



Edwards

KONECT RESILIA Aortic Valved Conduit, Model 11060A Accessory Care and Sterilization Instructions for Tray Model TRAY1190

Rx only

1.0 Tray Model TRAY1190

The Instructions For Use supplied with KONECT RESILIA aortic valved conduit (AVC), Model 11060A provide information on the use of this tray.

2.0 Device Description

TRAY1190 is an accessory to KONECT RESILIA aortic valved conduit (AVC), Model 11060A. It does not have direct patient contact. The product is comprised of a tray base, lid, inserts and latch and latch pin. The material for tray base, lid and inserts is made out of Radel polyphenylsulfone. The lid is secured onto the tray by means of two stainless steel latches and latch pins. This device is reusable, supplied non-sterile, and must be cleaned and sterilized prior to its use. Tray holds the sizers during sterilization, storage, and transfer to the surgical site.

3.0 Intended Use and Indications for Use

The Tray Model TRAY1190 is intended to hold the six Sizers Model 1190 during sterilization and storage and allows for multiple sterilization cycles (re-use) by steam (moist heat).

TRAY1190 is designed to contain, store and hold Sizer Model 1190 during product sterilization and transfer.

4.0 Contraindications

There are no known contraindications with the use of TRAY1190.

5.0 How Supplied

The tray is provided non-sterile and must be cleaned and sterilized before each use. It cannot be sterilized in its original packaging.

6.0 Intended User

Primary users are staff responsible for preparation of KONECT RESILIA aortic valved conduit devices prior to implant; operating room (OR) nurses and the cardiac surgeons who perform valve sizing and implantation during valve and/or aortic root repair/replacement procedures.

7.0 Cleaning Instructions

All trays and lids must be cleaned and sterilized prior to each use in accordance with appropriate hospital procedures and the following recommended instructions and parameters.

Accessories should be retired from use when signs of cracking, crazing, or other deterioration is evident. Contact your Edwards Lifesciences sales representative to obtain appropriate replacements.

CAUTION: Examine tray for signs of wear, such as dullness, cracking or crazing. Replace tray if any deterioration is observed.

7.1 Instructions for Manual Cleaning:

1. Post-operative transport of devices should be performed by hospitals or sterilization services in accordance with applicable local policies and procedures.
2. Prepare a solution of enzymatic detergent according to the detergent manufacturer's instructions. 27-35 °C potable water. Minimum contact time: 2 minutes.
3. Submerge the devices into the detergent solution and soak for a minimum of 5 minutes. Avoid direct contact between the devices.

4. After the 5-minute soak time, use a soft-bristled brush and scrub the devices for a minimum of 2 minutes to remove any visible soil.
5. Transfer the device into a sink of critical water for a minimum of 30 seconds to rinse detergent away.
6. If soil is visible, repeat the cleaning process.
7. Dry the devices with a lint free cloth prior to disinfection or sterilization.

7.2 Instructions for Automated Cleaning:

1. Post-operative transport of devices should be performed by hospitals or sterilization services in accordance with applicable local policies and procedures.
2. Prepare a solution of enzymatic detergent according to the detergent manufacturer's instructions. NB: For Serchem Triple-Zyme, 2-4 ml/L in 27-35 °C potable water. Minimum contact time: 2 minutes.
3. Submerge the devices into the detergent for a minimum of 1 minute, and remove all visible traces of contaminant, using suitable nylon brushes to scrub the equipment thoroughly.
4. Transfer devices into a container of 40-45 °C potable water to rinse detergent away.
5. Place the loaded tray into the automated washer with the lid detached.
6. Set motor speed to HIGH, if applicable, and select the cycle and cycle parameters per the following recommendations.

PHASE	RECIRCULATION TIME (MINUTES)	TEMPERATURE / WATER QUALITY	DETERGENT TYPE AND CONCENTRATION
Pre-wash	2:00	Cold potable water	N/A
Wash	2:00	50-60 °C (122-140 °F), potable water	Neutral or Alkaline detergent (e.g. Prolystica 2X Concentrate; concentration per detergent manufacturer's instructions)
Rinse	1:00	60-70 °C (140-158 °F), potable water	N/A
Drying	7:00	115 °C (239 °F)	N/A

8.0 Disinfection

8.1 Instructions for Thermal Disinfection:

1. Load tray with sizers into washer/disinfector with the lid detached.
2. Set the motor speed to HIGH, if applicable, and select the following recommended parameters:

PHASE	RECIRCULATION TIME (MINUTES)	WATER TEMPERATURE / WATER QUALITY	DETERGENT TYPE AND CONCENTRATION
Thermal rinse	1:00	90-95 °C (194-203 °F), Critical Water	N/A

8.2 Instructions for High Level Disinfection:

1. Equilibrate a bath of high-level disinfectant (Cidex OPA or equivalent) to a minimum of 20 °C (68 °F), or follow manufacturer's recommendations.
2. Fully immerse the tray in the disinfectant solution, and ensure all air bubbles are removed from the surface of the tray by wiping with a sterile lint-free cloth.
3. Allow the tray to soak for a minimum of 12 minutes.
4. Thoroughly rinse the tray by fully immersing in sterile purified water or equivalent, agitating, and soaking for a minimum of 1 minute.
5. Dry the tray using a sterile lint-free cloth.

9.0 Sterilization Instructions

CAUTION: Do not sterilize any of the accessories in their original packaging. Each institution should use procedures that include biological indicators to determine the effectiveness of the sterilization procedure.

CAUTION: Do not stack trays during sterilization.

The processing of the product according to the instructions outlined in this IFU is in compliance to ISO17644 and aligned with HTM 01-01, when using a validated decontamination cycle to ISO 15883 and sterilization to ISO 17665.

The user is responsible for the qualification of any deviations from the recommended method of cleaning or sterilization.

Sterilizer Type	Configuration	Preconditioning	Minimum Temperature	Exposure Time	Minimum Dry Time
Pre-vacuum	Double Wrapped per site specifications	4 pulses	134-137 °C (273-279 °F)	3 minutes	30 minutes

Examine all instruments prior to use. If particles are visible, repeat the cleaning and sterilization process.

10.0 Device Disposal

Devices that have signs of wear, cracking or crazing 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.

11.0 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	TRAY
Model	TRAY1190
Basic UDI-DI	0690103D002OBT000UR

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.

Symbol Legend

	ISO Reg. No. ¹	English
REF	2493	Catalogue Number
#	N/A	Quantity
LOT	2492	Lot Number
Rx only	N/A	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
 eifu.edwards.com + 1 888 570 4016	1641	Consult instructions for use on the website
	0434A	Caution
UDI	N/A	Unique Device Identifier

	ISO Reg. No. ¹	English
	2606	Do not use if package is damaged
EC REP	N/A	Authorized representative in the European Community
	3082	Manufacturer
	2497	Date of manufacture
	2609	Non-sterile
MD	N/A	Medical device
	N/A	Importer

¹ ISO 7000 *Graphical symbols for use on medical equipment - Registered symbols*



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