

TRANSCATHETER AORTIC VALVE REPLACEMENT WITH

The Edwards SAPIEN 3 Transcatheter Heart Valve

What You and Your Loved Ones Should Know



This booklet is for patients who feel sick from severe aortic stenosis (a narrowing of the aortic valve opening that does not allow normal blood flow) and who are at high-risk or too sick to undergo open-heart surgery. This information will help you and your loved ones learn more about your heart, how it works, and aortic stenosis. You will also learn about a less invasive procedure called transcatheter aortic valve replacement (TAVR).

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

See pages 16-17 to review the risks of the TAVR procedure.



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Table of Contents

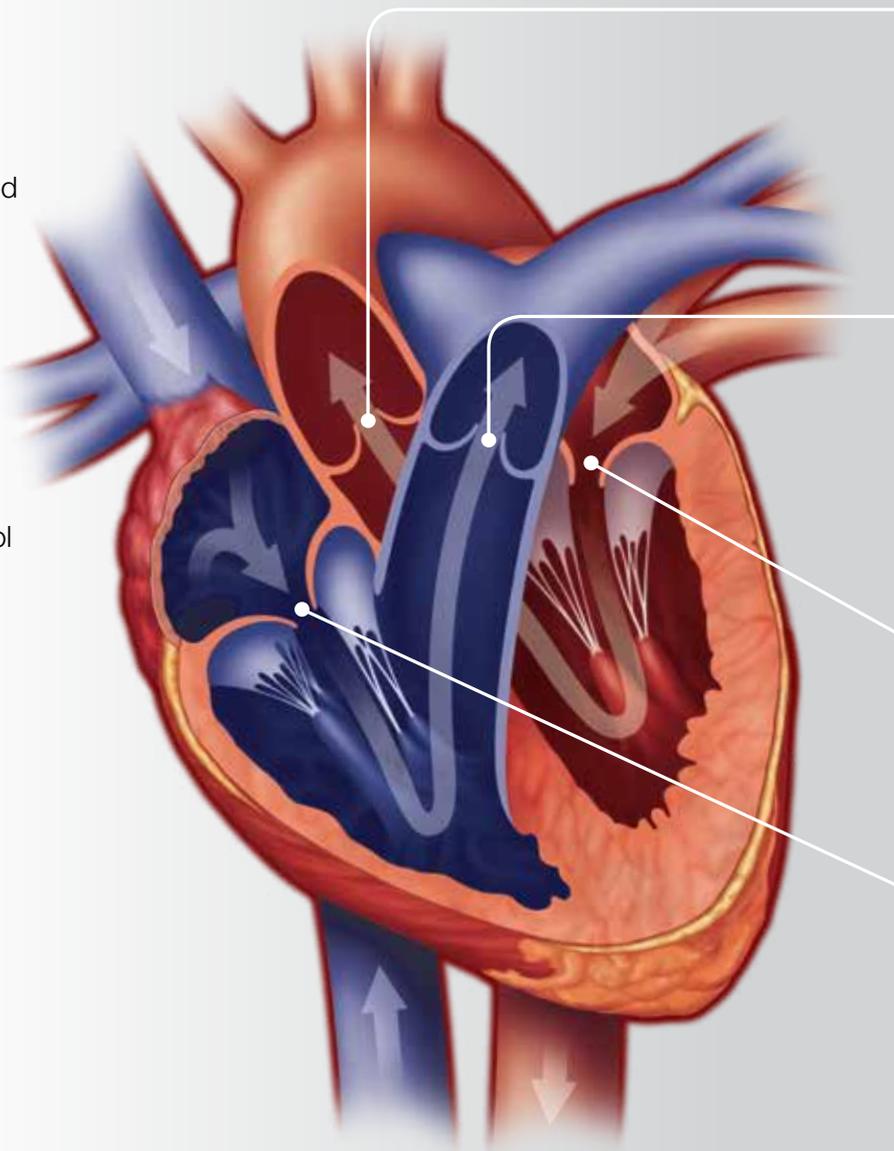
How Does Your Heart Work?	3
What is Severe Aortic Stenosis?	4
The Heart Team	5
What are Your Treatment Options?	6
Transcatheter Aortic Valve Replacement	6
Surgical Aortic Valve Replacement	6
Transcatheter Aortic Valve Replacement	7-11
Which Products Will Be Used During the Procedure?	8
What Do You Need to Do Before the Procedure?	8
TAVR Procedural Overview	9-10
What Happens After the Procedure?	11
For the Caregiver: What You Need to Know	11
Transcatheter Aortic Valve Replacement Clinical Data	12-17
The Clinical Trial Overview	12
Clinical Data Tables	13-15
What Are the Possible Benefits of TAVR?	15
What Are the Possible Risks of TAVR?	16-17
Precautions	17
Warnings	18
Who Should Not Have the Procedure?	18
How Long Will the Valve Last?	18
Contact Information	18

This information is not meant to tell you everything you need to know about your treatment options for aortic stenosis, or about the TAVR procedure. Regular check-ups with your doctor are important. Call or see your doctor whenever you have questions or concerns about your health, especially if you experience unusual symptoms or changes in your overall health.

HOW DOES YOUR HEART WORK?

The heart is a muscular organ located in your chest between your lungs. The heart is designed to pump blood through your body. The right side of your heart pumps blood through the lungs, where the blood picks up oxygen. The left side of the heart receives this blood and pumps it to the rest of your body.

There are four valves that control the flow of blood through your heart, as shown here.



The aortic valve has three leaflets. It controls blood flow from the left ventricle to the aorta, sending blood to the rest of the body.

The pulmonary valve has three leaflets. It controls blood flow from the right ventricle to the pulmonary artery, sending blood to the lungs to pick up oxygen.

The mitral valve has two leaflets. It controls blood flow between the left atrium and left ventricle.

The tricuspid valve has three leaflets. It controls blood flow from the right atrium to the right ventricle.

There are two common problems that can develop in heart valves:

- **Stenosis:** When your valve is narrowed and does not completely open. This can be caused by things like a build-up of calcium (mineral deposits), high cholesterol (a waxy fat), age or genetics (such as a birth defect).
- **Regurgitation:** When your valve does not fully close and allows blood to leak backwards through the valve.

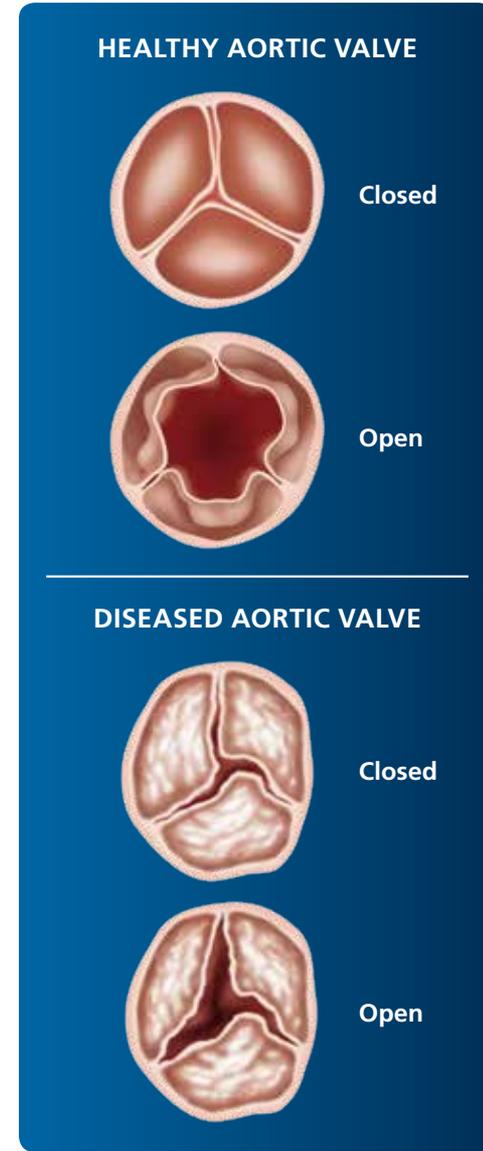
With either problem, your heart needs to work harder and may not pump enough blood to your body.

WHAT IS SEVERE AORTIC STENOSIS?

Severe aortic stenosis is a narrowing of your aortic valve opening that does not allow normal blood flow. It can be caused by a birth defect, rheumatic fever, radiation therapy or can be related to age.

In elderly patients, severe aortic stenosis is sometimes caused by the build-up of calcium (mineral deposits) on the aortic valve's leaflets. Over time the leaflets become stiff. This can reduce 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.

Eventually, your heart gets weaker. This increases the risk of heart failure (when your heart cannot keep up with its workload). Severe aortic stenosis is a very serious problem. Without aortic valve replacement, approximately 50% of the people who have developed symptoms will die within an average of 2 years.





THE HEART TEAM

When you have severe aortic stenosis, you may be evaluated by a team of experts called a “Heart Team.” This includes Interventional Cardiologists, Cardiothoracic Surgeons, Echocardiographers, Anesthesiologists, Valve Clinic Coordinators, and/or Cardiac Catheter Lab and O.R. Staff. Each specialist brings expertise that is critical to the total care process.



WHAT ARE YOUR TREATMENT OPTIONS?

Treatment for aortic stenosis depends on how far the disease has progressed. If your stenosis is mild, medication may be prescribed to help regulate your heartbeat and prevent blood clots. However, as your stenosis worsens, your Heart Team will recommend different options for replacing the diseased valve.

Transcatheter Aortic Valve Replacement

For people who have been diagnosed with severe aortic stenosis and who are high-risk or too sick for open heart surgery, transcatheter aortic valve replacement (TAVR) may be an option. TAVR can result in lengthening patients' lives.

This less invasive procedure allows a new valve to be inserted within your diseased aortic valve.

Surgical Aortic Valve Replacement

Surgical AVR has been performed for many years on patients who can undergo open heart surgery. Surgical AVR has lengthened patients' lives.

Surgical AVR is an open heart procedure. The surgeon removes the diseased aortic valve and replaces it with either a mechanical valve (made from man-made materials) or a biological valve (made from animal or human tissue).

Aortic valve replacement can also be performed through minimal incision valve surgery (MIVS). In MIVS, the surgeon can replace the diseased valve through a smaller incision while looking directly at the heart or through a small, tube-shaped camera.

For more information
on treatment options,
please visit



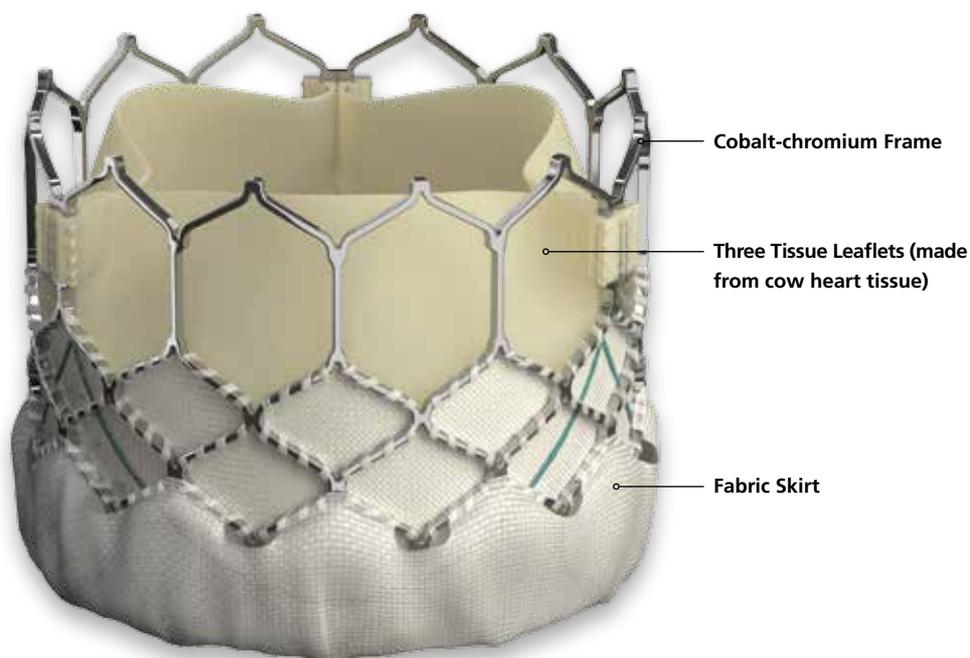
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TRANSCATHETER AORTIC VALVE REPLACEMENT

Which Products Will Be Used During the Procedure?

The Edwards SAPIEN 3 transcatheter heart valve is a biological valve (made from animal tissue) that replaces your diseased aortic valve. It is available in four sizes, 20 mm, 23 mm, 26 mm and 29 mm in diameter. Your Heart Team will determine the right size for you.



The Edwards SAPIEN 3 transcatheter heart valve (that replaces your diseased aortic valve) is pictured above.

Image is larger than actual valve size.

What Do You Need to Do Before the Procedure?

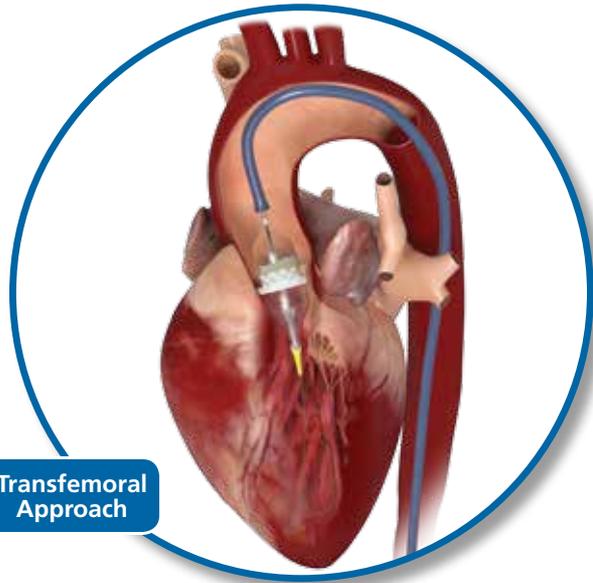
To determine the best TAVR approach for you, your Heart Team will review various tests such as a chest x-ray, echo, angiogram, and others.

Be sure to talk to your Heart Team about any medication you may be taking. They might advise you to stop taking certain medication up to one week prior to the procedure. Your doctor may tell you not to eat or drink anything after midnight. You should plan on making arrangements for a ride to and from the hospital, and arrange for help at home after the procedure.

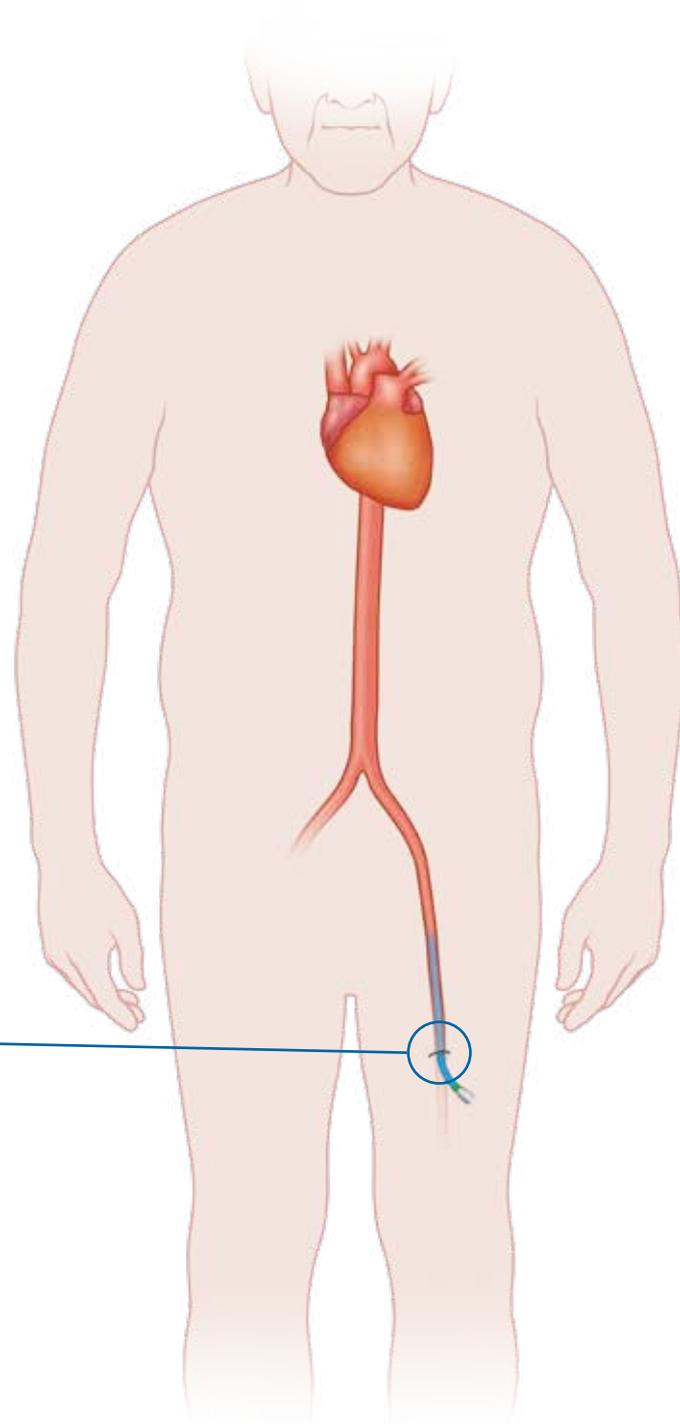
TAVR Procedural Overview

TAVR allows a new valve to be inserted through a catheter. The total procedure time varies from about 1 to 2 hours.

1. In preparation for your procedure, you will be placed under anesthesia (you will be in a deep sleep).
2. Your doctor will make an incision in your leg. A short, hollow tube called a sheath will be placed into the incision. This will allow your doctor to put various devices through the sheath to access your heart.

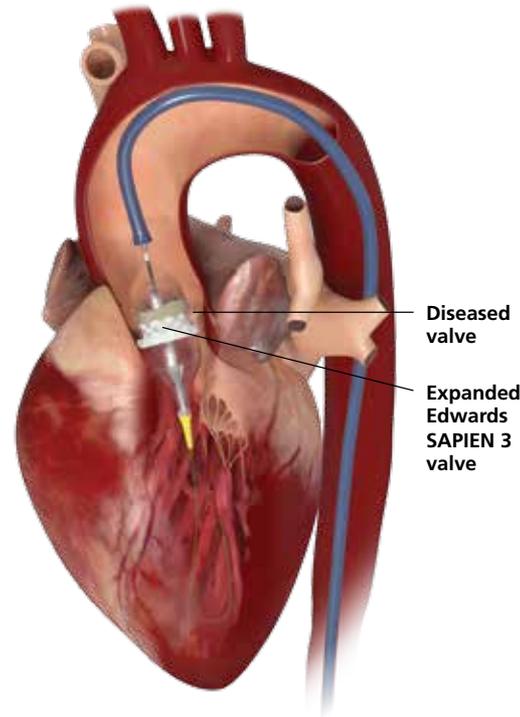


Transfemoral Approach

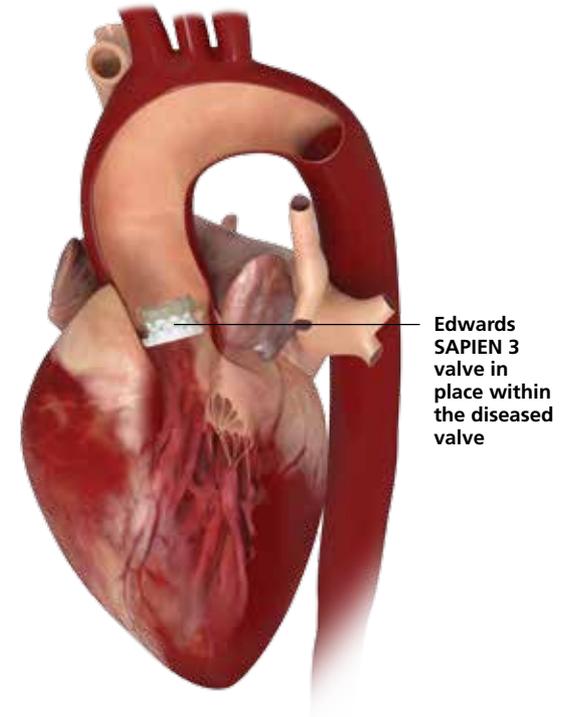




Edwards SAPIEN 3 valve compressed on balloon



Diseased valve
Expanded Edwards SAPIEN 3 valve



Edwards SAPIEN 3 valve in place within the diseased valve

3. Your new valve will be placed on a delivery system—a tube with a balloon on the end. The valve will be compressed on the balloon to make it small enough to fit through the sheath. The delivery system and compressed valve will be inserted into the sheath.

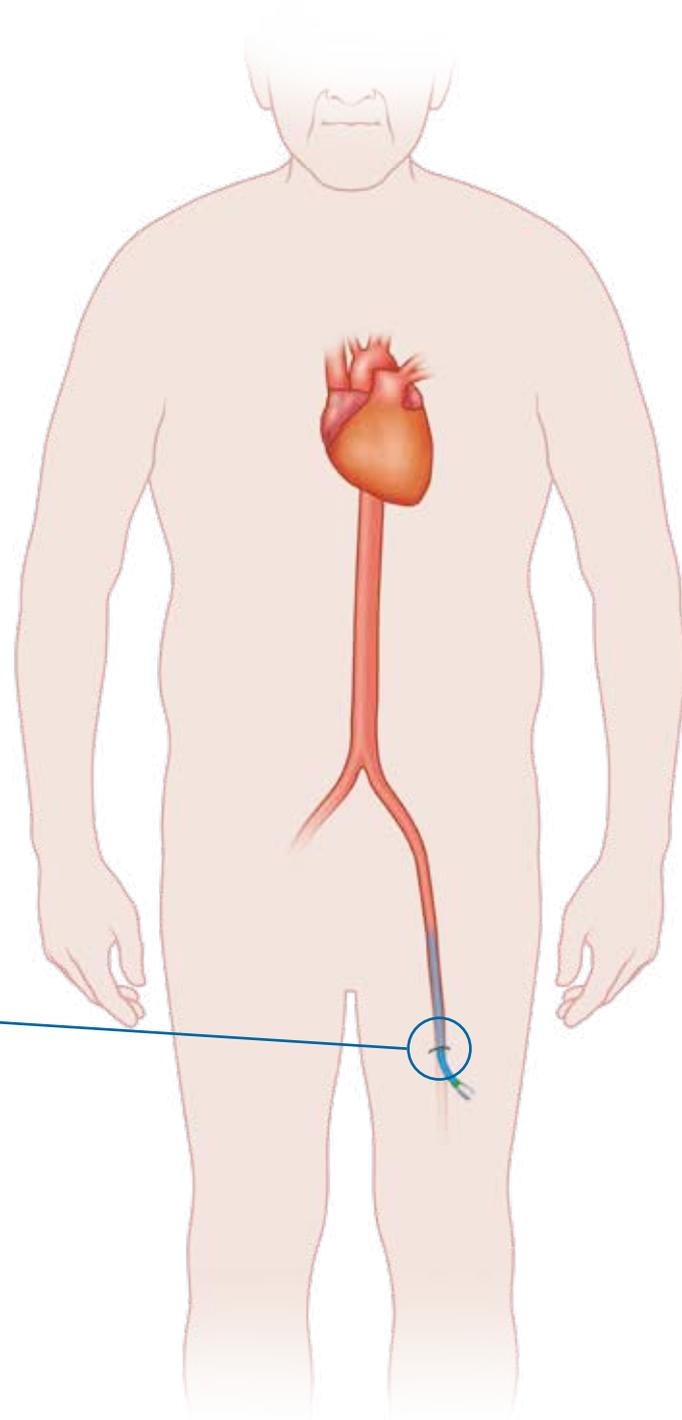
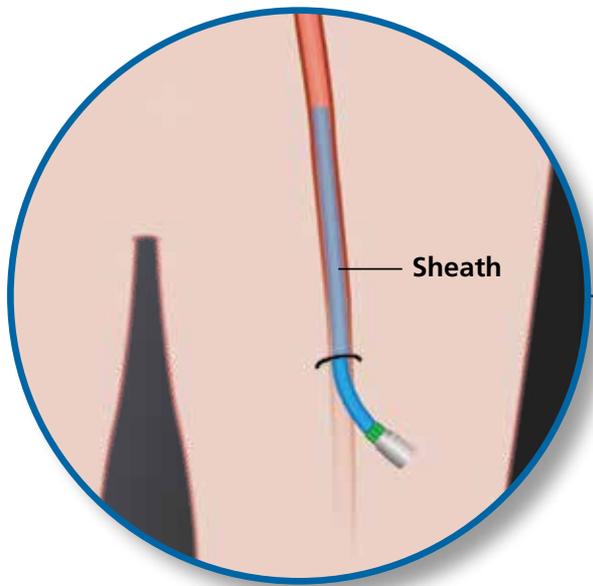
4. Once the delivery system reaches your diseased valve, the balloon will be inflated with fluid, expanding the new valve into place. The valve will push the leaflets of your diseased valve aside. The frame of the new valve will use the diseased valve leaflets to secure itself in place.

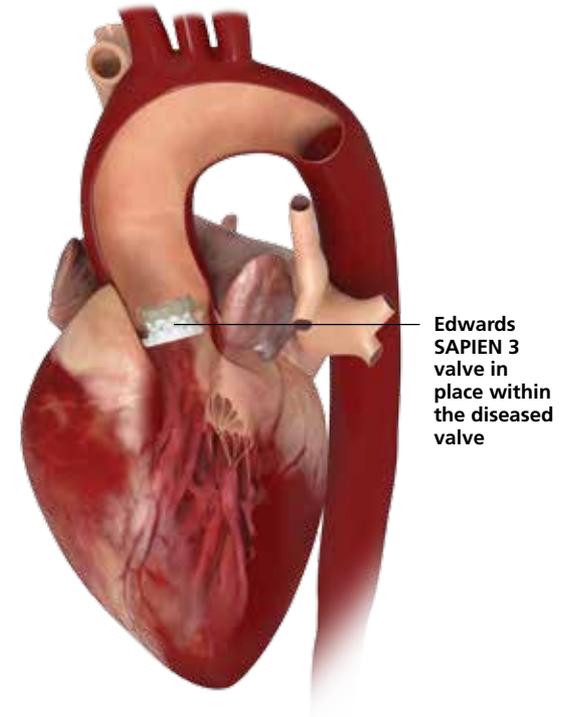
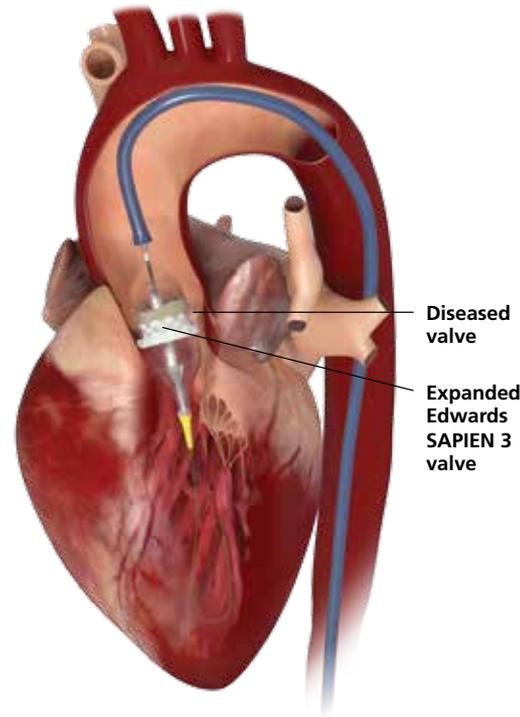
5. The balloon will then be deflated and removed. Your doctor will ensure the new valve is working properly before closing up the incision site.

TAVR Procedural Overview

TAVR allows a new valve to be inserted through a catheter. The total procedure time varies from about 1 to 2 hours.

1. In preparation for your procedure, you will be placed under anesthesia (you will be in a deep sleep).
2. Your doctor will make an incision in your leg. A short, hollow tube called a sheath will be placed into the incision. This will allow your doctor to put various devices through the sheath to access your heart.





3. Your new valve will be placed on a delivery system—a tube with a balloon on the end. The valve will be compressed on the balloon to make it small enough to fit through the sheath. The delivery system and compressed valve will be inserted into the sheath.

4. Once the delivery system reaches your diseased valve, the balloon will be inflated with fluid, expanding the new valve into place. The valve will push the leaflets of your diseased valve aside. The frame of the new valve will use the diseased valve leaflets to secure itself in place.

5. The balloon will then be deflated and removed. Your doctor will ensure the new valve is working properly before closing up the incision site.

What Happens After the Procedure?

Your Heart Team will determine your immediate after-care plan. Your Heart Team will give you specific instructions to help you with your recovery. This may include a special diet, exercise, and medicine. It is important to carefully follow your doctor's directions, especially if blood-thinning drugs are prescribed.

You will be expected to attend regular check-ups. Regular check-ups with your doctor are very important. Call or see your doctor whenever you have questions or concerns about your health. If you experience any unusual problems such as bleeding, pain, other discomfort, or changes in your overall health, be sure to contact your doctor.

Always inform other doctors about your heart valve replacement before any medical, dental or MRI (magnetic resonance imaging) procedures. Failure to do so may result in damage to the valve that could lead to death.

For the Caregiver: What You Need to Know

Most people are not prepared to be caregivers. There is no special training, you learn as you go and, most of the time, you have more questions than answers. There are daily challenges — emotional, physical, and financial. Put simply: it's not easy. But remember this: without caregivers like you, many people wouldn't get the help they need.

Whether you're near or far, you can play an important, active role in support. The Edwards Lifesciences sponsored website **NewHeartValve.com** is a good place to start your journey of taking care of your aortic stenosis patient.

TRANSCATHETER AORTIC VALVE REPLACEMENT CLINICAL DATA

TAVR with Edwards' transcatheter heart valves has been performed on thousands of patients since 2007. TAVR is a less invasive option and has been shown to lengthen patients' lives and significantly improve their quality of life.

The Clinical Trial Overview

The Clinical Trial studied the safety and effectiveness of the Edwards SAPIEN 3 transcatheter heart valve. The study was conducted in the United States (US) and outside the United States (OUS). This included approximately 700 patients whose doctors had determined them to be at high risk or too sick to undergo open-heart surgery.

Patients were treated with the Edwards SAPIEN 3 transcatheter heart valve. Patients were examined at 30 days, 6 months, and 1 year after the procedure. They will continue to be examined every year for 5 years.



The following tables are a summary of the clinical risks observed within 30 days in high-risk patients from The US Clinical Trial. The frequency is shown as the number of patients out of every 100.

Transfemoral TAVR with the Edwards SAPIEN 3 transcatheter heart valve	
	Risk within 30 days
Death from any cause	2 out of 100 patients
Death from cardiovascular (heart-related) causes	1 out of 100 patients
Major stroke	2 out of 100 patients
Aortic insufficiency (when the aortic valve does not close tightly and causes a backward flow of blood) \geq moderate	3 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	14 out of 100 patients
Life threatening bleeding	6 out of 100 patients
Major vascular complications (artery)	6 out of 100 patients
Myocardial infarction (heart attack)	1 out of 100 patients
Endocarditis (inflammation or infection of any internal heart structures, including the valves)	1 out of 100 patients

Additional Information on the Transfemoral TAVR Procedure	
	Transfemoral TAVR with Edwards SAPIEN 3 transcatheter heart valve
Average Procedure Time*	1-2 hours
Median Length of Stay (days)	7 days

* The average total procedure duration is based on data from The US Clinical Trial and may not reflect the actual procedure time at your TAVR hospital. Talk to your Heart Team if you have questions about the procedure.

The following table is a summary of the clinical risks observed within 30 days in high-risk patients from The OUS Clinical Trial. The frequency is shown as the number of patients out of every 100.

Transfemoral TAVR with the Edwards SAPIEN 3 transcatheter heart valve	
	Risk within 30 days
Death from any cause	4 out of 100 patients
Death from cardiovascular (heart-related) causes	4 out of 100 patients
Major stroke	2 out of 100 patients
Aortic insufficiency (when the aortic valve does not close tightly and causes a backward flow of blood) \geq moderate	2 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	13 out of 100 patients
Life threatening bleeding	6 out of 100 patients
Major vascular complications (artery)	2 out of 100 patients
Myocardial infarction (heart attack)	4 out of 100 patients
Endocarditis (inflammation or infection of any internal heart structures, including the valves)	0 out of 100 patients

The following table is a summary of the clinical risks observed within 1 year in high-risk patients from The OUS Clinical Trial. The frequency is shown as the number of patients out of every 100.

Transfemoral TAVR with the Edwards SAPIEN 3 transcatheter heart valve	
	Risk within 1 year
Death from any cause	13 out of 100 patients
Death from cardiovascular (heart-related) causes	4 out of 100 patients
Major Stroke	4 out of 100 patients
Aortic insufficiency (when the aortic valve does not close tightly and causes a backward flow of blood) \geq moderate	3 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	13 out of 100 patients
Myocardial infarction (heart attack)	4 out of 100 patients
Endocarditis (inflammation or infection of any internal heart structures, including the valves)	0 out of 100 patients

What Are the Possible Benefits of TAVR?

Benefits of the Procedure: For patients with severe aortic stenosis, there can be many benefits after the procedure. Not only does it replace your failing aortic valve helping you feel better, but it helps your heart work better. It may also shorten your recovery time to resume everyday activities.

Symptom Relief: Most patients receiving an Edwards SAPIEN 3 transcatheter heart valve can expect to feel better right away. Most patients who had limited activity and things like severe shortness of breath and chest pain felt better.

Quality of Life Improvement: These studies showed great improvement in patient health as soon as 30 days after the procedure. Patients had improvements with anxiety, and were able to take care of themselves better. They also had less pain.

*Kansas City Cardiomyopathy Questionnaire (KCCQ) and EuroQol/EQ-5D



What Are the Possible Risks of TAVR?

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

The most serious risks of the TAVR procedure with an Edwards SAPIEN 3 transcatheter heart valve include:

- **Death from any cause** – death due to any cause, whether cardiac related or not.
- **Major stroke** – a condition when blood stops flowing in the brain, which may cause severe disability.

- **Major vascular complications** – a tear or hole in blood vessels or a hematoma (a large blood clot under the skin), which will require another surgery.

- **Life threatening bleeding event** – a bleeding event that requires a blood transfusion.

Additional potential risks associated with the procedure include:

- Heart attack
- Failure of your heart to pump enough blood to the body 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, blood clots) floating in the blood stream or attached to an object, including the valve
- Infection to your heart, blood or other areas
- Injury to your blood vessels or heart that require treatment

What Are the Possible Risks of TAVR? (cont.)

- Blocking, narrowing or bulging of a blood vessel
- Blood clot, including a blood clot on the valve
- Trouble or inability to breathe
- Fluid build-up in your lungs
- Anemia
- Lab values that are not normal
- Abnormally high or low blood pressure
- Pain, inflammation and 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 build up 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

PRECAUTIONS

- TAVR patients should stay on blood-thinning medicine for 6 months after the procedure and aspirin for the rest of their lives, or as their doctor recommends. Patients who do not take blood-thinning medicine may be at increased risk of developing a dangerous blood clot. This may result in a stroke. Blood-thinning medicine may increase the risk of bleeding in the brain (stroke).
- TAVR patients who are going to have dental procedures should receive antibiotics to help decrease the chance of getting an infection.
- The safety of the transcatheter heart valve is not known for patients who have:
 - An existing artificial aortic heart valve.
 - A heart that does not pump efficiently.
 - An enlarged heart.
- The safety and performance of the transcatheter heart valve has not been established for patients who have:
 - An aortic heart valve that is not calcified.
 - An aortic heart valve that only has one or two leaflets.
- A diseased aortic valve in which the main problem is valve leakage.
- A previously implanted medical device in any heart valve.
- A diseased mitral valve that is calcified or leaking.
- Low white blood cell count, low red blood cell count, or other abnormalities in the blood.
- Unusual ultrasound images of the heart that could represent abnormalities such as a blood clot.
- Allergies to blood-thinning medications or dye that is injected during the procedure.
- An aortic valve that is too small or too big to fit the transcatheter heart valve.
- Diseased or abnormally shaped vessels leading to the heart.
- Femoral vessels that are heavily diseased or too small for the delivery device.
- Aortic valve leaflets with large pieces of calcium that may block the vessels that supply blood to the heart.

WARNINGS

- **Stroke may happen in patients who get TAVR procedures. This happens less if aortic stenosis is treated with medicine and by inflating a balloon inside the heart.**
- **Major blood vessel complications may occur in TAVR procedures. This occurs less if aortic stenosis is instead treated with medicine and by inflating a balloon inside the heart.**
- **The valve implant may not last as long in patients who do not process calcium normally.**
- **Talk to your doctor if you are allergic to the implant materials. These include anesthesia, contrast media, chromium, nickel, molybdenum, manganese, copper, silicon, and plastics.**
- **X-ray may cause radiation injury to the skin.**

Who Should Not Have the Procedure?

The Edwards SAPIEN 3 transcatheter heart valve and delivery systems should not be used in patients who:

- Cannot tolerate medications that thin the blood or prevent blood clots from forming.
- Have an active infection in the heart or elsewhere.

How Long Will the Valve Last?

How long your new valve will last is unknown at this time. Edwards Lifesciences has tested the valve in the laboratory to replicate 5-year durability. All valves tested for 5-year durability passed the test. The first Edwards transcatheter heart valve was implanted in 2002. However, at this time there is limited long-term information to assess durability beyond 5 years.

Talk to your Heart Team if you experience any symptoms. Regular medical follow-up is important to evaluate how your valve is performing.

CONTACT INFORMATION

For more information on the Edwards SAPIEN 3 transcatheter heart valve or the TAVR procedure:

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Irvine, California 92614

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

Data on file at Edwards Lifesciences.

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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