

1. DEVICE/EQUIPMENT:

The affected products are securement devices that are used to keep catheters, tubes and drains in situ, manufactured between August 2005 and November 2006, specifically:

- Drain-Fix 680M and 685M are sterile securement devices for pigtail catheters, balloon catheters, suprapubic catheters, PEG feeding tubes and other percutaneous catheters and tubes from sizes 5Ch. to 22Ch.
- Central Gard 667M and 668M are sterile securement devices for central line catheters. Central-Guard 667M can also be used to secure PICC lines.
- Epi-Fix 670M is a sterile securement device for epidural catheters.

Device description	Product code	Batch number
Drain-Fix small	680M	546736, 552477, 552750, 552751, 554457, 554463, 554721, 556132, 556321, 556327, 556813, 556818, 556820, 556824, 556825, 556826, 556829, 556838, 556840, 556840, 556858, 556887, 559002, 560074, 560773, 560778, 561129, 561130, 562191, 563390, 566850, 566866, 566867, 567246, 567247, 567768, 567830
Drain-Fix large	685M	543832, 552178, 552739, 554345, 555560, 556328, 556353, 556860, 559027, 561237, 561247, 562773, 562813, 564697, 564782, 564806, 566886
Central-Gard small	667M	551178, 552385, 552755, 554468, 555688, 556462, 556848, 559001, 562785, 562838, 563308, 566803, 566882, 566916, 566918,
Central-Gard large	668M	551761, 552621, 553349, 554545, 554546, 554763, 555654, 556331, 556352, 556849, 559626, 560814, 561234, 561235, 561405, 561413, 562204, 562770, 562771, 562772
Epi-Fix	670M	357250, 367250, 367538, 545394, 545503, 546585, 551770, 552079, 552623, 552746, 552747, 553336, 553337, 553338, 554514, 554524, 554738, 554739, 554740, 554741, 558995, 560148, 560149, 561207, 561208, 561398, 563051, 564569, 565461, 566816, 566817, 567250, 567252, 567537, 567538

2. PROBLEM:

The MHRA and NIAIC has issued this Alert to support the manufacturer's recall action (advisory notice issued March 2007) as the large number of devices being recalled have been widely distributed.

No problems associated with this manufacturing fault have been reported.

3. ACTION BY:

Medical, nursing and procurement staff who have responsibility for purchasing and applying securement devices.

4. ACTION:

- Ensure that all relevant staff are aware of this recall.
- Identify and quarantine affected stock. The model and lot numbers are listed above.
- Contact the manufacturer to organise the return and replacement of affected stock.

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:

- All clinical departments
- All wards
- Anaesthetic nursing staff
- Anaesthetists
- Clinical governance leads
- Day surgery units
- Dieticians
- Equipment stores
- Health and safety managers
- Infection control teams
- IV nurse specialists
- Medical directors
- Medical oncologists
- Nursing executive directors
- Nutrition nurse specialists
- Oncology nurse specialists
- Outpatient theatre managers
- Pain teams
- Palliative care teams
- Purchasing managers
- Risk managers
- Supplies managers
- Theatres
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Community children's nurses
- Community nurses
- Directors of public health
- District nurses

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Mr Clinton Broome
Unomedical Ltd
Unit 3
Brunel Way
Stroudwater Business Park
Stonehouse
Gloucestershire, GL10 3SX

Tel: 01453 820 201

Fax: 01453 820 280

E-mail: clbr@unomedical.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/51 and be addressed to:

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

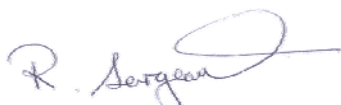
Tel: 028 9052 3868

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