

BY:
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#
#1 MAD100	160105	MAD130OS	160436	#4 MAD300	160409
	160137		160803		160422
	160302	#3 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	#4 MAD300	160108		160701
	160802		160117		160708
	160813		160126		160718
	160322		160145		160728
MAD100OS	160524		160146	160800	
160630	160200		160804		
MAD110	160217		160219	160814	
160507	160225		160816		
MAD110OS	160240		160231	160823	
160312	160300		MAD300B	160410	
#2 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.