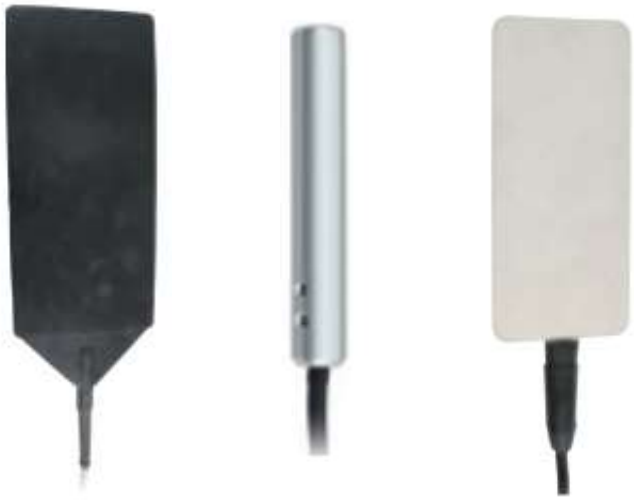
» NEUTRAL ELECTRODES «



TEKNO - MEDICAL Optik Chirurgie GmbH
Sattlerstrasse 11 – 78532 Tuttlingen, Germany
Phone +49(7461) 1701-0 – Fax +49(7461) 1701-50
mail@tekno-medical.com – www.tekno-medical.com

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

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

Content

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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

In order to keep risks to patients, users or third parties as low as possible, the instructions for use must be carefully observed. The use, preparation and testing of the electrodes may only be carried out by trained specialists. The entire instructions for use must be read before using the electrodes. This also applies to the instructions for use of the accessories used (HF generator, adapter, etc.). The specifications, safety instructions and warnings in the respective instructions for use must be strictly observed and followed.

The reusable neutral electrodes are delivered non-sterile and must go through the complete processing cycle (cleaning, disinfection and, if necessary, sterilization) before the first and each subsequent use.

1 SCOPE

MD These instructions for use apply to the reusable neutral electrodes for monopolar HF surgery (see article list in the last section of these instructions for use).

2 EXAMS

2.1 Electrodes

Visually inspect the electrode surfaces for damage (cracks, rough surfaces, etc.). Damaged electrodes must be discarded immediately.

2.2 Cables and plugs

Visually inspect the cables and plugs for damage (sharp edges, rough surfaces, etc.). Damaged products must be discarded immediately.

3 INTENDED PURPOSE

During electrosurgical procedures, the neutral electrodes conduct the high-frequency current from the patient back to the HF generator.

4 INDICATIONS

The instrument is intended for use in conventional monopolar RF procedures for use with an RF generator.

5 CONTRAINDICATIONS

HF treatment is contraindicated in patients with pacemakers, implanted defibrillators or other active implants.
There are also contraindications,

- in case of general inoperability;
- if the patient is unwilling;
- if the technical requirements are not met.

6 PATIENT POPULATION

There are no fundamental restrictions regarding the patient population.

7 DISPOSAL

Valuable raw materials can be recovered through environmentally friendly disposal.
Dispose of the product in an environmentally friendly manner according to current hospital guidelines.

8 WARNINGS

Always place patient cables (active electrode, neutral electrode) so that there is no contact with the patient or other cables.
When plugging or unplugging the cable, always hold the plug, never pull on the cable. Using damaged cables can lead to significant risks. Check the cable and plug for visible damage before each use.

Damaged electrodes must not be used!

Before use, ensure that the product has been properly prepared and inspected.
A new medical device must be subjected to a thorough visual and functional inspection after delivery. If the medical device has externally visible defects (scratches, breaks, cracks, notches, damaged insulation) or if it does not work as described in these instructions for use, we as the manufacturer or your sales partner must be notified immediately.

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9 REPROCESSING INSTRUCTIONS

The neutral electrodes must not be cleaned in an ultrasonic bath!

9.1 Preparation on-site

Wipe off surface contamination with a lint-free disposable cloth. Store the product properly to avoid damage.

9.2 Storage and transport

It is recommended to store the product in suitable containers for transport.

9.3 Preparation for cleaning / decontamination

Adapters must be removed from the product as the individual parts are cleaned and disinfected separately. Store individual parts properly to avoid damage.

9.4 Manual pre-cleaning

Required tools:

- sieve bowl, immersion tank,
- Cleaning solution with disinfectant effect: e.g. Sekusept 4%,
- 70% alcohol solution (if no disinfection after cleaning),
- tap water (15-20°C, max. 45°C),
- demineralized water,
- lint-free disposable cloth or swab.

Procedure:

Rinse products thoroughly with tap water (max. 45°C). Place parts in the sieve tray and then transfer to an immersion bath with the self-disinfecting cleaning solution.
After the recommended exposure time (according to the manufacturer's instructions for the cleaning solution):

- Rinse each electrode with deionized water for 5 minutes.
- Dry the outside with a lint-free disposable cloth or swab.

Do not use metal brushes or other metal tools for manual cleaning and check all parts for damage after manual cleaning.

9.5 Manual disinfection

Disassemble detachable products into their individual parts as far as possible. Place products in a sieve tray.

Required tools:

- Sieve tray, disinfection tray,
- disinfectant solution,
- 70% alcohol solution (ethanol, isopropanol),
- demineralized water,
- lint-free disposable cloth or swab.

Procedure :

- Place individual parts in the sieve tray and then transfer them to the immersion bath with the disinfectant solution. The concentration and exposure time of the disinfectant used can be found in the chemical manufacturer's instructions.
- Then rinse the electrodes thoroughly with deionized water for 5 minutes.
- Dry the outside with a lint-free disposable cloth or swab.
- Store individual parts properly to avoid damage.

Notes:

After manual disinfection, check all parts for damage.

Please follow the disinfectant manufacturer’s instructions regarding:

- disinfection effectiveness.
- Concentration.
- exposure time and standing time.

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9.6 Automated cleaning

Place products in a sieve tray on the trolley and start the cleaning process.

Step	parameter	
Pre-rinsing	rinsing temperature + water quality	Cold tap water
	exposure time	60 s
Pre-rinsing	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
	cleaning products	Neodisher Medizym
	concentration	0.50%
Neutralization	rinsing temperature	40°C
	water quality	Tap water
	exposure time	180 s
	neutralizing agent	Neodisher Z
	concentration	0.10%
Rinsing	rinsing temperature	40 °C
	water quality	Deionized water
	exposure time	120 s

9.7 Mechanical (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 through the drying cycle of the washer-disinfector (WD). If necessary, additional manual drying can be achieved using a lint-free cloth.	

9.8 Sterilization

Only applies to the sterilizable ("autoclavable") electrodes: 90029-00 & 90029-01!

Sterilization of the products using a fractionated pre-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 minutes
Drying time	20 minutes

The use of other sterilization methods is beyond our responsibility.

9.9 Storage

The electrodes must be stored in suitable packaging in a dry, clean and dust-free environment and at a constant humidity. The distance between the floor and the shelf should be at least 30 cm.
The storage period must be determined by the user.

9.10 Additional instructions

The instructions provided above have been assessed by Tekno-Medical as appropriate for the preparation of a medical device and its reuse. The user is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This requires validation and routine monitoring of the process. Likewise, any deviation from the instructions provided should be carefully evaluated by the user for effectiveness and possible adverse consequences.

The product must not be bent!

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10 REPORTABLE EVENTS

In accordance with the requirements of the Medical Device Regulation EU MDR 2017/745 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 e-mail to: safety@tekno-medical.com.
Serious incidents must also be reported to the competent authority in their place

11 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.

12 SERVICE AND REPAIR

Do not carry out repairs or modifications of the product on your own. Repairs only by authorized personnel.
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

13 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	CE marking

14 PRODUCT LISTING

REF

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90029-00	90029-01	90029-20	90029-22	90029-30

TEKNO GERMANY
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