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Gebrauchsanweisung
Operating Instructions
操作说明书
Manual de instrucciones
사용 설명서
Instructies voor gebruik

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Rx only

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Carefully read the operating instructions and processing instructions prior to clinical application and keep them safe and at hand. The instructions and notes contained therein must be followed.

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1 Intended Use

The bipolar electrodes (REF 88.90.20; 88.90.25; 88.90.40; 88.90.54; 88.90.59) 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}:

250 Vp , 500 Vp (depending on the type)

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

2 Contraindications

This instrument is not designed for use on the central nervous and circulatory system

The application of HF current can damage pacemakers and in vivo cardiac defibrillators

The instrument should not be used in the immediate vicinity of bone, tooth root and metal

3 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.

4 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.

Applies for monopolar mode of operation:
Ensure correct application of the neutral electrode on the patient; otherwise, there is a danger of burns.

5 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.

Complex instruments must be taken apart for cleaning and disinfection in accordance with pictogram.

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. The following step only applies to channels and the insides of tubes: Push the brush into and out of the tubes at least six times. Rinse the tubes with DI water. Repeat the procedure.
5. 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.
- 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.

6 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.

7 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 (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.

8 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.

9 Liability

CAUTION: According to US federal law, in the USA this product may be bought only by a physician or hospital or upon prescription!

In the event of any discrepancies between the non-German and the German version of these operating instructions, only the German version shall be authoritative. Only the latest revision of the operating instructions applies.

Due to constant technical development, the content of these MEDICON operating instructions is updated regularly. Please use the IFU-Website ifu.medicon.de to ensure that you are using the current version. The version date of the respective edition of the operating instructions is included in the printout. MEDICON eG assumes no liability for damage caused by improper use, incorrect postoperative conduct, care or maintenance, or non-compliance with the restrictions on use and other guidelines in the operating instructions. MEDICON eG will not accept liability either for changes or repairs made to the product without the prior written authorisation of MEDICON eG, nor for repairs that were not carried out by workshops authorised by MEDICON eG or the MEDICON Repair Service (MRS).

10 Disposal

Disposal of damaged instruments or of instruments that are not functionally reliable: To avoid a risk of infection to third parties, the instruments must be cleaned and sterilised before disposal.

In addition, the instruments must be disposed of in specific and appropriately labelled containers, in order to protect third parties from cutting injury. Observe the applicable national laws when disposing of reusable surgical instruments! The product, the packaging material and the accessories must be disposed of in accordance with the regulations and laws specific to the country in which they are used.

12 Description of symbols and icons

Icon	Description
	Manufacturer
	Production lot number, batch
	Item number
	Non-sterile
	Caution
	Observe the operating instructions
	CE label acc. to Directive 93/42/EEC
	Medical device