EN - Instructions for use

Uterine Manipulator

REF This manual relates to the following articles:

Product list
D300 120 100 to D300 120 115

Carefully read these instructions before using Delmont Imaging Microsurgery instruments. 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). The uterine manipulator 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.

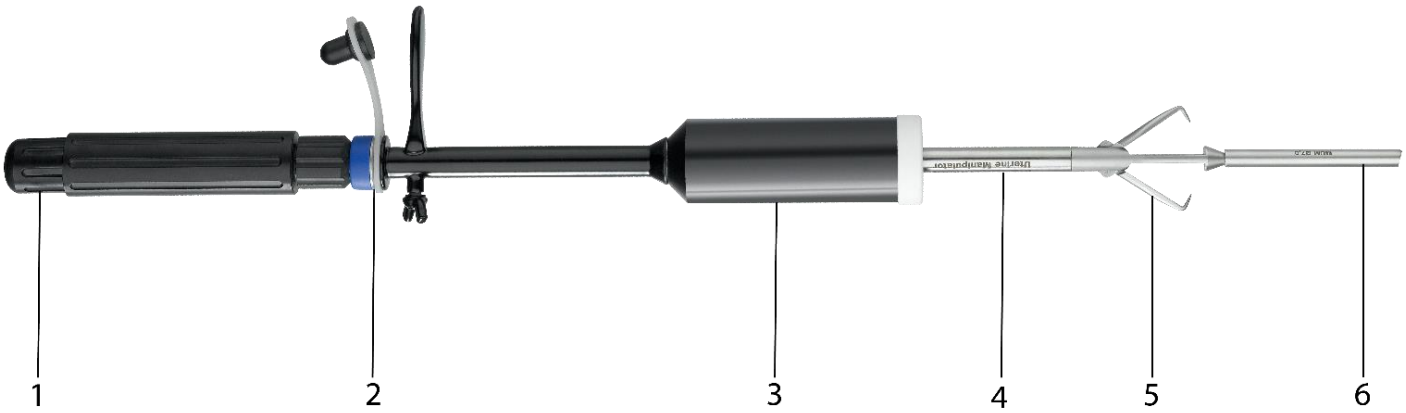
The Mangeshikar Uterus Manipulator by Delmont Imaging was developed for the mobilization and the manipulation of the uterus in case of a laparoscopic procedures such as complete hysterectomy, as well as for the protection of bladder, ureter, and rectum during the electrosurgical section of the uterus.

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 laparoscopic 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
2 : Sliding sheath

3 : Caps
4 : Outer sheaths
5 : Pozzi forceps
6 : Intrauterine element

The instrument consists of a rotationally symmetrical handle which enables guiding of the instrument and the opening and closing of the integrated cervix claw forceps (pozzi). For representation and preparation purposes, the uterus may be moved to any position desired with your hands. A sleeve with ceramic ring is slipped over the instrument shank in forward direction and thus allows the delineation of the vagina (vaginal delineating tube) and the protection of bladder, ureter and rectum. Depending on the uterus size, elements with different diameters are used.

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.

Use the device only with other certified devices specified for the same applications. There are different size of the cup and insert depending on the physical size of the uterus

REF	Ø cup (mm)	Photo
D300 120 104	Ø 35	
D300 120 105	Ø 40	
D300 120 106	Ø 45	

REF	Insert size (mm)	Photo
D300 120 108	4x40	
D300 120 109	5x50	
D300 120 110	6x60	
D300 120 111	7x70	
D300 120 112	8x80	
D300 120 113	8x120	
D300 120 114	8x150	

2. Safety instructions

Observe the manufacturer's operating and safety instructions. Failure to follow these operating and safety instructions may result in injury, malfunction or other unexpected incidents.

2.1. Warnings and precautions


W.III

Ensure that the products are used only by trained and qualified personnel. Make sure that the surgeon is familiar, both theoretically and practically, with the appropriate surgical techniques. The surgeon is responsible for the proper execution of the operation.

Always handle the uterine manipulator with care.

2.2. Contraindication

Do not use the device if one or more of the following conditions are 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 responsible physician must decide, on the basis of the patient's general condition, whether the planned application can be carried out. Do not use the device if, in the opinion of the attending physician, the risks to the patient outweigh the benefits.

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 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.V

New medical products must undergo a thorough visual and functional inspection after delivery and before each use.

W.VI

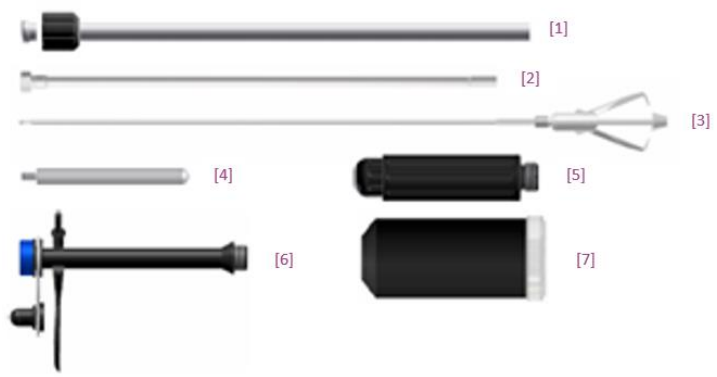
Do not use a damaged product or a product that does not function properly. Use of a damaged product or a product that does not function properly may result in electrical shock, mechanical injury, infection and/or thermal injury. Discard any damaged or malfunctioning product and replace it with a new one.

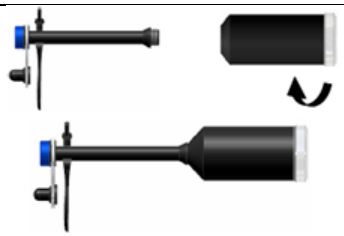
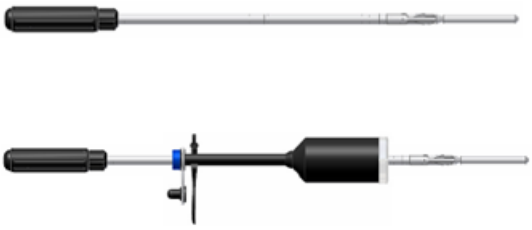
Always carry a spare unit.

Follow the instructions in this chapter before each use.

- Make sure that all products have been properly reprocessed.
- Visually inspect all products thoroughly. Products must be visually clean.
- Check that the operator has :
  - ✓ No damages, bumps, cracks, bends or deformations,
  - ✓ No scratches or corrosion,
  - ✓ No missing or loose parts,
  - ✓ Check that all markings are clearly visible.

3.2. Assembling / Disassembling

Assembling of the uterine manipulator	
	➢ Make sure you own all these parts

Assembling of the uterine manipulator	
	➢ Insert [2] in part [1]
	➢ Screw in [3] and part [4]
	➢ Insert and screw in [5] and your previous part
	➢ Screw in [4] and the previous part
	➢ Screw in part [7] and [6]
	➢ Insert the two last parts

➢ To disassemble, follow the previous instructions in reverse order.

3.3. Use of the device

When assembled correctly, the instrument can be held in both the right and left hand.

➢ Opening of the Pozzi forceps: Press the back part of the handle to extend it and turn it clockwise.

- Closing of the Pozzi forceps: Turn anticlockwise and press the back part of the handle once again to retract it.

4. Reprocessing

The devices are supplied non-sterile. They must be cleaned, disinfected, and sterilized before and after each use. Do not use a device that has not been reprocessed. Incomplete reprocessing may cause infection of the patient and/or medical staff and damage to the device.

W.VII

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.VIII

If the chemicals and machinery 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.IX

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

W.X

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

W.XI

It should be noted that only validated procedures sufficiently specific to the devices for cleaning, disinfection and sterilisation are used and that the validated parameters are met during each cycle. Also observe the legal requirements applicable in your country and 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 device as much as possible,
- 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 and plastic in accordance with the manufacturer's instructions. Do not use fixative cleaners or hot water (>40°C), as this will bind residues and may affect cleaning success. Do not use abrasive cleaners, wire brushes or ultrasonic baths. Do not apply strong manual pressure.

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.

Step	Automated cleaning instructions
Ultrasound pre-cleaning	➢ Immerse the device in cold water for at least 5 minutes. Brush the device under cold water until all visible residue has been removed. Internal channels, wires and holes must be rinsed with a water jet gun for at least 10 seconds in pulse mode. ➢ The instrument must be inserted in a bath with 0.5% alkaline cleaning detergent for 15min. ✓ Use solution: Neodisher Mediclean forte, Dr. Weigert, Hamburg. ➢ Remove the device and rinse completely with cold water.
Automated Cleaning	➢ Follow the operating and loading instructions of the washing machine and disinfector manufacturer and the recommendations for cleaning agents. ✓ Machine used: Miele G 7736 CD, Miele E 327-06 Insert Module, Miele E 450 CMI Module ➢ Pre-rinse with cold water for 1 min. ➢ Draining ➢ Pre-rinse for 3 minutes with cold water. ➢ Draining ➢ Wash for 5 min. at 55°C with a 0.5% alkaline solution or at 45°C with an enzymatic cleaning agent. ✓ Solution used: Neodisher FA; Dr. Weigert (alkaline) or Endozime, Ruhof (enzymatic). ➢ Draining ➢ Neutralize for 3 minutes with hot water (>40°C) and a neutralizing agent. ✓ Solution used: Neodisher Z; Dr. Weigert ➢ Draining ➢ Rinse with lukewarm water (>40°C) for 2 minutes.

Step	Automated cleaning instructions
	➢ Draining
Disinfection	➢ Machine operated thermal disinfection has to be carried out in consideration of the national requirements with regard to the A0 value (see ISO 15883) ➢ We recommend a final rinse with distilled, demineralized or fully desalinated water.
Drying	➢ Dry the outside of the instruments by carrying out a drying cycle of the cleaning/disinfection machine. ➢ If necessary, manual drying may additionally be carried out using a lintfree cloth. Dry cavities by blowing with sterile compressed air.

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

- ➢ If residue, liquids, impurities are visible, repeat cleaning process.
- ➢ Plastic components should be checked before sterilization.
- ➢ Discard damaged devices immediately.

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 sterilisation. 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.

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

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 devices according to a generally accepted hospital method.
- ➢ Follow the manufacturer's instructions for the products used.

- Ensure that the sterilization products are packaged in accordance with ISO 11607, EN 868 and/or AAMI/ANSI ST77:2006 (e.g. STERICLIN).
- Perform sterilization in accordance with EN 13060/DIN EN ISO 17665-1.
- Observe the country-specific requirements.
- For steam sterilization using the fractional vacuum method and sufficient drying of the product:

Fractionated vacuum	Temperature	Time	Drying
3 phases with a pressure of at least 60 millibars	134°C	At least 4 minutes	At least 10 minutes

4.4. Storage


W.XVI

Sterilized devices must be stored in a dry, clean and dust-free environment. Applicable national directives must be observed.

Non-sterile devices must be stored in a clean and dry environment. The storage life of non-sterile devices is not limited; the devices are made of a non-degradable material that retains its stability when stored under recommended conditions :

- ✓ Temperature: -5°C to +40°C.
- ✓ Humidity: 10% to 90%, non-condensing.
- ✓ Avoid direct exposure to sunlight.
- ✓ Store the device either in its original packaging or individually in a closed display tray/container.
- ✓ Ensure that the device is stored safely.

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. Repair and services


W.XVII

There is a risk of injury to the patient and/or user due to unauthorized repairs and/or modifications to the products. Possible injuries include mechanical injury, electrical shock, burns, and poisoning.


W.XVIII

There is a risk of infection when returning a used medical device. The return of used medical devices is only permitted when they are cleaned and sterilized/disinfected and with written verification of these. If reprocessing could completely damage the product, clean it as thoroughly as possible and mark it accordingly.

The Delmont Imaging Service Centre 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.

5.2. 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.

5.3. Disposal

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 damaged”
	Symbol for “Non-Sterile”
	Symbol for “Keep away from sunlight”
	Symbol for “Keep dry”
	Symbol for "Fragile, handle with care”

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