










 Kent Surgical Industries L.L.C Plot No.12, 54th Street, Companies Camp, Al Ain, Abu Dhabi, United Arab Emirates	This IFU Cover The following products: (SCF01600300), (SCF01460300), and (SCF01300300).	Ph.: +971 3 753 2555 Email: support@kentsurgical.com Website: www.kentsurgical.com
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Symbols Using in Labeling:

Symbol	Symbol Title	Description of symbol
	Catalogue number	Indicates the manufacturer's catalogue number.
	Consult instructions for use.	Indicates the need for the user to consult the instructions for use.
	Date of manufacture	Indicates the date when the medical device was manufactured.
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	Caution	Indicates that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Manufacturer	Indicates the medical device manufacturer.
	Batch code	Indicates the manufacturer's batch code.
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Keep dry	Indicates a medical device that needs to be protected from moisture.

	<p>Keep away from sunlight</p>	<p>Indicates a medical device that needs protection from sunlight.</p>
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Intend of use for Sterilization Aluminum Container with Filters of Kent Surgical®:

- Container for Steam Sterilization, transport, storage, and provision of sterile goods.

Loading information:

External dimensions (mm)			Max. load gross weights (Kg.)	
Length	Width	Height	Metal load	Textile load
600	300	160	6,2	4,6
460	300	160	4,7	3,5
300	300	160	3,1	2,3

Table (1)

Product Specification:

- **MATERIAL**
This range of containers is mainly constructed in soft anodized* Aluminum. Its chief characteristics are its lightweight and its excellent thermal conductivity capacity.

*SOFT ANODIZING:
Anodizing is a treatment process commonly used to harden the surface of the Aluminum to render it resistant to steam.
- **BODY RIM:**
The upper border of the body is rounded to give an increased strength to this part which has to ensure the seal against the gasket.
- **CLOSING LEVERS:**
The levers for closing are in stainless steel AISI 304-18/10 and guarantee an easy and secure opening and closing the container ensuring a contamination-free removal of the cover. To open the container, simply pull the levers upwards bringing them into a horizontal position, and raise the cover.
- **SLOT FOR THE SEAL:**
The opening levers have a slot to be used with the disposable seals to demonstrate that the container has been opened.
The seal is an accessory for the container (to be ordered separately).

- **IDENTIFICATION OF THE CONTAINER:**

To ensure the easy and rapid identification of the containers, there is the possibility of inserting in the specific label holders two Aluminum tickets where it is possible to engrave, for example, the section owning the container and its contents.

It is also possible to apply to the dedicated label holder a ticket on disposable paper where can be written the date, the name of the operator, and other information that may be useful for the organization.

- **HANDLES:**

Each container has two handles for carrying. These handles are in stainless steel AISI 304-18/10 partly covered by a silicone tube. The handles and their attachment system are strong enough to support a load of 50 kg.

- **UNION JOINTS:**

Every part (handles, closures, label carriers, etc.) is attached to the container using riveting, and these rivets are in stainless steel AISI 303.

This riveting confers a powerful mechanical union and an air-tight sealed joint.

- **FILTER BLOCK WITH GASKET:**

The attachment system for the filter is equipped with a gasket in silicone that allows for the use of either disposable paper filters or reusable ones. The filter block is made of hard anodized aluminum and stainless steel.

- **SYSTEM OF ATTACHMENT OF THE FILTERS:**

The system of attachment of the filters has been designed to make replacement of the filter rapid and safe, and further, the filter locks are easily removed for cleaning and checking.

General Safety Information:

- Read and follow these instructions and keep them accessible to the staff working with the device.
- Before using the containers for the first time, it is advised to run a sterilization cycle with the container being empty or to execute a complete cleaning process.
- All Containers must be cleaned, disinfected, and sterilized each time they are used; this also applies particularly to the first time they are used after delivery, as all containers are supplied unsterile.
- Effective cleaning and disinfection are an indispensable prerequisite for effective sterilization.
- For a secure seal use only original filters from **Kent Surgical®**.
- When using containers, please ensure that, as part of your responsibility for the sterility of products, only methods for cleaning/disinfection and sterilization, which have been adequately validated for the equipment and products, are implemented, that the equipment

used (washer-disinfector, sterilizer) is regularly maintained and tested, and that the validated parameters are maintained for each cycle.

- Please observe the legal regulations applicable in your country and the hygiene regulations of the medical practice or hospital.
- The sterilization parameters are only valid for devices that are adequately cleaned.
- The products must be used exclusively for the intended purpose by appropriately trained and qualified personnel.
- Visually inspect the containers before use.
- The following information is only valid for properly installed, maintained, calibrated, and compliant reprocessing equipment.
- The user and/or patient should report any serious incident that has occurred about the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Warning:

- Do not use steel wool, wire brushes, or abrasive cleaners.
- Possible danger to the life of patient, user, and third parties if these Instructions for Use are not observed.
- Possible danger to the life of others by shipping contaminated products.
- In case of return shipments, send only clean and disinfected products in sterile packaging.
- Non-sterile handling can result in danger to the life of the patient. Products supplied in non-sterile condition must be cleaned, disinfected, and sterilized before the first application.

Limits On Reprocessing:

- Repeated processing cycles that include mechanical washing, and sterilization have minimal effect on **Kent Surgical**® containers.

Preparation:

- Containers are reusable and must be cleaned and disinfected before initial use and subsequent reuse.

Instructions For Use:

- **REPLACING THE FILTER:**

To change the filter, proceed as follows:

1. Tighten the wings that hold the filter block and lift;
2. take the worn filter off
3. position the new one
4. close the filter block inserting it in its guides and pushing it down with your fingers positioned on the written instruction PUSH until you hear the four locks close; For perfect air-proof quality, the filter must protrude beyond the perimeter of the gasket.

Kent Surgical® only guarantees the air-proof quality of its containers if the original **Kent Surgical®** filters are used.



- **LOADING:**

Position the load inside the container in such a way as to have sufficient space for the ingress and the circulation of the steam. In the case of a metallic load, we recommend the use of metallic mesh baskets with corresponding accessories for subdivisions and blocking the instruments.

Do not exceed the maximum weights recommended in proportion to the dimensions of the container (see Table 1).

The containers can be stacked one on another.

- **SAFETY:**

Fix the seals to the closure and set the disposable paper labels with their chemical indicator in place in the seating provided.

- **STERILISATION:**

Load the container into the sterilization chamber.

If the load in the sterilizer is formed of more than one container, ensure that these have been inserted correctly, to consent steam movement between them.

If the sterilizer's load is formed of paper packages or envelopes ensure that these packages do not block or cover the inlets of steam to the inside of the containers.

It is important to adhere to the table of loading weights given in Table 1.

- **INSTRUCTIONS FOR A CORRECT DRYING OF THE LOAD:**

- a. **SOME ADVICE FOR THE LOAD:**

- 1. Respect the maximum allowed loads for the used container size (see Table 1).

- Do not forget that your equipment has been planned and verified concerning these maximum loads.

- Excessive loading could interfere with the drying performance of your autoclave.

- 2. Arrange the load uniformly, avoiding, if possible, the overlapping of big quantities of instruments.

- 3. Do not place the load directly in contact with the container bottom. The use of an inner basket allows better steam circulation and drying.

- 4. If possible, load the containers into the autoclave, close the door, and wait 5 minutes before starting the sterilization cycle. This procedure limits the development of condensation during the whole sterilization cycle.

- b. **CONTROLS AND ADVICE ON CONTAINER USE:**

- 1. Carefully choose the container according to the allowed load height (see Table 1), avoiding keeping too much free space in the container. Generally, the load should be included between 50% and 90% of the useful height, to allow adequate steam circulation and avoid an excessive presence of a moist atmosphere at the end of the drying phase.

- 2. Avoid the immediate positioning of the processed containers with direct contact with a wide cold surface. In this case, use rack shelves. This measure facilitates the reduction of the condensation effects.

- 3. If possible, let the containers cool down into the autoclave, possibly by slightly opening its drain door. This procedure avoids the formation of condensation due to the thermal leap that occurs during the discharging phase.

- c. **STORAGE AND MAINTAINING OF STERILITY:**

- Store the containers (as well as any kind of packages) in a clean and possibly dust-proof place, to reduce risks of contamination. It is possible to establish that a container can maintain sterility for up to 6 months when the following recommendations are respected:

- 1. The atmosphere of the storage room is dust-free;
 2. The storage room must have its temperature, humidity, and pressure controlled;
 3. The surfaces of the storage room must be smooth and easy to disinfect;
 4. The shelves must have their first bottom shelf at least 30cm above floor level;

5. The air channels must be controlled regularly;
6. All instructions for use maintenance, and cleaning, supplied by the makers must be followed carefully.

d. TRANSPORT:

We suggest the use of dust-proof trolleys, to avoid any risk of contamination.

e. OPENING:

Before opening a container, ensure that the container has been processed checking the disposable chemical indicator labels, and by verifying that the microbial barrier has not been broken checking the integrity of the seal.

Service Life

- **Lifetime of the Container:**

The lifetime of the container is better than 2,000 cycles if the container is used correctly and remains undamaged.

- **Lifetime of the Gasket for the Cover:**

The gasket for the covering lid has a working life of 2,000 cycles, although it is recommended anyway to replace it at least every 5 years, or every time any defect may be detected. This lifetime is only guaranteed on condition that the container is used correctly and that the gasket has not been damaged.

- **Lifetime of the Filter Block:**

The filter block has a working life exceeding 2,000 cycles, providing that the container is used correctly and is undamaged. The filter block and its gasket lifetime are higher than 2000 cycles. Such a lifetime is only granted if the filter block correctly works and the gasket is not damaged.

- **Lifetime of The Filters:**

The filters in Medical-grade paper are to be used once only, the filters in cotton are to be changed every 70 cycles, the filters in synthetic cloth are to be changed every 200 cycles, the filters in PTFE have a lifetime of 2.000 cycles.

It is found that the cleanliness of the material to be sterilized and the quality of the steam can adversely affect the lifetime of these filters.

Inspections:

- **Inspecting the Gasket of the Covering Lid:**

Each time the container is used the following items are to be checked:

1. That there are no tears in the gasket.

2. That the gasket is sufficiently flexible and elastic.
- **Inspection of the Filter Holder Gasket:**
Before proceeding to any sterilization cycle, you must control the following points:
 1. That there is no cut on the gasket;
 2. That the elasticity of the gasket is sufficient;
 3. That the gasket is not broken or disconnected.
 - **Inspection of the Position of the Filter:**
Before every sterilizing process check the following items:
 1. That the filter lies outside the borders of the gasket to make a perfect seal
 2. That it is positioned correctly
 3. That there are no tears or creases.
 4. That it has not been used previously if it is a single-use filter or if it has not exceeded the number of cycles allotted.
 - **Locks Inspection:**
Every time the container has to be processed you should check the following points:
 1. The pressure generated by the closure is sufficient to compress the gasket.
 2. The lock levers sufficiently oppose the force supplied in the opening.

Procedure For Cleaning:

The Single-use filters must be removed before the start of the washing operation.

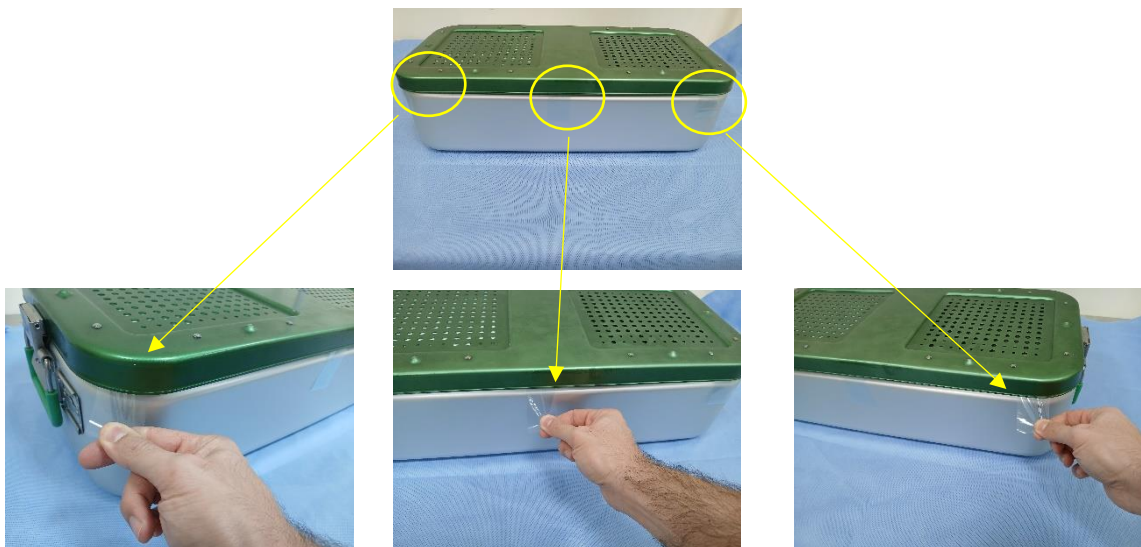
- Do not use detergents or disinfectants containing organic solvents, oxidizing agents, or sodium compounds.
- Use only **products with a neutral pH value (pH7-8)** for cleaning the container and rinse out abundantly with demineralized water being careful to remove all washing residues. Any detergent not in the range above (pH7-8) can cause serious damage to the surface of the container and will not be covered in the Warranty.
- While using or during washing avoid all contact with detergents, disinfectants, or other liquids containing chlorides or soda because these attack stainless steel and aluminum, in the event of any contact, immediate rinsing is recommended.
- **Washing and contact with alkaline detergents may damage the containers in aluminum, if it is impossible to avoid this, make a preliminary test for compatibility.**
- Do not use abrasive sponges that may damage the surface of the container.
- The gaskets and the filter blocks can be cleaned with alcohol-soaked cotton flock.
- Do not apply adhesive tape to the containers.

Maintenance:

- **Locking Levers Lubrication:**
Periodically lubricate locking levers with the same oil used for instrument lubrication, this procedure has to be performed after the washing cycle.
- **Replacing the Gasket of the Cover:**
The gasket of the cover must be substituted every time it becomes damaged or whenever it loses its elastic quality. This replacement is to be performed only by **Kent Surgical®** and/or by authorized persons.
- **Tightness Test:**
To verify the gasket has been correctly replaced and to check the container's tightness, carry out the following simple test:
Place some strips of paper and/or cellophane, about 3cm wide, on the edge of the container (in the middle and on the corners). Place the lid on the container and close it, then pull the strips gently.

If resistance is met it means the container edge matches the lid properly and tightness is assured, whereas if they come away easily the gasket must be repositioned.

It is however advisable that the replacement and the "tightness test" be performed by skilled and/or **Kent Surgical®** authorized personnel.



Substitution of the Filter Block:

The filter block must be substituted or repaired each time that:

- The gasket is damaged or disconnected.
- The locking pins do not close sufficiently.
- It has exceeded its lifetime.

We recommend that product maintenance and performance validation of the container be done every 2000 cycles or 5 years whichever comes first by **Kent Surgical**® Industries to continue our guarantee of maintenance of sterilization.

Disposal:

- For disposal, country-specific laws and regulations must be observed.

Guarantee:

Kent Surgical® guarantees its containers for one (1) year against any manufacturing defects or failure of their components, according to the judgment of **Kent Surgical**®, not due to misusage on the part of the operators. The guarantee does not cover items subject to wear and repairs or replacements carried out by persons not authorized by **Kent Surgical**®.

The **Kent Surgical**® company reserves the right to apply upgrade modifications to its products without pre-warning.