

Edwards Transcatheter Pulmonary Valve Replacement

*A guide for patients
and caregivers*



The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System
with Alterra Adaptive Present



This booklet is intended for those who may need a new pulmonary valve due to pulmonary regurgitation.

After reading this booklet, you and your loved ones should have a better understanding of transcatheter pulmonary valve replacement (TPVR) with the **Edwards SAPIEN 3 Transcatheter Pulmonary Valve System** and **Alterra Adaptive Presept**.

Speak with your doctor, so together you can decide if TPVR 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 helped critically ill patients for over 60 years.

Driven by a passion to help patients, Edwards works to improve outcomes and enhance patients' lives.

The Edwards SAPIEN 3 Pulmonary Valve System with Alterra Adaptive Prestent is a minimally invasive treatment option, designed to help treat severe pulmonary regurgitation in children, adolescents, and adults with a native or surgically-repaired right ventricular outflow tract (RVOT).

To learn more, go to:

PulmonaryValveReplacement.com

The Heart

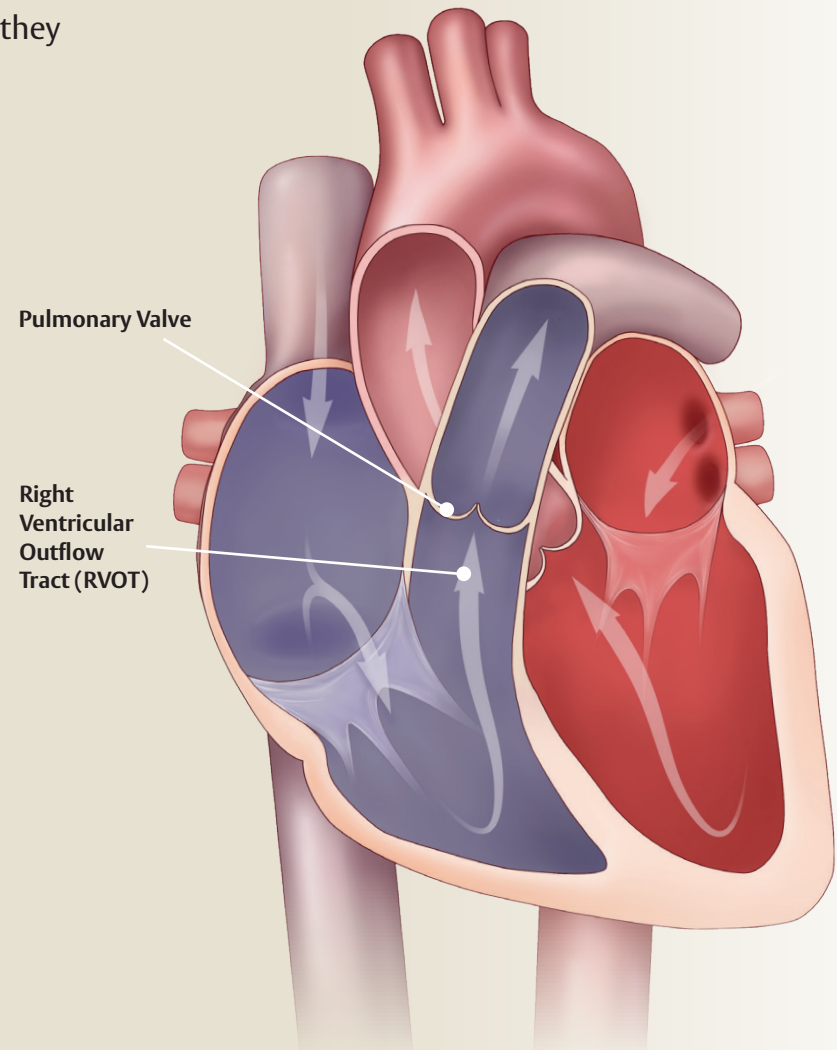
The heart is designed to pump blood in a specific pattern. Blood pumps through the right side of the heart, then out to the lungs to receive oxygen. It then passes back through the left side of the heart and travels out to the body.

A normal heart has four different valves: tricuspid, pulmonary, mitral, and aortic. Your valves' primary roles are to work like one-way doors, so blood can flow forward through the heart easily when they are open, and then when they close tightly, blood does not flow backwards.

The Pulmonary Valve and RVOT

The **pulmonary valve** is one of two valves that sends blood out of the heart. It sits between your heart's lower right chamber (right ventricle) and the blood vessels (pulmonary arteries) that carry blood from the heart to the lungs. The valve acts as a one-way door – opening and shutting tightly so that blood does not flow back into the heart.

The **Right Ventricular Outflow Tract**, also known as the **RVOT** for short, includes the area underneath the pulmonary valve, the pulmonary valve itself, and a portion of the main pulmonary artery.



Pulmonary Valve and RVOT Repair Procedures

If you were born with a congenital heart defect that affects your pulmonary valve or RVOT, you might have had open-heart surgery, or some other procedure at some time, to repair your defects. There are a few different procedures that can help restore proper blood flow to your heart.

Sometimes after the initial treatment to fix your heart, you may need multiple surgeries throughout your life to fix your CHD-related health problems. Having a less invasive option for patients can be life changing.



What is Pulmonary Regurgitation?

If you were born with a CHD that required surgery to temporarily repair your pulmonary valve or RVOT, your valve might begin to “leak” blood back into your heart as you get older.

Pulmonary regurgitation (PR) is when blood starts to leak backward from your pulmonary valve into your heart. Your heart must work harder than usual to pump the extra blood. And over time, the extra work becomes a burden and lessens your heart’s ability to pump blood. If this happens, your doctor may recommend your pulmonary valve be replaced.

If your pulmonary valve has minimal leakage, you may have little to no symptoms. As your pulmonary valve leaks more, it may cause you to have symptoms or your symptoms to become worse, like chest pain and fatigue, particularly with exercise.

Symptoms of Pulmonary Regurgitation



Difficulty breathing or fatigue (especially during exercise)



Dizziness or fainting



Chest pain, such as squeezing, pressure or tightness



Sensation of rapid or irregular heartbeat (palpitations)



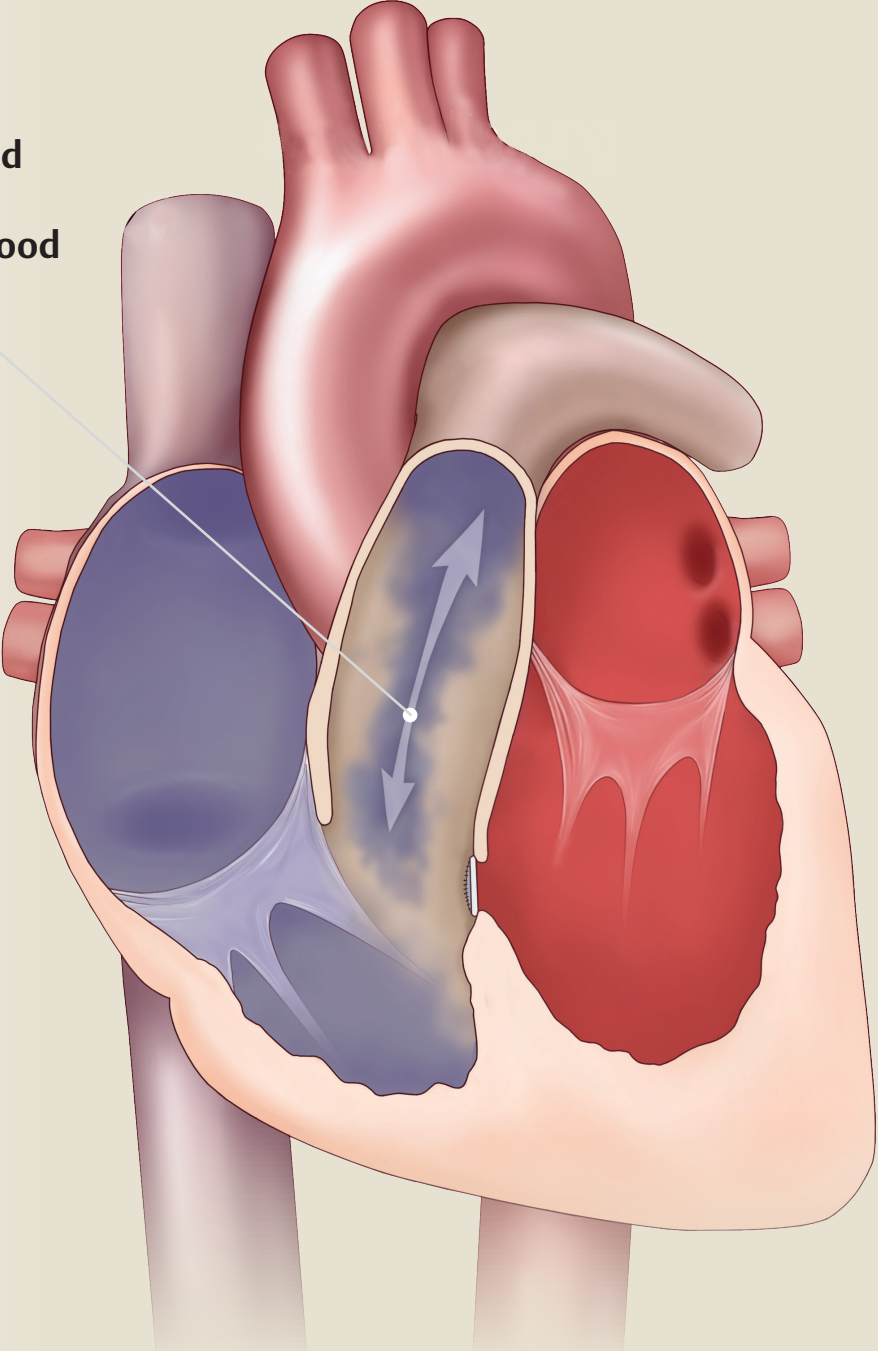
Bluish discoloration of the nails and lips (cyanosis)



Swelling of the legs or feet

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

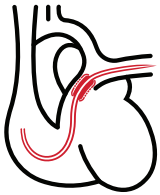
**Native or Surgically-repaired
RVOT in the heart, with the
pulmonary valve leaking blood
backwards (regurgitation)**





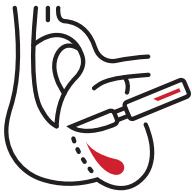
Understanding Your Treatment Options

If you need a new pulmonary valve, a catheter-based procedure called transcatheter pulmonary valve replacement, also known as TPVR or TPV Therapy (Transcatheter Pulmonary Valve Therapy), may be an option for you. Only a doctor trained in this procedure can tell you if TPVR is right for you.



Transcatheter Pulmonary Valve Replacement (TPVR)

During this minimally invasive procedure, a catheter holding a bioprosthetic heart valve is inserted in your leg through a small tube, and it is then guided to the correct location in your heart. Once the valve is in the right spot, your doctor will expand the replacement pulmonary valve into place using a balloon. The faulty valve will not be removed, but it will be pushed aside.



Open-Heart Surgical Valve Replacement

During open-heart surgery, the doctor will open the chest, remove the failing pulmonary valve, and sew in a bioprosthetic pulmonary valve. For those with CHD, your doctor will need to evaluate how many open-heart surgeries your heart can handle.

What Happens If Your RVOT is Too Big for Standard Transcatheter Pulmonary Valve Replacement?

For some people who have had open-heart surgery or surgical patch repair, it is common to experience a leaking pulmonary valve. If your RVOT becomes enlarged, it can be difficult for a valve to fit properly with TPVR. Previously for anyone with this issue, open-heart surgery was the only option for treatment. With the Alterra Adaptive Presept, people with an enlarged RVOT can now be considered for TPVR with the Edwards SAPIEN 3 valve system. This stent-like implant, which uses a transcatheter approach, fits a wide range of pulmonary artery anatomies. The presept helps reshape the RVOT and provide a “landing zone” for the new transcatheter pulmonary valve to ensure that it fits snug in your native RVOT.



The Edwards SAPIEN 3 Pulmonary Valve System with Alterra Adaptive Prestant could help people with CHD who have pulmonary regurgitation due to a prior procedure to fix their pulmonary valve or RVOT.

Most CHD patients will typically require multiple open-heart surgeries throughout their lifetimes. With each open-heart surgery, your surgical risk increases. However with the less invasive option of TPVR with the Edwards SAPIEN 3 Pulmonary Valve system and Alterra Adaptive Prestant, it is possible that you will need fewer repeat surgeries, as well as return home sooner to the activities you love.



TPVR could delay your next open heart surgery

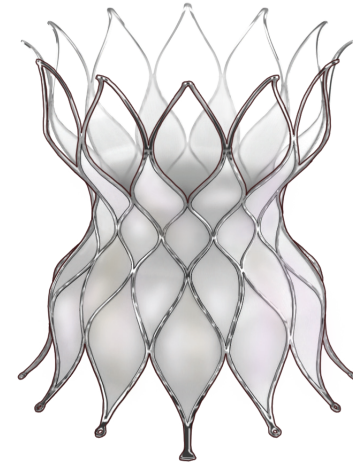


TPVR patients experienced improved heart valve function within the first year of treatment

Alterra Adaptive Prestant

The Alterra Adaptive Prestant

The prestant is designed to help make your RVOT suitable for implanting the Edwards SAPIEN 3 transcatheter heart valve. The Alterra Adaptive Prestant works as a landing zone for the Edwards SAPIEN 3 pulmonary valve within the RVOT. The prestant frame is made from a metal and has a fabric covering with designated inflow and outflow ends.



Edwards SAPIEN 3 Pulmonary Valve

The Edwards SAPIEN 3 Pulmonary Valve

The valve is designed to work like your pulmonary heart valve and help make your valve and heart work as it is intended. The Edwards SAPIEN 3 transcatheter heart valve is made up of three main components: three leaflets made from the tissue of a cow's heart, a metal frame, and a fabric skirt. Together with the Alterra Adaptive Prestant, the Edwards SAPIEN 3 pulmonary valve should begin working immediately after it is implanted.



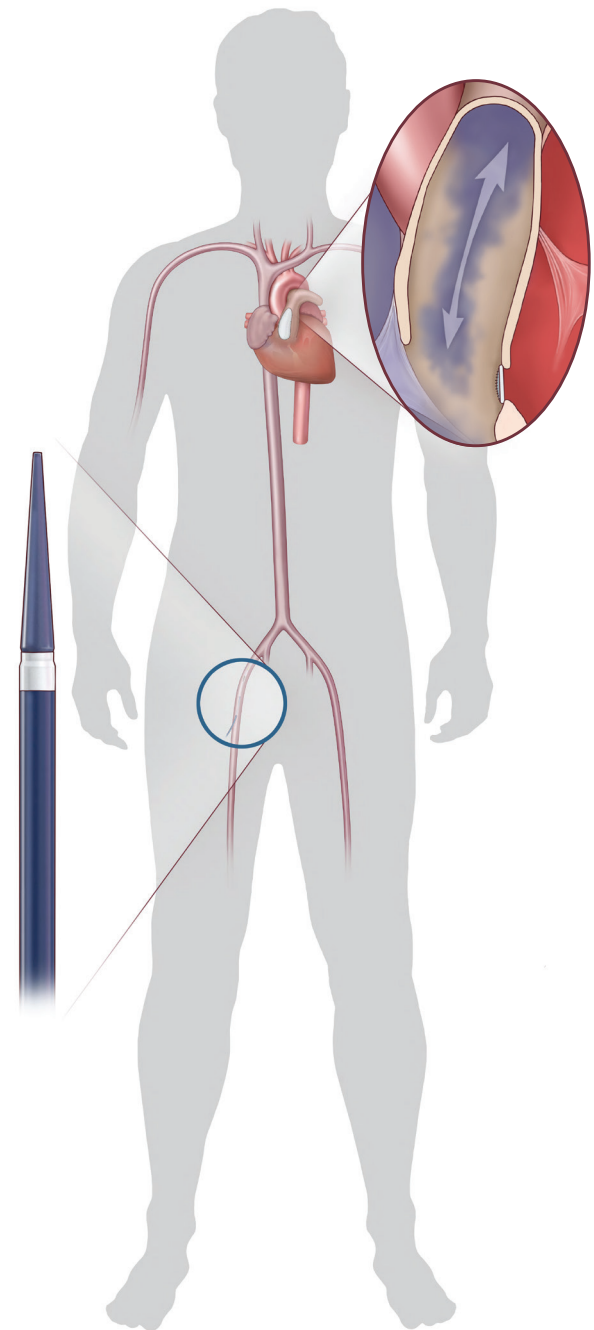
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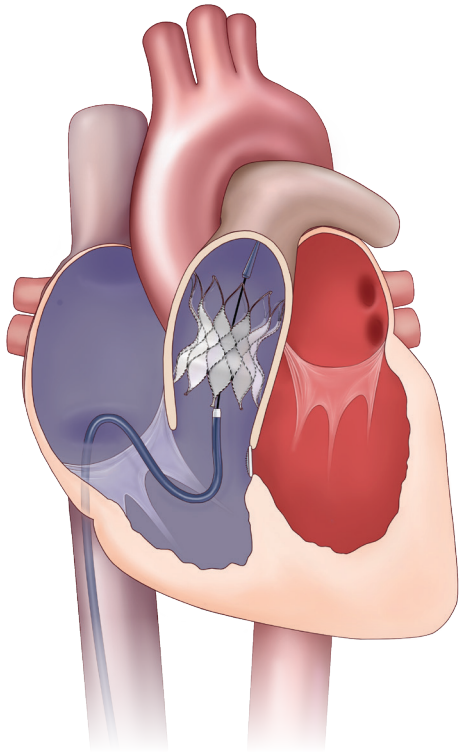
The TPVR Procedure

This is a general overview of what may happen during the procedure. Your experience may differ, please talk with your doctor about TPVR for any questions you may have.

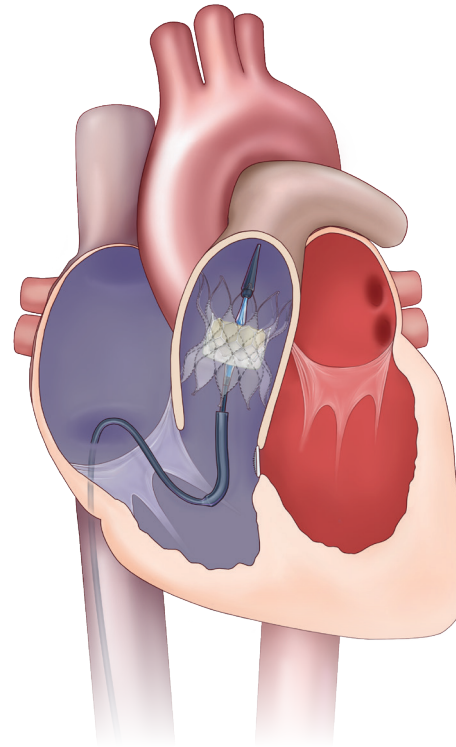
Transcatheter Pulmonary Valve Replacement Procedure

- 1.** Before your procedure, you will be placed either under general anesthesia or light sedation.
- 2.** Your doctor will make a small incision in your leg to access your vein. Once the doctor has access to the vein, a short, hollow tube called a sheath, will be inserted into the vein and used as a tunnel to deliver the Alterra Adaptive prestant to your heart.
- 3.** When the sheath is in place, your doctor will take the Alterra Adaptive prestant and insert the delivery catheter into the leg and guide it up the vein to reach the heart. Your doctor will begin to deploy the self-expanding prestant into the RVOT. Once it is fully expanded, your doctor will remove the delivery catheter leaving the prestant as a landing zone, making your RVOT ready for the new transcatheter pulmonary valve.
- 4.** Now that you have a docking station for your new valve, your doctor will use a different delivery system catheter with the Edwards SAPIEN 3 transcatheter pulmonary valve squeezed onto a balloon on the tip. This makes the valve small enough to fit into a catheter.
- 5.** Your doctor will insert the delivery system into the leg and guide the new valve up to the heart. Once it reaches the Alterra Adaptive Prestent, your doctor will expand the balloon on the catheter, opening up the Edwards SAPIEN 3 pulmonary valve and securing it in place.
- 6.** Your doctor will make sure your Edwards SAPIEN 3 pulmonary valve works properly before removing the delivery catheter from the leg and closing the small incision in your leg.





Delivery of the Alterra Adaptive Presept



Delivery of the Edwards SAPIEN 3 transcatheter valve in the Alterra Adaptive Presept



Be sure to tell your doctor if you are taking any medications or have any allergies.

Prior to TPVR, your doctor may require a dental clearance exam, including X-rays to help your dentist detect any damage or disease not visible during a regular dental examination.

To see an animation of the procedure, go to:
PulmonaryValveReplacement.com





Average length of stay
with Edwards TPVR:

1-2 days

On average, the TPV
procedure lasts
2-3 hours

What to Expect After TPVR with the Edwards SAPIEN 3 Pulmonary Valve System and Alterra Adaptive Prestant

It is important to understand that every patient is different in how they recover. You can expect to spend a day or two in the hospital after your procedure. Most patients should begin walking soon after their procedure.

Before you leave the hospital, your doctor will explain your aftercare plan. You will be given specific instructions to help with your recovery, including when to return to exercise, as well as any medicine you 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 TPVR. It can take about a week before you return to normal, everyday activities. Regular checkups with your doctor are essential. Take your medications as instructed and be sure to keep all follow-up appointments with your doctor.

Potential Benefits of The Edwards SAPIEN 3 Pulmonary Valve

Clinical data has shown signs of improvement in health up to six months. That means a lot in terms of improved quality of life, including:



Delay of next open-heart surgery



Ability to **care** for yourself after the procedure



Improved heart function



Return to **everyday** activities



Who Should Have the Procedure?

The Edwards SAPIEN 3 Pulmonary Valve System with Alterra Adaptive Prestant is a minimally invasive treatment option, designed to help treat severe pulmonary regurgitation in children, adolescents, and adults with a native or surgically-repaired right ventricular outflow tract (RVOT).




Who Should Not Have the Procedure?

The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestant should not be used with 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.


Your Edwards Lifesciences Implant Cards

Because you have both the Edwards SAPIEN 3 Pulmonary Valve System and Alterra Adaptive Prestant, you should receive two temporary implant cards for each device implanted into your heart. Your permanent cards will be sent to you in approximately 6-8 weeks after your procedure. Your implant registry cards have information about your Edwards SAPIEN 3 pulmonary valve and Alterra Adaptive Prestant. Share these cards with all members of your healthcare team, including your dentist. It is important to let your healthcare providers know 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 pulmonary valve and Alterra Adaptive Prestant.

Example: Edwards SAPIEN 3 Valve Implant Card

Edwards Lifesciences® Implanted Device ID Card			
SAMPLE PATIENT		 Edwards™	
Implanting Physician SAMPLE PHYSICIAN		Device BOVINE TRANSCATHETER HEART VALVE	
Hospital SAMPLE HOSPITAL CITY, STATE, COUNTRY ZIP CODE		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	
Serial XXXXXX	Model 9600TFX		
Implant Date DATE MONTH YEAR	Position POSITION	Size SIZE MM	

Example: Alterra Adaptive Prestant Implant Card

Edwards Lifesciences® Implanted Device ID Card		
SAMPLE PATIENT		 Edwards™
Implanting Physician SAMPLE PHYSICIAN		
Hospital SAMPLE HOSPITAL CITY, STATE, COUNTRY ZIP CODE		
Lot XXXXXX	Model 29AP4045A	Device SELF-EXPANDING ADAPTIVE PRESTENT
Implant Date DATE MONTH YEAR	Position POSITION	

For more information on your implant card, please go to Edwards.com or call (800) 424-3278.



Alterra Clinical Study

The Alterra Clinical Study was a single-arm, prospective, multicenter study. Sixty (60) patients were enrolled between August 2017 and September 2019 at 11 investigational sites in the U.S.

The following table summarizes the clinical risks observed within 6 months in patients who received the Edwards SAPIEN 3 pulmonary valve from the Alterra Clinical Trial.

The frequency shown is the number of patients out of every 100. The risks of the procedure may depend on the overall health of the patient.

Clinical Risks	within 6 months
Death from any cause	0 out of 100
Bleeding	22 out of 100
<i>Significant bleeding</i>	4 out of 100
Injury to veins or insertion site	5 out of 100
<i>Significant injury</i>	0 out of 100
Irregular heartbeat	34 out of 100
<i>Irregular heartbeat requiring permanent pacemaker</i>	0 out of 100
Valve leakage (moderate or severe)	2 out of 100
Infection of the heart	0 out of 100

Benefits

- Improvement in overall symptoms
- Delaying or avoiding open heart surgery to replace the pulmonary valve
- Relief of valve leakage (regurgitation)

Potential Risks You Should Know About

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

The most serious risks from the Edwards SAPIEN 3 transcatheter pulmonary valve system with Alterra Adaptive prestant, although rare, are death and stroke.

Other Possible Risks Associated With the Procedure Include:

- 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
- Blood clot in a deep vein
- Device movement after deployment requiring reintervention

- Device 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
- Abnormal lab values
- High or low blood pressure
- Formation of a blood clot
- Bleeding under the skin
- Allergic reaction to anesthesia or dye
- Fainting
- Pain
- Weakness or inability to exercise
- Swelling
- Chest pain
- Fever

The Edwards SAPIEN 3 pulmonary valve has been tested in a laboratory to mimic five years of use without failure. How long the Edwards SAPIEN 3 Pulmonary Valve with Alterra Adaptive Prestant will last depends on many patient factors and medical conditions. Follow all care instructions from your physician to ensure the best possible results. Regular follow-ups will help your doctor know how your valve is working.

Contact Information

For More Information about the Edwards SAPIEN 3 Pulmonary Valve System with Alterra Adaptive Prestant:

Toll-free phone in the USA:
1.800.424.3278

Email address:
TPVTherapy@Edwards.com

Online:
www.PulmonaryValveReplacement.com
www.Edwards.com

Mail:
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One Edwards Way
Irvine, CA 92614 USA

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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