



Urgent Medical Device Recall Notification

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

October 27, 2016

To: Distributor of Teleflex Medical Products

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	160322	MAD300		160117	160708
		160524			160126	160718
		160630			160145	160728
MAD110	160217	160146		160800		
	160507	160200		160804		
MAD110OS	160240	160219		160814		
	160312	160225		160816		
MAD130	160107	160231		160823		
	160138	160300		MAD300B	160410	
	160517	160313				
		160327				
		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.