



Republic of the Philippines  
Department of Health  
**FOOD AND DRUG ADMINISTRATION**



**FDA ADVISORY**  
No. **2021-1728**

12 JUL 2021

**TO: ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

**SUBJECT: Voluntary Recall of Terumo Sarns™ TCM II Cooling and Heating Systems**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Terumo Sarns™ TCM II Cooling and Heating Systems manufactured by Terumo Cardiovascular Systems Corporation, imported and distributed by Terumo Marketing Philippines, Inc.:

Item Code	Description	Affected Lot Numbers
164925	TCM II, with Cardioplegia, 110V/60Hz	All lot numbers distributed from 05/02/1985 to 06/10/2015
164930	TCM II, without Cardioplegia, 110V/60Hz	
164935	TCM II, with Cardioplegia, 220V/50Hz	
164940	TCM II, without Cardioplegia, 220V/50Hz	
15747	TCM	



Figure 1. Terumo Sarns™ TCM II Cooling and Heating Systems



Terumo Marketing Philippines, Inc. initiated the voluntary recall of the above-mentioned lots/batches of Terumo Sarns™ TCM II Cooling and Heating Systems in the Philippines due to the medical device recall done by the US FDA (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=187216>). Based on the medical device recall done by the US FDA, the Terumo Cardiovascular Systems Corporation initiated the removal of all lot numbers distributed from 05/02/1985 to 06/10/2015 of Terumo Sarns™ TCM II Cooling and Heating Systems after the manufacturer has 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.

In light of the foregoing, all concerned healthcare professional, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batches of Terumo Sarns™ TCM II Cooling and Heating Systems.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at [cdrrhr@fda.gov.ph](mailto:cdrrhr@fda.gov.ph), or call (02) 8857-1900 loc. 8301.

Dissemination of this advisory to all concerned is hereby requested.

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General

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