Class 2 Device Recall CooperSurgical

Date Posted: July 17, 2015
Recall Status: Open
Recall Number: Z-2098-2015
Recall Event ID: 71582
Product Classification: Diator, Vaginal - Product Code HDX
Product: Milex Vaginal-Hymenal Silicone Dilators Set of 4 P/N MX20 Product Usage: The CooperSurgical Milex Vaginal-Hymenal Silicone Dilators are used for progressive vaginal dilation therapy involving the treatment of vaginismus (muscular spasm of the vagina) and conditions that result in constriction of the vaginal and/or rectal orifice
Code Information: LOT 156966
Recalling Firm/Manufacturer: CooperSurgical, Inc.
75 Corporate Dr.
Trumbull, Connecticut 06611-1350
For Additional Information Contact: SAME
203-601-5200
Manufacturer Reason for Recall: Incorrect expiration date on outer carton kit label
FDA Determined Cause: EXPIRATION DATING: Incorrect or No Expiration Date
Action: CooperSurgical sent an Urgent Medical Device Recall dated June 19, 2015 to affected customers. The letter identified the affected product, problem and actions to be taken. Customers were instructed to discontinue use of the affected products and complete the attached Acknowledgement and Receipt Form for a replacement. For questions call 203.601.5200.
Quantity in Commerce: 40 kits
Distribution: US Nationwide Distribution in the states of: CA, FL, GA, HI, IL, KY, MD, MN, NC, NY, OH, TX, VT, and WA.
Total Product Life Cycle: TPLC Device Report

For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55.

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

Links on this page: