FDA

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

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Date Initiated by Firm	June 12, 2017
Date Posted	June 27, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2699-2017
Recall Event ID	77604[23]
510(K)Number	K122854[24]
Product Classification	Introducer, catheter[25] - **Product Code** DYB[26]
Product	Arrow Glide Thru Peel-Away 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 [2]	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[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.
[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.