



Digimed Medical Technology

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Products

These instructions for use are valid for all sterile container systems and accessories from Digimed Medizintechnik with the article number range:

REF 99.1XX.XXX -
99.8XX.XXX

Important note



Read these operating instructions carefully before each use and keep them easily accessible for the user or the relevant technical personnel.



Carefully read the warnings marked by this symbol. Improper use of the products may result in serious injury to the patient, users or third parties.

1 Scope

The products listed above may only be used by appropriately trained and qualified personnel. The products may only be used in a sterile environment.

2 Precautions and warnings



- Do not use steel wool or cleaning agents with an abrasive effect.
- Do not use cleaning solutions with iodine or high chlorine content.
- Do not place contaminated or used Digimed medical devices in a case for cleaning in the washer/disinfector. Contaminated Digimed products must be processed separately from the trays and cases. Cases are designed as organizational containers for steam sterilization, as storage containers for medical devices, and as organizational containers during surgery.
- Machine cleaning is to be preferred, as this leads to a more effective result. With machine cleaning and disinfection, there is greater safety in the process.
- Alkaline cleaning agents (pH > 10) are not suitable for all materials. The Robert Koch Institute points out potential problems caused by

increased wear in aluminum, silicone elastomers, adhesive joints, silver and tin solder joints, sealing materials,

plastic coatings, fiber optic light guides and optical surfaces with anti-reflective coating.

- Defective products must go through the entire remanufacturing process before being returned for repair or reclamation have. A decontamination certificate must be enclosed with the return shipment. - The sterilization parameters apply exclusively to adequately pre-cleaned components.

- The parameters listed apply exclusively to properly installed, maintained and calibrated preparation systems that meet the requirements of ISO 15883 and ISO 17665 standards.

- Operate on patients who are considered at risk for Creutzfeldt-Jakob disease (CJD) and associated infections using disposable instruments. Dispose of instruments used to operate on a patient with suspected or proven CJD after surgery and / or follow current national recommendations.

- For further information, see the applicable national laws and guidelines. The clinic's internal guidelines and procedural instructions as well as the recommendations and instructions of the manufacturers of the cleaning and disinfection agents and the systems for clinical reprocessing must also be followed.

3 Limits of clinical reprocessing

- Repeated/frequent reprocessing according to this instruction has little effect on the service life of the containers.

- The service life of a sterilization container is essentially determined by wear and damage from use.

- Proper application of an average of 4 times a week results in a service life of at least 10 years.

4 Application area

- DIGIMED sterile container systems combine proven filter technologies, tested materials and design features to create a reliable container system.

They are reusable container systems that offer a wide range of dimensions and equipment to provide effective packaging, storage and transport of the instruments to be sterilized. The container systems are ideally suited for fractionated vacuum processes.

Purpose

The DIGIMED Sterile Container Systems are intended for loading with medical devices that are sterilized. A sterilization and storage of the enclosed products is enabled and ensured until they are used.

The containers are available with perforated and non-perforated tray bottom and perforated lid, depending on the model. The 1/1, 3/4- and 1/2 - containers are also available with safety lid.

Combination products

DIGIMED sterile container systems consist of sterile containers, sieve baskets and filters. In addition, accessories can be used for the container systems should be used. A screen basket of the appropriate size should be used for the respective container size. The possible combinations are described below of the various container designs. A detailed overview of combinable products can be found in section COMBINATION PRODUCTS

- Standard container

Filter holders are located below/above the perforations in the lid and, if applicable, in the tank. Disposable filters must be inserted into these filter holders before sterilization. paper filter or permanent filter can be inserted.

On the lid of the standard container of sizes 1/1, 1/2 and 3/4 you can additionally put a safety lid as required. This protects against

Contamination during storage or transport of the sterile container.

- Screen baskets

For each container size, there are matching screen baskets in different heights, matching lids and matching feet.

- Security seal

Security seals are applied to the outside of the closures by passing the seal through the opening of the spring closure system and the seal is then locked. When opening/flipping up the latches, the seal breaks.

- Silicone mats

The sieve baskets are placed in the container and can be equipped with a silicone mat as required.

- Indicator labels

The indicator contained discolors during steam sterilization at 134° C.

Please note the shelf life of the labels according to the manufacturer's instructions. The indicator labels may only be used for the intended purpose. If the specifications are not observed, the result may be distorted.

Notes on the use of paper filters

- Paper filters are intended for single use only.
- Paper filters are manufactured according to EN ISO 11607-1.

- Paper filters must not be glued (e.g. for documenting the runs), as the glue may contain pollutants. Furthermore, due to Sticking destroys the germ barrier.

The paper filters must be sized to completely cover the perforation in the container lid.

Notes on the use of permanent filters

- PTFE filters are designed for multiple use.
- Permanent filters must not be glued (e.g. for documenting the runs), as the glue may contain pollutants. Furthermore, due to Sticking destroys the germ barrier.

- In case of coarse contamination, the filter must be removed and then cleaned.

The permanent filters must be sized so that the perforation in the container lid is completely covered.

5 Handling and preparation

⚠ General

DIGIMED sterilization containers are made of an aluminum alloy whose surface is anodized for corrosion protection. Aggressive cleaning agents, Metal brushes or scouring pads can permanently damage this surface and must therefore not be used. If this instruction is not followed, the warranty will be excluded.

⚠ **The sterilization containers may only be handled by instructed or trained personnel to prevent damage to the containers, closures, seals and sterile filters/cassettes.**

The sterilization containers are also offered with colored lids to facilitate assignment to the individual disciplines and departments. Sterilization indicator and colored identification labels provide information about contents, place of use and condition. In accordance with the normative specifications and recommendations, suitable measures (e.g. sealing, process indicators) must be taken to ensure that that sterilized and unsterilized sterilization containers cannot be confused. Only intact seals ensure that the sterilization container has not been opened without authorization.

⚠ Preparation for cleaning

- Separation of container tray and lid
- Remove the contents of the container (sieve basket, instruments, etc.)
- Removal of the filter holders/cassette from the inside of the lid and, if applicable, from the tray part (for containers with bottom perforation).
- For disposable paper filters: Dispose of disposable filters.
- Removal of the disposable seals as well as the indicator plates

Note: All paper filters are disposable and must be replaced after each use of the container.

⚠ Commissioning of a new container

- Before the first use, the container must be thoroughly cleaned.
- The container must be reprocessed in a validated, automated cleaning and disinfection process.
- A neutral cleaning agent should be used in the machine for this purpose.
- After reprocessing in the automated cleaning and disinfection process, steam sterilization of the products in the fractionated steam sterilization process at 134°C.

- In addition, all moving parts on the container must be regularly maintained with an approved instrument care oil.

- After cleaning, suitable new filters must be inserted (see Filter change).

6 Preparation

⚠ Additional information

- City water to be used must comply with COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
- The cleaning agents and disinfectants used for validation are specified in these reprocessing instructions. If an alternative cleaning agent and disinfectant (RKI or VAH listed) is used, the reprocessor is responsible.
- Reassemble disassembled products before sterilization.

Manual pre-cleaning

- For aluminum containers and lids, mild, neutral cleaning agents or chemical products should be used whenever possible, which have been expressly approved by the manufacturers for the treatment of aluminum products. If necessary, the products are to be tested in the appropriate procedure. A soft, suitable sponge should be used for manual cleaning. Scouring sponges are not to be used, as they destroy the surfaces and thus the passivation and lead to loss of warranty.
- After cleaning, careful rinsing with appropriate low-salt water (e.g., deionized water) and sufficient drying is required.
- Do not use metal brushes or abrasive cleaners.
- Finally, disinfection must be carried out in accordance with the relevant hygiene requirements.

- Ultrasound
If the pre-cleaning by the sponge and rinsing with water jet gun still left visually visible contamination, pre-cleaning by ultrasound should be performed.

Immerse container and sieves in ultrasonic bath filled with water <40°C, 0.5 % alkaline detergent (Neodisher FA, Dr. Weigert) for 5 minutes and clean for 10 minutes. Rinse container and sieves with a water jet gun (4 bar) > 10 sec.

Cleaning / Disinfection

Automatic cleaning/disinfection process:

(Washing machine, Washer - Disinfector G 7735 CD (Miele):

Step 1: 1 minute pre-cleaning with cold city water Drinking water quality <40°C

Step 2: Water drain

Step 3: 3 minutes pre-cleaning with cold city water Drinking water quality <40°C

Step 4: Water drain

Step 5: Cleaning for 5 minutes at 55°C±5°C with 0.5 % alkaline cleaner (Neodisher FA, Dr. Weigert).

Step 6: Water drain

Step 7: 3 minutes neutralization with cold city water drinking water quality <40°C

Step 8: Water drain

Step 9: 2 minutes rinsing with cold city water Drinking water quality <40°C

The special instructions of the manufacturer of the cleaning machine must be observed.

Automatic disinfection

Automatic thermal disinfection in washer-disinfector, taking into account the national requirements for the. A-0 value 3000:

>5 minutes at 92°C±2°C
with VE water.

Automatic drying

Automatic drying according to the automatic drying process of the washer-disinfector for at least 30 minutes (at 60°C±5°C in the rinsing chamber). If necessary, subsequent manual drying with a lint-free cloth and blowing out the corners using sterile, oil-free compressed air.

Filter change

After changing the filter, the filter holder must be brought into the correct position by pressing it until it audibly engages. DIGIMED lids may only be used with DIGIMED filter holders can be used.

- Disposable paper sterile filters must be reinserted before each new sterilization.
- Only when using the DIGIMED filters is the suitability and accuracy of fit guaranteed.
- Warranty claims can only be accepted if the original DIGIMED filters are used exclusively.
- PTFE filters have been tested for 1200 cycles and must be replaced thereafter.

⚠ Attention

Only combine original DIGIMED individual parts such as lids, trays, filters, seals, cassettes and filter holders with each other so that the tightness and germ barrier are not compromised. Otherwise DIGIMED will not assume any warranty.

Sterilization

Sterilization of the container systems using the fractionated pre-vacuum process (according to DIN EN ISO 17665-1), taking into account the respective national requirements. The products must be sterilized in suitable sterilization packaging in accordance with EN ISO 11607 and DIN EN 868.

EU standard

Sterilization is to be performed using a fractionated pre-vacuum process, with the following parameters:

134°C

≥5 minutes holding time,

3 Pre-vacuum cycles

Drying in vacuum for at least minutes 20

The autoclave manufacturer's instructions for use and the recommended guidelines for the maximum load of sterilization material must be observed. The autoclave must be installed, maintained, validated and calibrated in accordance with regulations.



Container loading

The total weight of the loading of the containers should not exceed the following quantities, otherwise satisfactory sterilization will not be ensured can be.

Model	Max. Load in kg
1/1 (Full-) Size Container	9,0 Kg
¾ Size container	7,0 Kg
½ Size container	5,0 Kg
Flat container	1,5 Kg
Mini container	1,0 Kg
Dental container	1,8 Kg

Placement in sterilizer

The containers are designed to be used in any commercial large sterilizer for moist heat sterilization. Note you that heavy containers are positioned at the bottom of the sterilization chamber. Due to their design, the containers can be easily and safely stacked on top of each other during sterilization without slipping. Stacking is recommended only for sterilization cycles using fractionated vacuum process. The stacking height should not exceed 46 cm to achieve effective air removal and steam penetration. The sterilizer manufacturer's instructions must be followed.

CAUTION!

Observe the following during sterilization: Never pack the container in another outer packaging. Never cover the perforation fields in the lid and base with any film packaging or similar, because this impedes the flow of air and steam into the container. The consequence is a vacuum-induced deformation of the container due to the insufficient pressure compensation and the sterility of the contents of the container is not guaranteed.

During loading and unloading of the sterilizer as well as during transport, the sterile container must always be held by the carrying handles and never by the lid. to carry.

Flow control

- Operate the loaded sterilizer according to the sterilizer manufacturer's specifications for the selected sterilization cycle (based on temperature and sterilization time) The validation results must be taken into account.
- In order to avoid the accumulation of condensate in the container, the container should cool down completely on the sterilization cart.
- After each sterilization, the sterile material must be assessed and released in accordance with the internal instructions and the validation results. be carried out. This is consistently done by employees with specialist knowledge 1.

Additional information

The reprocessor is responsible for ensuring that the reprocessing actually carried out with the equipment, materials and personnel used in the reprocessing facility achieves the desired results. This usually requires validation and routine monitoring of the process and equipment used.

7 Testing

The sterilization containers must be checked for proper functioning before each use. Damage to the caps, seals, filter holders, filters, cassettes, as well as bent and dented parts mean that the sterilization containers are need to be repaired and must not be used. Do not use damaged sterilization containers.

- All moving parts on the container must be maintained with an approved instrument care oil.

- If any damage is found on the seals, they must be replaced immediately.

- The seals should not be treated with spray, oil or solvent. Occasional wiping is sufficient for cleaning and care with a damp cloth.

- If any damage is found on the sterilization containers, they must be checked, repaired or replaced.

- Spare parts can be obtained from DIGIMED

Service and repair

Do not carry out any repairs or modifications to the product on your own. Only authorized personnel of the manufacturer is responsible and intended for this. If you have any complaints, claims or information regarding our products, please contact us.

Return transport

Defective or non-conforming products must have gone through the entire remanufacturing process before being returned for repair / service.

8 Storage, transport and disposal

Storage



For the storage period for medical devices in sterilization containers, please refer to DIN 58953-9 (Application technology of sterilization containers). Usually, the storage time depends on the storage conditions and must be determined by the responsible hygienist.

In case of a particularly high requirement for asepsis or in case of deviations from the specified storage conditions, shorter storage periods are or use additional packaging.



Storage conditions:
 - Temperature: 15 - 26° C
 - Humidity: 30 - 50%
 - Air pressure: normal atmospheric pressure

Various container loads, storage times and storage conditions are subject to determination by the responsible hygienic personnel.

The DIGIMED sterile containers have been tested for a storage period of 6 months by applying *Bacillus subtilis* - spore suspension. Based on this, a storage period of 6 months can be guaranteed. The containers must be stored under protected conditions (e.g. in closed cabinets), protected from dust, clean, dry and free from vermin.

Transportation

The sterile containers should only be transported using the carrying handles provided.












Disposal

The disposal of the products, the packaging material and the accessories must be carried out in accordance with the nationally applicable regulations and laws. The manufacturer does not provide specific instructions for this.

9 Liability and warranty

DIGIMED-Instrumente GmbH, as the manufacturer, is not liable for consequential damage resulting from improper use or handling. This also applies to repairs or modifications to the product carried out by non-authorized personnel of the manufacturer. These exclusions of liability also apply to warranty services.

10 Symbol description

	Attention!
	Observe operating instructions
	Item number
	Batch designation
	CE marking
	Non sterile
	Manufacturer
	Store dry
	Temperature limit
	Protect from sunlight
	Medical device

11 Applied standards

To ensure the safety of the sterilization containers during production and handling,

the following standards were taken into account:

DIN EN 868-2

Packaging materials and systems for medical devices to be sterilized - Part 2: Sterilization packaging; requirements and test methods

DIN EN 868-8

Packaging materials and systems for medical devices requiring sterilization - Part 8: Reusable sterilization containers for steam sterilizers according to EN 285; requirements and test methods

EN ISO 11607-1

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

DIN 58952-2

Sterilization; packaging materials for sterilized goods, metal sterilization baskets

DIN 58952-3

Sterilization; packaging materials for sterilization goods, metal sterilization trays

DIN 58953-9

Sterilization; sterile supply - Part 9: Application technology of sterilization containers

EN ISO 14937

Sterilization of health care products - General requirements for sterilant characterization and development, Validation and routine monitoring of a sterilization process for medical devices

EN ISO 17665-1

Sterilization of health care products - Moist heat - Part 1: Requirements for development, validation and guidance of use of a sterilization process for medical devices

DIN EN 285

Sterilization - Steam sterilizers - Large sterilizers

To ensure sterility safety, tests were performed by an independent and accredited testing laboratory. Purpose of these investigations was the validation of a moist heat sterilization process for the DIGIMED reusable sterile container systems.

Based on the results, we therefore prescribe the sterilization procedure indicated on page 3 of these instructions for use.

12 Materials

Our sterilization containers are made of anodized aluminum alloy and the accessories are made of stainless instrument steel.

13 Delivery condition



The DIGIMED Sterile Container Systems are shipped in a non-sterile state and must be prepared and sterilized by the user in accordance with the following instructions before the first and each subsequent use.

DIGIMED GMBH ASSUMES NO LIABILITY IF IT CAN BE PROVEN THAT THIS CUSTOMER INFORMATION HAS BEEN VIOLATED. WROTE.