

LMA NORTH AMERICA, INC.

LMATM
40 USE PROGRAM

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40 USE PROGRAM



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Dear Valued Customer,

This package has been put together to address the issue of patient safety as it pertains to care and maintenance of LMA™ airways.

This year I have required that our sales representatives make sure our customers are reminded about the correct cleaning, sterilization and tracking procedures for our reusable LMA™ airways. We have found that the majority of product issues reported are the result of improper customer handling and processing.

The Laryngeal Mask Company, our manufacturer, warrants reusable LMA™ products against manufacturing defects for 40 uses or a period of one (1) year from date of invoice, whichever comes first. The instruction manual states, "With proper cleaning, sterilization, and handling the reusable LMA™ airways can be used a maximum of 40 times." The manufacturer can accept no liability for failure beyond 40 uses.

Our packaging is clearly labeled in several places with a do-not-exceed 40 use symbol. We believe the 40 use guideline, which is based on the manufacturer's test results, is a reasonable limit with a sufficient margin of safety, provided the product passes all performance tests prior to use. It is also a good value when used 40 times.

This information packet answers three important questions:

1. What are the risks involved with overuse, failure to track the number of uses, and improper cleaning and sterilization?
2. What needs to be done to mitigate those risks?
3. What will it cost to achieve 40 use compliance?

Your LMA North America sales representative is ready to provide you with whatever assistance you require. He/she can help inspect your masks for signs of overuse, help you set up a tracking system for your masks and provide educational materials for those responsible for cleaning and sterilization.

Patient safety and customer satisfaction are our highest priorities. We believe that following the 40 use guideline significantly contributes to achieving those objectives.

Best Regards

A handwritten signature in black ink that reads "Steve C. Mendell".

Steve Mendell

President & Chief Executive Officer, LMA North America

2004 JCAHO Patient Safety Guidelines and LMA™ Airways

JCAHO 2004 National Patient Safety Goals



On July 18th of 2003, the Joint Commission on Accreditation of Healthcare Organization's (JCAHO's) Board of Commissioners approved the 2004 National Patient Safety Goals (NPSGs). These goals include the six from 2003 and their accompanying requirements, and add one new goal with two requirements that focus on reducing the risk of health care-acquired (nosocomial) infections:

1. Improve the accuracy of patient identification.
2. Improve the effectiveness of communication among caregivers.
3. Improve the safety of using high-alert medications.
4. Eliminate wrong-site, wrong-patient, wrong-procedure surgery.
5. Improve the safety of using infusion pumps.
6. Improve the effectiveness of clinical alarm systems.
7. Reduce the risk of health-care acquired infections **(New for 2004)**
 - a. Comply with current [CDC hand hygiene guidelines](#).
 - b. Manage as sentinel events all identified cases of unanticipated death or major permanent loss of function associated with a health care-acquired infection.

The first NPSGs were approved by the Joint Commission's Board of Commissioners in July 2002. JCAHO established these goals to help accredited organizations address specific areas of concern in regards to patient safety. Each goal includes no more than two succinct, evidence- or expert-based recommendations. Each year, the goals and associated recommendations are re-evaluated; some are continued while others are replaced because of emerging new priorities. New goals and recommendations are announced in July and become effective on January 1 of the following year.

Risk Reduction Strategies

Nearly \$5 billion are added to U.S. health costs every year as a result of infections that patients get while they are hospitalized for other health problems. In general, the number of extra days a patient has to spend in the hospital varies depending on the type of infection he or she gets: an estimated 1 to 4 days for a urinary tract infection, 7 to 8 days for an infection at the site of a surgery procedure, 7 to 21 days for a bloodstream infection, and 7 to 30 days for pneumonia. The costs vary, too, anywhere from \$600 or so for a urinary tract infection to \$5,000 or more for pneumonia. Prolonged bloodstream infections can top \$50,000. Because insurance companies and other payers, such as Medicaid, may reimburse the hospital on the basis of the patient's original condition, and not for the infection the patient acquired during treatment, hospitals can lose hundreds to thousands of dollars on each of these infections.¹

Numerous high profile media reports of incidences of patient death resulting from hospital-acquired infections indicate that such cases are seriously under-reported to JCAHO. JCAHO emphasizes that patient death or permanent injury/loss of function as a result of a nosocomial infection does indeed meet the criteria for reviewable sentinel events. As such, each event should undergo a root cause analysis to identify risk reduction strategies, and should be considered for reporting to JCAHO's Sentinel Event Database to expand the knowledge base about the scope and characteristics of serious nosocomial infections, the factors that lead to their occurrence, and effective strategies for prevention.

As a result of the sentinel events arising from infections and in response to the identified root causes, health care organizations implemented various risk reduction strategies, including:

1. Revising orientation and training processes and competency assessments.
2. Revising equipment cleaning processes.
3. Revising handwashing procedures.
4. Switching to the use of single-use IV flush vials.
5. Adding waterless handrubs.
6. Defining supervisory expectations.
7. Revising critical care privileging and ICU admission criteria.
8. Conducting in-service and team trainings.
9. Instituting tracking systems.

(The highlighted strategies should be of particular importance to hospitals and healthcare facilities that reprocess medical devices - such as the LMA™.)

What can LMA North America Do?

LMA North America believes that we can improve patient safety by:

1. Reinforcing the need to perform device tracking and assisting with the implementation of LMA™ tracking within your institution.
2. Reviewing the recommended, and proper, cleaning and sterilization procedures for LMA™ devices currently in use – and provide orientation, training, ongoing in-services and educational materials regarding pre-use performance inspection tests and cleaning and sterilization procedures for LMA™ airways when requested or needed.
3. Increasing awareness about the single-use (disposable) LMA Unique™ as a low-cost alternative or supplement to reusable laryngeal devices, further reducing the likelihood of nosocomial infection. If you are interested in having a value analysis performed in your facility, contact your local LMA™ sales representative or call LMA North America at (800) 788-7999.

¹ "Hospital infections cost U.S. billions of dollars annually" Centers for Disease Control Press Release - March 6, 2000

JCAHO Standards Regarding Reprocessing of Medical Devices.

The following Standards can be found in Section II, Management of the Environment of Care (EC), in the **2004 Hospital Accreditation Standards** published by the JCAHO. The standards in this chapter **require each hospital to develop a written plan** for (among others) Medical Equipment Management (EC.6.10).

The 2004 Hospital Accreditation Standards have undergone major revisions from the 2003 Hospital Accreditation Standards and the new on-site survey process shifts the focus from survey preparation and scores to the continuous improvement in support of safe, high-quality care, treatment and services. The 2004 survey activities and agenda now include two Environment of Care Sessions in which staff members are interviewed and processes are assessed as they relate to priority focus areas (PFA's) or to care of patients. PFA's are processes, systems, and structures in a health care organization that significantly impact safety and/or quality of care, treatment, and services. Included in the 2004 PFA's are Infection Control, Equipment Use and Patient Safety.



The following sections of the Standards (and the highlighted statements) should be of particular importance to hospitals and healthcare facilities that are reprocessing medical devices - such as the LMA™ airway. Please note: The Joint Commission defines medical equipment as fixed and portable equipment used for the diagnosis, treatment, monitoring, and direct care of individuals.

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Standard EC.6.10 The hospital manages medical equipment risks.

Rationale for EC.6.10

Medical equipment is a significant contributor to the quality of care. It is used in treatment, diagnostic activities and monitoring of the patient. It is essential that the equipment be appropriate for the intended use; that staff, including LIPs (Licensed Independent Practitioners), be trained to use the equipment safely and effectively; and that the equipment be maintained appropriately by qualified individuals.

Elements of Performance for EC.6.10

1. The hospital develops and maintains a written management plan describing the processes it implements to manage the effective, safe, and reliable operation of medical equipment.
2. The hospital identifies and implements a process(es) for selecting and acquiring medical equipment.
3. The hospital establishes and uses risk criteria for identifying, evaluating, and creating an inventory of equipment to be used in the medical management plan before the equipment is used. These criteria address the following:
 - Equipment function (diagnosis, care, treatment, and monitoring)
 - Physical risks associated with use
 - Equipment incident history
4. The hospital identifies appropriate strategies for all equipment on the inventory for achieving effective, safe, and reliable operation of all equipment in the inventory.
5. The hospital defines the intervals for inspecting, testing, and maintaining appropriate equipment on the inventory (that is, those pieces of equipment on the inventory benefiting from scheduled activities to minimize the clinical and physical risks) that are based upon criteria such as manufacturer's recommendations, risk levels, and current organization experience;
6. The hospital identifies and implements processes for monitoring and acting on equipment hazard notices and recalls.

7. The hospital identifies and implements processes from monitoring and reporting incidents in which a medical device is suspected or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990.
8. The hospital identifies and implements processes for emergency procedures that address the following:
 - What to do in the event of equipment disruption or failure
 - When and how to perform emergency clinical interventions when medical equipment fails
 - Availability of backup equipment
 - How to obtain repair services

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Standard EC.6.20 Medical Equipment is maintained, tested and inspected.

Elements of Performance of EC.6.20

1. The hospital documents a current, accurate, and separate inventory of all equipment identified in the equipment management plan, regardless of ownership.
2. The hospital documents performance and safety testing of all equipment identified in the management plan before initial use.
3. The hospital documents maintenance of equipment used for life support that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan (see Standard EC.6.10).
4. The hospital documents maintenance of non-life support equipment on the inventory that is consistent with maintenance strategies to minimize clinical and physical risks identified in the equipment management plan (see Standard EC.6.10).
5. The hospital documents performance testing of all sterilizers used.
6. The hospital documents chemical and biological testing of water used in renal dialysis and other applicable tests based upon regulations, manufacturers' recommendations, and hospital experience.

The following Standards can be found in Section II, Management of Human Resources (HR), in the **2004 Hospital Accreditation Standards** published by the JCAHO. The goal of this chapter is to ensure that the hospital determines the qualifications and competencies of all staff positions based on its mission, population(s), care, treatment, and services. Organizations must also provide the right number of competent staff to meet patients' needs. To meet this goal the hospital carries out the following processes and activities:

- Providing an adequate number of staff.
- Providing competent staff
- **Orienting, training and educating staff**
- Assessing, maintaining and improving staff competence.

Standard HR.2.30 Ongoing Education, including in-services, training, and other activities, maintains and improves competence.

Elements of Performance for HR.2.30

The following occurs for staff, students, and volunteers who work in the same capacity as staff providing care, treatment, and services.

1. Training occurs when job responsibilities or duties change
2. Participation in ongoing in-services, training, or other activities occurs to increase staff, student or volunteer knowledge of work-related issues

3. Ongoing in-services and other education and training are appropriate to the needs of the population(s) served and comply with law and regulation.
4. Ongoing in-services, training or other activities emphasize specific job-related aspects of safety and infection prevention and control.
5. Ongoing in-services, training, or other education incorporate methods of team training, when appropriate
6. Ongoing in-services, training, or other education reinforce the need and ways to report unanticipated adverse events
7. Ongoing in-services, training, or other education is offered in response to learning needs identified through performance improvement findings and other data analysis (that is, data from staff surveys, performance evaluations or other needs assessments)
8. Ongoing education is documented

Device Tracking and the LMA™ Airway

LMA North America provides a tracking card with every reusable product to facilitate the tracking process. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines specify that all facilities have a robust tracking procedure in place for all reusable medical devices (*JCAHO Hospital Accreditation Standards, Management of the Environment of Care Standards*) - which includes the LMA™ airway.

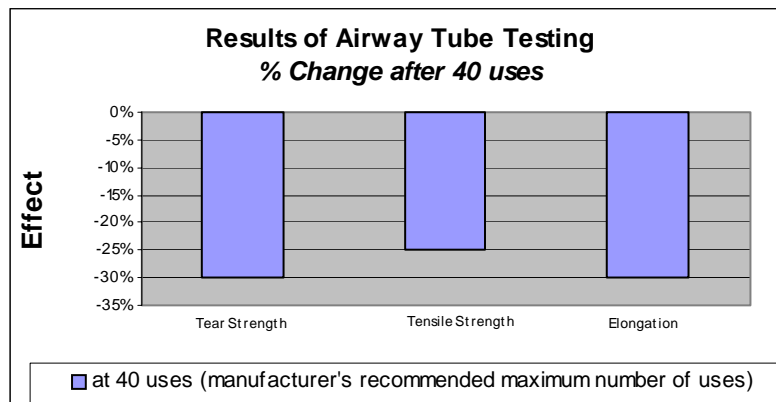
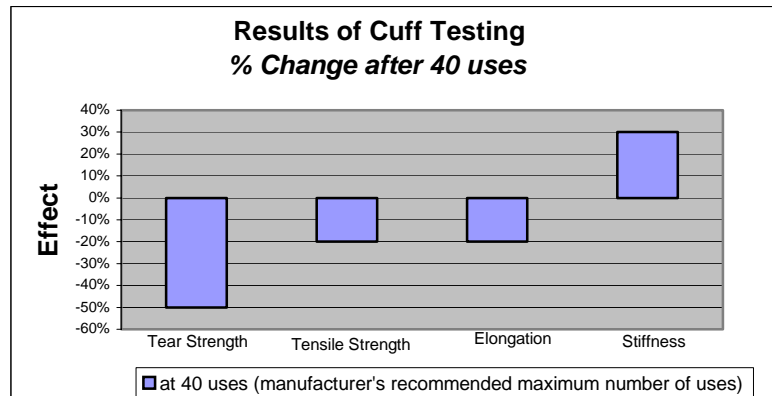
According to JCAHO, five percent of organizations accredited under the hospital accreditation program received a Random Unannounced Survey (RUS) in 2003 and **all regular accreditation surveys will be conducted on an unannounced basis beginning in January 2006**. If proper cleaning and tracking procedures are not specified and followed, hospitals may be cited and fined².

² Hospital in New York received a “Level 1 Citation” and a \$5,000.00 punitive fine by JCAHO for depositing dirty LMA’s™ in the sink of the anesthesia work room after cases; Hospital in Minnesota received a citation by JCAHO for not having a definitive cleaning procedure in place for the LMA™ airway.

Our Position on 40 Uses

The 40-use specification is to alert the practitioner that although the reusable LMA™ airway is very durable, like all materials, it degrades with use and should not be re-used to the point of abrupt failure. Over the past several years, there has been an increased amount of data available regarding the possible ways that LMA™ airways may fail, and the average number of uses to reach failure. Mechanical testing of LMA™ airway components found that as the number of uses increased, there were reductions in tear strength, tensile strength, and elongation, and an increase in stiffness (see charts below). Due to this material degradation, the manufacturer recommends that an LMA™ airway be used up to 40 times and only if the device passes the pre-use performance checks specified in the instructions before each use.

The following charts illustrate the degradation of materials associated with LMA™ airways after 40 uses.



Consistent with this data, the product warranty states that LMA™ airways are warranted against faulty materials or manufacturing defects for forty uses or a period of one year from date of invoice, whichever comes first. It is not the intention of the warranty statement that LMA™ airways that have been used fewer than 40 times be discarded after one year. Such devices should be discarded if they fail the performance tests.

We hope this explanation will be of help. As a valued LMA North America customer, your input is important. If you have additional questions or comments regarding LMA™ airways, please contact us at (800) 788-7999.

Overuse and Failure to Track Number of Uses of LMA™ Airways

Clinical Consequences

Tracking the number of uses is essential to preventing overuse of a reusable LMA™ airway. Continued use of LMA™ airways beyond 40 uses increases the probability of device malfunctions. For example, reports of airway failure, such as fractured airway tubes, have been associated with masks used more than the recommended number of times.

In most cases, the breaks have occurred on emergence, and have been associated with biting down on the tube. Occasionally, large air leaks from tube breaks have been noticed immediately after insertion. In one case, a large air leak was noticed after the airway circuit was moved, which created a twisting force, displacing the LMA™ cuff, and tearing the airway tube.

If a fractured airway tube occurs, there is the risk of airway obstruction, hypoxia, and aspiration of tube fragments. In all published cases and reports to LMA North America to date, there have been no permanent clinical sequelae.



LMA Classic™ used 71 times

Published Reports of Fractured LMA™ Airways

1. Crawford M, Davidson G. A problem with a laryngeal mask airway. *Anesthesia* 1992; 47:46 Reply by Woods
2. Hefferman AM, White M, Curran A, Colbert SA. Laryngeal mask airway severed by biting. *Eur J Anaesthesiol* 2003; 20:74-75
3. Kramer-Kipler OT. Removal of the laryngeal mask airway during light anesthesia. *Anesthesia* 1992; 47:816
4. Kuhn LH, Use of the LMA in patients with orthodontic appliances. *Am J Anesthesiol* 2000;27(3):64
5. Quinlan J. Reinforced laryngeal mask severed by biting. *Anaesthesia* 2000; 55:186
6. Squires SJ. Fragmented laryngeal mask airway. *Anaesthesia* 1992; 47:274. Reply by Woods.
7. Vickers R, Springer A, Hindmarsh J. Problem with the laryngeal mask airway. *Anaesthesia* 1992; 47:639
8. Wong DR, McGuire GP. Fractured laryngeal mask airway (LMA). *Can J Anesth* 2000; 47:716
9. Yamaguchi S, Mishio M, Okuda Y, Kitajima T. [Damage of a laryngeal mask airway during anesthesia.] *Masui* 2000;49:762-4
10. Zavaratto M. LMA Failure. *Anesth Intensive Care* 1996;24:119

Examples of Reports Received by LMA North America

Size 5 LMA Classic™, purchased 4 years earlier, broke during repositioning and occluded patient's airway. Airway was removed, patient was X-rayed, observed in PACU for 2.5 hours, and treated with Versed and Decadron.

Size 5 LMA Classic™, purchased 3 years earlier, tube broke from cuff after insertion. Cuff remained lodged in pharynx, emergency tracheostomy performed. Cuff eventually removed with McGill forceps. Patient observed in PACU.

How to Get the Best Results From Your Reusable LMA™ Airways

Follow the important points below to reduce the possibility of a fractured airway tube from occurring:

1. Track the number of times each LMA™ airway has been used and autoclaved, and limit the number to the recommended 40 uses. In one reported case the LMA™ airway had been manufactured 9 years earlier and had been used approximately 400 times. LMA North America provides a tracking card with every reusable device to facilitate the tracking process, or you may use one of your own design. Each reusable LMA airway has a unique serial number located at the proximal end of the airway tube. You can use this number or your own identification system.
2. Perform the pre-use tests prior to each use. Specific tests to ensure the integrity of the airway include checking its transparency, checking for cuts or tears, and doing the kink test. The airway tube will become discolored and lose its elasticity with age and autoclaving. Discoloration of the airway tube will prevent visualization of particles or fluid. A kinked tube may result in airway obstruction.
3. Use the standard insertion and fixation technique. Use of a rotational insertion technique or failure to secure the airway in place may result in significant torque on the airway tube, contributing to the likelihood of a fracture.
4. Use a bite-block. In most reported cases during emergence the patient bit down on the airway tube. If a bite-block had been in place this could have been prevented. Even if the tube had not been severed, cuts and tears can weaken the tube, making it more likely to fail in the future.

Improper Cleaning and Sterilization of LMA™ Airways

Clinical Consequences

There have been numerous reports of severe sore throats and dysphagia associated with use of LMA™ airways that have been exposed to germicides, disinfectants, or chemical agents, such as phenols, glutaraldehyde, and ethylene oxide. These substances can be absorbed by the silicone materials, and later leach out while in use.

In some instances, tissue sloughing and ulcerations have resulted. Patients have often been treated with steroids, antibiotics, and/or pain medications. In rare instances, patients have been admitted for observation. In all cases to date, there have been no permanent sequelae.

Once the silicone materials have been exposed to these chemical agents, there is no reliable method to remove these agents or to determine if potentially hazardous residue remains. Therefore, devices that have been exposed to improper cleaning and sterilization agents must be discarded.

Examples of Reports Received by LMA North America

Two patients had sore throats after LMA Classic™ airways were used that had been sprayed with a quaternary-ammonium based cleaner. Both patients were evaluated by an ENT consultant and ulcerations were seen on the posterior mucosa. One patient was treated with antibiotics and steroids, and admitted to the ICU overnight for observation. Both patients recovered without sequelae. Upon investigation, the cleaning procedures at the institution had recently changed in that masks were sent to central supply. All suspect masks were removed from service.

Site reported 5-6 patients had significant sore throats over a period of 2 months following use of LMA Classics™. Most of the events were treated with steroids and topical anesthetics. A few patients required referral to an ENT physician, who noted posterior pharyngeal ulcerations. All events resolved. Anesthesia tech reported that a phenol-based concentrated germicidal agent had been used to clean LMA™ airways. Because there was no way of identifying how many of their stock of 50-70 LMA™ airways had been exposed and the irritant could not be purged from the material, all masks were removed from service. Site subsequently switched to an enzymatic cleaner.

How To Get the Best Results From Your Reusable LMA™ Airways

Follow the important points below to prevent exposure of your patients to potentially severe tissue burns:

- Ensure all personnel (i.e., permanent or temporary, operating room, or central processing) who will clean and sterilize the LMA™ airways are trained in the proper cleaning and sterilization techniques. In many cases, these adverse events began after there was a change in cleaning personnel.
- If you have any doubts or questions about the suitability of a cleaning agent, obtain the materials safety data sheet (MSDS) from the manufacturer and/or contact Professional Services at LMA North America (800-788-7999).

Instructional materials, including a video and a poster are available from Professional Services or can be viewed on our website, www.lmana.com.

Review of Cleaning Procedures

All reusable LMA™ airways are delivered nonsterile and must be cleaned and sterilized prior to the first and each subsequent use with a patient using the following procedures.

1. Thoroughly wash the LMA™ airway cuff and airway tube in warm water with a dilute (8-10%) sodium bicarbonate solution until all visible foreign material is removed. A 10% sodium bicarbonate solution can be prepared by mixing 1 part baking soda with 10 parts water. Do not expose the valve to any cleaning solution as it may cause premature valve failure. Mild detergents are also acceptable when used per the manufacturer's instructions. The user must verify that the detergent contains no skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA™ airway use is Endozime® (Ruhof, Valley Stream, NY).
2. Clean the LMA Classic™ / LMA Flexible™ airway tube with a small soft brush (approximately 1/2" in diameter for adult sizes). Gently insert the brush through the aperture bars, taking care not to damage the bars. For the LMA Fastrach™, gently insert a brush (approximately 3/4" in diameter) past the epiglottic elevating bar into the airway tube, taking care not to damage the bar. Ensure the whole interior of the tube is thoroughly cleaned. A 1/4" diameter brush can be used on the LMA ProSeal™ tubes. Gently insert the brush through the front of the mask, taking care not to damage the tubes. Gently clean under the drain tube in the bowl of the mask. Ensure that any brush used on your LMA™ airway does NOT have a sharp tip.
3. Thoroughly rinse the cuff and airway tube in warm flowing tap water to remove cleaning residues. Carefully inspect the device to ensure that all visible foreign matter has been removed. Repeat Steps 1, 2 and 3 as necessary.

WARNING: Do not expose the LMA™ airway to germicides, disinfectants, or any agents containing glutaraldehyde, phenol, iodine, or quaternary ammonium compounds. Such substances are absorbed by the LMA™ airway materials, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the LMA™ airway. Do not use an LMA™ airway that has been exposed to any of these substances.

Listed on the next page are SOME products known to contain the above or other ingredients that should NOT be used on the LMA™ airway.

DO NOT USE			
Cleaner Name	Ingredient	Cleaner Name	Ingredient
Amerse [®]	Quaternary ammonium	LpH [®] se	Phenols
Beaucoup [®]	Phenols	Lysol [®] IC	Phenols
Betadine [®]	Phenols	Matar [®]	Phenols
Cidex [®]	Glutaraldehyde	Powder Keg [®]	Quaternary ammonium
Cidex OPA [®]	Ortho-phthalaldehyde	T.B.Q [®]	Quaternary ammonium
CIDA-FOAM [™]	Quaternary ammonium	Vesta-Syde [®]	Phenols
Coverage [®] Plus	Quaternary ammonium	Vesphene II [®] se	Phenols
Instra-Clean	Sulphur dioxide	Wavicide [®]	Glutaraldehyde
WARNING: Failure to properly clean, rinse and dry an LMA[™] airway may result in retention of potentially hazardous residue or inadequate sterilization.			

Review of Sterilization Procedures

Steam autoclaving is the only recommended method of sterilization for the LMA[™] airway. Do not expose any LMA[™] airway to ethylene oxide as it is absorbed by the LMA[™] airway materials, resulting in exposure of the patient to potentially severe tissue burns. **Do NOT use an LMA[™] airway that has been exposed to ethylene oxide.** The following procedures are essential to ensure sterilization without damage to the LMA[™] airway:

1. Immediately prior to autoclaving the LMA Classic[™], LMA Flexible[™], LMA Fastrach[™] or LMA ProSeal[™] **without manual vent**, fully deflate the LMA[™] airway cuff using a clean, dry syringe. Remove syringe from valve before autoclaving to avoid damage to valve. LMA Cuff-Deflators[™] available from LMA North America may be used to help achieve complete deflation.

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 inflation pilot balloon.

For the LMA ProSeal[™] with manual vent, it is not necessary to deflate the cuff prior to steam autoclaving provided the red vent plug is in the open position. Note that after autoclaving, the cuff of the LMA ProSeal[™] **with manual vent** will be inflated.

2. Steam autoclave the LMA[™] airway following the autoclave manufacturer's recommendations and applicable institution and industry guidelines for temperature and time. All autoclave cycles typically used for sterilization of porous items are acceptable for sterilization of the LMA[™] airway provided that the maximum autoclave temperature does not exceed 275°F or 135°C. Validated sterilization cycles and loading patterns, and proper monitoring of sterilization cycles must be followed to assure that the sterilization cycle is effective. **CAUTION: Do not exceed autoclave temperatures of 275°F or 135°C.**

After autoclaving, allow the LMA™ airway to cool to room temperature prior to use.

Minimum Exposure Times All cycles 270° - 275° F (132° - 135° C)		
Autoclave	Wrapped	Unwrapped (Flash)
Gravity Displacement	10-15 min	10 min*
Prevacuum	3-4 min	4 min*

*Mixed porous and nonporous items

The Association of Operating Room Nurses (AORN) guidelines³ recommend flash sterilization only in carefully selected clinical situations when certain conditions are met, including, but not limited to:

- Work practices dictating proper cleaning and decontamination, inspection, and arrangement of instruments in the sterilizing tray or containers are followed.
- Department or work area physical configuration provides for direct delivery of sterilized items to the point of use.
- Defined procedures for aseptic handling and personnel safety during transfer of sterilized items to the point of use are followed and audited.

Validation of Recommended Procedures

Studies have been conducted that validate the efficacy of our recommended cleaning and sterilization procedures for reusable LMA™ airways. These studies have demonstrated the effectiveness of recommended cleaning processes in removing soiling agents (e.g., proteins) and reducing the quantity of microorganisms on the airway prior to sterilization. Studies have included efficacy assessments of typical health care facility steam sterilization cycles for reusable LMA™ airways. In the studies, test devices were inoculated with microorganisms, cleaned and sterilized according to our recommended procedures and tested for sterility. The tested devices were found to be sterile. Additional sterilization studies have established a sterility assurance level of 10⁻⁶ for the recommended sterilization cycles.

In addition to evaluating the efficacy of the recommended cleaning and sterilization processes, we have performed dimensional and functional testing of devices following 40 use cycles. The reusable LMA™ airways met all dimensional and functional requirements following 40 use cycles when handled, cleaned and steam autoclaved in accordance with the methods described in the manual.

Studies have not been performed to validate alternate methods such as Steris®, Sterrad® or pasteurization. Therefore, The Laryngeal Mask Company Limited, manufacturer of the LMA™ airways, only recommends steam sterilization for their reusable products.

³ AORN (2002). 2002 Standards, Recommended Practices, and Guidelines. Denver, CO: AORN, Inc.

LMA™ Classic Performance Tests

Conduct all of the performance tests prior to each use of the device. Failure of any one test indicates that the device is past its useful life and should NOT be used. Consult the instruction manual for more complete information and for additional details on insertion technique and pre-use performance testing.

Test 1. Visual Inspection:

Discoloration

Examine the transparency of the airway tube. Discoloration of the airway tube through age or contamination, for example with iodine, prevents easy visualization of fluids entering the airway tube. The transparency of the tube is an important safety feature of the LMA™ airway.



Breakage

Examine the surface of the LMA™ for damage, including cuts, tears, or scratches. The airway tube can be bitten as a result of an inadequate bite-block. Once sustained, this type of damage will tend to propagate, as will nicks from sharp objects or cleaning instruments.



Tube Kinking

Flex the tube up to, but not beyond 180°. Do not use the LMA™ if the tube kinks when flexed through 180°.

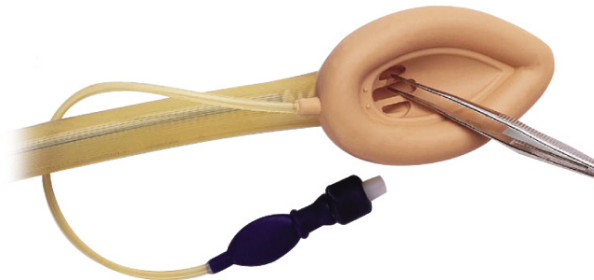


Blockage

Examine the interior of the airway tube 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.

Aperture Breakage

Examine the aperture in the mask. Gently probe the two flexible bars traversing the mask aperture to ensure they are not broken or otherwise damaged. Aggressive cleaning can damage the aperture bars. If the aperture bars are not intact, the epiglottis may obstruct the airway.



Crazing

Non-recommended cleaning solutions can cause severe damage. Extreme crazing and cracking caused by chemical degradation can cause weakening of the connector. An LMA™ airway with a damaged connector should not be used.

Note: Cleaning solution that is not adequately rinsed off the plastic 15 mm connector can cause the connector to craze during the autoclave cycle.



Test 2. Deflation and Inflation:

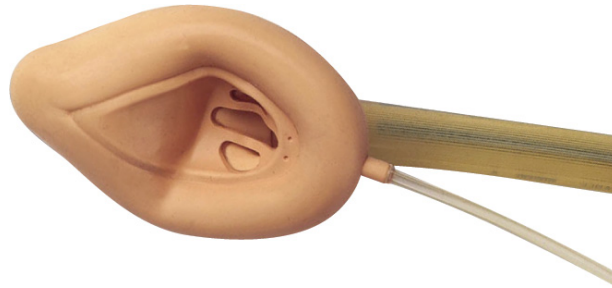
Cuff Leakage

Fully deflate the cuff so that the cuff walls are tightly flattened against each other. The cuff walls should remain tightly flattened against each other. Do not use the LMA™ airway if the cuff walls reinflate immediately and spontaneously even if only slightly. Inflate the cuff with air from complete vacuum to 50% over-inflation as shown in the table below:

TEST CUFF OVER-INFLATION VOLUMES	
LMA™ Size	Air Volume*
1	6 mL
1½	10 mL
2	15 mL
2½	21 mL
3	30 mL
4	45 mL
5	60 mL
6	75 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 within two minutes. Examine the symmetry of the inflated cuff. There should be no uneven bulging at either end or on the sides. Do not use the LMA™ airway if cuff leakage is present or there is uneven bulging of the cuff (as seen below).



Irregular Balloon

While the LMA™ airway remains 50% over-inflated, examine the blue inflation indicator balloon. The balloon shape should be elliptical, not spherical, and not bulging. Do not use the LMA™ airway if the inflation balloon is spherical or irregularly shaped (as seen below).



What Will It Cost to Achieve 40 Use Compliance?

Have You Considered All The Costs?

Obviously there are direct costs associated with tracking your LMA™ airways. But have you considered the indirect costs?

Direct Costs

- Labor & equipment costs
- Cleaning and sterilization
- Completion of tracking forms, detailed inventories, and current and accurate logs
- Performance of pre-use tests, device inspection

Indirect Costs

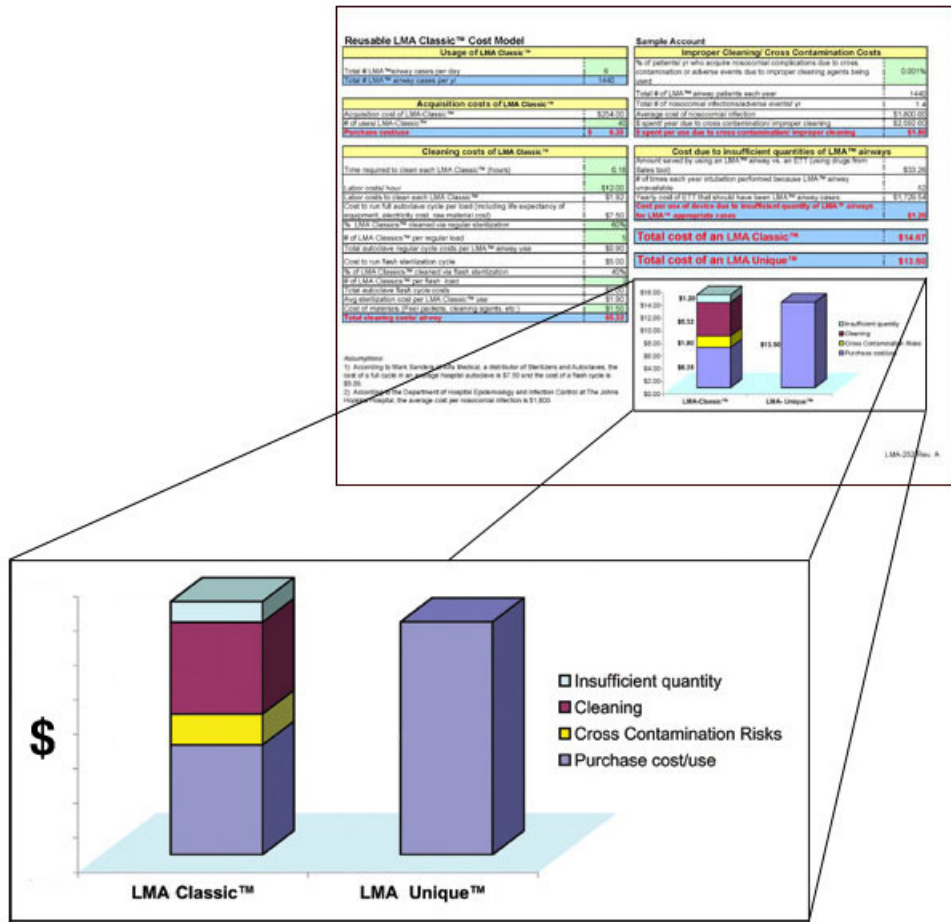
- Patient injury or infection
- Fines as a result of noncompliance with JCAHO requirements
- Additional costs of intubation due to inadequate LMA™ inventory
- Premature loss due to theft, accidentally discarding or contamination with improper agents.

What Are Your Choices?

In order to obtain the best performance from your LMA™ airways, you can implement recommended device tracking, cleaning, sterilization procedures and performance testing or you can evaluate the single use LMA™ Unique - not just financially, but from the standpoint of compliance, and elimination of device tracking and reprocessing costs.

Reusable vs. Disposable. What's Right For You?

LMA North America has developed a tool to help you determine your costs associated with reusable laryngeal mask airways so you can make an informed decision when evaluating disposables.



If you would like to have a value analysis performed at your facility, free of charge, contact your local sales representative or call Customer Service at (800) 788-7999.