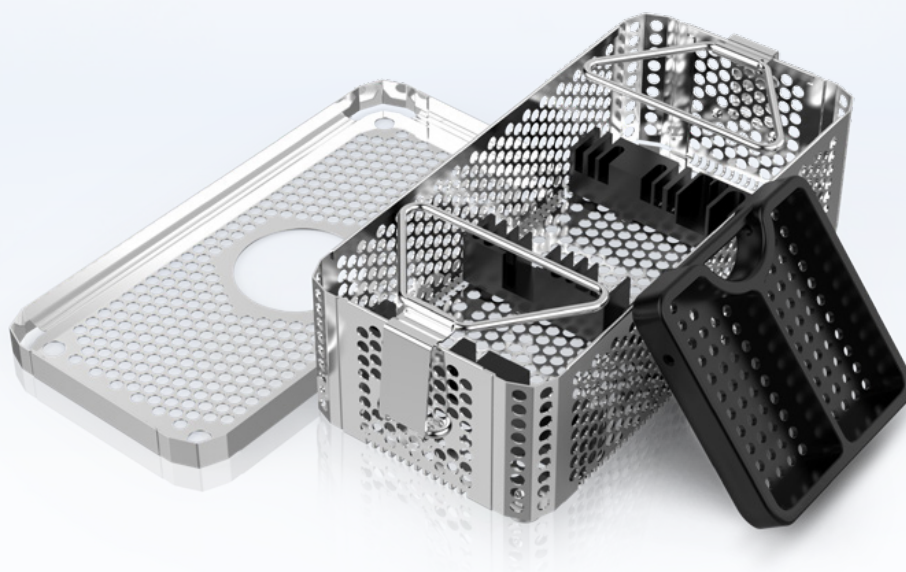


INSTRUCTION FOR USE

STERILIZATION OF CONTAINERS & TRAYS



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IMPORTANT NOTES



Before using the container, please read the instructions carefully. This will help you avoid damage caused by improper assembly or use, as there is no warranty claim for such damage.

SAFE USE



Before using the product, please make sure that all parts are working properly. Use the product according to the instructions for use and follow the safety and maintenance instructions. Never use faulty or damaged containers. Replace damaged parts with original spare parts. Never use other products together with AGOMED products.



- Improperly repaired containers do not ensure sufficient sterility of the contents. Inspect the container carefully before each use.
- The container and its accessories should only be used from qualified and experienced personnel.
- Filters, Filter holders and the silicone seals should be checked for damage and proper fit before each use.
- Keep the instructions for use available to personnel and store them in an easily accessible place.
- Handle the sterile material according to the general instructions for use of the material and aseptic principles.

PRODUCT DESCRIPTION

Intended use

The AGOMED container system is intended for sterilization and storage of instruments and textiles. Sterilization is performed by steam sterilization method according to ISO 17665. Sterilized materials are stored in the container after sterilization until the next use.

* Remark:

If you intend to use a different steam sterilization method for your container system, please contact your AGOMED representative.

Sterilization method

AGOMED's container systems comply with the following Standards: DIN EN 868-1, DIN EN 58953-9 and ISO 11607.

GENERAL INFORMATION FOR USE

First use

- Before first use, the container must be cleaned by hand or machine.
- After cleaning, suitable filters must be used. (We always recommend the use of original AGOMED filters).
- The filter system, which prevents the penetration of germs, is enclosed with every AGOMED container.

WORKING WITH STERILIZATION CONTAINERS

Assembly of the system

Removing the inner/outer lid If the outer lid (safety lid) has been used, it must be removed to clean the container.

To remove the outer and inner lids from the assembled container, proceed as follows:

- Remove the combined outer (1) and inner lid from the base (2).
- Release the lid lock (4) and remove the outer lid (1).

Cleaning and disinfection of the container

We recommend the following validated procedure for reprocessing our sterilization containers.

This applies to all anodized aluminum container parts and any accessories that are suitable for reprocessing.

Preparation for disinfection and cleaning

Containers should be disinfected and cleaned as soon as possible after use. Containers must be disassembled for cleaning. Contaminants should not dry on, so as not to make disinfection and cleaning even more difficult. Cleaning: Machine cleaning recommendation.

Preparation at the point of use:

Remove visible contamination with a soft brush and damp cloth. Do not allow contaminants such as blood to dry on. Remove contamination immediately or after 1 hour at the latest. If there is heavy soiling on cavities, crevices or slots (e.g. handle and hinges), these must be rinsed out and surrounded with a water pressure gun.

Manual pre-cleaning:

Rinse container in disassembled state under running, cold city water of drinking quality (<40°C) until all visible dirt is removed. Stubborn dirt should be removed with a soft brush (not a wire brush) and with a lint-free cloth soaked in water. Cavities, crevices and slots (at the handle and hinge) shall each be flushed intensively (>10 sec.) with cold city water (drinking water quality, <40°C) using a water pressure gun (or similar).

Mechanical cleaning:

A mechanical process (washer-disinfector) should be used for cleaning/disinfecting the containers. A manual procedure is not recommended due to the significantly lower effectiveness. Place containers in disassembled state in a sieve tray on the MIC trolley.

WD program parameters:

- 1 minute pre-cleaning with cold tap water, drinking water quality, <40°C.
- Emptying
- 3 minutes rinsing with cold tap water (< 40°C)
- Drainage
- 5 minutes cleaning with an enzymatic cleaner of 0.2 - 1 % neodisher® Medizym in tap water at 40 - 50°C
- Draining
- 3 minutes rinsing with tap water (< 40 °C)
- Drainage
- 2 minute rinse with demineralized cold water (<30°C)
- Draining

The specific instructions of the manufacturer of the washer-disinfector (RDG) must be followed.

Automatic disinfection:

Automatic thermal disinfection in washer-disinfector, considering A0- value 3000: 5 minutes at 93°C±2°C with deionized water.

Automatic drying:

Automatic drying according to automatic drying process of washer-disinfector for at least 30 minutes (device setting > 100°C). If necessary, subsequent manual drying with lint-free cloth and blowing out lumens using sterile, oil-free compressed air.

Validated procedures:

Manual pre-cleaning and mechanical process Equipment: basin, soft brush, lint-free cloths, water pressure gun.

Water temperature: < 40°C Cleaning agent: neodisher® Medizym 0.2%, 5 min. cleaning at 45°C WD Type: Miele G 7835 CD

Filter change

Depending on the type of filter used in the container, the filter should be changed as follows:

- Disposable filter: change before each sterilization.

- Textile filter: change after every 50 sterilizations.
- Remove the universal filter tensioner by continuously pressing the buttons (11).
- Insert a new filter (12) and mount the filter tensioner. Press the cap onto the universal filter tensioner (11) until it clicks into place.

Perform a visual inspection of all parts and record any damaged parts. Replace damaged parts or parts that do not function immediately with new spare parts.

SAFE USE

Filling the containers

Sterilization containers are filled in accordance with the DIN EN 868-8 and DIN 58953-9 standards. Accordingly, the recommended use capacities are as follows:

- 1/1 standard container: 10 kg
 - 3/4 container: 7 kg
 - 1/2 container: 5 kg
 - When placing the sterile items in the wire basket, please make sure to place the empty parts (with conical shape) downwards. These parts should be placed upside down and at a slight angle.
 - In the case of double packs of the sterilized items, the wire baskets are packed individually in accordance with DIN 58953-9.
 - When connecting the inner lid locks (6) to the container base (2), the locking pin should be visible.
- If the lock does not work, the container may be defective and you should contact your dealer.

Wipes

- Place the wipes in the container so that they can align themselves vertically in the container.
- Only fill the container so that one hand fits between the sterile items.

Placement of the label

- When filling the container, please note the sterilization date, sterilization no., expiry date, name and signature on the label (8).
- Put the label in place so that it fills the holders (7) on the sides of the lid lock.

Filling the sterilizers

- Place heavy containers on the bottom of the sterilizer.
- Stacked containers must not exceed a maximum stacking height of 60 cm.

- The air passage must not be blocked by materials such as aluminum foil. This applies to all container types.
- Stacked containers should not tip over. Therefore, hold them by the grab handles.
- Observe the operating instructions of the sterilizer Manufacturer.
- Perform steam sterilization in accordance with DIN EN ISO 17665-1.

Unloading the sterilizer

- Caution: Danger of burns, as the containers are hot immediately after sterilization. Are hot directly after sterilization.
- Always hold containers by the handles and wear gloves.
- Do not leave the containers, which are still hot directly after the sterilization process, in a drafty place or on a cold surface. In this case, the containers may become deformed as uniform cooling is not ensured.
- The storage of sterile containers is based on DIN 58953-9 standards.

Delivery and control of sterile materials

Sterile materials must be adequately sterilized in the container where they are stored until reuse after sterilization. Similarly, there is a risk of contamination if materials stored in the container have not been sterilized in a clean condition.

To avoid such problems, please observe the following:

- Ensure that the sterilization process has been carried out trouble-free before storing the sterile goods.
- Make sure that the color of the measuring display has changed before opening the sterilized container and that the seal of the display is undamaged.
- Make sure that all parts of the container, especially the lid locks, are working perfectly.

Storage of the sterile containers

- The storage period is maximum 6 months according to DIN 58953-9.
- Store sterile containers in a clean, dry and safe place.
- Sterile containers can be stored next to each other or on top of each other with a maximum stacking height of 60 cm.

MAINTENANCE

According to the DIN EN 868-8 standards, at least 500 sterilizations can be performed. This number of

sterilizations was determined by the service life of the seal in the container lid. However, if any damage is evident earlier, replace the damaged part or contact the AGOMED dealer.

TECHNICAL SERVICE

For service, maintenance or repairs, please contact your AGOMED representative. Any modification or correction to the containers and their accessories will void the warranty against our company.

SPECIFICATION

See container models and specifications.

APPLIED STANDARDS

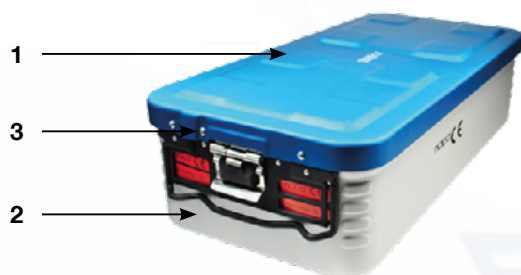
The following standards have been applied regarding sterilization containers:

- DIN 58953-9
- DIN EN ISO 11607
- EN 868-1
- EN 868-8
- DIN EN ISO 17665-1

Extract from DIN 58953-9 Storage times for sterile goods, deliveries of sterile goods.

Reasonable storage times are determined by the hygiene control committee. This time does not depend significantly on packaging, storage and transport. Reasonable storage times can therefore not be given in general terms. These must be checked by the user or the clinic management.

| Packaging of the sterile material | Type of packaging | Storage time |
|--|---|--------------|
| Sterile containers according to DIN EN 868-1 or DIN EN 868-8 Standards | Single or double packaging of sterile goods | 6 months |
| Remark: To ensure sterile use, the storage time of the sterile material should not exceed the time indicated on the container. Certain storage conditions, even under ideal conditions in dry, dust-free and normal temperature rooms, may increase the risk of contamination. Depending on the storage conditions, it is equally possible to store the sterile material for a longer period of time. | | |
| The use of an inner wrapper for double-wrapped sterile supplies represents an aseptically higher factor and is therefore recommended. | | |



1. Safety lid
2. Bottom
3. Lock of the safety lid
4. Lock of the safety lid
5. Inner lid
6. Lock of inner lid
7. Label holder
8. Label
9. Handle
10. Filter tensioner
11. Filter clamp fastening
12. Filter



SYMBOL EXPLANATION

REF Item number

LOT Batch designation

QTY Quantity

 Follow instructions for use

 Manufacturer

 Date of manufacture

 Conforms to the Medical Device Regulation (EU) 2017/745

