

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/044

Issued: 17th June 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: Electrosurgical single-use, sterile blades and needles. 'Universal' and 'Ultraclean' electrodes manufactured by ConMed.</p>	▶ ①
<p>Problem: A limited number of electrosurgical blades and needles may have an inadequate packaging seal, potentially compromising the sterility of the device (see appendix for list of relevant catalogue and lot numbers).</p>	▶ ②
<p>Action by: Surgeons, theatre managers, operating theatre and supplies staff</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify and quarantine those devices affected by this alert. Contact ConMed for replacements for affected devices. 	▶ 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 and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>	
<p>Acknowledge Receipt of Alert: 19th June 2008</p>	▶ ⑦
<p>Action Under Way: 1st July 2008</p>	
<p>Action Complete: 17th July 2008</p>	

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

1. DEVICE/EQUIPMENT:

Electrosurgical single-use, sterile blades and needles.
'Universal' and 'Ultraclean' electrodes manufactured by ConMed.

2. PROBLEM:

A limited number of electrosurgical blades and needles may have an inadequate packaging seal, potentially compromising the sterility of the device (see appendix for list of relevant catalogue and lot numbers).

3. ACTION BY:

Surgeons, theatre managers, operating theatre and supplies staff

4. ACTION:

- Identify and quarantine those devices affected by this alert.
- Contact ConMed for replacements for affected devices.

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:

- Clinical governance leads
- Day surgery units
- Equipment stores
- Health and safety managers
- Infection control teams
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Supplies managers
- Surgeons
- Theatre managers
- Theatre nurses
- Theatres
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Teresa Harris
ConMed Linatec
73/74 Shrivenham Hundred Business Park
Swindon
Wiltshire SN6 8TY

Tel: 01793 787 912

Fax: 01793 784 568

E-mail: tharris@linatec.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/044 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

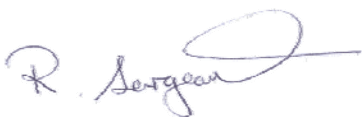
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
19th June 2008

Action Under Way:
1st July 2008

Action Complete:
17th July 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

APPENDIX to MDEA(NI)2008/044

URGENT – Voluntary Device Recall ConMed Electrosurgery

Catalog numbers and Lot Numbers Affected

Catalog Number	Lot number					
138107	0710191	0710231	0710232	0710241	0710242	0710251
138110	0711011	0711012	0711031			
138112	0711031	0711032	0711033	0711041	0711042	
138113	0711091					
139104ext	0711121					
139107	0710291	0710301	0710302	0710311		
139108	0711091					
139110 ext	0711051	0711052	0711053			
139112	711081	0711082				
139112ext	0711071	0711072	0711073	0711081		