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November 2, 2016

TO: ORANGE COUNTY EMS DISTRIBUTION LIST

FROM: SAM J. STRATTON, MD, MPH
MEDICAL DIRECTOR, ORANGE COUNTY EMS

SUBJECT: RECALL OF MAD NASAL™ INTRANASAL ATOMIZATION DEVICE

Orange County EMS has been notified of a recall of some lots of the MAD Nasal™ intranasal atomization device that may be in use in the Orange County EMS System for intranasal administration of midazolam for seizures or sedation, naloxone for opioid overdose, and fentanyl for pain. The recall notice which identifies the specific lot numbers of the devices under recall is attached.

At present it is recommended that any atomization nozzle identified in the attached recall notice be removed from service and that alternate routes (intramuscular or intravenous) be used as directed in Standing Orders or by Base Contact for administration of medications that could also be provided by the intranasal route.

SJS:sjs#2782

Customer Letter Template for Distributors

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
	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.

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