

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/051

Issued: 3<sup>rd</sup> July 2008



**HEALTH ESTATES**

creating healing environments

For:

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

	Section
<p><b>Medical Device/Equipment:</b> Procedure packs from various manufacturers which contain BD Medical Surgical Systems 2ml, 5ml and 10ml Plastipak Luer slip syringes.</p>	▶ ①
<p><b>Problem:</b> Potential for the BD Luer slip syringes supplied in procedure packs to spontaneously disconnect or fail 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 procedure packs and those involved in their supply and distribution.</p>	▶ ③
<p><b>Action:</b> Ensure local systems are in place so that where a procedure pack contains BD Luer slip syringes and when the use of the syringes is unavoidable:</p> <ul style="list-style-type: none"> <li>the syringes are used with caution and their use is avoided in situations where disconnection would pose a high risk to patients or users</li> <li>the syringe is firmly attached to all Luer connections</li> <li>syringes are not left unattended while connected to Luer fittings</li> </ul>	▶ ④
<p><b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p style="text-align: right;">Hospices</p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p>	
<p><b>Acknowledge Receipt of Alert:</b> 7<sup>th</sup> July 2008</p>	▶ ⑦
<p><b>Action Under Way:</b> 1<sup>st</sup> August 2008</p>	
<p><b>Action Complete:</b> 1<sup>st</sup> September 2008</p>	

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

## 1. DEVICE/EQUIPMENT:

Procedure packs from various manufacturers which contain BD Medical Surgical Systems 2ml, 5ml and 10ml Plastipak Luer slip syringes.

## 2. PROBLEM:

BD Medical Surgical Systems has identified that several batches of non sterile 2ml, 5ml and 10ml Plastipak syringes may spontaneously disconnect or fail to maintain a secure connection to Luer fittings (this problem was identified in relation to sterile products in Autumn 2007 and the NIAIC issued MDEA(NI)2007/077 to users).

BD has not supplied these non sterile syringes directly to users; the syringes have been provided in procedure packs via third party companies.

These syringes have the BD logo on them but do not carry a batch number or product code to enable them to be identified. The code associated with the procedure packs is not related to any syringe codes.

The following manufacturers have identified from their records that syringes from the affected batches have been included in their procedure packs.

Alcon Laboratories (UK) Ltd  
BD Ophthalmic Systems Ltd  
Molnlycke Healthcare Group  
Rociale  
Smiths Medical  
Sunlight Service Group  
Unisurge

These companies have or will be issuing Field Safety Notices advising users which of their products are affected. These Field Safety Notices can be found on the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk)).

The MHRA does not have complete details of the distribution of syringes from the affected batches and therefore cannot be confident that other procedure packs are not affected. Users are advised to treat BD Luer slip syringes found in any other procedure pack with the same caution.

## 3. ACTION BY:

All healthcare and care workers who use procedure packs and those involved in their supply and distribution.

## 4. ACTION:

Ensure local systems are in place so that where a procedure pack contains BD Luer slip syringes and when the use of the syringes is unavoidable:

- the syringes are used with caution and their use is avoided in situations where disconnection would pose a high risk to patients or users
- the syringe is firmly attached to all Luer connections
- syringes are not left 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:

- A&E departments
- All wards
- Medical directors
- Nursing executive directors
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics, Residential and Nursing Homes through RQIA

## 6. CONTACTS:

Enquiries to NIAIC should quote reference number MDEA(NI)2008/051 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)

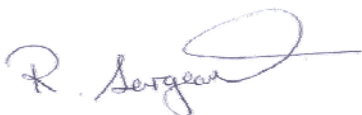
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

**Acknowledge Receipt of Alert:**  
7<sup>th</sup> July 2008

**Action Under Way:**  
1<sup>st</sup> August 2008

**Action Complete:**  
1<sup>st</sup> September 2008



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)2007/01. 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*