Class 2 Device Recall Arrow Glide Thru PeelAway Sheath/Dilator Introducer

Date Initiated by Firm: June 12, 2017
Date Posted: June 27, 2017
Recall Status: Open, Classified
Recall Number: Z-2699-2017
Recall Event ID: 77604
510(K) Number: K122854
Product Classification: Introducer, catheter - Product Code DYB
Product: Arrow Glide Thru PeelAway Sheath/Dilator Introducer
Code Information: Device Listing # D184260, Material # PL-01055
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 is recalling additional lots that were identified as part of an active recall. Arrow is recalling the affected product due to the possibility that the catheter peel-away component hub tabs may prematurely detach when the practitioner begins to peel apart the sheath body from the catheter.
FDA Determined Cause: Device Design
Action: Teleflex/Arrow International mailed an Urgent Medical Device Recall Notification Letter to affected customers on 06/12/2017 to inform them of the issue. Arrow requested that customers examine their inventory immediately for the affected lots and discontinue use and quarantine any products with the associated product codes identified in the notice and complete the Recall Acknowledgement Form and fax back to the number included in the notice.
Quantity in Commerce: 9,037 units in the U.S. and 4,505 Internationally
Distribution: Distributed to SC, AL, NJ, IN, MA, GA, CA, PA, AZ, VA, WA and Bangkok
Total Product Life Cycle: TPLC Device Report

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.
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
3 The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=156760
7/17/2017