Operating Instructions for rigid Endoscopes

In field of:

- Arthroscopy
- Otoscopy
- Sinuscopy
- ENT
- Laryngo-Pharyngoscopy
- Tele-Laryngo-Pharyngoscopy
- Urology
- Gynecology
- Resectoscopy
- Hysteroscopy
- Cystoscopy
- Laparoscopy
- Surgery
- Thoracoscopy
- Bronchoscopy
- Plastic Surgery
- Spine Surgery
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1. Area of Application and Instructions for Use

Endoscopes are for indicating visually body openings or cavities. Depending on the cross-section, length and locking possibilities, each of the endoscopes is designed for a specific purpose in a particular field of medicine.

Indications: The use of endoscopes is indicated in endoscopic procedures and other incisions in the field of minimal invasive surgery.
Contra indications: The use of endoscopes is contra-indicative to the extent that endoscopic procedures are contra-indicative.
Endoscopic procedures should only be carried out by qualified professionals (e.g. doctors) with corresponding training and familiarity with endoscopic procedures. It is the responsibility of the user to be continuously updated about indications, contraindications, possible complications and risks as well as developments of endoscopic procedures.

A thorough understanding of the principles and methods used in laser endoscopy and electro-surgical procedures is necessary to avoid shock or lesion risks to patients and users as well as damages to other equipment and instruments.

Claims for damages attributable to wrong use or combination with other devices and instruments will not be borne by the manufacturer.

Important: This instructions manual is meant to facilitate the use of endoscopes; it is in no way an instructions manual for endoscopic procedures.

Please read all instructions and hints carefully. If the instructions, warnings and preventative measures are not followed, this may lead to heavy risks and drastic consequences at the time of incision or injury to the patient.
2. Technical Features

Diagram of technical features including:
- Direction of view
- Working length
- Diameter
- Field of view
- ACM adapter
- Wolf adapter
- Storz/Olympus adapter
- Adapter for QuickSnap
- Closing cap
- Ocular DIN 58105 screwable
- Ocular DIN 58105 screwable
- Adaptor for QuickSnap
- Ström connector
- Working channel
- Complete length
### 3. Structure and Description

<table>
<thead>
<tr>
<th>Compatibility</th>
<th>Ocular DIN 58105 threaded, MEDI-TECH QuickSnap</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Instrument post</td>
<td>- Instrument post</td>
</tr>
<tr>
<td>- Light post</td>
<td>- Light post</td>
</tr>
<tr>
<td>- Eyepiece</td>
<td>- Eyepiece</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objektive</th>
<th>Tension-free objektive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Image transmission</td>
<td>CAD-designed rod lens system for optimal sharpness, colorsync and resolution</td>
</tr>
<tr>
<td>Light-guiding system</td>
<td>High quality light fibers</td>
</tr>
</tbody>
</table>
| Optical glass | Distal and proximal  
Sapphire |
| Biocompatibility | All materials that come in contact with the body are biocompatible  
All metals parts are made of high quality stainless steel |
| Sterilization | Autoclavable, max. 134° C / 2,2 bar / 5 min |

<table>
<thead>
<tr>
<th>Working length</th>
<th>in mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter</td>
<td>in mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Direction of view</th>
<th>Specials:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0°</td>
<td>15°</td>
</tr>
<tr>
<td>30°</td>
<td>45°</td>
</tr>
<tr>
<td>70°</td>
<td>90°</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Field of view</th>
<th>90° in degree</th>
</tr>
</thead>
</table>
4. Short Description

Note:
This short description is intended to give you a quick overview of the cleaning, desinfection and sterilization procedures for endoscopes. Detailed instructions and hints given in the operating instructions manual should be followed. Before each medical use, endoscopes should be checked to ensure that there are no damages and that the endoscopes must be disinfected and cleaned as per the medical indications.

4.1 Cleaning
Before cleaning, remove the adapters (e.g. for different light cables). To dissolve various impurities, use mild cleaning substances. Support this with a mechanical cleaning preferably by using soft cloth, cotton and special brushes. Finally, all parts are to be washed and rinsed thoroughly by extensively using deionised water and dried by using tissues or soft cloth. Channels and crevices should be dried and cleaned with compressed air.

4.2 Short testing
The endoscope surfaces must remain intact and should not have any sharp edges. Ensure that the distal and proximal glass surfaces remain undamaged. Visually inspect the image quality.

4.3 Steam sterilization
Endoscopes bearing the symbol on the casing can be autoclaved at 134°C at a pressure of 2.2 bar and an effective sterilization time of at least 5 minutes.

4.4 Gas sterilization
Endoscopes can be gas sterilized using ethyleneoxide or formaldehyd. For procedure parameters and instructions, please refer to the details provided by the respective manufacturers.

4.5 Low temperature Plasma Sterilization
Autoclavable endoscopes can also be sterilized using the low temperature plasma sterilization (STERRAD®). For procedure parameters and instructions, please refer to the details provided by the respective manufacturers.

4.6 STERIS®
Procedure
Endoscopes can also be prepared using the STERIS® procedure. For procedure parameters and instructions, please refer to the details provided by the respective manufacturers

Note:
It is the responsibility of the user to ensure that the sterilization procedures listed above are used to attain the desired or required sterilization effect.
5. Important Hints

5.1 General Hints
You have decided in favor of an endoscope; you have thus acquired a high-value product. It is however necessary to handle this equipment with care because rigid endoscopes —especially those with a shaft diameter of less than 4mm —are highly susceptible to bending pressure. This can lead to damage to the optical components resulting in malfunctioning of the equipment.

Endoscopes are delivered unsterilized and have to be cleaned and sterilized as per medical indications before they are put to use (for details refer the section on Cleaning and Sterilization). The endoscopes and corresponding endoscopic accessories must be checked for any possible optical or mechanical defects before each use to avoid risks of injury. Damaged or defective endoscopes should be put out of use. In case of doubt, please contact your dealer or the manufacturer.

Please pay attention to adequate cooling of the endoscope after autoclaving. You should not use the endoscope when it is hot.

The simultaneous use of NMR (Nuclear Magnetic Resonance) and endoscopes can lead to dangers and artifacts; please pay attention to the corresponding manufacturer’s guidelines and safety instructions.

5.2 Hints for combination with other medical products
There are numerous vistas opened for combinations with laser and HF surgery, pneumatic or electrohydraulic lithotriptors. In such cases, please follow the operating instructions manuals and safety instructions of devices and accessories used.

While using the endoscope in combination with electro-medical devices, ensure that the BF conditions (insulated, earth-free usage parts) are maintained.
When endoscopes are used with electro-medical devices and/or power-driven endoscopically used accessories, this can lead to an addition of the leakage current.

Failure of the used light source can lead to risks. Hence keep an additional light source at hand or use light sources that have a substitute lamp.

In combination with high performance light sources, the temperatures of the light source and the instruments can reach levels causing burns. Furthermore, light of high radiance energy can lead to an increased temperature in the tissue. Hence, avoid direct tissue contact and if possible, ensure adequate rinsing of the operation area.
Hints for using endoscopes with high frequency surgical instruments:
Before using endoscopic high frequency surgery, the patient should be suitably prepared for the incision.
Measures should be taken to remove or avoid formation of combustible gases (e.g. gastro-intestinal tract/coloscopy, urinary bladder/transurethral resection).

In contrast to conventional high frequency surgery, unsuitable (especially too low) performance setting can lead to a predominant depression in the surrounding tissue. Hence, performance tuning is to be done based on the experience of the person using this technique after considering clinical references and/or suitable training.
In order to avoid burns and/or undesirable depressions in the surrounding tissue or damage to the endoscope, it is advisable to switch on the high frequency current only after the application part (electrode) can be seen through the endoscope.

Hints for use in combination with laser devices:
If endoscopes or endoscopy accessories are used with laser devices, suitable protection glasses are to be used to avoid damage to the eyes. In order to avoid burns and/or undesirable depressions in the surrounding tissue, laser performance should be activated only after the tip of the laser fiber can be seen through the endoscope.

Hints for usage with lithotriptors:
In order to avoid risks and taking into account all possible restrictions for use, please pay attention to the device specific operating instructions and safety hints for all ultrasonic, pneumatic or mechanical lithotripsies.
Stone extractions using stone forceps can be done by using operation shafts or the working channel of the endoscope. The required specifications of the usable instruments can be taken from the technical specifications of the respective products.
6. Preparation (Disinfection, Cleaning, Sterilization)

6.1 Introduction
The procedures for preparation and maintenance listed in the following sections are to be viewed as recommendations. Endoscopes can also be disinfected, cleaned and sterilized using other methods. It is the responsibility of the user to prepare the endoscopes in order to attain the required degree of disinfection, cleaning and sterilization. Please note that the method in which the endoscopes will be prepared will eventually have considerable bearing on the life-span of the endoscopes.

6.2 Dismantling, Dehumidification and Decontamination
In order to avoid drying up of blood, protein or other substances on the endoscopes and also to protect the staff, it is necessary to dehumidify the endoscope immediately after it has been used for an operation. Dried up protein makes cleaning and disinfection a difficult task.
Tip: Endoscopes should not be decontaminated and cleaned in an ultrasonic bath.

Procedure:
• Unscrew the used adapters (e.g. for different lightcables) from the endoscope

• If the endoscope has a flanged working bridge (e.g. Uretero-Renoscope), this has to be removed. Also remove the screw caps of all cock plugs. Press hard on the loosened screw caps so that the cock plugs are ejected out of their positions. Then remove the screw caps fully and remove the cock plugs.

• Place the endoscope and the unscrewed parts in a suitable disinfection solution (can also double up as a cleaning solution). The disinfection solution used should be permitted by the manufacturer for such use. Irrespective of the material compatibility, disinfection materials normally have alcohol, aldehyd and quaternary compounds. These details are only with respect to material compatibility and they are in no way related to the germ-killing properties. The user has to ensure that the degree of disinfection is attained.

• For concentration and soaking time, please refer to the guidelines of the manufacturer of the disinfectant. As there are no advantages of soaking the equipment for a period longer than prescribed, avoid soaking the endoscope for a period exceeding the prescribed limit as it can perhaps only lead to damages to the endoscope. Also ensure that the solution reaches all the surfaces including working channels and crevices.

• If it is necessary to use a separate cleaning agent, it is advisable to use the disinfectant and a cleaning additive from the same manufacturer. Also pay attention to the mutual compatibility of the used solutions and strictly follow the instructions of the manufacturer with respect to concentration and soaking time.

• For carrying the instruments, use only washable packaging and avoid collision or contact with other instruments.

• Finally, the endoscopes must be rinsed with adequate deionised (distilled) water.
6.3 Cleaning
Cleaning is necessary for hygienic reasons and also for protecting the next patient. It can be done manually or mechanically.

Endoscopes should not be decontaminated and cleaned in ultrasonic baths.

Manual Cleaning
Procedure:
• Unscrew the used adapters (e.g. for different light cables) from the endoscope

• If the endoscope has a flanged working bridge (e.g. Uretero-Renoscope), this is to be removed. Also remove the screw caps of all cock plugs. Press hard on the loosened screw caps so that the cock plugs are ejected out of their positions. Then remove the screw caps fully and remove the cock plugs.

• Use only mild cleaning substances for dissolving the impurities. These cleaning agents should have been approved by the manufacturer for such use. While using the different substances, pay attention to the details provided by the manufacturer with respect to concentration and soaking time.

For mechanical cleaning, use soft cloth, cotton and special brushes. For channels and crevices, it is especially advisable to use suitable brushes. Dirt on the optical surfaces can be removed using cotton soaked in alcohol (70% ethanol) or a neutral cleanser.

• After cleaning, all the parts are to be thoroughly washed using deionised (distilled) water in order to remove the last traces of impurities and residues of cleaning agents.

• Finally dry the endoscope and all the individual accessories using atissue or soft absorbent cloth. Bridges and crevices should be cleaned and dried with compressed air.

• Unless an immediate sterilization is planned following the cleaning, it is advisable to fit back the adapters that had been removed.

Tips for manual cleaning:
• The optical surfaces should not be treated using sharp-edged objects. Generally, endoscopes should be cleaned with maximum care to avoid damage through use of excessive pressure, impact, bending or fall.

• Color eloxated endoscopy parts or the plastic components (e.g. serial rings, ocular funnel) may fade and lose their color intensity in the course of cleaning.
Mechanical Cleaning
Endoscopes without working channels can be cleaned and disinfected in suitable rinsing machines fitted with special endoscope cleaning programs. If a thermo-disinfector is used, ensure that only autoclavable endoscopes bearing the sign are put in as the temperature goes up to 110°C during drying. Furthermore, drying time should not exceed 20 min.

For soakable endoscopes, cleaning programs where the temperature does not exceed 60º C should be used. The mechanical procedures used must ensure that the endoscopes remain firm on the instrument holders and do not damage each other.

Procedure:
• Unscrew the used adapters (e.g. for light cables) from the
• If the endoscope has a flanged working bridge (e.g. Uretero-Renoscope), then this is also to be removed. Also remove the screw caps of all cock plugs. Press hard on the loosened screw caps so that the cock plugs are ejected out of their positions. Then remove the screw caps fully and remove the cock plugs.
• Place the endoscope and the unmounted accessories in an instrument carrier suited for use in cleaning in a manner prescribed by the manufacturer of the rinsing machine. Also ensure that there are no rinsing shadows.
• Select the appropriate endoscope cleaning program based on the machine load and the prescription of the manufacturer of the rinsing machine. For concentration and permissible additives, please refer to the instructions of the manufacturer.
• In case of mechanical cleaning, all residues of the rinsing program should be cleaned thoroughly, else there could be decoloring and formation of patches, especially if there is a subsequent sterilization. For the last rinsing round, use deionised water. This can be supported by the use of a suitable neutralization agent and the postrinse results can be improved.
• If another preparation (sterilization) is not going to be done immediately, the adapters removed earlier should be screwed back. Notes for mechanical cleaning:
• In case of extreme soiling and encrusting (e.g. through coagulated blood or secretion residues), it may become necessary to further clean the endoscope manually.
• Dirt residues on optical surfaces can be treated and removed using cotton soaked in alcohol (70% ethanol) or using a neutral cleaning agent.
• Check the water quality regularly to avoid formation of residues and corrosion.
• Do not use any greases or washing agents; there may be problems with respect to compatibility with plastics or adhesives and other disturbances concerning compatible accessories (e.g. electrical wires).
• Color eloxated endoscope components or plastic components (e.g. serial rings, ocular funnel) may show lightened color after being treated mechanically.
6.4 Inspection
The endoscope must be inspected directly before sterilization.

Checking the fiber optic:
• Hold one side of the fiber optic (e.g. the distal endoscope end) in the direction of a bright ceiling lamp. For this test, do not use any cold light source. View the other side (light connection) holding it relatively close to the eye. The individual fibers now appear to be bright. Move the side held against the lamp a little here and there. The brightness of the fibers now changes a little. If certain fibers remain dark, this is not a cause for concern. If the rupture rate is 10-20%, then it is difficult to work with the endoscope.

• The surfaces of the light inlets and outlets should be smooth and clean. If the surfaces show certain deposit layers, or rough fibers can be felt or are withdrawn, this can lead to inadequate illumination. If the endoscope is used or prepared in this condition, it may be continuously damaged. Endoscopes with damaged fiber optic should be sent for inspection to the manufacturer or a service center. Checking the proximal and distal glass surfaces of the endoscope surface:

• The glass surfaces must be clean and free from deposit layers. If at the time of visual inspection of the glass covers you notice stubborn encrusting, these can be removed using appropriate cleaning pastes. The cause of these precipitations is often the presence of foreign particles in the autoclave steam (water quality) and inadequate rinsing of the optics before steam sterilization.

• The image must be sharp and clear in the corresponding working distance as per the indication. The special optical properties in case of image bundle endoscopes are to be considered. A dull, dusky image is a pointer to damages.

• The endoscope surfaces must be free of damage and sharp edges. Pay attention to dents, mechanical/thermal defects due to high frequency or laser surgery instruments as well as cracks and spallings at the ocular funnel. If stubborn residues cannot be removed through cleaning, the endoscope must be sent to the manufacturer or a service center for inspection.
Endoscopes with damaged glass surfaces (e.g. cracks), impaired image quality or noticeable surface damages or distortions should not be used. They should be kept aside and sent for inspection to the manufacturer or an authorized service center.
6.5 Sterilization
First check the sterilization method most suitable for your endoscope. Endoscopes marked with the sign at the scope body can be steam sterilized or autoclaved and they are validated for the pre-vac steam sterilizing.
Before sterilization, ensure that the endoscope and especially the surfaces are clean and a testing of the endoscope as per point 6.4 does not lead to any findings that impose restrictions on the use.
It is the responsibility of the user to ensure that the sterilization procedures listed above are used to attain the desired or required sterilization effect. Steam sterilization While using steam sterilization, ensure that the sterilization steam does not contain any impurities (for guidelines, refer DIN 58946. section 7).
During steam sterilization, the following parameters are to be followed:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>134º C</td>
</tr>
<tr>
<td>Pressure</td>
<td>2.2 bar</td>
</tr>
<tr>
<td>Temperature to be maintained for (effective sterilization time):</td>
<td>min. 5 minutes</td>
</tr>
</tbody>
</table>

If your endoscope has a working channel or is to be sterilized in a packed state, the gravitational procedure cannot be recommended.

Hints:
- Please do not sterilize endoscopes by using a quick sterilization method.
- Due to longer sterilization duration, do not sterilize endoscopes at 120º C. This can lead to a reduction in the life-span of the endoscopes.
- Steam quality has a considerable effect on the steam sterilization process with respect to the following points: Impurities like oil, chemicals rust or metal shavings can lead to dirtying and/ or other resulting damages to the endoscopes and also a reduced sterilization effect. Inadequate water quality, especially high chloride concentration, can lead to corrosion of the endoscope. Hence, regularly check the water quality. The chloride concentration [CL-] should not exceed 240 mg/l; otherwise there are chances of perforated corrosion and precipitations on glass surfaces. A simple guiding value would be the electrical conductivity which should not exceed 10 ms/cm.
- Hot endoscopes are highly susceptible to shocks. Hence avoid shocks and vibrations.
- Drastic changes in temperature can lead to breakage of the glass components. After autoclaving, hot endoscopes should not be quenched; instead, they should be allowed to cool down to room temperature.
- If the given requirements for the steam sterilization process and the steam quality are not met, this can lead to defects, resultant damages or a reduction in the life-span of endoscopes and other sterilized items. Guarantee and warranty claims in such cases will be rejected.
• Should the image be lost immediately after autoclaving in the case of image bundle endoscopes, check the image quality after completely cooling down to room temperature. Further, the image bundle endoscopes are optimized for TV applications. Hence, no clear image may be visible at the time of visual inspection.

**Gas sterilization**
Endoscopes can also be gas sterilized using ethyleneoxide or formaldehyd. For procedure parameters and instructions, please refer to the details provided by the respective manufacturers.

Low temperature Plasma Sterilization Endoscopes can also be sterilized using the low temperature Plasma sterilization procedure STERRAD®. For procedure parameters and instructions, please refer to the details provided by the respective manufacturers.

**STERIS® Procedure**
Endoscopes can be prepared using the STERIS® procedure. For procedure parameters and instructions, please refer to the details provided by the respective manufacturers.
## 7. Trouble Shooting

<table>
<thead>
<tr>
<th>Defect</th>
<th>Possible cause</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milky, dusky image</td>
<td>• Dirty glass surfaces</td>
<td>• Clean the glass surfaces as per instructions in section 6.3 (manual cleaning)</td>
</tr>
<tr>
<td></td>
<td>• Stubborn residue, encrusting on the glass surfaces</td>
<td>• Remove residues as per instructions mentioned in section 6.3 Check water quality</td>
</tr>
<tr>
<td></td>
<td>• Untight, defective lens system</td>
<td>• Send endoscope for repair</td>
</tr>
<tr>
<td>Image too dark, too little</td>
<td>• Dirty glass</td>
<td>• Clean the glass surfaces as per instructions in section 6.3 (manual cleaning)</td>
</tr>
<tr>
<td>illumination</td>
<td>• Stubborn residue, encrusting on the glass surfaces</td>
<td>• Remove residues as per instructions mentioned in section 6.3 Check water quality</td>
</tr>
<tr>
<td></td>
<td>• Wrong light cable connection</td>
<td>• Check whether light cable sits well</td>
</tr>
<tr>
<td></td>
<td>• Defective fiber optic</td>
<td>• Check fiber optic as per section 6.4</td>
</tr>
<tr>
<td></td>
<td>• Defective light cable, light source</td>
<td>• Check light cable, light source</td>
</tr>
<tr>
<td>Yellowish light</td>
<td>• Dirty fiber optic</td>
<td>• Clean glass surfaces (diag. 1, Pos 3) as per instructions in section 6.3 (manual cleaning); if required, send the endoscope for servicing.</td>
</tr>
<tr>
<td></td>
<td>• Dirty, defective light cable</td>
<td>• Check light cable (by illuminating a white surface)</td>
</tr>
<tr>
<td>Corrosion, Formation of patches,</td>
<td>• Inadequate cleaning (e.g. protein residue)</td>
<td>• Subsequent cleaning up, if required by thorough rubbing</td>
</tr>
<tr>
<td>decoloring</td>
<td>• Inadequate rinsing of the endoscope between different preparation phases (esp. before sterilization)</td>
<td>• Ensure adequate rinsing between the individual preparation phases (refer section 6ff)</td>
</tr>
<tr>
<td></td>
<td>• High chloride concentration</td>
<td>• Check water quality (refer hints under section 6.5)</td>
</tr>
<tr>
<td></td>
<td>• Heavy metal ions and/or silicates, increased content of iron, copper,</td>
<td>• Check water quality; if required, use only distilled (deionised) water</td>
</tr>
<tr>
<td></td>
<td>manganese in water or sterilization steam</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• High concentration of mineral substances (e.g. calcium) or organic</td>
<td>• Check water quality; if required, use only distilled(deionised) water</td>
</tr>
<tr>
<td></td>
<td>substances</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Infected or too frequently used disinfection or cleaning solutions</td>
<td>• Regularly replace the disinfection and cleaning solutions</td>
</tr>
<tr>
<td></td>
<td>• Outside rust (e.g. through steam or preparation along with damaged or rust-prone instruments)</td>
<td>• Check maintenance systems; in case of common preparations, check for material compatibility, existing damages and avoid mutual contact</td>
</tr>
<tr>
<td></td>
<td>• Contact corrosion</td>
<td>• Avoid mutual contact</td>
</tr>
</tbody>
</table>
8. Guarantee, Maintenance and Repair

The manufacturer commits to a 12 month guarantee on the functioning of the endoscope. This guarantee is restricted to claims presented within the guarantee period starting from the date of purchase of the endoscope giving details about repairs along with the invoice number.

This guarantee is only applicable to defects that cannot be attributed to normal wear and tear, misuse or wrong handling, lack of proper care or Acts of God.

For maintenance and repairs, please contact Service or an authorized repairs center.

In order to facilitate quick processing of service requests, we request you to send the product giving the following details:

• Item number (REF)
• Serial number (SN)
• Error description as exact as possible

In order to protect your staff and the employees, please ensure that you send the endoscope (with/without the accessories) after thorough cleaning and sterilization.

Should this not be possible due to certain contingency reasons, the endoscope should be washed as far as possible and is to be marked accordingly.

For safety reasons, the Service may refuse to repair uncleaned or contaminated products.

All guarantee and warranty claims are lost if the repairs are done by the users or a non-authorized service center.