

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/004

Issued: 31st January 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION	

	Section
<p>Medical Device/Equipment: Umbilical cord clamp clipper manufactured by Unomedical Ltd. Product reference: 84006182 - Affected lot number: 163136</p>	▶ ①
<p>Problem: There is the potential for the blade to fall out of this device or break during use. This is an expansion of a recall previously carried out in November 2006, and referred to in MDEA(NI)2007 – 036.</p>	▶ ②
<p>Action by: Maternity units, neonatal intensive care units, midwives in the community, obstetricians.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Check stock and quarantine devices with affected lot number. • Return affected products to the manufacturer for replacement (contact details on page 2). 	▶ 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: 5th Feb 2008</p>	▶ ⑦
<p>Action Under Way: 15th Feb 2008</p>	
<p>Action Complete: 4th Mar 2008</p>	

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

1. DEVICE/EQUIPMENT:

The Unomedical umbilical cord clamp clipper (manufacturer product reference 84006182) this is a sterile, single-use device. Unomedical products are mainly distributed in Ireland by Armstrong Medical Ltd, Armstrong have not supplied any of this product into Northern Ireland, but it may have come in from other sources.

2. PROBLEM:

Unomedical initiated a recall of specific lots of these devices in November 2006 following complaints of the blade falling off or breaking during use. This was referred to in MDEA(NI)2007 – 036 and affected the following lot numbers: 102042, 118951, 121457, 115363, 134481, 136591, 142538, 152668, 146675, 151168 and 155746. As a result of the investigation of further failures, this recall has now been expanded to include lot number 163136. Should any Trust identify product from the affected batches, Armstrong Medical would be happy to liaise between customers and Unomedical in relation to any returns and replacements.

The moulding tool was modified in 2006 to resolve this problem and the quality assurance was improved to ensure the correct positioning of the blade in the tool prior to moulding. This expanded recall means that all lots made prior to the tool modification have now been recalled.

The manufacturer issued recall letters to distributors on 14 September 2007 (see appendix). However, the MHRA is concerned that affected devices may still be with users due to their wide distribution and therefore the manufacturer's field safety notice may not have reached all the end users.

3. ACTION BY:

Maternity units, neonatal intensive care units, midwives in the community, obstetricians.

4. ACTION:

- Check stock and quarantine devices with affected lot number.
- Return affected products to the manufacturer for replacement (contact details on page 2).

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Independent Health and Social Care Providers – Private Hospitals & Clinics, through RQIA
- Midwifery staff
- Neonatal nurse specialists
- Nursing executive directors
- Obstetricians
- Community midwives
- Private midwives

6. CONTACTS:

Enquiries to manufacturer should be addressed to either:

Andi Regan
Armstrong Medical Ltd.
Wattstown Business Park
Newbridge Road
Coleraine
BT52 1BS

Tel: 028 7035 6029
Fax: 028 7035 6875
E-mail: a.regan@armstrongmedical.net

Jackie Taylor
Customer Research Manager
Unomedical Ltd
Thornhill Road
Redditch
Worcestershire
B98 9NL

Tel: 01527 587 700
Fax: 01527 615 586
E-mail: jackie.taylor@unomedical.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/004 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

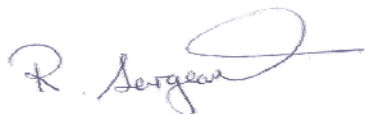
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
5th Feb 2008

Action Under Way:
15th Feb 2008

Action Complete:
4th Mar 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)2008/004

14/9/07

Our ref: R01-2006

URGENT– Recall of Unomedical umbilical cord clamp clipper Ref: 84006182

Dear Sir/Madam,

It is with regret that we have to inform you that we are requesting return of the umbilical cord clamp clipper products detailed on the attached form with immediate effect.

This is because we have received complaints of a problem with the blade in the clipper which although this has not resulted in an incident, we have decided to remove any risk by removing the suspect product from the market. The moulding tool that has been used to manufacture the product has since been modified to resolve the problem. However, we would like return of all product that was manufactured prior to this tool modification.

Therefore, we request that you stop using any of the products listed on the attached form immediately and return any that you still have in your possession, together with a copy of the completed form(s), to the address below:

Mrs J Taylor
Quality Assurance Dept
Unomedical Ltd,
FREEPOST (MID00326)
Redditch
B98 9BR

Or alternatively, if you would like someone to collect the products then please return a copy of the completed form(s) indicating this and we will arrange collection.

If you have any questions concerning the above, then please contact the undersigned on tel: 01527-587700, fax: 01527-592111 or e-mail: jmt@unomedical.com.

Yours sincerely,

Mike Kettle
Quality Assurance Manager

**RECALL R01-2006
QUESTIONNAIRE FOR END-USERS**

Consignee of the device:

The following devices have been forwarded to you:

Product ref	Lot no	Customer order	Quantity	Delivery date
84006182	163136			

The recipient confirms (please, tick off as applicable):

_____ that none of the devices mentioned above are in my possession any longer.

_____ that some of the devices mentioned above remain in my possession.

They will be returned as per the instructions given by Unomedical Ltd, Redditch/
We request collection by Unomedical Ltd.
(Please delete one of the above statements as applicable.)

Number to be returned: _____ pieces

NAME (CAPITAL LETTERS) AND POSITION

SIGNATURE

DATE

ADDRESS

This form has been submitted by a representative of the distributor:

NAME

SIGNATURE

DATE