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





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1 Symbols

Following symbols have been used either in this IFU or in our labels:

Symbol	Explanation	Symbol	Explanation
	Consult Instructions for use		Manufacturer
	Caution		Medical device
	Catalogue number		Fragile, handle with care
	Serial Number		Keep dry
	Non-Sterile		Keep away from sunlight
	Date of manufacturing		CE-Marking with Identification number of the notified body (mdc medical device certification GmbH)

2 General Information

 Read these Instruction for Use carefully before using the Endoscopes. Thereby you keep yourself, the patient and any third parties from damage, which could occur by incorrect combination or by improper use. The Instructions for Use may be updated without further notice.

Note: Report any serious incidents with the product to the manufacturer. If you are a user in the European Union, also report incidents to the responsible authority of your Member State.

2.1 Intended Purpose

2.1.1 Intended Use

Endoscopes are intended for visualization of the intraoperative site during short-term endoscopic procedures and minimally invasive surgery.

2.1.2 Indication

Hysteroscopes	Intended for endoscopic procedures for the uterine disorders.
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2.2 Contraindication

The use of endoscopes is contraindicated when endoscopic procedures are contraindicated.

2.3 Intended Users

The product must only be used by technically competent, medically qualified and in the functioning of the device, regarding minimally invasive surgery, trained medical staff. As well as staff of the processing and sterilization unit.

2.4 Patient population

Patients of all ages requiring endoscopic diagnosis and/or therapy in any area of the body where endoscopic diagnosis and therapy are necessary and feasible. The patient population varies for endoscopic procedures in terms of age, sex and body weight. The selection of the procedure is in responsibility of the physician, as well as the choice of the appropriate type of endoscope.

3 Safety Information



Before using the product, check the endoscope, the appropriate endoscopic accessories and all devices connected to optical and mechanical parts, for all possible external damages. See chapter 8 Check and visual inspection.

If the product is damaged, it must not be used!

Do not modify the product, modifications to the product reduce the safety of the product, and the user or patient can be injured.

Unauthorized opening, repair and modifications of the product relieve the manufacturer from any warranty for the reliability of the system.

3.1 Side effects, Risks and Complication

- Risk of infection to patient or medical staff.
- Risk of injury due to defect device

- Post-operative pain and fever or inflammation.
- Intraoperative bleeding

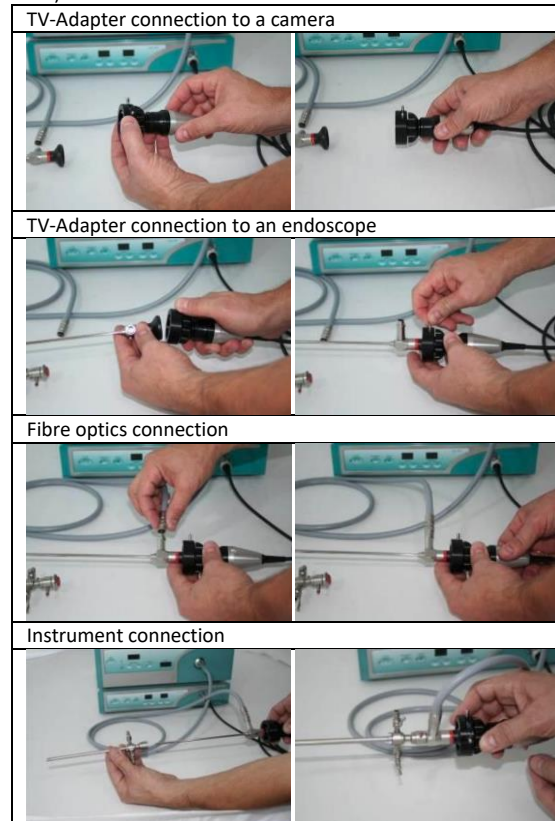
4 Combination with other Medical Devices

Due to the standardized connections used, BMT endoscopes are compatible with all common light sources, cameras and suction/irrigation devices.

Please observe the information in the instructions for use of the manufacturer of the combination devices for safety information!

5 Assembling

The following shows the minimum configuration of the endoscopes (this may vary depending on different combinations of units).



5.1 Accessories

You will need the following accessories to use the endoscope:

Description
Wolf-Adaptor
Storz-Adaptor
Brush for cleaning of the working channel and/or irrigation channel (if applicable)

6 Processing Procedures

The endoscope must be checked for damage before the first and each subsequent use.

6.1 Handling before first / subsequent use

Please carefully inspect the devices at the time of delivery and prior to each use. Special regard should be given for damages, such as cracks, bends and discoloration of the optical surface. Please note the following information.



The endoscopes are supplied non-sterile. Clean, disinfect and sterilize the product before the first and each subsequent use.

The endoscopes are reusable and can undergo reprocessing up to 100 times. However, their wear depends on usage type and duration. Hence, it's crucial to thoroughly inspect them before each subsequent use, paying close attention to optical surface integrity, discoloration, deformation, and corrosion.



Extreme heat from steam autoclaving and the high intensity lamp will cause debris on the optical surfaces to possibly discolor, burn and harden if not properly cleaned and removed.

Endoscopes must not be cleaned in an ultrasonic bath.

Never use ultrasonic cleaner as this will cause damage to the optical system.

Only use appropriate agents. Do not put the endoscopes in alcohol or other corrosive liquids.

6.2 Disassembly

Disassemble the endoscopes as soon as possible after use. Please remove all sealing caps and valves. Carefully remove all adaptors.

Please discard disposable items of endoscopes with working channels immediately properly.



Do not use excessive force, this will damage the endoscopes.

6.3 Precleaning

After all parts has been disassembled the endoscopes without irrigation and working channels must undergo the following steps:

1. Rinse the endoscope under running water at least 1 min and brush the surface with the soft brush.
2. Put all individual parts in a basket for small parts and rinse the parts.
3. Let the endoscope soak in precleaning solution for 5 min according the concentrations recommended by cleaning agent manufacturer.
4. Brush the surface by using soft brushes until visibly clean.
5. Rinse the instrument with cold tap water 3 times for 1 minute.

For Endoscopes with irrigation and working channels must undergo the following steps:

1. Rinse the endoscope under running water at least 1 min and brush all channels with the soft brush.
2. Put all individual parts in a basket for small parts and rinse the parts.
3. Let the instruments soak in precleaning solution for 5 min according the concentrations recommended by cleaning agent manufacturer.
4. Brush the surface by using soft brushes until visibly clean.
5. Brush the channels of the endoscope by using soft brushes until visibly clean.
6. Blow through all channels with compressed air for 5 seconds each.
7. Rinse all channels with cold tap water for 1 minute.
8. Rinse the instrument with cold tap water 3 times for 1 minute.



Endoscopes must not be cleaned in an ultrasonic bath.

6.4 Automated Cleaning

Please strictly follow the below procedure steps:

1. Disassemble the endoscopes as far as possible. Remove the fiber optic connector, adapter, handle, irrigation valves, etc.
2. If necessary, connect the rinsing adapter to the endoscopes.

3. Then position the pretreated endoscopes in a washer-disinfector (Miele PG 8535). Make sure that the instruments do not touch each other.
4. Connect the lumens (if applicable) with suitable, flexible irrigation tubing and adapters.
5. Start the program.
6. The machine cleaning was carried out using "neodisher MediClean forte" at a concentration of 0.5% as a cleaning agent.
7. The machine is cleaned at 50 ± 2 °C for at least 5 min. The thermal disinfection was carried out at 90 ± 2 °C for at least 5 min (A₀ 3000).
8. After completion of the machine cleaning / disinfection, remove the endoscopes from the washer- disinfector under low-germ conditions.

A visual inspection for damages and wear, in particular with regard to the optical surfaces has to be performed after each cleaning process.



Carefully clean each working and flushing channel and its taps separately.

6.5 Automated Disinfection

Automatic thermal disinfection in washer-disinfectors, taking into account the national requirements for the A₀ value; e.g. A₀- value 3000:

- 5 minutes disinfection with deionised water 90°C
- Water drainage



Care should be taken not to overload the washer-disinfector to avoid rinsing shadows.

6.6 Packaging

Prior to sterilisation, reassemble the disassembled endoscopes. The endoscope is placed and sealed in a standard-compliant packaging suitable for the respective device or in sterilisation trays for sterilisation according to national standards.

The packaging must meet the following requirements:

- Suitable for steam sterilization (temperature resistance up to at least 134° C (273° F) sufficient steam permeability)
- Sufficient protection of the devices or sterilization packaging against mechanical damage.
- Regular maintenance according to the manufacturer's specifications (sterilization container).

- A maximum weight of 10 kg per pack/contents of the sterilization container must not be exceeded.



Pay attention that there is no contact between the devices or between device and plug.

Avoid scratches on the surface of the endoscopes.

6.7 Sterilization

Sterilisation of the endoscopes using the fractioned pre-vacuum method taking into account the respective national requirements. The endoscopes must be sterilised in suitable sterilisation packaging.

Sterilisation must be carried out using a fractioned pre-vacuum process with three pre-vacuum cycles and drying on a vacuum for at least 20 minutes. The following parameters must be taken into account.

	Temperature	Time
Europe	134°C	≥ 3 minutes
USA	132°C	≥ 4 minutes

After sterilization, make sure that the sterile package of the endoscope is not damaged. If the package has been perforated, sealing has been opened, packaging is wet or damaged in any other way, re-sterilize the endoscope.

After sterilization, ensure gradual cool-down to room temperature without use of any additional cooling. Sudden changes of temperature may damage the devices.



When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.

Flash sterilization is not permitted.

Do not apply hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide, or plasma sterilization.

7 Storage

Endoscopes must be stored unit first and any subsequent use in a suitable environment. After complete reprocessing and drying, the

endoscopes must be placed in a suitable container/box for sterile storage.

- Store dry and dust-free
- Handle with great care, do not throw or drop
- Protect from mechanical damage

8 Check and visual inspection

The endoscope must be checked after cleaning / disinfection for:

8.1 Impurities

If impurities are recognized, the product must be cleaned and disinfected again. The endoscope must not have any traces of corrosion.

8.2 Damaged Surfaces

Damaged devices must not be used any further (limiting of the number of re-use cycles)



The endoscope surfaces have to be undamaged and in particular free of sharp edges. Check the devices for dents, bends, mechanical / thermal damage caused by radiofrequency or laser surgery equipment as well as for cracks and spalling.

8.3 Functionality

8.3.1 Inspection of the fibre optics

- The distal end of the endoscope is held toward a lighted window or a bright ceiling light.
- First, look at the light guide connector. The individual fibres now appear bright. The side, which is facing the bright ceiling light is moved slightly up and down. The brightness of the fibres changes a bit. It is uncritical if individual fibres remain dark. A breakage rate of about 20 to 30% impedes the endoscopic procedures severely.
- The surfaces of the light entry and exit surfaces should be smooth and clean.
- Rough surfaces with deposits, tangible or withdrawn individual fibres may lead to insufficient lighting. Further use and processing may result in progressive damage to the endoscope.



If a light source is powered on, handle carefully, do not look directly into the light beam. Otherwise, eye damage may occur.

Endoscopes with damaged fibre optics should be sent to the manufacturer for checking.

Do not use a cold-light source for this test. Direct view into the radiated light from a cold-light source can cause eye damage.

8.3.2 Verification of glass proximal and distal areas

Glass surfaces have to be clean and debris-free. Persistent encrustation, observed during visual examination, should be removed with appropriate cleaning pastes or alcohol-soaked cotton swab. Inadequate rinsing of the optics after cleaning and disinfection is often the cause of precipitates.

Corresponding to the indications appropriate working distance the image has to be sharp and clear. A fuzzy, non-circular, cloudy, foggy, image points out to damage.



Endoscopes with indelible persistent encrustations should be sent into the manufacturer or an authorized service specialist for checking.

Endoscopes with damaged glass surfaces (e.g. chips), impaired image quality or noticeable surface damage and deformations may no longer be used. They should be discarded or sent back to the manufacturer or an authorized service specialist for checking.

8.3.3 Troubleshooting

Problem	Possible cause	Remedying of defect
Picture cloudy, foggy	Glass surfaces contaminated	Cleaning of glass surfaces according to section "cleaning and disinfection" (see chapter 6.4 & 6.5)
	Deposits, coarse encrustations of glass surfaces	Remove deposits according to section "cleaning and disinfection" (see chapter 6.4 & 6.5), check water quality
	Leaky, defective lens system	Send in the endoscope for repair.
Picture too dark, too	Glass surfaces contaminated	Cleaning of glass surfaces according to section "cleaning and

Problem	Possible cause	Remedying of defect
small illumination		disinfection" (see chapter 6.4 & 6.5)
	Deposits, coarse encrustations of glass surfaces	Remove deposits according to section "cleaning and disinfection" (see chapter 6.4 & 6.5), check water quality
	Wrong light conducting cable connector	Check light conducting cable connector, replace if necessary
	Fibre optics defect	Check fibre optics according to section "Check and visual inspection" (see chapter 8)
	Defect light conducting cable, light source	Check light conducting cable, light source
Yellowish lighting	Dirty fibre optics	Cleaning of glass surfaces according to section 6.3. If necessary, send in the endoscope for service.
	Dirty, broken light conducting cable	Check light conducting cable (for example, shine on white surface), replace if necessary
Staining, discoloration	Inadequate cleaning (for example, remaining protein residues)	Clean up, possibly with thorough scrubbing

Problem	Possible cause	Remedying of defect
	Inadequate rinsing of endoscope between treatment phases (especially before sterilization)	Ensure thorough rinsing between the treatment phases
	Contaminated, too often used disinfectants and cleaning solutions	Replace disinfection and cleaning solutions regularly
Leakage	Leaking connections	Check connections between sealing cap and irrigation stopcock
	Defect irrigation stopcocks	Send in the endoscope for repair

9 Warranty

The LiteOptics Ltd provides 12 months warranty of the rigid endoscopes.

The duration of this warranty is limited to claims that are submitted within the specified warranty period from date of purchase of the endoscope, possibly related to repairs, stating the invoice number.

This warranty applies to defects only that are not normal wear and tear, misuse, improper or inadequate handling or due to force majeure. In cases of maintenance or repair, please contact the LiteOptics Ltd service.

9.1 Repairs

For repair or further information, please contact our service team: enquiries@liteoptics.com

When returning the device, please also include a detailed description of errors.



For the protection of your staff and LiteOptics Ltd employees, the endoscope (and any accessories) must be thoroughly cleaned and sterilized before shipping.

LiteOptics Ltd Service may refuse to repair soiled or contaminated products for safety reasons.

All warranty and guarantee claims will be lost if the user or an unauthorized repair company performs maintenance and repairs.

9.2 Maintenance

The endoscopes and accessories are maintenance-free. There are no components that require further maintenance as mentioned above by the user or the manufacturer.

10 Disposal

All national regulations on disposal must be observed. Discard non-conforming devices according to the respective national laws.