FDA

See Related Information [22]

Class 2 Device Recall Cardiovascular Procedure Kits, Tubing Pack

Date Initiated by Firm	December 18, 2017
Create Date	April 06, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1314-2018
Recall Event ID	79524[23]
Product Classification	Cardiovascular procedure kit[24] - **Product Code** OEZ[25]
Product	Terumo Cardiovascular Procedure Kits containing Pall LG6NS LeukoGuard¿ Leukocyte Reduction Arterial Blood Filters. The Cardiovascular Procedure Kit containing the Pall LG6NS LeukoGuard¿ Leukocyte Reduction Arterial Blood Filter for Exh¿acorporeal Service is indicated for use only in the exh¿acorporeal circuit for cardiopulmonary bypass procedures for which the user designed it. The product is a sterile, disposable kit, intended for one time use for period up to 6 hours, after which it must be discarded in a manner which is within acceptable laws and practices. The Pall LG6NS LeukoGuard ¿ Leukocy1e Reduction Arterial Blood Filter for Exh¿acorporeal Service is designed to reduce the levels of circulating leucocy1es and exclude microemboli greater than 40 ¿m in size from the perfu sate during exh¿acorporea l circulation. This included gas emboli, fat emboli and aggregates composed of platelets, red blood cells and other debris. The Pall LG6NS LeukoGuard ¿ Leukocyte Reduction Arterial Blood Filter can be included in Cardiovascular Procedure Kits (Convenience Kits). When the Pall LG6NS LeukoGuard¿ Leukocyte Reduction Arterial Blood Filters is included in the Kits, the intended use of the filter remains unaffected.
Code Information	662143, 735568, 752561, 767041, 774364, 775404, 778816, 783025, 785629, 794402, 794411, 735568.
Recalling Firm/ Manufacturer	Terumo Cardiovascular Systems Corp 28 Howe St Ashland MA 01721-1305
For Additional Information Contact	800-262-3304
Manufacturer Reason for Recall	Possible blood leaks through the hydrophobic portion of the Pall LG6NS LeukoGuard Leukocyte Reduction Arterial Blood Filters.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	*On December 18, 2017 a MEDICAL DEVICE RECALL letter was issued to customers with the specific lot codes and distribution dates listed on the customer response form. This letter requests customers to do the following: Review this Medical Device Recall Notice. Assure that all users receive notice of this issue. Refer to the Customer Response Form to identify your product that is subject to this action. Confirm receipt of this notification by completing and returning the attached Customer Response Form to the email address or fax number indicated on the form. Terumo CVS will issue a Returned Goods Authorization upon receipt*