

Medical Device Alert

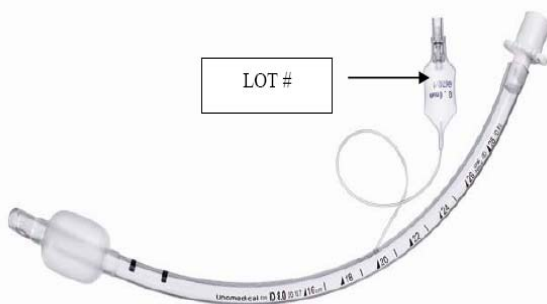
Immediate action update

Ref: MDA/2010/027 Issued: 08 April 2010 at 14:00

Device

Endotracheal (ET) tubes, adult and paediatric sizes. Manufactured by Unomedical (a ConvaTec company).

This MDA replaces MDA/2010/024, as additional lot numbers have been recalled by the manufacturer.



Problem

Risk of inadvertent disconnection of the endotracheal tube from the breathing system, interrupting patient ventilation until the tube is reconnected or replaced.

Action by

All medical and nursing staff involved in the use of these devices.

Action

- Check lot numbers to identify whether you have affected devices.
- Do not use affected devices.
- Return affected products to the supplier for credit.

CAS deadlines

Action underway: 14 April 2010
Action complete: 21 April 2010

Contact

Unomedical
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Device

The lot numbers for ET tubes without a guide balloon can be found on their packaging.

Specific product codes and lot numbers of affected devices:

| Catalogue number | Description | Inner diameter (mm) | Lot numbers |
|------------------|--|---------------------|--|
| MM61130025 | Magill, plain (without cuff) with Murphy Eye | 2.5 | 601501R001 |
| MM61130030 | Magill, plain (without cuff) with Murphy Eye | 3.0 | 602525R001 601982R001 602525R002 |
| MM61130035 | Magill, plain (without cuff) with Murphy Eye | 3.5 | 601983R001 601503R001 602526R001 |
| MM61130050 | Magill, Plain (without cuff) with Murphy Eye | 5.0 | 601125R001 |
| MM61110050 | Magill, HVLP cuff with Murphy Eye | 5.0 | 600401R001 601971R002 |
| MM61110055 | Magill, HVLP Cuff with Murphy Eye | 5.5 | 601767R001 |
| MM61110060 | Magill, HVLP cuff with Murphy Eye | 6.0 | 600402R002 600278R001 |
| MM61110065 | Magill, HVLP cuff with Murphy Eye | 6.5 | 600403R001 600403R002 600403R004 |
| MM61110070 | Magill, HVLP cuff with Murphy Eye | 7.0 | 600404R001 600076R001 600980R004 |
| MM61110075 | Magill, HVLP cuff with Murphy Eye | 7.5 | 600077R001 600981R001 |
| MM61110080 | Magill, HVLP cuff with Murphy Eye | 8.0 | 601449R001 699991R002 |
| MM61110085 | Magill, HVLP cuff with Murphy Eye | 8.5 | 699992R002 600405R002 600405R003 |

Problem

A manufacturing irregularity during production of these ET tubes from August 2008 to November 2009 has been identified. This has caused the potential for the connector to detach from the ET tube more easily than expected. To address this potential problem the manufacturer is recalling affected lots.

A Field Safety Notice (FSN) was issued by the manufacturer in January 2010. The manufacturer was having difficulties in identifying which of the affected lots had been distributed in the UK and therefore issued an updated FSN in March 2010. That FSN was supported by the MHRA with MDA/2010/024.

The manufacturer has now discovered that additional affected lots have been distributed in the UK and so has published a third [FSN in April 2010](#). This Update MDA has been issued to support the April FSN and contains the lot numbers of all affect devices.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- All wards
- Ambulance staff
- Anaesthetic nursing staff
- Anaesthetists
- Day surgery units
- High dependency units
- Intensive care units
- Maternity units
- Midwifery departments
- Operating department practitioners
- Paediatric outpatients
- Paediatric wards
- Paediatric intensive care units
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Theatres

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Independent treatment centres

Contacts

Unomedical

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/027 or 2010/001/012/081/007**

Technical aspects

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Medicines & Healthcare products Regulatory Agency

Market Towers

1 Nine Elms Lane

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Clinical aspects

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How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>
Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:
Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

Tel: 028 9052 3704
Fax: 028 9052 3900
E-mail: NIAIC@dhsspsni.gov.uk

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>
Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:
Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB
<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/>

Tel: 0131 275 7575
Fax: 0131 314 0722
E-mail: nss.irc@nhs.net

Wales

Enquiries in Wales should be addressed to:
Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
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Cardiff CF10 3NQ

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E-mail: Haz-Aic@wales.gsi.gov.uk