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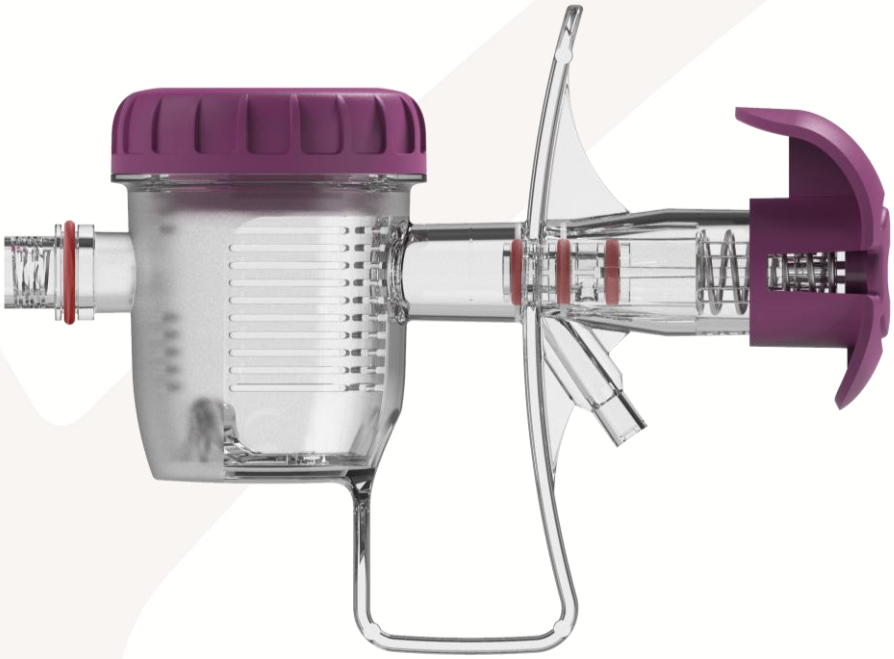
imaging



# EN - Instructions for use
# Resection chips extractor

D900 700 235 A EN

2025-09

***This manual is addressed exclusively to trained and qualified personnel. Carefully read these instructions before using Delmont imaging devices. Keep them in a safe place for future reference.***

***Delmont imaging***
***390 Avenue du Mistral – 13600 La Ciotat – France***
***Phone : +33 (0) 5 51 51 30 30 – Fax : +33 (0) 9 57 51 311 00***
***contact@delmont-imaging.com – www.delmont-imaging.com***

***This manual relates to the generic medical device group Resection chips extractor manufactured by Delmont imaging with basic UDI-DI 37012178CLVIHR. See declaration of conformity for the complete list of devices concerned.***

| Symbols used in this manual | |
|---|---|
| ⚠ | Safety information to prevent injury. |
| ⓘ | Special information requiring the user's attention. |
| ☑ | Prior information that the user must check. |
| → | Instruction information that the user must follow. |

***This instruction for use can be supplied in hard copy on request from our customer within 6 days by contacting ifu@delmont-imaging.com or calling +33 9 51 51 30 30.***

***You can access instructional videos to help you use of our medical devices on: https://www.youtube.com/@delmontimaging***

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# 1. General device information

## 1.1. Intended use


***This device and this manual are intended exclusively for trained and qualified personnel. This document describes the correct handling and function of the resection chips extractor. This document may not be used to carry out endoscopic examinations or surgeries, nor may be used for training purposes.***

***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.***

The resection chips extractor is a non-invasive, non-active, medical device intended to remove chips, clots, and debris generated during resection procedures.

## 1.2. Indication for use

The device is indicated for use by healthcare professionals in operative endoscopic resection procedures for gynaecology medical field, in a healthcare centre equipped with an appropriate endoscopic configuration.

## 1.3. Target population

| Population group | Target population |
|---|---|
| Sex | Female |
| Age | The device should not be used on paediatric populations |
| Weight | No restrictions |
| Health condition | Appropriate for treatment as assessed by the practitioner |

## 1.4. Device description

The device is supplied with the following items:

| REF | Description |
|---|---|
| D110 200 000 | Resection chips extractor. Sterile. Single use. |

The device is a non-invasive, non-active, hand-held device used during a standard resection procedure.

Once the user has generated debris in the uterine cavity with the resectoscope (not included with the device), the user set ups the present device in place of the working element of the resectoscopy system (see 3.2 for more details).

Once the setup is completed, the user, by pressing the piston button of the device, opens the suction flow generated by the vacuum in the container (not included with the device). The distension liquid goes from the uterine cavity through the device down to the container. The filtering basket in the device captures the debris.

The user can recover the debris from the filtering basket once the operation is completed. The device is disposed of after use.


*Figure 1 – Resection chips extractor description*

| Legend | Function |
|---|---|
| [1] Cap | Closes the device to make it airtight |
| [2] Screw type interface | Connects to the inner sheath (see 1.5) |
| [3] Filtering basket | Collects the chips and debris |
| [4] Piston button | Opens the suction flow |
| [5] Female luer lock | Connects to the suction tubing plugged ~~in~~to the container |
| [6] Handle | Allows the user to hold the device |

## 1.5. Combination and accessories

W.II

***Use only recommended accessories with Delmont imaging devices. Using incompatible equipment may lead to:***

- ***injury of the patient and/or the user,***
- ***damage to the device,***
- ***delay in procedure.***

***Contact your Delmont imaging representative if any doubt subsists regarding compatible equipment and for more details on accessories and details.***

The device shall be used with the following devices, whose characteristics are detailed below (not included with the device):

- One of the inner sheath depending on the size of the Delmont imaging resectoscope used for the resection:

| REF | Description |
|---|---|
| D300 130 107 | Chips extractor inner sheath. Compatible with 26Fr. resectoscope. |
| D300 130 108 | Chips extractor inner sheath. Compatible with 18,5Fr. resectoscope. |

- A suction tube set with a male luer lock compliant with ISO 80369-7, connected to a medical collection container compliant with EN ISO 10079-3,
- An irrigation pump and a suction pump to:
    - Inflate the uterine cavity and monitor the irrigation liquid pressure,
    - Create the vacuum inside the container between -30 kPa (-225mmHg) and -50 kPa (-375mHg),
- A distension liquid with electrolyte-free media such as glycine 1.5 % and sorbitol 3.0 %) or with isotonic, electrolyte containing media such as saline 0.9 % and Lactated Ringer's).

# 2. Safety instructions


***Observe the safety instructions of the manufacturer. Non-observance of these safety instructions may lead to injuries, malfunctions, or other unexpected incidents.***

***As the device is indicated for use during resectoscopy procedures, contraindications, side effects and residual risks listed here are related to the intended procedure and not directly to the present device.***

## 2.1. Contraindications


***Do not use the device if, in the opinion of a qualified physician, the general condition of the patient is not adequate, such as:***

- ***General inoperability state or lack of willingness of the patient,***
- ***Minimally invasive surgery is contraindicated,***
- ***Inability to distend the uterus,***
- ***Known pregnancy,***
- ***Recent uterine perforation.***

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

## 2.2. Side effects and residual risks


***Serum sodium concentration: It is necessary to monitor the concentration of sodium in the blood of the patient to prevent electrolyte disturbances and hyponatremia. Monitoring of the concentration of sodium in the blood must be performed by the physician.***


***Hypothermia (monitoring body temperature): Continuous flow of distention fluids can lead to a lowering of the patient's body temperature. Lower body temperatures can cause coronary and cardiovascular problems. Monitor the patient's body temperature during the entire surgery procedure must be performed by the physician. Make especially sure that the following hypothermia promoting operation conditions are avoided as best as possible:***

- ***Longer operating times,***
- ***Use of cold irrigation fluid.***

## 2.3. Warnings and precautions of use


W.VII

***Make sure that the devices 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.VIII

***Never use the system if it has suspected or confirmed defects.***


W.IX

***Always work exclusively with sterile fluids, and sterile accessories.***


W.X

***In case the device or any of the accessories fail during surgery, a replacement device and replacement accessories should be kept within proximity to be able to finish the operation with the replacement components.***

***Additional information for safety is placed in this supplied information where appropriate.***

## 2.4. Vigilance

***Definition of serious incident may depend on your local regulation. If any doubt exists, we encourage our users to proactively report any incidents. Contact your Delmont imaging representative for more information about reportability.***

***Medical information must be anonymized prior to be sent to us. Contact our data protection officer at dpo@delmont-imaging.com for more information related to confidentiality.***

→ Notify without delay any serious incident or risk of serious incident occurring during the use of this device to:
- vigilance@delmont-imaging.com,
- Your Delmont imaging representative,
- Your competent authorities in accordance with your local regulation.

→ We encourage the users to gather and transfer all appropriate information regarding the incident which includes but is not limited to:
- Patient condition prior the incident and after the incident,
- Indications of the procedure,
- Date of incident,
- Reference number and serial/lot number of the device,
- Any pertinent information related to the incident,
- A preferred contact that Delmont imaging can reach in the best delay.

→ Send back the device following recommendation from 4.1, if required by your Delmont imaging representative.

# 3. Use of the device

## 3.1. Initial set up of the device

### 3.1.1. Unpacking the device

| | |
|---|---|
| W.XI | ***Do not use the device if the integrity of the primary packaging is deteriorated as the device is delivered sterile.*** |
| W.XII | ***Do not use the device if it appears damaged, it could not work as intended and delay your procedure.*** |
| W.XIII | ***Make sure the device is unpacked in the operating room, before the procedure, to preserve the sterile state of the device.*** |
| | ***The device is delivered a double package*** |

☑ Check the sterile barriers has no integrity issue,
→ Discard the device immediately if it does.
→ Unpack the sterile device from the packaging following your internal guidance to avoid contamination.
☑ Check the material integrity of the device and check that there are no broken parts.

### 3.1.2. Assembling the device with inner sheath

To assemble the device, follow the instructions below:

| Step 1 | Step 2 |
|---|---|
|  |  |
| ☑ Check the cap [1] is tightly closed | → Screw the inner sheath clockwise to the screw-type interface [2] of the device.<br>☑ Check the inner sheath is safely attached. You should no longer see the red gasket. |

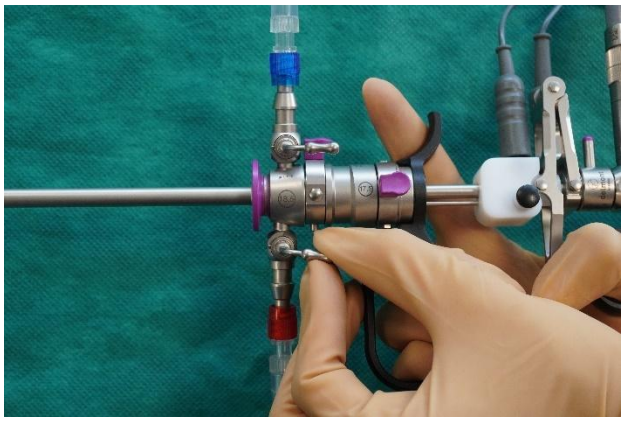
| Step 3 |
| --- |
|  |
| → Press the button piston 2 times. |
| ☑ Check that the piston button works as intended. |

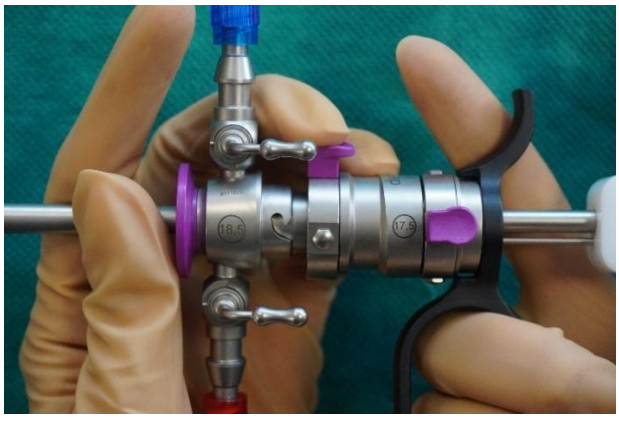
## 3.2. Assembling the device to the resectoscopy system

***The following instructions are to be performed whenever necessary during the endoscopic procedure using Delmont imaging's resectoscopy system.***

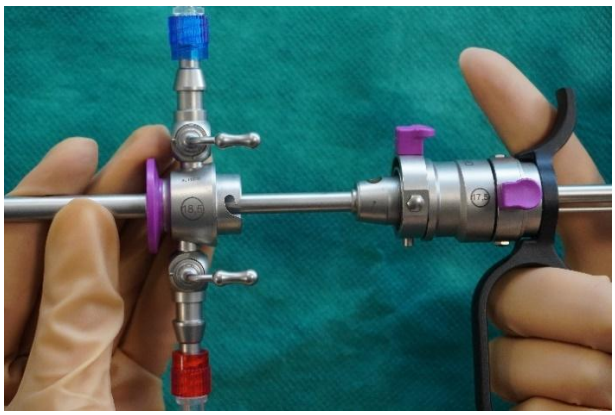
***The following instructions are to be performed while keeping the outer sheath of the resectoscopy system in place inside the uterine cavity.***

To operate the device when needed during a resectoscopy procedure:

| Step 1 |
| --- |
|  |
| → Close the irrigation and the suction stopcocks of the outer sheath of the Resectoscopy system. |
| ☑ Check the irrigation and suction flows are interrupted. |

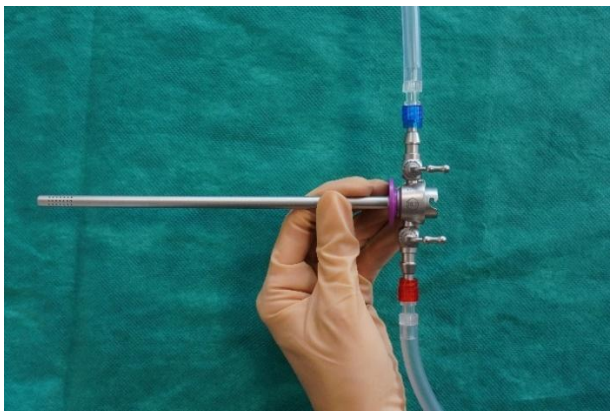
| Step 2 |
| --- |
|  |
| → Detach the resectoscopy system from the outer sheath by pressing on the purple Quick-Lock button. |

Step 3



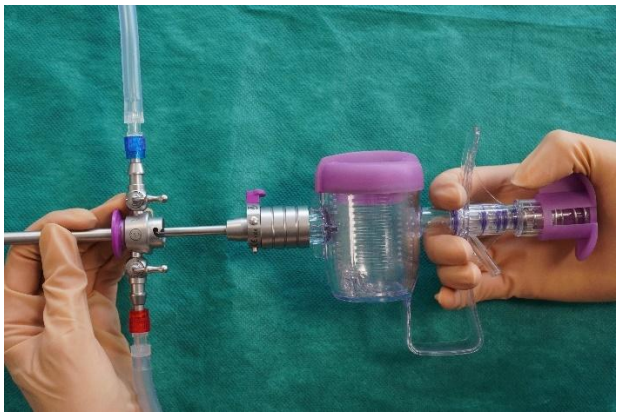
→ Pull out the inner resectoscopy system.

Step 4



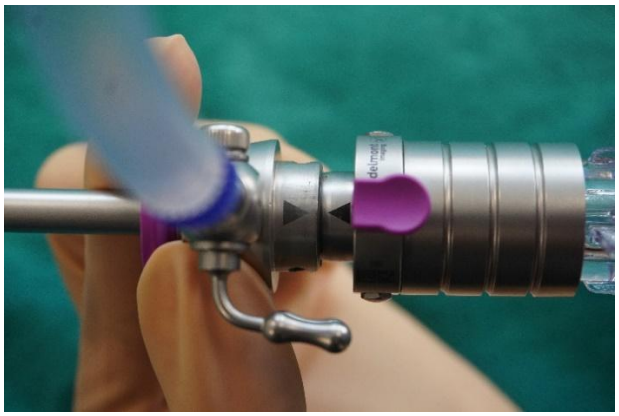
☑ Make sure the outer sheath stays in place inside the uterine cavity.

Step 5



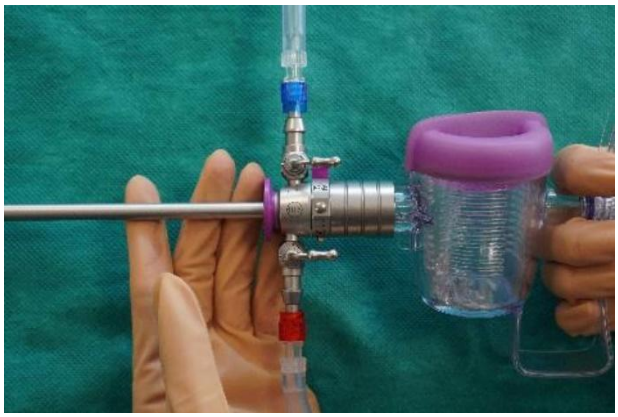
→ Insert device screwed with the inner sheath inside the outer sheath of the resectoscopy system.

Step 6



→ Lock the inner sheath with outer sheath by aligning the arrows and pressing the sheaths together.

Step 7



☑ Check the sheaths are safely connected.

Step 8

→ Transfer the suction tube from the outer sheath's luer lock to device's luer lock [5].

| Step 9 |
| --- |
|  |
| → Open the irrigation stopcock back up. |

## 3.3. Visual and functional inspection

W.XIV

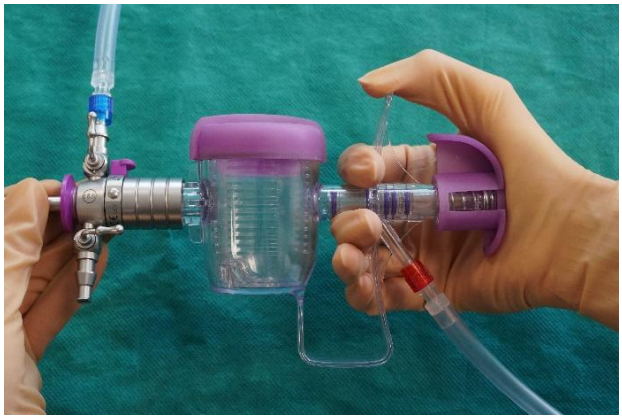
***Do not use a damaged device or a device with improper functioning. The use of a damaged device or of a device with improper functioning may cause mechanical injury, and/or infection. Replace a damaged device or a device with improper functioning.***

***Always have a spare device and tubing set ready to avoid postponing a surgery in case of a defective device.***

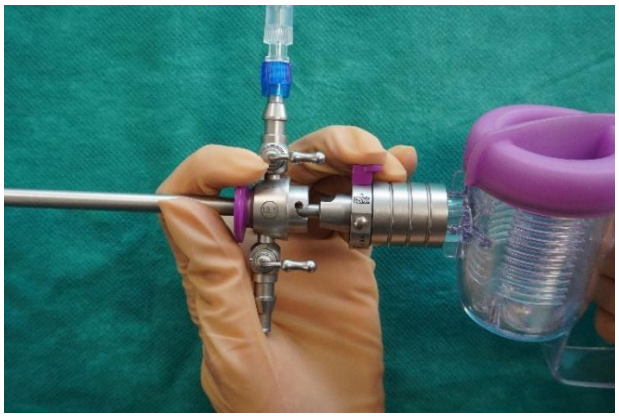
The user must perform this checklist after setting up the device prior to its use:

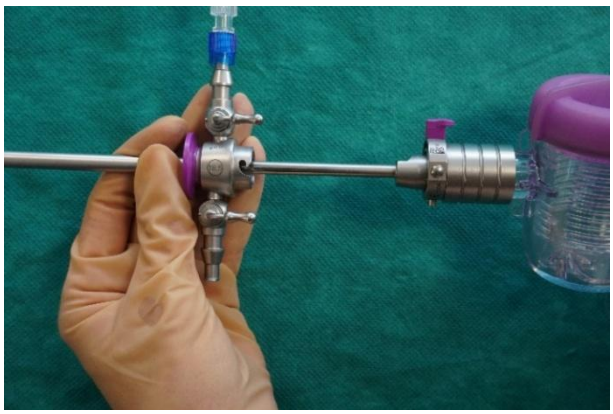
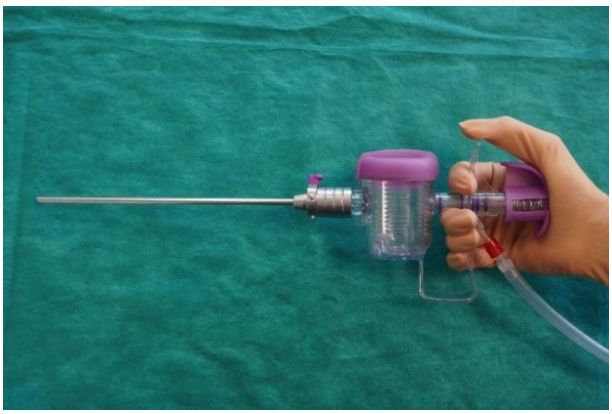
- ☑ Check that the inner sheath is safely attached to the device's outer sheath.
- ☑ Check that the suction tubing is safely attached to the device's luer lock.
- ☑ Check that the irrigation stopcock of the outer sheath is open.
- ☑ Check that the suction stopcock of the outer sheath is closed.
- ☑ Check the target pressure on the irrigation pump is set and reached.
- ☑ Check the suction pump is on and that a vacuum of at least 30 kPa (-225 mmHg) is achieved.

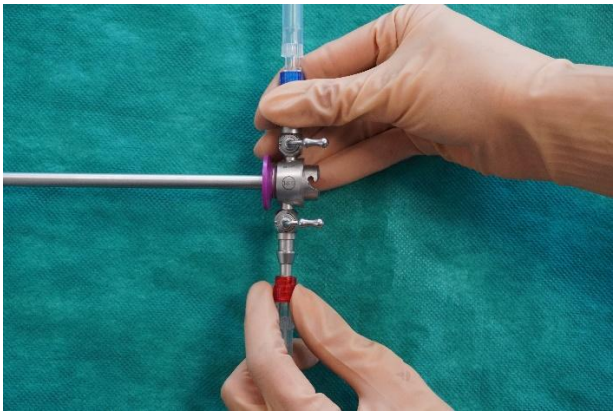
## 3.4. Operating the device

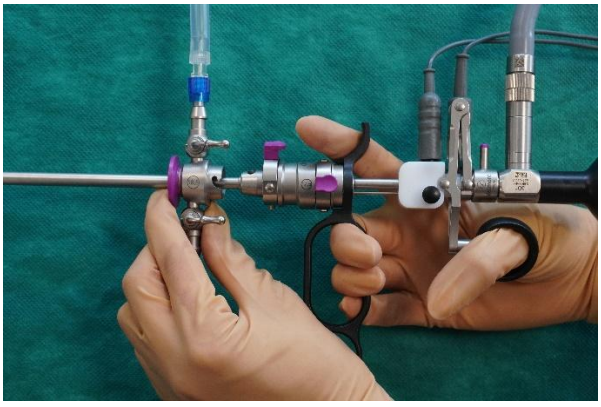
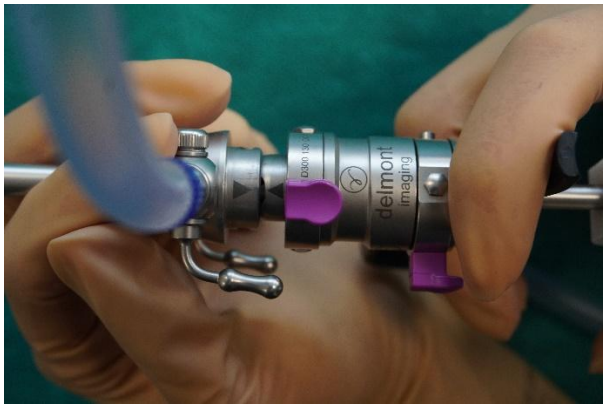
| Step 1 | Step 2 |
|---|---|
|  |  |
| → Hold the device by the handle [6].<br>→ Wait at least for a minimum of 5 seconds for the cavity to be filled with liquid, or wait until the target pressure of the irrigation pump is reached. | → Press the piston button [4] to open the suction flow.<br>→ Release the piston.<br>→ Repeat Step 1 and 2 if necessary. |

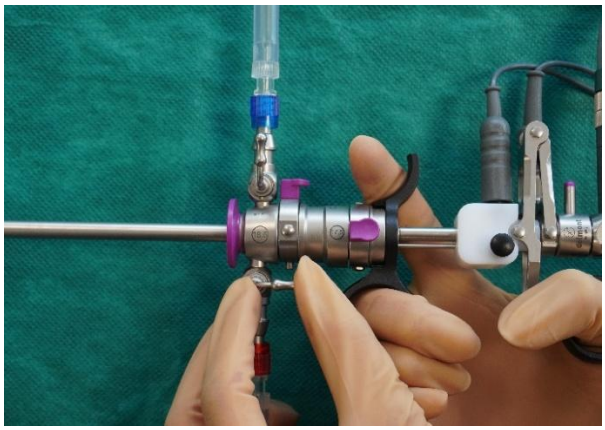
## 3.5. Disassembling the device from the resectoscopy system

| Step 3 | Step 4 |
|---|---|
|  |  |
| → Close the irrigation stopcock of the outer sheath. | → Disconnect the device from the outer sheath by pressing the quick lock button. |

| Step 5 | Step 6 |
| --- | --- |
|  |  |
| → Pull the device out of the outer sheath. | → Once the device is completely pulled out and the sheath is pointing upwards, press the piston button [4] to suck up any liquid left in the sheath and the device. |

| Step 7 | Step 8 |
| --- | --- |
|  |  |
| → Disconnect the suction tubing from the luer lock [5] of the device. | → Reconnect the suction tubing to the suction stopcock of the outer sheath. |

| Step 9 | Step 10 |
| --- | --- |
|  |  |
| → Reinsert the Resectoscopy system into the outer sheath. | → Lock the Resectoscopy system to the outer sheath by aligning the arrows and pressing |

| | |
|---|---|
| | the sheaths together. |
| Step 11 | Step 12 |
|  |  |
| → Open the suction and irrigation stopcocks back up.<br>→ Proceed with the procedure. | → Open the cap and remove the basket.<br>→ Collect the debris from the basket.<br>→ Discard the used device |

## 3.6. Trouble shooting

| Issue type | Solution |
|---|---|
| The inner sheath does not screw with the device | ☑ Check the screw thread of the device to make sure there is no shocks or marks.<br>☑ Check the screw thread of the inner sheath to make sure there is no shocks or marks.<br>☑ Check you screw them together clockwise.<br>→ If the issue persists, replace the device by a new one. |
| The suction flow does not start when the user presses the piston button. | ☑ Check the suction tubing is properly connected to the luer lock of the device.<br>☑ Check the other end of the suction tube is connected to the container.<br>☑ Check the void is on inside the container.<br>☑ Check that the cap of the filtering basket is tightly sealed. |
| The suction flow starts but no liquid comes in. | ☑ Check the irrigation stopcock is opened and connected to the irrigation tubing.<br>☑ Check the irrigation tubing is connected to the liquid bag and that the liquid bag is not empty.<br>☑ Check the target pressure indicated at the irrigation pump is reached.<br>→ If not, wait for 5 seconds, or until the pressure is reached and try again.<br>→ If the problem persists, remove the device with the inner sheath from |

| Issue type | Solution |
|---|---|
| | the outer sheath<br>☑ Check if there is a clog.<br>→ Replace the device if necessary. |
| The suction flow starts, the liquid comes in, but no debris or chips comes in. | ☑ Check the target pressure indicated on the irrigation pump is reached.<br>→ If not, wait for 5 seconds, or until the target pressure is reached and try again.<br>→ If the issue persists, try positioning the sheath in a different part of the cavity and/or make a slight movement from the back to the front of the cavity when you operate the device. |

→ Contact your Delmont imaging representative if the issue persists.

# 4. After-Sales service and maintenance

## 4.1. Return of the device


W.XV

***There is risk of infection when returning a used medical device. Returning used medical device is exclusively permitted when cleaned and disinfected, and with written verification thereof. Clean the device as thoroughly as possible before returning.***

***Contact your Delmont imaging representative to get the appropriate shipping instruction based on your location.***

If you need to return the device:

→ Clean the device as thoroughly as possible.

→ Use the original cardboard packaging for the transport of the device. If this is not possible, wrap the device in sufficient paper or sheets of foamed material and place it in a cardboard box.

## 4.2. Warranty

***Contact your Delmont imaging representative for more details on your warranty according to your country of use.***

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

The warranty for Delmont imaging devices shall become void if repairs, attempted repairs, alterations, or other tampering of this device is carried out by unauthorized personnel. Delmont imaging exclusively provides its customers with tested and impeccable devices. All devices are designed and manufactured to meet the highest quality requirements.

## 4.3. Disposal


W.XVI

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


W.XVII

***Disposing of the device: comply with the rules of hygiene when disposing of the device.***

***Contact your Delmont imaging representative for more details on disposal of the device according to your local rules and recycling opportunity.***

We encourage our customers to recycle the device whenever possible or to return the device to Delmont imaging who will then take the appropriate steps to recycle the device.

# 5. Technical data

## 5.1. General specifications of the device

| | |
|---|---|
| Weight of the device | 96 g |
| Dimension of the device | 157 x 115 x 56 mm |
| Final sterilization method | Ethylene oxide |

## 5.2. Conditions of use

### 5.2.1. Transport conditions

| | |
|---|---|
| Ambient temperature | -20°C to 50°C |
| Relative humidity | 10% to 90%, non-condensing |
| Atmospheric pressure | 20.0 kPa to 106.0 kPa |

### 5.2.2. Storage conditions

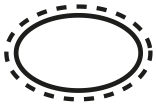
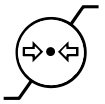
| | |
|---|---|
| Ambient temperature | 10°C to 35°C |
| Relative humidity | 10% to 85%, non-condensing |
| Atmospheric pressure | 70.0 kPa to 106.0 kPa |

### 5.2.3. Operating conditions

| | |
|---|---|
| Ambient temperature | 10°C to 30°C |
| Relative humidity | 30% to 75%, non-condensing |
| Atmospheric pressure | 70.0 kPa to 106.0 kPa |

# 6. Used symbols

| Symbol | Description |
|---|---|
|  | Symbol for “Caution”.<br>Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself. |
|  | Symbol for “Refer to operating instructions”.<br>Indicates to the user that it is necessary to consult the operating instructions. |
|  | Symbol for “Manufacturer”.<br>Indicates the manufacturer of the medical device. |
|  | Symbol for “Date of manufacture”.<br>Indicates the date the medical device was manufactured |
|  | Symbol for “Country of manufacture”.<br>Identifies the country in which the products were manufactured. |
|  | Symbol for “CE marking”.<br>Indicates that a device has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements. |
|  | Symbol for “Medical device”.<br>Indicates that the item is a medical device. |
|  | Symbol for “Lot code”.<br>Indicates the manufacturer's lot code so that the lot can be formally identified. |
|  | Symbol for “Catalogue number”.<br>Indicates the manufacturer's catalog number so that the medical device can be positively identified. |
|  | Symbol for “Unique Device Identifier”.<br>Denotes a medium that contains information about a unique device identifier. |
|  | Symbol for "Quantity".<br>Indicates the number of devices included in the package. |
|  | Symbol for “Not made with natural rubber latex”.<br>Indicates, that product is not made with natural rubber latex. |

| Symbol | Description |
|---|---|
|  | Symbol for “Sterilized with Ethylene Oxide”.<br>Denotes a medical device that has been sterilized with ethylene oxide. |
|  | Symbol for “Expiry Date”.<br>Indicates the date after which the medical device should no longer be used. |
|  | Symbol for “Do not reuse”.<br>Indicates a medical device intended for single use. |
|  | Symbol for “Single sterile barrier system with protective outer packaging”.<br>Denotes a single sterile barrier system with protective packaging on the outside. |
|  | Symbol for “Do not use if package is damaged”.<br>Indicates a medical device that should not be used if the packaging has been damaged or opened, and the user should consult the instructions for use for further information. |
|  | Symbol for “Temperature limit”.<br>Indicates the minimum and maximum temperatures to which the medical device may be safely exposed. |
|  | Symbol for “Atmospheric pressure limit”.<br>Indicates the range of atmospheric pressure to which the medical device may be safely exposed. |
|  | Symbol for “Humidity limit”.<br>Indicates the minimum and maximum humidity to which the medical device may be safely exposed. |
|  | Symbol for “Protect from heat and radioactive sources”.<br>Indicates a medical device that is sensitive to heat and radioactive sources. |
|  | Symbol for “Moisture Sensitive”.<br>Indicates a medical device that is moisture sensitive. |
|  | Symbol for “Fragile, handle with care”.<br>Indicates a medical device that may be broken or damaged if not handled with care |
|  | Symbol for “Transport conditions”.<br>Indicates the transport conditions that should be respected. |
|  | Symbol for “Storage conditions”.<br>Indicates the storage conditions that should be respected. |
|  | Symbol for “Handle with care”.<br>Indicates the package should be handled with precaution |
|  | Symbol for “This way up”.<br>To indicate correct upright position of the transport package. |

CE 1304

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