



Edwards

Care and Sterilization Instructions for Model 1140M and 1141M Handles, Model 1173B/R Sizers, and Model SET1173 Tray

Rx only

1.0 Accessories

These instructions apply to the following accessories: model 1140M handle, model 1141M handle, model 1173B/R sizers, and model SET1173 tray and lid, for use with MITRIS RESILIA mitral valve, model 11400M, and TRIFORMIS RESILIA tricuspid valve, model 11300T.

The Instructions For Use supplied with MITRIS RESILIA mitral valve, model 11400M, and TRIFORMIS RESILIA tricuspid valve, model 11300T, provide information on the use of these accessories.

2.0 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.

3.0 Cleaning Instructions

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

The 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 the accessories for signs of wear, such as dullness, cracking or crazing. Replace the accessory if any deterioration is observed.

WARNING: Fragments of handles and sizers are not radiopaque and cannot be located by means of an external imaging device.

3.1 Instructions for Manual Cleaning:

Step	Procedure
1	Rinse the accessories 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 (1 oz per 1 gallon (30 ml per 3.8 liters) of warm tap water).
3	Fully immerse the accessories in the cleaning solution and soak for a minimum of 5 minutes. Avoid contact between the accessories.
4	After the 5-minute soak time, use a soft-bristled brush and scrub the accessories for a minimum of 3 minutes to remove any visible soil.
5	Remove the accessories from the cleaning solution and rinse with cold, running tap water. Then rinse in reverse osmosis/deionized water for a minimum of 2 minutes.
6	If soil is visible, repeat the cleaning process.

3.2 Instructions for Automated Cleaning:

Step	Procedure																								
1	Rinse the accessories 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 (1 oz per 1 gallon (30 ml per 3.8 liters) of warm tap water).																								
3	Fully immerse the accessories in the cleaning solution and soak for a minimum of 1 minute. Avoid contact between the accessories.																								
4	Load the handle(s) and sizers into the SET1173 tray as indicated by the tray markings.																								
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: <table border="1" data-bbox="311 566 1487 1104"> <thead> <tr> <th>PHASE</th> <th>RECIRCULATION TIME (MINUTES)</th> <th>TEMPERATURE</th> <th>DETERGENT TYPE</th> </tr> </thead> <tbody> <tr> <td>Pre-wash</td> <td>2:00</td> <td>Cold tap water</td> <td>N/A</td> </tr> <tr> <td>Enzyme wash*</td> <td>2:00</td> <td>Hot tap water</td> <td>Neutral pH enzymatic detergent (Enzol or equivalent) 1 oz per 1 gallon (30 ml per 3.8 liters)</td> </tr> <tr> <td>Wash</td> <td>2:00</td> <td>50 °C (122 °F) (set temperature)</td> <td>Alkaline detergent (Neodisher Mediclean Forte or equivalent) 0.25 oz per 1 gallon (7 ml per 3.8 liters)</td> </tr> <tr> <td>Rinse</td> <td>1:00</td> <td>60 °C (140 °F) (set temperature)</td> <td>N/A</td> </tr> <tr> <td>Drying</td> <td>7:00</td> <td>115 °C (239 °F) (set temperature)</td> <td>N/A</td> </tr> </tbody> </table> <p>*The enzyme wash phase is optional and may vary based on the washer model.</p>	PHASE	RECIRCULATION TIME (MINUTES)	TEMPERATURE	DETERGENT TYPE	Pre-wash	2:00	Cold tap water	N/A	Enzyme wash*	2:00	Hot tap water	Neutral pH enzymatic detergent (Enzol or equivalent) 1 oz per 1 gallon (30 ml per 3.8 liters)	Wash	2:00	50 °C (122 °F) (set temperature)	Alkaline detergent (Neodisher Mediclean Forte or equivalent) 0.25 oz per 1 gallon (7 ml per 3.8 liters)	Rinse	1:00	60 °C (140 °F) (set temperature)	N/A	Drying	7:00	115 °C (239 °F) (set temperature)	N/A
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Drying	7:00	115 °C (239 °F) (set temperature)	N/A																						

CAUTION: Automated cleaning of Model 1141M handle may not adequately remove detergent residue, which could lead to sensitivity in some patients. Refer to Section 3.1 "Instructions for Manual Cleaning" for recommended cleaning parameters for the Model 1141M Handle.

4.0 Disinfection

4.1 Instructions for Thermal Disinfection:

Step	Procedure						
1	Load the handle(s) and sizers into the SET1173 tray, 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: <table border="1" data-bbox="311 1585 1487 1671"> <thead> <tr> <th>PHASE</th> <th>RECIRCULATION TIME (MINUTES)</th> <th>MINIMUM TEMPERATURE</th> </tr> </thead> <tbody> <tr> <td>Thermal rinse</td> <td>5:00</td> <td>90 °C (194 °F)</td> </tr> </tbody> </table>	PHASE	RECIRCULATION TIME (MINUTES)	MINIMUM TEMPERATURE	Thermal rinse	5:00	90 °C (194 °F)
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Thermal rinse	5:00	90 °C (194 °F)					

4.2 Instructions for High Level Disinfection:

Step	Procedure
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.

Step	Procedure
4	Thoroughly rinse 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 sterile, purified water or equivalent, for each rinse.
5	Dry accessories using a sterile, lint-free cloth.

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

Sterilizer Type	Configuration	Preconditioning	Minimum Temperature	Maximum Temperature	Exposure Time (minutes)	Minimum Dry Time (minutes)	Minimum Cool Time (minutes)
Gravity Steam Sterilization	Double-Wrapped	N/A	132 °C (270 °F)	137 °C (279 °F)	15:00	50:00	60:00
Pre-vacuum	Double-Wrapped	4 pulses	132 °C (270 °F)	137 °C (279 °F)	4:00	45:00	15:00

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

Symbol Legend

	ISO Reg. No. ¹	English
	2493	Catalogue Number
	N/A	Quantity
	2492	Lot Number
	2497	Date of manufacture
	3082	Manufacturer

	ISO Reg. No. ¹	English
	N/A	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	1641	Consult instructions for use on the website
	0434A	Caution
	2609	Non-sterile

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

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



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