

Medical Device Alert

Immediate action

Ref: MDA(NI)2009-007 Issued: 4 February 2009 at 16:00

Device

EasiCath intermittent urinary catheters manufactured by Coloplast – recall of various models and batches.

Problem

Some catheters have been caught in the welding of the packaging which has caused the catheter tip to be cut off or partly cut off, leaving a sharp edge. This would pose a risk of urethral injury if the user did not detect the sharp edges and tried to insert the catheter.

Action by

All healthcare and care workers who use these devices. Personnel involved in the purchase, supply and distribution of these devices.

SABS deadlines

Action underway: 11 February 2009
Action complete: 25 February 2009

Action

- Identify and quarantine affected products.
- Contact end users who have received affected stock and retrieve any unused devices.
- Contact Coloplast to arrange for return and replacement with an alternative product.

Contact

Manufacturer
Emma Branch
Coloplast Customer Care

Tel: 01733 368 989
Fax: 01733 392 827
E-mail: GBEBA@coloplast.com

Device

Coloplast EasiCath intermittent urinary catheters are used to remove urine from the bladder but do not remain in place after drainage is complete. They are supplied in boxes of 25 devices. The model name, model number and lot numbers of the devices being recalled are given in the table below.

Model name	Model number	Lot number
EASICATH CH12 BOY	05092	1721427
EASICATH CH8 MALE	05348	1702423
EASICATH CH10 MALE	05350	1664650
EASICATH CH16 MALE	05356	1702431
EASICATH CH20 MALE	05360	1722896
EASICATH CH10 TIEMANN	05380	1664684, 1702467
EASICATH CH12 TIEMANN	05382	1702473, 1736600
EASICATH CH14 TIEMANN	05384	1664704

Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency's Chief Executive's
- HSC Trust, HSS Board, and Agency's SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

Onward 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:

- A&E departments
- Adult and paediatric intensive care units
- All wards and departments
- Clinical governance leads
- Directors of midwifery
- Hospital at home units
- Medical directors
- Nursing executive directors
- Obstetrics and gynaecology departments
- Palliative care teams
- Purchasing managers
- Risk managers
- Supplies managers
- Theatres
- Community children's nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- District nurses
- Palliative care teams
- Practice managers
- Practice nurses
- School nurses

The Regulation and Quality Improvement Authority (RQIA) to:

Headquarters for onward distribution to:

- All Nursing and Residential Home providers
- Domiciliary care providers
- Independent treatment centres
- Nursing agencies

Boards to:

SABS liaison officers for onward distribution to:

- Risk manager

Central Services Agency (CSA) to:

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

- Staff with responsibility for purchasing

Contacts

Manufacturer

Emma Branch
Coloplast Customer Care
Unit 1 The Links
Bakewell Road
Orton Southgate
Peterborough
PE2 6BR
Tel: 01733 368 989
Fax: 01733 392 827
E-mail: GBEBA@coloplast.com

NIAIC

Enquiries in Northern Ireland, please send enquiries about this notice to the NIAIC quoting reference number **MDA(NI)2009-007** and addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523868
Fax: 02890 523900
E-mail: NIAIC@dhsspsni.gov.uk
<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the NIAIC website

Further information about SABS can be found at <http://sabs.dhsspsni.gov.uk>

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