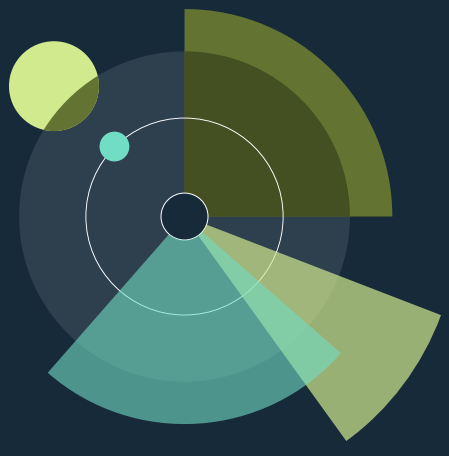
Airway Management Simplified

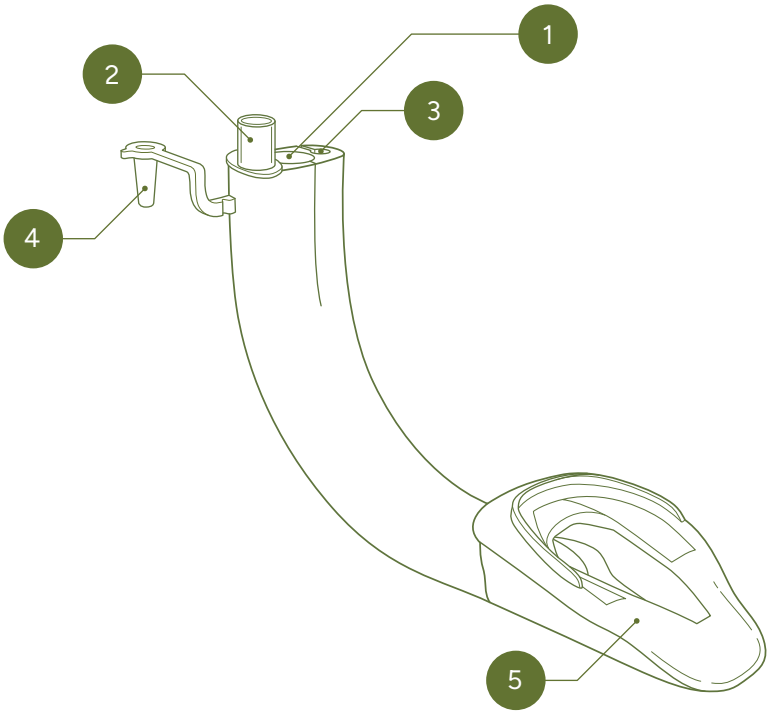
INSTRUCTIONS FOR USE

LIVVE™

Laryngeal, Intubating, Visualizing, Ventilating and Extubation Device



TOAD™ - Total Oral Airway Devices



1. Endotracheal Tube Placement Channel
2. Ventilation Port
3. Open Gastric Channel
4. Plug
5. Cushioned Cuff

Indication for Use

- The LIVVE™ is a single-use, non-sterile, fully disposable, soft, non-inflatable supraglottic airway 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 to provide visualization with ventilation.
- The TOAD™ Video Wand is designed to be placed within an endotracheal tube (6.0 and above) to provide continued visualization and guidance of endotracheal tube for intubation.
- The cushioned cuff is designed to provide a semi-closed system for ventilation. It can allow for positive pressure ventilation through either the ventilation port or the endotracheal tube placement channel.
- 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.
- It is recommended to follow ASA guidelines for airway management.

LIVVE™ Size 3.5 Product Number: LB1535
LIVVE™ Size 4.5 Product Number: LB1545

Contraindications

- Do not use the LIVVE™ device until you have read and understand this Instruction for Use.
- Do not use the LIVVE™ device if unfamiliar or not proficient in airway rescue management and techniques.
- 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.

Warnings

- Do not use excessive force during placement or removal of the LIVVE™ device, TOAD™ Video Wand, camera or gastric tube. Excessive force may harm structural integrity, and potentially harm the patient.
- Watch for ventilation leaks or potential obstructions while using this device as these could lead to improper ventilation and/or death.
- The LIVVE™ is not designed for continuous visualization beyond a 10 minute interval.
- Limit peak airway pressure of ventilation to 20 cm or less.
- It is recommended to use the TOAD™ Video Wand when placing an endotracheal tube. Blind placement could potentially cause excessive trauma or life-threatening harm.
- Placement of device does not guarantee proper ventilation.

Caution

- The LIVVE™ is intended for single use only.
- 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.
- The LIVVE™ Device is MRI compatible.
- The TOAD™ Video Wand is not MRI compatible.

Adverse Events

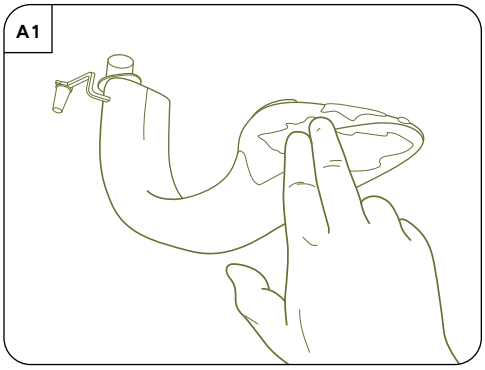
- All airway devices could stimulate patient to gag or aspirate.
- All airway devices may cause excessive pressure, ulcerations, tissue damage, nerve damage and puncture of vital airway structures.
- Misuse of this device can cause trauma, bleeding or puncture of vital tissues.
- This device may not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

Pre-Use Checks

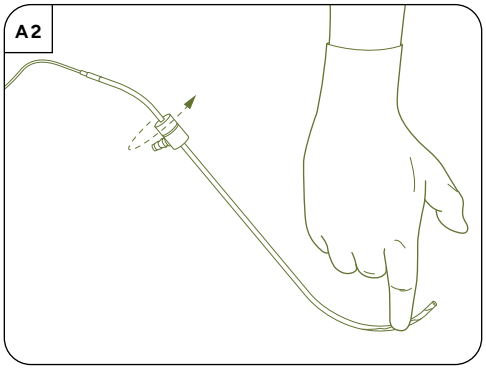
- All patients should be fasted and understand that multiple conditions can contribute to inadequate emptying of the stomach, increasing the likelihood of aspiration.
- Each individual patient medical history and present circumstances should be evaluated by a licensed practitioner prior to use. It is 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 the LIVVE™ ventilating cap is properly secured inside the ventilation lumen.
- Verify the proximal wings of the 15 mm ventilating cap do not obscure the opening of the endotracheal tube placement channel.
- 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

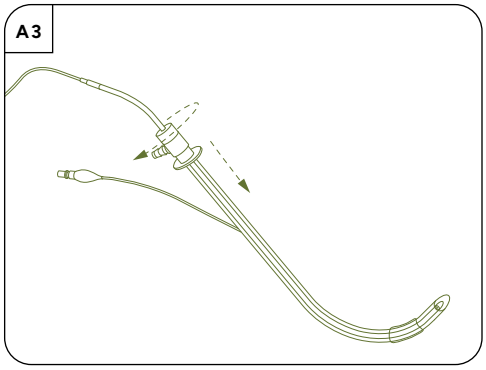
Using the LIVVE™ with the TOAD™ Video Wand



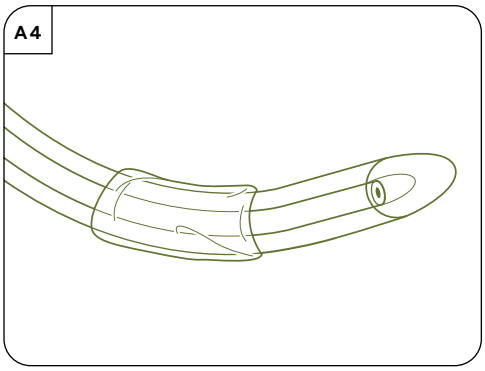
Open package and inspect for any defects. Maintain cleanliness and keep the LIVVE™ device inside its packaging until use. Just before use, lubricate anterior and posterior surfaces, distal edges and entire rim with water-based sterile lubricant.



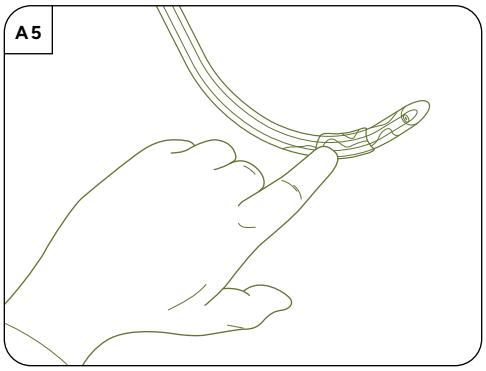
Loosen securing cap on Video Wand. Lubricate distal tip edges of Video Wand with water-based sterile lubricant. Do not get lubricant on camera lens. If camera is obscured with lubricant, gently wipe with a sterile alcohol swab.



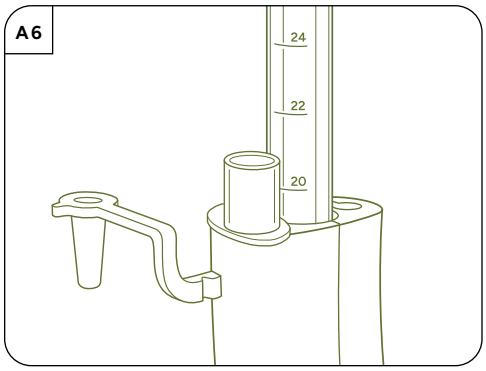
Carefully place Video Wand inside appropriate size endotracheal tube (6.0-9.0) being careful not to hit side walls. Firmly press Video Wand cap onto proximal end of endotracheal tube and tighten to secure.



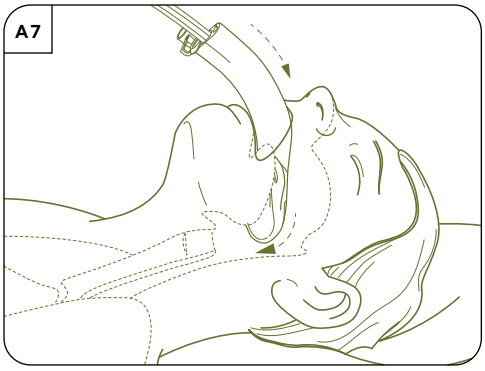
Adjust Video Wand camera to be proximal to the distal tip of the endotracheal tube making sure it is within the distal end of the endotracheal tube. (Video Wand should not be the leading device during placement).



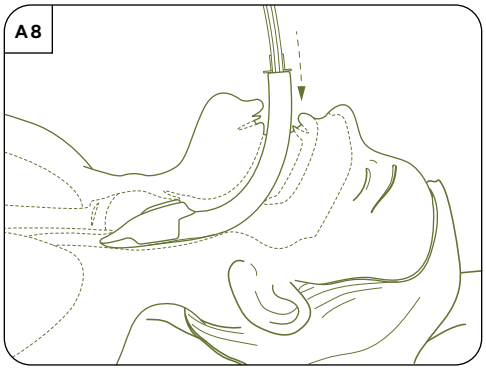
Lightly lubricate distal tip of appropriate size endotracheal tube (6.0-9.0) including deflated cuff prior to insertion into the LIVVE™ endotracheal tube placement channel.



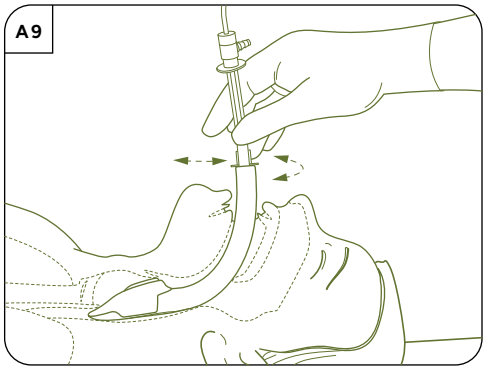
Place endotracheal tube into LIVVE™ to 19 cm at the proximal edge of the LIVVE™ endotracheal tube placement channel. Inflate 3-5 ml of air in endotracheal tube pilot balloon to secure within the LIVVE™.



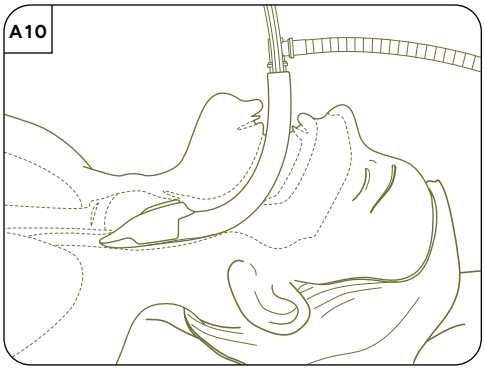
Make sure the patient's head and neck are in neutral sniffing position. Open mouth and advance the proximal end of the LIVVE™ (bowl facing anteriorly) into the mouth following curvature of the pharynx. Make sure tongue does not advance downward with the LIVVE™ device during placement.



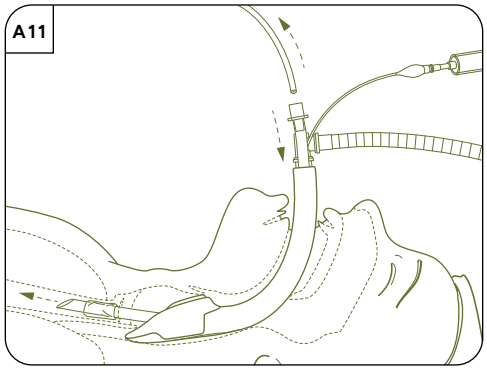
Use the Video Wand's visualization while advancing the distal tip along the hard palette downward until definitive resistance is felt. **Alternative Technique:** Hold anterior mandible and tongue forward with fingers or tongue blade, opening the mouth.



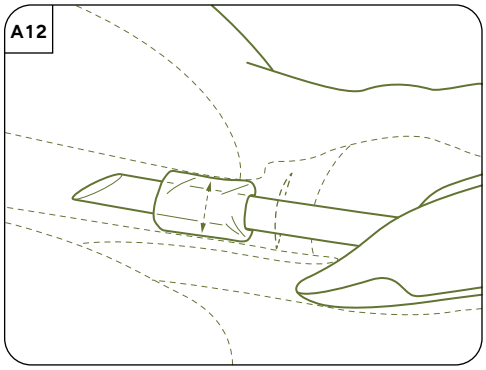
Subtle anterior, posterior, right, or left movements can help create a clear pathway to the glottis. This steerability also allows for navigation around or beneath the epiglottis for improved access.



Once the LIVVE™ device is in position, connect 15 mm ventilating cap to appropriate ventilator circuit. Follow standards guidelines for confirmation of any airway placements.



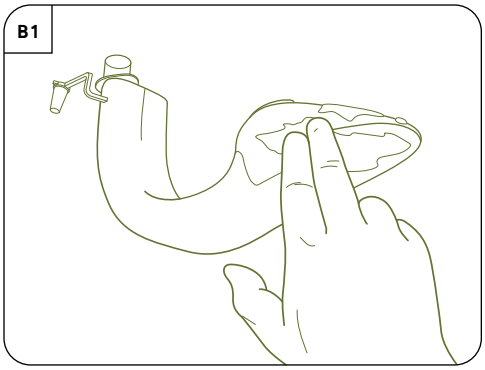
Deflate the endotracheal tube cuff and advance along with the Video Wand under direct visualization. Once the tube is in the appropriate position, carefully withdraw the Video Wand, following its natural contour.



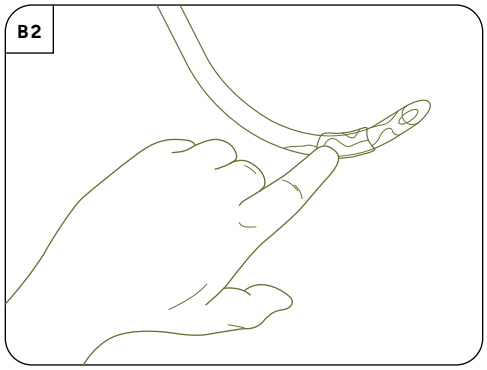
Inflate the endotracheal tube cuff, switch ventilation source to the endotracheal tube, and confirm proper placement and ventilation according to standards of care.

SECTION B

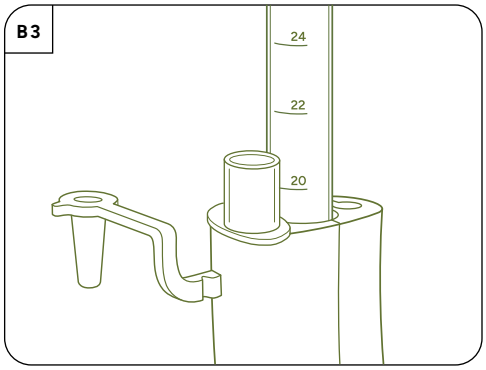
Using LIVVE™ as a Laryngeal Airway Mask Without Visualization



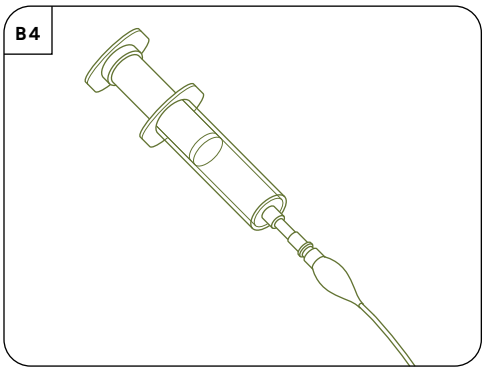
Open package and inspect for any defects. Maintain cleanliness and keep the LIVVE™ device inside its packaging until use. Just before use, lubricate anterior and posterior surfaces, distal edges and entire rim with water-based sterile lubricant.



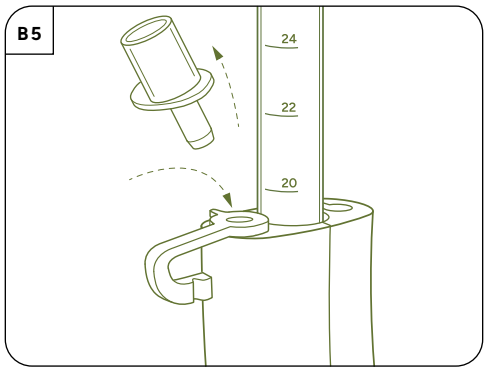
Lightly lubricate distal tip of appropriate size endotracheal tube (6.0-9.0) including deflated cuff prior to insertion into the LIVVE™ endotracheal tube placement channel.



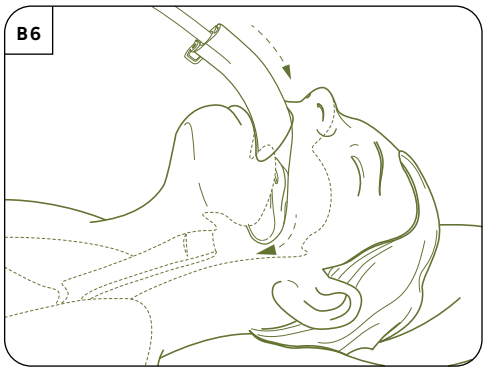
Place endotracheal tube into LIVVE™ to 19 cm at the proximal edge of the LIVVE™ endotracheal tube placement channel.



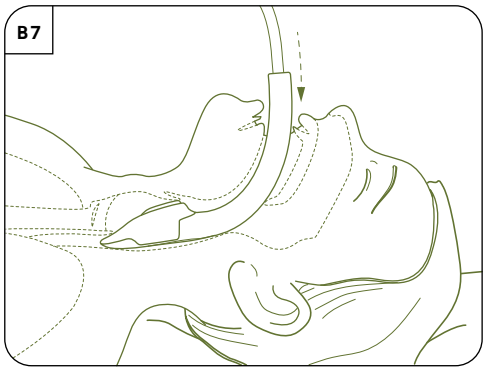
Inflate 3-5 ml of air in endotracheal tube pilot balloon. This secures endotracheal tube inside LIVVE™'s endotracheal tube placement channel.



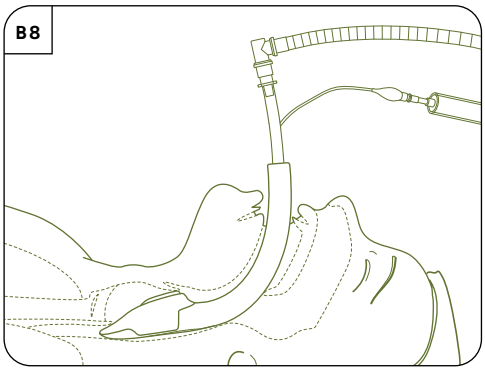
Remove ventilation cap from ventilating channel and secure plug firmly into ventilating lumen.



Make sure the patient's head and neck are in neutral sniffing position. Open mouth and advance the proximal end of the LIVVE™ (bowl facing anteriorly) into the mouth following curvature of the pharynx. Make sure tongue does not advance downward with the LIVVE™ device during placement.



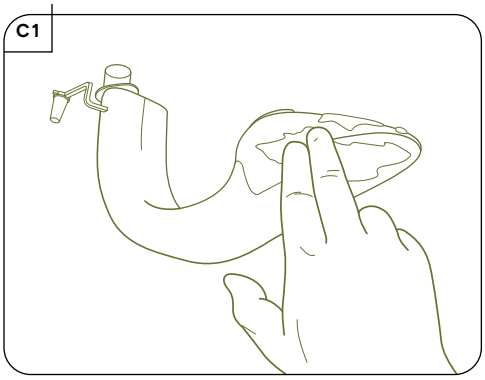
Advance the distal tip along the hard palette downward until definitive resistance is felt. Make sure tongue does not advance downward with the LIVVE™ device during placement. **Alternative Technique:** Hold anterior mandible and tongue forward with fingers or tongue blade, opening the mouth.



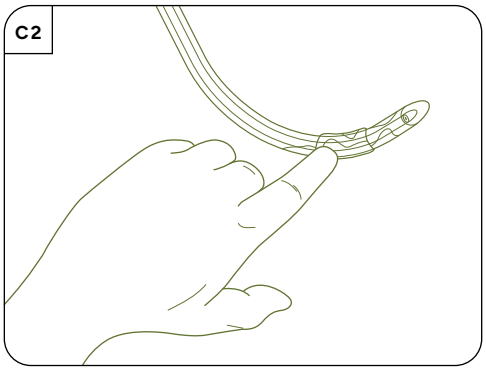
Once the LIVVE™ device is in position, connect 15 mm ventilating cap to appropriate ventilator circuit. Follow standards guidelines for confirmation of any airway placements.

SECTION C

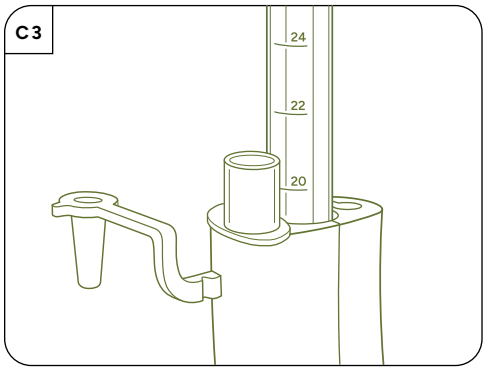
Using the LIVVE™ with Flexible Laryngoscope/Bronchoscope



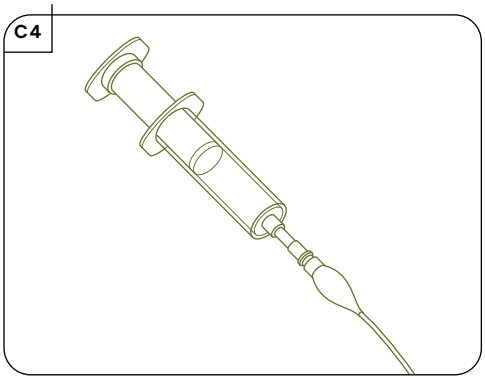
Open package and inspect for any defects. Maintain cleanliness and keep the LIVVE™ device inside its packaging until use. Just before use, lubricate anterior and posterior surfaces, distal edges and entire rim with water-based sterile lubricant.



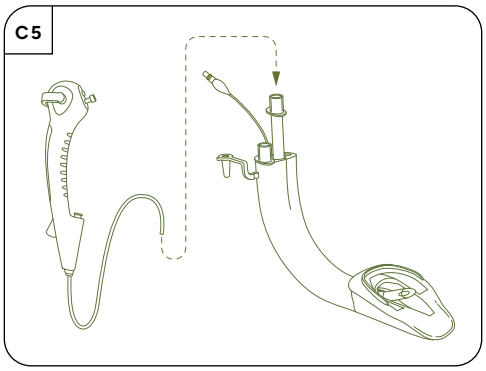
Lightly lubricate distal tip of appropriate size endotracheal tube (6.0-9.0) including deflated cuff prior to insertion into the LIVVE™ endotracheal tube placement channel.



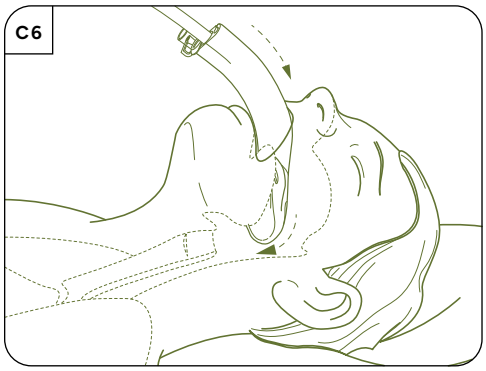
Place endotracheal tube into LIVVE™ to 19 cm at the proximal edge of the LIVVE™ endotracheal tube placement channel.



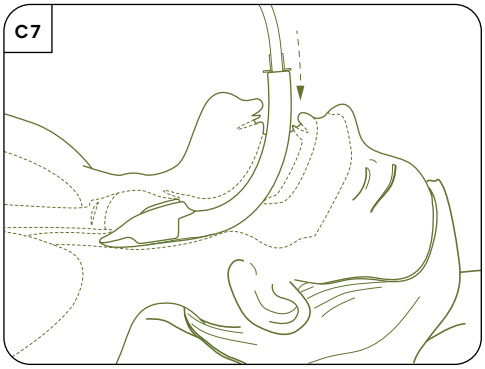
Inflate 3-5 ml of air in endotracheal tube pilot balloon. This secures endotracheal tube inside LIVVE™'s endotracheal tube placement channel.



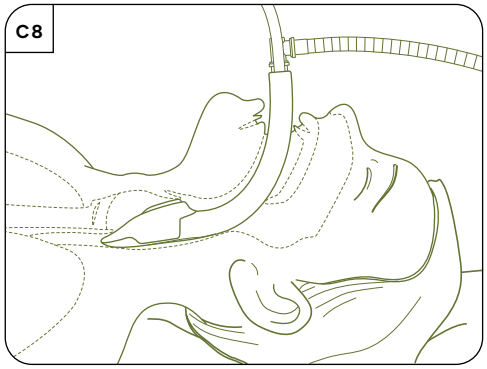
Place flexible laryngoscope/bronchoscope within endotracheal tube to provide visualization while advancing into place.



Make sure the patient's head and neck are in neutral sniffing position. Open mouth and advance the proximal end of the LIVVE™ (bowl facing anteriorly) into the mouth following curvature of the pharynx. Make sure tongue does not advance downward with the LIVVE™ device during placement.

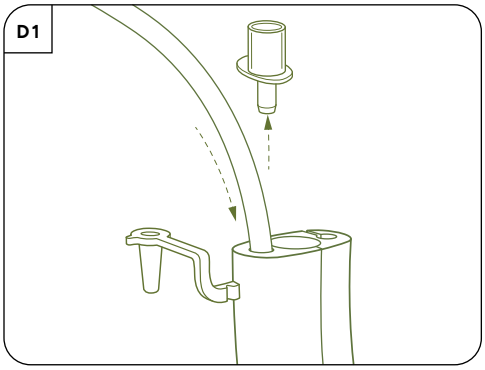


Use the Flexible Laryngoscope or bronchoscope to visualize the epiglottis and periglottic structures while advancing the LIVVE™ device. **Alternative Technique:** Hold anterior mandible and tongue forward with fingers or tongue blade, opening the mouth.

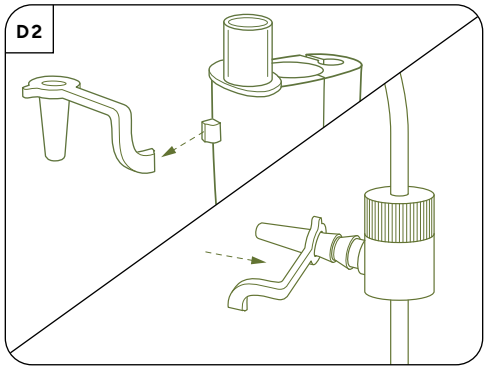


Once the LIVVE™ device is in position, connect 15 mm ventilating cap to appropriate ventilator circuit. Follow standards guidelines for confirmation of any airway placements.

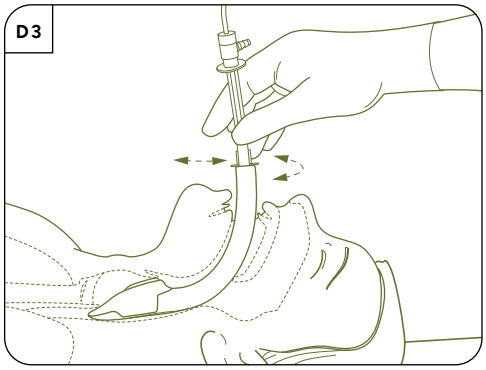
SECTION D
Tips & Tricks



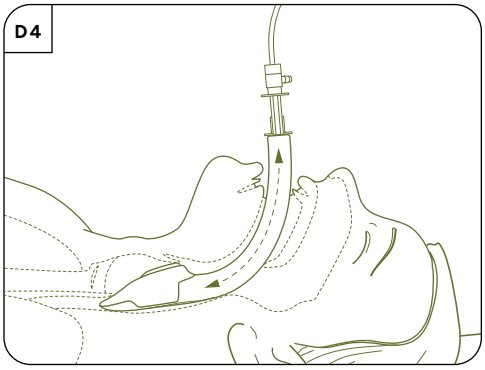
Alternatively, the ventilation lumen can be utilized for suctioning from the bowl of the LIVVE™ device. To do this, remove the plug from the ventilation lumen and advance a suction catheter (up to 18 FR).



The plug from ventilation lumen can be torn off from the LIVVE™ body and applied to the oxygenation/suction port on the Video Wand cap to prevent leakage while ventilating.



Do not engage the epiglottis while advancing the LIVVE™, TOAD™ Video Wand or endotracheal tube. Subtle anterior, posterior, right, or left movements can help create a clear pathway to the glottis. This steerability also allows for navigation around or beneath the epiglottis for improved access.



When encountering tissues obstructing the view, gently retract the LIVVE™ and/or TOAD™ Video Wand to create an open space, allowing for improved visualization and re-advancement.

Removal

- Do not use excessive force during removal of the LIVVE™ device, TOAD™ Video Wand, camera or gastric tube. Excessive force may harm structural integrity, potentially introducing foreign bodies into the patient.

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


Do not use if
package is
damaged


Read
Instructions
for Use

Reporting Problems or Adverse Events:

info@toadairways.com

Manufactured For:

WM & DG, Inc. Northbrook, Illinois 60062 USA
888.508.1550 | www.toadairways.com