Medical Device Alert

Ref: MDA/2013/076 Issued: 24 October 2013 at 14:00

Device

Ultrasound probe cover: burr hole probe cover with gel.

Manufactured by Microtek Medical Europe, a division of Ecolab.

Product reference (SKU number): 3688UK, PC3688, PC3688EU.

Problem

Risk of exposure to endotoxin levels above acceptable limits if the ultrasound probe cover comes into contact with the central nervous system.

The manufacturer has identified that the affected ultrasound probe covers have not undergone adequate endotoxin testing.

Microtek Medical Europe issued a Field Safety Notice (FSN) dated 10 July 2013 but has not received sufficient confirmation from users that they have received and acted on this information.

Action

- Ensure that relevant staff are aware of this Field Safety Notice.
- Identify all affected batches of these ultrasound probe covers.
- Quarantine all affected batches.
- Complete the recall response form and return it to Microtek Medical Europe as soon as possible.
- Follow the manufacturer's instructions for returning the affected devices.

Action by

- Operating theatre staff and surgical staff
- Neurosurgery departments
- Spinal surgery departments
- Radiology departments
- Supplies departments

CAS deadlines

Action underway: 07 November 2013

Action complete: 21 November 2013

Note: These deadlines are for staff to follow the instructions in the FSN and to ensure that affected probe covers are removed from use.

Contact

Manufacturer's authorised representative
Microtek Medical
Tel: +31 575 599 200
Email: custservnl@ecolab.com

Device

These ultrasound probe covers are disposable, single-use drapes. They are used as a cover for ultrasound probe scan heads and power cords, used for various surgical procedures, to provide a barrier over the equipment.

Affected batch numbers are listed in the Field Safety Notice (FSN).

Note that product ref (SKU number) 3688 is listed in the FSN but it is **not** for sale in the UK.

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams for information
- NHS trusts in England (chief executives)
- Public Health England (for information)

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:

- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Clinical pathologists
- Clinical pathology directors
- Day surgery units
- General surgical units, directors of
- Intensive care, directors of
- Medical directors
- Microbiologists
- Neurosurgeons
- Neurosurgery departments
- Nursing executive directors
- Orthopaedic surgeons
- Radiology departments
- Spinal surgery departments
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

Public Health England

Directors for onward distribution to:

- Divisional directors
- HPA laboratories

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres
- 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 and requesting this facility.

Contacts

Manufacturer's authorised representative
Microtek Medical
Hekkehorst 24
Zutphen
7207 BN
Netherlands

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/076** or **2013/009/002/291/013**

Technical aspects
Elke Kerwick and David Grainger
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 6826 or 7199
Fax: 020 8754 3965

Email: elke.kerwick@mhra.gsi.gov.uk
david.grainger@mhra.gsi.gov.uk

Clinical aspects
Mark Grumbridge
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7128
Fax: 020 8754 3965

Email: mark.grumbridge@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

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

All requests regarding return, replacement or modification of the devices mentioned in this alert should be directed to the relevant supplier or manufacturer.

Other enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk