Edwards Lifesciences

Edwards SAPIEN 3 Kit - Transapical and Transaortic

Instructions for Use

Implantation of the transcatheter heart valve should be performed only by physicians who have received Edwards Lifesciences training. 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 Certitude Delivery System[1]	9620TA20	9620TA23	9620TA26	9620TA29
Edwards Certitude Introducer Sheath Set	9620IS18 (18F)			9620IS21 (21F)
Crimper	9600CR			
Ascendra Balloon Aortic Valvuloplasty Catheter	Not included[2]	9100BAVC (20 mm)		

[1] Includes a loader, Qualcrimp crimping accessory, a 2-piece crimp stopper, and extension tubing

[2] Use 16 mm commercially available balloon valvuloplasty catheter

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, trileaflet bovine pericardial tissue valve, and 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 recommended 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 imaging, 2-D TEE imaging should be supplemented with 3-D area measures.

- **Crimper and Crimp Stopper (Figure 2)**

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

- **Edwards Certitude Delivery System (Figures 3a, 3b, & 3c)**

The Edwards Certitude delivery system includes a handle with a Flex Wheel for articulation of the Balloon Catheter and a Loader. The loader allows for the delivery of the crimped THV through the hemostasis valves of the sheath. The THV is crimped between the two radiopaque shoulders on the distal and proximal ends of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. An inflation and guidewire hub is housed in the handle assembly. The Qualcrimp crimping accessory (packaged with the Edwards Certitude delivery system) is used during crimping of the THV. The extension tubing (packaged with the delivery system) is used during THV deployment.

- **Edwards Certitude Introducer Sheath Set (Figure 4)**

The Edwards Certitude introducer sheath set is intended for use with the Edwards Certitude delivery system. The sheath has a radiopaque marker for visualization of the sheath tip and non-radiopaque depth markings on the distal end of the body of the sheath. The proximal end of the sheath includes a flush tube and three hemostasis valves. An introducer is supplied with the sheath. The entire introducer is radiopaque.

- **Ascendra Balloon Aortic Valvuloplasty Catheter**

Refer to Ascendra Balloon Aortic Valvuloplasty Catheter model 9100BAVC instructions for use.

- **Inflation Devices**

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

NOTE: For proper volume sizing, the Edwards Certitude delivery system and the Ascendra balloon aortic valvuloplasty catheter should be used with the inflation devices provided by Edwards Lifesciences.

2.0 Indications

The Edwards SAPIEN 3 valve, Edwards Certitude 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 Certitude 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.
- Accelerated deterioration of the THV may occur in patients with altered calcium metabolism.
- When using venous pacing, observation of the pacing lead throughout the procedure is essential to avoid the potential risk of the pacing lead causing a cardiovascular perforation.
- The THV must remain hydrated at all times and cannot be exposed to any solutions, chemicals, antibiotics, 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.
- 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 and accessories or use them if the packaging or any components are not sterile, have been opened or damaged (e.g. kinked or stretched), or the expiration date has elapsed.
- Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, and/or polymeric materials may have an allergic reaction to these materials.

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 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 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 function.
- 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 TAVI (transcatheter aortic valve implantation) procedure, the bioprosthesis, and the use of its associated devices and accessories include:

- 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
- Mediastinitis
- Mediastinal bleeding
- 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

- Cardiac catheterization/hybrid OR suite
- 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 system
- 18 gauge Seldinger needle (for transaortic)
- 145 cm x 0.035" (0.89 mm) soft guidewire
- 180 cm or 260 cm x 0.035" (0.89 mm) & Exchange length 0.035" (0.89 mm) extra-stiff guidewires
- Pacemaker and pacing leads
- Inflation devices provided by Edwards Lifesciences (x2)
- Edwards SAPIEN 3 valve
- Edwards Certitude delivery system
- Edwards Certitude introducer sheath set
- 20 mm Ascendra balloon aortic valvuloplasty catheter (BAVC) or equivalent for 23 mm, 26 mm, and 29 mm valves
- 16 mm commercially available valvuloplasty balloon catheter for 20 mm valve
- Crimper
- Sterile rinsing bowls; sterile physiological saline solution; sterile heparinized saline solution; radiopaque contrast medium (15:85 medium to saline dilution)
- Sterile table for THV and accessories preparation
- 20 mL or larger luer lock syringe
- 50 mL or larger luer lock syringe
- High-pressure 3-way stopcock

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.

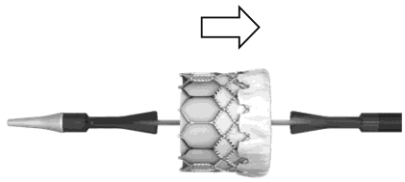
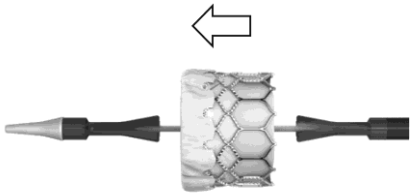
Step	Procedure
1	Remove the THV/holder assembly from the jar and inspect for any signs of damage. Verify that the serial number on the THV holder and the jar lid match. Record the serial number in the patient information documents.
2	Rinse the THV as follows: **Gently** swirl the THV/holder assembly in 500 mL sterile, physiologic 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 functionality.**

7.2.2 Prepare the System

Step	Procedure
1	Visually inspect all components for damage. Ensure the system is fully unflexed.
2	Prime and flush the introducer and sheath with heparinized saline. Hydrate the length of the introducer and sheath.
3	Advance the introducer fully into the sheath housing.
4	Unscrew the loader cap from the loader and flush the loader cap with heparinized saline.
5	Place the loader cap onto the delivery system with the inside of the cap oriented towards the tapered tip.
6	Flush the extension tubing and connect to the delivery system.
7	Partially fill a 50 mL or larger syringe with diluted contrast medium, and connect to the extension tubing.
8	Fill the inflation device with 20 mL of diluted contrast medium, lock the inflation device, and connect to the extension tubing. Close 3-way stopcock to inflation device.
9	De-air the delivery system using the luer lock syringe. Leave zero-pressure in the system. Close the 3-way stopcock to the luer lock syringe.
10	Remove 3 mL fluid from the delivery system by turning the knob of the locked inflation device. Keep the inflation device locked for THV crimping steps.

7.2.3 Mount and Crimp the THV onto the Delivery System

Step	Procedure
1	Completely submerge the Qualcrimp crimping accessory in a bowl of 100 mL physiological saline solution. Gently compress until fully saturated. Swirl for a minimum of 1 minute. Repeat this process in a second bowl.
2	Rotate the crimper until the aperture is fully opened. Attach the 2-piece Crimp Stopper to the crimper.
3	Remove the THV from the holder and remove the ID tag.
4	If necessary, partially crimp the THV in the crimper until it fits snugly 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.

Step	Procedure
6	The orientation of the THV on the delivery system is described below: **Antegrade Transapical Approach:** Inflow (outer skirt) end of the THV towards the **proximal end** of the delivery system. THV365  **Retrograde Transaortic Approach:** Inflow (outer skirt) end of the THV towards the **distal end** of the delivery system. THV366 
7	Place the THV and Qualcrimp crimping accessory in the crimper. Insert the delivery system coaxially into the THV.
8	Crimp the THV between the two internal shoulders of the delivery system until it reaches the Qualcrimp stop.
9	Remove the Qualcrimp crimping accessory from the THV/balloon assembly and Qualcrimp stop from the Crimp Stopper, leaving the Final Stop in place. **NOTE: Ensure that the THV remains centered and coaxial within the two internal shoulders.**
10	Place the THV/balloon assembly back in the crimper aperture, fully crimp the THV until it reaches the Final Stop and hold for 5 seconds.
11	Repeat the full crimp of the THV two times for a total of 3 crimps.
12	Flush the loader with heparinized saline. Immediately advance the loader over the THV until the tapered tip of the delivery system is exposed and the THV is within the distal end of the loader tube. **CAUTION: The THV should not remain fully crimped and/or in the loader over 15 minutes, as leaflet damage may result and impact valve functionality.**
13	Attach the loader cap to the loader and flush through the flush port on the loader. 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; the inflow (outer skirt) end of the THV should be oriented proximally for the antegrade transapical approach and distally for the retrograde transaortic approach to prevent the risk of severe patient harm.**
14	With 3-way stopcock still closed to the luer lock syringe, unlock the inflation device. Allow the delivery system to reach zero-pressure.
15	Close the 3-way stopcock to the delivery system. Use the luer lock syringe to de-air the inflation device if necessary.
16	Adjust the inflation device to the inflation volume required to deploy the THV, per the following: **Delivery System** / **THV** / **Inflation Volume** Model 9620TA20 / 20 mm / 12 mL Model 9620TA23 / 23 mm / 17 mL Model 9620TA26 / 26 mm / 23 mL Model 9620TA29 / 29 mm / 30 mL Re-lock the inflation device. Close the 3-way stopcock to the luer lock syringe and remove syringe. **CAUTION: Maintain the inflation device in a locked position until THV deployment to prevent premature balloon inflation and subsequent improper THV deployment.**

7.3 Native Valve Predilation and THV Delivery

Native valve predilation and THV delivery should be performed under general anesthesia with hemodynamic monitoring in a catheterization lab/hybrid operating room with fluoroscopic and echocardiographic imaging capabilities.

The following table shows the minimum required distances from the native valve annulus to the distal tip of the Edwards Certitude sheath to allow the Edwards Certitude delivery system balloon to inflate properly during THV deployment. **These distances do not include sheath insertion depth**, which should be considered during the transaortic approach when selecting the access site on the ascending aorta.

Delivery System	THV	Minimum Required Distance From Sheath Tip to Annulus
Model 9620TA20	20 mm	3.5 cm
Model 9620TA23	23 mm	3.5 cm
Model 9620TA26	26 mm	3.5 cm
Model 9620TA29	29 mm	4.0 cm

Administer heparin to maintain the ACT at ≥ 250 sec.

CAUTION: Contrast media use should be monitored to reduce the risk of renal injury.

7.3.1 Baseline Parameters

Step	Procedure
1	Advance a 5F (1.67 mm) or 6F (2.0 mm) pigtail catheter into the descending aorta and perform a supra-aortic angiogram with the projection of the native aortic valve perpendicular to the view.
2	Evaluate the distances of the right and left 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 Access

CAUTION: Care should be taken to avoid damage to soft tissue, chordae, aorta, native leaflet or ventricular wall during insertion, positioning and removal of devices.

Transapical Access	
Step	**Procedure**
1	Access the apex through an anterior mini thoracotomy at the 5th or 6th intercostal space. Incise the pericardium to expose the apex of the left ventricle (LV).
2	Attach epicardial pacing leads to left ventricle or insert transvenous pacing leads and secure proximal ends of leads into pacemaker. Set the stimulation parameters, test rapid pacing.
3	Place a reinforced double purse string on the LV apex to access the left ventricle.
4	Gain aortic valve access through standard transapical techniques.
5	Insert the tip of the Edwards Certitude introducer sheath set or desired introducer sheath for BAV through the apex of the LV to approximately 4 cm and locate the sheath tip in the LV outflow tract immediately below the aortic valve; withdraw the introducer slowly, keeping the sheath in place. Maintain guidewire position across the aortic valve.
Transaortic Access	
Step	**Procedure**
1	Access the ascending aorta using standard surgical technique (e.g., a partial J-sternotomy or right parasternal mini thoracotomy).
2	Place two reinforced purse string sutures at the intended access site in the ascending aorta. **NOTE: The selected access site should be soft by digital palpation.**
3	Introduce a pacemaker lead until its distal end is positioned in the right ventricle. Set the stimulation parameters and test pacing.
4	Gain aortic valve access through standard transaortic techniques.
5	Insert the Edwards Certitude introducer sheath set, or desired introducer sheath for BAV, into the aorta to approximately 2 cm. Withdraw the introducer slowly, keeping the sheath in place. Maintain guidewire position across the aortic valve.

7.3.3 Native Valve Predilation

CAUTION: Care should be taken to avoid damage to soft tissue, chordae, aorta, native leaflet or ventricular wall during insertion, positioning and removal of devices.

Step	Procedure
1	Prepare the valvuloplasty balloon catheter per its instructions for use.
2	Advance the prepared valvuloplasty balloon catheter through the sheath over the guidewire, cross the aortic valve, and position the balloon.
3	Begin predilation: – Begin rapid pacing. Once arterial blood pressure has decreased to 50 mmHg or below, balloon inflation can commence. – Inflate the valvuloplasty balloon catheter as per its instructions for use. – Completely deflate the balloon. Stop rapid pacing.
4	Remove the valvuloplasty balloon catheter, leaving the guidewire in place in the descending aorta if using the transapical approach, or in the ventricle if using the transaortic approach. **NOTE: If not using the Edwards Certitude sheath for native valve predilation, remove the sheath used for the valvuloplasty and advance the Edwards Certitude introducer sheath set over the guidewire.**

7.3.4 THV Delivery

CAUTION: Care should be taken to avoid damage to soft tissue, chordae, aorta, native leaflet or ventricular wall during insertion, positioning and removal of devices.

Step	Procedure
1	Confirm that the THV is oriented properly and the volume in the inflation device matches the indicated volume.
2	Advance the THV/balloon assembly with the loader over the guidewire.
3	Engage loader into the sheath housing while maintaining a firm grip.
4	Advance the valve out of the loader into the large section of the sheath. Tap on the sheath housing to release air bubbles to the proximal end of the loader. Depress button valve on loader to aspirate the loader.
5	Advance the THV/balloon assembly through the sheath and position within the native aortic valve leaflets. If needed, rotate the flex wheel on the handle to articulate the THV/balloon assembly into position. **CAUTION: To prevent possible leaflet damage that may impact valve functionality, the THV should not remain in the sheath for over 5 minutes.**
6	Ensure that the THV is correctly positioned between the two internal shoulders of the delivery system.
7	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 a slow, controlled inflation, deploy the THV by inflating the balloon 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. – Once the THV has been deployed, rapidly deflate the balloon catheter. When the delivery system balloon has been completely deflated, turn off the pacemaker.
8	If articulation was used, return the delivery system to the straight position prior to removal. Retract the delivery system and guidewire into the sheath. Remove the loader and delivery system from the sheath. **CAUTION: Properly deflate the balloon and straighten the delivery system prior to removal to prevent patient injury.**

7.4 Verification of THV Position and Measurements

Step	Procedure
1	Perform a supra-aortic angiogram to evaluate device performance and coronary patency.
2	Measure and record the transvalvular pressure gradients and assess valve competency.
3	Upon satisfactory deployment, remove all devices when the ACT level is appropriate (e.g., reaches < 150 sec).
4	Tie the purse string sutures in place and confirm hemostasis.

8.0 How Supplied

Delivery System Information

Model	9620TA20	9620TA23	9620TA26	9620TA29
Diameter of inflated balloon	20 mm	23 mm	26 mm	29 mm
Rated Burst Pressure	7 atm (709 kPa)			
Effective length of the balloon	26 mm	30 mm	32 mm	36 mm
Outside (Exterior) Diameter	17F (5.5 mm)			
Effective length of the delivery system (from the proximal end to the tapered tip of catheter)	55 cm			
Diameter of the largest guidewire that can be used	0.035" (0.89 mm)			

Introducer Sheath Set Information

Model	9620IS18	9620IS21
Sheath Inside Diameter	18F (6.1 mm)	21F (6.9 mm)
Sheath Effective Length	21 cm	21 cm
Introducer Size	OD: 6.3 mm	OD: 7.0 mm
Introducer Effective Length	33 cm	
Diameter of the largest guidewire that can be used	0.035" (0.89 mm)	

The THV is supplied sterile and non-pyrogenic, 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 Edwards Certitude delivery system, Edwards Certitude introducer sheath set, Ascendra balloon aortic valvuloplasty catheter and crimper are supplied sterilized by ethylene oxide.

8.1 Storage

The THV must be stored between 10 °C and 25 °C (50 °F and 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 included 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

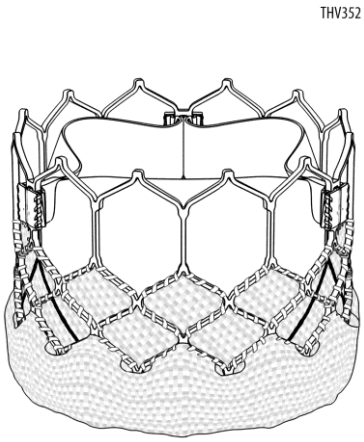
The explanted THV should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to the company. Refrigeration is not necessary under these circumstances. Contact Edwards Lifesciences to request an Explant Kit.

The used devices may be disposed of in the same manner that the hospital waste and biohazardous materials are handled. There are no special or unusual risks related to the disposal of the devices.

This product is manufactured and sold under one or more of the following US patents: 6,214,054; 6,547,827; 6,908,481; 7,214,344; 7,530,253; 7,895,876; 8,439,970; 8,475,522; 8,764,820; 8,945,208; 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	Height
20 mm	15.5 mm
23 mm	18 mm
26 mm	20 mm
29 mm	22.5 mm

Figure 2. Crimper and 2-piece Crimp Stopper

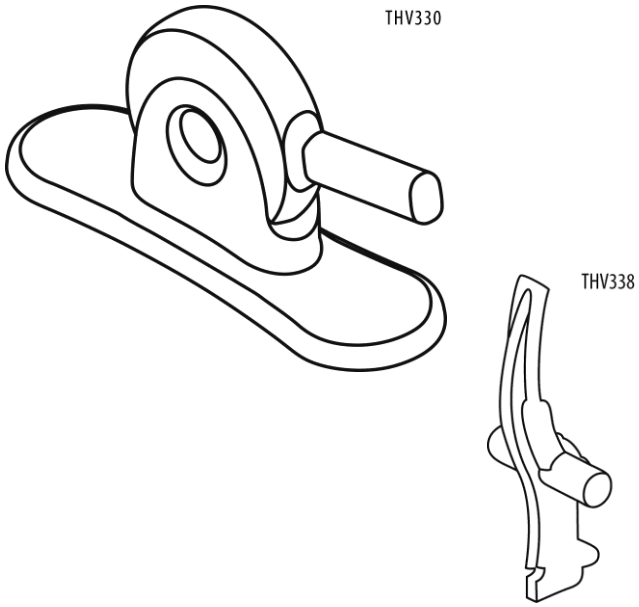


Figure 3a. Edwards Certitude Delivery System

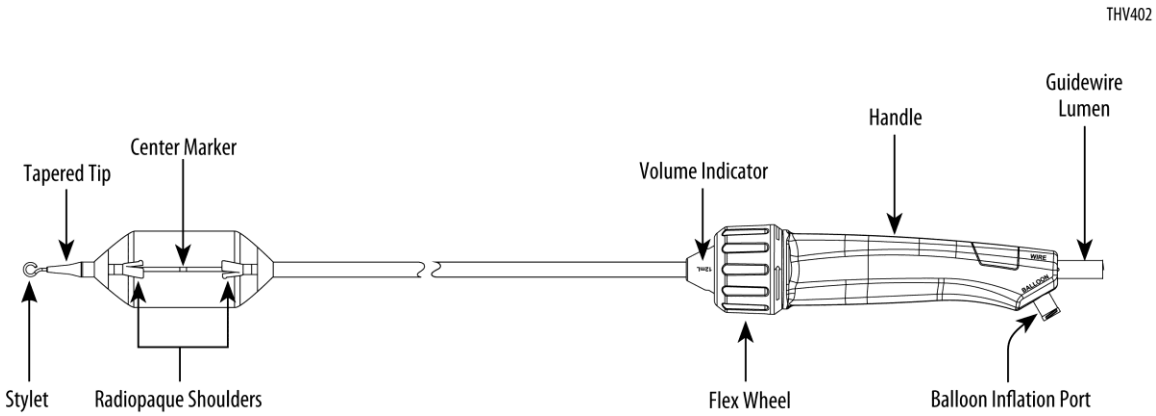


Figure 3b. Qualcrimp Crimping Accessory

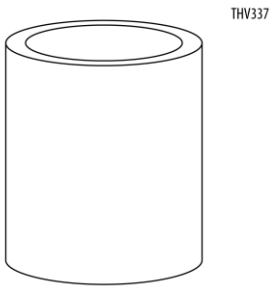


Figure 3c. Loader

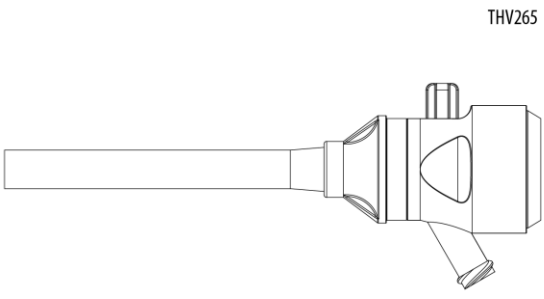
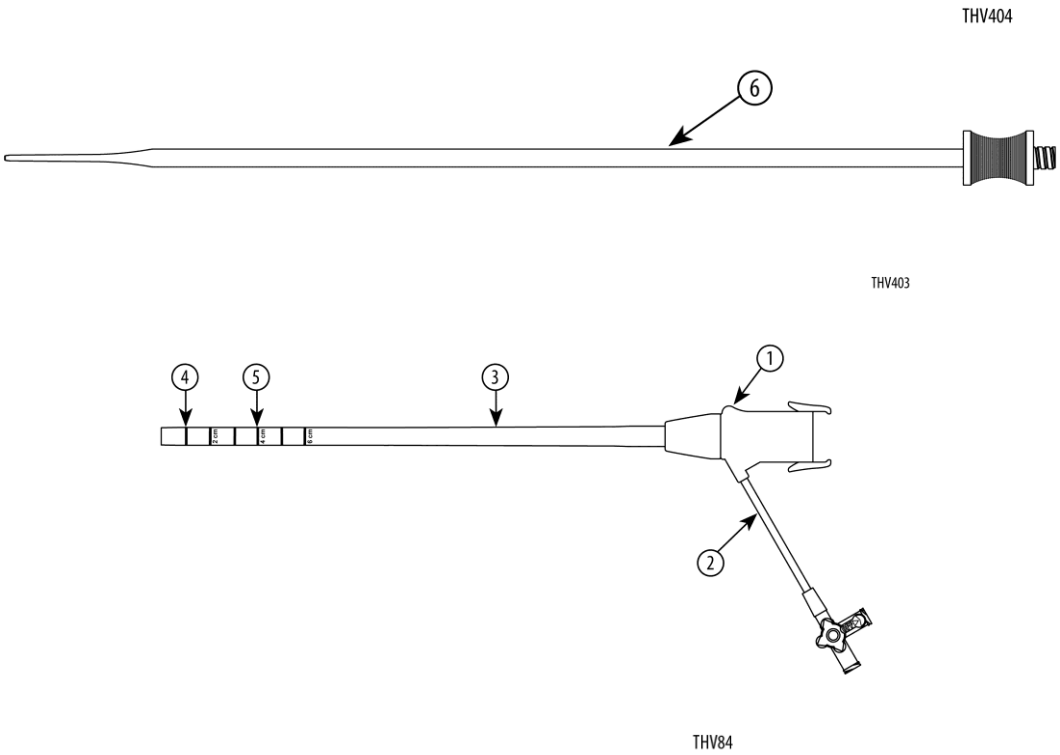
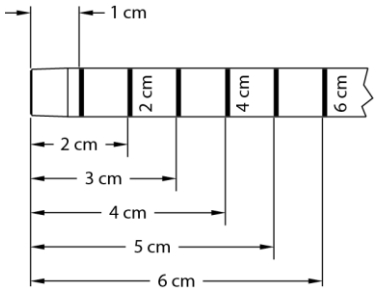


Figure 4. Edwards Certitude Introducer Sheath Set





1. Housing
2. Flush Tube with Stopcock
3. Sheath
4. Radiopaque Marker
5. Non-Radiopaque Depth Markers
6. Introducer

Symbol Legend

	English		English		English
REF	Catalogue Number		Use By	20 mm	For use with size 20 mm Edwards transcatheter heart valve
#	Quantity	SN	Serial Number	23 mm	For use with size 23 mm Edwards transcatheter heart valve
I	Minimum Introducer Size		Manufacturer	26 mm	For use with size 26 mm Edwards transcatheter heart valve
cm	Usable Length	EC REP	Authorised Representative in the European Community	29 mm	For use with size 29 mm Edwards transcatheter heart valve
	Single use	GW	Recommended Guidewire Size	23 mm 26 mm	For use with size 23 mm or size 26 mm Edwards transcatheter heart valve
LOT	Lot Number	SZ	Size	NON STERILE	Non-sterile
	Caution	GWC	Guidewire Compatibility	PHT	Contains phthalates
	Consult instructions for use	NP	Nominal Pressure	MR	MR Conditional
	Do not use if package is damaged	RBP	Rated Burst Pressure		Contents
	Do not use if package is opened or damaged.	STRAIGHT	Straight		Nonpyrogenic
	Exterior Diameter	DEFLECTED	Deflected	IPX1	Drip Proof Equipment
	Inner Diameter		Recommended Guidewire Length		Contents sterile and fluid path nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.
	Keep Dry	Sheath	Minimum Sheath Size		
	Store in a cool, dry place.	Catheter	Catheter Shaft Size		Contents sterile and nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.
	Temperature Limitation		Balloon Diameter		
STERILE	Sterile		Balloon Working Length		
STERILE EO	Sterilized Using Ethylene Oxide	USE	Use	Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
STERILE R	Sterilized Using Irradiation	USE	Do not use	eSheath	For use with eSheath, Edwards Expandable Introducer Sheath
STERILE	Sterile Using Steam or Dry Heat		Type CF applied part		

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

THV1SL8x11.9

EC REP

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85716 Unterschleissheim
Germany

CE 0344

11/16
DOC-0045537 B

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DATA MATRIX BARCODE FPO

Vendor: Do Not Print This Page.
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Edwards Lifesciences

Title:	IFU, CERTITUDE, EM, CE				
Label Item/Revision:	N/A	Graphic Artist:	Refer to supporting material for designer's signature	Page 11 of 11	
Visual Representation/Revision:	DOC-0045537/B	First Proof:	Refer to supporting material for reviewer's signature		
Drawing/Specification:	N/A	Second Proof:	Refer to supporting material for reviewer's signature		
English Master/Revision:	N/A	Final Proof:	N/A		

NOTE

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

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