



Edwards

## **Bioprosthetic Valve and Annuloplasty Ring Accessories Care and Sterilization Instructions for SET1173**

**CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.**

### **1.0 Accessories**

These instructions apply to SET1173 for bioprosthetic valves and annuloplasty rings. The Instructions For Use supplied with Edwards Lifesciences bioprosthetic valves and annuloplasty rings provide information on the use of SET1173.

### **2.0 Device Description**

Edwards trays are accessories to Edwards heart valves and annuloplasty rings. Trays do not have direct patient contact. They consist of metal hinges and a thermoformed or injection molded tray base and lid and secured with metal hinge clamps. Trays are available in multiple configurations designed to contain the appropriate accessories for the selected product. The trays are reusable, sold non-sterile, and must be cleaned and sterilized before use. Tray shall hold the valve or ring accessories during sterilization, and storage, and transfer to surgical site.

### **3.0 Intended Use and Indications for Use**

The Edwards trays are intended to aid in the organization, sterilization, and storage of sizers and handles.

An Edwards tray is designed to contain, store, and transfer accessory tools such as sizers and handles, and to hold the specified accessories during product sterilization.

### **4.0 Contraindications**

There are no known contraindications with the use of Edwards' heart valves and annuloplasty ring accessories.

### **5.0 How Supplied**

The accessories are packaged separately, provided non-sterile and must be cleaned, disinfected and sterilized before each use. They cannot be sterilized in their original packaging. There are no special storage conditions required for accessories. The accessories should not be used if the box is damaged.

### **6.0 Intended User**

The intended users for trays are medical professionals with the appropriate training and experience performing surgical aortic, mitral, or tricuspid valve repair.

### **7.0 Cleaning Instructions**

All trays and lids must be cleaned, disinfected 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 accessories for signs of wear, such as dullness, cracking or crazing. Replace accessories if any deterioration is observed.**

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

#### **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), SET TEMPERATURE, DETERGENT TYPE / WATER QUALITY
Pre-wash	2 minutes, Cold potable water, N/A
Wash	2 minutes, 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 minute, 60-70 °C (140-158 °F), potable water
Drying	7 minutes, 115 °C (239 °F), N/A

## 8.0 Disinfection

### 8.1 Instructions for Thermal Disinfection:

1. Load the tray with instruments, as indicated by the tray markings, 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
Thermal rinse	1:00, 90-95 °C (194-203 °F), Critical Water

### 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 accessories in the disinfectant solution, and ensure all air bubbles are removed from the surface by wiping with a sterile, lint-free cloth.
3. Allow the accessories to soak for a minimum of 15 minutes.
4. Thoroughly rinse the accessories by fully immersing in sterile, purified water or equivalent, agitating, and soaking for a minimum of 1 minute. Repeat for 3 times using fresh purified water after each rinse.
5. Dry the accessories using a sterile, lint-free cloth.

## 9.0 Sterilization Instructions

Threaded handles must be disassembled from any accessories before resterilization.

**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.

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

<b>Product</b>	Trays
<b>Model</b>	SET1173
<b>Basic UDI-DI</b>	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](http://ec.europa.eu/growth/sectors/medical-devices/contacts_en).

## Symbol Legend

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

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

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



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