

MEDICAL DEVICE ALERT

Issued: **03 December 2007** at 11:00 Ref: **MDA/2007/089**

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

Device: Intravenous (IV) infusion lines: all brands.	► Page 2								
Problem: Risk of back-tracking when more than one IV line is connected through a single access point (see diagram on page 2). This can lead to: 1. under infusion 2. bolus delivery of IV drugs.	► Page 2								
Action by: All medical and nursing staff.									
Action: <ul style="list-style-type: none"> Where appropriate, consider using IV lines with one-way valves to prevent backtracking. (Examples of one-way valves are check, non-return or anti-reflux valves or anti-siphon/anti free-flow valves). Apply clamps (where available) to lines not in use. Be aware that needle free connectors are not one-way valves and will allow back-tracking when connected to IV devices. 									
Distributed to: <table> <tr> <td>NHS trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>Commission for Social Care Inspection (CSCI)</td> <td>– Headquarters</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*	Commission for Social Care Inspection (CSCI)	– Headquarters	Healthcare Commission (CHAI)	– Headquarters	Primary care trusts in England	– Chief Executives*	► Page 2
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Primary care trusts in England	– Chief Executives*								
Contacts: Details of MHRA contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	► Page 3								

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 14 January 2008

Deadline (action complete): 25 February 2008

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

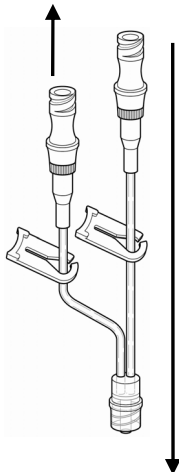
Device:

IV infusion lines that will allow fluid to flow in both directions. For example multi-lumen IV extension sets, IV administration sets with side port/Y-site and IV multi-way connectors such as stopcocks, Y-connectors and manifolds.

Problem:

When more than one IV line is connected to a single access point, back-tracking of fluids can occur if one line has no flow or a slower flow of fluid running through it. The fluid will back-track, as it will take the path of least resistance (see diagram below).

Backtracking flow



Intended flow

This can also occur during occlusions. If a downstream occlusion occurs when an infusion pump is being used, the occlusion alarm may not be activated.

Bolus delivery can occur following backtracking, when flow in the line is increased, the line is flushed or the occlusion is released.

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:

- All clinical departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Chief Pharmacists
- Clinical governance leads
- Hospital at home units
- Intensive care units
- IV nurse specialists
- Medical directors
- Modern matrons
- Neonatal nurse specialists
- Nursing executive directors
- Nutritional nurse specialists
- Outpatient clinics
- Outpatient theatre managers
- Palliative care teams
- Paramedics
- Pharmacists
- Radiographer superintendents
- Resuscitation officers and trainers
- Risk managers
- Supplies managers
- Theatre managers

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes providing nursing care

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

Primary care trusts to:

SABS 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

Contacts:

Enquiries to the MHRA should quote reference number **2007/007/027/291/004** and be addressed to:

Technical aspects:

Nicole Toyick or Jim Lefever
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3310 / 3262

Fax: 020 7084 3209

E-mail: nicole.toyick@mhra.gsi.gov.uk
jim.lefever@mhra.gsi.gov.uk

Clinical aspects:

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

Tel: 020 7084 3128

Fax: 020 7084 3111

E-mail: jonathan.plumb@mhra.gsi.gov.uk

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

CSCI Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

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

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