

# Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/018

Issued: 18<sup>th</sup> March 2008

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION	



**HEALTH ESTATES**

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	Section
<b>Medical Device/Equipment:</b> Oral hygiene swabs – all manufacturers.	▶ ①
<b>Problem:</b> Foam heads of oral swabs may detach from the stick during use. This may present a choking hazard for patients.	▶ ②
<b>Action by:</b> All those involved in the use and supply of these devices.	▶ ③
<b>Action:</b> <ul style="list-style-type: none"> <li>Check that the foam head is firmly attached to the stick before use in line with infection control procedures.</li> <li>Do not soak the oral swab in liquid before use as this may affect the strength of the head attachment.</li> <li>Ensure all users including patients and carers :                             <ul style="list-style-type: none"> <li>are aware of this advice, and</li> <li>follow manufacturer's instructions for use where available.</li> </ul> </li> </ul>	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b>	▶ ⑤ General Medical Practices General Dental Practitioners Hospices
<b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.	▶ ⑥
<b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b>	
<b>Acknowledge Receipt of Alert:</b> 21 <sup>st</sup> March 2008	<b>Action Under Way:</b> 1 <sup>st</sup> April 2008
<b>Action Complete:</b> 16 <sup>th</sup> June 2008	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

Oral hygiene swabs – all manufacturers.

## 2. PROBLEM:

The MHRA is aware of a number of incidents where the foam heads of oral swabs from various manufacturers have detached from the sticks during use. In some cases, there have been difficulties in retrieving the foam head from the patient's mouth. This has presented a serious choking hazard.

Larger packs have been broken up for wider distribution without including the manufacturer's instructions for use. Therefore users might not be aware of the need to check the integrity of the foam head before use.

## 3. ACTION BY:

All those involved in the use and supply of these devices.

## 4. ACTION:

- Check that the foam head is firmly attached to the stick before use in line with infection control procedures.
- Do not soak the oral swab in liquid before use as this may affect the strength of the head attachment.
- Ensure all users including patients and carers :
  - are aware of this advice, and
  - follow manufacturer's instructions for use where available.

## 5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Adult intensive care units
- All departments
- All staff
- All wards
- Dental departments
- Dental nurses
- Dentists
- ENT departments
- ENT medical staff
- ENT services, directors of
- Health and safety managers
- Hospital at home units
- Intensive care units
- Intensive care, directors of
- Paediatric wards
- Purchasing managers
- Risk managers
- Supplies managers
- Community dental practices
- Community hospitals
- Community nurses
- Dental practitioners
- District nurses
- Health visitors
- Practice managers
- Practice nurses
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Care at home staff
- Care management team managers
- Children's disability services
- 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
- Domiciliary care providers
- Nursing agencies

## 6. CONTACTS:

Enquiries to NIAIC should quote reference number MDEA(NI)2008/018 and be addressed to:  
Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868  
Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

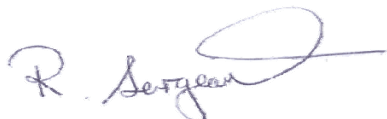
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

**Acknowledge Receipt of Alert:**  
21<sup>st</sup> March 2008

**Action Under Way:**  
1<sup>st</sup> April 2008

**Action Complete:**  
16<sup>th</sup> June 2008



Robert Sergeant  
NIAIC Operational Manager

#### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2007/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*