



April 2009

A patient **Safety Notice** strongly advises the implementation of particular recommendations or solutions to improve quality and safety.

We recommend you inform:

- Supply Department
- Biomedical Engineering
- Safety and Quality Unit
- Clinical Departmental Managers

Therapeutic Goods Administration (TGA) Recalls

Summary for April 2009

The established process for TGA medical device recalls/product corrections is for the manufacturer/sponsor to dispatch letters to the relevant service providers within two working days of the recall date. If affected, your health service will have received a letter from the manufacturer/sponsor advising of the recall.

Class I – Class I defects are potentially life-threatening or could cause a serious risk to health.

Class II – Class II defects could cause illness or mistreatment, but are not Class I.

Class III – Class III defects may not pose a significant hazard to health, but withdrawal may be initiated for other reasons.

Class I & II recalls are considered to be safety related recalls.

This Safety Notice is provided to reinforce the TGA process. It contains selected medical device hospital and retail level recalls/product corrections for your implementation, if relevant.



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Class I Recall

**AQUARIUS Automated Fluid Balance Monitors
GEF08200 with Software Version 4.01.11 and 4.01.12
Models GEF09600 with Software Version 6.01**

ARTG number: 144994

REFERENCE: RC-2009-RN-00254-3

DATE: 31/03/2009

COMPANY: Edwards Lifesciences Pty Ltd.

REASON: An additional Substitution Fluid Non-conformance has been identified.

PHONE: 1800 222 601 - Edwards Customer Service.

Class II Recall

Access Immunoassay Systems Total BhCG Reagent Kit

Lot 824542; Exp. 30/06/2009

Lot 825652; Exp. 31/07/2009

REF: 33500

REFERENCE: RC-2009-RN-00233-3

DATE: 25/03/2009

COMPANY: Beckman Coulter Australia Pty Ltd.

REASON: Reagent packs show decreased stability from the date of manufacture.

PHONE: 1800 060 881 - Technical Support Centre.

Lifemed® Pressure Monitoring Lines

Model L1833 - Lot # AUTC0005 &

Model L1835 - Lot # AUTC0075

ARTG number: 23818

REFERENCE: RC-2009-RN-00263-3

DATE: 3/04/2009

COMPANY: Bard Australia Pty Limited.

REASON: Two lots of Lifemed®, Single Sterile, Pressure Monitoring Lines distributed to customers with incorrect information on the label.

PHONE: 02 8875 4012 - Samantha Tham.

Class II Recall (cont.)

STERRAD® NX and STERRAD® 50 Sterilisation Systems

ARTG number: 123603

REFERENCE: RC-2009-RN-00265-3

DATE: 3/04/2009

COMPANY: Johnson & Johnson Medical Pty Ltd.

REASON: The manufacturer has identified that under certain circumstances an interaction involving the nylon oil fill plugs could generate an oil mist

PHONE: 1800 252 194 - Advanced Sterilisation Products (ASP) customer service team.

DARCO Cannulated Hex Screwdriver

Catalogue number: DC4261

Catalogue number: DMRSKIT1 (included with the WRIGHT EXPRESS Kit)

ARTG number: 141175

REFERENCE: RC-2009-RN-00248-3

DATE: 9/04/2009

COMPANY: Surgical Specialties.

REASON: Packaging insert lists three methods of sterilization, however, only one of the three methods has been validated.

PHONE: 1300 665 884 - Pamela Caterson.

Various Molnlycke ProcedurePak products

ARTG number: 133562 & 133564

REFERENCE: RC-2009-RN-00283-3

DATE: 14/04/09

COMPANY: Molnlycke Health Care Pty Ltd.

REASON: Potential sterility problem with selected lots of specific ProcedurePak products.

PHONE: 1800 005 231 – Juliet Hull.

ENDOPATH ETS-FLEX45 Articulating Endoscopic Linear Cutters

ARTG number: 132169

REFERENCE: RC-2009-00293-3

DATE: 15/04/09

COMPANY: Johnson & Johnson Medical Pty Ltd.

REASON: In some of the affected product, the mechanism which connects the articulation joint to the device shaft may be insufficient. Under certain conditions, this may cause the jaws of affected endoscopic linear cutter to remain closed and clamped down on tissue after the device is fired.

PHONE: 1800 257 210 – Mark Penno.

Class II Recall (cont.)

Caesarea Medical Electronics Syringe Driver Pumps

Catalogue Number: Niki T34 and T34L

Serial Numbers: All serial numbers

ARTG number: 131232

REFERENCE: RC-2009-RN-00282-3

DATE: 20/04/2009

COMPANY: REM Systems Pty Ltd

REASON: The pumps do not contain all the data parameters for known dimensional variations of BD Plastipak syringes supplied worldwide. As a result of the varying syringe dimensions "Volume" shown on the pump display may not exactly match that in the syringe.

PHONE: 1800 737 222 - Frank Elwin

GE Centricity PACS RA1000 Workstations

Picture Archiving & Communication System for diagnostic image analysis

Software Versions: PathSpeed 7.x, 8.x, Centricity 1.X, 2.0.X. , 2.1x & 3.0x

ARTG number: 115596

REFERENCE: RC-2009-RN-00245-3

DATE: 28/04/2009

COMPANY: GE Healthcare Australia Pty Ltd.

REASON: A series of potential safety issues has been identified relating to image orientation.

PHONE: 1800 659 465 - GE Customer Care Centre.

Philips Heartstart XL Defibrillators manufactured by Philips from March 2006 to December 2008, with a serial number within the range of US00442485 and US00469873.

ARTG number: 95661

REFERENCE: RC-2009-RN-00306-3

DATE: 23/04/2009

COMPANY: Philips Electronics Australia Ltd.

REASON: The rotary energy select switch in affected devices may fail and prevent the user from turning the device on, rendering the device unusable for monitoring and defibrillation therapy. In rare cases, the failure can be exhibited by the device spontaneously powering on.

PHONE: 1800 251 400 - Philips Customer Care Centre.



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Class II Recall (cont.)

Datex-Ohmeda S/5 Device Interfacing Solution N-DISVENT-02 interfaced between certain Datex-Ohmeda anesthesia machines or ventilators.

All N-DISVENT-02 modules are affected.

N-DISVENT-00 and N-DISVENT-01 are not affected.

ARTG number: 115304

REFERENCE: RC-2009-RN-00297-3

DATE: 23/04/2009

COMPANY: GE Healthcare Australia Pty Ltd.

REASON: There is the potential for the anaesthesia machine or ventilator to not receive the patient weight or height through N-DISVENT-02 when changed or entered in the patient monitor. The anaesthesia machine or ventilator sends its own entered or default patient weight or height to the patient monitor. This weight or height overrides the patient weight or height changed or entered in the patient monitor. This results in incorrect calculated BSA (body surface area). Incorrect calculated BSA value might further result in incorrect indexed hemodynamic, oxygenation, ventilation values on the patient monitor. Incorrect patient weight also may result in incorrect drug calculations.

PHONE: 1300 722 229 - GE Customer Care.

Newport HT50 Ventilator/Flight Medical Ltd

All models

ARTG number: 117560

REFERENCE: RC-2009-RN-00209-3

DATE: 23/04/2009

COMPANY: Swirl Technologies Pty Ltd T/A Parker Healthcare.

REASON: The internal battery may not last as long as expected followed by ventilator shut down with less advance warning than when the battery was new.

PHONE: 03 9872 0222 - Desmond Flynn (Technician).

Class II Recall (cont.)

Stryker Titanium Screws (used in hip replacements) Various lot numbers

Catalogue Number(s):		
202065251	202955151	202955201
202955251	202955301	202955351
202955401	202955501	203065161
203065201	203065251	203065301
203065351	203065401	203065451
203065501	203065551	203065601
20800015	20800020	20800025
20800030	20800035	20800040
20800045	20800050	20800055
20800060		

ARTG number: 128021

REFERENCE: RC-2009-RN-00321-3

DATE: 24/04/2009

COMPANY: Stryker Australia Pty Ltd.

REASON: The manufacturer is currently investigating a potential raw material quality issue.

PHONE: 1800 803 601 - Liam Beedling.

MRx Defibrillators manufactured by Philips from March 2006 to March 2009, with a serial number within the range of US00210406 & US00333123

ARTG number: 95661

REFERENCE: RC-2009-RN-00325-3

DATE: 28/04/2009

COMPANY: Philips Electronics Australia Ltd.

REASON: The therapy switch in affected devices has a small potential to fail. The most likely failure mode is a spontaneous turn-on which could deplete the battery, rendering the device unusable until power is restored. There is also the possibility of a failure mode in which the device fails to respond to user initiated turn-on, rendering it unusable for monitoring and therapy.

PHONE: 1800 251 400 - Philips Customer Care Centre.