



SBED Weekly Update 16-Oct-18

Dear,
SBED team is pleased to inform you that **32** new FSCA/recalls posted on [SFDA website](#)
(Please note: below list of FSCA/ recalls for the period of 10/8/2018 to 10/14/2018
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

Hospital Name

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
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Active Implantable Devices

New	8-Channel Lead for the St. Jude Medical Infinity™ DBS (Deep Brain Stimulation) System	10/11/2018	St. Jude Medical Inc	Al-Jeel Medical & Trading Co. LTD	FSN	https://nc.mdr.sfda	
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Anaesthetic and respiratory devices

Update	Suction Catheters, Gastro-enteral Tubes	10/11/2018	ConvaTec	Salehiya Trading Est.	FSN	https://nc	
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Assistive products for persons with disability

New	X-Short anti-tip tubes on certain TiLite manual wheelchairs	10/10/2018	TiSport	N/A	2	https://nc.mdr	
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Diagnostic and therapeutic radiation devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	Connex Spot Monitors with Masimo SpO2	10/8/2018	Welch Allyn Protocol Inc	ABDULREHMAN AL GOSAIBI GTB	FSN	https://nc	

# New	StealthStation S7 and i7 Systems with Synergy Cranial StealthStation Cranial Software	10/10/2018	Medtronic SA	Medtronic Saudi Arabia	2	Attached	
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Electro mechanical medical devices

New	ATRIUM OCEAN, OASIS, EXPRESS and EXPRESS MINI CHEST DRAINS	10/11/2018	Atrium Medical Corporation	Gulf Medical Co.	FSN	https://nc.mdr	
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New	Drill Bit	10/8/2018	Orthofix	Health Care Supply Co. (FSN	A/Ca	
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New	Espinex Tissue Retrieval System	10/8/2018	Fannin UK Ltd	TRUSTMED	FSN	https://nc	
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New	Shoulder arthroscopy plate for schaefer axis	10/8/2018	Schaefer Medical AG	ATTIEH MEDICO LTD	FSN	https://nc	
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New	The Hemotherm Dual Reservoir Cooler/Heater	10/10/2018	Cincinnati Sub-Zero Products Inc	Al Shoumoukh Trading for Technical and	2	https://nc	
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Healthcare facility products and adaptations

New	ekamove 300 lateral positioning systems	10/8/2018	ekamed GmbH & Co. KG	N/A	FSN	https://nc	
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In vitro diagnostic devices

# New	Access Cortisol Reagents	#####	Beckman Coulter...	an Coulter Saudi Arabia C	FSN	ttache	
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New	Aptio Automation	10/8/2018	is Healthcare Diagnostics	ULREHMAN AL GOSAIBI	FSN	A/Ca	
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New	BECKMAN COULTER MicroScan MICRoSTREP Plus Panel, MicroScan MuellerHinton Broth with 3 lysed horse b	10/10/2018	Beckman Coulter UK Ltd	Beckman Coulter Saudi Arabia Co Ltd	2	https://nc.mdr.sfda.gov.s	
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Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
New	FlexLab Automation	10/8/2018	is Healthcare Diagnostics	ULREHMAN AL GOSAIBI	FSN	A/Ca\	
Update	Pastorex Meningitis - reagent R4 (Streptococcus pneumoniae latex - green cap bottle).	10/8/2018	Bio Rad.	Al-Jeel Medical & Trading Co. LTD	2	https://nc.mdr.sfda.gov.s	

Non-active implantable devices

#	New	ePTFE Small Beading Vascular Graft Products	10/10/2018	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	2	Attac hed	
	New	Equinox Reverse Drill Bit Kit	10/10/2018	Exactech	N/A	2	https://nc	
	New	LifeStream Balloon Expandable Vascular Covered Stent	10/8/2018	C R Bard Inc	C.R. BARD Saudi Arabia	FSN	https://nc.mdr.	
	New	Ovation Abdominal Stent Graft System Platform	10/8/2018	Endologix international holding B.V.	Tart Medical	FSN	https://nc	
	New	Single-Use, Colpo-Pneumo Occluder	10/8/2018	CooperSurgical Inc..	ATTIEH MEDICO LTD	FSN	https://nc	

Ophthalmic and optical devices

	New	ellex I.Science iTRACK 250A	10/10/2018	Ellex iScience, Inc.	Albasar For Medical Supplies	2	https://nc	
	New	Integrated Gate Controller PCB (component of AlignRT Plus) Truebeam variant only	10/10/2018	Vision RT Ltd□	Varian Medical Systems Arabia Commercial Limited	2	https://nc.mdr.sfda.gov.s	
	Update	Vitrectomy Cutter ,	#####	Abbott Medical Optics Inc.	Gulf Medical Co.	2	A/CaV	

Reusable devices

Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	Affected Yes/No
# Update	Perifix Catheter Connector.	10/14/2018	B. BRAUN MEDICAL INC...	Medical supplies & Services Co.Ltd	FSN	Attac hed	

Single-use devices

New	BridgeMaster medical Fetal Scalp Blood Sampling Kits	10/8/2018	BridgeMaster medical Limited	MEDICAL INNOVATIONS EST.	FSN	https://nc.mdr.	
# New	EpiPen and EpiPen Jr Auto-Injectors ,	10/14/2018	Pfizer Limited	N/A	2	Attac hed	
# New	EXACTAMIX Empty EVA Bags	10/10/2018	Baxter Healthcare	Baxter AG	2	Attac hed	
# New	GHIATAS Beaded Breast Localization Wires	10/9/2018	Bard Pcripheral Vascular (BPV)	C.R. BARD Saudi Arabia	FSN	Attac hed	
# New	INFUSE X Small Bone Graft Kits	10/10/2018	Medtronic SA	Medtronic Saudi Arabia	2	Attac hed	
New	Micro-Fine Ultra 0,25mm (31G) x 5mm	10/8/2018	Becton Dickinson & Co. (BD)	Becton Dickinson B.V.	FSN	https://nc	
# New	Various Thermacare Heat Wraps	10/14/2018	Pfizer Limited	N/A	FSN	Attac hed	

* 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.