



EN Instructions for use
Forceps

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1. About this document

1.1. Purpose

This document describes the correct handling and function of hysteroscopy instruments, as well as recommended reprocessing methods. This document does not contain any description or explanation of endoscopy procedures.

1.2. Symbols used

This section explains each symbols used on the product packaging and in this instructions for use:

Symbols	Description
	Manufacturer
	Reference number
	Batch number
	Non sterile
	Follow the instructions for use
	Warning
	Keep dry
	Keep away from sunlight
	Don't use if the package is damaged

2. Intended use

Instruments are used during endoscopic explorations in gynecology exclusively, combined with suitable hysteroscopes and operative sheaths. Instruments allow diagnosis and treatment procedures of the cervical canal and the uterine cavity.

Gripping forceps and extraction forceps are used for the removal of tissue or foreign bodies. Scissors are used to cut tissue. Biopsy forceps are used for the endoscopic removal of tissue for histological examination.

Instruments must be used only in medical facilities by trained and skilled medical personnel.



Improper use can lead to hazardous situations.

3. Safety instructions

At the delivery of the instrument(s), inspect the delivery for completeness and damage.

Use the instruments only as intended. (See "Intended use" on page 4).



Carefully read, observe and keep these instructions of use.



Since infectious material from the patient represents an infection risk, appropriate protective clothing such as goggles, mouth masks, waterproof clothing and chemical-resistant gloves of an appropriate size and length to cover the skin must be used.



Carry out visual inspection and function check prior to each use. Only use products which are in a perfect condition and always have a replacement instrument available. Injuries such as perforations, bleeding or injuries to the mucosa, as well as damage to the product itself, may occur.

4. Testing, handling and maintenance

Instruments are medical devices and handling them requires great care. The jaws of the forceps must open and close easily and properly without the application of excessive force.

- Before and after use, inspect the products for possible damage: twisted, broken or loose parts, fissures or scratches. Damage or irregularities can compromise the safety of the patient or user, represent an infection risk, cause tissue irritation, perforation, bleeding, mucosal tissue injuries or serious damage to the equipment.
- If the product is damaged, discontinue use and contact Delmont Imaging.
- Do not expose the products to impact solicitation. Do not bend rigid tube shaft instruments.
- Do not use oils or greases for instruments.

5. Guideline conformity



The CE marking of the medical product complies with the guideline 93/42/EWG. It applies only when the products and/or packaging features this marking.

6. Available models



D300 120 000	D300 120 004
D300 120 001	D300 120 005
D300 120 002	D300 120 006
D300 120 003	D300 120 007

7. Preparation for use

7.1. Visual inspection and function check



Carry out visual inspection and function check at delivery and prior to each use. Only use products which are in a perfect condition.

- Clean, disinfect and sterilize the products prior to initial use as well as each subsequent use.
- Ensure that no parts are missing or loose.
- Ensure that there are no residual cleaning agents or disinfectants on the products.
- Before and after use, inspect the products for possible damage: twisted, broken or loose parts, fissures or scratches.

7.2. Provisioning



Products are delivered non-sterile as reusable products. Clean, disinfect and sterilize the products prior to initial use as well as each additional use of the products. See « Reprocessing » on page 8.

8. Use

8.1. Introducing the instrument into the endoscope

Pull on the slider to close the jaws. Guide the instrument with the jaws closed at the entrance of the working channel.



- When introducing it, hold the instrument in as much the same axis as the working channel as possible. Otherwise damage can occur to the products.
- Ensure that the instrument being used fits in the working channel. Hold the instrument properly when inserting it in the working channel and advance it slowly and carefully with the jaws closed until the instrument clearly appears in the viewing field of the hysteroscope. Take care when the instrument exits the working channel, since injuries such as perforations, bleeding and injuries

to the mucosal tissue can be inflicted on the patient or the products can be damaged.

- 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 products can also be damaged.
- Never advance the instrument suddenly. Doing so can cause injuries to the patient such as perforations, bleeding or mucosal tissue injuries. The products can also be damaged.
- When the instrument is inserted, do not move the lever on the stopcock because otherwise the instrument could be damaged or sheared off.

8.2. Removing the tissue sample or foreign body

Guide the instrument to the site from which the tissue sample or foreign body is to be removed. Open the jaws and grasp the tissue or object to be removed



Do not push too hard, since doing so can cause injuries to the patient such as perforations, bleeding or mucosal tissue injuries. The products can also be damaged.

8.3. Cutting tissue

Guide the instrument to the site at which the tissue is to be cut. Open and close the instrument to separate the tissue.



Do not push too hard, since doing so can cause injuries to the patient such as perforations, bleeding or mucosal tissue injuries. The products can also be damaged.

8.4. Rescuing tissue

Guide the instrument to the site from which the tissue is to be taken. Open the jaws, grasp a sample of tissue and carefully close the jaws of the biopsy forceps.



Do not push too hard, since doing so can cause injuries to the patient such as perforations, bleeding or mucosal tissue injuries. The products can also be damaged.

8.5. Withdrawing the instrument from the working channel



- Actuate the handle to close the jaws of the instrument. Slowly and carefully withdraw the instrument in a closed state out of the working channel. Otherwise blood, mucus and other bodily fluids could escape and represent an infection risk.
- Should you feel resistance, reduce the angular deflection of the working channel until the instrument can be withdrawn effortlessly. Forceful withdrawal can damage the products. Should the instrument no longer close fully, remove the instrument with the hysteroscope.
- Ensure that no infectious material is lost as this can represent an infection risk for the patient and operator.
- Prepare the products for reprocessing immediately after use to prevent surface drying of the contaminants.

9. Reprocessing

9.1. General principles

All instruments must be cleaned, disinfected and sterilized before every use. This is especially also true for the first use after delivery, since all instruments are shipped non-sterile. Effective cleaning and disinfection are an essential requirement for effective sterilization.

The reprocessing of endoscopic equipment must remain the special responsibility of one person or several people. These individuals must be thoroughly trained in reprocessing methods and be aware of and fully understand the following points:

- Your medical facilities reprocessing guidelines ;
- Health and safety guidelines as defined by employment law ;

- National and local medical facilities guidelines and principles ;
- The instructions in these instructions for use ;
- The mechanical aspects of the instrument ;
- Additional national specifications that must be complied with in relation to effective prion inactivation (e.g. mandatory use of a highly alkaline cleaning agent, prolonged sterilization times).

Please note as part of your responsibility for the sterilization of instruments in use:

- That essentially only methods for cleaning and disinfection and sterilization are used that are adequately validated for the specific equipment and product;
- That the cleaning, disinfection and sterilization equipment used is regularly maintained and checked ;
- That the validated parameters are maintained during each cycle.

Please note any other applicable legal requirements in your country as well as the hygiene regulations in force in your clinical practice or hospital. This is especially true for the various specifications governing effective prion inactivation.



- During use, the instrument comes into contact with potentially infectious tissue. To minimize the risk of infection, the instrument must be carefully and properly cleaned and disinfected after each use to remove micro-organisms and organic material. If an instrument is not adequately cleaned and disinfected, effective sterilization is not possible.
- During reprocessing, always wear suitable protective clothing such as goggles, mouth protection, waterproof protective clothing and chemical-resistant gloves, since you may be exposed to infectious material and potentially hazardous chemicals.
- The reprocessing of instruments must - within the deadlines set out below - be commenced immediately after use, since dried-on organic residue can hamper effective cleaning, disinfection and sterilization.

9.2. Cleaning and disinfection

For cleaning and disinfection purposes, a mechanical method (with a cleaning and disinfection device) should be used wherever possible. A manual method, even using an

ultrasound bath, should only be used if a mechanical method is not available due to the significantly inferior effectiveness and reproducibility.

Pre-treatment must be carried out in both cases.



The use of a manual cleaning and disinfection method must be safeguarded by additional product and method-specific validation which is the responsibility of the user.

Pre-treatment :

Coarse soiling must be removed from the instrument immediately after use (within a maximum of 2 hours).

The procedure is as follow:

- With the instrument immersed in cleaning solution, remove any soiling visible on the jaws using a clean soft brush (or a clean, soft and lint-free cloth) which is used solely for this purpose. Never use metal brushes or wire wool.
- Open and close the jaws, immersed in cleaning solution, at least 3 times.
- Dismantle the handle as explained in the section 10.
- Place the instrument with the jaws open, along with the handle, in an ultrasound bath filled with cleaning solution (the duration and concentration used in this step should be taken from the cleaning solution manufacturer's specifications).
- Rinse the instruments for at least 1 minute under running water (temperature should be less than 35 °C/95 °F).



If, for example for safety in the workplace reasons, you are using a cleaning and disinfectant agent for this, please be aware that it must be free of aldehydes (otherwise blood-based soiling may become fixed), must demonstrate tested effectiveness (e.g. VAH/DGHM or FDA/EPA approval / clearance / registration or bear the CE mark), be suitable for the disinfection of medical instruments and be compatible with the instrument (see section 9.7). Please note that disinfectant products used during pre-treatment are

used solely to protect personnel and do not replace the later disinfection stage that must be carried out after cleaning.

Mechanical cleaning and disinfection: (tested in thermal disinfection with the G 7836 CD machine, Miele & Cie. GmbH & Co., Gütersloh; and the cleaning agent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg)

When choosing a cleaning and disinfection machine, bear in mind:

- That the machine must essentially have a tested effectiveness (e.g. DGHM or FDA approval / clearance / registration or bear the CE mark in accordance with DIN EN ISO 15883);
- That, where possible, a thermal disinfection program should be used: with A0 value > 3000 or, on older equipment, at least 5 min. at 90 °C/194 °F (with chemical disinfection there is a risk of disinfectant residue on the instruments);
- That the program used is suitable for the instruments and includes adequate rinsing cycles;
- 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);
- That the air used for drying is filtered (oil free, low-germ and low-particle);
- That the machine is maintained and checked regularly.

When choosing the cleaning agent system to be used, bear in mind:

- That it must essentially be suitable for the cleaning of instruments made from metal;
- That, where no thermal disinfection method is used, a suitable disinfectant agent with tested effectiveness (e.g. VAH/DGHM or FDA/EPA approval / clearance / registration or bear the CE mark) is used and that this is compatible with cleaning materials being used.
- That the chemicals used are compatible with the instruments (see section 9.6).

- The concentrations, temperatures and exposure times specified by the cleaning and possibly disinfectant agent manufacturer, as well as rinsing specifications, must be complied with at all times.

The procedure is as follow:

- Place the dismantled instruments with the jaws open in the cleaning and disinfection machine. Ensure that the instruments are not touching.
- Place the handle parts in a small parts basket in the machine.
- Start the program.
- Remove the instruments from the machine when the program finishes.
- Check the instruments as soon as possible after removal, and, if necessary after additional drying.



In case of non-compliance with manufacturer's instructions, the products can be damaged.

Attach the handle, but with the screw sleeve on the handle loose. Place the cleaned and disinfected instruments coiled up in a single-use sterilisation pack (single or double packaging) and / or sterilisation containers. The specific instructions set out in Section 4.0 must be followed.

The packaging must meet the following requirements (material and process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- Suitable for steam sterilisation (temperature resistance up to at least 138°C (280 °F) with adequate steam permeability)
- Adequate protection of the instruments or sterilisation packaging against mechanical damage
- Regular maintenance in accordance with the manufacturer's specifications (sterilisation containers)
- Please also note the instructions for use on sterile packaging and the sealing device.

Please also note the instructions for use on sterile packaging and the sealing device.

Ensure that the sterile packaging is not damaged when the instrument is inserted into it. Do not bend rigid tube shaft instruments. Do not use excessive force and ensure that the shaft is not bent.

9.3. Sterilization



Prior to each sterilization, products must be cleaned and disinfected according to methods in these instructions for use

Only the sterilization methods listed below must be used for sterilization. Other sterilization methods are not permitted: hot air sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization or plasma sterilization, etc.

Steam sterilization: (tested with the steam steriliser HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum method Typical conditions found in hospitals and medical practices, as well as the method described above, were used.)

Attach the handle, but with the screw sleeve on the handle loose.

- Fractionated vacuum method: at least three vacuum steps. The product drying must be adequate: the actual drying time required depends directly on the parameters that are the sole responsibility of the user (loading configuration and density, sterilizer condition, etc.) and must therefore be determined by the user. Regardless of this, drying times must not be less than 20 minutes;
- Steam sterilizer compliant with DIN EN 13060 / DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance);
- Validated in accordance with DIN EN ISO 17665 (valid IQ/OQ picking and product-specific performance assessment);
- Maximum sterilization temperature 134 °C/273 °F (plus tolerance as defined in DIN EN ISO 17665);
- Sterilization time (exposure time at sterilization temperature) at least 20 min at 121°C/250 °F or at least 56 min. at 132 °C/270 °F - 134 °C/273 °F.



- Products must be sterilized in suitable packaging to avoid any subsequent contamination. The initial packaging in which non-sterile products have been delivered are not suitable for sterilization.
- After sterilization, check the sterile packaging for damage, adequate drying and to ensure that the seal is intact. If a defect is found, the packaging and sterilization steps must be repeated.

9.4. Control and testing

The products have to be visually examined for cleanliness after every cleaning and disinfection. They have to be macroscopically clean from visual residual and soil, corrosion, damaged surfaces, cracks, soiling and discoloration.

- If residue, liquids or impurities are visible, repeat cleaning process;
- Ensure that the instruments are in perfect working order before and after each cleaning and disinfection cycles by opening and closing the jaws several times;
- Remove any damaged instruments from use.

9.5. Reprocessing restrictions

The instruments can, with appropriate care and provided they are undamaged and unsoiled, be reused up to 100 times. Any further use beyond this or the use of damaged and / or soiled instruments is the responsibility of the user.

9.6. Material resistance

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

- Strong 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, benzenes);
- Fluorinated alcohols;
- Oxidizing agents (e.g. hydrogen peroxide);
- Halogens (chlorine, iodine, bromine);
- Aromatic / halogenated hydrocarbons;
- Formamide;
- Trichloroethylene / perchloroethylene.

Never clean any instruments with metal brushes or wire wool.

Do not expose any instrument to temperatures higher than 138 °C/280 °F.

10. Assembly and disassembly

To disassemble the handle of the instrument:

- Unscrew the locking screw;
- Unhook the second part from the handle;
- Unscrew the screw sleeve of the handle;
- Pull the first part of the handle out of the instrument.

To assemble the handle of the instrument:

- Insert the first part of the handle on the instrument;
- Screw the screw sleeve of the handle;
- Insert the second part of the handle;
- Screw the locking screw.

11. Storage

After sterilisation, the instruments must be stored in the sterilization packaging (sterilization basket or single use sterilization package) in a dry and dust-free environment. Keep the instrument at room temperature in a clean, dry place and protect it from direct sunlight.



Keep dry.



Keep away from sunlight.

Observe the respective valid national provisions when storing in a sterile condition.

12. Service and repairs

In spite of application in compliance with intended use, medical products are subject to variable wear and tear depending on the intensity of the application. Wear is technically inevitable.

- Do not repair. Service and repairs must be carried out by the manufacturer or by authorized personnel.
- Medical products have to be cleaned, disinfected and sterilized prior to sending for repair. Soiled or contaminated medical products should not be shipped.
- Ideally, send the products in the original packaging. If this is not possible, package the product to secure it for transport. Delmont Imaging is not liable for damage resulting from improper shipping.

13. Warranty

This product is guaranteed two years against defects in workmanship and material. In the event of defects under guarantee, the product will be repaired or replaced.

Repairs, attempted repairs, alterations or other tampering of this product carried out by unauthorized personnel renders the guarantee invalid.

14. Disposal

Observe country-specific regulations and laws for the disposal of medical products.



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