

# General Information

## THE **INTAVENT** REUSABLE LMA CLASSIC® AND LMA FLEXIBLE®

THESE RE-USABLE DEVICES MUST BE STERILISED BY AUTOCLAVING AFTER COMPLETE CUFF DEFLATION BEFORE EACH OF THE WARRANTED 40 USES.

### Choose the Correct Size of Device

Patient Weight/Size

1: up to 5kg	neonatal	3: 30kg - 50kg	paediatric
1½: 5kg - 10kg	paediatric	4: small/normal	adult
2: 10kg - 20kg	paediatric	5: normal/large	adult
2½: 20kg - 30kg	paediatric	6: very large	adult

Keep a clearly marked syringe for inflation and deflation of the cuff.

### Pre-Use Checks

It is most important that pre-use checks are carried out on these devices prior to use, in order to establish whether they are safe for use. These tests should be carried out as follows:

1. Examine the interior of the airway tube to ensure it is free from blockage or loose particles. Then examine the tube throughout its length. Should any cuts or indentations be found, discard the device.
2. Holding at each end flex the airway tube to increase its curvature up to but not beyond 180°. Should the tube kink during this procedure, discard the device.
3. Deflate the cuff fully. Reflate the device with a volume of air 50% greater than the maximum inflation value for each size.

Size 1	6ml,	Size 1½	10ml,	Size 2	15ml,	Size 2½	21ml,
Size 3	30ml,	Size 4	45ml,	Size 5	60ml,	Size 6	75ml,

Examine the cuff for leaks and herniations. If there is any indication of either, discard the device. A herniating mask may cause obstruction during use. Then deflate the mask again.

4. Examine the airway connector. It should fit securely into the airway tube and it should not be possible using reasonable force, to remove. Do not use excessive force or twist the connector as this may break the seal. If the connector is loose, discard the device to avoid the risk of accidental disconnection during use.
5. Discolouration. It is an important design feature of the device that the airway tube is transparent to permit instant detection of fluids in the tube. Discolouration of the tube prevents this and may also indicate a reduction in tear strength. If the airway tube is even slightly discoloured discard the device.

Should you require advice with regard to procedure, or assistance in checking safety of current stock, please do not hesitate to contact Intavent Direct Ltd.

### Preparation

Deflate completely using the Cuff Shaper™ (available from the distributor) in order to create the stiff thin leading edge necessary to wedge the tip behind the cricoid cartilage. The cuff should fold back away from the aperture bars. Lubricate the back of the cuff thoroughly just before insertion. Do not lubricate the front as this may result in aspiration of lubricant.

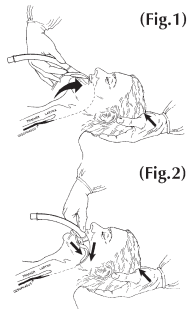
### Insertion

Note: gloves must be worn

1. Anaesthesia must be deep enough to permit insertion

Do not try to insert immediately following barbiturate induction, unless a relaxant drug has been given. A volatile agent or Propofol preceded by an opiate provide suitable insertion conditions.

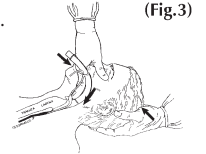
2. Position the head and neck as for normal intubation. Keep the neck **flexed** and the head **extended** by pushing on the occiput with one hand while inserting the mask into the mouth with the other hand (Fig.1).
3. When inserting the mask, hold it like a pen with the index finger placed anteriorly at the junction of the cuff and tube (Fig.1). 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.
4. Using the index finger, push the mask backwards still maintaining pressure against the palate (Fig.2).
5. As the mask moves downwards, the index finger maintains pressure backwards against the posterior pharyngeal wall to avoid collision with the epiglottis. Insert the index finger fully into the mouth to complete insertion (Fig.3). Keep other fingers out of the mouth. As insertion progresses, the flexor surface of the whole index finger should lie along the tube, keeping it firmly in contact with the palate. (Fig.3).



AVOID INSERTING WITH SEVERAL MOVEMENTS OR JERKING UP AND DOWN IN THE PHARYNX AFTER RESISTANCE IS FELT.

When resistance is felt the finger should already have been fully inserted into the mouth. Use the other hand to hold the tube while withdrawing the finger from the mouth (Fig.4).

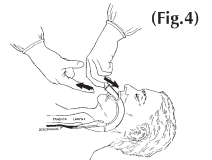
6. Check that the black line on the tube faces the upper lip. Now immediately inflate the cuff without holding the tube. Do this BEFORE connection to the gas supply. This will permit the device to position itself correctly. Inflate the cuff with sufficient air to obtain a low pressure seal. NEVER OVERINFLATE THE CUFF.



Maximum inflation volumes (ml)

Size 1	4ml	Size 3	20ml
Size 1½	7ml	Size 4	30ml
Size 2	10ml	Size 5	40ml
Size 2½	14ml	Size 6	50ml

7. Connect to gas supply, holding tube, to prevent displacement. Gently inflate lungs to confirm correct placement. Insert roll of gauze as bite-block (ensuring adequate thickness), and tape the device into place, ensuring that the proximal end of the airway tube is pointing caudally. When correctly placed, the tube should be pressed back into the palate and posterior pharyngeal wall. When using the LMA Flexible®, it is important to remember to insert a bite block at the end of the procedure.



### Maintaining the Airway

1. Remember that obstruction can occur if the device becomes dislodged or is incorrectly inserted. The epiglottis may be pushed down with poor insertion technique. Check by auscultation of the neck and correct by re-insertion or elevation of the epiglottis using a laryngoscope.
2. Malposition of mask tip into the glottis may mimic bronchospasm.
3. Avoid moving the device about in the pharynx when the patient is at a light plane of anaesthesia.
4. Keep the bite-block in place until the device is removed.
5. Do not deflate the cuff until reflexes have fully returned.
6. Air may be withdrawn from the cuff during anaesthesia to maintain a constant intracuff pressure (ideally about 60cm H<sub>2</sub>O).

### Removal

1. The device, together with the recommended bite-block, should be left in place until the return of consciousness. Oxygen should be administered using an appropriate oxygen enrichment device and standard monitoring should be in place. Before attempting to remove or deflate the device, it is essential to leave the patient completely undisturbed until protective reflexes have fully returned. Do not remove the device until the patient can open the mouth on command.
2. Look for the onset of swallowing which indicates reflexes are almost restored. It is usually unnecessary to perform suction because the correctly used device protects the larynx from oral secretions. Patients will swallow secretions on removal. Suction equipment should however be available at all times.
3. Deflate the cuff completely just prior to removal, although partial deflation can be recommended in order to assist in the removal of secretions. In small children, it is safe to allow the child to remove the device without cuff deflation provided the cuff is not excessively inflated.

### Caution

1. The LMA Classic® and LMA Flexible® do not prevent regurgitation or aspiration. Their use in anaesthetised patients should be restricted to fasting patients. A number of conditions predispose to regurgitation under anaesthesia. Do not use these devices without taking appropriate precautions to ensure the stomach is empty.
2. For safe use, new anaesthetic skills must be attained.
3. Laryngeal spasm may occur if the patient becomes too lightly anaesthetised during surgical stimulation or if bronchial secretions irritate the vocal cords during emergence from anaesthesia. If laryngeal spasm occurs, do not remove the device, but treat the cause. Only remove the device when reflexes are fully competent.
4. Do not pull or use undue force when handling the inflation line or try to remove the device from patient by the inflation tube as it may detach from the cuff spigot.

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# Decontamination and Sterilisation of Reusable LMA® Airways

Cleansing is an essential pre-requisite to effective disinfection or sterilisation. Where available, the use of a washer disinfectant is preferred to manual cleansing. The method used should be validated to ensure the effectiveness of the cleansing process without damage to the device.

The advantage of using automated cleansing equipment is that it provides an efficient,

reproducible process which can be more easily controlled than manual methods. Washer disinfectants are generally more convenient and also provide protection for the user by reducing exposure to processing chemicals. The use of thermal washer disinfectants also removes and destroys pathogenic microorganisms which may cause an infection hazard during subsequent handling, e.g. inspection and packaging.

Cleansing of the device should be carried out as soon as possible after removal from the patient. This enables secretions and other soil to be removed more easily. If there is to be a long delay between removal from the patient and decontamination of the device, it is advisable that gross soiling is removed before the device is returned for processing otherwise it may dry onto surfaces making subsequent removal difficult.

## Mechanical Cleansing:

### Use of Thermal Washer Disinfectors

#### 1. Equipment Required

- a. A washer disinfectant dedicated to anaesthetic/respiratory equipment. These are usually of the cabinet type. The machine chosen must have a validated cycle.
- b. A suitable load carrier which should ensure that all internal and external surfaces of each device can be accessed for cleansing. The device should be connected to a spigot through which water/detergent can be directed through the lumens during processing.
- c. A compatible detergent i.e. neutral, preferably supplied from a calibrated automatic dosing system. Rinse-aids should not be used.\*
- d. A mechanical drying facility either as a component stage in an automated process or in a separate temperature controlled, fan assisted drying cabinet.

#### 2. Procedure

- a. Ensure the washer disinfectant and all services are operational.
- b. Wearing protective clothing (i.e. apron, gloves and eye protection if splashing is likely), load the machine ensuring that the loading configuration does not impede the cleansing process and that the connector has already been cleaned manually.
- c. Secure the door, select and start the cycle.
- d. On completion of the cycle, ensure that all process stages and parameters have been achieved: remove the load and visually check and inspect the cleanliness of the device. Pay particular attention to the inner surface of the airway tube and the area behind the two bars in the bowl of the cuff. There should be no loose particles or secretions in evidence.
- e. If the device is not dry, drain off excess water and transfer to the drying facility. The device must be completely dry prior to sterilisation.
- f. Complete the documentation.

#### 3. Scope of action

Cleansing is achieved by the continual spraying, deluging or irrigation of the device with water and detergent during several stages of a timed cycle. A typical cycle comprises of the following stages:

- a. Cold rinse at or below 35°C (temperatures in excess of this may coagulate protein).
- b. Warm wash with neutral detergent at approximately 55°C.
- c. Thermal disinfection where the surface temperature of the device should reach a minimum temperature of 71°C for 3 minutes, 80°C for 1 minute or 90°C for 12 seconds.
- d. Drying  
Preferably the washer disinfectant should be purchased and used in compliance with BS 2745 Parts 1 and 3 and HTM 2030.

\* Some rinse-aids used in combination with high pressure temperatures damage the polysulfone connector of the device. Their use should therefore be avoided.

Handwashing should only be undertaken when other mechanical methods are inappropriate or unavailable.

## Manual Cleansing:

#### 1. Equipment Required

- a. A sink (not a wash hand basin), or a receptacle which will hold a sufficient volume of water/detergent such that the device to be cleaned can be fully immersed.
- b. A warm, compatible water/detergent solution at correct dilution and a temperature which will not coagulate protein or scald the skin.
- c. A receptacle to contain rinse water.
- d. A drainage surface and a mechanical drying facility (e.g. drying cabinet or industrial hot air dryer).
- e. Brushes, including a soft bristle brush for the external surfaces and a pipe cleaner brush for the lumen, and jet washer.

#### 2. Procedure

- a. Ensure that the cleansing receptacle is clean and dry.
- b. Wearing protective clothing (i.e. gloves, apron and eye protection if splashing is likely), fill the receptacle with a sufficient warm water/detergent solution to ensure complete immersion of the device.
- c. Carefully immerse the device in the solution in order to displace trapped air; it is important to ensure that the cleansing solution reaches all surfaces including internal lumens.
- d. Brush, wipe, irrigate or jetwash the device dislodge and remove all visible dirt, taking care that the action is undertaken beneath the surface of the solution to prevent splashing and aerosols. Brush the inside of the airway tube by inserting a pipe cleaner brush from the mask end taking care not to damage the bars in the bowl of the cuff.
- e. Remove the device from the cleansing

solution and drain before transferring to a clean rinse receptacle or sink.

- f. Rinse the device thoroughly with clean water or with a water jet gun, ensuring that it is fully immersed.
- g. Remove the device from the rinse water and drain. Carefully examine and inspect for cleanliness, paying particular attention to the inner surface of the airway tube and the area behind the two bars in the bowl of the cuff. There should be no loose particles or adherent secretions in evidence.
- h. Place in a drying cabinet. The device must be completely dry prior to sterilisation.
- i. Complete the documentation.

#### 3. Scope of the action

This process physically removes soil and other contaminants, but it does not incorporate a disinfection process. Subsequent handling prior to sterilising therefore constitutes an infection risk to processing staff.

## Sterilisation After Cleansing:

The device will tolerate steam sterilisation temperatures up to 137°C.

The use of a porous load steam steriliser (autoclave) is recommended as it incorporates a vacuum-assisted air removal stage prior to steam admission. It can therefore be used for lumened and wrapped items such as the LMA® airway.

The device must be completely dry.

It is important that the cuff is fully deflated immediately prior to autoclaving, using a dry syringe. If left for any period of time, it will

gradually reflate due to its inherent permeability. Failure to fully deflate may result in rupturing or herniation of the cuff and/or damage to the adhesives in the autoclave which may not be readily apparent. The device should be placed in sterilisation pouches and only with other LMA® airways. Autoclaving should be carried out within a standard steam sterilisation cycle e.g. 134°C (+3°/-0°) for 3 minutes.

### CAUTION

The device must not be sterilised/disinfected by

exposure to formaldehyde, glutaraldehyde or ethylene oxide. Prolonged immersion in chlorhexidine should be avoided, as these and iodine based antiseptics and silicone based lubricant sprays may cause damage. Cleansing or wiping with solvent based solutions and exposure to rinse aids has a detrimental effect on both the silicone compounds and other device components. This is often indicated by 'crazing' of the connector. Do not place the device in ultrasonic cleansing equipment or subject them to gamma irradiation.

## Key References:

British Standards Institution. Washer-disinfectors for medical purposes, EN ISO15883

Part 1: Washer-Disinfectors. General requirements

Part 2: Washer-Disinfectors. Requirements and Tests

Department of Health, July 1991, HC(91)33.

Decontamination of equipment, linen or other surfaces

contaminated with Hepatitis B and/or human immuno-deficiency virus.

HTM 2030: Washer disinfectors, Volume 1

Management Policy, 1995.

NHS Estates (subsequent volumes in preparation).

HTM 2010: Sterilisers parts 1-5 NHS Estates Sterilisation, disinfection and cleaning of medical equipment: guidance on decontamination from the Microbiology Advisory

Committee to Department of Health Medical Devices Agency.

Part 1: Principles. Part 2: Protocols.

Part 3: Procedures (in preparation). Assessment of the efficacy and suitability of automated cleansing systems for processing Laryngeal Mask Airways. Test Report prepared by Hospital Infection Research Laboratory, City Hospital NHS Trust, Dudley Road, Birmingham B18 7QH. May 1996.