

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/23

Issued: 27 August 2003

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> Marshall Products Ltd, Laryngeal Airway Device (LAD)	▶ ①
<b>Problem:</b> Cuff failures due to a small number of pilot balloon valves leaking (manufacturer's recall notice attached).	▶ ②
<b>Action by:</b> Medical, nursing and paramedic staff using LADs for anaesthesia or resuscitation.	▶ ③
<b>Action:</b> Remove all products from use and return to the manufacturer.	▶ 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
<b>Contacts</b> NIAIC contact details	▶ 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:

The Laryngeal Airway Device by Marshall Products Ltd is a new airway device supplied to Trusts for evaluation. It is of similar appearance to other single-use and reusable models of laryngeal mask. The manufacturer's name is clearly printed on the device for identification purposes. This recall is **NOT** related to the Laryngeal Mask Airway device manufactured or supplied by Intavent Orthofix.

## 2. PROBLEM:

NIAIC has been informed that the Medicines and Healthcare products Regulatory Agency (MHRA) has received reports of cuff failures during patient use. Investigation revealed that the device failures were due to a small number of pilot balloon valves leaking. Marshall Products Ltd are undertaking a full recall of all products, as detailed in the attached Recall Notice (see Appendix).

## 3. ACTION BY:

Medical, nursing and paramedic staff using LADs for anaesthesia or resuscitation.

## 4. ACTION:

Remove all products from use and return to the manufacturer.

## 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
- Directors of Anaesthetics
- Consultant Anaesthetists
- Anaesthetic Nurses
- Clinical Governance Leads
- Adult and Paediatric Intensive Care Units
- Special Care Baby Units
- Medical Directors
- Nurse Directors
- Medical and Nursing Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- All Wards
- Paediatric Units
- Operating Theatre Staff
- CSSD Managers
- Accident & Emergency Departments
- Independent Health Care Providers – Private Clinics (through R&I Units)

## 6. CONTACTS:

Enquiries to the manufacturer/supplier should be addressed to:

Mr Colin Marshall, Marshall Products Ltd, 13 Ferry Court, Bath, BA2 4JW, Tel: 01225 484 828  
Fax: 01225 484 868

Enquires to NIAIC should quote reference number MDEA(NI)2003/23 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 Safety Notice SN (NI) 2003/01. 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*



## **MEDICAL DEVICE RECALL**

### PILOT BALLOON VALVE FAILURE – LARYNGEAL AIRWAY DEVICE

Customer Name  
Address  
Address  
Address  
Postal Code

20<sup>th</sup> August 2003

<b>PRODUCT CODE</b>	<b>DESCRIPTION</b>
777100/700100	Laryngeal Airway Device Size 1
777150/700150	Laryngeal Airway Device Size 1.5
777200/700200	Laryngeal Airway Device Size 2
777250/700250	Laryngeal Airway Device Size 2.5
777300/700300	Laryngeal Airway Device Size 3
777400/700400	Laryngeal Airway Device Size 4
777500/700500	Laryngeal Airway Device Size 5

Due to a small number of Pilot Balloon Valves leaking, Marshall Products Ltd as a quality manufacturer are recalling all of the above products.

We have manufactured a new superior valve for the pilot balloon and this product will be available from September 2003.

Please contact our customer help line on 01225 484828 to organise your replacements and product return. In all circumstances please complete and return the attached re-call record slip.

We sincerely apologise for any inconvenience caused to you but assure you of our best service at all times.

Colin Marshall

Managing Director  
Marshall Products Ltd

Marshall Products Limited • 13 Ferry Court • Bath BA2 4JW  
Telephone: 01225 484828 • Fax: 01225 484868 • Email: sales@marshallproducts.co.uk • www.marshallproducts.co.uk



**RECALL RECORDS SLIP**

**Laryngeal Airway Device**

Hospital Name: \_\_\_\_\_ Tel: \_\_\_\_\_

Your Name: \_\_\_\_\_ Title: \_\_\_\_\_

Product Code: \_\_\_\_\_

Quantity of Products Purchased: \_\_\_\_\_

Order Number: \_\_\_\_\_ Delivery Note Number: \_\_\_\_\_

Quantity Returned: \_\_\_\_\_ Quantity Used: \_\_\_\_\_

Signed: \_\_\_\_\_ Date: \_\_\_\_\_