

Safety Notice

Medical Devices

MAXTER ENTRAL* ENFit® NASOGASTRIC (NG) FEEDING TUBES

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2017(36)

Issue Date: 27th October 2017

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Maxter	V33605

ISSUE

Maxter is recalling all product codes and production lots of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector (i.e., Purple Connector).

A field safety notice (FSN) has been issued advising customers of the appropriate actions to take.

Please refer to the accompanying FSN for further details and for a summarised table of the products affected. The HPRA understands that products supplied to the Irish market can be identified using the Halyard ALT Codes listed in the FSN. A tailor-made customer response form for the Irish market is provided alongside the accompanying FSN.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

- 1 Refer to the accompanying FSN and follow the instructions provided by the manufacturer.

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| 2 | Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation and to any other organisations/persons to which/whom these devices have been transferred. |
| 3 | Acknowledge receipt of the FSN if you have not already done so. |
| 4 | Report any adverse events/incidents associated with these devices to the manufacturer and the HPRRA. |

TARGET GROUPS	
Carers Clinical / Medical Directors Clinical engineers Clinical Nurse Managers Community care managers Community nurses General practitioners Healthcare professionals who use these devices Hospital Managers / CEOs Hospital personnel Intensive Care Units Neonatal units	Nursing staff Paediatric intensive care units Paediatric wards Paediatricians Palliative Care Units Pharmacists Practice nurses Private hospitals Private medical practitioners Procurement Purchasing Managers Risk Managers Supplies managers

BACKGROUND
<p>Maxter initiated this recall following receipt of 4 reports that the white cap that is attached to the retaining strap of the ENFit® Connector of affected catheters separated due to excessive patient manipulation. Such a situation represents a choking hazard should a patient place the separated cap into their mouth. Maxter advised that all of the reports of cap separation received to date occurred during feeding.</p> <p>For devices in use on patients, Maxter has advised the possibility for removal of the recalled catheters should be assessed by considering the risks associated with the removal and replacement of the catheter relative to the risk associated with the separation of the cap.</p> <p>Maxter advised that the risk of the cap separating from the retention strap is greatest during feeding of patients who have the potential strength and dexterity to cause separation of the cap.</p> <p>Maxter has advised that should the risk of replacing an affected catheter be unacceptable, action should be taken to ensure that the patient involved is unable to reach or manipulate the white cap, catheter, or connector strap. In such scenarios, Maxter also advise that the patient should be monitored frequently during extended feeding durations.</p> <p>Please refer to the accompanying FSN for further details.</p>

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION
<p>Enquiries to the distributor should be addressed to:</p> <p>ALLPHAR SERVICES LTD 4045 Kingswood Road</p> <p>Telephone: +353-1-4287777 Fax: +353-1-4287776</p>

Citywest Business Park
Co. Dublin

E-mail: recall@uniphar.ie
Website: www.uniphar.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie