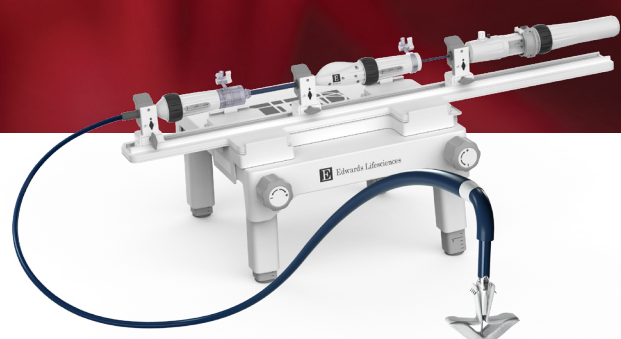
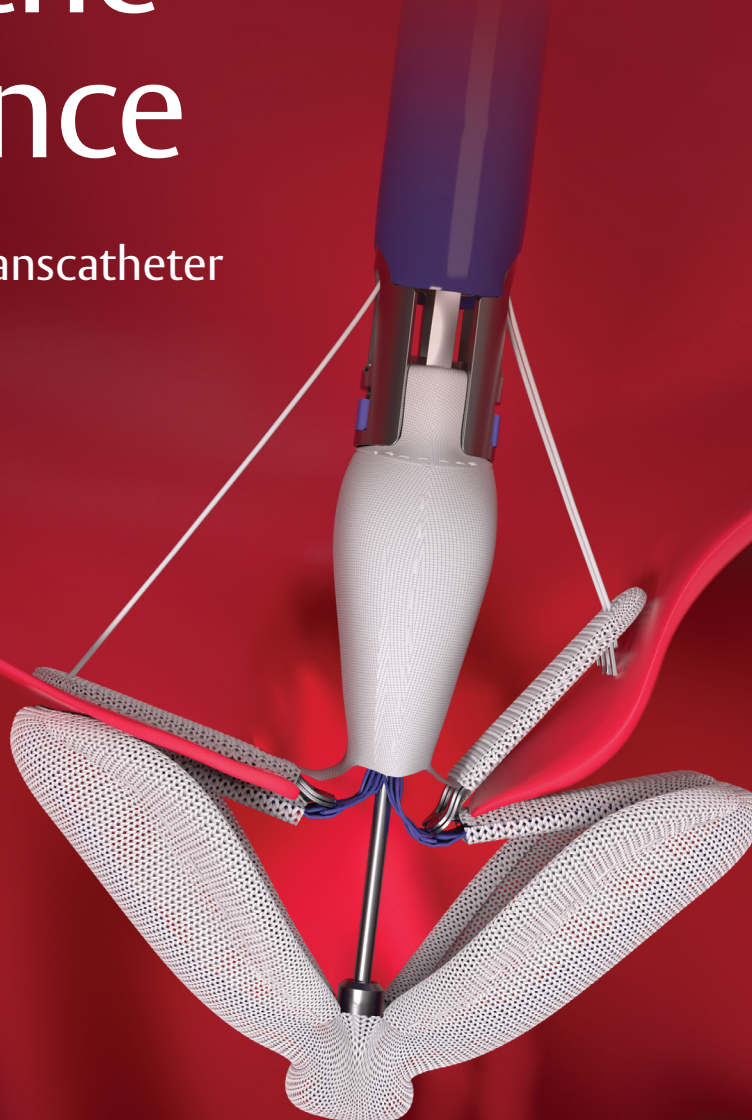


Grasp the difference

PASCAL Precision transcatheter valve repair system



The latest transcatheter mitral innovation from Edwards Lifesciences

For your patients with degenerative mitral regurgitation (DMR)



Edwards

Edwards Lifesciences

continues to build robust clinical evidence

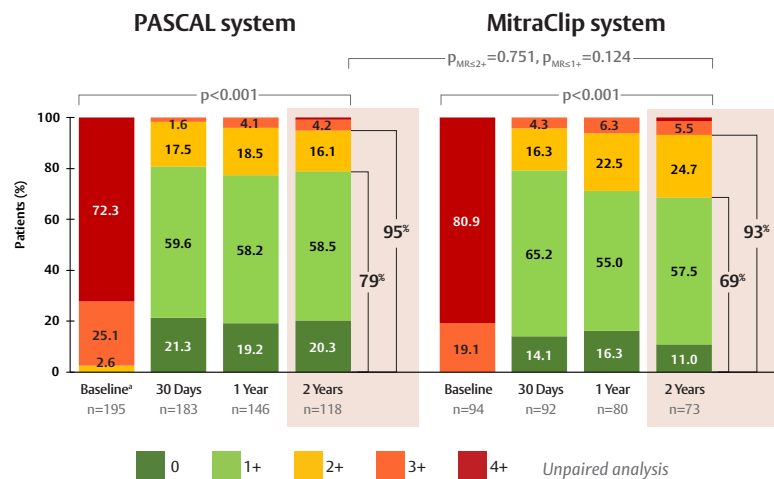


The first randomized, head-to-head trial to compare contemporary TEER technologies

Two-year results from the CLASP IID trial confirm the sustained safety and effectiveness of the PASCAL system for DMR patients at prohibitive risk of surgery.¹

Mitral regurgitation (MR) severity reduction

79%
of patients sustained MR 0/1+ at 2 years with the PASCAL system¹



88% of patients achieved NYHA Class I/II at 2 years with the PASCAL system.

The PASCAL system demonstrated a low 30-day MAE rate of 4.6% (9/195)¹

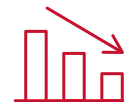
- Composite MAE rate includes cardiovascular mortality, stroke, myocardial infarction, new need for renal replacement therapy, severe bleeding, and non-elective mitral valve re-intervention (either percutaneous or surgical)



The PASCAL system demonstrated:



Durable and sustained MR reduction at 3 years along with significant improvement in functional status and evidence of LV reverse remodeling^{*2}



High survival and reduction in heart failure hospitalization rate at 3 years^{*2}

*CLASP study included 124 pts (69% FMR n=85, 31% DMR n=39). At 3 yrs, DMR patients showed 92% survival (Kaplan Meyer estimate); 91% freedom from heart failure hospitalization; 67% MR ≤ 1+; and 94% MR ≤ 2+.

The PASCAL Precision system

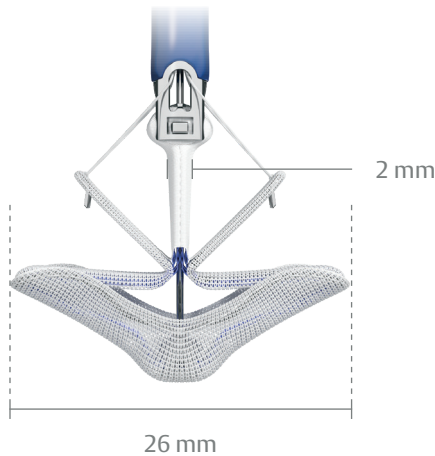
Featuring PASCAL Ace and PASCAL implants

Two different implant designs, same functionality

PASCAL Ace



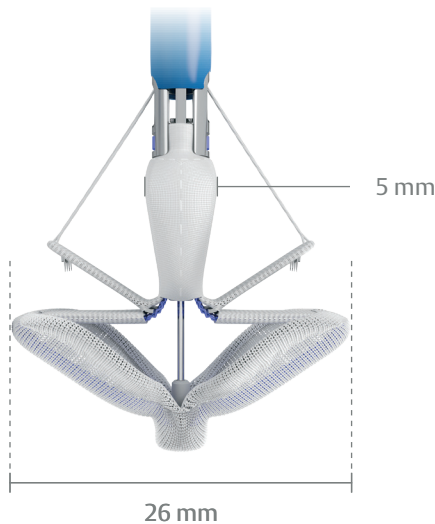
6 mm



PASCAL



10 mm



Versatile implant configuration to navigate even challenging anatomies

Adapt to specific procedural and anatomical needs

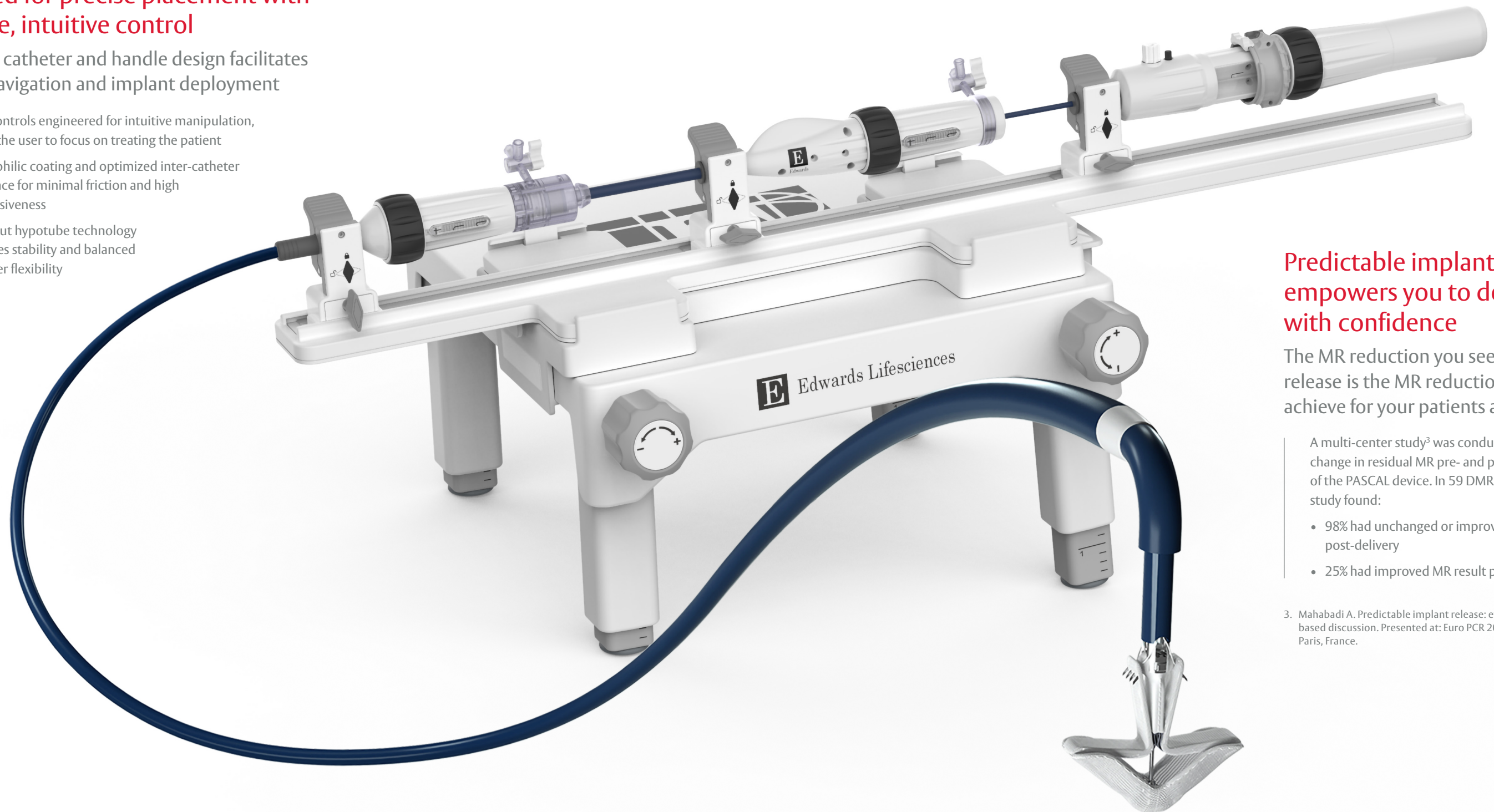
A wide range of paddle mobility and full elongation capabilities helps you maneuver, reconfigure and retrieve the implant prior to release.

Designed for precise placement with accurate, intuitive control

Advanced catheter and handle design facilitates smooth navigation and implant deployment

Handle controls engineered for intuitive manipulation, allowing the user to focus on treating the patient

- Hydrophilic coating and optimized inter-catheter clearance for minimal friction and high responsiveness
- Laser-cut hypotube technology provides stability and balanced catheter flexibility



Predictable implant release empowers you to deploy with confidence

The MR reduction you see before release is the MR reduction you can achieve for your patients after release

A multi-center study³ was conducted to assess change in residual MR pre- and post-delivery of the PASCAL device. In 59 DMR patients, the study found:

- 98% had unchanged or improved MR result post-delivery
- 25% had improved MR result post-delivery

3. Mahabadi A. Predictable implant release: evidence, and case-based discussion. Presented at: Euro PCR 2024; 2024 May 14-17; Paris, France.

Atraumatic clasp and closure helps you preserve leaflet integrity

Enhance leaflet capture with atraumatic reclasp capabilities

Each clasp features a single row of retention elements to clasp, reclasp and preserve leaflets

- Close the implant to conform to native anatomy and flex during the cardiac cycle
- Central spacer and contoured paddles respect native anatomy to reduce leaflet stress



Edwards Lifesciences, delivering structural heart innovation for over 65 years

Learn more at [Edwards.com/PASCAL](https://www.edwards.com/PASCAL)

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.

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: Federal (United States) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

References

1. Zahr F, et al. CLASP IID randomized trial and registry: two-year outcomes of transcatheter edge-to-edge repair for degenerative mitral regurgitation. Presented at: TCT Annual Congress; 2024 Oct 30; Washington, DC.
2. Spargias K, Lim DS, Makkar R, et al. Three-year outcomes for transcatheter repair in patients with mitral regurgitation from the CLASP study. *Catheter Cardiovasc Interv.* 2023;102:145-154.
3. Mahabadi A. Predictable implant release: evidence, and case-based discussion. Presented at: Euro PCR 2024; 2024 May 14-17; Paris, France.

Edwards, Edwards Lifesciences, the stylized E logo, CLASP, PASCAL, PASCAL Ace, and PASCAL Precision are trademarks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

© 2025 Edwards Lifesciences Corporation. All rights reserved. PP--US-7583 v 6.0

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • [edwards.com](https://www.edwards.com)



Edwards