» FLEXIBLE BIPOLAR HF-ELECTRODES «

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Content

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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.

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 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.
It is recommended to use a flue gas extraction system.

Maximum output voltage of the generator Umax: 500Vp!

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

4 INTENDED PURPOSE

The bipolar electrodes are used for ablating, cutting, vaporizing and coagulating tissue.

5 INDICATION

These electrodes are intended for use in the following surgical areas:

- Urology (resectoscopy),
- Gynaecology (hysteroscopy).

6 CONTRAINDICATIONS

The electrodes are 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.

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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.

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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!

Always check the electrodes for:

- Visibly exposed metal at the connection point of the RF cable,
- poor electrical connection between the electrode and the RF cable,
- Poor fit between the electrode 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 is 360 or 600 mm.

11 REPROCESSING

11.1 Generally

In general, surgical instruments may only be reprocessed by individuals who possess the necessary expertise for the intended tasks. Detailed instructions for reprocessing surgical instruments can be found in the AKI's " **Red Brochure ."** Links to laws, standards, and publications from reprocessing expert committees can also be found at www.aki.org .

Due to the product design and the materials used, no defined limit of maximum possible applications can be established. The service life of the medical devices is determined by their function and careful handling. Frequent reprocessing has minimal impact on the product. The end of the product's service life is typically determined by wear and tear and damage from use. Biological safety after 200 reprocessing cycles has been demonstrated; an accumulation of cleaning agents or other harmful substances can be ruled out with the reprocessing procedures described in these instructions .

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.

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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
Dry	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 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.

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 17665-1), 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.

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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.
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/

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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
MD	Medical device		Date of manufacturing
	Non-sterile		Read the instructions for use
REF	Catalogue number		Protect from sunlight
LOT	Lot-number		Store in a dry place
UDI	Unique device identification		
CE 0483	CE mark with the number of the notified body: **mdc – medical device certification GmbH** Kriegerstrasse 6, D – 70191 Stuttgart		

17 PRODUCT LISTING

REF

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