# Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System

# Edwards SAPIEN 3 and Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

# Edwards Commander Delivery System

## Instructions for Use

**Implantation of the transcatheter heart valve should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in balloon aortic valvuloplasty.**

**STERILE: The valve is supplied sterilized with glutaraldehyde solution. The delivery system, sheath, and crimper are supplied sterilized with ethylene oxide gas.**

## 1.0 Device Description

**Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System**

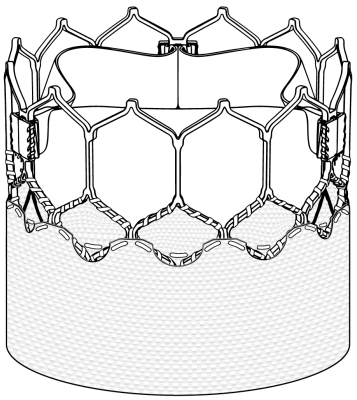
The Edwards SAPIEN 3 Ultra transcatheter heart valve (THV) system consists of the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves and delivery systems.

- **Edwards SAPIEN 3 Ultra Transcatheter Heart Valve - (Figure 1)**

The Edwards SAPIEN 3 Ultra transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) inner and outer fabric skirts. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

- **Edwards SAPIEN 3 Transcatheter Heart Valve - (Figure 2)**

The Edwards SAPIEN 3 transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

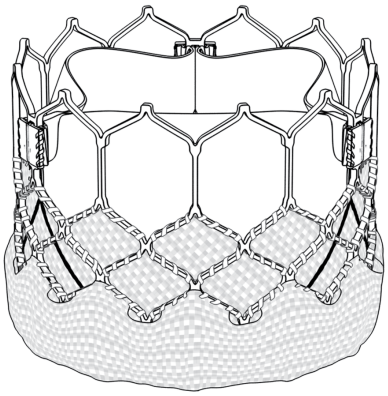


**9750TFX**

**Table 1**

| Valve Size | Valve Height |
|---|---|
| 20 mm | 15.5 mm |
| 23 mm | 18 mm |
| 26 mm | 20 mm |

**Figure 1: Edwards SAPIEN 3 Ultra Transcatheter Heart Valve**



**9600TFX**

**Table 2**

| Valve Size | Valve Height |
|---|---|
| 20 mm | 15.5 mm |
| 23 mm | 18 mm |
| 26 mm | 20 mm |
| 29 mm | 22.5 mm |

**Figure 2: Edwards SAPIEN 3 Transcatheter Heart Valve**

Sizing recommendations for implanting the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves in a native annulus are provided in the table below:

**Table 3**

| Native Valve Annulus Size (TEE) | Native Valve Annulus Size (CT) | | THV Size |
|---|---|---|---|
| | Area | Area Derived Diameter | |
| 16 - 19 mm | 273 - 345 $mm^2$ | 18.6 - 21 mm | 20 mm |
| 18 - 22 mm | 338 - 430 $mm^2$ | 20.7 - 23.4 mm | 23 mm |
| 21 - 25 mm | 430 - 546 $mm^2$ | 23.4 - 26.4 mm | 26 mm |
| 24 - 28 mm | 540 - 683 $mm^2$ | 26.2 - 29.5 mm | 29 mm |
| Valve size recommendations are based on native valve annulus size, as measured by transesophageal echocardiography (TEE) or computed tomography (CT). Patient anatomical factors and multiple imaging modalities should be considered during valve size selection.<br>**Note: Risks associated with undersizing and oversizing should be considered.** | | | |

Sizing recommendations for implanting the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves in a failing surgical bioprosthesis, except for the INSPIRIS RESILIA aortic valve sizes 19 - 25 mm, are provided in the table below:

**Table 4**

| Surgical Valve True Inner Diameter (ID) [1] | THV Size |
|---|---|
| 16.5 - 19.0 mm | 20 mm |
| 18.5 - 22.0 mm | 23 mm |
| 22.0 - 25.0 mm | 26 mm |
| 25.0 - 28.5 mm | 29 mm |

**Note: Surgical valve 'True ID' may be smaller than the labeled valve size. For THV-in-THV, the native valve annulus size should be considered to determine the appropriate THV size to implant. For a failing stentless bioprosthesis, consider sizing recommendations for a native annulus. The dimensions of the failed bioprosthesis should be determined so that the appropriate THV size can be implanted; and is best determined by using computed tomography, magnetic resonance imaging, and/or transesophageal echocardiography.**

Sizing recommendations for implanting the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves in a failing INSPIRIS RESILIA aortic surgical bioprosthesis in sizes 19 - 25 mm are provided in the table below:

**Table 5**

| INSPIRIS RESILIA Aortic Valve (model 11500A)* Labeled Size | THV Size |
|---|---|
| 19 mm | 20 mm or 23 mm |
| 21 mm | 23 mm or 26 mm |
| 23 mm | 26 mm |
| 25 mm | 29 mm |

*INSPIRIS RESILIA aortic valve model 11500A sizes 19 - 25 mm incorporate VFit technology which consists of expandable bands and fluoroscopically visible size markers designed for potential future valve-in-valve procedures. Clinical data are not currently available on the INSPIRIS RESILIA aortic valve Model 11500A valve-in-valve procedure or expansion feature. The impact of tissue ingrowth on the expansion feature of the INSPIRIS RESILIA aortic valve has not been assessed.

**WARNING: Do not perform stand-alone balloon aortic valvuloplasty procedures in the INSPIRIS RESILIA aortic valve for the sizes 19 - 25 mm. This may expand the valve causing aortic incompetence, coronary embolism or annular rupture.**

**Note: INSPIRIS RESILIA aortic valve model 11500A sizes 27 - 29 mm do not incorporate VFit technology and therefore follow the surgical valve True ID sizing provided in Table 4.**

**Note: Exact volume required to deploy the THV may vary depending on the bioprosthesis inner diameter. Factors such as calcification and pannus tissue growth may not be accurately visualized in imaging and may reduce the effective inner diameter of the failing bioprosthesis to a size smaller than the 'True ID'. These factors should be considered and assessed in order to determine the most appropriate THV size to achieve nominal THV deployment and sufficient anchoring. Do not exceed the rated burst pressure. See Table 6 for inflation parameters.**

- **Edwards Commander Delivery System (Figure 3)**

The Edwards Commander delivery system facilitates the placement of the bioprosthesis. It consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the valve. The delivery system includes a tapered tip to facilitate crossing of the valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the target location. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment. The inflation parameters for valve deployment are:

**Table 6**

| Model | Nominal Balloon Diameter | Nominal Inflation Volume | Rated Burst Pressure (RBP) |
|---|---|---|---|
| 9610TF20 | 20 mm | 11 ml | 7 atm |
| 9610TF23 | 23 mm | 17 ml | 7 atm |
| 9610TF26 | 26 mm | 23 ml | 7 atm |
| 9610TF29 | 29 mm | 33 ml | 7 atm |

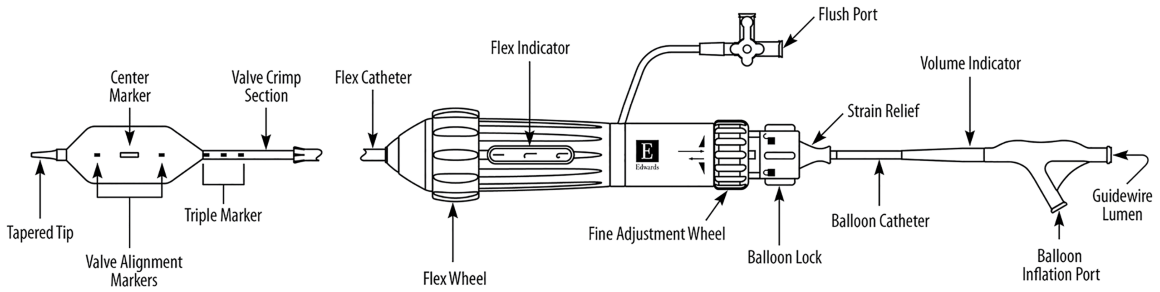



**Figure 3: Edwards Commander Delivery System**

**Additional Accessories**

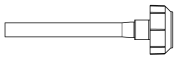


**Figure 4: Loader**

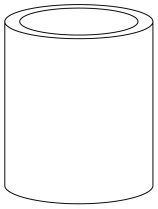


**Figure 5: Qualcrimp Crimping Accessory**

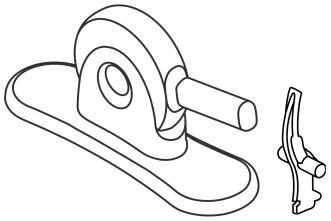


**Figure 6: Edwards Crimper and 2-piece Crimp Stopper**

- **Loader (Figure 4)**

The loader allows for the delivery of the crimped valve through the hemostasis valves of the sheath.

- **Qualcrimp Crimping Accessory (Figure 5)**

The Qualcrimp crimping accessory is used during crimping of the bioprosthesis.

- **Edwards Crimper (Figure 6)**

The Edwards crimper reduces the diameter of the valve to mount it onto the delivery system. The crimper is comprised of a housing and a compression mechanism that is closed with a handle located on the housing. A 2-piece crimp stopper is used to crimp the valve to its intended diameter.

- **Edwards Sheath**

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

## 2.0 Indications

1. The Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valve system is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a Heart Team, including a cardiac surgeon, to be appropriate for the transcatheter heart valve replacement therapy.
2. The Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valve system is indicated for patients with symptomatic heart disease due to failing (stenosed, insufficient, or combined) of a surgical or transcatheter bioprosthetic aortic valve or surgical bioprosthetic mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

## 3.0 Contraindications

The valve and delivery system are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

## 4.0 Warnings

- Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation.
- There may be an increased risk of stroke in transcatheter aortic valve replacement procedures, as compared to balloon aortic valvuloplasty or other standard treatments in high or greater risk patients.
- 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.
- Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch) and/or annular rupture.
- Accelerated deterioration of the valve due to calcific degeneration may occur in children, adolescents, or young adults and in patients with an altered calcium metabolism.
- Prior to delivery, the valve must remain hydrated at all times and cannot be exposed to solutions other than its shipping storage solution and sterile physiologic rinsing solution. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve.
- Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease.
- Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment.
- Do not use the valve if the tamper evident seal is broken, the storage solution does not completely cover the valve, the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed.
- Do not mishandle the delivery system or use it if the packaging or any components are not sterile, have been opened or are damaged (e.g. kinked or stretched), or the expiration date has elapsed.
- 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 injury could occur if the delivery system is not un-flexed prior to removal.

- Care should be exercised in patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials.
- 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.
- Valve 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 anticoagulation.
- Do not add or apply antibiotics to the storage solution, rinse solutions, or to the valve.
- Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets.

## 5.0 Precautions

- Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance.
- Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established.
- Glutaraldehyde may cause irritation of the skin, eyes, nose and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Material Safety Data Sheet available from Edwards Lifesciences.
- To maintain proper valve leaflet coaptation, do not overinflate the deployment balloon.
- Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis.
- Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; presence of Atrial Septal Occluder Device or calcium preventing safe transseptal access.
- Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation to avoid entrapment of the subvalvular apparatus.
- Safety and effectiveness have not been established for patients with the following characteristics/comorbidities:
  - Non-calcified aortic annulus
  - Severe ventricular dysfunction with ejection fraction < 20%
  - Congenital unicuspid aortic valve
  - Pre-existing prosthetic ring in any position
  - Severe mitral annular calcification (MAC), severe (> 3+) mitral insufficiency, or Gorlin syndrome
  - Blood dyscrasias defined as: leukopenia (WBC < 3000 cells/ml), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/ml), or history of bleeding diathesis or coagulopathy
  - Hypertrophic cardiomyopathy with or without obstruction (HOCM)
  - Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
  - A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated
  - Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta
  - Access characteristics that would preclude safe placement of the Edwards sheath, such as severe obstructive calcification or severe tortuosity
  - Bulky calcified aortic valve leaflets in close proximity to coronary ostia
  - A concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g. wireform frame fracture)
  - A partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium
- For left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential eSheath kinking, subclavian/axillary dissection and aortic arch damage.
- Ensure there is flow in Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor PA pressure in homolateral radial artery.
- Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

## 6.0 Potential Adverse Events

Potential risks associated with the overall procedure including potential access complications associated with standard cardiac catheterization, balloon valvuloplasty, the potential risks of conscious sedation and/or general anesthesia, and the use of angiography:

- Death
- Stroke/transient ischemic attack, clusters or neurological deficit
- Paralysis
- Permanent disability
- Respiratory insufficiency or respiratory failure
- Hemorrhage requiring transfusion or intervention
- Cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium or valvular structures that may require intervention
- Pericardial effusion or cardiac tamponade
- Thoracic bleeding
- Embolization including air, calcific valve material or thrombus
- Infection including septicemia and endocarditis
- Heart failure

- Myocardial infarction
- Renal insufficiency or renal failure
- Conduction system defect which may require a permanent pacemaker
- Arrhythmia
- Retroperitoneal bleed
- Arteriovenous (AV) fistula or pseudoaneurysm
- Reoperation
- Ischemia or nerve injury or brachial plexus injury
- Restenosis
- Pulmonary edema
- Pleural effusion
- Bleeding
- Anemia
- Abnormal lab values (including electrolyte imbalance)
- Hypertension or hypotension
- Allergic reaction to anesthesia, contrast media, or device materials
- Hematoma
- Syncope
- Pain or changes at the access site
- Exercise intolerance or weakness
- Inflammation
- Angina
- Heart murmur
- Fever

Additional potential risks associated with the use of the valve, delivery system, and/or accessories include:

- Cardiac arrest
- Cardiogenic shock
- Emergency cardiac surgery
- Cardiac failure or low cardiac output
- Coronary flow obstruction/transvalvular flow disturbance
- Device thrombosis requiring intervention
- Valve thrombosis
- Device embolization
- Device migration or malposition requiring intervention
- Left ventricular outflow tract obstruction
- Valve deployment in unintended location
- Valve stenosis
- Structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis)
- Device degeneration
- Paravalvular or transvalvular leak
- Valve regurgitation
- Hemolysis
- Device explants
- Nonstructural dysfunction
- Mechanical failure of delivery system, and/or accessories
- Non-emergent reoperation

## 7.0 Directions for Use

### 7.1 System Compatibility

**Table 7**

| Product Name | 20 mm System | 23 mm System | 26 mm System |
|---|---|---|---|
| | Model | | |
| Edwards SAPIEN 3 Ultra Transcatheter Heart Valve | 9750TFX20 | 9750TFX23 | 9750TFX26 |
| Edwards Commander Delivery System | 9610TF20 | 9610TF23 | 9610TF26 |
| Sheath provided by Edwards Lifesciences | | | |
| Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences | | | |
| Edwards Crimper | 9600CR | | |

**Table 8**

| Product Name | 20 mm System | 23 mm System | 26 mm System | 29 mm System |
|---|---|---|---|---|
| | Model | | | |
| Edwards SAPIEN 3 Transcatheter Heart Valve | 9600TFX20 | 9600TFX23 | 9600TFX26 | 9600TFX29 |
| Edwards Commander Delivery System | 9610TF20 | 9610TF23 | 9610TF26 | 9610TF29 |
| Sheath provided by Edwards Lifesciences | | | | |
| Inflation device, Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences | | | | |
| Edwards Crimper | 9600CR | | | |

Additional Equipment:

- Balloon catheter, per the discretion of the physician
- 20 cc syringe or larger (x2)
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)
- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and device preparation

**7.2 Valve Handling and Preparation**

Follow sterile technique during device preparation and implantation.

**7.2.1 Valve Rinsing Procedure**

Before opening the valve jar, carefully examine for evidence of damage (e.g. a cracked jar or lid, leakage, or broken or missing seals).

**CAUTION: Valves from containers found to be damaged, leaking, without adequate sterilant, or missing intact seals must not be used for implantation.**

1. Set up two (2) sterile bowls with at least 500 ml of sterile physiological saline to thoroughly rinse the glutaraldehyde sterilant from the valve.
2. Carefully remove the valve/holder assembly from the jar without touching the tissue. Verify the valve serial identification number with the number on the jar lid and record in the patient information documents. Inspect the valve for any signs of damage to the frame or tissue.
3. Rinse the valve as follows: Place the valve in the first bowl of sterile, physiological saline. Be sure the saline solution completely covers the valve and holder. With the valve and holder submerged, slowly agitate (to gently swirl the valve and holder) back and forth for a minimum of 1 minute. Transfer the valve and holder to the second rinsing bowl of sterile physiological saline and gently agitate for at least one more minute. Ensure the rinse solution in the first bowl is not used. The valve should be left in the final rinse solution until needed to prevent the tissue from drying.

   **CAUTION: Do not allow the valve to come into contact with the bottom or sides of the rinse bowl during agitation or swirling in the rinse solution. Direct contact between the identification tag and valve is also to be avoided during the rinse procedure. No other objects should be placed in the rinse bowls. The valve should be kept hydrated to prevent the tissue from drying.**

**7.2.2 Prepare the Components**

Refer to the Edwards sheath, Edwards Crimper and Edwards Balloon Catheter instructions for use for device preparation.

1. Visually inspect all components for damage. Ensure the Edwards Commander delivery system is fully unflexed and the balloon catheter is fully advanced in the flex catheter.

   **WARNING: To prevent possible damage to the balloon shaft, ensure that the proximal end of the balloon shaft is not subjected to bending.**
2. Flush the flex catheter.
3. Carefully remove the distal balloon cover from the delivery system.
4. Remove the stylet from the distal end of the guidewire lumen and set aside. Flush the guidewire lumen with heparinized saline and insert the stylet back into the distal end of the guidewire lumen.

   **Note: Failure to insert the stylet back into the guidewire lumen may result in damage to the lumen during crimping process.**
5. Place the delivery system into the default position and make sure that the flex catheter tip is covered by the proximal balloon cover. Unscrew the loader cap from the loader tube and flush the loader cap. Place the loader cap over the proximal balloon cover and onto the flex catheter with the inside of the cap oriented towards the distal tip.
6. Fully advance the balloon catheter in the flex catheter.
   Peel off the proximal balloon cover over the blue section of the balloon shaft.
7. Attach a 3-way stopcock to the balloon inflation port. Partially fill a 50 cc or larger syringe with 15-20 ml diluted contrast medium and attach to the 3-way stopcock.
8. Fill the inflation device provided by Edwards Lifesciences with excess volume relative to the indicated inflation volume. Lock the inflation device and attach to the 3-way stopcock.
9. Close the 3-way stopcock to the inflation device provided by Edwards Lifesciences and de-air the system using the 50 cc or larger syringe. Slowly release the plunger and leave zero-pressure in the system.

   **WARNING: Ensure there is no residual fluid left in the balloon to avoid potential difficulty with valve alignment during the procedure.**
10. Close the stopcock to the delivery system. By rotating the knob of the inflation device provided by Edwards Lifesciences, transfer the contrast medium into the syringe to achieve the appropriate volume required to deploy the valve.

11. Close the stopcock to the 50 cc or larger syringe. Remove the syringe. Verify that the inflation volume is correct and lock the inflation device provided by Edwards Lifesciences.

    **CAUTION: Maintain the inflation device provided by Edwards Lifesciences in the locked position until valve deployment.**

**7.2.3 Mount and Crimp the Valve on the Delivery System**

1. Set up two (2) additional sterile bowls with at least 100 ml of sterile physiological saline to thoroughly rinse the Qualcrimp crimping accessory.
2. Completely submerge the Qualcrimp crimping accessory in the first bowl and gently compress it to ensure complete saline absorption. Slowly swirl the Qualcrimp crimping accessory for a minimum of 1 minute. Repeat this process in the second bowl.
3. Remove the valve from the holder and remove the ID tag.
4. Attach the 2-piece crimp stopper to the base of the crimper and click into place.
5. With the crimper in the open position, gently place the valve into the crimper aperture. Gradually crimp the valve until it fits into the Qualcrimp crimping accessory.
6. Place the Qualcrimp crimping accessory over the valve making sure the valve is parallel to the edge of the Qualcrimp crimping accessory.
7. Place the valve and Qualcrimp crimping accessory in crimper aperture. Insert the delivery system coaxially within the valve on the Valve Crimp Section (2-3 mm distal to the balloon shaft) with the orientation of the valve on the delivery system as described below:

    **Antegrade approach:** Inflow (outer skirt end) of the valve towards the proximal end of the delivery system.

    **Retrograde approach:** Inflow (outer skirt end) of the valve towards the distal end of the delivery system.
8. Crimp the valve until it reaches the Qualcrimp stop located on the 2-piece Crimp Stopper.
9. Gently remove the Qualcrimp crimping accessory from the valve. Remove the Qualcrimp stop from the Final Stop, leaving the Final Stop in place.
10. Fully crimp the valve until it reaches the Final Stop.

    **Note: Ensure that the Valve Crimp Section remains coaxial within the valve.**
11. Repeat the full crimp of the valve two more times for a total of three full crimps.
12. Pull the balloon shaft and lock in the default position.
13. Flush the loader with heparinized saline. Immediately advance the valve into the loader until it is completely inside the loader.

    **CAUTION: To prevent possible leaflet damage, the valve should not remain fully crimped and/or in the loader for over 15 minutes.**
14. Attach the loader cap to the loader, re-flush the delivery system through the flush port and close the stopcock to the delivery system.

    Remove the stylet and flush the guidewire lumen of the delivery system.

    **CAUTION: Keep the valve hydrated until ready for implantation.**

    **CAUTION: The physician must verify correct orientation of the valve prior to its implantation.**

**7.3 Valvuloplasty and Valve Delivery**

Valvuloplasty and valve delivery should be performed under conscious sedation 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 during the procedure.

**Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets.**

**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.**

**CAUTION: Procedure may require an arterial cut-down with surgical closure of the puncture site due to the size of the arteriotomy.**

**7.3.1 Baseline Parameters**

1. Perform an angiogram with fluoroscopic view perpendicular to the valve.
2. Evaluate the distance of the left and right coronary ostia from the aortic annulus in relation to the valve frame height.
3. Introduce a pacemaker (PM) lead and position appropriately.
4. Set the stimulation parameters to obtain 1:1 capture, and test pacing.

**7.3.2 Valvuloplasty**

Pre-dilate the native aortic valve, per the discretion of the physician, according to the instructions for use for the selected balloon aortic valvuloplasty catheter.

**CAUTION: Valve implantation should not be carried out if the balloon cannot be fully inflated during valvuloplasty.**

**7.3.3 Valve Delivery**

1. Gain access using standard catheterization techniques.
2. Prepare and insert the Edwards sheath. Refer to the Edwards sheath IFU for information on device preparation and handling.
3. Insert the loader into the sheath until the loader stops.
4. Advance the Edwards Commander delivery system, with the Edwards logo in the proper orientation (the delivery system articulates in a direction opposite from the flush port), through the sheath until the valve exits the sheath.

    **Note: Maintain the proper orientation of the flex catheter throughout the procedure. The delivery system articulates in a direction opposite from the flush port.**

    **CAUTION: For iliofemoral access, the valve should not be advanced through the sheath if the sheath tip is not past the bifurcation.**

    **CAUTION: To prevent possible leaflet damage, the valve should not remain in the sheath for over 5 minutes.**
5. In a straight section of the vasculature, initiate valve alignment by disengaging the Balloon Lock and pulling the balloon catheter straight back until part of the Warning Marker is visible. Do not pull past the Warning Marker.

    **WARNING: To prevent possible damage to the balloon shaft, ensure that the proximal end of the balloon shaft is not subjected to bending.**

    Engage the Balloon Lock.

    Use the Fine Adjustment Wheel to position the valve between the valve alignment markers.

**CAUTION: Do not turn the Fine Adjustment Wheel if the Balloon Lock is not engaged.**

**WARNING: Do not position the valve past the distal Valve Alignment Marker. This will prevent proper valve deployment.**

**CAUTION: Maintain guidewire position during valve alignment.**

**WARNING: If valve alignment is not performed in a straight section, there may be difficulties performing this step which may lead to delivery system damage and inability to inflate the balloon. Utilizing alternate fluoroscopic views may help with assessing curvature of the anatomy. If excessive tension is experienced during valve alignment, repositioning the delivery system to a different straight section of the aorta and relieving compression (or tension) in the system will be necessary.**

6. Advance the catheter and use the flex wheel, if needed, and cross the valve.

**Note: Verify the orientation of the Edwards logo to ensure proper articulation. The delivery system articulates in a direction opposite from the flush port.**

7. Disengage the Balloon Lock and retract the tip of the Flex Catheter to the center of the Triple Marker. Engage the Balloon Lock.
8. Verify the correct position of the valve with respect to the target location.
9. As necessary, utilize the Flex Wheel to adjust the co-axiality of the valve and the Fine Adjustment Wheel to adjust the position of the valve.
10. Before deployment, ensure that the valve is correctly positioned between the Valve Alignment Markers and the Flex Catheter tip is over the Triple Marker.
11. Begin valve deployment:
    - Unlock the inflation device provided by Edwards Lifesciences.
    - Begin rapid pacing; once systolic blood pressure has decreased to 50 mmHg or below, balloon inflation can commence.
    - Deploy the valve by inflating the balloon with the entire volume in the inflation device provided by Edwards Lifesciences, hold for 3 seconds and confirm that the barrel of the inflation device is empty to ensure complete inflation of the balloon.
    - Deflate the balloon. When the balloon catheter has been completely deflated, turn off the pacemaker.

#### 7.3.4 System Removal

1. Unflex the delivery system while retracting the device, if needed. Verify that the Flex Catheter tip is locked over the Triple Marker. Retract the loader to the proximal end of the delivery system and remove the delivery system from the sheath.

**Note: For subclavian-axillary approach, keep delivery system inside sheath until ready to remove all devices as one unit.**

**CAUTION: Patient injury could occur if the delivery system is not unflexed prior to removal.**

2. Remove all devices when the ACT level is appropriate. Refer to the Edwards sheath instructions for use for device removal.
3. Close the access site.

## 8.0 How Supplied

STERILE: The valve is supplied sterilized with glutaraldehyde solution. The delivery system is supplied sterilized with ethylene oxide gas.

#### 8.1 Storage

The valve must be stored at 10 °C to 25 °C (50 °F to 77 °F). Each jar is shipped in an enclosure containing a temperature indicator to detect exposure of the valve to extreme temperature.

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

## 9.0 MR Safety


**MR Conditional**

Non-clinical testing has demonstrated that the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves are MR Conditional. A patient with this device can be scanned safely, immediately after placement of this device under the following conditions:

- Static magnetic field of 1.5 T or 3.0 T
- Maximum spatial gradient field of 2500 gauss/cm (25 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves are expected to produce a maximum temperature rise of 3.0 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 14.5 mm from the implant for spin echo images and 30 mm for gradient echo images when scanned in a 3.0 T MRI system. The artifact obscures the device lumen in gradient echo images.

The implant has not been evaluated in MR systems other than 1.5 T or 3.0 T.

For valve-in-valve implantation or in the presence of other implants, please refer to the MRI safety information for the surgical valve or other devices prior to MR imaging.

## 10.0 Patient Information

A patient registration form is provided with each THV. After implantation, please complete all requested information. The serial number may be found on the package and on the identification tag attached to the THV. Return the original form to the Edwards Lifesciences address indicated on the form and provide the temporary identification card to the patient prior to discharge.

## 11.0 Recovered Valve and Device Disposal

The explanted valve should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to the company. Refrigeration is not necessary under these circumstances. Contact Edwards Lifesciences to request an Explant Kit.

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

These products are manufactured and sold under one or more of the following US patent(s): US Patent No. 7,530,253; 7,780,723; 7,895,876; 8,382,826; 8,591,575; 8,690,936; 8,790,387; 9,061,119; 9,301,840; 9,301,841; 9,339,384; 9,393,110; and corresponding foreign patents.

## Symbol Legend

| | English |
|---|---|
| REF | Catalogue Number |
| REF | Catalogue Number |
| # | Quantity |
| I | Minimum introducer size |
| cm | Usable length |
| | Do not re-use |
| LOT | Lot Number |
| | Caution |
| | Attention, See Instructions for Use |
| | Do not use if package is damaged |
| | Do not use if package is opened or damaged. |
| | Exterior diameter |
| | Inner diameter |
| | Keep dry |
| | Store in a cool, dry place |
| UDI | Unique Device Identifier |
| | Temperature Limit |
| STERILE | Sterile |
| STERILE EO | Sterilized using ethylene oxide |
| STERILE R | Sterilized using irradiation |
| STERILE | Sterilized using steam or dry heat |

| | English |
|---|---|
| Axela™ | Axela Compatibility |
| | Use-by date |
| SN | Serial Number |
| SN | Serial Number |
| | Manufacturer |
| | Date of manufacture |
| EC REP | Authorized representative in the European Community |
| GW | Recommended guidewire size |
| SZ | Size |
| GWC | Guidewire compatibility |
| NP | Nominal pressure |
| RBP | Rated burst pressure |
| STRAIGHT | Straight |
| DEFLECTED | Deflected |
| | Recommended guidewire length |
| Sheath | Minimum sheath size |
| Catheter | Catheter shaft size |
| | Balloon diameter |
| | Balloon working length |
| | Consult instructions for use |
| eifu.edwards.com +1 888 570 4016 | Consult instructions for use on the website |

| | English |
|---|---|
| | Type CF applied part |
| | Defib Proof Type CF applied part |
| 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 |
| 23 mm 26 mm | For use with size 23 mm or size 26 mm Edwards transcatheter heart valve |
| NON STERILE | Non-sterile |
| PHT | Contains phthalates |
| MR | MR Conditional |
| | Contents |
| | Nonpyrogenic |
| IPX1 | Drip proof equipment |
| | Contents sterile and fluid path nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize. |
| | Contents sterile and nonpyrogenic if package is unopened and undamaged, Do not use if package is opened or damaged. Do not resterilize. |
| Rx only | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. |
| eSheath | eSheath compatibility |
| eSheath™ | eSheath compatibility |
| | Separate collection for batteries in accordance with EC Directive 2006/66/EC |

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

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