



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

October 9, 2015

Aesculap®, Inc.  
Peter Stoll  
Regulatory Affairs Specialist  
3773 Corporate Parkway  
Center Valley, PA 18034

Re: K151242  
Trade/Device Name: SterilContainer S  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: Class II  
Product Code: KCT  
Dated: September 8, 2015  
Received: September 9, 2015

Dear Mr. Stoll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**  
**Clinical Deputy Director**  
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.  
Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K151242

Device Name  
SterilContainer S

### Indications for Use (Describe)

The SterilContainer S System is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and single use polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the V-PRO maX Low Temperature Sterilization System Flexible Cycle.

**Table 1: Validated V-PRO maX Sterilizer Flexible Cycle Load Configurations**

|                                    |   |
|------------------------------------|---|
| <p><b>Load Configuration 1</b></p> | <p>Two SterilContainer S System containers each with a basket, mat, accessories and a flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and no additional load.</p> <p>The flexible endoscopes may contain either:</p> <ul style="list-style-type: none"><li>• a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter</li><li>• or two lumens: one lumen with an inside diameter of 1mm or larger and length of 990mm or shorter; the second lumen with an inside diameter of 1mm or larger and length of 850mm or shorter</li></ul>  |
| <p><b>Load Configuration 2</b></p> | <p>Two SterilContainer S System containers, each with a basket, mat and accessories.**</p> <p>The first SterilContainer S System container holds a flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and no additional load.</p> <p>The flexible endoscopes may contain either:</p> <ul style="list-style-type: none"><li>• a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter</li><li>• or two lumens: one lumen with an inside diameter of 1mm or larger and length of 990mm or shorter; the second lumen with an inside diameter of 1mm or larger and length of 850mm or shorter</li></ul> <p>The second SterilContainer S System container holds reusable metal and non-metal non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.</p> <p>The total load weight validated was 24 lbs.</p> |

\*\* The validation studies were conducted with a flexible endoscope in a SterilContainer S System container with basket, silicone mat, accessories and light cord (if not integral to endoscope). Also included in the load was an additional SterilContainer S System container with instruments for a total load weight of 24.0 lbs.

**Table 2: V-PRO maX Sterilizer Flexible Cycle Compatible SterilContainer S Container Systems**

| Lid   | Bottom | Description              | Total Loaded Container Weight (if container does not contain a flexible endoscope or bronchoscope)*                       |
|-------|--------|--------------------------|---|
| JM489 | JM440  | Full Size 90mm (4 1/4")  | <b>24 lbs</b> for one container in the chamber<br><br>OR<br><br><b>24 lbs</b> split between two containers in the chamber |
|       | JM441  | Full Size 120mm (5 1/2") |   |
|       | JM442  | Full Size 135mm (6")     |   |
| JM789 | JM740  | 3/4 Size 90mm(4 1/4")    |   |
|       | JM741  | 3/4 Size 120mm (5 1/2")  |   |
|       | JM742  | 3/4 Size 135mm (6")      |   |
| JM389 | JM340  | 1/2 Size 90mm (4 1/4")   |   |
|       | JM341  | 1/2 Size 120mm (5 1/2")  |   |
|       | JM342  | 1/2 Size 135mm (6")      |   |

\*Loads containing a flexible endoscope or bronchoscope should follow Table 1 recommendations

**Table 3: V-PRO maX Sterilizer Flexible Cycle Compatible Accessories**

| Accessories  | V-PRO maX Flexible Cycle |
|--|--------------------------|
| Stainless Steel baskets, basket lids, and dividers   | Yes                      |
| Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps) | Yes                      |
| Silicone mats  | Yes                      |
| Stainless Steel racks, trays, holders, clamps, brackets, and platforms                             | Yes                      |

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**K151242**

**510(k) SUMMARY (as required by 21 CFR 807.92)**

**SterilContainer™ S**

**COMPANY:** Tuesday, October 06, 2015  
Aesculap®, Inc.  
3773 Corporate Parkway  
Center Valley, PA 18034  
Establishment Registration Number: 2916714

**CONTACT:** Peter Stoll  
610-984-9076 (phone)  
610-791-6882 (fax)

**TRADE NAME:** SterilContainer S

**COMMON NAME:** Sterilization Container

**CLASSIFICATION NAME:** Sterilization Wrap

**REGULATION NUMBER:** 880.6850

**PRODUCT CODE:** KCT

**DEVICE CLASS:** Class II per 21 CFR §880.6850

**DEVICE DESCRIPTION**

The SterilContainer™ S is a container system that will allow for sterilization and storage of medical devices. This container system can be used in the Amsco® V-PRO™ maX Flexible Cycle. The SterilContainer™ S rigid containers are made from non-anodized Aluminum and utilize disposable (single use) polypropylene filters. The SterilContainer™ S includes accessories such as mats, baskets, trays, holders, organizers, filters, indicator cards and tamper proof locks.

**INDICATIONS FOR USE**

The SterilContainer S is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and single use polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the V-PRO maX Low Temperature Sterilization System Flexible Cycle.

**Table 1: Validated V-PRO maX Sterilizer Flexible Cycle Load Configurations**

|  |  |
|--|--|
| <p style="text-align: center;"><b>Load Configuration 1</b></p> | <p>Two SterilContainer <i>S</i> containers each with a basket, mat, accessories and a flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and no additional load.</p> <p>The flexible endoscopes may contain either:</p> <ul style="list-style-type: none"> <li>• a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter</li> <li>• or two lumens: one lumen with an inside diameter of 1mm or larger and length of 990mm or shorter; the second lumen with an inside diameter of 1mm or larger and length of 850mm or shorter</li> </ul>  |
| <p style="text-align: center;"><b>Load Configuration 2</b></p> | <p>Two SterilContainer <i>S</i> containers, each with a basket, mat and accessories.**</p> <p>The first SterilContainer <i>S</i> container holds a flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and no additional load.</p> <p>The flexible endoscopes may contain either:</p> <ul style="list-style-type: none"> <li>• a single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter</li> <li>• or two lumens: one lumen with an inside diameter of 1mm or larger and length of 990mm or shorter; the second lumen with an inside diameter of 1mm or larger and length of 850mm or shorter</li> </ul> <p>The second SterilContainer <i>S</i> container holds reusable metal and non-metal non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.</p> <p>The total load weight validated was 24 lbs.</p> |

\*\*The validation studies were conducted with a flexible endoscope in a SterilContainer *S* container with basket, silicone mat, accessories and light cord (if not integral to endoscope). Also included in the load was an additional SterilContainer *S* container with instruments for a total load weight of 24.0 lbs.

**Table 2: V-PRO maX Sterilizer Flexible Cycle Compatible SterilContainer *S* Container**

| Lid   | Bottom | Description            | Total Loaded Container Weight (if container does not contain a flexible endoscope or bronchoscope)*                   |
|-------|--------|------------------------|---|
| JM489 | JM440  | Full Size 90mm (4 ¼")  | <b>24 lbs</b> for one container in the chamber<br><br>OR<br><b>24 lbs</b> split between two containers in the chamber |
|       | JM441  | Full Size 120mm (5 ½") |   |
|       | JM442  | Full Size 135mm (6")   |   |
| JM789 | JM740  | ¾ Size 90mm(4 ¼")      |   |
|       | JM741  | ¾ Size 120mm (5 ½")    |   |
|       | JM742  | ¾ Size 135mm (6")      |   |
| JM389 | JM340  | ½ Size 90mm (4 ¼")     |   |
|       | JM341  | ½ Size 120mm (5 ½")    |   |
|       | JM342  | ½ Size 135mm (6")      |   |

\*Loads containing a flexible endoscope or bronchoscope should follow Table 1 recommendations

**Table 3: V-PRO maX Sterilizer Flexible Cycle Compatible Accessories**

| Accessories  | V-PRO maX Flexible Cycle |
|--|--------------------------|
| Stainless Steel baskets, basket lids, and dividers   | Yes                      |
| Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps) | Yes                      |
| Silicone mats  | Yes                      |
| Stainless Steel racks, trays, holders, clamps, brackets, and platforms                             | Yes                      |

## COMPARISON TO PREDICATE

The SterilContainer S that can be used in the Amsco® V-PRO™ maX Flexible Cycle is the same container system as was cleared in K093649. The materials and design have not changed.

|                       |                                |   |
|-----------------------|--------------------------------|---|
| System                | SterilContainer S (K151242)    | Aesculap SterilContainer S (K093649)                        |
| Sterilization process | Amsco V-PRO maX Flexible Cycle | Amsco V-PRO 1 and V-PRO 1 Plus (Lumen and Non Lumen Cycles) |
| Material              | Non-anodized aluminum          | Non-anodized aluminum                                       |
| Container type        | Perforated                     | Perforated  |
| Filter type           | Polypropylene                  | Polypropylene   |

|                     |   |  |
|---------------------|---|--|
| Indications for Use | The SterilContainer S is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and single use polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the V-PRO maX Low Temperature Sterilization System Flexible Cycle. | The Aesculap Sterilcontainer is a reusable sterilization container system intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the V-PRO 1 and V-PRO 1 Plus Systems. The Sterilcontainer S System includes accessories such as silicon mats, baskets, trays, and racks. |
|---------------------|---|--|

## PERFORMANCE DATA

The Aesculap SterilContainer S has been validated for the Amsco® V-PRO™ maX Flexible Cycle Low Temperature Sterilization System. These validations were conducted by a qualified testing laboratory. The performance testing demonstrates substantial equivalence to the predicate devices. The following performance testing has been completed to ensure substantial equivalence.

| Performance Properties                    | Results   |
|---|---|
| Sterilization Efficacy                    | Testing demonstrated a 6 log reduction and a sterility assurance level (SAL) of $10^{-6}$ using the biological (BI) overkill method and half-cycle validation.  |
| Whole Package Microbial Aerosol Challenge | After exposure to a defined amount of aerosol microorganisms contents maintained sterility  |
| Event Related Sterility Maintenance       | Testing demonstrated the ability to provide an effective barrier for maintaining sterility of the contents after processing followed by a 180 day event related storage under conditions which simulate hospital sterile package handling and storage conditions. |
| Material Compatibility                    | After 100 cycles of processing no visible or functional changes were observed   |

|               |   |
|---------------|---|
| Simulated Use | A worst case dual channel flexible endoscope was reproducibly sterilized under worst case simulated use testing conditions in the Flexible Cycle. |
|---------------|---|

**Conclusion**

The SterilContainer™ S is substantially equivalent to the predicate device cleared under K093649.