Instruction manual

For sterile containers with accessories CE

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dimeda®
SURGICAL INSTRUMENTS

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Products

These operating instructions are valid for all sterile container systems and accessories of Dimeda Instrumente GmbH with the article number range:

REF 88.XXX.XX

Important note

Read these instructions for use carefully before each use and keep them easily accessible for the user or the respective qualified personnel.

Read the warnings marked with this symbol carefully. Improper use of the products may result in serious injuries to the patient, users or third parties.

1 Scope of application

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

2 Precautions and Warnings

- Do not use steel wool or abrasive detergents.
- Do not use cleaning solutions with iodine or high chlorine content.
- Do not place contaminated or used Dimeda Instrumente medical devices in a case for cleaning in the washer-disinfector. Contaminated/used Dimeda Instrumente products need to be cleaned separately before putting them into the sterilizing container. Cases are designed as organization containers for steam sterilization, as storage containers for medical devices and as organization containers during surgery.
- Mechanical cleaning is preferable as it leads to a more effective result. Machine cleaning and disinfection provide greater safety in the process.
- Alkaline cleaning agents (pH>10) are not suitable for all materials. The Robert Koch Institute points out that potential problems can be caused such as increased wear of the following materials: aluminium, silicone elastomers, adhesive joints, soldered joints of silver and tin, sealing materials, plastic coatings, fibre-optic cables and optical surfaces with anti-reflection coating.
- Defective products must have undergone the entire reprocessing treatments before being returned for repair or complaint. Proof of decontamination must be enclosed with the return shipment. - The sterilization parameters only apply to adequately pre-cleaned components.
- The parameters performed only apply to properly installed, maintained and calibrated conditioning systems that meet the requirements of ISO 15883 and ISO 17665 standards.
- Patients, which are to be considered as “at high risk” regarding Creutzfeldt-Jakob Disease (CJD) and related infections, shall be operated with disposable instruments. Instruments which were used for operations on patients with suspected or evidenced CJD disease have to be disposed of and/or to be handled according to current valid national recommendations.

3 Limits of clinical preparation

- Repeated/frequent preparation in accordance with this instruction has only a minor effect on the service life of the containers.
- The service life of a sterilization container is essentially determined by wear and tear and damage caused by the application.
- In case of proper use 4 times a week on average, a service life of at least 10 years can be reached.

4 Application

- Dimeda Instrumente sterile container systems combine approved 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 perfectly suitable for fractionated vacuum processes.

Intended purpose

The Dimeda Instrumente sterile container systems are designed for the sterilization of medical instruments. The containers enable the sterilization and storage of the products inside until they are finally used. Depending on the model, the containers are available with perforated and non-perforated tub bottoms and perforated lids. The 1/1, ¾ and ½ containers are also available with a safety lid.

Combination products

Dimeda Instrumente sterile container systems consist of sterile containers, sieve baskets and filters. Accessories for the container systems are also available. A sieve basket of the appropriate size should be used for the respective container size. Possible combinations of the various container designs are described below. A detailed overview of combinable products can be found in section COMBINATION PRODUCTS

- **Standard container**
In the lid and, if applicable, in the tub, there are filter holders below/above the perforations. Disposable paper filters or permanent filters must be inserted into these filter holders before sterilization.
The lid of the standard container sizes 1/1, ½ and ¾ can additionally be covered with a safety lid if required. This safety lid enables additional protection against contamination during storage or transport of the sterile container.

- **Sieve baskets**
For each container size matching sieve baskets in different heights, corresponding lids and matching feet are available.

- **Security seals**
Security seals are attached to the outside of the closures by passing the seal through the opening of the spring closure system and then locking the seal. The seal breaks when the closure system is opened/raised.

- **Silicone mats**
The baskets sieve are to be put into the containers and can be equipped with a silicone mat if required.

- **Indicator labels**
The indicator inside the container changes colour during steam sterilization at 134°C. Please observe the shelf life of the labels according to the manufacturer's instructions. The indicator labels may only be used for the intended purpose. Non-compliance with the specifications may falsify the result.

Notes on the use of paper filters

- Paper filters are intended for single use only.

- Paper filters are manufactured according to EN ISO 11307-1.

- Paper filters must not be labelled with adhesive material (e.g. for documentation of the runs), as the adhesive material may contain harmful substances. In addition, the germ barrier is destroyed by glueing.

The paper filters used must have a size that makes sure that the perforation in the container lid is completely covered.

Notes on the use of permanent filters

- PTFE filters are designed for multiple use.

- Permanent filters must not be labelled with adhesive material (e.g. for documentation of the runs), as the adhesive may contain harmful substances. In addition, the germ barrier is destroyed by glueing.

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

The permanent filter must have a size that makes sure that the perforation in the container lid is completely covered.

5 Handling and preparation

General information

The Dimeda Instrumente sterilization containers consist of an aluminium alloy whose surface is anodized for corrosion protection. Aggressive cleaning agents, metal brushes or scouring cloths can permanently damage this surface and must therefore not be used. If these instructions are not followed, warranty shall be excluded.

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

The sterilisation containers are also available with coloured lids to facilitate allocation to the individual disciplines and specialist departments. Sterilisation indicators and coloured identification labels provide information on content, location and condition.

In accordance with the normative specifications and recommendations, suitable measures (e.g. sealing, process indicators) must be taken to ensure that sterilised and non-sterilised sterilisation containers cannot be confused. Only intact seals ensure that the sterilization container has not been opened without permission.

Preparation for cleaning

- Separation of container tray and lid

- Remove the contents of the container (sieve basket, instruments, etc.).

- Remove the filter holder/cassette from the inside of the lid and, if applicable, from the tub section (for containers with bottom perforation).

- For disposable paper filters: Dispose of disposable filter

- Removal of disposable seals and indicator labels

Commissioning of a new container

- The container must be thoroughly cleaned before it is used for the first time.

- The container shall be processed in a validated mechanical cleaning and disinfection process.

- For this purpose, a neutral cleaning agent should be used in the machine.

- After reprocessing in a mechanical cleaning and disinfection process, the products must be steam sterilised in a fractionated steam sterilisation 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 used (see filter change).

6 Preparation

Additional Information

- The urban water that is used must comply with Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.
- The reprocessing instructions shall specify the detergents and disinfectants used for validation. If an alternative detergent and disinfectant (RKI or VAH listed) is used, the responsibility lies with the person in charge.
- Reassemble dismantled products before sterilisation.

Manual pre-cleaning

- For aluminium containers and lids, mild, neutral cleaning agents shall be used or alternatively chemical products which have been expressly approved by manufacturers for the treatment of aluminium products. If necessary, the products must be tested for suitability by using the appropriate procedure. A soft, suitable sponge should be used for manual cleaning. Scrubbing sponges should not be used as they destroy the surfaces and thus the passivation and will lead to the loss of warranty.
- After cleaning, careful rinsing with low-salt water (e.g. deionised 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 sponge and rinsing with a water jet gun has left behind any visually visible impurities, a pre-cleaning by ultrasound must be carried out.
- Dip container and sieves into ultrasonic bath filled with water <40°C, 0.5% alkaline detergent (Neodisher FA, Dr. Weigert) for 5 minutes and clean for 10 minutes. Rinse containers 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 tap water Drinking water quality <40°C

Step 2: Water drain

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

Step 4: Water drain

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

Step 6: Water drain

Step 7: 3 minutes neutralisation with cold tap water Drinking water quality <40°C

Step 8: Water drain

Step 9: 2 minutes rinse with cold tap water Drinking water quality <40°C

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

Automatic disinfection

Automatic thermal disinfection in washer-disinfectors, taking into account the national requirements for the A0 value 3000:

>5 minutes at 92°C ± 2 °C with deionised 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 room). If necessary, subsequent manual drying with lint-free cloth and blowing out the corners with sterile, oil-free compressed air.

Filter change

After changing the filter, the filter holder must be pressed into the correct position until it snaps audibly into place. Dimeda Instrumente lids may only be used with Dimeda Instrumente filter holders.

- Disposable paper sterile filters must be replaced before each new sterilization.
- The suitability and accuracy of the filters can only be guaranteed if the Dimeda Instrumente filters are used.
- Warranty services can only be provided if the original Dimeda Instrumente filters are always used.
- PTFE filters have been tested for a service life of 1200 cycles and must then be replaced.

Attention

Combine only original Dimeda Instrumente component such as lids, tubs, filters, seals, cassettes and filter holders with each other, so that the tightness and the germ barrier are not put at risk. Otherwise, Dimeda Instruments does not assume any warranty.

Sterilization

Sterilization of container systems using fractionated pre-vacuum processes (according to DIN EN ISO 17665-14), taking into account the respective national requirements. Products must be sterilised in suitable sterilisation packaging in accordance with EN ISO 11607 and DIN EN 868.

EU standard

The sterilization shall be performed with a fractionated pre-vacuum method with the following parameters:
134°C
≥ 5 minutes holding time,
3 pre-vacuum cycles
Vacuum drying for at least 20 minutes.
The instructions for use provided by the manufacturer and recommended guidelines for maximum loading with sterilization material must be observed. The autoclave must be properly installed, maintained, validated and calibrated.

Container loading

The total weight of the container load should not exceed the following quantities, otherwise satisfactory sterilization cannot be guaranteed.

Model	Max. Loading 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 in such a way that they can be used in any commercial large sterilizer for sterilization with moist heat. Please note that heavy containers are to be positioned at the bottom of the sterilization chamber. Due to their design, the containers can be stacked on top of each other safely and easily during sterilization without slipping. Stacking is only recommended for sterilization cycles using fractionated vacuum processes. The stacking height should not exceed 46 cm to achieve effective air removal and steam penetration. Follow the instructions of the sterilizer manufacturer.

CAUTION!

Note the following when sterilizing: Never pack the container in another outer packaging. Never cover the perforation fields in the lid and base with any foil packaging or the like, as this would obstruct the air and steam flow into the container. This would result in a vacuum-induced deformation of the container due to insufficient pressure equalization and the sterility of the contents of the container is not guaranteed. When loading and unloading the steriliser and for any transports please always use the carrying handles and never the lid.

Sequence control

- Operate the loaded sterilizer according to the sterilizer manufacturer's specifications for the selected sterilization cycle (with reference to temperature and sterilization time) taking into account the validation results.
- To avoid condensate accumulating in the container, the container should cool down completely on the sterilization trolley.
- After each sterilisation, the sterile material must be assessed and released in accordance with the internal instructions and the validation results. This is consistently done by qualified employees with.

Additional information

It is the responsibility of the person in charge for conditioning to ensure that the actual treatment carried out with the equipment, materials and personnel, used in the treatment facility, achieves the desired results. This usually requires validation and routine monitoring of the process and the equipment used.

7 Examination

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

- All moving parts on the container must be treated with an approved instrument care oil.
- If damage to the seals is found, they must be replaced immediately.
- The seals should not be treated with spray, oil or solvent. For cleaning and care, an occasional wipe with a damp cloth is sufficient.
- If damage is found to the sterilization containers, they must be inspected, repaired or replaced.
- Spare parts can be obtained from Dimeda Instrumente

Service and repair

Do not carry out any repairs or modifications to the product yourself. Only authorized personnel of the manufacturer is responsible and intended for this. Should you have any complaints or remarks regarding our products, please contact us.

Return

Defective or non-compliant products must have undergone the entire reprocessing treatments before being returned for repair / service.

8 Storage, transport and disposal

Storage

Please refer to DIN 58953-9 (Application Technology of Sterilization Containers) for the storage period of medical devices in sterilization containers. The storage time usually depends on the storage conditions and must be determined by the responsible hygiene personnel. In case of a particularly high requirement for asepsis or in case of deviations from the specified storage conditions, shorter storage periods or additional packaging should be used..

Storage conditions:

- Temperature: 15 – 26°C
- Air humidity. 30 – 50%
- Air pressure: normal atmospheric pressure

Container loading in different ways, storage times and storage conditions are to be determined by the responsible hygiene personnel. The Dimeda Instrumente sterile containers were tested for a storage period of 6 months by applying Bacillus subtilis spore suspension. Therefore, a storage period of 6 months can be guaranteed. The containers must be stored under protected conditions (e.g. in closed cabinets) dust-protected, clean, dry and free from vermin.

Transport

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

Disposal

The products, packaging material and accessories must be disposed of in accordance with national regulations and laws. The manufacturer does not give any specific instructions for this.

9 Liability and Warranty

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

10 Symbol description

Attention!

Follow the instructions for use

REF Item number

LOT Batch indication

CE mark

NON STERILE Non sterile

Manufacturer

Store in a dry place

Temperature limitation

Protect from sunlight

11 Applied standards

In order to ensure the safety of the sterilization containers during production and handling, the following standards have been observed:

DIN EN 868-2
Packaging materials and systems for medical devices to be sterilized - Part 8:
Reusable sterilisation containers for steam sterilisers to EN 285; requirements and test methods

EN ISO 11607-1
Packaging for medical devices to be sterilized in the final packaging - Part 1:
Requirements for materials, sterile barrier systems and packaging systems

DIN 58952-2
Sterilization; packaging materials for sterile goods, metal sterilization trays

DIN 58952-3
Sterilization; packaging material for sterile goods,
Sterilizing sieve trays made of metal

DIN 58953-9
Sterilization; Sterile Supply - Part 9:
Application technology for sterilization containers

EN ISO 14937
Sterilisation of health care products - General requirements for characterisation of a sterilising agent and for development, validation and routine control of a sterilisation process for medical devices

EN ISO 17665-1
Sterilization of health care products - Moist heat - Part 1:
Requirements for the development, validation and control of the application of a sterilisation process for medical devices.

DIN EN 285
Sterilization - Steam Sterilizers - Large Sterilizers

To ensure sterility safety, tests were carried out by an independent and accredited testing laboratory. The purpose of these tests was to validate a moist heat sterilization process for the reusable Dimeda Instrumente sterile container systems.

Based on the results, we therefore stipulate the sterilization procedures indicated on page 3 of this instruction manual.

12 Materials

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

13 Delivery condition

NON STERILE The Dimeda Instrumente sterile container systems are delivered in a non-sterile condition and must be prepared and sterilized by the user according to the following instructions before the first and each further application.

DIMEDA INSTRUMENTE GMBH ACCEPTS NO LIABILITY IF IT CAN BE PROVEN THAT THIS CUSTOMER INFORMATION HAS BEEN VIOLATED.