



# Instruction for use Working sleeves

**Manufacturer address:**

asap endoscopic products GmbH  
Stöckmatten 19  
DE-79224 Umkirch

**Symbolism / Explanation:****Information for safety****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, may result in minor or moderate injury.

**Warranty:**

We provide a full guarantee in case of production or quality defects. In the case of obvious defects caused by faulty manufacture or the use of faulty materials, the products will be repaired or replaced free of charge.

In the event of damage due to improper handling, such as mechanical impact, falling, overloading, etc., the warranty claim is excluded. Repairs carried out by unauthorized persons will invalidate the warranty.

We recommend that you always have a spare endoscope and, if necessary, spare instruments ready for every endoscopic application. This reduces the risk in the surgical process and also prevents potential errors.

**Applied standards and guidelines:**

These products comply with Directive 93/42/EEC Class IIa. Class IIa products are additionally marked with the identifier of the notified body:



0124 = DEKRA Certification GmbH  
Handwerkstraße 15  
DE-70565 Stuttgart

**Intended purpose & indication**

asap working sleeves are intended for use in minimally invasive surgery, especially spinal surgery. The products are used as accessories for asap multiscopes or compatible endoscopes from other manufacturers.

The working sleeves are used for inserting multiscopes or endoscopes at the surgical site and draining liquids via the rinsing tap.



The decision to use the device also depends on the patient's general condition and is the ultimate responsibility of the treating specialist.

**Contraindication**

- CJK - Creutzfeld-Jakob disease
  - VCJK - Variant of Creutzfeld-Jakob disease
  - BSE - Bovine spongiform encephalopathy, so-called "mad cow disease"
  - TSE - Transmissible spongiform encephalopathy
- Currently, there are no known contraindications directly related to the products mentioned.



The working sleeves must not be used on the central nervous and circulatory system!

**Product description**

The working sleeves are available in 2 different variants with different tip angle. The tip shape serves as protection for the surrounding structures.



pointed 60°



pointed 50°

The working sleeves are also equipped with a flushing tap with Luer connection. The liquid introduced via the multiscopes can be drained again via this connection. Optionally, a hose or a liquid collection container can be connected via the Luer connection.






**Technical Data**

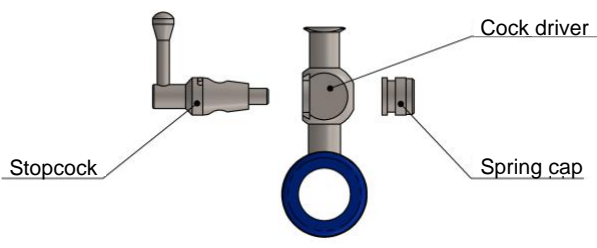
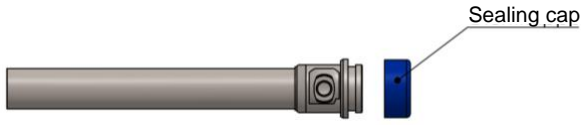
Articlenr.	Outer diameter [mm]	Inner diameter [mm]	Working length [mm]	Point angle
29-0201-00	8	7,2	170	60°
29-0204-00	8	7,2	170	50°



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<b>Compatibility</b>	<p>The working sleeves are pushed over the dilator during insertion. The products are compatible with asap dilators 29-0210-00 and 29-0218-00. Other dilators with the following specifications are also compatible:</p> <ul style="list-style-type: none"><li>• Outer diameter: 7,0 mm</li><li>• Length: mindestens 250 mm</li></ul> <p>Wenn die Arbeitshülsen im Körper positioniert sind, können Multiskope eingeführt werden. Die Produkte sind kompatibel mit den asap Multiskopen 10-0417-00, 10-1496-00 und 10-1498-00. Andere Multiskope mit folgenden Spezifikationen sind ebenfalls kompatibel:</p> <ul style="list-style-type: none"><li>• Outer diameter: max. 7,0 mm</li><li>• Working length: 177 mm</li></ul> <p>Before use, the responsible physician must check whether the combination of working sleeve and dilator or endoscope/multiscope permits safe operation. The combinability depends on the diameter and length.</p> <p>A hose or liquid collection container can be connected via the standardized Luer connector.</p>
<b>Attention</b>	<ul style="list-style-type: none"><li>• Only use products as intended, see purpose.</li><li>• Products may only be used by professionally trained physicians or operating room personnel. Improper use can lead to infection, harm to the patient or damage to the product.</li><li>• The country-specific laws and regulations must be observed. For further information, please refer to the current technical literature.</li><li>• Do not use a damaged or defective product. Sort out damaged products immediately.</li></ul>
<b>Visual and functional check</b>	<p><b>Visual inspection:</b> The products must be free of oxidation, dents and scratches. The distal end of the sleeves must not have nicks or a broken tip.</p> <p><b>Functional control:</b> The rinse water tap must be easy to open and close.</p>
<b>Operation</b>	<p><b>Before operation, ensure that the products have been properly prepared and checked.</b></p> <p>The rinsing tap is only intended for draining the rinsing liquid. Using the irrigation port to irrigate the surgical site may result in undesirable pressure build-up.</p> <ul style="list-style-type: none"><li>• Insert and position the working sleeves over the dilator in the working area (if necessary, under X-ray control)</li><li>• Insert multiscope</li><li>• Open or close the rinsing tap as required</li></ul>
<b>Preparation – general information</b>	<p> <b>The products are delivered unsterile. They must be properly cleaned and sterilized before first use and each subsequent use to prevent infection.</b></p> <p> The effectiveness of the cleaning and sterilization process described below has been verified by asap. Different settings can result in cleaning and sterilization being ineffective!</p> <ul style="list-style-type: none"><li>• The country-specific regulations and standards for the processing of medical products must be observed.</li></ul> <p><b>Precautions and Warnings:</b></p> <ul style="list-style-type: none"><li>• To avoid cross-contamination, never transport/clean/sterilize the instruments together with other devices and instruments. They may only be transported/ cleaned/ sterilized in the same container if each device and instrument is secured individually, and they do not come into contact with each other.</li><li>• Never use metal brushes, metal sponges or abrasive cleaning agents for manual cleaning.</li></ul> <p> <b>Restriction of reprocessing:</b></p> <ul style="list-style-type: none"><li>• The service life of the instruments is essentially determined by wear and damage caused by use. Before each use, a visual and functional check must be carried out to ensure that they are in good working order.</li></ul>
<b>Cleaning preparation</b>	<p> <ul style="list-style-type: none"><li>• To protect against infection, please wear protective gloves and goggles.</li><li>• Rinse the instruments with tap water immediately after use to remove coarse soiling.</li><li>• The instruments should be cleaned immediately after each use so that adhering substances do not dry out, to ensure adequate cleaning and sterilization! If immediate cleaning is not possible, the instruments should be immersed in distilled water until disinfected, but not longer than 45 minutes.</li></ul></p> <p></p>

<p><b>Preparation – Dismantling</b></p>	<p>⚠ The products must be dismantled before processing to ensure effective cleaning and sterilization.</p> <p>Disassemble the products as follows:</p>  <ul style="list-style-type: none"> <li>• Loosen the spring cap and remove the cock driver from the cock body.</li> <li>• Use a cloth and brush to remove the grease from the valve body and the valve driver.</li> </ul>  <ul style="list-style-type: none"> <li>• Pull of the sealing cap</li> </ul>
<p><b>Manual pre-cleaning</b></p>	<p>⚠ Working sleeves should be cleaned immediately after each use so that adhering substances do not dry out! Do not use any fixing agents (e.g. alcohols or aldehydes) or hot water (&gt;40° C), as this can lead to residues being fixed and affect the cleaning success. If cleaning is not possible immediately after use, the endoscope should be placed in distilled water until disinfected, but not longer than 45 minutes.</p> <ol style="list-style-type: none"> <li>1. Place the instrument parts in cold tap water for 5 minutes. Wet all surfaces and completely fill the lumens with water.</li> <li>2. Clean the surfaces under cold running tap water with a soft brush and brush the lumen three times with a bottle brush.</li> <li>3. Sonicate the instrument parts for 5 minutes in an ultrasonic bath with cleaning solution (e.g. 0.5% neodisher MediClean, Dr. Weigert, Hamburg). Fill the instrument parts with the cleaning solution before inserting them. Use agents that are available from specialist retailers specifically for cleaning and disinfecting medical endoscopes and accessories, and make sure you follow the manufacturer's specifications.</li> <li>4. Treat the lumen, crevices, and joints with a 3.8 bar water gun for 15 sec each.</li> </ol>
<p><b>Machine cleaning</b></p>	<p>The following description corresponds to the validated procedure for automatic cleaning with the Miele device G7836 CD.</p> <ul style="list-style-type: none"> <li>• Place all parts on the slide-in trolley (Miele E 429 ophthalmology trolley) so that the water can run off everywhere. Connect the sleeve tip to the insertion trolley via a hose.</li> <li>• Use the following parameters for automatic cleaning:             <ul style="list-style-type: none"> <li>- 2 min pre-cleaning with cold tap water - emptying</li> <li>- 5 min cleaning at 55° C with tap water and 0.5% cleaning solution (MediClean, Dr. Weigert, Hamburg) - emptying</li> <li>- 3 min neutralization with cold demineralized water – emptying</li> <li>- 2 min rinsing with cold demineralized water - emptying</li> </ul> </li> <li>• Check the parts for visible residual dirt when removing them. If necessary, repeat cycle or clean manually.</li> <li>• Finally, a disinfecting thermal rinsing cycle can be run.</li> </ul>
<p><b>Sterilization</b></p>	<p>⚠ <b>Never sterilize uncleaned instruments! The success of a sterilization depends on the previous cleaning status.</b></p> <p>Working sleeves can be steam sterilized in an autoclave.</p> <ul style="list-style-type: none"> <li>• Autoclave the disassembled, cleaned, and dried instruments, double wrapped in transparent sterilization bags.</li> <li>• Run the autoclave cycle with the following minimum sterilization parameters:             <ul style="list-style-type: none"> <li>- 3 pre-vacuum phases</li> <li>- Sterilization temperature 132° C</li> <li>- Holding time 3 min (full cycle)</li> <li>- Drying time 3 min</li> </ul> </li> <li>• Allow the instruments to cool at room temperature.</li> </ul>
<p><b>Assembly</b></p>	<ul style="list-style-type: none"> <li>• Apply a thin coat of special tap grease to the tap driver and insert it into the tap housing. Then screw the spring cap tight.</li> <li>• Press the sealing cap back on. If the sealing cap is damaged, it can be reordered as a spare part.</li> </ul>
<p><b>Storage</b></p>	<ul style="list-style-type: none"> <li>• Store the products in a sieve or container in such a way that they are protected from damage.</li> <li>• Store the products away from dust at room temperature in a dry, low-germ place.</li> </ul>






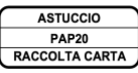


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<b>Repair/ Replacement</b>  	<ul style="list-style-type: none"> <li>• Even when used as intended, medical devices are subject to a greater or lesser degree of wear, depending on the intensity of use. The wear is due to technical reasons and unavoidable.</li> <li>• Do not carry out repairs yourself. Service and repairs may only be carried out by the manufacturer or persons authorized by us. Failure to do so could result in tissue damage or infection to the patient.</li> <li>• Medical devices sent for repair or replacement must be cleaned, disinfected, and sterilized with written proof.</li> </ul>
<b>Disposal</b>  	<ul style="list-style-type: none"> <li>• Working sleeves can be disposed of with normal clinical waste, taking into account the applicable hygiene requirements. The respective country-specific laws and guidelines must be observed.</li> <li>• Improper disposal can lead to infections of the user or third parties.</li> <li>• It is possible to return instruments that cannot be repaired to the manufacturer in a cleaned, disinfected, and sterilized condition with written evidence in a prepaid parcel with the addition "repair".</li> </ul>
<b>Spare parts</b>	<p>If the sealing cap of the working sleeve is damaged, you can reorder it as a spare part. → Replacement sealing cap, non-sterile 26-1006-00 – VPE 1 pc. / 26-1006-10 – VPE 10 pc.</p>

Only symbols that are not listed in ISO 15223-1 are explained below. For all other symbols used, see ISO 15223-1.

Symbol	Explanation
	Indicates that this is a prescription device. US Federal law restricts this device to sale by or on the order of a physician (US only).
	Denotes an autoclavable product at the specified temperature $\geq 132^{\circ}\text{C}$
	Indicates a soakable product
(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/irrigation channel
(T90R) (T180)	Direction of view in relation to the light connection with rotation $90^{\circ}$ right / $180^{\circ}$
	Indicates the recycling requirement for the packaging material with the number and abbreviation of the material
	Displays the Triman logo for the recycling of materials in France
	Indicates the material for recycling in Italy