

ilma[®]

THE INTUBATING LARYNGEAL MASK AIRWAY

Instruction Manual

INTAVENT[®]

ilma[®]

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Instruction Manual

Seventh Edition



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1 DEVICE DESCRIPTION

The ILMA[®] is an advanced type of LMA[®] airway designed to facilitate tracheal intubation with an endotracheal tube (ETT). It permits single-handed insertion from any position without moving the head and neck from a neutral position and without placing fingers in the patient's mouth. Because it can be used as an airway device in its own right, ventilatory control and patient oxygenation may be continuous during intubation attempts, lessening the likelihood of desaturation.

There are two versions of the ILMA[®]: reusable and single-use disposable. The reusable version has a silicone cuff and stainless steel airway while the single-use version is made primarily of PVC. Both versions are latex free. Unless stated otherwise, the information contained within this manual applies to both versions.

The ILMA[®] incorporates the following features (Figure 1):

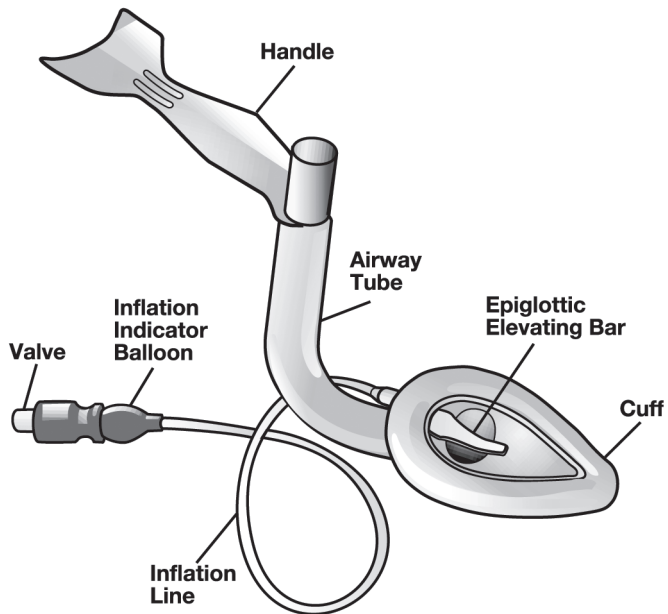


Figure 1

- A rigid, anatomically curved airway tube with a standard 15 mm connector. The tube is wide enough to accept a cuffed 8 mm ETT and short enough to ensure passage of the ETT cuff beyond the vocal cords. The tube is also fitted with a rigid handle to facilitate onehanded insertion, removal, and adjustment of the device's position.
- An inflatable cuff with a cuff-tube junction which, if firmly compressed between the fingers, is able to pass through an interdental gap as narrow as 20-25 mm.
- An epiglottic elevating bar (EEB) in the mask aperture. The caudal end of the EEB is not fixed, allowing it to elevate the epiglottis when an ETT is passed through the aperture.

2 INDICATIONS

The ILMA® is indicated for use as a guide for intubation of the trachea. It is also indicated as an alternative to the face mask for achieving and maintaining control of the airway in routine and emergency situations, including anticipated or unexpected difficult airways. The ILMA® is not indicated for use as a replacement for the endotracheal tube.

The ILMA® is also indicated as a method of establishing a clear airway in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes.

3 CONTRAINDICATIONS

When used alone, the ILMA® does not protect the airway from the effects of regurgitation and aspiration.

The ILMA® on its own is contraindicated for routine use in the following patients:

- Patients who have not fasted, including patients whose fasting cannot be confirmed.
- Patients who are grossly or morbidly obese, more than 14 weeks pregnant, or those with multiple or massive injury, acute abdominal or thoracic injury, any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.
- Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the ILMA® forms a low-pressure seal around the larynx.

- Patients where the peak airway inspiratory pressures are anticipated to exceed 20 cm H₂O.
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, since such patients may be contraindicated for ILMA[®] use.
- Patients whose head needs to be turned to the side during the case.
- Patients in the prone position.

When used in the profoundly unresponsive patient in the emergency situation (i.e., “cannot intubate, cannot ventilate”), the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway. The ILMA[®] should not be used in the emergency situation in patients who are not profoundly unconscious and who may resist ILMA[®] insertion.

Intubation through the ILMA[®] should not be done in the presence of known esophageal or pharyngeal pathology.

The metal tube and handle of the reusable ILMA[®] make it unsuitable as an airway during magnetic resonance imaging.

4 WARNINGS

The warnings below are applicable to both the reusable and single-use versions of the ILMA[®] unless stated otherwise.

- Do not use the ILMA[®] if the airway tube or cuff is damaged in any way.
- The single-use ILMA[®] contains Di (2-ethylhexyl) phthalate (DEHP). However, the device is not meant for long-term use and so is unlikely to pose any toxicity risk. There is no concern and/ or known risk for use of the device in children or nursing/ pregnant women as it is not meant for the following exposure scenarios:
 - Long-term haemodialysis in adults (testicular effects, fertility, toxicity to kidneys and developmental)
 - Long-term blood transfusion in children (testicular)
 - Transfusions in neonates (testicular and fertility)
 - Extracorporeal oxygenation in children (testicular effects, fertility, and toxicity to kidneys)

The risk and benefits of using the device shall be carefully evaluated by clinician on a case-by-case basis.

- The single-use ILMA[®] is supplied sterile for single use only and it shall not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.
- Before using the ILMA[®], the user should be familiar with the information in this manual and use it accordingly. It is recommended that initial experience be gained in elective, non-difficult airway patients. Practice in intubation mannequins is also recommended.

- It is possible to obtain an unreliable or obstructed airway if the device is inserted incorrectly.
- Lubricate only the posterior surface of the ILMA® mask tip to avoid blockage of the aperture or aspiration of the lubricant.
- Never use the handle to lever upwards during insertion as this will cause the mask to press into the tongue.
- Do not use force under any circumstances.
- Do not exceed the maximum recommended inflation volumes for the ILMA® cuff.
- There are data based on cadaveric and patient studies that ILMA® insertion causes a small amount of cervical spine motion. The clinical significance of this motion is unknown. The ILMA® has been used successfully in over 100 patients with unstable cervical spines.¹ However, clinicians must weigh the theoretical risk against the benefits of establishing an airway with the ILMA® in patients in whom cervical spine motion is undesirable.
- There are reports of pharyngeal edema² and increased mucosal pressure³ attributed to the rigidity of the airway tube. Therefore, it is recommended that the ILMA® be removed once intubation has been accomplished. If, however, a clinical decision is made to leave the ILMA® in place after intubation, the cuff should be deflated to 20-30 cm H₂O pressure and care taken to avoid unnecessary movement of the ILMA® or movement of the head or neck from the neutral position. There are currently no clinical data on how long the ILMA® may be left in place.
- The use of standard, curved, plastic endotracheal tubes is not recommended as this may be associated with a higher likelihood of laryngeal trauma.
- If the ILMA® is the sole airway, it is very important that cuff pressures are monitored and the tube stabilized in the neutral position to prevent unnecessary movement.

5 PRECAUTIONS

Careful handling is essential. Some components of the ILMA® can be torn or perforated. Avoid contact with sharp or pointed objects at all times.

Do not use if the sterile pack or sterilized pouch has been previously opened or damaged.

Gloves should be worn during the preparation and insertion of the ILMA® and ETT to minimize contamination.

Failure to remove the stabilizer rod prior to unthreading the ILMA® over the ETT may result in damage to the pilot balloon or inflation line of the ETT.

When passing a fiberoptic bronchoscope (FOB), it should not be passed through the ILMA® aperture unless protected by the ETT. Otherwise, the FOB tip may be damaged by contact with the epiglottic elevating bar.

6 ADVERSE EFFECTS

Both minor adverse effects (e.g., sore throat) and major adverse effects (e.g., aspiration) following use of LMA[®] airways have been reported in the published literature.¹ Review of published literature shows the incidence of aspiration with the LMA[®] airway is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anesthesia.¹ A review of case reports of aspiration associated with the LMA[®] airway describes one case in which an ILMA[®] was used.⁴

There is one report of an esophageal perforation following intubation attempts through the ILMA[®].⁵ The patient was subsequently found to have radiological evidence of pre-existing esophageal pathology. In addition to minor sore throat and hoarseness, there have been reports of bloodstaining and oral trauma,¹ pharyngeal edema,² and epiglottic edema⁶ with ILMA[®] use.

The incidence of sore throat following LMA[®] airway use is approximately 13%, and is usually mild and short-lived;¹ however, severe or prolonged sore throat, sometimes accompanied by dysphagia and tissue burns, has been reported in patients in whom an improperly cleaned or sterilized mask has been used.

Infrequent neurovascular events reported with LMA[®] airway use include cases of hypoglossal nerve injury, tongue numbness secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, recurrent laryngeal nerve injury, and vocal cord paralysis.

These complications are most likely the result of malposition or excessive cuff pressure, causing compression of nerves and/or blood vessels. Cuff malposition or excessive cuff pressure can be exacerbated by incorrect mask size, prolonged surgery, and use of nitrous oxide.

Adverse events reported with LMA[®] airway use include airway obstruction, arytenoid dislocation, aspiration, bleeding, breath holding, bronchospasm, coughing, dental/denture damage, dry mouth/throat, dysarthria, dysphagia, dysphonia, dysrhythmia, ear pain, gagging, gastric dilatation/insufflation/rupture, glottic closure, head and neck edema, hearing impairment, hiccup, hoarseness, hypersalivation, hypoglossal nerve paralysis, hypoxia, laryngeal hematoma, laryngeal spasm, lingual nerve paralysis, mouth ulcer, myocardial ischemia, nausea, parotid gland swelling, pharyngeal dysesthesia, pharyngeal ulcer, pulmonary edema, recurrent laryngeal nerve injury, regurgitation, retching, sore jaw, sore mouth, sore throat, stridor, submandibular gland swelling, temporomandibular joint dislocation, tissue trauma (epiglottis, larynx, lip, mouth, posterior pharyngeal wall, soft palate, uvula, tonsils), tongue cyanosis, tongue macroglossia, vocal cord paralysis, and vomiting.

7 PREPARATION FOR USE

The information presented in this section is very important to ensure the integrity of the ILMA® for use. Information in sections 7.1 (Cleaning) and 7.2 (Sterilization) apply to the reusable ILMA® while information contained in section 7.3 (Performance Tests) apply to both reusable and single-use versions of ILMA®.

WARNING: Do not attempt to clean, sterilize or reuse the single use version of the ILMA®.

7.1 CLEANING

7.1.1 Thoroughly wash in warm water using a dilute (8-10% v/v) sodium bicarbonate solution until all visible foreign matter is removed. A 10% sodium bicarbonate solution can be prepared by mixing 1 cup of baking soda with 10 cups of water. Mild detergents are also acceptable for cleaning when used per the manufacturer's instructions at the proper dilution. The detergent must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA® airway use is Endozime® (Ruhof, Valley Stream, NY).

WARNING: The reusable ILMA® is delivered nonsterile and must be cleaned and sterilized before initial use and before each subsequent use. Its packaging cannot withstand the high temperatures of autoclaving and is to be discarded before sterilization.

WARNING: Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex®), ethylene oxide, phenol-based cleaners, iodinecontaining cleaners, or quaternary ammonium compounds to clean or sterilize the ILMA®. Such substances are absorbed by the ILMA® materials resulting in exposure of the patient to unnecessary risk and possible deterioration of the ILMA®. Do not use an ILMA® that has been exposed to any of these substances.

WARNING: As with all reusable devices, the components of the ILMA® will degrade over time and therefore the number of uses must be limited. With proper cleaning, sterilization and handling, the ILMA® is warranted for a maximum of 40 uses. Continued use of the ILMA® beyond this number is not recommended as degradation of the components may occur, resulting in impaired performance or abrupt failure.

CAUTION: Do not expose the ILMA® valve (the white plastic piece protruding from the blue pilot balloon) to any cleaning solution as it may cause premature valve failure. If the inner valve is exposed to a cleaning solution, rinse thoroughly under warm flowing tap water, remove excess moisture, and allow to dry.

7.1.2 Clean the ILMA® using a small soft bristle brush (approximately 1/2-3/4 inch in diameter). Gently insert the brush through the epiglottic elevating bar (EEB) into the airway tube, taking care not to damage the bar. Ensure the whole interior of the metal tube is thoroughly cleaned.

7.1.3 Thoroughly rinse the ILMA® in warm flowing tap water to remove cleaning residues. Carefully inspect the ILMA® to ensure that all visible foreign matter has been removed. Repeat the above steps as necessary.

WARNING: Failure to properly clean, rinse, and dry a device may result in retention of potentially hazardous residues or in inadequate sterilization.

7.2 Sterilization of the ILMA®

Steam autoclaving is the only recommended method for sterilization. Do not use ethylene oxide gas sterilization.

Adherence to the following procedures is essential to ensuring sterilization without damage to the ILMA®:

7.2.1. Immediately prior to steam autoclaving, deflate the ILMA® cuff completely, drawing a vacuum with a syringe. Ensure that the ILMA® valve and the syringe used to deflate the cuff are dry.

CAUTION: Any air or moisture left in the cuff will expand in the high temperature and low pressure environment of the autoclave, causing irreparable damage to the cuff and/or blue pilot balloon. Do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port before autoclaving to avoid damage to the valve.

If a deflated mask immediately and spontaneously reinflates, even slightly, do not autoclave or reuse this mask. This indicates the presence of a defective device. It is normal, however, for the ILMA® cuff to reinflate slowly over a period of several hours, as the silicone is gas permeable.

7.2.2 Autoclave settings

Steam autoclave the ILMA® following the autoclave manufacturer's recommendations and applicable institution and industry guidelines for temperature and time. All steam autoclave cycles typically used for porous items are acceptable for sterilization of the ILMA®. Autoclaving should be carried out within a standard steam sterilization cycle e.g. 134°C (+3°/-0°) for 3 minutes.

CAUTION: The integrity of the ILMA® materials may be adversely affected by autoclave temperatures exceeding 137°C.

MINIMUM EXPOSURE TIMES

Autoclave	Wrapped	Unwrapped (Flash)
Gravity Displacement	10-15 minutes	10 minutes*
Prevacuum	3-4 minutes	4 minutes*

All cycles 134°C (+3°/-0°)

*Mixed porous and nonporous items

Reference: AAMI Standards and Recommended Practices⁷

As autoclaves vary in design and performance characteristics, cycle parameters should always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare facility personnel are responsible for adhering to the processes specified and validated in their facility and for maintaining process control. Failure to do so may invalidate the healthcare facility's sterilization process.

After autoclaving, allow the ILMA® to cool to room temperature before use.

7.3 PERFORMANCE TESTS

All of the nonclinical tests described below must be conducted before the device is used. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimizes contamination of the ILMA® before insertion.

WARNING: Failure of any one test indicates that the device should not be used.

CAUTION: Gloves should be worn during the preparation and insertion of the ILMA® to minimize contamination of the device.

Performance test 1: Visual Inspection

Examine the surface of the ILMA® for damage, including cuts, tears, or scratches. Examine the ILMA® to ensure that it is free from blockage or loose particles. Any particles present in the tube or on the exterior of the tube or mask should be removed as they may be inhaled by the patient after insertion.

WARNING: Do not use the ILMA® when visible particles cannot be removed from inside the airway.

Examine the angle between the straight part of the airway tube and the anterior plane of the inflated cuff. The angle should be just less than 90 degrees and it should never exceed 90 degrees.

Examine the aperture in the mask. Gently probe the flexible epiglottic elevating bar traversing the mask aperture to ensure it is not damaged. The free end of the bar should lie in contact with the floor of the mask. If it does not, it may fail to engage correctly with the epiglottis. Do not attempt to repair a broken or otherwise damaged bar. Do not remove the bar.

WARNING: Do not use the ILMA® if the epiglottic elevating bar (EEB) is broken or otherwise damaged, or if the free end does not lie in contact with the mask.

Performance test 2: Inflation and deflation

Carefully insert a syringe into the valve port and fully deflate the cuff to a vacuum so that the cuff walls are tightly flattened against each other. Examine the cuff walls to determine whether they remain tightly flattened against each other. If the mask spontaneously reinflates, this may indicate damage to the mask or the valve.

WARNING: Do not use the ILMA® if the cuff walls reinflate immediately and spontaneously, even if only slightly.

Overinflate the cuff with air from complete vacuum with volumes noted below.

Table 3

TEST CUFF OVERINFLATION VOLUMES	
ILMA® Size	Air Volume*
3	30 mL
4	45 mL
5	60 mL

*Inflate the cuff with these volumes for testing only.

Any tendency of the cuff to deflate indicates the presence of a leak and should be evident after two minutes. Examine the symmetry of the inflated cuff. There should not be uneven bulging at either end or on the sides.

WARNING: Do not use the ILMA® if cuff leakage is present or if there is uneven bulging of the cuff.

While the device remains overinflated, examine the inflation indicator balloon situated beneath the luer syringe port and valve. The balloon shape should be elliptical and not spherical, with no bulging.

WARNING: Do not use the ILMA® if the inflation indicator balloon is spherical or irregularly shaped.

8 INSERTION

8.1 PRE-INSERTION PREPARATION

Prior to insertion of the ILMA®, the cuff should be tightly deflated using a syringe so that no air is left in the cuff and it forms a smooth wedge shape without any wrinkles. This can be accomplished by compressing the mask tip between finger and thumb to achieve the correct shape. Alternatively, an LMA® Cuff-Deflator is available (Figure 2). While deflating, pull pack gently on the inflation line to obtain the correct shape. A completely smooth, tightly deflated leading edge facilitates insertion, avoids contact with the epiglottis, and is important to assure success when positioning the device.

Apply a bolus of lubricant to the posterior mask tip just before insertion, to prevent drying of the lubricant (Figure 3). A water-soluble lubricant, such as K-Y® Jelly, may be used. Do not use silicone-based lubricants as they degrade the ILMA® components. Lubricants containing lidocaine are not recommended for use as lidocaine may delay the return of protective reflexes, provoke an allergic reaction, or affect surrounding structures, including the vocal cords.

WARNING: Lubricate only the posterior surface of the ILMA® mask tip to avoid blockage of the aperture or aspiration of the lubricant.

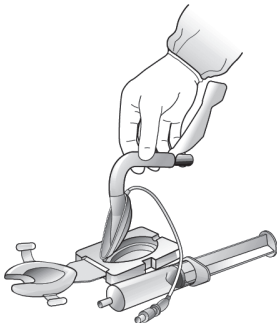


FIGURE 2: ILMA® being removed from LMA® Cuff-Deflator

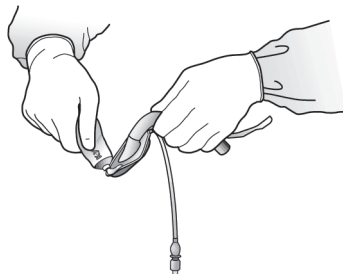


FIGURE 3: Lubricate only the posterior surface of the deflated mask tip with a water soluble lubricant.

8.2 INSERTION

WARNING: Before using the ILMA[®], the user should be familiar with the information in this manual and use it accordingly. It is recommended that initial experience be gained in elective, non-difficult airway patients. Practice in intubation mannequins is also recommended.

WARNING: There are data based on cadaveric and patient studies that the ILMA[®] insertion causes a small amount of cervical spine motion. The clinical significance of this motion is unknown. The ILMA[®] has been used successfully in over 100 patients with unstable cervical spines. However, clinicians must weigh the theoretical risk against the benefits of establishing an airway with the ILMA[®] in patients in whom cervical spine motion is undesirable.

WARNING: It is possible to obtain an unreliable or obstructed airway if the device is inserted incorrectly.

WARNING: Do not use force under any circumstances.

Important points to note are the avoidance of the use of force, correct approach to the mouth, and assurance of an adequate depth of anesthesia or unconsciousness.

8.2.1. Check that the size of the ILMA[®] is correct for the patient (Table 4). Ranges are approximate and clinical judgment must be used in selecting an appropriate size.

Table 4

ILMA[®] SELECTION GUIDELINES

ILMA[®]	Patient Sizes*
Size 3	Children 30-50 kg
Size 4	Adults 50-70 kg
Size 5	Adults 70-100 kg

*Laryngeal depth is not directly related to patient size or weight.

8.2.2 The cuff must always be fully deflated by firmly pulling back on the deflating syringe and gently pulling on the inflation line.

8.2.3 Check the shape of the cuff and correct lubrication, as described previously.

8.2.4 Have a spare ILMA[®] ready and prepared for immediate use.

8.2.5 Pre-oxygenate and follow standard monitoring procedures.

8.2.6 Ensure an adequate level of anesthesia or unconsciousness before inserting the ILMA®. The ILMA® may also be inserted with the patient awake after adequate pharyngeal topicalization.

8.2.7 Positioning the head. Insertion may be achieved from any position relative to the patient's head. When possible, a pillow should be placed under the head to achieve a neutral position. Provided a neutral position is achieved, no head or neck manipulation is required. Do not extend the head.

8.2.8 Inserting the ILMA®. Hold the ILMA® by its handle as shown in Figure 4, with the handle approximately parallel to the patient's chest. Carefully position the mask tip so it is flat (i.e., not folded) against the hard palate just inside the mouth immediately posterior to the upper incisors. Slide the mask tip briefly back and forth on the palate to distribute lubricant (Figure 4) while pressing it against the palate, to prevent accidental folding of the tip. Slide the mask backwards following the curve of the rigid airway tube. It may be necessary to draw the mouth open momentarily to permit the widest part of the mask to enter the oral cavity.



FIGURE 4: Rub the lubricant over the anterior hard palate with the device in position as shown here.

Do not use the handle as a lever to force the mouth open. The curved part of the airway tube should be advanced without rotation until it contacts the patient's chin, then kept in contact with the chin as the device is rotated inwards (Figures 5 & 6). Do not begin rotation as shown in Figure 6 until the straight part of the airway tube is in contact with the patient's chin.



FIGURE 5: Ensure the curved metal tube is in contact with the chin prior to rotation.

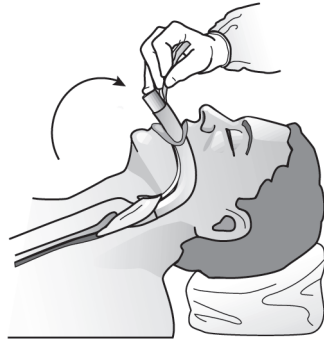


FIGURE 6: Swing the mask into place in a circular movement maintaining pressure against the palate and posterior pharynx.

The tube curvature closely follows the anatomical curve of the palate and the posterior pharyngeal wall with the head and neck in the neutral position. Keep the mask firmly applied to the soft palate and posterior pharyngeal wall as it is swung down into place to avoid accidental folding of the mask tip.

WARNING: Never use the handle to lever upwards during insertion as this will cause the mask to press into the tongue, making insertion more difficult.

After insertion, the tube should emerge from the mouth directed somewhat caudally, lying approximately parallel to the plane of the inner surface of the upper incisors. Inflate the cuff with just enough air to obtain a seal, corresponding to a pressure of approximately 60 cm H₂O (Figure 7). Frequently, only half of the maximum volumes are sufficient to obtain a seal.

WARNING: Do not exceed the maximum recommended inflation volumes (Table 5).

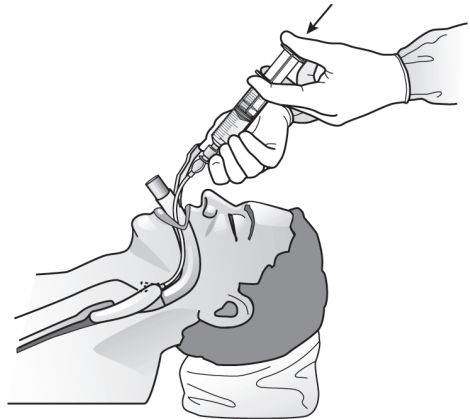


FIGURE 7: Inflate the mask, without holding the tube or handle, to a pressure of approximately 60cm H₂O

Table 5

MAXIMUM CUFF INFLATION VOLUMES

ILMA® Size	Air Volume
3	20 mL
4	30 mL
5	40 mL

8.2.9 Connecting to the anesthetic system. Taking care to avoid dislodgment, connect the ILMA® to the anesthetic circuit and oxygenate with gentle manual ventilation to airway pressures of less than 20 cm H₂O, and a tidal volume not greater than 8 mL/kg (Figure 8). Capnography should be used to confirm adequate gas exchange. If leaks occur at 60 cm H₂O cuff pressure, either too much force or tidal volume is being used, the ILMA® is too small, the ILMA® is not fully inserted, or the patient is not fully anesthetized.

*FIGURE 8: Ventilate the patient prior to intubation*

8.2.10 Stabilizing the ILMA®. Should the ILMA® be left in place (either as the sole airway or after intubation has been accomplished), care should be taken to ensure its stabilization in the neutral position, e.g., with bilateral bite blocks, as movement of the head or neck could result in less than ideal positioning. The bite blocks should be removed prior to intubation to permit adjustment of the ILMA® position.

WARNING: If the ILMA® is the sole airway, it is very important that cuff pressures are monitored and the tube stabilized in the neutral position to prevent unnecessary movement.

9 INTUBATION THROUGH THE ILMA®

In order to achieve optimal intubation success, it is highly recommended that the following type of endotracheal tube (ETT) be used: a straight, wire-reinforced, cuffed ETT with an internal diameter no greater than 8.0 mm, and is capable of being passed, with the pilot balloon and valve through the ILMA®.

WARNING: The use of standard, curved, plastic endotracheal tubes is not recommended as this may be associated with a higher likelihood of laryngeal trauma.

The user should be familiar with complete ETT instructions issued by the relevant manufacturer prior to use. It should be noted that the ILMA® cannot be removed after intubation unless the connector can be removed from the chosen ETT. The following instructions assume that the, straight, wire-reinforced ETT is being used.

9.1 INTUBATION WITHOUT FIBEROPTIC ASSISTANCE (BLIND INTUBATION)

9.1.1 Preoxygenate and follow standard monitoring procedures. Ensure adequate muscle relaxation prior to attempting intubation.

9.1.2 Prior to applying lubricant to the ETT cuff, gently fit the connector into the end of the ETT. The connector should be secure enough to allow adequate ventilation, but should not be so forcefully inserted to prevent its removal when the ILMA® is withdrawn after intubation.

9.1.3 Lubricate the ETT with a small amount of water-soluble lubricant, and gently pass the ETT into the ILMA®, rotating and moving the ETT up and down within the shaft to distribute the lubricant until it travels freely through the entire extent of the tube. If the ILMA® is not already in place, this step should be done prior to ILMA® insertion.

9.1.4 Insert the ETT with the longitudinal black line on the tube facing the handle of the ILMA®. At this point, the ETT should not be passed beyond 15 cm or the transverse line which corresponds to the point at which the ETT beveled tip is about to enter the mask aperture (Figure 9).

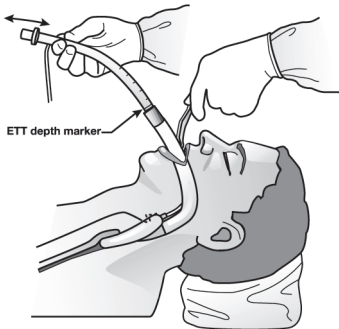


FIGURE 9: Hold the ILMA® handle steady while gently inserting the ETT into the metal shaft up to the 15 cm transverse depth marker

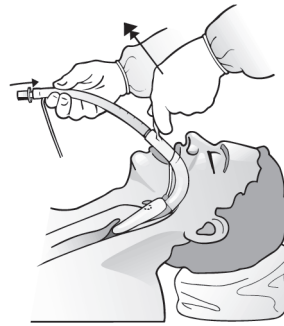


FIGURE 10: Use the handle to gently lift the device 2-5 mm in the direction shown by the large arrow as the ETT is advanced

9.1.5 Grip the handle firmly, as shown in Figure 10. Now use it to draw the larynx forwards a few millimeters. This is a lifting action and is not to be confused with a levering action. This “Chandy maneuver” increases seal pressure and ensures optimal alignment of the axes of the trachea and the ETT. It will also correct any tendency for the mask to be flexed which may happen if not positioned correctly. If the mask is flexed, the ETT will not emerge at the correct angle, making esophageal intubation more likely.

9.1.6 Very gently, attempt to pass the ETT 1.5 cm past the transverse (15 cm) line. Do not press the ILMA® handle downwards. If no resistance is felt, it is likely the epiglottic elevating bar (EEB) is lifting the epiglottis upwards as designed, allowing the ETT to pass easily into the trachea. Continue to advance the ETT, using clinical judgment to determine when intubation has been accomplished (Figure 11).

9.1.7 Inflate the ETT (Figure 12) and confirm intubation by standard methods.

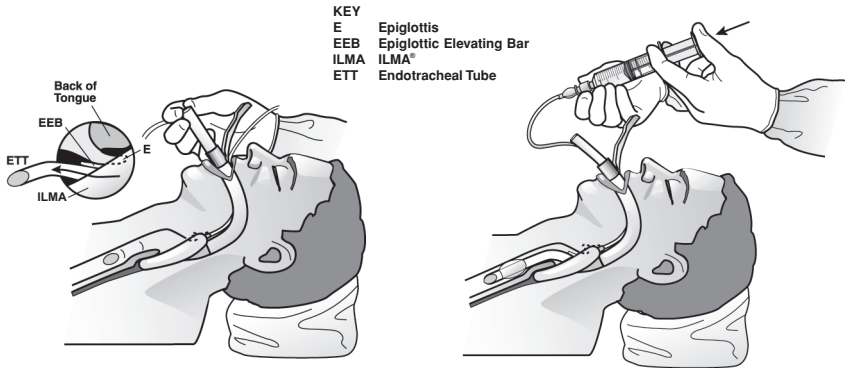


FIGURE 11: If no resistance is felt, continue to advance the ETT, while holding the ILMA® steady, until intubation has been accomplished.

FIGURE 12: Inflate the cuff of the ETT.

Failure to intubate may be caused by one of the following four problems which are discussed in more detail in Section 10 and summarized in Section 11:

- Downfolded epiglottis or tube impaction on vestibular wall,
- ILMA® is too small,
- ILMA® is too large, or
- Inadequate anesthesia and/or muscle relaxant.

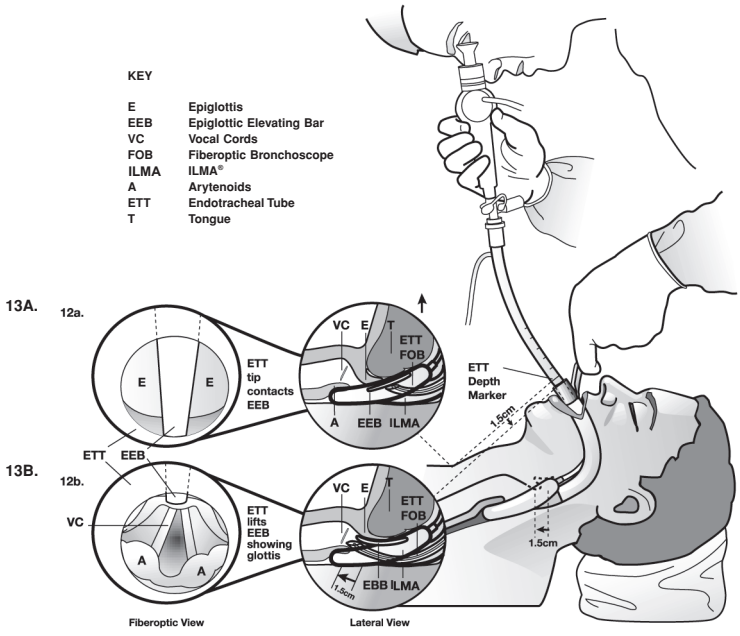
9.2 INTUBATION WITH FIBEROPTIC ASSISTANCE

Whenever possible, a fiberoptic bronchoscope (FOB) should be used to verify the position of the larynx either during or before intubation.

CAUTION: When passing an FOB, it should not be passed through the ILMA® aperture unless protected by the ETT. Otherwise, the FOB tip may be damaged by contact with the EEB.

9.2.1. Use an FOB of suitable diameter to pass within the ETT after passing through a selfsealing connector with a side-arm to permit continued ventilation. For example, an 8.0 mm ETT will accept a 5.0 mm FOB while still permitting ventilation. At 15 cm depth, the view through the FOB should be similar to the view in Figure 13a, or it may be possible to see the glottis beyond the EEB. Ensure effective ventilation before taking any further steps.

9.2.2 At 16.5 cm depth, the view through the FOB should be similar to the view in Figure 13b. It should then be possible to advance the ETT into the trachea under direct vision. Avoid pushing on the EEB with the fiberscope.



FIGURES 13A AND 13B: Intubation with fiberoptic bronchoscopy

9.3 REMOVAL OF ILMA® PRIOR TO EXTUBATION

WARNING: There are reports of pharyngeal edema and increased mucosal pressure² attributed to the rigidity of the airway tube. Therefore, it is recommended that the ILMA® be removed once intubation has been accomplished. If, however, a clinical decision is made to leave the ILMA® in place after intubation, the cuff should be deflated to 20-30 cm H₂O pressure and care taken to avoid unnecessary movement of the ILMA® airway tube or movement of the head or neck from the neutral position. There are currently no clinical data on how long the ILMA® may be left in place.

WARNING: Bronchial or esophageal intubation, accidental extubation, or other misplacement may occur if the airway removal procedure is not performed correctly. If misplacement occurs, a correctly deflated airway should be reinserted without delay to ensure patient oxygenation.

The procedure for removal of the ILMA®, keeping the ETT in place is as follows:

9.3.1 Use the Stabilizer Rod to measure the approximate distance between the proximal end of the ETT and the patient's teeth.

9.3.2 After ensuring the patient is well-oxygenated, remove the ETT connector, leaving its proximal end firmly attached to the anesthesia hosing to prevent accidental misplacement and facilitate reconnection.

9.3.3 Fully deflate the ILMA® cuff, but make sure to keep the ETT cuff inflated.

9.3.4 Ease the ILMA® out by gently tapping or swinging the handle caudally around the chin while exerting counterpressure on the proximal end of the ETT to keep it in place (Figure 14). Using the curvature of the airway tube, swing the ILMA® cuff out of the pharynx into the oral cavity.

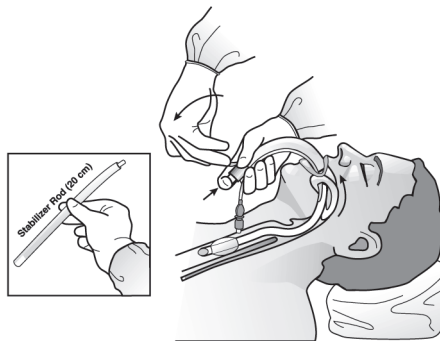


FIGURE 14: Swing the mask out of the pharynx into the oral cavity, applying counterpressure to the ETT with a finger as shown prior to insertion of a stabilizer rod.

9.3.5 When the proximal end of the ETT is level with the proximal end of the metal tube, insert the stabilizer rod to keep the ETT in place, as shown in Figure 15. Using the stabilizer rod, slide the ILMA® out over the rod until it is clear of the mouth.

9.3.6 Remove the stabilizer rod when the ILMA® cuff is clear of the mouth. Steady the ETT to prevent accidental dislodgment (Figure 16).

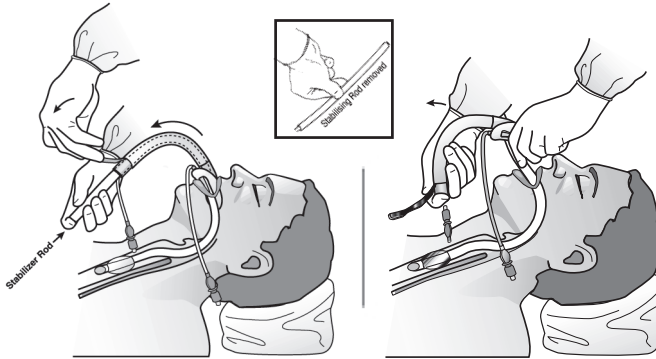


FIGURE 15: Slide the ILMA® over the ETT and stabilizer rod until it is clear of the mouth.

FIGURE 16: Remove the stabilizer rod and steady the ETT at the level of the incisors.

CAUTION: Failure to remove the stabilizer rod prior to unthreading the ILMA® over the ETT may result in damage to the pilot balloon or inflation line of the ETT.

9.3.7 Grasp the ETT firmly while gently unthreading its inflation line and pilot balloon from the ILMA® tube (Figure 17).

9.3.8 Replace the ETT connector and ventilate the patient (Figure 18). Use the stabilizer rod to ensure the ETT is protruding by the same amount as prior to removal of the ILMA®.

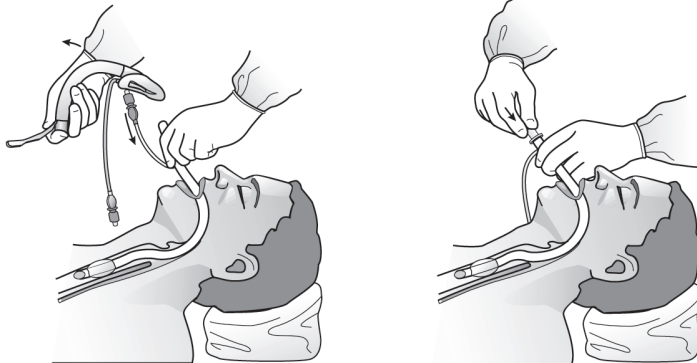


FIGURE 17: Remove the ILMA® completely, gently unthreading the inflation line and pilot balloon of the ETT.

FIGURE 18: Replace the ETT connector.

— TROUBLESHOOTING IN CASE OF FAILURE TO INTUBATE

10 TROUBLESHOOTING IN CASE OF FAILURE TO INTUBATE

10.1 DOWNFOLDED EPIGLOTTIS OR TUBE IMPACTION

If resistance is felt approximately 2 cm beyond the tranverse line (15 cm mark) on the ETT, this may indicate a fully downfolded epiglottis (Figure 19) or impaction of the ETT tip against the vestibular wall. Use of the FOB will help identify the specific cause of the resistance. Rotating the ETT bevel may overcome impaction of the ETT tip; to overcome a downfolded epiglottis, remove the ETT completely and proceed as follows:

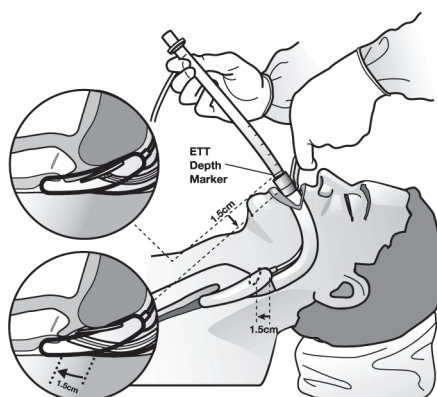


FIGURE 19: If resistance is felt 2 cm beyond the 15 cm depth marker, the epiglottis may be downfolded or the ETT is lodged against the vestibular wall.

10.1.1 Ensure full oxygen saturation. When the patient is optimally ventilated, swing the ILMA[®] outward about 6 cm and reinsert, without deflating the mask cuff (Figure 20). Use the “cm” markings on the ILMA[®] airway tube to guide this “up and down” maneuver. Take care to keep the cuff inflated and do not withdraw the ILMA[®] further than 6 cm.

10.1.2 Attempt intubation again. If still unsuccessful, it is likely the wrong size of ILMA[®] has been used.

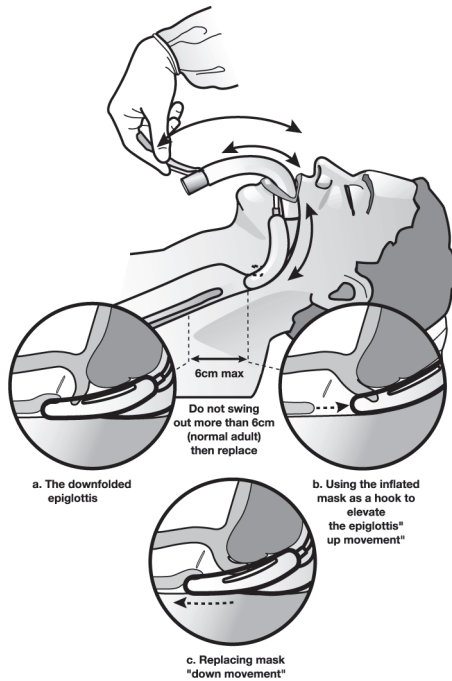


FIGURE 20: To overcome a downfolded epiglottis, swing the ILMA® outward about 6 cm and reinsert.

10.2 ILMA® TOO SMALL

If the ILMA® is too small, resistance may be felt approximately 3 cm beyond the transverse line on the ETT. In this case, the epiglottis will be out of reach of the EEB (Figure 21). Use a larger size of ILMA®. Note that the same situation may arise if the larynx is pushed downward caudally during insertion. This may result from inadequate anesthesia or incorrect insertion technique.

— TROUBLESHOOTING IN CASE OF FAILURE TO INTUBATE

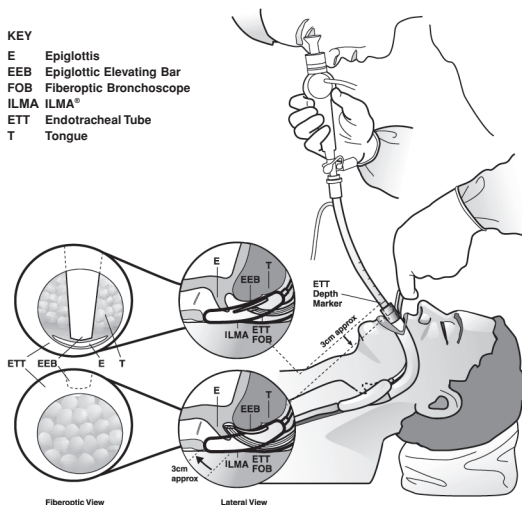


FIGURE 21: If the ILMA[®] is too small, resistance may be felt about 3 cm beyond the ETT depth marker.

It may be possible to reposition the larynx, using the fingers to press upward on the thyroid prominence. Inadvertent caudal displacement of the larynx can be measured by marking the position of the thyroid prominence prior to insertion of the ILMA[®], using a skin marker pen (see Figure 22). This is approximately equal to the level of the arytenoid cartilages. The free end of the EEB must lie proximal (but not more than 2 cm) to this level for successful intubation.



FIGURE 22: Identify the thyroid prominence to estimate the position of the lower border of the laryngeal inlet. An identical device held parallel to the inserted device can then be used to find the position of EEB in relation to the inlet.

10.3 ILMA® TOO LARGE

If the ILMA® is too large in patients with normal or thin necks, resistance may be encountered with the depth marker still visible or just a few millimeters into the ILMA® tube. In this case, the EEB may be trapped behind the arytenoids (Figure 23). If forceful intubation attempts are made with the ILMA® in this position, esophageal placement is likely and the epiglottis may be forced into the laryngeal vestibule. Avoid force at all times when intubating through the ILMA®.

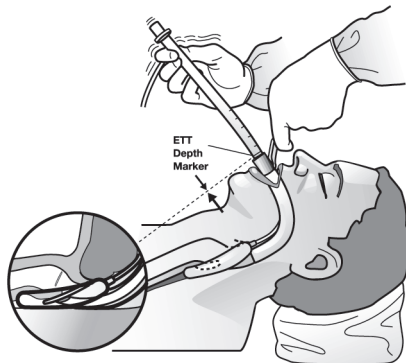


FIGURE 23: If the ILMA® is too large in patients with normal or thin necks, resistance may be felt with ETT depth marker still visible.

If the ILMA® is too large in patients with short, wide necks, resistance may be felt 4-5 cm beyond the depth marker. In this case, the ETT may be wedged between the inflated mask tip and the cricoid cartilage (Figure 24). If the epiglottis is not seen, but the arytenoid cartilages are noted in the middle or upper half of the fiberoptic view, this indicates the need for a smaller size of ILMA®. Figure 13 indicates the fiberoptic view if the correct ILMA® size has been used. If a smaller size is not available, the converse action to that described above for the situation “ILMA® Too Small” can be used. That is, the larynx may be manually slid in a caudal direction so the cricoid ring is moved out of the way of the EEB tip, allowing the EEB to swing outwards into the laryngeal vestibule.

If alternative sizes of the ILMA® are not available, it is possible to manipulate the larynx by external digital pressure to bring the epiglottis into the appropriate position in relation to the EEB. In the absence of fiberoptic aid, it is possible to

— TROUBLESHOOTING IN CASE OF FAILURE TO INTUBATE

predict whether intubation will be successful by placing an identical ILMA[®] parallel to the inserted device. The position of the EEB of the parallel device can then be compared with the level of the arytenoids which can be determined, as described previously. Finally, if the glottis is clearly seen, but the ETT cannot be made to pass through it, it may be helpful to rotate the ETT gently as it is passed. The straight design of the ETT specially made for use with the ILMA[®] facilitates rotation and optimizes the chances of passing through the glottis.

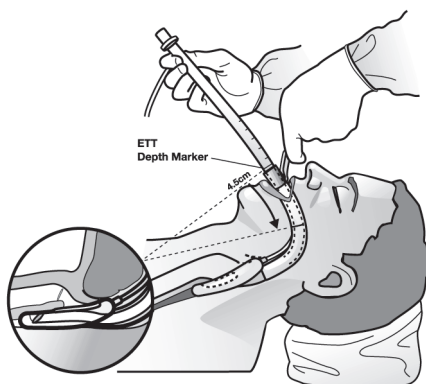


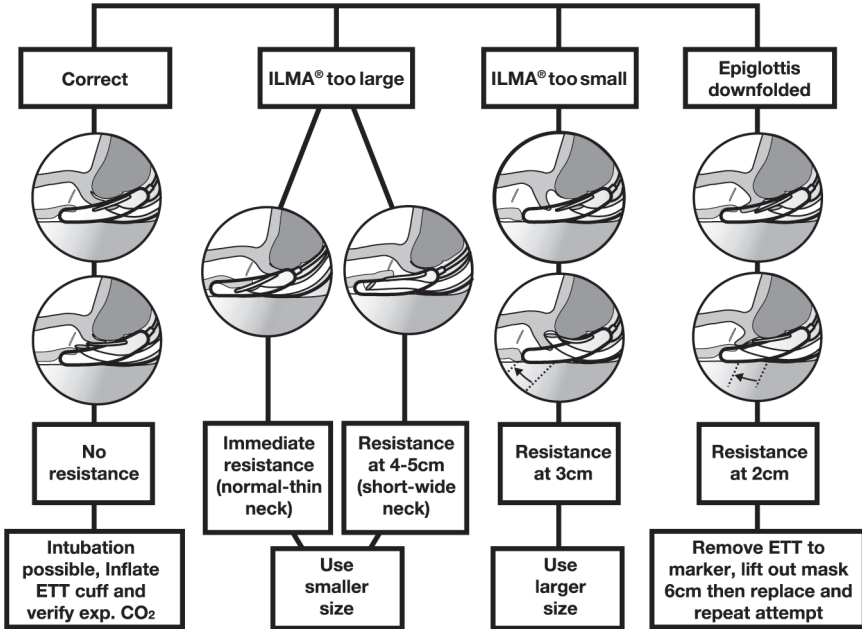
FIGURE 24: If the ILMA[®] is too large in patients with wide short necks, resistance may be felt 4-5 cm beyond the ETT depth marker.

10.4 INADEQUATE ANESTHESIA AND/OR MUSCLE RELAXANT

If anesthesia and/or muscle relaxant is inadequate, this may cause the glottis to be closed, preventing entry of the ETT into the larynx. Treat accordingly

11 ALGORITHM TO ASSIST INTUBATION

ALGORITHM TO ASSIST INTUBATION THROUGH ILMA® IN ABSENCE OF FIBEROPTIC BRONCHOSCOPE.



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Manufacturer's Warranty

Venner Medical (Singapore) Pte Ltd recommends that the reusable ILMA® be used a maximum of 40 times. Use beyond this recommendation may affect the product's performance. This device is warranted against faulty materials or manufacturing defects for forty (40) uses provided that the ILMA® is used in accordance with the procedures set forth in this instruction manual. A completed record card and the ILMA® must accompany any return for evaluation of a manufacturing defect. The single-use ILMA® airway products are warranted against faulty materials or manufacturing defects at time of delivery to customer. Warranty applicable only if purchased from an authorized distributor.

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