Class 2 Device Recall Esmark Elastic Bandage

Class 2 Recall Esmark Elastic Bandage See Related Information[21]

Date Posted	May 21, 2014
Recall Status[1]	Open
Recall Number	Z-1649-2014
Recall Event ID	67858[22]
Product Classification	Bandage, Elastic[23] - **Product Code** FQM[24]
Product	Individually wrapped Esmark Elastic Bandage (Sterile), 4" x 9'. 20 bandages per case. Packaged by Medline Industries Inc., Mundelein, IL 60060. This product is used as an elastic bandage to support and compress a part of a patient's body. It is also used as a tourniquet to restrict blood flow to a part of a patient's body.
Code Information	Product Number: DYNJ05116A . Lot Number: 13LA1009.
Recalling Firm/ Manufacturer	Medline Industries Inc 1 Medline Pl Mundelein, Illinois 60060-4485
For Additional Information Contact	Ms. Kassandra Cotner 866-359-1704
Manufacturer Reason for Recall	Medline Industries, Inc. is voluntarily recalling item DYNJ05116A, Esmark Elastic Bandage (Sterile), 4" x 9', with lot number 13LA1009 that did not go through the correct sterilization procedures. This product may potentially be non-sterile.
FDA Determined Cause [2]	TRAINING: Employee Error
Action	Medline Industries issued an Immediate Action Required letter dated March 20, 2014 to all affected customers. The letters included instructions to: 1) immediately check inventories for the recalled products and quarantine the recalled products; 2) complete and return the enclosed destruction form listing the quantity of destroyed product (credit will only be issued if the completed form is received); and 3) If the customer is a distributor, promptly notify the distributor's customers that may have received the recalled products about this recall. Direct accounts and their customers that have any questions can contact Medline Industries at 866-359-1704.
Quantity in Commerce	2,860 bandages
Distribution	Nationwide Distribution including AZ, CA, IA, IL, IN, KY, LA, MI, MS, NJ, NY, OH, PA, TX, and WA.
Total Product Life Cycle	TPLC Device Report[25]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[26]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain