»Endoscopes Class I«

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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, preparation and testing of the instruments may only be carried out by trained specialists. Before using the instrument, read the entire instructions for use. This also applies to the instructions for use of the accessories used (adapter, light guide, light source). The specifications, safety and warnings of the respective instructions for use must be strictly adhered to and followed.

The reusable endoscopes of Tekno-Medical Optik-Chirurgie GmbH and their accessories are delivered non-sterile and must go through the complete reprocessing cycle (cleaning, disinfection and sterilization) before the first and each subsequent use.

1 SCOPE

MD

These instructions for use are valid for the reusable endoscopes class I of Tekno-Medical Optik-Chirurgie GmbH. (See product listing in the last paragraph of these instructions for use.) Tekno-Medical´s endoscopes are available in different versions (different lengths/diameters/viewing directions).

The product group of rigid endoscopes contains the following instruments:

- laryngoscopes,
- otoscopes,
- sinuscopes (rhinoscopes).

2 INSPECTIONS

Before each use of the endoscopes, they must be examined for fractures, cracks, deformations, damage and functionality. Areas such as cover-glasses, connectors, eyepieces, etc. must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out.

The following tests should be carried out before each use:

Examination	Result
All surfaces should be level and bare (free of scratches and nicks).	Scratches and notches on the endoscope stem or on the distal or proximal end may indicate possible damage.
In daylight, look through the endoscope from the proximal end, rotating it around the longitudinal axis.	Damage to the optical system can cause blurred vision or complete loss of images.
	Adequate illumination is ensured when the escaping light forms a uniform point of light at the distal end without dark areas.

3 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 the selection of instruments for specific applications or operational use, appropriate training of personnel and experience in handling the products.

We recommend that you always have a replacement endoscope ready for every endoscopic application. In this way, you reduce the risk of disruptions in the surgical process or during diagnostic operations and also prevent potential errors.

4 INTENDED PURPOSES

4.1 Laryngoscopes

Laryngoscopes are used for visualization during operations on the larynx.

4.2 Otoscopes

Otoscopes are used for visualization during operations in the ear canals.

4.3 Sinuscopes

Sinuscopes are used to visualize the maxillary sinus.

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5 INDICATIONS

The optics are used in various human procedures. They are primarily used to visually display the surgical field or anatomical structures.

6 CONTRAINDICATIONS

The use of endoscopes is generally contraindicated when the use of other surgical techniques is indicated and in health conditions that inhibit the healing process, e.g.:

- impaired blood supply,
- extreme obesity,
- acute and chronic, local or systemic infections,
- deep and superficial infections,
- systemic diseases and metabolic dysfunction,
- mental states that make it impossible to participate in the rehabilitation program (Parkinson's disease, alcoholism, drug use, etc.),
- Allergies or other reactions to the material used.

In addition, there are contraindications,

- in case of general inoperability;
- in the absence of readiness on the part of the patient;
- if the technical requirements are not met.

Not for use on the heart and on the central circulatory and nervous system within the meaning of the regulation.

7 ACCESSORIES

Standard accessories:

- Light connection adapter Storz/Olympus, Wolf
- Protective sleeve (for all Tekno-Medical endoscopes with shaft diameter smaller than 5 mm)

Non-standard accessories:

- CCD camera and TV adapter
- Light source, cold light cable, various adapters
- Trocar

8 INTENDED USERS / USER GROUP

The products may only be used for their intended purpose in the medical field by appropriately trained and qualified personnel. The attending physician or user is responsible for selecting the instruments for specific applications or surgical use, for appropriate training and information, and for having sufficient experience in handling the products.

9 PATIENT POPULATION

There are no fundamental restrictions on the patient population.

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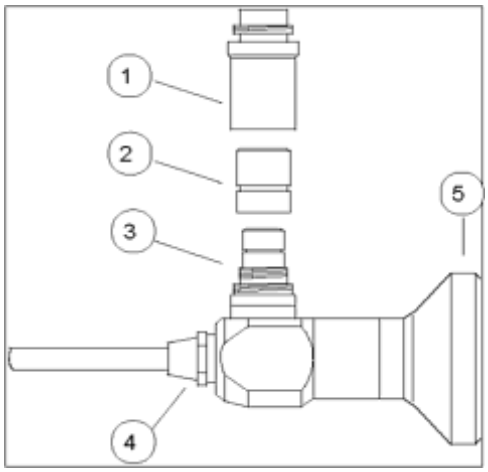
10 INSTALLATION



1 light connection – Storz / Olympus adapter
2 light connection – adapter Wolf
3 Light connection – adapter ACMI
4 Instrument coupling / interface
5 Ocular

Camera connection:
Lock the ocular in the TV adapter of your camera. Adjust the image sharpness and, if necessary, size on the TV adapter.

Light connection:
Your TEKNO endoscope can be connected to the light sources commonly used on the market using cold light cables. For this purpose, the Storz/Olympus and Wolf sleeves can be unscrewed from the light connection and, if required, additional light connection adapters are available.

⚠ **Caution:** Light is an energy that heats the endoscope due to its high light density. Depending on the type of light source, it is possible that the temperature of the distal end or the light connection exceeds 41°C. High surface temperatures can cause permanent tissue damage to the patient or the user. The safety distance to tissue should therefore be at least 5mm.

Mechanical stress, e.g., falling or holding on to the distal end of the endoscope can lead to damage or destruction.

11 REPROCESSING INSTRUCTIONS

The product´s lifespan is essentially determined by wear and damage caused by use. Repeated reprocessing has only a minor impact on the product life. Tekno-Medical has proven the safe use of endoscopes up to 50 reprocessing cycles. A much higher number of treatments is possible. The end of product life is usually determined by wear and damage caused by use.

11.1 On-site preparation

Immediately after use, remove coarse dirt from the instruments. Do not use any fixing agents or hot water (>40°C), as this will cause residues to freeze and may affect the success of cleaning.
Dissolve heavy soiling (coagulation residues) with a 3% H 2 O_2 solution (hydrogen peroxide) and wipe with a disposable cloth. Then rinse thoroughly with demineralized water.
Reprocess the instruments as soon as possible immediately after use.

11.2 Transport

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

11.3 Preparation for cleaning / decontamination

The instruments must be disassembled or opened for reprocessing.
The instruments must be stored on machine-compatible instrument carriers in a dishwasher-safe manner. The condition of the instrument panels must not impair the subsequent cleaning and disinfection by means of sound or rinsing shadows.

11.4 Manual pre-cleaning

Place the instruments in cold water for at least 5 minutes. If possible, disassemble the instruments and clean them under cold water with a soft brush until no residue is visible.

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Tekno-Medical endoscopes must not be cleaned in an ultrasonic bath, the endoscope would be damaged!

11.5 Automated cleaning

Place the instruments in an open state in a sieve tray on the slide-in carriage and start the cleaning process. Disassemble instruments into their individual parts as much as possible.

Step	Parameter	
Pre-rinsing 1	Rinsing-temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinsing 2	Rinsing-temperature + water quality	Cold tap water
	Exposure time	180 s
Cleaning	Cleaning-temperature	45°C
	Water quality	Tap water
	Exposure time	300 s (worst case condition) / RKI Recommendation: 600 s
	Detergent	Neodisher Medizym
	Concentration	0,50 %
Neutralization	Rinsing-temperature	40°C
	Water quality	Tap water
	Exposure time	180 s
	Neutralizing detergent	Neodisher Z
	Concentration	0,10 %
Post-rinsing	Rinsing-temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

11.6 Automated (thermal) disinfection

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

For UK: The washer disinfection cycle should run at a minimum of 90°C for a minimum of 1 minute.

11.7 Functional testing

The products must be macroscopically clean, i.e. free of visible dirt, after each cleaning.

- Stained products must be sorted out immediately and given special treatment.
- In the event of errors or damage, the products must be sorted out immediately.
- If there are signs of damage, deformation, the instrument must not be reused under any circumstances.

Functional testing and maintenance of the instruments must be carried out extremely thoroughly.

11.8 Packaging

Select standard-compliant packaging of the instruments for sterilization according to DIN EN ISO 11607-1, DIN EN 868-2 and DIN EN 868-8.

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11.9 Sterilization

Sterilization of the products using a fractionated vacuum process (according to DIN EN ISO 17665-1), taking into account the respective national requirements.

Pre-vacuum	3 times
Sterilization temperature	134 °C
Sterilization time	5 min
Drying time	20 min.

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.

11.10 Storage

The sterilized instruments must be stored in suitable packaging in a dry, clean and dust-free environment and at a constant level of humidity. The distance between the floor and the shelf should be at least 30cm. The storage period is to be determined by the user himself.

11.11 Information on the validation of the reprocessing

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

Detergent	Neodisher Medizym 0.5% (v/v)
Neutralizer	Neodisher Z 0.1 % (v/v)
Washer-disinfector (RDG)	Miele PG 8535
Steam autoclave	Lautenschläger ZentraCert
For details see test reports: 23277 / 23279 / 23278 (CleanControlling Medical GmbH & Co. KG, 08-2021)	

12 ADDITIONAL INSTRUCTIONS

If the chemicals and machines described above are not available, it is up to the user to validate his process accordingly. It is the responsibility of the user to ensure that the remanufacturing process, including resources, materials and personnel, is suitable to achieve the required results. The state of the art and national laws require the following of validated processes.
During reprocessing, the temperature acting on the instrument should **not** exceed **140°C**.
In principle, machine cleaning and disinfection are always preferable to manual cleaning. In the case of machine cleaning and disinfection, there is greater safety in the process.
For manual cleaning / pre-cleaning, never use metal brushes, metal sponges or abrasive cleaning agents. Highly alkaline cleaning agents damage plastics and anodized layers.
Do not use corrosive cleaning agents. Do not use highly oxidizing cleaning agents. Agents with a neutral pH value (7.0) are best suited.
National laws and guidelines must be observed.

13 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.

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14 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.
Caution: In the event of use of the instruments on patients with Creutzfeldt-Jakob disease, Tekno-Medical disclaims all responsibility for reuse.

15 SERVICE AND REPAIR

Do not attempt any repairs or modifications to the product yourself. This is the sole responsibility of authorized manufacturer personnel. Defective products must complete the entire refurbishment process before being returned for repair. For returns, please use our RMA application form and decontamination certificate.
You can find the forms on our homepage:
https://www.tekno-medical.com/de/service/reparaturservice/

16 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

17 PRODUCT LISTING

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Laryngoscopes			
700-046	700-049	700-057	710-141
700-047	700-055	700-058	710-145
700-048	700-056	710-140	710-146

Otoscopes		
700-080	700-093	710-181
700-083	700-094	710-185
700-090	710-180	710-186

Sinuscopes					
700-350	700-355SF	700-359	700-371	700-374SF	710-165
700-351	700-356	700-359SF	700-371SF	710-150	710-166
700-352	700-356SF	700-360	700-372	710-151	710-170
700-353	700-357	700-361	700-372SF	710-155	710-171
700-354	700-357SF	700-362	700-373	710-156	710-172
700-354SF	700-358	700-363	700-373SF	710-160	710-173
700-355	700-358SF	700-370	700-374	710-161	710-174

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