

Medical Device Alert

Ref: MDA/2014/036 Issued: 17 September 2014 at 14:30

Device

Portex® endotracheal tube holder (2.5mm and 3.0mm) sold as stand-alone products or packaged in intubation kits.

Manufactured by Smiths Medical.

Specific product codes and lot numbers.

Problem

Risk of extubation or delay to therapy as there may be difficulty passing a suction catheter through the endotracheal tube when the holder is locked. There may also be difficulty locking the holder.

This is due to a manufacturing problem, which means the holder might compress the endotracheal tube.

Smiths Medical has issued a [Field Safety Notice \(FSN\)](#) recalling affected devices but hasn't had sufficient confirmation that customers have received it and acted on it.

Action by

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

Action

- Identify affected devices as described in the [FSN](#) and quarantine them.
- Complete and return the confirmation form in the FSN.
- Arrange for replacement devices with Smiths Medical.

CAS deadlines

Action underway: 24 September 2014

Action complete: 08 October 2014

Note: These deadlines are for devices to be quarantined.

Contact

Manufacturer

Smiths Medical International Ltd

Tel: 0845 850 0445

Email: EndoTrachealTubeHolders@smiths-medical.com

Smiths Medical Reference:
9610530-07/03/14-003-R

Device

If relevant to you, the national supply codes are as follows:

Scotland SKU:

Smiths code	NDC code
H4001PS	054220
H4001S	007424
H4002PS	014408
H4002S	039364
H4051	-
H4052	-

England NPC: use manufacturer's codes in the FSN

Northern Ireland: use manufacturer's codes in the FSN

Wales NSV: use manufacturer's codes in the FSN

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- 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)
- Special health authorities for information

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
- A&E nurses
- Adult intensive care units
- Ambulance staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- ENT departments
- Health and safety managers
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult) paediatric)
- Medical directors
- Medical physics departments
- Microbiologists
- Midwives
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Paediatric intensive care units
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Purchasing managers
- Special care baby units
- Supplies managers
- Theatres

Independent distribution

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

This alert should be read by:

- Hospices
- 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.

Contacts

Manufacturer

Smiths Medical International Ltd
Boundary Road
Hythe
Kent
CT21 6JL

Tel: 0845 850 0445

Email: EndoTrachealTubeHolders@smiths-medical.com

Smiths Medical Reference: 9610530-07/03/14-003-R

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/036** or **2014/007/010/081/017**.

Technical aspects

Louise Mulroy or Elke Kerwick
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7344 / 6826

Fax: 020 8754 3965

Email: louise.mulroy@mhra.gsi.gov.uk
elke.kerwick@mhra.gsi.gov.uk

Clinical aspects

Neil McGuire
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6800

Fax: 020 8754 3965

Email: neil.mcguire@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other 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.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

Email: improvingpatientsafety@wales.gsi.gov.uk

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