EN - Instruction for use

Light cable

REF This manual relates to the following articles:

Product list
D200 150 000 à D200 150 005 ; D200 150 500 à D200 150 501

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 CONTENT

1. Device description

1.1. Intended Use

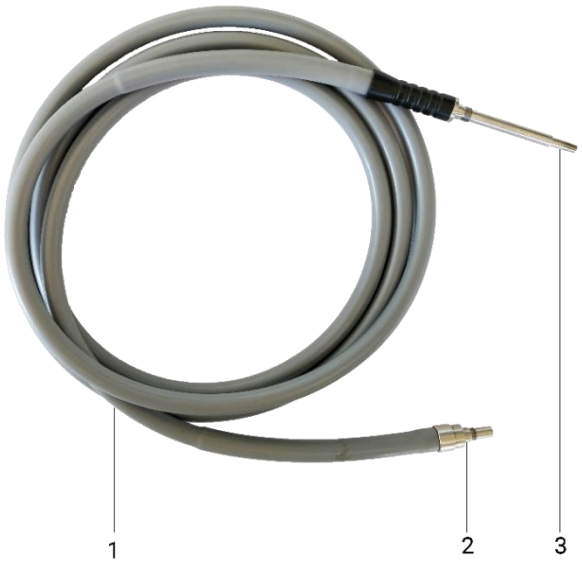
This manual is intended exclusively for trained and qualified personnel (doctors, medical assistants supervised by a doctor). Light cable should only be used by trained and qualified personnel to perform clinical applications in hospitals and medical rooms with appropriate endoscopic equipment. The products 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 universal light guide for endoscopic applications is used to transmit light during endoscopic diagnosis and treatment or for other medical applications with illumination, taking into account the properties and instructions for use. The light cables are designed for use with cold light sources designed with halogen bulbs, xenon bulbs or LEDs and intended for medical-technical applications with endoscopes, medical instruments or microscopes and have an optical coupling piece for beam diameters of 4.8 to 5.0mm or 3.5mm.

For the benefit and safety of patients, physicians should choose a method that they consider appropriate based on their experience. If, as a user of this device, you feel you require more detailed information regarding its use and care, please contact your representative.

W.I ***This document describes the correct use and operation of light cables. This document may not be used for endoscopic examinations or operations, nor for training purposes.***

1.2. Specific details



1: Light cable
2: Instrument end cap
3: End cap on light source side

The light guide consists of a bundle of environmentally friendly SCHOTT PURAVIS® glass fibers (type GOF70) which is thermally fused onto the light entry surface. The threads at the ends allow the connection of common adapters which can be screwed in by medical personnel for all common endoscopes and light sources.

The light guide is characterized by the following optical properties :

Angle of acceptance (2α)	≥ 70° à 587nm (V(λ), 1m in length) NA ≥ 0,57
Transmission	≥ 60% à 546nm (typically ≥ 65%)

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.

The use of the light cable in combination with laser light sources is prohibited.

Light cables should be used with a light source (D900 700 053) and an endoscope (D900 700 023). All performance and safety tests were performed using a combination of Delmont imaging devices only. Delmont imaging does not recommend the use of third-party devices with Delmont imaging devices for the same intended use. The user is responsible in case of use of a third-party device.

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.IV

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.V

Intensive light energy can cause heating of the coupling surfaces or illuminated surfaces and result in a risk of burns.


W.VI

Do not look directly at the end of a light guide connected to a light source: risk of blindness.


W.VII

The light guide is not designed for invasive use.

The light guide must never be pinched or crushed. A minimum bending radius of 50mm is permitted in the flexible area of the sheath. The light guide is not suitable for mechanical and dynamic movements. It may only be subjected to bending movements within the minimum bending radius.

2.2. Contraindication

No contraindications directly associated with the product are known to date.

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.

2.3. 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.VIII

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


W.IX

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 infection risk, tissue irritation, perforation, bleeding, mucosal tissue injuries or serious damage to the equipment. 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.

Follow the instructions in this chapter before each use.

- Make sure that all devices have been properly reprocessed.
- Visually inspect all devices thoroughly. Devices must be visually clean.
- Check that the light cables have :
  - ✓ No splinters, cracks, bends or deformations,
  - ✓ No scratches,
  - ✓ No corrosion,
  - ✓ No missing or loose parts,
  - ✓ Check that all markings on the device are clearly visible,
  - ✓ Make sure that there are no residues of cleaning agents or disinfectants on the device.

3.2. Assembly/disassembly

If in doubt about which adapters to use, contact your representative for more information.

To mount the light cable:

- Always assemble the light cable before switching on the light source.
- Make sure that the appropriate adapters are mounted on each side of the cable.
- Insert the end cap on the light source side up to the mechanical stop.
- Screw the light cable to the endoscope.

To disassemble the light cable:

- Always switch off the light source before dismantling the light cable.
- Unscrew the light cable from the endoscope.
- Gently remove the tip on the light source side.
- Unscrew the existing adapters.

4. Reprocessing

W.X

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.XI

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.XII

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.XIII

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.XIV

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


W.XV

Cleaning, disinfection and subsequent sterilization are not permitted with screwed-on adapter tips. These must be removed and prepared separately from the light guide.

- Treat contaminated devices as soon as possible,
- In case of contact with a corrosive substance, clean immediately with water,
- Disassemble the device and the adapters,
- Pack them safely and individually in a closed container,
- Trays should be inspected for visible contamination and cleaned before use.

4.2. Cleaning and disinfection


W.XVI

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. Never clean any instruments with metal brushes or wire wool. Do not expose any instrument to temperatures higher than 138 °C.


W.XVII

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.

When selecting the cleaning and disinfecting agent, make sure that it does not contain the following items:

- ***organic acids, minerals and oxidants (min. acceptable pH value: 5.5),***
- ***strongly alkaline solutions (max. acceptable pH value: 11; neutral/enzymatic or slightly alkaline cleaners are recommended),***
- ***organic solvents (e.g. alcohols, ether, ketones, essences),***
- ***oxidants (e.g. hydrogen peroxide),***
- ***halogens (chlorine, iodine, bromine),***
- ***aromatic/halogenated hydrocarbons,***
- ***tri-/perchloroethylene.***

Efficient cleaning/disinfection is a prerequisite for effective product sterilization. Start cleaning immediately after each use.

For cleaning and disinfection purposes, an automated method should be used wherever possible. A manual method should only be used if a automated method is not available due to the significantly inferior effectiveness and reproducibility.

Step	Automated cleaning instructions
Automated pre-cleaning	➢ Immerse the device in cold water for at least 5 minutes. Brush device under cold 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 device 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 water for at least 1 minutes

Step	Automated cleaning instructions
Nettoyage automatisé	➢ Follow the operating and loading instructions of the washer and disinfector manufacturer and the recommendations for cleaning products. ✓ Device used for validation: G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) ➢ Place the device on a tray. When doing so, make sure that the device do not touch each other and that the minimum permissible bending radius of 50mm is observed. ➢ 1 min pre-cleaning with cold water ➢ Draining ➢ 3 min pre-cleaning with cold water ➢ Draining ➢ 5 min cleaning at 55°C with a 0.5% alkaline solution. ✓ Use solution: Neodisher Mediclean forte; Dr. Weigert; Hamburg. ➢ Draining ➢ 3 min neutralisation with hot water (40°C-60°C) and a neutralising agent. ✓ Use solution: Neodisher Z; Dr. Weigert, Hamburg ➢ Draining ➢ 2 min rinsing with hot water (40°C-60°C) ➢ Draining
Désinfection	➢ Automated Thermal Disinfection under consideration of national requirements regarding A0-Value (see ISO 15883) : at least 5 minutes at 90°C. ➢ We recommend final rinse with distilled, demineralized or fully desalinated water.
Séchage	➢ Dry the outer surfaces in the drying cycle of the washer/disinfector. ➢ Let the device 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.

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.XVIII

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.XIX

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. Make sure that a sufficient number of Endoscopic Instruments are available.

- Sterilize the endoscopic instruments 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.
- 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 5 minutes	At least 20 minutes

4.4. Storage

Sterilized devices must be stored in a dry, clean and dust-free environment. The applicable national guidelines must be followed.

W.XX.

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: -20°C to 60°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

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”. Nevertheless, the ability of Delmont Imaging devices to withstand multiple reprocessing cycles has been validated up to 100 times.

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.XXI

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.XXII

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 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.

5.3. 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.

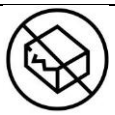
5.4. Disposal


W.XXIII

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 is damaged»
	Symbol for «Non-Sterile»
	Symbol for «Keep away from sunlight»
	Symbol for «Keep dry»

CE

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