

## Instructions for Use Dental Electrodes

### Scope:

Item number 300/01 to item number 301/36

### Intended Use:

Electrosurgical accessories may only be used by qualified medical personnel!

These instructions do not replace reading the instructions for use of the electrosurgery device and further accessories used.

HF electrodes are intended for open surgery and are used for cutting and coagulating biological tissue. They are not intended for direct contact with the heart or the central circulatory system. HF electrodes are connected to the monopolar output of the electrosurgical generator via an HF cable or an HF handle. The electrodes are activated by means of a foot switch or an HF handle.

### Indication:

Monopolar electrode for cutting and coagulating soft tissue during surgical-dental interventions, for example:

- cutting the labial frenulum
- opening acute abscesses
- in case of parodontal diseases
- for removing tumours and fistulas
- for exposing impacted teeth

### Contraindication:

- Restrictions for use in conjunction with cardiac pacemakers and implanted heart defibrillators
- Flammable vapours and liquids – explosion hazard
- Do not use in the immediate vicinity of bones or tooth roots
- Avoid contact with metal

### Undesired side effects:

- The contact with metallic objects will result in undesired remote effects

### Safety advice:

**Caution: The max. peak voltage of 1000 VP or 1 KvP must not be exceeded!**

New HF electrodes must be cleaned and sterilised according to a validated procedure (DIN EN ISO 17665) before first use. A functional test must be carried out before each use. It must be ensured that the HF electrode is firmly inserted into the handle. Care must be taken to avoid damage to the HF electrode and/or injury to the patient or surgical staff. The electrode tip may be damaged by excessive force. The HF electrode must not be activated while being in contact with metallic objects and/or optics. Make sure there are no flammable substances in the immediate vicinity during the entire application, as there is otherwise a risk of explosion. After switching off the electrosurgical current, the electrode tip may still be hot enough to cause burns.

The use of HF current may cause damage to cardiac pacemakers and implanted heart defibrillators, therefore affected patients must consult a cardiologist before the intervention.

Ensure that metallic restorations are insulated with plastic matrices and that dental mirrors, aspirators, cheek and lip retractors are made of non-conductive materials.

When exposing cavity and crown margins, make sure that the biological width does not fall below 3 mm.

### Performance data:

The HF generator should provide the following output power:

- cutting mode 50 watts at 600  $\Omega$
- coagulation mode 30 watts at 1200  $\Omega$

### Warnings:

Electrode tips may cause injuries!

- Electrode tips may be hot and cause burns after use!
- Never place the electrode on or in the immediate vicinity of the patient!
- Do not use in the presence of flammable or explosive substances!
- When using the electrode with rinsing instruments at the same time, use a non-conductive rinsing liquid, if possible!
- Deep incisions must not be made in one cut, take appropriate cooling pauses in order to avoid overheating or burning of the deep tissue resulting in wound healing disorders.

### Device recommendation/exception of Siemens devices:

We recommend using generator units manufactured by Gebrüder Martin, Berchtold, Erbe and Meyer-Haake. Compatibility with the handle for 1.6 mm shafts is required. To connect the electrosurgical accessories (e.g. handle, electrodes), the corresponding compatible cables are to be used in accordance with the device manufacturer's specifications.

**Warning:** Our electrodes cannot be used with Siemens devices/units, especially with the M1 model, as the insulation becomes very hot and may cause burns.

### Before use:

Before each use, the insulation of the HF electrodes must be checked for pressure marks or damage. HF electrodes with damage or pressure marks must not be used: the electrode must be checked for intact insulation, cleanliness and integrity.

Only use flawless and sterilised products!

A safe and perfect connection between electrode, handle and generator must be ensured before starting the operation. Therefore, the electrode connection must be completely and correctly inserted into the electrosurgical handle provided for this purpose, the metal parts of the electrode shaft must not be visible any more. The maximum permissible operating voltage of the handle must not be exceeded.

**Warning:** Only connect the electrode to the electrosurgical device when it is switched off or in standby mode. Failure to do so may result in burns and electric shock! Make sure that the neutral electrode is correctly applied.

### During use:

Always use the lowest power setting for the desired surgical effect.

### Cleaning and sterilisation:

**Non-sterile,** clean and sterilise before the first and each further use.

### Notes:

The tap water to be used must comply with Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

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This reprocessing instruction specifies the cleaning and disinfecting agents used for validation. When using an alternative cleaning and disinfecting agent (RKI- or VAH-listed), the responsibility lies with the reprocessor.

Due to the product design, the materials used and the intended use, no limit for the maximum number of reprocessing cycles that can be performed can be defined, however, tests carried out accordingly do not confirm any functional impairment of the electrodes after 20 reprocessing cycles. The service life of the instruments is determined by their function and their careful handling.

Instruments for electrosurgery are naturally subject to increased wear depending on the type and duration of use.



### Instruction for reprocessing:

#### Preparation for cleaning:

Take the HF electrodes out of their packaging. They must be placed in a container / device intended for cleaning / sterilisation.

#### Preparation and transport

Remove coarse dirt from the instruments immediately after use.

#### Information on cleaning in the CSSD:

Immediately after use, the products must be placed in cold water (<40°C). Do not use any fixing agents or hot water (>40°C), as this leads to the fixation of residues and may impair the cleaning result.

The electrodes must be stored and transported to the place of reprocessing in a closed container in order to avoid damage to the sensitive electrodes and contamination of the environment.

#### Manual precleaning

Rinse products under cold tap water (<40°C) until all visible soil has been removed. Use a soft brush to remove any adhering soil. Use a pressurized water sprayer (or similar) to rinse cavities, lumens thoroughly (>30 sec.) with cold tap water (<40°C).

#### Manual reprocessing

##### Cleaning

1. Immerse the products in an ultrasonic bath with an alkaline cleaner (e.g. 0.5% neodisher® LM2) for a time of exposure of 10 min. and a frequency of 35 kHz. Please follow the instructions of the cleaning agent manufacturer.
2. Post-clean the products completely with a soft brush. Rinse any existing cavities and lumens thoroughly (>30 sec.) using a pressurized water sprayer (or similar)
3. Rinse the products under running tap water to remove the cleaning agent (>15 sec.).

##### Disinfection

1. Immerse the products in an RKI- or a VAH-listed disinfectant. Please follow the instructions of the disinfectant manufacturer. It must be ensured that the disinfectant reaches all areas of the product.
2. The process is validated for the following disinfectant: 3% Korsolex® Plus, 15 minutes.
3. Rinse the products (complete rinsing inside, outside and cavities) in deionised water >15 sec.

##### Drying

Manual drying with lint-free disposable wipe. In order to avoid, as far as possible, water residues in cavities, it is recommended to blow them out using sterile, oil-free compressed air.

The product must never be heated over 140°C.

#### Machine reprocessing (Miele G7835 CD)

##### Cleaning

Place instruments in a sieve tray on the carriage and start the cleaning process.

1. 1 min. precleaning with cold tap water <40°C
2. Draining
3. 3 min. precleaning with cold tap water <40°C
4. Draining
5. 5 min. cleaning at 55°C ± 5°C with 0.5% alkaline detergent (0.5% neodisher® Mediclean Dental)
6. Draining
7. 3 min neutralisation (neodisher® Z, 0.1%) with cold tap water (<40°C)
8. Draining
9. 2 min. rinsing with deionised water
10. Draining

The special instructions of the manufacturer of the washer-disinfector must be observed.

##### Disinfection

Machine thermal disinfection in washer-disinfector, taking into account the national requirements regarding the A<sub>0</sub>-3000 value; >5 minutes at 92°C±2°C.

##### Drying

Automatic drying according to automatic drying process of the washer-disinfector 30 minutes at 60°C ± 5°C. If necessary, subsequent manual drying using a lint-free cloth and air blowing of lumens using sterile, oil-free compressed air.

#### Functional test

Before each use, the insulation of the HF electrodes must be checked for pressure marks or damage. HF electrodes with damage or pressure marks must not be used: the electrode must be checked for intact insulation, cleanliness and integrity.

If required, repeat the reprocessing process until the instrument is visually clean.

#### Sterilisation

Sterilisation of the products by applying a fractionated pre-vacuum process (according to ISO 17665-1) taking into account the respective national requirements.

Sterilisation must be carried out using a fractionated pre-vacuum process with the following parameters:

- 3 pre-vacuum phases with a pressure of at least 3 bar +/-0.5
- sterilisation temperature of at least 134°C
- hold time: ≥ 5 min.
- drying time: at least 20 min.



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**Warning:** Do not sterilise in hot-air.  
Differing process parameters such as higher temperatures >134°C and a longer sterilisation time >5 min will shorten the service life of the electrode.

### Information on the validation of reprocessing

The following test instructions, materials and machines were used for validation:

#### Cleaning agents:

- alkaline cleaner for manual reprocessing *neodisher® LM2*
- alkaline cleaner for machine reprocessing ® *neodisher mediclean Dental*

#### Washer-disinfector:

- Miele G7835 CD

#### Cleaning programme:

- DES-VAR-TD

#### Neutralising agent:

- neodisher® Z

#### Steam steriliser:

- Tuttnauer EHS3870

#### See report for details:

- Manual reprocessing / Report of Zwisler Laboratory # 1612.1459
- Machine reprocessing / Report of Zwisler Laboratory # 1612.1455
- Sterilisation / Report of Zwisler Laboratory # 1612.2119

If the chemicals and machines described above are not available, it is incumbent upon the user to validate the individual process accordingly.

### Repair and modification

Defective HF electrodes must not be repaired. They must be replaced by new HF electrodes. Unauthorised modifications and repairs are strictly prohibited and will void the manufacturer's warranty.

Any modification of the product or deviation from these instructions for use will result in the exclusion of liability by Otto Leibinger GmbH.

### Packing, storage, transport, handling

HF electrodes must be kept in a clean and dry environment. They should be stored separately in a protective container with individual compartments or in special electrode containers. During transportation, cleaning, care, sterilisation and storage, HF electrodes must always be handled with utmost care. This applies in particular to fine tips and other sensitive areas. The operator must ensure that the sterile condition is maintained after the sterilisation process.

### Returns







Returns will only be accepted if they have been marked as "hygienically harmless" or "not decontaminated" and safely packed for transport.

### Disposal

HF electrodes, packaging material and accessories must be disposed of in accordance with the applicable national regulations and laws.

Subject to change without notice.

### Symbols

	Manufacturer
	CE label including the number of the notified body, mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart / Germany
	Consult instructions for use
	Production year / Batch number
	Non-sterile
	Caution!