



SBED Weekly Update

10-Apr-17

Dear,

SBED team is pleased to inform you that **31** new FSCA/recalls posted on [SFDA website](#)

(Please note: below list of FSCA/ recalls for the period of 4/3/2017 to 4/9/2017

In order to view more details, click the links and for ECRI alerts see the attachments

NOTE:

FSCA / Recalls are classified into three categories, representing the potential risk to public health: Class I : High Risk, Class II : Medium Risk and Class III: Low Risk.

FSN (Field Safety Notice) : A communication to customers and/or users sent out by a manufacturer or its representative in relation to a Field Safety Corrective Action

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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Active Implantable Devices

New	SynchroMed II implantable drug infusion pump	4/3/2017	Medtronic SA	Medtronic Saudi Arabia	2	https://nc
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Anaesthetic and respiratory devices

New	Nonin, 8500M Handheld Pulse Oximeter	4/3/2017	Nonin Medical, Inc.	Thimar Al Jazirah Healthcare Co.	2	https
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Solus Flexible - small paediatric, wire-reinforced laryngeal mask airway 2 / large paediatric, wire-reinforced laryngeal mask airway 2.5 / small adult, wire-reinforced laryngeal mask airway 3 / medium adult, wire-reinforced laryngeal mask airway 4 / large	4/5/2017	Intersurgical Limited	Al Hammad Medical Services	FSN	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRecall.as

Dental devices

New	BIOMET 3i LTX DENTAL IMPLANTS	4/3/2017	Biomet 3i Inc	Asnan Medical Services	2	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRecall.as
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Diagnostic and therapeutic radiation devices

New	CT Exprès Contrast Injection System, Model Temperature Maintainer	4/9/2017	Bracco Injeneering S.A.	Sarabeel Commercial Est.	FSN	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRecall.as
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Electro mechanical medical devices

New	Alaris GS, GH, CC, TIVA, PK, Enteral Syringe Pump, Asena GS, GH, CC, TIVA, PK Syringe Pumps	4/4/2017	CareFusion Alaris A BD Co	Becton Dickinson B.V.	FSN	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRecall.as
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#	New	Da Vinci Si and Xi Surgical System Surgeon Side Consoles	4/9/2017	Intuitive Surgical Inc	Gulf Medical Co.	2	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRecall.as
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New	ERGO handle	4/5/2017	RBE Elektromedizin GmbH	el Medical & Trading Co.	FSN	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRecall.as
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#	New	GN Otometrics Hi-Pro USB and Hi-Pro2 Hearing Instrument Interface Units	4/6/2017	GN Otometrics	Gulf Medical Co.	2	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRecall.as
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#	New	IntelliVue MX40 WLAN Patient Wearable Monitors.	4/5/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	2	https://nc.mdr.sfda.gov.sa/Secure/CA/CAViewRecall.as
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	ParaTherm Heater/Coolers	4/9/2017	Chalice Medical Ltd	N/A	2	https://ncmdr.
	New	schaerer arcus	4/9/2017	Schaerer Medical AG	ATTIEH MEDICO LTD	FSN	A/Ca\

Hospital hardware

#	New	TotalCare Bed Systems with 3-Level Patient Position Monitoring	4/9/2017	Hill-Rom, Inc. &Subsidiaries	Arabian Medical Marketing Co. (AMCO)	2	https://ncmdr.
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In vitro diagnostic devices

	New	Dimension Vista 500 Intelligent Lab System, Dimension Vista 1500 Intelligent Lab System	4/4/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	FSN	https://ncmdr.
	New	Monolisa HCV	4/9/2017	Bio Rad.	el Medical & Trading Co.	FSN	A/Ca\

Non-active implantable devices

	New	Altius MINI OCT Posterior Spinal Fixation System	4/3/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https://ncmdr.
	New	LiquiBand FIX8	4/5/2017	DICAL SOLUTIONS (PLYM	tem I. Alshedwy Comm. E	FSN	A/Ca\
	New	Oxford Unicompartmental Cementless Tibial Trays	4/9/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	FSN	https://ncmdr.
	New	UOC Femoral driver	4/3/2017	ited Orthopedic Corporati	N/A	2	A/Ca\
	New	XTRAC Excimer Laser, Model No. AL8000, AL10000	4/3/2017	Strata Skin Sciences, Inc.	N/A	2	https://ncmdr.






Ophthalmic and optical devices

	New	atraumatic compact Cysto-Urethroscope 25°	4/5/2017	Richard Wolf GmbH	Al-Jeel Medical & Trading Co. LTD	FSN	https://ncmdr.
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Reusable devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	SmartLife Large Aseptic Housing.	4/4/2017	Stryker Instruments	Al-Faisaliah Medical System	FSN	https
New	Tecomet, OSTEOTOME BLADES	4/5/2017	Smith & Nephew	Alhaya medical co.	FSN	https

Single-use devices

	New	1mL Medallion® syringes	4/5/2017	Merit Medical Systems Inc	Majal Care for Trading Est	FSN	A/Ca
#	New	20 mL Romed 2-Part Syringes	4/9/2017	Van Oostveen Medical B.V.	Sehat Al-Jazeera EST.	2	
#	Update	Curity™ Eye Pad Oval and Curity™ Sodium Chloride Dressing	4/6/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	
#	New	Heart TraceCarts	4/6/2017	DeRoyal Industries Inc.	Alhaya medical co.	2	
#	New	TIVA Total Intravenous Anesthesia Sets	4/9/2017	GLOBAL COMPONENTS MEDICAL LTD	N/A	2	
#	Update	Various Products with a Blue/Polyisoprene Valve Design	4/9/2017	Cook Medical	NAFA Medical	FSN	
	New	Wingman 35 Crossing Catheter	4/5/2017	ReFlow Medical	N/A	FSN	https
	New	Zenith Alpha Thoracic Endovascular Graft.	4/9/2017	William Cook Europe ApS	NAFA Medical	FSN	https

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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- * The sign (#) on the left side of the FSN's indicates that the source of this FSN is ECRI
- *  indicates that medical devices subject to removal and/ or destroyed action.
- * SBED Team Recommend ensuring The listed Distributors in this report as they may differ from the distributors you are dealing with

SBED is devoted to receive the adverse event report and feedback information about any medical devices malfunction from hospitals and healthcare facilities all around KSA, studying them and collaborative working with manufacturers, authorized representatives and distributors to take the right action and assuring the proper safe performance.

To see recent recalls kindly visit the following link:

<http://ncmdr.sfda.gov.sa/Secure/CA/CaCompositeListing.aspx>

In case you find an effected medical devices by any of the published FSN/Recalls, we urges you to contact the local representative and the National Center for Medical Device Reporting in order to ensure corrective or planed action been implemented.