BfArM
Bundesinstitut für Arzneimittel
und Medizinprodukte

BfArM • Kurt-Georg-Kiesinger-Allee 3 • D-53175 Bonn

An die
AWMF-Geschäftstelle
z. Hd. Herr Müller
Ubierstrasse 20

D-40223 Düsseldorf

EINGEGANGEN
01. OKT. 2012
Erled. .....

Postanschrift:
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Ihre Zeichen und Nachrichten vom | Gesch.-Z.: Bitte bei Antwort angeben 92.15-5902/12 | Telefon: (0228) 207 - 5350, Fax: +49-228-207 - 5300, E-Mail: medizinprodukte@bfarm.de | Bonn, 28.09.2012

Durchführung des Medizinproduktegesetzes
Silicone Tracheostomie Tuben
diverse Hersteller und Modelle
BfArM-Fallnummer: 5902/12

Sehr geehrter Herr Müller,

Die britische Behörde informierte mit beiliegendem Schreiben über Vorkommnisse mit Silicon Tracheostomie Tuben. Es sind laut MHRA Information diverse Hersteller und Modelle betroffen. Tracheostomy Tuben seien durch nicht kompatible, scharfkantige Halter beschädigt worden, was zu Lockerungen und Luftverlust geführt habe. Es wird empfohlen, die Gebrauchsanweisungen für Halten **und** Tracheostomie-Tuben zu beachten.

Wir bitten Sie, die einschlägigen Fachgesellschaften entsprechend zu unterrichten.

Mit freundlichen Grüßen
Im Auftrag

Abteilung Medizinprodukte

Dieses Schreiben wurde elektronisch erstellt und ist ohne Unterschrift gültig.

Medical Device Alert

Ref: MDA/2012/062 Issued: 11 September 2012 at 15:00

Device

Silicone tracheostomy tubes

Various manufacturers

Various models

Problem

The MHRA is aware of several incidents where the eyelets of tracheostomy tubes appear to have been damaged by the holder. This led to dislodgement of the tube with the subsequent risk of airway loss.

Action by

All staff responsible for the care of patients with tracheostomy tubes.

CAS deadlines

Action underway: 25 September 2012

Action complete: 09 October 2012

Note: These deadlines are for systems to be in place to take actions.

Action

- Check the instructions for use for both the tracheostomy tube and the holder to ensure that they are compatible.
- Be aware that some manufacturers have recently updated their instructions for use to include a warning to users not to use their tracheostomy tubes with sharp-edged holders, for example some types of Velcro or metal edged holders.
- Ensure that the instructions for use are followed for both the tracheostomy tube and the holder.

Device

Tracheostomy tubes are held in position using holders (also known as neck ties). The holders are attached by being threaded through the eyelets on the flanges of the tracheostomy tube.

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)
- 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:

- Adult intensive care units
- All clinical departments
- All clinical staff
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- Health and safety managers
- Hospital at home units
- Medical directors
- Medical libraries
- Nursing executive directors
- Outpatient departments
- Paediatric intensive care units
- Purchasing managers
- Risk managers
- Supplies managers
- 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
- General practitioners
- Health visitors
- Minor injury units
- NHS walk-in centres
- Practice nurses
- School nurses
- Walk-in centres

Social services

Liaison officers for onward distribution to all relevant staff including:

- In-house residential care homes

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care
- Care homes providing personal care
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Issued: 11 September 2012 at 15:00 Ref: **MDA/2012/062**

Establishments registered with OFSTED
This alert should be read by:
- Educational establishments with beds for children
- Residential special schools

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/2012/062** or **2012/001/018/401/003**

Technical aspects
Louise Mulroy and Gica Leclerc
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gica.leclerc@mhra.gsi.gov.uk

Clinical aspects
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London SW1W 9SZ

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Fax: 020 8754 3965

Email: jonathan.plumb@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.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