

1. DEVICE/EQUIPMENT:

OP suction tubing is supplied as sterile suction tubing in 3m lengths. It is primarily used in operating theatres and intensive care units. Unomedical identified an error in the extrusion process for lot number 182281 and so has recalled it. All other lot numbers are unaffected. Many of these devices from the effected lot number have not been accounted for.

2. PROBLEM:

Due to a manufacturing error there is the potential for the tubing to collapse whilst in use, preventing suction.

3. ACTION BY:

All medical and nursing staff and theatre managers.

4. ACTION:

- Do not use affected devices.
- Identify and isolate any of the affected devices from lot number 182281.
- Contact manufacturer to arrange for return and replacement of 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
- All wards
- Ambulance staff
- Anaesthetists
- Dental Practitioners
- EBME departments
- Equipment libraries
- Health and safety managers
- Intensive care units (adult and paediatric)
- Maintenance staff
- Medical directors
- Nurse executive directors
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Independent Health and Social Care Providers – Private Hospitals, Clinics, and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Debbie Mertens
Quality Assurance
UK Regional Sales
Unomedical Limited
Thornhill Road
North Moons Moat
Redditch B98 9NL

Tel: 01527 587 700 Ext 7747
Fax: 01527 651 00
Email: debbie.mertens@unomedical.com

Enquiries to NIAIC should quote reference number MDEA(NI)2008/057 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

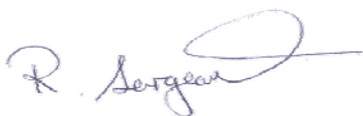
7. FEEDBACK:

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

Acknowledge Receipt of Alert:
24th July 2008

Action Under Way:
5th Aug 2008

Action Complete:
22nd Aug 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