STERILCONTAINER™ System – Reusable Filters

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 sterilization. It consists of various sizes of lids and bottoms, with assorted accessories such as baskets, filters (disposable and reusable), indicator cards and tamper proof locks. All accessories should only be used with the Aesculap SterilContainer System.

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:

For care and handling of the SterilContainer System, please refer to our instructions for use on the Sterilization Containers itself, which can be found online at www.aesculapusa.com.

These care and handling instructions are specifically for the reusable PTFE filters.

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 and reusable filter. If in doubt, contact the detergent manufacturer or supplier to determine suitability for use in cleaning the Aesculap SterilContainer and reusable filter.

Pre-Cleaning Preparation for Reusable PTFE Filter (each use):

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. Inspect reusable filters for rips, tears, pitting, cracks, dents, foreign material or other signs of damage. If any signs of damage exist, or if the recorded removal date is near, discard filter. If not, place filters back inside retention plates.

NOTE: When using a new filter, record the date of the 1st sterilization mm/dd/yy on the filter. Based on your hospitals average use of this STERILCONTAINER and reusable filter, estimate the date in which the filter must be removed mm/dd/yy (maximum 2,200 uses) and record it. Ensure that the estimated removal date encompasses high and low usage rates seen at the hospital. It is better to underestimate the removal date to ensure that filter usage does not exceed 2,200 uses.

Cleaning:

Manual Cleaning:

1. Use a soft sponge and a mild detergent (see recommended cleaners section) and clean the SterilContainer and all the components (including reusable filter) under water.
2. Rinse thoroughly under running water to remove all detergent residue, as residual detergents can affect the anodized 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.

NOTE: 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. Reusable filters can be cleaned mechanically inside the retention plate. 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.

NOTE: Ensure that the cleaning equipment has been properly maintained and that the cleaning cycle has been adequately validated prior to use.

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. (Reusable filters should not be used with ethylene oxide or gravity steam.)
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.

Filter Assembly:

1. Inspect reusable filters for rips, tears, pitting, cracks, dents, foreign material or other signs of damage. If any signs of damage exist, or if the recorded removal date is near, discard filter.
2. Secure each filter with the retention plate designed for use with the SterilContainer lid.
3. Perforated Bottoms: Place one sheet of the appropriate Aesculap filter over the perforated section in the SterilContainer bottom. Secure the filter with the retention plate designed for the SterilContainer bottom.

NOTE: Reusable PTFE filters are for use in steam (prevacuum) sterilization and Steam (prevacuum) Flash Sterilization only.

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.
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 and Quarter 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.

Extra Long Mini container: instruments and baskets can be loaded to the rim of the bottom of the container 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. In all methods of sterilization, the SterilContainer should be placed flat for effective sterilization and drying.
2. In all methods of sterilization, the SterilContainer should be positioned on the autoclave cart below wrapped items for optimum sterilization and drying conditions.
3. Stacking: Recommended for high-vacuum cycles only. Stacking should not exceed 16-18” in height for effective air removal and adequate steam penetration. Both solid and perforated bottom containers can be stacked.

PROCESSING:

1. Run loaded sterilizer according to time and temperature recommended by the sterilizer manufacturer for chosen cycle.
2. At completion of the cycle, the sterilizer door should be opened approximately 6” and left open for a period of 15 minutes to aid in drying, as recommended by the sterilizer manufacturer.
3. The SterilContainer needs to remain on the container cart, in a draft free area, until cool enough to handle. Cooling in a draft-free area minimizes the formation of condensation on the inside of containers. If condensation on the inside of containers comes into contact with outside contaminants, sterility may be compromised. Furthermore, condensation inside containers could cause rust to form on some instruments.

NOTE: A SterilContainer with a solid bottom may require additional cooling time; the additional required cooling time to be determined by the user.

SUGGESTED STERILIZER CYCLE PARAMETERS:
The following parameters are based on the generally accepted recommendations of most sterilizer manufacturers. Each facility may need to run internal testing to determine if adjustments are necessary for their facility.
CAUTION: DO NOT USE SOLID BOTTOM CONTAINERS OR THE REUSABLE FILTER IN GRAVITY STEAM CYCLES.

High Vacuum (pre-vacuum, three pulse, standard):

<table>
<thead>
<tr>
<th>Temp:</th>
<th>270° F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure Time:</td>
<td>4 Minutes (minimum)</td>
</tr>
<tr>
<td>Cycle Dry Time:</td>
<td>15 Minutes (minimum)</td>
</tr>
<tr>
<td>Cool Time:</td>
<td>Varies according to load contents</td>
</tr>
</tbody>
</table>

CAUTION: Cool drafts from air ducts or other air currents should be avoided during the cooling phase to avoid post-sterilization moisture caused by rapid cooling syndrome.

NOTE: Consult with the manufacturer of the sterilizer for specific recommendations.

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<table>
<thead>
<tr>
<th><strong>PREVACUUM FLASH CYCLE (Porous/Non-porous Loads):</strong></th>
<th><strong>PREVACUUM FLASH CYCLE (Non-porous Loads):</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature:</td>
<td>Temperature:</td>
</tr>
<tr>
<td>270° F/132°C</td>
<td>270° F/132°C</td>
</tr>
<tr>
<td>Exposure Time:</td>
<td>Exposure Time:</td>
</tr>
<tr>
<td>4 minutes</td>
<td>3 minutes</td>
</tr>
</tbody>
</table>

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

Please direct your questions concerning this product to:

**Aesculap, Inc.**
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