Edwards SAPIEN 3 Transcatheter Heart Valve System
Edwards SAPIEN 3 Transcatheter Heart Valve
Edwards Certitude Delivery System
Sistem transkatetrske srčne zaklopke Edwards SAPIEN 3
Transkatetrska srčna zaklopka Edwards SAPIEN 3
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Instructions for Use

Implantation of the transcatheter heart valve should be performed only by physicians who have received Edwards Lifesciences training. The implanting physician should be experienced in standard catheterization techniques. It is at the physician's discretion to choose the appropriate access route to implant the THV based on the patient anatomy and associated risks.

1.0 Device Description

Edwards SAPIEN 3 Transcatheter Heart Valve System

The Edwards SAPIEN 3 transcatheter heart valve (THV) 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.

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 as provided in Table 1:

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 THV in a failing bioprosthesis are provided in Table 2:

Table 2

Surgical Valve True Inner Diameter (ID) [1]	THV Size
16.5 - 19.0 mm	20 mm
18.5 - 22.0 mm	23 mm
22.0 - 25.0 mm	26 mm
25.0 - 28.5 mm	29 mm

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

Sizing recommendations for implanting the THV in a failing INSPIRIS RESILIA aortic surgical bioprosthesis in sizes 19 - 25 mm, based on bench testing, are provided in Table 3 below:

Table 3

INSPIRIS RESILIA Aortic Valve (model 11500A)* Labeled Size	THV Size
19 mm	20 mm or 23 mm
21 mm	23 mm or 26 mm
23 mm	26 mm
25 mm	29 mm

*INSPIRIS RESILIA aortic valve model 11500A sizes 19 - 25 mm incorporate VFit technology which consists of expandable bands and fluoroscopically visible size markers designed for potential future valve-in-valve procedures. Clinical data are not currently available on the INSPIRIS RESILIA aortic valve Model 11500A valve-in-valve procedure or expansion feature. The impact of tissue ingrowth on the expansion feature of the INSPIRIS RESILIA aortic valve has not been assessed.

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

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

Note: Exact volume required to deploy the THV may vary depending on the bioprosthesis inner diameter. Factors such as calcification and pannus tissue growth may not be accurately visualized in imaging and may reduce the effective inner diameter of the failing bioprosthesis to a size smaller than the 'True ID'. These factors should be considered and assessed in order to determine the most appropriate THV size to achieve nominal THV deployment and sufficient anchoring. Do not exceed the rated burst pressure. See inflation parameters in Table 4.

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

The Edwards Certitude delivery system facilitates the placement of the bioprosthesis. The delivery system consists of a flex catheter to aid in tracking and valve positioning. The delivery system includes a tapered tip to facilitate crossing of the valve. The handle contains a flex wheel to control flexing of the balloon catheter. A stylet is included within the guidewire lumen of the delivery system. A radiopaque center marker in the balloon is provided to help with valve positioning. The extension tubing is used during THV deployment.

The inflation parameters for valve deployment are:

Table 4

Model	Nominal Balloon Diameter	Nominal Inflation Volume	Rated Burst Pressure (RBP)
9620TA20	20 mm	12 ml	7 atm
9620TA23	23 mm	17 ml	7 atm
9620TA26	26 mm	23 ml	7 atm
9620TA29	29 mm	30 ml	7 atm

- **Edwards Certitude Introducer Sheath Set (Figure 3)**

The Edwards Certitude introducer sheath set facilitates the introduction and removal of devices utilized with the SAPIEN 3 transcatheter heart valve. 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.

Table 5

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 in (0.89 mm)	

- **Qualcrimp Crimping Accessory**

The Qualcrimp crimping accessory is used during THV crimping (Figure 4).

- **Loader**

The loader is used to aid insertion of the delivery system into the sheath (Figure 5).

- **Edwards Crimper and Crimp Stopper (Figure 6)**

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

- **Inflation Device**

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

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

2.0 Intended Use

The bioprosthesis is intended for use in patients requiring heart valve replacement. The delivery system and accessories are intended to facilitate the placement of the bioprosthesis via the transapical and transaortic access approaches.

3.0 Indications

1. The Edwards SAPIEN 3 transcatheter heart valve system is 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 heart surgery (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).
2. The Edwards SAPIEN 3 transcatheter heart valve system is indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve or a surgical bioprosthetic mitral valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (i.e., predicted risk of surgical mortality ≥ 8% at 30 days, based on the Society of Thoracic Surgeons (STS) risk score and other clinical comorbidities unmeasured by the STS risk calculator).

4.0 Contraindications

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

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

5.0 Warnings

- The devices are designed, intended, and distributed STERILE for single use only. **Do not resterilize or reuse the devices.** There are no data to support the sterility, nonpyrogenicity, and functionality of the devices after reprocessing.
- Correct sizing of the THV is essential to minimize the risk of paravalvular leak, migration, 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.
- 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 solutions, antibiotics, chemicals, etc. other than its shipping storage solution and sterile physiologic saline solution to prevent leaflet damage that may impact valve functionality. THV leaflets mishandled or damaged during any part of the procedure will require replacement of the THV.
- Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, bovine tissue, and/or polymeric materials may have an allergic reaction to these materials.
- Do not use the THV if the tamper evident seal is broken, as sterility may be compromised.
- Do not use the THV if the temperature indicator has been activated, as valve function may be compromised.
- Do not use the THV if the expiration date has elapsed, as either sterility or valve function may be compromised.
- Do not use the THV if the storage solution does not completely cover the valve or the valve is damaged.
- Do not mishandle the delivery system or use the delivery system and accessory devices if the packaging sterile barriers and any components have been opened or damaged, cannot be flushed, or the expiration date has elapsed.
- Valve recipients should be maintained on anticoagulant/antiplatelet therapy, except when contraindicated, to minimize the risk of valve thrombosis or thromboembolic events, as determined by their physicians. This device has not been tested for use without anticoagulation.
- The procedure should be conducted under fluoroscopic guidance. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin. These injuries may be painful, disfiguring, and long-lasting.
- Caution should be exercised in implanting a valve in patients with clinically significant coronary artery disease.
- Patients with pre-existing bioprostheses should be carefully assessed prior to implantation of the valve to ensure proper valve positioning and deployment.
- 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.

6.0 Precautions

- Long-term durability has not been established for the THV. Regular medical follow-up is advised to evaluate valve performance.
- Glutaraldehyde may cause irritation of the skin, eyes, nose and throat. Avoid prolonged or repeated exposure to, or breathing of, the solution. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water; in the event of contact with eyes, seek immediate medical attention. For more information about glutaraldehyde exposure, refer to the Material Safety Data Sheet available from Edwards Lifesciences.
- The safety and effectiveness of the THV implantation has not been established in patients who have:
  - Non-calcified aortic annulus
  - 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
  - A concomitant paravalvular leak where the failing bioprosthesis is not securely fixed in the native annulus or is not structurally intact (e.g., wireform frame fracture)
  - A partially detached leaflet of the failing bioprosthesis that in the aortic position may obstruct a coronary ostium
  - Bulky calcified aortic valve leaflets in close proximity to coronary ostia.
- Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis.
- Special care must be exercised in mitral valve replacement if chordal preservation techniques were used in the primary implantation to avoid entrapment of the subvalvular apparatus.
- Based on the treating physician's consideration of risks and benefits, the valve may be implanted in relatively young patients, although the longer-term durability is still the subject of ongoing clinical research.
- Do not overinflate the deployment balloon, as this may prevent proper valve leaflet coaptation and thus impact valve functionality.

- THV recipients should be maintained on anticoagulant/antiplatelet therapy to minimize risk of valve thrombosis or thromboembolic events, as determined by their physicians.
- Residual mean gradient may be higher in a "THV-in-failing bioprosthesis" configuration than that observed following implantation of the valve inside a native aortic annulus using the same size device. Patients with elevated mean gradient post procedure should be carefully followed. It is important that the manufacturer, model and size of the preexisting bioprosthetic valve be determined, so that the appropriate valve can be implanted and a prosthesis-patient mismatch be avoided. Additionally, pre-procedure imaging modalities must be employed to make as accurate a determination of the inner diameter as possible.

7.0 Potential Adverse Events

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

- Death
- Stroke/transient ischemic attack, clusters or neurological deficit
- Paralysis
- Permanent disability
- Respiratory insufficiency or respiratory failure
- Cardiovascular injury including perforation or dissection of vessels, ventricle, atrium, septum, myocardium or valvular structures that may require intervention
- Pericardial effusion or cardiac tamponade
- Thoracic bleeding
- Embolization including air, calcific valve material or thrombus
- Infection including septicemia and endocarditis
- Heart failure
- Myocardial ischemia or infarction
- Renal insufficiency or renal failure
- Conduction system defect which may require a permanent pacemaker
- Arrhythmias including ventricular fibrillation (VF) and ventricular tachycardia (VT)
- Retroperitoneal bleed
- Arteriovenous (AV) fistula or pseudoaneurysm
- Reoperation
- Ischemia or nerve injury or brachial plexus injury or compartment syndrome
- Restenosis
- Pulmonary edema
- Pleural effusion
- Bleeding, bleeding requiring transfusion or intervention
- Anemia
- Vessel thrombosis/occlusion
- Abnormal lab values (including electrolyte imbalance)
- Hypertension or hypotension
- Allergic reaction to anesthesia, contrast media, device materials or bovine pericardial tissue
- Hematoma
- Syncope
- Pain or changes (e.g., wound infection, hematoma, and other wound care complications) at the access site
- Exercise intolerance or weakness
- Inflammation
- Angina
- Vasovagal response
- Heart murmur
- Fever

Additional potential risks associated with the TAVR procedure, the bioprosthesis, and the use of its associated devices and accessories include:

- Cardiac arrest
- Cardiogenic shock
- Emergency cardiac surgery
- Cardiac failure or low cardiac output
- Coronary flow obstruction/transvalvular flow disturbance
- Device thrombosis requiring intervention
- Valve thrombosis
- Device embolization
- Device migration or malposition requiring intervention
- Left ventricular outflow tract obstruction
- Valve deployment in unintended location
- Valve stenosis
- Structural valve deterioration (wear, fracture, calcification, leaflet tear/tearing from the stent posts, leaflet retraction, suture line disruption of components of a prosthetic valve, thickening, stenosis)
- Device degeneration
- Paravalvular or transvalvular leak
- Valve regurgitation
- Hemolysis
- Device explants
- Mediastinitis

- Mediastinal bleeding
- Nonstructural dysfunction
- Mechanical failure of delivery system, and/or accessories, including balloon rupture and tip separation
- Non-emergent reoperation
- Allergic/immunologic reaction to the implant
- Injury to the mitral valve

For a patient/user/third party in the European Economic area; if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and your national competent authority, which can be found at https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

8.0 Directions for Use

8.1 System Compatibility

Table 6

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 transcatheter heart valve	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
Edwards Certitude delivery system	9620TA20	9620TA23	9620TA26	9620TA29
Edwards Certitude introducer sheath set	9620IS18 (18F)			9620IS21 (21F)
inflation device	96402			96406
Edwards crimper	9600CR			
Qualcrimp crimping accessory, crimp stopper, loader and extension tubing provided by Edwards Lifesciences				

Additional Equipment:

- Balloon catheter per the discretion of the physician
- 20 cc syringe or larger
- 50 cc syringe or larger
- High-pressure 3-way stopcock
- Standard cardiac catheterization lab equipment and supplies, and access to standard heart valve operating room equipment and supplies
- Fluoroscopy (fixed, mobile or semi-mobile fluoroscopy systems appropriate for use in percutaneous coronary interventions)
- Transesophageal or transthoracic echocardiography capabilities
- 18 gauge Seldinger needle (for transaortic)
- 145 cm x 0.035 in (0.89 mm) soft guidewire
- 180 cm or 260 cm x 0.035 in (0.89 mm) & Exchange length 0.035 in (0.89 mm) extra-stiff guidewires
- 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

8.2 THV Handling and Preparation

Follow sterile technique during device preparation and implantation.

8.2.1 THV Rinsing Procedure

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

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

1. Set up two (2) sterile bowls with at least 500 ml of sterile physiological saline to thoroughly rinse the THV.
2. Carefully remove the valve/holder assembly from the jar without touching the tissue. Verify the valve serial identification number with the number on the jar lid and record in the patient information documents. Inspect the valve for any signs of damage to the frame or tissue.
3. Rinse the THV as follows:
   a) Place the THV in the first bowl of sterile, physiological saline. Be sure the saline solution completely covers the THV and holder.
   b) With the valve and holder submerged, slowly agitate (to gently swirl the valve and holder) back and forth for a minimum of 1 minute.
   c) Transfer the THV and holder to the second rinsing bowl of sterile physiological saline and gently agitate for at least one more minute. Ensure the rinse solution in the first bowl is not used.
   d) The valve should be left in the final rinse solution until needed to prevent the tissue from drying.

   CAUTION: Do not allow the valve to come into contact with the bottom or sides of the rinse bowl during agitation or swirling in the rinse solution. Direct contact between the identification tag and valve is also to be avoided during the rinse procedure. No other objects should be placed in the rinse bowls. The valve should be kept hydrated to prevent the tissue from drying.

8.2.2 Prepare the System

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.

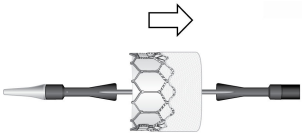
8.2.3 Mount and Crimp the THV onto the Delivery System

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.
6. The orientation of the THV on the delivery system is described below:

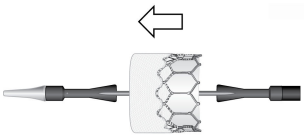
   Antegrade Approach:

   Inflow (outer skirt end) of the THV towards the **proximal end** of the delivery system.



   Retrograde Approach:

   Inflow (outer skirt end) of the THV towards the **distal end** of the delivery system.



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 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 table 4.

    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.

8.3 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 valvular plane to the distal tip of the 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.

Table 7

Delivery System	THV	Minimum Required Distance From Sheath Tip to Valvular Plane
Model 9620TA20	20 mm	3.5 cm

Delivery System	THV	Minimum Required Distance From Sheath Tip to Valvular Plane
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.

8.3.1 Baseline Parameters

1. Advance a 5F (1.67 mm) or 6F (2.0 mm) pigtail catheter and perform an angiogram with the projection of the 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 and position appropriately.
4. Set the stimulation parameters to obtain 1:1 capture, and test pacing.

8.3.2 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.

8.3.2.1 Transapical Access

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 access through standard transapical techniques.
5. Using the sheath depth markers, advance the introducer and sheath over the guidewire to the desired depth while following its progression on fluoroscopy.
6. Withdraw the introducer slowly, keeping the sheath in place. Maintain guidewire position across the valve.

8.3.2.2 Transaortic Access

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.

8.3.3 Valvuloplasty

Pre-dilate the native aortic valve, per the discretion of the physician, according to the instructions for use for the selected balloon aortic valvuloplasty catheter.

CAUTION: Valve implantation should not be carried out if the balloon cannot be fully inflated during valvuloplasty.

8.3.4 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.

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 de-air.
5. Advance the THV/balloon assembly through the sheath and position within the target valve.
   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:
   a) Unlock the inflation device provided by Edwards Lifesciences.
   b) Begin rapid pacing; once systolic blood pressure has decreased to 50 mmHg or below, balloon inflation can commence.
   c) Deploy the valve by inflating the balloon with the entire volume in the Inflation device provided by Edwards Lifesciences, hold for 3 seconds and confirm that the barrel of the inflation device is empty to ensure complete inflation of the balloon.
   d) Deflate the balloon. When the balloon has been completely deflated, turn off the pacemaker.

8.3.5 System Removal

1. If articulation was used, completely unflex the delivery system.

   Retract the delivery system and guidewire into the sheath. Remove the loader and delivery system from the sheath.

   CAUTION: Properly deflate the balloon and unflex the delivery system prior to removal.
2. Remove all devices when the ACT level is appropriate.
3. Remove the sheath from the access site, close the access site and confirm hemostasis.

8.4 Verification of THV Position and Measurements

Measure and record hemodynamic parameters.

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.

9.0 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.

9.1 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.

10.0 MR Safety

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN 3 transcatheter heart valve is MR Conditional. A patient with this device can be scanned safely, immediately after placement of this device under the following conditions:

- Static magnetic field of 1.5 tesla (T) or 3.0 tesla (T)
- Maximum spatial gradient field of 2500 Gauss/cm (25 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2.0 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 T or 3.0 T.

For valve-in-valve implantation or in the presence of other implants, please refer to the MRI safety information for the surgical valve or other devices prior to MR imaging.

11.0 Qualitative and Quantitative Information related to the THV

This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight:

Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical devices manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects.

For THV, the following table shows the qualitative and quantitative information on the materials and substances:

Table 8

Substance	CAS	Model Mass Range (mg)
Cobalt	7440-48-4	131 - 427
Nickel	7440-02-0	148 - 405
Chromium	7440-47-3	85.2 - 230
Polyethylene terephthalate	25038-59-9	102 - 170
Collagens, bovine, polymers with glutaraldehyde	2370819-60-4	58.3 - 141
Molybdenum	7439-98-7	40.3 - 115
Polytetrafluoroethylene	9002-84-0	17.5 - 25.5
Polyethylene	9002-88-4	14.2 - 19.7
Iron	7439-89-6	0 - 10.9
Titanium	7440-32-6	0 - 10.9
Manganese	7439-96-5	0 - 1.64
Silicon	7440-21-3	0 - 1.64
Titanium dioxide	13463-67-7	0.219 - 0.752
Polybutilate	24936-97-8	0.273 - 0.383

Substance	CAS	Model Mass Range (mg)
Carbon	7440-44-0	0 - 0.274
Antimony trioxide	1309-64-4	0.112 - 0.190
Boron	7440-42-8	0 - 0.164
Phosphorus	7723-14-0	0 - 0.164
Sulfur	7704-34-9	0 - 0.109
D&C Green No. 6	128-80-3	0.0394 - 0.0578
Silicon dioxide	7631-86-9	0.00422 - 0.00592
Erucamide	112-84-5	0.000683 - 0.00128
4-Dodecylbenzenesulfonic acid	121-65-3	0.000286 - 0.000430

12.0 Summary of Safety and Clinical Performance (SSCP)

The SSCP has been adapted in accordance with the clinical evaluation assessment by the Notified Body on which CE certification has been granted. The SSCP contains a relevant summary of the same information.

The Notified Body has taken notice of and agreed with the benefit-risk rationales for the short- and long-term safety and effectiveness of the SAPIEN 3 platform.

Conformity with the entire SAPIEN 3 platform of the performance requirements (GSPR) for safety (MDR GSPR1), performance (MDR GSPR1), acceptability of side-effects (MDR GSPR8), usability (MDR GSPR5), device lifetime (MDR GSPR6), and acceptable benefit-risk profile (MDR GSPR8) has been established for the labelled indications.

Refer to https://meddeviceinfo.edwards.com/ for a SSCP for this medical device.

After the launch of the European Database on Medical Devices/Eudamed, refer to https://ec.europa.eu/tools/eudamed for a SSCP for this medical device.

13.0 Basic Unique Device Identification-Device Identifier (UDI-DI)

The Basic UDI-DI is the access key for device-related information entered in the Eudamed. The Basic UDI-DI for the valve, delivery system and sheath can be used to locate the SSCP.

The following table contains the Basic UDI-DI:

Table 9

Product	Model				Basic UDI-DI
	20 mm System	23 mm System	26 mm System	29 mm System	
Edwards SAPIEN 3 transcatheter heart valve	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)	0690103D003SAP000VP
Edwards Certitude delivery system	9620TA20	9620TA23	9620TA26	9620TA29	0690103D003CER000QZ
Edwards Certitude introducer sheath set	9620IS18			9620IS21	0690103D003CIS000SL
inflation device	96402			96406	0690103D003IND000TG
Edwards crimper	9600CR				0690103D003CRI000TH

14.0 Expected Lifetime of the Device

The Edwards transcatheter heart valve has been subjected to rigorous pre-clinical durability testing per the valve testing requirements and in clinical studies and post market studies. The valves were successfully tested to 5 years of simulated wear. In addition, clinical data show durability with follow-up to 5 years. The actual lifetime performance is continuing to be studied and varies from patient to patient.

15.0 Patient Information

A patient implant card is provided with each THV. After implantation, please complete all requested information and provide the implant card to the patient. The serial number is found on the package. This implant card allows patients to inform healthcare providers what type of implant they have when they seek care.

16.0 Recovered THV and Device Disposal

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

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

17.0 Clinical Studies

Refer to the SSCP for clinical benefits.

18.0 References

1. Bapat V, Attia R, Thomas M. Effect of Valve Design on the Stent Internal Diameter of a Bioprosthetic Valve: A Concept of True Internal Diameter and Its Implications for the Valve-in-Valve Procedure. JACC: Cardiovascular Interventions. Vol. 7, No. 2. 2014: 115-127.

Slovenščina

Navodila za uporabo

Vsaditev transkatetrske srčne zaklopke smejo izvesti samo zdravniki, ki jih je usposobila družba Edwards Lifesciences. Zdravnik za vsajanje mora biti izkušen v standardnih tehnikah katetrizacije. Izbira ustrezne dostopne poti je prepuščena zdravnikovi presoji glede vsaditve THV na podlagi anatomije bolnika in povezanih tveganj.

1.0 Opis pripomočka

Sistem transkatetrske srčne zaklopke Edwards SAPIEN 3

Sistem transkatetrske srčne zaklopke (THV) Edwards SAPIEN 3 sestavljajo transkatetrska srčna zaklopka Edwards SAPIEN 3 in dovajalni sistemi.

- **Transkatetrska srčna zaklopka Edwards SAPIEN 3 (slika 1)**

Transkatetrska srčna zaklopka (THV) Edwards SAPIEN 3 je sestavljena iz radioneprepustne trikuspidalne zaklopke iz govejega perikardialnega tkiva z ohišjem iz zlitine kobalta in kroma, ki se razpre z balonom, ter notranjega in zunanjega krilca iz polietilen tereftalata (PET). Lističi so obdelani s postopkom Carpentier-Edwards ThermaFix.

THV je namenjena za vsaditev v nativni obroček z velikostjo, povezano s tridimenzionalnim območjem aortnega obročka, merjeno na bazalnem obročku med sistolo, kot je navedeno v preglednici 1:

Preglednica 1

Velikost nativnega obročka zaklopke (TEE)*	Velikost nativnega obročka zaklopke (CT)		Velikost THV
	Območje	Premer, izpeljan iz območja	
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

Priporočila glede velikosti THV temeljijo na naravni velikosti obročka zaklopke, izmerjeni s transezofagealno ehokardiografijo (TEE) ali z računalniško tomografijo (CT). Pri izbiri velikosti THV je treba upoštevati anatomske dejavnike bolnika in več načinov slikanja.

Opomba: Upoštevati je treba tveganja, povezana s premalo in preveliko velikostjo, da se zmanjšajo tveganja paravalvularnega puščanja, migracije in/ali rupture obroča.

* Zaradi omejitev na dvodimenzionalnih slikah je treba slikanje 2-D TEE zamenjati s 3-D merjenjem območja.

Priporočila glede velikosti za vsaditev THV v odpovedujočo biološko protezo so navedena v spodnji preglednici 2:

Preglednica 2

Dejanski notranji premer kirurške zaklopke (ID) [1]	Velikost THV
16,5 - 19,0 mm	20 mm
18,5 - 22,0 mm	23 mm
22,0 - 25,0 mm	26 mm
25,0 - 28,5 mm	29 mm

Opomba: 'True ID' (interni premer) kirurške zaklopke je lahko manjši od velikosti označene zaklopke. Za odpovedujočo biološko protezo brez stenta upoštevajte priporočila glede velikosti za nativni obroček. Mere odpovedujoče biološke proteze je treba določiti tako, da je mogoče vsaditi THV ustrezne velikosti; najbolje je, če jo določite z računalniško tomografijo, s slikanjem z magnetno resonanco in/ali transezofagealno ehokardiografijo.

Priporočila glede velikosti za vsaditev THV v odpovedujočo kirurško biološko protezo INSPIRIS RESILIA velikosti 19 - 25 mm, na podlagi testnega okolja, so navedena v spodnji preglednici 3:

Preglednica 3

Aortna zaklopka INSPIRIS RESILIA (model 11500A)*, označena velikost	Velikost THV
19 mm	20 mm ali 23 mm
21 mm	23 mm ali 26 mm
23 mm	26 mm
25 mm	29 mm

*Aortna zaklopka INSPIRIS RESILIA, model 11500A, velikosti 19 - 25 mm vključuje tehnologijo VFit, ki jo sestavljajo razširljivi trakovi in fluoroskopsko vidni označevalniki velikosti, zasnovani za potencialne prihodnje posege zaklopka v zaklopki. Klinični podatki trenutno niso na voljo za poseg zaklopka v zaklopki za aortno zaklopko INSPIRIS RESILIA, model 11500A, ali funkcijo razširitve. Vpliv vraščanja tkiva na funkcijo razširitve aortne zaklopke INSPIRIS RESILIA ni bil ocenjen.

Edwards, Edwards Lifesciences, stiliziran logotip E, Carpentier-Edwards, Certitude, Edwards SAPIEN, Edwards SAPIEN 3, INSPIRIS, INSPIRIS RESILIA, Qualcrimp, RESILIA, SAPIEN, SAPIEN 3, ThermaFix in VFit so blagovne znamke družbe Edwards Lifesciences. Vse druge blagovne znamke so lastnina njihovih zadevnih lastnikov.

OPOZORILO: Ne izvajajte posegov balonske aortne valvuloplastike v aortni zaklopki INSPIRIS RESILIA za velikosti 19 - 25 mm. To lahko razširi zaklopko, kar povzroči aortno inkompetenco, koronarno embolijo ali rupturo obročka.

Opomba: Aortna zaklopka INSPIRIS RESILIA, model 11500A, velikosti 27 - 29 mm ne vključujejo tehnologije VFit, zato ne sledijo velikosti True ID (interni premer) kirurške zaklopke, navedene v preglednici 2.

Opomba: Natančna količina, zahtevana za vstavljanje THV, se lahko razlikuje glede na notranji premer biološke proteze. Dejavniki, kot sta kalcifikacija in rast tkiva panus, morda niso natančno prikazani na slikah in lahko zmanjšajo efektivni notranji premer odpovedujoče biološke proteze na velikost, manjšo od 'True ID'. Te dejavnike je treba upoštevati in oceniti, da se določi najustreznejša velikost THV, da se doseže nazivno uvajanje THV in zadostno sidranje. Ne presezite nazivnega razpočnega tlaka. Glejte parametre za napihovanje v preglednici 4.

- **Dovajalni sistem Edwards Certitude (slika 2)**

Dovajalni sistem Edwards Certitude omogoča namestitev biološke proteze. Dovajalni sistem je sestavljen iz upogljivega katetra, ki pomaga pri usmerjanju in postavljanju zaklopke. Dovajalni sistem vključuje zašiljeno konico, ki omogoča prehajanje zaklopke. Ročaj vključuje kolesce za upogibanje, ki omogoča nadzorovanje upogibanja balonskega katetra. V svetlino vodilne žice na dovajalnem sistemu je vstavljen mandren. Radioneprepustni sredinski označevalec na balonu je namenjen kot pomoč pri nastavljanju položaja balona. Med namestitvijo zaklopke THV se uporabi razširitveno cevje.

Parametri za napihovanje za uvajanje zaklopke so:

Preglednica 4

Model	Nazivni premer balona	Nazivni volumen napihovanja	Nazivni razpočni tlak (RBP)
9620TA20	20 mm	12 ml	7 atm
9620TA23	23 mm	17 ml	7 atm
9620TA26	26 mm	23 ml	7 atm
9620TA29	29 mm	30 ml	7 atm

- **Komplet vodila z uvajalom Edwards Certitude (slika 3)**

Komplet vodila z uvajalom Edwards Certitude omogoča uvajanje in odstranjevanje pripomočkov, ki se uporabljajo skupaj s transkatetrsko srčno zaklopko SAPIEN 3. Vodilo ima radioneprepustni označevalec za vizualizacijo konice vodila in globinske oznake na distalnem koncu osnove vodila, ki so prepustne za rentgenske žarke. Proksimalni konec vodila vključuje izpiralno cevko in tri hemostatske ventile. Uvajalo je dobavljeno z vodilom. Celotno uvajalo je neprepustno za rentgenske žarke.

Preglednica 5

Informacije o kompletu vodila z uvajalom

Model	9620IS18	9620IS21
Notranji premer vodila	18F (6,1 mm)	21F (6,9 mm)
Učinkovita dolžina vodila	21 cm	21 cm
Velikost uvajala	ZP: 6,3 mm	ZP: 7,0 mm
Učinkovita dolžina uvajala	33 cm	
Premer največje vodilne žice, ki jo je mogoče uporabiti	0,035 palci (0,89 mm)	

- **Pripomoček za stiskanje Qualcrimp**

Pripomoček za stiskanje Qualcrimp se uporablja med stiskanjem THV (slika 4).

- **Nalagalnik**

Nalagalnik se uporablja kot pomoč pri vstavljanju dovajalnega sistema v vodilo (slika 5).

- **Naprava za stiskanje Edwards in ustavljalo stiskanja (slika 6)**

Naprava za stiskanje Edwards zmanjša premer zaklopke za namestitev v dovajalni sistem. Naprava za stiskanje je sestavljena iz ohišja in stiskalnega mehanizma, ki se zapre z ročajem na ohišju. Ustavljalo stiskanja iz 2 kosov se uporablja za stiskanje zaklopke na predvideni premer.

- **Pripomoček za napihovanje**

Pripomoček za napihovanje z zaklepnim mehanizmom se uporablja med uvajanjem zaklopke.

Opomba: Za ustrezni volumen je treba uporabiti dovajalni sistem s pripomočkom za napihovanje, ki ga zagotavlja družba Edwards Lifesciences.

2.0 Predvidena uporaba

Biološka proteza je namenjena za uporabo pri bolnikih, ki potrebujejo zamenjavo srčne zaklopke. Dovajalni sistem in dodatki so namenjeni namestitvi biološke proteze s transapikalnim in transaortnim dostopom.

3.0 Indikacije

1. Sistem transkatetrske srčne zaklopke Edwards SAPIEN 3 je indiciran pri bolnikih s hudo simptomatično kalcificirano stenozo aortne zaklopke, za katere kardiološka ekipa presodi, da so izpostavljeni zmernemu ali večjemu tveganju odprtega kirurškega posega (tj. predvidenemu tveganju kirurške umrljivosti ≥ 3 % po 30 dneh na osnovi ocene tveganja Društva torakalnih kirurgov (STS) in drugih kliničnih sočasnih bolezni, nemerljivih s kalkulatorjem tveganja STS).
2. Sistem transkatetrske srčne zaklopke Edwards SAPIEN 3 je indiciran pri bolnikih s simptomatično srčno boleznijo zaradi popuščanja biološke proteze s kirurško aortno zaklopko ali biološke proteze s kirurško mitralno zaklopko (stenoze, insuficience ali kombinacije), za katere kardiološka ekipa, vključno s kardiokirurgom, presodi, da so izpostavljeni velikemu ali večjemu tveganju odprtega kirurškega posega (tj. predvidenemu tveganju kirurške umrljivosti ≥ 8 % po 30 dneh na osnovi rezultata STS in drugih kliničnih sočasnih bolezni, nemerljivih s kalkulatorjem tveganja STS).

4.0 Kontraindikacije

Uporaba sistema transkatetrske srčne zaklopke Edwards SAPIEN 3 je kontraindicirana pri bolnikih, ki:

- ne prenašajo antikoagulacijskega/antitrombotičnega režima zdravljenja ali imajo aktivni bakterijski endokarditis oziroma druge aktivne okužbe.

5.0 Opozorila

- Pripomočki so ob dobavi STERILNI ter so zasnovani, predvideni in distribuirani samo za enkratno uporabo. **Pripomočkov ne sterilizirajte ali uporabite znova.** Podatkov za podporo sterilnosti, apirogenosti in funkcionalnosti pripomočkov po ponovni obdelavi ni.
- Za čim večje zmanjšanje tveganja paravalvularnega puščanja, premika in/ali rupture obročka je nujno pravilno določanje velikosti zaklopke THV.
- Zdravnik mora pred vsaditvijo transkatetrske srčne zaklopke preveriti, ali je usmerjena pravilno.
- Pri bolnikih s spremenjeno presnovo kalcija lahko pride do pospešenega poslabšanja THV.
- Če uporabljate vensko spodbujanje, je med posegom treba opazovati elektrodo spodbujevalnika, da preprečite morebitno tveganje srčno-žilne perforacije s spodbujevalnim vodilom.
- Zaklopka THV mora vedno ostati hidrirana in ne sme biti izpostavljena raztopinam, antibiotikom, kemikalijam itd., razen shranjevalni raztopini za transport in sterilni fiziološki raztopini, da se prepreči poškodba lističev, ki lahko vpliva na delovanje zaklopke. Če med katerim koli delom posega pride do poškodbe lističev zaklopke THV ali nepravilnega ravnanja z njimi, je treba zaklopko THV zamenjati.
- Bolniki s preobčutljivostjo za kobalt, nikelj, krom, molibden, titan, mangan, silicij, goveje tkivo in/ali polimerne materiale imajo lahko alergijsko reakcijo na te materiale.
- Ne uporabite zaklopke THV, če je pečat za zaščito pred nedovoljenimi posegi pretrgan, saj lahko to ogrozi sterilnost.
- Ne uporabite zaklopke THV, če je aktiviran temperaturni indikator, saj lahko to ogrozi delovanje zaklopke.
- Ne uporabite zaklopke THV, če je rok uporabnosti potekel, saj to lahko ogrozi sterilnost ali delovanje zaklopke.
- Ne uporabite zaklopke THV, če shranjevalna raztopina popolnoma ne prekrije zaklopke ali je zaklopka poškodovana.
- Dovajalnega sistema ne uporabljajte napačno oziroma ne uporabljajte dovajalnega sistema in dodatkov, če so sterilne pregrade ovojnine in katere koli komponente odprte ali poškodovane, jih ni mogoče izprati ali jim je potekel rok uporabnosti.
- Prejemniki zaklopke se morajo še naprej zdraviti z antikoagulanti/antitrombotiki (razen če je to kontraindicirano), za čim večje zmanjšanje tveganja tromboze zaklopke ali trombemboličnih dogodkov, kot določijo zdravniki. Pripomoček ni bil testiran za uporabo brez antikoagulacije.
- Poseg je treba izvesti pod fluoroskopskim nadzorom. Nekateri posegi, ki se izvajajo pod fluoroskopijo, so povezani s tveganjem poškodb kože zaradi obsevanja. Te poškodbe so lahko boleče, povzročajo iznakaženost in so dolgotrajne.
- Pri vsaditvi zaklopke pri bolnikih s klinično pomembno koronarno boleznijo je treba biti previden.
- Bolnike z bioloških protezami je treba pred vsaditvijo zaklopke pozorno oceniti, da se zagotovita pravilna postavitev in namestitev zaklopke.
- Pri zdravljenju okvarjenih bioloških protez se je treba izogibati balonski valvuloplastiki, saj lahko to privede do embolizacije materiala biološke proteze in mehanskih motenj v delovanju lističev zaklopke.

6.0 Previdnostni ukrepi

- Dolgotrajne trpežnosti zaklopke THV niso ugotovili. Za ocenjevanje učinkovitosti zaklopke so priporočljive redne zdravstvene kontrole.
- Glutaraldehid lahko povzroči draženje kože, oči, nosa in žrela. Izogibajte se dolgotrajnejšemu ali večkratnemu izpostavljanju oziroma vdihavanju raztopine. Uporabljajte jo samo, če je prezračevanje primerno. Če pride do stika s kožo, prizadeto območje takoj izperite z vodo; v primeru stika z očmi takoj poiščite zdravniško pomoč. Za več podatkov o izpostavljenosti glutaraldehidu glejte varnostni list, ki je na voljo pri družbi Edwards Lifesciences.
- Varnosti in učinkovitosti vsaditve THV niso ugotovili pri bolnikih z:
  - aortnim obročkom brez kalcifikacije,
  - prirojeno unikuspidalno aortno zaklopko,
  - že vsajenim protetičnim obročkom na katerem koli položaju,
  - hudo disfunkcijo prekata z iztisnim deležem < 20 %,
  - hipertrofično kardiomiopatijo z obstrukcijo ali brez nje,
  - aortno stenozo, za katero je značilna kombinacija majhnega AV-pretoka z majhnim gradientom,
  - sočasno paravalvularno puščanje, pri katerem okvarjena biološka proteza ni stabilno pritrjena znotraj nativnega obročka ali je strukturno oporečna (npr. zlom žičnatega ogrodja),
  - deloma ločenim lističem okvarjene biološke proteze, ki lahko v aortnem položaju ovira koronarno ustje,
  - odebeljenimi, kalcificiranimi lističi aortne zaklopke v neposredni bližini koronarnih ustij.
- Po posegu je pri bolnikih, izpostavljenih tveganju za okužbo protetične zaklopke in endokarditisu, priporočljiva uporaba ustrezne profilakse z antibiotiki.
- Če pri prvotni vsaditvi za preprečevanje ukleščenja subvalvularnega aparata uporabite tehnike za ohranitev horde, je treba biti pri zamenjavi mitralne zaklopke še posebej previden.
- Lečeči zdravnik lahko na podlagi premisleka o tveganjih in koristih vsadi zaklopko pri relativno mladih bolnikih, čeprav je dolgoročna trpežnost še vedno predmet potekajočih kliničnih raziskav.
- Namestitvenega balona ne napolnite preveč, ker lahko tako preprečite pravilen stik lističev zaklopke in s tem vplivate na delovanje zaklopke.
- Prejemniki zaklopke THV se morajo še naprej zdraviti z antikoagulanti/antitrombotiki, za čim večje zmanjšanje tveganja tromboze zaklopke ali trombemboličnih dogodkov, kot določijo zdravniki.
- Preostali povprečni gradient je lahko večji v »konfiguraciji« THV znotraj nedelujoče biološke proteze kot po vsaditvi zaklopke v nativnem aortnem obročku ob uporabi pripomočka enake velikosti. Bolnike s povečanim povprečnim gradientom po posegu je treba pozorno spremljati. Pomembno je določiti proizvajalca, model in velikost obstoječe biološke protetične zaklopke, da se lahko vsadi ustrezna zaklopka in prepreči neustrezno ujemanje proteze ter bolnika. Poleg tega je treba s slikanjem pred posegom čim bolj natančno določiti notranji premer.

7.0 Možni neželeni dogodki

Možna tveganja, povezana s celotnim posegom, vključno z dostopom, katetrizacijo srca in splošno anestezijo:

- smrt;
- možganska kap/tranzitorna ishemična ataka, crescendo ali nevrološki deficit,
- paraliza,
- trajna invalidnost,
- respiratorna insuficienca ali dihalna odpoved;
- srčno-žilna poškodba, ki vključuje perforacijo ali disekcijo struktur žil, prekata, preddvora, septuma, miokardija ali zaklopke in lahko zahteva poseg;
- perikardialni izliv ali tamponada srca,
- krvavitev v prsnem košu,
- embolizacija vključno z zrakom, kalcificiranim materialom zaklopke ali trombusom,

- okužbe, vključno s septikemijo in endokarditisom,
- srčno popuščanje,
- miokardna ishemija ali miokardni infarkt,
- ledvična nezadostnost ali ledvična odpoved,
- pomanjkljiv prevajalni sistem, zaradi katerega je lahko potreben trajni srčni spodbujevalnik,
- aritmije, vključno z ventrikularno fibrilacijo (VF) in ventrikularno tahikardijo (VT),
- retroperitonealna krvavitev,
- arteriovenska (AV) fistula ali psevdoanevrizma,
- ponoven kirurški poseg,
- ishemija, poškodbe živcev ali brahialnega pleksusa ali utesnitveni sindrom,
- restenoza,
- pulmonalni edem,
- plevralni izliv,
- krvavitve, krvavitve, zaradi katerih je potrebna transfuzija ali intervencija,
- anemija,
- tromboza/okluzija žil,
- nenormalne vrednosti laboratorijskih izvidov (vključno z neravnovesjem elektrolitov),
- hipertenzija ali hipotenzija,
- alergijske reakcije na anestezijo, kontrastno sredstvo, materiale pripomočka ali goveje perikardialno tkivo,
- hematom,
- sinkopa,
- bolečina ali spremembe (npr. okužba, hematom rane in drugi zapleti z nego rane) na mestu pristopa,
- intoleranca za telesno vadbo ali šibkost,
- vnetje,
- angina,
- vazovagalna sinkopa,
- šum na srcu,
- povišana telesna temperatura.

Dodatna možna tveganja, ki so povezana s posegom TAVR, biološko protezo in uporabo povezanih pripomočkov ter dodatkov vključujejo:

- srčni zastoj,
- kardiogeni šok,
- urgentni kirurški poseg na srcu,
- srčno popuščanje ali nizek minutni volumen srca,
- obstrukcijo koronarnega pretoka/motnje transvalvularnega pretoka,
- trombozo pripomočka, zaradi katere je potrebna intervencija,
- trombozo zaklopke,
- embolizacijo pripomočka,
- migracijo pripomočka ali slab položaj, zaradi katerega je potrebna intervencija,
- obstrukcijo iztočnega trakta levega prekata,
- namestitev zaklopke na nenamenskem mestu,
- stenozo zaklopke;
- strukturno deterioracijo zaklopke (obraba, zlom, kalcifikacija, trganje/odtrganje lističa iz opornic, retrakcija lističa, razpočenje suturne linije na komponentah protetične zaklopke, zadebelitev, stenoza);
- degeneracijo pripomočka;
- paravalvularno ali transvalvularno puščanje,
- regurgitacijo zaklopke,
- hemolizo,
- eksplantacijo pripomočka;
- mediastinitis;
- mediastinalno krvavitev;
- nestrukturno disfunkcijo;
- mehansko odpoved dovajalnega sistema in/ali dodatkov, vključno z razpokom balona in ločitvijo konice,
- neurgentno reparacijo,
- alergijsko/imunološko reakcijo na vsadek,
- poškodbe mitralne zaklopke.

Pri bolnikih/uporabnikih/tretjih osebah v Evropskem gospodarskem prostoru: če med uporabo tega pripomočka ali kot posledica njegove uporabe pride do resnega incidenta, je treba o tem poročati proizvajalcu in državnemu pristojnemu organu, ki je naveden na spletnem mestu https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

8.0 Smernice za uporabo

8.1 Združljivost sistema

Preglednica 6

Ime izdelka	20 mm sistem	23 mm sistem	26 mm sistem	29 mm sistem
	Model			
Transkatetrska srčna zaklopka Edwards SAPIEN 3	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)

Ime izdelka	20 mm sistem	23 mm sistem	26 mm sistem	29 mm sistem
	Model			
Dovajalni sistem Edwards Certitude	9620TA20	9620TA23	9620TA26	9620TA29
Komplet vodila z uvajalom Edwards Certitude	9620IS18 (18F)			9620IS21 (21F)
Pripomoček za napihovanje	96402			96406
Naprava za stiskanje Edwards	9600CR			
Napravo za stiskanje Qualcrimp, ustavljalo stiskanja, nalagalnik in podaljševalno cevko zagotavlja družba Edwards Lifesciences				

Dodatna oprema:

- Balonski kateter po presoji zdravnika
- 20- cc injekcijska brizga ali večja
- 50- cc injekcijska brizga ali večja
- Visokotlačni 3-potni zaporni ventil
- Standardna laboratorijska oprema in potrebščine za katetrizacijo srca ter dostop do standardne opreme in potrebščin operacijske dvorane za srčne zaklopke
- Fluoroskopija (fiksni, mobilni ali delno mobilni sistemi za fluoroskopijo, primerni za uporabo v perkutanih koronarnih posegih)
- Kapacitete za transezofagealno ali transtorakalno ehokardiografijo
- Seldingerjeva igla velikosti 18 G (za transaortni pristop)
- 145 cm x 0,035 palci (0,89 mm) mehka vodilna igla
- 180 cm ali 260 cm x 0,035 palci (0,89 mm) in izmenjevalna dolžina 0,035 palci (0,89 mm) zelo toge vodilne žice
- Začasni srčni spodbujevalnik (PM) in spodbujevalna elektroda
- Sterilne kadi za izpiranje, fiziološka raztopina, heparinizirana fiziološka raztopina, 15- % razredčeno radioneprepustno kontrastno sredstvo
- Sterilna miza za pripravo THV in dodatkov

8.2 Ravnanje s THV in priprava

Upoštevajte sterilno tehniko med pripravo in vsaditvijo pripomočka.

8.2.1 Postopek izpiranja THV

Pred odpiranjem kozarca z zaklopko skrbno preglejte glede morebitnih poškodb (npr. počen kozarec ali pokrov, puščanje oziroma zlomljena ali manjkajoča tesnila).

SVARILO: Če je vsebnik poškodovan, pušča, brez dovolj sterilnega sredstva ali z manjkajočimi tesnili, THV ne smete uporabiti za vsaditev, saj je lahko sterilnost ogrožena.

1. Pripravite dve (2) sterilni skledi z vsaj 500 ml sterilne fiziološke raztopine, da boste temeljito splaknili THV.
2. Skrbno odstranite sklop zaklopke/držala iz kozarca brez dotikanja tkiva. Primerjajte serijsko identifikacijsko številko zaklopke s številko na pokrovu kozarca in jo zapišite v dokumentacijo s podatki o bolniku. Preglejte zaklopko glede kakršnih koli znakov poškodb ogrodja ali tkiva.
3. Izperite THV, kot sledi:
   a) Vstavite THV v prvo skledo s sterilno fiziološko raztopino. Poskrbite, da fiziološka raztopina povsem pokriva THV in držalo.
   b) S potopljeno zaklopko in držalom počasi premikajte (nežno vrtite zaklopko in držalo) naprej in nazaj vsaj 1 minuto.
   c) Prestavite THV in držalo v drugo skledo za izpiranje s sterilno fiziološko raztopino in nežno premikajte vsaj še eno minuto. Poskrbite, da izpiralna raztopina v prvi skledi ni uporabljena.
   d) Zaklopko je treba pustiti v končni izpiralni raztopini, dokler je ne potrebujete, da boste preprečili izsušitev tkiva.

   SVARILO: Med mešanjem ali vrtinčenjem v izpiralni raztopni ne dovolite, da bi zaklopka prišla v stik z dnom ali stranico izpiralne sklede. Med postopkom izpiranja se izogibajte tudi neposrednemu stiku med identifikacijsko značko in zaklopko. V izpiralne sklede ni dovoljeno vstavljati nobenih drugih predmetov. Zaklopko morate ohranjati hidrirano, da preprečite izsušitev tkiva.

8.2.2 Priprava sistema

1. Vizualno preglejte vse komponente glede poškodb. Prepričajte se, da je sistem popolnoma neoviran.
2. Uvajalnik in vodilo napolnite in sperite s heparinizirano fiziološko raztopino. Hidrirajte dolžino uvajalnika in vodila.
3. Uvajalnik popolnoma potisnite v ohišje vodila.
4. Odvijte pokrovček nalagalnika z nalagalnika in splaknite pokrovček nalagalnika s heparinizirano fiziološko raztopino.
5. Pokrovček nalagalnika namestite na dovajalni sistem tako, da je notranjost pokrovčka obrnjena proti zašiljeni konici.
6. Sperite podaljševalno cevko in jo priključite na dovajalni sistem.
7. Delno napolnite 50 ml ali večjo injekcijsko brizgo z razredčenim kontrastnim sredstvom in jo priključite na podaljševalno cevko.
8. Napolnite pripomoček za napihovanje z 20 ml razredčenega kontrastnega sredstva, zaklenite pripomoček za napihovanje in ga priključite na podaljševalno cevko. Zaprite 3-potni zaporni ventil na pripomoček za napihovanje.
9. Z injekcijsko brizgo luer lock odzračite dovajalni sistem. V sistemu mora biti ničelni tlak. Zaprite 3-potni zaporni ventil na injekcijski brizgi luer lock.
10. Odstranite 3 ml tekočine iz dovajalnega sistema tako, da obrnete gumb zaklenjenega pripomočka za napihovanje. Med stiskanjem THV naj bo pripomoček za napihovanje zaklenjen.

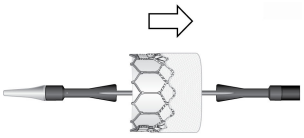
8.2.3 Namestite in stisnite THV na dovajalni sistem

1. Pripomoček za stiskanje Qualcrimp popolnoma potopite v posodo s 100 ml fiziološke raztopine. Nežno stisnite, dokler ni popolnoma nasičeno. Vrtite vsaj 1 minuto. Ponovite ta postopek v drugi posodi.
2. Obračajte stiskalnico, dokler se odprtina popolnoma ne odpre. Priključite 2-delno ustavljalo stiskanja na stiskalnico.
3. Odstranite THV iz nosilca in odstranite ID značko.
4. Po potrebi delno stisnite THV v stiskalnici, dokler se tesno ne prilega v napravo za stiskanje Qualcrimp.

   Opomba: Delno stiskanje ni potrebno za 20 mm zaklopko.
5. Postavite napravo za stiskanje Qualcrimp čez THV.
6. Usmerjenost THV na dovajalnem sistemu je opisana spodaj:

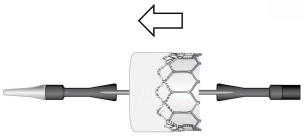
Antegradni pristop:

Dovod (zunanji konec obrobe) THV proti **proksimalnemu koncu** dovajalnega sistema.



Retrogradni pristop:

dovod (zunanji konec obrobe) THV proti **distalnemu koncu** dovajalnega sistema.



7. Vstavite THV in napravo za stiskanje Qualcrimp v stiskalnico. Vstavite dovajalni sistem koaksialno v THV.
8. THV stisnite med dvema notranjima ramenoma dovajalnega sistema, dokler ne doseže ustavljala naprave Qualcrimp.
9. Odstranite napravo za stiskanje Qualcrimp iz sklopa THV/balona in ustavljalo naprave Qualcrimp z ustavljala stiskanja, končno ustavljalo pa pustite nameščeno.

   Opomba: Zagotovite, da THV ostane centriran in koaksialen znotraj obeh notranjih ramen.
10. Sklop THV/balona namestite nazaj v odprtino stiskalnice, popolnoma stisnite THV, dokler ne doseže končne točke, in ga držite 5 sekund.
11. Ponovite polno stiskanje THV dvakrat, da naredite skupno 3 stiskanja.
12. Splaknite nalagalnik s heparinizirano fiziološko raztopino. Takoj potisnite nalagalnik čez THV, dokler ni zašiljena konica dovajalnega sistema izpostavljena in THV ni znotraj distalnega konca cevi nalagalnika.

    SVARILO: THV ne sme ostati povsem stisnjena in/ali v nalagalniku več kot 15 minut, saj je lahko posledica poškodba lističev, kar vpliva na delovanje zaklopke.
13. Namestite pokrovček nalagalnika na nalagalnik in sperite skozi izpiralno odprtino na nalagalniku. Odstranite mandren in splaknite svetlino vodilne žice dovajalnega sistema.

    SVARILO: Ohranite THV hidrirano, dokler ni pripravljena na vsaditev, da preprečite poškodbe lističev, kar lahko vpliva na delovanje zaklopke.

    OPOZORILO: Zdravnik mora pred vsaditvijo transkatetrske srčne zaklopke preveriti, ali je usmerjena pravilno, da prepreči tveganje hudih poškodb bolnika.
14. Z zaprtim 3-potnim zapornim ventilom na injekcijski brizgi luer lock odklenite pripomoček za napihovanje. Pustite, da dovajalni sistem doseže ničelni tlak.
15. Zaprite 3-potni zaporni ventil do dovajalnega sistema. Uporabite injekcijsko brizgo luer lock za odzračevanje pripomočka za napihovanje.
16. Prilagodite pripomoček za napihovanje na volumen napihovanja, ki je potreben za vstavitev THV, v skladu s tabelo 4.

    Ponovno zaklenite pripomoček za napihovanje. Zaprite 3-potni zaporni ventil na injekcijski brizgi luer lock in odstranite injekcijsko brizgo.

    SVARILO: Ohranite pripomoček za napihovanje v zaklenjenem položaju do vstavitve THV, da preprečite predčasno napihovanje balona ter posledično nepravilno vstavitev THV.

8.3 Predhodna dilatacija nativne zaklopke in vstavljanje THV

Predhodno dilatacijo nativne zaklopke in vstavljanje THV je treba izvesti pod splošno anestezijo s hemodinamskim nadzorom v laboratoriju za katetrizacijo/hibridni operacijski dvorani z možnostjo fluoroskopskega in ehokardiografskega slikanja.

V naslednji preglednici so prikazane minimalne zahtevane razdalje od ravnine zaklopke do distalne konice vodila, da se balon dovajalnega sistema Edwards Certitude med uvajanjem THV pravilno napihne. **Te razdalje ne vključujejo globine vstavitve vodila**, ki jo je treba upoštevati med transaortnim pristopom pri izbiri mesta dostopa na ascendentni aorti.

Preglednica 7

Dovajalni sistem	THV	Najmanjša zahtevana razdalja od konice vodila do ravnine zaklopke
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

Dovajajte heparin, da ohranite ACT na ≥ 250 sek.

SVARILO: Uporabo kontrastnega sredstva je treba spremljati, da se zmanjša tveganje za poškodbo ledvic.

8.3.1 Osnovni parametri

1. Vstavite 5F (1,67 mm) ali 6F (2,0 mm) zaviti (pigtail) kateter in izvedite angiogram s projekcijo zaklopke pravokotno na pogled.
2. Ocenite razdalje desnega in levega koronarnega ustja od aortnega obročka v zvezi z višino okvirja transkatetrske srčne zaklopke (THV).
3. Uvedite vodilo srčnega spodbujevalnika (PM) in ga primerno nastavite.
4. Nastavite parametre stimulacije, da dobite zajem 1:1 in preizkusite spodbujanje.

8.3.2 Dostop

SVARILO: Med vstavljanjem, nameščanjem in odstranjevanjem pripomočkov je treba biti previden in preprečiti poškodbe mehkega tkiva, kolagenskih vlaken, aorte, nativnega lističa ali stene prekata.

8.3.2.1 Transapikalni dostop

1. Dostop do apeksa s sprednjo mini torakotomijo na 5. ali 6. medrebrnem prostoru. Zarežite perikard, da razkrijete vrh levega prekata (LV).
2. Epikardialne spodbujevalne elektrode pritrdite na levi prekat ali vstavite transvenske spodbujevalne elektrode in proksimalne konce elektrod pritrdite v srčni spodbujevalnik. Nastavite parametre stimulacije in preizkusite hitro spodbujanje.
3. Za dostop do levega prekata namestite ojačani dvojni torbični šiv na apeks levega prekata (LV).
4. Dostop je mogoče doseči s standardnimi transaortnimi tehnikami.
5. Z uporabo globokih označevalcev vodila potisnite uvajalnik in vodilo čez vodilno žico do želene globine, medtem ko spremljate njuno pomikanje na fluoroskopiji.
6. Počasi izvlecite uvajalnik in pri tem držite vodilo na mestu. Ohranite položaj vodilne žice čez zaklopko.

8.3.2.2 Transaortni dostop

1. Dostop do ascendentne aorte opravimo s standardno kirurško tehniko (npr. delna J-sternotomija ali desna parasternalna mini torakotomija).
2. Na predvideno mesto dostopa v ascendentni aorti namestite dva ojačana torbična šiva.

   Opomba: Izbrano mesto dostopa mora biti pri digitalni palpaciji mehko.
3. Uvajajte elektrodo srčnega spodbujevalnika, dokler njen distalni konec ni nameščen v desnem prekatu. Nastavite parametre stimulacije in preizkusite spodbujanje.
4. Dostop do aortne zaklopke je mogoče doseči s standardnimi transaortnimi tehnikami.
5. V aorto vstavite komplet vodila z uvajalom Edwards Certitude ali želeno vodilo z uvajalom za BAV do približno 2 cm. Počasi izvlecite uvajalnik in pri tem držite vodilo na mestu. Ohranite položaj vodilne žice čez aortno zaklopko.

8.3.3 Valvuloplastika

Predhodno razširite nativno aortno zaklopko po presoji zdravnika skladno z navodili za uporabo izbranega balonskega katetra za aortno valvuloplastiko.

SVARILO: Vsaditve zaklopke ni dovoljeno izvesti, če balona ni mogoče povsem napihniti med valvuloplastiko.

8.3.4 Uvajanje THV

SVARILO: Med vstavljanjem, nameščanjem in odstranjevanjem pripomočkov je treba biti previden in preprečiti poškodbe mehkega tkiva, kolagenskih vlaken, aorte, nativnega lističa ali stene prekata.

1. Preverite, ali je THV pravilno usmerjena in ali se prostornina v pripomočku za napihovanje ujema z navedeno prostornino.
2. Sklop THV/balona z nalagalnikom potisnite naprej čez vodilno žico.
3. Vstavite nalagalnik v ohišje vodila, medtem ko ga trdno držite.
4. Zaklopko potisnite iz nalagalnika v večji del vodila. Tapnite po ohišju vodila, da sprostite zračne mehurčke na proksimalnem koncu nalagalnika. Pritisnite gumbni ventil na nalagalniku za odzračevanje.
5. Sklop THV/balona potisnite skozi vodilo in ga namestite v ciljno zaklopko.
   Po potrebi zavrtite kolesce za upogibanje na ročaju, da namestite sklop THV/balona v položaj.

   SVARILO: Za preprečevanje morebitnih poškodb lističev, ki bi lahko vplivale na delovanje zaklopke, THV ne sme ostati v vodilu več kot 5 minut.
6. Prepričajte se, da je THV pravilno nameščena med dvema notranjima ramenoma dovajalnega sistema.
7. Začnite z uvajanjem THV:
   a) Odklenite pripomoček za napihovanje družbe Edwards Lifesciences.
   b) Začnite s hitrim spodbujanjem; ko se sistolični krvni tlak zmanjša na 50 mmHg ali manj, lahko začnete z napihovanjem balona.
   c) Vstavite THV z napihovanjem balona s polnim volumnom v pripomočku za napihovanje družbe Edwards Lifesciences, zadržite za 3 sekunde in preverite, ali je valj pripomočka za napihovanje prazen, da boste zagotovili, da je balon povsem napihnjen.
   d) Izpustite zrak iz balona. Ko je balon povsem izpraznjen, izklopite srčni spodbujevalnik.

8.3.5 Odstranjevanje sistema

1. Če je bila uporabljena artikulacija, popolnoma sprostite dovajalni sistem.

   Povlecite dovajalni sistem in vodilno žico v vodilo. Odstranite nalagalnik in dovajalni sistem iz vodila.

   SVARILO: Pravilno izpraznite balon in sprostite dovajalni sistem pred odstranitvijo.
2. Odstranite vse pripomočke, ko je raven aktiviranega časa strjevanja krvi (activated clotting time, ACT) primerna.
3. Odstranite vodilo iz mesta dostopa, zaprite mesto dostopa in potrdite hemostazo.

8.4 Preverjanje položaja in meritev THV

Izmerite in zabeležite hemodinamske parametre.

1. Po potrebi opravite angiogram za oceno delovanja pripomočka in prehodnosti koronarnih arterij.
2. Izmerite in zabeležite transvalvularne gradiente tlaka.
3. Odstranite vse pripomočke, ko je raven ACT primerna (npr., ko doseže < 150 sek).
   Za odstranjevanje pripomočka glejte navodila za uporabo vodila z uvajalom.
4. Zaprite mesto dostopa.

9.0 Kako je dobavljeno

STERILNO: Zaklopka je ob dobavi sterilizirana z raztopino glutaraldehida.

Dovajalni sistem in dodatki so dobavljeni sterilizirani s plinom etilenoksidom.

THV je dobavljena apirogeno pakirana v pufranem glutaraldehidu v plastičnem kozarcu, na katerega je nameščen varnostni pečat proti odpiranju. Vsak kozarec je odpremljen v škatli, ki vsebuje indikator temperature za zaznavanje izpostavljenosti THV ekstremnim temperaturam. Škatla je vstavljena v stiropor pred odpremo.

9.1 Shranjevanje

THV je treba hraniti med 10 °C in 25 °C (50 °F in 77 °F). Vsak kozarec je odpremljen v vsebniku, ki vsebuje indikator temperature za zaznavanje izpostavljenosti THV ekstremnim temperaturam.

Dovajalni sistem in dodatke je treba hraniti na hladnem in suhem mestu.

10.0 Varno za uporabo v MR okolju

Pogojno uporabno v MR okolju

Neklinično testiranje je pokazalo, da je transkatetrska srčna zaklopka Edwards SAPIEN 3 pogojno varna za uporabo v MR okolju. Bolnika s tem pripomočkom je mogoče varno slikati takoj po namestitvi tega pripomočka pod naslednjimi pogoji:

- Statično magnetno polje z 1,5 tesla (T) ali 3,0 tesla (T)
- Največje prostorsko polje gradienta je 2500 Gauss/cm (25 T/m) ali manj
- Največja od sistema MR poročana povprečna specifična stopnja absorpcije (SAR) za celotno telo znaša 2,0 W/kg (normalni način delovanja)

Pri pogojih slikanja, opredeljenih zgoraj, se pričakuje, da bo transkatetrska srčna zaklopka proizvedla dvig temperature do največ 3,0 °C po 15 minutah neprekinjenega slikanja.

Pri nekliničnem testiranju slikovni artefakt, ki ga povzroči pripomoček sega do 14,5 mm od vsadka za slike spinskega odmeva in 30 mm za slike gradientnega odmeva pri slikanju v sistemu MRI z jakostjo 3,0 T. Artefakt zakrije svetlino naprave v slikah gradientnega odmeva.

Vsadek ni bil ovrednoten v drugih sistemih MR razen 1,5 T ali 3,0 T.

Za vsaditev zaklopke v zaklopko ali ob prisotnosti drugih vsadkov preberite varnostne informacije o MRI za kirurško zaklopko ali druge naprave pred slikanjem z MR.

11.0 Kvalitativne in kvantitativne informacije, povezane s THV

Ta pripomoček vsebuje naslednje snovi, opredeljene kot CMR 1B, v koncentraciji nad 0,1 % mase na maso:

kobalt; št. CAS 7440-48-4; št. ES 231-158-0

Trenutni znanstveni dokazi potrjujejo, da medicinski pripomočki, izdelani iz kobaltovih zlitin ali zlitin nerjavnega jekla, ki vsebujejo kobalt, ne povzročajo povečanega tveganja za nastanek raka ali škodljivih učinkov na reprodukcijo.

Za THV naslednja preglednica prikazuje kvalitativne in kvantitativne podatke o materialih in snoveh:

Preglednica 8

Snov	CAS	Masni razpon modela (mg)
Kobalt	7440-48-4	131 - 427
Nikelj	7440-02-0	148 - 405
Krom	7440-47-3	85,2 - 230
Polietilen tereftalat	25038-59-9	102 - 170
Kolageni, goveji, polimeri z glutaraldehidom	2370819-60-4	58,3 - 141
Molibden	7439-98-7	40,3 - 115
Politetrafluoroetilen	9002-84-0	17,5 - 25,5
Polietilen	9002-88-4	14,2 - 19,7
Železo	7439-89-6	0 - 10,9
Titan	7440-32-6	0 - 10,9
Mangan	7439-96-5	0 - 1,64
Silicij	7440-21-3	0 - 1,64
Titanov oksid	13463-67-7	0,219 - 0,752
Polibutilat	24936-97-8	0,273 - 0,383
Ogljik	7440-44-0	0 - 0,274
Antimonov trioksid	1309-64-4	0,112 - 0,190
Bor	7440-42-8	0 - 0,164
Fosfor	7723-14-0	0 - 0,164
Žveplo	7704-34-9	0 - 0,109
D&C zelena št. 6	128-80-3	0,0394 - 0,0578
Silicijev dioksid	7631-86-9	0,00422 - 0,00592
Erukamid	112-84-5	0,000683 - 0,00128
4-dodecilbenzensulfonska kislina	121-65-3	0,000286 - 0,000430

12.0 Povzetek varnosti in klinične učinkovitosti (SSCP)

Dokument SSCP je skladen s klinično oceno priglašenega organa, na podlagi katere je bil podeljen certifikat za oznako CE. Dokument SSCP vsebuje ustrezen povzetek istih informacij.

Priglašeni organ je preveril in potrdil utemeljitve razmerja med koristmi in tveganji, povezanimi s kratko- in dolgotrajno varnostjo ter učinkovitostjo platforme SAPIEN 3.

Skladnost celotne platforme SAPIEN 3 z zahtevami za učinkovitost (GSPR) za varnost (MDR GSPR1), učinkovitost (MDR GSPR1), sprejemljivost neželenih učinkov (MDR GSPR8), uporabnost (MDR GSPR5), življenjsko dobo (MDR GSPR6) in sprejemljiv profil razmerja med koristmi ter tveganji (MDR GSPR8) je bila določena za navedene indikacije.

Glejte https://meddeviceinfo.edwards.com/ za SSCP za ta medicinski pripomoček.

Po uvedbi Evropske baze podatkov o medicinskih pripomočkih/Eudamed glejte https://ec.europa.eu/tools/eudamed za SSCP za ta medicinski pripomoček.

13.0 Osnovni edinstveni identifikator pripomočka – identifikator pripomočka (UDI-DI)

Osnovni UDI-DI je dostopni ključ za informacije, povezane s pripomočkom, vnesene v Eudamed. Osnovni UDI-DI za zaklopko, dovajalni sistem in vodilo se lahko uporabljajo za iskanje SSCP.

Naslednja preglednica vsebuje osnovni UDI-DI:

Preglednica 9

Izdelek	**Model**				**Osnovni UDI-DI**
	20 mm sistem	**23 mm sistem**	**26 mm sistem**	**29 mm sistem**	
Transkatetrska srčna zaklopka Edwards SAPIEN 3	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)	0690103D003SAP000VP
Dovajalni sistem Edwards Certitude	9620TA20	9620TA23	9620TA26	9620TA29	0690103D003CER000QZ
Komplet vodila z uvajalom Edwards Certitude	9620IS18			9620IS21	0690103D003CIS000SL
Pripomoček za napihovanje	96402			96406	0690103D003IND000TG
Naprava za stiskanje Edwards	9600CR				0690103D003CRI000TH

14.0 Pričakovana življenjska doba pripomočka

Transkateterska srčna zaklopka Edwards je bila podvržena strogemu predkliničnemu testiranju vzdržljivosti v skladu z zahtevami za testiranje zaklopk ter v kliničnih študijah in študijah po trženju. Zaklopke so bile uspešno testirane do 5 let simulirane rabe. Poleg tega so klinični podatki pokazali trajnost pri spremljanju do 5 let. Dejansko življenjsko dobo še preučujejo in se razlikuje od bolnika do bolnika.

15.0 Informacije o bolniku

Kartica vsadka bolnika je priložena vsakemu THV. Po vsaditvi izpolnite vse zahtevane informacije in predajte kartico vsadka bolniku. Serijska številka je navedena na embalaži. Ta kartica vsadka omogoča bolniku, da obvesti zdravstvene delavce o tem, katero vrsto vsadka ima, če potrebuje nego.

16.0 Odvzeti THV in odlaganje pripomočka med odpadke

Odstranjeni THV je treba vstaviti v ustrezen histološki fiksativ, npr. 10 % formalin ali 2 % glutaraldehid ter ga vrniti družbi. Zamrzovanje v teh okoliščinah ni potrebno. Obrnite se na Edwards Lifesciences in naročite komplet za odstranitev vsadka.

Z rabljenimi pripomočki je treba ravnati in jih zavreči na enak način kot bolnišnični odpad in biološko nevarne materiale. Odlaganje teh pripomočkov ne vključuje posebnih tveganj.

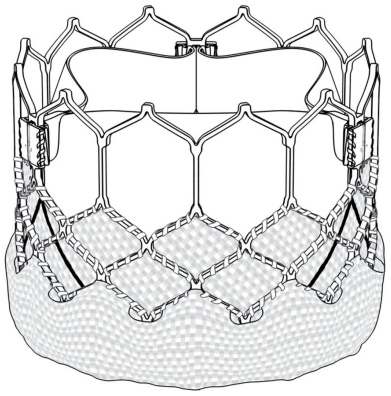
17.0 Klinične študije

Glejte SSCP za klinične koristi.

18.0 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.

Figures ■ Slike



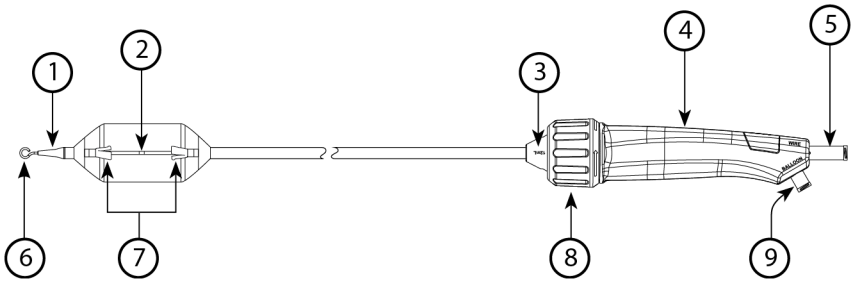
9600TFX

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

■ 9600TFX

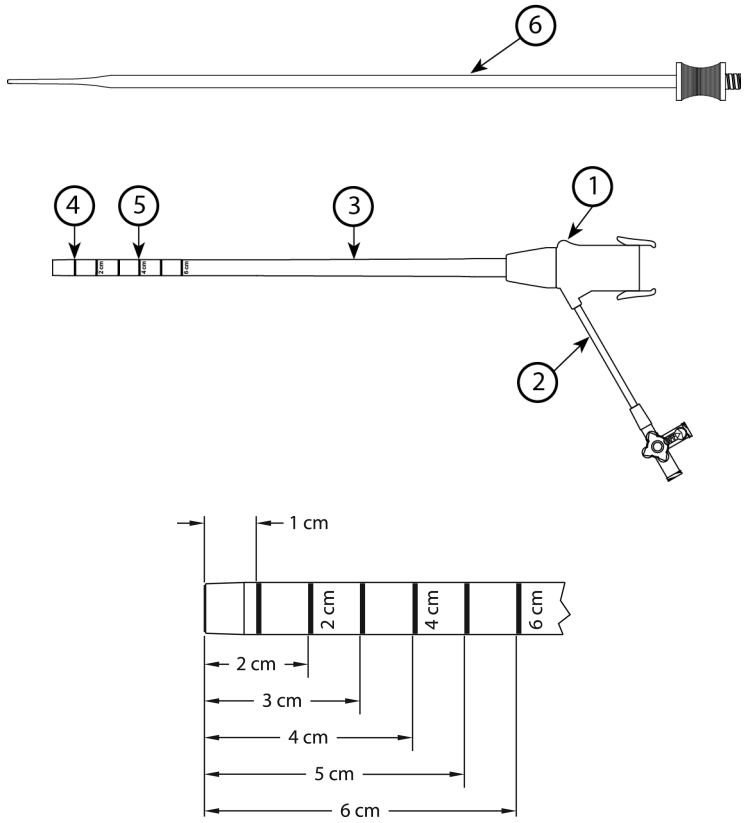
Velikost zaklopke	Višina zaklopke
20 mm	15,5 mm
23 mm	18 mm
26 mm	20 mm
29 mm	22,5 mm

Figure 1: Edwards SAPIEN 3 Transcatheter Heart Valve
■ Slika 1: Transkatetrska srčna zaklopka Edwards SAPIEN 3



1. Tapered Tip ■ Zašiljena konica
2. Center Marker ■ Sredinski označevalec
3. Volume Indicator ■ Indikator volumna
4. Handle ■ Ročaj
5. Guidewire Lumen ■ Svetlina vodilne žice
6. Stylet ■ Mandren
7. Radiopaque Shoulders ■ Radioneprepustna ramena
8. Flex Wheel ■ Kolesce za upogibanje
9. Balloon Inflation Port ■ Vhod za napihovanje balona

Figure 2: Edwards Certitude Delivery System ■ Slika 2: Dovajalni sistem Edwards Certitude



1. Housing ■ Ohišje
2. Flush Tube with Stopcock ■ Izplakovalna cev z zapornim ventilom
3. Sheath ■ Vodilo
4. Radiopaque Marker ■ Radioneprepustni označevalec
5. Non-Radiopaque Depth Markers ■ Ne-radioneprepustni globinski označevalci
6. Introducer ■ Uvajalo

Figure 3: Edwards Certitude Introducer Sheath Set ■ Slika 3: Komplet vodila z uvajalom Edwards Certitude

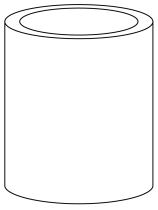


Figure 4: Qualcrimp Crimping Accessory ■ Slika 4: Naprava za stiskanje Qualcrimp

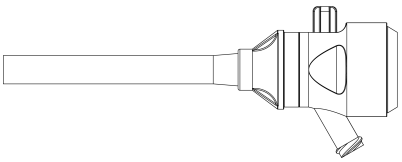


Figure 5: Loader ■ Slika 5: Nalagalnik

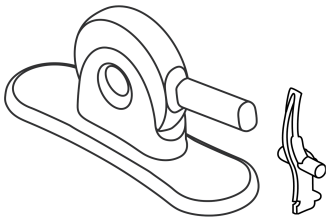


Figure 6: Edwards Crimper and 2-piece Crimp Stopper ■ Slika 6: Naprava za stiskanje Edwards in 2-delno ustavljalo stiskanja

Symbol Legend ■ Legenda simbolov

	English	Slovenščina
REF	Reorder Number	Številka za ponovno naročanje
#	Model Number	Številka modela
cm	Usable length	Uporabna dolžina
	Do not re-use	Ne uporabite znova
LOT	Lot Number	Številka serije
	Caution	Svarilo
	Consult instructions for use	Sledite navodilom za uporabo
eifu.edwards.com +1 888 570 4016	Consult instructions for use on the website	Sledite navodilom za uporabo na spletnem mestu
	Do not use if package is damaged and consult instructions for use	Ne uporabljajte, če je embalaža poškodovana, in preberite navodila za uporabo
	Exterior diameter	Zunanji premer
	Inner diameter	Notranji premer
	Store in a cool, dry place	Shranjujte na hladnem in suhem mestu.
	Keep dry	Ohranite suho
	Keep away from sunlight	Ne izpostavljajte sončnemu sevanju
UDI	Unique Device Identifier	Edinstveni identifikator pripomočka
	Temperature limit	Mejna temperatura
STERILE	Sterile	Sterilno
STERILE EO	Sterilized using ethylene oxide	Sterilizirano z etilen oksidom
STERILE R	Sterilized using irradiation	Sterilizirano z obsevanjem

	English	Slovenščina
STERILIZE	Do not resterilize	Ne sterilizirajte znova
eSheath	eSheath compatibility	Združljivost eSheath
eSheath™	eSheath compatibility	Združljivost eSheath
	Single sterile barrier system	Sistem z enojno sterilno pregrado
	Single sterile barrier system with protective packaging inside	Sistem enojne sterilne pregrade z notranjo zaščitno embalažo
QTY	Quantity	Količina
	Use-by date	Rok trajanja
SN	Serial Number	Serijska številka
	Manufacturer	Proizvajalec
	Date of manufacture	Datum proizvodnje
EC REP	Authorized representative in the European Community/ European Union	Pooblaščeni zastopnik v Evropski skupnosti/ Evropski uniji
GWC	Guidewire compatibility	Združljivost vodilne žice
NP	Nominal Pressure	Nazivni tlak
RBP	Rated burst pressure	Nazivni razpočni tlak
	Recommended guidewire length	Priporočena dolžina vodilne žice
Sheath	Minimum sheath size	Minimalna velikost vodila
Catheter	Catheter shaft size	Velikost ovojnice katetra
	Importer	Uvoznik

	English	Slovenščina
	Balloon diameter	Premer balona
	Balloon working length	Delovna dolžina balona
20 mm	For use with size 20 mm Edwards transcatheter heart valve	Za uporabo s transkatetrsko srčno zaklopko Edwards velikosti 20 mm
23 mm	For use with size 23 mm Edwards transcatheter heart valve	Za uporabo s transkatetrsko srčno zaklopko Edwards velikosti 23 mm
26 mm	For use with size 26 mm Edwards transcatheter heart valve	Za uporabo s transkatetrsko srčno zaklopko Edwards velikosti 26 mm
29 mm	For use with size 29 mm Edwards transcatheter heart valve	Za uporabo s transkatetrsko srčno zaklopko Edwards velikosti 29 mm
MR	MR Conditional	Pogojno uporabno v MR okolju
	Contents	Vsebine
	Non-pyrogenic	Apirogeno
MD	Medical device	Medicinski pripomoček
BIO	Contains biological material of animal origin	Vsebuje biološki material živalskega izvora
Rx only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Time & Temperature Sensitive	Občutljivo na čas in temperaturo
	Contains hazardous substances	Vsebuje nevarne snovi
SZ	Size	Velikost

Note: Not all symbols may be included in the labeling of this product. ■ **Opomba:** Pri označevanju tega izdelka morda niso vključeni vsi simboli.

EC REP

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