

INTERMEDIATE OR GREATER RISK

Transcatheter Aortic Valve Replacement

with the Edwards SAPIEN XT
Transcatheter Heart Valve

For Patients & Caregivers



Edwards

This patient booklet is for those who are suffering from severe aortic stenosis and are at intermediate or greater risk for surgical aortic valve replacement. This information will help you learn more about your heart, aortic stenosis and your treatment options, including a less invasive procedure called transcatheter aortic valve replacement (TAVR).

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



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Table of Contents

Your Heart Valves	3
What is Severe Aortic Stenosis?	4
Factors Associated With Aortic Valve Disease	4
What Are the Symptoms of Aortic Stenosis	4
Understanding Your Treatment Options for Severe Aortic Stenosis	5-6
Surgery	5
Transcatheter Aortic Valve Replacement (TAVR)	6
Edwards SAPIEN XT Transcatheter Heart Valve	8-16
What Do You Need to Do Before the Procedure?	9
Transfemoral Approach	9-10
Transapical Approach	11-12
Transaortic Approach	13-14
What Happens After the Procedure?	15
What Are the Benefits of TAVR?	15
How Long Will My Valve Last?	16
Clinical Data for Intermediate-Risk Patients	17-18
TAVR and Surgery 30-day Clinical Outcomes	17
TAVR and Surgery 2-year Clinical Outcomes	18
Clinical Data for High-Risk Patients	19-20
Transfemoral TAVR 30-day and 1-year Clinical Outcomes	19
Transapical/Transaortic TAVR 30-day and 1-year Clinical Outcomes	20
Clinical Data for Inoperable Patients	21-22
Transfemoral TAVR 30-day and 1-year Clinical Outcomes	21
Transapical/Transaortic TAVR 30-day and 1-year Clinical Outcomes	22
What Are the Risks of TAVR?	24
Precautions	25-26
Warnings	26
Who Should Not Have the Procedure?	26
Contact Information	27

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 specialized Heart Team can decide which treatment option is right for you.

YOUR HEART VALVES

The heart is a muscular organ in your chest that is about the size of your fist. The heart's main function is to pump blood to the rest of your body. Each valve usually has two or three leaflets (flaps of tissue) that open and close like gates to regulate the one-way flow of blood through the heart.

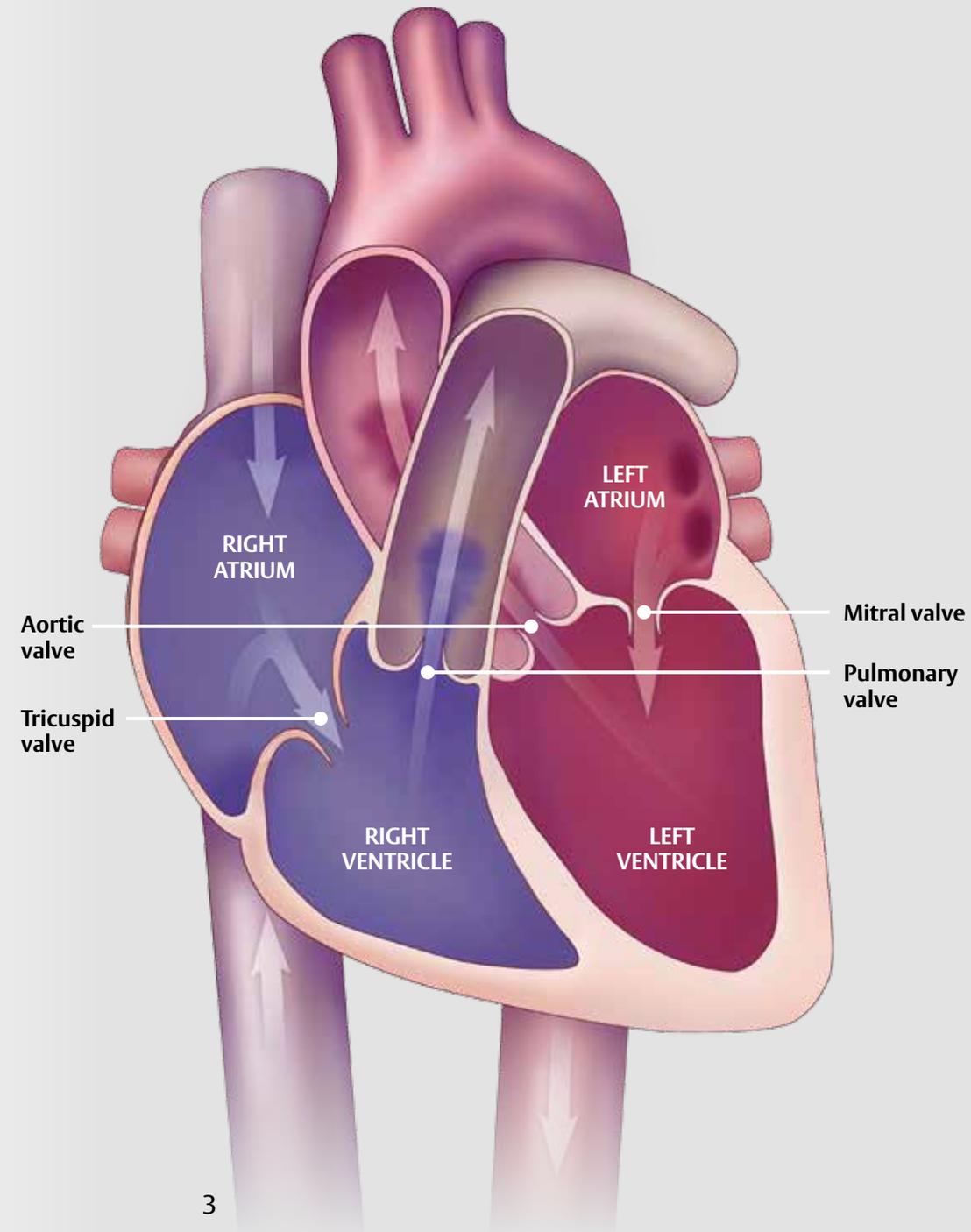
It is important that your valves are always working properly:

- Be properly formed and flexible
- Should 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

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



WHAT IS SEVERE AORTIC STENOSIS?

Aortic stenosis 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 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 rest of the body, which may cause symptoms. It's important to know that heart valve disease may occur with no outward symptoms.

Severe aortic stenosis is a very serious problem. Approximately 50% of the people who develop symptoms will die within an average of 2 years without aortic valve replacement.

Factors Associated With Aortic Valve Disease

- Increasing age
- High blood pressure
- High cholesterol
- Smoking

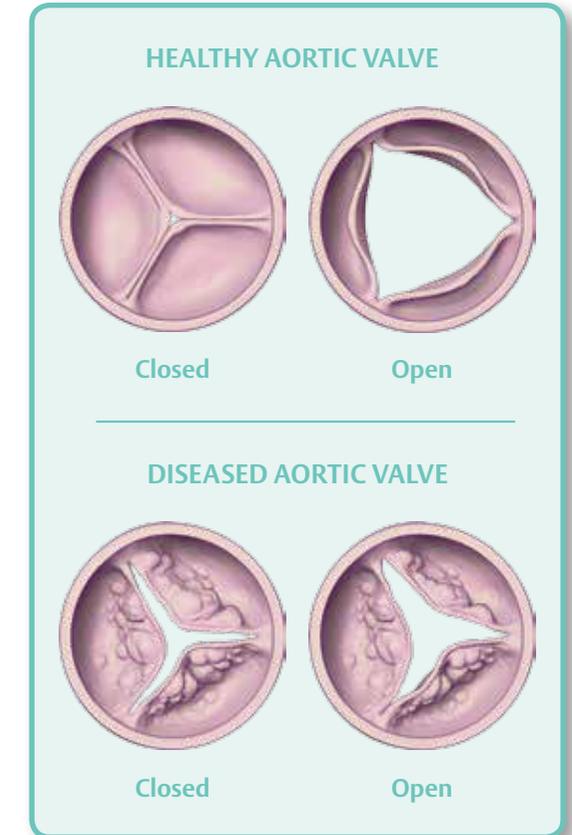
What Are The Symptoms of Aortic Stenosis

- Chest pain
- Fatigue
- Shortness of breath
- Lightheadedness, feeling dizzy, and/or fainting
- Difficulty when exercising

The symptoms of aortic stenosis are commonly misunderstood by patients as 'normal' signs of aging.

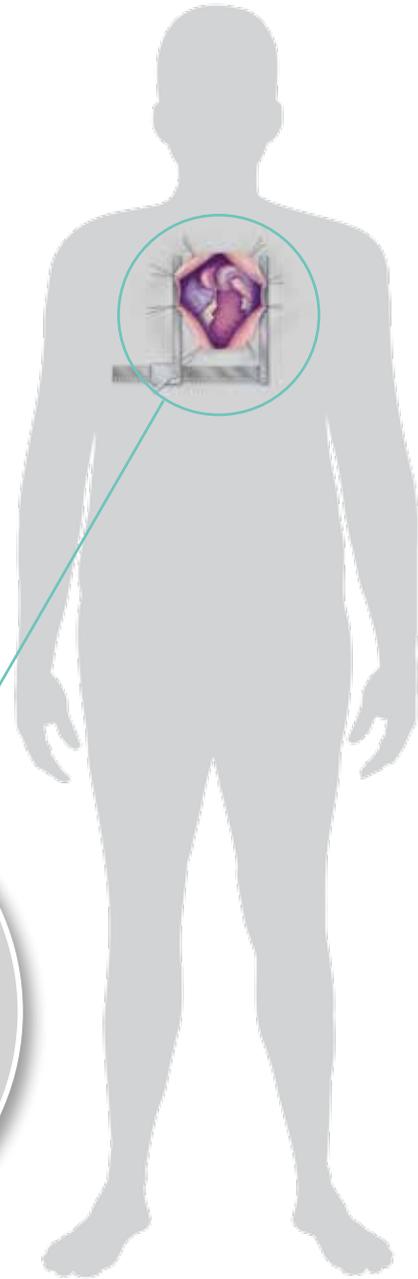
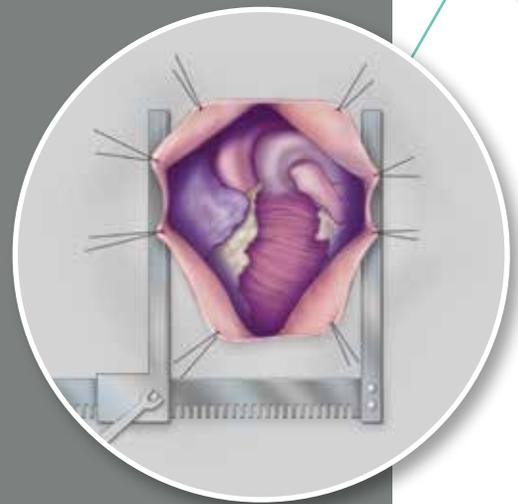


If you suspect any change in your ability to perform routine daily activities, consult your cardiologist right away.



UNDERSTANDING YOUR TREATMENT OPTIONS FOR SEVERE AORTIC STENOSIS

If you have been diagnosed with severe aortic stenosis and your doctor has evaluated you to be at intermediate or greater risk for surgery, TAVR may be a better alternative for you. However, only a specialized Heart Team can determine which treatment option is best for you.



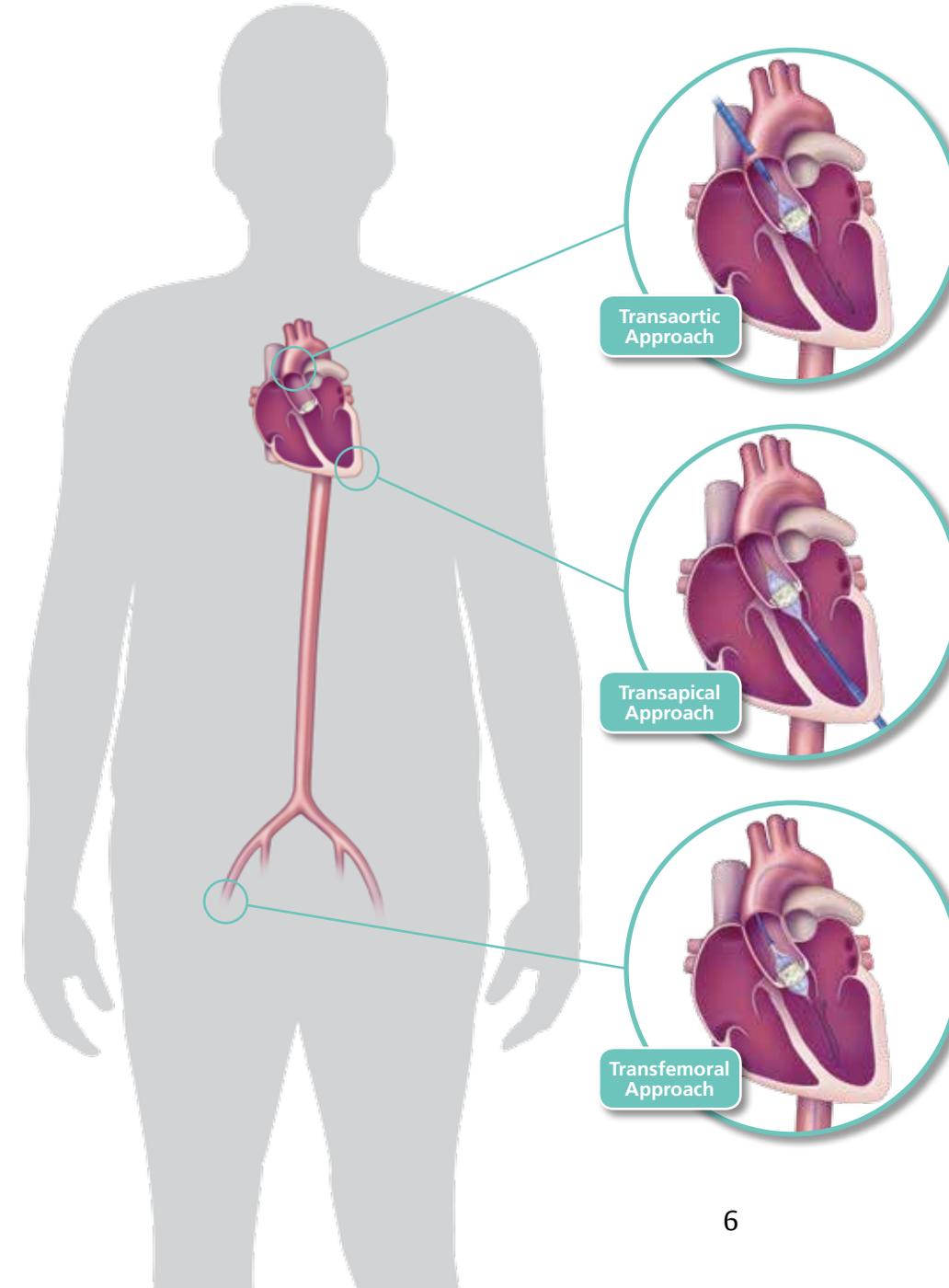
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Surgery

Most open heart surgeries are performed through an incision across the full length of the breast bone, or sternum. This incision is called a median sternotomy. Occasionally open heart surgeries can be performed through smaller incisions.

Open heart surgeries, including those performed through smaller incisions, both require the use of a heart lung machine which temporarily takes over the function of the heart. During the procedure, the surgeon will completely remove the diseased aortic valve and insert a new valve. There are two different types of surgical valves:

- Mechanical (man-made material)
- Biological (animal or human tissue)



6

Transcatheter Aortic Valve Replacement (TAVR)

TAVR is a less invasive, catheter-based technique for replacing the diseased aortic valve. TAVR can be performed through different delivery options. An interventional cardiologist along with a cardiothoracic surgeon will work together in the TAVR procedure. They will guide a new valve into the heart through an incision while the heart is still beating, using guidance from X-ray and echocardiography.

For more information on treatment options, please visit



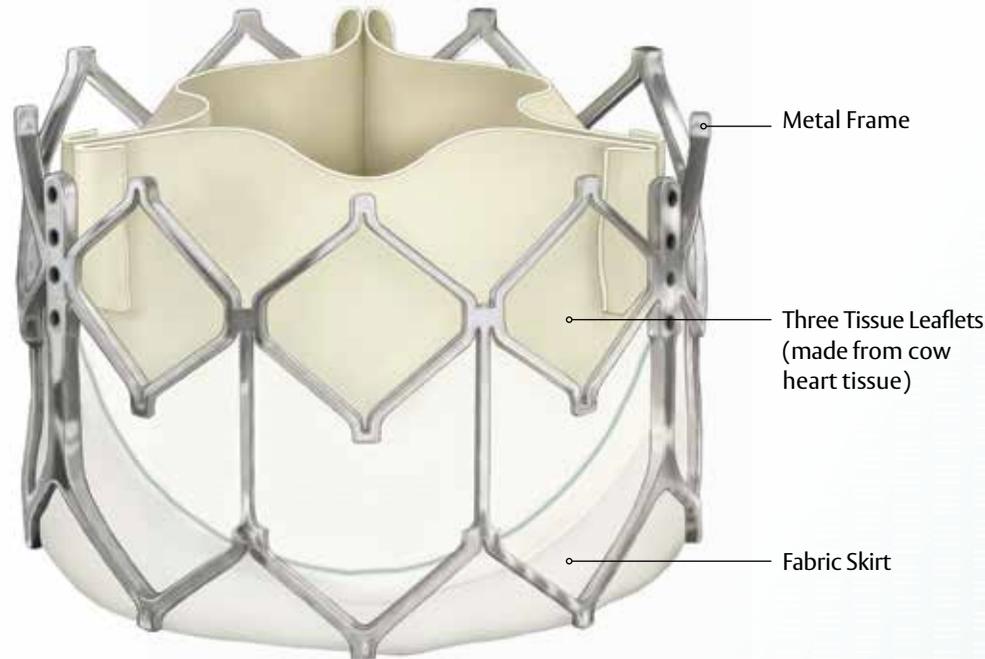
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EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE

The Edwards SAPIEN XT transcatheter heart valve is a biological tissue valve that will replace your diseased aortic valve. It is available in three sizes, 23, 26 and 29 mm in diameter. Your specialized Heart Team will determine which size is right for you.

Edwards' first transcatheter heart valve was approved commercially in Europe in 2007 and in the United States in 2011. To date, Edwards' transcatheter heart valves have treated more than 150,000 patients in over 65 countries around the world.



An illustration of the SAPIEN XT valve is pictured above.
Image is larger than actual valve size.

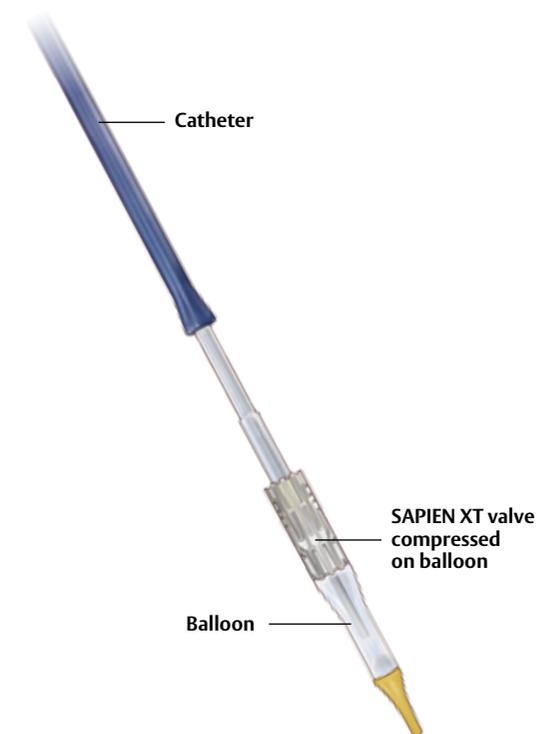
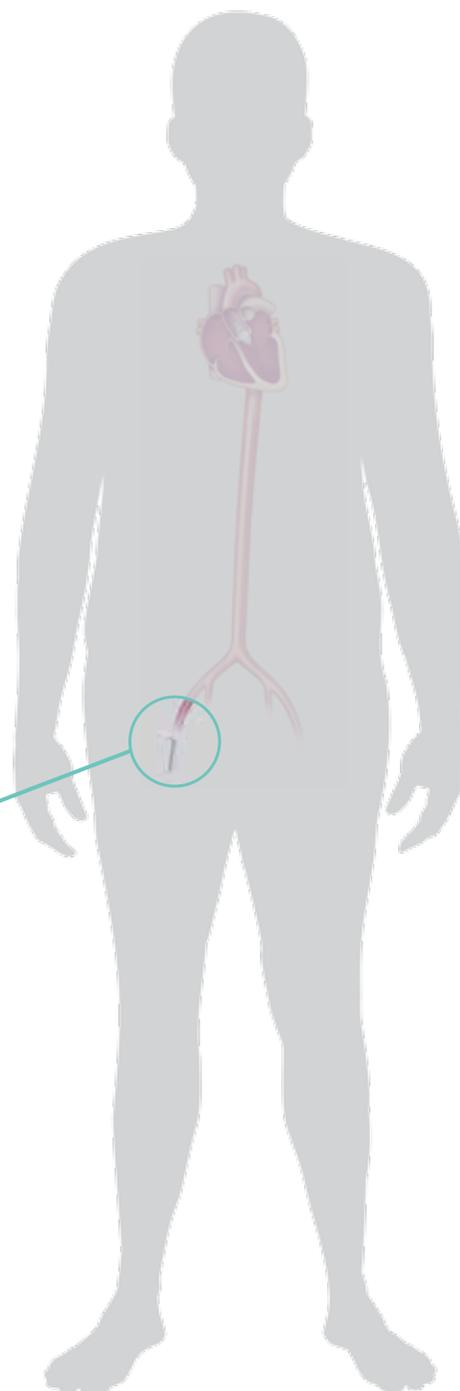
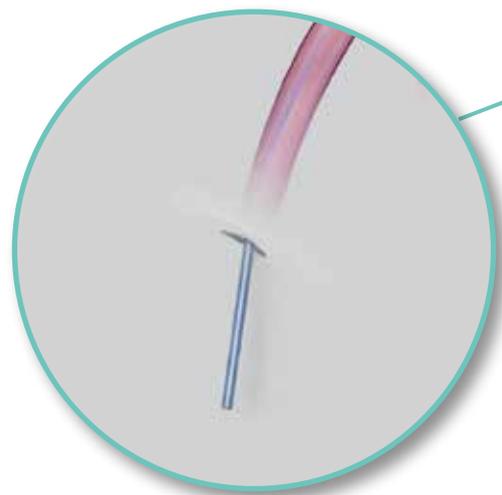
What Do You Need to Do Before the Procedure?

Be sure to talk with your specialized 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.

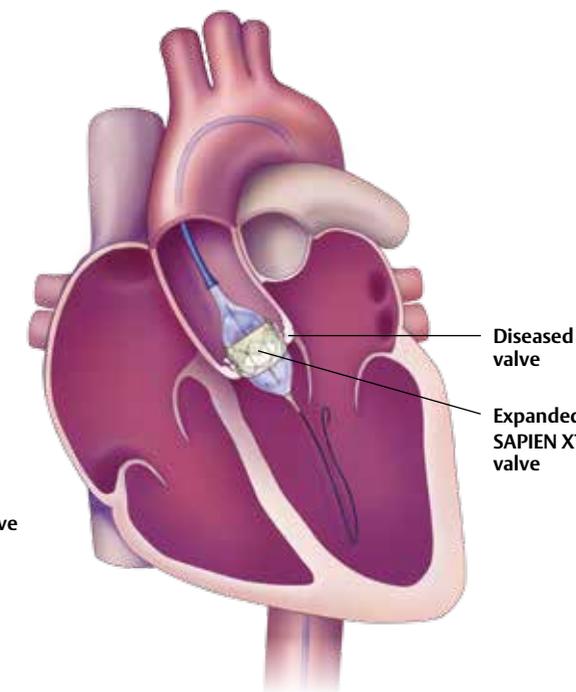
The average time required to perform the transfemoral TAVR procedure with the SAPIEN XT valve is between 1 to 2 hours.

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

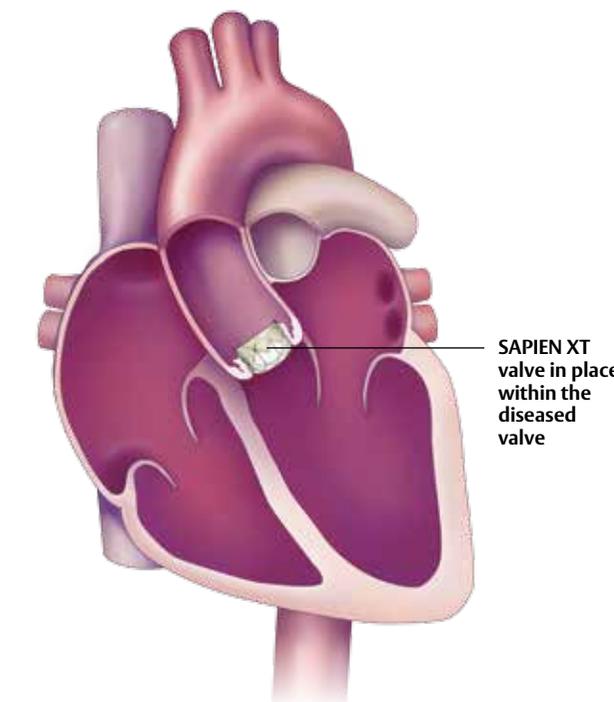
1. Before your procedure, you may be placed under anesthesia.
2. A small incision will be made in your leg where your doctor will insert a short, hollow tube called a sheath.



3. Your new valve will be placed on the delivery system tube and compressed on the balloon to make it small enough to fit through the sheath.



4. The balloon of the delivery system carrying the valve will be inflated, expanding this 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 it in place. The balloon will then be deflated and removed.

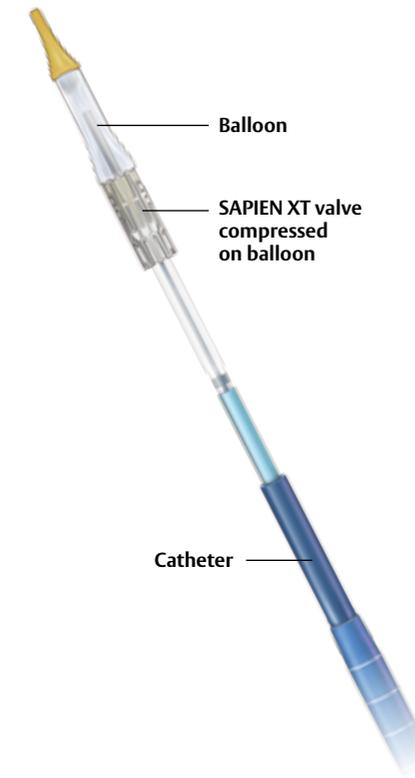
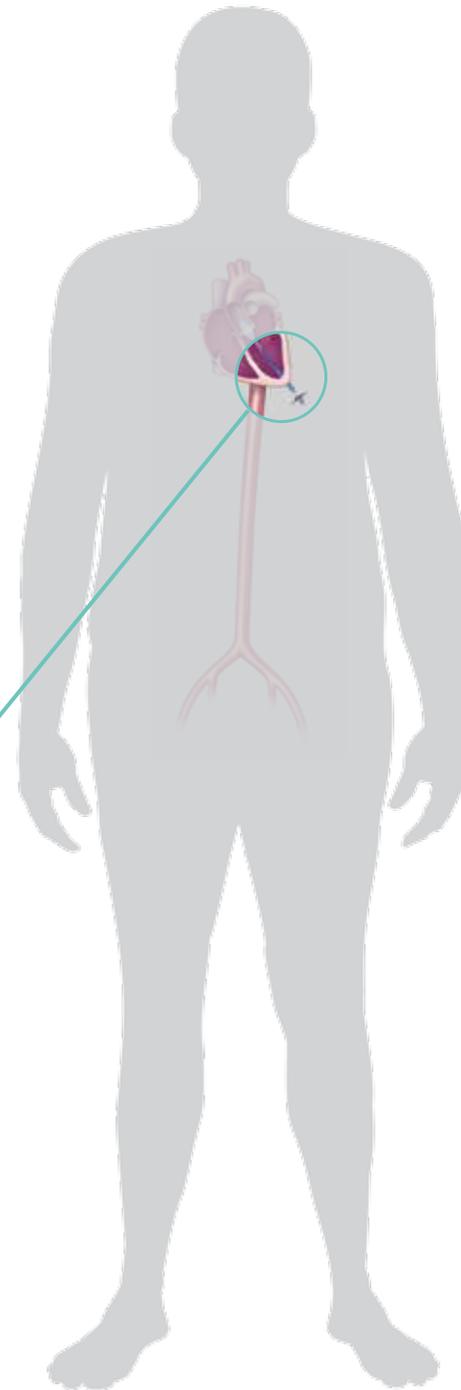
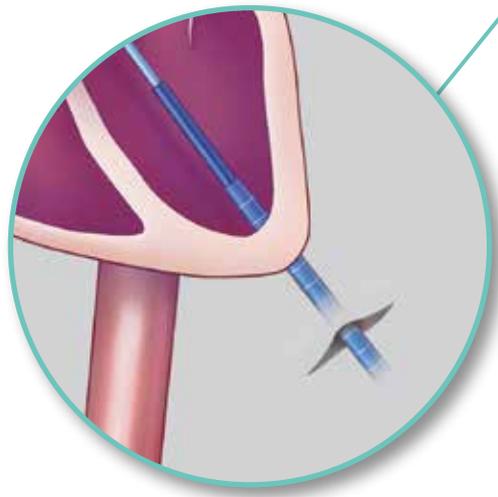


5. Your doctor will make sure that your new valve is working properly before removing the sheath and closing the incision in your leg.

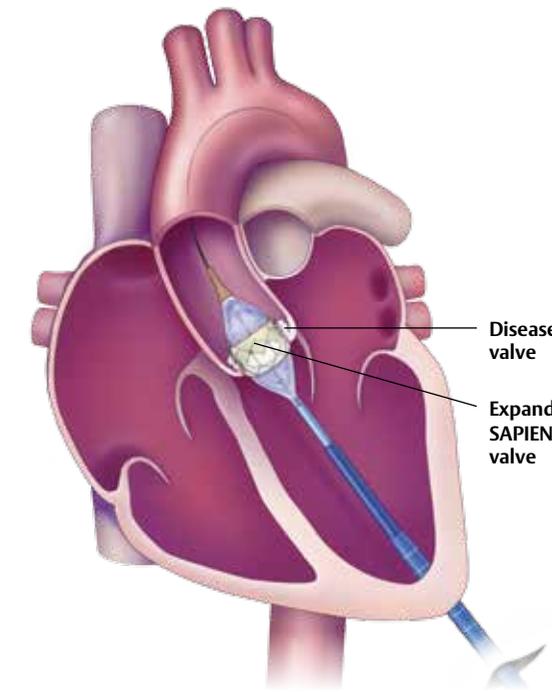
The average time required to perform the transapical TAVR procedure with the SAPIEN XT valve is between 1 to 2 hours.

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

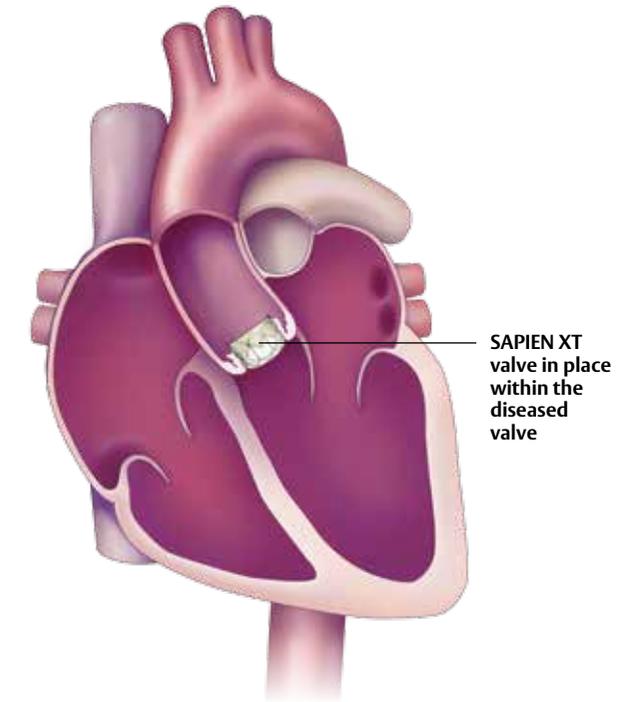
1. Before your procedure, you will be placed under anesthesia.
2. A small incision will be made in your chest between your ribs to access the lowest part of your heart. Your doctor will insert a short, hollow tube called a sheath.



3. Your new valve will be placed on the delivery system tube and compressed on the balloon to make it small enough to fit through the sheath.



4. The balloon of the delivery system carrying the valve will be inflated, expanding this 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 it in place. The balloon will then be deflated and removed.

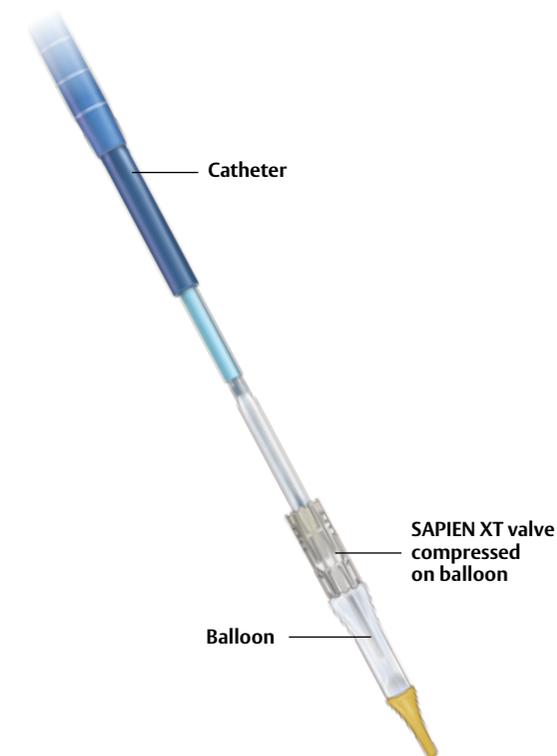
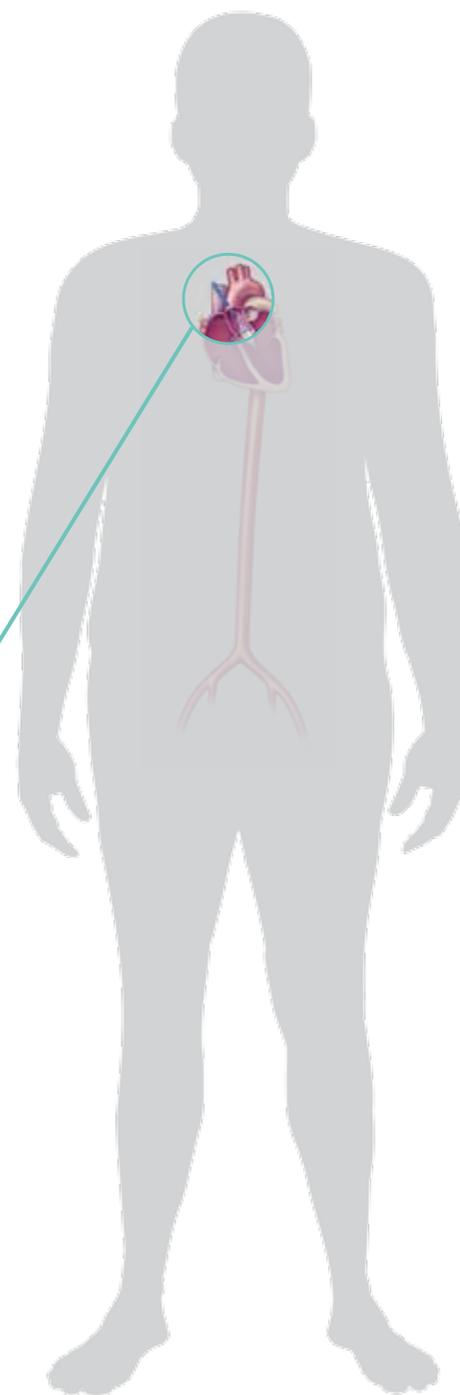
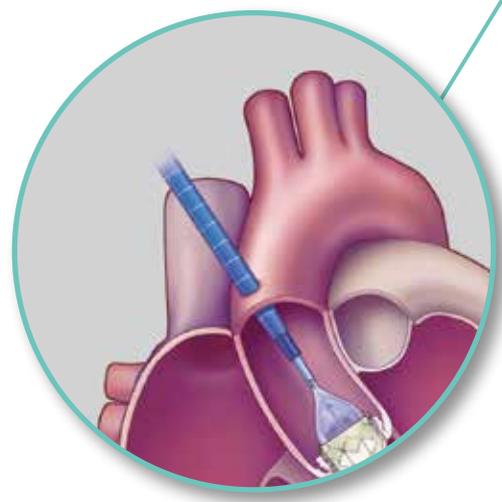


5. Your doctor will make sure that your new valve is working properly before removing the sheath and closing the incision in your chest.

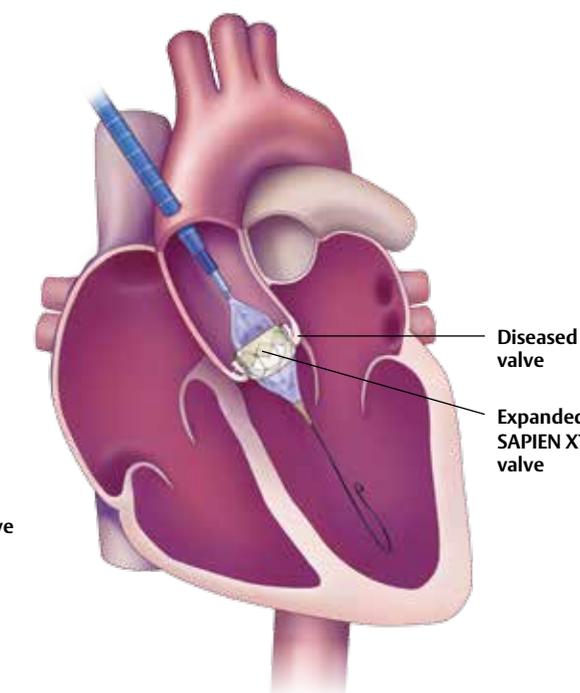
The average time required to perform the transaortic TAVR procedure with the SAPIEN XT valve is between 1 to 2 hours.

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

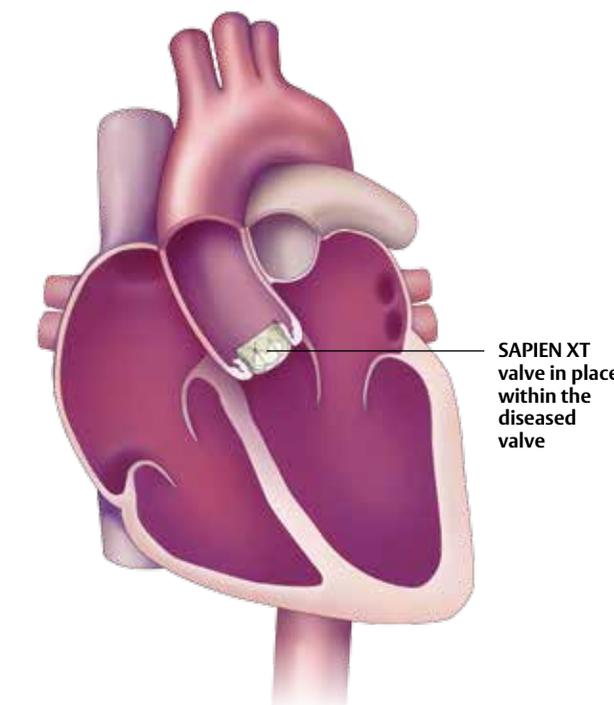
1. Before your procedure, you will be placed under anesthesia.
2. An incision will be made in your upper chest where your doctor will insert a short, hollow tube called a sheath.



3. Your new valve will be placed on the delivery system tube and compressed on the balloon to make it small enough to fit through the sheath.



4. The balloon of the delivery system carrying the valve will be inflated, expanding this 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 it in place. The balloon will then be deflated and removed.



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

What Happens After the Procedure?

Your specialized Heart Team will discuss your after-care plan with you. They 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 medication is prescribed.

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 have any unusual problems such as bleeding, pain, other discomfort or changes in your overall health, be sure to contact your doctor.

Always tell 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.

Make sure you speak to your specialized Heart Team regarding length of stay and how quickly you can expect to transition to home care.

What Are the Benefits of TAVR?

Benefits of the Procedure: If you have severe aortic stenosis, TAVR will help your heart to work better. It may also shorten your recovery time to getting back to everyday activities.

Quality of Life Improvement: Quality of life studies with the SAPIEN XT valve have shown patient health improvements within 30 days including: the ability to take care of themselves and to participate in everyday activities.

How Long Will My Valve Last?

How long your tissue valve will last depends on many patient factors and medical conditions. The long-term durability of the SAPIEN XT valve has not been established. However, regular follow-ups will help your doctor know how your valve is working.



TAVR AND SURGERY CLINICAL DATA FOR INTERMEDIATE-RISK PATIENTS

The risks associated with surgery depend on how healthy or sick a patient is. Based on their health, some patients may be considered intermediate-risk for surgery. If you are at intermediate-risk for surgery, these clinical data may resemble what you can expect.

As part of the PARTNER II Trial, the SAPIEN XT valve was studied in patients at intermediate-risk for surgery. The trial was conducted in the United States and enrolled about 1,000 patients for TAVR and about 1,000 patients for surgery. Patients were examined at 30 days and 2 years after the procedure and will continue to be followed every year for 10 years.

The following tables show results of both TAVR and surgery patients from this trial. Patients were treated with the Edwards SAPIEN XT valve by one of the following approaches: transfemoral, transapical or transaortic.

Clinical data for intermediate-risk patients at 30 days

The following table summarizes the 30-day results of patients at intermediate-risk who were treated with either TAVR or surgery.

30-day Clinical Outcomes		
	TAVR Risk Within 30 Days	Surgical Risk Within 30 Days
Death From Any Cause	4 out of 100 patients	4 out of 100 patients
Cardiovascular Death*	3 out of 100 patients	3 out of 100 patients
Major Stroke	3 out of 100 patients	4 out of 100 patients
Aortic Insufficiency ≥ Moderate†	4 out of 100 patients	1 out of 100 patients
New Pacemaker Implantation‡	8 out of 100 patients	7 out of 100 patients
Major Vascular Complications	8 out of 100 patients	5 out of 100 patients
Myocardial Infarction (heart attack)	1 out of 100 patients	2 out of 100 patients
Endocarditis§	0 out of 100 patients	0 out of 100 patients

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

Clinical data for intermediate-risk patients at 2 years

The following table summarizes the 2-years results of patients at intermediate-risk who were treated with either TAVR or surgery.

2-Year Clinical Outcomes		
	TAVR Risk Within 2 Years	Surgical Risk Within 2 Years
Death From Any Cause	16 out of 100 patients	17 out of 100 patients
Cardiovascular Death*	10 out of 100 patients	10 out of 100 patients
Major Stroke	6 out of 100 patients	6 out of 100 patients
Aortic Insufficiency ≥ Moderate†	8 out of 100 patients	1 out of 100 patients
New Pacemaker Implantation‡	11 out of 100 patients	9 out of 100 patients
Major Vascular Complications	9 out of 100 patients	5 out of 100 patients
Myocardial Infarction (heart attack)	3 out of 100 patients	4 out of 100 patients
Endocarditis§	1 out of 100 patients	1 out of 100 patients

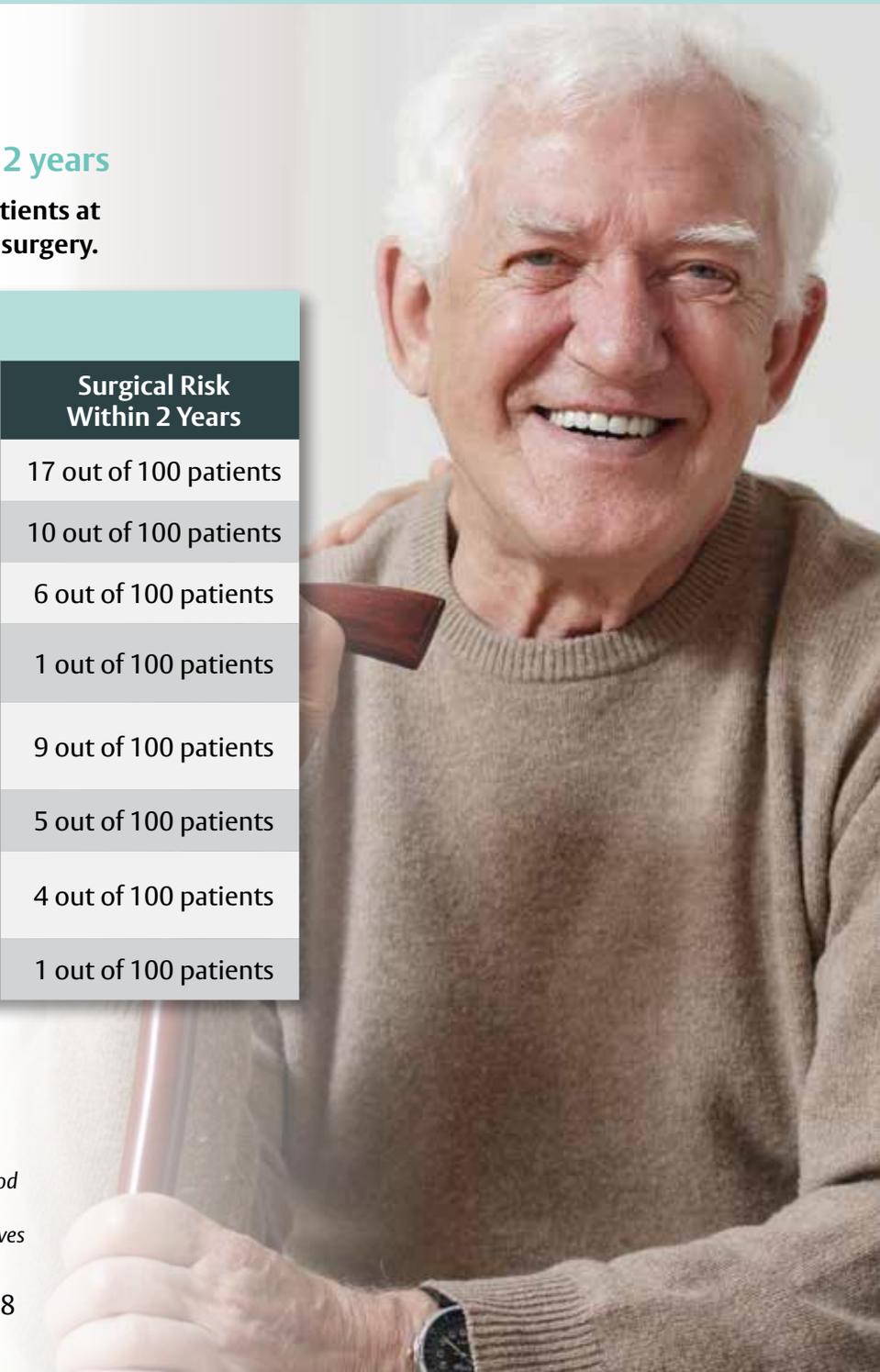
The frequency is shown as the number of patients out of every 100.

* From heart-related causes

† When the aortic valve does not close tightly and causes a backward flow of blood

‡ Device that can help regulate the heart

§ Inflammation or infection of any internal heart structures, including the valves



TAVR CLINICAL DATA FOR HIGH-RISK PATIENTS

The SOURCE XT Study

SOURCE XT studied the safety and effectiveness of TAVR with the SAPIEN XT valve in approximately 2,700 patients whose doctors had determined them to be at high-risk for surgery. If you are at high-risk for surgery, these clinical data may resemble what you can expect. Patients were treated with the SAPIEN XT valve by one of the following approaches: transfemoral, transapical or transaortic.

Clinical data for high-risk patients with transfemoral TAVR

The following table summarizes the 30-day and 1-year results of patients at high-risk who were treated with TAVR.

Transfemoral TAVR		
	Risk Within 30 Days	Risk Within 1 Year
Death From Any Cause	4 out of 100 patients	15 out of 100 patients
Cardiovascular Death*	2 out of 100 patients	7 out of 100 patients
Major Stroke	2 out of 100 patients	4 out of 100 patients
New Pacemaker 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
Myocardial Infarction (heart attack)	1 out of 100 patients	2 out of 100 patients
Endocarditis‡	1 out of 100 patients	1 out of 100 patients

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

Clinical data for high-risk patients with transapical/transaortic TAVR

The following table summarizes the 30-day and 1-year results of patients at high-risk who were treated with TAVR.

Transapical/Transaortic TAVR		
	Risk Within 30 Days	Risk Within 1 Year
Death From Any Cause	10 out of 100 patients	27 out of 100 patients
Cardiovascular Death*	5 out of 100 patients	14 out of 100 patients
Major Stroke	3 out of 100 patients	5 out of 100 patients
New Pacemaker 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
Myocardial Infarction (heart attack)	1 out of 100 patients	3 out of 100 patients
Endocarditis‡	1 out of 100 patients	1 out of 100 patients

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

* From heart-related causes
 † When the aortic valve does not close tightly and causes a backward flow of blood
 ‡ Device that can help regulate the heart
 § Inflammation or infection of any internal heart structures, including the valves



TAVR CLINICAL DATA FOR INOPERABLE PATIENTS

If a Heart Team says you are too sick for surgery, this population is referred to as inoperable. If you are inoperable, these clinical data may resemble what you can expect.

The PARTNER II Trial (Cohort B Arm) studied the safety and effectiveness of TAVR with the SAPIEN XT valve in patients who were inoperable. The study was conducted in the United States in approximately 800 patients.

Patients were treated with the SAPIEN XT valve by the transfemoral, transapical or transaortic approaches. Patients were examined at 30 days, 6 months, and 1 year after the procedure, and will continue to be examined every year for 10 years.

Clinical data for inoperable patients with transfemoral TAVR

The following table summarizes the 30-day and 1-year results of patients too sick for surgery who were treated with TAVR.

Transfemoral TAVR		
	Risk Within 30 Days	Risk Within 1 Year
Death From Any Cause	4 out of 100 patients	22 out of 100 patients
Cardiovascular Death*	3 out of 100 patients	16 out of 100 patients
Major Stroke	3 out of 100 patients	5 out of 100 patients
New Pacemaker Implantation†	8 out of 100 patients	13 out of 100 patients
Disabling Bleeding Event (fatal or life threatening)	4 out of 100 patients	5 out of 100 patients
Major Vascular Complications	11 out of 100 patients	12 out of 100 patients
Myocardial Infarction (heart attack)	2 out of 100 patients	7 out of 100 patients
Endocarditis‡	0 out of 100 patients	1 out of 100 patients

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

Clinical data for inoperable patients with transapical/transaortic TAVR

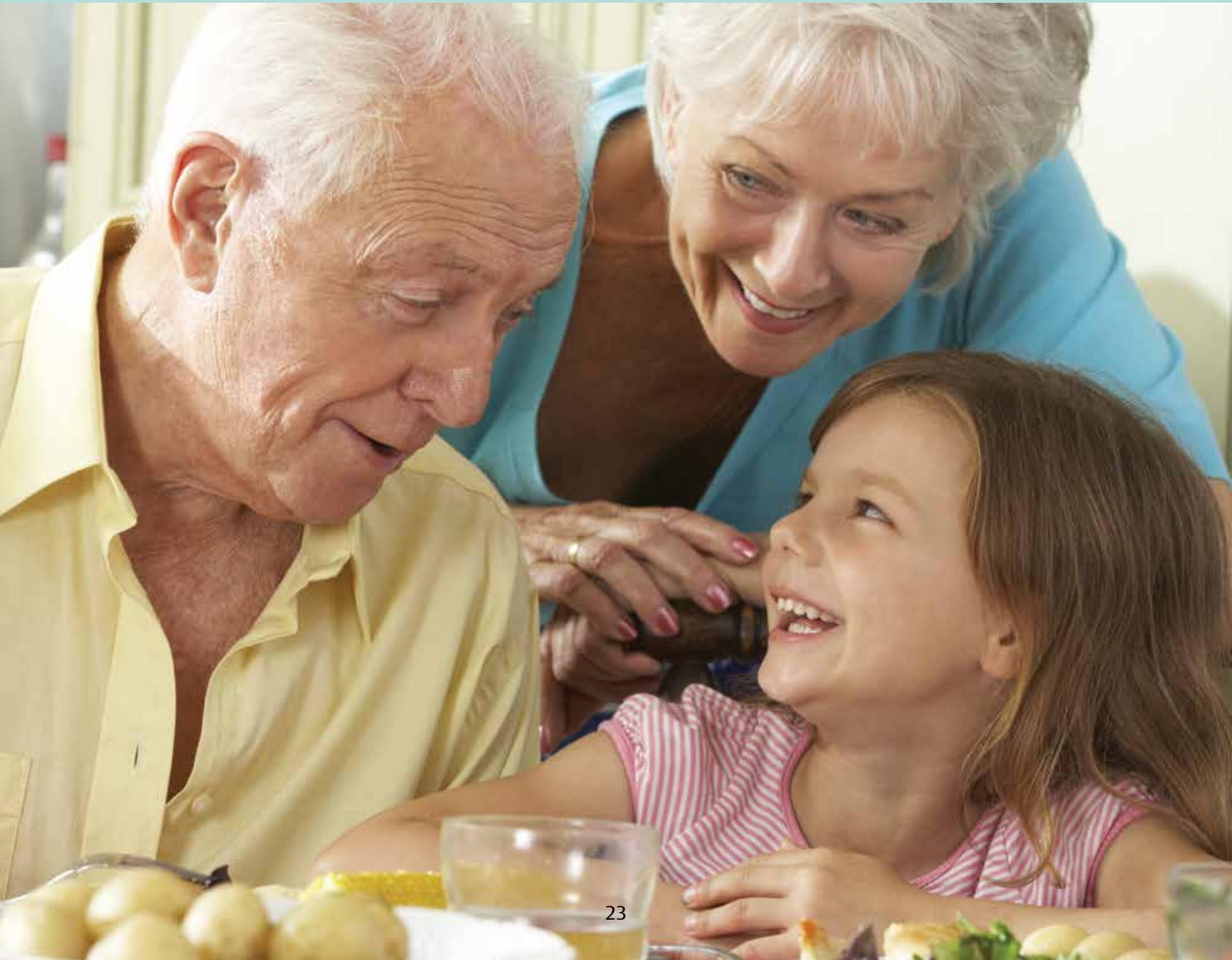
The following table summarizes the 30-day results of patients too sick for surgery who were treated with TAVR.

Transapical/Transaortic TAVR	
	Risk Within 30 Days
Death From Any Cause	8 out of 100 patients
Major Stroke	2 out of 100 patients
New Pacemaker Implantation†	5 out of 100 patients
Major Vascular Complications	6 out of 100 patients
Myocardial Infarction (heart attack)	2 out of 100 patients
Endocarditis‡	0 out of 100 patients

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

* From heart-related causes
 † When the aortic valve does not close tightly and causes a backward flow of blood
 ‡ Device that can help regulate the heart
 § Inflammation or infection of any internal heart structures, including the valves





WHAT ARE THE RISKS OF TAVR?

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

The most serious risks of the TAVR procedure with the SAPIEN XT valve include:

- Death
- Major stroke; a condition when blood stops flowing in the brain, which may cause severe disability
- Major vascular complications; 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
- 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 medication 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 medication 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 SAPIEN XT valve is not known for patients who have:
 - A heart that does not pump efficiently
 - An enlarged heart

- The safety and performance of the SAPIEN XT 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 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

- **Increased risk of stroke in TAVR procedures as compared to balloon aortic valvuloplasty and medical management for aortic stenosis.**
- **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 SAPIEN XT 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

CONTACT INFORMATION

**For more information on the
SAPIEN XT valve or the
TAVR procedure:**

Toll free phone in the USA:
1.800.424.3278

Phone from outside the USA:
+1.949.250.2500

Email Address:
Tech_Support@edwards.com

Mail:
Edwards Lifesciences
One Edwards Way
Irvine, California 92614

Online:
www.NewHeartValve.com
www.TAVRbyEdwards.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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