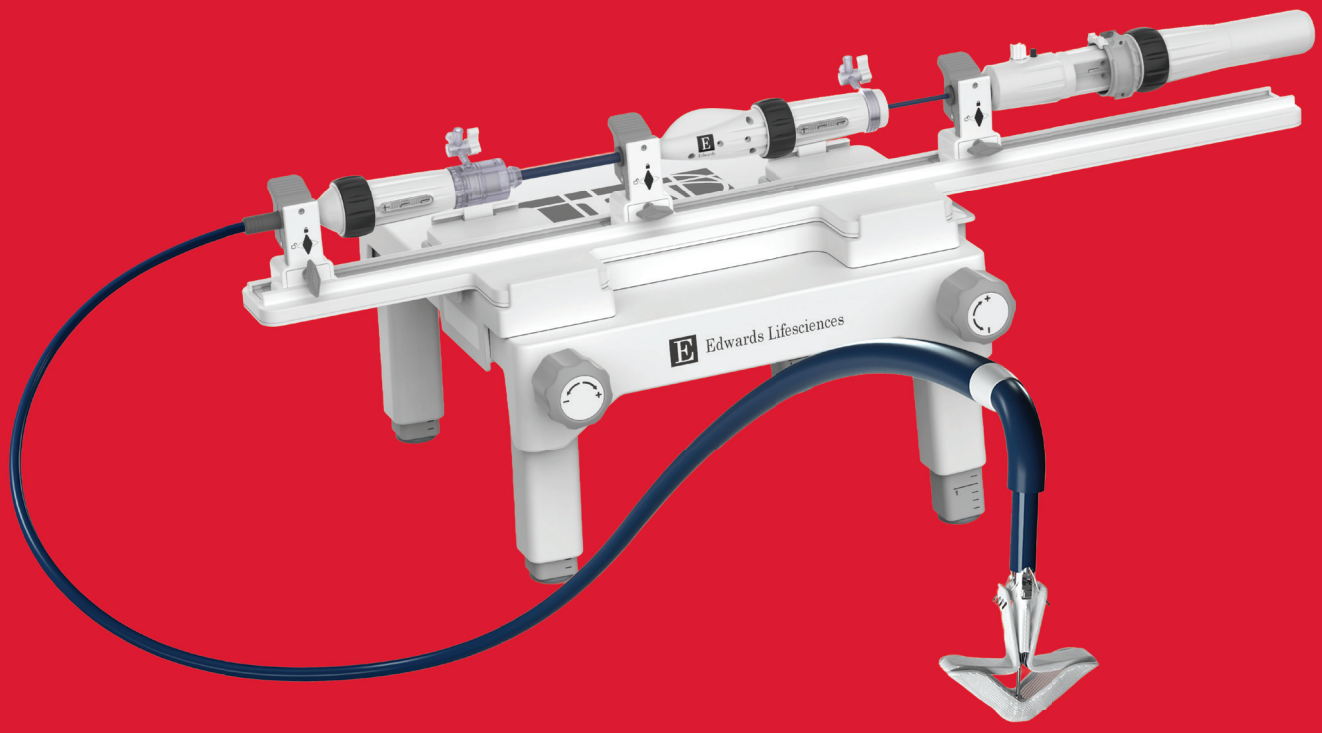
One-year US commercial experience with the PASCAL Precision system



Outcomes from the STS/ACC TVT Registry

In a highly complex population, patients treated with the PASCAL Precision system demonstrated:

High survival | **Low heart failure hospitalizations** | **Significant improvement in quality of life**

Edwards

Methods

1 year | **4,686** patients | **264** sites

Data entered into the STS/ACC TVT Registry between September 2022 and June 2025*

*Time period reflective of initial commercial approval and early use of the PASCAL Precision system.

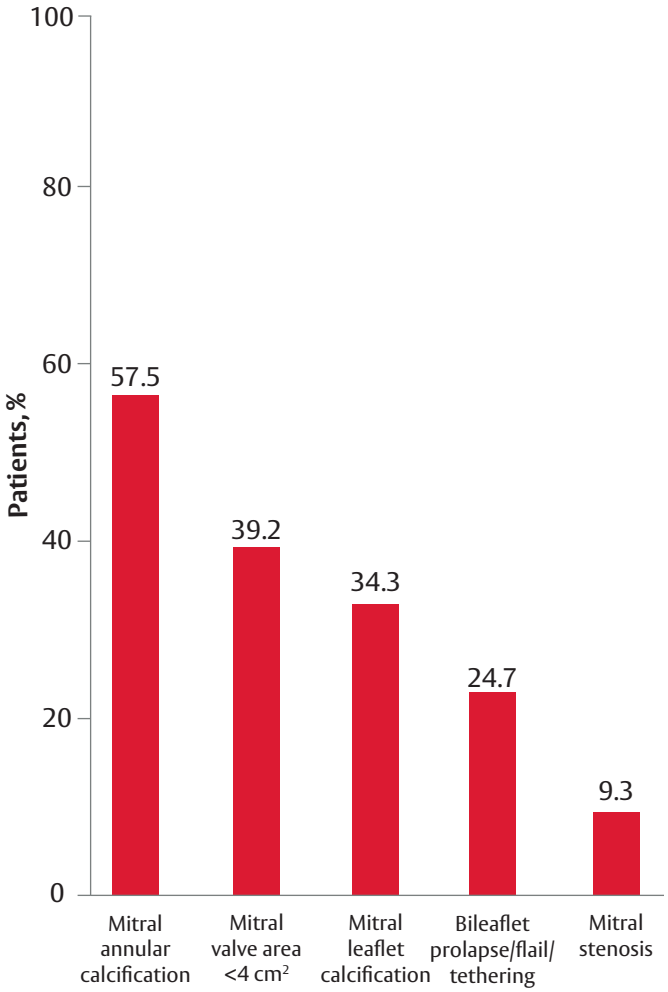
Patient demographics: Elderly with comorbidities

Median age
81 years old

NYHA class III/IV
69.3%

Heart failure
82.9%

2 out of 3
patients exhibited complex anatomy†



†Patients may have more than one complexity, resulting in a cumulative percentage exceeding 100%.

Results

The PASCAL Precision system demonstrated high survival and low event rates at 1 year

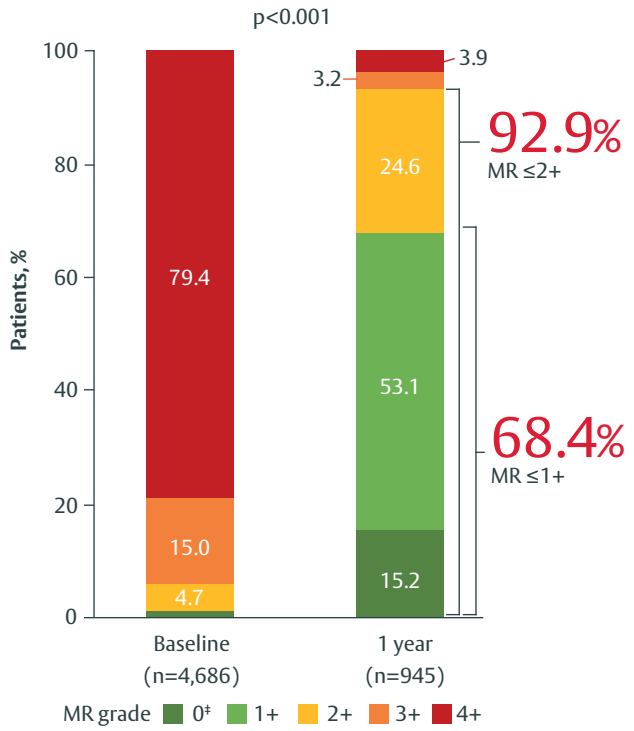
91.7%
Freedom from all-cause mortality

92.9%
Freedom from heart failure hospitalization

96.7%
Freedom from cardiovascular mortality

98.5%
Freedom from mitral valve reintervention

Significant MR reduction at 1 year



‡Grades none and trace/trivial were combined to follow a 5-grade scheme.

The PASCAL Precision system demonstrated a favorable safety profile, including **0.5% SLDA rate**

84.1%
NYHA class I/II

+24.6 points
KCCQ-OS

Conclusions

For patients with DMR, even those with complex anatomies, the **PASCAL Precision system delivers:**

High survival, low event rates, and a favorable safety profile

Clinically meaningful functional and quality-of-life improvements

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.

Contraindications: The PASCAL Precision system is contraindicated in patients with the following conditions: patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen; untreatable hypersensitivity or contraindication to nitinol alloys (nickel and titanium) or contrast media; active endocarditis of the mitral valve; rheumatic etiology for mitral regurgitation; evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus.

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.

Abbreviations
ACC, American College of Cardiology; DMR, degenerative mitral regurgitation; KCCQ-OS, Kansas City Cardiomyopathy Questionnaire overall summary score; LVOT, left ventricular outflow tract; MR, mitral regurgitation; NYHA, New York Heart Association; SLDA, single leaflet device attachment; STS, Society of Thoracic Surgeons; TVT, transcatheter valve therapy.

Reference
Latib A *et al*. One-year outcomes with the PASCAL Precision system in commercial experience from the STS/ACC TVT Registry. New York Valves, June 24–26, 2026, New York, NY, USA.

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