» LARYNGOSCOPES «

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

Tekno-Medical Optik Chirurgie GmbH
Sattlerstr. 11
78532 Tuttlingen
GERMANY
SRN: DE-MF-000005822

Phone: +49 (0) 7461 / 17 01 0
Fax: +49 (0) 7461 / 17 01 50

Mail: mail@tekno-medical.com
Web: www.tekno-medical.com

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

CONTENT

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

CE

In order to keep hazards to patients, users or third parties as low as possible, the instructions for use must be carefully observed. The application, reprocessing and testing of the instruments may only be carried out by trained specialists. The products are delivered non-sterile and must go through the complete processing cycle (cleaning, disinfection and, if necessary, sterilization) before the first and every subsequent use.

1 SCOPE

MD This instruction manual is valid for the laryngoscopes of Tekno-Medical Optik-Chirurgie GmbH. (See product list in the last section.)

2 INSPECTIONS

The instruments must be checked for functionality prior to each use. Damage to the surfaces such as scratches, cracks, nicks, notches, etc., as well as bent parts mean that the instrument must not be used. Damaged products must not be used!
Laryngoscopes consist of two components:

- Handle.
- Spatula with light system.

Before each use, the tight fit and compatibility of the components must always be checked.
Above all, it is important to pay attention to the tight fit of the light system!

3 HANDLING

The products may only be used for their intended purpose by appropriately trained and qualified personnel. The treating physician or user is responsible for the selection of instruments for specific applications or operational use, the appropriate training of personnel and the experience in handling the products.

4 PURPOSE

Laryngoscopes serve the inspection of the larynx, as an aid in oral intubation and to ensure clear airways. The duration of use is transient (under normal conditions intended for uninterrupted use for a period of less than 60 minutes) in accordance with Regulation (EU) 2017/745 on medical devices.

5 INDICATIONS

Laryngoscopes are part of the standard instruments for oral intubation and for the diagnosis of anatomical structures in the pharynx.

6 CONTRAINDICATION

The laryngoscope light sources can, in rare cases, cause heat-induced irritation of the mucous membrane. In general, the use of the laryngoscopes is contra-indicated in cases where the use of other techniques is indicated. In addition, there are contraindications:

- in case of unwillingness of the patient;
- if the technical requirements are not met.

Not for use on the central circulatory and nervous system within the meaning of the Regulation (EU) 2017/745 on medical devices.

7 PATIENT POPULATION

Apart from the contraindicated uses listed in these instructions for use, there are no restrictions on the patient population.

8 DISPOSAL

If the instruments can no longer be repaired or reprocessed, the instruments must be disposed in accordance with the applicable country-specific regulations and laws.
Defective products must usually have gone through the entire reprocessing process before disposal.

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

CE

9 WARNINGS

Instruments made of stainless steel must not be placed in physiological saline solution (NaCl), prolonged contact can lead to pitting or stress corrosion. Instruments may only be sterilized after prior cleaning and disinfection. Brand-new products must go through the entire processing process once before being used for the first time. A new medical device must be subjected to a thorough visual and functional inspection after delivery. If the medical device has externally visible defects (scratches, breaks, cracks, notches, bent parts and stiffness) or if it does not work as described in these instructions for use, we as the manufacturer or your sales partner must be notified immediately. To ensure the safe operation of the products mentioned, correct maintenance and care of the products is essential. Therefore, a functional or visual test should be carried out before each use. For this reason, we refer to the relevant sections in these instructions for use. There are no specific requirements for storing products before sterilization. We still recommend storing the medical devices in a clean and dry environment. All medical instruments should always be handled with the greatest care when transporting, cleaning, maintaining, sterilizing and storing. This applies in particular to work ends, barriers and other sensitive areas.

10 NOTES

With regard to the reprocessing of medical devices that have been used on patients suffering from, or suspected of suffering from, Creutzfeldt-Jacob disease (CJD) or its variant (vCJD), the requirements specified in the relevant annex to the Directive on Hospital Hygiene and Infection Prevention and in publications in the Federal Health Gazette must be observed. Medical devices used on this patient group must be safely disposed of by incineration (European Waste Catalogue EAK 180103) (Category IB). Dry heat, ethanol, formaldehyde, and glutaraldehyde have a fixative but not an inactivating effect on TSE pathogens. Of the available sterilization methods, only steam sterilization (particularly 134°C, 18 minutes) has been demonstrated to have limited effectiveness.

Attention : In case of use of the instruments in patients with Creutzfeldt-Jakob disease, Tekno-Medical declines any responsibility for reuse.

11 INSTRUCTIONS FOR REPROCESSING

11.1 General

In general, medical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities. Detailed information on the preparation of instruments 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 reprocessing expert committees. Steel instruments must not be placed in physiological saline solution (NaCl), prolonged contact can lead to pitting or stress corrosion. Due to the product design and the materials used, no defined limit of maximum feasible applications can be set. The lifespan of medical devices is essentially determined by their function and careful handling. Frequent reprocessing has little impact on the product. End of product life is typically determined by wear and damage from use.

11.1.1 Battery handles

The battery handles should not be sterilized in an autoclave or in hot air. They can only be sterilized in gas or disinfected in solution. The batteries can be removed from the handles. It is recommended to use only leak-proof batteries to avoid contact or corrosion damage.

11.1.2 Handles with cold light

In the case of handles with cold light, only gas sterilization or disinfection in solution is also permitted. The lamps must be removed from the handles before sterilization.

11.1.3 Fiberglass light carriers

All fiberglass light carriers can be sterilized in an autoclave up to 134° Celsius.
However, to extend the service life of the built-in fiberglass, gas sterilization or disinfection in solution is recommended. The fiberglass light carriers must not be cleaned with ultrasound under any circumstances. Flash autoclaving and hot air sterilization, as well as the use of other chemical agents (except a disinfectant solution) are also not permitted.

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

11.1.4 Accessories

⚠ Accessories with silicone or plastic pads must not be sterilized in an autoclave or in hot air. They can only be sterilised in gas or treated with disinfectant solution (wipe disinfection).

Accessories made of stainless steel can be sterilized in the autoclave.

11.2 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.

11.3 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.

11.4 Preparation for decontamination

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

11.5 Manual pre-cleaning

For manual cleaning / pre-cleaning, never use metal brushes, metal sponges or abrasive cleaning agents. 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. Pressure flush cavities, holes and threads with a water gun for at least 10 seconds (pulsed method, minimum pressure 2 bar).
The cleaning solution should be changed at least once a day, more often if necessary. Too much contamination impairs the cleaning effect and increases the risk of corrosion. National laws and guidelines must be observed.

The fiberglass light carriers must not be cleaned with ultrasound under any circumstances.

11.6 Automated cleaning

Place the opened instruments in a sieve tray on the slide-in carriage and start the cleaning process. Disassemble instruments 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

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

CE

11.7 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 the instruments with sterile compressed air. Allow products need to cool down to room temperature.	

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

11.8 Functional testing

After each cleaning, the products must be macroscopically clean, i.e., free of visible contamination. Stained products must be sorted out immediately and given special treatment. All moving parts must be checked with particular attention. If errors or damage occur, the products must be sorted out immediately.

11.9 Care of the instruments

“Care” basically means the application of instrument oil or instrument milk (emulsion of white oil in water). Products with movable jaws, joints, locks or with metal sliding surfaces must be treated with steam-sterilizable paraffin oil-based care products. The paraffin oil must comply with the applicable pharmacopoeia and be physiologically harmless. (Further information can be found in DIN 96298-4.)

11.10 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.

11.11 Sterilization

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

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

The use of other sterilization methods is beyond our responsibility.

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.

11.12 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.

Protect from sunlight!

11.13 Information on the validation of the reprocessing

The following materials and machines were used in the processing process:

Detergent	Neodisher Medizym 0,5 % (v/v)
Neutralisator	Neodisher Z 0.1% (v/v)
Washer-disinfector (RDG)	Miele PG 8535
Steam-autoclave	Lautenschläger ZentraCert
For details see test reports: 23277 / 23278 / 23279 (CleanControlling Medical GmbH & Co. KG, 08-2021)	

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

CE

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.

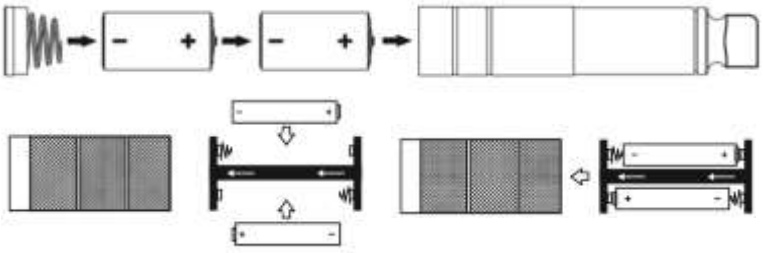
The state of the art and national laws require the following of validated processes.

During reprocessing, the temperature acting on the instrument should not exceed 140°C. In principle, mechanical cleaning and disinfection are always preferable to manual cleaning. With mechanical cleaning and disinfection, there is greater safety in the process. The instruments must not be sterilized in hot air sterilizers. Strongly alkaline cleaning agents damage plastics and anodized coatings.

13 BATTERIES AND LIGHT GUIDES

13.1 Battery Replacement

Check the battery charge level regularly. Decreasing battery voltage leads to reduced light intensity and possibly to flickering bulbs. In both cases, the batteries must be replaced. When changing, only use new, high-quality alkaline batteries (or fully charged batteries).



13.2 Inspection of the light guides

Verify the integrity of the light guide.

If the light intensity is too low, check the following causes:

- Charge level of the handle battery and replace it if necessary.
- Clean or replace the light source in the handle head if necessary.
- Carefully clean the input and output of the light fibre. Use a soft, clean cloth to avoid scratching.

Checking the optical fibre guides for damage, e.g. at the outer light guide tip.

14 REPORTING OF PRODUCT ISSUES

In accordance with the requirements of the Regulation (EU) 2017/745 on medical devices and our quality management system, all product issues must be reported to the manufacturer.
You can reach us by phone during business hours 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 responsible local authority.

15 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 a particular procedure. This must be determined by the user.

Tekno-Medical assumes no liability for incidental or consequential damages.
Tekno-Medical assumes no liability if it can be proven that these instructions for use have been violated.

Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

16 SERVICE AND REPAIR

Do not carry out repairs or modifications of the product on your own. Defective products must have gone through the entire remanufacturing process before being returned for repair. For returns, use our RMA request form and decontamination certificate.
Forms at: https://www.tekno-medical.com/de/service/repair service

17 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

18 Product listing

REF

Printed on: 13.01.2026

5100-00	5120-01	5145-01	5150-05	5162-04	5195-01	5200-05	5250-05	5252-00
5100-01	5120-02	5145-02	5160-00	5176-09	5195-02	5220-00	5250-06	5254-00
5100-02	5120-03	5150-00	5160-01	5176-10	5200-00	5220-01	5250-07	
5100-03	5120-04	5150-01	5160-02	5186-04	5200-01	5250-01	5251-00	
5100-04	5141-07	5150-02	5160-03	5190-01	5200-02	5250-02	5251-01*	
5100-05	5142-07	5150-03	5160-04	5190-02	5200-03	5250-03	5251-20*	
5120-00	5143-07	5150-04	5162-03	5190-03	5200-04	5250-04	5251-50	

TEKNO GERMANY
Tekno-Medical Optik-Chirurgie GmbH
Sattlerstraße 11 D-78532 Tuttlingen
Tel.: +49 (0) 7461 1701-0 Fax: +49 (0) 7461 1701-50
E-Mail: mail@tekno-medical.com www.tekno-medical.com

CE