

# Transcatheter Pulmonary Valve Therapy

with the Edwards SAPIEN XT Valve

*For Patients and Caregivers*



Edwards

This booklet was created to help you learn more about the Edwards SAPIEN XT Transcatheter Pulmonary Valve (TPV) therapy. The SAPIEN XT TPV therapy is intended to help adults and children who have a conduit in their Right Ventricular Outflow Tract (RVOT) and it has since become blocked (stenosis) and/or leaky (regurgitant). Your doctor can explain your treatment options and help you decide which option is best for you.

At Edwards Lifesciences, we are dedicated to providing innovative solutions for people fighting cardiovascular disease. Driven by a passion to help patients, we develop heart valve technologies that enable doctors to save and enhance lives.



[NewHeartValve.com](http://NewHeartValve.com)



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The information in this booklet is meant to help guide you through your journey. It may not answer all your questions about your treatment options or Transcatheter Pulmonary Valve (TPV) therapy.

TPV therapy is not meant for everyone. Please talk with your doctor about what treatment options are right for you.

## INFORMATION ABOUT THE HEART

### What Is Congenital Heart Disease?

Congenital Heart Disease, also known as CHD, is one of the most common birth defects in the United States. Approximately 40,000 babies are born each year with CHD. Most people with CHD have a heart that does not develop normally.

### How Does the Heart Work?

The heart is designed to pump blood through the body. The right side of the heart pumps blood to the lungs so blood can pick up oxygen. The left side of the heart receives this blood and pumps it to the rest of the body.

The heart is typically divided into four main areas, or chambers – two upper chambers (called the right or left atrium) and two lower chambers (called the right or left ventricle). There are four valves that control the flow of blood through the heart. They are called the aortic, mitral, pulmonary, and tricuspid valves. They work together with the heart chambers to move blood through the body.

### Types of Congenital Heart Diseases That Can Affect the Pulmonary Valve

TPV therapy can help adults and children who have had previous surgery to help repair or replace a pulmonary valve that was damaged by a CHD. If your doctor has considered TPV as treatment option for you, you may have had one of the following pulmonary valve conditions or surgical treatments:

- Tetralogy of Fallot
- Transposition of the Great Arteries
- Pulmonary Stenosis
- Pulmonary Atresia
- Truncus Arteriosus
- Double Outlet Right Ventricle (DORV)
- Defects resulting in a Ross operation

Children and adults with one of these conditions may have a narrowed, abnormal, or missing pulmonary valve. Some may need one or more surgeries throughout their life to keep their pulmonary valves working.

**Right Ventricular Outflow Tract (RVOT)**

**Right atrium**

**The pulmonary valve** has three leaflets. It controls blood flow from the right ventricle to the pulmonary artery and sends 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.

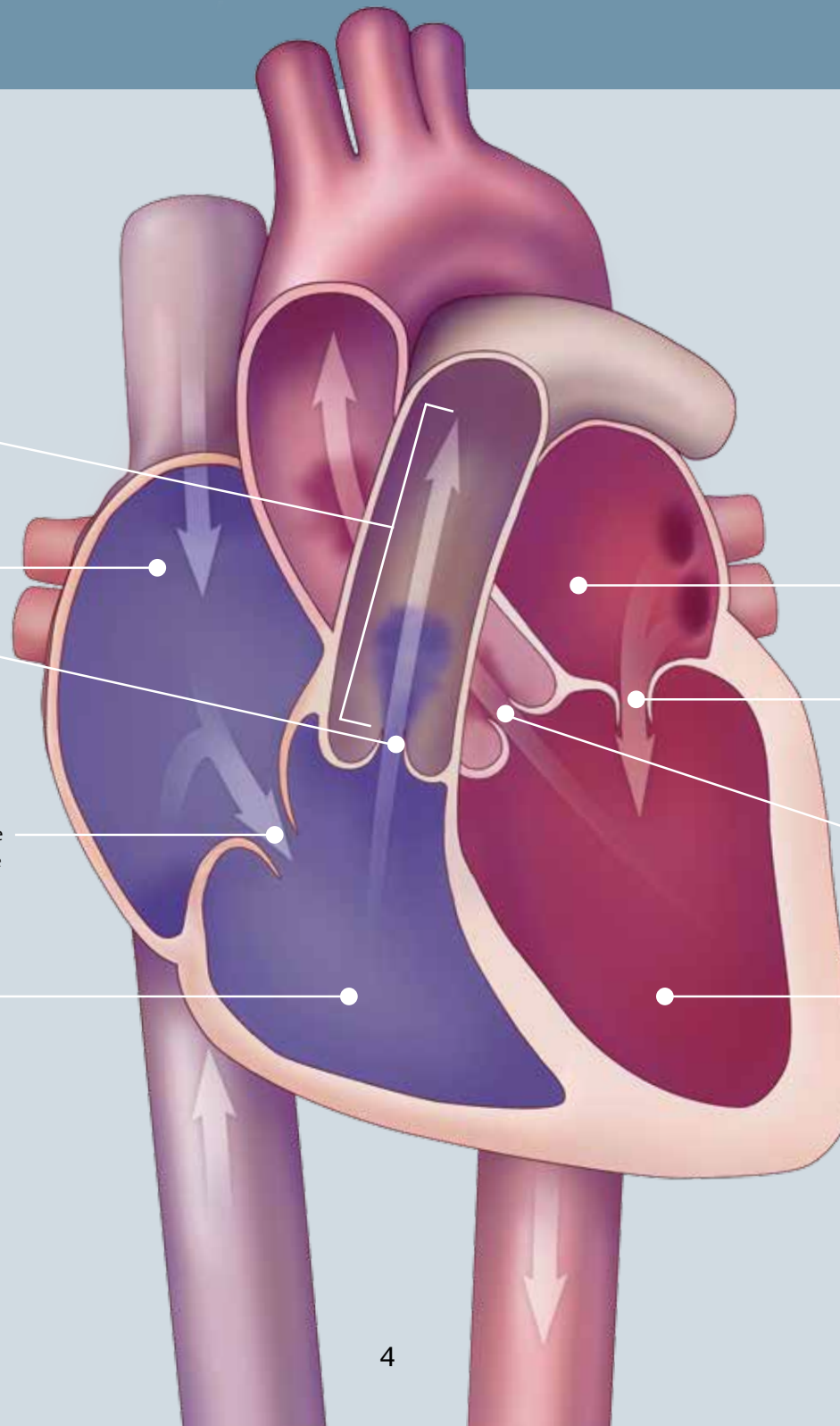
**Right ventricle**

**Left atrium**

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

**Left ventricle**



## PULMONARY VALVE AND RVOT FAILURE

As a result of a CHD, you may need multiple surgeries over the course of your life. Your valve or RVOT may narrow (stenosis) and/or leak (regurgitation).

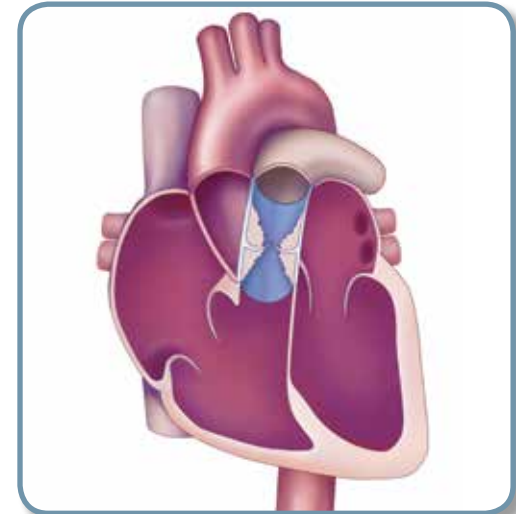
**Narrowing (Stenosis):** Calcium (mineral deposits) may form on the inside of the RVOT or pulmonary valve, causing it to narrow. This makes the heart work harder than normal to pump blood through a small opening to the lungs. Over time, the heart muscle can become damaged, and the lungs may not receive enough blood.

**Leaking (Regurgitation):** Leaking occurs when the valve does not close all the way or if no valve is present. If the valve cannot close completely, the blood can flow back into the chamber instead of flowing into the lungs. The heart's chamber must work harder to pump enough blood to the lungs. Leaking can cause damage to the muscle of the heart over time.

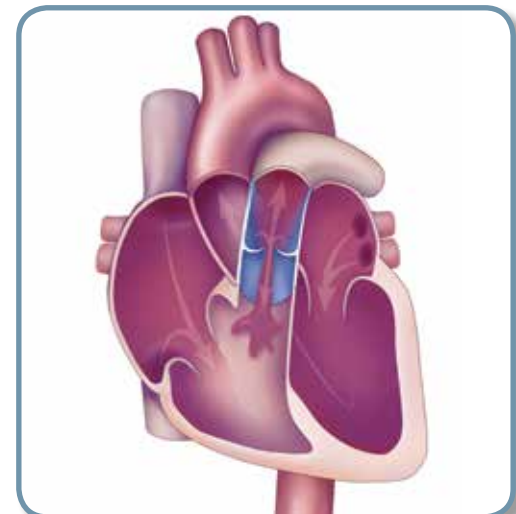
### Symptoms That Your Pulmonary Valve or RVOT May Be Failing

- Tired
- Short of breath
- Dizzy or fainting from exercise
- Chest pain
- Irregular heartbeats
- Too weak for normal activities

Talk to your doctor if you experience any of these symptoms. Regular checkups can help you and your doctor understand your current medical condition.



A Narrowed RVOT (Stenosis)



A Leaky RVOT (Regurgitation)

## TREATMENTS FOR PULMONARY VALVE AND RVOT FAILURE

### Surgical Repair or Replacement

For people who suffer from pulmonary valve or RVOT failure, it is common to have their valves replaced or repaired during open-heart surgery. During this procedure, the doctor will remove the failing valve and replace it with a new artificial valve or conduit.

### Balloon Angioplasty/Valvuloplasty

A thin tube (catheter) with a balloon at the tip is put into the body through a vein in the leg. The balloon is guided to the intended location and temporarily inflated. This opens the narrowed valve and/or RVOT and allows blood to flow better.

### Transcatheter Pulmonary Valve (TPV) Therapy

During this procedure, a catheter holding the new heart valve is inserted into a vein in the leg and guided up to the intended location. Once the valve has reached the correct location, it is expanded with the help of a balloon. The valve should immediately begin to work and help control blood flow.



## SAPIEN XT TRANSCATHETER PULMONARY VALVE (TPV) THERAPY

### Who Is the SAPIEN XT TPV Therapy Meant For?

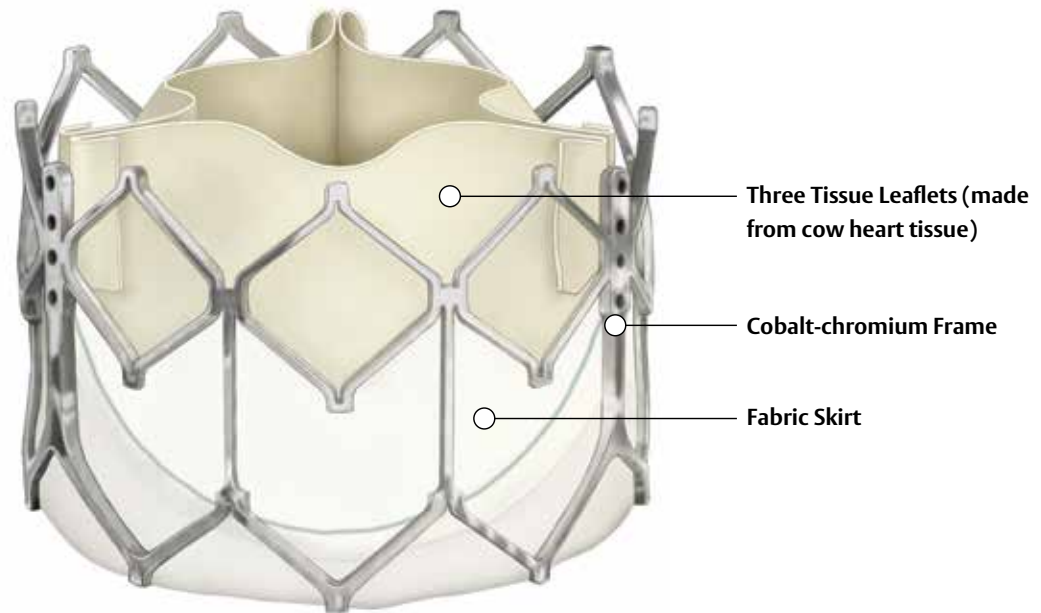
The SAPIEN XT TPV Therapy treats adults and children who have a narrowed (stenosis) and/or leaky (regurgitation) conduit in their RVOT.

### About the SAPIEN XT TPV Therapy

The Edwards SAPIEN XT transcatheter heart valve treats a pulmonary valve/ RVOT conduit that is narrowed (stenosis) or leaks (regurgitation). The Edwards SAPIEN XT valve is made of tissue from a cow's heart and sewn onto a metal frame. The new valve will help your heart to pump blood normally through the chambers to the rest of your body. TPV therapy with the Edwards SAPIEN XT valve is meant to delay the need for additional open-heart surgeries.

### Who Should Not Have the SAPIEN XT TPV Therapy?

The Edwards SAPIEN XT TPV should not be used in people who cannot tolerate an anticoagulation/antiplatelet regimen (blood-thinning medicine) or who have active bacterial endocarditis (inflammation or infection of any internal heart structures, including the valves) or other active infections.



*Image is larger than actual valve size.*



## The SAPIEN XT TPV Therapy

This information is meant to help you understand what may happen during TPV therapy. Each procedure is different.

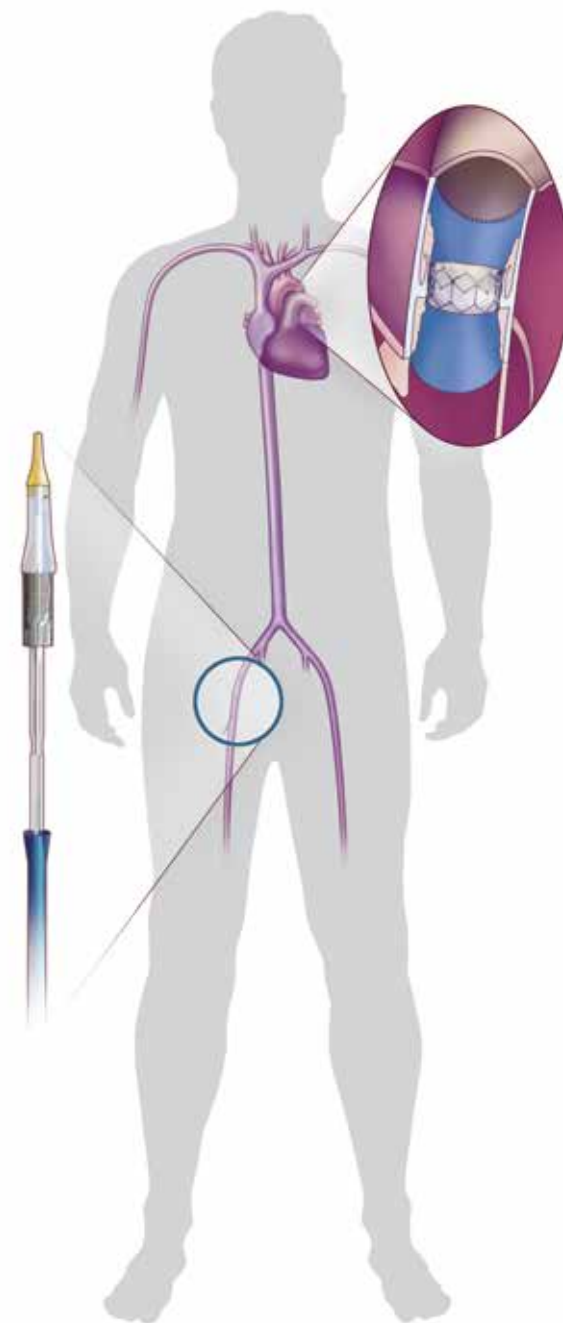
Be sure to tell your doctor if you are taking any medications or have any allergies. Your doctor will also explain the procedure and answer any questions you might have.

### Procedure Steps

As part of the TPV therapy, you will be placed under anesthesia at the hospital.

1. Your doctor will make an incision in your leg to access your vein.
2. A thin tube (catheter) holding the SAPIEN XT valve is inserted in your vein and guided to your heart.
3. The doctor will inflate the SAPIEN XT valve using the balloon on the catheter once the valve is in the correct location.
4. Once the SAPIEN XT valve is in place, it should immediately begin to work properly.
5. The catheter will be removed, and your doctor will make sure your new valve is working properly.
6. The incision in your leg will be closed, and your procedure will be over.

The average procedure time is 2-3 hours.





## BENEFITS AND RISKS OF THE SAPIEN XT TPV THERAPY

### Benefits of the SAPIEN XT TPV Therapy

Edwards Lifesciences conducted a clinical trial in the United States to study the safety and effectiveness of the SAPIEN heart valve in patients with failing pulmonary conduits. Patients were examined at specific time periods and will continue to be examined every year for 5 years. Based on the clinical trial data, possible benefits of TPV Therapy may include:

- Relief of valve narrowing (stenosis)
- Relief of valve leaking (regurgitation)
- Improvement in symptoms such as difficulty breathing, chest pain, rapid heart rate, fainting, weakness, and swelling of the arms and legs
- Delay of future open-heart surgery.

While the first-generation SAPIEN valve was used in the clinical trial, you will be receiving the second-generation SAPIEN XT valve. Both valves are similar in design and technology.

There have been no recorded Edwards SAPIEN or SAPIEN XT valve frame fractures.

## Potential Risks Associated with Edwards SAPIEN XT TPV Therapy

There are complications that may occur during the Edwards SAPIEN XT TPV Therapy that may be serious and could include death. Additional complications may include:

- Risks of a hole or tear in the heart muscle or a blood vessel, requiring repair
- Constriction or inability of the heart to pump due to buildup of blood or fluid around the lining of the heart.
- Inability of heart to pump blood as well as it should
- Need for additional heart surgery or catheter procedure
- Repeat procedure on the placed valve which may include removal
- Blood clot on the valve that may or may not require a repeat procedure on the valve
- Valve movement from its initial implantation site so that it is no longer in its original position
- Incorrect position of the valve that may or may not require a repeat procedure on the valve
- Valve dysfunctions including wear, break, buildup of calcium, tear or movement of valve leaflets from the normal position, break in the stitches (sutures) of the valve frame or leaflets, thickening, narrowing of the valve opening
- Leakage through or around the valve or valve frame
- Temporary or permanent stoppage of the heartbeat
- Heart Attack
- Problem with special muscle fibers that conduct electrical impulses through the muscle of the heart and a change from the normal heartbeat
- Inability of heart to pump as much blood as the body needs
- Blockage of vessels supplying heart muscle/ interruption of normal blood flow through the valve
- Risks to lungs, including difficulty breathing
- Bleeding that may be severe
- Dislodgement of an abnormal particle (air, valve material or blood clots) floating in the blood stream or attached to an object
- Bloodstream infection or valve inflammation or infection
- Poor kidney function or failure
- An abnormal channel or passage between an artery and a vein
- Lack of oxygen in body tissue or nerve damage
- Breakdown of red blood cells or low/ abnormal lab values
- Bruising
- Pain and discomfort at the site where the thin tube (catheter) entered your body
- Fluid buildup in or around the lungs
- Fainting, swelling, chest pain, fever, high or low blood pressure, weakness or inability to exercise
- Unfavorable reaction by the body during procedure to a drug or agent used to decrease the feeling of pain, or a substance used to increase the visualization of body structures

## TPV THERAPY CLINICAL DATA

The following table is a summary of the clinical risks observed within 30 days and 1 year in patients that received the Edwards SAPIEN Valve from the US Compassion Clinical Trial.

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

Transcatheter Pulmonary Valve Therapy with the Edwards SAPIEN Transcatheter Heart Valve		
Clinical Risks	Risk within 30 days	Risk within 1 year
Death	0 out of 100 patients	0 out of 100 patients
Any Reintervention	3 out of 100 patients	3 out of 100 patients
- Surgical Pulmonic Valve Repair / Replacement	0 out of 100 patients	2 out of 100 patients
- Transcatheter pulmonic valve implantation (TPVI or valve-in-valve)	3 out of 100 patients	3 out of 100 patients
- Balloon valvuloplasty	0 out of 100 patients	0 out of 100 patients
Endocarditis	1 out of 100 patients	3 out of 100 patients
Pulmonary embolism	0 out of 100 patients	1 out of 100 patients
Vascular Injury	0 out of 100 patients	1 out of 100 patients
Myocardial infarction (Heart attack)	0 out of 100 patients	0 out of 100 patients
Stroke	0 out of 100 patients	0 out of 100 patients
Valve Stent Fracture	0 out of 100 patients	0 out of 100 patients

## ADDITIONAL WARNINGS AND PRECAUTIONS

### Warnings

- If an incorrect valve size is implanted, it may lead to valve leakage, movement, dislodgement of the valve from where it was implanted and/or tearing of the conduit.
- The artificial valve may not last as long in patients whose bodies do not process calcium normally.
- During the procedure, your doctors should monitor the dye used in the body; if used in excess it could lead to kidney damage.
- Patients should talk to their doctor if they are allergic to chromium, nickel, molybdenum, manganese, copper, silicon, and/or polymeric materials.
- X-ray guidance used during the procedure may cause injury to the skin which may be painful, damaging, and long-lasting
- Transcatheter heart valve patients should stay on blood-thinning medicine as specified by their doctor. This heart valve has not been studied in patients not taking blood-thinning medicine.

### Precautions

Patient's anatomy should be evaluated prior to procedure to prevent the risk of patient not being able to receive the valve.

The safety, effectiveness, and durability of implanting a new transcatheter heart valve inside a previously implanted surgical or transcatheter tissue valve has not been established.

The safety and performance of the transcatheter heart valve has not been established for patients who:

- have ultrasound images of the heart that could represent abnormal growth in the heart or arteries, with or without blockage, or who have abnormalities such as blood clot
- have an allergy to blood-thinning medications or dye injected during the procedure
- may be pregnant
- are under the age of 10 years



## FOLLOW-UP AND AFTER-PROCEDURE CARE

### After the Procedure

You will be moved to a recovery room. You will then be moved to a regular hospital room once you are fully awake. Most patients need to stay in the hospital overnight and should be able to leave the hospital the second day after.

You should start feeling better soon after your procedure. It can take about a week before you can return to normal activities. Your doctor will give you instructions to help you recover. It is important to carefully follow these instructions. Please call your doctor if you have any questions.

### Follow-Up Instructions

Regular checkups with your doctor are important. Take your medications as instructed, and be sure to keep all follow-up appointments with your doctor.

Talk to your doctor whenever you have questions or concerns about your health, especially if you experience any unusual problems such as bleeding, pain, difficulty breathing, fever, discomfort, or other changes in your overall health.

Always inform other healthcare professionals about your heart valve before any medical or dental procedures, even routine dental cleanings.

Before undergoing an MRI (magnetic resonance imaging) procedure, always notify your doctor that you have an artificial heart valve.

### How Long Will Your New Valve Last?

How long the Edwards SAPIEN XT valve will last is unknown at this time and depends on many factors, including your specific anatomy and health conditions.

Edwards Lifesciences has tested the SAPIEN XT valve in the laboratory to imitate how the valve works in the heart. All valves tested for 5-years passed the test.

The most common reason your heart valve may fail is gradual build-up of minerals (calcium) on the valve. Mineral deposits could prevent your valve from working correctly. Talk to your doctor if you experience return of symptoms including shortness of breath, irregular heartbeat, fatigue, or pain. Regular medical follow-up is essential to evaluate how your valve is performing.

## CONTACT INFORMATION

Edwards Lifesciences is here to answer any questions you may have about your SAPIEN XT valve. For more information please contact Edwards Lifesciences.

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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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