

# **OLYMPUS**

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## SYSTEM GUIDE ENDOSCOPY

**SYSTEM-RELATED INSTRUCTIONS FOR USE**



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# 1 Introduction

Olympus instructions for use have been prepared to provide the user with all the necessary knowledge about the safe use of Olympus endoscopes and their related accessories.

For further questions about how to use the products, about the products' safety, or about this or other Olympus documents, feel free to contact your local Olympus representative or visit our website at [www.olympus-oste.eu](http://www.olympus-oste.eu)

## **Product-specific instructions for use**

Olympus products are supplied with product-specific instructions for use, which give all details necessary for the use of the product.

Some product-specific instructions for use make reference to the "System Guide Endoscopy". In these cases, all the related information given in the "System Guide Endoscopy" is applicable to the product.

If the information given in the "System Guide Endoscopy" is not applicable to a certain product, specific information is given in the product-specific instructions for use.

## **System Guide Endoscopy**

The system-related instructions for use "System Guide Endoscopy" combine information on those topics that apply to many instruments. Therefore, the "System Guide Endoscopy" must be considered as part of the instructions for use.

The "System Guide Endoscopy" applies to all products manufactured or distributed by Olympus Winter & Ibe, Germany, that reference to the "System Guide Endoscopy".

- To make sure that you use the most recent version of the "System Guide Endoscopy", check our website ([www.olympus-oste.eu](http://www.olympus-oste.eu)).

## **Carefully read all instructions for use**

- Before use, carefully read the product-specific instructions for use, the "System Guide Endoscopy" (this document), and all instructions for use pertaining to additional equipment used in the procedure.

- Follow all instructions given in these documents.  
Failure to understand these instructions may result in:
  - Death or severe injury to the patient
  - Severe injury to the user
  - Severe injury to a third party
  - Damage to the equipment

### **Use of instructions for use**

Instructions for use contain valuable specifications, care, and problem-solving information which will help ensure safe and effective operation of the equipment.

- Keep instructions for use in a safe, accessible location.

## **1.1 Potential Hazards and Signal Words**

Olympus instructions for use include safety information which help the user to identify potential hazards and to avoid them. Olympus instructions for use highlight potential hazards by using three signal words:

- Danger
- Warning
- Caution

In addition, the signal word Note has been introduced for helpful information.

### **DANGER**

Indicates an imminently hazardous situation which, if not avoided, may result in death or serious injury.

### **WARNING**

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

### **CAUTION**

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

This signal word may also be used to highlight unsafe practices or potential equipment damage.

## NOTE

Indicates additional helpful information.

## 1.2 Symbols

Potential hazards, mandatory actions, prohibitions, and user actions are illustrated using the same symbol shapes throughout the “System Guide Endoscopy”.



### Hazard alert

An equilateral triangle is used to convey hazard alert messages, regardless of their hazard level. Hazard level is conveyed by use of the appropriate signal word as described above.



### Mandatory actions

A solid color circle is used to signify a mandatory action.



### Prohibition

A circular band with a 45° diagonal slash from upper left to lower right is used to indicate prohibition.

### User actions

- A bullet at the beginning of a sentence indicates a required user action.

## 2 Use of Endoscopic Equipment

### **User qualification**

The user of endoscopic equipment must be a physician or medical personnel under the supervision of a physician. The user must have received sufficient training in clinical procedures. Olympus instructions for use do not explain or discuss clinical procedures.

### **Spare equipment**

- Always have spare equipment available in order to replace the equipment in case of a malfunction.



### **WARNING**

#### **Infection control risk with reusable equipment**

Improper and/or incomplete reprocessing can cause infection of the patient and/or medical personnel.

- Properly reprocess all reusable equipment before first and each subsequent use following the instructions in this “System Guide Endoscopy” and in the product-specific instructions for use.



### **WARNING**

#### **Infection control risk with sterile, single-use equipment**

The equipment is delivered in a sterilized condition.

- Use only if the package is undamaged.
- Only open the package immediately before use.
- Do not use the equipment after its expiration date (if an expiration date is given).
- Dispose of expired equipment according to national and local laws and guidelines.

### **Instrument compatibility**

The combinations of equipment and accessories that can be used with a certain product are listed in their product-specific instructions for use. The section is headed “Compatible Components” or “Compatible Equipment”.

New products released after the introduction of a product may also be compatible for use. For details, contact Olympus.





## **WARNING**

### **Risk of injury or equipment damage**

Using incompatible equipment can result in patient injury and/or equipment damage.

If combinations of equipment other than those listed in the “Compatible Components” section are used, the full responsibility is accepted by the user.

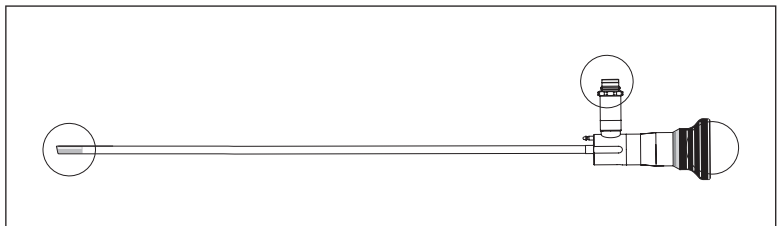
## **2.1 Inspection Before Each Use**

Before each use, perform the following inspection in addition to that described in the product’s product-specific instructions for use.

### **General inspection**

- The product must be free of damage (e.g., dents, cracks, bends).
- The product must be free of dirt.
- The product must be free of remaining cleaning agents or disinfectants.
- Make sure that no parts are missing or loose (e.g., sealing rings, sealing caps).
- Make sure that connecting elements between instruments function properly.
- Inspect working channels for free passage.
- Make sure that all instrument parts/modules of an instrument system are assembled correctly and properly fixed (e.g., electrodes, knives, etc.).

### **Inspecting telescopes**

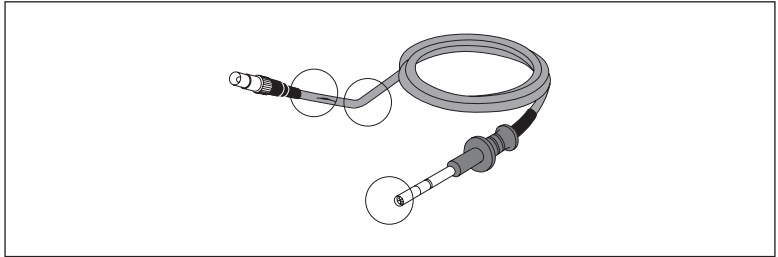


- Inspect for debris on the objective window, the ocular window and the light-guide connector.

- The telescope's image must not be cloudy, out of focus or dark.
- Make sure that there is efficient light transmission from the light-guide connector to the distal end. If in doubt, compare the telescope's light transmission with that of a new telescope.

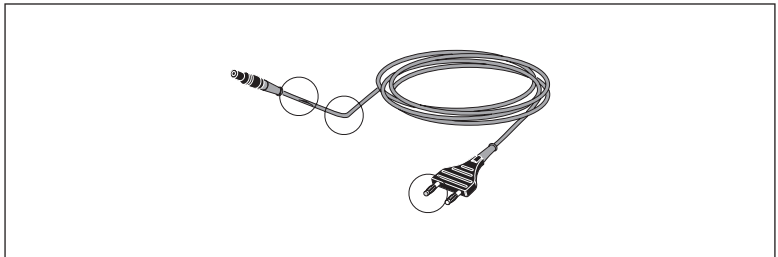
### **Inspecting light-guide cables**

- Make sure that efficient light transmission is obtained. If in doubt, compare the light-guide cable's light transmission with that of a new light-guide cable.



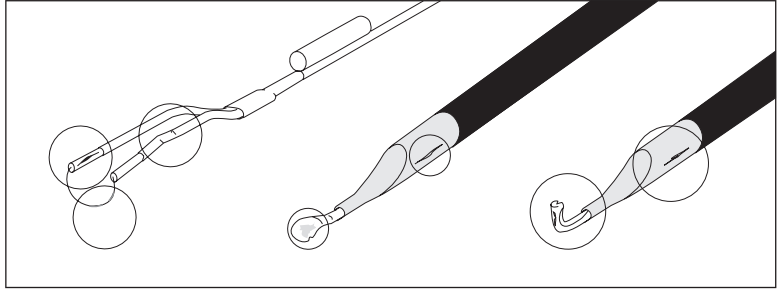
- Inspect for cuts or other damages to the cable's outer sleeve.
- Visually inspect the connector to be plugged into the light source. Make sure that the cover glass is not damaged.

### **Inspecting HF cables**

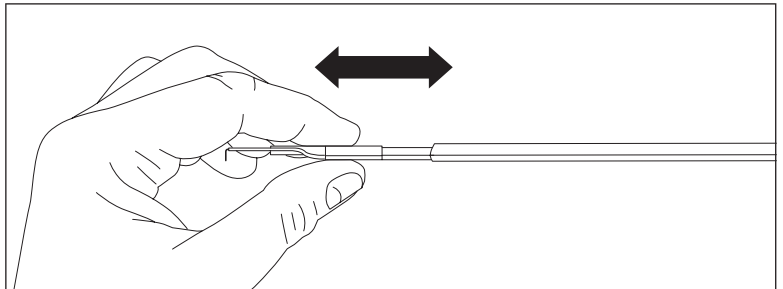


- Make sure that the cable is not broken.
- Make sure that the insulation is not defective.
- Make sure that connectors are not damaged (e.g., dents, cracks, bents) and free of corrosion.

## Inspecting electrodes



- Make sure that contact surfaces are free of damage, corrosion, and/or wear.
- Make sure that the insulation is not damaged.



- Make sure that the HF-resection electrodes are securely attached. To do so, hold the working element in one hand. With the other hand, hold the electrode guiding tube. Pull slightly at the electrode.
- Make sure that the electrode moves smoothly and freely within the assembled instrument.

## Inspecting hand instruments



- Make sure that the jaws and the handle move freely and are properly attached to the instrument.
- Make sure that the electrode's proximal part is not bent.
- Make sure that the shaft's insulation is not damaged.
- Make sure that the jaws insert can be inserted smoothly in the handle.
- Test scissors for cutting ability.
- Make sure that the sealing cap is not damaged (e.g., cracks).

# 3 Energetic Applications

## 3.1 Safety Precaution for Electro-Medical Equipment

### 3.1.1 General

The following instructions, based on the Notification No. 495 issued by the Pharmaceutical and Supply Bureau of the Ministry of Health and Welfare, Japan, June 1, 1972, describe general precautions which should be taken in the use of electro-medical equipment to ensure the safety of the patient, operator and surroundings.

In regard with specific safety precautions for particular types of equipment, refer to the individual operation manuals.

### 3.1.2 Installation



1. The equipment should not be installed in a location on which liquids may splash.
2. Avoid environmental conditions that are likely to be adversely affected by atmospheric pressure, temperatures, humidity, ventilation, sunlight, dusty, salty or sulfurous air, etc.
3. Exercise care so that the equipment is neither inclined nor subjected to vibration and impacts. (Including during transportation.)
4. Never install and operate the equipment where there is a risk of flammable gases.



5. The AC mains to which the equipment is connected should supply a power appropriate for the input frequency, rated voltage and amperage of the equipment.
6. Check the conditions of batteries (discharge, polarity, etc.)
7. Earth the equipment effectively.

### 3.1.3 Before use

1. Check electrical contacts of switches, polarity, dial setting, indicators, etc. and make sure that the equipment functions properly.
2. Make sure that the equipment is earthed effectively.
3. Make sure that all cords are connected correctly and securely.
4. Consideration should be taken if the equipment is used in conjunction with other instruments so that inaccurate diagnosis or a hazard will not result.
5. Check the external circuit directly connecting to the patient.
6. Check the batteries.

### 3.1.4 During use

1. A prolonged use or a dosage more than necessary for diagnosis and treatment may compromise patient safety.
2. Keep an eye continuously on the equipment at large as well as the patient for abnormality.
3. If any abnormality with the equipment or the patient is detected, take appropriate measures, e.g. by stopping the equipment in such a manner that it does not impair the patient safety.
4. Pay attention so that the patient does not come into contact with the equipment.

### 3.1.5 After use

1. After setting control switches, dials, etc. back to the home position in accordance with the procedures as prescribed, turn off the power switch.
2. When unplugging the connector, do not yank at the cord. Grasp the plug and pull to disconnect.
3. Storage
  - The equipment should not be stored in a location on which liquids may splash.

- Avoid environmental conditions that are likely to be adversely affected by atmospheric pressure, temperatures, humidity, ventilation, sunlight, dusty, salty or sulfurous air, etc.
  - Exercise care so that the equipment is neither inclined nor subjected to vibration and impacts.
  - Do not store the equipment where there is a risk of flammable gases.
4. After accessories, cords, leads, etc. have been cleaned, arrange them neatly, then put in storage.
  5. During storage keep the equipment clean and ready for next use.

### 3.1.6 Service and maintenance

1. If any failure has developed, leave repairs to the specialist. Attach appropriate information to the defective equipment and call qualified service personnel.
2. The user should not modify the equipment.
3. Maintenance and inspection
  - Inspect the equipment and accessories periodically.
  - When using the equipment after an extended period of time, make sure it functions normally and safely.

For specific safety precautions of particular equipment, refer to the product-specific instructions for use.

## 3.2 Light



### **Energy emission of light sources**

Light sources emit large amounts of light energy and thermal energy.

As a result:

- The light-guide connector and the telescope's distal end become extremely hot.
- The light energy is concentrated in a relatively small area.

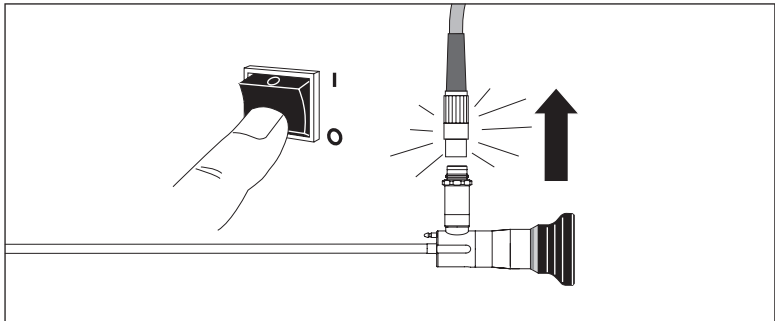


### Risks related to light sources

- Thermal injury to the patient's tissue (e.g., from prolonged exposure to the intense illumination in cavities with small lumens, or if the telescope's distal end is placed into close proximity with the tissue).
- Burns to the patient's or user's skin.
- Burns or thermal damage to surgical equipment (e.g., surgical drapes, plastic materials, etc.).

### Safety precautions

- Avoid prolonged exposure to intense illumination.
- Use the minimum level of illumination necessary to satisfactorily illuminate the target area.
- Do not place the telescope's distal end or the light-guide connector on the patient's skin, on flammable materials, or on heat-sensitive materials.
- Do not touch the telescope's distal end or the light-guide connector.

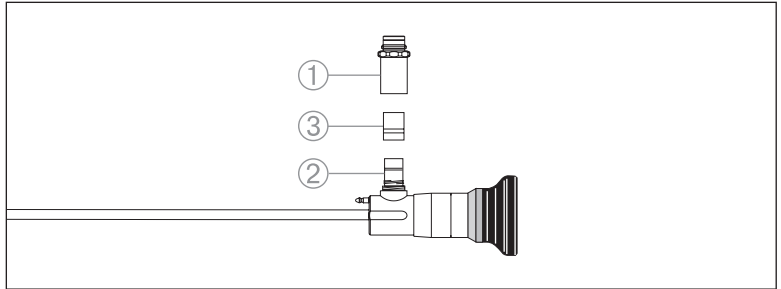


- Turn the light source off when detaching the telescope from the light-guide cable.
- Allow the telescope and the light-guide cable to cool down after use.



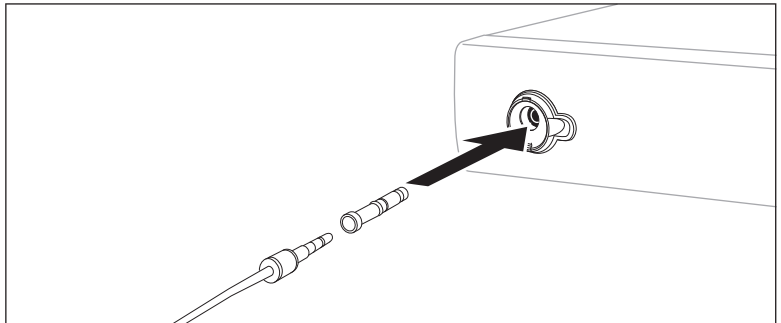
### Adapters on the telescope's light-guide connector

Light-guide adapters allow the telescope to be connected to light-guide cables of various manufacturers.



- 1) Olympus OES light-guide cable and Storz light-guide cables
- 2) Wolf light-guide cables
- 3) Olympus OES Pro and ACMI light-guide cables

### Adapters on the light-guide cable's connector plug



Light-guide adapters allow the light-guide cable to be connected to light sources of various manufacturers. The nested adapter A3200 allows the connection to an Olympus light source.

- To use other adapters, remove adapter A3200 and attach the required adapter.



#### CAUTION

#### Risk of loss in light transmission

- When using screw-type adapters, make sure to screw the adapter tightly onto the corresponding connector.

## NOTE

### Light-guide cable adapters

Olympus recommends the use of an Olympus light-guide cable and an Olympus light source. Only this combination will guarantee optimum illumination of the endoscopic image and excellent color reproduction.

### Interferences of light sources with imaging equipment

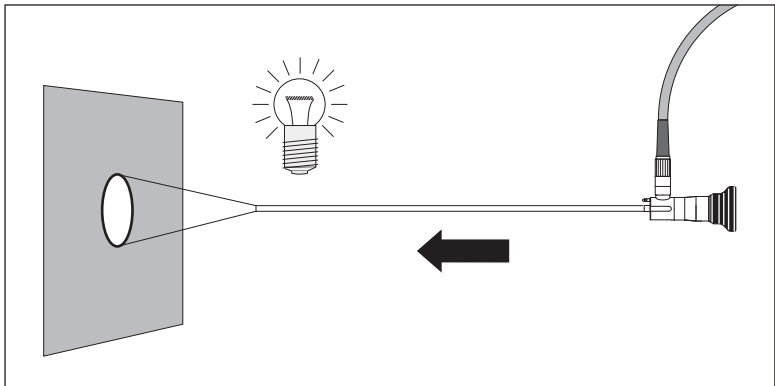
Video systems feature different brightness control functions, such as an electronic shutter and an auto focus function.

These mechanisms control the brightness of the video image on the monitor screen but do NOT control the light source's output. In the case of improper settings of the camera and light source, the light source might be set to full power output, although this is not visible on the monitor screen.

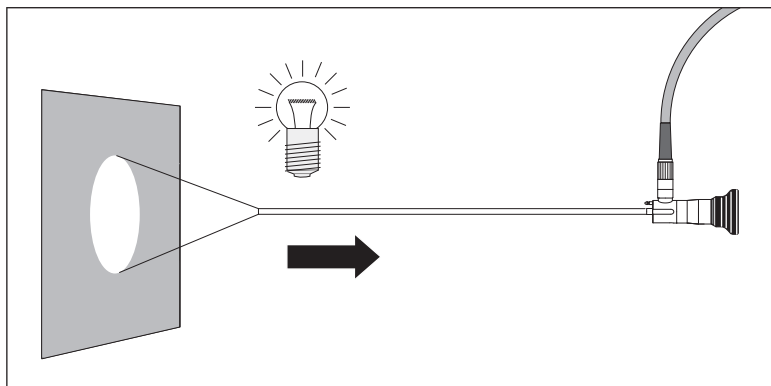
Such improper settings lead to enhanced heat emission at the telescope.

- For further information on the proper connection of light sources and video systems, refer to the product-specific instructions for use.

### Testing the light source's brightness control function



- Move the endoscope's distal end towards an object. The light emission from the telescope's distal end must decrease.



- Move the endoscope's distal end away from an object. The light emission from the telescope's distal end must increase.

### 3.3 HF Surgery

An electrical current applied to biological tissue generates three effects:

- a thermal effect, generating heat
- a Faraday effect, stimulating nerves and muscles
- an electrolytical effect, causing movement of ions

#### **Effects of HF current**

In HF surgery, the Faraday effect is avoided by using high-frequency alternating current with a frequency of more than 300 kHz. This current only generates heat. This heat can be used for three types of application:

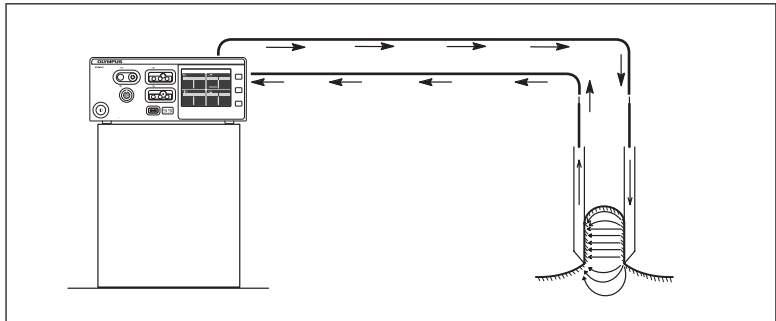
- thermal coagulation of tissue
- cutting of tissue
- vaporisation

In thermal coagulation, the electrical current heats the tissue only slowly. The water inside the tissue evaporates slowly and cellular proteins are denaturated, thus resulting in coagulation of the tissue.

For cutting tissue, the electrical current heats the tissue very quickly. The temperature of the tissue inside the cells increases quickly and the intracellular water evaporates, destroying cell membranes.

For vaporisation, the electrical current is set to high values. The intracellular water evaporates immediately, resulting in shrunk tissue and a large coagulation zone for TURIs or TCRIs.

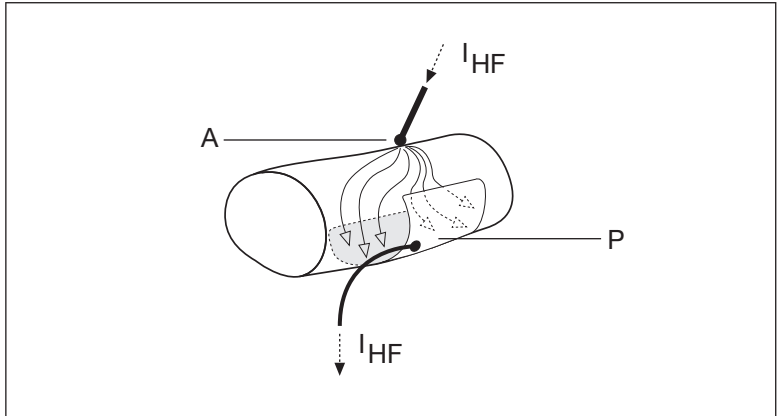
### **Bipolar HF surgery**



In bipolar HF surgery, the electrosurgical current passes between the two electrodes of the instruments (e.g., the jaws of a bipolar forceps). On the small surface between both electrodes, a high current density accumulates, which creates enough heat to coagulate and/or cut tissue.

As a result, bipolar HF surgery only requires electrosurgical current to be conducted over a very short distance through the patient's body.

## Monopolar HF surgery



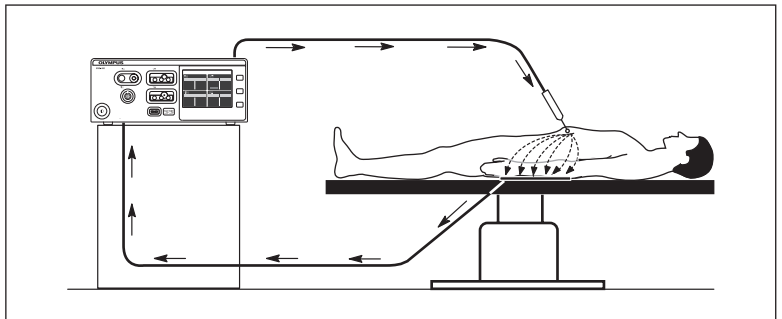
In monopolar HF surgery, the electro-surgical current passes from the point-shaped “active” electrode (A in the diagram) to the larger “patient plate” (P). On the small surface of the active electrode, a high current density accumulates, which creates enough heat to coagulate, cut and/or vaporize tissue.

Active electrodes as described in this “System Guide Endoscopy” are:

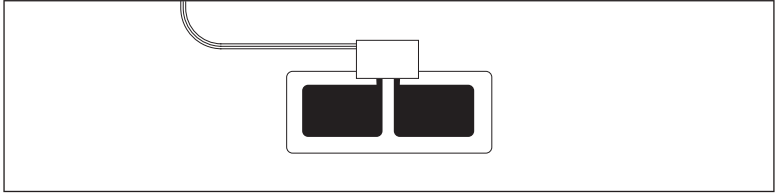
- all HF electrodes
- HF-resection electrodes (in resectoscopes)
- monopolar hand instruments (e.g., monopolar forceps and scissors)

Other terms used for a patient plate are:

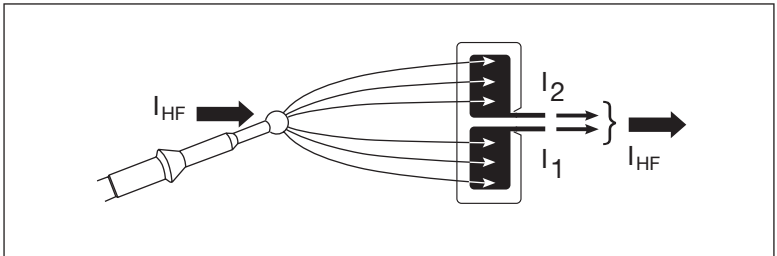
- neutral electrode
- indifferent electrode
- p-plate



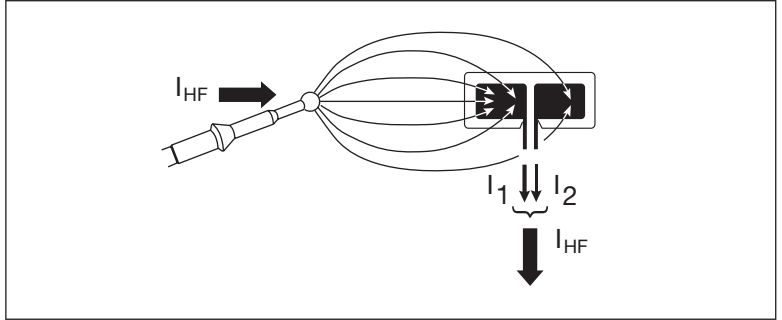
## Connecting the patient plate (only for monopolar HF surgery)



- Place the patient plate close to the operational field, if possible on the upper arm or on the thigh.
- Make sure that the skin is free from hair and grease.
- When using a reusable patient plate, apply conductive gel evenly on the patient plate. Refer to the patient plate's instructions for use. Most single-use patient plates do not require conductive gel.
- Make sure that contact has been established over the electrode's entire surface.
- Place the long edge of the patient plate towards the active electrode.



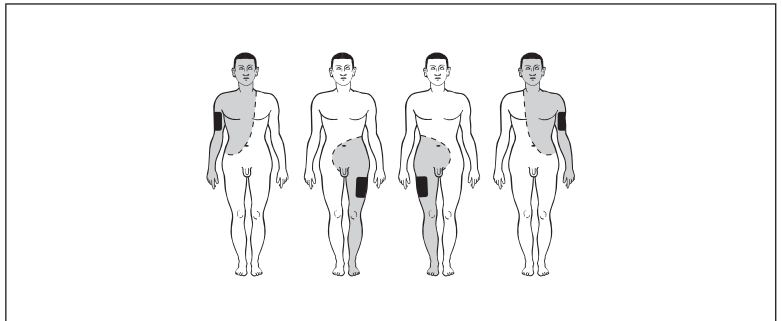
Correct application of a neutral electrode with even current distribution on the two electrode surfaces.



Incorrect application of a neutral electrode. This will result in uneven current distribution on the two electrode parts. An alarm is issued and the surgical instrument will not be able to be activated.

### Current flow in the body (only for monopolar HF surgery)

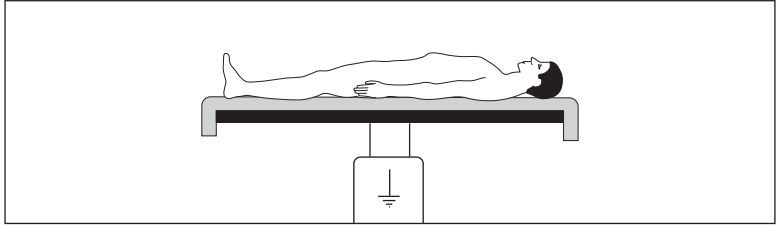
The current paths inside the patient's body should be short and must proceed diagonally. Current paths must never run transversely through the body or across the thorax.



Acceptable locations of the patient plate (black) and allowable range of application of the active electrodes (grey).

- Make sure that the current path is as short as possible!

## Patient position



- The patient must be insulated against all electrically conductive parts. Make sure that the patient does not come into contact with other metal parts (e.g., operating table) in any case.
- Ground the operating table.
- Place the patient on a dry, electrically insulating surface.
- Prevent any contact between different skin surfaces (arms, legs). Place dry gauze between the body and arms and legs to prevent such contact.

## HF cables

- Always use Olympus HF cables.
- Visually inspect the HF cable and its surface.
  - Make sure that it does not have any cracks, scratches, edges, dents, or bends.
  - Make sure that no wires protrude from the inside.
  - Make sure that all parts are securely in place.
- Replace defective HF cables.
- In order to plug or unplug an HF cable, always pull at the plug. Never pull at the cable.
- Do not place HF cables directly on the patient's skin.
- Do not lay HF cables in loops.
- Use only plastic clips or hook and loop fasteners to fix HF cables to surgical drapes. Do not use metal clips or forceps.

## Active instruments

- Do not use worn-out or defective active electrodes, forceps, or scissors. Dispose of these instruments when they are no longer in perfect working condition.
- Do not attempt to repair active electrodes, forceps, or scissors. Do not attempt to bend electrodes in shape.



## HF unit instructions for use

- Refer to the HF unit's instructions for use.

## Maximum power output

The maximum power output for the instruments is limited.

- Use the lowest possible output setting necessary.
- Always refer to the product-specific instructions for use for information on the output settings.



## WARNING

### Spray coagulation

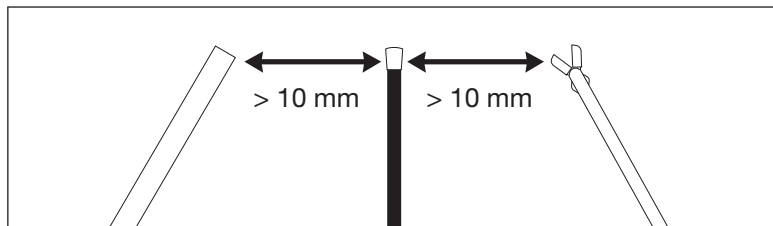
Some HF units have a so-called “spray coagulation” feature. The application of “spray coagulation” destroys the electrodes. There is a risk of spark-over to the patient, users or a third party.

- Do not apply the “spray coagulation” feature of the HF unit during endoscopic interventions.

Spray coagulation should only be used if the compatibility of the instruments to be used is certified in their product-specific instructions for use.

### Safety precautions for monopolar procedures

- Switch off the HF unit when not using it.
- To coagulate tissue, first position the electrode on the target area and then activate the HF current.
- Do not activate the HF current if the electrode is not in contact with tissue.



- Make sure that the electrode is at least 10 mm away from all other endoscopic equipment.
- Tissue areas that are in contact with the active electrode must not touch other tissue areas. Coagulate cord-like tissue parts on their narrowest point. Otherwise, side coagulation or perforation may result.

### **Safety precautions for bipolar interventions**

- Switch off the HF unit when not using it.
- First position the bipolar instrument on the target area and then activate the HF current.
- Do not activate HF current without tissue between both electrodes of the bipolar instrument. The bipolar instrument might be destroyed.

Some HF units feature a so-called AUTO START mode. In the case of accidental tissue contact, the AUTO START mode involves the risk of unintentional coagulation. Therefore electrodes and forceps used in endoscopy must not be operated in the AUTO START mode.

- Do not select the AUTO START mode.

### **Non-flammable gases**

- When performing electrosurgery, use only non-flammable gases (e.g., CO<sub>2</sub>) for insufflation.

### **Irrigation fluids**

- When performing monopolar electrosurgery, use only non-conductive fluids.
- For TURis/TCRis, use only conductive fluids.

### **Suction/irrigation**

- When using active electrodes with a suction channel, do not simultaneously activate the HF current and the suction/irrigation function.

### **Conductive lubricant**

- When inserting instruments into the urethra during electrosurgical procedures, use conductive lubricants only.



### **WARNING**

#### **Risk of injury**

- Do not use conductive lubricants to lubricate working elements. There is a risk of spark-over to the patient, users or a third party.

### **Malfunction**

- If the unit is set to a level which previously worked sufficiently but now does not satisfactorily coagulate the tissue, do not increase the output setting.

- Instead, make sure that:
  - the patient plate is seated correctly.
  - all HF cables and plugs are securely attached and free of corrosion.
  - the HF-resection electrode is securely attached.
  - the insulation of the HF cables, the HF electrode, and the instrument are not damaged.
  - the electrode's distal end is clean and free of corrosion.
  - the instrument has been assembled properly and all parts are securely attached.
  - for monopolar HF interventions: a non-conductive irrigation fluid is used.
  - for TURis/TCRIs interventions: a conductive irrigation fluid (0.9 % NaCl) is used.
  - a conductive lubricant is used with instruments inserted into the urethra.

### **Potential risks**

The application of HF current involves the risk of burns.

According to their causes, burns can be divided into:

- endogenous burns
- exogenous burns

### **Endogenous burns**

Endogenous burns are burns which are caused by a high current density in the patient's tissue.

Possible reasons are:

- the available conductive surface of the patient plate is too small in relation to the power output used (select a suitably sized patient plate!)
- the actual conductive surface of the patient plate is too small (make sure that the entire surface of the patient plate is in contact with the patient's skin),
- the patient is inadvertently positioned in contact with electrically conductive parts (make sure that the patient has been insulated against all electrically conductive parts),
- direct contact between skin areas and HF cables may lead to electrical capacitance which could cause burns.



### **Exogenous burns**

Exogenous burns are burns which are caused by the heat of ignited fluids or gases. They may also be caused by explosions. Possible reasons are:

- ignition of skin cleaning agents and disinfectants,
- ignition of narcotic gases,
- ignition of insufflated gases (use only non-flammable gases for insufflation!),
- ignition of endogenous gases (bowel),
- explosion of oxy-hydrogen gas inside the urinary bladder, ureter, kidney, or the uterine cavity (evacuate accumulated gas!).

### **Interferences**

The application of HF current interferes with other medical equipment. Interferences with ECG, cardiac pacemakers, laser applications, and video imaging are widely known.

- For other possible interferences, refer to the HF unit's instructions for use.

### **ECG**

- If an electrocardiograph is used, the neutral ECG cable must be attached to the patient plate of the HF unit. Place the active electrode at a minimum distance of 150 mm from the ECG electrodes.
- Do not use ECG needle electrodes for monitoring. All ECG electrodes must be equipped with protective impedances or HF choke coils.



### **Cardiac pacemakers**

Pacemakers may be damaged by electrosurgical current.

- Consult a cardiologist before the procedure. Never use electrosurgical current on outpatients with pacemakers.

### **Video imaging**

HF current may interfere with video images. To prevent such interference, HF equipment and video imaging equipment should be connected to different power supply circuits.

## 3.4 Laser Surgery



The term “laser” stands for “Light Amplification by Stimulated Emission of Radiation”. A laser is a device for producing monochromatic, coherent, luminous beams.

When a beam comes in contact with living tissue, its energy is converted into thermal energy, creating a cutting, vaporization or coagulation effect (depending on the laser type used).

### Instructions for use

- Refer to the laser unit’s instructions for use.

### Switch off laser

- If the laser is not being used or if surgical instruments are being changed, switch off the laser or switch it to standby mode.

### Power output

- Always select the lowest possible laser output for the procedure.



### Potential risks

The application of laser involves certain risks like:

- Eye damage
- Skin damage
- Chemical risks
- Mechanical risks
- Electrical risks

### Eye damage

Eye damage includes:

- in the range of wave lengths between 200–400 nm (UV): photophobia and/or damage to structures at the front eye (inflammation, watering),
- in the range of wave lengths between 400–1400 nm (visible light and near infrared): damage to the retina and the eye’s vitreous body,
- in the range of wave lengths between 1.4–1000  $\mu\text{m}$  (infrared): damage to the cornea and structures at the front of the eye.



### **Skin damage**

The most frequent skin damage is burns, which can be as serious as fourth-degree burns. Additionally, lasers in the range of wave lengths between 250–320 nm are carcinogenic.



### **Chemical risks**

Inflammable or explosive substances may be ignited by a laser beam.



### **Mechanical risks**

Particles can be emitted from the target and other surfaces following contact with the laser.

### **Electrical risks**

Electrical risks are caused by the high voltage applied to the laser.



### **Safety precautions**

- Protective glasses:  
When using a laser, always wear protective glasses that are designed to filter out the laser's wavelength(s).
- Patient's eyes:  
Cover the patient's eyes or use protective glasses that are designed to filter out the laser's wavelength(s).
- Non-reflective equipment:  
Do not use reflecting equipment within the laser range. All endoscopic instruments used in conjunction with the laser must be black or matted at the distal end.



### **WARNING**

#### **Interferences with insufflators**

Uncontrolled inflow of gaseous insufflation media may cause lethal embolisms. Besides the insufflator, other systems can act as gas supply sources. These may include: lasers with probe tips cooled using CO<sub>2</sub> or other gases, and Argon-Enhanced Coagulation Systems (AEC).

- When using such systems in laparoscopic procedures, make sure to use an insufflator with an active suction control system.
- If the insufflator emits a warning for intra-abdominal over-pressurization, quickly open the stopcock or valve of the insufflation instrument inserted into the patient.



**WARNING**

**Inflammable and/or explosive gases**

Lasersurgical procedures may only be performed if non-flammable gases (CO<sub>2</sub>) are used for insufflation.

- Do not perform lasersurgical procedures in areas where flammable or explosive gases are present.



In addition to anaesthetic agents, gases formed inside the patient's intestinal and urological tract represent an explosion hazard.

# 4 Reprocessing

## NOTE

Some reprocessing methods may lead to increased wear of the products.

- Inspect the products thoroughly before use for traces of wear.

## Information in this document

The following reprocessing information supplements the detailed reprocessing information in the product-specific instructions for use. However, if the information given in this chapter differs from that in the product-specific instructions for use, use the information given in the product-specific instructions for use.

## 4.1 General Policy

### The reprocessing cycle

Olympus endoscopic instrumentation (if not labelled as a single-use product) is to be reprocessed by the methods described in the product-specific instructions for use and in this chapter.

- To minimize the risk of infecting patients, users or third parties, reprocess the endoscopic instrumentation before each use.

### Standards

- Refer to the following standards:
  - ISO 17664 “Sterilization of medical devices”
  - ANSI/AAMI TIR12 “Designing, Testing, and Labeling of Reusable Medical Devices for Reprocessing in Health Care Facilities”
  - ANSI/AAMI ST79 “Comprehensive guide to steam sterilization and sterility assurance in health care facilities”

Additional standards and regulations may be applicable.

- Contact your local hygiene representative for local standards and regulations.

### Disinfection vs. sterilization

The decision on the reprocessing method must be made in accordance with international and national standards and guidelines. For thermostable equipment, sterilization should be preferred to disinfection.



### **Manual cleaning vs. automatic cleaning**

In general, instruments can be cleaned manually or automatically with sufficient results. Manual cleaning methods involve infection control risks for the personnel responsible for reprocessing. Automatic methods reduce these risks and provide the advantage of standardized, reproducible and validated procedures. Therefore, in general, Olympus recommends to prefer automatic cleaning procedures.

- Contact your local hygiene representative to determine the situation in which manual cleaning rather than automatic cleaning would be appropriate in your facility.

### **After use**

- After use, immediately treat the instruments as described in the product-specific instructions for use and in section “Preparation for Reprocessing at the Point of Use” in this document.

### **Brand-new instruments**

Always treat brand-new instruments as if they have been used. Brand-new instruments must be reprocessed using a complete reprocessing cycle.

## **4.2 Reprocessing Procedures and Agents**

The materials and construction of the Olympus endoscopic instrumentation may not be compatible with certain reprocessing methods.

Olympus differentiates between two degrees of compatibility:

- compatibility validated for microbiological efficacy.
- compatibility verified for material compatibility.

### **Validated for efficacy**

Validated for efficacy means that the efficacy of the process or agent has been validated for reprocessing an instrument as described in the product-specific instructions for use and in this document.

### **Verified for material compatibility**

Verified for material compatibility means that – according to current knowledge – the reprocessing process or agent does not negatively affect materials or functional performance of the instrument. Verified for material compatibility does not mean that microbiological efficacy can be guaranteed.

### **Choosing a reprocessing method**

The actual reprocessing method chosen by your institution should be determined by national and local guidelines as well as your hospital's infection control committee.

### **Choosing a reprocessing agent**

The actual cleaning or disinfection agent chosen by your institution should be determined by national and local guidelines as well as your hospital's infection control committee.

### **Monitoring**

- Regularly monitor and validate all disinfection and sterilization processes.

Although there are no biological indicators available to verify the disinfection processes, there are test strips which will permit monitoring the concentration of the disinfectant agent. Monitor the concentration according to the instructions of the disinfectant's manufacturer to ensure that the solution has not been diluted below its effective concentration.

To monitor sterilization processes, use an appropriate indicator.

### **Material compatibility chart**

The material compatibility chart in the appendix of this document lists those cleaning, disinfection, and sterilization processes and agents that have been thoroughly tested on components of rigid endoscopes and their accessories.



### **CAUTION**

#### **Risk of damage**

Not every instrument is compatible with all processes mentioned in this document.

- Before reprocessing an instrument, read the product-specific instructions for use. For more details, contact an Olympus representative.

## 4.3 Health and Safety at Work



### WARNING

#### Protection against infection or skin irritation

Patient debris and reprocessing chemicals are hazardous.



- Wear personal protective equipment to guard against dangerous chemicals and potentially infectious material. During cleaning and disinfection or sterilization, wear appropriate personal protective equipment, such as eye wear, face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that no part of the skin is exposed.
- Always remove contaminated protective equipment before leaving the reprocessing area.



### WARNING

#### Toxic chemical fumes

The disinfection/sterilization room must be adequately ventilated. Adequate ventilation helps protect against toxic chemical fumes.



### WARNING

#### Inflammable liquids

Alcohol stored in an open container is a fire hazard and will lose its efficacy due to evaporation.

- Store alcohol (ethanol, isopropanol) in an air-tight container.

## 4.4 Decontaminating the Surface of Electrical Units

This section describes how to decontaminate the surfaces of electrical units. Units are not sterilizable. The surface of electrical units should be cleaned and disinfected.

### Cleaning units

- Turn off the power switch.
- Disconnect the power cable.
- Let the unit cool down to room temperature.

- Remove all dust and debris with an appropriate, lint-free cloth which, if necessary, has been moistened.

### **Disinfecting the unit's surface**

- To disinfect the unit, wipe it with a cloth that has been moistened with a disinfection agent.
- Refer to national or local guidelines regarding the approval of using alcohol as disinfection agent. Select the disinfection agent according to its field of applications. The disinfection agent must be approved by the manufacturer for the (surface) disinfection of medical devices and for the material to be disinfected.
- Make sure not to exceed the manufacturer's specification on temperature, contact time and concentration.
- Make sure that the unit has been completely cooled down to room temperature to avoid any risk of ignition or explosion. Never immerse units in liquid!

## **4.5 Preparation for Reprocessing at the Point of Use**

Prepare reusable instruments for later reprocessing directly in the operating room immediately after use as described in this section.

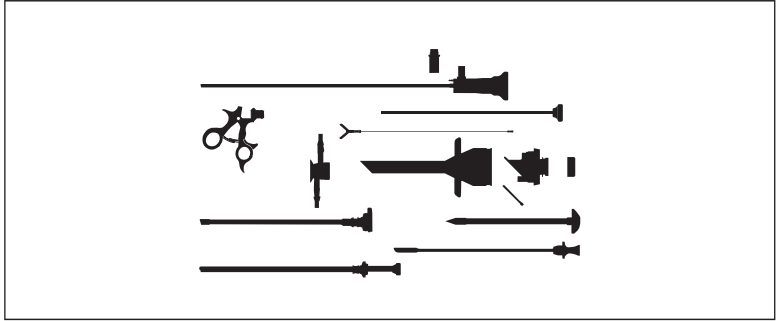
In order to avoid incrustations formed by residual blood or proteins, all equipment must be reprocessed immediately after use. If this is not the case, special measures must be taken to preclean the equipment.

### **Single-use products**

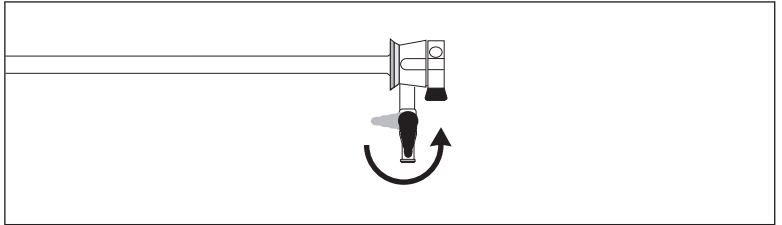
- Separate single-use products from reusable products.
- Dispose of single-use products.
- Dispose of waste according to legal requirements.
- If necessary, sterilize waste before disposal.

### **Reusable products**

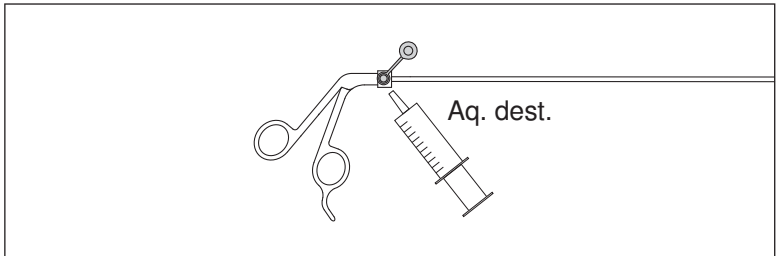
- Remove heavy debris from instruments by wiping with an appropriate, single-use lint-free cloth or sponge.



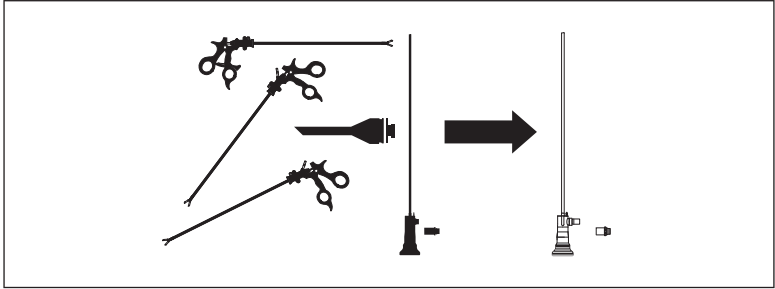
- Disassemble the instruments as described in the product-specific instructions for use. Do not use excessive force; this will damage the instruments.
- Clean the active parts of HF electrodes and jaws of monopolar and bipolar forceps using 3 % hydrogen peroxide.
- Remove the sealing caps.



- Open all stopcocks.

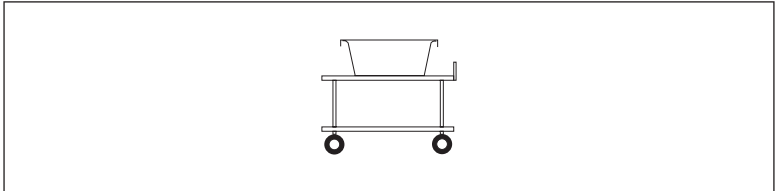


- Hand instruments that cannot be disassembled:  
Flush the lumen of the hand instrument with water until clear water flows from the hand instrument's distal end.



- Separate telescopes from other instruments.
- If desired, instruments can be immersed in cleaning or disinfectant solution immediately after use.

### Transport of reusable products



- Transport reusable products from the point of use to the reprocessing area.
- In general, the instrument can be transported wet or dry or immersed in liquids. Refer to the product-specific instructions for use for exceptions.
- Contain reusable products during transport to avoid possible environmental or personnel contamination.
  - If instruments are transported in dry condition, make sure that gross debris does not dry. Start the following cleaning procedure immediately after use. If this time frame has to be exceeded, the user has to take necessary measures to get an appropriate cleaning result.
  - If instruments are contained immersed in liquids, start the following cleaning procedure within 1 hr. after use. Do not use physiological saline solution for immersion.



## CAUTION

### Risk of instrument damage

If instruments are left in dry condition for a longer period, heavy debris may dry to the instrument, leading to incrustations that may be difficult to remove.

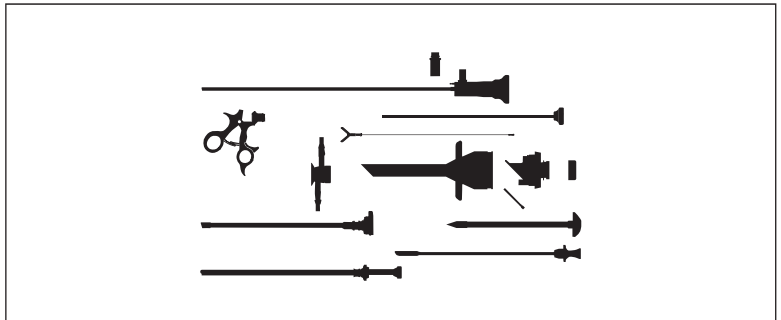
If instruments are left immersed in liquids for a longer period, the instrument may be damaged and the instrument's sealings may be damaged or fail.

- Reprocess the instruments immediately after use. Do not exceed the time limits for transport indicated above. Do not leave used instruments overnight before reprocessing.
- When using cleaning or disinfection agents, make sure not to exceed the manufacturer's specification on temperature, immersion time and concentration.

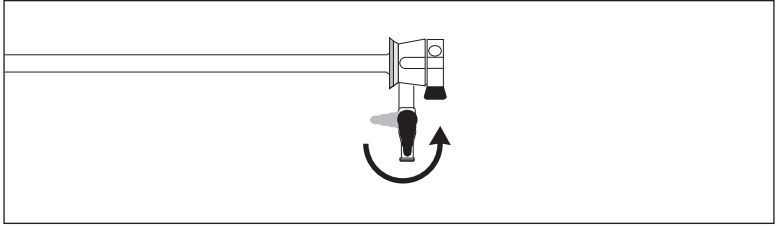
## 4.6 Manual Cleaning

This section describes how to perform manual cleaning of endoscopes and their accessories in general. Ask your local Olympus representative for the availability of reprocessing cards.

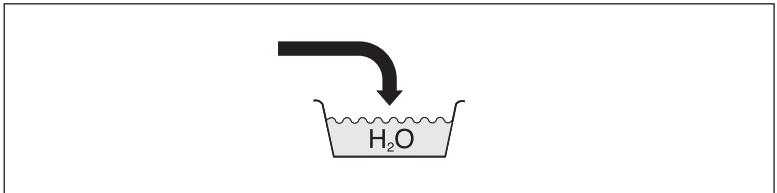
### Manual cleaning procedure



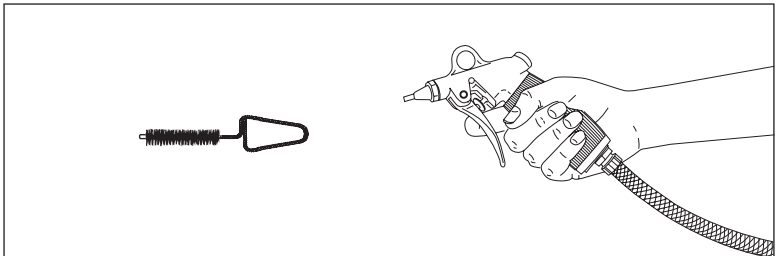
- Immediately after use, disassemble the instruments as described in the product-specific instructions for use.



- Open all stopcocks.

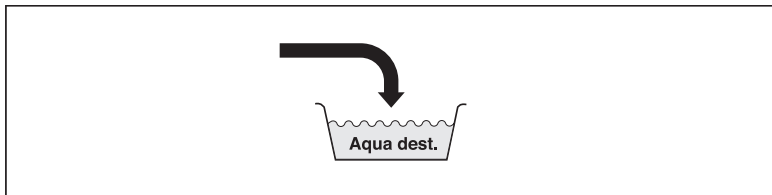


- Thoroughly rinse all instrument components with water (< 20 °C).
- Remove persistent debris with a non-acidic cleaning agent that has been verified and approved by its manufacturer for cleaning medical endoscopes. Make sure to observe the instructions of the cleaning agent's manufacturer.
- Do not immerse instrumentation for more than 60 min. Depending on the cleaning agent, the instrumentation may only be immersed for a shorter period. Refer to the instructions of the cleaning agent's manufacturer for immersion time.

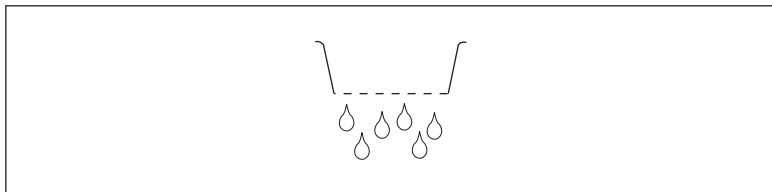


- To clean internal parts, use cleaning pistol, appropriate cleaning brushes, and cleaning wire.
- Perform this procedure until all visual debris has been completely removed.

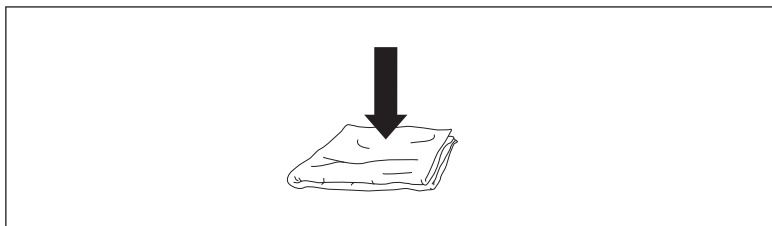




- After cleaning the instrument, rinse it with deionized water (Aq. dest.). Do not immerse instrumentation for more than 60 min.

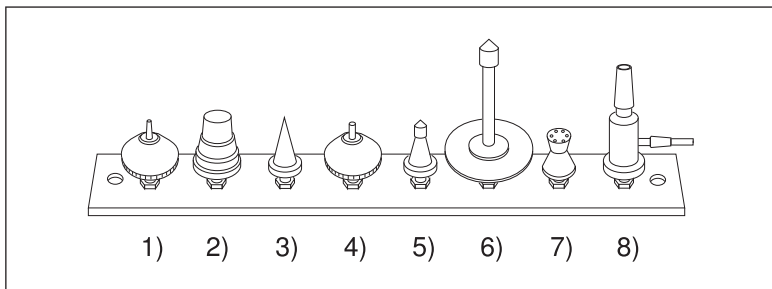


- Let all parts of the instrument drain completely.



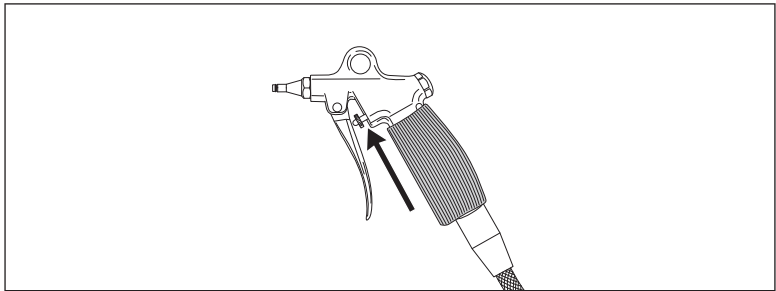
- Use an appropriate soft single-use and lint-free cloth or sponge to wipe off remaining water.
- Completely dry the instrument.

### Cleaning pistol O0190



- Select an appropriate attachment:

- 1) For syringes and cannulas with “Record”-connector
  - 2) For pipettes
  - 3) For catheters, stopcocks, valves, and endoscopes
  - 4) For syringes and cannulas with Luer-lock connector
  - 5) For drainage tubes
  - 6) For glass jars
  - 7) Spray nozzle
  - 8) Water jet blast for suction
- Immerse the instrument to be cleaned in water.
  - Firmly press the attachment onto the nozzle port of the cleaning pistol.
  - Open the water tap. If fiberscopes are cleaned, do not exceed a maximum pressure of 0.5 bar.
  - Firmly press the cleaning pistol with the attachment against the instrument to be cleaned (while submersed in water).



- Activate the handle several times until all debris is removed. Adjust the pressure of the water jet by means of the knurled nut (see arrow).
- Close the water tap after use.

#### **NOTE**

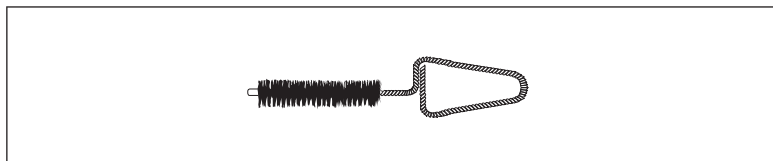
##### **Alternative cleaning device**

If cleaning pistol O0190 is not available, other suitable cleaning devices for medical devices may be used. The alternative cleaning device requires a minimum pressure of 1 bar (14.5 psi) for adequate rinsing/cleaning of the medical device.

## Cleaning brushes and cleaning wire

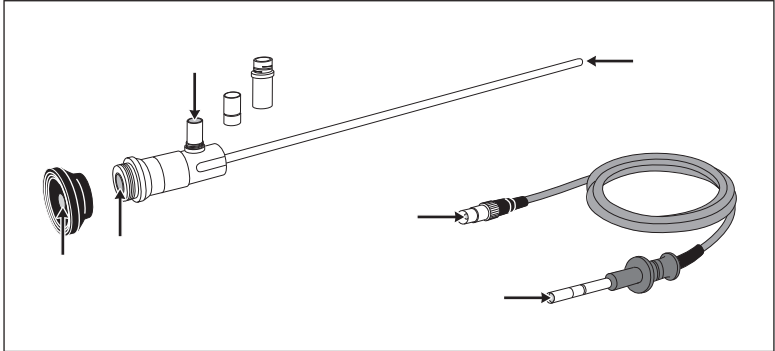
In the following reprocessing instructions, Olympus uses the terms “appropriate brush” and “appropriate surface brush”. Select an appropriate brush/surface brush according to the following information:

- The brush diameter must be greater than or equal to the diameter of the inner lumen being brushed.
- The brush bristles must fully extend and contact the surface of the inner lumen.
- The brush must move easily in and out of the instrument.
- The brush must be at least 50 mm longer than the lumen of the instrument.
- Tapered or irregular lumens may require the use of different brushes with different brush diameter.
- A surface brush is for outer surfaces only. Do not use a lumen brush for surfaces.
- Do not use a brush with metal bristles or any other types of bristle which can scratch and damage the instrument.
- Only use brushes which the manufacturer has designated for reprocessing of medical devices.



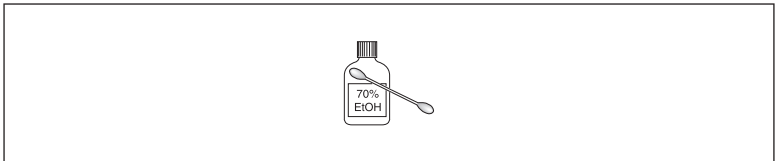
- Immerse the instrument and the cleaning brush/wire into the liquid in order to avoid splashing.
- Introduce the cleaning brush/wire into the instrument's distal opening and advance the cleaning brush/wire until it reaches the proximal opening.
- Move the cleaning brush/wire back and forth until the brush/wire is free of visible debris.
- Remove the cleaning brush/wire while the instrument and the cleaning brush/wire are immersed in the liquid.
- Check the channel's lumen for free passage. If this is not the case, repeat the procedure.

## Cleaning optical surfaces



Optical surfaces are:

- a telescope's objective cover glass
- a telescope's eyepiece cover glass
- a telescope's light-guide connector
- a camera head's lens window
- the video adapter's lens windows
- the light admission surface on the light-guide plug that is attached to the light source
- the light emission surface on the light-guide plug that is attached to the instrument
- Remove all adapters from the telescope's light-guide connector.
- Remove all adapters from light-guide cables.
- Remove the telescope's eyepiece cup (if applicable).



- Clean the optical surfaces with a cotton swab that has been moistened with 70 % alcohol (ethanol). Never wipe with a metal cotton applicator.
- Do not use other instruments for cleaning optical surfaces.



### WARNING

#### Infection control risk with cleaning agents

There is an infection control risk when using insufficient cleaning agents.

- Use only those cleaning agents which have been approved by their manufacturer for surgical instrument cleaning and which feature processes in accordance with national and local guidelines.



**WARNING**  
**Insufficient cleaning efficacy**

The cleaning efficacy may be compromised if the detergent fixes proteins to the instrument.

- For pre-cleaning or cleaning, use only detergents with good cleaning characteristics. Avoid any protein fixation prior to or during cleaning caused by the process.



**WARNING**  
**Risk of reduced cleaning effectiveness in instruments with small lumen**

If instruments with small lumen are cleaned, there is a risk that the inner lumen is not soaked with water and/or cleaning agent.

- Always rinse instruments with small inner lumen by connecting them to an irrigation tubing, a rinsing syringe or the cleaning pistol.



**CAUTION**  
**Risk of damage due to incompatible cleaning agents**

Incompatible cleaning agents may considerably damage Olympus endoscopes and accessories.

- Use only solutions that are certified by their manufacturers as safe for endoscopic instrument cleaning.



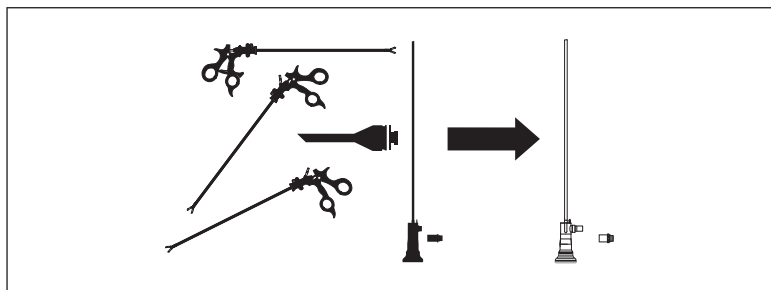
**CAUTION**  
**Risk of damage due to cleaning agents residues**

Cleaning solutions may contain various aggressive compounds which could lead to corrosion of the instrument.

- To effectively remove residues, rinse the instrument thoroughly with deionized water (Aq.dest.).
- Do not use tap water for rinsing because it might be chlorinated.



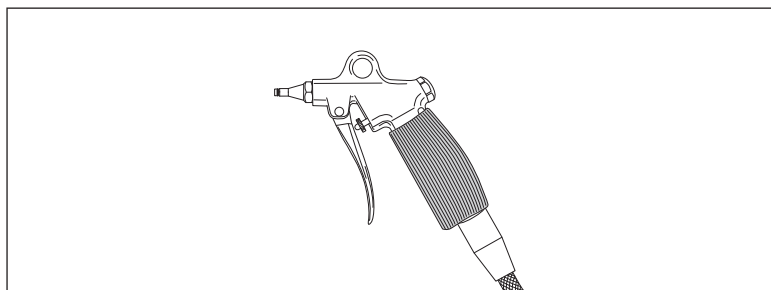
**CAUTION**  
Risk of damaging telescopes



- Always clean each telescope separately.
- Do not clean with other telescopes or other instruments.
- Make sure that telescopes do not touch each other.



**WARNING**  
Infection control risk with cleaning pistol



Water splashing from the cleaning pistol may contain infectious agents.

- Always use a face shield to protect your mouth and eyes.
- Adjust the water pressure to a minimum level to satisfactorily clean the instruments.
- Always immerse the instrument to be cleaned and the cleaning pistol in water before starting the process to prevent splashing.

## 4.7 Ultrasonic Cleaning

### **Ultrasonic cleaning procedure**

- Use only ultrasonic cleaners which have been approved and verified (for example by FDA, DGHM or a comparable institution).
- Use only ultrasonic cleaners which the manufacturer has indicated may be used to clean endoscopic instruments or a disinfectant suitable to be used for ultrasound cleaning of endoscopes.
- Refer to the instructions for use of the ultrasonic cleaner and the disinfectant.
- Switch off the bath's heating system. Only clean components at room temperature.
- Depending on the degree of contamination, immerse the instrument in an ultrasonic cleaner for 5 min. and a maximum of 15 min. at a frequency of 38–47 kHz.  
Make sure not to exceed the manufacturer's specification on immersion and concentration.
- Rinse the instruments.
- Let all parts drain.
- Use an appropriate, lint-free cloth or sponge to wipe off remaining fluid.
- Completely dry the instrument.



### **WARNING**

#### **Infection control risk with ultrasonic cleaning**

Vapors from ultrasonic cleaning units may contain infectious agents as aerosols.



- Always use a face shield and have adequate ventilation in place during ultrasonic cleaning.
- Refer to the instructions for use given by the manufacturer of the ultrasonic cleaner.



### **WARNING**

#### **Insufficient cleaning efficacy**

The cleaning efficacy may be compromised if the cleaning agent fixes proteins to the instrument.

- For pre-cleaning or cleaning, use only agents with good cleaning characteristics. Avoid any protein fixation prior to or during cleaning by the procedure.

## 4.8 Manual Disinfection

### **Prior cleaning**

Endoscopic instrumentation must be meticulously cleaned prior to disinfection. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases the effectiveness of the disinfection process.

### **High-level disinfection**

In the U.S., agents used to achieve high-level disinfection are defined as liquid chemical germicides registered with the Environmental Protection Agency as “sterilants/disinfectants” which are used according to time, temperature and dilution recommended by the disinfectant manufacturer for achieving high-level disinfection. These conditions usually coincide with those recommended by the disinfectant manufacturer for killing 100 % of *Mycobacterium tuberculosis*.

### **Germicidal effectiveness**

- For information on the germicidal effectiveness of any solution, refer to the solution’s instructions or contact the solution’s manufacturer.

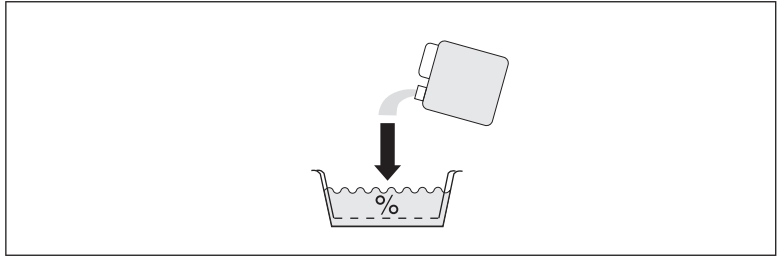
The chemical agent used for disinfection should be capable of killing/deactivating:

- *Mycobacteria*
- Vegetative bacteria
- Viruses (hepatitis, HIV, BPV etc.)
- Fungi
- Some bacterial spores

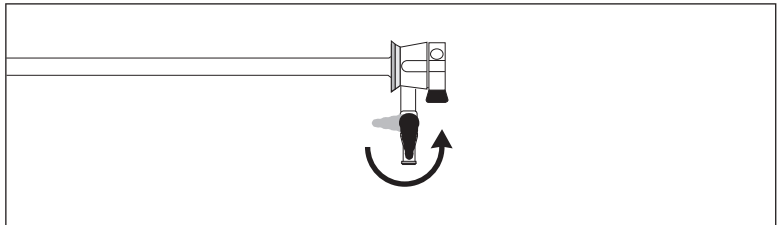


## Disinfection procedure

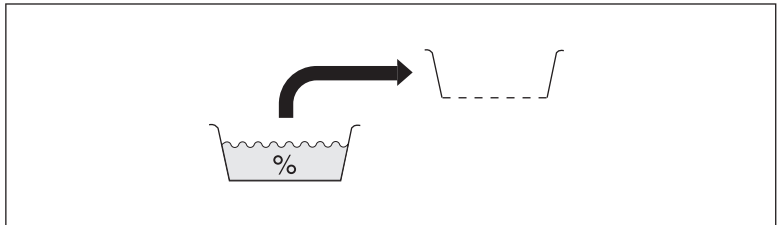
- Create a disinfectant solution in accordance to the instructions provided by the manufacturer of the disinfectant.



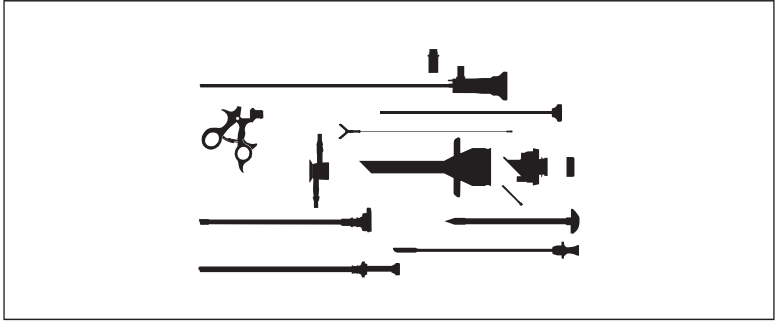
- Fill a basin, sink or disinfection tank (e.g., O0264) with disinfectant solution.



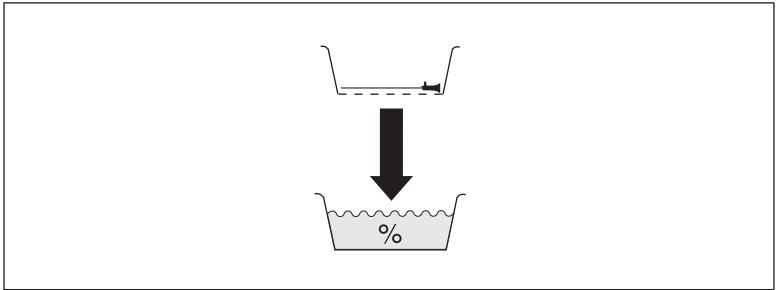
- Open the stopcocks.



- If using a disinfection tank:  
Remove the disinfection tank's sieve tray.



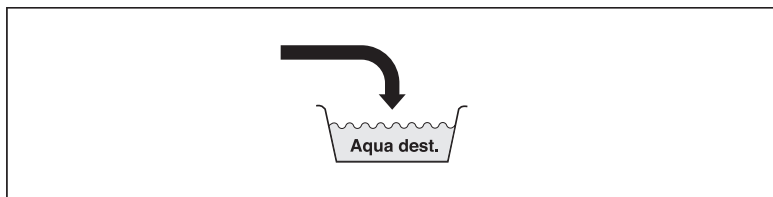
- Disassemble the instrument.



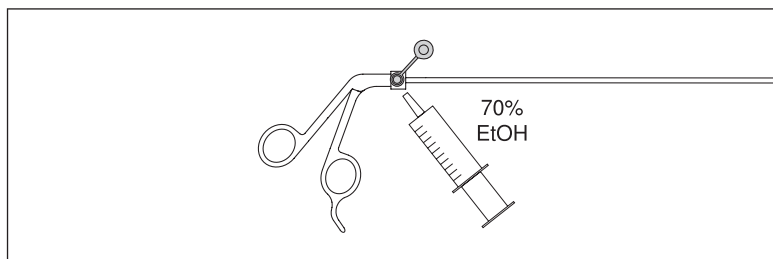
- If using a disinfection tank:
  - Place the instrument's components on the sieve tray.
  - Lower the sieve tray into the tank.
- If using a sink or basin:
  - Carefully place the instrument's components in a sink or basin large enough to immerse the instruments completely.
- Make sure that all components have been completely immersed.
- Make sure that no air bubbles stick to the instrument.
- Do not exceed the immersion time specified by the manufacturer of the disinfectant.. In any case, do not exceed an immersion time of 1 hr.
- Make sure that all lumens are completely filled with disinfectant solution.

### **Rinsing**

- Make sure that the area in which the instrument is rinsed is sterile.

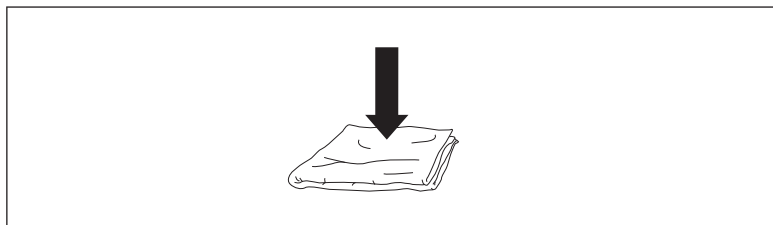


- Thoroughly rinse all of the instrument's components with sterile deionized water (Aq.dest.) to remove all disinfectant residues from the components.
- Make sure that the components are not contaminated again.
- Always rinse instruments with small inner lumens using a syringe. Connect the syringe to the instrument's Luer-lock connector, if applicable.
- If non-sterile water is used for rinsing, wipe the instrument components and flush the channels with 70 % alcohol (ethanol).



- Do not reuse rinsing water.

## Drying



- Dry the instruments with sterile appropriate, lint-free cloths or sponges.
- Use instruments immediately after disinfection.



### **WARNING**

#### **Risk of reduced disinfection effectiveness in instruments with small lumen**

If instruments with small lumen are disinfected, there is a risk that the inner lumen is not soaked with disinfectant solution.

- When disinfecting instruments with small inner lumen, disinfectant solution must be injected into the small lumen using a syringe.



### **CAUTION**

#### **Risk of damage due to incompatible disinfectants**

Incompatible disinfectant solutions may considerably damage Olympus endoscopes and accessories.

- Use only solutions that are approved and verified (for example by FDA, DGHM or a comparable institution) and that are certified by their manufacturers as safe for endoscopic instrument cleaning and disinfection.
- For further information on disinfectant agents, contact Olympus.

#### **Material compatibility**

Olympus instruments have been tested and found to be compatible with solutions of 1–4 % (w/v) glutaraldehyde (immersion). Information on material compatibility when using peracetic acid can be found in the material compatibility chart in the appendix.

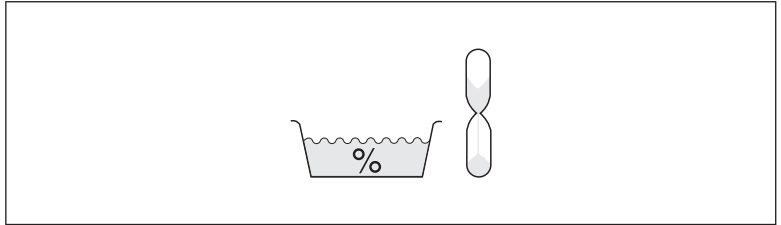
- Select the immersion time and the concentration of the solution according to the instructions given by the disinfectant solution's manufacturer. However, the maximum immersion time of 1 hr. should not be exceeded.

This statement only refers to material compatibility and does not indicate any germicidal effectiveness level.



### **CAUTION**

**Risk of damage due to exceeded concentration and immersion time**



- For information about the concentration and immersion time, refer to the instructions given by the disinfectant solution's manufacturer.
- Do not exceed the manufacturer's maximum recommended levels.



### **CAUTION**

**Infection control risk**

If the instruments are not used immediately after disinfection, they must be disinfected prior to next use.



### **CAUTION**

**Risk of instrument damage**

If instruments are left immersed in liquids for a longer period, the instrument and its sealings may be damaged.

- Do not immerse instruments for more than 60 min. in any liquids.



### **CAUTION**

**Risk of damage due to disinfectant residues**

Disinfectant solutions or tap water may contain various aggressive compounds that can corrode the instrument.

- To remove disinfectant residues, rinse the instrument thoroughly with (sterile) deionized water (Aq.dest.).

## **4.9 Automatic Cleaning/Disinfection**

Automatic cleaning processes are reproducible, standardizable and feature a validated cleaning process.

### **Appropriate washer/disinfectors**

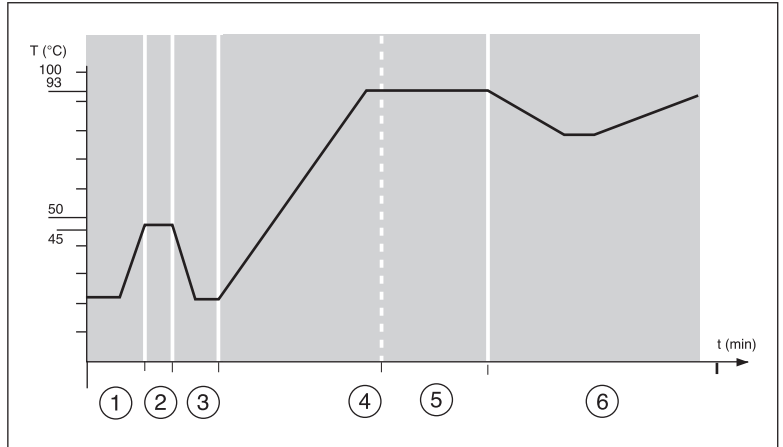
- Use only washer/disinfectors which are intended specifically for cleaning and disinfection of endoscopic instruments by the washer/disinfectors' manufacturer.
- Use only washer/disinfectors according to international standard series ISO 15883.
- Refer to the washer/disinfectors' instructions for use.

### **Selection of programs**

For all thermostable rigid endoscopes, use a program that complies with ISO 15883-2. This program must at least reach an A0 value of 3000 and must not exceed a temperature of 93 °C during the disinfection phase. The temperature of the first inlet water must not exceed 20 °C in order to avoid coagulation of proteins during the pre-rinse phase. During cleaning, a temperature of 55 °C must not be exceeded in order to achieve optimum cleaning results. After neutralization, rinsing cycles ensure that no residual cleaning or neutralizing agents remain and affect the next reprocessing step. Completely deionized water must be used for the final rinse and disinfection. Refer to the table on water and steam quality in the "Steam Sterilization" section.

- In order to avoid the formation of condensates, remove all instrument parts from the machine immediately after the program is completed.
- If necessary, dry the instruments.
- Do not use programs starting with high temperatures (e.g., 93 °C). This leads to a denaturation of proteins and debris, thus inhibiting effective cleaning.
- Make sure that the program does not include any sudden changes in temperature.

## Example for a program cycle:



- 1) Pre-Rinse
- 2) Cleaning
- 3) Rinsing
- 4) Heating
- 5) Disinfection
- 6) Drying

### Automatic cleaning/disinfection procedure

- Make sure that all instruments have been securely fixed to the unit's trays or baskets. Make sure that the instruments do not touch each other.
- For telescopes, use adequate instrument trays to fix the telescope.
- Instruments with lumens must be attached to special trays with irrigation devices or directly to the Luer-lock connectors of the machine. Refer to the table on water and steam quality in the "Steam Sterilization" section. Make sure that all lumens are sufficiently irrigated. Check lumens for free passage before starting the procedure.
- Open all stopcocks.
- Open the jaws of hand instruments.
- Do not overload the washer/disinfector.
- To prevent corrosion, remove the instruments from the washer/disinfector immediately after the automatic procedure has stopped.

### **Cleaning/disinfection agents in automatic cleaning**

- Use only agents that are certified by their manufacturers as safe for surgical instrument cleaning/disinfection.
- Make sure not to exceed the specification of agent's manufacturer.
- Use enzyme-based agents with neutral pH or alkaline agents with a pH value of up to 11 in the working solution.
- Avoid acidic agents. Even minor residues of non-pH-neutral agents may lead to corrosion of the endoscope's material (especially on older chromium-plated instruments). However, if rinsing with neutralizers after cleaning/disinfection is necessary, make sure to remove all traces of neutralizers by using a final rinsing cycle that employs deionized water.
- To remove all cleaning/disinfection residues, rinsing cycles must be run using deionized water (Aq.dest.)
- Refer to the table on water and steam quality in the "Steam Sterilization" section.
- Do not use tap water for rinsing because it might be chlorinated.
- For further information on agents for automatic cleaning/disinfection processes, please contact Olympus.



#### **WARNING**

##### **Infection control risk with cleaning agents**

There is an infection control risk when using insufficient cleaning agents.

- Use only verified cleaning agents which feature validated processes in accordance with national and local guidelines.



#### **CAUTION**

##### **Reduced cleaning effectiveness in automatic cleaning due to coagulation of proteins**

Preferably return the instruments from the point of use to the cleaning area in dry condition to avoid protein fixation caused by cleaning agents or disinfectants.

- Refer to the product-specific instructions for use.
- Make sure that the first water inflow into the washer-disinfector starts with cold temperatures (< 20 °C) to avoid thermal coagulation of proteins.





### **CAUTION**

#### **Risk of damage due to elevated concentration of cleaning/disinfection agents**

Defects of the washer's/disinfector's supply pump can cause an elevated concentration of cleaning/disinfection agents, which will damage the instruments.

- Regularly maintain the washer/disinfector as recommended by its manufacturer.

## **4.10 Maintenance**

### **Inspection**

- Visually inspect all parts. If necessary, clean them again. Instruments should be treated with lubricants in every reprocessing cycle to maintain their function and to protect them from corrosion and aging.

### **Lubrication**

Always use lubricants with the following characteristics:

- paraffin-based
- conforms to currently valid pharmacopeia
- biocompatible
- suitable for steam sterilization
- vapor permeable
- Apply lubricants sparingly.

### **NOTE**

Do not use lubricants containing silicone oil. Silicone oil can negatively affect the performance of the instrument and the result of steam sterilization.



### **CAUTION**

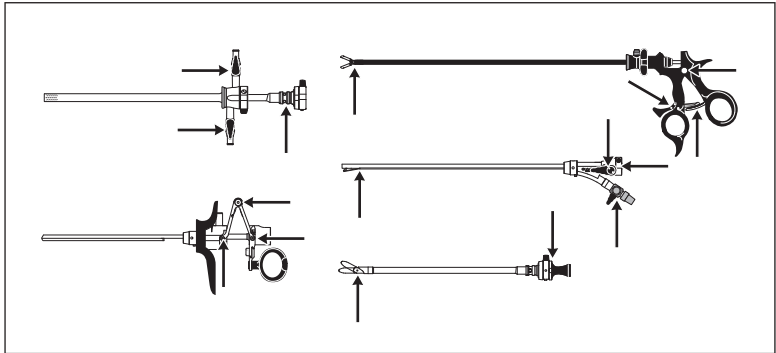
#### **Decrease of image quality**

Lubricants on objective or ocular windows considerably decrease viewability and image quality.

- Apply all lubricants sparingly.
- Make sure that the telescopes' objective or ocular windows are not smudged with lubricant.

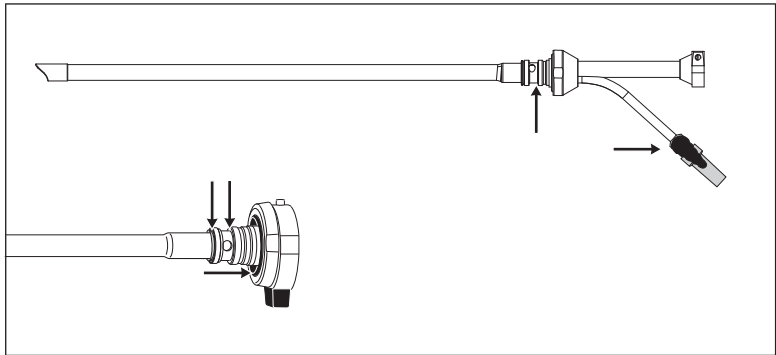
## Moving metal parts

Lubricate moving metal parts in joints or attachment devices.



- Apply a drop of lubricant to all parts to be lubricated.
- Use a cotton pad to remove excess oil.

## Silicone sealings



- Apply lubricant to the sealing rings.

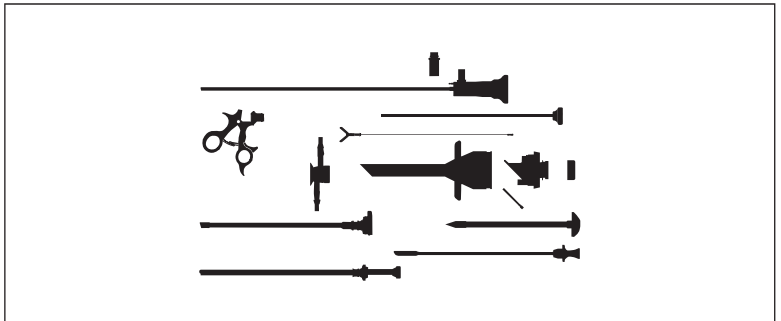
## 4.11 Steam Sterilization

If possible, Olympus recommends using fractionated prevacuum steam sterilization. Steam sterilization with prevacuum has been validated for its germicidal effectiveness with most of the Olympus endoscopes and accessories. Refer to the product-specific instructions for use for compatibility with steam sterilization.

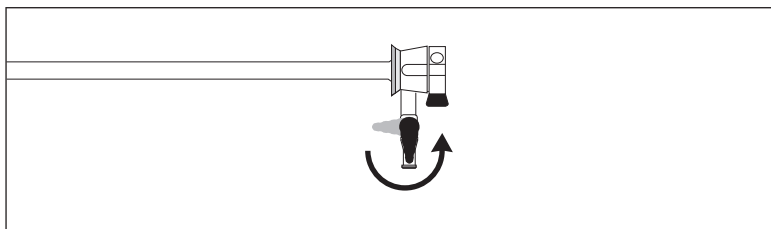
### Prior cleaning

Endoscopic instrumentation must be meticulously cleaned prior to sterilization. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases effectiveness of the sterilization process. After cleaning, make sure that the instrument is carefully dried.

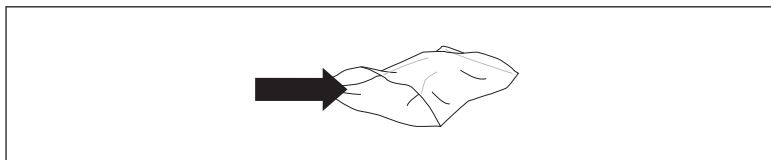
### Steam sterilization procedure



- Disassemble the instrumentation.
- Refer to the product-specific instructions for use for instruments which can be assembled before steam sterilization. For some products, reprocessing cards are available that also provide information on disassembly.



- Open all stopcocks.



- Place the instruments in appropriate instrument trays or pouches (for Olympus instrument trays, see the “Storage and Handling” section). Wrap or seal them adequately. Do not seal the instruments in close contact with each other as this might impair sterilization.
- Refer to the autoclave’s instructions for use.
- Use only prevacuum autoclave cycles to ensure that steam fills all lumens.
- After steam sterilization, let the instrument cool down gradually to room temperature without additional cooling. Sudden changes in temperature may damage the instruments. Never rinse the instruments with cold water for cooling. Be careful when unloading the autoclave, the contents may be hot.
- Make sure that the sterile package of the instruments is not damaged. If the package has been perforated, if the sealing has been opened, if the packaging is wet or if the packaging is damaged in any other way, resterilize the instruments.

### **Steam sterilization conditions**

Olympus recommends to autoclave the instruments for 5 min. at 134 °C with fractionated prevacuum.

Autoclavable Olympus products are designed for steam sterilization according to the following standards (in their respective latest approved version):

- US standard ANSI/AMMI ST46
- British standard BS 3970 and HTM-2010
- European standard EN 285



## CAUTION

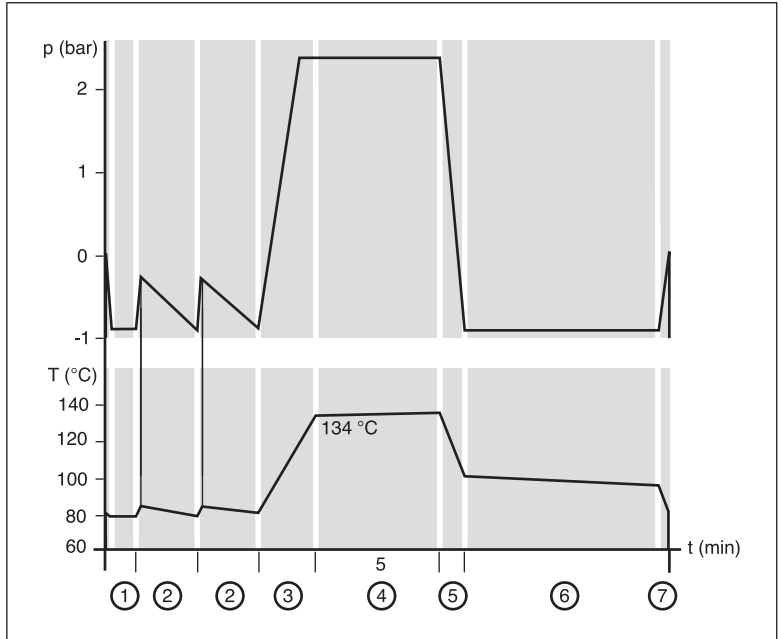
### Risk of instrument damage

Do not exceed a temperature of 138 °C. Otherwise, instrument damage may occur.

### Proposed water and steam quality acc. to EN 285

|   | Condensate.....    | Feed-water  |
|---|--------------------|---|
| Coke residues .....                                 | 1.0 mg/kg.....     | ≤ 10 mg/l   |
| SiO <sub>2</sub> .....                              | ≤ 0.1 mg/kg.....   | ≤ 1 mg/l  |
| Fe.....   | ≤ 0.1 mg/kg.....   | ≤ 0.2 mg/l  |
| Cd.....   | ≤ 0.005 mg/kg..... | ≤ 0.005 mg/l  |
| Pb.....   | ≤ 0.05 mg/kg.....  | ≤ 0.05 mg/l   |
| Traces of heavy metals<br>(except Fe, Cd, Pb) ..... | ≤ 0.1 mg/kg.....   | ≤ 0.1 mg/l  |
| Cl <sup>-</sup> .....                               | ≤ 0.1 mg/kg.....   | ≤ 2 mg/l  |
| P <sub>2</sub> O <sub>2</sub> .....                 | ≤ 0.1 mg/kg.....   | ≤ 0.5 mg/l  |
| Conductivity (at 25 °C) .....                       | ≤ 3 μS/cm.....     | ≤ 5 μS/cm   |
| pH.....   | 5–7.....           | 5–7.5   |
| Appearance.....                                     | colourless,.....   | colourless,<br>clear,..... clear,<br>without residues..... without residues |
| Water hardness<br>(total alkaline earth ions) ..... | ≤ 0.02 mmol/l..... | ≤ 0.02 mmol/l   |

## Example for fractionated prevacuum steam sterilization



- 1) Evacuation
- 2) Steaming and evacuation 2x
- 3) Heating
- 4) Sterilization
- 5) Evacuation
- 6) Drying
- 7) Aeration

### NOTE

#### Use of instrument trays

- Do not stack the instrument trays or load them on their side edges during steam sterilization.

For steam sterilization, Olympus recommends a drying time of at least 15–30 minutes.

- Choose an appropriate drying time, depending on the specific steam sterilization unit in your facility.

Users may want to consider the use of appropriate, lint-free absorbing cloth.

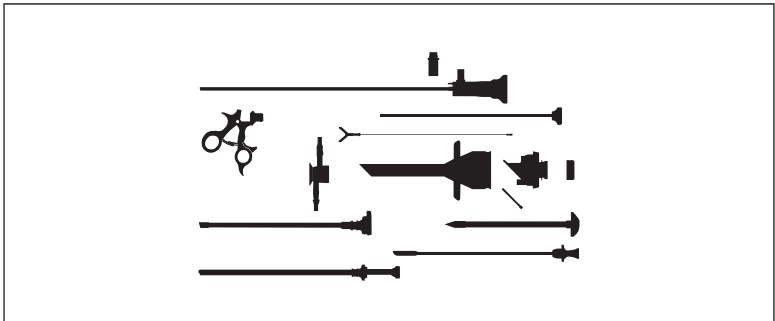
## 4.12 Gas Sterilization

### Prior cleaning

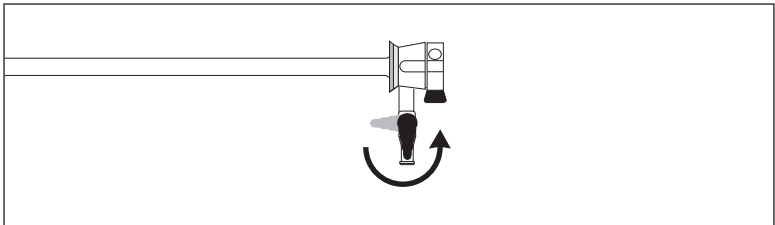
Endoscopic instrumentation must be meticulously cleaned prior to sterilization. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases the effectiveness of the sterilization procedure.

The information given in this section describes the instrument's material compatibility. It does not describe the microbiological efficacy of the procedure on the instruments.

### Gas sterilization procedure



- Disassemble the instruments according to the instructions provided in the product-specific instructions for use and the “System Guide Endoscopy” (this document).



- Open all stopcocks.
- Place the instruments in appropriate instrument trays or pouches (for Olympus instrument trays, see “Storage and Handling” section).
- Refer to the sterilizer’s instructions for use.
- Aerate the instruments sufficiently.



**Conditions for ethylene oxide gas sterilization**

- Refer to ANSI/AAMI ST41 or DIN 58 948 for recommendations and standards.
- Do not exceed the parameters outlined in the chart below.

|                                |                                  |
|--------------------------------|----------------------------------|
| Gas concentration .....        | 600–700 mg/l                     |
| Temperature .....              | 55 °C (130 °F)                   |
| Pressure .....                 | 0.1–0.17 MPa (16–24 psi)         |
| Humidity .....                 | 55 %                             |
| Exposure time .....            | > 2 h                            |
| Aeration cycle:                |                                  |
| - at room temperature .....    | 7 days                           |
| - in an aeration chamber ..... | 12 h at 50–60 °C<br>(122–135 °F) |

**Conditions for low temperature steam and formaldehyde gas sterilization (LTSF)**

- Refer to EN 14180 or DIN 58 948-16.
- Do not exceed the parameters outlined in the chart below.

|                         |                        |
|-------------------------|------------------------|
| Gas concentration ..... | 2–6 %                  |
| Temperature .....       | 60 °C (135 °F)         |
| Pressure .....          | max. 0.17 MPa (24 psi) |
| Humidity .....          | > 70 %                 |
| Exposure time .....     | > 1 hr.                |



**WARNING**

**Gas sterilization is toxic**

Ethylene oxide and formaldehyde are toxic and may present health hazards. Follow domestic health care regulations for compatibility of the processes. After sterilizing the instruments, aerate them to remove toxic residues.



**WARNING**

**Infection control risk**

Thoroughly clean and dry the instruments before gas sterilization. Residual water may inhibit sterilization.



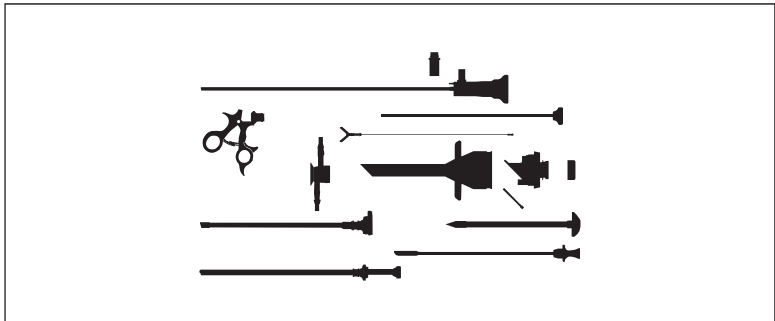
## 4.13 Other Sterilization Processes

### Prior cleaning

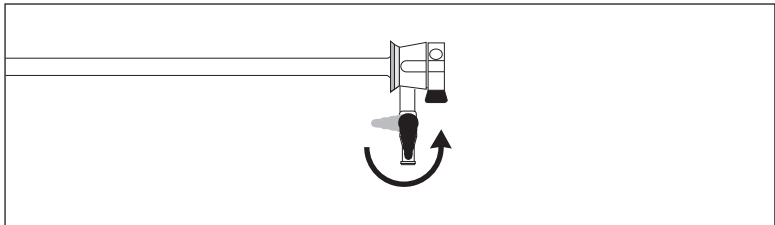
Endoscopic instrumentation must be meticulously cleaned prior to sterilization. Thorough cleaning removes both micro-organisms and organic material. Failure to remove organic material decreases the effectiveness of the sterilization process.

The information given in this section describes the instrument's material compatibility. It does not describe the microbiological efficacy of the specified process.

### STERRAD® low temperature plasma sterilization procedure



- For sterilization, disassemble the instrumentation according to the instructions provided in the product-specific instructions for use and the “System Guide Endoscopy” (this document).



- Open all stopcocks.
- Certain instruments with long narrow lumen might require boosters during sterilization. The use of boosters is not allowed in every country. For details, refer to the sterilizer's instructions for use.

- Place the instruments in sterilizing pouches or containers (any container/pouches must be certified by its manufacturer for STERRAD® use).
- Refer to the sterilizer's instructions for use.

#### NOTE

Different STERRAD systems with different cycles exist in the market. When the product-specific instructions for use or this document provide information on STERRAD for Olympus products, this applies to the following cycles:

- STERRAD 50: only one cycle exists
- STERRAD 100S: short cycle
- STERRAD 200: short cycle
- STERRAD NX: standard cycle
- STERRAD 100NX: standard cycle



#### CAUTION

##### **Risk of discoloring in STERRAD® processes**

Plasma sterilization may cause discoloring in some materials (e.g., aluminium). However, this does not impair the instrument's function.

More information on the wear of a product and points to consider are given in the material compatibility chart in the appendix.

## 4.14 Storage and Handling

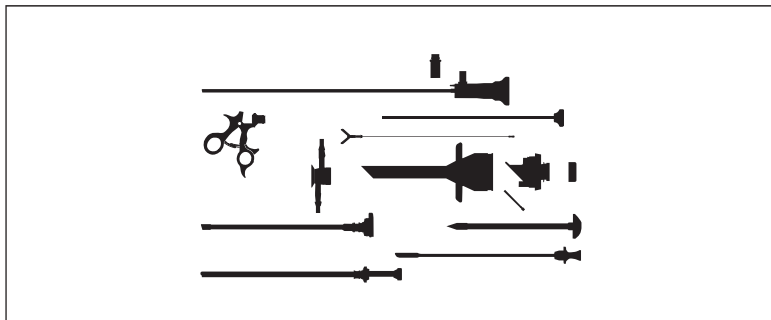


#### **Ambient conditions for storage**

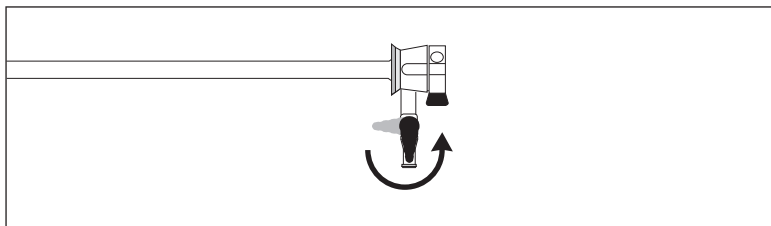
- Store the equipment in a clean and dry condition at room temperature (10–40 °C, 30–85 % humidity).
- Do not expose the equipment to direct sun light.
- Do not expose the equipment to sources of X-ray radiation.
- Do not store the equipment in a location where liquids may splash.
- Do not store the equipment under environmental conditions such as:
  - high atmospheric pressure
  - high or low temperatures
  - high or low humidity
  - direct ventilation
  - direct sunlight

- dust
- salty or sulfurous air
- Do not store the equipment where there is a risk of flammable gases.

### Preparation for long-term storage



- Disassemble the instruments according to the instructions provided in the product-specific instructions for use and the “System Guide Endoscopy” (this document).



- Open all stopcocks.
- Store electrical units on a flat surface. Do not incline the units. Make sure that units are not subjected to vibration and impacts.
- During long-term storage, make sure that the instruments remain in a disinfected condition and are ready for their next use.
- Make sure that cleaned and/or sterilized instruments do not come in contact with contaminated instruments.

## Instrument trays

As the product's transport packaging is not designed for storage, do not store the product in the transport packaging. Use instrument tray systems for storage (for Olympus instrument tray systems, see below).

## Storage life of sterilized instruments

The storage life of sterilized instruments depends on the type of packaging and the storage conditions. Refer to national and local laws and guidelines. Double sterile package according to DIN 58 946, Teil 9 prolongs the storage life.



### CAUTION

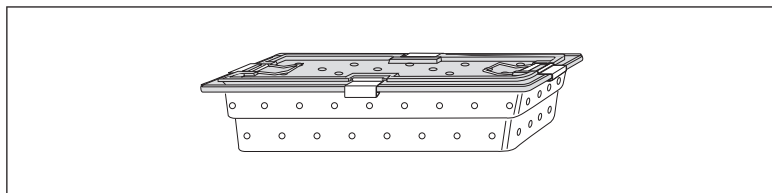
#### Handle with care

Instrument damage may occur.

- Handle and store endoscopic equipment carefully.
- Do not subject it to mechanical shocks such as impact or fall.



## Plastic instrument trays



The Olympus instrument tray system made of plastic features differently designed instrument trays:

- Instrument trays for telescopes (part of delivery of some telescopes)
- Universal instrument tray WA05970A
- Universal insert trays for WA05970A
- Customized insert trays for WA05970A

### Procedure

- Open the instrument tray's lid.
- Choose a compatible tray insert (only for instrument trays with tray inserts).
- Place compatible silicone mats into the tray and the tray insert (only for WA05970A, A5971, A5973).
- Place the tray insert into the instrument tray.

- Place the instruments into the instrument tray. Refer to the instrument tray's instructions for use for a loading chart.
- Close the instrument tray's lid.
- Before sterilization, seal the instrument tray in either an appropriate sterilizing pouch or sterilization container. Refer to the "Steam Sterilization" section.

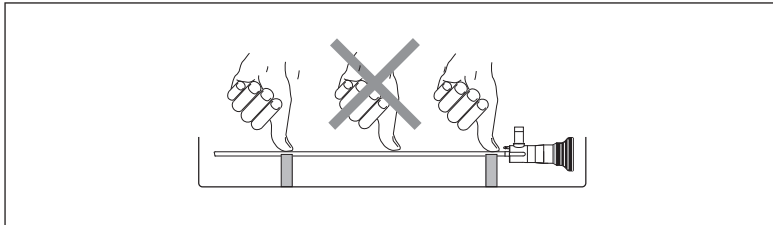
**NOTE**

**Use of instrument trays**

- Do not stack the instrument trays or load them on their side edges during steam sterilization.
- For steam sterilization, Olympus recommends a drying time of at least 15–30 minutes. Choose an appropriate drying time, depending on the specific steam sterilization unit in your facility.
- Users may want to consider the use of appropriate, lint-free absorbing cloth.



**CAUTION**  
**Risk of damage**



- When loading instrument trays, always press telescopes into the notches of the silicone bars as shown in the illustration.

# 5 Service

## 5.1 Repairs

### **Authorized service centers**

Repairs may only be carried out by qualified servicing personnel which have been authorized by Olympus Winter & Ibe. Otherwise, Olympus Winter & Ibe can not be held responsible for the safety, reliability, and performance of the product.



### **WARNING**

#### **Effects on patient and user safety**

There is a risk of damage to the product if the user or an unauthorized servicing agency attempts repair of a product. A damaged product may cause injury of the patient or the user.

#### **Loss of warranty**

Any guarantee or warranty claims towards Olympus Winter & Ibe are forfeited if the user or an unauthorized servicing agency attempts repair of a product.



Unauthorized repair (left) compared to authorized repairs (right).

### **Description of defects**

To enable the Service Center to perform repairs in a timely manner, send the product together with a detailed description of the damage or defect. The following particulars should be included:

- Catalog number
- Serial number or lot number (if possible)
- Precise description of the malfunction
- Delivery date
- Invoice copy (for possible guarantee or warranty claims)
- Internal order number of the customer (for correct accounting of the repair order)



### **Handling of products before shipment**

- As a protective measure for the safety of the servicing staff, perform a complete cleaning and disinfection/sterilization process before sending instruments for repair.
  - If this is not possible, for example because further disinfection or sterilization would damage the product completely, clean the product as thoroughly as possible and mark it accordingly.
- Service Centers are entitled to refuse to repair soiled or contaminated products for reasons of safety.

### **Shipment**

- For transportation of the defective product use the original cardboard packing.
- If this is not possible, wrap each component individually in sufficient paper or sheets of foamed material and place them in a cardboard box.

Service Centers do not accept warranty claims for damage caused by inadequate packaging.

Telescopes should be shipped in an appropriate Olympus instrument tray. Telescopes originally delivered with a protection tube should only be shipped inside this protection tube.

# 6 Appendix

This chart lists cleaning, disinfection and sterilization processes and agents that have been tested for material compatibility with products distributed by Olympus Winter & Ibe, Germany. This information only refers to material compatibility and does not indicate any germicidal effectiveness level.

The following reprocessing information supplements the detailed reprocessing information in the product-specific instructions for use. However, if the information given in this chapter differs from that in the product-specific instructions for use, use the information given in product-specific instructions for use.



**CAUTION**  
**Risk of damage**

Not every instrument is compatible with all processes mentioned in this document.

- Before disinfecting or sterilizing the instrumentation, refer to the product-specific instructions for use.

- + Compatible (refer to the remarks below)
- Not compatible
- ▲ Refer to the product-specific instructions for use
- ◆ Compatibility not tested or evaluated

|   | Manual cleaning and disinfection <sup>1)</sup> | Washer/disinfector (thermal disinfection) <sup>2) 5)</sup> | Steam sterilization 134 °C, 5 min., prevacuum | Oxivatio process <sup>3) 4)</sup> | STERRAD 50/100S | STERRAD 200/NX/100NX <sup>4)</sup> | PAA processes (manual and machine) |
|---|--|--|---|-----------------------------------|-----------------|------------------------------------|------------------------------------|
| Telescopes, autoclavable (sales before 2004)    | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Telescopes, autoclavable (sales since 2004)     | +  | +  | +   | +                                 | +               | +                                  | +                                  |
| OP telescopes, autoclavable (sales before 2004) | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| OP telescopes, autoclavable (sales since 2004)  | +  | +  | +   | +                                 | +               | +                                  | +                                  |

|  | Manual cleaning and disinfection <sup>1)</sup> | Washer/disinfector (thermal disinfection) <sup>2) 5)</sup> | Steam sterilization 134 °C, 5 min., prevacuum | Oxivario process <sup>3) 4)</sup> | STERRAD 50/100S | STERRAD 200/NX/100NX <sup>4)</sup> | PAA processes (manual and machine) |
|--|--|--|---|-----------------------------------|-----------------|------------------------------------|------------------------------------|
| Video telescopes, autoclavable (sales before 2004)                         | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Video telescopes, autoclavable (sales since 2004)                          | +  | +  | +   | +                                 | +               | +                                  | +                                  |
| Ureteroscopes, autoclavable  | +  | +  | +   | -                                 | +               | -                                  | -                                  |
| Neuroscopes, autoclavable  | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| Telescopes, non-autoclavable   | +  | -  | -   | -                                 | -               | -                                  | -                                  |
| Video adapters, autoclavable   | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Light-guide cables, standard (sales before 2004)                           | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Light-guide cables, standard (sales since 2004)                            | +  | +  | +   | +                                 | +               | +                                  | +                                  |
| Light-guide cables, fluid  | +  | -  | -   | -                                 | ◆               | ◆                                  | ◆                                  |
| Light-guide cables, mechanical (without optical elements)                  | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Light-guide cables, optical (with lense/fiber cone)                        | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Resection sheaths, irrigation rings, cystoscope sheaths                    | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Obturator  | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Bridges, optical obturators, working elements with/without working channel | +  | +  | +   | -                                 | +               | -                                  | -                                  |
| Working inserts with Albarran lever  | +  | +  | +   | -                                 | +               | -                                  | -                                  |
| Working elements (monopolar, bipolar, for knives, for probes)              | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Attachments  | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| HF-resection electrodes  | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| HF electrodes, rigid   | +  | ◆  | ▲   | ◆                                 | ▲               | ◆                                  | ◆                                  |
| HF electrodes, flexible  | +  | ◆  | -   | -                                 | +               | -                                  | -                                  |
| Knives   | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| Bladder syringes   | +  | +  | +   | -                                 | -               | -                                  | -                                  |
| Optical forceps  | +  | +  | +   | -                                 | +               | -                                  | -                                  |

|   | Manual cleaning and disinfection <sup>1)</sup> | Washer/disinfector (thermal disinfection) <sup>2),5)</sup> | Steam sterilization 134 °C, 5 min., prevacuum | Oxivario process <sup>3),4)</sup> | STERRAD 50/100S | STERRAD 200/NX/100NX <sup>4)</sup> | PAA processes (manual and machine) |
|---|--|--|---|-----------------------------------|-----------------|------------------------------------|------------------------------------|
| Hand instruments 3–9 Fr., flexible/semi-flexible                          | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| Trocar tubes, trocar spikes, valves, dilators, (thoracoscopy/laparoscopy) | +  | +  | +   | -                                 | +               | -                                  | -                                  |
| Reduction tubes, guiding tubes (thoracoscopy/laparoscopy)                 | +  | +  | +   | -                                 | +               | -                                  | -                                  |
| Trocar tubes, trocar spikes, bridges (arthroscopy)                        | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| EKL probes  | +  | ◆  | ◆   | ◆                                 | +               | +                                  | ◆                                  |
| EHL probes  | +  | ◆  | -   | ◆                                 | ◆               | ◆                                  | ◆                                  |
| Hand instruments, standard and monopolar (handles, shafts, jaws inserts)  | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| Bipolar hand instruments (handles, shafts, jaws inserts)                  | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| Needle holders (handles, jaws inserts)                                    | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| Suction/irrigation system (handle, valve tubing, suction/irrigation tube) | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| Palpation probes, retractors, curettes                                    | +  | +  | +   | -                                 | ▲               | ◆                                  | ◆                                  |
| HF cables   | +  | +  | +   | -                                 | +               | +                                  | -                                  |
| Tubing, autoclavable  | +  | ◆  | +   | ◆                                 | ▲               | ◆                                  | ◆                                  |
| Sealing caps and sealing rings  | +  | +  | +   | +                                 | +               | +                                  | -                                  |
| Instrument trays and insert trays   | +  | +  | +   | ◆                                 | -               | -                                  | ◆                                  |
| Instrument baskets, stainless steel                                       | +  | +  | +   | +                                 | +               | +                                  | ◆                                  |
| Chrome-plated instruments <sup>6)</sup>                                   | +  | +  | +   | -                                 | -               | -                                  | -                                  |
| Other products  | ▲  | ▲  | ▲   | ▲                                 | ▲               | ▲                                  | -                                  |

## NOTE

Reprocessing methods may lead to increased wear of the products. The lifetime of the products may be reduced using certain reprocessing methods.

### **Remarks**

- 1) For more information on cleaning and disinfection agents, contact your local Olympus representative.
- 2) Thermal washer/disinfector with alkaline cleaning agent with a pH value of up to 11 in the working solution
- 3) Oxivario is a process in a cleaning and disinfection machine developed by Miele & Cie. For more information on the process, contact the manufacturer of the machine.
- 4) Make sure to carefully inspect the products before each reprocessing cycle. Carefully check the adhesives and solders. If any changes occur, such as blistering, brittleness or maceration, do not use the product anymore.
- 5) Especially chrome-plated components may show a reduced lifetime.
- 6) For all systems before OES Pro: If you are not sure whether your instrument is chrome-plated, contact Olympus for more details.

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