

STERILCONTAINER™ System for Flash Sterilization (Prevacuum)

INTRODUCTION:

The Aesculap STERILCONTAINER™ System is a reusable rigid container system used for the packaging, transportation, and storage of instruments prior to, during, and after prevacuum steam flash sterilization. It consists of various sizes of lids and bottoms, with assorted accessories such as baskets, filters, indicator cards and tamper proof locks.

The Aesculap STERILCONTAINER™ System is an alternative to the traditional woven or non-woven wrapping materials used to package surgical instruments and other supplies for sterilization.

CARE & HANDLING:

INSPECTION PRIOR TO USE:

To ensure the performance of this product, a thorough inspection of the SterilContainer and its components must be conducted prior to **every** use. Pay close attention to the following:

- Container lids and bottoms should be free from:
 - Noticeable cracking
 - Any corrosion
 - Any misalignment in which the tops and bottoms do not adequately mate
 - Any pitting in the aluminum
- Retention plates and silicone gaskets should be free from:
 - Any sign of cracking or damage
 - Damage to the filter post preventing proper filter placement
 - Any misalignment (improper seating of the gasket to the lid)
 - Any pitting in the aluminum
 - If soiled, clean per instructions below otherwise proceed to Assembly for Use section
 - SterilContainer system must be cleaned at least once per day or when soiled.

If any of the above conditions occur with the Sterilcontainer, DO NOT USE. Return all unusable products to Aesculap for repair or replacement.

The Aesculap STERILCONTAINER System is manufactured of specially formulated aluminum alloy. The surface is protected by a layer of anodized oxide to prevent corrosion. If properly cared for using the instructions in this booklet, your Aesculap STERILCONTAINER can provide many years of instrument protection and sterility assurance.



Do not use abrasive cleaners, metal brushes or abrasive cleaning pads. Use of abrasive products can cause permanent damage to sterilcontainer surfaces. Use of abrasive cleaners or pads will result in warranty exclusion.

Recommended Cleaners:

Use only mild alkaline, sodium carbonate-free, neutral pH (7) detergents to clean effectively without causing damage to the anodized layer of aluminum. If in doubt, contact the detergent manufacturer or supplier to determine suitability for use in cleaning the Aesculap STERILCONTAINER.

Pre-Cleaning Preparation:

1. Remove the lid from the container bottom.
2. Remove the basket and any instruments from the container.
3. Remove the lid retention plate(s).
4. Remove the container bottom retention plate(s) if using perforated container bottoms.
5. Discard the disposable filter(s).
6. Remove all processing indicators and disposable locks.



Aesculap disposable non-woven filters are designed for one-time use only and should be discarded after each processing cycle.

Manual Cleaning:

1. Use a soft sponge and a mild detergent and clean the STERILCONTAINER and all the components under water.
2. Rinse thoroughly under running water to remove all detergent residue, as residual detergents can affect the anodized oxide layer of aluminum.
3. To remove sterilization adhesive tape remnant of surface abrasions, we recommend the use of Aesculap-Eloxal Cleaner (Catalog number JG601). This is a non-abrasive cleaner. Apply the cream with a soft dry cloth and rub to polish the surface. Thoroughly rinse the STERILCONTAINER under running water to remove all residual cleaning cream.
4. Thoroughly dry the STERILCONTAINER and all components with a soft dry cloth.



Always wear proper protective personal attire when cleaning the STERILCONTAINER.

Mechanical Cleaning:

1. Place the STERILCONTAINER bottom in the washer with the inside surface facing down to avoid water collection.
2. Fold the handles towards the inside of the lid. Place the lid with the inside surface facing down to avoid water collection.
3. Retention plates should be placed away from the direct force of pressurized washer jets to avoid damage during the washing cycle. The wire baskets provided by the mechanical washer manufacturer should be used to hold STERILCONTAINER components during the automated cleaning cycles.
4. Thoroughly dry (either with a soft, dry cloth or air dry) the STERILCONTAINER and components before final assembly.

If you have further questions regarding cleaning practices for the STERILCONTAINER System, contact your local Aesculap Sales Representative or the Customer Service department at 1-800-282-9000.

Assembly For Use:

Pre-Assembly Inspection and Preparation:

1. Identify surgical instrument set for sterilization.
2. Identify appropriate size basket and STERILCONTAINER, as well as STERILCONTAINER bottom type (perforated or solid) for the method of sterilization chosen. **(Solid bottom containers are to be used in PreVac Flash sterilizers.)**
3. Assure STERILCONTAINER component pieces are completely dry.
4. Inspect the rim of the lid to ensure the gasket is in good condition and free from cracks. A cracked gasket indicates age and/or deterioration and should not be used. Remove the lid from service and return for repair.



An optional inner drape may be used to wrap the basket and basket contents to facilitate the formation of a sterile field when opened.

Filter Assembly:

1. Place one sheet of the appropriate Aesculap filter paper over each perforated section on the inside of the STERILCONTAINER lid. When using Aesculap filter paper with indicator ink (US751), be sure indicator dot faces toward the inside of the container when the lid is in place and the indicator dot is visible through the retention plate on the inside of the lid.
2. Secure each filter with the retention plate designed for use with the STERILCONTAINER lid.

Instrument and STERILCONTAINER Assembly:

1. Sort and assemble thoroughly cleaned and dried instruments into the instrument basket(s), according to established hospital procedures.
2. Place assembled instrument basket(s) into the prepared STERILCONTAINER bottom.
3. Place assembled lid onto the STERILCONTAINER bottom, aligning handles on bottom with latches on lid.
4. Simultaneously close both locking latches on the STERILCONTAINER lid.



The weight of the fully loaded container should not exceed 35 lbs per the validation of this container*. It is important not to exceed the manufacturer's recommended maximum total chamber weight. All instruments should be disassembled per manufacturers' instructions to allow for uniform exposure to sterilization agents.

Caution:

Leave one inch of free space between the instruments and the rim of the container bottom for effective processing. Basket handles may encroach into this clearance space as long as they do not interfere with the Lid's filter retention plate or lid closure.

Mini size container: Leave one quarter of an inch of free space between the instruments and the rim of the container bottom for effective processing. Basket handles may encroach into this clearance space as long as they do not interfere with the Lid's filter retention plate or lid closure.

Processing Assembly:

1. Select the appropriate Aesculap Indicator Card and insert into the holding bracket on the outside of the STERILCONTAINER. A tab at one end of the indicator card will facilitate insertion and removal.
2. Insert the appropriate Tamper Proof Seal into the locking channel on each end.
3. Secure and lock the seals.



NOTE: Use of internal and external indicators should be in accordance with in-house protocol, determined by the user.

Loading the Sterilizer:

1. The Aesculap STERILCONTAINER™ container should be placed **flat** for effective sterilization.
2. The Aesculap STERILCONTAINER™ container should be positioned per the sterilizer manufacturer's guidelines for optimum flash sterilization conditions. Caution: Stacking is not recommended for Flash sterilization.

*** 35 pound loads were validated in the following representative containers deemed to be worst case based upon vent area to container volume ratios: Full size (JK446); Three-Quarter size (JK 742); and Half size (JK344).**

Processing:

Run loaded sterilizer according to time and temperature recommended by the sterilizer manufacturer for a prevacuum flash cycle.

Suggested Sterilizer Cycle Parameters:

The following validated parameters are based on the validation of the Aesculap® Sterilcontainer in a flash (prevacuum) sterilization cycle. Each facility may need to run internal testing to determine if adjustments are necessary for their facility.

High Vacuum (pre-vacuum, three pulse, standard) Steam Cycle:**PREVACUUM FLASH CYCLE (Porous/ Non-porous Loads):**

Temperature: 270°F/ 132°C
Exposure Time: 4 minutes

PREVACUUM FLASH CYCLE (Non-porous Loads):

Temperature: 270°F/ 132°C
Exposure Time: 3 minutes

CAUTION: When using pre-vac flash sterilization, a solid bottom must be used.

Aseptic Presentation:

Hospital procedures and AAMI guidelines should always be followed when using and presenting the STERILCONTAINER system. The following are a set of suggested steps for an aseptic presentation of a processed sterile container.

1. Non scrubbed person positions container on a separate dry flat surface at or slightly above the level of the sterile field
2. Non scrubbed person inspects physical integrity of the closed container system to assure seals are in place.
3. Non scrubbed person inspects the exterior chemical indicator(s)
4. Non scrubbed person breaks and removes the locks
5. Non scrubbed person opens the latch and removes the lid in one single step, making sure that the container edge/bottom is not contaminated
6. Non scrubbed person and/or scrubbed person assures chemical dot indicator on filter is "turned"
7. Non scrubbed person checks the integrity of the filter(s) by removing the filter retention plate and examining
8. Scrubbed person removes the sterile contents inside by grasping both handles using appropriate aseptic technique, lifting basket and contents out, and placing basket and contents on a sterile surface.
9. Non scrubbed person checks the filter(s) on the bottom if a perforated bottom container is used.

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