



## IRISH MEDICINES BOARD

## FIELD SAFETY NOTICE MONTHLY SUMMARY SHEET- MAY 2012

Product	Manufacturer	Type of Action taken by Manufacturer	FSN Issue Date	Is the Irish market affected?
ARCHITECT CA 19-9XR	Abbott Laboratories	Advice regarding a device removal	30 May 2012	Yes
i-STAT Celite ACT cartridges	Abbott Point of Care	Advice regarding changes/updates made to instructions for use	29 February 2012	Yes
STERRAD CycleSure 24 Biological Indicator	Advanced Sterilization Products, Inc.	Advice regarding a device removal	11 April 2012	Yes
Alcon 23G Non-Valved Trocar Cannula and Infusion Cannula	Alcon Labs	Advice regarding a device modification	25 May 2012	Yes
Alcon 23G Non-Valved Trocar Cannula and Infusion Cannula	Alcon Labs	Advice regarding a device modification	25 May 2012	Yes
Encore, Chorus and Sara Plus Standing Aids	ArjoHuntleigh	Advice regarding changes/updates made to instructions for use	14 May 2012	Yes
ARROWg+ard Blue®, ARROWg+ard Blue Plus®	Arrow International INC	Advice regarding a device modification	15 May 2012	Yes
Baxter pump compatible Blood Set	Baxter	Advice regarding a device removal	01 April 2012	Yes
Baxter pump compatible Blood Set – Product Code : VMC9609	Baxter Healthcare	Advice regarding a device removal	11 May 2012	Yes
CYTO-STAT TetroCHROME and tetraCXP Software	Beckman Coulter Inc.	Advice regarding the use of the device	22 May 2012	Yes
BD™ Gram Crystal Violet & BD™ Gram Stain Kit	Becton Dickinson & Company	Advice regarding a device removal	01 May 2012	Yes
Rotulator Single Use Stapler	Covidien USA	Advice regarding a device removal	21 May 2012	Yes
Patient set REF 000945 for Novalung Vision Alpha	DEAS S.r.L	Advice regarding changes/updates made to instructions for use	12 April 2012	Yes
DePuy DeltaMotion Acetabular Cup	DePuy Ireland	Advice regarding the use of the device	07 May 2012	Yes
Carpentier-Edwards® PERIMOUNT / Carpentier-Edwards® PERIMOUNT Magna / Carpentier-Edwards® PERIMOUNT Magna Ease / Carpentier-Edwards® PERIMOUNT Magna Mitral / Carpentier-Edwards® PERIMOUNT Magna Mitral Ease	Edwards Lifesciences Ltd	Advice regarding a device removal	21 May 2012	Yes
Carpentier-Edwards® PERIMOUNT / Carpentier-Edwards® PERIMOUNT Magna / Carpentier-Edwards® PERIMOUNT Magna Ease / Carpentier-Edwards® PERIMOUNT Magna Mitral / Carpentier-Edwards® PERIMOUNT Magna Mitral Ease	Edwards Lifesciences Ltd	Advice regarding a device removal	21 May 2012	Yes
XiO	Elekta Limited	Advice regarding a software upgrade	03 May 2012	Yes
Mitch TRH Acetabular Cup / Mitch TRH Modular Head when implanted with teh uncemented Accolade femoral stem	Finsbury Orthopaedics Ltd / DePuy and Stryker Orthopaedics	Advice regarding the use of the device	26 April 2012	Yes
Genius Eco and Factum	FREI AKTIVE REHA-SYSTEME	Advice regarding a device modification	11 May 2012	Yes
FUJIFILM QuickGene	Fujifilm Life Science	Advice regarding the use of the device	11 May 2012	Yes
Advantage Workstations and Seno Advantage workstations	GE Healthcare	Advice regarding a software upgrade	16 May 2012	Yes
Brilliant mouth mirror no. 4	Hager & Werken GmbH & Co. KG	Advice regarding a device removal	28 March 2012	Yes

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Dynamis and Gerialit Beds	Hill-Rom	Advice regarding the use of the device	01 March 2012	Yes
AEROTube®	HUM Gesellschaft für Homecare und Medizintechnik	Advice regarding a device removal	09 May 2012	Yes
Birdie & Flamingo Lifters	Invacare	Advice regarding a device modification	10 May 2012	Yes
Harrier Range Wheelchairs	Invacare	Advice regarding changes/updates made to instructions for use	08 May 2012	Yes
Unsterile Gauze with X-Ray Thread	Karl Beese (GmbH & Co. KG)	Advice regarding changes/updates made to instructions for use	21 March 2012	Yes
Drilling Guide for diameter 3.5 mm screw	Newdeal SAS	Advice regarding a device removal	23 May 2012	Yes
VITROS 5600 Integrated System	Ortho-Clinical Diagnostics	Advice regarding the use of the device	30 April 2012	Yes
Telaprep	Paul Hartmann AG	Advice regarding a device removal	03 May 2012	Yes
FRED easy / FRED easy Life defibrillators	Schiller Medical S.A.S.	Advice regarding a device modification	18 May 2012	Yes
FRED easy / FRED easy Life defibrillators	Schiller Medical S.A.S.	Advice regarding the use of the device	18 May 2012	Yes
IMMULITE 2000/2000 Xpi Erythropoietin (L2KEPN2/6) & IMMULITE 2500 Erythropoietin	Siemens Healthcare Diagnostics	Advice regarding the use of the device	30 April 2012	Yes
IMMULITE 1000 / IMMULITE 2000 / 2000 Xpi Insulin	Siemens Healthcare Diagnostics	Advice regarding the use of the device	30 April 2012	Yes
MicroScan LabPro V4.11	Siemens Healthcare Diagnostics	Advice regarding a software upgrade	09 May 2012	Yes
Specific Batches of Various Trauma Pins and Drills	Smith & Nephew Inc.	Advice regarding a device removal	19 April 2012	Yes
ABGII Modular Stems and ABGII Modular Necks Rejuvenate Modular Stems and Rejuvenate Modular Necks	Stryker	Advice regarding the use of the device	27 April 2012	Yes
Neptune Waste Management System	Stryker	Advice regarding the use of the device	22 May 2012	Yes
Spectra Optia® Apheresis System	Terumo BCT	Advice regarding the use of the device	25 May 2012	Yes
Venner A.P.Advance Video Laryngoscope difficult Airway Blade (DAB)	Venner Medical (Singapore) Pte. Limited	Advice regarding a device removal	05 July 2011	Yes
Zimmer Nexgen Complete Knee Solution Posterior Referencing Instruments (PRI) - Femoral and Provisional Impactor/Extractor	Zimmer	Advice regarding a device removal	02 May 2012	Yes