



Edwards

Bioprosthetic Valve and Annuloplasty Ring Accessories Care and Sterilization Instructions for Model 1173B and Model 1173R

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

1.0 Accessories

These instructions apply to Model 1173R Mitral Replica Sizer and Model 1173B Mitral Barrel Sizer 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 these accessories.

2.0 How Supplied

The accessories 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, disinfected and sterilized prior to each use in accordance with appropriate hospital procedures and the following recommended instructions and parameters.

Sizers 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 accessories 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), 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

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
Thermal rinse	1:00, 90-95 °C (194-203 °F), Critical Water

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 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 3 times using fresh, purified water after each rinse.
5. Dry the accessories using a sterile, lint-free cloth.

5.0 Sterilization Instructions

Sizers must be disassembled from any threaded handles before sterilization.

CAUTION: Do not sterilize any of the accessories in their shipping containers. Sizers must be removed from their plastic pouches prior to sterilization. Each institution should use procedures that include biological indicators to determine the effectiveness of the sterilization procedure.







Model 1173B and model 1173R can be sterilized using the following recommended autoclave sterilization method:




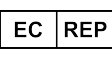

Sterilizer Type	Pre-vacuum
Configuration	Double Wrapped per site specifications
Preconditioning	4 pulses
Minimum Temperature	134 °C (273 °F)
Maximum Temperature	137 °C (279 °F)
Exposure Time	3 minutes
Minimum Dry Time	30 minutes

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.

Symbol Legend

	ISO Reg. No. ¹	English
	2493	Catalogue Number
	2492	Batch Code
	N/A	Quantity
	0434A	Caution
	1641	Consult instructions for use
	2606	Do not use if package is damaged and consult instructions for use

	ISO Reg. No. ¹	English
	N/A	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	3082	Manufacturer
	2497	Date of manufacture
	N/A	Authorized representative in the European Community
	2609	Non-sterile

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



EC REP

Edwards Lifesciences GmbH
Parkring 30
85748 Garching bei München
Germany



2026-03
60057070001 A
© Copyright 2026, Edwards Lifesciences LLC
All rights reserved.



Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA

Telephone 949.250.2500
800.424.3278
FAX 949.250.2525

Web IFU