

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/104

Issued: 6 December 2007



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: Wound drainage set for use in theatres: Privac pre-evacuated drainage set with 10ch drain and 600ml drainage bottle. Product code 24760. Batches 12032007 and 07052007.</p>	▶ ①
<p>Problem: Debris from the manufacturing and packaging processes has been found in the sterile packaging of some wound drainage sets from these batches. If used, there is a risk of introducing debris into the patient's wound.</p>	▶ ②
<p>Action by: All staff involved with the placement of wound drains and the purchase, supply and distribution of these devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify, quarantine and do not use any stock from the affected batches. Contact ProCare, the UK distributor, to arrange the return and replacement of products from the affected batches. 	▶ 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:

Wound drainage set for use in theatres: Privac pre-evacuated drainage set with 10ch drain and 600ml drainage bottle. Product code 24760. Batches 12032007 and 07052007.

2. PROBLEM:

The Privac set (product code 24760) is a complete wound drainage set for use in theatres containing a size 10ch drain/trocar and 600 ml drainage bottle. The set is manufactured by Primed Halberstadt and distributed in the UK by ProCare.

Affected drainage sets have product code 24760 and batch numbers 12032007 and 07052007.

The manufacturer has informed the MHRA that other product codes from this range of devices (i.e. sets containing different sized drains or drainage bottles), which have the same batch numbers, are not affected.

3. ACTION BY:

All staff involved with the placement of wound drains and the purchase, supply and distribution of these devices.

4. ACTION:

- Identify, quarantine and do not use any stock from the affected batches.
- Contact ProCare, the UK distributor, to arrange the return and replacement of products from the affected batches.

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 surgeons
- Clinical governance leads
- Medical directors
- Nursing executive directors
- Operating department practitioners
- Risk managers
- Supplies departments
- Supplies managers
- Surgical directors
- Theatre managers
- Theatre nurses
- Ward nurses
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Sue Cooper
Procure Limited
Unit 5
Blackwood Hall
North Duffield
Selby
North Yorkshire
Y08 5DD

Tel: 01757 288 694

Fax: 01757 288 689

E-mail: info@pro-care.co.uk

Enquiries to NIAIC should quote reference number MDEA(NI)2007/104 and be addressed to:

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

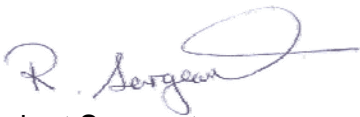
Tel: 028 9052 3868

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