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September 12, 2023


SUFFOLK CO DEPT OF HEALTH SERV
PO BOX 9006
GREAT RIVER, NY 11739-9006



Customer Number: 114544

Re: **Ambu-King LTS-D**

Dear Medical Inventory Controls/Supplies Coordinator/Buyer:

This letter pertains to a temporary cessation of sale and temporary cessation of use notification. If you are not the intended recipient of this correspondence, please ensure this notification reaches the individual/department responsible for stocking and distributing supplies within your organization.

Bound Tree Medical was recently advised by Ambu of a temporary cessation of sale and temporary cessation of use notification for certain sizes of the Ambu-King LTS-D. This action includes Bound Tree Item numbers 477-KLTSD420EA, 477-KLTSD421EA, 477-KLTSD422EA, 477-KLTSD4225EA, 2114-44430, 2114-44431, 2114-44432 and 2114-44325. Our records indicate that you may have purchased one or more of these items.

The enclosed letter from Ambu explains the King LTS-D, sizes 0, 1, 2, and 2 ½ are under further regulatory review by the FDA. Until this review is completed by the FDA, Ambu is recommending that all sale and use of the item numbers noted above cease.

Should you determine your inventory contains affected product, please quarantine it until further direction is provided by Ambu. Contact a Bound Tree Medical representative to identify appropriate airway alternatives.

We apologize for any inconvenience this action may cause. Thank you for allowing Bound Tree Medical to be your source for emergency medical supplies and equipment.

Sincerely,

Michelle Samples

Michelle Samples
Regulatory Affairs

Enclosure





Ambu USA
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31 August 2023

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Dear Customer,

This letter intends to inform you that Ambu has created a temporary delivery stop for Ambu® King LTS-D™ Disposable Laryngeal Tube, sizes 0, 1, 2 and 2½ in the U.S., due to concerns raised by the FDA on the regulatory pathway that King Systems, which is the manufacturer, has chosen for these sizes.

The adult sizes 3, 4, and 5 of Ambu® King LTS-D™ Disposable Laryngeal Tube remain available for purchase and can be used for the intended purpose, also in the US.

Until full clarity from the FDA on the rights to sell sizes 0, 1, 2 and 2½ has been obtained, users are encouraged to identify appropriate airway alternatives.

During the past 5 years, Ambu has sold more than 190 thousand Ambu® King LTS-D™ Disposable Laryngeal Tube, sizes 0, 1, 2 and 2½. During this time, no market feedback or complaint recordings indicate a compromise of product safety of any of the affected products. However, in order to respect the process initiated by the FDA, Ambu and King Systems deem it necessary to stop any further marketing and sales efforts of these sizes for children/pediatric until full clarity has been achieved.

Concretely, the following item numbers are affected:

KLTS420	AMBUKING LTSD,SIZE 0,W/SUCTION
KLTS421	AMBUKING LTSD,SIZE 1,W/SUCTION
KLTS422	AMBUKING LTSD,SIZE 2,W/SUCTION
KLTS4225	AMBUKING LTSD,SIZE 2.5,W/SUCTI
KLTS430	AMBUKING LTSD,SIZE 0, KIT
KLTS431	AMBUKING LTSD,SIZE 1,KIT
KLTS432	AMBUKING LTSD,SIZE 2,KIT
KLTS4325	AMBUKING LTSD,SIZE 2.5,KIT

For now, it is unknown when Ambu will resume delivery in the U.S., as it depends on the outcome of the dialogue with the FDA and the subsequent regulatory path forward.

Please note that Ambu® King LTS-D™ Disposable Laryngeal Tube, sizes 0, 1, 2 and 2½ for children, continue to be available for sale outside U.S. based on regulatory clearances in those markets.

We apologize sincerely for the inconvenience caused.

Kind regards,

Tim Gallagher
 Senior Market Manager
 Ambu USA