Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Edwards SAPIEN 3 Ultra RESILIA 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 and standard catheterization. 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

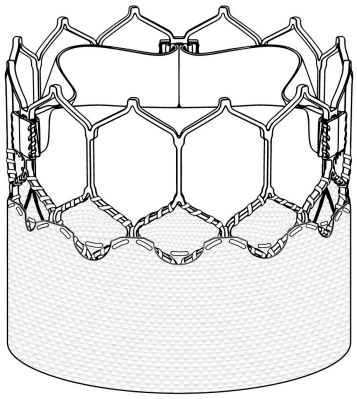
Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

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

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

The Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet RESILIA bovine pericardial tissue valve, and polyethylene terephthalate (PET) inner and outer fabric skirts.

RESILIA Tissue: RESILIA tissue is created with a novel technology called Edwards Integrity Preservation. The technology incorporates a stable capping anti-calcification process, which blocks residual aldehyde groups that are known to bind with calcium. The technology also incorporates tissue preservation with glycerol, which replaces the traditional storage in liquid-based solutions such as glutaraldehyde. The storage method eliminates tissue exposure to the residual unbound aldehyde groups commonly found in glutaraldehyde storage solutions.



9755RSL

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

Table 2

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.			
Note: Risks associated with undersizing and oversizing should be considered.			

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

Table 3

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 Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valves in a failing INSPIRIS RESILIA aortic surgical bioprosthesis in sizes 19 - 25 mm, based on bench testing, are provided in the table below:

Table 4

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 3.

Note: Exact volume required to deploy the THV may vary depending on the prosthesis 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 prosthesis 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 5.

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

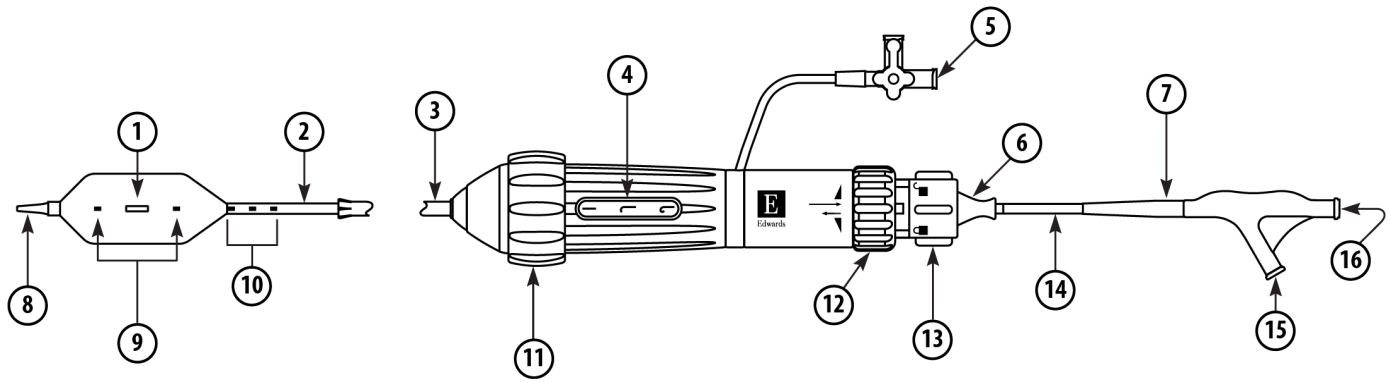
The Edwards Commander delivery system facilitates the placement of the bioprosthesis.

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 5

Model	Nominal Balloon Diameter	Nominal Inflation Volume	Rated Burst Pressure (RBP)
9750CM20	20 mm	11 ml	7 atm
9750CM23	23 mm	17 ml	7 atm
9750CM26	26 mm	23 ml	7 atm
9750CM29	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 2: Edwards Commander Delivery System

Additional Accessories

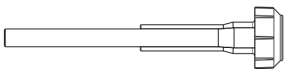


Figure 3: Loader

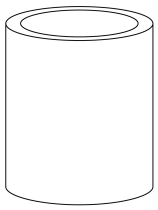


Figure 4: Qualcrimp Crimping Accessory

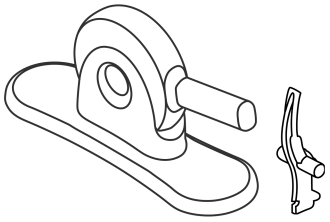


Figure 5: Edwards Crimper and Crimp Stopper

- **Loader (Figure 3)**

The loader is used to aid insertion of the delivery system into the sheath.

- **Edwards Sheath**

Refer to the sheath instructions for use for device description.

- **Qualcrimp Crimping Accessory (Figure 4)**

The Qualcrimp crimping accessory is used during THV crimping.

- **Edwards Crimper and Crimp Stopper (Figure 5)**

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.

- **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 bioprosthesis is intended for use in patients requiring heart valve replacement. The delivery system and accessories are intended to facilitate the placement of the bioprosthesis via the transfemoral, transseptal, subclavian/axillary access approaches.

3.0 Indications

1. The Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve system is indicated for use in patients with heart disease due to native calcific aortic stenosis at any or all levels of surgical risk for open heart surgery.
2. The Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve system is indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of an aortic transcatheter bioprosthetic or surgical aortic or mitral bioprosthetic 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

Use of the Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve system is 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.
- 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 valve due to calcific degeneration 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, antibiotics, chemicals, etc. other than its shipping storage solution and sterile physiologic saline solution to prevent leaflet damage that may impact valve functionality. 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 temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed, as either sterility or valve function may be compromised.
- 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 (e.g., kinked or stretched), cannot be flushed, or the expiration date has elapsed.
- 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, glycerol, bovine tissue, and/or polymeric materials may have an allergic reaction to these materials.

- 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 physician. This device has not been tested for use without anticoagulation.
- 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.
- The physician must verify correct orientation of the valve prior to its implantation.
- 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 Ultra RESILIA transcatheter heart valve) or 6.0 mm (for 29 mm SAPIEN 3 Ultra RESILIA transcatheter heart valve) may preclude safe placement of the sheath and should be carefully assessed prior to the procedure.

6.0 Precautions

- Long-term durability has not been established for the THV. 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.
- 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 RESILIA transcatheter heart valve in tortuous/challenging vessel anatomies.
- 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.
- Based on the treating physician's consideration of risks and benefits, the valve may be implanted in relatively young patients, although the longer-term durability is still the subject of ongoing clinical research.
- Safety and effectiveness of the THV implantation have not been established for patients who have:
  - 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/µL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/µL), or history of bleeding diathesis or coagulopathy
  - Hypertrophic cardiomyopathy with or without obstruction (HOCM)
  - Aortic stenosis characterized by a combination of AV low flow, low gradient
  - 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
  - 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
- The risks of subclavian/axillary access are low and acceptable, but subclavian/axillary access should be considered when the physician determines there is an increased risk associated with transfemoral access.
- 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 the Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery.
- Residual mean gradient may be higher in a "THV-in-failing prosthesis" 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 bioprosthesis 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.
- Post-procedure and follow-up assessment of TAVR device performance by Doppler echocardiography may be impacted by inherent limitations in the Bernoulli equation used to determine measurements such as mean gradient, EOA, and prosthesis-patient mismatch. These limitations may lead to an overstating or understating of valve performance measurements after TAVR implantation. Therefore, a post-TAVR echocardiogram should be used to establish a baseline from which future follow-up visits are compared to. Confirmatory direct pressure measurement via cardiac catheterization may be considered, when indicated, prior to reintervention.

7.0 Potential Adverse Events

Potential risks associated with the overall procedure including access, cardiac catheterization, local and/or general anesthesia:

- 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 ischemia or infarction
- Renal insufficiency or renal failure
- Conduction system defect which may require a permanent pacemaker
- Arrhythmias including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Retroperitoneal bleed
- Arteriovenous (AV) fistula or pseudoaneurysm
- Reoperation
- Ischemia or nerve injury or brachial plexus injury or compartment syndrome
- Restenosis
- Pulmonary edema
- Pleural effusion
- Bleeding, bleeding requiring transfusion or intervention
- Anemia
- Vessel thrombosis/occlusion
- Abnormal lab values (including electrolyte imbalance)
- Hypertension or hypotension
- Allergic reaction to anesthesia, contrast media, or device materials or bovine pericardial tissue
- Hematoma
- Syncope
- Pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site
- Exercise intolerance or weakness
- Inflammation
- Angina
- Vasovagal response
- Heart murmur

- Fever

Additional potential risks associated with the TAVR procedure, the bioprosthesis, and the use of its associated devices and 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
- Vessel spasm
- 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, including balloon rupture and tip separation
- Non-emergent reoperation
- Allergic/immunologic reaction to the implant
- Injury to mitral valve

8.0 Directions for Use

8.1 System Compatibility

Table 6

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	9755RSL20 (20 mm)	9755RSL23 (23 mm)	9755RSL26 (26 mm)	9755RSL29 (29 mm)
Edwards Commander Delivery System	9750CM20	9750CM23	9750CM26	9750CM29
Edwards eSheath+ Introducer Set	914ESP			916ESP
Inflation Device	96402			96406
Edwards Crimper	9600CR			
Qualcrimp crimping accessory, crimp stopper and loader provided by Edwards Lifesciences				

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 (x2)

- 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 in (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 accessories preparation

8.2 Valve Handling and Preparation

Maintain sterile technique during device preparation and implantation.

8.2.1 SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

The SAPIEN 3 Ultra RESILIA transcatheter heart valve is provided sterile and nonpyrogenic. The packaging consists of a carton containing a foil pouch. Within the foil pouch is a tray that is sealed with a Tyvek lid. Inside of the tray is the valve holder which contains the valve.

1. Remove the tamper evident label to open the carton.
2. Remove the foil pouch from the carton in the non-sterile field. Before opening, examine the package for evidence of damage and broken or missing seals. Open pouch and remove tray in the non-sterile field.

   WARNING: Do not open foil pouch into sterile field, as sterility may be compromised. The foil pouch is a protective cover only. Only the valve holder may be introduced into the sterile field.

   Note: If the foil pouch is opened during the procedure and the valve is not used, discard the valve.
3. The tray is labeled with the model, size, and serial number. The model, size, and serial number should be confirmed with the number on the valve package and valve implant data card.
4. Near the sterile field, hold the base of the tray and peel the lid from the tray.
5. The valve holder and contents are sterile. Transfer the valve holder to the sterile field.

   CAUTION: The contents of the valve holder must be handled using a sterile technique. Take care when removing the valve holder from the tray to ensure there is no contact with the nonsterile adhesive on the lip of the tray.

8.2.2 Valve Soaking/Rinsing Procedure

8.2.2.1 SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

1. Setup one (1) sterile bowl with at least 500 ml of sterile physiological saline to soak the valve.
2. Open the valve holder by holding the base and lifting the lid. Carefully remove the valve from the valve holder without touching the tissue. Inspect the valve for any signs of damage to the frame or tissue.
3. Place the valve in the sterile bowl of sterile physiological saline. Be sure that the sterile physiological saline completely covers the valve for at least two minutes to hydrate the leaflets. The valve should be left in the sterile physiological saline to prevent the tissue from drying.

   CAUTION: No other objects should be placed in the soak bowl. The valve should be kept hydrated to prevent the tissue from drying.

8.2.3 Prepare the System

1. Visually inspect all 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 through the flush port.
3. Carefully remove the distal balloon cover from the delivery system. Remove the stylet from the distal end of the guidewire lumen and set aside.
4. 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 the valve crimping process.
5. Place the delivery system into the default position (end of strain relief is aligned between the two white markers on the balloon shaft) 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 with heparinized saline. 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 of diluted contrast medium 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. Pull vacuum using the 50 cc or larger syringe to de-air the system. Slowly release the plunger to ensure that the contrast medium enters the lumen of the delivery system. Repeat until all air bubbles are removed from the system. 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.

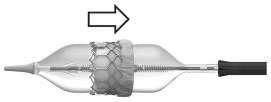
    CAUTION: Maintain the inflation device provided by Edwards Lifesciences in the locked position until THV deployment to minimize the risk or premature balloon inflation and subsequent improper THV deployment.

8.2.4 Mount and Crimp the Valve on the Delivery System

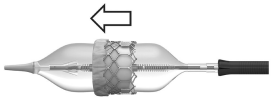
1. Set up two (2) additional sterile bowls with at least 100 ml of sterile physiological saline to thoroughly rinse the Qualcrimp crimping accessory.
2. Completely submerge the Qualcrimp crimping accessory in the first bowl and gently compress it to ensure complete saline absorption. Slowly swirl the Qualcrimp crimping accessory for a minimum of 1 minute. Repeat this process in the second bowl.
3. Remove the valve from the soaking/rinsing bowl.
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. 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.

   Note: This step is not necessary for the 20 mm valve.
6. Place the Qualcrimp crimping accessory over the THV making sure the THV 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. Center the balloon shaft coaxially within the THV. Crimp the THV until it reaches the Qualcrimp crimping accessory stop located on the 2-piece crimp stopper.
9. Gently remove the Qualcrimp crimping accessory from the THV. Remove the Qualcrimp crimping accessory 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.

Note: Ensure that the Valve Crimp Section remains coaxial within the THV. Ensure that the THV is fully within the crimper jaws during crimping.

11. Repeat the full crimp of the THV two more times for a total of three full crimps for 5 seconds each.
12. Pull the balloon shaft and lock in the default position.
13. Flush the loader with heparinized saline. Immediately advance the THV into the loader until it is completely inside the loader.

    CAUTION: The THV should not remain fully crimped and/or in the loader for over 15 minutes, as leaflet damage may result, and impact valve functionality.

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 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.

8.3 Native Valve Predilation and Valve Delivery

Native valve predilation 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.

8.3.1 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.

8.3.2 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 the balloon cannot be fully inflated during valvuloplasty.

8.3.3 Valve Delivery

1. Gain access using standard catheterization techniques.
2. Prepare and insert the Edwards sheath per its instructions for use.
3. Insert the loader into the sheath until the loader stops.
4. Advance the 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 to minimize the risk of vessel damage.

   CAUTION: To prevent possible leaflet damage and possible impact to valve functionality, 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 THV past the distal valve alignment marker to minimize the risk of improper valve deployment or THV embolization.

CAUTION: Maintain guidewire position during valve alignment to prevent loss of guidewire position.

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.

6. Advance the catheter and use the flex wheel, if needed, to 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 THV with respect to the target location.
9. 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.
10. Before deployment, ensure that the THV is correctly positioned between the valve alignment markers and the flex catheter tip is over the triple marker.
11. Begin THV 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.
    - Using slow controlled inflation, deploy the THV 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.

8.3.4 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.

9.0 How Supplied

STERILE: The SAPIEN 3 Ultra RESILIA valve, delivery system, and accessories are supplied sterilized with ethylene oxide gas.

The valves are supplied nonpyrogenic in packaging to which a tamper evident seal has been applied.

9.1 Storage

The valve must be stored at 10 °C to 25 °C (50 °F to 77 °F). Each valve 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.

10.0 MR Safety

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN 3 Ultra RESILIA 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 3000 gauss/cm (30 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 Ultra RESILIA transcatheter heart valves are expected to produce a maximum temperature rise of 1.9 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 9.0 mm from the implant for spin echo images and 23 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 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 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
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using irradiation

	English
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
	Importer

	English
	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
WO	Work Order

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

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