Instruction for use
Hysteroscope PG127

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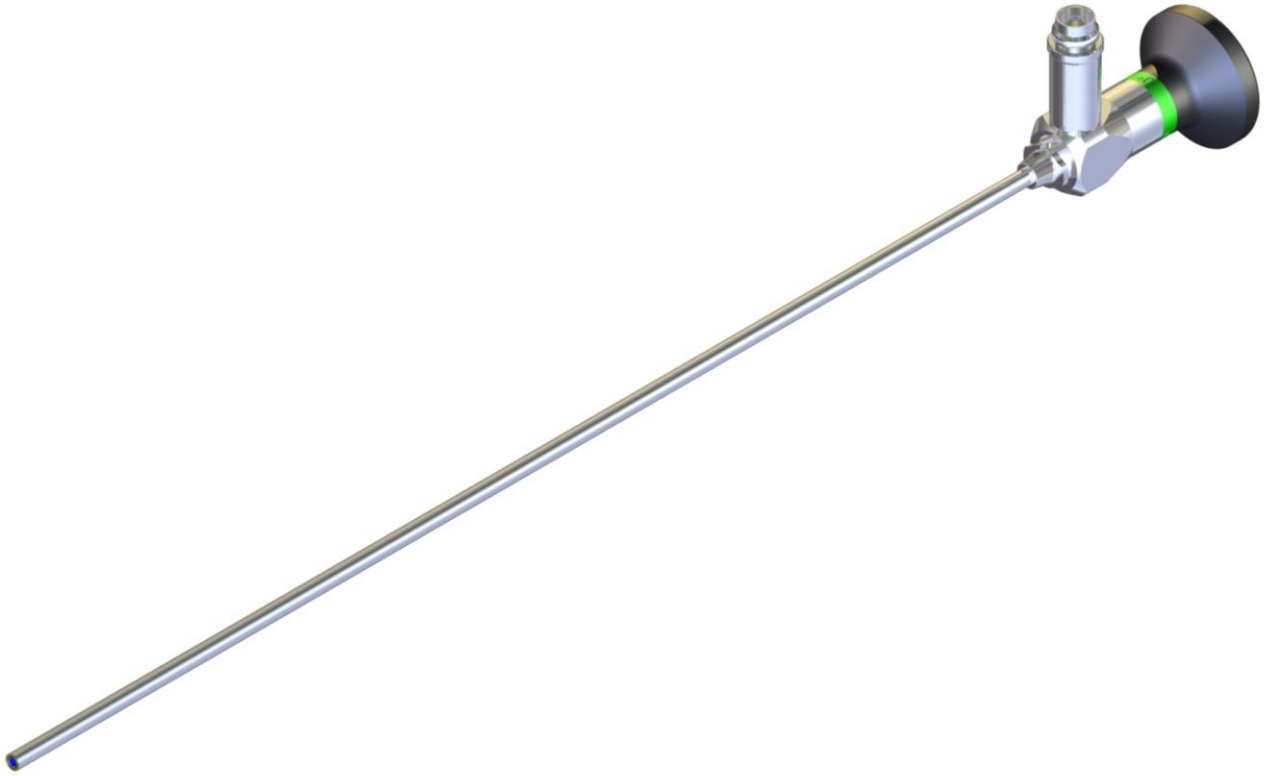
Uro.020.09.3120a 40k; 9AGC-1002BQ1



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1. Content

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2. Legal advices

Nomenclature which is at the same time a registered trade mark is not especially marked. In absence of trademark declaration it may not be gathered that a designation will be a free trademark.

LiteOptics Ltd. would greatly appreciate being informed about any errors or omissions that may be found in the content of this instruction manual.

With regard to continuous development and improvement of our products we reserve the right to alter technical features without written notice.

Dealer:

Manufacturer:

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3. Signs and Symbols

Please take notice.

Warning: Indicates to possible dangerous situations. No observance can lead to dead or serious injuries.

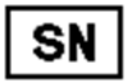
Attention: Indicates to possible dangerous situations. No observance could cause injuries or product damages

Please consider the technical manual.
Please read technical manual before use.

Please consider the technical manual.
Please read technical manual before use.

Attention! / Caution!
Please consider the accompanying documents.

Reference number

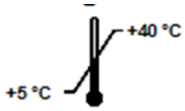


Serial Number

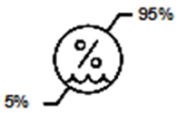
Date of manufacturing

Manufacturer

Non Sterile – Sterilize before use



Temperature



Humidity

Pressure

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Caution glass fragile

Do not expose to radiation

Do not expose to any weather

devices have to be disposed separately from household/consumer waste

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4. Introduction

We thank you that you have decided to purchase a rigid endoscope without working channel of LiteOptics Ltd..

Endoscopes are medical devices that are manufactured at the highest technical level and require careful handling, care and storage. Under the circumstances they will satisfy the high demands which are asked to them and will be usable over a long period to complete satisfaction.

LiteOptics Ltd. products are precision devices.

Please keep your endoscopes always with the utmost care, so you will enjoy them over a long period.

Read this manual carefully before using your new product. Thereby you keep yourself, the patient and any third parties from damage, which could occur by incorrect installation or by improper operation.

5. Security advices / warnings

Improper use of this device and non-observance of the given instructions, warnings and precautions can lead to serious risks and consequences of the surgery or to injury, damage and even death of the patient, user and any third parties or damage to the endoscope!

This manual is designed to get familiar with the equipment and its intended capabilities in detail and use. The manual has to be enclosed with the device therefore always.

The instruction manual contains important information needed for safe, proper and efficient operation of the device.

We reserve the right to alter technical features, so that deviations of the content or pictorial representation are possible.

This manual should help to make the use of rigid endoscopes with working channels of LiteOptics Ltd. easier, but it is not designed as a guidance for endoscopic procedures and does not contain detailed description of endoscopy, and is not suitable for beginners' introduction to this surgical technique!

This device may only be used by technically competent and trained persons who are instructed to handle the instrument.

All persons using the devices have to read these instructions carefully first.

Handling of the device has to be carried out in accordance with these instructions.

Use the endoscope for endoscopic purposes only!

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Inspect the endoscope, the appropriate endoscopic accessories and all devices connected to optical and mechanical parts for all possible damages to exclude the risk of injury before every use! Defective and loose parts affect the function and safety and have to be removed immediately! Endoscopes with damaged or defective parts must not be used any longer. The full function and intended use of the medical device has to be ensured and verified by the user when using accessories and other components before use.

In case of doubt, contact your dealer or the manufacturer.
The device is not intended for use in potentially explosive areas!

Mechanical stress due to falling off, strong buckling, bending in a narrow winding, strong shocks and torsion, tensile load or compressive stresses can result in damage or destruction of the endoscope and thus lead to malfunction!

We are not responsible for damages caused by misuse of the endoscope, no liability!

Endoscopic procedures should be performed by trained professionals (e.g. physicians) with appropriate training and experiences in performing endoscopic procedures only. It is within the responsibility of the user to consult information about indications, contraindications, potential complications, risks and the development of endoscopic methods continuously.

Notes on combinations with other medical devices

The connection of other equipment or supplies (such as TV adapter, light sources, optical fibre cables, cameras, monitors, printers, video recorder, image processing systems, filing systems, pumps, shavers, insufflator, RF devices, work items, laser devices, pneumatic or electro hydraulic lithotripters etc.) opens up a variety of therapeutic applications.
Follow the instructions and security advices of the used devices and accessories. Make sure that users are adequately trained.
In case of doubt, contact your dealer or the manufacturer.

Protective measures for RF applications, including laser application, high-energy applications are not integrated in the LiteOptics Ltd. device. Note that only the devices which are permitted for medical purposes may be adapted!

A thorough understanding of procedures used for endoscopic laser and electrosurgical treatment, applied principles and methods is needed to avoid shock and burn risks for patients and users as well as damage to other equipment and instruments. Liability claims arising from improper use or combination with other devices and instruments are excluded.
Make sure when joint operation of an endoscope with electronic medical devices is performed, that the BF conditions (isolated, floating applied part) are observed.

If endoscopes should be used with electronic medical devices and / or energy-powered endoscopic usable accessories, leakage currents may added up.

Notes for use with light sources

LiteOptics Ltd. rigid endoscopes can be adapted to all common light sources for medical endoscopy. The malfunction of a used light source might lead to hazards. Keep an operational replacement light source available, or use light sources that have a spare bulb. If bulb change is necessary during endoscopic application do not move the endoscope during the bulb change. Only if it is possible pull out the endoscope carefully for bulb change. Remember that light is an energy source that can heat each endoscope optics. The application time is limited by the selection of the light source.

In combination with high intensity light sources, both the light source side and the instrumental side optical fibre end can achieve temperatures that can cause burns. In addition, light of high energy radiation can lead to a temperature increase in tissue. During invasive application temperatures above +41 °C should be avoided, as this can cause tissue damage!

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Therefore, avoid direct tissue contact and if applicable, pay attention to adequate irrigation of the operative field and the respective device-specific instructions and safety precautions.

Notes for use with high frequency surgical equipment

Prior to application of endoscopic high frequency treatment, surgical patients should be prepared in a suitable manner for the intended intervention. This includes activities to eliminate and to prevent the formation of ignitable gases in particular. In contrast to conventional high-frequency surgery inappropriate (particularly to low) power settings in high-frequency endoscopic surgery can cause a distinctive depth effect in the surrounding tissue.

The power adjustment should be made according to the users experience with respect to appropriate clinical references and / or appropriate training.

To avoid burns and / or unwanted depth effects in the surrounding tissue and to avoid endoscope damage, the high-frequency current should be switched on only if the appropriate application part (electrode) can be seen through the endoscope. The corresponding manuals, specifications and security advices should be respected.
Never touch the endoscope while operating with an active electrode.

Notes for use with lasers

If endoscopes or endoscopic accessories are used with laser devices, suitable protective glasses have to be worn to avoid potential damage to the eyes.

To avoid burns and / or unwanted depth effects in the surrounding tissue or damage of the endoscope, the laser power should be activated only if the tip of the laser fibre can be seen through the endoscope. The respective device-specific instructions and safety precautions have to be observed.
Never touch the endoscope while operating with an activated laser fibre.

Notes for use with lithotripters

To avoid danger and in relation to possible restrictions on use of ultrasonic, electro-hydraulic, pneumatic and mechanical lithotripsy device-specific instructions and safety precautions have to be observed.
Appropriate surgery sheaths may be used for stone extraction with stone forceps. The required dimensions of suitable instrument can be gathered from technical specifications of the respective single devices.
Never touch the endoscope while operating with an activated **Lithotripsy unit.**

CT (Computer tomography)

Certain metals of the endoscope can be dangerous due to heating during the application, so that an X-ray examination may be contraindicated in such patients. Due to X-radiation, optical components can discolour and thus can lead to endoscope damage. Concomitant use of CT (computed tomography) / X-ray and endoscopes can lead to hazards.
Note therefore appropriate manufacturers and safety instructions.

MRT (Magnetic resonance tomography)

Due to magnetic field induced movements / relocations or heating some metals of the endoscope can be dangerous during the investigation, so that an MRI scan may be contraindicated in such patients.
The optical and electrical medical devices for endoscopy may be damaged by magnets. Metals of the endoscope can cause side effects and visual disturbances. Concomitant use of MRI / magnetic resonance imaging and endoscopes can lead to hazards.
Note therefore appropriate manufacturers and safety instructions.

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6. Intended use

LiteOptics Ltd. rigid endoscopes are optical devices which allow inspecting the body's interior through natural body openings or artificial cavities and the visualization of organs, tissues and structures.
To the human eye such insights remain hidden without the aid of an endoscope.

The following parameters of rigid endoscope optics without working channel can be varied:
Sizes, working length, probe diameter, direction of view and field of view.

Rigid endoscopes without working channel might be used for diagnostic purposes or in combination with surgical instruments (e.g. hysteroscopy, cystoscopy) for surgical purposes.

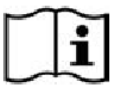
Endoscopic procedures performed both diagnostic and therapeutic way, are useful and far less stressful for the patient than traditional methods.

Indications:
LiteOptics Ltd. Hysteroscopes are rigid endoscope optics without working channel with a length of 100mm to 420mm and a diameter of 1.0 to 5.0mm. It is used for examination and treatment of the uterine cavity.
LiteOptics Ltd. Hysteroscopes without working channel are designed for invasive diagnostic use.

- bleeding disorders
- Abnormal ultrasound findings
- Diagnosis of benign and malignant tumours in the uterus
- Removal of polyps or myoma nodes protruding into the uterine cavity
- Diagnostics of factors which can lead to sterility (malformations or adhesions of the uterine cavity)
- Control examinations after previous uterine surgeries
- Locating and removing spirals

Contraindications:
The use of rigid LiteOptics Ltd. endoscopes is contraindicated, provided that endoscopic procedures are contraindicated. The guidelines of the German Society for Gynaecology and Obstetrics in the version of 2009 provide the relevant information in connection with comparative surgical procedures.

- pregnancy
- cancer of the female genital tract (cervical cancer, uterine cancer)
- Infection of the abdomen / pelvis



Please read carefully the instruction manual prior to operation.
These instructions have to be kept in a prominent position in proximity to the medical device.

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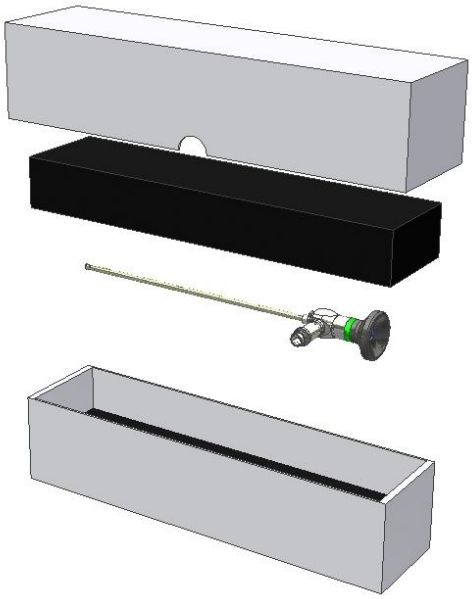
7. Initial operation

Remove the LiteOptics Ltd. rigid endoscope and its accessories from the packaging and carefully remove all packing materials.



The delivery includes:	1 piece	Rigid Endoscope
	1 piece	Wolf-Adaptor
	1 piece	Storz-Adaptor

Rigid endoscope and accessories have to be checked promptly for completeness and obvious damage after unpacking. Damage can be claimed only if the supplier is notified immediately (within 24 hours).
Please use for any necessary return of equipment or accessories the original packaging. Describe the problem, identify the malfunction and designate a contact person for possible inquiries.

Caution:
Please note the references made in section 5 (combinations with other medical devices) if equipment or other medical devices are connected to the endoscope.

Follow the instructions and safety advices of the used devices and the accessories strictly.

LiteOptics Ltd. rigid endoscopes are supplied non-sterile and have to be cleaned before first use according to the reprocessing instructions. Rigid endoscopes have to be disinfected or sterilized according to the medical indication (please note section 10, cleaning, disinfection, sterilization).

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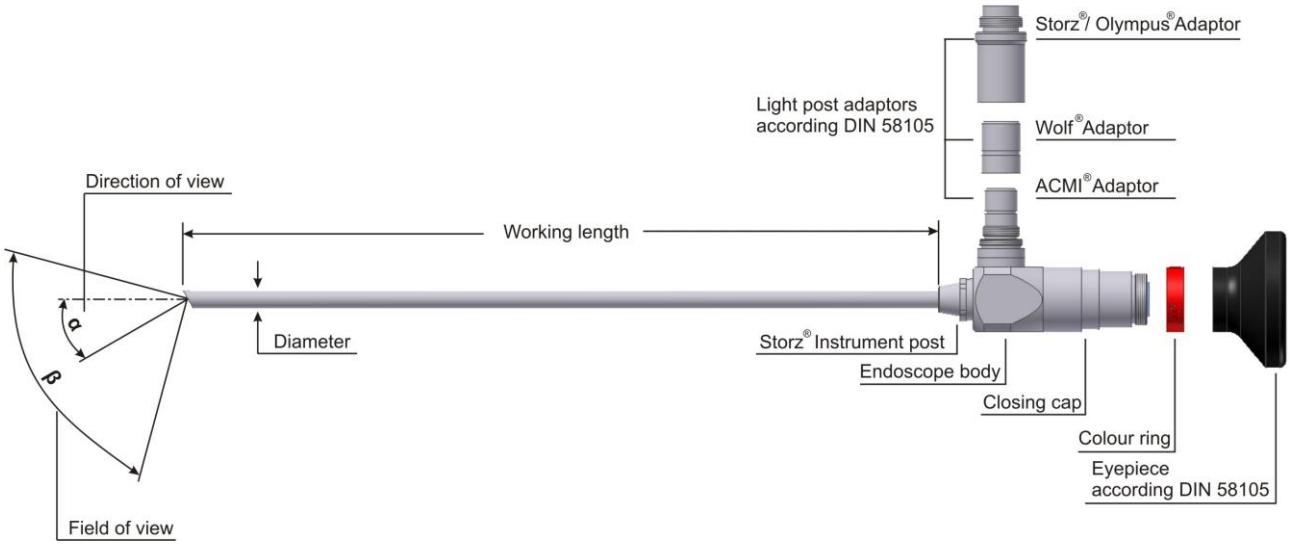
8. Device description / sketch / part description

8.1 Endoscope without working channel (e.g. hysteroscope, cystoscope)



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Compatibility	
• **Instrument connection**	Storz®-, Wolf®
• **Fibre optics connection**	ACMI®-, Wolf®-, Storz®/Olympus®
• **Eyepiece**	Eyepiece according to DIN 58105, screwable
Objective	CAD-designed tension-free composed-objective for optimal sharpness, colour sync and resolution,
Image transmission	CAD-designed rod lens system for optimal sharpness, colour rendering and resolution
Light-guiding system	High quality light fibres
Optical glass	Distal and proximal sapphire
Biocompatibility	All materials which come in direct contact with the body (stainless steel, glass, epoxy adhesives) are biocompatible. All outside metal parts are made of high quality “stainless steel” and are approved for medical equipment manufacturing. We do not use additional materials and manufacturing processes that have a negative impact on the biocompatibility.
Sterilization	Autoclavable, max. 134° C / 2,2 bar / 5 min
Certificates	Council Directive of 93/42/EEC (CE-mark) DIN EN ISO 13485

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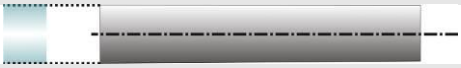
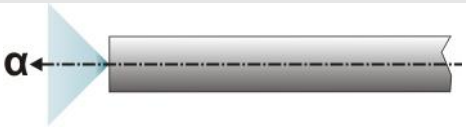
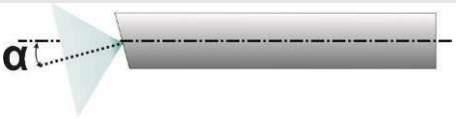
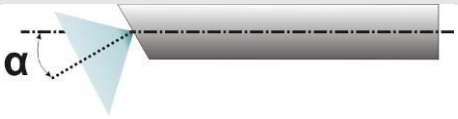
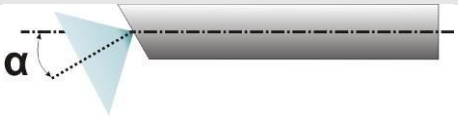
Working length		in mm		
Diameter		in mm		
Direction of view α		0°	Colour code green	
		15°	Colour code white	
		30°	Colour code red	
		45°	Colour code blue	
		70°	Colour code yellow	
Field of view β		in degree		

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9. Operation

Setup of minimum configuration in endoscopy (due to different combination of units this may vary)

TV-Adapter connection to a Camera

TV-Adapter connection to an endoscope

Pay attention to the eyepiece adjustment!

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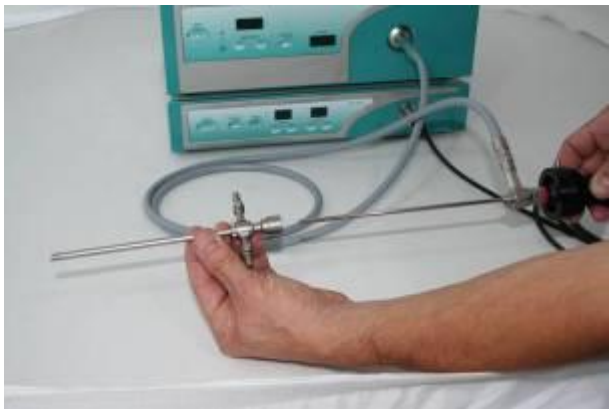
Fibre optics connection

Pay attention to fibre optics adjustment!

Instrument connection



Pay attention to the correct positioning of the instrument to the optics!

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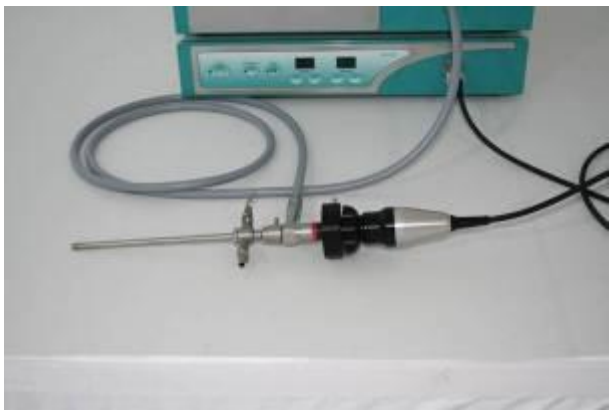
Pay attention to instrument adjustment!



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10. Cleaning, disinfection, sterilization

General Principles / Introductory Remarks
Note also that the manner of treatment can have significant impact on the life of endoscopes.
Check your endoscope optics function (such as adequate lighting of the fibres, clear, sharp, bright and round picture) and check your endoscope for possible damage (such as sharp edges, loose parts or visible deformation of materials) before each use.

All LiteOptics Ltd. endoscope optics have to be cleaned before each use, disinfected and sterilized, and this is especially true for first-time use after delivery, because all instruments are supplied non-sterile (cleaning and disinfection after removal of the protective packaging; sterilization after packaging). An effective cleaning and disinfection is an essential prerequisite for effective sterilization.

As part of your responsibility for the sterility of the instruments / devices in use always ensure:

- that adequate equipment and product-specific validated procedures for cleaning / disinfection and sterilization are used in principle only,

- that used equipment (disinfector, sterilizer) is serviced and checked regularly and

- that validated parameters are strictly adhered to in each cycle.

During the application please pay special attention to the collection and separation of soiled / contaminated instruments. Keep them separated and do not place them back on the instrument tray in order to avoid higher contamination of the assembled instrument tray. Clean / disinfect contaminated instruments. Place them back on the instrument tray and sterilize the instrument tray fully stocked afterwards.

The endoscope optics should be cleaned immediately after each use. To avoid adverse effects on the components of the endoscope lens use demineralised water for cleaning if possible only.
An effective cleaning and disinfection is an essential prerequisite for effective sterilization.
Before each use, the endoscope optics has to be cleaned, disinfected and sterilized. Please observe the applicable regulations of your country as well as the hygiene directives applicable to medical practices/hospitals.

This especially applies to the different guidelines / requirements for effective prion inactivation.

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Procedure according to DIN EN ISO 17664 processing of medical devices (cleaning, disinfection and sterilization)

10.1. Instructions for reprocessing

A mechanical process (disinfector) should be used for cleaning and disinfection wherever possible. A manual method should be used in case non-availability of an automated procedure only due to the significantly lower efficacy and reproducibility.

The pre-treatment is carried out in both cases.

As endoscope optics are provided with irrigation and aspiration stopcocks, these should be disassembled for sterilization. We recommend a **steam sterilization / autoclave process**.

When using a manual cleaning and disinfection procedure, product and process specific validation is entirely responsibility of the user.

10.2. Limitations and restrictions on reprocessing, durability

Frequent reprocessing of rigid endoscope optics has an impact on their usability. The end of product lifetime is usually determined by wear and damage caused by use.

Please note:
If appropriate care is used and if the rigid endoscopes are undamaged and clean they can be used up to 100 times. Any further re-use or the use of damaged and / or contaminated instruments is the responsibility of the user.
If you are unsure, however, if your endoscope optics is ready for use, we recommend to return the rigid endoscope for inspection or for replacement to our service-address.

10.3. Preparation at the site of use

In clinical practise used endoscope optics get sometimes in contact with corrosive etching agents and drugs. Endoscopes have to be removed from other equipment after use immediately. Surface contamination should be cleaned with a lint-free soft coarse cloth / paper towel.

Please note:
"Dropping" of instruments (optics) during surgery will inevitably lead to damage.
Please pay special attention to place back the device gentle after use..

10.4. Preparation before purification

In clinical practise used endoscope optics get sometimes in contact with corrosive etching agents and drugs. Coarse impurities on the instruments have to be removed directly after use (within 2 h).

A wet clean up should be performed immediately after surgery in order to avoid drying out of blood, protein and other substances on the endoscope and to protect personnel. Dried protein complicates the cleaning, disinfection and sterilization.

Use running water or a disinfectant solution. The disinfectant should be free of aldehyde (otherwise fixation of blood smears), exhibit proven efficacy (e.g. VAH/DGHM - or FDA approval or CE mark) and suitable for the disinfection of instruments.

For manual removal of impurities use a soft brush or a clean soft cloth only, which is used for this purpose only. Never use metal brushes or steel wool or other sharp objects.

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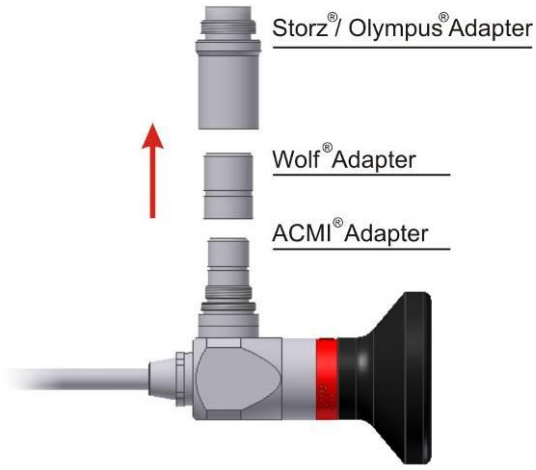
Please note:
The disinfectant used in the pre-treatment serves for personal security only. It does not replace the next disinfection step carried out after cleaning.

Caution:
Endoscopes must not be cleaned in an ultrasonic bath.

Caution:
Use approved cleaning agents only. Do not put the endoscope in alcohol or other corrosive liquids.

Procedure:

- Remove all sealing caps, valves, bushing grommets from the endoscope (discard disposable items immediately)
- Remove all adaptors from the endoscope (discard disposable items immediately)
- Remove the handle (discard disposable items immediately)



Please do not forget to screw the adapter, the flow valves again after sterilization. Fat the flow valves after sterilization always. Use fats approved for medical devices only.

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10.5. Cleaning and disinfection

10.5.1 Basics

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered[1].

The pre-treatment step is to be performed in both cases.

[1] In case of application of a manual cleaning and disinfection procedure a product and procedure specific validation under sole responsibility of the user is required.

10.5.2 Pre-treatment

Please remove coarse impurities of the instruments directly after application (within a maximum of 2 h). For this, directly after disconnection of the plug from the device, close the plug by the attached plug protective cap.

Procedure:

1. Check for closure of the plug with the plug protective cap.
2. Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F). Push each button at least three times during pre-rinsing.
3. Soak the disassembled instruments for the given soaking time in the pre-cleaning solution[2], so that the instruments are sufficiently covered.
   Pay attention that there is no contact between the instruments or between instrument and plug. Assist cleaning by careful brushing of surfaces (but not the glass surface of the camera) with a soft brush (at beginning of soaking). Push each button at least three times during pre-cleaning.
4. Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Push each button at least three times during post-rinsing.

Pay attention to following points during selection of the cleaning detergent[2]:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- compatibility of the cleaning detergent with the instruments (see chapter „material resistance„)

[2] In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel´s safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), should possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), should be suitable for the disinfection of instruments made of metallic or plastic material, and should be compatible with the instruments (see chapter „material resistance„).

Please consider, that a disinfectant used in the pre-treatment step serves only the personnel`s safety, but cannot replace the disinfection step later to be performed after cleaning.

Caution:
Endoscopes must not be cleaned in an ultrasonic bath.

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

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10.5.2 Manual cleaning and disinfection

When choosing the cleaning agent and disinfectant ensure:

- that these are basically suitable for the cleaning and disinfection of instruments made of metals and plastics,
- that a disinfectant with proven efficacy (e.g. VAH/DGHM- or FDA approval or CE mark) is used and that it is compatible with the cleaning agent,
- that chemicals used are compatible with the instruments (see "material resistance").

Combined cleaning / disinfecting agents should not be used if possible. Only in cases of very low contamination (no visible impurities) can combine cleaning / disinfecting agents are used.

Cleaning and disinfectant concentrations and contact times which are specified by the manufacturer must be strictly adhered.

Use freshly prepared solutions only. Use sterile or germ-poor (up to 10 bacteria / ml) and endotoxin-poor (max. 0.25 endotoxin units / ml) water (e.g. purified water / highly purified water) only. Use filtered air for drying only.

Procedure: **Cleaning**

1. Rinse endoscopes under running water. Remove surface contamination with a soft cloth.
2. Rinse the lumens five times with water using a disposable syringe (working channel 50 ml, rinsing and suction channel 10 ml).
3. Disassemble the endoscopes as far as possible. Remove the fiber optic connector, adapter, handle, irrigation valves, etc.
4. After pretreatment, place the endoscopes in the cleaning solution for at least 5 minutes so that the instruments are sufficiently covered and thoroughly cleaned with a soft cloth or soft brush. Make sure that the instruments do not touch each other. Move moving parts back and forth several times during cleaning.
5. Clean the lumens with a soft plastic brush.
6. If necessary, connect the rinsing adapter to the endoscopes.
7. At the beginning and at the end of the cleaning, rinse the lumens five times with cleaning solution (working channel 50 ml, rinsing and suction channel 10 ml).
8. Then rinse the products three times with sterile, deionized water.
9. Using a disposable syringe, rinse the lumens five times with sterile, deionized water (50 ml working channel, 10 ml irrigation and suction channel).
10. For cleaning the endoscopes, use a fresh cleaning solution.
11. Check the instruments (see chapter "Control" and "Maintenance").

Disinfection

12. Disassemble the endoscopes as far as possible. Remove the fiber optic connector, adapter, handle, irrigation valves, etc.
13. If necessary, connect the rinsing adapter to the endoscopes.
14. Place the endoscopes in the disinfectant solution for 12 minutes so that the instruments are adequately covered. Make sure that the instruments do not touch each other.
15. At the beginning and at the end of the disinfection, rinse the lumens five times with disinfectant solution (working channel 50 ml, rinsing and suction channel 10 ml).
16. Then rinse endoscopes five times with sterile, deionized water.
17. Using a disposable syringe, rinse the lumens five times with sterile, deionized water (50 ml working channel, 10 ml irrigation and suction channel).
18. Use a fresh disinfectant solution for the disinfection of the endoscopes.
19. ***The evidence of the general suitability of the instruments/devices for effective manual cleaning and disinfection has been provided by an independent accredited test laboratory using the detergent Cidezyme / Enzol and the disinfectant Cidex Opa (Johnson & Johnson GmbH, Norderstedt). The method described above has been considered.***

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10.5.3 Automated cleaning/disinfection (WD (Washer-Disinfector))

Pay attention to following points during selection of the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- possibility for an approved program for thermal disinfection (A_0 value ≥ 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter „material resistance„)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

Procedure:

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 (Disinfector G 7836 CD, Miele, Gütersloh). Make sure that the instruments do not touch each other.
4. Connect the lumens with suitable, flexible irrigation tubing and adapters.
5. Start the program.
6. The machine cleaning was carried out using "neodisher MediClean forte" 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.
8. After completion of the machine cleaning / disinfection, remove the endoscopes from the washer-disinfector under low-germ conditions.
9. *The fundamental suitability of the instruments for an effective automated cleaning and disinfection was demonstrated by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-cleaning and cleaning detergent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.*

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10.6. Drying
The endoscope, the camera head must be completely dry after disinfecting. Disinfected endoscopes should always be stored in a closed sterile area or cabinet and protected against heat, radiation, dust, moisture, temperature changes and contamination.

10.7. Check
Check the device after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities as functionality. Do not further use damaged device (for limitation of the numbers of re-use cycles see chapter „reusability„). Still dirty device is to be cleaned and disinfected again.

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

Inspection of the fibre optics
• Hold the distal endoscope end toward a lighted window or a bright ceiling light.

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

Look at the light guide connector. The individual fibres now appear bright. Move the bright ceiling light facing side slightly up and down. The brightness of the fibres changes a bit. It is uncritical if individual fibres remain dark. A fracture rate of about 20 to 30% impedes the endoscopic procedures strongly.

- 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 application and processing may result in progressive endoscope damage.

Caution:
Endoscopes with damaged fibre optics should be sent in to the manufacturer or an authorized service specialist for checking.

Verification of the proximal and distal areas of glass

- 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 or toothpick. 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.

Caution:
Endoscopes with indelible persistent encrustations should be sent in to the manufacturer or an authorized service specialist for checking.

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

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10.8. Maintenance

Instrument oils or grease must not be applied.
Put the disassembled endoscopes (fibre optic light guide, handles) together again.

Please note:
Endoscopes do not require regular maintenance carried out by the manufacturer.

10.9. Packaging

Please insert the cleaned and disinfected device in single-use sterilization packaging's (single or double packaging), which fulfil the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 138 °C (280 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packaging against mechanical damage

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

Avoid contact of the aluminium ferrule with the plug and camera surface.

Avoid scratches on the surface.

10.10. Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure[3, 4] (with sufficient product drying[5])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature):

Area	**fractionated vacuum/dynamic air removal**	**gravity displacement**
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min[5]	not recommended
other countries	at least 5 min[6] at 132 °C (270 °F) / 134 °C (273 °F)	not recommended

[3] at least three vacuum steps

[4] The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure, requires significantly longer sterilization times as well as a sterilizer, procedure, parameter, and product specific validation under sole responsibility of the user.

[5] The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

[6] respectively 18 min (inactivation of prions, not relevant for USA)

The flash/immediate use sterilization procedure must not be used.

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Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

This results in the following parameters for use on our endoscopes:

max.138°C
AUTOCLAVE
max.3 bar / 18 min

[1] The use of less effective gravitational method is permitted for non-availability of the fractionated vacuum method only ,can have significantly longer exposure times and has to be validated by the user as to suitability and effectiveness.

The evidence of the general suitability of the instruments/devices for effective steam sterilization has been provided by an independent accredited test laboratory using the steam sterilizer Systec V-150 (System GmbH Labor Systemtechnik, Wettenberg) and the fractionated vacuum procedure. At this, typical conditions in clinics and medical practices as well as the method described above has been considered.

Caution:
Flash sterilization is not permitted.

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

Caution:
Other settings of autoclave and autoclave cycles might have negative effects on the device or its components.

Caution:
Weight and load of the sterilization material must not be exceeded as it may cause excessive condensate and result in rust damage.

Caution:
When sterilizing multiple instruments in a sterilization cycle, do not exceed the maximum load of the sterilizer.

Caution:
Please note that with increasing number of instruments in a sterilization cycle the success of sterilization will be decreased.
Please refer to the manufacturer's instructions.

Caution:
The dryness of the optics has be achieved after cooling to room temperature.

Caution:
Please follow the sterilizer manufacturer's instructions, especially the ventilation times after sterilization. The relevant national legal regulations have to be observed.

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Hint:
It is the user's responsibility to implement the listed sterilization processes in order to achieve the desired and required sterilization effects.


The instructions of the sterilizer manufacturer have to be strictly adhered to.

Note:
Please do not forget to attach the adapter, the one-way cocks and other accessories after sterilization again. The one-way cocks have to be greased after sterilization always. Use approved medical sterile fats only.

10.11. Storage
Please store the device after sterilization in the sterilization packaging's at a dry and dust-free place.

10.12. Material resistance
Be careful in the selection of cleaning and disinfecting agents. Ensure that the following components are not included:

Substances that are:
- organic, mineral and oxidizing acids (minimum admissible value pH 5.5)
- strong alkalis (maximum admissible value pH 11, neutral / enzymatic or slightly alkaline detergent recommended)
- organic solvents (for example: alcohols, ethers, ketones, benzenes)
  oxidizing agents (for example: hydrogen peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic / halogenated hydrocarbons
- oils

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.
Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments by use of metal brushes or steel wool.

Please do not expose any instruments to temperatures higher than 138 °C (280 °F)

10.13. Reusability
Frequent reprocessing of rigid endoscope optics has an impact on their usability. The end of product lifetime is usually determined by wear and damage caused by use.

Please note:

If appropriate care is taken and if the rigid endoscopes are undamaged and clean, they can be used up to 10 cycles. Any further re-use or the use of damaged and / or contaminated instruments is the responsibility of the user.

If you are unsure, however, if your endoscope optics is ready for use, we recommend to return the rigid endoscope for inspection or for replacement to our service-address.

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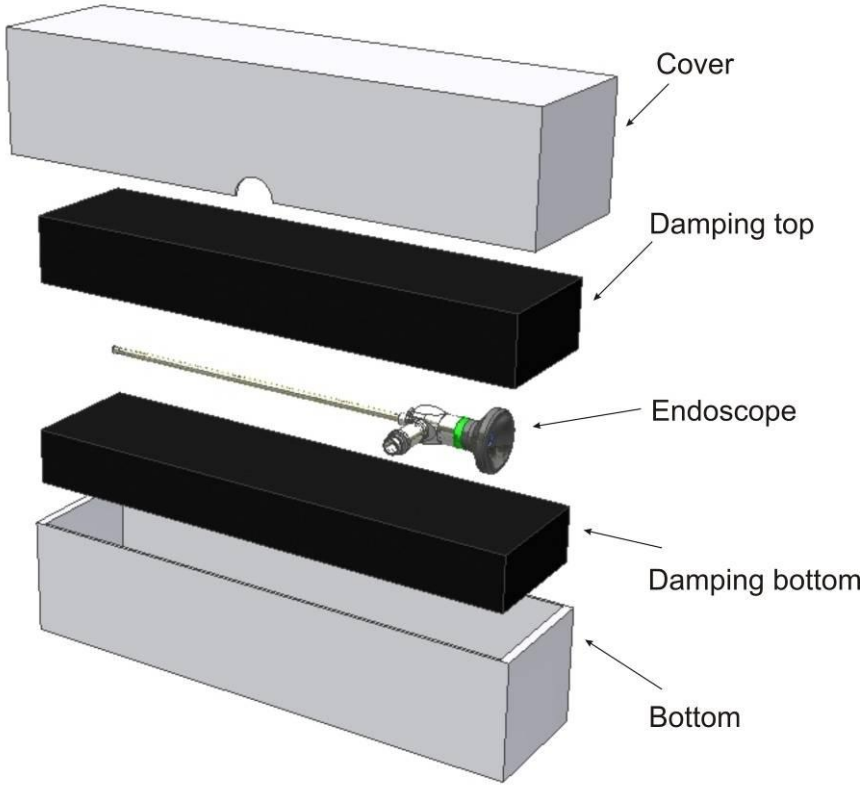
11. Packaging / storage / transport

Caution!
LiteOptics Ltd. rigid endoscopes are supplied non-sterile

The original package includes:	1 piece	Cover topside made of cardboard
	1 piece	Damping-top part made of foam
	1 piece	Damping-bottom made of foam
	1 piece	Bottom-lower shell made of cardboard



Please use for any necessary return of endoscopes or accessories the original packaging.

Make sure that sterile endoscopes are returned only.

Store non-sterilized endoscopes protected against heat, radiation, dust, moisture and temperature fluctuations always.

Store sterilized endoscopes in sterile and suitable containers always. Store closed containers in a sterile area or cabinet protected safely from heat, radiation, dust, moisture, temperature fluctuations and contamination.

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11.1 Storage

Store non-sterilized endoscopes always protected from heat, radiation, dust, moisture and temperature changes.

Sterilized endoscopes should always be stored in sterile containers or storage containers in a closed sterile area or cabinet provided safe and protected from heat, radiation, dust, moisture and temperature fluctuations.

Temperature range of the storage should be between 5°C till 40°C.

The humidity should be between 10% till 90%.

The air pressure should be between 50kPa till 107kPa.

11.2 Transport

When returning endoscopes or accessories, please always use the original packaging.

Please mark the packaging with
! Caution Risk of breakage !

Avoid strong vibrations and shocks.

Avoid piercing objects through the box.

Make sure that only sterile endoscopes are returned.

Temperature range of the storage should be between -10°C till 60°C.

The humidity should be between 5% till 95%.

The air pressure should be between 50kPa till 107kPa.

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12. Trouble shooting

Problem	Possible cause	Remedying of defect
Picture cloudy, foggy	- Glass surfaces contaminated	- Cleaning of glass surfaces according to section 10.5 (manual cleaning)
	- Deposits, coarse encrustations of glass surfaces	- Remove deposits according to section 10.5, check water quality
	- Leaky, defective lens system	- Send in the endoscope for repair
Picture too dark, too small illumination	- Glass surfaces contaminated	- Cleaning of glass surfaces according to section 10.5 (manual cleaning)
	- Deposits, coarse encrustations of glass surfaces	- Remove deposits according to section 10.5, 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 10.8
	- Defect light conducting cable, light source	- Check light conducting cable, light source
Yellowish lighting	- Dirty fibre optics	- Cleaning of glass surfaces according to section 10.5 (manual cleaning) 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
	- Inadequate rinsing of endoscope between treatment phases (especially before sterilization)	- Ensure thorough rinsing between the treatment phases (see section 10.5 and 10.6)
	- 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

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13. Warranty, service and repair

The LiteOptics Ltd. provides 12 months warranty of the rigid endoscope without working channel function.
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, mishandling, improper or inadequate treatment or due to force majeure. In cases of maintenance or repair, please contact the LiteOptics Ltd. service or an authorized repair specialists:

LiteOptics Ltd
The Nucleus
Chesterford Park
Little Chesterford
Essex
CB10 1XL
United Kingdom

Telephone Number; +44(0) 1799542716
Email; enquiries@liteoptics.com

In the interest of rapid processing of service requests, we ask you to send in the product with the following information:
• Item number (REF)
• Serial number (SN)
• Detailed fault description

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Caution:
To protect your personnel and LiteOptics Ltd. staff, please clean and sterilize the endoscope (possibly related accessories) thoroughly before sending in.
Is it for compelling reasons not possible the endoscope should be reprocessed as far as possible and labelled appropriate.
For safety reasons LiteOptics Ltd. service can decline the repair of soiled or contaminated products.
If the user does repair the endoscope himself or hand it out to an unauthorized repair/service facility all warranty and guarantee claims will be lost.

Unauthorized opening, repair and modifications of the device relieve the manufacturer from any liability for the reliability of the system. During warranty period therefore all warranty will void.

The manufacturer is obliged to warrant the function of the device for a period of 12 month.
This warranty is limited to claims made within the warranty period, which begins with the date of purchase**.** This warranty applies to defects only that are not normal wear and tear, misuse or mishandling, lack of care or force majeure. This warranty excludes wear parts.
For inquiries or ordering of spare parts, the type and serial number should be specified always.

Specialist supplier:

Manufacturer:

LiteOptics Ltd.
Abbey House
51 High Street
Saffron Walden
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CB10 1AF
United Kingdom

Telephone Number: +44(0) 1799542716
Email; enquiries@liteoptics.com

If you have further questions, we will be pleased to answer them.

You can contact us from 8:00 - 16:30 daily.

14. Waste management

The implementation of European legislation into national laws and regulations obliges you to dispose medical devices appropriately.
The symbol below indicates that medical devices have to be disposed separately from household/consumer waste.
Please dispose medical device waste according to national and local regulations.

Dispose used and contaminated medical equipment at a collection point of a suitable waste authority.
Medical waste is classified according to dangerous goods legislation (for transportation) to the UN number UN 3291 (Medical Waste).
Please attach the symbol below at the waste container.
Please dispose medical waste according to national and local regulations.

Packaging material, as long as not contaminated, dispose according to relevant national and local regulations.

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