Teleflex Medical
IDA Business & Technology Park
Dublin Road, Athlone
Co. Westmeath, Ireland

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#
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		160712
	160115		160324		160411		160809
	160206		160509		160442		160818
	160220		160709		160525	MAD710	160120
	160227		160810		160703	MAD720	160142
	160303		160833		160807		160404
	160315	MAD510P	151231	MAD700	160111		160511
	160323		160213		160129		160725
	160328		160325		160141		160909
	160401		160420		160209	MAD730	160427
	160426		160510		160233	MAD730OS	160305
	160501		160623		160316	MAD800	160208
	160519		160710		160329		160625
	160603		160811		160403	MAD900	160605

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

1. 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.

2. 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: Shane Kenny
FAX: +353 (0)1 4370773
Telephone: +353 (0)90 6460869
E-mail: Recalls.intl@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,

[redacted]

Padraig Hegarty VP, QA

Appendix 1

Customer No. _____

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: +353 (0)1 4370773 **E-mail**: Recalls.intl@teleflex.com

☐ 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.	☐ 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** _____

PLEASE PRINT PRODUCT QUANTITY NUMBERS CLEARLY.

COMMERCIAL NAME OF AFFECTED PRODUCTS:	**LMA® Mucosal Atomization Devices**	
PRODUCT NUMBER	**LOT NUMBER**	**QUANTITY**

- 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	