PLEASE READ AND FOLLOW THESE INSTRUCTIONS CAREFULLY!

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

PRODUCT DESCRIPTION

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

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

Markings on Marina 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 0483</td>
<td>Designed, manufactured and tested in compliance with 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>Colour coding on light connection</td>
<td>Viewing angle:</td>
</tr>
<tr>
<td></td>
<td>Green = 0°</td>
</tr>
<tr>
<td></td>
<td>Black = 12°/15°/20°/45°</td>
</tr>
<tr>
<td></td>
<td>Red = 30°</td>
</tr>
<tr>
<td></td>
<td>Yellow = 70°</td>
</tr>
<tr>
<td></td>
<td>Blue = 90°</td>
</tr>
</tbody>
</table>

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

Standard accessories
- Light-connection adapters Storz/Olympus, Wolf
- Protective sleeve (for all Marina Medical endoscopes with shank 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, bronchii</td>
</tr>
<tr>
<td>Cystoscope</td>
<td>Urology: Bladder, prostate</td>
</tr>
<tr>
<td>Hysteroscope</td>
<td>Gynaecology: Uterus, vagina</td>
</tr>
<tr>
<td>Laparoscope</td>
<td>Abdomen: peritoneal organs</td>
</tr>
<tr>
<td>Laryngoscope</td>
<td>Throat</td>
</tr>
<tr>
<td>Oesophagoscope</td>
<td>Oesophagus</td>
</tr>
<tr>
<td>Otoscope</td>
<td>Ears</td>
</tr>
<tr>
<td>Sinuscope</td>
<td>Head: Sinuses</td>
</tr>
<tr>
<td>Thorakoscope</td>
<td>Thorax</td>
</tr>
</tbody>
</table>

In human medical interventions, Marina Medical endoscopes must only be used in aseptic/ sterile area by properly trained physicians, without exception.

The physician treating the patient is ultimately responsible for the decision to use the endoscope, regardless of the field of use (see previous table).
The decision to use a Marina Medical endoscope will also depend on the overall condition of the patient and must be critically evaluated by the physician in charge in each case before use.

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

Abide by the laws and regulations of the country of use.
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 to relate directly to a Marina Medical endoscope.

BEFORE USE

Immediately after receiving your Marina Medical endoscope and each time before using it, check to make sure it is suitable 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 physician in charge 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 RF instruments and lasers is prohibited! |
| Your Marina Medical endoscope is supplied non-sterile. Clean and sterilise/disinfect the endoscope according to the preparation instructions each time before use. | Not cleaning and sterilising/disinfecting the endoscope can lead to infections and damage the endoscope. |
INSTALLATION

1. Storz / Olympus light-connection adapters
2. Wolf light-connection adapters
3. ACMI light-connection
4. Instrument coupling
5. Eyepiece

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 Marina Medical 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 for this purpose. Other light connection adaptors are available if necessary. Light is an energy source which heats up the endoscope due to the high light density. When choosing the light source (lamp type and power), according to DIN EN 60601-2-18 it is important that excessive temperatures are avoided where the light emerges. You must also take into account how long the Marina Medical endoscope is in use.

SPECIAL INSTRUCTIONS
Marina Medical endoscopes are made to the highest quality standards. Always treat your Marina Medical 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.

Marina 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 operation and will also prevent potential mistakes. Marina Medical cannot accept liability for damage or consequential damages caused by failure to follow instructions, improper handling or improper use of Marina Medical endoscopes.
STORAGE

Keep your Marina Medical 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 Marina Medical endoscope, please contact us to have it repaired or contact your reputable dealer to replace it. Endoscopes may only be returned with proof in writing that they have been cleaned and sterilised/disinfected.

NOTE!
Marina Medical strongly recommends not to use an unauthorized service company or service organisation to do any service or repair on Marina Medical products. For service or repair please submit all products back to Marina Medical.

DISPOSAL

All Marina Medical endoscopes can be disposed of with normal clinical waste according to the latest hygiene requirements. The relevant national laws and regulations must also be followed. Unrepairable Marina Medical endoscopes can be returned to the manufacturer in an approved package for disposal with proof in writing that they have been cleaned, disinfected/sterilised.

If you have further questions, please contact your reputable dealer.
PREPARATION INSTRUCTIONS

**NOTE!**
Marina Medical endoscopes which are labelled “soakable” may only be cleaned and disinfected manually or by machine. They must not be steam sterilised in an autoclave!

To avoid cross-contamination, never transport/ clean/ sterilise/ disinfect your Marina Medical endoscope together with other equipment and instruments. They may only be transported/ cleaned/ sterilised/ 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.

Undo your Marina Medical 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.

Marina Medical endoscopes should be cleaned immediately after use to prevent adhering substances from drying onto the surface! If it is not possible to clean the endoscope immediate 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.

Unscrew the light connection adaptor and if present, also remove the handle, tap and instrument adaptor.

**MANUAL CLEANING / DISSINFECTION**

**NOTE!**
Marina Medical endoscopes must not be cleaned in an ultrasonic bath!

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

2. If present, rinse the bore with cold tap water or (preferably) distilled water for at least 20 seconds at a constant pressure of at least 4.2 bar.

   **NOTE!**
   When cleaning with water under pressure, make sure that the water gun is only directed proximal to the endoscope working channel otherwise the fiber array and objective lens will be damaged!

3. Use a soft brush, sponge or cloth to brush/ wipe the endoscope and parts inside and outside under cold tap water or (preferably) distilled water. If present, gently but thoroughly clean the bore with the enclosed round brushes. All visible debris must be removed.

   **NOTE!**
   Any residues of cleaning/ disinfectant solution remaining may harm the patient!
4. Dry all parts with a clean, soft, lint-free cloth.

**CLEANING / DISINFECTION BY MACHINE**

All Marina Medical endoscopes are suitable for cleaning/ disinfection by machine. The following describes the validated method for automatic cleaning using the Miele G 7735 CD cleaning and disinfecting unit.

1. Place all the parts on an OR instruments receptacle (Miele) so that water can flow all over them.

2. Set to program Vario TD (without disinfection):
   - Pre-wash with cold water for 1 min – allow to drain
   - Pre-wash with cold water for 3 min – allow to drain
   - Wash for 5 min with 0.5% enzymatic cleaner at 55°C (Neodisher Mediclean) – allow to drain
   - Neutralise with cold water for 3 min – allow to drain
   - 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 residues of dirt. 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 sterilisation may result in increased deposits on the optical system which can cause damage!
STERILISATION

STERRAD®
All, autoclave and soakable Marina Medical endoscopes may be processed with STERRAD® 50, 200 (Short Cycle), 100S (Short Cycle), NX (Standard Cycle) and 100NX (Standard Cycle).

PLEASE STRICTLY FOLLOW THE DIRECTIVES OF THE MANUFACTURER

AUTOCLAVE
Marina Medical endoscopes labelled “autoclave at 134°C/ 273°F” can be steam sterilised in an autoclave.

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

   **NOTE!**
   Never sterilise contaminated endoscopes! The success of the sterilisation will be determined by the previous state of cleanliness!

2. Run the autoclave sterilisation cycle with the following parameters:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary vacuum</td>
<td>3 x</td>
</tr>
<tr>
<td>Sterilisation temp.</td>
<td>min. 132°C - max. 134°C</td>
</tr>
<tr>
<td>Stand time</td>
<td>3 - 18 min (full cycle)</td>
</tr>
<tr>
<td>Drying time</td>
<td>10 min</td>
</tr>
</tbody>
</table>

   **NOTE!**
   Other autoclave settings and cycles can have detrimental effects on the endoscope or its individual parts!

   Make sure that the optical components of the endoscope do not come into contact with hot metal surfaces. The thermal bridges which this causes will destroy 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 Marina Medical endoscope to Marina Medical for servicing. Endoscopes may only be returned with proof in writing that they have been cleaned and sterilised/ disinfected.