

NSW HEALTH

Safety Alert 002/10

13 Jan 2010

RECALL of Breathing Systems with Intersurgical #1986 Connector

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations
- Directors of Corporate Services
- Clinical Product Managers

Action required by:

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

For response by:

 Directors of Clinical Governance

We recommend you also inform:

- Directors of Intensive Care
- Directors of Emergency Departments
- Biomedical Engineering
- Directors of Medical Services
- Directors of Nursing and Midwifery
- Relevant Medical staff
- Relevant Nurses and Midwives

Deadline for completion of action

15 January 2010

Clinical Safety, Quality and Governance Branch

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Internet Website:

http://www.health.nsw.gov.au/quality/sabs

Intranet Website

http://internal.health.nsw.gov. au/quality/sabs/

Background

Mayo Healthcare Pty Ltd has advised the Therapeutic Goods Administration (TGA) of a voluntary recall for product correction of Breathing Systems with Intersurgical #1986 Connector.

Due to a moulding fault, some T-pieces of these breathing systems have been found to contain a plastic membrane causing a partial occlusion.

- Intersurgical #1986 Connector 22F, 22M, 22M/15F T-Piece;
- Intersurgical #2108 Mapleson C anaesthetic breathing system; and
- Mayo Healthcare breathing circuit numbers 99249, 99396, 99396A, 99458, 99467, 99476.

All lots of the above supplied in 2009

ARTG number 122364.

Mandatory actions for Health Services

Health Services are to

- Urgently review current stock of Breathing Systems with Intersurgical #1986 Connector as outlined above.
- Withdraw any of this stock.
- Ensure sufficient alternate stock is available for use so that clinical care is not compromised.
- Report any incidents through IIMS.

Additional Information

Mayo Healthcare Pty Ltd Mr Geoff Braid (02) 8337 7942

Action required by Area Health Services

- 1. Withdraw all Breathing Systems with Intersurgical #1986 Connector with the specifications listed above.
- 2. Report any incidents through IIMS.
- 3. Verify withdrawal of above products and any other actions by close of business Friday 15 January 2010.