Medical Device Alert

Ref: MDA/2013/075 Issued: 16 October 2013 at 14:00

Device

Vacutainer® multiple sample Luer adaptor for blood sample collection. Specific lot numbers affected.

Manufactured by Becton, Dickinson and Company (BD).

Problem

Increased risk to users of exposure to blood, and a risk of under filling blood collection tubes which could lead to unexpected results in some laboratory tests.

This problem was first identified in May 2013 (see BD's Field Safety Notice and the MHRA's MDA/2013/061). BD has now identified that further lots are affected and has issued a second Field Safety Notice providing full details of all affected lots.

BD has received reports where the retractable sleeve, which covers the non-patient cannula before and after a blood collection tube is filled, has either failed to recover on removal of the sample tube, leaked, or fallen off. Reports have also been received of leakage at the Luer tip connection.

Action

Identify whether you have any of the lots that are affected and ensure that all relevant staff are aware of the recommended actions in the manufacturer's new Field Safety Notice including:
- to continue the use of universal/standard precautions
- to ensure that filled blood collection tubes meet the required fill volume as indicated on the specific tube prior to processing.

Contact BD for replacements of products from affected lots if a local risk assessment indicates this is necessary, or if this is preferred.

Action by:
All healthcare workers who use these devices or process blood samples, and those involved in their purchase, supply and distribution.

CAS deadlines

Action underway: 30 October 2013

Action complete: 13 November 2013

Note: These deadlines are for systems to be in place to ensure that healthcare workers are aware of the Field Safety Notice, and where necessary request replacements.

Contact

Manufacturer
Jonathan Fleet

Becton, Dickinson and Company

Tel: 01865 781 529
Email: Jonathan_fleet@europe.bd.com

Device

All BD Vacutainer multiple sample Luer adaptors catalogue number 367300, NHS Supply Chain Code KFK036 (England only), which have a lot number that falls within the following numerical range (inclusive) are affected:

Lot number **1326169**, expiry date 11/2014 **to** lot number **3072890**, expiry date 03/2016

Note: This does not affect any other BD products which have a lot number within this range.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- Local authorities in Scotland (equipment co-ordinators)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams
- NHS trusts in England (chief executives)
- Public Health England (for information)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

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

- All clinical departments
- All clinical staff
- All wards
- Biomedical scientists
- Clinical governance leads
- Community children's nurses
- Community hospitals
- Community midwives
- Community nurses
- District nurses
- Haematologists
- Hospital at home units
- Hospital pharmacies
- IV nurse specialists
- Laboratory directors
- Medical directors
- NHS walk-in centres
- Nursing executive directors
- Outpatient clinics
- Outpatient theatre managers
- Phlebotomists
- Purchasing managers
- Risk managers
- Supplies managers
- Walk-in centres

Public Health England Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- Laboratory managers
- Regional directors
- Regional epidemiologists
- Regional leads
- Regional microbiologists
- Risk manager
- Safety officers

NHS England area teams

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

- Practice managers
- Practice nurses

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- 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.

Contacts

Manufacturer

Jonathan Fleet
Becton, Dickinson and Company
The Danby Building
Edmund Halley Road
Oxford Science Park
Oxford
OX4 4DQ

Tel: 01865 781 529

Email: jonathan_fleet@europe.bd.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/075** or **2013/004/023/081/008**.

Technical aspects

Ainsley Wickens or Roopa Prabhakar
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7273 / 7293
Fax: 020 8754 3965

Email: ainsley.wickens@mhra.gsi.gov.uk
roopa.prabhakar@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare Products Regulatory Agency
Floor 4, 151 Buckingham Palace Road, London SW1W 9SZ
Tel: 020 3080 7128 Fax: 020 8754 3965
Email: mark.grumbridge@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group, Room 17, Annex 6, Castle Buildings, Stormont Estate, Dundonald BT4 3SQ

Tel: 02890 523 704 Fax: 02890 523 900 Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland, Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB

Tel: 0131 275 7575 Fax: 0131 314 0722 Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ

Tel: 029 2082 3922 Email: Haz-Aic@wales.gsi.gov.uk