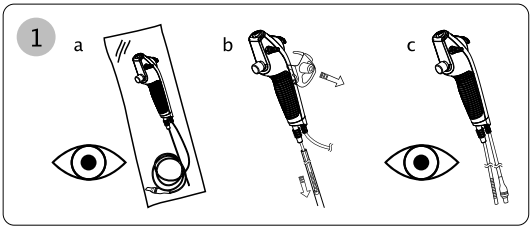
INSTRUCTIONS FOR USE

Ambu® aScope™ 4 RhinoLaryngo Intervention

Ambu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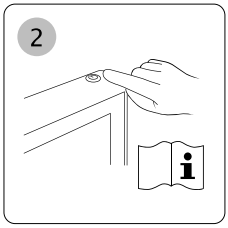
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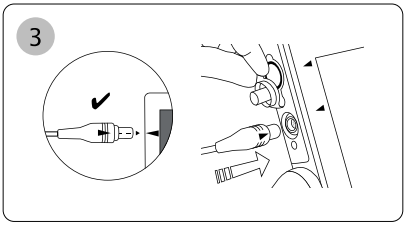
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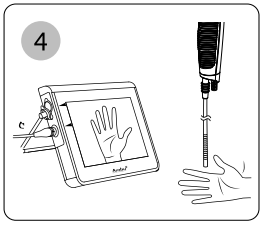
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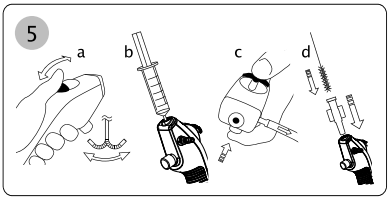
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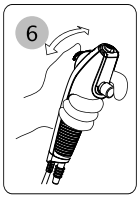
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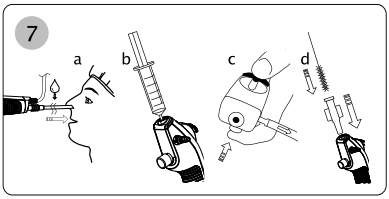
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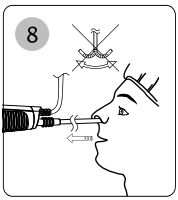
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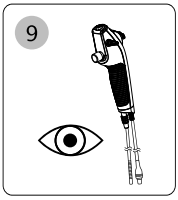
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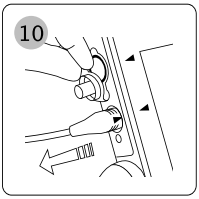
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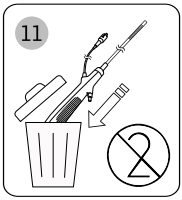
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1. Important information – Read before use

Read the safety instructions carefully before using the Ambu® aScope™ 4 RhinoLaryngo Intervention. 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 operations of aScope 4 RhinoLaryngo Intervention.

Before initial use of the aScope 4 RhinoLaryngo Intervention it is essential for operators to have received sufficient training in clinical endoscopic techniques and to be familiar with the intended use, warnings and cautions mentioned in these instructions.

In this *Instructions for use*, the term *endoscope* refers to instructions for aScope 4 RhinoLaryngo Intervention, and *system* refers to aScope 4 RhinoLaryngo Intervention and the compatible Ambu displaying unit. This *Instructions for use* applies for the endoscope and information relevant for the system.

1.1. Intended use

The endoscope is a sterile, single-use, flexible endoscope intended for endoscopic procedures and examination within the nasal lumens and upper airway anatomy. The endoscope is intended to provide visualization via Ambu displaying unit.
The endoscope is intended for use in a hospital environment. It is designed for use in adults.

1.2. Contra indication

None known.

1.3. Clinical benefit

Single use application minimises the risk of cross-contamination of the patient.

1.4. Warnings and cautions

WARNINGS ⚠

1. Only to be used by physicians, trained in clinical endoscopic techniques and procedures.
2. The endoscope is a single-use product and must be handled in a manner consistent with accepted medical practice for such devices in order to avoid contamination of the endoscope prior to insertion.
3. Do not soak, rinse, or sterilize this device as these procedures may leave harmful residues or cause malfunction of the device. Reuse of the endoscope can cause contamination, leading to infections.
4. Do not use the endoscope if the sterilisation barrier or its packaging is damaged.
5. Do not use the endoscope if it is damaged in any way or if the preuse check fails (see section 4.1).
6. The images must not be used as an independent diagnostic of any pathology. Physicians must interpret and substantiate any finding by other means and in the light of the patient's clinical characteristics.
7. Do not use active endoscopic accessories such as laser probes and electrosurgical equipment in conjunction with the endoscope, as this may result in patient injury or damage the endoscope.
8. The endoscope is not to be used when delivering highly flammable anaesthetic gases to the patient. This could potentially cause patient injury.
9. Always watch the live endoscopic image on the compatible displaying unit during suctioning. Failure to do so may harm the patient.
10. Patients should be adequately monitored at all times. Failure to do so may harm the patient.
11. Always make sure that the bending section is in a straight position when inserting and withdrawing the endoscope. Do not operate the control lever and never use excessive force, as this may result in injury to the patient and/or damage to the endoscope.
12. Do not use excessive force when advancing, operating or withdrawing the endoscope as this may result in patient injury or damage to the endoscope.

13. Do not advance or withdraw the endoscope or operate the bending section if endoscopic accessories are protruding from the distal tip of the working channel as this may result in injury to the patient.
14. The distal tip of the endoscope may get warm due to heating from the light emission part. Avoid long periods of contact between the distal tip of the device and the mucosal membrane as sustained contact with the mucosal membrane may cause mucosal injury.
15. Insert the syringe completely into the working channel port before instilling fluid. Failure to do so may result in the fluid spilling from the working channel port.

CAUTIONS

1. Have a suitable backup system readily available in case a malfunction should occur.
2. Be careful not to damage the insertion cord or distal tip. Do not allow other objects or sharp devices such as needles to strike the endoscope.
3. US federal law restricts these devices for sale only by, or on the order of, a physician.
4. The color representation of blue dye might be impaired on the live endoscopic image.
5. Operating the aScope 4 RhinoLaryngo Intervention with reverse grip of the handle will cause an image on the display that is upside down.

1.5. Adverse events

Potential adverse events in relation to flexible rhinolaryngoscopy (not exhaustive):	Epistaxis, Laryngospasm, Damage to vocal cords, Damage to mucosa, Gag reflex, Pain/discomfort, Desaturation.

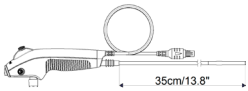
1.6. General notes

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. System description

The endoscope can be connected to the compatible displaying unit. For information about the compatible displaying unit, please refer to its *Instructions for use.*

2.1. System parts

Endoscopes	**Part numbers:**
	512101000 aScope 4 RhinoLaryngo Intervention

Product name	**Colour**	**Outer diameter [mm]**	**Inner diameter [mm]**
aScope 4 RhinoLaryngo Intervention	Green	min 5.0; max 5.5	min 2.0

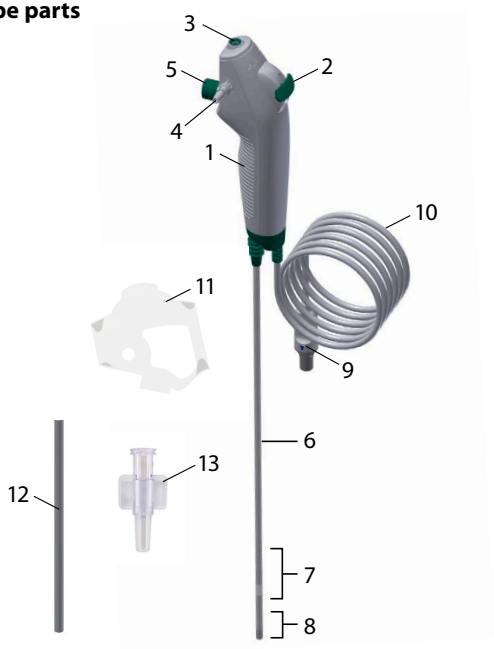
2.2. Product compatibility

The aScope 4 RhinoLaryngo has been designed to be used in conjunction with:

Displaying unit
– Ambu aView
– Ambu aView 2 Advance

Endoscopic accessories
– Suctioning tubes of inner diameter between 6,5 and 9,5 [mm].
– Standard 6 % conical Luer syringe up till 50 ml.
– Adaptor compatible with working channel port and standard 6 % conical Luer lock syringes.
– Endoscopic accessories labeled for diameter (ID) 2.2 mm or less.
– Tracheostomy tubes size 6 or larger.

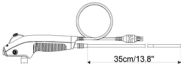
2.3. Endoscope parts



No.	Part	Function
1	Handle	Suitable for left and right hand.
2	Control lever	Moves the distal tip up or down in a single plane.
3	Working channel port	Allows for instillation of fluids and insertion of endoscopic accessories.
-	Working channel	Can be used for instillation of fluids, suction and insertion of endoscopic accessories.
4	Suction connector	Allows for connection of suction tubing.
5	Suction button	Activates suction when pressed down.
6	Insertion cord	Flexible airway insertion cord.
-	Insertion portion	Same as insertion cord.
7	Bending section	Manoeuvrable part.
8	Distal tip	Contains the camera, light source (two LEDs), as well as the working channel exit.
9	Endoscope cable connector	Connects to blue socket on the displaying unit.
10	Endoscope cable	Transmits the image signal to the displaying unit.
11	Handle protection	Protects the suction connector during transport and storage. Remove before use.

No.	Part	Function
12	Protection pipe	Protects the insertion cord during transport and storage. Remove before use.
13	Introducer	To facilitate introduction of Luer Lock syringes and soft endoscopic accessories through the working channel port.

3. Explanation of symbols used

Symbols for the endoscope devices	Description
	Working length of the endoscope insertion cord.
Max OD	Maximum insertion portion width (Maximum outer diameter).
Min ID	Minimum working channel width (Minimum inner diameter).
	Field of view.
	Electrical Safety Type BF Applied Part.
	Packaging level ensuring sterility.
	UL Recognized Component Mark for Canada and the United States.
GTIN	Global trade identification number.
	Do not use if the product sterilisation barrier or its packaging is damaged.
	Relative humidity limitation.
	Atmospheric pressure limitation.

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

4. Use of the endoscope

Optimize patient position and consider applying relevant anesthetics to minimize patient discomfort.
Numbers in gray circles below refer to illustrations on page 2.

4.1. Preuse check of the endoscope

1. Check that the pouch seal is intact before opening. **1a**
2. Make sure to remove the protective elements from the handle and from the insertion cord. **1b**
3. Check that there are no impurities or damage on the product such as rough surfaces, sharp edges or protrusions which may harm the patient. **1c**

Refer to the *Instructions for use* for the compatible displaying unit for preparation and inspection of the displaying unit. 2

4.2. Inspection of the image

1. Plug in the endoscope cable connector into the corresponding connector on the compatible displaying unit. Please ensure the colours are identical and be careful to align the arrows. **3**
2. Verify that a live video image appears on the screen by pointing the distal tip of the endoscope towards an object, e.g. the palm of your hand. **4**
3. Adjust the image preferences on the compatible displaying unit if necessary (please refer to the displaying unit *Instructions for use*).
4. If the object cannot be seen clearly, clean the distal tip.

4.3. Preparation of the endoscope

1. Carefully slide the control lever forwards and backwards to bend the bending section as much as possible. Then slide the control lever slowly to its neutral position. Confirm that the bending section functions smoothly and correctly and returns to a neutral position. **5a**
2. Using a syringe insert 2ml of sterile water into the working channel port (if applying a Luer Lock syringe use the enclosed introducer). Press the plunger, ensure that there are no leaks, and that water is emitted from the distal tip. **5b**
3. If applicable, prepare the suction equipment according to the supplier's manual. **5c** Connect the suctioning tube to the suction connector and press the suction button to check that suction is applied.
4. A pre-check of compatibility of accessories is recommended. If applicable, verify that endoscopic accessory of appropriate size can be passed through the working channel without resistance. The enclosed introducer can be used to facilitate the insertion of soft accessories. **5d**

4.4. Operating the endoscope

Holding the endoscope and manipulating the tip **6**

The handle of the endoscope can be held in either hand. The hand that is not holding the endoscope can be used to advance the insertion cord into the patient's nose or mouth. Use the thumb to move the control lever and the index finger to operate the suction button. The control lever is used to flex and extend the distal tip of the endoscope in the vertical plan. Moving the control lever downward will make the distal tip bend anteriorly (flexion). Moving it upward will make the distal tip bend posteriorly (extension). The insertion cord should be held as straight as possible at all times in order to secure an optimal distal tip bending angle.

Insertion of the endoscope **7a**

To ensure the lowest possible friction during insertion of the endoscope the insertion cord may be lubricated with a medical grade lubricant. If the images of the endoscope becomes unclear, clean the distal tip. When inserting the endoscope orally, it is recommended to use a mouthpiece to protect the scope from being damaged.

Instillation of fluids **7b**

Insert a syringe into the working channel port at the top of the endoscope to inject fluids. When using a Luer Lock syringe, use the included introducer. Insert the syringe completely into the working channel port or the introducer and press the plunger to inject fluid. Make sure suction is not applied during this process, as this will direct the injected fluids into the suction collection system. To ensure that all fluid has left the channel, flush the channel with 2 ml of air. It is recommended to remove introducer from the working channel port when it is not in use.

Aspiration **7c**

When a suction system is connected to the suction connector, suction can be applied by pressing the suction button with the index finger. If the introducer and/or an endoscopic accessory is placed inside the working channel note that the suction capability will be reduced. For optimal suction capability it is recommended to remove the introducer or syringe entirely during suction.

Insertion of endoscopic accessories 7d
Always make sure to select the correct size endoscopic accessory for the endoscope (See section 2.2). Inspect the endoscopic accessory before using it. If there is any irregularity in its operation or external appearance, replace it. Insert the endoscopic accessory into the working channel port and advance it carefully through the working channel until it can be seen on the live image on the displaying unit. The enclosed introducer can be used to facilitate the insertion of soft accessories.

Withdrawal of the endoscope 8
When withdrawing the endoscope, make sure that the control lever is in the neutral position. Slowly withdraw the endoscope while watching the live image on the displaying unit.

4.5. After use

Visual check 9
Inspect the endoscope for any evidence of damage on the bending section, lens, or insertion cord. In case of corrective actions needed based on the inspection act according to local hospital procedures.

Disconnect 10
Disconnect the endoscope from the Ambu displaying unit.

Disposal 11
Dispose of the endoscope, which is a single-use device . The endoscope is considered contaminated after use and must be disposed of in accordance with local guidelines for collection of infected medical devices with electronic components.

5. Technical product specifications

5.1. Standards applied

The endoscope function conforms with:
– EN 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
– EN 60601-2-18 Medical electrical equipment – Part 2-18 Particular requirements for the basic safety and essential performance of endoscopic equipment.

5.2. Endoscope specifications

Insertion cord	**aScope 4 RhinoLaryngo Intervention**
Bending section[1] [°]	130 ↑ ,130 ↓
Insertion cord diameter [mm, (")]	5.0 (0.20)
Distal end diameter [mm, (")]	5.4 (0.21)
Maximum diameter of insertion portion [mm, (")]	5.5 (0.22)
Minimum tracheostomy tube size (ID) [mm]	6.0
Working length [mm, (")]	350 (13.8)
Working channel	**aScope 4 RhinoLaryngo Intervention**
Minimum instrument channel width[2] [mm, (")]	2.0 (0.079)
Storage	**aScope 4 RhinoLaryngo Intervention**
Storage temperature[3] [°C, (°F)]	10 – 25 (50 – 77)
Relative humidity [%]	10 – 85
Atmospheric pressure [kPa]	50 – 106

Transportation	**aScope 4 RhinoLaryngo Intervention**
Temperature[3] [°C, (°F)]	-10 – 55 (14 – 131)
Relative humidity [%]	10 – 95
Atmospheric pressure [kPa]	50 – 106
Optical system	**aScope 4 RhinoLaryngo Intervention**
Field of View [°]	85
Depth of Field [mm]	6 – 50
Illumination method	LED
Suction connector	**aScope 4 RhinoLaryngo Intervention**
Connecting tube ID [mm]	Ø6.5 – 9.5
Sterilisation	**aScope 4 RhinoLaryngo Intervention**
Method of sterilisation	ETO
Operating environment	**aScope 4 RhinoLaryngo Intervention**
Temperature [°C, (°F)]	10 – 40 (50 – 104)
Relative humidity [%]	30 – 85
Atmospheric pressure [kPa]	80 – 106
Altitude [m]	≤ 2000

1. Please be aware that the bending angle can be affected if the insertion cord is not kept straight.
2. There is no guarantee that accessories selected solely using this minimum instrument channel width will be compatible in combination.
3. Storage under higher temperatures may impact shelf life.

6. Trouble shooting

If problems occur with the system, please use this trouble shooting guide to identify the cause and correct the error.

Problem	**Possible cause**	**Recommended action**
No live image on the screen but user interface is present on the display or the image is frozen.	The endoscope is not connected to compatible displaying unit.	Connect an endoscope to the blue port on the displaying unit.
	The displaying unit and endoscope have communication problems.	Restart the displaying unit.
	The endoscope is damaged.	Replace the endoscope with a new one.
	A recorded image is shown on the displaying unit screen.	Return to live image on the displaying unit.
Low picture quality.	Blood, saliva etc. on the lens (distal tip).	If the object cannot be seen clearly, clean the distal tip.

Problem	Possible cause	Recommended action
Absent or reduced suction capability or difficulty in inserting endoscopic accessory through the working channel.	Working channel blocked.	Withdraw the endoscope and clean the working channel using a cleaning brush or flush the working channel with sterile saline using a syringe. Do not operate the suction button when instilling fluids.
	Suction pump is not turned on or not connected.	Turn the pump on and check the suction line connection.
	Suction button is damaged.	Prepare a new endoscope.
	Endoscopic accessory inserted in working channel (applicable if suction is absent or reduced).	Remove endoscopic accessory. Check that the accessory used is of the recommended size.
	Bending section not in neutral position.	Move bending section into neutral position.
	Soft endoscopic accessory difficult to pass through working channel port.	Use the enclosed introducer.

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