



# SafeLM™ Disposable Video Laryngeal Mask

(Model: *FlexiView*)

## Instruction For Use

### Foreword

This *Instruction for Use SafeLM™ of Disposable Video Laryngeal Mask* mainly covers instructions and information regarding SafeLM™ Disposable Video Laryngeal Mask (may referred as "device" or "laryngeal mask" hereafter unless specified) and fundamental use of SafeLM™ Videoscope (may referred as "Videoscope" hereafter unless specified), an endoscopic device designed to work in combination with Disposable Video Laryngeal Mask, which is also produced by Changsha Magill Medical Technology Co., Ltd. (may referred as *Magill Medical* hereafter unless specified) This manual may refer to the parts and components name of the SafeLM™ Videoscope, therefore it is advised to have an *Instruction for Use of SafeLM™ Videoscope* available for reference while reading this document. For more detailed information and operating guide of SafeLM™ Videoscope, please refer to *Instruction for Use of SafeLM™ Videoscope*.

When Disposable Video Laryngeal Mask is assembled with Videoscope, it is referred as *Video laryngeal mask system*.

### 1. Safety Guide

Please read the entire instruction manual before using Disposable Video Laryngeal Mask. It will give operator a better understanding of how the device works.

#### 1.1 Warnings

- Disposable Video Laryngeal Mask is fully sealed in a package which has been sterilized by ethylene oxide. It should not be used on patient and be removed from clinical service if its sterile package is found compromised or beyond its marked expiration date.
- Examine the integrity of Disposable Video Laryngeal Mask before using it on patient. It should be removed from clinical service if any sign of tear, scratch or detached component on the device is observed.
- Disposable Video Laryngeal Mask is designed as single-use device and should be discarded in accordance with local medical waste processing regulations after single use.
- Disposable Video Laryngeal Mask should only be operated by trained and certificated healthcare personnel.
- ONLY assemble SafeLM™ Videoscope model with its compatible SafeLM™ Disposable Video Laryngeal Mask model listed later in this manual. Mismatching will result in the devices fail to assemble and may cause damage to the videoscope or laryngeal mask, and delay in treatment. For information regarding laryngeal mask and videoscope model matching, refer to section 2.2 *models*.
- If ventilation is difficult or inadequate after Disposable Video Laryngeal Mask is inserted, the device should be removed, then attempt to reinsert or switch to other methods for securing airway.
- All components of the anesthetic ventilation system's safety function should be verified before assembling the breathing circuit.
- To reduce to risk of contamination or infection for the patient, medical staff should wear proper personal protecting equipment when operating medical procedures with Disposable Video Laryngeal Mask.
- The Disposable Video Laryngeal Mask is NOT compatible with environment with the presence of strong magnetic field, such as working with Magnetic Resonance Imaging (MRI). Therefore, use of this device under strong radio magnetic field should be restricted.
- Do not use endotracheal tube or orogastric tube beyond maximum allowed size for each corresponding laryngeal mask size. Doing so may result in tubes being lodged in the laryngeal mask's channels, causing delay in treatment and safety risk to the patient.
- The Inflation Valve of Disposable Video Laryngeal Mask should only be connected to syringe or intracuff pressure gauge with male Luer connector conforming to ISO 80369-7.
- Do not inflate the cuff with air volume beyond its maximum cuff volume for each corresponding laryngeal mask size. Overinflating the cuff may result in suboptimal ventilation or oppressive injury to patient's pharynx structure in prolonged procedure.
- This device contains di (2-ethylhexyl) phthalate (DEHP), a substance that is considered potentially toxic to reproduction in current state of scientific knowledge. Medical products containing phthalates should be used only temporarily with pregnant women, nursing mothers, babies, and infants.
- The Disposable Video Laryngeal Mask may be flammable when used with laser and electrocautery equipment.
- Cuff volume or intracuff pressure may change in the presence of nitrous oxide, oxygen, or other diffusive gases.

1



### 1.2 Precautions

- It is not advised to remain Disposable Video Laryngeal Mask in patient for more than 8 hours.
- Back-up Disposable Video Laryngeal Mask or other airway management devices should be confirmed available before inserting Disposable Video Laryngeal Mask.
- When being ventilated via Disposable Video Laryngeal Mask, patient's vital signs should be closely monitored.
- Reinforced endotracheal tube should NOT be used due to its greater outer diameter (OD) than regular ETT with same ID which make it less conforming to the curvature to the airway tube.

### 1.3 Contraindications

- Patients at high risk of regurgitation and aspiration, for instance, full stomach, pyloric or intestinal obstacle, etc.
- Patients with high airway resistance, for instance, asthma, hemoptysis, etc.
- Patients with severe oral or pharyngeal injury, or those with limited range of motion of neck due to cervical injury.
- Responsive patients with an intact gag reflex that require CPR (Cardiopulmonary Resuscitation).
- Patients with planned surgery where the presence of laryngeal mask may potentially obstruct or limit the access to the surgical site, such as certain oropharyngeal procedures.
- Patients with inadequate interdental gap to permit insertion of the device.

### 1.4 Adverse reactions

N/A

### 1.5 Special Population

N/A

### 1.6 Intended Use

Disposable Video Laryngeal Mask is intended as a supraglottic airway management device. While isolating respiratory and esophageal tracts, provides and maintains an open airway channel and assisted or controlled ventilation during spontaneous breathing. When deemed clinically necessary, intubation can be performed through airway tube of the laryngeal mask. (Note: Intubation functionality is ONLY available for SafeLM™ Disposable Video Laryngeal Mask with model FlexiView #3, FlexiView #4 and FlexiView #5, when assembled with SafeLM™ Videoscope with model MGL-SP-6) The device also includes a gastric channel that allows drainage of esophageal and gastric content.

### 1.7 Indication

Disposable Video Laryngeal Mask is indicated for use in achieving and maintaining control of airway during routine and emergency anesthetic procedures in either spontaneous or positive pressure ventilation.

## 2. Device Description

### 2.1 General Description

Disposable Video Laryngeal Mask is a sterile single-use airway management device that is designed to be assembled with Videoscope from the same manufacturer. It is intended to be inserted through patient's oral cavity and situated at supraglottic space during medical procedure. It allows visualization during various laryngeal mask applications, including laryngeal mask insertion, cuff position inspection and adjustment, post-insertion video inspection of laryngeal structure during medical procedure, and intubation through laryngeal mask when clinically necessary. This device is offered in different models with different sizes and specifications for patients with various weight range, age groups and laryngeal anatomical features.

### 2.2 Models

Available Laryngeal Mask Model: **FlexiView #2, FlexiView #2.5, FlexiView #3, FlexiView #4, FlexiView #5**

SafeLM™ Disposable Video Laryngeal Mask with models of **FlexiView #3, FlexiView #4 and FlexiView #5** are designed for adult size and compatible with Magill Medical's **MGL-SP-6 Videoscope**.

SafeLM™ Disposable Video Laryngeal Mask with models of **FlexiView #2, FlexiView #2.5** are designed for junior size and compatible with Magill Medical's **MGL-SP-C Videoscope**.

### 2.3 Device Image



FlexiView #3, FlexiView #4, FlexiView #5



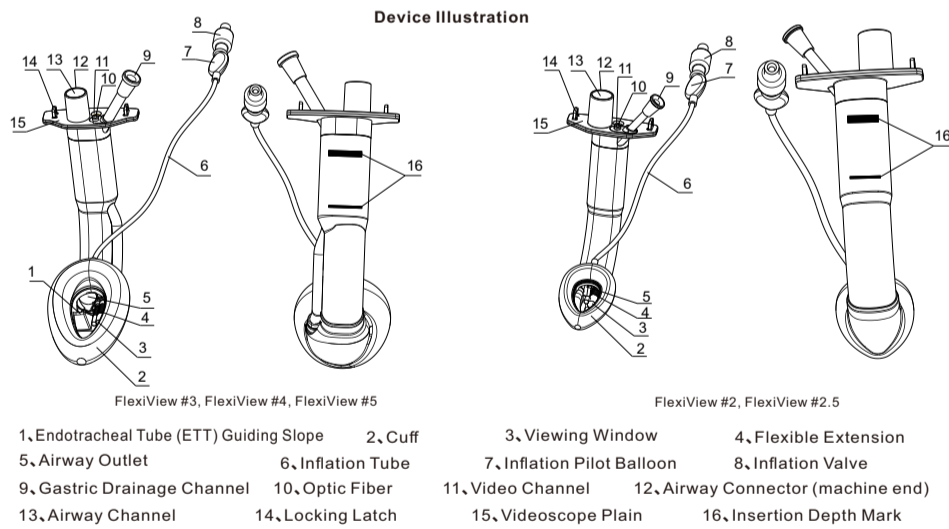
FlexiView #2, FlexiView #2.5

2



### 2.4 Device Components

Disposable Video Laryngeal Mask mainly consists of Cuff, Airway Tube, Gastric Drainage Channel, Videoscope Channel, Videoscope Latch, and Flexible Extension.



### 2.5 Specifications

| Product name  |   | Disposable Video Laryngeal Mask |                             |              |              |              |
|---|---|---------------------------------|-----------------------------|--------------|--------------|--------------|
| Model   |   | FlexiView #2                    | FlexiView #2.5              | FlexiView #3 | FlexiView #4 | FlexiView #5 |
| Disposable Video Laryngeal Mask Size                |   | #2                              | #2.5                        | #3           | #4           | #5           |
| Compatible Videoscope Model                         |   | MGL-SP-C                        |                             |              | MGL-SP-6     |              |
| Ventilation tube                                    | Length from machine end to ventilatory opening (cm) | 12±0.5                          | 12±0.5                      | 13.8±0.5     | 14.5±0.5     | 15.7±0.5     |
|   | Internal volume(ml)                                 | 8                               | 10                          | 12           | 18           | 22           |
| Cuff  | Recommended cuff volume (ml)                        | 10                              | 14                          | 20           | 30           | 30           |
|   | Max. cuff volume(ml)                                | 15                              | 21                          | 30           | 45           | 45           |
| Pressure drop                                       |   | ≤0.2                            | ≤0.2                        | ≤0.2         | ≤0.2         | ≤0.2         |
| Recommended patient weight <sup>1</sup> (kg)        |   | 10-20                           | 20-30                       | 30-50        | 50-70        | 70-100       |
| Min. interdental gap required for insertion (mm)    |   | 16.5                            | 19                          | 22           | 24.5         | 24.5         |
| Max. endotracheal tube allowed ID <sup>2</sup> (mm) |   | Not Applicable <sup>3</sup>     | Not Applicable <sup>3</sup> | 6.5          | 7.0          | 7.0          |
| Max. Orogastric Tube Allow (Fr)                     |   | 8                               | 8                           | 14           | 14           | 14           |

#### Note:

- Patient Weight for laryngeal mask size selection is for reference only, size selection should also consider other criteria such as patient's gender, clinical symptoms, airway anatomical structure, etc.
- Regular endotracheal tube only. For purpose of intubation via laryngeal mask, reinforced endotracheal tube should NOT be used due to its greater outer diameter (OD) than regular ETT with same ID which make it less conforming to the curvature to the airway tube.
- The airway channel of FlexiView #2 and FlexiView #2.5 does NOT allow passing of ETT, DO NOT attempt to intubate the patient through these two models.

3



## 3. Using Instructions

### 3.1 Ventilation via Video laryngeal mask system

#### 3.1.1 Preparation and Assembling

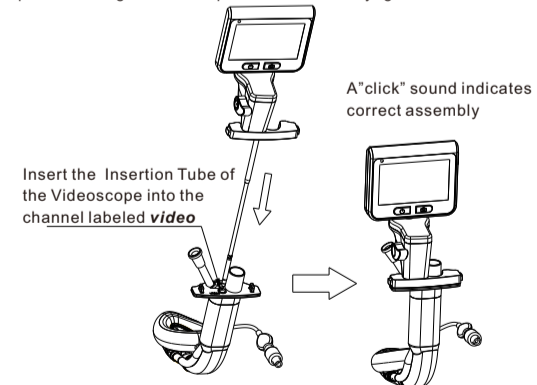
- On the Videoscope, remove the protective cap on the camera at the distal end of the insertion tube.
- Peel the protective cover paper of Disposable Video Laryngeal Mask's packaging. While the laryngeal mask remains in its bottom case, connect an empty syringe to the Inflation Valve of the laryngeal mask. Gently pull the syringe plunger to deflate the cuff. Stop when resistance on the plunger is felt. Make sure the edge of vacuumed cuff is flattened and spread (not folded inward) while deflating.
- Take out the laryngeal mask from its case. Apply and evenly spread sterile water-based lubricant on the back of the cuff.



#### Warning:

Do not use silicone-based lubricants as they degrade Disposable Video Laryngeal Mask's components.

- Locate the Video Channel entry on the Videoscope Plain of the laryngeal mask, which is marked by a blue circle and labeled "video". Insert a segment of the Videoscope's Insertion Tube into the Video Channel of the laryngeal mask. If necessary, rotate the Videoscope to a correct orientation. When fully inserted, the Ventilator Connector of laryngeal masks should rest in the Videoscope's Hollow Opening on the base of Control Body. When firmly pressed together, the Locking Orifices on the Videoscope are automatically secured to Locking Latches on laryngeal mask with a "click" sound. Camera lens at distal end of the Videoscope should be in close contact with internal surface of laryngeal mask's Flexible Extension, and Illumination Orifice of the Videoscope should align with the Optic Fiber on the laryngeal mask.



#### Warning:

If excessive resistance is felt when inserting the Insertion Section along the Videoscope channel, stop the process, pull out the Videoscope and inspect the Insertion Soft Tube or Flexible Tip for any bump or tearing. Remove the Videoscope from clinical service if any sign of damage or wear is sighted.

- Press the Power Button under the Display Screen to power on the videoscope. The Display Screen will show Magill Medical's logo shortly, then switch to live video captured by camera. Illumination is turned on automatically and video footage recorded by the camera are automatically saved after videoscope is powered on. The light from videoscope's Illumination Orifice is guided to the distal end of the optic fiber at the laryngeal mask's airway opening and illuminate the dome around the cuff.

**Note:** After the videoscope is powered on, observe whether the video quality on display screen is optimal before inserting it into patient. If video appears blurry or flared and causes obstacle in normal use, power off and remove the videoscope from laryngeal mask and gently wipe the camera lens with cloth that has been dipped in cleaning agent.



#### Warning:

DO NOT look directly into Light Orifice or point the Light Orifice to open eyes of others within proximity when the illumination is ON. Shining intense light to eyes may cause temporary flash blindness.

4



### 3.1.2 Insertion of Video laryngeal mask system

1. Place the head in the neutral position and aim the distal tip of the laryngeal mask at the mouth with one hand. See figure 3.1.1 .
2. Gently slide the distal tip of the laryngeal mask inward and downward along the trail of "behind upper teeth- surface of hard palate-surface of soft plate-curvature behind the tongue". When inserting, avoid advancing distal tip of laryngeal mask into base of tongue or glottis. Use live video to help determine the position of the distal tip of the laryngeal mask as it advances. See figure 3.1.2 .
3. If necessary, rotate the display apparatus to ensure its image remains visible as its angle changes during laryngeal mask insertion. Resistance should be felt when the distal end of the cuff pressed to the upper esophageal sphincter. Press down the angulation handle on the videoscope to tilt the camera angle upward, lift the handle to tilt the camera downward. If laryngeal mask is in proper position. glottis opening and its surrounding tissue should be visible on screen in full. See figure 3.1.3 .
4. Inflate the cuff through Inflation Valve with an empty syringe. Cuff volume to be injected is suggested in section 2.4 Specifications table. Observe the cuff as it is inflated and contact with supraglottic structure. Use live video to check for a secure supraglottic seal and separation of airway and esophagus track. See figure 3.1.4 .

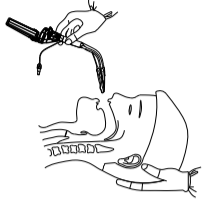


Figure 3.1.1

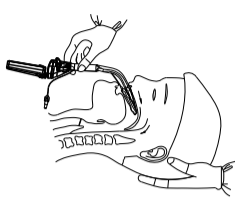


Figure 3.1.2

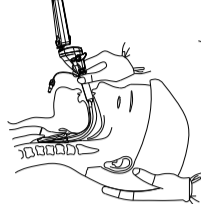


Figure 3.1.3

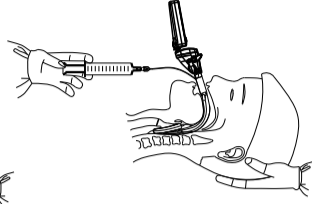


Figure 3.1.4

| Illustration | Anatomic Landmarks  |
|--------------|---------------------|
|              | 1 Soft palate       |
|              | 2 Hard palate       |
|              | 3 Incisors          |
|              | 4 Tongue            |
|              | 5 Hyoid bone        |
|              | 6 Epiglottis        |
|              | 7 Laryngeal inlet   |
|              | 8 Thyroid cartilage |
|              | 9 Cricoid cartilage |
|              | 10 Trachea          |
|              | 11 Esophagus        |
|              | 12 Vocal folds      |
|              | 13 Cuff             |

Table 3.1 Anatomic Structure with Laryngeal Mask in Position

#### Potential Problems During Insertion

Cough reflex, respiration pause, or resistance felt when attempting to pull down patient's lower jaw may indicate inadequate anesthetic depth during laryngeal mask insertion. In such case, increase anesthetic depth intermediately via inhalational or intravenous means, and use manual ventilation.

It is common having difficulties adjusting root of tongue's position when inserting laryngeal mask. Distal end of laryngeal mask should be pressed against hard palate, or curved inward to the airway tube to conform to the irregular shape of posterior larynx (for instance, enlarged tonsil). If the edge of the cuff seemed curved inwardly or cuff is folded as it is being inserted, retreat the laryngeal mask slightly and try to advance again. To prevent the insertion path being obstructed by tonsil, it is advised to advance the laryngeal mask diagonally.

#### 3.1.3 Removing Videoscope and Connecting to Ventilator

1. After making sure laryngeal mask is in correct position, power off the Videoscope by pressing and holding the Power Button. Screen displays a power off countdown, See Figure 3.1.5. When the display screen is darkened, release the Power Button to complete the process.



Figure 3.1.5 Power Off Countdown

5



### 3.5 Intubation through Video Laryngeal Mask System

|  |  |
|--|--|
|  | Warning:<br>Do not use endotracheal tube beyond maximum allowed size for each corresponding laryngeal mask size. Doing so may result in tubes being stuck in the laryngeal mask's channels, causing delay in treatment and safety risk to the patient.<br>Use non-reinforced endotracheal tube ONLY. For purpose of intubation via laryngeal mask, use of reinforced endotracheal tube is NOT advised due to its greater outer diameter than regular endotracheal tube with the same inner diameter.<br>DO NOT attempt to intubate the patient through FlexiView #2 and FlexiView #2.5. The airway channel of these two models does NOT allow passing of ETT. Forceful intubation may result in ETT being stuck in the laryngeal mask's airway channels, causing delay in treatment and safety risk to the patient.<br>Steps for intubation outlined in this section are manufacturer's recommendation only. Alternative maneuvers, such as removing laryngeal mask after intubation, inserting laryngeal mask with ETT in its Airway Channel, etc. can be performed based on operator's clinical needs and relevant guidelines. |
|--|--|

1. Before performing intubation of ETT through Video Laryngeal Mask System, a proper size laryngeal mask shall be in place in patient's supraglottic airway. Verify the correct positioning of laryngeal by ensuring patient's glottic opening and vocal folds are clearly visible on videoscope's monitor. Refer to section 3.1.2 for detailed guidance of inserting laryngeal mask and accessing proper ventilation.
2. Check whether the endotracheal tube's cuff is completely deflated. Use a syringe to deflate it if air residue remains in the cuff.
3. In addition to lubricating the back of the cuff, also apply lubricant to the surface of endotracheal tube and use it to rub on the interior surface of laryngeal mask's Airway Channel. Make sure the ETT can move freely in the Airway Channel.
4. Insert the ETT through laryngeal mask's Airway Channel until ETT's tip (patient end) appears on the monitor of videoscope.
5. With live video monitoring, carefully advance the ETT through glottis. The laryngeal mask and ETT can be slightly tilted if necessary to align the tip of ETT with glottic opening.
6. When the ETT has pass through the vocal cords, insert the ETT to proper depth and inflate its cuff.
7. After confirming the secure positioning of ETT though videoscope, remove the videoscope from the laryngeal mask.
8. Connect the ventilator to the ETT's machine end and start ventilation. Monitor patient's vital sign to confirm satisfactory oxygenation.
9. Use segments of adhesive medical tape, fixate both positions at 1) ETT to the Airway Connector of the laryngeal mask, and 2) laryngeal mask to the patient. Then deflate laryngeal mask's Cuff.
10. Timing and maneuver for ETT extubation during recovery should be decided based on relevant clinical guidelines and status of patient. The laryngeal mask and ETT could be removed together.

#### 4. Transportation and Storage

Temperature Range: -20 to +55°C

Humidity Range: 0 to 93%

Atmospheric Pressure Range: 50 kPa to 106 kPa

- Do not leave the device under heavy weight, direct sunlight, rain, or snow.
- Devices should be handled with care during transportation and avoid compression and collision.
- Devices should be stored in clean and well-ventilated environment, and free from source of ignition or corrosive.

#### 5. Shelf life

Refer to the expiration date printed on the protective cover paper of sterile packaging.

#### 6. Label Symbols

Label symbols are shown in the following table:

|  |                                    |
|--|------------------------------------|
|  | Batch code                         |
|  | Date of Manufacture                |
|  | Use-by Date                        |
|  | Manufacturer                       |
|  | European Authorized Representative |

7



2. Press the Release Buttons on both side of the Connecting Base of the Videoscope and gently pull its Insertion Tube from laryngeal mask's Video Channel.
3. Fix the laryngeal mask to patient's face using adhesive medical tape. The tape should be adhered transversely across the patient's cheek and wrapped at least one circle around the surface of the airway tube.
4. Connect ventilator/anesthetic system's air tube connector with laryngeal mask's Ventilator Connector. Matching female connector of the breathing circuit should be compliant to relevant requirements regarding 15mm connectors stated in Standard ISO 5356-1.
5. Once ventilator starts working, assess lung ventilation by neck and chest auscultation, observing for chest and abdominal fluctuation and stable ventilator readings (peak airway pressure, SpO<sub>2</sub> and tidal volume etc.).

### 3.2 Gastric Drainage

The Gastric Drainage Channel of Disposable Video Laryngeal Mask allows passage of orogastric tube into the stomach, allowing drainage and suctioning of fluids or gases in the stomach at any time during the procedure. Refer to section 2.4 Specifications table for maximum size of orogastric tube allowed though the drainage channel. The orogastric tube should be well lubricated before being inserted.

|  |   |
|--|---|
|  | Warning:<br>Do not attempt to pass a gastric drainage tube into the stomach via the gastric channel in the presence of known or suspected oesophageal pathology.<br>There is a theoretical potential risk of causing oedema or hematoma if suction is applied directly to the end of the gastric channel. |
|--|---|

### 3.3 Maintenance During Medical Procedure

Position shift of the laryngeal mask cuff may occur due to head/neck position change during medical procedure. If cuff position shift is observed or suspected, follow the following to readjust cuff position.

1. Disconnect ventilator/anesthetic system's air tube connector from laryngeal mask's Ventilator Connector.
2. Assemble the Videoscope with the laryngeal mask through its Video Channels, and power on the Videoscope.
3. Inspect the cause of compromised airway seal using Videoscope's Angulation Handle and Camera. Adjust cuff position, slightly deflate the Cuff if necessary.
4. After the cuff position is corrected, remove the Videoscope from laryngeal mask, and reconnect ventilator/anesthetic system to laryngeal mask.

|  |   |
|--|---|
|  | Warning:<br>To insert the videoscope back into the laryngeal mask for supraglottic inspection during medical procedure, Airway Connector of the laryngeal mask needs to be temporarily removed from the breathing circuit. When oxygen supply is temporarily interrupted, pay close attention to patient's vital sign's reading (e.g., respiration rate, SpO <sub>2</sub> etc.). Intermediately remove the videoscope and reconnect the laryngeal mask to the breathing circuit once supraglottic inspection is completed. NEVER leave the patient in hypoventilation. Otherwise, hypoxic/anoxic related injuries or death may occur. |
|--|---|

### 3.4 Recovery And Removal of Laryngeal Mask

1. Monitoring for vital signs and ventilation support should continue throughout the recovery stage. If suction is required around the oral cavity or down the airway tube, it should be carried out prior to reemergence of laryngeal muscle reflex.
2. Since anesthetic recovery involves reemergence of pharyngeal muscle tone, it is advised to partially reduce the cuff volume as the pharyngeal muscle reflex starts to reemerge.
3. The laryngeal mask should be removed ONLY after the patient's protective reflexes have returned and able to open mouth on verbal commands.
4. To remove the laryngeal mask, fully deflate the cuff and gently remove it from patient's laryngeal and oral cavity.

|  |   |
|--|---|
|  | Warning:<br>Monitoring and care during post-operative recovery and removal of laryngeal mask should be performed by trained and certificated healthcare personnel.<br>The cuff must NEVER be fully deflated before performing removal of laryngeal mask. Completely deflating the cuff before the return of effective swallowing and cough reflexes may allow secreta in the upper pharynx to enter the larynx, stimulating coughing or laryngeal spasm.<br>While the SafeLM™ Videoscope is a reusable electronic device provided having followed proper cleaning and disinfecting procedure, the SafeLM™ Video Laryngeal Mask is ONLY designed for single use. After being removed from patient, it should be discarded and handled in accordance with local medical waste processing regulations. |
|--|---|

6



|  |  |
|--|--|
|  | CE mark  |
|  | Do not re-use  |
|  | Do not use if the product sterile barrier system or its packaging is compromised                           |
|  | Consult Instruction For Use  |
|  | Warning, Failure to follow those instruction may cause damage to the device or harm to operator or patient |
|  | Sterilized using ethylene oxide  |
|  | Not made with natural rubber latex   |
|  | Contains or Presence of Phthalate  |
|  | Single sterile barrier system with protective packaging outside  |
|  | Unique Device Identifier   |
|  | Patient weight   |
|  | Air inflation volume/Intra-cuff pressure   |
|  | Fragile, Handle with Care  |
|  | Keep Away from Rain or Splash of Liquid  |
|  | Keep Away from Sunlight  |
|  | This Way Up  |
|  | Stacking limit by number:5   |
|  | Temperature limitation   |
|  | Humidity limitation  |
|  | Atmospheric pressure limitation  |

REV. : V1.3

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8