MADE

The University of Iowa

Abrons Oral Airway

Instructions for Use

IMPORTANT

1. This product is intended to be used by a physician or nurse anesthetist with appropriate training and experience.
2. Do not attempt to use the Abrons Oral Airway before completely reading and understanding the information contained in this Instructions for Use.

Device Description

The Abrons Oral Airway is an oral airway with an articulating hinge intended for patients who are difficult to mask ventilate or require flexible scope (fiberoptic) intubation. The locking hinge improves airway management by displacing the tongue, creating a greater cross-sectional area for mask ventilation and improving glottic view during flexible scope exam. Consisting of HDPE, the device can be intubated through, disarticulated and removed without disturbing the endotracheal tube. The AOA is currently in a clinical trial at the University of Iowa Hospitals and Clinics. It is intended to be used in a clinical setting as an alternative to current airway management devices.
The Abrons Oral Airway is comprised of two components, an anterior half and a posterior half, connected at a hinge for articulation. The device is intended to be used with both halves connected until removal.

Articulation at the hinge allows for two positions. The device, as shown in Figure 1, can either be closed (left, for insertion) or open (right).

Figure 1
Articulating confirmations “closed” (Left) and “open” (Right).

Contents of Packaging

- Abrons Oral Airway
- One instructions for use

How Supplied

Devices are individually packaged, clean and non-sterile.

Indications for Use

The Abrons Oral Airway is an oropharyngeal airway indicated for adult patients who may be difficult to mask ventilate or require flexible scope (fiberoptic) intubation.

Contraindications

The Abrons Oral Airway should not be used on any patient who:

- Is Pediatric
- Has acute oropharyngeal trauma
- Has palatal abnormalities

Warnings ⚠

- For single use only.
- Do not re-process
- Do not sterilize.
- Do not use one half of the airway without the other.
- Improper use of this device may cause injury.
- May cause dental damage.

- May cause mucosal abrasions.
- May cause pharyngeal injury.

Precautions

- If there are any variations between these Instructions for Use and either your facility's policies, those variations should be brought to the attention of the appropriate responsible hospital personnel for resolution before proceeding with device.
- Prior to use, inspect devices to ensure proper function and condition.
- Do not use the Abrons Oral Airway if it does not satisfactorily perform its intended function or if it has physical damage.
- Do not use Abrons Oral Airway if package is open or damaged.
- Do not use in a patient for more than 1/2 hour.
- Avoid mechanical shock or overstressing the devices.
- Avoid using device in conjunction with flexible scopes or subglottic suction tubes with an ID larger than 9mm.

Adverse Events

Patient Population
At least 30 people have been ventilated using the Abrons Oral Airway.

Observed Adverse Events
Zero adverse events have been observed using the Abrons Oral Airway.

Adverse Event Reporting
Any adverse event involving the Abrons Oral Airway should be reported to Iowa MADE immediately. To report an incident, call (319) 384-3425 or email iowa-made@uiowa.edu

Directions for Use

Abrons Oral Airway (AOA) Procedure

1. Ensure that device is in closed conformation such that the distal portion is closed and the proximal is open.
2. Insert the AOA through the mouth using standard oropharyngeal airway placement procedures. Jaw thrust may facilitate advancement and is recommended.
3. Close the proximal end, causing the distal end to open. The device will lock in this confirmation.
4. Proceed with standard mask ventilation or flexible scope intubation.
5. Once mask ventilation (or flexible scope intubation) is completed, the AOA is removed by disarticulating the two halves and sliding them out independently.
6. To disarticulate, use the middle or index finger to gently draw the end plate of the bottom half towards you and the thumb of the same hand to gently push the end plate of the top piece away from you. This scissoring action will separate the two halves, which are removed independently.

Instrument Cleaning and Sterilization

Abrons Oral Airway is intended for single use only and is provided ready for use. Do not clean or sterilize the device.

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For product ordering or reporting of adverse events, please call (319) 384-3425, email iowa-made@uiowa.edu, or visit iowamade.org

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