Class 2 Device Recall Access Tray

See Related Information[22]

Date Initiated by Firm	January 11, 2017
Create Date	February 22, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1228-2017
Recall Event ID	76237[23]
510(K)Number	K930129[24]
Product Classification	Catheter,intravascular,therapeutic,long-term greater than 30 days[25] - **Product Code** LJS[26]
Product	Vascular catheter introduction kit The PICC is indicated for short or long term peripheral access to the central Venous system for intravenous therapy, blood sampling, infusion and power injection of contrast media.
Code Information	Material # , ASK-01663-MST, ASK-04001-DU4, ASK-04001-DU5, PI-01351-LS, PI-01351-LS5, PI-01351-SS, PI-01552-LS, PI-01552-LS5, PI-01552-SS, PL-05041, PL-05041, PL-05052, PR-05041, PR-05041, PR-05041-T, PR-05042, ASK-01663-MST, ASK-04001-DU4, ASK-04001-DU5, PI-01351-LS, PI-01351-LS5, PI-01351-SS, PI-01351-SS, PI-01451-LS, PI-01451-LS5, PI-01451-SS, PI-01451-SS, PI-0-1552-LS
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	610-378-0131
Manufacturer Reason for Recall	There have been complaints for peel away sheaths flaring
FDA Determined Cause [2]	Device Design
Action	Arrow International mailed an Urgent Medical Device Advisory Notification letter to affected customers on 01/13/2017 to inform them of the issue. Customers with questions were instructed to contact their local sales representative or Customer Service at 1-866-246-6990.
Quantity in Commerce	215,703 units
Distribution	Nationwide Distribution
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].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.