The FDA is posting the company's urgent medical device recall notification due to the high level of public interest.

Urgent Medical Device Recall Notification

LMA® Mucosal Atomization Devices

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#	Product Code	Batch/ Lot#
MAD500	160127	MAD510	160612	MAD600	160110	MAD700	160431
	160314		160622		160119		160502
	160441		160633		160128		160520
	160508		160702		160140		160604
	160632		160719		160207		160624
	160805		160808		160228		160634
MAD510	160109	MAD510L	160118		160304		160712
	160115		160324		160411		160809
	160206		160509		160442		160818
	160220		160709		160525	MAD710	160120
	160227		160810		160703	MAD720	160142
	160303		160833		160807		160404
	160315	MAD510P	151231	MAD700	160111		160511
	160323		160213		160129		160725
	160328		160325		160141		160909
	160401		160420		160209	MAD730	160427
	160426		160510		160233	MAD730OS	160305
	160501		160623		160316	MAD800	160208
	160519		160710		160329		160625
	160603		160811		160403	MAD900	160605

These products are used for the delivery of topical anesthesia via an atomized spray to the oral, nasal, pharyngeal or laryngeal mucosa. Teleflex Medical is recalling these products as they may produce a straight stream instead of a fully atomized plume of medication. It is unlikely that serious adverse health consequences will occur in the event of a failure to deliver an atomized plume; however, this may result in inadequate topical anesthesia which may lead to some discomfort, further attempts to deliver topical anesthesia, or the use of alternative methods of anesthesia.

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