

Medical Device Alert

Action

Ref: MDA/2011/036 Issued: 13 April 2011 at 15:00

Device

Alaris[®] infusion set GP 150ml burette set.
Product reference 60103E.

Alaris[®] GP infusion set, low sorbing, 0.2mm filter.
Product reference 60033E.

Manufactured by Carefusion.

Specific lot numbers are affected.

Problem	Action
<p>Potential for leakages and/or set disconnections in devices from specific lots due to a manufacturing problem.</p> <p>The MHRA is issuing this alert as there has been a poor response from users to the Carefusion Field Safety Notices, which have been sent to affected customers.</p>	<p>Identify and isolate the affected devices with lot numbers listed in CareFusion's Field Safety Notice for 60103E and Field Safety Notice for 60033E set (both dated January 2011).</p> <p>Contact Carefusion to arrange for credit or replacement of products 60103E and 60033E.</p>
Action by	<p>Ensure that the verification form is returned to Carefusion.</p>
<p>All medical and nursing staff involved in the use of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 03 May 2011</p> <p>Action complete: 17 May 2011</p>	<p>Manufacturer Peter Highmoor CareFusion</p> <p>Tel: 01256 388 481 Fax: 01256 388 388 Email: peter.highmoor@carefusion.com</p>

Device

The following product references and lot numbers are affected:

Product reference	NHS Supply Chain Code (England only)	Lot number
60103E	FKA329	09106235
		09115190
		09115506
		09125107
		09125632
		09126171
		09126172
		10015460
60033E	FKA321	09125844

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)
- 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:

- Accident and emergency departments
- All clinical departments
- All wards
- Ambulance services directors
- Anaesthesia, directors of
- Chief pharmacists
- Clinical governance leads
- EBME managers
- Hospital at home units
- Intensive care units (adult and paediatric)
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Oncology nurse specialists
- Outpatient clinics
- Outpatient theatre managers
- Palliative care teams
- Paramedics
- Pharmacists
- Purchasing managers
- Radiation and medical oncology departments
- Radiation oncologists
- Radiographer superintendents
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers

Primary care trusts

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

- Community children's nurses
- Community hospitals
- Community nurses
- District nurses
- Equipment libraries and stores
- Nutritional nurse specialists
- Palliative care teams
- Walk-in centres

Independent distribution

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

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

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

Peter Highmoor
Director Customer Support UK & Ireland
CareFusion
The Crescent
Jays Close
Basingstoke RG22 4BS
Tel: 01256 388 481
Fax : 01256 388 388
Email: peter.highmoor@carefusion.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/036** or **2011/001/030/291/007** and **2011/001/007/291/008**

Technical aspects

Roopa Prabhakar or Louise Mulroy
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 7293 / 7344
Fax: 020 8754 3965
Email: roopa.prabhakar@mhra.gsi.gov.uk
louise.mulroy@mhra.gsi.gov.uk

Clinical aspects

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
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151 Buckingham Palace Road
London SW1W 9SZ
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Fax: 020 8754 3965
Email: jonathan.plumb@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

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:

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

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