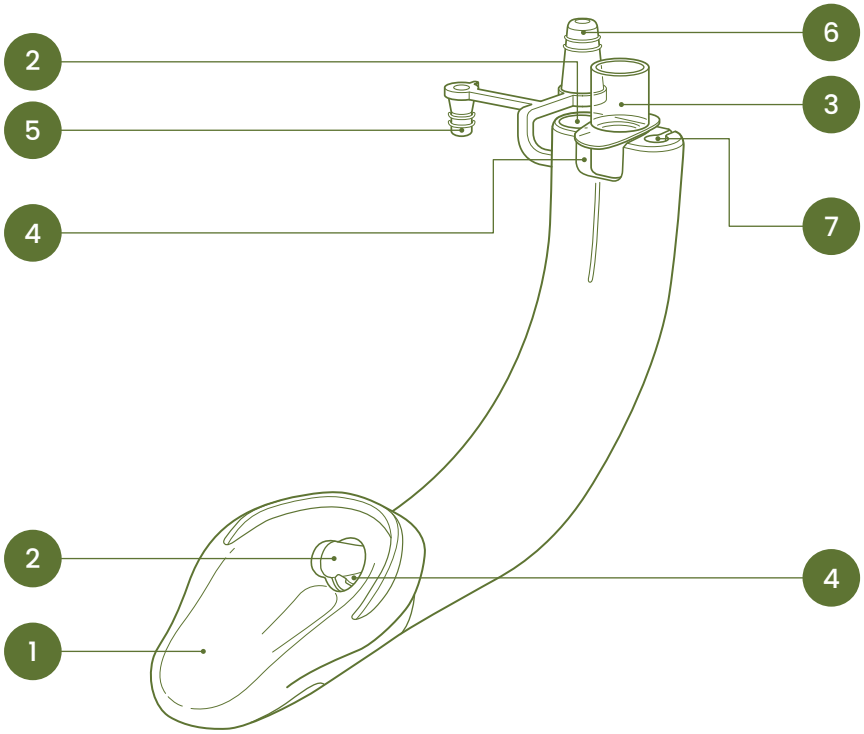
LIVVE™

Laryngeal, Intubating, Visualizing, Ventilating and Extubating Device

Size 3.5 Item Number: **LB1535**
Size 4.5 Item Number: **LB1545**



1. Cushioned Cuff
2. Camera Lumen
3. Ventilation Tube
4. Ventilation Lumen
5. Small Plug
6. Large Plug
7. Open Gastric Channel

Prior to use, you must familiarize yourself with the Instructions For Use and the unique features of the LIVVE™ device.

The LIVVE™ is a single-use, non-sterile, 2-lumen channel device with a cushioned cuff to provide and maintain a semi-closed ventilation system during ventilation and oral intubation. The 2-lumen channels are a camera port and ventilating lumen. In the camera port, either the TOAD™ Camera or a standard bronchoscope can be utilized to visualize the periglottic structures. This assists in the intubation of an endotracheal tube with standard acceptable practice. The LIVVE™ has 2 plugs to seal the camera port when no visualization system is inside the camera lumen. The ventilating tube allows for ventilation similar to a standard laryngeal airway mask.

Upon removal of the ventilating tube a standard endotracheal tube (6.5 mm – 8.5 mm) can be placed inside the ventilating lumen. The endotracheal tube cuff can be inflated to occlusion while inside the ventilating lumen. The LIVVE™ device also includes an open gastric channel to allow for a gastric tube to be guided posteriorly into the esophagus.

The LIVVE™ is provided in two adult sizes (Sizing may vary based on anatomical differences, not necessarily weight. Clinical judgment must be used.) Recommended sizing is as follows:

- **Size 3.5:** 55 kg (121 lbs) – 90 kg (198 lbs)
- **Size 4.5:** > 90 kg (> 198 lbs)

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INDICATION FOR USE:

- The LIVVE™ is a single-use, non-sterile, 2-lumen channel device with a cushioned cuff to provide and maintain a semi-closed ventilation system during ventilation and oral intubation.
- The two separate lumens can be used for a flexible scope to assist in the intubation of an endotracheal tube and alternatively for airway suctioning above the vocal folds.
- The cushioned cuff is intended to ensure that inspiratory and expiratory gases are routed through the tube and not escaping into the patient's upper airway, thus maintaining ventilation.
- The LIVVE™ is provided in two adult sizes. Recommended sizing is as follows:
    - **Size 3.5:** 55 kg (121 lbs) – 90 kg (198 lbs)
    - **Size 4.5:** > 90 kg (> 198 lbs)
- The indwelling time of the LIVVE™ device should not exceed three (3) hours.
- Both plugs must be firmly inserted into the camera lumen when using the LIVVE™ device without a camera in order to provide closed ventilation.
- It is recommended to follow ASA guidelines for airway management.

CONTRAINDICATIONS:

- Do not use the LIVVE™ device as part of instrumentation of a surgical procedure.
- Do not use the LIVVE™ device near electric cautery as this device is flammable.
- Do not use sharp instruments within this device as damage to structural integrity is possible.
- Do not use the LIVVE™ device if patient exhibits severe airway bleeding, morbid obesity, pharyngo-perilaryngeal abscess, tumors or masses.
- Do not use the LIVVE™ device if unfamiliar or not proficient in airway rescue management and techniques.

WARNINGS:

- Do not use excessive force during placement or removal of the LIVVE™ device, camera and sheath or gastric tube. Excessive force may destroy the integrity of the sheath, jeopardizing sterility of the camera and potentially introducing foreign bodies into the patient.
- Watch for ventilation leaks, unsecure camera plugs or potential obstructions while using this device as these could lead to improper ventilation and/or death.
- Limit peak airway pressure of ventilation to 20 cm or less.
- At this time it is not recommended to leave the LIVVE™ device and endotracheal tube together in the patient after intubation. No studies have taken place to show safety profile in leaving both devices in the patient.
- It is recommended to use a visualization device when placing an endotracheal tube. Blind placement could potentially cause excessive trauma or life-threatening harm.

CAUTION:

- Caution: Federal (USA) law restricts this device to the sale by or on the order of a physician.
- Do not use if device or package is damaged.
- Do not reprocess, alter or reuse the LIVVE™ device. Reprocessing, altering or reusing may compromise the device's ability to perform as intended.
- This device is MRI compatible. The camera and camera sheath are not MRI compatible.

ADVERSE EVENTS:

- All airway devices could stimulate patient to gag or aspirate.
- All airway devices may cause excessive pressure, ulcerations, tissue damage, nerve damage and puncture of vital airway structures.
- Misuse of this device can cause trauma, bleeding or puncture of vital tissues.
- This device may not be compatible with patients who are awake or semi-awake.

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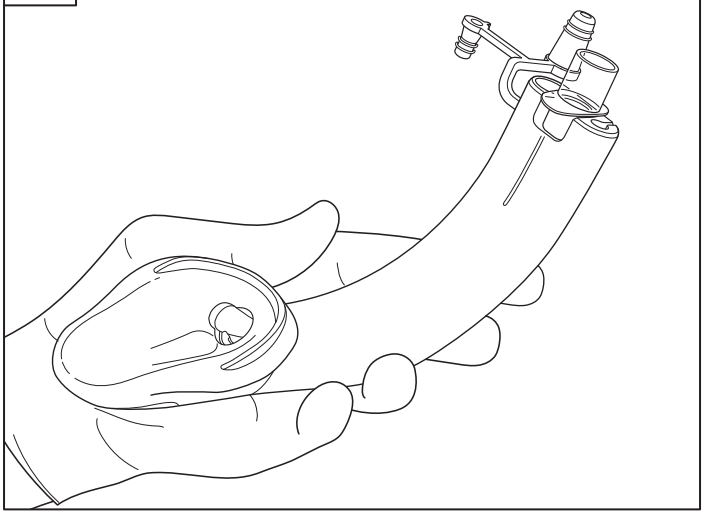
PRE-USE CHECKS:

- Remove protective plastic shell at distal end of device prior to use and discard appropriately.
- All patients should be fasted and understand that multiple conditions can contribute to inadequate emptying of the stomach, increasing the likelihood of aspiration.
- Each individual patient medical history and present circumstances should be evaluated by a licensed practitioner prior to use. It is incumbent to be familiar with this airway device and system prior to use.
- Inspect all airway devices prior to use.
- Do not contaminate packaging with foreign objects that may adhere to the device while being inserted into patient.
- Examine all structures of the LIVVE™ device to ensure it is free from blockage, loose particles, cuts, or indentations. Discard device if any defects are detected.
- Verify ventilating tube is not damaged, abnormal or deformed.
- Verify the LIVVE™ ventilating tube is properly secured inside the ventilation lumen.
- Verify the proximal wings of the 15 mm ventilating cap do not obscure the opening of the camera tube or gastric lumen.
- Both plugs must be firmly inserted into the camera lumen when using the LIVVE™ device without a camera in order to provide closed ventilation.
- Water-based lubrication must be used prior to insertion of the LIVVE™ device.
- Always maintain proper vigilance in maintaining and verifying adequate ventilation.
- Always practice in accordance with recognized airway management techniques and practices.
- As in all airway devices, always have a backup plan and multiple airway rescue management devices at disposal.
- Always maintain clean technique and keep device inside packaging until just prior to use.

SECTION A

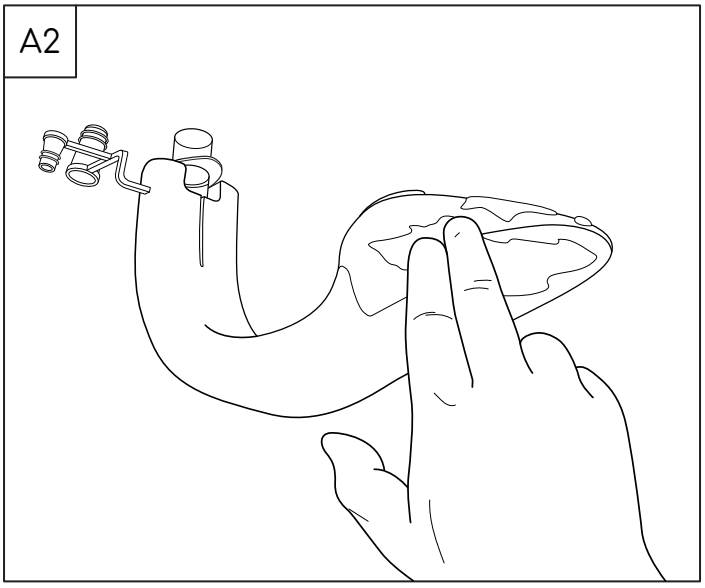
LIVVE™ PLACEMENT - WITHOUT CAMERA (both plugs must be firmly inserted into the camera lumen)

A1



Open package and inspect for any defects. Maintain cleanliness and keep the LIVVE™ device inside its packaging until use.

A2



Just before use, lubricate anterior and posterior surfaces, distal edges and entire rim with water-based sterile lubricant.

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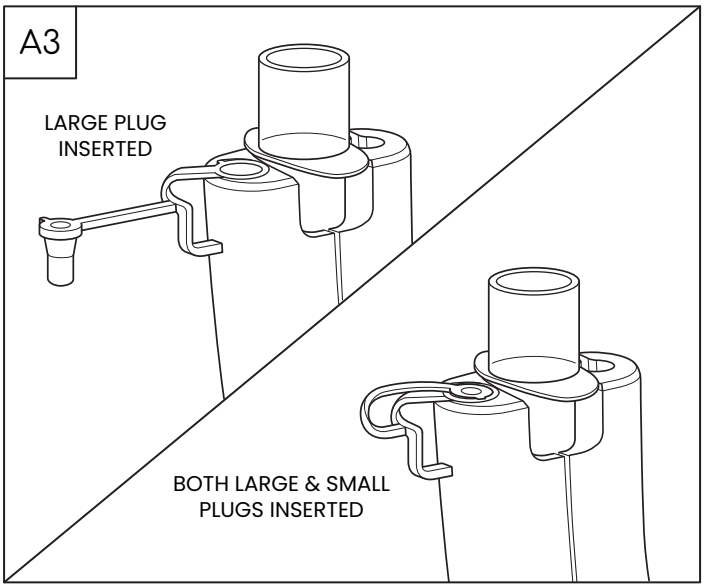
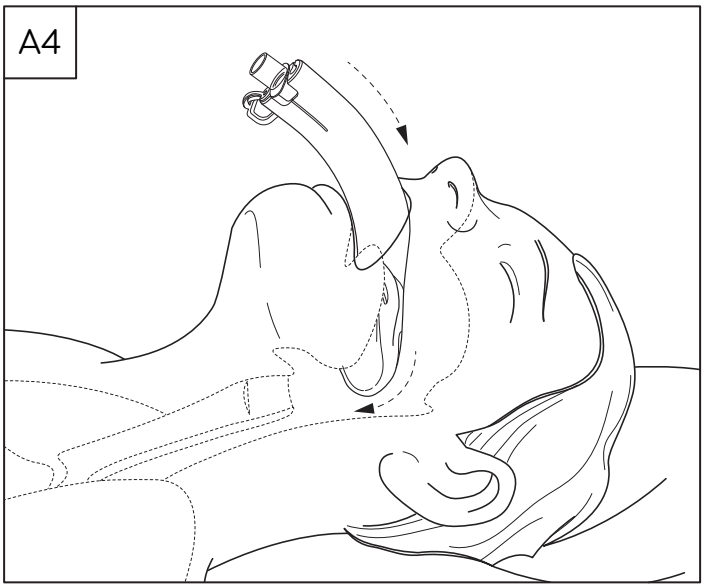
LIVVE™ PLACEMENT – WITHOUT CAMERA (both plugs must be firmly inserted into the camera lumen)

A3



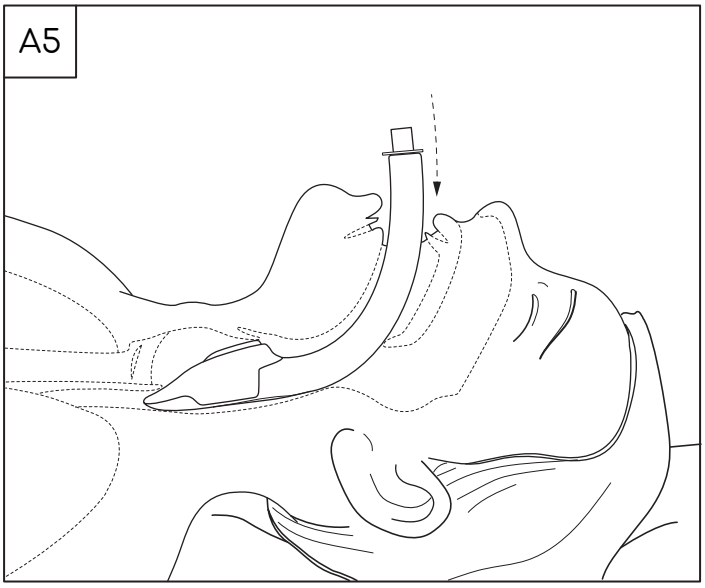
When camera is not in use, make sure the camera port is closed with both plugs secured flush to camera lumen. The large plug must be inserted first followed by the smaller plug. Recheck that ventilating tube is properly secured inside device. If airway leak is detected, recheck proper placement of the plugs.

A4



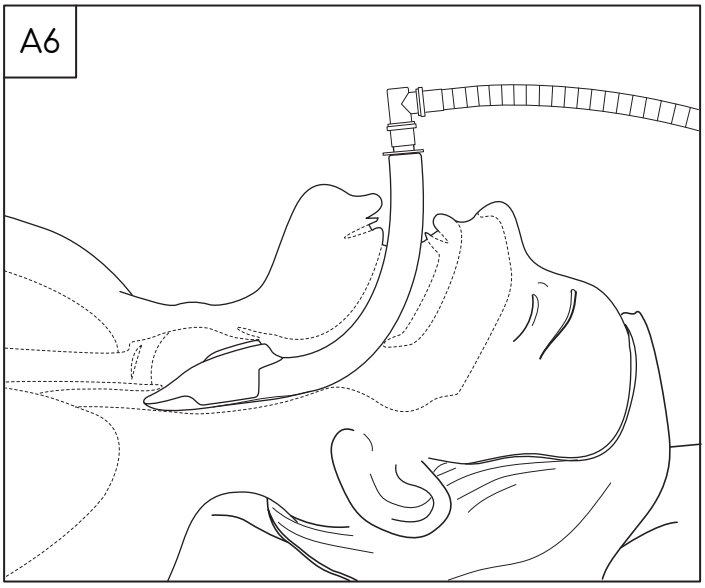
Make sure the patient's head and neck are in the proper position. Open mouth, grasp lubricated LIVVE™ and begin to advance the proximal end of the LIVVE™ (bowl facing anteriorly) into the mouth ensuring distal tip follows curvature of pharynx.

A5



Advance the distal tip along the hard palette downward until definitive resistance is felt. Make sure tongue does not advance downward with the LIVVE™ device during placement.
ALTERNATIVE TECHNIQUE: Hold anterior mandible and tongue forward with fingers or tongue blade, opening the mouth. Follow placement of the device as previously described.

A6



Once the LIVVE™ device is in position, connect 15 mm ventilating cap to appropriate ventilator circuit. Ensure that the device is properly placed utilizing accepted airway management procedures and techniques (auscultation of lungs and neck, capnography, pulse oximetry, visualizing chest rise, etc.)

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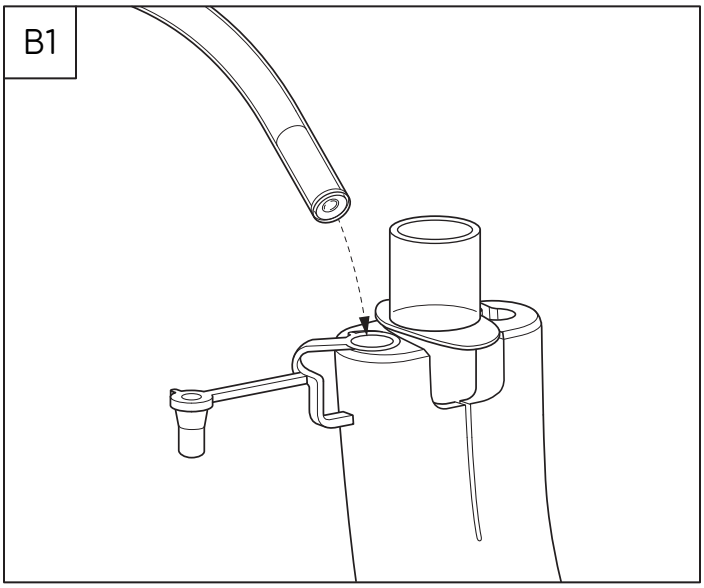
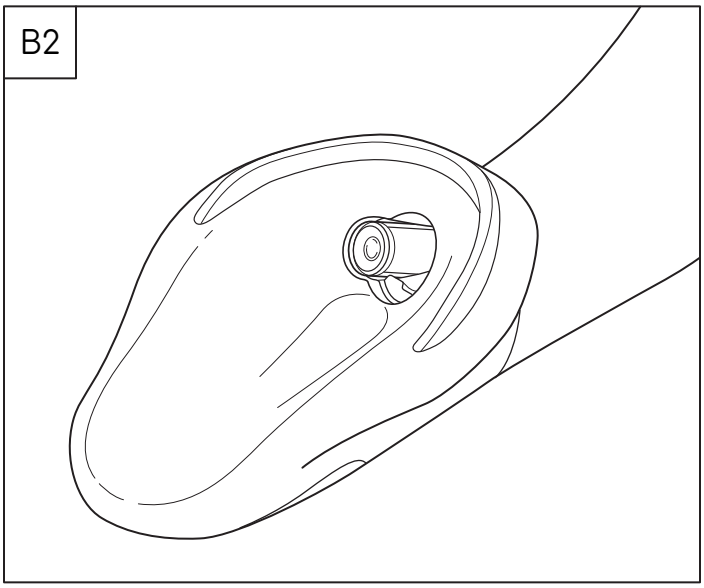
SECTION B
LIVVE™ PLACEMENT – WITH CAMERA

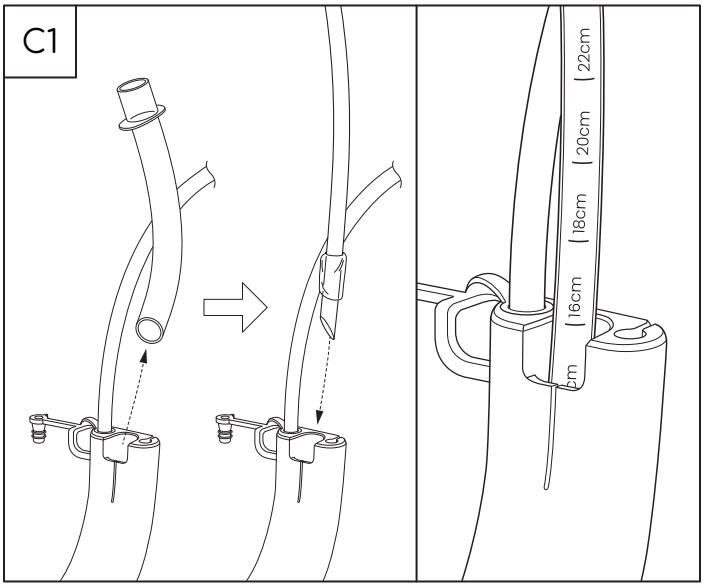


While outside patient make sure the camera and sheath are properly mated (see instructions for use for the TOAD™ camera and sheath). Insert mated camera and sheath inside proximal large plug already engaged within the LIVVE™ device.

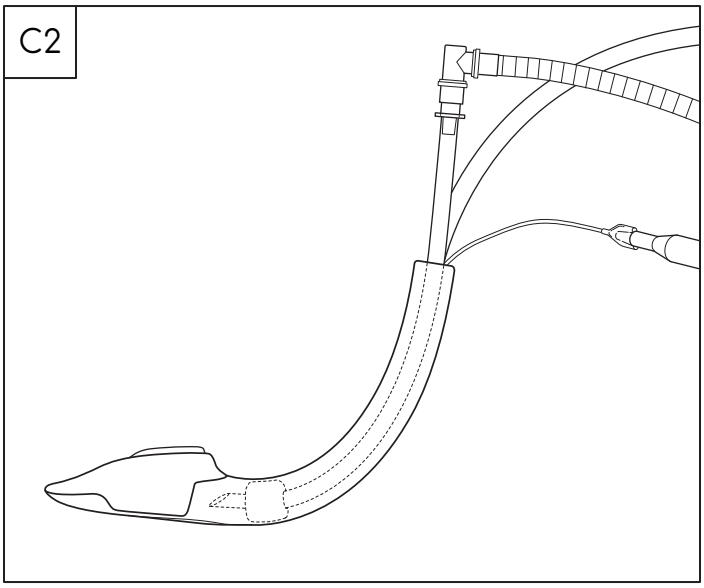


Advance camera and sheath to the proper position at the distal end of camera lumen of the LIVVE™ device. Make sure lubrication does not touch distal end of camera or camera sheath. Place the LIVVE™ device with camera and sheath in patient following LIVVE™ placement instructions from Section A.

SECTION C
VENTILATION WITH ENDOTRACHEAL TUBE



Remove ventilation tube. Insert endotracheal tube into ventilating lumen and advance until the proximal end reaches 16 cm.



Inflate endotracheal tube cuff to occlusion within the LIVVE™ device. Connect endotracheal tube to ventilation circuit.
NOTE: This procedure could take place with the LIVVE™ device inside the patient. This may add risk in delaying ventilation.

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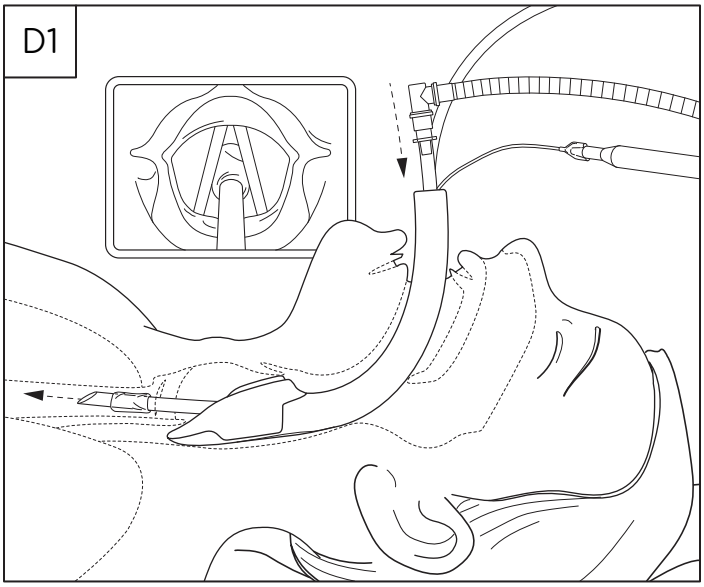
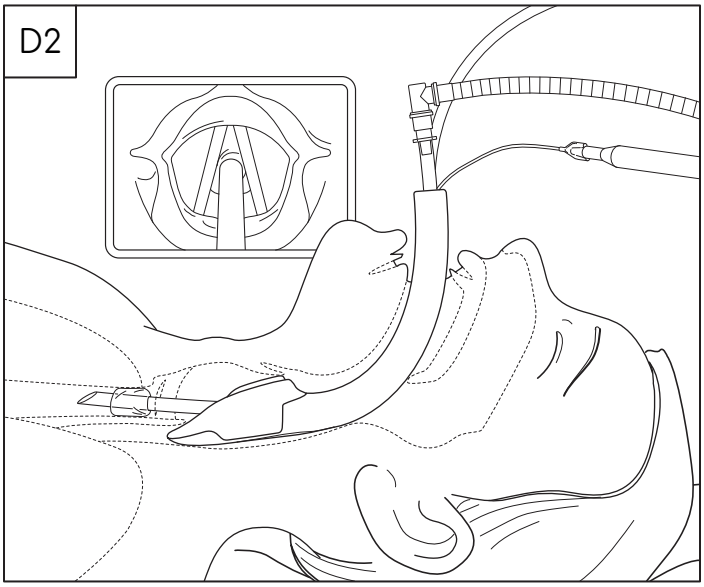
SECTION D
INTUBATION



Verify ventilation has been established with the endotracheal tube connected to a ventilation circuit. Under continued vision with the TOAD™ camera, air is removed from endotracheal tube cuff and the endotracheal tube is advanced through the vocal cords as visualized on the TOAD™ monitor. **NOTE: Moving the LIVVE™ slightly forward or back and/or rotating counterclockwise 30° may assist in accurate placement of the endotracheal tube.** Advance the endotracheal tube slightly through the larynx until the cuff is visualized beyond the vocal cords.



Inflate the endotracheal tube cuff to occlusion beyond the vocal cords. Check and verify accurate placement and ventilation with standard accepted techniques. Reaffirm with visualization, capnography, auscultation and pulse oximetry. Do not leave the LIVVE™ device in the patient after intubation (no studies have taken place to provide any recommendations).

SECTION E
BLIND INTUBATION

Alternatively, the LIVVE™ device is designed for blind intubation with the ventilation tube removed. Once the LIVVE™ is seated and ventilation is verified, advance an endotracheal tube (6.5-8.5) through the ventilation lumen at least until 20 cm is noted on the proximal end of the LIVVE™ device. As the endotracheal tube is advanced through the periglottic opening, some resistance will be felt and then lost. Do not force the well lubricated endotracheal tube or bougie through the ventilation lumen. This may result in trauma, tissue puncture, bleeding or severe adverse effects to patient. Maintain accepted airway management procedures and techniques (auscultation of lungs and neck, capnography, pulse oximetry, visualizing chest rise, etc.) Follow proper technique and reestablish ventilation. Be careful of endobronchial intubation. Inflate the endotracheal tube cuff to occlusion. Check and verify accurate placement and ventilation with standard accepted techniques.
NOTE: Smaller endotracheal tube sizes are more easily placed.

SECTION F
EXTUBATION

Remove air from the endotracheal tube cuff and pull back to 16 cm to the lip of the proximal end of the ventilation lumen. Reinflate the endotracheal tube cuff to occlusion. Reestablish ventilation and verification through standard accepted procedures and techniques.

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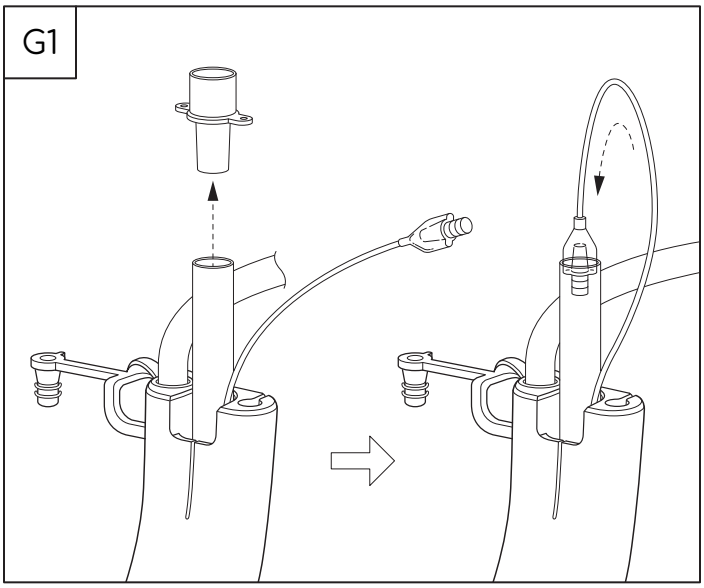
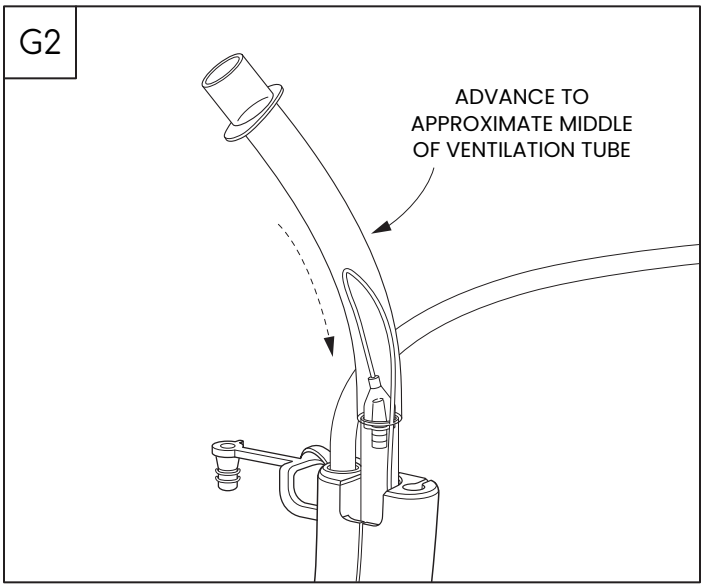
SECTION G

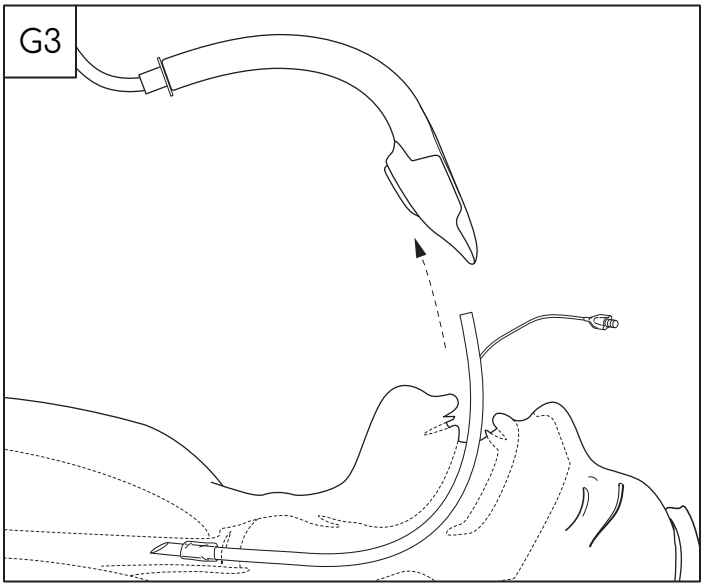
REMOVING THE LIVVE™ & MAINTAINING THE ENDOTRACHEAL TUBE



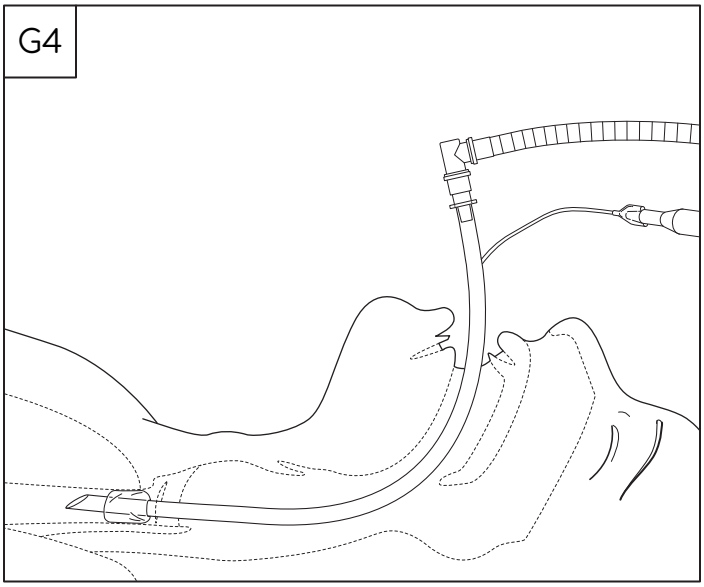
Deflate the endotracheal tube cuff. Remove the endotracheal tube cap at proximal end and insert the pilot.



Place the LIVVE™ ventilator tube over the endotracheal tube and pilot. Using the ventilator tube to push the endotracheal tube, distally advance both until the middle of the ventilator tube is at the proximal edge of the LIVVE™ device. **NOTE: Alternatively a bougie could be used to remove the LIVVE™ following standard accepted practice.**



With one hand reach in patient's mouth and hold endotracheal in place. Use other hand to slide the LIVVE™ device proximally off the endotracheal tube and out of patient. **NOTE: Extubation or endobronchial intubation may occur. Proper vigilance and verification are of the utmost importance.**



Grasp the endotracheal tube in patient's mouth. Remove the pilot from the proximal end and reattach the ventilator cap. Reinflate the endotracheal tube cuff to occlusion. Maintain accepted airway management procedures and techniques (auscultation of lungs and neck, capnography, pulse oximetry, visualizing chest rise, etc.) Follow proper technique and reestablish ventilation. Be careful of extubation or endobronchial intubation.

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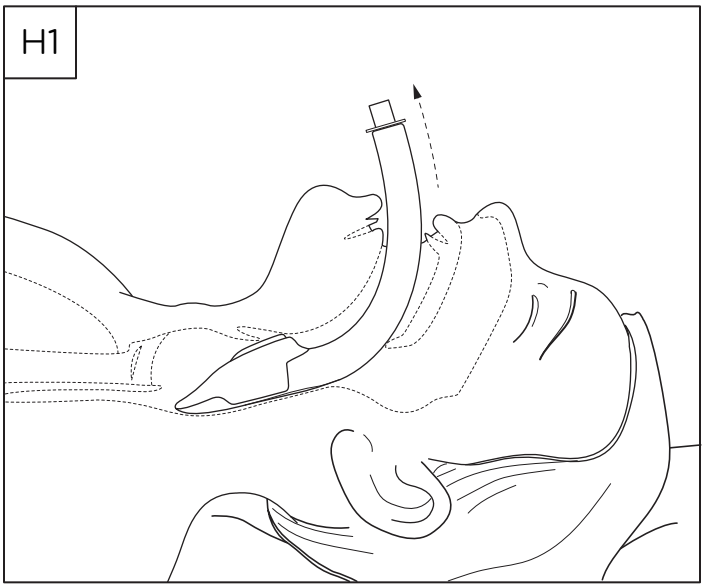
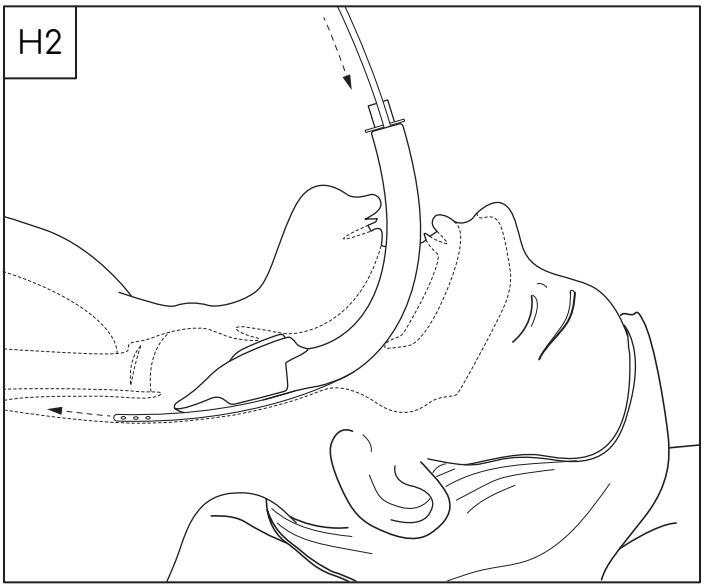
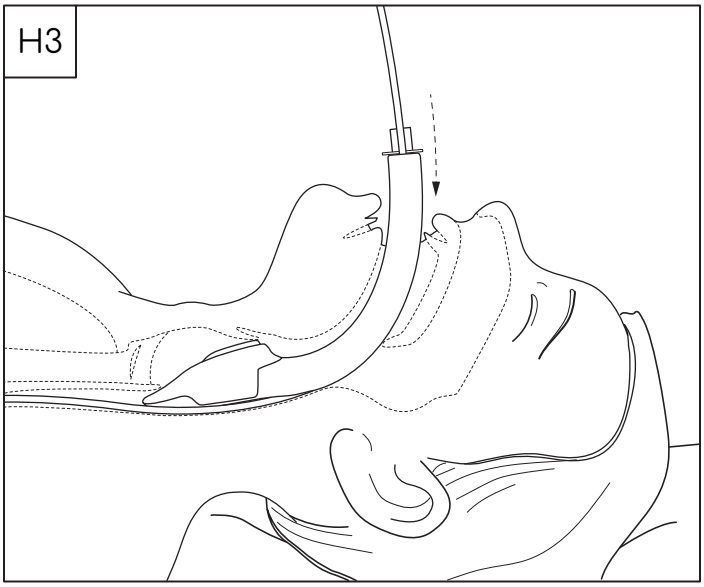
SECTION H
PLACEMENT OF GASTRIC TUBE



Withdraw the LIVVE™ proximally to disengage the device from the hypopharynx.



Insert a well lubricated gastric tube (up to 18 Fr) into the proximal end of the gastric port. Advance the gastric tube posterially into device following channel until it is advanced into stomach. Verification of proper gastric tube placement should follow standard of care.



Re-engage the LIVVE™ device into the hypopharynx until resistence is felt. Reverify proper ventilation using standard practice guidelines.

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SECTION I

ADDITIONAL VERIFICATION METHODS

Remove the camera and sheath unit from the LIVVE™ device and place them inside the endotracheal tube. Advance them to the distal end of endotracheal tube for visual verification of tracheal rings and placement above the carina. **NOTE: The TOAD™ camera and sheath are not intended to be advanced beyond the distal tip of an endotracheal tube. Practitioners must have prior skill sets and knowledge of typical bronchoscopic visualization of endotracheal tubes.**

REMOVAL:

- Do not use excessive force during removal of the LIVVE™ device, camera and sheath or gastric tube. Excessive force may destroy the integrity of the sheath, jeopardizing sterility of the camera and potentially introducing foreign bodies into the patient. If resistance is felt in removing camera and sheath, remove LIVVE™, camera and sheath together as one unit.

DISPOSAL:

- A used LIVVE™ device shall follow handling and disposal process for bio-hazard products, in accordance with all local and national regulations.

STORAGE:

- Do not store the LIVVE™ device in a damp or wet area.
- Keep the LIVVE™ device away from sunlight. Sunlight may affect device and cause it to be less flexible.
- The LIVVE™ device should be stored in conditions not less than -10° C (14° F) or greater than 40° C (104° F).

MANUFACTURER'S WARRANTY:

The LIVVE™ device is designed for single patient use and warranted against manufacturing defects at the time of delivery. Warranty is applicable only if purchased from an authorized distributor. WM & DG DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATIONS, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

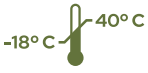
Rx only


Single use.
Do not re-use

Non-sterile

Does not contain DEHP

Does not contain natural rubber latex



Temperature limit


Keep away from sunlight


Keep dry


Read Instructions for Use


Do not use if package is damaged

REPORTING PROBLEMS OR ADVERSE EVENTS:

info@toadairways.com

MANUFACTURED FOR:

WM & DG, Inc. Deerfield, Illinois 60015 USA

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