

Medical Device Alert

Ref: MDA/2012/009 Issued: 01 March 2012 at 14:30

Device

Level 1[®] Normothermic IV fluid administration sets, specific lots of model numbers D-60 HL and DI-60HL.

Hotline[®] Blood and IV fluid warming sets, specific lots of model numbers L-70, L-70NI, L-80, L-270, and L-370.

Manufactured by Smiths Medical.

Problem

Smiths Medical has become aware of an increase in the number of reports of disconnections of the Luer lock connector at the patient end of the tubing for these fluid warming sets. This can lead to a risk of fluid/ blood loss or delay in therapy.

The MHRA cannot be confident that these recalls have been effective and that users have received and acted on the information provided in the manufacturer's Field Safety Notices (FSNs).

Action

- Do not use the affected devices.
- Contact Smiths Medical to arrange the return and replacement of the affected sets as advised in the two Smiths Medical Field Safety Notices (FSNs) issued on 28 November 2011 for:
 - > [Level 1[®]](#)
 - > [Hotline[®]](#)

The FSNs list the lot numbers of all affected devices.
- Send the confirmation return form to Smiths Medical.

Action by

All those involved in the supply and use of these devices.

CAS deadlines

Action underway: 08 March 2012
Action complete: 29 March 2012

Contact

Manufacturer
Smiths Medical
Mr Philip York
Tel: 01923 241 411
Fax 01233 722 153
Email: ukcs@smiths-medical.com

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)

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:

- A&E departments
- A&E directors
- A&E nurses
- Adult and paediatric intensive care units
- All theatres
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- EBME departments
- Equipment stores
- Health and safety managers
- IV specialist nurses
- Medical directors
- Midwifery departments
- Midwifery staff
- Nursing executive directors
- Operating department practitioners
- Perfusionists
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre nursing staff

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can 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.

Contacts

Manufacturer

Smiths Medical
Mr Philip York
1500 Eureka Park
Lower Pemberton, Ashford
Kent TN25 4BF

Tel: 01923 241 411

Fax: 01233 722 153

Email: ukcs@smiths-medical.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/009** or **2011/011/022/291/002** and **2012/001/013/291/001**.

Technical aspects

Louise Mulroy and Sharon Knight
Medicines & Healthcare products Regulatory Agency
Floor 4
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London SW1W 9SZ

Tel: 020 3080 7344 or 7202

Fax: 020 8754 3965

Email: louise.mulroy@mhra.gsi.gov.uk
sharon.knight@mhra.gsi.gov.uk

Clinical aspects

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Medicines & Healthcare products Regulatory Agency
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London SW1W 9SZ

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Fax: 020 8754 3965

Email: jonathan.plumb@mhra.gsi.gov.uk

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.irc@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Dr Chris Jones

Medical Director

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk

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