

1. DEVICE/EQUIPMENT:

Arterial pressure monitoring kit – single, red 3ml/hour xtrans[®] series.

2. PROBLEM:

Due to a manufacturing error, there may be loose tap inserts in these kits. This may result in the stopcock becoming dislodged, leading to arterial bleeding.

3. ACTION BY:

All medical and nursing staff. In particular theatre staff/managers, intensive care staff and supplies.

4. ACTION:

Check the date of manufacture on the external packaging for these devices. The example below shows a manufacturing date of August 2008.



2008 – 08

If the date of manufacture was before September 2008 (i.e. 2008 – 08 or earlier), then quarantine the devices and contact Codan UK to arrange for collection and replacement of the product.

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 intensive care units
- Anaesthetic nursing staff
- Anaesthetists
- EBME departments
- ENT medical staff
- Equipment stores
- General surgical units, directors of
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Operating department practitioners
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Ms Charlie Callaghan
Field Sales Manager
Codan Ltd
Eastheath Avenue
Wokingham
RG41 2PR

Tel: 0118 978 3663

Fax: 0118 977 6274

E-mail: cc@codanmed.co.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2008/088 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

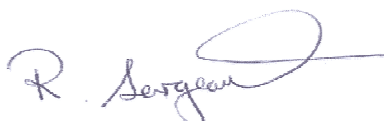
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
11 December 2008

Action Under Way:
18 December 2008

Action Complete:
29 December 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)2007/01. 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