Ambu

Ideas that work for life

Product Information

Ambu® **Aura-i™**

Single Use Laryngeal Mask - Sterile

For use by trained clinicians only

RESPIRATORY CARE

Product information

This product information may be updated without further notice. Copies of the current version are available from the manufacturer.

Contents **Page**

US: Rx only

1. Warnings/Cautions

Throughout these directions for use, appropriate warnings are given describing potential safety hazards associated with use of the Ambu Aura-i.

WARNING ⚠

The user should be familiar with the following warnings prior to use of the Ambu Aura-i.

- The Ambu Aura-i is delivered sterile.
- To avoid trauma, do not use force at any time during insertion of the Ambu Aura-i.
- Adhere strictly to the recommended cuff inflation volumes, or lower, as specified in Table 3. Never over-inflate the cuff after insertion.
- Ambu Aura-i is to be used in patients, who have been clinically evaluated by a clinician familiar with anaesthesia as eligible for a Supraglottic Airway Device or in situations where other attempts to establish an airway has failed.
- In patients with severe oropharyngeal trauma, the Ambu Aura-i should only be employed when all other attempts to establish an airway have failed.
- The Ambu Aura-i is flammable in the presence of lasers and electrocautery equipment.
- Use of a nasogastric tube may make regurgitation likely because the tube may interfere with the function of the lower esophageal sphincter.
- Do not attempt to clean and reuse the Ambu Aura-i.
- Re-use can result in cross-infection

CAUTION ⚠

- US federal law restricts this device to be sold to or on the order of a physician.
- For use only by clinicians trained in the use of a Ambu Aura-i.
- Ensure that the device is not in any way damaged before use
- Make a brief functional check as described in section 6 before using the device. Failure of any test indicates that the device should not be used.
- If airway problems persist or ventilation is inadequate, the Ambu Aura-i should be removed and reinserted or a secure airway established by other means.
- Patients should be adequately monitored at all times during use.
- The secure function of all anaesthetic breathing system connectors should be checked before the breathing circuit is established.
- To minimize contamination, always wear gloves during the preparation and insertion of the Ambu Aura-i.
- Have a spare Ambu Aura-i ready and prepared for immediate use.
- When used with MRI, care should be taken to monitor the patient carefully to ensure that correct positioning of the tube is maintained.

2. Introduction

2.1. Intended use

The Ambu Aura-i 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 patients evaluated as eligible for a supraglottic airway or in situations where other attempts to establish an airway have failed.
The Ambu Aura-i may also be used where unexpected difficulties arise in connection with airway management.
The mask may also be preferred in some critical airway situations.
The Ambu Aura-i may also be used to establish a clear airway during resuscitation in profoundly unconscious patients with absent glossopharyngeal and laryngeal reflexes who may need artificial ventilation.
The device is not intended for use as a replacement of the endotracheal tube, and is best suited for use in surgical procedures where tracheal intubation is not deemed necessary.

2.2. Contraindications

The Ambu Aura-i does not protect the patient from the consequences of regurgitation and aspiration. Ambu Aura-i should only be used in patients, who have been clinically evaluated by a clinician familiar with anaesthesia, as eligible for a laryngeal mask or in a situation where other attempts to establish and airway have failed.
When the Ambu Aura-i is used in profoundly unconscious patients in need of resuscitation or in an emergency patient with a difficult airway situation (i.e. "cannot intubate, cannot ventilate"), there is a risk of regurgitation and aspiration. This risk must be carefully balanced against the potential benefit of establishing an airway (see the guidelines established by your own local protocol). The Ambu Aura-i should not be used for resuscitation or emergency treatment of patients who are not profoundly unconscious and who may resist insertion.

3. Specifications

The Ambu Aura-i function is in conformity with Council Directive 93/42/EEC concerning Medical Devices and ASTM standard no. ASTM F 2560-06 Standard Specification for Supralaryngeal Airways and Connectors. A summary of the methods, materials, data and results of clinical studies that validate the requirements of this standard is available on request, if applicable.
The Ambu Aura-i is a sterile and single use device.

CE 0086

See figure ① Ambu Aura-i

	Mask size							
	#1	**#1½**	**#2**	**#2½**	**#3**	**#4**	**#5**	**#6**
① Airway connector	15 mm male (ISO 5356-1)							
② Min. I.D. Tube	6.3 mm	6.9 mm	8.7 mm	10.0 mm	11.0 mm	12.4 mm	12.7 mm	12.7 mm
④ Inflation Valve	Luer cone (ISO 594-1)							
Appropriate storage temperature	10 °C (50 °F) to 25 °C (77 °F)							
Weight	11 g	15 g	21 g	35 g	38 g	56 g	77 g	98 g
Internal volume of ventilatory pathway	5 ml	6 ml	9 ml	14 ml	14 ml	24 ml	31 ml	36 ml
Pressure drop	<1.25 cm H_2O at 15 l/min	<1.25 cm H_2O at 15 l/min	<1.25 cm H_2O at 30 l/min	<1.25 cm H_2O at 30 l/min	<1.25 cm H_2O at 60 l/min	<1.25 cm H_2O at 60 l/min	<1.25 cm H_2O at 60 l/min	<1.25 cm H_2O at 60 l/min
Min. interdental gap	15 mm	17 mm	20 mm	24 mm	26 mm	30 mm	33 mm	35 mm
⑦ Internal pathway	9.1 cm	10.7 cm	12.2 cm	14.6 cm	14.2 cm	16.2 cm	17.8 cm	19.2 cm

Table 1. Specifications for the Ambu Aura-i

3.1. Materials

The Ambu Aura-i is 100% latex free. The materials used for the product and packaging are:

Part	**Material**
① Airway connector	PVC
②/③ Tube/Cuff	PVC
④/⑤ Pilot balloon with inflation valve	PVC/Silicone
⑥ Pilot tube	PVC
Packaging - Vacuum shaped tray	GPET
Packaging - Pouch	Tyvek

Table 2. Material used for the Ambu Aura-i

See figure ① Ambu Aura-i.

4. Principles of operation

The Ambu Aura-i comes in eight different sizes for use in patients of different weight. See table below for selection guidelines and max. inflation volumes. Please note that the cuff inflation volumes shown in table 3 are maximum volumes. Applying the stated maximum inflation volume may respond to a cuff pressure above the maximum of 60 cm H_2O. It is recommended to continuously monitor the cuff pressure.

	Mask size							
	#1	#1½	#2	#2½	#3	#4	#5	#6
Patient weight	<5 kg	5 – 10 kg	10-20 kg	20 – 30 kg	30 – 50 kg	50 – 70 kg	70 – 100 kg	> 100kg
Maximum cuff inflation volume	4 ml	7 ml	10 ml	14 ml	20 ml	30 ml	40 ml	50 ml
Maximum intra-cuff pressure	60 cm H_2O							

Table 3. Selection guidelines for the Ambu Aura-i

The mask is designed to conform to the contours of the hypopharynx with its lumen facing the laryngeal opening.
When correctly inserted, the distal tip of the cuff rests against the upper oesophageal sphincter.

See figure ② Correct position of the Ambu Aura-i in relation to anatomical landmarks

Anatomical Landmarks	
A - Esophagus	H - Tongue
B - Trachea	I - Buccal cavity
C - Cricoid ring	J - Nasopharynx
D - Thyroid cartilage	K - Incisors
E - Laryngeal inlet	
F - Epiglottis	
G - Hyoid bone	

Aura-i parts
1 - Patient end
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 optical scope

Table 4. Description of anatomical landmarks and Ambu Aura-i parts

5. Adverse effects

Use of the Ambu Aura-i may cause minor adverse effects (e.g., sore throat) and major adverse effects (e.g., aspiration).

6. Preparation for use

6.1. Functional testing

Functional testing as described below must be carried out before using the device. The tests should be conducted in a manner consistent with accepted medical practice that minimizes contamination of the Ambu Aura-i prior to insertion.

CAUTION ⚠

- Handle the Ambu Aura-i carefully as it is made of PVC, which can be torn or punctured. Avoid contact with sharp or pointed objects.
- Always wear gloves during the preparation and insertion of the Ambu Aura-i to minimize contamination.
- Make sure that the cuff protector has been removed from the cuff

WARNING ⚠

- Do not use the device if any test fails.
- Dispose of the Ambu Aura-i in a safe manner according to local guidelines of medical waste.

6.1.1. Test 1 - Visual inspection

Closely examine the Ambu Aura-i for any damage, such as perforation, scratches, blockage, loose parts, etc. Do not use the Ambu Aura-i if it is damaged in any way.

6.1.2. Test 2 - Inflation/deflation test

Ambu recommends deflating the cuff of the Ambu Aura-i completely. Once deflated, check the cuff thoroughly for any wrinkles or folds. Over-inflate the cuff to the appropriate volume as specified in Table 5. 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.

WARNING ⚠

Do not use the Ambu Aura-i if there are any bulges on the cuff or if there are any signs of leakage.

Table 5. Test cuff over-inflation volumes for the Ambu Aura-i

	Mask size							
	#1	#1½	#2	#2½	#3	#4	#5	#6
Over-inflation cuff volumes	6 ml	10 ml	15 ml	21 ml	30 ml	45 ml	60 ml	75 ml

Table 5. Test cuff over-inflation volumes for the Ambu Aura-i

CAUTION ⚠

The inflation volumes specified in Table 5 are for testing purposes only. These volumes are not to be used during normal use of the device – the recommended standard inflation volumes can be found in Table 3.

7. Insertion

7.1. Pre-insertion preparation

Before insertion Ambu recommends to deflate the cuff completely so that the cuff is flat and free of wrinkles.
Simply press 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. Complete deflation results in a shape similar to the rim of a saucer, and facilitates insertion and correct positioning of the device.
Studies show that insertion of the laryngeal mask airway with the cuff either deflated or partly inflated is equally successful in experienced hands. See figure ③. Deflation of Ambu Aura-i.

WARNING ⚠

Lubricate the posterior tip of the cuff prior to insertion.
To further facilitate insertion into the patient, a sterile, water-based lubricant (e.g. K-Y Jelly®) should be applied to the distal posterior surface of the cuff (local anaesthesia is not recommended).

7.2. Insertion

Before insertion, it is essential that all clinicians using the Ambu Aura-i are familiar with the warnings, precautions, indications, and contraindications found in this Product Information.

The following points are extremely important:
- Check for correct deflation and lubrication as described above.
- The size of the Ambu Aura-i must fit the patient. Use the guidelines in Table 3 combined with clinical judgement to select the correct size.
- Always have a spare Ambu Aura-i ready for use.
- Pre-oxygenate and use standard monitoring procedures.
- Check that the level of anaesthesia (or unconsciousness) is adequate before attempting insertion.
- The head of the patient should be position extended with flexion of the neck in a position normally used for tracheal intubation (i.e. "the sniffing position").
- Never use excessive force.

7.3. Insertion Techniques

There are many insertion techniques currently in use. Insert the Ambu Aura-i in accordance with currently accepted medical techniques. One commonly used technique is the Pencil Insertion Technique, which is described below.

When inserting the Ambu Aura-i correctly, you must be careful about the following: Ensure that the cuff tip avoids entering the valleculae or the glottic opening and does not become caught up against the epiglottis or the arytenoids. The cuff should be deflated and pressed against the patient's posterior pharyngeal wall.

When the mask is in place, resistance will be felt.

7.3.1. Placement Technique
Provided that access to the patient's head from above is feasible, the below described insertion technique is recommended. The airway tube is held like a flute, with three fingers placed on the flat part of the connector shell. (Figure 4) and the thumb on the vertical line on the connector shell, which is oriented anteriorly toward the patient's nose. Your other hand should be placed under the patient's head.

See figure ④ Positioning the Ambu Aura-i during insertion.

Insert the tip of the cuff pressing upwards against the hard palate and flatten the cuff against it. Look carefully into the mouth to verify that the tip of the cuff is correctly flattened against the palate before proceeding – push the jaw gently downwards with your middle finger to open the mouth further.

See figure ⑤ Positioning the Ambu Aura-i for insertion.

As the tip of the cuff is placed correctly in the mouth opening, continue the movement by swinging the mask inward with a circular motion, pressing the contours of the hard and soft palate. Then advance the Ambu Aura-i into the hypopharynx until a definite resistance is felt (Figure 5). The motion of the placement should be smooth.
Do not use force. The Ambu Aura-i should now be correctly located with its tip resting against the upper esophageal sphincter.

7.4. Insertion Problems
Coughing and breath-holding during Ambu Aura-i insertion indicates inadequate depth of anaesthesia – Immediately deepen anaesthesia 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.
Difficulty in manoeuvring the angle at the back of the tongue is one of the most common problems encountered when inserting the Ambu Aura-i. The tip must be pressed 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.

WARNING ⚠
Force should never be used during insertion.

7.5. Inflation
After insertion, the vertical line on the airway tube should be oriented anteriorly towards the patient's nose. The typical range of intended depth insertion is marked by the two horizontal lines on the airway tube (see figure ②, item 5). The Ambu Aura-i is inserted correctly when the patient's incisors are between these markings.
Reposition the mask if the patient's incisors are outside this range. Without holding the tube, inflate the cuff with just enough air to obtain a seal, equivalent to intracuff pressures of approximately 60 cm H_2O. In many cases, only half of the maximum volume is sufficient

to achieve a seal – please refer to Table 3 for maximum volumes. Check the cuff pressure continuously during the surgical procedure, either with a cuff pressure gauge or by feeling the tension in the pilot balloon. This is especially important when N_2O gases are used.

See figure ⑥ Inflation of Ambu Aura-i.

Never over-inflate the cuff. Avoid prolonged intracuff pressures greater than 60 cm H_2O.
The initial cuff pressure varies according to patient, mask size, head position, and depth of anaesthesia It is recommended to keep the cuff pressure as low as possible.
Do not hold the tube during inflation as this prevents the mask from seating itself correctly. A small outward movement of the tube may be seen as the mask is inflated.
To avoid over inflation, it is very important to strictly adhere to the cuff-inflation volumes stated in Table 3.

Over-inflation can be entirely avoided by completely deflating the cuff prior to insertion by withdrawing all of the air with a suitable syringe. This is the method recommended by Ambu. In instances where an alternative technique is adopted, for example, if the cuff is inserted in a neutral or semi-inflated state, there is a risk that the cuff may be over-inflated. Once the mask is inserted extra care must be taken to compensate for the air already in the mask when subsequently inflating the cuff. The maximum extra volume depends on mask size and initial volume of air in the mask when inserted.

Ambu recommends using a cuff pressure gauge for continuously monitoring the cuff pressure.

WARNING ⚠

Never overinflate the cuff after insertion. Keep the cuff pressure as low as possible to provide best possible seal.

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.

7.6. Connecting to the Anaesthetic System

Carefully connect the Ambu Aura-i to the anaesthetic circuit or ventilation bag and initiate gentle manual ventilation, looking for any signs of leakage. Auscultation over the lungs and epigastrium and capnography should be used to determine sufficient respiration. Auscultate in the anterolateral neck region to check for abnormal sounds that might indicate mild laryngeal spasm or light anaesthesia.
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 anaesthesia and that the pulmonary inflation pressures are low before assuming that reinsertion of the Ambu Aura-i is necessary.
As with other methods of airway management, use of pulse oximetry and capnography is recommended when using the Ambu Aura-i. The mask can be used for either spontaneous or controlled ventilation.

WARNING ⚠

- Any signs of airway problems or inadequate ventilation must be monitored regularly and the Ambu Aura-i must be replaced or removed as required to maintain a patent airway.
- During anaesthesia, nitrous oxide may diffuse into the cuff causing an increase in cuff volume/pressure. Cuff pressure should be monitored and adjusted routinely.
- The anaesthetic breathing system must be adequately supported when connected to the Ambu Aura-i to avoid rotation of the mask.
- The patency of the Ambu Aura-i should be reconfirmed after any change in the patient's head or neck position

7.7. Fixation

Secure the Ambu Aura-i to the patient's face with adhesive tape or with a mechanical tube holder suited for this purpose. Do not use an oral Guedel airway as a bite block because it will prevent correct positioning of the mask increasing the risk of trauma and reducing seal effectiveness.

See figure ⑦ Fixation of Ambu Aura-i.

In order to prevent stimulation of the patient's airway do not reposition or move the laryngeal mask during use and avoid moving the patient during anaesthesia to prevent stimulation of the airway.

WARNING ⚠

Avoid disturbing the mask during use.

7.8. Usage with Spontaneous Ventilation

The Ambu Aura-i is suitable for spontaneously breathing patients when used with volatile agents or intravenous aesthesia on condition that anaesthesia is adequate to match the level of surgical stimulus and the cuff is not overinflated.
Coughing, breath-holding, or movement may occur if the level of anaesthesia is inadequate for maintenance. This may well occur following the introduction of an external stimulus such as surgery or turning the patient if the level of anaesthesia has been misjudged. Gently assist ventilation until breathing returns.

7.9. Usage with Positive Pressure Ventilation

Before using the Ambu Aura-i with positive pressure ventilation (PPV), the operator should first acquire experience in its usage in spontaneously breathing patients.
Choose a ventilatory pattern giving peak airway pressures less than 20 cmH_2O and tidal volumes less than 8 ml/kg while the capnography is closely monitored.
In the event of leakage occurring during PPV, check for the following:
• light anaesthesia causing a degree of glottis closure
• inadequate neuromuscular block
• a reduction in lung compliance related to the surgical or diagnostic procedure
• displacement of the Ambu Aura-i by head turning or traction.

After identifying the cause of the leakage, take appropriate corrective measures.
If leakage should occur around the cuff, **do not simply add more air**. This will not necessarily improve the seal pressure and may even increase the leak by adding tension to the normally soft cuff, pushing it away from the larynx. Instead remove the mask and reinsert while providing that anaesthetic depth is adequate.

7.10. Critical observations during use

Inadequate level of anaesthesia: The most likely problem following insertion is failure to maintain an adequate level of anaesthesia. Administer an additional bolus of induction agent and/or increase the concentration of volatile agent while gently assisting ventilation.
Incorrect positioning of the Ambu Aura-i can be assessed by capnography, the observation of equal movements or by observation of changes in tidal volume, e.g. a reduction in expired tidal volume. If you suspect that the Ambu Aura-i has been positioned incorrectly, remove and reinsert – and provide that anaesthetic depth is adequate.
Unexpected regurgitation: Regurgitation may occur even in fasted patients (1:10,000).
This may be caused by inadequate level of anaesthesia. The first signs of regurgitation may be spontaneous breathing, coughing or breath-holding.
If regurgitation occurs, provided that oxygen saturation remains at acceptable levels, the Ambu Aura-i should not be removed. This should be managed by putting the patient in a "head-down" position. Briefly disconnect the anaesthetic circuit so that the gastric contents are not forced into the lungs. Check that anaesthetic depth is adequate and deepen anaesthesia intravenously, if appropriate.

Apply suction through the mask's airway tube and through the mouth. Suction the tracheobronchial tree and inspect the bronchia using a flexible optical scope.
If clinically indicated, commence preparation for immediate tracheal intubation. If aspiration has occurred, the patient should be given a chest X-ray and be treated with antibiotics, physiotherapy, and tracheal suction, as appropriate.

WARNING ⚠

If airway problems persist or ventilation is inadequate, the Ambu Aura-i should be removed and the airway managed as clinically indicated.

7.11. Recovery

On completion of surgery, the supraglottic airway (SGA) should be removed only after the patient's protective reflexes have returned and the patient responds to verbal commands.
Patient monitoring should continue throughout the recovery stage. Oxygen should be continuously administered through the anaesthetic circuit or via a T-piece. If suction is required around the oral cavity or down the airway tube, it should be carried out prior to recovery of reflexes.

7.12. 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 fully deflate the cuff until after its removal to avoid secretions entering the larynx and to prevent laryngospasm.

Alternatively, it may be removed moderately inflated to aid complete removal of secretions.
If the mask is to be removed in the Post-Anesthesia Care Unit, recovery room staff should receive thorough training in all aspects of the Ambu Aura-i.

WARNING ⚠

The sterile Ambu Aura-i is for single use only. Destroy after use.
Do not re-sterilise.

8. Specialized use

8.1. Intubation through the Ambu Aura-i

Direct optical scope assisted endotracheal intubation can be performed through the Aura-i.
It is important to pre-oxygenate the patient and to use standard monitoring procedures.
For paediatric use special clinical precautions must be taken. See section 8.3 of this document
Select the appropriate ET-tube size. See table 6 for appropriate ET-tube size. Apply lubricant to the ET-tube and verify that it moves freely inside the airway of the Aura-i.

The Ambu Aura-i is placed in the patient and the ET-tube is threaded over the optical scope.
The optical scope is inserted until carina is seen and ET-tube is advanced and left in the trachea.
Integrated navigation marks provide guidance as to how far the optical scope has been introduced. The first mark, Fig ② item 8a, indicates that the scope tip should be flexed to visualize the tracheal opening. The second mark, Fig ② item 8b, indicates that the optical scope has been introduced too far.
The Ambu Aura-i may be removed, taking care not to dislodge the ET-tube. Ambu recommends the "tube-to-tube" method for retaining the ET-tube when removing the Ambu Aura-i.
For certain procedures it is advantageous to leave the Ambu Aura-i in place after endotracheal intubation. In this case it is important to deflate the cuff of the Ambu Aura-i completely.

The below table provides information on the maximum ET-tube size that can be used with each Aura-i mask size

	Mask size							
	#1	#1½	#2	#2½	#3	#4	#5	#6
Max. ETT size	3.5	4.0	5.0	5.5	6.5	7.5	8.0	8.0

Table 6. Guide for appropriate ETT size selection

CAUTION ⚠

Remove the air completely from the cuff of the Ambu Aura-i if it is left in place after endotracheal intubation.

We do not recommend removing the airway connector on the Ambu Aura-i.

8.2. Use of the Ambu Aura-i for blind tracheal intubation

There is currently no published data on blind tracheal intubation through the Ambu Aura-i.
We have no clinical evidence to verify success rate and useful technique. We can therefore not recommend blind tracheal intubation through Ambu Aura-i.

8.3. Pediatric use

The Ambu Aura-i comes in four different sizes for infant/pediatric patients. See Table 3 for selection guidelines and maximum inflation volumes.
It is recommended that the Ambu Aura-i in neonates and small children is used by a clinician familiar with pediatric anesthesia.
There are several recommended methods for flexible optical scope assisted intubation of paediatric patients via a supraglottic airway (laryngeal mask). These include, but are not limited to, the use of a guide-wire or direct railroading the ET-tube over the flexible scope. Ambu recommends that users adhere to the method outlined in the local guidelines for paediatric airway management. Depending on the type of flexible scope used for paediatric 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.

It is important that an adequate level of anesthesia (or unconsciousness) is achieved before insertion of the Ambu Aura-i. The insertion should be successful at the same level of anesthesia that would be suitable for tracheal intubation.

Please note that with the Ambu Aura-i, as with any form of airway management and anesthesia in pediatric patients, where ventilation is insufficient, desaturation is likely to occur faster because of the higher oxygen consumption of pediatric patients.

8.4. Critical situations and emergencies

8.4.1. Critical situations

The Ambu Aura-i is not intended for use as a replacement for the endotracheal tube. However, in cases where tracheal intubation is not suitable or has failed, the Ambu Aura-i may be used successfully to establish an airway.

8.4.2. Emergencies

The Ambu Aura-i may be used during cardiopulmonary resuscitation, either as a temporary rescue airway or as a conduit for intubation. In the resuscitation situation, the patient must be profoundly unconscious with obtunded airway reflexes. The risk of regurgitation and aspiration must be balanced against the potential benefit of establishing an airway and providing oxygenation.

8.5. Magentic Resonance Imaging (MRI)

The Ambu Aura-i has been determined to be MRI safe and compatible. That is, when placed in a patient undergoing an MRI procedure, the Ambu Aura-i will nor present any additional risk to the patient, neither affect image quality.

WARNING ⚠

Care should be taken to monitor the patient carefully during MRI to ensure that correct positioning of the tube is maintained.

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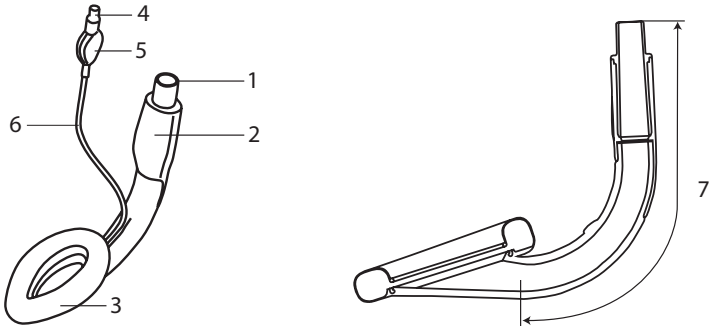

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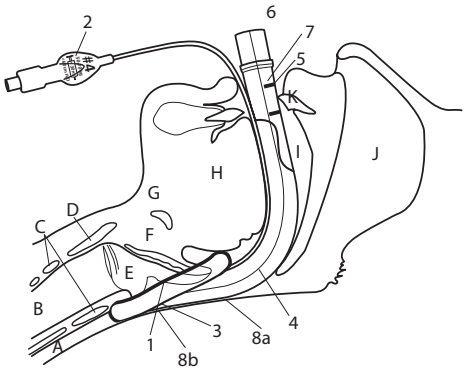

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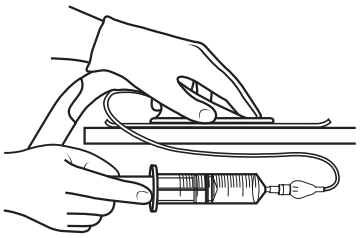

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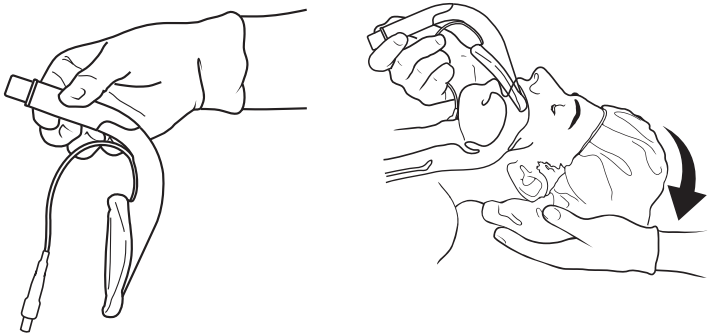

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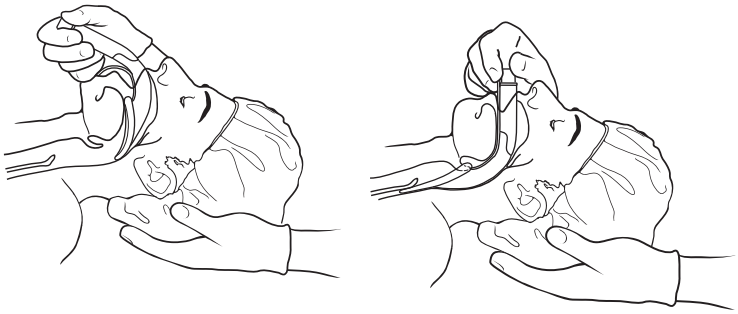

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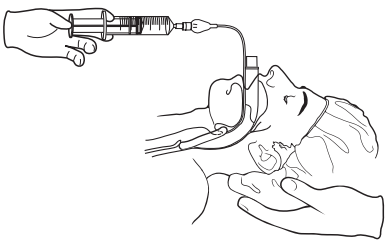

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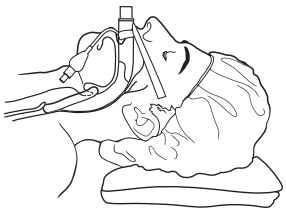

Symbol	Indication
	No latex. Stated when products are latex free.
	Single use only
	Caution, consult accompanying documents
	Use by date
LOT	Traceable number
REF	Catalogue number/Catalog number
	Product contains DEHP

This product information may be updated without further notice.
Copies of the current version are available from the manufacturer.

Corporate Head Office & Manufacturer:
Ambu A/S
Baltorpbakken 13
DK-2750 Ballerup
Denmark
Tel.: +45 7225 2000
Fax: +45 7225 2050
www.ambu.com

USA
Ambu Inc.
6740 Baymeadow Drive
Glen Burnie, MD 21060
Tel.: +1 410 768 6464
+1 800 262 8462
Fax: +1 410 760 4907
www.ambuusa.com

France
Ambu S.A.R.L
Airspace — 6, Rue Gagarine
F-33185 Le Haillan
Tel.: +33 5 57 92 31 50
Fax: +33 5 57 92 31 59
www.ambu.fr

Germany
Ambu GmbH
In der Hub 5
D-61231 Bad Nauheim
Tel.: +49 6032 92500
Fax: +49 800 ambude
www.ambu.de

UK
Ambu Ltd.
8 Burrel Road
St. Ives
Cambridgeshire PE27 3LE
Tel.: +44 (0) 1480 498 403
Fax: +44 (0) 1480 498 405
www.ambu.co.uk

Italy
Ambu S.R.L
Via Paracelso, 18
Centro Direzionale Colleoni
20041 Agrate Brianza - Milano
Italia
Tel.: +39 039 657811
Fax: +39 039 6898177
www.ambu.it

Spain
Firma Ambu S.L.
Alcalá, 261-265, Edf. 2-3º dcha.
28027 Madrid
Tel: +34 91 411 68 30
Fax: +34 91 564 50 82
www.ambu.es

Netherlands
Ambu B.V.
Edisonstraat 16j
2809 PB Gouda
Tel.: +31 0182 526060
Fax: +31 0182 527073
www.ambu.nl

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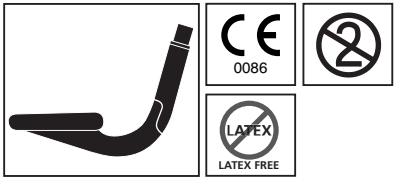

Ambu A/S
Baltorpbakken 13
DK-2750 Ballerup
Denmark
T +45 7225 2000
F +45 7225 2050
www.ambu.com

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