Medical Device Alert

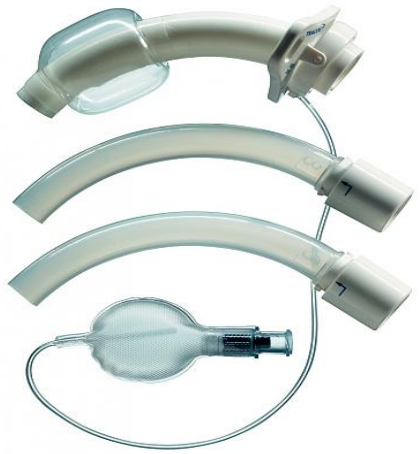
Ref: MDA/2013/063 Issued: 13 August 2013 at 14:00

Device

TRACOE twist tracheostomy tubes.
Various catalogue numbers.

Manufactured by TRACOE Medical.

Distributed in the UK by Kapitex Healthcare Ltd.



Problem

Risk of delay in treatment.

Difficulty changing the inner cannula as the locking system can be too tight.

Action

Identify the affected devices.

Follow the advice in the TRACOE Field Safety Notice dated 07 August 2013 and in particular:

- Check the lock of the inner cannula before use to ensure it fits correctly e.g. not too tight.
- If too tight, attempt to lock and unlock 3 times. If it remains too tight use a different tube

Action by

All staff that use these devices.

CAS deadlines

Action underway: 28 August 2013

Action complete: 10 September 2013

Note: These deadlines are for systems to be in place to ensure the recommended checks occur before use.

Contact

Supplier
Liv Hodge
Kapitex

Tel: 01937 580 911
Email: lth@kapitex.com

Device

Affected tubes have a manufacturing date from 12/2012 to 06/2013.

Catalogue numbers:

- TRACOE twist tracheostomy tubes

REF 301, 302, 303, 304, 305, 306, 888-306, and 309.

- TRACOE twist spare inner cannulas

REF 501 (-X), REF 503, REF 506 (-X).

- TRACOE twist tracheostomy tubes with low pressure cuff and atraumatic inserter

REF 301-P, REF 302-P, REF 306-P, REF 888-306-P.

- TRACOE experc Set twist

REF 320, REF321, Ref 322, and REF 888-322.

Please note this only applies to the TRACOE twist range of products and does not apply to the TRACOE twist plus range.

Distribution

This MDA has been sent to:

- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- 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:

- A&E departments
- Adult intensive care units
- All wards
- Anaesthetists
- Community children's nurses
- Community nurses
- Day surgery units
- District nurses
- ENT departments
- Hospital at home units
- Intensive care units
- Maxillofacial departments
- Medical directors
- Minor injury units
- Out patients clinics
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector

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

Supplier
Liv Hodge,
Kapitex Healthcare Ltd,
Kapitex House
1 Sandbeck Way
Wetherby LS22 7GH

Tel: 01937 580 211
Email: lth@kapitex.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/063** or **2013/006/021/081/006**

Technical aspects
Douglas McIvor or Emma Rooke
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7193 / 6609
Fax: 020 8754 3965

Email: douglas.mcivor@mhra.gsi.gov.uk
emma.rooke@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128
Fax: 020 8754 3965

Email: 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

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
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: nss.iric@nhs.net

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

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