

MEDICAL DEVICE ALERT

Issued: **10 September 2007 at 15:00** Ref: **MDA/2007/071**

<input checked="" type="checkbox"/>	Immediate action
<input type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

Device: Syringes: BD Medical Surgical Systems Plastipak™ 1ml, 2ml, 5ml and 10ml hypodermic Luer slip syringes manufactured between April 2007 and August 2007.	▶ Page 2												
Problem: BD Medical Surgical Systems has recently received multiple reports of these syringes spontaneously disconnecting from, or failing to maintain a secure connection to, Luer fittings of other devices.	▶ Page 3												
Action by: All healthcare and care workers who use these devices and those involved in their purchase, supply and distribution.													
Action: Ensure local systems are in place to make sure that users: <ul style="list-style-type: none"> • use these syringes with caution and avoid their use in situations where disconnection would pose a high risk to patients or users (refer to Problem section) • follow the manufacturer's instructions for use provided on the packaging carton to reduce the risk of disconnection (see extract in the Appendix) • do not leave these syringes unattended while connected to Luer fittings. 													
Distributed to: <table border="0"> <tr> <td>NHS trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>OFSTED</td> <td>– Directors of Children's Services</td> </tr> <tr> <td>Commission for Social Care Inspection (CSCI)</td> <td>– Headquarters</td> </tr> <tr> <td>Healthcare Commission (CHAI)</td> <td>– Headquarters</td> </tr> <tr> <td>Primary care trusts in England</td> <td>– Chief Executives*</td> </tr> <tr> <td>Health Protection Agency (HPA)</td> <td>– Directors</td> </tr> </table> <p style="text-align: right;">* via CE Bulletin</p>	NHS trusts in England	– Chief Executives*	OFSTED	– Directors of Children's Services	Commission for Social Care Inspection (CSCI)	– Headquarters	Healthcare Commission (CHAI)	– Headquarters	Primary care trusts in England	– Chief Executives*	Health Protection Agency (HPA)	– Directors	▶ Page 3
NHS trusts in England	– Chief Executives*												
OFSTED	– Directors of Children's Services												
Commission for Social Care Inspection (CSCI)	– Headquarters												
Healthcare Commission (CHAI)	– Headquarters												
Primary care trusts in England	– Chief Executives*												
Health Protection Agency (HPA)	– Directors												
Contacts: Details of manufacturer contacts and MHRA contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.	▶ Page 4												
Appendix: Extract from instructions for use on the carton.	▶ Page 6												

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 17 September 2007

Deadline (action complete): 08 October 2007

Device:

BD Medical Surgical Systems Plastipak™ 1ml, 2ml, 5ml and 10ml hypodermic Luer slip syringes manufactured between April 2007 and August 2007.

No other BD Medical Surgical Systems products are affected.

For your information details of the affected devices are given in the table below.

Syringe size	Product code	NHS Supply Chain Code	Batch number
1ml concentric luer slip tip	300013	FWC003	0705004, 0705007, 0705013, 0705017, 0705020, 0705027, 0705031, 0706008, 0706014, 0706034, 0707003, 0707005, 0707031, 0707035, 0707039
2ml concentric luer slip tip	300185	FWC000	0704029, 0704035, 0705003, 0705010, 0705015, 0705018, 0705022, 0705026, 0705030, 0706001, 0706010, 0706011, 0706015, 0706022, 0706033, 0706036, 0707002, 0707006, 0707010, 0707014, 0707017, 0707027, 0707032
5ml concentric luer slip tip	302187	FWC306	0704033, 0704031, 0704034, 0704037, 0705002, 0705001, 0705005, 0705009, 0705012, 0705014, 0705016, 0705019, 0705023, 0705025, 0705029, 0705033, 0706003, 0706006, 0706007, 0706009, 0706013, 0706017, 0706021, 0706026, 0706030, 0706032, 0706035, 0706037, 0707004, 0707007, 0707009, 0707013, 0707015, 0707018, 0707022, 0707024, 0707030, 0707033, 0707038
10ml eccentric luer slip tip	302188	FWC128	0704177, 0704178, 0704180, 0704181, 0704182, 0705105, 0705107, 0705108, 0705110, 0705111, 0705112, 0705113, 0705116, 0705118, 0705120, 0705121, 0705122, 0705124, 0705127, 0705129, 0705130, 0705133, 0705136, 0705138, 0705141, 0705143, 0705146, 0706104, 0706102, 0706104, 0706106, 0706108, 0706110, 0706111, 0706113, 0706115, 0706117, 0706118, 0706120, 0706122, 0706124, 0706125, 0706126, 0706128, 0706129, 0706131, 0706134, 0706136, 0706137, 0706138, 0706139, 0706142, 0706143, 0706144, 0706104, 0706102, 0706104, 0706106, 0706108, 0706110, 0706111, 0706113, 0706115, 0706117, 0706118, 0706120, 0706122, 0706124, 0706125, 0706126, 0706128, 0706129, 0706131, 0706134, 0706136, 0706137, 0706138, 0706139, 0706142, 0706143, 0706144

Problem:

BD Medical Surgical Systems and the MHRA have recently received an unusually high number of reports relating to 1ml, 2ml, 5ml and 10ml Plastipak™ Luer slip hypodermic syringes where the syringe has spontaneously disconnected from, or failed to maintain a secure connection to, a Luer fitting.

Disconnections have particularly been associated with these products when used with needle-free connectors. However, disconnections from other devices have also been reported.

If disconnection and leakage could result in an unknown or reduced dose of a critical medication, or users/patients being splashed with hazardous substances, these should be considered high risk situations.

BD Medical Surgical Systems has identified that the problems reported relate to syringes manufactured between April 2007 and August 2007. BD Medical Surgical Systems are extensively investigating these reports to identify the root cause of the problems reported. This period coincides with the use of a new plastic for the manufacture of the syringes and BD currently believes this to be a significant factor. Since August 2007 BD Medical Surgical Systems has reverted to the original material for these products. Devices manufactured with the new plastic between April 2007 and August 2007 will no longer be supplied. However, there is insufficient replacement product immediately available to effect a recall of these devices.

Distribution:

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

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

- Adult intensive care units
- All clinical departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anti-coagulation clinics
- Biochemists
- Chief pharmacists
- Clinical governance leads
- Dental staff
- Health and safety managers
- IV nurse specialists
- Laboratory staff
- Medical staff
- Midwifery staff
- Nursing staff
- Occupational health departments
- Palliative care teams
- Paramedics
- Pharmacists
- Purchasing managers
- Risk managers
- Theatre managers

OFSTED to:

Directors of children's services for onward distribution to:

- Children's services providing nursing care

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Children's hospices
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Laboratories in the independent sector
- Private medical practitioners
- Private midwives

Commission for Social Care Inspection (CSCI) to:

Headquarters for onward distribution to:

- Care homes providing nursing care (adults)
- Nursing agencies

Primary care trusts to:

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

- Community children's nurses
- Community dental practices
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- District nurses
- General dental practitioners
- General practitioners
- Health visitors
- Immunisation co-ordinators
- Infection control nurses
- Minor injury units
- NHS walk-in centres
- Nutritional nurse specialists
- Occupational health departments
- Palliative care team
- Pharmaceutical advisors
- Podiatrists
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Health Protection Agency to:

Directors for onward distribution to:

- Heads of health, safety and quality
- Health protection nurses
- HPA laboratories
- Laboratory managers
- Risk manager
- Safety officers

Contacts:

Enquiries to the manufacturer should be addressed to:

Tina Lattimer
BD Medical Surgical Systems
The Danby Building
Edmund Halley Road
Oxford Science Park
Oxford OX4 4DQ

Customer Services Dept.
BD Medical Surgical Systems
The Danby Building
Edmund Halley Road
Oxford Science Park
Oxford OX4 4DQ

Tel: 01865 781 518
Fax: 01865 781 501

Tel: 01865 781 666
Fax: 01865 781 627

E-mail: tina_lattimer@europe.bd.com

Enquiries to the MHRA should quote reference number **2007/007/012/401/008** and be addressed to:

Technical aspects:

Ainsley Wickens or Catriona Blake
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3273 / 3219
Fax: 020 7084 3209

E-mail: ainsley.wickens@mhra.gsi.gov.uk
catriona.blake@mhra.gsi.gov.uk

Clinical aspects:

Jonathan Plumb
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3128
Fax: 020 7084 3111

E-mail: jonathan.plumb@mhra.gsi.gov.uk

Change of address or removal from address list for CSCI and Healthcare Commission:

CSCI Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0845 015 0120

E-mail: enquiries@csci.gsi.gov.uk

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre
Medicines and Healthcare products Regulatory Agency
Market Towers, 1 Nine Elms Lane, London SW8 5NQ
Telephone 020 7084 3080 or Fax 020 7084 3109
or e-mail: aic@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

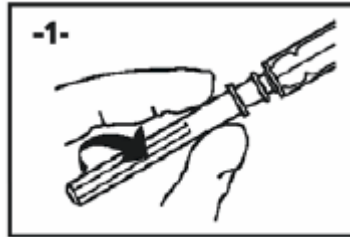
Further information about **SABS** can be found at www.info.doh.gov.uk/sar2/cmopatie.nsf

MHRA is an executive agency of the Department of Health
© Crown Copyright 2007

Addressees may take copies for distribution within their own organisations

Appendix to MDA/2007/071

Extract from instructions for use provided on the packaging carton. These instructions relate to attachment of a syringe to a needle. The instruction to push while turning is applicable when connecting a syringe to any device with a female Luer slip connector.



Push while turning

CAUTION: Where local and/or institutional procedures permit/require transportation of the filled syringe, use a passive recapping technique to cover the needle before transporting to the point of administration. Needle stick with a contaminated needle may lead to serious illness such as HIV, AIDS, Hepatitis and other infectious diseases. Do not force the shield onto the needle, as the needle may penetrate the shield causing injury. Seat the needle firmly on the syringe with a push and a clockwise twist. Pull the shield straight off.