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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.

Contents

1 Scope

Monopolar electrosurgical handle Artikel.-No.:
Monopolar electrosurgical handles only are allowed to be operated with the following maximum rated voltage:

Articles	Max. rated voltage
87.33.80; 87.33.81	≤ 4,0 MHz

Maximum rated voltage of accessory:

Artikel-Nr.	Umax
87.33.80; 87.33.81	4,3 kVp

In any combination with another electrosurgical accessory, the maximum rated voltage of the combination corresponds to the lowest rated voltage of the accessories used.

2 Intended use

Only skilled medical personnel are permitted to use the product. The product must be connected with the appropriate cable to the output provided for the purpose on the electrosurgical generator. Refer to the Instructions for use provided by the manufacturer of the electrosurgical generator and to the defined performance limits (Umax and max. rated voltage in the table under paragraph 1. Scope).

The product is intended for open or endoscopic surgery and is used as contact and switching elements. They are activated by means of a foot-operated switch or via the manual switch on the handle. It is recommended to use a smoke evacuation system.

Improper use will result in immediate loss of warranty. Liability for any damages incurred will not be accepted.

3 Safety notices - WARNING!

The maximum rated for voltage of the product, see these Instruction for Use. Additionally the determined maximally allowed frequency of the high frequency current listed in section 1 has to be considered.
If anything is unclear, contact the manufacturer. Prior to each application, the product has to be cleaned, disinfected and sterilized (DIN EN ISO 17665) according to a validated procedure, (refer also to paragraph 5 „cleaning, disinfection and sterilization “). Prior to each application, a visual check and functional test has to be done (see paragraph 6 „Visual and function test”). It must be ensured that the product is correctly connected to the generator. In addition, it is necessary to check whether the electrode is inserted firmly in the product. This must be done carefully, in order to avoid damage to the product and/or injuries to the patient or surgical personnel. The product may be damaged if excessive force is applied. It is not permissible to activate the product as long as it is in contact with metal objects and/or optics. Throughout the complete procedure, care must be taken that no flammable substances are present in the immediate vicinity, since otherwise a danger of explosion exists.
The high-frequency current used in electrosurgery may interfere with cardiac pacemakers and implanted heart defibrillators, and so affected patients must consult a cardiologist prior to the operation.

4 Excerpt from general safety instructions for the application of HF Technology

In addition to the acknowledged benefits of HF surgery, the procedure involves some risks that need to be considered. **Ein unsachgemäßer Improper use and disregard of the instructions for use may lead to unwanted burns of the patient as well as injury to the user or third parties.** The following is a summary of important general safety notices when using HF technology. Medicon eG recommends continuous advanced training of the staff

a) Read and observe the guidelines in the instructions for use. Before using the electrosurgical instruments, read the entire instructions for use. This also applies to the instructions for use of the accessories used, including the electrosurgical neutral electrodes to be used during the monopolar application and with the electrosurgical generator. The specifications, safety instructions and warnings of the respective instructions for use must always be kept and followed.

b) Environment
It is very important to ensure that no flammable substances (anesthetics, oxidizing gases, endogenous gases, etc.) are present in the immediate vicinity during the complete electrosurgical application; otherwise there is a danger of explosion. Use non-flammable disinfectants agents; do not use e.g. alcohol-based tinctures or similar. All oxygen compounds must be tight and leak-proof during the procedure.

c) Patient Positioning and Patient Preparation
Ensure proper patient positioning, i.e. use insulating surgical table supports that are dry, absorbent and impervious to liquids. Isolate conductive surfaces and points of contact with the patient. Dry folds of pulp are required in skin folds, breast creases and between the extremities; fluids accumulated in body cavities, for example, should be removed before starting the procedure. Use non-combustible disinfectants. Use non-conductive rinsing solutions where medically possible. Prior to use, remove any type of body jewelry from the patient.
d) Circuit Points
Before starting the application, make sure that the handle or cable used is correctly connected to the electrosurgical generator and that the correct power setting is selected and displayed. Follow the guidelines in the instructions for use of the electrosurgical generator and electrosurgical handle / cable.
e) Patient Reactions
All electrosurgical instruments can potentially cause muscle stimulation during use. The design of the products herein has been chosen to minimize the risk of this undesirable effect, but nevertheless, muscle stimulation can cause unexpected movement of the patient in the surgical field.
f) Handling Electrosurgical Instruments
Make sure the accessories used are compatible.
The tip of the instrument should not be touched during use. After switching off the electrosurgical current, the instrument tip may still be hot and may cause burns. If the electrosurgical instrument is not in use, it should be placed on a dry, clean, non-conductive and well-visible surface that is not in contact with the patient. Inadvertent activation of the instrument may result in patient burns. Mostly, it is advisable to keep the activation times as short as possible or to observe longer pauses between the activation phases and to set the lowest possible performance values.
g) System integrity confirmation at the end of the operation
At the end of the operation, the completeness of the system must be confirmed.

5 Cleaning, disinfection and sterilization

Medicon eG recommends the validated treatment processes described in the following. Equivalent deviant processes are possible. It is the sole responsibility of the user to safeguard the suitability of the actual applied procedure by suitable means, e.g. validation, routine examination, verification of material compatibility, etc.

In view of the design, the materials used and the intended use of the product, a maximum limit cannot be defined for the number of cleaning, disinfection or sterilization cycles that may be possible. During proper use of the product is subject to natural wear and tear depending on type and duration of their application. Therefore, a visual check and functional test has to be done prior to each application.

(See point 6 "Visual inspection").

Note: The information and specifications in the instructions for use of the respective manufacturer of the cleaning/disinfectant and other accessories used for reprocessing must be followed.
In addition, please observe the legal regulations applicable in your country and the Hygiene regulations of the medical practice or hospital. This applies to especially for the different specifications (e.g. in Germany according to the KRINKO RKI BfArM recommendation for reprocessing) regarding effective prion inactivation (not applicable to USA).

Translated with www.DeepL.com/Translator (free version)

5.1 Preparation for cleaning:
Where applicable, remove electrode from the handle. If it is about handles with removable cable, remove the cable.

5.2 Manual pre-Cleaning:
The product must be disinfected immediately after each use.
According to the instructions of the cleaning agent manufacturer, prepare a cleaning bath. The cleaning agent should be suitable for metals and plastics and have a pH between 5.5 and 12.3. Highly alkaline cleaning agents with pH levels between 10 and below 13 have no detrimental influence on the lifetime of the product. We recommended CIDEZYME®. When using the cleaning agent CIDEZYME® you have to mix 8 ml CIDEZYME® with 1 l water. The exposure time must be in accordance with manufacturer's instructions for the cleaning agent.
Make sure that the products do not touch any other parts in the bath. Clean surfaces thoroughly with a soft plastic brush. Do not use sharp or abrasive agents. Rinse the product thoroughly under tap water for at least one minute to remove any detergent residue. It must be ensured that areas with difficult access are thoroughly cleaned then rinsed several times. Visually inspect the handles for any remaining dirt. If there is still visible contamination, repeat the previous steps until they are removed.

5.3 Automated cleaning and disinfection
Only apply cleaning and disinfecting machines that are efficiency tested according to DIN EN ISO 15883. Please refer to the information of the manufacturer of the cleaning or disinfecting agent, and only use agents that are suitable to be applied for medical devices made from metal and steel and have a pH-value between 5,5 and 12,3. It is recommended to use neodisher® mediclean forte (Dr. Weigert GmbH & Co. KG). Do not use neutralization agents. Select the program for thermal disinfection. Regarding the program course, follow the instructions of use of the manufacturer of the agents. Do not clean the product together with sharp-edged or pointed objects.
Put the product in a suitable rinsing device and take care that when cleaning and disinfecting products with integrated cables, the cable is not folded or squeezed.
Start the program course of the following features:
– Thermal disinfection: 5 to 10 minutes at 90°C to 93 °C (tolerance according to DIN EN ISO 15883-1 or -2), A0 ≥ 3000.
– Final rinsing with demineralized water.
– Drying of product
At end of program course, remove the products and verify if there are any staining residues. If staining/bonded residues are present, repeat the automated cleaning and disinfecting process as long as no visible residues are present. Dry any cavities and insufficiently dried areas with sterile compressed air < 2 bar. After the products are taken out (after additional re-drying on a clean place), immediately pack them in a single-use sterilization package (single or double package) made of paper/foil or put them in a sterilization container (according to DIN EN ISO 11607 and DIN EN 868).

5.4 Sterilisation
It is only allowed to sterilize instruments that have been cleaned and disinfected beforehand. The product is designed exclusively for steam sterilization in autoclaves (fractionated fore-vacuum procedure with sufficient product drying). The product has to be sterilized at a minimum of 134°C and maximum of 137°C in saturated steam during a holding time of at least 5 minutes to at most 20 minutes, then dried in a vacuum and sterilized for at least 10 minutes. Sterilizer (Class B) in accordance with valid national Norms and Guidelines (e.g. DIN EN 13060 or DIN EN 285). The sterilization process has been validated according to DIN EN ISO 17665. Please follow the recommendations and instructions of the sterilizer manufacturer regarding loading, handling and drying times. It is not permissible to sterilize the product with hot air, EO gas, gamma radiation or plasma.

NOTE: Before use, product must be cooled to room temperature. It is the sole responsibility of the user to safeguard and maintain the sterile condition of the product after the sterilization process. In case the aforementioned described and recommended chemicals and machines for manual pre-cleaning and/or automated cleaning and disinfection are not available, it is the responsibility of the user to validate their procedure. Also, if another sterilization procedure is chosen, the procedure deviant from the procedure to be validated accordingly by the user.
Limitation of reconditioning: The lifetime of the product will depend on wear, damage and frequency of reconditioning.

6 Visual and function test

Before each use, the product must be inspected for pressure points or damage. Products with switching function must also be tested for correct functioning. It is not permissible to use products exhibiting damage, pressure points or defective switching function.

7 Repair and modification

It is not permissible to repair defective products. They must be replaced by new products. Unauthorized modifications and repairs are strictly prohibited and will entail invalidation of the manufacturer's warranty.

8 Packaging, storage, transportation, handling

The product must be stored in a clean and dry environment. It should be individually stored in a protective container with individual compartments or heat-sealed in film. The product must always be handled with the utmost care during transportation, cleaning, upkeep, sterilization and storage. This applies in particular for sensitive areas. It is the operator's responsibility to ensure that the sterile condition is preserved after the sterilization process.

9 Returns

Returns will be accepted only if they are marked as "hygienically safe" or "not contaminated" and have been securely packaged for shipping. Use our return form for returns

10 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 in-structions 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).

11 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.

Rx only

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12 Description of symbols and icons

Icon	Description
	Manufacturer
LOT	Production lot number, batch
REF	Item number
	Non-sterile
	Caution
	Observe the operating instructions
CE 0123	CE label acc. to Directive 93/42/EEC
MD	Medical device
	Store in dry conditions
	Protect from sunlight