# 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