

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/22

Issued: 20 August 2003

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: All Baxter Healthcare Ltd Viaflo intravenous solution containers	▶ ①
Problem: Risk of disconnection of intravenous administration sets from solution containers due to inadequate and inappropriate insertion technique.	▶ ②
Action by: All nursing and medical personnel using these containers.	▶ ③
Action: Follow the manufacturer's instructions for use as outlined overleaf on how to secure intravenous sets to the outlet port of this container.	▶ 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 Hospices	▶ ⑤
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:

All Baxter Healthcare Ltd Viaflo intravenous solution containers

2. PROBLEM:

NIAIC has been informed that the MHRA has received several reports of intravenous administration sets disconnecting from the outlet port of Viaflo containers, which have resulted in an interruption in intravenous therapy.

The manufacturer (Baxter Healthcare Ltd) has informed the MHRA that the containers are manufactured from polyolefine, resulting in a rigid outlet port. These containers require a different method of securing an administration set than that used for other similar types of containers. Inadequate and inappropriate insertion of the spike into the port has resulted in the set disconnecting from the outlet port.

3. ACTION BY:

All nursing and medical personnel using these containers.

4. ACTION:

Follow the manufacturer's instructions for use on how to access the outlet port of the container via the spike of an administration set. Adopt the following technique:

- Remove the twist-off protector from the outlet port.
- Hold the base of the outlet port and **firmly** insert the spike to its **maximum** depth using a twisting motion.
- **Do not** apply excessive twisting motions as this will increase the bore size of the outlet port.
- If the set becomes disconnected from the outlet port, **do not** reinsert.

The above instructions for use are not provided with the container; please contact the manufacturer for training material and/or to arrange training sessions (see contacts section).

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 Co-ordinators
- Medical Directors
- Nurse Directors
- IV Specialist Nurses
- All Wards
- Special Care Baby Units
- Trust Pharmacy Managers
- Operating Theatres and Recovery
- Adult and Paediatric Intensive Care Units
- Renal Units and their satellites
- Accident & Emergency Departments
- Board R&I Units for distribution to Independent Health and Social Care Providers specifically Care Homes providing nursing care and private clinics
- Practice Nurses
- District Nurses
- Directors of Public Health
- Community Care Staff

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Medical Information
Baxter Healthcare Ltd
Salthouse Road
Brackmills Industrial Estate
Northampton
NN4 7UF

Tel:01842 767189

Customer Services
Baxter Healthcare Ltd
Wallingford Road
Compton
Newbury
RG20 7QW

Tel:01635 206060 or 01635 206161

Enquires to NIAIC should quote reference number MDEA(NI)2003/22 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