EN - Instructions for use

Endoscopic instrument

REF This manual relates to the following articles:

Product list
D300 120 000 to D300 120 015

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 intended exclusively for trained and qualified personnel (doctors, medical assistants supervised by a doctor). Endoscopic instrument should only be used by trained and qualified personnel to perform clinical applications in hospitals and medical rooms with appropriate endoscopic equipment. The products should not be used if, in the opinion of a qualified physician, the general condition of the patient is not adequate or if endoscopic methods are contraindicated.

Endoscopic instruments have been developed for use in the gynecology field in combination with a suitable endoscope and hysteroscopy system. There are different intended uses depending on the type of instruments :

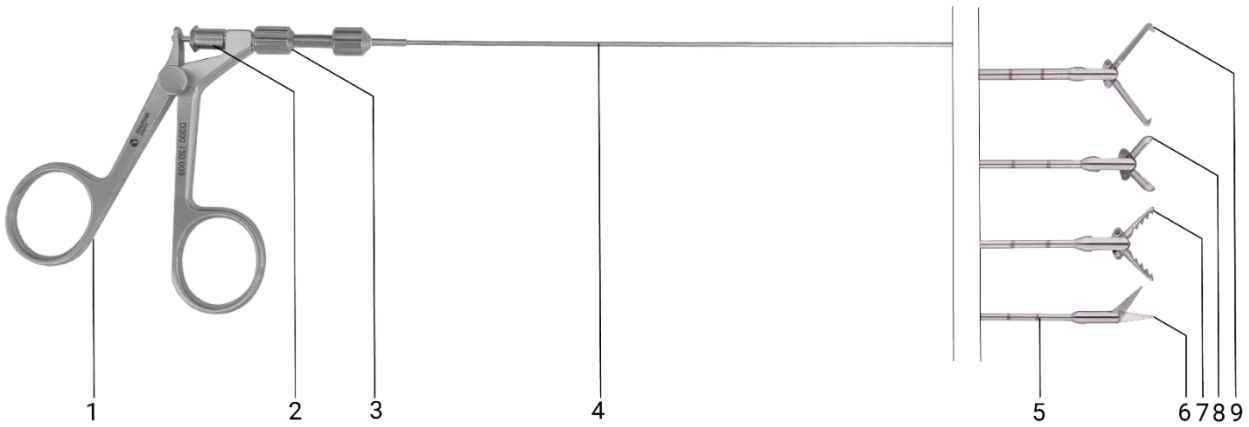
- Biopsy forceps are used for the endoscopic removal of tissue for histological examination,
- Foreign body forceps and foreign body grabbers are used for the removal of foreign bodies,
- Scissors are used to cut tissue or sutures,

For the benefit and safety of patients, doctors must choose a method that they deem appropriate based on their experience. If, as a user of this device, you feel you need more detailed information regarding the use and care of the product, please contact your representative.

W.I.

This document describes the correct handling, function as well as recommended reprocessing methods. This document may not be used to carry out endoscopic examinations or surgeries, nor may be used for training purposes. This product is designed to be used by qualified people only.

1.2. Specific details



1: Handle of the instruments
2: Flushing port
3: Rotation wheel
4: Flexible shaft
5: Graduated marking
6: Scissor tip
7: Alligator forceps tip
8: Biopsy forceps tip
9: IUD grasping forceps tip

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.

Endoscopic instruments should be used in combination with Endoscopes (D900 700 023) and Hysteroscopy System with a working channel (D900 700 026). All performance tests and safety have been conducted with Delmont imaging's products combination only. Delmont imaging does not recommend using third party's device with Delmont Imaging endoscopic instruments. The user is responsible in case of use of third-party equipment.

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


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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

When using forceps with spikes, do not touch the spike due to the risk of injury and infection.


W.V

Improper use can lead to hazardous situations

2.2. Contraindication

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


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- ***General inoperability state of the patient***
- ***Ambiguous diagnosis***
- ***Lack of willingness on the part of the patient***
- ***Combustible vapors and liquids present in the environment***
- ***Technical preconditions not met***
- ***Acute inflammation of the abdominal area***
- ***Infection of the vagina***
- ***Existing pregnancy***
- ***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.

2.3. 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. Visual inspection and functional test


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


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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 infection risk, tissue irritation, perforation, bleeding, mucosal tissue injuries or serious damage to the equipment. 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.

Before each use, observe the instruction in this chapter.

- Make sure that all devices have been properly reprocessed.
- Visually inspect all products thoroughly. The products must be visually clean.
- Check that the endoscopic instruments 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.
- Check that the jaws of the instruments can open and close easily and properly without the application of excessive force.

3.2. Introducing/Withdrawing the endoscopic instrument


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Take care when the instrument enters or exit the working channel. Do not push too hard and never advance the instrument suddenly. since injuries such as perforations, bleeding and injuries to the mucosal tissue can be inflicted on the patient or the endoscope can be damaged.


W.X

Do not insert the instrument against resistance. Reduce the angular deflection until the instrument can be inserted effortlessly. Failing to do so can cause injuries to the patient such as perforations, bleeding or mucosal tissue injuries. The endoscope and/or instrument can also be damaged.


W.XI

Slowly and carefully withdraw the instrument in a closed state out of the working channel to ensure that no infectious material is lost as Otherwise blood, mucus and other bodily fluids could escape and represent an infection risk for the patient and for the operator.

When introducing it into the working channel, hold the instrument in as much the same axis as the endoscope as possible. Otherwise damage can occur to the instrument and / or endoscope.

Forcible withdrawal can damage the instrument and/or endoscope.

For introducing the endoscopic instruments:

- Ensure that the instrument being used fits in the combined working channel,
- Actuate the handle to close the instrument before Introducing the instruments,
- Grip the instrument approximately 3 cm up from the working channel and advance it slowly and carefully with the jaws closed into the working channel valve,
- Reduce the angular deflection to insert the instrument effortlessly,
- Guide the instrument with the jaws closed and gently slide it until the instrument clearly appears in the viewing field.

For withdrawing the endoscopic instruments:

- Actuate the handle to close the instrument. Otherwise blood, mucus and other bodily fluids could escape and represent an infection risk,
- Slowly and carefully withdraw the instrument in a closed state out of the endoscope,
- Should you feel resistance, reduce the angular deflection of the endoscope until the instrument can be withdrawn effortlessly,
- Should the instrument no longer close fully, remove the endoscope and the hysteroscopy system with the instrument.

4. Reprocessing

W.XII

Delmont Imaging devices are supplied non-sterile. 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.XIII

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.XIV

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.XV

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

W.XVI

If necessary, repeat the reprocessing process until the device is visually 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,
- Dismantle the endoscopic instruments top part from the handle as follows:
  - Unscrew the locking screw,
  - Unhook the handle section from the forceps top part,
  - Unscrew the screw sleeve on the handle,
  - Pull the endoscopic instruments top part out of the handle,
- 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

Use only appropriate cleaning and disinfectant agents, certified for use on stainless steel 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 clean any instruments with metal brushes or wire wool. Do not expose any instrument to temperatures higher than 138 °C.

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.

When choosing cleaning and disinfection agents, please ensure that they do not contain the following:

- ***Organic, mineral or oxidizing acids (lowest permissible pH value 5.5)***
- ***Strong alkalis (highest permissible pH 11, neutral / enzymatic or slightly alkaline cleaners are recommended)***
- ***Organic solvents (e.g. ether, ketones, benzines), fluorinated alcohols***
- ***Oxidizing agents (e.g. hydrogen peroxide)***
- ***Halogens (chlorine, iodine, bromine)***
- ***Aromatic / halogenated hydrocarbons***
- ***Formamide***
- ***Trichloroethylene / perchloroethylene***

Efficient cleaning/disinfection is a prerequisite for effective product sterilization. Start cleaning immediately after each use.

For cleaning and disinfection purposes, an automated method should be used wherever possible. 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 water for at least 1 minutes.
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 t the device on a tray. If applicable, connect the LUER lock connection with the CCD flushing system. ➢ Put the device on the inserts of the cart. ➢ 1 min pre-cleaning with cold water ➢ Draining ➢ 3 min pre-cleaning with cold water ➢ 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) : at least 5 minutes at 90°C. ➢ We recommend final rinse with distilled, demineralized or fully desalinated water.
Drying	➢ Dry the outer surfaces in the drying cycle of the washer/disinfector. ➢ Let the device 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.

4.3. Sterilization

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 acc. to ISO 11607 and/or AAMI / ANSI ST77:2006 in order to be sterilized.

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

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Other sterilization methods not listed in this manual may be compatible with the device. When using methods other than those listed in this manual, the user is responsible for the sterility. Make sure that a sufficient number of Endoscopic Instruments are available.

- Sterilize the endoscopic instruments 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.
- 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 5 minutes	At least 20 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: -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. Limitation 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”. Nevertheless, the ability of Delmont Imaging devices to withstand multiple reprocessing cycles has been validated up to 50 times.

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

W.XXII ***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.XXIII ***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 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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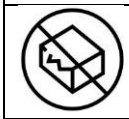
Keep the used device out of the reach of unauthorized persons.

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 «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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