

# Medical Device Alert

Ref: MDA/2013/029 Issued: 08 May 2013 at 14:00

## Device

Reinforced endotracheal (ET) tubes – Murphy; Magill; Murphy with stylet; Magill with stylet.

Manufactured by Unomedical (a ConvaTec company).

Available under three brand names:

- Unomedical UnoFlex™
- Euromedical™ TrachealFlex™
- PharmaPlast

Specific sizes and lots are affected.

## Problem

Potential for inadequate patient ventilation.

The affected tubes may delaminate, which can lead to constriction of the lumen, resulting in a reduction of airflow to the patient.

The manufacturer issued a [Field Safety Notice](#), dated 13 March 2013, to withdraw the affected devices but has not had confirmation from a significant number of users that they have received and acted upon this information.

This alert has been issued in support of the manufacturer's actions.

## Action by

All staff who use these devices

## Action

- Identify, quarantine and do not use affected devices.
- Seek alternative devices immediately.
- Return affected devices and the recall questionnaire to the manufacturer.

## CAS deadlines

Action underway: 22 May 2013

Action complete: 07 June 2013

**Note: These deadlines are for systems to be in place to identify and arrange for replacements of affected tubes.**

## Contact

### Manufacturer

Jo Snead – Customer Services  
ConvaTec Limited

Tel: 01244 832 206

Email: [Unomedical-uk.customerservice@convatec.com](mailto:Unomedical-uk.customerservice@convatec.com)

## Device

Reinforced endotracheal tubes are single-use medical devices comprised of an armoured, hollow cylinder inserted orally or nasally into the trachea.

Pages 4-6 of the Field Safety Notice (FSN) provide guidance on how to identify the devices. The reference numbers and lot numbers of all the affected devices are listed on pages 10-38 of the FSN.

## Problem

Delamination is the detachment of the plastic inner layers of the endotracheal tube from one another because of poor adhesion. The problem has now been rectified.

## Distribution

This MDA has been sent to:

- HSC trusts in Northern Ireland (chief executives)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS England area teams (chief executives)
- NHS England regional teams
- NHS trusts in England (chief executives)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

### Trusts

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

- All clinical departments
- All clinical staff
- All wards
- Ambulance staff
- Anaesthetists
- Clinical governance leads
- Community hospitals
- Directors of nursing
- Medical directors
- Resuscitation officers and trainers
- Risk managers
- Supplies departments
- Theatres

### NHS England area teams

CAS liaison officers for onward distribution to all relevant staff including:

- Resuscitation officers

### Independent distribution

#### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer

Jo Snead – Customer Services

Address: ConvaTec Limited, Deeside Industrial Park, Deeside, Flintshire, UK

Tel: 01244 832 206 Fax: 01244 832 207

Email: [Unomedical-uk.customerservice@convatec.com](mailto:Unomedical-uk.customerservice@convatec.com)

Tobias Davis – Regulatory Affairs Executive

Address: ConvaTec Limited, Harrington House, Milton Road, Ickenham, Uxbridge, Middlesex, UB10 8PU

Tel: 01895 628 440 Fax: 01895 628 339 Email: [tobias.davis@convatec.com](mailto:tobias.davis@convatec.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/029** or **2013/003/014/081/008**

### Technical aspects

Emma Rooke and Patrick Sweeney

Medicines & Healthcare Products Regulatory Agency

Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ

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[patrick.sweeney@mhra.gsi.gov.uk](mailto:patrick.sweeney@mhra.gsi.gov.uk)

### Clinical aspects

Mark Grumbridge

Medicines & Healthcare Products Regulatory Agency

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Email: [mark.grumbridge@mhra.gsi.gov.uk](mailto:mark.grumbridge@mhra.gsi.gov.uk)

### 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

Tel: 02890 523 704 Fax: 02890 523 900 Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### 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

Tel: 0131 275 7575 Fax: 0131 314 0722 Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team

Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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