

# INSTRUCTIONS FOR USE (EN) CONTAINER SYSTEMS INCL. MINI CONTAINERS

## WARNINGS & PRECAUTIONS

- The container systems may only be used for steam sterilization. Other sterilization methods must not be used.
- For the gravity method, use only containers with a lid and bottom perforation.
- Containers without a lid and bottom perforation (without filter system) that will be used for the handling of medical devices can only be used for the transport of medical devices and must not be sterilized when closed. Due to pressure/vacuum in the sterilizer, they may become deformed and thus unusable.
- Use and combine only original RUDOLF Medical components such as lids, bottoms, gaskets, filters, and filter holders as well as security seals making sure the sizes match each other. This is the only way to ensure the functionality and safety of the container. Otherwise, RUDOLF Medical will not accept any guarantee or warranty claims.
- Should the container system come into contact with CJD-contaminated instruments or if it is just suspected that the container system has come into contact with a CJD-contaminated instrument, the container system as well as the instruments must be disposed of in accordance with the applicable national regulations.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.

## MATERIALS AND TECHNICAL DESCRIPTION

- Containers are made of anodized aluminum alloys and stainless steels in accordance with the standards DIN EN 868-8, DIN 58952-2, and DIN 58952-3.
- The container systems have been tested in accordance with the EN ISO 868-8 standard, Annex D, and are designed and manufactured in a such way that the containers of different sizes can be stacked on top of each other.
- Sterilization container systems consist of container (bottom and lid), filter system, if necessary, baskets and accessories (e.g., silicone mats, identification labels).



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## PLEASE READ BEFORE REPROCESSING AND KEEP IT IN A SAFE PLACE

## PRODUCTS

These instructions for use are valid for the RUDOLF Medical sterilization container systems.

You are receiving a high-quality product whose proper handling and use are described below.



RUDOLF Medical container systems are supplied non-sterile and must be cleaned, disinfected, and sterilized before first use and immediately after each use. Protective caps and transport packaging must be removed beforehand.

## INTENDED PURPOSE

The RUDOLF Medical container systems are intended for the sterilization, packaging, transport, and storage of sterile goods as well as for handling the contaminated sterile goods. The containers are exclusively designed and tested for steam sterilization, especially for the fractionated vacuum sterilization.

The sterilization containers are intended for the use by adequately instructed or trained personnel.

## CONTAINER SYSTEMS (without mini container)

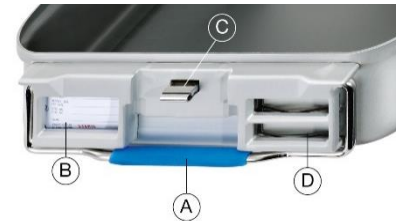


Figure: Example of the container system ½

- 1 = Container bottom
- 2 = Container lid
- 3 = Safety lid

### Container bottom (1)

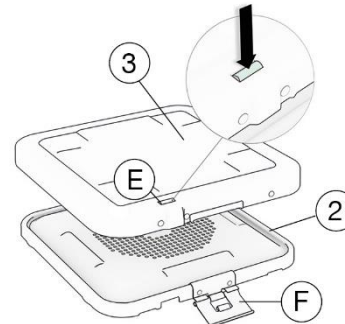
The following elements of the front panel are located on both sides of the container bottom.



### Front panel

- A = Handle
- B = Slot for indicator labels
- C = Locking device
- D = Slots for identification labels

### Container lid (2) and safety lid (3)



- E = Release button (safety lid)
- F = Latches (on both sides of the lid)

As required, safety lids (3) (PROSAFE containers) can additionally be placed on the container lids (2) of the ½, ¾ and 1/1 (BASIC containers) container systems. These protect against contamination during storage or transport of the containers.

**Note:** The sterilization containers are offered with colored lids. The color coding facilitates assignment to the individual specialties and departments.

### Removing and attaching the safety lid

1. Remove the safety lid (3) from the container lid (2) by pressing the release button (E).
2. Attach the safety lid (3) with the non-locking edge first, and then press the other edge onto the lid (2).

## Filter system

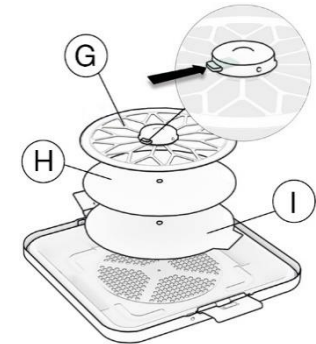


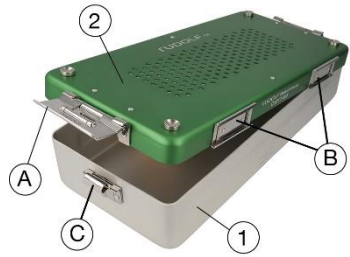
Figure: Container lid

- G = Filter holder with release button – suitable for paper and PTFE filters.
- H = Paper filter for single use
- I = Alternative: permanent filter (PTFE filter)

Filter holders (G) are located below/above the perforations in the container lid (2) and/or in the bottom (1). Before sterilization, new single-use paper filters or reusable filters (PTFE filters) must be inserted into these filter holders:

1. Release the lock of the filter holder (G) using the knob shown in the picture.
2. After the filter has been placed, put on the filter holder.
3. Lock the filter holder by applying pressure from the center. A click can be heard when the holder locks into place.
4. Make sure that the holder is properly locked.

## MINI CONTAINER SYSTEMS



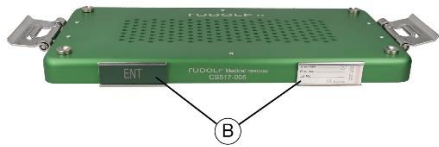
- 1 = Container bottom
- 2 = Container lid
- A = Latch (on both sides of the lid)
- B = Slots for indicator labels and identification labels
- C = Locking device

### Mini container bottom (1)

The container bottom has a locking device on each side and, depending on the design, a perforation for filter.

### Mini container lid (2)

The container lid has a latch on each side, slots for indicator and identification labels and, depending on the design, a perforation for filter.



**Note:** The sterilization containers are offered with colored lids. The color coding facilitates assignment to the individual specialties and departments.

## Filter system

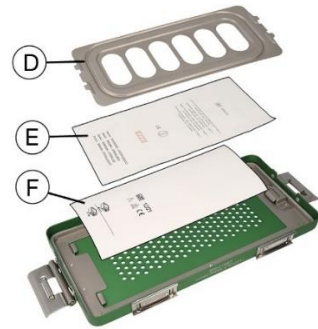


Figure: Removing the filter holder

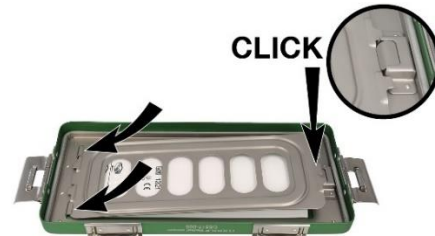


Figure: Attaching the filter holder

- D = Filter holder – suitable for paper and PTFE filters
- E = Paper filter for single use
- F = Alternative: Permanent filter (PTFE Filter)
- G = Locking button for filter holder

In the container lid (2) and/or in the bottom, there are filter holders above/below the perforations. Before sterilization, single-use paper filters or permanent filters (PTFE filters) must be inserted in these filter holders:

1. Press the locking button to remove the filter holder (D) and the filter.
2. After placing a paper filter (E) or alternately a permanent filter (F), position the filter holder (D) into the insert and lock the filter holder.
3. Lock the filter holder by pressing the filter holder (D) down from the outer rim towards the locking button (G). A click can be heard when the holder locks into place.
4. Make sure that the holder is properly locked.

## BOTH CONTAINER SYSTEMS



### Indicator labels for steam sterilization

The indicator labels are placed in the indicator slot (B) and are used to document the sterilized items:

- The included process indicator changes color during sterilization. The change in color (dark brown to black) provides afterwards a visual check as to whether a sterilization process has been completed.
- The indicator labels may only be used for the intended purpose. Failure to adhere to the instructions may falsify the result.
- If the indicator color changes only partially or not fully, the sterilization process must be repeated.
- Observe the shelf life of the labels according to the manufacturer's instructions (packaging label).

### Identification labels

To list the container contents, suitable identification labels with or without engraving / inscription are available. These identification labels can be inserted into the slots (D) of the front panel.



### Paper filter (H)

There is a chemical indicator (process indicator) on the single-use paper filter. This changes color during sterilization. The change in color (dark brown to black) provides afterwards a visual check as to whether a sterilization process has been completed:

- Paper filters are for single use only.
- Observe the shelf life of the paper filters according to the manufacturer's instructions (packaging label).
- Paper filters must not be marked or labeled, as this may compromise the microbial barrier.
- When inserting a new filter, make sure that it is free of damage, otherwise the sterility of the products cannot be guaranteed.
- The paper filters have the corresponding size and must be placed in such a way that the perforation of the container lid / bottom is completely covered.

### Reusable filter (I) (PTFE filter)

- PTFE filters are designed for multiple use (up to 1,200 reprocessing cycles).
- PTFE filters must not be labelled, as this may impair the microbial barrier.
- The indication of the first use and the expected expiration date may only be made on the labeling area specially printed outside the functional area on the filter, e.g., by using a pen with permanent ink (permanent marker), as otherwise the microbial barrier of the filter may be impaired.
- In case of coarse contamination, the filter must be removed and cleaned first manually, and then in the automated method.

- The PTFE filters must have the corresponding size as to completely cover the perforation in the container lid and bottom.



### Plastic security seals for single use

Figure: Container system

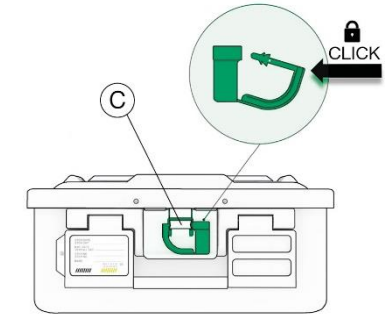
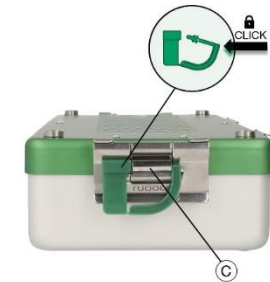


Figure: Mini container system



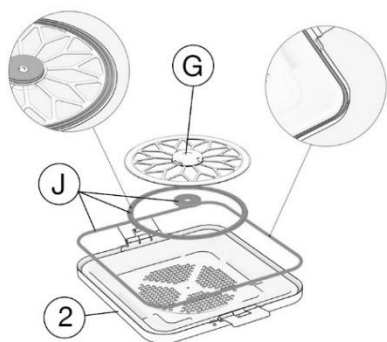
- Click = Locks
- C = Locking device

- Before sterilization, security seals must be inserted through the slots on the latches (C) on both sides outside the container.
- When flipping the latches, the security seals break.
- Broken security seals indicate an unauthorized opening of the container after sterilization.
- Containers where a security seal has been opened after sterilization must be sterilized again in order to rule out manipulation of the container or contamination of the contents.

### Silicone gaskets (J)

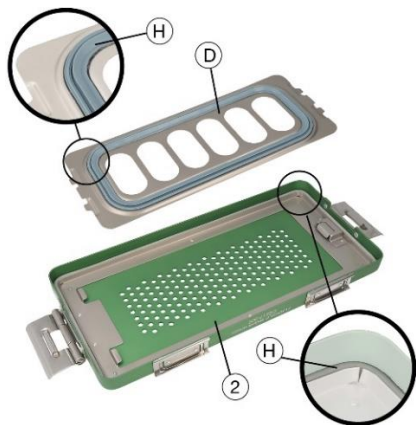
Both the container lid (2) and the filter holder (G) contain gaskets to maintain a biobarrier (microbial retention system) after the sterilization.

Figure: Container system



- 2 = Container lid
- G = Filter holder
- J = Silicone gaskets

Figure: Mini container system



- 2 = Container lid
- D = Filter holder
- H = Silicone gaskets

### Notes:

- The silicone gaskets may only be replaced by the manufacturer or authorized persons.
- The durability of the silicone gaskets is up to 500 sterilization cycles. After that, the gaskets must be checked carefully and replaced if necessary.

### Baskets

For each container size there are suitable stainless-steel baskets in various designs, heights and, if necessary, with matching lids.

### Silicone mats

The baskets are placed in the containers and can be additionally equipped with silicone mats.

### Handling tags

The stainless-steel handling tags can be attached to the baskets when returning the used instruments for reprocessing and thus serve an optimized logistics in the reprocessing cycle.

### POSSIBLE COMBINATIONS OF CONTAINERS AND ACCESSORIES

- The container systems are available in various designs and sizes.

### Container lid and bottom

The lids can be combined only with bottoms of the same container system, e.g., lid of container system 1/1 with the bottom of system 1/1.

### Containers and baskets

To select the right basket for a container, you need to consider the following points:

- Container and basket dimensions
- For the filter holder in the lid, at least 10mm must be subtracted from the internal dimension.
- For a container with perforation, at least another 3mm must be subtracted from the internal dimension for the filter holder in the bottom.
- For perforated bottoms, the basket should not rest on the filter holder.
- The maximum container loading according to these operating instructions must be observed.

### BEFORE EACH USE:

#### VISUAL AND FUNCTIONAL INSPECTION

All parts of the container must be checked for proper functioning and damage before each use:

- All parts are undamaged and not deformed. There must be no loose, bent, broken, cracked or worn parts.
- The surface of the container and its components must not have any cracks, fractures, wear & tear signs, burrs, discoloration, stains, rust or corrosion.
- Gaskets are placed on the lid and the filter holders. They are undamaged (without cracks) and are properly fitted.
- Filter holders and container locking devices are functional and audibly engage.
- There is no discoloration or damage on the surface coating of the anodized components of the container (bottom, lid).
- Damaged containers and their components may only be repaired by the manufacturer. Defective products must have gone through the entire reprocessing cycle before being returned for repair or complaint.
- Paper or PTFE filters are undamaged.
- Paper filters have been replaced.

- The PTFE filter was replaced after the maximum reprocessing cycles (1,200 cycles).
- The security seals are correctly attached before sterilization.

### REPROCESSING INSTRUCTIONS

#### Restrictions


- For the gravity method, use only containers with a lid and bottom perforation.
- For sterilization, use only containers that have either a lid perforation or a bottom perforation (both with filter system).
- Containers without a lid and bottom perforation (without filter system) that will be used for the handling of medical devices can only be used for the transport of medical devices and must not be sterilized when closed. Due to pressure/vacuum in the sterilizer, they may become deformed and thus unusable.
- The durability of the silicone gaskets is up to 500 sterilization cycles. After that, the silicone gaskets must be checked carefully and replaced if necessary.
- PTFE filters have been tested for a product life cycle of 1,200 reprocessing cycles and must be replaced thereafter.
- With regular maintenance, proper use, and compliance with the storage and maintenance requirements, the containers can be used for about 10 years.

#### Transportation

- The containers may only be transported using the handles.
- To avoid damage and resulting contamination to container parts or the load, we recommend that containers are always transported with the lid closed and, if necessary, with an additional safety lid.
- Filters must be protected against damage, especially perforations, during transport.

#### Preparation before cleaning

1. Separate the lid and the bottom from each other.
2. Remove the container contents (basket, instruments, etc.).
3. Remove the filter holders from the inside of the lid and, if applicable, remove the bottom part (for containers with bottom perforation).
4. Discard the paper filters or remove the PTFE filters, respectively.
5. Remove any security seals and indicator labels.
6. Rinse all parts under cold tap water to remove any coarse and visible contamination.

-  A temperature of 25°C for pre-cleaning must not be exceeded.
- Improper cleaning and disinfection can lead to corrosion and stress fracture. Therefore, the manufacturers' instructions for the cleaning and disinfection agents and for the cleaning and disinfection machines must be followed.

- Before first use and after each subsequent use, containers, baskets, handling tags, and silicone mats must be cleaned and disinfected.


#### Water quality

- Drinking water (tap water): Used for the first rinse and the intermediate rinse. Drinking water quality according to EC Directive 98/83/EC or AAMI TIR34
- Softened water: water hardening substances (calcium and magnesium cations) are reduced.
- Demineralized water: minerals are largely removed by one of the following methods:
  - Reverse osmosis
  - Cation and anion exchangers
  - Electrode ionization
  - Electrode distillation
- For steam sterilization and final rinsing of the cleaning process, threshold values for drinking water quality are specified in DIN EN 285 and DIN EN ISO 17665-1.

#### Manual cleaning/disinfection

##### Detergent

- For aluminum containers, mild and neutral cleaning agents must be used, if possible, or chemical products that have been expressly approved by manufacturers for the treatment of aluminum products. If necessary, the products must be tested for suitability with the appropriate method. Use only process chemicals that are suitable for anodized aluminum and stainless steel.
- Use alkaline cleaning agents (8.0 - 10.5 pH).
- If silicone products are immersed for too long in alkylamine-based disinfectants, this can lead to the hardening of the silicone.
- Cleaning agents with a disinfecting effect must comply with DIN EN 14885 or equivalent national guidelines.
- The cleaning solutions should be changed daily. If the solution is visibly dirty, it can be replaced earlier.

-  Never use metal brushes or metal sponges, as they can damage the surfaces and lead to loss of warranty.
- Make sure not to exceed the maximum permissible cleaning temperature of 45°C. Otherwise, denaturation of the proteins may occur.
- The following agents must **not** be used:
  - Chlorine solutions (saline solutions, bleach, Ringer's solution)
  - Protein-fixing cleaning solution containing aldehyde, phenol, and QUAT (quaternary ammonium compounds) with a disinfecting effect
  - Abrasive detergents

- In the case of permanent filters (PTFE filters), manual cleaning is carried out only in the event of severe contamination of the filter, otherwise automated cleaning is performed. The filter is removed from the container and cleaned carefully. Only cleaning agents approved by the hospital for containers and surgical

instruments are used. Information on concentration, temperature and contact time can be found in the instructions of the cleaning agent manufacturer.

1. Cleaning/pre-disinfection<sup>1</sup> (room temperature 15 - 26°C)
  - a) Pour 25ml of the enzymatic, pH-neutral detergent solution into 5 liters of water (tap water of drinking water quality). This corresponds to a 0.5% dilution.
  - b) Completely immerse the container components bottom, lid, and filter holder in the solution and shake gently to avoid air bubbles.
  - c) Operate all hinges and moving parts to ensure that the surfaces come into contact with the solution.
  - d) Remove all visible contamination while soaking the container components. For this purpose, use soft brushes and compressed air.
2. First rinse  
This must be done with water (tap water of drinking water quality) and a temperature of 1 - 16°C for a duration of 1 minute.
  - a) Remove the container components bottom, lid, and filter holder from the solution and rinse them with cold tap water for at least 1 minute.
  - b) Move all hinges and moving parts during the rinse.
  - c) Areas that are difficult to clean should be rinsed particularly thoroughly.
3. Disinfection<sup>1</sup> (room temperature 15 - 26°C)
  - a) Pour 125ml of disinfectant solution into 5 liters of water. This corresponds to a 2.5% dilution.
  - b) Completely immerse the container components bottom, lid, and filter holder in the disinfectant solution and allow them to soak for at least 10 minutes.
  - c) Operate all hinges and moving parts to ensure that the surfaces come into contact with the solution.
  - d) Remove any remaining visible soiling with a soft brush.
4. Final rinsing process (room temperature 15 - 26°C)  
The final rinsing process must be performed under running, demineralized water for a duration of 2 minutes at room temperature.
5. Drying (room temperature 15 - 26°C)
  - a) Dry the container components with a soft, clean, lint-free cloth and, if necessary, with compressed air.
  - b) Perform a visual and functional inspection of the container components according to the "MAINTENANCE, CONTROL, AND INSPECTION" section in these instructions. Take a closer look at hinges, joints, etc., as well as at places that are difficult to clean. If necessary, repeat the procedures.

<sup>1</sup>ANIOS ANIOSYME DD1 was used to verify the cleaning/disinfection.

### Automated cleaning and disinfection


#### Cleaning agent and machine

- Use alkaline cleaning agents (8.0 - 10.5 pH).
- Use a washer-disinfector (WD) that is validated according to DIN EN ISO 15883.
- Contamination that cannot be removed during the given cleaning process regardless of the method (adhesive labels, indicator strips, labels) can be removed with anode cleaners.
- Neutral or other suitable cleaning and disinfecting agents which have been expressly approved for the reprocessing of aluminum products must be used. The exact dose is to be taken from the manufacturer's specifications.
- When using neutralizers, their suitability for aluminum must be tested.
- It is essential that the cleaning machine and inserts are suitable for the reprocessing of containers and lids. This applies in particular to the proper loading of the inserts for sufficient and unhindered rinsing, media drainage and drying of the containers and lids.

#### Loading the WD

- Avoid overloading the WD to ensure that the surfaces of all container components come into contact with the detergent and disinfectant.
- Load the WD so that rinse residues cannot occur.
- Containers must not be cleaned and disinfected when closed.
- The container bottom must be placed in the WD with the opening facing downward to prevent the accumulation of water and to ensure adequate drainage of the media.
- The container lid must be cleaned with the inside down and the latches folded inwards.
- Arrange the containers in such a way that mechanical damage due to contact is prevented.
- When loading the WD, ensure sufficient media flow during the process.
- When cleaning the PTFE filter, make sure that the filter is cleaned outside the container and is not damaged during cleaning.

#### Unloading the WD

-  Unload the WD immediately after completing the procedure to avoid possible corrosion, but allow the products to cool to room temperature, as the container and instruments may still be too hot to touch.
- If residues can still be detected, the position of the containers and accessories in the machine must be checked and changed if necessary. In such cases, the cleaning and disinfection must be repeated.

### Recommended cleaning and disinfection procedure:

Phase	Temperature	Duration
1. Pre-cleaning with softened water*	< 25°C	2 min
2. Cleaning with demineralized water*	45 - 55°C	5 min
3. First rinse / neutralization** with fully demineralized water*	> 10°C	2 min
4. Intermediate rinsing with demineralized water*	> 10°C	2 min
5. Thermal disinfection/final rinse with fully demineralized water*	90°C	5 min
6. Drying***	--	--

\* See the "Water Quality" section in these instructions.

\*\* If a strongly alkaline cleaning solution is to be used, neutralization may be required.

\*\*\* Drying times vary depending on the loading capacity and must be observed according to the manufacturer's instructions.

#### Inspection

- At the end of each cleaning, disinfection and drying process, all container components, such as the bottom, lid, and filter holder, must be visually inspected for cleanliness, especially at hinges, joints and difficult-to-clean areas. If necessary, repeat the process.
- See the section "BEFORE EACH USE: VISUAL AND FUNCTIONAL INSPECTION" in these instructions.

#### Filter replacement

- Only one filter is used per filter holder.
- The paper filter must be changed before each new sterilization.
- PTFE filters have been tested for a service life of 1,200 reprocessing cycles and must then be replaced.

### MAINTENANCE, CONTROL, AND INSPECTION

#### Control and inspection

- See the section "BEFORE EACH USE: VISUAL AND FUNCTIONAL INSPECTION" in these instructions.
- Visually check for possible contamination such as blood residues. Only clean containers or their components may be further reprocessed and treated with a lubricant.
- Moving parts must be able to move freely without jamming or rubbing.
- Make sure that the components that are to be treated have been thoroughly cleaned beforehand. If dirt residues / liquids are still visible, repeat the cleaning and disinfection process.

#### Treatment with lubricant


-  The silicone gaskets of the containers (lids, filter holders) must not be treated with lubricants or solvents.
- The lubricant used must be a physiologically safe product that meets the requirements of DAB, Ph. Eur., USP-NF. This includes lubricants based on paraffin or white oil that are biocompatible and suitable for steam sterilization (steam permeability).
- Silicone-based lubricants must not be used.
- The national regulations must be observed before using a lubricant.
- Apply the lubricant directly to joints, hinges, and friction surfaces.
- Operate the moving parts a few times to distribute the lubricant evenly. If the moving parts are not sufficiently treated with a lubricant, this can lead to damage caused by friction and corrosion.
- Wipe off excess lubricant with a lint-free cloth.



Figure: Latch of the container lid

## STERILIZATION

- Only containers with either a lid or a bottom perforation (both with filter system) are to be used.
- Only damage-free container lids and bottoms with an undamaged silicone gasket and filter system are to be used for sterilization.
- If one of the above precautions or checks leads to a negative result and the safety or handling of the container system is impaired as a result, the container must no longer be used. In such cases, the components must either be replaced or repaired.

### Loading the container with instruments

- The maximum permissible load according to the manufacturer's specifications must not be exceeded.
- After loading the baskets with surgical instruments, they are placed in the container.

### Loading the container with cotton sterilization wraps (according to DIN 58953-9)

- The sterilization wraps are folded and are placed vertically in the container. They are not inserted too tightly. When the container is fully packed, it should still be possible to slide an outstretched hand between the folded sterilization wraps without difficulty.
- The container is loaded in such a way that its contents cannot impede the filter functionality. To achieve this, keep the required distance between the load and the lid.
- The sterilizer load must be placed so that the filter perforations of the containers are not covered. In doing so, a cavity between the placed packages must not exceed a distance of 45cm to ensure effective venting and steam penetration. Observe the loading instructions of the sterilizer manufacturer.
- Lock the container by placing the lid completely parallel to the container. Make sure that the lid rests correctly on the bottom.
- Heavy and larger containers should be placed as far down as possible in the sterilization chamber.
- In the case of a mixed loading consisting of containers and soft packaging, the containers should be placed under the absorbent materials so that condensate cannot build up.
- For sterilization, the containers can be easily and safely stacked on top of each other. Stacking is recommended only for the fractionated vacuum sterilization.
- Always hold the containers by their handles during loading.
- After sterilization, allow the containers to cool down to room temperature to avoid possible condensation.



- Containers must not have any additional packaging and must not be wrapped from the outside.
- According to DIN EN 868-8 and DIN 58953-9, the load weight of instruments in a full-size sterilization container (including the basket) must not exceed

10 kg in order to prevent condensation from forming and to ensure correct sterilization:

**Table: Loading the containers**

Model, loading capacity, height (mm)	Instruments, max. load in kg	Cotton sterilization wraps, max. load in kg
<b>Flat container</b>		
45	1,0	---
75	1,7	---
<b>½ Container</b>		
90	1,8	1,4
120	2,4	1,9
140	2,8	2,2
190	3,8	3,0
250	5,0	4,0
<b>¾ Container</b>		
90	2,9	2,3
120	3,9	3,1
140	4,5	3,6
190	6,1	4,9
250	8,0	6,4
<b>1/1 Container</b>		
90	3,6	2,9
120	4,8	3,8
140	5,6	4,5
190	7,6	6,1
250	10	8,0

**Table: Loading the mini containers**

Model, loading capacity, height (mm)	Instruments, max. load in kg
<b>Mini container</b>	
40	0.4
70	0.7
100	1.0



- During loading and unloading of the sterilizer as well as during transport, the sterilization container must always be carried by the handles and never by the lid.
- Never cover the perforation of the filter systems in the lid and the bottom with foil packaging or similar, as this will obstruct the flow of air and steam into the container. The result is vacuum-induced deformation of the container due to insufficient pressure equalization, so that the sterility of the container contents cannot be guaranteed.

- The sterilizers are validated according to DIN EN 13060 and DIN EN 285, respectively.
- The steam sterilization method (fractionated vacuum method) is validated according to ISO 17665-1.
- The RUDOLF Medical container systems have been validated with the following sterilization parameters:

Method:	3 x pre-vacuum steam sterilization
Temperature:	134 °C (273 °F)
Holding time:	5 minutes
Drying time:	20 minutes

## STORAGE

- Newly purchased products should be stored in a dust and moisture free environment.
- Containers containing sterile items should be stored in a designated area with limited access that is well ventilated and provides protection from dust, moisture, insects, and extreme temperature and humidity fluctuations.
- The containers maintain their sterility for 6 months under appropriate storage conditions. This has been tested according to DIN EN ISO 11607-1.
- For the storage duration of medical devices in sterilization containers, please refer to DIN 58953- 8. The storage duration usually depends on the storage conditions and must be determined by the responsible hygiene specialists.

### Storage conditions:

- Temperature: 15 - 26°C
- Humidity: 30 – 50%
- Air pressure: 500 - 1060 hPa

## SHELF LIFE OF THE CONTAINERS

Depending on the average intensity of use, regular maintenance, proper use, and the compliance of the storage and maintenance requirements the containers can be used for about 10 years.

## DISPOSAL

- Only after successful cleaning and disinfection may products be properly disposed of.
- If sharp edges formed, disposal must be carried out in such a way as to avoid endangering persons.
- Comply with national regulations and applicable hospital guidelines when disposing of or recycling the product or its components.

## REPAIRS / RETURNS

- If any damage is found on the containers, the containers must be inspected and repaired if necessary, or the containers must be replaced.
- Never carry out repairs yourself. Service and repairs may only be performed by instructed and qualified persons. Contact RUDOLF Medical or your medical technology department with any related questions.
- Defective products must have gone through the entire reprocessing cycle before being returned for repair.
- A decontamination certificate must be enclosed with the return shipment. A form for this purpose can be downloaded from the RUDOLF Medical website.

## PROBLEMS / INCIDENTS

- The user should report any problem related to RUDOLF Medical products to the respective distributor.
- In case of serious incidents with the products, the user must report them to RUDOLF Medical as the manufacturer and to the competent authority of the member state in which the user resides.

## WARRANTY

- The container system is made of high-quality materials and is subjected to strict quality control before delivery. In case of any discrepancies, please contact RUDOLF Medical.
- Repairs carried out by companies that are not authorized by RUDOLF Medical will void the warranty.
- Warranty period for containers: 2 years

## CONSUMABLES, SPARE PARTS AND ACCESSORIES

### Container systems

- CS950-000 Single use paper filters, Ø 19,0 CM/7 1/2", ½, ¾, 1/1 and flat containers
- CS950-006 Teflon filter F.1/1, 3/4 A.1/2 container ½, ¾, 1/1 and flat containers
- CS950-011 Universal filter holder for container systems ½, ¾, 1/1 and flat containers
- CS950-020 Indicator labels for container systems ½, ¾, 1/1 and flat containers, 1,000 pieces/package
- CS950-028 Seals, 1,000 pieces/package
- Baskets and other accessories upon request

### Mini container systems
















- CS950-002 Single-use paper filters for mini containers
- CS950-008 Teflon filter for mini container
- CS950-012 Filter holder (mount) for mini container
- CS950-025 Indicator labels for small container, 1.000 pieces/package
- CS950-028 Seals, 1.000 pieces/package
- Baskets and other accessories upon request

## APPLIED STANDARDS AND GUIDELINES

To ensure the safety of the containers during manufacture and handling, the following standards were taken into account:

- AAMI TIR34 - Water for the Reprocessing of Medical Devices
- DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers
- DIN EN 868-2 Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods
- DIN EN 868-8 Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
- DIN EN ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- DIN EN 13060 Small steam sterilizers
- DIN 58952-2 Sterilization - Transport baskets for sterile barrier systems - Part 2: Sterilizing baskets made of metal
- DIN 58952-3 Sterilization - Transport baskets for sterile barrier systems - Part 3: Instrument trays for sterilizing goods made of metal
- DIN 58953-8 Sterilization - Sterile supply - Part 8: Logistics of sterile medical devices
- DIN 58953-9 Sterilization - Sterile supply - Part 9: Use of sterilization container
- DIN EN 14885 Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics
- DIN EN ISO 15883 Washer-disinfectors
- DIN EN ISO 17664-1 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
- DIN EN ISO 17665-1 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- 98/83/EC: Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
- DAB - German Pharmacopoeia
- NF - National Formulary
- Ph. Eur. - European Pharmacopoeia
- USP - United States Pharmacopoeia

## SYMBOLS

	Consult instructions for use.
	Batch code
	Article no.
	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
	Do not re-use
	CE marking according to Medical Device Regulation (EU) 2017/745 (MDR)
	Temperature limit
	Keep dry
	Protect from sunlight
	Lubricate with silicon-free, biocompatible white medical oil approved for steam sterilization.
	Medical device