Edwards

KONECT RESILIA Aortic Valved Conduit, Model 11060A

Instructions for Use

1.0 Device and Accessories Description

1.1 Device Description

The KONECT RESILIA aortic valved conduit, model 11060A, is a stented trileaflet valve pre-assembled to a woven polyester graft impregnated with gelatin (Figure 1). The valve is comprised of RESILIA bovine pericardial tissue that is mounted on a flexible frame. The graft is a Terumo Aortic Gelweave Valsalva aortic root graft. The KONECT RESILIA aortic valved conduit is stored in a dry packaging condition (Table 1). The KONECT RESILIA aortic valved conduit is available in sizes 21, 23, 25, 27, and 29 mm, with a standard 10 cm usable graft length which can be cut to size at time of implant (Table 1).

RESILIA Tissue

RESILIA tissue is created with a technology called Edwards Integrity Preservation. The technology incorporates a stable-capping anticalcification process, which permanently 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 and maintains long-term protection of collagen.

The combined impact of the Edwards Integrity Preservation technology's stable capping and glycerolization features makes it a superior, resilient tissue. In juvenile sheep, valves with RESILIA tissue demonstrated a statistically significant reduction in leaflet calcification ($p = 0.002$) and significant improvement in hemodynamic performance ($p = 0.03$) over commercially available pericardial tissue valves (Carpentier-Edwards PERIMOUNT Plus pericardial mitral bioprosthesis, model 6900P) [Refs. 1 and 2].

Valve Structure

The valve is based on the proven design and performance of the Carpentier-Edwards PERIMOUNT Magna Ease pericardial aortic bioprosthesis, model 3300TFX (also referred to as the Magna Ease aortic bioprosthesis).

The frame is designed to be compliant at the orifice, as well as at the commissures. The compliance of the commissure supports is intended to reduce the loading shock at the valve commissures and free margin of the leaflets [Ref. 3]. The compliance of the orifice is intended to reduce the stress on the leaflets. The compliant orifice concept is based on the physiology and mechanics of natural heart valves and reported experience with implantation of unstented homografts [Refs. 4 and 5].

The lightweight wireform is made of a corrosion-resistant cobalt-chromium alloy, chosen because of its superior spring efficiency and fatigue-resistant characteristics, and is covered with a polyester fabric.

A cobalt-chromium alloy/polyester film laminate band surrounds the base of the wireform frame. The DualFit silicone sewing ring is covered with a porous polytetrafluoroethylene (PTFE) cloth and has three equally spaced black silk suture markers at each of the valve commissures, to aid in bioprosthesis orientation and alignment for coronary re-attachment. The versatile DualFit sewing ring design gives surgeons the flexibility to choose between a supra-annular or an intra-annular implant position in the type of procedure in which this device is used (Bentall procedure). A Bentall procedure is a cardiac surgery operation involving replacement of the aortic valve and ascending aorta, with re-implantation of the coronary arteries into the graft.

Graft

The graft portion of the device is made of woven polyester which has been impregnated with gelatin and plasticized with glycerol. The aim of the impregnation is to provide a polyester vascular prosthesis which does not require preclotting. The gelatin is a modified mammalian gelatin which has been cross-linked to a set level to control its rate of removal. It serves in place of fibrin, which seals the polyester prosthesis during normal preclotting. The graft mimics the geometry of the Sinuses of Valsalva as shown in the diagram in Table 1. The graft features a skirt at its proximal end that allows the creation of an anatomical configuration similar to the natural aortic root. The graft also features a single marker line on the skirt to aid in

Edwards, Edwards Lifesciences, the stylized E logo, Carpentier-Edwards, COMMENCE, DualFit, KONECT, KONECT RESILIA, Magna, Magna Ease, PERIMOUNT, PERIMOUNT Magna, PERIMOUNT Plus, and RESILIA are trademarks of Edwards Lifesciences Corporation. All other trademarks are the property of their respective owners.

coronary re-attachment and along the body to facilitate graft alignment with the ascending aorta.

Holder

The holder is a single piece that is physically mounted to the KONECT RESILIA aortic valved conduit by means of sutures. The holder features an integrated handle and a single-cut release channel beyond the distal end of the graft, which allows for removal by the surgeon (refer to Figure 11).

1.2 Sizers and Tray

The use of a sizing instrument facilitates selection of the correct size device for implantation. The translucent model 1190 sizers permit direct observation of their fit within the annulus. Each sizer consists of a handle with a different sizing configuration at each end (Figure 2). On one side of the handle is a barrel end used to size the annulus. On the other side of the handle is a replica end with an integrated lip that reflects the bioprosthesis sewing ring geometry. A sizer is available for each size of the model 11060A (21, 23, 25, 27, and 29 mm). The complete set of sizers is housed in a tray, model TRAY1190, which can be reused and resterilized. Refer to the sizer and tray IFU for cleaning and sterilization instructions.

The benefits of the KONECT RESILIA aortic valved conduit include improvement in aortic valve function and longevity, repair or replacement of a damaged or diseased ascending aorta, acute relief of symptoms, and improvement in morbidity and mortality.

2.0 Intended Use and Indications for Use

The KONECT RESILIA aortic valved conduit, model 11060A, is intended for use as a replacement for the aortic heart valve and the ascending aorta.

The KONECT RESILIA aortic valved conduit, model 11060A, is indicated for patients who require replacement of their diseased native or prosthetic aortic valve, and the associated repair or replacement of a damaged or diseased ascending aorta per current guidelines.

3.0 Target Population

The target patient population includes adult candidates who require replacement of their native or prosthetic aortic valve, and the associated repair or replacement of a damaged or diseased ascending aorta.

4.0 Contraindications

There are no known contraindications associated with the use of the KONECT RESILIA aortic valved conduit, model 11060A.

5.0 Warnings

FOR SINGLE USE ONLY. This device is designed, intended, and distributed for SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE THIS DEVICE. There are no data to support the sterility, non-pyrogenicity, and functionality of the device after reprocessing. Resterilization could lead to injury or infection, as the device may not function as intended.

DO NOT FREEZE OR EXPOSE THE KONECT RESILIA AORTIC VALVED CONDUIT TO EXTREME HEAT. Exposure of the bioprosthesis to extreme temperatures will render the device unfit for use.

DO NOT USE THE KONECT RESILIA aortic valved conduit if:

- **The "OK" symbol is not apparent on the temperature indicator**
- **The foil pouch, sealed trays, or lids are opened, damaged, or stained**
- **There is visible staining on the Tyvek lids, since staining could indicate a compromised sterile barrier (Refer to Figure 5)**
- **The expiration date has elapsed, or**
- **It is dropped, damaged, or mishandled in any way.**

The above may result in dehydration of the tissue, contamination, and/or compromised sterility.

Should a bioprosthesis be damaged during insertion, do not attempt repair.

DO NOT EXPOSE the KONECT RESILIA aortic valved conduit to any solutions, chemicals, antibiotics, etc., except for sterile physiological saline solution. Irreparable damage to the leaflet tissue, which may not be apparent under visual inspection, may result.

DO NOT GRASP the leaflet tissue of the valve with instruments or cause any damage to the KONECT RESILIA aortic valved conduit. Even the most minor leaflet tissue perforation may enlarge in time to produce significant impairment of bioprosthesis function.

DO NOT PASS CATHETERS or transvenous pacing leads across the valve since they may cause tissue damage. Care must be exercised when passing a surgical instrument across the valve to avoid leaflet tissue damage.

The device should not be immersed in saline for longer than five minutes to preserve the hemostatic properties of the graft gelatin coating. The graft must not be allowed to dry out after soaking.

The manufacturing process for gelatin sealed vascular grafts uses the cross-linking agent formaldehyde to achieve the graft performance. All gelatin sealed grafts are thoroughly rinsed with RO water to reduce residual formaldehyde, however residual amounts may be present in the finished graft. Formaldehyde is also found at low levels naturally in the body, some of which is derived from food. Formaldehyde is known to be mutagenic and carcinogenic. The risks of these potential harms from the product have not been established clinically.

Failure to keep the valve moist can cause the leaflets to dry out, which may compromise the valve function. Hydrating the leaflets with saline every one to two minutes is recommended.

Use of a cautery for any sealed polyester graft can cause burning. This can be prevented by wetting the device with saline at the site of cauterization.

DO NOT PRECLOT. The graft is sealed and must not be preclotted. Preclotting may increase the risk of thromboembolic episodes.

As with any implanted medical device, there is a potential for the patient to develop an immunological response. Refer to Section 14.0 Qualitative and Quantitative Information Section for a listing of materials and substances in this device. Patients with hypersensitivities to cobalt, chromium, nickel, molybdenum, manganese, carbon, beryllium, iron, glycerol, bovine tissue, and bovine gelatin may have an allergic reaction to these materials. Care should be exercised in patients with hypersensitivities to these materials.

This device was manufactured without latex, but may have been produced in a latex-containing environment.

6.0 Precautions

The safety and effectiveness of the KONECT RESILIA aortic valved conduit has not been established for the following specific populations because it has not been studied in these populations:

- Patients who are pregnant;
- Nursing mothers;
- Patients with abnormal calcium metabolism (e.g., chronic renal failure, hyperparathyroidism);
- Patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's syndrome);
- Children and adolescents;
- Patients with hypersensitivity to metal alloys that contain cobalt, chromium, nickel, molybdenum, manganese, carbon, beryllium, and iron;
- Patients with hypersensitivity to latex;
- Patients with hypersensitivity to tissue with alpha-gal antigen.

Although the device has not been studied in the above listed patient population, this device is lifesaving. The decision to use the device in the above patient populations is left to the discretion of the surgeon.

7.0 Adverse Events

7.1 Observed Adverse Events - Bioprosthetic Heart Valves

As with all prosthetic heart valves, serious adverse events, sometimes leading to death, may be associated with the use of tissue valves. In addition, adverse events due to individual patient reaction to an implanted device or to physical or chemical changes to the components, particularly those of biological origin, may occur at varying intervals (hours or days), necessitating reoperation and replacement of the prosthetic device.

The valve portion of the KONECT RESILIA aortic valved conduit, model 11060A, is similar in design to the Carpentier-Edwards PERIMOUNT Magna Ease pericardial aortic bioprosthesis model 3300TFX combined with RESILIA tissue. Adverse events associated with the use of Carpentier-Edwards PERIMOUNT pericardial bioprostheses compiled from the literature and from reports received through the product surveillance system include stenosis, regurgitation through an incompetent valve, perivalvular leak, endocarditis, hemolysis, thromboembolism, thrombotic obstruction, bleeding diatheses related to the use of anticoagulation therapy, malfunctions of the valve due to distortion at implant, fracture of the wireform, and physical or chemical deterioration of valve components. Types of tissue deterioration include infection, calcification, thickening, perforation, degeneration, suture abrasion, instrument trauma, and leaflet detachment from the valve stent posts. These complications may present clinically as abnormal heart murmur, shortness of breath, exercise intolerance, dyspnea, orthopnea, anemia, fever, arrhythmia, hemorrhage, transient ischemic attack, stroke, paralysis, low cardiac output, pulmonary edema, congestive heart failure, cardiac failure, and myocardial infarction.

7.2 Potential Adverse Events – Polyester Grafts

Adverse events potentially associated with the use of polyester vascular grafts include hemorrhage, thrombosis, graft infection, embolism, aneurysm, pseudoaneurysm, seroma, occlusion (anastomotic intimal hyperplasia), immunological reaction to gelatin (shown to be a weak immunogen; infrequent, mild, localized and self-limiting), intimal peel formation, and conduit dilatation.

7.3 Potential Adverse Events - KONECT RESILIA Aortic Valved Conduit

Adverse events potentially associated with the use of the KONECT RESILIA aortic valved conduit and the surgical procedure include:

- Allergic reaction
- Aneurysm
- Angina
- Annulus (damage, dissection, tear)
- Aorta (damage, dissection, tear)
- Arterial dissection
- Asystole and/or cardiac arrest
- Bleeding/hemorrhage
  - Peri- or post-procedural
  - Anticoagulant related
  - Pericardial tamponade
  - Hematoma
  - Cerebrovascular
- Blood - Anemia
- Blood - Coagulopathy
- Blood - Hemolysis/Hemolytic Anemia
- Blood Pressure alteration (hypotension, hypertension)
- Cardiac - Arrhythmias/Conduction Disturbances
- Cardiac failure
- Cardiogenic shock
- Conduit dilatation
- Coronary artery ostia occlusion
- Coronary button - detachment, kinking, pseudoaneurysm, tear/damage
- Deep vein thrombosis (DVT)
- Device component dislodgement/instability/migration/ embolization

- Disseminated intravascular coagulation (DIC)
- Embolism
- Endocarditis
- Esophageal tear/rupture
- Graft infection
- Hypoxemia
- Infection - local, wound or systemic
- Intimal peel formation
- Multi-system organ failure (MOF)
- Myocardial infarction
- Myocardial perforation
- Neurologic events
  - Stroke (CVA)
  - Transient ischemic attack (TIA)
- Occlusion (anastomotic intimal hyperplasia)
- Pericardial effusion
- Pleural effusion
- Pneumonia
- Prosthetic Insufficiency - Regurgitation/Stenosis
- Prosthesis - Nonstructural dysfunction
  - Paravalvular leak
  - Leaflet impingement
  - Leaflet tissue damage (instruments/sutures)
  - Pannus
  - Prosthesis mismatch (PPM) (due to inappropriate sizing)
  - Distortion at implant
- Prosthesis - Structural dysfunction/Deterioration
- Prosthesis - Thrombosis
- Prosthesis Wireform/Stent Fracture or Distortion
- Pseudoaneurysm
- Pulmonary edema
- Reduced exercise tolerance
- Renal failure, acute
- Renal insufficiency
- Respiratory failure
- Seroma
- Thrombocytopenia (Non-HIT)
- Thrombocytopenia, heparin induced (HIT)
- Thromboembolism
  - Arterial, venous, peripheral, central
- Transvalvular or valvular leaking

Calcific and non-calcific (fibrotic) degeneration of bioprosthetic valves is reported with use of chemo-radiotherapy to treat malignant conditions [Refs. 6 and 7]

It is possible that these complications may lead to:

- Reoperation
- Explantation
- Permanent disability
- Death

8.0 Clinical Studies

The clinical safety and effectiveness of the KONECT RESILIA aortic valved conduit has been established based on the outcome of the KONECT RESILIA aortic valved study, which assessed the KONECT RESILIA aortic valved conduit, model 11060A. The clinical safety and effectiveness of the KONECT RESILIA aortic valved conduit is also based on the outcome data of the COMMENCE trial, which assessed the safety and effectiveness of the RESILIA tissue.

The KONECT RESILIA aortic valved conduit study is a multi-center, retrospective, observational study. Following a pre-surgical assessment, subjects were evaluated for one year to assess primary safety and effectiveness.

The objective of the KONECT RESILIA aortic valved conduit study was to collect data on the safety and performance of the KONECT RESILIA aortic valved conduit in the treatment of patients who required replacement of their native or prosthetic aortic valve, and the associated repair or replacement of a damaged or diseased ascending aorta.

The reporting period for the KONECT RESILIA aortic valved conduit study is July 2020 through September 2023. There were three hundred twenty-nine (329) subjects which were treated at three (3) sites in the US.

Table 2 provides trial demographics and pre-operative NYHA classification; Table 3 lists safety outcomes; Table 4 provides site reported valve related adverse events; and Table 5 lists hemodynamic parameters.

The COMMENCE trial is an open-label, prospective, non-randomized, multicenter trial without concurrent or matched controls. Following a pre-surgical assessment, subjects are followed for one year to assess primary safety and effectiveness. Subjects are followed annually thereafter for a minimum of five years post-surgical experience. Long term follow-up beyond five years is ongoing.

The objective of the COMMENCE trial is to confirm that the tissue processing, valve sterilization, and packaging for the Edwards pericardial aortic bioprosthesis model 11000A, do not raise new questions of safety and effectiveness in subjects who require replacement of their native or prosthetic aortic valve.

The trial population consists of adult subjects (18 years or older) diagnosed with aortic valve disease requiring a planned replacement of the native or prosthetic aortic valve. Concomitant coronary bypass surgery and ascending aorta resection and replacement from the sinotubular junction without the need for circulatory arrest are permitted.

Trial candidates with prior valve surgery which included the implant of a prosthetic valve or annuloplasty ring that will remain *in situ* are excluded. Concomitant valve repair or replacement are excluded. Surgical procedures outside the cardiac area are not permitted. Various clinical presentations and histories may cause exclusion from the trial.

The reporting period for the COMMENCE trial aortic arm is January 2013 through March 2023. At the time of the database lock, six hundred ninety-four (694) subjects were enrolled at twenty-seven (27) investigational sites in the US and Europe. Of the enrolled population, six hundred eighty-nine (689) subjects were successfully implanted

with the model 11000A and left the operating room with the trial valve.

Table 6 provides trial demographics, NYHA Classification and Risk Scores; Table 7 lists the observed adverse event rates during the study; Table 8 provides NYHA Classification data at baseline, 1-, 5- and 7-year follow-up; and Table 9 lists hemodynamic parameters at 1, 5 and 7 years.

9.0 Individualization of Treatment

Bioprosthetic heart valve recipients should be maintained on anticoagulant therapy, except where contraindicated, during the initial stages after implantation, as determined by the physician on an individual basis and as per guidelines [Refs. 8 and 9]. Long-term anticoagulation and/or antiplatelet therapy should be considered for patients with risk factors for thromboembolism. Guidelines also recommend how to manage patients with bioprosthetic valve dysfunction and prophylaxis for infective endocarditis [Refs. 8 and 9].

9.1 Considerations in bioprosthetic valve selection

The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all the circumstances presented by that patient. The ESC/EACTS (Ref. 8) and ACC/AHA (Ref. 9) Guidelines contain the complete recommendations for bioprosthetic valve selection.

Edwards encourages surgeons to participate in available registries when the KONECT RESILIA aortic valved conduit is implanted in younger patients.

10.0 Patient Counseling Information

Careful and continued medical follow-up (at least by an annual visit to the physician) is advised so that device-related complications, particularly those related to material failure, can be diagnosed and properly managed. Patients with valves are at risk from bacteremia (e.g., undergoing dental procedures) and should be advised about prophylactic antibiotic therapy.

Patients should be encouraged to carry their implant card at all times and to inform their healthcare providers that they have an implant when seeking care.

It is recommended that patients be briefed on warnings, precautions, contraindications, measures to be taken and limitations of use associated with the KONECT RESILIA aortic valved conduit, model 11060A.

11.0 How Supplied

11.1 Packaging

The KONECT RESILIA aortic valved conduit, model 11060A, is provided sterile and non-pyrogenic, in a double-barrier tray package. The KONECT RESILIA aortic valved conduit is sterilized by ethylene oxide. The net content of the package is one (1) valved conduit. The double tray package is in a foil pouch which is in a carton. Upon receipt of the carton, inspect the exterior for signs of damage.

Each device is contained in a carton with a temperature indicator displayed through a window on the side panel. The temperature indicator is intended to identify products that were exposed to transient temperature extremes. Upon receipt of the bioprosthesis, immediately inspect the indicator and refer to the carton label to confirm a "Use" condition. If the "Use" condition is not apparent, do not use the KONECT RESILIA aortic valved conduit and contact the local supplier or Edwards Lifesciences representative to make arrangements for return authorization and replacement.

WARNING: Carefully inspect the KONECT RESILIA aortic valved conduit before implantation for evidence of extreme temperature exposure or other damage. Exposure of the KONECT RESILIA aortic valved conduit to extreme temperatures will render the device unfit for use.

11.2 Storage

The KONECT RESILIA aortic valved conduit, model 11060A, should be stored at 10 °C to 25 °C (50 °F to 77 °F), in the foil pouch and shelf carton.

12.0 Directions for Use

12.1 Physician Training

The techniques for implanting this device are similar to those used for the placement of any aortic valved conduit. No specific training or special facilities beyond that required for cardiac surgical procedures are required to implant the model 11060A.

The primary intended users are staff responsible for preparation of the device prior to implant (operating room (OR) nurses or scrub technicians) and the cardiac surgeons who perform valve sizing and aortic valve and ascending aorta replacements (aka: Bentall procedures). Additional users are support staff that are trained to assist in the receiving, inspection, transfer, and/or preparation of the device for surgery.

12.2 Sizing

Because of the complexity and variation of cardiac valve replacement surgery, the choice of surgical technique, appropriately modified in accordance with the previously described warnings, is left to the discretion of the individual surgeon. In general, the following steps should be employed:

Step	Procedure
1	Surgically remove the valve leaflets and all associated structures deemed necessary.
2	Surgically remove any calcium from the annulus to ensure proper seating of the sewing ring of the KONECT RESILIA aortic valved conduit to avoid damage to the delicate leaflet tissue.
3	Measure the annulus using only the Edwards Lifesciences sizer model 1190 (Figure 2). The sizer model 1190 can be used to measure for either supra-annular or intra-annular placement, depending on surgeon preference.

CAUTION: Do not use other manufacturers' prosthesis sizers, or sizers for other Edwards devices, to size the KONECT RESILIA aortic valved conduit, model 11060A. Incorrect sizing may occur, which may result in damage to the bioprosthesis, localized native tissue damage, and/or inadequate hemodynamic performance.

CAUTION: When choosing a bioprosthesis for a given patient, the size, age, and physical condition of the patient in relation to the size of the bioprosthesis must be taken into consideration to minimize the possibility of obtaining a suboptimal hemodynamic result. The selection of a bioprosthesis, however, must ultimately be made by the physician on an individual basis after carefully weighing all the risks and benefits to the patient.

CAUTION: Examine sizers for signs of wear, such as dullness, cracking, or crazing. Replace sizer if any deterioration is observed. Continued use may result in fragmentation, embolization, or prolonged procedure.

WARNING: Fragments of sizers are not radiopaque and cannot be located by means of an external imaging device. Loose fragments in the vasculature have the potential to embolize.

CAUTION: Avoid using excessive force during sizing as it may damage the annulus tissue.

12.2.1 Supra-Annular Sizing

Step	Procedure
1	For supra-annular implantation, the sewing ring of the KONECT RESILIA aortic valved conduit is placed above the annulus, thereby maximizing valve orifice area. When sizing for supra-annular implantation, the sizer should be parallel with the plane of the annulus and the following sizing technique should be used:
2	Using the KONECT RESILIA aortic valved conduit sizer model 1190, select the barrel end of the largest diameter sizer that fits comfortably in the patient's annulus (Figure 3a).
3	Once the appropriate barrel end is verified, use the replica end of the same sizer to verify that the sewing ring will fit comfortably on top of the annulus. If satisfied with the fit of the replica end, choose this size of the KONECT RESILIA aortic valved conduit implant (Figure 3b).

12.2.2 Intra-Annular Sizing

Step	Procedure
1	For intra-annular implantation, the sewing ring of the KONECT RESILIA aortic valved conduit is placed inside the annulus. When sizing for intra-annular implantation, the following technique should be used:
2	Using the KONECT RESILIA aortic valved conduit sizer model 1190, select the barrel end of the largest diameter sizer that fits comfortably in the patient's annulus (Figure 4a).
3	Once the appropriate barrel end is verified, use the replica end of the same sizer to verify that the sewing ring will fit comfortably inside of the annulus. The sizer should be parallel with the plane of the annulus and the entire sizer including the simulated sewing ring portion, should pass through the annulus. If satisfied with the fit of the replica end, choose this size of the KONECT RESILIA aortic valved conduit for implant (Figure 4b).

12.3 Handling and Preparation Instructions

An in-service on the device is recommended prior to handling and preparing the KONECT RESILIA aortic valved conduit, model 11060A.

Step	Procedure
1	**CAUTION: Do not open foil pouch upon receipt of the device and until ready for implantation. Long-term exposure of the KONECT RESILIA aortic valved conduit to some environmental conditions may compromise the device function.**
2	Once the appropriate size of the KONECT RESILIA aortic valved conduit is chosen, remove the foil pouch from the carton in the non-sterile field. Before opening, examine the pouch for evidence of damage and broken or missing seals. **WARNING: Do not open foil pouch in sterile field. The foil pouch is a protective cover only. The outer surface of the outer tray is not sterile and may compromise the sterile field. The innermost package tray is sterile and may be introduced into the sterile field, in order to minimize the potential for contamination.**

Step	Procedure
3	Remove the double barrier tray package from the foil pouch in the non-sterile field. Examine the outer tray for evidence of damage, stains, and broken or missing seals. **CAUTION: Any damage to the trays renders the bioprosthesis non-sterile.** In the event of damage to the primary packaging, the product may not be used and should be returned immediately to Edwards Lifesciences (See Section 12.6 Return of the KONECT RESILIA Aortic Valved Conduit).
4	Near the sterile field, hold the base of the outer tray and peel the lid from the outer tray.
5	The inner tray and contents are sterile. Transfer the inner tray to the sterile field. The contents of the inner tray must be handled using a sterile surgical technique to prevent contamination.
6	**CAUTION: Do not open the inner package until implantation is certain and the surgeon is ready to place the KONECT RESILIA aortic valved conduit. Once the inner package is opened, the device must be used immediately or discarded to minimize the potential for contamination, tissue dehydration, and gelatin degradation.** Before opening, examine the inner tray and lid for evidence of damage, stains, and broken or missing seals. Hold the base of the inner tray and peel the lid from the inner tray. **WARNING: Do not use the KONECT RESILIA aortic valved conduit if there is visible staining on the inner tray Tyvek lid. Staining could indicate a compromised sterile barrier (Figure 5).** Droplets may be visible in the inner tray. This is a result of the glycerolization process and does not impact product function and is not an indication of sterile barrier breach or improper product storage or conditioning (Figure 6).
7	While holding the tray securely, pull up on the holder grip to remove the KONECT RESILIA aortic valved conduit from the tray (Figure 7). **CAUTION: The holder is required for implantation and should not be removed until the KONECT RESILIA aortic valved conduit is sutured to the annulus. To avoid damaging the device, do not grasp the KONECT RESILIA aortic valved conduit with hands or surgical instruments.**
8	A serial number tag is attached to the holder grip by a thread. This serial number should be confirmed with the number on the KONECT RESILIA aortic valved conduit package and patient implant card. Do not remove the tag. The serial number is also provided on the silver label located outside of the inner tray. **CAUTION: If any difference in model, size, or serial number is noted, the KONECT RESILIA aortic valved conduit should not be implanted. If the incorrect device is used, valve damage, localized native tissue damage, and/or inadequate hemodynamic performance may result.** **CAUTION: If the tag is inadvertently removed, ensure the attachment threads are fully removed from the holder.**
9	The KONECT RESILIA aortic valved conduit must be immersed in a sterile saline solution for 5 minutes. Thereafter, the KONECT RESILIA aortic valved conduit must be kept hydrated with saline throughout the remainder of the procedure and must not be allowed to dry out. **CAUTION: Do not immerse the device in saline for longer than five minutes, in order to preserve the hemostatic properties of the graft gelatin coating. The graft must not be allowed to dry out after soaking.** **CAUTION: After soaking, hydrating both sides of the valve leaflets with saline every one to two minutes is recommended. Failure to keep the valve moist thereafter can cause the leaflets to dry out, which may compromise the valve function.** **CAUTION: Avoid contact of the leaflet tissue with towels, linens, or other sources of particulate matter that may be transferred to the leaflet tissue.**

12.4 Device Implantation

The KONECT RESILIA aortic valved conduit, model 11060A, is designed for supra-annular and intra-annular implantation.

Step	Procedure
1	Orient the KONECT RESILIA aortic valved conduit so that the coronary ostia are not compromised. The sewing ring has three equally spaced black suture markers at each of the commissures to aid in bioprosthesis orientation and alignment for coronary re-attachment (Figure 8).
2	For supra-annular placement of the KONECT RESILIA aortic valved conduit, employ a suture technique such as a non-everting horizontal mattress technique. For intra-annular placement of the KONECT RESILIA aortic valved conduit, employ a suture technique such as an everting mattress technique.
3	Parachute the aortic valved conduit along the sutures until it is in contact with the patient's native annulus, then tie the sutures (Figures 9 and 10). **CAUTION: To avoid perforation, care must be taken when using suture fastening devices with vertical fasteners.** **CAUTION: Avoid placement of annular sutures deep into the adjacent tissue to avoid arrhythmias and conduction abnormalities.**
4	Remove the holder at the completion of the suturing procedure. a) Using a scalpel, cut the exposed sutures that are visible in the single-cut release channel of the holder, near the top of the graft (Figure 11). Avoid cutting or damaging the graft when cutting the sutures. **WARNING: Failure to cut within the single-cut release channel may prevent the holder from releasing and may result in suture tails left in the device. Do not use excessive force when removing the holder to avoid device damage. Multiple cuts may result in the creation of suture fragments and potential embolism.** b) After the sutures are cut, ensure the KONECT RESILIA aortic valved conduit remains seated while removing the holder. Remove the holder along with its suture tails. c) Discard the holder; it is for single use only.
5	A sterile cautery should be used to cut the graft for adjusting the length and creating coronary ostia. A cautery is not provided with the KONECT RESILIA aortic valved conduit. The coronary arteries should be anastomosed to the skirted section of the graft. **CAUTION: Care should be taken to not touch the valve leaflets when creating the coronary ostia. Irreparable damage to the leaflet tissue may occur.** To prevent focal burning of the graft, which may result during cauterization, wet the valsalva graft with saline at the intended site of cauterization, immediately prior to cauterization (Figure 12). **CAUTION: Use of a cautery for any sealed polyester graft can cause burning. This can be prevented by wetting the device with saline at the site of cauterization.** **CAUTION: Clamping may damage the vascular prosthesis. Atraumatic clamps, ideally with soft-shod jaws, should be used with the minimum application of force. Excessive force or tension should be avoided, as these will damage the polyester fibers and the gelatin impregnation. Care should be taken to prevent fraying or fiber damage when suturing through the graft.**
6	Use the single marker line along the body of the graft to facilitate alignment for distal anastomosis. **CAUTION: If de-airing is required, then the smallest possible needle should be used; 19 gauge is normally sufficient. Hypodermic needles have a cutting point, which may result in blood leakage and may require repair by suturing.**

12.5 Accessory Cleaning and Sterilization

The accessories for the KONECT RESILIA aortic valved conduit, model 11060A, are packaged separately. The model 1190 sizers and model TRAY1190 are reusable and supplied nonsterile. Refer to the Instructions for Use supplied with the reusable accessories for cleaning and sterilization instructions.

12.6 Return of the KONECT RESILIA Aortic Valved Conduit

Edwards Lifesciences is interested in obtaining recovered clinical specimens of the KONECT RESILIA aortic valved conduit, model 11060A, for analysis. Contact the local representative for return of recovered bioprostheses.

- Unopened Package with Sterile Barrier Intact: If the foil pouch or trays have not been opened, return the device in its original packaging.
- Package Opened but Bioprosthesis Not Implanted: Contact the local representative for return of recovered bioprostheses.

- Explanted Device: Contact the local representative for return of recovered bioprostheses.

12.7 Device Disposal

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

13.0 MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated that the KONECT RESILIA aortic valved conduit, model 11060A, is MR Conditional. A patient with the model 11060A can be scanned safely under the following conditions:

- Static magnetic field of 1.5 tesla or 3 tesla only.
- Spatial magnetic field gradient of 3000 gauss/cm (30 T/m) or less.
- Maximum MR system-reported whole-body averaged specific absorption rate (SAR) of 2.0 W/kg in Normal Operating Mode.

Under the scan conditions defined above, the KONECT RESILIA aortic valved conduit, model 11060A, is expected to produce a maximum *in vivo* temperature rise of less than 2.0 °C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 33 mm from the model 11060A valve when imaged with a spin echo or gradient echo pulse sequences and a 3 tesla MRI system. The artifact obscures the device lumen.

14.0 Qualitative and Quantitative Information

This device contains or incorporates tissues or cells of animal origin. The valve leaflets are made of bovine pericardial tissue. The graft portion of the device is impregnated with bovine-sourced gelatin.

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.

The following table shows the qualitative and quantitative information on the materials and substances:

Substance	CAS	Model Mass Range (mg)
Polyethylene terephthalate	25038-59-9	2686 - 3061
Polytetrafluoroethylene	9002-84-0	802 - 1210
Polydimethylsiloxane	63148-62-9	435 - 648
Cobalt	7440-48-4	112 - 273
Silicon dioxide	7631-86-9	180 - 272
Glycerol	56-81-5	109 - 152
Limed bone gelatin	9000-70-8	124 - 146
Succinylated limed bone gelatin	68915-24-2	124 - 146
Collagens, bovine, polymers with glutaraldehyde	2370819-60-4	57.6 - 146
Chromium	7440-47-3	54.4 - 140
Iron	7439-89-6	29.0 - 127
Nickel	7440-02-0	41.5 - 107
Polyethylene	9002-88-4	63.5 - 82.1
Molybdenum	7439-98-7	19.3 - 50.0
Barium sulfate	7727-43-7	12.7 - 18.6
Manganese	7439-96-5	5.01 - 15.0
Titanium dioxide	13463-67-7	8.29 - 9.78
Fibroin Silk	9007-76-5	6.22 - 7.60
Silicon	7440-21-3	0 - 6.66
Carbon black	1333-86-4	2.02 - 2.26
Antimony trioxide	1309-64-4	1.74 - 1.99
Octamethylcyclotetrasiloxane; D4	556-67-2	0.671 - 0.985
Carbon	7440-44-0	0 - 0.666
Beeswax	8012-89-3	0.200 - 0.283
Decamethylcyclopentasiloxane; D5	541-02-6	0.177 - 0.260
Dodecamethylcyclohexasiloxane; D6	540-97-6	0.120 - 0.177
Phosphorus	7723-14-0	0 - 0.0666
Sulfur	7704-34-9	0 - 0.0666
Logwood Extract Dye	475-25-2	0.0501 - 0.0608
4-Dodecylbenzenesulfonic acid	121-65-3	0.0145 - 0.0163
Beryllium	7440-41-7	0 - 0.00666
Erucamide	112-84-5	0.000764 - 0.00135

15.0 Summary of Safety and Clinical Performance (SSCP)

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.

16.0 Patient Labeling

A patient implant card is provided with each KONECT RESILIA aortic valved conduit. 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.

17.0 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 following table contains the Basic UDI-DI:

Product	KONECT RESILIA Aortic Valved Conduit
Model	11060A
Basic UDI-DI	0690103D002KON000WA

18.0 Expected Lifetime of the Device

The claimed lifetime of the KONECT RESILIA aortic valved conduit is five (5) years.

The KONECT RESILIA aortic valved conduit has been subjected to rigorous pre-clinical durability and fatigue reliability testing in accordance with internationally recognized standards to 5 years. In addition, durability is supported by one year of clinical follow-up in the KONECT RESILIA aortic valved conduit study and seven years of follow-up in the COMMENCE trial; refer to **Section 8.0 Clinical Studies**. Actual lifetime performance depends on multiple biological factors and can vary from patient to patient.

19.0 References

1. Flameng W, Hermans H, Verbeken E, Meuris B. A randomized assessment of an advanced tissue preservation technology in the juvenile sheep model. *J Thorac Cardiovasc Surg*. Jan 2015;149(1):340-5. doi:10.1016/j.jtcvs.2014.09.062. [Valves with Edwards XenoLogiX™ treatment were used as controls.]
2. Rabbit Calcification Study on Edwards and Competitor Tissue Heart Valves. Study on file at Edwards.
3. Reis RL, Hancock WD, Yarbrough JW, Glancy DL, Morrow AG. The flexible stent. A new concept in the fabrication of tissue heart valve prostheses. J Thorac Cardiovasc Surg. Nov 1971;62(5):683-9 passim.
4. Barratt-Boyes BG, Roche AH. A review of aortic valve homografts over a six and one-half year period. Ann Surg. Sep 1969;170(3):483-92. doi:10.1097/00000658-196909010-00016
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7. Yusuf SW, Sami S, Daher IN. Radiation-induced heart disease: a clinical update. Cardiol Res Pract. Feb 27 2011;2011:317659. doi:10.4061/2011/317659
8. Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. Feb 12 2022;43(7):561-632. doi:10.1091/ eurheartj/ehab395
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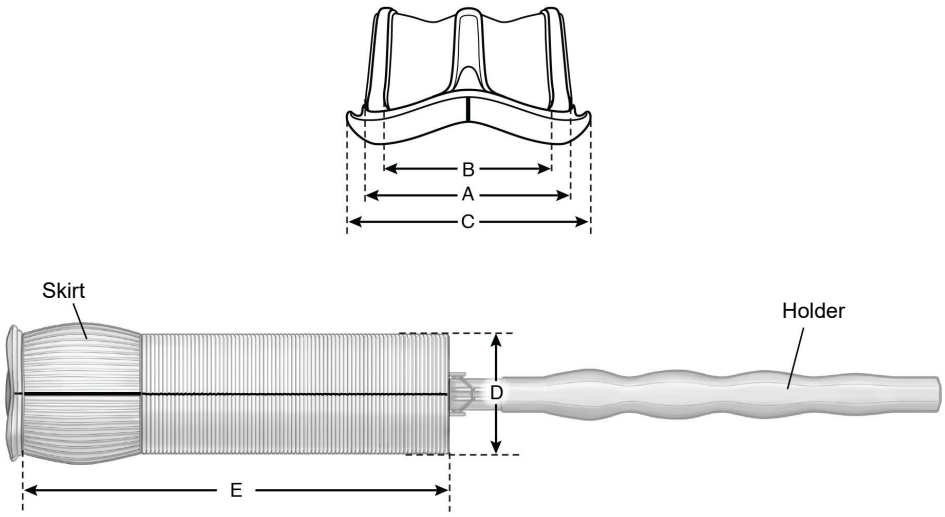
10. Isselbacher EM, Preventza O, Black JH, et al. 2022 ACC/AHA Guideline for the Diagnosis and Management of Aortic Disease: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. Review. *Circulation*. 2022;146(24):E334-E482. doi:10.1161/CIR.0000000000001106
11. Erbel R, Aboyans V, Boileau C, et al. 2014 ESC Guidelines on the diagnosis and treatment of aortic diseases: Document covering acute and chronic aortic diseases of the thoracic and abdominal aorta of the adult. The Task Force for the Diagnosis and Treatment of Aortic Diseases of the European Society of Cardiology (ESC). Eur Heart J. Nov 1 2014;35(41):2873-926. doi:10.1093/eurheartj/ehu281

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 http://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

Refer to the symbol legend at the end of this document.

Table 1: Nominal Dimensions for Valve and Graft



Valve Size	21 mm	23 mm	25 mm	27 mm	29 mm
A. Tissue Annulus Diameter (Stent Diameter, mm)	21	23	25	27	29
B. Valve Internal Diameter (Stent ID, mm)	20	22	24	26	28
C. External Sewing Ring Diameter (mm)	33	35	36	38	40
D. Graft Diameter (mm)	24	26	28	30	32
E. Graft Usable Length (cm)	10	10	10	10	10
Geometric Orifice Area (GOA) (mm^2)	292	357	424	503	575

Table 2: KONECT RESILIA Aortic Valved Conduit Trial Study Demographics

Age at Implant	**N: Mean ± SD**
Age (years)	329: 61.8 ± 11.0
Sex	**% (n / N)**
Female	14.6% (48 / 329)
Male	85.4% (281 / 329)
NYHA Classification	**% (n/N)**
Class I	38.3% (126 / 329)
Class II	37.4% (123 / 329)
Class III	9.7% (32 / 329)
Class IV	2.1% (7 / 329)
Not documented	12.5% (41 / 329)
N is the number of subjects with available data for the given parameter.	

Table 3: KONECT RESILIA Aortic Valved Conduit Trial Summary of Safety Outcomes (Freedom from Event Rates) (N = 329)

Outcome	30 Days	1 Year
All-cause mortality	98.2% (0.7%) 6, 6	94.9% (1.3%) 15, 15
Operative death	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Cardiovascular mortality	99.4% (0.4%) 2, 2	98.5% (0.7%) 4, 4
Aortic valve or aortic root reoperation	100.0% (0.0%) 0, 0	99.6% (0.4%) 1, 1

Outcome	30 Days	1 Year
Aortic valve reoperation	100.0% (0.0%) 0, 0	99.6% (0.4%) 1, 1
Aortic root reoperation	100.0% (0.0%) 0, 0	99.6% (0.4%) 1, 1
Bleeding requiring reintervention[a]	95.1% (1.2%) 18, 16	95.1% (1.2%) 18, 16
Each cell contains Kaplan-Meier estimate % (standard error %), cumulative number of events, and number of subjects with the event. Standard error is based on Greenwood's formula. [a] All bleeding events requiring reintervention were reported as surgical re-explorations. Of these, one was reported as requiring reintervention on the graft. The graft was not explanted, and the reintervention was not on the valve or the aortic root. None of the other reinterventions were reported as requiring reintervention on the device.		

Table 4: KONECT RESILIA Aortic Valved Conduit Trial Site-Reported Valve-Related Adverse Events (Freedom from Event Rates) (N = 329)

Event	30 Days	1 Year
Thromboembolism	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Stroke	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Transient ischemic attack	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Non-cerebral thromboembolism	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Endocarditis	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Valve thrombosis	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Hemorrhage	99.7% (0.3%) 1, 1	99.7% (0.3%) 1, 1
Aortic graft-related pseudoaneurysm	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Graft infection	100.0% (0.0%) 0, 0	100.0% (0.0%) 0, 0
Other (hypo-attenuated leaflet thickening)	100.0% (0.0%) 0, 0	99.6% (0.4%) 1, 1
Each cell contains Kaplan-Meier estimate % (standard error %), cumulative number of events, and number of subjects with the event. Standard error is based on Greenwood's formula.		

Table 5: KONECT RESILIA Aortic Valved Conduit Trial Hemodynamic Parameters (N = 329)

Parameter	30 Days	3 Months	6 Months	1 Year	> 1 Year
Mean gradient (mmHg)	9.1 ± 4.0 (67)	7.5 ± 2.4 (18)	9.5 ± 4.1 (23)	8.9 ± 4.6 (110)	10.5 ± 4.6 (34)
Peak gradient (mmHg)	16.3 ± 6.2 (63)	12.4 ± 5.1 (17)	16.0 ± 6.9 (23)	16.8 ± 7.1 (106)	18.0 ± 9.7 (35)
Effective orifice area (cm^2)[a]	2.1 ± 0.7 (39)	2.3 ± 0.4 (6)	2.2 ± 0.7 (12)	2.0 ± 0.7 (42)	1.9 ± 0.5 (26)
Left ventricular ejection fraction (%)	53.1 ± 11.7 (74)	57.7 ± 6.8 (18)	57.0 ± 9.2 (25)	57.5 ± 7.0 (119)	56.6 ± 8.4 (36)
Left ventricular mass (g)	235.1 ± 71.8 (51)	209.8 ± 68.5 (15)	176.3 ± 64.3 (13)	206.4 ± 71.3 (87)	190.7 ± 59.1 (16)
Transvalvular leak					

Parameter	30 Days	3 Months	6 Months	1 Year	> 1 Year
None/trace	98.7% (75 /76)	100.0% (19 /19)	100.0% (23 /23)	98.2% (111 /113)	89.5% (34 /38)
Mild	1.3% (1 /76)	0.0% (0 /19)	0.0% (0 /23)	1.8% (2 /113)	10.5% (4 /38)
Moderate	0.0% (0 /76)	0.0% (0 /19)	0.0% (0 /23)	0.0% (0 /113)	0.0% (0 /38)
Severe	0.0% (0 /76)	0.0% (0 /19)	0.0% (0 /23)	0.0% (0 /113)	0.0% (0 /38)

The 30-day window is defined as POD 1 to 60, 3-month as POD 61 to 119, 6-month as POD 120 to 244, 1-year as POD 245 to 485, and > 1-year as POD > 485.
Categorical measures: % (n/total number) where the total number only includes subjects with valid values.
Continuous measures: mean ± standard deviation (n) where 'n' represents the number of subjects with evaluable data within the defined window.
Echo after reoperation are excluded from the analysis.

[a] Reporting effective orifice area is not standard of care at all institutions.

Table 6: COMMENCE Trial Study Demographics

Age at Implant	N: Mean ± SD
Age (years)	694: 67.0 ± 11.6 (20.0, 90.0)
Sex	**% (n / N)**
Female	28.2% (196/694)
Male	71.8% (498/694)
NYHA Classification	**% (n/N)**
Class I	23.6% (164/694)
Class II	50.0% (347/694)
Class III	24.5% (170/694)
Class IV	1.9% (13/694)
Risk Scores	**N: Mean± SD (Min, Max)**
STS risk of mortality (%) [1]	539: 2.0 ± 1.8 (0.3, 17.5)
EuroSCORE II (%)	694: 2.6 ± 3.0 (0.5, 24.6)

N is the number of subjects with available data for the given parameter.

[1]STS scores only calculated for subjects undergoing isolated AVR or AVR+CABG.

Table 7: Observed Adverse Events

Adverse Event or Outcome	Early[1] (N=694) n,m(%)	Late[2] (LPY[3] = 3609.5) n,m (%/pt-yr)	Freedom- from Event at 7 Years (SE)[4]
All mortality	9, 9 (1.3%)	80, 80 (2.2%)	85.31 (1.67)
Valve-related mortality	3, 3 (0.4%)	19, 19 (0.5%)	96.03 (0.93)
Reoperation	1, 1 (0.1%)	12, 12 (0.3%)	97.22 (0.89)
Explant	0, 0 (0.0%)	9, 9 (0.2%)	97.89 (0.78)
Thromboembolism	16, 16 (2.3%)	51, 58 (1.6%)	90.54 (1.20)
Valve thrombosis	0, 0 (0.0%)	2, 2 (0.1%)	99.43 (0.43)
Endocarditis	0, 0 (0.0%)	15, 16 (0.4%)	97.26 (0.75)
All bleeding	7, 7 (1.0%)	77, 108 (3.0%)	85.64 (1.67)
Major bleed	5, 5 (0.7%)	43, 56 (1.6%)	90.94 (1.46)
All Paravalvular Leak	2, 2 (0.3%)	3, 3 (0.1%)	99.23 (0.34)
Major PVL	1, 1 (0.1%)	2, 2 (0.1%)	99.54 (0.26)

Adverse Event or Outcome	Early[1] (N=694) n,m(%)	Late[2] (LPY[3] = 3609.5) n,m (%/pt-yr)	Freedom- from Event at 7 Years (SE)[4]
Structural Valve Deterioration	0, 0 (0.0%)	3, 3 (0.1%)	99.29 (0.51)

[1]For 'Early Events' (events occurring thru post-implant day 30): For 'Early' m is the number of events; n is the number of subjects experiencing an event; % = n/N.

[2]For 'Late Events' (events occurring after post-implant day 30): m is the number of events; n is the number of subjects experiencing an event; and % = m/LPY.

[3]LPY: Late patient-years; LPY are calculated from post-implant day 31 until the last patient contact.

[4]Based on Kaplan-Meier analysis of time to first occurrence (early or late). Standard Error (SE) based on Greenwood's formula.

Table 8: NYHA Classification at Baseline, 1, 5 and 7 Years

NYHA Class	Baseline NYHA %(n/N[1])	1-Year NYHA %(n/N[1])	5-Year NYHA %(n/N[1])	7-Year NYHA %(n/N[1])
Class I	23.8% (164/689)	81.8% (523/639)	75.9% (372/490)	78.6% (143/182)
Class II	49.9% (344/689)	16.4% (105/639)	21.4% (105/490)	14.8% (27/182)
Class III	24.4% (168/689)	1.4% (9/639)	2.0% (10/490)	6.6% (12/182)
Class IV	1.9% (13/689)	0.3% (2/639)	0.6% (3/490)	0.0% (0/182)

[1]N is the number of subjects with known NYHA at the specified post-operative visit.

Table 9: Hemodynamic Parameters at 1, 5 and 7 Years

Visit	21mm N: Mean±SD	23mm N: Mean±SD	25mm N: Mean±SD	27mm N: Mean±SD	29mm N: Mean±SD
EOA (cm^2)					
1 Year	120:1.33±0.35	188:1.56±0.42	183:1.79±0.44	92:2.25±0.58	18:2.39±0.53
5 Years	82:1.20±0.31	123:1.43±0.38	133:1.69±0.49	76:2.09±0.58	12:2.24±0.44
7 Years	25:1.33±0.40	36:1.58±0.38	49:1.82±0.42	33:2.15±0.45	9:2.96±0.51
Mean Gradient (mmHg)					
1 Year	122:12.59±4.82	193:10.37±3.78	185:9.11±3.35	93:8.07±3.30	18:6.19±2.06
5 Years	83:14.10±6.34	125:12.01±5.07	133:10.32±4.18	76:8.67±4.06	12:7.98±2.51
7 Years	26:12.27±6.35	38:9.96±3.83	50:8.87±3.52	33:7.56±3.24	9:6.88±2.73

N represents the number of subjects with evaluation data.

Figures

Figure 1: KONECT RESILIA Aortic Valved Conduit, Model 11060A

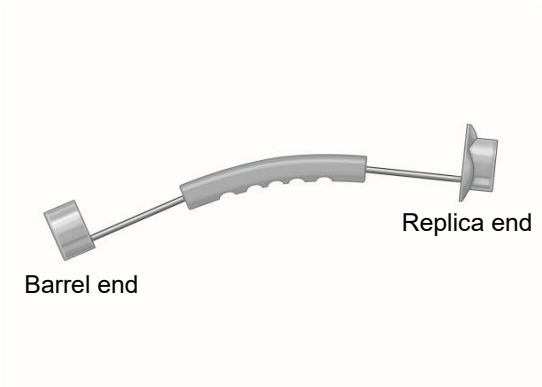


Figure 2: Sizer Model 1190

a) Barrel End **b) Replica End**

Figure 3: Supra-annular Sizing

a) Barrel End **b) Replica End**

Figure 4: Intra-annular Sizing

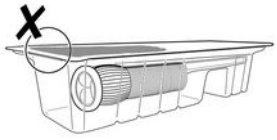


Figure 5: STAIN - DO NOT USE

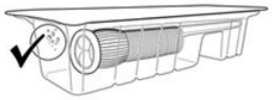


Figure 6: DROPLETS - OK TO USE

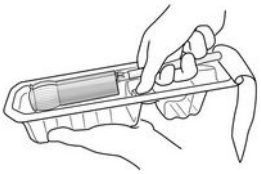


Figure 7: Removal from Inner Tray

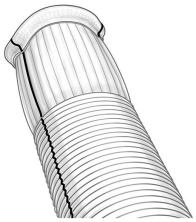


Figure 8: Sewing Ring Markers

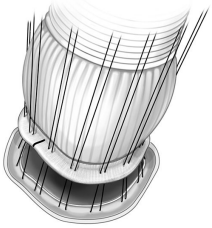


Figure 9: Non-everting Technique

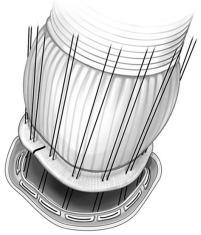


Figure 10: Everting Technique

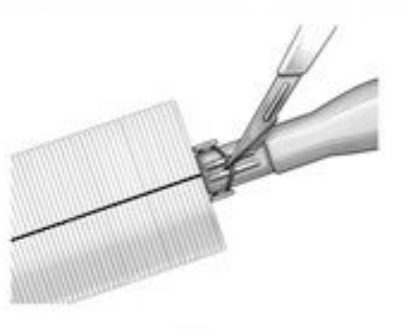


Figure 11: Single-cut Release Channel in Holder

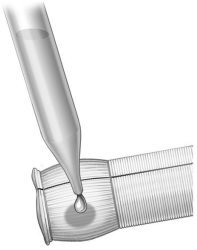
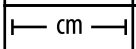


Figure 12: Wetting the Graft

Symbol Legend

	English
	Model Number
	Do not re-use
	Caution
	Consult instructions for use
	Consult instructions for use on the website
	Do not use if package is damaged and consult instructions for use
	Temperature Limit
	Use-by date
	Manufacturer
	Date of manufacture

	English
	Double sterile barrier system
	Sterilized using ethylene oxide
	Non-pyrogenic
	Size
	Quantity
	Unique device identifier
	Use product if indication is shown
	Do not use product if indication is shown
	Medical device
	Contains biological material of animal origin

	English
	Stain - Do Not Use
	Droplets - OK to Use
	Usable length
	MR Conditional
	Contains hazardous substances
	Authorized representative in the European Community/European Union
	Importer
	Conformité Européenne (CE Mark)
	Work Order
	Do not resterilize

Edwards

EC REP

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CE 0123

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