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Class 2 Device Recall Arrow Percutaneous Sheath Introducer Kit

Date Initiated by Firm: May 23, 2018
Create Date: July 30, 2018
Recall Status: Open, Classified
Recall Number: Z-2576-2018
Recall Event ID: 8037823
510(K) Number: K79053224

Product Classification: Percutaneous Sheath Introducer Kit, Product Code DVB

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-99807. 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 Baylan
866-396-2111


FDA Determined Cause: 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 these 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

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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=165304
8/8/2018