

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/27

Issued: 4 May 2006

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	✓
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section								
<p>Medical Device/Equipment: Universal Hospital Supplies Guedel airways – Lot numbers beginning with the year of manufacture e.g. 2005 B 11. (Lot numbers with the prefix WO are not affected.) Size 1 – Ref: UN 38/1 Size 2 – Ref: UN 38/2 Size 3 – Ref: UN 38/3 Size 4 – Ref: UN 38/4</p>	▶ ①								
<p>Problem: The supplier is recalling affected lot numbers of Universal Guedel Airways sizes 1, 2, 3 and 4. This is an update to MDEA(NI)2006/24 – identifying additional sizes of the product.</p>	▶ ②								
<p>Action by: Anaesthetists, operating department practitioners, anaesthetic nurses, adult and paediatric intensive care unit (ICU) staff, accident and emergency unit (A&E) staff, ambulance staff and resuscitation officers.</p>	▶ ③								
<p>Action:</p> <ul style="list-style-type: none"> Remove this product from use and quarantine. Arrange collection and refund of recalled stock (see suppliers contact, section 6). Be aware that comparable product is available from other manufacturers. If alternatives are not immediately available, ensure there are no splits or occlusion before use and that staff are aware of the possible failures. 	▶ ④								
<p>Distributed by NIAIC to:</p> <table> <tr> <td>Chief Executive of each HSS Board</td> <td>General Medical Practices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>General Dental Practitioners</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> <p>For onward distribution see Section 5</p>	Chief Executive of each HSS Board	General Medical Practices	Chief Executive of each HSS Trust	General Dental Practitioners	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practices								
Chief Executive of each HSS Trust	General Dental Practitioners								
Chief Executive of each Agency	Hospices								
NIAIC Liaison Officers									
<p>Contacts Details of supplier contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥								
<p>Feedback Requirements to NIAIC None</p>	▶ ⑦								

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

1. DEVICE/EQUIPMENT:

Universal Hospital Supplies Guedel airways – Lot numbers beginning with the year of manufacture e.g. 2005 B 11. (Lot numbers with the prefix WO are not affected.)

Size 1 – Ref: UN 38/1	Size 2 – Ref: UN 38/2
Size 3 – Ref: UN 38/3	Size 4 – Ref: UN 38/4

This is an update to MDEA(NI)2006/24 – identifying additional sizes of the product.

Guedel airways are oropharyngeal airway devices used in anaesthesia and resuscitation to maintain a patient's airway. They are sometimes part of resuscitation kits.

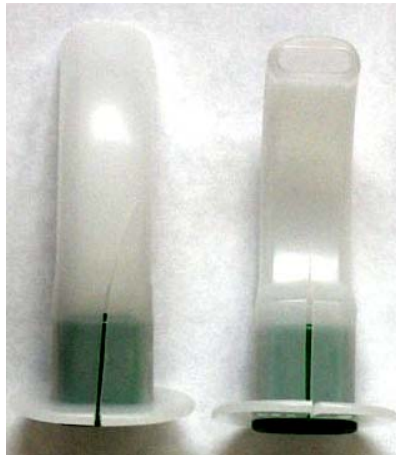


Figure 1

2. PROBLEM:

Due to manufacturing problems the Universal Guedel airways they may split around the bite block allowing the coloured insert to become dislodged from the main body of the airway (figure 1, page 2). The supplier is recalling affected lot numbers of Universal Guedel Airways sizes 1, 2, 3 and 4. See appendix for supplier's recall notice.

3. ACTION BY:

Anaesthetists, operating department practitioners, anaesthetic nurses, adult and paediatric intensive care unit (ICU) staff, accident and emergency unit (A&E) staff, ambulance staff and resuscitation officers.

4. ACTION:

- Remove this product from use and quarantine.
- Arrange collection and refund of recalled stock via usual distribution channels (see appendix).
- Be aware that comparable product is available from other manufacturers. If alternatives are not immediately available, ensure there are no splits or occlusion before use and that staff are aware of the possible failures.

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 Hospitals and Clinics through RQIA
- Accident & Emergency Departments

6. CONTACTS:

Enquiries to the supplier should be addressed to:

Marcus Nabi
Sales Executive, Macartney Surgical
Tel: 07734 012328

or

Sharon Gilbert
General Manager, Macartney Surgical
Tel: 0870 873 4914

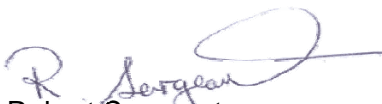
Enquires to NIAIC should quote reference number MDEA(NI)2006/27 and be addressed to:

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



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)2006/01. 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

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

Revised 28 April 2005

Urgent
Medical Device Recall Notice

Universal Guedel Airways
Sizes 1,2,3,4

Product Ref: UN38/1 – UN38/2 – UN38/3 – UN38/4

Restricted Lot Numbers

We have recently been made aware that a number of Guedel Airways have a manufacturing defect.

Despite the fact that there have been no reported patient incidents, we feel that the appropriate and ethical action is to recall the Universal Guedel Airways referenced above, with immediate effect.

These are produced in two factories, only one is affected by this recall. The affected products are easily identifiable by:-

- The Lot number of the affected products start with the year of manufacture e.g. 2005 B 15
- The Lot number of products that are not affected by the recall are in the following format - WO****. These do not need to be returned
- The transparent individual pouch containing the airway has a 30mm white strip on the reverse side.
- Printed on this strip are the manufacturing details and lot number.
- The lot number starts with the year of manufacture
- 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 refund of the recalled stock via your usual distribution channels. Comparable products are available from other manufacturers.

Please note it is only sizes 1 to 4 Universal Guedel Airways affected by this notice. For reference we have attached an illustration of the packaging of the products affected.

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

The MHRA have been notified of this action

Appendix to MDEA(NI)2006/27

A confirmation of receipt of this notice is attached. Please complete and return by **FRIDAY 26th May**.

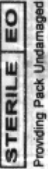
Should you have any further questions relating to this matter, please call our Customer Services on 0845 082 0182 or email customerservices@uhs.co.uk

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

Universal Hospital Supplies recall notice

 Universal	GUEDEL AIRWAY	SIZE: 1	Ref: UN 38/1	Universal Hospital Supplies Ltd Unit 6, George House, Delta park Industrial Estate, Millmarsh lane, Enfield, EN 3 7QJ. Tel: 0845 082 0182 Fax: 0845 082 0180 E mail: sales@uhs.co.uk www.uhs.co.uk	 0088	 Providing Pack Undamaged	
 Universal	GUEDEL AIRWAY	SIZE: 2	Ref: UN 38/2	Universal Hospital Supplies Ltd Unit 6, George House, Delta park Industrial Estate, Millmarsh lane, Enfield EN 3 7QJ. Tel: 0845 082 0182 Fax: 0845 082 0180 E mail: sales@uhs.co.uk www.uhs.co.uk	 0088	 Providing Pack Undamaged	
 Universal	GUEDEL AIRWAY	SIZE: 3	Ref: UN 38/3	Universal Hospital Supplies Ltd Unit 6, George House, Delta park Industrial Estate, Millmarsh lane, Enfield, EN 3 7QJ. Tel: 0845 082 0182 Fax: 0845 082 0180 E mail: sales@uhs.co.uk www.uhs.co.uk	 0088	 Providing Pack Undamaged	
 Universal	GUEDEL AIRWAY	SIZE: 4	Ref: UN 38/4	Universal Hospital Supplies Ltd Unit 6, George House, Delta park Industrial Estate, Millmarsh lane, Enfield, EN 3 7QJ. Tel: 0845 082 0182 Fax: 0845 082 0180 E mail: sales@uhs.co.uk www.uhs.co.uk	 0088	 Providing Pack Undamaged	

GFPL
LOT NO. EXP. DT. LOT N
MFG. DT.

Universal Hospital Supplies recall notice

RECALL NOTICE
CONFIRMATION OF RECEIPT

I/We confirm receipt of the recall notice relating to Universal Guedel Airways:

Product Ref: UN38/1 UN38/2 UN38/3 UN38/4

I/We will ensure that all necessary personnel will be made aware of the notice.

Name of Organisation: _____

Department: _____

Name and Title:
(please print) _____

Signed: _____

Date: _____

Please return to Customer Support Services

Fax: 0845 082 0180

Alternatively, respond by email to:

Email: customerservices@uhs.co.uk

By Friday 26th May 2006