Aesculap® SterilContainer™ System Instructions for Use

Steam, Ethylene Oxide and Vapor Hydrogen Peroxide Sterilization Modalities

Instructions for Use Intended for US Only

As of June 2020

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1.0 Purpose of Instructions for Use

The purpose of this document is to:

Describe the components of the SterilContainer™ System, how each should be used, and which components can be used together in each of the sterile processing modalities.
Provide detailed instructions on how to use, decontaminate, clean and process the SterilContainer™ System properly in different sterilization modalities.
Give guidance for verifying the SterilContainer™ System in your facility and application.

Instructions included in this document are based on validation testing by Aesculap® in a medical device testing laboratory using worst case scenario.

Each facility should ensure their processing system provides similar results. Personnel training and competency is required to perform all phases of processing. Equipment, water supply, and practices all contribute to providing an effective reprocessing system and should be monitored by the facility.

2.0 SterilContainer™ System

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 the various sizes of container bottoms, container lid, and basket options, and Aesculap® accessories such as instrument holders, baskets, filters, indicator cards and tamper evident locks.

The first two letters of the part number are the series name, and identify the product family and attributes of each bottom and lid. See chart. Each container bottom must ***ONLY*** be used with the specific lid designed for that series of container, and it should not be combined with other Aesculap® or non-Aesculap® series of bottoms or lids.

Product Family	**SterilContainer™**						**SterilContainer™ S**	**SterilContainer™ S2**
Bottom Series	**JK** *Solid, Anodized*			**JN** *Perforated, Anodized*			**JM** *Perforated, Non-Anodized*	**JS** *Perforated, Anodized*
Lid Series[3, 5]	**JK**	**PrimeLine™[4]**	**PrimeLine Pro[4]**	**JK**	**PrimeLine[4]**	**PrimeLine Pro[4]**	**JM**	**JS**
PreVac Steam	X	X	X	X	X	X	X	X
PreVac IUSS	X	X	X					
Gravity				X			X	X
EtO	X			X			X	X
Low Temp STERRAD®[1]							X	X
Low Temp STERIS®[2]							X	X
Low Temp STERIZONE[6]							X	X

1. See section 8.0 SterilContainer™ System Sterilizer Cycle Parameters – ASP STERRAD® for more details on sterilizer cycle details.
2. See section 9.0 SterilContainer™ System Sterilizer Cycle Parameters – STERIS® V-PRO® for more details on sterilizer cycle details.
3. JK, JN, JM, JS and PrimeLine Pro lids are made of aluminum. PrimeLine is made of High-Grade, Thermostable Plastic.
4. PrimeLine and PrimeLine Pro lids have a reusable filter and are only available for JK and JN Series full-size, three-quarter size and half size containers.
5. See 6.0 Preparation and Assembly of SterilContainer™ System for filter modality compatibility.
6. See section 10.0 SterilContainer™ System Sterilizer Cycle Parameters – STERIZONE® for more details on sterilizer cycle details.

Figure 1: SterilContainer™ System

Throughout this IFU document, references to the SterilContainer™ System include the SterilContainer™, SterilContainer™ S and the SterilContainer™ S2 product families. References to the SterilContainer™ only include the JK / JN Series of products, references to SterilContainer™ S only include JM Series of products, and references to SterilContainer™ S2 only include JS Series of products.

JK Solid Bottom

JN Perforated Bottom

JS Perforated Bottom
Identified by the Gold Handle & Latch

The SterilContainer™ System full, three-quarter and half size JK Series and JN Series have three lid options.

JK Series Aluminum Lids
with Metal Retention Plate

JP1 Series PrimeLine™ Pro

JP0 Series PrimeLine

Aesculap® has performed the required validation tests, including accepted aerosol testing methodology for medical devices, and received FDA clearance for its sterile container products when used in the following sterilizations modalities. The modalities for each container series vary. Please refer to Sections 7.0 (Steam and EtO), 8.0 (STERRAD®) and 9.0 (STERIS®) Cycle Parameters to determine appropriate container bottom, lid, filter, lock and indicator card for sterilization cycle being used.

Primary Name	Which Includes	May Also Be Referred to As
Steam Sterilization[1]	Dynamic Air Removal PreVacuum Steam	PreVacuum Steam, PreVac Steam[1,2]
	Dynamic Air Removal Immediate Use	PreVacuum Immediate Use, PreVac IUSS[1,2]
	Gravity	Gravity[1]
Ethylene Oxide	Ethylene Oxide	EtO[1]
Hydrogen Peroxide	Gas Plasma Vapor Hydrogen Peroxide	Low Temperature[1], H2O2, STERRAD®[3], STERIS®[3], V-PRO®[3]
Hydrogen Peroxide and Ozone	Ozone	Low Temperature1 TS03[3], STERIZONE[3], VP4[3]

1. These terms will be used throughout the remainder of the Instructions for Use (IFU).
2. Aesculap® validations for PreVac Steam can be applied to Steam Flush Pressure Pulse (SFPP) with like cycles
3. May also be generically referred to by the sterilizer manufacturer's model name and/or cycle name.

Figure 2: Sterilizations Modality Nomenclature and SterilContainer™ System Compatibility

The SterilContainer™ System is designed to be processed on a daily basis and provide years of continual use. When selecting a container system, make sure the container and instruments match the application and sterilization requirements properly. AAMI ST79 Annexes on the "Development of a Pre-purchase Evaluation Protocol for Rigid Sterilization Container Systems", provides guidelines on how to conduct an evaluation.

SterilContainer™ System Processing Supplies include single use paper and polypropylene filters, tamper evident locks and indicator cards. See Section 6.0 Preparation and Assembly of SterilContainer™ System for more information and for filter modality compatibility.

All Aesculap® filters, locks and indicator cards have been designed and validated specifically for the SterilContainer™ System. They should not be used with other brand container systems. Aesculap® does not recommend using non-Aesculap® brand filters, locks and indicator cards, and cannot guarantee proper performance with these products. All processing supplies are shipped non-sterile.

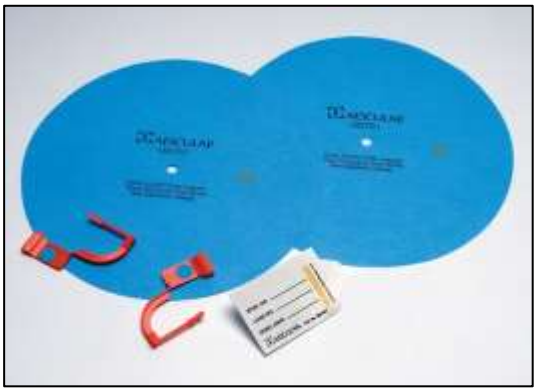


Image 1: Single Use Processing Supplies, Filters, Tamper Evident Locks, Indicator Cards

SterilContainer™ System accessories include the following:

- Identification labels or tags
- Mats
- Instrument Organization System (IOS)
- Racks and scope holding platform
- Instrument stringers

Contact an Aesculap® sales representative or customer service for more details on accessories.

Notes:

- *Each facility should ensure its processing system provides similar results. Personnel training and competency is required to perform all phases of manual processing. Equipment, water supply, and practices all contribute to providing an effective reprocessing system and should be monitored by the facility.*
- *Visit www.youtube.com/Aesculapusa SterilContainer™ System section for informational videos on SterilContainer™ System proper sterile reprocessing preparation.*
- *See AAMI ST79 for more details and recommendations.*
- *Silicone instrument holders, mats and the gasket in lid and filter retention plate are not made with natural rubber latex*
- *The Aesculap® reusable PTFE filters have been validated and are FDA cleared for PreVac Steam and PreVac Immediate Use Steam Sterilization (IUSS) for up to 2,200 cycles (decontaminate–wash–inspect-assemble–sterilize–use).*
- *Using a non-toxic permanent marking pen, record the date put into service and the estimated remove from service date, in mm/dd/yy format. Calculate the remove from service date based on the average expected reprocessing levels for your facility. Do not exceed 2,200 cycles.*

- *Aesculap® baskets and accessories can be cleaned and sterilized following accepted industry guidelines and by using the same processes as Aesculap® sterile container bottoms.*
- *Aesculap® IOS pieces (IOS Mounting Type B & C) and mats are made of silicone and cutting them does not change the characteristics of the material and/or its function.*
- *Aesculap® SterilContainer™ System only performs container testing with baskets and does not recommend using containers without baskets or with only mats. The only exception is the JK187 and JN187 because of their size and height, a mat only is acceptable.*
- *Aesculap® Sterilit® JF598 and JG600 are non-silicone lubricants and do not require any additional PPE during use. The drops and the spray can be used interchangeably unless specified by an instrument manufacturers' IFU. The drops will provide more precise application in small area. When applying oil, a reasonable amount should be used. For the drops this would be one or two drops, and for the spray it would be a light even coating of the area that requires lubrication. Excess oil should be removed with a clear lint-free cloth after proper application. The oil should not cause build up when excess oil is removed and the instrument is cleaned properly. pH by its definition specifically requires a product to be in a water-based solution to be measured, which Sterilit products are not. Therefore it does not have a pH. MSDS sheets are available for products on Aesculap® website, www.Aesculapusa.com/en/company/quality-assurance.html.*

3.0 SterilContainer™ System Service

Like all reusable medical devices, the SterilContainer™ System requires inspection prior to use (refer to Section 5.0 Inspection Prior to Use), and proper care and handling.

The Aesculap® SterilContainer™ System is a FDA Class II device that requires extensive testing and FDA 510(k) clearance. An Aesculap® trained technician can service containers to the original equipment manufacturer dimensions and specifications of the original containers used in the validation and replace parts such as gaskets, filter systems and handles with the same Aesculap® components.

ONLY Aesculap® trained technicians are authorized to service the Aesculap® SterilContainer™ System. Using a non-Aesculap® service technician to service containers will void the Aesculap® Warranty on the container and may void any of the validation testing associated with Aesculap® containers.

Aesculap® offers a wide variety of container service programs that can be performed by either our highly trained technicians at our central service facility in St. Louis, or by our mobile van service specialists. All of the service specialists are Aesculap® employees who go through extensive training on Aesculap® products.

Contact an Aesculap® representative or call customer service (1-800-214-3392 or atscsr.us@Aesculap®.com) for more details.

Notes:

- *All products being returned for maintenance/service must be thoroughly cleaned and decontaminated before service.*
- *Retention plates should be replaced when they show wear, age and/or are damaged. The retention plate on the metal lids should not spin freely when properly installed and in proper working condition. Note that the retention plate may move a little if significant amount of pressure is applied while trying to twist or turn (especially when filter is installed).*
- *The black PEEK feet on the Aesculap® JF baskets assist in aligning the JF baskets when stacking them in a container or during the reprocessing process. These feet may wear and/or break overtime depending on the processing (number of times, chemicals, water quality), application (type of set) and use (handling of the product). Inspect basket and feet prior to use. Replace if desired, using Aesculap® part number JF112210.*

4.0 Decontamination and Cleaning Process

Follow facility's policies, procedures, and AAMI ST79 recommended guidelines for the transportation of soiled instruments and containers. Always wear appropriate personal protective equipment (PPE) per the healthcare facility's policy and procedures when transporting and cleaning the SterilContainer™ System.

DO NOT USE abrasive cleaners, metal brushes or abrasive cleaning pads. Use of abrasive products can cause permanent damage to container surfaces. Use of abrasive cleaners or pads will result in warranty exclusion.

If the container and/or lid are soiled, they must be fully cleaned. For containers and/or lids that are not soiled and have been removed from the operating room before the patient entered, the facility should determine best cleaning practice based on its established policy and procedures.

Container, lids and baskets that may not be used or needed right away should be decontaminated and cleaned prior to storage. The SterilContainer™ System should be stacked neatly, either assembled or unassembled, in a dry, clean area.

Notes:

- *Thoroughly clean all Aesculap® container products, baskets, accessories and replacement parts prior to first use and after container service has been performed. Items are shipped nonsterile.*
- *Cleaning wipes with pH range of 6.5 to 8.5 that do not contain chlorides will not harm the aluminum surface. The effectiveness of wipes in cleaning the container system has not been evaluated by Aesculap®. The use of wipes should be determined based on established facility policy and procedures. See cleaning wipe manufacturer Instructions for Use and AAMI ST79. Aesculap® has no validation testing for the use of wipes in the decontamination and cleaning process.*
- *Remove container bottom and JK Series, JM Series and JS Series aluminum lid retention plate(s) by pushing inward simultaneously on the two buttons on the center section of the retention plate.*
- *To replace container bottom and JK Series, JM Series and JS Series aluminum lid retention plate(s), press down evenly on retention plate. Listen to audible "click" to confirm filter is locked in place.*
- *Aesculap® baskets may be processed in an ultrasonic cleaner. The ultrasonic cleaner may loosen basket accessors and Instrument Organization System (IOS). Aesculap® has not evaluated the use of SterilContainer™ bottoms and lids in ultrasonic cleaners.*

4.1 Water Quality

Water quality is an important consideration in all stages of medical device reprocessing and can contribute to providing an effective reprocessing system and should be monitored by the facility. AAMI TIR34:2014 outlines the different types of water and the specific use of each.

4.1.1 Utility Water

Utility water, per AAMI TIR34, is water as it comes from the tap that might require further treatment to achieve the specifications. See AAMI TIR34 for specifications table. This water is mainly used for flushing, washing, and rinsing.

4.1.2 Critical Water

Critical water, per AAMI TIR34, is water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is recommended for the final rinse and steam generation to avoid discoloration or damage resulting from minerals found in utility water.

4.2 Detergent Solutions

Use detergent in a water solution where the detergent and water have a pH range of 6.5 to 8.5 to clean effectively and without causing damage to the SterilContainer™ or SterilContainer™ S containers.

Notes:

- *The use of utility water in mechanical washers may result in the water having a high alkaline level which could be harmful to the container surface. Critical water should be used for the final rinse.*
- *If white residue is observed on the container, this may have been caused by a high pH, alkaline cleaning solution. Check pH level of water and detergent solution throughout the process—reduce to a pH of 6.5 to 8.5. The white residue does not impact form, fit or function.*
- ***DO NOT USE** solvents such as acetone or benzene, which may be found in chemical drying rinses on the PrimeLine™ and PrimeLine Pro Lids. Use of these products can cause permanent damage to lid surfaces and/or filter housing, and result in warranty exclusion.*

4.3 Decontamination and Mechanical Cleaning

1. Remove all remaining external process indicators and disposable locks.
2. Remove lid from bottom of container.
3. Remove the basket and any instruments from the container.
4. Single Use Filter
   a. Remove retention plate(s).
   b. Remove single use filter(s) and discard (if present).
   c. Rinse visible debris from retention plate(s).
   d. The metal retention plate may be washed separately or installed during mechanical washing.
5. Reusable Filter
   a. Remove retention plate while leaving filter in place.
   b. Rinse visible debris from retention plate(s).
   c. Do not discard reusable filter if in good working condition and within recorded date. Reusable filter may remain held in place by the retention plate during cleaning provided there is no visible sign of wear, damage and/or bioburden. The PTFE filter material is hydrophobic so blood and other liquids can be rinsed off the filter if bioburden is observed.
   d. Replace retention plate(s).
6. Rinse visible debris from all container components.
   a. Critical water is recommended for the final rinse and steam generation to avoid discoloration or damage resulting from minerals found in utility water.
   b. For PrimeLine™ and PrimeLine Pro - Exclusively use critical water for the final rinse and make sure no residues from the cleaning process remain on the lid.
7. Place components on washer rack facing down to avoid water collection.
   a. Fold the lid handles towards the inside of the lid to avoid water collection and damage.
   b. Retention plates should face away from the direct force of pressurized washer jets to avoid damage during wash cycles.
8. After mechanical cleaning cycle
   a. Thoroughly dry (either with a soft, dry cloth or air dry) all components, and retention plate and retention plate housing (PrimeLine™ and PrimeLine Pro) before proceeding to preparation and packaging.
   b. If retention plates were installed during mechanical washing, remove retention plate(s) and dry area between retention plate and container.

(From Aesculap® DOC1006) 		
Remove filter retention plate by turning counter clockwise.	Retention plate should be free of cracks and damage.	Reusable filter may remain inside lid during inspection. Check filter integrity for rips/tears. Retention plates may be installed during mechanical washing.

Figure 3: PrimeLine™ Pro Lid Inspection Process

Notes:

- *After cleaning, visually inspect and repeat the cleaning process if a visually clean endpoint has not been achieved.*
- ***DO NOT USE** solvents such as acetone or benzene, which may be found in chemical drying rinses on the PrimeLine™ and PrimeLine Pro lids. Use of these products can cause permanent damage to lid surfaces and/or filter housing, and result in warranty exclusion.*
- *The integrated filter system, and the decontamination, cleaning, inspection and aseptic presentation process are the same for PrimeLine™ and PrimeLine Pro.*
- *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, the size of penny with a soft dry, non-linting cloth and rub to polish the surface. If needed, repeat with an increasing volume. Thoroughly remove all residual cleaning cream. Critical water is recommended for the final rinse. Cleaner may cause discoloration and/or fading of colored surfaces. **DO NOT USE** cleaner on PrimeLine™ lid, and PrimeLine Pro lid filter housing and stainless steel covers.*

4.4 Decontamination and Manual Cleaning

Each facility should ensure their processing system provides similar results. Personnel training and competency is required to perform all phases of manual processing. Equipment, water supply, and practices all contribute to providing an effective reprocessing system and should be monitored by the facility.

1. Remove all remaining external process indicators and disposable locks.
2. Remove lid from bottom of container.
3. Remove the basket and any instruments from the container.
4. Single Use Filter
   a. Remove retention plate(s).
   b. Remove single use filter(s) and discard (if present).
   c. Rinse visible debris from retention plate(s).
   d. The retention plate should be washed separately.
5. Reusable Filter
   a. Remove retention plate while leaving filter in place.
   b. Rinse visible debris from retention plate(s).
   c. Do not discard reusable filter if in good working condition and within recorded date. Reusable filter may remain held in place by the retention plate during cleaning provided there is no visible sign of wear, damage and/or bioburden. The PTFE filter material is hydrophobic, so blood and other liquids can be rinsed off the filter if bioburden is observed.
   d. Replace retention plate(s).
6. Rinse visible debris from all container components.

a. Critical water is recommended for the final rinse and steam generation to avoid discoloration or damage resulting from minerals found in utility water.
b. For PrimeLine™ and PrimeLine Pro - Exclusively use critical water for the final rinse and make sure no residues from the cleaning process remain on the lid.

7. Use a soft sponge and detergent, as described in Section 4.2 Detergent Solutions, to clean the components of the SterilContainer™.
8. After manually cleaning
   a. Thoroughly dry (either with a soft, dry cloth or air dry) all components, and retention plate and retention plate housing (PrimeLine™ and PrimeLine Pro) before proceeding to preparation and packaging.
   b. If retention plates were installed during washing, remove retention plate(s) and dry area between retention plate and container.

Notes:

- *After cleaning, visually inspect and repeat the cleaning process if a visually clean endpoint has not been achieved.*
- *If the container and/or lid are soiled, they must be fully cleaned. For containers and/or lids that are not soiled and have been removed from the operating room before the patient entered, the facility should determine best cleaning practice based on its established policy and procedures.*
- *Cleaning wipes with pH range of 6.5 to 8.5 that do not contain chlorides will not harm the aluminum surface. The effectiveness of wipes in cleaning the container system has not been evaluated by Aesculap®. The use of wipes should be determined based on established facility policy and procedures. See cleaning wipe manufacturer Instructions for Use and AAMI ST79. Aesculap®has no validation testing for the use of wipes in the decontamination and cleaning process.*
- ***DO NOT USE** Alcohol wipes – alcohol will harm the PrimeLine™ lid or PrimeLine Pro filter housing.*
- *If components are too large to be immersed at the facility, then the components should be cleaned in a manner that will not produce aerosols. Please refer to AAMI ST79 for recommended practices.*
- *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, the size of penny with a soft dry, non-linting cloth and rub to polish the surface. If needed, repeat with an increasing volume. Thoroughly remove all residual cleaning cream. Critical water is recommended for the final rinse. Cleaner may cause discoloration and/or fading of colored surfaces. **DO NOT USE** cleaner on PrimeLine™ lid, and PrimeLine Pro lid filter housing and stainless steel covers.*
- ***DO NOT USE** solvents such as acetone or benzene, which may be found in chemical drying rinses on the PrimeLine™ and PrimeLine Pro Lids. Use of these products can cause permanent damage to lid surfaces and/or filter housing, and result in warranty exclusion.*
- *The integrated filter system, and the decontamination, cleaning, inspection and aseptic presentation process are the same for PrimeLine™ and PrimeLine Pro.*
- *Aesculap®baskets and accessories can be cleaned and sterilized following accepted industry guidelines and by using the same processes as Aesculap®sterile container bottoms.*

5.0 Inspection Prior to Use

Inspection of the container and its components must be conducted ***PRIOR TO EVERY USE***.

If any of the conditions described in this section are observed ***DO NOT USE*** the SterilContainer™ or SterilContainer™ S container bottom and/or lid. Contact Aesculap®for service. Using a non-Aesculap®service technician to service containers will void the Aesculap®Warranty on the container and may void any of the validation testing associated with Aesculap® containers. See Section 3.0 SterilContainer™ System Service for full details regarding service.

Please refer to Sections 7.0 (Steam and EtO), 8.0 (STERRAD®), 9.0 (STERIS®) Cycle Parameters to determine appropriate container bottom, lid, filter, lock and indicator card for sterilization cycle being used.

Notes:

- *After cleaning, and before use, visually inspect and repeat the cleaning process if a visually clean endpoint has not been achieved.*
- *Remove container bottom and JK Series and JM Series aluminum lid retention plate(s) by pushing inward simultaneously on the two buttons on the center section of the retention plate.*
- *To replace container bottom and JK Series and JM Series aluminum lid retention plate(s), press down evenly on retention plate. Listen to audible "click" to confirm filter is locked in place.*
- *The metal retention plate may be washed separately or installed during mechanical washing. Retention plates should face away from the direct force of pressurized washer jets to avoid damage during wash cycles.*

5.1 SterilContainer™ System Inspection Criteria

1. All container components should be inspected and free from
   a. Observable cracking in aluminum and/or plastic.
   b. Any misalignment and/or dents in which the lid and bottoms do not adequately mate.
   c. Any pitting in the aluminum.
2. Lid silicone gasket should be inspected and free from any sign cracking or damage.
3. For metal retention plates.
   a. Remove retention plate by pressing in on the two tabs and lifting.
      For reusable filter, leave filter in place during inspection.

Reusable filter may remain in place inside lid during inspection. Check filter integrity for damage. The retention plate may be installed during mechanical washing.

Image 2: JK, JN and JM Lid Reusable Filter Inspection

   b. Metal filter retention plate and silicone gasket should be inspected and free from:
      i. Any sign of cracking or damage.
      ii. Any misalignment or damage in which retention pin, filter, retention plate and/or gasket do not adequately mate.
   c. Confirm retention plate is not bent by placing retention plate on flat surface to check for continuous contact around edge. Note that when performing the inspection, there will be a uniform space between the outer most edge of the retention plate and the surface since the retention plate has a raised gasket.

(From Aesculap® DOC1006) 		
Remove filter retention plate by pressing in on the two tabs and lifting.	Place retention plate on flat surface to check for continuous contact around edge. Retention plate gasket should be free of cracks or damage.	Pin for filter retention plate must be secure and firm. The retention plate may be installed during mechanical washing.

Image 3: Filter Retention Plates and Silicone Gaskets Inspection Process

d. Confirm filter retention pin is secure and firm.
e. Confirm filter retention plate is secure and firm on retention pin.
f. Remove retention plate from service if it does not meet criteria above, and replace with Aesculap® part number JK100 round, JK098 rectangle.

4. For PrimeLine™ and PrimeLine Pro lids.

(From Aesculap® DOC1006) 		
Remove filter retention plate by turning counter clockwise.	Retention plates should be free of cracks and damage.	Reusable filter may remain inside lid during inspection. Check filter integrity for rips/tears. Check that filter is within use-by date. Retention plate may be installed during mechanical washing.

Image 4: PrimeLine™ Lid Inspection Process

a. Remove retention plate by turning counter clockwise. Leaving filter in place.
b. Inspect reusable filter for holes, tears and rips. If observed, remove filter from service and replace with Aesculap® part number JP050.
c. Confirm filter is within use-by date (<2,200 cycles). Replace as needed.
d. Filter retention plate(s) and filter housing(s) should be inspected and free from:
    i. Any sign of cracking or damage.
    ii. Any misalignment or damage in which retention plate, filter and/or filter housing do not adequately mate.
e. Confirm filter, retention plate and filter housing are secure and firm.
f. Remove retention plate from service if it does not meet criteria above, and replace with Aesculap® part number JP001204.
g. Replace retention plate by turning clockwise.
h. Confirm outside cover is secured firmly.
    i. PrimeLine™ lid black cover may be replaced with Aesculap® part number JP001202. PrimeLine Pro lid should be serviced by Aesculap®. See 3.0 SterilContainer™ System Service for full details regarding service.

Notes:

- *If white residue is observed on the container, this may have been caused by a high pH, alkaline cleaning solution. Check pH level of water and detergent solution throughout the process—reduce to a pH of 6.5 to 8.5. The white residue does not impact form, fit or function.*
- *The SterilContainer™ S is made of non-anodized aluminum which undergoes a natural oxidation process. This oxidation process produces a very thin layer on the surface which may appear brown or black. This oxidation process will continue until the entire raw surface is oxidized. This brown or black discoloration is part of the natural processes. Please contact an Aesculap® representative for more information, if needed.*
- *Retention plates should be replaced when they show wear, age and/or are damaged. The retention plate on the metal lids should not spin freely when properly installed and in proper working condition. Note that the retention plate may move a little if significant amount of pressure is applied while trying to twist or turn (especially when filter is installed).*
- *Excessive removal and replacement of reusable filter over center pin may cause tearing of the center hole.*
- *Metal retention plate may be washed separately or installed during mechanical washing. Retention plates should face away from the direct force of pressurized washer jets to avoid damage during wash cycles.*
- *Using inspection and test methods other than those outlined in this IFU are not recommended and have not been validated by Aesculap®.*
- *The integrated filter system, and the decontamination, cleaning, inspection and aseptic presentation process are the same for PrimeLine™ and PrimeLine Pro.*
- *If the PrimeLine™ or PrimeLine Pro internal or external cover falls off after sterilization and before the set is used, the set can maintain sterility if no other event related incidence has occurred since it is a sealed filter system. The broken dustcover should be replaced and/or the lid should be serviced by Aesculap®. See Section 3.0 SterilContainer™ System Service for full details regarding service.*

5.2 Basket, Tray and Platforms Inspection Criteria

Baskets, trays and platforms should be inspected and free from:

1. Observable cracking and/or dents
2. Any misalignment of sides, bottom or handles
3. Any loose or worn handles, parts, feet, accessories or instrument organization system components

Notes:

- *Baskets with or without feet maybe used with SterilContainer™ System. Using baskets with feet may help reduce the possibility of scratching of basket on the container bottom.*
- *The black PEEK feet on the Aesculap® JF baskets assist in aligning the JF baskets when stacking them in a container or during the reprocessing process. These feet may wear and/or break overtime depending on the processing (number of times, chemicals, water quality), application (type of set) and use (handling of the product). Inspect basket and feet prior to use. Replace if desired, using Aesculap® part number JF112210.*

6.0 Preparation and Assembly of SterilContainer™ System

Inspection of the container and its components must be conducted ***PRIOR TO EVERY USE***. Please refer to Section 5.0 Inspection Prior to Use to learn how to properly inspect a container and its components. Ensure all container components are completely dry.

Each container bottom must ***ONLY*** be used with the specific lid designed for that series of container, and it should not be combined with other Aesculap® or non-Aesculap® series of bottoms or lids.

Determine the type of SterilContainer™ bottom and lid being assembled and proceed to that section. Please refer to Sections 7.0 (Steam and EtO), 8.0 (STERRAD®), 9.0 (STERIS®) Cycle Parameters to determine appropriate container bottom, lid, filter, lock and indicator card for sterilization cycle being used. All Aesculap® filters, locks and indicator cards have been designed and validated specifically for the SterilContainer™ System. They should not be used with other brand container systems.

Aesculap® does not recommend using non-Aesculap® brand filters, locks and indicator cards, and cannot guarantee proper performance with these products. All processing supplies are shipped non-sterile.

Filter Type	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp
Paper Filter w/ Indicator[1] US751	X[1]	X[1]	X[1]	X[1]	
Paper Filter w/o Indicator US994, US999	X	X	X	X	
Polypropylene Filter w/o Indicator MD344, MD355	X	X		X	X
Metal Retention Plate Lid PTFE Reusable Filter JK090, JK091	X	X			
PrimeLine™ & PrimeLine Pro PTFE Reusable Filter JP050	X	X			

1. *Filter contains a dual indicator dot, which changes from blue to brown in steam, and to orange in EtO.*

Figure 4: Filters for Perforated Bottoms and Lids

Notes:

- *Visit www.youtube.com/Aesculapusa SterilContainer™ System section for informational videos on SterilContainer™ System proper sterile reprocessing preparation.*
- *All information and steps outlined in this IFU should be followed. Aesculap® DOC1006 and DOC1007 may be used as a reference guide in Prep and Pack, and the OR respectively once personnel training and competency is achieved.*
- *The Aesculap® US756, US998, US992, JK092 and JK089 filters are designed for the Aesculap® generation 2 container, circa 1980s. The Generation 2 container filters have a different size and shape compared to the current SterilContainer™ System.*

6.1 SterilContainer™ System Assembly

1. ***ONLY USE*** containers and components that have passed the inspection criteria outlined in Section 5.0 Inspection Prior to Use.
2. Please refer to Sections 7.0 (Steam and EtO), 8.0 (STERRAD®), 9.0 (STERIS®) Cycle Parameters based on container system for proper filter selection.
3. For metal retention plates.
   Remove retention plate by pushing inward on the two buttons on the side of the center section of the retention plate.
   a. For single use filters.
      Place one sheet of the appropriate Aesculap® single use filter over each perforated section on the inside of the container lid and if used, the perforated bottom.
   b. For reusable filters.
      Leave filter in place during inspection.

Reusable filter may remain in place inside lid during inspection. Check filter integrity for damage. The retention plate may be installed during mechanical washing.

Image 5: Aluminum Lid with Metal Retention Plate and Reusable Filter

c. Confirm the filter lays flat, and secure each filter with the retention plate. Listen to audible "click" to confirm filter is locked in place.

Confirm the filter is laying flat, and secure each filter with the retention plate. Listen for audible "click" to confirm filter is locked in place.

Image 6: Aluminum Lid with Metal Retention Plate and Single Use Filer Assembly

4. For PrimeLine™ and PrimeLine Pro retention plates.

(From Aesculap® DOC1006) 		
Remove filter retention plate by turning counter clockwise.	Retention plate should be free of cracks and damage.	Reusable filter may remain inside lid during inspection. Check filter integrity for rips/tears. Check that filter is within use-by date. Retention plate may be installed during mechanical washing.

Image 7: PrimeLine™ Lid Inspection Process

a. Remove retention plate by turning counter clockwise. Leaving filter in place.
b. Inspect reusable filter for holes, tears and rips. Confirm filter is within use-by date (<2,200 cycles). Replace as needed with Aesculap® part number JP050. Arrows on filter and filter housing will align when filter is properly installed, see photo.
c. Replace retention plate by turning clockwise.

Notes:

- *The orientation of the paper filter with indicator can be placed in either orientation, indicator dot facing in or out of the retention plate. Facility should determine orientation based on its established policy and procedures.*
- *Single use paper filters are not compatible with Low Temperature sterilizers.*
- *Aesculap®only used one filter under each retention plate during our validation testing. If multiple filters are placed under retention plate accidentally we recommend that the set be rejected and be reprocessed.*
- *Container lid must ONLY be used with Aesculap®brand retention plate(s). Aesculap®retention plates may be identified by the Aesculap®name, the two release buttons on the center section and/or the part number.*

6.2 Assembly of Surgical Instrumentation

Instruments and all components of the SterilContainer™ System must be completely dry prior to sterilization processing to allow for adequate sterilant penetration. Sort and assemble thoroughly cleaned and dried instruments into the instrument basket(s), according to established hospital procedures. Follow instrument manufacturers' Instructions for Use.

6.3 Loading of Basket, Lifting Platform and Tray

The Aesculap®SterilContainer™ System may be used with a variety of baskets, trays and platforms.

Instruments set(s) should meet the following requirements:

1. Fit in the container with the proper clearance between the top of the set(s) and the lid;
2. Able to be aseptically removed in the OR;
3. Total weight should not exceed 25 lbs [AAMI ST79, Section 8.2] or the sterilizer manufacturer's weight limit, whichever is lower; and
4. Instrument(s) and container IFUs parameters (time/temperature and dry time) can be reconciled.

Please refer to Sections 7.0 (Steam and EtO), 8.0 (STERRAD®), 9.0 (STERIS®) Cycle Parameters to determine maximum weight of SterilContainer™ System for sterilization modality selected.

1. Place assembled instrument basket(s), lifting platform or support racks into the prepared container bottom.
2. Place assembled lid onto the container bottom, aligning handles on bottom with latches on lid.
3. Simultaneously close both locking latches on the container lid.

Notes:

- *All instruments should be arranged per the instrument manufacturers' Instructions for Use (IFU).*
- *Hospitals should refer to AAMI and accepted industry guidelines, and sterilization manufacturers' Instructions for Use (IFU) regarding weights and weight limits.*
- *Hospitals should reconcile the Aesculap®SterilContainer™ System, instrument manufacturers' and sterilization manufacturers' Instructions for Use (IFU) regarding sterilization parameters, set configurations and weight limit.*
- *Trays and baskets may be stacked inside the SterilContainer™ System if clearance requirements (below) are met and the set follows proper acetic presentation guidelines.*
  - ***Full-Size, Three-Quarter Size, Half-Size Wide-Body, Extra-Long Container —*** *Leave one inch of free space between the instruments and the rim of the container 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-Size Container —*** *Instruments and baskets can be loaded to the rim of the container as long as they do not interfere with the lid's filter retention plate or lid closure.*
  - ***Mini-Size and Quarter-Size Container —*** *Leave one quarter of an inch of free space between the instruments and the rim of the container 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.*

- *Baskets with or without feet maybe used with SterilContainer™ System. Using baskets with feet may help reduce the possibility of scratching of basket on the container bottom.*
- *The black PEEK feet on the Aesculap® JF baskets assist in aligning the JF baskets when stacking them in a container or during the reprocessing process. These feet may wear and/or break overtime depending on the processing (number of times, chemicals, water quality), application (type of set) and use (handling of the product). Inspect basket and feet prior to use. Replace if desired, using Aesculap® part number JF112210.*
- *The SterilContainer™ System PreVac Steam validation studies were performed with a silicone mat and non-linting surgical towel placed in the tray under the instruments as part of the "worst case" validation. Per ANSI/AAMI ST79 "Non-linting absorbent material may be placed in the tray to facilitate drying…It is important that the absorbent material be non-linting because lint can carry microorganisms into the surgical site as well as cause foreign-body reactions."*

6.4 Internal Process Indicators

Per AAMI ST79, internal process indicators are used to indicate that the container has been exposed to the sterilization process. If more than one basket/tray is used inside the container system, an indicator should be placed on each basket/tray.

The internal biological and/or chemical indicators may be placed in the center of each tray, unless the user feels a more challenging position exists elsewhere. In that case, place the chemical indicator where the user has determined the most challenging location. Use of internal indicators should be in accordance with the facility's policies and procedures.

Process indicators are designed to indicate that the device was exposed to the sterilization process while, integrating indicators are designed to react to all critical variables, with the stated values having been generated to be equivalent to, or exceed, the performance requirements given in the ISO 11138 series for BIs. See AAMI ST79 for full description and use of each type of chemical indicator.

Notes:

- *See Section 12.0 Customer Verification for information on chemical and biologic indicator placement and on how to perform a verification.*
- *Aesculap® does not validate containers with paper count sheets containing ink. Users to process count sheets according to their facility's protocol.*

6.5 External Process Indicators and Tamper Evident Seals

Per AAMI ST79, external process indicators are used to indicate that the container has been exposed to the sterilization process and to distinguish between processed and unprocessed containers. Use of external indicators should be in accordance with the facility's policies and procedures.

Please refer to Sections 7.0 (Steam and EtO), 8.0 (STERRAD®), 9.0 (STERIS®) Cycle Parameters to determine appropriate container bottom, lid, filter, lock and indicator card for sterilization cycle being used.

1. If desired, select the appropriate Aesculap® Indicator Card and insert into the holding bracket on the outside of the container. A tab at one end of the indicator card will facilitate insertion and removal.
2. Insert the appropriate tamper evident lock into the locking channel on each end.
3. Secure and close the tamper evident lock.

Tamper Evident Locks	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp
Blue / US900 No Indicator	X	X	X	X	X
Green / US905 Change[1] Yellow to Orange				X	
Orange / US906 Change[1] Blue to Brown	X	X	X		
Pink / US910[2] Change[1] Magenta to Blue					X[2]
Yellow / US399 Change[1] Blue to Brown		X			

1. *After sterilization, the external indicator should change from the original indicator color to indicate exposure to sterilant.* ***The post sterilization indicator color may vary and not be evenly shaded.***
2. *Locks must be stored in a controlled room temperature, away from alkaline chemicals, acids and sources of light.*

Figure 5: Tamper Evident Locks

Insert the lock into the channel, close and confirm it is secure. Repeat on the other side of container.

Installation Instructions for All Tamper Evident Locks		
		
Close the latch to secure the lid to container bottom. Insert the tamper evident lock through the channel. Indicator should be facing up (away from container.)	To close, insert end into the base until it clicks and locks in place.	Gently pull on the lock to confirm it is fully fastened and secure. Repeat on the other side of container.

Indicator & Communication Cards	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp
MD334, MD335 w/ Indicator Change[1] Blue					X
MD346, MD876, US754 w/ Indicator Change[1,2] Brown in Steam Change[1,2] Orange in EtO	X	X	X	X	
US963 w/o Indicator	X	X	X	X	X
MD399, MD345 w/ Indicator Change[1] Brown		X			

1. *After sterilization, the external indicator should change from the original indicator color to indicate exposure to sterilant.* ***The post sterilization indicator color may vary and not be evenly shaded.***
2. *Filter contains a dual indicator dot, which changes to brown in steam, and to orange in EtO.*

Figure 6: Indicator and Communication Cards

Notes:

- *The Aesculap® tamper evident locks with indicator and/or process indicator card may be used as external process indicators. See the outside product packaging label for care and handling information.*
- *After sterilization, the external indicator should change from the original indicator color to indicate exposure to sterilant. The post sterilization indicator color may vary and not be evenly shaded.*
- *There is no industry standard for the color shift of pre- and post-sterilization indicators to distinguish if a set has been exposed to sterilization. Refer to filter, lock and indicator card charts for proper Aesculap® indicator color changes.*
- ***Tamper Evident Locks US900, US905, US906 and US399 —*** *Store in a cool, dry place. Temperatures between 15° C/60° F and 30° C/86° F should be maintained. Significant changes in storage conditions for prolonged periods can have an adverse effect on the product. (Minor variations over short periods of time will have little or no effect on product.) Extreme storage conditions such as exposure to direct sunlight and/or storage on top of or near heat source should be avoided.* ***DO NOT USE*** *if the indicator dot color has changed before being processed.*
- ***Tamper Evident Lock US910 —*** *Low Temperature external Chemical Indicators (CIs) are particularly sensitive and must be stored in a controlled room temperature, away from alkaline chemicals, acids and sources of light prior to use.* ***DO NOT USE*** *beyond the expiration date provided on the outside product packaging. Change of color prior to use in the sterilizer could indicate that these CIs were exposed to too much light or high temperatures during storage. After being processed, low temperature tamper evident lock should be stored at a controlled room temperature away from alkaline chemicals, acids and sources of light. Indicators may turn white post-sterilization if not stored out of direct lighting.*
- ***Indicator & Communication Cards MD334, MD335 —****Store in original packaging until needed. Store unused indicators in controlled room temperature, away from any alkaline chemicals, acids and sources of light.* ***DO NOT USE*** *beyond the expiration date provided on the outside product packaging.*
- *Indicator & Communication Cards MD346, MD876, US754, MD399 — Store in dry cool place.*
- *The Aesculap® MD347 external indicator card is designed for the Aesculap® generation 3 container, circa 1990's. The current SterilContainer™ System has a slightly different card holder size than the generation 3 container. The functionality and performance of the MD347 is the same as our current MD346 external indicator card.*

6.6 Container Storage and Transportation

The Aesculap® rigid SterilContainer™ System is stackable. After sterilization, containers should be stored in a manner that reduces the potential for contamination, see AAMI ST79 and ASHRAE guidelines for further details. ***DO NOT*** stack more than three, 25 lbs each, containers high. Follow shelf manufacturer weight and height limit recommendations when stacking the containers during sterile storage.

The SterilContainer™ System has shown to maintain the sterility of its contents following successful event related sterility maintenance validation testing, see chart.

Product Family	SterilContainer™						SterilContainer™ S	SterilContainer™ S2
Bottom Series	**JK** *Solid, Anodized*			**JN** *Perforated, Anodized*			**JM** *Perforated, Non-Anodized*	**JS** *Perforated, Anodized*
Lid Series	**JK**	**PrimeLine™**	**PrimeLine Pro**	**JK**	**PrimeLine**	**PrimeLine Pro**	**JM**	**JS**
PreVac Steam	**360 Days**	**360 Days**	**360 Days**	**360 Days**	**360 Days**	**360 Days**	**360 Days**	**360 Days**
PreVac IUSS	*	*	*					
Gravity				**360 Days**			**360 Days**	**360 Days**
EtO	**360 Days**			**360 Days**			**360 Days**	**360 Days**
Low Temp STERRAD®							**360 Days**	**360 Days**
Low Temp STERIS®							**360 Days**	**360 Days**
Low Temp STERIZONE®							**180 Days**	**180 Days**

** Each facility should define how to handle immediate use instrument sets in their setting.*

Store processed SterilContainer™ Systems in a dry, clean and protected place. The loss of sterility is normally event-related and not time-related. Loss of sterility is not so much connected to the storage periods as to outside influences and the effects of storage, transportation, and handling. Therefore, blanket statements cannot be made regarding appropriate storage periods, see EN ISO 11607-1, ANSI/AAMI ST79 and DIN 58953-8. Facilities should establish processes and procedures related to storage and shelf life.

The storage period of the SterilContainer™ System has been investigated in various long-term studies. The preservation of sterility was demonstrated over this entire period. The storage conditions used in the tests met the requirements of ANSI/AAMI ST79 and ASHRAE.

Follow AAMI ST79 guidelines for transportation of sets between buildings and off-site.

7.0 SterilContainer™ System Sterilizer Cycle Parameters – Steam and EtO

This section provides detailed charts that identify the SterilContainer™ System configurations, locks, indicator cards and filter(s), which should be used together for **Steam and EtO modalities**.

Aesculap® has performed validation testing that support the configurations shown. These configurations are supported by the numerous FDA 510(k) clearances held by Aesculap®. Configuring the SterilContainer™ System in a manner not shown in the tables constitutes an off label use of the product. Each container bottom must ***ONLY*** be used with the specific lid designed for that series of container, and it should not be combined with other Aesculap® or non-Aesculap® series of bottoms or lids.

In the event the instrument IFU does not match the SterilContainer™ System IFU, the instrument IFU should take precedence. See AAMI ST79 for information on how to reconcile multiple IFUs.

See Section 2.0 SterilContainer™ System for an explanation of the SterilContainer™ System.

Notes:

- *Container size abbreviations on modality charts.*

Detailed Size Description	*Abbreviation Size Description*
Full-Size	*1:1*
Three-Quarter	*3:4*
Half	*1:2*
XL-Long	*XLL*
Wide Body	*Wide*
XL-Mini	*XLM*
Quarter	*Qtr*
Mini	*Mini*

7.1 Steam and EtO Sterilization Modality Cycle Parameters

Primary Name	Which Includes	May Also Be Referred to As
Steam Sterilization[1]	Dynamic Air Removal PreVacuum Steam	PreVacuum Steam, PreVac Steam[1,2]
	Dynamic Air Removal Immediate Use	PreVacuum Immediate Use, PreVac IUSS[1,2]
	Gravity	Gravity[1]
Ethylene Oxide	Ethylene Oxide	EtO[1]

1. These terms will be used throughout the remainder of the Instructions for Use (IFU).
2. *Aesculap®validations for PreVac Steam may be applied to Steam Flush Pressure Pulse (SFPP) with like cycles.*

	Accessories Compatible with Steam and EtO			
	PreVac Steam	PreVac IUSS	Gravity Steam	EtO
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes
Silicone mats	Yes	Yes	Yes	Yes

Notes:

- *The numbers in parentheses after each description below correlates with the numbers in the Sterilization Modality columns on the tables that follow.*
- *Max Total Weight = SterilContainer® System (bottom and lid) + Baskets (including mats) + Instruments + Container Accessories.*
- *For steam cycles, running a longer exposure time and/or drying time than those stated will not harm the SterilContainer® System. See instrument IFU regarding the effect on instruments.*
- *For steam cycles, if different times or temperatures are used, they must be equivalent or greater than the minimum parameters noted.*
- *Position containers on the autoclave cart below wrapped sets.*
- *For Immediate Use Steam Sterilization (IUSS), Aesculap®recommends that each facility establish its own guidelines and policies for processing, holding/transporting and using IUSS sets based on accepted industry standards, and OR and patient needs.*

- ❖ *For PreVac Steam, stacking should not exceed 18 inches in height for effective air removal and adequate steam penetration. Both solid and perforated bottoms can be stacked during sterilization and in storage.*
- ❖ *See Section 14.0 Indications for Use for additional information on the SterilContainer™ System and accessories.*

7.1.1 PreVac Steam Sterilization Cycle Parameters (1)

Minimum dry times requirements. Actual dry time may be longer in practice depending on sterilization load density, quantity of instruments, instrument material, container size, lid used and water/steam quality.

- Exposure Time: 270° F for 4 minutes
- Dry Time – Aluminum lid with metal retention plate(s): 15 minutes minimum
- Dry Time – PrimeLine™ & PrimeLine Pro lids: 30 minutes minimum

7.1.2 PreVac IUSS Sterilization Cycle Parameters (2)

Only Aesculap® JK Series solid bottom containers can be used for PreVac IUSS.
Do not stack containers in the IUSS cycle. Minimum dry times requirements

Porous Instruments

- Exposure Time: 270° F for 4 minutes
- Dry Time: 0 minutes

Non-Porous Instruments

- Exposure Time: 270° F for 3 minutes
- Dry Time: 0 minutes

7.1.3 Gravity Steam Sterilization Cycle Parameters (3)

Do not stack containers in the gravity cycle.

- Exposure Time: 250° for 30-60 minutes, depending on load size
- Dry Time: 15 minutes minimum

7.1.4 EtO Cycle Parameters (4)

- Temp: 125°F - 130° F
- PreVac (minimum): 25" Hg
- Humidity: 40-60% RH
- Gas Pressure (minimum): 600 mg/L
- EO Gas Mixtures may vary i.e. 10/90% by weight or 100%
- Exposure Time (minimum): 60 Minutes
- Post Vac (minimum): 20" Hg
- Aeration (minimum): 8 Hours

7.1.5 PreVac Steam Sterilization Cycle Parameters (5)

This cycle is only for the JK744 and JN744 container. Aesculap's JK744 and JN744 have a 30 minute dry time because they have the lowest vent to volume ratio.

- Exposure Time: 270° F at 4 minutes
- Dry Time (minimum): 30 minutes minimum

7.1.6 Steam and EtO – SterilContainer™ JK Series

			Validated and FDA 510(k) Cleared Sterilization Modalities				
JK Series Bottom	**Lid**	**Processing Supplies**	PreVac Steam (1)	PreVac IUSS (2)	Gravity (3)	EtO (4)	**Max Total Weight[A]**
1:1 JK440 JK441 JK442 JK444 JK446	**1:1** JK485 JK486 JK487 JK488 JK489	**Filter**	US751, US994 MD344, JK090	US751, US994 MD344, JK090	N/A	US751, US994, MD344	25 Pounds
3:4 JK740 JK741 JK742 JK744	**3:4** JK785 JK786 JK787 JK788 JK789	**Indicator Card**	MD345, MD346	MD399	N/A	MD345, MD346	
1:2 JK340 JK341 JK342 JK344 JK346	**1:2** JK385 JK386 JK387 JK388 JK389	**Lock**	US900, US906	US900, US399	N/A	US900, US905	
Wide JK817 JK821	**Wide** JE601						
XLL JK443	**XLL** JK490						
Mini JK187 JK188	**Mini** JK170 JK171 JK172 JK173 JK174	**Filter**	US999, MD355, JK091	US999, MD355, JK091	N/A	US999, MD355	25 Pounds
		Indicator Card	MD876	N/A	N/A	MD876	
		Lock	US900, US906	US900, US399	N/A	US900, US905	

A. Max weight based on industry guidelines. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

7.1.7 Steam and EtO – SterilContainer™ JK Series with PrimeLine™ Pro / PrimeLine Lid

			Validated and FDA 510(k) Cleared Sterilization Modalities				
JK Series Bottom	**Lid**	**Processing Supplies**	PreVac Steam (1)	PreVac IUSS (2)	Gravity (3)	EtO (4)	**Max Total Weight[A]**
1:1 JK440 JK441 JK442 JK444 **3:4** JK740 JK741 JK742 JK744 **1:2** JK340 JK341 JK342 JK344	**1:1** JP101 JP102 JP103 JP104 JP105 **3:4** JP111 JP112 JP113 JP114 JP115 **1:2** JP121 JP122 JP123 JP124 JP125	**Filter, Lid[B]**	JP050	JP050	N/A	N/A	25 Pounds
		Filter, Bottom	N/A	N/A	N/A	N/A	
		Indicator Card	MD345, MD346	MD399	N/A	N/A	
		Lock	US900, US906	US900, US399	N/A	N/A	
1:1 JK440 JK441 JK442 JK444 **3:4** JK740 JK741 JK742 JK744 **1:2** JK340 JK341 JK342 JK344	**1:1** JP001 JP002 JP003 JP004 JP005 JP006 JP007 **3:4** JP011 JP012 JP013 JP014 JP015 JP016 JP017 **1:2** JP021 JP022 JP023 JP024 JP025 JP026 JP027	**Filter, Lid[B]**	JP050	JP050	N/A	N/A	25 Pounds
		Filter, Bottom	N/A	N/A	N/A	N/A	
		Indicator Card	MD345, MD346	MD399	N/A	N/A	
		Lock	US900, US906	US900, US399	N/A	N/A	

A. Max weight based on industry guidelines. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

B. JP050 reusable filter is integrated into the PrimeLine™ and PrimeLine Pro lids

7.1.8 Steam and EtO – SterilContainer™ JN Series

			Validated and FDA 510(k) Cleared Sterilization Modalities				
JN Series Bottom	**Aluminum Lid**	**Processing Supplies**	PreVac Steam (1)	PreVac IUSS (2)	Gravity (3)	EtO (4)	**Max Total Weight[A]**
1:1 JN440 JN441 JN442 JN444 JN446 **3:4** JN740 JN741 JN742 JN744 **1:2** JN340 JN341 JN342 JN344 JN346 **XLL** JN443 JN445 **Wide** JN817 JN821	**1:1** JK485 JK486 JK487 JK488 JK489 **3:4** JK785 JK786 JK787 JK788 JK789 **1:2** JK385 JK386 JK387 JK388 JK389 **XLL** JK490 **Wide** JE601	**Filter**	US751, US994 MD344, JK090	N/A	US751, US994	US751, US994, MD344	25 Pounds
		Indicator Card	MD345, MD346	N/A	MD345, MD346	MD345, MD346	
		Lock	US900, US906	N/A	US900, US906	US900, US905	
Qtr JN086 JN088 JN089 JN090 **Mini** JN187 JN188 **XLM** JN021	**Qtr** JN091 MD151 S76115 **Mini** JK170 JK171 JK172 JK173 JK174 MD149 S76113 **XLM** JK020 MD153	**Filter**	US999, MD355, JK091	N/A	US999	US999, MD355	25 Pounds
		Indicator Card	N/A	N/A	N/A	N/A	
		Lock	US900, US906	N/A	US900, US906	US900, US905	

A. Max weight based on industry guidelines. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

7.1.9 Steam and EtO – SterilContainer™ JN Series, PrimeLine™ Pro / PrimeLine Lid

			Validated and FDA 510(k) Cleared Sterilization Modalities				
JN Series Bottom	**Lid**	**Processing Supplies**	PreVac Steam (1)	PreVac IUSS (2)	Gravity (3)	EtO (4)	**Max Total Weight[A]**
1:1 JN440 JN441 JN442 JN444 JN446	**1:1** JP101 JP102 JP103 JP104 JP105	**Filter, Lid[B]**	JP050	N/A	N/A	N/A	25 Pounds
3:4 JN740 JN741 JN742 JN744	**3:4** JP111 JP112 JP113 JP114 JP115	**Filter, Bottom**	US751, US994 MD344, JK090	N/A	N/A	N/A	
1:2 JN340 JN341 JN342 JN344	**1:2** JP121 JP122 JP123 JP124 JP125	**Indicator Card**	MD345, MD346	N/A	N/A	N/A	
		Lock	US900, US906	N/A	N/A	N/A	
1:1 JN440 JN441 JN442 JN444 JN446	**1:1** JP001 JP002 JP003 JP004 JP005 JP006 JP007	**Filter, Lid[B]**	JP050	N/A	N/A	N/A	25 Pounds
3:4 JN740 JN741 JN742 JN744	**3:4** JP011 JP012 JP013 JP014 JP015 JP016 JP017	**Filter, Bottom**	US751, US994 MD344, JK090	N/A	N/A	N/A	
1:2 JN340 JN341 JN342 JN344	**1:2** JP021 JP022 JP023 JP024 JP025 JP026 JP027	**Indicator Card**	MD345, MD346	N/A	N/A	N/A	
		Lock	US900, US906	N/A	N/A	N/A	

A. Max weight based on industry guidelines. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

B. JP050 reusable filter is integrated into the PrimeLine™ and PrimeLine Pro lids

7.1.10 Steam and EtO – SterilContainer™ JM Series

			Validated and FDA 510(k) Cleared Sterilization Modalities				
JM Series Bottom	**Aluminum Lid**	**Processing Supplies**	PreVac Steam (1)	PreVac IUSS (2)	Gravity (3)	EtO (4)	**Max Total Weight[A]**
1:1 JM440 JM441 JM442 JM444	**1:1** JM489	**Filter**	US751, US994 MD344, JK090	N/A	US751, US994	US751, US994, MD344	25 Pounds
3:4 JM740 JM741 JM742	**3:4** JM789	**Indicator Card**	MD345, MD346	N/A	MD345, MD346	MD345, MD346	
1:2 JM340 JM341 JM342	**1:2** JM389	**Lock**	US900, US906	N/A	US900, US906	US900, US905	
Mini JM188	**Mini** JM174 MD152	**Filter**	US999, MD355, JK091	N/A	US999	US999, MD355	25 Pounds
XLM JM021	**XLM** JM020 MD150 S76114	**Indicator Card**	N/A	N/A	N/A	N/A	
		Lock	US900, US906	N/A	US900, US906	US900, US905	

A. Max weight based on industry guidelines. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

7.1.11 Steam and EtO – SterilContainer™ JS Series

			Validated and FDA 510(k) Cleared Sterilization Modalities				
JS Series Bottom	**Aluminum Lid**	**Processing Supplies**	PreVac Steam (1)	PreVac IUSS (2)	Gravity (3)	EtO (4)	**Max Total Weight[A]**
1:1 JS440 JS441 JS442 JS444	**1:1** JS489	**Filter**	US751, US994 MD344, JK090	N/A	US751, US994	US751, US994, MD344	25 Pounds
3:4 JS740 JS741 JS742	**3:4** JS789	**Indicator Card**	MD345, MD346	N/A	MD345, MD346	MD345, MD346	
1:2 JS340 JS341 JS342	**1:2** JS389	**Lock**	US900, US906	N/A	US900, US906	US900, US905	

A. Max weight based on industry guidelines. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.0 SterilContainer™ System Sterilizer Cycle Parameters – ASP STERRAD®

This section provides detailed charts that identify the SterilContainer™ S and SterilContainer™ S2 configurations, locks, indicator cards and filter(s) that should be used together for the **Low Temperature modality when used with ASP STERRAD® sterilizers**.

Aesculap® has performed validation testing that support the configurations shown. These configurations are supported by the numerous FDA 510(k) clearances held by Aesculap®. Configuring the SterilContainer™ S and SterilContainer™ S2 in a manner not shown in the tables constitutes an off label use of the product. Each container bottom must ***ONLY*** be used with the specific lid designed for that series of container, and it should not be combined with other Aesculap® or non-Aesculap® series of bottoms or lids.

In the event the instrument IFU does not match the SterilContainer™ S IFU, the instrument IFU should take precedence. See AAMI ST79 for information on how to reconcile multiple IFUs.

See Section 2.0 SterilContainer™ System for an explanation of the SterilContainer™ System.

Notes:

- *The SterilContainer™ S is made of non-anodized aluminum which undergoes a natural oxidation process. This oxidation process produces a very thin layer on the surface which may appear brown or black. This oxidation process will continue until the entire raw surface is oxidized. This brown or black discoloration is part of the natural processes.*
- *Stacking is **NOT** permitted in Low Temperature sterilizers per the manufacturer of the sterilizer.*
- *Single use paper filters are **NOT** compatible with Low Temperature sterilizers.*
- *Nylon coated metal holding clamps are **NOT** compatible with Low Temperature sterilizers.*
- *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.*
- *Confirm basket, instruments and basket accessories are completely dry before assembling instrument set.*
- *See Section 14.0 Indications for Use for additional information on the SterilContainer™ System and accessories.*
- *Container size abbreviations on modality charts.*

Detailed Size Description	*Abbreviation Size Description*
Full-Size	*1:1*
Three-Quarter	*3:4*
Half	*1:2*
XL-Long	*XLL*
Wide Body	*Wide*
XL-Mini	*XLM*
Quarter	*Qtr*
Mini	*Mini*

8.1 STERRAD® Sterilization Modality Cycle Parameters

Primary Name	Which Includes	May Also Be Referred to As
Hydrogen Peroxide	Gas Plasma	Low Temperature[1], H2O2, STERRAD®[2]

1. These terms will be used throughout the remainder of the Instructions for Use (IFU).
2. Magnolia are generically referred to by the sterilizer manufacturers' model name and/or cycle name.

The JM Series and JS Series have received FDA clearance for the following STERRAD® cycles. Refer to each section identified in the chart for proper container configuration and processing supplies.

	STERRAD®							
	100S	200	NX[1] Standard	NX[1] Advanced	100NX[1] Standard	100NX[1] Flex	100NX[1] Express	100NX[1] Duo
JM Series	8.1.1	8.1.3	8.1.4	8.1.6	8.1.8	8.1.10	8.1.12	8.1.14
JS Series	8.1.2	N/A	8.1.5	8.1.7	8.1.9	8.1.11	N/A	8.1.13

1. Includes NX AllClear® and 100NX AllClear® sterilizers. See STERRAD® IFU for full details.

	Accessories Compatible with STERRAD®					
	NX Standard	NX Advanced	100NX Standard	100NX Flex	100NX Express	100NX Duo
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes	Yes	Yes
Silicone mats	No	Yes	No	No	Yes	Yes

8.1.1 STERRAD® 100S Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERRAD® 100S Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Standard Cycle	13.90 Pounds
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		
Mini	JM188	JM174 MD152	**Filter**	MD355	Standard Cycle	See Notes
			Indicator Card	MD335		
			Lock	US900, US910		
XLM	JM021	JM020 MD150 S76114	**Filter**	MD355	Standard Cycle	See Notes
			Indicator Card	MD335		
			Lock	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

Notes:

- *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.*

8.1.2 STERRAD® 100S Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERRAD® 100S Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Standard Cycle	13.90 Pounds
			Indicator Card	MD334		
3:4	JS740 JS741 JS742	JS789	**Lock**	US900, US910		
1:2	JS340 JS341 JS342	JS389				

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.3 STERRAD® 200 Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERRAD® 200 Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Standard Cycle	21.46 Pounds
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		14.42 Pounds
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		14.42 Pounds
Mini	JM188	JM174 MD152	**Filter**	MD355	Standard Cycle	7.64 Pounds
XLM	JM021	JM020 MD150 S76114	**Indicator Card**	MD335		
			Lock	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.4 STERRAD® NX Standard Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERRAD® NX Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Standard Cycle	10.70 Pounds
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		
Mini	JM188	JM174 MD152	**Filter**	MD355	Standard Cycle	7.64 Pounds
XLM	JM021	JM020 MD150 S76114	**Indicator Card**	MD335		
			Lock	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.5 STERRAD® NX Standard Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERRAD® NX Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Standard Cycle	10.70 Pounds
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.6 STERRAD® NX Advanced Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERRAD® NX Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Advanced Cycle	10.70 Pounds
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		
Mini	JM188	JM174 MD152	**Filter**	MD355	Advanced Cycle	7.64 Pounds
XLM	JM021	JM020 MD150 S76114	**Indicator Card**	MD335		
			Lock	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.7 STERRAD® NX Advanced Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERRAD® NX Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Advanced Cycle	10.70 Pounds
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.8 STERRAD® 100NX Standard Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERRAD® 100NX Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Standard Cycle	21.46 Pounds
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		13.85 Pounds
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		13.85 Pounds
Mini	JM188	JM174 MD152	**Filter**	MD355	Standard Cycle	7.64 Pounds
XLM	JM021	JM020 MD150 S76114	**Indicator Card**	MD335		
			Lock	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.9 STERRAD® 100NX Standard Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERRAD® 100NX Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Standard Cycle	21.46 Pounds
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		13.85 Pounds
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		13.85 Pounds

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.10 STERRAD® 100NX FLEX Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERRAD® 100NX Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489 J	**Filter**	MD344	Flex Cycle	See Notes
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

8.1.11 STERRAD® 100NX FLEX Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERRAD® 100NX Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Flex Cycle	See Notes
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

Notes:

- *Max Total Weight*
  - *Full-size: 10.95 Pounds – one container, 21.6 Pounds – total chamber load*
  - *Three-quarter size: 10.35 Pounds – one container, 21.6 Pounds – total chamber weight*
  - *Half-size: 10.35 Pounds – one container, 21.6 Pounds – total chamber weight*

8.1.12 STERRAD® 100NX Express Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERRAD® 100NX Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Express Cycle	25 Pounds
			Indicator Card	MD334		
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

Notes:

- *During validation, chamber load consisted of one container placed on bottom shelf with an otherwise empty chamber.*
- *The container should be placed flat on the shelf and should not touch the walls of the chamber.*
- *The container should not be stacked in the chamber.*

8.1.13 STERRAD® 100NX DUO Cycle – SterilContainer™ S2 JS Series

Customers that wish to use the JS Series in the STERRAD®100NX Duo cycle must use:

- only the JS Series containers listed in table 2 of the K193582 cleared Indications for Use below;
- an internal biological and/or chemical indicator per the facility's policies and procedures;
- the Aesculap®MD344 round polypropylene filter(s);
- the Aesculap®US900 blue locks without indicator;
- a STERRAD®100NX Duo cycle FDA 510(k) cleared external indicator; and
- follow sterilizer manufacturer's Instructions for Use (IFU).

Notes:

- *Aesculap®has performed validation testing that support the configurations shown in this section.*
- *As part of the FDA submission, Aesculap®has performed validation testing and event related sterility maintenance testing on the SterilContainer™ System.*
- *Facilities should follow industry guidelines and establish written policies and procedures on how shelf life is determined and tracked, see section 6.6 Container Storage and Transportation.*
- *Aesculap®US910 lock may **NOT** be used with STERRAD®100NX Duo.*
- *Consult with the manufacturer of the sterilizer for specific recommendations. Complex devices such as lumened instruments should be sterilized in accordance with the instrument IFU.*

FDA 510(k) clearance Indications for Use:

The Aesculap®SterilContainer™ S2 System is a reusable rigid 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 in the STERRAD®100NX DUO sterilization modality.

The Aesculap®SterilContainer™ S2 System includes accessories such as silicone mats and organizers, stainless steel baskets, trays, holders, sterilization indicator cards and tamper proof locks.

The attached table identifies the validated load configurations for each of the modalities.

SterilContainer™ S2 System Validated Load Configurations

Sterilization Cycle	Container Size	Validated Load Configuration
STERRAD®100NX DUO *(bottom shelf only)*	Full	Flexible scope (≥ 1mm ID x ≤ 850mm L)
	Three-Quarter	
	Half	

SterilContainer™ S2 System Load Weights

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container (lb)
STERRAD®100NX DUO	Full Size - 4 ¼"	JS440	JS489	10.97
	Full Size - 5 ¼"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4	JS740	JS789	10.04
	Three-Quarter Size - 5	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	11.7
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		

Sterilization Cycle Compatible Accessories

Accessories	Compatible with STERRAD®DUO
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel rack brackets, holders, and clamps)	Yes
Silicone mats	No
Tamper Evident locks and indicator cards	Yes

8.1.14 STERRAD® 100NX DUO Cycle – SterilContainer™ S JM Series

Customers that wish to use the JM Series in the STERRAD®100NX Duo cycle must use:

- only the JM Series containers listed in table 2 of the K182032 cleared Indications for Use below;
- an internal biological and/or chemical indicator per the facility's policies and procedures;
- the Aesculap®MD344 round polypropylene filter(s);
- the Aesculap®US900 blue locks without indicator;
- a STERRAD®100NX Duo cycle FDA 510(k) cleared external indicator; and
- follow sterilizer manufacturer's Instructions for Use (IFU).

Notes:

- *Aesculap®has performed validation testing that support the configurations shown in this section.*
- *Facilities should follow industry guidelines and establish written policies and procedures on how shelf life is determined and tracked, see section 6.6 Container Storage and Transportation.*
- *Aesculap®US910 lock may **NOT** be used with STERRAD®100NX Duo.*

FDA 510(k) clearance Indications for Use:

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. This container system has been validated with flexible endoscopes and accessories, cables, and camera heads. 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 STERRAD® 100NX Duo cycle. The SterilContainer™ S System includes accessories such as silicone mats, baskets, trays, racks, filters, indicator cards, locks, and instrument holders.

Validation testing for event related sterility maintenance has been conducted for up to 365 days.

Table 1: Validated STERRAD 100NX DUO Cycle Load Configurations

Load Configuration	Container # 1	Container # 2
1	• 135mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (1x)	• 135mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)
2	• 187mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)	• N/A – Top shelf is removed to allow the container to fit in the chamber
3	• 90mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)	• 135mm Half Size Container Bottom • Half Size Container Lid • Half Size Basket • Half Size Mat • Camera Head for Endoscope

Table 2: STERRAD 100NX DUO Compatible SterilContainer S Container Systems

Lid	Bottom	Description	Container Load Weight *
JM489	JM440	Full Size 90mm (4 ¼")	13.2 lbs total weight. (1 or 2 shelves based on container)
	JM441	Full Size 120mm (5 ½")	
	JM442	Full Size 135mm (6")	
	JM444	Full Size 187mm (8")	
JM789	JM740	¾ Size 90mm(4 ¼")	
	JM741	¾ Size 120mm (5 ½")	
JM389	JM340	½ Size 90mm (4 ¼")	
	JM341	½ Size 120mm (5 ½")	
	JM342	½ Size 135mm (6")	
	JM344	½ Size 187mm (8")	

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

Table 3: STERRAD 100NX DUO Cycle Compatible Accessories

Accessories	STERRAD 100NX DUO Cycle
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, instrument holders, and clamps)	Yes
Silicone mats	Yes
Stainless Steel racks, trays, instrument holders, clamps, brackets, tamper-proof locks, indicator cards and platforms	Yes

9.0 SterilContainer™ System Sterilizer Cycle Parameters – STERIS® V-PRO®

This section provides detailed charts that identify the SterilContainer™ S and SterilContainer™ S2 configurations, locks, indicator cards and filter(s) that should be used together for the **Low Temperature modality when used with STERIS® V-PRO® sterilizers**.

Aesculap® has performed validation testing that support the configurations shown. These configurations are supported by the numerous FDA 510(k) clearances held by Aesculap®. Configuring the SterilContainer™ S and SterilContainer™ S2 in a manner not shown in the tables constitutes an off label use of the product. Each container bottom must ***ONLY*** be used with the specific lid designed for that series of container, and it should not be combined with other Aesculap® or non-Aesculap® series of bottoms or lids.

In the event the instrument IFU does not match the SterilContainer™ S IFU, the instrument IFU should take precedence. See AAMI ST79 for information on how to reconcile multiple IFUs.

See Section 2.0 SterilContainer™ System for an explanation of the SterilContainer™ System.

Notes:

- *The SterilContainer™ S is made of non-anodized aluminum which undergoes a natural oxidation process. This oxidation process produces a very thin layer on the surface which may appear brown or black. This oxidation process will continue until the entire raw surface is oxidized. This brown or black discoloration is part of the natural processes.*
- *Stacking is **NOT** permitted in Low Temperature sterilizers per the manufacturer of the sterilizer.*
- *Single use paper filters are **NOT** compatible with Low Temperature sterilizers.*
- *Nylon coated metal holding clamps are **NOT** compatible with Low Temperature sterilizers.*
- *Confirm basket, instruments and basket accessories are completely dry before assembling instrument set.*
- *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.*
- *See Section 14.0 Indications for Use for additional information on the SterilContainer™ System and accessories.*
- *Container size abbreviations on modality charts.*

Detailed Size Description	*Abbreviation Size Description*
Full-Size	*1:1*
Three-Quarter	*3:4*
Half	*1:2*
XL-Long	*XLL*
Wide Body	*Wide*
XL-Mini	*XLM*
Quarter	*Qtr*
Mini	*Mini*

9.1 STERIS® Sterilization Modality Cycle Parameters

Primary Name	Which Includes	May Also Be Referred to As
Hydrogen Peroxide	Vapor Hydrogen Peroxide	Low Temperature[1], H2O2, STERIS®[2], V-PRO®[2]

1. These terms will be used throughout the remainder of the Instructions for Use (IFU).
2. [illegible] may also be generically referred to by the sterilizer manufacturers' trade or proprietary cycle name.

The JM Series and JS Series have received FDA clearance for the following STERIS® cycles. Refer to each section identified in the chart for proper container configuration and processing supplies.

	STERIS®					
	V-PRO® 60			maX[1]		
	Lumen	Non-Lumen	Flexible	Flexible	Lumen	Non-Lumen
JM Series	9.1.1	9.1.3	9.1.5	9.1.7	*N/A*	*N/A*
JS Series	9.1.2	9.1.4	9.1.6	9.1.8	9.1.9	9.1.10

1. The STERIS® maX2 and S2 sterilizers includes the Lumen, Flexible and Non-Lumen V-PRO® cycles. See STERIS® IFU for full details.

	Accessories Compatible with STERIS®					
	V-PRO® 60			maX		
	Lumen	Non-Lumen	Flexible	Flexible	Lumen	Non-Lumen
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes	Yes	Yes
Silicone mats	No	No	No	No	No	No

9.1.1 STERIS® V-PRO® 60 Lumen Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® 60 Efficacy[B]	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Lumen Cycle	11.10 Pounds
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		9.60 Pounds
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		9.60 Pounds
Mini	JM188	JM174 MD152	**Filter**	MD355	Lumen Cycle	7.64 Pounds
XLM	JM021	JM020 MD150 S76114	**Indicator Card**	MD335		
			Lock	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

9.1.2 STERIS® V-PRO® 60 Lumen Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® 60 Efficacy[B]	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Lumen Cycle	11.10 Pounds
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		9.60 Pounds
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		9.60 Pounds

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

B. The V-PRO® cycle validation with the subject device was conducted with the V-PRO® maX. V-PRO® 60 cycles were not directly utilized in validation testing.

9.1.3 STERIS® V-PRO® 60 Non-Lumen Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® 60 Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Non-Lumen Cycle	12.00 Pounds
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		
Mini	JM188	JM174 MD152	**Filter**	MD355	Non-Lumen Cycle	7.64 Pounds
XLM	JM021	JM020 MD150 S76114	**Indicator Card**	MD335		
			Lock	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

9.1.4 STERIS® V-PRO® 60 Non-Lumen Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® 60 Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Non-Lumen Cycle	12.00 Pounds
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

B. The V-PRO® cycle validation with the subject device was conducted with the V-PRO® maX. V-PRO® 60 cycles were not directly utilized in validation testing.

9.1.5 STERIS® V-PRO® 60 Flexible Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® 60 Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Flexible Cycle	See Notes
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

9.1.6 STERIS® V-PRO® 60 Flexible Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® 60 Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Flexible Cycle	See Notes
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.
B. The V-PRO® cycle validation with the subject device was conducted with the V-PRO® maX. V-PRO® 60 cycles were not directly utilized in validation testing.

Notes:

- *Max Total Weight*
  - *Load limit defined by load configuration and not load weight.*
  - *1 flexible scope (single or dual lumens >1mm ID and <990 mm L) with light cord (if not integral to endoscope) and mat without any additional load.*

9.1.7 Amsco® STERIS® V-PRO® maX Flexible Cycle – SterilContainer™ S JM Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® maX Efficacy	Max Total Weight[A]
1:1	JM440 JM441 JM442 JM444	JM489	**Filter**	MD344	Flexible Cycle	10.00 Pounds
3:4	JM740 JM741 JM742	JM789	**Indicator Card**	MD334		
1:2	JM340 JM341 JM342	JM389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

9.1.8 Amsco® STERIS® V-PRO® maX Flexible Cycle – SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® maX Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Flexible Cycle	10.00 Pounds
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

9.1.9 Amsco® STERIS® V-PRO® maX Lumen Cycle– SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® Max Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Lumen Cycle	11.10 Pounds
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		9.60 Pounds
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		9.60 Pounds

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

9.1.10 Amsco® STERIS® V-PRO® maX Non-Lumen Cycle– SterilContainer™ S2 JS Series

Size	Bottom	Lid	Processing Supplies		STERIS® V-PRO® maX Efficacy	Max Total Weight[A]
1:1	JS440 JS441 JS442 JS444	JS489	**Filter**	MD344	Non-Lumen Cycle	18.6 Pounds
3:4	JS740 JS741 JS742	JS789	**Indicator Card**	MD334		
1:2	JS340 JS341 JS342	JS389	**Lock**	US900, US910		

A. Max weight used during validation testing. Weight limit may also be impacted by container size. Follow sterilizer manufacturer IFU weight limits if less.

10.0 SterilContainer™ System Sterilizer Cycle Parameters – STERIZONE®

This section provides detailed charts that identify the SterilContainer™ S configurations, locks, indicator cards and filter(s) that should be used together for the **Low Temperature modality when used with STERIZONE® sterilizers**.

Aesculap® has performed validation testing that support the configurations shown. These configurations are supported by the numerous FDA 510(k) clearances held by Aesculap®. Configuring the SterilContainer™ S and S2 in a manner not shown in the tables constitutes an off label use of the product. Each container bottom must ***ONLY*** be used with the specific lid designed for that series of container, and it should not be combined with other Aesculap® or non-Aesculap® series of bottoms or lids.

In the event the instrument IFU does not match the SterilContainer™ IFU, the instrument IFU should take precedence. See AAMI ST79 for information on how to reconcile multiple IFUs.

See Section 2.0 SterilContainer™ System for an explanation of the SterilContainer™ System.

Notes:

- *The SterilContainer™ S is made of non-anodized aluminum which undergoes a natural oxidation process. This oxidation process produces a very thin layer on the surface which may appear brown or black. This oxidation process will continue until the entire raw surface is oxidized. This brown or black discoloration is part of the natural processes.*
- *Stacking is **NOT** permitted in Low Temperature sterilizers per the manufacturer of the sterilizer.*
- *Single use paper filters are **NOT** compatible with Low Temperature sterilizers.*
- *Nylon coated metal holding clamps are **NOT** compatible with Low Temperature sterilizers.*
- *Confirm basket, instruments and basket accessories are completely dry before assembling instrument set.*
- *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.*
- *See Section 14.0 Indications for Use for additional information on the SterilContainer™ System and accessories.*
- *Container size abbreviations on modality charts.*

Detailed Size Description	*Abbreviation Size Description*
Full-Size	*1:1*
Three-Quarter	*3:4*
Half	*1:2*
XL-Long	*XLL*
Wide Body	*Wide*
XL-Mini	*XLM*
Quarter	*Qtr*
Mini	*Mini*

10.1 STERIZONE® Sterilization Modality Cycle Parameters

Primary Name	Which Includes	May Also Be Referred to As
Hydrogen Peroxide and Ozone	Ozone	Low Temperature[1] TS03[2], STERIZONE®[2], VP4[2]

1. These terms will be used throughout the remainder of the Instructions for Use (IFU).
2. May also be generically referred to by the sterilizer manufacturers' model name and/or cycle name.

10.1.1 STERIZONE® VP4 Cycle – SterilContainer™ S2 JS Series

Customers that wish to use the JS Series in the STERIZONE® VP4 cycle must use:

- only the JS Series containers listed in table 2 of the K193582 cleared Indications for Use below;
- an internal biological and/or chemical indicator per the facility's policies and procedures;
- the Aesculap® MD344 round polypropylene filter(s);
- the Aesculap® US900 blue locks without indicator; and
- follow sterilizer manufacturer's Instructions for Use (IFU).

Notes:

- *Hospital procedures and AORN guidelines for aseptic presentation should always be followed. Employees should be trained to the facility's procedures before performing aseptic presentation or participating in the Operation Room.*
- *Stacking is **NOT** permitted in Low Temperature sterilizers per the manufacturer of the sterilizer.*
- *Single use paper filters are **NOT** compatible with Low Temperature sterilizers.*
- *Nylon coated metal holding clamps are **NOT** compatible with Low Temperature sterilizers.*
- *Aesculap® US910 lock may **NOT** be used with VP4.*
- *Aesculap® has performed validation testing that support the configurations shown in this section.*
- *As part of the FDA submission, Aesculap® has performed validation testing and event related sterility maintenance testing on the SterilContainer™ System.*
- *Facilities should follow industry guidelines and establish written policies and procedures on how shelf life is determined and tracked.*
- *Consult with the manufacturer of the sterilizer for specific recommendations. Complex devices such as lumened instruments should be sterilized in accordance with the instrument IFU.*

FDA 510(k) clearance Indications for Use:

The Aesculap® SterilContainer™ S2 System is a reusable rigid 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 in the STERIZONE® VP4 sterilization modalities:

The Aesculap® SterilContainer™ S2 System includes accessories such as silicone mats and organizers, stainless steel baskets, trays, holders, sterilization indicator cards and tamper proof locks.

The attached table identifies the validated load configurations.

SterilContainer™ S2 System Validated Load Configurations

Sterilization Cycle	Container Size	Validated Load Configuration
STERIZONE® VP4 Validated Loads 1 & 2 (Based on STERIZONE® Load #7)	Full Three-Quarter Half	Non Lumened Instruments
STERIZONE® VP4 Validated Load 3 (Based on STERIZONE® Load #8)	JS440 (base) + JS489 (lid)	(1) Single Channel Flexible Scope (≥1mm ID x ≤ 850mm L) OR (1) Dual Channel Flexible Scope (≥1mm ID x ≤850 mm L and ≥1 mm ID x ≤ 989mm L)
STERIZONE® Validated Load 4 (Based on STERIZONE® Load #4)	JS440 (base) + JS489 (lid)	(1) Semi-rigid dual channel scope (≥0.7mm ID x ≤500mm L and ≥1.1mm ID x ≤500mm L) AND one of the following: (4) Stainless steel lumens (≥ 5.5mm ID x ≤ 166mm L; ≥ 7mm ID x ≤ 105mm L; ≥ 7.0mm ID x ≤ 227mm L; ≥ 7.8mm ID x ≤ 198mm L) OR (2) Stainless steel lumens (≥ 4mm ID x ≤ 370mm L; ≥ 2mm ID x ≤ 152mm L) OR (3) Stainless steel lumens (≥ 2.2mm ID x ≤ 173mm L; ≥ 4.7mm ID x ≤ 270mmL ; ≥ 4mm ID x ≤ 445mm L)

SterilContainer™ S2 System Load Weights

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container (lb)
STERIZONE® Validated Loads 1 & 2 (Based on STERIZONE® Load #7)	Full Size - 4 ¼"	JS440	JS489	25
	Full Size - 5 ¼"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4	JS740	JS789	25
	Three-Quarter Size - 5	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	25
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIZONE® Validated Load 3 (Based on STERIZONE® Load #8)	Full Size - 4 ¼"	JS440	JS489	See load configuration in table 1 above

STERIZONE® Validated Load 4 (Based on STERIZONE® Load #4)	Full Size - 4 ⅘"	JS440	JS489	See load configuration in table 1 above

Sterilization Cycle Compatible Accessories

Accessories	VP4
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel rack brackets, holders, and clamps)	Yes
Silicone mats	Yes
Tamper Evident locks and indicator cards	Yes

10.1.2 STERIZONE® VP4 Cycle – SterilContainer™ S JM Series

Customers that wish to use the JM Series in the STERIZONE® VP4 cycle must use:

- only the JM Series containers listed in table 2 of the K162815 cleared Indications for Use below;
- an internal biological and/or chemical indicator per the facility's policies and procedures;
- the Aesculap® MD344 round polypropylene filter(s);
- the Aesculap® US900 blue locks without indicator; and
- follow sterilizer manufacturer's Instructions for Use (IFU).

Notes:

- *Hospital procedures and AORN guidelines for aseptic presentation should always be followed. Employees should be trained to the facility's procedures before performing aseptic presentation or participating in the Operation Room.*
- *The SterilContainer™ S is made of non-anodized aluminum which undergoes a natural oxidation process. This oxidation process produces very thin layer on the surface which may appear brown or black. This oxidation process will continue until the entire raw surface is oxidized. This brown or black discoloration is part of the natural processes.*
- *Stacking is NOT permitted in Low Temperature sterilizers per the manufacturer of the sterilizer.*
- *Single use paper filters are **NOT** compatible with Low Temperature sterilizers.*
- *Nylon coated metal holding clamps are **NOT** compatible with Low Temperature sterilizers.*
- *Aesculap® US910 lock may **NOT** be used with VP4.*

FDA 510(k) clearance Indications for Use:

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. This container system has been validated with stainless steel and Teflon lumens, hinged, and knurled instruments. 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 STERIZONE® VP4 Low Temperature Sterilization System. The SterilContainer™ S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

Table 1: Validated VP4 Cycle Load Configurations

Load Configuration 1 (31.2 lb)	Flexible endoscopes load accommodating three single channel flexible endoscopes, one per container: • Internal channel diameter of 1 mm and length of 850 mm.
Load Configuration 2 (29.4 lb)	Semi-rigid and rigid channel devices load accommodating three double channel semi-rigid endoscopes and one length of medical grade stainless steel tubing. • Length of tubing: ○ Internal channel diameter of 1.0 mm and length of 500 mm. • Double channel semi-rigid endoscope ○ Internal channel diameters of 0.7 mm and 1.1 mm, and length of 500 mm
Load Configuration 3 (10.2 lb):	Worst-case volume to surface perforation area ratio using a perforated container including two stacked baskets. Each basket was covered with a full length silicone mat. At least one inoculated medical device was added per level of the container.
Load Configuration 4 (25 lb)	Worst-case volume to surface perforation area ratio using a perforated container with maximum weight of instrument, for a total mass of 25 lb. At least three inoculated medical devices were added in the container.
Load Configuration 5 (75 lb)	Heavy weight load composed of three perforated containers, with a total mass of 25 lb per container. The heavy validation load was prepared based on the Aesculap® SterilContainer™ S container lethality studies (PRO-169) and adapted to include a maximum weight in a single load.

Table 2: VP4 Sterilizer 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 [3.54"]	25 lbs for one container in the chamber
	JM441	Full Size 120mm [4.72"]	
	JM442	Full Size 118mm [4"]	
	JM444	Full Size 187mm [7"]	
JM789	JM740	3/4 Size 90mm [3.54"]	
	JM741	3/4 Size 120mm [4.72"]	
	JM742	3/4 Size 118mm [4"]	
JM389	JM340	1/2 Size 90mm [3.54"]	
	JM341	1/2 Size 120mm [4.72"]	
	JM342	1/2 Size 118mm [4"]	

**Loads containing a flexible endoscope or bronchoscope should follow Table 1 recommendation.*

Table 3: VP4 Sterilizer Cycle Compatible Accessories

Accessories	VP4
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

11.0 Aseptic Presentation

Hospital procedures and AORN 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).
   a. After sterilization, the external indicator should change from the original indicator color to indicate exposure to sterilant. The post sterilization indicator color may vary and not be evenly shaded.
   b. Tamper Evident Lock US910 — Low Temperature external Chemical Indicators (CIs) are particularly sensitive and must be stored in a controlled room temperature, away from alkaline chemicals, acids and sources of light prior to use. DO NOT USE beyond the expiration date provided on the outside product packaging. Change of color prior to use in the sterilizer could indicate that these CIs were exposed to too much light or high temperatures during storage. After being processed, low temperature tamper evident lock should be stored at a controlled room temperature away from alkaline chemicals, acids and sources of light. Indicators may turn white post-sterilization if not stored out of direct lighting.
4. Non-scrubbed person breaks locks by simultaneously moving the latches into the open position. Before removing the lid, discard all broken pieces of the locks.
5. Non-scrubbed person opens the latches the rest of the way 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(s) changed, if using filters with indicators.
7. Non-scrubbed person checks the integrity of the filter(s) with the naked eye by removing the filter retention plate and examining. Reusable filter may remain in place inside lid during inspection. Replace filter retention plates after examining filter.
8. Scrubbed person removes the sterile contents inside by grasping both handles using appropriate aseptic technique, lifting basket and contents out.
9. Non-scrubbed person checks the filter(s) on the bottom if a perforated bottom container is used. Replace filter retention plates after examining filter.
10. Scrubbed person may move the sterile contents into the sterile field once inspection has been completed successfully.

Notes:

- *Hospital procedures and AORN guidelines for aseptic presentation should always be followed. Employees should be trained to the facility's procedures before performing aseptic presentation or participating in the Operation Room.*
- *Before the instruments are placed on the sterile field, the inside surface of the container should be inspected for debris, contamination, or damage per AAMI ST79.*
- *Visit www.youtube.com/Aesculapusa SterilContainer™ System section for informational videos on SterilContainer™ System proper sterile reprocessing preparation.*
- *Using inspection and test methods other than those outlined in this IFU are not recommended and have not been validated by Aesculap®.*
- *Baskets with or without feet maybe used with SterilContainer™ System. Using baskets with feet may help reduce the possibility of scratching of basket on the container bottom.*
- *The black PEEK feet on the Aesculap® JF baskets assist in aligning the JF baskets when stacking them in a container or during the reprocessing process. These feet may wear and/or break overtime depending on the processing (number of times, chemicals, water quality), application (type of set) and use (handling of the product). Inspect basket and feet prior to use. Replace if desired, using Aesculap® part number JF112210.*

- *Retention plates should be replaced when they show wear, age and/or are damaged. The retention plate on the metal lids should not spin freely when properly installed and in proper working condition. Note that the retention plate may move a little if significant amount of pressure is applied while trying to twist or turn (especially when filter is installed).*
- *Inspect reusable filter for holes, tears and rips. Confirm filter is within use-by date (<2,200 cycles). Arrows on filter and filter housing will align when filter is properly installed, see photo.*
- *If the PrimeLine™ or PrimeLine Pro internal or external cover falls off after sterilization and before the set is used, the set can maintain sterility if no other event related incidence has occurred since it is a sealed filter system. The broken dustcover should be replaced and/or the lid should be serviced by Aesculap®. See Section 3.0 SterilContainer™ System Service for full details regarding service.*
- *Through the sterilization process the filter may become wavy from moisture but should remain held in place by the retention plate and cover the filter openings.*
- *Reusable filters and the integrated reusable filter, PrimeLine™, should also be checked prior to use. See Section 6.0.*
- *Hospital procedures and AORN guidelines for aseptic presentation should always be followed. Employees should be trained to the facility's procedures before performing aseptic presentation or participating in the Operation Room.*

For Reference Only, See Section 6.0 Preparation and Assembly of SterilContainer™ System *for more information.*

Filter Type	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp
Paper Filter w/ Indicator[1] US751	X[1]	X[1]	X[1]	X[1]	
Paper Filter w/o Indicator US994, US999	X	X	X	X	
Polypropylene Filter w/o Indicator MD344, MD355	X	X		X	X
Metal Retention Plate PTFE Reusable Filter JK090, JK091	X	X			
PrimeLine™ & PrimeLine Pro PTFE Reusable Filter JP050	X	X			

1. *Filter contains a dual indicator dot, which changes from blue to brown in steam, and to orange in EtO.*

Tamper Evident Locks	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp
Blue / US900 No Indicator	X	X	X	X	X
Green / US905 Change[1] Yellow to Orange				X	
Orange / US906 Change[1] Blue to Brown	X	X	X		
Pink / US910[2] Change[1] Magenta to Blue					X[2]
Yellow / US399 Change[1] Blue to Brown		X			

1. *After sterilization, the external indicator should change from the original indicator color to indicate exposure to sterilant.* ***The post sterilization indicator color may vary and not be evenly shaded.***
2. *Locks must be stored in a controlled room temperature, away from alkaline chemicals, acids and sources of light.*

Notes:

- *The expiration date on the product labels, filters and indicator cards are a pre-sterilization date. This means that the product should be processed (gone through the sterilization process) by this time to achieve maximum results. If processed after this date the product may still work. The indicator will remain the post sterilization color for up to three years, when stored properly. This is known as the post-sterilization date. After this time, the color of the indicator may shift or fade over time. Proper sterilization care, handling and storage instructions can be found on the labels of each product.*

For Reference Only, See Section 6.0 Preparation and Assembly of SterilContainer™ System *for more information.*

Indicator & Communication Cards	PreVac Steam	PreVac IUSS	Gravity	EtO	Low Temp
MD334, MD335 w/ Indicator Change[1] Blue					X
MD346, MD876, US754 w/ Indicator Change[1,2] Brown in Steam Change[1,2] Orange in EtO	X	X	X	X	
US963 w/o Indicator	X	X	X	X	X
MD399, MD345 w/ Indicator Change[1] Brown		X			

1. *After sterilization, the external indicator should change from the original indicator color to indicate exposure to sterilant.* ***The post sterilization indicator color may vary and not be evenly shaded.***
2. *Filter contains a dual indicator dot, which changes to brown in steam, and to orange in EtO.*

11.1 SterilContainer™ System Reference Guidelines

All information and steps outlined in this IFU should be followed. Aesculap® DOC1006 and DOC1007 may be used as a reference guide in Prep and Pack, and the OR respectively once personnel training and competency is achieved. Contact Aesculap® customer service to order.

Guidelines During Prep and Pack (Aesculap® DOC1006)

Guidelines During Aseptic Presentation (Aesculap® DOC1007)

Figure 7: Easy Reference Handout

11.2 SterilContainer™ System Transportation to Decontamination

Aesculap® suggests following AAMI ST79 guidelines for the handling and transportation of contaminated instruments and containers in conjunction with facility policies and procedures.

If the container and/or lid are soiled, they must be fully cleaned. For containers and/or lids that are not soiled and have been removed from the operating room before the patient entered, the facility should determine best cleaning practice based on its established policy and procedures.

Aesculap® offers bio bins that are specifically designed for transport of soiled instruments. Aesculap® bio bins should be decontaminated following the same processes and practices as sterile containers. See Aesculap® container catalog for more information on bio bins. Contact Aesculap® customer service to order.

12.0 Sterile Container Validation Summary

Aesculap®, the world's leader in rigid sterile container systems, has been at the forefront of sterile packaging technology for more than 120 years. Aesculap® was the first vendor to introduce rigid sterile container systems to the United States at the 1980 AORN Congress.

Rigid sterile containers, which are part of a medical sterilization packaging system, are classified in the United States as FDA Class II devices and therefore require rigorous validation testing to strict FDA guidance in order to be cleared for marketing and sale by the FDA.

Since the introduction of the SterilContainer™ System for Steam sterilization in 1980, Aesculap® has expanded sterilization modalities and product offerings to meet the changing needs of healthcare.

Over the last 35 years, Aesculap® has performed the required validation tests and received FDA clearance for sterile container products that include PreVac, PreVac IUSS, Gravity Steam, EtO, and Low Temperature sterilization modalities.

12.1 Validation Testing

To achieve FDA clearance, the container system must undergo validation tests, which can be grouped into three categories:

1. Reprocessing Validation and Verification
2. Sterilization Efficacy
3. Sterility Maintenance

Critical to the effective operation of the Sterile Processing Department (SPD) in an acute care surgical facility is the need to efficiently decontaminate, clean, sterilize, store and deliver sterile containers and instruments to the Operating Room (OR).

12.1.1 Reprocessing Validation and Verification

The Aesculap® SterilContainer™ System of rigid containers are designed to be reused, as long as they meet the inspection criteria outlined in Section 5.0 Inspection Prior to Use of the Aesculap® Instructions for Use (IFU). If these criteria cannot be achieved, the product should be serviced to bring it back within standards or replaced if standards cannot be achieved. See Section 3.0 SterilContainer™ System Service for full details regarding service.

As part of obtaining FDA clearance on the SterilContainer™ System, Aesculap® performed cleaning validation tests.

12.1.2 Sterilization Efficacy

The SterilContainer™ System includes many different sizes and designs and can be used to sterilize a wide variety of surgical instruments and tools while maintaining package integrity.

As part of obtaining FDA clearance on the SterilContainer™ System, Aesculap® performed efficacy validation tests related to the sterilization of container contents, such as surgical instruments, scopes, power tools etc. As per the FDA Guidance, Aesculap® performed Sterilant Penetration and Thermal Profile testing with a variety of 'worst case' loads and configurations to validate the container system.

The SterilContainer™ System was validated using the overkill method. The sterility assurance level (SAL) of 10^{-6} was achieved by placing spores of Geobacillus stearothermophilus in the most challenging locations inside the container system and then sterile processing at one-half the expected full cycle sterilization exposure.

12.1.3 Sterility Maintenance

To accommodate surgical schedules, packaged sterile instrument sets may need to maintain integrity for storage periods of days, weeks or even months. Instrument sets that maintain the sterile barrier throughout storage periods ensure confidence that the surgeon will have the necessary tools when needed to provide optimal care of the surgical patient.

As part of obtaining FDA clearance on the SterilContainer™ System, Aesculap® performed sterility maintenance validation tests to ensure post sterilization transport, storage and delivery of sterile instruments to the Operating Room (OR).

Event Related Storage Study

SterilContainer™ System test units that were reprocessed for more than 100 cycles were sterilized and then stored in a simulated SPD environment at an ISO certified laboratory for a period of time. The container system was handled on a routine basis to simulate a SPD storage environment. At the end of the test period, the container system was aseptically opened and evaluated for sterility. The Aesculap® SterilContainer™ System successfully completed the validation test.

Aerosol Challenge Test

SterilContainer™ System test units that were reprocessed for more than 100 cycles were sterilized and then placed in an aerosol chamber[1]. At the end of the test period, the container system was aseptically opened and evaluated for sterility. The Aesculap® SterilContainer™ System successfully completed the validation test, Zero Colony Forming Units (CFU) were detected.

Notes:

- *In order to minimize potential contamination of sterilized surgical instruments in the clinical setting, health care institutions should always establish and follow internal written policies and procedures for instrument sterilization, transport, storage and maintenance of sterile packaging, following the guidelines of AAMI ST79 and AORN standards.*
- *SterilContainer™ System should be used, cleaned, inspected, serviced and maintained as specified in the Aesculap® Instructions For Use (IFU). The Aesculap® SterilContainer™ System should only be serviced by an Aesculap® service center.*

12.2 Aesculap® SterilContainer™ System and FDA Clearances

Excerpts from the FDA website, www.fda.gov, are included here to provide a brief overview of the 510(k) process.

- Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k).
- A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, substantially equivalent, to a legally marketed device.
- Until the submitter receives an order declaring a device SE (substantially equivalent), the submitter may not proceed to market the device. Once the device is determined to be SE, it can then be marketed in the U.S.

The table below identifies the sterilization systems/modalities for which the Aesculap® SterilContainer™ Systems have received FDA 501(k) Clearance.

Container System Description	FDA 510 (k) Clearance
SterilContainer™ System for Steam Sterilization, Gravity, Steam Pre Vacuum and Ethylene Oxide (ETO)	K792558
SterilContainer™ System for Steam Pre Vacuum IUSS (Flash)	K053389
SterilContainer™ S System for Advanced Sterilization Products, STERRAD® Systems	K040865,K093493
SterilContainer™ S System for STERIS® Amsco® V-PRO® 1 and V-PRO® 1 Plus Low Temperature Sterilization System	K093649
Aesculap® Reusable Sterile Container Filter for Steam Pre Vacuum and Steam Pre Vacuum IUSS (Flash)	K041623
Aesculap® SterilContainer™ with PrimeLine™ Lid for Steam Pre Vacuum and Steam Pre Vacuum IUSS (Flash)	K073168
Aesculap® SterilContainer™ for PreVac Steam, Immediate Use Steam, and EtO Sterilization	K112671
SterilContainer™ S System for STERRAD 100NX Express Cycle	K142970
SterilContainer™ S System for V-PRO® 60 Sterilization System	K143729
SterilContainer™ S System for V-PRO® maX Flex Cycle	K151242
SterilContainer™ With PrimeLine Pro Lid	K172850
SterilContainer™ S2 System	K182414
SterilContainer™ S System for STERRAD 100NX Duo Cycle	K182032
SterilContainer™ S System for STERIZONE® VP4 Cycle	K162815
SterilContainer™ System for STERRAD 100NX Duo Cycle, 10L, STERIZONE® VP4 Cycle	K193582

References:

1. *ANSI/AAMI ST-77:2013 Containment devices for reusable medical device sterilization*
2. *ANSI/AAMI ST-79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*

13.0 Customer Verification

There is a difference between validation and verification. Aesculap® has performed testing to **validate** that its SterilContainer™ System can achieve and maintain sterility in Steam, EtO and Low Temperature sterilization modalities. Aesculap® validation parameters are the basis for the recommended parameters included in this IFU. Facilities **verify** the performance of Aesculap® Instructions for Use can be achieved in their application.

This information is intended to provide a guide for users on how to perform product testing in regards to the SterilContainer™ System and does not supersede policies and procedures of the healthcare facility.

Product Testing can be broken into three sub-categories:

1. Pre-Purchase Evaluation
2. Product Testing
3. Periodic Product Quality Assurance Testing

Aesculap® recommends the SPD Manager or Technician performing the tasks to reference AAMI ST79, Annex on the "Development of a Pre-Purchase Evaluation Protocol for Rigid Sterilization Container Systems", and to consult with the risk management and infection control departments within the facility regarding actual test protocols.

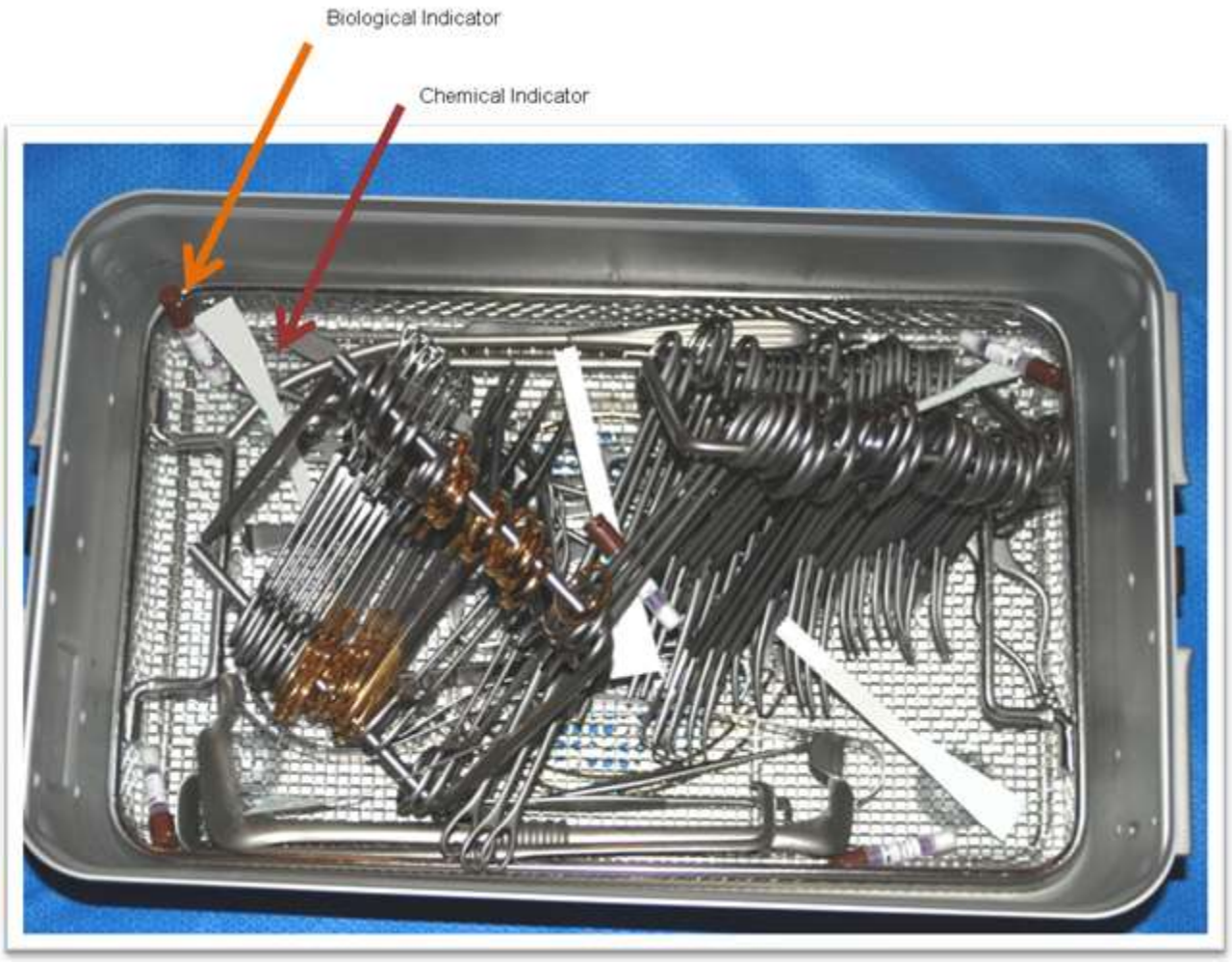
The purpose of performing a pre-purchase evaluation of a rigid container system is to evaluate sterilization efficacy of the master product instrument set under worst case sterilization parameters prior to purchasing the product.

Per AAMI ST79:
The concept of product families is used to group products similar in construction, materials, size, and packaging. The most difficult-to-sterilize device in each group is designated the master product and is used as the PCD for that family when product testing is performed. The sterilization process used for the master product can then be applied to all members of its product family. The concept of product families enables the health care facility to ensure a high level of sterility assurance without testing all products being sterilized.

Product testing should be performed more than once in each sterilizer that may be used during routine use for the master product instrument set.

A biological indicator (BI) and internal chemical indicator (CI) should be placed in each internal tray/basket in each corner and center.

Picture below shows a single tray with a BI and CI in each corner and in the center.



Placement of Chemical and Biological Indicators for Product Testing

The sterilization load should be configured as worst case.

Dry time should be evaluated for the master product instrument set to determine the appropriate drying time. Aesculap® recommends after the sterilization load has been removed from the sterilization chamber, allow the load to cool for safe handling. Open the container system and visually inspect interior of the container for moisture. If moisture is present, reevaluate dry time parameters and repeat test.

Per AAMI ST79:
Every sterilization load should be physically monitored. Every packaged item should be labeled externally with a process indicator ... and should contain an internal CI...

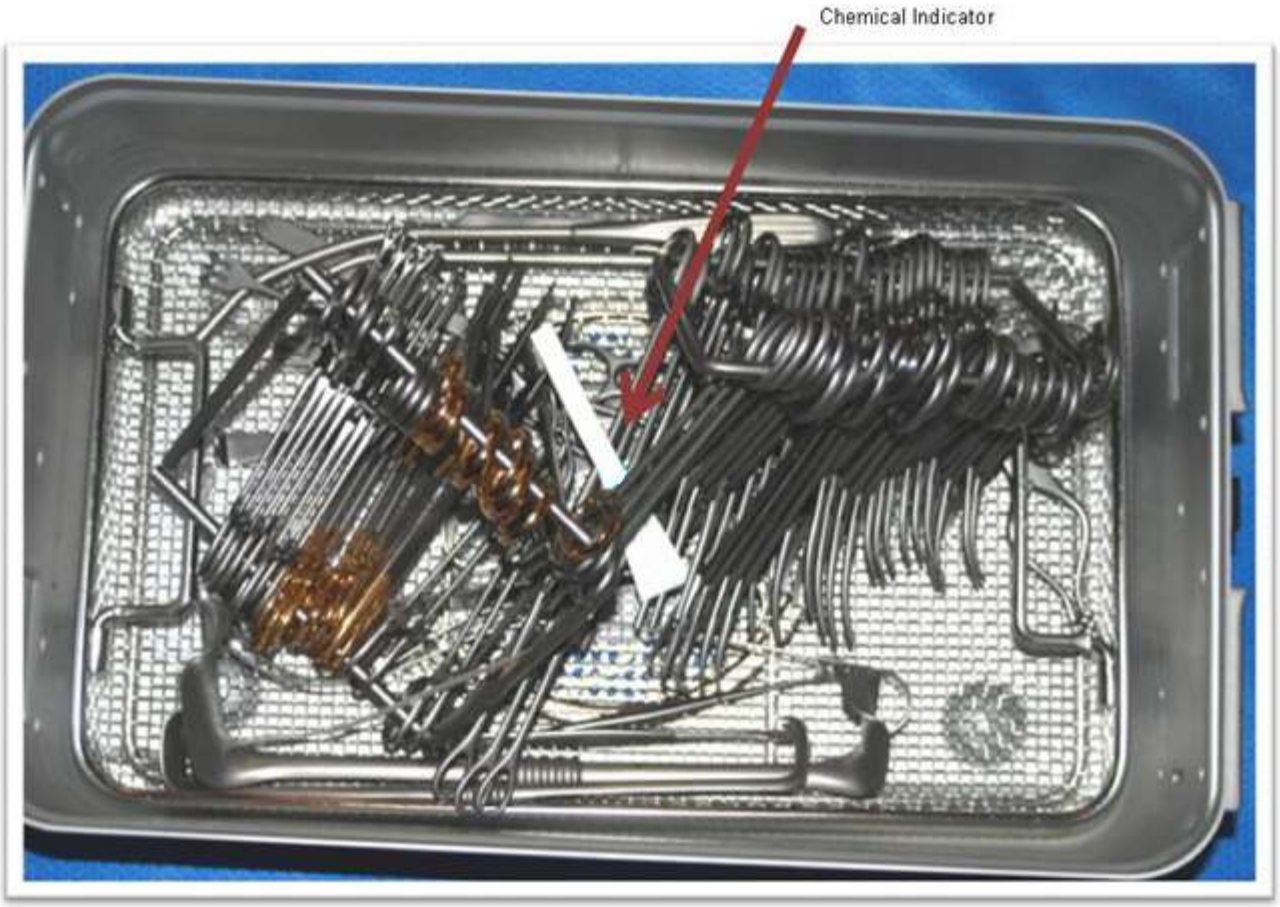
Following table summarizes Aesculap® suggestions on meeting the above guidelines:

AAMI ST79 Guideline	Aesculap® Product	Placement
External Package Process Indicator	Tamperproof lock with Indicator Process Card with Indicator	Externally on Lock or Indicator card
Internal Chemical Indicator (CI)	Offered by 3rd parties such as SPSMedical and 3M	Place at least one CI per instrument tray in center, unless other location in tray is considered more challenging based on device and/or other contents. (reference AAMI ST79 Internal Chemical Indicators)

Picture below shows external Chemical Indicators for the Aesculap® SterilContainer™.

Example of External Chemical Indicators

Picture below shows placement of an internal Chemical Indicator in the center of the tray for routine load release.



Example placement of Chemical Indicator for Routine Load Release

3. Periodic Product Quality Assurance Testing

AAMI ST79 Section 10.9 recommends periodic product testing as part of the healthcare facility's overall quality assurance program.

Aesculap® recommends performing periodic testing of SterilContainer™ systems using the same test methodology as the Pre-Purchase Evaluation procedure outlined above. The interval of periodic testing should be determined by healthcare facility's SPD Manger, OR Coordinator and Infection Control departments to ensure it is realistic, achievable and meets the overall quality assurance goals of the organization.

AAMI ST79 Reference

References in this document stated as *per AAMI ST79* are specifically referring to ANSI/AAMI ST79:2010 & A1&A2&A3 (Consolidated Text), Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

AAMI is the primary source of consensus and timely information on medical instrumentation and technology, please refer to www.aami.org for more information.

Pertinent definitions from AAMI ST79 are listed below.

- **Biological indicators (BIs):**
  - Test systems containing viable microorganisms providing a defined resistance to a specified sterilization process.
- **Chemical indicators (CIs):**
  - Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or are used in specific tests of sterilization equipment.
- **Master product:**
  - (Sterilization) product designated as representative of all members of a product family.
  - This product has the most difficult-to-sterilize attributes of any member of the family.
- **Product family:**
  - (Sterilization) group or subgroup of product that is characterized by similar attributes, such as mass, material, construction, set weight, shapes, lumens, and packaging system, and that presents a similar challenge to the sterilization process.

Notes:

- *Contact instrument manufacturer for their Instructions for Use (IFU).*
- *Users, not Aesculap®, are responsible for the final determination of verifying the instrument set to the sterile package selection.*
- *Please refer to* Sections 7.0 (Steam and EtO), 8.0 (STERRAD®), 9.0 (STERIS®) Cycle Parameters *to determine appropriate container bottom, lid, filter, lock and indicator card for sterilization cycle being used.*

14.0 Indications for Use

The following are FDA 510(k) cleared Indications for Use for the SterilContainer™ System. The FDA sterile packaging 510(k) submission requirements have evolved over the years so the same information may not be shown for each section.

See Section 6.6 Container Storage and Transportation for details related to storage, stacking and shelf life.

14.1 SterilContainer™ and SterilContainer™ S – Steam and EtO Sterilization

The Aesculap® SterilContainer™ System 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 for 360 days. The SterilContainer™ System includes accessories such as mats, baskets, trays, holders, organizers, filters, indicator cards and tamper proof locks.

The container system consists of a three-quarter size, 8" tall perforated (JN744) or solid (JK744) aluminum bottom and a three-quarter size aluminum or PrimeLine™ Lid*. The lids are available in different colors to aide in set recognition. There are three types of filter materials. A single use paper filter (US751, US994), a single use polypropylene filter (MD344), and a reusable PTFE filter (JK090). The reusable PTFE is validated for 2,200 uses. There are a variety of accessories for use with the container system.

14.2 SterilContainer™ – PreVac IUSS Sterilization

The Aesculap® SterilContainer™ is a reusable sterilization container system (consisting of a solid bottom, a perforated lid w/ filter retention plates, and disposable paper 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 has been validated with stainless steel lumens, hinged, and knurled instruments (stainless steel lumens of greater than 3 mm inner diameter or less than 400 mm in length*).

This container system is compatible for use in PreVac IUSS. The SterilContainer™ System for includes accessories such as baskets, trays, and racks.

14.3 SterilContainer™ – JK / JN744 PreVac Steam, IUSS and EtO Sterilization

The Aesculap® SterilContainer™ System 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 for 360 days. The SterilContainer™ System includes accessories such as mats, baskets, trays, holders, organizers, filters, indicator cards and tamper proof locks.

The container system consists of a three-quarter size, 8" tall perforated (JN744) or solid (JK744) aluminum bottom and a three-quarter size aluminum or PrimeLine™ lid. The lids are available in different colors to aide in set recognition. There are three types of filter materials for aluminum lids: single use paper filters (US751, US994), single use polypropylene filter (MD344), and a reusable PTFE filter (JK090). The reusable PTFE is validated for 2,200 uses. There are a variety of accessories for use with the container system.

Validated Sterilization Cycle Parameters

AAMI and AORN guidance's recommend maximum load weights of 25 Pounds or less in the healthcare setting. Validation testing for event related sterility maintenance has been conducted for up to 360 days.

Sterilization Cycle Parameters	Max No. of Lumens/Lumen Configuration*
PreVac IUSS for Nonporous Instruments	
PreVac IUSS for Porous Instruments	1 lumen with ≥ 3mm I.D. x ≤ 400mm L and a second lumen ≥ 3.8mm I.D. x ≤ 370mm L
PreVac Steam	1 lumen with ≥ 3mm I.D. x ≤ 400mm L and a second lumen ≥ 3.8mm I.D. x ≤ 370mm L
EtO	1 lumen with ≥ 3mm I.D. x ≤ 400mm L and a second lumen ≥ 3.8mm I.D. x ≤ 370mm L

Accessories	PreVac Steam	PreVac IUSS	EtO
Stainless Steel baskets, basket lids and dividers	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes
Silicone mats	Yes	Yes	Yes
Stainless Steel racks, trays, holders, clamps, rackets and platforms	Yes	Yes	Yes

14.4 SterilContainer™ with PrimeLine™ Lid

The Aesculap® SterilContainer™ System is a reusable sterilization container system (consisting of solid and perforated bottoms, a perforated lid w/ filter retention plates, and reusable polytetrafluoroethylene 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 in PreVac Steam and PreVac IUSS sterilization. The SterilContainer™ System includes accessories such as silicon mats, baskets, trays, and racks.

14.5 SterilContainer™ with PrimeLine™ Pro Lid

The Aesculap® SterilContainer™ System is a reusable sterilization container system consisting of a solid & perforated bottoms, a perforated lid w/ filter retention plates, and reusable polytetrafluoroethylene (PTFE) filter(s) 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 in pre-vacuum steam and IUSS (Immediate Use Steam Sterilization) sterilization modalities. The SterilContainer™ System includes accessories such as silicone mats, baskets, trays, and racks.

Steam and IUSS Compatible SterilContainer™ with PrimeLine™ Pro Lid

A combined maximum load validated for all container configurations is 25lbs			
Sterilization Cycle Parameters	**PrimeLine™ Pro Container Lid with JP050 – Lid Size**	**Solid Base to be used with Lid**	**Max No. of Lumens Lumen Configuration**
Immediate Use – Non-porous 270ºF Temp, 3 min. Exposure No stacking recommended **Immediate Use – porous** 270ºF Temp, 4 min. Exposure No stacking recommended **PreVacuum Dry Time Study** 270ºFTemp, 4min.Exposure, 30 min. Dry Time Stacking should not exceed 16-1/2" height	½ size Lid (298 x281 x36) Art. No. JP121 JP125	JK340 (4-1/4 in height) JK341 (5-1/2 in height) JK342 (6 in height) JK344 (8 in height) JK346 (10-1/2 in height)	**Immediate Use – Non-Porous** No lumens, a hinged device, and a knurled (irregular surface) device. **Immediate Use – Porous** 1 SS lumen with 3mm I.D. x 400mm L and a hinged device.
	¾ size Lid (465 x 281 x 36) Art. No. JP111 JP115	JK740 (4-1/4 in height) JK741 (5-1/2 in height) JK742 (6 in height) JK744 (8 in height)	
	Full size Lid (588 x 281 x 36) Art. No. JP101 JP105	JK440 (4-1/4 in height) JK441 (5-1./2 in height) JK442 (6 in height) JK444 (8 in height) JK446 (10-1/2 in height)	
Prevacuum Dry Time Study 270ºFTemp, 4min.Exposure, 30 min. Dry Time Stacking should not exceed 16-1/2" height	½ size Lid (298 x281 x36) Art. No. JP121 JP125	JN340 (41/2 in height) JN341 (51/2 in height) JN342 (6 in height) JN344 (8 in height) JN346 (101/2 in height)	
	¾ size Lid (465 x 281 x 36) Art. No. JP111 JP115	JN740 (4-1/4 in height) JN741 (5-1/2 in height) JN742 (6 in height) JN744 (8 in height)	
	Full size Lid (588 x 281 x 36) Art. No. JP101 JP105	JN440 (4-1/4 in height) JN441 (5-1/2 in height) JN442 (6 in height) JN444 (8 in height) JN446 (10-1/2 in height)	

Table 2: Steam and IUSS Cycle Compatible Accessories

Accessories	Steam and IUSS
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

14.6 SterilContainer™ with Aluminum Lid and Metal Retention Plate – Reusable Filter

The Aesculap® reusable SterilContainer™ filter (JK090) is a PTFE (Polytetrafluoroethylene) filter that allows for thorough penetration and evacuation of the sterilant (steam), while maintaining an effective barrier against microbial contamination for a maximum of 2,200 uses. This filter is for use with the Aesculap® SterilContainer™ in PreVac Steam sterilization cycle for 4 minutes at 270° F and in PreVac IUSS*.

14.7 SterilContainer™ – JS Series

The Aesculap® SterilContainer™ S2 System is a reusable rigid 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 in the following sterilization modalities:

- Dynamic-air removal steam (PreVac) (Exposure: 270°F for 4 minutes with 15 minute dry time)
- Gravity Steam (Exposure: 250°F for 30-60 minutes with 15 minute dry time)
- STERRAD® 100S, STERRAD® NX Standard, STERRAD® NX Advanced, STERRAD® 100NX Standard, STERRAD® 100NX Flex Cycles
- STERIS® V-PRO® 60 Lumen, V-PRO® 60 Non-Lumen, V-PRO® 60 Flex, V-PRO® maX Lumen, V-PRO® maX Non-Lumen, and V-PRO® maX Flex Cycles.

The Aesculap® SterilContainer™ S2 System includes accessories such as silicone mats and organizers, stainless steel baskets, trays, holders, sterilization indicator cards and tamper proof locks.

The attached table identifies the validated load configurations for each of the modalities

Table 1. SterilContainer™ S2 Validated Load Configurations

Sterilization Cycle	Container Size	Validated Load Configuration
Dynamic Air Removal Steam (PreVac)	Full	1 lumen with ≥ 3mm ID x ≤400mm L and a second lumen ≥ 3.8mm ID x ≤370mm L
	Three-Quarter	
	Half	
Gravity Steam	Full	Non lumen stainless steel instruments
	Three-Quarter	
	Half	
STERRAD® 100S	Full	5 Stainless steel lumens ≥ 3.0mm ID and ≤400mm L
	Three-Quarter	
	Half	
STERRAD® NX Standard	Full	5 Stainless steel lumens ≥ 2mm ID and≤400mm L
	Three-Quarter	
	Half	
STERRAD® NX Advanced	Full	1 Flexible lumens (≥ 1mm ID and ≤850mm L)
	Three-Quarter	

Sterilization Cycle	Container Size	Validated Load Configuration
	Half	
STERRAD® 100NX Standard	Full	5 Stainless steel lumens ≥ 0.7mm ID and ≤ 500mm L
	Three-Quarter	
	Half	
STERRAD® 100NX Flex	Full	1 Flexible Lumen 1mm ID and ≤850mm L
	Three-Quarter	
	Half	
STERIS® V-PRO® 60 Lumen	Full	Stainless steel lumens 1 lumen ≥ 0.77mm ID and ≤410mm L 1 lumen ≥ 1.2mm ID and ≤275mm L 1 lumen ≥ 1.8mm ID and ≤310mm L 1 lumen ≥ 2.8mm ID and ≤317mm L
	Three-Quarter	
	Half	
STERIS® V-PRO® 60 Non-Lumen	Full	Non-lumen stainless steel instruments
	Three-Quarter	
	Half	
STERIS® V-PRO® 60 Flex	Full	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Three-Quarter	
	Half	
STERIS® V-PRO® maX Lumen	Full	Stainless steel lumens 1 lumen ≥ 0.77mm ID and ≤527mm L 1 lumen ≥ 1.2mm ID and ≤275mm L 1 lumen ≥ 1.8mm ID and ≤310mm L 1 lumen ≥ 2.8mm ID and ≤317mm L 1 lumen ≥ 3.0mm ID and ≤400mm L
	Three-Quarter	
	Half	
STERIS® V-PRO® maX Non-Lumen	Full	Non-lumen stainless steel instruments
	Three-Quarter	
	Half	
STERIS® V-PRO® maX Flex	Full	2 flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The scopes can have: a single lumen that is ≥ 1 mm ID and ≤ 1050 mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L OR 1 flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. The scope can have: a single lumen that is ≥ 1 mm ID and ≤ 1050 mm L or two lumens with one ≥ 1 mm ID and ≤ 990 mm L and the other ≥ 1 mm ID and ≤ 850 mm L
	Three-Quarter	
	Half	

Table 2. SterilContainer™ S2 System Configurations – PreVac Steam and Gravity Steam

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight*
Dynamic-air removal steam (PreVac) & Gravity Steam	Full Size - 4 ¼"	JS440	JS489	25 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ½"	JS740	JS789	25 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ½"	JS340	JS389	25 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		

*Maximum load weight is 25 Pounds or the maximum indicated weight for the sterilizer, whichever is less.

Table 3. Sterilization Cycle Compatible Accessories – PreVac Steam and Gravity Steam

Accessories	Compatible with	
	PreVac Steam	Gravity Steam
Stainless Steel baskets, basket lids, and dividers	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes
Silicone mats	Yes	Yes

Table 4. SterilContainer™ S2 System Configurations – STERRAD® Sterilization Systems

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
STERRAD®100 S	Full Size - 4 ¼"	JS440	JS489	13.95 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼ "	JS740	JS789	13.90 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	13.90 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD® NX Standard	Full Size - 4 ¼"	JS440	JS489	10.70 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4¼"	JS740	JS789	10.70 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	10.70 Pounds

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD® NX Advanced	Full Size - 4 ¼"	JS440	JS489	10.70 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.70 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	10.70 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD® 100NX Standard	Full Size - 4 ¼"	JS440	JS489	21.45 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	13.85 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	13.85 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD® 100NX Flex	Full Size - 4 ¼"	JS440	JS489	10.95 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.35 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	10.35 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		

Table 5. Sterilization Cycle Compatible Accessories – STERRAD® Sterilization Systems

Accessories	Compatible with STERRAD®				
	100S	NX Standard	NX Advanced	100NX Standard	100NX Flex
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes	Yes
Silicone mats	Yes	No	Yes	No	No

Table 6. SterilContainer™ S2 System Configurations – STERIS® Sterilization Systems

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
STERIS® V-PRO® 60 Lumen	Full Size - 4 ¼"	JS440	JS489	11.1 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	9.6 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	9.6 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIS® V-PRO® 60 Non-Lumen	Full Size - 4 ¼"	JS440	JS489	12.0 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	12.0 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	12.0 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
	Full Size - 4 ¼"	JS440	JS489	

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
STERIS® V-PRO 60 Flex	Full Size - 5 ½"	JS441		1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	1 flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumens that are >1mm ID and <990 mm L
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIS® V-PRO® maX Lumen	Full Size - 4 ¼"	JS440	JS489	11.1 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	9.6 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	9.6 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIS® V-PRO® maX Non-Lumen	Full Size - 4 ¼"	JS440	JS489	18.6 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	18.6 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	18.6 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container Weight
STERIS® V-PRO® maX Flex	Full Size - 4 ¼"	JS440	JS489	10.3 Pounds
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4 ¼"	JS740	JS789	10.0 Pounds
	Three-Quarter Size - 5 ½"	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	10.0 Pounds
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		

Table 7. Sterilization Cycle Compatible Accessories – STERIS® Sterilization Systems

Accessories	Compatible with STERIS® V-PRO®					
	60 Lumen	60 Non-Lumen	60 Flex	maX Lumen	maX Non-Lumen	maX Flex
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes	Yes	Yes	Yes
Silicone mats	No	No	No	No	No	No

14.8 SterilContainer™ S – STERRAD® 100S

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 STERRAD®100S.

14.9 SterilContainer™ S – STERRAD® 200 System, NX™ System, and 100NX System

The Aesculap® SterilContainer™ S is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and disposable polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container has been validated with stainless steel lumens, hinged, and knurled instruments. 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 STERRAD® 200, STERRAD® NX (Standard cycle and Advanced cycle), and STERRAD® 100NX (Standard cycle and Flex cycle). The SterilContainer™ S includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

The SterilContainer™ S is recommended for surface and lumens:

- STERRAD® 200, stainless steel lumens ≥ 3mm I.D. x ≤ 400mm L
- STERRAD® NX standard cycle, stainless steel lumens ≥ 2mm I.D. x ≤ 400mm L
- STERRAD® NX advanced cycle, stainless steel lumens ≥ 1mm I.D. x ≤ 500mm L
- STERRAD® 100NX standard cycle, stainless steel lumens ≥ 0.7mm I.D. x ≤ 500mm L
- STERRAD® 100NX flex cycle, porous lumens (flexible endoscope) ≥ 1mm I.D. x ≤ 850mm L

Validation testing for event related sterility maintenance has been conducted for up to 360 days.

For STERRAD® 200 System, STERRAD® NX System (Standard and Advanced cycle), and STERRAD® 100NX System (Standard)—full, three-quarter, half and quarter size containers have been validated with 5 stainless steel lumens per container system. The extra-long mini and mini container have been validated with 2 stainless steel lumens per container system.

For STERRADR® 100NX System Flex cycle—full, three-quarter, half and quarter size containers have been validated with 1 PTFE/PE lumen per container system.

14.10 SterilContainer™ S – STERRAD® 100NX EXPRESS Cycle

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. This container system has been validated with hinged, and knurled instruments. 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 STERRAD® 100NX EXPRESS Cycle. The SterilContainer™ S includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

Testing has been completed on the SterilContainer™ S Full size container to maintain the sterility of its contents for 360 days following successful sterilization.

Testing has been completed on the SterilContainer™ S ½ size container to maintain the sterility of its contents for 360 days following successful sterilization.

The validated chamber load for the SterilContainer™ S Full and Half sizes in the STERRAD® 100NX EXPRESS Cycle consisted of one SterilContainer™ S placed on the bottom shelf in an otherwise empty chamber.

Container Configuration	Intended Load
JM440, JM441, JM442 bottom with JM489 lid	Reusable metal and non-metal medical devices without lumens including endoscopes without lumens OR the da Vinci Scope Platform (MD425) and two Si or S series da Vinci Scopes
JM340, JM341, JM342 bottom with JM389 lid	Reusable metal and non-metal medical devices without lumens including endoscopes without lumens

Accessories	STERRAD® 100NX Express 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, rackets and platforms	Yes

14.11 SterilContainer™ S – STERRAD® 100NX DUO Cycle

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. This container system has been validated with flexible endoscopes and accessories, cables, and camera heads. 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 STERRAD® 100NX Duo cycle. The SterilContainer™ S System includes accessories such as silicone mats, baskets, trays, racks, filters, indicator cards, locks, and instrument holders.

Validation testing for event related sterility maintenance has been conducted for up to 365 days.

Table 1: Validated STERRAD 100NX DUO Cycle Load Configurations

Load Configuration	Container # 1	Container # 2
1	• 135mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (1x)	• 135mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)
2	• 187mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)	• N/A – Top shelf is removed to allow the container to fit in the chamber
3	• 90mm Full Size Container Bottom • Full Size Container Lid • Full Size Basket • Full Size Mat • Flexible Endoscope (1.2 mm x 785 mm) • Guide Cable (2x)	• 135mm Half Size Container Bottom • Half Size Container Lid • Half Size Basket • Half Size Mat • Camera Head for Endoscope

Table 2: STERRAD 100NX DUO Compatible SterilContainer S Container Systems

Lid	Bottom	Description	Container Load Weight *
JM489	JM440	Full Size 90mm (4 ¼")	13.2 lbs total weight. (1 or 2 shelves based on container)
	JM441	Full Size 120mm (5 ½")	
	JM442	Full Size 135mm (6")	
	JM444	Full Size 187mm (8")	
JM789	JM740	¾ Size 90mm(4 ¼")	
	JM741	¾ Size 120mm (5 ½")	
JM389	JM340	½ Size 90mm (4 ¼")	
	JM341	½ Size 120mm (5 ½")	
	JM342	½ Size 135mm (6")	
	JM344	½ Size 187mm (8")	

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

Table 3: STERRAD 100NX DUO Cycle Compatible Accessories

Accessories	STERRAD 100NX DUO Cycle
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, instrument holders, and clamps)	Yes
Silicone mats	Yes
Stainless Steel racks, trays, instrument holders, clamps, brackets, tamper-proof locks, indicator cards and platforms	Yes

14.12 STERIS® V-PRO® 60 – SterilContainer™ S with Aluminum Lid

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. This container system has been validated with stainless steel and Teflon lumens, hinged, and knurled instruments. 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® 60 Low Temperature Sterilization System's Lumen, Non-Lumen and Flexible Cycles.

The SterilContainer™ S includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders. The SterilContainer™ S was demonstrated to maintain the sterility of its contents for 360 days following successful sterilization.

Lumen Cycle

Validated Container Load

- Lumened and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including single, dual and triple channeled rigid and semi rigid endoscopes, with the following configurations:
  - Single or dual lumen devices with stainless lumen(s) that is (are)
    - ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm length
  - Triple lumen devices with stainless steel lumens that are
    - ≥ 1.2 mm ID and ≤ 275 mm length
    - ≥ 1.8 mm ID and ≤ 310 mm length
    - ≥ 2.8 mm ID and ≤ 317 mm length

Each container held six (6) lumens for a total of 12 total lumens per load.

For full, three-quarter and half size containers, the validation chamber load consisted of one container containing a basket and basket lid, mat, accessories, 12 lumens, and metal and non-metal medical devices.

For extra-long mini and mini, the validation chamber load consisted of two containers containing a basket and basket lid, mat, accessories, and metal and non-metal medical devices for a total chamber load weight of 15.30 lbs.

Non-Lumen Cycle

Validated Container Load

Non-lumened devices including devices with stainless steel or titanium diffusion restricted spaces such as the hinged portion of forceps and scissors.

For full, three-quarter and half size containers, the validation chamber load consisted of one container with a basket and basket lid, mat, accessories, and metal and non-metal medical devices.

For extra-long mini and mini, the validation chamber load consisted of two containers with a basket and basket lid, mat, accessories, and metal and non-metal medical devices for a total chamber load weight of 15.30 lbs.

Flexible Cycle

Validated Container Load

One flexible surgical endoscope or bronchoscope with a light cord (if not integral to the endoscope) and mat without any additional load.

The flexible endoscopes may contain: single or dual lumen devices with lumens that are ≥ 1 mm ID and ≤ 990 mm lengths.

The validation chamber load consisted of one container with a basket and lid, mat, accessories, three (3) 1 x 1000mm lumens, one flexible endoscope, and one light cable.

Accessories	V-PRO® 60
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, rackets and platforms	Yes

14.13 STERIS® V-PRO® maX Flexible Cycle – SterilContainer™ S with Aluminum Lid

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.

Validated V-PRO® maX Sterilizer Flexible Cycle Load Configurations

Load Configuration 1	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. The flexible endoscopes may contain either: • A single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • 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
Load Configuration 2	Two SterilContainer™ S System containers, each with a basket, mat and accessories[1]. 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. The flexible endoscopes may contain either: • A single lumen with an inside diameter of 1 mm or larger and a length of 1050 mm or shorter • 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 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. The total load weight validated was 24 lbs.

1. *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.*

V-PRO® maX Sterilizer Flexible Cycle Compatible SterilContainer™ S Container Systems

Total Loaded Container Weight (if container does not contain a flexible endoscope or bronchoscope)

24 lbs for one container in the chamber OR 24 lbs split between two containers in the chamber. Loads containing a flexible endoscope or bronchoscope should follow Load Configurations recommendations.

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, rackets and platforms	Yes

14.14 STERIS® V-PRO® 1 and V-PRO® 1 Plus— SterilContainer™ S with Aluminum Lid

The Aesculap® SterilContainer™ S 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 includes accessories such as silicon mats, baskets, trays, and racks

Processing STERIS® V-PRO® Low Temperature Sterilization Systems Lumen and Non-Lumen Cycles

Choose appropriate cycle and run loaded sterilizer according to the sterilizer manufacturer's instructions for use

Suggested Sterilizer Cycle Parameters for SterilContainer™ S products:

The following validated parameters are based on the validation of the non-anodized Aesculap® SterilContainer™ S in the Amsco® V-PRO® Sterilization Systems.

The V-PRO® 1 System has one pre-programmed and unalterable sterilization cycle, Non-Lumen. The SterilContainer™ S System is validated and FDA cleared in the V-PRO® 1 System.

The V-PRO® 1 Plus System has two pre-programmed and unalterable sterilization cycles: Non-Lumen and Lumen cycles. The SterilContainer™ S System is validated and FDA cleared in the V-PRO® 1 Plus System.

The V-PRO® maX System has three pre-programmed and unalterable sterilization cycles: Non-Lumen, Lumen, and Flex cycles. The SterilContainer™ S System is validated and FDA cleared in the V-PRO® maX Non-Lumen and Lumen cycles.

- V-PRO® 1; V-PRO® 1 Plus and V-PRO® maX Lumen Cycles
  - Condition: 3 minutes
  - Sterilization: 8 minutes per injection, 4 injections, (32 minutes total)
  - Aeration: 6 minutes
- V-PRO® 1 Plus and V-PRO® maX Non-Lumen Cycles
  - Sterilization: 3 minutes per injection, 4 injections, (12 minutes total)
  - Aeration: 6 minutes

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 system has been validated with 5 stainless steel lumens per container. Do not exceed a maximum of 20 lumens per load. Only load lumens that fall within the following limitations:

- *> 1mm internal diameter and < 125 mm in length*
- *> 2mm internal diameter and < 250 mm in length*
- *> 3mm internal diameter and < 400 mm in length*

Notes:

- *Aesculap® has performed validation testing that support the configurations shown in this section.*
- *As part of the FDA submission, Aesculap® has performed event related validation testing on the SterilContainer™ System. To determine if the SterilContainer™ maintained sterility during the event related validation testing, the container was opened to check sterility of the contents.*
- *Facilities should follow industry guidelines and establish written policies and procedures on how shelf life is determined and tracked.*
- *Consult with the manufacturer of the sterilizer for specific recommendations. Complex devices such as lumened instruments should be sterilized in accordance with the instrument.*

14.15 STERIZONE® VP4– SterilContainer™ S with Aluminum Lid

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. This container system has been validated with stainless steel and Teflon lumens, hinged, and knurled instruments. 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 STERIZONE® VP4 Low Temperature Sterilization System. The SterilContainer™ S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

Table 1: Validated VP4 Cycle Load Configurations

Load Configuration 1 (31.2 lb)	Flexible endoscopes load accommodating three single channel flexible endoscopes, one per container: • Internal channel diameter of 1 mm and length of 850 mm.

Load Configuration 2
(29.4 lb)
	Semi-rigid and rigid channel devices load accommodating three double channel semi-rigid endoscopes and one length of medical grade stainless steel tubing.
	• Length of tubing:
	  ○ Internal channel diameter of 1.0 mm and length of 500 mm.
	• Double channel semi-rigid endoscope
	  ○ Internal channel diameters of 0.7 mm and 1.1 mm, and length of 500 mm

Load Configuration 3 (10.2 lb):	Worst-case volume to surface perforation area ratio using a perforated container including two stacked baskets. Each basket was covered with a full length silicone mat. At least one inoculated medical device was added per level of the container.
Load Configuration 4 (25 lb)	Worst-case volume to surface perforation area ratio using a perforated container with maximum weight of instrument, for a total mass of 25 lb. At least three inoculated medical devices were added in the container.
Load Configuration 5 (75 lb)	Heavy weight load composed of three perforated containers, with a total mass of 25 lb per container. The heavy validation load was prepared based on the Aesculap® SterilContainer™ S container lethality studies (PRO-169) and adapted to include a maximum weight in a single load.

Table 2: VP4 Sterilizer 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 305mm [12"]	25 lbs for one container in the chamber
	JM441	Full Size 127mm [5"]	
	JM442	Full Size 203mm [8"]	
	JM444	Full Size 381mm [15"]	
JM789	JM740	½ Size 305mm [12"]	
	JM741	½ Size 127mm [5"]	
	JM742	½ Size 203mm [8"]	
JM389	JM340	¼ Size 305mm [12"]	
	JM341	¼ Size 127mm [5"]	
	JM342	¼ Size 203mm [8"]	

**Loads containing a flexible endoscope or bronchoscope should follow Table 1 recommendation.*

Table 3: VP4 Sterilizer Cycle Compatible Accessories

Accessories	VP4
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

Notes:

- *Aesculap®has performed validation testing that support the configurations shown in this section.*
- *As part of the FDA submission, Aesculap®has performed event related validation testing on the SterilContainer™ System. To determine if the SterilContainer™ maintained sterility during the event related validation testing, the container was opened to check sterility of the contents.*
- *Facilities should follow industry guidelines and establish written policies and procedures on how shelf life is determined and tracked.*
- *Consult with the manufacturer of the sterilizer for specific recommendations. Complex devices such as lumened instruments should be sterilized in accordance with the instrument.*

14.16 SterilContainer™ – JS Series EtO, STERRAD®100NX DUO & STERIZONE® VP4

The Aesculap® SterilContainer™ S2 System is a reusable rigid 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 in the following sterilization modalities:

- Ethylene Oxide
- STERRAD®100NX DUO cycle
- STERIZONE® VP4

The Aesculap® SterilContainer™ S2 System includes accessories such as silicone mats and organizers, stainless steel baskets, trays, holders, sterilization indicator cards and tamper proof locks.

The attached table identifies the validated load configurations for each of the modalities.

SterilContainer™ S2 System Validated Load Configurations

Sterilization Cycle	Container Size	Validated Load Configuration
EtO *(130°F, 60 minute exposure, ≥50% RH 725mg/L gas pressure)*	Full Three-Quarter Half	(1) lumen (≥ 3mm ID x ≤ 400mm L) AND (1) lumen (≥ 3.8mm ID x ≤ 370 mm L)
STERRAD®100NX DUO *(bottom shelf only)*	Full Three-Quarter Half	Flexible scope (≥ 1mm ID x ≤ 850mm L)
STERIZONE® VP4 Validated Loads 1 & 2 (Based on STERIZONE® Load #7)	Full Three-Quarter Half	Non Lumened Instruments
STERIZONE® VP4 Validated Load 3 (Based on STERIZONE® Load #8)	JS440 (base) + JS489 (lid)	(1) Single Channel Flexible Scope (≥1mm ID x ≤ 850mm L) OR (1) Dual Channel Flexible Scope (≥1mm ID x ≤850 mm L and ≥1 mm ID x ≤ 989mm L)
STERIZONE® Validated Load 4 (Based on STERIZONE® Load #4)	JS440 (base) + JS489 (lid)	(1) Semi-rigid dual channel scope (≥0.7mm ID x ≤500mm L and ≥1.1mm ID x ≤500mm L) AND one of the following: (4) Stainless steel lumens (≥ 5.5mm ID x ≤ 166mm L; ≥ 7mm ID x ≤ 105mm L; ≥ 7.0mm ID x ≤ 227mm L; ≥ 7.8mm ID x ≤ 198mm L) OR (2) Stainless steel lumens (≥ 4mm ID x ≤ 370mm L; ≥ 2mm ID x ≤ 152mm L) OR (3) Stainless steel lumens (≥ 2.2mm ID x ≤ 173mm L; ≥ 4.7mm ID x ≤ 270mmL ; ≥ 4mm ID x ≤ 445mm L)

SterilContainer™ S2 System Load Weights

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container (lb)
EtO	Full Size - 4 ¼"	JS440	JS489	25
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4	JS740	JS789	25
	Three-Quarter Size - 5	JS741		
	Three-Quarter Size - 6"	JS742		
	Three-Quarter Size - 8"	JS744*		
	Half Size - 4 ½"	JS340	JS389	25
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERRAD®100NX DUO	Full Size - 4 ¼"	JS440	JS489	10.97
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4	JS740	JS789	10.04
	Three-Quarter Size - 5	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	11.7
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIZONE® Validated Loads 1 & 2 (Based on STERIZONE® Load #7)	Full Size - 4 ¼"	JS440	JS489	25
	Full Size - 5 ½"	JS441		
	Full Size - 6"	JS442		
	Full Size - 8"	JS444		
	Three-Quarter Size - 4	JS740	JS789	25
	Three-Quarter Size - 5	JS741		
	Three-Quarter Size - 6"	JS742		
	Half Size - 4 ¼"	JS340	JS389	25
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
	Half Size - 5 ½	JS341		
	Half Size - 6"	JS342		
STERIZONE® Validated Load 3 (Based on STERIZONE® Load #8)	Full Size - 4 ¼"	JS440	JS489	See load configuration in table 1 above

Sterilization Method	Container Size	Container Bottom Part #	Container Lid Part #	Total Loaded Container (lb)
STERIZONE® Validated Load 4 (Based on STERIZONE® Load #4)	Full Size - 4 ⅘"	JS440	JS489	See load configuration in table 1 above

*JS744 is for use in Ethylene Oxide only.

Sterilization Cycle Compatible Accessories

Accessories	Compatible with Ethylene Oxide	Compatible with STERRAD®DUO	Compatible with STERIZONE® VP4
Stainless Steel baskets, basket lids, and dividers	Yes	Yes	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes	Yes	Yes
Silicone mats	Yes	No	Yes
Tamper Evident locks and indicator cards	Yes	Yes	Yes

Notes:

- *Aesculap®has performed validation testing that support the configurations shown in this section.*
- *As part of the FDA submission, Aesculap®has performed event related validation testing on the SterilContainer™ System. To determine if the SterilContainer™ maintained sterility during the event related validation testing, the container was opened to check sterility of the contents.*
- *Facilities should follow industry guidelines and establish written policies and procedures on how shelf life is determined and tracked.*
- *Consult with the manufacturer of the sterilizer for specific recommendations. Complex devices such as lumened instruments should be sterilized in accordance with the instrument.*

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Reference to AAMI (Association for the Advancement of Medical Instrumentation) and AORN (Association of periOperative Registered Nurses) recommended practices are based on the guidelines that were available at the time of this publication. Since these standards are regularly updated, it is recommended to review the most current document and standards from these organizations.

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Instructions for Use intended for US Only

The most current version of Aesculap® Sterilization Instructions for Use are published on www.Aesculap®usaifus.com/