



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

Product	Manufacturer	Type	Link to FSN
Internal handles and paddles LIFEPAK®9, LIFEPAK 9P, LIFEPAK 12, LIFEPAK 20 or LIFEPAK 20e defibrillator/monitors	Medtronic	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Clinical Chemistry Total Bilirubin	Abbott Laboratories	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
MaxiMove Scoop Stretcher	ArjoHuntleigh	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
ApexPro Telemetry System	GE Healthcare	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
GE Centricity™ RIS, software versions: 4.1.24, 4.1.25 and 4.1.26	GE Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Philips Intera and Achieva systems, T1 Perfusion	Philips Healthcare	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Arrow Select IV Tubing Sets, Accessories, and Certain Embolectomy Catheters	Teleflex Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Primary SYMBIQ® Set List number 16096-28, lot 82-028-5H and Primary I.V. Set List number 19689-01, lot 81-147-5H	Hospira	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Symbiq infusers (Lists 16026 and 16027)	Hospira	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Armstrong Grommet. 1.14MM Lumen FL	Micromedics Inc.	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
CA 4 Amalgam Separator	Durr Dental	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a> <a href="#">Manufacturer's FSN</a>
Stryker® Orthopaedics Passport® A.R. Knee Instrumentation Anterior Skim Guide	Stryker® Orthopaedics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Stryker® Orthopaedics Passport® A.R. Knee Instrumentation Distal Guide Stand	Stryker® Orthopaedics	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a> <a href="#">Manufacturer's FSN</a>
Scorpio Punch Thru Tibial Baseplates	Stryker® Orthopaedics	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a> <a href="#">Manufacturer's FSN</a>
Syngo Imaging VB20, VB30A, VB30B, VB35	Siemens Healthcare Sector	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>

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Symbiq™ infusers (Lists 16026 and 16027)	Hospira	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a> <a href="#">Manufacturer's FSN</a>
FL400 Fluorescence Imaging Feature for M720 OH5	Leica Microsystems	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Varta Microbattery power one p312, rechargeable battery	Siemens	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Receptal	Hospira	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
AVS TL Spacer Trial 7-18	Stryker UK Limited	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Constellation Vision System	Alcon	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
PLT GP/Receptors Kit	Stago	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Pioneer Plus	Medtronic Inc.	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Easy Cyst Suprapubic Exchange Set for Children	Teleflex Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
ANTIREFLUX VALVE URETERAL STENT SETS FOR CHILDREN	Teleflex Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Futurabond NR Single Dose	Voco GmbH	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Hypromellose Ophthalmic Solution USP 2% w/v BD HPMC 2ml Sterile Solution	BD Medical	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Surgical Ablation Probe	Cardima	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
XiO	Elekta	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
COBAS® AMPLICOR® HIV-1 MONITOR Test, v1.5	Roche Diagnostics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
LIFEPAK® 20 and LIFEPAK 20e Defibrillator/Monitors	Medtronic Physio-Control	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Teleflex Medical TAUT ADAPt Balloon Open Access Port 10/12mm	Teleflex Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
PM1000 Flow Selector	Precision Medical	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Endothelin ELISA	Biomedica Medizinprodukte GmbH & Co. KG	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
MIKA speedblock (sizes 8-12)	DJO Medical	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
XiO Treatment Planning Software	Elekta	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>

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XVI	Elekta	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Imaxeon Avidia Angiographic Contrast Injector	IMAXEON	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
CIBA VISION® Softperm® (synergicon A) contact lenses	CIBA VISION®	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Paradym DR, Paradym CRT-D and Paradym CRT-D sonR ICD	Sorin Group	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
G8 Hemoglobin F&A2 Control Set	TOSOH Europe N.V./S.A.	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
HeartStart MRx Monitor/Defibrillator (M3535A/M3536A)	Philips Healthcare	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
ARCHITECT Sirolimus Reagent	Abbott Laboratories	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Cobas® Ampliprep / Cobas® Taqman® HBV Test, Version 2.0 (CAP/CTM HBV V2.0)	Roche Diagnostics UK Limited	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
INNO-LiPA HBN DR V2 / V3	Innogenetics	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Corail Hip Cemented Femoral Stem Without Collar Size 11, Product Code - L96411, Lot Number 3028743; and Corail Hip Cemented Femoral Stem Without Collar Size 9, Product Code - L96409, Lot Number 3028308	Depuy	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
LightCycler MRSA Advanced Test	Roche Diagnostics	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Delta and Gamma XXL	Dräger Medical	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
VERSANT Sample Preparation 1.0 Reagents	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Accurate Pregnancy Test	Clonmel Helathcare Limited	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
PhaSeal Infusion Adapter C70	Carmel Pharma AB	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Atlantic Bed Rails	Park House Healthcare	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
DIC version 1.54.09d, ARIA Standard version 1.1	Varian	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
SwitchPoint Infinity 2 and SwitchPoint Element DOM Cards	Stryker UK Limited	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Völker Healthcare Beds, models: 2080, 3010 and 3080	Völker AG	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
LIRAS for Infectious Diseases v2.01	Innogenetics	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>

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Oxoid Giolitti-Cantoni Broth CM0523	ThermoFisher Scientific	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Meliseptol® Foam pure, Canister, 5 Litres	B.Braun Medical / B.Braun Melsungen	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
XiO	Elekta	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
HeartStart FR2+	Philips Healthcare	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
GM11002560 Flexible Applicator Probe, 3.2mm, braced PVDF	Varian Medical Systems	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Lens Cleaning Sheath for LTF- Type VH , Deflecting Tip Laparoscope	Olympus Keymed	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Mölnlycke Procedure Pak®	Mölnlycke Healthcare	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
P3, P4, P3B, P4B Plates	Beckman Coulter UK Ltd.	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
StealthStation S7 Power Cord Retractor	Medtronic Navigation	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a> <a href="#">Manufacturer's FSN</a>
Synchro™-14 and Synchro2™ Guidewires	Boston Scientific	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Dyonics II Shaver Controller	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Corgi Powered Wheelchairs	Activate	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
i-STAT PT/INR Cartridges	Abbott Point of Care	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Exclaim and Lamitrode Paddle Leads	St Jude Medical	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
TruCal Apo A1	DiaSys Diagnostic Systems GmbH	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Symbiq Admsintation Set	Hospira	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Dimension TACR Flex Reagent Cartridge	Siemens Healthcare Diagnostics Inc.	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
IMx Sirolimus Reagent Pack	Abbott GmbH	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
5.5 mm TroQ Trocar Spikes	Olympus	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
LithoDiagnost and UroDiagnost	Philips Healthcare	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
AMPLILINK Software 3.2 series	Roche Diagnostics	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>

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TrueBeam and TrueBeam STx	Varian	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
Memokath 051, MK 051 CW DC - 60mm	PNN	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Enzymatic Creatinine Flex reagent cartridges	Siemens Healthcare Diagnostics	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Protack™ Fixation device	Covidien	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
INNOTEST B-Amyloid	Innogenetics	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Ultimate T-Bag Oxygen Enrichment Device	Ultimate Medical Pty Ltd.	Advice has been provided by the manufacturer regarding changes/updates made to instructions for use	<a href="#">Manufacturer's FSN</a>
Skylux C4VS Theatre Operating Light	Yamada Shadowless Co Ltd / Peacocks Surgical and Medical Ltd.	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
Columbus CR/PS Trial GL.SURF.T2/2+14mm (NQ527), lot 4502550283, part of Columbus Set Basic Tibial Trial Impl. (NQ404)	Aesculap AG	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Genesis II Tibial Drill Guide	Smith & Nephew	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Bard® DORADO® PTA Balloon Dilatation Catheters	Bard Peripheral Vascular	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Hi-Art® Treatment System	TomoTherapy	Advice has been provided by the manufacturer regarding a software upgrade	<a href="#">Manufacturer's FSN</a>
AV-Set FMC (FA404E/FV404E) for 4008 dialysis machine	Fresenius Medical Care	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Universal Rectangular Extension	Civco Medical Solutions	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
C Series Clinac®	Varian Medical Systems	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Innova® 2000 cardiovascular X-ray imaging system	GE Healthcare	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Trachidress TR DRE 0001	Kapitex Healthcare Limited	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>
Waste Reservoir Assembly (waste chamber) Cell-Dyn Analyzer	Abbott Laboratories	Advice has been provided by the manufacturer regarding the use of the device	<a href="#">Manufacturer's FSN</a>
Huntleigh Contoura 880 Hospital Beds	ArjoHuntleigh	Advice has been provided by the manufacturer regarding a device modification	<a href="#">Manufacturer's FSN</a>
IOtest® 3 CD5- FITC/CD-10 PE/CD-19 ECD	Beckman Coulter	Advice has been provided by the manufacturer regarding a device removal	<a href="#">Manufacturer's FSN</a>