Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra, and Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

Edwards Commander Delivery System
Sistem transkatetrskih srčnih zaklopk Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA

Transkatetrske srčne zaklopke Edwards SAPIEN 3, Edwards SAPIEN 3 Ultra in Edwards SAPIEN 3 Ultra RESILIA

Dovajalni sistem Edwards Commander

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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 balloon aortic valvuloplasty and standard catheterization. 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, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valve (THV) system consists of the Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves and delivery systems.

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

The Edwards SAPIEN 3 transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet bovine pericardial tissue valve, and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Carpentier-Edwards ThermaFix process.

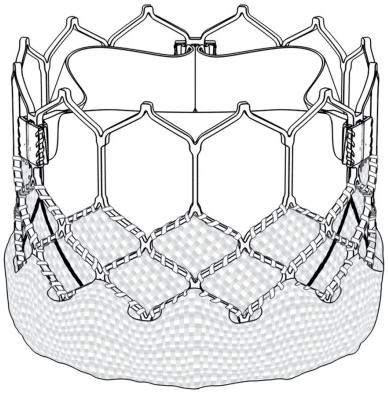
- **Edwards SAPIEN 3 Ultra Transcatheter Heart Valve - (Figure 2)**

The Edwards SAPIEN 3 Ultra transcatheter heart valve 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 SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve - (Figure 3)**

The Edwards SAPIEN 3 Ultra RESILIA transcatheter heart valve is comprised of a balloon-expandable, radiopaque, cobalt-chromium frame, trileaflet RESILIA bovine pericardial tissue valve, and polyethelyne terephthalate (PET) inner and outer fabric skirts.

RESILIA Tissue: RESILIA tissue is created with a novel technology called Edwards Integrity Preservation. The technology incorporates a stable capping anti-calcification process, which blocks residual aldehyde groups that are known to bind with calcium. The technology also incorporates tissue preservation with glycerol, which replaces the traditional storage in liquid-based solutions such as glutaraldehyde. The storage method eliminates tissue exposure to the residual unbound aldehyde groups commonly found in glutaraldehyde storage solutions.

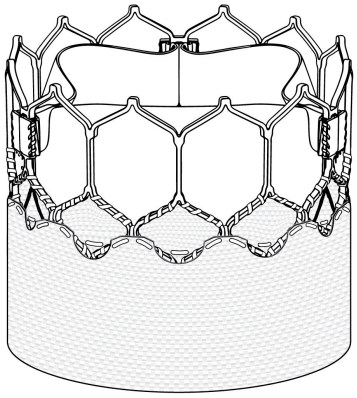


9600TFX

Table 1

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

Figure 1: Edwards SAPIEN 3 Transcatheter Heart Valve

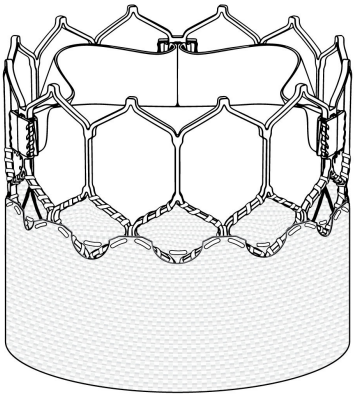


9750TFX

Table 2

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

Figure 2: Edwards SAPIEN 3 Ultra Transcatheter Heart Valve



9755RSL

Table 3

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

Figure 3: Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

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. Sizing recommendations for implanting the Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves in a native annulus are provided in the table below:

Table 4

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 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
Valve 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 valve size selection.			
Note: Risks associated with undersizing and oversizing should be considered.			

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, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves in a failing bioprosthesis, except for the INSPIRIS RESILIA aortic valve sizes 19 - 25 mm, are provided in the table below:

Table 5

Surgical Valve True Inner Diameter (ID)[1]	THV-in-THV (Native Valve Annulus Size)	THV 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.

Sizing recommendations for implanting the Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves in a failing INSPIRIS RESILIA aortic surgical bioprosthesis in sizes 19 - 25 mm, based on bench testing, are provided in the table below:

Table 6

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 5.

Note: Exact volume required to deploy the THV may vary depending on the prosthesis 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 prosthesis 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 7.

- **Edwards Commander Delivery System (Figure 4)**

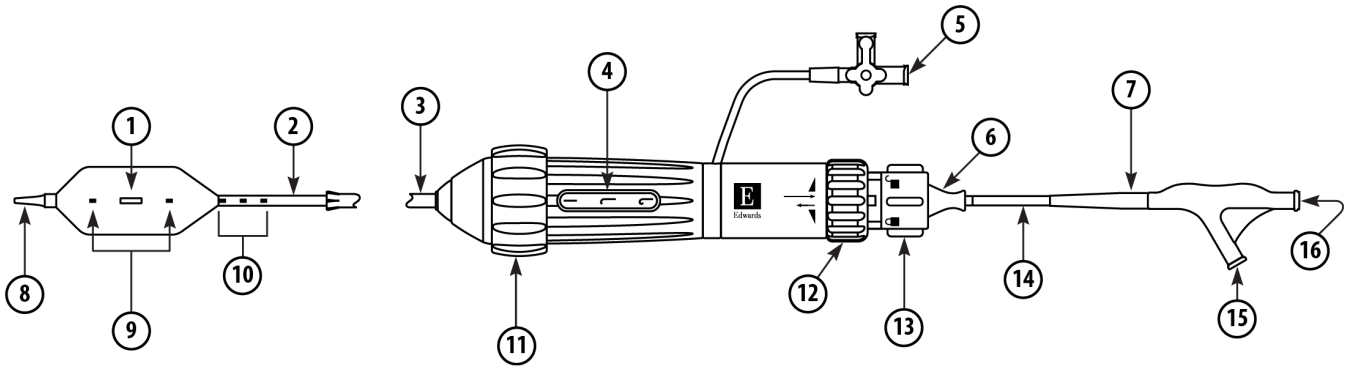
The Edwards Commander delivery system facilitates the placement of the bioprosthesis.

It consists of a flex catheter to aid in valve alignment to the balloon, tracking, and positioning of the valve. The delivery system includes a tapered tip to facilitate crossing of the valve. The handle contains a flex wheel to control flexing of the flex catheter, and a balloon lock and fine adjustment wheel to facilitate valve alignment and positioning of the valve within the target location. A stylet is included within the guidewire lumen of the delivery system. The balloon catheter has radiopaque valve alignment markers defining the working length of the balloon. A radiopaque center marker in the balloon is provided to help with valve positioning. A radiopaque triple marker proximal to the balloon indicates the flex catheter position during deployment.

The inflation parameters for valve deployment are:

Table 7

Model	Nominal Balloon Diameter	Nominal Inflation Volume	Rated Burst Pressure (RBP)
9610TF20 9750CM20	20 mm	11 ml	7 atm
9610TF23 9750CM23	23 mm	17 ml	7 atm
9610TF26 9750CM26	26 mm	23 ml	7 atm
9610TF29 9750CM29	29 mm	33 ml	7 atm



1. Center Marker
2. Valve Crimp Section
3. Flex Catheter
4. Flex Indicator
5. Flush Port
6. Strain Relief
7. Volume Indicator
8. Tapered Tip
9. Valve Alignment Markers
10. Triple Marker
11. Flex Wheel
12. Fine Adjustment Wheel
13. Balloon Lock
14. Balloon Catheter
15. Balloon Inflation Port
16. Guidewire Lumen

Figure 4: Edwards Commander Delivery System

Additional Accessories

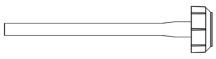


Figure 5: Loader

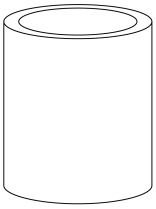


Figure 6: Qualcrimp Crimping Accessory

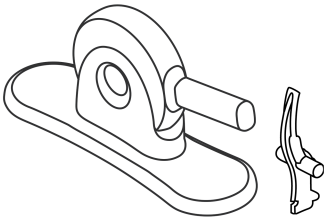


Figure 7: Edwards Crimper and Crimp Stopper

- **Loader (Figure 5)**

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

- **Edwards Sheath**

Refer to the sheath instructions for use for device description.

- **Qualcrimp Crimping Accessory (Figure 6)**

The Qualcrimp crimping accessory is used during THV crimping.

- **Edwards Crimper and Crimp Stopper (Figure 7)**

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 transfemoral, transseptal, subclavian/axillary access approaches.

3.0 Indications

1. The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valve system is indicated for use in patients with asymptomatic or symptomatic heart disease due to native calcific aortic stenosis at any or all levels of surgical risk for open heart surgery.
2. The Edwards SAPIEN 3, SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valve system is indicated for patients with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of an aortic transcatheter bioprosthetic or surgical aortic or mitral bioprosthetic 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 co-morbidities unmeasured by the STS risk calculator).

4.0 Contraindications

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

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

5.0 Warnings

- Observation of the pacing lead throughout the procedure is essential to avoid the potential risk of pacing lead perforation.
- 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.
- Incorrect sizing of the valve may lead to paravalvular leak, migration, embolization, residual gradient (patient-prosthesis mismatch) and/or annular rupture.
- Accelerated deterioration of the valve due to calcific degeneration may occur in patients with an altered calcium metabolism.
- Prior to delivery, the valve 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. Valve leaflets mishandled or damaged during any part of the procedure will require replacement of the valve.
- 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.
- Do not use the valve if the tamper evident seal is broken, the storage solution does not completely cover the valve (SAPIEN 3 and SAPIEN 3 Ultra transcatheter heart valve only), the temperature indicator has been activated, the valve is damaged, or the expiration date has elapsed, as either sterility or valve function may be compromised. Do not use the SAPIEN 3 Ultra RESILIA transcatheter heart valve if the foil pouch has been opened or damaged, as exposure to moisture can potentially impact leaflet performance.
- 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 (e.g., kinked or stretched), cannot be flushed, or the expiration date has elapsed.
- Patient injury could occur if the delivery system is not un-flexed prior to removal.
- Patients with hypersensitivities to cobalt, nickel, chromium, molybdenum, titanium, manganese, silicon, glycerol, bovine tissue, and/or polymeric materials may have an allergic reaction to these materials.
- 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 physician. This device has not been tested for use without anticoagulation.
- 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.
- The physician must verify correct orientation of the valve prior to its implantation.
- 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/SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA transcatheter heart valve) or 6.0 mm (for 29 mm SAPIEN 3 and SAPIEN 3 Ultra RESILIA transcatheter heart valve) may preclude safe placement of the sheath and should be carefully assessed prior to the procedure.

6.0 Precautions

- Long-term durability has not been established for the THV. Regular medical follow-up is advised to evaluate valve performance.
- Limited clinical data are available for transcatheter aortic valve replacement in patients with a congenital bicuspid aortic valve who are deemed to be at low surgical risk. Anatomical characteristics should be considered when using the valve in this population. In addition, patient age should be considered as long-term durability of the valve has not been established.
- 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.
- 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. As compared to SAPIEN 3, system advancement force may be higher with the use of SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA transcatheter heart valve in tortuous/challenging vessel anatomies.
- Do not overinflate the deployment balloon, as this may prevent proper valve leaflet coaptation and thus impact valve functionality.
- Appropriate antibiotic prophylaxis is recommended post-procedure in patients at risk for prosthetic valve infection and endocarditis.
- Additional precautions for transseptal replacement of a failed mitral valve bioprosthesis include, presence of devices or thrombus or other abnormalities in the caval vein precluding safe transvenous femoral access for transseptal approach; presence of Atrial Septal Occluder Device or calcium preventing safe transseptal access.
- 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.
- Safety and effectiveness of the THV implantation have not been established for patients who have:
  - Non-calcified aortic annulus
  - Severe ventricular dysfunction with ejection fraction < 20%
  - Congenital unicuspid aortic valve
  - Pre-existing prosthetic ring in any position
  - Severe mitral annular calcification (MAC), severe (> 3+) mitral insufficiency, or Gorlin syndrome
  - Blood dyscrasias defined as: leukopenia (WBC < 3000 cells/µL), acute anemia (Hb < 9 g/dL), thrombocytopenia (platelet count < 50,000 cells/µL), or history of bleeding diathesis or coagulopathy
  - Hypertrophic cardiomyopathy with or without obstruction (HOCM)
  - Aortic stenosis characterized by a combination of AV low flow, low gradient
  - Echocardiographic evidence of intracardiac mass, thrombus, or vegetation
  - A known hypersensitivity or contraindication to aspirin, heparin, ticlopidine (Ticlid™), or clopidogrel (Plavix™), or sensitivity to contrast media, which cannot be adequately premedicated

- Significant aortic disease, including abdominal aortic or thoracic aneurysm defined as maximal luminal diameter 5 cm or greater; marked tortuosity (hyperacute bend), aortic arch atheroma (especially if thick [> 5 mm], protruding, or ulcerated) or narrowing (especially with calcification and surface irregularities) of the abdominal or thoracic aorta, severe "unfolding" and tortuosity of the thoracic aorta
- Bulky calcified aortic valve leaflets in close proximity to coronary ostia
- 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

- The risks of subclavian/axillary access are low and acceptable, but subclavian/axillary access should be considered when the physician determines there is an increased risk associated with transfemoral access.
- For Left axillary approach, a left subclavian takeoff angle ~ ≥ 90° from the aortic arch causes sharp angles, which may be responsible for potential sheath kinking, subclavian/axillary dissection and aortic arch damage.
- For left/right axillary approach, ensure there is flow in the Left Internal Mammary Artery (LIMA)/Right Internal Mammary Artery (RIMA) during procedure and monitor pressure in homolateral radial artery.
- Residual mean gradient may be higher in a "THV-in-failing prosthesis" 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 bioprosthesis 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.
- Post-procedure and follow-up assessment of TAVR device performance by Doppler echocardiography may be impacted by inherent limitations in the Bernoulli equation used to determine measurements such as mean gradient, EOA, and prosthesis-patient mismatch. These limitations may lead to an overstating or understating of valve performance measurements after TAVR implantation. Therefore, a post-TAVR echocardiogram should be used to establish a baseline from which future follow-up visits are compared to. Confirmatory direct pressure measurement via cardiac catheterization may be considered, when indicated, prior to reintervention.

7.0 Potential Adverse Events

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

- Death
- Stroke/transient ischemic attack, clusters or neurological deficit
- Paralysis
- Permanent disability
- Respiratory insufficiency or respiratory failure
- Hemorrhage requiring transfusion or intervention
- 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, or 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
- Vessel spasm
- 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
- 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 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 8

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Transcatheter Heart Valve	9600TFX (20 mm)	9600TFX (23 mm)	9600TFX (26 mm)	9600TFX (29 mm)
Edwards Commander Delivery System	9610TF20	9610TF23	9610TF26	9610TF29
Edwards eSheath Introducer Set or Edwards eSheath+ Introducer Set	9610ES14 or 914ESP			9610ES16 or 916ESP
Inflation Device	96402			96406
Edwards Crimper	9600CR			
Qualcrimp crimping accessory, crimp stopper and loader provided by Edwards Lifesciences				

Table 9

Product Name	20 mm System	23 mm System	26 mm System
	Model		
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX (20 mm)	9750TFX (23 mm)	9750TFX (26 mm)
Edwards Commander Delivery System	9610TF20 or 9750CM20	9610TF23 or 9750CM23	9610TF26 or 9750CM26
Edwards eSheath Introducer Set or Edwards eSheath+ Introducer Set	9610ES14 or 914ESP		
Inflation Device	96402		
Edwards Crimper	9600CR		
Qualcrimp crimping accessory, crimp stopper and loader provided by Edwards Lifesciences			

Table 10

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	9755RSL20 (20 mm)	9755RSL23 (23 mm)	9755RSL26 (26 mm)	9755RSL29 (29 mm)
Edwards Commander Delivery System	9750CM20	9750CM23	9750CM26	9750CM29

Product Name	20 mm System	23 mm System	26 mm System	29 mm System
	Model			
Edwards eSheath+ Introducer Set	914ESP			916ESP
Inflation Device	96402			96406
Edwards Crimper	9600CR			
Qualcrimp crimping accessory, crimp stopper and loader 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 (x2)
- 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
- Exchange length 0.035 in (0.89 mm) extra-stiff guidewire
- Temporary pacemaker (PM) and pacing lead
- Instrumentation for transseptal access and septostomy, as applicable
- Sterile rinsing basins, physiological saline, heparinized saline, 15% diluted radiopaque contrast medium
- Sterile table for valve and accessories preparation

8.2 Valve Handling and Preparation

Maintain sterile technique during device preparation and implantation.

8.2.1 SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

The SAPIEN 3 Ultra RESILIA transcatheter heart valve is provided sterile and nonpyrogenic. The packaging consists of a carton containing a foil pouch. Within the foil pouch is a tray that is sealed with a Tyvek lid. Inside of the tray is the valve holder which contains the valve.

1. Remove the tamper evident label to open the carton.
2. Remove the foil pouch from the carton in the non-sterile field. Before opening, examine the package for evidence of damage and broken or missing seals. Open pouch and remove tray in the non-sterile field.

   WARNING: Do not open foil pouch into sterile field, as sterility may be compromised. The foil pouch is a protective cover only. Only the valve holder may be introduced into the sterile field.

   Note: If the foil pouch is opened during the procedure and the valve is not used, discard the valve.
3. The tray is labeled with the model, size, and serial number. The model, size, and serial number should be confirmed with the number on the valve package and valve implant data card.
4. Near the sterile field, hold the base of the tray and peel the lid from the tray.
5. The valve holder and contents are sterile. Transfer the valve holder to the sterile field.

   CAUTION: The contents of the valve holder must be handled using a sterile technique. Take care when removing the valve holder from the tray to ensure there is no contact with the nonsterile adhesive on the lip of the tray.

8.2.2 Valve Soaking/Rinsing Procedure

8.2.2.1 SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

1. Setup one (1) sterile bowl with at least 500 ml of sterile physiological saline to soak the valve.
2. Open the valve holder by holding the base and lifting the lid. Carefully remove the valve from the valve holder without touching the tissue. Inspect the valve for any signs of damage to the frame or tissue.
3. Place the valve in the sterile bowl of sterile physiological saline. Be sure that the sterile physiological saline completely covers the valve for at least two minutes to hydrate the leaflets. The valve should be left in the sterile physiological saline to prevent the tissue from drying.

   CAUTION: No other objects should be placed in the soak bowl. The valve should be kept hydrated to prevent the tissue from drying.

8.2.2.2 SAPIEN 3 and SAPIEN 3 Ultra Transcatheter Heart Valve

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: Valves from containers found to be damaged, leaking, without adequate sterilant, or missing intact seals 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 glutaraldehyde sterilant from the valve.
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.

8.2.3 Prepare the System

1. Visually inspect all 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. Carefully 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 and insert the stylet back into the distal end of the guidewire lumen.

   Note: Failure to insert the stylet back into the guidewire lumen may result in damage to the lumen during the valve 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. Unscrew the loader cap from the loader tube and flush the loader cap with heparinized saline. Place the loader cap over the proximal balloon cover and onto the flex catheter with the inside of the cap oriented towards the distal tip.
6. Fully advance the balloon catheter in the flex catheter.
   Peel off the proximal balloon cover over the blue section of the balloon shaft.
7. Attach a 3-way stopcock to the balloon inflation port. Partially fill a 50 cc or larger syringe with 15 - 20 ml diluted contrast medium and attach to the 3-way stopcock.
8. Fill the inflation device provided by Edwards Lifesciences with excess volume of diluted contrast medium relative to the indicated inflation volume. Lock the inflation device and attach to the 3-way stopcock.
9. Close the 3-way stopcock to the inflation device provided by Edwards Lifesciences. Pull vacuum using the 50 cc or larger syringe to de-air the system. 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.
10. Close the stopcock to the delivery system. By rotating the knob of the inflation device provided by Edwards Lifesciences, transfer the contrast medium into the syringe to achieve the appropriate volume required to deploy the valve.
11. Close the stopcock to the 50 cc or larger syringe. Remove the syringe. Verify that the inflation volume is correct and lock the inflation device provided by Edwards Lifesciences.

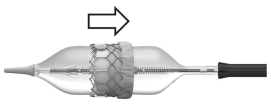
    CAUTION: Maintain the inflation device provided by Edwards Lifesciences in the locked position until THV deployment to minimize the risk or premature balloon inflation and subsequent improper THV deployment.

8.2.4 Mount and Crimp the Valve on the Delivery System

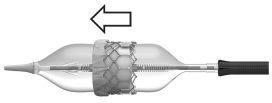
1. Set up two (2) additional sterile bowls with at least 100 ml of sterile physiological saline to thoroughly rinse the Qualcrimp crimping accessory.
2. Completely submerge the Qualcrimp crimping accessory in the first bowl and gently compress it to ensure complete saline absorption. Slowly swirl the Qualcrimp crimping accessory for a minimum of 1 minute. Repeat this process in the second bowl.
3. Remove the valve from the soaking/rinsing bowl. When using the SAPIEN 3 or SAPIEN 3 Ultra valve remove the valve from the holder and remove the ID tag.
4. 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.
5. With the crimper in the open position, gently place the valve into the crimper aperture. Gradually crimp the valve until it fits into the Qualcrimp crimping accessory.

   Note: This step is not necessary for the 20 mm valve.
6. Place the Qualcrimp crimping accessory over the THV making sure the THV is parallel to the edge of the Qualcrimp crimping accessory.
7. Place the valve and Qualcrimp crimping accessory in crimper aperture. Insert the delivery system coaxially within the valve on the Valve Crimp Section (2-3 mm distal to the balloon shaft) with the orientation of the valve on the delivery system 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.



8. Center the balloon shaft coaxially within the THV. Crimp the THV until it reaches the Qualcrimp crimping accessory stop located on the 2-piece crimp stopper.
9. Gently remove the Qualcrimp crimping accessory from the THV. Remove the Qualcrimp crimping accessory stop from the crimp stopper, leaving the final stop in place.
10. Center the THV within the crimper aperture. Fully crimp the THV until it reaches the final stop and hold for 5 seconds.

    Note: Ensure that the Valve Crimp Section remains coaxial within the THV. Ensure that the THV is fully within the crimper jaws during crimping.
11. Repeat the full crimp of the THV two more times for a total of three full crimps for 5 seconds each.
12. Pull the balloon shaft and lock in the default position.
13. Flush the loader with heparinized saline. Immediately advance the THV into the loader until it is completely inside the loader.

    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.
14. Attach the loader cap to the loader, re-flush the delivery system through the flush port and close the stopcock to the delivery system.
    Remove the stylet and flush the guidewire lumen of the delivery system.

    CAUTION: Keep 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.

8.3 Native Valve Predilation and Valve Delivery

Native valve predilation and valve delivery should be performed under conscious sedation 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 during the procedure.

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.

CAUTION: Use of excessive contrast media may lead to renal failure. Measure the patient's creatinine level prior to the procedure. Contrast media usage should be monitored.

CAUTION: Procedure may require an arterial cut-down with surgical closure of the puncture site due to the size of the arteriotomy.

8.3.1 Baseline Parameters

1. Perform an angiogram with fluoroscopic view perpendicular to the valve.
2. Evaluate the distance of the left and right coronary ostia from the aortic annulus in relation to the valve 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 Native Valve Predilation

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.

8.3.3 Valve Delivery

1. Gain access using standard catheterization techniques.
2. Prepare and insert the Edwards sheath per its instructions for use.
3. Insert the loader into the sheath until the loader stops.
4. Advance the delivery system, with the Edwards logo in the proper orientation (the delivery system articulates in a direction opposite from the flush port), through the sheath until the valve exits the sheath.

   Note: Maintain the proper orientation of the flex catheter throughout the procedure. The delivery system articulates in a direction opposite from the flush port.

   CAUTION: For iliofemoral access, the valve should not be advanced through the sheath if the sheath tip is not past the bifurcation to minimize the risk of vessel damage.

   CAUTION: To prevent possible leaflet damage and possible impact to valve functionality, the valve should not remain in the sheath for over 5 minutes.
5. 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.

   Engage the balloon lock.

   Use the fine adjustment wheel to position the valve between the valve alignment markers.

   CAUTION: Do not turn the fine adjustment wheel if the balloon lock is not engaged.

   WARNING: Do not position the THV past the distal valve alignment marker to minimize the risk of improper valve deployment or THV embolization.

   CAUTION: Maintain guidewire position during valve alignment to prevent loss of guidewire position.

   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 vasculature and relieving compression (or tension) in the system will be necessary.
6. Advance the catheter and use the flex wheel, if needed, to cross the valve.

   Note: Verify the orientation of the Edwards logo to ensure proper articulation. The delivery system articulates in a direction opposite from the flush port.
7. Disengage the balloon lock and retract the tip of the flex catheter to the center of the triple marker. Engage the Balloon Lock.
8. Verify the correct position of the THV with respect to the target location.
9. 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.
10. Before deployment, ensure that the THV is correctly positioned between the valve alignment markers and the flex catheter tip is over the triple marker.
11. Begin THV deployment:
    - Unlock the inflation device provided by Edwards Lifesciences.
    - Begin rapid pacing; once systolic blood pressure has decreased to 50 mmHg or below, balloon inflation can commence.
    - Using slow controlled inflation, deploy the THV by inflating the balloon with the entire volume in the inflation device provided by Edwards Lifesciences, hold for 3 seconds and confirm that the barrel of the inflation device is empty to ensure complete inflation of the balloon.
    - Deflate the balloon. When the balloon catheter has been completely deflated, turn off the pacemaker.

8.3.4 System Removal

1. Unflex the delivery system while retracting the device, if needed. Verify that the flex catheter tip is locked over the triple marker. Retract the loader to the proximal end of the delivery system and remove the delivery system from the sheath.

   Note: For subclavian-axillary approach, keep delivery system inside sheath until ready to remove all devices as one unit.

   CAUTION: Patient injury could occur if the delivery system is not unflexed prior to removal.
2. Remove all devices when the ACT level is appropriate. Refer to the Edwards sheath instructions for use for device removal.
3. Close the access site.

9.0 How Supplied

STERILE: The SAPIEN 3 and SAPIEN 3 Ultra valves are supplied sterilized with glutaraldehyde solution. The SAPIEN 3 Ultra RESILIA valve, delivery system, and accessories are supplied sterilized with ethylene oxide gas.

The valves are supplied nonpyrogenic in packaging to which a tamper evident seal has been applied.

9.1 Storage

The valve must be stored at 10 °C to 25 °C (50 °F to 77 °F). Each valve is shipped in an enclosure containing a temperature indicator to detect exposure of the valve to extreme temperature.

The delivery system should be stored in a cool, dry place.

10.0 MR Safety

MR Conditional

Non-clinical testing has demonstrated that the Edwards SAPIEN 3, and SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves are 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 T or 3.0 T
- Maximum spatial gradient field of 3000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the SAPIEN 3, and SAPIEN 3 Ultra, and SAPIEN 3 Ultra RESILIA transcatheter heart valves are expected to produce a maximum temperature rise of 1.9 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends as far as 9.0 mm from the implant for spin echo images and 23 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 valve

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 tables show the qualitative and quantitative information on the materials and substances:

Table 11: SAPIEN 3 Transcatheter Heart Valve

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
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

Substance	CAS	Model Mass Range (mg)
4-Dodecylbenzenesulfonic acid	121-65-3	0.000286 - 0.000430

Table 12: SAPIEN 3 Ultra Transcatheter Heart Valve

Substance	CAS	Model Mass Range (mg)
Cobalt	7440-48-4	131 - 314
Nickel	7440-02-0	148 - 298
Polyethylene terephthalate	25038-59-9	142 - 212
Chromium	7440-47-3	85.2 - 169
Collagens, bovine, polymers with glutaraldehyde	2370819-60-4	58.3 - 97.5
Molybdenum	7439-98-7	40.3 - 84.6
Polyethylene	9002-88-4	19.4 - 22.0
Polytetrafluoroethylene	9002-84-0	12.3 - 15.1
Iron	7439-89-6	0 - 8.06
Titanium	7440-32-6	0 - 8.06
Manganese	7439-96-5	0 - 1.21
Silicon	7440-21-3	0 - 1.21
Titanium dioxide	13463-67-7	0.307 - 1.03
Polybutilate	24936-97-8	0.273 - 0.340
Antimony trioxide	1309-64-4	0.161 - 0.243
Carbon	7440-44-0	0 - 0.201
Boron	7440-42-8	0 - 0.121
Phosphorus	7723-14-0	0 - 0.121
Sulfur	7704-34-9	0 - 0.0806
D&C Green No. 6	128-80-3	0.0394 - 0.0513
Silicon dioxide	7631-86-9	0.00422 - 0.00525
Erucamide	112-84-5	0.00110 - 0.00178
4-Dodecylbenzenesulfonic acid	121-65-3	0.000330 - 0.000453

Table 13: SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve

Substance	CAS	Model Mass Range (mg)
Glycerol	56-81-5	0 - 487
Cobalt	7440-48-4	131 - 427
Nickel	7440-02-0	148 - 405
Polyethylene terephthalate	25038-59-9	142 - 284
Chromium	7440-47-3	85.2 - 230
Collagens, bovine, polymers with glutaraldehyde	2370819-60-4	61.7 - 157
Molybdenum	7439-98-7	40.3 - 115
Polyethylene	9002-88-4	26.7 - 38.6
Polytetrafluoroethylene	9002-84-0	13.6 - 19.6
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	0.365 - 1.41
Polybutilate	24936-97-8	0.273 - 0.383
Antimony trioxide	1309-64-4	0.161 - 0.328
Carbon	7440-44-0	0 - 0.274
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

Substance	CAS	Model Mass Range (mg)
Silicon dioxide	7631-86-9	0.00422 - 0.00592
Erucamide	112-84-5	0.00110 - 0.00246
4-Dodecylbenzenesulfonic acid	121-65-3	0.000330 - 0.000587

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/SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA platform.

Conformity with the entire SAPIEN 3/SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA 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 valves, delivery system and sheath can be used to locate the SSCP.

The following tables contain the Basic UDI-DIs:

Table 14: Edwards SAPIEN 3 Transcatheter Heart Valve System

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 Commander Delivery System	9610TF20	9610TF23	9610TF26	9610TF29	0690103D003COM000TC
Edwards eSheath Introducer Set or Edwards eSheath+ Introducer Set	9610ES14 or 914ESP			9610ES16 or 916ESP	0690103D003S3E000NT
Inflation Device	96402			96406	0690103D003IND000TG
Edwards Crimper	9600CR				0690103D003CRI000TH

Table 15: Edwards SAPIEN 3 Ultra Transcatheter Heart Valve System

Product	Model			Basic UDI-DI
	20 mm System	23 mm System	26 mm System	
Edwards SAPIEN 3 Ultra Transcatheter Heart Valve	9750TFX (20 mm)	9750TFX (23 mm)	9750TFX (26 mm)	0690103D003SAP000VP
Edwards Commander Delivery System	9610TF20 or 9750CM20	9610TF23 or 9750CM23	9610TF26 or 9750CM26	0690103D003COM000TC
Edwards eSheath Introducer Set or Edwards eSheath+ Introducer Set	9610ES14 or 914ESP			0690103D003S3E000NT
Inflation Device	96402			0690103D003IND000TG
Edwards Crimper	9600CR			0690103D003CRI000TH

Table 16: Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve System

Product	Model				Basic UDI-DI
	20 mm System	23 mm System	26 mm System	29 mm System	
Edwards SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve	9755RSL (20 mm)	9755RSL (23 mm)	9755RSL (26 mm)	9755RSL (29 mm)	0690103D003SAP000VP
Edwards Commander Delivery System	9750CM20	9750CM23	9750CM26	9750CM29	0690103D003COM000TC
Edwards eSheath+ Introducer Set	914ESP			916ESP	0690103D003S3E000NT
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 balonski aortni valvuloplastiki in 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 transkatetrskih srčnih zaklopk Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA

Sisteme transkatetrskih srčnih zaklopk Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA sestavljajo transkatetrske srčne zaklopke Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA in dovajalni sistemi.

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

Transkatetrska srčna zaklopka 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 krilca iz polietilen tereftalata (PET). Lističi so obdelani s postopkom Carpentier-Edwards ThermaFix.

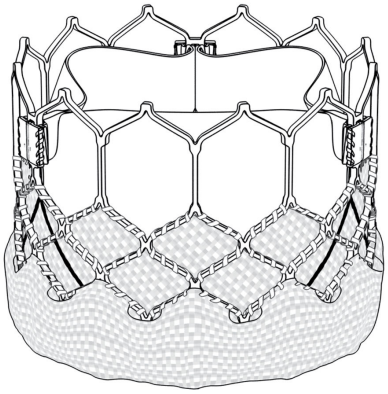
- **Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra (slika 2)**

Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra 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.

- **Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra RESILIA - (slika 3)**

Transkatetrska srčna zaklopka (THV) Edwards SAPIEN 3 Ultra RESILIA je sestavljena iz radioneprepustne trikuspidalne zaklopke RESILIA 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).

Tkivo RESILIA: tkivo RESILIA je ustvarjeno z novo tehnologijo, ki se imenuje Edwards Integrity Preservation. Tehnologija vključuje postopek stabilne zaščite proti kalcifikaciji, ki blokira preostale aldehidne skupine, za katere je znano, da se vežejo s kalcijem. Tehnologija vključuje tudi ohranjanje tkiva z glicerolom, ki zamenjuje tradicionalno shranjevanje v raztopini na podlagi tekočine, kot je glutaraldehid. Metoda shranjevanja odpravlja izpostavljenost tkiva preostalim nevezanim aldehidnim skupinam, ki so običajno v raztopinah za hrambo glutaraldehida.

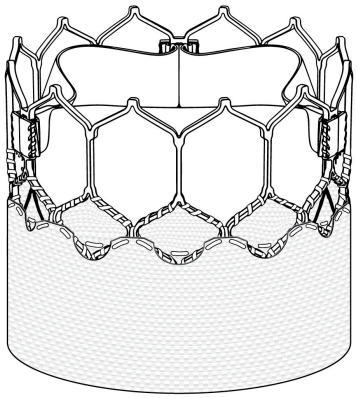


9600TFX

Preglednica 1

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

Slika 1: Transkatetrska srčna zaklopka Edwards SAPIEN 3

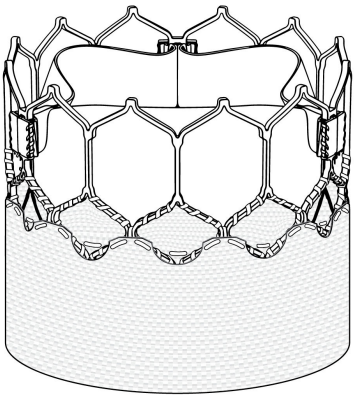


9750TFX

Preglednica 2

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

Slika 2: Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra



9755RSL

Preglednica 3

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

Slika 3: Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra RESILIA

THV je namenjen za vsaditev v nativni obroček z velikostjo, povezano s tridimenzionalnim območjem aortnega obročka, merjeno na bazalnem obročku med sistolo. Priporočila glede velikosti za vsaditev transkatetrskih srčnih zaklop Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA nativni obroček so navedena v spodnji preglednici:

Preglednica 4

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 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 zaklopke temeljijo na naravni velikosti obročka zaklopke, izmerjeni s transezofagealno ehokardiografijo (TEE) ali z računalniško tomografijo (CT). Pri izbiri velikosti zaklopke je treba upoštevati anatomske dejavnike bolnika in več načinov slikanja. **Opomba: Upoštevati je treba tveganja, povezana s premalo in preveliko velikostjo.**			

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 transkatetrskih srčnih zaklop Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA v odpovedujoči biološki protezi, razen za velikosti aortnih zaklopk INSPIRIS RESILIA 19 - 25 mm, so navedena v spodnji preglednici:

Preglednica 5

Dejanski notranji premer kirurške zaklopke (ID)[1]	THV v THV (Velikost nativnega obročka zaklopke)	Velikost THV
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

Opomba: 'True ID' kirurške zaklopke je lahko manjši od velikosti označene zaklopke. Za THV v THV je treba upoštevati velikost nativnega obročka zaklopke, da se določi ustrezna velikost THV za vsaditev. 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 transkatetrskih srčnih zaklop Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA v odpovedujoči aortni kirurški biološki protezi INSPIRIS RESILIA velikosti 19 - 25 mm na podlagi testnega okolja, so navedena v spodnji preglednici:

Preglednica 6

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 vključujejo tehnologijo VFit, ki jo sestavljajo razširljivi trakovi in fluoroskopsko vidni označevalniki velikosti, zasnovani za potencialne 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.

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 kirurške zaklopke, navedene v preg. 5.

Opomba: Natančna količina, zahtevana za vstavljanje THV, se lahko razlikuje glede na notranji premer proteze. Dejavniki, kot sta kalcifikacija in rast tkiva panus, morda niso natančno prikazani na slikah in lahko zmanjšajo efektivni notranji premer odpovedujoče 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 preg. 7.

- **Dovajalni sistem Edwards Commander (slika 4)**

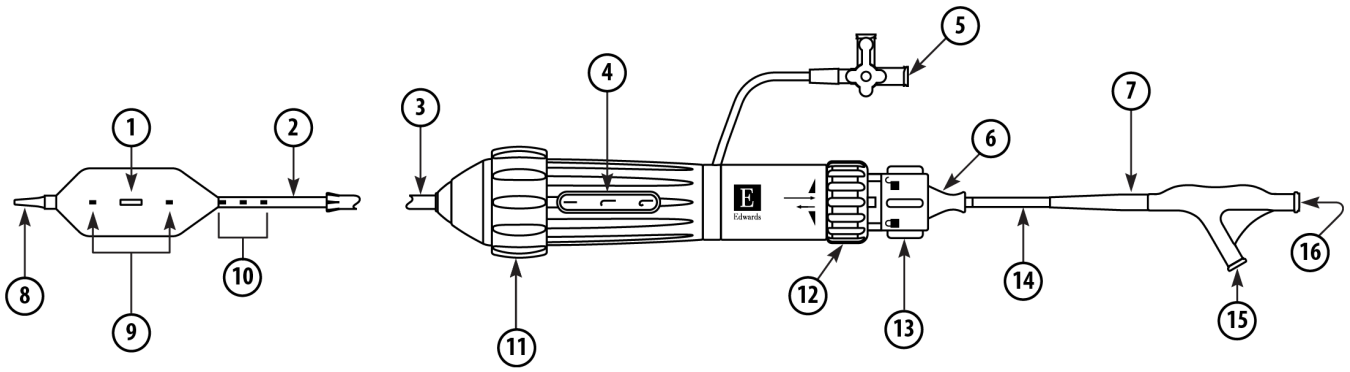
Dovajalni sistem Edwards Commander olajša nameščanje biološke proteze.

Sestavlja ga upogljivi kateter, namenjen za pomoč pri poravnavi zaklopke z balonom, sledenje in nastavljanje položaja zaklopke. Dovajalni sistem vključuje zašiljeno konico za olajšanje prečkanja zaklopke. Ročaj vsebuje kolesce za upogibanje, s katerim se nadzoruje upogibanje upogljivega katetra, zaklepni mehanizem balona in kolesce za fino prilagajanje, ki olajša poravnavo zaklopke in nastavljanje položaja zaklopke na ciljnem mestu. V svetlino vodilne žice na dovajalnem sistemu je vstavljen mandren. Balonski kateter ima radioneprepustne oznake za poravnavo zaklopke, ki določajo delovno dolžino balona. Radioneprepustni sredinski označevalec na balonu je namenjen kot pomoč pri nastavljanju položaja zaklopke. Radioneprepustni trojni označevalec proksimalno od balona kaže položaj upogljivega katetra med dovajanjem.

Parametri za napihovanje za uvajanje zaklopke so:

Preglednica 7

Model	Nazivni premer balona	Nazivni volumen napihovanja	Nazivni razpočni tlak (RBP)
9610TF20 9750CM20	20 mm	11 ml	7 atm
9610TF23 9750CM23	23 mm	17 ml	7 atm
9610TF26 9750CM26	26 mm	23 ml	7 atm
9610TF29 9750CM29	29 mm	33 ml	7 atm

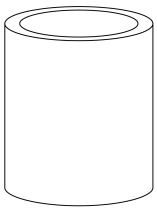


1. Sredinski označevalec
2. Območje stiskanja zaklopke
3. Upogljivi kateter.
4. Indikator upogibanja
5. Vhod za splakovanje
6. Razbremenilnik napetosti
7. Indikator volumna
8. Zašiljena konica
9. Označevalci za poravnavo zaklopke
10. Trojni označevalec
11. Kolesce za upogibanje
12. Kolesce za fino prilagajanje
13. Zaklepni mehanizem balona
14. Balonski kateter
15. Vhod za napihovanje balona
16. Svetlina vodilne žice

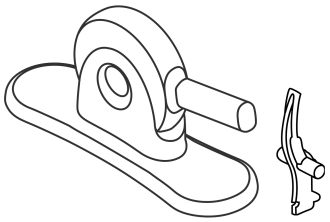
Slika 4: Dovajalni sistem Edwards Commander

Dodatni pripomočki

Slika 5: Nalagalnik



Slika 6: Naprava za stiskanje Qualcrimp



Slika 7: Naprava za stiskanje Edwards in ustavljalo stiskanja

- **Nalagalnik (slika 5)**

Nalagalnik se uporablja kot pomoč pri vstavljanju dovajalnega sistema v vodilo.

- **Vodilo Edwards**

Za opis pripomočka glejte navodila za uporabo vodila.

- **Pripomoček za stiskanje Qualcrimp (slika 6)**

Pripomoček za stiskanje Qualcrimp se uporablja med stiskanjem THV.

- **Naprava za stiskanje Edwards in ustavljalo stiskanja (slika 7)**

Naprava za stiskanje Edwards manjša 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. Uvajalni sistem in dodatki so namenjeni za olajšanje namestitve biološke proteze prek dostopa s transfemoralnim, transseptalnim ali subklavikularnim/aksilarnim pristopom.

3.0 Indikacije

1. Sistemi transkatetrske srčne zaklopke Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA so indicirani za uporabo pri bolnikih z asimptomatsko ali simptomatsko srčno boleznijo zaradi nativne kalcificirane aortne stenoze na kateri koli stopnji ali vseh stopnjah kirurškega tveganja za kirurški poseg na odprtem srcu.
2. Sistemi transkatetrske srčne zaklopke Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA so indicirani za bolnike s simptomatsko srčno boleznijo zaradi popuščanja (stenoza, nezadostnost ali kombinacija stanj) aortne transkatetrske biološke protetične, kirurške aortne ali biološke protetične zaklopke, za katere kardiološka ekipa, vključno s srčnim kirurgom, presodi, da so izpostavljeni visokemu ali večjemu tveganju za odprt kirurški poseg (tj. napovedano tveganje kirurške umrljivosti ≥ 8 % po 30 dneh na podlagi ocene tveganja po Družbi torakalnih kirurgov (Society of Thoracic Surgeons ali STS) in drugih kliničnih sočasnih boleznih, ki jih kalkulator tveganja STS ne meri).

4.0 Kontraindikacije

Uporaba sistema transkatetrskih srčnih zaklopk Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA je kontraindicirana pri bolnikih, ki:

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

5.0 Opozorila

- Opazovanje spodbujevalne elektrode med posegom je ključnega pomena, da preprečite morebitno tveganje perforacije s spodbujevalno elektrodo.
- 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.
- Izbira nepravilne zaklopke lahko povzroči paravalvularno puščanje, migracijo, embolizacijo, preostali gradient (neujemanje proteze bolnika) in/ali rupturo obročka.
- Pri bolnikih s spremenjeno presnovo kalcija lahko pride do pospešenega poslabšanja zaklopke zaradi degeneracije s kalcifikacijo.
- Zaklopka mora pred dovajanjem vedno ostati hidrirana in ne sme biti izpostavljena raztopinam, antibiotikom, kemikalijam itd., razen raztopine za shranjevanje med dobavo in sterilne fiziološke raztopine, da se prepreči poškodbe lističev, kar lahko vpliva na delovanje zaklopke. Če pride do poškodb lističev zaklopke ali nepravilnega ravnanja z njimi kadar koli med posegom, je treba zaklopko zamenjati.
- Pri vsaditvi zaklopke pri bolnikih s klinično pomembno koronarno boleznijo je treba biti previden.
- Bolnike z biološkimi protezami je treba pred vsaditvijo zaklopke pozorno oceniti, da se zagotovita pravilna postavitev in namestitev zaklopke.
- Zaklopke ne uporabljajte, če je pečat proti poseganju pretrgan, shranjevalna raztopina ne prekrije popolnoma zaklopke (samo zaklopka (SAPIEN 3 in transkatetrska srčna zaklopka SAPIEN 3 Ultra), če je bil indikator temperature aktiviran, če je zaklopka poškodovana ali je rok uporabnosti potekel, saj sta lahko sterilnost ali delovanje zaklopke morda ogrožena. Ne uporabite transkatetrske srčne zaklopke SAPIEN 3 Ultra RESILIA, če je bila vrečka iz folije odprta ali poškodovana, saj lahko izpostavljenost vlagi potencialno vpliva na delovanje lističa.
- Dovajalnega sistema ne uporabljajte napačno oziroma ne uporabljajte dovajalnega sistema in dodatkov, če so sterilne pregrade ovojnine in katere koli komponente odprte ali poškodovane (npr. prepognjene ali raztegnjene), jih ni mogoče izprati ali jim je potekel rok uporabnosti.
- Če dovajalnega sistema pred odstranjevanjem ne razvijete iz upognjenega položaja, lahko pride do poškodb bolnika.
- Bolniki, ki so preobčutljivi na kobalt, nikelj, krom, molibden, titan, mangan, silikon, glicerol, goveje tkivo in/ali polimerne materiale, imajo lahko alergijsko reakcijo na te materiale.
- Prejemniki zaklopke se morajo še naprej zdraviti z antikoagulacijskimi sredstvi/antitrombotiki, razen če je kontraindicirano, da se minimizira tveganje tromboze zaklopke ali trombemboličnega dogodka, kot to določi njihov zdravnik. Pripomoček ni bil preskušen za uporabo brez antikoagulacijskih sredstev.
- 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.
- Zdravnik mora pred vsaditvijo zaklopke preveriti, ali je usmerjena pravilno.
- Lastnosti dostopa, kot so huda obstruktivna ali cirkumferencialna kalcifikacija, huda vijugavost, premeri žil, ki so manjši od 5,5 mm (za transkatetrske srčne zaklopke SAPIEN 3/SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA) velikosti 20, 23 in 26 mm) ali 6,0 mm (za 29 mm transkatetrske srčne zaklopke SAPIEN 3 in SAPIEN 3 Ultra RESILIA) lahko preprečijo varno namestitev vodila in jih je treba previdno oceniti pred posegom.

6.0 Previdnostni ukrepi

- Dolgotrajne trpežnosti zaklopke THV niso ugotovili. Za ocenjevanje učinkovitosti zaklopke so priporočljive redne zdravstvene kontrole.
- Za transkatetrsko zamenjavo aortne zaklopke pri bolnikih s prirojeno bikuspidalno aortno zaklopko, ki se obravnavajo kot nizko tveganje za kirurški poseg, so na voljo omejeni klinični podatki. Pri uporabi zaklopke pri tej populaciji je treba upoštevati anatomske lastnosti. Poleg tega je treba upoštevati starost bolnika, ker dolgoročna vzdržljivost zaklopke ni bila ugotovljena.
- Glutaraldehid lahko povzroči draženje kože, oči, nosa in žrela. Izogibajte se dolgotrajni ali večkratni izpostavljenosti raztopini ali njenem vdihavanju. Uporabljajte samo ob zadostnem prezračevanju. Če pride do stika s kožo, prizadeto območje takoj izperite z vodo; ob stiku z očmi takoj poiščite zdravniško pomoč. Za več podatkov o izpostavljenosti glutaraldehidu glejte varnostni list, ki je na voljo pri družbi Edwards Lifesciences.
- Če pride pri potiskanju katetra skozi žilje do pomembnega povečanja upora, prekinite potiskanje in pred nadaljevanjem poiščite vzrok upora. Potiskanja ne izvajajte na silo, ker lahko tako povečate tveganje za žilne zaplete. Sila za potiskanje sistema je lahko pri uporabi transkatetrske srčne zaklopke SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA v vijugastih/težavnih anatomskih predelih žil večja od tiste pri uporabi SAPIEN 3.
- Namestitvenega balona ne napolnite preveč, ker lahko tako preprečite pravilen stik lističev zaklopke in s tem vplivate na delovanje zaklopke.
- Po posegu je pri bolnikih, izpostavljenih tveganju za okužbo protetične zaklopke in endokarditisu, priporočljiva uporaba ustrezne profilakse z antibiotiki.
- Dodatni previdnostni ukrepi za transseptalno zamenjavo okvarjene mitralne biološke protetične zaklopke vključujejo prisotnost pripomočkov ali trombusa ali drugih abnormalnosti v votli veni, ki preprečuje varen transvenski femoralni pristop za transseptalni dostop; prisotnost atrijskega septalnega okluzijskega pripomočka ali kalcifikacije, ki preprečuje varen transseptalni pristop.
- 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.

- Varnost in učinkovitost vsaditve transkatetrske srčne zaklopke nista bili dokazani pri bolnikih, ki imajo:
  - aortni obroček brez kalcifikacije,
  - hudo ventrikularno disfunkcijo z iztisno frakcijo < 20 %,
  - prirojeno unikuspidalno aortno zaklopko,
  - že vsajenim protetičnim obročkom na katerem koli položaju,
  - hudo kalcifikacijo mitralnega obročka (MAC), hudo (> 3+) mitralno insuficienco ali Gorlinov sindrom,
  - diskrazijo krvi, ki je opredeljena kot: levkopenija (bele krvne celice < 3.000 celic/µl), akutna anemija (Hb < 9 g/dl), trombocitopenija (število trombocitov < 50.000 celic/µl) ali anamneza hemoragične diateze ali koagulopatije
  - hipertrofično kardiomiopatijo z obstrukcijo ali brez nje (HOCM),
  - aortno stenozo, za katero je značilna kombinacija majhnega AV-pretoka z majhnim gradientom,
  - z ehokardiografijo potrjeno intra-kardialno maso, trombusom ali vegetacijo;
  - znano preobčutljivost ali kontraindikacije na aspirin, heparin, tiklopidin (Ticlid™) ali klopidogrel (Plavix™), oziroma preobčutljivost na kontrastno sredstvo, ki je ni mogoče ustrezno zdraviti,
  - hujšo aortno bolezen, vključno z abdominalno aortno ali torakalno anevrizmo, opredeljeno kot največji premer lumna 5 cm ali več; izrazito vijugavostjo (hiperakutne krivine), aterom aortnega loka (še posebej, če je debel [> 5 mm], štrleč ali so v njem prisotne razjede) ali zožanje ((še posebej kalcificirano in s površinskimi nepravilnostmi) abdominalne ali torakalne aorte, hudim »razširjenjem« in vijugavostjo torakalne aorte.
  - odebeljene, kalcificirane lističe aortne zaklopke v neposredni bližini koronarnega ustja.
  - sočasnim paravalvularnim puščanjem, pri katerem okvarjena biološka proteza ni stabilno pritrjena znotraj nativnega obročka ali je strukturno oporečna (npr. zlom žičnatega ogrodja),
  - deloma ločenim lističem odpovedujoče biološke proteze, ki lahko v aortnem položaju ovira odprtino koronarnega žilja,
- Tveganja subklavikularnega/aksilarnega pristopa so majhna in sprejemljiva, vendar je treba o tem pristopu razmisliti, če zdravnik ugotovi, da obstaja povečano tveganje, povezano s transfemoralnim dostopom.
- Pri levem aksilarnem pristopu levi subklavialni kot odcepa ~ ≥ 90° iz aortnega loka povzroči ostre kote, ki so lahko odgovorni za morebitno pregibanje vodila, disekcijo subklaviarne/aksilarne aorte in poškodbe aortnega loka.
- Pri levem/desnem aksilarnem pristopu poskrbite, da v levi notranji mamarni arteriji (LIMA)/desni notranji mamarni arteriji (RIMA) obstaja pretok med posegom in spremljajte tlak v homolateralni radialni arteriji.
- Preostali povprečni gradient je lahko večji pri konfiguraciji »THV znotraj nedelujoče proteze« kot po vsaditvi zaklopke v nativnem aortnem obročku pri uporabi pripomočka enake velikosti. Bolnike s povečanim povprečnim gradientom po posegu je treba pozorno spremljati. Pomembno je ugotoviti proizvajalca, model in velikost predhodno obstoječe biološke proteze, tako da se lahko vsadi ustrezna zaklopka in se izognete neprimernemu neujemanju proteze ter bolnika. Poleg tega je treba s slikanjem pred posegom čim bolj natančno določiti notranji premer.
- Na ocenjevanja učinkovitosti pripomočka za TAVR z Dopplerjevo ehokardiografijo po posegu in opazovalnem obdobju lahko vplivajo omejitve, ki so neločljivo povezane z Bernoullijevo enačbo, s katero se določa meritve, kot so povprečni gradient, EOA in neujemanje med protezo in bolnikom. Te omejitve lahko povzročijo višje ali nižje rezultate meritev učinkovitosti zaklopke po vsaditvi s TAVR. Zato je treba za določitev izhodiščnih vrednosti, s katerimi bodo primerjali vrednosti iz prihodnjih kontrolnih obiskov, uporabiti ehokardiogram po izvedbi TAVR. Če je pred ponovno intervencijo indicirano potrdilno neposredno merjenje tlaka s kateterizacijo srca, je treba razmisliti o tem.

7.0 Možni neželeni dogodki

Možna tveganja, povezana s celotnim posegom, vključno s pristopom, kateterizacijo srca, lokalno in/ali splošno anestezijo:

- smrt,
- možganska kap/tranzitorna ishemična ataka, crescendo ali nevrološki deficit,
- paraliza,
- trajna invalidnost,
- respiratorna insuficienca ali dihalna odpoved,
- krvavitev, ki zahteva transfuzijo ali poseg,
- srčno-žilna poškodba, ki vključuje perforacijo ali disekcijo žil, ventrikla, preddvora, septuma, miokarda ali struktur zaklopke, zaradi katerih je lahko potrebna intervencija,
- 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,
- žilni spazem,
- 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,
- 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 8

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)
Dovajalni sistem Edwards Commander	9610TF20	9610TF23	9610TF26	9610TF29
Uvajalni komplet Edwards eSheath ali Uvajalni komplet Edwards eSheath+	9610ES14 ali 914ESP			9610ES16 ali 916ESP
Pripomoček za napihovanje	96402			96406
Naprava za stiskanje Edwards	9600CR			
Naprava za stiskanje Qualcrimp, ustavljalo stiskanja in nalagalnik zagotavlja družba Edwards Lifesciences				

Preglednica 9

Ime izdelka	20 mm sistem	23 mm sistem	26 mm sistem
	Model		
Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra	9750TFX (20 mm)	9750TFX (23 mm)	9750TFX (26 mm)
Dovajalni sistem Edwards Commander	9610TF20 ali 9750CM20	9610TF23 ali 9750CM23	9610TF26 ali 9750CM26
Uvajalni komplet Edwards eSheath ali Uvajalni komplet Edwards eSheath+	9610ES14 ali 914ESP		

Ime izdelka	20 mm sistem	23 mm sistem	26 mm sistem
	Model		
Pripomoček za napihovanje	96402		
Naprava za stiskanje Edwards	9600CR		
Naprava za stiskanje Qualcrimp, ustavljalo stiskanja in nalagalnik zagotavlja družba Edwards Lifesciences			

Preglednica 10

Ime izdelka	20 mm sistem	23 mm sistem	26 mm sistem	29 mm sistem
	Model			
Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra RESILIA	9755RSL20 (20 mm)	9755RSL23 (23 mm)	9755RSL26 (26 mm)	9755RSL29 (29 mm)
Dovajalni sistem Edwards Commander	9750CM20	9750CM23	9750CM26	9750CM29
Uvajalni komplet Edwards eSheath+	914ESP			916ESP
Pripomoček za napihovanje	96402			96406
Naprava za stiskanje Edwards	9600CR			
Naprava za stiskanje Qualcrimp, ustavljalo stiskanja in nalagalnik 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 (2x)
- 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)
- Zmogljivosti za transezofagealno ali transtorakalno ehokardiografijo
- 0,035 palci (0,89 mm) zelo toga vodilna žica z izmenjevalno dolžino
- Začasni srčni spodbujevalnik (PM) in spodbujevalna elektroda
- Instrumentarij za transseptalni pristop in septostomijo, kot je primerno
- Sterilne kadi za izpiranje, fiziološka raztopina, heparinizirana fiziološka raztopina, 15- % razredčeno radioneprepustno kontrastno sredstvo
- Sterilna miza za pripravo zaklopke in dodatkov

8.2 Ravnanje z zaklopko in priprava

Ohranite sterilno tehniko med pripravo in vsaditvijo pripomočka.

8.2.1 Transkatetrska srčna zaklopka SAPIEN 3 Ultra RESILIA

Transkatetrska srčna zaklopka SAPIEN 3 Ultra RESILIA je dobavljena sterilna in apirogena. Embalaža je sestavljena iz kartona, ki vsebuje vrečko iz folije. V vrečki iz folije je pladenj, ki je zatesnjen s pokrovom Tyvek. V pladnju je držalo zaklopke, ki vsebuje zaklopko.

1. Za odpiranje škatle odstranite varnostno nalepko.
2. Vzemite vrečko iz folije iz škatle v nesterilnem polju. Pred odpiranjem preglejte embalažo glede poškodovanega oziroma zlomljenega ali manjkajočega pečata. Odprite vrečko in iz nje vzemite pladenj v nesterilnem polju.

   OPOZORILO: Ne odprite vrečke iz folije v sterilno polje, saj lahko ogrozite sterilnost. Vrečka iz folije služi le kot zaščitni ovoj. Samo držalo zaklopke je dovoljeno vstaviti v sterilno polje.

   Opomba: Če vrečko iz folije odprete med postopkom in zaklopke ne uporabite, zaklopko zavrzite.
3. Pladenj je označen z modelom, velikostjo in s serijsko številko. Model, velikost in serijsko številko je treba primerjati s številko na embalaži zaklopke in podatkovni kartici za vsaditev zaklopke.
4. V bližini sterilnega polja držite podnožje pladnja in odstranite pokrov s pladnja.
5. Držalo zaklopke in vsebine so sterilne. Prenesite držalo zaklopke v sterilno polje.

   SVARILO: Z vsebino držala zaklopke je treba ravnati z uporabo sterilne tehnike. Bodite previdni pri odstranjevanju držala zaklopke s pladnja, da zagotovite, da ne pride do stika z nesterilnim lepilom na tesnilnem robu pladnja.

8.2.2 Postopek namakanja/izpiranja zaklopke

8.2.2.1 Transkatetrska srčna zaklopka SAPIEN 3 Ultra RESILIA

1. Pripravite eno (1) sterilno skledo z vsaj 500 ml sterilne fiziološke raztopine, da namočite zaklopko.
2. Odprite držalo zaklopke tako, da držite podnožje pladnja in dvignete pokrov. Skrbno odstranite zaklopko iz držala zaklopke brez dotikanja tkiva. Preglejte zaklopko glede kakršnih koli znakov poškodb ogrodja ali tkiva.
3. Vstavite zaklopko v sterilno skledo s sterilno fiziološko raztopino. Poskrbite, da sterilna fiziološka raztopina povsem pokriva zaklopko vsaj dve minuti, da se lističi hidrirajo. Zaklopko morate pustiti v sterilni fiziološki raztopini, da preprečite izsušitev tkiva.

   SVARILO: V namakalno skledo ni dovoljeno vstavljati nobenih drugih predmetov. Zaklopko morate ohranjati hidrirano, da preprečite izsušitev tkiva.

8.2.2.2 Transkatetrska srčna zaklopka SAPIEN 3 in SAPIEN 3 Ultra

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

SVARILO: Zaklopke iz vsebnikov, ki so poškodovani, puščajo, brez dovolj sterilnega sredstva ali z manjkajočimi tesnili, 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 sterilno sredstvo glutaraldehid z zaklopke.
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.

8.2.3 Priprava sistema

1. Vizualno preglejte vse komponente glede poškodb. Poskrbite, da je dovajalni sistem povsem nenapet in balonski kateter povsem potisnjen v upogljivi kateter.

   OPOZORILO: Za preprečevanje morebitnih poškodb tulca balona poskrbite, da proksimalni konec tulca balona ni podvržen upogibanju.
2. Splaknite dovajalni sistem s heparinizirano fiziološko raztopino skozi vhod za splakovanje.
3. Previdno odstranite distalno prevleko balona z dovajalnega sistema. Odstranite mandren z distalnega konca svetline vodilne žice in ga odložite.
4. Splaknite svetlino vodilne žice s heparinizirano fiziološko raztopino in znova vstavite mandren v distalni konec svetline vodilne žice.

   Opomba: Če ne vstavite mandrena nazaj v svetlino vodilne žice, lahko pride do poškodbe svetline med postopkom stiskanja zaklopke.
5. Namestite dovajalni sistem v privzeti položaj (konec razbremenilnika napetosti je poravnan med dvema belima označevalnikoma na tulcu balona) in poskrbite, da je konica upogljivega katetra pokrita s proksimalno oblogo balona. Odvijte pokrovček nalagalnika s cevke nalagalnika in splaknite pokrovček nalagalnika s heparinizirano fiziološko raztopino. Namestite pokrovček nalagalnika prek proksimalne prevleke balona in na upogljivi kateter z notranjostjo pokrovčka usmerjenega proti distalni konici.
6. Povsem potisnite balonski kateter v upogljivi kateter.
   Odstranite proksimalno oblogo balona prek modrega dela tulca balona.
7. Priključite 3-potni zaporni ventil na vhod za napihovanje balona. Delno napolnite 50 cc ali večjo injekcijsko brizgo s 15 - 20 ml razredčenega kontrastnega sredstva in jo priključite na 3-potni zaporni ventil.
8. Napolnite pripomoček za napihovanje družbe Edwards Lifesciences z odvečno količino razredčenega kontrastnega sredstva glede na indicirani volumen napihovanja. Zaklenite pripomoček za napihovanje in ga priključite na 3-potni zaporni ventil.
9. Zaprite 3-potni zaporni ventil do pripomočka za napihovanje družbe Edwards Lifesciences. Izvlecite vakuum z uporabo 50 cc ali večje injekcijske brizge, da odzračite sistem. Počasi spustite bat, da zagotovite, da kontrastno sredstvo vstopi v svetlino dovajalnega sistema. Ponavljajte, dokler ne odstranite vseh zračnih mehurčkov iz sistema. V sistemu mora biti ničelni-tlak.

   OPOZORILO: Zagotovite, da v balonu ne ostane nič preostale tekočine, da se preprečijo morebitne težave s poravnavo zaklopke med posegom.
10. Zaprite zaporni ventil do dovajalnega sistema. Z vrtenjem gumba pripomočka za napihovanje družbe Edwards Lifesciences prenesite kontrastno sredstvo v injekcijsko brizgo, da dosežete ustrezni volumen, potreben za vstavljanje zaklopke.
11. Zaprite zaporni ventil do 50 cc ali večje injekcijske brizge. Odstranite injekcijsko brizgo. Preverite, ali je volumen pravilen in zaklenite pripomoček za napihovanje družbe Edwards Lifesciences.

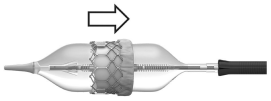
    SVARILO: Ohranite pripomoček za napihovanje družbe Edwards Lifesciences v zaklenjenem položaju do vstavitve THV, da zmanjšate tveganje ali predčasno napihovanje balona ter posledično nepravilno vstavitev THV.

8.2.4 Namestite in stisnite zaklopko na dovajalni sistem

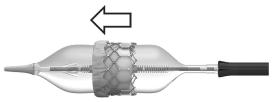
1. Pripravite dve (2) dodatni sterilni skledi z vsaj 100 ml sterilne fiziološke raztopine, da temeljito splaknete napravo za stiskanje Qualcrimp.
2. Povsem potopite napravo za stiskanje Qualcrimp v prvo skledo in jo nežno stisnite, da zagotovite popolno absorpcijo fiziološke raztopine. Počasi ožemajte napravo za stiskanje Qualcrimp vsaj 1 minuto. Ponovite ta postopek v drugi skledi.
3. Odstranite zaklopko iz namakalne/splakovalne sklede. Pri uporabi zaklopke SAPIEN 3 ali SAPIEN 3 Ultra odstranite zaklopko iz držala ter odstranite ID značko.
4. Zavrtite ročaj stiskalnice, da bo odprtina povsem odprta. Priključite 2-delno ustavljalo stiskanja na podnožje stiskalnice, da se zaskoči.
5. S stiskalnico v odprtem položaju nežno namestite zaklopko na odprtino stiskalnice. Postopno stiskajte zaklopko, da se prilega v napravo za stiskanje Qualcrimp.

   Opomba: Ta korak ni potreben za 20 mm zaklopko.
6. Namestite napravo za stiskanje Qualcrimp nad THV, pri tem pa poskrbite, da je THV vzporedna z robom naprave za stiskanje Qualcrimp.
7. Vstavite zaklopko in napravo za stiskanje Qualcrimp v odprtino stiskalnice. Vstavite dovajalni sistem koaksialno v zaklopko na območju za stiskanje zaklopke (2-3 mm distalno do tulca balona) z usmerjenostjo zaklopke na dovajalni sistem, kot je opisano spodaj:

   Antegradni pristop: dovod (zunanji konec obrobe) zaklopke proti proksimalnemu koncu dovajalnega sistema.



   Retrogradni pristop: dovod (zunanji konec obrobe) zaklopke proti distalnemu koncu dovajalnega sistema.



8. Poravnajte tulec balona koaksialno znotraj THV. Stiskajte THV, dokler ne doseže ustavljala naprave za stiskanje Qualcrimp na 2-delnem ustavljalu stiskanja.
9. Nežno odstranite napravo za stiskanje Qualcrimp s THV. Odstranite ustavljalo naprave za stiskanje Qualcrimp z ustavljala stiskanja, končno ustavljalo pa pustite nameščeno.
10. Usredinite THV znotraj odprtine stiskalnice. Povsem stisnite THV, da doseže končno ustavljalo in zadržite za 5 sekund.

    Opomba: Poskrbite, da stiskalni del zaklopke ostane koaksialen znotraj THV. Poskrbite, da je THV med stiskanjem povsem znotraj čeljusti stiskalnice.
11. Ponovite polno stiskanje THV še dvakrat, da boste vsakič trikrat povsem stisnili za 5 sekund.
12. Povlecite tulec balona in ga pritrdite v privzetem položaju.
13. Splaknite nalagalnik s heparinizirano fiziološko raztopino. Takoj potisnite THV v nalagalnik, da bo povsem v nalagalniku.

    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.
14. Pritrdite pokrovček nalagalnika na nalagalnik, znova splaknite dovajalni sistem skozi vhod za splakovanje in zaprite zaporni ventil do dovajalnega sistema.
    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.

8.3 Predhodna dilatacija nativne zaklopke in vstavljanje zaklopke

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

Dovajajte heparin, da ohranite ACT na ≥ 250 sek. med posegom.

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.

SVARILO: Uporaba prevelike količine kontrastnih sredstev lahko privede do ledvične odpovedi. Pred postopkom izmerite raven bolnikovega kreatinina. Spremljajte uporabo kontrastnih sredstev.

SVARILO: Postopek lahko zahteva arterijsko prerezovanje s kirurškim zaprtjem mesta preboda zaradi velikosti arteriotomije.

8.3.1 Osnovni parametri

1. Izvedite angiogram s fluoroskopskim pogledom pravokotno na zaklopko.
2. Ocenite razdaljo levega in desnega koronarnega ustja od aortnega obročka v zvezi z višino okvirja zaklopke.
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 Predhodna dilatacija nativne zaklopke

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.

8.3.3 Uvajanje zaklopke

1. Pridobite dostop s standardno tehniko katetrizacije.
2. Pripravite in vstavite vodilo Edwards skladno z navodili za uporabo.
3. Vstavite nalagalnik v vodilo, da se nalagalnik ustavi.
4. Potiskajte dovajalni sistem s primerno usmerjenim logotipom Edwards (dovajalni sistem deluje v obratni smeri vhoda za splakovanje) skozi vodilo, dokler zaklopka ne zapusti vodila.

   Opomba: Ohranite ustrezno usmerjenost upogljivega katetra skozi ves postopek. Dovajalni sistem deluje v obratni smeri od vhoda za splakovanje.

   SVARILO: Za iliofemoralni dostop zaklopke ne smete potiskati skozi vodilo, če konica vodila ni prešla razcepa, da se zmanjša tveganje poškodb žil.

   SVARILO: Za preprečevanje morebitnih poškodb lističev in morebitnega vpliva na delovanje zaklopke le-ta ne sme ostati v vodilu več kot 5 minut.
5. Na ravnem delu žilja začnite s poravnavanjem zaklopke tako, da sprostite zaklepni mehanizem balona in povlečete balonski kateter ravno nazaj, dokler ni viden del opozorilne oznake. Ne vlecite prek opozorilne oznake.

   OPOZORILO: Za preprečevanje morebitnih poškodb tulca balona poskrbite, da proksimalni konec tulca balona ni podvržen upogibanju.

   Aktivirajte zaklepni mehanizem balona.

   Uporabite kolesce za fino prilagajanje, da nastavite položaj zaklopke med oznake za poravnavo zaklopke.

   SVARILO: Ne zavrtite kolesca za fino prilagajanje, če zaklepni mehanizem balona ni aktiviran.

   OPOZORILO: Ne nameščajte THV prek distalne oznake za poravnavo zaklopke, da boste zmanjšali tveganje nepravilnega vstavljanja zaklopke ali embolizacije THV.

   SVARILO: Vzdržujte položaj vodilne žice med poravnavo zaklopke, da preprečite izgubo položaja vodilne žice.

   OPOZORILO: Če se poravnava zaklopke ne izvede v ravnem delu, lahko pride do težav z izvajanjem tega koraka, kar lahko povzroči poškodbe dovajalnega sistema in nezmožnost polnjenja balona. Z različnimi fluoroskopskimi pogledi lahko pomagate oceniti ukrivljenost anatomije. Če pride med poravnavo zaklopke do čezmerne napetosti, bo treba premestiti dovajalni sistem v drug raven del žilja in sprostiti stisnjenost (ali napetost) sistema.
6. Potisnite kateter in po potrebi uporabite kolesce za upogibanje, da preidete zaklopko.

   Opomba: Preverite usmerjenost logotipa Edwards, da zagotovite pravilno artikulacijo. Dovajalni sistem deluje v obratni smeri od vhoda za splakovanje.

7. Sprostite zaklepni mehanizem balona in umaknite konico upogljivega katetra do sredine trojnega označevalca. Aktivirajte zaklepni mehanizem balona.
8. Preverite pravilni položaj THV glede na ciljno lokacijo.
9. Po potrebi uporabite kolesce za upogibanje za prilagoditev koaksialnosti THV in kolesca za fino prilagajanje, da nastavite položaj THV.
10. Pred nameščanjem poskrbite, da je THV pravilno nameščena med oznakami za poravnavo zaklopke in konica upogljivega katetra nad trojnim označevalcem.
11. Začnite z uvajanjem THV:
    - Odklenite pripomoček za napihovanje družbe Edwards Lifesciences.
    - Začnite s hitrim spodbujanjem; ko se sistolični krvni tlak zmanjša na 50 mmHg ali manj, lahko začnete z napihovanjem balona.
    - S počasnim, nadzorovanim napihovanjem 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.
    - Izpustite zrak iz balona. Ko je balonski kateter povsem izpuščen, izklopite srčni spodbujevalnik.

8.3.4 Odstranjevanje sistema

1. Po potrebi razvijte dovajalni sistem med umikanjem pripomočka. Preverite, ali je konica upogljivega katetra zaklenjena prek trojnega označevalca. Umaknite nalagalnik do proksimalnega konca dovajalnega sistema in odstranite dovajalni sistem z vodila.

   Opomba: Za subklavikularno-aksilarni pristop obdržite dovajalni sistem znotraj vodila, dokler ni pripravljen za odstranjevanje vseh pripomočkov kot eno enoto.

   SVARILO: Če dovajalnega sistema pred odstranjevanjem ne razvijete iz upognjenega položaja, lahko pride do poškodb bolnika.
2. Odstranite vse pripomočke, ko je raven ACT primerna. Za odstranjevanje pripomočka glejte navodila za uporabo vodila Edwards.
3. Zaprite mesto dostopa.

9.0 Kako je dobavljeno

STERILNO: Zaklopke SAPIEN 3 in SAPIEN 3 Ultra so ob dobavi sterilizirane z raztopino glutaraldehida. Zaklopka SAPIEN 3 Ultra RESILIA, dovajalni sistem in dodatki so dobavljeni sterilizirani s plinom etilenoksidom.

Zaklopke so dobavljene apirogeno v embalaži, na katero je nameščen varnostni pečat proti odpiranju.

9.1 Shranjevanje

Zaklopko je treba hraniti med 10 °C in 25 °C (50 °F in 77 °F). Vsaka zaklopka je odpremljena v vsebniku, ki vsebuje indikator temperature za zaznavanje izpostavljenosti zaklopke ekstremnim temperaturam.

Dovajalni sistem 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 so transkatetrske srčne zaklopke Edwards SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA pogojno varne za uporabo v MR okolju. Bolnika s tem pripomočkom je mogoče varno slikati takoj po namestitvi tega pripomočka pod naslednjimi pogoji:

- statično magnetno polje jakosti 1,5 T ali 3,0 T
- Največje prostorsko gradientno polje je 3000 gauss/cm (30 T/m) ali manj
- Največja za sistem MR poročana povprečna specifična stopnja absorpcije (SAR) za celotno telo znaša 2 W/kg (normalni način delovanja) slikano na zaporedju

Pri pogojih slikanja, opredeljenih zgoraj, se pričakuje, da bodo transkatetrske srčne zaklopke SAPIEN 3, SAPIEN 3 Ultra in SAPIEN 3 Ultra RESILIA proizvedle dvig temperature do največ 1,9 °C po 15 minutah neprekinjenega slikanja.

Pri nekliničnem testiranju slikovni artefakt, ki ga povzroči pripomoček, sega do 9,0 mm od vsadka za slike spinskega odmeva in 23 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 z zaklopko

Ta pripomoček vsebuje naslednje snovi, opredeljene kot CMR 1B, v koncentraciji nad 0,1 % masnega deleža:

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 naslednje tabele prikazujejo kvalitativne in kvantitativne informacije o materialih in snoveh:

Preglednica 11: Transkatetrska srčna zaklopka SAPIEN 3

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

Snov	CAS	Masni razpon modela (mg)
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

Preglednica 12: Transkatetrska srčna zaklopka SAPIEN 3 Ultra

Snov	CAS	Masni razpon modela (mg)
Kobalt	7440-48-4	131 - 314
Nikelj	7440-02-0	148 - 298
Polietilen tereftalat	25038-59-9	142 - 212
Krom	7440-47-3	85,2 - 169
Kolageni, goveji, polimeri z glutaraldehidom	2370819-60-4	58,3 - 97,5
Molibden	7439-98-7	40,3 - 84,6
Polietilen	9002-88-4	19,4 - 22,0
Politetrafluoroetilen	9002-84-0	12,3 - 15,1
Železo	7439-89-6	0 - 8,06
Titan	7440-32-6	0 - 8,06
Mangan	7439-96-5	0 - 1,21
Silicij	7440-21-3	0 - 1,21
Titanov oksid	13463-67-7	0,307 - 1,03
Polibutilat	24936-97-8	0,273 - 0,340
Antimonov trioksid	1309-64-4	0,161 - 0,243
Ogljik	7440-44-0	0 - 0,201
Bor	7440-42-8	0 - 0,121
Fosfor	7723-14-0	0 - 0,121
Žveplo	7704-34-9	0 - 0,0806
D&C zelena št. 6	128-80-3	0,0394 - 0,0513
Silicijev dioksid	7631-86-9	0,00422 - 0,00525
Erukamid	112-84-5	0,00110 - 0,00178
4-dodecilbenzensulfonska kislina	121-65-3	0,000330 - 0,000453

Preglednica 13: Transkatetrska srčna zaklopka SAPIEN 3 Ultra RESILIA

Snov	CAS	Masni razpon modela (mg)
Glicerol	56-81-5	0 - 487
Kobalt	7440-48-4	131 - 427
Nikelj	7440-02-0	148 - 405
Polietilen tereftalat	25038-59-9	142 - 284
Krom	7440-47-3	85,2 - 230

Snov	CAS	Masni razpon modela (mg)
Kolageni, goveji, polimeri z glutaraldehidom	2370819-60-4	61,7 - 157
Molibden	7439-98-7	40,3 - 115
Polietilen	9002-88-4	26,7 - 38,6
Politetrafluoroetilen	9002-84-0	13,6 - 19,6
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	0,365 - 1,41
Polibutilat	24936-97-8	0,273 - 0,383
Antimonov trioksid	1309-64-4	0,161 - 0,328
Ogljik	7440-44-0	0 - 0,274
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	0,00110 - 0,00246
4-dodecilbenzensulfonska kislina	121-65-3	0,000330 - 0,000587

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/SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA.

Skladnost celotne platforme SAPIEN 3/SAPIEN 3 Ultra/SAPIEN 3 Ultra RESILIA z zahtevami za učinkovitost (splošne zahteve glede varnosti in učinkovitosti) za varnost (splošne zahteve glede varnosti in učinkovitosti 1 uredbe o medicinskih pripomočkih), učinkovitost (splošne zahteve glede varnosti in učinkovitosti 1 uredbe o medicinskih pripomočkih), sprejemljivost neželenih učinkov (splošne zahteve glede varnosti in učinkovitosti 8 uredbe o medicinskih pripomočkih), uporabnost (splošne zahteve glede varnosti in učinkovitosti 5 uredbe o medicinskih pripomočkih), življenjsko dobo (splošne zahteve glede varnosti in učinkovitosti 6 uredbe o medicinskih pripomočkih) in sprejemljiv profil razmerja med koristmi ter tveganji (splošne zahteve glede varnosti in učinkovitosti 8 uredbe o medicinskih pripomočkih) 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 zaklopke, dovajalni sistem in vodilo se lahko uporabljajo za iskanje SSCP.

Naslednje preglednice vsebujejo osnovne UDI-DI-je:

Preglednica 14: Sistem transkatetrske srčne zaklopke Edwards SAPIEN 3

<table>
<tr><th rowspan="2">Izdelek</th><th colspan="4">Model</th><th rowspan="2">Osnovni UDI-DI</th></tr>
<tr><th>20 mm sistem</th><th>23 mm sistem</th><th>26 mm sistem</th><th>29 mm sistem</th></tr>
<tr><td>Transkatetrska srčna zaklopka Edwards SAPIEN 3</td><td>9600TFX (20 mm)</td><td>9600TFX (23 mm)</td><td>9600TFX (26 mm)</td><td>9600TFX (29 mm)</td><td>0690103D003SAP000VP</td></tr>
<tr><td>Dovajalni sistem Edwards Commander</td><td>9610TF20</td><td>9610TF23</td><td>9610TF26</td><td>9610TF29</td><td>0690103D003COM000TC</td></tr>
<tr><td>Uvajalni komplet Edwards eSheath
ali
Uvajalni komplet Edwards eSheath+</td><td colspan="3">9610ES14
ali
914ESP</td><td>9610ES16
ali
916ESP</td><td>0690103D003S3E000NT</td></tr>
<tr><td>Pripomoček za napihovanje</td><td colspan="3">96402</td><td>96406</td><td>0690103D003IND000TG</td></tr>
<tr><td>Naprava za stiskanje Edwards</td><td colspan="4">9600CR</td><td>0690103D003CRI000TH</td></tr>
</table>

Preglednica 15: Sistem transkatetrske srčne zaklopke Edwards SAPIEN 3 Ultra

Izdelek	Model			Osnovni UDI-DI:
	20 mm sistem	23 mm sistem	26 mm sistem	
Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra	9750TFX (20 mm)	9750TFX (23 mm)	9750TFX (26 mm)	0690103D003SAP000VP
Dovajalni sistem Edwards Commander	9610TF20 ali 9750CM20	9610TF23 ali 9750CM23	9610TF26 ali 9750CM26	0690103D003COM000TC
Uvajalni komplet Edwards eSheath ali Uvajalni komplet Edwards eSheath+	9610ES14 ali 914ESP			0690103D003S3E000NT
Pripomoček za napihovanje	96402			0690103D003IND000TG
Naprava za stiskanje Edwards	9600CR			0690103D003CRI000TH

Preglednica 16: Sistem transkatetrske srčne zaklopke Edwards SAPIEN 3 Ultra RESILIA

Izdelek	Model				Osnovni UDI-DI
	20 mm sistem	23 mm sistem	26 mm sistem	29 mm sistem	
Transkatetrska srčna zaklopka Edwards SAPIEN 3 Ultra RESILIA	9755RSL (20 mm)	9755RSL (23 mm)	9755RSL (26 mm)	9755RSL (29 mm)	0690103D003SAP000VP
Dovajalni sistem Edwards Commander	9750CM20	9750CM23	9750CM26	9750CM29	0690103D003COM000TC
Uvajalni komplet Edwards eSheath+	914ESP			916ESP	0690103D003S3E000NT
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 za 5 let simulirane rabe. Poleg tega klinični podatki kažejo obstojnost s spremljanjem 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.

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
	Balloon diameter	Premer balona

	English	Slovenščina
	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
WO	Work Order	Delovni nalog

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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