

URGENT FIELD SAFETY NOTICE (EMEA-2018-014)
ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr – (SMALL)

03 December 2018

Dear Valued Maxter Catheters Customer,

Maxter Catheters is issuing this Field Safety Notice to alert users of a potential choking hazard associated with an accessory Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr (Small) distributed by Halyard Health.

What is the reason for this Field Safety Notice?

Maxter Catheters received one unconfirmed report of a young patient, who was observed playing with and eventually placing an accessory ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr in their mouth, which caused them to begin choking. A healthcare provider was able to remove the clamp from the airway/mouth, and the patient recovered. This ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr (see below for representative label and photo) is distributed for use with Maxter Catheter ENTRAL™ NG Feeding Tubes as a stand-alone accessory or within kits.

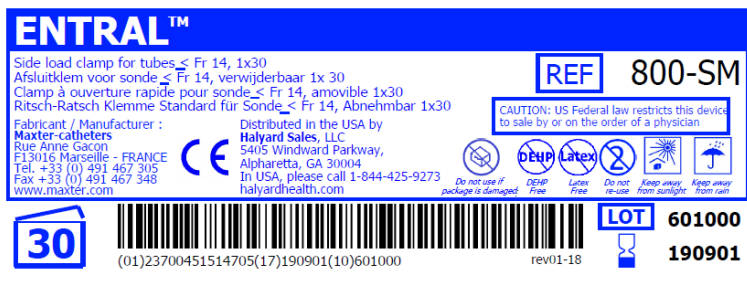

Although the likelihood of harm occurring is improbable, this notice is intended to inform all users of the Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr (Small) about this potential choking hazard.

Which Products are impacted?

All small-sized Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr products (Product Code: 800-SM) are impacted. To date, two lots only of stand-alone clamps have been distributed and might be found in your facility's inventory, either as individual clamps or within kits. The potentially impacted products are summarized in the following table:

Product Label Description	Product Code	Halyard ALT Code	Lot Code
Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr (Small)	800-SM	106192800	175025
			180507
ENTRAL™ Gastrostomy Tube Care Kit, 12Fr	QW3154	QW315401	18050108
ENTRAL™ Gastrostomy Tube Care Kit, 14Fr	QW3155	QW315501	18050107 18070020
MIC* Gastrostomy Tube Care Kit, 12Fr	QW3161	QW316101	18060088
MIC* Gastrostomy Tube Care Kit, 14Fr	QW3162	QW316201	18050545

The following photos show the representative package label and picture of the impacted stand-alone Maxter ENTRAL™ Side Load Clamp:

ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr (Small), Product Code: 800-SM	
Representative Primary Package Label (Stand-Alone Clamp)	Representative Product Image
	

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As a Clinical Facility/Customer, what should I do in response to this Field Safety Notice?

1. Distribute this advisory notice within your clinical facility to all departments that may have received the Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr (Product Code: 800-SM), either in its original packaging or within finished kits, or may use it in the future.
2. Inform all concerned personnel about the potential choking risk associated with allowing a young or cognitively impaired patient to have access to the ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr or any other small-sized medical product. At a minimum, notification should include all clinicians and support staff who manage patients requiring Enteral Feeding.
3. Notify the caregivers/family members of patients who may use the Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr.
4. Take action to ensure that young or cognitively impaired patients are not able to reach or manipulate the Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr.
5. Monitor the patient frequently when using the Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr to restrict fluid flow on their feeding tube.
6. In case you experience any incident, please immediately report the incident to Halyard Health at: PIQ.EMEA@hyh.com
7. Please complete the **Field Safety Notice Customer Acknowledgement Form** provided in **Annex 1** and return it **within five (5) business days of receipt** via e-mail to Veronique.Paulin@hyh.com

Maxter Catheters is updating the package labeling of the Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr (Small) to include a WARNING Statement that alerts users of the potential choking hazard. If you require further assistance, please contact your Halyard Health Representative. The Competent Authorities in your country have been informed of this Field Safety Notice. Please be informed that the Competent Authorities can request evidence from your records associated with the affected products mentioned in this Field Safety Corrective Action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Halyard Health sales representative.

We thank you for your assistance.

Sincerely,

Halyard Health



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Annex 1: Field Safety Notice Customer Acknowledgement Form

Please complete this form and email to Veronique.Paulin@hyh.com within 5 business days of receipt.

Our records indicate we have shipped to you at least one of the following products:

Product Label Description	Product Code	Halyard ALT Code	Lot Code
Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr (Small)	800-SM	106192800	175025
			180507
ENTRAL™ Gastrostomy Tube Care Kit, 12Fr	QW3154	QW315401	18050108
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MIC* Gastrostomy Tube Care Kit, 14Fr	QW3162	QW316201	18050545

Please return this form to the above email address as soon as possible. We expressly point out that the reply is mandatory, as the Competent Authority can request proof of receipt of this notice.

Your Maxter / Halyard Health representative is available and can provide you additional information.

[] I certify that this facility has read and understood the information provided in the Field Safety Notice, and the information provided in this notice will be distributed to the appropriate clinical staff and patient caregivers who are known to use the impacted Maxter ENTRAL™ Side Load Clamp for Tubes ≤ 14Fr.

Facility Information	Contact Person Completing Form
(Facility Name)	(Name/Signature of Person Completing Form)
(Facility Address)	(Phone Number)