INSTRUCTIONS FOR USE

Ambu® Silicone Face Mask

Reusable face mask

Ambu

1. Important information – Read before use

Read these safety instructions carefully before using the Ambu® Silicone Face Mask. The instructions for use may be updated without further notice. Copies of the current version are available upon request. Please be aware that these instructions do not explain or discuss clinical procedures. They describe only the basic operation and precautions related to the operation of the Ambu Silicone Face Mask.

Before initial use of the Ambu Silicone Face Mask, it is essential for operators to have received sufficient training in using the product and to be familiar with the intended use, warnings, cautions, and indications mentioned in these instructions.

There is no warranty on the Ambu Silicone Face Mask.

1.1. Intended use

The Ambu Silicone Face Mask is a reusable face mask intended for oxygenating and ventilating the airways or to direct anesthetic gases to the upper airways.

1.2. Indications for use

The Ambu Silicone Face Mask is used for respiratory care and support. The Ambu Silicone Face Mask is also intended for use during procedures where anaesthetic gasses are being supplied.

1.3. Intended patient population

The Ambu Silicone Face Mask is intended to be used on patients of all ages and comes in 6 sizes with 7 variants to ensure that the inner shape of the dome is spacious enough for the mouth and nose.

- Ambu Silicone Face Mask, #0A
- Ambu Silicone Face Mask, #0
- Ambu Silicone Face Mask, #0 with boring
- Ambu Silicone Face Mask, #2
- Ambu Silicone Face Mask, #3/4
- Ambu Silicone Face Mask, #5
- Ambu Silicone Face Mask, #6

1.4. Intended user

The Ambu Silicone Face Mask is for use by medical professionals, rescue- and emergency personnel trained in airway management.

1.5. Intended use environment

The Ambu Silicone Face Mask is intended to be used in pre-hospital (EMS) and hospital environments including MR system rooms.

1.6. Contra indications

None known.

1.7. Clinical benefits

The Ambu Silicone Face Mask will allow for passage of air and anesthetic gases to the patient and visualization through the dome.

1.8. Warnings and cautions

Failure to observe these precautions may result in inefficient ventilation of the patient, cross-infection, or damage to the equipment.

WARNINGS ⚠

1. Only to be used by intended users who are familiar with the content of this manual, as incorrect use might harm the patient.
2. Professionals performing the procedure should assess the choice of face mask size and compatible devices (e.g. resuscitator etc.) in accordance with the patient's specific condition(s), as incorrect use may harm the patient.
3. Always ensure to remove all packaging material from the Ambu Silicone Face Mask prior to use as the pouch could block the patient's airways and prevent ventilation.
4. Always visually inspect the product after unpacking, assembly and prior to use as defects and foreign matter can lead to no or reduced ventilation of the patient or reduced delivery of anesthetic gases.
5. Do not use the product if inspection fails, as this can lead to no or reduced ventilation or reduced delivery of anesthetic gases.
6. Do not use the product if contaminated by external sources, as this can cause infection.
7. Always ensure correct positioning of the face mask on the patient by performing, with either hand, an appropriate jaw thrust through relevant hand grip strategy. Reposition if applicable, as improper sealing of the face mask could lead to insufficient ventilation of the patient or reduced delivery of anesthetic gases.

8. Always inspect the proper inflation of the Ambu Silicone Face Mask cushion before use, as poor sealing might lead to insufficient ventilation of patient.
9. Always visually inspect the inflation and sealing properties of the face mask cushion while in use on the patient, as improper sealing might lead to leakage and reduced or no ventilation of the patient or reduced delivery of anesthetic gases.
10. Always ensure correct positioning and sealing of the Ambu Silicone Face Mask, as improper sealing can lead to spreading of airborne infectious disease to the user.
11. When using the size #0 with boring, always ensure that the boring is not blocked, as blocking the boring can prevent the intended function of reducing the pressure delivered to the child, since high ventilation pressures may cause barotrauma.
12. Do not apply excessive force on the Ambu Silicone Face Mask when keeping it in position, as it might lead to pressure marks on the patient's face.
13. Always reprocess the Ambu Silicone Face Mask after each use in order to avoid the risk of infection.
14. Do not reuse the Ambu Silicone Face Mask on another patient without reprocessing it due to the risk of cross-infection.
15. Do not reuse the Ambu Silicone Face Mask if visible residues are left inside the device in order to avoid the risk of infection or malfunction.
16. Do not use the Ambu Silicone Face Mask after reprocessing a maximum of 30 times in order to avoid the risk of infection or malfunction of the device.
17. When using supplemental oxygen, do not allow smoking or use the device near an open flame, oil, grease, other flammable chemicals or equipment and tools, which cause sparks, due to the risk of fire and/or explosion.
18. Do not use the product when ventilating patients with severe facial trauma and/or eye injury due to the risk of improper sealing and aggravation of injury unless a medical assessment indicates the necessity. Switch to an alternative method for directing air to the patient, if available.

CAUTIONS

1. Never store the Ambu Silicone Face Mask in a deformed state, otherwise permanent distortion of the mask could occur, which may reduce the ventilation efficiency or delivery of anesthetic gases.

2. Please see packaging for more specific information about the expiration date, as the use of an expired device might lead to decreased performance or malfunction of the product.
3. Do not reprocess the Ambu Silicone Face Mask any other way than described in this IFU. Other procedures may cause deformation or damage to the device.
4. Always keep components from the same device together during reprocessing to avoid reassembly of components with different durability leading to the risk of product failure.
5. Do not use substances containing phenols to clean the product. Phenols will cause premature wearing and degradation of the materials resulting in a reduced product life span.
6. Only use compatible connections or adapters, as forcing non-compatible connections or adapters into the connector of the Ambu Silicone Face Mask could damage the device, rendering it unusable.
7. US federal law restricts this device to sale by or on the order of a licensed health care practitioner.

1.9. Potential adverse events

Potential adverse events related to use of face masks (not exhaustive): Pressure marks, hypoxia and aggravation of already existing facial and eye injuries.

1.10. General notes

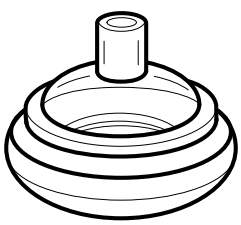
If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and to your national authority.

2. Device description

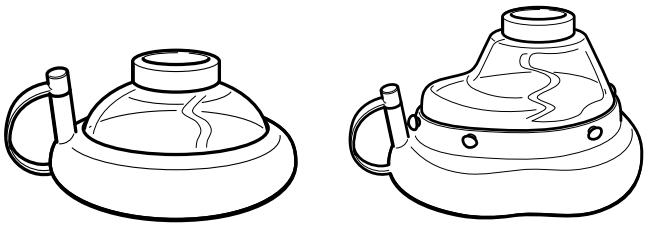
The Ambu Silicone Face Mask is a non-sterile, non-conductive, reusable face mask. It functions as a means for connection between the breathing device or anaesthetic circuit and the patient's upper airways and allows for direction of air and medical gasses to the patient.

Size 0A with a 15mm connector

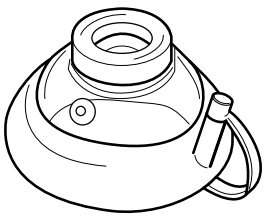
The mask dome is transparent. The cushion of the 0A model is filled with foam and the internal volume is not inflatable.



Sizes 0, 2, 3/4, 5 and 6 with a 22 mm connector
The mask dome is transparent. The cushion has a valve for self-inflation which is closed with a plug.



Size 0 with boring
The mask dome is transparent. The model 0 with boring is designed to limit the ventilation pressure to below 40 cmH_2O (4 kPa).



3. Explanation of symbols used

Symbol indication	Description	Symbol indication	Description
CN	Country of Manufacturer	31	May not be used more than 30 times
MD	Medical Device	MR	MR Safe
Rx only	Prescription use only		

A full list of symbol explanations can be found on ambu.com/symbol-explanation.

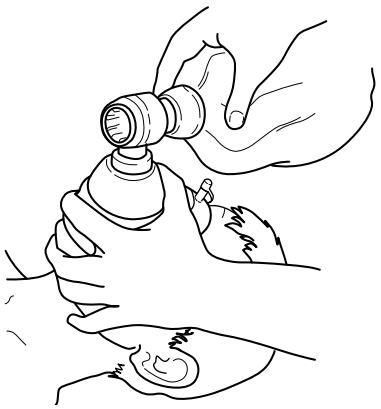
4. Product use

4.1. Inspection and preparation

1. Remove the Ambu Silicone Face Mask from its packaging and inspect for proper inflation of the cushion.
2. Inspect the cushion for any damage or leakage.

4.2. Operation

1. Apply the mask firmly to the patient's face to achieve a tight seal.
2. Hold the mask tight against the face while securing an open airway through a jaw thrust.

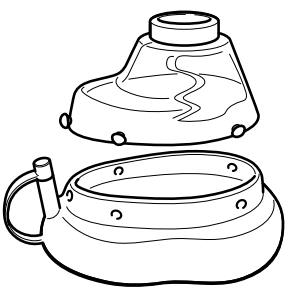


4.3. Reprocessing: cleaning, disinfection, sterilization

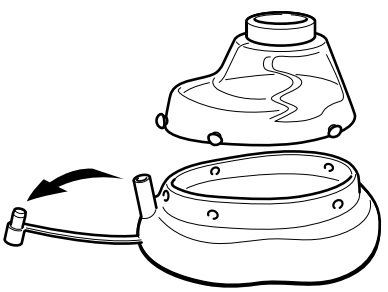
Follow these reprocessing instructions after each use to reduce the risk of cross-contamination.

Disassembly

Prior to reprocessing the Ambu Silicone Face Mask, manually disassemble the face mask according to the illustration below. Make sure to remove the plug from the inflation tube (not applicable to #0A).
Unbutton or remove mask cushion from dome.



Example of disassembled mask



Example of disassembled mask with plug removed from the inflation tube

Keep components from the same device together during reprocessing to avoid reassembly of components with different durability.

Recommended reprocessing cycles

For a complete reprocessing cycle of the device, use one of the cycles listed in the table below.

	Applicability to the Ambu Silicone Face Mask	
Recommended reprocessing cycles	**Size 0, 2, 3/4, 5 and 6**	**Size 0A**
Manual cleaning followed by chemical disinfection	Yes	Yes
Manual cleaning followed by steam sterilization	Yes	No
Automated cleaning, including a thermal disinfection stage, followed by steam sterilization	Yes	No
Automated cleaning, including a thermal disinfection stage, followed by chemical disinfection	Yes	Yes

Table 1: Recommended reprocessing procedures.

Product testing has shown that the Ambu Silicone Face Mask is fully functional after 30 full reprocessing cycles, as listed above.

It is the user's responsibility to qualify any deviations from the recommended cycles and methods of processing, and to monitor that the recommended number of reprocessing cycles is not exceeded.

Procedures for reprocessing
MANUAL CLEANING

1. Rinse the components under running cold utility (tap) water to remove gross soil.
2. Prepare a detergent bath using a cleaning detergent solution, e.g., Neodisher® MediClean Forte or equivalent, for the removal of residues of dried blood and other body fluids, using the detergent manufacturer's recommended concentration.
3. Fully immerse the components to keep them submerged in the solution according to the detergent's instruction label. During the soak time, thoroughly clean the components with a soft brush until all visible soil is removed.
4. Rinse the components with running utility (tap) water for one minute.
5. Dry the components with a clean lint-free cloth and compressed air.

AUTOMATED CLEANING WITH THERMAL DISINFECTION

1. Rinse the components under running cold utility (tap) water to remove gross soil.
2. Place the components onto a manifold rack or in a wire basket inside the washer.
3. Select the appropriate cycle as listed below:

Stage	Recirculation time (minutes)	Temperature	Detergent type and concentration (if applicable)
Pre-wash	02:00	Cold tap water	N/A
Wash	01:00	43 °C (110 °F) tap water	Neodisher® MediClean Forte or an equivalent detergent using manufacturer's recommended concentration
Rinse	01:00	43 °C (110 °F) tap water	N/A
Thermal disinfection	05:00	90 °C (194 °F)	N/A
Dry time	07:00	90 °C (194 °F)	N/A

Table 2: Automated cleaning with thermal disinfection cycles.

CHEMICAL DISINFECTION

1. Equilibrate the bath of Cidex OPA, or an equivalent OPA (ortho-phthalaldehyde) disinfectant at the temperature specified in the OPA disinfectant manufacturer's instructions.
2. Ensure the minimum effective concentration (MEC) of the OPA disinfectant using the OPA test strips specified in the OPA disinfectant manufacturer's instructions.
3. Fully immerse the device in the OPA and ensure all air bubbles are removed from the device surface by agitating the device.
4. Allow the device to soak for the time specified in the manufacturer's instructions for the OPA disinfectant.
5. Thoroughly rinse the device by fully immersing it in purified water, agitating and allowing it to set for a minimum of 1 minute.
6. Repeat step 5 two more times for a total of 3 rinses using a fresh batch of purified water each time.
7. Dry the device using a sterile lint-free cloth.

STEAM STERILIZATION
Sterilize the product using a gravity steam autoclave running a full cycle at 134 – 135 °C (274 – 275 °F) with an exposure time of 10 minutes and a dry time of 45 minutes. Leave the parts to dry and/or cool completely.

Inspection of components
After reprocessing, carefully inspect all components for damage, residuals or excessive wear and replace if necessary. Some methods may cause discoloration of rubber components without impact on their lifetime. In case of material deterioration e.g. cracking, the Ambu Silicone Face Mask should be discarded.

Reassembly
Manually reassemble the mask and ensure tight assembly between dome and cushion. Make sure to insert the plug (not applicable to #0A). Refer to section 4.1 Inspection and preparation.

4.4. Disposal
Used products must be disposed of according to local procedures.

5. Technical product specifications

5.1. Specifications

Ambu Silicone Face Mask variants	0A, 0 (with boring), 0, 2, 3/4, 5 and 6.
Connector size	15 mm OD connector for size 0A according to ISO 5356-1. 22 mm ID connector for size 0, 2, 3/4, 5 and 6 compatible with ISO 5356-1.
Operation temperature limits	-20 °C to 50 °C (-4 °F to 122 °F) according to EN 1789 and ISO 10651-4.
Storage temperature limits	-40 °C to 70 °C (-40 °F to 158 °F) according to EN 1789 and ISO 10651-4.
Recommended long term storage in closed packaging at room temperature, away from sunlight.	

5.2. MRI Safety information MR
The Ambu Silicone Face Mask is MR Safe.

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