Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2018/021 Issued: 21 June 2018 at 11:00 Valid until: June 2019

Alaris Smartsite Add-On Bag Access device – removal and destruction of specific batches due to risk of disconnection or leakage

Summary

Manufactured by BD (formerly Carefusion) – specific batches manufactured from July 2015 to Sept 2016 inclusive. Risk of leakage or disconnection of tubing caused by inadequately sealed connections. This may cause delay to infusion, under infusion, or exposure to hazardous infusates.

Action

- Refer to the manufacturer's FSN for further details of affected products
- Identify, quarantine and destroy affected devices as per local procedure.

Action by
All healthcare professionals who are responsible for, or who use these devices

Deadlines for actions
Actions underway: 12/07/2018
Actions complete: 02/08/2018

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

Manufacturer contacts

Pranil Patil
BD
Tel: 0118 921 6221
Email: Pranil.Patil@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 consultants
- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiothoracic departments
- Cardiothoracic surgeons
- Chief pharmacists
- Clinical perfusionists
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- District nurses
- Endocrinology units
- Equipment stores
- Equipment libraries and stores
- Gastroenterology departments
- General surgery
- General surgical units, directors of
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Hospital at home units
- Infection control departments
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)

- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Minor injury units
- Maternity units
- Medical directors
- Medical libraries
- Neonatal nurse specialists
- Neonatology departments
- Nursing executive directors
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Operating department practitioners
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Paramedics
- Peritoneal dialysis units
- Radiation & medical oncology departments
- Renal medicine departments
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urology departments

Independent distribution

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

- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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 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/2018/021** or **2018/004/019/291/003**.

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
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).