



IRISH MEDICINES BOARD  
FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- FEBRUARY 2010

Product	Manufacturer	Type	Link to FSN
Foot Lok Cushion	CIVCO Medical Solutions	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
LIST No 16026 Symbiq™ Once-Channel Infuser and LIST No 16027 Symbiq™ Two-Channel Infuser	Hospira	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Centricity* Enterprise Archive Versions 3.0 to 3.0.7	GE	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
TASCI, Centrifuge Blood	Andreas Hettich GmbH & Co KG	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
DePuy DNP Anatomic Fracture Repair System	DePuy	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Legend® AF01 Footed Attachment	Medtronic	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
HeartStart HS1, HeartStart First Aid, HeartStart Home automated external defibrillators	Philips Healthcare	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
B. Braun Space Pumps using the B. Braun Space Pole Clamp	B. Braun Medical Ltd	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a> <a href="#">Instructions for Use Poster</a>
Oxford Revision Stems (19mm diameter)	Biomet UK Ltd	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
G006 ECO Ultrasound Gel bottle 260ml	FIAB	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Hill-Rom beds with Monkey pole	Hill-Rom	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Dorsal Height Adjuster	Zimmer Spine	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Restoration Modular Plasma Distal Stem	Stryker Orthopaedics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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Phaco Needle Wrench	Bausch & Lomb	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Inion CPS Baby Screw	Inion Oy	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Eosin Stain SS-035C	Wescor Biomedical Systems	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
ABL505/555, EML105, ABL600, ABL700 Series, ABL800 FLEX and ABL800 BASIC Analyzers	Radiometer Medical Aps	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Endotracheal (ET) Tubes	Unomedical Limited	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
MR Eclipse 1.5T RF Connector Block	Philips Medical Systems	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Locator Abutment Model ILOA002	Biomet 3i	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
IMTEC MDI Hybrid Implant (O-Ball Abutment), 2.9 x 13mm and 2.9 x 15mm	IMTEC	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
MOLTECH / ACCUTRONICS Battery Rev. D and E used in the LEGENDAIR® and SUPPORTAIR® ventilators and associated accessory, Open Pack®.	Covidien	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Modified Novy Cornual Cannulation Set	Cook Ireland Limited	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
MTP 031123-10 Gas Filters	Karl Storz Endoscopy (UK)	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
DRB1*11 SSP Unitray, DRB1*11 SSP Unitray kit with Taq and AllSet Gold DRB1*11 High Res SSP	Invitrogen	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Coseal Surgical Sealant	Baxter	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
iSleep 20/20+/20i	Breas	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
ARTISTE digital linear accelerator	Siemens AG	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Huber needles	Nipro Europe	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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Syramed® µSP6000 PREMIUM and Volved® µVP7000 PREMIUM pumps	Acromedical	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
AccuChek Inform II Meter	Roche Diagnostics Limited	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
SEQUENCER for MOSAIQ	IMPAC/ELEKTA	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Promos® Standard Inclination Set	Smith&Nephew	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Epsylar Percutaneous Introducer Sheath	OptiMed	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Foundation® Knee System – Tibial Baseplate, Model 324-01-108	Encore Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
HM 550 Cystostat	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
FasTracker®-325 Infusion Catheter / FasTracker®-325 Vascular Access System	Boston Scientific	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
GEHC Surgery Products	GE Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Polident Ultra and Poligrip Total Care	GlaxoSmithKine	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
ECREA Flex reagent cartridges (K1270)	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
GE Centricity™ PACS RA1000 Workstation; Software Versions: 2.1.x and 3.0.x	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
GE Centricity™ PACS RA1000 Workstation; Software Versions: 1.0x and 2.0.	GE Healthcare	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Alaris® GP Volumetric Pump with Plus software and Alaris® GP Guardrails Volumetric Pump with Plus software	CareFusion	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Cobas Ampliprep Instrument / Cobas s401 / Cobas s201	Roche Diagnostics Limited	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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Acrobat 2000 spring arms used with Merilux ceiling mounted medical lamp systems	Merivaara Oy	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
F1 Dental chair	Fimet Oy	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Curved Scissors 5mm for <i>da Vinci</i> ® Surgical Systems	Intuitive Surgical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Bound Tree Economy Extremity Vacuum Splints SP040, SP041, SP042 and SP043	Bound Tree Medical	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
SYNCHRON® LX®i 725 and UniCel® DxC 600i	Beckman Coulter, Inc.	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
SKY fast & fixed abutment 0° DH 2mm	Bredent Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Appollo Special Needs Bathing Products, models: Elegance, Excalibur and	Reva Industries Limited	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
QWIX® screws dia. 4.3mm	Newdeal	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Flowmeter FLM 0-12 l/min, O2	GCE Norden AB	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Adaptor R3/8" to 9/16"	GCE Norden AB	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Powerheart and Responder AEDs	Cardiac Science	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Panorama HFO System	Philips Healthcare	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
CA-1500	Sysmex Europe GmbH	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
COULTER® PrepPlus / COULTER® PrepPlus 2	Beckman Coulter, Inc.	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Evolis Femur Standard Cementless	Medacta	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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EnRhythm® EnRhythm MRI® Advisa® Pacemakers	Medtronic	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
BD FACS Sample preparation Assistant II Instrument (SPA II)	Becton Dickinson	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Gamma 3 Nailing System	Stryker	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Advantage, 2-Button Turbo Handpiece	ConMed Linvatec	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Tessier Osseous Microtome (TOM®) – BONE MILL	Stryker Osteosynthesis Freiburg,	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Access AccuTnl Reagent Kit	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
AIA-2000 ST , AIA-2000 LA	Tosoh Corporation	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Ulnar Shortening saw Blade - Hub Style L	Acumed	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Cyberknife Robotic Radiosurgery System, Multiplan® Treatment Planning System Versions 3.0, 3.1, 3.5.0, 3.5.1	Accuray	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Artis Zee, Axiom Artis MP, Axiom Artis dMP	Siemens Helathcare	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Newdeal® Hallu®-C Plate	Newdeal® SAS	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Amerlex FT3 kit	Trinity Biotech	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
i-STAT cartridges / i-STAT Hematocrit/HCT and Calculated Hemoglobin/HB Cartridge	Abbott Point of Care	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Philips Switched Internal Defibrillator Paddles (for HeartStart and HeartStart XL portable external defibrillators)	Philips Healthcare	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Spike set PN gravity Prime KM1.EE.138.2 - Portable IV Infusion Pumps	Micrel Medical Devices S.A.	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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syngo Dynamics Reporting System on version 6.X, 7.X and 8.X	Siemens Solutions USA Inc.	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
ETD3 GA Plus, ETD3 GA Basic, ETD2 GA, ETD2 Plus GA, mini ETD2 GA, mini ETD	Miele & Cie. KG	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Birmingham Knee replacement bearing insert	Joint Medica ltd	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
APTUS Radius 2.5 Drill Block	Medartis AG	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
ABL80 Flex CO-OX Analyser	Radiometer	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
PK7200 Blood Grouping System	Beckman Coulter Biomedical Ltd	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
VersaCell Interface wheel kits to ADVIA 1800 Chemistry Analyser	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
i-CAT Classic	Imaging Sciences International	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Coulter LH 750 / LH 780 / GEN'S Analysers	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Coulter LH 500 Analyser	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
UniCel DxH 800 Coulter Cellular Analysis System	Beckman Coulter Inc.	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Aks-Patient Hoists	Aks Aktuelle Krankenpflege Systeme GmbH	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
VASOVIEW HEMOPRO Endoscopic Vessel Harvesting System	Maquet Cardiovascular	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Zimmer Reconstruction System Tenaculum Instruments	Zimmer Ltd.	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>

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Ondal Acrobat 2000 Sprung Arm used to carry Helion and Xenion surgical lights and monitors	TRUMPF Medizin Systeme GmbH	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
LifeCycle for Prenatal Screening	PerkinElmer	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Blue Max, Blue Max 20 and Ultra-thin Diamond Balloon Dilation Catheters	Boston Scientific International	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Access Cortisol Reagent Kit	Beckman Coulter	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>