



Safety Information

SI:01/06

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Distributed to:

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

Quality and Safety Branch

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Welcome to the first *Safety Information* sheet published under the **Safety Alert Broadcast System (SABS)**. The information reinforces other resources available to Health Services and is provided for your action as appropriate.

Alaris SE Pumps recall – 30 August 2006

The Therapeutic Goods Administration (TGA) has advised a Class 1 recall for product correction of Alaris SE Pumps (formerly known as Signature Edition Infusion Pumps) of all models. The recall is due to a potential for over infusion caused by key bounce. If not detected during programming verification, key bounce may result in serious patient harm or death. The sponsor, Cardinal Health Australia 316 Pty Ltd advised that all sites were formally notified on 5 September 2006. For further information contact the sponsor, Alex Leung on 9624 9006.

Filshie Clip System

There have been several incidents relating to the Filshie Clip System reported through the Incident Information Management System (IIMS). This system involves the use of clips and applicator for tubal ligation procedures. Users must ensure that the applicator handle and barrel of the device are not interchanged and that both components share the same serial number making one complete unit. Failure to adhere to the instructions may result in the performance of the device being compromised. The Filshie Clip Applicators must be serviced and calibrated in accordance with the manufacturers instructions. Reference to this information is at the TGA website: <http://www.tga.gov.au/>

Peanut Allergies

A number of incidents have been reported relating to food given to patients with nut allergies. The Australian Society of Clinical Immunology and Allergy Inc (ASCIA) advises that whilst most allergic reactions to peanuts are mild, some people who are allergic to peanuts develop serious symptoms which can be triggered by even a trace amount of food. Staff serving food must be alert to food products that may contain nuts or a nut derivative. For further information on peanut allergies go to ASCIA website: www.allergy.org.au and http://www.health.nsw.gov.au/public-health/pdf/peanut_fs.pdf

Bisphosphonates Medications

The Australian Drug Evaluation Committee (ADEC) has advised, through the TGA, that based on evidence, that there is a class effect operating in relation to the occurrence of osteonecrosis of jaws (ONJ) and adynamic bone disease after the use of bisphosphonates. A copy of the ADEC letter to the Department concerning this matter has been forwarded to Chief Pharmacists through the Pharmaceutical Services, to Area Health Service Chief Executives and to senior dentists through the Centre for Oral Health. For further information go to ADRAC Bulletin Volume 25, Number 4, August 2006 at <http://www.tga.gov.au/adr/aadrb/aadr0608.htm>

Recommended actions by Area Health Services

1. Forward information to appropriate area for action.
2. Ensure a system is in place to document actions taken.