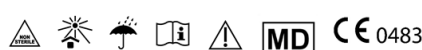




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DEUTSCH / ENGLISH

1 Scope

Non-sterile, reusable product (up to 5x)
Monopolar HF-Arthroscopic Electrodes, Article No.: 8M910331 to 8M910334, 8M910481 to 8M910490, 8M910934, 8M910954, 8M911006
Bipolar HF-Arthroscopic Electrodes, Article No.: 8M910491 to 8M910500, 8M911008, 8M910983

Maximum rated voltage/accessory:

Article No.	U _{max} / P _{max}	Bemerkung
8M910331 bis 8M910334, 8M910481 bis 8M910490, 8M910934, 8M910954, 8M911006	1,3 kVp/120 W	-
8M910491 bis 8M910500, 8M911008, 8M910983	1,0 kVp/120 W	⚠ CAUTION Not to be used for vaporization, only for cutting.

See also labeling or catalogue.
In any combination with another electro-surgical accessory, the maximum rated voltage of the combination corresponds to the lowest rated voltage of the accessories used. (See also section "Intended Use")
See this Instructions for Use, the label, or the current product catalog for the maximum rated voltage of the product.
In case of uncertainties, contact the manufacturer.
Prior to usage, read the entire IFU of this product and of any used accessory as well as HF-generator and HF-neutral electrode (monopolar application).
All requirements, safety notices and warnings included in the respective IFUs have to be followed strictly.
This medium is not intended for users in the USA

2 Intended use
Cutting, coagulating and vaporizing of biological tissue, while applying irrigation fluid (see below). (Exclusions refer to aforementioned table).
Only for use by skilled medical professionals who were introduced into the product (for example by the means of this IFU).
It is strictly prohibited to manipulate the electrode tip or to bend the product.
Indication:
Product intended for use in arthroscopy.
The product is designed to be used in large joints, e.g. knee, hip, shoulder, etc.
Contraindication:
Product is not intended for direct contact with the heart or the central circulatory or central nervous system and not in spine area.
The product is not intended for use in small joints.
Application of high-frequency current may interfere with cardiac pacemakers and in vivo heart defibrillators, so affected patients must consult a cardiologist prior to the intervention.

Side effects:
Electrosurgical interventions may lead to undesired damages or undesired burns of surrounding tissue.
Tissue damage due to extensive forces during but dissection is possible.
It is the sole responsibility of the physician to include this aspect into their professional decision regarding the selection of treatment process.
All electro-surgical products potentially may lead to muscle stimulation during the application.
The frequency of the used HF-generator shall not exceed the maximum frequency of 4 MHz and not exceed the maximum rated voltage of the accessory (see section "Scope").
Follow the instructions, safety notices and warnings included in the User Manuals or IFUs of the used accessories and used HF-generator.
The product is recommended to use a smoke evacuation system.
IMPORTANT:
Handle with utmost care.
This does not only apply for the duration of the surgery but also for the complete duration of storage, processing and transport as well as during the process of connecting the product with the respective HF-handle, HF-cable and/or HF-generator.
This applies especially for the thin tips and other sensitive areas, for example, the insulation.
Always ensure sufficient flushing flow of the joint (min. 100 ml/min.).
The product must be cleaned and disinfected as well as sterilized before first use and after each use (see section "Re) Processing: Cleaning, Disinfection and Sterilization").
Improper use will result in immediate loss of warranty.
No liability is accepted for any damage that may occur.

Irrigation fluid for bipolar products:
During application, the active electrode as well as the neutral electrode of the product have to be always completely surrounded at 100% with conductive irrigation fluid.
Use 0.9% saline solution or Ringer's solution, for example.
NEVER use non-conductive irrigation fluid (e.g. sterile water, glycine, Purisol, etc.) for bipolar products.
Ensure sufficient and adequate flow of irrigation fluid to the joint (at least 100 ml/min.). Do not use without irrigation fluid. Products with suction always have to be connected to the active suction system.
Irrigation fluid for monopolar products:
During application, the active electrode has to be always completely surrounded at 100% with electrolyte-free irrigation fluid. Use Purisol i.e. Do not use without irrigation fluid.

3 Safety notices - WARNING!
See these instructions for use, the label, or the current product catalog for the maximum rated voltage of the product.
Prior to each application, the product has to be cleaned, disinfected and sterilized according to a validated procedure (see section "Re) Processing: Cleaning, Disinfection and Sterilization").
Prior to usage a visual inspection and function test has to be done (see section "Visual inspection").
In case damages, deformation or similar is detected on the product, it is not allowed to use the device.
It has to be replaced by a new one.
At least one (1) cleaned, disinfected and sterilized backup product has to be available.
It is the responsibility of the user to determine the appropriate product size and product type according to their professional judgement and based on the patient's specific indication, preferred surgical technique and history, etc.
Prior to application, verify that the product is inserted firmly in the HF-handle/HF-cable.
This must be done carefully, in order to avoid damages on the product and/or injuries of patient, surgical personnel or third party.
Excessive force can damage the product.
Therefore, the product has to be observed during the complete application.
Exclusion:
Do not activate the product as long as it is in contact with metal objects and/or optics.
During an electro-surgical intervention the patient must not come into contact with grounded metal objects such as i.e. surgical desk frame, instrument trays etc.
Pay attention that no flammable substances are present in immediate vicinity as otherwise there is danger of explosion.
Do not use in the product in the immediate vicinity of inflammable or combustible materials or substances. Active electrodes must not come into contact with inflammable or combustible substances such as disinfectants, gases etc. as otherwise there is a danger of fire or explosion due to heat or sparking.
Do not activate the product uninterrupted over a longer period.
(Refer to section "General Safety Notices for HF-Technology")
After switching off the electro-surgical current, the product tip may still be hot and can lead to unintentional burns.
While the product is activated, do not insert or withdraw the tip from the surgical site.
Inadvertent activation of the product or moving the tip outside of the field-of-vision can lead to unintentional injury of tissue.
Do not make contact between the product and the arthroscope during activation as this may damage the product and/or the arthroscope.
Do not use metal cannula, as these may damage the product insulation (capacitive coupling). This can lead to undesired sparks.
It is recommended to use cannula systems made of plastics.
It is the responsibility of the user to apply low performance settings on the HF-Generator in order to achieve the envisaged effect for the respective intervention.
During and after application, tissue may adhere to the product, or sooting may be present on the distal end of the active electrode.
Such adhesions or sooting do not represent a reason for complaint and the product has to be exchanged by a new one.
Due to longer application time, mechanical forces or plasma seam or similar, the product may exhibit deformation or abrasion of the insulation material.
Also, such aspects do not represent a reason for complaint and the product has to be replaced by a new one.
Blockage of the suction channel (if applicable), does not represent a reason for complaint.
A product, that exhibits a blocked suction channel (if applicable), has to be replaced by a new one.
Intervention:
Insert the product tip through the arthroscopic portal into the surgical field of vision. Ensure the tip of the product is fully submerged in conductive fluid.
Only activate the product in the immediate vicinity of the tissue to be treated. WARNING: an active product tip must NEVER be outside of the user's field-of-vision during the surgery as this can cause unintentional tissue damage.
Whenever the product is not in use, place it on a dry, clean, non-conductive and highly visible field and is not in contact with the patient.
Unintentional activation of the product can lead to burns of the patient.

NOTE: If products with suction are used: after connecting to a suction source, open the roller clamp of the suction electrode completely prior to and during use. To shut off suction feature, close the clamp on the suction tube when the electrode is outside of the patient's body.
No continuous activation.
Apply only short activation times.
At least up to 6 minutes cumulated ablation time and no longer than up to 6 seconds single activation.
Keep on longer breaks between activation phases.
Only adjust low power settings.
End of surgery:
At the end of the surgery, remove product carefully from the patient's body and confirm completeness of the system.
Switch off HF-generator
Remove the plug of the used cable completely from the socket.
Disconnect suction (if applicable)

4 General Safety Notices for HF-Technology (Excerpt)
In addition to the acknowledged benefits of HF-Technology, the application includes several risks that have to be attended:
Improper use and non-observance of the IFU can lead to unintentional burns of the patient, user or third party.
Continued further education of the surgical personnel is recommended.
a) Environment
Pay attention that no flammable substances (anesthetics, oxidizing gases, endogenous gases etc.) are present in immediate vicinity as otherwise there is danger of explosion.
Only use non-flammable cleaning or disinfection agents.
All oxygen connections must be tight and leak-proof during the procedure.
b) Patient Positioning and Preparation
Ensure proper patient positioning, i.e. only use insulating surgical drapes that are dry, absorbent and liquid-light.
Isolate conductive surfaces and contact points towards the patient.
Dry tissues of pulp are necessary to use for skin and breast folds as well as between the electrodes.
Prior to application, remove any liquids that potentially accumulated in body cavities.
Only use non-flammable disinfectants.
Do not use alcohol-based lotions for example.
Only use non-conducting fluid, if medically possible.
Attend the requirements on irrigation fluid for monopolar and bipolar products.
Remove all body jewelry from the patient.
Putting a band aid over the body jewelry is not sufficient!

c) Connections
Prior to application, make sure the used HF-handle/HF-cable is connected properly to the HF-generator and make sure the correct power and performance setting is adjusted and displayed.
It is the responsibility of the user to apply low performance settings on the HF-Generator in order to achieve the envisaged effect for the respective intervention.
d) HF-Neutral Electrode for Monopolar Application
In case of monopolar application, select a HF-neutral electrode suitable for the patient, apply it correctly and connect it properly with the respective HF-generator.
Follow all instructions for proper application of the HF-neutral electrode, incl. patient protection and patient monitoring, monitoring of the HF-neutral electrode and all further provisions, safety notices and warnings included in the IFU of the HF-neutral electrode.

e) Patient Reactions
All electro-surgical devices potentially can cause muscle stimulation during the application.
The design of this product minimizes the risk of this undesirable effect.
Nevertheless, muscle stimulation can lead to an unexpected movement of the patient in the surgical field.
f) Handling HF-Accessory
Make sure the accessory is compatible.
Do not touch the instrument tip during the complete application.
As long as the product is not applied, place it on a dry, clean and non-conductive and well-ventilated surface, that is not in contact with the patient.
Never store product on the patient.
Unintended activation of the product can lead to unintentional burns or other injuries of patient, user or third party.
Never wrap cables around the patient and never lay cables over the patient.
Apply only short activation times.
Keep on longer breaks between activation phases.
Only adjust low power settings.

g) Completeness of the System
At the end of the surgery, confirm completeness of the system.

5 (Re) Processing: Cleaning, disinfection and sterilization

5.1. Maximum number of reprocessing cycles
Due to the materials used and due to the intended use of the products, the articles listed in the Scope of the IFU only are allowed to run through a maximum of up to 5 reprocessing cycles (refer to section "Visual Inspection and Function Test").
When applied according to the Intended Use, the product underlies natural wear and tear, considering manner and duration of the application as well as manner and frequency of reprocessing. Therefore, a visual inspection and function test has to be done prior to each usage. (Refer to section "Visual inspection" and "function test").
Visual inspection and function test, especially the condition of the insulation and product tip are decisive for whether the product can be applied again.

5.2. Time requirements for cleaning and disinfection.
Preparation for cleaning, pre-cleaning and automated cleaning and disinfection has to be done immediately after the application, however not later than 1 hour after the application.
Avoid idle time.
5.3. After the Application
Clean and disinfect product immediately after the application. However not later than 1 h after application. After application of the product, deposit the product carefully (protection of lifetime of the product). After application, separate contaminated product and deposit it in a suitable container (deposit means "do not drop"). Immediately remove gross stain.
Immediately mark damaged or defective products.
Accessory, that do not fit for the sieves of the cleaning and disinfection device (CDD), shall be deposited separately in suitable containers.
Close firmly all disposal-transport containers, in order to avoid drying of stain.
On-site transport of contaminated products the way that contamination of the transport ways and environment also is avoided (closed transport).
Unused reusable products have to be reprocessed as well.
(Refer to Akl) (German organization for instrument reprocessing), Red Brochure, page 30-32)
Take care, all and any transport containers are cleaned and disinfected after transport as well.

5.4. Validation of (Re)Processing
The following validated processing procedure is recommended.
Equivalent deviant processes are possible.
It is the sole responsibility of the user to safeguard the suitability of the actually applied procedure by suitable means (i.e. validation, routine monitoring, verification of material compatibility etc.).
Automated cleaning and disinfection always are preferred.
The following procedure was validated according to EN ISO 17665.
Additionally, applicable requirements for the use of the respective clinical place (operator) as well as national or country specific regulations have to be followed as well.
Never use sharp objects for cleaning.
Disinfectants always have to be rinsed carefully.
5.5. Preparation for Cleaning and Disinfection
Remove product from their packaging.
Place it in a container provided for cleaning.
It is not necessary to disassemble the product.
5.6. Pre-Cleaning
Immediately after the application is completed, pre-clean the product. This however not later than 1 hour after the end of the surgery.
Use tap water (potable water quality) (<40°C) and aldehyde-free, non-oxidizing disinfectants if applicable.
Thoroughly remove surface stain with a soft brush or synthetic fleece, as otherwise particles or dried secretions may adhere.
This could make subsequent cleaning and sterilization difficult or impossible.
Ensure that areas difficult to reach are cleaned thoroughly and rinsed several times.
Cavities and lumens have to be rinsed intensively using at least 3x20 ml cold tap water (<40°C) with the aids of a rinsing adapter (for example from the company Medsafe), or with a syringe or with a water jet pistol (>30 Sec).

5.7. Manual Cleaning and Disinfection
Prepare an immersion bath with a suitable fluid cleaning agent.
Use a cleaning agent that is compatible to the disinfectant and suitable for immersion baths.
Follow the instructions of the manufacturer of the cleaning agent and disinfectant.
Only use agents suitable for medical devices made from metal and plastics with a pH-value between 5.5 and 12.3.
Recommendation: Cleaning agent gigazyme® (Schülke & Mayr) and disinfectant Korsolex Plus.
Do not use high alkaline cleaning agents.
These will impair the lifetime of the product.
• Prepare immersion bath with cleaning agent according to the specific cleaning agent IFU.
• Prepare a separate immersion bath with disinfectant according to the specific disinfectant IFU.
• Immerse the product completely in the ultrasonic bath with cleaning agent (e.g. 0.5% gigazyme®).
• Clean product in ultrasonic bath using a sonication time of 5 Min. and a frequency of 45 kHz.
• Follow all instructions set forth in the IFU of the cleaning agent, disinfectant and ultrasonic bath.
• Ensure the product will not touch other products or parts in the ultrasonic bath.
• Ensure sonic shadows in the ultrasonic bath are avoided.
• Then, clean product with a soft brush under cold running tap water (<40°C).
• Intensively rinse cavities and lumens with a water jet pistol (>30 Sec.) or similar for at least 1 min.
• Afterwards, rinse product thoroughly for at least 1 min. under running tap water (>40°C) in order to remove any residues of the cleaning agent.
• Inspect product visually on remaining stain.
• If any stain is still present, repeat aforementioned cleaning steps as long as it needs until no soil is present.
• Afterwards: immerse product completely in a disinfectant bath including e.g. Korsolex Plus 3%, for at least 15 Min.
• Follow the manufacturer's data for residence time.
• Ensure the disinfectant will contact all areas on the product.
• Rinse cavities and lumen several times, that means at least 3x with 20 ml each of disinfectant bath fluid.

• Afterwards: Rinse product thoroughly for at least 1 Min. with demineralized cold water, in order to remove all disinfectant residues.
• Additionally: Rinse all narrow and areas difficult to access, all cavities and lumen with a syringe several times (at least 3x) using each time 20 ml cold demineralized water.
• Dry product with a lint free wipe and sterile compressed air.
• Dry cavities, lumen and channels with sterile compressed air.

5.8. Automated Cleaning and Disinfection
Only use cleaning and disinfection devices (CDD) with proven efficiency according to EN ISO 15883.
Follow data of the manufacturer of the cleaning and disinfectant machine.
Only use agents suitable for medical devices made from metal and plastics with a pH-value between 5.5 and 12.3.
Recommendation: neodisher® mediclean forte (Dr. Weigert GmbH & Co. KG).
Apply program for thermal disinfection.
Follow instructions and data regarding program course and machine.
Product has to be stored safely and protected against mechanical damages during automated cleaning and disinfection.
Do not clean together with sharp edged or pointed objects.
Deposit product in a suitable rinsing basket.
Follow data for loading of the cleaning and disinfection device (CDD).
Use rinsing adapters for products with lumen and connect them according to the instructions in the User Manual of the cleaning and disinfection device (CDD).

Cleaning Program
Start the program course with following parameters:
• 1 Min. pre-rinsing with cold water
• Emptying
• 3 Min. pre-rinsing with cold water
• Emptying
• 5 Min. cleaning at 55°C with 0.5% alkaline cleaning agent
• Emptying
• 3 Min. neutralization with warm tap water (>40°C) and neutralizer (0.1% Neodisher® Z)
• Emptying
• 2 Min. interim rinsing with warm demineralized water (>40°C)
• Emptying

Disinfection Program
Start the program course for disinfection considering national requirements regarding AO value (see EN ISO 15883, AO value >3000).
5 min. cleaning at 92°C +/-2°C
Drying
30 Min. at 90°C
Remove rinsing adapter
At the end of program course, remove product and inspect it on remaining stain.
In case of residues, repeat automated cleaning and disinfection step as long as it takes until stain is no longer present.
Dry cavities and not sufficiently dried areas with sterile compressed air <2 bar.
Immediately after removal of product and immediately after additional drying on a clean plate, put product in a single use sterilization packing (double packing) from paper or foil or put product in a sterilization container.

Respect requirements for sterilization packaging according to EN ISO 11607 and EN 868.
5.9. Sterilization
Only products that have been cleaned and disinfected are allowed to be sterilized.
Only apply steam sterilization in autoclave (fractioned pre-vacuum with sufficient product drying) for the product.
Adjust sterilization parameters:
• Minimum 134°C and maximum 137°C in saturated steam.
• Holding time at least 5 Min. until max. 20 Min.
• Drying in vacuum for at least 9 Min.
Sterilizer (Class B) according to valid national standards and regulation (e.g. EN 13060 or EN 285).
Recommendation: Sterilizer Class B, manufacturer: Tuttnauer.
Respect data of the sterilizer's manufacturer regarding load, handling and drying times.

Exclusion:
Do not apply hot air, EO-gas, Radiation or Plasma for sterilization, or any other sterilization method for this product.
IMPORTANT:
Prior to usage, let product cool to room temperature.
It is the sole responsibility of the user to maintain the sterile condition of the product after the sterilization process.
In case the aforementioned chemicals and machines for cleaning, disinfection or sterilization are not available, it is the responsibility of the user to validate the procedure actually applied.
Also, if a sterilization method other than described above is applied, this deviating procedure has to be validated by the user accordingly.

5.10. Limitation of Reprocessing
The product life time is depending on wear and tear, handling, application time, damages as well as frequency of reprocessing.
Due to the materials used and due to the intended use of the products, the articles listed in the Scope of this IFU only are allowed to run through a maximum of up to 5 reprocessing cycles (refer to section "Visual Inspection and Function Test").
Also, if a sterilization method other than described above is applied, this deviating procedure has to be validated by the user accordingly.
5.11. Limitation of Reprocessing
The product life time is depending on wear and tear, handling, application time, damages as well as frequency of reprocessing.
Due to the materials used and due to the intended use of the products, the articles listed in the Scope of this IFU only are allowed to run through a maximum of up to 5 reprocessing cycles (refer to section "Visual Inspection and Function Test").
Also, if a sterilization method other than described above is applied, this deviating procedure has to be validated by the user accordingly.

6 Visual inspection and Function Test
Prior to each usage, the complete product, especially insulation and product tip has to be inspected for pressure points and damages.
A product exhibiting damages, pressure points or questionable condition is not allowed to be used and has to be replaced by a new one.
During and after application, tissue may adhere to the product, or sooting may be present on the distal end of the active electrode.
Such adhesions or sooting do not represent a reason for complaint and the product has to be exchanged by a new one.
Due to longer application time, mechanical forces or plasma seam or similar, the product may exhibit deformation or abrasion of the insulation material.
Also, such aspects do not represent a reason for complaint and the product has to be replaced by a new one.
Blockage of the suction channel (if applicable), does not represent a reason for complaint.
A product, that exhibits a blocked suction channel (if applicable), has to be replaced by a new one.
Prior to usage an electrical continuity test has to be done.
In case the product does not pass the electrical continuity test, it is not allowed to use the product any longer and has to be replaced by a new one.

7 Exclusion of repair and modification
Unauthorized repairs and modification (e.g. bending) is strictly prohibited.
Especially product, having a hook as active part, are never allowed to be bent.
According to their Intended Use, or that have been handled or applied improperly, or in case of any other deviation from the instructions set forth in this IFU.
Furthermore, the manufacturer denies any liability for any accidental, intentional damage or for a damage or loss arising out of handling or application of the product.
Additionally, all liability and warranty is omitted in case our product was repaired by a company that has not been authorized by us.
Unauthorized repairs are strictly prohibited.

8 Packaging, storage and transport
Store in a clean and dry environment, avoid direct sunlight.
Handle with utmost care during transport, cleaning, disinfection, maintenance, sterilization and storage (see also section "after the application").
This especially applies for fine tips and other sensitive areas.
Do not store or transport the product together with sharp edged or pointed objects.
Storage only in protective cases with individual compartments or individually sealed in foil.
Maintenance of the sterile condition after sterilization process is the sole responsibility of the user.

9 Manufacturer
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11 Warranty
Our products satisfy the highest quality standards.
Liability and warranty is excluded for all products that have been modified in any way, not applied according to their Intended Use, or that have been handled or applied improperly, or in case of any other deviation from the instructions set forth in this IFU.
Furthermore, the manufacturer denies any liability for any accidental, intentional damage or for a damage or loss arising out of handling or application of the product.
Additionally, all liability and warranty is omitted in case our product was repaired by a company that has not been authorized by us.
Unauthorized repairs are strictly prohibited.

12 Return
Returned products 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.

13 Disposal
Disposal of the product, their packaging material as well as any accessory has to be done according to the applicable country specific requirements, regulations and laws.
Additionally, the applicable requirements of the respective clinical place(s) in regards to disposal of medical devices have to be followed as well.

14 Regulatory Remark
Report serious incidents with the product to us. If you are a user in the European Union, also report incidents to the responsible authority in your Member State.

15 About these Instructions for Use
Throughout the period of usage these IFU must be kept freely accessible for the user.
For a current revision of these IFU, please contact medimex GmbH or visit the medimex Homepage for a download of this document:
www.medimex.de/informations
Changes reserved.
This medium is not intended for users in the USA.

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