Class I Medical Device Recall: Lee Medical International Inc., Custom Dialysis Trays / Kits

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: August 15, 2011

Products: Custom Dialysis Trays/Kits (For product names, lot/serial numbers, expiration dates, BIN numbers, please see table below).

These products were manufactured from November 17, 2010 through January 11, 2011 and distributed from November 23, 2010 through January 12, 2011.

See related Class I Recall Notice under **Additional Links** below.

Use: The custom dialysis trays/kits are designed to include all the components (gloves, bandages, fistula needles, Povidone Iodine (PVP), alcohol swabs and prep pads, and specific bloodlines) used in preparing the hemodialysis vascular access sites for patients undergoing dialysis procedures.

Recalling Firm:

Lee Medical International, Inc.
612 Distributors Row
Harahan, Louisiana 70123-3206

Reason for Recall : These custom dialysis trays/kits contain alcohol swabs and prep pads that were recalled by H & P Industries. The alcohol swabs and prep pads may not be sterile. Patients receiving hemodialysis who use the swabs and pads may be at potential risk for serious or life threatening infection.

Public Contact: Customers may contact the company at 1-800-433-8950.

FDA District: New Orleans

FDA Comments:

Summary of Recall: On August 17, 2011, the company notified their customers (hospitals and clinics) by email and by telephone.

Product Names, Cases, Lot Numbers, Expiration Dates, BIN Numbers
• ADV-CARE-ISL44, 100/CS, LOT #K1018, EXP 5-12, BIN 34B • COMMUNITY-CATH, 150/CS, LOT #K1052, EXP 5-12, BIN 36B • COLUMBUS-CATH, 50/CS, LOT #1080, EXP 05-12, BIN 39B • RENALSG-CATH, 75/CS, LOT #L1046, EXP 6-12, BIN 40B

- SUNYDOWN-HEMO, 100/CS, LOT #l1015, EXP 6-12, BIN 28A
- KIDNEYCARE, 125/CS, LOT #l1070, EXP 6-12
- METHODIST-CATH, 75/CS, LOT #L1072, EXP 6-12
- METHODIST-HEMO, 150/CS, LOT #L1073, EXP 6-12
- MERCYMED-CATH, 75/CS, LOT #L1077, EXP 6-12, BIN 39A
- SANTACLA-CATH, 75/CS, LOT #A1118, EXP 7-12, BIN 44A

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

Additional Links:

- Related Class I Recall Notice [2]
- Related Recall - Firm Press Release [3]

SOURCE [4]

Source URL (retrieved on *09/15/2014 - 8:54pm*):
http://www.mdtmag.com/news/2011/10/class-i-medical-device-recall-lee-medical-international-inc-custom-dialysis-trays/kits

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm272167.htm
[3] http://www.fda.gov/Safety/Recalls/ucm247658.htm
[4] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm274192.htm