Laryseal LMA Sterilization Guidelines (Flexicare)

Mechanical Cleansing
Use of Thermal washer Disinfectors

Equipment Required

A. Dedicated washer / disinfector for anaesthetic / respiratory equipment. Machine must have validated cycle.

B. Suitable load carrier which will ensure all internal and external surfaces of the Laryseal Multiple can be accessed for cleaning. The Laryseal Multiple should be connected to a spigot allowing water / detergent to flow through the tube during processing.

C. A compatible detergent preferably supplied from a metered automatic dosing system. Rinse aids should not be used (Some rinse aids used in combination with high temperatures may damage the breathing system connector).

D. A mechanical drying facility. This may form part of the automated process or be a separate purpose built drying cabinet.

Method

A. Check to see if the washer disinfector is certified ready for use.

B. Wearing the correct PPE (Personal Protective Equipment) load the washer disinfector ensuring that the loading configuration does not impede the cleansing process.

C. Secure the door, select the cycle and start the washer disinfector.

D. When the cycle has run its course, check to make sure all stages and parameters have been achieved. Unload the machine and visually assess the cleanliness of the Laryseal Multiple. Pay particular attention to the internals of the cuff and main tube. There should be no loose particles present.

E. If a drying process is not present, drain off excess water and transfer to the automated dryer. Laryseal Multiple must be completely dry prior to sterilization.

F. Complete the necessary documentation supplied with the Laryseal multiple.

Scope of cleansing action

Cleansing is only achieved after continuous spraying or irrigation of Laryseal Multiple with water and detergent during several stages of a pre set cycle. A typical cycle may comprise the following:

A. Cold rinse cycle below 35°C (higher temperatures may coagulate protein).

B. Warm wash with detergent at approximately 55°C.

C. Thermal disinfection. The surface temperature of Laryseal Multiple should exceed 71°C for three minutes, 80°C for one minute or 90°C for 12 seconds.

D. Drying It is preferable that the washer disinfector chosen should be purchased and operated in accordance with BS 2745 Parts 1 and 3. Manual Cleansing Hand washing of Laryseal Multiple should only be undertaken when other automated methods are either inappropriate or unavailable.

Equipment Required

A. Suitable sink (not a wash hand basin) of a size capable of ensuring complete submersion of the Laryseal Multiple.

B. Compatible detergent solution at the correct dilution at a temperature which will not permit proteins to coagulate or skin to become scalded.

C. A supply of rinse water (clean sink or receptacle).

D. A surface to allow Laryseal Multiple to drain, and a suitable drying cabinet.

E. Brushes, (including soft bristle and pipe cleaner) and a jet washer.

Method

A. Ensure the cleansing tools are clean and dry.

B. Wearing the correct PPE, fill the sink with the correct water / detergent solution allowing for complete submersion of the Laryseal multiple.

C. Immerse the Laryseal Multiple in the solution and ensure that all air is displaced.

D. Brush, wipe, irrigate or jet wash all surfaces of the Laryseal Multiple and remove all visual contamination. Keep the Laryseal Multiple submerged at all times to prevent splashes and the creation of an aerosolized mist. Clean the inside of the main tube using an appropriate pipe cleaner. Brush from the cuff end of the Laryseal Multiple.

E. Remove Laryseal Multiple from the solution and allow draining before transferring to the rinsing area.

F. Rinse thoroughly with clean water.

G. Remove from rinse water and allow to drain. Inspect Laryseal Multiple for cleanliness paying particular attention to the inner main tube and inner patient cuff. There should be no loose particles remaining.

H. Place Laryseal Multiple in a suitable drying cabinet.

I. Complete the appropriate documentation provided with Laryseal Multiple. Scope of Cleansing Action Manual cleansing will remove visual debris and other contaminants, but it does not incorporate a disinfection process. Handling prior to sterilization therefore poses a risk of cross contamination to processing staff.

Sterilization

To be completed after cleansing. Laryseal Multiple has been designed to withstand steam sterilization to temperatures up to 137°C. Flexicare recommend that a steam sterilizer (autoclave) be used which

incorporates a vacuum air removal cycle. This allows for use on items which have inner lumens like for example Laryseal Multiple. Laryseal Multiple must be completely dry.

The patient cuff must be completely deflated immediately prior to entering the autoclave. Failure to completely eradicate air in the cuff may result in herniation of the patient cuff and will dramatically reduce the working life of your Laryseal Multiple.

Laryseal Multiple should be placed in sterilization pouches and only with other laryngeal masks. Autoclaving should be carried out within a standard steam sterilization cycle, for example at a minimum of 134°C or a maximum of 137°C for three minutes.

Caution

Do Not Expose Laryseal multiple to:

A. Formaldehyde

B. Gluteraldehyde

C. Ethylene Oxide

D. Prolonged Exposure to Chlorohexidene

E. Iodine based antiseptics

F. Silicone based lubricant sprays

G. Solvent based solutions

H. Rinse Aids

I. Ultrasonic cleansing equipment

J. Gamma Irradiation Laryseal Multiple is not suitable for sterilization using Sterrad NX or similar.