

28th October 2016

URGENT - FIELD SAFETY NOTICE

Type of Action				Recall					
Teleflex Reference:				EIF-000100					
Commercial Name				LMA [®] Mucosal Atomization Devices					
Product Code	Batch/ Lot#	Product Code	Batch/ Lot#	Product Code	Batch/ Lot#	Product Code	Batch/ Lot#		
Product Code	Batch/ Lot#	Product Code	Batch/ Lot#	Product Code	Batch/ Lot#	Product Code	Batch/ Lot#		
MAD500	160127	MAD510	160612	MAD600	160110	MAD700	160431		
	160314		160622		160119		160502		
	160441		160633		160128		160520		
	160508		160702		160140		160604		
	160632		160719		160207		160624		
	160805		160808		160228		160634		
MAD510	160109	MAD510L	160118		160304		160411	160712	160809
	160115		160324		160442		160818		
	160206		160509		160525		MAD710	160120	
	160220		160709		160703		160142		
	160227		160810		160807		160404		
	160303		160833		160111		MAD720	160511	
	160315	MAD510P	151231	160129	160141	160725	160909		
	160323		160213	160209	MAD730	160427			
	160328		160325	160233	MAD730OS	160305			
	160401		160420	160316	MAD800	160208			
	160426		160510	160329	160625				
	160501		160623	160403	MAD900	160605			
	160519		160710						
	160603		160811						

Dear Customer,

Details of affected devices

Teleflex has initiated a voluntary Field Safety Corrective Action for the above listed products.

Description of the problem

These products are used for the delivery of topical anesthesia via an atomized spray to the oral, nasal, pharyngeal or laryngeal mucosa. Teleflex Medical is recalling these products as they may produce a straight stream instead of a fully atomized plume of medication. It is unlikely that serious adverse health consequences will occur in the event of a failure to deliver an atomized plume; however, this may result in inadequate topical anesthesia which may lead to some discomfort, further attempts to deliver topical anesthesia, or the use of alternative methods of anesthesia.

FIELD SAFETY CORRECTIVE ACTION INSTRUCTIONS

ADVICE ON ACTION TO BE TAKEN BY MEDICAL STAFF

- We request that you check your inventory for product within the scope of this field action. Users should cease use and distribution of stock of the affected product batch and quarantine immediately.
- If you do not have stock in scope of this field action as referred to in above table then mark the according checkbox on the Acknowledgement form (Appendix 1) and return the form to the fax number or e-Mail-address mentioned below.

3. If you have stock from the affected product as referred to in above table, mark the according checkbox on the Acknowledgement form (Appendix 1). Contact customer service by calling the phone number mentioned below who will issue you with a return number. Write this return number into the respective field in the Acknowledgement form.
4. Complete 'Appendix 1' for all products in your possession and under control. Return this form immediately to Customer Service.
5. Teleflex (or your local dealer) will issue a credit note upon receipt of the returned affected product.

INSTRUCTION FOR DISTRIBUTORS OF AFFECTED PRODUCT

1. If you are a distributor, provide this field safety notice to all of your customers who have received product in scope of this Field Action. Your customer is then required to complete the acknowledgement form and return this to you.
2. As a Distributor you are required to confirm to Teleflex that you have completed the field activity outlined above. Upon completion of your actions, please forward the completed Acknowledgement Form to Customer Service.
3. Please be aware that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities in which Teleflex distribute directly will be notified by Teleflex.
4. If you are a distributor and/or have a reporting responsibility within or outside the EEA/CH/TK area, please notify your local Competent Authority of this action. Please forward the notification and all communication with your local competent authority to Teleflex.

Teleflex

Teleflex informs all customers, employees of Teleflex and distributors on this Field Action.

Transmission of this Field Safety Notice

This notice should be passed on to all persons who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please consider end users, clinicians, risk managers, supply chain/distribution centres etc. in the circulation of this notice. Maintain awareness of this notice until all required actions have been completed in your organisation.

Contact reference person

Should you require any further information or support concerning this issue, please contact:

Customer Service

Contact: Herr Horst Erbe

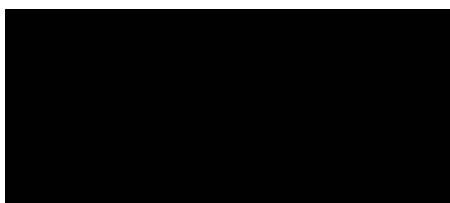
Fax: +49 7151 / 406-566

Telephone: 07151 / 406 – 431

e-mail: horst.erbe@teleflex.com

Please be advised that all European Economic Area/Switzerland (EEA/CH) and Turkey Member State Competent Authorities to which Teleflex distribute directly will be notified by Teleflex. Teleflex is committed to providing high quality, safe and effective products. We sincerely apologize for any inconvenience this action may cause your operations. If you have any other questions, feel free to contact your local sales representative or Customer Service.

For and on behalf of Teleflex,



**FIELD SAFETY CORRECTIVE ACTION
ACKNOWLEDGEMENT FORM**

PRODUCT FIELD ACTION BY TELEFLEX - IMMEDIATE ATTENTION REQUIRED
Ref. EIF-000100: LMA® Mucosal Atomization Devices

RETURN COMPLETED FORM IMMEDIATELY TO:

FAX: +49 7151 /406-566

E-mail: horste.erbe@teleflex.com

<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm that our inventory does NOT include products affected by this Field Action.	<input type="checkbox"/> We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory does include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned. Return Authorisation No _____
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PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	LMA® Mucosal Atomization Devices	
PRODUCT NUMBER	LOT NUMBER	QUANTITY
<ul style="list-style-type: none"> Include a copy of the completed Acknowledgement Form in the returns package with the returned units Ensure the RAN number is clearly visible on the returns package. Please label returns as "Field Action Returns" 		

Complete this Acknowledgement form and return immediately by using the fax number or e-mail address above.

INSTITUTION NAME (EG NAME OF HOSPITAL, HEALTH CARE ORGANISATION)	
INSTITUTION ADDRESS	Phone / Fax
FORM COMPLETED BY:	Stamp
PRINT NAME: _____ SIGNATURE: _____	
DATE	