Instructions for use

KING LT® Oropharyngeal Airway

KING SYSTEMS CORPORATION
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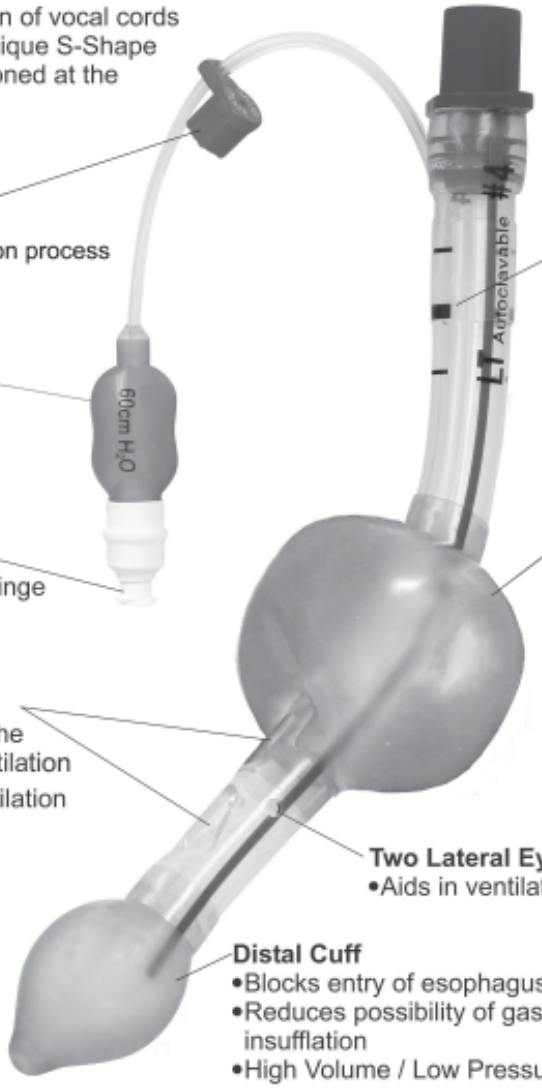
KING LT® Oropharyngeal Airway

The KING LT Oropharyngeal Airway is an alternative to ventilation with a face mask or for procedures where tracheal intubation is not necessary.

Shorter Tube Length and S-Shape
- No instruments needed to insert tube
- Minimal risk of irritation of vocal cords and trachea due to unique S-Shape
- KING LT is self-positioned at the esophageal inlet

High Grade Silicone material
- 100% Latex-free
- Autoclavable at 134°C
- Reusable up to 50 cycles



Valve Actuator
- Vents during sterilization process

Insertion Marks
- Reference markings to aid in determining depth of insertion

Pilot Balloon
- Single inflation line fills both cuffs simultaneously

Inflation Valve
- Luer connector for valve actuator and syringe connection

Anatomically Shaped Proximal Cuff
- Stabilizes tube by anchoring at the base of the tongue
- Blocks nasopharynx and oropharynx
- High volume / low pressure cuff

Ventilation Outlets
- Positioned in front of the larynx for efficient ventilation
- Positive pressure ventilation over 30 cm/H_2O
- Allows passage of a fiberoptic bronchoscope or tube exchange catheter.

Two Lateral Eyelets
- Aids in ventilation

Distal Cuff
- Blocks entry of esophagus
- Reduces possibility of gastric insufflation
- High Volume / Low Pressure Cuff

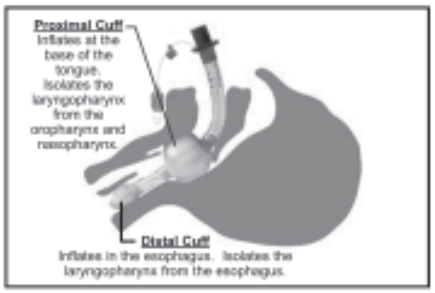
Size	Description	Connector Color	OD	ID	Inflation Pressure	Inflation Volume
3	4-5 feet (122-155 cm) in height	Yellow	14 mm	10 mm	60 cm H_2O	45-60 ml
4	5-6 feet (155-180 cm) in height	Red	15.5 mm	15.5 mm	60 cm H_2O	60-80 ml
5	greater than 6 feet (180 cm) in height	Purple	15.5 mm	15.5 mm	60 cm H_2O	70-90 ml

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

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

DESCRIPTION

The KING LT is supplied clean and is a non-sterile device intended for airway management that must be cleaned thoroughly and sterilized before initial use and before each subsequent use. 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.



INDICATIONS FOR USE

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

- 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 use.

WARNINGS

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

- 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. After placement, perform standard checks for breath sounds and utilize an appropriate carbon dioxide monitor as required by hospital protocol.
- Lubricate only the beveled distal tip and posterior surface of the KING LT to avoid blockage of the aperture or aspiration of the lubricant.
- Failure to properly clean, rinse, and dry the KING LT device may result in retention of potentially hazardous residues or inadequate sterilization.
- Caution should be used when considering the use of the KING LT on patients with fixed decrease pulmonary compliance, such as patients with pulmonary fibrosis.

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

INSTRUCTIONS FOR USE

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

NOTE: The KING LT is supplied clean and non-sterile. Before initial use, remove from original packaging and autoclave as described in following procedures.

CLEANING
The KING LT is a reusable device that must be thoroughly cleaned and sterilized after each use.

- Thoroughly wash the KING LT in warm water with soap or a mild detergent (e.g., Ivory or surgical instrument cleaner). Note: pH-neutral or mild alkaline cleaning agents are recommended.
- Use appropriate sized test tube brushes to clean all foreign matter from the ventilatory channel and airway openings of the KING LT. Special attention may be needed to ensure removal of all matter from the small side eyelets.
- Do not use hard brushes or other materials that might damage the silicone cuffs or surface.
- Eliminate all residue of the cleaning agent by thoroughly rinsing under warm running water for at least 30 seconds.
- Carefully inspect the KING LT to make sure all visible foreign matter has been removed before sterilization.

STERILIZATION – AUTOCLAVE ONLY
CAUTION: Do not use formaldehyde, glutaraldehyde, ethylene oxide, Steris™, or Cidex™ to clean or sterilize the KING LT as they are absorbed by the silicon rubber and may be exposed to the patient. The use of alkaline cleaning agents or harsh chemicals may cause deterioration of the silicon rubber and should not be used.

The KING LT can be sterilized up to 50 cycles. Strictly adhere to the following instructions to prevent damage to the KING LT and to ensure proper sterilization.

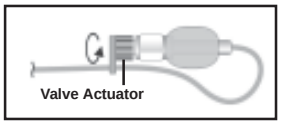
IMPORTANT: The Valve Actuator acts as a vent during the sterilization procedure and allows free passage of air to and from the cuffs, preventing damage to cuffs. The inflation valve is opened while it is connected correctly to the red Valve Actuator. When attaching the Valve Actuator, ensure that the valve is secured tightly and inflation lumen is not kinked.

CAUTION: Only use the Valve Actuator for the Sterilization procedure.

NOTE: If the Valve Actuator is not connected correctly or the Valve Actuator has been damaged or lost, damage to the cuffs during autoclaving may occur. Damage resulting from autoclaving without the use, or correct use, of the Valve Actuator is NOT covered by warranty and product will not be replaced.

STERILIZATION PROCEDURE

1. Immediately before autoclaving, completely evacuate the cuffs of the KING LT.
2. Attach the Valve Actuator tightly to the Inflation Valve, using a twisting motion, checking to make sure the lumen is not kinked. To ensure that the Valve Actuator is attached correctly, squeeze a cuff of the KING LT to validate that air can escape from the Valve Actuator. If Valve Actuator is missing, do not autoclave until replacement actuator is obtained. To order replacement Valve Actuators contact King Systems Corporation's customer service department at 800-642-(KING) 5464 or 317-776-6823.



3. Place in an appropriate autoclaveable bag. AUTOCLAVE ONLY.
4. Always follow the autoclave manufacturer's recommendations.
5. Steam autoclave in pre-vacuum cycle at 132°-135° C and 2.4 bar with exposure time ranging from 4-10 minutes (270°-275° F and 35 psi with exposure time ranging from 4-10 munutes).

6. Complete the included Sterilization Warranty Record Card each time the KING LT is sterilized.
7. Allow the KING LT to cool to room temperature prior to use.

NOTE: The KING LT will gradually discolor with age and reuse.

CUFF DAMAGE – NON REPLACEABLE
Failure to evacuate air completely and secure Valve Actuator will result in rupture of cuffs during autoclaving. This type of damage is NOT covered by warranty and product will not be replaced.

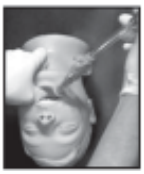
PRE-USE CHECK
Before each use of the KING LT, the device must pass the following:

1. Check to ensure proper sterilization.
2. Inspect all components of the KING LT for visible damage.
3. Examine the interior of the airway tube to ensure that it is free from blockage or loose particles.
4. Disconnect the Valve Actuator from Inflation Valve. Inflate the cuffs by injecting the maximum recommended volume of air into the cuffs (size 3 – 60 ml; size 4 – 80 ml; size 5 – 90 ml) and check for leaks.

   Do not use the KING LT if the cuffs fail to inflate and hold air.

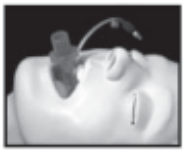
INSERTION INSTRUCTIONS

1. Using the information provided, choose the correct KING LT size, based on patient height.
2. Test cuff inflation system by injecting the maximum recommended volume of air into the cuffs (size 3 – 60 ml; size 4 – 80 ml; size 5 – 90 ml). Prior to insertion, disconnect Valve Actuator from Inflation Valve and remove all air from both cuffs.
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 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. 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 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 at the connector with dominant hand. With non-dominant hand, hold mouth open and apply chin lift.
9. With the KING LT rotated laterally 45-90°, introduce tip into mouth and advance behind base of tongue.



10. Rotate the tube back to the midline as the tip reaches the posterior wall of the pharynx.


11. Without exerting excessive force, advance KING LT 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 to 60 cm H_20. If a cuff pressure gauge is not available and a syringe is being used to inflate the KING LT, 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. 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. Reference marks are provided at the proximal end of the KING LT which, when aligned with the upper teeth, give an indication of the depth of insertion.
15. Confirm proper position by auscultation, chest movement and verification of CO_2 by capnography.
16. Readjust cuff inflation to 60 cm H_2O (or to just seal volume).
17. Secure KING LT to patient using tape or other accepted means. A bite block can also be used, if desired.

REMOVAL OF THE KING LT

- KING LT removal should always be carried out in an area where suction equipment and the ability for rapid intubations are present.
- Suction above cuffs in the oral cavity if indicated.
- FULLY deflate both cuffs before removal of the KING LT.
- Remove the KING LT when protective reflexes have returned.
- Carefully avoid the teeth while removing the airway.

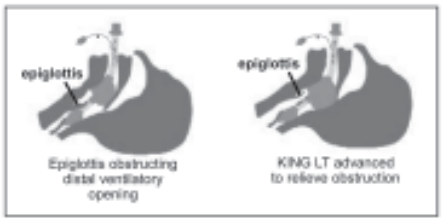
NOTE: It may require more than one filling of the syringe to achieve complete evacuation of the KING LT cuffs.

USER TIPS

1. The key to insertion is to get the distal tip of KING LT 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. Alternatively, a laryngoscope or tongue depressor can be used to lift the tongue anteriorly to allow easy advancement of the KING LT 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 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 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 KING LT 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 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 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 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 60 cm H_2O. 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.

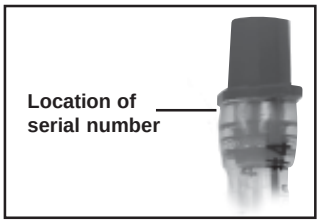
LIMITED MANUFACTURER'S WARRANTY

The KING LT is recommended for a maximum of 50 uses and autoclave cycles. The packaged Sterilization Card is the product's warranty and must be filled out to keep the warranty valid. King Systems will replace the KING LT product if it fails due to a manufacturing defect up to 50 uses.

Failure to strictly follow the instructions for autoclaving will result in damage to the product that is not covered by this warranty. In particular, to avoid rupture of the cuffs, all air must be evacuated from the cuffs and the Valve Actuator properly secured to the Inflation Valve prior to autoclaving. Damage from mishandling of the Valve Actuator is not covered by warranty. If Valve Actuator is missing, do not autoclave until replacement actuator is obtained. To order replacement Valve Actuators contact King Systems Corporation's customer service department at 800-642-(KING) 5464 or 317-776-6823.

Fill out the Sterilization Card after each use. If a defect is detected during the initial 50 uses, return the original product and its card, showing usage and proper serial number, to King Systems for evaluation and potential replacement.

KING SYSTEMS DISCLAIMS ALL OTHER WARRANTIES. THERE ARE NO OTHER WARRANTIES WHETHER EXPRESSED OR IMPLIED.



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