STERILCONTAINER™ System with PrimeLine Lid

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, 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:

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INSPECTION PRIOR TO USE FOR TERMINAL AND FLASH STERILIZATION:

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:

- PrimeLine Container lids should be free from:
  - Noticeable cracking
  - Any misalignment in which the tops and bottoms do not adequately mate

- Silicone gaskets should be free from:
  - Any sign of cracking or damage.

- Flash Cycle only- if soiled, clean per instructions below otherwise proceed to Assembly for Use section. Lid must be cleaned at least once per day or when soiled.

- Terminal Sterilization – clean prior to each use.

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, the plastic lid, and reusable filter. If in doubt, contact the detergent manufacturer or supplier to determine suitability for use in cleaning the Aesculap STERILCONTAINER with PRIMELINE LID.

Do not use solvents such as acetone of benzene, which may be found in chemical drying rinses. Exclusively use fully de-mineralized water for the final rinse and make sure not residues from the cleaning process remain on the lid.

Pre-Cleaning Preparation for PrimeLine lid with 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.

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.
Manual Cleaning:
1. Use a soft sponge and a mild detergent (see recommended cleaners section) and clean the STERILCONTAINER and all the components (including PrimeLine lid with reusable filter) under water.
2. Rinse thoroughly under running water to remove all detergent residue, as residues can affect the container system.
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 under running water to remove all residual cleaning cream.
4. Thoroughly dry all components with a soft dry cloth.

Wear proper protective personal attire when cleaning.

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 PRIMELINE LID. Place the lid with the inside surface facing down to avoid water collection.
3. Retention plates inside the PRIMELINE LID 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.
4. Thoroughly dry (either with a soft, dry cloth or air dry) the STERILCONTAINER and PRIMELINE LID before final assembly.

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 or the PrimeLine lid, 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. (PrimeLine Lids should not be used with ethylene oxide or gravity steam. When using the PrimeLine Lids for pre-vac flash sterilization, a solid bottom must be used.)
3. Assure STERILCONTAINER and PRIMELINE LID 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, 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 reusable filter with the retention plate designed for use with the PRIMELINE 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.

Reusable PTFE filters are for use in steam (prevacuum) terminal or flash sterilization only and have a life of 2200 cycles. Do not exceed. When using a new reusable filter, record the date of the 1st sterilization on mm/dd/yy on the filter. Based on your hospitals average use of this STERILCONTAINER and PRIMELINE LID with reusable filter, estimate the date on which the filter must be removed mm/dd/yy. 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.
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 PRIMELINE LID onto the STERILCONTAINER bottom, aligning handles on bottom with latches on lid.
4. Simultaneously close both locking latches on the PRIMELINE LID.

Aesculap has validated a combined instrument and container weight of 35 pounds. Validation was based on two stainless steel lumens as small as 3mm inner diameter and 400mm in length. All instruments should be assembled 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.

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.

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 terminal 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. Caution: Stacking is not recommended for Flash sterilization.

PROCESSING:

1. Run loaded sterilizer according to time and temperature recommended by the sterilizer manufacturer for chosen cycle. Please see below for suggested cycle parameters.
2. For terminal sterilized sets- 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. For terminal sterilized set- 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.

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 validated parameters are based on the validation of the Aesculap Sterilcontainer with PrimeLine Lids. 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:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temp:</td>
<td>270° F</td>
</tr>
<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>
<tr>
<td>CAUTION:</td>
<td>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.</td>
</tr>
</tbody>
</table>
The Aesculap SterilContainer with PrimeLid has a validated post-sterilization shelf-life of up to 360 days.

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

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

**CAUTION:** When using the PrimeLine Lids for pre-vac flash sterilization, a solid bottom must be used.

Flash sterilization is for immediate or imminent use of devices, therefore no drying time is specified.

Consult with the manufacturer of the sterilizer for specific recommendations.

**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 checks the integrity of the filter(s) by removing the filter retention plate and examining
7. 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.
8. Non scrubbed person checks the filter(s) on the bottom if a perforated bottom container is used.