

Now's the time
to turn the page.

Patient Information Kit

A proven, breakthrough therapy
for severe symptomatic tricuspid
regurgitation could help you
start a new chapter of life.



Edwards Lifesciences

Let's Rewrite the Story of Heart Valve Disease

Understanding a diagnosis of severe tricuspid regurgitation (TR) can help simplify navigating the condition.

Use this guide to learn how your heart works, what happens when your heart's valve doesn't close tightly, and how a breakthrough treatment, transcatheter tricuspid valve replacement (TTVR), could change your quality of life.

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“My disease affected my playing.
It was affecting my daily exercise, walking.
I needed to do something about it.”

Ed, Real TR Patient

A Closer Look at Your Heart

Your heart has four chambers¹

The **two upper chambers**, called the **atria**, receive blood from the body.

The **two lower chambers**, called the **ventricles**, pump blood out of the heart and into the body.

You have four valves that open and close to keep blood flowing in the correct direction¹

(A)

The **aortic valve** controls blood flow from the left ventricle to the aorta, sending blood to the rest of the body.

(B)

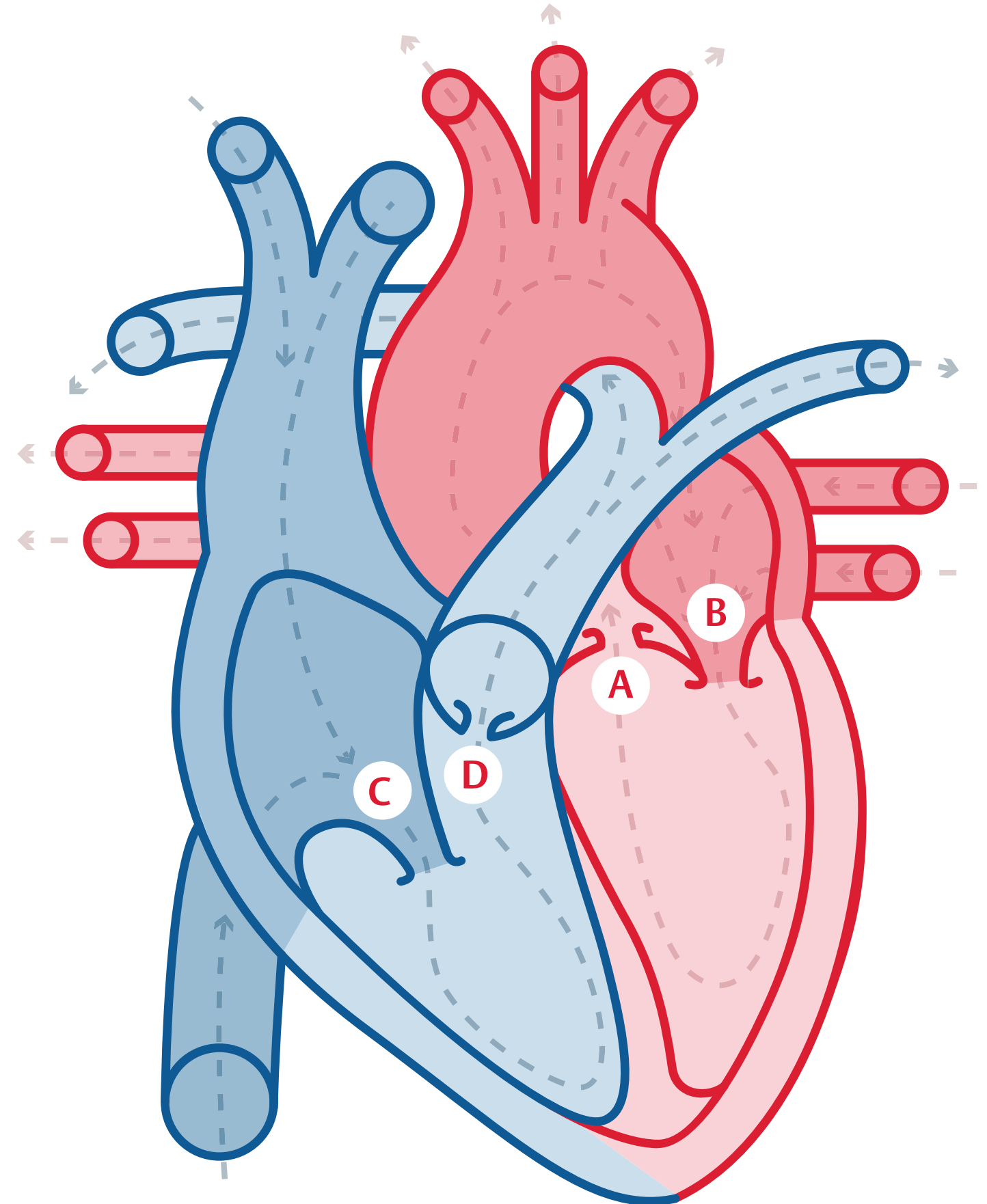
The **mitral valve** controls blood flow between the left atrium and the left ventricle.

(C)

The **tricuspid valve** directs flow from the right atrium to the right ventricle.

(D)

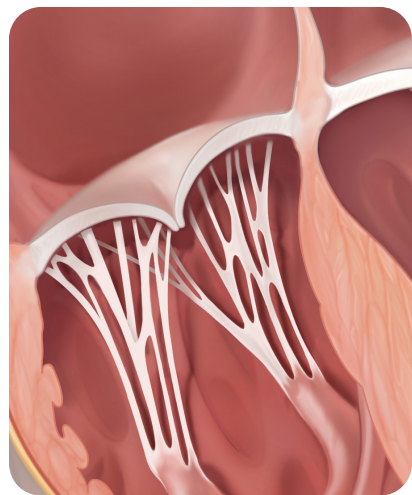
The **pulmonary valve** directs flow from the right ventricle to the lungs.



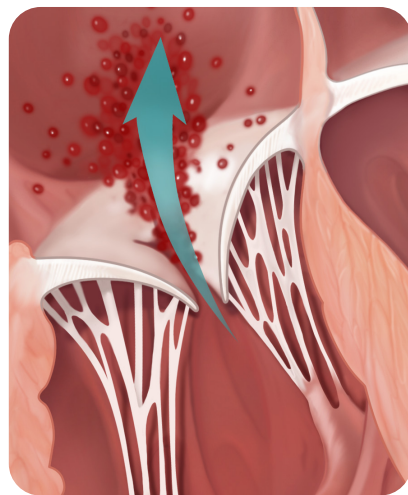
Understanding Heart Valve Disease

What is tricuspid regurgitation?

Tricuspid regurgitation is the backward flow of blood through the tricuspid valve from the right ventricle to the right atrium.^{2,3}



The leaflets in a healthy valve close to keep blood flowing in the right direction.^{2,3}



When the tricuspid valve is diseased, the leaflets don't close properly, causing blood to leak backward through the valve, reducing overall blood flow.^{2,3}

Causes of tricuspid regurgitation

Tricuspid regurgitation can develop when:

- The right lower chamber (ventricle) becomes bigger and pulls the muscles connected to the tricuspid 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 tricuspid valve leaflets or other valve anatomy are damaged.

TR can be missed

The signs of severe tricuspid regurgitation can be mistaken for the normal consequences of aging or other chronic conditions. This may delay treatment.^{4,5}

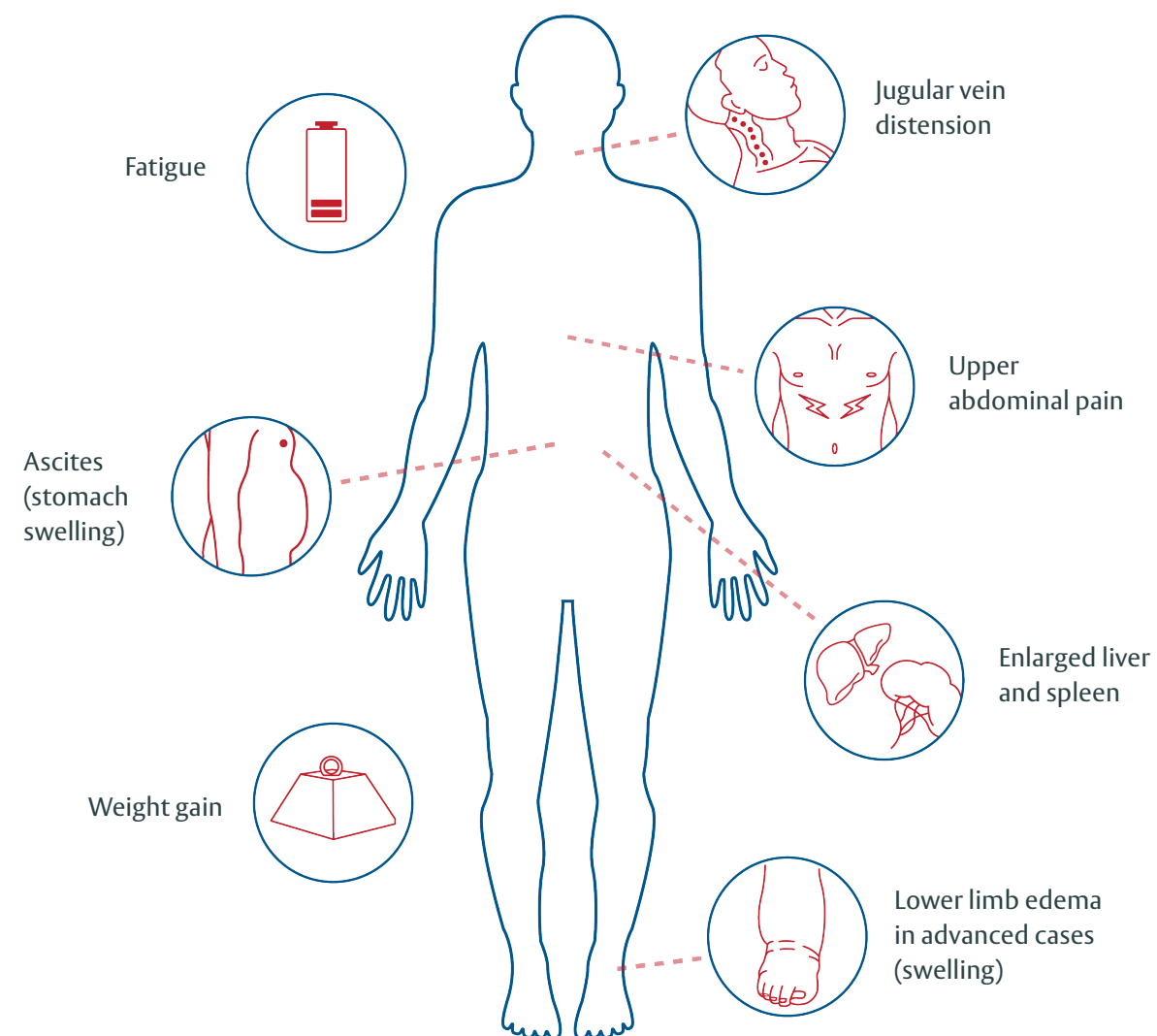
How common is TR?



1.5 million+ people in the United States are estimated to have moderate or greater TR.^{6,7,8}

Symptoms of Severe Tricuspid Regurgitation (TR)

When you have a tricuspid valve that doesn't close properly, you might experience shortness of breath or feel weak. The disease can also cause abnormal heartbeats or swelling in your abdomen, ankles, feet, or the veins in your neck.



How severe TR can impact your life

Severe tricuspid regurgitation symptoms often lead to a substantial decrease in your quality of life.^{9,10}

Activities like taking walks or just moving from room to room can become extremely challenging and limit your independence.

It is important to note that tricuspid regurgitation doesn't always show signs or symptoms until the disease is severe.^{11,12}

Medications, such as diuretics, may treat symptoms but not the tricuspid regurgitation itself, which can continue to progress.¹²






The good news is that there are treatment options that can improve your daily life and help you turn the page on severe symptomatic tricuspid regurgitation.



How Symptomatic Severe Tricuspid Regurgitation Is Treated

Treatments for symptomatic severe tricuspid regurgitation can range from oral medications to surgical intervention to minimally invasive procedures. Transcatheter tricuspid valve replacement (TTVR) offers a minimally invasive option that can provide near-immediate and lasting relief.

	 Medication	 Open Heart Surgery	 Transcatheter Procedures
Treats the Root Cause of TR	✗	✓	✓
Less Invasive	✓	✗	✓
Less Bleeding Risk	✓	✗	✗



Medication

- You may be prescribed medicine to help manage the symptoms of tricuspid regurgitation. However, medicine is unlikely to fix the underlying cause of severe symptomatic tricuspid regurgitation.¹⁵



Open Heart Surgery

- Open heart surgical valve repair or replacement* is where the doctor will open your chest and repair or replace the damaged valve.
- During the procedure, 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.
- The normal recovery period from standard heart valve surgery requires 4 to 8 weeks. Recovery may be somewhat shorter with minimally invasive surgery.



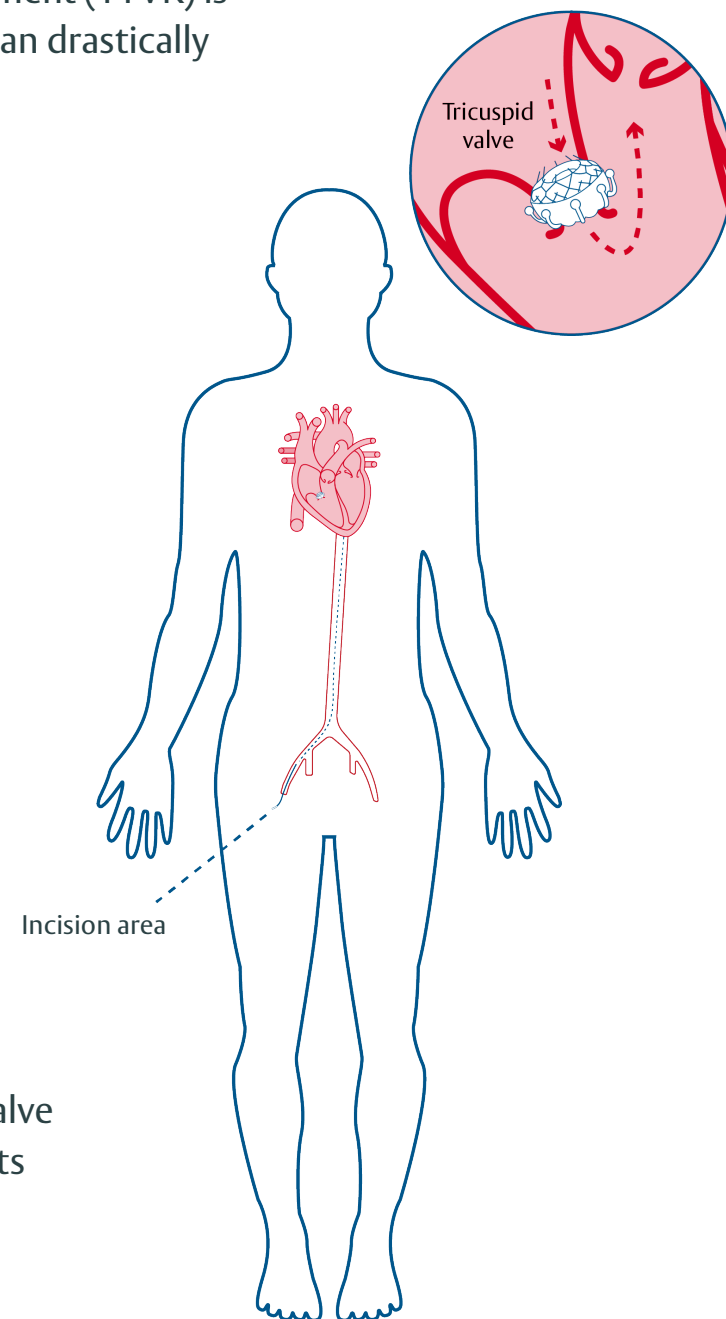
Transcatheter Procedures

- During a transcatheter tricuspid valve replacement (TTVR) or an edge-to-edge repair (TEER) procedure, the doctor replaces or repairs your tricuspid valve using a delivery catheter with an artificial device attached to its tip.

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

Discover the Latest Breakthrough Treatment

Transcatheter tricuspid valve replacement (TTVR) is a minimally invasive procedure that can drastically improve your quality of life.¹⁶



A transcatheter tricuspid valve replacement procedure lasts **less than two hours**.

A general overview of the transcatheter tricuspid valve replacement (TTVR) procedure^{13,14}

While you are under general anesthesia, your doctor will make a small incision in your groin to access your femoral vein. They will then insert a tube-like device called a delivery catheter. The crimped implant is positioned in the delivery catheter.

Benefits of TTVR^{5,16,17}

Compared to surgery, the transcatheter procedure:

- ✓ Is less invasive
- ✓ Causes less pain
- ✓ Is a short hospital stay
- ✓ Involves a shorter recovery time

By addressing the underlying problem rather than just the symptoms, you can improve your quality of life affected by severe tricuspid regurgitation.

There are risks to TTVR

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

The TTVR procedure's most serious risks are death, stroke, serious bleeding, problems with the electrical pathway of your heart that require a pacemaker, unplanned repeat procedure, hospitalization or surgery, major vascular complications, or permanent disability.

2X







Clinical trial data showed that patients who went through TTVR + medical therapy experienced **twice the clinical benefit** versus medical therapy alone.

Your Heart Team Evaluation

Once you have received a diagnosis of severe symptomatic tricuspid regurgitation, it's time to be evaluated by a Heart Team to determine if a transcatheter treatment is an option.





This team is made up of qualified healthcare professionals who specialize in the treatment of heart valve disease. They will work closely with you, your cardiologist, and your primary care physician.

A Heart Team may include:

- **Interventional cardiologist:**
A physician who specializes in heart procedures using small tubes called catheters that are inserted into blood vessels through the arm or leg and are guided to the heart.
- **Interventional echocardiographer:**
A physician who specializes in ultrasound imaging that sees the heart using soundwaves to help guide heart procedures.
- **Cardiac surgeon:** A physician who performs surgery on the heart and the major blood vessels around it.
- **Electrophysiologist:** A physician who specializes in the treatment of heart rhythm problems that control your heartbeat.
- **Cardiologist with training and experience in heart failure management.**
- **Multi-modality imaging specialist:**
A physician who specializes in the use of different types of imaging procedures to view the heart.



Tests you may need:

- **Transthoracic echocardiogram (TTE)**
An ultrasound imaging procedure using soundwaves that takes pictures of your heart through a probe that is placed on your chest.
- **Transesophageal echocardiogram (TEE)**
An ultrasound imaging procedure using soundwaves that takes pictures of your heart from the inside of your body through a small probe that is placed down your throat.
- **Cardiac catheterization**
A procedure that uses small tubes called catheters that are inserted into blood vessels through the arm or leg and are guided to the heart.
- **CT scan**
An imaging procedure that uses x-rays and computer technology to produce images of the inside of the body.

What Treatment Option Is Right for You?

Seeing a Heart Team in addition to your cardiologist will ensure all treatment options are thoroughly evaluated. They will discuss which option is most suitable for you, considering various factors related to your heart, including:

- ✓ 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

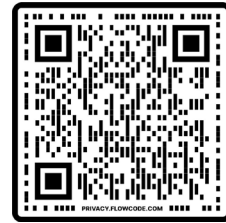


What should I ask my doctor?

1. What is causing my tricuspid valve to leak?
2. What are my treatment options?
3. How long should I take medications?
4. How often should I get an echocardiogram to see how my valve is functioning?
5. What lifestyle changes should I expect from the treatment?
6. When should I get my leaking valve fixed?
7. What could happen if I do not get my leaking valve fixed?
8. Am I a candidate for a catheter-based procedure?
9. Will I have pain after the catheter-based procedure?
10. Would it be helpful for me to see a heart team?
11. How long will my recovery take after getting my valve fixed?
12. What medications will I need to take after TTVR?
13. After my valve is fixed, will I need to be monitored or have follow-up echocardiograms?
14. What, if any, limitations will I have after my procedure?

Real Patient Stories

See patient stories at
heartandvalves.com/tr



If there's one thing that can help you navigate treatment options, it's connecting with those who have faced the same challenges. Hear from somebody who had the TTVR procedure.

Meet Ed



"So now, as we like to say in the music world, I'm back in the groove."

Ed, Real TR Patient

Ed's been a professional wind instrument musician for more than 60 years. But shortness of breath caused by tricuspid regurgitation was preventing him from doing what he loved. TTVR changed everything for Ed. It helped him turn the page and got him "back in the groove."

Meet Mary



"It's time for living. It's time for engaging. I feel like I have a purpose now."

Mary, Real TR Patient

Mary had a chronic lung condition that damaged her heart valve. Over time, her symptoms grew so severe she could hardly live her life. A transcatheter valve replacement was her only option.

Insurance and Resources

Taking control of your health can help you get the care you need. Free resources are available below for you and your loved ones to better understand tricuspid regurgitation and the TTVR procedure.



General Resources

For information on heart valve disease and TTVR, along with patient stories, go to heartandvalves.com/tr.



Caregiver Resources

For caregiver support, visit the family caregiver alliance at caregiver.org.



Financial Resources

If you need free professional assistance to help navigate insurance and reimbursement, visit structuralheart.pfcareline.org or call (800)-532-5274.



Patient Support Center

Figuring out the next steps in treating heart valve disease may feel overwhelming. Edwards' Patient Support Center helps patients find a Heart Team with access to TTVR. Please call 888-713-1564.



Insurance Coverage and TTVR

Your Valve Clinic Coordinator will help you with any questions you have about TTVR, including your insurance coverage and financial needs.

Contact your insurance provider before meeting with your Heart Team to find out if the evaluation and TTVR procedure are covered. A referral is sometimes needed.

Meet Linda



When Linda was diagnosed with severe symptomatic TR, her symptoms restricted her active lifestyle. Her doctors saw that medical therapy wasn't going to be effective and that a transcatheter valve replacement could improve her quality of life.

Risks of the Transcatheter Tricuspid Valve Replacement Procedure

Who can be treated:

The EVOQUE tricuspid valve replacement system (the EVOQUE system) is approved for treating patients with symptomatic severe tricuspid regurgitation (TR) for the improvement of health status. TR is a condition in which the tricuspid valve on the right side of the heart doesn't close properly. When the valve does not fully close, blood flows backward from the lower chamber (ventricle) into the upper chamber (atrium), making the patient's heart work harder to move blood through the valve. Patients should work with their doctor and a specialized Heart Team to determine if the patient is a suitable candidate for the EVOQUE valve.

Who should not use:

The EVOQUE system should not be used in patients 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.

Warnings:

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 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.

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.

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

- Who are dependent on their pacemaker without other pacing 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

Precautions:

Precautions prior to use

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

General precautions

- Problems with the electrical pathway of your heart that require a pacemaker may occur before, during, or following implantation of the EVOQUE valve.
- 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.

Potential risks

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

The most serious risks associated with the procedure are:

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

Additional potential risks include:

- Abnormal lab values
- Abnormal low or high blood pressure
- Additional cardiac surgery, vascular surgery, or intervention, including removal of the transcatheter heart valve
- Allergic reaction
- Anemia
- Blood leak around the valve
- Chest pain
- Collection of fluid or blood around your heart
- Damage to blood cells
- Damage to the swallowing passage (esophagus), with possible puncture or narrowing
- 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
- Failure to retrieve any EVOQUE system components
- Fluid buildup in your lungs

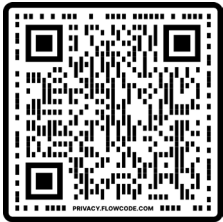
- Having an abnormal particle (air or blood clots) floating in the bloodstream or attached to an object, including the valve
- Heart attack or heart failure/decreased heart pumping
- Incorrect position of valve or valve movement
- Infection in your heart, blood, or other areas
- Interference/damage with an existing permanent pacemaker or defibrillator
- Irregular heart rate
- Kidney failure
- Nausea and/or vomiting
- Nerve injury, paralysis or neurological symptoms, including problems with movement or walking
- Organ failure, including heart failure
- Pain, inflammation, or fever
- Right ventricular outflow tract (RVOT) obstruction
- Severe bleeding or fluid in or around the heart or in the body that could require a transfusion or surgery
- Skin burn, injury or tissue changes due to exposure to X-rays
- Sudden or unexpected loss of heart function
- Swelling
- Trouble or inability to breathe
- Valve regurgitation (new or worsening tricuspid, aortic, mitral, or pulmonary)

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

Ready to Start Your Next Chapter?

Talk to your doctor about transcatheter tricuspid valve replacement (TTVR) to see if it could be right for you.

Learn about next steps at
heartandvalves.com/tr



For more information about the Edwards transcatheter tricuspid valve replacement procedure:

Toll-free phone in the USA:

888-713-1564

Email address:

patient_support@edwards.com

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