

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/10

Issued: 9 February 2006

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: Intersurgical Clear-Therm heat and moisture exchanging filter (HMEF) with Luer lock port and retainable cap: (check Model & Batch No.)</p>	▶ ①
<p>Problem: The Luer port (used for connection to CO₂ monitoring) may be occluded by plastic.</p>	▶ ②
<p>Action by: Anaesthetists, operating department practitioners, anaesthetic nurses, adult intensive care unit (ICU) and accident and emergency unit (A&E) staff, ambulance staff, respiratory function staff and those responsible for the provision of domiciliary ventilation.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Before using a filter from this batch ensure that the Luer port is checked for blockages. 	▶ 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 manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Intersurgical Clear-Therm HMEF with Luer lock port and retainable cap, for use in adult breathing systems.

Model number 1841 – batch number 2051272

Model number 1841351 – batch number 2051082

Model number 1841012 – batch number 2051012.

Products distributed outside the UK are being notified to the appropriate regulatory authorities.

2. PROBLEM:

The Luer port on some devices may be occluded by plastic due to a moulding defect. The manufacturer has now corrected this manufacturing problem. Product from the affected batch was distributed between June and October 2005.

The Luer port is used for connection to CO₂ monitoring. If a filter with a blocked Luer port connection is used for connection to CO₂ monitoring, it would result in an error message such as 'no sample' or 'occlusion detected'. Additionally, no CO₂ reading would be available. The occlusion would not impede the patient's ability to breathe through the filter, but the continued obstruction would cause the monitor to alarm.

End-tidal CO₂ monitoring is used to confirm the correct position of the endo-tracheal tube. In certain emergency situations, the unknown use of a blocked Luer port could lead to confusion and have life-threatening consequences.

3. ACTION BY:

Anaesthetists, operating department practitioners, anaesthetic nurses, adult intensive care unit (ICU) and accident and emergency unit (A&E) staff, ambulance staff, respiratory function staff and those responsible for the provision of domiciliary ventilation.

4. ACTION:

- Before using a filter from this batch ensure that the Luer port is checked for blockages, either by:
 - attaching a fresh gas supply to one side of the filter, occluding the other side of the filter, removing the Luer cap and feeling for a flow of gas coming out of the Luer portor
- attaching the Luer port to the CO₂ monitor prior to use and ensuring the monitor does not alarm for occlusion.
- Return any filters with blockages to Intersurgical to obtain a replacement.
- If CO₂ monitoring is required and no unblocked filters are immediately available then alternative Luer access for CO₂ monitoring must be used.

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
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Independent Health and Social Care Providers – Private Clinics through RQAI
- Operating Theatre Staff
- Accident & Emergency Departments
- Intensive Care
- Resuscitation Officers
- Anaesthetic nurses
- Anaesthetists
- Day surgery units
- Directors of anaesthetics

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Maxine Taylor
Intersurgical Ltd
Crane House
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)2006/10 and be addressed to:

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

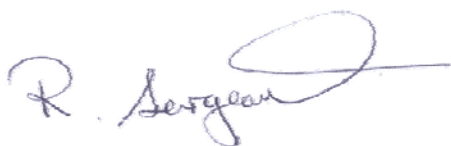
Tel: 028 9052 3868

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