Medical Device Alert

Ref: MDA/2014/034 Issued: 27 August 2014 at 15:00

Device

Basin/bowl liner or equipment cover (drape).

Manufactured by Microtek Medical.

Product codes: 17700, 16700A, 3109N, 3109NT, 3108N, 33099, 9386001, 3309N, TP1909A, TP1909B.

All lot numbers.

Problem

The manufacturer has found that some of these devices within the above product codes may have small cracks or holes. This could compromise the sterile field.

The manufacturer issued a Field Safety Notice (FSN) dated 14 July 2014 but hasn't had enough confirmation that customers have received and acted on it.

Action by

Those responsible for the purchase, storage and use of these devices, including theatre staff.

Action

- Identify affected devices as described in the FSN.
- Remove and quarantine any affected stock and return to Microtek Medical.
- Complete the response form and return it to Microtek Medical.

CAS deadlines

Action underway: 10 September 2014

Action complete: 24 September 2014

Note: These deadlines are for devices to be quarantined.

Contact

Manufacturer
Microtek Medical BV
Tel: +31 575 599 200
Email: custservnl@ecolab.comk

Device

These products (a type of surgical drape) are manufactured by Microtek Medical, but may be distributed by other companies. These devices will have been supplied in procedure packs. See page 5 of the manufacturer's FSN for full product descriptions.

All devices manufactured since August 2009 are affected by this recall.

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)
- Local authorities in Scotland (equipment co-ordinators)
- 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)
- Special health authorities 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:

- Day surgery units
- Infection control departments
- Medical directors
- Nursing executive directors
- Purchasing managers
- Risk managers
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatres

Independent distribution

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

This alert should be read by:

- Hospitals in the independent sector

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
Microtek Medical BV
Hekkehorst 24
7207 BN Zutphen
Netherlands

Tel: +31 575 599 200
Fax: +31 575 599 299

Email: custservnl@ecolab.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/034** or **2014/006/024/081/003**

Technical aspects
Sara Vincent and Catriona Blake
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7169 or 7219
Fax: 020 8754 3965

Email: sara.vincent@mhra.gsi.gov.uk
catriona.blake@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

Email: improvingpatientsafety@wales.gsi.gov.uk