STERILISATION CONTAINER

USER MANUAL

Item no. 500613 ff. / 500710 ff.

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1. GENERAL DESCRIPTION

These aluminum containers are reusable, metal, sterilisation containers. They are designed for holding operating room instruments and/or textiles during vacuum-steam sterilisation procedures and for maintaining sterility during storage and transport under proper hospital conditions. Sterilisation containers consist of three main parts such lid, bottom and filter retainers. The sterilisation containers should be handled by qualified personnel that are trained and instructed about sterilisation containers, hospital hygiene and sterilisation technology, in order to prevent damage to the containers, fasteners, seals and sterilisation filters, during usage. This user manual describes important instructions on the proper usage and maintenance of aluminum containers and possible hazards that could result from failure to observe the instructions.

Endoscopes, instruments with lumen, compressed air driven instruments or power systems and canalised instruments should be prepared and sterilised according to manufacturer's instructions. Container lids are offered in several different colors in order to ease identification of the instruments that are used by different departments in hospitals. The colored identification labels that are used with containers provides information about the content and where these instruments are used in.

2. FILTER SYSTEM

The aluminum containers are available with a perforated bottom and lid. They are designed to be used with single use (disposable) filters, reusable textile filters (500500, 500510) or PTFE filters (500511). It is necessary to use same type of filters during usage of the containers. In case of use of filters, which are not supplied from EICKEMEYER®, the user must validate the permeability and barrier properties of the filters himself.

Filters:

- Disposable single use paper sterilisation filters have to be changed before each new sterilisation.
- Long-tem textile filters can be used for about 45 – 50 sterilisation cycles. Visually deformed and dirty textile filters should not be used.
- Permanent filters (PTFE) can be used for over 1,000 sterilisation cycles. During storage after sterilisation, in order to prevent damage (puncture, tear) to sterilisation filters, sharp and pointed objects should not be placed on the containers. We recommend usage of safety lids on the containers during transportation and the storage of the containers in order to prevent contamination risks that may be caused by such negative situations.

3. CONTROL BEFORE USAGE

During storage, usage of metal sterilisation containers is safer than other storage method of sterile materials regard to protection against contamination. Like all reusable equipment, however, the aluminum containers though robust also need to be treated with care in order to ensure that their protective qualities are preserved. The relevant staff must therefore be familiar with the correct handling practices.

Caution!

Careless handling or the use of inappropriate chemicals can cause damage on the containers, thereby putting at risk the ability to attain and preserve sterility. The containers therefore require regular visual and, if necessary, functional checks. If pre-cautions and the instructions in the user manual are followed, containers may serve for 1,000 sterilisation cycles and seals may serve for 500 sterilisation cycles.

Undamaged shape:

- Containers must be checked visually before each usage.
- Container bottoms, container lids and the surfaces where the seal is must be free of dents and visible deformations.
- Do not use any spray, oil or solvents on the lid seals.
- The seal in the inner lid must be completely inserted and undamaged. If any kind of damage detected lids should not be used.
- When the container is closed, tray, lid and locking parts have to be stable (no “wobble”).
- Maintenance and repairs of the sterilisation containers must be carried out by qualified staff. Do not attempt to carry out repairs on containers, lids, fasteners and seals yourself, in order not to jeopardise the safety in use of the containers.

Filters and Filter Retainers

These parts must show no visual deformations. These parts must also be checked visually and for their functionality before usage. Filters should cover all the perforation holes properly. Filter retainers should function properly when mechanically checked and filter retainers should be easily attachable and detachable. After any accident (such as a container being dropped on the ground), it is essential that the sterile container undergoes a thorough check. Make sure that filters and filter retainers are placed in to their places properly. “Click” sound that is heard while placing filter retainers by pressing on them indicates that locking is realised.

4. SAFETY SEAL

It is recommended that containers are sealed in such a way as to prevent inadvertent opening of containers and to ensure that it is evident whether or not a container has been opened. The containers can be protected by disposable plastic seals (“security seals”), which, once attached, can be opened by breaking only.

5. INTERNAL PACKING

We recommend using the containers with simple internal packaging (e. g. cloth wraps or drip sheets). These assist the final drying stage, allow a longer storage period and makes aseptic presentation of the sterile goods possible. The size of the cloth wraps should be calculated so that when they are unfolded all the external walls of the container can be covered. As an alternative to reusable cloths, easily wrapable (non-woven) disposable materials can also be used. In internal packing case we recommend, corner of the package materials should be fixed with the adhesive tape. In this way the package cannot then open during sterilisation and block the inlet and outlet filter holes of the container and raised flow pressure won't damage the container. Because of the problem associated with folding, the use of sterilisation paper is not recommended. In order to prevent colors leaching and thereby staining the containers, non-colored materials (or in the case of green or blue cloths, previously washed sheets) should be used.

Caution!

Never sterilise the container wrapped in additional packaging. Apart from the risk of lack of sterility, the increased flow resistance could impair the sterilisation effect (non-sterility) or even destroy the container.

6. STERILISATION

Operational Limits

In order to ensure that the lid can close properly, sterilisation containers must not be filled above the level of the lower ridge of the edge indentation on the container buttoms. The lid must lie flat on the lower section without being forced and so that it does not wobble even when the clasps are open. It must also be possible to close the clasps without additional pressure on the lid. In the case of instrument sterilisation, the load weight (including perforated tray) should not exceed 10 kg for 1/1 size containers. Load weigh should be 5 kg for 1/2 size containers and smaller loads should be arranged for smaller containers.

With cloth loads (or similar), the load weight should not exceed 7 – 8 kg. Make sure that folded textile or cloth loads are placed horizontally in containers. When using internal packaging (non-woven or cloth), care should be taken that the correct closing of the lid is not impeded, for example, by a protruding corner of the packaging.
In order to prevent damage to the parts of the container and/or its load, we recommend that the container should be transported with its lid closed whenever possible.

Caution!

There is a risk of non-sterility if protruding cloth corners prevent the container from closing correctly.
If the sterilisation procedure causes sterilisation containers to become deformed in any way, there is no guarantee of sterility. In such cases, the entire batch must not be used, they should be sterilised again and an investigation should be started to determine the cause.

Placing into Sterilisers

Sterilisation containers are made for use in general steam sterilisers. Make sure that heavier containers are placed at the bottom of the sterilisation chamber first. Our aluminum containers were designed that they can be stacked during sterilisation. In order to prevent accidents and mechanical damages on the containers it is important to work very carefully with the stacked containers. To prevent condensation collecting on one side (and thus causing drying problems), the containers should be placed horizontally in the steriliser. The loading instructions of the steriliser manufacturer should also be observed.

Indicators

We recommend use of information cards with chemical sterilisation indicators in the outer holding frame of the containers.

Caution!

If chemical sterilisation indicators are not used, then other organisational measures should be taken to ensure validation of the sterilisation and non-sterile-containers being used (released) by mistake.

7. AFTER STERILISATION

To safeguard against accidents (burns, dropping, etc.), containers that are still hot should never be handled with bare hands. The containers should not be cooled to room temperature too rapidly (e. g. do not place on cold surfaces or expose to a cold draught), as excessively rapid external cooling can lead to recondensation of the water vapour inside the container with an unwanted accumulation of condensation.

8. STORAGE/TRANSPORTATION

In practice sterility can be maintained for unlimited period with proper packaging, during storage in controled hospital storage room conditions temperature, humidity, air filtration etc. Acceptable storage period should be determined by responsible hygiene staff.
Legal requirements and suggestions should be taken under consideration while determining storage time and storage conditions. Depending upon storage duration and conditions, however, external contamination occurs, and this represents a potential risk during subsequent use, transport and aseptic presentation. This risk factor can be reduced by the following measures:

- The use of internal packaging.
- Storage under dust protected conditions.
- Containers with internal packaging, protected storage up to 6 months
- Containers with internal packaging, unprotected storage up to 6 weeks
- Containers without internal packaging, protected storage up to 6 weeks
- Containers without internal packaging, unprotected storage use “as soon as possible”

Special Cases

When storing or transporting sterile containers under non-standard conditions (e. g. in case of getting sterilisation service for containers from places such as central sterilistion departments), then internal packaging and transport packaging should be used to reduce the contamination risks that are associated with outer environment conditions.

Aseptic Presentation

If containers are to be opened after a long period of storage or after storage under non-ideal conditions, then we recommend wiping the unperforated cover with a disinfectant before handling in order to minimise the risk of contamination by air-borne particles.

9. CLEANING AND DISINFECTION

Users have to specify by means of a disinfection and cleaning plan, when and how the sterilisation containers have to be cleaned and/or disinfected.
Containers used for waste disposal have to be cleaned and disinfected each time after use.
Cleaning materials should be suitable to available water quality in hand.

Manual Cleaning

Only use neutral cleaners or neutral cleaners and disinfectants for cleaning.
Do not use metal brushes or cleaning materials that may cause chemical or physical corrosions.
All part must be rinsed with demineralised water without leaving any stain or residue on them and dried by hand and stored.

Mechanical Cleaning

Mechanical cleaning of the containers is to be preferred to manual cleaning.
Cleaning of the containers with machines is only recommended if the washing machine has a special washing program for aluminum containers.
Only use neutral cleaners or neutral cleaners and disinfectants for cleaning. Do not use any cleaning solutions that contains soda or caustic soda.
Do not use additional acidic neutralisers.
Observe the instructions of the manufacturer of neutral cleaners and disinfectants for cleaning aluminum containers.
Use demineralised water for final rinsing since salt in the water may cause spotting during subsequent sterilisations.
Cleaning (washing) machine has to be designed for cleaning sterilisation containers. This applies in particular to ensure secure replacement in the washing baskets and the arrangement of the spray jets or arms.
Remove the lids and filter retainers before cleaning the containers and clean them individually.

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