

MEDICAL DEVICE ALERT

Issued: **30 January 2008** at 15:00

Ref: **MDA/2008/004**

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input checked="" type="checkbox"/>	Update
<input type="checkbox"/>	Information request

<p>Device: Umbilical cord clamp clipper manufactured by Unomedical Ltd. Product reference: 84006182 NHS Supply Chain catalogue code: FFK004 Affected lot number: 163136</p>	► Page 2						
<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 MDA/2007/033.</p>	► Page 2						
<p>Action by: Maternity units, neonatal intensive care units, midwives in the community, obstetricians.</p>							
<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). 							
<p>Distributed to:</p> <table> <tr> <td>NHS trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>Healthcare Commission (CHAI)</td> <td>– Headquarters</td> </tr> <tr> <td>Primary care trusts in England</td> <td>– Chief Executives*</td> </tr> </table> <p style="text-align: right;">* via CE Bulletin</p>	NHS trusts in England	– Chief Executives*	Healthcare Commission (CHAI)	– Headquarters	Primary care trusts in England	– Chief Executives*	► Page 2
NHS trusts in England	– Chief Executives*						
Healthcare Commission (CHAI)	– Headquarters						
Primary care trusts in England	– Chief Executives*						
<p>Contacts: Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.</p>	► Pages 2-3						
<p>Appendix: Manufacturer's recall notice.</p>	► Pages 4-5						

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 12 February 2008

Deadline (action complete): 03 March 2008

This notice is also on our website: <http://www.mhra.gov.uk>

Device:

The Unomedical umbilical cord clamp clipper (manufacturer product reference 84006182) is distributed in the UK mainly by NHS Supply Chain (catalogue code: FFK004) and Southern Syringe Ltd. It is a sterile, single-use device.

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 MDA/2007/033 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.

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.

Distribution:

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Maternity units
- Medical directors
- Midwifery staff
- Neonatal nurse specialists
- Nursing executive directors
- Obstetricians
- Paediatric intensive care units
- Purchasing managers
- Risk managers
- Supplies managers

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospitals in the independent sector
- Private medical practitioners
- Private midwives

Primary care trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Community midwives
- Health visitors

Contacts:

Enquiries to the manufacturer should be addressed to:

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

Contacts (continued):

Enquiries to the MHRA should quote reference number **2007/010/003/291/012** and be addressed to:

Technical aspects:

Enitan Taiwo or Geoff Ali
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3122 / 3102

Fax: 020 7084 3209

E-mail: enitan.taiwo@mhra.gsi.gov.uk
geoff.ali@mhra.gsi.gov.uk

Clinical aspects:

Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3123

Fax: 020 7084 3111

E-mail: susanne.ludgate@mhra.gsi.gov.uk

Change of address or removal from address list for Healthcare Commission:

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

Further information about **SABS** can be found at www.info.doh.gov.uk/sar2/cmopatie.nsf

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