

Medical Device Alert

Ref: MDA/2013/009 Issued: 26 February 2013 at 14:00

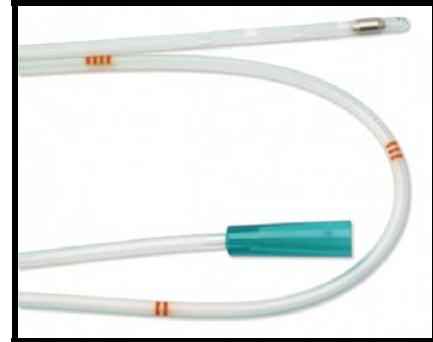
Device

Nasogastric feeding tubes –
Ryles tubes (weighted tip).

Manufactured by Vygon Ltd.

Size 12FG 125cm, product code: 392.12,
lot number: 160412FG.

Size 14FG 125cm, product code: 392.14,
lot number: 100512FF.



Problem

Risk of incorrect placement of the feeding tube due to incorrectly applied depth markings.

Despite issuing two Field Safety Notices in January 2013, Vygon Ltd has not received sufficient confirmation from users that they have received and acted on this information.

Action by

All medical staff and nursing staff who use these devices.

Action

- Identify and quarantine any affected devices.
- Ensure all users are aware of the manufacturer's Field Safety Notices (dated [03 January 2013](#) and [21 January 2013](#)).
- Return the confirmation requests in the FSNs to the manufacturer.
- If patients have affected tubes in situ, confirm correct placement before further use, following local protocols

CAS deadlines

Action underway: 05 March 2013

Action complete: 19 March 2013

Note: These deadlines are for unused devices to be removed from use.

Contact

Manufacturer
Vygon UK Ltd
Kate O'Connell

Tel: 01793 748800

Email: kate.oconnell@vygon.co.uk

Device

The affected product codes on the manufacturer's website and device labels are specified as '392.12' and '392.14'. The same products are referred to as '0392.12' and '0392.14' respectively in the manufacturer's Field Safety Notices.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

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
- Anaesthetists
- Day surgery units
- Dieticians
- ENT departments
- Gastroenterology departments
- General surgery
- Hospital at home units
- Intensive care units
- Medical directors
- Nursing executive directors
- Nutrition nurses
- Palliative care teams
- Radiology departments
- Supplies managers
- Theatre managers

Primary care trusts

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

- Community hospitals
- Community nurses
- District nurses
- Nutritional nurse specialists
- Palliative care teams

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:

- Children's services
- 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

Vygon UK Ltd
The Pierre Simonet Building
V Park
Gateway North
Latham Road
Swindon
Wiltshire
SN25 4DL

Tel: 01793 748800

Fax: 01793 748899

Email: kate.oconnell@vygon.co.uk

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/009** or **2013/001/004/601/032**

Technical aspects

Patrick Sweeney or Claire Dunne
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 6898 / 7162
Fax: 020 8754 3965

Email: patrick.sweeney@mhra.gsi.gov.uk
claire.dunne@mhra.gsi.gov.uk

Clinical aspects

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Medicines & Healthcare products Regulatory Agency
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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

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre

Health Facilities Scotland

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-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

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