Urgent Medical Device Correction 1st Notice

ARROW® EZ-IO® 45mm 15ga Intraosseous Vascular Access Needle Set

March 29, 2017

To: Customer of Teleflex Medical Products

Teleflex Medical has issued a voluntary correction notice for the following product code and lot:

Product Code	Lot/Batch Number
Product code on product labeling: **9079** Reference/reorder code: **9079-VC-005**	4799431

Teleflex Medical is contacting customers that received the product referenced above because some individual unit packaging (pouches) may be missing the lot number and expiration date. These individual units are packaged five per box, and the boxes do list the correct lot number and expiration date. It is unlikely that the use of these products will result in any adverse health consequences. Teleflex Medical is issuing this correction in an effort to provide our customers and their patients with the highest quality product possible.

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 catalog number and lot number listed above.
2. Inspect affected products within your control to identify if the individual units in each box are labeled with the lot number and expiration date. Products missing lot numbers and expiration dates should be returned to Teleflex Medical. Products which are properly labeled with the lot number and expiration date 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 Teleflex Medical.
4. If you have no affected stock, or if the products in your stock are properly labeled with the lot number and expiration date, 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.

Teleflex Medical 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 Teleflex,

[redacted]

Karen Boylan
VP, Global RA/QA