Instructions for use of asap endoscopes

Symbols

Only symbols not listed in ISO 15223-1 are explained below. Refer to ISO 15223-1 for all other symbols used.

Symbol	Explanation
℞ 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)
≥132° C	Indicates an autoclavable device at the indicated sterilization temperature ≥ 132°C
	Indicates a soakable device
(O) (C) (W) (DY) (S)	(O) Olympus compatible instrument coupling (C) Circon compatible instrument coupling (W) Wolf compatible instrument coupling (DY) Dyonics compatible instrument coupling (S) Stryker compatible instrument coupling
(IC) (SRC)	(IC) Instrument channel (SRC) Suction/rinsing channel
(T90R) (T180)	View direction in relation to light connection with turn 90° right / 180°
04 PE-LD 07 O 20 PAP 22 PAP	Indicates the recycling requirement for the packaging material with number and abbreviation of the material
	Indicates the Triman-Logo for recycling of material in France
ASTUCCIO PAP20 RACCOLTA CARTA	Indicates the material for recycling in Italy

INTENDED USE

Product description & intended purpose

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.

asap endoscopes are available in different models (different lengths/diameters/viewing directions; suitable for HD/4K; semiflex; autoclavable or immersible).

Endoscope name	Area of use
Cystoscope	Bladder, prostate
Hysteroscope	Uterus, vagina

⚠ In medical interventions on humans, your asap endoscope should only be used, without exception, by professionally trained physicians and only in aseptic/sterile environments.

⚠ The treating specialist has the ultimate responsibility in deciding whether to perform an intervention, regardless of area (see table above).

⚠ The use of an asap endoscope also depends on the patient's general condition and thus should be assessed critically by the physician in charge before each use.

⚠ Do not use on the central nervous or circulatory systems! Do not use on the heart!

The country-specific laws and regulations must be adhered to. You will find further instructions in the current technical literature.

Contraindications

BSE - Bovine spongiform encephalopathy, AKA "mad cow disease"

CJD - Creutzfeldt-Jakob disease

TSE - Transmissible spongiform encephalopathy

VCJK - Variant of Creutzfeldt-Jakob disease

Markings

Marking	Explanation
asap	Manufacturer
Autoclave 134°C/273°F	Can be steam sterilized at 134°C or 273°F
Soakable	Only immersible
HD	Suitable for HD camera systems
4K	Suitable for 4K camera systems
0°, 30°, 70° …	Viewing direction
Color coding at light connection	Viewing direction: Green = 0° Black = 12°/15°/20°/45° Red = 30° Yellow = 70° Blue = 90°
Semiflex	Endoscopes that allow for a greater deflection of the shaft

Accessories

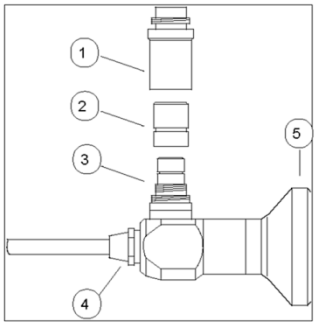
Standard accessories:

- Light connection adapter Storz/Olympus, Wolf
- Protection sleeve (for all asap endoscopes with shaft diameters smaller than 5 mm)

Non-standard accessories:

- CCD camera and TV adapter
- Light source, cold light cable, diverse adapters
- Trocar

Installation



① Light connection adapter Storz/Olympus
② Light connection adapter Wolf
③ Light connection ACMI
④ Instrument coupling
⑤ Eyepiece

Camera connection:

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. To this end, the Storz/Olympus and Wolf sleeves can be unscrewed from the light connection and other light connection adapters are available as needed.

⚠ The light produces energy that heats up the endoscope due to its high light density. Depending on the type of light source it is possible that the temperature of the distal end or of the light connection could exceed 41°C. The patient or user could suffer permanent tissue damage due to the high surface temperatures. Therefore, the safety distance to the tissue should be a minimum of 5 mm.

Instructions for use of asap endoscopes

Before use

Check your asap endoscope for proper function and possible damage immediately after receiving it and before every use:

Your asap endoscope is shipped in non-sterile condition. Clean and sterilize/disinfect it in accordance with the reprocessing instructions, before every use.

All surfaces should be smooth and bare, without any scratches or nicks.	→	Scratches or nicks on the probe or on the distal or proximal ends could be signs of possible damage.
Under daylight, inspect the length of the endoscope starting from the proximal end and rotating it along its axis.	→	Damage to the optical system could produce a cloudy view or cause a complete loss of image.
Connect the cold light cable to the light connection of the endoscope and turn on the light source.	→	Sufficient lighting is ensured when the light emitted at the distal end forms a uniform point of light without dark areas.

Special instructions for use

asap endoscopes satisfy the highest quality standards. Always handle your asap endoscope with great care.

Any mechanical stress, such as being dropped or being held from the distal end of the endoscope, can lead to damage or destruction.

asap endoscopes may only be used by qualified personnel.

Improper use can result in infections and damage to your patients or damage to your endoscope.

We recommend that you always have a replacement endoscope on hand every time you use your endoscope. In this way you will be reducing the risk of disruptions in the OR workflow or during diagnostic procedures, furthermore avoiding potential mistakes.

asap endoscopic products GmbH does not assume any liability for damages or consequential damages caused by non-observance of the instructions for use, improper handling, or incorrect use of the asap endoscope.

REPROCESSING INSTRUCTIONS

General warnings

asap endoscopes are supplied in non-sterile condition and must be cleaned and sterilized before first use and every subsequent use.

The instructions listed below have been validated by the medical device manufacturer as suitable for the preparation of a medical device for reuse. The reprocessor is responsible for ensuring that the reprocessing actually carried out, with the equipment, materials, and personnel in the reprocessing facility, achieves the desired result. To this end, a verification and/or validation and routine monitoring of the procedure are required.

To avoid cross-contamination, endoscopes may not be transported together with other devices or instruments. They may only be handled in the same container when each endoscope is individually fastened and the endoscopes are not in contact with one another.

Improper cleaning/sterilization may result in infections or may damage the endoscope.

asap endoscopes with the label “soakable” shall not be steam-sterilized in an autoclave!

Further specific warnings are found in the corresponding section of the reprocessing instructions and are labeled with a warning symbol.

Limitations of treatment

The product lifetime is fundamentally determined by wear and damage caused by use. Repeated reprocessing only has a minor effect on the product lifetime. asap has proven the safe use of the endoscope in up to 50 reprocessing cycles. A much higher number of reprocessings is possible. The end of the product lifetime is ultimately determined through the measures described in the section “Maintenance, control and testing”.

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
- Never immerse the endoscope or rinse it with a saline solution in order to avoid corrosion

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 60 minutes.

Preparation before cleaning

Wear protective gloves and goggles to protect from infections

- Thoroughly rinse the endoscope under running cold water
- Remove stubborn deposits on the endoscope using a soft brush

Manual cleaning

Manual cleaning may not be performed on asap endoscopes!

Machine cleaning

asap endoscopes may not be cleaned in an ultrasonic bath as the endoscope could be damaged!

asap endoscopes are suited for machine cleaning in washer-disinfectors that satisfy the ISO 15883 series of standards, and have been validated with such a device.

- Position the endoscope in the load carrier
- Start the cleaning 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 minutes / drain water
  - Rinsing – medium: tap water / temperature: 10-30°C / duration: 1 minute / drain water

Disinfection

- Thermal disinfection – medium: desalinated water / temperature: 90-93°C / duration: min. 5 minutes / drain water
- Observe country-specific requirements pertaining to the A0 value!

Drying

- Drying – temperature: 95-100°C / duration: min. 25 minutes

Allow endoscope to cool at room temperature. Faster cooling by using compressed air may cause damage to the endoscope!

Control and maintenance

Only touch endoscope and components with thoroughly clean and disinfected hands.

- Inspect visually for
  - residual contamination
  - 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.

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- 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 may not be any cloudiness, dirt, or other defect in the image

Packaging

- Pack the endoscope in proper sterilization packaging (e.g. sterilization film, rigid reusable container)

Sterilization

Never sterilize an endoscope that hasn't been cleaned! The success of sterilization depends on the prior cleaning condition!

asap endoscopes are suited for sterilization with moist heat (steam sterilization) in accordance with the ISO 17665 series of standards and have been validated with an appropriate autoclave.

Other sterilization procedures are not validated by asap! The reprocessor bears the responsibility for using other sterilization procedures!

Description of process:

- Prevacuum: 3x
- Temperature: min. 132°C – max. 137°C
- Temperature hold time: min. 4 – max. 30 minutes
- Drying: min. 10 minutes
- Allow sterilized endoscope to cool down at room temperature in the sterile goods packaging. Avoid exposure to cold.

Storage

Store the sterilized endoscope in the sterile goods packaging, protected from moisture, temperature fluctuations, dust, and direct sunlight.

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.

Repairs/returns

- 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.

Ship the endoscope in suitable protective packaging, preferably in its original packaging

Disposal

All asap endoscopes can be disposed of with normal hospital waste, taking into account the applicable hygiene requirements. Here, the respective, country-specific laws and guidelines must be observed.

It is possible to send non-repairable asap endoscopes back to the manufacturer, in cleaned and sterilized/disinfected condition, with a written proof of disposal, in a postage-paid package, with the addendum "Repair".

If you have further questions, please contact your trusted retailer.

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