Transcatheter Aortic Valve Replacement with the Edwards SAPIEN XT Transcatheter Heart Valve

What You and Your Loved Ones Should Know

Edwards

This booklet was created 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 cannot have open-heart surgery, in order to inform them of their options. This information will help you and your loved ones learn more about your heart, how it works, and aortic stenosis. In addition, you will learn about a minimally 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, to help you decide which option is best for you.

See pages 20-25 to review the risks of the TAVR procedure.

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Please remember, 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 Heart Team are essential. Call or see your Heart Team 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?

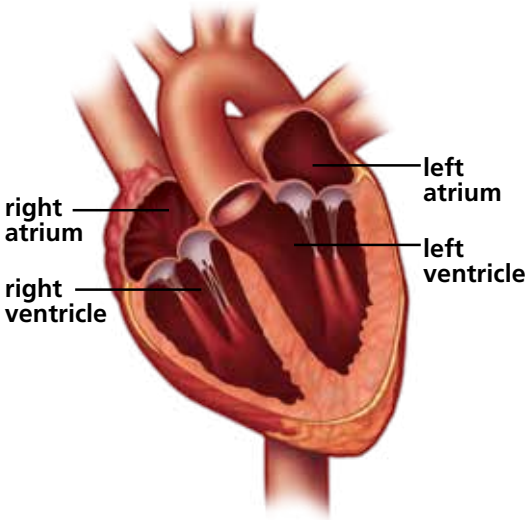
The heart is a muscular organ located in your chest between your lungs. The heart is designed to pump blood through your body. The right side of your heart pumps blood through the lungs, where the blood picks up oxygen. The left side of the heart receives this blood and pumps it to the rest of your body.

DID YOU KNOW?

"Your heart normally beats between 60 and 100 times per minute. At 60 beats per minute, that's approximately 31.5 million beats per year."

Chambers and Valves

The heart is divided into four main areas, or chambers—two upper chambers (called the left and right atrium) and two lower chambers (called the left and right ventricle). There are four valves that control the flow of blood through your heart. They are called the aortic, mitral, pulmonary, and tricuspid valves, and each includes flaps of tissue called leaflets *(see figure on page 4).*



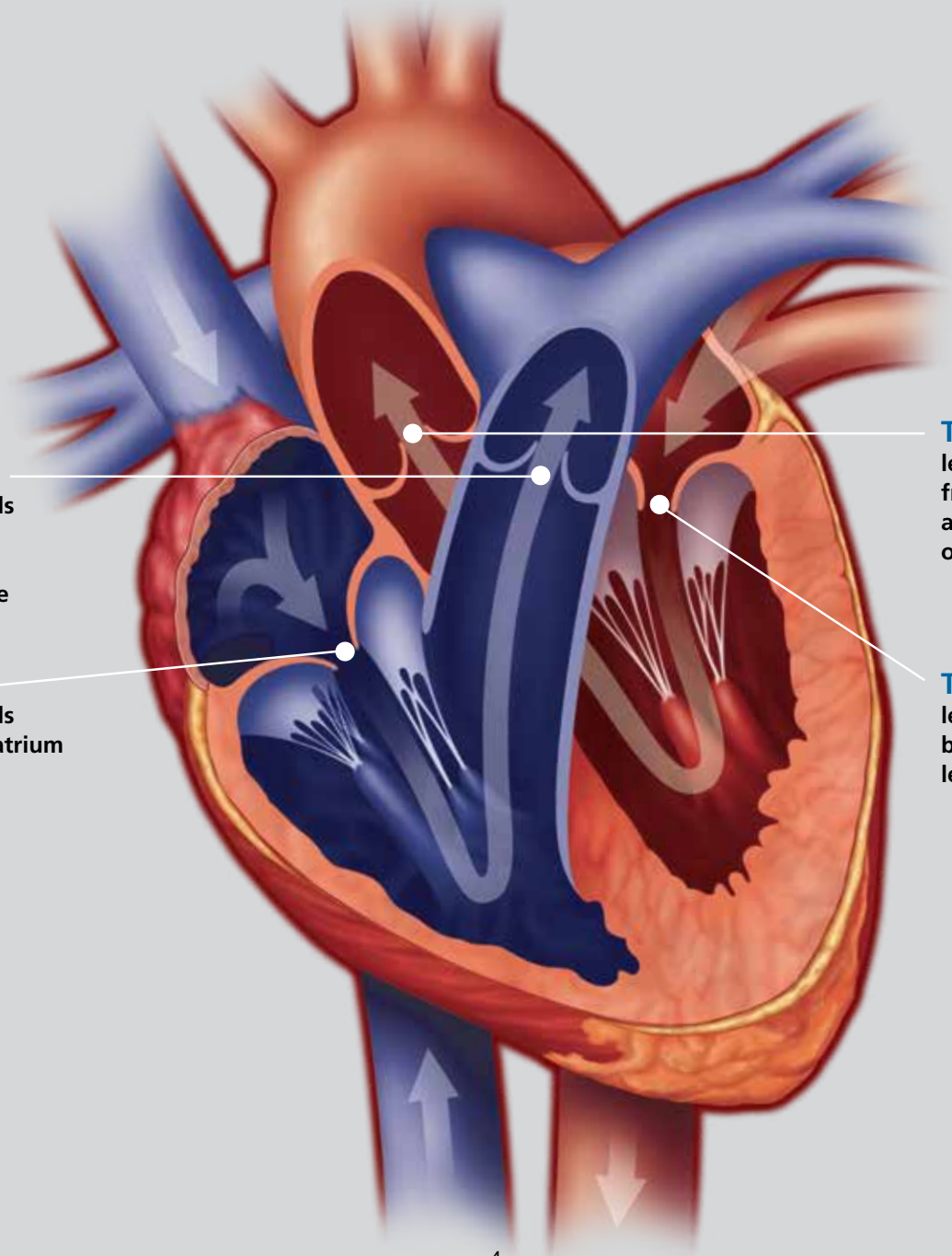
NOTE: The left and the right side of the heart is pictured as the heart sits in your body.

Each time your heart beats, it pumps blood through these valves by contracting (squeezing) its chambers. These valves open in one direction, like one-way gates, allowing blood to flow forward. In between beats, the heart's chambers quickly relax, and its valves close, preventing blood from flowing backward.

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

- **Stenosis:** When your valve is narrowed and does not completely open because of 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 oxygen-rich blood to your 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 tricuspid valve has three leaflets. It controls blood flow from the right atrium to the right ventricle.

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

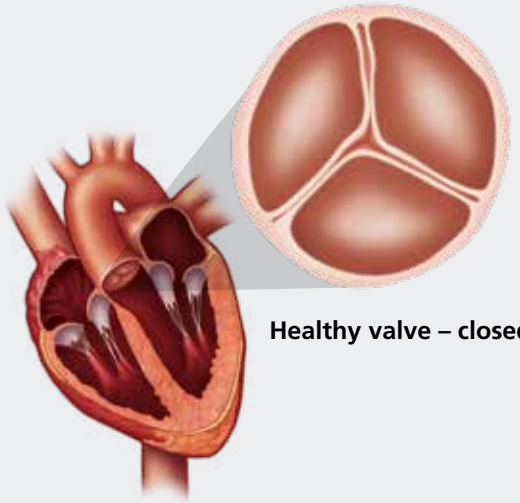
WHAT IS SEVERE AORTIC STENOSIS?

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.

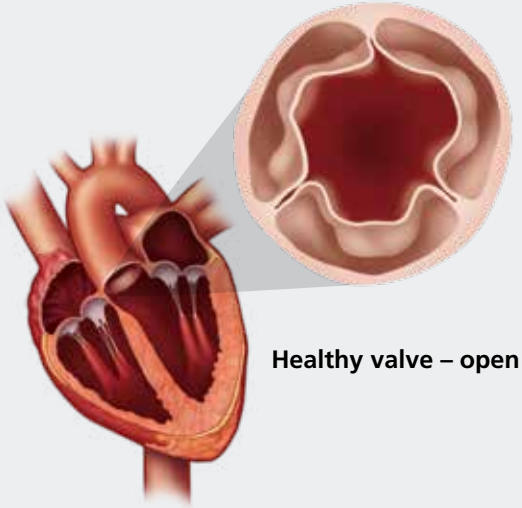
In elderly patients, severe aortic stenosis is sometimes caused by the build-up of calcium (mineral deposits) on the aortic valve's leaflets. Over time the leaflets become stiff, reducing their ability to fully open and close. When the leaflets don't fully open, your heart must work harder to push blood through the aortic valve to your body.

Eventually, your heart gets weaker, increasing the risk of heart failure (when your heart cannot supply enough blood to your body). Severe aortic stenosis is a very serious problem. Without treatment, approximately half of the people who feel sick from this problem die within an average of 2 years.

HEALTHY AORTIC VALVE

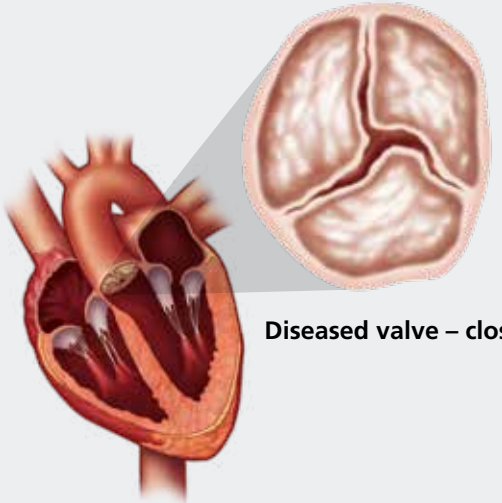


Healthy valve – closed

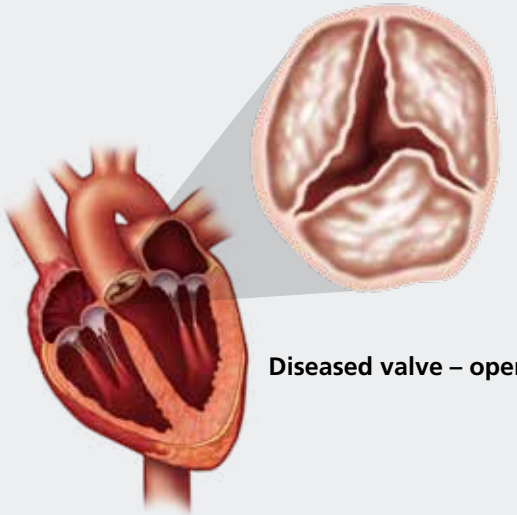


Healthy valve – open

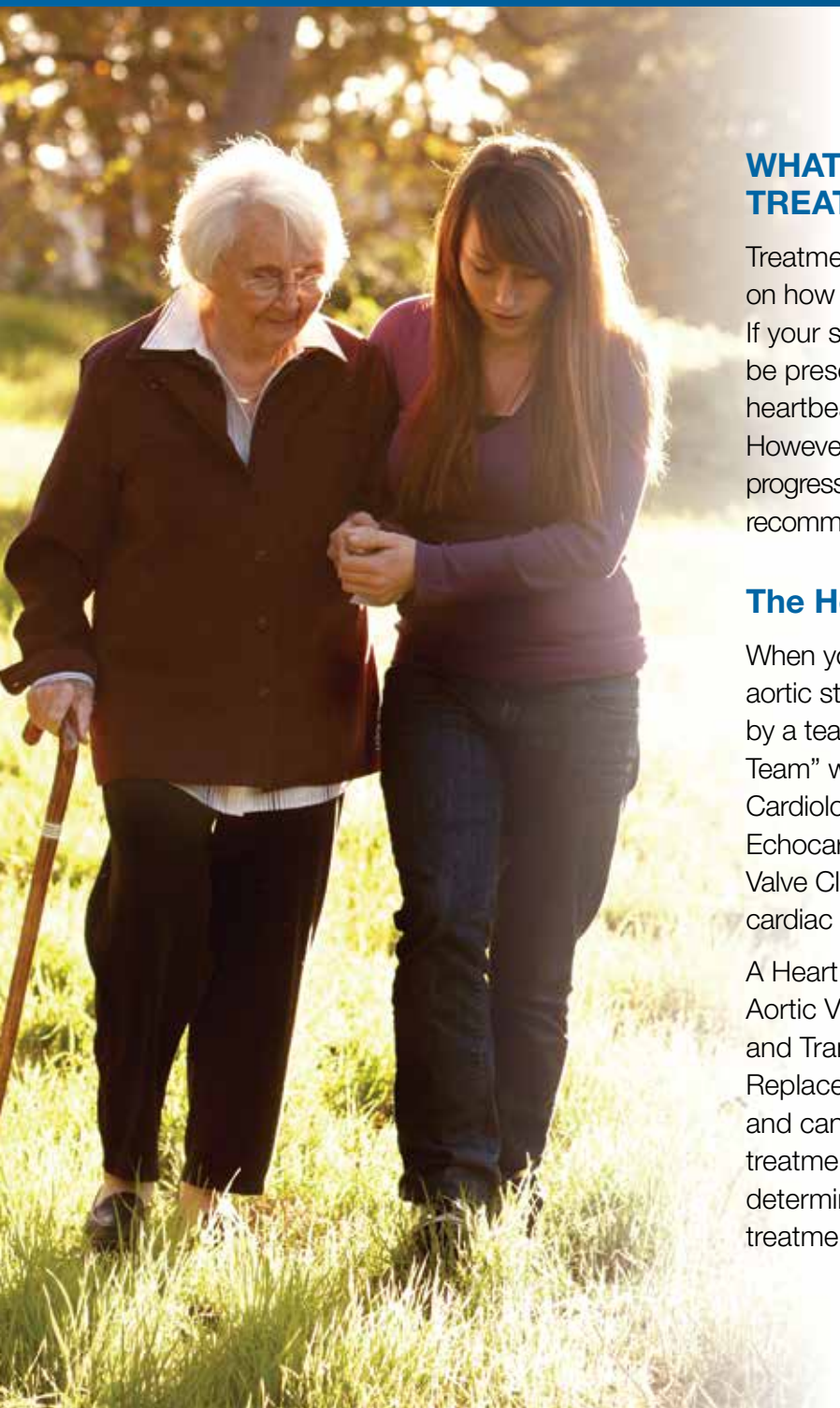
DISEASED AORTIC VALVE



Diseased valve – closed



Diseased valve – open



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 the severity of your stenosis progresses, your Heart Team may recommend replacing the diseased valve.

The Heart Team

When you are diagnosed with severe aortic stenosis, you may be evaluated by a team of physicians called a "Heart Team" which includes Interventional Cardiologists, Cardiothoracic Surgeons, Echocardiographers, Anesthesiologists, Valve Clinic Coordinators, and/or cardiac cath lab staff.

A Heart Team is experienced in both Aortic Valve Replacement (AVR) and Transcatheter Aortic Valve Replacement (TAVR) procedures, and can help you understand your treatment options and help you determine what is the most appropriate treatment option for you.

Aortic valve replacement (AVR) through open-heart surgery is the most common treatment for patients with aortic stenosis. In this operation, your diseased heart valve is removed and a new heart valve is inserted. However, some patients may be at high-risk or too sick to undergo open-heart surgery.

A minimally invasive procedure, referred to as minimal incision valve surgery (MIVS), can also be performed to replace a malfunctioning valve. In minimal incision valve surgery, the surgeon can replace the diseased valve through a smaller incision while looking directly at the heart or through a small, tube-shaped camera. The incisions are made either between the ribs or in the chest, and may use a small incision in the leg for the heart-lung machine. Minimal incision valve surgery may be an option for some patients. However, some patients may be at high-risk or too sick to undergo minimally invasive open-heart surgery. Please consult your Heart Team for more information on minimally invasive procedures.

Another treatment option for patients who are either at high-risk or too sick for open-heart surgery or minimal incision valve surgery is transcatheter aortic valve replacement. TAVR is a procedure that inserts a new valve through a catheter via multiple delivery approaches. For example, a new valve may be inserted through an incision in the leg (or slightly higher up) that does not require the chest to be opened. This procedure is intended for patients with calcified aortic stenosis. Your Heart Team will recommend the best treatment option for you based on your overall health.

What is Surgical Aortic Valve Replacement?

Surgical AVR is an open-heart procedure. During surgical AVR, 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). Surgical AVR has been performed for many years on patients who are able to undergo surgery. Surgical AVR has lengthened patients' lives.

What is Transcatheter Aortic Valve Replacement?

If a Heart Team determines that you are at high-risk or too sick for surgery, and if medicine is not helping you feel better, TAVR may be an alternative. This less invasive procedure allows a new valve to be inserted within your diseased aortic valve while your heart is still beating. Just like surgical AVR, TAVR has been shown to consistently lengthen patients' lives and improve their quality of life. Cardiopulmonary bypass is usually not required. The TAVR procedure is not right for everyone. Your Heart Team will inform you if you are a good candidate for TAVR.

TAVR maybe performed through multiple approaches. Your Heart Team will determine the best approach for you.

	Transfemoral TAVR	Transapical TAVR	Transaortic TAVR
Anesthesia	General	General	General
Cardiopulmonary bypass	Usually not required	Usually not required	Usually not required
Entry site	Incision in the leg (or slightly higher up)	Incision in the apex (the lowest part) of your heart	Incision in the upper chest

TRANSCATHETER AORTIC VALVE REPLACEMENT PROCEDURE

Who Should Not Have the Procedure?

Patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

Which Products Will Be Used During the Procedure?

The Edwards SAPIEN XT transcatheter heart valve and other accessories are used to perform the TAVR procedure. The Edwards SAPIEN XT transcatheter heart valve is a biological valve (made from animal tissue) that replaces your aortic valve. It is provided in three sizes, 23 mm, 26 mm and 29 mm in diameter. Your Heart Team will determine the right size for you.

The Edwards SAPIEN XT transcatheter heart valve (that replaces your diseased aortic valve) is pictured to the right.

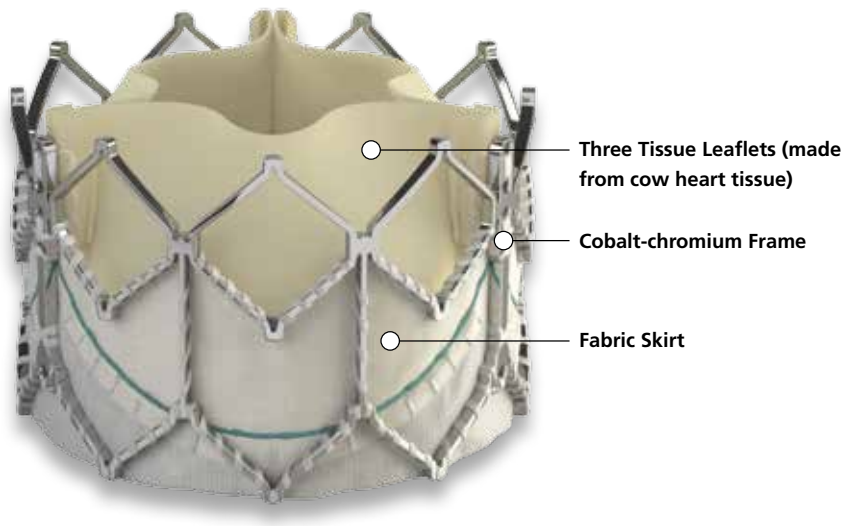


Image is larger than actual valve size.

What Do You Need to Do Before the Procedure?

Be sure to tell your Heart Team what medicine you are taking and whether you have any allergies. You may be asked to change the medicine you are on before the procedure. Your Heart Team will also explain the procedure and answer any questions you may have.

What Will Happen During the Procedure?

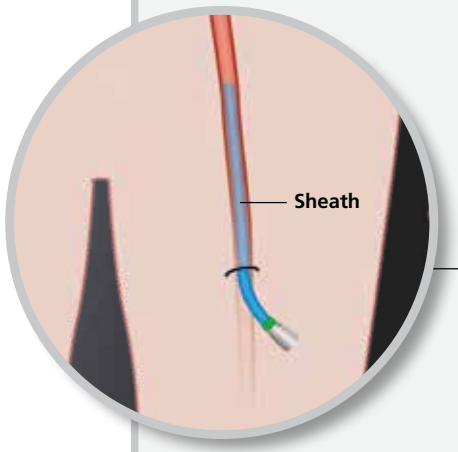
During the procedure, you will be placed under general anesthesia to put you into a deep sleep. Your doctor will use fluoroscopy (a type of X-ray that temporarily delivers radiation to you) during the procedure to view your aortic valve.

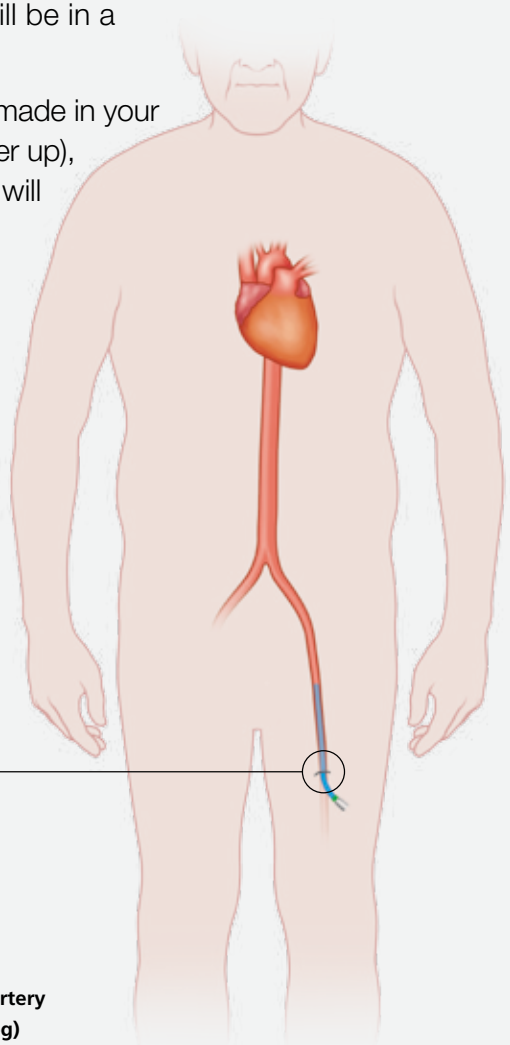
TAVR allows a new valve to be inserted through a catheter via multiple delivery approaches. For example, a new valve may be inserted through an incision in the leg (or slightly higher up) that does not require the chest to be opened.

Transfemoral Procedure

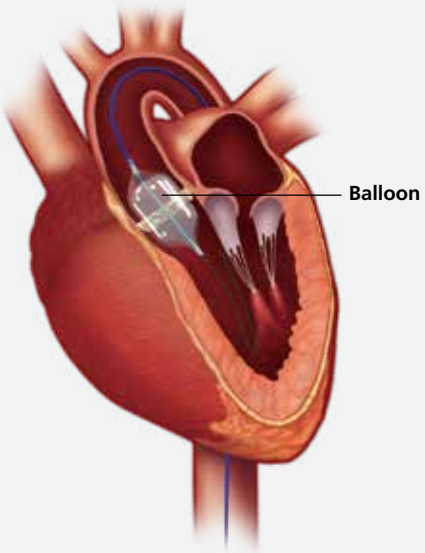
The average time required to perform the transfemoral TAVR procedure is between 1 to 2 hours.

1. You will be placed under general anesthesia (you will be in a deep sleep).
2. An incision will be made in your leg (or slightly higher up), where your doctor will put in a sheath (a short hollow tube) that is about the width of a pencil.



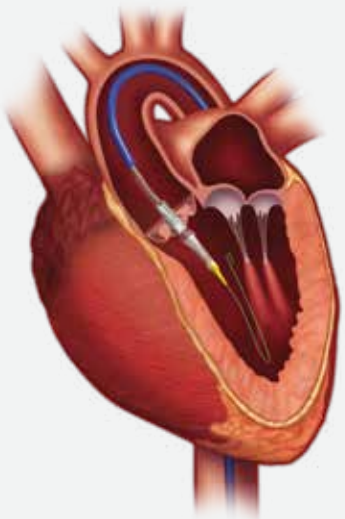


Sheath is placed in femoral artery (large artery in your upper leg)

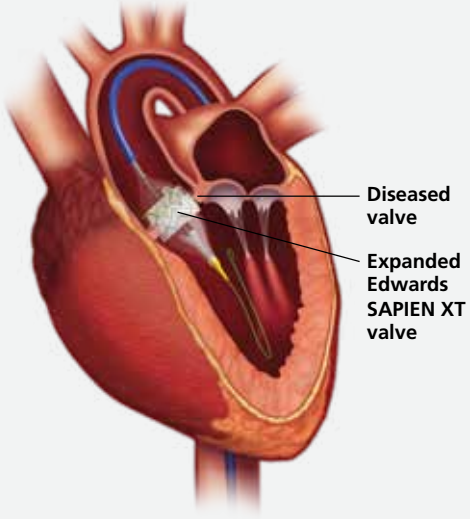


3. Your doctor will take a balloon and put it through the sheath into your femoral artery to reach your aortic valve. The balloon will be inflated with fluid to open your narrowed valve, deflated, and then removed.

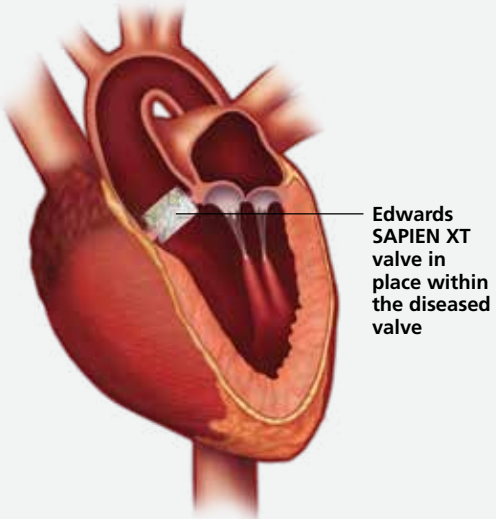
4. The Edwards SAPIEN XT transcatheter heart valve will be placed on the delivery system (long tube with a balloon on the end), and compressed on the balloon to make it small enough to fit through the sheath.



5. The delivery system carrying the valve will be placed through the sheath and pushed to your aortic valve, guided by a type of X-ray.



6. The balloon of the delivery system carrying the valve will be inflated with fluid, expanding this new valve within your diseased valve. During valve expansion, the heart is stabilized by temporarily speeding up the heartbeat. The new valve will push the leaflets of your diseased valve aside. The frame of the new valve is very strong and it will use the leaflets of your diseased valve to secure in place. Next, the balloon will be deflated.



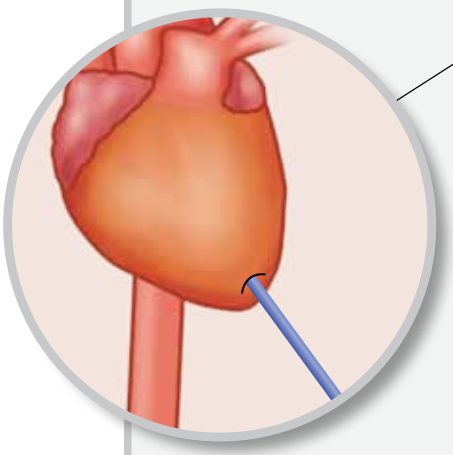
7. Your doctor will make sure that your new valve is working properly before removing the delivery system and closing the incision in your leg (or slightly higher up).

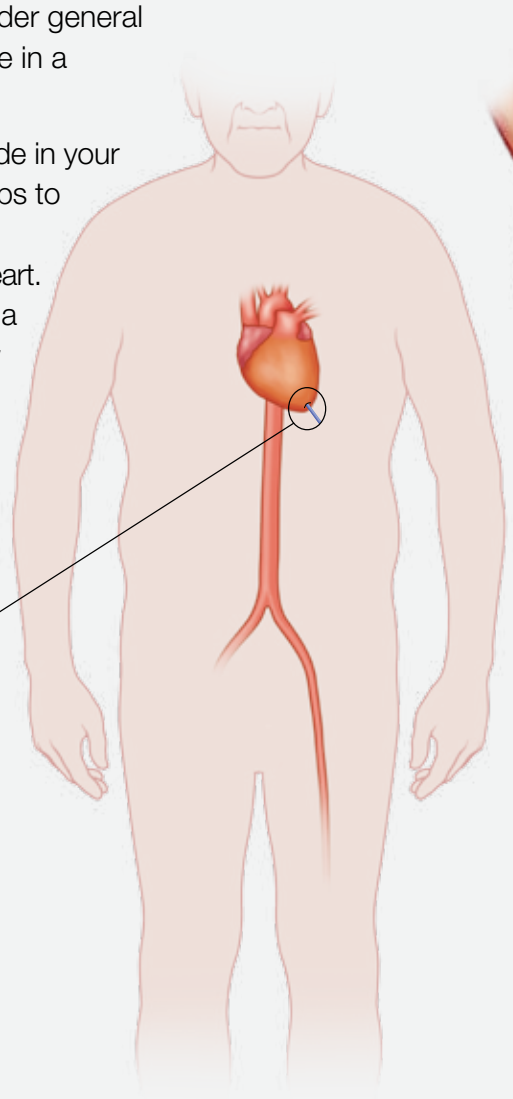
TAVR allows a new valve to be inserted through a catheter via multiple delivery approaches. For example, a new valve may be inserted through an incision in the apex (lowest part) of the heart.

Transapical Procedure

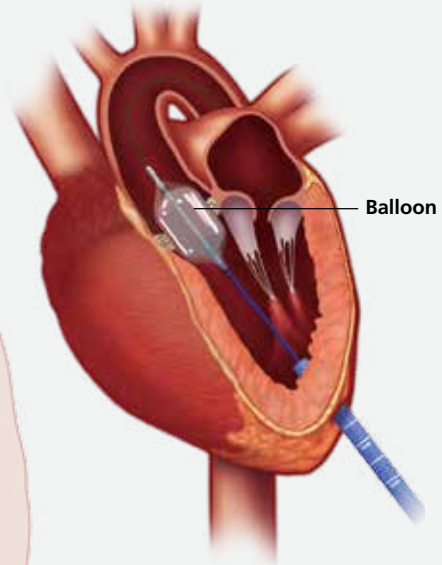
The average time required to perform the transapical TAVR procedure is between 1 to 2 hours.

1. You will be placed under general anesthesia (you will be in a deep sleep).
2. An incision will be made in your chest between your ribs to access the apex (the lowest part) of your heart. Your doctor will place a sheath (a short hollow tube) that is slightly larger than the width of a pencil through the apex and into the left ventricle.

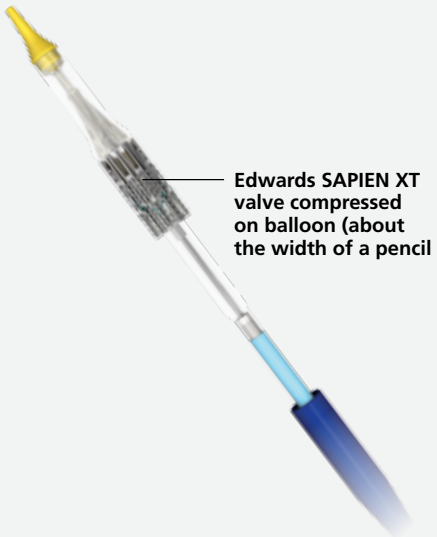




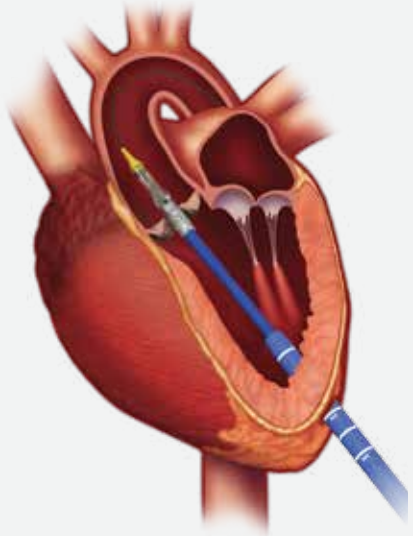
Sheath is placed in the apex (the lowest part) of your heart



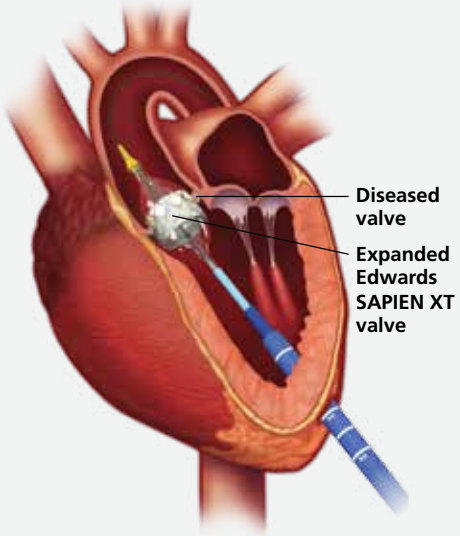
3. Your doctor will take a balloon and put it through the sheath to reach your aortic valve. The balloon will be inflated with fluid to break open your narrowed valve, deflated, and then removed.



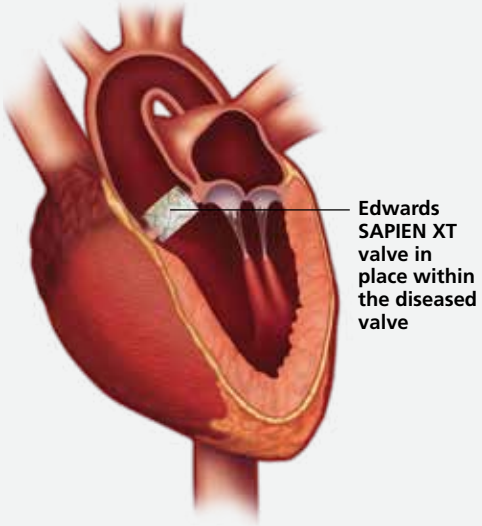
4. The Edwards SAPIEN XT transcatheter heart valve will be placed on the delivery system (long tube with a balloon on the end), and compressed on the balloon to make it small enough to fit through the sheath.



5. The delivery system carrying the valve will be placed through the sheath and pushed to your aortic valve, guided by a type of X-ray.



6. The balloon of the delivery system carrying the valve will be inflated with fluid, expanding this new valve within your diseased valve. During valve expansion, the heart is stabilized by temporarily speeding up the heartbeat. The new valve will push the leaflets of your diseased valve aside. The frame of the new valve is very strong and it will use the leaflets of your diseased valve to secure in place. Next, the balloon will be deflated.



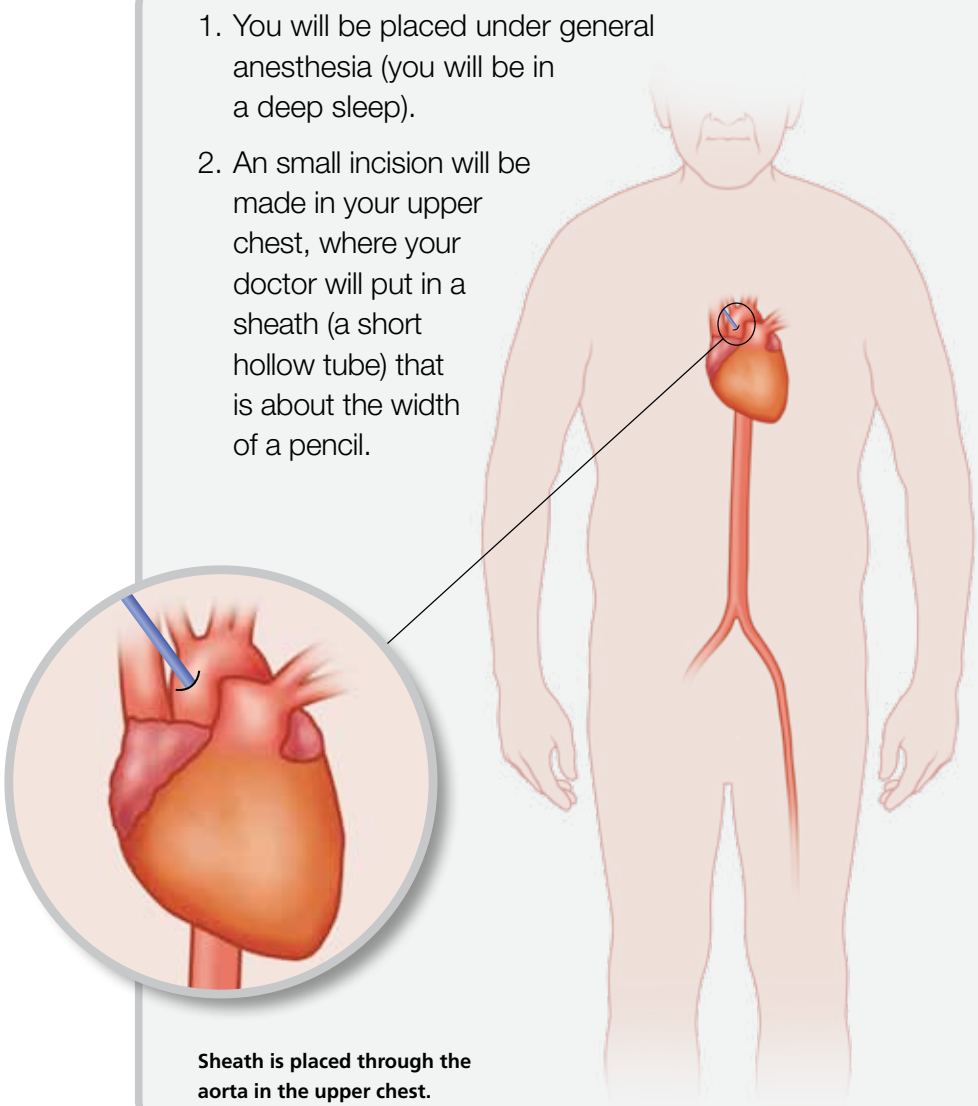
7. Your doctor will make sure that your new valve is working properly before removing the delivery system and closing the chest incision between your ribs.

TAVR allows a new valve to be inserted through a catheter via multiple delivery approaches. For example, a new valve may be inserted through an incision in the upper chest

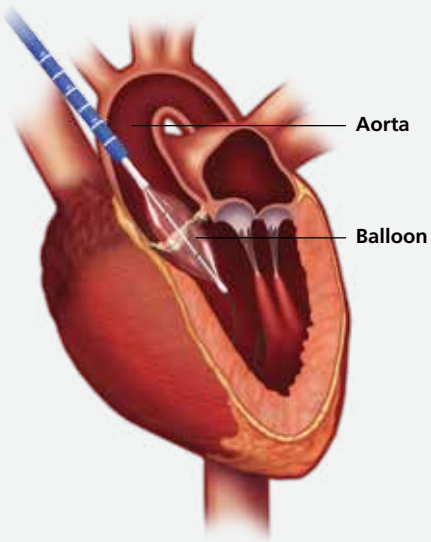
Transaortic Procedure

The average time required to perform the transaortic TAVR procedure is between 1 to 2 hours.

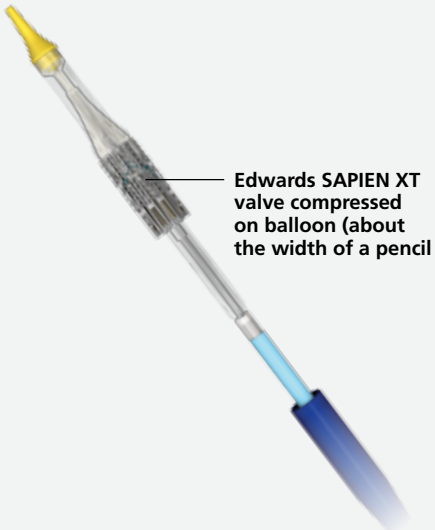
1. You will be placed under general anesthesia (you will be in a deep sleep).
2. An small incision will be made in your upper chest, where your doctor will put in a sheath (a short hollow tube) that is about the width of a pencil.



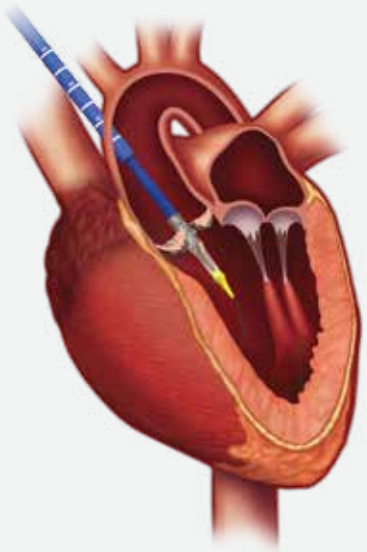
Sheath is placed through the aorta in the upper chest.



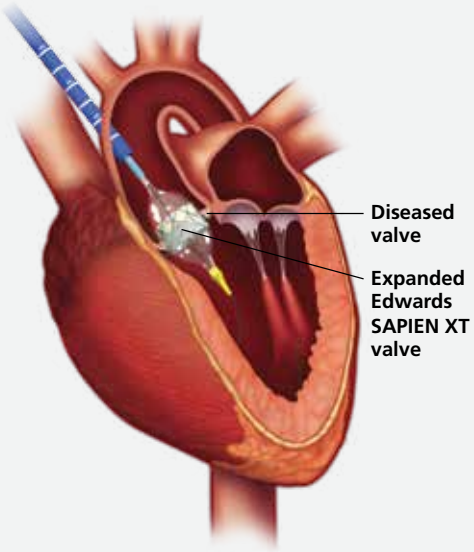
3. Your doctor will take a balloon and put it through the sheath into your aorta to reach your aortic valve. The balloon will be inflated with fluid to open your narrowed valve, deflated, and then removed.



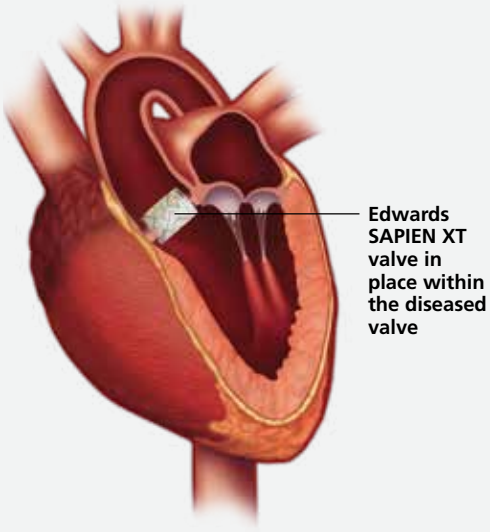
4. The Edwards SAPIEN XT transcatheter heart valve will be placed on the delivery system (tube with a balloon on the end), and compressed on the balloon to make it small enough to fit through the sheath.



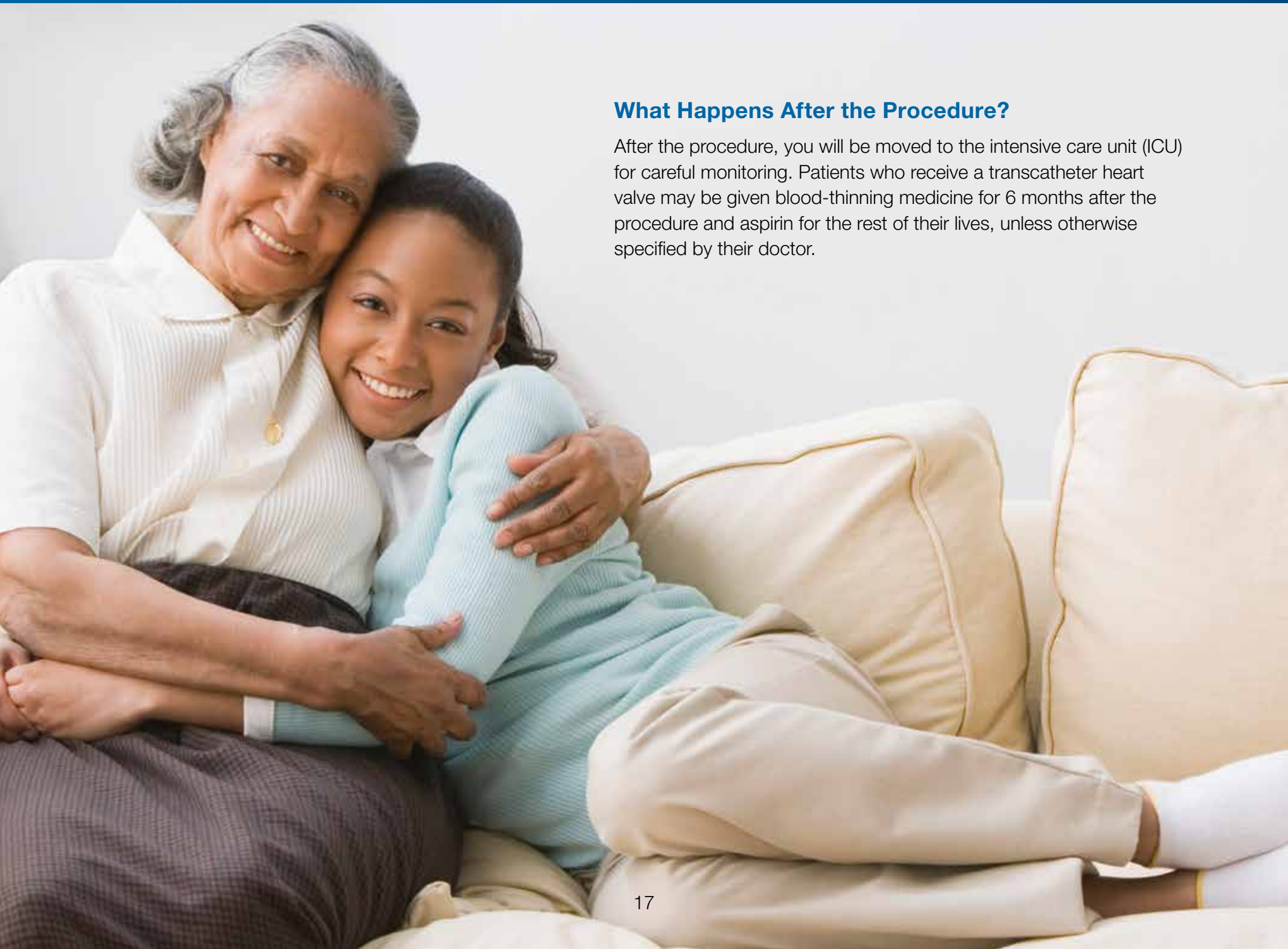
5. The delivery system carrying the valve will be placed through the sheath and pushed to your aortic valve, guided by a type of X-ray.



6. The balloon of the delivery system carrying the valve will be inflated with fluid, expanding this new valve within your diseased valve. During valve expansion, the heart is stabilized by temporarily speeding up the heartbeat. The new valve will push the leaflets of your diseased valve aside. The frame of the new valve is very strong and it will use the leaflets of your diseased valve to secure in place. Next, the balloon will be deflated.



7. Your doctor will make sure that your new valve is working properly before removing the delivery system and closing the incision in your upper chest.



What Happens After the Procedure?

After the procedure, you will be moved to the intensive care unit (ICU) for careful monitoring. Patients who receive a transcatheter heart valve may be given blood-thinning medicine for 6 months after the procedure and aspirin for the rest of their lives, unless otherwise specified by their doctor.

While in the hospital after the TAVR procedure, the following examinations will be completed:

- Physical exam that includes an exam for stroke
- Chest X-ray
- Blood tests
- Electrocardiography (ECG or EKG - a test that records your heart's electrical activity)
- Ultrasound of your heart

You will remain in the ICU until your Heart Team feels you can be transferred to a regular hospital room, where you will continue to be monitored until you leave the hospital.

You should feel better soon after your procedure. Your Heart Team will give you specific instructions to help you with your recovery, which 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. Your doctor will monitor your medicine and advise you when or if you can stop taking it.

Regular check-ups by your Heart Team are very important. It is easier for patients with an artificial heart valve to get infections, which could lead to future heart damage. Failure to do so may result in damage to the valve that could lead to death.

Call or see your Heart Team whenever you have questions or concerns about your health, especially if you experience any unusual problems such as bleeding, pain, other discomfort or changes in your overall health.

Even after you have fully recovered from the procedure, your Heart Team may want to check your progress occasionally.

You will need to take all medications as prescribed and have your heart checked from time to time. Be sure to discuss all your medications (including over-the-counter medicine) with your Heart Team, and don't change any dosage unless instructed to, even if you feel better.

Always inform other doctors about your heart valve replacement before any medical or dental procedure. Before undergoing an MRI (magnetic resonance imaging) procedure, always notify the doctor (or medical technician) that you have an implanted heart valve. Failure to do so may result in damage to the valve that could lead to death.

TRANSCATHETER AORTIC VALVE REPLACEMENT CLINICAL DATA

TAVR with Edwards' transcatheter heart valves has been performed on thousands of patients since 2007 who are either at high-risk or too sick for open-heart surgery. TAVR is a minimally invasive option and, just like surgical AVR, has been shown to lengthen patients' lives and significantly improve their quality of life.

The PARTNER II Trial Overview

The PARTNER II Trial (Cohort B) studied the safety and effectiveness of the Edwards SAPIEN XT transcatheter heart valve. The study was conducted on more than 800 patients whose doctors had determined them to be too sick to undergo open-heart surgery. This patient population is referred to as "inoperable." Patients were treated with the Edwards SAPIEN XT transcatheter heart valve by the transfemoral, transapical, and transaortic approaches. Patients in Cohort B were examined at 30 days, 6 months, and 1 year after the procedure, and will continue to be examined every year for 5 years.

What Are the Possible Benefits and Risks After the Procedure?

Benefits of the Procedure:
For patients with severe aortic stenosis, TAVR can provide many benefits after the procedure. Not only does it replace your failing aortic valve providing you symptom relief, it also increases heart function and improves overall quality of life. In addition, TAVR may have a shorter recovery time to resume everyday activities.

Symptom Relief: Most patients receiving a SAPIEN XT transcatheter heart valve can expect immediate symptom relief. The majority of patients who had severe or marked limitation in activity and symptoms such as severe shortness of breath and angina before the procedure experienced significant improvement in symptoms and activity level after receiving TAVR with the Edwards SAPIEN XT transcatheter heart valve.

Quality of Life Improvement: The clinical trial assessed quality of life using a combination of standardized tools* to determine the improvement in patient's health after the procedure. These assessments showed substantial improvement in patient health as soon as 30 days after the procedure. At 1 year patients continued to experience improvement. Patients reported significant improvements in quality of life including: reduction in pain and anxiety, and the ability to take care of themselves and participate in everyday activities.

As with any medical procedure, there is a possibility that complications may occur during or after receiving an Edwards SAPIEN XT transcatheter heart valve, even after leaving the hospital.

The most serious risks of the TAVR procedure with the Edwards SAPIEN XT transcatheter heart valve in inoperable patients 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.
- **Disabling bleeding event** – a fatal or life threatening bleeding event or bleeding event that requires 4 or more units of a blood transfusion within the procedure.

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

Transfemoral TAVR with Edwards SAPIEN XT Transcatheter Heart Valve - Clinical Data Tables

The following tables are a summary of the clinical risks observed within 30 days and within 1 year in inoperable patients (Cohort B) from The PARTNER II Trial. The frequency is shown as the number of patients out of every 100.

Transfemoral TAVR with the Edwards SAPIEN XT transcatheter heart valve		
	Risk within 30 days after the Transfemoral TAVR procedure	**Risk within 1 year after the Transfemoral TAVR procedure**
Death from any cause	4 out of 100 patients	22 out of 100 patients
Death from cardiovascular (heart-related) causes	3 out of 100 patients	16 out of 100 patients
Major stroke	3 out of 100 patients	5 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	6 out of 100 patients	8 out of 100 patients
Disabling bleeding event (fatal or life threatening)	8 out of 100 patients	13 out of 100 patients
Major vascular complications	11 out of 100 patients	12 out of 100 patients
Repeat hospitalizations	9 out of 100 patients	22 out of 100 patients
Myocardial infarction (heart attack)	2 out of 100 patients	7 out of 100 patients
Endocarditis (inflammation or infection of any internal heart structures, including the valves)	0 out of 100 patients	1 out of 100 patients
New atrial fibrillation (abnormal heartbeat)	3 out of 100 patients	6 out of 100 patients

***Note:* Risks within 1 year after the TAVR procedure only include clinical data from 23 mm and 26 mm transcatheter heart valve (THV) sizes, and do not include 29 mm THV data.**

Additional Information on the Transfemoral TAVR Procedure	
	Transfemoral TAVR with Edwards SAPIEN XT transcatheter heart valve
Average Procedure Time*	1-2 hours
Median Length of Stay (days)	6 days

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

Transapical/Transaortic TAVR with Edwards SAPIEN XT Transcatheter Heart Valve - Clinical Data Tables

The following tables are a summary of the clinical risks observed within 30 days in inoperable patients (Cohort B) from The PARTNER II Trial. The frequency is shown as the number of patients out of every 100.

Transapical/Transaortic TAVR with the Edwards SAPIEN XT transcatheter heart valve	
	Risk within 30 days after the Transapical/Transaortic TAVR procedure
Death from any cause	8 out of 100 patients
Major stroke	2 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	5 out of 100 patients
Major vascular complications	6 out of 100 patients
Repeat hospitalizations	3 out of 100 patients
Myocardial infarction (heart attack)	2 out of 100 patients
Endocarditis (inflammation or infection of any internal heart structures, including the valves)	0 out of 100 patients
New atrial fibrillation (abnormal heartbeat)	6 out of 100 patients

Additional Information on the Transapical/Transaortic TAVR Procedure	
	Transapical/Transaortic TAVR with Edwards SAPIEN XT transcatheter heart valve
Average Procedure Time*	1-2 hours
Median Length of Stay (days)	8 days

* The average total procedure duration is based on data from The PARTNER II 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 SOURCE XT STUDY

SOURCE XT studied safety and effectiveness of the Edwards SAPIEN XT transcatheter heart valve in approximately 2700 patients whose doctors had determined them to be at high risk for open-heart surgery. Patients were treated with the Edwards SAPIEN XT transcatheter heart valve by the transfemoral, transapical, and transaortic approaches.

Transfemoral TAVR with Edwards SAPIEN XT Transcatheter Heart Valve - Clinical Data Table

The following table is a summary of the clinical risks observed within 30 days and within 1 year in high-risk patients in The SOURCE XT Study. The frequency is shown as the number of patients out of every 100.

Transfemoral TAVR with the Edwards SAPIEN XT transcatheter heart valve		
	Risk within 30 days after the Transfemoral TAVR procedure	**Risk within 1 year after the Transfemoral TAVR procedure**
Death from any cause	4 out of 100 patients	15 out of 100 patients
Death from cardiovascular (heart-related) causes	2 out of 100 patients	7 out of 100 patients
Major stroke	2 out of 100 patients	4 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	9 out of 100 patients	10 out of 100 patients
Disabling bleeding event (fatal or life threatening)	4 out of 100 patients	5 out of 100 patients
Major vascular complications	8 out of 100 patients	8 out of 100 patients
Repeat hospitalizations	5 out of 100 patients	26 out of 100 patients
Myocardial infarction (heart attack)	1 out of 100 patients	2 out of 100 patients
Endocarditis (inflammation or infection of any internal heart structures, including the valves)	1 out of 100 patients	1 out of 100 patients
New atrial fibrillation (abnormal heartbeat)	3 out of 100 patients	6 out of 100 patients

Transapical/Transaortic TAVR with Edwards SAPIEN XT Transcatheter Heart Valve - Clinical Data Table

The following table is a summary of the clinical risks observed within 30 days and within 1 year in high-risk patients in The SOURCE XT Study. The frequency is shown as the number of patients out of every 100.

Transapical/Transaortic TAVR with the Edwards SAPIEN XT transcatheter heart valve		
	Risk within 30 days after the Transapical/Transaortic TAVR procedure	**Risk within 1 year after the Transapical/Transaortic TAVR procedure**
Death from any cause	10 out of 100 patients	27 out of 100 patients
Death from cardiovascular (heart-related) causes	5 out of 100 patients	14 out of 100 patients
Major stroke	3 out of 100 patients	5 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	11 out of 100 patients	13 out of 100 patients
Disabling bleeding event (fatal or life threatening)	9 out of 100 patients	11 out of 100 patients
Major vascular complications	4 out of 100 patients	6 out of 100 patients
Repeat hospitalizations	9 out of 100 patients	37 out of 100 patients
Myocardial infarction (heart attack)	1 out of 100 patients	3 out of 100 patients
Endocarditis (inflammation or infection of any internal heart structures, including the valves)	1 out of 100 patients	1 out of 100 patients
New atrial fibrillation (abnormal heartbeat)	9 out of 100 patients	12 out of 100 patients

PRECAUTIONS

- How long your new valve will last is unknown at this time. Regular medical follow-up is essential to evaluate how your valve is performing.
- Transcatheter heart valve patients should stay on blood-thinning medicine for 6 months after the procedure and aspirin for the rest of their lives, unless otherwise specified by their doctor. Patients who do not take blood-thinning medicine may be at increased risk of developing a dangerous blood clot after the procedure which may result in a stroke. Blood-thinning medicine may increase the risk of bleeding in the brain (stroke).
- Transcatheter heart valve patients who are undergoing dental procedures should receive prophylactic antibiotic therapy to minimize the possibility of infection.
- The safety of the transcatheter heart valve has not been established in patients who have:
  - A previously implanted artificial aortic heart valve.
  - A ventricle 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

- **There is an increased risk of stroke in transcatheter aortic valve replacement procedures as compared to balloon aortic valvuloplasty and medical management for aortic stenosis.**
- **There is an increased risk of major blood vessel complications in transcatheter aortic valve replacement procedures as compared to balloon aortic valvuloplasty and medical management for aortic stenosis.**
- **The artificial valve may not last as long in patients whose bodies process calcium abnormally.**
- **Talk to your doctor if you are allergic to materials such as chromium, nickel, molybdenum, manganese, copper, silicon, and/or polymeric materials.**
- **X-ray is used during the procedure and may cause radiation injury to the skin.**

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 3 years.

The most common reason that a biological valve may fail is a gradual build-up of calcium (mineral deposits). In this situation, the valve may not work properly, which may cause your aortic stenosis to return, and possibly chest pain, shortness of breath, irregular heartbeat, and fatigue. If your stenosis returns or the valve leaks, you may need an additional procedure. Talk to your Heart Team if you experience any of these symptoms. Regular medical follow-up is essential to evaluate how your valve is performing.

CONTACT INFORMATION

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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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