Edwards SAPIEN 3 Ultra System
Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve
Edwards Commander Delivery System
Transfemoral, Subclavian / Axillary

Instructions for Use

Implantation of transcatheter heart valves should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in standard catheterization techniques. It is at the physician's discretion to choose the appropriate access route to implant the THV based on the patient anatomy and associated risks.

1.0 Device Description

Edwards SAPIEN 3 Ultra System

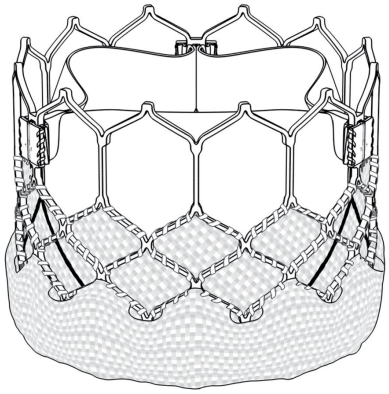
The Edwards SAPIEN 3 Ultra system consists of the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valves and delivery systems.

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

The Edwards SAPIEN 3 Ultra transcatheter heart valve (THV) 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 (THV) 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.

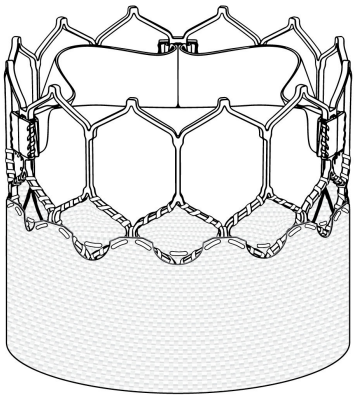


9600TFX

Table 1

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

Figure 1: Edwards SAPIEN 3 Transcatheter Heart Valve



9750TFX

Table 2

Valve Size	Valve Height (mm)
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm

Figure 2: Edwards SAPIEN 3 Ultra Transcatheter Heart Valve

The THV is intended to be implanted in a native annulus size range associated with the three-dimensional area of the aortic annulus measured at the basal ring during systole as provided in Table 3:

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 - 21.0 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

THV 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 THV size selection.

Note: Risks associated with undersizing and oversizing should be considered to minimize the risk of paravalvular leak, migration, and/or annular rupture.

*Due to limitations in two-dimensional images, 2-D TEE imaging should be supplemented with 3-D area measurements.

Sizing recommendations for implanting the THV in a failing surgical and transcatheter bioprosthesis, except for the INSPIRIS RESILIA aortic valve sizes 19 - 25 mm, as provided in the table 4:

Table 4

Surgical Valve True Inner Diameter (ID)[1]	THV-in-THV (Native Valve Annulus Size)	THV Size
16.5 - 19.0 mm	18.6 - 21.0 mm	20 mm
18.5 - 22.0 mm	20.7 - 23.4 mm	23 mm
22.0 - 25.0 mm	23.4 - 26.4 mm	26 mm
25.0 - 28.5 mm	26.2 - 29.5 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 THV in a failing INSPIRIS RESILIA aortic surgical bioprosthesis in sizes 19 - 25 mm are provided in the table 5 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 inflation parameters in Table 6.

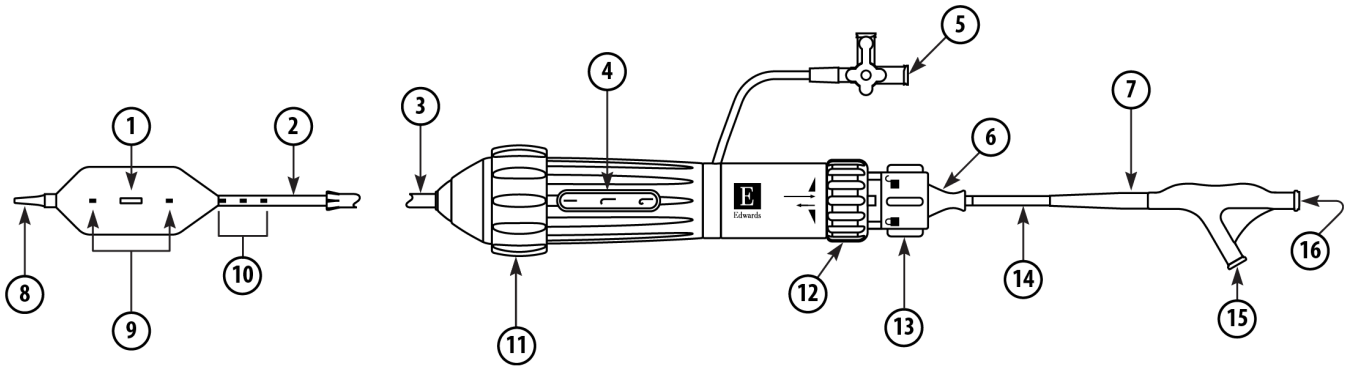
- **Edwards Commander Delivery System (Figure 3)**

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 THV. 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



1. Center Marker
2. Valve Crimp Section
3. Flex Catheter
4. Flex Indicator
5. Flush Port
6. Strain Relief
7. Volume Indicator
8. Tapered Tip
9. Valve Alignment Markers
10. Triple Marker
11. Flex Wheel
12. Fine Adjustment Wheel
13. Balloon Lock
14. Balloon Catheter
15. Balloon Inflation Port
16. Guidewire Lumen

Figure 3: Edwards Commander Delivery System

Additional Accessories

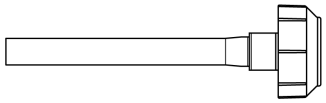


Figure 4: Loader

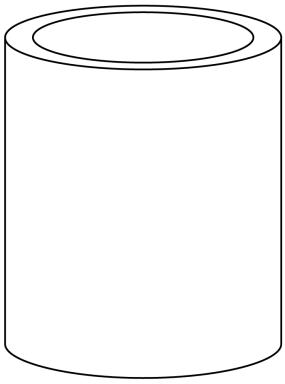


Figure 5: Qualcrimp Crimping Accessory

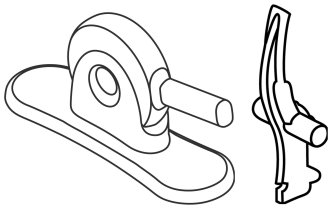


Figure 6: Crimper and 2-piece Crimp Stopper

- **Edwards Sheath**

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

- **Qualcrimp Crimping Accessory**

The Qualcrimp crimping accessory is used during THV crimping (Figure 5).

- **Loader**

The loader is used to aid insertion of the delivery system into the sheath (Figure 4).

- **Edwards Crimper and Crimp Stopper**

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. (Figure 6)

- **Inflation Device**

An inflation device with locking mechanism is used during valve deployment.

Note: For proper volume sizing, the delivery system must be used with the inflation device provided by Edwards Lifesciences.

2.0 Intended Use

The devices are intended for use in patients requiring heart valve replacement.

3.0 Indications

- 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.
- 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).

4.0 Contraindications

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

5.0 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 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.
- 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 THV may occur 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.
- The physician must verify correct orientation of the THV prior to its implantation.
- 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.
- Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, bovine tissue, and/or polymeric materials may have an allergic reaction to these 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.
- Access characteristics such as severe obstructive or circumferential calcification, severe tortuosity, vessel diameters less than 5.5 mm (for size 20, 23 and 26 mm SAPIEN 3/SAPIEN 3 Ultra transcatheter heart valve) or 6.0 mm (for 29 mm SAPIEN 3 transcatheter heart valve) may preclude safe placement of the sheath and should be carefully assessed prior to the procedure.
- Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, to minimize the risk of valve thrombosis or thromboembolic events, as determined by their physicians. 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.
- Subclavian/axillary access carries a higher risk of stroke/TIA than femoral access. Severe obstructive calcification, severe tortuosity or vessel diameters less than the minimum recommended are characteristics that may make subclavian/axillary access preferable to femoral access and the risks acceptable.

6.0 Precautions

- Long-term durability has not been established for the valve. Regular medical follow-up is advised to evaluate valve performance.
- 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.
- Do not overinflate the deployment balloon, as this may prevent proper valve leaflet coaptation and thus impact valve functionality.
- 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.

- The safety and effectiveness of the THV implantation has 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
  - Hypertrophic cardiomyopathy with or without obstruction
  - Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
  - 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.
  - Bulky calcified aortic valve leaflets in close proximity to coronary ostia.
  - Aortic stenosis characterized by a combination of AV low flow, low gradient
  - 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
- If a significant increase in resistance occurs when advancing the catheter through the vasculature, stop advancement and investigate the cause of resistance before proceeding. Do not force passage, as this could increase the risk of vascular complications. As compared to SAPIEN 3 system advancement force may be higher with the use of SAPIEN 3 Ultra transcatheter heart valve in tortuous/challenging vessel anatomies.
- Based on the treating physician's consideration of risks and benefits, the SAPIEN 3 valve may be implanted in relatively young patients, although the longer-term durability is still the subject of ongoing clinical research.
- Patients with pre-existing mitral valve devices should be carefully evaluated before implantation of the THV to ensure proper THV positioning and deployment.
- 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.
- The risks of subclavian/axillary access are low and acceptable and should be considered when the physician determines an increased risk associated with transfemoral access characteristics, such as severe obstructive calcification, severe tortuosity or vessel diameters less than the minimum recommended.
- For left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage.
- For left / right axillary approach, ensure there is flow in Left Internal Mammary Artery (LIMA) / Right Internal Mammary Artery (RIMA), respectively, during procedure and monitor pressure in homolateral radial artery.

7.0 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:

- Abnormal lab values (including electrolyte imbalance)
- Allergic reaction to anesthesia, contrast media, device materials or bovine pericardial tissue
- Anemia
- Arteriovenous (AV) fistula or pseudoaneurysm
- Angina
- Arrhythmias including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Bleeding, bleeding requiring transfusion or intervention
- Cardiogenic shock
- Conduction system defect which may require a permanent pacemaker
- Death
- Cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium or valvular structures, that may require intervention
- Embolization including air, calcific valve material or thrombus
- Exercise intolerance or weakness
- Fever
- Heart failure
- Heart murmur
- Hematoma
- Hemorrhage requiring transfusion or intervention
- Hypertension or hypotension
- Infection including septicemia and endocarditis
- Inflammation
- Ischemia or nerve injury or brachial plexus injury or compartment syndrome
- Myocardial ischemia or infarction
- Pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site
- Paralysis
- Permanent disability
- Pericardial effusion or cardiac tamponade
- Pleural effusion
- Pulmonary edema
- Renal insufficiency or renal failure
- Respiratory insufficiency or respiratory failure
- Reoperation

- Restenosis
- Retroperitoneal bleed
- Stroke/transient ischemic attack, clusters or neurological deficit
- Syncope
- Thoracic Bleeding
- Vasovagal response
- Vessel thrombosis/occlusion

Additional potential risks associated with the TAVR procedure, the bioprosthesis, and the use of its associated devices and accessories include:

- Allergic/immunologic reaction to the implant
- Cardiac arrest
- Cardiac failure or low cardiac output
- Coronary flow obstruction/transvalvular flow disturbance
- Device degeneration
- Device embolization
- Device explants
- Device thrombosis requiring intervention
- Emergency cardiac surgery
- Hemolysis
- Injury to mitral valve
- Left ventricular outflow tract obstruction
- Mechanical failure of delivery system, and/or accessories, including balloon rupture and tip separation
- Non-emergent reoperation
- Nonstructural dysfunction
- Paravalvular or transvalvular leak
- Structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture linedisruption of components of the prosthetic valve, thickening, stenosis)
- Valve deployment in unintended location
- Valve migration or malposition requiring intervention
- Valve regurgitation
- Valve stenosis
- Valve thrombosis
- Vessel spasm

It is recommended that patients be briefed on warnings, precautions, contraindications, measures to be taken and limitations of use associated with the THV.

8.0 Directions for Use

8.1 System Compatibility

Table 7

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 transcatheter heart valve	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
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			
*If using the eSheath introducer set, use 16F or equivalent				

Table 8

Product Name	20 mm System	23 mm System	26 mm System
	Model		
Edwards SAPIEN 3 Ultra transcatheter heart valve	9750TFX (20 mm)	9750TFX (23 mm)	9750TFX (26 mm)
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		

Additional Equipment

- Balloon catheter per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock
- Standard cardiac catheterization lab equipment and supplies, and access to standard heart valve operating room equipment and supplies
- 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 THV and device preparation

8.2 Valve Handling and Preparation

Follow sterile technique during device preparation and implantation.

8.2.1 THV 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: If the container is found to be damaged, leaking, without adequate sterilant, or missing intact seals, the THV must not be used for implantation, as sterility may be compromised.

Step	Procedure
1	Set up two (2) sterile bowls with at least 500 ml of sterile physiological saline to thoroughly rinse the THV.
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 THV as follows: • Place the THV in the first bowl of sterile, physiological saline. Be sure the saline solution completely covers the THV 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 THV and holder to the second rinsing bowl of 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.**

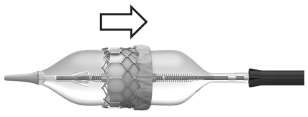
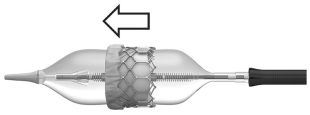
8.3 Valve Handling and Preparation

8.3.1 Prepare the System

Step	Procedure
1	Visually inspect all the components for damage. Ensure the 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 delivery system with heparinized saline.
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.
6	Unscrew the loader cap from the loader and flush the loader cap with heparinized saline.
7	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. Fully advance the balloon catheter in the flex catheter. Peel off the proximal balloon cover over the blue section of the balloon shaft.
8	Attach a 3-way stopcock to the balloon inflation port. Fill a 50 cc or larger syringe with 15 - 20 ml diluted contrast medium and attach to the 3-way stopcock.
9	Fill the inflation device provided by Edwards Lifesciences with excess volume of diluted contrast medium relative to the indicated inflation volume. Lock and attach to the 3-way stopcock. Close stopcock to the inflation device.
10	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.** Close stopcock to the delivery system.

Step	Procedure
11	Rotate the knob of the inflation device provided by Edwards Lifesciences to remove the contrast medium into the syringe and achieve the appropriate volume required to deploy the THV. Close the stopcock to the 50 cc or larger syringe. Remove the syringe.
12	Verify that the inflation volume in the inflation device 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 THV deployment to minimize the risk of premature balloon inflation and subsequent improper THV deployment.**

8.3.2 Mount and Crimp the THV on the Delivery System

Step	Procedure
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 a bowl of 100 ml physiological saline. Gently compress until fully saturated. Swirl for a minimum of 1 minute. Repeat this process in a second bowl.
3	Remove the THV from the holder and remove the ID tag.
4	Rotate the crimper handle until the aperture is fully open. Attach the 2-piece crimp stopper to the base of the crimper and click into place.
5	If necessary, partially crimp the THV in the crimper until it snugly fits inside the Qualcrimp crimping accessory. **Note: Partial crimping is not necessary for the 20 mm valve.**
6	Place the Qualcrimp crimping accessory over the THV aligning the edge of the Qualcrimp crimping accessory with the outflow of the THV.
7	Place the THV and Qualcrimp crimping accessory in crimper aperture. Insert the delivery system coaxially within the THV 2-3 mm distal to the blue balloon shaft (in the valve crimp section) of the delivery system 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	Center the balloon shaft coaxially within the THV. Crimp the THV until it reaches the Qualcrimp stop.
9	Gently remove the Qualcrimp crimping accessory from the THV. Remove the Qualcrimp stop from the crimp stopper, leaving the final stop in place.
10	Center the THV within the crimper aperture. Fully crimp the THV until it reaches the final stop and hold for 5 seconds. Repeat this crimp step two (2) more times for a total of 3 crimps. **Note: Ensure that the valve crimp section is coaxial within the THV.**
11	Pull the balloon shaft and engage the balloon lock so the delivery system is in default position.
12	Flush the loader with heparinized saline. Immediately advance the THV 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.**
13	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 THV hydrated until ready for implantation to prevent damage to the leaflets which may impact valve functionality.** **WARNING: The physician must verify correct orientation of the THV prior to its implantation to prevent the risk of severe patient harm.**

8.4 Native Valve Predilation and THV Delivery

Native valve predilation and THV 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: Contrast media usage should be monitored to reduce the risk of renal injury.

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

8.4.1 Baseline Parameters

Step	Procedure
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.

8.4.2 Native Valve Predilation

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 balloon cannot be fully inflated during valvuloplasty.

8.4.3 THV Delivery

Step	Procedure
1	Gain access using standard catheterization techniques. If necessary, predilate the vessel.
2	Prepare and insert the Edwards sheath. Refer to the Edwards sheath IFU for information on device preparation and handling.
3	Introduce the sheath per its instructions for use.
4	Insert the loader into the sheath until the loader stops.
5	Advance the delivery system until the THV exits the sheath. **CAUTION: For iliofemoral access, the THV should not be advanced through the sheath if the sheath tip is not past the bifurcation to minimize the risk of vessel damage.** **CAUTION: The THV should not remain in the sheath for over 5 minutes as leaflet damage may result and impact valve functionality.**
6	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.** **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 vasculature and relieving compression (or tension) in the system will be necessary.** **CAUTION: Maintain guidewire position during valve alignment to prevent loss of guidewire position.**
7	Engage the balloon lock. Utilize the fine adjustment wheel to position the THV 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 THV past the distal valve alignment marker to minimize the risk of improper THV deployment or THV embolization.**
8	Advance the catheter over the arch and cross the valve, utilizing the flex wheel if needed. **Note: Verify the orientation of the Edwards logo to ensure proper articulation.** **Note: The delivery system articulates in a direction opposite from the flush port.**
9	Disengage the balloon lock and retract the tip of the flex catheter to the center of the triple marker. Engage the balloon lock.
10	Verify the correct position of the delivery system and valve with respect to the target location.
11	As necessary, utilize the flex wheel to adjust the co-axiality of the THV and the fine adjustment wheel to adjust the position of the THV.
12	Before deployment, ensure that the THV is correctly positioned between the valve alignment markers and the flex catheter tip is over the triple marker.
13	Begin THV deployment: a) Unlock the balloon inflation device. b) Begin rapid pacing; once systolic blood pressure has decreased to 50 mmHg or below, balloon inflation can commence. c) Using slow controlled inflation, deploy the THV with the entire volume in the inflation device, hold for 3seconds 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.

8.4.4 System Removal

Step	Procedure
1	Unflex the delivery system while retracting the device. Verify that the flex catheter tip is locked over the triple marker. Retract the loader to the proximal end of the delivery system. Remove the delivery system from the sheath. **Note: To minimize bleeding for subclavian/axillary approach, keep delivery system inside of the sheath until ready to remove all devices as one unit.** **CAUTION: Completely unflex the delivery system prior to removal to minimize the risk of vascular injury.**
2	Refer to the Edwards sheath instructions for use for device removal.

8.5 Verification of Prosthetic Valve Position and Measurements

Measure and record hemodynamic parameters

Step	Procedure
1	Perform an angiogram to evaluate device performance and coronary patency, where applicable.
2	Measure and record the transvalvular pressure gradients.
3	Remove all devices when the ACT level is appropriate (e.g., reaches < 150 sec). Refer to the introducer sheath instructions for use for device removal.
4	Close the access site.

9.0 How Supplied

STERILE: The valve is supplied sterilized with glutaraldehyde solution.

The delivery system and accessories are supplied sterilized by ethylene oxide gas.

9.1 Storage

The THV must be stored at 10 °C to 25 °C (50 °F to 77 °F). The delivery system and accessories should be stored in a cool, dry place.

10.0 MR Safety

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valve 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 2.0 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the transcatheter heart valve is 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.

11.0 Patient Information

A patient implant card is provided with each THV. 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 THV and Device Disposal

The explanted THV 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.

13.0 References

[1] Bapat V, Attia R, Thomas M. Effect of Valve Design on the Stent Internal Diameter of a Bioprosthetic Valve: A Concept of True Internal Diameter and Its Implications for the Valve-in-Valve Procedure. JACC: Cardiovascular Interventions. Vol. 7, No. 2 2014: 115-127.

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

	English
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation
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

	English
Sheath	Minimum sheath size
Catheter	Catheter shaft size
	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	MR Conditional
	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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