CE

Instructions for Use
Laryngoscope, Otoscope, Sinuscope

asap

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Safety information

WARNING
Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury

CAUTION
Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury

asap endoscopes are optical precision devices for viewing the inside of the body, conceived for use during minimally invasive, endoscopically performed diagnostic and/or surgical procedures.

Do not use if package is damaged.

Handle with care. Excessive force in use, any manipulation and mechanical stress, such as being bent, being dropped or being held from the distal end of the endoscope, can lead to damage or destruction.

Before use, the responsible medical doctor must check whether the combination of endoscope and trocar sleeve permits safe operation. The combination option depends in particular on the diameter and length.

Before each use, inspect the endoscope for any defects and verify correct function.

asap endoscopes must be reprocessed before the first use and each subsequent use.

Third party connecting medical electric devices must comply to IEC 60601-2-18. Electric protection must be of type BF or CF. Read the instructions for use of the third party device and ensure proper functioning prior use.

Always have spare devices available in case of any failure and immediate replacement needs.

Any serious incident that has occurred in relation to asap devices should be reported to asap endoscopic products gmbh and the relevant Competent Authority.

CAUTION: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

WARNING
Residual risks from the use of asap rigid endoscopes relate to the following hazards:

- General risks from minimally invasive surgery
- Misuse
- Packaging & instrument damages incl. material degradation, sharp edges and corrosion
- Biological incompatibility with substances used
- Biological contamination
- Spread of biohazard
- Traces of cancerogenic, mutagenic and reprotoxic substances
- Loss of the IFU

This information should be provided to the patient.
Strictly follow all safety information provided to avoid hazards and hazardous situations to occur.

Warranty:

We offer a full warranty in the event of production or quality defects. In the case of obvious defects caused by production errors or the use of defective materials, the products will be repaired or replaced free of charge.

In the case of damage caused by improper handling such as mechanical impact, dropping the device, etc., the warranty claim is invalidated. If repairs are conducted by non-authorized persons, any warranty claim is rendered void.

§ ISO 13485
CE ((EU) 2017/745 Article 52(7)), I

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Product description		
Intended purpose/use	The asap rigid endoscopes are optical precision devices intended to visualize and access the inside of the body.	
Type of use	Multiple patient multiple use.	
Indications for use	Laryngoscope	Throat
	Otoscope	Ears
	Sinuscope	Sinuses (paranasal sinuses)
Contraindications	There are currently no known contraindications that relate directly to the asap endoscopes. The use of an asap endoscope also depends on the patient´s general condition and thus should be assessed critically by the healthcare professional before each use.	
Intended user	asap rigid endoscopes must be used only by medical doctors experienced in endoscopic procedures and dedicated healthcare professionals for the reprocessing and maintenance.	
Intended patient population	The asap rigid endoscopes are intended for adults and children except pregnant, breast feeding or vulnerable patients.	
Foreseeable side effects	Bleeding , pain, infection, dysphagia, teeth chipping and laceration of lips and vocal cords. This information should be provided to the patient.	
Clinical benefit	The clinical benefit of asap rigid endoscopes is given by their intended performance and safe use. No clinical claims are made.	

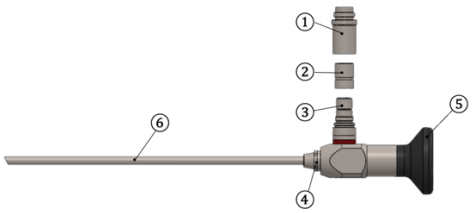
Product overview

Introduction

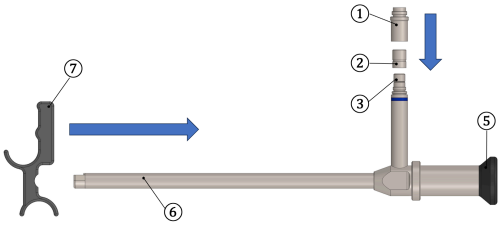
asap endoscopes are optical precision devices for viewing the inside of the body, conceived for use during minimally invasive, endoscopically performed diagnostic and/or surgical procedures.

Endoscope

Sinuscope, Otoscope



Laryngoscope



① Light guide connector adapter Storz/Olympus
② Light guide connector adapter Wolf
③ Light guide connector ACMI
④ Instrument connector (If applicable)
⑤ Eyepiece cap
⑥ Insertion portion
⑦ Handle (If applicable)

Variants

Item	Sinuscope	Laryngoscope	Otoscope
Working length (mm)	min 60 max 187.5	min 175 max 302	min 50 max 141
Diameter (mm)	min 1.9 max 5.0	min 2.7 max 12.4	min 1.9 max 4.0
Direction of view (°)	0, 10, 15, 25, 30, 45, 70, 90	0, 15, 30, 45, 70, 90	0, 30, 45, 70
Dimensions of eyepiece cap	Comply with ISO/TS 18339		
Light guide adapter	Compatible with Storz, Wolf, Olympus		
Field of view (°)	No specification (sa) small angle (wa) wide angle		

Other technical specifications	HD	Suitable for HD camera systems
	4K	Suitable for 4K camera systems
	Color coding at light connection	Indicates viewing direction: Green = 0°/10° Black = 15°/45° Red = 25/30° Yellow = 70° Blue = 90°
	Semiflex	Endoscopes that allow for a greater deflection of insertion portion
Initial delivery	• Endoscope • Light connection adapter Storz/Olympus, Wolf • Protection sleeve (for models with D ≤ 4mm) • Instructions for use	
Accessories	asap accessories • TV adapter Third party accessories: • CCD camera system (C-mount compatible) • Light source, cold light cable, diverse adapters (ISO/TS 18339 compatible) • Sterilization baskets, containers (ISO 17665-1 compatible)	

Preparation for use / operating instructions

Check initial delivery for completeness and general condition as per product description above.

Before use:

Before each use, inspect the endoscope for any defects and verify correct function.

Do not use a damaged or defective product.

Do not use an endoscope if the image is cloudy or dark spots are present within the field of view.

Do not use an endoscope with scratches and/or dents on the tubing and/or the distal or proximal ends.

asap endoscopes must be reprocessed before the first use and each subsequent use.

Preparation for use:

- Camera connection (if used):
  Affix the eyepiece onto your camera's TV adapter. Set the image sharpness and image size, if required, on the TV adapter.
- Light connection:
  Your asap endoscope can be connected to commercially available light sources by using cold light cables. For this purpose, the Storz/Olympus and Wolf sleeves can be unscrewed from the light connection. Additional light connection adapters are available if required.

Third party connecting medical electric devices must comply to IEC 60601-2-18. Electric protection must be of type BF or CF. Read the instructions for use of the third party device and ensure proper functioning prior use.

Operating instructions:

Before use, the responsible medical doctor must check whether the combination of endoscope and trocar sleeve permits safe operation. The combination option depends in particular on the diameter and length.

Reprocessing instructions

Limitations / Lifetime

The endoscope has been validated for 200 cycles of reprocessing under typical usage conditions and 30 cycles under maximum temperature and time exposure. The lifetime may be longer given that all criteria listed in section control and maintenance remain fulfilled.

Initial treatment at the point of use

- Release the endoscope from the TV adapter and light connection

In order to prevent corrosion or the surface drying of residue, do the following immediately after use:

- rinse the endoscope with cold water
- wipe the endoscope clean

Do not immerse the endoscope in hot water (> 40° C) or in detergents with protein-fixing properties (e.g. alcohols, aldehydes), or rinse with such detergents, as this may result in the fixation of residue accompanied by an adverse cleaning effect.

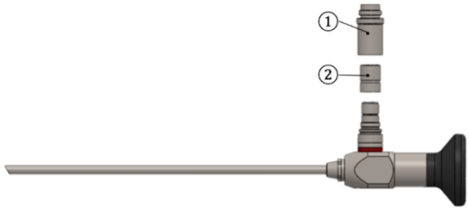
Immediately submit the endoscope to the next cleaning step. If this is not possible, place the endoscope in cold water for a max. of 45 minutes.

Preparation before cleaning

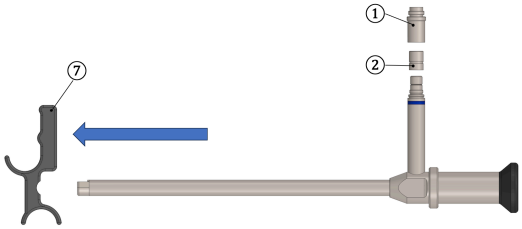
Wear protective gloves and goggles to protect from infections

- Thoroughly rinse the endoscope under running cold water
- Disassemble the following components
  - ① + ② Light guide connection adapter (if used)
  - ⑦ Handle (if applicable)

Sinuscope, Otoscope



Laryngoscope



- Rinse the disassembled components under cold water;
- If necessary remove persistent deposits with a soft brush and store components in a suitable container (e.g. small parts sieve)
- Immediately submit the endoscope to the next cleaning step. If this is not possible, place the endoscope in cold water for max. 45 minutes

Cleaning and disinfection

Only use the reprocessing procedures described in the IFU.

Do not clean asap rigid endoscopes in an ultrasonic bath as the optics could be damaged!

asap medical devices used on patients with Creutzfeld-Jacob syndrome or similar diseases must be disposed after use.

Manual Cleaning for soakable endoscopes

- Place the endoscope in cleaning solution. Use commercially available agents for thermolabile instruments, e.g. neodischer endo MED 15 g/l (1.5 %), 5 min (20 °C). Bear in mind that your asap endoscope may contain parts made of anodised aluminium.
- Rinse the endoscope under cold tap water for at least 2 min. Make sure covered surfaces on movable parts can be rinsed. Wipe surfaces with a sponge or soft cloth surface and, if applicable, use appropriate brushes for any lumen.
- Visually check removal of all residues.

Dry all parts with a soft, lint-free cloth. Make sure covered surfaces on movable parts are dry.

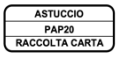
Manual High-level disinfection for soakable endoscopes	• Place the endoscope in cleaning and disinfection solution. Use commercially available agents for thermolabile instruments, e.g. CIDEX OPA; 5.5 g/l (0.55 %), 12 min (20 °C). Bear in mind that your asap endoscope may contain parts made of anodised aluminium. • Rinse the endoscope under distilled water for at least 2 min. Make sure covered surfaces on movable parts can be rinsed. Flush a minimum of 500 mL of water through all lumens to remove the disinfectant. Dry all parts with a soft, lint-free cloth. Make sure covered surfaces on movable parts are dry. Continue with the sections on “Control and maintenance”, “Additional informations” and following.

Automated cleaning and disinfection for autoclavable products only	asap rigid endoscopes must be reprocessed in a washer / disinfectors compliant to the ISO 15883 standard series. The asap rigid endoscopes have been validated with the washer disinfector “Miele PG 8535” from an accredited lab.
	• Position the endoscope in the load carrier
	• Position the container for small parts on the load carrier
	• Start the reprocessing process
	  ○ Precleaning – medium: tap water / temperature: 10-30 °C / duration: 1 minute / drain water
	  ○ Cleaning – medium: tap water / cleaning agent: neodisher MediClean forte / dosing 0.5% / temperature: 55 °C / duration: 10 minutes / drain water
	  ○ Neutralize – Medium: tap water / temperature: 10-30 °C / duration: 2 minute / drain water
	  ○ Rinsing – medium: tap water / temperature: 10-30 °C / duration: 2 minute / drain water
	  ○ Thermal disinfection – medium: desalinated water / temperature: 90-93 °C / duration: min. 5 minutes / drain water
	  ○ Drying – temperature: 95-100 °C / duration: min. 25 minutes
	Adapt A0 values in accordance with local laws and regulations.

Control and maintenance	Only touch endoscopes with thoroughly cleaned and disinfected hands.
	• Inspect visually for
	  ○ residual contamination / deposits
	  ○ cleaning agent residue
	  ○ damage
	  ○ sharp edges
	  ○ loose or missing parts
	  ○ rough surfaces or scratches
	  ○ readability of labels
	  ○ coatings on optical surfaces (lens, eyepiece, optical fiber connection). These should be removed before sterilization, since otherwise they can only be removed with difficulty. Deposits can be removed with a clean cotton pad that has been soaked in distilled water or in 70% isopropanol.
	• Assemble individual parts on the endoscope
	• Perform a functional check
	  ○ Hold the distal end against light and check the fiber field at the optical fiber connection – a max. of 1/3 of the fiber field may be dark (due to fiber breakage)
	  ○ Hold the distal end against light and look through the eyepiece – there should not be any cloudiness, dirt, or other defect in the image

Packaging	Sterilization wrap and other packaging used for sterilization must be compliant with the EN 868-5 or ISO 11607-1 standard. Fasten and separate the endoscope from other devices if transported together in the same container to prevent cross-contamination and damage.
Sterilization for autoclavable products only	asap endoscopes must be autoclaved in sterilizers compliant to the ISO 17665-1 standard. The asap devices have been validated with the autoclave “Lautenschläger ZentraCert” from an accredited lab. Devices and accessories must be cleaned and disinfected prior to sterilization. Recommended sterilization parameters: • Prevacuum: 3 x • Temperature: min. 132 °C – max. 137 °C • Temperature hold time: min. 4 – max. 18 minutes • Drying: min. 10 minutes

	Allow endoscope to cool at room temperature. Faster cooling by using compressed air or similar means may cause damage to the endoscope.
Additional information	The instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.
Storage and transport	New unused endoscopes should be kept dry and protected from sunlight in its original packaging. Store reprocessed and sterilized endoscopes according to the healthcare facility´s guidelines and local laws and regulations.
Repair/Exchange	asap endoscopes may only be repaired by asap or by asap-authorized professional operations. To protect workers, the endoscopes must be reprocessed prior to shipment to the repair shop. Transport the endoscopes in suitable protective packaging, preferably in its original packaging.
Disposal	Handle and dispose of all products in accordance with accepted medical practice and with applicable local laws and regulations. asap endoscopes should be reprocessed and sterilized prior to disposal. It is possible to return non-repairable endoscopes or instruments to the manufacturer in a cleaned, disinfected and sterilized condition with written proof in a postage paid package with the addition “Repair”.

Symbol explanations				
Ref: ISO 15223-1 – 5.4.3 Consult instructions for use  Indicates the need for the user to consult the instructions for use	Ref: ISO 15223-1 – 5.4.4 Caution/ Warning  Indicates operator action/ awareness needs in order to avoid undesirable consequences	Ref.: ISO 7010 – M001 General mandatory action sign  Indicates mandatory action which, if not followed, could result in injury	Ref.: ISO 7010 – P001 General prohibition sign  Indicates a prohibition which, if not followed, could result in injury	REF: EU legislation Indicates compliance with EU harmonization legislation, the number indicates the notified body involved
Ref: ISO 15223-1 – 5.7.7 Medical device  Indicates the item is a medical device	Ref: ISO 15223-1 - 5.1.1 Manufacturer  Indicates the medical device manufacturer	Ref: ISO 15223-1 - 5.1.6 Catalogue number  Indicates the manufacturer´s catalogue number so that the medical device can be identified	Ref: ISO 15223-1 - 5.1.7 Serial number  Indicates the manufacturers serial number so that the specific medical device can be identified	Ref: ISO 15223-1 - 5.1.11 Country of manufacture  Indicates the country of manufacture, date of manufacture may be added
Ref: ISO 15223-1 – 5.1.5 Batch code  Indicates the manufacturer´s batch code so that the batch or lot can be identified	Ref: Manufacturer specific Qty Indicates the quantity contained in the packaging.	Ref: ISO 15223-1 – 5.7.10 Unique device identifier  Indicates a carrier that contains unique device identifier information	Ref: ISO 8859-1 – 167 § Indicates the legal specification of the system	Ref: ISO 15223-1 – 5.2.8 Do not use if package is damaged and consult instructions for use  Indicates do not use the device if package is damaged
Ref: ISO 15223-1 – 5.2.7 Non-sterile  Indicates a medical device that has not been subjected to a sterilization process	Ref: ISO 7000 – 2868 Sterilizable in a steam sterilizer (autoclave) at temperature specified  To indicate that the instrument is sterilizable in a steam sterilizer(autoclave).	Ref: Deduced from IEC 60417 – 5995  Indicates a soakable/immersible device	Ref: ISO 15223-1 – 5.4.10 Contains hazardous substances  Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR)	Ref: US regulation § 801.109(b) ℞ Only Indicates a Prescription Device U.S. Federal law restricts this device to sale by or on the order of a physician (for US only)
Ref: ISO 15223-1 – 5.3.1 Fragile, handle with care  Indicates a medical device that can be broken or damaged if not handled carefully	Ref: ISO 15223-1 – 5.3.2 Keep away from sunlight  Indicates a medical device that needs protection from light sources	Ref: ISO 15223-1 – 5.3.4 Keep dry  Indicates a medical device to be protected from moisture	Ref: 97/129/EC  Indicates the recycling requirement for the packaging material with number and abbreviation of the material	Ref.: AGEC France  Indicates the Triman-Logo for recycling of material in France
Ref: Decr. 116/2020 ITA  Indicates the material for recycling in Italy	Ref: Manufacturer specific (O) (C) (W) (DY) (S) Indicates type of instrument connector compatibility, i.e. (O) Olympus, (C) Circon, (W) Wolf, (DY) Dyonics (S) Stryker	Ref: Manufacturer specific (IC) (SRC) Indicates channel type, i.e. (IC) Instrument channel, (SRC) Suction/rinsing channel	Ref: Manufacturer specific (T90R) (T180) Indicates view direction in relation to light connection with turn 90° right / 180°	Ref: Manufacturer specific (HSW) Indicates compatibility with Henke-Sass, Wolf instruments