Class 2 Device Recall Cardiovascular Procedure Kits, Tubing Pack

Date Initiated by Firm December 18, 2017
Create Date April 06, 2018
Recall Status Open, Classified
Recall Number Z-1314-2018
Recall Event ID 79524
Product Classification Cardiovascular procedure kit - Product Code OEZ
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_acroporeal Service is indicated
for use only in the exh_acroporeal 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
Leukocyte Reduction Arterial Blood Filter for Exh_acroporeal Service is designed
to reduce the levels of circulating leucocytes and exclude microemboli greater than
40 μm in size from the perfu sate during exh_acroporeal 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, 752651, 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 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. Ensure
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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=162581
4/10/2018