Teleflex
MEDICAL

Amended 11/22/2016

Urgent Medical Device Recall Notification

LMA® MAD Nasal™ Intranasal Mucosal Atomization Device

November 22, 2016

To: Distributor of Teleflex Medical Products

Teleflex Medical Incorporated ("Teleflex Medical") has issued a recall for the product codes and lot numbers listed on Attachment A. Teleflex is recalling these products as they may not deliver a fully atomized plume of medication. Teleflex Medical has received complaints that the affected lots produced a straight stream instead of an atomized spray. Because the device is inserted into the nose to deliver medication, it may not be possible during actual use to determine whether it is delivering a plume or a stream.

The failure of the device to deliver an atomized plume may impair the effectiveness of the medication with which it is used. This is most critical in certain emergency situations, such as where the device is used in an off-label manner for delivery of drugs for reversal of life threatening narcotic overdose, reversal of life threatening hypoglycemia, or treatment of epileptic seizures.

Please continue to return affected product for a full refund per the procedures set forth in our letter of October 27, 2016.

Some customers have indicated that, due to medical necessity, they plan to continue using the affected lots rather than return them. By this letter, Teleflex is advising all such customers to follow the supplemental Instructions for Use included as Attachment B. These supplemental instructions allow non-destructive testing of each unit prior to the procedure to determine if it is defective. Please ensure there are replacement devices available. Please ensure these instructions are distributed to all customers as required.

If your customers intend to continue using affected lots with this supplemental testing, please have them send the acknowledgement form to you so that you may return it to us and we may track who is following this procedure. Customers may choose to follow either or both pathways – for example, returning lots 1 and 2, while retaining lot 3 for use in accordance with the supplemental instructions enclosed with this letter.

The U.S. Food and Drug Administration has been notified of this supplement to our original recall letter.

Teleflex Medical 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 at 1-866-246-6990.

1. Immediately discontinue distribution and quarantine any products with the catalog numbers and lot numbers listed above.
2. Using the provided customer letter and Recall Acknowledgement Form templates, communicate this recall to any of your customers who have received product included within the scope of the recall.

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3. Have the customers complete the Recall Acknowledgment Form and return it to you, together with any affected products which they choose to return, for consolidation and return to Teleflex Medical. In the event that an alternative approach is needed, contact Teleflex Medical Customer Service for more information at 1-866-246-6990.
4. Complete the enclosed Recall Acknowledgement Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document your response to this recall and the amount of product you will return. A customer service representative will contact you with a Return Goods Authorization (RGA) Number and will provide instructions for the return of product to Teleflex Medical.
5. Once you have completed your response to this recall including return of products from your own inventory, and collecting and consolidating your customers' Recall Acknowledgment Forms and returned products, please check the box on the enclosed Recall Acknowledgment Form that indicates that you have completed the recall and fax it to 1-855-419-8507, Attn: Customer Service, or email it to recalls@teleflex.com. This will allow us to document completion of the recall.
6. If you and your customers have no affected stock, please complete the enclosed Recall Acknowledgment Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recalls@teleflex.com. This will allow us to document your receipt of this letter.

The U.S. Food and Drug Administration has been notified of this action.

Teleflex Medical 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 at 1-866-246-6990.

For and on behalf of Teleflex,

Karen Boylan

Karen Boylan
VP, Global RA/QA

Enclosure

Attachment A

LMA® MAD Nasal™ Intranasal Mucosal Atomization Device

Products and Lots/Batches

Product Code	Batch/ Lot#	Product Code	Batch/ Lot#	Product Code	Batch/ Lot#
MAD100	160105	MAD130OS	160436	MAD300	160409
	160137		160803		160422
	160302	MAD140	160125		160432
	160321		160218		160440
	160402		160437		160500
	160435		160610		160518
	160506		160801		160602
	160523	MAD140OS	160226		160611
	160609		160438		160621
	160620		160727		160631
	160707	MAD300	160108		160701
	160802		160117		160708
	160813		160126		160718
MAD100OS	160322		160145		160728
	160524		160146		160800
	160630		160200		160804
MAD110	160217		160219		160814
	160507		160225		160816
MAD110OS	160240		160231		160823
	160312		160300	MAD300B	160410
MAD130	160107		160313		
	160138		160327		
	160517		160400		

Attachment B

LMA® MAD Nasal™ Intranasal Mucosal Atomization Device

Supplemental Instructions for Continued Use of Recalled Lots

To continue the use of products affected by this recall please follow the below pre-test procedure.
Note: This pre-test is not required for lots not affected by this recall.

Ensuring Appropriate Device Output:

Prior to use, please test the device as follows:

- ***Attach a syringe containing 1ml of either sterile water or sterile saline to the device.***
- ***Briskly compress the plunger on the syringe so as to deliver the liquid through the device and observe how the liquid comes out at the [distal] end.***
- ***If the liquid sprays in a fine mist then the device is atomizing as intended***
- ***If testing the device demonstrates streaming, select another MAD device for testing and use.***

Immediate Attention Requested

Amended Recall Acknowledgment Form for:

LMA® MAD Nasal™ Intranasal Mucosal Atomization Device

Check the appropriate box and fax this form to [distributor fax number].

☐ We have no inventory within the scope of this recall.

☐ We have the following affected product at our facility and have discontinued use and distribution. We have quarantined the affected product, and will return the following quantities and once received your account will be credited:

Product Code	Batch/Lot#	Quantity

Product Code	Batch/Lot#	Quantity

☐ We have the following affected product at our facility and will continue to use and follow the supplemental instructions for non-destructive pre-testing.

Product Code	Batch/Lot#	Quantity

Product Code	Batch/Lot#	Quantity

☐ We have distributed the supplemental instructions for use to all users as required.

Please print legibly.

(Print Name)	**(Date)**
(Signature)	**(Telephone Number)**
(Institution Name)	**(Email Address)**
(Institution Street Address)	**Alternate Mailing Address**
(Institution City, State, Zip)	**(Street Address)**
(Country)	**(City, State, Zip)**