

## MESSAGE REGARDING PROCEDURE MASK WARNING LABELING

### **VERSIONS:**

**May 19, 2020: Original**

Recently, the FDA has begun requiring that certain types of Personal Protective Equipment (PPE) originating in China be labeled with a warning that states “Non-Medical.” In the upcoming days and weeks your base or business unit may receive procedural masks that include this messaging. The FDA requires this messaging to be in place to ensure that the buyer is aware that these procedural masks should not be utilized in a setting where a surgical mask is required (i.e. sterile environments) and it must be present to clear US customs. This message does not mean that this mask is unsafe or not for use in the pre-hospital environment.

### **Surgical Mask and Procedure Mask Differences**

- Surgical masks are intended to be used in medical setting where a sterile field must be maintained
- Procedural masks are not sterile
- Surgical masks have straps or ties that are meant to work with hoods, surgical caps or hair covers
- Procedural masks have ear loops
- Surgical masks offer some protection from bodily fluids
- Procedural masks are not typically fluid impervious

### **A Few Things to Keep in Mind**

- Procurement has not ordered surgical masks, they continue to order and stock procedural masks which will begin to arrive with the FDA required (Not for Medical Use) message
- Procedure masks are intended to be used for source control (patient and provider)
- Anytime there is potential for exposure to droplets or aerosolized particles (intubation, suctioning, etc.) an N95 or greater, gown, gloves and eye protection are used.