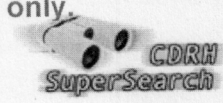


FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>  
**Class 2 Device Recall Optionvf Urinary Catheter. Female use only. Latex Free. Sterile, Rx only.**

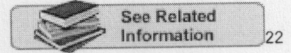


6 510(k)|DeNovo<sup>8</sup> | Registration & | Adverse |Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
 7 Listing<sup>9</sup> Events<sup>10</sup>  
 CFR Title 21<sup>16</sup>|Radiation-Emitting Products<sup>17</sup>|X-Ray Assembler<sup>18</sup>|Medsun Reports<sup>19</sup>|CLIA<sup>20</sup>|TPLC<sup>21</sup>

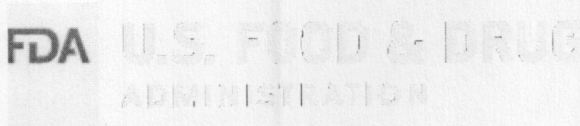
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**Class 2 Device Recall Optionvf Urinary Catheter. Female use only. Latex Free. Sterile, Rx only.**

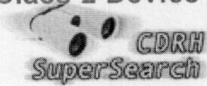


<b>Date Initiated by Firm</b>	July 11, 2016
<b>Create Date</b>	September 15, 2016
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2830-2016
<b>Recall Event ID</b>	74712 <sup>23</sup>
<b>510(K)Number</b>	<u>K023090</u> <sup>24</sup>
<b>Product Classification</b>	<u>Catheter, retention type, balloon</u> <sup>25</sup> - <b>Product Code</b> <u>EZL</u> <sup>26</sup>
<b>Product</b>	Option-vf Urinary Catheter. Female use only. Latex Free. Sterile, Rx only.
<b>Code Information</b>	Device Listing No.: D022512. CatalogNo.: FV14218. Lot No.: P1007637, P1007638, P1007461. Exp Date: 08/01/2016.
<b>Recalling Firm/Manufacturer</b>	C.R. Bard, Inc. 8195 Industrial Blvd NE Covington GA 30014-1497
<b>For Additional Information Contact</b>	Bard Medical Division Field Assurance 800-526-4455
<b>Manufacturer Reason for Recall</b>	During an FDA inspection it was found out that the Practical Foley Catheters to be potentially nonsterile.
<b>FDA Determined Cause<sup>2</sup></b>	Device Design
<b>Action</b>	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.
<b>Quantity in Commerce</b>	274 units
<b>Distribution</b>	US Distribution to the states of : AL, CA, CO, FL, IL, IN, MA, MD, NJ, NY, OR, PA, TN, WA, and WI.
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <sup>27</sup>



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

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

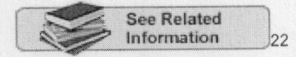


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>3</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

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



<b>Date Initiated by Firm</b>	July 11, 2016
<b>Create Date</b>	September 15, 2016
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-2831-2016
<b>Recall Event ID</b>	<a href="#">74712</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K041983</a> <sup>24</sup>
<b>Product Classification</b>	Catheter, retention type, balloon <sup>25</sup> - <b>Product Code EZL</b> <sup>26</sup>
<b>Product</b>	Option-vm Urinary Catheter. Male use only. Latex Free. Sterile, Rx only.
<b>Code Information</b>	Device Listing No.: D022515. CatalogNo.: MV39016. Lot No.: P1007642, P1007465, P1007466, P1007643, P1007641, P1007640, P1007468, P1007467. Exp Date: 08/01/2016.
<b>Recalling Firm/ Manufacturer</b>	C.R. Bard, Inc. 8195 Industrial Blvd NE Covington GA 30014-1497
<b>For Additional Information Contact</b>	Bard Medical Division Field Assurance 800-526-4455
<b>Manufacturer Reason for Recall</b>	During an FDA inspection it was found out that the Practical Foley Catheters to be potentially nonsterile.
<b>FDA Determined Cause<sup>2</sup></b>	Device Design
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<b>Quantity in Commerce</b>	274 units
<b>Distribution</b>	US Distribution to the states of : AL, CA, CO, FL, IL, IN, MA, MD, NJ, NY, OR, PA, TN, WA, and WI.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

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