Edwards

Edwards Alterra Adaptive Prestent System

Instructions for Use

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician.

Implantation of the Edwards Alterra adaptive prestent should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in balloon valvuloplasty.

Please verify that you have the latest version of the instructions for use prior to using the device by visiting http://eifu.edwards.com/ or by calling 1.888.570.4016.

STERILE: The Edwards Alterra adaptive prestent system is supplied sterilized with e-beam sterilization. The sheath is supplied sterilized with ethylene oxide gas.

1.0 Device Description

Edwards Alterra Adaptive Prestent System

The Edwards Alterra adaptive prestent system consists of an Alterra adaptive prestent that is fully loaded in an Alterra delivery system and supplied together in one package:

- **Edwards Alterra Adaptive Prestent (Figure 1)**

The Edwards Alterra adaptive prestent is used as a docking adaptor for the 29 mm Edwards SAPIEN 3 transcatheter heart valve (THV). It is comprised of a self-expanding, radiopaque, nitinol frame assembly and polyethylene terephthalate (PET) fabric covering. The prestent has designated inflow and outflow sides. The proximal inflow section is identifiable by the presence of two triangular tabs (prestent connector) that are attached to the catheter of the delivery system. The distal outflow section is distinguished by the open cells for blood flow. The PET fabric is attached by sutures to the inside surface of the frame to create sealing at the inflow section and opening for the outflow. Sutures are also used in the center to support the middle section when an Edwards SAPIEN 3 transcatheter heart valve is implanted. Three (3) radiopaque markers are positioned at the prestent waist.

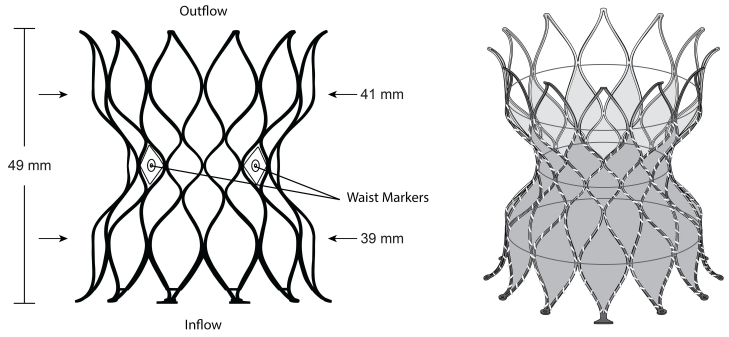

Figure 1: Edwards Alterra Adaptive Prestent

Table 1

Inflow Sealing OD	Outflow Sealing OD	Height
39 mm	41 mm	49 mm

Sizing recommendation for the prestent in the right ventricular outflow tract/pulmonary valve (RVOT/PV) landing zone are shown in the table below:

Table 2: Prestent Sizing in RVOT landing zone

Perimeter	Perimeter Derived Diameter[1]	Prestent Size Diameter[2] x Length	Valve Size
84.9 mm - 119.3 mm	27 mm - 38 mm	40 mm x 49 mm	29 mm

[1] Diameter range during systole

[2] Diameter is average of inflow and outflow diameters

Note: ***For Edwards SAPIEN 3 transcatheter heart valve implantation, refer to the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent instructions for use.***

- **Edwards Alterra Delivery System (Figure 2)**

The delivery system includes a handle which consists of a wheel that allows for deployment, two primary shafts with a flush port to flush the delivery system, and a long tapered tip at the distal end to facilitate tracking through the vasculature. A radiopaque delivery system marker band shows the location of the tip of the outer shaft. The prestent is fully loaded in the delivery system. A stylet is included within the guidewire lumen.

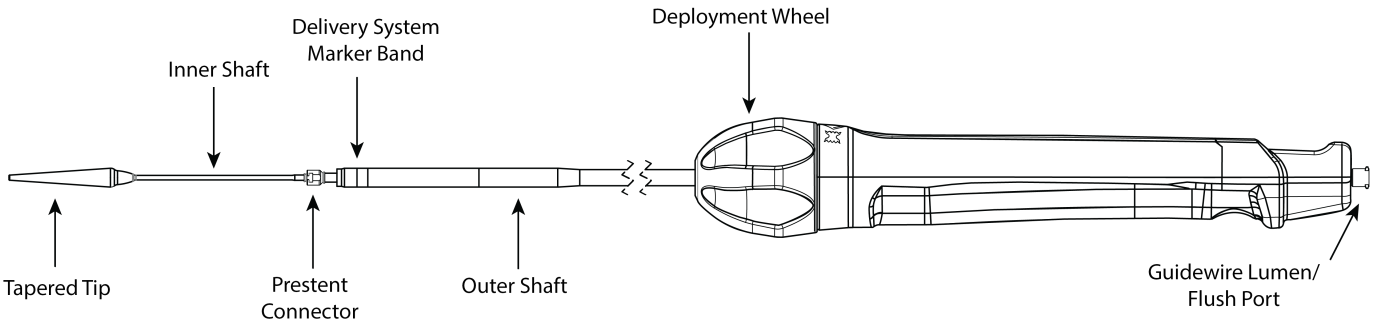

Figure 2: Edwards Alterra Delivery System

Additional Accessories

- **Edwards Sheath**

Refer to the provided Edwards sheath instructions for use for device description.

2.0 Indications

The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation as measured by echocardiography who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for pulmonary valve replacement.

3.0 Contraindications

The Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent is contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

4.0 Warnings

- The devices are designed, intended, and distributed for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.
- Do not mishandle the delivery system or use if the packaging sterile barriers and any components have been opened or damaged, the expiration date has elapsed, or the delivery system cannot be flushed.

5.0 Precautions

- Correct sizing of the prestent into the RVOT is essential to minimize risks such as paravalvular leak, migration, embolization, and/or RVOT rupture.
- Long-term durability has not been established for the prestent. Medical follow-up is advised so that device related complications can be diagnosed and properly managed.
- Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials may have an allergic reaction to these materials.
- Assessment for coronary compression risk prior to implantation is recommended.
- Patient venous anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device.
- Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored.
- Fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. Patient radiation dose should be monitored during the procedure.
- Patient should be heparinized to maintain the ACT at ≥ 250 sec prior to introduction of the delivery system in order to prevent thrombosis.
- Prestent recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, as determined by their physician. This device has not been tested for use without antiplatelet therapy.
- It is recommended that all prestent recipients be prophylactically treated for endocarditis to minimize the risk of infection.
- If a prestent fracture is detected with significant loss in valve functionality, reintervention should be considered.
- Safety and effectiveness have not been established for patients with the following characteristics/comorbidities:
  - Blood dyscrasias defined as: leukopenia, acute anemia, thrombocytopenia, or history of bleeding diathesis or coagulopathy
  - A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated
  - Positive urine or serum pregnancy test in female patients of child-bearing potential

6.0 Potential Adverse Events

Potential risks associated with the anesthesia, interventional procedure and imaging include but are not limited to:

- Death
- Stroke/transient ischemic attack
- Respiratory insufficiency or respiratory failure
- Cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium or valvular structures including rupture of the RVOT that may require intervention
- Pericardial effusion/cardiac tamponade
- Cardiac failure
- Embolic event: air, calcific material, thrombus
- Infection including incisional site infection, septicemia and endocarditis
- Myocardial infarction
- Renal insufficiency or renal failure
- Conduction system injury
- Arrhythmia
- Deep vein thrombosis
- Arteriovenous (AV) fistula
- Systemic or peripheral nerve injury
- Systemic or peripheral ischemia
- Pulmonary edema
- Pneumothorax
- Pleural effusion
- Dyspnea
- Atelectasis
- Dislodgement of previously implanted devices (i.e., pacing lead)
- Blood loss requiring transfusion
- Anemia
- Radiation injury
- Electrolyte imbalance
- Hypertension or hypotension
- Allergic reaction to anesthesia, contrast media, antithrombotic therapy, device materials
- Hematoma or ecchymosis
- Syncope
- Pain
- Exercise intolerance or weakness
- Inflammation
- Angina
- Fever

Potential risks that may or may not require intervention associated with the prestent, delivery system and/or accessories include, but may not be limited to, the following:

- Cardiac arrest
- Cardiogenic shock
- Coronary flow obstruction/transvalvular flow disturbance
- Device thrombosis
- Injury to tricuspid valve
- Device fracture
- Device embolization
- Device migration or malposition
- Endocarditis
- Chest pain/discomfort
- Device penetration/perforation into surrounding vasculature and patients with a native RVOT that has not been surgically repaired have an observed higher risk of perforation requiring surgical intervention due to the absence of scar tissue
- Device dysfunction (regurgitation and/or stenosis)
- Aortic root distortion
- Embolic event: device fragments
- Mechanical failure of delivery system, and/or accessories

7.0 Directions for Use

7.1 System Compatibility

Table 3

Product Name	Model
Edwards Alterra Adaptive Prestent System[1]	29AP4045

Product Name	Model
Sheath provided by Edwards Lifesciences or equivalent	

[1]Includes an Alterra adaptive prestent that is fully loaded in an Alterra delivery system

Additional Equipment:

- Balloon tip catheter
- Sizing balloons
- 20 cc syringe or larger
- 50 cc syringe or larger
- Standard cardiac catheterization lab equipment
- Fluoroscopy (appropriate for use in percutaneous coronary interventions)
- Exchange length 0.035 inch (0.89 mm) stiff guidewire
- Physiological saline
- Sterile table for device preparation

Refer to the *Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent instructions for use* for additional materials required to prepare the *Edwards SAPIEN 3 Transcatheter Pulmonary Valve System*.

7.2 Device Handling and Preparation

Follow sterile technique during device preparation and implantation.

7.2.1 Prepare the System

Refer to the Edwards sheath instructions for use for device preparation.

1. Remove the delivery catheter with the preloaded prestent from packaging. Visually inspect all components for damage.
2. Ensure there is a small gap between the outer shaft and the tapered tip to facilitate flushing of the inner lumen. If needed retract the outer shaft using the deployment wheel.

   Note: Do not allow the end of the prestent to begin to exit the delivery system.
3. With the stylet still in place, flush the guidewire lumen with heparinized saline.
4. Using the deployment wheel, re-advance the outer shaft until it is even with the tapered tip.

   Note: Do not overdrive the outer shaft onto the tapered tip.
5. Remove the stylet and repeat flushing the guidewire lumen.

7.3 Prestent Delivery

Prestent delivery should be performed under local and/or general anesthesia with hemodynamic monitoring in a catheterization lab/hybrid operating room with fluoroscopic imaging capabilities.

Administer heparin to maintain the ACT at ≥ 250 sec.

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

1. Gain access using standard catheterization techniques.
2. If necessary, predilate the vessel.
3. Introduce the sheath per its instructions for use.
4. Insert and advance the delivery system to the RVOT landing zone.

   Note: Advance the delivery system from the shaft. Do not push the delivery system in by using the handle. Do not rotate the deployment wheel during advancement of the delivery system.
5. Position the delivery system marker band distal to the intended landing zone.
6. Begin deployment by rotating the deployment wheel to retract the outer shaft.

   Note: The delivery system marker band is located slightly proximal to the distal edge of the outer shaft.

   Note: Waist markers on the prestent indicate the middle of the prestent.

   Note: The prestent can be recaptured into the outer shaft and repositioned if deployed approximately 65%.

   CAUTION: Once deployment has begun, do not reposition the device more distally. Advancement of the device with the prestent exposed may increase the risk for vascular damage.
7. Continue deploying the Alterra pausing at approximately 30%, 50%, and 65% to assess for Alterra positioning, coaxiality, and deployment angulation.
8. If needed, recapture and reposition the prestent by rotating the deployment wheel in the reverse direction from deployment until the outer shaft fully covers the prestent as shown by the delivery system marker band.

   Note: The prestent can be recaptured and redeployed one time. If a second recapture of the partially deployed prestent is performed, remove and replace the device.

   Note: Several rotations of the deployment wheel may be necessary before the Alterra begins to be recaptured.

   CAUTION: Do not overdrive the outer shaft onto the tapered tip when recapturing the prestent. This may cause the delivery system to cinch down on the guidewire preventing independent movement of the delivery system and guidewire.

   CAUTION: Recapturing and redeploying a prestent more than one time may impact implant integrity.

   CAUTION: Recapturing a prestent that has been deployed more than 65% may cause system damage.

9. After achieving an acceptable position, completely deploy the prestent by continuing to rotate the deployment wheel until the delivery system marker band is beyond the prestent connector.
10. Confirm release of prestent.

CAUTION: Failure to identify release of the prestent connector tabs from the prestent connector may lead to prestent embolization during removal of the Alterra delivery system.

7.4 System Removal

1. Slowly retract the system through the prestent. Remove the delivery system.

CAUTION: Ensure that the tapered tip and delivery system do not interfere with the prestent upon removal to prevent movement of the prestent.

2. Assess Alterra prestent stability by evaluating apices engagement in surrounding tissue, wall apposition, and/or motion of prestent within the anatomy. If adequate stability is not noted, consider staging valve deployment after allowing sufficient time for prestent endothelialization.

CAUTION: Failure to identify prestent instability may lead to prestent migration/embolization when tracking interventional devices through the prestent.

8.0 How Supplied

The Edwards Alterra adaptive prestent system is supplied pouched and sterilized by e-beam sterilization.

8.1 Storage

The prestent and delivery system must be stored in a cool, dry place.

9.0 Magnetic Resonance (MR) Safety Information

MR Conditional

A person with the Edwards Alterra adaptive prestent, alone or with a deployed SAPIEN 3 transcatheter heart valve implant may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.	
Device Name	Edwards Alterra adaptive prestent in conjunction with Edwards SAPIEN 3 transcatheter heart valve
Static Magnetic Field Strength (B0)	1.5 tesla (T) or 3.0 tesla (T)
Maximum Spatial Field Gradient	3000 gauss/cm (30 T/m)
RF Excitation	Circularly Polarized (CP) / Multichannel-2 (MC-2)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2.0 W/kg
Scan Duration	2.0 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/ scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact.

10.0 Patient Information

Patient education brochures are provided to each site and should be given to the patient to inform them of the risks and benefits of the procedure and alternatives in adequate time before the procedure to be read and discussed with their physician. A copy of this brochure may also be obtained from Edwards Lifesciences by calling 1.800.822.9837. A patient implant card request form is provided with each prestent. After implantation, all requested information should be completed on this form. The lot number may be found on the package. The original form should be returned to the Edwards Lifesciences address indicated on the form and upon receipt, Edwards Lifesciences will provide an identification card to the patient.

11.0 Recovered Prestent and Device Disposal

The explanted prestent should be placed into a suitable container and returned to the company. Refrigeration is not necessary under these circumstances. Contact Edwards Lifesciences to request an explant kit.

Used devices may be handled and disposed of in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of these devices.

12.0 Clinical Studies

For clinical studies and results related to the use of the Edwards Alterra Adaptive Prestent System, refer to the Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent instructions for use.

2026-06
10043119005 A

Manufacturer
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone +1 949.250.2500
+1 800.424.3278
FAX +1 949.250.2525

Web IFU