Medical Device Alert

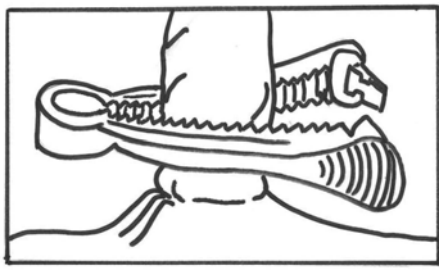
Action

Ref: MDA/2010/094 Issued: 14 December 2010 at 10:00

Device

Umbilical cord clamp.

All makes and models.



Problem

Incorrect placement of the clamp on the umbilical cord has lead to an inadequate seal and blood loss in a small number of cases.

Such blood loss could prove fatal for some babies.

Action by

Midwifery and obstetric staff.

CAS deadlines

Action underway: 18 January 2011
Action complete: 01 February 2011

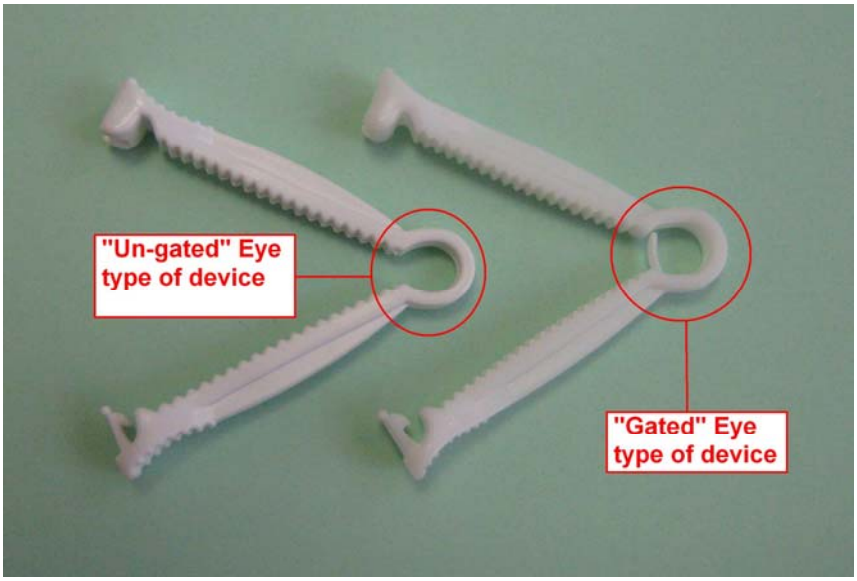
Action

Ensure that all users:

- are aware of design differences that have an impact on:
  - > **positioning** – position the clamp correctly around the umbilical cord. It is important to centre the cord within the clamp body.
  - > **closing the clamp** – the clamp is closed by squeezing the clamp at the grips until a click is heard.
- are aware of the risks of inadequate sealing of the umbilical cord
- check cord site regularly for signs of bleeding with all types of cord clamps.

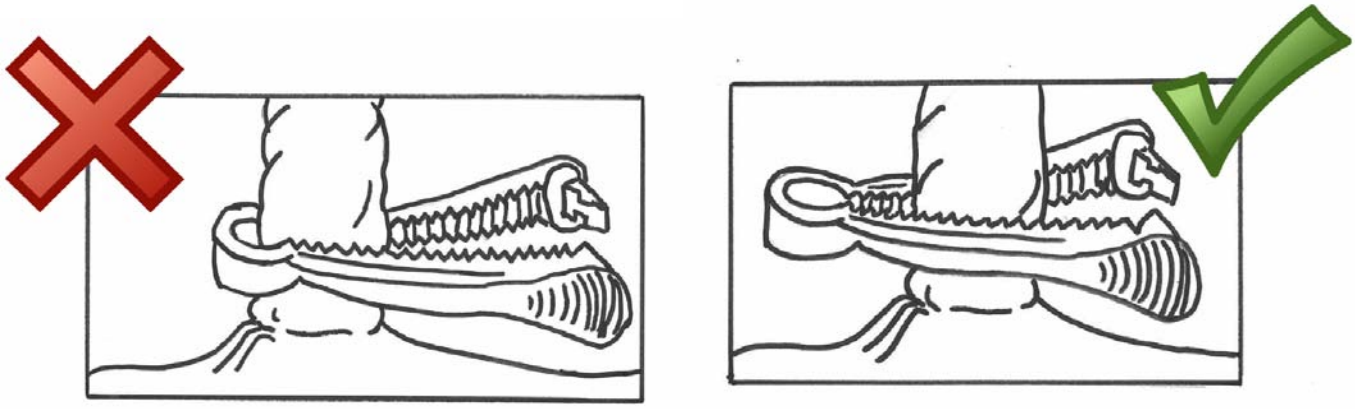
Problem

Umbilical cord clamps are available in a variety of designs. The photograph below shows examples of two of the simpler single-use designs on the market. One design has an additional extension that acts as a 'gate' protecting the hinge (eye) of the device and prevents the cord from entering this area. Some users, unfamiliar with the 'un-gated' design, have failed to apply the clamp correctly.



Action

Ensure all users are aware of the differences in design and the correct positioning of the device as shown below:



Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)
- Local Supervising Authority Midwifery Officers

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Ambulance services directors
- Ambulance staff
- Health and safety managers
- Maternity units
- Midwifery departments
- Midwifery staff
- Neonatal nurses
- Nursing executive directors
- Obstetricians
- Obstetrics departments
- Obstetrics theatres
- Obstetrics nurses
- Paramedics
- Purchasing managers
- Risk managers
- Supplies managers

Primary care trusts

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

- Community midwives
- General Practitioners

Local Supervisory Authority Midwifery Officers

LSAMOs for onward distribution to all relevant staff including:

- Independent midwives

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector

Please note: CQC and OFSTED do not distribute these alerts. Sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/094 or 2010/007/001/401/016**.

Technical aspects

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Clinical aspects

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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900
Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722
Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes
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Medical Device Alerts
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Cathays Park
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Tel: 029 2082 3922
Email: Haz-Aic@wales.gsi.gov.uk