

January 24, 2011

15011 Herriman Boulevard
Noblesville, IN 46060

URGENT DEVICE RECALL **KING SYSTEMS LTS-D AIRWAY**

P 317.776.6823
TF 800.642.5464
F 317.776.6827

This is to inform you of a voluntary product recall involving King Systems LTS-D Airway:

King Systems Product Code	Product Description	Lot Number(s)
KLTS414	KING LTS-D Kit, Size 4 - 5/Case	IV715
KLTS405	KING LTS-D, SIZE 5	201011-169

See enclosed product label to assist in identifying recalled items.

This recall has been initiated due to product below specified hardness. The tubes are too pliable and may be difficult to use for intubation. There is a possibility that the tube could fold over in the narrower areas of assembly.

The above listed product was shipped December 27, 2010 through January 4, 2011.

Please immediately examine your inventory and quarantine product subject to recall.

King Systems has informed the FDA that this recall is being initiated and is working with the FDA in the execution of the recall.

DISTRIBUTORS: CEASE ALL SALES.

- 1. If you have any inventory of product listed above: CEASE ALL SALES. Secure and quarantine inventory.*
- 2. For product distributed to end user facilities, COMMUNICATE the lot information and details of this recall to end users. Include a copy of this recall notification letter, including a copy of the Recall Acknowledgement Form in your notice to end users. Instruct end users to follow end user instructions below.*
- 3. Complete the attached Recall Acknowledgement Form indicating that the action(s) taken, including information about quarantined inventory: product, lot number, quantity. Return Recall Acknowledgement Form to King Systems.*
 - a. Completed Recall Acknowledgement Forms can be faxed to: 317-776-5197 – Attention LTS-D Recall, or emailed to LTSDrecall@kingsystems.com.*
- 4. After providing King Systems with the completed Recall Acknowledgement Form, contact King Systems Customer Service Department to receive a Return Goods Authorization Number (RGA #). Customer Service may be reached at 1-800-642-5464.*
- 5. Return all recalled product to King Systems. King Systems will honor authorized returns for the products and lot numbers identified on the attachment and is prepared to replace these products as quickly as possible or provide an acceptable substitute. Our Customer Service representatives will provide additional details and work with you to minimize the impact to you.*

END USER FACILITIES: CEASE ALL USE.

1. *If you have any inventory product listed above: CEASE ALL USE. Secure and quarantine inventory.*
 2. *Complete the attached Recall Acknowledgment Form indicating that the action(s) taken, including information about quarantined inventory: product, lot number, quantity. Return Recall Acknowledgement Form to King Systems.*
 - a. *Completed Recall Acknowledgement Forms can be faxed to: 317-776-5197 – Attention LTS-D Recall, or emailed to LTSDrecall@kingsystems.com.*
3. *After providing King Systems with the completed Recall Acknowledgement Form, contact King Systems Customer Service Department to receive a Return Goods Authorization Number (RGA #). Customer Service may be reached at 1-800-642-5464.*
4. *Return all recalled product to King Systems. King Systems will honor authorized returns for the products and lot numbers identified on the attachment and is prepared to replace these products as quickly as possible or provide an acceptable substitute. Our Customer Service representatives will provide additional details and work with you to minimize the impact to your facility.*

If you have questions regarding product return, replacement, hospital notification or concerning the information requested above, please contact Customer Service at 1-800-642-5464.

If you have any regulatory questions about the recall, please contact me at 1-800-642-5464.

Thank you for your prompt attention to this matter.

Sincerely,

Tony L. Barbour
Director of Quality Assurance and Regulatory Affairs
Tel 317-776-6823 ext. 257

King Systems Corporation
Recall Acknowledgement Form

King Systems Product Code	Product Description	Lot Number(s)
KLTS414	KING LTS-D Kit, Size 4 - 5/Case	IV715
KLTS405	KING LTS-D,SIZE 5	201011-169

The company listed below, through its representative whose name, title and signature appear below, confirms that it has completed the tasks requested by King Systems in relation to this product recall.

I. Please check all that apply:

<input type="checkbox"/>	Distributor – all sales ceased.
<input type="checkbox"/>	Distributor – I have notified my customers who were shipped or may have been shipped this product by (specify date and method of notification)
<input type="checkbox"/>	End user facility – all use ceased
<input type="checkbox"/>	All affected product secured and quarantined
<input type="checkbox"/>	No affected product on hand.

Any adverse event associated with recalled product? Yes No (check one)
 If yes, please explain.

II. The following product is on hand, secured and quarantined:

Product	Lot Number	Quantity

III. Distributor / End user facility Information

Please Print	
Company/Facility Name	
Street Address	
City, State, Zip Code	
Phone	
Completed By: Name/Title	
Date: (mm/dd/yy)	

Signature	
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Completed Recall Acknowledgement Forms can be faxed to: 317-776-5197 – Attention LTS-D Recall, or emailed to LTSDrecall@kingsystems.com.

KING SYSTEMS



A Consort Medical Company



REF

KLTS414



QUANTITY: 5 PER CASE
KING LTSD
KIT SIZE 4

Manufacturer

KING SYSTEMS

15011 Herriman Blvd.

Noblesville, IN 46060

Tel 317-776-8823 Fax 317-776-8827

Made in the U.S.A

EU Regulatory Representative

Medical Product Service GmbH

Bornhage 20

35619 Braunfels, Germany

830-071 03/10

LOT



(01)00812848168808(30)8.0(10)

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KING SYSTEMS

A Consort Medical Company

REF #

KLTS405

KING LTS-D SIZE 5

Quantity 10 each

LOT

KING SYSTEMS

A Consort Medical Company

Noblesville, IN 46060
317-776-6823
www.kingsystems.com



32-5431.10/08