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## Class 2 Device Recall Arrow MultiLumen Central Venous Catheterization

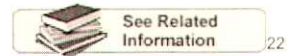


6 510(k)<sup>7</sup> | DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | Classification<sup>13</sup> | Standards<sup>14</sup>  
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### Class 2 Recall Arrow MultiLumen Central Venous Catheterization



Date Posted	October 16, 2014
Recall Status <sup>1</sup>	Open
Recall Number	Z-0076-2015
Recall Event ID	<u>69290</u> <sup>23</sup>
Premarket Notification 510(K) Number	<u>K862056</u> <sup>24</sup>
Product Classification	<u>Catheter, Percutaneous</u> <sup>25</sup> - <b>Product Code</b> <u>DQY</u> <sup>26</sup>
Product	Multi-Lumen Central Venous Catheterization Kit
Code Information	Catalog No - AK-12703 lot number RF3039028
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Road Reading, Pennsylvania 19605
For Additional Information Contact	Customer Support 610-378-0131
Manufacturer Reason for Recall	Arrow International, Inc. has initiated a voluntary recall for product code AK- 12703, lot number RF3039028 because the label on the outer corrugate is labeled with the incorrect expiration date. All kits packaged within the corrugate are correctly labeled. There is no risk to the patient as the kits within the corrugate are labeled with the correct expiration date.
FDA Determined Cause <sup>2</sup>	MISBRANDING: Labeling False and Misleading
Action	Arrow International sent an Medical Device Advisory Notifications letter dated September 18, 2014, sent to direct accounts to notify them about the product, problem, and actions to be taken. Arrow International, Inc. (Arrow) is notifying customers that the label on the outer corrugate for the above mentioned product code and lot number is labeled with the incorrect expiration date. All kits packaged within the corrugate are correctly labeled. There is no risk to the patient as the kits within the corrugate are labeled with the correct expiration date. Arrow International, Inc. is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service at 1-866-246-6990.
Quantity in Commerce	65
Distribution	US Distribution including the states of MD, NC , LA , IN , OH, KY, CA , PA , NY and NV.
Total Product Life Cycle	<u>TPLC Device Report</u> <sup>27</sup>

<sup>1</sup> For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55<sup>28</sup>

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database 510(K)s with Product Code = DQY and Original Applicant = ARROW INTL., INC.<sup>29</sup>