

MONOPOLAR ELECTRODES:

Item #s B68000 - B68035
B65227 & B65228

Important Information - Please read before use!

Caution

Please read all information contained in this insert. Incorrect handling and care as well as misuse can lead to premature wear or can cause hazards to patients and users.

Indications for Use

The monopolar electrodes are designed to cut and coagulate selected biological tissue. They are used in conjunction with a suitable electrosurgical handle that is connected to the monopolar output of an electrosurgical generator and operated with the parameter settings as indicated. Do not exceed the maximum power output allowed for the electrosurgical handle.

Attention: Instruments for electrosurgery should be used only by persons who have been specially trained in the use of such instruments.

Use and safety instructions

- All instruments have to be completely cleaned, disinfected and sterilized before initial use and any other 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.
- Coagulation should only be performed if the contact surfaces are visible. Do not touch any other metallic instruments during coagulation.

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 with a 0.5% alkaline or 45°C with an enzymatic cleaning agent.
6. Discharging
7. Neutralize for 3 min. with warm tap water (>40°C) and a neutralizing agent.
8. Discharging
9. Rinse for 2 min. with warm tap water (>40°C).
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 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) 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 submersed. 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 lint free 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.

Never attempt to make repairs yourself. Service and repairs should be referred to trained qualified persons only. Refer questions about repair to the manufacturer or your biomedical engineering department.

Sterilization

Sterilization 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 sterilization temperature of min.
- 132°C and max. 137°C
- Shortest exposure time: 3 min.
- Drying time: at least 10 min.

Storage

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

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):

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 above are not available, the user has to validate the used process accordingly.

Handling

All surgical instruments must be handled with the greatest care when being transported, cleaned, treated, sterilized and stored. This is especially true for fine tips and other sensitive areas. Surgical instruments corrode and their functions are impaired if they come into contact with aggressive materials. The instruments must not be exposed to acids or other aggressive cleaning agents.

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