

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/51

Issued: 13 September 2004

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section		
<p><b>Medical Device/Equipment:</b> Lancing devices for obtaining blood samples.</p>	▶ ①		
<p><b>Problem:</b> Inappropriate use of some lancing devices with the risk of:</p> <ul style="list-style-type: none"> <li>• Cross infection between patients.</li> <li>• Needlestick injury to healthcare and care workers.</li> </ul>	▶ ②		
<p><b>Action by:</b> All healthcare and care workers using lancing devices.</p>	▶ ③		
<p><b>Action:</b> Healthcare and care workers should not use lancing devices intended only for self use to obtain a patient's blood sample.</p>	▶ ④		
<p><b>Distributed by NIAIC to:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">                     Chief Executive of each HSS Board                      Chief Executive of each HSS Trust                      Chief Executive of each Agency                      NIAIC Liaison Officers                 </td> <td style="width: 50%; border: none;">                     General Medical Practitioners                      Community Pharmacists                      Hospices                 </td> </tr> </table>	Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	General Medical Practitioners Community Pharmacists Hospices	▶ ⑤
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<p><b>Contacts</b> Details of NIAIC contacts for technical aspects.</p>	▶ ⑥		
<p><b>Feedback Requirements to NIAIC</b> If you have concerns about the instructions for use for a particular device then please contact the manufacturer. If after discussion with the manufacturer you are not satisfied with the instructions, then please report the matter to the NIAIC.</p>	▶ ⑦		

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

## **1. DEVICE/EQUIPMENT:**

There are three types of lancing device commonly available:

### **1) Disposable single-use lancing devices**

In these lancing devices the firing mechanism and the lancet are integral and the entire device is disposed of after a single use.

### **2) Lancing devices intended only for self use**

This type of lancing device is usually provided to patients, or purchased from retail outlets, as part of a blood glucose system for self-monitoring (i.e. in combination with a glucose meter, reagents and test strips etc.).

The lancing device supplied in these systems is intended to be used by one patient only on themselves and not by healthcare and care workers. A new lancet is used on each occasion but the lancing device itself may be used repeatedly by that patient as long as instructions for decontamination provided by the manufacturer are followed.

### **3) Lancing devices intended for use by healthcare and care workers to obtain blood samples from more than one patient**

This type of lancing device is usually supplied directly to healthcare and care workers by the manufacturer's sales team. Often this type of lancing device is supplied separately from the other components of the blood monitoring system.

These lancing devices are intended to be used by healthcare and care workers to obtain blood samples from more than one patient. A new lancet must be used on each occasion that a blood sample is obtained but the lancing device may be used repeatedly, on multiple patients, as long as instructions for decontamination provided by the manufacturer are followed.

## **2. PROBLEM:**

- NIAIC has been informed that the Medicines and Healthcare products Regulatory Agency (MHRA) is aware that lancing devices intended only for self use have been used for obtaining blood samples from more than one patient. This practice has been identified as a risk factor in a case where a patient acquired hepatitis B.
- Commonly the method of removal of the used lancet is different for devices intended for use by healthcare and care workers on multiple patients and devices intended only for self use. In the latter case the used lancet may be exposed during the disposal process. The risk of a needlestick injury to a healthcare or care worker is likely to be increased if they use this type of lancing device for obtaining blood samples.

## **3. ACTION BY:**

All healthcare and care workers using lancing devices.

## **4. ACTION:**

- If you are using a lancing device to take blood samples from multiple patients check that it is intended for this use. This should be clearly indicated in the instructions for use that the manufacturer provides with the lancing device or blood monitoring system.
- Healthcare and care workers should not use lancing devices intended only for self use to obtain a patient's blood sample. Healthcare and care workers should use a disposable single-use device or a device for multiple testing.

## 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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Adult and Paediatric Intensive Care Units
- All Wards
- Anaesthetists
- Anticoagulation Clinics
- Anticoagulation Service Providers
- Anticoagulation Therapy Nurses
- Consultant Diabetologists
- Consultant Endocrinologists
- Consultant Physicians
- Diabetes Specialist Nurses
- Infection Control Teams
- Medical Directors
- Nursing Directors
- Occupational Health Departments
- Trust Pharmacy Managers
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Outpatient Departments
- Accident & Emergency Departments
- Allied Health Professionals
- Day Procedure Units
- Practice Nurses
- Directors of Public Health
- Community Care Staff
- Day Care Centres
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSS Board R&I Units

## 6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2004/51 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:

If you have concerns about the instructions for use for a particular device then please contact the manufacturer. If after discussion with the manufacturer you are not satisfied with the instructions, then please report the matter to the NIAIC.



Brian Godfrey  
NIAIC 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)2004/01. 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*