Edwards Transcatheter Tricuspid Valve Replacement

A guide for patients with tricuspid regurgitation

The Edwards EVOQUE Tricuspid Valve Replacement System

Edwards

This patient guide is for those who have severe tricuspid regurgitation (TR) but continue to have symptoms despite being on heart failure medications.

The information in this guide will help you and your family understand more about your diagnosis, your disease, and a less invasive procedure called transcatheter tricuspid valve replacement (TTVR).

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

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Edwards Lifesciences is the global leader in patient focused medical innovations for structural heart diseases 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 EVOQUE tricuspid valve replacement system is designed to replace the native tricuspid valve without open heart surgery and help reduce or eliminate tricuspid regurgitation.

What is tricuspid regurgitation (TR)?

TR happens when the tricuspid valve on the right side of the heart does not close properly. When the valve does not fully close, blood flows backward from the lower chamber (ventricle) into the upper chamber (atrium) making your heart work harder to move blood through the valve.

This is typically because:

- The right lower chamber becomes bigger and pulls the muscles connected to the valve leaflets (flaps), causing them to spread apart.
- The right upper chamber becomes bigger, causing the tricuspid valve annulus (a ring-shaped structure between the right lower chamber and right upper chamber) to become bigger.
- The leaflets are damaged.

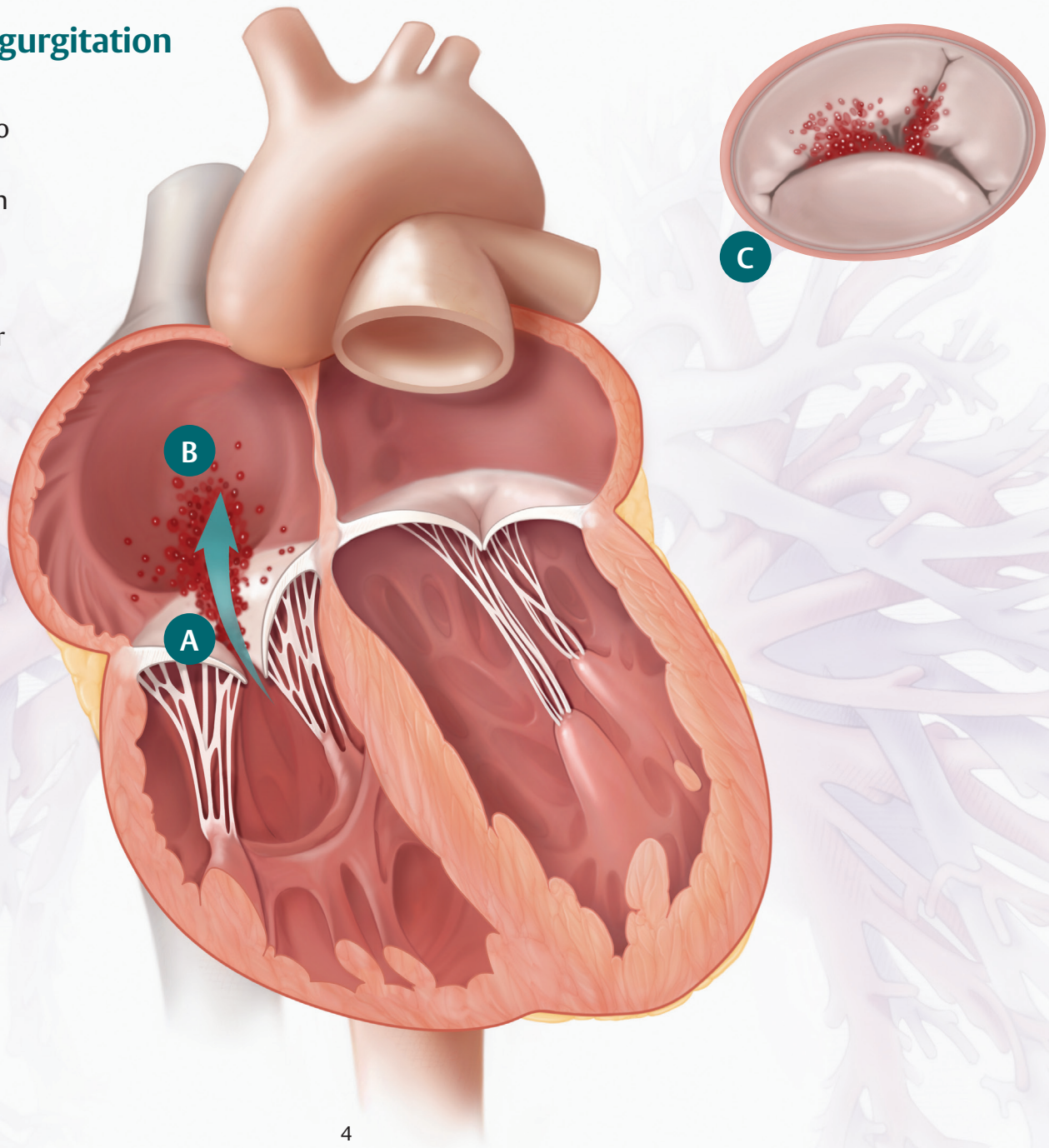
TR worsens with time. It often does not show signs or symptoms until the disease is severe. With TR, you may have shortness of breath or feel weak. It may also cause abnormal heart beats or swelling in your abdomen, ankles, veins in your neck or feet. These symptoms can seriously affect your quality of life.

Heart with Tricuspid Regurgitation

A The tricuspid valve does not close properly due to an enlarged heart chamber or an issue with the valve's leaflets

B As a result, blood leaks backward into the upper chamber (right atrium) instead of moving forward into the lower chamber (right ventricle)

C Top view of the valve that allows blood to leak backward



Understanding Your Treatment Options

If you have severe TR and continue to have heart failure symptoms on medical therapy, transcatheter tricuspid valve replacement may be an option for you.

Only a specialized Heart Team can determine which treatment option is best for you.

Medication

Your doctor may prescribe certain medications to help some symptoms of the failure of your heart valve. However, it will not cure or fix the valve.

Surgical Valve Intervention

Open heart surgical valve repair or replacement* is where the doctor will open your chest and repair or replace the damaged valve. It is often in conjunction with another heart valve procedure. During a surgical valve procedure, various treatments (repair with bands, rings, stitches, or replacement with an artificial valve) can be used. You will be connected to a heart-lung machine that temporarily does the work of your heart and keeps the blood flowing throughout your body. Patients usually need to stay in the hospital for a week or more; beginning an extended period of recovery.

Transcatheter Valve Replacement

During a transcatheter tricuspid valve replacement procedure, the doctor replaces your old leaky tricuspid valve without open heart surgery, using a delivery catheter (a tube-like device) with an artificial valve attached to its tip. Compared to surgery, the transcatheter procedure is less invasive and you are expected to have less pain, a shorter hospital stay, and a shorter recovery time.

***There are no surgical valve replacement devices approved by FDA for use in the tricuspid valve.**

Deciding on the Appropriate Treatment Option for You

What Is the Best Treatment Option for You?

Seeing a specialized doctor on a Heart Team will ensure you are evaluated for all treatment options. They will consider factors about your health to decide the most appropriate treatment option for you.

Your doctor will consider these factors:

- Your medical history
- Your age
- Your current health status
- Your ability to undergo the procedure and recover from it
- The overall condition of your heart

What Are the Benefits of Transcatheter Valve Replacement?

Potential benefits may include:

- Reduced TR
- Improved quality of life
- Relief of symptoms
- Improved exercise capacity

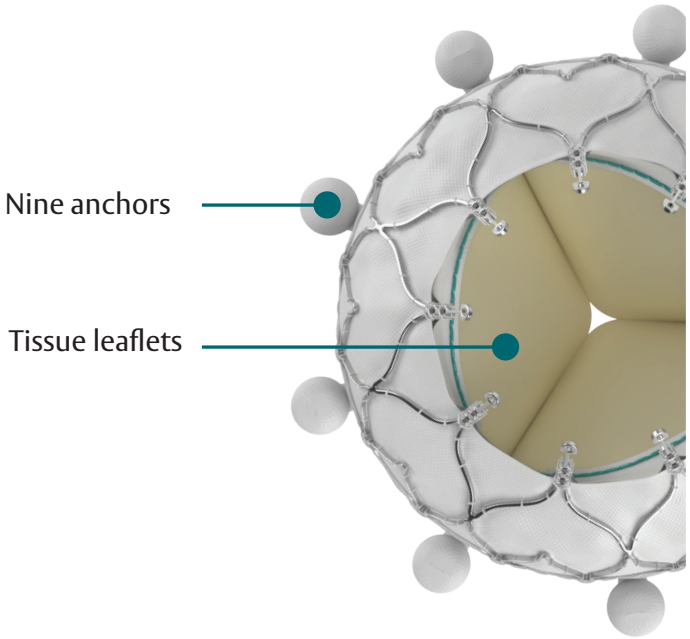
Quality of Life Improvement:

Clinical trial data showed patients who received an EVOQUE valve could experience health improvements within 30 days, including the ability to take care of themselves and participate in everyday activities.

Designed to replace your tricuspid valve and help reduce or eliminate tricuspid regurgitation

The EVOQUE system is part of the latest technology from Edwards Lifesciences. The EVOQUE valve is an artificial heart valve that can be used to replace your own tricuspid valve. The valve is put into place using a minimally invasive delivery system through a small puncture in your groin. The EVOQUE valve frame is made of nitinol (nickel titanium). Nitinol is a flexible metal material that allows the valve frame to expand and fit safely within your heart. The anchors and sealing skirt allow the EVOQUE valve to stay secured and prevent possible leakage around the valve. The leaflets in the EVOQUE valve are made from cow heart tissue, which is the same material used in Edwards' surgical and transcatheter aortic valves*. Your Heart Team will do tests to determine the exact size of the new valve you should receive. They will communicate what to expect.

The EVOQUE Valve



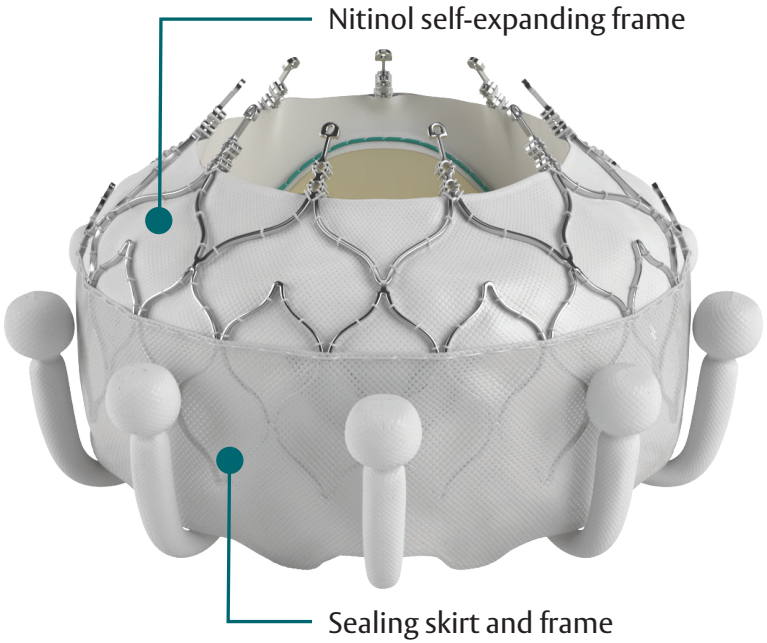


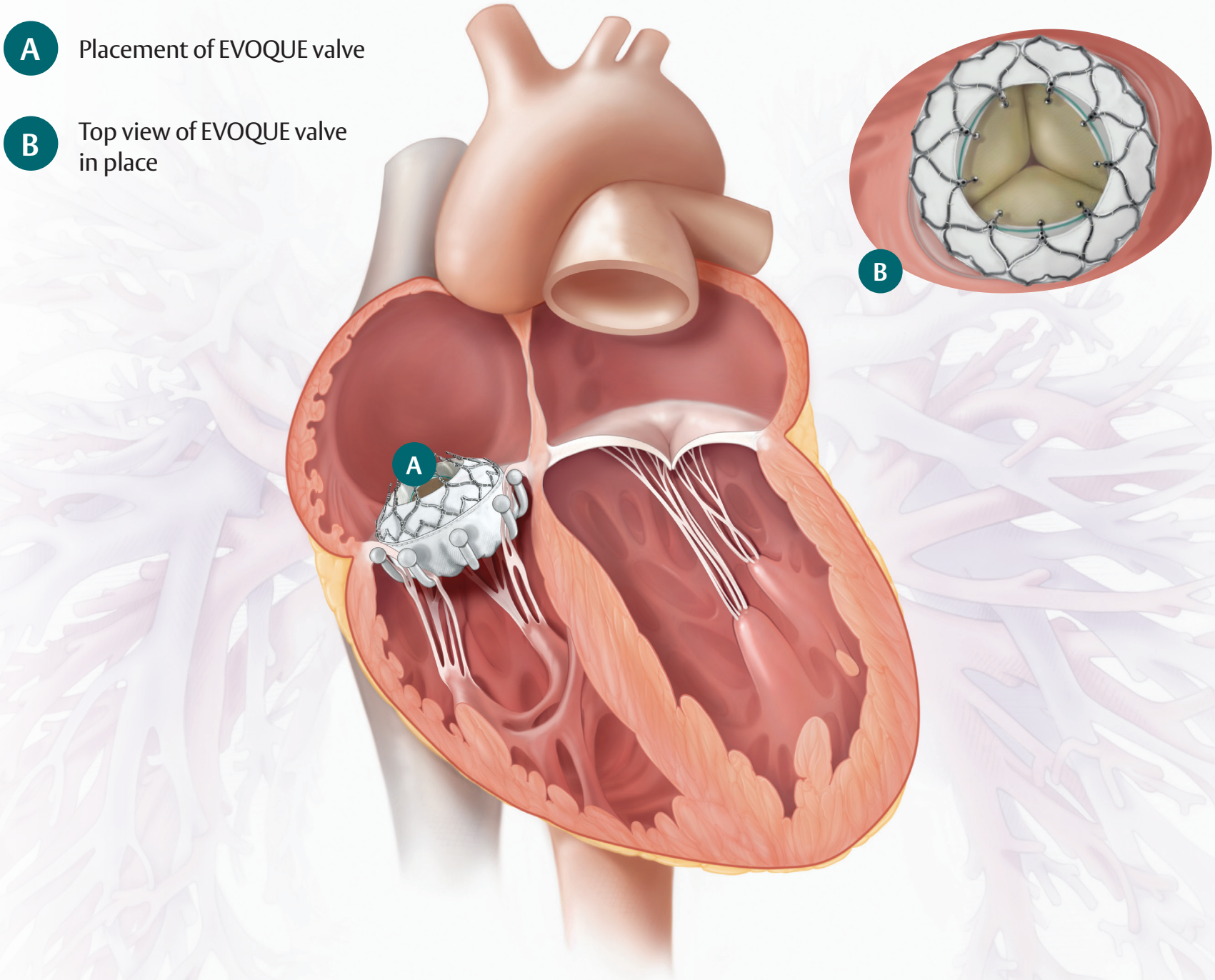
Image is larger than actual valve size.

The Transcatheter Tricuspid Valve Replacement Procedure

This section describes what happens during transcatheter tricuspid valve replacement. This section is intended as a general overview, and your experience may be different. Please talk to your doctor for more information about what you should expect.

1. Your doctor will make a small puncture in your groin to access your vein and insert a delivery system to reach your heart
2. The delivery system with the EVOQUE valve compressed at the tip will be moved through the vein to the diseased valve and positioned to the appropriate location within your heart
3. The valve will be deployed and replace your original tricuspid valve to restore proper function and your doctor will make sure your new valve is working properly

On average, a TTVR procedure with the EVOQUE system lasts about 2 hours.


A
Placement of EVOQUE valve
B
Top view of EVOQUE valve in place
A
B

After Your Transcatheter Heart Valve Replacement Procedure

What Happens After the Transcatheter Heart Valve Replacement Procedure?

After your procedure, you may spend a number of days in the hospital. Every patient's recovery is different. 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.

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

Transcatheter Valve Replacement Follow-Up Visits

Regular check-ups with your doctor are very important. You may be asked to return to your doctor to have your heart valve checked at 30 days and annually up to 5 years after your procedure.

However, you should call or see your doctor whenever you have questions or concerns about your health.

Your Edwards TTVR 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 about 6-8 weeks. This card has information about your Edwards TTVR heart 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 TTVR heart 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

Edwards Transcatheter Tricuspid Valve Replacement Clinical Data

If you undergo tricuspid valve replacement with the EVOQUE valve, the data shown in the table on the right displays possible complications that may occur based on clinical trial data.

Transcatheter Tricuspid Replacement with the EVOQUE System

Major Complications	Risk Within 30 Days	Risk Within 6 Months
Death from any cause	4 out of 100	10 out of 100
Death from heart related cause	4 out of 100	8 out of 100
Heart attack (myocardial infarction)	2 out of 100	2 out of 100
Stroke	0 out of 100	3 out of 100
Renal Replacement Therapy (for example, dialysis)	2 out of 100	3 out of 100
Severe bleeding	11 out of 100	18 out of 100
Major vascular complications	4 out of 100	4 out of 100
Non-elective re-intervention or surgery	0 out of 100	0 out of 100
Major cardiac structural complications	3 out of 100	3 out of 100
New permanent pacemaker	15 out of 100	18 out of 100
Device related pulmonary embolism	2 out of 100	2 out of 100

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

Risks of the Transcatheter Tricuspid Valve Replacement Procedure

What Are the Risks?

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

The Edwards TTVR procedure's most serious risks are:

- Death
- Stroke
- Serious bleeding (with the potential to be given blood)
- Problems with the electrical pathway of your heart that requires a pacemaker
- Unplanned repeat procedure, hospitalization, or surgery
- Major vascular complications
- Permanent disability

The EVOQUE System Cannot Be Used in People Who:

- Cannot take blood thinning medications
- Have an active infection in the heart or elsewhere
- Have an untreatable allergy to nickel or titanium

If used in the patients mentioned above, it will not work properly and could make you feel sick or even cause death.

Additional Potential Risks Associated With the Procedure Include:

- Allergic reaction
- Irregular heart rate
- Collection of fluid or blood around your heart
- Having an abnormal particle (air or blood clots) floating in the bloodstream or attached to an object, including the valve
- Infection in your heart, blood, or other areas
- Trouble or inability to breathe
- Fluid buildup in your lungs
- Anemia
- Abnormal lab values
- Abnormally high or low blood pressure
- Pain, inflammation, or fever
- Incorrect position of valve or valve movement
- Blood leak around the valve
- Additional cardiac surgery, vascular surgery, or intervention, including removal of the transcatheter heart valve
- Kidney failure
- Chest pain
- Damage to blood cells
- Swelling
- Sudden or unexpected loss of heart function
- Nerve injury, paralysis or neurological symptoms, including problems with movement or walking
- Damage to the swallowing passage (esophagus) with possible puncture or narrowing
- Failure to retrieve any EVOQUE system components
- Organ failure, including heart failure
- Nausea and/or vomiting
- Skin burn, injury or tissue changes due to x-ray exposure

Risks to the heart:

- Damage to the valve or deterioration (wear, tear, fracture, leaflet thickening, stenosis), malposition, clotting, movement, or embolization of the valve, which might require removal of the valve
- Heart attack or heart failure/ decreased heart pumping
- Interference/damage with an existing permanent pacemaker or defibrillator
- Severe bleeding or fluid in or around the heart or in the body that could require a transfusion or surgery
- Valve regurgitation (new or worsening tricuspid, aortic, mitral, or pulmonary)
- Right ventricular outflow tract (RVOT) obstruction

Warnings and Precautions

Warnings

- Serious complications, sometimes leading to surgical intervention and/or death, may be associated with use of the EVOQUE system. Talk to your doctor for a full explanation of the benefits and risks associated with this procedure
- As with any implanted medical device, there is potential for adverse allergic or immunological response
- X-rays used during the procedure may cause radiation injury to the skin

Warnings (continued)

- Blood-thinning medication may increase the risk of bleeding in the brain (stroke)

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

Precautions

- Follow all care instructions to ensure the best possible results. Regular follow-up is advised to evaluate the performance of your device
- Blood thinning medication may be necessary after valve replacement with the EVOQUE system. Your doctor should prescribe this and other medical therapy per standard guideline
- Talk to your doctor about risk of infection and needing antibiotics if you require a dental procedure after your heart valve replacement
- Long-term durability has not been established for the EVOQUE valve. Clinical data is reflective of short-term follow-up, and regular medical follow-up is advised

The safety and effectiveness of the transcatheter heart valve is not known for patients:

- Who are dependent on their pacemaker without other options
- Who had a pacemaker implanted within the last 3 months before the valve implantation procedure
- Who have severe pulmonary hypertension not managed by medication
- Who have severe right ventricular dysfunction

For More Information about the Edwards Transcatheter Tricuspid Valve Replacement Procedure:

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Irvine, California 92614

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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