» TV-ADAPTER & LENSES«







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In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully observed. The application, preparation and testing of the products may only be carried out by trained specialists.

The products are delivered non-sterile and must go through the complete reprocessing cycle before the first and each subsequent use.

1 SCOPE

MD

These instructions for use are valid for all **camera lenses** (TV adapters, lenses and beam splitters) of Tekno-Medical Optik-Chirurgie GmbH (hereinafter referred to as "Tekno-Medical").

(See product list in the last section.)

2 HANDLING

The products may only be used for their intended purpose by appropriately trained and qualified personnel. The attending physician or user is responsible for selecting the instruments for specific applications, ensuring adequate staff training, and possessing experience in handling the products. This product may only be used in medical facilities by trained medical professionals.

3 INTENDED PURPOSE

Camera lenses are designed for adjusting image focus and transmitting the image in endoscopic applications.

4 INDICATION

The camera lenses are precision optical devices designed for use in endoscopic applications.

5 CONTRAINDICATION

The use of these products is generally contraindicated when the use of other, non-endoscopic techniques is indicated.
Furthermore, there are contraindications:

- in case of the patient's lack of willingness;
- if the technical requirements are not met.

The responsible physician or user must decide, based on the patient's general condition, whether the intended application can take place.

6 ACCESORIES

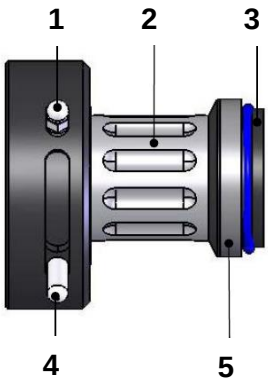
Camera lenses can only be operated together with a camera head, camera and monitor

7 PATIENT POPULATION

Apart from the contraindicated uses, there are no restrictions on the patient population.

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8 INSTALLATION



1: Locking screw
2: Focusing drive
3: C-mount interface
4: Locking pin
5: Marking

Focusing pinion:

- 1 Rotating sleeve: Adjusting the image sharpness
- 2 Rotating Sleeves: Enlarge/Reduce the Image with the Wide Silver Rotating Sleeve, Correct Image Sharpness with the Narrow Blue Rotating Sleeve

Screw the TV adapter to the camera head via the C-mount thread (**3**). The TV adapter is supplied with the opened locking screw (**1**). Before each use, please make sure that the locking screw is really open, otherwise the endoscope eyepiece funnel could be damaged. The locking pin (**4**) locks the endoscope holder via a ball snap lock. Carefully insert the endoscope with the eyepiece funnel with the release pin (**4**) held. Release the pin and check that the endoscope is properly engaged. Now carefully tighten the locking screw (**1**) so that the endoscope is locked. In use, the image sharpness of TV adapters without a zoom function can be corrected via the focusing drive (**2**). For TV adapters with zoom function, both rotary tubes (**2**) must first be brought into approximate centre position and then the image sharpness must be adjusted with the blue rotary sleeve. After that, the desired image size can be set with the silver rotating sleeve and the sharpness can be corrected with the blue one if necessary. After endoscopic application, first loosen the locking screw (**1**) so as not to damage the endoscope eyepiece funnel. Then press the release pin (**4**); now the endoscope can be removed.

9 REPROCESSING INSTRUCTIONS

Detailed information on reprocessing can be found in the "Red Brochure" of the AKI. Under www.a-k-i.org you will also find links to laws, standards and publications of treatment committees.

9.1 Preparation on site

Remove coarse dirt from the adapters immediately after use. Do not use fixatives or hot water (>40°C), as this leads to the fixation of residues and can affect the success of cleaning. Never use metal brushes, metal sponges or abrasive cleaning agents for cleaning / pre-cleaning. Highly alkaline cleaning agents damage plastics and anodizing layers.

Reprocess the products as soon as possible immediately after use.

9.2 Transport

Safe storage in a closed container and transport of the instruments to the reprocessing site to avoid damage to the instruments and contamination with the environment.

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9.3 Cleaning / Disinfection

Only TV adapters marked " **soakable** " may be cleaned and disinfected by immersion in disinfectant solution. Use commercially available disinfectants for thermolable instruments (e.g., neodisher Endo® MED; 15 g/l (1.5%), 5 min (20 °C)).
Adapters marked " **non-soakable"** must never be immersed in liquid, but only wiped with a damp cloth.

Please note that your TV adapter contains parts made of anodized aluminum.

Under no circumstances should any TV adapters be thermally or mechanically cleaned, disinfected, or autoclaved.

TV adapters must not be cleaned in an ultrasonic bath!

Notes:

- Rinse the TV adapter with cold tap water immediately after use to remove any contaminants.
- Visually check that the contaminants have been removed. If the contamination does not dissolve, increase the rinsing time or use a suitable wipe for optical medical devices.
- Wipe the TV adapter under cold tap water or (preferably) distilled water with a sponge or soft cloth for at least 1 minute. Make sure to rinse any hidden areas.
- Visual inspection to ensure all residues have been removed.
- Dry all parts with a soft, lint-free cloth. Ensure that hidden areas are completely dry.

Clean the optical lenses on the top and bottom of the TV adapter using clean cotton swabs and pure alcohol. Ensure no dust or smudges remain, as these could negatively affect the picture.

10 ADDITIONAL INSTRUCTIONS

If the procedures described above are not available, it is the responsibility of the user to validate his procedure accordingly.

⚠ It is the responsibility of the user to ensure that the reprocessing process, including resources, materials and personnel, is suitable to achieve the required results.

The state of the art and national laws require validated processes to be followed.

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 service department. Tekno-Medical cannot guarantee that the products are suitable for any specific procedure. Tekno-Medical accepts no liability for accidental or consequential damages. Tekno-Medical accepts no liability if these instructions for use have been demonstrably violated.

⚠ **Caution** : In the event of use of the instruments on patients with Creutzfeldt-Jakob disease or its variants (vCJD, BSE, TSE), Tekno-Medical disclaims all responsibility for reuse.

13 SERVICE AND REPAIR

⚠ Do not attempt any repairs or modifications to the product yourself. This work should only be carried out by Tekno-Medical or authorized personnel.

Defective products must undergo the entire reprocessing procedure before being returned for repair. Please use our RMA application form and decontamination certificate for returns.
Forms available at: 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 in accordance with DIN EN ISO 15223-1:

	Attention!		Manufacturer
	Medical device		Manufacturing date
	Non-sterile		Follow the instructions for use
	Catalogue number		Protect from sunlight
	Batch designation		Store in a dry place
	Unique product identification		CE marking

15 PRODUCT LIST



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754-3900-15	754-3901	754-3905	754-3908	754-3909-21 UHD	754-3909-25HD	754-3909-35 UHD
754-3900-21	754-3903	754-3906	754-3909-14 UHD	754-3909-21HD	754-3909-28 UHD	754-3913
754-3900-35	754-3904	754-3907	754-3909-14HD	754-3909-25 UHD	754-3909-28HD	754-3918

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