Medical Device Alert

Ref: MDA/2012/020 Issued: 13 April 2012 at 12:00

Device

Oral swabs with a foam head.

All manufacturers.

Problem

Foam heads of oral swabs may detach from the stick during use. This may present a choking hazard for patients.

Action by

All those involved in the use and supply of these devices including those who advise patients and carers.

CAS deadlines

Action underway: 27 April 2012

Action complete: 14 May 2012

Action

Follow the manufacturer's instructions for use (where available).

Check that the foam head is firmly attached to the stick before use.

Do not leave the swabs soaking in liquid prior to use as this may affect the strength of the foam head attachment.

If required moisten the swab immediately before use.

If the patient is likely to bite down on the swab consider using an alternative such as a small headed toothbrush with soft bristles.

Ensure that all users, including unsupervised patients and carers, are aware of this advice and the manufacturer's instructions for use.

Discard oral swabs after use.

This advice supersedes the advice given in MDA/2008/017.

Problem

The MHRA is aware of a recent incident in Wales where the foam head detached from the stick of an oral swab while a carer was providing mouth care to an elderly patient. The foam head could not be retrieved. The patient subsequently died.

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)
- OFSTED (Directors of Children's Services) for information
- 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 nursing staff
- All wards
- Clinical governance leads
- Dental departments
- Dental nurses
- Dentists
- ENT departments
- ENT medical staff
- ENT services, directors of
- Health and safety managers
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Nursing executive directors
- Oral and maxillofacial surgeons
- Risk managers

Primary care trusts

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

- Community children's nurses
- Community dental services
- Community hospitals
- Community nurses
- District nurses
- General dental practice
- Palliative care teams

Social services

- Care at home staff
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- In-house domiciliary care providers (personal care services in the home)
- 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 (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies

Establishments registered with OFSTED
This alert should be read by:
- Children's services
- 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/2012/020** or **2012/003/001/401/005**

Technical 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

This alert supersedes Hazard Notice HAZ(SC)08/06, issued by Scottish Healthcare Supplies on 19 March 2008

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:

Dr Chris Jones
Medical Director
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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