

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/31

Issued: 2 July 2004

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> Universal Hospital Supplies Ltd., Guedel Airways sizes 2 and 3.	▶ ①
<b>Problem:</b> There is the possibility that the green (size 2) or orange (size 3) coloured bite blocks can become dislodged from inside the main body of the airway. The manufacturer is recalling affected batches.	▶ ②
<b>Action by:</b> All medical, nursing, paramedical and technical staff responsible for the use and purchase of these devices.	▶ ③
<b>Action:</b> Remove all affected batches from use and return to the manufacturer in accordance with the attached recall notice.	▶ 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 General Medical Practitioners Hospices	▶ ⑤
<b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None Required	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

Universal Hospital Supplies Ltd., Guedel Airways sizes 2 and 3.

## 2. PROBLEM:

The manufacturers have requested assistance with this recall action due to the widespread distribution of their devices.

## 3. ACTION BY:

All medical, nursing, paramedical and technical staff responsible for the use and purchase of these devices.

## 4. ACTION:

Remove all affected batches from use and return to the manufacturer in accordance with the attached recall notice.

## 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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Clinical Directors
- Nursing Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Anaesthetic Nurses
- Anaesthetists
- High Dependency Units
- All wards and Departments
- Directors of Anaesthetics
- Obstetric Units
- Respiratory Care Nurse Specialists
- Resuscitation Officers
- Practice Nurses
- Directors of Public Health
- Independent Health and Social Care Providers – Private Clinics through HSS Board R&I Units
- Accident & Emergency Departments

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Nigel Small, Universal Hospital Supplies Ltd, Unit 6 George House, Delta Park Industrial Estate Milmarsh Lane, Enfield, EN3 7QJ, Tel: 020 8443 7836, E-mail: nsmall@uhs.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2004/31 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

## 7. FEEDBACK:

None Required



Brian Godfrey, NIAIC 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)2004/01. 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*

# URGENT

## Medical Device Recall Notice

### Universal Guedel Airways

<b>Product Ref</b>	<b>UN38/2 Size 2</b>	<b>UN38/3 Size 3</b>
<b>Lot Number</b>	<b>2003 L15 : 2003 L16</b>	<b>2003 L17: 2003 L18</b>

We have recently been made aware that a number of Guedel Airways manufactured with the above mentioned lot numbers have a manufacturing defect.

In some cases there is a possibility of the bite block becoming dislodged from the main body of the airway if the patient exerts pressure on the proximal end on the bite block. It may also occur if the airway is not correctly inserted in the patient's mouth.

Despite the fact that a minimal number of incidents have been reported to us, we feel that the appropriate and ethical action is to recall the Universal Guedel Airways referenced above, with immediate effect.

- The only products affected by this notice are easily identifiable by:-
- The transparent individual pouch containing the airway has a white strip on the reverse side.
- Printed on this strip are the manufacturing details and lot number.

Both the individual pouch and the carton are marked with the following address:

**Universal Hospital Supplies Ltd  
Unit 6 George House  
Delta Park Industrial Estate  
Millmarsh Lane, Enfield, EN3 7QJ**

Would you please remove the referenced products from use and quarantine the stock. Arrangements will be made for the collection and exchange of the recalled stock via your usual distribution channels.

No other sizes of Universal Guedel Airways are affected by this notice.

Please ensure that all possible users of the product are made aware of this recall notice.

The MHRA have been notified of this action.

Should you have any further questions relating to this matter, please call Nigel Small on 020 8443 7836 or email [sales@uhs.co.uk](mailto:sales@uhs.co.uk).

We apologise for any inconvenience this may cause your organisation and thank you in advance for your cooperation in handling this matter.

Yours faithfully

Roy H Whitehair  
**General Manager**