

Medical Device Alert

Ref: MDA/2014/003 Issued: 17 January 2014 at 14:00

Device
<p>Single-use syringes: Plastipak™ 50ml Luer Lok Manufactured by BD Medical.</p> <p>Product codes affected: 300223 non sterile, 300865 sterile (NHS Supply Chain code FWC034 England only), 300869 Amber – sterile.</p> <p>All lot numbers are affected.</p>

Problem	Action
<p>Risk of delay or interruption to treatment when these syringes are used in power-driven syringe pumps.</p> <p>BD continues to receive reports of occlusion alarms triggering due to an increased plunger movement force, which was introduced by a design change in April 2012.</p> <p>BD is in the process of modifying the design to lower plunger forces. The new design will not be available before the end of January 2014.</p>	<p>Be aware of this issue and the likelihood that you may continue to experience unexpected occlusion alarms if using the current syringes in power-driven syringe pumps.</p> <p>Be aware that BD has issued a Field Safety Notice (FSN) informing users of this issue. This replaces their FSN of 11 April 2013.</p> <p>Contact BD for further advice on dealing with this issue.</p> <p>When new stock is available, contact BD to discuss a managed changeover.</p> <p>MDA/2013/024 has been withdrawn.</p>
Action by	
<p>All healthcare and care workers who use these devices and those involved in their purchase, supply and distribution. All those responsible for the maintenance and service of syringe pumps.</p>	
CAS deadlines	Contact
<p>Action underway: 31 January 2014</p> <p>Action complete: 14 February 2014</p> <p>Note: These deadlines are for systems to be in place for users to be aware of the problem.</p>	<p>Manufacturer BD Medical UK Ltd General enquiries 01865 781517 Email: bdmedical_complaints@bd.com</p>

Device

Stock of the new design (with lower plunger forces) can be identified by an 'N' preceding the product code for example: **N** Ref 300865

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)

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 staff
- All wards
- Ambulance services directors
- Anaesthetists
- Directors of nursing
- EBME departments
- Equipment libraries
- Maintenance staff
- Medical device trainers
- Medical directors
- Supplies departments
- Theatres

NHS England area teams

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

- Community children's nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- District nurses
- Equipment libraries and stores
- Minor injury units
- NHS walk-in centres
- Palliative care teams
- Pharmaceutical advisors
- Walk-in centres

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- 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

BD Medical UK Ltd
The Danby Building
Edmund Halley Road
Oxford Science Park
Oxford, Oxfordshire
OX4 4DQ

General enquiries telephone: 01865 781517

Email: BDmedical_complaints@bd.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/003** or **2013/008/030/401/002**

Technical aspects

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

Tel: 020 3080 7273 / 7122

Fax: 020 8754 3965

Email: ainsley.wickens@mhra.gsi.gov.uk
enitan.taiwo@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

Please note the equivalent National Distribution Centre (NDC) product codes are as follows:

Product code 300223 – This product is not on the NDC catalogue

Product code 300865 – NDC code **021666**

Product code 300869 – NDC code **101276**

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.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 5801

Email: Haz-Aic@wales.gsi.gov.uk

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