RUDOLF
BECAUSE WE CARE

INSTRUCTIONS FOR USE (EN)
STERILIZATION CONTAINERS INCLUDING MINI CONTAINERS

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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 and their accessories.

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

NON STERILE RUDOLF Medical sterilization container systems are supplied non-sterile and must be cleaned and disinfected 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.

Filters for RUDOLF Medical container systems are intended for a microbial barrier for steam sterilization. Two types of filters are used, paper filters with a process indicator for single use (disposable product) or PTFE filters for multiple use (reusable).

Indicator labels with process indicators are used to document production-relevant information for RUDOLF Medical container systems. The process indicators show the sterilization status. These are products for single use (disposable products).

Security seals (plastic, disposable product) for RUDOLF Medical container systems are used to make unauthorized opening visible.

Patient population: There are no restrictions concerning the patient population. It may be left to the discretion and experience of the medical professional to decide whether the benefit outweighs the risk in the given population.

For professional use only: The instruments are intended for use by the professional users only (surgeons, operating room nurses, medical device reprocessing technicians).

⚠ WARNINGS AND PRECAUTIONS

- The sterilization containers can only be used for steam sterilization. Other sterilization methods must not be used.
- For the gravity method, use only sterilization containers with a lid and bottom perforation.
- Sterilization 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 could become deformed and thus unusable.
- When opening the sterilization container make sure that the sterilized devices are not contaminated.
- Avoid damages to the sterilization containers and their accessories by improper handling.
- Use and combine only original RUDOLF Medical components such as lids, bottoms, gaskets, filters, filter holders, as well as security seals making sure that the sizes match each other. This is the only way to ensure the functionality and safety of the sterilization container. Otherwise, RUDOLF Medical will not accept any guarantee or warranty claims.

- There is a risk of infection when using worn-out sterilization containers (e.g., those with damaged gaskets). A proper visual and functional inspection before each use, carried out by trained personnel, reduces the likelihood of a damaged product being used to only a minimal residual risk. The procedure for the inspection is described in these instructions for use and is part of standard practice in everyday clinical settings.
- If the sterilization container comes into contact with instruments that have been used on patients with incurable infections such as CJD (Creutzfeldt-Jakob disease), hepatitis, HIV, possible variants of these infections, or suspected infections, the applicable national regulations regarding the disposal and reprocessing of the medical devices must be applied.
- Insufficient reprocessing can also result in a risk of infection.
- The sterilized content of a sterilization container must only be used for a single procedure und must be reprocessed afterward.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.

MATERIALS AND TECHNICAL DESCRIPTION

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

STERILIZATION CONTAINER SYSTEMS (without mini containers)

1 = Sterilization container bottom

2 = Sterilization container lid

3 = Safety lid

Figure: Example of the sterilization container system ½

Sterilization container bottom (1)

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

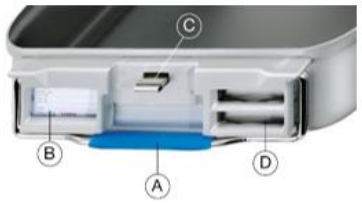
Front panel

A = Handle

B = Slot for indicator labels

C = Locking device

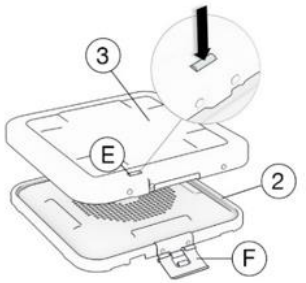
D = Slots for identification labels



Sterilization container lid (2) and safety lid (3)

E = Release button (safety lid)

F= Latch (on both sides of the lid)



Removing and attaching the sterilization container lid

1. To remove or attach the sterilization container lid (2), or to open or lock the sterilization container, place the sterilization container on a stable, level surface (table).
2. To remove the sterilization container lid (2), open both latches (F) fully, lift them from the sterilization container bottom (1), and then remove them.
3. To attach the sterilization container lid (2), first align it fully with the sterilization container bottom (1), place it on the top of the bottom, and lock it in with both latches (F).

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

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

Removing and attaching the safety lid

1. Remove the safety lid (3) from the sterilization 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

G = Filter holder with release button – suitable for paper and PTFE filters

H = Filter: paper filter for single use or PTFE filter (reusable)

Important: Always use only one filter type (paper filter or PTFE filer) at a time per sterilization container and only one filter per filter holder.

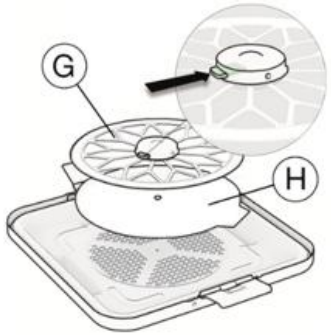


Figure: Sterilization container lid of system ½

In the sterilization container lid (2) and/or in the bottom (1), the filter holder (G) is above/below the perforations. Before the sterilization process, a single-use paper filter or a PTFE filter must be placed in this filter holder:

1. Release the lock of the filter holder (G) using the button shown in the figure above.
2. After inserting the filter, place the filter holder.
3. Lock in the filter holder by applying pressure from the center. You will hear a click when the filter holder locks into place.
4. Make sure that the filter holder is properly locked in place.

MINI CONTAINER SYSTEMS

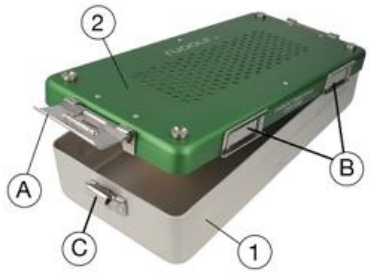
1 = Sterilization container bottom

2 = Sterilization container lid

A = Latch (on both sides of the lid)

B = Slots for indicator labels and identification labels

C = Locking device

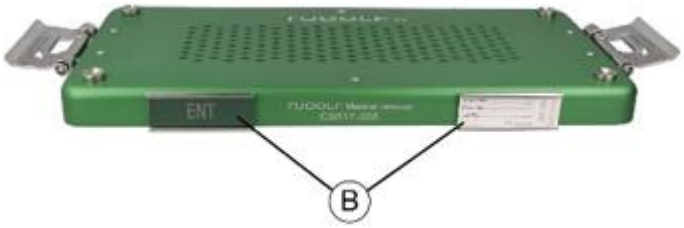


Mini container bottom (1)

The sterilization container bottom has a locking device (C) on both sides and, depending on the design, a perforation for a filter.

Mini container lid (2)

The sterilization container lid has a latch (A) on both sides, slots for indicator and identification labels (B) and, depending on the design, a perforation for a filter.



Removing and attaching the sterilization container lid

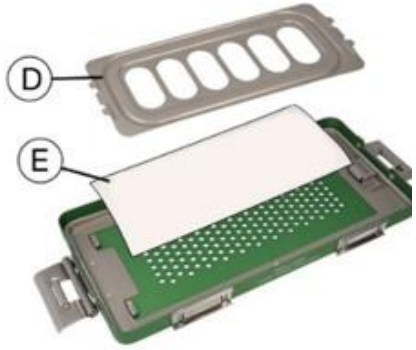
1. To remove or attach the sterilization container lid (2), or to open or lock the sterilization container, place the sterilization container on a stable, level surface (table).
2. To remove the sterilization container lid (2), open both latches (A) fully, lift them from the sterilization container bottom (1), and then remove them.
3. To attach the sterilization container lid (2), first align it fully with the sterilization container bottom (1), place it on the top of the bottom, and lock it in with both latches (A).

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

Filter system

D = Filter holder – suitable for paper filter or PTFE filter
E = Paper filter for single use or reusable PTFE filter
G = Locking button for the filter holder

Important: Always use only one filter type (paper filter or PTFE filter) at a time per sterilization container and only one filter per filter holder.



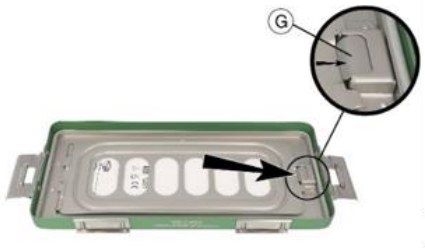


Figure: Removing the filter holder

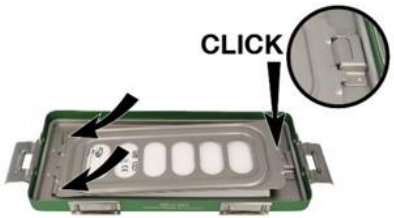


Figure: Attaching the filter holder

In the sterilization container lid (2) and/or in the bottom (1), there is the filter holder (G) above/below the perforations. Before the sterilization process, a single-use paper filter or a PTFE filter must be placed in this filter holder:

1. To remove the filter holder (D) and the filter, press the locking button (G).
2. Insert a paper filter or a PTFE filter, slide the folder holder (D) into the corresponding groove and lock in the filter holder.
3. Lock in the filter by pressing the filter holder (D) down from the outer edge towards the locking button. You will hear a click when the filter holder locks into place.
4. Make sure that the filter holder is properly locked in place.

BOTH STERILIZATION CONTAINER SYSTEMS

Indicator labels for steam sterilization

The indicator labels are placed in the indicator label slot and are used to document the sterilized items:

- The included process indicator changes color during sterilization. The change in color from yellow to dark brown/black provides afterwards a visual check as to whether a sterilization process has been completed.
- The indicator labels can only be used for the intended purpose. Failure to adhere to the instructions could falsify the result.
- If the indicator color has changed only partially or not fully, the sterilization process must be repeated.
- Note the shelf life of the indicator labels on the primary packaging label.

Identification labels

To label the sterilization container contents, suitable identification labels with or without engraving / inscription are available. These identification labels can be inserted into the corresponding slots.

Paper filter

A chemical indicator (process indicator) is on the single-use paper filter. It 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.
- Note the shelf life of the paper filters on the primary packaging label.
- Paper filters must not be marked or labeled, as this can 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 must have the corresponding size and must be placed in such a way that the perforation of the sterilization container lid / bottom is completely covered.

PTFE filter (reusable)

- PTFE filters are designed for multiple use (up to 2,000 reprocessing cycles).
- PTFE filters must not be labelled, as this can impair the microbial barrier.
- The date of the first use and the expected expiration date can only be written on the designated labeling fields outside the functional area of the filter, e.g., by using a waterproof marker (permanent marker), as otherwise the microbial barrier of the filter could be impaired.
- In case of coarse contamination on the filter, the filter must be removed and first cleaned manually and then in an automated cleaning process.
- The PTFE filter must have the corresponding size to completely cover the perforation in the sterilization container lid / bottom.

② Plastic security seals for single use

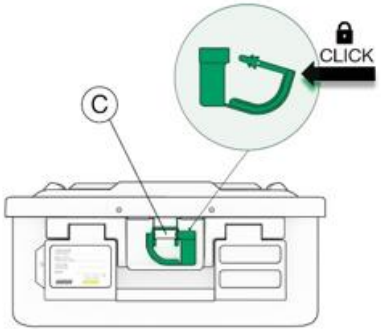


Figure: Sterilization container system

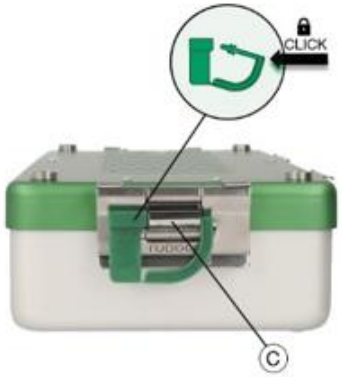


Figure: Mini sterilization container system

Click = Locking in
C = Locking device

- Before sterilization, attach the security seals outside on both locks by inserting them through the opening of the locking devices or spring locks (C), respectively, and then closing them.
- When the latches are flipped up, the security seals break.
- Broken security seals after sterilization indicate an unauthorized opening of the sterilization container. In such cases, sterilization must be repeated, because tampering with the sterilization container or contamination of its contents cannot be ruled out.

Silicone gaskets

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

2 = Sterilization container lid
G = Filter holder
J = Silicone gaskets

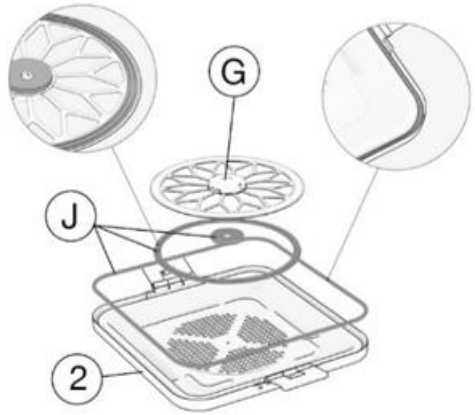


Figure: Sterilization container system

2 = Sterilization container lid
D = Filter holder
H = Silicone gaskets

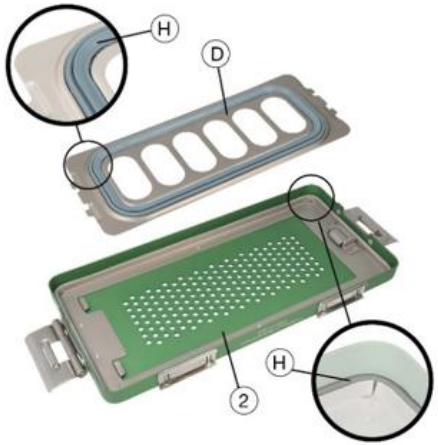


Figure: Mini sterilization container system

Notes:

- The silicone gaskets should only be replaced by the manufacturer or authorized personnel.
- When handled and maintained properly, the silicone gaskets can withstand up to 500 sterilization cycles. Before each sterilization, the gaskets must be carefully inspected and replaced if necessary to ensure proper sterilization.

Baskets

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

Silicone mats

The baskets are placed into the sterilization 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 optimized logistics in the reprocessing cycle.

POSSIBLE COMBINATIONS OF THE STERILIZATION CONTAINERS AND ACCESSORIES

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

Sterilization container lid and bottom

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

Sterilization containers and baskets

To select the suitable basket for a sterilization container, consider the following points:

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

PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION

After cleaning and disinfection, the sterilization container must undergo a visual and functional inspection according to these instructions for use before it is used again (loaded with items for sterilization). There is a risk of infection when using worn-out sterilization containers (e.g., those with damaged gaskets). A proper visual and functional inspection before each use, carried out by trained personnel, reduces the likelihood of a damaged product being used to only a minimal residual risk:

- All parts are undamaged and not deformed. There must be no loose, bent, broken, cracked or worn parts.
- The surface of the sterilization container and its components must not have any cracks, fractures, wear & tear signs, burrs, cutting edges, discoloration, stains, rust or corrosion.
- The gaskets in the lid and on the filter holders are present and undamaged (without cracks); they are also fitted properly.
- Filter holders and sterilization container locking devices are functional and audibly lock in.
- There is no discoloration or damage on the surface coating of the anodized components of the sterilization container (bottom, lid).
- Damaged sterilization containers and their components can only be repaired by the manufacturer. Defective products must have undergone the entire reprocessing cycle before being returned for repair or complaint.
- The paper or the PTFE filter, respectively, is undamaged.
- If a paper filter had been used, it has been replaced.
- If a PTFE filter has been used, it must be replaced after the maximum reprocessing cycles (2,000 cycles).
- The security seal is correctly attached before the sterilization process.

REPROCESSING INSTRUCTIONS

- Sterilization containers and their components must be cleaned and disinfected using a validated procedure.
- Automated cleaning / disinfection should be preferred to manual cleaning / disinfection, since automated processes can be standardized, reproduced, and thus validated.

Restrictions

- For the gravity method, use only sterilization containers with a lid and bottom perforation.
- For the sterilization, use only sterilization containers that have either a perforated lid or a perforated base (bottom); both must be equipped with a filter system.
- Sterilization 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 transportation of medical devices and must not be sterilized when closed. Due to pressure/vacuum in the sterilizer, they could become deformed and thus unusable.

- The silicone gaskets can withstand up to 500 sterilization cycles. If the silicone gaskets are used beyond that cycle number it is necessary to carefully inspect the gaskets, and when necessary, to replace them.
- PTFE filters have been tested for 2,000 reprocessing cycles and should be replaced after that number of usages.

Transportation

- Sterilization containers must be carried only by the handles intended for that purpose.
- To prevent damage and resulting contamination to parts of the sterilization containers or the contents, we recommend transporting the sterilization containers with the lid closed and, if necessary, with an additional safety lid. The safety lid is not available for the mini containers.
- Filters must be protected from all types of damage during transport, especially perforations.
- Sterilization containers must be transported in a horizontal position with as little shaking as possible.

Preparation before cleaning

1. Separate the lid and the bottom from each other.
2. Remove the sterilization container contents (basket, instruments, etc.).
3. Remove the filter holders from the inside of the lid and, if applicable, remove the bottom part (for sterilization containers with bottom perforation).
4. Discard the paper filter or remove the PTFE filter, 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, sterilization containers, baskets, handling tags, and silicone mats must be cleaned and disinfected.

Water quality

- Drinking water (tap water): Drinking water is used for the first rinse and the intermediate rinse. Drinking water quality is 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 sterilization containers, mild and neutral cleaning agents must be used. Chemical products that have been expressly approved by the manufacturers for the treatment of aluminum products can also be used. 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 alkalescent 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 disinfecting properties must comply with DIN EN 14885 or equivalent national guidelines.
- The cleaning solutions should be changed daily. If the solution is visibly dirty, it should be replaced earlier.
- ⚠ Never use metal brushes or metal sponges, as they can damage the surface and lead to loss of warranty.
- Make sure not to exceed the maximum permissible cleaning temperature of 45°C. Otherwise, denaturation of the proteins can 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 disinfecting properties
  - Abrasive detergents

- In the case of PTFE filters, manual cleaning is carried out only in situations where the filter is heavily contaminated; otherwise, automated cleaning is performed. The filter is removed from the sterilization container and cleaned carefully. Only cleaning agents approved by the hospital for sterilization containers and surgical instruments are used. Information on concentration, temperature and contact time can be found in the instructions of the cleaning agent manufacturer.
- ANIOS ANIOSYME DD1 was used to verify the cleaning/disinfection.

Cleaning/pre-disinfection (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 such as bottom, lid, and filter holder in the solution and shake the solution gently to avoid air bubbles.
c) Move 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.

1. First rinse

The first rinse must be done with water (tap water of drinking water quality) and at a temperature of 1 - 16°C for a duration of 1 minute.

a) Remove the sterilization container components such as 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.

2. Disinfection (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 sterilization container components such as bottom, lid, and filter holder in the disinfectant solution and let them soak for at least 10 minutes.
c) Move all hinges and moving parts to ensure that the surfaces come into contact with the solution.
d) Remove any remaining visible contamination with a soft brush.

3. 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.

4. Drying (room temperature 15 - 26°C)

a) Dry the sterilization container components with a soft, clean, lint-free cloth and, if necessary, with compressed air.
b) Perform a visual and functional inspection of the sterilization container components according to the "PRIOR TO EACH USE: VISUAL AND FUNCTIONAL INSPECTION" section in these instructions. Inspect closely hinges, joints, etc., as well as places that are difficult to clean. If necessary, repeat the procedures.

Automated cleaning and disinfection

Cleaning agent and machine

- Use alkalescent 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 sterilization containers and lids. This applies in particular to the proper loading of the inserts for sufficient and unhindered rinsing, fluid drainage and drying of the sterilization containers and lids.

Loading the washer-disinfector (WD)

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

Unloading the washer-disinfector (WD)

- ⚠ Unload the washer-disinfector immediately after the completion of the cleaning and disinfection process to avoid possible corrosion but allow the products to cool down to room temperature, since the sterilization container and instruments may still be too hot to touch.
- If there are still residues, the position of the sterilization 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

Step	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 could 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 sterilization 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 replaced before each new sterilization.
- The reusable PTFE filters must be removed, cleaned and disinfected for each reprocessing cycle and then inserted into the sterilization container prior to the sterilization process. They have been tested for 2,000 reprocessing cycles and should be replaced after that number of usages.

MAINTENANCE, CONTROL, AND INSPECTION

Control and inspection

- See the section "BEFORE EACH USE: VISUAL AND FUNCTIONAL INSPECTION" in these instructions.
- Check visually for possible contamination such as blood residues. Only clean sterilization containers and their components can 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 contamination / liquid residues are still visible, repeat the cleaning and disinfection process.

Treatment with a lubricant

⚠ **The treatment with a lubricant is after cleaning and disinfection and before sterilization.**

- ⚠ The silicone gaskets of the sterilization 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 damages caused by friction and corrosion.
- Wipe off excess lubricant with a lint-free cloth.

Figure: Latch of the sterilization container lid

STERILIZATION

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

Loading the sterilization container

- The maximum permissible load stated in these instructions for use must not be exceeded. If the sterilization container is loaded too densely or the loading weight is exceeded, the moisture cannot completely escape from the sterilization container. This results in residual moisture in the sterilization container so that sterility inside the sterilization container cannot be maintained.
- After loading the surgical instruments into the basket place the basket into the sterilization container.
- Cotton sterilization wraps can be used to facilitate improved drying or aseptic delivery. They do not constitute a sterile barrier system.
- When the sterilization container is loaded with cloth items, the folded cloth items should be placed upright into the sterilization container. The sterilization containers must be loaded in such a way that it is still possible to easily slide an outstretched hand between the cloth items.
- Load the sterilization containers in such a way that its contents do not impede the functionality of the filter. Keep the required distance between the load and the lid.
- Load the sterilizer in such a way that the perforation in the bottom / lid of the sterilization container is not covered. Also follow the sterilizer manufacturer's loading instructions.
- Lock the sterilization container by placing the lid parallelly on the bottom. Make sure that the lid is correctly placed on the bottom.
- Place heavier and larger sterilization containers as low as possible in the sterilizer.
- Due to their design, the sterilization containers can be stacked on top of one another easily and safely, and they will not slip during sterilization. Stacking is recommended only for sterilization cycles with a fractionated vacuum process.
- Always hold sterilization containers by their handles while loading.
- After sterilization, allow the sterilization containers to cool down to room temperature to avoid condensation built-up.
- ⚠ For sterilization, the outside of the sterilization containers must not be wrapped, because this would prevent steam circulation and thus damage the sterilization containers.
- According to DIN EN 868-8 and DIN 58953-9, the load weight with instruments in a full-size sterilization container (including the basket) must not exceed 10 kg in order to prevent condensation and to ensure correct sterilization:

Table: Loading the containers

Model, load capacity, height (mm)	Instruments, maximum load in kg	Cotton sterilization wraps, maximum load in kg
Flat container		
45	1.0	---
75	1.7	---
½ container		
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
¾ container		
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
1/1 container		
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, load capacity, height (mm)	Instruments, maximum load in kg
Mini container	
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 / the bottom, because this will impede the flow of air and steam in the sterilization container. The result is vacuum-induced deformation of the sterilization container due to insufficient pressure equalization, so that a sterility of the sterilization 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 sterilization 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.
- Sterilization containers containing sterile items should be stored in a designated are with limited access that is well ventilated and provides protection from contamination, dust, moisture, insects, and extreme temperature and humidity fluctuations.
- When opening the sterilization container make sure that the sterilized contents are not contaminated.
- For storage conditions of sterile medical devices, refer to DIN 58953-8. The storage duration of sterile medical devices usually depends on the storage conditions, the packaging, and the proper handling.
- The sterilization containers maintain their sterility under appropriate storage conditions:
    - 6 months when PTFE filters are used
    - 12 months when single-use paper filters are used

  This has been tested according to DIN EN ISO 11607-1.

Storage conditions:

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

SHELF LIFE OF THE STERILIZATION CONTAINERS

With proper use, adequate handling, and compliance to storage and care conditions, the sterilization containers can be used for about 10 years. It is also important to ensure that the product marking is legible.

DISPOSAL

- Only after successful cleaning and disinfection should the products be properly disposed of.
- If sharp edges have formed, disposal must be carried out in such a way as to prevent injury to 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 sterilization containers, the sterilization containers must be inspected and repaired if necessary, or the sterilization containers must be replaced.
- Never carry out repairs yourself. Service and repairs can only be performed by instructed and qualified personnel. Contact your medical technology department, your distributor or RUDOLF Medical with any related questions.
- Defective products must have gone through the entire reprocessing cycle before being returned for repair.
- A proof of decontamination must be enclosed with the return shipment. A form for this purpose can be downloaded from the RUDOLF Medical website.

PROBLEMS / EVENTS

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

WARRANTY

- The sterilization containers are made of high-quality materials and undergo strict quality control before delivery. If there are any discrepancies, please contact your respective distributor or 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

Sterilization container systems:

- CS950-000 Paper filters, single use for ½, ¾, 1/1 and flat containers
- CS950-006 PTFE filter (reusable), for container, Ø 19 CM-7 1/2", systems: 1/1, 3/4, 1/2, Flat, for a maximum of 2,000 cycles
- CS950-011 Filter holder, for container systems ½, ¾, 1/1 and Flat container
- CS950-020 Indicator labels for container systems ½, ¾, 1/1 and Flat container, 1,000 pieces/package
- CS950-028 Seals, 1,000 pieces/package
- Baskets and other accessories upon request

Mini container systems:

- CS950-002 Paper filters, single use for mini container systems
- CS950-008 PTFE filter (reusable) for mini containers, for a maximum of 2,000 cycles
- CS950-012 Filter holder for mini container systems
- CS950-025 Indicator labels for mini container systems, 1,000 pieces/package
- CS950-028 Seals, 1,000 pieces/package
- Baskets and other accessories upon request

APPLICABLE STANDARDS FOR THE REPROCESSING PROCEDURE

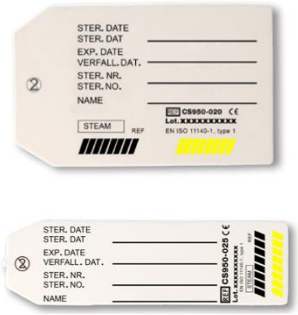
To ensure the safety of the sterilization containers during manufacturing and handling, the following standards were taken into account:

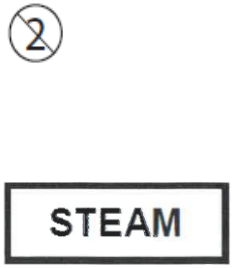
- AAMI TIR34 – Water for the Reprocessing of Medical Devices
- DIN EN 285 Sterilization - Steam sterilizers - Large sterilizers
- DIN EN 868-2 Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods
- DIN EN 868-8 Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods
- DIN EN ISO 11140-1 Sterilization of health care products - Chemical indicators - Part 1: General requirements
- 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 Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing
- 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 58953-6 Sterilization - Sterile supply - Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized
- DIN 58953-8 Sterilization - Sterile supply - Part 8: Logistics of sterile medical devices
- DIN 58953-9 Sterilization - Sterile supply - Part 9: Use of re-usable sterilization containers
- 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 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices, Parts 1 and 2
- 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.
LOT	Batch code
REF	Article no.
QTY	No. per package
	Non-sterile
	Caution
	Manufacturer
	Date of manufacture
	Do not re-use
CE	CE marking according to the Medical Device Regulation (EU) 2017/745 (MDR)
	Temperature limit
	Keep dry
	Keep away from sunlight
	Lubricate with silicone-free, biocompatible white oil approved for medical devices and steam sterilization.
UDI	Unique Device Identification
MD	Medical Device

TECHNICAL DATA SHEET FOR THE INDICATOR LABELS (EN)





PRODUCT DESCRIPTION

- CS950-020 Indicator labels for container systems ½, ¾, 1/1 and Flat container, 1,000 pieces/package; dimensions: 71mm x 38mm
- CS950-025 Indicator labels for mini container systems, 1,000 pieces/package; dimensions: 60mm x18mm

SPECIFICATIONS

Material	Properties
Paper	- Single use - Packaging unit: 1,000 pieces
Chemical indicator	- Specific gravity: 0.87 - Viscosity: 1075 cps - VOCs: 606 g/L - Water steam indicator, yellow - Chemical ink indicator of Type 1 - Initial color = yellow - Signal color = dark brown/black - Performance conditions: • 2 minutes ± 5s • 134°C / 273°F • Saturated steam
Sterilization method	Steam sterilization
Shelf life	24 months
Applicable standards	ISO 11140-1

TECHNICAL DATA SHEET FOR THE PAPER FILTERS (EN)

PRODUCT DESCRIPTION

- CS950-000 Paper filters, single use for container systems ½, ¾, 1/1 and Flat container; dimensions: 190mm
- CS950-002 Paper filters, single use for mini container systems; dimensions: 95mm x 215mm

SPECIFICATIONS

Material	Properties
Paper	- Single use - Packaging unit: 1,000 pieces
Chemical indicator	- Specific gravity: 0.87 - Viscosity: 1075 cps - VOCs: 606 g/L - Water steam indicator, yellow - Chemical ink indicator of Type 1 - Printing ink toxicity: No known significant effects or critical hazards - Initial color = yellow - Signal color = dark brown/black - Performance conditions: • 2 minutes ± 5s • 134°C /273 °F • Saturated steam
Sterilization method	Steam sterilization
Shelf life	24 months
Applicable standards	ISO 11140-1