

Urgent Medical Device Correction

Inspect Arrow EZ-IO® Package to
Ensure Safety Cap is Attached to Needle

Arrow® EZ-IO® Intraosseous Vascular Access Needle Sets

EIF-000372

October 08, 2019

To: Customer of Arrow EZ-IO® Intraosseous Vascular Access Needle Sets**Device: Arrow® EZ-IO® Intraosseous Vascular Needle Sets**

Scope: Teleflex and its subsidiary Arrow International are issuing this correction for the following product codes:

Product Name	Product Code	Lot/Batch Number
Arrow® EZ-IO® 15mm Needle+Stabilizer Kit	9018P-VC-005	All
Arrow® EZ-IO® 25mm Needle+Stabilizer Kit	9001P-VC-005	All
Arrow® EZ-IO® 45mm Needle+Stabilizer Kit	9079P-VC-005	All

Summary of Issue: Teleflex and Arrow International have recently received 38 complaints reporting that the safety cap attached to needles within the EZ-IO needle sets may become dislodged exposing the needle and potentially causing the needle to protrude through the packaging. To date, there is only one reported needle stick. If this issue is not detected, the immediate risk of exposure to the affected devices is needle stick injury to the clinician or health care professional. In addition, a puncture of the packaging may compromise the sterility of the needle. As instructed in the IFU, Teleflex reminds healthcare providers "Do not recap Needle Sets or reconnect separated components. Use biohazard and sharps disposal precautions."

Customer Action: Our records indicate you have received product that is subject to this correction. Place a copy of this notice with the product to ensure all users are aware of the need to perform this inspection. Removing the kits from the shelf box and placing them into bags (e.g. backpacks) could increase the potential for caps to become loose and product should be visually inspected again at point of use. To acknowledge receipt of this Urgent Medical Device Recall Notice or to return product, complete the enclosed Recall Acknowledgement Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com.

We are now notifying our customers to take the following actions:

1. If you have stock in inventory, visually inspect the product.
 - a) If the safety cap covers the needle, per Figure 1 below, this product is acceptable for use.

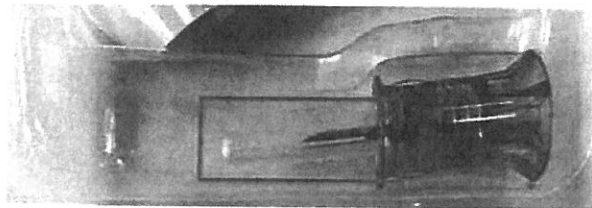


Figure 1

b) If, after inspection, you identify codes/lots as defective, please:

- dispose of such product locally; and inform us of the affected codes/lots by completing the enclosed Recall Acknowledgement Form in order for your account to be credited.

Containment: Corrective actions are being implemented at the manufacturing facility to reduce the risk of the safety cap dislodging from the needle.

Adverse reactions or quality issues: If you experience any adverse events or observe quality issues with this product, this should be reported to Teleflex Customer Service at 1-866-396-2111, 8am to 7pm ET Monday through Friday, or email recalls@teleflex.com or may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax, or to your national authorities.

Teleflex and Arrow International are committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause you.

If you have any other questions, feel free to contact your local sales representative or Customer Service at 1-866-396-2111, 8am to 7pm ET Monday through Friday, or email recalls@teleflex.com.

For and on behalf of Teleflex and Arrow International,

Mario Wijker
Vice President, Global Quality Assurance/Regulatory Affairs