

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/04

Issued: 17 January 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: Vygon (UK) Ltd paediatric IV bacterial filter with extension line. Product code: 0807.205. Batch numbers: 050805AA, 020905AA, 160905AA, 180205AA, 030605AA and 180705AA.</p>	▶ ①
<p>Problem: Cracking of the green hub on the filter has resulted in leakage. The manufacturer has recalled specific batches and they believe that this is now complete in Northern Ireland.</p>	▶ ②
<p>Action by: Theatre managers; nursing/medical staff working in paediatric/neonatal units.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify and quarantine stock from affected batches. Contact the manufacturer (Tel: 01285 886 016) to organise return and replacement of stock. 	▶ ④
<p>Distributed by NIAIC to:</p> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p style="text-align: right;">Hospices</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:

Vygon (UK) Ltd paediatric IV bacterial filter with extension line.

Product code: 0807.205

Batch numbers: 050805AA, 020905AA, 160905AA, 180205AA, 030605AA and 180705AA.

2. PROBLEM:

Cracking of the green hub on the filter has resulted in leakage. The manufacturer has recalled specific batches and they believe that this is now complete in Northern Ireland.

3. ACTION BY:

Theatre managers; nursing/medical staff working in paediatric/neonatal units.

4. ACTION:

- Identify and quarantine stock from affected batches.
- Contact the manufacturer (Tel: 01285 886 016) to organise return and replacement of stock.

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:

- Anaesthetists
- Clinical governance leads
- Independent Health and Social Care Providers
– Private Hospitals & Clinics through RQIA
- Intensive care medical staff/paediatrics and neonatal
- Intensive care nursing staff/paediatrics and neonatal
- IV nurse specialists
- Medical and nursing paediatric oncology staff
- Neonatal nurse specialists
- Neonatology departments
- Nursing executive directors
- Paediatric nurse specialists
- Paediatric wards
- Pharmacists
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Dawn Kulling
Vygon reference 0610/15987/12IV
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.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2007/04 and be addressed to:

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

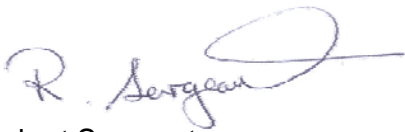
Tel: 028 9052 3868

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