Medical Device Alert

Ref: MDA/2012/049 Issued: 23 July 2012 at 15:00

Device

Neonatal and paediatric endotracheal tube clamp/holder.

All product codes.

All lot numbers.

Manufactured by EMS Medical.

Examples of packaging

Problem

Risk of airway loss due to slippage of the clamp/holder

or

airway obstruction as a result of over-tightening of the clamp/holder.

EMS Medical has gone into administration and therefore cannot be contacted.

The MHRA has issued this Medical Device Alert to ensure that all users are aware of this issue.

Action

Identify, do not use and dispose of affected devices.

Action by

All staff who may use or handle this device, particularly supplies and paediatric departments.

CAS deadlines

Action underway: 30 July 2012

Action complete: 13 August 2012

Note: These deadlines are for devices to be identified and disposed of.

Contact

No contact available

Device

This device assists in securing an endotracheal tube (ETT) in position for neonatal and paediatric patients.

Problem

The composition of the plastic used to make the clamp/holder was changed to a DEHP-free material. This affected the physical properties of these components, resulting in an increased risk of slippage or tube obstruction.

EMS Medical went into administration before this issue was identified and it is not known how many affected devices have been supplied.

Distribution

This MDA has been sent to:
- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities 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:
- A&E departments
- Ambulance staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- Health and safety managers
- Intensive care medical staff (paediatric)
- Intensive care nursing staff (paediatric)
- Maternity units
- Medical directors
- Midwives
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Paediatric surgery, directors of
- Paediatric intensive care units
- Paediatric wards
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatres

Primary care trusts

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:
- Hospitals in the independent sector
- Independent treatment centres

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.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/049** or **2012/007/005/081/015.**

Technical aspects
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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

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.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