

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/06

Issued: 23 January 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Chest drain: Portex chest drainage system with adjustable straw. Product code 200/870/000, lot number 489962. Manufactured by Smiths Medical.</p>	▶ ①
<p>Problem: Failure to create a seal when the system is connected to the chest drainage bottle leaving the patient at risk of a pneumothorax. The manufacturer is recalling one lot of this device.</p>	▶ ②
<p>Action by: All theatre staff, ward staff and those involved in the supply and/or distribution of this device.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Ensure that all relevant staff are aware of this recall. • Identify and remove all affected stock (lot number 489962) from use. • Contact the manufacturer to arrange collection and replacement of stock from this lot number. 	▶ 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:

Chest drain: Portex chest drainage system with adjustable straw. Product code 200/870/000, lot number 489962. Manufactured by Smiths Medical.

2. PROBLEM:

The manufacturer has identified that lot 489962 of product code 200/870/000 may contain a tubing set which has been incorrectly assembled and which would leave the patient at risk of pneumothorax if used.

Smiths Medical International Ltd is recalling chest drainage systems with lot number 489962 and issued a recall letter to users on 11 September 2006. Because the NIAIC cannot be confident that customers who received affected product can be traced and contacted, and because of the serious nature of the risk to patient safety, the NIAIC has issued this Medical Device Alert to ensure that users are aware of the recall and to support the manufacturer's ongoing recall action.

Similar Portex chest drainage systems with other codes and/or lot numbers are not affected by this recall.

3. ACTION BY:

All theatre staff, ward staff and those involved in the supply and/or distribution of this device.

4. ACTION:

- Ensure that all relevant staff are aware of this recall.
- Identify and remove all affected stock (lot number 489962) from use.
- Contact the manufacturer to arrange collection and replacement of stock from this lot number.

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
- A&E directors
- Adult intensive care units
- All wards
- Anaesthesia, directors of
- Cardiothoracic departments
- Cardiothoracic surgery directors
- Clinical governance leads
- General surgical units, directors of
- Health and safety managers
- Independent Health and Social Care Providers – Private Clinics & Hospitals through RQIA
- Intensive care units
- Intensive care, directors of
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers
- Theatres

6. CONTACTS:

Enquires to manufacturer should be addressed to:

David Poore
Smiths Medical International Ltd
Military Road
Hythe
CT21 5BN

Tel: 01303 260 551

Fax: 01303 236 835

E-mail: david.poore@smiths-medical.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/06 and be addressed to:

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

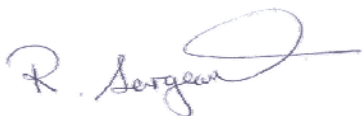
Tel: 028 9052 3868

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