

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/087

Issued: 23<sup>rd</sup> October 2007

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
<b>UPDATE</b>	✓
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section								
<p><b>Medical Device/Equipment:</b> Syringes: BD Medical Surgical Systems Plastipak™ 1ml, 2ml, 5ml and 10ml hypodermic Luer slip syringes manufactured between April 2007 and August 2007.</p>	▶ ①								
<p><b>Problem:</b> 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.</p>	▶ ②								
<p><b>Action by:</b> All healthcare and care workers who use these devices and those involved in their purchase, supply and distribution.</p>	▶ ③								
<p><b>Action:</b> Ensure local systems are in place to make sure that users:</p> <ul style="list-style-type: none"> <li>• 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 on pages 2 and 3)</li> <li>• follow the manufacturer's instructions for use provided on the packaging carton to reduce the risk of disconnection (see extract in the Appendix)</li> <li>• Do not leave these syringes unattended while connected to Luer fittings.</li> </ul>	▶ ④								
<p><b>Distributed by NIAIC to:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>General Dental Practitioners</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Community Pharmacists</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td>Hospices</td> </tr> </table> <p><b>For onward distribution see Section 5</b></p>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	General Dental Practitioners	Chief Executive of each Agency	Community Pharmacists	NIAIC Liaison Officers	Hospices	▶ ⑤
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<p><b>Contacts</b> Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥								
<p><b>Feedback Requirements to NIAIC</b> In accordance with PEL(06)17 acknowledgment of assurance should be given:-</p>	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

## 1. DEVICE/EQUIPMENT:

BD Medical Surgical Systems Plastipak™ 1ml, 2ml, 5ml and 10ml hypodermic Luer slip syringes manufactured between April 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. **Batch numbers added to the list of affected 10ml syringes since the issue of MDEA(NI)2007/77 appear in bold italic.**

Syringe size	Product code	Batch number
1ml concentric Luer slip tip	300013	0705004, 0705007, 0705013, 0705017, 0705020, 0705027, 0705031, 0706008, 0706014, 0706034, 0707003, 0707005, 0707031, 0707035, 0707039
2ml concentric Luer slip tip	300185	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	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	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, 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, <b>0707103, 0707105, 0707106, 0707107, 0707109, 0707110, 0707113, 0707114, 0707116, 0707117, 0707119, 0707120, 0707122, 0707124, 0707125, 0707127, 0707128, 0707130, 0707132, 0707134, 0707135, 0707137, 0707138, 0707139, 0707140, 0707141</b>

## 2. 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 is 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.**

### **3. ACTION BY:**

All healthcare and care workers who use these devices and those involved in their purchase, supply and distribution.

### **4. ACTION:**

Ensure local systems are in place to make sure that users:

- 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.

### **5. ONWARD DISTRIBUTION TO:**

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

- 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
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Sterile Services Departments
- Community children's nurses
- Community midwives
- Community nurses
- Community pharmacists
- District nurses
- Health visitors
- Immunisation co-ordinators
- Infection control nurses
- Minor injury units
- Nutritional nurse specialists
- Occupational health departments
- Palliative care team
- Podiatrists
- Practice managers
- Practice nurses
- School nurses

## 6. 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  
Tel: 01865 781 518  
Fax: 01865 781 501

E-mail: [tina\\_lattimer@europe.bd.com](mailto:tina_lattimer@europe.bd.com)

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

Tel: 01865 781 666  
Fax: 01865 781 627

Enquiries to NIAIC should quote reference number MDEA(NI)2007/87 and be addressed to:

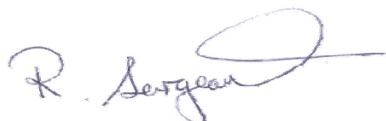
Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868  
Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

<b>Deadline (Email received)</b>	<b>: 24<sup>th</sup> Nov 2007</b>
<b>Deadline (action underway)</b>	<b>: 29<sup>th</sup> Oct 2007</b>
<b>Deadline (action complete)</b>	<b>: 22<sup>nd</sup> Nov 2007</b>



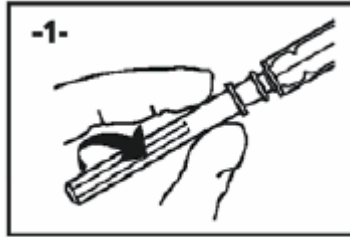
Robert Sergeant  
NIAIC Operational Manager

### HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*

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.