

# Medical Device Alert

## Immediate action update

Ref: MDA/2011/023 Issued: 03 March 2011 at 15:30

### Device

Alcohol skin preparation pads, swabs, and swabsticks manufactured by Triad Group Inc for H&W cv since 2007.

Also supplied in various manufacturers' drug administration kits, needle exchange packs, and other device packs.

### Problem

Potential bacterial contamination of alcohol swabs which may lead to skin infection. Immunocompromised individuals are at greater risk of serious infection.

**This is confined to the alcohol swabs and does not affect the medicines or other components of the drug administration kits or device packs.**

This MDA updates [MDA/2011/013R](#) (issued on 11 February 2011) with details of **additional** manufacturers' device packs and kits that contain the affected swabs.

### Action

If you supply these swabs, quarantine them and do not supply the affected products.

Recipients of drug administration kits, needle exchange packs, or other device packs which include affected swabs should be advised to :

- not use the affected swabs
- use an alternative product for skin preparation or, if appropriate, alternative means of skin preparation.

Dispose of affected swabs safely and securely.

### Action by

All those who supply and use these affected swabs, drug administration kits and device packs, in particular :

- pharmacists and needle and syringe programmes
- supplies departments.

### Contact

#### Manufacturer/supplier

CSL Behring : Tel: 01444 447 402

ICU Medical Ltd : Tel: +39 346 233 6423

UK Medical Ltd: Fax: 0114 268 8881

### CAS deadlines

Action underway: 10 March 2011

Action complete: 24 March 2011

## Device



Refer to the manufacturers' [Field Safety Notices](#) for details of product codes, catalogue numbers and lot numbers of the following affected products:

- Orbit Infusion Sets and Orbit Micro Infusion Sets supplied by ICU Medical Inc that include Triad Alcohol Preparation Pads.
- PleurX™ Drainage Kits supplied by UK Medical Ltd / CareFusion that contain the sterile alcohol preparation pads manufactured by Triad Group.
- Helixate® NexGen administration kits supplied by CSL Behring containing Con-Zellin alcohol swabs by Paul Hartmann AG.

These are in **addition** to the products listed in [MDA/2011/013R](#).

**Note:** the CAS deadlines given for MDA/2011/013R remain unchanged

## Problem

Triad Group Inc, a sub-contractor of H&W cv, has identified a potential *Bacillus cereus* contamination of these swabs and has therefore initiated a recall of all swab products manufactured since September 2007.

## Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Health Protection Agency (HPA) (Directors)
- Health Protection Scotland
- Local Authorities in Scotland (Equipment Co-ordinators)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)
- Social services in England (Directors)

### Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

#### Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All clinical departments
- All outpatient clinics

- All staff
- All wards
- Chief pharmacists
- Clinical governance leads
- Clinical pathologists
- Dentists
- Dermatologists
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Drug treatment service managers
- Haematologists
- Haemodialysis nurses
- Hospital pharmacies
- Hospital pharmacists
- Infection prevention and control directors
- IV nurse specialists
- Medical directors
- Microbiologists
- Needle and syringe programme co-ordinators
- Nursing executive directors
- Nutrition nurses
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Pharmacists
- Phlebotomists
- Point of care testing co-ordinators
- Purchasing managers
- Risk managers
- Staff supporting patients receiving haemodialysis at home
- Supplies managers

### **Health Protection Agency**

Directors for onward distribution to:

- Consultants in communicable disease control
- Health protection nurses

### **Primary care trusts**

CAS liaison officers for onward distribution to all relevant staff including:

- Chiropodists
- Commissioners of drug treatment services
- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Community pharmacists
- District nurses
- General practitioners
- Health visitors
- Immunisation co-ordinators
- Infection control nurses
- Minor injury units
- Needle and syringe programme co-ordinators
- NHS walk-in centres
- Occupational health departments
- Palliative care teams
- Pharmaceutical advisors
- Podiatrists
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

### **Social services**

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Community care staff
- In-house domiciliary care providers (personal care services in the home)
- Occupational health departments

## Independent distribution

### Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Care homes providing nursing care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Contacts

### Manufacturer/Supplier – all

#### CSL Behring UK Ltd

Hayworth House  
Market Place  
Haywards Heath  
West Sussex  
RH16 1DB  
Tel: 01444 447 402  
Fax: 01444 447 403  
Email: [medinfo@cslbehring.com](mailto:medinfo@cslbehring.com)

#### ICU Medical

ICU Medical Europe, Srl  
Via Martiri Della Liberta '1 A/B  
Ronconaova Verona, 37060  
Italy  
Tel: +39 346 233 6423  
Email: [CTamani@icumed.com](mailto:CTamani@icumed.com)

#### UK Medical Ltd / CareFusion

Albreda House  
Lydgate Lane  
Sheffield  
S10 5FH  
Fax: 0114 268 8881  
Email: [quality@ukmedical.com](mailto:quality@ukmedical.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2011/023** or **2011/001/024/081/008**.

### Technical aspects

Sally Mounter  
Medicines & Healthcare products Regulatory  
Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7168  
Fax: 020 8754 3965  
Email: [sally.mounter@mhra.gsi.gov.uk](mailto:sally.mounter@mhra.gsi.gov.uk)

### Clinical aspects

Dr Nicola Lennard  
Medicines & Healthcare products Regulatory  
Agency  
Floor 4  
151 Buckingham Palace Road  
London SW1W 9SZ  
Tel: 020 3080 7126  
Fax: 020 8754 3965  
Email: [nicola.lennard@mhra.gsi.gov.uk](mailto:nicola.lennard@mhra.gsi.gov.uk)

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

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