

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/84

Issued: 28 November 2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section								
<p>Medical Device/Equipment: Lancing devices - including Roche Accu-Chek Softclix, Softclix II, Softclix Plus and Multiclix lancing devices.</p>	▶ ①								
<p>Problem: These, and some other, lancing devices are intended for self-use by one patient only, to take blood samples for self-monitoring. The use of Softclix and Softclix II lancing devices by healthcare and care workers to take blood samples from multiple patients has been implicated in the transmission of hepatitis B between patients.</p>	▶ ②								
<p>Action by: All healthcare and care workers involved in the purchase, supply, provision or use of lancing devices.</p>	▶ ③								
<p>Action: When obtaining blood samples from more than one patient healthcare and care workers must ensure that the lancing device that they use is intended for this purpose.</p>	▶ ④								
<p>Distributed by NIAIC to:</p> <table border="0"> <tr> <td>Chief Executive of each HSS Board</td> <td>General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> <p>For onward distribution see Section 5</p>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Community Pharmacists	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
Chief Executive of each HSS Trust	Community Pharmacists								
Chief Executive of each Agency	Hospices								
NIAIC Liaison Officers									
<p>Contacts Details of manufacturer contacts, NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p>Feedback Requirements to NIAIC None Required</p>	▶ ⑦								

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

1. DEVICE/EQUIPMENT:

Lancing devices - including Roche Accu-Chek Softclix, Softclix II, Softclix Plus and Multiclix lancing devices.

2. PROBLEM:

These and some other, lancing devices are intended for **self-use** by **one patient** only, to take blood samples for self-monitoring.

The use of Softclix and Softclix II lancing devices by healthcare and care workers to take blood samples from multiple patients has been implicated in the transmission of hepatitis B between patients.

3. ACTION BY:

All healthcare and care workers involved in the purchase, supply, provision or use of lancing devices.

4. ACTION:

When testing multiple patients, healthcare and care workers **should not use** single patient lancing devices such as the Roche Accu-Chek Softclix, Softclix II, Softclix Plus or Multiclix lancing devices to obtain blood samples.

When obtaining blood samples from more than one patient healthcare and care workers must ensure that the lancing device that they use is intended for this purpose.

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Consultant Diabetologists
- Consultant Endocrinologists
- Obstetrics
- Anticoagulation Service Providers
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- All Wards
- Practice Nurses
- Diabetes Specialist Nurses
- Pharmacy Managers
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Day Care Centres
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSSRIA
- Operating Theatre Staff
- Outpatient Departments
- Infection Control Staff
- Accident & Emergency Departments
- Allied Health Professionals
- Day Procedure Units

6. CONTACTS:

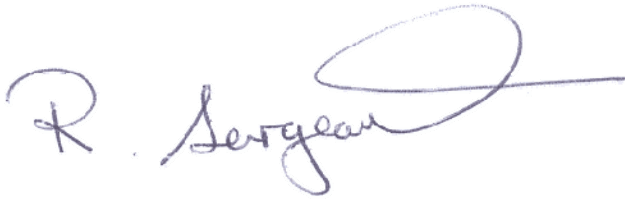
Enquires to NIAIC should quote reference number MDEA(NI)2005/84 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868
Fax: 028 9052 3900
Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required.

A handwritten signature in blue ink that reads "R. Sergeant". The signature is fluid and cursive, with a large loop at the end.

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)2005/01. 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

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