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

New Search

Back to Search Results

See Related Information 22

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[1]	Open[3], Classified
Recall Number	Z-2830-2016
Recall Event ID	74712[23]
510(K)Number	K023090[24]
Product Classification	Catheter, retention type, balloon[25] - **Product Code** EZL[26]
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 [2]	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[27]

Class 2 Device Recall Optionvm Urinary Catheter. Male use only. Latex Free. Sterile, Rx only.

See Related Information[22]

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[1]	Open[3], Classified
Recall Number	Z-2831-2016
Recall Event ID	74712[23]
510(K)Number	K041983[24]
Product Classification	Catheter, retention type, balloon[25] - **Product Code** EZL[26]
Product	Option-vm Urinary Catheter. Male use only. Latex Free. Sterile, Rx only.
Code Information	Device Listing No.: D022515. CatalogNo.: MV39016. Lot No.: P1007642, P1007465, P1007466, P1007643, P1007641, P1007640, P1007468, P1007467. 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 [2]	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[27]

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