

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/77

Issued: 4 November 2005

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	✓



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section								
Medical Device/Equipment: Astra Tech Ltd Exudrain, Exudrain Mini and AbdoVac vacuum wound drains.	▶ ①								
Problem: Potential for leakage between the bulb and the exit connector which may lead to one or more of the following problems: <ul style="list-style-type: none"> • Conversion of the system from active to passive drainage (loss of vacuum). • Increased risk of infection on breaking the closed circuit, should the device need to be changed. • Exposure of healthcare workers to exudate. A manufacturer initiated recall of products from this range is ongoing.	▶ ②								
Action by: Supplies departments and all staff responsible for wound drain placement and care.	▶ ③								
Action: <ul style="list-style-type: none"> • Ensure that all relevant staff are aware of this recall. 	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">Hospices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td></td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	Hospices	Chief Executive of each HSS Trust		Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	Hospices								
Chief Executive of each HSS Trust									
Chief Executive of each Agency									
NIAIC Liaison Officers									
Contacts Details of manufacturer contacts, NIAICA contacts for technical aspects.	▶ ⑥								
Feedback Requirements to NIAIC Ensure that any problems encountered with devices from this range are reported to Astra Tech Ltd and NIAIC.	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Astra Tech Ltd vacuum wound drains from the Exudrain, Exudrain Mini and AbdoVac product ranges affected by the recall are detailed below.

Product Name	Product Code	Batch Number(s)
Exudrain FG10	68406	22023
Exudrain FG14	68407	22970
Exudrain FG18	68408	21996
Exudrain FG10 with trocar	68409	21993, 22971, 21997, 22140
Exudrain FG14 with trocar	68410	21987, 22972
Exudrain FG18 with trocar	68411	21998, 22796
AbdoVac FG10	68413	22219
AbdoVac FG14	68414	22412
AbdoVac FG18	68415	21877
AbdoVac FG10 with trocar	68416	21901
AbdoVac FG14 with trocar	68417	22191
AbdoVac FG18 with trocar	68418	22192
Exudrain Mini FG8	68412	21999

This Medical Device Alert has been issued to ensure that users are aware of the recall and to support the manufacturer's ongoing recall action.

2. PROBLEM:

The wound drains are supplied in sets which comprise a bulb which is used to create a vacuum, a collection bag, and a catheter (with or without trocar). The systems have a variety of volume capacities, and suction power and are used following various surgical procedures. Astra Tech Ltd received several complaints of leakage between the bulb and the exit connector to the collection bag.

The following risks are associated with a failure of this type:

- Conversion of the system from active to passive drainage and the potential for formation of a haematoma.
- Potential for infection on breaking the closed circuit, should a defective device need to be changed.
- Exposure of healthcare workers to exudate.

Astra Tech Ltd has identified that the probable cause of the defect is a new glue that was used following a redesign of the product in June 2004. In some circumstances this glue may crack, allowing leakage. Astra Tech Ltd has made a further modification to the design to address the problem.

3. ACTION BY:

Supplies departments and all staff responsible for wound drain placement and care.

4. ACTION:

- Ensure that all relevant staff are aware of this recall.
- Identify and quarantine devices which are affected by this recall.
- Return unused devices affected by the recall to Astra Tech Ltd.

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
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Supplies Staff (RSS)
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSSRIA
- Sterile Services Departments
- Operating Theatre Staff
- Infection Control Staff
- Accident & Emergency Departments
- Intensive Care
- All Surgical Units
- All Wards
- High Dependency Unit

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Simon Talbot
Product Manager – Surgery
Astra Tech Ltd
Brunel Way
Stonehouse
Gloucestershire
GL10 3SX

Tel: 01453 791 763
Fax: 01453 791 001

E-mail: simon.talbot@astratech.com

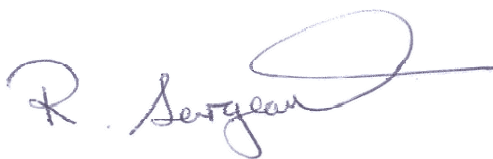
Enquires to NIAIC should quote reference number MDEA(NI)2005/77 and be addressed to:

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:

Ensure that any problems encountered with devices from this range are reported to Astra Tech Ltd and MHRA.



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)2005/01. 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