Medical Device Alert

Ref: MDA/2013/081R Issued: 06 December 2013

This alert has been re-issued due to a technical problem with the email distribution.
There are no changes to the advice.

Device

Intravenous pump set: Lifeshield Primary Plumset.

Manufactured by Hospira.

Specific list numbers and lot numbers are affected.

Problem

Risk of embolism and allergic reaction due to exposure to particulates and non-biocompatible materials, especially during administration of parenteral lipids.

Due to a manufacturing fault, these devices may be fitted with an incorrect filter which has not undergone biocompatibility testing.

Hospira issued a Field Safety Notice (FSN) dated 22 October 2013, but has not received confirmation from enough users that they have received and acted on this information.

Action

Identify, quarantine and do not use affected product lots.

Use alternatives until new product is available from Hospira.

Liaise with Hospira for the collection of affected product.

Complete and return the reply form to Hospira.

Report any adverse incidents to Hospira and the MHRA.

Action by

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

CAS deadlines

Action underway: 13 December 2013

Action complete: 27 December 2013

Note: These deadlines are for affected devices to be identified and quarantined.

Contact

Manufacturer
John McIlvaney
Hospira UK Ltd

Tel: 0800 028 7304
Email: custserv@hospira.com

Device

List number	Lot numbers	Set description
14000-92-28	27112-5H 30079-5H	Lifeshield, latex-free, non-DEHP, Primary Plumset, 15 micron filter in sight chamber, Prepierced Y-site, 272 cm
14001-92-38*	28187-5H	Lifeshield, latex-free, non-DEHP, Primary Plumset, 15 micron filter in sight chamber, Clave port, Clave Y-site, 272 cm

*the equivalent NHS Supply Chain code for this list number is FSB1314 (England only).

NHS Supply Chain has sent its own customer notice about this recall (reference NHS SC 32).

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
- Intensive care, directors of
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Oncology units
- Paediatric intensive care units
- Purchasing managers
- 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/2013/081** or **2013/010/002/291/008**

Technical aspects
Patrick Sweeney or Claire Dunne
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6898 / 7162
Fax: 020 8754 3965

Email: Patrick.sweeney@mhra.gsi.gov.uk
claire.dunne@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 5801

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

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