

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

For Patients with a Failing Surgical Heart Valve



This booklet is created for patients who feel sick from a failing aortic surgical heart valve and who are at high-risk or too sick for open heart surgery. This information will help you and your loved ones learn more about your heart and how it works. 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 page 12 to review the risks of the TAVR procedure.



NewHeartValve.com



Table of Contents

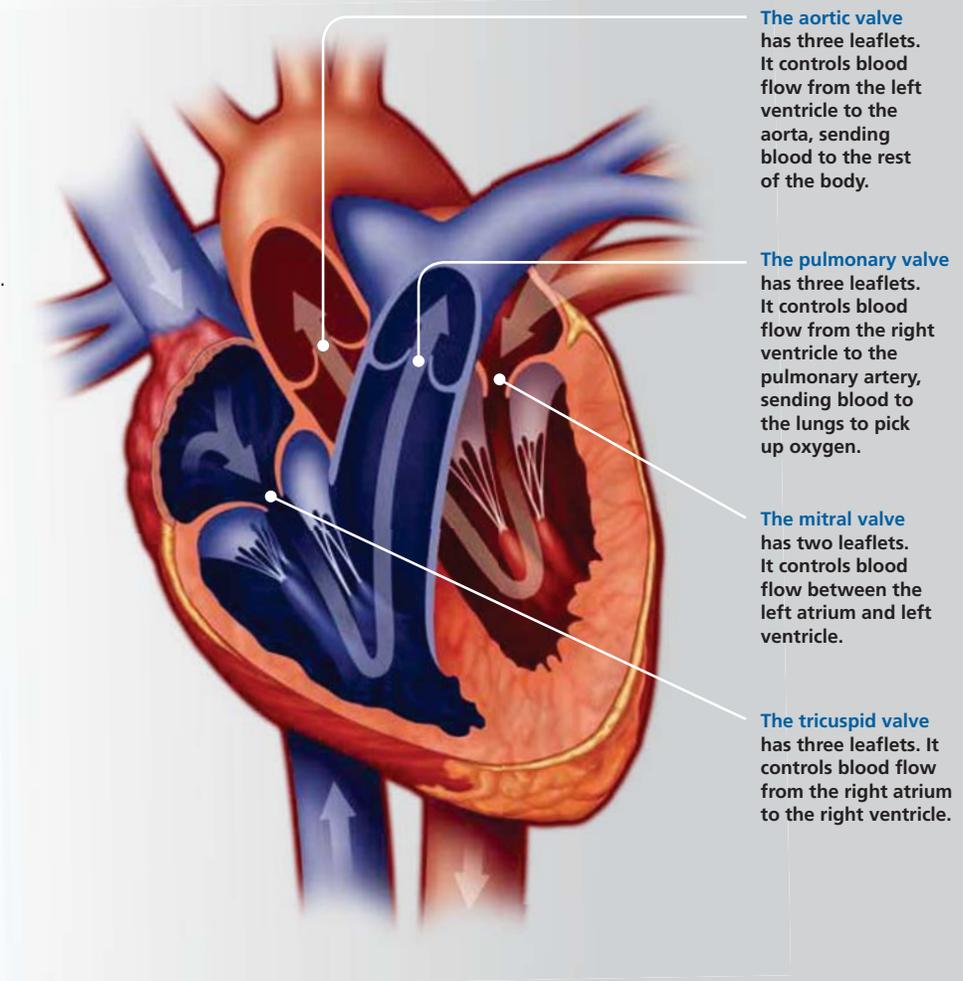
How Does Your Heart Work?	3
Why Could Your Surgical Heart Valve be Failing?	4
The Heart Team	5
What are Your Treatment Options?	6
Transcatheter Aortic Valve Replacement.....	6
Surgical Aortic Valve Replacement.....	6
Transcatheter Aortic Valve Replacement	8-11
Which Products Will Be Used During the Procedure?.....	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 Surgical Valve Replacement Clinical Data	12-15
Clinical Trial Overview.....	12
Clinical Data Table.....	13
What Are the Possible Benefits of TAVR?.....	14
What Are the Possible Risks of TAVR?.....	15
Precautions	16
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 a failing surgical aortic valve, 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 problems such as bleeding, pain, unexplained fever, other discomfort, 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.



WHY COULD YOUR SURGICAL HEART VALVE BE FAILING?

Your original heart valve may have been replaced with a surgical heart valve. Over time, there are two common problems that can develop with a surgical heart valve:

- **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) or high cholesterol (a waxy fat).
- **Regurgitation:** When your surgical 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. In elderly patients, failing surgical valves are sometimes caused by the build-up of calcium (mineral deposits) on the valve's leaflets. Over time, the leaflets become stiff, reducing their ability to fully open and close. When the leaflets don't fully open and close, your heart must work harder to push blood through the 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). Stenosis or regurgitation of your surgical valve can be a very serious problem.





THE HEART TEAM

When you have a failing surgical heart valve, 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 a failing surgical heart valve depends on how far the disease has progressed. Medication may be prescribed as a treatment option to help regulate your heart beat and prevent blood clots. However, your Heart Team may recommend different options to treat your failing surgical valve.

Transcatheter Aortic Valve Replacement

If a Heart Team determines that you are at high-risk or too sick for open heart surgery, TAVR may be an option. This less invasive procedure allows a new valve to be inserted within your failing surgical valve.

Surgical Aortic Valve Replacement

Surgical aortic valve replacement (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 failing surgical 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 failing surgical 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



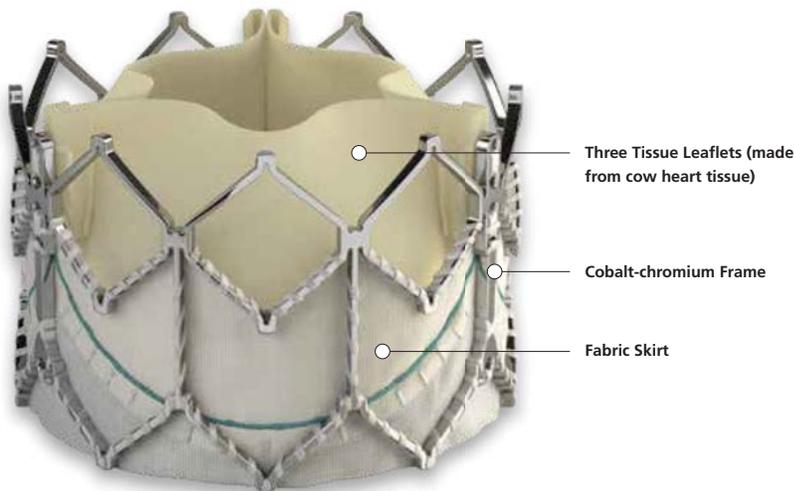
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TRANSCATHETER AORTIC VALVE REPLACEMENT PROCEDURE

Which Products Will Be Used During the Procedure?

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



The Edwards SAPIEN XT transcatheter heart valve (that replaces your failing surgical valve) is pictured above.

Image is larger than actual valve size.

What Do You Need to Do Before the Procedure?

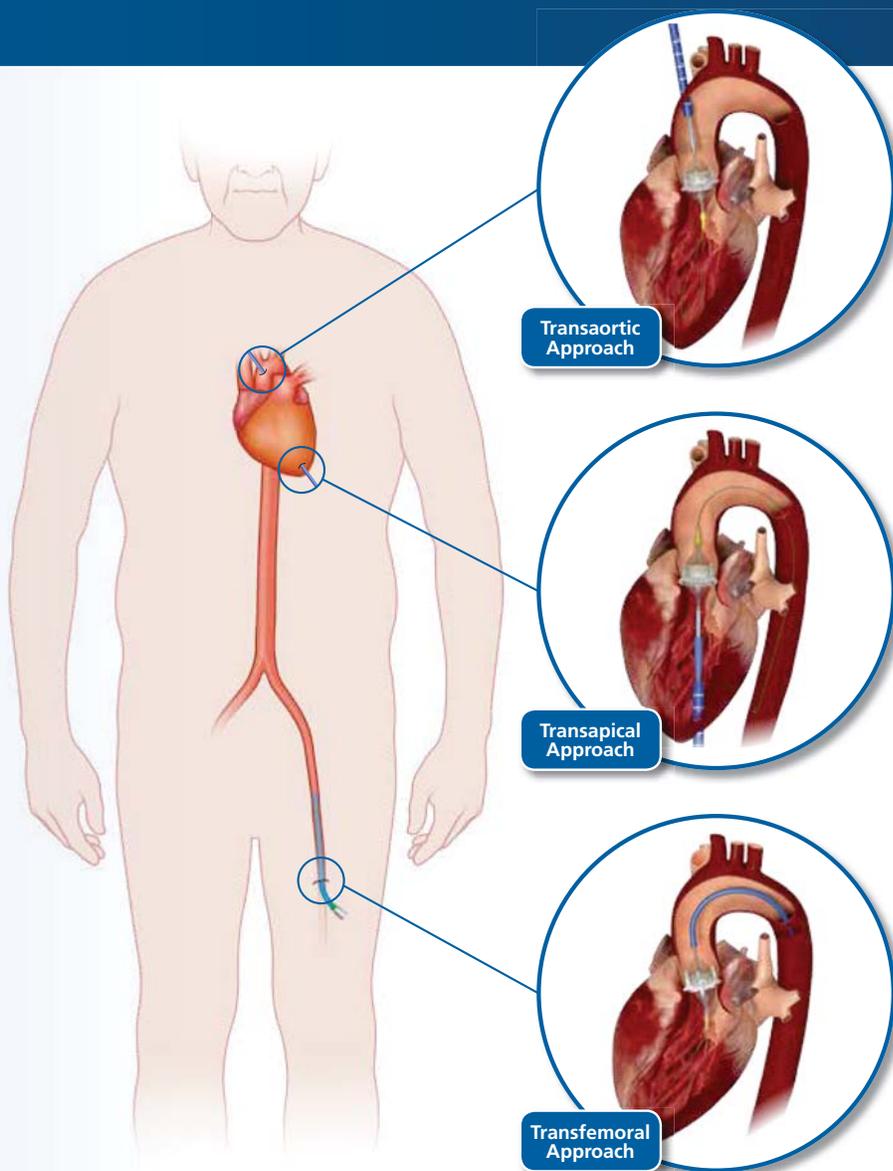
To determine the best TAVR approach for you, your Heart Team will review various tests such as a chest x-ray, echo, angiogram, and others.

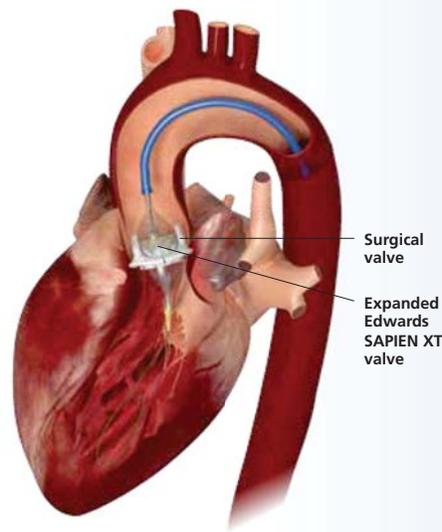
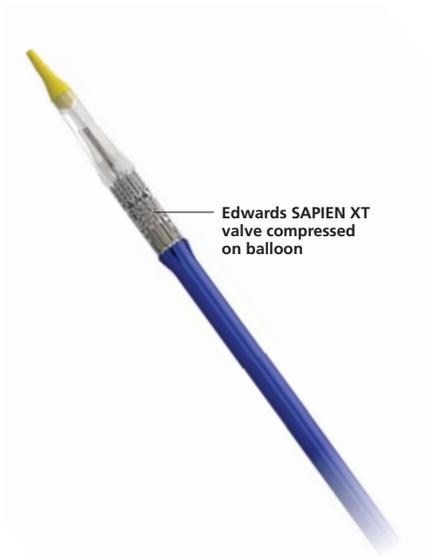
Be sure to talk to your Heart Team about any medication you may be taking. They might advise you to stop taking certain medication up to one week prior to the procedure. Your doctor may tell you not to eat or drink anything after midnight. You should plan on making arrangements for a ride to and from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

TAVR Procedural Overview

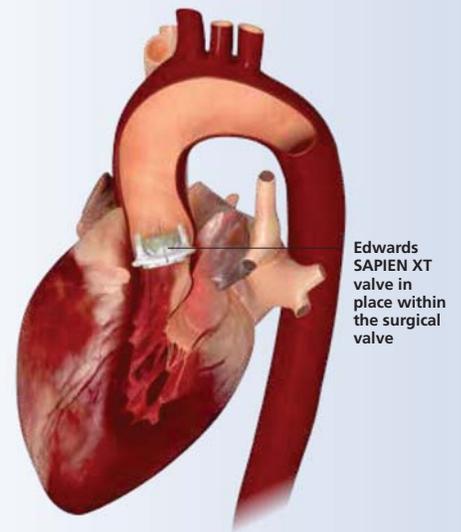
TAVR allows a new valve to be inserted using a delivery system (tube with a balloon on the end). Your doctor may use one of the following delivery approaches: transfemoral (through an incision in your leg), transapical (through an incision in the bottom of your heart), or transaortic (through an incision in the top of your heart). The total procedure time varies from about 1 to 2 hours depending on what approach is used.

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 based on the TAVR approach planned. 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.





This image shows the transfemoral approach



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 surgical valve, the balloon will be inflated with fluid, expanding the new valve into place. The valve will push the leaflets of your surgical valve aside. The frame of the new valve will use the surgical 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, unexplained fever, 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 patient.

TRANSCATHETER AORTIC SURGICAL VALVE REPLACEMENT CLINICAL DATA

Clinical Trial Overview

A clinical trial studied the safety and effectiveness of the Edwards SAPIEN XT transcatheter heart valve placed in patients with a failing surgical valve. The study was conducted in the United States (US). The study included 97 patients with a failing surgical valve whose doctors had determined them to be at high risk or too sick to undergo open heart surgery. These 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.

In addition to the 97 patients noted above, an additional 100 patients were enrolled and were examined at 30 days. These 100 patients will continue to be examined at 1 year and every year for 5 years.

The 30-day data shown on the next page includes all 197 patients. The 1 year data shown only includes the first 97 patients.



CLINICAL DATA FOR TAVR PATIENTS

TAVR with Edwards SAPIEN XT Transcatheter Heart Valve In a Failing Surgical Valve

The following table is a summary of the clinical risks observed within 30 days and within 1 year in inoperable patients from the US Clinical Trial. The numbers below are shown as the quantity of patients out of every 100.

TAVR with the Edwards SAPIEN XT Transcatheter Heart Valve		
	Risk within 30 days	Risk within 1 year
Death from any cause	4 out of 100 patients	20 out of 100 patients
Death from cardiovascular (heart-related) causes	4 out of 100 patients	15 out of 100 patients
Major stroke	3 out of 100 patients	3 out of 100 patients
New pacemaker (device that can help regulate the heart) implantation	2 out of 100 patients	1 out of 100 patients
Disabling bleeding event (fatal or life threatening)	10 out of 100 patients	16 out of 100 patients
Major vascular complications	4 out of 100 patients	6 out of 100 patients
Myocardial infarction (heart attack)	3 out of 100 patients	3 out of 100 patients
New atrial fibrillation (abnormal heartbeat)	3 out of 100 patients	4 out of 100 patients

Additional Information on the TAVR Procedure	
	TAVR with Edwards SAPIEN XT transcatheter heart valve
Average Procedure Time*	1-2 hours
Median (middle value) Length of Stay (days)	5 days

* The average total procedure time 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.

What Are the Possible Benefits of TAVR?

Possible Benefits of the Procedure:

For patients with a failing surgical heart valve, there can be many benefits after the procedure. Not only does it replace your failing surgical valve helping you feel better, but it helps your heart work better. It may also shorten your recovery time compared to open heart surgery so you can resume everyday activities more quickly.

Symptom Relief: Most patients receiving a SAPIEN XT 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.



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 the Edwards SAPIEN XT transcatheter heart valve in a surgical 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
- 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 transcatheter heart valve (THV) 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, a break in the frame, or re-narrowing of the valve
- Incorrect position of valve or valve movement
- Blood leak through or around the valve
- Additional cardiac surgery, vascular surgery or intervention, including removal of the THV
- Fainting or dizziness
- Weakness or trouble exercising
- Allergic reaction
- Inability to move (paralysis)
- Permanent disability
- Kidney failure
- Chest pain
- Damage to blood cells
- Repeat hospitalization
- Sudden or unexpected loss of heart function
- Injury to nerve
- Partial or complete blockage of coronary artery (artery supplying blood to the heart)
- Extra or unusual sound during heartbeat (heart murmur)

PRECAUTIONS

- 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 heart that does not pump efficiently.
 - An existing transcatheter aortic heart valve.
 - An enlarged heart.
- The safety and performance of the transcatheter heart valve in a surgical heart valve has not been established for patients who have:
 - 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 surgical 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 surgical valve leaflets with large pieces of calcium that may block the vessels that supply blood to the heart.
- An aortic surgical valve that does not have an internal frame.
- A surgical valve with a torn leaflet that may block the vessels that supply blood to the heart.
- A surgical valve that is not securely in place.
- A surgical valve that has an internal frame that is damaged.



WARNINGS

- **Stroke may happen in patients who get TAVR procedures.**
- **Major blood vessel complications may occur in TAVR procedures.**
- **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 XT 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. 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 problems. Regular medical follow-up is important to evaluate how your valve is performing.

CONTACT INFORMATION

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

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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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