EN - Instruction for use

Sterilization basket

REF This manual relates to the following articles:

Product list
D200 160 006 to D200 160 023 and D200 160 503 to D200 160 508.

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. Sterilization baskets are to be used exclusively by trained personnel qualified to carry out the reprocessing applications in hospitals and medical rooms with appropriate equipment.

The Delmont Imaging sterilization basket is a packaging system for reprocessing Delmont imaging medical devices such as endoscopes, hysteroscopy system, resectoscopy system, etc. It is a reusable device and features an assortment of sizes and configurations that provide an effective packaging method for sterilization, storage and transportation of surgical instrument by healthcare providers. This sterilization basket is intended for use in pre-vacuum Steam Sterilizers. It is intended to allow sterilization of the enclosed device.

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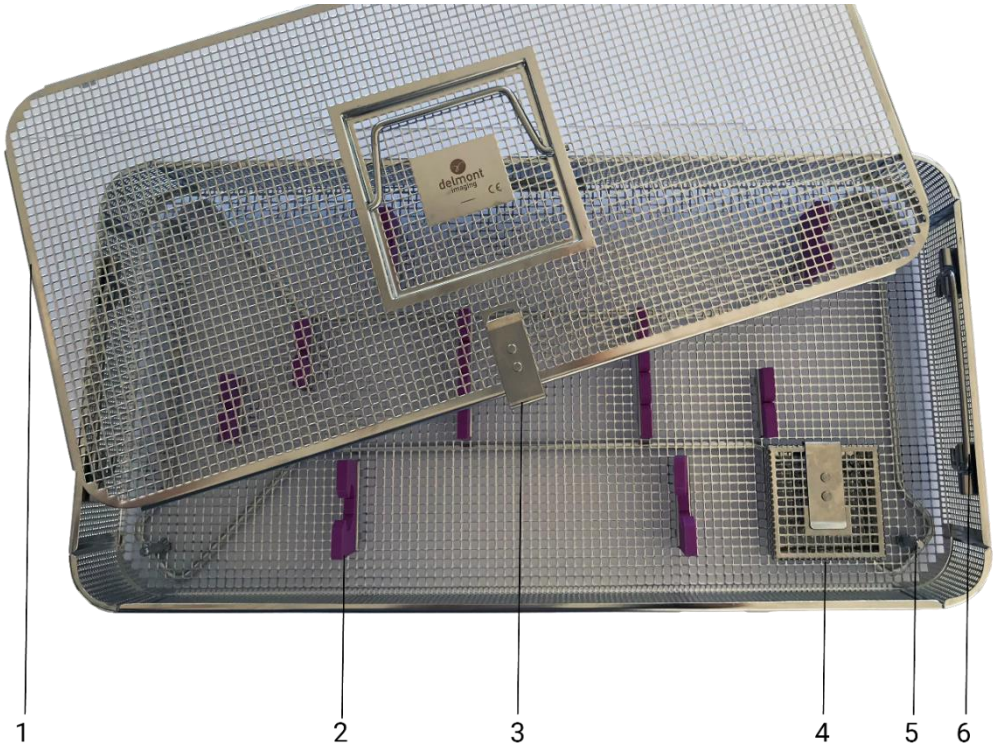
This document describes the correct handling, function, as well as recommended processing methods. This document may not be used for training purposes. This product is designed to be used by qualified people only.

1.2. Specific details



1: Sterilization basket cover

2: Silicon holder for instruments
3: Locking slider
4: Basket for accessories
5: Rod for winding cables
6: Handle

The Delmont Imaging sterilization basket is made of Stainless Steel Aisi304 (X5CrNi18/10) with an anodised oxide surface which prevents corrosion.

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 sterilization baskets are manufactured so that they can be used in any conventional large steam sterilizer.

Delmont Imaging proposed specific arrangement of sterilization basket to ease the reprocessing of other Delmont Imaging products. Contact your Delmont representative for more details.

2. Safety instructions

Observe the use and safety instructions of the manufacturer sterilization basket device. 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.


W.IV

Abrasive cleaners, metal brushes or abrasive cleaning pads can cause permanent damage to the basket surface and therefore must not be used

Use only appropriate cleaning and disinfectant agents, certified for use on stainless steel and plastic, in accordance with the manufacturer's instructions

2.2. Contraindication

No specific contraindications have been reported in the use of the sterilization baskets. Pay attention to section for functional test prior to each use to ensure a safe use.

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.V

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


W.VI

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 ready to use.

- Prior to subsequent use and before each use, it is very important to check every basket for visible damage and wear, such as cracks, breaks.
- Check that function is as described in the instructions.
- Damaged or faulty products should not be used and should be taken out of circulation immediately.
- Damaged parts should be immediately replaced by original manufacturer parts

3.2. Load/Unload the baskets


W.VII

The overall weight for loading baskets should not exceed a certain load, as otherwise satisfactory sterilization of the devices cannot be ensured. The sterilization of various basket loads, and packaging configurations has to be validated by the responsible specialist hygiene personnel.

Please see details about Delmont Imaging baskets, and metal sterilizing trays in our product catalogue.

To load the basket:

- Before loading complex instruments like endoscopes resectoscope, instruments with a lumen, compressed air-driven instruments or power systems and instruments with cannulae, prepare them for the sterilization according to the manufacturers' instructions,
- Small baskets, trays, other types of accessories, especially with cover or lids, should only be used with the sterilization basket, if the sterilization basket has been specifically designed and tested for that purpose,

- Place the devices in the corresponding lockers,
- Once all are in place, close the lid to the bottom.

To unload the basket:

- Separate lid and bottom,
- Remove the devices from the inside of the basket,
- Remove disposable locks and indicators if any.

3.3. Placement in the sterilizer

Pay attention that heavy baskets are placed at the bottom of the sterilization chamber.

During loading and unloading of the sterilizer and during transport, the sterile basket must always be carried by the handles and never by the lid.

4. Reprocessing

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.

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W.IX

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.X

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.XI

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.XII

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

It should be noted that only validated device-specific procedures for cleaning, disinfection and sterilization should be used and that validated parameters should be followed during each cycle. Also observe the legal requirements applicable in your country and the hygiene regulations of the hospital or clinic.

4.1. Preparation

Each basket must correspond to a validated and automated cleaning and disinfection program. Each facility may need to conduct internal testing to determine if adjustments are required for their facility. Trays must be inspected for visible contamination and cleaned prior to use.

4.2. Cleaning and disinfection

W.XIII

Do not use fixing agents or hot water (>40°C) as this will fix residues and may affect the cleaning success.


W.XIV

Mechanical cleaning is absolutely preferable if the washer/disinfector has a special program for aluminium basket


W.XV

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.I

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

Never use brushes or other objects that could damage the device.

Improper cleaning and disinfection can lead to corrosion and stress cracks. Therefore, follow the specifications of the manufacturer of cleaning and disinfecting agent.

Only fully deionized water (quality according to EN 285 Annex B) is recommended for reprocessing the product.

- Before and every use, the basket must be cleaned and disinfected.

For manual cleaning:

- Use mild detergents or neutral cleansers that are specially recommended to be used in combination with a soft sponge and water,
- After cleaning, careful rinsing and sufficient drying is necessary.

For Mechanical cleaning use:

- The basket lid and bottom need to be cleaned separated from each other,
- The basket bottom needs to be placed upside down in the washer/disinfector to avoid the collection of water,
- The inside of the basket lid should face the machine-bottom with the latching mechanism folded into the inner part of the lid,
- All component parts of the basket (bottom, lid, filter-holders…) should be disassembled and placed in the washer/disinfector baskets that are specially designed for baskets and accessories,
- After the washing/disinfection program is finished, the basket and accessories need to be dried with a soft dry cloth or by air.
- Procced with the following cleaning process :
  - 1 min pre-wash with cold water
  - 3 min cleaning with Mediclean 0,5% by 45°C

➢ Neutralisation with purified water

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.

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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.XVII

Plasma sterilization is not possible due to 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. Make sure that a sufficient number of Hysteroscopy Systems is available.

✓ Follow the time and temperature specifications of the sterilizer manufacturer for every chosen sterilization cycle and the sterilization required by the instruments.

✓ To minimize condensate inside the basket, leave basket on basket carts until cool enough to handle.

✓ After each sterilization, the sterilization performance has to be stated according to internal instructions and the validation results. The basket lid and bottom, closures and sealing must be checked for damages before release. The sealing of the basket must be closed and undamaged.

4.4. Storage

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

W.XVIII

Store sterilized instruments in a dry, clean and dust-free environment at moderate temperatures between 5°C and 40°C. Please refer to DIN 58953-9: recommendation about the storage of sterile material in a basket. Usually the storage period depends on the storage conditions and must be defined by the responsible specialist hygiene personnel. Various baskets loads, storage periods and storage conditions have to be validated by the responsible specialist hygiene personnel.

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. 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.XIX

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.XX

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 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.

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


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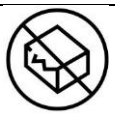
Keep the used device out of the reach of unauthorized persons.

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 “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”

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