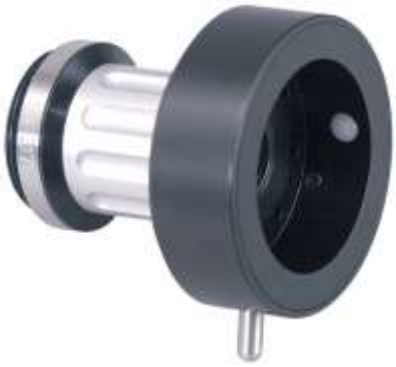
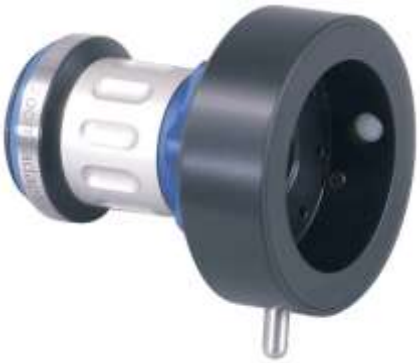
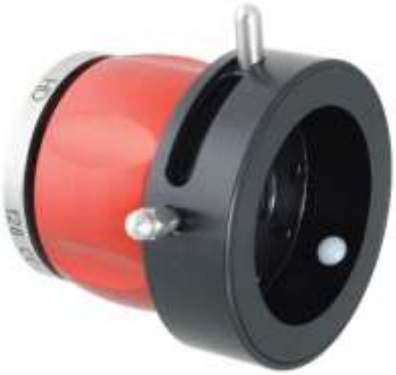
» TV-ADAPTER «







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Content

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

This manual applies to the reusable **TV-adapters** 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 use by appropriately trained and qualified personnel. The attending physician or user is responsible for the selection of the instruments for specific applications, the appropriate training of the staff and the experience in the handling of the products. This product should only be used in medical facilities by trained healthcare professionals.

3 INTENDE USE

TV adapters are camera lenses for adjusting the image sharpness in endoscopic applications.
They are used between a camera unit and an endoscope. The image is directed to a monitor via the endoscope, the TV adapter and the camera. The image sharpness can be adjusted via a focusing drive on the TV adapter. With TV adapters with zoom function, the image size can be changed via an additional rotary sleeve.

4 INDICATION

The TV-adapters are precision optical devices designed for use in endoscopic applications.

5 CONTRAINDICATION

The use of TV-adapters is generally contraindicated if the use of other, non-endoscopic techniques is indicated.
There are also contraindications:

- if the patient is unwilling;
- if the technical requirements are not met.

The responsible physician or user must decide whether the intended application can be carried out on the basis of the patient's general condition.

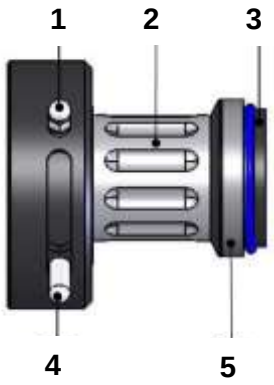
6 ACCESSORIES

TV adapters can only be operated together with the camera head, camera and monitor.

7 PATIENT POPULATION

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

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.

9.3 Cleaning / disinfection

Only TV adapters marked "**soakable**" may be cleaned and disinfected by placing them in disinfectant solution.

Adapters marked "**non-soakable"** must not be soaked in liquid under any circumstances, but only wiped with a damp cloth.

All TV adapters are successfully tested and approved for use with STERRAD® 50, 200 (Short Cycle), 100S (Short Cycle), NX (Standard Cycle) and 100NX (Standard Cycle) procedures. Please follow the procedure instructions of the sterilizer manufacturer exactly.

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

All TV adapters must under no circumstances be thermally or mechanically cleaned or disinfected nor autoclaved.

TV adapters must not be cleaned in an ultrasonic bath!

To avoid cross-contamination, never transport your TV adapter with other devices and instruments.

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 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 in the event of 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. If errors still 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 assumes no liability for incidental or resulting damages. Tekno-Medical accepts no liability if it is proven that these instructions for use have been violated.

13 SERVICE AND REPAIR

⚠ Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer are responsible and provided for this.

Defective products must have gone through the entire remanufacturing process before being returned for repair. For returns, use our RMA application form and decontamination certificate.

Forms at: https://www.tekno-medical.com/de/service/reparaturservice/

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

Printed on 02.04.2025

754-3900-14	754-3900-35	754-3905	754-3909-14HD	754-3909-25 UHD	754-3913
754-3900-15	754-3901	754-3906	754-3909-21	754-3909-25HD	754-3918
754-3900-21	754-3902	754-3907	754-3909-21 UHD	754-3909-28	
754-3900-25	754-3903	754-3908	754-3909-21HD	754-3909-28 UHD	
754-3900-28	754-3904	754-3909-14 UHD	754-3909-25	754-3909-28HD	