Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2019/034 Issued: 09 October 2019 at 11:00

Intraoperative probe cover with long Surgi-tip – risk of infection due to manufacturing failure (specific lot numbers affected)

Summary

Manufactured by Ecolab/Microtek Medical Malta Ltd – bacterial contamination may cause an infection in patients.

Action

- Identify and quarantine affected lot numbers as listed in the manufacturer's Field Safety Notice.
- Contact the manufacturer to arrange for return of unused devices.
- Report suspected or actual adverse events involving these devices through your local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales. You should also report directly to manufacturers if your local or national systems do not.

Action by
All healthcare professionals who are responsible for, or who use these devices. In particular:

- Theatre managers
- Theatre nurses

Deadlines for actions
Actions underway: 23 October 2019
Actions complete: 31 October 2019

Medical Device Safety Officers (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation of FSN actions against distributed devices.

Remember: if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.

Department of Health An Roinn Sláinte Männystrie O Poustie www.health-ni.gov.uk

NHS National Services Scotland

Llywodraeth Cymru Welsh Government

Manufacturer contacts

Microtek Medical Malta Ltd
Tel: +49-2173-599-1626
Email: Elahe.Varzandeh@ecolab.com

Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including: A&E consultants

- A&E departments
- A&E directors
- A&E nurses
- Adult intensive care units
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Cardiothoracic departments
- Cardiothoracic surgeons
- Cardiothoracic surgery directors
- Day surgery units
- Dental departments
- Dental nurses
- Dentists
- ENT departments
- ENT medical staff
- ENT services, directors of
- Equipment stores
- Equipment libraries and stores
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Operating department practitioners
- Ophthalmic nurses
- Ophthalmologists

- Ophthalmology departments
- Ophthalmology, directors of
- Oral surgeons
- Orthopaedic surgeons
- Outpatient theatre managers
- Outpatient theatre nurses
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urological surgery, directors of
- Urology departments

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only) Hospitals in the independent sector

- Independent treatment centres

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 Central Alerting System (CAS) by sending an email to: safetyalerts@mhra.gov.uk and requesting this facility.

Enquiries

England

Send enquiries about this notice to MHRA, quoting reference number MDA/2019/034 or MHRA Ref: 2019/007/016/487/008.

Technical aspects

Leanne Simpson, MHRA

Tel: 020 3080 6000

Email: DSS-TM@mhra.gov.uk

Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: dct@mhra.gov.uk

To report an adverse incident involving a medical device in England use the Yellow Card reporting page

Northern Ireland

Northern Ireland Adverse Incident Centre (NIAIC), CMO Group, Department of Health (Northern Ireland)

Tel: 028 9052 3868

Email: niaic@health-ni.gov.uk

To report an adverse incident involving a medical device in Northern Ireland use the forms on the website.

Alerts in Northern Ireland are distributed via the NICAS system.

Scotland

Incident Reporting and Investigation Centre (IRIC), Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: nss.iric@nhs.net

To report an adverse incident involving a medical device in Scotland, email IRIC to request a webform account.

For more information, or if you can't access the webform, visit the website: how to report an adverse incident

Wales

Population Healthcare Division, Welsh Government

Tel: 03000 250986 / 03000 255510

Email: haz-aic@wales.gov

To report an adverse incident involving a medical device in Wales, use the Yellow Card reporting page and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).