Edwards Lifesciences

Transcatheter Tricuspid Valve Repair

A guide for patients with tricuspid regurgitation

This patient brochure is for those who have severe tricuspid regurgitation (TR) and are considered at prohibitive risk for tricuspid valve surgery by their specialized care team. The information in this brochure will help you understand more about tricuspid regurgitation and a minimally invasive procedure called transcatheter tricuspid valve repair.

The Edwards PASCAL transcatheter valve repair system is designed to repair the tricuspid valve and reduce tricuspid regurgitation.[1,2]

Ask your specialized care team to explain this treatment option and the possible risks and benefits.

Learn more at www.TreatMyValve.com/gb

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What is Tricuspid Regurgitation (TR)?

As your heart pumps blood throughout your body, four valves open and close to help blood flow at the right time and in the right direction. The heart's four valves are called aortic, mitral, pulmonary, and tricuspid.

Tricuspid regurgitation is a condition in which the tricuspid valve doesn't close properly, causing blood to leak back through the valve.[3,4]

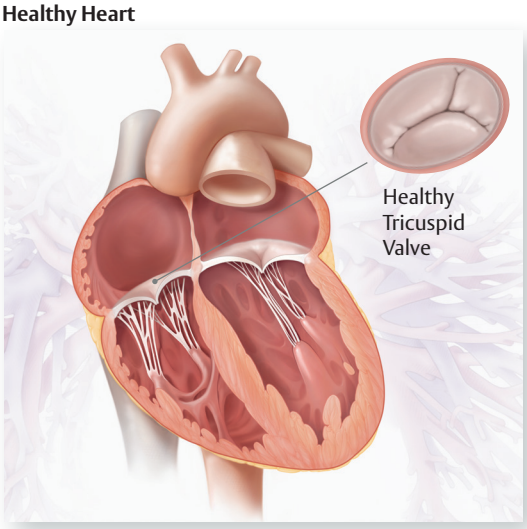
Because this leakage can reduce overall blood flow, the heart must work harder. TR can worsen over time and you may not develop symptoms until your condition is severe.[4]

With TR, you may experience symptoms that cause an overall decrease in your quality of life:

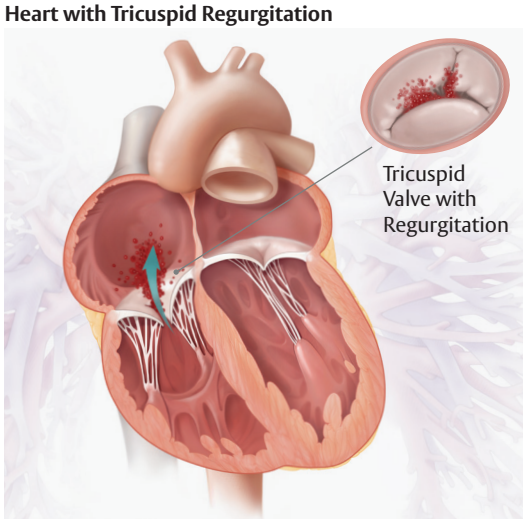
- Shortness of breath
- Fatigue
- Abnormal heart rhythms
- Swelling in your abdomen, legs, or neck veins[4]

There are two types of tricuspid regurgitation: primary (also called degenerative) and secondary (functional). Primary TR is a disease that is commonly caused by an abnormality of the valve structure. Secondary TR is the result of right ventricle or right atrium abnormalities/disease.[5]

Healthy Heart



Heart with Tricuspid Regurgitation



What is Transcatheter Tricuspid Valve Repair?

Transcatheter tricuspid valve repair (TTVr) is a catheter-based procedure to repair 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

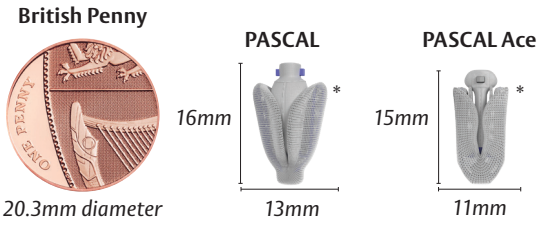
The following is a general overview of the procedure:

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 implant is attached to the tip of the delivery catheter
2. The implant will be guided to your tricuspid valve using imaging equipment
3. The implant will be positioned to clasp together 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 heart[2]

The Edwards PASCAL Transcatheter Valve Repair System for TR

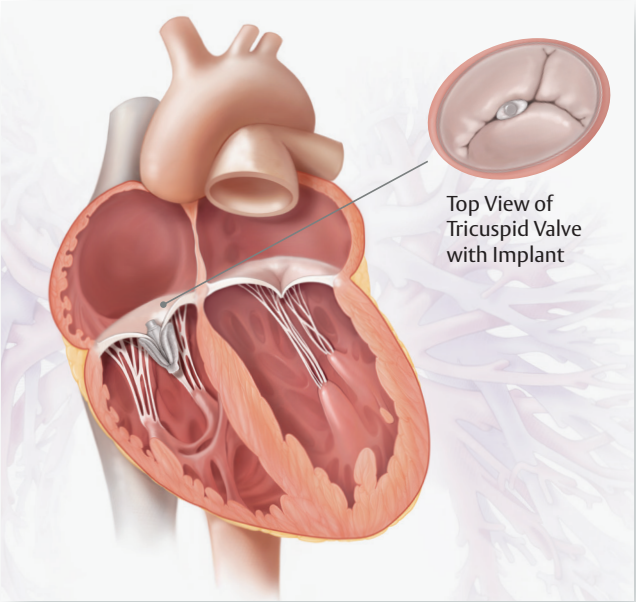
The Implants

The PASCAL and PASCAL Ace implants are made of nitinol (nickel and titanium) and have paddles that clasp the leaflets of the tricuspid valve together. Your physician will determine the best implant option for your valve.



*Actual implant size comparison shown

The implant will be placed in between your tricuspid valve leaflets. It is designed to prevent blood from leaking back through the valve.[2]



Safety & Efficacy

88%

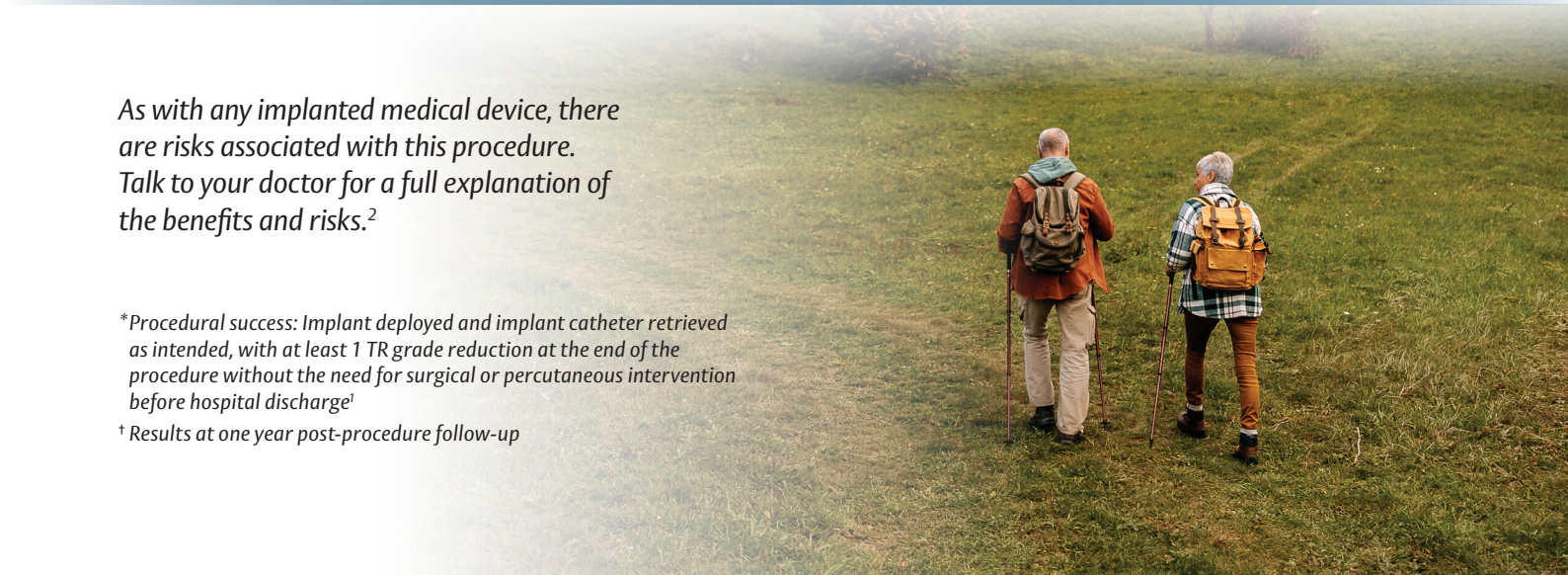
Procedural success was achieved in 88% of patients[1]*

86%

of patients achieved moderate to no TR[1†]

Patients experienced improvement of symptoms and exercise capacity[1†]

As with any implanted medical device, there are risks associated with this procedure. Talk to your doctor for a full explanation of the benefits and risks.[2]



*Procedural success: Implant deployed and implant catheter retrieved as intended, with at least 1 TR grade reduction at the end of the procedure without the need for surgical or percutaneous intervention before hospital discharge[1]

† Results at one year post-procedure follow-up

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.[1]
- **How long will I stay in the hospital after the procedure?** After your procedure, you may spend a few days in the hospital.[1] 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?** Tricuspid implants are MRI-conditional, which means they can be safely scanned under certain conditions.[2] Please tell your physician that you have a tricuspid implant if you are considering an MRI.
- **How long will my implant last?** The implant should not need to be replaced. Your cardiologist will regularly check the status of your implant.

Learn more at www.TreatMyValve.com/gb

References

1. Kodali S, et al. 1-Year outcomes of transcatheter tricuspid valve repair. J Am Coll Cardiol. 2023 May 9; 81(18): 1766-1776.
2. Edwards PASCAL Transcatheter Valve Repair System: Instructions for Use
3. "Heart Valves and Circulation, Roles of Your Four Heart Valves" www.heart.org, 1 Sept. 2021, https://www.heart.org/en/health-topics/heart-valve-problems-and-disease/about-heart-valves/heart-valves-and-circulation.
4. "Tricuspid Valve Regurgitation- What Is Tricuspid Regurgitation?" Pennmedicine.org, PennMedicine, https://www.pennmedicine.org/for-patients-and-visitors/patient-information/conditions-treated-a-to-z/tricuspid-regurgitation#:~:text=Tricuspid%20regurgitation%2C%20or%20tricuspid%20valve,move%20blood%20through%20the%20valve.
5. Mulla S, Asuka E, Siddiqui WJ. Tricuspid Regurgitation. [Updated 2022 Jun 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK526121/

Medical device for professional use. For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (consult eifu.edwards.com where applicable).

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