FDA

Class 2 Device Recall ARROW MAC TwoLumen Central Venous Access Kit

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Class 2 Device Recall ARROW MAC TwoLumen Central Venous Access Kit

Date Initiated by Firm	May 09, 2017
Create Date	June 12, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2335-2017
Recall Event ID	77232[23]
510(K)Number	K002507[24]
Product Classification	Catheter,intravascular,therapeutic,short-term less than 30 days[25] - **Product Code** FOZ[26]
Product	Arrow MAC Two-Lumen Central Venous Access Kit Introducer Catheter The Arrow Two-Lumen Central Venous Access device permits venous access and catheter introduction to the central circulation
Code Information	Material number: CDC-11242-1A, Device Listing D025760
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	610-378-0131
Manufacturer Reason for Recall	Arrow International is recalling the affected product because the packaging may not be completely sealed, which may compromise sterility.
FDA Determined Cause [2]	Packaging
Action	Arrow International sent an Urgent Medical Device Recall Notification Letter dated May 11, 2017, to affected customers. The firm's notification letter is requesting that customers immediately assess their current inventory and to discontinue and quarantine any product with the specific lot codes listed in the letter. In addition, customers were asked to complete the Recall Acknowledgement form and fax or email it back to Customer Service so they can receive a Returns Good Authorization Number for the product's return. Customers with questions were instructed to contact their local sales representative or Customer Service at 1-866-246-6990.
Quantity in Commerce	27,485 units distributed in U.S., 4,371 units distributed internationally
Distribution	Worldwide Distribution - US (nationwide) and Canada
Total Product Life Cycle	TPLC Device Report[27]

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[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].