AESCULAP

STERILCONTAINER S™ System (Sterrad 100S)

INTRODUCTION:
The Aesculap Sterrad compatible STERILCONTAINER S™ System (Sterrad 100S) is a reusable rigid container system used for the packaging, transportation, and storage of instruments prior to, during, and after sterilization in the Sterrad 100S system. It consists of various sizes of lids and bottoms, with assorted accessories such as baskets, filters, indicator cards and tamper proof locks.

The Aesculap Sterrad compatible STERILCONTAINER S™ 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:
The Aesculap Sterrad compatible STERILCONTAINER S™ System is manufactured of specially formulated non-anodized aluminum. If properly cared for using the instructions in this booklet, your Aesculap Sterrad compatible STERILCONTAINER S™ 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.

INSPECTION PRIOR TO USE:
To ensure the performance of this product, a thorough inspection of the Sterrad compatible 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 any of the above conditions occur with the Sterrad compatible Sterilcontainer, DO NOT USE. Return all unusable product to Aesculap for repair or replacement.

CLEANING:

Recommended Cleaners:
Use only mild alkaline, sodium carbonate-free, neutral pH (7) detergents to clean effectively without causing damage to the aluminum surface. If in doubt, contact the detergent manufacturer or supplier to determine suitability for use in cleaning the Aesculap Sterrad compatible STERILCONTAINER S™ containers.

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.

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

Manual Cleaning:
1. Use a soft sponge and a mild detergent and clean the Sterrad compatible STERILCONTAINER S™ and all the components under water.
2. Rinse thoroughly under running water to remove all detergent residues.
3. To remove sterilization adhesive tape remnants or 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 Sterrad compatible STERILCONTAINER S™ container under running water to remove all residual cleaning cream.
4. Thoroughly dry the Sterrad compatible STERILCONTAINER S™ container and all components with a soft dry cloth.

Note: Wear proper protective personal attire when cleaning the Sterrad compatible STERILCONTAINER S™ container.

Mechanical Cleaning:
1. Place the Sterrad compatible STERILCONTAINER S™ 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 that are provided by the mechanical washer manufacturer should be used to hold Sterrad compatible STERILCONTAINER S™ components during the automated cleaning cycles.
4. Thoroughly dry (either with a soft, dry cloth or air dry) the Sterrad compatible STERILCONTAINER S™ and components before final assembly.

If you have further questions regarding cleaning practices for the Sterrad compatible STERILCONTAINER S™ 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 Sterrad compatible (100S) STERILCONTAINER S™.
3. Assure Sterrad compatible STERILCONTAINER S™ component pieces are completely dry.
4. Inspect the container for serviceability paying special attention to 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. Place one sheet of the polypropylene Aesculap filter paper over each perforated section on the inside of the Sterrad compatible STERILCONTAINER S™ lid and bottom. When using Aesculap filter with indicator ink, 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.

   NOTE: Only Polypropylene filters should be used for Sterrad® sterilization.

2. Secure each filter with the retention plate designed for use with the Sterrad compatible STERILCONTAINER S™ lid.

Instrument and Aesculap Sterrad compatible 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 Aesculap Sterrad compatible STERILCONTAINER S™ bottom.
3. Place assembled lid onto the Aesculap Sterrad compatible STERILCONTAINER S™ bottom, aligning handles on bottom with latches on lid.
4. Simultaneously close both locking latches on the Aesculap Sterrad compatible STERILCONTAINER S™ lid.
NOTE: The weight of the instrument load should not exceed 14 pounds (validated with an 8" full size container) or 7 pounds each when using two smaller containers for effective sterilization and drying. It is important not to exceed the manufacturer’s recommended maximum total chamber weight. 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 inside of the container lid for effective processing.

Processing Assembly:

1. Select the appropriate Aesculap Indicator Card and insert into the holding bracket on the outside of the Sterrad compatible STERILCONTAINER S™ bottom. A tab at one end of the indicator card will facilitate insertion and removal.
   
   NOTE: Non-Cellulose cards must be used for Sterrad® sterilization.

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 Sterrad compatible STERILCONTAINER S™ container should be placed flat for effective sterilization and drying.
2. The Aesculap Sterrad compatible STERILCONTAINER S™ container should be positioned per the sterilizer manufacturers guidelines for optimum sterilization and drying conditions.

PROCESSING

Sterrad® 100S System:

Run loaded sterilizer according to time and temperature recommended by the sterilizer manufacturer for chosen cycle.

CAUTION: For Sterrad® 100S system sterilization, only use Aesculap Sterrad® Compatible STERILCONTAINER S™ bottoms and lids. Do not use other, non-Sterrad® compatible, Aesculap STERILCONTAINER™ bottom and lids.

SUGGESTED STERILIZER CYCLE PARAMETERS:

The following validated parameters are based on the validation of the non-anodized Aesculap® Sterilcontainer in the Sterrad 100S system. Each facility may need to run internal testing to determine if adjustments are necessary for their facility.

**STERRAD® 100S CYCLE:**

<table>
<thead>
<tr>
<th>Step</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Plasma</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Injection/Diffusion</td>
<td>8 minutes (16 minutes total injection/diffusion time)</td>
</tr>
<tr>
<td>Plasma</td>
<td>2 minutes (4 minutes total plasma time)</td>
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</tbody>
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NOTE: Consult with the manufacturer of the sterilizer for specific recommendations. Complex devices such as lumened instruments should be sterilized in accordance with the instrument manufacturer’s instructions. This container has been validated with 5 stainless steel lumens. Do not load with lumens of less than 3 mm inner diameter nor greater than 400 mm in length.
SUMMARY OF TESTING

Sterilization performance studies were conducted for the Aesculap® Sterilcontainer in the Sterrad 100S system and all acceptance criteria were met. Event related shelf life testing has been conducted for the non-anodized Aesculap Sterilcontainer with a polypropylene filter after processing in the Sterrad 100S. Reuse testing up to 100 complete cycles showed no effect on the function of the container. Further details on this testing can be obtained from Aesculap.

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