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Product of Malaysia

air-Q[®] INTUBATING LARYNGEAL AIRWAY INDICATIONS

The air-Q is indicated as a primary airway in applications which do not require an endotracheal tube. It is also especially suited as an aid for intubation in difficult airway situations when an OETT is desired.

Thank you for purchasing the air-Q Intubating Laryngeal Airway by Cookgas[®] LLC. Due to its patented design, the air-Q is user-friendly. Placement is easy, air movement is outstanding, and intubation using standard oral endotracheal tubes (OETT), sizes 8.5mm - 3.0mm is straightforward and reliable. air-Q removal following intubation is quickly accomplished using the patented air-Q Removal Stylet, also by Cookgas[®] LLC.

Welcome to the Next Generation of Airway Management!
 Say Goodbye to the Difficult Airway, and Hello to the air-Q.

**The Only Airway You'll Want,
 The Only One You'll Need!**

This product is to be used by trained personnel only.

Available in Reusable/Single Use Instructions For Use:

Recommendations:

Size	IBW	Max. OETT	Mouth Opening ¹	← → ²	Volume ³	Inf. Vol. ⁴
4.5	70-100 kg	8.5mm	25 mm	20 cm	25 ml	4-5 ml
3.5	50-70 kg	7.5mm	23 mm	18 cm	18 ml	3-4 ml
2.5	30-50 kg	6.5mm	20 mm	16 cm	12 ml	2-3 ml
2.0	17-30 kg	5.5mm	17 mm	13 cm	8 ml	1-2 ml
1.5	7-17 kg	5.0mm	14 mm	10 cm	5 ml	1 ml
1.0	4-7 kg	4.5mm	11 mm	8 cm	3 ml	.5-1 ml
0.5	< 4 kg	4.0mm	8 mm	6 cm	2.5 ml	0-5 ml

¹ Minimum mouth opening for insertion.
² Distance from the external edge of the airway tube to the internal ventilatory opening.
³ Internal volume from the external edge of the connector to the internal ventilatory opening.
⁴ Recommended inflation volume following insertion with inflation valve open to air.

air-Q Placement Procedure

The procedure below is intended as a guide. Many techniques can be successfully used to properly place the air-Q into the pharynx.

- Open the inflation valve to air (either leave the red tag on or insert an empty syringe barrel into the inflation valve). Lubricate the external surface including the mask cavity ridges.
- Open the patient's mouth and elevate the tongue. Elevating the tongue lifts the epiglottis off the posterior pharyngeal wall and allows the air-Q easy passage into the pharynx. A mandibular lift is especially recommended. A tongue blade placed at the base of the tongue also works well for this purpose.
- Place the front portion of the air-Q mask between the base of the tongue and the soft palate at a slight forward angle, if possible.
- Pass the air-Q into position within the pharynx by gently applying inward and downward pressure using the curvature of the air-Q mask and airway tube as a guide. Simply rotate the air-Q forward and inward. Minimal manipulation may be necessary to turn the corner into the upper pharynx. Continue to advance until fixed resistance to forward movement is felt. Correct placement is determined by this resistance to further advancement. Some users place the back of the left index finger behind the mask, flexing the finger forward to help guide the mask around the corner into the pharynx. Once the mask has negotiated the turn, the left hand is then used to do a mandibular lift while exerting downward and inward pressure on the air-Q with the right hand during final advancement into the pharynx. This technique seems to be easy to learn and is particularly successful.
- Tap the air-Q in place and inflate the air-Q cuff according to Recommendations Table. Do not overinflate. Cuff pressure <60 cm H₂O, ideal 20-30 cm.
- Check the air-Q connector to ensure it is fully engaged within the airway tube, and attach the connector to the appropriate breathing device. Check for adequate ventilation.
- Place a bite block between the patient's teeth. Keep the bite block in place until the air-Q is removed.

air-Q Intubation Procedure

The air-Q by Cookgas[®] LLC is intended not only to be an outstanding airway for general use, but also to be a simple and reliable tool for intubation of the trachea with OETT's. Due to its patented design, standard OETT's (sizes 8.5mm - 3.0mm) can be easily passed through the air-Q and into the trachea. Further, the air-Q can be easily removed following intubation with the aid of the patented air-Q Removal Stylet, also by Cookgas[®] LLC. The following procedure for intubation is only intended as a guide. Many techniques can be successfully used for tracheal intubation using the air-Q.

- Prior to intubation, the laryngeal musculature and vocal cords must be relaxed, either by an aerosolized local anesthetic or with the aid of a muscle relaxant.
- Pre-oxygenate.
- Prepare the appropriately-sized OETT by completely deflating the OETT cuff and lubricate well. It is important to deflate the OETT cuff completely to allow the OETT to slide easily within the air-Q.
- Disconnect the air-Q from the airway device and remove the air-Q connector. This can be easily done by squeezing the air-Q tube between the index finger and thumb just distal to the connector with one hand, then rocking the air-Q connector back and forth while pulling the connector outward away from the airway tube with the other.

- Insert the previously deflated and lubricated OETT through the air-Q to a depth of approximately 8 - 20 cm, depending on the air-Q size. This will place the distal tip of the OETT at or just proximal to the opening of the air-Q airway tube within the mask cavity. It is very important to lubricate the OETT and the air-Q airway tube completely to ensure easy passage of the OETT through the air-Q.
- The following suggestions for advancement of the OETT are intended as a guide. Many techniques can be successfully used to further advance the OETT into the trachea.

CAUTION: Always check for adequate ventilation and oxygenation following placement of the OETT.

- Fiber Optic Technique:** Using a Fiber Optic Endoscope, pass the scope through the OETT and into the trachea under direct visualization. Stabilize the Fiber Optic Endoscope and pass the OETT through the laryngeal inlet and into the proximal trachea, using the scope as a guide. Check the position of the OETT with direct visualization of the tracheal carina. Remove the Fiber Optic Endoscope. Add a small amount of air to the OETT cuff, then replace the OETT connector if necessary. Check for adequate ventilation. (If epiglottic intrusion or down-folding is seen during visualization, the air-Q usually need not be completely removed. Perform an external mandibular lift to elevate the epiglottis and pass the endoscope beneath the epiglottis and into the trachea followed by the OETT.
 - Stylet Technique:** Using an appropriate coude tipped intubating stylet or a lighted stylet, pass the intubation stylet through the OETT within the air-Q, through the laryngeal inlet and into the trachea. Pass coude-tipped stylets with tip pointing upward (anterior). By gently placing the fingers of the left hand over the cricoid area of the patient's throat, the stylet can usually be felt as a scraping or rubbing sensation as it passes through the cricoid ring. If properly positioned, the lighted stylet will also produce a bright yellow/red illumination over the cricoid area. Once the stylet passes into the trachea, simply advance the OETT over the stylet, through the laryngeal inlet and into the trachea, using the intubation stylet as a guide. Add a small amount of air to the OETT cuff, replace the OETT connector and check for adequate ventilation.
- NOTE:** If the OETT fails to advance over the stylet into the trachea, it is usually helpful to rotate the OETT counter clockwise while passing the OETT. If this fails, try again with a smaller size OETT.

air-Q Removal Procedure

Removing the air-Q following OETT intubation is easily accomplished with the aid of the air-Q Removal Stylet by Cookgas[®] LLC. The air-Q Removal Stylet consists of an adapter connected to a rod. The adapter is tapered from bottom to top, and has horizontal ridges and vertical grooves. The taper allows the stylet to accommodate multiple OETT sizes. The ridges engage the OETT in a firm, secure grip, giving the user control of the OETT during the air-Q removal process. The grooves allow spontaneously breathing patients unimpeded air passage within the OETT during removal of the air-Q. By immobilizing and exerting an inward stabilizing force on the OETT, the air-Q Removal Stylet allows for the swift removal of the air-Q without dislodging the previously-placed OETT from the patient.

- Remove the OETT connector from the OETT.
- Squeeze the proximal portion of the OETT between the index finger and the thumb, leaving enough room for the adapter portion of the stylet to enter the proximal opening of the OETT. Alternatively, squeeze the proximal end of the air-Q airway tube, trapping the OETT inside.

Discard all defective air-Q's.

Warranties

Cookgas® LLC recommends reuse of the air-Q reusable a maximum of sixty (60) times. Usage beyond this recommended time period may diminish the effectiveness of the product. Cookgas® LLC agrees to warrant the air-Q reusable for (60) uses or a period of one (1) year following the invoice date whichever comes first. Cookgas® LLC agrees to warrant the disposable air-Q for a period of 30 days following the invoice date. Warranty covers materials and manufacturing defects provided that the airway is used according to the procedures outlined in the Instructions For Use (IFU) manual. Warranty is valid only following purchase from authorized distributors.

The original completed reusable air-Q Usage tracking Form or the disposable package label must accompany the defective air-Q device for valid warranty returns.

Cookgas® LLC disclaims all other warranties whether expressed or implied.

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Mercury Medical[®]



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Patents U.S.	US 5,937,860	US 6,705,321 B2	Patents CAN	2,231,331	Patents UK	GB2324040B
	US 6,422,239 B1	US 7,357,845 B2		2,371,435		GB2407293B
	US 6,892,731 B2	US 7,780,900 B2		2,410,043		GB2405589B
	US 7,331,347 B2	US 7,784,464 B2				GB2357437B
	US 7,900,632 B2	US 7,934,502 B2				

Other USA & Foreign Patents Pending



ATTENTION
SEE
DIRECTIONS
FOR USE



Latex Free



Keep Dry



Keep Away
From Sunlight



Max. use 60
(reusable only)



Rx
ONLY
By Prescription
Only



EXP.
Expiration
Date



Single Use
(disposable
version only)



Non-Sterile
(reusable only)



STERILE EO
PHT DEHP
DINP
(disposable
version only)

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- Insert the tapered end of the air-Q Removal Stylet into the proximal OETT (the long axis should be in the 12 o'clock - 6 o'clock position) until the adapter fits snugly within the OETT.
- For larger sizes, (2.0 - 4.5), with firm inward pressure, rotate the stylet adapter in a clockwise direction (into the 3 o'clock - 9 o'clock position) until the adapter firmly engages the OETT. For smaller sizes (1.0-1.5) simply push the stylet firmly into the OETT. Please practice this a few times prior to attempting on a patient.
- Completely deflate the air-Q cuff and pilot balloon.
- Deflate and lubricate the pilot balloon on the OETT prior to withdrawing the air-Q. Reinflate the OETT following air-Q removal.
- While exerting an inward stabilizing force on the stylet, slowly withdraw the air-Q outward over the stylet rod.
- For larger sizes (2.0-4.5) pass the stylet through and through. For smaller sizes (1.0-1.5) remove the stylet from the proximal end of the air-Q while stabilizing the OETT at the mouth. Following removal, place the reusable air-Q into a suitable container for sterilization and reuse. Discard single-use air-Q's following use.
- Reposition the OETT to the proper depth within the patient, if needed, and then tape into place.
- Replace the OETT connector within the OETT. Inflate the OETT, if needed, and attach to an appropriate breathing device. Check for adequate ventilation.

Cautions/Warnings

- The reusable air-Q is delivered non-sterile. Wash thoroughly and autoclave prior to use.
- Inspect all air-Q devices prior to use. Discard defective devices.
- Do not use sharp instruments on or near the air-Q.
- Confirm that the air-Q size matches the connector size prior to use.
- Confirm complete connector engagement within the airway tube prior to use.
- Do not use excessive force during air-Q placement or removal.
- Immediately check for adequate ventilation following placement.
- If airway problems occur and persist, remove the air-Q and establish an effective airway by another method. Back-up means for ventilation should be readily available.
- Deflate the air-Q cuff and pilot balloon completely prior to removal.
- Separate the connector from the reusable air-Q airway tube during cleaning and autoclaving. Replace prior to use.
- Wash the reusable air-Q and connector thoroughly with a mild soap and de-ionized water prior to autoclaving.
- air-Q connectors may dislodge during use following lubrication. Clean the breathing tube and connector thoroughly with alcohol prior to re-use.
- REUSABLE air-Q: AUTOCLAVE ONLY** Completely deflate the reusable air-Q cuff and pilot balloon prior to autoclaving. Do not exceed a maximum temperature of 275°F/135°C.
- Allow the reusable air-Q and connector to completely cool following sterilization and before use.
- If patients have, or are suspected of having, a transmissible spongiform encephalopathy, destroy the air-Q following use. DO NOT REUSE.
- air-Q single-use airways are constructed using Di (2-ethylhexyl) phthalate (DEHP) and Di-isononyl phthalate (DINP). air-Q airways are designed for short term oral use which is not considered part of the known risk group for DEHP AND DINP which includes hemodialysis, blood transfusion, and extra corporeal oxygenation. Risk benefits will be evaluated on a per case basis.
- Maximum air-Q cuff pressure 60cm H₂O. Cuff volume and/or pressure may change with the use of nitrous oxide or other medical gases. **DO NOT OVERINFLATE.**

- Supralaryngeal Airways, including the air-Q, do not fully protect the patient from aspiration.
- Recheck airway position and patency following all changes in the patient's head or neck position.
- Supralaryngeal Airways are potentially flammable in the presence of lasers and electrical cautery.
- Placement and maintenance of a bite block is recommended during air-Q use.
- Re-use of single-use devices may lead to mechanical malfunction and potential micro biological contamination.
- Discard all single-use air-Q's following use.**
- The single-use air-Q was sterilized utilizing Ethylene Oxide, a known carcinogen.

Contraindications

The air-Q is contraindicated in patients at high risk for regurgitation and/or aspiration. This includes, but is not limited to, patients undergoing major thoracic or abdominal surgery, patients who are non-fasted, morbidly obese, pregnant > 14 weeks, or suffer from delayed gastric emptying or esophageal reflux. Users must weigh the benefits of emergency airway needs with the potential risk of aspiration in these patients. air-Q's should be used in unconscious or topically anesthetized patients only.

Adverse Effects

Previously reported adverse events with masked laryngeal airways include: sore throat, aspiration, regurgitation, vomiting, bronchospasm, gagging, hiccup, coughing, transient glottic closure, airway obstruction, laryngeal spasm, retching, breath holding, arytenoid dislocation, trauma and/or abrasion to the epiglottis, larynx, pharynx, uvula, larynx and tonsils, tongue cyanosis, lingual nerve, vocal cord and hypoglossal nerve paralysis, tongue macroglossia, parotid gland swelling, dry mouth, dysphagia, feeling of fullness, mouth ulcer, dysarthria, dysphonia, hoarseness, stridor, pharyngeal ulcer, pulmonary edema, laryngeal hematoma, head and neck edema, myocardial ischemia and dysrhythmia.

Reusable air-Q Cleaning Procedure

- Wash air-Q's thoroughly with a mild detergent and water or an 8 - 10% sodium bicarbonate solution until all foreign material is removed.

CAUTION: DO NOT USE chemical cleaning agents such as ethylene oxide, glutaraldehyde (Cidex®), phenols, iodine solutions, or quaternary ammonium compounds. Do not use germicides, disinfectants, or any other chemical cleaners. Contamination by these agents may cause tissue irritation and/or burns. They may also damage the air-Q and its parts.

- Remove the connector and wash the air-Q, airway tube, and connector with a small bristle brush.
- Rinse thoroughly with warm de-ionized water and inspect the air-Q and connector for foreign material. Repeat the cleaning procedure if necessary.
- Deflate the air-Q cuff and pilot balloon completely, if applicable, then autoclave both the air-Q and connector. (Do not exceed a maximum temperature of 275°F/135°C.)

Autoclave: a. Gravity 10 - 15 minutes
b. Prevacuum 3 - 4 minutes
270° - 275° F (132° - 135°C)
2.2 Kgs/CM²

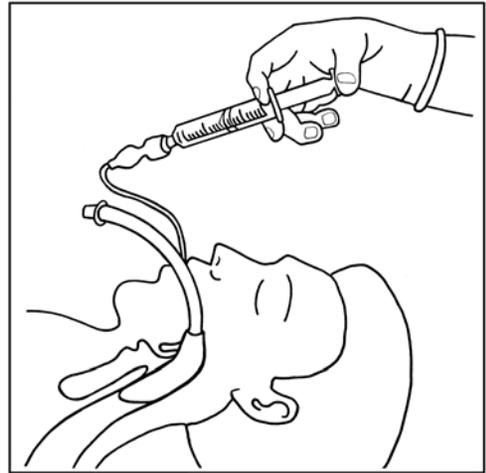
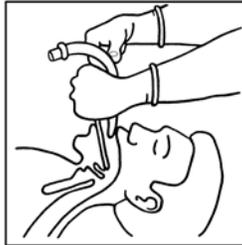
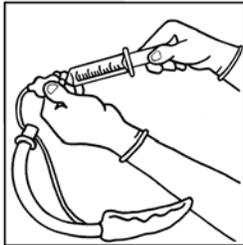
(Minimum
Exposure)

Always strictly follow the autoclave manufacturer's and your institution's guidelines for autoclaving.

- Allow the air-Q and connector to completely cool prior to reuse.
- Securely replace the connector and fully inspect all air-Q's prior to reuse. Check for adequate air-Q cuff inflation and deflation.

Recommended insertion Technique

Anbefalet indføringsteknik
Aanbevoelen inbrenge techniek
Technique d'insertion recommandée
Empfohlenes Einführungsverfahren
Συσιτώμενη τεχνική εισαγωγής
Tecnica di inserimento consigliata
Anbefalt innføringsteknikk
Zalecana technika wsuwania
Técnica de Inserção Recomendada
Técnica de inserción recomendada
Rekommenderad införselsteknik
Önerilen Sokma Tekniği



Recommended Depth of Insertion Range

Anbefalet område for indføringsdybde
Aanbevoelen inbrenge diepte bereik
Profondeur recommandée de la portée d'insertion
Empfohlener Einführtiefenbereich
Συσιτώμενο βάθος εύρους εισαγωγής
Gamma di profondità di inserimento raccomandata
Anbefalt område for innføringsdybde
Zalecany zakres głębokości wsuwania
Intervalo de Profundidade de Inserção Recomendada
Profundidad recomendada del rango de inserción
Rekommenderat djup för införselsspänn
Önerilen Sokma Aralığı Derinliği



Optimal Placement

- Optimal placing
- Optimale plaatsing
- Mise en place optimale
- Optimale Platzierung
- Βέλτιστη τοποθέτηση
- Posizionamento ottimale
- Optimal plassering
- Optymalne polożenie
- Colocação correta
- Colocación óptima
- Optimal placering
- Optimal Yerleşirme

LEGEND	
1	Incisors
2	Tongue
3	Hyoid Bone
4	Vocal Cords/folds
5	Thyroid Cartilage
6	Trachea
7	Esophagus
8	Laryngeal Inlet
9	Epiglottis
10	Arytenoid Cartilages
11	Sealing Mechanism
12	Ventilatory Opening
13	Recommended Depth of Insertion Marks
14	Connector
15	Cervical Vertebrae #2
16	Oral Pharynx
17	Nasal Pharynx
18	Mandible

