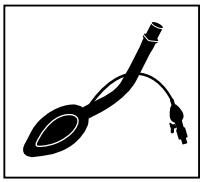

CE 0086

LATEX FREE

Pat. Pending

Product Information

Ambu® AuraOnce™

Single Use Laryngeal Mask – Sterile

For use by trained clinicians only.

Ideas that work for life

Product information

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

Contents **Page**

1. Warnings/Cautions

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

⚠ WARNING

The user should be familiar with the following warnings prior to use of the Ambu AuraOnce.

- The Ambu AuraOnce is delivered sterile.
- Lubricate only the posterior tip of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.
- To avoid trauma, do not use force at any time during insertion of the Ambu AuraOnce.
- Adhere strictly to the recommended cuff inflation volumes as specified in Table 3. Never over-inflate the cuff after insertion.
- Ambu AuraOnce is to be used in patients, who have been clinically evaluated by a physician as eligible for a laryngeal mask airway.
- In patients with severe oropharyngeal trauma, the Ambu AuraOnce should only be employed when all other attempts to establish an airway have failed.
- The Ambu AuraOnce 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 AuraOnce.

⚠ 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 AuraOnce.
- 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 AuraOnce 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 AuraOnce.
- Have a spare Ambu AuraOnce 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 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.
The Ambu AuraOnce 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 AuraOnce 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 AuraOnce does not protect the patient from the consequences of regurgitation and aspiration.

The following contraindications apply in the case of routine use in elective surgical procedures or in difficult airway patients:

- Patients who have not fasted (including those cases where fasting cannot be confirmed).
- Patients who are pathologically obese or more than 14 weeks pregnant.
- Patients with massive or acute injury to the abdomen or thorax.
- Patients with any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.
- Patients where peak airway inspiratory pressures are anticipated to exceed 20 cm H_2O (because the Ambu AuraOnce forms a low-pressure seal around the larynx).

When the Ambu AuraOnce 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 AuraOnce 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 AuraOnce function is in conformity with
Council Directive 93/42/EEC concerning Medical Devices
and ASTM standard no. ASTM 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.

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The Ambu AuraOnce is a sterile and single use device.

See figure ①. Ambu AuraOnce.

	Mask size							
	#1	**#1½**	**#2**	**#2½**	**#3**	**#4**	**#5**	**#6**
① Airway connector	15 mm male (ISO)							
② Min. I.D. Tube	5,2 mm	7,3 mm	8,6 mm	8,5 mm	8,5 mm	9,6 mm	10,6 mm	11,3 mm
② Max. O.D. Tube	10,5 mm	13 mm	15 mm	17,5 mm	17,5 mm	20 mm	22,5 mm	25 mm
④ Inflation Valve	Luer cone (DIN 13090 F6)							
Appropriate storage temperature	10 °C (50 °F) to 25 °C (77 °F)							
Dimensions (mm) (length x width x height)	97x 24x70	112x 29x82	128x 34,5x95	148x 41x109	148x 49x116	168x 56x132	187x 64x148	200x 69x165
Weight	9,2 g	13,4 g	19,3 g	27,8 g	30,8 g	43,7 g	59,9 g	75,1 g
Internal volume of ventilatory pathway	5,5 ml	8 ml	11 ml	15 ml	16 ml	21 ml	30 ml	38 ml
Pressure drop	<1,2 cmH_2O at 15 l/min	<0,8 cmH_2O at 15 l/min	<1,0 cmH_2O at 30 l/min	<0,8 cmH_2O at 30 l/min	<2,0 cmH_2O at 60 l/min	<1,2 cmH_2O at 60 l/min	<0,8 cmH_2O at 60 l/min	<0,5 cmH_2O at 60 l/min
Min. interdental gap	15 mm	17 mm	19 mm	21 mm	25 mm	29 mm	31 mm	32 mm
⑦ Internal pathway	10,3 cm	12,0 cm	13,8 cm	15,9 cm	15,9 cm	17,8 cm	20,0 cm	22,0 cm

Table 1. Specifications for the Ambu AuraOnce

3.1. Materials

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

Part	**Material**
① Airway connector	Polypropylene (PP)
②/③ Tube/Cuff	PVC Medical compound
④ Pillotballoon with inflationvalve	PVC/PC/Silicone
⑥ Pilot tube	PVC Medical compound
Packaging - Vacuum shaped tray	GPET
Packaging - Pouch	Tyvek

Table 2. Material used for the Ambu AuraOnce
See figure ① Ambu AuraOnce

4. Principles of operation

The Ambu AuraOnce 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 tabel 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	>100 kg
Maximum cuff inflation volume	4 ml	7 ml	10 ml	14 ml	20 ml	30 ml	40 ml	50 ml
Maximum intracuff pressure	60 cm H_2O							

Table 3. Selection guidelines for the Ambu AuraOnce

The mask is designed to conform with 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 AuraOnce in relation to anatomical landmarks

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

AuraOnce part
1 - Patient end
2 - Size marking
3 - Ventilatory opening
4 - Ventilatory pathway
5 - Normal depth of insertion marks
6 - Machine end

Table 4. Description of anatomical landmarks and Ambu AuraOnce parts

5. Adverse effects

Use of the Ambu AuraOnce 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 AuraOnce prior to insertion.

⚠ **CAUTION**

- Handle the Ambu AuraOnce 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 AuraOnce to minimize contamination.

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

6.1.1. Test 1 - Visual inspection

Closely examine the surface of the Ambu AuraOnce for any damage, perforation, scratches, etc. Do not use the Ambu AuraOnce if it is damaged in any way.
Check that the interior of the tube and cuff are free from blockage and any loose parts. Parts and blockages should be removed as these may prevent the device from functioning properly. Do not use the Ambu AuraOnce if any loose parts or blockages cannot be removed.
Check that the airway connector on the Ambu AuraOnce is fitted tightly to the airway tube. Ensure that it cannot easily be pulled off. Do not twist the connector as this may break the seal.

⚠ WARNING
- Do not use the Ambu AuraOnce if the mask connector does not fit tightly into the outer end of the airway tube.

6.1.2. Test 2 - Inflation/deflation test

Deflate the cuff of the Ambu AuraOnce 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 AuraOnce if there are any bulges on the cuff or if there are any signs of leakage.

	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 AuraOnce

⚠ 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 of the Ambu AuraOnce, the cuff should be completely deflated 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.

See figure ③. Deflation of Ambu AuraOnce.

> ⚠ **WARNING**
> Lubricate only the posterior tip of the cuff to prevent blockage of the airway aperture or aspiration of the lubricant.

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 AuraOnce are familiar with the warnings, precautions, indications, and contraindications found in these Product Information.

The following points are extremely important:

- Check for correct deflation and lubrication as described above.
- The size of the Ambu AuraOnce must fit the patient. Use the guidelines in Table 3 combined with clinical judgement to select the correct size.
- 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 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 AuraOnce in accordance with currently accepted medical techniques. One commonly used technique is the Pencil Insertion Technique, which is described below.

When inserting the Ambu AuraOnce 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 Pencil Insertion Technique provides better positioning than other insertion techniques. The airway tube is held like a flute, with three fingers placed above the junction of the cuff and the tube (Figure 4) and the thumb on the vertical line on the airway tube, 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 AuraOnce using the Pencil Insertion Technique

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 AuraOnce using the Pencil Insertion Technique

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 AuraOnce into the hypopharynx until a definite resistance is felt (Figure 5). The motion of the placement should be smooth. Do not use force. Do not hold the jaws open during this movement as this may allow the tongue and epiglottis to drop downwards, blocking passage of the mask. The Ambu AuraOnce should now be correctly located with its tip resting against the upper esophageal sphincter.

7.4. Insertion Problems

Coughing and breathholding 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. However, do not maintain downward jaw traction while the mask is being inserted behind the tongue.
Difficulty in manoeuvring the angle at the back of the tongue is one of the most common problems encountered when inserting the Ambu AuraOnce. The reinforced 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 AuraOnce 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 at start and periodically, either with a cuff pressure gauge or by feeling the tension in the pilot ballon. This is especially important when N_2O gases are used.

See figure ⑥. Inflation of Ambu AuraOnce.

Never over-inflate the cuff. Avoid prolonged intracuff pressures greater than 60 cmH_2O. The initial cuff pressure varies according to patient, mask size, head position, and depth of anaesthesia. 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 overinflation, 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. Extra care therefore must be taken after insertion 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.

> ⚠ **WARNING**
> Never overinflate the cuff after insertion.

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 AuraOnce 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 AuraOnce is necessary.
As with other methods of airway management, use of pulse oximetry and capnography is recommended when using the Ambu AuraOnce. 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 AuraOnce 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 AuraOnce to avoid rotation of the mask.

7.7. Fixation

Secure the Ambu AuraOnce 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. It is recommended to use a gauze bite block.

See figure ⑦. Fixation of Ambu AuraOnce.

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 AuraOnce 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 AuraOnce 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 anesthesia 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 AuraOnce 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 AuraOnce 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 AuraOnce has been positioned incorrectly, remove and reinsert – and provide that anaesthetic depth is adequate.

Unexpected regurgitation: Some regurgitation may occur even in fasted patients. This may be caused by inadequate level of anaesthesia. One early sign of regurgitation is the appearance of fluid travelling up the Ambu AuraOnce airway tube. If the patient is breathing spontaneously, coughing or breath-holding may be the first sign.

If regurgitation occurs, provided that oxygen saturation remains at acceptable levels, the Ambu AuraOnce should not be removed. The patient should immediately be tilted head down. Briefly disconnect the anaesthetic circuit so that the gastric contents are not forced into the lungs. Check that anaesthetic depth is adequate and deepen anesthesia intravenously, if appropriate. Apply

suction through the mask's airway tube and through the mouth. Suction of the tracheobronchial tree using a fiberoptic bronchoscope through the mask may be employed if the airway reflexes are adequately obtunded.
If clinically indicated, commence preparation for immediate tracheal intubation. If aspiration has occured, 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 AuraOnce should be removed and the airway managed as clinically indicated.

7.11. Recovery

On completion of surgery the laryngeal mask 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 anesthetic 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 AuraOnce.

> ⚠ **WARNING**
> The sterile Ambu AuraOnce is for single use only. Destroy after use.
> Do not re-sterilise.

8. Specialized use

8.1 Use of the Ambu AuraOnce for endoscopy and fiberoptic intubations

A flexible fiberoptic bronchoscope can be used through the Ambu AuraOnce to view the airway. It is important to pre-oxygenate the patient and to use standard monitoring procedures.

Table 1 shows the internal diameters and tube lengths of the different Ambu AuraOnce sizes. Table 6 shows the maximum fiberoptic bronchoscope and endotracheal tube that can be placed through the different Ambu AuraOnce sizes.

	Mask size							
	#1	**#1½**	**#2**	**#2½**	**#3**	**#4**	**#5**	**#6**
Max. ETT size	3,5	4,0	4,5	5,0	6,0	6,0	7,0	7,0
Max. FOB size	2,7	3,0	3,5	4,0	5,0	5,0	5,5	5,5

Table 6. Maximum endotracheal tube (ETT) and fiber optic bronchoscopes (FOB) sizes

Fiberoptic intubation through the Ambu AuraOnce can be done using a well-lubricated, fully de-

flated endotracheal tube threaded over the fiberoptic bronchoscope. Since the outside diameter of endotracheal tubes may vary, the compatibility between the endotracheal tube and the Ambu AuraOnce should be tested before the procedure to make sure that the chosen endotracheal tube may be helpful in fiberoptic intubation through the Ambu AuraOnce.

> ⚠ **CAUTION**
> We do not recommend removing the airway connector on the Ambu AuraOnce. Therefore, the chosen ET tube must be able to pass through the Ambu AuraOnce

> ⚠ **CAUTION**
> Pre-oxygenate the patient before initiating fiberoptic intubation and monitor the patient during the fiberoptic intubation using standard monitoring procedures.

When the vocal cords are visualized, the tip of the fiberoptic bronchoscope is passed into the trachea, and endotracheal tube is threaded downwards into the trachea over the fiberoptic bronchoscope. The endotracheal tube cuff is inflated, and ventilation is initiated while correct position is checked by auscultation and capnography. Leave the Ambu AuraOnce in place with the cuff slightly deflated. The Ambu AuraOnce may be removed when protective reflexes have returned.

If a larger endotracheal tube is needed, insert a tube changer through the endotracheal tube and remove both the Ambu AuraOnce and the endotracheal tube. Use the tube changer to guide a larger endotracheal tube into place.

8.2 Use of the Ambu AuraOnce for Blind tracheal intubation

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

8.3. Pediatric use

The Ambu AuraOnce 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 AuraOnce in neonates and small children is used by an anesthesiologist familiar with pediatric patients and already experienced in adult laryngeal mask airway management.
The insertion of the Ambu AuraOnce in pediatric patients can be performed in the same way as described for adults following either intravenous or gaseous induction. It is important that an adequate level of anesthesia (or unconsciousness) is achieved before insertion. The insertion should be successful at the same level of anesthesia that would be suitable for tracheal intubation.
Please note that with the Ambu AuraOnce, 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 AuraOnce is not indicated for use as a replacement for the endotracheal tube. However, in cases where tracheal intubation is not suitable or has failed, the Ambu AuraOnce may be used successfully to establish an airway.

8.4.2. Emergencies

The Ambu AuraOnce may be used during cardiopulmonary resuscitation, either as a temporary rescue airway or as a conduit to 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.

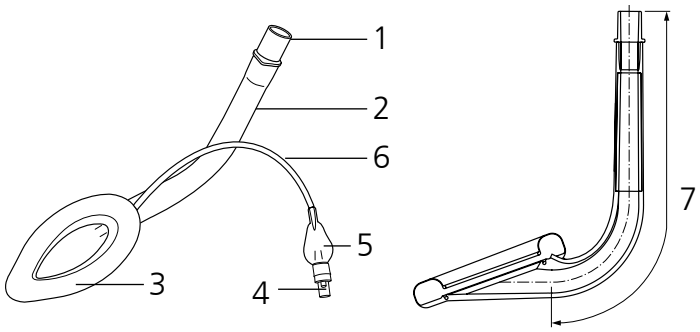
8.5 Magentic Resonans Imaging (MRI)

The Ambu AuraOnce has been determined to be MRI safe. That is, when placed in a patient undergoing an MRI procedure, the Ambu AuraOnce will not present any additional risk to the patient, but may affect image quality depending on the pulse sequence that is used and the imaging area of interest.

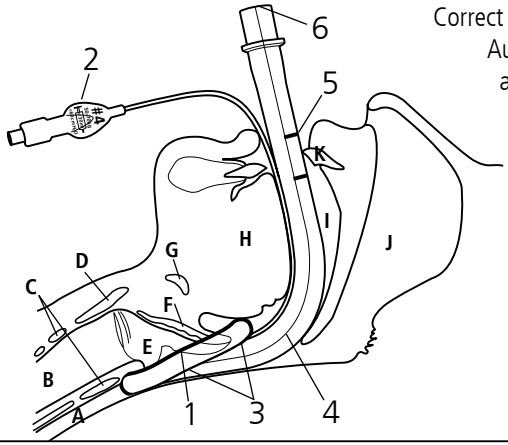
⚠ **WARNING**

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

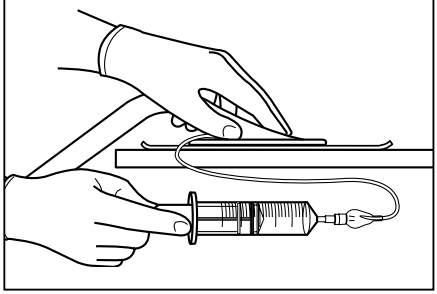
① Ambu AuraOnce



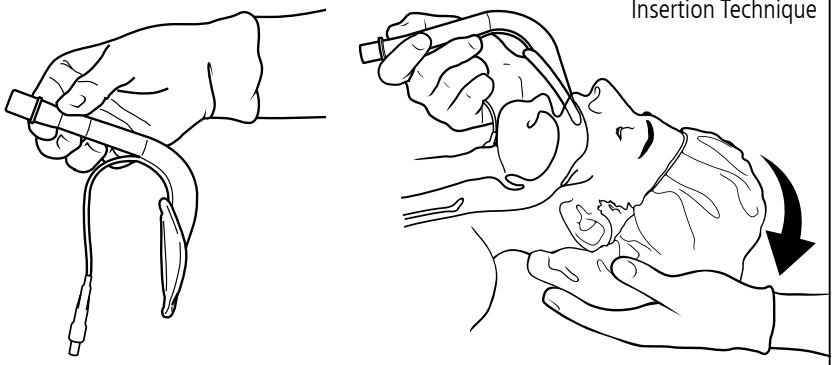
② Correct position of the Ambu AuraOnce in relation to anatomical landmarks



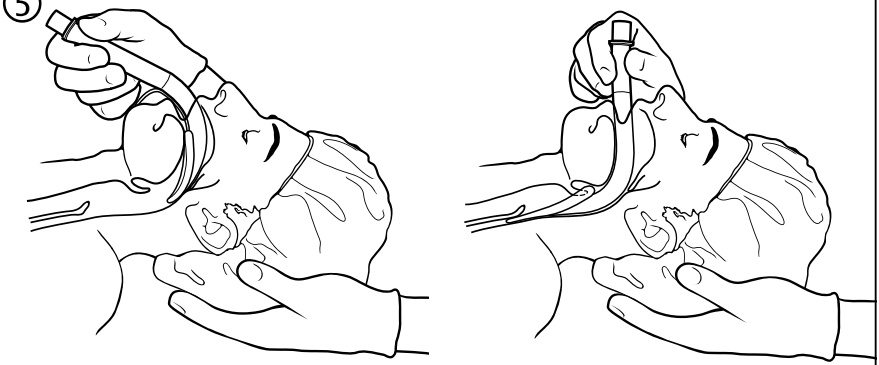
③ Deflation of the Ambu AuraOnce



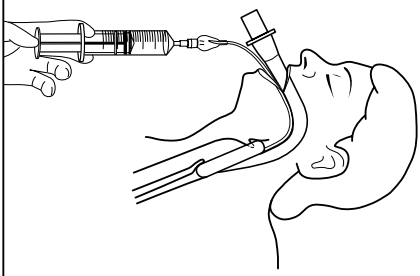
④ Position of the Ambu AuraOnce using Pencil Insertion Technique



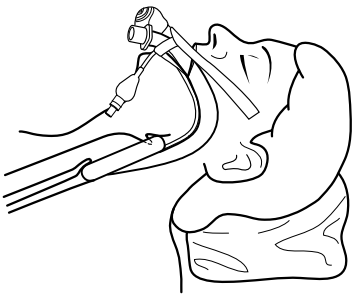
⑤



⑥ Inflation of Ambu AuraOnce



⑦ Fixation of Ambu AuraOnce



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

SN Serial number

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

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