

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/75

Issued: 26 October 2005

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section								
Medical Device/Equipment: Intersurgical adult oxygen mask with ear loops: model number 1104001 and lot number 3055625.	▶ ①								
Problem: Intersurgical has initiated a recall of their adult oxygen mask with ear loops: model number 1104001 and lot number 3055625 due to a manufacturing problem that has caused a blockage in the oxygen ports.	▶ ②								
Action by: All those who purchase and use oxygen masks.	▶ ③								
Action: <ul style="list-style-type: none"> Identify all devices of the above model and lot number. Request replacements from Intersurgical. Destroy the affected devices. 	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</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>	Chief Executive of each HSS Board	General Medical Practitioners	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 Practitioners								
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NIAIC Liaison Officers									
Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥								
Feedback Requirements to NIAIC	▶ ⑦								

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

1. DEVICE/EQUIPMENT:

Intersurgical adult oxygen mask with ear loops: model number 1104001 and lot number 3055625.

2. PROBLEM:

The MHRA has received two reports of Intersurgical oxygen masks having blocked oxygen connection ports. Intersurgical has confirmed that faulty moulding machinery used during the production of lot number 3055625 has resulted in excess plastic in the connection, causing it to be blocked.

3. ACTION BY:

All those who purchase and use oxygen masks.

4. ACTION:

- Identify all devices of the above model and lot number.
- Request replacements from Intersurgical.
- Destroy the affected devices.

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Fire Officers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Practice Nurses
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSSRIA
- Sterile Services Departments
- Operating Theatre Staff
- Accident & Emergency Departments
- Coronary Care
- Intensive Care
- Resuscitation Officers
- Day Procedure Units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Customer Care
Intersurgical
Molly Millars Lane
Wokingham
Berkshire
RG41 2RZ

Tel: 0118 9656 351

Fax: 0118 9656 356

E-mail: mct@intersurgical.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2005/75 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

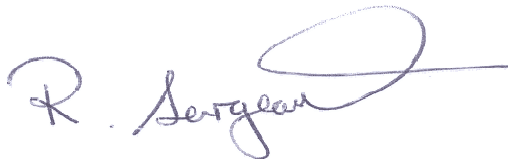
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



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)2005/01. 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