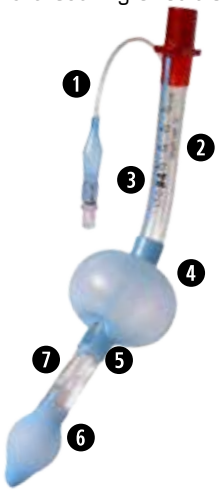
King Airway Device

Instructions For Use

King LT-D Specs

The KING LT-D 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.

1. **Single Valve/ Pilot Balloon:** Inflates both cuffs
2. **cm Depth Markings**
3. **Orientation / X-ray Line**
4. **Proximal Cuff:** Stabilizes tube and seals the Oropharynx
5. **Bi-lateral Eyes:** Additional eyelets to supplement ventilation
6. **Distal Cuff:** Blocks entry of esophagus. Reduces the possibility of gastric insufflation
7. **Two Ventilation Outlets:** In front of the larynx for efficient ventilation and allows passage of fiberoptic bronchoscope or tube exchange catheter.



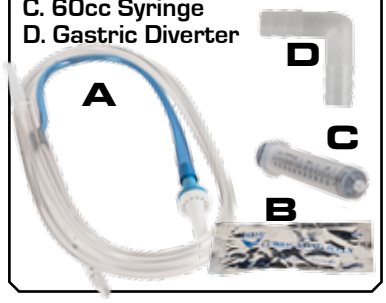
King LTS-D Specs

The KING LTS-D consists of a curved double-lumen tube with separate pathways for ventilation and access to the stomach. The ventilation lumen ends between the two inflatable cuffs with a variety of openings intended to align with the laryngeal inlet. Attached to the proximal end of the ventilation lumen is a 15 mm connector for attachment to a standard breathing circuit or resuscitation bag. The gastric access lumen is a separate conduit that allows passage of up to an 18 Fr standard gastric tube from its external proximal opening to the distal tip of the KING LTS-D, which is intended to be positioned in the upper esophagus. This allows the gastric tube to be easily inserted into the stomach for removal of fluids. In the absence of a gastric tube, the gastric access lumen allows channeling of gases and fluids from the esophagus and stomach to a point outside the patient's mouth.

1. **Single Valve/ Pilot Balloon:** Inflates both cuffs
2. **Proximal opening of Gastric Access Lumen:** Allows passage of 18Fr gastric tube after removal of gastric diverter
3. **cm Depth Markings**
4. **Proximal Cuff:** Stabilizes tube and seals the Oropharynx
5. **Bi-lateral Eyes:** Additional eyelets to supplement ventilation
6. **Distal Cuff:** Blocks entry of esophagus. Reduces the possibility of gastric insufflation
7. **Distal Opening of Gastric Lumen**
8. **Ventilatory Openings:** In front of the larynx for efficient ventilation and allows passage of fiberoptic bronchoscope or tube exchange catheter.
9. **Orientation / X-ray Line**

Kit also Includes:

A. Gastric Tube Includes Blue Pigtail and 5-1 adapter
B. Sterile Lubricant
C. 60cc Syringe
D. Gastric Diverter



The KING LT-D or KING LTS-D (AIRWAY DEVICE) is a single use device intended for airway management.

The KING LT-D or KING LTS-D (AIRWAY DEVICE) is provided non-sterile.

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INDICATIONS FOR USE

The AIRWAY DEVICE is indicated for airway management by providing a patent airway to allow patient ventilation.

CONTRAINDICATIONS

The following contraindications are applicable for routine use of the AIRWAY DEVICE:

- Responsive patients with an intact gag reflex.
- Patients with known esophageal disease.
- Patients who have ingested caustic substances.
- The AIRWAY DEVICE is not proven to protect the airway from the effects of regurgitation and aspiration. The risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway.

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

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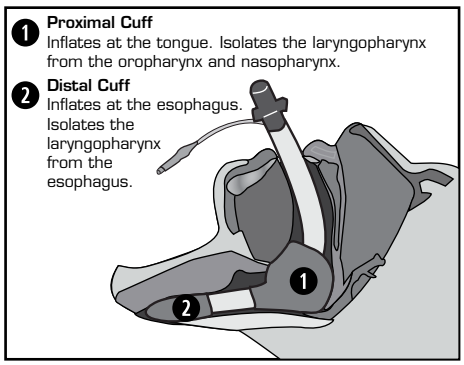
King Airway Device

Instructions For Use

Warnings/Precautions

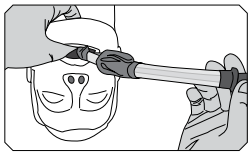
- High airway pressures may divert gas to the atmosphere.
- Intubation of the trachea cannot be ruled out as a potential complication of the insertion of the AIRWAY DEVICE.
- After placement, perform standard checks for breath sounds and utilize an appropriate carbon dioxide monitor as required by protocol.
- Lubricate only the posterior surface of the AIRWAY DEVICE to avoid blockage of the ventilation apertures or aspiration of the lubricant.
- The AIRWAY DEVICE is not intended for re-use.

SIZING INFORMATION				
Size	**Patient Criteria**	**Connector Color**	**Inflation Vol. LT-D**	**Inflation Vol. LTS-D**
3	4 - 5 ft (122 - 155cm)	Yellow	45 - 60 ml	40 - 55ml
4	5 - 6 ft (155 - 180cm)	Red	60 - 80 ml	50 - 70 ml
5	greater than 6 ft (>180cm)	Purple	70 - 90 ml	60 - 80 ml



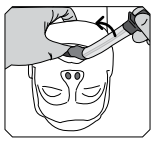
Airway Device Insertion Instructions

1. Using the information provided, choose the correct AIRWAY DEVICE size, based on patient height.
2. Test cuff inflation system by injecting the maximum recommended volume of air into the cuffs (refer to Sizing Information chart). Remove all air from 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 ventilator openings.
4. Have a spare AIRWAY DEVICE ready and prepared for immediate use.
5. Pre-oxygenate.
6. Ensure gag reflex is not intact.
7. Position the head. The ideal head position for insertion of the AIRWAY DEVICE 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 AIRWAY DEVICE at the connector with dominant hand.



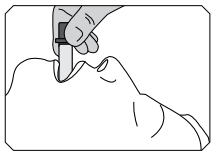
With non-dominant hand, hold mouth open and apply chin lift unless contraindicated by C-spine precautions or patient position.

9. With the AIRWAY DEVICE Rotated laterally 45-90º such that the blue orientation line is touching the corner of the mouth, introduce tip into mouth and advance behind base of tongue. Never force the tube into position.

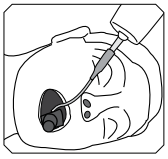


10. As tube tip passes under tongue, rotate tube back to midline (blue orientation line faces chin).

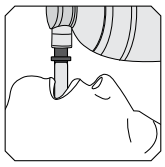
11. Without exerting excessive force, advance AIRWAY DEVICE until base of connector aligns with teeth or gums.



12. Inflate cuffs using the maximum volume of the syringe provided.
13. Attach resuscitator bag. While gently bagging, 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 AIRWAY DEVICE which refer to the distance from the distal ventilatory openings. 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, to the vocal cords.



15. Confirm proper position by auscultation and chest movement or verification of CO2 by capnography.
16. Readjust cuff inflation to 60 cm H2O (or to just seal volume).
17. Secure AIRWAY DEVICE to patient using tape or other accepted means. A bite block can also be used, if desired.

If using the KING LTS-D DO NOT COVER THE PROXIMAL OPENING OF THE GASTRIC ACCESS LUMEN OF THE KING LTS-D.

ONLY FOR USE WITH KING LTS-D

1. Using the gastric tube as a measuring device, determine the length of the gastric tube to be inserted by measuring the length from nose to earlobe and earlobe to xiphoid process.
2. Add the measurements together and note this total distance in reference to the black marks on the gastric tube.
3. Remove gastric diverter then lubricate gastric tube (up to 18 Fr) prior to inserting into the KING LTS-D's gastric access lumen.
4. Advance gastric tube the total distance noted in step #2 and confirm placement in stomach.
5. Seat 5-in-1 adapter snugly to prevent suction loss.
6. Always use the least amount of suction that effectively decompresses the stomach.
7. Follow any irrigation with an injection of air through the blue pigtail.
8. To cap tube, fit blue pigtail over 5-in-1 adapter.

Removal of the Airway Device

1. Once it is in the correct position, the AIRWAY DEVICE is well tolerated until the return of protective reflexes.
2. AIRWAY DEVICE removal should always be carried out in an area where suction equipment and the ability for rapid intubations are present.
3. For AIRWAY DEVICE removal, it is important that both cuffs are completely deflated.

USER TIPS

1. The key to insertion is to get the distal tip of AIRWAY DEVICE 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 AIRWAY DEVICE. Alternatively, a laryngoscope or tongue depressor can be used to lift the tongue anteriorly to allow easy advancement of the AIRWAY DEVICE 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 AIRWAY DEVICE 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 AIRWAY DEVICE 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 AIRWAY DEVICE deeper (until base of connector aligns 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 AIRWAY DEVICE is withdrawn, the initial ventilation opening exposed to or 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 AIRWAY DEVICE 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 ventilator opening, resulting in obstruction. Advancing the AIRWAY DEVICE 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 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. If applicable, 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 AIRWAY DEVICE 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.