

# Medical Device/Equipment ALERT

Ref.MDEA(NI)2008/033

Issued: 14 May 2008

For:

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



**HEALTH ESTATES**

creating healing environments

	Section
<p><b>Medical Device/Equipment:</b> Robertshaw endobronchial tubes (PVC, disposable) all sizes – manufactured by Phoenix Medical, a P3 Medical Ltd company.</p>	▶ ①
<p><b>Problem:</b> There is a risk of plastic debris from the intubation stylet entering the patient's airway due to a manufacturing defect.</p>	▶ ②
<p><b>Action by:</b> Anaesthetists, operating department practitioners and anaesthetic nurses.</p>	▶ ③
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>Identify affected devices (see product code list on page 2) and remove from use.</li> <li>Return affected devices to the manufacturer for replacement.</li> </ul>	▶ ④
<p><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></p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p>	
<p><b>Acknowledge Receipt of Alert:</b> 16<sup>th</sup> May 2008</p>	▶ ⑦
<p><b>Action Under Way:</b> 21<sup>st</sup> May 2008</p>	
<p><b>Action Complete:</b> 28<sup>th</sup> May 2008</p>	

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

## 1. DEVICE/EQUIPMENT:

Robertshaw endobronchial tube with introducing stylet is a double lumen tube used during thoracic surgery where it is necessary to isolate one lung.

## 2. PROBLEM:

Due to a manufacturing defect there is a risk of damage to the intubation stylet on its removal from the endobronchial tube. The resulting plastic debris may enter the patient's airway. The manufacturer has recalled all stock supplied directly to trusts. However, affected devices have been distributed via third party suppliers and are not yet accounted for.

## 3. ACTION BY:

Anaesthetists, operating department practitioners and anaesthetic nurses.

## 4. ACTION:

The following disposable, PVC, Robertshaw endobronchial tubes are being recalled. Note that lot numbers are a date code in the format dd-mm-yyyy or yyyy-mm-dd

Product code	Description	Lot number
PRS-26L	Endobronchial tube, 26ch Left	All dates before 2008
PRS-26R	Endobronchial tube, 26ch Right	All dates before 2008
PRS-28L	Endobronchial tube, 28ch Left	All dates before 2008
PRS-28R	Endobronchial tube, 28ch Right	All dates before 2008
PRS-32L	Endobronchial tube, 32ch Left	All dates before 2008
PRS-32R	Endobronchial tube, 32ch Right	All dates before 2008
PRS-35L	Endobronchial tube, 35ch Left	All dates before 2008
PRS-35R	Endobronchial tube, 35ch Right	All dates before 2008
PRS-37L	Endobronchial tube, 37ch Left	All dates before 2008
PRS-37R	Endobronchial tube, 37ch Right	All dates before 2008
PRS-39L	Endobronchial tube, 39ch Left	All dates before 2008
PRS-39R	Endobronchial tube, 39ch Right	All dates before 2008
PRS-41L	Endobronchial tube, 41ch Left	All dates before 2008
PRS-41R	Endobronchial tube, 41ch Right	All dates before 2008

This recall is not related to the previous recall of Phoenix Medical rubber disposable Robertshaw endobronchial tubes, NIAIC Medical Device/Equipment Alert ref: MDEA/2007/108.

## 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:

- Anaesthesia, directors of
- Anaesthetic nurses
- Anaesthetists
- Cardiothoracic surgeons
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Operating department practitioners
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Thoracic surgeons
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr M J Caudwell  
P3 Medical Limited  
1 Newbridge Close  
Bristol  
BS4 4AX

Tel: 0117 972 8888

Fax: 0117 972 4863

E-mail: [info@p3-medical.com](mailto:info@p3-medical.com)

Enquiries to NIAIC should quote reference number MDEA(NI)2008/033 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](mailto:NIAIC@dhsspsni.gov.uk)

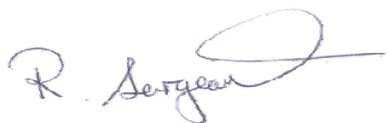
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:  
16<sup>th</sup> May 2008

Action Under Way:  
21<sup>st</sup> May 2008

Action Complete:  
28<sup>th</sup> May 2008



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)2007/01. 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*