Ambu
Ideas that work for life

Product Information

Ambu® **AuraFlex**

Single Use Laryngeal Mask – Sterile

For use by medical professionals trained in airway management only

US: Rx only

Ambu A/S is certified according to ISO 13485.

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 AuraFlex.

WARNINGS ⚠

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

- All Ambu AuraFlex masks must, prior to use, be investigated and inspected for any potential foreign body.
- The cuff-protector only serves as protecting the Ambu AuraFlex during storage and transportation and must be removed prior to use.
- The Ambu AuraFlex is delivered sterile.
- Do not attempt to clean and reuse the Ambu AuraFlex.
- 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 AuraFlex.
- Adhere strictly to the recommended cuff inflation volumes as specified in Table 3. Never over-inflate the cuff after insertion.
- Ambu AuraFlex is to be used in patients, who have been clinically evaluated by a clinician familiar with anaesthesia as eligible for a Supraglottic Airway Device.
- In patients with severe oropharyngeal trauma, the Ambu AuraFlex should only be employed when all other attempts to establish an airway have failed.
- Use of a nasogastric tube may make regurgitation likely because the tube may interfere with the function of the lower esophageal sphincter.
- The AuraFlex may be ineffective for use in patients with decreased pulmonary compliance due to fixed obstructive airways disease because positive pressure requirement may exceed seal pressure
- The benefits of establishing ventilation with the AuraFlex must be weighed against the potential risk of aspiration in some situations including symptomatic or untreated gastro-oesophageal reflux, pregnancy over 14 weeks, multiple or massive injury, conditions associated with the delayed gastric emptying, such as the use of opiate medication in patients with acute injury or peritoneal infectious or inflammatory processes
- The Ambu AuraFlex is flammable in the presence of lasers and electrocautery equipment.

CAUTIONS ⚠

- 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 AuraFlex.
- Ensure that the device is not in any way damaged before use.
- To minimize contamination, always wear gloves during the preparation and insertion of the Ambu AuraFlex.
- 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.
- Patients should be adequately monitored at all times during use.
- If airway problems persist or ventilation is inadequate, the Ambu AuraFlex should be removed and reinserted or a secure airway established by other means.
- The secure function of all anaesthetic breathing system connectors should be checked before the breathing circuit is established.
- Have a spare Ambu AuraFlex ready and prepared for immediate use.
- Ambu AuraFlex is not MRI safe nor MRI compatible.

2. Introduction

2.1. Intended use

The Ambu AuraFlex 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 AuraFlex 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 AuraFlex 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 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 with inadequate mouth opening to permit insertion
- Patients who have had radiotherapy to the neck involving the hypopharynx
- Patients representing for emergency surgery who are at risk of massive reflux, such as acute intestinal obstruction or patients having been injured shortly after ingesting a substantial meal

The Ambu AuraFlex does not protect the patient from the consequences of regurgitation and aspiration. Ambu AuraFlex should only be used in patients, who have been clinically evaluated by a clinician familiar with anesthesia, as eligible for a laryngeal mask airway.

When the Ambu AuraFlex 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 etablished by your own local protocol). The Ambu AuraFlex 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 AuraFlex function is in conformity with Council Directive 93/42/EEC concerning Medical Devices, and ISO 11712 Anaesthetic and respiratory equipment - Supralaryngeal airways and connectors. A summary of the methods, materials, data and results of clinical studies that validate the requirements of these standards are available on request, if applicable.
CE 0086
The Ambu AuraFlex is a sterile and single use device. A summary of the methods, materials, data and results of clinical studies that validate the requirements of these standards are available on request, if applicable.
The Ambu AuraFlex is a sterile and single use device.

Additional Product information

	Mask size					
	#2	**#2½**	**#3**	**#4**	**#5**	**#6**
① **Airway connector**	15mm ISO 5356-1					
② **Min. I.D. Tube**	6,0 mm	6,0 mm	7,5 mm	7,5 mm	8,5 mm	8,5 mm
② **Max. O.D. Tube**	9,7 mm	9,7 mm	11,5 mm	11,5 mm	12,5 mm	12,5 mm
④ **Inflation Valve**	Luer cone ISO 594-1					
Appropriate storage temperature	+10°C (50°F) to +25°C (77°F)					
Dimensions (mm) (length x width x height)	261x 34,5x95	270x 41x109	305x 49x116	315x 56x132	347x 64x148	357x 69x165
Weight	19,5 g	23,1 g	31,0 g	35,2 g	46,3 g	53,4 g
Internal volume of ventilatory pathway	8,5 ml	8,5 ml	14 ml	14 ml	19 ml	19,5 ml
Pressure drop	<0,2 cm H_2O at 30 l/min	<0,2 cm H_2O at 30 l/min	<0,3 cm H_2O at 60 l/min	<0,3 cm H_2O at 60 l/min	<0,2 cm H_2O at 60 l/min	<0,2 cm H_2O at 60 l/min
Min. interdental gap	19 mm	22 mm	23 mm	27 mm	30 mm	33 mm
⑦ **Internal pathway**	22 cm	22 cm	24,5 cm	24,5 cm	26,5 cm	27,0 cm

Table 1. Specifications for the Ambu AuraFlex

Specialized Use

	Mask size					
Mask size	**#2**	**#2½**	**#3**	**#4**	**#5**	**#6**
Max. FOB size	3,0 mm	3,0 mm	3,5mm	3,5mm	4,0 mm	4,0 mm

3.1. Materials

The Ambu AuraFlex is not made with natural rubber latex nor phthalates. The materials used for the product and packaging are:

Part	**Mask size**
① Airway connector	PCTG
②/③ Aurway tube / Cuff	PVC / Stainless Steel
⑤ Pilot balloon	PVC
④ Inflation valve	PC / Silicone / PP
⑥ Pilot tube	PVC
Packaging	Tyvek / HDPE

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

4. Principles of operation

The Ambu AuraFlex comes in six 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 applied to an evacuated cuff. 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.

	#2	**#2½**	**#3**	**#4**	**#5**	**#6**
Patient weight	10-20 kg	20-30 kg	30-50 kg	50-70 kg	70-100 kg	>100 kg
Maximum cuff inflation volume	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 AuraFlex

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 AuraFlex 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	

AuraFlex 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 AuraFlex parts

5. Adverse effects

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

WARNING ⚠

- Cuff malposition is usually due to incorrect insertion technique or inadequate depth of anaesthesia, and excessive cuff pressure due to over-inflation of the cuff following insertion, inappropriate size selection or diffusion of nitrous oxide into the cuffs. The effects of an incorrectly positioned and an overinflated cuff are most likely to be seen following prolonged surgery

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 AuraFlex prior to insertion.

CAUTIONS

- Handle the Ambu Auraflex 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 AuraFlex to minimize contamination.

WARNINGS

- Do not use the device if any test fails.
- Dispose of the Ambu AuraFlex 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 AuraFlex for any damage, perforation, scratches, etc. Do not use the Ambu AuraFlex 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 AuraFlex if any loose parts or blockages cannot be removed.
Check that the airway connector on the Ambu AuraFlex 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 AuraFlex 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 AuraFlex 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 AuraFlex if there are any bulges on the cuff or if there are any signs of leakage.

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

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

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. Therefore the clinician can insert the Ambu AuraFlex with a deflated or partly inflated cuff, since both ways works succesfully.

See figure ③. Deflation of Ambu AuraFlex.

WARNING

- 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 AuraFlex 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 AuraFlex must fit the patient. Use the guidelines in Table 3 combined with clinical judgement to select the correct size.
- Always have a spare Ambu AuraFlex 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 normaly 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 AuraFlex in accordance with currently accepted medical techniques. One commonly used technique is the Index-Finger Insertion Technique, which is described below.
When inserting the Ambu AuraFlex 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 Index-Finger Insertion Technique provides better positioning than other insertion techniques. Hold the Ambu AuraFlex like a pencil, with the index finger placed at the transition between the cuff and the airway tube.
With the wrist of the hand flexed, press the tip of the cuff upwards against the hard palate with the cuff flattened against it.

Make sure that the tip of the cuff is correctly flattened against the palate before proceeding. To ease the insertion, open the mouth by pushing the jaw downward with your middle finger, or instruct an assistant to pull the lower jaw downward.

Push the mask further into the mouth, while beginning the extension of the middle finger. Make sure the jaw is not held widely open during this procedure, as this could impose a risk of the tongue and epiglottis dropping downward, thereby blocking passage of the mask.

Using the index finger, press backward, while exerting counter pressure with the other hand. Avoid excessive force. Proceed the insertion of the mask into the hypopharynx until a definite resistance is felt.

Before pulling back the hand holding the mask, the other hand is used to press down on the airway tube. This ensures that the Ambu AuraFlex stays in place when the finger is removed.
Ambu AuraFlex should now be correctly positioned with its tip firmly pressed up against the upper esophageal sphincter.

See figure ④. Positioning the Ambu AuraFlex using the Index-Finger Insertion Technique
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 AuraFlex should now be correctly located with its tip resting against the upper esophageal sphincter.

7.4. Insertion Problems

Coughing and breathholding during Ambu AuraFlex 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 AuraFlex. 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 AuraFlex 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 ©. Inflation of Ambu AuraFlex.

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 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. 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 over-inflate 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 AuraFlex 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 AuraFlex is necessary. As with other methods of airway management, use of pulse oximetry and capnography is recommended when using the Ambu AuraFlex. The mask can be used for either spontaneous or controlled ventilation.

WARNINGS ⚠

- The anaesthetic breathing system must be adequately supported when connected to the Ambu AuraFlex to avoid rotation of the mask.
- Any signs of airway problems or inadequate ventilation must be monitored regularly and the Ambu AuraFlex 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 patency of the Ambu AuraFlex should be reconfirmed after any change in the patient's head or neck position

7.7. Fixation

Place a Boyle-Davis Gag if needed and fixate the Ambu AuraFlex according to surgical needs. It is recommended to use a gauze bite block.
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 AuraFlex 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 AuraFlex with positive pressure ventilation (PPV), the operator should first acquire experience in its usage in spontaneously breathing patients.
Choose a ventilatory pattern with the appropriate peak airway pressure and tidal volume 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 AuraFlex 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 AuraFlex 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 AuraFlex 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 AuraFlex 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 AuraFlex 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 AuraFlex 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.
The mask should not be removed with the cuff fully inflated. The mask may be removed with moderately inflated cuff to aid removal of secretions. Do not fully deflate the cuff until after its removal to avoid secretions entering into the larynx and to prevent laryngospasm.
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 AuraFlex.

WARNING ⚠

- The sterile Ambu AuraFlex is for single use only. Destroy after use.
- Use on other patients can cause cross infection. 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.

8. Specialized use

8.1 Use of the Ambu AuraFlex for endoscopy and fiberoptic intubations

The Ambu AuraFlex is not designed to support tracheal intubation. Direct intubation through the product is not recommended.

A flexible scope can be used through the Ambu AuraFlex to view the airway. It is important to preoxygenate the patient and to use standard monitoring procedures.

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

	Mask size					
	#2	#2½	#3	#4	#5	#6
Max. FOB O.D. (mm)	3,0	3,0	3,5	3,5	4,0	4,0

Table 6. Maximum fiber optic bronchoscopes (FOB) sizes

CAUTION ⚠

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

8.2 Use of the Ambu AuraFlex for blind tracheal intubation

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

8.3. Pediatric use

The Ambu AuraFlex comes in two different sizes for pediatric patients. See Table 3 for selection guidelines and maximum inflation volumes.
It is recommended that the Ambu AuraFlex in small children is used by an anesthesiologist familiar with pediatric patients and already experienced in adult flexible laryngeal mask airway management. The insertion of the Ambu AuraFlex 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 AuraFlex, 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

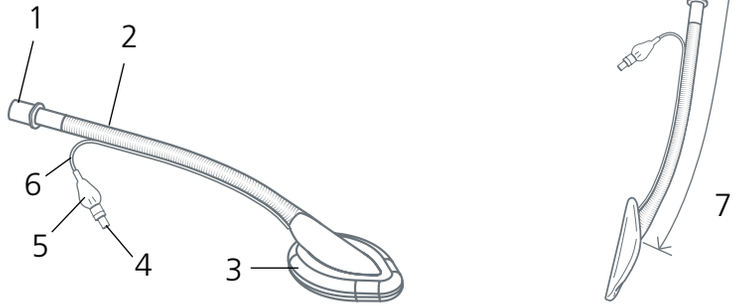
8.4.1. Critical situations

The Ambu AuraFlex 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 AuraFlex may be used successfully to establish an airway.

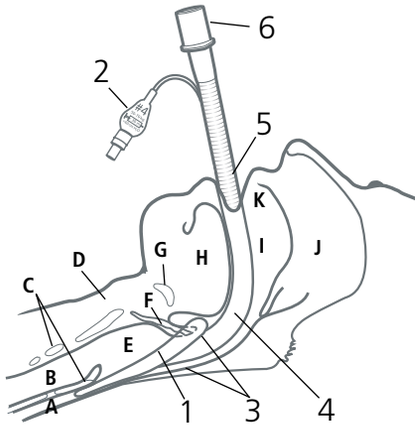
8.4.2. Emergencies

The Ambu AuraFlex 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.

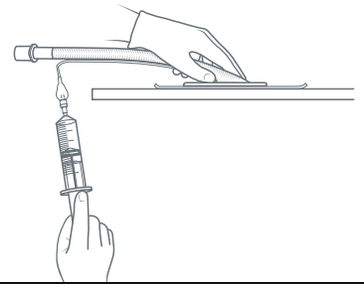
① Ambu AuraFlex



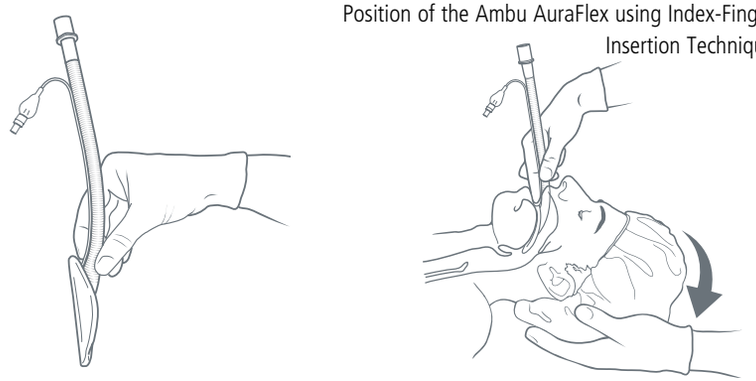
② Correct position of the Ambu AuraFlex in relation to anatomical landmarks



③ Deflation of the Ambu AuraFlex



④ Position of the Ambu AuraFlex using Index-Finger Insertion Technique



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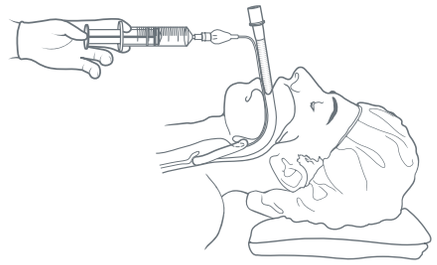
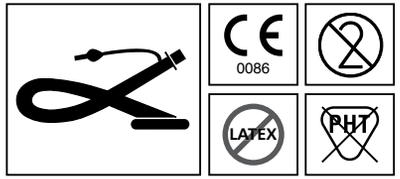
⑥ Inflation of Ambu AuraFlex



Symbol	Indication
	This product is not made with natural rubber latex
	Do not re-use
	Consult instructions for use
	Use-by date
LOT	Batch Code
REF	Catalogue number
	This product is not made with phthalates
	Manufacturer
STERILE R	Sterile Product, Sterilisation by irradiation (R)
	Do not use if the product sterilisation barrier or its packaging is damaged
	Warning



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

Corporate Head Office & Manufacturer:
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