



November 3, 2016

Risk Manager/Director of Purchasing:

Teleflex Medical has issued a recall for the following product code and lot numbers that were shipped to Southeastern Emergency Equipment.

Product Code	Batch/Lot#	Product Code	Batch Lot#
MAD300	160313	MAD300	160631
	160400		160701
	160518		160718
	160602		

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 used in an off label manner for needle-free delivery of drugs for 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. Immediately discontinue use and quarantine any products with the product code and lot numbers listed above. There is an additional list of lot numbers that you may have received from another source attached.
2. If you have affected stock, please complete the enclosed Recall Acknowledgement form and fax to 919-435-5963.
3. Once the fax is received we will provide instructions on how to return any affected products directly to Southeastern Emergency Equipment.

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

We apologize for an inconvenience this notification may cause

Sincerely,

A handwritten signature in blue ink that reads "April Phelps".

April Phelps
Purchasing Manager

PO Box 1097 • Youngsville, NC 27596
(800) 334-6656 • FAX (888) 556-1048
www.seequip.com

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)	<u>Alternate Mailing Address</u>
(Institution City, State, Zip)	(Street Address)
(Country)	(City, State, Zip)

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 *
	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 †			