Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

MUSCAT

سلطنة عمان

وزارة الصحة

المديرية العامة للصيدلة والرقابة الدوائية

مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 15 **dated** 23/01/12 **Regarding NCMDR Recall of EZ-IO Needle & Stabilizer KIT (Mfr: Teleflex Medical)**

Copy to:

- **Director, Office of H.E. The Undersecretary for Health Affairs**
- **Director of Medical Device Control, DGPA&DC**
- **Director of Pharmacovigilance & Drug Information Dept, DGPA&DC**
- **Director of Drug Control Department, DGPA&DC**
- **Director of Pharmaceutical Licensing Department, DGPA&DC**
- **Director of Central Quality Control Lab., DGPA&DC**
- **Supdt. of Central Drug Information**

dg-padc@moh.gov.om : البريد الإلكتروني ٢٢٣٥٨٤٨٩ - فاكس: ٢٢٣٥٧١١١ - هاتف: ١٠٠ - الرمز البريدي: ٣٩٣ مسقط - ص . ب:

P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 15 / 2020

27 -03-1441 H

23 -01-2020

Recall of EZ-IO Needle & Stabilizer KIT from Teleflex Medical

Source of Recall	**NCMDR** National Centre for Medical Devices Reporting, SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14999
Product	EZ-IO Needle & Stabilizer KIT
Manufacturer	Teleflex Medical
Local agent	Muscat pharmacy & Stores L.L.C
The affected products	Product codes (All Lot/Batch Numbers) 9018P-EE-005, 9018P-EU-005, 9018P-ME-005, 9018P-NO-005, 9018P-VC-005, 9001P-EE-005, 9001P-EU-005, 9001P-ME-005, 9001P-NO-005, 9001P-VC-005, 9079P-EE-005, 9079P-EU-005, 9079P-ME-005, 9079P-NO-005, 9079P-VC-005
Reason for Recall	Teleflex and Arrow have recently received 32 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.
Action	1. Kindly check your stock, contact your local agent for remedial action 2. If you have stock in inventory, visually inspect the product If the safety cap covers the needle, per Figure 1 (See attached FSN), this product is acceptable for use. 3. If, after inspection, you identify codes/lots as defective, please:-Dispose of such product
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical Device to Director of Medical Device Control contact E-mail dg-padc@moh.gov.om

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

Dr. Mohammed Hamdan Al Rubaie

DIRECTOR GENERAL

سلطنة عمان - وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
SULTANATE OF OMAN - MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS & DRUG CONTROL

dg-padc@moh.gov.om : البريد الإلكتروني ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

Teleflex MEDICAL

ARROW INTERNATIONAL

Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland
02nd Oct 2019

URGENT - FIELD SAFETY NOTICE

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

Commercial Name of Affected Product:		Arrow® EZ-IO® Intraosseous Vascular Access Needle Sets 15mm Needle + Stabilizer Kit (9018P) 25mm Needle + Stabilizer Kit (9001P) 45mm Needle + Stabilizer Kit (9079P)		
Type of action:		Advisory Notice		
Teleflex Reference:		EIF-000372		
Product codes (All Lot/Batch Numbers)				
9018P-EE-005	9018P-EU-005	9018P-ME-005	9018P-NO-005	9018P-VC-005
9001P-EE-005	9001P-EU-005	9001P-ME-005	9001P-NO-005	9001P-VC-005
9079P-EE-005	9079P-EU-005	9079P-ME-005	9079P-NO-005	9079P-VC-005

Dear Customer,

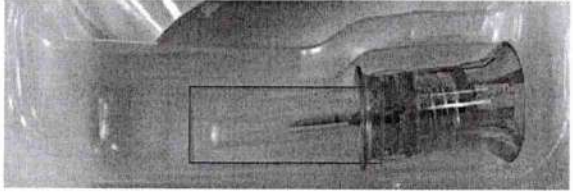
Teleflex and its subsidiary Arrow International are issuing this Field Safety Notice for the above listed product codes.

Description of the problem & immediate actions required
Teleflex and Arrow have recently received 32 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.

Customer Action: Our records indicate that you have received products that are subject to this Field Safety Notification. Place a copy of this notice with the product to ensure all users are aware of the need to perform this inspection.

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.
   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 calling the phone number or emailing the customer service contact mentioned below in order for your account to be credited.



Teleflex MEDICAL

ARROW INTERNATIONAL

Figure 1.

Please provide this Field Safety Notice to all those who need to be aware of it within your organisation and place a copy with affected product. Please consider, clinicians, risk managers, supply chain/distribution centres, etc. in the circulation of this notice. There is no further action required.

Distributors:
If you are a distributor, please perform Action 1.
Provide this field safety notice to all your customers who have received product in scope of this Field Action.
There is no further action required.

If you have further distributed product outside of your country, please notify Teleflex by return email to the e-Mail address below. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TR region, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

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

Teleflex
Teleflex informs all customers, employees of Teleflex and distributors on this Field Action.

Transmission of this Field Safety Notice
This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice.
Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person
Should you require any further information or support concerning this issue, please contact:

Customer Service
Contact: Shane Kenny
FAX: +353(0)1 4370773
Telephone: +353 (0)90 6460869
E-mail: Recalls.Intl@teleflex.com

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.

[redacted]