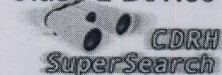


FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Gambro Cartridge Blood Set

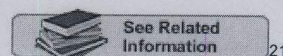


510(k)⁷|Registration & Listing⁸|Adverse Events⁹|Recalls¹⁰|PMA¹¹|Classification¹²|Standards¹³|Inspections¹⁴
CFR Title 21¹⁵|Radiation-Emitting Products¹⁶|X-Ray Assembler¹⁷|Medsun Reports¹⁸|CLIA¹⁹|TPLC²⁰

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Class 2 Recall Gambro Cartridge Blood Set



Date Posted	April 11, 2014
Recall Status¹	Open
Recall Number	Z-1455-2014
Recall Event ID	<u>67797²²</u>
Product Classification	<u>Set, Tubing, Blood, With And Without Anti-Regurgitation Valve²³ - Product Code FJK²⁴</u>
Product	Gambro Cartridge Blood Set, blood transport system for hemodialysis, Model Number(s): 101025 (003410510) - Cartridge set, STND PRM LN and 103401 (003414500) - Cartridge set, PRM_LN_INJ_PT. The Gambro Cartridge Sets are single use sterile tubing sets intended to provide extracorporeal blood transport circuit for hemodialysis treatments for Gambro Phoenix and COBE Centrisystem 3 (and 3+) Dialysis Delivery Systems.
Code Information	Lot number: 1000039228, 1000048340, 1000050644, 1000050648, 1000054032, 1000058516, 1000064913, 1000065817, 1000065823, 1000066430, 1000063347, 1000067984, 1000068071, 1000071417, 1000071430, 1000073434, 1000073436, 1000073438, 1000074660, 1000074661, 1000074662, 1000075553
Recalling Firm/ Manufacturer	Gambro Renal Products, Incorporated 14143 Denver West Pkwy Lakewood, Colorado 80401-3266
Manufacturer Reason for Recall	Occluded heparin tubing events preventing anticoagulation dosing on the Gambro Cartridge Blood Sets.
FDA Determined Cause²	PRODUCTION CONTROLS: Process Control
Action	On 12/9/13 and 3/12/14, a field safety notice sent via UPS overnight delivery informing customers of issue and if any customer wants to return product, a hold at distribution centers and manufacturer quarantine areas. Upon reconciliation of returned product a destruction disposition with certification.
Quantity in Commerce	306,525 sets (20435 boxes of 15 sets)
Distribution	Worldwide Distribution-USA (nationwide) and the countries of Canada, Mexico, and Colombia.
Total Product Life Cycle	<u>TPLC Device Report²⁵</u>

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55²⁶](#)

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

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