Edwards SAPIEN 3 Transcatheter Pulmonary Valve System with Alterra Adaptive Prestent

Instructions for Use

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.

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 with 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) fluoroscopically visible radiopaque markers at the prestent waist help with positioning.

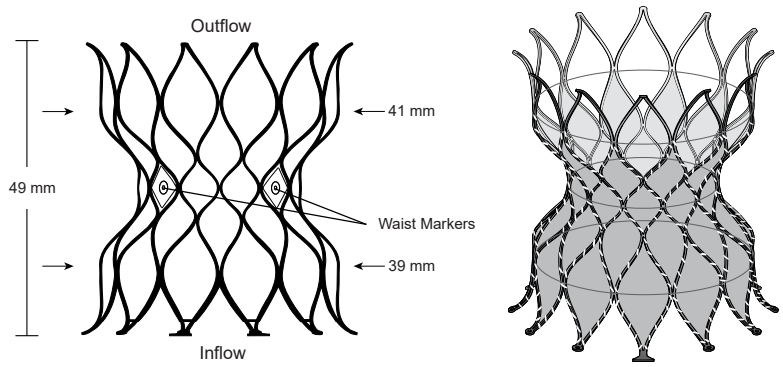


Figure 1: Edwards Alterra Adaptive Prestent

Table 1

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

Sizing recommendation for implanting the prestent in the right ventricular outflow tract/pulmonary valve (RVOT/PV) landing zone are provided in Table 2:

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

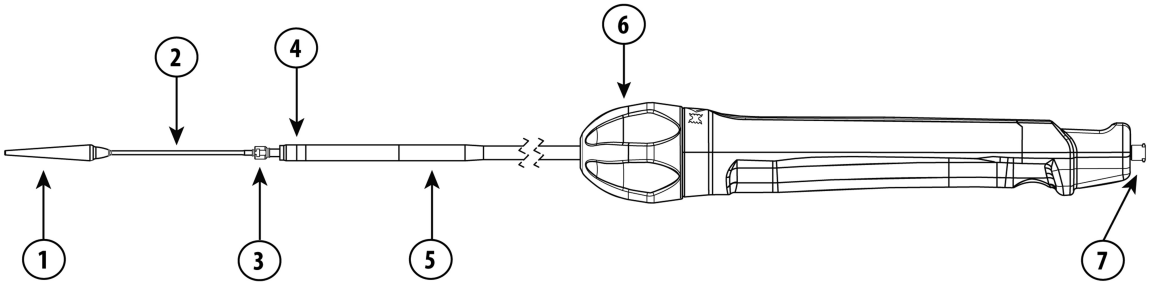
[1] Diameter range during systole

[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 fluoroscopically visible radiopaque 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.



1. Tapered Tip
2. Inner Shaft
3. Prestent Connector
4. Delivery System Marker Band
5. Outer Shaft
6. Deployment Wheel
7. Guidewire Lumen/Flush Port

Figure 2: Edwards Alterra Delivery System

Additional Accessories

- **Edwards Sheath**

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

2.0 Intended Use

The bioprosthesis with prestent is intended for use in patients requiring pulmonary heart valve replacement. The delivery systems and accessories are intended to facilitate placement of the bioprosthesis and prestent via the transfemoral access approach.

3.0 Indications

The Edwards SAPIEN 3 transcatheter pulmonary valve system with Alterra adaptive prestent is indicated for use in the management of patients with pulmonary regurgitation who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for pulmonary valve replacement.

4.0 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.

5.0 Warnings

- The devices are designed, intended, and distributed STERILE 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.
- Assessment for coronary compression risk prior to implantation is essential to prevent the risk of severe patient harm.
- Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials may have an allergic reaction to these materials.
- Do not mishandle the delivery system or use the delivery system and accessory devices if the packaging sterile barriers and any components have been opened or damaged, cannot be flushed, or the expiration date has elapsed.
- The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting.

6.0 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.
- 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.
- 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

7.0 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
- Device dysfunction (regurgitation and/or stenosis)
- Aortic root distortion
- Embolic event: device fragments
- Mechanical failure of delivery system, and/or accessories

8.0 Directions for Use

8.1 System Compatibility

Table 3

Product Name	Model
Edwards Alterra adaptive prestent system[1]	29AP4045
Edwards eSheath+ introducer set[2]	916ESP

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

[2] Sheath provided by Edwards Lifesciences or equivalent

Additional Equipment:

- Balloon tip catheter
- Sizing balloons
- 20 cc syringe or larger
- 50 cc syringe or larger
- Standard cardiac catheterization lab equipment and supplies, and access to standard heart valve operating room equipment and supplies
- Fluoroscopy (bi-plane, fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Exchange length 0.035 in (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 heart valve system.*

8.2 Device Handling and Preparation

Follow sterile technique during device preparation and implantation.

8.2.1 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.

8.3 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 and echocardiographic 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 fluoroscopically visible 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 adaptive prestent pausing at approximately 30%, 50%, and 65% to assess for Alterra adaptive prestent 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 adaptive prestent 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.

8.4 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.

9.0 How Supplied

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

9.1 Storage

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

10.0 MR Safety

MR Conditional

Non-clinical testing has demonstrated that the Edwards Alterra adaptive prestent, alone or with a deployed SAPIEN 3 transcatheter heart valve, is MR Conditional. A patient can be scanned safely immediately after placement of this implant in an MR system meeting the following conditions:

- Static magnetic fields of 1.5 Tesla and 3.0 Tesla
- Spatial magnetic gradient field of 3000 Gauss/cm (30 T/m) or less
- Maximum MR system-reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (normal operating mode) scanning per sequence
- Gradient system is in normal operating mode

Under the scan conditions defined above, the Edwards Alterra adaptive prestent, alone or with a deployed SAPIEN 3 transcatheter heart valve, is expected to produce a maximum temperature rise of 4.0 °C or less after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 15 mm for gradient echo images when scanned using a 3.0 T MRI system. The artifact obscures the device lumen in spin and gradient echo images.

The delivery system has not been evaluated for MR compatibility and is considered MR unsafe.

11.0 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 is provided with each prestent. After implantation, please complete all requested information and provide the implant card to the patient. The serial number is found on the package. This implant card allows patients to inform healthcare providers what type of implant they have when they seek care.

12.0 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.

13.0 Qualitative and Quantitative Information related to the Alterra Prestent System

The device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight:

Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

For the Alterra adaptive prestent, the following table shows the qualitative and quantitative information on the materials and substances:

Table 4

Substance	CAS	Model Mass Range (mg)
Nickel	7440-02-0	430 - 450
Titanium	7440-32-6	337 - 359
Polyethylene terephthalate	25038-59-9	146
Polyethylene	9002-88-4	27.5
Tantalum	7440-25-7	9.68 - 9.70
Titanium dioxide	13463-67-7	0.319 - 0.613
Iron	7439-89-6	0 - 0.396
Cobalt	7440-48-4	0 - 0.395
Oxygen	7782-44-7	0 - 0.317

Substance	CAS	Model Mass Range (mg)
Carbon	7440-44-0	0 - 0.317
Niobium	3/1/7440	0 - 0.207
Antimony trioxide	1309-64-4	0.176
Chromium	7440-47-3	0 - 0.0789
Copper	7440-50-8	0 - 0.0789
Nitrogen	7727-37-9	0 - 0.0404
Hydrogen	1333-74-0	0 - 0.0396
Tungsten	7440-33-7	0 - 0.00485
Molybdenum	7439-98-7	0 - 0.00194
Erucamide	112-84-5	0.00149 - 0.00152
Silicon	7440-21-3	0 - 0.000485
4-Dodecylbenzenesulfonic acid	121-65-3	0.000160

14.0 Summary of Safety and Clinical Performance (SSCP)

The SSCP has been adapted in accordance with the clinical evaluation assessment. The SSCP contains a relevant summary of the same information.

Conformity with the Alterra platform of the performance requirements for safety, performance, acceptability of side-effects, usability, device lifetime, and acceptable benefit-risk profile has been established for the labelled indications.

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

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

Table 5

Product Name	Model	Basic UDI-DI
Edwards Alterra Adaptive Prestent	29AP4045	0690103D003AAP000ND
Edwards eSheath+ introducer set	916ESP	0690103D003S3E000NT

16.0 Expected Lifetime of the Device

The Edwards SAPIEN 3 transcatheter pulmonary valve system with Alterra adaptive prestent has been subjected to rigorous pre-clinical durability testing per the testing requirements and in clinical studies and post market studies. The valve with prestent has been successfully tested to 5 years of simulated wear. In addition, clinical data show durability with follow-up to 2 years. The actual lifetime performance is continuing to be studied and varies from patient to patient.

Symbol Legend

	English
REF	Reorder Number
#	Model Number
cm	Usable length
	Do not re-use
LOT	Lot Number
	Caution
	Consult instructions for use
eifu.edwards.com + 1 888 570 4016	Consult instructions for use on the website
	Do not use if package is damaged and consult instructions for use
	Exterior diameter
	Inner diameter
	Store in a cool, dry place
	Keep dry
	Keep away from sunlight
UDI	Unique Device Identifier
	Temperature limit
STERILE	Sterile
STERILE EO	Sterilized using ethylene oxide

	English
STERILE R	Sterilized using irradiation
2 STERILIZE	Do not resterilize
eSheath	eSheath compatibility
eSheath™	eSheath compatibility
	Single sterile barrier system
	Single sterile barrier system with protective packaging inside
QTY	Quantity
	Use-by date
SN	Serial Number
	Manufacturer
	Date of manufacture
EC REP	Authorized representative in the European Community/European Union
GWC	Guidewire compatibility
NP	Nominal Pressure
RBP	Rated burst pressure
	Recommended guidewire length
Sheath	Minimum sheath size
Catheter	Catheter shaft size

	English
	Importer
	Balloon diameter
	Balloon working length
20 mm	For use with size 20 mm Edwards transcatheter heart valve
23 mm	For use with size 23 mm Edwards transcatheter heart valve
26 mm	For use with size 26 mm Edwards transcatheter heart valve
29 mm	For use with size 29 mm Edwards transcatheter heart valve
MR	[Implant only] The implant device has been determined to be MR Conditional when used under the conditions listed in the instructions for use.
	Contents
	Non-pyrogenic
MD	Medical device
BIO	Contains biological material of animal origin
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Time & Temperature Sensitive
	Contains hazardous substances
SZ	Size

Note: Not all symbols may be included in the labeling of this product.

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