URGENT FIELD SAFETY CORRECTIVE ACTION (EMEA/M-001)
MAXTER ENTRAL* ENFit® NASOGASTRIC (NG) FEEDING TUBES

17 October 2017

ATTENTION: DIRECTOR, PURCHASING DEPARTMENT

Dear Valued Maxter Products Partner,

The purpose of this letter is to advise you that Maxter is recalling all product codes and production lots of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector.

What is the reason for this Voluntary Medical Device Field Safety Corrective Action (i.e., Recall)?
Maxter Catheters has received four reports indicating that the White Cap that is attached to the retaining strap of the ENFit® Connector found on ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector (i.e., Purple Connector) separated from the retaining strap due to excessive patient manipulation (See following page for representative photo). This situation may result in the patient (primarily paediatric) placing the cap into their mouth, which could cause a choking hazard. In all instances, the cap separated from the retention strap during feeding.

Although the reported risk of occurrence is rare (i.e., less than 4 per million) this notice is intended to inform all users of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector about this potential choking hazard and requests to quarantine and return (RECALL) of all unused impacted products summarised in the table below.

Which Products are impacted?
The products impacted include only the model numbers of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector (i.e., Purple Connector) products summarized in the following table.

Maxter International Code		Halyard ALT Code	ENTRAL* Product label Description
503…	503-04-4-B10	Not Applicable	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane ORX Fr xx - Lg yy cm
	503-04-5	Not Applicable	
	503-06	Not Applicable	
	503-06-5	Not Applicable	
	503-08	Not Applicable	
	503-08-5	Not Applicable	
	503-08-B10	Not Applicable	
	503-10	Not Applicable	
	503-10-5	Not Applicable	
503T…	503T04	NST4-120	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane LORX Fr xx - Lg yy cm
	503T04-4	NST4-40	
	503T04-5	NST4-50	
	503T04-5SL	NST4-50	
	503T04-8	NST4-80	
	503T04-16	NST4-160	
	503T05	NST5-120	
	503T05-4	NST5-40	
	503T05-5	NST5-50	
	503T05-8	NST5-80	

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Maxter International Code		Halyard ALT Code	ENTRAL* Product label Description
503T…	503T06	NST6-120	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane LORX Fr xx - Lg yy cm
	503T06-4	NST6-40	
	503T06-5	NST6-50	
	503T06-5SL	NST6-50	
	503T06-8	NST6-80	
	503T06-10	NST6-100	
	503T06-16	NST6-160	
	503T08	NST8-120	
	503T08-4	NST8-40	
	503T08-5	NST8-50	
	503T08-5SL	NST8-50	
	503T08-6	NST8-60	
	503T08-8	NST8-80	
	503T08-16	NST8-160	
	503T10	NST10-120	
	503T10-4	NST10-40	
	503T10-5	NST10-50	
	503T10-5SL	NST10-50	
	503T10-8	NST10-80	
	503T12	NST12-120	
	503T12-8	NST12-80	
	503T14-8	NST14-80	
503TL…	503TL04-5	NST4-50W	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane LORX Tungsten weighted Fr xx - Lg yy cm
	503TL06	NST6-120W	
	503TL06-5	NST6-50W	
	503TL06-8	NST6-80W	
	503TL08	NST8-120W	
	503TL08-5	NST8-50W	
	503TL08-8	NST8-80W	
	503TL10-8	NST10-80W	
	503TL12-8	NST12-80W	
505…	505-04	PVC4-120	ENTRAL* - ENFit® Nasogastric feeding tube PVC LORX Fr xx - Lg yy cm
	505-04-4	PVC4-40	
	505-04-5	PVC4-50	
	505-06	PVC6-120	
	505-06-4	PVC6-40	
	505-06-5	PVC6-50	
	505-08	PVC8-120	
	505-08-4	PVC8-40	
	505-08-5	PVC8-50	
	505-10	PVC10-120	
	506-04	NST4-120SIL	

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Maxter International Code		Halyard ALT Code	ENTRAL* Product label Description
506…	506-06	NST6-120SIL	ENTRAL* - ENFit® Nasogastric feeding tube Silicone ORX Fr xx - Lg yy cm
	506-08	NST8-120SIL	
	506-08-5	NST8-50SIL	
	506-09	NST9-120SIL	
	506-10	NST10-120SIL	
506L…	506L04-85	NST4-85WSIL	ENTRAL* - ENFit® Nasogastric feeding tube Silicone ORX Tungsten weighted Fr xx - Lg yy cm
	506L06-85	NST6-85WSIL	
	506L08	NST8-120WSIL	
	506L08-85	NST8-85WSIL	
	506L10-85	NST10-85WSIL	
507…	507-06-55	SFT6-55	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane ORX Guidewire Fr xx - Lg yy cm
	507-06-75	SFT6-75	
	507-06-85	SFT6-85	
	507-08	SFT8-120	
	507-08-55	SFT8-55	
	507-08-75	SFT8-75	
	507-08-85	SFT8-85	
	507-10	SFT10-120	
	507-10-85	SFT10-85	
	507-10-85B	SFT10-85B	
	507-12-85	SFT12-85	
507L…	507L08-85	SFT8-85W	ENTRAL* - ENFit® Nasogastric feeding tube Polyurethane ORX Guidewire Tungsten weighted Fr xx - Lg yy cm
	507L10-85	SFT10-85W	
508..	508-06	SJT6-120	ENTRAL* - ENFit® Nasojejunal Tube Polyurethane ORX Guidewire Fr xx - Lg yy cm

The following photos show one of the representative affected products. The image depicts the cap separated from the retaining strap following excessive patient manipulation.

WHITE CAP ATTACHED TO STRAP	WHITE CAP SEPARATED FROM STRAP
	

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As a Partner, what should I do in response to this Field Safety Corrective Action Notice?

Actions

1. Please update the contact information on the Word document Customer Field Safety Corrective Action Notice (provided with this communication) to reflect your Facility and Contact Person, so your direct customers can contact you.
2. Immediately distribute your customized Customer Field Safety Corrective Action Notice to all your direct customers/partners to whom your facility shipped any of the impacted ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector products.
3. Evaluate your inventory of the Maxter ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector referenced in this recall, and immediately quarantine and place on hold all unused units.
4. Please complete and sign the **Field Safety Corrective Action Partner Response Form (Annex 1)** and return it within five (5) business days of receipt via e-mail to camille.chavy@hyh.com or fax to No: +33 491 467 348. A Customer Service representative will contact you with further instructions.

Maxter Catheters is implementing design enhancements to these products to address this issue and further reduce the risk of White Cap separation from the retention strap due to excess manipulation. If you require further assistance, please contact your Maxter Catheters Representative. The Competent Authorities in your country have been informed of this Field Safety Action. Please be informed that the Competent Authorities can request from you 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 sales representative.

We thank you for your assistance.

Sincerely,

Maxter Catheters

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Annex 1: Field Safety Corrective Action Partner Response Form

Please complete this form and FAX to No: +33 491 467 348, or email to camille.chavy@hyh.com within 5 business days of receipt.

Using the following table please indicate which Product Reference Numbers of the impacted devices remain in your Distribution Inventory along with quantities of each. If your facility does not have remaining inventory for any specific Reference Number category, enter zero (0) in the corresponding row.
Our records indicate that we have shipped to you the following products:

Maxter Product Reference Numbers	**Enter Each Reference Number and Quantity Quarantined** (e.g. *503-08-B10 = 12 units or enter "0" if none remaining, and please indicate if the quantity mentioned is in units, box or carton)*	
	Units	**Cases**
503-##-## 503T##-## 503TL##-##		
505-##-##		
506-##-## 506L##-##		
507-##-## 507L##-##		
508-##-##		

Please return this form duly completed and signed to the above fax number as soon as possible. We expressly point out that the reply is mandatory, as the competent authority can request proof of the whereabouts of the goods in individual cases.

Your Maxter Catheters representative will contact you after reception of this form duly completed and can provide you additional details regarding return of ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector and future availability of corrected product.

[ ] I certify that this Partner facility has read and understood the information provided in this Field Safety Notice and will distribute this Notice to customers who were shipped any of the impacted ENTRAL* Neonates and Paediatric Nasogastric Feeding Catheters with ENFit® Connector.

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

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