NSW HEALTH

Safety Alert 001/10

8 Jan 2010

RECALL of Unomedical Endotracheal Tubes

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 Specialty Training Units
- Directors of Nursing and Midwifery
- Relevant Medical staff
- Relevant Nurses and Midwives

Deadline for completion of action

11 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.

Background

Unomedical has advised of a voluntary recall of the following Batch/Lot numbers of Endotracheal Tubes due to a potential manufacturing irregularity during production whereby the connector of some units may potentially detach more easily than is usual from the Endotracheal tube during product usage.

Product Description	Product Code	Batch/Lot Number
HVLP CUFF MURPHY 6mm	MM61110060	601692 600345
HVLP CUFF MURPHY 6.5mm	MM61110065	602167
HVLP CUFF MURPHY 7 mm	MM61110070	600867 600367 600614 602168
HVLP CUFF MURPHY 8 mm	MM61110080	600369 600613 602170
HVLP CUFF MURPHY 8.5 mm	MM61110085	600370
HVLP CUFF MURPHY 9 mm	MM61110090	600869 600349 601511
UNO PLAIN MURPHY 2.5 mm	MM61130025	600211
UNO PLAIN MURPHY 4.5 mm	MM61130045	602232
PLAIN REGULAR MAGILL TIP 3.5 mm	MM61140035	600932
PLAIN REGULAR MAGILL TIP 4.0 mm	MM61140040	602567
PLAIN REGULAR MAGILL TIP 4.5 mm	MM61140045	603221
PLAIN REGULAR MAGILL TIP 5.0 mm	MM61140050	600870
PLAIN REGULAR MAGILL TIP 6.0 mm	MM61140060	601512
SVLP CUFF MURPHY 7.5mm	MM61150075	600871 602171
SVLP CUFF MURPHY 8 mm	MM61150080	602274

Mandatory actions for Health Services

Health Services are to:

- Urgently review current stock of these Endotracheal tubes
- Withdraw any of the above Batch/Lot numbers.
- Ensure sufficient alternate stock of Endotracheal tubes are available for use so that clinical care is not compromised.
- Report any incidents through IIMS.

Action required by Area Health Services

1. Withdraw all ET tubes with the above Batch/Lot numbers.
2. Report any incidents through IIMS.
3. Verify withdrawal of above products and any other actions by close of business Monday 11 January 2010.