

13 October 2008

Safety Alert 002/08

The actions specified are mandatory in accordance with NSW Health Policy Directive PD2006 102

Peripherally Inserted Central Catheter (PICC Line)

This Safety Alert supersedes Safety Alert 001/08

Background

The Therapeutic Goods Administration (TGA) has received several reports of serious adverse events associated with the use of Peripherally Inserted Cental Catheter (PICC) Lines.

TGA received a medical device adverse event report from a hospital concerning an incident during a procedure to insert an Arrow brand PICC Line in a child.

The report advises that the outer winding of the indwelling wire separated from the inner core and embolised into the pulmonary artery of the patient after the length of line was trimmed to an appropriate length for a small patient. Subsequent scaps showed the presence of wire fragment in the pulmonary artery that was successfully removed.

The TGA investigated similar incidents in 2002 and 2005, and on three previous occasions has issued warning about the risks of cutting the catheter guidewires in PICC and central lines.

Further reports have been received about difficulties with the insertion of this device.

Area Health Services are advised to suspend use of the Arrow 3FG (PC-01-351-TW) PICC lines until an internal review is undertaken and further notice provided by NSW Health.

Distributed to:

- Chief Executives
- Directors of Clinical Operations
- Director of Clinical Governance
- Clinical Product Managers

Action required by:

 Director of Clinical Governance.

For response by:

 Directors of Clinical Governance.

We recommend you also inform:

- Vascular Access Teams
- Nurses and doctors of paediatric units
- Nurses and doctors of NICU
- Clinical Heads NICU
- Clinical Heads PICU
- Area Directors of Nursing
- Nurses
- Medical staff

Deadline for completion of action

15th October 2008

Quality and Safety Branch

NSW Department of Health Tel. 02 9391 9200 Fax. 02 9391 9556 Email

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www.health.nsw.gov.au/quality/s abs/register.html

Actions required by Area Health Services

- 1. Suspend use of the Arrow branded 3FG (PC-01-351-TW) until further notice.
- Wherever possible shortening of any catheter should be avoided, but if necessary to do so, the manufacturer's instructions should be very carefully followed.
- 3. AHS to respond to SABS email address within 2 working days of receipt of this alert.