

Safety Notice

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Issued by SA Department of Health, Safety and Quality Unit
www.safetyandquality.sa.gov.au



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

We recommend you inform:

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

Contact details:

T: (08)8226 6188
F: (08)8226 0725

Therapeutic Goods Administration (TGA) Alerts & Recalls

Summary for June 2010

The established process for TGA medical device alerts, recalls and 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.

The aim of the Safety Notice is to inform health services about potential safety and quality issues requiring risk assessment at the local level to determine appropriate action(s) regarding any identified problems.

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

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

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

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

Class I recall – considered to be safety related recalls.

Class II recall – considered to be safety related recalls.

Persons receiving this notice should ***NOT*** take any further action unless the affected goods are supplied to/in use in their health service.

FOR SA HEALTH STAFF ONLY

Due date for response to the Department of Health is
29th July 2010



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Alert

St Jude Medical Neuromodulation Paddle Leads

REFERENCE: RC-2010-RN-00608-3
DATE AGREED: 22/06/2010
COMPANY: St Jude Medical Australia Pty Ltd
PHONE: 0410 330 346 - Jeffrey Esbjerg
REASON: The paddle leads have been associated with neurological deficit adverse events such as, autonomic symptoms, pain or paralysis in a small number of cases
SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites

Product Name	Model Number #'s
Exclaim™	3224
Lamitrode S4™	3243, 3246, 3266, 3267
Lamitrode S8™	3268, 3269, 3283, 3286
Lamitrode Tripole 8™	3208
Lamitrode Tripole 8C™	3210
Lamitrode Tripole 16™	3219
Lamitrode Tripole 16C™	3214
Lamitrode 4™	3240, 3254, 3255
Lamitrode 44™	3244, 3262, 3263
Lamitrode 44C™	3245, 3264, 3265
Lamitrode 8™	3280
Lamitrode 88™	3288
Lamitrode 88C™	3289
Lamitrode Penta™	3228

Lens Cleaning Sheath MAJ-1537 (for Olympus LTF type VH – a Laparo-Thoraco Videoscope)

ARTG NUMBER: 146069
REFERENCE: RC-2010-RN-00613-3
DATE AGREED: 23/06/2010
COMPANY: Olympus Australia Pty Ltd
REASON: The distal tip of the lens cleaning sheath attached to the LTF VH has the potential to become detached and fall into the patient body.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites

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Class I Recalls

Nil this month

Class II Recalls

NexGen Broach Impactors found in NexGen orthopaedic procedure kits Numbers: 00597701100 & 00588108000

ARTG NUMBER: 109936
REFERENCE: RC-2010-RN-00498-3
DATE AGREED: 3/06/2010
COMPANY: Zimmer Pty Ltd
PHONE: 02 9950 5426 - Clifton Pereira
REASON: The manufacturer has determined that there is a potential for the thumb pin detaching from the device during impact. This presents the possibility of the thumb pin being left in the surgical site.

SITES AFFECTED: (Only those sites listed are required take appropriate action)
Royal Adelaide Hospital, Queen Elizabeth Hospital, Lyell McEwin Health Service, Modbury Hospital, Repatriation General Hospital, Mt Gambier Hospital, Pt Augusta Hospital, Pt Pirie Hospital, Whyalla Hospital, Flinders Private Hospital, Memorial Hospital, Ashford Hospital, Parkwynd Private Hospital, Stirling District Hospital.

COBAS AmpliPrep/ COBAS TaqMan HBV v2.0 (*An in vitro diagnostic medical device (IVD)*) Material Number 04894570190

REFERENCE: RC-2010-RN-00549-3
DATE AGREED: 31/05/2010
COMPANY: Roche Diagnostics Australia Pty Limited
PHONE: 1800 645 619 - National Support Centre
REASON: Suspected contamination of cassettes by native HBV DNA. The contamination could cause false positive and over-quantitated results.

SITES AFFECTED: (Only those sites listed are required take appropriate action)
SA Pathology



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Class II Recalls (Cont)

VAPR Integrated Handpiece Electrode – All Lots

ARTG NUMBER: 138488
REFERENCE: RC-2010-RN-00585-3
DATE AGREED: 9/6/2010
COMPANY: Johnson & Johnson Medical Pty Ltd T/A Depuy Australia
PHONE: 1800 257 210 – Customer Support Centre
REASON: Some of the products within the affected codes did not meet the required packaging specifications for pouch seal width dimensions, which could potentially lead to a breach in sterility.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
Queen Elizabeth Hospital, Lyell McEwin Health Service, Ashford Community Hospital, Calvary Central Districts Hospital, Calvary Hospital, North Eastern Community Hospital.

Product code	Product Description
225370	VAPR S90 Suction Electrode
227355	VAPR S50 Knee Electrode
227504	VAPR Premiere50 Electrode
227204	VAPR Premiere90 Electrode
227301	VAPR Side Effect Electrode
227312	VAPR Flexible Side Effect Electrode
227302	VAPR Angled Side Effect Electrode
227305	VAPR Hook Electrode
227211	VAPR Side Effect Short Electrode
227202	VAPR End Effect Electrode
227203	VAPR Wedge Electrode
227213	VAPR Wedge Short Electrode
227252	VAPR Temperature Control Electrode

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Class II Recalls (Cont)

Oridion Medical Filterline CO2 sampling lines for use with Microstream Capnography
Catalogue Numbers: 009818, 010209, XS-04620, XS-04624, 010579 & 010580
Batch numbers between Q0901006 and Q0908223

ARTG NUMBER: 150026
REFERENCE: RC-2010-RN-00596-3
DATE AGREED: 17/06/2010
COMPANY: Endovations Pty Ltd
PHONE: 1300 361 839 - Marcus Picthall
REASON: The affected filterlines may not be recognised by the patient monitor or defibrillators equipped with Microstream Capnography. No CO2 value will be displayed on the monitor nor will there be any alarms until CO2 monitoring starts.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
Royal Adelaide Hospital

GE Centricity Laboratory; all software versions

ARTG NUMBER: 128084
REFERENCE: RC-2010-RN-00603-3
DATE AGREED: 22/06/2010
COMPANY: GE Healthcare IITS Australia Pty Ltd
PHONE: 1800 659 465 GE Customer Care Centre
REASON: Results from interfaced external reference laboratories may not be displayed or stored correctly if an unexpected alpha character is encountered in a result message that is expected to have a numeric value.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
SA Pathology, Women's and Children's Hospital.

IMMAGE Immunochemistry Systems Buffer 1 (BUF 1) **Part no: 447650 Lots T908069, T908104 & T909110**

REFERENCE: RC-2010-RN-00612-3
DATE AGREED: 21/06/2010
SPONSOR: Beckman Coulter Australia Pty Ltd
PHONE: 1800 060 881- Customer Support Centre
REASON: Some lots of BUF1 have been reported to cause high shifts in recovery of control or patient samples. Quality Control failures may result after replacing BUF1 with a different lot.
SITES AFFECTED: (Only those sites listed are required take appropriate action)
Flinders Medical Centre

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Class II Recalls (Cont)

Survival Saline Solution 15ml Lot 20090715 supplied in the following St John First Aid Kits purchased during Sep-Dec 09.

Leisure small – Batch SJ0902

Leisure medium – Batch SJ0903

Leisure Large – Batch SJ0904

ART NUMBER: 155522

REFERENCE: RC-2010-RN-00578-3

DATE AGREED: 16/06/2010

SPONSOR: St John Ambulance Australia Inc

PHONE: 1300 598 829 - Customer Service

REASON: The batch of Survival Saline solution has been found to be contaminated and may cause infection.

SITES AFFECTED: (Only those sites listed are required take appropriate action)
All sites

Class III Recalls

Nil this month