

Medical Device Alert

Ref: MDA/2011/068 Issued: 15 June 2011 at 15:30

Device

Needle-free intravenous connectors.

All manufacturers.

All models.

Problem

- Incompatibility of some pre-filled glass syringes with various needle-free connectors.
- Possible risk of infection and/or air embolus to patients when an adaptor remains attached to a needle-free connector after use.

Action by

Medical, nursing, pharmacy and procurement staff who have responsibility for accessing and purchasing intravenous devices.

CAS deadlines

Action underway: 29 June 2011

Action complete: 13 July 2011

Action

- Ensure procedures are in place to determine the compatibility of needle-free connectors in use with pre-filled syringes contained in emergency drug boxes. Refer to the compatibility warnings and Luer size limits in the instructions for use of the connector. The summary product characteristics (SPC) of the medicine may also include compatibility warnings.
- Follow the advice on page 2 of this alert if they are not compatible.
- Ensure procedures are in place to prevent adaptors being left attached to a needle-free connector after use.

Device

All brands of needle-free connectors for vascular access. This includes extension and administration sets with integral connectors.

When the valve is activated by an IV device with a male Luer fitting, such as a syringe (without a needle) or an administration set, the fluid pathway is opened to allow the administration of fluids or aspiration of blood for sampling. Upon removal of the device, the top/septum should automatically return to its closed/home position and seal the fluid pathway. These connectors are **not** IV caps, bungs or obturators.

Problem

The MHRA issued [MDA/2004/005](#) in January 2004 to raise awareness of incompatibility between some needle-free connectors and Luer tips of pre-filled syringes.

The MHRA continues to receive reports of damage to the needle-free connector and/or to the pre-filled syringe where force has been used to connect incompatible devices together. In some cases fragments may block the syringe outflow. Such damage has resulted in a delay in administering therapy during the resuscitation of patients.

The MHRA also continues to receive reports of adverse incidents involving pre-filled glass syringes used with an adaptor which enables compatibility with a needle-free connector. If the adaptor is not removed from the needle-free connector after administration of fluid via an intravenous catheter, the IV pathway remains open. This poses a risk of infection and the potential for air embolus.

Action

If the needle-free connector is not compatible with the pre-filled syringe:

- follow any advice given in the instructions for use
- seek an alternative connector or syringe that is compatible, or
 - use alternative venous access, or
 - in an emergency, consider removing the connector or the extension line possessing integral connectors from the intravenous catheter to access the catheter directly
- ensure adaptors are removed immediately after use.

The MHRA does not hold a list of incompatible devices.

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)
- Primary care trusts in England (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
- Adult & paediatric intensive care units
- All medical and nursing staff
- All wards and clinical departments
- Ambulance staff
- Anaesthesia, directors of
- Clinical governance leads
- Health and safety managers
- Infection prevention nurses
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Pharmacists
- Purchasing managers
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Theatre managers

Health Protection Agency

Directors for onward distribution to:

- Health protection nurses

Primary care trusts

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

- Clinical governance leads
- Community hospitals
- District nurses

Independent distribution

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

This alert should be read by:

- Clinics
- Hospices
- Hospitals in the independent sector
- 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.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/068** or **2011/002/025/081/017**

Technical aspects

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Clinical 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.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:

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Medical Device Alerts
Welsh Assembly Government
Cathays Park
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Email: Haz-Aic@wales.gsi.gov.uk

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