

Medical Device Alert

Immediate action

Ref: MDA/2011/024 Issued: 07 March 2011 at 15: 00

Device

The Great Ormond Street GOS tracheostomy cannula set manufactured by Teleflex Medical (formerly known as Rusch).

All lot numbers of the following part numbers are affected:

121001	121002	121003
858812	858813	-



Problem

Due to a manufacturing error, the tube is too straight.

Teleflex has initiated a product recall.

Teleflex is not aware of any incidents of injury related to this issue. However, if the tube is too straight, there is a risk of damage to the tracheal wall during insertion or over time following insertion.

Action by

Supplies departments and all staff responsible for tracheostomy procedures and care.

CAS deadlines

Action underway: 14 March 2011

Action complete: 21 March 2011

Action

- Identify affected devices.
- Quarantine and do not insert affected devices.
- Return affected unused devices to Teleflex as advised in the Teleflex [Field Safety Notice](#).
- Ensure that the acknowledgment form is returned to Teleflex.
- If a patient has one of the affected devices in situ, perform a local risk assessment to determine if elective replacement of the tube is necessary.

Contact

Manufacturer
 Raychel Murtagh
 Teleflex Medical
 Tel: +353 906 460 838
 Email: orders.intl@teleflexmedical.com

Device

The affected devices are intended for use on paediatric and adult patients. The device is inserted into a patient's trachea surgically via the neck to maintain an open airway.

- Part numbers 121001, 121002 and 121003 are intended for hospital use.
- Part number 858812 and 858813 are intended for homecare use.

These devices have been discontinued by Teleflex.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care 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:

- Accident and emergency departments
- Anaesthetists
- Clinical governance leads
- Directors of nursing
- ENT departments
- ENT medical staff
- Health and safety managers
- Hospital at home units
- Intensive care medical staff (adult and paediatric)
- Intensive care nursing staff (adult and paediatric)
- Intensive care units
- Medical directors
- Neonatal nurse specialists
- Neonatology departments
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric outpatients
- Paediatric surgeons
- Paediatric wards
- Paediatricians
- Paramedics
- Purchasing managers
- Respiratory nurse specialists
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Primary care trusts

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

- Community children's nurses
- Community hospitals
- Community nurses
- District nurses
- Health visitors

Independent distribution

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

This alert should be read by:

- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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 and requesting this facility.

Contacts

Manufacturer

Raychel Murtagh
Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland
Tel: +353 906 460 838
Email: orders.intl@teleflexmedical.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/024** or **2010/012/015/291/001**

Technical aspects

Louise Mulroy and Douglas McIvor
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7344 or 7193
Fax: 020 8754 3965
Email: louise.mulroy@mhra.gsi.gov.uk
douglas.mcivor@mhra.gsi.gov.uk

Clinical aspects

Tom Clutton-Brock
Medicines & Healthcare products Regulatory Agency
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London SW1W 9SZ
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Fax: 020 8754 3965
Email: tom.clutton-brock@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

<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

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

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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