MILWAUKEE COUNTY
EMERGENCY MEDICAL SERVICES DIVISION
BEN WESTON, MD, MPH, EMS MEDICAL DIRECTOR
TOM ENGEL, MD, MPH, ASST. MEDICAL DIRECTOR
TOM GRAWEY, DO, ASST. MEDICAL DIRECTOR
DAN POJAR, BSEMS, FP-C, NRP, EMS DIVISION DIRECTOR

NUMBERED NOTICE

Number: 23-03
Date: 9/20/2023
From: Ben Weston, MD, MPH, Medical Director
To: All EMS Providers
Subject: Pediatric King LTDs
Purpose: Directive

Situation:
The King LTD Supraglottic Airway devices are not FDA approved for use in Children.

Background:
The FDA recently sent a Warning Letter to King Systems Corp. dba Ambu, Inc. identifying several issues with the pediatric sized airways as currently only the adult sized airways are currently approved for use. The device sizes currently affected are as follows:

1. Less than 5 kg (Size 0)
2. 5 kg to 12 kg (Size 1)
3. 12 kg to 25 kg (Size 2)
4. 25 kg to 35 kg (Size 2.5)

A copy of the warning letter is here: King Systems Corp. dba Ambu, Inc. - 661617 - 08/16/2023 | FDA

Assessment:
It is our understanding that many services have transitioned away from these already in favor of the iGel Supraglottic Airway devices.

Recommendation:
All King LTD Pediatric sized Supraglottic Airway devices (size 2.5 and smaller) shall be removed from service on all apparatus and replaced with an FDA and OEM approved device as soon as feasible. OEM stands ready to assist any agency in getting connected to a supply of FDA approved devices through a reputable vendor.

Ben Weston, MD, MPH, EMS Medical Director
Office of Emergency Management

Dan Pojar, EMS Division Director
Office of Emergency Management