» Flexible Endoscopes «

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In order to minimise risks to patients, users or third parties, the instructions for use must be carefully observed. The use, 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 flexible endoscopes (hereinafter referred to as "**endoscopes**") from 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 any subsequent use.

1 SCOPE

This instruction manual is valid for the following reusable flexible endoscopes:

MD

- Bronchoscopes,
- Ureterorenoscopes,
- Cystoscopes.

(See article listing in the last paragraph of this instruction manual.)

2 HANDLING

Flexible endoscopes may only be used for their intended use in medical specialties, only in medical facilities and by trained and qualified medical professionals (doctors, medical assistants under the supervision of a doctor). The attending physician or the user/operator is responsible for the selection of the instruments for specific applications or surgical use, the appropriate training and information and the sufficient experience for the use of the instruments.

The reprocessing and sterilization of endoscopes and accessories is only permitted by qualified personnel with qualified training.

We recommend that you always have a spare endoscope ready for each endoscopic application. This reduces the risk of disruptions in the surgical procedure or diagnostic procedures and also prevents potential errors.

3 PURPOSES

3.1 Bronchoscopes

For examination, diagnosis and / or in conjunction with endoscopic accessories for treatment, flexible bronchoscopes are used exclusively to visualize the trachea and bronchi.

3.2 Ureterorenoscopes

For examination, diagnosis and / or in conjunction with endoscopic accessories for treatment, flexible ureterorenoscopes are used exclusively to visualize the upper urinary tract, including the ureters and renal pelvis.

3.3 Cystoscopes

For examination, diagnosis and / or in conjunction with endoscopic accessories for treatment, flexible cystoscopes are used exclusively to visualize the lower urinary tract, including the urethra and bladder.

4 INDICATIONS

4.1 Bronchoscopes

Flexible bronchoscopes are indicated as an aid in examinations and for visualization of the trachea and bronchi, e.g., for the diagnosis of lung tumours, foreign bodies or narrowing of the airways, for performing bronchial lavage, for biopsies or for local radiotherapy.

4.2 Ureterorenoscopes

Flexible ureterorenoscopes are indicated as an aid in examinations and for the visualization of the upper urinary tract including ureters and renal pelvis, e.g., in the case of ureteral narrowing, for the diagnosis of ureteral and renal pelvic tumours, for the clarification of unclear haematuria and for the removal of urinary and kidney stones or stone debris after intra- or extracorporeal shock wave lithotripsy.

4.3 Cystoscopes

Flexible cystoscopes are indicated as an aid in examinations and for visualization of the lower urinary tract including urethra and urinary bladder, e.g., for diagnosis and suspicion of tumours, 6 foreign bodies, urinary stones, fistula formation, urethral narrowing, recurrent or permanent bladder infections or urinary tract infections, haematuria, unclear urinary incontinence or tumour aftercare.

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5 CONTRAINDICATIONS

5.1 General

The use of flexible endoscopes is generally contraindicated when the use of other surgical techniques is indicated.
In addition, there are generally contraindications:

- in the event of general inoperability,
- if the patient is not willing,
- if the technical requirements are not met,
- for non-purpose applications.

Not for use on the central circulatory and nervous systems as defined in the Regulation.

5.2 Bronchoscopy

The following contraindications apply to flexible bronchoscopy:

- acute myocardial infarction,
- unstable hemodynamic with arrhythmia,
- severe blood clotting disorder,
- inadequate oxygenation during the examination / severe respiratory insufficiency,

severe tracheal stenosis, massive endobronchial haemorrhage.

5.3 Ureterorenoscopy

The following contraindications apply to flexible ureterorenoscopy:

- urinary tract infection, urosepsis,
- Contraindications to a lithotomy layer,
- Anticoagulation or coagulation disorders:
  - in the case of diagnostic URS, there is no contraindication,
  - in the case of stone therapy, a relative contraindication,
  - in the case of planned biopsy (tissue sampling), an absolute contraindication.

5.4 Cystoscopy

The following contraindications apply to flexible cystoscopy:

- acute infection or inflammation of the urinary tract,
- severe blood clotting disorders.

6 PATIENT POPULATION

With regard to flexible bronchoscopes, ureterorenoscopes and cystoscopes, there are no restrictions and restrictions on the patient population, unless there is at least one contraindication.

7 DISPOSAL

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

8 COMBINATION PRODUCTS

In combination with energetically operated, endoscopic accessories, there is a possible risk of excessive voltages and currents. It must be ensured that patient leakage currents are minimized in combinations. In order to avoid electrical coupling between the patient and the device, Tekno-Medical recommends the use of Tekno-Medical devices and accessories.
Flexible endoscopes can only combine with other medical devices if:

- the intended use in the operating instructions permits this,
- the technical data in the operating instructions allow this,
- the standard of the TV lenses or cameras complies with the general standard.

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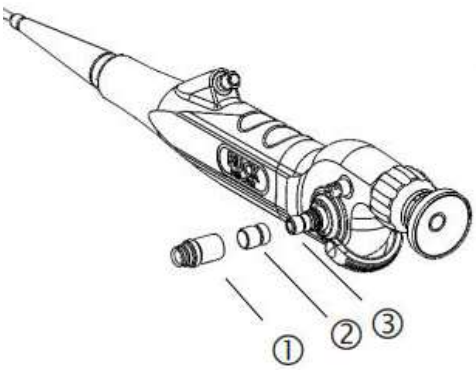
9 ASSEMBLY & DISASSEMBLY

- Install or disassemble the fibre optic connection according to the following figure.
- Make sure that the adapters of the fibre optic cables match the adapters of the flexible endoscopes. Corresponding connection systems only fit into the adapters provided. Adapters for fibre optic connections of Storz® / Aesculap® / Olympus® and Wolf® are included as standard.
- To prevent the endoscope from fogging up during surgery, the proximal end of the optics must be completely dry before adapting the camera or camera adapter. To ensure a firm and secure connection of the individual components, the closure of the endoscope and that of the adapter must not be dirty or damaged.
- Always hold the flexible endoscope by the main body or eye funnel. Handle the insertion tube carefully, i.e., do not squeeze or squeeze it.
- Ensure that glass surfaces are not touched by other instruments

Disassembly	Assembly
Fiber optic connection: Adapter (**1**) or (**2**) Unscrew from the endoscope.	Fiber optic connection: Adapter (**1**) or (**2**) screw on.
For working channels, if available: • Peel off the sealing cap. • Unscrew the valve body. • Remove the valve.	For working channels, if available: • insert a new valve. • Screw on the valve body. • Put on the sealing cap.



(**1**) Storz® / Aesculap® / Olympus® - Adapter
(**2**) Wolf® - Adapter
(**3**) ACMI® - Connection (fixed to the device)

10 CONTROL AND MAINTENANCE

10.1 General inspection (visual inspection)

- Before each inspection and maintenance, allow endoscopes and accessories to cool to room temperature. Assemble dismountable endoscopes and accessories.
- After each cleaning and disinfection, inspect flexible endoscopes and accessories for protein residues and contamination. Re-clean contaminated endoscopes and accessories. The flexible endoscopes must not contain any residues of cleaning agents and disinfectants.
- Before each sterilization and before each use, the flexible endoscopes must be checked for cleanliness, function and damage.
- There must be no damage to the entire endoscope such as loose, bent, deformed, broken, cracked, rough, broken parts, worn surfaces, sharp edges, defective insulation, etc.
- Sort out and replace damaged, defective, stained or cloudy endoscopes and accessories. Defective cables must be replaced immediately.
- Make sure that no parts are missing or loose (e.g., gaskets) and that the fasteners between the instruments are working correctly.
- Visual inspection of the glass surfaces: The surfaces must be clean and smooth.
- Discontinue use a product with damaged fibre optics, damaged glass surfaces, or stubborn debris that cannot be removed by cleaning.
- If any of the above deviations occur, the endoscope must not be used any further and must be sent to the manufacturer or an authorized service centre for repair or disposed of properly.

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10.2 Manual leak test

A leak test is absolutely necessary before any use, cleaning, disinfection and sterilization or other immersion procedures. It is carried out by means of a leak tester with a pressure gauge, as follows:

- Provide containers with clean water or cleaning solution.
- Test connection and test connection hose must be dry.
- Place the cap firmly on the valve and turn it 90° counter clockwise. The tester is then firmly attached to the endoscope and cannot be removed.
- Generate test pressure of max. 160 mmHg by pumping on the leak tester, visible by slight inflation of the deflection rubber on the distal angle part.
- If the pressure gauge indicator drops continuously, do not place the endoscope in the liquid, as the device is leaking. Please send the device in for repair.
- If there is a leak tightness, the leak tester must still be connected to the endoscope. The leak tester must not be placed in water. Dip the endoscope in liquid and watch the bubbles rise. If bubbles (or bubble flows) rise evenly over a period of more than 1 minute, this is a sign of leakage. Please send the endoscope for repair.
- Initial bubble formation arises from external niches and is insignificant.
- Always pay attention to the pressure gauge of the leak tester. If the pressure drops, build up pressure again, if necessary, otherwise there is a risk of water damage.
- After a successful test, remove the endoscope from the water, bleed the system and disconnect the leak tester.
- In case of positive leak test (= proven perforation):
  - Remove the device from the solution under pressure.
  - Wipe the outer jacket with disinfectant solution (microcide wipes).
  - Dry duct systems and contacts using compressed air.
  - Wrap the endoscope in a foil protective cover, pack it in a shipping box and send it in for repair with the note "leaking, not disinfected".

⚠ **Never connect or disconnect the tester underwater!**
Never submerge the endoscope in liquids if there is a pressure drop!

10.3 Testing for consistency

Before each use, cleaning, disinfection and sterilization, the working channel must be checked for consistency:

- The working channel must be flushed with water using a disposable syringe.
- Attention must be paid to consistency and tightness.
- The test can be combined with the manual leak test

10.4 Testing the articulation mechanism

- Slowly press the articulation lever to test the function.
- Check that full articulation is achieved.

⚠ Any restrictions on the articulation options may indicate a defect in the endoscope. In order to avoid major damage to the endoscope in this case, use the endoscope only if the angle is smooth.

10.5 Fiber Optics Testing

Before each application, it is necessary to check the image quality (clear and distortion-free) and the light transmission through the optical fibres:

- Point the end of the distal endoscope against glare-free light, e.g., in front of a bright ceiling light (no cold light source), hold the light guide connection close to your eyes (10 cm distance) and move it back and forth.
- The brightness of the fibres changes. If the glass fibres appear as dark dots at the distal end, the glass fibres are broken and sufficient illumination may no longer be ensured. If individual fibres remain dark, this is harmless. From a breakage rate of approx. 10-20%, it is recommended to send the endoscope for repair.

10.6 Maintenance and servicing

- Flexible endoscopes and accessories are maintenance-free. There are no components included that require user or manufacturer maintenance.

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11 REPROCESSING INSTRUCTIONS

The flexible endoscopes are not supplied sterile and must be cleaned, disinfected and sterilized before the first and each subsequent use.
Flexible endoscopes must not be cleaned in an ultrasonic bath.
Flexible endoscopes must not be exposed to gamma rays.
Flexible endoscopes must not be autoclaved/steam sterilized. Temperatures of **> 60 °C** must not be exceeded.

11.1 General application instructions for safe reprocessing

- After each cleaning/disinfection and before each use, the endoscopes must be checked for cleanliness, function and damage. Do not use damaged or defective endoscopes. Damaged parts must be replaced immediately with original spare parts. Damaged endoscopes must be sorted out immediately.
- Reprocess contaminated endoscopes and accessories as quickly as possible.
- Manual or mechanical (automatic) cleaning and disinfection must be carried out after each use. Observe the manufacturer's instructions (e.g., dosage).
- Do not apply strong pressure by hand.
- Ensure that endoscopes and accessories do not touch each other during cleaning.
- Only use detergents for the complete dissolution of proteins.
- Avoid any fixation of proteins before and during processing.
- Do not use abrasive cleaners or metal brushes.
- The parameters specified by the manufacturer of the detergent for concentration, temperature, service life and exposure time must be complied with and automatic dosing devices must be controllable.
- If there are elevated chloride concentrations in the water, pitting and stress corrosion cracking can occur on the instruments. Such corrosion can be minimized by using demineralized water or alkaline cleaning agents.
- The choice of detergent and disinfectant is based on the characteristics of the instruments and national guidelines and recommendations.
- The applicable country-specific laws and regulations must always be observed.
- In case of contact with corrosive agents, clean immediately with water. If possible, use fully demineralized water (demineralized water).
- Incorrect cleaning can lead to damage.

Always clean automatically after contact with:

- Blood,
- Wounds,
- Inner tissues,
- Organs.

11.2 Preparation of instruments and pre-cleaning

11.2.1 Preparation of the instruments at the location of use

- Remove visible residues and surface dirt as completely as possible with a clean, damp, lint-free cloth.
- Always carry out a leak test before placing them in liquids.

Do not use warm water **(> 40 °C**) or fixing disinfectants, as this can lead to a fixation of the residues on the product (risk of protein coagulation or denaturation), which can affect the success of the subsequent treatment steps.

11.2.2 Transport

- The instruments can be transported to the respective treatment rooms both wet and dry.
- We recommend using designated storage systems (e.g., disposal containers) for safe and smooth transport for processing

Drying of residues should be avoided at all costs!

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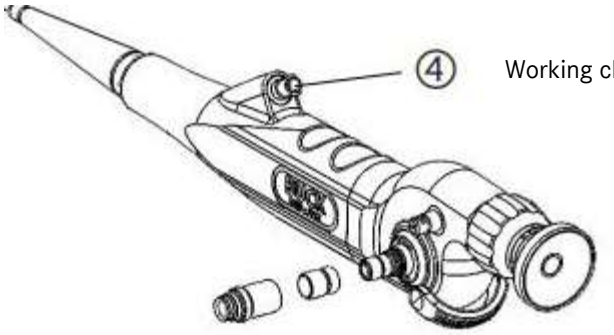
11.2.3 Manual pre-cleaning

Pre-cleaning must always be carried out before both manual and mechanical (automatic) cleaning:

- Disassemble dismountable endoscopes and accessories into individual parts. Disassemble the flexible endoscope as much as possible. Remove all fibre optic adapters before reprocessing.
- To remove stubborn dirt, soak the product in cold water **(< 40°C**) for at least 5 minutes.
- Use a soft cleaning brush (natural brushes) to clean the product under cold running city water **(< 40°C**) until all visible dirt has been removed.
- Cavities, lumens, narrow gaps and slits should be rinsed intensively (**> 30 seconds**) with cold city water using a water pressure gun (or syringe).



Working channel with Luer-Lock connection

- Insert the long cleaning brush into the working channel only from proximal to distal without force.
- Push the cleaning brush through the working channel (4) in one direction only and only retract it when the brush head is visible at the distal end. Do not pull the cleaning brush back and forth, as this can cause damage.
- Clean the optical surfaces (proximal eye funnel (eyepiece), distal tip, optical cable connection) with a lint-free cleaning cloth and clean them carefully under cold running tap water (< 40°C). Do not use cleaning brushes as scratches may occur. Impurities and scratches that impair optical quality can be made visible by light reflections on the optical surface.

⚠ If there are still residues on the surface of the optical fibres after cleaning, these residues can burn on the surface when using a light source and thus impair fibre transmission (light transmission).

11.3 Manual reprocessing

11.3.1 Manual cleaning

Validated with the alkaline detergent Neodisher® MediClean forte.

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

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11.3.2 Manual disinfection

Validated with the aldehyde-free disinfectant Korsolex® plus

- Immerse instruments in an RKI or VAH-listed disinfectant (e.g., 3% Korsolex® plus for 15 min). The instructions of the disinfectant manufacturer must be followed.
- 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. Rinse cavities, lumens, narrow gaps and slits in the disinfectant bath with a syringe (without cannula) several times (**min. 3 x 20 ml**).
- After the exposure time, rinse the instrument thoroughly with cold demineralized water (**min. 30 sec.**). Cavities and lumens must be rinsed with demineralized water several times (**min. 3 x 20 ml**) using a syringe (without cannula).
- Manual drying is carried out using a lint-free disposable cloth. In order to avoid water residues in cavities as much as possible, it is recommended to blow them out using sterile, oil-free compressed air.

11.4 Automated reprocessing (cleaning and thermal disinfection)

It is recommended to use an RDG-E washer-disinfector in accordance with the requirements of the ISO 15883 series of standards.

- Instruments must be placed on machine-compatible instrument carriers for flushing.
- The instrument panels (e.g., sieve trays) must be designed in such a way that subsequent cleaning in the washer-disinfector is not hindered by rinsing shadows.
- The instruments should be fixed in the cleaning basket at a minimum distance from each other.
- Overlapping with each other must be avoided in order to avoid damage to the instruments caused by the cleaning process.
- Temperatures **must not exceed 60 °C** to avoid damage to the flexible endoscope.
- Manufacturer's specifications of the appliance and cleaning agent manufacturers must always be observed.

Suitable pH-neutral or alkaline cleaners should be used as cleaners for machine cleaning. We recommend the cleaning solution THERMOSHIELD® NR (formerly: THERMOTON® NR) from Dr. Schumacher GmbH with a dosage of 0.5 % (according to the manufacturer's instructions for endoscope reprocessing).
For chemical disinfection, we recommend the disinfectant THERMOSHIELD® DISINFECTANT (formerly: THERMOTON® DISINFECTANT) from Dr. Schumacher GmbH.

Automatic reprocessing process validated with Belimed WD 425 washer and disinfector, pH-neutral detergent THERMOTON® NR (identical composition and formulation to THERMOSHIELD® NR), disinfectant THERMOTON® DISINFECTANT (identical composition and formulation to THERMOSHIELD® DISINFECTANT):

- Manual pre-cleaning.
- Automatic leak test in the RDG-E.
- Pre-clean for 3 minutes with cold tap water **(< 40 °C**)
- Clean for 5 minutes at 55 °C ± 2 °C 0.6 % pH neutral detergent (e.g., THERMOSHIELD® NR)
- 1 minute rinse with demineralized water (**< 40 °C**)
- 5 minutes chemical disinfection with e.g., 1% THERMOSHIELD® DISINFECTANT at **55 °C ± 2 °C**, demineralized water
- 1 minute final rinse with demineralized water **55 °C ± 2 °C**
- 15 minutes of automatic drying according to the automatic drying process of the washer-disinfector at **55 °C ± 2 °C**
- Subsequently, manual drying with a lint-free cloth or blowing out lumens using sterile, oil-free compressed air can also be carried out.

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

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12 STERILIZATION

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

- Sterilize endoscopes individually packaged in suitable sterilization containers.
- Make sure that the entire surface is in contact with the sterilization medium.
- Ensure that the fixation holds the endoscopes securely.
- The endoscopes must not be subjected to mechanical stress, as this could damage the sensitive lens systems.
- Once the sterilization process is completed, the endoscopes should be slowly cooled down to room temperature. The endoscope must not be rinsed with cold water or other liquids for cooling, as this can cause damage to the optics

12.1 Sterilization Procedures

Only special methods for thermolabile optics that have been tested and approved for this purpose may be used.

⚠ Flexible endoscopes must not be exposed to gamma rays

⚠ Flexible endoscopes must not be steam sterilized or autoclaved. Temperatures of **60 °C** must not be exceeded.

Recommended sterilization methods:

• Gas sterilization with EtO (validated parameters).
• Gas sterilization with hydrogen peroxide using the STERIS® V-PRO® process.

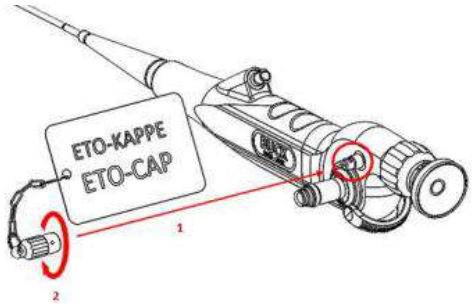
Select the appropriate sterilization process for thermally labile instruments in accordance with national legislation and recommendations.
It is possible that sterilization procedures not listed in this manual are also compatible with the endoscopes. In the case of the use of procedures other than those listed as validated in this manual, the responsibility for sterility lies with the operator.

12.1.1 Ethylene oxide sterilization (gas sterilization)

Sterilization with ethylene oxide (gas sterilization) according to DIN EN ISO 11135. In doing so, take into account relevant national requirements. According to the manufacturer, EtO devices that work according to a validated procedure in accordance with DIN EN 1422 ensure safe sterilization and desorption. When sterilizing with ethylene oxide gas, follow all reprocessing protocols from national authorities, health departments, professional associations, and your facility, as well as the instructions of the manufacturer of your sterilization equipment.
The result of sterilization depends on several factors, such as how the sterilized instrument is packaged or stored, or how the instrument is placed in the sterilizer. Check the degree of sterilization with the help of biological or chemical indicators.

⚠ Ethylene oxide gas is toxic and can be hazardous to health. Comply with the applicable health protection regulations to determine the suitability of the procedure.

- Before gas sterilization, clean and dry the instruments thoroughly. Water residue can prevent sterilization or cause damage to the endoscope.
- Before sterilization, attach the pressure compensation cap (**EtO cap**) to the endoscope connection (see figure). If the EtO cap is not attached to the endoscope during ethylene oxide gas sterilization, the air inside the endoscope will expand and may cause the coating of the angulation part to crack and / or damage the articulation mechanism.



Allow the instruments to outgas sufficiently after sterilization and dry properly after sterilization to eliminate toxic residues of the ethylene oxide gas.

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Validated Sterilization Parameters:

EtO Sterilization	**Temperature**	55 °C ± 3 °C
	Chamber Pressure	1.7 bar (0.17 MPa)
	Relative humidity	40 – 100 %
	Exposure time (exposure time)	120 min (2 hours)
	EtO Concentration	7 -8.5 % EtO (≥ 260 mg/l) 91.5 – 93 % CO_2
Outgassing (desorption)	**Minimum**	≥ 6 hours at 52 – 58 °C

If the specified desorption conditions are met, in conjunction with the listed sterilization parameters, the flexible endoscopes are free of residual gas in the sense of the limits specified in DIN EN ISO 10993-7.

12.1.2 Gas sterilization with hydrogen peroxide in the STERIS® V-PRO® process

Gas sterilization with hydrogen peroxide is another alternative method to the sterilization of thermolabile flexible endoscopes. For this method, the efficacy was validated and the material compatibility was tested over 30 cycles. The validation of Tekno-Medical's flexible endoscopes is valid for the following STERIS® V-PRO® low temperature sterilization system:

Sterilizer (Low Temperature Sterilization System)	Flexible Cycle
V-PRO® maX	✔
V-PRO® maX 2	✔
V-PRO® 60	✔
V-PRO® s2	✔

The suitability of the flexible endoscopes for effective sterilization was demonstrated by an independent accredited testing laboratory. Sterilization is considered sufficiently effective if a reduction of viable microorganisms is achieved by at least a factor of 10^6 (sterility assurance level (SAL): 10^{-6}).
For information on packaging and weight restrictions, please refer to the information provided by the sterilizer manufacturer.

13 STORAGE AND TRANSPORT

13.1 Storage / Retention and Packaging

- Flexible endoscopes sterilized with gas or equivalent methods must be stored in a closed cabinet to protect against contamination after appropriate desorption.
- Before storage, flexible endoscopes must be completely dry.
- Flexible endoscopes should only be stored and packaged individually.
- Store flexible endoscopes in a dry, clean, dust-free and well-ventilated environment and in a protected place at room temperature (free of corrosive fumes). To avoid the formation of condensate, major temperature fluctuations should be avoided.
- Flexible endoscopes should preferably be stored hanging on suitable holders in a special closed endoscope cabinet.
- The transport packaging of the flexible endoscopes is not intended for cleaning, sterilization and storage, therefore flexible endoscopes are not stored in the transport packaging.
- After 7 days at the latest, the flexible endoscopes must be reprocessed.
- Before use, after storage, rub the outer coat with microcide cloth and rinse channels with 20 ml of 70% alcohol.

13.2 Transport

- For transport, the flexible endoscope must be transported contamination-protected in suitable closed containers to avoid recontamination.
- It is not permitted to transport endoscopes for evaluation examinations in the transport packaging. The transport packaging may only be used to ship a defective device to the manufacturer for repair.

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14 SERVICE AND REPAIR

To ensure the operational safety of the flexible endoscopes:

- Repairs must be carried out exclusively by the respective dealer or by a qualified after-sales service authorized by Tekno-Medical.
- Only use original spare parts for repairs.
- The guarantee and warranty claim expires in the case of repairs that are not carried out by Tekno-Medical authorized service centres.
- Further information about repairs and warranties is available from Tekno-Medical.

14.1 Shipping

Returns of used medical devices are only permitted in a cleaned and sterilized state with written proof. Always use original transport packaging when returning. The packaging must ensure optimal protection of the endoscopes during transport. 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/

15 LIFETIME

Flexible endoscopes are reusable instruments. The service life of the flexible endoscopes depends on the frequency of use, as well as the care and careful handling. When used as directed, the flexible endoscopes can be applied and remanufactured for 30 cycles without maintenance/breakage. Before each use, the flexible endoscope must be checked for cleanliness, function and damage.
At the end of its life cycle, dispose of the flexible endoscope properly, if necessary.

16 DISPOSAL

When disposing of the property, the following must be observed:

- Clean and sterilize flexible endoscopes thoroughly before disposal.
- Dispose packaging and used parts in accordance with country-specific regulations.
- Protect flexible endoscopes from unauthorized access.

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.

18 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 it can be proven that these instructions for use have been violated.

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

Tekno-Medical Optik-Chirurgie GmbH
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19 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
MD	Medical		Manufacture
	Non-sterile		Follow the instructions for use
REF	Catalogue		Protect from sunlight
LOT	Batch designation		Store in a dry place
UDI	Unique device identification		
CE 0483	CE marking with Notified Body number: **mdc – medical device certification GmbH** Kriegerstrasse 6, D – 70191 Stuttgart		

REF

20 ARTICLE LISTING

Printed on: 16.04.2024

Bronchoscopes	
710-280	710-281
Ureterorenoscopes	
710-290	
Cystoscopes	
710-295	710-296

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