



October 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 September 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.



Safety Notice

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Class I Recall

Spacelabs Medical Telemetry Receiver – Model 90478

(ARTG number: 129296)

(REFERENCE: RN-2008-0629)

Date: 25/08/2008

Reason: The Telemetry Receiver Module may fail to alarm for low heart rate and asystole.

Further information: Medtel Pty Ltd, 0419 149 364 – David Baker, 0419 495 182 – Denise Pater.

THERMOSKIN® Hot/Cold Gel Pack (Blue)

Small (20cm x 13cm)

Medium (30cm x 13cm)

Large (37cm x 18cm)

Product Codes: 86901, 86902 and 86903.

(ARTG number: 109477)

(REFERENCE: RN-2008-0701)

Date: 02/09/2008

Reason: This product contains the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: United Pacific Industries Pty Ltd, 1800 188 019 Customer Service.

Hot & Cold Pack (labelled with 'Atacand® candesartan cilexetil' or 'Crestor® rosuvastatin')

(ARTG number: 145712)

(REFERENCE: RN-2008-0747)

Date: 15/09/2008

Reason: This product contains the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: Brand Promotions (supplied to AstraZeneca), 1800 805 342 AstraZeneca.

Eye Mask

Full Face Mask

Face Mask

REDI™ Hot/Cold Pack – small dual colour

REDI™ Hot/Cold Pack with compression wrap – small dual colour

REDI™ Hot/Cold Pack – small PVC

Frosty Bear™ REDI™ Hot/Cold Pack

(ARTG number: 116111)

(REFERENCE: RN-2008-0748)

Date: 15/09/2008

Reason: These products contain the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: Westcoast Surgical and Medical Supplies, 08 9455 6676.

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Class I Recall (cont.)

Blue Healer Hot/Cold reusable icepacks

Regular & Large Size without bandage & Regular & Large Size with bandage.

(ARTG number 147709)

(REFERENCE: RN-2008-0749)

Date: 23/09/2008

Reason: This product contains the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: Cool Blue Health Family Trust T/a Blue Healer, 07 5447 5579 Customer Service.

SOFT Cold Hot Pack (label on product) sold as OAPL Professional Reusable Hot and Cold Pack.

(ARTG number 130191)

(REFERENCE: RN-2008-0750)

Date: 15/09/2008

Reason: This product contains the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: Orthopaedic Appliances Pty Ltd, 1800 033 207 Customer Service.

Surgical Basics Hot / Cold Pack item SB700, Small size 11x27cm

Surgical Basics Hot / Cold Pack item SB701, Large size 17x29cm

Surgical Basics Hot / Cold Pack item SB703

(ARTG number 132987)

(REFERENCE: RN-2008-0752)

Date: 15/09/2008

Reason: This product contains the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: 3P Pty Ltd, 02 4962 3822 or 02 9232 7820 Customer Service.

smartchoices™ Breast Soother®

(ARTG number 131335)

(REFERENCE: RN-2008-0753)

Date: 16/09/2008

Reason: This product contains the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: Glenageary Pty Ltd.

Medispot Soft Hot/Cold Packs – Medium (Product #2160) & Medispot Soft Hot/Cold Packs – Large (Product #2161)

(ARTG number 149339)

(REFERENCE: RN-2008-0754)

Date: 15/09/2008

Reason: This product contains the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: Tinsonax NSW Pty Ltd, 1800 079 937.

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Class I Recall (cont.)

**Surgipack SOFT Hot/Cold Pack – Large (Product #6230), Batch 1055213 (only)
(ARTG number: 99853)**

(REFERENCE: RN-2008-0756)

Date: 15/09/2008

Reason: This batch contains the toxic substance ethylene glycol (rather than the non-toxic ingredient propylene glycol).

Further information: Kendall (a division of Tyco Healthcare Pty Ltd).

Class II Recall

**AXIOM Artis systems with software versions VB23A, VB23B, VB23C, and VB23D
or with SW Versions VB31A, VB31B, and VB31C.**

(ARTG number: 102182)

(REFERENCE: RN-2008-0660)

Date: 5/09/2008

Reason: Software defect may lead to incorrect sizing of measured anatomy.

Further information: Siemens Ltd, 1800 227 587 - Mr John Selakovic

Medtronic Physio Control LIFEPAK CR Plus defibrillators, Model Nos: 99403-00013, 99403-000010 and 99403-000222 (All Serial numbers manufactured between November 2006 and March 2008)

(ARTG number: 124228)

(REFERENCE: RN-2008-0679)

Date: 27/08/2008

Reason: LIFEPAK CR Plus defibrillators manufactured between November 2006 and March 2008 have an identified, lead-free material component that may be susceptible to failure. Failure of this component (PFC) can cause a short that may prevent the device from being powered on.

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

Liko Universal Sling Bar

(ARTG number: 133067)

(REFERENCE: RN-2008-0658)

Date: 27/08/2008

Reason: When mounted on Viking or LikoLight mobile lifts, a component securing the Universal Sling Bar to the lift, under certain circumstances, may experience unanticipated fatigue.

Further information: Medtec Products Australia Pty Ltd, 03 8761 6956 – Mr Phil Jones.



Class II Recall (cont.)

Infinia, Infinia Hawkeye, Infinia Hawkeye 4

Nuclear Medicine Systems

(ARTG number 96485)

(REFERENCE: RN-2008-0681)

Date: 28/08/2008

Reason: Potential for registration mismatch in CT/SPECT studies of brain scans obtained with Infinia-Hawkeye and Infinia-Hawkeye 4.

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

ABL700 Series Calibration 1 Solution S170, Part number: 944-024, Batch

Number: WA-04

(ARTG number)

(REFERENCE: RN-2008-0717)

Date: 18/09/2008

Reason: Radiometer have identified that the barcode used to identify calibration points for electrolytes and Lactate are incorrect for this lot number.

Further information: Radiometer Pacific Pty Ltd, 1800 247 254 – Carolyn Sloman.

ConMed VCare® Uterine Manipulators manufactured between 12 October 2007 and 11 April 2008. Lot codes from 0710121 through to and including 0804111

(ARTG number :129389)

(REFERENCE: RN-2008-0718)

Date: 8/09/2008

Reason: There was an increase in the number of reports that the cup separated from the stainless steel tube.

Further information: ConMed Linvated Australia Pty Ltd, 1800 238 238 – Kevin Samuels.

HD3 Ultrasound Systems with software level 2.0 and below

(ARTG number 93851)

(REFERENCE: RN-2008-0720)

Date: 8/09/2008

Reason: A software defect that affects the display of Estimated Fetal Weight (EFW) Growth Percentile results values.

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

Class II Recall (cont.)

Lithium Polymer Batteries used in Philips Magnetic Resonance Imaging Systems with Basic Triggering Units.

(ARTG number 98887)

(REFERENCE: RN-2008-0726)

Date: 9/09/2008

Reason: Affected lithium polymer batteries may fail after being physically dropped from a height (ie. from waist height to floor) onto a hard surface.

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

Haag Streit Tonometer Doubling Prisms.

The reusable tonometer prism is used with a tonometer and slit lamp for examination of diseases of the human eye.

(ARTG number 107264)

(REFERENCE: RN-2008-0727)

Date: 10/09/2008

Reason: The manufacturer is asking users to test prisms for the presence of cracks or scratches.

Further information: Device Technologies Australia Pty Ltd, 02 9972 8321 Mark Altman.

Signa MR (Magnetic Resonance) Systems with TRM gradient subsystems

(ARTG number 108415)

(REFERENCE: RN-2008-0728)

Date: 10/09/2008

Reason: Spatial Distortion when using 3D Pulse Sequences. This issue is of particular concern when performing breast biopsy procedures with the VIBRANT application, since lesion localization misregistration could potentially result in repetition of the biopsy.

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

Weck, brand ligating clips including Hem-O-Lok, Horizon, Hemoclip Traditional and Hemoclip Plus. Vascular clips with broad surgical application.

All clips manufactured between Jan 2006 – July 2008

(ARTG number 126369)

(REFERENCE: RN-2008-0737)

Date: 12/09/2008

Reason: Holes have been detected in the thermoformed tray of certain sterile packaged units meaning the sterile integrity cannot be guaranteed.

Further information: N Stenning & Co Pty Ltd, 02 8594 9155 – Mr Ange Ledru.

Class II Recall (cont.)

VASOVIEW™ 4 Endoscopic Vessel Harvesting System (Kit Only)

Model number VH-10242, Lot numbers 7100172 to 8081371 and

Model number VH-10243, Lot numbers 7100171 to 8081271

(ARTG number 124878)

(REFERENCE: RN-2008-0757)

Date: 17/09/2008

Reason: A small number of devices have been found to exhibit signs of damaged packaging, which may lead to compromised sterility.

Further information: Guidant Australia Pty Ltd, 0411 957 700 – Chloe Brown.

BD Vacutainer® 16x100mm Serum Blood Collection Tubes (Plain Red top)

Catalogue no. 367895

Lots 8015159, 8029093, 8059728, 8095550, 8113634

(ARTG number 53987)

(REFERENCE: RN-2008-0762)

Date: 18/09/2008

Reason: On rare occasions the product may feel tight when inserted into some Needle Holders. 16mm red Hemogard™ caps, moulded from tool number U56, are slightly larger than other Hemogard™ caps, which results in tightness with some needle holders.

Further information: Becton Dickinson Pty Ltd, 1800 656 100 – BD Customer Service.

Premise Unidose dental composite

Product manufactured between March and May 2008, 106 lot numbers

(ARTG number 99818)

(REFERENCE: RN-2008-0764)

Date: 19/09/2008

Reason: The material appears to stiffen and become difficult to extrude over time.

Further information: Kerr Australia Pty Ltd, 1800 643 603 – Kerr Customer Care.

Class II Recall (cont.)

RN-2008-0764 – Premise Unidose - List of Affected Lot Numbers						
PART NO	DESCRIPTION	10-PACK UNIDOSE LOT NUMBER(S)				
32650	10 PACK UNIDOSE PREMISE A1	2981424	3001270	3001273	3027780	3031654
32651	10 PACK UNIDOSE PREMISE A2	2981427	2990911	2997977	3001277	3018924
		2983068	2991212	3001276	3008211	3018925
		2990753				
32652	10 PACK UNIDOSE PREMISE A3	2989376	2998295	3027232	3032714	2979610
		2992904	3001278	3032367	2961138	2999887
		2994827				
32653	10 PACK UNIDOSE PREMISE A3.5	3001279	3001280	3027784	3031663	3045735
32654	10 PACK UNIDOSE PREMISE A4	3001281	3031666			
32655	10 PACK UNIDOSE PREMISE B1	2981430	3001285	3001286	3001288	
32656	10 PACK UNIDOSE PREMISE B2	3001289	3001290	32656		
32657	10 PACK UNIDOSE PREMISE B3	3001292	3001293			
32658	10 PACK UNIDOSE PREMISE B4	3001295	3001296			
32659	10 PACK UNIDOSE PREMISE C1	2999213	2999888	3001298	3032735	
32660	10 PACK UNIDOSE PREMISE C2	3001299				
32661	10 PACK UNIDOSE PREMISE C3	2999220	3001301	3001302	3018174	3031244
		2999889				
32662	10 PACK UNIDOSE PREMISE C4	3001304	3001305	3019086	3032740	
32663	10 PACK UNIDOSE PREMISE D2	3001306	3001307	3001308		
32664	10 PACK UNIDOSE PREMISE D3	3001309	3001311	3032745		
32665	10 PACK UNIDOSE PREMISE D4	2999264	3028525			
32666	10 PACK UNIDOSE PREMISE XL1	3001312	3001313	3009770		
32667	10 PACK UNIDOSE PREMISE XL2	3001314	3027204			
32668	10 PACK UNIDOSE PREMISE A2 OPAQ	3001335	3001336	3032769		
32669	10 PACK UNIDOSE PREMISE A3 OPAQ	3001338				
32670	10 PACK UNIDOSE PREMISE A3.5 OPAQ	3001339				
32672	10 PACK UNIDOSE PREMISE B1 OPAQ	3001341	3001342			
32673	10 PACK UNIDOSE PREMISE B2 OPAQ	3001343				
32674	10 PACK UNIDOSE PREMISE C2 OPAQ	3001345	3001346			
32676	10 PACK UNIDOSE PREMISE TRANS AMBER	3015352	3001330			
32677	10 PACK UNIDOSE PREMISE TRANS GREY	3001332				
32678	10 PACK UNIDOSE PREMISE TRANS CLEAR	3001334	3018923			
34086	10 PACK UNIDOSE PREMISE A2 SAMPLE	2990913				
32811	10 PACK PREMISA UNIDOSE, A1	3001316	3011566			
32812	10 PACK PREMISA UNIDOSE, A2	3001318	3018916			
32813	10 PACK PREMISA UNIDOSE, A3	3001320	3018915			
32814	10 PACK PREMISA UNIDOSE, A3.5	3001322	3018914			
32815	10 PACK PREMISA UNIDOSE, A4	3001323	3001324			
32817	10 PACK PREMISA UNIDOSE, B2	3001326	32817			
32818	10 PACK PREMISA UNIDOSE, B3	3001327	32818			
32822	10 PACK PREMISA UNIDOSE, C3	3034871	32822			
32823	10 PACK PREMISA UNIDOSE, C4	3001328	32823			
32824	10 PACK PREMISA UNIDOSE, D2	3018912	32824			
32830	10 PACK PREMISA UNIDOSE DENTIN A3	3001351	32830			
32837	10 PACK PREMISA UNIDOSE TRANSLUCENT AMBER	3001347	3016070			

Class II Recall (cont.)

The table below lists the Premise Kit Lot Numbers that contain the affected 10-Pack Unidose Lot Numbers listed above.

PART NO.	DESCRIPTION	KIT LOT NUMBER(S)				
32612	UNIDOSE PREMISE MASTER KIT	3000205	3013662			
33882	UNIDOSE PREMISE MINI KIT	2989348	2993142	2993144	3004342	3028177
		2993141	2993143	2993145	3005798	

Microbore Extension Sets, Cat No. 50.307m, Lots 80405-1 & 80726-1

(ARTG number 96165)

(REFERENCE: RN-2008-0776)

Date: 23/09/2008

Reason: There have been complaints of the Component Female Luer Lock cracking on exposure to certain substances including Alcohol and Propofol.

Further information: Tuta Healthcare Pty Ltd, 1300 361 162 Customer Service.

Class III Recall

Synchron® ACTM Reagent

Lot number M702524, Expiry 30/04/2009

Lot number M703276, Expiry 31/05/2009

(ARTG number: 98679)

(REFERENCE: RN-2008-0593)

Date: 4/09/2008

Reason: Specific lots of Synchron® ACTM reagents have been confirmed to have been manufactured using amounts of the heparin contaminated with Oversulfated Chondroitin Sulfate (OSCS). These lots shown a negative bias in performance when compared to uncontaminated lots but are not clinically significant.

Further information: Beckman Coulter Australia Pty Ltd.

Wipe Out Isopropyl hard surface wipes, Part 200021, Batch no. BN0608

(ARTG number :130235)

(REFERENCE: RN-2008-0706)

Date: 4/09/2008

Reason: Pungent odour in single batch of wipes.

Further information: Steeldrill International Pty Ltd, 03 9790 6411 – Purchasing Manager.

Leckey Squiggles Stander on Pivot Chassis, Patient standing frame

(ARTG number: 130629)

(REFERENCE: RN-2008-0759)

Date: 18/09/2008

Reason: There is a possibility for loose castors on this version of child posture support

Further information: Otto Bock Australia Pty Ltd, 02 8818 2800 - Terry Gallagher



Class III Recall (cont.)

Look 3/0 Black Mono Nylon 18"/45cm C7 Needle (925B)

(ARTG number 141193)

(REFERENCE: RN-2008-0760)

Date: 17/09/2008

Reason: Mislabelling of suture products. There is a possibility that Lot M335780 of item code 925B may contain mixed product.

Further information: Multi Medical Group Pty Ltd, 07 5527 6311, Ian McKinnon.

Look/Sharpoint Suture

925B 3-0 Black Mono Nylon with C7 Needle, Lot no: M335780

(ARTG number 143981)

(REFERENCE: RN-2008-0769)

Date: 19/09/2008

Reason: The product should contain 925B 3-0 Black Mono Nylon with C7 Needle, however due to a product mix-up this one lot may instead contain 4-0 Black Braided Silk with C6 Needle.

Further information: W9 Pty Ltd, 02 9987 4224 – W9 Customer Service.