



GIMA

PROFESSIONAL MEDICAL PRODUCTS

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

Manuale d'uso - User Manual - Notice d'utilisation - Manual del usuario - Benutzerhandbuch - Manual de utilizare

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. - **VORSICHT:** Bediener müssen dieses Handbuch vollständig lesen und verstehen, bevor sie das Produkt verwenden. **ATENȚIE:** Operatorii trebuie să citească și să înțeleagă complet acest manual înainte de a utiliza produsul.

- 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.
- Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.
- Orice accident grav produs, privitor la dispozitivul medical fabricat de firma noastră, trebuie semnalat producătorului și autorității competente în statul membru pe teritoriul căruia își are sediul utilizatorul.

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Fatma Ceylan - Ceylan Medikal İmalat İthalat İhracat Dış Ticaret
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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 in compliance 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 consist of three main parts such as 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 provide 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 cycles. 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 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.

3. CONTROL BEFORE USAGE

During storage, usage of metal sterilization containers is safer than other storage methods of sterile materials regard to protection against contamination. Like all reusable equipment, however, the CEYLAN Aluminum Containers too robust also need 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 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 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. 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 undergo a thorough check. Make sure that filters and filter retainers are placed in 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 make 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 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 5 kg 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

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. 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 also 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 (DIN 58953/9).

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 controlled hospital storage room conditions (temperature, humidity, air filtration etc. controlled). Acceptable storage period should be determined by responsible hygiene personnel. Requirements 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

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 or neutral cleaners and disinfectants for cleaning.
- Do not use metal brushes or cleaning materials that may cause chemical or physical corruptions.
- 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 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

IT - Indice dei simboli GB - Symbol index FR - Index des symboles
ES - Índice de símbolos DE - Symbolindex RO - Index de simboluri

	IT - Data di fabbricazione GB - Date of manufacture FR - Date de fabrication ES - Fecha de fabricación DE - Herstellungsdatum RO - Data fabricației
	IT - Fabbricante GB - Manufacturer FR - Fabricant ES - Fabricante DE - Hersteller RO - Producător
	IT - Dispositivo medico GB - Medical Device FR - Dispositif médical ES - Producto sanitario DE - Medizinprodukt RO - Dispozitiv medical
	IT - Numero di lotto GB - Lot number FR - Numéro de lot ES - Número de lote DE - Chargennummer RO - Număr de lot
	IT - Codice prodotto GB - Product code FR - Code produit ES - Código producto DE - Erzeugniscode RO - Cod produs
	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 DE - Medizinprodukt im Sinne der Verordnung (EU) 2017/745 RO - Dispozitiv medical conform regulamentului (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 DE - Unique Device Identifier (Eindeutige Kennung des Geräts) RO - Identificatorul unic al dispozitivului
	IT - Leggere le istruzioni per l'uso GB - Consult instructions for use FR - Consulter les instructions d'utilisation ES - Consultar las instrucciones de uso DE - Gebrauchsanweisung beachten RO - Citiți instrucțiunile de utilizare
	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 DE - Achtung - Anweisungen (Warnungen) sorgfältig lesen RO - Atenție - Citiți și respectați cu atenție instrucțiunile (avertismentele) de utilizare
	IT - Importato da GB - Imported by FR - Importé par ES - Importado por DE - Eingeführt von RO - Importat de



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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 5 kg 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

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. 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 also 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 (DIN 58953/9).

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 controlled hospital storage room conditions (temperature, humidity, air filtration etc. controlled). Acceptable storage period should be determined by responsible hygiene personnel. Requirements 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

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 or neutral cleaners and disinfectants for cleaning.
- Do not use metal brushes or cleaning materials that may cause chemical or physical corruptions.
- 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 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

IT - Indice dei simboli GB - Symbol index FR - Index des symboles
ES - Índice de símbolos DE - Symbolindex RO - Index de simboluri

	IT - Data di fabbricazione GB - Date of manufacture FR - Date de fabrication ES - Fecha de fabricación DE - Herstellungsdatum RO - Data fabricației
	IT - Fabbricante GB - Manufacturer FR - Fabricant ES - Fabricante DE - Hersteller RO - Producător
	IT - Dispositivo medico GB - Medical Device FR - Dispositif médical ES - Producto sanitario DE - Medizinprodukt RO - Dispozitiv medical
	IT - Numero di lotto GB - Lot number FR - Numéro de lot ES - Número de lote DE - Chargennummer RO - Număr de lot
	IT - Codice prodotto GB - Product code FR - Code produit ES - Código producto DE - Erzeugniscode RO - Cod produs
	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 DE - Medizinprodukt im Sinne der Verordnung (EU) 2017/745 RO - Dispozitiv medical conform regulamentului (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 DE - Unique Device Identifier (Eindeutige Kennung des Geräts) RO - Identificatorul unic al dispozitivului
	IT - Leggere le istruzioni per l'uso GB - Consult instructions for use FR - Consulter les instructions d'utilisation ES - Consultar las instrucciones de uso DE - Gebrauchsanweisung beachten RO - Citiți instrucțiunile de utilizare
	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 DE - Achtung - Anweisungen (Warnungen) sorgfältig lesen RO - Atenție - Citiți și respectați cu atenție instrucțiunile (avertismentele) de utilizare
	IT - Importato da GB - Imported by FR - Importé par ES - Importado por DE - Eingeführt von RO - Importat de