

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/22

Issued: 14th March 2007



HEALTH ESTATES

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For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: Laryngoscope: Callisto Macintosh size 3 (adult) single-use laryngoscope blade, manufactured by Timesco of London Ltd. Part number: DS.3940.150.20/21. Affected lots: GE, GF, GG, GH, GI, GJ, GK, GL, HA.</p>	▶ ①
<p>Problem: The fiberoptic core may break and separate from the blade. The manufacturer has initiated a recall of all affected product.</p>	▶ ②
<p>Action by: All wards, anaesthetists, operating department practitioners, anaesthetic nurses, adult intensive care unit (ICU) staff, accident and emergency unit (A&E) staff, ambulance staff, and all staff using anaesthetic equipment and associated devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify and quarantine stock from affected lots. Only use devices from affected lots if an alternative is not available in an emergency and ensure pre-use checks are carried out. 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</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required.</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Laryngoscope: Callisto Macintosh size 3 (adult) single-use laryngoscope blade, manufactured by Timesco of London Ltd.

Part number: DS.3940.150.20/21.

Affected lots: GE, GF, GG, GH, GI, GJ, GK, GL, HA.

2. PROBLEM:

Timesco has initiated a recall due to a manufacturing fault of the fibreoptic core and will be replacing all affected product. This Medical Device Alert has been issued to ensure that users are aware of this recall and to support the manufacturer's ongoing recall action. An example of a failed device is shown below.



3. ACTION BY:

All wards, anaesthetists, operating department practitioners, anaesthetic nurses, adult intensive care unit (ICU) staff, accident and emergency unit (A&E) staff, ambulance staff, and all staff using anaesthetic equipment and associated devices.

4. ACTION:

- Identify and quarantine stock from affected lots.
- Only use devices from affected lots if an alternative is not available in an emergency and ensure pre-use checks are carried out.
- 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
- Adult intensive care units
- All wards
- Ambulance paramedics and technicians
- Ambulance trusts operations directors
- Anaesthetic nurses
- Anaesthetists
- Clinical departments
- Day surgery units
- Directors of anaesthesia
- Health and safety managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA
- Medical directors
- Nursing executive directors
- Operating department practitioners (ODPs)
- Resuscitation officers and trainers
- Risk managers
- Theatre managers

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Andy Boylett
Timesco of London Ltd
Timesco House
1 Knights Road
London E16 2AT
Tel: 020 7511 9960
Fax: 020 7511 7888

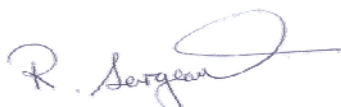
E-mail: andy.boylett@timesco.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/22 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)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