Edwards

Edwards SAPIEN 3 System

Edwards SAPIEN 3 Transcatheter Heart Valve

Edwards Commander Delivery System

Pulmonic Valve Implantation

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 standard catheterization techniques.

1.0 Device Description

Edwards SAPIEN 3 Transcatheter Heart Valve System

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

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

The Edwards SAPIEN 3 transcatheter heart valve (THV) is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, a 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.

The following table identifies the sizing recommendations for the non-compliant Right Ventricular Outflow Tract (RVOT) conduit and THV-in-THV in the pulmonic position using balloon sizing:

Table 1

Landing Zone Diameter	THV Size
16.5 – 20.0 mm	20 mm
20.0 – 23.0 mm	23 mm
23.0 – 26.0 mm	26 mm
26.0 – 29.0 mm	29 mm

Note: For a failing stentless bioprosthesis, consider sizing recommendations for a non-compliant Right Ventricular Outflow Tract (RVOT) conduit landing zone.

For THV-in-surgical valve procedures, size recommendations for bioprosthesis True Inner Diameter (True ID) are shown in the table below:

Table 2

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. The dimensions of the failed bioprosthesis should be determined so that the appropriate THV size can be implanted and is best determined by using balloon sizing and/or computed tomography.

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

Table 3

INSPIRIS RESILIA Valve (model 11500A)* Labeled Size	THV Size
19 mm	20 mm or 23 mm

INSPIRIS RESILIA Valve (model 11500A)* Labeled Size	THV Size
21 mm	23 mm or 26 mm
23 mm	26 mm
25 mm	29 mm

*INSPIRIS RESILIA 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 valve Model 11500A valve-in-valve procedure or expansion feature. The impact of tissue ingrowth on the expansion feature of the INSPIRIS RESILIA valve has not been assessed.

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

Note: INSPIRIS RESILIA valve model 11500A sizes 27 - 29 mm do not incorporate VFit technology and therefore follow the surgical valve True ID sizing provided in Table 2.

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 4.

- **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 4

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

- **Qualcrimp Crimping Accessory (Figure 3)**

The Qualcrimp crimping accessory is used during THV crimping.

- **Loader (Figure 4)**

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

- **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.

- **Edwards Sheath**

Refer to the sheath instructions for use for device description.

- **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, access approach.

3.0 Indications

The Edwards SAPIEN 3 transcatheter heart valve (THV) System with Edwards Commander delivery system is indicated for use in the management of pediatric and adult patients who have a clinical indication for intervention on a dysfunctional right ventricular outflow tract (RVOT) conduit or surgical bioprosthetic valve in the pulmonic position with ≥ moderate regurgitation and/or a mean RVOT gradient of ≥ 35 mmHg.

4.0 Contraindications

Use of the Edwards SAPIEN 3 system is contraindicated in patients who:

- Cannot tolerate anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.

5.0 Warnings

- The devices are designed, intended, and distributed STERILE for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.
- Correct sizing of the THV is essential to minimize the risk of paravalvular leak, migration, valve embolization and/or RVOT rupture.
- The physician must verify correct orientation of the THV prior to its implantation.
- Accelerated deterioration of the THV may occur in patients with an altered calcium metabolism.

- Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation.
- Assessment for coronary compression risk prior to valve implantation is essential to prevent the risk of severe patient harm.
- The THV 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. THV leaflets mishandled or damaged during any part of the procedure will require replacement of the THV.
- 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.
- Do not use the THV if the tamper evident seal is broken, as sterility may be compromised.
- Do not use the THV if the temperature indicator has been activated, as valve function may be compromised.
- Do not use the THV if the expiration date has elapsed, as either sterility or valve function may be compromised.
- Do not use the THV if the storage solution does not completely cover the THV or the THV is damaged.
- Do not mishandle the delivery system or use the delivery system and accessory devices if the packaging sterile barriers and any components have been opened or damaged, cannot be flushed, or the expiration date has elapsed.
- Patient injury could occur if the delivery system is not un-flexed prior to removal.
- 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.
- 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.
- Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment.

6.0 Precautions

- Long-term durability has not been established for the THV. 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.
- The safety and effectiveness of the THV implantation has not been established for patients who have:
  - Blood dyscrasias defined as: leukopenia, acute anemia, thrombocytopenia, or history of bleeding diathesis or coagulopathy
  - A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated
  - Positive urine or serum pregnancy test in female subjects of child-bearing potential
  - 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)
- 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.
- Caution should be used in vessels that have diameters less than 5.5 mm or 6 mm as it may preclude safe placement of the 14F and 16F Edwards eSheath introducer set respectively.
- Use caution in tortuous or calcified vessels that would prevent safe entry of the introducer set.
- Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis.
- Do not overinflate the deployment balloon, as this may prevent proper valve leaflet coaptation and thus impact valve functionality.
- Patient venous anatomy should be evaluated to prevent the risk of access that would preclude the delivery and deployment of the device.
- Patient should be heparinized to maintain the ACT at ≥ 250 sec prior to introduction of the delivery system in order to prevent thrombosis.
- Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native 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.

7.0 Potential Adverse Events

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

- Death
- Stroke/transient ischemic attack
- Respiratory insufficiency or respiratory failure
- Cardiovascular or vascular injury, such as perforation or damage (dissection) of vessels, myocardium or valvular structures including rupture of the pulmonary RVOT that may require intervention
- Pericardial effusion/cardiac tamponade
- Embolic event: air, calcific material, thrombus, device fragments
- Infection including incisional site infection, septicemia and endocarditis
- Myocardial infarction
- Renal insufficiency or renal failure
- Conduction system injury
- Arrhythmia
- Arteriovenous (AV) fistula
- Systemic or peripheral nerve injury
- Systemic or peripheral ischemia
- Pulmonary edema
- Pneumothorax
- Pleural effusion
- Atelectasis
- Blood loss requiring transfusion or intervention
- Anemia

- Radiation injury
- Electrolyte imbalance
- Hypertension or hypotension
- Allergic reaction to anesthesia, contrast media, antithrombotic therapy, device materials or bovine pericardial tissue
- Hematoma or ecchymosis
- Syncope
- Pain
- Exercise intolerance or weakness
- Inflammation
- Angina
- Fever
- Cardiac failure

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

- Cardiac arrest
- Cardiogenic shock
- Coronary flow obstruction/transvalvular flow disturbance
- Device thrombosis requiring intervention
- Injury to tricuspid valve
- Device embolization requiring intervention
- Device acute migration or malposition requiring intervention
- Endocarditis
- Hemolysis / hemolytic anemia
- Structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of the prosthetic valve, thickening, stenosis)
- THV dysfunction resulting in pulmonary valve symptoms
- Paravalvular or transvalvular leak
- Mechanical failure of delivery system, and/or accessories
- Emergent and non-emergent re-intervention
- Dyspnea

8.0 Directions for Use

8.1 System Compatibility

Table 5

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
Edwards eSheath Introducer Set	9610ES14			9610ES16
Inflation Device	96402			96406
Edwards Crimper	9600CR			
Qualcrimp crimping accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				

Additional Equipment

- Other compatible sheath:
  Valve size: 20, 23, 26 mm, GORE DrySeal flex introducer sheath (24F, 65 cm)
  Valve size: 29 mm, GORE DrySeal flex introducer sheath (26F, 65 cm)
- 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)
- Transthoracic echocardiography capabilities
- Exchange length 0.035 in (0.89 mm) stiff guidewire
- Temporary pacemaker (PM) and pacing lead, per the discretion of the physician
- Sterile rinsing basins; physiological saline, heparinized saline, and 15% diluted radiopaque contrast medium
- Sterile table for THV and accessories preparation

8.2 THV 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: a) Place the valve in the first bowl of sterile, physiological saline. Be sure the saline solution completely covers the THV and holder. b) With the valve and holder submerged, slowly agitate (to gently swirl the valve and holder) back and forth for a minimum of 1 minute. c) 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. d) 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.**

8.2.2 Prepare the System

Refer to the Edwards sheath, GORE DrySeal flex introducer sheath, and balloon catheter instructions for use for device preparation.

Step	Procedure
1	Visually inspect all the 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 replace the stylet in 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	If using the Edwards provided sheath, 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. If using the GORE DrySeal flex introducer sheath, proceed to step 7.
7	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 of diluted contrast medium and attach to the 3-way stopcock.
9	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.
10	Close 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.**
11	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, per the inflation parameters.
12	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.**

8.2.3 Mount and Crimp the THV onto the Delivery System

8.2.3.1 Procedure with Edwards Provided Sheath

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 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 crimper from packaging.
4	Rotate the crimper handle until the aperture is fully open.
5	Remove the valve from the holder and remove the ID tag.
6	Attach the 2-piece crimp stopper to the base of the crimper and click into place.
7	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.

Step	Procedure
8	Place the Qualcrimp crimping accessory over the valve making sure the valve is parallel to the edge of the Qualcrimp crimping accessory.
9	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 with the Inflow (outer skirt end) of the valve towards the proximal end of the delivery system.
10	Crimp the valve until it reaches the Qualcrimp stop located on the 2-piece crimp stopper.
11	Gently remove the Qualcrimp crimping accessory from the valve. Remove the Qualcrimp stop from the final stop, leaving the final stop in place.
12	Fully crimp the valve until it reaches the final stop. **Note: Ensure that the valve crimp section remains coaxial within the valve.**
13	Repeat the full crimp of the valve two more times for a total of three full crimps.
14	Pull the balloon shaft and lock in default position.
15	Flush the loader with heparinized saline. Immediately advance the valve into the loader until the tapered tip of the delivery system is exposed. **CAUTION: To prevent possible leaflet damage, the valve should not remain fully crimped and/or in the loader for over 15 minutes.**
16	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 valve hydrated until ready for implantation.** **CAUTION: The physician must verify correct orientation of the valve prior to its implantation.**

8.2.3.2 Procedure with GORE DrySeal Flex Introducer Sheath

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 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 crimper from packaging.
4	Rotate the crimper handle until the aperture is fully open.
5	Remove the valve from the holder and remove the ID tag.
6	Attach the 2-piece crimp stopper to the base of the crimper and click into place.
7	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.
8	Place the Qualcrimp crimping accessory over the valve making sure the valve is parallel to the edge of the Qualcrimp crimping accessory.
9	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 with the Inflow (outer skirt end) of the valve towards the proximal end of the delivery system.
10	Crimp the valve until it reaches the Qualcrimp stop located on the 2-piece crimp stopper.
11	Gently remove the Qualcrimp crimping accessory from the valve. Remove the Qualcrimp stop from the final stop, leaving the final stop in place.
12	Fully crimp the valve until it reaches the final stop. **Note: Ensure that the valve crimp section remains coaxial within the valve.**
13	Repeat the full crimp of the valve two more times for a total of three full crimps.
14	Pull the balloon shaft and lock in default position.
15	Flush the catheter with heparinized saline. **CAUTION: To prevent possible leaflet damage, the valve should not remain fully crimped and/or in the loader for over 15 minutes.**
16	Close the stopcock to the delivery system. **CAUTION: Keep valve hydrated until ready for implantation.** **CAUTION: The physician must verify correct orientation of the valve prior to its implantation.**
17	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.**
18	Open the stopcock and flush the flex catheter using heparinized saline. Close the stopcock.
19	Engage the balloon lock.

Step	Procedure
20	Under fluoroscopy, utilize 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.**
21	Remove the stylet and flush the guidewire lumen of the delivery system.

8.3 Landing Zone Predilation and Valve Delivery

Landing zone predilation prior to implantation is optional as deemed appropriate by physician.

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

Administer heparin to maintain the ACT at ≥ 250 sec during the procedure.

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.

8.3.1 Landing Zone Predilation

Pre-dilate the landing zone, per the discretion of the physician, according to the instructions for use for the selected balloon catheter.

CAUTION: To minimize the risk of conduit rupture, use caution when using a balloon with a diameter greater than the nominal diameter (original implant size) of the conduit for predilation of the intended deployment site.

8.3.2 THV Delivery

8.3.2.1 Procedure with Edwards Provided Sheath

Step	Procedure
1	Gain access using standard catheterization techniques.
2	Prepare the Edwards sheath. Refer to the Edwards sheath IFU for information on device preparation and handling.
3	If necessary, predilate the vessel.
4	Introduce the sheath per its instructions for use.
5	Insert the loader assembly into the sheath until the loader stops.
6	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. Retract the loader to the proximal end of the delivery system. **Note: The delivery system articulates in a direction opposite from the flush port.** **CAUTION: The valve should not be advanced through the sheath if the sheath tip is not past the IVC bifurcation to minimize the risk of damage to the iliac vessel(s).** **CAUTION: To prevent possible leaflet damage, the valve should not remain in the sheath for over 5 minutes.**
7	In the vena cava, 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. Utilize 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 vena cava and relieving compression (or tension) in the system will be necessary.**
8	Advance the catheter and use the flex wheel, if needed, and cross the landing zone. **Note: Verify the orientation of the Edwards logo to ensure proper articulation. The delivery system articulates in a direction opposite from the flush port.**
9	If additional working length is needed, remove the loader by unscrewing the loader cap and peeling the loader tubing from the delivery system.
10	Disengage the balloon lock and retract the tip of the flex catheter to the center of the triple marker. Engage the balloon lock.
11	Verify the correct position of the valve with respect to the landing zone.
12	As necessary, utilize the flex wheel to adjust the coaxial orientation of the valve and the fine adjustment wheel to adjust the position of the valve.

Step	Procedure
13	Before deployment, ensure that the valve is correctly positioned between the valve alignment markers and the flex catheter tip is locked over the triple marker.
14	Begin valve deployment: • Unlock the inflation device provided by Edwards Lifesciences. • Using slow controlled inflation, 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.

8.3.2.2 Procedure with GORE DrySeal Flex Introducer Sheath

Step	Procedure
1	Gain access using standard catheterization techniques.
2	Prepare the GORE DrySeal flex introducer sheath. Refer to the GORE DrySeal flex introducer sheath IFU for information on device preparation and handling.
3	If necessary, predilate the vessel.
4	Introduce the sheath per its instructions for use.
5	Insert the delivery system into the sheath.
6	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. **Note: The delivery system articulates in a direction opposite from the flush port.** **CAUTION: The valve should not be advanced through the sheath if the sheath tip is not past the IVC bifurcation to minimize the risk of damage to the iliac vessel(s).** **CAUTION: To prevent possible leaflet damage, the valve should not remain in the sheath for over 5 minutes.**
7	Advance the catheter to the landing zone.
8	Expose the valve by retracting the GORE DrySeal flex introducer sheath tip beyond the triple marker.
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 valve with respect to the landing zone.
11	As necessary, utilize the flex wheel to adjust the coaxial orientation of the valve and the fine adjustment wheel to adjust the position of the valve.
12	Before deployment, ensure that the valve is correctly positioned between the valve alignment markers and the flex catheter tip is locked over the triple marker.
13	Begin valve deployment: • Unlock the inflation device provided by Edwards Lifesciences. • Using slow controlled inflation, 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.

8.3.3 System Removal

Step	Procedure
1	Unflex the delivery system. Verify that the flex catheter tip is locked over the triple marker. If using the Edwards provided sheath, remove the delivery system from the sheath. If using the GORE DrySeal flex introducer sheath, retract the sheath and delivery system into the vena cava, then remove the delivery system from the sheath. **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 or the GORE DrySeal flex introducer sheath instructions for use for device removal.
3	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 with ethylene oxide gas.

The THV is supplied nonpyrogenic packaged in buffered glutaraldehyde, in a plastic jar to which a tamper evident seal has been applied. Each jar is shipped in a shelf box containing a temperature indicator to detect exposure of the THV to extreme temperature. The shelf box is enclosed in Styrofoam prior to shipping.

9.1 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 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 transcatheter heart valve is 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 tesla (T) or 3.0 tesla (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 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

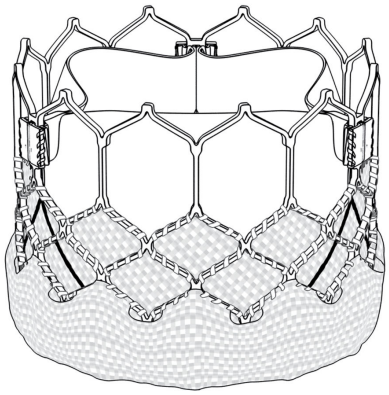
The explanted THV should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to the company. Refrigeration is not necessary under these circumstances. Contact Edwards Lifesciences to request an explant kit.

Used 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.

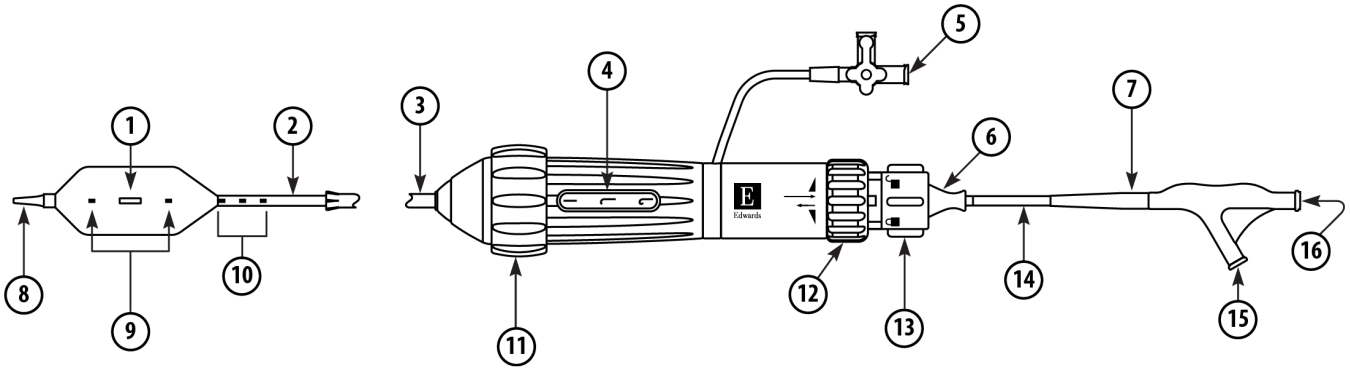
Figures



9600TFX

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



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

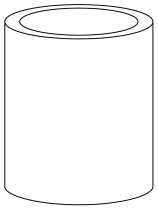


Figure 3: Qualcrimp Crimping Accessory

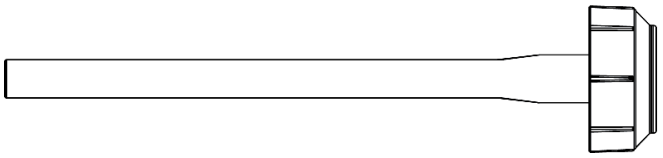


Figure 4: Loader

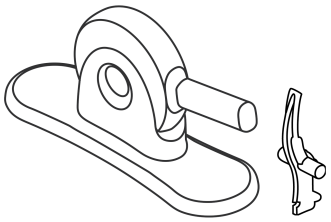


Figure 5: Edwards Crimper and 2-piece Crimp Stopper

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
	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
	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
GWC	Guidewire compatibility
NP	Nominal Pressure
RBP	Rated burst pressure
	Recommended guidewire length
Sheath	Minimum sheath size
Catheter	Catheter shaft size
	Importer
	Balloon diameter
	Balloon working length

	English
	Patient Name
31	Date of implantation
	Name and address of the health care center or doctor
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
	Patient information website
MD	Medical device
BIO	Contains 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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Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone +1.949.250.2500
+1.800.424.3278
FAX +1.949.250.2525

Web IFU