

KING LT-D™ Airway - INSTRUCTIONS FOR USE

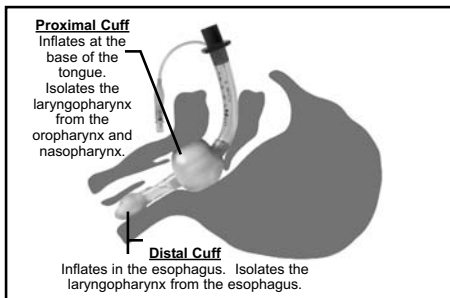
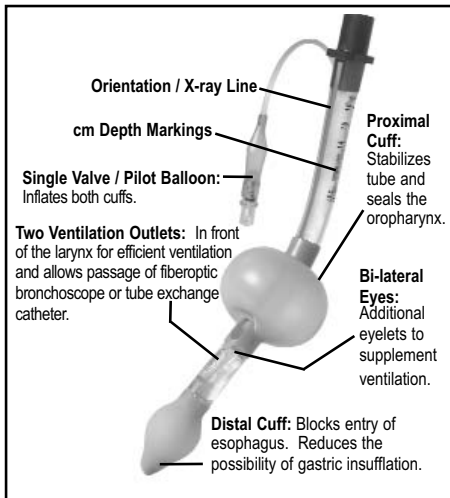
ENGLISH

Caution: Federal law restricts this device to sale by or on the order of a physician.

In order to use the KING LT-D safely, the user must first be familiar with the following instructions, cautions, and warnings.

DESCRIPTION

The KING LT-D is a sterile single use device intended for airway management. It consists of a curved tube with ventilation apertures located between two inflatable cuffs. Both cuffs are inflated using a single valve/pilot balloon. The distal cuff is designed to seal the esophagus, while the proximal cuff is intended to seal the oropharynx. Attached to the proximal end of the tube is a 15 mm connector for attachment to a standard breathing circuit or resuscitation bag. Sterilization is by ethylene oxide.



INDICATIONS FOR USE

The KING LT-D is intended for airway management in patients over 4 ft in height (122 cm) for delivery of controlled ventilation when the patient is considered to have a low risk of aspiration of stomach contents. Also indicated for difficult and emergent airway cases and is well suited for ambulatory and office-based anesthesia.

CONTRAINDICATIONS

The KING LT-D does not protect the airway from the effects of regurgitation and aspiration. The following contraindications are applicable for routine use of the KING LT-D:

- Patients who have not fasted, including

patients whose fasting cannot be confirmed, and in other situations where there may be retained gastric contents. Situations where gastric contents may be present include, but are not limited to, gross or morbid obesity, pregnancy, multiple or massive injury, acute abdominal or thoracic injury, any condition associated with delayed gastric emptying, or use of opiate medication prior to fasting.

- Patients with a hiatal hernia, unless effective measures have been taken to empty their stomach contents beforehand.
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, because these patients may be contraindicated for KING LT-D use.

WARNINGS

The user should be familiar with the following warnings when considering or attempting to use the KING LT-D:

- High airway pressures may divert gas either to the stomach or to the atmosphere.
- Intubation of the trachea cannot be ruled out as a potential complication of the insertion of the KING LT-D. After placement, perform standard checks for breath sounds and utilize an appropriate carbon dioxide monitor as required by hospital protocol.
- Lubricate only the posterior surface of the KING LT-D to avoid blockage of the aperture or aspiration of the lubricant.
- Caution should be used when considering the use of the KING LT-D on patients with fixed decrease pulmonary compliance, such as patients with pulmonary fibrosis.

The KING LT-D is supplied sterile and is not intended for re-use.

During transition to spontaneous ventilation at emergence from anesthesia, airway manipulations or other methods may be needed to maintain airway patency.

LATEX-FREE

The KING LT-D is 100% latex-free and should be considered safe to use on patients who are latex sensitive.

Size	Description	Connector Color	OD	ID	Inflation Volume
3	4-5 feet (122-155 cm) in height	Yellow	14 mm	10 mm	45-60 ml
4	5-6 feet (155-180 cm) in height	Red	14 mm	10 mm	60-80 ml
5	greater than 6 feet (180 cm) in height	Purple	14 mm	10 mm	70-90 ml

KING LT-D INSERTION INSTRUCTIONS

1. Using the information provided, choose the correct KING LT-D size, based on patient height.
2. Test cuff inflation system by injecting the maximum recommended volume of air into the cuffs (size 3 - 60ml; size 4 - 80ml; size 5 - 90ml). Remove all air from both cuffs prior to insertion.
3. Apply a water-based lubricant to the beveled distal tip and posterior aspect of the tube, taking care to avoid introduction of lubricant in or near the ventilatory openings.
4. Have a spare KING LT-D ready and prepared for immediate use.
5. Pre-oxygenate.
6. Achieve the appropriate depth of anesthesia. (An adequate level of anesthesia is required before attempting insertion of the KING LT-D. Standard monitoring techniques should be followed when inducing anesthesia. In general, the depth of anesthesia needed is a little more than that required for the insertion of a Guedel-type airway. It is recommended that the less experienced user choose a slightly deeper level of anesthesia.)
7. Position the head. The ideal head position for insertion of the KING LT-D is the "sniffing position". However, the angle and shortness of the tube also allows it to be inserted with the head in a neutral position.
8. Hold the KING LT-D at the connector with dominant hand. With non-dominant hand, hold mouth open and apply chin lift.
9. With the KING LT-D rotated laterally 45-90° such that the blue orientation line is touching the corner of the mouth, introduce tip into mouth and advance behind base of tongue.
10. As tube tip passes under tongue, rotate tube back to midline (blue orientation line faces chin).



11. Without exerting excessive force, advance KING LT-D until base of connector is aligned with teeth or gums.
12. Holding the KLT 900 Cuff Pressure Gauge in non-dominant hand, inflate cuffs of the KING

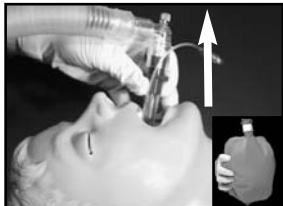


LT-D to 60 cm H₂O. If a cuff pressure gauge is not available and a syringe is being used to inflate the KING LT-D, inflate cuffs with the minimum volume necessary to seal the airway at the peak ventilatory pressure employed (just seal volume).

Typical inflation volumes are as follows:

Size 3	45-60ml
Size 4	60-80ml
Size 5	70-90ml

13. Attach the breathing circuit to the 15 mm connector of the KING LT-D.



- While gently bagging the patient to assess ventilation, simultaneously withdraw the airway until ventilation is easy and free flowing (large tidal volume with minimal airway pressure).
14. Depth markings are provided at the proximal end of the KING LT-D which refer to the distance from the distal ventilatory opening. When properly placed with the distal tip and cuff in the upper esophagus and the ventilatory openings aligned with the opening to the larynx, the depth markings give an indication of the distance, in cm, from the vocal cords to the upper teeth.
15. Confirm proper position by auscultation, chest movement and verification of CO₂ by capnography.
16. Readjust cuff inflation to 60 cm H₂O (or to just seal volume).
17. Secure KING LT-D to patient using tape or other accepted means. A bite block can also be used, if desired.

REMOVAL OF THE KING LT-D

- Once it is in the correct position, the KING LT-D is well tolerated until the return of protective reflexes.
- KING LT-D removal should always be carried out in an area where suction equipment and the ability for rapid intubations are present.

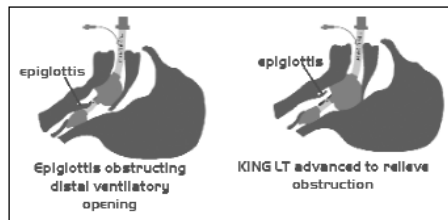
- For KING LT-D removal, it is important that both cuffs are completely deflated

USER TIPS

1. The key to insertion is to get the distal tip of the KING LT-D around the corner in the posterior pharynx, under the base of the tongue. Experience has indicated that a lateral approach, in conjunction with a chin lift, facilitates placement of the KING LT-D. Alternatively, a laryngoscope or tongue depressor can be used to lift the tongue anteriorly to allow easy advancement of the KING LT-D into position.
2. Insertion can also be accomplished via a midline approach by applying a chin lift and sliding the distal tip along the palate and into position in the hypopharynx. In this instance, head extension may also be helpful.
3. As the KING LT-D is advanced around the corner in the posterior pharynx, it is important that the tip of the device is maintained at the midline. If the tip is placed or deflected laterally, it may enter the piriform fossa and the tube will appear to bounce back upon full insertion and release. Keeping the tip at the midline assures that the distal tip is placed properly in the hypopharynx/upper esophagus.
4. Depth of insertion is key to providing a patent airway. Ventilatory openings of the KING LT-D must align with the laryngeal inlet for adequate oxygenation/ventilation to occur. Accordingly, the insertion depth should be adjusted to maximize ventilation. Experience has indicated that initially placing the LT-D deeper (base of connector is aligned with teeth or gums), inflating the cuffs and withdrawing until ventilation is optimized results in the best depth of insertion for the following reasons:
 - It ensures that the distal tip has not been placed laterally in the piriform fossa (see item #3 above).
 - With a deeper initial insertion, only withdrawal of the tube is required to realize a patent airway. A shallow insertion will require deflation of the cuffs to advance the tube deeper (several added steps).
 - As the KING LT-D is withdrawn, the initial ventilation opening exposed to/aligned

with the laryngeal inlet is the proximal opening. Since the proximal opening is closest to and is partially surrounded by the proximal cuff, airway obstruction is less likely, especially when spontaneous ventilation is employed.

- Withdrawal of the KING LT-D with the balloons inflated results in a retraction of tissue away from the laryngeal inlet, thereby encouraging a patent airway.
5. When the patient is allowed to breathe spontaneously, airway obstruction can occur even though no obstruction was detected during assisted or positive pressure ventilation. During spontaneous ventilation, the epiglottis or other tissue can be drawn into the distal ventilatory opening, resulting in obstruction. Advancing the KING LT-D 1-2 cm or initial deeper placement (see item #4 above) normally eliminates this obstruction.



6. Ensure that the cuffs are not over inflated. Cuff pressure should be adjusted to 60cm H₂O. If a cuff pressure gauge is not available, inflate cuffs with the minimum volume necessary to seal the airway at the peak ventilatory pressure employed (just seal volume). Note that nitrous oxide is known to diffuse into cuffs and increase pressure; accordingly, if using nitrous oxide, cuff pressures should be monitored periodically to avoid over-inflation.
7. Maintain appropriate depth of anesthesia. In general, the depth of anesthesia needed is a little more than that required for insertion of a Guedel-type airway. It is recommended that the less experienced user choose a slightly deeper level of anesthesia.
8. Removal of the KING LT-D is well tolerated until the return of protective reflexes. For later removal, it may be helpful to remove some air from the cuffs to reduce the stimulus during wake-up.

KING SYSTEMS CORPORATION

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