



Urgent Medical Device Recall
Arrow® EZ-IO® 45mm Needle + Stabilizer Kit

EIF-000299

November 01st, 2018

To: Customer of Teleflex Inc. Products

Teleflex is voluntarily withdrawing the following product from the market:

Product Name	Product Code	Lot/Batch Number	GTIN
Arrow® EZ-IO® 45mm Needle + Stabilizer Kit	9079P-VC-005	6073321	00816000011904

Teleflex is voluntarily recalling the product referenced above because the product may be packaged in an incorrect display box.

- The correct size 45mm needle (Yellow) is packed into the correct 45mm pouch (color-coded Yellow)
- Incorrect display boxes may have been used to pack the 45mm pouches. The incorrect display box references Arrow® EZ-IO® 25mm Needle + Stabilizer Kit, and is color-coded Blue, but in fact may contain Arrow® EZ-IO® 45mm Needle Set + Stabilizer Kit, Product Code 9079P-VC-005 Lot Number 6073321.
- Labels on incorrect display boxes list the correct Product Code 9079P-VC-005 and Lot Number 6073321 for the 45mm Needle Set + Stabilizer Kits.

Product code and lot combinations not referenced above are not impacted by this field action.

Our records indicate you have received products that are subject to this field action.

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

1. If you have affected stock in inventory, immediately discontinue use and quarantine the products.
2. Please complete the enclosed Acknowledgement Form as soon as possible indicating whether you do or do not have stock and fax it to 1-855-419-8507 or email to recalls@teleflex.com. A customer service representative will contact you with a Return Goods Authorization (RGA) number and provide instructions for the return of products.

Adverse reactions or quality problems experienced with the use of this product should be reported to Teleflex Inc. by calling Customer Service at 1-866-246-6990 or may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Teleflex 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 1-866-396-2111.

For and on behalf of Teleflex Inc.,

Karen Boylan

Karen Boylan
VP, Global RA/QA

Recall Acknowledgement Form

Response Required

Arrow® EZ-IO® 45mm Needle + Stabilizer Kit

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Read the recall letter, complete this form and
fax it to 1-855-419-8507 or email to recalls@teleflex.com

We **do not have** inventory within the scope of this recall.

We **do have** affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following units

Product Code	Lot Number	Quantity
9079P-VC-005	6073321	

When the product is received, your account will be credited.

If you have experienced an adverse event associated with these products, please call customer service at 1-866-246-6990.

Print legibly

Print Name:	Signature:
Institution Name:	Date:
Institution Street Address:	Telephone Number:
Institution City, State, Zip, Country:	Email Address: