



## » FLEXIBLE HF-BIPOLAR ELECTRODES «





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# Instructions for use – Please read before use 4 / 8



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.



The flexible **bipolar** 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

**MD**

These instructions for use are valid for the flexible bipolar 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 of the electrodes, they must be checked for breaks, cracks, deformation, damage and functionality. Areas such as insulation, connections and working ends must be checked particularly carefully. Worn, corroded, deformed, porous or otherwise damaged instruments must be discarded.

## 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 the instruments for specific applications or surgical use, the appropriate training of the staff and the experience in handling the products.

## 4 PURPOSES

HF-flexible bipolar electrodes are connected to suitable HF-Cable to perform endoscopic procedures. The electrodes must only be used with a recovery peak voltage of **max. 500 Vp**.

## 5 INDICATION

These products are intended for ablation, cutting, vaporization and coagulation of tissue in the following surgical fields:

- Urology – Resectoscopy
- Gynaecology – Hysteroscopy.

## 6 CONTRAINDICATIONS

The instrument is not intended for use on the central nervous and circulatory system. Do not use the devices if one or more below reported conditions is present:

- Acute inflammation of the abdominal area
- Infection of the vagina
- Existing pregnancy

Risks from improper use:

- Material fatigue and loss of function due to exceeding the product service life.
- Risk of electric shock due to damage to the insulation, which can occur if the operating conditions and product service life are exceeded and the reprocessing instructions are disregarded.
- Risk of injury due to use of the instrument without HF current.

## 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 touch the distal end.
- Do not touch sharp edges and tips.
- Do not bend the distal end.
- 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!

### 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 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.
- 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.
- 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.
- To minimize the associated health hazards, specially designed smoke evacuation systems should be used where available and surgical filtration masks donned for all surgical procedures.

#### Always check the electrodes for:

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

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.

**Damaged HF cables must not be used!**

## 10 REPROCESSING

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](http://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. The legibility of the marking has been verified over 200 preparations.



**10.1 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.

**10.2 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.

**10.3 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.

**10.4 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.

**10.5 Automated cleaning**

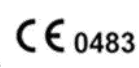
Place the opened instruments in a sieve tray on the slide-in carriage and start the cleaning process. Disassemble instruments as much as possible.

Step	Parameter	
<b>Pre-rinsing 1</b>	Rinsing-temperature + water quality	Cold tap water
	Exposure time	60 s
<b>Pre-rinsing 2</b>	Rinsing-temperature + water quality	Cold tap water
	Exposure time	180 s
<b>Cleaning</b>	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 %
<b>Neutralization</b>	Rinsing-temperature	40°C
	Water quality	Tap water
	Exposure time	180 s
	Neutralizing detergent	Neodisher Z
	Concentration	0,10 %
<b>Post-rinsing</b>	Rinsing-temperature	40 °C
	Water quality	Deionized water
	Exposure time	120 s

**10.6 Automated (thermal) disinfection**

Step	Parameter	
<b>Thermal Disinfection</b>	Disinfection-temperature	90°C (A <sub>0</sub> 3000)
	Water quality	Deionized water
	Exposure time	300 s
<b>Dry</b>	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.





## 10.7 Functional testing

After each cleaning and disinfection, the electrodes must be visually inspected for cleanliness. They must be macroscopically free of visible residues and contamination. If residues, liquids or contamination are visible, repeat the cleaning process.

Before each use, ensure that the insulation and the RF connection are intact. Plastic parts should be checked before sterilization. The electrode must be replaced if plastic parts are brittle, cracked or worn.



## 10.8 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.

## 10.9 Sterilization

Sterilization of the products using a fractionated vacuum process (according to DIN EN ISO 17665-1), taking into account the respective national requirements.

<b>Pre-vacuum</b>	3 times
<b>Sterilization temperature</b>	134 °C
<b>Sterilization time</b>	5 min
<b>Drying time</b>	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.

## 10.10 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.

## 10.11 Information on the validation of the reprocessing

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

<b>Detergent</b>	Neodisher Medizym 0,5 % (v/h)
<b>Neutralisator</b>	Neodisher Z 0.1% (v/v)
<b>Washer-disinfector (RDG)</b>	Miele PG 8535
<b>Steam-autoclave</b>	Lautenschläger ZentraCert

For details see test reports: 23277 / 23278 / 23279 (CleanControlling Medical GmbH & Co. KG, 08-2021)

## 11 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.

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.





## 12 REPORTABLE EVENTS



In accordance with the requirements of the Regulation (EU) on Medical Devices 2017/745 (MDR) and our quality management system, even the smallest problems with this product should always be reported to TEKNO.

If you cannot reach us directly for reportable events, please send an email to:

[safety@tekno-medical.com](mailto:safety@tekno-medical.com)

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

## 13 WARRANTY

The products are made of high-quality materials and undergo quality control before delivery. However, if errors occur, please contact our service. Tekno cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno accepts no liability for any incidental or consequential damages. Tekno assumes no liability if it can be proven that these instructions for use have been violated.



**Attention:** In case of use of the instruments in patients with Creutzfeldt-Jakob disease or its variants (vCJD, BSE, TSE), Tekno declines any responsibility for reuse.

## 14 SERVICE AND REPAIR



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

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](https://www.tekno-medical.com/de/service/repair_service)

## 15 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: <b>mdc – medical device certification GmbH</b> Kriegerstrasse 6, D – 70191 Stuttgart		

**REF**

## 16 PRODUCT LISTING

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790-150	790-152	790-151-60*
790-151	790-153	