Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/024 Issued: 11 July 2018 at 11:00 Valid until: July 2019

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

Summary

Manufactured by CareFusion, now Becton Dickenson (BD) Medical – identify and replace the back-plate 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).
- Make arrangements for the syringe plunger back-plate assembly to be replaced as soon as possible as described in the FSN
- Prioritise devices used in paediatric/neonatal/critical care areas.
- Ensure all syringe pumps are regularly maintained and serviced in accordance with the manufacturer's updated preventative maintenance.
- Ensure users are aware of the updated alarms and warnings section in the new version of the Alaris Directions For Use, which clarifies the "Check Syringe" alarm and the actions that should be taken.
- **Note that this alert replaces MDA/2017/006, published in April 2017**.

Action by
All staff who use or are responsible for maintenance of these devices.

Deadlines for actions
Actions underway: 08 August 2018
Actions complete: 03 October 2018

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

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

Problem / background

In 2016 the manufacturer identified the potential for unintended movement of the syringe plunger, which could result in an unintentional bolus occurring due to siphonage. The risk was greater when the syringe pump was positioned above the patient's heart level.

The manufacturer determined that this risk arose from a broken spring in the syringe plunger assembly. MDA/2017/006 was the most recent MDA published to alert users to this risk and inform users of preventative actions to take.

The manufacturer has now redesigned the syringe plunger back-plate assembly to address the problem. The latest Field Safety Notice advises customers to replace the complete back-plate assembly as soon as reasonably possible

Manufacturer contacts

Pranil Patil
BD
Tel: 0118 921 6221
Email: fsca.infusion@bd.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 NICAS 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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/024** or **2018/006/020/081/027**.

Technical aspects
Roopa Prabhakar or Jenifer Hannon, MHRA

Tel: 020 3080 7293 or 020 3080 7153

Email: roopa.prabhakar@mhra.gov.uk
Jenifer.hannon@mhra.gov.uk

Clinical aspects
Devices Clinical Team, 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 NICAS 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

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).