Medical Device Alert

Ref: MDA/2013/079 Issued: 13 November 2013 at 14:00

Device

Intravenous administration sets: Primary PlumSet Clave secondary port.

Manufactured by Hospira.

Specific list numbers are affected.

Problem

Risk of interruption to IV therapy, which may require medical intervention.

This is due to leakage of fluids from the break in the bond between the Clave needle-free connector and the secondary port of the PlumSet.

Hospira issued a Field Safety Notice (FSN) dated 08 August 2013 to advise users how to minimise the possibility of breakage, but has not received confirmation from enough users that they have received and acted on this information.

Action

Identify affected administration sets.

Ensure that all users are aware of the recommendations given in the FSN. In particular, do not bend or twist the Clave needle-free connector when accessing the secondary port.

Return the completed reply form to Hospira.

Action by

All medical, nursing and technical staff involved in the use of these devices.

CAS deadlines

Action underway: 20 November 2013

Action complete: 27 November 2013

Note: These deadlines are for systems to be in place to bring the Field Safety Notice to the attention of users.

Contact

Manufacturer
John McIlvaney
Hospira UK Ltd
Tel: 0800 028 7304
Email: custserv@hospira.com

Device

All lots manufactured after July 2007 of the following list numbers have been supplied to the UK and are affected:

140010728

140018328

140019228

140149228

142129228

196735324

Note that any other list numbers detailed in the FSN have **not** been supplied to the UK.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams (for information)
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information

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 and paediatric intensive care units
- All wards
- Biomedical engineering staff
- Biomedical science departments
- Clinical governance leads
- Day surgery units
- EBME departments
- Equipment libraries and stores
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Oncology units
- Paediatric intensive care units
- Risk managers
- Supplies managers
- Theatres

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

Establishments registered with OFSTED

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

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

John McIlvaney
Customer Services Manager
Hospira UK Ltd
Queensway
Royal Leamington Spa
CV31 3RW

Tel: 0800 028 7304
Fax: 0800 028 7305

Email: custserv@hospira.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/079** or **2013/007/018/081/016**.

Technical aspects

Ian Sealey or Sharon Knight
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6691 / 7202
Fax: 020 8754 3965

Email: ian.sealey@mhra.gsi.gov.uk
sharon.knight@mhra.gsi.gov.uk

Clinical aspects

Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128
Fax: 020 8754 3965

Email: mark.grumbridge@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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
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:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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