

**SBD Weekly Update** 2010-أكتوبر-25

Dear,

SBD team is pleased to inform you that **44** new recalls posted on [SFDA website](#)  
(Please note: below list of recalls for the period of 18/10/2010 to 24/10/2010  
In order to view more details, click the links and for ECRI alerts see the attachments below.

**NOTE:**

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

MedicalDevice	Post Date	Manufacturer	Source	Class	Link
ARRAY and POLARIS Spinal System	23/10/2010	Ebi, Llc	FDA	2	October
BeneHeart D6 Defibrillator/Monitors	18/10/2010	Shenzhen Mindray Bio-Medical Electronics Co.Ltd	ECRI	2	Attach
CELL-DYN 1700 Analyzer	20/10/2010	Abbott	NCMDR	2	s/Octo
Cholestech LDX	24/10/2010	Medical Device Safety Service (MDS)	MHRA	FSN	/recalls
COBAS Glucose Hexokinase (reagent)	18/10/2010	Roche Diagnostics Corp	ECRI	2	Attach
cobas IT 3000 Software	18/10/2010	Roche Diagnostics Corp	ECRI	2	ttache
Digital image processing unit	24/10/2010	E-COM Technology Limited	MHRA	FSN	ls/Octo
Dual-Chamber External Temporary Pulse Generator	20/10/2010	Medtronic Inc	NCMDR	2	http://
EasyLink Informatics Systems	23/10/2010	Siemens Healthcare Diagnostics	FDA	2	ents/re
EasyRA Cuvette Segment for EasyRA Clinical Chemistry Analyzer	19/10/2010	Medica Corporation	FDA	2	http://
E lance Vital Signs Monitor	23/10/2010	Spacelabs Healthcare Inc	MHRA	FSN	lls/Octo
ENDOPATH XCEL with OPTIVIEW Technology Trocars	18/10/2010	Ethicon Endo Surgery Inc	ECRI	2	Attach

MedicalDevice	Post Date	Manufacturer	Source	Class	Link
EXaCT Targeting Couch	24/10/2010	Varian Medical Systems	NCMDR	2	<a href="#">s/Octo</a>
Excelsior Disposable Syringe	24/10/2010	Excelsior Medical Corp	FDA	1	<a href="#">lls/Octo</a>
flush syringes in Cook Central Venous Catheter Trays	18/10/2010	Cook Medical	ECRI	2	<a href="#">Attcah</a>
GE Centricity Laboratory Instrument Interface Software	24/10/2010	GE Healthcare	FDA	2	<a href="#">http://</a>
Hematology Analyzers	18/10/2010	Sysmex Europe GmbH	ECRI	2	<a href="#">ttache</a>
hole long plate	24/10/2010	Biomet Microfixation	FDA	2	<a href="#">ts/reca</a>
Hush Slush Unit	18/10/2010	OR Solutions Inc	ECRI	2	<a href="#">ttache</a>
Image-intensified fluoroscopic X-ray system	20/10/2010	GE Medical Systems	NCMDR	2	<a href="#">http://</a>
IMMULITE® 2500 System	23/10/2010	mens Healthcare Diagnostics Prod	MHRA	FSN	<a href="#">calls/O</a>
Intra-Aortic Balloon Catheters	18/10/2010	Arrow International Inc	ECRI	2	<a href="#">ttache</a>
i-STAT Celite and Kaolin Activated Clotting Time Test Cartridges	18/10/2010	Abbott Point of Care	ECRI	2	<a href="#">Attach</a>
MagNa Pure LC 2.0 Instruments	18/10/2010	Roche Diagnostics Corp	ECRI	2	<a href="#">ttache</a>
NexGen® Complete Knee Solution	23/10/2010	Zimmer inc	FDA	2	<a href="#">/Octob</a>
Panocell®-20 (mmnunoheamatology (Blood Grouping))	20/10/2010	Immucor GmbH	NCAR	1	<a href="#">http://www.s</a>
PathFinder end screw extender sleeve.	19/10/2010	Zimmer inc	FDA	2	<a href="#">http://</a>
Philips IntelliVue Information Center	20/10/2010	Philips Medical Systems	NCMDR	2	<a href="#">http://</a>
R3 Constrained Acetabular Liner(Hip prosthesis)	19/10/2010	Smith & Nephew inc	FDA	2	<a href="#">http://</a>
ScanPoint Communication Cradles Used with BladderScan Ultrasound Systems	18/10/2010	Verathon Inc	ECRI	FSN	<a href="#">Attach ed</a>
Sequencer (Sequencer Verify & Record System	19/10/2010	IMPAC Medical Systems Inc	FDA	2	<a href="#">http://</a>
Servo-i Ventilators	18/10/2010	MAQUET Inc	ECRI	2	<a href="#">ttache</a>
SoftMic (Software)	20/10/2010	SCC Soft Computer	FDA	2	<a href="#">ents/re</a>
SoftPath GUI ( Software)	24/10/2010	SCC Soft Computer	FDA	2	<a href="#">ts/reca</a>
Symbiq OneChannel and Two Channel Infuser	23/10/2010	Hospira Inc	FDA	1	<a href="#">http://</a>

MedicalDevice	Post Date	Manufacturer	Source	Class	Link
Test Cartridges	24/10/2010	Bio-Rad Laboratories Inc	FDA	2	s/recal
Tosoh AIA-PACK B12	24/10/2010	Tosoh Corporation	MHRA	FSN	ecalls/
TrueBeam and TrueBeam STx	24/10/2010	Varian Medical Systems	FDA	2	lls/Octo
TruLink Pre-wired Neonate ECG Electrodes	23/10/2010	Spacelabs Healthcare Inc	MHRA	FSN	http://
Universal Flat Panel Yoke	23/10/2010	Stryker Communications	MHRA	FSN	alls/Oc
Vacutainer Push Button Blood Collection Sets	18/10/2010	Becton Dickinson & Co. (BD)	ECRI	2	Attach
Various REALIZE/SAGB Adjustable Gastric Banding Products:	18/10/2010	Ethicon Endo Surgery Inc	ECRI	FSN	attach ed
Vertex Max Reconstruction System Drill Guides	18/10/2010	Medtronic Navigation Inc	ECRI	2	Attach
Vision Alpha Ventilators	18/10/2010	Novalung GmbH	ECRI	2	ttache



Indicates that medical devices subject to removal and/ or destroyed action.

SBD 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://www.sfda.gov.sa/services/md\\_Recalls/recallsDispaly.aspx](http://www.sfda.gov.sa/services/md_Recalls/recallsDispaly.aspx)

SFDA urges all hospitals that have medical devices subjected to these recalls to contact the local representative in order to ensure corrective or planed action been implemented.