



IRISH MEDICINES BOARD  
FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- APRIL 2013

Case ID	Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Link to FSN on IMB website	Is the Irish market affected?
V17627	ARCHITECT STAT High Sensitive Troponin-I Calibrators and Controls	Abbott Diagnostic Division, Longford	Advice regarding the use of the device	18 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17489	STERRAD® 100NX® and STERRAD® 200 Sterilization Systems	Advanced Sterilization Products	Advice regarding the use of the device	27 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17705	STERRAD® CYCLESURE® 24 Biological Indicator	Advanced Sterilization Products	Advice regarding the use of the device	25 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17710	ALBAcyte Antibody Screening Cells	Alba Biosciences	Advice regarding the use of the device	19 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17634	Constellation® Pneumatic Handpiece, DSP, 725.01	Alcon	Advice regarding a device removal	17 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17442	STERRAD® 200 System Carriage REF 10208	ASP	Advice regarding the use of the device	19 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17610	Afinion CRP	Axis-Shield	Advice regarding a device modification	15 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17100	Diacap Ultra Dialysis Fluid Filter	B Braun	Advice regarding the use of the device	28 February 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17709	Bard® RF Cardiac Ablation Generator	Bard Limited	Advice regarding the use of the device	26 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V16847	Baxter Dialysers / Nikkiso Blood Tubing Lines for Hemodialysis, AV06JA-P	Baxter Healthcare	Advice regarding the use of the device	20 February 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17416	AU5800 Clinical Chemistry Analyser	Beckman Coulter Inc.	Advice regarding the use of the device	28 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17425	Access Immunoassay Systems Vitamin B12 Reagent Kit	Beckman Coulter Inc.	Advice regarding a device removal	02 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17542	BD Plastipak™ 50ml Luer Lok Syringes 300223, 300865, 300869	Becton Dickinson Medical UK Limited	Advice regarding a device removal	08 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17664	BD Plastipak™ 50ml Luer Lok Syringes	Becton, Dickinson U.K. Limited	Advice regarding a device removal	11 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17685	VIDAS D-Dimer Exclusion II	BioMérieux Inc	Advice regarding the review of patient results/patient recall/sample retesting is required	18 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17541	Seraclone Anti-S	Bio-Rad Medical Diagnostics GmbH	Advice regarding a device removal	08 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17596	iPlan RT Dose version 4.0 and 4.1	Brainlab AG	Advice regarding a software upgrade	09 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17700	Brainlab Cranial Navigation System	Brainlab AG	Advice regarding the use of the device	22 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17474	OPTEASE® Retrievable Vena Cava Filter	Cordis	Advice regarding the use of the device	03 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17488	Crimper for Transcatheter Heart Valve Systems	Edwards Lifesciences LLC	Advice regarding the use of the device	02 April 2013	<a href="#">Manufacturer's FSN</a>	Yes

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V17582	Integrity™ 1.1	Elekta	Advice regarding a software upgrade	01 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17501	epoc BGEM Test Card	Epocal	Advice regarding a device removal	28 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17712- V17713	LIGACLIP® 10 mm M/L Endoscopic Rotating Multiple Clip Appliers	Ethicon	Advice regarding a device removal	26 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17481	Standard and Safety Blood Collection Sets	Grenier BioOne	Advice regarding a device removal	03 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17292	MODULAR ANALYTICS EVO	Hitachi High-Technologies Corp	Advice regarding a device removal	07 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17521	cobas 8000 modular analyzer series	Hitachi High-Technologies Corp	Advice regarding a software upgrade	04 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17285	GemStar Infusion Systems	Hospira Inc.	Advice regarding the use of the device	21 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17288	GemStar Infusion Systems	Hospira Inc.	Advice regarding the use of the device	21 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17289	GemStar Infusion Systems	Hospira Inc.	Advice regarding the use of the device	21 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17466	1L Receptal System (Liner and Canister)	Hospira Inc.	Advice regarding a device removal	04 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17581	Integra Ojemann Cortical Stimulator	Integra	Advice regarding the use of the device	10 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17640	da Vinci S, Si and Si-e System	Intuitive Surgical	Advice regarding the use of the device	01 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17520	Rad-8 Pulse Oximeter	Masimo Corporation	Advice regarding a device removal	08 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17512	Oncentra® External Beam and Oncentra® Brachy v4.0 and v4.1	Nucletron	Advice regarding a software upgrade	29 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17530	Bracket Buccal Tubes	Ormco BV Europe	Advice regarding a device removal	05 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17731	Brilliance CT 64, Ingenuity Core, Ingenuity Core128 Software versions 2.6.1 or 3.5.4	Philips Healthcare	Advice regarding a software upgrade	15 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17404	AQURE Version 1.4.0 to 1.5.3	Radiometer Medical ApS	Advice regarding a software upgrade	20 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17693	Elecsys β-CrossLaps	Roche Diagnostics GmbH	Advice regarding a device modification	24 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17663	syngo Workflow MLR	Siemens AG	Advice regarding a software upgrade	27 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17300	Artis systems	Siemens Healthcare	Advice regarding a software upgrade	09 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V16268	Dimension® Tacrolimus (TACR) Flex® reagent cartridge	Siemens Healthcare Diagnostics	Advice regarding the use of the device	19 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V16775	Iconos R200 C20 or Iconos R200 T20	Siemens Healthcare Diagnostics	Advice regarding the use of the device	15 January 2013	<a href="#">Manufacturer's FSN</a>	Unknown

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V17081	Dade® Actin® FSL Activated PTT Reagent	Siemens Healthcare Diagnostics	Advice regarding a device removal	06 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17500	MicroCel 500 and MicroCel 300 Buffer Chamber	Siemens Healthcare Diagnostics	Advice regarding the use of the device	02 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17643	Dimension TACR Flex® reagent cartridge (DF107)	Siemens Healthcare Diagnostics	Advice regarding the use of the device	17 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17668	Fortify ST™ ICD Models CD1235 and CD2235	St. Jude Medical	Advice regarding a software upgrade	18 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17648	Neptune Waste Management System.	Stryker Instruments	Advice regarding a device modification	18 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17545	OtisMed ShapeMatch Cutting Guides, TR3100-L and TR3100-R	Stryker Orthopaedics Mahwah	Advice regarding the use of the device	18 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17572	DHS/DCS® Screw, sterile.	Synthes	Advice regarding a device removal	05 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17603	Synthes CMF MatrixNEURO Screws	Synthes GmbH	Advice regarding a device removal	12 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17603	Synthes CMF MatrixMIDFACE, MANDIBLE and ORTHOGNATHIC Screws	Synthes GmbH	Advice regarding a device removal	12 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17443	Rusch® Belly Bag® Urine Collection Bag with Hip Belt	Teleflex Medical	Advice regarding a device removal	27 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V14706	Spectra Optia® Apheresis System	Terumo BCT	Advice regarding the use of the device	08 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17569	Remel Streptex™ Group D Latex Reagent (R30950901) Lot 1215767	ThermoFisher Scientific	Advice regarding a device removal	04 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17637	Remel Streptex™ Group D Latex Reagent (R30950901) Lot 1154057	ThermoFisher Scientific	Advice regarding a device removal	04 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17549	G-6-PDH Control, Normal	Trinity Biotech	Advice regarding a device removal	08 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17670	X-Ray detectable Swabs 10 X 10cm 32Ply Double Wrapped, F82215	Unisurge International Limited	Advice regarding a device removal	10 April 2013	<a href="#">Manufacturer's FSN</a>	Yes
V16979	Vitreia Enterprise Suite, VitreaAdvanced, VitreaCore (VitalConnect) and Vitea fX including all versions 6.3.2 and prior	Vital Images Inc.	Advice regarding a software upgrade	25 March 2013	<a href="#">Manufacturer's FSN</a>	Yes
V17487	Vitreia CT Brain Perfusion 2D	Vital Images Inc.	Advice regarding the use of the device	15 March 2013	<a href="#">Manufacturer's FSN</a>	Yes