Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/026 Issued: 24 July 2019 at 14:00

Professional use capillary blood specimen collection: BD Microtainer® tubes – risk of blood leakage and/or incorrect test results due to defective tubes

Summary

Manufactured by Becton Dickinson (BD) – tubes may contain a hole or be damaged or deformed, potentially causing blood leakage and/or an inadequate blood-to-additive ratio leading to incorrect test results.

Action

- Identify affected devices, distributed from July 2018 to April 2019 inclusive, as listed in the manufacturer's Field Safety Notice (FSN). NHS Supply Chain codes are provided on page 2 of this alert.
- Follow actions recommended in the manufacturer's FSN.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
- Laboratory director / manager
- Pathologists
- Point of care testing co-ordinators
- Purchasing and supplies managers
- Paediatric medical and nursing staff

Deadlines for actions
Actions underway: 07 August 2019
Actions complete: 21 August 2019

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

Details of affected product, including NHS Supply Chain codes:

Product Name	Product Code	NHS Supply Chain code	Lot
BD Microtainer® Z Tubes	365964	KCM058	8212774
BD Microtainer® LH Tubes	365966	KCM062	821472N
BD Microtainer® SST™ Tubes	365968	KCM059	8086508
			8086517
			8129651
			8173674
			8178701
			8178708
			8220936
			8284578
BD Microtainer® K2E Tubes	365975	KCM002	8201643
			8201645
			8204883
			8241537
			8253627
			8253658
BD Microtainer® SST™ Amber Tubes	365979	KCM060	8180719
			8264509
			8282816
BD Microtainer® PST™ LH Tubes	365986	KCM063	808582N
			808586N
			813766N
			821893N
			827650N
BD Microtainer® PST™ LH Amber Tubes	365988	KCM064	819351N
			822560N
			826456N
			827756N
BD Microtainer® FE Microcollection Tubes	365993	KCM067	8213607
			8213615

Manufacturer contacts

Becton Dickinson
Contact Name: Kaye Glaysher
Mobile: 07818 579 088
Email: BDUKFieldAction@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 departments
- All staff
- All wards
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Biochemists
- Biomedical science departments
- Cardiologists
- Clinical pathologists
- Clinical pathology directors
- Community children’s nurses
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- District nurses
- Endocrinology units
- ENT departments
- ENT medical staff
- Equipment stores
- Gastroenterology departments
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- Gynaecologists
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Hospital at home units
- 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
- Maxillofacial departments
- Medical directors

- Medical oncologists
- Medical oncology, directors of
- Midwifery departments
- Midwifery staff
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- NHS walk-in centres
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Orthopaedic surgeons
- Outpatient clinics
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Peritoneal dialysis units
- Phlebotomists
- Point of care testing co-ordinators
- Renal medicine departments
- Renal medicine, directors of
- Special care baby units
- Staff supporting patients receiving haemodialysis at home
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urology departments
- Virologists
- Walk-in centres

NHS England area teams

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

- General practitioners
- General practice managers
- General practice nurses

This Medical Device Alert is being sent to GPs for information only, in circumstances where patients may seek advice about the contents of this notice. GPs need take no further action on receipt of this alert.

Independent distribution

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

- Clinics
- 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/2019/026** or 2019/005/020/291/011

Technical aspects

Anna Biela, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales
Population Healthcare Division, Welsh Government
Tel: 03000 250986 / 03000 255510
Email: haz-aic@wales.gov
To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page 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 and Social Care.
© Crown Copyright 2019
Addressees may take copies for distribution within their own organisations