Ortimplant® Sterilization Container Systems

Basic Sterilization Container Instruction for Use

COMPENDIUM page

1. ORTİMPLANT STERILE CONTAINER COMPONENTS

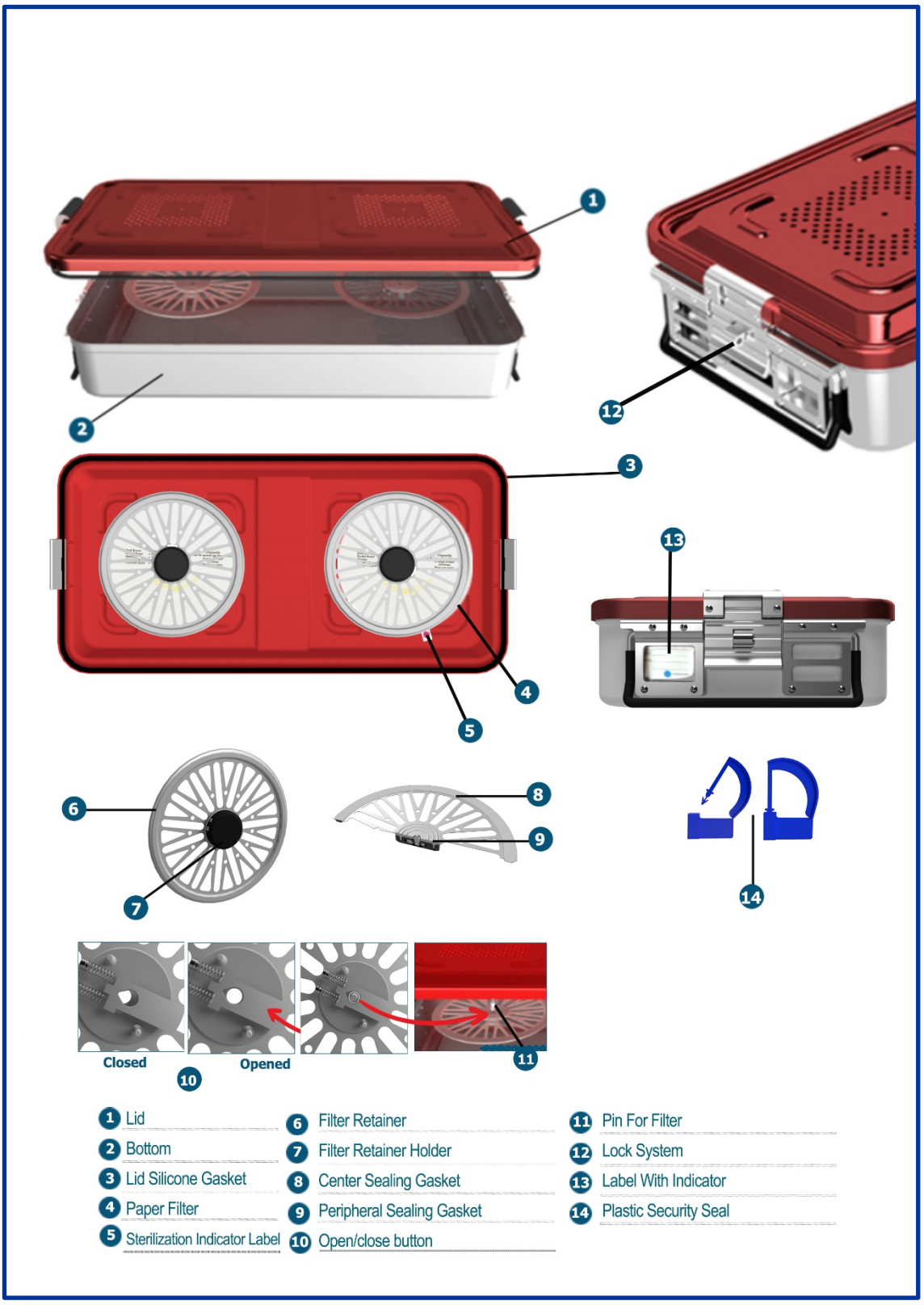


Figure 1. Construction components of Ortimplant Basic Sterile Container.

2. PURPOSE of INSTRUCTIONS FOR USE

The purpose of this document prepared for Ortimplant Basic Sterilization Container Systems is as follows:

1- To introduce the raw materials, components, and working principles of the Sterilization Container; to demonstrate their quality and validity,

2- To describe how the products and components has to be used,

3- To specifically define the transportation, storage, steam sterilization, and cleaning processes of the containers in details; to indicate the issues that need attention,

4- To detailly schematize the applicability of steam sterilization steps according to container types,

5- To guide the long-term use of sterilization container systems in your institution, company or unit.

6- To create a guideline for the training-competence of the relevant staff and the constitution of work instructions.

Intended User Profile

Ortimplant Basic Sterilization Container Systems must be used by healthcare professionals.

Before surgical operation; Sterilization (with pressurized hot water steam in an autoclaves) of the products such as surgical instruments, surgical sets, implants, screws, surgical cloths, gauzes and its accessories shall only be performed by qualified and trained assistant healthcare personnel. Likewise; handling and storage should be provided by competent allied healthcare professionals. Before using the product, all instructions regarding safety features should be read carefully; All necessary documents and materials must be provided by the authorized distributor.

Only NEUTRAL detergents and disinfectants should be used for cleaning and disinfection of sterilization containers. It should be kept in mind that acidic and alkaline detergents and disinfectants will damage the containers and therefore they should never be used.

Failure to use purified water for product cleaning will cause chloride to form on the product and will result in insufficient cleaning of the product.

Failure to read the user's manual will result in sterilization by reusing the paper filters, and failure to read the warnings will cause infection in the patient by not checking the product before use and sterilization.

The absence of explanations of the symbols on the labels in the user manual will result in erroneous application as a result of not being able to understand the warnings by the healthcare personnel.

Failure to consider the negative effects of damaged containers may result in injury during surgery.

Incomplete or incorrect information in the user manual will cause misuse and / or misuse of container boxes and sterilization application errors.

Using the product for other than its intended use will cause injury due to lack of user information.

3. PRODUCT INTRODUCTION

Ortimplant Basic Sterilization Container Systems are being packed and shipped non-sterile. Before the surgical procedure, Container Systems must be sterilized together with its contents.

Ortimplant Basic Sterilization Container Systems are reusable and anodized containers which are in use to sterilize implants, surgical instruments equipment and textiles; to keep and carry them as sterile. Ortimplant Basic Sterilization Containers are being described in this guide, are high-tech products and utilizing their variety of sizes, that provide major benefits for regular sterilization, preservation of implants, surgical instruments-equipment and textiles.

Ortimplant Basic Sterilization Container Systems are designed for daily use and provide years of use.

Thus, when choosing sterilization container systems, make sure that the container and instruments comply with the application and sterilization requirements.

The disposable&consumable parts of the Basic Container Systems are consist of paper, textile, and PTFE(publicly used as Teflon) filters, plastic security seals and sterilization indicator labels (Figure 2).

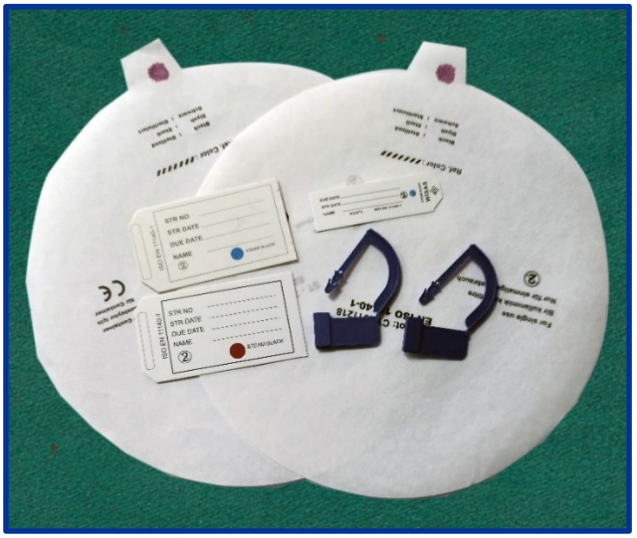


Figure 2. *Some disposable consumables: paper filters, plastic security seals, and sterilization indicator labels*

Ortimplant Sterilization Containers are made of EN AW 1050 quality aluminum and AISI 304 stainless steel (EN 1.4301) in accordance with territorial and international standards. Due to the large number of aluminum parts in design; handling and transporting are easier.

Anodization has been applied to the lids, bottom, and other aluminum components of the Basic Sterile Containers to increase its resistance against external factors and to gain a decorative appearance.

Paper Filter: It is placed on the lid and/or bottom of the container to ensure steam passage during sterilization and to maintain sterility after sterilization. Disposable paper filters provide effective protection by preventing microorganisms from entering the container after sterilization. It has a chemical indicator prepared in accordance with the ISO 11140-1 standard. After sterilization, the indicator of the paper filter should change color (for example, it should change from red/blue to black). In this way, it can be easily understood whether the container is sterilized or not. Circular filters are 190 mm in diameter and rectangular filters are 201x95 mm in size.

Textile Filter: It is placed on the lid and/or bottom of the container to ensure steam passage during sterilization and to maintain sterility after sterilization. Textile filters provide effective protection by preventing microorganisms from entering the container after sterilization. It can withstand up to 20 uses. Circular filters are 190 mm in diameter and there is no chemical indicator on them.

Teflon Filter: It is placed on the lid and/or bottom of the container to ensure steam passage during sterilization and to maintain sterility after sterilization. Teflon (PTPFE) filters prevent microorganism and particles from entering after sterilization and are for 2000 uses. Circular filters are 190 mm in diameter and there is no chemical indicator on them.

Sheet/Wire baskets: The sterilization basket is used for grouping, cleaning and transporting surgical instruments and equipment in sterilization containers. There are metal handles on both sides of the baskets that are convenient to hold and lift. The width, length and height of the baskets are suitable for the containers in which they are used. They are not products suitable for steam sterilization alone. Steam sterilization process can be applied by wrapping it in surgical textile (green cloth).

Colored Identification Labels: They are used to indicate which surgical unit (such as general surgery, neurosurgery, pediatric surgery, etc.) or procedure (such as spinal surgery, microsurgery, hip arthroplasty, etc.) the sterilization container will be used for. All products are made of aluminum raw material (1050,7075) and their dimensions are 68 x 18 x 0.3 mm in length, width and thickness, respectively. All products are colored with anodization process. Descriptive information is made by laser marking process. They are produced in six different colors in total as gray,

black, green, red, yellow and blue. The reference numbers of the colors are specified in the container catalogue. The use of different colors and inscriptions on the labels, make them easy to distinguish the containers. Colored identification labels are inserted into the label slot in the container botom. Color definitions and laser writings may vary according to customer request.
Paper Label with Indicator: Paper label is used for sterilization process and tracking details. They are placed on the label holder on the container. It has a chemical indicator prepared in accordance with the ISO 11140-1 standard. After sterilization, the indicator of the paper filter should change color (for example, it should change from red/blue to black). In this way, it can be easily understood whether the container is sterilized or not.
Silicone mats and gaskets: Silicone mat (grass) is used for the safe stacking of surgical instruments and equipment inside the container. Silicone gaskets provide the tightness between the lid and the box. It has a custom mix (VMQ mix).

Plastic Security Seal: The plastic security seal is disposable, and these locks can only be opened by breaking them in the surgical environment. The container is locked before the sterilization process and acts as a security to prevent unauthorized persons from opening it after the sterilization process. It is the simplest method that can be used to mark and identify the containers, trays, devices to be sterilized. It is offered for sale without an indicator.

The use of sterilization containers other than the indications mentioned above may cause damage or breakage of the product and its accessories. Proper cleaning, handling, sterilization and routine standard maintenance procedure will ensure the sterilization containers to work as intended and extend the lifetime.

Before using the product, you have unpacked, check the completeness and integrity of the product, the lid mechanic suitability, the locks and filter retainers to work properly and flexibly. Return problematic products to Ortimplant or Authorized Distributor.

Each container's bottom must ONLY be used with the specific lid designed for that series of the container, and should not be combined with other Ortimplant or non-Ortimplant series of lids.

Although the selection of raw materials, design stages and R&D studies of sterilization containers have been carried out in accordance with the standards, they may become unstable as a result of adverse mechanical and chemical effects as a result of misuse, improper cleaning and sterilization.

If there is an error in the sterilization container dimensions, there may be incompatibility in the fragmented components.

In case of burrs in the sterilization container during the production phase, it may cause infection and tissue damage to the carrier or healthcare worker.

Failure to blunt the sharp lines in the sterilization container during the production phase may cause tissue damage to the healthcare worker.

Due to insufficient quality controls, a loss of function may occur in the product.

Failure to calibrate the monitoring and measuring instruments or to measure correctly as a result of impacts and falls may result in the sterilization container being produced in inappropriate sizes and consequently unusable.

Errors may occur in the measurement of the product due to the lack of measurement information and measurement application.

Production errors may occur as a result of not following the calibration tracking list of the monitoring-measurement devices and not looking at the calibration label of the device during the measurement.

If measurement control is carried out by bringing together worn or deteriorated gauges, no realistic measurement control can be made in any way. This will result in an inaccurate measuring instrument.

The increase in the risk of infection in the patient due to the inability to clean the product as a result of the use of acidic or alkaline cleaning agents in the cleaning of the product will cause injuries due to the lack of user information.

Risk control measures cannot reduce the risk to the acceptance level and can be reduced to the AFAP level, there are risks remaining at the AFAP level from the design, production and use processes in the product, product deformation and damage to the health workers may occur.

Note: All surgical sterilization containers are classified as Class I according to Regulation 1 of Annex VIII of the Medical Device Regulation 2017/745.

LID

In Ortimplant Basic Sterilization Container Systems, there are holes for air passage on the lid.

There is a silicone gasket on the inner surface of the lid, providing air and waterproof along the edge. In the middle of the lid, there is a lockable filter retainer, that holds the filters tightly and has a sealing gasket on the top (center and peripheral parts), made of stainless steel or plastic (Figure 3).

There are spring latches on both sides of the lid that provide locking by springing into the bottom.

The silicones in the lid, filter retainer, and handles are made of materials resistant to hot application in the autoclave. They are not deformed until the change period.

Figure 3. *Bottom view of the Sterilization Container lid*

Paper, textile, and Teflon (poly-tetra-fluoro-ethylene, PTFE) filters provide effective protection by preventing microorganisms from entering the container after sterilization.

Paper filters are for single (1) use and should be changed for each sterilization process. Textile filters for 20 uses; Teflon (PTPFE) filters are 2000 uses (or they can be used for a maximum of 5 years). In addition, it is recommended that Teflon (PTPFE) filters should not be thicker than 8 mm.

It is recommended that Teflon (PTPFE) filters should not be thicker than 0.8 mm, as this makes it difficult for the filter holder to close.

BOTTOM (SUBSTRUCTURE)

On both sides of full, middle, half, and special size sterilization container bottoms, there are label attachment compartments, handles, and lock parts in which plastic disposable security seal passes through (Figure 4).

Figure 4. *Label attachment compartments, handle, and lock parts are seen in the container box.*

Paper labels with indicator are placed in the label attachment compartments of full, middle, half, and special size sterilization container bottoms for sterilization process and follow-up details (Figure 5).

In mini, dental, and flat sterilization containers, there are aluminum label placement pieces on the side of the lid, suitable for paper label indicator.

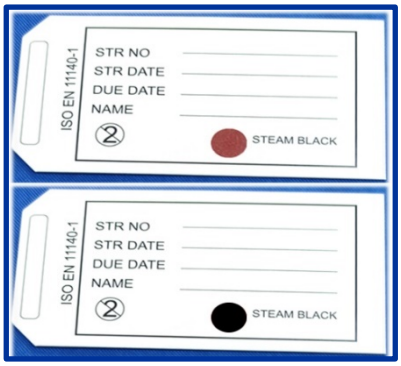


Figure 5. *The color change is seen on the indicator paper label before (red) and after (black) sterilization*

The paper label and filter paper indicator in sterilized containers should change color (eg from red/blue to black). Before opening the container, make sure that the color of the indicator has changed to the specified color.

Usage of Plastic Security Seal: Before the sterilization process, the container locks are closed and sealed with the plastic security seal. As long as the plastic security seals remain intact, they indicate that the contents of the container are kept sterile after the sterilization process. These seals on both sides are broken when the container locks are opened in the operating room before the surgery. Afterward, sterile surgical instruments are taken on the operating table (Figure 6).

Sterilization container contents brought to the operating room with broken plastic security seals should be considered non-sterile and must not be used without re-sterilization.

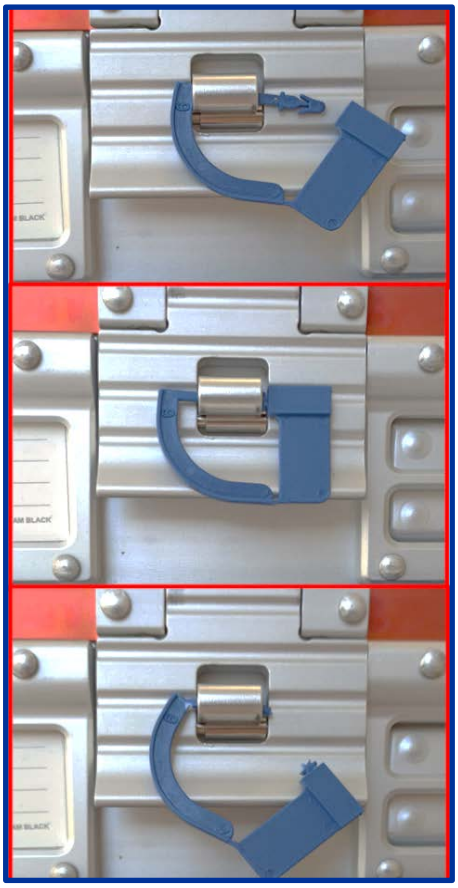


Figure 6. The open (upper picture), sealed (middle picture), and broken (lower picture) photos of the Plastic Security Seal can be seen in the container lock.

4.TRANSPORTATION AND STORAGE

In order to prevent impacts, damage, and consequential negativities (such as the inability to sterilize the contents of the container) that may occur in the sterilization container due to incorrect transportation and storage, container and surgical equipment should be transported and stored by trained and competent personnel.

The sterile container should always be transported & used (with gloves as possible) by the handles.

In post-sterilization storage rooms, the temperature range should be at 15-26˚C, humidity 30-40%, and normal atmospheric pressure (1 atm).

Sterilization container lids are manufactured in six different colors like gray (silver), black, green, red, yellow, and blue. These color differences provide convenience for you in storage (Figure 7).

Figure 7. Ortimplant Sterile Container lids are produced in six different colors as gray, black, green, red, yellow, and blue.

Check the stacking capacity and the maximum weight/loading of sterilization containers from Table 1.

For detailed information, you can visit www.ortimplant.com.tr or contact the authorized distributor.

Table 1. Ranges of Ortimplant Sterile Container Systems product and maximum weights that can be safely carried by handles.

Model	**Height** (mm)	**Weight to Carry** (kg)	**Stacking Capacity** (pieces; maximum 60cm)
Full - Medium - Special - Half	100	20	4
Full - Medium - Special - Half	135	23,5	3
Full - Medium - Special - Half	150	25	3
Full - Half	200	30	2
Full - Half	260	36	2
Mini	50	-	15
	60	-	8
	100	-	6
Dental	50	-	12
	65	-	9
	100	-	6
	130	-	4
Flat	95	-	7

When the stacking capacity of sterilization containers is exceeded, it may cause permanent deformation to their lids.

Due to the effects that may occur from adverse physical conditions during transportation or storage, the raw material may be damaged and the product may become unusable.

As a result of the formation of unwanted scratches during transportation and storage, sterilization may cause unwanted substances to remain on the surface of the container and cause scratches.

5. CLEANING AND DISINFECTION

General Info

Ortimplant Basic Sterile Container Systems are packed and shipped as non-sterile. Sterilization Containers must be sterilized in autoclaves with the surgical instruments inside before Surgical Operation.

When handling and cleaning the Sterilization Container Systems, always wear appropriate Personal Protective Equipment (PPE) in accordance with the norms of healthcare provider and procedures.

Before sterilization, thoroughly clean the container, basket, and other accessories by using a soft cloth, sponge, etc.

Ortimplant recommends a manuel and automatic cleaning before Sterilization process.

The cleaning solutions should be changed frequently without allowing them to become too dirty. In the cleaning process (whatever method is used); Employees should always use appropriate personal protective equipment (PPE) and equipment. Particular attention should be paid to the instructions for the correct handling and use of the product provided by the cleaning agent manufacturer.

During cleaning, do not use cleaning chemical agents that can scratch and scrape the container, metal brushes, and cleaning tools made of scotch, steel, and aluminum wire. Using abrasive and corrosive chemical products in the cleaning may cause permanent damage to the container surfaces. Besides, the use of abrasive cleaners or brushes/pads will result in the exclusion of the container warranty.

The quality of the water used for cleaning is important. The application of freshly prepared distilled water or ultra-pure water is recommended. Mineral residues in hard water may cause staining of the surgical instrument. In addition, it can prevent effective cleaning and decontamination with a high risk of contamination with

microorganisms and endotoxins.

Sterilization Baskets are constructed with a wide mesh design promoting sterilant penetration and ease of cleaning portable located inside sterilization containers to hold the surgical instruments or any instrument needs to be sterile. During cleaning process (before hot steam in atuoclaves) all intsruments have to be removed from sheet baskets and to be located seperately with instruments inside to be washed.

Steps to Follow Prior to Cleaning

Take the sterilization containers and their contents to the place of cleaning as soon as possible. If transfer to the processing area is likely to be delayed, cover sterilization containers with a damp cloth or store instruments in sealed boxes to prevent soiling from drying out.

Before cleaning the sterile container, you must apply the following procedures.

Separate the container lid from its bottom.

Remove any baskets, surgical instruments, or textiles in the container.

Remove all disposable items (such as seals, labels, and paper filters) and your special markers on the container lid or bottom.

Immediately after surgical procedures (within a maximum of 2 hours) remove dirt with absorbent paper towels. Also, wash the sterilization containers copiously under warm-cold (below 43 °C / 110 °F) tap water. Do not use hot water, alcohol, disinfectants, antiseptics, saline or chlorinated solutions.

Table 2. *Recommended cleaning solutions for Sterile Containers*

Tested Suitable Cleaning Solutions	
Brand	***Cleaning Solution Name***
Dr. Weigert®	*Neodisher MediClean* *Neodisher Mediclean Forte*
Anios®	*Anyosme DLM Maxi* *Anios NDT*
Ecolab®	*Sekumatic MultiClean* *Sekumatic FRE*

During cleaning, do not use cleaners that can scratch and abrade the container such as metal brushes and cleaning tools made of scotch, steel and aluminum wire. The use of abrasive and corrosive chemical products in cleaning may cause permanent damage to the container surfaces. Use of abrasive cleaners or brushes/pads will void the warranty.

Ortimplant Sterilization Containers are manufactured using anodized aluminum. Since anodized aluminum is sensitive to acidic and alkaline products, attention should be paid to the cleaning products to be used. Acetone, benzene, or acid neutralized products should not be used for sterilization container cleaning. The Sterile Container should be rinsed with pure water after neutral cleaning.

To avoid injury and product damage, pay attention to the sharp edges of containers during transport, cleaning, disinfection, sterilization and packaging. Prioritize your personal health and safety.

Microsurgical plates and precision instruments should be cleaned chemically or manually. It should not be placed in an ultrasonic cleaner. During the entire cleaning and sterilization process, care must be taken to protect the sensitive tips of the microsurgical instrument.

Pre-Cleaning

Required equipment:

Personal Protective Equipment (apron, gloves, face/eye shield),

Cleaning bath/container large enough to contain all the tools,

Freshly prepared cleaning solution containing a cleaning agent for manual cleaning,

Soft/hard brushes

Absorbent paper

Procedure:

Immerse the sterilization containers in the cleaning agent solution. Remove accumulated dirt with a paper towel and cleaning agent solution.

Clean the products thoroughly, using suitable brushes or cleaning wires (in general, use only soft brushes, do not use metal brushes or steel wool).

Rinse under running water for at least 1 minute until all traces of the cleaning solution are gone.

Visually inspect for any remaining dirt and repeat the above steps if necessary.

Wait for the instrument to float on absorbent paper or proceed to the cleaning step immediately.

Manual cleaning and disinfection

Cleaning

Required equipment:

Detergent (low foaming and protein solvent, etc.) and rinse aid designed for manual cleaning and suitable for ultrasonic cleaning

Suitable brushes (soft brushes only, never use metal brushes or steel wool) or cleaning wires (for small ducts) to reach all parts of the appliance.

Freshly prepared purified water, ultra-pure water or sterile water for rinsing.

Procedure:

Thoroughly clean the device using suitable brushes or cleaning wires (for small ducts) and paying attention to rough surfaces and lines where dirt may not be brushed off. In addition, pay special attention to cannulations and blind holes, connections between the hinge and mating parts. Rinse cannulations with the syringe at least three times.

Rinse for at least 1 minute under running water of the specified quality until no traces of the cleaning solution remain. Pay particular attention to cannulations and blind holes, connections between hinges and mating parts. Rinse the cannulations with the syringe (volume 1-50 ml) at least three times.

After completing the cleaning step in the ultrasonic bath, if encrusted dirt remains on the device that needs to be removed with a brush, repeat the cleaning step as above.

Only NEUTRAL detergents and disinfectants should be used for cleaning and disinfection of sterilization containers. Acidic and alkaline detergents and disinfectants should never be used.

Mechanic cleaning by washing machine

For aluminum containers, mechanic cleaning should only be done in washing machines with a special washing program.

The pH of the washing water should be between 6.5 and 8.5.

Make the final rinse with demineralized water. In rinsing other than demineralized water, it may cause white stains on the surface due to the alkalinity of the water and the salts it contains.

During mechanical cleaning, always follow the instructions of the washing machine manufacturer. Also, make sure that the number of cleaners and disinfectants follow the manufacturer's instructions.

DO NOT use solvents such as acetone or benzene for chemical drying/rinsing of container lids. The use of these products can cause permanent damage to the lid surfaces and/or filter housing, and void the warranty.

Disinfection

Required equipment:

Disinfectant designed for manual disinfection and compatible with the applied cleaning detergent.

Injector (1 - 50 ml, depending on the size of the channels to be washed).

Freshly prepared purified water, ultra-pure water or sterile water for rinsing.

Filtered medical compressed air (if available) or clean, lint-free disposable wipes.

Only NEUTRAL detergents and disinfectants should be used for cleaning and disinfection of sterilization containers. Acidic and alkaline detergents and disinfectants should never be used.

Procedure:

Thoroughly disinfect sterilization container parts with appropriate equipment such as soft brushes. Prepare a bath with disinfectant solution at the concentration and temperature specified in the detergent manufacturer's instructions. Completely immerse the device at least for the time specified in the detergent manufacturer's instructions. Rinse the cannulations with the syringe at least 3 times.

Rinse under running water of specified quality for at least 1 minute until no trace of disinfectant solution remains. Pay particular attention to cannulations and blind holes, connections between hinges and mating parts. Rinse with the syringe (volume 1-50 ml) at least 5 times.

Dry the Surgical device with medical compressed air and clean, lint-free disposable wipes (if necessary, allow to dry for a maximum of 2 hours in a clean area) or by heating in an oven below 110 °C.

Visually inspect and repeat the entire manual cleaning and disinfection process if necessary.

Decontamination/Disinfection process Does not sterilize surgical instruments. Recall that it must undergo additional processing as outlined in the STERILIZATION section.

Drying

The sterilization container, and the devices/instruments inside, should be thoroughly dried and all residual moisture removed before being packaged and sterilized. Use a soft, absorbent towel/cloth to dry exterior surfaces. Compressed air or rinsing with 70% alcohol can additionally be used to aid the drying process.

Inspection/Observation

All sterilization containers should be examined in detail before sterilization preparation. For this, visual inspection without the use of a magnifying glass under adequate lighting conditions will suffice. All parts of the containers should be inspected for visible dirt and/or corrosion.

The product should be visually inspected for damage or wear. Bent, bent, broken, cracked, chipped or worn parts should not be used and should be replaced.

The preferred filter(s) should be installed after the cleaning process. Removing and attaching the filter retainer and changing the filter are shown in Figure 9.

Figure 9. Removing and attaching the filter retainer and changing the filter.

Failure to comply with the cleaning and disinfection conditions may result in the formation of white spots on the surface of the product and the decrease in material strength and performance, leading to infection.

6. LOADING BEFORE STERILIZATION

When storing sterilization containers, it is necessary to avoid stacking the boxes as much as possible. In cases where stacking is mandatory, large containers should be placed on the lower shelf and small containers on the upper shelf. While loading, shelves should be used to allow steam to circulate between the containers, or textile or silicone wedges should be placed.

Bundles must be in vertical/horizontal position, instrument trays must be loaded horizontally on the lower shelf.

The packages should have a space between themselves and there should be a 5-10 cm gap between the wall of the sterilizer. If the container is vertical, it should be fixed with clothes so that it can wrap around it.

The contents of the container should be placed in the bottom so that they do not move freely inside the container, and the container lid can be freely closed and locked without any difficulty. The materials packaged with sterilization bags should be loaded considering that the package will expand almost twice during sterilization and so these packages should never be compressed.

Maximum 70% of the autoclave volume should be filled.

For the stacking of small, mini, and micro-instruments in the container, it is recommended to use a silicone mat (grass) on the floor. For detailed information, you can visit our website www.ortimplant.com.tr (Figure 8).

After the sterile container is filled, the label with the indicator should be placed in its slot in the container for the sterilization process and follow-up details (See Figure 4).

Sterilization date, sterilization number, validity date, etc. information on the label must be filled (See Figure 5).

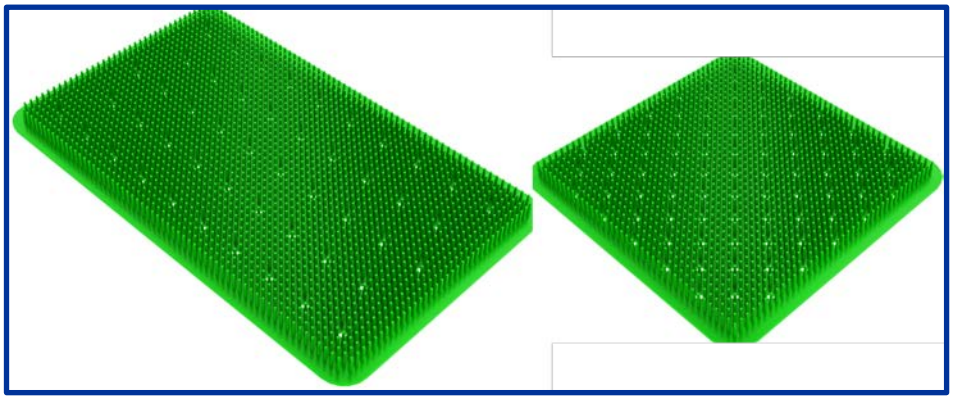


Figure 8. Various sizes of silicone mats for Ortimplant Basic Sterilization Containers are produced in green and blue colors.

Loading with the instrument

Total weight should not exceed 10 kg in full-size containers, 7 kg in medium-size containers, 6 kg in special-size containers, 5 kg in half-size containers, and 4 kg in flat containers. Total weight should not exceed 3 kg in a dental container and 2 kg in a mini container. Otherwise, sterilization may not fully achieve its purpose (DIN 58953-9).

Loading with textile

Maximum loading weight allowed in full-size containers is 8 kg. This weight is 3 kg in small-size containers. Make sure that the folded textiles must be horizontal. For the burden less movement of hot steam inside the internal volume, it should be possible to push an outstretched hand without effort between the pieces of laundry (DIN 58953-9).

7. STERILIZATION and CONTAINER STACKING

Ortimplant Sterilization Containers are sterilized by applying steam with autoclaves. Ortimplant recommends steam sterilization processes. Ortimplant Basic Sterile Containers have been verified to be sterile as a result of steam sterilization (autoclave), but it should be kept in mind that the design and performance of the autoclave may differ the effectiveness of sterilization. In each sterilization process, various indicators to be used, as explained above, to verify that the instruments are sterile.

Sterilization Process

Ortimplant recommends steam autoclave sterilization with pre-vacuum (air extraction from the autoclave) function. Autoclaves must be validated/calibrated, maintained, checked, and comply with their requirements under EN 285 / EN 13060, EN ISO 17665, and ANSI AAMI ST79.

Ortimplant has validated an autoclave cycle for the complete sterilization of Biobarrier Sterilization Containers. Instruments must be sterilized in the mounting condition as stored in the tray. If brackets or recesses in the tray are designed to accommodate multi-component instruments in their assembled state, these instruments do not need to be disassembled for sterilization.

The process parameters shown below are recommended by Ortimplant:

The ultimate responsibility for the verification of sterility using the equipment and processes of the healthcare facility and the parameters provided by Ortimplant rests with the healthcare facility. To ensure optimum processing, all cycles and methods should be validated for different sterilization chambers, packaging methods, and/or various loading configurations.

An exemplary sterilization processes

		Minimum Exposure Time
Sterilization Method	**Temperature**	**Container System**
Prevacuum	132°-135°C (270°-275°F)	4 mins (classic or bottom perforated)
Gravity	121°-123°C (250°-254°F)	40 mins (only bottom perforated)
	132°-135°C (270°-275°F)	30 mins (only bottom perforated)
IUSS Pre-vacuum (Immediate use steam sterilization)	132°C/270°F	3 mins (non-porous products) 4 mins (non-porous and porous products)
IUSS Gravity	132°C/270°F	See manufacturer's instructions for use

An alternative sterilization process

Method	Steam heat sterilization under EN ISO 17665 or ANSI/AAMI ST79
Loop	Pre-Vacuum or steam saturated with fractional compressed air
Exposure Time[1]	3-4 mins (WHO and Robert Koch Institute etc. Can be extended up to 18 minutes to comply with the recommendations.)
Temperature	132-137 °C (270-277 °F) or 134-138 °C (273-280 °F)
Drying Time[2]	30 min. (minimum, reservoir)
Cooling Period	60 min. (minimum, at ambient temperature)

[1] Exposure time: The time of the load and the entire room are at sterilization temperature

[2] Drying time: The period of time which steam is removed from the chamber and the chamber pressure is reduced to allow condensation to evaporate from the load through prolonged evacuation or injection and extraction of hot air. Since drying times vary depending on the configuration of the load, packaging method and material, the healthcare provider should verify the appropriate drying time with the sterilization equipment used.

For a successful sterilization; the autoclave cabinet, sterilization containers must be free of water/moisture residues. A wet package and excessive moisture can create favorable environments for the growth of microorganisms and cause biological contamination problems.

Before the surgery, in the operating room, Sterilization Containers should be checked whether there is water/moisture at the bottom of the container and whether the surgical cloths are moist, together with the control of biological and chemical indicators inside the sterilization container.

ORTİMPLANT and it's authorized representatives can't be hold responsible for non-sterile results due to Autoclave problems (errors in the pressure and vacuum system, clogged drain filter, etc.) and/or operator errors (closing the filter part of the container with material, filling the autoclave with too much material (overloaded containers), closing the discharge part of the autoclave, choosing the wrong sterilization cycle, etc.).

Ortimplant does not recommend using "high speed" sterilization for reusable instruments.

Stack the containers so that the heavy ones are at the bottom.

Follow the loading instructions of your autoclave manufacturer.

Do not cover outside of sterile containers.

Since the container will be hot after the sterilization process, you should be very careful about the risk of burns due to hot outer skin of Sterilization Containers.

After the sterilization process, open the door of the autoclave and wait for it to cool down to room temperature.

Immediately after sterilization, do not leave sterile containers that are still hot on a windy or cold floor to cool. As this situation will cause heterogeneous cooling on the surfaces, it may cause deformation of the container.

After the sterilization with pressurized steam cleaner, the color change (as black) of the indicator paint on the label should be observed (See Figure 5). **The absence of color change indicates that sterilization was not performed properly.**

Sheet/wire baskets of Ortimplant containers can be cleaned and sterilized following the accepted instructions and using the same procedures as Ortimplant Sterilization Containers.

DO NOT use Ortimplant Sterilization Containers with Plasma Sterilization Devices (i.e., hydrogen peroxide gas (H_2O_2) plus radiofrequency procedure). Be aware that this procedure can damage container

components.

 *When placing Ortimplant Sterilization containers in autoclaves, do not cover the surface (especially the lid and box sections with filters or valves) with a surgical cloth. This will cause the sterilization to fail as it will prevent the entry/exit of hot steam.*

 *Inadequate holes in the device cover that allow steam entry may cause the sterilization process to fail.*

 *Using surgical hand tools in the box with a non-locking mechanism and not using raw materials that comply with standards may cause infection, allergic reaction and sensitivity.*

 *If the container box and lid are not compatible with each other, if the assembled parts do not lock each other, sterility may not continue after the sterilization process.*

 *Failure to perform proper sterilization may result in the risk of infection and allergy.*

 *As a result of sterilization without using a filter due to insufficient knowledge of the user, the sterility of the product will deteriorate and the autoclave vacuuming system will operate at high speed, causing deformation in the product due to not reading the user manual.*

 *Loading not intended to be carried in the container system and not paying attention to overloads may harm the healthcare worker and/or cause product deformation.*

 *Using the container boxes more than once without proper sterilization will cause infection.*

 *Failure to use the recommended required sterilization method will result in damage to the container components by the user's non-compliance with the warnings and precautions.*

 *Since it will be hot after the sterilization process, burns and injuries may occur as a result of the user handling the product after sterilization due to lack of knowledge.*

8. STORAGE

It is recommended to use dust-proof trolleys for the transportation of Ortimplant Basic Sterilization Containers.

Before the sterile materials are stored, it should be ensured that the sterilization process is done properly and the indicator label at the bottom should be checked.

Store sterile containers in a clean, dry, and safe place.

Shelf life of the container and the device/tools in it; can take up to one year depending on the sterile barrier, storage method, environmental and usage conditions.

The maximum shelf life for the sterilized container and its contents should be defined by each healthcare facility prior to use.

9. MAINTENANCE AND REPAIR

If your Ortimplant Sterilization Containers require repair or maintenance, you can use sponge, foam, bubble wrap etc. to protect the instruments. Wrap it in a protective package and return it in a sturdy box. Send packed instruments to:

Kirazlık Mah 1034 Cd. No:14 TEKKEKÖY/SAMSUN/TÜRKİYE
+90 362 435 3772
+90 362 420 02 94
info@ortimplant.com

Periodical maintenance time for all container models and accessories is *six (6) months*.

All products of Ortimplant Sterilization Container Systems returned for maintenance/service should be thoroughly cleaned and decontaminated before service. Failure to provide proof of cleaning and disinfection will also result in a cleaning fee and delayed repair of your device.

Products repaired by Ortimplant are warranted for 90 days for labor and parts when used normally for surgical purposes. Any workmanship or parts proven to be defective will be replaced or repaired free of charge to the customer, at Ortimplant's sole discretion.

If you have any questions, you can contact your local Ortimplant authorized representative.

When properly attached to the cover and in proper operating conditions, the seals of the filter holder should not rotate easily. The seals of the filter holder should be replaced when they are worn, aged and/or damaged.

Before each sterilization, inspect the lid gasket to verify that the gasket is not cut or damaged and that it is flexible enough.

Container lid gaskets are silicone and you can find the cutting dimensions in Table 3.

In order for the sterilization process to be successful and for the products to be preserved afterwards, the cover silicones and filter/barrier silicones must be strong and sit/press firmly on the metal surface. For this reason, the durability, softness and tight fit of the filter/biobarrier silicones with the cover should be checked frequently.

Table 3. *Lid gasket cutting sizes of Sterile Containers.*

Lid	Basic				Dental
	Full	Middle	Half	Special	
Gasket cutting size (cm)	165	140	110	114	79

Changing the lid gasket

Scrape off the rubber and silicone parts in the gasket channel, and then wipe with a cotton swab and alcohol.

Apply thin silicone rubber to the channel.

Its curved surface will enter the channel; place the new gasket in the channel with the flat surface out.

Remove excess silicone rubber residue from the contact surface with a cloth or cotton.

Contanın kanala düz bir şekilde sıkışması için, kapağı kutusunun üzerinde kapatın ve birkaç dakika kapalı şekilde bekleyin. Ardından kapağı ters olarak en az 12 saat süre ile kuruması için bekletiniz.

Sterilizasyon konteynerleri kapağının her açılışında, contada kesik ya da zedelenmenin olmadığı, contanın yeterince esnek olduğu ve konteynerin yuvarlak kenarlarında contaya zarar verebilecek keskin veya hasar görmüş parçaların

olmadığından emin olunuz

Adhesive selection is important for gasket changes in sterilization containers. As Ortimplant, Würth silicone adhesive is recommended.

Gaskets should never come into contact with spray, oil or solvents. For cleaning and maintenance, simply wipe with a clean, damp cloth.

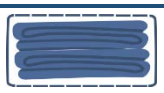
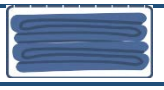
Never use damaged or defective containers.

You can contact Ortimplant sales representatives or our authorized distributors for the maintenance and repair of sterilization containers.

10. TROUBLESHOOTING CHART

Problem	Cause	Solution
Excess moisture inside the Sterile Container	Before sterilization, the temperature of the materials is too low	Put the materials to be sterilized at minimum initial room temperature (20˚C).
	The clothes are very damp.	The clothes you place in the sterilization container must be dry.
	Containers are not properly placed in the sterilizer.	With big/heavier containers at the bottom, stack the containers at appropriate intervals so that their total height does not exceed 60cm.
	An improper cooling process was performed after the sterilization.	Follow the container cooling procedure after sterilization
	Autoclave features do not meet TS EN 285 standard.	When using the autoclave, follow the manufacturer's recommendations. Check the drying time and steam quality. Calibrate if necessary.
	Empty cycle and vacuum testing are not done daily before sterilization.	Before sterilization, do your empty cycle and vacuum tests. Make sure your sterilizer is working properly.
	The sterile container is overloaded.	Check the appropriate weight from the transport and storage table.
The indicator does not change color after sterilization	Sterilization is not suitable.	Have the autoclave repaired by the manufacturer.
Deformation of the container after sterilization	Filter holes are closed during sterilization.	Never cover the holes in the bottom and lid. Using a safety cover does not cover the filter holes on the lid.
Lid lock problem	During the transportation of the container, locks were used instead of carrying handles.	Please contact Ortimplant sales representative. The broken locked container is not suitable for sterilization.
	Physical impact on container lid locks	Please contact the Ortimplant representative. Broken locked containers are not suitable for sterilization.

Compliance Scheme of Ortimplant Sterilization Container Systems for Steam Sterilization Procedures

Sterile Container	Packing		Steam Sterilization Procedure According to DIN 58946 Part 1				
	Description (according to DIN 58952 part 1)	Symbolic Repre-sentation and Packing System	Gravity Procedure	Pre-Vacuum Procedure	Fractional Vacuum Procedure	Fractional Flow Procedure	Steam Injection Procedure
With Filters	Textiles and instruments in sterilization container with the filter in lid and bottom		✓	✓	✓	✓	✓
			○	○	✓	✓	✓
	Textiles and instruments in sterilization container with the filter in lid and bottom not perforated		✗	✗	✓	✓	✓
			✗	✗	✓	✓	○

	Textiles and instruments in sterilization container with the filter in bottom and lid not perforated		○	⊕	⊕	⊕	⊕
			⊖	○	⊕	⊕	⊕
	Instruments in wire basket acc.		✓	✓	✓	✓	✓
			✗	✓	✓	✓	✓
			○	⊕	⊕	⊕	⊕

Explanation of Symbols: ✓ Applicable ✗ Not Applicable ○ Limited Application

11. CONTACT INFORMATION

ORTİMPLANT ORTHOPAEDICS AND MEDICAL DEVICES

Ortimplant Samsun
Kirazlık Mahallesi 1034.Cadde No: 14 Tekkeköy / SAMSUN
Tel: +90 362 266 97 28 Fax: +90 362 266 58 72
sales@ortimplant.com

12. COMPLAINTS AND RECOMMENDATIONS

The healthcare professional who has any complaints about the sterilization containers or is not satisfied with the quality, identity, durability, reliability, safety, functionality and/or performance of the product should inform the authorized distributor or Ortimplant.

In case of malfunction and/or damage to the container, or serious injury or death, the authorized distributor and Ortimplant shall immediately in writing, telephone, fax, etc. should be informed.

When filling out the complaint form, please fill in the complaint reason section. Indicate whether you want a written response report for the serial number and lot number of the containers, the description of the complaint, your name and address, and the distributor.

More information: For any complaints or additional information of this system, please contact the above mentioned contact address.

13. SYMBOLS

PRODUCER-Indicates the medical device manufacturer as defined in US Directives 90/385/EEC, 93/42/EET, 98/79/EC and EU Regulation 2017/745.

PRODUCTION DATE-Indicates the date of manufacture of the medical device.

LOT CODE/LOT NUMBER-Indicates the manufacturer's lot code so that the lot or lot can be identified.

CATALOG NUMBER - Indicates the manufacturer's catalog number so that the medical device can be identified.

NON-STERILE—Indicates that the medical device has not been sterilized.

DO NOT USE IF THE PACKAGE IS DAMAGED AND REFER TO THE INSTRUCTIONS FOR USE-Indicates that the medical device must not be used if the package is damaged or opened, and the user should refer to the instructions for use for additional information.

KEEP AWAY FROM SUNLIGHT - Indicates a medical device that must be protected from light sources.

KEEP DRY—Indicates a medical device that must be protected from moisture.

TEMPERATURE LIMIT—Indicates the temperature limits to which the medical device can be safely exposed.

HUMIDITY LIMITATION—Indicates the humidity range in which the medical device can be safely exposed.

REFER TO THE INSTRUCTIONS FOR USE OR REFER TO THE ELECTRONIC INSTRUCTIONS FOR USE - Indicates that the user should refer to the instruction for use.

CAUTION-Indicates that the user should refer to the instructions for use for important information (such as warnings and precautions) that cannot be found on the medical device for various reasons and requires attention.

MEDICAL DEVICE—Indicates that the relevant product is a medical device.

UNIQUE DEVICE IDENTIFIER-Identifies a bearer that contains the Unique Device Identifier information.

CE MARKING MAY INCLUDE NOTIFIED BODY. REFERENCE NO. XXXX-Indicates European technical compliance.

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