

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/69

Issued: 11 October 2005

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Central venous catheter and pacing lead introducer kits.	▶ ①
Problem: Misuse of guidewire straighteners; potential for venous embolisation.	▶ ②
Action by: All clinicians who use this device.	▶ ③
Action: Be aware of the intended use of this device and the risks associated with off-label use.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
Contacts NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Central venous catheter and pacing lead introducer kits.

2. PROBLEM:

Guidewire straighteners are being used to assist in the placement of central venous lines and pacing leads during direct, 'cut-down' procedures for vascular access.

The guidewire straightener has been manufactured to fit on to the hub of an introducer needle, enabling the J-shaped guidewire to pass easily into the vasculature. Reports to the MHRA have indicated that the straightener has also been placed in the venotomy when accessing the vasculature during central venous line and permanent pacemaker wire placement. This has resulted in embolisation of the straightener on several occasions. This type of incident was highlighted in the MHRA publication 'One Liners' in December 2004. Further similar incidents have been reported subsequent to this.

The MHRA considers this to be a generic product-wide problem because it has had reports involving introducer kits from different manufacturers.

The NIAIC has previously warned against the off-label use of medical devices and emphasises the importance of reading the instructions for use and using devices as intended by the manufacturer (Ref: MDEA(NI)2004 06).

3. ACTION BY:

All clinicians who use this device.

4. ACTION:

- Ensure that you are aware of the instructions for use for the device employed.
- Do not introduce guidewire straighteners into the venotomy site. Use dilators which are designed for this purpose.
- If you choose to use the straightener in an off-label manner, be aware of the risks involved and the liabilities that may arise in the event of an adverse incident.
- Refer to MDEA(NI)2004 06 for further advice regarding off-label use.
- Healthcare professionals inserting central venous lines and permanent pacing systems should receive adequate training.

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
- Directors of Anaesthetics
- Nurse Directors
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Coronary Care
- Consultant Cardiologists
- Consultant Surgeons
- Adult & Paediatric Intensive Care Units

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2005/69 and be addressed to:

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

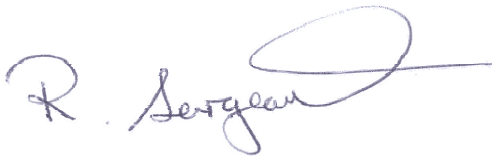
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



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