INSTRUCTIONS FOR USE

Ambu® Aura-i™

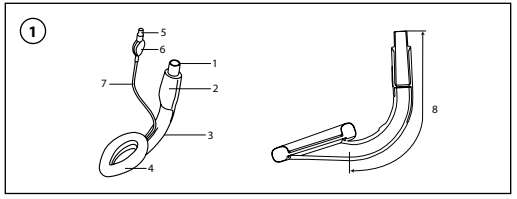
Single Use Laryngeal Mask – Sterile.

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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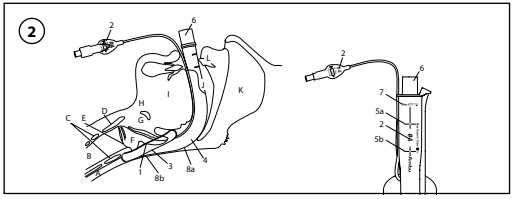
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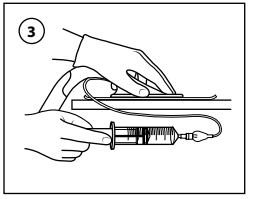
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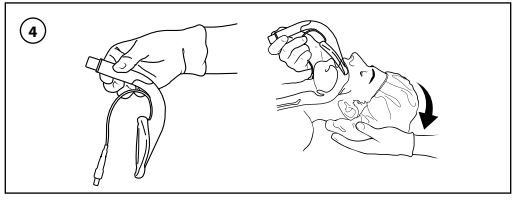
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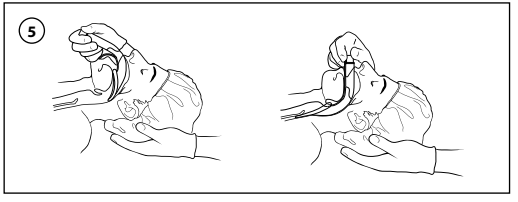
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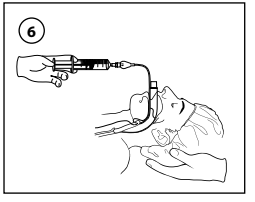
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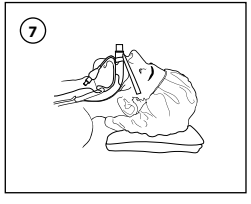
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1.1. Intended use/Indication for use
The Ambu Aura-i is intended for use as an alternative to a face mask for achieving and maintaining control of the airway during routine and emergency anaesthetic procedures in patients evaluated as eligible for a supraglottic airway.

1.2. Intended users and use environment
Medical professionals trained in airway management. Aura-i 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 Aura-i 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 Aura-i on another patient as it is a single use device. Re-use of a contaminated product can lead to infection.
4. Aura-i does not protect the trachea or lungs from the risk of aspiration.
5. Do not use excessive force when inserting and removing Aura-i 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 Aura-i in the presence of lasers and electrocautery equipment as this could lead to airway fire and tissue burns.
8. Do not perform blind endotracheal tube (ET-tube) intubation through Aura-i due to risk of failed intubation which can result in tissue damage and hypoxia.
9. In general, Aura-i 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 Aura-i and the external device to avoid the use of devices not being able to pass through lumen of Aura-i.
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 Aura-i 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.
6. For pediatric patients, if removal of Aura-i is planned after an ET-tube is placed through the mask, an ET-tube without cuff must be used to ensure the pilot balloon of the ET-tube does not block the removal of Aura-i.

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

Aura-i 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.

The design of the connector and patient tube allow intubation with ET-tubes.

Aura-i comes in 8 different sizes. The main components of Aura-i are seen in figure (1).

Figure 1 *(page 7)*: Overview of Aura-i parts:
1. Connector; **2.** Connector Shell; **3.** Patient tube; **4.** Cuff; **5.** Check valve; **6.** Pilot balloon; **7.** Pilot tube; **8.** Nominal length of internal ventilatory pathway*
** See Table 1 for the nominal length provided in centimeters.*

Figure 2 (*page 7*): Correct position of Aura-i in relation to Aura-i parts and anatomical landmarks
Aura-i parts: 1. Inflatable cuff; **2.** Size marking; **3.** Ventilatory opening; **4.** Ventilatory pathway; **5.** Normal depth of insertion marks; **6.** Machine end; **7.** Max. ET-tube size indication; **8.** Navigation marks for flexible scope.

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

Aura-i can be used in conjunction with:

- Ventilation equipment; 15 mm conical connectors in compliance with ISO 5356-1.
- Airway management devices; Bronchoscopes*, ET-tubes*, Intubation 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 and the maximum ET-tube size that can be used with each Aura-i mask size.*

3.0. Product use

3.1. Preparation before use

SIZE SELECTION

Ambu Aura-i comes in different sizes for use in patients of different weights.

For pediatric patients, it is recommended that Ambu Aura-i 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 AURA-I

Always wear gloves during the preparation and insertion of Ambu Aura-i to minimize contamination.

Handle Aura-i 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 Aura-i if the pouch seal has been damaged.

Closely examine Aura-i 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 Aura-i if it is blocked or damaged.

Deflate the cuff of Aura-i 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 Aura-i 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 connector shell with the thumb on the vertical line on the connector shell and three fingers placed on the opposite side of the connector shell. 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 connector shell 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 Aura-i 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 Aura-i, 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 Aura-i 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 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 Aura-i 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 connector shell should be oriented anteriorly towards the patient's nose.
- Aura-i is inserted correctly when the patient's incisors are between the normal depth of insertion marks (the two horizontal lines) on the connector shell. (2), item 5. Reposition the mask if the patient's incisors are outside this range.
- The position of Aura-i 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 Aura-i 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, Aura-i 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 Aura-i to avoid rotation of the mask.

USAGE WITH SPONTANEOUS VENTILATION
Aura-i 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 Aura-i 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.

INTUBATION THROUGH AURA-I
See Table 1 for selection of appropriate ET-tube size.

Always check the compatibility between the ET-tube and Aura-i before the procedure. Apply lubricant to the ET-tube and verify that it moves freely inside the patient tube of Aura-i.

INTUBATION INSTRUCTIONS
Direct flexible scope assisted endotracheal intubation can be performed through Aura-i, using a well-lubricated, fully deflated ET-tube. Integrated navigation marks provide guidance as to how far the flexible scope has been introduced. The first mark, Figure ② item 8a, indicates that the scope tip should be flexed to visualize the tracheal opening. The second mark, Figure ② item 8b, indicates that the flexible scope has been introduced too far.

Ambu Aura-i may be removed, taking care not to dislodge the ET-tube.

Do not remove the connector on Aura-i.

DIFFERENT TYPES OF ET-TUBES FOR PEDIATRIC PATIENTS
Aura-i is compatible with both cuffed and un-cuffed ET-tubes for intubation.

For Aura-i pediatric sizes, it is important to note that if removal of Aura-i is planned after an ET-tube is placed through the mask, an ET-tube without cuff must be used.

Intubation through Aura-i should always be performed in accordance with local guidelines.

Depending on the type of flexible scope used for pediatric patients, it may not be possible to flex the tip of the scope right at the first navigation mark. Instead, the tip may be flexed once the letter “u” of “use” has been visualized.

MAGNETIC RESONANCE IMAGING (MR)
Aura-i 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 Aura-i with the cuff fully inflated to prevent tissue trauma and laryngospasm.

3.9. Disposal
Dispose of used Ambu Aura-i in a safe manner according to local procedures.

4.0. Specifications
Ambu Aura-i 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*	5.0 mm	6.0 mm	8.2 mm	9.5 mm	10.2 mm	11.5 mm	12.5 mm	12.5 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	11 g	15 g	21 g	35 g	38 g	56 g	77 g	98 g
Internal volume of ventilatory pathway	4.8 ± 0.6 ml	5.9 ± 0.4 ml	8.8 ± 1.0 ml	13.8 ± 0.6 ml	15.3 ± 0.7 ml	23.6 ± 1.3 ml	30.7 ± 0.7 ml	36.1 ± 0.4 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	0.3 cmH_2O at 30 l/min	0.2 cmH_2O at 30 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	0.2 cmH_2O at 60 l/min
Max. ETT size	3.5	4.0	5.0	5.5	6.5	7.5	8.0	8.0
Min. Interdental gap	12 mm	14 mm	16 mm	19 mm	22 mm	25 mm	28 mm	31 mm
Nominal length of the Internal ventilatory pathway	9.1 ± 0.5 cm	10.5 ± 0.6 cm	12.2 ± 0.7 cm	14.5 ± 0.9 cm	14.2 ± 0.9 cm	16.6 ± 1.0 cm	17.8 ± 1.1 cm	19.3 ± 1.2 cm

Table 1: Specifications for Ambu Aura-i.

** 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 Aura-i.*

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

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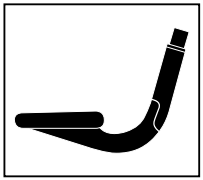

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