



Medical Devices Sector

قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

NCMDR Weekly Update

23-Apr-19

Dear,
NCMDR team send a weekly update every week containing the latest Field Safety Corrective Action/Recalls of medical devices/products on SFDA website.

عزيزي،
يقوم المركز الوطني لبلاغات الأجهزة والمنتجات الطبية بإرسال تقرير اسبوعي عن آخر اشعارات إنذارات السلامة / الاستدعاءات للأجهزة والمستلزمات الطبية المنشورة على موقع الهيئة العامة للغذاء والدواء

* Role of NCMDR officer:

* مسؤولية ضابط الاتصال:

- Disseminate and share the information with other Departments within healthcare facility and Ensuring that the healthcare facility is free of any affected device/product.
- Communicate with NCMDR Team and Authorized Representative of the manufacturer if there is any affected device/product.

- التعميم على الإدارات / الأقسام المختلفة داخل المنشأة الصحية والتأكد من خلوها من أي جهاز/مستلزم طبي متأثر بأي من إشعارات إنذارات السلامة.
- التواصل مع المركز الوطني لبلاغات الأجهزة والمنتجات الطبية ومع الممثل القانوني للمصنع في حالة وجود جهاز/مستلزم طبي متأثر بأي من إشعارات إنذارات السلامة.


Hospital name:
Date:
Hospital affected by any medical device/product in this report: No Yes


اسم المستشفى:
التاريخ:
يوجد أجهزة متأثرة بالمستشفى ضمن القائمة: لا نعم

- The yellow highlights Indicates that medical devices subject to removal and/ or destroyed action.
- NCMDR Team Recommend ensuring the listed Authorized representative/Distributor in this report as they may differ from the Authorized representative/Distributor you are dealing with
- The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI.
- Open the links or attachments to find the affected product identifier, models, serial numbers or codes.

- الإشعارات المظلمة بالأصفر تشير الى سحب او إتلاف جهاز طبي.
- الممثلين القانونيين/الموزعين في هذا التقرير قد يختلفون عن الممثلين القانونيين/الموزعين الذين تتعاملون معهم.
- هذه العلامة (#) في الجهة اليسرى من التقرير تشير إلى ان اشعار انذار السلامة من منظمة (ECRI).
- لمعرفة الطراز او الارقام التسلسلية افتح الروابط او المرفقات.



NCMDR Weekly Update 23-Apr-19

Dear,
 NCMDR team is pleased to inform you that **28** new FSCA/recalls for medical devices and products posted on [SFDA website](#) for the period of **15-Apr-19** to **18-Apr-19** In order to view more details, [click the links or attachments](#) 

عزيزي،
 يود فريق عمل المركز الوطني لبلاغات الأجهزة والمنتجات الطبية إعلامكم بنشر **28** إشعارات إنذارات السلامة للأجهزة والمستلزمات الطبية على موقع الهيئة العامة للغذاء والدواء للفترة **15-Apr-19** إلى **18-Apr-19** ، لعرض مزيد من التفاصيل يرجى الضغط على الروابط أو المرفقات 

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
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Assistive products for persons with disability

#	E-Pacer, TRAM, and Low-Base TRAM Lifts	Community Products, LLC, d/b/a Rifton	alsandross international		
#	Size 3 Wombat Living Assistive Ergonomic Chairs	R82	N/A		

Diagnostic and therapeutic radiation devices

Azurion FlexArm	Philips Burton	hilips Healthcare Saudi Arabia Ltd	/Secure/CA/CaViewRecal	
CyberKnife M6 and CyberKnife VSI Secondary Collimation Subsystem .	Accuray Inc	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=10&rid=14163	

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Elekta Unity	Elekta Inc	Medical Regulations Gate	/Secure/CA/CaViewRecal	
Foot Switches used with the Multiple systems	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	

Electro mechanical medical devices

6 Fr Sherpa Active Catheters	Medtronic SA	Medtronic Saudi Arabia	https://ncmdr.sfda.gov.s	
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# da Vinci X and Xi Surgical Systems	Intuitive Surgical Inc	Gulf Medical Co.		
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Heated OR Torso pad of the Pintler Patient Warming System	Pintler Medical LLC	N/A	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
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Mercury Advance V1 Control Unit ,	Direct Healthcare Services Ltd	N/A	https://ncmdr.sfda.gov.s	
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TactiSys Quartz Equipment operating.	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRec	
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In vitro diagnostic devices

Alinity c Cuvette Segment.	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.s	
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Bilirubin Total Gen.3, Tina-quant IgM Gen.2 and Lactate Gen.2	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
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MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
OXOID MICE Strip MA0122 – Ceftriaxone32	Oxoid Ltd Div Thermo Fisher Scientific Inc	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14169	
Quantia RF ,	Abbott	Medical supplies & Services Co.Ltd Mediserv	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14169	

Non-active implantable devices

Beaver Xstar Slit Knife 2.4 mm, 45	Beaver Visitec International Ltd	Al Amin Medical Instruments Co. Ltd.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14169	
CORAIL AMT STANDARD OFFSET NECK SEGMENT, CORAIL AMT HIGH OFFSET NECK SEGMENT and CORAIL AMT COXA VARA NECK SEGMENT	DePuy Ireland UC	Johnson & Johnson Medical Saudi Arabia Limited	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14169	
Exprt Precision System	Encore Medical, Lp	AL EWAN MEDICAL COMPANY	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14186	
Salto Talaris Tibial Total Ankle Prosthesis Tray, Talar Dome Total Ankle Prosthesis	Integra LifeSciences	Bio Standards	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14186	

Ophthalmic and optical devices

ACUVUE OASYS for ASTIGMATISM	Johnson & Johnson Vision Care	Allied Medical International	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14186	
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Reusable devices

MedicalDevice	Manufacturer	Authorized Representative /Distributor	Link	Affected Yes/No
Posey Connected Twice-as-Tough Cuffs	POSEY PRODUCTS, LLC	Osama Julaidan & Sons Trading Company	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
ULRICH Torque Limiting HandleTorque Wrench	Ulrich GmbH & Co. KG	Isam Economic Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	

Single-use devices

BD Gravity IV Set	Becton Dickinson & Co. (E)	Becton Dickinson B.V.	/Secure/CA/CaViewRecall.aspx?caid=2&rid=14	
Dilapan-5-Hygroscopic cervical dilator	MEDICEM Technology s.r.o.	Marina Pioneers Trading Est. (Marsa AlRowad)	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
F-Octane & F-Decalin	Fluoron GmbH	Gulf Medical Co.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
Pericardiocentesis Catheter Set.	Cook Medical	Majal Care for Trading Est.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14	
# Pericardiocentesis Catheter Set.	Cook Medical	Majal Care for Trading Est.		
Revas"- Dual Lumen cannula, REVAS Venous Femoral cannula, REVAS' Universal ECLS cannula V/A, and REVAS Venous Femoral cannula pre-bent tip	free life medical GmbH	Rashid Ali AlTamimi Trading Est	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=14180	