Edwards

Edwards PASCAL Transcatheter Valve Repair System

Instructions for Use

The Edwards PASCAL transcatheter valve repair system (herein referred to as the PASCAL system) includes the following:

Device	Model
Implant System (PASCAL)	10000IS
Implant System (PASCAL Ace)	10000ISM
Guide Sheath	10000GS
Stabilizer	10000ST
Stabilizer Rail System	20000ST
Table	10000T

- **Implant System**

  The Implant System consists of the Steerable Catheter (outermost layer), the Implant Catheter (innermost layer), and the Implant (hereinafter refers to implants from Model 10000IS and Model 10000ISM). The Implant System percutaneously delivers the Implant to the valve via a femoral vein access using a transvenous approach.
- **Implant (Figures 1-3)**

  The Implant is deployed and secured to the leaflets of the valve, acting as a filler in the regurgitant orifice. The primary components of the Implant are the Spacer, Paddles, and Clasps constructed from Nitinol and covered in polyethylene terephthalate. The 10000IS Implant comprises a titanium nut and bolt, PEEK bushing, and a silicone seal. The 10000ISM Implant is a smaller size implant and also comprises a titanium nut, bolt, distal and proximal plate, and a silicone seal.

  The Implant has four main paddle positions: Elongated, Closed, Leaflet-Capture-Ready, and Leaflet-Captured.
- **Steerable Catheter (Figure 4)**

  The Steerable Catheter has a rotational control knob (Flex Knob) that actuates the flexion mechanism to navigate and position the Implant to the target location. A radiopaque marker band located on the distal portion of the catheter indicates the end of the flex section.
- **Implant Catheter (Figure 4)**

  The Implant is provided attached to the Implant Catheter by sutures and a threaded shaft. The Implant Catheter controls the deployment of the Implant. The three primary controls are the Sliders, the threaded Actuation Knob, and the Release Knob. The Sliders control the Implant Clasps (retracting the Sliders raises the Clasps and advancing the Sliders lowers the Clasps). The threaded Actuation Knob controls the Implant Paddles (retracting the Actuation Knob closes the Paddles and advancing the Actuation Knob opens the Paddles). The Release Knob controls the release of the Implant from the Implant Catheter. The Implant Catheter is provided assembled within the Steerable Catheter.
- **Guide Sheath (Figure 5)**

  The Guide Sheath set includes a steerable Guide Sheath and Introducer. The Guide Sheath provides atrial access. It has a hydrophilic coating and a rotational control knob (Flex Knob) which actuates the flexion mechanism to position the Guide Sheath at the target location. The Introducer is compatible with a 0.035 inch (0.89 mm) guidewire.
- **Stabilizer (Figures 6 and 7)**

  The Stabilizer is indicated to aid with positioning and stabilization of the PASCAL system during implantation procedures. The Stabilizer can be attached to the system as needed any time during the procedure. The use of the Stabilizer is optional.
- **Table (Figure 8)**

  The Table is used outside of the sterile field to provide a stable platform for the Implant System, Guide Sheath, and Stabilizer. The Table is height-adjustable. The use of the Table is optional.
- **Loader (Figure 9)**

  The Peel Away Loader is used to introduce the Implant and delivery catheters through the Guide Sheath seals. The Loader is included in the Implant System and/or Guide Sheath packaging for user convenience.

1.0 Indications

The Edwards PASCAL transcatheter valve repair system is indicated for the percutaneous reconstruction of an insufficient mitral valve through tissue approximation.

2.0 Contraindications

The PASCAL system is contraindicated in patients with:

- Patient in whom a TEE is contraindicated or screening TEE is unsuccessful
- Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
- Presence of an occluded or thrombosed IVC filter that would interfere with the delivery catheter, or ipsilateral deep vein thrombosis is present
- Known hypersensitivity to nitinol (nickel or titanium) or contraindication to procedural medications which cannot be adequately managed medically
- History of bleeding diathesis or coagulopathy or patient who refuses blood transfusions

Additionally, the PASCAL System is contraindicated in mitral patients with contraindication to transseptal catheterization.

3.0 Warnings

3.1 Anatomic Considerations

For optimal results, the following anatomic patient characteristics should be considered. The safety and effectiveness of the PASCAL system outside of these conditions has not been established. Use outside these conditions may interfere with placement of the Implant or native valve leaflet insertion.

- Evidence of moderate to severe calcification in the grasping area
- Evidence of severe calcification in the annulus or subvalvular apparatus
- Presence of significant cleft or perforation in the grasping area
- Flail width > 15 mm and/or flail gap > 10 mm
- Leaflet mobility length < 8 mm
- Transseptal puncture height < 3.5 cm
- LA diameter ≤ 35 mm
- Presence of two or more significant jets

- Presence of one significant jet in the commissural area
- Mitral valve area (MVA) < 4.0 cm^2
- LVEDD > 8.0 cm

3.2 Device Handling

- 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.

3.3 Clinical Warnings

- 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.

4.0 Precautions

4.1 Precautions Prior to Use

- Patient selection should be performed by a multi-disciplinary heart team specializing in the treatment of mitral regurgitation to assess patient risk and anatomical suitability.

4.2 Precautions After Use

- Long-term durability has not been established for the implant. Regular medical follow-up is advised to evaluate implant performance.
- Short-term anticoagulation therapy may be necessary after valve repair with the PASCAL device. Prescribe anticoagulation and other medical therapy per institutional guidelines.

5.0 Potential Adverse Events

Complications associated with standard cardiac catheterization, the use of anesthesia and use of the PASCAL system could lead to the following outcomes: conversion to open surgery, emergent or non-emergent reoperation, explant, permanent disability, or death. Physicians are encouraged to report suspected device related events to Edwards or the assigned hospital authorities.

The following anticipated adverse events have been identified as possible complications of the PASCAL procedure:

- Abnormal lab values
- Allergic reaction to anesthetic, contrast, heparin, Nitinol
- Anemia or decreased Hgb, may require transfusion
- Aneurysm or pseudoaneurysm
- Angina or chest pain
- Anaphylactic shock
- Arrhythmias – atrial (i.e. AF, SVT)
- Arrhythmias – ventricular (i.e. VT, VF)
- 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 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
- Nausea and/or vomiting
- Nerve injury
- Neurological symptoms, including dyskinesia, without diagnosis of TIA or stroke
- Non-neurological thromboembolic events
- Pain
- Papillary muscle damage
- Paralysis
- PASCAL system component(s) embolization
- Peripheral ischemia
- 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
- Valve injury
- Valve stenosis
- Valvular regurgitation

- Vascular injury or trauma, including dissection or occlusion
- Vessel spasm
- Ventricular wall damage or perforation
- Wound dehiscence, delayed or incomplete healing
- Worsening of heart failure
- Worsening regurgitation / valvular insufficiency

6.0 How Supplied

6.1 Packaging

The Guide Sheath, Implant System, and Stabilizer are individually packaged and ethylene oxide sterilized. The Table is packaged and provided non-sterile.

6.2 Storage

The PASCAL system should be stored in a cool, dry place.

7.0 Directions for Use

7.1 Physician Training

The implanting physician shall be experienced in transcatheter techniques and trained on the PASCAL system and implant procedure. The final decision for PASCAL device implantation should be made by physicians specializing in treatment of mitral regurgitation in specialized centers who can determine a reasonable chance of significant clinical improvement should be expected based on stage of disease and comorbidity.

7.2 Equipment and Materials

- Standard cardiac catheterization lab equipment
- Fluoroscopy system
- Transesophageal echocardiography (TEE) capabilities (2D and 3D)
- Pigtail catheter for contrast injection (with compatible sheath)
- Venous puncture kit
- Transseptal needle, sheath, and guidewire
- Exchange length 0.035 inch (0.89 mm) guidewire
- Basins
- 50-60 cc syringes with Luer fitting
- Heparinized saline
- Hemostat
- Surgical towels (e.g. size 43 x 69 cm)
- Optional: Step-up dilators
- Optional: Continuous physiological saline drip (Rolling IV pole, IV tubing with thumbwheel occluders, 1-liter bags of heparinized sterile saline solution)
- Optional: Pressure monitoring device

7.3 Device Preparation

7.3.1 Table

Step	Procedure
1	Remove the Table(s) from packaging and inspect for damage.
2	Assemble the Table(s) as seen in Figure 8.

7.3.2 Stabilizer

Step	Procedure
1	Remove Stabilizer components from packaging and inspect for damage.
2	Assemble the Stabilizer as necessary as seen in Figure 6.

7.3.3 Guide Sheath

Step	Procedure
1	Remove the Guide Sheath, Loader, and Introducer from packaging and inspect for gross damage.
2	While keeping distal tip raised, flush and de-air Guide Sheath with heparinized saline.
3	While keeping the distal tip raised, insert Introducer into Guide Sheath. Flush the Introducer and wipe Guide Sheath with heparinized saline prior to use.

7.3.4 Implant System

Step	Procedure
1	Remove Implant System and Loader from packaging and inspect for gross damage. Verify both Slider Stopcocks are in open position. **WARNING: If Slider Stopcocks are not in open position, use of the device may result in infection.**
2	Advance the Actuation Knob (rotate the Actuation Knob counterclockwise or press the Actuation Button to push forward the Actuation Knob) until it is flush against the Clasp Positioning Tool.
3	Remove the Slider Pin and remove suture slack. Lock Slider Stopcocks and secure Slider Pin. Remove Clasp Positioning Tool.
4	Fully retract and advance Sliders to confirm proper Clasp motion and close the Implant (rotate the Actuation Knob clockwise or press the Actuation Button to retract the Actuation Knob).
5	Advance the Steerable Catheter. Ensure Sliders are fully retracted and Actuation Knob fully retracted. Orient Implant Catheter Handle vertically so the Release Knob is against the table.
6	Flush heparinized saline through the Implant Catheter.
7	Once Saline is seen exiting from the distal end of the Implant Catheter, lower the Implant Catheter Handle and raise the distal end of the Implant Catheter while continuing to flush with heparinized saline.
8	Fully retract Steerable Catheter. Advance the Sliders and the Actuation Knob to set Implant in Elongated position.
9	Remove Loader cap and guide the Loader cap onto the Implant System.
10	Insert the Implant through the proximal end of the Loader until it exits the distal end. Connect the Loader and Loader cap.
11	While keeping Loader and distal tip raised, flush heparinized saline through the Steerable Catheter.
12	Gradually retract Implant Catheter into Steerable Catheter and Implant into the Loader while continuing to flush through Steerable Catheter until the distal end of the Implant is fully in the Loader.

7.4 Implant Procedure

Delivery of the implant should be performed under general anesthesia with hemodynamic monitoring in an operating room, hybrid operating room or cath lab with fluoroscopic and echocardiographic imaging capabilities.

Note: Prior to implant procedure, refer to Anatomic Considerations (Section 3.1) as use outside of stated conditions may interfere with placement of the Implant or native valve leaflet insertion.

CAUTION: During the procedure, heparin should be administered so that the ACT is maintained at ≥ 250 sec.

CAUTION: Excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored.

7.4.1 Patient Preparation

Step	Procedure
1	Prior to sterile draping the patient, assemble and position the Table(s) between the legs of the patient, adjusting height of the Table(s) as needed. Use towels as support between Table(s) and patient's legs. **WARNING: The Table is provided non-sterile; introduction of the Table into the sterile field may result in infection.**
2	After sterile draping, assemble and attach Stabilizer as needed any time during procedure.

7.4.2 Femoral Vein Access and Sheath Introduction

Step	Procedure
1	Access the common femoral vein using conventional percutaneous puncture methods.
2	Access the left atrium via transvenous, transseptal techniques using conventional percutaneous methods and place guidewire in left atrium. Dilate the vessel, as needed. **CAUTION: Inappropriate puncture may result in cardiac structure damage requiring surgical repair or other intervention.**
3	Insert Guide Sheath with Introducer over guidewire until Guide Sheath tip is securely across the septum, using flex mechanism as needed. **CAUTION: Excessive manipulation may result in dislodgement or disturbance of a previously implanted device, cardiac structure damage requiring surgical repair or other intervention.**
4	Remove the Introducer and guidewire. Do not aspirate and flush the Guide Sheath until the Implant System is inserted. **CAUTION: Aspiration or connection of a continuous physiological saline flush to the Guide Sheath prior to Implant System insertion may result in air embolism.**

7.4.3 Implant Delivery

Step	Procedure
1	Insert the Implant System with the Loader into the Guide Sheath.
2	Advance Implant System until the Implant exits the Loader. Retract and peel away the Loader.
3	Aspirate and flush Guide Sheath with heparinized saline. Utilizing the specified syringe, aspirate a minimum of 45 cc. **CAUTION: Failure to fully aspirate Guide Sheath may result in air embolism.**
4	If desired, connect the continuous physiological saline drip to the Implant Catheter. **CAUTION: Connection of the continuous physiological saline drip to the Implant System prior to aspiration may result in air embolism.**
5	Advance Implant System until the Implant exits the distal end of the Guide Sheath.
6	Retract the Actuation Knob to get the Implant in Closed position. Retract the Sliders.
7	Adjust Guide Sheath as needed.
8	At the discretion of the treating physician, if pressure monitoring is used to continuously assess atrial pressure during procedure, please follow the pressure monitor manufacturer's instruction of use. Connect a fluid filled pressure monitoring device to the steerable catheter. Aspirate and then calibrate at the patient's heart level before obtaining measurement. **Note: Pressure monitoring should be used in conjunction with echo. Pressure should be reconciled against echo and Doppler readings. When assessing atrial pressure, ensure that the distal tip of the Implant Catheter is fully exposed from the Steerable Catheter.**
9	Advance Implant System as needed. Manipulate Steerable Catheter and Guide Sheath (flex-unflex, torque in opposing directions, advance-retract) as needed until Implant is centered in the target coaptation zone with the appropriate trajectory. **CAUTION: Excessive manipulation may result in dislodgement or disturbance of a previously implanted device, cardiac structure damage requiring surgical repair, or other intervention.** **Note: The radiopaque marker band on the Steerable Catheter indicates the end of the flex section and can be visualized on fluoroscopy.**
10	Advance the Actuation Knob to get the Implant into Leaflet-Capture-Ready position.
11	Torque the Implant Catheter, as needed, to orient the Paddles.
12	Advance the Implant through the valve until Paddles are below the free edge of the leaflets.
13	Verify location and orientation of the Implant and adjust position slightly as needed. **CAUTION: Excessive manipulation of the Implant below the leaflets may cause the Implant to be entangled in the chords; chordal entanglement may result in cardiac injury, worsening regurgitation, difficulty or inability to remove the Implant requiring additional intervention.**
14	Under imaging guidance, retract the Implant until leaflets are positioned between Paddles and Clasps.
15	Advance Slider(s) so the leaflet(s) are secured between the Clasps and Paddles. This can be performed for both leaflets simultaneously (Slider Pin engaged to move both Clasps) or each leaflet individually (Slider Pin disengaged to move individual Clasp).
16	Verify leaflet insertion with imaging. If leaflets are not secured between Clasps and Paddles, retract the Sliders to release the leaflets and reattempt.
17	Once leaflets are secured between the Clasps and Paddles, close the Implant.
18	Advance Implant Catheter slightly to release tension on leaflets.
19	Assess regurgitation, and reposition as needed. Once the Implant position is confirmed, ensure Implant is closed. If repositioning within the ventricle is needed, retract the Sliders and advance the Actuation Knob to set the Implant in Leaflet-Capture-Ready position. Adjust Clasps and Implant orientation as needed. If repositioning within the atrium is needed, retract the Sliders and advance the Actuation Knob to elongate the Implant slowly under fluoroscopic guidance while ensuring that the Actuation Wire does not bend, and retract the Implant back into the atrium. **CAUTION: Failure to elongate the Implant when retracting into the atrium during repositioning may result in leaflet damage or chordal entanglement.** **CAUTION: Failure to release leaflets from Clasps and Paddles prior to repositioning may result in leaflet damage.**
20	To release the Implant from the catheter: a) Ensure that the distal tip of the Implant Catheter is fully exposed from the Steerable Catheter. b) Cut outside suture on the proximal end of each Slider. Open both Slider Stopcocks to unlock sutures. Pull the Slider Pin to fully remove sutures. c) Close both Slider Stopcocks after removal of sutures. d) Remove the Release Pin. Rotate counterclockwise and retract the Release Knob until the Implant is released, as confirmed via imaging.

Step	Procedure
	Note: Prior to Implant release, if needed, it is possible to retrieve the Implant System back into the Guide Sheath for removal. To retrieve: a) Retract the Sliders. b) Elongate the Implant slowly under fluoroscopic guidance while ensuring that the Actuation Wire does not bend. Then retract Implant into the atrium. Set the Implant in Closed position. c) Unflex the Steerable Catheter and retract the Implant System until the Implant is adjacent to the tip of the Guide Sheath. d) Advance the Sliders. e) Set the Implant in Elongated position. f) Retract the Sliders to open the Clasps to approximately 45° on each side. g) Retract entire Implant System through the Guide Sheath. **CAUTION: Failure to cut suture in prescribed location may result in inability to release implant or introduction of fiber that may lead to micro-embolism.** **CAUTION: Failure to follow prescribed release steps may result in difficulty or inability to release Implant, requiring additional intervention.** **CAUTION: Releasing the Implant prior to confirmation that leaflets are securely captured between Paddles and Clasps may result in Implant movement or dislodgement leading to a single leaflet device attachment (SLDA) or other potential adverse events requiring additional intervention.** **WARNING: Re-use of the devices (including Implant System and Guide Sheath) after retrieval may cause embolism of foreign material or infection. Device may malfunction if re-use is attempted.** **Note: If an additional implant is placed at the decision of the treating physician, caution should be taken to avoid dislodgement of the previously placed implant. Crossing the valve in a low profile implant configuration can minimize interaction with the previously placed implant.** **CAUTION: Excessive manipulation may result in dislodgement or disturbance of a previously implanted device, cardiac structure damage requiring surgical repair or other intervention.**

7.4.4 Device Removal and Closure

Step	Procedure
1	Retract Implant Catheter completely into Steerable Catheter. Gradually unflex and remove Implant System. Gradually unflex and remove Guide Sheath. **CAUTION: Failure to unflex devices prior to removal may result in vessel damage.**
2	Perform standard percutaneous closure of access site.

8.0 Magnetic Resonance (MR) Safety

Non-clinical testing has demonstrated that the PASCAL implant is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic fields of 1.5 T and 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system-reported, whole body averaged specific absorption rate (SAR) of 4 W/kg (First Level Controlled Operating Mode).

Under the scan conditions defined above, the Implant is expected to produce a maximum temperature rise of less than 4 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device in a worst case multiple implant configuration extends up to 15 mm from the implant when imaged in the worst case gradient echo pulse sequence in a 3.0 T MRI system.

9.0 Recovered Implant and Device Disposal

Edwards Lifesciences is interested in obtaining recovered clinical specimens of the Implant for analysis. A written report summarizing our findings will be provided upon completion of our evaluation. Please contact Edwards for return of the recovered Implant.

If you do decide to return any of the devices, please follow the following instructions:

- **Unopened Package with Sterile Barrier Intact:**

  If the pouches have not been opened, return the device in its original packaging.
- **Package Opened but Not Implanted:**

  If a pouch is opened, the device is no longer sterile. Please return the device in its original packaging.
- **Explanted Implant:**

  The explanted implant should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to Edwards.

9.1 Disposal

Used devices may be handled and disposed of in the same manner as hospital waste and bio-hazardous materials in accordance with local regulations as there are no special risks related to the disposal of these devices.

10.0 Summary of Clinical Experience

10.1 CLASP Study

Clinical data in this section includes information obtained from the CLASP clinical study which studied the PASCAL transcatheter valve repair system in the mitral valve.

A multi-center, multi-national, prospective, single-arm study (CLASP) was conducted to assess the safety, performance, and clinical outcomes of the PASCAL system. All enrolled study patients were assessed for clinical follow-up at 30 days, 6 months, 1 year, and will continue annually for 5 years post-implant procedure.

The primary safety endpoint of the CLASP study was a composite of major adverse events (MAEs) at 30 days. The MAEs include: cardiovascular mortality, stroke, myocardial infarction, new need for renal replacement therapy, severe bleeding, and re-intervention for study device-related complications.

The primary performance endpoints of the study include device success, procedural success, and clinical success. The secondary endpoints of the study include clinical, safety, and functional outcomes at 30-day, 6 month, 1 year, and annual follow-up time points.

Device success is defined as device deployment as intended and successful delivery system retrieval as intended at the time of the patient's exit from the cardiac catheterization laboratory. Analysis of device success was performed per device.

Procedural success is defined as device success with MR severity ≤ 2+ at discharge (Echo Core Lab-evaluated) and without the need for a surgical or percutaneous intervention prior to hospital discharge. Procedural success was analyzed per patient.

Clinical success is defined as procedural success with evidence of MR reduction MR ≤ 2+ and without MAEs at 30 days (analyzed per patient).

An independent core lab assessed all echocardiographic data. An independent clinical events committee (CEC) adjudicated safety events and a data safety monitoring board (DSMB) independently reviewed aggregate safety data and evaluated trends of adverse events and their effect on trial conduct and device risk assessment.

10.1.1 CLASP Study Results

The mean age of the patients treated was 75.4 years and 55.0% were male. All patients had NYHA Class II, III or IV heart failure. The mean Logistic EuroSCORE I, EuroSCORE II and STS Mortality Score were 14.4%, 5.8% and 4.7%, respectively. At baseline, 50.9% had moderate-severe MR, and 48.1% had severe MR.

10.1.2 Performance

The performance endpoint included three components of success: device, procedural, and clinical. Device success was achieved in 92.0% of devices attempted. Procedural success was achieved in 93.5% of patients. Clinical success was achieved in 86.0% of patients.

10.1.3 Safety

At 30 days, the composite MAE rate was 8.0%. Nine patients experienced 11 MAEs prior to 30-day follow-up. The CEC Adjudicated MAE at 30 Days by Counts are shown below.

Major Adverse Event (MAE)	Summary Statistics
Cardiovascular Mortality	0.9% (1/112)
Stroke	0.9% (1/112)
Myocardial Infarction	0.0% (0/112)
New Need for Renal Replacement Therapy	0.0% (0/112)
Severe Bleeding	7.1% (8/112)
Re-Intervention for Study Device Related Complications	0.9% (1/112)
Composite MAE Rate	**8.0% (9/112)**

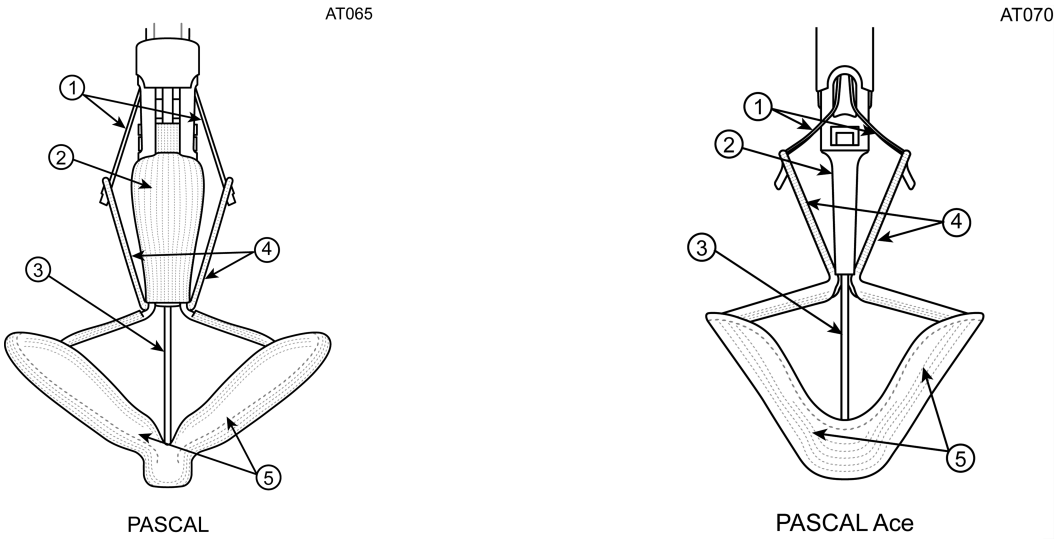
Note: Categorical measures - % (n/Total no)

In the overall population, MR grade reduction (i.e. MR ≤ 2+) was observed in 95.3% of patients at discharge, 96.1% at 30 days, 98.8% at 6 months, and 100% at 1 year.

10.1.4 Study Conclusion

The data collected in the CLASP study supports the safety and performance of the PASCAL system in patients with mitral regurgitation. The number of patients with follow-up of one year or more is limited and long-term follow-up data is collected by means of a Post Marketing Clinical Follow-up study.

Figures



1. Sutures
2. Spacer
3. Actuation Wire
4. Clasps
5. Paddles

Figure 1: Implant

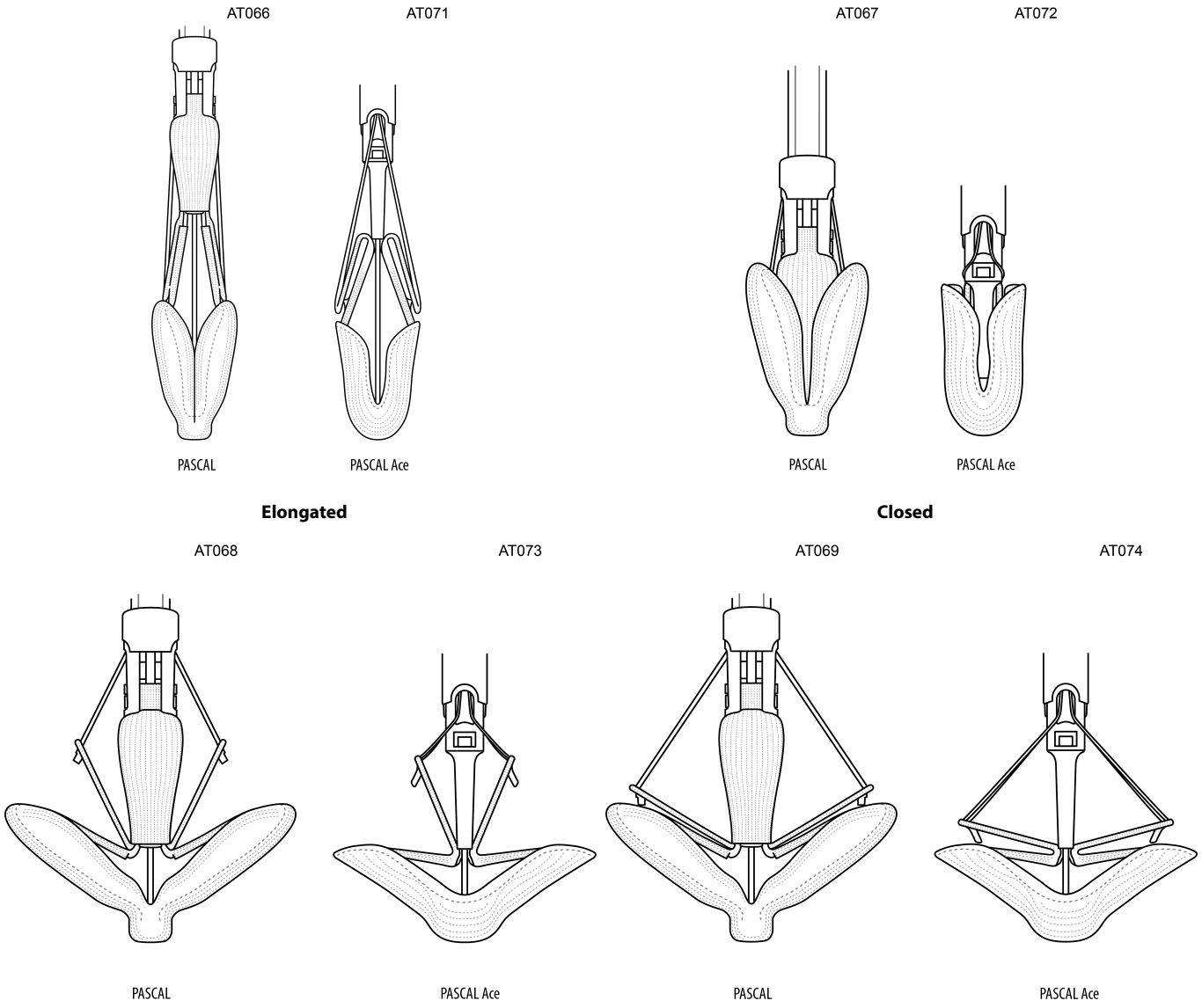
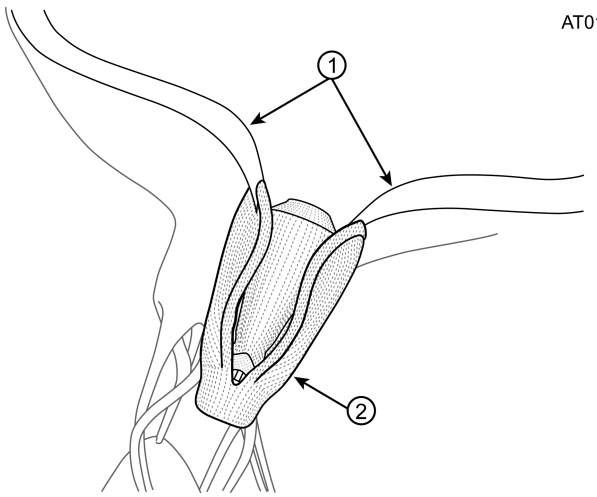


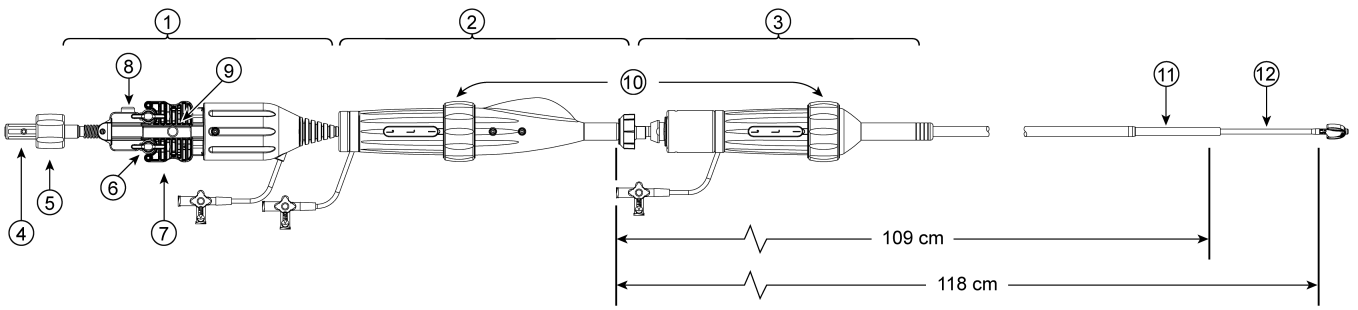
Figure 2: Implant Paddle Configurations



Note: Figure 3 is representative of both PASCAL and PASCAL Ace Implants.

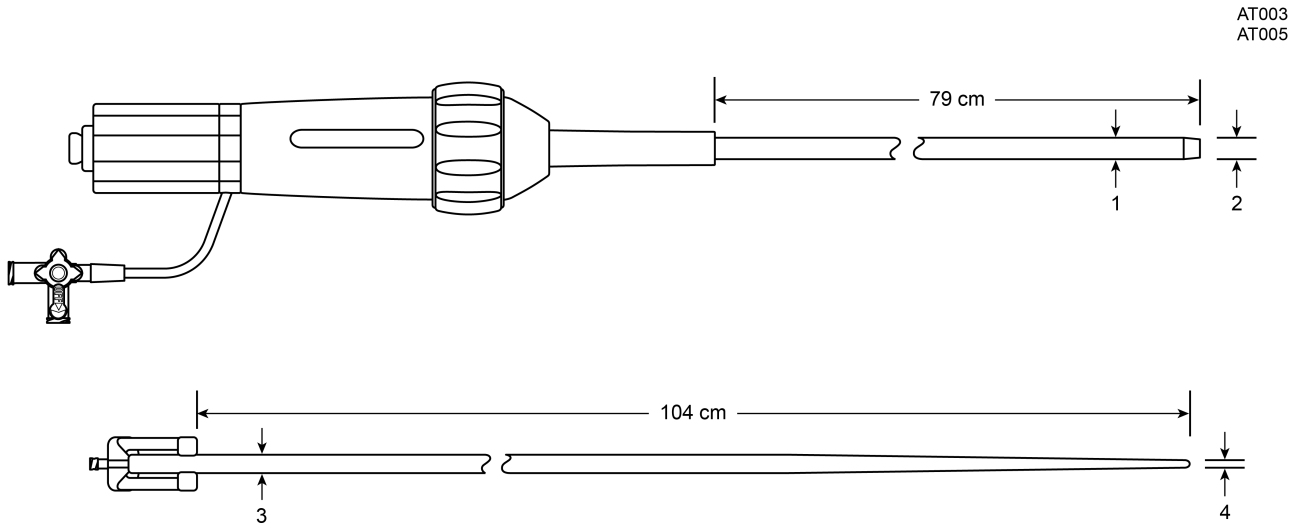
1. Leaflets
2. Implant

Figure 3: Implant in Final Implanted Position



1. Implant Catheter Handle
2. Steerable Catheter Handle
3. Guide Sheath Handle
4. Release Knob
5. Actuation Knob
6. Slider Stopcock
7. Sliders
8. Actuation Button
9. Slider Pin
10. Flex Knob
11. Steerable Catheter
12. Implant Catheter

Figure 4: Implant System and Guide Sheath



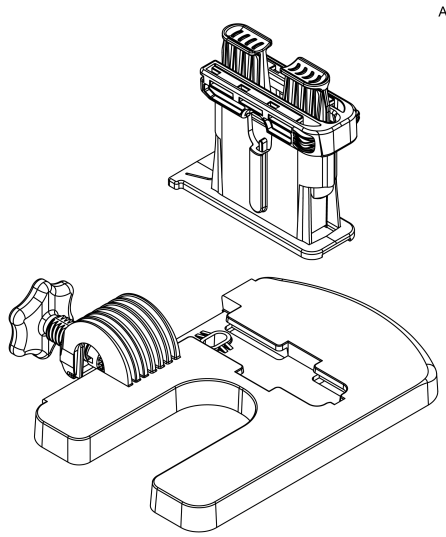
Guide Sheath:

1. OD 7.3 mm (22 Fr)
2. ID 5.5 mm

Introducer:

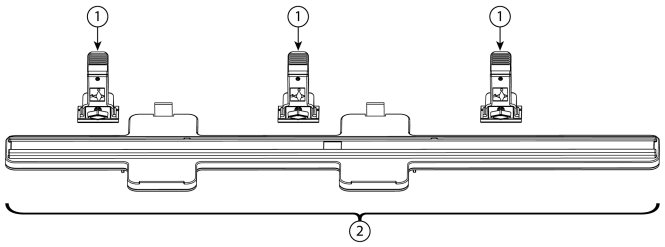
3. OD 5.7 mm (17 Fr)
4. ID 1.0 mm

Figure 5: Guide Sheath and Introducer



Model 10000ST

Figure 6: Stabilizer



Model 20000ST

Figure 7: Stabilizer Rail System

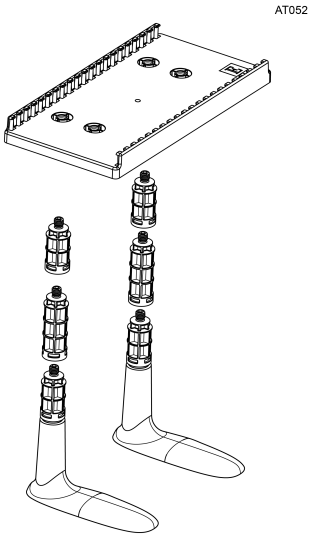
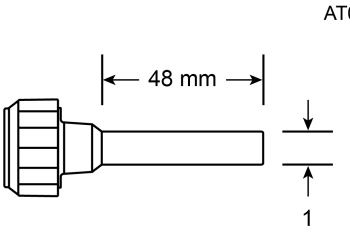


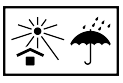
Figure 8: Table



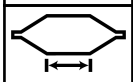
1. ID 6.2 mm

Figure 9: Loader

Symbol Legend

	English
REF	Catalogue Number
LOT	Lot Number
#	Quantity
	Contents
cm	Usable length
	Do not re-use
	Caution
	Warning
	Note
	Consult instructions for use
	Do not use if package is damaged
	Store in a cool, dry place
	Keep away from sunlight
	Keep dry

	English
MD	Medical device
eifu.edwards.com + 1 888 570 4016	Consult instructions for use on the website
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
STERILE LC	Sterilized using liquid chemical
	Do not resterilize
	Non-sterile
	Non-pyrogenic
	Non-DEHP
	Use-by date
SN	Serial Number
EC REP	Authorized representative in the European Community
	Manufacturer
	Date of manufacture

	English
44 mm	For use with size 44 mm Edwards transcatheter heart valve
48 mm	For use with size 48 mm Edwards transcatheter heart valve
	Temperature limit
	Exterior diameter
	Inner diameter
	Recommended guidewire length
GW	Recommended guidewire size
GWC	Guidewire compatibility
SZ	Size
Catheter 	Catheter shaft size
	Balloon diameter
	Balloon working length
MR	[Implant only] The implant device had been determined to be MR Conditional when used under the conditions listed in the instructions for use.
MR	MR Unsafe

Note: The labeling of this product may not contain every symbol depicted in this legend.

EC REP

Edwards Lifesciences Services GmbH
Edisonstr. 6
85716 Unterschleissheim
Germany

CE 0344

05/2021
10043280002 A

Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU