

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/66

Issued: October 2006



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	✓

	Section
<p>Medical Device/Equipment: Blood administration set: volumed blood set manufactured by Sendal SA and distributed by Arcomedical Infusion Ltd. Model number: 3101-TJ, batch number: C6766.</p>	▶ ①
<p>Problem: Risk of blood leakage due to a crack at the Y-site on a single batch of the blood set. This alert is to reinforce the recall undertaken by NHS Supply Chain - England, while it is understood that this product is not on Regional Contract through RSS, assurance can not be given that it has not been purchased as a non-stock item across Northern Ireland.</p>	▶ ②
<p>Action by: All medical and nursing staff, theatre managers and anaesthetists.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Check for and isolate any of the affected batch in stock. • Contact your local supplier to arrange for return and replacement of any of the above product. • Report any incidents involving this device to the NIAIC. 	▶ 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 supplier 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:

**Blood administration set: volumed blood set
manufactured by Sendal SA and distributed by Arcomedical Infusion Ltd.
Model number: 3101-TJ, batch number: C6766.
NHS Supply Chain code: FSB123.**

2. PROBLEM:

Risk of blood leakage due to a crack at the Y-site on a single batch of the blood set. This alert is to reinforce the recall undertaken by NHS Supply Chain - England, while it is understood that this product is not on Regional Contract through RSS, assurance can not be given that it has not been purchased as a non-stock item across Northern Ireland.

3. ACTION BY:

All medical and nursing staff, theatre managers and anaesthetists.

4. ACTION:

- Check for and isolate any of the affected batch in stock.
- Contact your local supplier to arrange for return and replacement of any of the above product.
- Report any incidents involving this device to the NIAIC.

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
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- All Wards
- Independent Health and Social Care Providers – Private Clinics and Hospitals through RQIA
- Sterile Services Departments
- Operating Theatre Staff
- Accident & Emergency Departments
- Intensive Care
- Resuscitation Officers

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mrs Catherine Battersby
Arcomedical Infusion Ltd
5J West Horndon Industrial Estate
Essex
CM13 3XL

Tel: 01277 810 432

Fax: 01277 811 967

E-mail: sales@arcomed.co.uk

Enquires to NIAIC should quote reference number MDEA(NI)2006/66 and be addressed to:

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

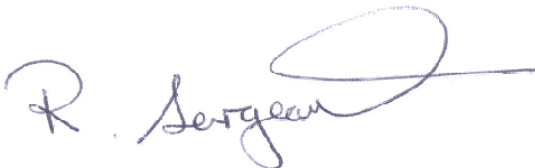
Tel: 028 9052 3868

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