EN - Instructions for use

Endoscopes

REF This manual relates to the following articles:

Product list
D300 100 000 to D300 100 100

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 addressed exclusively to trained and qualified personnel (medical doctors, medical assistants supervised by a doctor). Endoscopes are to be used exclusively 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 endoscopes are used in endoscopy for the purpose of visualization, investigation, diagnosis and treatment of endoscopic surgery. Each endoscope was developed for diagnostic and surgical procedures in one of the following fields of application:

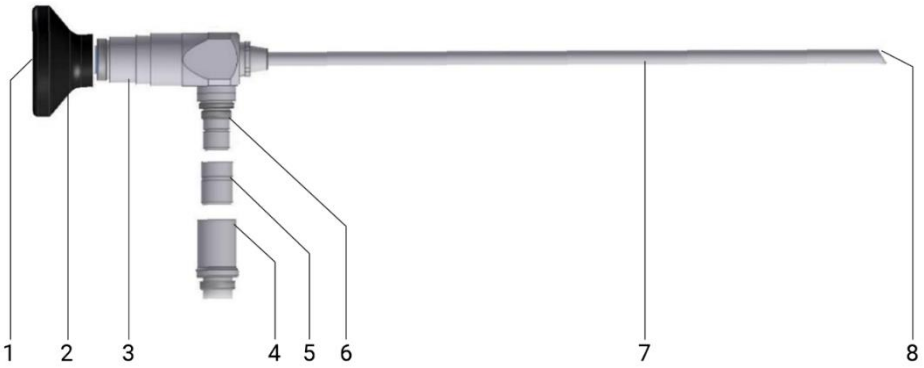
- Arthroscope: arthroscopic procedures,
- Sinuscope: sinuscopic procedures,
- Otoscope: otoscopic procedures,
- Laryngoscope: laryngoscopic procedures,
- Laparoscope: laparoscopic procedures,
- Hysteroscope and operative hysteroscope: hysteroscopic procedures,
- Cystoscope: cystoscopic procedures.

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 endoscope believes that you require more detailed information regarding the product's use and maintenance, please contact your representative.

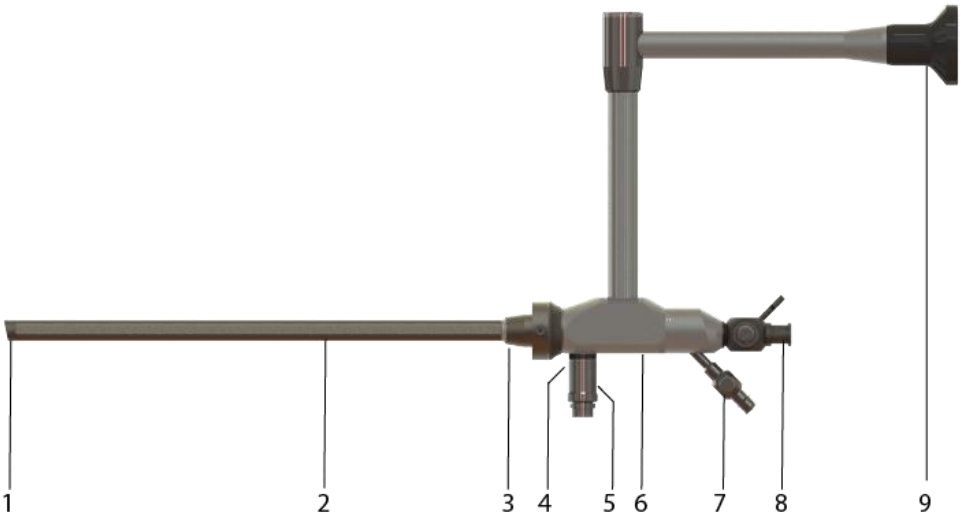
This document describes the correct handling and function of endoscopes, as well as recommended processing methods. This document may not be used to carry out endoscopic examinations or surgeries, nor may be used for training purposes. This product is designed to be used by qualified people only.

1.2. Specific details

1: Proximal end
2: Eyepiece
3: Main part
4: Connection for illumination fibre, type Delmont, Storz, Olympus
5: Connection for illumination fibre, type Wolf
6: Irradiation surface of the illumination fibre, connection type ACMI.
7: Sheath
8: Distal end



1: Objective with sapphire distal window
2: Tube
3: Quick-lock system
4: Irradiation surface of the illumination fibres
5: Connection for illumination fibre, type Delmont, Storz, ACMI, Olympus, pre-assembled
6: Body
7: Irrigation channel stopcock
8: Working channel stopcock
9: Eyepiece



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.

The Delmont Imaging endoscopes should be used with sheaths supplied by Delmont Imaging only and with Delmont, Storz, Stryker, ACMI or Olympus light cables. Contact your authorized representative for more information.

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.


W.IV

There is a risk of an electric shock when using endoscopic equipment in combination with energized endotherapy devices such as thermal injury, burns or arc-over between the endoscopic equipment and the HF electrode.

- ***Always keep a distance of at least 10mm between the endoscope and HF electrodes.***
- ***Always connect the endoscopic equipment before inserting the endoscope into the patient.***

The endoscope is a precise optical device. Careless handling may damage the endoscope:

- ***Do not hold the endoscope by the distal end only.***
- ***Do not bend the outer tube.***
- ***Always store and transport the endoscope in the supplied protective tube.***
- ***Remove the endoscope from the protective tube only before direct use, manual cleaning, automated cleaning and disinfection.***
- ***Carefully insert the endoscope through a trocar to prevent damage to the working end.***

2.2. Instructions specific to the light source


W.V

There is a risk of damaging the eye when looking into the distal end of the endoscope and the light source is switched on. Do not look into the distal end of the endoscope when the light source is switched on.


W.VI

If the light cable is not properly connected to the endoscope or to the light source, the endoscopic image may disappear during the procedure. This may lead to mechanical injury of the patient:

- ***Properly connect the adapters to the light cable and to the endoscope.***
- ***Properly connect the light cable to the light source and to the endoscope***

Light sources emit large amount of energy. As a result, the connector of the endoscopic equipment and the distal end of the endoscope can become hot. To avoid risks such as thermal injury, burns to the patient's or user's skin or thermal damage to surgical equipment:

- ***Do not place the endoscopic equipment on the patient skin, on inflammable material, or on heat sensitive material.***
- ***Set the output power of the light source to the minimum level that is necessary to have sufficient illumination of the operating field.***
- ***Avoid prolonged exposure to intense illumination.***
- ***Switch off the light source or set it to standby mode whenever the light source is not use.***
- ***Do not use high intensity illumination when the distal tip of the endoscope is placed into close proximity to the tissue.***
- ***Ensure that the surface temperature of the main body does not exceed 41°C.***
- ***During longer applications, allow main body to cool down if necessary.***

2.3. Contraindication

- ***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***
- ***Cardiac pacemakers: to prevent danger to life due to a defective Cardiac pacemaker: consult a cardiologist before the operation.***
- ***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.

2.4. Vigilance

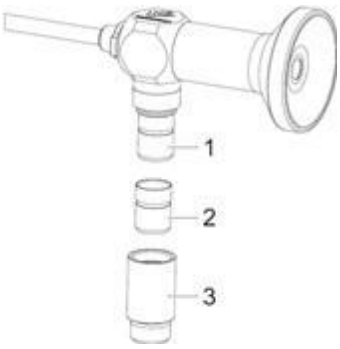
Any serious incident occurring during the use of this device must be notified to the manufacturer Delmont Imaging (vigilance@delmont-imaging.com), or its representative and to the competent authorities in accordance with the national laws in force.

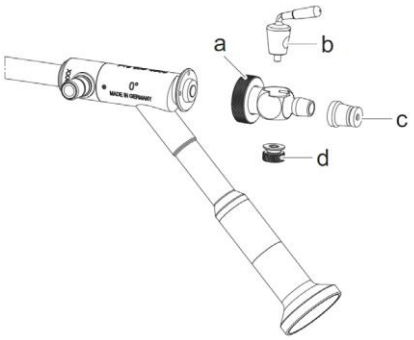
3. Use of the device

3.1. Assembling/Disassembling

Assemble the set as follows:

- If applicable, insert the endoscope sheaths.
- If applicable, connect the light guide adapters.
- If applicable, connect the camera head.
- Connect the light cable from the light source to the endoscope.
- Switch On the light source.





1. Connection for illumination fibre, type ACMI.
2. Adapter type Wolf.
3. Adapter type Delmont, Storz, Olympus.

a. Union nut.
b. Stopcock
c. Sealing cap,
d. Stopcock nut

Disassemble the set as follows:

- Switch off the light source.
- Disconnect the light cable from the light source.
- Disconnect the light cable from the endoscope.
- If applicable, remove the camera head.
- If applicable, remove the light guide adapters.
- If applicable, remove the sheaths.

3.2. Visual inspection and functional test


W.IX

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


W.X

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.

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 endoscope has:
  - ✓ No dents, cracks, kinks, or deformations,
  - ✓ No scratches,
  - ✓ No corrosion,
  - ✓ No lens damage or cover glass damages,
  - ✓ No missing or loose parts,
  - ✓ Check all marking for clear visibility.

- Check the light transmission by:
  - ✓ Holding the distal end of the endoscope against a lamp,
  - ✓ Looking into the light guide connector of the endoscope,
  - ✓ Black dots indicate defective optical fibers. Do not use an endoscope with more than 25% defective optical fibers.

- Check the image quality:
  - ✓ Hold a writing paper at 20mm from the objective cover glass,
  - ✓ Only use endoscope if the writing is clearly visible through the device,
  - ✓ Check that the image is not cloudy, out of focus or dark.

4. Reprocessing


W.XI

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.XII

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.XIII

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.XIV

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.XV

If necessary, repeat the reprocessing process until the device is optically 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 endoscopes and accessories as soon as possible.
- In case of contact with a corrosive substance, clean immediately with water.
- Remove the removable parts of the endoscope and accessories.
- 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.

Step	Automated Cleaning Instructions
Automated pre-cleaning	➢ Immerse the instrument in cold tap water for at least 10 minutes. Brush the disassembled instrument 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. ➢ Take the instrument 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 G7736 CD. ➢ Fix the endoscope to the loading rack in such a way that damage is prevented during cleaning. ➢ 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 FA; Dr. Weigert; Hamburg ➢ Draining ➢ 3 min neutralization with warm water (40°C) and neutralizer agent. ✓ Use solution: Neodisher Z; Dr. Weigert, Hamburg ➢ Draining ➢ 2 min rinse with warm water (40°C-60°C) ➢ Draining

Step	Automated Cleaning Instructions
Disinfection	➢ Automated Thermal Disinfection under consideration of national requirements regarding A0-Value (see EN ISO 15883) ➢ We recommend final rinse with distilled, demineralized or fully desalinated water.
Drying	➢ Ensure that the exteriors of the endoscope are dry. If necessary, dry with a soft cloth. ➢ If necessary, dry working channels with compressed air.

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 (e.g. STERICLIN pouch used during sterilization validation) acc. to ISO 11607 and/or AAMI / ANSI ST77:2006 in order to be sterilized.

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

Endoscopes marked autoclave/autoclavable must only be vapor-sterilized. Do not gamma-sterilize endoscopes and accessories. The optical quality can be affected negatively.

After the sterilization process has come to an end, the endoscopes should be slowly cooled to room temperature. The endoscope must not be cooled by rinsing with cold water or other fluids as this can lead to lens damage.

The endoscope tip may not come into direct contact with the metal container. Otherwise the heat of the container will be directly transferred to the endoscope which would damage the lens.

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

- ➢ Sterilize endoscopes 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/DIN 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 4 minutes	At least 10 minutes

4.4. Storage


W.XIX

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.
- ✓ Store endoscopes with small diameters (3.0 mm and less) in the protective transport and storage sheaths.

4.5. Limitations on reprocessing

Delmont Imaging´s devices are made out of different materials. These were chosen regarding their ability to withstand to several cleaning, disinfection and sterilization cycles and thus, the multiple high temperature application. There are no concerns regarding material resistance or any known sensitivity to process parameters during reprocessing which may affect the safety of our devices. Repeated processing has only minimal effect on the device. The service life of the units is usually determined by wear, damage and improper reprocessing parameters. Nevertheless, the ability of Delmont Imaging devices to withstand several reprocessing cycles has been validated up to 300 times.

5. After-Sales service and maintenance

5.1. Repairs and services


W.XX

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.XXI

There is risk of infection when returning a used medical device. Returning used medical devices is exclusively permitted when cleaned and sterilized/disinfected, 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. Always send endoscopes with protective tube in.

5.2. Removing deposits from optical end surfaces

If deposits are found when checking the image quality, they can be removed with the provided polishing paste as follows:

- Only clean with polishing paste if the image which you see through the endoscope is cloudy and blurry.
- Apply polishing paste to a clean cotton swab.
- For large end surfaces: press cotton swab lightly on the end surface to be cleaned and rub it over the glass.

- For small end surfaces: place cotton swab lightly on the end surface to be cleaned and turn it.
- Clean all optical end surfaces with warm water and mild detergent to remove all polishing paste residue.
- Rinse optical end surfaces under running water.
- Dry optical end surfaces with a soft cloth.
- Reprocess completely the endoscope (see 4).
- Carry out visual inspection. If the deposits were not removed: contact Delmont Imaging or its representative.

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.

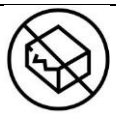
5.4. Disposal


W.XXII

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. Contact Delmont imaging or its representative for more information about recycling.

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»
Autoclavable	Symbol for autoclavable endoscope
HD	Symbol for High Definition endoscope
HM	Symbol for High Magnification endoscope
12°	Symbol for Direction of View

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