INSTRUCTIONS FOR USE – AES LARYNGEAL MASK AIRWAYS

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING: Product is supplied sterile for single use, should be used straight from the pack and should be discarded after use. It must not be re- used. Reuse may cause cross infection and reduce product reliability and functionality.

DEVICE DESCRIPTION:

The Laryngeal Mask Airway can be used for a wide range of routine applications ranging from general anaesthesia to emergency use or as a resuscitation device.
AES Ultra, Ultra Clear and Ultra Flex are made primarily of medical grade silicone and PVC and is not made with natural rubber latex. AES Ultra PVC is made primarily of medical grade PVC and is not made with natural rubber latex.
The device is only for use by medical professionals trained in airway management.

INTENDED USE:

It is indicated for use in achieving and maintaining control of the airway during routine and emergency anaesthetic procedures in fasted patients using either spontaneous or Positive Pressure Ventilation (PPV). It is best suited for use in elective surgical procedures where tracheal intubation is not necessary.

CONTRAINDICATIONS:

Due to the potential risk of regurgitation and aspiration, do not use the Laryngeal Mask Airway as a substitute for an endotracheal tube in the following elective or difficult airway patients on a non- emergency pathway:

1. Patients who have not fasted, including patients whose fasting cannot be confirmed.

2. Patients who are grossly or morbidly obese, more than 14 weeks pregnant.

3. Patients with massive or acute injury to the abdomen or thorax.

4. Patients with any condition associated with delayed gastric emptying or using opiate medication prior to fasting.

5. Patients with fixed decreased pulmonary compliance, or peak inspiratory pressure anticipated to exceed 20 cm H_2O, because the device forms a low-pressure seal (approximately 20 cm H_2O) around the larynx.

ADVERSE EFFECTS:

There are reported adverse reactions associated with the use of laryngeal mask airways. Standard textbooks and published literature should be consulted for specific information.

WARNINGS/CAUTIONS:

1. Lubricate only the posterior of the cuff to avoid blockage of the airway or aspiration of the lubricant.

2. To avoid trauma, excessive force should not be used at any time when using the devices.

3. Do not use if the device is damaged or the unit packaging is damaged or opened.

4. Never over-inflate the cuff of the device over 60cm H_2O. Excessive intra-cuff pressure can result in malposition and pharyngo-laryngeal morbidity, including sore throat, dysphagia and nerve injury.

5. It is most important that pre-use checks are carried out on the device prior to use, in order to establish whether it is safe for use. Failure of any one test indicates the device should not be used.

6. The device is flammable in the presence of lasers and electrocautery equipment.

7. The Laryngeal Mask Airway does not prevent regurgitation or aspiration. Its use in anaesthetised patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anaesthesia. Do not use the device without taking appropriate precautions to ensure the stomach is empty.

8. The Device is not compatible for MRI

PRE-USE CHECKS:

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

Testing should include, but not be limited to:

1. The laryngeal mask should be inflated to twice the normal range to test for any herniation in the cuff and inflation valve and pilot balloon are working.

2. The shaft of the tube should be flexed between thumb and forefinger to show a 30% arc and NO KINKING OF THE SHAFT.

3. Examine the airway connector. If the connector is loose, discard the device to avoid the risk of accidental disconnection during use.

4. Gently pull the inflation line to ensure it is securely attached to both the cuff and balloon.

SUGGESTED DIRECTIONS FOR USE:

1. Deflate cuff prior to insertion

2. To facilitate insertion into the patient, a sterile, water based lubricant can be applied to the distal posterior surface of the cuff.

3. Anesthesia must be deep enough to permit insertion

4. Position the head and neck as for normal tracheal intubation. Keep the neck flexed and the head extended by pushing the head from behind with one hand while inserting the mask into the mouth with the other hand.

5. When inserting the mask, hold it like a pen with the index finger placed anteriorly at the junction of the cuff and tube**.** Press the tip up against the hard palate and verify it lies flat against the palate and that the tip is not folded over, before pushing further into the pharynx.

6. Using the index finger, push the mask backwards still maintaining pressure against the palate.

7. Proceed with the insertion of the mask into the hypopharynx until a definite resistance is felt.

8. Before pulling back the hand holding the mask, the other hand is used to press down on the airway tube. This ensures that the AES Laryngeal Mask stays in place when the finger is removed.

9. Inflate the cuff slowly while using the minimum amount of air required to provide an effective seal. DO NOT overinflate the cuff.
If using an AES Tru-Cuff, inflate the laryngeal mask cuff until the Tru- Cuff Black Indicator line is in the lower Green Zone (40-60 cmH_2O).

10. Disconnect inflation syringe or Tru-Cuff after desired inflation pressure is achieved.

11. Air may be withdrawn from the cuff during anesthesia to maintain a constant intracuff pressure (always less than 60cm H2O).

12. Deflate the cuff completely just prior to removal, although partial deflation can be recommended in order to assist in the removal of secretions.

13. Dispose devices and device packaging in accordance to hospital practices and applicable state, federal and other regulations.

The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification

AES, Inc.
24301 Roberts Dr.
Black Diamond, WA 98010
253.631.8008
www.aesol.com