FDA

Class 2 Device Recall Arrow Percutaneous Sheath Introducer Kit

See Related Information[22]

Date Initiated by Firm	May 23, 2018
Create Date	July 30, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-2576-2018
Recall Event ID	80378[23]
510(K)Number	K780532[24]
Product Classification	Percutaneous Sheath Introducer Kit[25]- **Product Code** DYB[26]
Product	Percutaneous Sheath Introducer Kit for use with 7 - 7.5 Fr. Catheters (8 Fr. 10 cm sheath length .035 inch dia. spring-wire guide), REF ES-09807. The percutaneous sheath introducer permits venous access and catheter introduction to the central circulation.
Code Information	Lot/Batch Number: 13F18A0037 Expiration Date/Expected Life: Apr 2019
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	Karen Boylan 866-396-2111
Manufacturer Reason for Recall	Product contains dry natural rubber latex. Label states Latex Free.
FDA Determined Cause [2]	Process control
Action	On May 23, 2018, Arrow International issued Urgent Medical Device Recall notices and response forms to their customer. Customers are advised to take the following actions: 1. Immediately discontinue distribution and quarantine affected product. 2. Using the provided customer letter and Recall Acknowledgement Form templates, customers who have further distributed product should contact those individuals. 3. To return affected products from your inventory, complete and return the Recall Acknowledgement Form via to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. 4. If you and your customers have no affected stock, please complete and return the Recall Acknowledgment Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. 5. If you have any other questions, feel free to contact your local sales representative or Customer Service at 1-866-396-2111.
Quantity in Commerce	60 units
Distribution	Puerto Rico
Total Product Life Cycle	TPLC Device Report[27]

[1] A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA