Edwards

Edwards PASCAL Precision Transcatheter Valve Repair System

Instructions for Use

Carefully read these instructions for use, which address the warnings, precautions, and residual risks for this medical device.

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

Model Number	Device
20000IS	PASCAL Precision system – implant system
20000ISM	PASCAL Precision system – PASCAL Ace implant system
20000GS	PASCAL Precision system – guide sheath

The PASCAL Precision system is compatible with the following single-use accessories:

Model Number	Device
10000T	PASCAL system – table
20000ST	PASCAL system – stabilizer rail system

The PASCAL Precision system is compatible with the following reusable accessories:

Model Number	Device
10000UP	Edwards reusable platform
10000PT	Edwards reusable plate
10000CR	Edwards reusable cradle

- **Implant System (Figure 4)**

  The implant system consists of the steerable catheter (outermost layer), the implant catheter (innermost layer), and the implant (hereinafter refers to the PASCAL and PASCAL Ace implants). The implant system percutaneously delivers the implant to the valve via a femoral vein access using a transvenous, transseptal 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 PASCAL Ace implant is a smaller size to provide physicians options. Suggested considerations for selecting PASCAL Ace implant include smaller landing zones and dense chordal regions. Refer to the PASCAL Precision system Physician Training Materials for additional information on the differences in size of spacer and other components for PASCAL and PASCAL Ace implants, including additional considerations for implant selection.

  The implant has four main paddle positions: elongated, closed, leaflet-capture-ready, and leaflet-captured.

  Note: PASCAL Ace implant is a naming convention that refers to an additional implant size with the same indication for use as the PASCAL implant.
- **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 four primary controls are the clasp sliders, the paddle knob, the implant release knob, and the suture locks. The clasp sliders control the clasps (retracting the clasp sliders raises the clasps and advancing the clasp sliders lowers the clasps). The paddle knob controls the paddles (rotating the paddle knob clockwise closes the paddles and rotating the paddle knob counterclockwise opens the paddles). The implant release knob controls the release of the implant from the implant catheter. The suture locks control release of the sutures from the clasps. The implant catheter is provided assembled within the steerable catheter.
- **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.
- **Guide Sheath (Figure 5)**

  The guide sheath is used to provide 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.
- **Introducer (Figure 5)**

  The introducer is used to facilitate tracking the guide sheath to the desired location. The introducer is compatible with a 0.035 inch (0.89 mm) guidewire. The introducer is included in the guide sheath packaging.
- **Loader (Figure 8)**

  The loader is used to introduce the implant and delivery catheters through the guide sheath seals. The loader is included in the implant system and guide sheath packaging for user convenience.
- **Stabilizer Rail System (Figure 6)**

  The stabilizer rail system is intended to aid with positioning and stabilization of the PASCAL Precision system during implantation procedures. The stabilizer can be attached to the guide sheath and implant system as needed any time during the procedure. The use of the stabilizer rail system is optional.
- **Table (Figure 7)**

  The table is intended to provide a stable platform for the implant system, guide sheath, and stabilizer rail system of the PASCAL Precision

system. The table is used outside of the sterile field. The table is height-adjustable. The use of the table is optional.

- **Reusable Accessories**

  For reusable accessories, refer to the Edwards Reusable Accessories: Reusable Platform (Model 10000UP), Reusable Plate (Model 10000PT), and Reusable Cradle (Model 10000CR) Instructions for Use (herein referred to as the Edwards Reusable Accessories IFU).

1.0 Indications for Use

1.1 Intended Use

The PASCAL Precision system is intended to repair an insufficient mitral valve via percutaneous reconstruction through tissue approximation.

1.2 Target Patient Population

The PASCAL Precision system is intended for adult patients with clinically significant, symptomatic mitral regurgitation (moderate-to-severe or severe MR).

Patient selection should be performed by a multidisciplinary expert heart team specializing in the treatment of mitral regurgitation. The heart team should weigh the benefits and risks of all possible interventions prior to treating patients with the PASCAL Precision system. Patients are candidates for the PASCAL Precision system if they are not deemed suitable for cardiac surgery, including minimally invasive cardiac surgery, and are anatomically suitable for treatment with the PASCAL Precision system.

2.0 Contraindications

The PASCAL Precision system is contraindicated in mitral 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 Precision 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. Valve anatomy which might limit proper PASCAL Precision system access, use and/or deployment, or sufficient reduction in mitral regurgitation should be considered by a multi-disciplinary heart team. Safety and effectiveness have not been established for patients with anatomic characteristics including, but not limited to, the following:

- 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
- Leaflet mobility length < 8 mm
- Flail width > 15 mm and/or flail gap > 10 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

3.2.1 PASCAL Precision System, Table, and Stabilizer Rail System

- 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. Such action could lead to illness or an adverse event as the device may not function as originally intended.
- 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.

3.2.2 Edwards Reusable Platform, Reusable Plate, and Reusable Cradle

- The devices are designed, intended, and distributed for multiple uses. For reusable accessories, refer to the Edwards Reusable Accessories IFU.

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.
- The PASCAL Precision system has not been evaluated in pregnant or pediatric patients.

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 after considering the various device treatment options.

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 Precision system. 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 Precision 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 Precision 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 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
- 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 Precision 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 implant system, guide sheath, and stabilizer rail system are individually packaged and ethylene oxide sterilized. The table is packaged and provided non-sterile. The Edwards reusable platform, reusable plate and reusable cradle are individually packaged and provided non-sterile.

6.2 Storage

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

7.0 Directions for Use

7.1 Physician Training

The PASCAL Precision system is intended for use by interventional cardiologists and cardiac surgeons, with other support staff that are trained to assist in mitral heart valve repair.

The implanting physician shall be experienced in transcatheter techniques and trained on the PASCAL Precision system and procedure. All physicians conducting a procedure with the PASCAL Precision system must be trained per Edwards training requirements summarized below:

- PASCAL Precision system Physician Training Manual Didactic Session: device design, procedural imaging, procedural steps and challenging situations
- Hands-on Benchtop Model: practical exercise of procedural steps
- Physiologic Simulation Model: practical exercise of procedural steps with procedural imaging

The final decision for PASCAL Precision 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)
- 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: pigtail catheter for contrast injection (with compatible sheath)
- 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 from packaging and inspect for damage. If using the Edwards reusable platform and reusable cradle in lieu of the table, refer to the Edwards Reusable Accessories IFU.
2	Assemble the table as seen in Figure 7.

7.3.2 Stabilizer Rail System

Step	Procedure
1	Remove stabilizer rail system components from packaging and inspect for damage.

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 – System Check, Clasp Check, and Resetting

Step	Procedure
1	Remove implant system and loader from packaging and inspect for gross damage. **CAUTION: If vented cap is not present on the implant catheter flush port, use of the device may result in infection.**
2	Fully elongate implant. Fully retract and advance clasp sliders to confirm proper clasp motion.
3	If clasps do not move properly, follow steps below to reset. If clasps do move properly, continue to next section "Implant System – Flushing and Preparation."
4	Ensure implant is fully closed. Loosen and remove suture locks from suture lock base. **Note: Ensure free end of suture is not pulled into handle while loosening suture lock.**
5	Fully retract clasp sliders and place clasp setting tool flush with suture locks, suture lock bases, and implant release knob.
6	Pull free end of suture on one suture lock base to remove suture slack. Release tension on free end of suture, replace and tighten the suture lock. Repeat for second suture lock.
7	Remove clasp setting tool. Fully elongate implant. Fully advance and retract clasp sliders to confirm proper clasp motion.

7.3.5 Implant System – Flushing and Preparation

Step	Procedure
1	Close implant.
2	Ensure clasp sliders are fully retracted and implant is fully closed.
3	Remove vented cap from implant catheter flush port. Raise distal end of the implant catheter and flush with heparinized saline.
4	Attach flush port cap to implant catheter flush port.
5	Attach implant release cover to implant catheter handle.
6	Fully retract implant catheter. Advance the clasp sliders and set implant in elongated position.
7	Remove loader cap and guide the loader cap onto the implant system.
8	Insert the implant through the proximal end of the loader until it exits the distal end. Connect the loader and loader cap.
9	Advance implant catheter fully so implant exits loader.
10	While keeping loader and distal tip raised, flush heparinized saline through the steerable catheter.
11	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 between the legs of the patient, adjusting height of the table as needed. Use towels as support between table and patient's legs. **CAUTION: The table is provided non-sterile; introduction of the table into the sterile field may result in infection.** OR Prior to sterile draping the patient, assemble and position the reusable accessories around the legs of patient, adjusting the height and angle of the platform as needed. Place the cradle on the platform in line with the intended femoral vein access site. Refer to the Edwards Reusable Accessories IFU. **CAUTION: The reusable accessories are non-sterile; introduction of the reusable accessories into the sterile field may result in infection.**
2	After sterile draping, assemble and attach stabilizer rail system 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 Navigation and Placement

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 or aspiration without the presence of the flush port cap on the implant catheter flush port 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	Set the implant in closed position. Retract the clasp 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. Refer to the PASCAL Precision system Physician Training Material for additional guidance on atrial pressure monitoring, including limitations. **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	Rotate the paddle knob to set the implant into leaflet-capture-ready position.
11	Torque the implant catheter, as needed, to orient the paddles.
12	Move one clasp slider to identify which clasp it controls via imaging. Once identified, ensure sliders are fully retracted.
13	Advance the implant through the valve until paddles are below the free edge of the leaflets.
14	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.**
15	Under imaging guidance, retract the implant until leaflets are positioned between paddles and clasps.
16	Advance clasp slider(s) so the leaflet(s) are secured between the clasps and paddles. This can be performed for both leaflets simultaneously (clasp lock engaged to move both clasps) or each leaflet individually (clasp lock disengaged to move individual clasp).
17	Verify leaflet insertion with imaging. If leaflet(s) are not secured between clasps and paddles, retract the clasp slider(s) to release the leaflet(s) and reattempt.
18	Once leaflets are secured between the clasps and paddles, close the implant.
19	Advance implant catheter slightly to release tension on leaflets.
20	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 clasp sliders and set the implant in leaflet-capture-ready position. Adjust clasps and implant orientation as needed. If repositioning within the atrium is needed, retract the clasp sliders and 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.**

Step	Procedure
	CAUTION: Failure to release leaflets from clasps and paddles prior to repositioning may result in leaflet damage.

7.4.4 Implant Retrieval (if needed)

Prior to implant release, if needed, it is possible to retrieve the implant system back into the guide sheath for removal. Follow the steps below to retrieve the implant.

Refer to the PASCAL Precision system Physician Training Materials for additional considerations on implant retrieval maneuvers.

CAUTION: Excessive manipulation may result in dislodgement or disturbance of a previously implanted device, cardiac structure damage requiring surgical repair or other intervention.

Step	Procedure
1	Retract the clasp sliders.
2	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.
3	Unflex the steerable catheter and retract the implant system until the implant is adjacent to the tip of the guide sheath.
4	Advance the clasp sliders.
5	Set the implant in elongated position.
6	Retract the clasp sliders to open the clasps to approximately 45° on each side.
7	Retract entire implant system through the guide sheath.

7.4.5 Implant Release

To release the implant follow the steps below:

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.

CAUTION: 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 [PASCAL or PASCAL Ace] 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.

Step	Procedure
1	Ensure that the distal tip of the implant catheter is fully exposed from the steerable catheter.
2	Unscrew and remove implant release cover from implant catheter handle.
3	Unthread and remove one suture lock from the suture lock base.
4	Pull suture lock away from handle to fully remove suture.
5	Repeat steps for other suture lock.
6	Rotate counterclockwise and retract the implant release knob until the implant is released, as confirmed via imaging.
7	Replace suture locks, as needed.

7.4.6 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 and PASCAL Ace implants are 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

Use universal precautions for biohazards and sharps to avoid user injury. Used devices (includes all devices that come in contact with patients) should be handled and disposed of in accordance with institutional guidelines on biohazardous materials and hospital waste to avoid possible cross-contamination.

For disposal of the reusable accessories, refer to the Edwards Reusable Accessories IFU.

10.0 Summary of Clinical Experience

A high-level summary of all clinical experience is provided below. A detailed summary of all clinical experience can be found in the SSCP.

10.1 CLASP Study

Results from the CLASP study, a multi-center, multi-national, prospective, single-arm study, show high rates of device, procedural, and clinical

success, a reduction in MR grade through 2 years, an improvement in quality of life, exercise capacity, and functional status through 1 year, and an acceptable MAE rate.

10.2 CLASP IID/IIF (IID Roll-In Cohort) Study

Results from the DMR roll-in cohort of the pivotal, randomized, controlled CLASP IID/IIF study, show an improvement in MR grade and clinical outcomes through 30 days along with an MAE rate within the anticipated range.

10.3 MiCLASP PMCF Study

Results from the MiCLASP PMCF study, a multi-center, single-arm, prospective post market clinical follow up study, show a reduction in MR grade and an improvement in functional status, exercise capacity, and quality of life through 1 year. Evaluation of the MAE rate at 1 year indicates an acceptable safety profile.

10.4 Additional Studies

The following PASCAL implant studies, PASCAL implant post-market Registry, and CLASP IID/IIF (Mitral) Registry and Randomized Cohorts are currently ongoing and have yet to reach their primary endpoints; therefore, results are not presented here.

11.0 Summary of Safety and Clinical Performance (SSCP)

The SSCP (Summary of Safety and Clinical Performance) has been adapted in accordance with the clinical evaluation assessment by the Notified Body on which the CE certification has been granted. The SSCP contains a relevant summary of the same information.

The Notified Body has taken notice of and agreed with the benefit-risk rationales for the short- and long-term safety and effectiveness of the PASCAL Precision system.

Conformity of the PASCAL Precision system of the Performance Requirements (GSPR) for safety (MDR GSPR 1), performance (MDR GSPR 1), acceptability of side-effects (MDR GSPR 8), usability (MDR GSPR 5), device lifetime (MDR GSPR 6), acceptable benefit-risk profile (MDR GSPR 8) has been established for the labelled indications.

Refer to https://meddeviceinfo.edwards.com/ for a SSCP for this medical device.

After the launch of the European Database on Medical Devices/Eudamed, refer to https://ec.europa.eu/tools/eudamed for a SSCP for this medical device.

12.0 Clinical Benefits

The clinical benefits of the PASCAL Precision system for the treatment of MR include the following:

- Effective and stable reduction in mitral regurgitation.
- Enables minimally invasive percutaneous treatment option for mitral regurgitation.
- Improvement in functional status, exercise capacity, and quality of life.

There are no clinical benefits specific to the table, as the table is an optional non-patient contacting accessory. Benefits of the table are functional in nature and related to the intended use of the accessory to support the PASCAL Precision system.

There are no clinical benefits specific to the stabilizer rail system, as the stabilizer rail system is an optional non-patient contacting accessory used only during the implant procedure. Benefits of the stabilizer rail system are functional in nature and related to the intended use of the accessory to support the PASCAL Precision system.

13.0 Basic Unique Device Identification-Device Identifier (UDI-DI)

The Basic UDI-DI is the access key for device-related information entered in the Eudamed. The Basic UDI-DI for the PASCAL Precision system can be used to locate the SSCP.

The following table contains the Basic UDI-DIs for the PASCAL Precision system and compatible devices:

Product	Model	Basic UDI-DI
PASCAL Precision system – implant system	20000IS	0690103S004PAS000BC
PASCAL Precision system – PASCAL Ace implant system	20000ISM	0690103S004PAS000BC
PASCAL Precision system – guide sheath	20000GS	0690103S004PAS000BC
PASCAL system – stabilizer rail system	20000ST	0690103D004PAC000S6
PASCAL system – table	10000T	0690103D004PAC000S6

The following table contains the Basic UDI-DIs for reusable accessories compatible with the PASCAL Precision system:

Product	Model	Basic UDI-DI
Reusable platform	10000UP	0690103D004REU000YA
Reusable plate	10000PT	0690103D004REU000YA
Reusable cradle	10000CR	0690103D004REU000YA

14.0 Expected Lifetime of the Device

The PASCAL and PASCAL Ace implants are subject to rigorous pre-clinical durability testing per the testing requirements and were successfully tested to a minimum of 5 years of simulated wear. The actual lifetime performance in humans depends on multiple biological factors and varies widely from patient to patient. Specific activities or conditions that could shorten or lengthen the device lifetime have not been established.

15.0 Patient Information

A patient implant card is provided with each implant system. After implantation, please complete all requested information and provide the implant card to the patient. This implant card allows patients to inform healthcare providers what type of implant they have when they seek care.

16.0 Performance Characteristics

Device performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions For Use.

The design of the PASCAL Precision delivery catheters is based on user feedback. The claim for "Precision" will be confirmed during post-market monitoring.

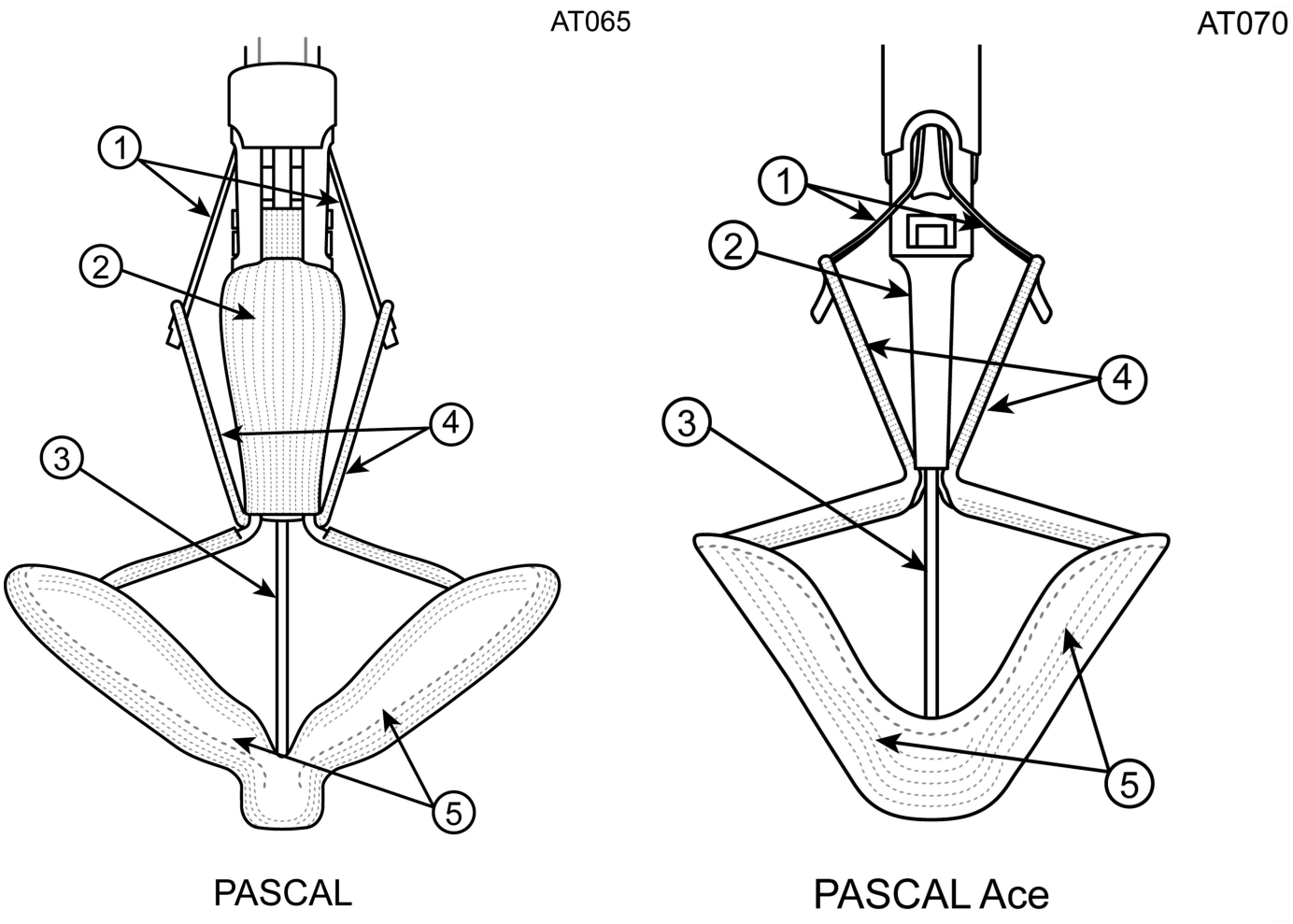
17.0 Qualitative and Quantitative Information related to the PASCAL and PASCAL Ace Implants

The PASCAL implant comprises a titanium nut and bolt, PEEK bushing, and a silicone seal. The PASCAL Ace implant comprises a titanium nut, bolt, distal and proximal plate, and a silicone seal.

The following table shows the qualitative and quantitative information on the materials and substances:

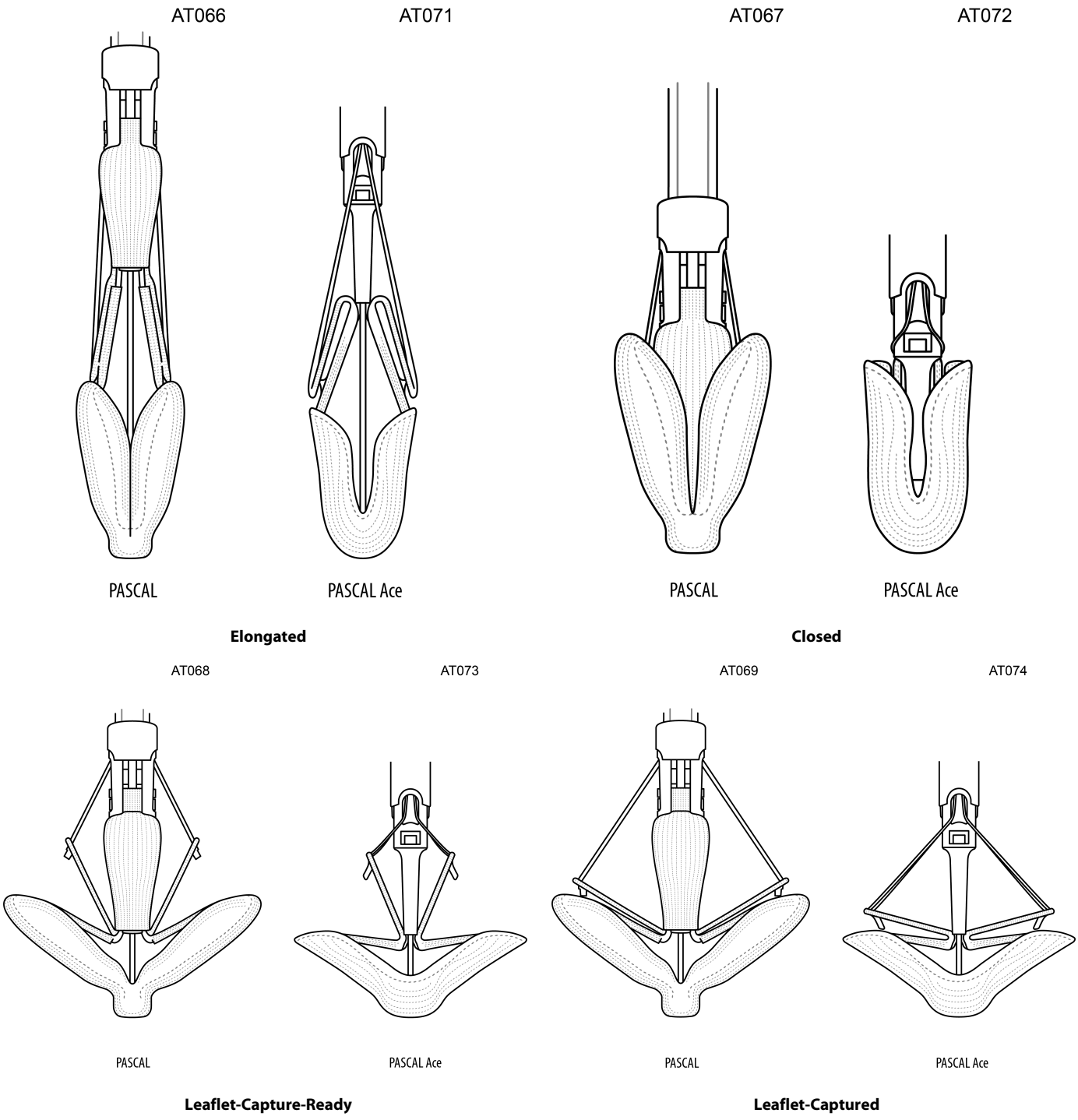
Substance	CAS	Model Mass Range (mg)
Titanium	7440-32-6	254 - 324
Nickel	7440-02-0	235 - 258
Polyethylene terephthalate	25038-59-9	82.5 - 98.1
Polyethylene	9002-88-4	14.3 - 42.6
Polyether ether ketone	29658-26-2	0 - 23.2
Aluminium	7429-90-5	3.39 - 9.13
Vanadium	7440-62-2	2.16 - 6.32
Silicon dioxide	7631-86-9	5.08 - 5.40
Polydimethylsiloxane	63148-62-9	3.86 - 4.16
Perfluoropolyether	69991-67-9	2.44 - 2.52
Polytetrafluoroethylene	9002-84-0	1.15 - 1.22
Iron	7439-89-6	0 - 0.567
Titanium dioxide	13463-67-7	0.180 - 0.541
Oxygen	7782-44-7	0 - 0.355
Carbon	7440-44-0	0 - 0.285
Cobalt	7440-48-4	0 - 0.226
Antimony trioxide	1309-64-4	0.0847 - 0.118
Niobium	2023505	0 - 0.113
Nitrogen	7727-37-9	0 - 0.0918
Chromium	7440-47-3	0 - 0.0452
Copper	7440-50-8	0 - 0.0452
Hydrogen	1333-74-0	0 - 0.0384
4,4'-Difluorobenzophenone	345-92-6	0 - 0.00141
Diphenyl sulfone	127-63-9	0 - 0.00114
Erucamide	112-84-5	0.000516 - 0.00102
4-Dodecylbenzenesulfonic acid	121-65-3	0.0000906 - 0.00857
Decamethylcyclopentasiloxane; D5	541-02-6	0 - 0.000698
Dodecamethylcyclohexasiloxane; D6	540-97-6	0 - 0.000698
Octamethylcyclotetrasiloxane; D4	556-67-2	0 - 0.000651

Figures



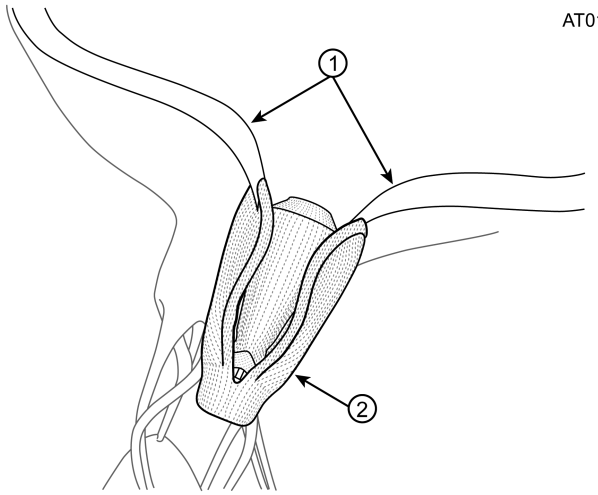
1. Sutures
2. Spacer
3. Actuation Wire
4. Clasps
5. Paddles

Figure 1: Implant



Images may not be to scale.

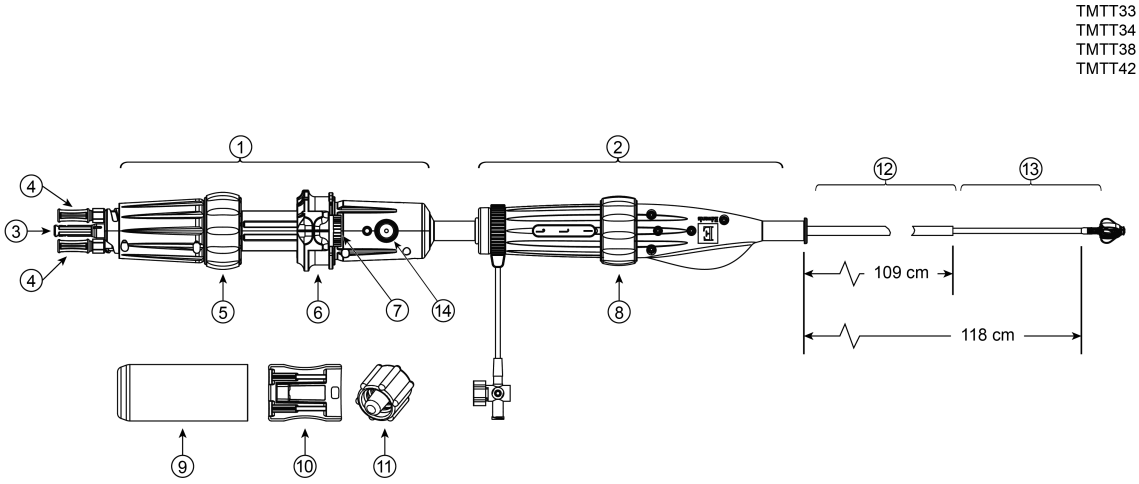
Figure 2: Implant Paddle Configurations



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

1. Leaflets
2. Implant

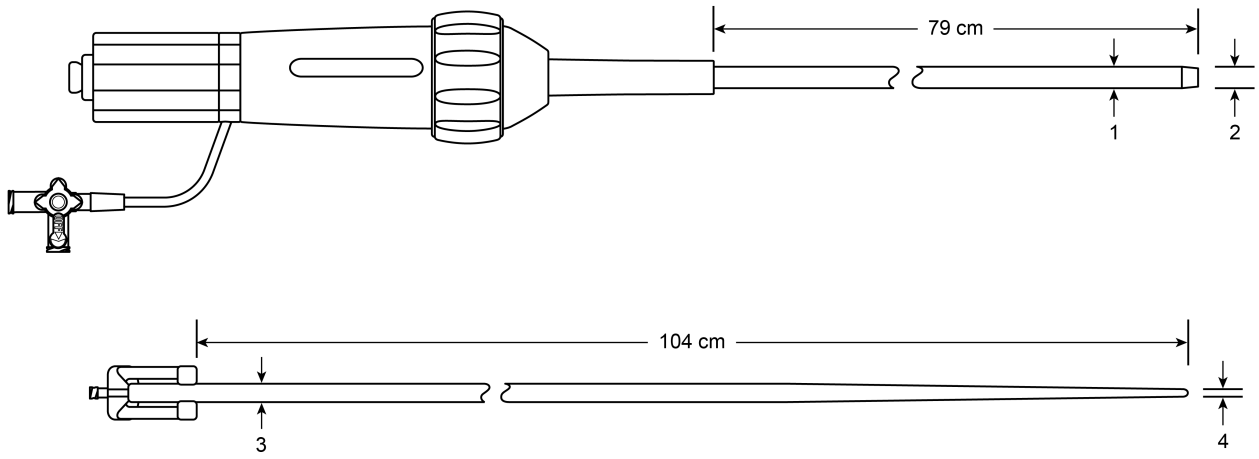
Figure 3: Implant in Final Implanted Position



1. Implant Catheter Handle
2. Steerable Catheter Handle
3. Implant Release Knob
4. Suture Locks
5. Paddle Knob
6. Clasp Sliders
7. Clasp Lock
8. Flex Knob
9. Implant Release Cover
10. Clasp Setting Tool
11. Flush Port Cap
12. Steerable Catheter
13. Implant Catheter
14. Vented Cap

Figure 4: Implant System

AT003
AT005



Guide Sheath:

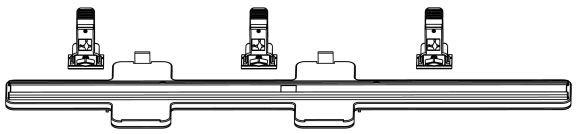
1. OD 7.3 mm (22 Fr)
2. ID 5.5 mm

Introducer:

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

Figure 5: Guide Sheath (top) and Introducer (bottom)

TMTT30



Model 20000ST

Figure 6: Stabilizer Rail System

AT052

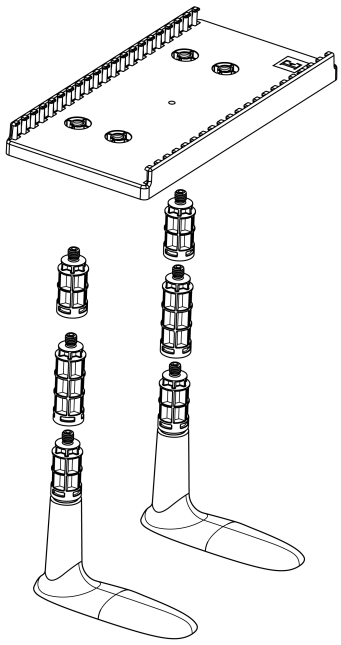
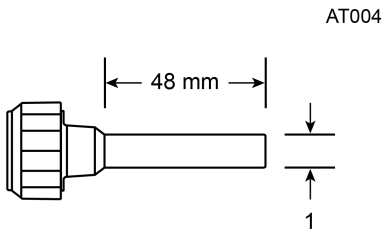


Figure 7: Table

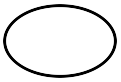


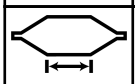
1. ID 6.2 mm

Figure 8: Loader

Symbol Legend

	English
REF	Catalogue Number
LOT	Lot Number
#	Model Number
	Contents
cm	Usable length
	Do not re-use
	Caution
	Consult instructions for use or consult electronic instructions for use
	Do not use if package is damaged and consult instructions for use
	Store in a cool, dry place
	Keep away from sunlight
	Keep dry
	Importer
UDI	Unique device identifier
QTY	Quantity
	Date of implantation

	English
MD	Medical device
	Single sterile barrier system
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/European Union
	Manufacturer
	Date of manufacture
	Patient information website

	English
	Patient Name
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.
MR	MR Unsafe
	Name and Address of the implanting healthcare institution/ provider

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

EC REP

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08/2023
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