The Sarns Temperature Control and Monitor unit (TCM) is a source of temperature-controlled water for blood heat exchangers used in an extracorporeal circuit and for blankets to externally heat or cool the patient. The TCM with options will also supply water for cardioplegia, freeze water for an ice supply, monitor temperatures in the patient and extracorporeal circuit, and allow gradient rewarming relative to a venous blood temperature.

Device Name / Model Number:
TCM II TUV, 115V (P/N 4415),
TCM II TUV, 220V (P/N 4416),

Catalog Number:
4416, 164940

Recalling Firm/Manufacturer
Terumo Cardiovascular Systems Corporation
6200 Jackson Rd
### For Additional Information Contact

Mary Swift  
734-741-6056

### Manufacturer Reason for Recall

Terumo CVS 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.

### FDA Determined Cause

Device Design

### Action

On 04/30/2021, Terumo issued an Urgent Medical Device Removal notice to customer via letter notifying users to discontinue the use of and dispose of HX2, TCM I and TCM II devices. Customers were instructed to confirm receipt of this communication by completing and returning the attached Customer Response Form as indicated on the form. For questions contact Terumo CVS Customer Service: 1-800-521-2818.

### Quantity in Commerce

1176 devices

### Distribution

Domestic: Foreign: Australia, Belgium, Canada, Chile, China, Colombia, Dominican Republic, England, France, Germany, Greece, Hong Kong, India, Indonesia, Iran, Israel, Italy, Japan, Korea, Malaysia, Mexico, Netherlands, New Zealand, Norway, Philippines, Russia, Saudi Arabia, Singapore, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, UNITED ARAB EMIRATES (UAE), Vietnam

### Total Product Life Cycle

TPLC Device Report

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1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls.

2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

3 The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

### 510(K) Database

510(K)s with Product Code = DWC and Original Applicant = SAMS, INC.