

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/045

Issued: 17th June 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section								
Medical Device/Equipment: Chest drain: Thoraseal II chest drainage unit manufactured by Covidien, formerly Tyco Healthcare.	▶ ①								
Problem: Inadvertent disconnection of the drainage tubing from the bottle.	▶ ②								
Action by: All involved in the use of these devices.	▶ ③								
Action: <ul style="list-style-type: none"> Be aware that there is an increased risk of unintended disconnection of the tube from the unit. Three batches are affected, as stated in the 'Device' section page 2. Ensure that all personnel are aware of the recent addition to the instructions for use that warns against using the tube to carry or lift the unit. 	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Hospices</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Hospices	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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NIAIC Liaison Officers									
Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.	▶ ⑥								
Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)									
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; color: magenta;"> Acknowledge Receipt of Alert: 19th June 2008 </td> <td style="width: 33%; color: magenta;"> Action Under Way: 15th July 2008 </td> <td style="width: 33%; color: magenta;"> Action Complete: 17th Sept 2008 </td> </tr> </table>	Acknowledge Receipt of Alert: 19 th June 2008	Action Under Way: 15 th July 2008	Action Complete: 17 th Sept 2008	▶ ⑦					
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

Chest drain: Thoraseal II chest drainage unit manufactured by Covidien, formerly Tyco Healthcare.
Catalogue number: 1180571570
Batch Numbers: 07I742E, 07I751E, 07J513E

2. PROBLEM:



Point of potential disconnection of the tubing from the bottle.

Covidien (formerly Tyco Healthcare) has identified that in some chest drainage units the joint between the drainage tube and the bottle has been weakened. This joint may become compromised when subjected to external forces. If this joint disconnects, the underwater seal of the chest drainage system is lost and the patient is at risk of pneumothorax and infection.

The manufacturer has also recently included an additional warning in the instructions for use which warns against using the tube to carry or lift the unit as this may disconnect the tube from the unit. There is a blue hanging strap on the unit, which is intended for lifting the chest drainage device

3. ACTION BY:

All involved in the use of these devices.

4. ACTION:

- Be aware that there is an increased risk of unintended disconnection of the tube from the unit. Three batches are affected, as stated in the 'Device' section above.
- Ensure that all personnel are aware of the recent addition to the instructions for use that warns against using the tube to carry or lift the unit.

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 departments
- All intensive care units
- All staff
- All theatres
- All wards
- Medical directors
- Nurse executive directors
- Supply managers
- Independent Health and Social Care Providers – Private Hospital and Clinics, and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Elaine Hambling
PMS Manager EMEA
Covidien (UK)
154 Fareham Road
Gosport
Hampshire
PO13 0AS

Tel: 01329 224 267

Fax: 01329 224 418

E-mail: elaine.hambling@covidien.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/045 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

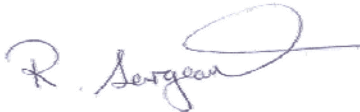
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
19th June 2008

Action Under Way:
15th July 2008

Action Complete:
17th Sept 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

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety