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Date: December 15, 2016

System Memo: # 362

To: All Chiefs; Provider EMSCs, Hospital EMSCs/Educators; Paramedics & EMTs; ECRNs

From: Connie J. Mattera, M.S., R.N., EMT-P

EMS Administrative Director

RE: MAD Supplemental Instructions for continued use of

Recalled Lots

The Teleflex company has issued Supplemental Instructions for Continued Use of Recalled Lots of the MAD Devices. A copy of the full recall notice is attached to this System Memo.

Dr. Ortinau believes these steps to be reasonable when there is time to check the device (pain management). If a patient is in urgent need of a drug (active seizures), an alternative drug delivery route (IM, IV) will likely need to be considered.

Please pass this information to all EMS personnel (EMTs, paramedics, and ECRNs). It may have the most urgent use if IN naloxone is needed.

To continue the use of products affected by this recall please follow the below pre-test procedure. This pre-test is not required for lots not affected by this recall.

Ensuring Appropriate Device Output:

Prior to use, please test the device as follows:

- Attach a syringe containing 1mL of either sterile water or sterile saline to the device. (May use preloaded syringes of NS for IV flush)
- Briskly compress the plunger on the syringe so as to deliver the liquid through the device and observe how the liquid comes out at the [distal] end.
- If the liquid sprays in a fine mist then the device is atomizing as intended and may be used.
- If testing the device demonstrates streaming, select another MAD device for testing and use.

Note: These supplemental instructions are being provided to ensure adequate supply of these products due to medical necessity. If you chose not to use the affected products, please follow the return procedures included in the original recall notice.

The U.S. Food and Drug Administration has approved the distribution of the affected stock with the Supplemental Instructions. Please contact Teleflex Customer Service at 1-866-246-6990 or e-mail recalls@teleflex.co, with questions or to process returns.