



## IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- MAY 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
NX - Modality Workstation	Agfa Healthcare	Advice regarding a software upgrade	14 April 2011	Yes
Legendair	Airox S.A.	Advice regarding a device modification	11 May 2011	Yes
Elevate Pelvic Floor Repair Systems with IntePro Lite	American Medical Systems	Advice regarding a device removal	24 May 2011	Yes
AMS 800 Control Pump	American Medical Systems	Advice regarding a device removal	09 May 2011	Yes
Omniflush prefilled syringes	B Braun	Advice regarding a device removal	09 March 2011	Yes
Access Immunoassay Sytems	Beckman Coulter Inc.	Advice regarding the use of the device	18 April 2011	Yes
UniCel Dxl Immunoassay Systems	Beckman Coulter Inc.	Advice regarding the use of the device	18 April 2011	Yes
AU Clinical Chemistry Systems	Beckman Coulter Inc.	Advice regarding the use of the device	27 April 2011	Yes
Access® PAPP-A	Beckman Coulter Inc.	Advice regarding the use of the device	13 May 2011	Yes
BD FACS 7-Color Setup Beads	Becton Dickinson Biosciences	Advice regarding a software upgrade	27 May 2011	Yes
Stolen Boston Scientific Endoscopy and Urology / Women's Heath Devices	Boston Scientific	Advice regarding a device removal	05 May 2011	Yes
VNS Therapy Generators Models 103 and 104	Cyberonics	Advice regarding a device removal	23 May 2011	Yes
NovaFlex Delivery System, models 9350FS23 & 9350FS26	Edwards Lifesciences	Advice regarding a device removal	09 May 2011	Yes
Precise Digital Accelerator, Synergy Platform, Synergy, Synergy S, Infinity, Axesse	Elekta	Advice regarding the use of the device	06-May-11	Yes
Optima MR450w, Discovery MR450, Discovery MR750, Signa HDx, Signa HDxt, Signa HFO, GE 1.5T Signa HDc, GE 1.5T Signa HDsv, Signa Excite 1.5T & 3T	GE Healthcare	Advice regarding a device modification	03 May 2011	Yes
7F SafeSheath Tearaway Kit - 13 cm, 9F SafeSheath Tearaway Kit - 13 cm, Transvalvular Insertion Tool Kit, SafeSheath Sealing Adapter Kit, SafeSheath Sealing Adapter Kit with Wing Extension Kit	GE Healthcare	Advice regarding a device removal	13 May 2011	Yes
Discovery VCT, Discovery RX VCT, Discovery STE, Discovery RX and Discovery ST systems with Dimension console.	GE Healthcare	Advice regarding a software upgrade	30 May 2011	Yes
Infusable and InfusaScan Pressure Infusors	GE Healthcare / Vital Signs Inc.	Advice regarding a device removal	02 May 2011	Yes
Orthoralix 8500 DDE, Orthoralix 9200 DDE	Gendex Dental System	Advice regarding changes/updates made to instructions for use	31 March 2011	Yes
Sensodyne Repair & Protect Toothpaste 75ml	GlaxoSmithKline	Advice regarding a device removal	13 May 2011	Yes
orthoPAT	Haemonetics Corporation	Advice regarding a device removal	11 May 2011	Yes
Jasmine Mobile Lifter	Invacare	Advice regarding a device removal	16 May 2011	Yes
HEMOCHRON Jr. PT Cuvettes	ITC	Advice regarding a device removal	20 May 2011	Yes

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Bond Oracle HER2 IHC System	Leica Biosystems	Advice regarding a device removal	19 May 2011	Yes
Connection fixtures 1002.65A0 and 1002.65S0	MAQUET GmbH & Co. KG	Advice regarding the use of the device	12 May 2011	Yes
GENius Multi-Channel RF generator	Medtronic	Advice regarding a device removal	03 May 2011	Yes
GENius Multi-Channel RF generator	Medtronic	Advice regarding a device removal	03 May 2011	Yes
Sprint Fidelis® Lead Family Models 6949 6931, 6948, 6930	Medtronic Inc.	Advice regarding the use of the device	01 April 2011	Yes
Biogel Eclipse Indicator System, Biogel Eclipse Reveal System	Molnlycke	Advice regarding a device removal	21 April 2011	Yes
NIKKISO Blood tubin Lines	Nikkiso	Advice regarding a device removal	09 May 2011	Yes
Nova StatStrip Glucose Hospital Monitoring System	Nova Biomedical	Advice regarding the use of the device	02 May 2011	Yes
Microstream Filterline	Oridion	Advice regarding a device removal	15 March 2011	Yes
Cortoss Delivery Guns	Orthovita	Advice regarding a device removal	15 April 2011	Yes
ARTISTE MV and ONCOR Linacs	Siemens	Advice regarding the use of the device	03 May 2011	Yes
Ysio F and Ysio S	Siemens	Advice regarding the use of the device	28 April 2011	Yes
ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) Assay	Siemens Healthcare Diagnostics Inc.	Advice regarding a device modification	01 May 2011	Yes
ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) Assay	Siemens Healthcare Diagnostics Inc.	Advice regarding a device modification	17 May 2011	Yes
PERI PREP Wipes Box / SKIN PREP Wipes Box / REMOVE Wipes Box / UNISOLVE Wipes Box / NO STING SKIN PREP Wipes Box	Smith & Nephew	Advice regarding a device removal	29 April 2011	Yes
LogiCal®, NovaTrans®, and TranStar® Invasive Pressure Monitoring Systems	Smiths Medical	Advice regarding a device removal	18 May 2011	Yes
Eco Mini and Brio Implantable Pulse Generators for Neurostimulation	St. Jude Medical	Advice regarding a device removal	24 May 2011	Yes
Optical Guidance Platform (OGP)	Varian	Advice regarding a software upgrade	02 May 2011	Yes
Optical Guidance Platform (OGP), version 2.6 and 2.6.1	Varian	Advice regarding a software upgrade	10 May 2011	Yes
Waters Acquity TQD, SQD, 3100 Mass Spectrometers	Waters Corporation	Advice regarding a device modification	03 May 2011	Yes
NexGen® Complete Knee Solution Cruciate Retaining Articular Surface	Zimmer	Advice regarding a device removal	05 May 2011	Unknown
ARIATM, RT Chart Application v8.0 - v8.9	Varian	Advice regarding the use of the device	01 June 2011	Yes
Pinnacle™ Pelvic Floor Repair Kit	Boston Scientific	Advice regarding a device removal	18 May 2011	Yes
HandyVac Low Vacuum Surgical Wound Drainage Systems CH (Fr.) 14, HandyVac ATS Low Vacuum Surgical Wound Drainage Systems CH (Fr.) 14., Drain Spiral CH14/green X-ray., Drain CH14 soft/steel troac., Passive drainage system set/1 drn CH14. Female Connector CH14.	Unomedical	Advice regarding a device removal	31 May 2011	Yes