

STERILE MONOPOLAR **ELECTRODES** FOR ONE-TIME USE

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INSTRUCTIONS FOR USE

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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.

The monopolar electrodes serve cutting and coagulation of biological tissue. They are connected to the monopolar output of an HF generator with the electrical surgery handle and must only be used with the intended parameters. The maximum admissible operating voltage of the handle must not be exceeded (see information in the catalogue).

Suitable electrical surgery handles include:

- for electrodes with shaft Ø4 mm:
- 89215040, 89217040, 89218040 for electrodes with shaft Ø 2.4 mm: 89215024, 89217024, 89218024

Attention: Instruments for HF surgery must only be used by persons specifically trained or instructed for this.

Application and safety notes

- Product and packaging must be inspected for impeccable condition and damage before use.
- Only use products if the packaging is not damaged.
- It is very important that every surgical instrument must be examined for visible damage and wear, e.g. cracks, reaks or defects at the insulation, before every use.
- Particularly areas such as blades, tips, closures, locks and latches, as well as all moving parts, insulation and ceramics elements must be inspected carefully
- Never use any damaged instruments
- Do not use in patients with pacers or other active implants without collecting the corresponding specialist advice.
- Do not use in the presence of flammable or explosive
- Observe correct application of the neutral electrode at the patient to avoid danger of burning.
- The instrument must not be put down on the patient. Only active when the contact areas are in sight. Do not

touch any other metal instruments. Observe the use and safety instructions of the manufacturer of the high-frequency surgical device.

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

Unintended activation with resulting tissue injury on the wrong spot 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

Perforation of organs. Sudden severe bleedings.

Bipolar forceps have proved inefficient for tubular sterilisation or coagulation in the context of sterilisation and should therefore not be used for this purpose.

STERILITY Attention: STERILE ONLY IF THE PACKAGING IS UNDAMAGED!

The monopolar electrodes are delivered packed separately and sterile.

If the sterile packaging has been opened, torn or damaged the monopolar electrodes must be considered unsterile This also applies if the expiration date of the monopolar electrodes has been exceeded. In both cases, the monopolar electrode must not be used.

Monopolar electrodes are intended for single use Contaminated products must not be re-conditioned. Monopolar electrodes that have come into contact with blood, tissue or bodily fluids must be disposed of.

Attention: Monopolar electrodes that have already been in contact with the patient or contaminated must not be reconditioned and must be disposed of/rejected.

Attention: For reasons of safety towards our user, the onetime electrode must not be reconditioned. Specifically cleaning and reconditioning of the one-time electrode with sharp edges and fine tips may cause injury of the users.

Preparation is not required, since monopolar electrodes that have already been in contact with the patient or that have been contaminated must not be used again.

Storage

The instruments must be stored in a dry, clean and dustfree environment at moderate temperatures of 5°C to 40°C.

<u>Handling</u> All instruments should be treated with the greatest care when storing and transporting them. This specifically applies to blades, fine tips and other sensitive areas. Observe that the sterile packaging is not damaged when transporting the instrument. This will cause failure of the

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

Explanation of symbols



Batch code



Article number



Attention



Attention to the user manual



Sterilized with ethylene oxide



to be used designating



Do not reuse





Do not use with package damaged



Manufacturer



Production Date



CE-marking and Number of notified Box DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 Frankfurt, Germany