



» TEKNO LIZARD «





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In order to keep risks to patients, users or, if necessary, third parties as low as possible, the instructions for use must be carefully observed. The use, preparation and testing of the instruments may only be carried out by trained specialists.



The Tekno LIZARD pliers are delivered non-sterile and must go through the complete reprocessing cycle (cleaning, disinfection and sterilization) before the first and every subsequent use.

1 SCOPE

This instruction manual is valid for the dismountable LIZARD forceps from Tekno-Medical Optik-Chirurgie GmbH. (See article list in the last paragraph of this instruction manual.)

2 INSPECTIONS

Before each use of the pliers, they must be inspected for breaks, cracks, deformations, damage and functionality. Areas such as interlocks, working channels, working ends, connections and all moving parts must be checked with particular care. Worn, corroded, deformed, porous or otherwise damaged instruments must be sorted out. In addition to the efforts made by the manufacturer to select the right materials and to process them carefully, the coagulation pliers must be properly and continuously cared for and processed by the user.

3 HANDLING

The products may only be used for their intended use by appropriately trained and qualified personnel. The attending physician or user is responsible for the selection of the instruments for certain applications or surgical use, the appropriate training of the staff and the experience in the handling of the products. This product should only be used in medical facilities by trained healthcare professionals.

The LIZARD knives (tk 707-055) are intended for single use and must be disposed of after disassembly.



Maximum output voltage of Umax generator:

400 Vp.

The power of the RF generator must always be set as low as possible to achieve the desired effect.

4 INTENDED PURPOSE

The endoscopic electro-surgical forceps are primarily used for grasping, compressing and coagulating or thermal sealing of tissues in the context of minimally invasive procedures.

5 INDICATION

The bipolar LIZARD vascular sealing and coagulation instrument with cutting mechanism was developed for use in minimally invasive surgery, especially laparoscopy, and is inserted through a trocar sleeve with a diameter of 5.5mm.

6 CONTRAINDICATION

The use of endoscopy forceps is generally contraindicated if the use of other surgical techniques is indicated. 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.

Do not use for tube sterilization or tube coagulation for sterilization.

Not for use on the central circulatory and nervous system within the meaning of the Medical Device Regulation (EU) 2017/745 (MDR). The doctor in charge must decide on the basis of the patient's general condition whether the intended application can be carried out. The instrument should not be used if, in the opinion of the responsible physician, the risks to the patient exceed the benefits.



7 SIDE EFFECTS AND RESIDUAL RISKS

Electrodissection leads to higher collateral tissue damage compared to incisions with a scalpel and can therefore lead to histological changes at the incision site.

Thermal damage can lead to carbonization at the exit site, vascular thrombosis and collagen changes; a thorough assessment of the advantages and appropriateness of the planned application is therefore appropriate.

Incidents reported in connection with the use of RF systems:

- Unintentional activation resulting in tissue damage in the wrong place or damage to equipment.
- Fire in conjunction with drapes and other flammable materials.
- Alternating current paths that lead to burns in places where the patient or user comes into contact with uninsulated components.
- Explosions caused by sparking in the vicinity of flammable gases.
- Perforation of organs.
- Sudden severe bleeding.

When electrosurgery is applied to patients with pacemakers or other active implants, special requirements apply (e.g. low RF power, patient monitoring). In any case, a cardiologist or appropriate specialist must be consulted.

Endogenous burns: Endogenous burns are burns caused by high current density in the patient's tissue. Causes can include:



- The patient unintentionally comes into contact with electrically conductive parts.
- In case of direct skin contact with the electrode or the RF cable, capacitive currents can lead to burns.

Exogenous burn hazard: Exogenous burns are burns caused by the heat of ignited liquids or gases. Explosions are also possible. Causes can be:



- Inflammation of skin cleansers and disinfectants,
- Inflammation of anesthetic gases, etc.



To avoid bleeding and secondary bleeding, only use the cutting mechanism when the enclosed tissue or blood vessel has been completely coagulated or sealed.

8 PATIENT POSITIONING AND PATIENT PREPARATION

Ensure proper patient positioning, i.e., use insulating operating table pads that are dry, absorbent and liquid-tight. Isolate conductive surfaces and points of contact with the patient. In skin folds, breast folds and between the extremities, dry cellulose interlayers are required, such as fluids accumulated in body cavities, should be eliminated before starting the procedure. Use non-flammable disinfectants, use non-conductive rinsing solutions where medically possible.

As a rule, any type of body jewelry of the patient must be removed before HF-use.

9 PATIENT POPULATION

There are no fundamental restrictions on the patient population.

10 COMBINATIONS

Note (in accordance with DIN EN IEC 60601-2-2, subsection 202.7.9.2.14 k):

The length of the connection cables, which are considered antennas, is between 3 – 5 meters.

The working length of the instrument is between 25 – 35 centimeters.



A faulty combination of the products can lead to injury to the patient, user or third parties or damage to the products!

The application and safety instructions of the generator manufacturer must be observed.

11 DISPOSAL

If the instruments can no longer be repaired and reconditioned, the instruments must be disposed of in accordance with the applicable country-specific regulations and laws.



12 WARNINGS



Always lay patient lines in such a way that there is no contact with the patient or other lines. Instruments that are not used at times must always be placed in isolation from the patient in order to avoid patient harm in the event of accidental activation of the RF current.

Activate RF current only when the contact surfaces are in the field of vision and have good contact with the tissue to be treated. Do not touch any other metallic instruments, trocar sleeves, optics or the like. Do not use in the presence of flammable or explosive substances!

Brand-new products must have gone through the entire reprocessing process once before being used for the first time. Coagulation forceps corrode and are impaired in their function when they come into contact with aggressive substances. For this reason, it is imperative to follow the reprocessing and sterilization instructions.

A new medical device must be subjected to a thorough visual and functional inspection. If the medical device has externally recognizable defects (scratches, breaks, cracks, nicks, damaged insulation, bent parts and binding) or if it does not work as described in this instruction manual, we as the manufacturer or your distributor must be notified immediately

To ensure the safe operation of the aforementioned products, correct maintenance and care of the products is essential. Therefore, a functional or visual inspection should be carried out before each application. For this reason, we refer to the relevant sections in this instruction manual.

There are no specific requirements for storing the products before sterilization. Nevertheless, we recommend storing the medical devices in a clean and dry environment.

All surgical instruments should always be handled with the utmost care during transport, cleaning, maintenance, sterilization and storage. This is especially true for cutting edges, fine tips and other sensitive areas.

To plug in and unplug the cable, always only touch the plug, never pull the cable. The use of damaged cables can lead to significant dangers. Check the cable for visible damage before each use.

Damaged HF cables must not be used!

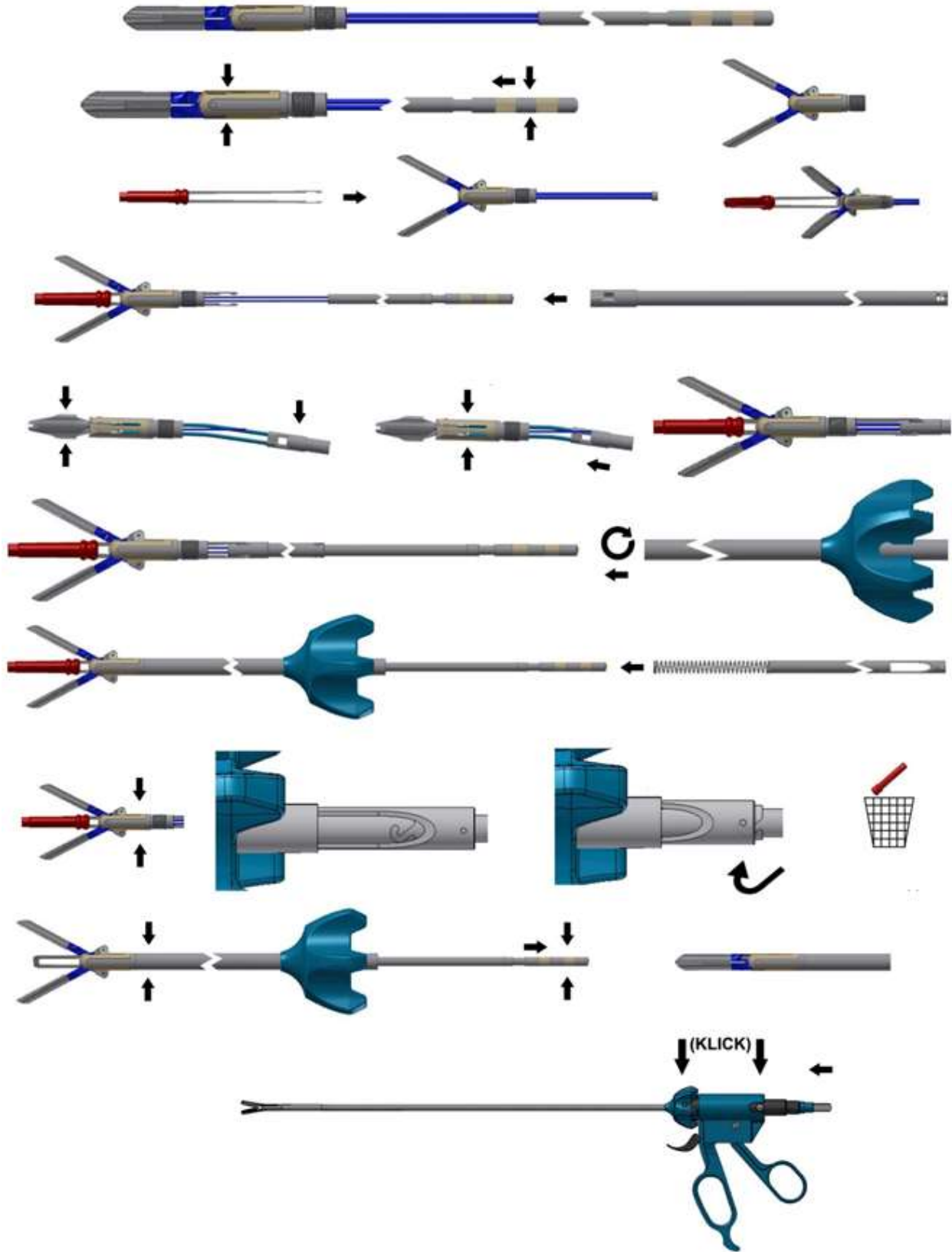
To minimise any health risks, specific smoke extraction systems should be used and, if possible, surgical filter masks should be worn.

Before use, ensure that the product has been properly prepared and checked.



13 ASSEMBLY & DISASSEMBLY

13.1 Assembly



**14 REPROCESSING**

In general, surgical instruments may only be reprocessed by those 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 treatment committees. Due to the product design and the materials used, no defined limit of maximum feasible applications can be set. The service life of medical devices is essentially determined by their function and gentle handling. Frequent reprocessing has little impact on the product. The end of product life is usually determined by wear and damage from use. (The legibility of the marking has been verified over 200 reprocessing cycles.)

15 REPROCESSING INSTRUCTIONS

The service life of medical devices is essentially determined by their function and gentle handling. Frequent reprocessing has little effect on the product. The end of product life is usually determined by wear and damage caused by use. (The legibility of the marking is verified over 200 reprocessing cycles.)

15.1 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% **H₂O₂** 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.

These instruments cannot be disassembled, but have a flush connection.

15.2 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.

15.3 Preparation for cleaning / decontamination

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.

15.4 Manual pre-cleaning

Soak the instruments in cold water for at least 5 minutes. If possible, clean the instruments under cold water with a soft brush until no residue is visible. Pressure flush cavities, holes and threads for at least 10 seconds with a water gun (pulsed method).

The shaft should be rinsed several times via the flush connection.

Place instruments in an ultrasonic bath at 40°C for 15 minutes with 0.5% alkaline or enzymatic cleaner and sonicate. Remove instruments and rinse with cold water. 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.



15.5 Automated cleaning

Place the instruments in a sieve tray on the slide-in trolley, connect the flushing port of the shaft to the corresponding port of the cleaning machine and start the cleaning process.

Step	Parameter	
Pre-rinse	Rinsing temperature + water quality	Cold tap water
	Exposure time	60 s
Pre-rinse	Rinsing temperature + water quality	Cold tap water
	Exposure time	180 s
Clean	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 agents	Neodisher Z
	Concentration	0,10 %
Rinse	Rinsing temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

15.6 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.

15.7 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.
- Particular attention must be paid to all moving parts.
- In the event of errors or damage, the products must be sorted out immediately.
- Live parts must always be undamaged and in perfect condition.
- All plastic components must be checked before sterilization. The plastic parts must not be cracked, brittle or worn. In these cases, the electrode must be replaced.

Functional testing and maintenance of the instruments must be carried out extremely thoroughly. A proper maintenance procedure increases the service life of the instruments.

15.8 Maintenance of the instruments

Products with movable jaws, joints, closures or with metallic sliding surfaces must be treated with steam-sterilizable care products based on paraffin oil. The paraffin oil must comply with the applicable pharmacopoeia and be physiologically harmless. (Further information can be found in DIN 96298-4.)



15.9 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.

15.10 Sterilization

Sterilization of the products with fractionated pre-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	20 min.

The use of other sterilization methods is beyond our responsibility.

15.11 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.

15.12 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.

15.13 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)	

16 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 reprocessing 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 detergents damage plastics.

The instruments must not be sterilized in hot air sterilizers.

Do not use corrosive cleaning agents. Do not use highly oxidizing cleaning agents. Agents with a neutral pH value (7.0) are best suited.

17 REPORTING PRODUCT ISSUES



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 competent authority in their locality.



18 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. If errors still occur, please contact our service. Tekno-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself.

Tekno-Medical assumes no liability for incidental or resulting damages.

Tekno-Medical accepts no liability if it is proven that these instructions for use have been violated.

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

19 SERVICE AND REPAIR

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

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

You can find the forms on our homepage: <https://www.tekno-medical.com/de/service/reparaturservice/>

20 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		Manufacturing date
	Non-sterile		Observe the instructions for use
	Catalogue no.		Protect from sunlight
	Batch designation		Store in a dry place
	Unique device identification		
	CE mark with number of the Notified Body mdc 0483: mdc – medical device certification GmbH Kriegerstrasse 6, D – 70191 Stuttgart		

21 PRODUCT LISTING



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707-050	707-051	707-052	707-053	707-054	707-055
707-056	707-057	707-058	707-059	707-060	707-061