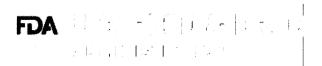
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Class 2 Device Recall Arrow Glide Thru PeelAway Sheath/Dilator Introducer

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Listing⁹ Events¹⁰

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Class 2 Device Recall Arrow Glide Thru PeelAway Sheath/Dilator

Introducer

Date Initiated by Firm

June 12, 2017

Date Posted

June 27, 2017

Recall Status¹

Open³, Classified

Recall Number

Z-2699-2017

Recall Event ID

77604²³

510(K)Number

K122854²⁴

Product Classification

Introducer, catheter²⁵ - Product Code DYB²⁶

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 Report²⁷

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 recalls²⁸

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.