Operating instructions for endoscopes

Please read and follow these instructions carefully!

These operating instructions conform to standards BS EN 1041, ISO 17664 and Directive 93/42/EEC and 2007/47/EC.

Product description

Endoscopes are precision optical instruments for visualizing the inside of the body and are designed to be used in minimally invasive, endoscopic diagnoses and/or surgical procedures.

Different versions of endoscopes are available (e.g. different lengths/ diameters/ viewing directions and with or without a working channel, autoclavable or immersible).

Markings on RB Medical endoscopes:

<table>
<thead>
<tr>
<th>Mark</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>SN (and no.)</td>
<td>Serial number</td>
</tr>
<tr>
<td>CE 0088</td>
<td>Designed, manufactured and tested in compliance with the requirements of Directive 93/42/EEC Appendix II</td>
</tr>
<tr>
<td>Autoclave 134°C/273°F</td>
<td>Steam sterilisable at 134°C or 273°F</td>
</tr>
<tr>
<td>Soakable</td>
<td>Immersible</td>
</tr>
<tr>
<td>0°, 30°, 70° ...</td>
<td>Viewing angle</td>
</tr>
<tr>
<td>Color coding on light connection</td>
<td>Viewing angle</td>
</tr>
<tr>
<td>green</td>
<td>= 0°</td>
</tr>
<tr>
<td>black</td>
<td>= 12°/15°/20°/45°</td>
</tr>
<tr>
<td>red</td>
<td>= 30°</td>
</tr>
<tr>
<td>yellow</td>
<td>= 70°</td>
</tr>
<tr>
<td>blue</td>
<td>= 90°</td>
</tr>
</tbody>
</table>

The package label also shows the designation with the main specifications and the manufacturer’s address.

Accessories

- Standard accessories
  - Light connection adapters Storz/Olympus, Wolf
  - Protective sleeve (for all endoscopes with shaft diameters smaller than 5 mm)
- Non-standard accessories
  - CCD camera and TV-adaptor
  - Light source, cold light cable, various adaptors
  - Vacuum rinse pumps and accessories
  - Insufflators and accessories
  - Trocars
  - Various instruments

Intended use

Applications / Indications

<table>
<thead>
<tr>
<th>Endoscope name</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthroscope</td>
<td>Joints</td>
</tr>
<tr>
<td>Bronchoscope</td>
<td>Trachea, bronchi</td>
</tr>
<tr>
<td>Cystoscope</td>
<td>Urology: Bladder, prostate</td>
</tr>
<tr>
<td>Hysteroscope</td>
<td>Gynecology: Uterus, vagina</td>
</tr>
<tr>
<td>Laparoscope</td>
<td>Abdomen: peritoneal organs</td>
</tr>
<tr>
<td>Laryngoscope</td>
<td>Throat</td>
</tr>
<tr>
<td>Esophagoscope</td>
<td>Esophagus</td>
</tr>
<tr>
<td>Otoscope</td>
<td>Head: Sinuses</td>
</tr>
<tr>
<td>Sinuscope</td>
<td></td>
</tr>
<tr>
<td>Thoracoscope</td>
<td>Thorax</td>
</tr>
</tbody>
</table>

In human medical interventions, endoscopes must without exception only be used in an aseptic/ sterile environment by professionally trained physicians.

Irrespective of the field of use (see previous table) the physician treating the patient is ultimately responsible for the decision to use the endoscope.

The decision to use an endoscope also depends on the overall condition of the patient and must be critically assessed in each case by the responsible physician before use.

Do not use on the central nervous or circulatory system! Do not use on the heart!

The country-specific laws and regulations must be observed. Please refer to the current literature for further information.

Contraindications

-in alphabetical order-

- BSE - Bovine spongiform encephalopathy, so-called “mad cow disease”

- CJK - Creutzfeldt-Jakob disease
- TSE - Transmissible spongiform encephalopathy
- VCJD - Variant Creutzfeldt-Jakob disease

Currently, no contraindications are known that are directly related to an endoscope.

Before use

Immediately after receiving your endoscope and each time before use, check to make sure it is suitable for use and check for possible damage.

All surfaces must be smooth and bright with no scratches and nicks. → Scratches and nicks on the probe or at the distal or proximal end may indicate possible damage.

Look through the endoscope by daylight from the proximal end and rotate it along the longitudinal axis. → Damage to the optical system can cloud vision or result in complete loss of the image.

Connect the cold light cable to the light connection of the endoscope and switch on the light source. → Adequate lighting is assured when the emitted light at the distal end forms a uniform point of light without dark areas.

Before using endoscopes with working channels, the responsible physician must make sure that the combination of surgical instruments in the working channel will allow a safe working procedure.

The compatibility will depend on the diameter and length of the instruments. → The working channel is exclusively intended for using with non-active surgical instruments. Operating the endoscope with lasers is prohibited!

Your endoscope is supplied non-sterile. Clean and sterilize/disinfect the endoscope according to the preparation instructions each time before use.

Not cleaning and sterilizing: disinfesting the endoscope can lead to infections and damage the endoscope.

Installation

Camera connection

Lock the eyepiece in your TV camera adapter. Adjust the picture sharpness and size if necessary at the TV adapter.

Light Connection

Your endoscope can be connected to the usual light sources using cold light cables. The Wolf and Storz/Olympus sleeves can be unscrewed from the light connection of the endoscope.

The compatibility will depend on the diameter and length of the instruments. Operating the endoscope with lasers is prohibited!

Required parameters are missing or incorrect.

Attention: the distal end and the light connection of the endoscope must not come into contact with easily inflammable or heat sensitive materials or with patient tissue. The safety distance should be at least 5 mm.

Special instructions

RB Medical endoscopes are made to the highest quality standards. Always treat your endoscope with great care.

Mechanical stress caused by bending the probe, dropping it or holding the endoscope at the distal end can damage or destroy it.

RB Medical endoscopes must only be used by qualified personnel.

Improper use can lead to infections and harm your patient and/ or cause injury or damage your endoscope.

We recommend that you have another endoscope available as a spare every time you use it. This will reduce the risk during the surgical procedure or diagnostic intervention and will also prevent potential mistakes.

RB Medical Engineering Ltd cannot accept liability for damage or consequential damages caused by failure to follow the instructions, improper handling or improper use of endoscopes.
Operating instructions for endoscopes

Storage
Keep your endoscope in the original packaging or in a colander or container with the protective sleeve attached (if present). Store the endoscope in a dry place at room temperature, protected from dust and protected from falling.

Repair and replacement
If you are having problems with your endoscope, please contact your preferred dealer for repair service or replacement. Endoscopes may only be returned with written proof that they have been cleaned and sterilized/ disinfected.

Note: RB Medical strongly recommends not to use unauthorized service companies or service organizations to do any service or repair on RB Medical products. For service or repair please return all products to RB Medical.

Disposal
All endoscopes can be disposed of with normal clinical waste according to the current hygiene requirements. The relevant national laws and regulations must also be observed.

Irreparable endoscopes can be returned to the manufacturer in a postage paid package for disposal labeled with "Repair" with written proof that they have been cleaned, disinfected/sterilized.

If you have further questions, please contact your preferred dealer.

PREPARATION INSTRUCTIONS

1. Note! Endoscopes which are labeled "soakable" may only be cleaned and disinfected manually or by machine. They must not be steam sterilized in an autoclave!

2. To avoid cross-contamination, never transport/ clean/ sterilize/ disinfect your endoscope together with other equipment and instruments. They may only be transported/ cleaned/ sterilized/ disinfected in the same container if all the devices/ instruments are individually secured and have no contact with each other.

Preparation for cleaning
To protect against infection, please wear protective gloves and goggles.

Remove your endoscope from the TV adaptor and disconnect the cold light cable. Rinse the endoscope with cold tap water immediately after use in order to remove gross contamination.

Endoscopes should be cleaned immediately after use to prevent adhering substances from drying on the surface! If it is not possible to clean the endoscope immediately after use, it can be placed in distilled water until it can be disinfected, but not left in the distilled water for longer than 45 minutes.

Disassembly
Disassemble your endoscope by detaching all removable components: Unscrew the light connection adapter and if present remove the handle.

Disassembly instructions for working channel extension, if present:

1. Stopcock
2. Sealing cap
3. Spring cap
4. O-ring

Unscrew the working channel extension; pull off the sealing cap/ silicone cap/ O-ring; unscrew the spring cap and pull out the stopcock.

Manual cleaning/ disinfection

Note: RB Medical endoscopes must not be cleaned in an ultrasonic bath!

1. Place the endoscope and the parts that have been removed in the cleaning/ disinfectant solution. If present, fill the lumen with cleaning/ disinfectant solution using a syringe. Use a commercially available agent specially designed for cleaning/ disinfecting medical endoscopes and strictly observe the specifications of the manufacturer (e.g. 0.5% Neodisher Mediclean – immerse for 5 minutes).

2. If present, rinse the lumen with cold tap water or (preferably) distilled water. If present, gently but thoroughly clean the bore with the enclosed round brushes. All visible residues must be removed.

Note! Any remaining residues of cleaning/ disinfectant solution may harm the patient!

3. Wash with cold tap water for 1 min – allow to drain
4. Rinse with cold water for 3 min – allow to drain
5. Wash for 5 min with 0.5% enzymatic cleaner at 55°C (Neodisher Mediclean) – allow to drain
6. Neutralize with cold water for 3 min – allow to drain
7. Rinse with cold water for 2 min – allow to drain

3. When taking out the endoscope and the parts which have been removed, check them for visible residual contaminations. If necessary, repeat the cycle or clean them by hand.

4. You can then run a thermal disinfection rinse cycle.

Note! During thermal cleaning/ disinfection cycles, the cooling phases must be adhered to! Speeding up the cooling phase can damage the optical components!

Cleaning the optical lenses
Clean the optical lenses at the distal and proximal end of the endoscope and clean off the light connector with pure alcohol using clean cotton sticks (buds) to leave no residue.

Neglecting cleanliness during sterilization may result in increased deposits on the optical system which can cause damage!

Sterilization

STERRAD®: All autoclavable and soakable endoscopes may be processed with STERRAD® 50, 200 (Short Cycle), 100S (Short Cycle), 90 (Standard Cycle) and 100NX (Standard Cycle). Please strictly follow the directives of the manufacturer AS®.

Autoclave: Endoscopes labeled "autoclave at 134°C/ 273°F" can be steam sterilized in an autoclave.

1. Place the cleaned and dried endoscope in a suitable sterilization box.

Note! Never sterilize contaminated endoscopes! The success of the sterilization will be determined by the previous condition of cleanliness!

2. Run the autoclave sterilization cycle with the following parameters

<table>
<thead>
<tr>
<th>Preliminary vacuum</th>
<th>min.</th>
<th>Sterilization temperature</th>
<th>min.</th>
<th>max.</th>
<th>min. 132°C</th>
<th>max. 134°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holding time</td>
<td>3 - 18 min (full cycle)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drying time</td>
<td>10 min</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note! Other autoclave settings and cycles can have detrimental effects on the endoscope or its individual components!

Ensure that the optical components of the endoscope do not come into contact with hot metal surfaces as these thermal bridges can lead to destruction of the materials and can therefore cause the entire system to leak.

3. Allow the endoscope to cool at room temperature.

Note! Speeding up the cooling phase can damage the endoscope. Under no circumstances should cold water or other cooling liquids be poured over the endoscope!

After 250 autoclave cycles, send the endoscope to RB Medical Engineering Ltd for servicing. Endoscopes may only be returned with proof in writing that they have been cleaned and sterilized/ disinfected.

Assembly of working channel extension, if present

Thirtly coat the stopcocks with special stopcock grease before you reinsert them. Please make sure that the sealing cap/ the silicone cap/ the O-ring (see Fig. Disassembly) are not damaged. Otherwise, please replace the components.