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INTRODUCTION

Olympus instruction manuals have been prepared to provide the user with all necessary knowledge about the safe use of Olympus endoscopes and their related accessory equipment.

For further questions about how to use the products, about the products' safety, or about this or other Olympus manuals, please feel free to contact your local Olympus representative or visit our website, www.olympusamerica.com.

■ Instruction Manuals
Olympus provides two different manuals with each product:
- A system-related instruction manual, the “Olympus Endoscopy System Guide” (this manual), and
- A product-specific instruction manual

■ Olympus Endoscopy System Guide
The system-related instruction manual “Olympus Endoscopy System Guide” combines information on those topics that apply to virtually all instruments. Therefore, the Olympus Endoscopy System Guide must be considered a companion to all instruction manuals.

This System Guide applies to:
- All products manufactured by Olympus Winter & Ibe in Germany. These products are labeled “OLYMPUS Germany”.
- Products distributed by Olympus Winter & Ibe, Germany, which are accompanied by a product-specific instruction manual that references this System Guide.

■ Product-Specific Instruction Manuals
Olympus products are supplied with their own specific instruction manuals, which give all of the information necessary for the use of the product. In some instances, the product-specific instruction manuals only make reference to the System Guide. In these cases, all the related information given in
the System Guide is applicable to the product. 
If the information given in the System Guide is not applicable to a certain product, specific information for that product is given in the product-specific instruction manual.

■ Latest Version of the Olympus Endoscopy System Guide
Due to continuous development in technology, the content of the Olympus Endoscopy System Guide is regularly updated. To make sure that you use the most recent version of the Olympus Endoscopy System Guide, a list of all current versions of the Olympus Endoscopy System Guide in all languages can be found at Olympus Winter & Ibe's website, www.olympus-owi.com. The version number of any issue of the Olympus Endoscopy System Guide can be found on the bottom of its back cover. It is the number following the 7-digit order number (for example: 7.035.001 9.0_05/05).

■ Carefully Read all Instruction Manuals
Before use, carefully read the product-specific instruction manual, the Olympus Endoscopy System Guide (this manual) and all instruction manuals pertaining to any additional equipment used in the procedure. Follow all instructions given in these manuals. Failure to understand these instructions may result in:
- Death or severe injury to the patient,
- Severe injury to the user, or
- Damage to the equipment

■ Use of Instruction Manuals
Instruction manuals contain valuable specifications, care and problem-solving information which will help ensure safe and effective operation of the equipment. Keep all instruction manuals in a safe, accessible location.
Potential Hazards and Signal Words

Safety is the most important issue when using medical devices - for both the patient and all medical personnel. Therefore, Olympus manuals include safety information to help the user identify and avoid potential hazards. Olympus instruction manuals highlight potential hazards using three signal words: Danger, Warning and Caution. In addition, the signal word 'Note' is included to signify helpful information.

■ DANGER!
Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

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

■ CAUTION!
Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. This signal word may also be used to alert against unsafe practices or potential equipment damage.

■ NOTE
Indicates additional helpful information.
Symbols

Potential hazards, mandatory actions, prohibitions and user actions are illustrated by the same symbols throughout all instruction manuals.

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

■ Mandatory Actions
A solid circle that contains a symbol is used to signify a mandatory action.

■ Prohibition
A circle with a 45° diagonal slash from upper left to lower right is used to indicate an action that cannot be performed or a condition that must be avoided.

■ User Actions
A bullet at the beginning of a sentence indicates a required user action.
USE OF ENDOSCOPIC EQUIPMENT

General Policy

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.

WARNING!
Infection Control Risk with Reusable Equipment
Properly reprocess all reusable equipment before the first and each subsequent use, following the instructions in this Endoscopy System Guide and in the product-specific instruction manual. Improper and/or incomplete reprocessing can cause infection of the patient and/or medical personnel.

WARNING!
Infection Control Risk with Sterile, Single-Use Equipment
The equipment is delivered in a sterilized condition. Use it only if the package is undamaged. Only open the package immediately before use.

WARNING!
Infection Control Risk with Non-Sterile, Reusable Equipment
Properly reprocess the equipment before use, following the instructions in this Endoscopy System Guide and in the product-specific instruction manual. Improper and/or incomplete reprocessing can pose an infection-control risk to the patient and/or medical personnel.
Instrument Compatibility
The combinations of equipment and accessories that can be used with a certain product are listed in its product-specific instruction manual, in the section titled “Compatible Components”. 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 of the product-specific instruction manual are used, the full responsibility is accepted by the user.

Inspection
Before each use, perform the following inspection in addition to that described in the product-specific instruction manual.

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 all cleaning agent, disinfectant or sterilant residues.
- Make sure that no parts are missing or loose (e.g. sealing rings, sealing caps).
- Make sure that connecting elements between instruments function properly.
- Confirm that all working channels are not clogged or obstructed.
- Make sure that all modules of an instrument system are assembled correctly and securely attached (e.g. electrodes, knives).
- **Inspecting Telescopes**
  - Inspect for stains or 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 between the light guide connector and the distal end. If you are 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 you are in doubt, compare the cable’s light transmission with that of a new light guide cable.
  - Inspect for cuts or other damage to the cable’s outer sleeve.
  - Visually inspect the connector to be plugged into the light source. Make sure that its 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 free of corrosion and not defective.

■ Inspecting Electrodes

- Confirm that all parts of the HF resection electrodes are securely attached.
- Inspect for free movement in the assembled instrument.
- Make sure that contact surfaces are free of damage, corrosion, and/or wear.
- Make sure that the insulation is not damaged.
Inspecting Hand Instruments

- Make sure that the jaws and the handle move freely and are properly attached to the instrument.
- Make sure that the shaft’s insulation is not damaged.
- Confirm that the scissors have a proper cutting motion.
Wiring Video Equipment

■ Cable Types

There are several ways to connect video equipment. Common cable types are:

- BNC type
- Y/C type
- RGB type
- Cinch type
- Digital type

A BNC cable is a two-pole coaxial cable. The color, luminance and synchronizing signals are transmitted through this cable.

A Y/C cable is a four-pole cable. The luminance signal is transmitted separately from the other signals. Therefore the transmission quality is higher. Y/C cables are used for S-VHS and Hi-8 systems.

A RGB cable is an eight-pole cable. Color signals for red, green, blue, and the synchronizing signal are transmitted separately. RGB wiring provides the highest transmission quality.

A cinch cable is a two-pole cable. It is used for transmitting audio signals.

Digital cables transmit video and audio signal as digital data. There are several different types of plug connectors and transmission protocols.
The user's choice of cables depends on the interfaces featured by the video equipment being used.

## Principles of Wiring
There are a few basic principles to follow when wiring video equipment:
1. Always connect the OUT connector of the source unit to the IN connector of the receiving unit.
2. If a unit features a 75 Ω terminal impedance, check the IN and OUT connectors of the unit.
   - If the IN connector is occupied and the OUT connector is free, switch on the terminating impedance.
   - If IN and OUT connectors are occupied, switch off the terminating impedance.
3. Make sure that all cables are connected to a unit at both ends. If a cable cannot be connected at both ends, do not use the cable.
4. Always use the connection with highest possible transmission quality.
   - Transmission quality decreases in the following order: RGB, Y/C, BNC.
5. If a cable connection is used for documentation of signals (VCR, video printer), use the connection with highest possible transmission quality.
For example:
- Connect a printer via Y/C cable.
- Connect the monitor via BNC cable.

6. If possible, avoid passing the signal through several units. If available, use multiple source connectors on one unit to connect other equipment directly.

7. When using endoscopes with fiber bundle optics (e.g. fiberscopes, ureteroscopes), Y/C or RGB wiring is recommended to prevent moiré.

**Video Equipment: Troubleshooting**

Always perform a functional check of the imaging equipment before each use. Take the following steps if any irregularities are observed:

- **No Image Appears on the Monitor Screen.**
  - Make sure that camera control unit and monitor are connected to a wall-mains outlet.
    Connect to a wall-mains outlet if necessary.
  - Are the power switches on the camera control unit and the monitor illuminated?
    If not, check the fuses. Replace them if necessary.
  - Check the wiring of the camera control unit and monitor:
    Is the camera control unit’s VIDEO OUT connector connected to the monitor’s VIDEO IN connector?
  - If the monitor features a selector for more than one video signal source:
    Check the selector switch (e.g. LINE A, LINE B).
    Select the appropriate video signal source.
  - Set all monitor settings (brightness, color, contrast) to their default values.
  - Make sure that the camera head’s connecting cable is securely connected to the camera control unit.
  - Replace the video cable between the camera control unit and the monitor, to rule out cable defects.
• If the camera control unit features a color bar test chart, switch it on to test the monitor.
If the color bars do not appear on the monitor screen, contact an authorized Olympus Service Center for repair.

■ "Running" or "Rolling" Image on the Monitor Screen.
• Turn the V-HOLD knob on the monitor’s rear panel until the image becomes stable.

■ Blue Cast or Green Cast Image.
• Condensation has penetrated into the camera head’s connecting plug. Carefully dry the camera head at 60°C (140°F) for 30 minutes.

■ Image Disappears Temporarily.
• Make sure that all cables and connectors are securely connected.
• Visually inspect all cables for externally visible damage.

■ Image on the Monitor Screen Appears Dark.
• Check the optical surfaces of the light guide cable and the telescope’s light guide cable connectors for stains, debris or other foreign substances.
  If necessary, clean the optical surfaces with a cotton swab soaked in 70% alcohol (ethanol or isopropanol).
• Replace the light guide cable, to rule out light guide defects.
• Check the intensity setting of the light source.
  If necessary, readjust the intensity setting.
• Check the light source’s lamp.
  Has the emergency lamp been switched on?
  If necessary, switch on or replace the main lamp.
• If the light source has any filters, make sure that they have been switched off.
• Contact an authorized Olympus Service Center.

Unacceptable Color Reproduction.
• Set all monitor settings (brightness, color, contrast) to their default values.
• If any of the units in the imaging chain has a 75Ω terminal impedance, check the IN and OUT connectors of the unit. If the IN connector is occupied and the OUT connector is free, switch on the terminal impedance. If IN and OUT connectors are occupied, switch off the terminal impedance.
• If the monitor features a selector for color temperature, select 6500 Kelvin.
• Try to adjust the color reproduction using the camera control unit’s red and blue balancing functions.
• If this does not help, perform a white balance on the camera. Turn the camera control unit’s red and blue balancing functions to their default settings. Point the endoscope’s distal end at a white surface from about 30 mm away, with the light source turned on. Use only matte white paper when performing this inspection. Do not use shiny or colored paper. Make sure that the endoscope’s illumination does not interfere with any lighting in the operating room while performing a white balance. Perform the camera control unit’s white balancing function.

Image on the Monitor Screen is Out of Focus.
• Adjust the focus by turning the video adapter’s focusing ring.
• Check the connections of the telescope, video adapter, and camera head for proper attachment.
• Check the optical surfaces of the telescope, video adapter, and camera head for soiling and condensation. If necessary, clean the optical surfaces with a cotton swab soaked in 70% alcohol (ethanol, isopropanol). If necessary, dry optical surfaces using a soft cotton cloth.
• Check the imaging of the telescope itself.
  Disconnect the telescope from the video adapter and look through the eyepiece.
  If the telescope itself is out of focus, contact an authorized Olympus Service Center.

• Check the imaging of the camera head itself.
  Disconnect the telescope from the video adapter.
  Leave the video adapter attached to the camera head.
  Check the image on the monitor screen.
  If this image is out of focus, contact an authorized Service Center.

■ **Image on the Monitor Screen is Off-Center.**
  • Disconnect the telescope, video adapter and camera head.
  • Make sure that the telescope’s eyepiece cup, the video adapter and the camera head’s connecting threads are not damaged.
  • Make sure that the eyepiece cup is securely attached to the telescope.
  • Make sure that the video adapter’s fixation mechanisms are not damaged and work properly.
  • Connect the telescope, video adapter, and camera head.
  Make sure that all components are securely fixed.
  • If the image is still off-center, contact an authorized Olympus Service Center.
ENERGY APPLICATIONS

Electro-Medical Equipment

This section describes general precautions that should be taken when using electro-medical equipment. Specific safety precautions for particular equipment can be found in the product-specific instruction manual.

Installation

- Do not install the equipment in a location where liquids may splash onto or into it.

- Do not install the equipment under environmental conditions such as:
  - high atmospheric pressure
  - high or low temperatures
  - high or low humidity
  - ventilation
  - direct sunlight
  - dust
  - salty or sulfurous air

- Install the equipment on a flat surface. Do not incline the equipment. Make sure that the equipment is not subjected to vibration and impacts.
• Never install and operate the equipment where flammable gases are present.

• Connect the equipment only to a grounded hospital grade AC mains supply that complies with IEC requirements.
• Connect the equipment to a supply circuit that meets the input requirements indicated on the rating plate on the equipment’s rear panel.

• Where applicable, make sure that batteries are properly charged and inserted in the correct polarity.

• Connect the equipment to a potential equalization line if:
  - it is required by national or local hospital regulations.
  - CF certified equipment is used during procedures involving the heart or areas near the heart.

**Before Use**

• Inspect:
  - electrical contacts of switches and connectors
  - polarities
  - dial settings
  - indicators
  Make sure that the equipment functions properly.

• Make sure that the electrical contacts on connectors are dry. Remove condensation after steam sterilization using a clean, lint-free cloth.
• Make sure that all cables are connected correctly and securely.
• Inspect for possible interferences with other equipment.
• Test the batteries (when applicable).
During Use
• Prolonged use or a higher output than necessary for diagnosis and treatment may compromise patient safety.
• Continuously observe the equipment and the patient for abnormal reactions.
• If any abnormal reactions of the equipment or the patient are observed, stop using the equipment immediately.

After Use
• Reset control switches, dials, etc. to their initial positions.
• Switch off the unit.
• When disconnecting cables, do not pull at the cable. Grasp the plug and pull it to disconnect.

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 view 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 before 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, as shown at left.

1. Olympus OES light guide cables 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 connection to an Olympus light source. To use other adapters, remove adapter A3200 and attach the required adapter.
■ 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.

■ Interference 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 instructions on the proper connection of light sources and video systems, refer to the product-specific instruction manuals.

■ 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.

High-Frequency (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 electrolytic effect, causing movement of ions

Effects of High-Frequency (HF) Current

In high-frequency (HF) surgery, the Faraday effect is avoided by generating heat using high-frequency alternating current with a frequency of more than 300 kHz. This heat can be used for three types of applications:
- thermal coagulation of tissue
- cutting of tissue
- vaporization
In thermal coagulation, the electrical current heats the tissue slowly. The water inside the tissue evaporates slowly and cellular proteins are denatured, 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 vaporization, the electrical power is set to high values. The intracellular water evaporates immediately, resulting in tissue shrinkage and a large coagulation zone.

**Unipolar HF Surgery**

In unipolar HF surgery, the electrosurgical current passes from the point-shaped “active” electrode (A in the diagram at left) 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 are:
- all HF-electrodes
- HF-resection electrodes (in resectoscopes)
- unipolar hand instruments (e.g. unipolar forceps and scissors)

Other terms used for a patient plate are:
- neutral electrode
- indifferent electrode
- P-plate
■ Bipolar HF Surgery

In bipolar HF surgery, the electrosurgical current passes between the two electrodes of an instrument (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. Bipolar HF surgery does not require current to travel long distances through the patient’s body.

■ Connecting the Patient Plate
(only for unipolar HF surgery)

- Place the patient plate close to the operational field, ideally on the upper arm or the thigh.
- Make sure that the skin is free from hair and grease.
- Apply conductive gel evenly on the patient plate. Refer to the patient plate’s instruction manual. 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 facing the active electrode.

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

Incorrect application of a neutral electrode. This will result in uneven current distribution between the two electrodes. An alarm will be issued and the surgical instrument will not be able to be activated.
Current Flow in the Body
(only for unipolar 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.

Illustration:
Acceptable locations of the patient plate (black) and the 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 equipment. Make sure that the patient does not come in contact with other metal parts (e.g. operating table).
- 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.
Do not use HF-cables with brittle or defective insulation. Replace defective HF-cables. In order to plug or unplug an HF-cable, always hold the plug.
Never pull on the cable itself.
Do not place HF-cables directly on the patient’s skin.
Lay HF-cables straight, without looping.
Use only plastic clips to fix HF-cables to surgical drapes. Do not use metal clips.

■ **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 into shape.

■ **HF-Unit Instruction Manual**
Refer to the HF-unit’s instruction manual.

■ **Power Output and Electric Strength**
The maximum power output and the electric strength for the instruments is limited as indicated in the table below. Always use the lowest possible output setting necessary.

<table>
<thead>
<tr>
<th></th>
<th>Maximum Power Output</th>
<th>Electric Strength (recovered peak voltage)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unipolar applications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>400 W</td>
<td>2000 $V_p$</td>
</tr>
<tr>
<td>Pediatric urology</td>
<td>100 W (cutting)</td>
<td>1000 $V_p$</td>
</tr>
<tr>
<td></td>
<td>50 W (coagulation)</td>
<td>1000 $V_p$</td>
</tr>
<tr>
<td><strong>Bipolar applications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard</td>
<td>150 W</td>
<td>1200 $V_p$</td>
</tr>
<tr>
<td>BiQ+ series</td>
<td>100 W</td>
<td>800 $V_p$</td>
</tr>
</tbody>
</table>

Always refer to the product-specific instruction manual, in case there are recommended variations from these values.
WARNING!

Spray Coagulation

Some HF-units have a so-called “spray coagulation” feature. The application of “spray coagulation” may damage or destroy the electrodes. There is also a risk of spark-over to the patient. Do not apply the “spray coagulation” function of the HF-unit during endoscopic procedures. Spray coagulation should only be used if the compatibility of the instruments being used is certified in their product-specific instruction manuals.

Safety Precautions for Unipolar 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, non-target tissue areas. Coagulate cord-like tissue parts at their narrowest point. Otherwise, side coagulation or perforation may result.

Safety Precautions for Bipolar Procedures

- 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 damaged.
- Some HF-units feature a so-called AUTO START mode. In case of accidental tissue contact, the AUTO START mode poses a risk of unintentional coagulation. Therefore, some equipment does not operate 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. CO₂) for insufflation.

**Irrigation Fluids**
When performing unipolar electrosurgery, use only non-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.

**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.
- a non-conductive irrigation fluid 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 those 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 electrode is in contact with the patient’s skin,
- the patient is inadvertently in contact with electrically conductive parts (make sure that the patient has been insulated against all electrically conductive parts),
- direct contact between skin and HF-cables may lead to electrical capacitance which could cause burns.

■ Exogenous Burns
Exogenous burns are those 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 (anesthesia, etc.),
- ignition of insufflated gases (use only non-flammable gases for insufflation!),
- ignition of endogenous gases (bowel),
explosion of oxygen or hydrogen gas inside the urinary bladder, 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 images are widely known. For other possible interferences, refer to the HF unit’s instruction manual.

**Electrocardiography**
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 wall-mains outlets.
Laser Surgery

The term “laser” stands for “Light Amplification by Stimulated Emmission of Radiation”. A laser is a device that produces monochromatic, coherent, luminous beams. When a beam comes in contact with live tissue, its energy is converted into thermal energy, creating a cutting or coagulation effect.

- **Instruction Manual**
  Refer to the laser unit’s instruction manual.

- **Switch Off Laser**
  If the laser is not being used or if surgical instruments are being changed, switch off the laser.

- **Power Output**
  Always select the lowest possible laser output for the procedure.

- **Potential Risks**
  The application of laser energy involves certain risks, such as:
  - Eye damage
  - Skin damage
  - Chemical risks
  - Mechanical risks
  - Electrical risks

- **Eye Damage**
  Eye damage can include:
  - in the range of wavelengths between 200-400nm (UV): photophobia and/or damage to structures at the front of the eye (inflammation, watering),
  - in the range of wavelengths between 400-1400nm (visible light and near infrared): damage to the retina and the eye’s vitreous fluid,
  - in the range of wavelengths between 1.4-1000μm (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 with wavelengths between 250-320 nm can be carcinogenic.

■ **Chemical Risks**

Flammable or explosive substances may be ignited by a laser.

■ **Mechanical Risks**

Parts can be thrown away from the spot of the incident laser beam.

■ **Electrical Risks**

Electrical risks are caused by the high voltage supplied 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 reflective equipment within range of the laser. All endoscopic instruments used in conjunction with the laser must be black or matted.
DANGER!

Interference with Insufflators

Uncontrolled inflow of gaseous insufflation media can cause lethal embolisms. Besides the insufflator, other systems can act as gas supply sources. These may include: lasers with probe tips cooled using CO₂ or other gases, and Argon-Enhanced Coagulation (AEC) Systems.

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!

Flammable and/or Explosive Gases

Laser surgical procedures may only be performed if non-flammable gases (such as CO₂) are used for insufflation.

Do not perform laser surgical procedures in areas where flammable or explosive gases are present.

In addition to anesthetic agents, gases formed inside the patient's intestinal tract can pose an explosion hazard.
WARNINGS, INDICATIONS AND CONTRAINDICATIONS

ARTHROSCOPY

Safety

■ WARNING!
Closely Monitor Irrigation Fluids and Volumes
Since most arthroscopic procedures utilize irrigation fluids, it is important that the correct fluid be chosen and that inflow and outflow volumes be strictly observed. Appropriate measures should be taken to prevent the possibility of fluid overload.

Indications

■ Indications include the following joints:
  - Ankle
  - Knee
  - Shoulder
  - Wrist
Recommended reprocessing methods

CAUTION!

Incompatible Sterilization Processes
- The materials and construction of Olympus arthroscopic products vary from product to product and may not be compatible with certain reprocessing methods. Refer to “Compatible Reprocessing Procedures and Chemical Agents” on page 56 and the appropriate product-specific instruction manuals for a list of compatible reprocessing methods.

- The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that enter sterile tissues, including the vascular system, as critical. After meticulous manual cleaning, these should be sterilized prior to each patient use. Many Olympus instruments can be sterilized with either steam or ethylene oxide (see the instrument-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56).

The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that come into direct or indirect contact with mucous membranes, but do not ordinarily penetrate body surfaces, as semi-critical. After meticulous manual cleaning, these should, at a minimum, receive high-level disinfection prior to each patient use. Many Olympus products can be high-level disinfected with liquid chemical sterilant/disinfectants (see the product-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Contact Olympus for a current list of compatible liquid chemical sterilant/disinfectants.

- Arthroscopy products (e.g. telescopes, trocar tubes, hand instruments, accessories) should be reprocessed prior to each use, following the procedures described in the Reprocessing chapter of this guide (also see “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Olympus arthroscopic equipment can be steam-sterilized unless otherwise indicated in the product-specific instruction manual. All reprocessing procedures should be conducted as outlined in this guide.
Safety

A comprehensive nasal exam and/or computerized tomography (CT) scan prior to sinus surgery may identify clinical conditions that alter patient management.

Indications

Indications include diagnosis and treatment in:
- Nasal endoscopy
- Sinoscopy

Recommended reprocessing methods

CAUTION!

Incompatible Sterilization Processes
- The materials and construction of Olympus nasal and sinus products vary from product to product and may not be compatible with certain reprocessing methods. Refer to “Compatible Reprocessing Procedures and Chemical Agents” on page 56 and the appropriate product-specific instruction manuals for a list of compatible reprocessing methods.

- The U.S. Centers for Disease Control and Prevention (CDC) characterizes reusable medical devices and instruments that enter sterile tissues, including the vascular system, as critical. After meticulous manual cleaning, these should be sterilized prior to each patient use. Many Olympus instruments can be sterilized with either steam or ethylene oxide (see the instrument-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56).
- The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that come into direct or indirect contact with mucous membranes, but do not ordinarily penetrate body surfaces, as semi-critical. After meticulous manual cleaning, these should, at a minimum, receive high-level disinfection prior to each patient use. Many Olympus products can be high-level disinfected with liquid chemical sterilant/disinfectants (see the product-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Contact Olympus for a current list of compatible liquid chemical sterilant/disinfectants.

- ENT products (e.g. telescopes, trocar tubes, hand instruments, accessories) should be reprocessed prior to each use following the procedures described in the Reprocessing chapter of this guide (also see “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Olympus ENT equipment can be steam-sterilized (autoclaved) unless otherwise indicated in the product-specific instruction manual. All reprocessing procedures should be conducted as outlined in this guide.

**HYSTEROSCOPY**

**Safety**

■ **DANGER!**

Control gas inflow

Uncontrolled inflow of the gaseous dilation medium may cause lethal embolisms. Never use lasers with laser probe tips that are cooled with CO₂ or other gases; there is a danger of an uncontrolled inflow of gas and life-threatening embolism.
WARNING!
- If pregnancy is suspected, a pregnancy test should be given prior to the diagnostic hysteroscopy procedure.
- During continuous-flow hysteroscopy, strict fluid intake and output surveillance should be maintained. Intrauterine instillation exceeding 2 liters should be undertaken with great care due to the possibility of fluid overload.
- When performing hysteroscopic electrosurgery, the distention medium must be electrically nonconductive.

NOTE
- Vaginal ultrasonography prior to hysteroscopy may identify clinical conditions that could alter patient management.

Indications, contraindications, complications

Diagnostic and operative indications include:
- Abnormal uterine bleeding
- Amenorrhea
- Directed biopsy
- Endometrial ablation
- Evaluation of an abnormal hysterosalpingogram
- Infertility and pregnancy wastage
- Intrauterine foreign body
- Pelvic pain
- Removal of submucosal fibroids and large polyps
- Submucous myomectomy
- Transection of intrauterine adhesions
- Transection of intrauterine septa

Absolute contraindications include:
- Acute pelvic inflammatory disease (PID)
Relative contraindications include:
- Cervical/vaginal infection
- Inability to distend the uterus
- Invasive carcinoma of the cervix
- Known pregnancy
- Medical contraindication of or intolerance to anesthesia
- Recent uterine perforation
- Uterine bleeding or menses

Relative contraindications to endometrial ablation include:
- Adenomatous endometrial hyperplasia
- Pelvic pain (subtle PID)
- Severe adenomyosis
- Surgical skill (“Acute Technical”).
Hysteroscopic endometrial ablation, whether laser or electrosurgical, should not be performed without adequate training and clinical experience. Additionally, tissue sampling is required prior to destruction of the endometrium. The following are clinical conditions that can significantly complicate hysteroscopic endometrial ablation:
- Uterine anomalies
- Uterine leiomyoma

Relative contraindications to hysteroscopic myomectomy include:
- Inability to circumnavigate the myoma (re: myoma size) - predominantly intramural myomas with small submucous components.
- Severe anemia
- Surgical skill (see above)

Complications may include:
- Cerebral edema
- Hyponatremia
- Hypothermia
- Idiosyncratic reaction
- Pulmonary edema
- Rupture of a fallopian tube secondary to tubal obstruction.
- Uterine perforation resulting in possible injury to the bowel, bladder, major blood vessels and ureter.

**Recommended reprocessing methods**

**CAUTION!**

**Incompatible Sterilization Processes**
- The materials and construction of Olympus hysteroscopic products vary from product to product and may not be compatible with certain reprocessing methods. Refer to “Compatible Reprocessing Procedures and Chemical Agents” on page 56 and the appropriate product-specific instruction manuals for a list of compatible reprocessing methods.

- The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that enter sterile tissues, including the vascular system, as *critical*. After meticulous manual cleaning, these should be sterilized prior to each patient use. Many Olympus instruments can be sterilized with either steam or ethylene oxide (see the instrument-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56).

- The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that come into direct or indirect contact with mucous membranes, but do not ordinarily penetrate body surfaces, as *semi-critical*. After meticulous manual cleaning, these should, at a minimum, receive high-level disinfection prior to each patient use. Many Olympus products can be high-level disinfected with liquid chemical sterilant/disinfectants (see the product-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Contact Olympus for a current list of compatible liquid chemical sterilant/disinfectants.
Hysteroscopic products (e.g. telescopes, trocar tubes, hand instruments, accessories) should be reprocessed prior to each use, following the procedures described in the Reprocessing chapter of this guide (also see “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Olympus hysteroscopic equipment can be steam-sterilized (autoclaved) unless otherwise indicated in the product-specific instruction manual. All reprocessing procedures should be conducted as outlined in this guide.

LAPAROSCOPY/ THORACOSCOPY

Safety

■ WARNING!

- Ultrasonography prior to laparoscopy may identify clinical conditions that could alter patient management.
- Abdominal puncture sites 10 mm or greater (for the introduction of auxiliary instrumentation) may be a source of herniation.
- Care must be taken during the procedure (e.g., insertion of the Veress needle, placement of trocars), as the following complications may occur: gas embolism, vascular injury, perforation of hollow viscus, subcutaneous emphysema, extraperitoneal emphysema and/or tension pneumoperitoneum.
- Hypothermia. Check the patient’s body temperature regularly throughout the procedure. Carbon dioxide (CO₂) gas, flowing continuously, absorbs heat and can cause hypothermia.
- Insufflation. Electrosurgical procedures may only be carried out safely if nonflammable gases (such as CO₂) are used for insufflation. Direct access of insufflated CO₂ gas to the vascular system (e.g., through an open vessel in the intra-abdominal or intra-thoracic cavity, or an improperly
inserted Veress needle) may result in gas embolism. The thoracoscopic insufflation pressure should not exceed 10 mm Hg.

**Indications, contraindications, complications**

- **General surgery indications include:**
  - Abdominal trauma
  - Appendectomy
  - Colon resection
  - Diagnosis and treatment of abdominal pain.
  - Gall bladder and biliary tree disease
  - Gastric diseases
  - Hernia repair
  - Laparoscopic cholecystectomy
  - Liver biopsy
  - Liver disease
  - Nissen fundoplication
  - Pelvic infection
  - Pelvic lymph node dissection
  - Pelvic mass
  - Pelvic pain
  - Perihepatic adhesions
  - Removal of intraperitoneal foreign body
  - Varix ligation

- **OB/GYN indications include:**
  - Determination of the presence and extent of pelvic inflammatory disease (if not in an acute stage)
  - Determination of the presence, extent and therapy of pelvic endometriosis
  - Diagnosis and/or treatment of ectopic pregnancy
- Evaluation, diagnosis and/or treatment of small pelvic tumors, including myomata
- Evaluation of congenital anomalies
- Evaluation of ovarian endocrinopathy
- Infertility work-up
- Laparoscopy assisted vaginal hysterectomy (LAVH)
- Ovarian biopsy
- Ovarian cyst
- Retrieval of foreign bodies
- Unexplained pelvic pain (acute, chronic)
- Unexplained primary or secondary amenorrhea
- Urinary incontinence
- Uterine suspension
- Visualization, diagnosis and/or treatment of perforated abdominal (pelvic) organs

■ **Laparoscopy absolute contraindications include:**
  - Bowel obstruction
  - Class IV cardiac decompensation
  - Diaphragmatic hernia
  - Ileus
  - Infection with acute peritonitis
  - Intraperitoneal hemorrhage

■ **Laparoscopy relative contraindications include:**
  - Bleeding diathesis
  - Cardiac disease
  - Cardiovascular instability
  - Chronic obstructive lung disease
  - Hypovolemic shock
  - Hypoxemia
  - Infection with acute peritonitis
  - Invasive carcinoma of the cervix
  - Liver failure with established collateral vessels
  - Medical contraindication or intolerance to anesthesia
- Obesity
- Pregnancy longer than 16 weeks gestation or abdominal mass of comparable size
- Previous abdominal surgery
- Septic peritonitis
- Thin nulliparous patient

■ **Laparoscopy complications may include:**
- Abdominal adhesions
- Ascites, hyponatremia, axotemia
- Delayed hemorrhage
- Fever, peritonitis
- Gas embolism
- Incisional hernia
- Infection
- Pain
- Perforation of solid organs
- Perforation of the hollow viscus
- Peripheral nerve damage
- Vascular injury

■ **Thoracoscopy indications include:**
- Blebs and bullous lung disease
- Cysts of the thorax
- Esophageal disease
- Lung disease
- Mediastinal and hilar masses
- Pericardial disease
- Pleural disease
- Spinal disease
- Sympathectomy
- Trauma

■ **Thoracoscopy absolute contraindications include:**
- Bleeding diathesis
- Cardiovascular instability
- Chronic obstructive lung disease
- Hypovolemic shock
- Hypoxemia
- Infection (excluding empyema)
- Insufficient space in pleural cavity
- Medical contraindication or intolerance to single-lung anesthetic

Thoracoscopy relative contraindications include:
- Multiple previous thoracotomies
- Multiple previous pleurodesis
- Presence of pleural adhesions

Thoracoscopy complications may include:
- Arrhythmia
- Atelectasis
- Bronchopleural fistula
- CO₂ embolism tension pneumothorax
- Extrapleural trocar placement
- Hypercarbia
- Hypotension
- Hypoxemia
- Infection
- Lung injury
- Mediastinal Compression
- Pain
- Parenchymal hemorrhage and air leak
- Pneumothorax
- Trocar damage to intercostal bundle
- Ventilator dependence (>48 hrs.)
Recommended reprocessing methods

- **CAUTION!**
  **Incompatible Sterilization Processes**
  - The materials and construction of Olympus laparoscopic/thoracoscopic products vary from product to product and may not be compatible with certain reprocessing methods. Refer to “Compatible Reprocessing Procedures and Chemical Agents” on page 56 and the appropriate product-specific instruction manuals for a list of compatible methods.

- **NOTE**
  - Olympus rigid telescopes have two (2) identification aids; either one will identify the instrument as compatible with steam sterilization: “Autoclave” is marked on the main shaft at the light guide post, or the distal tip of the telescope is colored gold.
  - The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that enter sterile tissues, including the vascular system, as critical. After meticulous manual cleaning, these should be sterilized prior to each patient use. Many Olympus instruments can be sterilized with either steam or ethylene oxide (see the instrument-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56).
  - The U.S. Centers for Disease Control and Prevention (CDC) characterizes reusable medical devices and instruments that come into direct or indirect contact with mucous membranes, but do not ordinarily penetrate body surfaces, as semi-critical. After meticulous manual cleaning, these should, at a minimum, receive high-level disinfection prior to each patient use. Many Olympus products can be high-level disinfected with liquid chemical sterilant/disinfectants (see the product-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Contact Olympus for a current list of compatible liquid chemical sterilant/disinfectants.
Laparoscopic and thoracoscopic products (e.g. telescopes, trocar tubes, hand instruments, accessories) should be reprocessed prior to each patient use, following the appropriate procedures described in the Reprocessing chapter of this guide (also see “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Olympus laparoscopic and thorascopic equipment can be steam-sterilized (autoclaved) unless otherwise indicated in the product-specific instruction manual. All reprocessing procedures should be conducted as outlined in this guide.

**SUBCUTANEOUS SURGERY**

**Safety**

**WARNING!**
- During cavity enlargement, the dissection can become too thin, resulting in skin perforation and/or burning. To prevent injury, constant observation of the patient’s skin is recommended.

An increase in intensity of transilluminated light and a change in light color from pink/red to white indicates that a subcutaneous dissection is becoming too superficial. Carefully observe the plane of dissection and monitor the light transmitted to help guard against complication.

**Indications, complications**

**Endoscopic subcutaneous dissection/resection indications include:**
- Aesthetic surgery
- Plastic/reconstructive surgery
- Subfascial endoscopic perforating vein surgery (SEPS)
Complications may include:
- Alopecia
- Arterial injury
- Deep venous thrombosis
- Extrusion (tissue expanders)
- Hematoma
- Hypesthesia
- Infection
- Insertion site dehiscence (tissue expanders)
- Intraperitoneal injury
- Pulmonary embolism
- Nerve injury
- Seroma
- Skin ischemia

Recommended reprocessing methods

CAUTION!
Incompatible Sterilization Processes
- The materials and construction of Olympus products for endoscopic dissection vary from product to product and may not be compatible with certain reprocessing methods. Refer to “Compatible Reprocessing Procedures and Chemical Agents” on page 56 and the appropriate product-specific instruction manuals for a list of compatible methods.

- The U.S. Centers for Disease Control and Prevention (CDC) characterizes reusable medical devices and instruments that enter sterile tissues, including the vascular system, as critical. After meticulous manual cleaning, these should be sterilized prior to each patient use. Many Olympus instruments can be sterilized with either steam or ethylene oxide (see the instrument-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56).
- The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that come into direct or indirect contact with mucous membranes, but do not ordinarily penetrate body surfaces, as semi-critical. After meticulous manual cleaning, these should, at a minimum, receive high-level disinfection prior to each patient use. Many Olympus products can be high-level disinfected with liquid chemical sterilant/disinfectants (see the product-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Contact Olympus for a current list of compatible liquid chemical sterilant/disinfectants.

- Subcutaneous surgery products (e.g. telescopes, hand instruments, accessories) should be reprocessed prior to each patient use, following the appropriate procedures described in the Reprocessing chapter of this guide (also see “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Olympus arthroscopic equipment can be steam-sterilized (autoclaved) unless otherwise indicated in the product-specific instruction manual. All reprocessing procedures should be conducted as outlined in this guide.

UROLOGY

Safety

- WARNING!

- Since most urological endoscopy procedures utilize irrigation fluids, it is important that the correct fluid be chosen and that the volumes of inflow and outflow be strictly observed. Appropriate measures should be undertaken to prevent the possibility of fluid overload of the patient.
CAUTION!
Spray coagulation and resectoscopes
- New HF units feature a “spray coagulation” mode. Use of this “spray coagulation” mode together with a resectoscope could destroy the instrument’s distal tip or make it unusable. Never apply the “spray coagulation” function of the HF-unit during endoscopic procedures with Olympus resectoscopes.

Indications

Indications include:
- Cystoscopy
- Resection
- Ureterorenoscopy
- Urethroscopy

CAUTION!
Incompatible Sterilization Processes
- The materials and construction of Olympus urologic products vary from product to product and may not be compatible with certain reprocessing methods. Refer to “Compatible Reprocessing Procedures and Chemical Agents” on page 56 and the appropriate product-specific instruction manuals for a list of compatible reprocessing methods.
- The U.S. Centers for Disease Control and Prevention (CDC) characterizes reusable medical devices and instruments that enter sterile tissues, including the vascular system, as critical. After meticulous manual cleaning, these should be sterilized prior to each patient use. Many Olympus instruments can be sterilized with either steam or ethylene oxide (see the instrument-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56).
- The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that come into direct or indirect contact with mucous membranes, but do not ordinarily penetrate body surfaces, as semi-critical. After meticulous manual cleaning, these should, at a minimum, receive high-level disinfection prior to each patient use. Many Olympus products can be high-level disinfected with liquid chemical sterilant/disinfectants (see the product-specific instruction manual and/or “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Contact Olympus for a current list of compatible liquid chemical sterilant/disinfectants.

- Urology products should be reprocessed prior to each patient use, following the appropriate procedures described in the Reprocessing chapter of this guide (also see “Compatible Reprocessing Procedures and Chemical Agents” on page 56). Olympus urologic equipment can be steam-sterilized (autoclaved) unless otherwise indicated in the product-specific instruction manual. All reprocessing procedures should be conducted as outlined in this guide.
REPROCESSING

General Policy

■ The Reprocessing Cycle
Olympus endoscopic instrumentation that is not labeled as a single-use product is to be reprocessed by the methods described in this chapter. To minimize the risk of cross-contaminating patients, reprocess all endoscopic instrumentation after each use.

■ Disinfection vs. Sterilization
The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that enter sterile tissues, including the vascular system, as critical. After meticulous manual cleaning, these should be sterilized prior to each patient use.

The U.S. Centers for Disease Control and Prevention (CDC) characterizes those reusable medical devices and instruments that come into direct or indirect contact with mucous membranes, but do not ordinarily penetrate body surfaces, as semi-critical. After meticulous cleaning, these should, at a minimum, receive high-level disinfection prior to each patient use.

Contact your local hygiene representative to determine the situation in which disinfection rather than sterilization would be appropriate in your facility.

■ Manual Cleaning vs. Automatic Cleaning
In general, instruments (with the exception of flexible and semi-rigid endoscopes) can be cleaned manually or automatically with satisfactory results. Manual cleaning methods pose infection control risks for cleaning personnel. Automatic methods reduce these risks and provide the advantage of standardized and validated procedures. Therefore, in general, Olympus recommends automatic cleaning procedures. Contact your local infection-control representative to determine which cleaning method would be appropriate in your facility for a given instrument (also see the product-specific instruction manual and/or “Compatible
Reprocessing Procedures and Chemical Agents” on page 56.

■ Standards
Refer to American National Standard ANSI/AAMI ST35 “Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Non-Clinical Settings”.
Contact your local infection-control representative for local standards and regulations.

■ After Use
After use, immediately inspect the instruments as described in “Preparation for Reprocessing at the Point of Use” on pages 59-60.

■ Brand-New Reusable Instruments
Always treat brand-new instruments as if they have been used. Brand-new instruments must be manually cleaned before disinfection or sterilization.

Compatible Procedures and Agents

The materials and construction of the Olympus endoscopic instrumentation may not be compatible with certain reprocessing methods.
Olympus classifies methods by two criteria:
- microbiocidal efficiency
- material compatibility

■ Microbiocidal Efficiency
Microbiocidal efficiency means that the efficacy of the reprocessing procedure for achieving high-level disinfection or sterilization of an instrument has been verified.
Material Compatibility
Material compatibility of an Olympus instrument with a particular reprocessing step or method means that negative effects on the material of the instruments have not been observed. Material compatibility does not necessarily mean that the microbiocidal effectiveness of a particular reprocessing method or material 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.

Monitoring
Regularly monitor all disinfection and sterilization processes. Although there are no biological indicators available to verify disinfection processes, there are test strips which will permit monitoring the concentration of the disinfectant agent. Monitor the concentration at the frequency recommended by the manufacturer to ensure that the solution has not been diluted below its effective concentration. To monitor sterilization processes, use an appropriate biological indicator.

Compatibility Chart
The compatibility chart on the following page lists those cleaning, disinfection, sterilization procedures and agents that have been tested on components of rigid endoscopes and their accessories.
## CAUTION!

**Risk of Damage**

Not every instrument is compatible with all procedures mentioned in this guide. Before disinfecting or sterilizing an instrument, read the product-specific instruction manual.

### Compatible Reprocessing Procedures and Chemical Agents

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<th>Sterrad 100/50/50S+</th>
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<th>Manual Cleaning</th>
<th>High-Level Disinfection</th>
<th>Ethylene oxide (ETO)</th>
<th>Autoclaving, 130°C (273°F)</th>
<th>Tested for material compatibility</th>
<th>Tested for material compatibility and validated for efficacy</th>
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<td>Probes with Plug</td>
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<tr>
<td>Camera Heads, not autoclavable</td>
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<td>Camera Adapters, autoclavable</td>
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<td>Light Guide Cables</td>
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<td>Sealing Caps/Sealing Rings</td>
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<td>Instrument Trays</td>
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<td>Other Products</td>
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<td>⚤</td>
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</tr>
</tbody>
</table>

1. Do not allow equipment immersion time to exceed 1 hour.
2. Also see the Olympus America Inc. Technical Bulletin entitled “Compatibility of Olympus Endoscopic Products with Sterrad 100/500/50/200 Sterilizers”.
3. Use enzymatic, neutral-pH agents during automatic cleaning/disinfection. Even minor residues of non-pH-neutral agents can corrode the endoscope’s material - particularly on older, chromium-plated instruments.
4. When using 2-3% glutaraldehyde solutions for disinfection, do not allow the immersion time to exceed 1 hour.
5. Refer to the camera head’s instruction manual to determine and/or confirm whether or not the device may be autoclaved.
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 shield, face mask, moisture-resistant clothing and chemical-resistant gloves that fit properly and are long enough so that your skin is not exposed. Always remove contaminated protective equipment before leaving the cleaning area.

■ WARNING!
Toxic Chemical Fumes
The disinfection/sterilization room must be adequately ventilated. Adequate ventilation helps protect against the buildup of toxic chemical fumes.

■ WARNING!
Flammable Liquids
Store alcohol (ethanol, isopropanol) in an air-tight container. Alcohol stored in an open container is a fire hazard and will lose its efficacy due to evaporation.
Decontaminating Electrical Units

This section describes how to decontaminate the surfaces of electrical units. These units are not sterilizable; they should only be cleaned and disinfected.

■ Cleaning Units
• Turn off the power switch.
• Disconnect the power cable.
• Let the unit cool down to room temperature.
• Remove dust with a soft cloth.
• Remove hard-to-clean soil with a damp cloth.

■ Decontaminating the Unit’s Surface
• Should the unit become soiled with blood or other potentially infectious material, wipe off all gross debris and then decontaminate the unit using a surface disinfectant (e.g., one registered by the U.S. Environmental Protection Agency (EPA)). Always follow the manufacturer’s recommendations for surface disinfection. Make sure that the unit is completely dry before use.

■ CAUTION!
• Electrical units cannot be immersed, ETO gas sterilized or steam sterilized. Do not submerge or allow fluid to enter electrical units, and do not autoclave or gas sterilize them. Otherwise, equipment damage will occur.
Preparation for Reprocessing at the Point of Use

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

■ Single-Use Products
  • Separate single-use products from reusable products.
  • Destroy/dispose of single-use products.
  • Dispose of refuse according your hospital's policy and local regulations.

■ Reusable Products
  • Remove debris from instruments by wiping with a soft cloth.
  • Disassemble the instruments.
  • Remove sealing caps.
  • Open all stopcocks.
Separate telescopes from other instruments.

Transport of Reusable Products

- Transport reusable products from the point of use to the reprocessing area.

The instrument can be transported wet or dry. However, it is preferable to return the instruments from the point of use to the cleaning area when the instruments are dry, to prevent protein coagulation caused by cleaning agents.

- If the instruments are dry, make sure that debris does not solidify. Close the container’s lid.

- Transport wet and dry reusable products in a container with a lid in place, to avoid possible environmental or personnel contamination.

- If transporting wet instruments, the temperature of the fluid in which the instruments are placed should not exceed 20°C (68°F)

- Do not allow instruments to be immersed in liquids for more than 1 hour.

- Do not use physiological saline solution for immersion.

CAUTION!

Risk of Instrument Damage

Reprocess the instruments immediately after use. Do not leave used instruments overnight before reprocessing.

If unreprocessed instruments are left dry for a long period, debris may dry onto them, leading to encrustations that may be more difficult to remove.

If instruments are left immersed in liquids for a prolonged period, the instrument’s sealings could be damaged and/or fail.
Manual Cleaning

This section describes how to perform manual cleaning of endoscopes and their accessories.

Manual Cleaning Procedure

- Immediately after use, disassemble the instruments.
- Open all stopcocks.
- Thoroughly rinse all instrument components with water. The water temperature should not exceed 20° C (68° F).
• Use a medical-grade, low-foaming, neutral pH detergent or enzymatic detergent and follow the manufacturer's dilution and temperature recommendations.

• Do not immerse instrumentation in cleaning solution for more than 1 hour.

• Perform manual cleaning until all visible debris has been completely removed.

• After cleaning the instrument, rinse it with deionized or sterile water.

• Let all parts drain completely.

• Use a soft cloth to wipe off any remaining water.
# Cleaning Brushes and Cleaning Wire

- Select an appropriate cleaning brush/wire:

<table>
<thead>
<tr>
<th>Cat.No.</th>
<th>Dimensions</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>A0440</td>
<td>0.6 x 500 mm</td>
<td>channels in uretero-renaloscopes, channels for guidance of catheters</td>
</tr>
<tr>
<td>A0441</td>
<td>2.5 x 360 mm</td>
<td>sheaths (5-7.5 Fr.), working inserts, bridges, channels for guidance of resection electrodes</td>
</tr>
<tr>
<td>A0442</td>
<td>2.5 x 500 mm</td>
<td>channels in uretero-renaloscopes</td>
</tr>
<tr>
<td>A0443</td>
<td>6 x 360 mm</td>
<td>4-5 mm trocar tubes, sheaths (15-17 Fr.), arthroscope trocar tubes, telescope channels of urologic and gynecologic instruments</td>
</tr>
<tr>
<td>A0444</td>
<td>4 x 500 mm</td>
<td>shafts of HiQ hand instruments with a length of 450 mm</td>
</tr>
<tr>
<td>A0445</td>
<td>9 x 360 mm</td>
<td>sheaths (19.5-27 Fr.)</td>
</tr>
<tr>
<td>A0446</td>
<td>4 x 360 mm</td>
<td>sheaths (8-12 Fr.), shafts of HiQ hand instruments with lengths of 250 and 330 mm</td>
</tr>
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<td>A0447</td>
<td>12 x 360 mm</td>
<td>sheaths (28.5-30 Fr.), 8-11 mm trocar tubes</td>
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<td>A0448</td>
<td>4 x 60 mm</td>
<td>stopcocks</td>
</tr>
<tr>
<td>A0449</td>
<td>16 x 360 mm</td>
<td>13-15 mm trocar tubes, rectoscopes, anoscopes, proctoscopes</td>
</tr>
<tr>
<td>A0450</td>
<td>20 x 360 mm</td>
<td>20 mm trocar tubes, rectoscopes, anoscopes, proctoscopes, amnioscope sheaths</td>
</tr>
<tr>
<td>A0451</td>
<td></td>
<td>for all surfaces</td>
</tr>
<tr>
<td>A0452</td>
<td>1.0 x 700 mm</td>
<td>channels in uretero-renaloscopes</td>
</tr>
</tbody>
</table>

- Introduce the cleaning brush/wire into the instrument’s distal opening and advance the brush/wire until it reaches the proximal opening.
- Move the brush/wire back and forth until it is free of visible debris.
- Remove the cleaning brush/wire.
- Reprocess the brush/wire after use.
Cleaning Optical Surfaces

- 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, isopropanol). Never wipe with an abrasive material, as it could scratch the optical surfaces.

Do not use other instruments for cleaning optical surfaces, which include:
- a telescope’s objective lens window
- a telescope’s eyepiece lens window
- 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

WARNING!

Infection Control Risk with Cleaning Agents
Use only those cleaning agents which feature validated processes in accordance to national and local guidelines. There is an infection control risk when using cleaning agents whose processes are not validated.

WARNING!

Risk of Reduced Cleaning Effectiveness in Instruments with Lumens
When instruments with lumens are cleaned, ensure that the cleaning solution contacts all surfaces of the lumen. Always rinse residual cleaning solution and debris from lumens by connecting them to a water hose or a syringe.
■ CAUTION!
Risk of Damage due to Incompatible Cleaning Agents
Incompatible cleaning agents may damage Olympus endoscopes and accessories. Use only solutions that are certified by their manufacturers as safe for endoscopic instrument cleaning. For detailed information on cleaning agents, please contact Olympus.

■ CAUTION!
Risk of Damage due to Cleaning Agent Residues
Cleaning solutions may contain various aggressive compounds (e.g. chlorine) which can corrode the instrument.
To remove all residues, rinse the instrument thoroughly with deionized or sterile water. Do not use tap water for rinsing, as 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.
Ultrasonic Cleaning

■ CAUTION!
Confirm Instrument Compatibility with Ultrasonic Cleaning
Do not subject any instrument to ultrasonic cleaning that is listed as incompatible in the table on page 56. Doing so may cause equipment damage.

■ Ultrasonic Cleaning Procedure
• Use only ultrasonic cleaners which the manufacturer has indicated may be used to clean endoscopic instruments. Also refer to the ultrasonic cleaner's instruction manual.
• Switch off the cleaner’s heating system.
• Immerse the instrument in an ultrasonic cleaner for at least 5 minutes and no more than 15 minutes at a frequency of 38-47 kHz.
• Use grasping forceps with padded jaws (O0185) to remove instruments from the ultrasonic cleaner.
• Let all parts drain.
• Use a soft cloth to wipe off remaining fluid.

■ WARNING!
Infection Control Risk with Ultrasonic Cleaning
Aerosols from ultrasonic cleaning units may contain infectious agents. If the ultrasonic cleaner has a lid or cover, cover the cleaner when it is in use. Always use a face mask and have adequate ventilation in place during ultrasonic cleaning.

Automatic Cleaning/Disinfection

Certain automatic cleaning procedures reduce infection-control risks and are reproducible. For information on the compatibility of Olympus equipment...
with automatic cleaning, refer to "Compatible Reprocessing Procedures and Chemical Agents" on page 56.

**Appropriate Washer-Disinfectors**

Use only washer-disinfectors which are intended specifically for cleaning and disinfection of endoscopic instruments and accessories by the washer-disinfector manufacturer. Also refer to the washer-disinfector's instruction manual.

**Selection of Programs**

Select a program optimized for endoscope cleaning. The program should start with a precleaning cycle running at a temperature no higher than 20°C (68° F). The washing cycle with cleaning agent should run within a range of 40-45°C (104-113° F) for at least 5 min. The final rinse should run at 93° C (200° F) for at least 10 min.

Do not use programs that begin at high temperatures (e.g. 93° C/200° F). This leads to a denaturation of proteins and debris, thus inhibiting effective cleaning. Make sure that the program does not impose any sudden changes in temperature.
The unit's program should include at least the following stages:
1. Pre-rinse
2. Cleaning
3. Rinsing
4. Disinfection
5. Final rinse
6. Drying

■ Automatic Cleaning/Disinfection Procedure

- Make sure that all instruments have been securely fixed in the unit’s trays and that the instruments do not touch each other.
- Instruments with lumens must be placed in special trays with irrigation devices. Confirm that the lumens are clear before starting the procedure, and that all lumens are sufficiently irrigated.
- Open the jaws of hand instruments.
- Do not overload 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 endoscopic instrument cleaning/disinfection.

Use enzyme-based agents with neutral pH, since they do not affect the endoscope’s material. Avoid agents containing highly alkaline or acidic compounds, such as citric or phosphoric acid. 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 or sterile water.

To remove all cleaner/disinfectant residues, rinsing cycles must be run using deionized water. 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**
Use only those cleaning agents which feature validated processes in accordance to national and local guidelines. Cleaning agents without validated processes could pose an infection control risk.

**CAUTION!**
**Reduced Cleaning Effectiveness in Automatic Cleaning due to Coagulation of Proteins**
It is preferable to return the instruments from the point of use to the cleaning area when the instruments are dry, to prevent protein coagulation caused by cleaning agents. Make sure that the water inflow into the cleaning units is at a temperature below 20° C (68° F) to prevent thermal coagulation of proteins.

**CAUTION!**
**Risk of Damage due to Excessive Concentrations of Cleaning/Disinfection Agents**
Defects of the washer’s/disinfector’s feeding pump can cause an excess concentration of cleaning/disinfection agents, which could cause instrument damage. Regularly maintain the washer/disinfector as recommended by its manufacturer.

**Maintenance**
Instruments should be regularly treated with lubricants to maintain their functionality and to protect them from corrosion and aging.

**Lubricants**
Olympus distributes two lubricants:
- stopcock grease (O0170)
- oil (A0273)
CAUTION!
Decrease of Image Quality
Apply all lubricants sparingly. Make sure that the telescopes’ objective or eyepiece lens windows are not smudged with lubricant. Lubricants on objective or eyepiece lens windows considerably decrease visibility and image quality.

Moving Metal Parts
Lubricate moving metal parts in joints or attachment devices with oil A0273 (see figure on page 71).
- Apply a drop of oil to all parts to be lubricated.
- Use a cotton pad to remove excess oil.

Stopcocks
Olympus instruments are equipped with two different types of stopcocks:
① Stopcocks that may be dismantled (featuring a knurled nut)
② Maintenance-free stopcocks (no knurled nut, cannot be disassembled)
Disassemble Stopcocks with Knurled Nut
After each use of an instrument whose stopcock can be disassembled, perform the following steps:
• Detach the knurled nut from the stopcock’s plug.
• Remove the plug.
• Thoroughly clean all components.
• Lightly grease plug with stopcock grease O0170.
• Reinsert the plug.
• Fasten the knurled nut.

Maintenance-Free Stopcocks
Do not disassemble maintenance-free stopcocks.
Do not grease maintenance-free stopcocks.
Stopcocks should always be opened prior to reprocessing and storage.

Silicone Sealings
• Apply oil A0273 to sealing rings and sealing caps.
**Disinfection**

**Prior Cleaning**
Endoscopic instrumentation must be meticulously cleaned and dried prior to disinfection. Thorough cleaning removes both micro-organisms and organic soil. Failure to adequately clean decreases the effectiveness of the disinfection procedure.

**High-Level Disinfection**
In the U.S., agents used to achieve high-level disinfection are defined as liquid chemical germicides registered with the U.S. Food and Drug Administration as “sterilants/disinfectants” which are used according to the 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 100% kill 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.

**WARNING!**

**Risk of Reduced Disinfection Effectiveness in Instruments With Lumens**
When disinfecting instruments with small lumens, inject disinfectant solution into the lumens using a syringe.

**Disinfection Procedure**
- Fill a disinfection tank (e.g. O0264) with disinfectant solution.
• Remove the disinfection tank’s perforated tray.

• Ensure that the instrument is completely disassembled.

• Open the stopcocks.

• Place the instrument’s components on the perforated tray.

• Lower the perforated tray into the tank.

• Inject disinfectant solution into all lumens.
• Separate telescopes from other equipment and accessories.
• Soak the equipment in the disinfectant solution for the amount of time and at the temperature recommended by the disinfectant manufacturer.
• Make sure that all components are completely immersed and that no air bubbles adhere to the any equipment. Do not exceed an immersion time of 1 hour.

• To avoid damaging the instruments, use grasping forceps with rubber-padded jaws (O0185) to handle instruments once they are immersed. Grasp telescopes, sheaths, and trocar tubes at their main body.

• Remove all instruments and equipment from the disinfectant solution by removing the tank’s perforated tray.

### Rinsing

- Thoroughly rinse all of the instrument’s components with deionized or sterile water to remove all disinfectant residues.
- Always rinse instruments with inner lumens using a syringe.
- If non-sterile water is used for rinsing, wipe the instrument components and flush the channels with 70% ethyl or isopropyl alcohol.
- After the alcohol rinse, flush air through the channels to remove all alcohol.

Do not reuse rinsing water.

### Drying

- Dry the instruments with sterile, lint-free cloths.
CAUTION!
Risk of Damage due to Incompatible Disinfectants
Incompatible disinfectant solutions may considerably damage Olympus endoscopes and accessories. Use only solutions that are certified by their manufacturers as safe for endoscopic instrument cleaning and disinfection. For more-detailed information on disinfectant agents, please contact Olympus.

Material Compatibility
Olympus instruments have been tested regarding material compatibility with aqueous solutions of 2-3% (w/v) glutaraldehyde (immersion). The maximum immersion time is 1 hour.

CAUTION!
Risk of Damage due to Excessive Concentration and/or Temperature
Refer to the instructions given by the disinfectant solution’s manufacturer for recommendations on the temperature and concentration of the solution. Do not exceed the manufacturer’s recommendations, or equipment damage could occur.

CAUTION!
Risk of Instrument Damage
Do not immerse instruments for more than 1 hour in any liquid. If instruments remain immersed in liquids for a longer period of time, the instrument’s seals may be damaged.
CAUTION!
Risk of Damage due to Disinfectant Residues
Disinfectant solutions may contain various aggressive compounds (e.g. chlorine) that can corrode the instrument. To remove all disinfectant residues, rinse the instrument thoroughly with deionized water. Do not use tap water for rinsing because it might be chlorinated.

Steam Sterilization (Autoclaving)

If possible, Olympus recommends using steam sterilization (autoclaving) in a pre-vacuum sterilizer. This method has been validated for its germicidal effectiveness with most Olympus rigid endoscopes. Refer to the product-specific instruction manual and to “Compatible Reprocessing Procedures and Chemical Agents” on page 56 for information on the compatibility of specific equipment with steam sterilization.

Prior Cleaning
Endoscopic instrumentation must be meticulously cleaned, disinfected and dried prior to sterilization according to the current state of the art. Olympus recommends thermal washer-disinfectors. Thorough cleaning removes both micro-organisms and organic soil. Failure to adequately clean can decrease the effectiveness of the sterilization procedure.

Steam Sterilization Procedure
- Disassemble the instrumentation.
  Refer to the product-specific instruction manual to determine which instruments should be disassembled before steam sterilization.
• Open all stopcocks.

• Seal the instruments in appropriate trays, and then in sterilizing wrap (for compatible instrument trays, see “Storage and Handling”, page 79).

• For further details on autoclave operation, refer to its instruction manual.

• Use only prevacuum autoclave cycles to ensure that steam gets into all lumens.
• After steam sterilization, allow the instruments to cool down gradually to room temperature. Sudden changes in temperature may damage the instruments.
  Never use cold water or other liquids to accelerate cooling.

### Steam Sterilization Conditions
Olympus recommends that the instruments be autoclaved for 5 minutes at 134 °C (273 °F) in a pre-vacuum sterilizer.

Other common autoclaving parameters are:

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Temperature</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-vacuum</td>
<td>132 °C (270 °F)</td>
<td>4 minutes</td>
</tr>
<tr>
<td>Pre-vacuum</td>
<td>135 °C (275 °F)</td>
<td>3 minutes</td>
</tr>
</tbody>
</table>

Autoclavable Olympus products are designed for steam sterilization according to the following standards:

- US standard ANSI/AAMI ST46 “Steam Sterilization and Sterility Assurance in Health Care Facilities”

Do not exceed a temperature of 138 °C (280 °F).
Autoclavable Olympus instruments are compatible with quick steam sterilization cycles utilized for sterilizing unwrapped instruments in emergency situations ("flash cycles"). Olympus instruments are resistant to the temperature changes associated with these cycles, which may have little or no cooling or drying phase. Olympus suggests gradual air cooling after a flash cycle and recommends against using liquids which would subject the instruments to extremely rapid cooling. The Association of Operating Room Nurses (AORN) and the Association for the Advancement of Medical Instrumentation (AAMI) also caution that flash-sterilized items must be used immediately, since sterility assurance of unwrapped items cannot be maintained.
Ethylene Oxide (ETO) Gas Sterilization

■ Prior Cleaning
Endoscopic instrumentation must be meticulously cleaned and dried prior to sterilization. Thorough cleaning removes both micro-organisms and organic soil. Failure to clean adequately can decrease the effectiveness of the sterilization procedure.

■ Gas Sterilization Procedure
• Disassemble the instrumentation as described in the respective product-specific instruction manual(s).
• Open all stopcocks.
• Seal the instruments in appropriate instrument trays and in sterilizing wraps (for compatible Olympus instrument trays, see “Storage and Handling” on page 81).
• Refer to the sterilizer’s instruction manual.
• Aerate the instruments sufficiently after sterilization.

■ Conditions for Ethylene Oxide Gas Sterilization
Refer to AAMI ST41:1999, "Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness"
Do not exceed the parameters given 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
  ......................................................................................(122-135 °F)
**WARNING!**

**Ethylene Oxide (ETO) Gas is Toxic**

Ethylene oxide is toxic and may present health hazards. Follow domestic health care regulations for compatibility of the procedures. After sterilizing the instruments, aerate them to remove toxic residues.
Storage and Handling

■ Ambient Conditions for Storage
• Store the equipment in a clean and dry condition at room temperature (10-40°C/50-104°F, 30-85% humidity).
• Do not expose the equipment to direct sunlight.
• Do not expose the equipment to sources of X-rays.
• Do not store the equipment in a location where it could become wet.
• Do not store the equipment in environmental conditions such as:
  - high atmospheric pressure
  - direct sunlight
  - dust
  - salty or sulfurous air
• Do not store the equipment in any areas where flammable gases are present.

■ Preparation for Storage
For disinfected instruments:
• Disassemble the instruments
  - 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 storage, make sure that the instruments remain in a disinfected condition and are ready for their next use.
For sterilized instruments:
• Store the packaged sterile units in an area where they will not be subjected to vibrations and impacts.
• During storage, make sure that the instruments remain in a sterile condition and are ready for their next use.

■ 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 page 84).

■ Storage Life of Sterilized Instruments
The storage life of sterilized instruments depends on the type of packaging used and the conditions under which the instruments are stored.

■ CAUTION!
Handle with Care
Handle and store endoscopic equipment carefully. Do not subject it to impacts or allow it to fall. Instrument damage may occur.

■ Olympus Instrument Tray Systems
Olympus features two types of instrument tray systems, to meet the demands of individual customers:
- Molded plastic instrument trays
- Stainless steel instrument trays

For more details on these product lines and their availability, please contact your local Olympus representative. Olympus instrument tray systems are compatible with steam and gas sterilization.

■ Molded Plastic Instrument Trays
The Olympus instrument tray system is made of molded plastic and features many different designs, such as:
- Instrument trays for telescopes (delivered with some telescopes)
- Universal instrument tray A5970
- Universal insert trays for A5970
- Customized insert trays for A5970

■ Stainless Steel Instrument Trays
The Olympus stainless steel instrument tray system features two different tray designs:
- Instrument trays with filters
- Tray inserts customized for various instruments
- Instrument trays without filters and integrated tray inserts
Instrument trays with filters can be directly used for steam sterilization. No other sealing is required.
For gas sterilization procedures, use instrument trays without filters or remove the filter from the instrument tray.
SERVICE

The Olympus Organization

■ Manufacturer of this Equipment
If there is no other statement in the product specific instruction manual, items labelled "OLYMPUS GERMANY" are manufactured by:
Olympus Winter & Ibe GmbH
Kuehnstraße 61
22045 Hamburg, Germany
Phone: +49 40 66 96 60
Fax: +49 40 66 96 62 06
Web: www.olympus-owi.com

■ U. S. Distributor
Olympus America Inc.
3500 Corporate Parkway
P.O. Box 610
Center Valley
Pennsylvania 18034-0610
Phone: (484) 896-7128
Fax: (484) 896-5000

■ U. S. Repair Center
Olympus Medical Endoscopy Service America Inc.
2400 Ringwood Avenue
San Jose
California, 95131
Phone: (408) 935-5000
Repairs

- **Authorized Service Centers**
  Repairs may only be carried out by qualified servicing personnel who have been authorized by Olympus Winter & Ibe. Otherwise, Olympus Winter & Ibe cannot be held responsible for the compatibility, 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 defect. A damaged product may cause injury to 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 defect.
Unauthorized repairs (left) compared to authorized repairs (right).

**Description of Defects**
To enable the Service Center to effect repairs in a timely manner, send the product together with a detailed description of the defect. The following particulars should be included:
- Catalog number
- Serial number or lot number (if available)
- Precise description of the malfunction
- Delivery date
- Invoice copy (for possible guarantee or warranty claims)
- The customer’s internal order number (for correct accounting of the repair order)
■ Hygiene
As a protective measure for the safety of Olympus' repair staff, perform a complete cleaning and disinfection/sterilization procedure before sending instruments to Olympus for repair.
If this is not possible, for example because further disinfection or sterilization would cause further equipment damage, clean the product as thoroughly as possible and clearly indicate the product's condition so that repair personnel may take adequate precautions.
Olympus Service Centers are entitled to refuse to repair soiled or contaminated products for reasons of safety.

■ Shipment
When transporting the defective product, use the original cardboard packing. If this is not possible, wrap each component individually in cushioning material and place them in a cardboard box.
Olympus 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 inside of a protection tube should be shipped back to Olympus inside the protection tube.