TERUMO
CARDIOVASCULAR

URGENT MEDICAL DEVICE RECALL

Attention:	**Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Risk Management**
Affected Product:	**Sarns™ TCM and TCM II Cooling and Heating Systems; HX2™ Temperature Management Systems**
Reference Number:	**AA-2021-001-C**
Effective Date:	**April 30, 2021**

REASON FOR RECALL

This letter is to advise you that Terumo Cardiovascular Systems (Terumo CVS) is conducting a voluntary Urgent Medical Device Recall of the HX2 and TCM I, TCM II Heater Cooler devices in use in the field. Users should discontinue the use of and dispose of HX2, TCM I and TCM II devices. No other Terumo CVS products are affected by this action.

ISSUE DESCRIPTION

In recent years, safety issues have been raised by regulators, including FDA, regarding water system quality of temperature controllers, regardless of the manufacturer. The concern stems from the potential for bacterial growth in the water systems that may be transmitted to patients during surgery and is likely related to the recommended water system cleaning practices and protocols employed.

Terumo CVS has collaborated with regulators to develop a revised cleaning protocol for the HX2, TCM I and TCM II devices, but after significant efforts, we have been unable to validate a cleaning protocol to satisfy current regulatory concerns and expectations. As a result, an updated cleaning protocol will not be developed by Terumo CVS and it has been determined that the best course of action is for users to discontinue use of and dispose of HX2, TCM I and TCM II devices. Terumo CVS records indicate that you may have one or more remaining affected HX2, TCM I and TCM II devices in your possession.

NEXT STEPS

Review this Medical Device Recall and assure that all users have received notice of this issue.

Confirm receipt of this communication by completing and returning the attached Customer Response Form.

Terumo CVS recommends that you discontinue use of your Heater Cooler device and discard the device.

If you have any questions regarding this notice, please contact Terumo CVS Customer Service:

800.521.2818

Customer Service Hours:
Monday – Friday,
8 a.m. – 6 p.m. ET

CORRECTION

HX2, TCM I and TCM II devices should no longer be used for clinical procedures. An updated cleaning protocol will not be developed by Terumo CVS. Dispose of any devices in your possession per your normal equipment obsolescence procedures. Do not resell for clinical use.

AFFECTED POPULATION

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

AFFECTED PRODUCT

Catalog Number	Product Description	Lot Number or Serial Number Range	Dates of Distribution
15747	Sarns TCM Cooling and Heating Systems	All	May 2,1985 through June 10, 2015
4415, 4416, 164925,164935, 164930, 164940	Sarns TCM II Cooling and Heating Systems		
809810	HX2 Temperature Management Systems		

CUSTOMER INSTRUCTIONS

1. Review this Medical Device Recall communication and ensure that all users have received notice of this issue.
2. This notice needs to be passed on to any organization where the potentially affected products have been transferred.
3. Discontinue use of the HX2, TCM I and TCM II devices in your possession and dispose of the device using your normal equipment obsolescence procedures.
4. Confirm receipt of this communication by completing and returning the attached Customer Response Form as indicated on the form.

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
  MedWatch Online Voluntary Reporting Form (mail to address on form): www.fda.gov/Safety/MedWatch/HowtoReport