EN - Instructions for use

Hysteroscopy System

REF This manual relates to the following articles:

Product list
D300 100 000 to D300 100 005 ; D300 100 050 to D300 100 051 ; D300 110 000 to D300 110 002 ; D300 110 020 to D300 110 023 ; D300 110 032 to D300 110 034 ; D300 110 045 to D300 110 048

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

TABLE OF CONTENTS

1. Device description 4
1.1. Intended Use 4
1.2. Specific details 4
1.3. Combination 5
2. Safety instructions 6
2.1. Warning and precautions 6
2.2. Contraindication 6
2.3. Vigilance 7
3. Use of the device 8
3.1. Visual inspection and functional test 8
3.2. Assembling/Disassembling the Hysteroscopy System 8
4. Reprocessing 10
4.1. Preparation 10
4.2. Cleaning and disinfection 11
4.3. Sterilization 12
4.4. Storage 13
4.5. Limitation of reprocessing 14
5. After-Sales service and maintenance 15
5.1. Maintenance 15
5.2. Repair 15
5.3. Warranty 15
5.4. Disposal 16
6. Used Symbols 17

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). Hysteroscopy system 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.

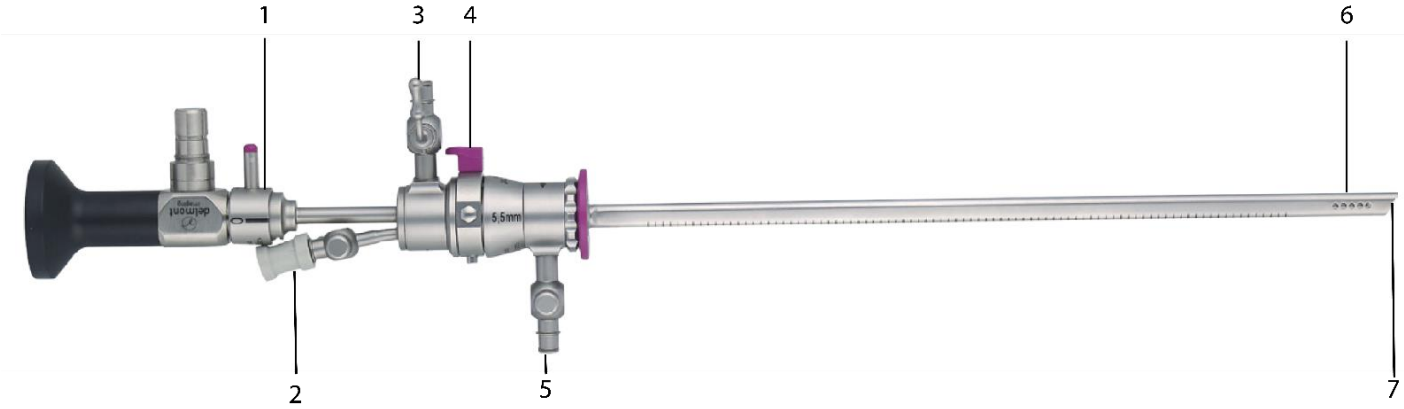
The Hysteroscopy systems are used in hysteroscopy for the purpose of visualization, investigation, diagnosis and treatment of gynecological cavity parts. Continuous irrigation sheaths allow visual examination of the cervical canal and uterine cavity and should be used with hysteroscope.

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 hysteroscopic system 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 Hysteroscopy 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: Inner Sheath
2: Working channel for semi rigid instrument
3: Irrigation channel Luer Lock

4: Outer sheath. Quick Lock system
5: Aspiration channel Luer Lock
6: Aspiration holes
7: Distal end

1.3. Combination

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.

A hysteroscopy system must be used with an endoscope (D900 700 023). All performance and safety tests have been conducted with Delmont's products combination only. Delmont imaging do not recommend using third party's device. The user is responsible in case of use of third-party equipment.

Endoscopes	Combination sheaths	Combination sheaths
D300 100 000	D300 110 002	/
	D300 110 032	D300 110 034
D300 100 001; D300 100 002	D300 110 020	/
	D300 110 045	D300 110 046
	D300 110 047	D300 110 048,
D300 100 003	D300 110 000	D300 110 001
	D300 110 023	/
D300 100 004	D300 110 032	D300 110 034
D300 100 005	D300 110 021	/

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.

2.2. Contraindication

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


W.IV

- ***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


W.V

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


W.VI

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.

Before each use, observe the instruction in this chapter.

- Make sure that all products have been properly reprocessed.
- Visually inspect all products thoroughly. The products must be visually clean.
- Check that the Hysteroscopy 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.

3.2. Assembling/Disassembling the Hysteroscopy System

If you want to assemble the hysteroscope with the sheath, please follow the steps:

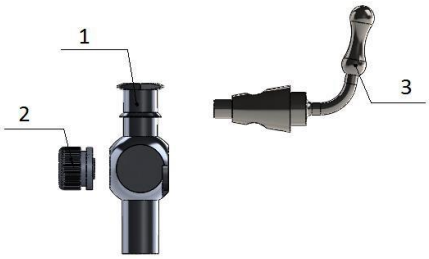
- Check the combination of the sheaths and the endoscope.
- Take a diagnostic sheath or combine the two operative sheaths using the arrow marks.
- Insert the endoscope slowly in the sheath and turn clockwise the lock.

If you want to dissemble the Hysteroscopy system, make sure that the endoscope used, and its potential accessories are switched off and disconnected the follow the following steps:

- Unlock anticlockwise the lock to free the endoscope.

- Disassemble the sheaths from the endoscope.
- Press the quick lock buttons loosen the sheaths.
- Disassemble the sheaths.

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



4. Reprocessing


W.VII

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.VIII

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.IX

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.X

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.XI

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.
- Disassemble the device and accessories
- Open stopcocks (if present).
- Remove sealing caps.
- 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.

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 Hysteroscopy 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 Hysteroscopy 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.
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 ➢ Draining

Step	Automated Cleaning Instructions
Automated cleaning	➢ 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 in the drying cycle of the washer/disinfector. ➢ Let the devices 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 device 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.
- ➢ Ensure that the device is faultless prior to each application.
- ➢ Plastic components should be checked before sterilization.
- ➢ Discard damaged device immediately.

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.

W.XIII

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

W.XIV

Plasma sterilization is not possible due to the plastic components.

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.

- 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.

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

Les dispositifs de Delmont Imaging sont fabriqués à partir de différents matériaux. Ils ont été choisis pour leur capacité à supporter de multiples cycles de nettoyage, de désinfection et de stérilisation et donc, de multiples applications à haute température. Un traitement répété a un effet minimal sur le dispositif. La durée de vie est généralement déterminée par l'usure et des paramètres de retraitement inappropriés. Vous pouvez vérifier le bon fonctionnement du dispositif en suivant les instructions de la section "Inspection visuelle et test fonctionnel".

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.XVI

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.XVII

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.

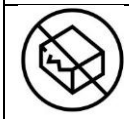
5.4. Disposal


W.XVIII

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 “Serial 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”

CE 1304

Delmont imaging - Zone Athélia V
390, Avenue du Mistral - 13600 La Ciotat - FRANCE
Tel. +33 (0) 9 51 51 30 30
Fax. +33 (0) 9 57 51 31 00
contact@delmont-imaging.com
www.delmont-imaging.com

delmont imaging