Class 2 Device Recall Arrow QuadLumen Central Venous Catheterization Kit

See Related Information[22]

Class 2 Device Recall Arrow QuadLumen Central Venous Catheterization Kit

Date Initiated by Firm	August 06, 2019
Create Date	September 23, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-2556-2019
Recall Event ID	83593[23]
Product Classification	Introducer, catheter[24] - **Product Code** DYB[25]
Product	Arrow 8.5 Fr. X 16 cm Quad-Lumen Central Venous Catheterization Kit Product Code:AK-42854-P1A - Product Usage: The Arrow Central Venous Catheters are intended to permit venous access to the central circulation by way of the femoral, jugular or subclavian veins.
Code Information	Lot Number: 13F18H0499
Recalling Firm/ Manufacturer	Arrow International Inc 2400 Bernville Rd Reading PA 19605-9607
For Additional Information Contact	SAME 610-378-0131
Manufacturer Reason for Recall	Products may contain the incorrect banner card within the kit
FDA Determined	Packaging process control

Cause [2]	
Action	Arrow International issued notification dated 8/6/19 stating problem, health risk and action to take: If you have affected stock in inventory, immediately discontinue use and quarantine any products with the product codes and lot numbers. 2. Inspect affected products within your control to confirm the product code on the lidstock matches the product code on the banner card of the same kit. Products confirmed to have an incorrect banner card should be returned to Arrow International. Products which properly match should not be returned. 3. If you have product with an incorrect banner card, please complete the enclosed Acknowledgement Form and fax it to 1-855-419-8507 Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document the amount of product you have on hand for return. A customer service representative will contact you with a Return Goods Authorization (RGA) number and provide instructions for the return of products. 4. If you have no affected stock, please complete the enclosed Acknowledgement Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. Questions, feel free to contact your local sales representative or Customer Service at 1-866-396-2111.
Quantity in Commerce	231 units
Distribution	US Nationwide distribution.
Total Product Life Cycle	TPLC Device Report[26]

[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[27].

[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.

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83593
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB
26. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=DYB
27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

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