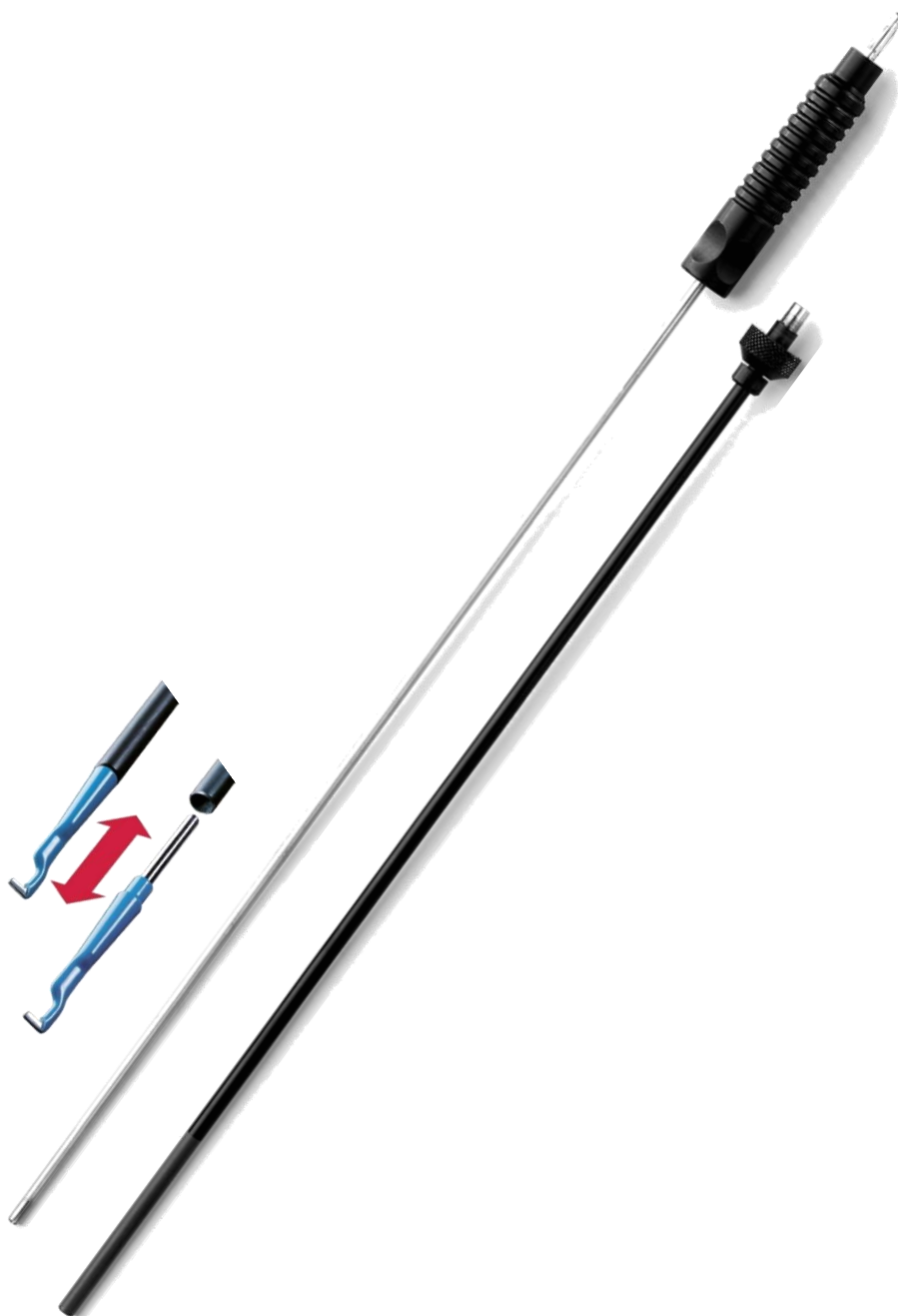




» MONOPOLAR MIS-ELEKTRODES «





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In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully followed. The use, reprocessing and testing of the instruments may only be carried out by trained specialists. Before using the instrument, the entire instructions for use must be read. This also applies to the instructions for use of the accessories used including the neutral electrode and the hf-generator. The specifications, safety instructions and warnings in the respective instructions for use must be strictly adhered to and followed.



The **monopolar MIS-electrodes** from Tekno-Medical Optik-Chirurgie GmbH (Tekno) and their accessories are supplied non-sterile and must undergo the complete reprocessing cycle (cleaning, disinfection and sterilisation) before the first and each subsequent use.

1 SCOPE



These instructions for use are valid for the **monopolar MIS-electrodes** (hereinafter referred to as "**electrodes**") from Tekno-Medical Optik-Chirurgie GmbH. (See article list in the last paragraph of these instructions for use).

2 INSPECTIONS

Before each use, the electrodes must be inspected for breaks, cracks, deformations, damage, and functionality. Particular care must be taken to check areas such as insulation, connections, and working ends. Worn, corroded, deformed, porous, or otherwise damaged instruments must be discarded. In addition to the manufacturer's efforts in selecting the right materials and ensuring their careful processing, the user must provide the electrodes with proper and continuous maintenance and reprocessing.

3 HANDLING

The products may only be used for their intended purpose by appropriately trained and qualified personnel. The attending physician or user is responsible for selecting the instruments for specific applications or surgical use, for ensuring adequate staff training, and for possessing experience in handling the products. This product may only be used in medical facilities by trained medical professionals.

If indicated, a targeted monopolar coagulation or cutting current can be used.

Maximum output voltage of the generator U_{max} : 2000 Vp!

Caution: Electrosurgical instruments may only be used by persons who are specially trained for this purpose.

4 PURPOSE

The monopolar electrodes and microneedle electrodes are designed for preparing, coagulating, and cutting tissue. The instrument is connected to the monopolar output of an RF generator using a suitable monopolar cable.

5 INDICATION

The instruments are intended for use in minimally invasive surgery, especially laparoscopy.

6 CONTRAINDICATIONS

The instrument is not intended for use on the central nervous and circulatory systems.

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

- Impairment of blood supply,
- acute and chronic, local or systemic infections,
- deep and superficial infections,
- severe muscle, nerve or vascular diseases,
- systemic diseases and metabolic dysfunctions,
- Mental conditions that make participation in the rehabilitation program impossible (Parkinson's disease, alcoholism, drug addiction, etc.).



Furthermore, there are contraindications,

- in cases of general inoperability,
- in the event of the patient's lack of willingness,
- if the technical requirements are not met,
- in patients with implanted pacemakers, defibrillators or monitors,
- in acute emergency situations,
- in cases of severe coagulation disorders,
- in cases of severe impairment of the lungs or the cardiovascular system.

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 and reconditioned, the instruments must be disposed of in accordance with the applicable country-specific regulations and laws.

9 WARNINGS



Failure to observe these application and safety instructions can lead to injuries, malfunctions or other unexpected incidents!

9.1 General safety-notes

- Do not grasp the distal end.
- Do not use or repair damaged instruments.
- Do not touch sharp edges and tips.
- Do not bend the distal end.
- Tissue punching due to the use of a trocar sleeve with too large a diameter. Only use trocar sleeves with a diameter slightly larger than that of the instrument.
- All types of reusable instruments must be completely cleaned, disinfected and sterilised before they are used for the first time and before each subsequent use.
- Before each use, the instrument must be inspected for correct function and visible damage and wear, e.g., cracks or breaks.
- The transport packaging is unsuitable for the high temperatures during autoclaving and must be discarded before the first sterilisation.
- Do not overload the instruments. Overloading due to excessive force can lead to breakage, bending and malfunction of the medical device and to injury to the patient or user. Do not bend bent instruments back into their original position, risk of breakage.
- Do not use a damaged or defective product. Sort out and label damaged product immediately and exclude further use.

9.2 HF-specific safety-notes

- Risk of burns due to HF current
- The instrument may only be used by qualified, medically and technically trained personnel.
- For patients with pacemakers, check their compatibility with HF radiation.
- Do not use explosive / flammable substances during the operation.
- Do not place the instrument on the patient.
- Avoid carbonisation of the tissue!
- The power of the HF generator must always be set as low as possible in order to achieve only the desired effect.
- Do not use the instrument for spray coagulation.
- Always position the patient leads (active electrode, neutral electrode) so that there is no contact with the patient or other leads.
- Instruments that are temporarily not in use must always be isolated from the patient in order to avoid patient injury in the event of accidental activation of the HF current.
- Check the possible use of bipolar applications if there is a risk that the HF current could flow through relatively small cross-sectional areas of the patient's body (avoid unintentional tissue damage).



- Only activate the HF current if the contact surfaces are within the visual range and have good contact with the tissue to be treated. Do not touch any other metallic instruments, trocar sleeves, optics, cables or similar.
- Only suction may be used while the electrode is in operation.
- Remove disinfectant residues from the patient's body.
- Use a suitable neutral electrode.
- Position the neutral electrode so that the patient lies on the entire surface of the neutral electrode.
- Risk of burns due to excessive heating of the neutral electrode!
- Only use the instrument if the insulation is undamaged.
- Only touch the insulated areas with your fingers, not the contact pin.
- Adjust the voltage of the HF generator to the cutting speed to support primary haemostasis.

Always check the electrodes and handles for:

- Visibly exposed metal of the shaft of the active electrode at the connection point to the active handle,
- poor electrical connection between the active handle and the shaft of the active electrode,
- poor fit between the active handle and the shaft of the active electrode.

To connect and disconnect the cable, always hold the plug only, never pull on the cable. The use of damaged cables can lead to considerable danger. Check the cable for visible damage before each use.

10 COMBINATIONS

10.1 Generally

The electrodes are designed for connection to RF generators using appropriate cables. Always grasp the cable by the connector when plugging and unplugging; never pull on the cable itself. Using damaged cables can pose significant hazards. Inspect the cable for visible damage before each use.

Damaged RF cables must not be used!



Incorrect combination of products can lead to injuries to the patient, user, or third parties, or damage to the products! The generator manufacturer's application and safety instructions must be observed!

The instrument is inserted through a 5.5 mm trocar sleeve.

Always check the handles for:



- Visibly exposed metal at the connection point of the RF cable,
- poor electrical connection between the handle and the RF cable,
- Poor fit between the handle and the RF cable.

10.2 Length of the accessories

Note (according to DIN EN IEC 60601-2-2, subsection 202.7.9.2.14 k):

The length of the connecting cables, which act as antennas, is between 3 and 5 meters.

The working length of the electrodes is 350 - 450mm.

11 REPROCESSING

11.1 Generally

In general, surgical instruments may only be reprocessed by persons who have the necessary expertise for the intended activities. Detailed information on the reprocessing of surgical 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 publications of processing expert 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 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. Biological safety after 200 reprocessing cycles has been demonstrated; an accumulation of cleaning agents or other harmful substances can be ruled out in the reprocessing procedures described in this instruction.

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 dishwasher-safe manner. The condition of the instrument panels must not impair the subsequent cleaning and disinfection by means of sound or rinsing shadows.

11.5 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). 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.

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

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



11.9 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.

11.10 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.

11.11 Storage



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

The storage period is to be determined by the user himself.

11.12 Information on the validation of the reprocessing

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

Detergent	Neodisher Medizym 0,5 % (v/h)
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)

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. Never use metal brushes, metal sponges or abrasive cleaning agents for manual cleaning/pre-cleaning. Strongly alkaline cleaning agents damage plastics and anodized coatings.

The instruments must not be sterilized in hot air sterilizers. Do not use caustic cleaning agents. Do not use strong oxidizing cleaning agents. Agents with a neutral pH value (7.0) are best suited.

13 REPORTING PRODUCT PROBLEMS



In accordance with the requirements of Regulation (EU) 2017/745 on medical devices and our quality management system, all product problems must be reported to the manufacturer.

During business hours you can reach us by phone at +49 (0) 07461 / 1701-0.

Outside of regular business hours, please send an email to safety@tekno-medical.com.

Serious incidents must also be reported to the local authority responsible for their location.

14 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.

**15 SERVICE AND REPAIR**

Do not attempt any repairs or modifications to the product yourself. This work should only be carried out by Tekno-Medical or Tekno-Medical authorized personnel.

Defective products must undergo the entire reprocessing procedure 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/>

16 SYMBOLS

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

	Attention!		Manufacturer
	Medical device		Date of manufacturing
	Non-sterile		Read the instructions for use
	Catalogue number		Protect from sunlight
	Lot-number		Store in a dry place
	Unique device identification		
	CE mark with the number of the notified body: mdc – medical device certification GmbH Kriegerstrasse 6, D – 70191 Stuttgart		

REF**17 PRODUCT LISTING**

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706-170	706-172	706-175	706-192	706-195
706-170-45*	706-173	706-176	706-193	706-196
706-171	706-174	706-191	706-194	Z0000128723