

Driving tricuspid repair and replacement solutions forward

The only company with a commercially approved portfolio of transcatheter repair and replacement technologies for the tricuspid valve

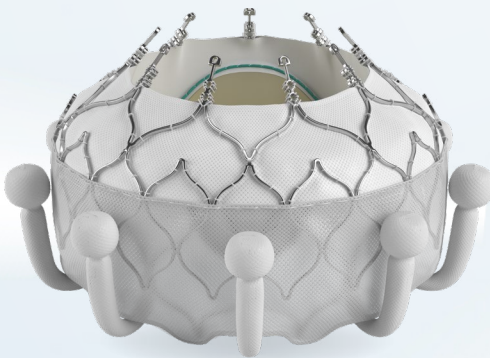
Transcatheter repair The PASCAL implant

The first and only FDA-approved TEER system with elongation capabilities and leaflet capture up to and beyond 180°



Transcatheter replacement The EVOQUE valve

The first and only FDA-approved transcatheter tricuspid valve replacement (TTVR) system



Single communication containing both repair and replacement case plans.



The Edwards tricuspid portfolio enables individualized treatment decisions beyond a single therapeutic path.

Severe TR is prevalent, often undertreated, and may be life-threatening¹⁰⁻¹²



Scan to learn more about the PASCAL Precision system for T-TEER.

PASCAL Precision System - Important Safety Information

Edwards PASCAL Precision Transcatheter Valve Repair System

Indications: The PASCAL Precision transcatheter valve repair system (the PASCAL Precision system) is indicated for the percutaneous reduction of significant, symptomatic mitral regurgitation (MR $\geq 3+$) due to primary abnormality of the mitral apparatus (degenerative MR) in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the MR. The PASCAL Precision system is also indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy who are deemed at intermediate or greater risk for surgery and deemed appropriate for transcatheter edge-to-edge tricuspid valve repair by a multidisciplinary heart team.

Contraindications: The PASCAL Precision system is contraindicated in patients with the following conditions:

- Applicable to mitral patients:**
 - Patients who cannot tolerate procedural anticoagulation or post procedural antiplatelet regimen
 - Untreatable hypersensitivity or contraindication to nitinol alloys (nickel and titanium) or contrast media
 - Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus
 - Active endocarditis of the mitral valve
 - Rheumatic etiology for mitral regurgitation
- Applicable to tricuspid patients:**
 - Patients who cannot tolerate procedural anticoagulation or post procedural antiplatelet regimen
 - Untreatable hypersensitivity or contraindication to nitinol alloys (nickel and titanium) or contrast media
 - Active endocarditis or other active infections of the tricuspid valve

Warnings: The devices are designed, intended, and distributed for single use only. There are no data to support the sterility, non-pyrogenicity, and functionality of the devices after reprocessing. Devices should be handled using standard sterile technique to prevent infection. Do not expose any of the devices to any solutions, chemicals, etc., except for the sterile physiological and/or heparinized saline solution. Irreparable damage to the device, which may not be apparent under visual inspection, may result. Do not use any of the devices in the presence of combustible or flammable gases, anesthetics, or cleaners/disinfectants. Do not use the devices if the expiration date has elapsed. Do not use if the packaging seal is broken or if the packaging is damaged for sterile devices. Do not use if any of the devices were dropped, damaged or mishandled in any way. Standard flushing and de-airing technique should be used during preparation and throughout procedure to prevent air embolism.

As with any implanted medical device, there is a potential for an adverse immunological response. Serious adverse events, sometimes leading to surgical intervention and/or death, may be associated with the use of this system ("Potential Adverse Events"). A full explanation of the benefits and risks should be given to each prospective patient before use. Careful and continuous medical follow-up is advised so that implant-related complications can be diagnosed and properly managed. Anticoagulation therapy must be determined by the physician per institutional guidelines.

Precautions: Prior to use, patient selection should be performed by a heart team to assess patient risk and anatomical suitability. After use, short-term anticoagulation therapy may be necessary after valve repair with the PASCAL Precision system. Prescribe anticoagulation and other medical therapy per institutional guidelines

Potential Adverse Events: Below is a list of the potential adverse effects (e.g., complications) associated with the use of the PASCAL Precision system: death; abnormal lab values; allergic reaction to anesthetic, contrast, heparin, Nitinol; anemia or decreased hemoglobin (may require transfusion); aneurysm or pseudoaneurysm; angina or chest pain; anaphylactic shock; arrhythmias – atrial (i.e. atrial fibrillation, Supraventricular tachycardia); arrhythmias – ventricular (i.e. ventricular tachycardia, ventricular fibrillation); arterio-venous fistula; atrial septal injury requiring intervention; bleeding; cardiac arrest; cardiac failure; cardiac injury, including perforation; cardiac tamponade/pericardial effusion; cardiogenic shock; chordal entanglement or rupture that may require intervention; coagulopathy, coagulation disorder, bleeding diathesis; conduction system injury which may require permanent pacemaker; deep vein thrombosis (DVT); deterioration of native valve (e.g., leaflet tearing, retraction, thickening); dislodgement of previously deployed implant; dyspnea; edema; electrolyte imbalance; embolism/embolization including air, particulate, calcific material, or thrombus; endocarditis; esophageal irritation; esophageal perforation or stricture; exercise intolerance or weakness; failure to retrieve any PASCAL Precision system components; fever; gastrointestinal bleeding or infarct; heart failure; hematoma; hemodynamic compromise; hemolysis; hemorrhage requiring transfusion or intervention; hypertension; hypotension; implant deterioration (wear, tear, fracture, or other); implant embolization; implant malposition or failure to deliver to intended site; implant migration; implant thrombosis; infection; inflammation; LVOT obstruction; mesenteric ischemia; multi-system organ failure; myocardial infarction; native valve injury; native valve stenosis; nausea and/or vomiting; need for open surgery (conversion, emergent or nonemergent reoperation, explant), nerve injury neurological symptoms, including dyskinesia, without diagnosis of TIA or stroke; non-neurological thromboembolic events; pain; papillary muscle damage; paralysis; PASCAL Precision system component(s) embolization; peripheral ischemia; permanent disability; pleural effusion; pulmonary edema; pulmonary embolism; reaction to anti-platelet or anticoagulation agents; renal failure; renal insufficiency; respiratory compromise, respiratory failure, atelectasis, pneumonia – may require prolonged ventilation; retroperitoneal bleed; septal damage or perforation; septicemia, sepsis; skin burn, injury or tissue changes due to exposure to ionizing radiation; single leaflet device attachment (SLDA); stroke; syncope; transient ischemic attack (TIA); urinary tract infection and/or bleeding; valvular regurgitation; vascular injury or trauma, including dissection or occlusion; vessel spasm; ventricular wall damage or perforation; worsening native valve regurgitation / valvular insufficiency; worsening of heart failure; wound dehiscence, delayed or incomplete healing.

CAUTION: US law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

References:

1. Pozzoli A, et al. *Front Cardiovasc Med.* 2018;5:80. Published 2018 Jun 29. 2. Muraru D. *J Am Soc Echocardiogr.* 2024;37(4):405-407. 3. Gupta K. *JACC Cardiovasc Interv.* 2026;19(9):1183-1185. 4. Hahn RT, et al. *JACC Cardiovasc Imaging.* 2021;14(7):1299-1305. 5. ClinicalTrials.gov. Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial (CLASP II TR). Updated March 13, 2024. Accessed July 7, 2026. <https://clinicaltrials.gov/study/NCT04097145>. Identifier: NCT04097145. 6. Hausleiter J, et al. *N Engl J Med.* 2026;395(14):1363-1373. 7. Geisler T. PCR London Valves 2025, 16–18 November 2025, London, UK. 8. Wild MG, et al. *J Am Coll Cardiol.* 2024 Oct 24;S0735-1097(24)09955-8. 9. Kodali SK, et al. *J Am Coll Cardiol.* 2023;81(18):1766-1776. 10. Fender EA, et al. *Heart.* 2018;104(10):798-806. 11. Topolsky Y, et al. *JACC Cardiovasc Imaging.* 2014;7(12):1185-1194. 12. Ren QW, et al. *ESC Heart Fail.* 2020;7(6):4051-4060.

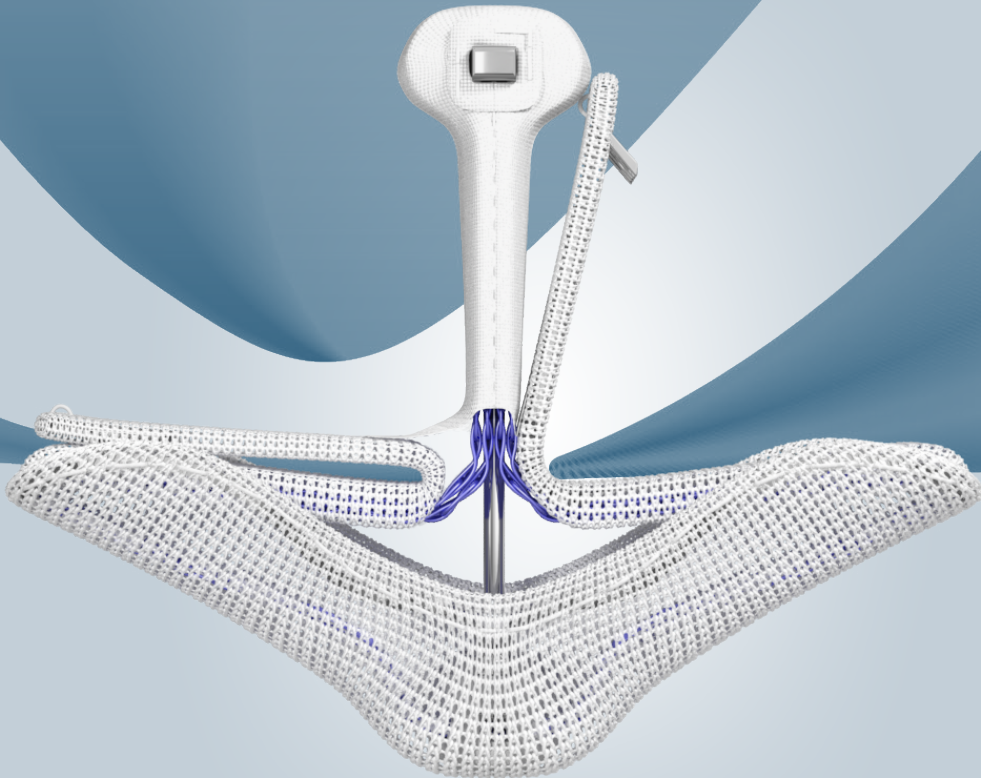
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Edwards



DRIVE T-TEER FOR WARD

PASCAL Precision System for Tricuspid Regurgitation (TR)

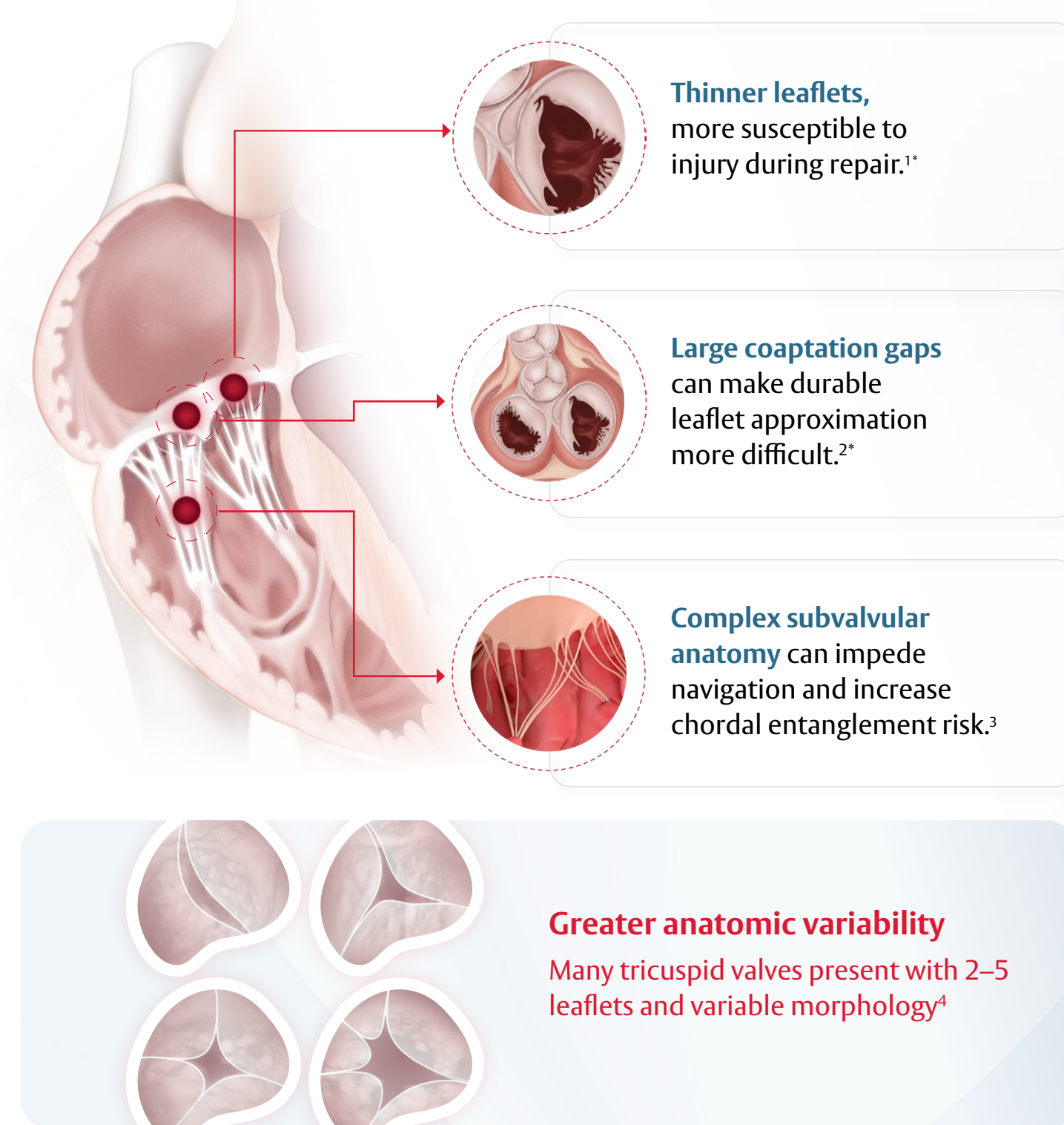
The PASCAL Precision System is indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy who are deemed at intermediate or greater risk for surgery and deemed appropriate for transcatheter edge-to-edge tricuspid valve repair by a multidisciplinary heart team.



Edwards

The tricuspid valve demands its own playbook

The PASCAL Precision system is designed to manage these complexities



Built to perform in the tricuspid position

Atraumatic

Optimize TR reduction **while preserving leaflet integrity**

Capture the leaflet **where retention is strongest**

Designed to **conform to native anatomy** throughout the cardiac cycle



Versatile

Elongate to **navigate dense chordae**

Cover large gaps with a 26 mm capture-ready width at 180°

Secure leaflet capture during **independent grasping**



Accurate

Unkeyed system with 3 independent catheters

Designed to optimize positioning when height and trajectory are critical



Backed by an already robust and growing body of evidence⁵⁻⁹

CLASP II TR Trial



Data forthcoming

Pivotal, randomized controlled trial of the PASCAL system for T-TEER

TRIC-I-HF Trial



Randomized controlled trial at 29 centers in Germany (N=360)

TRIC-I-HF reported a hard endpoint benefit for transcatheter tricuspid repair plus medical therapy versus medical therapy alone in severe TR patients^{†‡}

TriCLASP Study



Broad EU post-market validation (N=204)

Significant, sustained TR reduction out to 2 years in a high-risk population

PASTE Registry

The PASTE Registry

Real-world European registry evidence (N=1059)

Large, real-world dataset demonstrating favorable safety profile with durable clinical outcomes through 1 year

CLASP TR Study



Foundational 1 year data (N=65)

First prospective evidence establishing favorable safety and sustained TR reduction

CVPath Study



Research from a leading cardiovascular institute

An independent cadaver study supporting atraumatic leaflet optimization through re-grasping

[†]In patients with symptomatic, severe tricuspid regurgitation who were at increased risk for future heart-failure events.
[‡]Nearly two-thirds of patients undergoing transcatheter repair were treated with the PASCAL system.