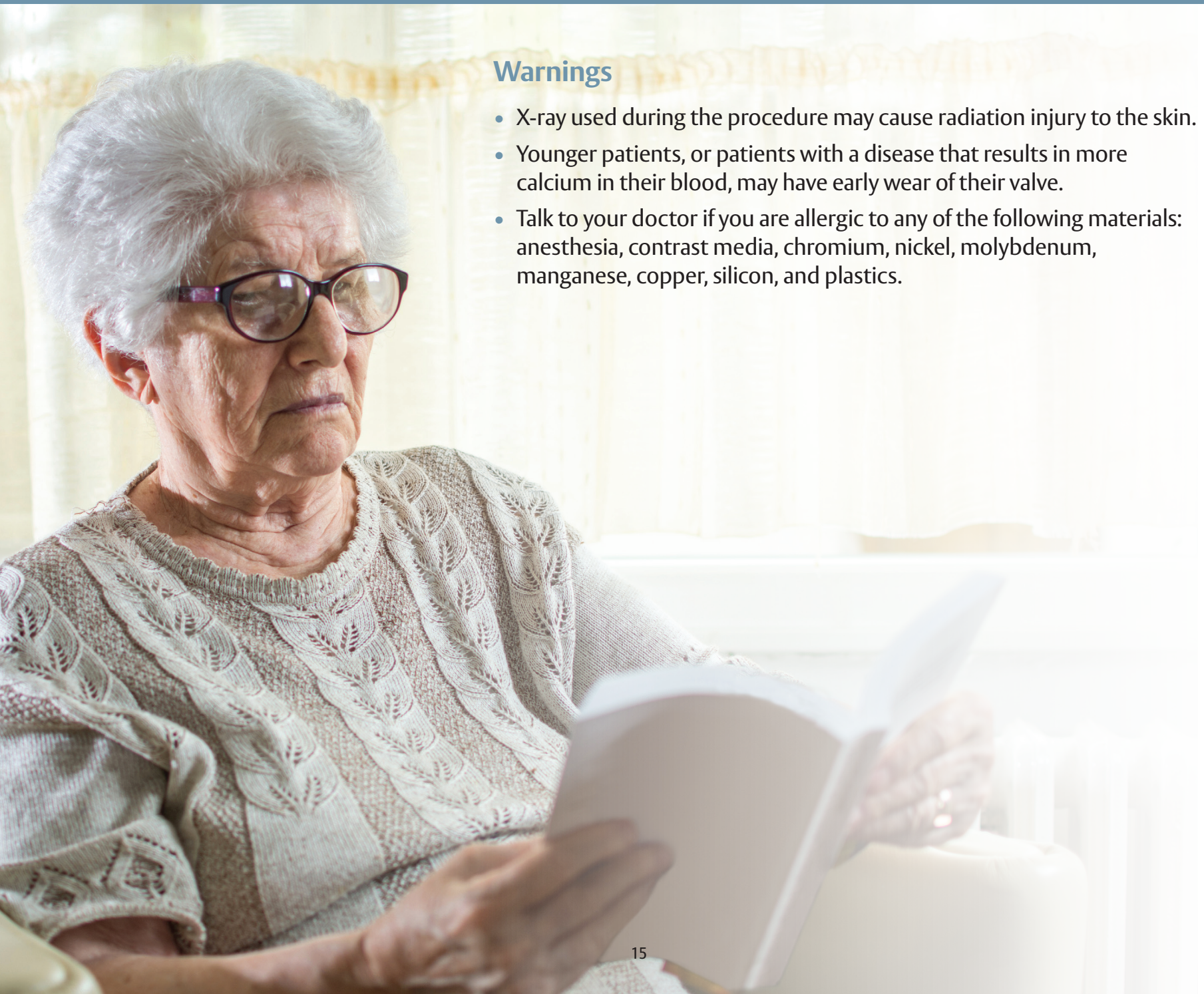
If one of the Edwards SAPIEN 3 TAVR valves is used in the patients mentioned above, it will not work correctly, which could make you feel very sick or even cause death.

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, 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
- 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
- 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 and Precautions With Edwards SAPIEN 3 TAVR Valves



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 materials: anesthesia, contrast media, chromium, nickel, molybdenum, manganese, copper, silicon, and plastics.

Precautions

- 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 build-up 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 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 transcatheter heart 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 for Low-Risk Patients

The PARTNER 3 Low-Risk Trial

The risks with the procedure may depend on the overall health of the patient.

If you are at low-risk for open heart surgery, the clinical data shown in these charts could be what you would expect.

As part of the PARTNER 3 Trial, the SAPIEN 3 valve was studied in patients at low risk for open heart surgery.

The trial enrolled about 1,000 patients, mostly in the United States. Patients were randomly chosen for either TAVR with an Edwards valve or open heart surgery (SAVR).

Patients were examined at 30 days and 1 year after the procedure and will continue to be followed every year for 10 years. The balloon-expandable SAPIEN 3 valve was equally effective as open heart surgery at five 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 & 23mm).
- 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 five 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 & 23mm).
- 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 Confirmatory Study

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

As a single-arm study, the SAPIEN 3 Ultra valve was studied in patients at intermediate risk for open heart surgery.

The study enrolled about 100 patients in Canada and the United Kingdom, who had severe aortic stenosis.

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.

This chart summarizes 30-day and 5-year data of a study with 100 patients to confirm the procedural safety and performance of the SAPIEN 3 Ultra valve in treating patients with severe aortic stenosis (heart valve failure) who are at intermediate operative risk for open heart surgery. The results from this trial confirmed the safety and effectiveness of the design updates of the SAPIEN 3 Ultra system compared to its previous generation of the SAPIEN 3 valve (see clinical data on page 20).

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.

The PARTNER II Intermediate-Risk Trial

The risks with the TAVR procedure may depend on the overall health of the patient.

If you are at intermediate risk for open heart surgery, the clinical data shown in this chart could be what you would expect.

As part of the PARTNER II Trial, the SAPIEN 3 valve was studied in patients at intermediate risk for open heart surgery.

The trial enrolled about 1,000 patients, mostly in the United States. The outcomes in this trial were compared to those patients who participated in another trial and were treated with surgery.

Patients were examined at 30 days and 1 year after the procedure and will continue to be followed every year for 10 years.

Edwards TAVR Clinical Data for High-Risk and Inoperable Patients

The PARTNER II High-Risk/Inoperable Study

The risks with the TAVR procedure may depend on the overall health of the patient.

If you 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 US patients that were either high risk or too sick for open heart surgery.

Patients were examined at 30 days, 1 year, and 5 years after the procedure.

All data presented in charts are the transfemoral approach population only.

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

This review of the registry showed results of 545 bicuspid valve patients who received a SAPIEN 3 valve.

Over 90% of these patients were either at high risk or ineligible for open heart surgery.

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.

This review of the registry showed results of 71 bicuspid valve patients who received a SAPIEN 3 valve.

All 71 patients were at low risk for open heart surgery.

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.

Clinical Data for Bicuspid Patients

The risks with the TAVR procedure may depend on the overall health of the patient. If your doctor has confirmed that you have a bicuspid aortic valve (a valve with two-leaflets) and you are at high risk or cannot have open heart surgery, the clinical data shown in the first chart could be what you would expect.

The SAPIEN 3 valve was studied in bicuspid aortic valve patients using the TVT registry*. The TVT Registry collects safety and efficacy data from hospitals in the US treating patients with TAVR.

If you are at low-risk for open heart surgery, the clinical data shown in the second chart could be what you would expect.

As part of the PARTNER 3 Trial, the SAPIEN 3 valve was studied in bicuspid aortic valve patients at low risk for open heart surgery.

The trial enrolled 75 patients in the United States and treated 71.

**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.*

For More Information on Edwards SAPIEN 3 TAVR:

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www.Edwards.com

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*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.

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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