GIMA
PROFESSIONAL MEDICAL PRODUCTS

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CONTENITORI PER LA STERILIZZAZIONE
STERILIZATION CONTAINER SYSTEM
RÉCIPIENTS DE STÉRILISATION
CONTENEDORES DE ESTERILIZACIÓN

Manuale d'uso - User Manual
Notice d'utilisation - Manual del usuario

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*

ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*

AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*

ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*

CE

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VALIDITY

These instructions of use are valid for all GIMA aluminium sterilizing containers and accessories, sold by GIMA. GIMA aluminium sterilizing containers and accessories are in compliance with its current catalog.

DESCRIPTION

GIMA aluminium containers are reusable, metal, sterilization containers. They are designed for holding operating room instruments and/or textiles during vacuum-steam sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions. (EN 285, EN 868-1, EN 868-8). Sterilization containers consist of three main parts such lid, bottom and filter retainers. The sterilization containers should be handled by qualified personnel who are trained and instructed about sterilization containers, hospital hygiene and sterilization technology, in order to prevent damage to the containers, fasteners, seals and sterilization filters, during usage.
This user manual describes important instructions on the proper usage and maintenance of GIMA aluminium 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 canalized instruments should be prepared and sterilized according to manufacturer's instructions. Container lids are offered in six 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.

FILTER SYSTEM

GIMA aluminium containers are available with an unperforated base and perforated filter lid or with perforated bottom and lid (can be covered by an unperforated lid). They are designed to be used with single use (disposable) filters or reusable textile filters. It's necessary to use same type of filters during usage of the containers. In case of use of filters, which are not supplied from GIMA, the user must validate the permeability and barrier properties of the filters himself.

Filters:
Disposable single use paper sterilization filters have to be changed before each new sterilization.
Long-term textile filters can be used for about 45-50 sterilization cycles. Visually deformed and dirty textile should not be used. Permanent filters (PTFE) can be used for over 1000 sterilization cycle.

During storage after sterilization, in order to prevent damage (puncture, tear) to sterilization filters, sharp and pointed objects should not be placed on the containers. GIMA recommends 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.

CONTROL BEFORE USAGE

During storage, usage of metal sterilization containers is safer than other storage method of sterile materials in regards to protection against contamination. Like all reusable equipment, GIMA aluminium containers needs to be treated with care in order to ensure that their protective qualities are preserved. The relevant personnel (including delivery and collection services) 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. GIMA aluminium containers therefore require regular visual and, if necessary, functional checks. If cautions and the instructions in the user manual are followed, containers may serve for 1000 sterilization cycles and seals may serve for 500 sterilization cycles.

Undamaged shape:

- Containers must be checked visually before each usage.
- Container bottoms, container lids and the surfaces where the seals sit 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 is 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 sterilization containers must be carried out by qualified personnel. Do not attempt to carry out repairs on containers lids, fasteners and seals yourself, in order not to jeopardize 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. Filters 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 undergo a thorough check.

Make sure that filters and filter retainers are placed into their places

properly. A “Click” sound that is heard while placing filter retainers by pressing on them indicates that locking is realized.

SAFETY SEAL

It is recommended and required by DIN 58953-9 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. GIMA aluminium containers can be protected by disposable plastic seals (“security seals”), which, once attached, can be opened by breaking only.

INTERNAL PACKING

We recommend using GIMA aluminium containers with simple internal packaging (e.g. cloth wraps or drip sheets). These assist the final drying stage, allow a longer storage period according to DIN58953-9, and makes aseptic preservation 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 cloth, easily wrap able (non-woven) disposable materials can also be used. In internal packing case, we recommend to fix the corners of package materials with adhesive tape. In this way the package cannot then open during sterilization 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 sterilization 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 sterilize the container wrapped in additional packaging. Apart from the risk of lack of sterility, the increased flow resistance could impair the sterilization effect (non-sterility) or even destroy the container.

STERILIZATION OPERATIONAL LIMITS

- In order to ensure that the lid can close properly, sterilization containers must not be filled above the level of the lower ridge of the edge indentation on the container bottoms. 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 sterilization, the load weight (including perforated tray) should not exceed 10 kg for 1/1 size containers. Load weight should be 5 kg for ½ size containers

and smaller loads should be arranged for smaller containers (DIN 58953-9).
- 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 (DIN 58953-9). When using internal packaging (nonwoven 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.

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

PLACING INTO STERILIZERS

Sterilization containers are made for use in general steam sterilizers (EN 285). Make sure that heavier containers are placed at the bottom of the sterilization chamber first. The design of GIMA aluminium containers allows them to be stacked during sterilization. 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 sterilizer. The loading instructions of the sterilizer should also be observed.

DATA CARDS / INDICATORS

We recommend use of information cards with chemical sterilization indicators in the outer holding frame of the containers (DIN58953-9).
CAUTION: If chemical sterilization indicators are not used, then other organizational measures should be taken to ensure validation of the sterilization and non-sterile containers being used (released) by mistake.

AFTER STERILIZATION

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.

STORAGE / TRANSPORTATION

In practice sterility can be maintained for an unlimited period with proper packaging, during storage in controlled hospital storage room conditions (temperature, humidity, air filtration etc.). The acceptable storage period should be determined by responsible hygiene personnel.
Requirements and suggestions of DIN58953-9 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. According to DIN 58953/9 this risk factor can be reduced by the following measures:

- The use of internal packaging.
- Storage under dust protected conditions. The recommendations of DIN 58953-9 on limitation of storage period.
- 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 sterilization service for containers from places such as central sterilization 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 minimize the risk of contamination by air-borne particles.

CLEANING AND DISINFECTION

Requirements according to DIN 58953-9:

- Users have to specify by means of a disinfection and cleaning plan, when and how the sterilization 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 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 demineralized water without leaving any stain or residue on them and dried by hand and stored.

MECHANICAL CLEANING

- Mechanical cleaning of the containers is preferred to manual cleaning.
- Cleaning of the containers with machines is recommended only if the washing machine has a special washing program for aluminium containers.
- Only use neutral cleaners or neutral disinfectants for cleaning. Do not use any cleaning solutions that contain soda or caustic soda.
- Do not use additional acidic neutralizers.
- Observe the instructions of the manufacturer of neutral cleaners and disinfectants for cleaning aluminium containers.
- Use demineralized water for final rinsing since salt in the water may cause spotting during subsequent sterilizations.
- Cleaning (washing) machine has to be designed for cleaning sterilization 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.

GIMA WARRANTY CONDITIONS

Congratulations for purchasing a GIMA product.This product meets high qualitative standards both as regards the material and the production.
The warranty is valid for 12 months from the date of supply of GIMA.
During the period of validity of the warranty, GIMA will repair and/or replace free of charge all the defected parts due to production reasons.
Labor costs and personnel traveling expenses and packaging not included.
All components subject to wear are not included in the warranty.
The repair or replacement performed during the warranty period shall not extend the warranty. The warranty is void in the following cases: repairs performed by unauthorized personnel or with non-original spare parts, defects caused by negligence or incorrect use. GIMA cannot be held responsible for malfunctioning on electronic devices or software due to outside agents such as: voltage changes, electro-magnetic elds, radio interferences, etc. The warranty is void if the above regulations are not observed and if the serial code (if available) has been removed, cancelled or changed.
The defected products must be returned only to the dealer the product was purchased from. Products sent to GIMA will be rejected.