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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 Teflon 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 OF THE LID:

The lid is in stainless steel AISI 304-18/10, which has a superior resistance to wear and to corrosion, thus ensuring that the product has a prolonged life.

- **MATERIAL OF THE BODY:**

The body is constructed in Aluminum, soft anodized*, 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 Aluminum to render it resistant to steam, characterizing the surface with a grey coloring.

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 of 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 STOP WITH GASKET:**

The filter stop (cartridge) is manufactured in stainless steel AISI 304-18/10, it has a silicone gasket and it is provided with a reusable PTFE filter.

- **PROTECTION OF THE FILTER:**

The container has been constructed in such a way as to protect the filter from possible damage from outside, from dust, and is designed in a manner such that the entry of condensation from other containers is obstructed. Inside the container, a stainless-steel mesh (grid) protects the filter.

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.
- 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 (disinfectant, 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:

- **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.

Checks to be Made Before Each Use**KENT SURGICAL® GRANTS THE INTEGRITY OF THE STERILE BARRIER ONLY IF ALL THE FOLLOWING CHECKS ARE SUCCESSFULLY PERFORMED****CHECKLIST:**

1. Verify that the body and the lid have the same identification number and on the same side the body and the lid are marked with the same number for their traceability to keep them always in couple and avoid their separation. Each body of the container must always be associated with its own lid.
2. Check that the filter protection grid is not damaged.
3. Make sure the lid gasket is not damaged, it must be correctly placed in its location.
4. Closing the lid you should hear a double “click” and feel a slight resistance.
5. Do not use after MONTH / YEAR: 
- 6.
7. Verify that the expiring date of the container has not exceeded “Logo Hourglass” + “Do Not Use After Month / Year.

Consider the expiry date if the container must be stored with sterile materials inside.

Procedure For Cleaning:

- 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:

All the maintenance operations must be performed only by the **Kent Surgical®** Team or authorized personnel.

Disposal:

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

Guarantee and Duration:

The “Sterilization Containers with Teflon Filter” is guaranteed for 1 years.
The Sterile Barrier System (S.B.S.) of “Sterilization Containers with Teflon Filter” is guaranteed for a

use of 5 years or 2,000 cycles with the obligation of maintenance at **Kent Surgical®** after this period.

If the container has been broken or deformed in its essentials it is recommended an anticipated return.

The expiration date/maintenance required is marked on the lid and the filter cartridge inside the container. After 5 years Kent Surgical® will require the return of the container to perform the complete revision, after which the container can be used for 5 years or 2,000 cycles.