T-TEER with the PASCAL System

1-Year Results from the CLASP II TR Trial



Edwards

THE CLASP II TR TRIAL

The PASCAL system + OMT delivered significant, sustained TR reduction with low procedural risk and significant QoL improvements at 30 days and 1 year.

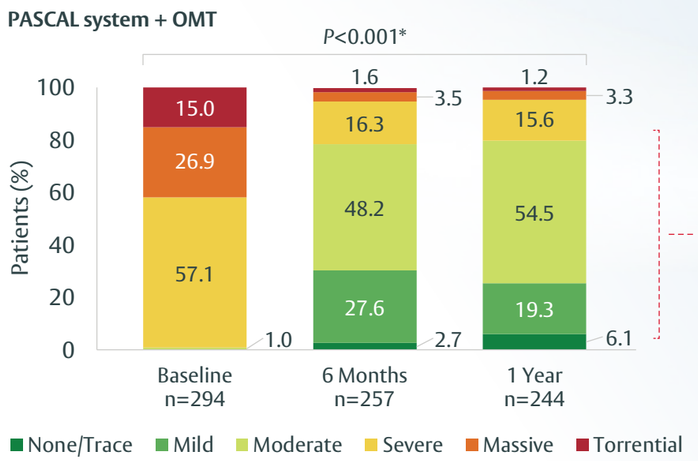
Proven safety for the PASCAL system

0.3%
cardiovascular mortality
at 30 days

0.3%
incidence of stroke
at 30 days

3.4%
SLDA
at 30 days

Patients receiving a PASCAL device showed significant sustained improvement in TR severity



80% **of patients achieved TR ≤ moderate** at 1 year†

*Wilcoxon Signed Rank Test, paired analysis.
†at 1-year vs. 30.4% with OMT alone, *P*<0.001.

Significant improvement in QoL

+18 point **KCCQ-OS score improvement** at 1 year‡

57% **achieved moderate to large improvement in health status** at 6 months

Study design

Multicenter, randomized 2:1 trial conducted at 58 centers across the United States and Canada

Follow-up at discharge, 30 days, 3 months, 6 months, 1 year, and annually to 5 years

Randomized cohort: the PASCAL system + OMT (n=302) vs. OMT alone (n=148). Analysis population: the PASCAL system + OMT (n=294) vs. OMT alone (n=148)

Baseline characteristics

% (n) or mean ± SD	PASCAL system + OMT n=294	OMT alone n=148
Age, years	79.1 ± 7.3	80.2 ± 6.7
Female	48.0%	49.3%
STS PROM (MV Repair)	7.6 ± 6.0	7.3 ± 5.4
Prior valve intervention	33.7%	35.8%
Atrial fibrillation	91.8%	91.2%
RV lead CIED or ICD	13.3%	14.9%
HFH within the last year	29.6%	23.0%

Conclusions

The PASCAL system + OMT was superior to OMT alone for the primary endpoint at 6 months, with improvements in patient-reported health status sustained at 1 year

- Low incidence of stroke, cardiovascular mortality, and SLDA
- Achieves high rates of moderate-or-less TR
- Clinically meaningful improvements in KCCQ-OS score

‡17.7 points with the PASCAL system + OMT vs. 6.5 with OMT alone, P<0.001.

Abbreviations: KCCQ-OS, Kansas City Cardiomyopathy Questionnaire Overall Summary; OMT, optimal medical therapy; QoL, quality of life; SLDA, single leaflet device attachment; TR, tricuspid regurgitation; T-TEER, tricuspid transcatheter edge-to-edge repair

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 ≥ 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:

1. **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
2. **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; emboli/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.

Reference:
Davidson CJ, Arnold SV. Transcatheter Tricuspid Valve Repair in Symptomatic Severe Tricuspid Regurgitation: The Randomized CLASP II TR Trial. Presented at TCT 2026; November 2nd; San Diego, CA, 2026.

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