URGENT MEDICAL DEVICE CORRECTION

This is a voluntary Urgent Medical Device Correction intended to update cooler-heater cleaning instructions.

Attention: Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Materials Management

Affected Products: Sarns™ TCM and TCM II Cooling and Heating Systems; HX2™ Temperature Management Systems

Reference Number: AA-2018-002-C

Effective Date: March 9, 2018

REASON FOR CORRECTION

As part of on-going discussions with the U.S. Food and Drug Administration (FDA) regarding cooler-heater cleaning guide adequacy, Terumo Cardiovascular Systems (Terumo CVS) has updated its cooler-heater instructions for use (cleaning guides).

Despite the lack of confirmed complaints for infection associated with the use of any Terumo CVS cooler-heater device, Terumo CVS is issuing updates to its cleaning guides for specific products in order to provide customers with the most up-to-date information possible.

POTENTIAL HAZARD

While Terumo CVS has not received any confirmed reports of infection resulting from the use of Terumo cooler-heater devices, it is important to follow cleaning guide recommendations when performing cleaning of cooler-heater devices. For additional information on FDA’s recommendations for healthcare facilities, please visit: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm

AFFECTED PRODUCT

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Description</th>
<th>Lot Number or Serial Number Range</th>
<th>Dates of Distribution</th>
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<tbody>
<tr>
<td>15747</td>
<td>Sarns TCM Cooling and Heating Systems</td>
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<tr>
<td>4415, 4416,</td>
<td>Sarns TCM II Cooling and Heating Systems</td>
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<td>809810</td>
<td>HX2 Temperature Management Systems</td>
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</tbody>
</table>
Affected Product:
Sarns TCM and TCM II Cooling and Heating Systems; HX2 Temperature Management Systems
Reference Number: AA-2018-002-C
Effective Date: February 15, 2018

AFFECTED POPULATION

All patients requiring cardiac, vascular or cardiothoracic surgery with the support of Sarns TCM or TCM II Cooling and Heating Systems, or HX2 Temperature Management Systems.

CORRECTION

Updates to the cleaning guides for the products listed in this notice include:

- Clarifying the use of disinfectant wipes when wiping the surfaces of the devices
- Using a 0.22-micron filter
- Performing fill and prime, and draining three times
- Using maintain mode for running the cooling section of the HX2 system
- Meeting the chlorine level
- Using a new 3’ tubing for each cleaning process. Then replacing the tubing used between the cooler-heater and heat exchangers after the completion of each cleaning.

Each of these changes aligns with the FDA published recommendations provided to health care providers that use cooler-heater devices.

CUSTOMER INSTRUCTIONS

1. Discard your current Sarns TCM or TCM II Cooling and Heating Systems, or HX2 Temperature Management Systems cleaning guides.

2. Review this notice and the attached updated cleaning guides, and ensure that all users receive notice of the updated cleaning guides.

3. Return the attached Customer Response Form acknowledging receipt of this notice.

QUESTIONS?

We encourage you to contact Terumo CVS with any questions or concerns:

- **Terumo CVS Customer Service**: 1.800.521.2818 Monday – Friday, 8 a.m. – 6 p.m. ET
- **Recall Fax**: 1.734.741.6149

REPORTING

Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA’s MedWatch Program:

- **Phone**: 1.800.FDA.1088, **Fax**: 1.800.FDA.0178
- **Web**: [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)
  MedWatch Online Voluntary Reporting Form (mail to address on form): [www.fda.gov/Safety/MedWatch/HowtoReport](http://www.fda.gov/Safety/MedWatch/HowtoReport)
GUIDE, TCM CLEANING

11" X 16 1/2"
1 PAGE
PRINT 1 SIDE
PAPER: 80# WHITE COVER
INK: BLACK, PANTONE 301 BLUE
20% SCREEN, PANTONE 301 BLUE WHERE SPECIFIED
3 HOLE DRILL LEFT MARGIN
LAMINATE
FOLD TO 8 1/2" X 11"

NOTE: ARTWORK COPY MUST ACCOMPANY THIS PRINT.

D 91083 CHANGE FROM REMOVE TO MAY HELP MINIMIZE
C 90829 CLEANING GUIDELINE UPDATES
B 89175 REMOVED REFERENCE TO EPA REGISTRATION NUMBER

TERUMO CARDIOVASCULAR SYSTEMS CORPORATION
Ann Arbor, Michigan

TITLE
GUIDE, TCM CLEANING

PART NUMBER 873694

SHEET DRAWING NUMBER REV.
1 873950 D
Observe proper safety precautions when using

• Clean the Coils (every 3 months)

Descale more frequently in areas with a high mineral content in the water supply.

WARNING: Observe proper safety precautions when using Cage Klenz-100. Follow the manufacturer’s directions and safety precautions for proper handling.

Clean with Detergent

- Per Setup, close circuits. Fill and prime if necessary.
- Select Defrost; turn the Cardioplegia on with Large to Small Tank mode and 3 RPM.
- To ≤ 8°C water, add 11 oz. (325.3 ml) of Cage Klenz-100 to large tank. Run for 5 minutes.
- Select Rewarm and Small Tank modes; run for 5 minutes.
- Per Setup, drain. Wipe any debris from the tanks and the tank outlet screens. Screws should be replaced periodically. Do not operate the unit without screens.
- Fill, prime, and drain the system three times using 0.22μm filtered water per the Setup Procedure in these instructions.
- Fill tank and prime.

Add Chlorine per Sanitization Procedure

- Select Defrost; turn the Cardioplegia on with Large to Small Tank mode and 3 RPM.
- To ≤ 8°C water, add 11 oz. (325.3 ml) of Cage Klenz-100 to large tank. Run for 5 minutes.
- Select Rewarm and Small Tank modes; run for 5 minutes.
- Test and confirm the chlorine level is 3 to 5 ppm. Adjust the chlorine level within prescribed limits.

Note: This cleaning guideline supersedes the operator’s manual, 873949, cleaning instructions.

Cage Klenz-100 and S-Klenz are products of Stena Marine, Mentor, Ohio. G 5 A
S-Klenz 1J8108 4X4 Liters/case
Cage Klenz 100 1K1005 5 Gallon Pail
Pall Medical

Product Name Part Number
In-Line Disposable Water Filter AQINA or AQIN for other countries
0.22μm filter
Clorox Healthcare®

Product Name Part Number
Germaline Wipes
05775 or equivalent

TERUMO CARDIOVASCULAR SYSTEMS CORPORATION
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TERUMO AUSTRALIA PTY LTD
Macquarie Park NSW 2113 Australia
TERUMO CORPORATION
Tokyo 151-0072, Japan

Preparations: Descalde Rinse and Drain according to the Descalping Procedure. Wipe any debris from the tanks and the tank outlet screens.

May Help Minimize Biofilm

- Add 20-30 lbs. (9.1-13.6 kg) of ice to the large tank (or make a full block of ice); add ice to small tank.
- Fill tanks and prime.
- Select Defrost; turn Cardioplegia on with Large to Small Tank mode and 3 RPM.
- To ≤ 8°C water; slowly add 11 oz. (325.3 ml) of the 10% Sodium Hypochlorite solution to the large tank. Run for at least 1 hour, adding ice if necessary to keep water below 20°C.
- Select Rewarm and Small Tank modes. Run for at least 1 hour.

Note: If biofilm is still visible, continue alternating between Defrost and Rewarm, running for 1/2 hour at each setting. Keep below 20°C when in Defrost. Do not add more sanitizer. As much as four hours additional time may be required to remove excessive biofilm.

Rinse

- Drain the system.
- Fill, prime, and drain the system three times using 0.22μm filtered water per the Setup Procedure in these instructions.
- Fill tank and prime.
- Select Defrost; turn Cardioplegia on with Large to Small Tank mode and 3 RPM. Run for 2 minutes.
- Select Rewarm and Small Tank modes. Run for 2 minutes. Test the chlorine level. Sanitize and Descalpe Procedure. Replace all external water lines once the unit is drained.
- Make new ice or store the unit.
- Wipe any debris from the tanks and the tank outlet screens.