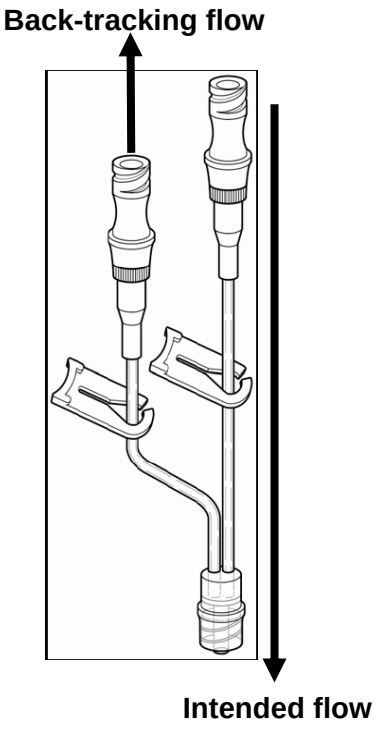
Medical Device Alert

Action

Ref: MDA/2010/073 Issued: 20 September 2010 at 14:30

Device

Intravenous (IV) extension sets with multiple ports: all brands.



Problem

Risk of back-tracking when an IV line has multiple access ports.

This can lead to under-infusion or bolus delivery of IV drugs.

Action by

All medical and nursing staff.

CAS deadlines

Action underway: 04 October 2010

Action complete: 01 November 2010

Action

- Consider if an IV extension set with multiple ports is appropriate for your intended use and be aware of alternatives.
- Where appropriate, consider using IV lines with one-way valves to prevent back-tracking (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.
- This MDA supersedes MDA/2007/089.

Device

All IV lines with multiple ports that will allow fluid to flow in both directions:

- multi-lumen IV extension sets
- IV administration sets with side port/Y-site
- IV multi-way connectors such as stopcocks
- Y-connectors
- manifolds.

This issue is not limited to any particular manufacturer or model.

Problem

The MHRA continues to receive reports of incidents involving intravenous (IV) extension sets with multiple ports. These incidents have led to serious consequences e.g. patients receiving an inadvertent bolus of anaesthetic agent due to back-tracking, resulting in respiratory arrest.

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 and take the path of least resistance. 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.

Such back-tracking can lead to bolus delivery when: flow in the line is increased; or the line is flushed; or the occlusion is released.

Distribution

This MDA has been distributed 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)

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:

- Accident and emergency departments
- 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
- 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

Establishments registered with the Care Quality Commission (CQC) (England only) to:
The MHRA considers this information to be important to:
- Adult placement
- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

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
- NHS walk in centres

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/073** or **2010/002/023/601/003**.

Technical 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
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