



December 2008

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 November 2008

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.

Class I Recall

Class II Recalls

FLO-GARD 6201 Volumetric Infusion Pump

(ARTG number)

(REFERENCE: RN-2008-0896)

Date: 30/10/2008

Reason: Potential failure in keypad operability due to internal cable disconnection.

Further information: Baxter Healthcare Pty Ltd, 02 8845 1582 – Stuart Cash.

Vitros Chemistry Product PROT Slides (for CSF)

An in vitro diagnostic medical device (IVD)

Slide Generations 21 to 28; Lot Numbers 0586, 0597, 0507, 0518

(ARTG number)

(REFERENCE: RN-2008-0900)

Date: 7/11/2008

Reason: Calibrator values differ from reference method and require updating.

Further information: Ortho-Clinical Diagnostics, 1800 032 359 – Customer Technical Services.

Zilver 635 Vascular Stent (Renal Artery)

ZIV6-80-12-8.0 Lot number E2168970

ZIV6-80-7-4.0 Lot number E2154270

(ARTG number 143275)

(REFERENCE: RN-2008-0906)

Date: 11/11/2008

Reason: The size of the device inside the Zilver box (ZIV6-80-7-4.0) does not correspond with the size on the label of the outer packaging (ZIV6-80-12-8.0).

Further information: William A Cook Australia Pty Ltd, 07 3841 1188 – Selina Hoenen.

Ventri Nuclear Systems

(ARTG number 128982)

(REFERENCE: RN-2008-0914)

Date: 12/11/2008

Reason: During patient unload following Cardiac SPECT scan on Ventri in Prone orientation; the patient hand may be pinched between the tabletop and the lower edge of the gantry ring while the table is moving downward.

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



Class II Recalls (cont.)

V40 ORTHINOX femoral head 28/-4mm & 28/0mm

**Catalogue Numbers: 63642128 (lot G2606990) and 63642028 (lot G2606387)
(ARTG number 139227)**

(REFERENCE: RN-2008-00925-3)

Date: 12/11/2008

Reason: Following a recent recall of V40 Orthinox Femoral Heads due to a potential mix up in packaging, surgeons are being sent a Hazard Alert letter to notify them of the Company's medical assessment for devices that have been implanted.

Further information: Stryker Australia Pty Ltd, 02 9467 1070 Ms Jenny Burke.

BIOBALL (MERETE) METAL FEMORAL HEADS

(ARTG number 115543)

(REFERENCE: RN-2008-00929-3)

Date: 17/11/2008

Reason: High Nitrogen Stainless Steel (Vivium) femoral heads have been supplied instead of Cobalt-Chrome alloy heads. This has resulted in some stainless steel femoral heads being implanted with incompatible liners.

Further information: Global Orthopaedic Technology Pty Ltd, 02 8887 0100 – Dr Peter Hannaford.

EnTrust® Implantable Cardioverter Defibrillators

EnTrust D153DRG – AUST1119250

EnTrust D153VRC – AUST1119252

EnTrust D153ATG – AUST1119253

EnTrust D154ATG – AUST1119254

EnTrust D154DRG – AUST1119255

EnTrust D154VRC – AUST1119256

(ARTG number)

(REFERENCE: RN-2008-00939-3)

Date: 19/11/2008

Reason: Installation or removal of Lead Integrity Alert (LIA) software in these devices will inadvertently disable two audible patient alerts.

Further information: Medtronic Australasia Pty Ltd, 03 8851 1005 – Mr John Allen

Medtronic Physio-control TSU328 External Sterilisable Defibrillation Paddles and Paediatric Paddle attachments used with LIFEPAK® 9, LIFEPAK 9P, LIFEPAK 12 and LIFEPAK 20/20e defibrillator/monitors

Model numbers: 11133-000001, 11134-000003 and 11134-000004

(ARTG number: 120810)

(REFERENCE: RC-2008-RN-00944-3)

Date: 20/11/2008

Reason: Paddles supplied with defibrillators require update to cleaning and sterilising instructions

Further information: Medtronic Australasia Pty Ltd, 0404 014 741 - Sam Toscano



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Stephan F120 Mobil neonatal transport ventilator, All serial numbers

(ARTG number 135604)

(REFERENCE: RN-2008-00951-3)

Date: 24/11/2008

Reason: Product modification to mitigate risk of administering high pressure without alarm.

Further information: In Vitro Technologies Pty Ltd, 02 9879 0755 – Mr Michael Fatouris

Electrode Unilect 42mm Foam Biotack

Product Code: 4841P, Batch Nos. 62130, 706394, 705400, 705953 & 707419

and Electrode Unilect 37.5mm Foam Biotack

Product Code: 4831Q, Batch Nos. 627814 & 705399

(ARTG number: 141878)

(REFERENCE: RC-2008-RN-00946-3)

Date: 19/11/2008

Reason: Unomedical recently discovered a problem with samples of the 4831Q electrode which typically show a degradation of normal performance when subject to testing for defibrillation recovery. As a result of the currents applied to the ECG electrode during the "electrical shock", the electrode may not regain its ECG capability and this may prompt the clinician to attempt further defibrillation of the patient unnecessarily.

Further information: Unomedical Pty Limited - Nicci Ramsay, 02 9979 0838

DLP Pericardial/ Intracardiac Sump, 20Fr.

Lot numbers 2006100723 and 2006101229

(ARTG number: 123150)

(REFERENCE: RC-2008-RN-00968-3)

Date: 28/11/2008

Reason: The sump tip assembly may separate from the tubing during use

Further information: Medtronic Australasia Pty Ltd, 1800 660 670 - Medtronic Sales Representative

COLLEAGUE Triple Channel CX and CXE Volumetric Infusion Pumps

with software versions 5.09.92 and 6.13.92

(ARTG number: 128345)

(REFERENCE: RC-2008-RN-00954-3)

Date: 28/11/2008

Reason: The piggyback function in the COLLEAGUE triple channel pumps (CX software version 5.09.925 and CXE version 6.13.92) does not operate in the same manner as previous software versions. User manuals will be updated to reflect these changes.

Further information: Baxter Healthcare Pty Ltd, 1800 063 093 - Baxter Technical Service