

Transcatheter Tricuspid Valve Replacement



A guide for patients with tricuspid regurgitation

This patient guide is for those who have severe tricuspid regurgitation (TR), but continue to have heart failure symptoms despite being on heart failure medications, and in whom no other surgical or transcatheter treatment option exists per their specialized care team's decision.

The information in this guide will help you understand more about the Edwards EVOQUE Tricuspid Valve Replacement System and a minimally invasive procedure called transcatheter tricuspid valve replacement (TTVR).

The EVOQUE system is designed to replace the native tricuspid valve without the need for conventional open-heart surgery and intended to reduce TR.¹



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What is Tricuspid Regurgitation?

Tricuspid regurgitation (TR) is when the leaflets of your tricuspid valve don't close properly.^{2,3}

This causes blood to leak back through the valve.^{2,3}

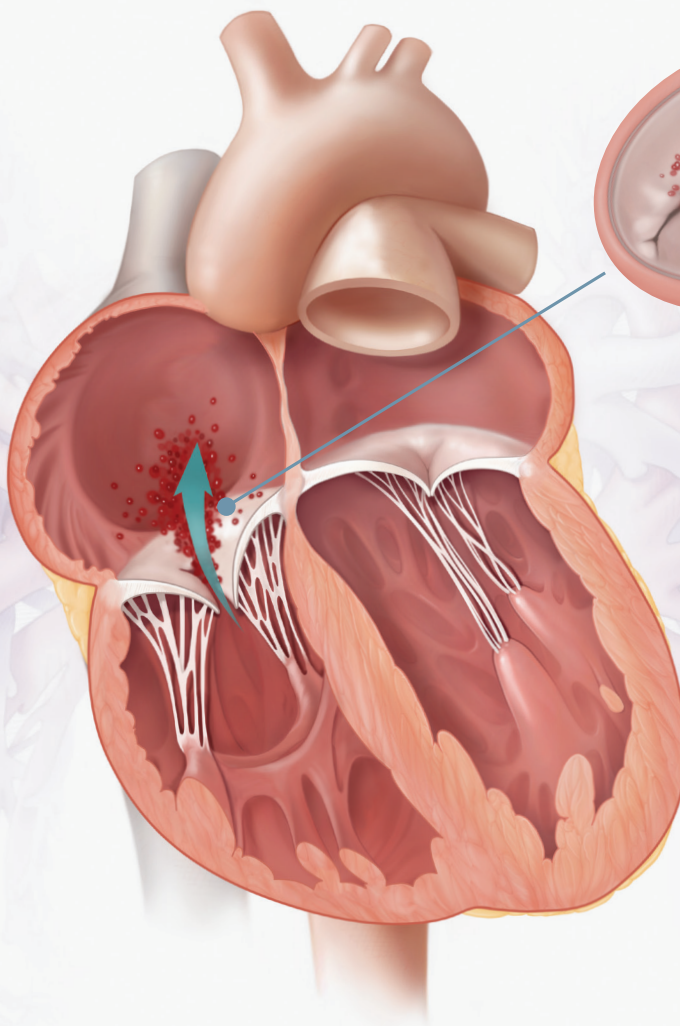
Because this leakage can reduce overall blood flow, the heart must work harder. TR can worsen over time, and you may not develop symptoms until your condition is severe.³

TR can cause symptoms such as fatigue, shortness of breath, abnormal heart rhythms and swelling of your legs, abdomen, or neck veins.³

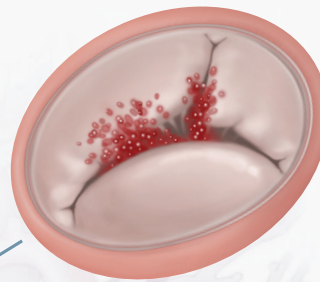
There are two different types of TR:

"Primary" or "degenerative": A disease that is commonly caused by an abnormality of the valve structure.

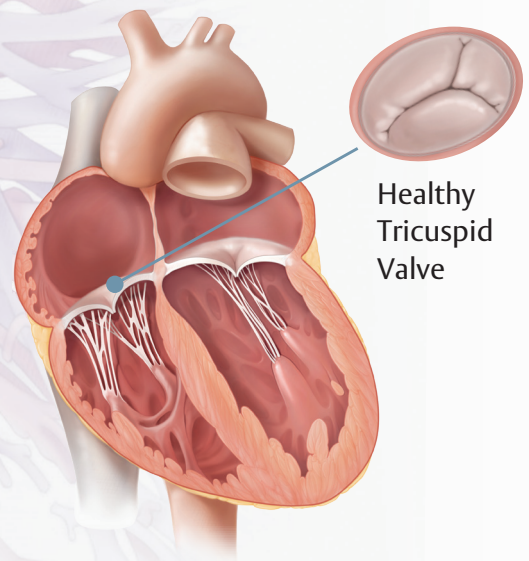
"Secondary" or "functional": The result of right ventricle or right atrium abnormalities/disease.⁴



A Heart with Tricuspid Regurgitation



Tricuspid Valve with Regurgitation



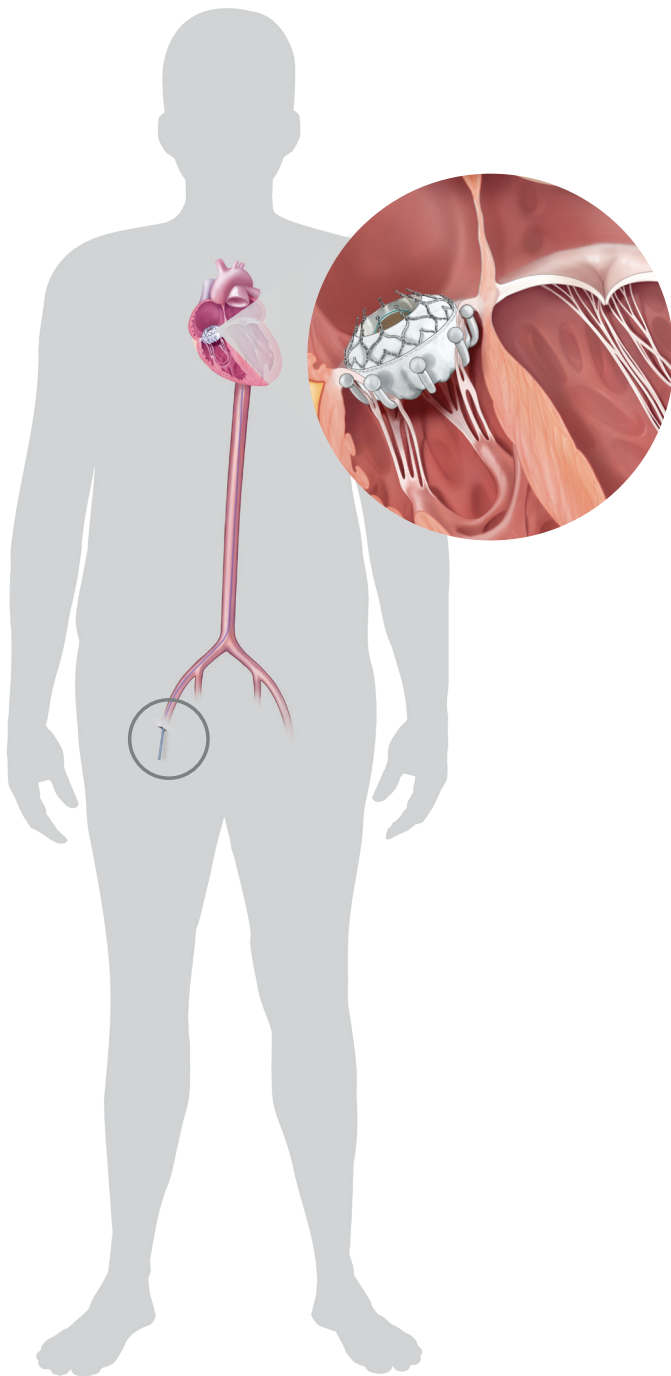
Healthy Tricuspid Valve

A Healthy Heart

The tricuspid valve opens and then closes properly, preventing blood from leaking back.²

What is Transcatheter Tricuspid Valve Replacement?

Transcatheter tricuspid valve replacement (TTVR) is a catheter-based procedure to replace your tricuspid valve. Unlike traditional heart surgery, in which the surgeon cuts through the chest wall and then the heart to access the valve, TTVR involves implanting a device through a small incision in your groin.



The Procedure

The following is a general overview of the procedure:

1. 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
2. The implant will be guided to your tricuspid valve using imaging equipment
3. The implant will be positioned to fully engage your tricuspid leaflets to reduce the blood leak
4. After verifying the final position of the implant, your doctor will release it from the delivery system. The implant will stay in your heart¹



On average, a transcatheter tricuspid valve replacement procedure with the EVOQUE system lasts about 2 hours⁵

What is the EVOQUE valve?

The EVOQUE valve is a bioprosthetic heart valve that is positioned within your original tricuspid valve. The implant frame is made of self-expanding nitinol (nickel and titanium alloy) and the implant leaflets are made from the bovine pericardial tissue leaflets.

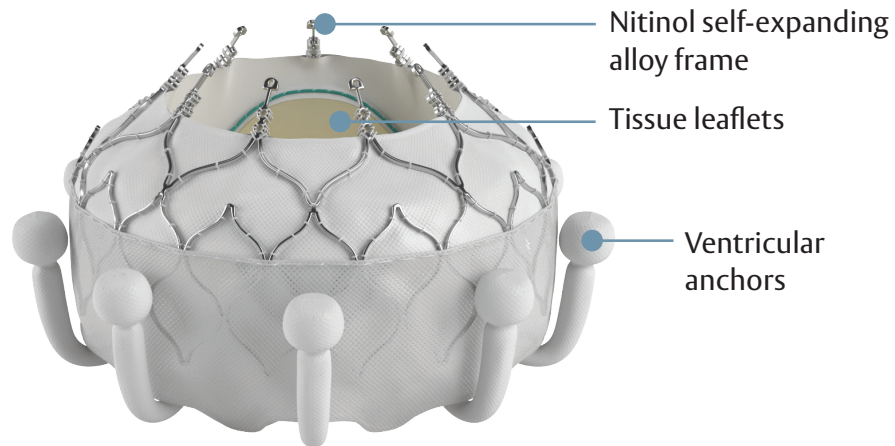


Image is larger than actual valve size.

Quality of Life Improvement:

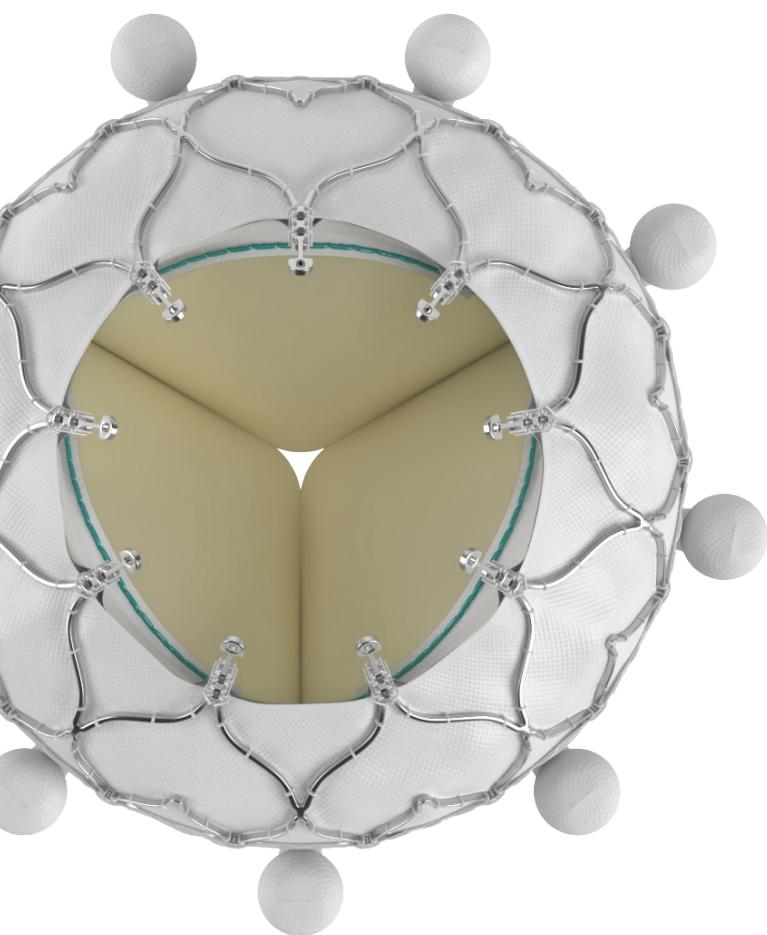
In the analysis of the first 150 patients, the TRISCEND II pivotal trial met the endpoint consisting of clinically meaningful functional and quality of life outcomes at 6 months for patients treated with the EVOQUE valve and optimal medical therapy.¹



Frequently Asked Questions

- **How long will the procedure take?** Although procedure times may vary due to your anatomy and the severity of your condition, on average the procedure takes 2 hours.⁵
- **How long will I stay in the hospital after the procedure?** After your procedure, you may spend a few days in the hospital.⁵ Before you leave the hospital, your doctor will discuss your aftercare plan to help with your recovery.
- **What can I expect after the procedure?** Regular check-ups with your doctor are very important. You may be asked to return to your doctor for a follow-up appointment and to have your heart valve checked after your procedure.
- **When can I resume my regular activities?** It is important to carefully follow your doctor's directions, especially if you need to take any medications. Ask your doctor if and when you can resume other medications, travel, exercise, and other medical procedures like dental work.
- **Is it safe for me to have an MRI scan?** The EVOQUE valve is MRI-conditional, which means they can be safely scanned under certain conditions. Please tell your physician that you have a tricuspid implant if you are considering an MRI.¹
- **How long will my implant last?** The implant should not need to be replaced. Your cardiologist will regularly check the status of your implant.

Be sure to ask your specialized care team to explain all your treatment options and the possible risks and benefits of each.



For More Information about Edwards Transcatheter Tricuspid Valve Replacement Procedure:

Online:

www.edwards.com/gb/patients-care-partners/patient-support-center

Mail:

Edwards Lifesciences Sàrl
Route de l'Etraz 70,
1260 Nyon, Switzerland



References

1. Edwards EVOQUE Transcatheter Tricuspid Valve Replacement System: Instructions for Use (DOC-0177129F)
2. "Heart Valves and Circulation, Roles of Your Four Heart Valves" www.heart.org, 1 Sept. 2021 [cited 2024 June 13]. Available from: <https://www.heart.org/en/health-topics/heart-valve-problems-and-disease/about-heart-valves/heart-valves-and-circulation>.
3. Tricuspid Valve Regurgitation [Internet]. University of Pennsylvania; 2023 [cited 2024 June 13]. Available from: <https://www.pennmedicine.org/for-patients-and-visitors/patient-information/conditions-treated-a-to-z/tricuspid-regurgitation>
4. Mulla S, et al. Tricuspid Regurgitation. [Updated 2022 Jun 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-2024 [cited 2024 June 13]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK526121/>
5. Kodali S. (26 October 2023). TRISCEND II Trial: A randomized trial of transcatheter tricuspid valve replacement in patients with severe tricuspid regurgitation. TCT 2023 Conference, San Francisco, CA, United States.

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