EN - Instructions for use

High Frequency Electrodes

REF This manual refers to the following articles :

Devices list
D300 120 649 to D300 120 653; D300 120 762 to D300 120 767; D300 120 771; D300 120 813 to D300 120 816; D300 140 010 to D300 140 011;

Read these instructions carefully before using Delmont Imaging devices. Keep them in a safe place for future reference.

Symbols Used in this manual	
⚠	Instructions for preventing personal injury
❗	Instructions for preventing material damage
ⓘ	Information to facilitate understanding or workflow optimization
✓	Prerequisite
➢	Instruction

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1. Device description

1.1. Intended Use

This manual is addressed exclusively to trained and qualified personnel (medical doctors, medical assistants supervised by a doctor). High Frequency Electrodes are to be used exclusively by trained personnel qualified to carry out clinical applications in hospitals and medical rooms with appropriate endoscopic equipment. The products must not be used if, according to a qualified physician, the general condition of the patient is not adequate or if the endoscopic methods are contraindicated.

HF Electrodes have been designed for use in minimally invasive endoscopic surgical procedures, in particular in laparoscopy and hysteroscopy. HF electrodes are used to grasp, cut, clamp, dissect, retract and coagulate tissue if necessary, by use of monopolar or bipolar electrical current.

With the help of suction cocks, the suction and flushing of tissue structures is controlled during the operation so that the surgeon has a clear view.

For the benefit and safety of patients, physicians must select a method which they consider suitable based on their experience. If you, as the user of this device, believe that you require more detailed information regarding the product's use and maintenance, please contact your representative.

W.I

This document describes the correct handling and operation of the HF electrodes, as well as recommended treatment methods. This document should not be used for endoscopic examinations, surgery, or training purposes.

1.2. Specific details

The HF electrodes systems consist of one single component with or without a flushing port:

1: Tip of the HF electrode
2: Shaft
3: High Frequency Plug
4: Manipulation Handle
5: Luer-lock plug for suction

1: Tip of the HF electrode
2: Shaft
3: High Frequency Plug
4: Manipulation Handle

1.3. Combination

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Using incompatible equipment may lead to injury of the patient and/or the user as well as damage to the product. Delmont imaging recommends to only use Delmont Imaging devices and accessories.

The HF Electrode must be connected with the appropriate cable - to monopolar or bipolar output of an HF generator. Cutting or coagulation current is then activated by a footswitch that is part of the electrosurgical generator. Please refer to the corresponding User manual of the generator you use.

The rated peak voltage for Delmont HF electrodes is given below. The HF device must be set in such way that the maximum output voltage is equal to or smaller than the rated peak voltage (see IEC/DIN EN 60601-2-2).

Instruments	Operation	Rated peak voltage
Monopolar 2-3 mm	Endoscopic, spray coagulation, cutting	1,5 kVp
Monopolar ≤ 4mm	Endoscopic, spray coagulation, cutting	3 kVp
Bipolar 2-3 mm	Endoscopic, spray coagulation, cutting	0,3 kVp
Bipolar ≤ 4mm	Endoscopic, spray coagulation, cutting	0,5 kVp

The HF electrodes can be connected to the HF generators from Aesculap, Berchtold, Erbe, KLS/Martin, Olympus, Siemens, Storz, Valleylab and other similar HF generators. The connection possibilities depend on the plug of the connection cable. A monopolar cable is connected to the connector of a Ø 4 mm socket on the device panel. The corresponding connection for the HF device

must be selected on the device side. When inserting the connection cable make sure that the plug connection ensures a permanent contact. This is achieved by plugging the plugs completely up to the mechanical limit.

2. Safety instructions

Observe the use and safety instructions of the manufacturer of the high-frequency surgical device. Non-observance of these use and safety instructions may lead to injuries, malfunctions or other unexpected incidents.

2.1. Warning and Precautions


W.III

Make sure that the products are used exclusively by trained and qualified personnel. Make sure that the surgeon is proficient, theoretically and practically, in the approved surgical techniques. The surgeon is responsible for the correct execution of the operation.


W.IV

The HF cable and the HF electrode must not be placed directly on the patient's skin, as this may result in burns due to capacitive currents. The device may not be placed on or beside the patient.


W.V

The HF cable must not be in loops, otherwise inductive leakage currents may occur.


W.VI

Earth the operating table. Make sure to insulate the patient against contact with other conductive parts. Do not use any non-insulated electrodes for HF surgery.


W.VII

Use only under visual contact. 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.


W.VIII

Deactivate the automatic switch-on mode of HF electrodes when using laparoscopic or endoscopic accessories


W.IX

There is a risk of fire or explosion. Never use the electrodes in the presence of flammable or explosive substances. Do not use the electrode in contact with surgical drapes and other flammable materials.

2.2. Instructions specific to monopolar use


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Ensure correct application of the neutral electrode on the patient; otherwise, there is a danger of burns.


W.XI

Avoid skin-to-skin contact with the patient's arms and legs by, for example, inserting dry gauze.


W.XII

Do not switch on the HF current until the electrode is in contact with the tissue to be coagulated.


W.XIII

The tissue parts to be coagulated must not come into small contact with other tissue parts, otherwise unwanted coagulations may occur in other places.


W.XIV

Make sure that the current paths between the neutral electrode and the monopolar electrodes are as short as possible. The current path must not pass through the body, and under no circumstances through the thorax.


W.XV

The distance between the coagulating HF electrode tip and other surgical electrodes during coagulation must be at least 10 mm.


W.XVI

When using gases, e.g. insufflation gases, it must be ensured that only non-flammable gases are used, as otherwise explosions and exogenous burns may occur.


W.XVII

The size of the neutral electrode must be in proportion to the HF current used, otherwise this can lead to burns in the wrong place.


W.XVIII

Ensure correct application of the neutral electrode on the patient; otherwise, there is a danger of burns.

2.3. Contraindication

Do not use the devices if one or more below reported condition is present:


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- ***Minimally invasive surgery is contraindicated,***
- ***Not intended to be used for tubal sterilization or tubal coagulation following sterilization,***
- ***General inoperability state of the patient,***
- ***Ambiguous diagnosis,***
- ***Lack of willingness on the part of the patient,***
- ***Technical preconditions not met,***
- ***Acute inflammation of the abdominal area,***
- ***Existing pregnancy,***
- ***For use with pacemaker patients:***
    - ***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,
    - ***Never perform outpatient procedures on patients with cardiac pacemakers. Pacemakers can be damaged by HF current.***
- ***Suspicion of one of the following diseases:***
    - ***CJD (Creutzfeldt-Jacob disease),***
    - ***vCJD (variant Creutzfeldt-Jakob disease),***
    - ***BSE (Bovine Spongiform Encephalopathy),***
    - ***TSE (Transmissible spongiform Encephalopathy).***

A comprehensive explanation of the necessary preventative measures with regard to above listed agents would go beyond the scope of this document. It is assumed that such pathogens cannot be killed using normal disinfection and sterilization processes. Therefore, the standard methods for decontamination and sterilization are not sufficient if there is a risk of transferring disease.

The responsible physician must decide, on the basis of the patient's general condition, whether the planned application can be carried out. Country-specific regulations and laws must be observed. Further information can be found in the current literature.

2.4. Materiovigilance

Any serious incident occurring during the use of this device must be notified to the manufacturer Delmont imaging (vigilance@delmont-imaging.com) or its official representative and to the competent authorities according to the national laws in force.

3. Use of the device

3.1. Visual inspection and functional test


W.XX

New medical products must be inspected thoroughly visually and functionally after delivery and prior to each use.


W.XXI

Do not use a damaged product or a product with improper functioning. The use of a damaged product or of a product with improper functioning may cause an electric shock, mechanical injury, infection, and/or thermal injury. Discard any damaged product or a product with improper functioning and replace it by a new one.

Always have a spare device ready to use.

- Prior to subsequent use and before each use, it is very important to check every surgical electrode for visible damage and wear, such as cracks, breaks or insulation defects before each use. In particular areas such as tips, notches, insulations elements must be checked carefully.
- Check that function is as described in the instructions.
- Damaged or faulty products should not be used and should be taken out of circulation immediately.
- Damaged parts should be immediately replaced by original manufacturer parts.

4. Reprocessing


W.XXII

The products are delivered in a non-sterile condition. They must be cleaned, disinfected and sterilized before and after each use. Do not use a device that has not been reprocessed. Incomplete reprocessing can lead to infection of the patient and/or medical staff and damage to the device.


W.XXIII

This device must be reprocessed by trained professionals and the protocols used must be designed in accordance with applicable national and local standards and regulations.


W.XXIV

If the chemicals and machines described below are not available, it is the responsibility of the user to validate the process accordingly. It is the responsibility of the user to ensure that the reprocessing process, including resources, materials and personnel, is appropriate to achieve the required results. The state of the art and national laws require compliance with validated processes.


W.XXV

The instructions of manufacturers of machinery, cleaning agents and disinfectants must be followed. The results of cleaning and disinfection must be confirmed by the manufacturers of machines, cleaning agents and disinfectants in cooperation with the user.


W.XXVI

If necessary, repeat the reprocessing process until the device is visually clean.

Please note that only sufficiently device specific validated procedures for cleaning, disinfection and sterilization are used and that the validated parameters are adhered to during each cycle. Please also observe the legal regulations applicable in your country as well as the hygiene regulations of the hospital or clinic.

4.1. Preparation

- Treat contaminated devices as soon as possible,
- In case of contact with a corrosive substance, clean with water immediately,
- Pack them safely in a closed container,
- Trays must be inspected for visible contamination and cleaned prior to use.

4.2. Cleaning and disinfection

Use only suitable cleaning and disinfecting agents certified for use on stainless steel, ceramics and plastics in accordance with the manufacturer's instructions. Do not use fixative cleaners or hot water (>40°C), as this will bind residues and may impair cleaning success.

Make sure that only sterile or low-germ (max. 10 bacteria /ml) and low-endotoxin (max. 0.25 endotoxin units /ml) water is used, e.g. purified water / highly purified water.

Never use abrasive cleaners, brushes or other objects that could damage the appliance.

Effective cleaning/disinfection is the indispensable prerequisite for effective sterilization of the products. Start the cleaning immediately after each use.

Automated cleaning as described is the most preferable. Please observe the legal regulations applicable in your country as well as the hygiene regulations of the hospital or clinic. A manual method should only be used if an automated method is not available due to the significantly inferior effectiveness and reproducibility.

Step	Automated Cleaning Instructions
Automated pre-cleaning	➢ Immerse the device in cold water for at least 5 minutes. Brush device under cold water until all visible residues have been removed. Inner lumens, threads and holes must be flushed with a water jet pistol for a minimum of 10 seconds in the pulse mode. ➢ Immerse the device in an ultrasonic bath with alkaline (0,5%) and treat with ultrasound for 15 minutes at 40°C. ✓ Use solution: Neodisher Mediclean forte; Dr. Weigert; Hamburg. ➢ Take the device out of the bath and rinse with cold tap water.

Step	Automated Cleaning Instructions
Automated cleaning	➢ Observe the operating and loading instructions of the washer and disinfector manufacturer and the cleaning agent recommendations. ✓ Device used for validation: Miele G7835 CD, with program: Design Vario TD AD. ➢ Place the device on a tray. If applicable, connect the LUER lock connection with the MIC flushing system. ➢ 1 min pre-cleaning with cold water ➢ Draining ➢ 3 min pre-cleaning with cold water
Automated cleaning	➢ Draining ➢ 5 min cleaning at 55°C with 0,5 % alkaline solution ✓ Use solution: Neodisher Mediclean forte; Dr. Weigert; Hamburg. ➢ Draining ➢ 3 min neutralization with warm water (40°C-60°C) and neutralizer agent. ✓ Use solution: Neodisher Z; Dr. Weigert, Hamburg ➢ Draining ➢ 2 min rinse with warm water (40°C-60°C) ➢ Draining
Disinfection	➢ Automated Thermal Disinfection under consideration of national requirements regarding A0-Value (see ISO 15883) ➢ We recommend final rinse with distilled, demineralized or fully desalinated water.
Drying	➢ Dry the outer surfaces of the electrodes in the drying cycle of the washer/disinfector. ➢ Let electrodes cool down to room temperature. If necessary, additional manual drying can be performed through a lint free towel. ➢ Use medical compressed air for cavities in the device.

The devices must be visually examined for cleanliness after every cleaning and disinfection. They must be macroscopically clean from visual residual and soil.

- ➢ If residue, liquids, impurities are visible, repeat cleaning process.
- ➢ The insulation and HF connector must be intact.

- Ensure that the HF electrodes are faultless prior to each application.
- Plastic components should be checked before sterilization.
- Discard damaged HF electrodes immediately.
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4.3. Sterilization

The products are delivered non-sterile in sealed plastic packaging or in a protective box/foam wrapping. The transport packaging is not suitable for sterilization. The devices must be packed in suitable sterilization packaging systems in accordance with ISO 11607 and/or AAMI / ANSI ST77:2006 in order to be sterilized.

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In cases of suspected prion contamination (CJD), different national guidelines should be followed and longer waiting times (i.e. 18 minutes) may apply.

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Plasma sterilization is not possible due to plastic components.

- Sterilize the hysteroscopy system according to generally accepted hospital method.
- Observe manufacturer‘s indications for products used.
- Make sure that sterilization products are packaged according to ISO 11607, EN 868 and/or AAMI/ANSI ST77:2006 (e.g. STERICLIN).
- Carry out sterilization according to EN 13060/EN ISO 17665-1.
- Observe applicable country-specific requirements.
- Steam sterilization using fractionated vacuum method (in the sterilization container) and sufficient product drying:

Forevacuum	Temperature	Time	Drying
3 phases with at least 60 millibars pressure	134°C	At least 4 minutes	At least 10 minutes

4.4. Storage

Sterilized devices must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.

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Unsterile devices must be stored in a clean, dry environment. The storage time of unsterile units is not limited; the units are made of a non-degradable material which maintains its stability when stored under the recommended conditions:

- ✓ Temperature: -5°C to +40°C.
- ✓ Humidity: 10% to 90%, without condensation.
- ✓ Avoid direct sunlight.
- ✓ Store the device either in the original packaging or individually in a screen tray/closed container.
- ✓ Ensure that the device is stored securely.

4.5. Limit of reprocessing

Delmont Imaging´s devices are made of different materials. They were chosen for their ability to withstand multiple cycles of cleaning, disinfection and sterilization and therefore, multiple applications at high temperatures. Repeated treatment has minimal effect on the device. The service life is generally determined by wear and tear and inappropriate reprocessing parameters. You can verify the proper functioning of device following instruction in section “Visual inspection and functional test”.

5. After-Sales service and maintenance

5.1. Maintenance

No specific maintenance is required for the use of this device. Make sure to follow instruction from section “Visual inspection and functional test” prior to each use.

5.2. Repair

There is a risk of injury to the patient and/or the user caused by unauthorized repairs and production modification of the devices. Possible injuries include mechanical injuries, electric shock, burns and intoxication.

There is risk of infection when returning a used medical device. Returning used medical devices is exclusively permitted when cleaned and sterilized/disinfected, and with written verification thereof. If reprocessing will damage the product completely, clean the product as thoroughly as possible and mark it accordingly.

The Delmont Imaging service center does not accept warranty claims for damage caused by improper packaging.

Do not attempt to repair or modify the device. Repairs may only be performed by qualified service personnel authorized by Delmont Imaging, using genuine parts supplied by Delmont Imaging. The original technical specifications and operational safety of our devices can only be guaranteed by using original parts. Contact a Delmont Imaging representative or an authorized service center for repair information.

The warranty on Delmont Imaging products is void if repairs are performed by a workshop not authorized by Delmont Imaging. In this case, Delmont Imaging is also no longer responsible for the technical specifications or safety of the product.

Use the original cardboard packaging for transporting the product. If this is not possible, wrap each component individually in a sufficient amount of paper or foam sheets and place them in a cardboard box.

5.3. Warranty

This device is warranted against defects in workmanship and materials. In the event of a defect, the device will be replaced or charges will be refunded, at the manufacturer's discretion.

Any repair, attempted repair, modification or other alteration of this device by unauthorized personnel will void the warranty. Delmont Imaging provides only tested and flawless devices to its customers. All devices are designed and manufactured to meet the highest quality requirements. We accept no responsibility for devices that have been modified from the original device or have been subject to misuse.

5.4. Disposal


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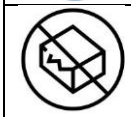
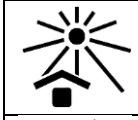
Keep the used device out of the reach of unauthorized persons.

We encourage our customers to recycle this product whenever possible. Disposal of this device should be carried out in accordance with applicable national and local environmental regulations.

6. Used Symbols

Symbol	Description
	Symbol for “Manufacturer”
	Symbol for “Date of manufacture”
	Complies with European directive 93/42/EEC
	Symbol for “Catalogue number”
	Symbol for “Lot number”
	Symbol for “Consult the Instruction for Use”
	Symbol for “Operating Instructions”
	Symbol for “Do not use if package is damaged”
	Symbol for “Non-Sterile”
	Symbol for “Keep away from sunlight”
	Symbol for “Keep dry”

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