



Edwards

KONECT RESILIA Aortic Valved Conduit, Model 11060A Accessory Care and Sterilization Instructions for Sizer Model 1190

Rx only

1.0 Sizer Model 1190

The Sizer Model 1190 is intended to facilitate the selection of the appropriate size of KONECT RESILIA aortic valved conduit (AVC), Model 11060A. Sizers are available in sizes 19, 21, 23, 25, 27 and 29 mm. Sizer Model 1190 allows for direct observation of KONECT AVC fit within the annulus after the native leaflets have been removed or prior prosthetic valve is removed.

The Instructions For Use supplied with KONECT RESILIA AVC provide information on the use of these sizers.

2.0 How Supplied

The sizers are packaged separately, provided non-sterile and must be cleaned and sterilized before each use. They cannot be sterilized in their original packaging.

3.0 Cleaning Instructions

All sizers 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 sizers for signs of wear, such as dullness, cracking or crazing. Replace sizer if any deterioration is observed.

WARNING: Fragments of the sizers cannot be located by means of an external imaging device.

3.1 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.

3.2 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

4.0 Disinfection

4.1 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

4.2 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 sizers in the disinfectant solution, and ensure all air bubbles are removed from the surface of the sizers by wiping with a sterile lint-free cloth.
3. Allow the sizers to soak for a minimum of 12 minutes.
4. Thoroughly rinse the sizers by fully immersing in sterile purified water or equivalent, agitating, and soaking for a minimum of 1 minute.
5. Dry the sizers using a sterile lint-free cloth.

5.0 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.






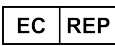





The processing of the product according to the instructions outlined in this IFU is in compliance to ISO 17644 and aligned with HTM 01-01, when using a validated decontamination cycle to ISO 15883 and sterilization to ISO 17665.

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.

Symbol Legend

	ISO Reg. No. ¹	English		ISO Reg. No. ¹	English
	2493	Catalogue Number		2609	Non-sterile
	0434A	Caution		2606	Do not use if package is damaged
 eifu.edwards.com + 1 888 570 4016	1641	Consult instructions for use on the website		N/A	Authorized representative in the European Community
	N/A	Quantity		2492	Lot Number
	N/A	Size		3082	Manufacturer
Rx only	N/A	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.		2497	Date of manufacture

Note: The labeling of this product may not contain every symbol depicted in this legend.

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



EC REP

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