

Medical Device Alert

Ref: MDA/2014/032 Issued: 20 August 2014 at 12:00

Device
<p>Gastrostomy devices:</p> <ol style="list-style-type: none"> 1. Measuring device – product code: BM01 2. Direct dilation kit – product codes: DD12fr, DD14fr and DD16fr 3. Balloon gastrostomy kit – product codes: EK12fr, EK14fr, EK16fr, EK18fr, EK20fr, EK22fr and EK24fr <p>All batches. Manufactured by Medicina Ltd.</p>

Problem	Action
<p>Risk of infection as the balloon gastrostomy kit may contain out-of-date devices. The sterility of these devices cannot be assured.</p> <p>In addition, the safety and performance of these devices has not been properly evaluated and so the CE marking of all of these devices is invalid.</p> <p>Medicina issued three Field Safety Notices (FSNs) in June 2014 but has not had sufficient confirmation that customers have received and acted on these notices.</p>	<p>Do not use affected devices. Quarantine and return them to the manufacturer as described in the FSNs:</p> <ol style="list-style-type: none"> 1. Measuring device FSN 2. Direct dilation kit FSN 3. Balloon gastrostomy kit FSN <p>For patients with gastrostomy catheters the MHRA currently considers that the benefits of continuing to use the device outweigh the risks of removal and replacement.</p> <p>Return the email / fax back form in the FSNs to the manufacturer.</p>
Action by	
<p>All healthcare workers who use these devices.</p> <p>Personnel involved in the purchase, supply and distribution of these devices.</p>	
CAS deadlines	Contact
<p>Action underway: 04 September 2014</p> <p>Action complete: 18 September 2014</p> <p>Note: These deadlines are for systems to be in place.</p>	<p>Manufacturer Carol Cole Medicina Ltd Tel: 01204 695 050 Email: carol@medicina.co.uk</p>

Device

If relevant to you, the NHS Supply Chain Codes are as follows:

Medicina Ltd product code	NPC	Product description
DD12fr	FWM1726	Gastrostomy Kit Direct dilation gastrostomy kit 12FR
DD14fr	FWM1727	Gastrostomy Kit Direct dilation gastrostomy kit 14FR
DD16fr	FWM1728	Gastrostomy Kit Direct dilation gastrostomy kit 16FR
EK12fr	FWM1729	Gastrostomy Kit Universal balloon gastrostomy kit with clamp 12FR
EK14fr	FWM1730	Gastrostomy Kit Universal balloon gastrostomy kit with clamp 14FR
EK16fr	FWM1731	Gastrostomy Kit Universal balloon gastrostomy kit with clamp 16FR
EK18fr	FWM1732	Gastrostomy Kit Universal balloon gastrostomy kit with clamp 18FR
EK20fr	FWM1733	Gastrostomy Kit Universal balloon gastrostomy kit with clamp 20FR
EK22fr	FWM1734	Gastrostomy Kit Universal balloon gastrostomy kit with clamp 22FR
EK24fr	FWM1735	Gastrostomy Kit Universal balloon gastrostomy kit with clamp 24FR

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
- NHS trusts in England (chief executives)
- OFSTED (directors of children's services) for information
- Social services in England (directors)
- 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:

- A&E departments
- All wards
- Clinical governance leads
- Community children's nurses
- Community hospitals
- Community nurses
- Day surgery units
- Dietetics departments
- Dieticians
- District nurses
- Gastroenterology departments
- Gastro-intestinal surgeons
- General surgery
- Health and safety managers
- Hospital at home units
- Intensive care units
- Medical directors
- Neonatology departments
- Nursing executive directors
- Nutrition nurses
- Paediatrics departments
- Palliative care teams
- Purchasing managers
- Risk managers
- Supplies managers
- Theatre managers

NHS England area teams

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

- Nutritional nurse specialists

Social services

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes

Independent distribution

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

This alert should be read by:

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres

Establishments registered with OFSTED

This alert should be read by:

- Educational establishments with beds for children
- Residential special schools

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

Medicina Ltd
Carol Cole
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Rivington View Business Park
Station Road
Blackrod
Bolton BL6 5BN

Tel: 01204 695 050

Fax: 01204 697 755

Email: carol@medicina.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2014/032** or **2014/006/013/601/008**.

Technical aspects

Claire Dunne and Sharon Knight
Medicines & Healthcare Products Regulatory Agency
Floor 4
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London SW1W 9SZ

Tel: 020 3080 7162 / 7202

Fax: 020 8754 3965

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sharon.knight@mhra.gsi.gov.uk

Clinical aspects

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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.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:

Improving Patient Safety Team
Medical Directorate, Welsh Government, Cathays Park, Cardiff CF10 3NQ
Email: improvingpatientsafety@wales.gsi.gov.uk