



# Medical Device Alert

MDA/2017/035

Issued: 19 December 2017 at 14:00

Valid until: Dec 2018

Nasogastric (NG) feeding tubes – recall due to risk of neonatal or paediatric patient choking on ENFIT connector cap

## Summary

Manufactured by Maxter Catheters – patients could accidentally pull off the connector cap and choke on it.

## Action

- Return all unused, affected devices to the manufacturer – product codes of affected stock are listed in the [Field Safety Notice \(FSN\)](#).
- Ensure relevant healthcare professionals are aware of the [FSN](#).
- Follow the [FSN](#) actions for managing patients with these NG tubes.
- Fill in the acknowledgement form in Annex 1 of the FSN and return it to the manufacturer.

### Action by

All staff who use the affected devices

### Deadlines for actions

Actions underway: 22 January 2018

Actions complete: 20 April 2018

## Manufacturer contacts

Maxter Catheters/Halyard Health

Tel: +33 491 467 305, +32 2 711 27 19

Email: [RA.EMEA@hyh.com](mailto:RA.EMEA@hyh.com) or [Camille.chavy@hyh.com](mailto:Camille.chavy@hyh.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:

- Community children's nurses
- Dietetics departments
- Dieticians
- District nurses
- Equipment stores
- Equipment libraries and stores
- Gastroenterology departments
- Gastroenterology, directors of
- Gastro-intestinal surgeons
- Health visitors
- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (paediatric)
- Medical directors
- Neonatal nurse specialists
- Neonatology departments
- Neonatology directors
- Nutrition nurses
- Paediatric intensive care units
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres

### 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:

- Children's disability services

### ***Independent distribution***

#### **Establishments registered with OFSTED**

- 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](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Enquiries**

### **England**

Send enquiries about this notice to MHRA, quoting reference number **MDA/2017/035** or 2017/010/023/701/012.

### **Technical aspects**

Rebecca Flint or Jenifer Hannon, MHRA

Tel: 020 3080 6083 / 7153

Email: [Rebecca.flint@mhra.gov.uk](mailto:Rebecca.flint@mhra.gov.uk) or [Jenifer.Hannon@MHRA.gov.uk](mailto:Jenifer.Hannon@MHRA.gov.uk)

### **Clinical aspects**

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto:dct@mhra.gov.uk)

### **Reporting adverse incidents in England**

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

### **Northern Ireland**

Alerts in Northern Ireland are distributed via the [NICAS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,  
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: [niaic@health-ni.gov.uk](mailto:niaic@health-ni.gov.uk)  
<https://www.health-ni.gov.uk/niaic>

### **Reporting adverse incidents in Northern Ireland**

Please report directly to NIAIC using the [forms on our website](#).

## Scotland

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

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

Tel: 0131 275 7575

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

### Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to [Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to [Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

## Wales

Enquiries in Wales should be addressed to:

Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

### Reporting adverse incidents in Wales

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health  
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