

South Plains Emergency Medical Services, Inc.

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Bailey
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November 9, 2016

TO: All SPEMS EMS Services

SUBJECT: LMA® Teleflex™ Intranasal (IN) Mucosal Atomization Device (MAD)

There has been a recall issued for several batches of the LMA® Teleflex™ MAD Intranasal (IN) Mucosal Atomization Device (MAD) which potentially could result in a shortage of the product.

Effective immediately, all recalled MAD devices (see attached list) must be removed from all EMS units and supply stocks. DO NOT remove any devices that are NOT on the list of recalled items.

BASIC SERVICES: In the event your unit has a patient that would require administration of Narcan, and you do not have the MAD device available, ensure that an ALS/MICU unit has been requested.

ALS/MICU SERVICES: In the event your unit does not have a MAD device, you are advised to administer medications via an alternate route as allowed by the protocols.

This is a **temporary** variance and is ONLY used if an EMS service is unable to secure MAD devices that are unaffected by the recall. This variance will remain in effect until such time that all recalled MAD devices can be replaced.

A copy of this letter will need to be placed in each Protocol book in each ambulance.

Sincerely,

Charles E. Addington II, D.O.
Medical Director



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		160125		160432
	160321	160218	160440		
	160402	MAD140	160437		160500
	160435		160610		160518
	160506		160801		160602
	160523		160226		160611
	160609	MAD140OS	160438		160621
	160620		160727		160631
	160707		160108		160701
	160802	MAD300	160117		160708
	160813		160126		160718
	160322		160145		160728
MAD100OS	160524		160146	160800	
	160630		160200	160804	
	160217		160219	160814	
MAD110	160507		160225	160816	
	160240		160231	160823	
MAD110OS	160312		160300	MAD300B	160410
	160107		160313		
MAD130	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