Edwards

Bioprosthetic Valve and Annuloplasty Ring Accessories Care and Sterilization Instructions for 1140M Handle

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

1.0 Accessories

These instructions apply to the 1140M handle 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 the 1140M handle.

2.0 Device Description

The 1140M handle consists of three sections: a proximal grip section (either polyphenylsulfone or stainless steel), a distal end (either polyphenylsulfone or stainless steel) that attaches to sizers or annuloplasty ring/heart valve holder through a threaded or snap-fit connection, and a middle malleable section made of nitinol or stainless steel, which allows the handle to be bent to the appropriate angle.

3.0 Intended Use and Indications for Use

The 1140M handle is intended to be used in conjunction with Edwards annuloplasty ring sizers and valve annulus sizers to facilitate the selection of the correct size annuloplasty ring or heart valve, and with annuloplasty ring holders or replacement heart valve holders to facilitate the placement of the annuloplasty ring or valve.

The 1140M handle is indicated for use with sizers when sizing the annulus for valve repair or valve replacement is required. The 1140M handle is also indicated for use with annuloplasty ring holders and valve holders during the implantation of annuloplasty rings and heart valve.

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 handles are medical professionals with the appropriate training and experience performing surgical aortic, mitral, or tricuspid valve repair.

7.0 Cleaning Instructions

All handles 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.

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

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)

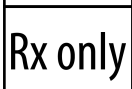
The Basic UDI-DI is the access key for device-related information entered in the Eudamed.

The following table contains the Basic UDI-DI:

Product	Handle
Model	1140M
Basic UDI-DI	0690103D002REH000UD

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
	6050	Model Number
	N/A	Quantity
	2492	Lot Number
	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
	N/A	Unique Device Identifier
	1641	Consult instructions for use on the website

	ISO Reg. No.[1]	English
	2606	Do not use if package is damaged
	N/A	Authorized representative in the European Community
	3082	Manufacturer
	2497	Date of manufacture
	2609	Non-sterile
	N/A	Medical device
	N/A	Conformité Européenne (CE Mark)

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

EC REP

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