

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/57

Issued: 8 November 2004

For:

|                         |   |
|-------------------------|---|
| <b>IMMEDIATE ACTION</b> | ✓ |
| ACTION                  |   |
| UPDATE                  |   |
| INFORMATION REQUEST     |   |



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

|  | Section                           |                               |                                   |                       |                                |                        |     |
|--|-----------------------------------|-------------------------------|-----------------------------------|-----------------------|--------------------------------|------------------------|-----|
| <p><b>Medical Device/Equipment:</b><br/>Intravenous administration and extension sets manufactured by Alaris Medical Systems and Clinico.</p>  | ▶ ①                               |                               |                                   |                       |                                |                        |     |
| <p><b>Problem:</b><br/>The MHRA has been informed that several thousand intravenous extension and administration sets that are packaged and labelled as 'STERILE' have been stolen in transit prior to being sterilized. If used, these non-sterile sets will present a risk of infection.</p>   | ▶ ②                               |                               |                                   |                       |                                |                        |     |
| <p><b>Action by:</b><br/>All medical and surgical staff and in particular all staff responsible for the procurement of medical devices.</p>  | ▶ ③                               |                               |                                   |                       |                                |                        |     |
| <p><b>Action:</b><br/>The list of devices and batches affected is provided overleaf. Local systems should ensure that relevant staff:</p> <ul style="list-style-type: none"> <li>are aware of the theft of these devices and remain vigilant in the event that these are offered for sale</li> <li>check current and incoming stock and quarantine affected devices in a secure location</li> <li>ensure that affected devices are not put into use</li> <li>notify NIAIC immediately if any of these affected devices are offered for sale or have already been purchased.</li> </ul> | ▶ ④                               |                               |                                   |                       |                                |                        |     |
| <p><b>Distributed by NIAIC to:</b></p> <table border="0"> <tr> <td>Chief Executive of each HSS Board</td> <td>General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>NIAIC Liaison Officers</td> </tr> </table> <p><b>For onward distribution see Section 5</b></p>  | Chief Executive of each HSS Board | General Medical Practitioners | Chief Executive of each HSS Trust | Community Pharmacists | Chief Executive of each Agency | NIAIC Liaison Officers | ▶ ⑤ |
| Chief Executive of each HSS Board  | General Medical Practitioners     |                               |                                   |                       |                                |                        |     |
| Chief Executive of each HSS Trust  | Community Pharmacists             |                               |                                   |                       |                                |                        |     |
| Chief Executive of each Agency   | NIAIC Liaison Officers            |                               |                                   |                       |                                |                        |     |
| <p><b>Contacts</b><br/>Details of manufacturers and NIAIC contact for technical aspects.</p>   | ▶ ⑥                               |                               |                                   |                       |                                |                        |     |
| <p><b>Feedback Requirements to NIAIC</b><br/>None</p>  | ▶ ⑦                               |                               |                                   |                       |                                |                        |     |

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

## 1. DEVICE/EQUIPMENT:

| Manufacturer           | Product code | Product name                     | Description                    | Batch/Lot number                               |
|------------------------|--------------|----------------------------------|--------------------------------|--|
| Alaris Medical Systems | G59693       | IVAC 590 series                  | Infusion set, pump             | 331414, 331434, 332424, 332454, 333434, 333464 |
| Clinico                | 43421520     | Perfudrop(R) Air 21 G            | Infusion set, gravity          | 331444, 331454                                 |
| Clinico                | 48404615     | Perfudrop(R) Air M-P RS          | Infusion set, gravity and pump | 331464, 331474                                 |
| Clinico                | 62420010     | Sangodrop(R) B                   | Transfusion set                | 325424   |
| Clinico                | 76400200     | Verbinder LC-2                   | Double lumen extension set     | 325434, 325454, 325474, 325484                 |
| Clinico                | 77403000     | Heidelberger Verlängerung 30 cm  | Extension set 30 cm            | 325464   |
| Clinico                | 77414000     | Heidelberger Verlängerung 140 cm | Extension set 140 cm           | 325414, 325444, 331424                         |

## 2. PROBLEM:

The MHRA has been informed that several thousand intravenous extension and administration sets that are packaged and labelled as 'STERILE' have been stolen in transit prior to being sterilized. If used, these non-sterile sets will present a risk of infection.

## 3. ACTION BY:

All medical and surgical staff and in particular all staff responsible for the procurement of medical devices.

## 4. ACTION:

Any information received by MHRA regarding the location of these devices will be passed onto the appropriate manufacturer to assist in their attempts with the police to recover the stolen goods and to identify those responsible.

## 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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Clinical Directors
- Nursing Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Adult and Paediatric Intensive Care Units
- Practice Nurses
- Directors of Public Health
- Community Care Staff
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSS Board R&I Units
- Outpatient Departments
- Accident & Emergency Departments
- Day Procedure Units

## 6. CONTACTS:

Enquiries to the manufacturers should be addressed to:

Dr R Hopf  
Safety Security Officer  
Clinico GmbH  
Robert-Koch-Strasse 5  
D-36251 Bad Hersfeld  
Germany

Tel: +00 49 6621 168 419

Fax: +00 49 6621 168 111

E-mail: HopfR@clinico.de

Pierre Rebours  
Director of Quality & Regulatory Affairs  
Alaris Medical Systems  
The Crescent, Jays Close  
Basingstoke  
RG22 4BS

Tel: 0800 917 8776

Fax: 01256 330 860

E-mail: PRebours@alarismed.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/57 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:



Robert Sergeant  
Operational Manager NIAIC

### 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)2004/01. 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](http://www.dhsspsni.gov.uk/niaic)

*Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety*