

The ***Kotler Nasal Airway***™

INSTRUCTIONS FOR USE

This **KOTLER NASAL AIRWAY**™ kit consists of:

- ✓ The latex-free medical-grade silicone **double nasal airway** connected by a bridge.
- ✓ A standard flexible **10Fr suction catheter**.
- ✓ **3 cc Luer-Lok syringe** and "Christmas tree" **adaptor tip**.

The double-tube airway device and the suction catheter are for use in surgery. The syringe and tip are for post-operative irrigation.

INDICATIONS FOR USE:

The ***Kotler Nasal Airway***™ is used to provide the post-nasal and/or sinus surgery patient a patent and highly functional airway despite the nose being packed by any means including solid or gel materials. The device also provides the anesthesiologist uncomplicated access to suction the pharynx following completion of surgical procedure.

WARNING:

As with any surgical procedure, care should be exercised in the insertion and maintenance of the device.

PRECAUTIONS:

Inspect packing before use. **DO NOT USE** if package is damaged. The contents of this package are for single use only. **Do NOT** re-sterilize. **Do NOT** use after expiration date.

ADVERSE REACTIONS:

1. In clinical studies, with the airway device in place for up to six days, there were no adverse reaction to
2. Note that standard surgical complications, particularly related to packing, can occur including, but not limited to, hematoma, infection, toxic shock syndrome, and other complications that are possible with any surgery.

CAUTION:

Federal Law restricts this device for sale by, or on the order of, a licensed physician.

For Insertion Instructions, continue.

INSERTION INSTRUCTIONS

The tube is introduced at the conclusion of the surgery prior to insertion of any packing, whether solid or gel. For ease of insertion, the tubes can be lubricated with saline, ointment, or lubricating jelly.



After initial insertion, using a standard, thin-tip nasal speculum, inspect the nasal interior to ascertain the position of the tubes within the nasal cavity.



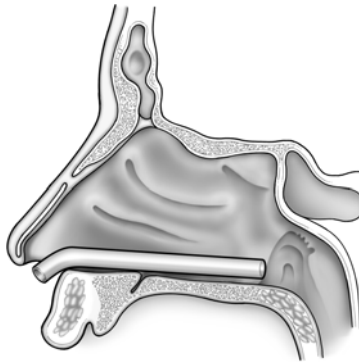
Then, advance the airway tubes further into the nose and seat the tube onto the floor of the nose by downward action either using the speculum itself, or another instrument such as a bayonet forceps. The airway tube "snaps" into place onto the floor.

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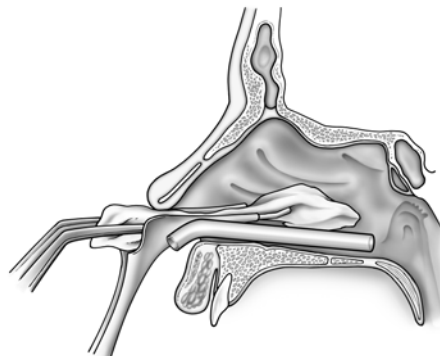


When both nasal tubes are properly seated, the bridge connecting the two will be flush against the columella.

NOTE: If an open rhinoplasty procedure has been performed, the surgeon may wish to divide the bridge and secure each tube separately, rather than have the bridge contact the transcolumellar incision.

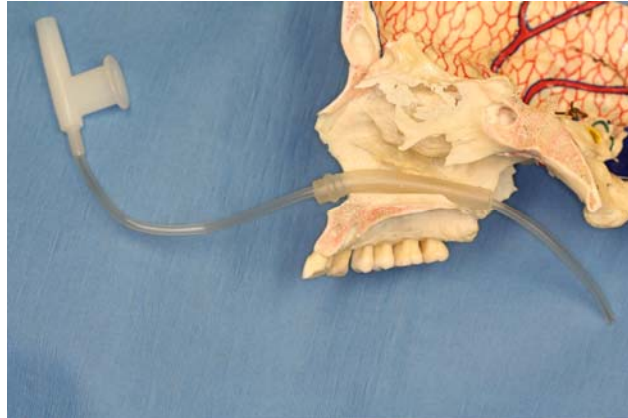


The airways maintain their proper position on the floor, lateral to the pre-maxillary bone and medial to the inferior turbinate.



While the packing of choice or gel is placed, the nasal speculum stabilizes the airway tube.

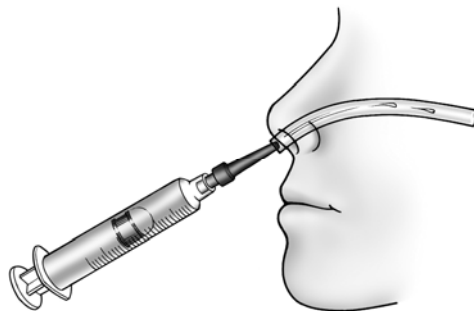
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A standard 10Fr plastic suction catheter is another kit component. After insertion and seating of the nasal airway, the surgeon passes the catheter through each tube and suctions fluids from the pharynx. This maneuver confirms that tube placement is satisfactory, that there is no obstructing of the back opening of the device.

Later, the anesthesia specialist, using the same flexible suction catheter, will happily avail himself of this direct pathway to the pharynx for suctioning blood and mucous from throat. This avoids the typical struggle with the awakening patient, as the anesthesia specialist seeks to traverse the oral pharynx to withdraw fluids from the throat just prior to removing the oral endotracheal tube or laryngeal mask.

HOME CARE



Supplied in a separate envelope, labeled **NOT FOR USE IN O.R.**, are a standard 3cc Luer-Lok syringe and a “Christmas tree” irrigating tip. Irrigation of the tubes’ lumens will relieve any clogging by mucous or blood. Enclosed in that packet is a Patient Home Care Instruction Sheet which should be reviewed by the recovery room nurse with the caretaker and patient, before discharge,

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OFFICE REMOVAL OF DEVICE

Prior to removal of airway and pack (if present), instill a topical anesthetic/decongestant mixture into the nasal passage . Shrinking and anesthetizing the mucosa will facilitate removal and provide a smooth and comfortable patient experience. To remove the device, grasp exposed wall of each of the tubes with a hemostat and extract the device.

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