

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/29

Issued: 22 March 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: Reusable flexible laryngeal mask airway size 2.5 supplied by Intavent Orthofix Ltd. Model codes: 7125R and 7125DR. <i>See appendix for serial numbers of affected devices.</i></p>	▶ ①
<p>Problem: Risk of the tube kinking in the proximity of the connector, which could lead to the obstruction of airflow to the patient. The supplier has initiated a recall of specific serial numbers and has been unable to account for the serial numbers listed in the appendix.</p>	▶ ②
<p>Action by: Anaesthetists, operating department practitioners, anaesthetic nurses, accident and emergency unit (A&E) staff, ambulance staff, sterile services department staff, supplies staff and all staff using anaesthetic equipment and associated devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify and quarantine affected devices (see appendix for serial numbers of devices that have not been accounted for). Contact the manufacturer to arrange the return and replacement of affected stock. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of supplier contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Reusable flexible laryngeal mask airway size 2.5 supplied by Intavent Orthofix Ltd.

Model codes: 7125R and 7125DR. See appendix for serial numbers of affected devices. The manufacturer's intended use of this device is for children weighing 20-30kg.

2. PROBLEM:

Due to a manufacturing failure there is a 4mm gap between the coil that reinforces the tube and the connector, which could potentially lead to the kinking of the tube. Intavent Orthofix has initiated a recall and will be replacing all affected product.

To identify affected product, look for the serial number either on the device (Fig 1) or on the packaging (Fig 2) as shown in the sample photographs below.

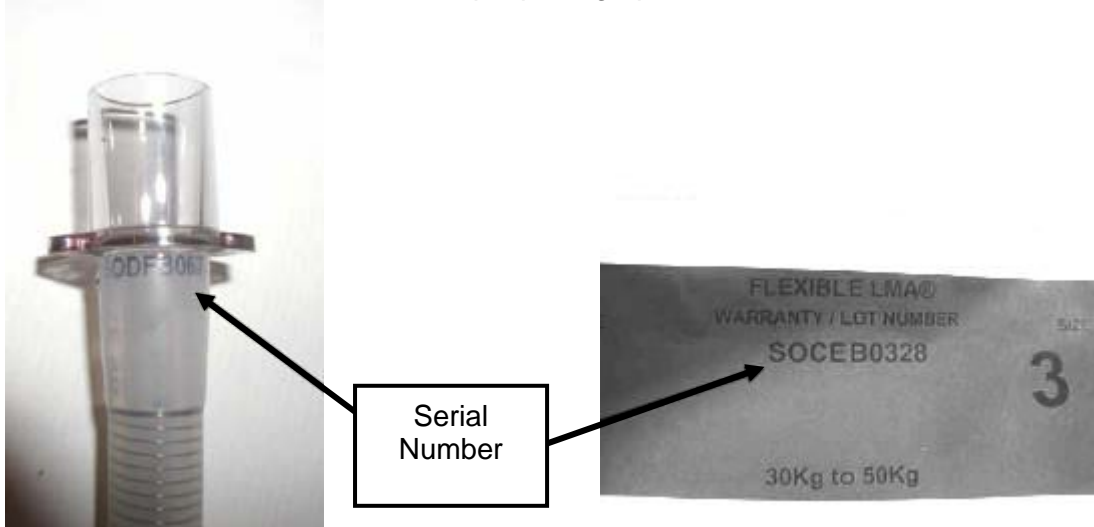


Fig 1

Fig 2

Some hospitals have had difficulties in tracing all affected devices, therefore this Medical Device Alert has been issued to ensure that users are aware of this recall and to help the manufacturer account for all affected devices.

3. ACTION BY:

Anaesthetists, operating department practitioners, anaesthetic nurses, accident and emergency unit (A&E) staff, ambulance staff, sterile services department staff, supplies staff and all staff using anaesthetic equipment and associated devices.

4. ACTION:

Identify and quarantine affected devices (see appendix for serial numbers of devices that have not been accounted for).

Contact the manufacturer to arrange the return and replacement of affected stock.

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:

- A&E departments
- All wards
- Ambulance paramedics and technicians
- Ambulance trusts operations directors
- Anaesthetic nurses
- Anaesthetists
- Day surgery units
- Directors of anaesthesia
- Health and safety managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Intensive care units
- Medical directors
- Nursing executive directors
- Operating department practitioners (ODPs)
- Paediatric intensive care units
- Resuscitation officers and trainers
- Risk managers
- Sterile services departments
- Sterile services managers
- Theatre managers
- Dental practices performing surgery under general anaesthetic

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Alice Tidy
Intavent Orthofix Limited
Burney Court
Cordwallis Park
Maidenhead
Berkshire SL6 7BZ
Tel: 01628 594 500
Fax: 01628 789 400
E-mail: atidy@intaventorthofix.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/29 and be addressed to:

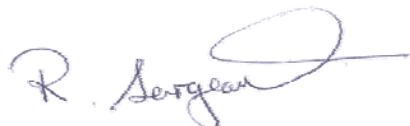
Northern Ireland Adverse Incident Centre
(NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 23 March 2006
Deadline (action underway)	: 30 March 2006
Deadline (action complete)	: 25 April 2006



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

APPENDIX TO MDEA(NI)2007/28

Serial numbers		
SOCCD0251	SOICB0206	SOICB0344
SOCCD0252	SOICB0207	SOICB0350
SOCCD0253	SOICB0215	SOICB0351
SOCCD0257	SOICB0216	SOICB0352
SOCCD0258	SOICB0217	SOICB0357
SOCCD0276	SOICB0218	SOICB0358
SOCCD0277	SOICB0219	SOICB0359
SOCCD0278	SOICB0220	SOICB0360
SODCB1767	SOICB0225	SOICB0369
SODCB1783	SOICB0226	SOICD0004
SODCB1792	SOICB0228	SOICD0019
SODCB1793	SOICB0229	SOICD0020
SODCB1794	SOICB0231	SOICD0021
SODCB1795	SOICB0232	SOICD0022
SODCB1796	SOICB0233	SOICD0023
SOECB0151	SOICB0234	SOICD0040
SOECB0152	SOICB0235	SOICD0045
SOECB0153	SOICB0236	SOICD0047
SOECB0154	SOICB0237	
SOECB0165	SOICB0238	
SOECB0166	SOICB0239	
SOECB0167	SOICB0240	
SOECB0168	SOICB0260	
SOECB0180	SOICB0264	
SOECB0181	SOICB0265	
SOECB0183	SOICB0266	
SOECB0184	SOICB0267	
SOECB0196	SOICB0284	
SOECD0455	SOICB0285	
SOECD0465	SOICB0286	
SOECD0467	SOICB0293	
SOECD0470	SOICB0294	
SOECD0471	SOICB0295	
SOECD0472	SOICB0304	
SOECD0473	SOICB0315	
SOECD0475	SOICB0316	
SOECD0476	SOICB0317	
SOECD0482	SOICB0318	
SOECD0490	SOICB0326	
SOGCD0101	SOICB0333	
SOGCD0103	SOICB0334	
SOGCD0104	SOICB0336	
SOGCD0105	SOICB0339	
SOGCD0106	SOICB0340	
SOGCD0107	SOICB0341	
SOICB0203	SOICB0342	
SOICB0205	SOICB0343	