GIMA
PROFESSIONAL MEDICAL PRODUCTS

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.*

- È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.
- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.
- Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.
- Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

GIMA	REF	GIMA	REF	GIMA	REF	GIMA	REF	GIMA	REF
37000	CAK-10-001	**37052**	CAO-15-001	**37110**	CAB-10-003	**37180**	CAK-B-10-014	**37243**	CAO-B-20-014
37001	CAK-13-001	**37053**	CAO-20-001	**37112**	CAB-15-003	**37181**	CAK-B-13-014	**37250**	CAB-B-10-001
37002	CAK-15-001	**37060**	CAO-10-003	**37130**	CAB-10-014	**37182**	CAK-B-15-014	**37251**	CAB-B-13-001
37003	CAK-20-001	**37062**	CAO-15-003	**37131**	CAB-13-014	**37183**	CAK-B-20-014	**37252**	CAB-B-15-001
37004	CAK-26-001	**37080**	CAO-10-014	**37132**	CAB-15-014	**37200**	CAO-B-10-001	**37253**	CAB-B-20-001
37010	CAK-10-003	**37081**	CAO-13-014	**37133**	CAB-20-014	**37201**	CAO-B-13-001	**37254**	CAB-B-26-001
37012	CAK-15-003	**37082**	CAO-15-014	**37150**	CAK-B-10-001	**37202**	CAO-B-15-001	**37260**	CAB-B-10-003
37030	CAK-10-014	**37083**	CAO-20-014	**37151**	CAK-B-13-001	**37203**	CAO-B-20-001	**37262**	CAB-B-15-003
37031	CAK-13-014	**37100**	CAB-10-001	**37152**	CAK-B-15-001	**37210**	CAO-B-10-003	**37280**	CAB-B-10-014
37032	CAK-15-014	**37101**	CAB-13-001	**37153**	CAK-B-20-001	**37212**	CAO-B-15-003	**37281**	CAB-B-13-014
37033	CAK-20-014	**37102**	CAB-15-001	**37154**	CAK-B-26-001	**37240**	CAO-B-10-014	**37282**	CAB-B-15-014
37050	CAO-10-001	**37103**	CAB-20-001	**37160**	CAK-B-10-003	**37241**	CAO-B-13-014	**37283**	CAB-B-20-014
37051	CAO-13-001	**37104**	CAB-26-001	**37162**	CAK-B-15-003	**37242**	CAO-B-15-014		

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ENGLISH

INSTRUCTION OF USE FOR CEYLAN ALUMINUM STERILISING CONTAINERS AND ACCESSORIES

These instructions of use are valid for all CEYLAN Aluminum Sterilizing Containers and accessories CEYLAN Aluminum Sterilizing Containers and accessories are incompliance with its current catalog. CEYLAN declares that above mentioned products are manufactured in its Quality Management System which has been created in compliance with ISO 13485 and ISO 9001 and under scopes of the standards declares own responsibility.

1. DESCRIPTION

CEYLAN Aluminum 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 are consist of three main parts such lid, bottom and filter retainers. The sterilization containers should be handled by qualified personnel that 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 CEYLAN 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 7 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

CEYLAN Aluminum Containers are available with a unperforated base and perforated filter lid or with perforated bottom and lid (can be covered by a 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 CEYLAN, 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 100-150 sterilization cycles.Visually deformed and dirty textile filters 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. CEYLAN recommendes usage of safety lids on the containers during transportaion 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 sterilization containers is safer than other storage method of steril materials regard to protection against contamination. Like all reusable equipment, however, the CEYLAN Aluminum Containers tough robust also needs to be treated with care in order to ensure that its 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. CEYLAN Aluminum Containers therefore require regular visual and, if necessary, functional checks. If cautions and the instructions in the user manual is followed, containers may serve for 1000 sterilization cycle 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 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 sterilizations containers must be carried out by qualified personnel. Do not atempt 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 in to their places properly. “Click” sound that is heard while placing filter retainers by pressing on them indicates that locking is realized.

4. 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. CEYLAN Aluminum 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 CEYLAN Aluminum 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 DIN 58953/9, and makes aseptic presentation of the strile 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 wrap able (non- woven) disposable materials can also be used. In internal packing case we recommend, corner of the package materials should be fix with the 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.

6. 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 claps are open. It must also be possible to close the claps 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 5kg for 1/2 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.

- 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.

7. PLACING INTO STERILIZERS

Serilization 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. Ceylan aluminum containers were designed that they can 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 manufacturer should aslo be observed. Sterilization Containers should be used at maximum 134 degrees. The duration of sterilization should be between 90 and 110 minutes.

8.DATA CARDS / INDICATORS
We recommend use of information cards with chemical sterilization
indicators in the outer holding frame of the containers (DIN58953/9).

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.

10. 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.

11. 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. controled). Acceptable storage period should be determined by responsible hygiene personnel. Requirments and suggestions of DIN 58953- 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”

12. 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.

13. 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.

14. CLEANING AND DISINFECTION
Requirments 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 shoul be suitable to available water quality in hand.

Manual Cleaning
- Only use neutral cleners 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 prefered 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 cleners or neutral cleaners and disinfectants for cleaning. Do not use any cleaning solutions that contains soda or caustic soda.
- Do not use additional acidic neutralizers.
- 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 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 TERMS
The Gima 12-month standard B2B warranty applies

Indice dei simboli - Symbol index - Index des symboles - Índice de símbolos

	**IT -** Data di fabbricazione **GB -** Date of manufacture **FR -** Date de fabrication **ES -** Fecha de fabricación
	**IT -** Fabbricante **GB -** Manufacturer **FR -** Fabricant **ES -** Fabricante
	**IT -** Dispositivo medico **GB -** Medical Device **FR -** Dispositif médical **ES -** Producto sanitario
	**IT -** Numero di lotto **GB -** Lot number **FR -** Numéro de lot **ES -** Número de lote
	**IT -** Codice prodotto **GB -** Product code **FR -** Code produit **ES -** Código producto
	**IT -** Dispositivo medico conforme al regolamento (UE) 2017/745 **GB -** Medical Device compliant with Regulation (EU) 2017/745 **FR -** Dispositif médical conforme au règlement (UE) 2017/745 **ES -** Producto sanitario conforme con el reglamento (UE) 2017/745
	**IT -** Identificatore univoco del dispositivo **GB -** Unique device identifier **FR -** Identifiant unique de l'appareil **ES -** Identificador de dispositivo único **PT -** Identificador exclusivo do dispositivo
	**IT -** Leggere le istruzioni per l'uso **GB -** Consult instructions for use **FR -** Consulter les instructions d'utilisation **ES -** Consultar las instrucciones de uso
	**IT -** Attenzione - Leggere e seguire attentamente le istruzioni (avvertenze) per l'uso **GB -** Caution - read instructions (warnings) carefully **FR -** Attention - lisez attentivement les instructions (avertissements) **ES -** Precaución - lea las instrucciones (advertencias) cuidadosamente
	**IT -** Distribuito da **GB -** Distributed by **FR -** Distribué par **ES -** Distribuido por