» URETERORENOSCOPES «

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To minimize risks to patients, users, or potentially third parties, the instructions for use must be carefully followed. The use, reprocessing, and testing of the instruments may only be carried out by trained personnel. The entire instructions for use must be read before using the instrument. This also applies to the instructions for use of any accessories (adapters, fiber optics, light sources). The specifications, safety information, and warnings in the respective instructions for use must be strictly adhered to and followed.

Reusable ureterorenoscopes (hereinafter referred to as " **endoscopes** ") and their accessories are delivered non-sterile and must undergo the complete reprocessing cycle (cleaning, disinfection and sterilization) before the first and every subsequent use.

1 SCOPE

These instructions for use are valid for the following products: see the product list for the instructions for use.
This instruction manual is part of the product set and contains all the information that users and operators need for safe and proper use.
This instruction manual does not describe the application of endoscopic procedures or techniques during a medical intervention.
These instructions for use are intended for physicians, medical assistants and sterile supply staff who are entrusted with the operation, handling and preparation of the products.
Keep the instructions for use in a designated location and ensure that they are accessible to the target audience at all times.

2 INTENDED PURPOSE

Ureterorenoscopes are designed for visualizing anatomical structures in the urethra, bladder, ureter, and renal pelvis during minimally invasive procedures via the natural urethral opening. Ureterorenoscopes allow the insertion of working instruments through the integrated working channel.

The instrument bridges are used to insert instruments into the integrated working channel of the ureterorenoscope, as well as to connect irrigation accessories and to allow the passage of irrigation fluids. Adapters for EMS lithotripters can also be attached to the instrument bridges.

Membranes and sealing caps serve to prevent fluids from leaking out of the body's interior and to maintain pressure within the anatomical structures.

3 INDICATIONS

The indication for an endoscopic procedure depends on the patient's condition and the individual risk-benefit assessment of the treating physician.

4 CONTRAINDICATIONS

The use of rigid endoscopes with a working channel is generally contraindicated when the use of other surgical techniques is indicated.
Furthermore, there are generally contraindications:

- in cases of general inoperability,
- in the event of the patient's lack of willingness,
- if the technical requirements are not met,
- for applications outside of its intended purpose.

Contraindications may be based on the patient's general health or specific medical condition. The decision to perform an endoscopic procedure rests with the treating physician and must be made based on an individual risk-benefit assessment.
Not for use on the central circulatory and nervous system as defined in Regulation (EU) 2017/745 on medical devices.

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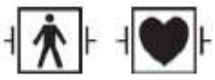
5 PRODUCT DESCRIPTION

5.1 Combinations

5.1.1 Protection class

The product is intended for use in combination with medical electrical equipment that meets **at least** the **BF conditions** (according to DIN EN 60601-1) for increased protection against electric shock.

This isolation barrier can be implemented by the devices themselves or by the connecting cables to the endoscope and must exist for every connection between the endoscope and connected devices.

	Devices or connecting cables that meet the BF conditions are marked with the symbol shown alongside.
	Devices or connecting cables that meet CF requirements offer even greater protection. They are marked with the symbol shown alongside and are approved for direct application to the heart.
	Devices or connecting cables that are resistant to defibrillator impulses are also compatible. They are marked with one of the symbols shown, according to their insulation.

5.1.2 Additional instruments

Additional instruments are required to perform endoscopic procedures. It is the responsibility of the performing physician to assemble and have ready the necessary instruments for an endoscopic procedure.

Note : For this medical application, please observe all applicable national laws and guidelines. For example, for the treatment of urolithiasis, refer to the Guidelines on Urolithiasis of the European Association of Urology (EAU).

5.1.3 Recommended fiber optic cables

The specifications of usable optical fibers are:

- active diameter from 3.5 to 4.8 mm,
- Length up to 300 cm.

5.2 Features and Functionality

The ureterorenoscopes within the scope of this document are semi-flexible endoscopes for the visual representation of the surgical area during surgical procedures in the urinary tract and kidneys.

5.2.1 Structure and Function

A semi-flexible endoscope consists of fiber optics and a sensitive image transmission system with an eyepiece. The fiber optics transmit light into the body. At the proximal end of the endoscope is the connector for the light guide, which connects to the light source. The necessary adapters for connecting the light guide are included. At the distal end of the endoscope is an objective lens into which the image from inside the body is projected. The image is then transmitted to the eyepiece via the image transmission system. The eyepiece connects to an endocoupler, which relays the image to a camera. The camera's control unit converts the signal for display on a monitor.

5.2.2 Use with instrument bridge

The endoscope is designed for use with an instrument bridge, which allows the supply of instruments, probes and irrigation fluid during the procedure.

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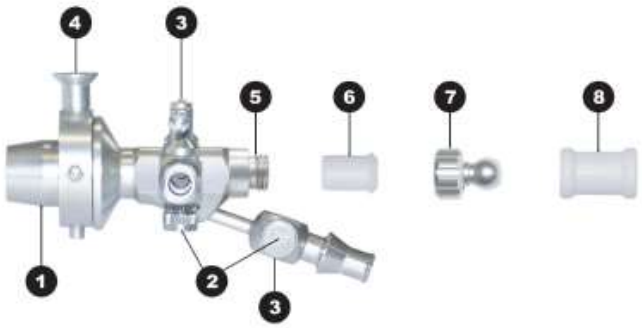
5.3 Overview

(1) Ureterorenoscope
(2) Instrument bridge
(3) Adapter for connecting Storz-type fibre optic cables
(4) Adapter for connecting Wolf-type fibre optic cables
(5) Fibre optic cable connection (ACMI)
(6) Eyepiece

5.3.2 Instrument bridge

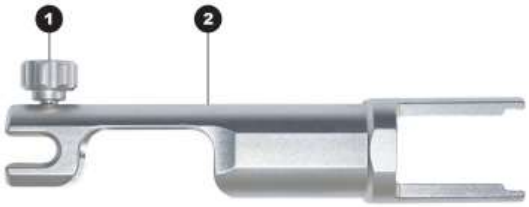


(1) Coupling piece
(2) Tap nuts
(3) Taps for flushing channels and instrument channel
(4) Release lever
(5) Membrane uptake
(6) Three-slot membrane
(7) Instrument holder (standard)
(8) Sealing cap

5.3.3 Adapter for EMS Swiss Lithoclast 1

(1) Instrument connector
(2) Adapter EMS Swiss Lithoclast 1

5.3.4 Adapter for EMS Swiss Lithoclast 2



(1) Locking screw
(2) Adapter EMS Swiss Lithoclast 2

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6 SAFETY INSTRUCTIONS

Although this product conforms to current technological standards, hazards may arise during commissioning, use, or in connection with preparation and maintenance. Therefore, please read these instructions carefully. Observe and follow the warnings in this document.
Only operate the product in perfect working order, in accordance with its intended purpose and the operating instructions. Before each use, ensure that the product and all accessories are undamaged and functioning correctly.
Keep the original packaging and use it for returns in case of service issues.
Please observe the instructions for use of all devices and instruments used in connection with the application of the product.

Caution: Danger from unauthorized modifications to the product. People can be seriously injured. Do not make any unauthorized modifications.

Caution: Component failure during a procedure. Patient safety is at risk. Have a ready-to-use replacement component on hand.

Caution: High-intensity light source. Risk of eye damage. Do not look directly into the free end of the light guide or the light exit point of the endoscope.

Caution: Magnetic resonance imaging (MRI). Magnetic forces, electromagnetic interactions, heating of metal parts. Do not use this product near MRI scanners.

Caution: Rough handling. Patient endangerment due to damaged product. Handle product with care. Do not use the product after severe mechanical stress or dropping; return it to the manufacturer for inspection.

Caution: Improper handling and care, as well as misuse, can lead to risks for the patient and user or premature wear and tear of the product.

Caution: When using powered endoscopes with powered endotherapy devices, patient leakage currents can add up. To minimize total patient leakage currents, especially when using CF-type powered endoscopes, ensure they are used in conjunction with CF-type powered endotherapy devices.

7 OPERATION INSTRUCTIONS

7.1 Safety instructions

Interactions with simultaneously used devices (e.g., lasers, lithotripters):

- Risk to patient and user, image distortions, product damage
- Ensure that all equipment used meets at least BF conditions according to IEC 60601-1.
- Observe the labeling and operating instructions of the equipment used.

Display of a recording instead of the live image or changed image orientation:

- Endangering the patient,
- Ensure that the live image from the endoscopic camera is displayed on the monitor.
- Ensure that the live image is displayed in the correct orientation (not mirrored).

Use of non-sterile parts:

- Risk of infection for the patient,
- Use only properly processed endoscopes and endoscopic accessories,
- Prepare non-sterile accessories (e.g., three-slot diaphragm and sealing cap) before use.
- Perform a visual inspection before use.
- Fix the fiber optic cable in the surgical field and secure it against slipping, ensuring strain relief.

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Recontamination due to improper handling:

- Risk of infection for the patient
- Follow hygiene regulations

High temperatures in combination with light sources:

- Irreversible tissue damage or unwanted coagulation, user injury, property damage,
- Use a suitable light guide for the endoscope.
- Avoid prolonged use of intense light.
- Choose the lowest possible illuminance to illuminate the target area,
- Do not touch the light source near the lamp.
- Do not touch fiber optic connections
- Do not allow the distal end of the endoscope to come into contact with patient tissue, flammable or heat-sensitive materials.
- Do not exceed the maximum permissible ambient temperature for the light source.

Coupling laser beams into the endoscope:

- Eye damage from looking directly into the eyepiece
- Wear laser safety glasses

7.2 Staff qualifications

The product may only be operated by physicians and medical assistants who have been instructed in its use and who meet the requirements for training or further education, expertise and practical experience applicable at the place of use for the endoscopic procedure employed.

7.3 Visual inspection

Perform a visual inspection **before each use** :

- **External damage** : Ensure that the endoscope and all components used are free from external damage. Do not use the product if it has any sharp corners or edges, protrusions, or rough surfaces that could injure the patient.

- **Intact fiber optics:** Ensure the endoscope's fiber optics are intact. Hold the distal end towards a bright lamp (not a cold light source) and the fiber optic connector towards your eyes. Gently move the endoscope back and forth and observe the brightness of the fibers. Do not use the endoscope if more than 20% of the fibers remain dark. In this case, send the endoscope in for repair**.**

- **Clean and smooth surfaces:** Ensure that the glass surfaces and fiber optic end faces of the endoscope are clean and smooth. Do not use the endoscope if any surfaces are dirty or scratched. Discard the endoscope in this case.

- **Clear, bright, complete image:** Ensure that a clear, bright, and complete image is visible. Look through the eyepiece and assess the image quality. Do not use the endoscope if the image is yellowish, dark, patchy, or cropped. In this case, discard the endoscope.

- **Compatible surgical equipment:** Ensure that the equipment intended for the procedure is compatible with each other. Only use the surgical equipment if the insulation barrier for protection against electric shock meets **at least** the **BF requirements .**

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7.4 Functional test

Perform **before each procedure** a functional test.

- Connect a camera and a monitor.
- Turn on all system components that you intend to use for the intervention.
- Point the camera head at an object in the room and focus the image.
- Make sure you see a sharp, bright image of good quality.

Do not use the system if you notice banding, color shifts or image flickering, or if it cannot produce a sharp, bright image of good quality.

8 ASSEMBLY AND DISASSEMBLY

8.1 Install instrument bridge

⚠ **Caution:** Non-sterile three-slot membranes and sealing caps for single use. Risk of infection for the patient! Sterilize three-slot membranes and sealing caps before use and do not reuse.

Prepare the instrument bridge:

- Insert the tap plugs and screw them on with the tap nuts. Check that the taps move freely and then open them fully.
- Place a three-slot membrane in the membrane holder.
- Screw the instrument holder (standard) onto the instrument bridge.
- Place a sealing cap on the instrument holder (standard).
- Lock the instrument bridge on the ureterorenoscope.

Note: For proper sealing, the coupling piece must be clean and free of grease. Do not grease the coupling piece!

Align the coupling piece of the instrument bridge on the endoscope so that the arrows are opposite each other.

Press the coupling piece into the receptacle on the base of the endoscope until it audibly clicks into place. Ensure that the instrument bridge is securely attached to the endoscope.

8.2 Mount adapter for EMS Swiss Lithoclast 1

Screw the instrument holder (adapter) onto the instrument bridge in place of the standard instrument holder. Tighten the adapter slightly onto the instrument holder (adapter).

Note: Do not screw the adapter on too tightly, otherwise it will be difficult to remove later!

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8.3 Mount adapter for EMS Swiss Lithoclast 2

Fully tighten the locking screw on the adapter. Slide the adapter, with its recesses aligned, completely onto the instrument bridge so that the lateral recesses below the locking screw engage the lavage tap prongs on the instrument bridge. Secure the adapter using the locking screw, ensuring it engages in the recess on the instrument bridge.

8.4 Connection of a fiber optic cable

Depending on the type of fiber optic cable used, you will need different adapters to connect it to the endoscope.

- Screw the appropriate adapter onto the fiber optic connector of the endoscope and, if necessary, onto the fiber optic cable.
- Connect the fiber optic cable to the fiber optic connector.

8.5 Disassembly and pre-cleaning

Perform pre-cleaning immediately after use:

- Disconnect the endoscope from the endocoupler and remove the light guide.
- **Danger:** The eyepiece is not removable.
- Remove the instrument bridge from the endoscope and disconnect the adapters from the fiber optic connector.
- Disassemble the instrument bridge into its individual components and dispose of the disposable sealing cap and three-slot diaphragm.
- Remove the instrument holder and, if applicable, the Lithoclast adapter from the instrument bridge.
- Remove any visible surgical residue as completely as possible with a lint-free cloth moistened with enzymatic cleaning solution.
- Rinse the lumens of all parts with tap water. Use a 20 ml disposable syringe.
- Dry the product with a soft, lint-free cloth.
- Place all parts in a dry disposal container and close it.
- Arrange for the reprocessing and ensure that all components of the product are reprocessed within 6 hours.

9 REPROCESSING INSTRUCTIONS

9.1 Safety instructions

⚠ **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.

⚠ **Contact of bladder cancer patients with Cidex OPA:** Anaphylactic reaction possible! Patients with a history of bladder cancer should not come into contact with products disinfected with Cidex OPA; if necessary, use machine cleaning and thermal disinfection.

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Improper cleaning and disinfection

- Patient endangerment due to insufficient cleaning and disinfection, damage to the product
- Use a washer-disinfector (WD) that meets the requirements of DIN EN ISO 15883-5.
- Load the appliance in such a way that all items to be washed are completely rinsed and cleaned (no "rinse shadows").
- Connect items to be washed with lumens and channels directly to the designated connections of the processing basket.
- Remove all taps and the instrument mount from the instrument bridge.
- Pre-clean products immediately after use and reprocess them within 6 hours.
- Do not use fixing temperatures above 45 °C during pre-cleaning.
- Do not use any fixing cleaning and disinfecting agents (active ingredient base: aldehyde, alcohol) during pre-cleaning.

Contact with chloride-containing solutions

Avoid contact with chloride-containing solutions, such as those found in surgical residues, tinctures, medications, and saline solutions. Rinse products thoroughly with deionized water and dry completely after contact with chloride-containing solutions.

Application of ultrasonic bath

Do not expose the endoscope to the ultrasonic bath!

9.2 Staff qualifications

The qualification requirements for personnel entrusted with the reprocessing of medical devices are regulated by law in many countries. In any case, the reprocessing of medical devices may only be carried out by qualified personnel who possess the necessary expertise.

9.3 Validated procedures

The procedures for manual cleaning and disinfection, machine cleaning and thermal disinfection and sterilization specified in this document have been validated for their effectiveness.
It is the operator's responsibility to implement, document, apply, and maintain a validated reprocessing procedure. Ensure that the equipment used for reprocessing is properly maintained.

9.4 Reprocessing instructions

Pre-cleaning : The preparation of the product for reprocessing begins immediately after use with pre-cleaning.
The product processing procedure described in this document consists of:

- Pre-cleaning immediately after use
- Cleaning and disinfection (manual or machine-based)
- Sterilization.

Users should wear personal protective clothing during reprocessing.
The product must be thoroughly cleaned at the start of reprocessing. It is essential that the sterilizing medium reaches all parts of the product. The best and safest reprocessing results are achieved through machine cleaning and disinfection followed by steam sterilization using a fractional vacuum process.
Observe the applicable national legal regulations, national and international standards and guidelines, and the hygiene regulations in place at your facility regarding reprocessing. Brand new products and returned items from repairs must undergo the entire reprocessing process before they can be used.
Alternating between different processing methods can lead to premature aging of the product. Overdosing on cleaning agents can damage the product and cause the laser marking to fade.
Further detailed information on hygienically safe, material-friendly and value-preserving reprocessing can be found at www.aki.org

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9.5 Cleaning detergent

Manual **cleaning and disinfection** can be carried out using:

- Cidezyme / Enzole (Johnson & Johnson)
- Cidex OPA (Johnson & Johnson)

Automated **cleaning** can be carried out using:

- neodisher Mediclean forte 0.5% (Chem. Fabrik Dr. Weigert GmbH & Co. KG)

Use only these cleaning and disinfecting agents whenever possible. Before use, carefully read the manufacturer's instructions and follow the guidelines regarding concentration, temperature, duration of use, water volume, and contact time.

9.6 Manual reprocessing

9.6.1 Manual cleaning

Validated with the alkaline cleaning agent Neodisher® MediClean forte:

- Immerse the instruments completely in the alkaline cleaning bath (e.g., 0.5% Neodisher® MediClean forte for 5 minutes). Observe the contact time according to the manufacturer's instructions.
- It must be ensured that the cleaning solution reaches all areas of the instrument. Moving parts of the instrument must be moved several times (**at least 3 times) in the cleaning bath. Cavities, lumens, narrow gaps, and slits in the cleaning bath** must be rinsed thoroughly and repeatedly (**at least 3 x 20 ml)** using a syringe (without a needle).
- After the required contact time, the instruments are cleaned again under running, cold tap water (**< 40 °C**) using a soft brush. Cavities, lumens, narrow gaps and slits are rinsed again with a water pressure gun (or syringe) **for at least 30 seconds** .
- Then rinse the endoscopes again under running, cold tap water (**< 40 °C**) and clean them further with a brush to completely remove the cleaning agent (**min. 30 sec.**).

9.6.2 Manual disinfection

Validated with the aldehyde-free disinfectant BODE Bomix® Plus

- Immerse instruments in an RKI- or VAH-listed disinfectant (e.g., 1% BODE Bomix® Plus for 15 minutes). Follow the disinfectant manufacturer's instructions.
- It must be ensured that the disinfectant reaches all areas of the instrument. Moving parts of the instrument must be moved several times (at least 3 times) in the disinfectant bath. Cavities, lumens, narrow crevices, and slots must be thoroughly rinsed and flushed several times (at least 3 x 20 ml) in the disinfectant bath using a syringe (without a needle).
- After the contact time, brush the instrument with a soft brush and rinse thoroughly with cold deionized water (min. 3 min). Cavities and lumens must be rinsed several times (min. 3 x 20 ml) with deionized water using a syringe (without a needle).
- Manual drying is carried out using a lint-free disposable cloth. To largely avoid water residue in cavities, it is recommended to blow these out with sterile, oil-free compressed air.

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9.7 Automated reprocessing (automatic cleaning and thermal disinfection)

Only specialized optical cleaning processes that have been tested and approved for this purpose (e.g., thermal disinfection) may be used. The use of a washer-disinfector (WD) in accordance with the requirements of the DIN EN ISO 15883-1 series of standards is recommended. Suitable pH-neutral or alkaline cleaning agents should be used for machine cleaning.

- Instruments must be placed on machine-washable instrument trays in a manner suitable for washing.
- The instrument carriers (e.g. sieve trays) must be designed in such a way that the subsequent cleaning in the cleaning and disinfection device is not hindered by rinsing shadows.
- The instruments should be fixed in the cleaning basket with a minimum distance between each other.
- Overlapping should be avoided to prevent damage to the instruments during the cleaning process.
- Manufacturer's instructions from the equipment and cleaning product manufacturers must always be followed.

Automatic reprocessing process, validated with Miele G7835 CD cleaning and disinfection unit, "Des-Var-TD" program, neodisher® MediClean forte alkaline cleaning agent, neodisher® Z neutralizing agent:

- Pre-clean for 1 minute with cold tap water (**< 40 °C**).
- Water drain
- Pre-clean for 3 minutes with cold tap water (**< 40 °C**).
- Water drain
- 5-minute cleaning at **55 °C +/- 2 °C** with alkaline cleaning agent (e.g. 0.5% neodisher® MediClean forte)
- Water drain
- 3 minutes neutralization (e.g. 0.1% neodisher® Z) with warm tap water (**40°C +/- 2°C**)
- Water drain
- Rinse for 2 minutes with warm demineralized water (**40 °C +/- 2 °C**)
- Automatic thermal disinfection in the cleaning and disinfection unit, taking into account the national requirements for the A0 value (e.g. > 90 °C (**A_0 3000**), 5 min)
- Automatic drying according to the automatic drying process of the cleaning and disinfection device (e.g. **90 °C +/- 2 °C** , 30 min).
- If necessary, manual drying with a lint-free cloth or blowing out the lumens with sterile, oil-free compressed air can then be carried out.

⚠ After machine cleaning, remove the endoscopes from the cleaning device immediately to prevent corrosion. Accelerated cooling of the instrument must be avoided!

9.8 Sterilization

Only perform steam sterilization with products that are labelled as autoclavable. AUTOCLAVE

⚠ The endoscopes are not supplied sterile and must be cleaned, disinfected, and sterilized before first use and before each subsequent use. Before each sterilization, the endoscopes must be thoroughly cleaned (manually or mechanically) and disinfected.

Check endoscopes for cleanliness, function and damage before each sterilization.

- Sterilize endoscopes individually in suitable sterilization containers.
- Ensure that the entire surface is in contact with the sterilization medium.
- Ensure that the fasteners securely hold the endoscopes.
- The endoscopes must not be subjected to any mechanical stress, as this could damage the sensitive optics.
- The endoscope tip must not be in direct contact with the metal container. Otherwise, the heat from the container will be transferred directly to the endoscope, which would then damage the optics.
- After the sterilization process is complete, the endoscopes should be cooled slowly to room temperature. The endoscope must not be rinsed with cold water or other liquids for cooling, as this can damage the optics.

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9.8.1 Sterilization process

- Only procedures that have been tested and approved for this purpose may be used.
- Sterilize endoscopes according to generally accepted hospital procedures.
- Follow the manufacturer's instructions for the aids used.

Endoscopes must not be exposed to gamma rays!

Recommended sterilization method (validated procedure):

Steam sterilization / autoclaving (validated parameters).

It is possible that sterilization methods not listed in these instructions may also be compatible with the endoscopes.

When using procedures other than those listed as validated in these instructions, the operator is responsible for sterility.

9.8.2 Steam sterilization (autoclaving)

Perform sterilization in accordance with DIN EN ISO 17665. Take into account relevant national requirements.

The sterilization result depends on various factors, such as how the sterilized instrument is packaged or stored, or how it is positioned in the autoclave. Verify the degree of sterilization using appropriate indicators.

Validated sterilization parameters:

Steam sterilization using fractional vacuum technology (in a sterilization container) and sufficient product drying in accordance with DIN EN ISO 17665:

Fractionated pre-vacuum steps	4
Temperature	134 °C (273 °F)
Holding time	5 minutes
Drying time	30 minutes
Packaging	Sterilization film

10 ENVIRONMENTAL CONDITIONS

10.1 Transport and storage conditions

- Temperature: 20°C to +70°C
- Relative humidity: 5% to 95%
- Air pressure: 70 kPa to 106 kPa

Store processed products in a dry, well-ventilated, dust-free, light-protected and uniformly temperature-controlled place to protect them from recontamination.

Direct sunlight, high temperatures, high humidity or radiation can damage the product or pose a risk of infection.

When storing the product, ensure it cannot be damaged by other instruments. Therefore, it is best to store it individually or use containers in which it can be secured.

10.2 Operating conditions

- Temperature: +15°C to +32°C
- Relative humidity: 30% to 85%
- Air pressure: 70 kPa to 106 kPa

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11 PROCEDURE IN CASE OF MALFUNCTIONS

Disturbance	Possible causes	remedy
Image blurry	Glass surfaces dirty	Manual cleaning, followed by reprocessing, Check water quality
	Leaky, defective lens system	Send in endoscope for repair
Image too dark	Glass surfaces dirty	Manual cleaning, followed by reprocessing, Check water quality
	Inappropriate optical fiber	Use a suitable fiber optic cable
	Fiber optic cable not correctly attached to the endoscope	Check the position of the light guide
	Fiber optics defective	Check fiber optics, replace if necessary.
	Optical fiber or light source defective	Check the light guide and light source
Image with yellowish discoloration	Fiber optics become contaminated	Manual cleaning, followed by reprocessing, Check water quality
	Optical fiber is dirty or defective	Check the light guide (e.g., shine a light onto a white surface)
Corrosion, stains, discoloration	Inadequate cleaning (e.g., remaining protein residues)	Manual cleaning, including thorough wiping if necessary, followed by reconditioning.
	Insufficient rinsing between processing phases, especially before sterilization	Rinse thoroughly between processing phases.
	Excessive chloride concentration	Check water quality
	Excessive concentration of minerals (e.g., lime) or organic substances	Check water quality; if necessary, use only demineralized water.
	Heavy metal ions and/or silicates, increased levels of iron, copper, manganese in the water or sterilization steam	Check water quality; if necessary, use only demineralized water.
	Contaminated, overused cleaning and disinfection solution	Regularly renew the cleaning and disinfection solution.
	Foreign rust, e.g. from rust-containing steam, joint processing with damaged or non-rust-resistant instruments	Check supply systems, pay attention to material compatibility and pre-existing damage during joint processing, and avoid mutual contact.
	Contact corrosion	Avoid contact with other products

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12 SPARE PARTS AND ACCESSORIES

Use only original spare parts and accessories.

illustration	Designation	Article number
	Adapter for EMS Swiss Lithoclast 1	790-384
	Adapter for EMS Swiss Lithoclast 2	790-404
	Three-slit membrane, non-sterile disposable item, pack of 10	790-402
	Sealing caps, non-sterile disposable item, pack of 10	790-413
	Tap plugs, steel, pack of 12 (4x clockwise, 8x counterclockwise)	790-403
	Storz fiber optic adapter system	700-997
	Wolf fiber optic adapter system	700-998
	Instrument bridge	790-382*
	URS reprocessing basket	707-654

13 REPAIR AND SHIPPING

13.1 Repairs

To ensure the operational safety of the endoscopes:

- Repairs should only be carried out by qualified personnel authorized by Tekno-Medical.
- Use only original spare parts for repairs.
- The warranty and guarantee claim is void if repairs are carried out by service centers not authorized by Tekno-Medical.
- Information about repairs and warranties is available from Tekno-Medical.

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13.2 Shipment

Returns of used medical devices are permitted only if they are cleaned and sterilized, and must be accompanied by written proof. Always use the original shipping packaging for returns. The packaging must ensure optimal protection of the endoscopes during transport. Defective products must have undergone the entire reprocessing process 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/

14 LIFETIME

The endoscopes are reusable instruments. Their lifespan depends on the frequency of use, as well as proper care and handling. When used as intended, the endoscopes can be used and reprocessed for 100 cycles without maintenance or breakage. Before each use, the endoscope must be checked for cleanliness, proper function, and damage.
At the end of its life cycle, dispose of the endoscope properly, if necessary.

15 DISPOSAL

Irreparable or non-recyclable products should be disposed of through standard hospital waste disposal procedures.
The following must be observed when disposing of the waste:

- Thoroughly clean and sterilize endoscopes before disposal.
- Dispose of packaging and used parts in accordance with country-specific regulations.
- Protect endoscopes from unauthorized access.

16 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.

17 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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18 SYMBOLS

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

	Caution!		Manufacturer
	Medical device		Date of manufacturing
	Non-sterile		Follow the instructions for use.
	Catalog number		Protect from sunlight
	Batch designation		Store in a dry place
	Unique product identification		Note regarding autoclavability
	CE marking with the number of the notified body: **mdc – medical device certification GmbH** Kriegerstrasse 6, D – 70191 Stuttgart		

19 ARTICLE LISTING

REF

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710-190	710-192	710-196	790-380	790-390
710-191	710-195	710-197	790-381	790-391

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