

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/14

Issued: 9 July 2003

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Vygon Intravenous Extension Lines with a white slide clamp – Octopus and Single Bionector with Extension.	▶ ①
Problem: A change of design of the slide clamp has resulted in a number of lines being partially cut during use with the potential for interruption of therapy, air embolus, or blood loss.	▶ ②
Action by: All nursing and medical personnel using these devices.	▶ ③
Action: Arrange substitution as soon as is practical. In the meantime, follow manufacturer's advice overleaf to reduce any immediate risk to patients.	▶ 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 For onward distribution see Section 5	▶ ⑤ Hospices
Contacts NIAIC contact details	▶ ⑥
Feedback Requirements to NIAIC None	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Product Code	Product Description	Lot Numbers
5222.01	Bionector with 13.5cm extension and clamp	090402EG to 240403EG
841.03	Octopus 3 lumen with clamps	260402AH to 110403AH
841.24	Double lumen Octopus with two Bionectors and clamps	050402AD to 060603AD
841.25	Double lumen Octopus with one Bionector and clamp	050402AE to 060603AE
841.26	Double equal lumen Octopus with two Bionectors and clamps	030502AA to 060603AA
841.34	Triple lumen Octopus with three Bionectors and clamps	050402AD to 250503AD

2. PROBLEM:

NIAIC has been informed that the MHRA has received several reports of damage occurring to the tubing of these devices when the slide clamp is used. This has resulted in the interruption of intravenous infusion therapy with the potential for air embolus or blood loss.

3. ACTION BY:

All nursing and medical personnel using these devices.

4. ACTION:

- Follow the manufacturer's advice on how to reduce the risk of device damage i.e.
 - Move the clamp to a new position each time it is used
 - Clamp in the middle section of the tube (away from the hub)
 - Only push the tube halfway across the slit of the clamp
- Examine the line for any signs of damage after the clamp has been released. Change the line promptly if damage has occurred and report the fault to NIAIC.
- Where patients are discharged home with these devices in situ, the above advice should be made available to the patient and their carers.
- Vygon will contact Trusts to arrange delivery of new stock, which will be exchanged for any affected product as listed above. The new product will incorporate a slightly larger clamp to eliminate the problem. Vygon aim to complete this action within 8 weeks.

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
- Medical Device/Equipment Co-ordinators
- All wards and departments including Theatres
- Adult & paediatric intensive care units
- Oncology units including outpatients
- Special care baby units
- Paediatric units including outpatients
- Accident & emergency departments
- Operating theatres
- Recovery Rooms
- Medical Directors
- Nursing Executive Directors
- Consultant Clinicians
- IV Specialist Nurses
- All Community nurses
- Directors of Public Health
- Independent Health and Social Care Providers including residential, nursing homes and private clinics

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/14 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.



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 Safety Notice SN (NI) 2003/01. 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