



**SBED Weekly Update** 06-Jun-17

Dear,  
SBED team is pleased to inform you that **46** new FSCA/recalls posted on [SFDA website](#)  
(Please note: below list of FSCA/ recalls for the period of 5/29/2017 to 6/4/2017  
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	SpFXL IIB 2/DM and SpFPLUS Implantable Stimulators	5/29/2017	Zimmer Biomet	Al Amin Medical Instruments Co. Ltd.	2	<a href="https://nc">https://nc</a>
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**Diagnostic and therapeutic radiation devices**

New	AMICA PROBE.	6/1/2017	HS Hospital Service	nights Of Technology. Es	FSN	<a href="#">A/Ca\</a>
New	D2RS, including VISIONARY DRF and DX-D800 models	5/31/2017	Stephanix	N/A	FSN	<a href="https://nc">https://nc</a>
# New	DRX-Revolution Mobile X-Ray Systems..	6/4/2017	Carestream Health	Samir Photographic Supplies Co. Ltd.	2	<a href="https">https</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
#	New	Eaton 9130 Uninterruptable Power Supplies Used with MRI Systems Connected to MR Operator Consoles	5/29/2017	GE Healthcare	GE Healthcare	2	<a href="#">Attac hed</a>
	New	OEC Elite systems	5/29/2017	GE Healthcare	GE Healthcare	2	<a href="#">A/CaV</a>
	New	Pausch Medical Uroview FD	6/1/2017	Hans Pausch Rontgengeratebau	N/A	2	<a href="#">https</a>
#	New	SIGNA MR Scanners ,	5/30/2017	GE Healthcare	GE Healthcare	2	<a href="#">ttache</a>
	New	The DuraDiagnost systems ,	5/31/2017	Philips Healthcare	Philips Healthcare Saudi Arabia Ltd.	FSN	<a href="#">https</a>
	New	Toshiba Angio WorkStation (XIDFAWS801)	6/1/2017	Toshiba Medical Systems Corporation	Gulf Medical Co.	2	<a href="#">https://nc</a>
#	New	Various CT, NM, and PET Scanners	5/29/2017	GE Healthcare	GE Healthcare	2	<a href="#">Attac</a>

### Electro mechanical medical devices

	New	Arrow VPS Access Kit	5/29/2017	Arrow International Inc	Gulf Medical Co.	2	<a href="#">A/CaV</a>
#	New	CardioSTAT 7-Day Recorders	6/4/2017	Icentia Inc.	N/A	2	<a href="#">Attac</a>
	New	Proctoscope	5/31/2017	Wing Plast AB	N/A	FSN	<a href="#">A/CaV</a>
#	New	SmartMonitor 2 PS/PSL Monitors	5/29/2017	Circadianc LLC	N/A	2	<a href="#">Attac</a>




### In vitro diagnostic devices

	New	ALBAclone Advanced Partial RhD Typing Kit.	5/29/2017	Alba Bioscience	Bio Standards	2	<a href="#">https</a>
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Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link	
New	Bioscot Anti-M Monoclonal Murine IgG Blood Grouping Reagent	5/31/2017	Millipore Corporation.	DAR ALAALMIYAH TRADING EST	FSN	<a href="https://nc">https://nc</a>	
New	cobas p 512 pre-analytical system, cobas p 612 pre-analytical system	5/31/2017	Roche Diagnostics Corp	FAROUK, MAAMOUN TAMER & COMPANY	FSN	<a href="https://nc">https://nc</a>	
#	New	N Antiserum to Human Ceruloplasmin	6/4/2017	Siemens Healthcare Diagnostics Product	AL-KAMAL Import	2	<a href="https">https</a>
#	New	N Latex CDT Kits	5/29/2017	s Healthcare Diagnostics I	AL-KAMAL Import	2	<a href="ttache">ttache</a>
#	New	Phadia EliA Ro Wells	6/1/2017	Phadia Ltd	ULREHMAN AL GOSAIBI	2	<a href="ttache">ttache</a>
New	Pointe Scientific Lactate Dehydrogenase (Liquid) Reagent	5/29/2017	Medtest Holdings, Inc	N/A	2	<a href="https://nc">https://nc</a>	
#	New	Trypticase Soy Agar with 5% Sheep Blood (TSA II) Plated Media	5/29/2017	BD Biosciences	Becton Dickinson B.V.	2	<a href="Attached">Attached</a>
New	VITEK 2 AST-GN colistin	5/31/2017	bioMerieux Inc	el Medical & Trading Co.	FSN	<a href="A/Ca">A/Ca</a>	
New	V-Lyte Dilution Check & V-Lyte Integrated Multisensor Technology (IMT).	5/29/2017	Siemens Healthcare Diagnostics GmbH	ABDULREHMAN AL GOSAIBI GTB	2	<a href="https://nc.mdr">https://nc.mdr.</a>	

### Non-active implantable devices

New	Acumed SlideLoc Anatomic Radial Head System	6/1/2017	Acumed LLC	N/A	2	<a href="https://nc">https://nc</a>
New	BeGraft Peripheral Stent Graft System	6/1/2017	Bentley InnoMed GmbH	Ameesa Medical Instruments	FSN	<a href="https">https</a>

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Equinoxe Modular and No.-Modular Pilot Tip Reamers	6/1/2017	Exactech	N/A	FSN	<a href="https://nc">https://nc</a>
New	Kii abdominal trocars	5/29/2017	Applied Medical Resource:	Dawha Medical	2	<a href="#">A/CaV</a>
New	Logic Fit Tibial Tamp Head Instrument	6/1/2017	Exactech	N/A	FSN	<a href="https">https</a>
New	Novation Calcar Planer Guide Tip	5/30/2017	Exactech	N/A	FSN	<a href="https">https</a>
# New	T.E.S.S. Components ,	6/4/2017	Zimmer Biomet	in Medical Instruments C	2	<a href="#">ttache</a> 
Update	Trauma Implants - intramedullary nails	6/4/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	<a href="https">https</a>
# New	Vertefix Radiopaque Bone Cement	5/29/2017	Cook Inc,	NAFA Medical	2	<a href="#">Attac</a> 
<b>Reusable devices</b>						
# New	Various Trauma and Extremity Instruments ,	6/4/2017	Zimmer inc	Ebrahim M. Al-Mana & Bros. Co. Ltd.	2	<a href="#">Attac</a> 
<b>Single-use devices</b>						
# New	1,000 mL 0.9% Sodium Chloride Injections	5/30/2017	Fresenius Medical Care.	Fresenius Medical Care GmbH	2	<a href="#">Attac</a> 
New	AbbVie PEG, PEG Kit 15FR, 20FR	6/1/2017	AbbVie Inc..	FAROUK, MAAMOUN TAMER & COMPANY	2	<a href="https">https</a>
# New	Clear Flashback and Winged Arterial Needles	6/4/2017	Argon Medical Devices	Al Amin Medical Instruments Co. Ltd.	2	<a href="#">Attac</a> 
New	dolphin Inflation Device	6/1/2017	Vascular Solutions Inc	cal Technology Establish	2	<a href="#">A/CaV</a>
# New	Extension Sets Used with PCA Pumps	6/4/2017	BD Biosciences	Becton Dickinson B.V.	2	<a href="#">Attac</a> 

Data Type	MedicalDevice	Post Date	Manufacturer	Distrbutor	Class	Link
New	Flocare Gastrostomy tubes (G-tube) ENFit	5/30/2017	Nutricia Medical Devices	cigalah group	FSN	<a href="https://ncmdr.gov">https://ncmdr.gov</a>
# New	Helical Infusion Catheters and Morph Universal Deflectable Guide Catheters	6/4/2017	Biocardia, Inc.	Medical Technology Establishment	2	<a href="#">Attached</a>
New	ProcedurePak trays containing specific i.e. codes and Polysurb Suture	6/1/2017	Molnlycke Health Care AB.	Branch of Molnlycke Health Care AB	FSN	<a href="https://ncmdr.gov">https://ncmdr.gov</a>
# New	QuikClot TraumaPads	5/29/2017	Z-Medica LLC	N/A	2	<a href="#">Attached</a>
# New	Various Arrow Arterial, CVC, Hemodialysis, MAC, PICC, and PSI Kits ,	5/30/2017	Teleflex Medical..	Gulf Medical Co.	2	<a href="#">Attached</a>
# New	Yankaeur Suction Tubes	5/30/2017	Rocket Medical	Modern Quality Est.	2	<a href="#">Attached</a>

\* 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.sfd.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.