

Medical Device Alert

Ref: MDA/2013/061 Issued: 01 August 2013 at 16:00

Device
<p>Vacutainer[®] multiple sample Luer adaptor for blood sample collection.</p> <p>Catalogue number 367300 (England only - NHS Supply Chain code KFK036). Specific lot numbers are affected.</p> <p>Manufactured by Becton, Dickinson and Company (BD).</p>

Problem	Action
<p>Increased risk to users of exposure to blood, and a risk of underfilling of blood collection tubes which could lead to unexpected results in some laboratory tests.</p> <p>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.</p> <p>BD has issued a Field Safety Notice with advice to users, and will replace products from affected lot numbers on request.</p>	<p>Identify affected lots and ensure that all relevant staff are aware of the recommended actions in the manufacturer's Field Safety Notice including:</p> <ul style="list-style-type: none"> - 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. <p>Contact BD for replacements of products from affected lots if a local risk assessment indicates this is necessary, or if this is preferred.</p>
Action by	
<p>All healthcare workers who use these devices or process blood samples, and those involved in their purchase, supply and distribution.</p>	
CAS deadlines	Contact
<p>Action underway: 15 August 2013</p> <p>Action complete: 29 August 2013</p> <p>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.</p>	<p>Manufacturer Lorna Darrock Becton, Dickinson and Company Tel: 01865 781 545 Email: lorna_darrock@europe.bd.com</p>

Device



Affected lot numbers:

1333588	2123767	2249601	2289883
1333589	2213775	2249602	2297780
2024564	2213776	2255659	2305611
2051820	2222725	2282697	2314818
2061445	2226828	2282699	
2108597	2242559	2289881	

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

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

Tel: 01865 781 545

Email: lorna_darrock@europe.bd.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/061** or **2013/004/023/081/008**.

Technical aspects

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

Tel: 020 3080 7273 / 6716

Fax: 020 8754 3965

Email: ainsley.wickens@mhra.gsi.gov.uk
francesca.edelmann@mhra.gsi.gov.uk

Clinical aspects

Jonathan Plumb
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6648

Fax: 020 8754 3965

Email: jonathan.plumb@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

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.irc@nhs.net

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

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

MHRA is an executive agency of the Department of Health

© Crown Copyright 2013

Addressees may take copies for distribution within their own organisations