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ITLS Editorial Board Responds to Issue with King Airway Device, FDA Warning

The ITLS Editorial Board has released the following statement in response to a U.S. Food and Drug Administration (FDA) warning issued to King Systems regarding its marketing for the King LT(S)-D oropharyngeal airway for off-label use:

ITLS incorporates various medical equipment and medication management options within its instructional materials based on currently available scientific evidence and expert consensus. Ability for providers to use and apply these patient care options is dependent on approval by their medical oversight and laws of the country and locality where they practice.

The Editorial Board also referenced the following statement from the FDA on "off-label" use of marketed drugs, biologics and medical devices:

"Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgment. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects."

The Editorial Board's position is the result of a warning issued by the FDA in October. The Office of Compliance in the Center for Devices and Radiological Health reviewed King Systems' website for the King LT(S)-D oropharyngeal airway product and found that the device was being marketed as "intended for airway management in patients over four feet in height for controlled or spontaneous ventilation ... for difficult and emergency airway cases ... and as well-suited for ambulatory and office-based anesthesia."

However, the FDA said the device was solely approved for use of "controlled ventilation during anesthesia" for short procedures in adults, when patients are considered at low risk of aspiration of stomach contents. A link to the complete warning letter can be viewed online at the ITLS website, www.itrauma.org.