Edwards Lifesciences

Edwards SAPIEN 3 Kit – Transfemoral

Instructions for Use

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

Product Name	20 mm	23 mm	26 mm	29 mm
	Model/REF			
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
Edwards Commander Delivery System[1]	9610TF20	9610TF23	9610TF26	9610TF29
Edwards eSheath Introducer Set	14F or equivalent			16F or equivalent
Edwards Transfemoral Balloon Catheter	9350BC16	9350BC20	9350BC23	9350BC25
Crimper	9600CR			
[1] Includes a Loader, Qualcrimp Crimping Accessory and a 2-piece Crimp Stopper				

1.0 Device Description

- **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 alloy frame, a trileaflet bovine pericardial tissue valve, a polyethylene terephthalate (PET) inner skirt, and a PET outer skirt. The valve is treated according to the Edwards ThermaFix process, and is packaged and terminally sterilized in glutaraldehyde.

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:

Transesophageal Echocardiogram (TEE)*	Native Annulus Area (mm^2)	Area-derived diameter (mm)	THV Size
16-19 mm	273-345	18.6-21.0	20 mm
18-22 mm	338-430	20.7-23.4	23 mm
21-25 mm	430-546	23.4-26.4	26 mm
24-28 mm	540-683	26.2-29.5	29 mm

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

- **Edwards Commander Delivery System (Figures 2a, 2b and 2c)**

The Edwards Commander delivery system (Figure 2b) consists of a balloon catheter for deployment of the THV, and 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 native 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 native annulus. 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 Qualcrimp crimping accessory (packaged with the Edwards Commander delivery system) is used during crimping of the THV (Figure 2a).

The loader (packaged with the Edwards Commander delivery system) is used to aid insertion of the delivery system into the sheath, and may be removed to utilize the full working length of the inserted device (Figure 2c).

The inflation parameters for THV deployment are:

Model	Nominal Balloon Diameter	Nominal Inflation Volume	Rated Burst Pressure (RBP)
9610TF20	20 mm	11 mL	7 atm (709 kPa)
9610TF23	23 mm	17 mL	7 atm (709 kPa)
9610TF26	26 mm	23 mL	7 atm (709 kPa)
9610TF29	29 mm	33 mL	7 atm (709 kPa)

The following table identifies the access vessel diameters that should be used for delivery system access. Access vessels should be without severe obstructive calcification or severe tortuosity.

Ilio-Femoral Vessel Diameter	Delivery System
≥ 5.5 mm	20 mm
≥ 5.5 mm	23 mm
≥ 5.5 mm	26 mm
≥ 6.0 mm	29 mm

- **Edwards eSheath Introducer Set**

Refer to Edwards eSheath Introducer Set instructions for use.

Note: The Edwards Commander delivery system should be used with the sheath provided by Edwards Lifesciences.

- **Edwards Transfemoral Balloon Catheter**

Refer to Edwards Transfemoral Balloon Catheter instructions for use.

- **Crimper and Crimp Stopper (Figure 3)**

The crimper reduces the diameter of the THV to mount it to the delivery system. The crimper is comprised of a compression mechanism that is closed with a handle located on the housing. The crimper is used with a 2-piece crimp stopper (packaged with the delivery system) to correctly crimp the THV.

- **Inflation Devices**

An Inflation device with locking mechanism is used during native valve predilation and THV deployment.

Note: For proper volume sizing, the Edwards Commander delivery system and the Edwards transfemoral balloon catheter should be used with the inflation device provided by Edwards Lifesciences.

2.0 Indications

The Edwards SAPIEN 3 valve, Edwards Commander delivery system and accessories are indicated for use in patients with severe, symptomatic, calcific aortic valve stenosis who are judged by a Heart Team, to be at intermediate or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 3% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

3.0 Contraindications

Use of the Edwards SAPIEN 3 valve with the Edwards Commander delivery system and accessories is contraindicated in patients with:

- Evidence of intracardiac mass, thrombus, vegetation, active infection or endocarditis.
- Inability to tolerate anticoagulation/antiplatelet therapy.

4.0 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, and/or annular rupture.
- The physician must verify correct orientation of the THV prior to its implantation; the inflow (outer skirt end) of the THV should be oriented distally towards the tapered tip to prevent the risk of severe patient harm.
- 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.
- 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, 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 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.

5.0 Precautions

- 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 in patients who have:
  - Congenital unicuspid or congenital bicuspid aortic valve
  - Pre-existing prosthetic heart valve in the aortic position
  - Severe ventricular dysfunction with ejection fraction < 20%
  - Hypertrophic cardiomyopathy with or without obstruction
  - Aortic stenosis characterized by a combination of AV low flow, low gradient
- Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis.
- THV recipients should be maintained on anticoagulant/antiplatelet therapy to minimize the risk of valve thrombosis or thromboembolic events, as determined by their physicians.
- Long-term durability has not been established for the THV. Regular medical follow-up is advised to evaluate valve performance.
- 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.
- Do not overinflate the deployment balloon, as this may prevent proper valve leaflet coaptation and thus impact valve functionality.
- Patients with pre-existing mitral valve devices should be carefully evaluated before implantation of the THV to ensure proper THV positioning and deployment.

6.0 Potential Adverse Events

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

- Allergic reaction to antithrombotic therapy or contrast medium or anesthesia
- Anemia
- Aneurysm
- Angina
- Arrhythmias including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- AV fistula or pseudoaneurysm
- Cardiogenic shock
- Compartment syndrome
- Death
- Dissection: aortic or other vessels
- Emboli, distal (air, tissue or thrombotic emboli)
- Hematoma
- Hypertension or hypotension
- Inflammation
- Myocardial ischemia or infarction
- Pain or changes at the access site
- Perforation or rupture of cardiac structures
- Perforation or rupture of vessels
- Pericardial effusion or cardiac tamponade
- Peripheral ischemia or nerve injury
- Pulmonary edema
- Renal insufficiency or renal failure
- Respiratory insufficiency or respiratory failure
- Syncope
- Vasovagal response
- Vessel spasm
- Vessel thrombosis/occlusion
- Vessel trauma requiring surgical repair or intervention

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
- Atrial fibrillation/Atrial flutter
- Bleeding requiring transfusion or intervention
- Cardiac arrest
- Cardiac failure or low cardiac output
- Cardiogenic shock
- Conduction system injury (defect) including AV block, which may require a permanent pacemaker
- Coronary occlusion
- Dissection, rupture, trauma of the aortic annulus and surrounding structures including ascending aorta, coronary ostia and ventricular septum
- Emergency cardiac surgery
- Hemolysis

- Infection, fever, septicemia, abscess, endocarditis
- Injury to mitral valve
- Mechanical failure of delivery system, and/or accessories, including balloon rupture and tip separation
- Silent cerebral ischemia, stroke, transient ischemic attack, cognitive impairment
- Structural valve deterioration (wear, fracture, calcification, stenosis)
- Valve deployment in unintended location
- Valve explants
- Valve migration, malposition or embolization requiring intervention
- Valve regurgitation, paravalvular or transvalvular
- Valve thrombosis

7.0 Directions for Use

7.1 Required Equipment

- Standard cardiac catheterization lab equipment
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- Exchange length 0.035 inch (0.89 mm) extra-stiff guidewire
- Pacemaker (PM) and pacing lead
- Edwards SAPIEN 3 valve
- Edwards Commander delivery system
- Edwards eSheath Introducer Set or equivalent provided by Edwards Lifesciences
- Edwards Transfemoral Balloon catheter or equivalent
- Crimper
- Inflation Devices provided by Edwards Lifesciences (x2)
- Sterile rinsing bowls; sterile physiological saline solution; sterile heparinized saline solution, and diluted radiopaque contrast medium (15:85 medium to saline dilution)
- Sterile table for THV and device preparation
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock (x2)

7.2 THV Handling and Preparation

Follow sterile technique during device preparation and implantation.

7.2.1 THV Rinsing Procedure

The THV is packaged sterile in a plastic jar with a screw-cap closure and seal. Before opening, carefully examine the jar 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	Remove the THV/holder assembly from the jar and inspect for any signs of damage. Verify that the serial number on the THV holder and the jar lid match. Record the serial number in the patient information documents.
2	Rinse the THV as follows: **Gently** swirl the THV/holder assembly in 500 mL sterile, physiological saline solution for a minimum of 1 minute. Repeat this process in the second bowl for a minimum of 1 minute. Leave the THV in the second bowl until needed. **CAUTION: Do not allow the THV to come in contact with the rinse bowl or the identification tag. No other objects should be placed in the rinse bowls to minimize the risk of contamination or damage to the leaflets which may impact valve function.**

7.2.2 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 through the flush port.
3	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. Insert the stylet back into the guidewire lumen. **NOTE: Failure to replace the stylet in the guidewire lumen may result in damage to the lumen during the THV 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.
6	Unscrew the loader cap from the loader and flush the loader cap with heparinized saline.
7	Place the loader cap onto the delivery system 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 of diluted contrast medium and attach to the 3-way stopcock.
9	Fill the inflation device 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	Pull vacuum with the syringe to remove air. 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. Close stopcock to the delivery system.
11	Rotate the knob of the inflation device to remove the contrast medium into the syringe and achieve the appropriate volume required to deploy the THV. Close the stopcock to the syringe and remove syringe.
12	Verify that the inflation volume in the inflation device is correct. **CAUTION: Maintain the inflation device in the locked position until THV deployment to minimize the risk of premature balloon inflation and subsequent improper THV deployment.**

7.2.3 Mount and Crimp the THV on the Delivery System

Step	Procedure
1	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.
2	Remove the THV from the holder and remove the ID tag.
3	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.
4	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.**
5	Place the Qualcrimp crimping accessory over the THV aligning the edge of the Qualcrimp crimping accessory with the outflow of the THV.
6	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 inflow of the THV towards the distal end of the delivery system.
7	Center the balloon shaft coaxially within the THV. Crimp the THV until it reaches the Qualcrimp stop.
8	Remove the Qualcrimp crimping accessory from the THV and Qualcrimp stop from the Crimp Stopper, leaving the Final Stop in place.
9	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.**
10	Pull the balloon shaft and engage the Balloon Lock so the delivery system is in Default Position.
11	Flush the loader with heparinized saline. Immediately advance the THV into the loader until the tapered tip of the delivery system is exposed. **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.**
12	Attach the loader cap to the loader, re-flush the Flex Catheter 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; the inflow (outer skirt end) of the THV should be oriented distally towards the tapered tip to prevent the risk of severe patient harm.**

7.3 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.

7.3.1 Baseline Parameters

Step	Procedure
1	Perform a supra-aortic angiogram with the projection of the native aortic valve perpendicular to the view.
2	Evaluate the distance of the left and right coronary ostia from the aortic annulus in relation to the THV frame height.
3	Introduce a pacemaker (PM) lead until its distal end is positioned in the right ventricle.
4	Set the stimulation parameters to obtain 1:1 capture, and test pacing.

7.3.2 Native Valve Predilation

Refer to Edwards Transfemoral Balloon Catheter Instructions for Use.

7.3.3 THV Delivery

Step	Procedure
1	Prepare the Edwards eSheath introducer set per its instructions for use.
2	If necessary, predilate the femoro-iliac vessel.
3	Introduce the sheath per its instructions for use.
4	Insert the loader assembly into the sheath until the loader stops.
5	Advance the delivery system until the THV exits the sheath. Retract the loader to the proximal end of the delivery system. **CAUTION: The THV should not be advanced through the sheath if the sheath tip is not past the aortic bifurcation to minimize the risk of damage to the iliac vessel(s).** **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 aorta, 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 THV between the Valve Alignment Markers. **NOTE: 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.** **CAUTION: Maintain guidewire position in the left ventricle during valve alignment to prevent loss of guidewire position.**
7	Utilize the Flex wheel to traverse the aortic arch and cross the native valve. **NOTE: Verify the Edwards logo is facing up.** **NOTE: The delivery system articulates in a direction opposite from the flush port.**
8	If additional working length is needed, remove the loader by unscrewing the loader cap and peeling the loader tubing from the delivery system.
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	Position the THV with respect to the native valve.

Step	Procedure
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: • Unlock the inflation device. • Ensure hemodynamic stability is established and begin rapid pacing; once arterial blood pressure has decreased to 50 mmHg or below, balloon inflation can commence. • Using slow controlled inflation, deploy the THV with the entire volume in the inflation device, hold for 3 seconds and confirm that the barrel of the inflation device is empty to ensure complete inflation of the balloon. • Deflate the balloon. When the balloon catheter has been completely deflated turn off the pacemaker.

7.3.4 System Removal

Step	Procedure
1	Unflex the delivery system while traversing the aortic arch. Verify that the Flex Catheter tip is locked over the Triple Marker and remove the delivery system from the sheath. **CAUTION: Completely unflex the delivery system prior to removal to minimize the risk of vascular injury.**

7.4 Verification of Prosthetic Valve Position and Measurements

Measure and record hemodynamic parameters.

Step	Procedure
1	Perform a supra aortic angiogram to evaluate device performance and coronary patency.
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.

8.0 How Supplied

Delivery System Information

Model	9610TF20	9610TF23	9610TF26	9610TF29
Diameter of Inflated balloon	20 mm	23 mm	26 mm	29 mm
Effective length of balloon	2.6 cm	3.2 cm	3.2 cm	3.6 cm
Outside (exterior) diameter	16F (5.3 mm)	16F (5.3 mm)	16F (5.3 mm)	16F (5.3 mm)
Usable length of delivery system	105 cm	105 cm	105 cm	105 cm
Guidewire compatibility	0.035" (0.89 mm)	0.035" (0.89 mm)	0.035" (0.89 mm)	0.035" (0.89 mm)

The THV is supplied sterile and 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.

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

8.1 Storage

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

9.0 MR Safety

MR Conditional

Non-clinical testing has demonstrated that the THV (implant) is MR Conditional. It can be scanned safely, immediately under the following conditions:

- Static magnetic field of 1.5 Tesla (T) or 3.0 Tesla (T).
- Spatial gradient field of 2500 Gauss/cm or less.
- Maximum whole body averaged specific absorption rate (WB-SAR) of 2.0 W/kg for 15 minutes of scanning.
- Normal mode of operation, as defined in IEC 60601-2-33 Ed.2.0, of the MR system.

In non-clinical testing and analysis, the implant was determined to produce an *in vivo* temperature rise of less than 1.3 °C above background for a WB-SAR of 2.0 W/kg for 15 minutes of MR scanning in a 1.5 T whole body coil from a GE Signa MR system. The projected *in vivo* rise above background was 1.5 °C for a WB-SAR of 2.0 W/kg in a 3.0 T GE Signa HDxt 3T MR system. These calculations overestimate the true *in vivo* rise, since the cooling effects of blood are not considered.

The image artifact extends as far as 14.5 mm from the implant for spin echo images and 30 mm for gradient echo images when scanned in non-clinical testing using a 3.0 T GE Signa HDx MR 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.

10.0 Patient Information

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

11.0 Recovered THV and Device Disposal

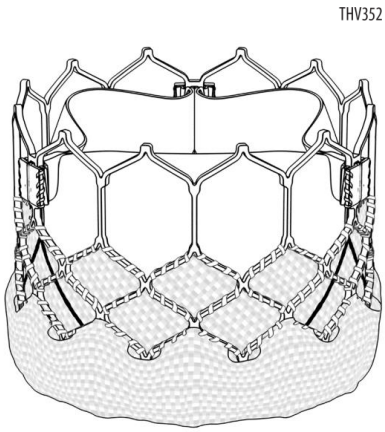
The explanted THV should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to the company. Refrigeration is not necessary under these circumstances. Contact Edwards Lifesciences to request an Explant Kit.

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.

These products are manufactured and sold under one or more of the following US patent(s): US Patent No. 6,214,054; 6,547,827; 6,908,481; 7,214,344; 7,530,253; 7,585,321; 7,780,723; 7,846,203; 7,895,876; 8,057,540; 8,382,826; 8,591,575; 8,690,936; 8,790,387; 9,301,840; 9,301,841; and 9,393,110; and corresponding foreign patents. Additional patents are pending.

12.0 Figures

Figure 1. Edwards SAPIEN 3 Transcatheter Heart Valve



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

Figure 2a. Qualcrimp Crimping Accessory

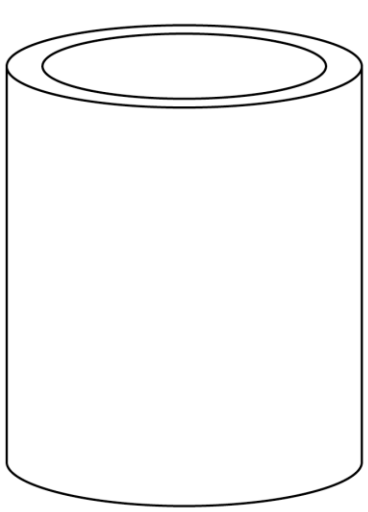


Figure 2b. Edwards Commander Delivery System

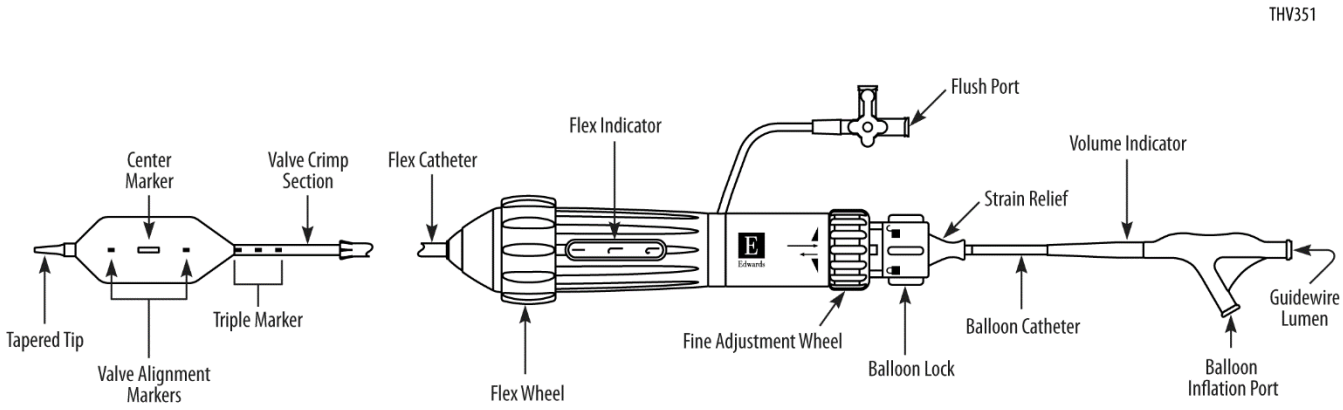


Figure 2c. Loader

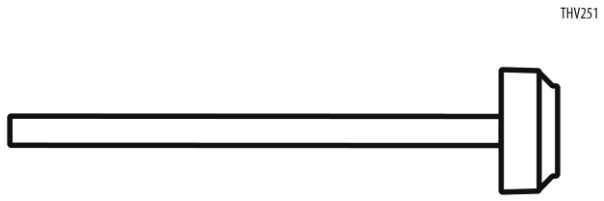
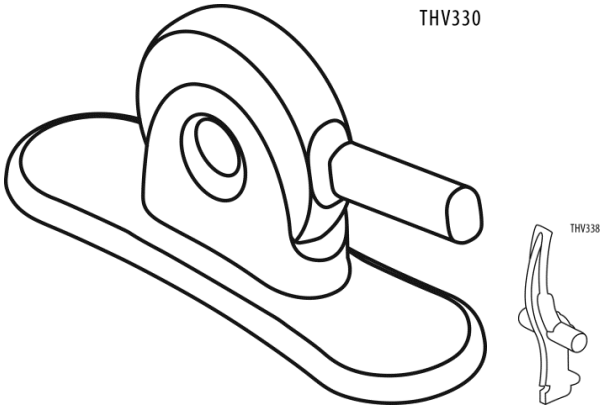


Figure 3. Crimper and 2-piece Crimp Stopper



Symbol Legend

	English
REF	Catalogue Number
#	Quantity
I	Minimum Introducer Size
cm	Usable Length
	Single use
LOT	Lot Number
	Caution
	Consult instructions for use
	Do not use if package is damaged
	Do not use if package is opened or damaged.
	Exterior Diameter
	Inner Diameter
	Keep Dry
	Store in a cool, dry place.
	Temperature Limitation
STERILE	Sterile
STERILE EO	Sterilized Using Ethylene Oxide
STERILE R	Sterilized Using Irradiation
STERILE	Sterile Using Steam or Dry Heat

	English
	Use By
SN	Serial Number
	Manufacturer
EC REP	Authorised Representative in the European Community
GW	Recommended Guidewire Size
SZ	Size
GWC	Guidewire Compatibility
NP	Nominal Pressure
RBP	Rated Burst Pressure
STRAIGHT	Straight
DEFLECTED	Deflected
	Recommended Guidewire Length
Sheath	Minimum Sheath Size
Catheter	Catheter Shaft Size
	Balloon Diameter
	Balloon Working Length
USE	Use
USE	Do not use
	Type CF applied part

	English
20 mm	For use with size 20 mm Edwards transcatheter heart valve
23 mm	For use with size 23 mm Edwards transcatheter heart valve
26 mm	For use with size 26 mm Edwards transcatheter heart valve
29 mm	For use with size 29 mm Edwards transcatheter heart valve
23 mm 26 mm	For use with size 23 mm or size 26 mm Edwards transcatheter heart valve
NON STERILE	Non-sterile
PHT	Contains phthalates
MR	MR Conditional
	Contents
	Nonpyrogenic
IPX1	Drip Proof Equipment
	Contents sterile and fluid path nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.
	Contents sterile and nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
eSheath	For use with eSheath, Edwards Expandable Introducer Sheath

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

THV15L8x11.9

Edwards

EC REP

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CE 0344

11/2016
DOC-0045533 B

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DATA MATRIX
BARCODE FPO

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Label Item/Revision: N/A	Graphic Artist: Refer to supporting material for designer's signature	Page 9 of 9	
Visual Representation/Revision: DOC-0045533/B	First Proof: Refer to supporting material for reviewer's signature		
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NOTE

1. ALL ART PRINTS 100% BLACK UNLESS OTHERWISE NOTED.

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