INSTRUCTIONS FOR USE

Ambu® AuraOnce™

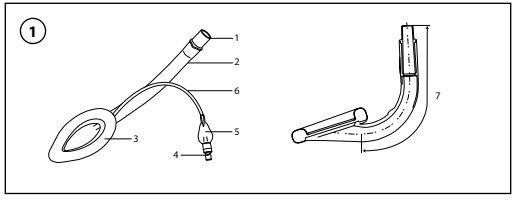
Single Use Laryngeal Mask – Sterile.

For use by medical professionals trained in airway management only.

Abridged version

Ambu

Symbol Indication								
en	Medical Device	MR safe	Sterilized using irradiation Single sterile barrier system	Do not use if the product sterilization barrier or its packaging is damaged	Country of manufacturer	UK Conformity Assessed	UK Responsible Person	Importer (For products imported into Great Britain only)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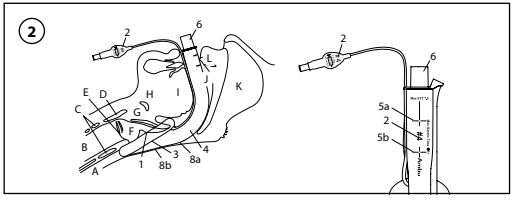
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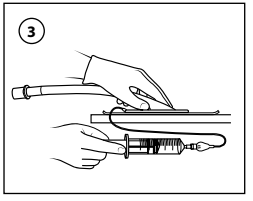

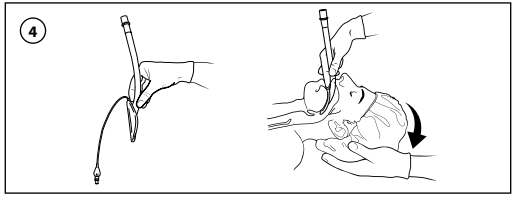

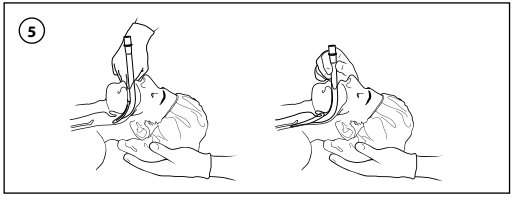

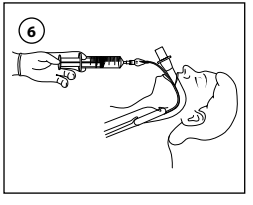

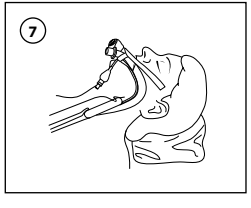

Content **Page**

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1.1. Intended use/Indication for use
The Ambu AuraOnce is intended for use as an alternative to a facemask for achieving and maintaining control of the airway during routine and emergency anaesthetic procedures in fasted patients.

1.2. Intended users and use environment
Medical professionals trained in airway management. AuraOnce is intended to be used in a hospital setting.

1.3. Intended patient population
Adult and pediatric patients from 2 kg and above evaluated as eligible for a supraglottic airway.

1.4. Contraindications
None known.

1.5. Clinical benefits
Keeps the upper airway open to allow passage of gases.

1.6. Warnings and cautions
Before insertion, it is essential that all medical professionals using Ambu AuraOnce are familiar with the warnings, precautions, indications, and contraindications found in *Instruction for use.*

WARNINGS ⚠

1. The product is intended to be used by medical professionals trained in airway management only.
2. Always visually inspect the product and perform a functional test after unpacking and prior to use according to section 3.1 Preparation before use, as defects and foreign matters can lead to no or reduced ventilation, mucosal damage, or infection of the patient. Do not use the product if any steps in Preparation before use fails.
3. Do not re-use AuraOnce on another patient as it is a single use device. Re-use of a contaminated product can lead to infection.
4. AuraOnce does not protect the trachea or lungs from the risk of aspiration.
5. Do not use excessive force when inserting and removing AuraOnce as this can lead to tissue trauma.
6. The cuff volume or pressure may change in the presence of nitrous oxide, oxygen, or other medical gases which can lead to tissue trauma. Ensure to monitor cuff pressure continuously during the surgical procedure.
7. Do not use AuraOnce in the presence of lasers and electrocautery equipment as this could lead to airway fire and tissue burns.
8. Do not perform direct intubation through AuraOnce as the endotracheal (ET) tube may get stuck leading to insufficient ventilation.
9. In general, AuraOnce should only be used in patients who are profoundly unconscious and will not resist insertion.
10. The overall complication rate for laryngeal mask is low, but the user must exercise professional judgement when deciding whether the use of a laryngeal mask will be appropriate.
    The following patients are at higher risk of serious complications including aspiration and inadequate ventilation:
    - Patients with upper airway obstruction.
    - Non-fasted patients (including those cases where fasting cannot be confirmed).
    - Patients suffering from upper gastrointestinal issues (e.g., esophagectomy, hiatal hernia, gastroesophageal reflux disease, morbid obesity, pregnancy > 10 weeks).
    - Patients requiring high pressure ventilation.
    - Patients who present with pharyngeal/laryngeal pathology potentially complicating anatomical fit of the mask (e.g., tumors, radiotherapy to the neck involving the hypopharynx, severe oropharyngeal trauma).
    - Patients with inadequate mouth opening to permit insertion.

CAUTIONS

1. Do not soak, rinse, or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. The design and material used are not compatible with conventional cleaning and sterilization procedures.
2. Before use, always check for compatibility between AuraOnce and the external device to avoid the use of devices not being able to pass through lumen of AuraOnce.
3. The cuff pressure should be kept as low as possible while still providing sufficient seal and should not exceed 60 cmH_2O.
4. Any signs of airway problems or inadequate ventilation must be monitored regularly and AuraOnce must be repositioned, reinserted or replaced as required to maintain a patent airway.
5. Always reconfirm the patency of the airway after any change in the patient's head or neck position.

1.7. Potential adverse events

The use of laryngeal masks is associated with minor adverse effects (e.g., sore throat, bleeding, dysphonia, dysphagia) and major adverse effects (e.g., regurgitation/aspiration, laryngospasm, nerve injury).

1.8. General notes

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

2.0. Device description

AuraOnce is a sterile, single-use laryngeal mask consisting of a curved patient tube with an inflatable cuff at the distal end. The cuff can be inflated through the check valve allowing the pilot balloon to indicate the inflation/deflation status. The cuff conforms to the contours of the hypopharynx and with its lumen facing the laryngeal opening of the patient. The tip of the cuff presses against the upper oesophageal sphincter and the proximal end of the cuff rests against the base of the tongue.

AuraOnce comes in 8 different sizes. The main components of AuraOnce are seen in figure ①.

Figure 1 *(page 7)*: Overview of AuraOnce parts:
1. Connector; **2.** Patient tube; **3.** Cuff; **4.** Check valve; **5.** Pilot balloon; **6.** Pilot tube; **7.** Nominal length of internal ventilatory pathway*.
**See Table 1 for the nominal length provided in centimeters.*

Figure 2 *(page 7)*: Correct position of AuraOnce in relation to AuraOnce parts and anatomical landmarks
AuraOnce parts: 1. Inflatable cuff; **2.** Size marking; **3.** Ventilatory opening; **4.** Ventilatory pathway; **5.** Normal depth of insertion marks; **6.** Machine end.

Anatomical landmarks: A. Esophagus; **B.** Trachea; **C.** Cricoid ring; **D.** Thyroid cartilage; **E.** Vocal cords; **F.** Laryngeal inlet; **G.** Epiglottis; **H.** Hyoid bone; **I.** Tongue; **J.** Buccal cavity; **K.** Nasopharynx; **L.** Incisors.

COMPATIBILITY WITH OTHER DEVICES/EQUIPMENT

AuraOnce can be used in conjunction with:

- Ventilation equipment; 15 mm conical connectors in compliance with ISO 5356-1.
- Airway management devices; Bronchoscopes and exchange catheters*.
- Other accessories; Standard 6 % conical Luer syringe, Manometer with standard 6 % conical Luer connector, Water-based lubrication, Suction catheter.

When using instruments through the mask ensure that the instrument is compatible and well lubricated before insertion.

** See Table 1 for information on maximum instrument size.*

3.0. Product use

3.1. Preparation before use

SIZE SELECTION

Ambu AuraOnce comes in different sizes for use in patients of different weights.

For pediatric patients, it is recommended that Ambu AuraOnce is used by a medical professional familiar with pediatric anesthesia.

See selection guidelines and max. intracuff pressure in Table 1, section 4.0. (Specifications).

INSPECTION OF AURAONCE

Always wear gloves during the preparation and insertion of Ambu AuraOnce to minimize contamination.

Handle AuraOnce carefully as it can be torn or punctured. Avoid contact with sharp or pointed objects.

Check that the pouch seal is intact before opening and discard Ambu AuraOnce if the pouch seal has been damaged.

Closely examine AuraOnce for any damage, such as perforation, scratches, cuts, tears, loose parts, sharp edges etc.

Make sure that the cuff protector has been removed from the cuff.

Check that the interior of the patient tube and the cuff are free from blockage and any loose parts. Do not use AuraOnce if it is blocked or damaged.

Deflate the cuff of AuraOnce completely. Once deflated, check the cuff thoroughly for any wrinkles or folds. Inflate the cuff to the volume as specified in Table 1. Check that the inflated cuff is symmetrical and smooth. There should not be any bulge nor any sign of leakage in the cuff, pilot tubing or pilot balloon. Deflate the cuff again before insertion.

3.2. Preparations for use

PRE-INSERTION PREPARATION

- Deflate the cuff completely so that the cuff is flat and free of wrinkles by pressing the cuff down onto a flat sterile surface (e.g., a piece of sterile gauze) while at the same time deflating the device with a syringe (3).
- Lubricate the posterior tip of the cuff prior to insertion by applying a sterile, water-based lubricant to the distal posterior surface of the cuff.
- Always have a spare Ambu AuraOnce ready for use.
- Pre-oxygenate and use standard monitoring procedures.
- Check that the level of anesthesia (or unconsciousness) is adequate before attempting insertion. The insertion should be successful at the same level of anesthesia that would be suitable for tracheal intubation.
- The head of the patient should be positioned extended with flexion of the neck in a position normally used for tracheal intubation (i.e., “the sniffing position”).

3.3. Insertion

- Never use excessive force.
- Hold the patient tube with the thumb on the vertical line close to the machine end of the patient tube and three fingers placed on the opposite side of the patient tube. Your other hand should be placed under the patient’s head (4).
- Insert the tip of the cuff pressing upwards against the hard palate and flatten the cuff against it (5).
- Verify that the tip of the cuff is flattened against the palate before proceeding – push the jaw gently downwards with your middle finger to open the mouth further.
- Ensure that the tip of the cuff avoids entering the valleculae or the glottic opening and does not become caught up against the epiglottis or the arytenoids. The cuff should be pressed against the patient’s posterior pharyngeal wall.

- When the mask is in place, resistance will be felt.
- After insertion ensure lips are not trapped between patient tube and teeth to avoid trauma to lips.

INSERTION PROBLEMS

- For pediatric patients, a partial rotational technique is recommended in case of placement difficulties.
- Coughing and breath-holding during Ambu AuraOnce insertion indicates inadequate depth of anesthesia – Immediately deepen anesthesia with inhalational or intravenous agents and initiate manual ventilation.
- If you cannot open the patient's mouth sufficiently to insert the mask, check that the patient is adequately anesthetized. Ask an assistant to pull the jaw downwards thus making it easier to see into the mouth and verify the position of the mask.
- For difficulty in maneuvering the angle at the back of the tongue when inserting AuraOnce, press the tip against the palate throughout or else the tip may fold on itself or meet an irregularity in the posterior pharynx, e.g., hypertrophied tonsils. Should the cuff fail to flatten or begin to curl over as it is inserted, withdraw the mask and reinsert it. In case of tonsillar obstruction, a diagonal movement of the mask is recommended.

3.4. Fixation

If deemed necessary, secure AuraOnce to the patient's face with adhesive tape or with a mechanical tube holder suited for this purpose. (7) It is recommended to use a gauze bite block.

3.5. Inflation

- Without holding the tube, inflate the cuff with just enough air to obtain a seal, equivalent to intracuff pressures of a maximum of 60 cmH_2O. (6) Often only half of the maximum volume is sufficient to achieve a seal – please refer to Table 1 for maximum intracuff volumes.
- Monitor the cuff pressure continuously during the surgical procedure with a cuff pressure gauge. This is especially important during prolonged use or when nitrous oxide gases are used.
- Look for the following signs of correct placement: The possible slight outward movement of the tube upon cuff inflation, the presence of a smooth oval swelling in the neck around the thyroid and cricoid area, or no cuff visible in the oral cavity.
- The mask may leak slightly for the first three or four breaths before settling into position in the pharynx. In case leakage persists, check that there is adequate depth of anesthesia and that the pulmonary inflation pressures are low before assuming that reinsertion of AuraOnce is necessary.

3.6. Verification of correct position

- Correct placement should produce a leak-free seal against the glottis with the tip of the cuff at the upper oesophageal sphincter.
- The vertical line on the patient tube should be oriented anteriorly towards the patient's nose.
- AuraOnce is inserted correctly when the patient's incisors are between the two horizontal lines on the patient tube. (2), item 5. Reposition the mask if the patient's incisors are outside this range.
- The position of AuraOnce can be assessed by capnography, by observation of changes in tidal volume (e.g., a reduction in expired tidal volume), by auscultating bilateral breath sounds and an absence of sounds over the epigastrium and/or by observing chest rise with ventilation. If you suspect that AuraOnce has been positioned incorrectly, remove and reinsert – and ensure that anesthetic depth is adequate.
- Visual confirmation of anatomically correct position is recommended, e.g., by using a flexible scope.

UNEXPECTED REGURGITATION

- Regurgitation may be caused by inadequate level of anesthesia. The first signs of regurgitation may be spontaneous breathing, coughing or breath-holding.

- If regurgitation occurs, if oxygen saturation remains at acceptable levels, AuraOnce should not be removed. This should be managed by putting the patient in a "head-down" position. Briefly disconnect the anesthetic circuit so that the gastric contents are not forced into the lungs. Check that anesthetic depth is adequate and deepen anesthesia intravenously, if appropriate.
- Apply suction through the mask's patient tube and through the mouth. Suction the tracheobronchial tree and inspect the bronchi using a flexible scope.

3.7. Usage with other devices/equipment

ANESTHETIC SYSTEM AND VENTILATION BAG

The mask can be used for either spontaneous or controlled ventilation.

During anesthesia, nitrous oxide may diffuse into the cuff causing an increase in cuff volume/ pressure. Adjust cuff pressure just enough to obtain an adequate seal (cuff pressure should not exceed 60 cmH_2O).

The anesthetic breathing system must be adequately supported when connected to AuraOnce to avoid rotation of the mask.

USAGE WITH SPONTANEOUS VENTILATION

AuraOnce is suitable for spontaneously breathing patients when used with volatile agents or intravenous anesthesia on condition that anesthesia is adequate to match the level of surgical stimulus and the cuff is not overinflated.

USAGE WITH POSITIVE PRESSURE VENTILATION

When applying positive pressure ventilation, ensure that the seal is adequate. To improve the seal the following is suggested:

- Optimize placement of AuraOnce by head turning or traction.
- Adjust the cuff pressure. Try both lower and higher pressures (a poor cuff seal may be caused by either too low or too high cuff pressure).
- If leakage should occur around the cuff, remove the mask and reinsert while ensuring that anesthetic depth is adequate.

MAGNETIC RESONANCE IMAGING (MR)

AuraOnce is MR-safe.

3.8. Removal procedure

Removal should always be carried out in an area where suction equipment and the facility for rapid tracheal intubation are available.

Do not remove AuraOnce with the cuff fully inflated to prevent tissue trauma and laryngospasm.

3.9. Disposal

Dispose of used Ambu AuraOnce in a safe manner according to local procedures.

4.0. Specifications

Ambu AuraOnce is in conformity with ISO 11712 Anaesthetic and respiratory equipment – Supralaryngeal airways and connectors.

	Pediatric				Adult			
Mask Size	**#1**	**#1½**	**#2**	**#2½**	**#3**	**#4**	**#5**	**#6**
Patient weight	2 – 5 kg	5 – 10 kg	10 – 20 kg	20 – 30 kg	30 – 50 kg	50 – 70 kg	70 – 100 kg	> 100 kg
Maximum intracuff volume	4 ml	7 ml	10 ml	14 ml	20 ml	30 ml	40 ml	50 ml
Maximum intracuff pressure	60 cmH_2O							
Connector	15 mm male (ISO 5356-1)							
Maximum instrument size*	4.5 mm	5.0 mm	6.5 mm	8.2 mm	8.5 mm	9.5 mm	11.0 mm	11.0 mm
Inflation Valve Luer cone compatibility	Luer cone compatible with ISO 594-1 and ISO 80369-7 compliant equipment							
Appropriate storage condition	10 °C (50 °F) to 25 °C (77 °F)							
Approximate mask weight	10 g	14 g	20 g	28 g	32 g	44 g	63 g	77 g
Internal volume of ventilatory pathway	5.1 ± 0.6 ml	7.5 ± 0.7 ml	10.9 ± 0.6 ml	13.8 ± 0.4 ml	13.6 ± 0.4 ml	19.4 ± 0.6 ml	27.3 ± 0.5 ml	33.1 ± 0.5 ml
Pressure drop as determined according to ISO 11712 annex C	0.3 cmH_2O at 15 l/min	0.2 cmH_2O at 15 l/min	0.2 cmH_2O at 30 l/min	0.2 cmH_2O at 30 l/min	0.3 cmH_2O at 60 l/min	0.3 cmH_2O at 60 l/min	0.2 cmH_2O at 60 l/min	0.2 cmH_2O at 60 l/min
Min. Interdental gap	13 mm	15 mm	17 mm	20 mm	21 mm	24 mm	27 mm	29 mm
Nominal length of the Internal ventilatory pathway	10.5 ± 0.6 cm	12.3 ± 0.7 cm	14.1 ± 0.8 cm	16.2 ± 1.0 cm	16.2 ± 1.0 cm	18.2 ± 1.1 cm	20.4 ± 1.2 cm	21.8 ± 1.3 cm

Table 1: Specifications for Ambu AuraOnce.

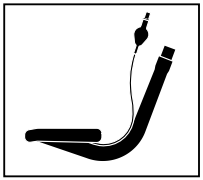
** The maximum instrument size is intended as a guide for selecting the appropriate diameter of a device to be passed through the patient tube of AuraOnce.*

A full list of symbol explanations can be found on https://www.ambu.com/symbol-explanation

Ambu

Ambu A/S
Baltorpbakken 13
2750 Ballerup
Denmark
T +45 72 25 20 00
ambu.com

Ambu Ltd
First Floor, Incubator 2
Alconbury Weald Enterprise Campus
Alconbury Weald
Huntingdon PE28 4XA
United Kingdom
www.ambu.co.uk



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