



SBED Weekly Update

18-Apr-17

Dear,

SBED team is pleased to inform you that **44** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 4/10/2017 to 4/16/2017
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

Update	Drug Infusion Pumps, SynchroMed® II Implantable	4/12/2017	Medtronic SA	Medtronic Saudi Arabia	2	https://nc
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Anaesthetic and respiratory devices

New	Frazier Sauger 3 mm, Länge 200 mm-SUGGF3533	4/13/2017	Yellow's Medical Instruments GmbH	N/A	FSN	https://nc
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New	Newport™ HT70 and Newport™HT70 Plus Ventilators	4/12/2017	Medtronic SA	Medtronic Saudi Arabia	FSN	https://nc
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Diagnostic and therapeutic radiation devices


Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	18L6 HD transducer on the ACUSON S Family ultrasound systems	4/13/2017	SIEMENS	Siemens Medical Solutions	FSN	https://nc
New	Accu-Chek Connect diabetes management app.	4/13/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	https://nc
New	CSM1901	4/13/2017	Nihon Kohden Corporation	Medical Marketing Co. (2	A/Ca
# Update	Eye Station and Eye Care PACS	4/13/2017	Merge Healthcare Corp.	N/A	FSN	Attac
New	GE Centricity Web Diagnostic (WebDx)	4/13/2017	GE Medical Systems	GE Healthcare	2	https
New	Kappa, Delta, Delta XL	4/13/2017	raeger Medical Systems Ir	Draeger Arabia Co. Ltd.	2	A/Ca



Electro mechanical medical devices

New	eCare Coordinator	4/10/2017	Philips Burton	s Healthcare Saudi Arabi	2	A/Ca
New	AESCLAP (FH620R) MINOP InVent 30 Trocar System	4/13/2017	Aesculap	Gulf Medical Co.	2	https://nc
New	ARROW Antimicrobial/Antithrombogenic PICC Kits	4/10/2017	Arrow International Inc	Gulf Medical Co.	2	https://nc
New	ARTIS 230V and ARTIS 230V Physio	4/16/2017	Baxter Corp Canada	Baxter AG	FSN	https
# New	Batteries Used with Accu-Chek Insight Insulin Pumps	4/11/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac hed
# New	CORFLO PEG Y Adapters with ENFit Connectors	4/13/2017	CORPAK MedSystems .	Medical Experts Company	2	Attac


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#	New	Da Vinci Xi EndoWrist Suction Irrigators ,	4/16/2017	Intuitive Surgical Inc	Gulf Medical Co.	2	https 
	New	FibriJet Endoscopic Catheter Introducer	4/13/2017	Micromedics Inc	N/A	2	https
#	New	Gaymar Medi-Therm Hypothermia Systems	4/16/2017	Stryker Communications	Al-Faisaliah Medical System	2	Attac 
#	New	K9 Orthopedic Scooters	4/13/2017	REIDsteel	N/A	2	ttache 
#	New	Microlife ProBP 2400 Digital Blood Pressure Devices	4/10/2017	Welch Allyn Protocol Inc	ABDULREHMAN AL GOSAIBI GTB	2	https://nc
	Update	Model 105109 HeartMate II LVAS System Pocket Controllers,	4/12/2017	Thoratec Corp	Arabian Trade House Est.	2	https://nc
#	Update	PureWick External Catheter	4/10/2017	Purewick Corporation	N/A	2	Attac 
	New	REFINITY	4/13/2017	VOLCANO CORPORATION	Ikar Establishment	2	A/Ca
	New	ViperWire Advance Peripheral Guide Wire with Flex Tip	4/13/2017	Cardiovascular Systems, Inc	N/A	2	https://nc
	New	washer-disinfectors PG 8527 / 8528 / 8535 / 8536	4/13/2017	Miele	Scientific & Medical Equipment House	FSN	https
	New	Wilson Frame Pads	4/13/2017	Mizuho OSI	Medical Express Services	FSN	A/Ca

In vitro diagnostic devices

	New	NucliSENS Lysis Buffer	4/10/2017	bioMerieux Inc	el Medical & Trading Co.	2	A/Ca
#	New	Premier Buffer Reagents	4/10/2017	Trinity Biotech plc.	DL MEDICAL TRADING CO	2	ttache 

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Specimen Gate Laboratory	4/12/2017	Mer Life and Analytical S	ULREHMAN AL GOSAIBI	2	A/Cal
# New	TCAutomation and enGen Laboratory Automation Systems	4/11/2017	Thermo Fisher ,	Samir Photographic Supplies Co. Ltd.	2	Attac hed 
# New	XN-550 Hematology IVD Analyzers	4/10/2017	Sysmex America Inc	FAROUK, MAAMOUN TAMER & COMPANY	2	Attac 


Non-active implantable devices

# New	Regenerex Series A Patella Pegs .	4/12/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	Attac 
New	SwiveLock SP Suture Anchor	4/13/2017	Arthrex Inc	Al Amin Medical Instruments Co. Ltd.	FSN	https
New	Vanguard Rocc / Vanguard Alpina / Alpina APS / Alpina APR / Alpina Uni / Exception stem / Avantage cup	4/13/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	FSN	https://nc mdr. sfda.
New	VarioFit Classic cementfree hip prostheses	4/13/2017	aap Implantate AG	Saudi Import Co. Banaja	FSN	https
New	Volt Resistance	4/13/2017	2k Innovations Inc	N/A	2	A/Cal


Reusable devices

New	Ophthalmic Pack	4/13/2017	stone Medical Packaging	Gulf Medical Co.	2	A/Cal
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Single-use devices

# New	100 mL Plastipak Syringes with Catheter Neck	4/11/2017	BD Biosciences	Becton Dickinson B.V.	2	Attac 
New	Bond Elut Dried Matrix Spotting (DMS) cards	4/10/2017	Agilent Technologies, Inc.	N/A	2	https

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Custom Tubing Pack with Bioline Coating	4/13/2017	Maquet Cardiopulmonary AG	Al-Faisaliah Medical System	2	https
New	Homepump C-Series with DEHP-free tubing	4/13/2017	Halyard Health Co.	Arabian Health Care Supply Co. (AHCSC)	FSN	https
New	PreludeSYNC Radial Compression Device	4/13/2017	Merit Medical Systems Inc	Majal Care for Trading Est.	2	https
# New	ProSet Infusomat Space Lines	4/10/2017	B Braun Medical Inc	Medical supplies & Services Co.Ltd	2	Attac
New	V Gripp Nova Variceal Ligation System	4/13/2017	Indus Medical Instruments	N/A	FSN	https

- * 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.