Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2017/006 Issued: 12 April 2017 at 14:30

All Alaris™ GS, GH, CC, TIVA, PK, enteral syringe pumps & Asena™ GS, GH, CC, TIVA, PK, syringe pumps – risk of uncontrolled bolus of medicine.

Summary

Manufactured by CareFusion/BD Medical – identify and replace broken backplate spring in the plunger assembly and note updated preventative maintenance schedule for these pumps.

Action

- Identify all devices with the product codes listed in the Field Safety Notice (FSN).
- Ensure hospital or Carefusion service specialist checks pumps as detailed in the FSN.
- Prioritise devices used in paediatric/neonatal/critical care areas and all devices more than three years old.
- Ensure hospital or CareFusion replace broken springs.
- Ensure all syringe pumps are regularly maintained and serviced in accordance with the manufacturer's updated preventative maintenance.
- **Note that this alert replaces MDA/2017/003, which we published in February 2017**.

Action by
All staff who use these devices.

Deadlines for actions

Actions underway: 15 May 2017

Actions complete: 12 July 2017

Please note: These deadlines are for plans to be in place to complete the pump checks.

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru
Welsh Government

Device details

Product name: Alaris™ GS, GH, CC, TIVA, PK, Enteral Syringe Pump
Product codes with prefix (all variants): 8001, 8002, 8003, 8004, 8005, 8007

Product name: Asena™ GS, GH, CC, TIVA, PK Syringe Pumps
Product codes with prefix (all variants): 8001, 8002, 8003, 8004, 8005

Manufacturer contacts

CareFusion
Tel: 0800 917 8776
Email: UK-customer-service@carefusion.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)
CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Adult intensive care units
- All wards
- Anaesthetists
- Biomedical engineering staff
- Clinical governance leads
- Day surgery units
- EBME departments
- Equipment stores
- IV nurse specialists
- Medical directors
- Neonatology departments
- Nursing executive directors
- Paediatric intensive care units
- Paediatric wards
- Paediatricians
- Risk managers
- Special care baby units
- Supplies managers
- Theatres

Independent distribution

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

- Care homes providing nursing care (adults)
- Clinics
- Hospices
- 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.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/006** or **2016/010/017/401/005**.

Technical aspects
Roopa Prabhakar or Emma Rooke, MHRA
Tel: 020 3080 7293 / 6609
Email: roopa.prabhakar@mhra.gov.uk or emma.rooke@mhra.gov.uk

Clinical aspects
Mark Grumbridge, MHRA
Tel: 020 3080 7274
Email: dct@mhra.gov.uk

Reporting adverse incidents in England
Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland
Alerts in Northern Ireland are distributed via the NI SABS system.
Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
CMO Group,
Department of Health, Social Services and Public Safety
Tel: 028 9052 3868
Email: niaic@health-ni.gov.uk
https://www.health-ni.gov.uk/niaic

Reporting adverse incidents in Northern Ireland
Please report directly to NIAIC using the forms on our website.

Scotland
Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland, NHS National Services Scotland
Tel: 0131 275 7575
Fax: 0131 314 0722
Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland
NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.
Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.
Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).