



» ARTHROSCOPY ELECTRODES

(reusable up to 5 times) «





Tekno-Medical Optik-Chirurgie GmbH

Sattlerstr. 11
78532 Tuttlingen
GERMANY
SRN: DE-MF-000005822

Phone: +49 (0) 7461 / 17 01 0

Mail: mail@tekno-medical.com

Web: www.tekno-medical.com



Content

1	SCOPE	4
2	INSPECTIONS	4
3	HANDLING	4
4	PURPOSES	4
5	INDICATION	4
6	CONTRAINDICATIONS	4
7	PATIENT POPULATION	4
8	DISPOSAL	5
9	WARNINGS	5
9.1	GENERAL SAFETY-NOTES	5
9.2	HF-SPECIFIC SAFETY-NOTES	5
9.3	LENGTH OF ACCESSORIES	6
10	REPROCESSING	6
10.1	ON-SITE PREPARATION	6
10.2	TRANSPORT	6
10.3	PREPARATION FOR DECONTAMINATION	6
10.4	MANUAL PRE-CLEANING	6
10.5	AUTOMATED CLEANING	6
10.6	AUTOMATED (THERMAL) DISINFECTION	7
10.7	FUNCTIONAL TESTING	7
10.8	PACKAGING	7
10.9	STERILIZATION	7
10.10	STORAGE	7
10.11	INFORMATION ON THE VALIDATION OF THE REPROCESSING	7
11	ADDITIONAL INSTRUCTIONS	8
12	REPORTING PRODUCT ISSUES	8
13	WARRANTY	8
14	SERVICE AND REPAIR	8
15	SYMBOLS	8
16	PRODUCT LISTING	9
16.1	MONOPOLAR ARTHROSCOPY ELECTRODES 115MM LENGTH	9
16.2	MONOPOLAR ARTHROSCOPY ELECTRODES 170MM LENGTH	9
16.3	BIPOLAR ARTHROSCOPY ELECTRODES 115MM LENGTH	9
16.4	BIPOLAR ARTHROSCOPY ELECTRODES 170MM LENGTH	9
16.5	CABLES & ADAPTERS	9



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



These instructions for use are valid for the reusable **monopolar** and **bipolar** arthroscopy electrodes (herein after “**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 PURPOSES

The arthroscopy electrodes are intended for coagulating or cutting tissue. They are connected to an HF generator using an electrode handle.

The maximum frequency of the generator must not exceed **4 MHz!**

5 INDICATION

The electrodes are intended for use in arthroscopy and are used to cut, vaporize and coagulate biological tissue. The bipolar electrodes are intended for use on larger joints such as the knee, shoulder or hip.

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.

9 WARNINGS



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.

9.2 HF-specific safety-notes

- Risk of burns from HF current
- Monopolar arthroscopy electrodes may only be used together with neutral electrodes.
- When using monopolar electrodes, electrolyte-free solutions (e.g. Purisol) must be used.
- When using bipolar electrodes, the active electrode and the neutral electrode must be 100% surrounded by conductive rinsing fluid (0.9 percent saline or Ringer's solution); never use non-conductive rinsing fluids.
- In patients with pacemakers, check their tolerance to HF radiation.
- Instruments that are not in use for a time must always be placed in isolation from the patient in order to avoid patient harm if the HF current is accidentally activated.
- Only activate HF current if the contact surfaces are within the visible range and have good contact with the tissue to be treated. Do not touch any other metallic instruments, trocar sleeves, optics, lines or the like.
- Remove disinfectant residues from the patient's body.
- Only use the instrument if the insulation is undamaged.
- Do not use explosive/flammable materials during the operation.
- Avoid carbonizing of 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 lines so that there is no contact with the patient or other lines.
- For monopolar use: Consider 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.
- Place 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!

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 cables for visible damage before each use.



9.3 Length of accessories

Note on accessories that can be considered antennas (according to DIN EN IEC 60601-2-2, subsection 202.7.9.2.14 k):

The length of the connection cables is between 3 – 5 meters.
The length of the electrodes is between 115 – 170 mm (see article list).

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.

Due to the product design and the materials used, a limit of a **maximum of 5 reprocessing-cycles** is set.

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.

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), 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.

Protect from sunlight!

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 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.

13 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. 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 or its variants (vCJK, 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
	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		



16 PRODUCT LISTING

Printed on 30.07.2025

16.1 Monopolar Arthroscopy Electrodes 115mm Length

Maximum accessory rated voltage 4.3 kVp (120W)				
39200-01	39200-04	39200-11	39210-02	39210-10
39200-02	39200-09	39200-12	39210-04	39210-11
39200-03	39200-10	39210-01	39210-09	39210-12

16.2 Monopolar Arthroscopy Electrodes 170mm Length

Maximum accessory rated voltage 4.3 kVp (120W)			
39200-05	39200-06	39200-07	39200-08

16.3 Bipolar Arthroscopy Electrodes 115mm Length

Maximum Accessory Rated Voltage 1.0 kVp (180W)	
39300-01	39300-02
Maximum Accessory Rated Voltage 1.0 kVp (120W)	
(Use for cutting only, do not vaporize!)	
39300-03	

16.4 Bipolar Arthroscopy Electrodes 170mm Length

Maximum Accessory Rated Voltage 1.0 kVp (180W)	
39300-05	39300-06
Maximum Accessory Rated Voltage 1.0 kVp (120W)	
(Use for cutting only, do not vaporize!)	
39300-07	

16.5 Cables & Adapters

Art. No.	Designation
707-010	ADAPTER FOR FLAT PLUG BIPOLAR CABLES
707-300	3m bipolar cable, flat connector for Erbe / WISAP / Storz devices
707-301	Bipolar cable 3m, flat plug for Martin / Berchthold devices
707-302	BIPOLAR CABLE 3M, FLAT PLUG FOR TEKNO / VALLEYLAB USA
707-303	3M BIPOLAR CABLE, FLAT PLUG FOR TEKNO / VALLEYLAB EUROPA DEVICES
707-303-4*	Connection cable for bipolar instruments, 4 m devices, ValleyLab Europe / flat plug
707-306*	CONNECTION CABLE FOR BIPOLAR INSTRUMENTS 4 M FOR ERBE/WISAP/STORZ DEVICES / FLAT STATION
707-309	Bipolar cable 3m, 2-pin connector for TEKNO / VALLEYLAB Europe devices
707-310	BIPOLAR CABLE 3M, 2-PIN CONNECTOR FOR ERBE / WISAP / STORZ DEVICES
707-311	Bipolar cable 3m, 2-pin connector for Martin / Berchthold devices
707-312	BIPOLAR CABLE 3M, 2-PIN CONNECTOR FOR TEKNO / VALLEYLAB USA
707-315*	CONNECTION CABLE FOR BIPOLAR INSTRUMENTS 3 M DEVICE SIDE MARTIN, 2-PIN ETHICON INSTRUMENTS
707-317*	CONNECTION CAP FOR BIPOLE INSTRUMENT 3M, VALLEY LAB USA / 2-PIN CONNECTOR, ANGLED, 45°
707-322*	Bipolar cable for Storz, Erbe ICC/ACC devices and Storz instruments, 3M
707-330	BIPOLAR CABLE 3M, ROUND FLAT CONNECTOR FOR ERBE/WISAP/STORZ DEVICES
707-331	BIPOLAR CABLE 3M, ROUND FLAT PLUG FOR MARTIN/BERCHTOLD DEVICES



707-332	BIPOLAR CABLE 3M, ROUND FLAT CONNECTOR FOR TEKNO/VALLEYLAB USA
707-333	3M BIPOLAR CABLE, ROUND FLAT PLUG FOR TEKNO/VALLEYLAB EUROPA DEVICES
707-338	BIPOLAR CABLE 3M, ROUND FLAT PLUG, PIN SPACING 18.7MM
707-339	Bipolar cable 3m, round flat connector for ValleyLab Europe devices, pin spacing
707-340	Bipolar cable for 3mm coagulation forceps Erbe/WISAP/Storz, length 3m
707-341	BIPOLAR CABLE FOR 3MM COAGULATION DUCT MARTIN/BERCHTOLD, LENGTH 3M
707-343	BIPOLAR CABLE FOR 3MM CAGULATION DUCT TEKNO/VALLEYLAB EUROPA, LENGTH 3M
707-350	Cable for bipolar resection microscope, 5m for TEKNO, VALLEYLAB devices
707-360*	Bipolar cable, 5m, flat connector for Erbe ICC/ACC, WISAP, Storz devices
707-361*	Bipolar cable, 5m, flat plug for Martin and Berchtold devices
707-362*	Bipolar cable, 5m, flat plug for TEKNO / VALLEYLAB USA devices
707-430*	BIPOLAR CABLE 5M, ROUND FLAT CONNECTOR FOR ERBE/WISAP/STORZ DEVICES
707-433*	Connection cable for bipolar instruments, 5 m, devices, Valleyle Europe / flat plug, round
707-510	MONOPOLAR CABLE, 3M, MALE 4MM / MALE 4MM
707-511	MONOPOLAR CABLE, 5M, MALE 4MM / MALE 4MM
707-519	3M monopolar cable, male 8mm for RF devices, Conmed female 4m
707-520	MONOPOLAR CABLE 3 M, MALE 4MM / FEMALE 4 MM
707-521	MONOPOLAR CABLE 5 M, MALE 4MM / FEMALE 4 MM
707-523*	MONOPOLAR CABLE FOR ERBE HF DEVICES, WITH SLIDING PROTECTION FUNCTION
707-525	MONOPOLAR CABLE 3M, MALE 8MM / FEMALE 4MM
707-526	MONOPOLAR CABLE 5M, MALE 8MM / FEMALE 4MM
707-540*	MONOPOLAR CABLE 3M, MALE 8MM/ MALE 4MM SAFETY PLUG
790-310	MONOPOLAR CABLE, LENGTH 3M, D.4MM (AESCULAP/BERCHTOLD/MARTIN)
790-311	MONOPOLAR CABLE, LENGTH 3M, D.5MM (STORZ/ERBE)
790-312	MONOPOLAR CABLE,LENGTH 3M, D.8MM (TEKNO/VALLEYLAB/BOVIE)
790-313	MONOPOLAR CABLE, LENGTH 3M, D.4MM (BERCHTOLD/MARTIN)