

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/71

Issued: 14 October 2005

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: bms Critical Care extension sets: part numbers 25-7200 and 25-7150.	▶ ①
Problem: Fluid leakage through Luer lock connector.	▶ ②
Action by: All those who purchase and use these sets.	▶ ③
Action: <ul style="list-style-type: none"> • Immediately remove affected stock from the clinical area and destroy. • Contact the manufacturer or your supplier for replacements or credit. 	▶ 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	Hospices ▶ ⑤
Contacts	▶ ⑥
Feedback Requirements to NIAIC Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑦

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

1. DEVICE/EQUIPMENT:

bms Critical Care Extension Sets:

part numbers 25-7200 (NPC FWL065; PE/PVC Line 200 cm x 1 mmID, M/F, LL) and 25-7150 (NPC FWL064; PE/PVC Line 150 cm x 1 mmID, M/F, LL):

lot numbers 11120, 11304, 11435 and 11451.

2. PROBLEM:

In February 2005, bms Critical Care initiated a recall of these devices (lot numbers 11117 and 11118) in order to address a problem of leakage of drugs and other fluids through the Luer lock. A modified female connector was introduced in an attempt to resolve the problem, but reports of leakage continued, necessitating a further design change. The manufacturer has determined that leakage only occurred if propofol had been administered through the set.

The material of the Luer lock has now been changed to prevent this problem and, to date, no further incidents have been reported with the latest design. However, the MHRA continues to receive reports of connector failure from earlier affected stock that hospitals still hold.

Users should check their stock and, if product from affected batches is identified, it should be removed from use and destroyed.

A total of 10,102 affected sets have been sold in the UK, which would have been purchased either through the NHS Logistics Authority or direct from bms Critical Care Ltd. It is understood that bms have only sold directly to one Trust within Northern Ireland.

3. ACTION BY:

All those who purchase and use these sets.

4. ACTION:

- Immediately remove affected stock from the clinical area and destroy.
- Contact the manufacturer or your supplier for replacements or credit.

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
- Nurse Directors
- Supplies Staff (RSS)
- Special Care Baby Units
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Sterile Services Departments
- Operating Theatre Staff
- Accident & Emergency Departments
- Intensive Care

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Pamela Warren
Sales Office Manager
bms Critical Care Ltd
Springside House
Montague Street
Blackburn
Lancashire
BB2 1ED
Tel: 01254 503 900
Fax: 01254 503 911
E-mail: sales@bmscriticalcare.com

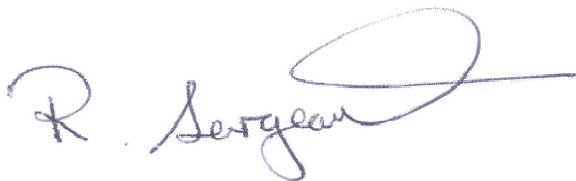
Enquires to NIAIC should quote reference number MDEA(NI)2005/71 and be addressed to:

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:

No 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