Medical Device Alert

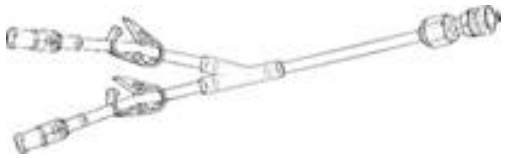
Immediate action

Ref: MDA/2010/068 Issued: 06 September 2010 at 14:00

Device

IV extension sets with multiple ports and vented caps.

Various manufacturers.



Problem

Risk of air embolism and death.

Action by

All staff who use these devices.

CAS deadlines

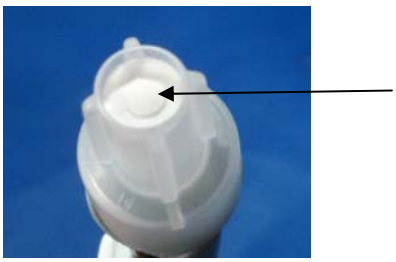
Action underway: 17 September 2010
Action complete: 27 September 2010

Action

- Ensure that IV extension sets are inspected to identify any vented caps prior to connecting them to a patient.
- Do not leave vented caps on unused ports; replace immediately with a non-vented cap or appropriate alternative. If in doubt, replace the cap.
- Be aware that there are alternative devices available, which are supplied with non-vented caps.

Device

An example of a vented cap.



Problem

An incident has been reported where a patient suffered a stroke when an IV extension set, which had a vented cap attached to its Y-port, was connected to a central line.

Manufacturers use vented caps to allow the ethylene oxide gas to penetrate and then exit the IV extension set during the sterilisation process. If these sets are put into use with the vented caps still in place, air can enter the line and pose a risk of air embolism and death.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Health Protection Agency (HPA) (Directors)
- 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)

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:

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

- A&E departments
- All intensive care units
- All outpatient departments
- All theatres
- All wards
- Clinical or medical engineering departments
- Medical directors
- Nursing directors
- Risk managers
- Supplies managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector

Primary care trusts to:

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

- Community children's nurses
- Community hospitals
- Community midwives
- Community nurses
- District nurses
- Nutritional nurse specialists
- Palliative care teams

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/068 or 2010/007/029/601/006**.

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

Tel: 020 7084 3344 or 3310
Fax: 020 7084 3209
Email: louise.mulroy@mhra.gsi.gov.uk
nicole.small@mhra.gsi.gov.uk

Clinical aspects
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Medicines & Healthcare products Regulatory Agency
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1 Nine Elms Lane
London SW8 5NQ

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Fax: 020 7084 3111
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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
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922
Email: Haz-Aic@wales.gsi.gov.uk