



SBED Weekly Update 16-May-17

Dear,

SBED team is pleased to inform you that **43** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 5/8/2017 to 5/14/2017
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	Dale Medical Stabilock Endotracheal Tube Holder, Adhesive Base	5/9/2017	Dale Medical Products, Inc.	Medical Oasis Establishment	2	https://nc.mdr
#	New	Model V60 Ventilators ,	5/10/2017	Philips Healthcare	s Healthcare Saudi Arabia	2	https://nc.mdr
	New	MONNAL T50	5/11/2017	ir Liquide Medical System	N/A	FSN	A/Cal
	New	TB2000 Disposable t-piece infant resuscitation circuit with adjustable PEEP,	5/10/2017	Parker Healthcare	N/A	2	https://nc.mdr.sfda

Assistive products for persons with disability

#	New	Flexx HD Wheelchairs ,	5/14/2017	Karma Mobility Limited	N/A	2	https://nc.mdr
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#	New	Stealth Flip Down Stems	5/14/2017	Stealth Products Inc.	N/A	2	https://ncmdr.sfda.gov.sa
	New	Table and attachments, operating-room	5/11/2017	The Anspach Effort, Inc.	Al-Nozha Medical Est	2	https://ncmdr.sfda.gov.sa

Dental devices

	New	Linear Straight Broach Handle, (Rasp Handle) EZ Clean" Linear Broach Handle	5/11/2017	Greatbatch Medical.	Al-Jeel Medical & Trading Co. LTD	2	https://ncmdr.sfda.gov.sa
	New	Microfil Composite Instruments	5/14/2017	Almore International Inc	N/A	2	https://ncmdr.sfda.gov.sa

Diagnostic and therapeutic radiation devices

	New	MEDHOT MTI 2000 THERMAL IMAGING SYSTEMMed	5/11/2017	Med-Hot Thermal Imaging, Inc	N/A	2	https://ncmdr.sfda.gov.sa
	New	NDI P7 Position Sensor, Stereotaxic Instrument	5/11/2017	Orthosoft, Inc	N/A	2	https://ncmdr.sfda.gov.sa
	New	Sensis system ,	5/8/2017	SIEMENS	iemens Medical Solution	2	A/CaV
	New	SOMATOM Force with software version VA50A	5/10/2017	SIEMENS	Siemens Medical Solutions	2	https://ncmdr.sfda.gov.sa

Electro mechanical medical devices

#	New	1,000 mL Canisters with Gel Used with InfoV.A.C. and V.A.C.ULTA Therapy Systems	5/14/2017	KCI USA Inc	Al-Jeel Medical & Trading Co. LTD	2	https://ncmdr.sfda.gov.sa
	New	Caliber Inflation Device ,	5/9/2017	C R Bard Inc	C.R. BARD Saudi Arabia	FSN	A/CaV
	New	JETSTREAM	5/9/2017	Boston Scientific.	nar Al Jazirah Healthcare	2	A/CaV

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#	New	Med X Change DRSHD 1080P High Definition Recording Systems	5/11/2017	ConMed Corporation.	ProMedEx	2	
	New	Mederi Stretta Catheter and Accessory Kit	5/11/2017	Mederi Therapeutics, Inc	FAROUK MAAMOUN TAMER and COMPANYY	2	https://nc
#	New	Monica Novii Wireless Patch Systems	5/10/2017	GE Healthcare	GE Healthcare	2	
	New	Monopolar HF Resection Electrodes	5/10/2017	Olympus	Salehiya Trading Est.	2	https://nc
#	New	Phagenyx Base Station Treatment Cables	5/14/2017	Phagenesis Ltd	N/A	2	
	New	Visum LED Surgical Lighting system	5/10/2017	Stryker Communications	Al-Faisaliah Medical System	2	https://nc

In vitro diagnostic devices

	New	ETEST OX 256	5/11/2017	bioMerieux Inc	el Medical & Trading Co.	FSN	A/Ca
	New	Sysmex XN Series Automated Hematology Analyzers	5/9/2017	Sysmex America Inc	FAROUK, MAAMOUN TAMER & COMPANYY	2	https://nc.mdr.
#	New	Uni-Gold H. pylori Antigen Kits	5/14/2017	Trinity Biotech plc.	AL OSOOL MEDICAL TRADING COMPANYY	2	
	New	VIDAS FT4	5/11/2017	bioMerieux Inc	el Medical & Trading Co.	FSN	A/Ca
	New	Xpert CT/NG	5/11/2017	Cepheid	A FOUAD HOLDING COI	FSN	A/Ca

Non-active implantable devices

	New	Cook Biodesign 1-Layer Tissue Graft and Cook Biodesign 4-Layer Tissue Graft	5/10/2017	Cook Inc,	NAFA Medical	2	https://nc.mdr.sfda.
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New	Halo Vest/Lil Angel Halo Vest	5/11/2017	Ossur	Al Ewan Medical Company	2	https://nc
New	PAK NEEDLE BEVELED AND TROCAR TIPS	5/11/2017	Medtronic SA	Medtronic Saudi Arabia	2	https://nc
New	PERILOC VOLAR DISTAL RADIUS RIGHT 3H STD HEAD LOCKING PLATE	5/9/2017	Smith & Nephew inc	Smith & Nephew inc	2	https://nc.mdr
# New	Various Trauma Implants ,	5/10/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	_

Ophthalmic and optical devices





New	EZ-Load Lens Delivery System	5/10/2017	Valeant Pharmaceuticals	Medical Regulations Gate	1	https://nc
Update	Healon Ophthalmic Viscoelastic Devices	5/14/2017	Abbott Medical Optics Inc.	Gulf Medical Co.	2	https://nc
New	neoBLUE blanket LED Phototherapy Systems ,	5/10/2017	Natus Medical Inc.	Saudi Health Services Co. Ltd.	2	https://nc


Reusable devices

New	Brennen Skin Graft Mesh	5/11/2017	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	FSN	https://nc
# New	Richardson and Kelly Retractors ,	5/11/2017	Rudolf Medical GmbH & Co. KG	Omar Saeed Al-Amoudi Sons Co.	2	_

Single-use devices

New	BodyGuard Pump IV Administration Set	5/10/2017	Caesarea Medical Electronics Ltd	N/A	2	https://nc
# New	Covidien 5 mm Endo Peanut Devices	5/14/2017	Medtronic SA	Medtronic Saudi Arabia	2	_

	Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
#	New	Pleur-Evac Connectors,	5/11/2017	Teleflex Medical.	Arabian Trade House Est.	2	
#	New	Resuscitation Devices ,.	5/11/2017	Vyair Medical	N/A	2	
#	New	Various Products,,	5/11/2017	Cook Medical	NAFA Medical	2	
#	Update	Venture RX, OTW and CS Catheters	5/11/2017	Vascular Solutions Inc	Medical Technology Establishment	2	

- * 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.