



February 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 January 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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Safety Notice

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Class I Recall

Pneumo Sure XL High Flow Insufflator

Catalogue No. 0620040611, Serial range 0805CE304 to 0811CE663

(ARTG number 139712)

(REFERENCE: RC-2009-RN-000035-3)

Date: 16/1/2009

Reason: The insufflator may power down during surgery, and while it can be rebooted, this failure may occur again at anytime.

Further information: Stryker Australia Pty Ltd, 1800 667 558 – Alison Pratt.

Convoy® Advanced Delivery Sheath Kits and Soft Tip Sheath

Multipurpose Introducing Sheath Kits

All Catalogues and Serial numbers

(ARTG number 131086)

(REFERENCE: RC-2008-RN-01035-3)

Date: 2/1/2009

Reason: The Sheath's radiographic tip marker band may become dislodged or detached from the sheath during the interventional procedure posing an embolic risk to the patient.

Further information: Boston Scientific Pty Ltd, 02 8063 8147 – Dana Leydon.

Class II Recall

Philips Omni, Multi and Easy Diagnost X-ray Systems with Velara Generators

(ARTG number 98560)

(REFERENCE: RC-2009-RN-00003-3)

Date: 5/1/2009

Reason: Failures in the grid switch, which is not always detected automatically by the System, can lead to slightly higher fluoroscopy dose levels than expected.

Further information: Philips Electronics Australia Ltd, 1800 251 400 – Philips Customer Care.

Abbott ARCHITECT Rhtlv – I/II reagent;

List# 6L61-25 and 6L61-35 Masterlots 67161HN00 and 67162HBN00

in vitro diagnostic medical device

(ARTG number)

(REFERENCE: RC-2009-RN-00009-3)

Date: 7/1/2009

Reason: Over time, these masterlots show a shift in the negative plasma population to higher S/CO values, leading to reduced specificity and increased false reactive results (≥ 1.00 S/CO). Assay sensitivity is not impacted.

Further information: Abbott Australasia Pty Ltd Diagnostic Division, 1800 816 696.

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Class II Recall (cont.)

100 mL CADD Medication Cassette Reservoir

Product Code 21-7002-24, Batch 213X18

(ARTG number)

(REFERENCE: RC-2009-RN-00014-3)

Date: 8/1/2009

Reason: Increased trend of leakage in a single batch of CADD Medication Cassette Reservoirs filled with customer specified drugs that are within expiry. A result of a recall by Smith's Medical (Recall No RC-2008-RN-00998-3).

Further information: Baxter Healthcare Pty Ltd, 02 9848 1110 or 02 9848 1394.

Centricity Enterprise Web (for viewing/distributing digital medical images)

Versions: CW3.0, CW3.0.1, CW3.0.1.1, CW3.0.2, CW3.0.3 and CW3.0.4

(ARTG number 115596)

(REFERENCE: RC-2009-RN-00040-3)

Date: 28/1/2009

Reason: There are two (2) potential problems identified with this device: 1) A forced log-off may occur while using the Centricity Enterprise Web during an open session; and 2) Under specific conditions the wrong measurement may be displayed in Webviewer.

Further information: GE Healthcare Australia Pty Ltd, 1800 659 465 – GE Customer Care Centre.

Discovery Scooters

Product codes: HS-895-RD2 (red), HS-895-BU1 (blue), HS-895-SG1 (silver)

Serial numbers between 08GGD0001 and 08GGD0035

(ARTG number 119338)

(REFERENCE: RC-2009-RN-01023-3)

Date: 24/12/2008

Reason: A batch of Discovery scooters may have a potential problem related to the manufacturing process of one component within their transaxles.

Further information: Invacare Australia Pty Ltd, 02 8839 5304 Sarah Wood.

CT/e and HiSpeed X/i families of Computer Tomography systems

(ARTG number 93337)

(REFERENCE: RC-2009-RN-00024-3)

Date: 15/1/2009

Reason: Excess leakage radiation, from the diagnostic source assembly, may be able to exit the collimator adjacent to the collimator's aperture control mechanism.

Further information: GE Healthcare Australia Pty Ltd, 1800 659 465 – GE Customer Care Centre.

Class III Recall

3.2mm Threaded Guide Pin

Catalogue No 71687000, Lot No 08KM22270

(ARTG number 108558)

(REFERENCE: RC-2009-RN-00059-3)

Date: 27/1/2009

Reason: Graduation levels on the pin are incorrect.

Further information: Smith & Nephew Surgical Pty Ltd, 02 9857 3397 – Carolyn Cameron.

ULTRAVIST 370 iopromide 38.443g/50mL injection vial

Batch 82761J, Expiry June 2011

(ARTG number 15681)

(REFERENCE: RC-2009-RN-00038-3)

Date: 16/1/2009

Reason: Increase number of complaints of crystallisation for one sub batch of Ultravist 370.

Further information: Bayer Australia Limited, Local Bayer Australia Limited representative.

Rapidlab 1245 and 1265 Systems Blood Gas AQC cartridges

Lot 1568 only, an in vitro diagnostic medical device

(ARTG number)

(REFERENCE: RC-2009-RN-00019-3)

Date: 13/1/2009

Reason: Incorrect assignment of AQC value. A data point for Carboxyhaemoglobin (COHb) was entered as 0 in the AQC EEPROM, rather than the correct value of 2.9.

Further information: Siemens Healthcare Diagnostics Pty Ltd, 07 3332 8489 – Mr Craig O'Sullivan.