Transcatheter Pulmonary Valve Therapy

A guide for patients and caregivers

The Edwards SAPIEN 3 Transcatheter Heart Valve System
With The Edwards Commander Delivery System

Edwards

This booklet is for those who need a new pulmonic valve and will help you and your loved ones understand more about the Edwards transcatheter pulmonic valve (TPV) therapy.

Speak with your doctor, so together you can decide if TPV therapy is right for you.

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Edwards Lifesciences is the global leader in patient-focused medical innovations for structural heart disease and has been helping critically ill patients for over 60 years. Driven by a passion to help patients, Edwards works to improve outcomes and enhance the lives of patients.

The Edwards SAPIEN 3 pulmonic valve enables the treatment of adult and pediatric patients who have a conduit or a previously implanted surgical valve and who suffer from either a narrowed valve or moderate or greater pulmonic regurgitation.

To learn more, go to:

www.PulmonicValveTherapy.com

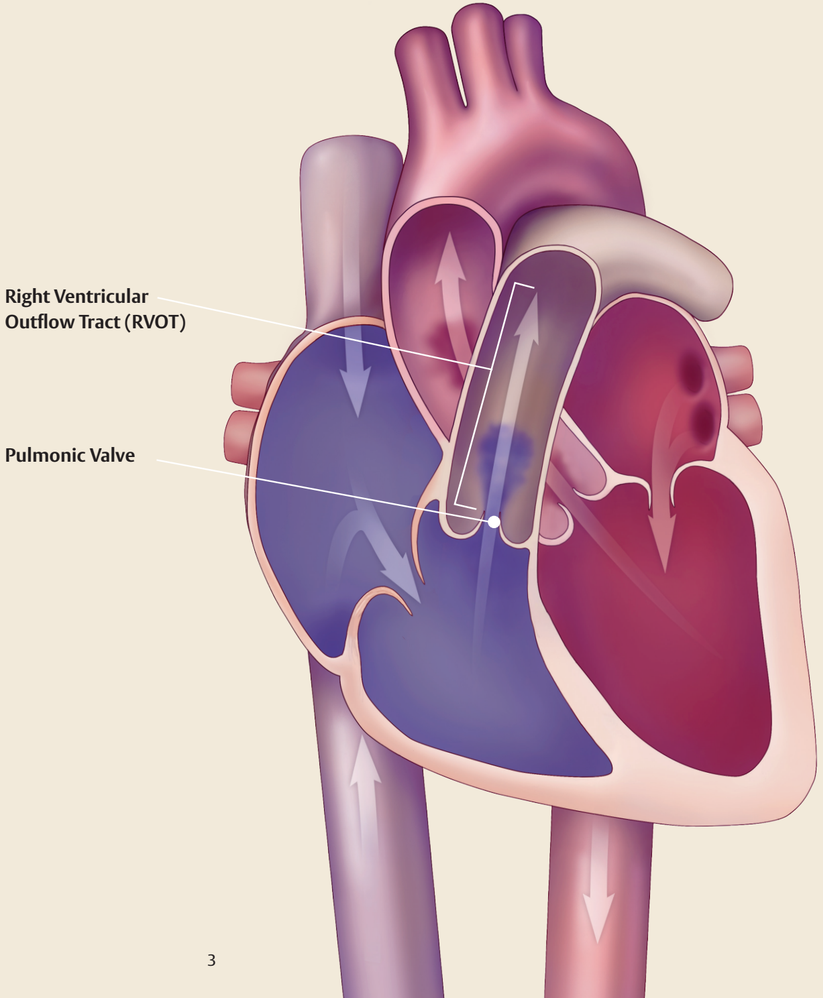
What Is Congenital Heart Disease?

Congenital Heart Disease, also known as CHD, is one of the most common birth defects in the United States. CHD is a defect or abnormality of the heart present from birth. It results when the heart or blood vessels near the heart do not develop normally before birth.

Approximately 40,000 babies are born each year with CHD.

About 1 in 4 babies born with a heart defect has a critical CHD (also known as critical congenital heart disease). Babies with a critical CHD need surgery or other procedures in the first year of life.

Approximately
1.4 million
adults in the United States are living with congenital heart disease



Types of Congenital Heart Diseases That Can Affect the Pulmonic Valve

There are at least 18 types of congenital heart defects with different sub-variations. In both children and adults, CHDs may manifest in a variety of different ways. Some are serious and may need several surgeries and treatments over time. This list is not all inclusive. We have highlighted some of the defects common to the pulmonic valve:

- Tetralogy of Fallot
- Pulmonary Valve Stenosis
- Pulmonary Atresia
- Double Outlet Right Ventricle (DORV)
- Defects resulting in a Ross operation

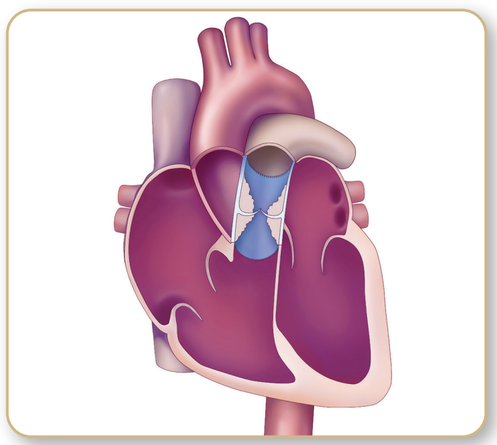
Symptoms That Your Pulmonic Valve or RVOT May Be Failing

- Tiredness
- Shortness of breath
- Chest pain
- Dizziness or fainting from exercise
- Irregular heartbeat
- Too weak for normal exercise
- Fever caused by infection of prosthetic valve

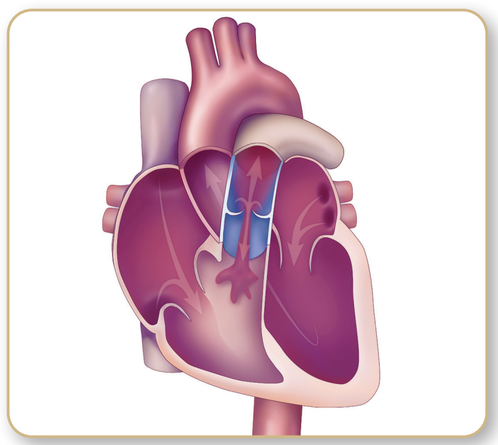
Talk to your doctor if you experience any of these symptoms.

Regular checkups can help you and your doctor understand your current medical condition.

As a result of CHD, one may need multiple surgeries over the course of their life. The right ventricular outflow tract (RVOT) is the part of the heart that carries blood out of the right ventricle to the lungs. Problems with the RVOT are common for congenital heart defects. This may cause the valve or RVOT to eventually narrow (stenosis) and/or leak (regurgitation).



A Narrowed RVOT (Stenosis)



A Leaky RVOT (Regurgitation)

Narrowing (Stenosis): Calcium (mineral deposits) may form on the inside of the RVOT, pulmonic valve, or previously placed surgical corrections, 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 may become damaged and will need to work harder to get blood to the lungs.

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 right ventricle chamber instead of flowing into the lungs. The right ventricle chamber must work harder to pump enough blood to the lungs. Leaking can cause damage to the muscle of the heart over time.

Understanding Your Treatment Options

If you need a new pulmonic valve, TPV therapy may be an option for you. Only a doctor trained in this procedure can tell you if TPV therapy is right for you.

Transcatheter Pulmonic Valve (TPV) Therapy

During this minimally invasive procedure, a catheter holding a new heart valve is inserted through a small tube and guided to the intended location in your heart. 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.

Surgical Repair or Replacement

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

Balloon Angioplasty/ Valvuloplasty

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

Patients who received Edwards TPV therapy experienced the following:

Patients were able to delay their next open heart surgery

Generally, patients experienced improved heart valve function within the first year of treatment

TPV Therapy With the Edwards SAPIEN 3 Pulmonic Valve

TPV therapy with The Edwards SAPIEN 3 pulmonic valve provides a less invasive treatment option for a group of patients who typically face the burden of multiple open heart surgeries, often times beginning at birth. As surgical risk increases with each open heart surgery, minimally invasive options can help patients recover and return to normal activities sooner.

TPV therapy with the Edwards SAPIEN 3 pulmonic valve, is a less invasive option that uses a thin tubed like catheter to insert the new valve in place. Your doctor will guide the new valve into the heart while the heart is still beating, using guidance from X-ray and echocardiography. The valve is expanded into place with the help of a balloon, and begins working immediately once it is in place. The Edwards SAPIEN 3 pulmonic valve is designed to work like your native pulmonic heart valve.

The Edwards SAPIEN 3 Pulmonic Valve

The Edwards SAPIEN 3 pulmonic valve is part of the latest technology of heart valves from Edwards Lifesciences. The Edwards SAPIEN 3 pulmonic valve is a bioprosthetic, balloon-expandable valve. The frame of the valve is made from cobalt chromium to help with strength and durability. The leaflets in the valves are made from the same bovine pericardial tissue (from a cow's heart) as Edwards long standing surgical valves. An outer sealing skirt surrounds the bottom of the valve, to help stop any possible leakage around the valve.

The valves are available in fours sizes: 20, 23, 26, and 29 mm in diameter.

Your doctor will determine which valve and which size is right for you.

The Edwards SAPIEN 3 Pulmonic Valve

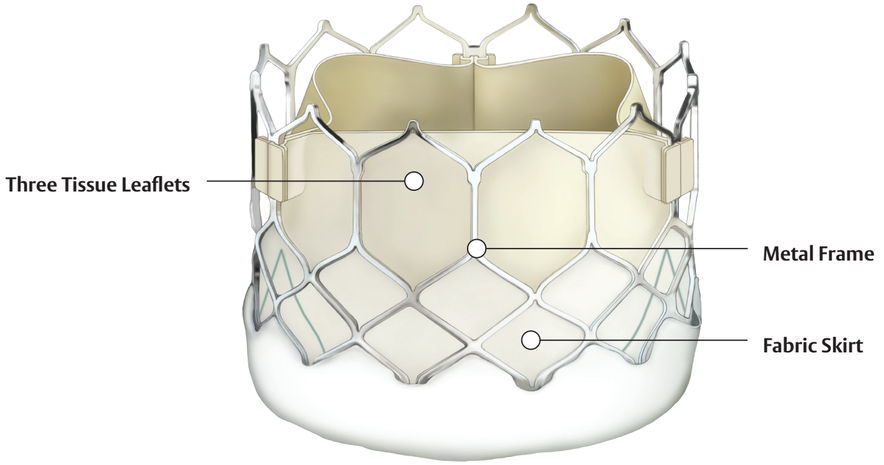


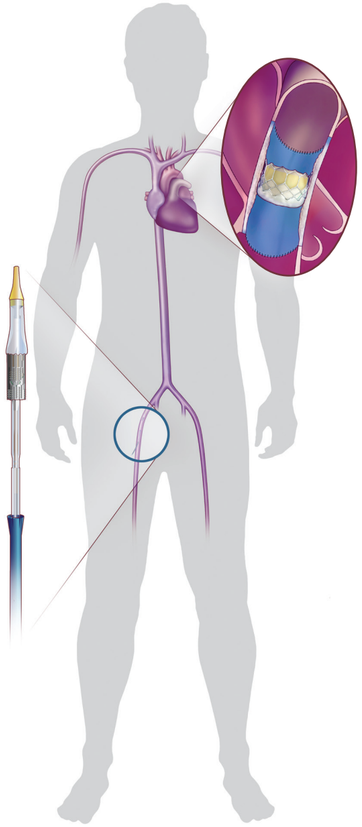
Image is larger than actual valve size.

Who Should Have the Procedure?

The Edwards SAPIEN 3 pulmonic valve is for people who want a less invasive option to replace their failing surgical valve or conduit. It is approved for use in adults and children who have a narrowed (stenosis) and/or leaky (regurgitation) RVOT conduit or previously implanted surgical valve.

Who Should Not Have the Procedure?

TPV therapy with the Edwards SAPIEN 3 pulmonic valve should not be performed on anyone who cannot tolerate medications that thin the blood or prevent blood clots from forming or who have an active infection in the heart or elsewhere.

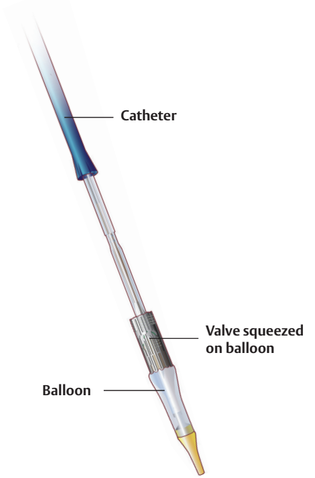


Be sure to tell your doctor if you are taking any medications or have any allergies. Your doctor will also explain the procedure and answer any questions you might have.

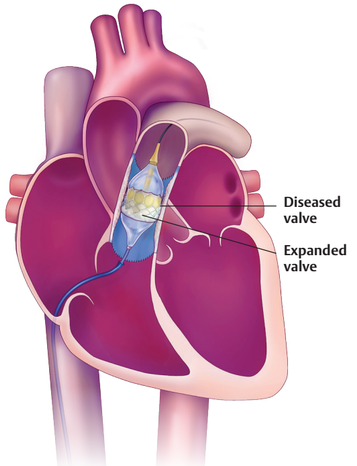
Steps of the TPV Therapy Procedure

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

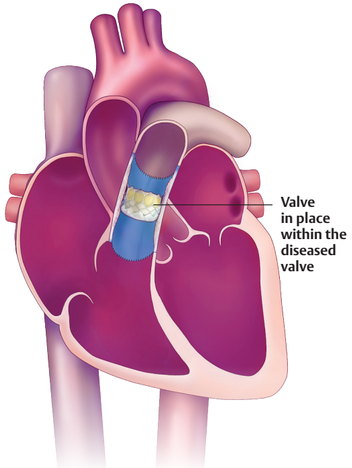
Watch a video on the Edwards TPV Therapy at
PulmonicValveTherapy.com/ video



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



4. The delivery system carrying the valve will be inflated using the balloon on the catheter once the valve is in the correct location.



5. Your doctor will make sure your new valve is working properly.

On average, the TPV procedure lasts about **2-3 hours**

Life After TPV Therapy with the Edwards SAPIEN 3 Pulmonic Valve

After your procedure, you may spend a day or two in the hospital. Every patient is different in how they recover. Most patients should begin walking very soon after their procedure.

Before you leave the hospital, your doctor will discuss your aftercare plan with you. They will give you specific instructions to help you with your recovery. This may include a special diet, when to return to exercise, and any medicine you may need to take.

It is important to carefully follow your doctor's directions, especially if you need to take any blood thinning medication.

You should start feeling better soon after TPV therapy. It can take about a week before you can return to normal activities. Regular checkups with your doctor are important. Take your medications as instructed, and be sure to keep all follow-up appointments with your doctor.

Average length of stay with Edwards TPV Therapy:

1-2 days

Quality of Life Improvement:

TPV therapy clinical data have shown signs of improvement in health in six months. **That means a lot in terms of improved quality of life, including:**

- **Reduction** in symptoms
- **Improved** heart function
- Ability to **care** for yourself
- Return to **everyday** activities

Edwards SAPIEN 3 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 3 pulmonic valve from the US COMPASSION S3 Clinical Trial.

The frequency is shown as the number of patients out of every 100. The risks with the procedure may depend on the overall health of the patient. The clinical data shown in this chart could be what you would expect.

Clinical Risks	within 30 days	within 1 year
Endocarditis	0 out of 100	0 out of 100
Valve Stent Fracture	0 out of 100	0 out of 100
Valve Dysfunction: Regurgitation	0 out of 100	3 out of 100
Valve Dysfunction: Reintervention	0 out of 100	0 out of 100
Valve Dysfunction: Stenosis	2 out of 100	3 out of 100
Pulmonary Embolism	0 out of 100	0 out of 100

Benefits of the Edwards SAPIEN 3 Pulmonic Valve

- Improvement in over all symptoms
- Future delay in further open heart surgeries
- Relief of valve narrowing (stenosis) and leaking (regurgitation)

What Are the Potential Risks You Should Know

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

With TPV therapy with the Edwards SAPIEN 3 pulmonic valve, potential risks could be serious, including death.

Other Possible Risks Associated With the Procedure Include:

- Stroke
- Risks to the lungs including:
  - difficulty breathing
  - buildup of fluid in or around the lungs
  - collapsed lung
  - loss of lung volume
- Risks to the heart including:
  - injury to the heart, arteries, heart muscle or valves including the pulmonary RVOT that may require intervention
  - heart attack
  - heart failure or heart does not pump properly
  - irregular heartbeat that may result in a need for a permanent pacemaker
  - too much fluid around the heart
  - sudden loss of heart function
  - disruption or blockage of blood flow through the heart
  - infection of the heart
  - injury to your tricuspid valve
  - additional heart surgery
- Dislodgement of calcified material, air embolism (air bubbles in the blood vessels), blood clots, or pieces of the device
- Injury to blood vessels
- Valve movement after deployment requiring reintervention
- Transcatheter Valve not working properly
- Life-threatening infection
- Poor kidney function or failure
- Abnormal connection between an artery and vein
- Nerve injury
- Limited blood supply
- Severe bleeding requiring transfusion
- Decrease in red blood cells including at a fast rate
- Formation of a blood clot
- Abnormal lab values
- High or low blood pressure
- Allergic reaction to anesthesia or dye
- Fainting
- Pain
- Weakness or inability to exercise
- Swelling
- Chest pain
- Fever

Additional Warnings and Precautions With Edwards SAPIEN 3 TPV Therapy

Warnings

- If an incorrect size of the valve is implanted, it may lead to valve leakage, movement, or dislodgement of the valve from where it was implanted and/or tearing of the conduit.
- Patients with a disease that results in more calcium in their blood, may have early wear of their valve.
- Patients should be evaluated prior to treatment for coronary compression risk.
- Talk to your doctor if you are allergic to the materials used during the procedure: cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or plastics.
- X-ray used during the procedure may cause radiation injury to the skin.

Precautions

- Patients should be pretreated for heart infection as a precaution.
- Transcatheter heart valve patients should stay on blood-thinning medicine as specified by their doctor.
- Patient's anatomy should be evaluated prior to procedure to prevent the risk of patient not being able to receive the valve.
- The safety and effectiveness of the transcatheter heart valve have not been established for patients who:
  - have a disease or disorder of the blood (low white or red blood cell count, low platelets or history of slow blood clotting)
  - have an allergy to blood-thinning medications or dye injected during the procedure
  - may be pregnant

How long your tissue valve will last depends on many patient factors and medical conditions. Follow all care instructions to ensure the best possible results. The Edwards SAPIEN 3 pulmonic valve has been tested in a laboratory to mimic 5 years of use without failure. Regular follow-ups will help your doctor know how your valve is working.

Your Edwards SAPIEN 3 Pulmonic Valve Implant Card

As you leave the hospital, your valve clinic coordinator or nurse should give you a temporary implant card. A permanent card will be sent to you in approximately 6-8 weeks. This card has information about your Edwards SAPIEN 3 pulmonic valve. Share this card with all members of your healthcare team, including your dentist. It is important to share about your heart valve replacement before any medical, dental, or MRI (magnetic resonance imaging) procedures. If you need an MRI, tell your doctor that you have an Edwards SAPIEN 3 pulmonic valve.

Edwards Lifesciences® Implanted Device ID Card

SAMPLE PATIENT

Edwards™

Implanting Physician
SAMPLE PHYSICIAN

Hospital
SAMPLE HOSPITAL
CITY, STATE, COUNTRY ZIP CODE

Serial
xxxxxx

Model
9300TFX

Implant Date
DATE MONTH YEAR

Position
POSITION

Size
SIZE MM

Device
BOVINE TRANSCATHETER HEART VALVE

Appropriate antibiotics may be reasonably prescribed for you prior to certain dental and invasive procedures due to a higher risk of adverse outcomes from prosthetic valve related-infection (endocarditis). Additional information available at www.edwards.com/antibiotics

For more information on your implant card, please go to Edwards.com

For More Information about the Edwards SAPIEN 3 Pulmonic Valve:

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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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