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Safety Notice

SN:004

12 October 2006

Distributed to:

- Chief Executives
- Directors of Clinical Operations
- Directors of Clinical Governance

Action required by:

- Directors of Clinical Governance

We recommend you also inform:

- Clinical Product Managers
- Directors of Nursing
- Directors of Pharmacy

Quality and Safety Branch

NSW Department of Health

Tel. 02 9391 9200

Fax. 02 9391 9556

Email

quality@doh.health.nsw.gov.auwww.health.nsw.gov.au/quality/sabs/register.html

Therapeutic Goods Administration (TGA) Recalls

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. TGA **Class I** defects are potentially life-threatening or could cause serious risk to health. **Class II** defects could cause illness or mistreatment, but are not Class I.

This Safety Notice is provided to reinforce the TGA process. It contains TGA Class 1 and selected Class II medical device recalls/product corrections for your implementation, if relevant.

Class I

GE Healthcare Disposable Compact Absorber (Reference: RN-2006-0645)

Recall date: 14 Sep 2006

Codes: RC: 427002100 (white to violet colour change) Lots 23066, 102076 and 145015 ARTG numbers 127297 and 127301

Issue: Certain Compact Absorbers may have an increased resistance to gas flow due to an improperly manufactured foam filter. The increased resistance can cause an elevated pressure at the ventilator end of the inspiratory circuit, but the pressure at the patient may be reduced. This could result in patient hyperventilation and hypoxia.

Further information: Datex-Ohmeda Pty Ltd on 1300 722 229 National Service and Customer Support.

i-Pad Defibrillator NF1200 (Reference: RN-2006-0657)

Recall date: 19 Sep 2006

Code: ARTG number 95542

Issue: The battery low state cannot be detected in the device when the battery level is too low. Additionally it also appears that there has been a decrease in the estimated battery life.

Further information: Biomedex (Aust) Pty Ltd on 02 4285 9600 (Frazer Davey).

Class II

Panbio Bordetella Pertussis IgA Elisa test kit (Reference: RN-2006-0678)

Recall date: 28 Sep 2006

Code: ARTG number 22341

Issue: The cut-off determination point was set too low resulting in false positive results.

Further information: Panbio Limited, Ms Myriam Boyle 07 3363 7100

Disposable Anaesthetic Circuit (Reference: RN-2006-0647)

Recall date: 26 Sep 2006

Code: PHC/05-WT-E; PHC/10-WT-E; PHC/3560; PHC/3560/1; PHC/3560/1/SNIP; PHC/3560/SNIP; ARTG number 61072

Issue: Under rare circumstances, a component of a range of Disposable Anaesthetic Circuits may become occluded.

Further information: Swirl Technologies Pty Ltd T/A Parker Healthcare, Sue Connolly on 03 9872 0222

AGA Amplatz Delivery and Exchange System (Reference: RN-2006-0689)

Recall date: 4 Oct 2006

Code: All Lot Numbers; ARTG number 64237 & 78362

Issue: Microscopic tears can occur in the delivery system sterile packaging under accelerated stress testing with routine shipping configurations. These microscopic tears are a potential breach of the sterile barrier.

Further information: Medtel Pty Ltd Therese Turner, Interventional Business Unit Manager on 02 9413 6275 or 0408 212 410

Suggested Actions by Area Health Services

1. Determine if this Safety Alert is relevant for your Area Health Service
2. Ensure that this Safety Alert is distributed to all relevant stakeholders
3. Ensure that relevant areas have received letters from sponsor of implementation strategies necessary.