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. 23 **dated** 29/01/12 **Regarding Health council**

Recall of Arrow EZ-IO-Intraosseous vascular access needle sets (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 - فاكس: ٢٢٣٥٨٤٨٩ - هاتف: ٢٢٣٥٧١١١ - ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠
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

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سلطنة عمان
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مسقط

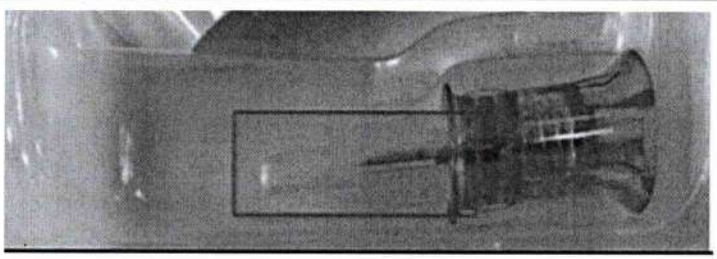
Circular No. 23 / 2020

Ref: 16/2020

04 -06-1441 H

29 -01-2020

Recall of Arrow EZ-IO from Teleflex Medical

Source of Recall	Gulf Health council file:///C:/Users/moh76697/Downloads/Intraosseous%20vascular%20access%20needle%20sets.pdf
Product	Arrow EZ-IO-Intraosseous vascular access needle sets
Manufacturer	Teleflex Medical
Local agent	Muscat pharmacy & Stores L.L.C
The affected products	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; 9018P-EE-005; 9018P-EU-005; 9018P-ME-005
Reason for Recall	Safety cap attached to needles within the needle sets may become dislodged exposing the needle and potentially causing the needle to protrude through the packaging. If this issue is not detected, the immediate risk of exposure to the affected devices is needle stick injury to the clinician or healthcare professional. In addition, a puncture of the packaging may compromise the sterility of the needle
Action	1. Kindly check your stock, contact your local agent for remedial action
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

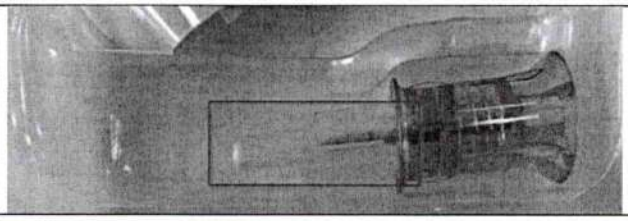
ص . ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١٢١ - فاكس: ٢٢٣٥٨٤٨٩ البريد الإلكتروني: dg-padc@moh.gov.om
P.O. Box : 393 Muscat, Postal Code: 100, Tel: 22357111 - Fax: 22358489 - E-mail : dg-padc@moh.gov.om

مجلس الصحة
لدول مجلس التعاون
Gulf Health Council

التاريخ الهجري : 3/5/1441
التاريخ الميلادي : 29/12/2019
المرفقات :
رقم : 29-12-19/2823

تقارير السلامة للأجهزة والمستلزمات الطبية
Safety Alerts of Medical Device Products

To: HE / Members of the Executive Committee of the Cooperation Council States Members	**إلى:** سعادة/ أعضاء الهيئة التنفيذية بدول مجلس التعاون.

Subject:	تقرير سلامة لمنتجات طبية	**الموضوع:**
Product Name:	Intraosseous vascular access needle sets (Arrow EZ-IO)	**اسم المنتج:**
Company Name:	Teleflex Medical	**اسم الشركة:**
Product Photo:		**صورة المنتج:**
Affected Devices:	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	**الأجهزة المتضررة:**
Product Reg. Status in GHC:	None	**وضع المنتج في مجلس الصحة:**
Source of warning:	Teleflex Medical / SFDA	**مصدر التحذير:**
Reason for warning:	Safety cap attached to needles within the needle sets may become dislodged exposing the needle and potentially causing the needle to protrude through the packaging. If this issue is not detected, the immediate risk of exposure to the affected devices is needle stick injury to the clinician or healthcare professional. In addition, a puncture of the packaging may compromise the sterility of the needle.	**سبب التحذير:**

P.O Box 7431 Riyadh 11462
T. +966 11 4885262
F. +966 11 4885266

http://www.ghc.sa

تقارير السلامة للأجهزة والمستلزمات الطبية
Safety Alerts of Medical Device Products

Recommendation:	1- Visually inspect the product. 2- Dispose of product If you identify codes/lots as defective 3- Pass on this notice to all persons who need to be aware within your organization.		**التوصيات:**
Authorized Representative Details	**AR name:**	First United Medical Company	**بيانات التواصل مع الشركة**
	Assigned Contact Person:	Khalid Mohammad AlFuhaid	
	Mobile/Phone:	0544081009	
	Email:	shivappa.gowda@fumedco.net	

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Link of Circular	**لا يوجد**	**رابط التعميم:**
Any Comment & Report Adverse Reaction:	pms@ghc.sa	**للاستفسارات والإبلاغ عن الآثار الجانبية للدواء:**