

Pat. Pending

Ambu

Product Information

Ambu[®] **AuraStraight**[™] 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.

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1. Warnings/Cautions

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



WARNING

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

- The Ambu AuraStraight 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 AuraStraight.
- Adhere strictly to the recommended cuff inflation volumes as specified in Table 3. Never over-inflate the cuff after insertion.
- Ambu AuraStraight 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 AuraStraight should only be employed when all other attempts to establish an airway have failed.
- The Ambu AuraStraight 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 AuraStraight.



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 AuraStraight.
- 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 AuraStraight 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 AuraStraight.
- Have a spare Ambu AuraStraight 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 AuraStraight 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 AuraStraight 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 AuraStraight 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 AuraStraight 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 H₂O (because the Ambu AuraStraight forms a low-pressure seal around the larynx).

When the Ambu AuraStraight 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 AuraStraight 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 AuraStraight 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.



The Ambu AuraStraight is a sterile and single use device.

See figure ①. Ambu AuraStraight.

	Mask size							
	#1	#1½	#2	#2½	#3	#4	#5	#6
① Airway connector	15 mm male (ISO)							
② Min. I.D. Tube	5.7 mm	6.5 mm	7.4 mm	8.9 mm	9.8 mm	10.7 mm	11.0 mm	12.1 mm
② Max. O.D. Tube	9.6 mm	11 mm	12.2 mm	14.4 mm	16.1 mm	17.6 mm	19.3 mm	19.5 mm
④ Inflation Valve	Luer cone ISO 594-1							
Appropriate storage temperature	30°C (86°F) to 55°C (131°F)							
Weight	9.5 g	13.5 g	17.5 g	26.6 g	37.1 g	46.0 g	63.4 g	69.7 g
Internal volume of ventilatory pathway	3.5 ml	5.4 ml	6.7 ml	9.7 ml	13 ml	15 ml	20 ml	22 ml
Pressure drop	<1.5 cmH ₂ O at 15 l/min	<0.8 cmH ₂ O at 15 l/min	<1.9 cmH ₂ O at 30 l/min	<1.0 cmH ₂ O at 30 l/min	<2.2 cmH ₂ O at 60 l/min	<1.8 cmH ₂ O at 60 l/min	<1.2 cmH ₂ O at 60 l/min	<1.2 cmH ₂ O at 60 l/min
Min. interdental gap	12.8 mm	15.1 mm	17.1 mm	20 mm	23 mm	25.4 mm	27.4 mm	28.7 mm
⑦ Internal pathway	10.9 cm	11.6 cm	14.4 cm	15.9 cm	16.0 cm	17.1 cm	18.8 cm	20.4 cm

Table 1. Specifications for the Ambu AuraStraight

3.1. Materials

The Ambu AuraStraight 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 Pilotballoon with inflationvalve	PVC/PC/Silicone
⑥ Pilot tube	PVC Medical compound
Packaging - Cuff protection	Polyethylene (PE)
Packaging - Pouch	Tyvek/Polyethylene Terephthalate (PET)/Polyethylene (PE)

Table 2. Material used for the Ambu AuraStraight

See figure ① Ambu AuraStraight

4. Principles of operation

The Ambu AuraStraight 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 H₂O. 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 ₂ O							

Table 3. Selection guidelines for the Ambu AuraStraight

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 AuraStraight in relation to anatomical landmarks

Anatomical Landmarks		AuraStraight part
A - Esophagus	G - Hyoid bone	1 - Patient end
B - Trachea	H - Tongue	2 - Size marking
C - Cricoid ring	I - Buccal cavity	3 - Ventilatory opening
D - Thyroid cartilage	J - Nasopharynx	4 - Ventilatory pathway
E - Laryngeal inlet	K - Incisors	5 - Normal depth of insertion marks
F - Epiglottis		6 - Machine end

Table 4. Description of anatomical landmarks and Ambu AuraStraight parts

5. Adverse effects

Use of the Ambu AuraStraight 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 AuraStraight prior to insertion.



CAUTION

- Handle the Ambu AuraStraight 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 AuraStraight to minimize contamination.

**WARNING**

- Do not use the device if any test fails.
- Dispose of the Ambu AuraStraight 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 AuraStraight for any damage, perforation, scratches, etc. Do not use the Ambu AuraStraight 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 AuraStraight if any loose parts or blockages cannot be removed.

Check that the airway connector on the Ambu AuraStraight 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 AuraStraight if the mask connector does not fit tightly into the outer end of the airway tube.

6.1.2. Test 2 - Inflation/deflation test

Studies show that insertion of the laryngeal mask airway with the cuff either deflated or partly inflated is equally successful in experienced hands.

Ambu recommends to deflate the cuff of the Ambu AuraStraight 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 AuraStraight 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 AuraStraight

**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 it is up to the trained clinicians decision to insert the AuraStraight with a deflated or partly inflated cuff, since both ways work successfully.

See figure ③. Deflation of Ambu AuraStraight.

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).



WARNING

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

7.2. Insertion

Before insertion, it is essential that all clinicians using the Ambu AuraStraight 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 AuraStraight must fit the patient. Use the guidelines in Table 3 combined with clinical judgement to select the correct size.
- Always have a spare Ambu AuraStraight 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 AuraStraight 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 AuraStraight 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.

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 can be used. Hold the AuraStraight 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 AuraStraight stays in place when the finger is removed.

AuraStraight should now be correctly positioned with its tip firmly pressed up against the upper esophageal sphincter.

See figure ④. Positioning the Ambu AuraStraight 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 AuraStraight should now be correctly located with its tip resting against the upper esophageal sphincter.

7.4. Insertion Problems

Coughing and breathholding during Ambu AuraStraight 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 AuraStraight. 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 AuraStraight 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 H₂O. 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 balloon. This is especially important when N₂O gases are used.

See figure ③. Inflation of Ambu AuraStraight.

Never over-inflate the cuff. Avoid prolonged intracuff pressures greater than 60 cmH₂O. 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 AuraStraight 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 AuraStraight is necessary.

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

7.7. Fixation

Secure the Ambu AuraStraight 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 ②. Fixation of Ambu AuraStraight.

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 AuraStraight is suitable for spontaneously breathing patients when used with volatile agents or intravenous anaesthesia 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 AuraStraight 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 cmH₂O 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 AuraStraight 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 AuraStraight 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 AuraStraight 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 AuraStraight 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 AuraStraight 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 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 AuraStraight 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 AuraStraight.



WARNING

The sterile Ambu AuraStraight is for single use only. Dispose after use according to local guidelines. Do not re-sterilise.

8. Specialized use

8.1 Use of the Ambu AuraStraight for endoscopy and fiberoptic intubations

A flexible fiberoptic bronchoscope can be used through the Ambu AuraStraight 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 AuraStraight sizes. Table 6 shows the maximum fiberoptic bronchoscope and endotracheal tube that can be placed through the different Ambu AuraStraight sizes.

	Mask size							
	#1	#1½	#2	#2½	#3	#4	#5	#6
Max. ETT size	3.0	3.5	4.0	5.0	5.5	6,0	6.5	6.5
Max. FOB size	2.7	2.7	3.9	3.9	5.4	5.4	5.4	5.4

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

Fiberoptic intubation through the Ambu AuraStraight can be done using a well-lubricated, fully deflated 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 AuraStraight should be tested before the procedure to make sure that the chosen endotracheal tube may be helpful in fiberoptic intubation through the Ambu AuraStraight.



CAUTION

We do not recommend removing the airway connector on the Ambu AuraStraight. Therefore, the chosen ET tube must be able to pass through the Ambu AuraStraight



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 AuraStraight in place with the cuff slightly deflated. The Ambu AuraStraight 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 AuraStraight and the endotracheal tube. Use the tube changer to guide a larger endotracheal tube into place.

8.2 Use of the Ambu AuraStraight for blind tracheal intubation

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

8.3. Pediatric use

The Ambu AuraStraight 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 AuraStraight 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 AuraStraight 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 AuraStraight, 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 AuraStraight 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 AuraStraight may be used successfully to establish an airway.

8.4.2. Emergencies

The Ambu AuraStraight 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 Magnetic Resonance Imaging (MRI)

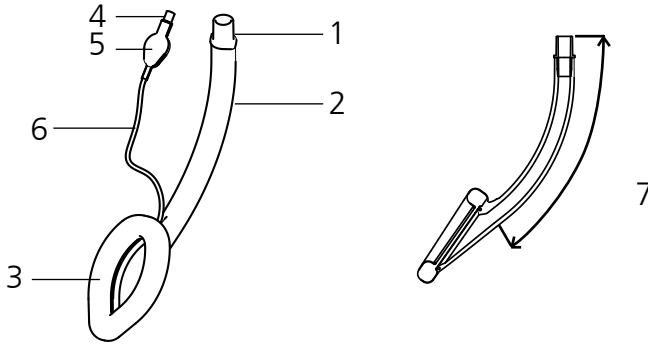
The Ambu AuraStraight has been determined to be MRI safe and compatible. That is, when placed in a patient undergoing an MRI procedure, the Ambu AuraStraight will not present any additional risk to the patient, neither affect image quality.



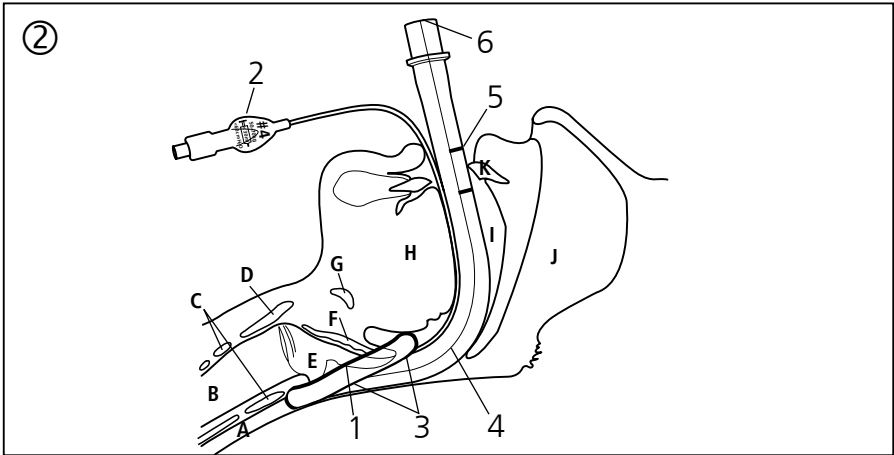
WARNING

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

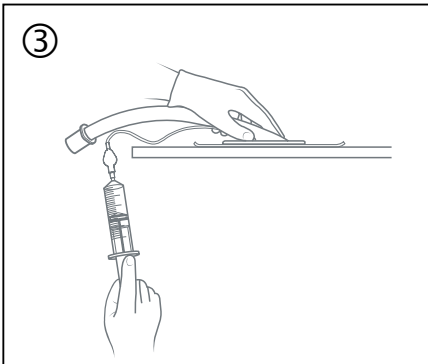
①

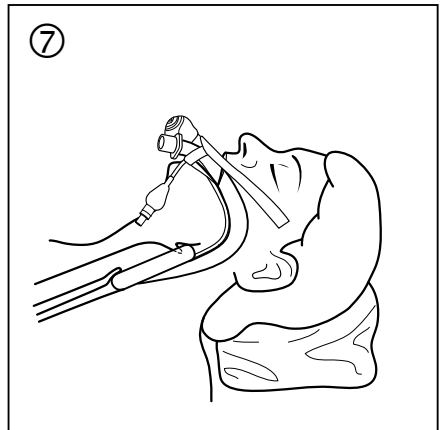
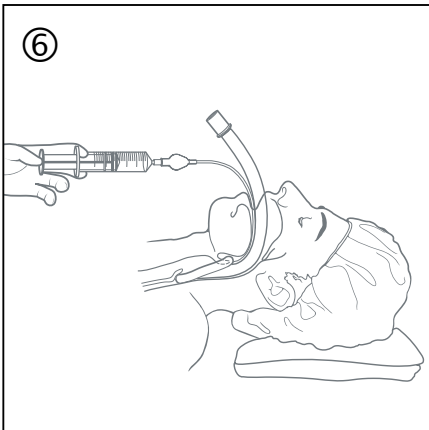
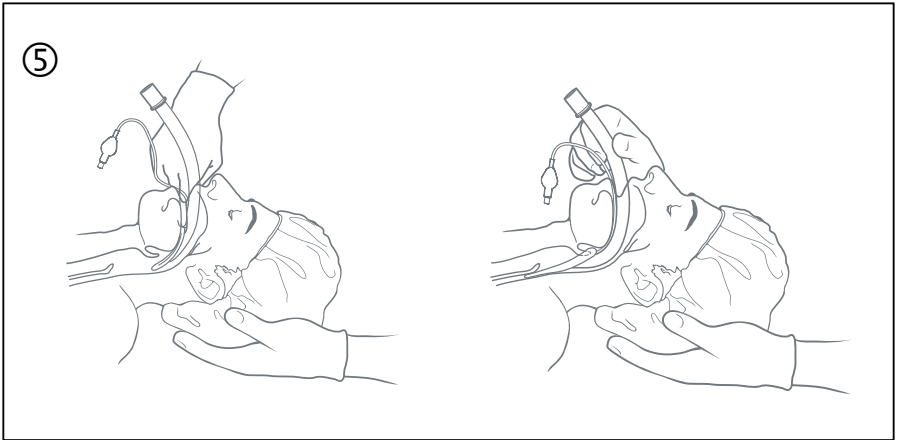
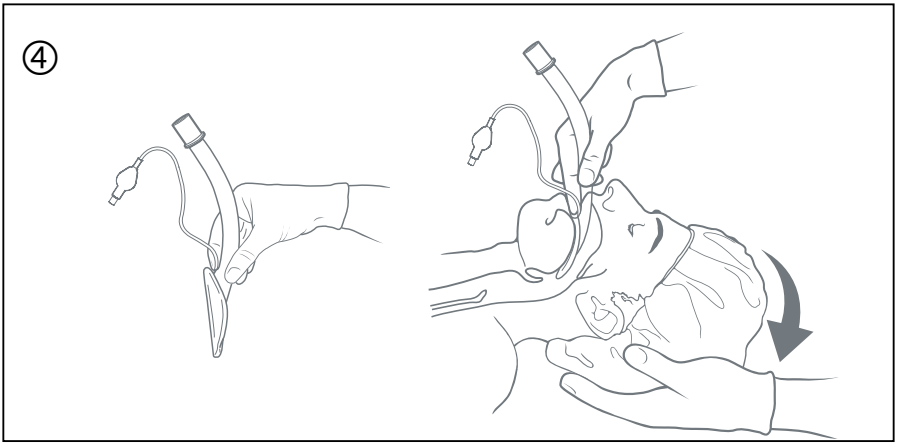


②



③







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

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Corporate Head Office:**Ambu A/S**

Baltorpbakken 13

DK-2750 Ballerup

Denmark

Tel.: +45 72 25 20 00

Fax: +45 72 25 20 50

E-mail: ambu@ambu.comwww.ambu.com**USA****Ambu Inc.**

6740 Baymeadow Drive

Glen Burnie, MD 21060

Tel.: +1 410 768 6464

Fax: +1 410 760 3993

www.ambuusa.com**France****Ambu S.A.R.L**

Airspace – Rue Gagarine 6

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 6032 9250200

www.ambu.de**UK****Ambu Ltd.**

8 Burrell Road

St. Ives

Cambridgeshire PE27 3LE

Tel.: +44 1480 498 403

Fax: +44 1480 498 405

www.ambu.co.uk**Italy****Ambu S.R.L**

Via Paracelso, 18

Centro Direzionale Colleoni

20041 Agrate Brianza - Mi

Tel. +39 039 657811

Fax +39 039 6898177

www.ambu.it**Spain****Ambu S.L.**

C/ Alcalá 261-265, Edificio 1 3º

izquierda

28027 Madrid

Telefon: 91 411 68 30

Fax: 91 564 50 82

www.ambu.es**Netherlands****Ambu B.V.**

Edisonstraat 16-j

2809 PB Gouda

Tlf.: +31 0182 573293

Fax: 031 0182 531364

www.ambu.nl**US: Rx only**

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