Class 2 Device Recall Optionvf Urinary Catheter. Female use only. Latex Free. Sterile, Rx only.

Date Initiated by Firm: July 11, 2016
Create Date: September 15, 2016
Recall Status: Open, Classified
Recall Number: Z-2830-2016
Recall Event ID: 74712
510(K)Number: K023092
Product Classification: Catheter, retention type, balloon - Product Code EZL
Product: Option-vf Urinary Catheter. Female use only. Latex Free. Sterile, Rx only.
Code Information: Device Listing No.: D022512. CatalogNo.: FV14218. Lot No.: P1007637, P1007638, P1007461. Exp Date: 08/01/2016.
Recalling Firm/Manufacturer: C.R. Bard, Inc.
8195 Industrial Blvd NE
Covington GA 30014-1497
For Additional Information Contact: Bard Medical Division Field Assurance
800-526-4455
Manufacturer Reason for Recall: During an FDA inspection it was found out that the Practical Foley Catheters to be potentially nonsterile.
FDA Determined Cause: Device Design
Action: C.R. Bard sent an Urgent - Medical Device Product Recall letter dated July 8, 2016, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. The firm notifies customers of the recall, provides a clinical risk statement, and gives instructions regarding product disposition. Facilities are instructed to examine their inventory and quarantine any recalled product. The firm requested that customers complete the Recall & Effectiveness Check Form if product is or is not in inventory. If product was further distributed, customers should be forwarded the recall notification letter and Recall & Effectiveness Check Form. If you or the patient using these catheters has had an adverse event related to the recalled catheters, please contact Bard Medical Division Field Assurance at 1-800-526-4455 (option 5, then option 4) or via email at BMD.FieldAssurance@crbard.com.
Quantity in Commerce: 274 units
Distribution: US Distribution to the states of: AL, CA, CO, FL, IL, IN, MA, MD, NJ, NY, OR, PA, TN, WA, and WI.
Total Product Life Cycle: TPLC Device Report

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=148278
10/18/2016
Class 2 Device Recall Optionvm Urinary Catheter. Male use only. Latex Free. Sterile, Rx only.

Date Initiated by Firm: July 11, 2016
Create Date: September 15, 2016
Recall Status: Open, Classified
Recall Number: Z-2831-2016
Recall Event ID: 74712
510(K) Number: K041983
Product Classification: Catheter, retention type, balloon - Product Code EZL
Product: Option-vm Urinary Catheter. Male use only. Latex Free. Sterile, Rx only.
Recalling Firm/Manufacturer: C.R. Bard, Inc.
8195 Industrial Blvd NE
Covington GA 30014-1497
For Additional Information Contact: Bard Medical Division Field Assurance
800-526-4455
Manufacturer Reason for Recall: During an FDA inspection it was found out that the Practical Foley Catheters to be potentially nonsterile.
FDA Determined Cause: Device Design
Action: C.R. Bard sent an Urgent - Medical Device Product Recall letter dated July 8, 2016, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. The firm notified customers of the recall, provides a clinical risk statement, and gives instructions regarding product disposition. Facilities are instructed to examine their inventory and quarantine any recalled product. The firm requested that customers complete the Recall & Effectiveness Check Form if product is or is not in inventory. If product was further distributed, customers should be forwarded the recall notification letter and Recall & Effectiveness Check Form. If you or the patient using these catheters has had an adverse event related to the recalled catheters, please contact Bard Medical Division Field Assurance at 1-800-526-4455 (option 5, then option 4) or via email at BMD.FieldAssurance@crbard.com.
Quantity in Commerce: 274 units
Distribution: US Distribution to the states of: AL, CA, CO, FL, IL, IN, MA, MD, NJ, NY, OR, PA, TN, WA, and WI.
Total Product Life Cycle: TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA