NSW HEALTH

Safety Notice

SN:007/06

14 December 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 Imaging

Quality and Safety Branch
NSW Department of Health
Tel. 02 9391 9200
Fax. 02 9391 9556
Email
quality@doh.health.nsw.gov.au

www.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 selected Class II medical device recalls/product corrections for your implementation, if relevant.

Class II

Bremer Halo and Skull Pins **(Reference: RN-2006-0720)**
Date: 18/10/2006
Details: ARTG No 97979
Reason: Depuy Spine has made a decision to recall a series of Bremer Halo and Skull Pin products based on compromised packaging seals on the sterile packaging. The compromised seals may result in the skull pins being non sterile.
Further information: Johnson & Johnson Medical Pty Ltd T/A Depuy Australia; Peter Witherspoon phone 03 9538 9318

ApexPro/ApexPro CH Telemetry System **(Reference: RN-2006-0753)**
Date: 3/11/2006
Details: ARTG No 118986
Reason: The manufacturer has identified a potential missing SYSTEM WARNING alarm under certain conditions.
Further information: GE Medical Systems Australia Pty Ltd, phone 1300 722 229

Vinyl Examination Gloves **(Reference: RN-2006-0807)**
Date: 29/11/2006
Details: ARTG No 96408
Powder Free Vinyl Examination gloves (Small). Batch:007F64709
Low Powder Vinyl Examination gloves (Medium). Batch: 006F63372
Reason: These batches may not meet the water tightness standard for medical use.
Further information: Livingstone International P/L, phone 1300 556 556

Precedence and Gemini Nuclear Medicine Systems **(Reference: RN-2006-0825 & RN-2006-0823)**
Date: 1/12/2006
Details: ARTG Nos 117440 & 118077; Systems using Brilliance 1.2 software
Reason: An issue with the Gemini GLX and Precedence NM Systems that could result in the delivered CT radiation dose being different than the calculated dose reported to the operator.
Further information: Philips Electronics Australia Ltd, Rolf Stoekle phone 03 9945 2048

Conmed Corporation Frazier and Poole Instruments **(Reference: RN-2006-0829)**
Date: 4/12/2006
Details: Lot codes 0110041 to 0610041; ARTG No. 75664
Reason: Specific lot numbers of Frazier and Poole instruments may have a compromised sterile barrier.
Further information: Medtel Pty Ltd; Kathy Mitrangas phone 03 8564 0806

Suggested Actions by Area Health Services

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