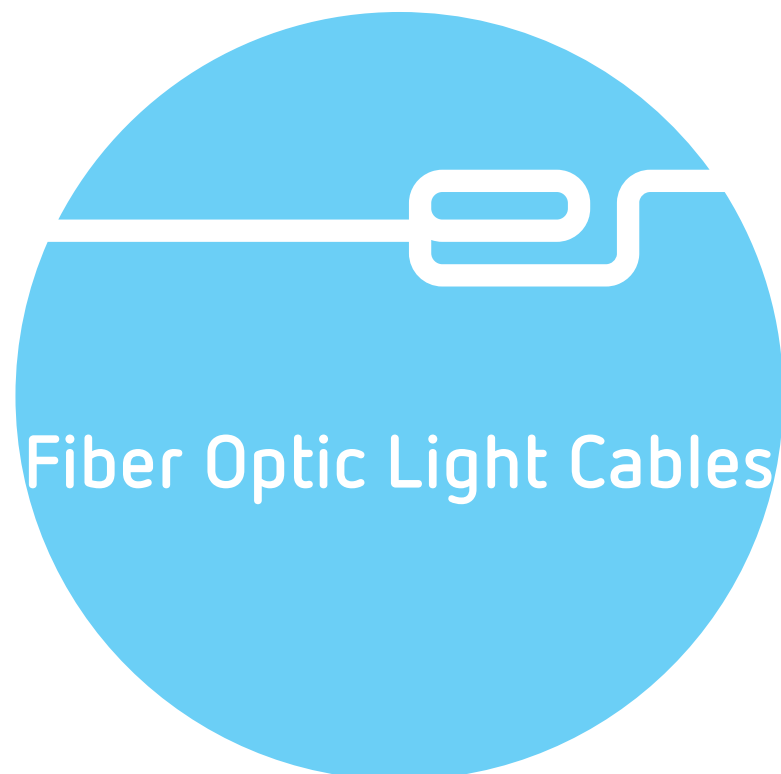


USER MANUAL





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USER MANUAL

Fiber optic light cables



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Chapter 1

Safety instructions

Safety instructions and levels of danger

IMPORTANT! || Please read these safety instructions carefully, before using the camera system on a patient, it is extremely important that you are familiar with the equipment operation and control.

WARNING! || Failure to observe can result in death or severe injury.

CAUTION! || Failure to observe can result in slight injury or damage to the product.

IMPORTANT! || Failure to observe can result in damage to the product or surrounding.

NOTE! || Tips for optimum use and other useful information.

Chapter 2

Safety information

- WARNING!**
- Always have back-up fiber optic light cables available in case of failure during a procedure.
 - Immediately before and after every use, the fiber optic light cable and accessories used with it must be examined for fault free state, correct functioning, and completeness!
 - Damaged fiber optic light cables must be withdrawn from use immediately!
 - Because of the high amounts of light energy, the light input surfaces and illuminated surfaces can heat up to an extent that may result in burns!
 - Light sources may be used for the above purpose only if the maximum temperatures of use (see above) are complied with.
 - Never look into the open end of a fiber optic light cable which is connected to a light source! Risk of blinding!
 - The fiber optic light cable is not provided in a sterile state. Consequently, before first use and every subsequent use, the fiber optic light cable must be cleaned, disinfected, and/or sterilised by means of validated processes!
 - A minimum bending radius of 50 mm is permissible in the flexible section of the hose.
 - Bending of fiber optic light cable beyond permissible minimum bending radius may cause fiber breakages.
 - Installation information: The fiber optic light cable may not be bent or crushed at any time.
 - The fiber optic light cable is not suitable for mechanical, dynamic movements. It may only be subjected to manual bending movements that are within the limits of the minimum bending radius.
 - The fiber optic light cable must not be used under tension during installation and use.
 - The fiber optic light cable is not intended for invasive use!

- IMPORTANT!**
- User should check legibility of markings before each use. Do not use the product if it is not clearly legible. Report the product to manufacturer in such case.



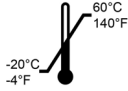

Chapter 3

General information

This user manual is for following article no.

20820-000 and 20821-000

Symbols

Symbols	Meaning
	Caution
	Read the operating instructions prior to use
	Storage conditions (-20°C to +60°C)
	Identification in conformity with Medical Devices Regulation 2017/745.

Intended use

The universal fiber optic light cable is used for endoscopic applications to transmit light during endoscopic diagnosis and therapy, or for other medical illumination applications when the properties and operating instructions are complied with.

The fiber optic light cables are designed for use with halogen, xenon or LED based sources of cold light that are utilised in medical applications that involve endoscopes, medical instruments or microscopes and are equipped with an optical injection element for fiber optic light cables with a bundle diameter of 4.8 mm or 3.5 mm. High intensity visible light is conducted to the instrument through flexible fiber optic light cables.

The use of the fiber optic light cable together with LASER light sources and/or HF devices is not permitted. When selecting the light sources, follow the information provided under instructions on use and reprocessing, regarding the temperatures of use.

Contraindication

Contraindications related directly to the product are currently not known

Chapter 4

Product description

The fiber optic light cable is composed of an environmentally friendly fibre optic bundle, which is hot fused to the light input surface. The end sleeves make it possible to connect any ordinary adapter sleeves (not included) which can be screwed on by the medical staff for all common endoscopes and light sources. The fiber optic light cable is distinguished by the following optical characteristics:

Angle of acceptance (2α):	$\geq 70^\circ$ at 587 nm ($V(\lambda)$, 1m length) →NA ≥ 0.57
Transmission:	$\geq 60\%$ at 546 nm (typically $\geq 65\%$)

Combinations

The fiber optic light cable shall be used with Light sources and telescopes from Erbe vision.

Recommended Fiber optic cable sizes for different telescopes:

- Fiber optic cable \varnothing 3.5 mm for telescopes \varnothing 2 - \varnothing 5.5 mm
- Fiber optic cable \varnothing 4.8 mm for telescope \varnothing 10 mm

CAUTION! || Risk of Telescope heating!
|| Use only recommended sizes of fiber optic cable with the corresponding telescopes.

WARNING! || Risk of injury due to unapproved configuration using additional components!
|| For all applied components, ensure that their classification matches that of the application component (e.g. Type BF or Type CF) of the respective device.

CAUTION! || Risk of product damage!
|| Use only recommended adapters for connection with telescopes and light sources.

Chapter 5

Instructions on use and reprocessing

General principles

WARNING! Risk of Burns from the hot ends of optical fibers!

- When using the product with a cold light source, make sure that the ends of the optical fibers do not touch human tissue or highly inflammable or heat-sensitive materials.
- Do not touch the distal end of the fiber optic light cable.

The fiber optic light cable must be cleaned, disinfected and sterilised prior to each application. This is of particular importance when the fiber optic light cable is used for the first time after delivery as all fiber optic light cables ship in a non-sterile state (clean and disinfect after removing the transport packaging; sterilise after packaging). Efficient cleaning and disinfection is an essential requirement for effective sterilisation.

The user's responsibility with regard to ensuring sterility comprises

- the exclusive use of device and product specific procedures that have been validated as sufficient for cleaning/disinfecting and sterilising,
- the assurance that all devices used (disinfector, steriliser) are serviced and checked on a regular basis, and
- the assurance that the validated parameters are observed during every cycle.

The user is also required to observe all applicable statutory regulations and the rules established by the doctor's office or the hospital that concern hygiene. This applies in particular to the different regulations regarding an effective inactivation of prions.

Cleaning and disinfection

If possible, a mechanical procedure (disinfector) must be used for cleaning and disinfection. A manual procedure – even if involving the use of an ultrasonic bath – should be not be used unless a mechanical procedure is not at hand due to the significantly lower effectiveness and reproducibility of a manual procedure.

The following pre-treatment must be performed in either case:

Coarse impurities must be removed from the fiber optic light cable immediately following each application (within no more than 2 hrs).

CAUTION! Cleaning, disinfection and subsequent sterilisation with the adapter sleeves screwed on is not permitted. They must be removed and reprocessed separately prior to the reprocessing of the fiber optic light cable.

Use running water or a disinfectant solution for this purpose; the disinfectant should be aldehyde free (otherwise, blood contamination will become fixed in place), be of certified effectiveness (e.g. have VAH/DGHM or FDA approval or be labelled with the CE mark), be suitable for disinfecting the fiber optic light cable and be compatible with the instruments (see Chapter Material stability). Use only a soft brush and a soft cloth or cotton swabs to manually remove all visible impurities on the fiber optic light cable and the light input and light output surfaces, respectively. Use these items only for the purpose of removing impurities and refrain from using metal brushes or steel wool. Abrasive cloths or sponges may scratch these surfaces as well and are not suitable for cleaning.

Please note that the disinfectant used during the pre-treatment is only intended to provide operator protection and cannot substitute for the disinfecting step that needs to be completed later – when cleaning is finished.

Mechanical cleaning/disinfection

When selecting the disinfector (combined cleaning and disinfecting unit), make sure

- that the effectiveness of the disinfectant has been proven in principle (e.g. DGHM or FDA approval / CE mark in accordance with DIN EN ISO 15883),
- that, if possible, a certified program for thermal disinfection (A0 value > 3000 or – for older units – at least 5 min at 90°C) is employed (risk of disinfectant residue on the fiber optic light cable during chemical disinfection),
- that the employed program is suitable for the fiber optic light cable and comprised of a sufficient number of rinsing cycles,
- that you use only water that is sterile or has a low germ (max. 10 germs/ml) and a low endotoxin (max. 0.25 endotoxin units/ml) content (e.g. purified water / highly purified water),
- that the air used for drying is filtered, and
- that the disinfector is serviced and checked on a regular basis.

When selecting the cleaning agent system to be used, make sure

- that this system is, in principle, suitable for cleaning instruments made of metals and plastics,
- that – if no thermal disinfection is employed – a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval / CE mark) is used and that this disinfectant is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the fiber optic light cables (see Chapter Material stability).

The concentrations specified by the manufacturer of the cleaning agent and, if applicable, the disinfectant must be strictly observed.

Process:

1. Place the fiber optic light cable in the disinfectant. Make sure the instruments do not come into contact with one another and the minimum permissible bending radius is 50 mm.
2. Start the program.
3. Remove the instruments from the disinfectant when the program is complete.
4. Check and package the fiber optic light cables as quickly as possible after taking them out - if necessary after additional drying in a clean location.

The general suitability of the instruments for efficient mechanical cleaning and disinfection was proven by an independent, accredited test laboratory using the disinfectant G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the cleaning agent NEODISHER MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was applied for this process.

Manual cleaning and disinfection

When selecting the cleaning agents and disinfectants to be used, make sure

- that they are, in principle, suitable for cleaning / disinfecting instruments made of metals and plastics,
- that the cleaning agent – if applicable – is suitable for ultrasonic cleaning (no foam generation),
- that a suitable disinfectant with proven effectiveness (e.g. VAH/DGHM or FDA approval / CE mark) is used and that this disinfectant is compatible with the cleaning agent used, and
- that the chemicals used are compatible with the fiber optic light cables (see Chapter Material stability).

Combined cleaning agents/disinfectants should be avoided if possible. Combined cleaning agents/disinfectants may only be used if contamination is low (no visible impurities).

The concentrations and residence times specified by the manufacturer of the cleaning agents and disinfectants as well as the specifications for rinsing must be strictly observed. Use only freshly made solutions as well as water that is sterile or has a low germ (max. 10 germs/ml) and a low endotoxin (max. 0.25 endotoxin units/ml) content (e.g. purified water/highly purified water) and filtered air for drying.

Process:**Cleaning**

1. Immerse the fiber optic light cable in the cleaning bath for the specified residence time. While doing so, make sure the fiber optic light cables do not come into contact with one another and are covered sufficiently. Completely brush off the fiber optic light cable*, – using a soft brush after half of the residence time has elapsed. – *But do not brush the light input and light output surfaces use only a soft cloth or cotton swabs for cleaning the light input and light output surfaces.
2. Proceed by removing the fiber optic light cables from the cleaning bath and rinse them completely at least three times for 1 minute under running water.
3. Check the fiber optic light cables for any damage.

Disinfection

4. Immerse the cleaned and checked fiber optic light cable in the disinfectant bath for the specified residence time, making sure that the fiber optic light cables are covered sufficiently. Ensure that the fiber optic light cables are not in contact with one another.
5. Proceed by removing the fiber optic light cables from the disinfectant bath and rinse them completely at least five times for 1 minute under running water.
6. Dry the fiber optic light cables by blowing them off with filtered compressed air.
7. Package the instruments as quickly as possible after taking them out - if necessary after additional drying in a clean location.

The general suitability of the instruments for efficient manual cleaning and disinfection was proven by an independent, accredited test laboratory using the cleaning agent Cidezyme/Enzol and the disinfectant Cidex opa (Johnson & Johnson GmbH, Norderstedt). The procedure described above was applied for this process.

Inspection

When cleaning or cleaning/disinfection is complete, check all fiber optic light cables for corrosion, damaged surfaces, chippings, markings and impurities and sort out any damaged fiber optic light cables. The fiber optic light cables must be disposed off after no more than 100 reprocessing cycles (see Chapter Reusability). If still soiled, the fiber optic light cables must be cleaned and disinfected again.

WARNING! || Risk of burns/ Product damage!
|| Improper cleaning of fiber optic light cable can cause the heating of telescope.

CAUTION! || Improper cleaning of fiber optic light cable can reduce the light transmission.

Maintenance

Neither maintenance nor installation are required. The use of instrument oils is not permitted.

It is recommended to the user to check light transmission output every year or whenever there is doubt.

Do not modify the product. For service and repairs, please contact the manufacturer.

Packaging

Please package the fiber optic light cable in single use packages (single or twin packaging) made of paper/film (mandatory for steam sterilisation) or Tyvek/film (mandatory for LTP sterilisation) which meet the following requirements:

- DIN EN ISO/ANSI AAMI ISO 11607
- suitable for steam sterilisation (min. temperature resistance up to 141 °C (286 °F), sufficient vapour permeability) or LTP sterilisation (Tyvek)
- sufficient protection of the fiber optic light cables or sterilisation packages against mechanical damage

Sterilisation

Only the sterilisation procedures listed below may be used for sterilisation; other sterilisation procedures are not permissible:

Steam sterilisation

- fractionated vacuum process or gravitation procedure¹ (with sufficient product drying)
- Steam steriliser according to DIN EN 13060 or DIN EN 285
- validated in accordance with DIN EN ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134) (valid IQ/OQ (commissioning) and product-specific performance qualification (PQ))
- maximum sterilisation temperature 138°C (280°F; plus tolerance according to DIN EN ISO 17665 (formerly: DIN EN 554/ANSI AAMI ISO 11134))
- Sterilisation time (exposure time with sterilisation temperature) at least 5 min² (gravitation procedure) and 3 min² (fractionated vacuum process) at 132°C (270°F)/134°C (273°F)

CAUTION!

- As a basic principle, the use of Tyvek/film sterilisation packaging is not permissible for steam sterilisation; only the use of paper/film sterilisation packaging is permitted!
The use of a sterilisation container requires that the client be responsible for conducting inspections that are specific to the product, load capacity, procedure, and steriliser and establish that the sterilisation efficiency is unaffected.
- The use of flash sterilisation or other procedures that are intended exclusively for use without sterilisation packaging is not permissible under any circumstances!

The general suitability of the instruments for efficient steam sterilisation was proven by an independent, accredited test laboratory using the steam steriliser Systec V-150 (Systec GmbH Labor-Systemtechnik, Wettenberg); this proof has been established for both the fractionated vacuum process and the gravitation procedure. This process considered both conditions typically found in hospitals and doctor's offices and the procedure described above.

¹ The use of the less effective gravitation procedure is not permitted unless the fractionated vacuum process is not available.

² or 18 min (prior inactivation)

Low-temperature plasma (LTP) sterilisation

- LTP steriliser in accordance with DIN EN ISO 14937
- validated according to DIN EN ISO 14937 (valid IQ/OQ (commissioning) and product-specific performance qualification (PQ))
- maximum sterilisation temperature 60°C (140°F; including permissible tolerance)
- Long cycle (Sterrad 100S)

CAUTION!

- As a basic principle, the use of paper/film sterilisation packaging is not permissible for LTP sterilisation; only the use of Tyvek/film sterilisation packaging is permitted!
- The use of short cycles is not permissible under any circumstances!

The general suitability for efficient LTP sterilisation was proven by an independent, accredited test laboratory using the STERRAD 100S procedure (ASP Inc., U.S.A.) and the long cycle/a sterilisation period (H₂O₂ exposure time during sterilisation temperature plus plasma phase) of 20 min at 45-55°C (113-131°F) and 6 mg/l H₂O₂. The procedure described above was applied for this process. When applying the LTP procedure, observe the applicable regulations applicable in your country; certain application restrictions may apply.

Do not use heated air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation!

Storage

Once sterilised, the fiber optic light cable must be stored dry, dust free and protected against light in the sterilisation packaging.

Storage temperature: - 20°C to +60°C

Material stability

When choosing the cleaning agent and disinfectant, make sure that they do not contain the following components:

- organic, mineral and oxidising acids (minimum permissible pH-value 5.5)
- strong bases (maximum permissible pH-value 11; neutral/enzymatic or weakly alkaline cleaning agents are recommended)
- organic solvents (such as alcohols, ether, ketone, and gasoline)
- Oxidising agents (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, and bromine)
- aromatic/halogenated hydrocarbons
- Tri-/perchloroethylene

Never use metal brushes, steel wool, abrasive cloths or sponges to clean the fiber optic light cables.

The fiber optic light cables must never be exposed to temperatures exceeding 141°C (286°F)!

Temperatures of use:

For the overall fiber optic light cable: +10°C to +40°C

For the light input and light output surface: max. 350° C on the input side (long sleeve)

max. 150° C on the output side (short sleeve)

Reusability

If handled with the necessary care and remaining undamaged and unsoiled, the fiber optic light cables can be reused up to 100 times; using them beyond this limit or using damaged and/or soiled instruments is the responsibility of the user.

No liability in case of non-observance.

The fact that the fiber optic light cable is reusable up to 100 times was validated in the following conditions:

Cleaning and disinfection Mechanical cleaning and disinfection in MIELE Professional PG8535 disinfectant using NEODISHER MediClean forte (0.5 vol. %) cleaner; thermal disinfection at 95° C with a residence time of 10 min.

Sterilisation Fractionated vacuum process (triple) in a LAUTENSCHLÄGER PROTOCERT 839 steam steriliser (134° C, 10 min., 3 bar)

Information on disposal

WARNING! || Risk of contamination/ infection to the user.

After use and prior to disposal, the fiber optic light cable must be disinfected or disposed of as hazardous medical waste.

For the disposal observe the relevant regulations and laws valid in your country.

NOTE! || Please note that any serious incident should be reported to the manufacturer and the national competent authority.



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