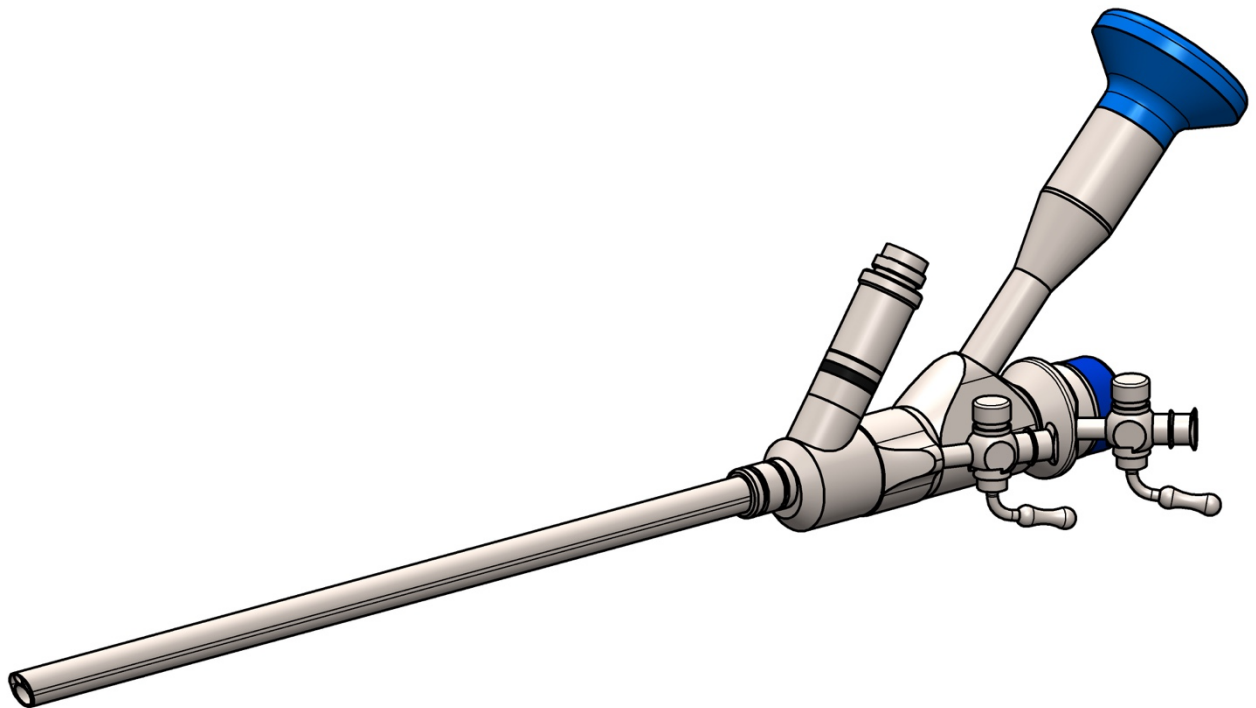


# Instructions for Use

## Multiscope

Article number: 10-1496-00, 10-1498-00, 10-1492-00, 10-1493-00





# Instructions for Use

## Multiscope and Multiscope Instruments



**Manufacturer address:**  asap endoscopic products GmbH  
Stöckmatten 19  
79224 Umkirch, Germany

### 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

### 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, overloading etc., the warranty claim is invalidated. If repairs are carried out by non-authorized persons, any warranty claim is rendered void.

We recommend that you always have a replacement endoscope and any necessary replacement instruments on hand every time you use your endoscope. In this way you will be reducing the risk in the OR workflow, furthermore avoiding potential mistakes.

### Applied standards and guidelines:

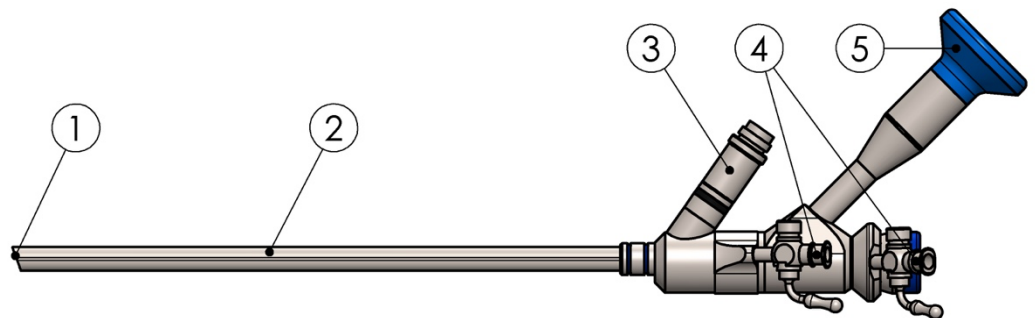
These endoscopes comply with Directive 93/42/EEC Class IIa. Products from Class IIa are additionally marked with the identification of the notified body:



0124 = DEKRA  
Handwerkstrasse 15  
70565 Stuttgart, Germany

### Multiscope

The asap multiscope is a precision optical device for visualizing the interior of the body, and is designed for use in minimally invasive surgical procedures performed endoscopically. It is an angled rigid endoscope with working channel and multiple rinsing options. *Image: Variant 10-1496-00.*



- ① Optical surface at the distal end
- ② Endoscope shaft
- ③ Light connection adapter Storz/Olympus, including: Light connection adapter Wolf, including: Light connection ACMI
- ④ Suction/rinsing connections
- ⑤ Eyepiece

### Variants

	Shaft: oval 6.9 mm x 6.1 mm, l = 177 mm Working channel: Ø 4.1 mm, l = 264 mm 1x suction/rinsing channel: Ø 1.8 mm	Shaft: 6.3 mm, l = 177 mm Working channel: Ø 3.7 mm, l = 264 mm 1x suction/rinsing channel: Ø 1.5 mm
Viewing direction 20°	<b>10-1496-00</b>	<b>10-1492-00</b>
Viewing direction 30°	<b>10-1498-00</b>	<b>10-1493-00</b>

### Multiscope markers

N (and number)	= serial number
CE 0124	= Designed, manufactured and tested according to the requirements of Directive 93/42/EEC Annex II
Autoclave 134°C/273°F	= Can be steam sterilized at 134°C or 273°F
HD	= HD capable
20° / 30°	= Viewing direction
Color coding at light connection	= Viewing direction: black = 20°, red = 30°



# Instructions for Use Multiscope and Multiscope Instruments



asap

= Manufacturer

The packaging label also indicates the designation with the main specifications and the manufacturer's address.

## Multiscope accessories

### Standard accessories

- Light connection adapter Storz/Olympus, Wolf
- Cleaning brush 26-2017-00 for rinsing channel
- Cleaning brush 26-2040-00/ 26-2045-00 for working channel
- Replacement valves 26-1004-05 set of 5, non-sterile

### Non-standard accessories:

- CCD camera and TV adapter
- Light source, cold light cable, diverse adapters
- Suction-rinsing pumps and accessories
- Various instruments, working sleeves, dilators
- Sterilization baskets, containers

## Multiscope instruments

### Puncture needle

29-0010-00



### Guide wire

29-0128-00



### Dilators

29-0210-00

29-0218-00 (compatible  
with 10-1496 -00 / 10-1498-  
00)

29-0217-00 (compatible  
with 10-1492-00 / 10-1493-00)



### Hammer

29-1080-00



### Impactor

29-1081-00

(compatible with 10-1496 -00 /  
10-1498-00)



### Working sleeve

29-0201-00

29-0204-00

(compatible with 10-1496-00/  
10-1498-00)



### Trephine drill

29-1031-00

29-1032-00

29-1033-00



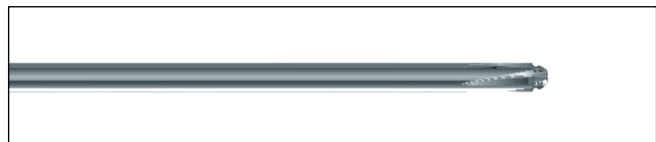
### Facet rasp

29-1028-00

29-1029-00 / 29-1059-00

29-1057-00 / 29-1057-00


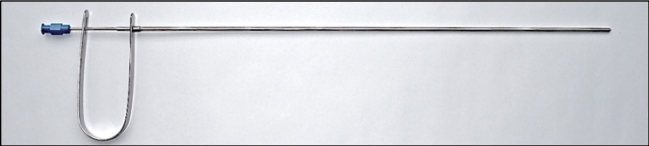
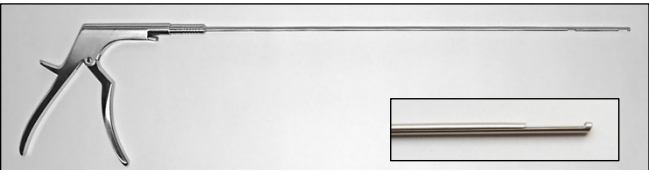
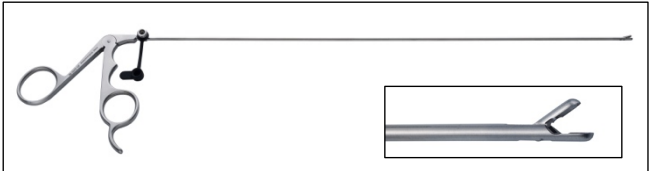
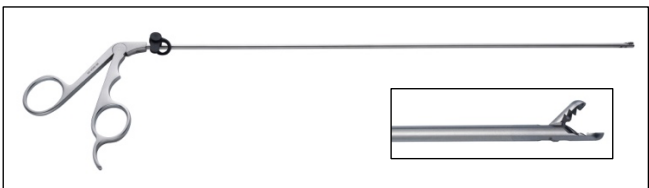
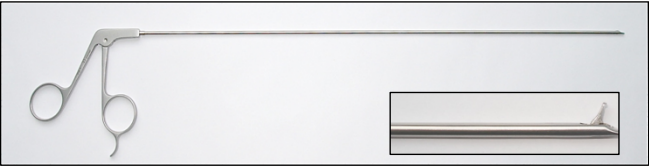
29-1030-00 / 29-1060-00






## Instructions for Use Multiscope and Multiscope Instruments




<b>Dissector</b> 29-1022-00	
<b>Tactile and rinsing probe</b> 29-0301-00	
<b>Endoscopic Kerrison bone punch</b> 29-2020-00 to 29-2025-00 / 29-1920-00 to 29-1925-00 / 29-1930-00 to 29-1935-00 / 29-1940-00 to 29-1945-00 / 29-2029-00 29-2069-00	
<b>Micro spoon grasper</b> 29-2002-00 / 29-2003-00 29-2005-00 / 29-2008-00	
<b>Drum grasper</b> 29-2004-00 29-2006-00 29-2007-00 29-2052-00	
<b>Endoscopic punch</b> 29-2031-00 29-2032-00	

<b>Markings on multiscope instruments</b>	Manufacturer, CE mark, order and batch no. The packaging label also indicates the designation and sterilization method, as well as the manufacturer's address.
<b>Additional guidances for asap instruments</b>	76-0119-00 Kerrison Instruction Sheet 76-0120-00 Sergej Instructions Sheet 76-0104-00 Instructions for Use (tactile and rinsing probe) 76-0112-00 Instructions for Use (working sleeves)
<b>Area of application</b>	<p>Multiscopes are used together with multiscope instruments for endoscopic treatment of spinal disorders, such as herniated discs or stenoses.</p> <p>The puncture needle, guide wire and dilators are used to create the surgical body opening (piercing and expanding the skin under X-ray monitoring). The hammer and impactor can be used as tools for this purpose. The working sleeves are used to guide the multiscope and for rinsing. The trephine drill, facet rasp and dissector are used through the multiscope working channel and used to expose the actual treatment site; the facet rasp and trephine drill can also be applied directly through the working sleeve. The tactile and rinsing probe can be used to rinse through the working channel directly at the treatment site. Graspers, punches and rongeurs are used to remove tissue.</p> <p>Do not use them for other purposes! These products may only be used in medical facilities by trained medical personnel who have been trained in the use of multiscopes and multiscope instruments.</p> <p> The decision on whether to use the device also depends on the patient's general condition and is the ultimate responsibility of the treating specialist.</p> <p>Do not use on the central nervous system! Do not use on the heart!</p>
<b>Contraindications</b>	<ul style="list-style-type: none"> <li>• CJD - Creutzfeldt-Jakob disease</li> </ul>



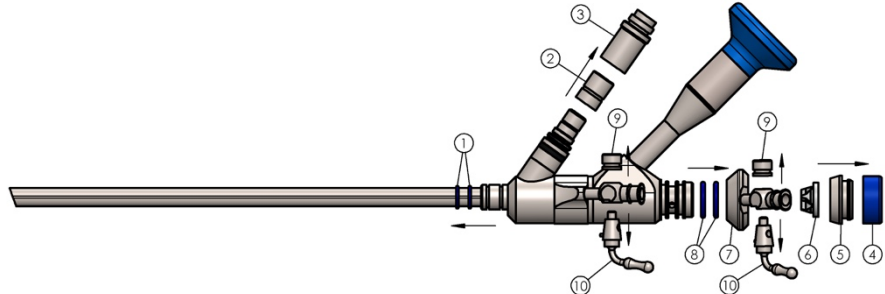
## Instructions for Use Multiscope and Multiscope Instruments



	<ul style="list-style-type: none"><li>• VCJK - Variant of Creutzfeldt-Jakob disease</li><li>• BSE - Bovine spongiform encephalopathy, AKA "mad cow disease"</li><li>• TSE - Transmissible spongiform encephalopathy</li></ul> <p>Currently, there are no known contraindications directly related to an asap endoscope or instrument.</p>
<b>Verification and compliance</b>	<ul style="list-style-type: none"><li>• Read, observe and retain the instruction manual.</li><li>• Use products only as intended, see field of application.</li><li>• Country-specific laws and regulations must be adhered to. You will find further instructions in the current technical literature.</li><li>• All endoscopes and instruments must be completely cleaned and sterilized before the first use and each subsequent use.</li><li>• Do not use a damaged or defective product. Discard damaged products immediately.</li></ul>
<b>Special instructions for use</b> 	<ul style="list-style-type: none"><li>• asap multiscopes and instruments meet the highest quality standards. Always handle them with great care. Any mechanical stress, such as being bent, being dropped or being held from the distal end of the endoscope, can lead to damage or destruction.</li><li>• We recommend that you always have a replacement endoscope and any necessary replacement instruments on hand every time you use your endoscope. In this way you will be reducing the risk in the OR workflow or during diagnostic procedures, furthermore avoiding potential mistakes.</li><li>• Caution! Operating lasers in the working channel is prohibited!</li><li>• Caution! The valve in the working channel is not intended to build up pressure but to reduce the backflow of rinsing liquid through the working channel.</li></ul>
<b>Visual and functional check</b>	<p><b>Visual inspection:</b></p> <ul style="list-style-type: none"><li>• All surfaces must be free of oxidation, dents and scratches.</li><li>• Under daylight, inspect the length of the multiscope 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.</li></ul> <p><b>Functional check:</b></p> <ul style="list-style-type: none"><li>• Connect the cold light cable to the light connection of the multiscope 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.</li><li>• The rinsing taps must be easy to open and close. The rinsing tap at the proximal end must rotate smoothly.</li></ul>
<b>Operating and assembly instructions</b>  	<p><b>Before operating it, ensure that the product has been properly decontaminated and inspected.</b></p> <p>Before use, the responsible physician must check whether the combination of endoscope and instruments permits safe operation. The combination option depends on the diameter and length.</p> <ul style="list-style-type: none"><li>• Camera connection: Affix the eyepiece onto your camera's TV adapter. Set the image sharpness and image size, if required, on the TV adapter.</li><li>• Light connection: Your asap multiscope 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. The light is an energy source that heats up the multiscope due to its high light density. When selecting the light source (type and power of the lamp), care must be taken in accordance with DIN EN 60601-2-18 to ensure that no excessive temperatures occur at the light outlet. Taking into account the intended duration of use of multiscopes, the power of the light source must not exceed 300 W. Caution! The distal end and the light connection of the multiscope must not come into contact with easily flammable or heat-sensitive materials or with patient tissue. The safety distance should be at least 5 mm.</li><li>• Suction/rinsing connections: Connect the suction/rinsing hoses. The suction/rinsing connections may only be used for suction and/or rinsing. The user is responsible for using suitable rinsing liquids. To avoid the risk of bacterial contamination of the patient, the number of manipulations on the connections during surgery must be kept to a minimum.</li></ul>

**Disassembly instructions  
Multiscope**

Disassemble the multiscope by removing all detachable parts:



- ① O-ring, dark blue x2      ④ Sealing cap for working channel      ⑦ Rotatable rinsing connection      ⑩ Stopcock x2
- ② Wolf adapter              ⑤ Cone working channel              ⑧ O-ring, large
- ③ Storz/Olympus adapter    ⑥ Cross-slit valve                      ⑨ Spring cap x2

Please refer to additional guidances for asap instruments section for the assembly / disassembly of asap instruments, tactile and rinsing probes and working sleeves.



Do not remove the screw on any punch or grasper as it has been riveted for safety reasons.

**General warnings**



- asap multiscope and instruments 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, multiscope may not be transported together with other devices or instruments! They may only be handled in the same container when each multiscope is individually fastened and the multiscope are not in contact with each another.
- Improper cleaning/sterilization may result in infections or may damage the multiscope.

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 multiscope in up to 50 reprocessing cycles. A much higher number of reprocessing cycles is possible. The end of the product lifetime is ultimately determined through the measures described in the "Control and maintenance" section.

**Initial treatment at point of use**

- Release the multiscope from the TV adapter and light connection
- Loosen rinsing connections

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

- rinse the multiscope with cold water
- wipe the multiscope clean
- Rinse working and rinsing channels with cold water



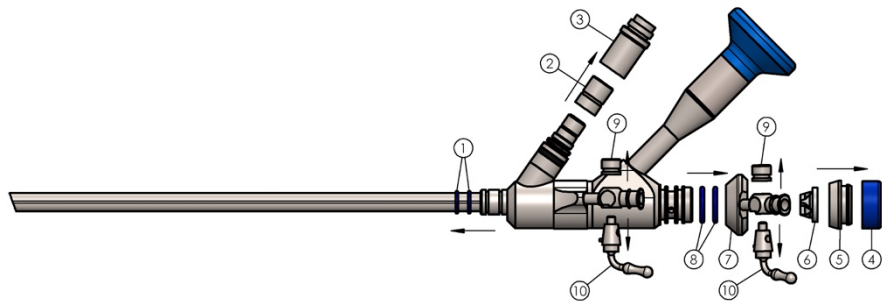
- Never immerse the multiscope or rinse it with a saline solution in order to avoid corrosion
- Do not immerse the multiscope in hot water (> 40°C) or in detergents with protein-fixing properties (e.g. alcohols, aldehydes), or rinse with such detergents, as this may result in the fixation of residue accompanied by an adverse cleaning effect.
- Immediately submit the multiscope to the next cleaning step. If this is not possible, place the multiscope in cold water for a max. of 45 minutes.

**Preparation before cleaning**



- Wear protective gloves and goggles to protect from infections

- Thoroughly rinse the multiscope and instruments under running cold water
- Disassemble the following components
  - ① + ⑧ + O-rings (if present)
  - ② + ③ Fiber-optic adapter (if used)
  - ⑨ + ⑩ Rinsing Stopcocks components
  - ⑦ Rotatable rinsing connection
  - ⑥ Cross-slit valve
  - ⑤ Cone working channel
  - ④ Sealing cap working channel



*The illustration shows multiscope 1U-1496-00 as an example. The models listed in the variants section have the same design layout. Please refer to additional guidances for asap instruments section for asap instruments for the assembly / disassembly of asap instruments, tactile and rinsing probes and working sleeves.*

- Dispose of used O-rings, sealing cap and sealing valve. O-rings, sealing cap and sealing valves are intended for single use and must be renewed after each application.
- 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)
- Remove persistent deposits on the multiscope using a soft brush
- Clean the rinsing and working channels using a suitable brush
- Flush the rinsing and working channels by attaching a cleaning gun and suitable attachment to the distal end (rinse channels for at least 5 seconds each at a water pressure of at least 3 bar)

**Manual cleaning**

Manual cleaning may not be performed on asap multiscope!

**Machine cleaning**



- asap multiscope may not be cleaned in an ultrasonic bath as the multiscope 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.
- Connect the multiscope/instrument at the distal end to the active rinsing system of the load carrier to ensure rinsing of the working and rinsing channels (e.g. by means of a flexible hose or sleeves)
  - Position the multiscope/instrument in the load carrier
  - Position the container for small parts on 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 minute / 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!





## Instructions for Use Multiscope and Multiscope Instruments



	<ul style="list-style-type: none"> <li>To protect workers, the multiscope or instrument must be reprocessed prior to shipment to the repair shop.</li> <li>Transport the multiscope and instrument in suitable protective packaging, preferably in its original packaging</li> </ul>																					
<b>Disposal</b>	<ul style="list-style-type: none"> <li>Multiscopes and multiscope instruments can be disposed of along with normal hospital waste, taking into account the applicable hygiene requirements. In this case, the respective, country-specific laws and guidelines must be observed.</li> <li>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".</li> </ul>																					
<b>Spare parts</b>	<table border="1"> <tr> <td>• Replacement sealing cap (item 4), non-sterile</td> <td>26-1022-10</td> <td>PU 10 pcs</td> </tr> <tr> <td>• Spare valve (item 6), non-sterile</td> <td>26-1004-05</td> <td>PU 5 pcs</td> </tr> <tr> <td>• Spare O-ring, dark blue (item 1), non-sterile</td> <td>26-1008-10</td> <td>PU 10 pcs</td> </tr> <tr> <td>• Spare O-ring, light blue (item 8), non-sterile</td> <td>26-1021-10</td> <td>PU 10 pcs</td> </tr> <tr> <td>• Replacement cleaning brush, non-sterile for rinsing channels 10-1492-00, 10-1493-00, 10-1496-00 and 10-1498-00</td> <td>26-2017-00</td> <td>PU 1 pcs</td> </tr> <tr> <td>• Replacement cleaning brushes, non-sterile for working channel 10-1492-00 and 10-1493-00</td> <td>26-2040-00</td> <td>PU 1 pcs</td> </tr> <tr> <td>• Replacement cleaning brushes, non-sterile for working channel 10-1496-00 and 10-1498-00</td> <td>26-2045-00</td> <td>PU 1 pcs</td> </tr> </table>	• Replacement sealing cap (item 4), non-sterile	26-1022-10	PU 10 pcs	• Spare valve (item 6), non-sterile	26-1004-05	PU 5 pcs	• Spare O-ring, dark blue (item 1), non-sterile	26-1008-10	PU 10 pcs	• Spare O-ring, light blue (item 8), non-sterile	26-1021-10	PU 10 pcs	• Replacement cleaning brush, non-sterile for rinsing channels 10-1492-00, 10-1493-00, 10-1496-00 and 10-1498-00	26-2017-00	PU 1 pcs	• Replacement cleaning brushes, non-sterile for working channel 10-1492-00 and 10-1493-00	26-2040-00	PU 1 pcs	• Replacement cleaning brushes, non-sterile for working channel 10-1496-00 and 10-1498-00	26-2045-00	PU 1 pcs
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Only symbols not listed in ISO 15223-1 are explained below. Refer to ISO 15223-1 for all other symbols used.

Symbol	Explanation
	Indicates a Prescription Device U.S. Federal law restricts this device to sale by or on the order of a physician (for US only)
	Indicates an autoclavable device at the indicated sterilization temperature $\geq 132^{\circ}\text{C}$
	Indicates an immersible/soakable device
(O) (C) (W) (DY) (S)	(O) Olympus compatible instrument coupling (C) Circon compatible c 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 $60^{\circ}$ right / $180^{\circ}$
	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
	Indicates the material for recycling in Italy