

Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/067

Issued: 5th September 2008



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section								
<p>Medical Device/Equipment: Obturator – Venflon™ IV cannula obturator manufactured by BD. Product code numbers 394252 and 394253. Various lot numbers.</p>	▶ ①								
<p>Problem: Due to a manufacturing problem, there may be cracks and holes in the packaging of the listed obturators for Venflon™ cannulae, which could compromise sterility.</p>	▶ ②								
<p>Action by: All staff who use, supply or purchase this device.</p>	▶ ③								
<p>Action:</p> <ul style="list-style-type: none"> Identify and isolate the affected devices. Do not use the affected devices. Contact the manufacturer to arrange for return and replacement of the devices. 	▶ ④								
<p>Distributed by NIAIC to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">Hospices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>GP's and GP Practices Managers</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	Hospices	Chief Executive of each HSS Trust	GP's and GP Practices Managers	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
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NIAIC Liaison Officers									
<p>Contacts Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥								
<p>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</p>									
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%; border: none;"> <p>Acknowledge Receipt of Alert: 8th Sept 2008</p> </td> <td style="width: 33%; border: none;"> <p>Action Under Way: 18th Sept 2008</p> </td> <td style="width: 33%; border: none;"> <p>Action Complete: 6th Oct 2008</p> </td> </tr> </table>	<p>Acknowledge Receipt of Alert: 8th Sept 2008</p>	<p>Action Under Way: 18th Sept 2008</p>	<p>Action Complete: 6th Oct 2008</p>	▶ ⑦					
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

1. DEVICE/EQUIPMENT:

BD obturators for use with BD Venflon™ IV cannulae. The obturator protects the inner lumen of the catheter from coagulation and thrombus formation after discontinuation of infusion. The following lot numbers and product codes are being recalled. All other lot numbers are unaffected.

Product code	Product description	Lot number
394252 NHS supply chain code N/A	Obturator for Venflon™ 20G x 32mm	7241019 7268675 7268676 7277850 7284053 7290890 7295151 7304342 7304343 7311555 7311556 7318790 7325820 7325821 7332478 7332479
394253 NHS supply chain code N/A	Obturator for Venflon™ 18G x 45mm	7268672 7277848 7284051 7290891 7295152

The MHRA has issued this Medical Device Alert to support the manufacturer's recall action (field safety notice issued May 2008), as the devices being recalled have been widely distributed.

2. PROBLEM:

Due to a manufacturing problem, there may be cracks and holes in the packaging of the listed obturators for Venflon™ cannulae, which could compromise sterility.

3. ACTION BY:

All staff who use, supply or purchase this device.

4. ACTION:

- Identify and isolate the affected devices.
- Do not use the affected devices.
- Contact the manufacturer to arrange for return and replacement of the devices.

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
- Adult and paediatric intensive care units
- All wards
- Ambulance staff and paramedics
- Director of anaesthetists
- IV nurse specialists
- Lead nurse infection control
- Medical directors
- Nursing executive directors
- Outpatient clinics
- Risk managers
- Supplies managers
- RSS Supplies managers
- Theatre managers
- District nurses
- Practice managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Val Mummery
BD Customer Services
c/o Medical Surgical Systems
The Danby Building
Edmund Halley Road
Oxford
OX4 4DG

Tel: 01865 781 666
Fax: 01865 781 501

Enquiries to NIAIC should quote reference number MDEA(NI)2008/67 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

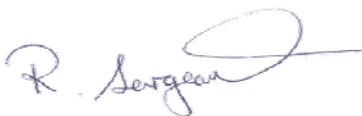
7. FEEDBACK:

Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:
8th Sept 2008

Action Under Way:
18th Sept 2008

Action Complete:
6th Oct 2008



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)2008/01. 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