Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Medical Device Alert

MDA/2020/008 Issued: 27 February 2020 at 12:00

Various Olympus duodenoscope models: do not use if elevator wires are frayed or damaged as these may cause lacerations to patients and users

Summary

Manufactured by Olympus Medical Systems Corp – instructions for use now say to inspect for frayed elevator wires before and after use to improve the detection of damage.

Action

- Identify if you have any of the affected models listed in the manufacturer's Field Safety Notice (FSN).
- Inspect all potentially affected devices for frayed elevator wires.
- Remove from service and quarantine any devices with frayed or damaged elevator wires and contact the manufacturer to arrange for repair, as stated in the instructions for use (IFU) of the device.
- Attach the updated IFU from the FSN to existing device documentation.
- Implement the pre-use inspections described in the updated IFU and ensure all relevant staff are trained in the new procedures.
- Continue to remove and quarantine all devices identified as having frayed or damaged elevator wires.
- Complete and return the manufacturer response form in the FSN.
- 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 staff responsible for the use and reprocessing of the device.

Deadlines for actions
Actions underway: 12 March 2020
Actions complete: 23 April 2020

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.

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

Olympus Medical
Ms Lucas - Regulatory Affairs Associate
Email: ra@olympus.co.uk
Fax: 01702 465 677

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:

- Clinical governance leads
- Community hospitals
- Day surgery units
- EBME departments
- Equipment stores
- Equipment libraries and stores
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Operating department practitioners
- Outpatient theatre nurses
- Point of care testing co-ordinators
- Risk managers
- Sterile services departments
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

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/2020/008 or 2019/011/015/291/002.

Technical aspects

Ben Satchell, 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 255278 or 03000 255510

Email: Haz-Aic@gov.wales

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).