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Gebrauchsanweisung
Operating Instructions
操作说明书
Manual de instrucciones
사용 설명서
Instructies voor gebruik
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CE 0123 NON STERILE Rx only

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MONOPOLAR ARTHROSCOPIC-ELECTRODES

EN

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 arthroscopic electrodes, article no.:
Maximum rated voltage/accessory:

Article No.	Umax
87.34.30; 87.34.31; 87.34.32; 87.34.33; 87.34.34; 87.34.35; 87.34.36; 87.34.37	1,3 kVp / 120 W

In any combination with another electrosurgical accessory, the maximum rated voltage of the combination corresponds to the lowest rated voltage of the accessories used.
(See also point 2 "Intended use")

2 Intended use

Only for the use by skilled medical professionals, who have been trained on the usage of the arthroscopic electrodes mentioned in Section 1 "Scope". Read the entire IFU carefully prior to application. Arthroscopic electrodes are intended for arthroscopic use. They are designed for cutting, vaporizing and coagulating biological tissue (please refer to the table above for exceptions), using 0.9% saline solution. They are not intended for direct contact with the heart or central circulatory system. The bipolar arthroscopic electrodes are indicated for the use in large joints such as knee, shoulder and hip. The arthroscopic electrodes are connected by an electrosurgical cable, electrosurgical handle or handle with suction to the monopolar/ bipolar output of the electrosurgical generator. They are activated by means of a foot-operated switch or electrosurgical handle.

Monopolar arthroscopic electrodes can be operated in combination with the following electrosurgical generators:

▪ ERBE	▪ KLS Martin
▪ Covidien	▪ ValleyLab
▪ EMED	▪ Tekno
▪ BOWA	▪ Berchtold
▪ Medevo ARTro200	

Bipolar arthroscopic electrodes can be operated together with the following electrosurgical generators:

- ERBE VIO
- KLS Martin Maximum
- Mitek VAPR
- Medevo ARTro200

The voltage of the used generator may not exceed the maximum rated voltage (See section 1 "Scope") of the arthroscopic electrodes and shall not exceed the frequency 4 MHz. Please follow the instructions for use provided by the manufacturer of the electrosurgical generator.
IMPORTANT: Monopolar arthroscopic electrodes may only be used in combination with a neutral electrode. Prior to usage of the monopolar arthroscopic electrodes it has to be verified that the designated neutral electrode is put on the patient correctly and that the neutral electrode is connected properly with the HF-Generator (electrosurgical generator). The instructions for use of the neutral electrode must be observed.
Improper use will result in immediate loss of warranty. Liability for any damages incurred will not be accepted.

3 Safety notices - WARNING!

Refer to these Instructions for Use for the maximum rated voltage of the arthroscopic electrodes.
If anything is unclear, contact the manufacturer.

Prior to each use arthroscopic electrodes must be cleaned, disinfected and also sterilized according to a validated procedure (DIN EN ISO 17665) (In this regard see Section 5 "Cleaning, disinfection and sterilization"). A visual inspection must be performed before each use (see Section 6 "Visual inspection"). It must be ensured that the arthroscopic electrode is inserted firmly in the handle. This must be done carefully, in order to avoid damage to the arthroscopic electrode and/ or injuries to the patient or surgical personnel. The arthroscopic electrode may be damaged if excessive force is applied.
IMPORTANT:
When using bipolar arthroscopic electrodes, the active electrode and the neutral electrode must be completely surrounded with conductive irrigation fluid (0.9% saline or Ringer's solution).
In regards to the application of bipolar arthroscopic electrodes, **NEVER** use nonconductive irrigation fluids (sterile water, glycine, Purisole, etc.). Always ensure an adequate flow of irrigation fluid (at least 100 mL/min) to the joint. When applying monopolar arthroscopic electrodes, electrolyte-free solutions, e.g. Purisole, can be used. It is not permissible to activate the arthroscopic electrode as long as it is in contact with metal objects and/ or optics. During the whole application, make sure the patient will not come into contact with grounded metal objects such as surgical table frames, instrument plates, etc.
Throughout the complete procedure, care must be taken that no flammable substances such as anesthetics, oxidizing gases, endogenous gases etc. are present in the immediate vicinity, since otherwise a danger of explosion exists. Proceed with non-flammable agents for disinfection and cleaning. Do not use alcohol based fluids or similar. Make sure all oxygen connections are dense and leak proof throughout the complete duration of the surgery. After the electrosurgical current has been turned off, the electrode tip may still be hot enough to cause burns.
The high-frequency current used in electro surgery may interfere with cardiac pacemakers and implanted heart defibrillators, and so affected patients must consult a cardiologist prior to the operation.

Contraindication
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

4 Preparation and application

Make sure the patient is prepared and stored correctly. That means, use insulating table cloth that is dry, absorbent and liquid tight. Insulate the leading areas and contact points towards the patient. It is necessary to use dry cellulose tissues for skin folds, breast folds and between the extremities. Fluid that potentially pooled in body cavities has to be removed prior to the application.
Furthermore it has to be safeguarded that the HF-handle/cable intended for the application has been connected properly to the HF-generator and that the correct performance adjustment has been set. Please follow the IFU of the electrosurgical generator, handle/cable.
Potentially all electrosurgical instruments may cause muscle stimulation during their application. The arthroscopic electrodes have been designed in such way that the risk of this undesired effect is minimized; however it is still possible that muscle stimulation causes an unexpected movement of the patient in the surgery area.
Do not touch the tip of the electrode during the application. After switching off the HF current the tip of the electrode may still be hot and cause burns.
As soon as the arthroscopic electrode is not applied, it shall be deposited on a dry, clean, nonconductive and well visible place that is not in contact with the patient.
Any unintended activation of the instrument can lead to burns of the patient. At completion of the surgery/application the completeness of the system/instrument has to be confirmed.
After switching off the electrosurgical current, the electrode tip may still be hot, causing burns.

5 Cleaning, disinfection and sterilization

In view of the design, the materials used and the intended use, as well as the respective duration of use, the arthroscopic electrodes mentioned under section 1 "Scope" may undergo a maximum of 5 cleaning and sterilization cycles. Furthermore, when used as intended, arthroscopic electrodes are subject to natural wear, depending on the nature and duration of the application. It is therefore necessary to perform a visual inspection before each use. Medicon eG recommends a machine cleaning / disinfection. Manual cleaning is not recommended due to the significantly lower effectiveness. Never use sharp objects for cleaning. Disinfectants must be rinsed well after use.
Medicon eG recommends the validated treatment procedures described below. Equivalent deviating procedures are possible. It is the responsibility of the user to ensure the suitability of the actual procedures by means of appropriate measures (such as validation, routine monitoring, material compatibility testing).

Please also 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).

5.1 Preparation for cleaning:

Remove the arthroscopic electrodes from their packaging. Place them in a container/ device provided for cleaning/ sterilization.
It is not necessary to dismantle the arthroscopic electrodes.

5.2 Pre-cleaning

Arthroscopic electrodes have to be cleaned immediately after each usage. Use for the pre-cleaning mains water (drinking quality) (<40° C). Clean the arthroscopic electrodes thoroughly with a soft brush or synthetic fleece pad and rinse under running since otherwise particles or dried secretions may adhere to them. This could make subsequent cleaning and sterilization difficult or impossible. It must be ensured that areas with difficult access are thoroughly cleaned then rinsed several times.
Cavities and lumens (e.g. irrigation / suction channel) must be thoroughly rinsed with at least 3 x 20 ml cold mains water (<40° C) with the aid of a rinsing adapter (e.g. the Medisafe company), with a syringe or a water pressure pistol (> 30 sec.).
This precleaning step must be carried out prior to further manual cleaning or prior to cleaning with the cleaning and disinfection machine.

5.3 Manual cleaning and disinfection

For cleaning, please prepare an immersion bath with a suitable fluid cleaning agent. Use a disinfection agent that is compatible to the cleaning agent; take care to use a disinfection agent that also can be used for immersion baths. Follow the instructions and recommendations of the manufacturer of the cleaning and disinfection agent. Only use agents that are suitable to clean medical devices made of metal and plastic with a pH-level of between 5.5 and 12.3. We recommend the cleaning agent gigazyme® (Schülke & Mayr). Do not use highly alkaline cleaning agents. Highly alkaline cleaning agents with pH levels above 10 and below 13 have a detrimental influence on the lifetime of the arthroscopic electrodes.

1. According to the instructions of the manufacturer please prepare two separate immersion baths, one for cleaning and one for disinfection using the appropriate and respective agents.
2. Place the arthroscopic electrode completely in an ultrasonic bath with a cleaner (e.g. 0.5% gigazyme®). The arthroscopic electrodes must be cleaned in an ultrasonic bath applying a sonication time of 5 min. and a frequency of 35 kHz. Follow the instructions of the manufacturer of the cleaning agent. Furthermore, follow the instructions of the manufacture of the ultrasonic bath. Make sure that the products do not touch any other parts in the ultrasonic bath. Take care that sonic shadows are avoided inside the ultrasonic bath.
3. Then, clean the arthroscopic electrodes with a soft brush under cold mains water (<40° C). Cavities and lumen have to be rinsed intensively by using a water pressure pistol (>30 sec.) or similar for 1 minute. Afterwards rinse the arthroscopic electrodes thoroughly for at least 1 minute under mains water (<40° C) in order to remove any residues of the cleaning agent.
4. Inspect the arthroscopic electrodes visually regarding remaining stain. If there is still visible soiling/stain, repeat the aforementioned steps until all soiling/stain is removed.
5. Afterwards place the arthroscopic electrodes completely in a disinfecting bath with e.g. Korsolex Plus 3% for 15 min. The exposure time according to the Manufacturer information must be followed. Make sure the disinfectant reaches all areas of the arthroscopic electrodes. Cavities and lumen have to be rinsed with the disinfectant for several times using a syringe e.g. and at least min. 3 times using 20 ml.
6. Then, rinse the arthroscopic electrodes thoroughly for at least 1 minute with cold demineralized water in order to remove any and all residues of the disinfectant. The arthroscopic electrodes that have a rinsing/suction channel must have this channel at least 3 times using each time 20 ml with cold demineralized water. Rinse the channel with a rinsing adapter (e.g. from the company Medisafe) or with a syringe.
7. In addition, all narrow and hard-to-reach areas on the arthroscopic electrodes, all cavities and lumens must be rinsed several times with a syringe (at least 3 times using 20ml) of cold demineralized water.
8. Dry the arthroscopic electrodes with a lint-free cloth and sterile, compressed air. Also dry the cavities and channels with sterile compressed air.

5.4 Automated cleaning and disinfection

Only apply cleaning and disinfecting machines that are efficiently 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). Select the program for thermal disinfection. Follow the instructions for use provided by the manufacturer of the cleaning and disinfecting machine. The arthroscopic electrodes must be mounted securely and protected against mechanical damage during machine cleaning/ disinfection. Do not clean arthroscopic electrodes together with sharp-edged or pointed objects. Put the arthroscopic electrodes in a suitable rinsing device and rinsing adapter if applicable.
Start the program course with following features:

- Pre rinse with cold water for 1 Min.
- Emptying
- Pre rinse with cold water for 3 Min.
- Emptying
- Wash at 55° C for 5 Min. with a 0.5% alkaline cleaner
- Emptying
- Neutralize with warm mains water (>40° C) and Neutralizer (0.1% Neodisher®Z)
- Emptying
- Intermediate flushing: rinse with warm demineralized water (>40° C) for 2 Min.
- Emptying

5.5 Disinfection

Proceed with the automated thermic disinfection according to the national requirements regarding the AO-value (see ISO 15883, AO-value >3000): 5 Min. for 92° C +/- 2° C.

5.6 Drying

- 30 Min. at 90° C
- Remove rinsing adapter

At end of program course, remove the arthroscopic electrodes and rinsing adapter if applicable, 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 arthroscopic electrodes are taken out (after additional re-drying on a clean place), immediately pack them in a single-use sterilization package (double package) made of paper/foil or put them in a sterilization container (according to DIN EN ISO 11607 and DIN EN 868).

5.7 Sterilization

The arthroscopic electrodes are exclusively designed for steam sterilization in autoclaves (fractionated pre-vacuum method with sufficient product drying). They must be sterilized at a minimum of 134° C and maximum 137° C in saturated steam with holding time of at least 5 minutes to a maximum of 20 minutes and vacuum drying for at least 10 minutes. Sterilizer (Class B) must be in accordance with applicable national standards and regulations (e.g. DIN EN 13060 or DIN EN 285). The sterilization standards DIN EN ISO 17665 (Sterilization of health care products - Moist heat) must be observed. Arthroscopic electrodes should not be sterilized with hot air, EtO gas, gamma radiation or plasma.
A suitable sterilizer is, for example, the autoclave 3870 EHS from the Tuttnauer company. Arthroscopic electrodes should not be sterilized with hot air, EtO gas, gamma radiation or plasma.
Please follow the recommendations and instructions of the manufacturer regarding loading, handling and drying times of the sterilization device.
NOTE: Before use, the arthroscopic electrodes must be cooled to room temperature.

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It is the sole responsibility of the user to safeguard and maintain the sterile condition of the arthroscopic electrodes after the sterilization process.

In case the aforementioned described and recommended chemicals and machines for automated cleaning and disinfection are not available, it is the responsibility of the user to validate their procedure. Also, if another sterilization procedure or sterilizers according to other standards are chosen, the procedure or device deviant from the procedure or device described has to be validated and qualified by the user accordingly.

Reconditioning Limitation:

The lifetime of the product will depend on natural wear and tear, handling, and duration of use, damage and frequency of reconditioning. The arthroscopic electrodes mentioned in Section 1 "Scope" must not be cleaned, disinfected and sterilized more than up to 5 times maximum. See also paragraph 6 "visual inspection".

6 Visual inspection

Prior to each use, a visual inspection must be carried out on the arthroscopic electrodes. In particular the insulation of the arthroscopic electrodes must be inspected for pressure points or damage. Arthroscopic electrodes with damage or pressure points shall not be used and must be replaced by new ones. At completion of the surgery residues of tissue may adhere to the distal end of the active electrode or sooting may be visible at the distal end. Such adhering tissue or sooting is not regarded as a replacement cause. Additionally, due to the plasma seam and due to mechanical force, deformation of the device may occur or consumption of the insulating material. Also such consumption does not permit a replacement. If it is detected during a long application/surgery that insulating material is consumed, the operator has to exchange the used arthroscopic electrode by a new one. Arthroscopic electrodes that exhibit consumption of insulating material are not allowed to be reprocessed, they have to be exchanged by new ones and have to be disposed of according to paragraph 10 of this IFU „disposal ".

7 Exclusion of repair and modification

Defective arthroscopic electrodes shall not be repaired. They must be replaced by new arthroscopic electrodes. Furthermore, unauthorized modifications and repairs are strictly prohibited and will entail invalidation of the manufacturer's warranty. A blockage of the suction channel does not permit a replacement.

CAUTION: Arthroscopic electrodes which have a hook as active part are never allowed to be bent.

For service and repair please contact your national representative of MEDICON eG.

8 Packaging, storage, transportation, handling

The arthroscopic electrodes must be stored in a clean and dry environment. They should be individually stored in a protective container with individual compartments or heat-sealed in film. The arthroscopic electrodes must always be handled with the utmost care during transportation, cleaning, upkeep, sterilization and storage. This applies in particular for fine tips and other 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.

12 Description of symbols and icons

Icon	Description
	Manufacturer
LOT	Production lot number, batch
REF	Item number
NON STERILE	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