

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/57

Issued: 13 June 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: IV extension lines: model 6222 range of V-Green narrow bore extension lines manufactured by Vygon (UK) Ltd.</p>	▶ ①
<p>Problem: There is a potential for the female connector of the line to crack when used to deliver propofol (an intravenous anaesthetic agent). This may result in leakage of this drug and failure to induce and maintain general anaesthesia. The manufacturer has initiated a recall of specific batch numbers irrespective of the drugs they are being used with.</p>	▶ ②
<p>Action by: Anaesthetists, operating department practitioners, theatre managers, anaesthetic nurses and supplies departments.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify and quarantine affected devices. The batch numbers are listed overleaf. If propofol is not used in your department, the affected devices should still be quarantined. Contact the manufacturer to organise return and appropriate alternatives to affected stock. Contact details are provided overleaf. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical 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:

This device is a disposable IV extension line with a male/female Luer lock and clamp and is made from polyethylene-lined PVC.

The affected models and batch numbers are:

Model number	Recalled batch number
6222.011	K06N280, K07B060
6222.051	K06N281, K07C098
6222.071	K06N282, K07B064, K07C091
6222.101	K06N283, K07B061, K07B065, K07C092, K07C099
6222.151	K06N293, K07A027, K07B062, K07B066, K07C096
6222.201	K06N284, K07B063, K07B067, K07C097

2. PROBLEM:

Propofol is an intravenous anaesthetic agent and is lipid-based, which may affect the plastic used in the manufacture of the female Luer lock connector of this device.

The manufacturer is in the process of changing the material of the connector to offer greater resistance to propofol. In the meantime, the manufacturer has recommended the use of alternative products to replace the affected stock.

3. ACTION BY:

Anaesthetists, operating department practitioners, theatre managers, anaesthetic nurses and supplies departments.

4. ACTION:

- Identify and quarantine affected devices. The batch numbers are listed above.
- If propofol is not used in your department, the affected devices should still be quarantined.
- Contact the manufacturer to organise return and appropriate alternatives to affected stock. Contact details are provided overleaf.

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:

- A&E departments
- All clinical areas
- All wards
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiology department
- Clinical governance leads
- Haemodialysis units
- Hospital at home units
- Hospital pharmacies
- Intensive care consultants
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- IV nurse specialists
- Maternity units
- Medical directors
- Medical oncology, directors of
- Midwifery departments
- Neonatology departments
- Nursing executive directors
- Palliative care teams
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics, Residential and Nursing Homes through RQIA
- Community children's nurses
- Community hospitals
- Community nurses
- District nurses
- Equipment libraries and stores
- Nutritional nurse specialists

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Dawn Kulling Ref 0704/16849/19

Vygon (UK) Ltd

Bridge Road

Cirencester

Gloucestershire GL7 1PT

Tel: 01285 886 016 or 886 656

Fax: 01285 650 293

E-mail: dawn.kulling@vygon.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/57 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates

Estate Policy Directorate

Stoney Road

Dundonald

Belfast BT16 1US

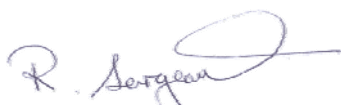
Tel: 028 9052 3868

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)2006/01. 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