Teleflex
MEDICAL

Urgent Medical Device Recall Notification

LMA® MAD Nasal™ Intranasal Mucosal Atomization Device

October 27, 2016

To: Distributor of Teleflex Medical Products

Teleflex Medical has issued a recall for the following product codes and lot numbers:

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		

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

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Our records indicate that you have received products that are subject to the recall. We are now notifying our distributors to take the following actions:

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.
3. Have the customers return any affected product to you, together with a completed Recall Acknowledgement Form, 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. To return your inventoried product, 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 the amount of product you have on hand for 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 returning all of the recalled products from your own inventory, and collecting and consolidating all of the recalled products from your customers, 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

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Immediate Attention Requested

1st Distributor Acknowledgment Form for:

LMA® MAD Nasal™ Intranasal Mucosal Atomization Device

Check the appropriate box and fax this form to 1-855-419-8507 or email it to recalls@teleflex.com

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

☐ We have the following affected product at our facility. We have quarantined the affected product, and will return the following quantities.

Product Code	Batch/Lot#	Quantity

Product Code	Batch/Lot#	Quantity

Your account will be credited when the returned product is received.

☐ We have communicated this recall to our customers who have received affected products. The following products have been returned to us and quarantined at our facility, and are being returned to Teleflex.

Product Code	Batch/Lot#	Quantity

Product Code	Batch/Lot#	Quantity

Your account will be credited when the returned product is received.

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☐ We have accounted for all of the affected products at our facility as well as those which were distributed to our customers. Our handling of this recall is now complete.

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)**

Teleflex, Inc. Use Only

Received By:	Date:

URGENT MEDICAL DEVICE RECALL NOTIFICATION

LMA® MAD Nasal™ Intranasal Mucosal Atomization Device

[Date]

To: Risk Manager / Director of Purchasing

Teleflex Medical has issued a recall for the following product codes and lot numbers:

Product Code	Batch/ Lot#	Product Code	Batch/ Lot#	Product Code	Batch/ Lot#
MAD100	160105	MAD130OS	160436	MAD300	160409
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Our records indicate that you have received products that are subject to this recall. We are now notifying our customers to take the following actions:

1. Immediately discontinue use and quarantine any products with the catalog numbers and lot numbers listed above.
2. If you have affected stock, please complete the enclosed Recall Acknowledgement Form and fax to **[distributor fax number]**.
3. Once the fax is received, we will provide instructions on how to return any affected product directly to **[distributor name]**.

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

We apologize for any inconvenience this notification may cause and remain committed to providing high quality, safe and effective products.

Sincerely,

[Distributor Representative]
Enclosure

Immediate Attention Requested

First 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

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)**