



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

Product	Manufacturer	Type	Link to FSN
Triathlon® MIS 4:1 Cutting Block – Size 1-8	Stryker Orthopaedics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Crossover Sheath Introducer	Thomas Medical Products, distributed by Cordis	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Xcelerate Ceramic 4:1 Cutting Blocks	Stryker Orthopaedics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Haematocrit Rotors	Hettich Centrifuges	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
GreenLight HPS Fiber Model: 0010-2090	American Medical Systems	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Various products packaged in Tyvek Puch, Single-Use, sold as singles or in boxes	ConMed Linvatec	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Osseous Microtome (TOM®) – BONE MILL	Stryker Osteosynthesis Freiburg	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Exeter Cement Centralizer	Stryker	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
SINUX Nucleus Replacement (SIN 0001)	Sinitec AG	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Ellipse PPT & MultiFlex	Ellipse A/S	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Impella	Abiomed Europe	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
HeartStart Mrx	Philips Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	Manufacturer's FSN
Nimbus Pico μ	Clearstream	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Leica Surgical Microscopes	Leica Microsystems	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
CELL-DYN Sapphire System	Abbott Laboratories	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
CeCon 3000	DWA Dialyse Wasser Aufbereitungsanlagen GmbH & co. KG	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Aneroid Sphygmomanometer with Stethoscope	Wenzhou Bokang Instruments Co., Ltd.	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Diagnost 76, EasyDiagnost and EasyDiagnost Digital Systems	Philips	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN

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Seraclone Anti-k (KEL2)	Bio-Rad Medical Diagnostics GmbH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Drager Sola 300 Examination Lights	Drager Medical	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
VITROS® Immunodiagnostic Products CA 125 II™ Reagent	Ortho Clinical Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Consulta® CRT-D, Secura® DR/VR, Concerto® II CRT-D, Virtuoso® II DR/VR, Maximo® II CRT-D, Maximo® II DR/VR	Medtronic	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Back-Up Meier Steerable Guidewire	Boston Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Corail AMT HA Femoral Stem Std With Collar Size 11 and Corail AMT HA Femoral Stem Std Without Collar Size 8	DePuy	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Medstream Implantable Drug Pump	Codman	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Varisource iX Console	Varian	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Convert+ Model V-195 Implantable Cardioverter-Defibrillator	St Jude Medical	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Large Qwix screws	Newdeal SAS	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Pitt-Easy	Sybron Implant Solutions	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Innova□ 2100IQ, 3100, 3100IQ, 4100 and 4100IQ cardiovascular X-ray imaging systems with InnovalQ	GE Healthcare	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
DBP-2800 Battery Pack	Defibtech	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Zoll E Series BLS Defibrillator	Zoll	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Acheeva Learning Station	The Helping Hand Company	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
TruSat Pulse Oximeter (GE Healthcare or Datex Ohmeda) with external power supply	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Fred Easy AED	Schiller	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
BlastAssist 12160010, 10ml, lot number 10100321	Origio	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Aimer Endofemoral	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Flexima Biliary Stent System	Boston Scientific	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN

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CARESCAPE™ Monitor B850	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
CalMed custom procedure packs - various	Caledonian Medical Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
GE Centricity™ Laboratory, software version: v4.1	GE Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Cutera Titan XL Handpiece	Med-Unlimited GMBH	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Nexgen Mis Total Knee Procedure, Stemmed Tibial Component, Fixed Bearing	Zimmer	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Alpha Pinnacle 10kVA UPS with External BaAlpha Pinnacle 10kVA UPS with External Battery Pack (EBP)	Alpha Technologies Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Panocell - 10	Immucor Gamma	Advice has been provided by the manufacturer regarding the review of patient results/patient recall/sample retesting s required	Manufacturer's FSN
Eclipse Version 7.3.10 (multiple workstations) or VARiS Vison system 7.x	Varian	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
O-ARM® Imaging System	Medtronic	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
"Swan-Ganz Continuous Cardiac Output (CCO)" Catheters	Edwards LifeScience	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Heartware Ventricular Assist System Controller	Heartware	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Arrow 4 Fr Peripherally Inserted Central Catheter (PICCs) Kits	Teleflex	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Chiron RIBA HIV-1/HIV-2 SIA	Novartis Diagnostics	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Vicryl Rapide suture	Ethicon	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Visulas 532sVite	Carl Zeiss Meditec	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
Olympus Electrosurgical Snare Tube	Olympus	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Stanmore Total Knee (Right and Left)	Biomet UK Ltd	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Clinical Chemistry Phosphorus	Abbott Laboratories	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
BrainLab Digital Lightbox 2.0 with data export	BrainLab	Advice has been provided by the manufacturer regarding a software upgrade	Manufacturer's FSN
NicoletOne® System	CareFusion	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN

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Spacelabs Healthcare Vital Signs Monitor Model 91220	Spacelabs Healthcare	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Advia Centaur Systems Calibrator A	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Nickel metal hydride battery packs used in the Freeway and Companion A and B	Possum	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
A High Res SSP UniTray	Invitrogen	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Immulite 2000/2500 Substrate Module L2SUBX	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding the review of patient results/patient recall/sample retesting is required	Manufacturer's FSN
Reflection Line Adapters Product Code 71323144 Lot 09JM07674, Product Code 71323145 Lot 09KM04756 and 09KM11702	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
TriniLIA Auto Dimer	Tcoag Ireland Ltd	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
C500 S-10 R-Net and other R-Net chairs with ESP	Permobil AB	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
Trial Gage	Acumed LLC	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Online Substitution Line for Dialog	B. Braun Avitum AG	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Ventnor Shower Chair	James Spencer & Co. Ltd.	Advice has been provided by the manufacturer regarding a device modification	Manufacturer's FSN
OIC Peek Cage	Stryker	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
IMMAGE Systems Buffer 1 (BUF1)	Beckman Coulter	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
XiO / Elekta	Elekta	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
CellTracks Autoprep System	Veridex LLC	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN
Custom Procedure Trays	DeRoyal Europe Limited	Advice has been provided by the manufacturer regarding a device removal	Manufacturer's FSN
Talley G3 Quattro Plus mattresses, 99-01-05-306 (from April 2006) fitted to Linet Eleganza Smart bed frames with 3/4 (three quarter) side rails	Talley Group	Advice has been provided by the manufacturer regarding the use of the device	Manufacturer's FSN