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## **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. Rinse the sizers under cold, running tap water to remove gross soil.
2. Prepare a neutral pH cleaning solution (such as Enzol or equivalent) per the manufacturer's recommendation.
3. Fully immerse the sizers in the cleaning solution and soak for a minimum of 5 minutes. Avoid contact between the sizers.
4. After the 5 minute soak time, use a soft-bristled brush and scrub the sizers for a minimum of 2 minutes to remove any visible soil.
5. Remove the sizers from the cleaning solution and rinse with cold, running tap water, then in reverse osmosis/deionized water for a minimum of 1 minute.
6. If soil is visible, repeat cleaning process.

##### **3.2 Instructions for Automated Cleaning**

1. Rinse the sizers under cold, running tap water to remove gross soil.
2. Prepare a neutral pH cleaning solution (such as Enzol or equivalent) per the manufacturer's recommendation.
3. Fully immerse the sizers in the cleaning solution and soak for a minimum of 1 minute. Avoid contact between the sizers.
4. Load the sizers into the TRAY1190 tray as indicated on the base of the tray.
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            | DETERGENT TYPE AND CONCENTRATION                             |
|--------------|------------------------------|------------------------|--------------------------------------------------------------|
| Pre-wash     | 2:00                         | Cold tap water         | N/A                                                          |
| *Enzyme wash | 2:00                         | Hot tap water          | Neutral pH enzymatic detergent (Enzol or equivalent)         |
| Wash         | 2:00                         | 50-60 °C (122-140 °F)  | Alkaline detergent (Neodisher Mediclean Forte or equivalent) |
| Rinse        | 1:00                         | 60-70 °C (140-158 °F)  | N/A                                                          |
| Drying       | 7:00                         | 90-115 °C (194-239 °F) | N/A                                                          |

\*The enzyme wash phase is optional and may vary based on the washer model.

## 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 | DETERGENT TYPE AND CONCENTRATION |
|---------------|------------------------------|-------------------|----------------------------------|
| Thermal rinse | 5:00                         | 90 °C (194 °F)    | 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.**

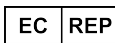
The user is responsible for the qualification of any deviations from the recommended method of cleaning or sterilization.

| Sterilizer Type      | Configuration  | Preconditioning | Minimum Temperature     | Exposure Time | Minimum Dry Time |
|----------------------|----------------|-----------------|-------------------------|---------------|------------------|
| Gravity Displacement | Double Wrapped | N/A             | 132-137 °C (270-279 °F) | 15-18 minutes | 40 minutes       |
| Pre-vacuum           | Double Wrapped | 4 pulses        | 132-137 °C (270-279 °F) | 3-18 minutes  | 30 minutes       |

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

## Symbol Legend

|                                                                                                                       | ISO Reg. No. <sup>1</sup> | English                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------------------------------------------------------------------------------|
|                                       | 2493                      | Catalogue Number                                                                            |
|                                      | 0434A                     | Caution                                                                                     |
|  eifu.edwards.com<br>+ 1 888 570 4016 | 1641                      | Consult instructions for use on the website                                                 |
|                                      | N/A                       | Quantity                                                                                    |
|                                       | N/A                       | Size                                                                                        |
| Rx only                                                                                                               | N/A                       | Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. |

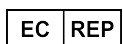
|                                                                                   | ISO Reg. No. <sup>1</sup> | English                                             |
|-----------------------------------------------------------------------------------|---------------------------|-----------------------------------------------------|
|  | 2609                      | Non-sterile                                         |
|  | 2606                      | Do not use if package is damaged                    |
|  | N/A                       | Authorized representative in the European Community |
|  | 2492                      | Lot Number                                          |
|  | 3082                      | Manufacturer                                        |
|  | 2497                      | Date of manufacture                                 |

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

<sup>1</sup> ISO 7000 *Graphical symbols for use on medical equipment - Registered symbols*



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