

Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/65

Issued: 27 October 2006

For:

| | |
|------------------|---|
| IMMEDIATE ACTION | |
| ACTION | ✓ |
| UPDATE | |
| INFORMATION | |



HEALTH ESTATES

creating healing environments

| | Section |
|--|---------|
| <p>Medical Device/Equipment: Urine bag: Coloplast Conveen urine bag 1500ml, 90cm tube, non-sterile. Product code: 5062. Lot numbers: 546740, 568782, 576109.</p> | ▶ ① |
| <p>Problem: Failure to drain urine due to blocked non-return valve. The manufacturer is recalling specific batches of the device.</p> | ▶ ② |
| <p>Action by: Continence advisors, nurses and all others involved in the use, supply and/or distribution of this device.</p> | ▶ ③ |
| <p>Action:</p> <ul style="list-style-type: none"> Identify and quarantine stock from these lot numbers. Contact the manufacturer to arrange collection and replacement of affected stock. | ▶ 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 manufacturer 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/niac>

1. DEVICE/EQUIPMENT:

Urine bag: Coloplast Conveen urine bag 1500ml, 90cm tube, non-sterile.
Product code: 5062.
Lot numbers: 546740, 568782, 576109.

The affected devices were first delivered on 01 February 2006. The final delivery was made on 04 April 2006.

2. PROBLEM:

Coloplast has received nine reports of blocked non-return valves in their Conveen 1500ml urine bags.

The blockage of the non-return valve is due to defective foil used during manufacturing. The defective foil causes the valve to stick together during storage, resulting in the inability to collect urine.

Coloplast has initiated a recall and will be replacing affected product with product manufactured to the correct specification. This Medical Device Equipment Alert has been issued to ensure that users are aware of this recall and to support the manufacturer's ongoing recall action.

3. ACTION BY:

Continence advisors, nurses and all others involved in the use, supply and/or distribution of this device.

4. ACTION:

- Identify and quarantine stock from these lot numbers.
- Contact the manufacturer to arrange collection 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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Occupational Therapists
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Supplies Staff (RSS)
- All Wards
- Practice Nurses
- Pharmacy Managers
- Directors of Public Health
- Social Care Staff
- Community Care Staff
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Sterile Services Departments
- Outpatient Departments
- Infection Control Staff
- Accident & Emergency Departments
- Intensive Care

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Urology and Continence Care Division
Coloplast Limited
Peterborough Business Park
Peterborough
Cambridge
PE2 6FX

Tel: 01733 392 000
Fax: 01733 392 827

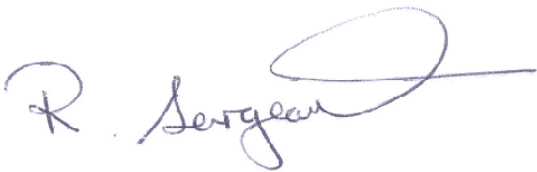
Enquires to NIAIC should quote reference number MDEA(NI)2006/65 and be addressed to:

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