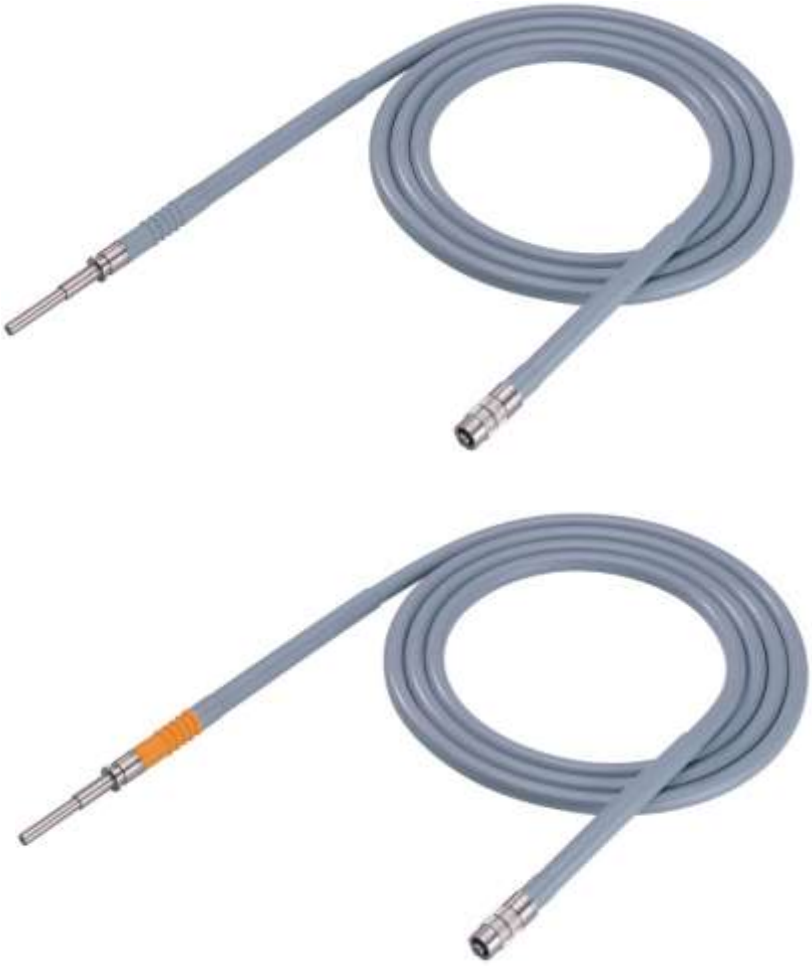
» UNIVERSAL COLD LIGHT CABLES FOR ENDOSCOPY «



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Content

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In order to keep hazards to patients, users or, if necessary, third parties as low as possible, the instructions for use must be carefully observed. The application, reprocessing and testing of the instruments may only be carried out by trained specialists. The products are delivered non-sterile and must go through the complete processing cycle (cleaning, disinfection and, if necessary, sterilization) before the first and every subsequent use.

1 SCOPE

MD

These instructions for use apply primarily to the reusable universal cold light cables for endoscopy that are fused at the light entrance, hereinafter also referred to as “products” light guide cables from Tekno-Medical Optik-Chirurgie GmbH (hereinafter “Tekno-Medical”)

(See product list in the last section.)

2 EXAMS

2.1 Checking the 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 not contain any contamination.
- The product must not contain any residues of cleaning agents or disinfectants.
- make sure no parts are missing or loose.
- Inscriptions and markings that are required for safe and intended use must be legible.

WARNING: Be careful with damaged and incomplete products (injuries to the patient, user or third parties are possible)
The cable cross-sections must be matched to the light entry diameter of the endoscope so that reflection does not cause damage to the light exit of the universal cold light cable (Ø 3.5 for thin endoscopes and Ø 4.8 for thick endoscopes).

2.2 Checking the optics

Ensuring efficient light transmission.
Hold one side of the universal cold light cable towards a light source (e.g. window) and carry out a visual check:

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

The black dots indicate broken light fibres and the proportion of these should not be more than 30%, otherwise the transmission is noticeably impaired.
If in doubt, compare the light transmission of the universal cold light cable with the light transmission of another universal cold light cable.

2.3 Checking the cable ends

Carry out a visual inspection of the cable ends for damage (sharp edges, rough surfaces, etc.).
Select the adaptation system, i.e. which adapters should be used at the light entrance and exit. Carry out a functional test, i.e. dismantling and assembling the adapters at the light inlet and outlet.

3 INTENDED USE

The Tekno-Medical universal cold light cable is intended for the use of halogen, xenon or LED-based cold light sources.

4 INDICATIONS

The universal cold light cable is used to receive light from a light source and forward light with targeted light extraction and coupling into an endoscope or into another optical medical product during a medical endoscopic examination and treatment.

5 CONTRAINDICATIONS

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

6 COMBINATIONS

Rigid endoscopes for medical applications have special connections for universal cold light cables.
As a rule, endoscopes are delivered with a Wolf connection screwed onto the permanently installed ACMI connection and a Storz connection screwed onto it. Commercially available endoscopes can be combined with any of the three light exit adapters (Storz, Wolf, ACMI). The Storz adapter fits directly.
For the Wolf adapter, the Storz connector must be unscrewed and for the ACMI adapter, the Storz and Wolf connectors must be removed. If in doubt, use the universal light guide cable with ACMI light output adapter.

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LIGHT ENTRY ADAPTER	
Reference	**For cold light sources of**
39524-00*	Pentax
39524-10*	Fuji
39524-20*	MLW
39525-00	Tekno-Medical (Xenon & Halogen-Lichtquellen), Karl Storz, RfQ, Aesculap
39526-00*	Winter + IBE
39527-00	Olympus
39527-01*	Olympus / für 300Watt Xenon Boost
39528-00	Tekno-Medical (LED-Lichtquellen), Wolf, HSW, Dyonics, Comeg, Medicon, Effner, Biomet
39529-00*	Heine, Optotechnik
39530-00	ACMI, British Standard, Codman, Welch Allyn, Circon, Kli, Stryker
Z0000125285	Volpi, Schölly, Fiegert

Light exit adapter	
Reference	**For endoscopes of**
39525-10	Tekno-Medical, Karl Storz, Olympus, Winter & Ibe, Aesculap
39528-10*	Wolf (Alte Generation)
39528-20	Wolf, HSW, Dyonics
39528-30*	Stryker (Neu)
39530-10	ACMI, British Standard, Codman, Welch Allyn
39530-15*	Stryker

7 PATIENT POPULATION

There are no fundamental restrictions regarding the patient population.

8 DISPOSAL

Valuable raw materials can be recovered through environmentally friendly disposal.
Dispose of the product in an environmentally friendly manner in accordance with applicable hospital guidelines

9 WARNINGS

The high concentration of light at the end of the universal cold light cable creates heat. The end of the universal cold light cable must never be placed on the drape or the patient's skin to avoid the intensity of the light causing burns to the patient or setting the drape on fire.
The universal cold light cable must not be kinked or bent in too tight a radius to avoid damaging the sheathing. Damage to the sheathing will result in a defect in the universal cold light cable. It is also important to avoid hitting anything, especially the adapter and the fused light entrances, as this can lead to the destruction of the fusion. Damage to the product caused by incorrect handling is not covered by the warranty.
The use of xenon cold light sources is not permitted for standard cables glued to the light entrance and this type of light guide cable must not be processed using a thermolabile sterilization process (plasma).

10 REPROCESSING INSTRUCTIONS

These recommended & validated reprocessing instructions apply primarily to the reusable universal cold light cables fused at the light entrance, hereinafter referred to as “products”.
Frequent reprocessing has little impact on these products. End of product life is usually determined by wear and damage during use.
Attention: The following procedures may not be used to prepare the products:

- ultrasonic cleaning,
- flash autoclaving,
- Hot air sterilization.

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10.1 Preparation on site

Wipe off surface contamination 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 dry-disposing: it is important to ensure that no residue dries on. Close container. Cleaning should be done within 3 hours
For wet disposal: cleaning must begin within one hour and use the recommended combined cleaning and disinfectant solution (see manual cleaning).
Do not exceed the time windows mentioned above.

10.3 Preparation for cleaning/decontamination

Adapters must be removed from the product as the individual parts are cleaned and disinfected separately. Store individual parts properly to avoid damage.

10.4 Manual pre-cleaning

Required tools:

- sieve bowl, dipping tank,
- Cleaning solution with a disinfectant effect: e.g. Example: Sekusept 4%,
- 70% alcohol solution (if no disinfection after cleaning),
- Tap water (15-20°C, max. 45°C),
- VE (fully desalinated) water,
- Lint-free disposable cloth or swab.

Procedure:
Rinse individual parts thoroughly with tap water (max. 45°C). Place the parts in the sieve bowl and then transfer them to an immersion bath with the self-disinfecting cleaning solution.
After the recommended exposure time (according to the cleaning solution manufacturer's instructions):

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

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

10.5 Manual disinfection

Disassemble products into their individual parts as much as possible. Place products in a sieve bowl.
Required tools:

- sieve bowl, disinfection tray,
- disinfectant solution,
- 70% alcohol solution (ethanol, isopropanol),
- VE (fully desalinated) water,
- Lint-free disposable cloth or swab.

Procedure:
Place individual parts in the sieve bowl and then transfer them to the immersion bath with the disinfectant solution. The concentration and exposure time of the disinfectant used can be found in the information provided by the chemical manufacturer.
Then rinse the universal cold light cable thoroughly with demineralised water for 5 minutes.
Dry the outside with a lint-free disposable cloth or swab.
Clean mechanical parts and the optical surfaces (= light entry and exit) with a soft cloth or soaked cotton ball and the 70% alcohol solution
Store individual parts properly to avoid damage.
Hints:
Disinfectants that contain peracetic acid or chlorine components must not be used.
After manual disinfection, check all individual parts for damage (see section: "Inspection and maintenance").
Follow the instructions from the disinfectant manufacturer regarding: disinfection effectiveness, concentration, exposure time and service life

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10.6 Machine cleaning and disinfection

We recommend the “Vario-TD program” as a mechanical cleaning and disinfection method:
After an intensive pre-rinse with cold water, the cleaning phase takes place at temperatures up to 55°C - a holding time of 5 minutes. The final step is thermal disinfection with >90°C and a holding time of 5 minutes. To ensure optimal protection of the instruments, the final rinse is preferably carried out with demineralised water without rinsing agent.
Notes: The universal light guide cable should be stored in a suitable container (sieve tray/basket) in the machine to avoid damage to the product. Water containing chloride can cause corrosion on the product, which is why the final rinsing process should be done with demineralised water. For cleaning and subsequent thermal disinfection, the machine manufacturer's operating instructions and loading instructions must be strictly adhered to. The cleaning agents used must be dosed exactly according to the manufacturer's instructions. The disinfection temperature must not exceed 93°C.
For UK: The washer disinfection cycle should run at a minimum of 90°C for a minimum of 1 minute.

10.7 Drying

Required tools:

- lint-free cloth,
- Compressed air.

Procedure: Dry cleaned and disinfected individual parts using a lint-free cloth and/or compressed air and reassemble them, store the product properly to avoid damage.
We recommend a visual inspection to check the product for the following defects:

- damage,
- sharp edges,
- loose or missing parts,
- rough surfaces,
- Residues of cleaning and disinfecting agents (must be removed),
- Inscriptions and markings that are required for safe and intended use must be legible

Warning: Be careful with damaged and incomplete products (injuries to the patient, user or third parties are possible). Checks must be carried out before and after each use. Stop using damaged or incomplete products. Send damaged product with loose parts for repair. Do not attempt repairs yourself

10.8 Inspection and maintenance

We recommend a visual inspection of the optical surfaces for:

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

Notes: 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 reprocessing prevents deposits.

10.9 Sterilization

Required tools:

- Sterilization storage system,
- Steam sterilizer according to DIN EN 285,
- Sterile packaging.

Method: For steam sterilization, the fractional vacuum method (3 times) is recommended at a sterilization temperature of 134°C (max. 138°C) and a holding time of 5 minutes.
Notes: Cleaned and disinfected individual parts must be reassembled before sterilization. must be sufficiently clean and dry. Follow the sterilizer manufacturer’s information/instructions for use (maintenance intervals must be adhered to). Observe national and international standards for sterile packaging. Brand new light guide cables must be sterilized before first use.

Sterilization parameters UK:

Sterilization of the instruments by applying a fractionated pre-vacuum process (according to Health Technical Memorandum 01-01 Part C):

- Heat up to a minimum sterilization temperature of 134° - 137°C (maximum temperature 137°C).
- Minimum holding time: at least 3 min.

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10.10 Storage

After disinfection, store the product under the following conditions:

- completely dry,
- dust-proof,
- In a closed container,
- under germ-poor conditions.

Notes: If stored for several days, the product must be disinfected again before sterilization. After sterilization, store the product in sterile packaging as follows:

- protected from moisture and temperature fluctuations,
- protected from direct sunlight,
- dust protected.

Improper storage can lead to loss of sterility; Tekno-Medical assumes no liability in this regard

10.11 Additional Instructions

The instructions listed above have been deemed suitable by Tekno-Medical for the preparation of a medical device and its reuse. The re-processor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results.
This requires validation and routine monitoring of the process. Likewise, any deviation from the instructions provided should be carefully evaluated by the re-processor for effectiveness and possible adverse consequences. The product must not be kinked or bent in too narrow a radius. It is essential to avoid hitting the fused light entrances in particular, as this can lead to the destruction of the fusion. To avoid damage during transport of the products, we recommend using the original packaging for shipping.

11 REPORTABLE EVENTS

In accordance with the requirements of the Medical Device Regulation EU MDR 2017/745 and our quality management system, even the smallest problems with this product should always be reported to Tekno-Medical.
If you cannot reach us directly for reportable events, please send an e-mail to: safety@tekno-medical.com.
Serious incidents must also be reported to the competent authority in their place

12 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service. Tekno-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno-Medical accepts no liability for any incidental or consequential damages. Tekno-Medical assumes no liability if it can be proven that these instructions for use have been violated.

Attention: In case of use of the instruments in patients with Creutzfeldt-Jakob disease or its variants (vCJD, BSE, TSE), Tekno-Medical declines any responsibility for reuse.

13 SERVICE AND REPAIR

Do not carry out repairs or modifications of the product on your own. Repairs only by authorized personnel.
Defective products must have gone through the entire remanufacturing process before being returned for repair. For returns, use our RMA request form and decontamination certificate.
Forms at: https://www.tekno-medical.com/de/service/repair service

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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:

	Attention!		Manufacturer
	Medical device		Date of manufacturing
	Non-sterile		Read the instructions for use
	Catalogue number		Protect from sunlight
	Lot-number		Store in a dry place
	Unique device identification		CE marking

REF

15 PRODUCT LISTING

Printed on: 11.03.2024

39520-18	39521-25	39523-40*	39540-18
39520-23	39521-30	39524-00*	39540-23
39520-23B*	39521-30R*	39525-00	39541-18
39520-23G*	39521-40	39525-10	39541-23
39520-23R*	39521-50	39527-00	39562-18
39520-23Y*	39522-18	39527-01*	39562-23
39520-30	39522-23	39528-00	39562-30
39520-40	39522-23R*	39528-10*	39563-18
39521-18	39522-30	39528-20	39563-23
39521-23	39523-18	39528-30*	39563-30
39521-23B*	39523-23	39530-00	
39521-23R*	39523-30	39530-10	

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