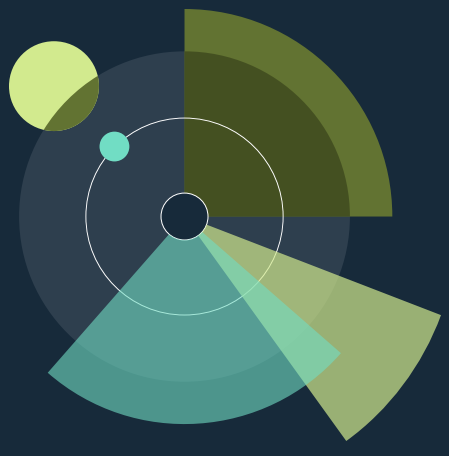
Airway Management Simplified

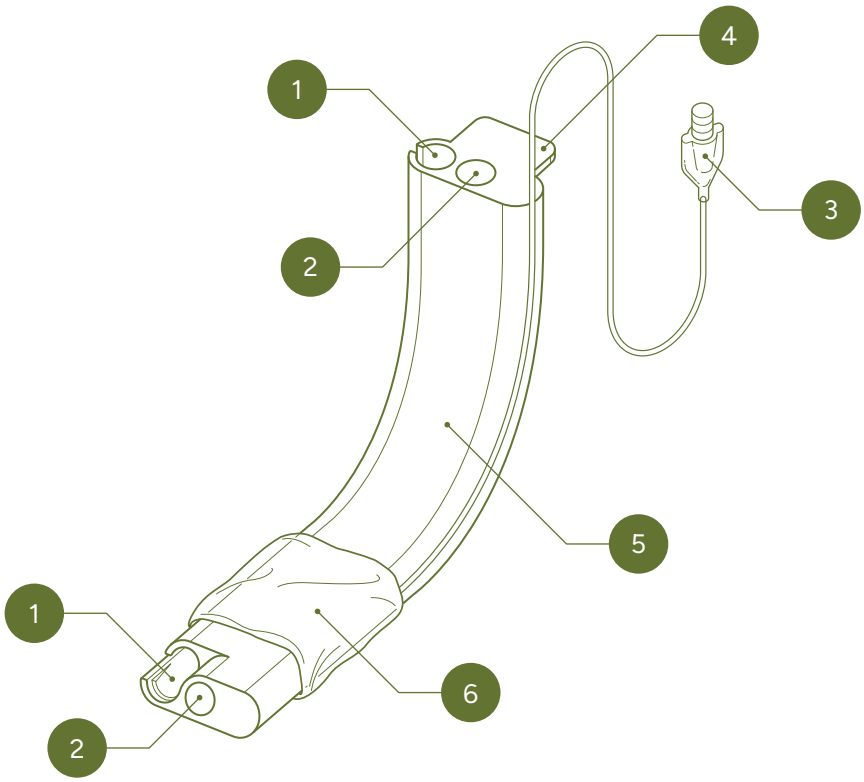
INSTRUCTIONS FOR USE

TOAD™ Big Mouth™ Oral Airway

with Balloon



TOAD™ - Total Oral Airway Devices



1 **Bougie Channel**

2 **Camera Lumen**

3 **Balloon Pilot**

4 **Lifting Handle**

5 **Flexible Body**

6 **Inflatable Balloon**

Indication for Use

- The Big Mouth™ Oral Airway with Balloon is a single-use, non-sterile, 2-lumen channel device with the ability to be flexible between 95° and 130°. It is intended to be used for maintaining an open airway and facilitating intubation in airway management. The Big Mouth™ Oral Airway with Balloon will accommodate a standard 15 Fr bougie and is designed to be used with the TOAD™ Video Bougie, TOAD™ Flexible Laryngoscope, or a compatible bronchoscope to assist in facilitating visualization of the periglottic structures and assisting in intubation.
- The indwelling time of the Big Mouth™ Oral Airway with Balloon should not exceed three (2) hours.
- Maximum balloon inflation should not exceed 50 ml of air and should be measured if balloon is inflated. Maximum pressure should not exceed 60 cm of water.
- Tissue necrosis or damage can occur in low perfusion or compromised tissues despite having 60 cm or less of pressure.
- It is recommended to follow ASA guidelines for airway management.

The Big Mouth™ Oral Airway with Balloon device is to be used for adults ≥ 55 kg (≥ 121 lbs).

Product Number: OA4100

Contraindications

- Do not use the Big Mouth™ Oral Airway with Balloon as part of instrumentation of a surgical procedure.
- Do not use the Big Mouth™ Oral Airway with Balloon 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 Big Mouth™ Oral Airway with Balloon if patient exhibits severe airway bleeding, morbid obesity, pharyngo-perilaryngeal abscess, tumors or masses.
- Do not use the Big Mouth™ Oral Airway with Balloon if unfamiliar or not proficient in airway rescue management an techniques.

Warnings

- This device is a supraglottic oral airway device which does not protect or prevent patient from aspiration.
- Do not use excessive force during placement or removal of the Big Mouth™ Oral Airway with Balloon. Excessive force may harm structural integrity, and potentially harm the patient.
- Do not inflate balloon beyond 50 ml of air. Overinflation of the balloon could result in tissue harm or necrosis.
- When used for intubation, this device must always be accompanied by visualization using standard accepted practice. Verification of ventilation is not guaranteed by using this device. Always verify ventilation using standard accepted practice.
- Do not flex the Big Mouth™ Oral Airway with Balloon repeatedly as this could cause internal stylet to break and adversely affect its ability to maintain its intended curvature. The Big Mouth™ Oral Airway with Balloon's intended curvature for use is designed to range between 95° and 130°.
- The flexing and adjustment to reflect curvature of patient's pharyngeal structures prior to use should always be performed outside of the patient's oral cavity.
- Advancing too far may place the distal end of the device in the hypopharynx. If this occurs, pull back device to establish ventilation.

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 Big Mouth™ Oral Airway with Balloon. Reprocessing, altering or reusing may compromise the device's ability to perform as intended.
- This device is MRI unsafe and should not be placed at or near MRI.

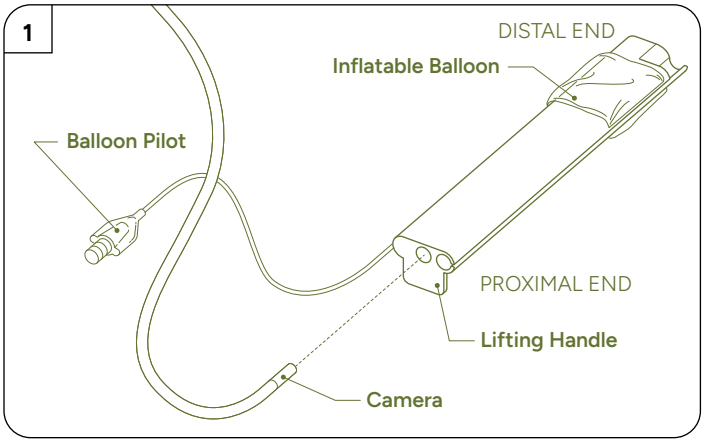
Adverse Events

- 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.

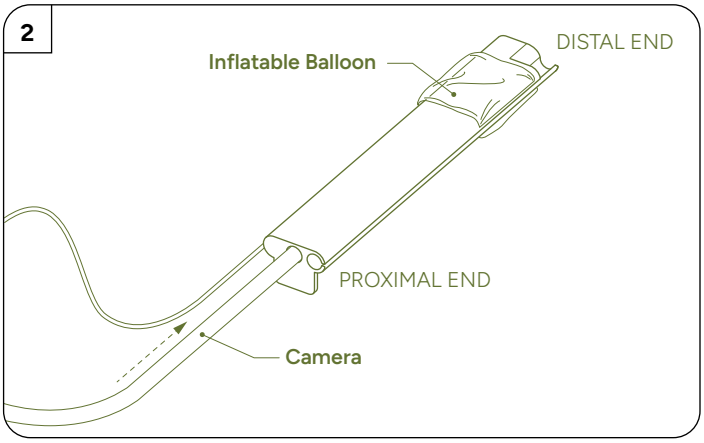
Pre-Use Checks

- All patients should be fasted and device users must 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 the interior lumens of the Big Mouth™ Oral Airway with Balloon to ensure it is free from blockage, loose particles, cuts, or indentations. Discard device if any defects are detected.
- Do not flex the Big Mouth™ Oral Airway with Balloon repeatedly as this could cause internal stylet to break and adversely affect its ability to maintain its intended curvature. The Big Mouth™ Oral Airway with Balloon device's intended curvature for use is designed to range between 95° and 130°.
- Water-based lubrication must be applied lightly over balloon, distal end, and body prior to insertion of the 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.

Using the Big Mouth™ Oral Airway with Balloon



Insert camera through into the center lumen at the proximal end of the Big Mouth™ Oral Airway with Balloon. The proximal end is identified by having the protruding handle.



Gently push the camera through the Big Mouth™ Oral Airway with Balloon to the desired position at distal end. Slide camera into center lumen on the device and hold in place. The camera is not intended to extend beyond the distal tip of the device.

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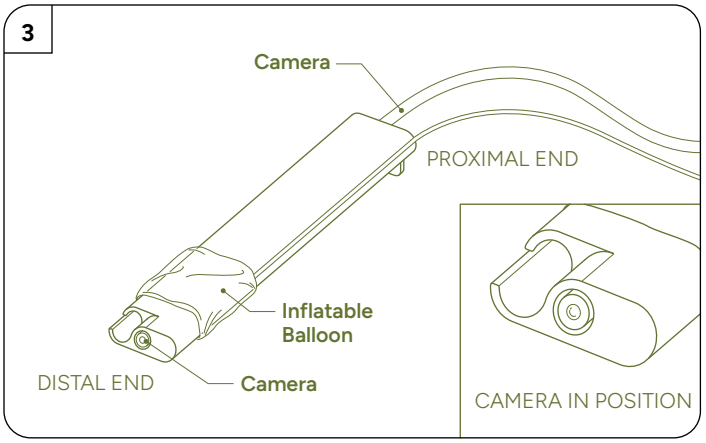

Once the camera is in place, the configuration is ready for the next step. Alternately, this airway device can be used without the camera to stent open the airway.

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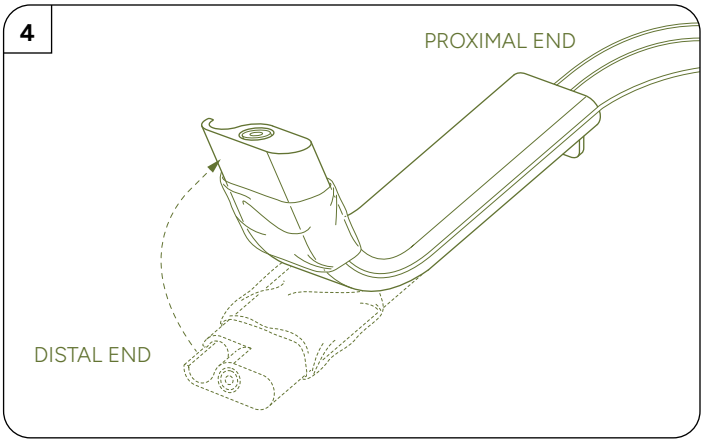

The Big Mouth™ Oral Airway with Balloon comes packed flat but is flexible and must be adjusted to reflect curvature of patient's pharyngeal structures prior to insertion.

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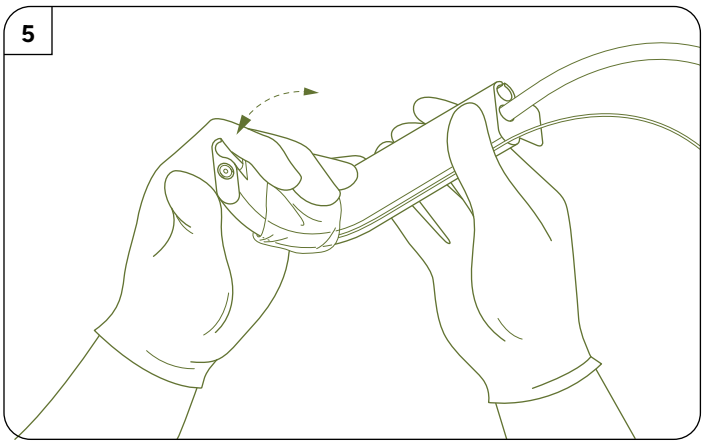

Readjust curvature as necessary. Lightly lubricate around all distal edges of the device with water-based lubricant.

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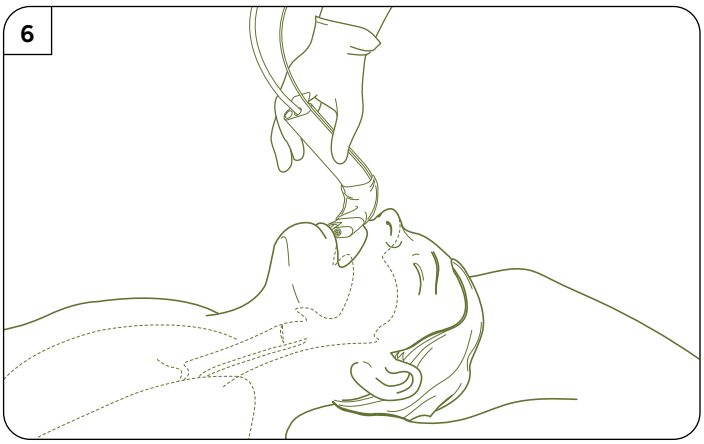

Position the patient's head and neck for normal tracheal intubation. The patency of the Big Mouth™ Oral Airway with Balloon should be reconfirmed after any change in the patient's head and neck position.

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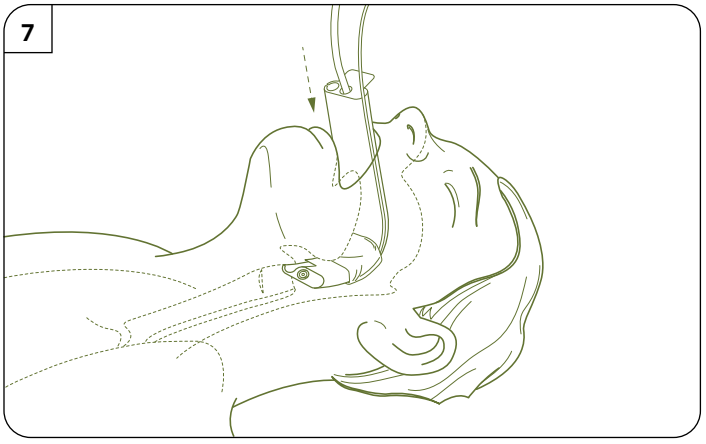

As the Big Mouth™ Oral Airway with Balloon is inserted do not apply excessive force. Once in place, use the TOAD™ Video Bougie, TOAD™ Flexible Laryngoscope, or a compatible bronchoscope for viewing. Alternatively, the TOAD™ Video Bougie can be used in place of a standard adult bougie.

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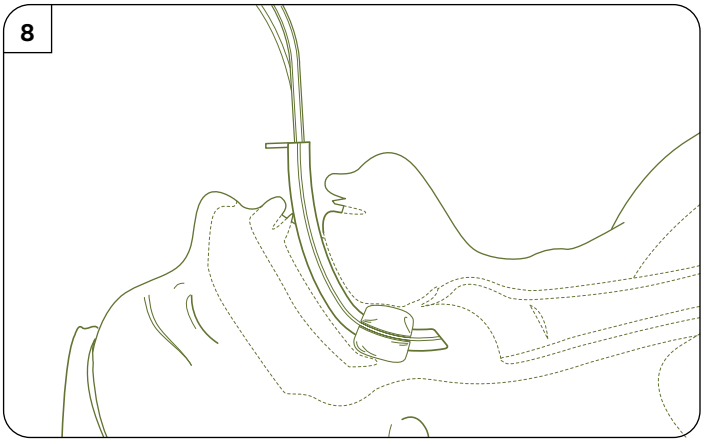
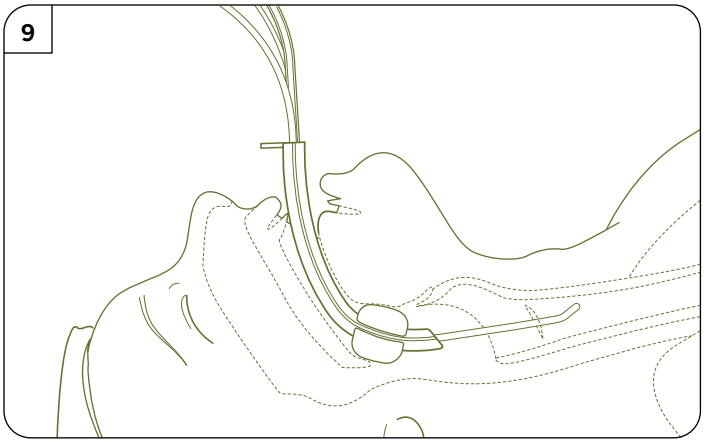
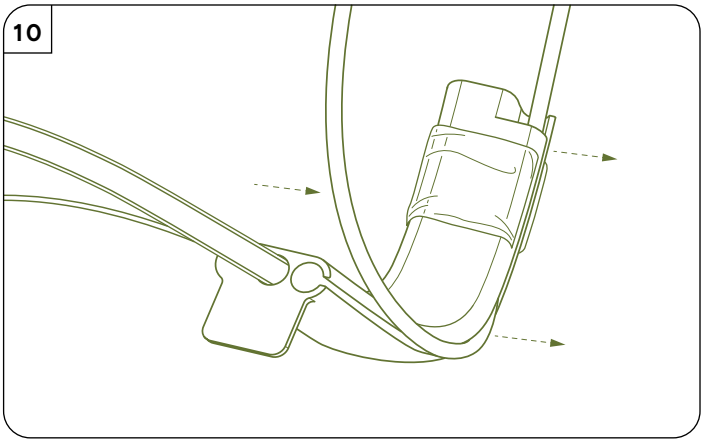


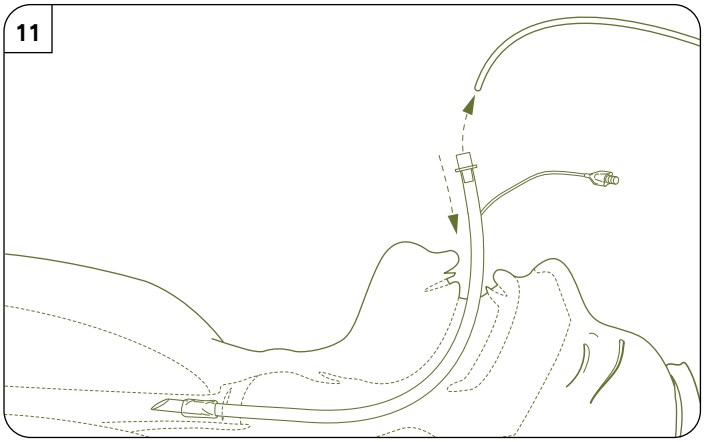
The balloon can be inflated up to 50 ml of air to elevate the tongue and stent the airway open. Ventilation may be spontaneous or assisted with bag mask ventilation.



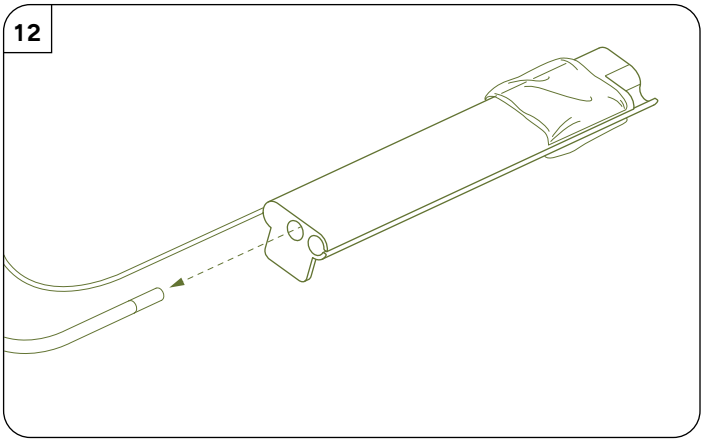
A well lubricated bougie (15 Fr) or TOAD™ Video Bougie can be advanced within the bougie channel under direct vision as it exits. Visualization must be maintained of the distal tip of the bougie and the advancing tissues. It is intended to place the bougie beyond the vocal cords utilizing standard accepted techniques and precautions.



The bougie or TOAD™ Video Bougie can be pushed laterally out of the device. Standard practice for advancing an endotracheal tube over a bougie can now take place. Continued visualization throughout this process is recommended.



A well lubricated endotracheal tube can be advanced over the bougie while under direct vision. The bougie or TOAD™ Video Bougiecan then be removed from the endotracheal tube. Verify proper placement of endotracheal tube utilizing standard accepted practice.



Deflate the balloon to remove the device, camera and sheath from patient. Straighten device, then remove the camera and sheath together out of proximal end. Do not use excessive force.

Removal

- Do not use excessive force during placement or removal of the Big Mouth™ Oral Airway with Balloon. Excessive force may harm structural integrity, and potentially harm the patient.

Disposal

- A used Big Mouth™ Oral Airway with Balloon shall follow handling and disposal process for bio-hazard products, in accordance with all local and national regulations.

Storage

- Do not store the Big Mouth™ Oral Airway with Balloon in a damp or wet area.
- Keep the Big Mouth™ Oral Airway with Balloon away from sunlight. Sunlight may affect device and cause it to be less flexible.
- The Big Mouth™ Oral Airway with Balloon should be storage in conditions not less than -18° C (-0.4° F) or greater than 40° C (104° F).

Manufacturer's Warranty

The Big Mouth™ Oral Airway with Balloon 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

MR Unsafe

Temperature limit


Keep away from sunlight


Keep dry


Do not use if package is damaged


Read Instructions for Use

Reporting Problems or Adverse Events:

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