

Urgent Medical Device Correction 1st Notice

ARROW[®] CVC, MAC, PI CVC, PICC, and PSI Kits

Internal Reference: EIF-000207

November 29, 2017

To: Customer of Arrow International Products

Arrow International is issuing a voluntary correction notice for the following product codes and lots:

Product Code	Lot / Batch Number
Refer to attachment	Refer to attachment

Some of the products referenced above may be missing a sticker that contains the lot number, expiration date, and Unique Device Identification (UDI) information. It is unlikely that the use of these products will result in any adverse health consequences.

Our records indicate that you have received products that are subject to this action. We are now notifying our customers to take the following actions:

1. If you have affected stock, immediately discontinue use and quarantine any products with the product codes and lot numbers listed above.
2. Inspect affected products within your control to identify whether they have the sticker with the lot number, expiration date, and UDI information. Products missing this sticker should be returned to Arrow International. Products which are properly labeled should not be returned.
3. If you have mislabeled product to return, 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 will provide instructions for the return of product to Arrow International.
4. If you have no affected stock, or if the products in your stock are properly labeled, please complete the enclosed Acknowledgment Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document your receipt of this letter.

The U.S. Food and Drug Administration has been notified of this action.

Arrow International is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service at 1-866-246-6990.

For and on behalf of Arrow International,

Karen Boylan

Karen Boylan
VP, Global RA/QA