» COLD LIGHT CABLES AND ADAPTERS FOR ENDOSCOPY «





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To minimize risks to patients, users, or potentially third parties, the instructions for use must be carefully followed. The use, preparation, and testing of the cables may only be carried out by trained personnel. The entire instruction manual must be read before using the cables. This also applies to the instructions for use of any accessories (endoscope, light source, etc.). The specifications, safety instructions, and warnings in the respective instructions for use must be strictly adhered to and followed.

NON STERILE

The reusable cold light cables and their accessories are delivered non-sterile and must undergo the complete reprocessing cycle (cleaning, disinfection and, if necessary, sterilization) before the first and every subsequent use.

1 SCOPE

These instructions for use apply to the reusable cold light cables and adapters for endoscopy, hereinafter also referred to as " **products** " (see the list of items in the last section of these instructions for use).

For the standard fiber optic cables of Tekno-Medical Optik-Chirurgie GmbH (hereinafter "Tekno-Medical") which are glued at the light entry point, the use of xenon cold light sources is not permitted and furthermore this type of fiber optic cable may not be processed with a thermolabile sterilization process (e.g. plasma).

2 EXAMS

2.1 cold light cable

The following visual inspections must be carried out:

- The product must not show any damage (sharp edges, rough surfaces).
- The product must be free of impurities.
- The product must not contain any residues of cleaning or disinfecting agents.
- It must be ensured that no parts are missing or loose.
- Labels and markings necessary for safe and proper use must be legible.

WARNING: Exercise caution with damaged and incomplete products (injury to the patient, user or third parties is possible)

The cable cross-sections must be matched to the light entry diameter of the endoscope to prevent damage to the light exit of the universal cold light cable due to reflection (Ø 3.5 for thin endoscopes and Ø 4.8 for thick endoscopes).

2.2 Optics

Efficient light transmission must be ensured.
Hold one end of the universal cold light cable towards a light source (e.g., a window) and perform a visual inspection:

- Deposits on the glass surfaces,
- the number of black dots.

Black dots indicate broken optical fibers, and their proportion should not exceed **30%** , otherwise transmission will be noticeably impaired. If in doubt, the light transmission of the cold light cable should be compared with that of another cold light cable.

2.3 Cable ends & adapters

Visually inspect the cable ends for damage (sharp edges, rough surfaces, etc.).
Select adapter (light entry and exit).
Perform a functional test, i.e., disassembly and assembly of the adapters at the light inlet and outlet.

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3 INTENDED PURPOSE

Fiber optic cables and adapters for transmitting light from a light source to accessories.

4 INDICATIONS

The cables and adapters are used for light reception and transmission and coupling into an endoscope or other optical medical device as part of a medical endoscopic examination and treatment.

5 CONTRAINDICATIONS

Use in conjunction with laser light sources or RF devices is not permitted.

6 COMBINATIONS

6.1 Generally

Rigid endoscopes for medical applications have special connectors for universal cold light cables.
Endoscopes are typically supplied with a Wolf connector screwed onto the permanently mounted ACMI connector, and a Storz connector screwed onto the Wolf connector. Standard endoscopes are compatible with any of the three light output adapters (Storz, Wolf, ACMI). The Storz adapter fits directly.
With the Wolf adapter, the Storz connector must be unscrewed, and with the ACMI adapter, both the Storz and Wolf connectors must be removed. If in doubt, use the universal fiber optic cable with the ACMI light output adapter.

6.2 Light entry adapter

Article number	For cold light sources of
39524-00*	Pentax
39525-00	Tekno-Medical (Xenon & Halogen light sources), Karl Storz, RfQ, Aesculap
39527-00	Olympus
39528-00	Tekno-Medical (LED light sources), Wolf, HSW, Dyonics, Comeg, Medicon, Effner, Biomet
39530-00	ACMI, British Standard, Codman, Welch Allyn, Circon, Kli, Stryker

6.3 Light output adapter

Article number	For endoscopes from
39525-10	Tekno-Medical, Karl Storz, Olympus, Winter & Ibe, Aesculap
39528-20	Wolf, HSW, Dyonics
39528-30*	Stryker (New)
39530-10	ACMI, British Standard, Codman, Welch Allyn

7 PATIENT POPULATION

There are no fundamental restrictions regarding the patient population.

8 DISPOSAL

Environmentally sound disposal allows valuable raw materials to be recovered.
Dispose of the product in an environmentally sound manner according to applicable hospital guidelines.

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9 SAFETY NOTICES

The high light concentration at the end of the cold light cable generates heat. To avoid injury, the end of the cold light cable must never be placed on the covering or the patient's skin.
The cold light cable must not be kinked or bent at too tight a radius to avoid damaging the sheathing. Damage to the sheathing will render the cold light cable defective.
Likewise, bumping, especially of the adapter and the fused light inlets, must be strictly avoided, as this can lead to the destruction of the fusion.
Damage to the product resulting from improper handling is not covered by the warranty.

10 REPROCESSING INSTRUCTIONS

Frequent reprocessing has little effect on these products. The end of their lifespan is typically determined by wear and tear and damage during use.

Caution : The following procedures must not be used for the reprocessing of the products :

- Ultrasonic cleaning
- Flash autoclaving
- Hot air sterilization.

10.1 Preparation at the deployment site

Wipe surface soiling with a lint-free disposable cloth. Store the product properly to avoid damage.

10.2 Storage and transport

It is recommended to store the product in suitable containers for transport.
Transport to the processing rooms can be done either wet or dry.
When **disposing of dry waste,** ensure that no residues dry out. Close the container. Cleaning should be carried out within 3 hours.
In the case of **wet disposal** , cleaning must begin within one hour and the recommended combined cleaning and disinfectant solution must be used.
Do not exceed the time windows mentioned above.

10.3 Preparation for cleaning / decontamination

Adapters must be removed from the product, as each part undergoes separate manual cleaning and disinfection. Place individual parts properly to avoid damage.

10.4 Manual pre-cleaning

10.4.1 Required aids

- Sieve tray, immersion tray,
- Cleaning solution with disinfectant effect: e.g.: Sekusept 4%,
- 70% alcohol solution (if no disinfection after cleaning),
- Tap water (15-20°C, max. 45°C),
- VE (fully demineralized) water,
- lint-free disposable cloth or swab.

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10.4.2 Proceedings

Rinse individual parts thoroughly with tap water (max. 45°C). Place the parts in the sieve tray and then transfer them to an immersion bath with the disinfecting cleaning solution.
After the recommended exposure time:

- Rinse each cold light cable with demineralized water for 5 minutes.
- Dry the outside with a lint-free disposable cloth or swab.
- Clean mechanical parts and optical surfaces (light entry and exit) with a soft cloth or soaked cotton ball and the 70% alcohol solution (if no disinfection is used).
- Place individual parts properly to avoid damage.

For manual cleaning, do not use metal brushes or metal cotton swabs, do not use any other instruments to clean the optical surfaces, and after manual cleaning check all parts for damage (see section: “Inspection and Maintenance”).

10.5 Manual disinfection

Disassemble products that can be disassembled into their individual parts as much as possible. Place the products in a sieve tray.

10.5.1 Required aids

- Sieve tray, disinfection tray,
- Disinfectant solution,
- 70% alcohol solution (ethanol, isopropanol),
- VE (fully demineralized) water,
- lint-free disposable cloth or swab.

10.5.2 Proceedings

- Place individual parts in the sieve tray and then transfer them to the immersion bath containing the disinfectant solution. Refer to the chemical manufacturer's instructions for the concentration and contact time of the disinfectant used.
- Then thoroughly rinse the cold light cable with demineralized water for 5 minutes.
- Dry the outside with a lint-free disposable cloth or swab.
- Clean mechanical parts and optical surfaces (light entry and exit points) with a soft cloth or soaked cotton ball and the 70% alcohol solution.
- Place individual parts properly to avoid damage.

Disinfectants containing peracetic acid or chlorine components must not be used!

After manual disinfection, check all individual parts for damage.
Please observe the disinfectant manufacturer's instructions regarding:

- Disinfection effectiveness
- concentration
- Exposure time and
- Stand time

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10.6 Machine cleaning

Disassemble products that can be disassembled into their individual parts as much as possible.

Step	parameter	
Pre-rinse	Washing temperature + water quality	Cold city water
	Exposure time	60s
Pre-rinse	Washing temperature + water quality	Cold city water
	Exposure time	180s
Clean	Cleaning temperature	45°C
	Water quality	City water
	Exposure time	300 s (worst-case condition) RKI recommendation 600 s
	Cleaning agent	Neodisher Medizyme
	concentration	0.50%
Neutralization	Washing temperature	40°C
	Water quality	City water
	Exposure time	180s
	Neutralizing agent	Neodisher Z
	concentration	0.10%
Rinse	Washing temperature	40 °C
	Water quality	demineralized water
	Exposure time	120 s

10.7 Mechanical (thermal) disinfection

Step	parameter	
Thermal disinfection	Disinfection temperature	90°C (A_0 3000)
	Water quality	demineralized water
	Exposure time	300 s
Drying	Dry the exterior of the instruments using the drying cycle of the washer/disinfector. If necessary, additional manual drying with a lint-free cloth can be achieved. Dry instrument cavities and channels with sterile compressed air. Allow products to cool to room temperature.	

10.8 Control and maintenance

We recommend a visual inspection of the optical surfaces. on:

- Light output,
- broken fibers (black dots at the cold light connection, the proportion should not be > 30%)
- Deposits on the glass surfaces (can impair light transmission, clean glass surfaces).

Note: Do not attempt repairs yourself if deposits cannot be removed with the recommended cleaning and disinfecting agents (see Cleaning & Disinfection). Regular cleaning with the 70% alcohol solution after each use will prevent deposits from forming.

10.9 sterilization

Sterilization of the products using a fractionated pre-vacuum process (according to DIN EN ISO 17665) taking into account the respective national requirements.

Forevac	3 times
Sterilization temperature	134 °C
Sterilization time	5 min
Drying time	20 min.

The use of any other sterilization method is outside our responsibility.

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10.10 storage




Sterilized instruments must be stored in suitable packaging in a dry, clean, and dust-free environment with consistent humidity. The distance between the floor and the shelf should be at least 30 cm. The storage duration is to be determined by the user.
Protect from sunburn!

10.11 Information on the validation of the processing

The following test instructions, materials and machines were used during validation:

Cleaning agent	Neodisher Medizym 0.5% (v/v)
Neutralizer	Neodisher Z 0.1% (v/v)
Cleaning and disinfection device (RDG)	Miele PG 8535
Steam autoclave	Lautenschläger ZentraCert
For details see test reports: 23277 / 23279 / 23278 (CleanControlling Medical GmbH & Co. KG)	

10.12 Additional instructions

The instructions listed above have been deemed suitable by Tekno-Medical for the preparation and reuse of a medical device. The reprocessor is responsible for ensuring that the reprocessing actually carried out, using the equipment, materials, and personnel employed in the reprocessing facility, achieves the desired results.
Validation and routine monitoring of the process are necessary. Likewise, any deviation from the provided instructions should be carefully evaluated by the processor for effectiveness and potential adverse consequences. The product must not be kinked or bent at too tight a radius. Impact, especially on the fused light inlets, must be strictly avoided, as this can destroy the fusion. To prevent damage during transport, we recommend using the original packaging for shipping.

11 REPORTING PRODUCT PROBLEMS



In accordance with the requirements of Regulation (EU) 2017/745 on medical devices and our quality management system, all product problems must be reported to the manufacturer.
During business hours you can reach us by phone at +49 (0) 07461 / 1701-0.
Outside of regular business hours, please send an email to safety@tekno-medical.com .
Serious incidents must also be reported to the local authority responsible for their location.

12 WARRANTY

The products are manufactured from high-quality materials and undergo quality control before delivery. Should any defects occur, please contact our customer service.
Tekno-Medical cannot guarantee that the products are suitable for any given procedure. This must be determined by the user. Tekno-Medical accepts no liability for accidental or consequential damages. Tekno-Medical accepts no liability if these instructions for use have been demonstrably violated.

13 SERVICE AND REPAIR

Do not attempt any repairs or modifications to the product yourself. Only authorized manufacturer personnel are responsible for this. Defective products must complete the entire reprocessing procedure before being returned for repair. For returns, please use our RMA application form and decontamination certificate. These forms can be found on our website: https://www.tekno-medical.com/de/service/reparaturservice/

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14 SYMBOLS

The symbols used in this instruction and on the label have the following meaning according to DIN EN ISO 15223-1:

	Danger!		Manufacturer
	Medical device		Date of manufacture
	Non-sterile		Follow the instructions for use.
	Catalog number		Protect from sunlight
	Batch designation		Store in a dry place
	CE marking		Unique product identification

15 ARTICLE LIST



Printed on: 23.09.2026

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