Handles and electrode inserts for electrosurgery

ENGLISH

Handles and electrode inserts for elektrosurgery

INSTRUCTIONS FOR USE

REF
8921xx24, 8921xx40,
89216025, 89220040,
89221040,
89500001 – 89509113

CE 0297

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⚠ Please read all information contained in this insert. Incorrect handling and care, as well as misuse, can lead to premature wear of surgical instruments or risks to patients and users.

Intended Use

Handles for electrodes

The HF electrode handles (REF 8921xx24, 8921xx40, 89216025, 89220040, 89221040) are made for cutting and coagulating biological tissue. They are used to hold shaft electrodes of any known electrode shape with a shaft Ø4 mm (± 0.1 mm) or Ø2.4 mm (± 0.1 mm) (depending on design). The electrode can be inserted twist-proof in different positions.
The fully assembled instrument (if assembly is needed) has to be connected – with the appropriate cable - to monopolar or bipolar output of an HF generator.
Only the defined parameters has to be used.

Maximum power output allowed Umax: 5 kVp

The cutting or coagulation current is set at the HF generator. It is triggered via a button at the handle (yellow button = activation of the cutting current, blue button = activation of the coagulation current or grey button = activation of the mode set at the device). Triggering is also possible via the foot switch connected to the HF generator.

Suitable monopolar electrodes include:
Ø 4 mm: Bissinger REF 89500xxx
Ø 2,4 mm: Bissinger REF 89503xxx, 89505xxx

Appropriate connecting cables:
Bissinger REF 89101071, 89101072.

Monopolar electrodes

The monopolar electrodes (REF 89500001–89509113) serve cutting and coagulation of biological tissue. The fully assembled instrument (if assembly is needed) has to be – with the appropriate cable - to monopolar or bipolar output of an HF generator. Only the defined parameters has to be used.

Maximum output voltage of the generator, U_{max}:
500 V_p , 2 kV_p , 4,3 kV_p
(depending on the type, see catalogue)

Suitable electrosurgical handles for Bissinger monopolar electrodes are i. e.:
Ø 4 mm: Bissinger REF 8921xx40
Ø 2,4 mm: Bissinger REF 8921xx24

⚠ *Instruments for electrosurgery must only be used by persons who have been specially trained or instructed in this.*

Contraindications

- Do not use the instrument if the risks to the patient outweigh the benefits in the opinion of the attending physician.

Incidents that have been reported in connection with the use of electrosurgical systems

- Unintended activation with resulting tissue injury in the wrong location and/or damage to the equipment.
- Fire in connection with surgical drapes and other inflammable materials.
- Alternating current paths leading to burns on spots where the patient or user comes into contact with components without insulation.
- Explosions caused by sparks in the proximity of inflammable gases.
- Perforation of organs. Sudden severe bleedings.

Use and safety instructions

Non-observance of these use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.

- When using electrosurgery in patients with pacemakers or other active implants, special requirements apply (e.g. low HF-current, patient monitoring). In any case, a cardiologist or appropriate medical specialist must be consulted.
- Before initial use and any further use, all instruments must be completely cleaned, disinfected and sterilised and their function must be checked.
- It is very important to check every surgical instrument for visible damage and wear, such as cracks, breaks or insulation defects before each use. In particular areas such as blades, tips, notches, locking and blocking devices, as well as all movable parts, insulations and ceramic elements must be checked carefully.
- Never use any damaged instruments.
- Never use the instruments in the presence of flammable or explosive substances.
- When temporarily not in use, the instrument must be placed electrically insulated from the patient.
- Activate electrosurgical current only if the contact areas are in full view and have good contact with the tissue that needs to be treated. Do not touch any other metallic instruments, trocar sleeves, optics or similar objects during use.
- Observe the use and safety instructions of the manufacturer of the high-frequency surgical device.

⚠ Ensure correct application of the neutral electrode on the patient; otherwise, there is a danger of burns.

Reprocessing

Due to the product design, the materials used and the intended purpose, it is not possible to define a limit with regard to the maximum possible number of reprocessing cycles. The serviceable life of the instruments is determined by their function as well as by a careful handling.
Instruments for electrosurgery are by their nature subject to increased wear depending on the type and time of use.

Preparation and transport

Immediately after each use, clean the instruments with a soft brush under cold tap water until all visible contamination is removed. Do not use fixation agents or hot water (>40°C). Storage and transport of the instruments to the reprocessing location must take place in a sealed container.

Machine reprocessing

Cleaning

Place the instruments in a basket on the insert module or on the inserts of the MIS module and start the cleaning process.

1. Prerinse. with cold water for 1 min
2. Discharge
3. Prerinse with cold water for 3 min.
4. Discharge
5. Wash at 55°C with a 0.5% alkaline or at 45°C with an enzymatic cleaning agent for 5 min.
6. Discharge
7. Neutralise with warm tap water (>40°C) and a neutralising agent for 3 min.
8. Discharge
9. Rinse with warm tap water (>40°C) for 2 min.
10. Discharge

Disinfection

Machine-operated thermal disinfection must be carried out under observation of the national requirements regarding the A0 value (see ISO 15883).

Drying

Dry the outside of the instruments by carrying out a drying cycle of the cleaning/disinfection machine.
If necessary, manual drying may additionally be carried out using a lint-free cloth. Dry cavities by blowing with sterile compressed air.

Manual reprocessing

Ultrasonic pre-cleaning

1. The instruments are placed in an ultrasonic bath with 0.5% enzymatic cleaning detergent and treated with ultrasound for 15 minutes at 40°C/104°F.
2. Remove the instrument and rinse them completely with cold water to remove the cleaning detergent.

Cleaning

Prepare a cleaning bath according to the manufacturer's instructions.

1. Rinse products with cold tap water (<40°C) until all visible contamination has been removed. Remove adhering dirt by using a soft brush.
2. Place products in the prepared cleaning bath so that they are completely submersed. Observe residence time according to the manufacturer's instructions.
3. Clean the instrument in the bath manually using a soft brush. Brush all surfaces several times.
4. Rinse the products thoroughly with DI water to remove the cleaning agents without residue.

Disinfection

Prepare a disinfectant bath according to the instructions of the disinfectant manufacturer. Place the instruments in the disinfectant bath and observe the specified residence time. Rinse the products very thoroughly with DI water to remove the disinfectant without residue.

Drying

Manual drying is carried out using a lint-free cloth and sterile compressed air, in particular for drying cavities and channels.

Functional test and packaging

Perform visual inspection for cleanliness and integrity, if required, perform an assembly and functional test.
If necessary, repeat reprocessing until the instrument is visually clean.

Packaging must comply with the ISO 11607 and EN 868 standards for packaging for sterilised instruments.

Sterilisation

Sterilisation of the products with fractional pre-vacuum procedure (in accordance with ISO 13060 / ISO 17665) under observation of the respective national requirements.

- 3 pre-vacuum phases with a pressure of at least 60 mbar.
- Heating up to a sterilisation temperature of at least 132°C and at most 137°C
- Exposure time: at least 3 min; at most 18 min.
- Drying time: at least 10 min.

⚠ If contamination with prions (CJD) is suspected, differing national guidelines are to be followed and longer holding times (i.e. 15 min.) may apply.

Storage

Sterilised instruments must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.

Repairs

Never attempt to perform repairs yourself. Service and repair work must only be performed by persons trained and qualified accordingly. If you have any question regarding these matters, contact either the manufacturer or your medico-technical department.

⚠ *Defective products must complete the entire reprocessing process before being returned for repair.*

Information on the validation of the reconditioning

The following testing instructions, materials and equipment have been used for validation:

Cleaning agents (for machine use):
Neodisher FA by Dr. Weigert (alkaline)
Endozime by Ruhof (enzymatic)
Cleaning agents (manual cleaning):
Cidezyme, Enzol Enzym detergent, Johnson&Johnson
Disinfectants (manual disinfection):
Cidex OPA, Johnson&Johnson
Neutralising agent:
Neodisher Z by Dr. Weigert
Cleaning and disinfection device:
Miele Desinfector G 7735 CD
Miele insert module E 327-06
Miele MIS module E 450

For details, see report.
SMP GmbH # 01707011901 (machine cleaning)
MDS GmbH # 135196-10 (man. cleaning/disinfection)
Nelson Labs # 200432706-02 (sterilisation)
MDS GmbH Testbericht 084183-10 (sterilisation)

If the chemicals and machines described above are not available, the user has to validate the used process accordingly.

Handling

During transport, cleaning, care, sterilisation and storage, all surgical instruments should be handled with maximum care.
This applies particularly to blades, fine tips and other sensitive areas.

Disposal

Disposal must be carried out in accordance with the respective applicable local and national laws and regulations.

Warranty

Günter Bissinger Medizintechnik GmbH exclusively supplies tested and faultless products to its customers.
All products are designed and manufactured to comply with maximum quality requirements. We refuse any liability for products which have been modified as compared to the original product, misused or handled or used improperly.

Explanation of symbols

LOT	Batch code
NON STERILE	Unsterile
REF	Reference number
⚠	Attention
	Refer to instructions for use

CE 0297 — CE-Mark and registration number of the Notified Body
DQS Medizinprodukte GmbH
August-Schanz-Straße 21
60433 Frankfurt, Germany

Manufacturer
Production date

℞ ONLY — Attention:According to US-laws, this device must only be sold by a doctor or on the instruction of a doctor.