



Medical Device Alert

MDA/2017/009

Issued: 24 April 2017 at 14:00

Valid until: 30 April 2018

BD Plastipak 100ml catheter tip syringe with Luer slip adaptor, specific lots – risk of leakage and delayed therapy

Summary

Manufactured by Becton Dickinson (BD) – product recall due to leak around the stopper which can result in under-dose or exposure of clinicians or patients to cytotoxic drugs.

Action

- Identify all lots of syringes that have an expiry date up to and including April 2021.
- Ensure all users are aware of the manufacturer's [Field Safety Notice](#) published in February 2017.
- Contact the manufacturer to acknowledge the FSN and arrange to return affected syringes for replacement.

Action by

All staff who use these devices

Deadlines for actions

Actions underway: 16 May 2017

Actions complete: 31 May 2017

Device details

BD catalogue number 300605.

Note: These syringes may be included in clinical/surgery packs supplied by other companies so this catalogue number might not appear or be obvious.

Manufacturer contacts

BD Medical
Tel: 01865 781534
Email: andrew.milton@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 SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Adult intensive care units
- All departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiologists
- Cardiology departments
- Cardiothoracic departments
- Chief pharmacists
- Clinical governance leads
- Clinical perfusionists
- Community children's nurses
- Community hospitals
- Community nurses
- Coronary care departments
- Day surgery units
- Dental departments
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- District nurses
- General surgery
- General surgical units, directors of
- Gynaecology departments
- Haematologists
- Haemodialysis units

- Hospital at home units
- Hospital pharmacies
- Intensive care medical staff/paediatrics
- Intensive care units
- IV nurse specialists
- Maternity units
- Medical directors
- Medical oncologists
- Midwifery departments
- Neonatology departments
- Nursing executive directors
- Oncology nurse specialists
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric oncologists
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Peritoneal dialysis units
- Pharmacists
- Phlebotomists
- Purchasing managers
- Radiology departments
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

NHS England area teams

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

- Community pharmacists
- General practice managers
- General practice nurses

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Equipment supplies managers
- In-house residential care homes

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only) Care homes providing nursing care (adults)

- Clinics
- Domiciliary care providers
- Hospices
- 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 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/2017/009** or **2017/001/024/701/005**.

Technical aspects

Enitan Taiwo and Sharon Knight, MHRA

Tel: 020 3080 7122 / 7202

Email: enitan.taiwo@mhra.gov.uk and sharon.knight@mhra.gov.uk

Clinical aspects

MHRA Devices Clinical Team

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.irc@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 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health
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