EN - Instructions for use

Resectoscopy System

REF This manual relates to the following articles:

Product list
D300 130 000 to D300 130 006; D300 130 008; D300 130 009; D300 130 021; D300 130 022; D300 140 000 to D300 140 009; D300 140 012 to D300 140 044; D300 140 059 to D300 140 070; D300 140 078 to D300 140 083; D300 140 087 to D300 140 150

Carefully read these instructions 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). Resectoscopy Systems 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.

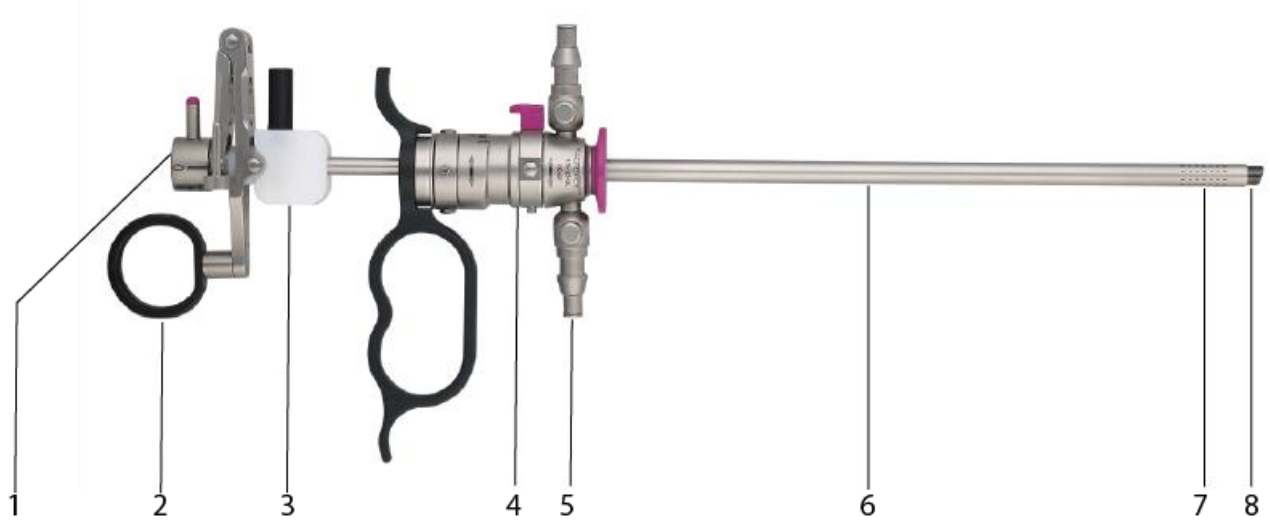
Resectoscopy Systems have been designed for use in minimally invasive endoscopic surgical procedures. Resectoscopy Systems are used for resectoscopy operation such as removal of polyps or treatment of myoma with monopolar or bipolar electrical current and the help of irrigation and suction system so 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 function of the Resectoscopy System. This document may not be used to carry out endoscopic examinations or surgeries, nor may be used for training purposes.

1.2. Specific details



1: Endoscope plug
2: Handle ring
3: High Frequency Plug
4: Quick lock system
5: Irrigation and suction plug Luer Lock
6: Sheaths
7: Aspiration holes
8: Ceramic tip

The Resectoscopy System is divided in four parts:

- Working element (passive or active),
- Inner sheath,
- Outer sheath,
- Resectoscopy electrode.

1.3. Combination


W.II

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 Resectoscopy system must be used with an appropriate endoscope provided by Delmont Imaging. Please refer to the corresponding IFU.

The Resectoscopy system must be connected with the appropriate cable - to monopolar or bipolar output of an HF generator. Cutting current is then activated by a footswitch that is part of the electrosurgical generator. Please refer to the corresponding User manual of the generator and cables you use. The appropriate solution should be used depending on the current used.

Electrical safety tests were conducted in combination with the HF surgical generator ME MB2 by KLS Martin. Comparable HF-generators can be used in combination with Delmont imaging's products if it is ensured that maximum power outputs (max. 2.0 kVp) are not exceeded and the connection with suitable cables is ensured (see IEC EN 60601-2-2).

When inserting the connection cable make sure that the plug connection ensures a permanent contact. This is achieved by plugging the plugs completely into the HF generator up to the mechanical limit or by plugging them onto the HF accessories.

Size (Fr.)	Electrodes	Working element	Outer sheath	Inner sheath	Obturator
17.5/18.5	D300 140 000 D300 140 001 D300 140 002 D300 140 003 D300 140 044	D300 130 002 D300 130 009 D300 130 079	D300 130 000 D300 130 081 D300 130 083 D300 130 084	D300 130 001 D300 130 080 D300 130 082	D300 130 003 D300 130 004
19/22	D300 140 039 D300 140 040 D300 140 041 D300 140 042 D300 140 043	D300 130 066 D300 130 067 D300 130 068 D300 130 069	D300 130 071 D300 130 073 D300 130 075 D300 130 077	D300 130 070 D300 130 072 D300 130 076	D300 130 074 D300 130 78
24/26	D300 140 004 D300 140 005 D300 140 006 D300 140 007 D300 140 009 D300 140 012 D300 140 013 D300 140 014 D300 140 016 D300 140 017 D300 140 018 D300 140 019 D300 140 021 D300 140 023 D300 140 025 D300 140 026 D300 140 029 D300 140 030 D300 140 033 D300 140 035 D300 140 036 D300 140 037	D300 130 006 D300 130 008 D300 130 013 D300 130 014 D300 130 018 D300 130 020 D300 130 021 D300 130 027	D300 130 029 D300 130 030 D300 130 031 D300 130 036 D300 130 037 D300 130 038 D300 130 039 D300 130 040 D300 130 041	D300 130 004 D300 130 005 D300 130 023 D300 130 024 D300 130 028 D300 130 035 D300 130 057 D300 130 059	D300 130 007 D300 130 032 D300 130 042 D300 130 045 D300 130 046 D300 130 048 D300 130 061
27/28.5	D300 140 017 D300 140 024 D300 140 027	D300 130 011 D300 130 012 D300 130 013 D300 130 015 D300 130 017 D300 130 018 D300 130 019 D300 130 020 D300 130 022	D300 130 049 D300 130 051 D300 130 053 D300 130 055 D300 130 056	D300 130 024 D300 130 026 D300 130 027 D300 130 050 D300 130 054 D300 130 058 D300 130 060	D300 130 043 D300 130 044 D300 130 047 D300 130 052 D300 130 062

2. Safety instructions

Observe the use and safety instructions of the manufacturer. 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 Resectoscopy system 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

Never use the electrodes in the presence of flammable materials such as surgical drapes or explosive substances such flammable gases, otherwise explosions and exogenous burns may occur.

2.2. Instructions specific to monopolar use


W.IX

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


W.X

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


W.XI

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

W.XII ***The tissue parts to be coagulated must not come into small contact with other tissue parts, otherwise unwanted coagulations may occur in other places. The distance between the coagulating Resectoscopy system tip and other surgical electrodes during coagulation must be at least 10mm.***

W.XIII ***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.XIV ***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.***

2.3. Instructions specific to single use electrodes

W.XV ***Do not reprocess single use electrodes. The single use electrodes are labelled accordingly.***

W.XVI ***Respect the "Use-by-date" instruction on the label otherwise you have a risk for infection.***

W.XVII ***Discard immediately single use electrodes with a damaged or a suspected damaged sealed barrier otherwise you have a risk for infection.***

Electrodes for resectoscopy system are either supplied as sterile single use electrode, or reusable. Refer to their respective labelling.

2.4. Contraindication

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

W.XVIII

- ***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 medical doctor responsible has to decide on the basis of the general condition of the patient, whether the intended application can be carried out. The country-specific regulations and laws must be respected. Further information can be found in the current literature.

It is immediately necessary to take measures in case of suspicion or diagnosis of CJD, vCJD, BSE or TSE to avoid contamination to other patients, users or third persons.

2.5. Side effects and residual risks

When direct or low-frequency current enters the body, electrolysis occurs at the electrode-tissue interface. The chemical effects of electrolysis disappear at higher frequencies. Direct or low frequency current can depolarize cell membranes and cause neuromuscular excitation.

Electrosection results in more collateral tissue damage compared to scalpel surgery, creating some histologic distortion of surgical margins. Thermal damage may cause carbonization at the excision margin, vessel thrombosis, and collagen denaturation.

Therefore, careful evaluation of the advantages and suitability of the intended application is recommended.

2.6. Vigilance

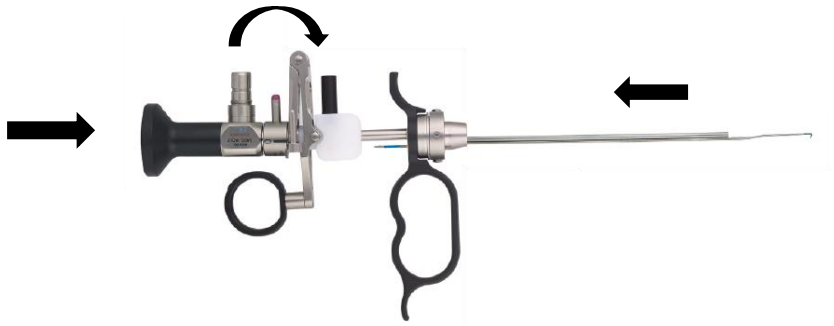
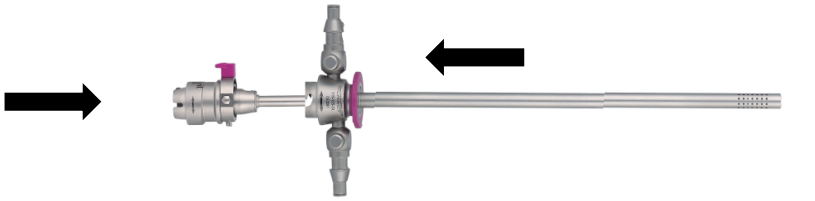
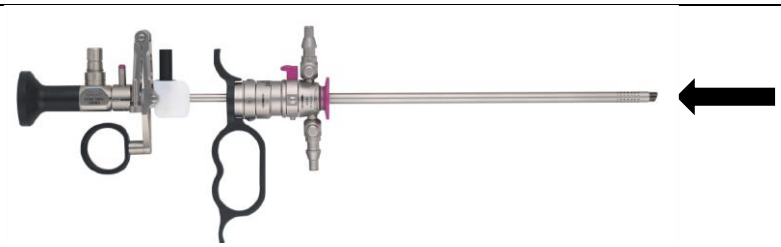
Any serious incident occurring during the use of this device must be notified to the manufacturer Delmont Imaging (vigilance@delmont-imaging.com), or its representative and to the competent authorities in accordance with the national laws in force.

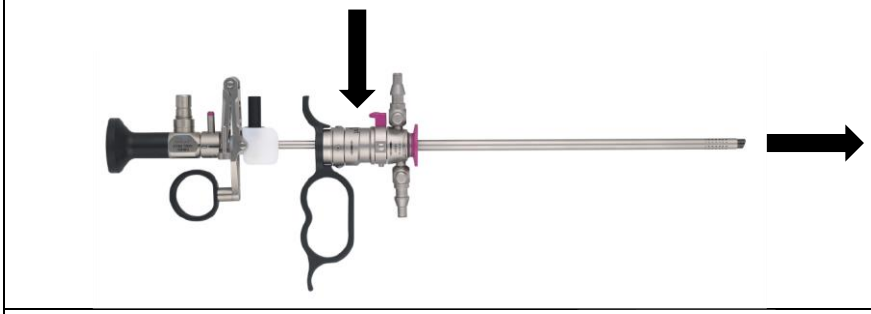
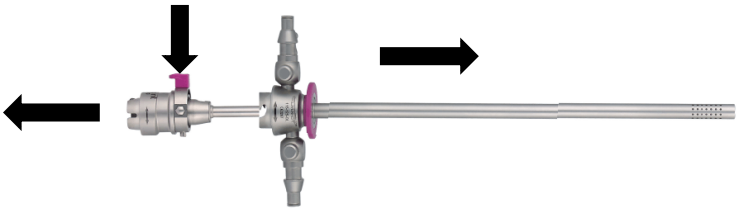
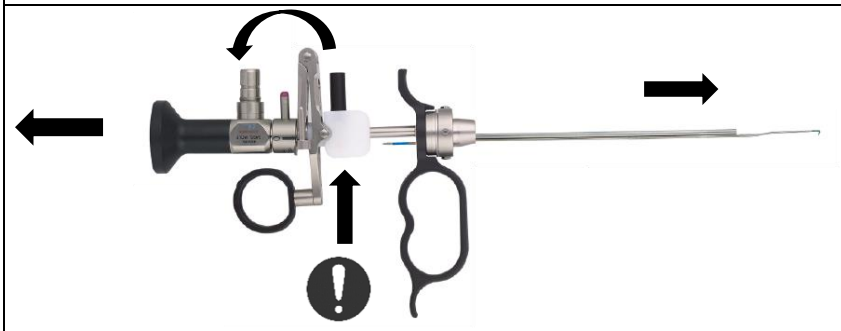
3. Use of the device

3.1. Assembling/Disassembling the Resectoscopy System

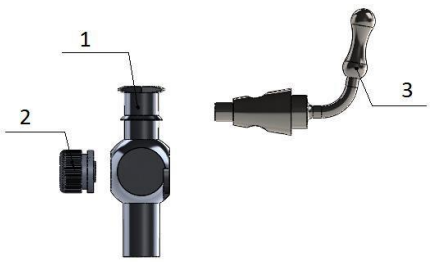
W.XIX

Resectoscopy systems could be damaged by excessive force.

Assembling a resectoscopy system	
	➢ Insert the endoscope used through the working element ➢ Turn clockwise the lock ➢ Slide the electrode on the endoscope tip, through the working element hole, until it clicks in the working element
	➢ Assemble the inner sheath with corresponding outer sheaths until the click of the quick lock
	➢ Assemble the assembled working element with the assembled sheaths until the click of the quick-lock

Disassembling a resectoscopy system	
	➢ Press the quick-lock button of the working element to free the sheaths. ➢ Draw back the sheaths.
	➢ Press the quick-lock button of the inner sheath to free the outer sheath. ➢ Separate the sheaths
	➢ Press the black button to free the electrode ➢ Draw back the electrode. Don't try to do so before pushing the button. ➢ Unlock anticlockwise the lock to free the endoscope. ➢ Draw it back.

If you want to disassemble the stopcock from the housing (1), unscrew the thumbscrew (2) from the stopcock plug (3) :



3.2. Specific instructions when applying high frequency

W.XX

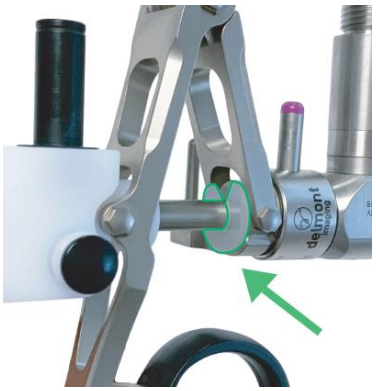
Never re-bend or tamper with the shape of the loop wire. It may damage the electrode and lead to hazards for both patient and user.

W.XXI

Inadequate distance between HF conductive components and other conductive parts, may lead to unintentional damage of tissue and/or instruments.

✓ During application of high frequency to the HF electrodes, a distance of at least 8mm is required from the HF application tip (i.e. loop wire, ball, and knife) to the distal end of the endoscope or sheath. That distance ensures the electrode while active is always visible. To help you to respect that distance, you can use a blocker provided by Delmont Imaging that will warrantee that distance.

8mm



3.3. Visual inspection and functional test

W.XXII

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

W.XXIII

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 resectoscopy system including every surgical electrode for visible damage and wear, such as cracks, breaks or any defects before each use. In particular areas such as blades, tips, insulations elements must be checked carefully. Damaged or faulty products should not be used and should be taken out of circulation immediately and replaced by original manufacturer parts.

- Check that function is as described in the instructions.
- Make sure that all products have been properly reprocessed.
- Visually inspect all products thoroughly. The products must be visually clean.

- Check that the Resectoscopy systems have:
  - ✓ No dents, cracks, kinks, or deformations,
  - ✓ No scratches,
  - ✓ No corrosion,
  - ✓ No missing or loose parts,
  - ✓ Check all marking on the device for clear visibility,
  - ✓ Ensure that there are no residual cleaning agents or disinfectants on the device.
- Checking the shaft rotation and working element function:
  - ✓ Turn the distal rotating ring and check that the outer tube can rotate in both directions,
  - ✓ Activate the working element and check if it comes at its original position smoothly.
- Check the HF electrodes as follow:
  - ✓ In resting position, the electrode loop has to remain approximately 1.0mm behind the distal end of the sheath,
  - ✓ The distance between non-insulated tip of the electrode and the tip of the endoscope must be at least 2mm.
  - ✓ Check the table below of the usual sign of deterioration of the electrodes.

	Correct	Damaged
Proximal end		
Distal Tip		

4. Reprocessing


W.XXIV

Except single use electrodes which are labelled as such, products are delivered in a non-sterile state. They must be cleaned, disinfected and sterilized always before and after each use. Do not use a device that has not been reprocessed. Incomplete reprocessing can cause infection of the patient and/or medical personnel as well as damage to the device.


W.XXV

This device must be reprocessed by trained professionals and the protocols used should be designed according to the applicable national and local standards and regulations.


W.XXVI

If the chemicals and machines described below are not available, it is the responsibility of the user to validate his process accordingly. It is the user's responsibility 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.XXVII

The instructions of the machine, cleaning agent and disinfectant manufacturers must be observed. The cleaning and disinfection results must be confirmed by the machine, cleaning agent and disinfectant manufacturers in cooperation with the user.


W.XXVIII

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

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. 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.
- Disassemble the device and accessories
- Open stopcocks (if present).
- Pack them safely and alone in a closed container.
- Trays must be inspected for visible contamination and cleaned prior to use.

4.2. Cleaning and disinfection


W.XXIX

Use only appropriate cleaning and disinfectant agents, certified for use on stainless steel, ceramic and plastic, in accordance with the manufacturer's instructions. Do not use fixating cleaning agents or hot water (>40°C) as this will fix residues and may affect the cleaning success.

Never use abrasive cleaning agent, brushes or other objects that could damage the device. Resectoscopy systems must never be rinsed in the jaw section towards the handle with a manual or mechanical water pressure hose. Resectoscopy systems may only be flushed across the device axis to prevent damage to the inner seal.

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

Step	Automated Cleaning Instructions
Automated pre-cleaning	➢ Immerse the Resectoscopy systems in cold tap water for at least 5 minutes. Brush device under cold tap 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 Resectoscopy systems 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: Niagara SI PCF - Medisafe ➢ Place the Resectoscopy system on a tray. ➢ 3 min pre-cleaning with 25°C water ➢ Draining ➢ 20 min cleaning with pulsed activation of ultrasonic cleaning at 40°C with 0,35% enzymatic solution ✓ Use solution: M20029 3E-Zyme Scope Plus, Medisafe. ➢ 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	➢ Ensure that the exteriors of the endoscope are dry. If necessary, dry with a soft cloth. ➢ If necessary, dry working channels with compressed air.

The Resectoscopy systems 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 Resectoscopy systems are faultless prior to each application.
- ➢ Plastic components should be checked before sterilization.
- ➢ Discard damaged Resectoscopy systems immediately.

4.3. Sterilization

Except for single use sterile electrodes which are labelled as such, the products are delivered non-sterile in sealed plastic or in a protective box/foam packaging. Transport packaging is not suitable for sterilization. Devices have to be packed into suitable sterilization packaging systems (e.g. STERICLIN pouch used during sterilization validation) acc. to ISO 11607 and/or AAMI / ANSI ST77:2006 in order to be sterilized.

If contamination with prions (CJD) is suspected, differing national guidelines are to be followed and longer holding times (i.e. 18 min.) may apply.

Plasma sterilization is not possible due to plastic components.

- Sterilize the devices 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/DIN EN ISO 17665-1. Observe applicable country-specific requirements.
- Devices must be packed into suitable sterilization packaging systems acc. to ISO 11607 in order to be sterilized.
- 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.

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: -10°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 out of different materials. These were chosen regarding their ability to withstand to several cleaning, disinfection and sterilization cycles and thus, the multiple high temperature application. There are no concerns regarding material resistance or any known sensitivity to process parameters during reprocessing which may affect the safety of our devices. Repeated processing has only minimal effect on the device. The service life of the units is usually determined by wear, damage and improper reprocessing parameters. Nevertheless, the ability of Delmont Imaging devices to withstand several reprocessing cycles has been validated up to 300 times for sheaths and working elements and up to 20 times for electrodes.

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 Visual inspection and functional test prior to each use.

5.2. Repair

W.XXXIII

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

W.XXXIV

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

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

Do not attempt to repair or modify the product. Repairs may only be performed by qualified servicing personnel that have been authorized by Delmont Imaging using original parts supplied by Delmont Imaging. The original technical specifications and the 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 for Delmont Imaging products shall become void if repairs are carried out 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 the transport of the product. If this is not possible, wrap each component individually in sufficient paper or sheets of foamed material and place them in a cardboard box.

5.3. Warranty

This product is guaranteed against defects in workmanship and material. In the event of defects, the product will be replaced, or the charges refunded at the manufacturer's discretion.

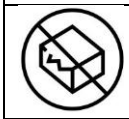
Repairs, attempted repairs, alterations or other tampering of this product carried out by unauthorized personnel renders the guarantee invalid. Delmont Imaging exclusively provides its customers with tested and impeccable products. All products are designed and manufactured to

meet the highest quality requirements. We accept no responsibility for products that have been modified from the original product or misused.

5.4. Disposal

Dispose of packaging and used parts in accordance with country-specific regulations. Keep the Resectoscopy systems out of reach of unauthorized persons.

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 «Do not use if package is damaged»
	Symbol for «Non-Sterile»
	Symbol for «Keep away from sunlight»
	Symbol for «Keep dry»
	Symbol for «Sterilized by ethylene oxide »
	Symbol for “Single Use”
	Symbol for “Do not resterilize”
	Symbol fur “Use-by date”

CE 1304

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