



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

November 4, 2016

Dear Colleague:

Teleflex Medical, the manufacturer of the MAD300 mucosal atomization device used by opioid overdose prevention programs across New York State, has issued the attached recall notification. Recall information is also attached from McKesson Medical-Surgical (MMS), a pharmaceutical distributor.

The Teleflex recall identifies specific lot numbers of affected MAD300 devices. It also provides instruction to discontinue use of affected product and to quarantine your current inventory for affected lots. Teleflex has confirmed that the affected product began shipping from Teleflex January 1, 2016 and was discontinued on October 6, 2016. Not all devices shipped during this period are impacted by the recall notice—only those with matching lot numbers.

It is very important that you check the lot numbers on the MAD300 device cartons in your inventory and follow the instructions in the attached recall notices. A pharmaceutical distributor (either MMS or Cardinal) will contact you regarding how to handle any product you have quarantined.

Teleflex may have difficulty satisfying the demand for its MAD300 device in the near future. The Department is working diligently to ensure that you receive naloxone as expeditiously as possible. The NYSDOH AIDS Institute is evaluating these events and will provide additional information. Please send any questions to overdose@health.ny.gov.

Thank you for your continued commitment to protecting the lives of New Yorkers who may be at risk of opioid overdose.

Sincerely,

Johanne E. Morne, MS
Director
AIDS Institute



Urgent Medical Device Recall Notification

LMA[®] MAD Nasal[™] Intranasal Mucosal Atomization Device

October 27, 2016

To: Customer of Teleflex Medical Products

Teleflex Medical Incorporated ("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	160108			160701	
	MAD100OS	160802	MAD300		160117	160708
		160813			160126	160718
		160322			160145	160728
MAD110	160524	160146		160800		
	160630	160200		160804		
MAD110OS	160217	160219		160814		
	160507	160225		160816		
MAD130	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.



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. If you have affected stock, immediately discontinue use and quarantine any products with the catalog numbers listed above.
2. ~~To return 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.~~
3. ~~If you 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 Medical,

Karen Boylan

Karen Boylan
VP, Global RA/QA

Enclosure

URGENT MEDICAL DEVICE RECALL

November 3, 2016

Dear Valued McKesson Customer:

Teleflex Medical has notified McKesson Medical-Surgical (MMS) of an Urgent Medical Device Recall regarding specific lots of their LMA Intranasal Mucosal Atomization Device. This notice has been issued due to 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. Affected product first shipped January 1, 2016.

This Urgent Medical Device Recall is being done with the knowledge of the U.S. Food and Drug Administration.

For questions regarding this notification, please contact Teleflex at **(866) 246-6990**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table on Page 2 for a list of affected items and lot numbers distributed by McKesson Medical-Surgical

McKesson Customer Instructions:

- 1.) Immediately discontinue use of any product matching the affected items and lot numbers listed below.
- 2.) Review the enclosed Urgent Medical Device Recall from Teleflex for details and a complete listing of the affected product(s).
- 3.) If you have product affected by this recall, fill out the McKesson Reply Form and fax it back to our Corporate Customer Service Center at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this recall, please respond within 30 days.
- 4.) Your submitted McKesson Reply Form indicates that you have affected product. Customer Service will send you return goods authorization and call tags. Please list the fax number or the e-mail address on the McKesson Reply Form that it should be sent to. Once the product is returned, credit will be issued to you. **Please note:** Credit will only be issued for unused products from the affected lots listed below.
- 5.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this notification and request that they return the affected product directly to you.

(Continued on next page)

MMS #	Catalog #	Description	Affected Lots
844538	MAD100	ATOMIZATION DEVICE, MUCOSAL LL 3ML SYR (25/BX)	160105,160137,160302, 160321, 160402, 160435, 160506, 160523, 160609, 160620, 160707, 160802 160813
928761	MAD100OS	ATOMIZATION DEVICE, MUCOSAL 3ML ORAL SYR (25/BX)	160322, 160524, 160630
844541	MAD110	SYRINGE, NASAL MAD DRUG DEL 1ML (25/BX)	160217, 160507
898895	MAD130	MUCOSAL ATOMIZER DEVICE 25BX 25/BX 1ML SYRINGE W/ADAPTER	160107, 160138, 160517
852261	MAD140	ATOMIZATION DEVICE, W/VIAL ADPT 3ML SYR (25/BX)	160125, 160218, 160437, 160610, 160801
844475	MAD300	ATOMIZATION DEVICE, MUCOSAL LL W/O SYR (25/BX)	160108, 160117, 160126, 160145, 160146, 160200, 160219, 160225, 160231, 160300, 160313, 160327, 160400, 160409, 160422, 160432, 160440, 160500, 160518, 160602, 160611, 160621, 160631, 160701, 160708, 160718, 160728, 160800, 160804, 160814, 160816, 160823

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at mmsrecalls@mckesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical, Inc.

McKesson Medical-Surgical
 Teleflex - LMA Intranasal Mucosal Atomization Device (MAD)
 Recall Reply Form: RC-2016-229

November 3, 2016

Attn: Corporate Customer Service Center

Fax Number: 866.871.0270

Fill out this reply form if you have product affected by this Urgent Medical Device Recall and fax all pages to our Corporate Customer Service Center at the number listed above. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days of receipt of this notice.

_____ I acknowledge that I DO HAVE affected product as indicated below and have followed the instructions for return.

Qty	Unit of Measure	MMS #	Catalog #	Description
		844538	MAD100	ATOMIZATION DEVICE, MUCOSAL LL 3ML SYR (25/BX)
		928761	MAD100OS	ATOMIZATION DEVICE, MUCOSAL 3ML ORAL SYR (25/BX)
		844541	MAD110	SYRINGE, NASAL MAD DRUG DEL 1ML (25/BX)
		898895	MAD130	MUCOSAL ATOMIZER DEVICE 25BX 25/BX 1ML SYRINGE W/ADAPTER
		852261	MAD140	ATOMIZATION DEVICE, W/VIAL ADPT 3ML SYR (25/BX)
		844475	MAD300	ATOMIZATION DEVICE, MUCOSAL LL W/O SYR (25/BX)

*Return Affected lot numbers only

**** Please Note: the affected lot numbers are listed on the customer letter included in this package. Credit will only be issued for unused product(s) from the affected lots. ****

This completed reply form will serve as your request for a credit should you have affected product.

Ship to Account Number: _____ Address: _____
 Customer Name: _____ City, State Zip: _____
 Date: _____ Phone Number: _____
 Your Name (printed): _____ Fax Number: _____
 Email Address: _____ Number of UPS parcels to be returned: _____

(PLEASE SEND MY UPS LABEL/RETURN LABEL BY _____ FAX OR _____ EMAIL)

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at mmsrecalls@mckesson.com or call (800) 688-8840.