



Medicines and Healthcare products
Regulatory Agency

Medical Device ALERT

Ref. MDA/2005/063
Issued: 28 November 2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	

	Further Information												
<p>DEVICE: Lancing devices - including Roche Accu-Chek Softclix, Softclix II, Softclix Plus and Multiclix lancing devices.</p>													
<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>	▶												
<p>ACTION BY: All healthcare and care workers involved in the purchase, supply, provision or use of lancing devices.</p>													
<p>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.</p>	▶												
<p>DISTRIBUTED to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">NHS Trusts (England)</td> <td style="width: 50%;">– Chief Executives*</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 (England)</td> <td>– Chief Executives*</td> </tr> <tr> <td>Social Services (England)</td> <td>– Directors*</td> </tr> <tr> <td>Health Protection Agency (HPA)</td> <td>– Directors</td> </tr> </table> <p style="text-align: right; margin-right: 20px;">* via CE Bulletin</p>	NHS Trusts (England)	– Chief Executives*	Commission for Social Care Inspection (CSCI)	– Headquarters	Healthcare Commission (CHAI)	– Headquarters	Primary Care Trusts (England)	– Chief Executives*	Social Services (England)	– Directors*	Health Protection Agency (HPA)	– Directors	▶
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Health Protection Agency (HPA)	– Directors												
<p>CONTACTS: Details of manufacturer contacts, MHRA contacts for technical and clinical aspects. Change of address or removal from address list for CSCI and Healthcare Commission.</p>	▶												

▶ **Further information supplied in the following pages.**

The full text of this notice is on our website: <http://www.mhra.gov.uk>

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PROBLEM:

Single patient lancing devices e.g. Roche Accu-Chek Softclix, Softclix II, Softclix Plus and Multiclix are intended for self-use by one patient only, to take blood samples for self-monitoring. They are not intended for use by healthcare or care workers to obtain blood samples from multiple patients because there is a risk of cross infection and the transmission of blood borne viruses.

The MHRA is aware that the inappropriate use of the Softclix and Softclix II devices by healthcare and care workers to obtain blood samples from multiple patients has been implicated in recent outbreaks of hepatitis B in care homes in England, in which two patients have died.

ACTION:

When obtaining blood samples from patients, healthcare and care workers must ensure that they use **either** a lancing device that is intended for use by healthcare and care workers to obtain blood samples, **or** a disposable single-use lancing device (Please see MDA/2004/044 – Lancing devices for obtaining blood samples).

Healthcare and care workers should not use lancing devices intended for single patient use such as the Roche Accu-Chek Softclix, Softclix II, Softclix Plus or Multiclix lancing devices to obtain blood samples from multiple patients.

Lancing devices such as the Accu-Chek Softclix Pro have been developed for use by healthcare and care workers to obtain blood samples from multiple patients. Multiple patient lancing devices and disposable single-use lancing devices are also available from other manufacturers.

Since August 2005 disposable single-use lancing devices have been available on prescription.

ACTION DEADLINES FOR THE SAFETY ALERT BROADCAST SYSTEM (SABS)

Trust managers should ensure that measures to implement the 'Actions' specified above are planned and completed in line with the following SABS deadlines.

Deadline (Action underway): 12 December 2005

Action plan to be agreed and actions started.

Deadline (Action complete): 30 January 2006

All actions to be completed.

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

DISTRIBUTION:

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

TRUSTS to:

- Liaison officers (for onward distribution)
- Accident & emergency departments
- Adult & paediatric intensive care units
- All wards
- Ambulance paramedics and technicians
- Ambulance service directors
- Ambulance trust operations directors
- Anaesthetists
- Anticoagulation clinics
- Anticoagulation service providers
- Anticoagulation therapy nurses
- Clinical governance leads
- Consultant diabetologists
- Consultant endocrinologists

- Consultant physicians
- Diabetes specialist nurses
- Directors of anaesthetics
- Directors of clinical pathology
- Health & safety officers
- Infection control teams
- Medical directors
- Nursing executive directors
- Occupational health departments
- Out patients clinics and departments
- Pharmacists
- Pharmacy departments
- Point of care advisory committees
- Procurement managers/departments
- Risk managers
- Supplies managers/departments

DISTRIBUTION (continued):

PRIMARY CARE TRUSTS to:

- Liaison officers (for onward distribution)
- Clinical governance leads
- Community diabetes specialist nurses
- Community diabetologists
- Community hospitals
- Community pharmacists
- Directors of public health
- District nurses
- General medical practitioners
- Health visitors
- Infection control teams
- Lead nurses
- Midwives
- Pharmaceutical advisors
- Practice nurses
- Prison healthcare managers
- Retail pharmacists
- School nurses

COMMISSION FOR SOCIAL CARE INSPECTION (CSCI) to:

- Headquarters (for onward distribution)
- Care homes providing nursing care
- Care homes providing personal care
- Domiciliary care providers

HEALTH PROTECTION AGENCY to:

- Directors (for onward distribution)
- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Head of health, safety & quality
- Heads of department
- Health protection nurses
- HPA laboratories
- Regional directors
- Regional epidemiologists
- Regional leads
- Regional microbiologists
- Risk managers
- Safety officers

HEALTHCARE COMMISSION (CHAI) to:

- Headquarters (for onward distribution)
- Clinics
- Hospices
- Hospitals in the independent sector
- Mental health hospitals
- Private medical practitioners

SOCIAL SERVICES to:

- Liaison officers (for onward distribution)
- Care at home staff
- Day centres

CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Laurence Teague
Business Improvement Manager
Roche Diagnostics Ltd
Bell Lane
Lewes
East Sussex
BN7 1LG

Tel: 01273 484847
Fax: 01273 484645

E-mail: laurence.teague@roche.com

CONTACTS (continued):

Enquiries to the MHRA should quote reference number **2005/007/026/401/004** and be addressed to:

Technical aspects:

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

Tel: 020 7084 3273 / 3271

Fax: 020 7084 3209

E-mail: ainsley.wickens@mhra.gsi.gov.uk
mojisola.ajeneye@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>

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