Terumo Recalls Sarns™ TCM and TCM II Cooling and Heating Systems and HX2™ Temperature Management Systems Due to Revised Cleaning Instructions

The FDA has identified this as Class II recall, a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- Recalled Product: Sarns™ TCM and TCM II Cooling and Heating Systems; HX2™ Temperature Management Systems
- Product Code: DWC
- Catalog Numbers:
  - Sarns™ TCM: 15747
  - Sarn™s ™TCM II: 4415, 4416, 164925, 164930, 16435, 164940
  - HX2™: 809810
- Distribution Dates: May 2, 1985 to June 10, 2015
- Manufacturing Dates: May 2, 1985 to March 20, 2013
- Devices Recalled in the U.S.: 450

Device Use

The Sarns™ TCM and TCM II Cooling and Heating Systems and the HX2™ Temperature Management Systems, are **Heater-Cooler Devices (/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm)** used during surgeries to warm or cool patients as part of their care. These heater-cooler devices include tanks that provide temperature-controlled water to external heat exchangers or to warming/cooling blankets through closed water circuits.

Reason for Recall

In response to **FDA's ongoing Investigation of Nontuberculous Mycobacteria Infections Associated with Heater-Cooler Devices (/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492590.htm)**, Terumo has revised their cleaning instructions for their Sarns™ TCM ,TCM II, and HX2™ heater-cooler devices to reduce the risk of infection to patients.

There is the potential for non-tuberculous mycobacteria (NTM) to grow in the water tank of the heater-cooler units. While the water in the heater-cooler unit does not encounter the patient's blood or body fluids, the contaminated water droplets from the tank may disperse bacteria into the air (aerosolize) as it escapes from the heater-cooler unit into the operating room environment. This may lead to infection or other adverse events, primarily in cardiovascular patients undergoing open-chest surgical procedures.

Who May be Affected

- Patients undergoing cardiac, vascular or cardiothoracic surgery with the support of these affected heather-cooler devices.
- Health care providers using the affected heater-cooler devices in the operating room, during cardiac, vascular or cardiothoracic surgery.

What to Do

On March 19, 2018 Terumo sent an Urgent Medical Device Correction notice to all affected customers informing them of the updated cleaning guides. The notice asked customers to:

1. Discard any current Sarns™ TCM or TCM II Cooling and Heating Systems, or HX2™ Temperature Management Systems cleaning guides.
2. Review the Medical Device Correction notice and the updated cleaning guides, and ensure the appropriate staff is aware of the updated cleaning guides. The updated cleaning guides include:
    - Clarifying the use of disinfectant wipes when wiping the surfaces of the devices
    - Using a 0.22-micron filter when filling, refilling, topping off and/or rinsing the devices
    - 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.
3. Return the Customer Response Form, acknowledging receipt of this notice, to Terumo Recall Email: **tcvs.recall@terumomedical.com (mailto:tcvs.recall@terumomedical.com)** or Terumo Recall Fax: 734-741-6149.

Health care providers and staff at health care facilities should also continue to follow **FDA's recommendations (/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/ucm492583.htm)** *when using heater-cooler devices to help reduce the risk of infection to* patients.

Contact Information

Customers with questions may contact Terumo Cardiovascular Systems at:

Phone: 1.800.521.2818 Monday – Friday, 8 a.m. – 6 p.m. ET
Fax: 1.734.741.6149

Date Recall Initiated

March 16, 2018

Additional Resources

- **FDA's Heater-Cooler Devices web page (/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-CoolerDevices/default.htm)**
- ***FDA's Heater-Cooler Devices: Information for Patients* (/MedicalDevices/ProductsandMedicalProcedures/CardiovascularDevices/Heater-**

CoolerDevices/ucm492585.htm)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)**either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)