Kingsystems
King Systems
15011 Herriman Boulevard
Noblesville, IN 46060
USA
P 317.776.6823

Urgent Field Safety Notice

King LTS-D Disposable Laryngeal Tube - Pediatric Sizes

September 26, 2024

Dear Customers,

King Systems is committed to have timely, sufficient, and transparent communication with our customers. The purpose of this notice is to inform all customers to cease usage of King LTS-D™ Disposable Laryngeal Tube pediatric sizes 0, 1, 2 and 2.5 in the U.S., due to concerns raised by the FDA on the regulatory pathway that applied to King LTS-D™ Disposable pediatric sizes.

Details on affected devices:

Item No.	Product Name	UDI-DI in Shipper Label	UDI-DI in Piece Label
KLTSD420	KING LTSD,SIZE 0,W/SUCTION PORT STERILE	00612649210131	00612649210148
KLTSD421	KING LTSD,SIZE 1,W/SUCTION PORT STERILE	00612649210162	00612649210155
KLTSD422	KING LTSD,SIZE 2,W/SUCTION PORT STERILE	00612649210186	00612649210179
KLTSD4225	KING LTSD,SIZE 2.5, W/SUCTION PORT STERILE	00612649210193	00612649210209
KLTSD430	KING LTSD,SIZE 0, W/SUCTION PORT NON-STERILE KIT	00612649212692	00612649212685
KLTSD431	KING LTSD,SIZE 1, W/SUCTION PORT NON-STERILE KIT	00612649212708	00612649212715
KLTSD432	KING LTSD,SIZE 2, W/SUCTION PORT NON-STERILE KIT	00612649212722	00612649212739
KLTSD4325	KING LTSD,SIZE 2.5, W/SUCTION PORT NON-STERILE KIT	00612649212746	00612649212753

Description of the Problem:

The FDA indicated the King LTS-D™ Disposable Laryngeal Tube pediatric sizes exceed the limitations to the 510 (k) exemption in 21 CFR 868.9(a) because it introduces a new indication for pediatric use in an Oropharyngeal Airway. King Systems has been made aware of one complaint related to this. King Systems has not been made aware of any safety and effectiveness concerns according to current market feedback, but deems it is necessary to stop the marketing of these pediatric devices until FDA premarket notification or premarket approval has been achieved.

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Actions to be taken by the Customer:

You must discontinue use and dispose of King LTS-D™ Disposable Laryngeal Tube pediatric sizes and identify alternative devices for appropriate airway management.

Within one month of receipt of this notice, please provide return response for this Field Safety Notice (See Appendix 1).

Note:

- King LTS-D™ Disposable Laryngeal Tube Adult Sizes 3, 4, and 5 remain available and will continue to be legally marketed in the U.S. and not affected by this field safety notice.

Transmission of this Field Safety Notice:

This Notice needs to be passed on to all those who might concern within your organization where the devices could have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Patient safety remains our highest priority. If you have additional questions regarding this information, please contact your local Ambu-King Systems sales representative.

For any reportable adverse event, you will find links below to FDA medical device reporting. MedWatch: The FDA Safety Information and Adverse Event Reporting Program | FDA

King Systems has provided this Field Safety Notice to appropriate regulatory authorities. Should you have additional questions, please do not hesitate to contact Tammy Feyerherm at tfey@ambu.com.

Sincerely,

Name: Wen Gao

Title: Manager, Regulatory Affairs

Date: Sep 26, 2024

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Appendix 1

Confirmation on Field Safety Notice Completed

Return to Tammy Feyerherm at tfey@ambu.com

The undersigned person hereby confirms that the Hospital/ Clinic/ Emergency Center/ Consignee identified below, has received and understood the Field Safety Notice issued by King System dated September 26, 2024, regarding Pediatric KLTSD.

Entity Name	Address

(Street number and name, City, State, Zip Code)

☐ **Does your organization have existing Pediatric KLTSD (size 0, 1, 2, and 2.5) inventory. Please fill in Table 1 with pertinent information.**

Or

☐ **Does your organization no longer have Pediatric KLTSD (size 0, 1, 2, and 2.5) in inventory and all devices have been previously used and/or discarded.**

Table 1:

KLTSD Size	Catalog/Product Number	Lot Number	Quantity Discarded	Quantity Returned
0				
1				
2				
2.5				

☐ By signing this Field Safety Notice, I hereby certify that the product identified in the table above has been discarded as is no longer available for use,

Or

☐ Should you prefer to return the devices to King Systems, please contact Tammy Feyerherm at tfey@ambu.com to obtain RMA Number.

Date:	
Name:	
Title:	
Signature:	