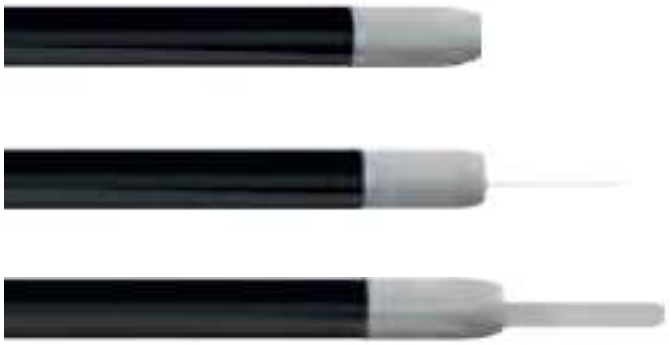
» REUSABLE ARGON-PLASMA-ELECTRODES «



TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49 (7461) 17 01-0 – Fax +49 (7461) 17 01-50
mail@tekno-medical.com – www.tekno-medical.com

CE 0483

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

Phone: +49 7461 17 01 0
Fax: +49 7461 17 01 50
Mail: mail@tekno-medical.com
Web: www.tekno-medical.com

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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 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 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 reusable **argon-plasma** electrodes (hereinafter "**electrodes**") from Tekno-Medical Optik-Chirurgie GmbH. (See item 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 PURPOSE

The argon plasma electrodes are intended for coagulating or cutting tissue. They are connected to the corresponding output of the HF generator using a special cable or a special handle.

5 INDICATION

The argon plasma electrodes are intended for open or endoscopic surgery and are used to cut and coagulate biological tissue.

6 CONTRAINDICATIONS

The use of HF instruments is generally contraindicated when the use of other surgical techniques is indicated and in 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.).

There are also contraindications,

- with general inoperability;
- if the patient is not prepared;
- if the technical requirements are not met.

The instruments are not intended for use on the central nervous and circulatory 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.

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9 WARNINGS AND SAFETY NOTES

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

9.1 General safety-notes

- 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.
- The country-specific guidelines for transport, storage and use of argon gas must be adhered to.

9.2 HF-specific safety-notes

- Risk of burns due to HF current
- Monopolar laparoscopy electrodes may only be used together with neutral electrodes.
- For patients with pacemakers, check their compatibility with HF radiation.
- Instruments that are temporarily not in use must always be stored away from the patient to prevent 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.
- Remove any disinfectant residue from the patient's body.
- Use non-conductive rinsing solutions where medically possible.
- Remove all body jewellery from the patient before use.
- Only use the instrument if the insulation is undamaged.
- Do not use explosive / flammable substances during the operation.
- 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.
- Always lay patient leads so that there is no contact with the patient or other leads.
- 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.
- Position the neutral electrode so that the patient rests on the entire surface of the neutral electrode.
- Risk of burns due to excessive heating of the neutral electrode!

Always check the electrodes and handles for:

- visibly exposed metal of the electrode shaft at the connection point to the handle or cable,
- poor electrical connection between the handle or cable and the shaft of the electrode,
- poor fit between the handle or cable and the shaft of the 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 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 you will also find links to laws, standards and publications of processing expert committees.

Limitation of reprocessing: Due to the design, the materials used and the intended use, a maximum limit of feasible cleaning, disinfection and sterilisation cycles for the laparoscopy electrode cannot be specified. The product service life depends on wear, handling and duration of use, damage and frequency of reprocessing.

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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. 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	
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

10.6 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.	

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, 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.

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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.

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.

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:

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)	

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 must **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-Medical. If you cannot reach us directly for reportable events, please send an email to:

safety@tekno-medical.com

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

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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-Medical cannot guarantee that the products are suitable for the respective procedure. This must be determined by the user himself. Tekno-Medical accepts no liability for any incidental or consequential damages.

Tekno-Medical 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-Medical 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

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
MD	Medical device		Date of manufacturing
NON STERILE	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		

REF

16 PRODUCT LISTING

Printed on 08.01.2024

Maximum accessory rated voltage 4,3 kVp			
90301-11	90301-13	90301-15	90301-17
90301-12	90301-14	90301-16	

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