



SBED Weekly Update 29-May-17

Dear,

SBED team is pleased to inform you that **30** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 5/22/2017 to 5/28/2017
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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Anaesthetic and respiratory devices

New	Carestation 620, 650 and 650c	5/25/2017	GE Healthcare	GE Healthcare	FSN	https
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New	ROSA Brain 3.0.0, ROSA Spine 1.0.2, ROSA One 3.1 .0 ,	5/25/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	FSN	https://nc
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#	New	Unomedical Oxygen Masks,	5/22/2017	ConvaTec	Salehiya Trading Est.	2	https	
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Assistive products for persons with disability

#	New	Stealth Ultra Suboccipital Head Pads	5/23/2017	Stealth Products Inc.	N/A	2	Attac	
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Dental devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
# New	HLA3-5 Legacy Full Contour Abutment Assemblies	5/22/2017	Implant Direct LLC	N/A	2	https://nc

Diagnostic and therapeutic radiation devices

New	Leksell Gamma Knife Icon	5/25/2017	Elekta Inc	Medical Regulations Gate	FSN	A/CaV
Update	Sensis system ,	5/25/2017	SIEMENS	iemens Medical Solution	2	A/CaV

Electro mechanical medical devices

New	Conductivity/TDS Calibrator Solution	5/25/2017	Mesa Laboratories, Inc.	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https
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New	CSI, Orbital Atherectomy System (OAS) Saline Infusion Pump	5/24/2017	Cardiovascular Systems, Inc	N/A	2	https://nc
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New	HeartMate 3™ Left Ventricular Assist System	5/23/2017	Abbott Cardiovascular and Neuromodulation	Arabian Trade House Est.	FSN	https
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New	MiniMed 640G Insulin Infusion Pump..	5/25/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https
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# New	Spectra Optia Apheresis Systems,	5/22/2017	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	Attac
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# New	Spine Tools Install CDs Used with StealthStation S7 Systems	5/23/2017	Medtronic SA	Medtronic Saudi Arabia	2	Attac hed
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New	StatLock IV Premium Catheter Stabilization Device	5/25/2017	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	2	https://nc
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# New	Trima Accel Automated Blood Collection Systems	5/22/2017	Terumo BCT Inc	ABDULREHMAN AL GOSAIBI GTB	2	Attac
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In vitro diagnostic devices

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Dynabeads Reagents	5/22/2017	thermo Fisher Scientific Inc	Supplies & Services Co.Ltd	2	ttache 
	New	ETEST Ceftriaxone	5/24/2017	bioMerieux Inc	el Medical & Trading Co.	2	A/Ca\
	New	LABType DNA Typing Tests	5/24/2017	Life Technologies Corporation	Salehiya Trading Est.	2	https
	New	Magellan Diagnostics LeadCare Ultra Blood Analyzer	5/24/2017	Magellan Diagnostics Inc	N/A	1	https://nc
	New	ORTHO Workstation ,	5/25/2017	Ortho-Clinical Diagnostics	Photographic Supplies C	FSN	A/Ca\

Non-active implantable devices

#	New	Birmingham Hip Resurfacing Acetabular Cups	5/22/2017	Smith & Nephew inc	Smith & Nephew inc	2	Attac hed 
#	New	KYPHON Directional Bone Void Fillers	5/22/2017	Medtronic SA	Medtronic Saudi Arabia	2	Attac 
	New	NexGen Offset Stem Extension	5/24/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https
	New	Trauma Implants - intramedullary nails	5/24/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	https
#	New	Vitality T27 Final Drivers and Torque-Limiting Handles	5/22/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	Attac hed 

Ophthalmic and optical devices



	New	VFI Pack for Silicone Oil syringes.	5/28/2017	D.O.R.C. Dutch Ophthalmic Research	Albasar For Medical Supplies	FSN	https
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Reusable devices

	New	Inflation Device 30 atm	5/25/2017	ArcRoyal	N/A	FSN	A/Ca\
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
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Single-use devices

#	New	Kiwi Omni Cups	5/23/2017	MINICAL INNOVATIONS, LI	MEDICAL INNOVATIONS ES	2	ttache	
	Update	Microcatheter SONIC 1.5F	5/25/2017	Balt Extrusion	nar Al Jazirah Healthcare	2	A/CaV	
#	New	Probe Cover Kits .	5/23/2017	Merit Medical Systems Inc	Majal Care for Trading Est	2	ttache	

* 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.