Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System
愛德華瑟皮恩三和瑟皮恩三優創經導管心臟瓣膜套管組
Edwards SAPIEN 3 Transcatheter Heart Valve – Edwards COMMANDER Kit
愛德華瑟皮恩三經導管心臟瓣膜及股動脈套管組

TWFDA License No. 029439

DIRECTORY

English

Carefully read the manufacturer's manual prior to use and follow the instructions for use.

Instructions for Use
Implantation of transcatheter heart valves should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in standard catheterization techniques.

Product Name	20 mm	23 mm	26 mm	29 mm
Edwards SAPIEN 3 Transcatheter Heart Valve Edwards COMMANDER Kit	Model/Catalogue Number			
	S3TF120	S3TF123	S3TF126	S3TF129
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	9610ES14 (14F)			9610ES16 (16F)
Edwards Transfemoral Balloon Catheter	9350BC16	9350BC20	9350BC23	9350BC25
Crimper	9600CR			
Inflation Device	96402			-
Locking Syringe	-			96406
[1] Including a loader, a Qualcrimp, crimping accessory and a 2-piece crimp stopper				

1.0 Device Description

Edwards SAPIEN 3 System

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

- 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, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) inner and outer fabric skirts. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

Edwards, Edwards Lifesciences, the stylized E logo, Carpentier-Edwards, Edwards COMMANDER, Edwards eSheath, Edwards SAPIEN, Edwards SAPIEN 3, eSheath, Qualcrimp, SAPIEN, SAPIEN 3, and ThermaFix are trademarks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

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:

Table 1

Native Valve Annulus Size (TEE)*	Native Valve Annulus Size (CT)		THV Size
	Area	Area Derived Diameter	
16 – 19 mm	273 – 345 mm^2	18.6 – 21.0 mm	20 mm
18 – 22 mm	338 – 430 mm^2	20.7 – 23.4 mm	23 mm
21 – 25 mm	430 – 546 mm^2	23.4 – 26.4 mm	26 mm
24 – 28 mm	540 – 683 mm^2	26.2 – 29.5 mm	29 mm

THV size recommendations are based on native valve annulus size, as measured by transesophageal echocardiography (TEE) or computed tomography (CT). Patient anatomical factors and multiple imaging modalities should be considered during THV size selection.

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

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

Sizing recommendations for implanting the Edwards SAPIEN 3 transcatheter heart valve in a failing bioprosthesis are provided in the table below:

Surgical Valve True Inner Diameter (ID)[1]	THV-in-THV (Native Valve Annulus Size)	SAPIEN 3 Valve Size
16.5 - 19.0 mm	18.6 – 21.0 mm	20 mm
18.5 - 22.0 mm	20.7 - 23.4 mm	23 mm
22.0 - 25.0 mm	23.4 - 26.4 mm	26 mm
25.0 - 28.5 mm	26.2 - 29.5 mm	29 mm

NOTE: Surgical valve 'True ID' may be smaller than the labeled valve size. For THV-in-THV, the native valve annulus size should be considered to determine the appropriate THV size to implant. For a failing stentless bioprosthesis, consider sizing recommendations for a native annulus. The dimensions of the failed bioprosthesis should be determined so that the appropriate THV size can be implanted; and is best determined by using computed tomography, magnetic resonance imaging, and/or transesophageal echocardiography.

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 below.

Table 2

Access 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 COMMANDER Delivery System (Figure 3)**

The Edwards COMMANDER delivery system facilitates the placement of the bioprosthesis. It consists of a Flex Catheter to aid in valve alignment to the balloon, tracking, and positioning of the THV. The delivery system includes a tapered tip to facilitate crossing of the valve. The handle contains a Flex Wheel to control flexing of the Flex Catheter, and a Balloon Lock and Fine Adjustment Wheel to facilitate valve alignment and positioning of the valve within the target location. A stylet is included within the guidewire lumen of the delivery system. The Balloon Catheter has radiopaque Valve Alignment Markers defining the working length of the balloon. A radiopaque Center Marker in the balloon is provided to help with valve positioning. A radiopaque Triple Marker proximal to the balloon indicates the Flex Catheter position during deployment.

The inflation parameters for valve deployment are:

Table 3

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

- **Edwards Sheath**

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

- **Qualcrimp Crimping Accessory**

The Qualcrimp crimping accessory is used during THV crimping (Figure 2).

- **Loader**

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

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

The Edwards crimper reduces the diameter of the valve to mount it onto the delivery system. The crimper is comprised of a housing and a compression mechanism that is closed with a handle located on the housing. A 2-piece crimp stopper is used to crimp the valve to its intended diameter.

- **Inflation Device**

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

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

2.0 Indications

1. The Edwards SAPIEN 3 system is indicated for use in patients with heart disease due to native calcific aortic stenosis at any or all levels of surgical risk for open heart surgery, and who are appropriate as judged by a Heart Team.
2. The Edwards SAPIEN 3 system is indicated for use in patients with symptomatic heart disease due to a failing aortic bioprosthetic valve or a failing mitral surgical bioprosthetic valve (stenosed, insufficient, or combined) who are judged by a heart team to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical co-morbidities unmeasured by the STS risk calculator).

3.0 Contraindications

Use of the Edwards SAPIEN 3 system 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.**
- **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.**
- **Access characteristics such as severe obstructive or circumferential calcification, severe tortuosity, vessel diameters less than 5.5 mm (for size 20, 23 and 26 mm SAPIEN 3 transcatheter heart valve) or 6.0 mm (for 29 mm SAPIEN 3 transcatheter heart valve) may preclude safe placement of the sheath and should be carefully assessed prior to the procedure.**

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 aortic valve**
  - **Pre-existing prosthetic ring in any 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**
- **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.**
- **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**
- **Left ventricular outflow tract obstruction**
- **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 System Compatibility

Table 4

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
Edwards SAPIEN 3 Transcatheter Heart Valve	Model			
	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
Edwards COMMANDER Delivery System	9610TF20	9610TF23	9610TF26	9610TF29*
Sheath provided by Edwards Lifesciences				
Inflation device, Qualcrimp Crimping Accessory, Crimp Stopper and Loader provided by Edwards Lifesciences				
Edwards Crimper	9600CR			
*If using the eSheath introducer set, use 16F or equivalent				

Additional Equipment:

- Edwards Transfemoral Balloon Catheter or equivalent
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock
- 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
- Temporary pacemaker (PM) and pacing lead
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for THV and accessories preparation

7.2 Valve Handling and Preparation

Follow sterile technique during device preparation and implantation.

7.2.1 THV Rinsing Procedure

Before opening the valve jar, carefully examine for evidence of damage (e.g. a cracked jar or lid, leakage, or broken or missing seals).

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

Step	Procedure
1	Set up two (2) sterile bowls with at least 500 mL of sterile physiological saline to thoroughly rinse the THV.
2	Carefully remove the valve/holder assembly from the jar without touching the tissue. Verify the valve serial identification number with the number on the jar lid and record in the patient information documents. Inspect the valve for any signs of damage to the frame or tissue.
3	Rinse the THV as follows: • Place the THV in the first bowl of sterile, physiological saline. Be sure the saline solution completely covers the THV and holder. • With the valve and holder submerged, slowly agitate (to gently swirl the valve and holder) back and forth for a minimum of 1 minute. • Transfer the THV and holder to the second rinsing bowl of sterile physiological saline and gently agitate for at least one more minute. Ensure the rinse solution in the first bowl is not used. • The valve should be left in the final rinse solution until needed to prevent the tissue from drying. **CAUTION: Do not allow the valve to come into contact with the bottom or sides of the rinse bowl during agitation or swirling in the rinse solution. Direct contact between the identification tag and valve is also to be avoided during the rinse procedure. No other objects should be placed in the rinse bowls. The valve should be kept hydrated to prevent the tissue from drying.**

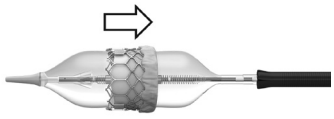
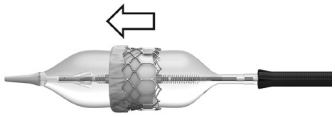
7.3 Valve Handling and Preparation

7.3.1 Prepare the System

Step	Procedure
1	Visually inspect all the components for damage. Ensure the delivery system is fully unflexed and the balloon catheter is fully advanced in the flex catheter. **WARNING: To prevent possible damage to the balloon shaft, ensure that the proximal end of the balloon shaft is not subjected to bending.**
2	Flush the delivery system with heparinized saline 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. **WARNING: Ensure there is no residual fluid left in the balloon to avoid potential difficulty with valve alignment during the procedure.** Close stopcock to the delivery system.
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.**

7.3.2 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.

Step	Procedure
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 orientation of the valve on the delivery system as described below: **Antegrade approach:** Inflow (outer skirt end) of the valve towards the **proximal end** of the delivery system.  **Retrograde approach:** Inflow (outer skirt end) of the valve towards the **distal end** of the delivery system. 
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 to prevent the risk of severe patient harm.**

7.4 Native Valve Predilation and THV Delivery

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

Administer heparin to maintain the ACT at ≥ 250 sec.

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

Balloon valvuloplasty should be avoided in the treatment of failing bioprostheses as this may result in embolization of bioprosthesis material and mechanical disruption of the valve leaflets.

7.4.1 Baseline Parameters

Step	Procedure
1	Perform an angiogram with the projection of the valve perpendicular to the view.
2	For aortic implantation, 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 and position appropriately.
4	Set the stimulation parameters to obtain 1:1 capture, and test pacing.

7.4.2 Native Valve Predilation

Refer to Edwards Transfemoral Balloon Catheter or equivalent Instructions for Use.

7.4.3 THV Delivery

Step	Procedure
1	Prepare the Edwards sheath introducer set per its instructions for use.
2	If necessary, predilate the 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. **CAUTION: For iliofemoral access, the THV should not be advanced through the sheath if the sheath tip is not past the bifurcation to minimize the risk of vessel damage.** **CAUTION: The THV should not remain in the sheath for over 5 minutes as leaflet damage may result and impact valve functionality.**
6	In a straight section of the vasculature, initiate valve alignment by disengaging the Balloon Lock and pulling the balloon catheter straight back until part of the Warning Marker is visible. Do not pull past the Warning Marker. **WARNING: To prevent possible damage to the balloon shaft, ensure that the proximal end of the balloon shaft is not subjected to bending.** **WARNING: If valve alignment is not performed in a straight section, there may be difficulties performing this step which may lead to delivery system damage and inability to inflate the balloon. Utilizing alternate fluoroscopic views may help with assessing curvature of the anatomy. If excessive tension is experienced during valve alignment, repositioning the delivery system to a different straight section of the aorta and relieving compression (or tension) in the system will be necessary.** 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 during valve alignment to prevent loss of guidewire position.**
7	Utilize the Flex wheel to access and cross the valve. **NOTE: Verify the orientation of the Edwards logo to ensure proper articulation.** **NOTE: The delivery system articulates in a direction opposite from the flush port.**
8	Disengage the Balloon Lock and retract the tip of the Flex Catheter to the center of the Triple Marker. Engage the Balloon Lock.
9	Position the THV with respect to the valve.
10	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.
11	Before deployment, ensure that the THV is correctly positioned between the Valve Alignment Markers and the Flex Catheter tip is over the Triple Marker.
12	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.

7.4.4 System Removal

Step	Procedure
1	Unflex the delivery system while retracting the device. Verify that the Flex Catheter tip is locked over the Triple Marker. Retract the loader to the proximal end of the delivery system. Remove the delivery system from the sheath. **CAUTION: Completely unflex the delivery system prior to removal to minimize the risk of vascular injury.**

7.5 Verification of Prosthetic Valve Position and Measurements

Measure and record hemodynamic parameters

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

8.0 How Supplied

STERILE: The valve is supplied sterilized with glutaraldehyde solution.

The delivery system and accessories are supplied sterilized by 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.

8.1 Storage

The THV 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 THV to extreme temperature.

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 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 tesla
- Maximum spatial gradient field of 2500 Gauss/cm (25 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the transcatheter heart valve is expected to produce a maximum temperature rise of 3.0 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 14.5 mm from the implant for spin echo images and 30 mm for gradient echo images when scanned in a 3.0 T MRI system. The artifact obscures the device lumen in gradient echo images.

The implant has not been evaluated in MR systems other than 1.5 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.

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

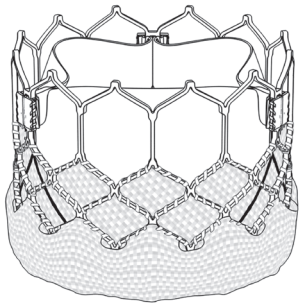
The explanted THV should be placed into a suitable histological fixative such as 10% formalin or 2% glutaraldehyde and returned to the company. Refrigeration is not necessary under these circumstances. Contact Edwards Lifesciences to request an Explant Kit.

Used delivery system may be disposed of in the same manner that hospital waste and biohazardous materials are handled. There are no special risks related to the disposal of these devices.

12.0 Reference

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.

13.0 Figures



9600TFX

Valve Size	Valve Height (mm)
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

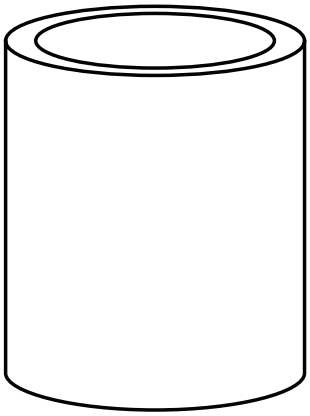


Figure 2. Qualcrimp Crimping Accessory

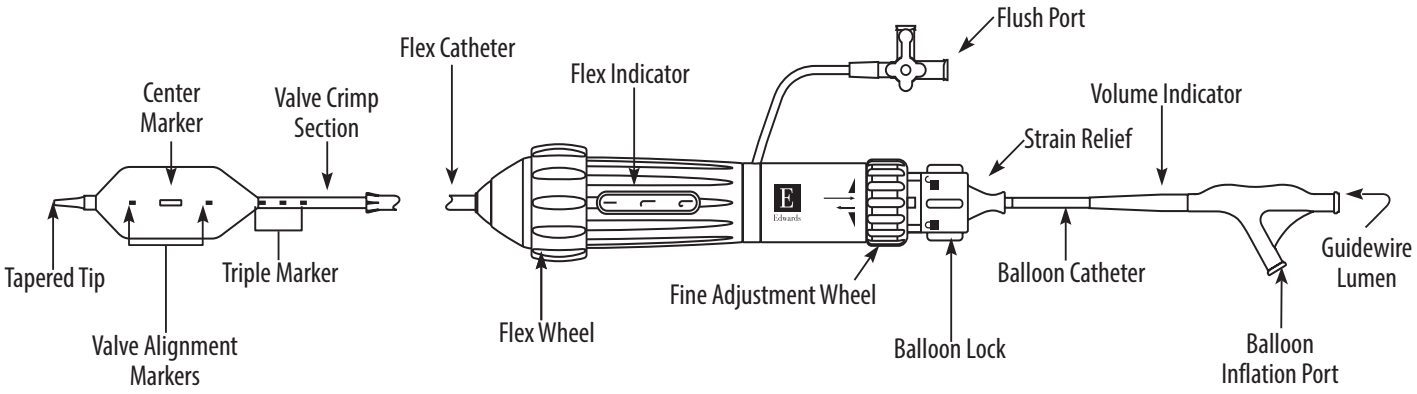


Figure 3. Edwards COMMANDER Delivery System

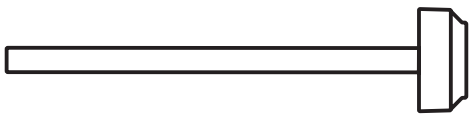


Figure 4. Loader

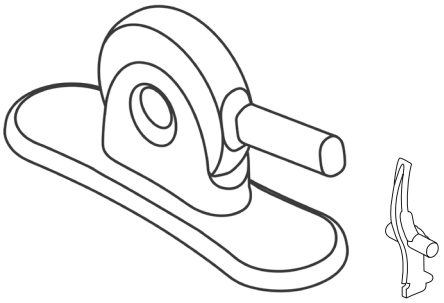


Figure 5. Crimper and 2-piece Crimp Stopper

14.0 Conditions of Medical Institutions and Operator Qualifications for Transcatheter Aortic Valve Replacement

Conditions of Medical Institutions	1. The following full-time medical personnel are provided: 1) Specialist physician of Department of Cardiac Surgery 2) Specialist physician of Cardiology Department 3) Specialist physician of Anesthesia 4) Sonographer 5) Operating room nurse and cardiac catheter technician 2. The hospital must have more than 500 cases of cardiac catheters (including more than 200 cases of interventional cardiac catheter operations) and more than 25 surgical cases of aortic valve replacement on a yearly basis. 3. The following devices are provided: 1) Cardiac ultrasonic equipment. 2) Computed tomography scanner or magnetic resonance imaging machine with 64 or more sections. 3) The operation should be performed in a hybrid operating room equipped with an X-ray camera for cardiac catheter and a high-efficiency air filter (at least HEPA-10000). 4) Space equipment >75 square meters. 5) Cardiopulmonary bypass equipment 6) Cardiac Intensive Care Unit
Operator Qualifications	1. Operating physicians shall have the following qualifications: 1) More than five years of being a specialist physician. 2) Having the experience of more than 25 cases of aortic valve replacement, or more than 300 cases of cardiac interventional treatment, as well as the supporting documents issued by the service hospital and the Taiwan Association of Thoracic & Cardiovascular Surgery, the Taiwan Society of Cardiology or the Taiwan Society of Cardiovascular Interventions after review. 3) Having the experience of receiving the training courses of "Transcatheter Aortic Valve Replacement" with the relevant certificates and participating in more than five cases of practical operation.
Matters Concerned	When performing the treatment, specialist physicians of Department of Cardiac Surgery and specialist physicians of Cardiology Department who have the above operation qualifications must be present to perform the operation together and take necessary emergency measures at any time.

Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System
Edwards SAPIEN 3 Transcatheter Heart Valve – Edwards COMMANDER Kit
Edwards Transfemoral Balloon Catheter

Carefully read the manufacturer's manual prior to use and follow the instructions for use.

Instructions for Use

1.0 Device Description

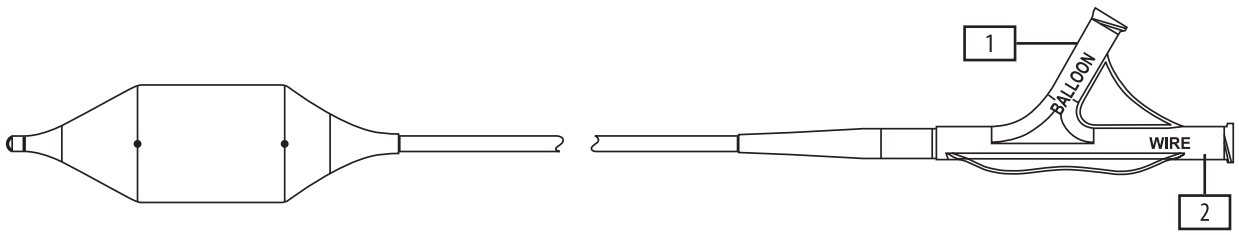
The Edwards transfemoral balloon catheter consists of a shaft and balloon with two radiopaque marker bands that indicate the working length of the balloon. The proximal end of the device has a "Y-connector" with a balloon inflation port labeled as "BALLOON" and a guidewire lumen port labeled as "WIRE".

The inflation parameters are as follows:

Table 1: Inflation Parameters

Model	Nominal		
	Balloon Diameter	**Inflation Volume**	**Inflation Pressure**
9350BC16	16 mm	10 mL	4 atm (405 kPa)
9350BC20	20 mm	16 mL	4 atm (405 kPa)
9350BC23	23 mm	21 mL	4 atm (405 kPa)
9350BC25	25 mm	26 mL	4 atm (405 kPa)

Edwards Transfemoral Balloon Catheter



Black dots indicate position of radiopaque marker bands.

1 – Balloon Inflation Port

2 – Guidewire Lumen Port

Device compatibility specifications are as follows:

Table 2: Device Compatibility

Model	Max. Guidewire Diameter	Min. Sheath Compatibility
9350BC16	0.035" (0.89 mm)	14F (4.7 mm)
9350BC20	0.035" (0.89 mm)	14F (4.7 mm)
9350BC23	0.035" (0.89 mm)	14F (4.7 mm)
9350BC25	0.035" (0.89 mm)	16F (5.3 mm)

NOTE: For proper volume sizing, the balloon catheter should be used with the inflation device provided by Edwards Lifesciences.

2.0 Indications

The balloon catheter is indicated for dilation of stenotic native aortic valve leaflets.

3.0 Contraindications

The device is contraindicated for patients with:

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

Edwards, Edwards Lifesciences, and the stylized E logo are trademarks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

4.0 Warnings

- **The device is designed, intended, and distributed for single use only. Do not resterilize or reuse the device. There are no data to support the sterility, nonpyrogenicity, and functionality of the device after reprocessing.**
- **Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation.**
- **Use only appropriate balloon inflation medium. Do not use air or gaseous medium to inflate the balloon.**
- **The balloon inflation diameter must not be significantly greater than the annulus diameter being pre-dilated.**
- **The device is not intended for post-dilatation of deployed transcatheter heart valves.**
- **While exposed within the body, device advancement and retrieval should not be done without the aid of fluoroscopy. Do not advance or retract the device unless the balloon is fully deflated under vacuum.**
- **Do not mishandle the balloon catheter or use it if the packaging or any components are not sterile, have been opened or are damaged (i.e. kinked or stretched), or the expiration date has elapsed.**

5.0 Precautions

The safety and effectiveness of the balloon catheter has not been established in patients who have a congenital unicuspid or congenital bicuspid aortic valve.

6.0 Potential Adverse Events

Complications associated with standard catheterization, balloon aortic valvuloplasty, and the use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media, injury including perforation or dissection of vessels, thrombosis, emboli formation, renal failure; renal insufficiency, and plaque dislodgement which may result in myocardial infarction, stroke, and/or death. Additional complications may include arrhythmia development, cardiac perforation, conduction system injury, hematoma, infundibulum injury, annular tear or rupture and/or valvular tearing or trauma.

7.0 Directions for Use

Dilate native valve leaflets using standard technique and rapid cardiac pacing.

Step	Procedure
1	Prepare vascular access site for catheter insertion and position guidewire using standard techniques.
2	With the balloon cover in place, flush the guidewire lumen of the Edwards transfemoral balloon catheter with heparinized saline. Attach a high pressure 3-way stopcock to the balloon inflation port.
3	Prepare a syringe with diluted contrast solution (15:85 medium to saline dilution) and attach to the stopcock.
4	Fill the inflation device with excess diluted contrast medium relative to the indicated volume, attach in the locked position to the stopcock, close the stopcock to the inflation device.
5	Slowly pull vacuum with the syringe repeatedly to remove air, leaving zero pressure in the system.
6	Close the stopcock to the balloon catheter. Gradually remove contrast medium into the syringe to achieve the appropriate volume (as specified in Table 1: Inflation Parameters). Lock the inflation device, close the stopcock to the syringe and remove the syringe from the system.
7	Remove the balloon cover and hydrate the length of the balloon catheter.
8	Advance the balloon catheter over the guidewire, through the introducer sheath, across the aortic valve, and position the balloon markers at the intended site.
9	Ensure hemodynamic stability is established and begin rapid pacing. Once the blood pressure has decreased to 50 mmHg or below, balloon inflation can commence.
10	Fully and rapidly inflate the balloon with the inflation device. In case of balloon instability, repeat balloon inflation while ensuring rapid ventricular pacing. When the balloon is fully deflated, the pacing should be turned off.

8.0 How Supplied

Supplied pouched and sterilized by ethylene oxide.

9.0 Storage

Store in a cool, dry place.

10.0 Device Disposal

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.

Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System
Edwards SAPIEN 3 Transcatheter Heart Valve – Edwards COMMANDER Kit
Edwards eSheath Introducer Set

Carefully read the manufacturer's manual prior to use and follow the instructions for use.

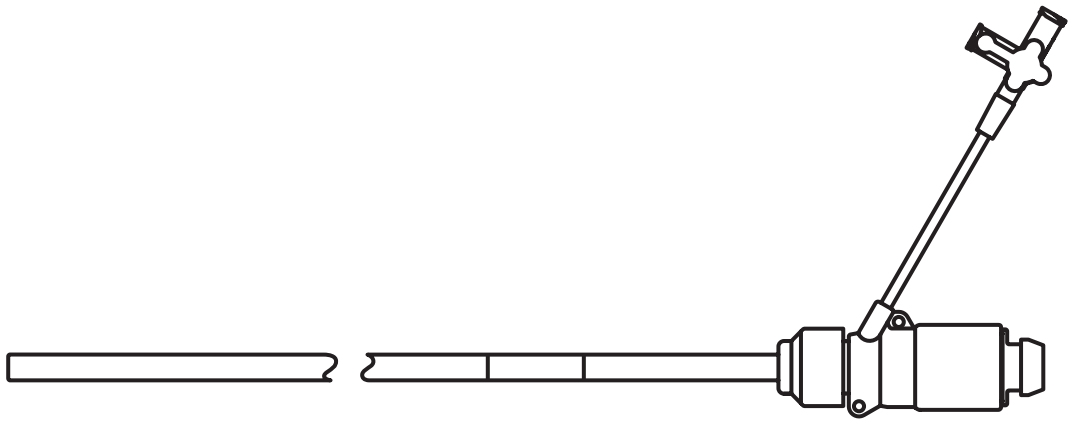
Instructions For Use

1.0 Device Description

The Edwards eSheath introducer set contains:

a) an expandable sheath (eSheath) (Fig 1) that provides access into the target vessel while maintaining hemostasis and temporarily enlarges its diameter to allow for passage of a device.

Figure 1



Model	eSheath I.D. (unexpanded)	eSheath O.D. (unexpanded)
9610ES14	14F (4.6 mm)	6.0 mm
9610ES16	16F (5.3 mm)	6.7 mm

Figure 2

b) two dilators (Fig 2) with hydrophilic coating that can either be used to dilate the vessel to accommodate the sheath and/or facilitate entry and trackability of the sheath into the vessel.

2.0 Intended Use

The Edwards eSheath introducer set is intended for introduction of interventional devices into the vascular system. The product is intended for use by physicians trained and experienced in interventional techniques. Standard techniques for placement of vascular access sheaths should be employed.

3.0 Contraindications

This product is contraindicated for patients with tortuous or calcified vessels that would prevent safe entry of the dilators and sheath.

4.0 Warnings

The devices are designed, intended, and distributed 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.

The Edwards eSheath introducer set must be used with a compatible 0.035" (0.89 mm) guidewire to prevent vessel injury.

Do not mishandle the device or use it if the packaging or any components are not sterile, have been opened or are damaged (i.e., kinked or stretched, etc.), or the expiration date has elapsed.

Edwards, Edwards Lifesciences, the stylized E logo, Edwards eSheath, and eSheath are trademarks of Edwards Lifesciences Corporation.
All other trademarks are the property of their respective owners.

5.0 Precautions

- **The sheath temporarily enlarges to allow the passage of devices; ensure that the vasculature can accommodate the maximum diameter of the expanded sheath.**
- **When inserting, manipulating or withdrawing a device through the sheath, always maintain orientation of the sheath position.**
- **When puncturing, suturing or incising the tissue near the sheath, use caution to avoid damage to the sheath.**

6.0 Potential Adverse Events

Complications associated with standard catheterization and use of angiography include, but are not limited to, allergic reaction to anesthesia or to contrast media; injury including perforation or dissection of vessels; injury at the site of access that might require vessel repair; thrombosis and/or plaque dislodgment which may result in emboli formation; distal vessel obstruction; stroke; ischemia and/or death.

7.0 Directions for Use

1. Visually inspect device components for damage.
2. Flush the dilators using heparinized saline through the guidewire lumen.
3. Flush the sheath using heparinized saline through the flush port; close the flush port.
4. Hydrate the length of the introducer/dilators and sheath with heparinized saline to activate the hydrophilic coating.
5. Insert one dilator completely into the sheath.
6. Using standard catheterization techniques, gain access to the vessel and dilate as necessary with the other dilator to accommodate the sheath.
7. Orient the sheath appropriately and maintain orientation throughout the procedure. Insert the sheath assembly using standard technique and advance into the vessel while following its progression under fluoroscopy.

NOTE: The proximal tapered end of the sheath working length is larger in diameter.

8. If possible, suture the sheath into place using the suture rings and remove the dilator from the sheath.
9. Insert the device into the sheath.

NOTE: The sheath should be intermittently flushed with heparinized saline throughout the procedure, per standard interventional technique.

10. After the completion of the procedure and removal of the device, remove the suture, and then remove the sheath entirely without torquing and do not reinsert.

8.0 How Supplied

The Edwards eSheath introducer set is supplied in a pouch and sterilized with ethylene oxide.

9.0 Storage

The Edwards eSheath introducer set should be stored in a cool, dry place.

10.0 Device Disposal

Used sheath sets 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.

Manufacturer Name: Edwards Lifesciences LLC

Manufacturer Address: One Edwards Way, Irvine, CA 92614, USA "Made (partly made) in Singapore"

Dealer Name: Edwards Lifesciences (Taiwan) Co. Ltd.

Dealer Address: 9F-1, No. 2, Sec. 3, Minsheng E. Rd, Zhongshang Dist., Taipei City 104, Taiwan R.O.C.

愛德華瑟皮恩三和瑟皮恩三優創經導管心臟瓣膜套管組
Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System
愛德華瑟皮恩三經導管心臟瓣膜及股動脈套管組
Edwards SAPIEN 3 – Edwards COMMANDER Kit

衛部醫器輸字第 029439 號

繁體中文

使用前請務必詳閱原廠之使用說明書並遵照指示使用

使用說明

醫師必須接受愛德華公司相關訓練，才可執行經導管心臟瓣膜的植入手術。負責植入手術的醫師應具備標準心導管技術的經驗。

產品名稱	20 mm	23 mm	26 mm	29 mm
愛德華瑟皮恩三經導管心臟瓣膜及股動脈套管組 (Edwards SAPIEN 3 – Edwards COMMANDER Kit)	型號/目錄編號			
	S3TF120	S3TF123	S3TF126	S3TF129
Edwards SAPIEN 3 經導管心臟瓣膜 (Transcatheter Heart Valve)	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
Edwards COMMANDER 輸送系統[1] (Delivery System)	9610TF20	9610TF23	9610TF26	9610TF29
Edwards eSheath 導引器套組(Introducer Set)	9610ES14(14F)			9610ES16 (16F)
Edwards 經股動脈氣球導管 (Transfemoral Balloon Catheter)	9350BC16	9350BC20	9350BC23	9350BC25
壓折器(Crimper)	9600CR			
Inflation Device	96402			-
Locking Syringe	-			96406
[1]包括裝填器、Qualcrimp 壓折器配件(Crimping Accessory)及兩件式壓折器擋片(Crimp Stopper)				

1.0 裝置介紹

Edwards SAPIEN 3 系統

瑟皮恩三 (Edwards SAPIEN 3) 系統由 Edwards SAPIEN 3 經導管心臟瓣膜及輸送系統組成。

• 瑟皮恩三 (Edwards SAPIEN 3) 經導管心臟瓣膜(圖1)

瑟皮恩三 (Edwards SAPIEN 3) 經導管心臟瓣膜(transcatheter heart valve，簡稱THV)的組成包括：一組可藉氣球擴張、不透射線的鈷鉻合金支架；利用牛心包膜製成的三葉結構瓣膜；聚對苯二甲酸乙二酯 (polyethylene terephthalate，簡稱PET)材質的內層裙緣及外層裙緣。瓣膜依照Carpentier-Edwards ThermaFix (熱固定)程序處理。

經導管心臟瓣膜適合植入的原生瓣環尺寸範圍，係以心臟收縮時、在瓣環基部(basal ring)測得之主動脈瓣環三度空間面積推算而得：

表1

經食道心臟超音波 (Transesophageal Echocardiogram，簡稱TEE) *	原生瓣環尺寸(CT)		經導管心臟瓣膜(THV)尺寸
	面積	面積換算直徑	
16 - 19 mm	273 - 345 mm²	18.6 - 21.0 mm	20 mm
18 - 22 mm	338 - 430 mm²	20.7 - 23.4 mm	23 mm
21 - 25 mm	430 - 546 mm²	23.4 - 26.4 mm	26 mm
24 - 28 mm	540 - 683 mm²	26.2 - 29.5 mm	29 mm

THV尺寸建議是基於通過經食道心臟超音波 (TEE)或電腦斷層掃描(CT)所測量的原生瓣環尺寸。選擇THV尺寸時應考慮患者的解剖構造因素和多種成像方式。

註：應考慮與尺寸不足和尺寸過大的相關風險，以將瓣週漏、移位和/或瓣環破裂的風險降至最低。

*由於二度空間影像的限制，二度空間的經食道心臟超音波影像應以三度空間的面積測量結果補足

有關植入 Edwards SAPIEN 3 經導管心臟瓣膜至功能衰竭的人工生物瓣膜內的尺寸建議如下表：

外科瓣膜真內徑 [1] (ID)	THV-in-THV (原生瓣環尺寸)	SAPIEN 3 瓣膜尺寸
16.5 - 19.0 mm	18.6 – 21.0 mm	20 mm
18.5 - 22.0 mm	20.7 - 23.4 mm	23 mm
22.0 - 25.0 mm	23.4 - 26.4 mm	26 mm
25.0 - 28.5 mm	26.2 - 29.5 mm	29 mm

註：外科瓣膜(surgical valve)的真內徑可能小於標籤所示的瓣膜尺寸。對於經導管心臟瓣膜內植經導管心臟瓣膜(THV-in-THV)，應考慮原生瓣環尺寸以確定植入適合的經導管心臟瓣膜尺寸。對於功能衰竭的無支架人工生物瓣膜應考慮原生瓣環的尺寸建議。應確定功能失效的人工生物瓣膜尺寸，以便植入適當尺寸的經導管心臟瓣膜；並最好使用電腦斷層(CT)、磁振造影(MRI)或經食道心臟超音波進行尺寸測量。

註：展開經導管心臟瓣膜所需的確切體積，可能依人工生物瓣膜的內部孔徑而異。諸如鈣化和血管組織生長等因素可能在成像中不能準確地顯現，並且可能將功能衰竭的人工生物瓣膜有效內徑減少至小於 "True ID" 一 個尺寸。應考慮和評估這些因素以確定最合適的經導管心臟瓣膜尺寸，達到經導管心臟瓣膜公稱的展開和充足錨固。請勿超出額定破裂壓力。有關擴張參數請參閱表2。

表2

介入血管直徑	輸送系統
≥ 5.5 mm	20 mm
≥ 5.5 mm	23 mm
≥ 5.5 mm	26 mm
≥ 6.0 mm	29 mm

- **Edwards COMMANDER 輸送系統(圖 3)**

Edwards COMMANDER 輸送系統用於置放人工生物瓣膜。其包括一組Flex 導管，用於協助調整瓣膜相對於氣球的位置、追蹤定位經導管心臟瓣膜。輸送系統的錐形末梢有助於通過原生瓣膜。把手的Flex控制環可控制Flex 導管的彎曲狀態，氣球鎖定裝置及微調環則能協助瓣膜定位與調整瓣膜在原生瓣環內的位置。輸送系統的導引線管腔內附有一通管針。氣球導管具有不透射線的瓣膜定位標記，標示出氣球的有效長度。不透射線的氣球中央標記可協助瓣膜的定位。氣球近端、不透射線的三重標記則可在展開時標示出Flex 導管的位置。

展開經導管心臟瓣膜時的擴張參數：

表3

型號	標稱氣球直徑	標稱擴張體積	額定破裂壓力 (Rated Burst Pressure，簡稱 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

- **Edwards Sheath (套管)**

請參考 Edwards sheath 使用說明關於裝置的敘述。

- **Qualcrimp 壓折器配件**

Qualcrimp 壓折器配件用於經導管心臟瓣膜的壓折(圖2)。

- **裝填器**

裝填器用於將輸送系統放入套管(圖4)。

- **Edwards 壓折器及壓折器擋片(圖5)**

壓折器可縮小經導管心臟瓣膜的直徑，並將其裝上輸送系統。壓折器由外殼和壓縮裝置組成，壓縮裝置可利用位於外殼的把手闔起。壓折器應搭配兩件式壓折器擋片使用，用以壓折經導管心臟瓣膜至預期直徑。

- **擴張裝置**

具有鎖定機制的擴張裝置用於展開經導管心臟瓣膜。

註：為達到適當體積，使用 Edwards COMMANDER 輸送系統及 Edwards 經股動脈氣球導管時應搭配愛德華公司提供的擴張裝置。

2.0 適應症

1.Edwards SAPIEN 3 系統適用於原生鈣化性主動脈瓣狹窄，並對於開放性外科手術具有任何或所有風險程度，與經心臟專科團隊判定後適合的心臟疾病患者。

2.Edwards SAPIEN 3 系統適用於，患者先前植入的主動脈瓣人工生物瓣膜、或二尖瓣外科人工生物瓣膜功能衰竭(狹窄、閉鎖不全、或複合性)，並經由心臟專科團隊判定為對於開放性外科手術具有高度或更高風險(即：依據胸腔外科醫師學會(STS)風險評分及STS風險計算式未測量之其他臨床合併症，預期30天的手術致死率風險≥ 8%)的患者。

3.0 禁忌症

Edwards SAPIEN 3 系統禁用用於出現下列狀況的患者：

- 心臟內部有明顯腫塊、血栓、贅生物、急性感染或心內膜炎
- 無法耐受抗凝血/抗血小板治療。

4.0 警告

- 本裝置基於設計、用途及銷售目的，以無菌狀態供應且僅限單次使用。切勿再次滅菌或重複使用本裝置。目前尚無資料證明，本裝置經重新處理後無菌性、無致熱原性及功能是否仍符合標準。
- 為降低瓣膜周圍滲漏、移位、及/或瓣環破裂的風險，務必選擇尺寸適當的經導管心臟瓣膜。
- 醫師必須在植入前確認經導管心臟瓣膜的方向是否正確。
- 患者鈣質代謝功能有所改變時，可能會加快經導管心臟瓣膜的劣化速度。
- 為避免節律導極穿孔的風險，務必全程觀察節律導極的傳輸情形。
- 經導管心臟瓣膜必須隨時保持濕潤，而且為避免瓣葉組織受損而影響瓣膜功能，除專用運送保存液及無菌生理食鹽水溶液外，不可讓瓣膜接觸其他溶液、化學物質、抗生素等。若經導管心臟瓣膜的瓣葉在流程中受到不當操作或損傷，必須更換整組經導管心臟瓣膜。
- 若患者對鈷、鎳、鉻、鉬、鈦、錳、矽及/或聚合材料過敏，可能會因這些材質而引發過敏反應。
- 當防變造封條破損時，無菌狀態可能受到破壞，切勿使用該組經導管心臟瓣膜。
- 當溫度指示裝置啟動時，瓣膜功能可能受到影響，切勿使用該組經導管心臟瓣膜。
- 當超過保存期限時，無菌狀態或瓣膜功能可能受到影響，切勿使用該組經導管心臟瓣膜。
- 切勿不當操作輸送系統；若包裝無菌屏障及組件已經開啟或毀損、無法沖洗、超過保存期限，亦不可使用該組輸送系統及配件裝置。
- 介入條件如嚴重阻塞或圓周向鈣化、嚴重扭曲、血管直徑小於5.5 mm（尺寸為20、23和26 mm SAPIEN 3 經導管心臟瓣膜）或6.0 mm（尺寸為29 mm SAPIEN 3 經導管心臟瓣膜）可能阻礙套管安全地放置，應在手術前仔細評估。

5.0 注意事項

- 戊二醛可能會刺激皮膚、眼、鼻及喉嚨，因此應避免長時間或反覆接觸、吸入其溶液。務必在通風良好的環境中使用。若接觸到皮膚，應立即以清水沖洗影響範圍；若接觸到眼睛，應立即就醫處理。如需更多關於接觸戊二醛的資訊，請參考愛德華公司提供的物質安全資料表(Material Safety Data Sheet)。
- 目前尚未驗證下列患者接受經導管心臟瓣膜植入手術時的安全性及效能：
  - 先天性單尖瓣型主動脈瓣
  - 任何位置已裝有人工瓣膜修補環
  - 心室功能嚴重異常，射出分率低於 20%
  - 肥厚性心肌病變，不論有無阻塞
  - 主動脈狹窄，特徵為併發主動脈瓣流速偏低、瓣膜兩側壓力差異過小
- 如果在脈管系統中推進導管時阻力顯著增加，請在繼續操作之前停止前進並檢查阻力原因。請勿強行推進，因為這可能會增加血管併發症的風險。
- 對於有可能出現人工瓣膜感染或心內膜炎風險的患者，建議術後給予適當的抗生素預防治療。
- 患者接受經導管心臟瓣膜植入手術後，應由其醫師判斷，是否維持抗凝血/抗血小板藥物治療，以降低瓣膜血栓或血栓栓塞事件的風險。

- 目前尚未驗證經導管心臟瓣膜的長期耐用性，因此建議患者定期接受醫療追蹤以評估瓣膜表現。
- 根據主治醫師對風險和效益的考量，可將 SAPIEN 3 瓣膜植入相對年輕的患者，雖然長期耐用性仍待持續進行臨床研究。
- 切勿對展開用氣球過度充氣，以免瓣葉無法適當接合而影響瓣膜功能。
- 若患者已裝有人工生物瓣膜，為確保經導管心臟瓣膜適當定位及展開，進行經導管心臟瓣膜植入手術前應先審慎評估。

6.0可能發生的不良事件

整個手術過程(包括裝置導入、心導管手術、局部及/或全身麻醉)的相關潛在風險：

- 抗血栓治療藥物、顯影劑或麻醉劑引發過敏反應(Allergic reaction)
- 貧血(Anemia)
- 動脈瘤(Aneurysm)
- 心絞痛(Angina)
- 心律不整(Arrhythmia)，例如心室纖維顫動(ventricular fibrillation，簡稱 VF)及心室頻脈(ventricular tachycardia，簡稱 VT)
- 動靜脈瘻管(AV fistula)或假性血管瘤(pseudoaneurysm)
- 心因性休克(Cardiogenic shock)
- 腔室症候群(Compartment syndrome)
- 死亡(Death)
- 剝離(Dissection)：主動脈或其他血管
- 遠端栓塞(Emboli)（空氣、組織或血栓栓塞）
- 血腫(Hematoma)
- 高血壓(Hypertension)或低血壓(hypotension)
- 發炎(Inflammation)
- 心肌局部缺血(Myocardial ischemia)或梗塞(infarction)
- 導管插入部位(access site)疼痛或變化
- 心臟構造穿孔或破裂(Perforation or rupture of cardiac structures)
- 血管穿孔或破裂(Perforation or rupture of vessels)
- 心包積液(Pericardial effusion)或心包填塞(cardiac tamponade)
- 周邊局部缺血(Peripheral ischemia)或神經損傷(nerve injury)
- 肺水腫(Pulmonary edema)
- 腎功能不全(Renal insufficiency)或腎臟衰竭(renal failure)
- 呼吸功能不全(Respiratory insufficiency)或呼吸衰竭(respiratory failure)
- 暈厥(Syncope)
- 血管迷走神經反應(Vasovagal response)
- 血管痙攣(Vessel spasm)
- 血管血栓/阻塞(Vessel thrombosis/occlusion)
- 血管損傷(Vessel trauma)，必須以手術修復或進行處置

經導管主動脈瓣置換術(TAVR)、人工生物瓣膜及相關裝置與配件的其他相關潛在風險包括：

- 植入物引發過敏/免疫反應(Allergic/immunologic reaction)
- 心房纖維顫動(Atrial fibrillation)/心房撲動(Atrial flutter)
- 出血(Bleeding)，必須輸血或進行處置
- 心跳停止(Cardiac arrest)

- 心臟衰竭(Cardiac failure)或心輸出量偏低(low cardiac output)
- 心因性休克(Cardiogenic shock)
- 傳導系統(Conduction system)損傷(缺陷)，例如房室傳導阻滯(AV block)，可能必須使用永久性心律調節器
- 冠狀動脈阻塞(Coronary occlusion)
- 主動脈瓣環及周邊構造(例如升主動脈、冠狀動脈口、心室中膈)出現剝離(Dissection)、破裂(rupture)、損傷(trauma)
- 緊急心臟手術(Emergency cardiac surgery)
- 溶血(Hemolysis)
- 感染(Infection)、發燒(fever)、敗血症(septicemia)、膿瘍(abscess)、心內膜炎(endocarditis)
- 二尖瓣損傷(Injury to mitral valve)
- 左心室出口通道阻塞(LVOT obstruction)
- 輸送系統及/或配件出現機械性故障，例如氣球破裂或末梢分離
- 縱膈炎(mediastinitis)
- 縱膈腔出血(mediastinal bleeding)
- 無症狀性腦缺血(Silent cerebral ischemia)、中風(stroke)、暫時性腦缺血發作(transient ischemic attack)、認知功能障礙(cognitive impairment)
- 瓣膜結構性劣化(磨損、斷裂、鈣化、狹窄)
- 瓣膜在預期以外位置展開
- 瓣膜移除(Valve explants)
- 瓣膜移位(Valve migration)、位置錯誤(malposition)或栓塞，必須進行處置
- 瓣膜逆流(Valve regurgitation)、瓣膜周圍或經瓣膜
- 瓣膜血栓(Valve thrombosis)

7.0 操作說明

7.1 系統相容性

表4

產品名稱	20 mm 系統	23 mm 系統	26 mm 系統	29 mm 系統
Edwards SAPIEN 3 經導管心臟瓣膜 (Transcatheter Heart Valve)	型號			
	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
Edwards COMMANDER 輸送系統 (Delivery System)	9610TF20	9610TF23	9610TF26	9610TF29*
套管 (Sheath) 由愛德華提供				
擴張裝置、Qualcrimp 壓折器配件、壓折器擋片及裝填器皆由愛德華提供				
壓折器(Crimper)	9600CR			
*如果使用 Edwards eSheath 導引器套組 (Introducer Set)，請使用16F或等同尺寸產品				

附加設備：

- Edwards 經股動脈氣球導管或類似功能產品
- 20 cc 或容量更大的針筒
- 50 cc 或容量更大的針筒
- 高壓型三向調節閥
- 一般心導管室設備
- 螢光鏡(適用於經皮冠狀動脈介入治療的固定式、移動式或半移動式螢光鏡系統)

- 執行經食道或經胸腔心臟超音波的設備
- 交換長度0.035 inch (0.89 mm)的超硬型導引線
- 暫時性心律調節器(Pacemaker，簡稱PM)及節律導極
- 無菌沖洗盆、無菌生理食鹽水溶液、無菌肝素食鹽水溶液、15%稀釋的不透射線顯影劑
- 準備經導管心臟瓣膜及裝置的無菌工作台

7.2 經導管心臟瓣膜的處理及準備

準備及植入裝置期間，必須使用無菌操作技術。

7.2.1 經導管心臟瓣膜沖洗程序

開啟前，應仔細檢查寬口瓶有無受損跡象(例如瓶身或瓶蓋有無裂痕、滲漏，或者封條破損或遺失)。

注意：若容器有破損、滲漏、消毒劑不足或缺少完整封條的情形，無菌狀態可能受到破壞，切勿將該組經導管心臟瓣膜使用於植入手術。

步驟	操作流程
1	為充分沖洗經導管心臟瓣膜，請準備兩組裝有至少500 mL無菌生理食鹽水溶液的無菌沖洗盆。
2	小心地從寬口瓶取出經導管心臟瓣膜/固定器組件，並不觸碰到組織。確認經導管心臟瓣膜固定器與寬口瓶瓶蓋的序號是否相符，並將序號記錄於患者資訊文件。檢查瓣膜確認支架或組織有無受損跡象。
3	請依以下步驟沖洗經導管心臟瓣膜: • 將經導管心臟瓣膜放入第一組裝有無菌生理食鹽水溶液的沖洗盆。確保生理食鹽水完全浸沒經導管心臟瓣膜和固定器。 • 將經導管心臟瓣膜/固定器組件浸沒，緩慢地來回攪動(輕輕旋轉瓣膜和固定器) 至少1分鐘。 • 將經導管心臟瓣膜/固定器組件移置於第二組裝有無菌生理食鹽水溶液的沖洗盆，並緩慢地來回攪動至少再1分鐘。請確定第一組沖洗盆內的溶液不被使用。 • 瓣膜應留至於最終的沖洗液內直至使用時以避免組織乾燥。 **注意：攪動或轉動時不可讓經導管心臟瓣膜接觸沖洗盆底部或側邊。沖洗時亦避免瓣膜和識別標籤直接接觸。沖洗盆中不可放入其他物品。瓣膜應保持濕潤以防止組織乾燥。**

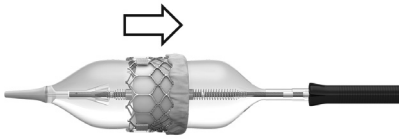
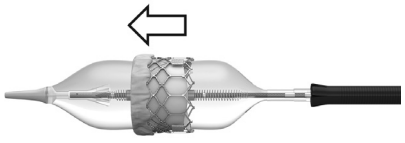
7.3 瓣膜操作及準備

7.3.1 準備系統

步驟	操作流程
1	目視檢查各項組件是否受損。確認輸送系統是否完全伸直，氣球導管是否完全推入 Flex 導管。 **警告：為避免氣球囊體受損，應確保氣球囊體的近端未受到彎折。**
2	以含有肝素的生理食鹽水、經由沖洗口沖洗輸送系統。
3	移除輸送系統的遠端氣球護罩。從導引線管腔遠端取出通管針，將其放在一旁。
4	以含有肝素的生理食鹽水沖洗導引線管腔。將通管針插回導引線管腔。 **註：若未將通管針放回導引線管腔，可能導致管腔在經導管心臟瓣膜壓折過程中受損。**
5	將輸送系統放入預定位置(應力消除裝置端應在氣球囊體表面兩白色標記間)，並確認Flex導管末梢為氣球近端護罩所覆蓋。
6	旋開裝填器的護蓋，以含有肝素的生理食鹽水沖洗裝填器護蓋。
7	將裝填器護蓋裝上輸送系統，護蓋內側朝向遠端末梢。 將氣球導管完全推入Flex導管。 移除覆蓋於氣球囊體藍色部分的氣球近端護罩。
8	將三向調節閥接上氣球擴張口。在 50 cc 或容量更大的針筒裝入 15 - 20 mL 稀釋顯影劑，然後將其接上三向調節閥。
9	將擴張裝置裝入超出所示擴張體積的過量稀釋顯影劑，鎖定後接上三向調節閥。關閉通往擴張裝置的調節閥。

步驟	操作流程
10	利用針筒抽出空氣以抽成真空。慢慢鬆開針筒活塞推桿，確認顯影劑流入輸送系統管腔。重複操作，直到排除系統內所有氣泡為止。讓系統保持零壓力。 **警告：確保氣球中沒有殘留的液體，以避免在手術過程中可能造成瓣膜對齊的困難度。** 關閉通往輸送系統的調節閥。
11	轉動擴張裝置旋鈕，使顯影劑流入針筒並達到展開經導管心臟瓣膜所需的適當體積。關閉通往針筒的調節閥，然後取下針筒。
12	確認擴張裝置內的擴張體積是否適當。 **注意：在經導管心臟瓣膜展開前，擴張裝置必須維持鎖定狀態，以降低氣球提前擴張、導致經導管心臟瓣膜不當展開的風險。**

7.3.2 將經導管心臟瓣膜裝上輸送系統並予以壓折

步驟	操作流程
1	將 Qualcrimp 壓折器配件完全浸入裝有100 mL生理食鹽水的沖洗盆；輕輕加壓，直到配件吸滿食鹽水溶液。旋轉配件至少1分鐘。在第二個沖洗盆重複前述步驟。
2	從固定器取下經導管心臟瓣膜，並拆下識別標籤。
3	轉動壓折器把手，直到開口完全打開為止。將兩件式壓折器擋片裝於壓折器底座並卡入定位。
4	如果必要, 對壓折器內的經導管心臟瓣膜進行局部壓折，直到瓣膜緊貼 Qualcrimp 壓折器配件內側為止。 **註：對於20mm的瓣膜，局部壓折為非必要**
5	將 Qualcrimp 壓折器配件放在經導管心臟瓣膜上方，使 Qualcrimp 壓折器配件邊緣對齊經導管心臟瓣膜的流出側。
6	將經導管心臟瓣膜及 Qualcrimp 壓折器配件放入壓折器開口。將輸送系統沿著軸線插入經導管心臟瓣膜內部，使瓣膜位於距輸送系統藍色氣球囊體(瓣膜壓折部分)遠端2 - 3 mm處，經導管心臟瓣膜的流入側必須朝向輸送系統的遠端，如下圖所示： **順行心尖法：** 將經導管心臟瓣膜流入側(外層裙緣)末端朝向輸送系統**近端**。  **逆行心尖法：** 將經導管心臟瓣膜流入側(外層裙緣)末端朝向輸送系統**遠端**。 
7	將氣球囊體沿著軸線放入經導管心臟瓣膜內的中心位置。壓折經導管心臟瓣膜，直到其接觸到Qualcrimp擋片為止。
8	從經導管心臟瓣膜取下 Qualcrimp 壓折器配件，然後從壓折器擋片取下 Qualcrimp 擋片，僅將最終擋片留在原位。
9	將經導管心臟瓣膜放入壓折器開口的中心位置。將經導管心臟瓣膜壓折到底，直到其接觸到最終擋片為止，然後固定不動5秒鐘。重複前述壓折步驟兩次，總共進行三次壓折。 **註：確認瓣膜壓折部分與經導管心臟瓣膜同一軸線。**
10	拉回氣球囊體，然後啟動氣球鎖定裝置，使輸送系統留在預定位置。

步驟	操作流程
11	以含有肝素的生理食鹽水沖洗裝填器。隨即將經導管心臟瓣膜推入裝填器，直到輸送系統的錐形末梢露出。 **注意：經導管心臟瓣膜維持壓折到底及/或停留於裝填器的時間不可超過15分鐘，否則瓣葉可能會受損，進而影響瓣膜功能。**
12	將裝填器護蓋裝回裝填器，再次沖洗Flex導管，然後關閉通往輸送系統的調節閥。取出通管針，然後沖洗輸送系統的導引線管腔。 **注意：經導管心臟瓣膜在準備植入前必須保持濕潤，以免瓣葉受損，進而影響瓣膜功能。** **警告：醫師必須在植入前確認經導管心臟瓣膜的方向是否正確，以免患者受到嚴重傷害。**

7.4 預先撐開原生瓣膜與送入經導管心臟瓣膜

預先撐開原生瓣膜與送入經導管心臟瓣膜兩項步驟，應在血液動力學監控下採取局部或全身麻醉方式進行；執行手術的心導管室/複合式手術室，必須配備螢光鏡與心臟超音波等造影設備。

給予肝素，使活化凝血時間(ACT)維持不低於250秒的程度。

注意：為降低腎臟受損的風險，應監控顯影劑的用量。

在治療功能衰竭的人工生物瓣膜時應避免使用氣球瓣膜成形術，這可能導致生物瓣膜材質栓塞和瓣葉的機械性破壞。

7.4.1 基準參數

步驟	操作流程
1	進行主動脈瓣上血管攝影，使原生主動脈瓣的投影與畫面垂直。
2	以經導管心臟瓣膜的支架高度為依據，評估左側及右側冠狀動脈口至主動脈瓣環的距離。
3	插入心律調節器(pacemaker，簡稱PM)的導極，直到其遠端位於右心室為止。
4	設定刺激參數直到1:1，測試節律。

7.4.2 預先撐開原生瓣膜

請參考 Edwards 經股動脈氣球導管使用說明。

7.4.3 送入經導管心臟瓣膜

步驟	操作流程
1	依照使用說明，準備 Edwards sheath 導引器套組。
2	必要時，應預先撐開血管。
3	依照使用說明，插入套管。
4	將裝填器總成插入套管，直到裝填器無法前進為止。
5	推進輸送系統，直到經導管心臟瓣膜從套管伸出。 **注意：於髂股動脈進入時，為降低腸骨動脈血管受損風險，當套管末梢尚未越過主動脈分叉部位時，不可推進經導管心臟瓣膜通過套管。** **注意：經導管心臟瓣膜停留於套管的時間不可超過5分鐘，否則瓣葉可能會受損，進而影響瓣膜功能。**
6	在脈管系統的直線段進行瓣膜定位步驟，首先解除氣球鎖定裝置，接著連續抽回氣球導管，直到部分警告標記出現為止。抽回時切勿超過警告標記。 **警告：為避免氣球囊體受損，應確保氣球囊體的近端未受到彎折。** **警告：如果閥門對齊不是直線段，則執行此步驟可能會遇到困難，這可能導致輸送系統損壞並且無法給氣球充氣。利用交替的透視圖可以幫助評估解剖結構的曲率。 如果在瓣膜對準期間經歷過度張力，則需要將輸送系統重新定位到主動脈的不同直線部分並且減輕系統中的壓縮（或張 力）。** 啟動氣球鎖定裝置。 利用微調環，將經導管心臟瓣膜移至瓣膜定位標記間的位置。 **註：當氣球鎖定裝置未啟動時，切勿轉動微調環。** **警告：為降低經導管心臟瓣膜不當展開或經導管心臟瓣膜栓塞的風險，切勿將經導管心臟瓣膜置放於超過遠端瓣膜定位標記的位置。** **注意：為避免導引線離開定位，瓣膜定位時應維持導引線位置不變。**

步驟	操作流程
7	解除氣球鎖定裝置，將Flex導管末梢收入三重標記中央。啟動氣球鎖定裝置。 **註：確認 Edwards 標誌方向，以確保正確連接。** **註：朝沖洗口相反方向彎曲輸送系統。**
8	解除氣球鎖定裝置，將Flex導管末梢收入三重標記中央。啟動氣球鎖定裝置。
9	調整經導管心臟瓣膜相對於原生瓣膜的位置。
10	必要時，可利用Flex控制環調整經導管心臟瓣膜的同軸性，利用微調環調整經導管心臟瓣膜的位置。
11	展開前，應確認經導管心臟瓣膜已正確置放於瓣膜定位標記間，而Flex導管末梢位於三重標記上方。
12	開始展開經導管心臟瓣膜： • 解除擴張裝置的鎖定狀態。 • 確認血液動力學各項參數達到穩定狀態後，開始傳送快速節律；等動脈血壓下降至不超過50 mmHg時，開始擴張氣球。 • 利用緩慢且受到控制的擴張方式，以擴張裝置的全部體積展開經導管心臟瓣膜並維持此狀態3秒鐘，然後確認擴張裝置活塞筒徹底排空，以確保氣球完成擴張。 • 排空氣球。氣球導管徹底排空後，關閉心律調節器。

7.4.4 移除系統

步驟	操作流程
1	縮回裝置時，應先將其伸直。確認Flex導管末梢固定於三重標記上方。將裝填器縮回輸送系統近端，然後從套管取出輸送系統。 **注意：為降低血管損傷的風險，取出輸送系統前應將其完全伸直。**

7.5 確認人工瓣膜的位置並進行測量

測量並記錄血液動力學參數。

步驟	操作流程
1	進行主動脈瓣上血管攝影，評估裝置的表現及冠狀動脈的暢通程度(如適用)。
2	測量並記錄瓣膜兩側的壓力差異。
3	等活化凝血時間降至適當程度(例如低於150秒)，便可移除所有裝置。 關於移除裝置的方法，請參考導引套管使用說明。
4	縫合導管插入部位。

8.0 供應方式

無菌：瓣膜係以戊二醛溶液處置方式無菌供應。

輸送系統及配件經氧化乙烯滅菌後供應。

經導管心臟瓣膜以無菌且不含致熱原的狀態供應，容器為貼有防變造封條的塑膠寬口瓶，瓶中裝有戊二醛緩衝溶液。寬口瓶均以保存箱包裝運送，箱內備有溫度指示裝置，用以偵測經導管心臟瓣膜是否曾暴露於極端溫度。保存箱在運送前還會利用聚苯乙烯泡沫塑料封箱。

8.1 儲存

經導管心臟瓣膜必須儲存於10℃ - 25℃ (50℉ - 77℉)。寬口瓶均以保存箱包裝運送，箱內備有溫度指示裝置，用以偵測經導管心臟瓣膜是否曾暴露於極端溫度。

輸送系統及配件應儲存於低溫、乾燥處所。

9.0 磁振造影安全資訊

MR 與磁振造影有條件相容

非臨床測試證實，Edwards SAPIEN 3 經導管心臟瓣膜與磁振造影有條件相容。在下列條件下，患者在植入本裝置後即可接受掃描而無安全疑慮：

- 靜磁場強度1.5 Tesla (T)或3.0 Tesla (T)。
- 最大空間梯度場為2500 Gauss/cm (25 T/m)或以下

- 磁振造影系統回報的全身平均特定吸收率(SAR)為2.0 W/kg (正常操作模式)

在前述掃描條件下，預期經導管心臟瓣膜在連續掃描15分鐘後，體內溫度最高幅度低於3.0℃。

依據非臨床資料，以3.0 T的磁振造影系統進行掃描時，自旋回波(spin echo)造影的假影超出植體最多至14.5 mm，梯度回波(gradient echo)造影則為30 mm。梯度迴訊影像內的假影會使裝置管腔變模糊。

目前尚未評估植體在1.5 T或3.0 T以外磁振造影系統的表現。

對於瓣膜內植瓣膜(valve-in-valve)或存在的其他植入物，在磁振造影前請參閱外科瓣膜或或其他裝置的MRI安全資訊。

10.0 患者資訊

經導管心臟瓣膜的包裝內均附有患者註冊表格。植入後，請填寫各項要求資訊。序號標示於包裝表面，以及繫於經導管心臟瓣膜的識別標籤。請依據表格指示地址，將原始表格寄回愛德華公司，並在出院前將臨時識別卡交給患者。

11.0 回收的經導管心臟瓣膜與裝置的處置

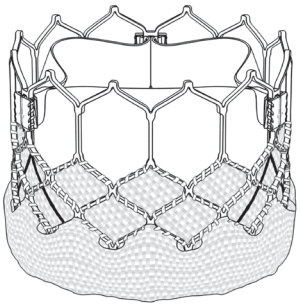
取出的經導管心臟瓣膜應置入適當的組織固定液，例如10%福馬林或2%戊二醛，然後再送回公司；這種情況下不須冷藏。如須索取移除工具組，請聯絡愛德華公司。

使用過的裝置應視為醫院廢棄物及生物危害性物質，並以相同方式處理及處置。處理這類裝置並無特殊風險。

12.0 參考文獻

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.

13.0 附圖



9600TFX

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

圖1：Edwards SAPIEN 3 經導管心臟瓣膜

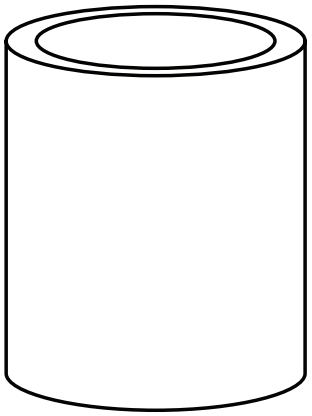


圖2：Qualcrimp 壓折器配件

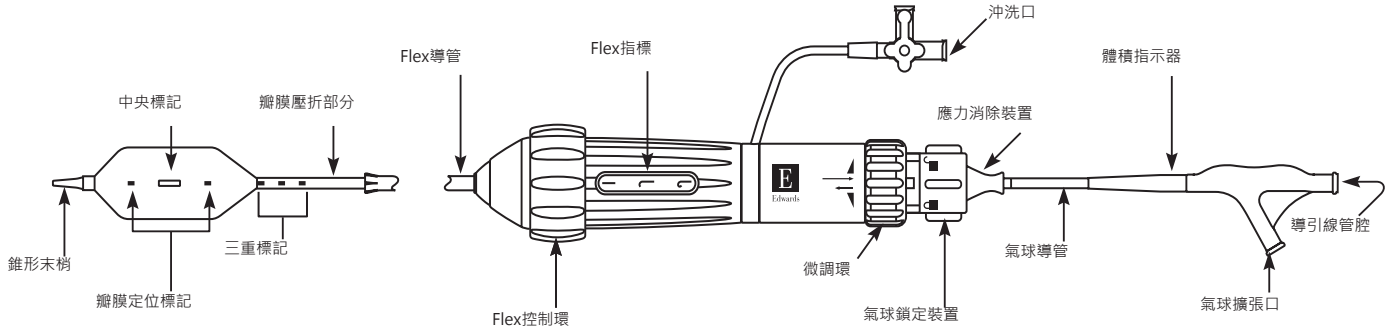


圖3：Edwards COMMANDER 輸送系統

圖4：裝填器

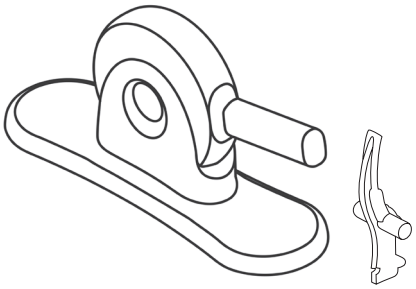


圖5：壓折器及兩件式壓折器擋片

14.0 經導管主動脈瓣膜置換術之醫療機構條件及操作人員資格

醫療機構條件	1. 具有下列專任之醫事人員: 1) 心臟外科專科醫師 2) 心臟內科專科醫師 3) 麻醉專科醫師 4) 超音波醫師 5) 開刀房護理師及心導管之技術人員 2. 醫院每年須具500例以上心導管(含200例以上介入性心臟導管手術)及25例以上主動脈瓣膜置換之手術案例。 3. 具有下列設備: 1) 心臟超音波設備。 2) 64切面以上之電腦斷層掃描儀或磁振造影機。 3) 手術應在具心導管X光攝影機等及高效率空氣過濾器至少HEPA-10000等級之複合式(hybrid)手術室進行。 4) >75 平方公尺的空間設備。 5) 體外循環設備 6) 心臟重症加護病房
操作人員資格	1. 操作之醫師須具有下列各項之資格： 1) 具有專科醫師五年以上資格。 2) 具25例以上主動脈瓣膜置換手術，或300例以上心臟介入治療之經歷，經服務醫院及台灣胸腔及心臟血管外科學會、中華民國心臟學會或台灣介入性心臟血管醫學會審查通過發給之證明文件。 3) 接受「經導管主動脈瓣置換手術」之訓練課程，領有證明，且參與實際操作五例以上之經歷。
相關事項	施行治療時，須由符合上述操作資格之心臟內科專科醫師及心臟外科專科醫師在場共同操作，隨時提供必要之緊急措施。

愛德華瑟皮恩三和瑟皮恩三優創經導管心臟瓣膜套管組
Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System
愛德華瑟皮恩三經導管心臟瓣膜及股動脈套管組
Edwards SAPIEN 3 – Edwards COMMANDER Kit

愛德華經股動脈氣球導管(Transfemoral Balloon Catheter)

使用前請務必詳閱原廠之使用說明書並遵照指示使用

使用說明

1.0 裝置介紹

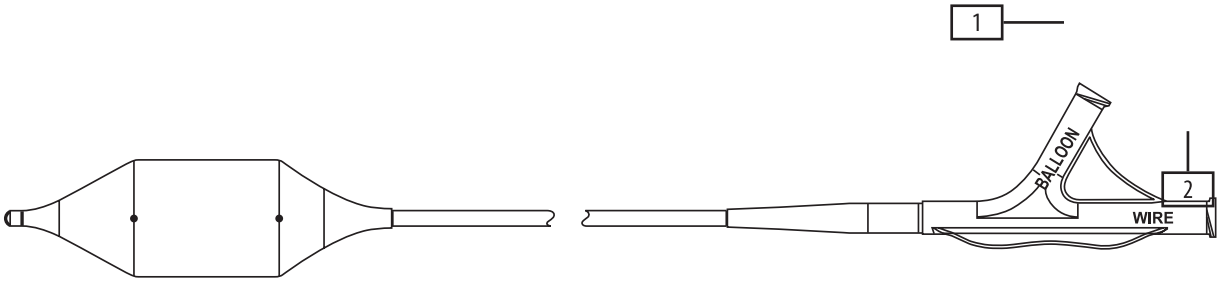
Edwards 經股動脈氣球導管包括管體及氣球，氣球有兩道不透射線的條紋標記，用以指示氣球的有效長度。裝置近端為一組Y型接頭構造，氣球擴張口標示為BALLOON (氣球)，導引線管腔開口標示為WIRE (導引線)。

擴張參數如下：

表1：擴張參數

型號	標稱		
	氣球直徑	擴張體積	擴張壓力
9350BC16	16 mm	10 mL	4 atm (405 kPa)
9350BC20	20 mm	16 mL	4 atm (405 kPa)
9350BC23	23 mm	21 mL	4 atm (405 kPa)
9350BC25	25 mm	26 mL	4 atm (405 kPa)

Edwards 經股動脈氣球導管



黑點表示不透射線條紋標記的位置。

1 - 氣球擴張口

2 - 導引線管腔開口

裝置相容規格如下：

表2：裝置相容性

型號	導引線直徑上限	套管相容性下限
9350BC16	0.035″ (0.89 mm)	14F (4.7 mm)
9350BC20	0.035″ (0.89 mm)	14F (4.7 mm)
9350BC23	0.035″ (0.89 mm)	14F (4.7 mm)
9350BC25	0.035″ (0.89 mm)	16F (5.3 mm)

註：為達到適當體積，使用氣球導管時應搭配愛德華公司提供的擴張裝置。

2.0 適應症

氣球導管適用於擴張原生主動脈瓣的狹窄瓣葉。

3.0 禁忌症

本裝置不適用於出現下列狀況的患者：

- **心臟內部有明顯團塊、血栓、贅生物、急性感染或心內膜炎；**
- **無法耐受抗凝血/抗血小板治療。**

4.0 警告

- **本裝置基於設計、用途及銷售目的，以無菌狀態供應且僅限單次使用。切勿再次滅菌或重複使用本裝置。目前尚無資料證明，本裝置經重新處理後無菌性、無致熱原性及功能是否仍符合標準。**
- **為避免節律導極穿孔的風險，務必全程觀察節律導極的傳輸情形。**
- **務必使用適合的氣球擴張介質，切勿使用空氣或氣體介質擴張氣球。**
- **氣球擴張直徑不可超出預定擴張瓣環直徑過多。**
- **本裝置不可用於經導管心臟瓣膜展開後的擴張。**
- **當裝置在體內露出時，不可在沒有螢光鏡影像的協助下推進或抽回。除非氣球在負壓作用下徹底排空，否則不可推進或抽回裝置。**
- **切勿不當操作氣球導管；若包裝或其他組件喪失無菌狀態、開啟或毀損(例如扭結或拉伸)、或超過使用期限，亦不可使用。**

5.0 注意事項

目前尚未驗證氣球導管應用於先天性單尖或雙尖瓣型主動脈瓣患者時的安全性及效能。

6.0 可能發生的不良事件

標準導管插入技術、主動脈瓣氣球成形術與血管攝影可能引起的併發症包括、但不限於：麻醉劑或顯影劑引發過敏反應；血管穿孔或剝離之類的損傷；血栓、栓塞形成；腎臟衰竭、腎功能不全；血塊移位，可能因而造成心肌梗塞、中風及/或死亡。其他併發症還可能包括：心律不整；心臟穿孔；傳導系統損傷；血腫；漏斗部損傷；瓣環撕裂或破裂及/或瓣膜撕裂或損傷。

7.0 操作說明

利用標準技術擴張原生瓣葉，然後傳送快速心臟節律。

步驟	操作流程
1	準備插入導管的血管通道，並利用標準技術放置導引線。
2	在氣球護罩仍留在原位的情形下，以含有肝素的生理食鹽水沖洗 Edwards 經股動脈氣球導管的導引線管腔。將高壓型三向調節閥接上氣球擴張口。
3	準備裝有稀釋顯影劑的針筒(顯影劑與生理食鹽水溶液以15:85比例稀釋)，將其接上調節閥。
4	將擴張裝置裝入超出所示體積的過量稀釋顯影劑，以鎖定狀態接上調節閥，並關閉通往擴張裝置的調節閥。
5	利用針筒反覆抽出空氣緩慢抽成真空，讓系統保持零壓力。
6	關閉通往氣球導管的調節閥。將顯影劑緩緩抽入針筒以達到適當體積(如表1：擴張參數所示)。鎖住擴張裝置、關閉通往針筒的調節閥，然後從系統拆下針筒。
7	移除氣球護罩，對整段氣球導管進行水合處理。
8	沿著導引線推進氣球導管通過導引套管，跨越主動脈瓣，然後將氣球標記移動至預定位置。
9	確認血流達到穩定後，開始傳送快速節律。當血壓降至50 mmHg或更低時，便可開始進行氣球擴張步驟。
10	利用擴張裝置完全且快速地擴張氣球。若氣球出現不穩定的情形，應在確保快速心室節律的情形下重新進行氣球的擴張。當氣球完全排空時，應關閉節律的傳送。

8.0 供應方式

本裝置以經氧化乙烯滅菌後供應。

9.0 儲存

本裝置應儲存於低溫、乾燥處所。

10.0 裝置處置

使用過的裝置應視為醫院廢棄物及生物危害性物質並以相同方式處理及處置。處理這類裝置無特殊風險。

愛德華瑟皮恩三和瑟皮恩三優創經導管心臟瓣膜套管組
Edwards SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve System
愛德華瑟皮恩三經導管心臟瓣膜及股動脈套管組
Edwards SAPIEN 3 – Edwards COMMANDER Kit
愛德華導引套組 (Edwards eSheath Introducer Set)

使用前請務必詳閱原廠之使用說明書並遵照指示使用

使用說明

1.0 裝置介紹

愛德華 (Edwards eSheath) 導引器套組包括：

a)一組擴張式套管(eSheath) (圖1)，提供進入目標血管的通道，同時持續防止血液流出，並暫時擴張血管直徑供裝置通過。

圖1

型號	eSheath 內徑(擴張前)	eSheath 外徑(擴張前)
9610ES14	14F (4.6 mm)	6.0 mm
9610ES16	16F (5.3 mm)	6.7 mm

圖2

b) 兩組具有親水性塗層的擴張器(圖2)，可用於擴張血管以容納套管，和/或協助套管進入血管及其追蹤定位。

2.0 用途

愛德華 (Edwards eSheath) 導引器套組的用途為將介入治療裝置導入血管系統。本產品必須由受過介入治療技術訓練且擁有相關經驗的醫師操作使用。操作時應採取安裝血管通道套管的標準技術。

3.0 禁忌症

本產品不適用於血管構造彎曲或鈣化、可能妨礙擴張器及套管安全進入血管的患者。

4.0 警告

本裝置基於設計、用途及銷售目的，僅限單次使用。切勿再次滅菌或重複使用本裝置。目前尚無資料證明，本裝置經重新處理後無菌性、無致熱原性及功能是否仍符合標準。

為避免損傷血管，愛德華 (Edwards eSheath) 導引器套組必須搭配相容的0.035" (0.89 mm) 導引線使用。

切勿不當操作本裝置；若包裝或其他組件喪失無菌狀態、開啟或毀損(例如扭結或拉伸)、超過使用期限，亦不可使用。

5.0 注意事項

- **套管會暫時擴張血管直徑供裝置通過，因此應確認血管構造能容納套管擴張後的最大直徑。**
- **經由套管放入、操作或抽出裝置時，必須維持套管位置的方向。**
- **為防止損傷套管，在套管附近組織進行穿刺、縫合或切割時應小心謹慎。**

6.0 可能發生的不良事件

標準導管插入技術與血管攝影可能引起的併發症包括、但不限於：麻醉劑或顯影劑引發過敏反應；血管穿孔或剝離之類的損傷；血管進入部位的損傷，可能必須進行血管修復；血栓及/或血塊移位，可能因而形成栓塞；遠端血管阻塞；中風；局部缺血及/或死亡。

7.0 操作說明

1.目視檢查裝置組件有無受損跡象。

2.以含有肝素的生理食鹽水、經由導引線管腔沖洗擴張器。

3.以含有肝素的生理食鹽水、經由沖洗口沖洗套管；沖洗後關閉沖洗口。

4.以含有肝素的生理食鹽水對整段導引器/擴張器及套管進行水合處理，以活化親水性塗層。

5.將一組擴張器完全插入套管。

6.利用標準導管插入技術，形成進入血管的通道，並視需要使用另一組擴張器撐開以容納套管通過。

7.適當地調整套管方向並全程維持這個方向。利用標準技術插入套管組件，然後將其推入血管，同時利用螢光鏡影像追蹤其進展。

註：套管有效長度的近端錐形構造直徑較大。

8.如果可能的話，利用縫合環將套管縫於定位，然後從套管取出擴張器。

9.將裝置放入套管。

註：手術進行期間，應依照標準介入治療技術，不時以含有肝素的生理食鹽水沖洗套管。

10. 完成手術並取出裝置後，應先移除縫線，然後在不扭轉的情形下完全取出套管，而且不可將其再次插入。

8.0 供應方式

愛德華 (Edwards eSheath) 導引器套組以經氧化乙烯滅菌處理的袋裝形式供應。

9.0 儲存

愛德華 (Edwards eSheath) 導引器套組應儲存於低溫、乾燥處所。

10.0 裝置處置

使用過的套管套組應視為醫院廢棄物及生物危害性物質，並以相同方式處理及處置。處理這類裝置並無特殊風險。

製造業者名稱：Edwards Lifesciences LLC

製造業者地址：One Edwards Way, Irvine, CA 92614, USA「Made (部分製程) in Singapore」

醫療器材商名稱：台灣愛德華生命科學股份有限公司

醫療器材商地址：臺北市中山區民生東路三段2號9樓之1

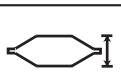
Symbol Legend ▪ 符號圖例

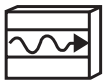
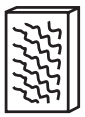
	English	繁體中文 (台灣)
REF	Catalogue Number	型錄編號
#	Quantity	數量
I	Minimum introducer size	最小導引器尺寸
⟵ cm ⟶	Usable length	可用長度
	Do not re-use	請勿重複使用
LOT	Lot Number	批號
	Caution Attention, see instructions for use	注意注意，請參閱使用說明
	Do not use if package is damaged	如果包裝有損壞，請勿使用
	Do not use if package is opened or damaged.	如果包裝已打開或有損壞，請勿使用
	Exterior diameter	外徑
	Inner diameter	內徑
	Keep dry	保持乾燥
	Store in a cool, dry place	存放於陰涼乾燥處
UDI	Unique Device Identifier	醫療器材單一識別碼
	Temperature Limit	溫度限制
STERILE	Sterile	無菌

	English	繁體中文 (台灣)
STERILE EO	Sterilized using ethylene oxide	經環氧乙烷 (Ethylene Oxide) 滅菌
STERILE R	Sterilized using irradiation	經輻射滅菌
STERILE	Sterilized using steam or dry heat	經蒸氣或乾熱滅菌
Axela™	Axela Compatibility	Axela 相容性
	Use-by date	保存期限
SN	Serial Number	序號
	Manufacturer	製造商
	Date of manufacture	製造日期
EC REP	Authorized representative in the European Community	歐盟授權代表
GW	Recommended guidewire size	建議導線尺寸
GWC	Guidewire compatibility	標稱壓力
SZ	Size	尺寸
NP	Nominal pressure	標稱壓力
RBP	Rated burst pressure	額定爆裂壓力
STRAIGHT	Straight	直向
DEFLECTED	Deflected	偏轉

Note: Not all symbols may be included in the labeling of this product. ▪ **註：** 本產品標示中未必包含所有符號。

Symbol Legend ▪ 符號圖例

	English	繁體中文 (台灣)
	Recommended guidewire length	建議導線長度
	Minimum sheath size	最小套管鞘尺寸
	Catheter shaft size	導管管身尺寸
	Balloon diameter	球囊直徑
	Balloon working length	球囊工作長度
	Consult instructions for use	請詳閱使用說明
	Consult instructions for use on the website	請詳閱網站上的使用說明
	Type CF applied part	CF 型應用組件
	Defib Proof Type CF applied part	防去顫 CF 型應用組件
	Non-sterile	未滅菌
	Separate collection for batteries in accordance with EC Directive 2006/66/EC	依歐盟 2006/66/EC 指令單獨回收電池
	eSheath compatibility	eSheath 相容性
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	注意：美國聯邦法律 僅限醫師銷售或遵醫囑銷售此器材。
	Contents	內容物

	English	繁體中文 (台灣)
	For use with size 20 mm Edwards transcatheter heart valve	適用於尺寸為 20 mm 的 Edwards 經導管心臟瓣膜
	For use with size 23 mm Edwards transcatheter heart valve	適用於尺寸為 23 mm 的 Edwards 經導管心臟瓣膜
	For use with size 26 mm Edwards transcatheter heart valve	適用於尺寸為 26 mm 的 Edwards 經導管心臟瓣膜
	For use with size 29 mm Edwards transcatheter heart valve	適用於尺寸為 29 mm 的 Edwards 經導管心臟瓣膜
	For use with size 23 mm or size 26 mm Edwards transcatheter heart valve	適用於尺寸為 23 mm 或 26 mm 的 Edwards 經導管心臟瓣膜
	Contains phthalates	含磷苯二甲酸酯
	MR Conditional	與磁振造影有條件相容
	Nonpyrogenic	非熱原性
IPX1	Drip proof equipment	防滴設備
	Contents sterile and fluid path nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.	如果包裝未打開或破損，則內容物為無菌 且流體路徑為無熱原。 如果包裝已打開或損壞，請勿使用。請勿重複滅菌。
	Contents sterile and nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.	如果包裝未打開或破損，則內容物為無菌 且無熱原。 如果包裝已打開或損壞，請勿使用。請勿重複滅菌。

Note: Not all symbols may be included in the labeling of this product. ▪ **註：** 本產品標示中未必包含所有符號。

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