



HANDLING INSTRUCTIONS

ARTHEC BIPOLAR ELECTRODE FOR ARTHROSCOPY

Article No.

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Attention

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

Intended Use

The ARTHEC Bipolar Electrode for Arthroscopy is designed for the electrosurgical resection, ablation, excision and coagulation of tissue during arthroscopic operations of the shoulder, knee and hip.

The electrode must only be used within conductive irrigating solution (saline solution).

The electrode is to apply electrical energy, generated by electrosurgical generators. This device can be connected by a suitable cable to the bipolar output of compatible electrosurgical generators such as Erbe, Martin, Berchtold, Valleylab, Alsa, Söring, Emed and comparable generators.

The maximum output voltage of the generator must not exceed 550 V_p. The maximum power must not exceed 120 W.

Suitable Cables:

Bissinger Art. No 801 000xx.

Caution: Bipolar instruments should be used only by individuals who are trained and licensed to use such devices.

Examples of such training and experience include: Training through qualified residency program, surgical skills workshops, training programs offered by equipment manufacturers or preceptorship/surgical assistant training.

Use and safety instructions

- Use only in conductive media (saline solution).
- The tip of the electrode can remain hot even after use and cause burns.
- All instruments have to be completely cleaned, disinfected and sterilised before initial use and any subsequent use.
- It is very important to check each 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 mobile parts, insulations and ceramic elements have to be checked carefully.
- Never use damaged instruments.
- Never use the instruments in the presence of flammable or explosive substances.
- The instrument may not be laid down on the patient.
- Activation should only be performed if the contact surfaces are visible. Do not touch any other metallic instruments during activation.

Reprocessing

Due to the product design, the raw materials used and the intended purpose it is not possible to determine a precise 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 nature subject to increased wear depending on the type and time of use.

Preparation and transport

Remove coarse dirt from the instruments immediately after each use. Do not use fixation agents or hot water (>40°C) as this may result in the fixation of residues and could reduce the cleaning success.

Storage and transport of the instruments to the reprocessing location must be ensured in a sealed container to avoid any damage to the instruments and any contamination of the environment.

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 for 1 min. with cold water
2. Discharging
3. Prerinse for 3 min. with cold water
4. Discharging
5. Wash for 5 min. at 55°C/131°F with a 0.5% alkaline or at 45°C/113°F with an enzymatic cleaning agent.
6. Discharging
7. Neutralise for 3 min. with warm tap water (>40°C/104°F) and a neutralising agent.
8. Discharging
9. Rinse 2 min. with warm tap water (>40°C/104°F).
10. Discharging

Disinfection

Machine operated thermal disinfection has to be carried out in consideration of the national requirements with regard to 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 all cavities of the instruments by blowing with sterile compressed air.

Manual reprocessing

Cleaning

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

1. Rinse products with cold tap water (<40°C/104°F) until all visible accumulations of dirt have been removed. Remove stuck dirt by using a soft brush.
2. Place products in the prepared cleaning bath so that they are completely submerged. Observe residence time according to the manufacturer's instructions.
3. Clean the instrument in the bath manually using a soft brush. All surfaces have to be brushed several times.
4. **The following steps only apply to channels and the insides of tubes:** The brush has to be pushed in and out of the tubes at least six times. Rinse the tubes with distilled water and repeat the procedure.
5. Rinse the products thoroughly with running tap 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 thoroughly with fully demineralised water to remove the disinfectant without residue.

Drying

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

Functional test and packaging

Perform visual inspection for cleanliness; if required, perform an assembly and functional test according to the operating instructions.

If necessary, repeat the reprocessing process until the instrument is optically clean.

Packaging has to comply with 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) in consideration of the respective national requirements.

- 3 pre-vacuum phases, pressure at least 60 mbar
- Heating up to a sterilisation temperature of min. 132°C/270°F and max. 137°C/278°F
- Shortest exposure time: 3 min.
- Drying time: at least 10 min.

Storage

Sterilised instruments have to be stored in a dry, clean and dust-free area at moderate temperatures from 5°C to 40°C.

Repairs

Never attempt to perform repairs yourself. Service and repair work may only be performed by persons qualified and trained accordingly. For any question on these matters, please contact either the manufacturer or your medical-technical department.

Attention: Defect products must pass the complete reprocessing process before being returned for repair.

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.

Information about the validation of the reprocessing instructions

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 agent (ultrasound)

Neodisher FA by Dr. Weigert

Cleaning agents (manual cleaning):

Enzol Enzym, detergent by Johnson&Johnson

Neutralising agent:

Neodisher Z by Dr. Weigert

Cleaning and disinfection device:

Miele G 7736 CD

Miele insert module E 327-06

Miele MIS module E 450

For details, see report.

SMP GmbH # 01707011901-2 (machine cleaning)

Northview Laboratories #P8H066 (manual cleaning, sterilisation)

Nelson Labs # 200432706-02 (sterilisation)

MDS GmbH Testbericht 084183-10 (Sterilisation)

If the chemicals and machines described before are not available, the user is obliged to validate the process used.

Warranty

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