

LUT GmbH

**Instruction Manual
for
Flexible Endoscopes**



Naso - Pharyngoscope

CE

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1 Introduction

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

Indications: The use of *LUT* endoscopes is indicated in endoscopic procedures and other incisions in the field of minimal invasive surgery.

Contra indications: The use of *LUT* endoscopes is contra-indicative to the extent that endoscopic procedures are contra-indicative.

Attention: The instruction manual gives sound information about the correct use and possible applications of the unit. Therefore the instruction manual should always stay with the camera.

All persons who are handling those units should have read the instruction carefully. The use of the units is only allowed after studying the manual.

The instruction manual contains important information which is needed to ensure a safe, a correct and an economic operation of these units.

Future technical changes are reserved to be changed compared to current pictures.

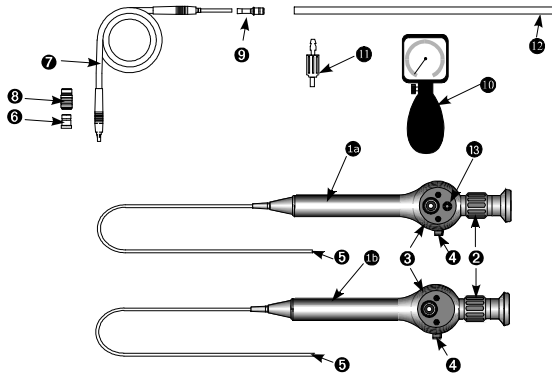
This instruction manual is meant to facilitate the use of *LUT* endoscopes; it is in no way an instruction manual for endoscopic procedures.

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

Attention:

U.S. Federal law restricts this product to sale by or on the order of the physician.

2 Setup of Appliance



- 1a Flexible endoscope with air-exhaust valve
- 1b Flexible endoscope without air-exhaust valve
- 2 Diopter setting (focussing)
- 3 Light cable connection for ACMI/British Standard (on opposite casing sides)
- 4 Lever for distortion (on/off)
- 5 Lens
- 6 Throw-over cover for light cable
- 7 Light cable
- 8 Light cable connection cover for ACMI cover
- 9 Light cable connection cover for light source
- 10 Density tester (optional)
- 1 Valve cap (optional)
- 12 Silicon tube (optional)
- 13 Air-exhaust valve (optional)

3 Key to the Symbols

	Warning: indicates a hazard. If not avoided, the hazard can result in death or serious injury.
	Caution: indicates a potential hazard. If not avoided, this hazard may result in minor personal injury or product/property damage.
	CE-mark according to relevant EC directives
	Safety standard BF according EN60601-1
	Manufacturer

4 CE - Label

The CE-mark certifies that the product corresponds to the following directives:

Medical Devices

according to Medical Device Directive 93/42/EEC respectively Medical Device Law (MPG).

Products for Industrial Applications

according to Low Voltage Directive 2006/95/EEC and/or EMC-Directive 89/336/EEC respectively EMC-Law and/or Machinery Directive 98/37/EEC.

5 Short Description

This short description is intended to give you a quick overview of the cleaning, disinfection and sterilization procedures for **LUT** endoscopes. Detailed instructions and hints given in the operating instructions manual should be followed.

Before each medical use, **LUT** endoscopes should be checked to ensure that there are no damages and that the endoscopes must be disinfected and cleaned as per the medical indications.

5.1 Cleaning

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



Caution: Endoscopes should not be decontaminated and cleaned in an ultrasonic bath.



Caution: Do only use released disinfectant. Do not insert the endoscope in alcohol.

5.2 Short testing

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

5.3 Gas sterilization

Flexible **LUT** endoscopes with air-exhaust valve can be gas sterilized using ethylene-oxide or formaldehyd. For procedure parameters and instructions, please refer to the details provided by the respective manufacturers.

5.4 Low temperature Plasma Sterilization

Flexible *LUT* endoscopes with air-exhaust valve can also be sterilized using the low temperature plasma sterilization procedures STERRAD® 50, STERRAD® 100S and STERRAD® 200®. For procedure parameters and instructions, please refer to the details provided by the respective manufacturers.

Note

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

6 Important Hints

General Hints

You have decided in favor of a *LUT* endoscope; you have thus acquired a high-value product. It is however necessary to handle this equipment with care because flexible endoscopes are highly susceptible to bending pressure, tight wrapping, sudden impacts as well as torsion, drawing or pressure strain. This can lead to damage to the optical components resulting in malfunctioning of the equipment.

When accessories or additional components are used in conjunction with the medical product, the unrestricted function of the medical product's intended purpose must be guaranteed. This needs to be verified by the operator before use.

Note

If there is light shining through the highly flexible, thin-walled probe tube, this is due to the loss of sheathing taking place continuously in the case of light fibers. This appearance in varying intensity has no effect on the illumination intensity at the tip of the flexible endoscope.

LUT endoscopes are delivered unsterilized and have to be cleaned and sterilized as per medical indications before they are put to use (for details refer the section on Cleaning and Sterilization).



Caution: Endoscopes should not be decontaminated and cleaned in an ultrasonic bath.



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Endoscopic procedures should only be carried out by qualified professionals (e.g. doctors) with corresponding training and familiarity with endoscopic procedures. It is the responsibility of the user to be continuously updated about indications, contra-indications, possible complications and risks as well as developments of endoscopic procedures.

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

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

The endoscopes and corresponding endoscopic accessories must be checked for any possible optical or mechanical defects before each use to avoid risks of injury. Damaged or defective endoscopes should be put out of use. In case of doubt, please contact your dealer or the manufacturer.

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

Hints for combination with other medical products

There are numerous vistas opened for combinations with laser and HF surgery, pneumatic or electro-hydraulic lithotriptors. In such cases, please follow the operating instructions manuals and safety instructions of devices and the accessories used.

While using the endoscope in combination with electro-medical devices, ensure that the BF conditions (insulated, earth-free usage parts) are maintained.

When endoscopes are used with electro-medical devices and/or power-driven endoscopically used accessories, this can lead to an addition of the leakage current. Failure of the used light source can lead to risks. Hence keep an additional light source at hand or use light sources that have a substitute lamp.

In combination with high performance light sources, the temperatures of the light source and the instruments can reach levels causing burns. Furthermore, light of high radiance energy can lead to an increased temperature in the tissue. Hence, avoid direct tissue contact and if possible, ensure adequate rinsing of the operation area.

Hints for using endoscopes with high frequency surgical instruments

Before using endoscopic high frequency surgery, the patient should be suitably prepared for the incision. Measures should be taken to remove or avoid formation of combustible gases.

In contrast to conventional high frequency surgery, unsuitable (especially too low) performance setting can lead to a predominant depression in the surrounding tissue. Hence, performance tuning is to be done based on the experience of the person using this technique after considering clinical references and/or suitable training.

In order to avoid burns and/or undesirable depressions in the surrounding tissue or damage to the endoscope, it is advisable to switch on the high frequency current only after the application part (electrode) can be seen through the endoscope.

Hints for use in combination with laser devices

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

In order to avoid burns and/or undesirable depressions in the surrounding tissue, laser performance should be activated only after the tip of the laser fiber can be seen through the endoscope.

Hints for usage with lithotriptors

In order to avoid risks and taking into account all possible restrictions for use, please pay attention to the device specific operating instructions and safety hints for all ultrasonic, pneumatic or mechanical lithotripsy.

Stone extractions using stone forceps can be done by using operation shafts or the working channel of the endoscope. The required specifications of the instruments usable can be taken from the technical specifications of the respective products.

7 Preparation (Disinfection, Cleaning, Sterilization)

7.1 Introduction

The procedures for preparation and maintenance listed in the following sections are to be viewed as recommendations. *LUT* endoscopes with air-exhaust valve can also be disinfected, cleaned and sterilized using other methods.

It is the responsibility of the user to prepare the endoscopes in order to attain the required degree of disinfection, cleaning and sterilization.

Please note that the method in which the endoscopes will be prepared will eventually have considerable bearing on the life-span of the endoscopes.

7.2 Dismantling, Dehumidification and Decontamination

In order to avoid drying up of blood, protein or other substances on the endoscopes and also to protect the staff, visible impurities should be removed immediately after the surgery using a soft cloth. It is necessary to dehumidify the endoscope immediately after it has been used for an operation. Dried up protein makes cleaning and disinfection a difficult task.



Caution: Endoscopes should not be decontaminated and cleaned in an ultrasonic bath.



Caution: Do only use released disinfectant. Do not insert the endoscope in alcohol.

Procedure

- Unscrew the used adapters (e.g. for different light cables) from the endoscope (refer diagram 1).
- If the flexible endoscope has an air-exhaust valve, conduct a density test before soaking it in any liquids. Conduct the following test:
Unscrew the valve cap, connect the silicon tube and using the pressure unit, set up a pressure of 160 mm Hg. Wait for 30 seconds and observe the fall in pressure. A fall in pressure of max. 2 mm Hg is normal.
- Place the endoscope and the unscrewed parts in a suitable disinfection solution (can also double up as a cleaning solution). The disinfection solution used should be permitted by the manufacturer for such use.

Material compatibility releases exist for the following disinfectants:

- Gigasept FF, Schülke & Mayr GmbH
- Lysetol FF
- Helipur HplusN, B. Braun Medical AG
- Cidex, Johnson & Johnson
- Please use one of the released disinfectants. These details are only with respect to material compatibility and they are in no way related to the germ-killing properties. The user has to ensure that the degree of disinfection is attained.
- For concentration and soaking time, please refer the guidelines of the manufacturer of the disinfectant. As there are no advantages of soaking the equipment for a period longer than prescribed, avoid soaking the endoscope for a period exceeding the prescribed limit as it can perhaps only lead to damages to the endoscope. Also ensure that the solution reaches all the surfaces including working channels and hollow spaces.

- If it is necessary to use a separate cleaning agent, it is advisable to use the disinfectant and a cleaning additive from the same manufacturer. Also pay attention to the mutual compatibility of the used solutions and strictly follow the instructions of the manufacturer with respect to concentration and soaking time.
- Finally, the endoscopes must be rinsed with adequate deionised (distilled) water.
- If there is no possibility for dehumidification, the external layer of the flexible endoscope must be cleared of all impurities (secretions, etc.) This is best done by using a disposable cloth soaked in disinfection solution or rinsing the flexible endoscope carefully using a hand spray.

7.3 Cleaning

Cleaning is necessary for hygienic reasons and also for protecting the next patient.



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- Unscrew the used adapters (e.g. for different light cables) from the endoscope (refer diagram 1).
- If the flexible endoscope has an air-exhaust valve, conduct a density test before soaking it in any liquids. Conduct the following test:
Unscrew the valve cap, connect the silicon tube and using the pressure unit, set up a pressure of 160 mm Hg. Wait for 30 seconds and observe the fall in pressure. A fall in pressure of max. 2 mm Hg is normal.
- Use only mild cleaning substances for dissolving the impurities. These cleaning agents should have been approved by the manufacturer for such use. While using the different substances, pay attention to the details provided by the manufacturer with respect to concentration and soaking time.
- For mechanical cleaning, use soft cloth, cotton and special brushes. For channels and hollow spaces, it is especially advisable to use suitable brushes.
- Dirt at the endoscope can be removed using cotton soaked in alcohol (70 % ethanol) or a neutral cleanser.
- After cleaning, all the parts are to be thoroughly washed using deionised (distilled) water in order to remove the last traces of impurities and residues of cleaning agents.
- Finally dry the endoscope and all the individual accessories using a tissue or soft absorbent cloth. Bridges and crevices should be cleaned and dried with compressed air.
- Unless an immediate sterilization is planned following the cleaning, it is advisable to fit back the adapters that had been removed.

Tips for manual cleaning

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

Color eloxated endoscopy parts or the plastic components (e.g. serial rings, ocular funnel) may fade and lose their color intensity in the course of cleaning.

7.4 Inspection

The endoscope must be inspected directly before sterilization.

Density Test (for endoscopes with air-exhaust valve)

- Unscrew the valve cap, connect the silicon tube and using the pressure unit, set up a pressure of 160 mm Hg. Wait for 30 seconds and observe the fall in pressure. A fall in pressure of max. 2 mm Hg is normal.

Checking the fiber optic

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

Note

If there is light shining through the highly flexible, thin-walled probe tube, this is due to the loss of sheathing taking place continuously in the case of light fibers. This appearance in varying intensity has no effect on the illumination intensity at the tip of the flexible endoscope.

- The surfaces of the light inlets and outlets should be smooth and clean. If the surfaces show certain deposit layers, or rough fibers can be felt or are withdrawn, this can lead to inadequate illumination. If the endoscope is used or prepared in this condition, it may be continuously damaged.



Caution: Endoscopes with damaged fiber optic should be sent for inspection to the manufacturer or a service center.

Checking the proximal and distal glass surfaces of the endoscope surface

- The glass surfaces must be clean and free from deposit layers. If at the time of visual inspection of the glass covers you notice stubborn encrusting, these can be removed using appropriate cleaning pastes. The cause of these precipitations is often inadequate rinsing of the optics after cleaning and disinfection procedures.
- The image must be sharp and clear in the corresponding working distance as per the indication. The special optical properties in case of image bundle endoscopes are to be considered. A dull, dusky image is a pointer to damages.
- The endoscope surfaces must be free of damage and sharp edges. Pay attention to dents, mechanical/thermal defects due to high frequency or laser surgery instruments as well as cracks and spallings at the ocular eye cup.



Caution: If stubborn residues cannot be removed by cleaning, the endoscope must be sent to the manufacturer or a service center for inspection.

Endoscopes with damaged glass surfaces (e.g. cracks), impaired image quality or noticeable surface damages or distortions should not be used. They should be kept aside and sent for inspection to the manufacturer or an authorized service center.

7.5 Sterilization

First check the sterilization method most suitable for your flexible endoscope. Please note that flexible endoscopes cannot be autoclaved.

Before sterilization, ensure that the endoscope and especially the surfaces are clean and a testing of the endoscope as per point 7.4 does not lead to any findings that impose restrictions on the use.

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

Gas sterilization

Flexible *LUT* endoscopes with air-exhaust valve can also be gas sterilized using ethyleneoxide or formaldehyd. For procedure parameters and instructions, please refer to the details provided by the respective manufacturers.

Low temperature Plasma Sterilization

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