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Product Information

Ambu® **AuraGain™**

Single Use Laryngeal Mask - Sterile

For use by medical professionals trained in airway management only

US: Rx only

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

All Ambu AuraGain masks must, prior to use, be investigated and inspected for any potential foreign body. The cuff-protector only serves as protecting the AuraGain during storage and transportation and must be removed prior to use.

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

WARNINGS ⚠

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

- The AuraGain is delivered sterile.
- 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 AuraGain.
- To avoid trauma, do not use force at any time during insertion of the AuraGain.
- Adhere strictly to the recommended maximum intra cuff pressure and maximum inflation volumes, as specified in Table 3.
- Never over-inflate the cuff after insertion.
- AuraGain is to be used in patients, who have been clinically evaluated by a clinician familiar with anaesthesia as eligible for a Supraglottic Airway Device or in situations where other attempts to establish an airway have failed.
- Re-use can result in cross-infection.
- The AuraGain is flammable in the presence of lasers and electrocautery equipment.
- In patients with severe oropharyngeal trauma, the AuraGain should only be employed when all other attempts to establish an airway have failed.

CAUTIONS ⚠

- US federal law restricts this device to be sold to or on the order of a physician.
- To minimize contamination, always wear gloves during the preparation and insertion of the AuraGain.
- For use by medical professionals trained in airway management only.
- 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 AuraGain should be removed and reinserted or a secure airway established by other means.
- Have a spare AuraGain 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 SGA is maintained.
- The secure function of all anaesthetic breathing system connectors should be checked before the breathing circuit is established.
- Patients should be adequately monitored at all times during use.

2. Introduction

2.1. Intended use

The Ambu AuraGain is intended for use as an alternative to a face mask for achieving and maintaining control of the airway during routine and emergency anaesthetic procedures.

The AuraGain may be used where unexpected difficulties arise in connection with airway management. The device is intended for use as a conduit for an endotracheal tube in cannot intubate - cannot ventilate situations, as well as situations where is it necessary to place an endotracheal tube after insertion of the AuraGain.

The device is not intended as a replacement of an endotracheal tube, and is best suited for use in surgical procedures where tracheal intubation is not deemed necessary.

The AuraGain 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.

During use the gastric channel of AuraGain may be used as a conduit for passing a tube into the gastrointestinal system for removal of air and gastric fluids.

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

The AuraGain does not protect the patient from the consequences of regurgitation and aspiration. Ambu AuraGain should only be used in patients, who have been clinically evaluated by a clinician familiar with anaesthesia, as eligible for a laryngeal mask or in a situation where other attempts to establish and airway have failed.

When the AuraGain 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 AuraGain should not be used for resuscitation or emergency treatment of patients who are not profoundly unconscious and who may resist insertion.

3. Specifications

The AuraGain function is in conformity with Council Directive 93/42/EEC concerning Medical Devices and ASTM standard no. ASTM F 2560 Standard Specification for Supralaryngeal Airways and Connectors, 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 AuraGain is a sterile and single use device.

See figure ① AuraGain

	Mask size						
	#1	**#1½**	**#2**	**#2½**	**#3**	**#4**	**#5**
Airway connector 15 mm male (ISO 5356-1)	15 mm male (ISO 5356-1)						
Min. I.D. Tube	6,6 mm	7,2 mm	9,0 mm	10,2 mm	11,0 mm	12,6 mm	12,9 mm
Inflation Valve Luer cone (ISO 594-1)	Luer cone (ISO 594-1)						
Appropriate storage temperature	10 °C (50 °F) to 25 °C (77 °F)						
Weight	14 g	18 g	25 g	40 g	45 g	63 g	88 g
Internal volume of ventilatory pathway	3,3 ml	4,4 ml	10,2 ml	18,3 ml	17 ml	25 ml	33 ml
Pressure drop	0,0 cm H_2O at 15 l/min	0,0 cm H_2O at 15 l/min	0,1 cm H_2O at 30 l/min	0,1 cm H_2O at 30 l/min	<0.1 cm H_2O at 60 l/ min	<0.1 cm H_2O at 60 l/ min	0.0 cm H_2O at 60 l/ min
Min. interdental gap	11,6 mm	13,2 mm	16,2 mm	18,5 mm	21,0 mm	24,0 mm	27,0 mm
Internal pathway	9,4 cm	11,0 cm	12,7 cm	15,6 cm	14,2 cm	16,2 cm	19,0 cm

Table 1. Specifications for the Ambu AuraGain

3.1. Materials

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

Part	**Material**
① Airway connector	PCTG
② Bite absorption area	PVC
③ Cuff	PVC
④/⑤ Pilot balloon with inflation valve	PVC/Silicone
⑥ Pilot tube	PVC
⑦ Gastric channel	PVC
Packaging - Cuff protection	HDPE
Packaging - Pouch	Tyvek / PET

Table 2. Materials used for the Ambu AuraGain

See figure ① Overview of product parts for AuraGain.

4. Principles of operation

The Ambu AuraGain 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 will 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
Patient weight	< 5 kg	5-10 kg	10-20 kg	20-30 kg	30-50 kg	50-70 kg	70-100 kg
Maximum intracuff volume	4 ml	7 ml	10 ml	14 ml	20 ml	30 ml	40 ml
Maximum intracuff pressure	60 cm H_2O						

Table 3. Selection guidelines for the Ambu AuraGain.

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

See figure ② Correct position of the AuraGain in relation to anatomical landmarks

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

AuraGain parts
1 - Patient end
2 - Size marking
3 - Ventilatory opening
4 - Ventilatory pathway
5 - Normal depth of insertion marks
6 - Machine end
7 – Max. ET-tube size indication
8 - Navigation marks for flexible scope
9 – Max. gastric tube size indication
10 – Gastric channel

Table 4. Description of anatomical landmarks and AuraGain parts

5. Adverse effects

There is currently no data documenting adverse effects with the AuraGain™. Use of the AuraGain may cause minor adverse effects (e.g., sore throat) and major adverse effects (e.g., aspiration). However review of published literature shows the incidence of aspiration with a Supraglottic Airway is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anaesthsia[1].

Infrequent neurovascular events reported with Aura product use include tongue numbness, tongue cyanosis, recurrent nerve injury. Although this has not proven for individual cases, malposition and/or excessive intracuff pressure are likely on anatomical grounds to cause compression of nerves and/or blood vessels.

[1] Brimacombe JR, Laryngeal Mask Anesthesia, Principles and Practice, Saunders 2005.

WARNINGS ⚠

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 AuraGain prior to insertion

CAUTIONS ⚠

- Handle the Ambu AuraGain 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 AuraGain to minimize contamination.
- Make sure that the cuff protector has been removed from the cuff

WARNINGS ⚠

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

6.1.1. Test 1 - Visual inspection

Closely examine the Ambu AuraGain for any damage, such as perforation, scratches, cuts, tears, loose parts, etc.

Check that the interior of the airway tube, the drain tube and the 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 AuraGain if any loose parts or blockages cannot be removed.

Check that the airway connector on the Ambu AuraGain 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. Do not use the Ambu AuraGain if it is blocked or damaged in any way.

WARNINGS ⚠

Do not use the Ambu AuraGain if the mask connector does not fit tightly into the outer end of the airway tube.

6.1.2. Test 2 - Inflation/deflation test

Ambu recommends deflating the cuff of the AuraGain 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 AuraGain 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**
Over-inflation cuff volumes	6 ml	10 ml	15 ml	21 ml	30 ml	45 ml	60 ml

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

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 maximum intra cuff pressure and maximum inflation volumes can be found in Table 3.

7. Insertion

7.1. Pre-insertion preparation

Before insertion Ambu recommends to deflate the cuff completely so that the cuff is flat and free of wrinkles.

Simply press the cuff down onto a flat sterile surface (e.g. a piece of sterile gauze) while at the same time deflating the device with a syringe. Complete deflation results in a shape similar to the rim of a saucer, and facilitates insertion and correct positioning of the device.

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

See figure ③. Deflation of AuraGain.

WARNINGS ⚠

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

7.2. Insertion

Before insertion, it is essential that all clinicians using the Ambu AuraGain are familiar with the warnings, precautions, indications, and contraindications found in this Product Information.
The following points are extremely important:

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

7.3. Insertion Techniques

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

When inserting the AuraGain 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 Techniques

Provided that access to the patient's head from above is feasible, the below described insertion technique is recommended. The airway tube is held like a flute, with three fingers placed on the flat part of the bite absorption area (Figure 4) and the thumb on the vertical line on the bite absorption area, 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 AuraGain during insertion.

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

See figure ⑤ Positioning the AuraGain for insertion.

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

7.4. Insertion Problems

For pediatric patients a partial rotational technique is recommended in case of placement difficulties.

Coughing and breath-holding during Ambu AuraGain insertion indicates inadequate depth of anaesthesia – Immediately deepen anaesthesia with inhalational or intravenous agents, and initiate manual ventilation.
If you cannot open the patient's mouth sufficiently to insert the mask, check that the patient is adequately anesthetized. Ask an assistant to pull the jaw downwards thus making it easier to see into the mouth and verify the position of the mask.
Difficulty in manoeuvring the angle at the back of the tongue is one of the most common problems encountered when inserting the AuraGain. The tip must be pressed against the palate throughout or else the tip may fold on itself or meet an irregularity in the posterior pharynx, e.g. hypertrophied tonsils. Should the cuff fail to flatten or begin to curl over as it is inserted, withdraw the mask and reinsert it. In case of tonsillar obstruction, a diagonal movement of the mask is recommended.

WARNING ⚠

• Force should never be used during insertion.

7.5. Inflation

After insertion, the vertical line on the airway tube should be oriented anteriorly towards the patient's nose. The typical range of intended depth insertion is marked by the two horizontal lines on the airway tube (see figure ②, item 5). The AuraGain 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 a maximum of 60 cm H_2O. In many cases, only half of the maximum volume is sufficient to achieve a seal – please refer to Table 3 for maximum volumes.

Check the cuff pressure continuously during the surgical procedure with a cuff pressure gauge. This is especially important when N_2O gases are used.
See figure ⑥ Inflation of AuraGain.

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

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

WARNING ⚠

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

Look for the following signs of correct placement: The possible slight outward movement of the tube upon cuff inflation, the presence of a smooth oval swelling in the neck around the thyroid and cricoid area, or no cuff visible in the oral cavity.

7.6. Connecting to the Anaesthetic System

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

WARNINGS ⚠

- Any signs of airway problems or inadequate ventilation must be monitored regularly and the Ambu AuraGain 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 AuraGain to avoid rotation of the mask.
- The patency of the Ambu AuraGain should be reconfirmed after any change in the patient's head or neck position

7.7. Fixation

If deemed necessary, secure 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 AuraGain.

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 AuraGain is suitable for spontaneously breathing patients when used with volatile agents or intravenous anesthesia 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 AuraGain 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 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 AuraGain by head turning or traction.
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 AuraGain 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 AuraGain has been positioned incorrectly, remove and reinsert – and provide that anaesthetic depth is adequate.

Unexpected regurgitation: Regurgitation may occur even in fasted patients (1:10,000)[2].
This may be caused by inadequate level of anaesthesia. The first signs of regurgitation may be spontaneous breathing, coughing or breath-holding.
If regurgitation occurs, provided that oxygen saturation remains at acceptable levels, the AuraGain should not be removed. This should be managed by putting the patient in a "head-down" position. Briefly disconnect the anaesthetic circuit so that the gastric contents are not forced into the lungs. Check that anaesthetic depth is adequate and deepen anaesthesia intravenously, if appropriate.

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

If regurgitation is anticipated, it is recommended that a gastric tube is passed through the gastric channel of the AuraGain into the patient's stomach.

[2] Bernardini A, Natalini G, Risk of pulmonary aspiration with laryngeal mask airway and tracheal tube: analysis on 65.712 procedures with positive pressure ventilation, Anaesthsia 2009,64(12):1289-94

WARNINGS ⚠

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

7.11. Recovery

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

7.12. Removal procedure

Removal should always be carried out in an area where suction equipment and the facility for rapid tracheal intubation are available.
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 AuraGain.

WARNINGS ⚠

- The sterile Ambu AuraGain 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. Intubation through the Ambu AuraGain

Direct flexible scope assisted endotracheal intubation can be performed through the AuraGain, using a well-lubricated, fully deflated endotracheal tube.

For paediatric use special clinical precautions must be taken. See section 8.2 of this document .
Select the appropriate ET-tube size. See table 6 for appropriate ET-tube size.
Since the outside diameter and rigidity of endotracheal tubes may vary, the compatibility between the endotracheal tube and the AuraGain should be tested before the procedure. Apply lubricant to the ET-tube and verify that it moves freely inside the airway of the AuraGain.

The AuraGain is placed in the patient and the ET-tube is threaded over the flexible scope. The flexible scope is inserted until carina is seen and ET-tube is advanced and left in the trachea. Integrated navigation marks provide guidance as to how far the flexible scope has been introduced. The first mark, Fig ② item 8a, indicates that the scope tip should be flexed to visualize the tracheal opening. The second mark, Fig ② item 8b, indicates that the flexible scope has been introduced too far.

For most procedures it is advantageous to leave the AuraGain in place after endotracheal intubation. In this case it is important to deflate the cuff of the Ambu AuraGain completely.

The Ambu AuraGain may be removed, taking care not to dislodge the ET-tube. Ambu recommends the "tube-to-tube" exchange method for retaining the ET-tube when removing the AuraGain.

For specific combinations of AuraGain and ET-tube variants for pediatric patients, it is not possible to remove the AuraGain after the ET-tube is placed through the mask. Please refer to section 8.2 for more information.

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

	Mask size						
	#1	**#1½**	**#2**	**#2½**	**#3**	**#4**	**#5**
Max. ETT size	3,5	4,0	5,0	5,5	6,5	7,5	8,0

Table 6. Guide for appropriate ET-tube size selection

CAUTIONS ⚠

- Remove the air completely from the cuff of the Ambu AuraGain if it is left in place after endotracheal intubation.
- We do not recommend removing the airway connector on the Ambu AuraGain.

8.2. Pediatric use

The Ambu AuraGain comes in four different sizes for infant/pediatric patients. See Table 3 for size selection guidelines and maximum inflation volumes. Also see Table 6 for appropriate ET-tube size selection overview.
It is recommended that the Ambu AuraGain in neonates and small children is used by a clinician familiar with pediatric anesthesia.

There are several recommended methods for flexible scope assisted intubation of pediatric patients via a supraglottic airway (laryngeal mask). These include, but are not limited to, the use of a guide-wire or direct railroading the ET-tube over the flexible scope. Ambu recommends that users adhere to the method outlined in the local guidelines for pediatric airway management. Depending on the type of flexible scope used for pediatric patients, it may not be possible to flex the tip of the scope right at the first navigation mark. Instead, the tip may be flexed once the letter "u" of "use" has been visualized.

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

Please note that with the Ambu AuraGain, 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.

Different types of ET-tubes for pediatric patients
Depending on local product availability and practice guidelines, different types of ET-tubes may be available for intubation. Some ET-tubes are equipped with a cuff and others are not.
AuraGain is compatible with both types of ET-tubes for intubation.
For AuraGain pediatric sizes, it is important to note that if removal of the AuraGain is planned after an ET-tube is placed through the mask, an ET-tube without cuff must be used.
Intubation through the AuraGain should always be performed in accordance with local guidelines.

8.3. Use of the Ambu AuraGain for blind tracheal intubation

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

8.4 Verification of correct position

Correct placement should produce a leak-free seal against the glottis with the tip of the mask at the upper oesophageal sphincter.

To facilitate diagnosis of correct placement, a small bolus of lubricant (1-2 ml) is placed in the proximal end of the gastric channel. In a properly placed mask, there should be a slight up-down movement of the lubricant following gentle manual positive pressure is applied to the airway through the device.

WARNINGS ⚠

- Regardless of positive outcome of bubble test, the mask may be placed incorrectly. Visual confirmation of anatomically correct position is recommended, e.g. by using a flexible scope.

8.5 Gastric drainage through the Ambu AuraGain

The gastric channel facilitates channeling of fluids and gases emerging from the stomach. To facilitate gastric drainage, a gastric tube may be passed through the gastric channel into the stomach at any time during the anaesthetic procedure. The gastric tube should be well lubricated and passed through the gastric channel slowly and carefully. Suction should not be performed until the gastric tube has reached the stomach. Suction should not be applied directly to the end of the drain tube, as this may cause the drain tube to collapse and might theoretically cause injury to the upper sphincter.

The below table provides information on the maximum gastric tube size that can be used with each AuraGain mask size.
Since the outside diameter of gastric tubes may vary, the compatibility between the gastric tube and the AuraGain should be tested before the procedure. Apply lubricant to the gastric tube and verify that it moves freely inside the airway of the AuraGain.

	Mask size						
	#1	**#1½**	**#2**	**#2½**	**#3**	**#4**	**#5**
Max gastric tube size	6 Fr	8 Fr	10 Fr	10 Fr	16 Fr	16 Fr	16 Fr

Table 7. Guide for appropriate gastric tube selection

Air leakage through the gastric channel

A small air leak, air venting, through the gastric channel may be a useful mechanism to protect against gastric insufflation. However an excessive leak means the device is incorrectly inserted and removal of the device and reinsertion is needed.

WARNINGS ⚠

- The presence of a gastric channel does not rule out the possibility of aspiration if the device is not correctly located and fixed in place.
- Do not attempt to pass a gastric tube into the stomach via the gastric channel in the presence of known suspected oesophageal pathology
- There is a theoretical risk of causing oedema or haematoma if suction is applied directly to the end of the gastric channel

8.6. Critical situations and emergencies

8.6.1. Critical situations

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

8.6.2. Emergencies

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

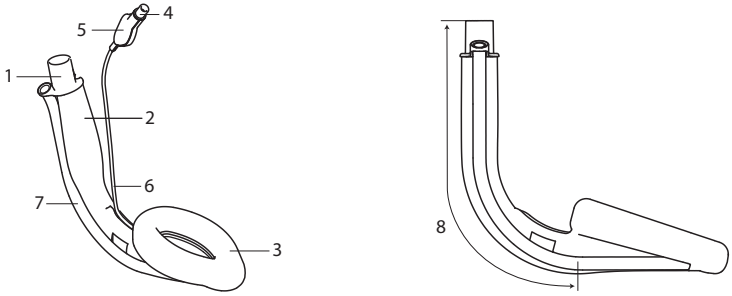
8.7. Magentic Resonance Imaging (MR)

The AuraGain has been determined to be MR-safe. That is, when placed in a patient undergoing an MR procedure, the AuraGain will not present any additional risk to the patient, neither affect image quality.

WARNINGS ⚠

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

①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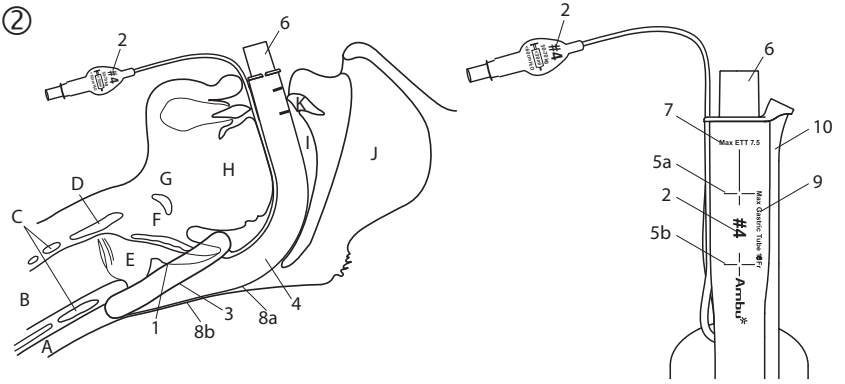
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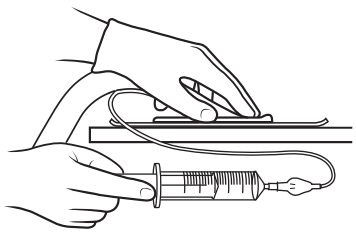
Max Gastric Tube 16Fr
#4
Ambu

③



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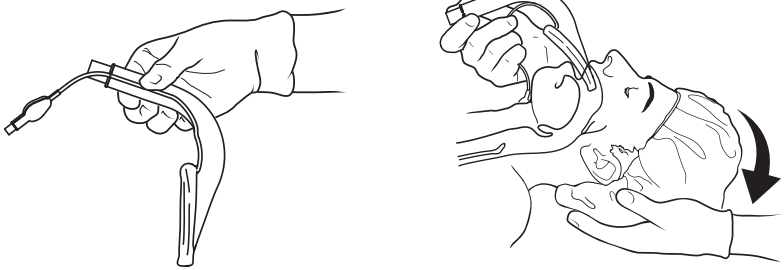

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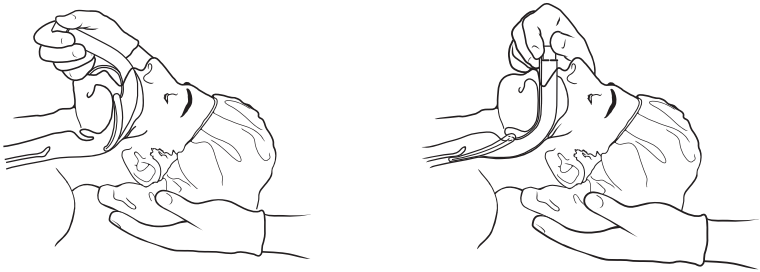

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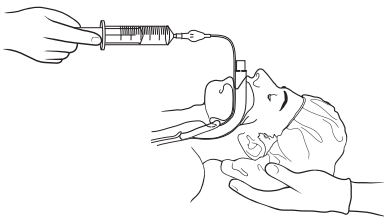

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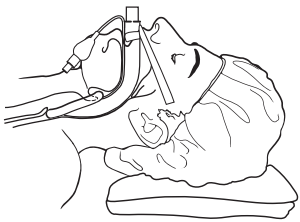

Symbol	Indication
	This product is not made with natural rubber latex
	Do not re-use
	Consult instructions for use
	Use-by date
STERILE R	Sterile Product, Sterilisation by irradiation (R)
LOT	Batch Code
REF	Catalogue number
	This product is not made with phthalates
	Manufacturer
	Warning
	Do not use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

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

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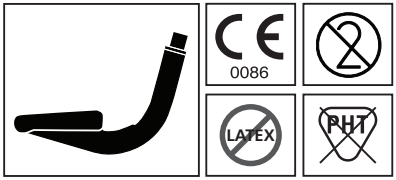

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