



## IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- JULY 2011

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
ARCHITECT C-Peptide Reagent	Abbott Laboratories	Advice regarding a device removal	11 July 2011	Yes
STAR S4 IR Excimer Laser System (software versions 5.00-5.22)	Abbott Medical Optics	Advice regarding a software upgrade	18 July 2011	Yes
STAR S4 IR Excimer Laser System (software version 5.30)	Abbott Medical Optics	Advice regarding a software upgrade	18 July 2011	Yes
STAR S4 IR Excimer Laser System (for users of Wavescan WaveFront System)	Abbott Medical Optics	Advice regarding the use of the device	18 July 2011	Yes
METHA MODULAR HIP ENDOPROSTHESIS SYSTEM	Aesculap AG	Advice regarding the use of the device	18 July 2011	Yes
Entroy Pool Lifter	Arjo Hospital Equipment AB	Advice regarding a device modification	14 July 2011	Yes
ROLKO strap and handle, type TGN-R100GR	ArjoHuntleigh	Advice regarding a device removal	07 July 2011	Yes
HomeChoice Automated PD System and HomeChoice PRO Automated PD System	Baxter	Advice regarding a software upgrade	01 July 2011	Yes
Ceragem-E	Ceragem Europe	Advice regarding changes/updates made to instructions for use	19 July 2011	Yes
Wispa Portable Hoist and Attachment Handle	Chiltern Invadex (UK) Ltd.	Advice regarding the use of the device	05 July 2011	Yes
MEDSTREAM Pump	Codman Neurosciences	Advice regarding a device removal	21 July 2011	Yes
DSX/BEST 2000	Dynex Technologies	Advice regarding the use of the device	20 July 2011	Yes
Theralite	Gambro	Advice regarding a device removal	10 July 2011	Yes
Seno Advantage 2.1 and 2.2 Workstations with RIS CCOW integration	GE Healthcare	Advice regarding a software upgrade	14 July 2011	
Acheeva Learning Station	Helping Hand Ltd.	Advice regarding a device modification	07 June 2011	Yes
HI VISION Ascendus, HI VISION Preirus, HI VISION Avius	Hitachi Medical Corporation	Advice regarding a software upgrade	26 April 2011	Yes
IDI MammoWorkstation; software versions v.4.5.0, v.4.5.2, v4.5.3 and v.4.6.0	Image Diagnost International GmbH	Advice regarding a software upgrade	06 July 2011	Yes
GEM® Premier 4000 Cartridge	Instrumentation Laboratory	Advice regarding the use of the device	21 July 2011	Yes
Intuitive Surgical® da Vinci Si Surgical System (IS3000)	Intuitive Surgical Inc.	Advice regarding a device modification	01 July 2011	Yes
Scanbed 400 Nursing Bed	Invacare	Advice regarding changes/updates made to instructions for use	16 May 2011	Yes
Preparation Balls - Ref 1171	Karl Beese GmbH & Co. KG	Advice regarding a device removal	12 May 2011	Yes
Cryomatic Probes	Keeler	Advice regarding the use of the device	06 June 2011	Yes
Comfort Sling M cotton 35300305	Liko AB	Advice regarding a device removal	09 February 2011	Yes
FlexCath 12 Steerable Sheaths	Medtronic	Advice regarding the use of the device	18 July 2011	Yes

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SynchroMed® II Implantable Drug Infusion Pumps	Medtronic	Advice regarding the use of the device	08 July 2011	Yes
Moving Solutions Slings	Nottingham Rehab Supplies	Advice regarding changes/updates made to instructions for use	10 June 2011	Yes
Allura Xper various models, Allura CV20	Philips	Advice regarding a software upgrade	12 July 2011	Yes
IntelliVue Clinical Information Portfolio (ICIP)	Philips Medical Systems	Advice regarding a software upgrade	06 July 2011	Yes
Waverly Glen Transactive (TA) Hoists and Waverly Glen Transportable (TP)	Prism Medical UK	Advice regarding a device modification	10 June 2011	Yes
Single Use LED Macintosh Combination Set size 3 & 4	SG Manufacturers	Advice regarding a device removal	30 March 2011	Yes
LANTIS System	Siemens	Advice regarding the use of the device	06 July 2011	Yes
Guide Pin Trocar Point (1.3mm x 140mm), Intermediate Twist Drill (2.7mm - Sterile), Intermediate Guide Pin Sterile (2.4mm x 152mm), 2.7mm {} Short Drill Bit with Quick Connect, Peri-Lock-Wire 1.6mm x 150mm length Trocar Point.	Smith & Nephew	Advice regarding a device removal	29 June 2011	Yes
CADD®-Solis Ambulatory Infusion Pump	Smiths Medical	Advice regarding the use of the device	15 July 2011	Yes
CADD®-Solis Ambulatory Infusion Pump	Smiths Medical	Advice regarding the use of the device	15 July 2011	Yes
Harmony LA, LC 500 and LA 700 Surgical Lighting and Media System	STERIS Corporation	Advice regarding the use of the device	23 February 2010	Yes
QuickClinch, lot 54425	Surgical Innovations	Advice regarding a device removal	17 March 2011	Yes
Ureter Catheter, curved, coaxial with no eyes	Teleflex	Advice regarding a device removal	07 July 2011	Yes
Tobii C-Series batteries of type TB8A, TB8B and TB12A	Tobii Technology AB	Advice regarding a device removal	20 May 2011	Yes
Varian High Energy Clinacs® and TrueBeam™ Systems	Varian	Advice regarding the use of the device	20 June 2011	Yes
Optical Guidance Platform	Varian	Advice regarding the use of the device	29 June 2011	Yes
Eclipse Release 6.5 through 10 (build 7.3.10 through 10.0.34)	Varian	Advice regarding the use of the device	07 July 2011	Yes
Eclipse	Varian	Advice regarding the use of the device	21 July 2011	Yes
Eclipse	Varian	Advice regarding the use of the device	21 July 2011	Yes
CP200 Electrocardiograph	Welch Allyn Inc.	Advice regarding a software upgrade	16 July 2010	Yes
V-600, Reciprocating saw attachment	W&H Dentalwerk Buermoos GmbH	Advice regarding a device modification	20 June 2011	Yes