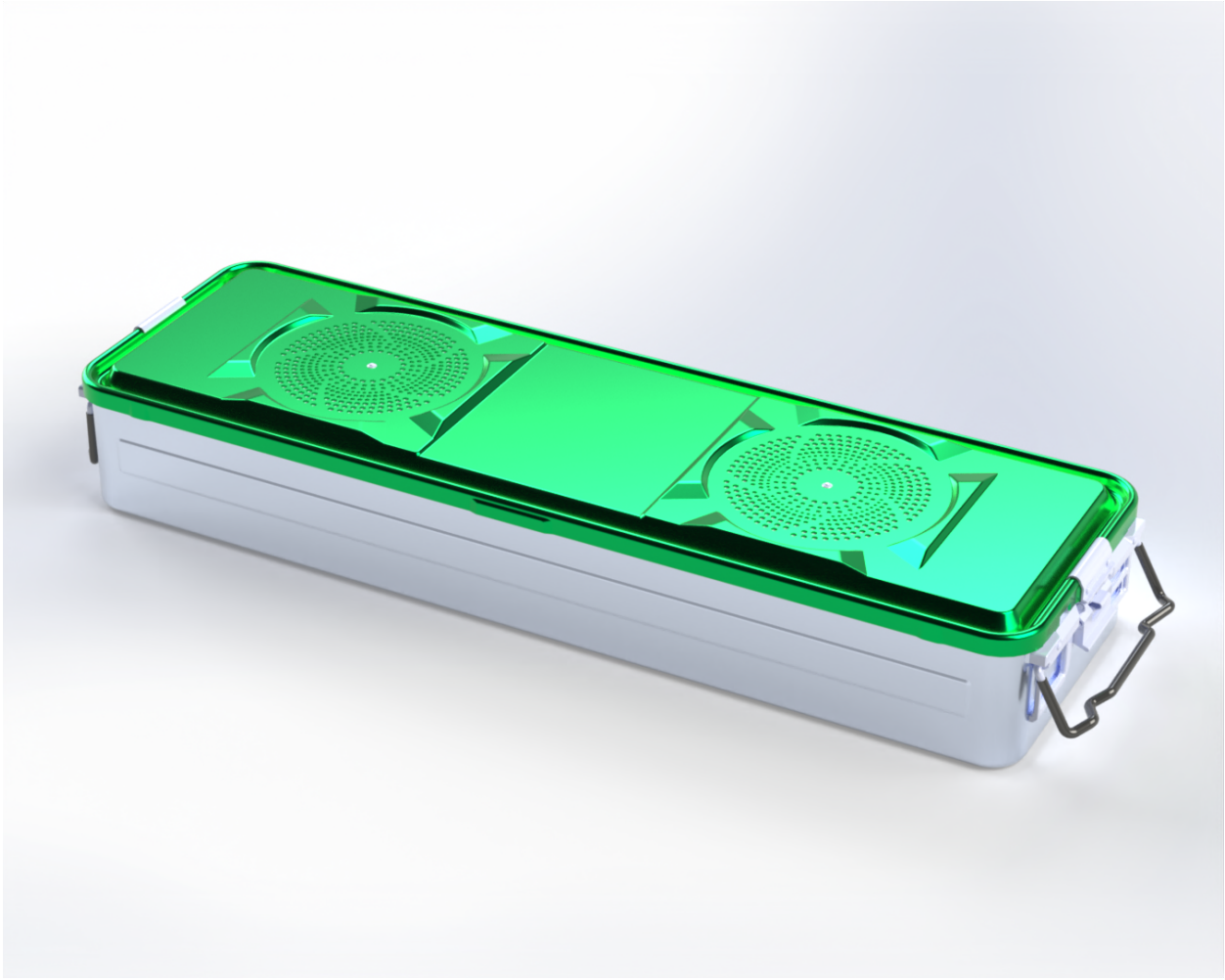
ContainMed SteriPod™ Container Systems

Instructions for Use for SteriPod™ (IFU)



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CAT: 923
De Mayo Knee Positioner® Sealed Container - Filtered Container & Insert
Version 0

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Introduction:

This document provides comprehensive information about the ContainMed SteriPod™ Container Systems, detailing their usage, cleaning process and the relation between the various components and accessories. It is crucial to ensure that the personnel using ContainMed SteriPod™ container systems are adequately trained and competent. The necessary equipment, water supply and other resources that are required for processes such as usage, cleaning and sterilization of ContainMed SteriPod™ Container Systems should be provided and monitored by the respective facility. The information given in this document is based on validations and tests carried out at a medical device testing laboratory or within the OEM based on best-case, middle-case, and worst-case representative samples.

1.0 Indications for Use:

The ContainMed SteriPod™ Container Systems is indicated for use by hospitals and health care facilities to:

- Organize and protect stainless steel, aluminum, titanium, plastic, and silicone surgical instruments during the reprocessing process,
- Facilitate the sterilization of the enclosed instruments via pre-vacuum steam sterilization cycles,
- Maintain the sterility of the contents for up to 180 days during storage and transport within the healthcare facility, as long as the integrity of the container remains uncompromised,
- The system has not been tested for maintenance of sterility after transportation outside the health care facility. The system is designed for use with stainless steel, aluminum, titanium, plastic, and silicone surgical instruments.

For effective sterilization and drying of any size ContainMed SteriPod™ Container System, the recommended maximum combined weight of the single container, lid, basket/tray, and basket/tray contents is defined below. The qualified lumen size, representing the minimum diameter and maximum length, which has been qualified for use, is also shown below.

Type: Pre-vacuum Steam Sterilization.

Cycle: Temperature: 270°F/132°C, Exposure Time: 4 minutes, Drying Time: 30 minutes.

Stackable: No.

Instrument Type: stainless steel, aluminum, titanium, plastic, and silicone surgical instruments.

Lumen Size: ≥ Full Size:1mm x 500mm, ≤ Three Quarter Size: 1mm x 200mm

Maximum Weight: ≥ Three Quarter Size: 25 lbs., ≤ Half Size 15 lbs.

Table 1. ContainMed SteriPod™ Container Systems Configurations

Sterilization Method	Container Model	Container Size	Container Non-Perforated Bottom Part	Container Perforated Lid Part	Total Loaded Container Weight
Vacuum Steam Sterilization (270°F/132°C for 4 minutes	SteriPod™	1/1 Full Size	CM-10011-100	CM-10011-500	Maximum load weight for Full and Three Quarter size is 25 pounds, and for Half size is 15 pounds or the maximum indicated weight for the sterilizer, whichever is
		3/4 Quarter Size	CM-10011-200	CM-10011-400	
		Extra Long Size	CM-10011-300	CM-10011-600	

Table 2. Sterilization Cycle Compatible Accessories

Accessories	Compatible with Pre-vac Steam
Paper Labels	Yes
Aluminum Identification Labels	Yes
Security Seals	Yes
Auto Lock Mechanism	Yes
Paper Filters	Yes
Filter Retainers	Yes
Silicone Meshes	Yes
Silicone Gaskets	Yes
Silicone Fixation Systems	Yes
Holders	Yes
Dividers	Yes
Baskets	Yes
Identification Labels with or without Clips	Yes

1.1 Symbols Glossary

Table 3. Labeling Symbols and Explanations

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223- 1:2021 Reference no. 5.1.1. (ISO 7000-3082)	Manufacturer	Indicates the medical device manufacturer
	ISO 15223- 1:2021 Reference no. 5.1.2	Authorized Representative in the European Community	Indicates the authorized representative in the European Community / European Union
	ISO 15223- 1:2021 Reference no. 5.1.3. (ISO 7000-2497)	Date of manufacture	Indicates the date when the medical device was manufactured
	ISO 15223- 1:2021 Reference no. 5.1.5. (ISO 7000-2492)	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	ISO 15223- 1:2021 Reference no. 5.1.6. (ISO 7000-2493)	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified
	ISO 15223- 1:2021 Reference no. 5.2.7. (ISO 7000-2609)	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
60°C  -20°C	ISO 15223- 1:2021 Reference no. 5.3.7. (ISO 7000-0632)	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
70%  10%	ISO 15223- 1:2021 Reference no. 5.3.8. (ISO 7000-2620)	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
1050HPa  500HPa	ISO 15223- 1:2021 Reference no. 5.3.9 (ISO 7000-2621)	Atmospheric pressure limitation Atmospheric Pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	ISO 15223-1:2021 Reference no. 5.4.3. (ISO 7000-1641) Reference no. 5.4.3. (ISO 7000-1641)	Consult instructions for use Operator's manual; operating instructions	Indicates the need for the user to consult the instructions for use
	ASTM F2503 Reference no. Table 2, Symbol 7.3.3; 7.4.9.1; Fig. 9	(MR) Unsafe	3.1.14: An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment
	ISO 15223- 1:2021 Reference no. 5.4.4. (ISO 7000-0434A)	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol is placed, or to indicate that the current situation needs operator awareness or operator action to avoid undesirable consequences
	EU 2017-745 EU 2017-746 Reference no. ANNEX V	CE marking	(43) 'CE marking of conformity' or 'CE marking' means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonization legislation providing for its affixing

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
	ISO 15223-1:2021 Reference No. 5.1.9	Distributor	To indicate the entity distributing the medical device into the locale

2.0 ContainMed SteriPod™ Container Systems

ContainMed SteriPod™ Container Systems, which are reusable, are designed for transporting and maintaining the sterility of the enclosed medical products for up to 180 days. Sterilization Container System can be used in hospitals, surgical clinics, and other health units. Each ContainMed SteriPod™ Container Systems comprises container bottoms, lids, gaskets, filter retainers, paper labels, silicone meshes, baskets and other necessary accessories in various sizes, determined according to customer needs and industry standards. Each container bottom should only be used with a specific lid designed for that particular model of container, and it should not be combined with other OEM or competing OEM series of lids.

Table 4. Bottom-Lid-Sterilization Method Configuration Table

Sterilization Type	SteriPod™ Container System
Pre-Vac Steam Sterilization	Yes
	Yes

Throughout this IFU document, references to the ContainMed SteriPod™ Container Systems include the SteriPod™ product model. Designed for daily operation, ContainMed SteriPod™ Container Systems can provide sterile storage for 180 days. When choosing a sterilization container system, it is important to ensure that the container bottom, lid, and accessories are compatible both with the chosen sterilization method and with each other. The container system should align with the application and sterilization requirements. Guidelines for this can be found in the AAMI ST79 Annex H “Development of a prepurchase evaluation protocol for rigid sterilization container systems”.

The OEM carried out the necessary validation tests for its medical devices. These tests conducted both internally within the OEM and external testing laboratories and companies, have resulted in FDA clearance for the OEM sterilization container products to be used in steam sterilization processes. Please refer to Section 1.0 Indications of Use to determine which steam sterilization methods are compatible with ContainMed SteriPod™ Container Systems.
Please note that all ContainMed SteriPod™ Container Systems are shipped in a non-sterile condition.

Notes and Warnings:

- Precautions should be taken to ensure that the personnel using ContainMed SteriPod™ container systems are adequately trained and competent.
- The equipment, water supply and other necessary resources for the use, cleaning, and sterilization of ContainMed SteriPod™ Container Systems during the reprocessing process should be provided and monitored by the facility.
- For additional information, please refer to AAMI ST79.
- OEM branded silicone products such as silicone meshes and gaskets, are latex-free.
- OEM baskets and accessories can be cleaned and sterilized following accepted industry guidelines using the same processes as for ContainMed SteriPod™ container bottoms.
- Cutting OEM branded silicone products, such as silicone gaskets and mesh mats, do not change the characteristics and function of these products.
- The OEM recommends using containers with baskets.

- The integrity validation test was performed only with the OEM filter, the suitability and accuracy of fit can only be guaranteed if OEM filters are used. - Warranty claims can only be accepted if OEM filters are used exclusively.

2.1 SteriPod™ Container Systems- Steam Sterilization

SteriPod™ container systems are designed to facilitate steam flow and penetration for suitable loads according to the standards and should be used with single use paper filter(s). The ContainMed code for this model is CM-10011.

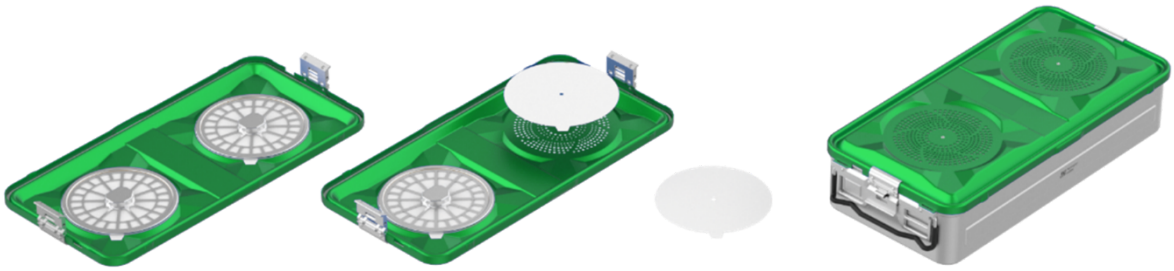


Table 5. SteriPod™ Bottoms and Lids

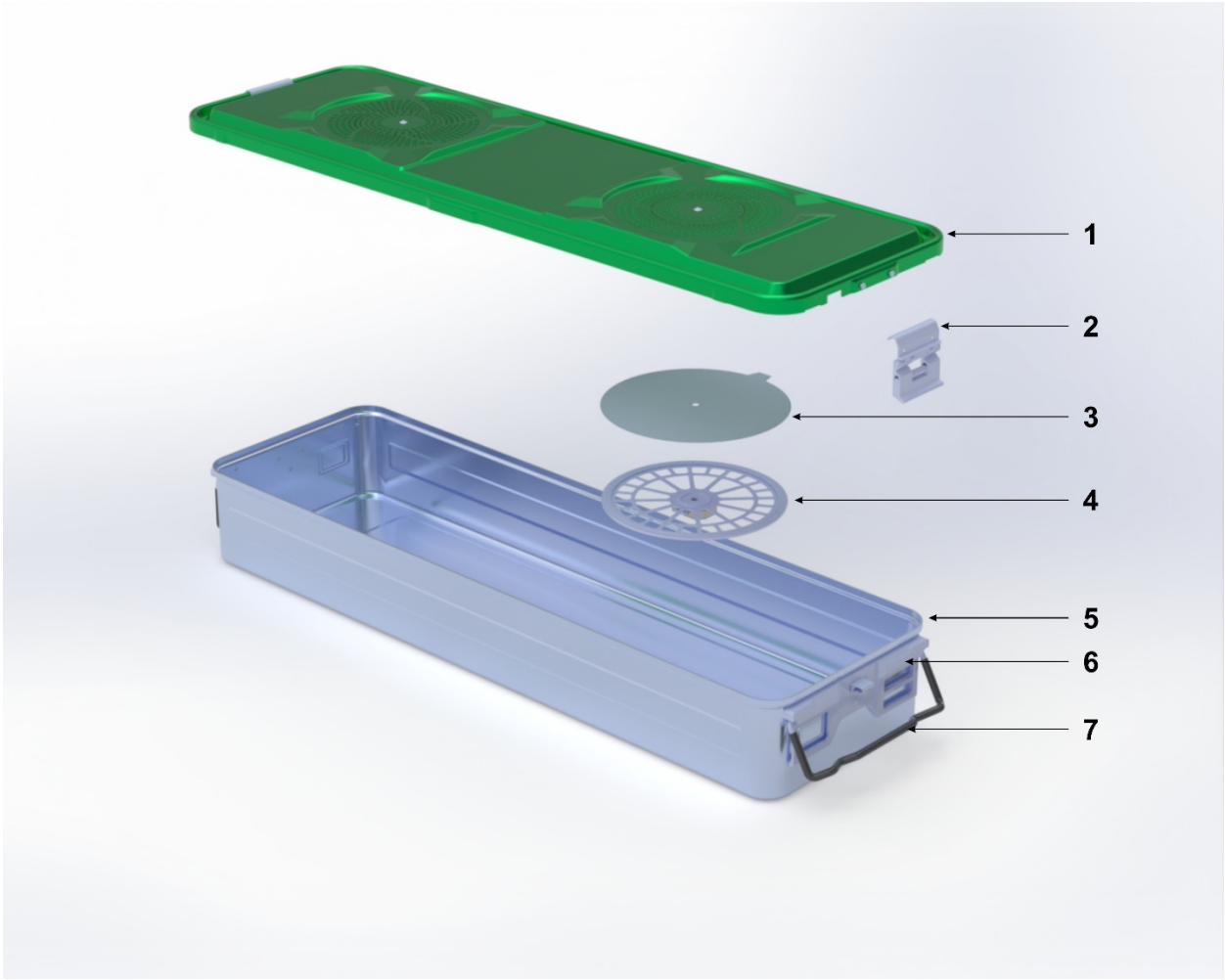
Sterilization Method	Container Size	Length x Width x Height (Inch)	Container Non-Perforated Bottom Part	Container Perforated Lid Part
	1/1 Full Size	23.66 x 10.71 x 9.25	CM-10011-100	CM-10011-500
	¾ Quarter Size	18.78 x 10.79 x 7.28	CM-10011-200	CM-10011-400
	Extra Long Size	32.28 x 9.92 x 4.49	CM-10011-300	CM-10011-600

2.2 ContainMed SteriPod™ Container Systems Accessories and Components

Below you can see the ContainMed SteriPod™ Container System Accessories:

- Paper Filters
- Filter Retainers
- Silicone Gaskets

Product components and accessories are described in more detail below:



Container Lid
Latching and Locking Mechanism
Paper Filter
Filter Retainer
Container Bottom
Container Faceplate
Handle

Table 6. Sterilization Container Systems Accessories and Components

No	Name	Category	Function
1	Container Lids	Component	Lids are used to maintain sterility after sterilization.
2	Latching and Locking Mechanism	Component	It is used to secure and lock the lid on the container, thereby ensuring the system is sealed.
3	Paper Filters	Single Use Accessory	Disposable paper filters provide effective protection by preventing the ingress of microorganisms into the sealed container after sterilization.
4	Filter Retainer	Component	It is used to secure the filter onto the container lid. In conjunction with the filter, it prevents the entry of microorganisms from the outside into the sealed container system.

No	Name	Category	Function
5	Container Bottoms	Component	Sterilization containers are designed for transport, and storage of sterilized medical products in a sterile condition for 180 days. The medical devices to be sterilized should be placed into the container bottom.
6	Container Faceplate	Component	The faceplate which is located on the front of the container is designed to place the paper labels used to identify the medical devices in the container.
7	Handle	Component	It is used to hold the container from the sides during transportation.

Table 7. ContainMed SteriPod™ Container Systems Configurations – Accessories

Accessory Group	Code	Dimensions (Inch)	Description
Paper Filter	CM-10011-851B	7.24 Dia.	Single Use Paper Filter - (100 Pcs)
Filter Retainer	CM-10011-850	7.32 Dia.	Filter Retainer for Disposable Round Paper Filter

Accessory Group	Code	Dimensions (Inch)	Description
3/4 Silicone Gasket	CM-10011-853	53.59	Silicone Gasket for 3/4 Lids
1/1 Silicone Gasket	CM-10011-852	63.43	Silicone Gasket for 1/1 Lids
Extra Long Silicone Gasket	CM-10011-854	72.91	Silicone Gasket for Extra Long Lids

3.0 ContainMed SteriPod™ Container Systems Service

Like all reusable medical products, ContainMed SteriPod™ Container Systems must pass the necessary checks before each use. You can find detailed information about these inspections in "Section 5. Inspection Prior to Use." These pre-use inspections are critical for the Container System to function optimally and to ensure and maintain sterility. ContainMed SteriPod™ Container Systems are Class II devices within the scope of FDA and have undergone detailed tests. Personnel who carry out cleaning, washing, inspection, loading and unloading of the ContainMed SteriPod™ Container Systems should be trained in using this manual as well as having experience and training in their fields.

Notes and Warnings:

- Before each use, these containers must be cleaned/washed, inspected, and loaded by trained personnel. You can find detailed information on how to do the cleaning process in "Section 4 Decontamination and Cleaning Process".
- In case the part replacement is performed by the customer, the personnel performing the process must be trained and authorized by ContainMed. Replacement parts must be obtained from ContainMed.
- The components and accessories should be replaced in case of wear, aging and/or damage. See Section "5. Inspection Prior to Use" for detailed information.

4.0 Decontamination and Cleaning Process

If the container system becomes soiled, it must be thoroughly cleaned. Sterilization containers should be rinsed promptly after use to prevent the hardening of intensive medical tissue and bloodstains. Follow facility's policies and procedures, as well as guidelines recommended by AAMI ST79, for the transportation of soiled instruments and containers. Always wear appropriate personal protective equipment (PPE) as per the healthcare facility and procedures when transporting and cleaning the System.

Containment methods should be accomplished by any means that prevents personnel from coming into contact with the contaminated items during transfer.

The choice of container type depends on the items being transported. Options include bins with lids, enclosed or covered carts, rigid sterilization container systems, and impermeable bags. These types of containers can be used alone or in combination to transport contaminated items.

OSHA requires that:
a) all containers, devices, or carts used for containing contaminated items be marked with a biohazard label, a red bag, or other means of identifying contaminated contents; and
b) puncture-resistant, leak-proof on the sides and bottom, closable, and labeled containers must be used for devices with edges or points capable of penetrating container or skin.
Contaminated items should be kept moist in the transport container by adding a towel moistened with water (not saline) or a pretreatment product specifically intended for this use, or by placing items inside a package that can maintain moist conditions.

Notes and Warnings:

- ContainMed SteriPod™ Container Systems are shipped cleaned, but not sterile. The Sterilization Container Systems should be cleaned in accordance with this IFU before first use.
- For containers lids that are not soiled and have been removed from the operating room before the patient entered, the facility should determine the best cleaning practice based on its established policy and procedures.
- The decontamination and cleaning conditions determined for ContainMed SteriPod™ Container Systems are deemed to be approved by the customer.
- The decontamination and cleaning processes of ContainMed SteriPod™ Containers should be carried out according to the guidelines contained in the IFU.
- Single use accessories specified in "Section 2.6 Use Life" must be discarded after each sterilization process.
- ContainMed SteriPod™ Container Systems should be cleaned before the sterilization process. See Section "4 Decontamination and Cleaning Process" for detailed information.
- The selection of the solutions to be used during the decontamination and washing process of ContainMed SteriPod™ Container Systems should be made according to the IFU. See Section "4.2 Detergent Solutions" for detailed information.
- Abrasive cleaners, pads and brushes SHOULD NOT be used. The usage of these abrasive materials can lead to the damage of the container system. The OEM is not responsible for any damage to the container system resulting from the use of abrasive materials.
- The use of these cleaning wipes must be determined and implemented by the facility in accordance with the AAMI ST79 standard. The OEM has not conducted any validation studies on the use of cleaning wipes.
- Containers and accessories which may not be used right away should be decontaminated and cleaned according to Section “4. Decontamination and Cleaning Process” prior to storage.
- Sterilization container systems should be stored in a dry and clean area. See Section "6.6 Container Storage and Transportation" for detailed information.
- After the decontamination and cleaning process, all the container components should be inspected for proper cleanliness and potential damage. Damaged components may prevent ContainMed SteriPod™ Container Systems from operating at full efficiency.
- All personnel involved in the decontamination and cleaning process must wear appropriate protective equipment.

NOTE—The burn threshold for contact duration of 10 minutes has been quantified at 48 °C (118 °F) (CENELEC 2007).

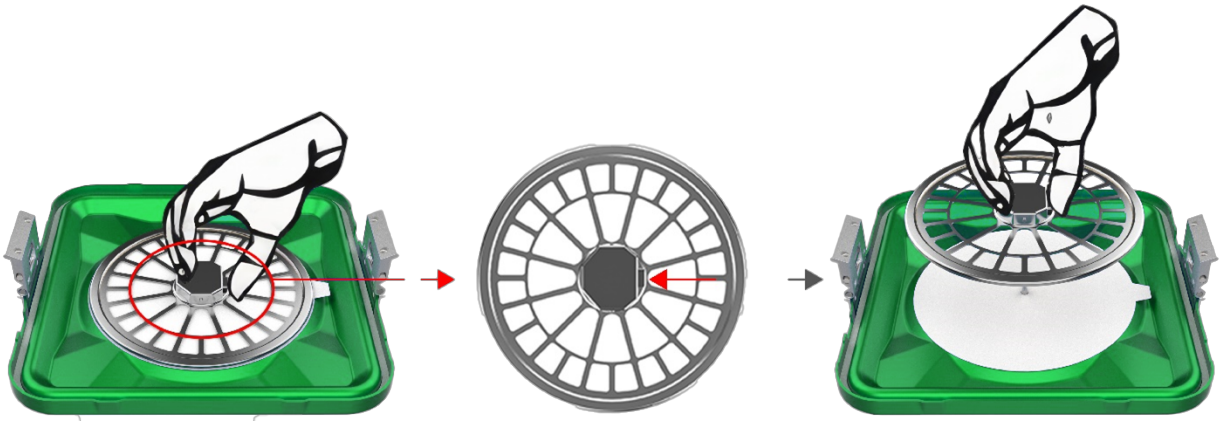
4.1 De-assembly of Components and Accessories Prior to Cleaning

All detachable parts must be removed before the cleaning and decontamination process. Disassembly of accessories prior to cleaning is critical for proper cleaning of both the container and accessories. Otherwise, the effectiveness of the cleaning process may be compromised. This process should be followed as described in this documentation. 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 the best cleaning practice based on its established policy and procedures.

- Before the decontamination and cleaning process, the detachable accessories on the bottom part of the container must be removed. This includes accessories such as the aluminum label, and paper label. Disposable accessories such as single use paper labels and security seals should be discarded.

- The lid is separated from the bottom of the container. As can be seen in the illustration below, this process is performed by simultaneously opening the locking mechanisms of the lid.

- The basket in the container and the medical devices in the basket should be removed.
- After removing the medical devices in the basket, silicone fixation systems, meshes, dividers, and similar basket accessories fixed to the basket should be detached from the basket. Otherwise, the effectiveness of the cleaning process may be compromised.
- Next step is the removal of the detachable parts on the lid. As can be seen in the illustration below, the filter retainer attached to the lid can be removed by pressing the latch on the filter retainer.



- After the filter retainer is removed from the lid, the disposable paper filter must be discarded.

4.2 Water Quality

The water quality used in the facility plays an important role in all stages of reprocessing medical devices, including the decontamination and cleaning phase. The facility should monitor the quality of the water used during these stages. Please refer to the AAMI TIR34 standard to learn more about the different water qualities and areas of use.

Notes and Warnings:

- The anodized coating on the containers, which provides both corrosion resistance and antiseptic properties, can be damaged over time if the water type recommended in this document is not used.
- For the final rinse of the sterilization containers, the critical water described in 4.2.2 must be used.

4.2.1 Utility Water

AAMI TIR34 defines utility water as "water that comes from the tap that may require further treatment" This type of water can be used for flushing, washing, and rinsing. For more detailed information, please refer to the AAMI TIR34 standard.

4.2.2 Critical Water

AAMI TIR34 defines critical water as "water that is extensively treated to ensure microorganisms, inorganic, and organic materials are removed". This type of water should be used for the final rinse or steam generation. For more detailed information, please refer to the AAMI TIR34 standard.

4.3 Detergent Solutions

For optimum cleaning of container systems, the pH range of the water and detergent solution should be between 6.5-8.5. Solutions outside the 6.5-8.5 pH range may damage the container and its components.

Notes and Warnings:

- Container systems may be damaged if utility water, which has a high alkaline value, is used in mechanical washers. Critical water must be used for the final rinse.
- High pH alkaline cleaning solutions can leave a white residue on containers. In such cases, the pH value of the solution used should be checked and adjusted if it is outside the specified range.
- Avoid using alkaline, caustic, and acidic solvents and solutions. Utilizing such solutions and solvents can cause permanent surface damage to the containers and the product will no longer be under warranty.

4.4 Decontamination and Mechanical Cleaning

All personnel involved in the decontamination and cleaning process must wear appropriate protective equipment. The decontamination and cleaning stages of ContainMed SteriPod™ Container Systems for mechanical washing are as follows:

1. Rinse visible debris and residues off the filter retainer and the lid.
   The filter retainer is placed separately from the mechanical washer.
2. Rinse visible debris and residues off the container bottom and all components especially recessed and/or grooved accessories and parts such as the locking mechanism, faceplate openings and filter retainer. Ensure no visible debris and residues remain before cleaning.
   When rinsing avoid using any abrasive products.
3. Place the container and components to be washed in the mechanical washer.
   a) Ensure that the inserted parts are placed face down to avoid water accumulation in the parts.
   b) Sensitive parts such as filter retainers when placed separately, should be positioned in such a way that they are not directly exposed to the pressurized water from the mechanical washer.
4. Use critical water for final rinse as described in Section 4.2.
5. After the final rinse, ensure that no residue is left on the container system and its components.
6. After the mechanical washing phase, ensure that the container and its components are properly dried.
   a) Thoroughly dry either with a soft, dry cloth or air dry.

Notes and Warnings:

- After the cleaning process, a visual inspection of the container and all components should be performed., If the desired level of cleanliness is not achieved, repeat the process.
- Do not use alkaline, caustic, and acidic solvent and solutions. The use of such solutions and solvents can cause permanent surface damage on the containers and void the product’s warranty.
- Apply the detergents in accordance with the manufacturer’s instructions. Refer to Section 4.3 or AAMI ST79 standard for detailed information.
- Thorough rinsing is crucial for the removal of detergent and other residues. Hidden surfaces and crevices can make thorough cleaning difficult. Residual organic matter can significantly reduce the effectiveness of the decontamination process. Damaged components of container systems could interfere with the sterilization process or cause contamination of the contents.

4.5 Decontamination and Manual Cleaning

All personnel involved in the decontamination and cleaning process must wear appropriate protective equipment. All personnel assigned to perform manual cleaning must be trained and competent. The equipment, water supply and other resources necessary for the cleaning process should be provided and monitored by the facility.

The following steps outline the decontamination and cleaning stages of ContainMed SteriPod™ Container Systems for manual washing:

1. Rinse visible debris and residues on the filter retainer and the lid.
2. The filter retainer should be cleaned separately.
3. Rinse visible debris and residues on the container bottom.
   a) When rinsing avoid using any abrasive products.
4. When washing the container manually:
   a) Immerse the container and its components in the appropriate detergent solution and allow it to soak for at least 5 minutes. Please refer to Section 4.3 to select suitable detergents.
   b) Scrub the container with a non- abrasive product until it reaches the desired level of cleanliness.
   c) DO NOT use any abrasive products while scrubbing the container and its components. The usage of abrasive products can lead to the damage of the container system.
5. Use critical water for the final rinse as described in Section 4.2.
6. After the final rinse, ensure that no residue remains on the container system and its components.
7. After the manual washing phase, ensure that the container and its components are properly dried.
   a) When drying avoid using any abrasive products.

Notes and Warnings:

- After the cleaning process, a visual inspection of the container and all components should be performed. If the desired level of cleanliness is not achieved, repeat the process.
- Do not use alkaline, caustic, and acidic solvent and solutions. The use of such solutions and solvents can cause permanent surface damage on the containers and void the product's warranty.
- If the products are too large to be immersed, refer to the AAMI ST79 standard for alternative cleaning methods.
- Only apply the detergents in accordance with the manufacturer's instructions. Refer to Section 4.3 or AAMI ST79 standard for detailed information.
- The use of cleaning wipes should be determined by the facility in accordance with the AAMI ST79 standard. The OEM has not conducted validation studies on the use of cleaning wipes.
- Thorough rinsing is crucial for the removal of detergent and other residues. Hidden surfaces and crevices can make thorough cleaning difficult. Residual organic matter can significantly reduce the effectiveness of the decontamination process. Damaged components of container systems could interfere with the sterilization process or cause contamination of the contents.

5.0 ContainMed SteriPod™ Container System Inspection Criteria

ContainMed SteriPod™ Container Systems must be inspected after each cleaning process and before each use. Containers should not be used if any of the conditions mentioned in this section of the IFU are detected. In these cases, please contact an authorized ContainMed representative. Be aware if any service other than ContainMed is used, the warranty for the product will be void. For detailed information about ContainMed SteriPod™ Container Systems Service, see Section 3.

5.1 First Use Inspection

Upon receipt, All ContainMed SteriPod™ Container Systems should be inspected in detail by the customer. The recipient must perform the following controls:

- In case of any tear, cut, warping and similar damage on the Container Systems, please contact a ContainMed authorized representative.
- Ensure that there are no warps, tears, cracks, or any problems with the anodized coating on the bottoms and/or lids.
- Ensure all gaskets are not torn, broken, or cut. Verify that the gaskets are fully seated on the surface they are fixed to, with no gaps in between. See Sections 5.2.1 and 5.2.3 for detailed

information.

- Ensure that the filters completely cover the relevant perforations and are not torn or damaged. Otherwise, sterilization will be compromised.
- Make sure that the filter retainer is fully seated on the filter retainer pin and the gaskets of the filter retainer are intact. See Section 5.2.3 for detailed information.
- Ensure that the locking mechanism secures the lid completely and that the lid is fully seated on the bottom. See Section 5.2.2 for detailed information.
- Ensure that there is no deformation, rust, and similar damage on all parts such as rivets, screws and nuts used in Container Systems. If any damage is discovered, please contact a ContainMed authorized representative.
- Clean the Sterilization Container Systems in accordance with this IFU before first use.

5.2 Inspection Prior to Use

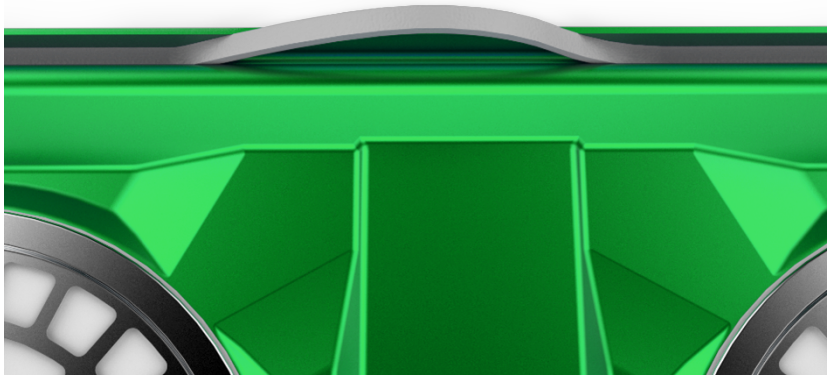
Prior to each use, the inspections should be carried out are given below:

- Ensure that there are no warps, tears, cracks or any problems with the anodized coating or similar damages on the bottoms and/or lids.
- Ensure that all gaskets are not torn, broken, or cut. Verify that the gaskets are fully seated on the surface they are fixed to and with no gaps in between. See Sections 5.2.1 and 5.2.3 for detailed information.
- Ensure that the filters completely cover the relevant perforations and are not torn or damaged. Otherwise, sterilization will be compromised.
- Make sure that the filter retainer is fully seated on the filter retainer pin and the gaskets of the filter retainer are intact. See Section 5.2.3 for detailed information.
- Ensure that the locking mechanism secures the lid completely and that the lid is fully seated on the bottom. See Section 5.2.2 for detailed information.
- Ensure that there is no deformation, rust, and similar damage on all parts such as rivets, screws and nuts used in Container Systems. If any damage are discovered, please contact a ContainMed authorized representative.

5.2.1 Lid Gaskets Seal Inspection

The silicone gasket at the bottom-lid contact point plays a critical role in both achieving sterilization and maintaining it. This silicone gasket seals the sterilization container system and completely prevents the penetration of microorganisms at these points. Therefor the lid gaskets must be checked before each use. The inspection steps of the lid gasket are given below:

1. First, remove the lid from the container bottom as described in Section 4.1.
2. Visually inspect the silicone gasket at the bottom-lid contact point by turning the lid upside down.



3. Ensure that the lid gasket is not torn, broken, or cut. Checked that the gasket is fully seated on the surface and that there are no gaps.

4. If the above conditions or any other problem that may affect the sterilization are observed in the silicone gasket, it must be replaced. This subject is explained in detail in Section 5.2.1.1.

5.2.1.1 Changing the Lid Gasket

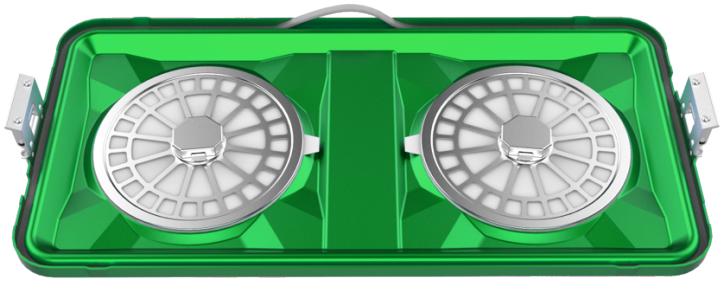
If the lid gasket replacement is deemed necessary based on the observations, the following steps should be applied:

1. First, select the appropriate silicone gasket size. Refer to the table below, to determine the suitable gasket cut size for the lid. The designated gasket must be obtained from ContainMed.

Table 8 Lid Gasket Dimensions

Container / Gasket Size	Silicone Gasket Code	Dimension (cm)	Dimension (Inc)
3/4 Silicone Gasket	CM-10011-853	136 cm	53.59
1/1 Silicone Gasket	CM-10011-852	161 cm	63.43
Extra Long Silicone Gask	CM-10011-854	185 cm	72.91

2. Pour a small amount of acetone into the seal groove and allow it to sit for 3-5 minutes. Find the place where the gasket ends meet and start removing the gasket from there. If you are having difficulty removing the gasket, increase the waiting time after pouring a little more acetone.



3. After removing the damaged silicone gasket with the help of acetone, clean the gasket channel with alcohol. Make sure that there is no silicone residue remaining.
4. Apply the adhesive silicone into the gasket channel with a pneumatic silicone gun. Before application, make sure that the gasket channel is completely clean and dry.
5. Position the selected silicone gasket from the first step on the adhesive silicone.
6. Press the gasket down to ensure that it is seated properly.
7. Allow the lid to dry for 12 hours.

Notes and Warnings:

- Before performing any maintenance, repairs, or service, ensure the products are thoroughly cleaned. Detailed information on the cleaning process can be found in “Section 4 Decontamination and Cleaning Process”.
- Repair and maintenance performed by the customer must be done by personnel trained and authorized by ContainMed. Replacement parts must be obtained from ContainMed.

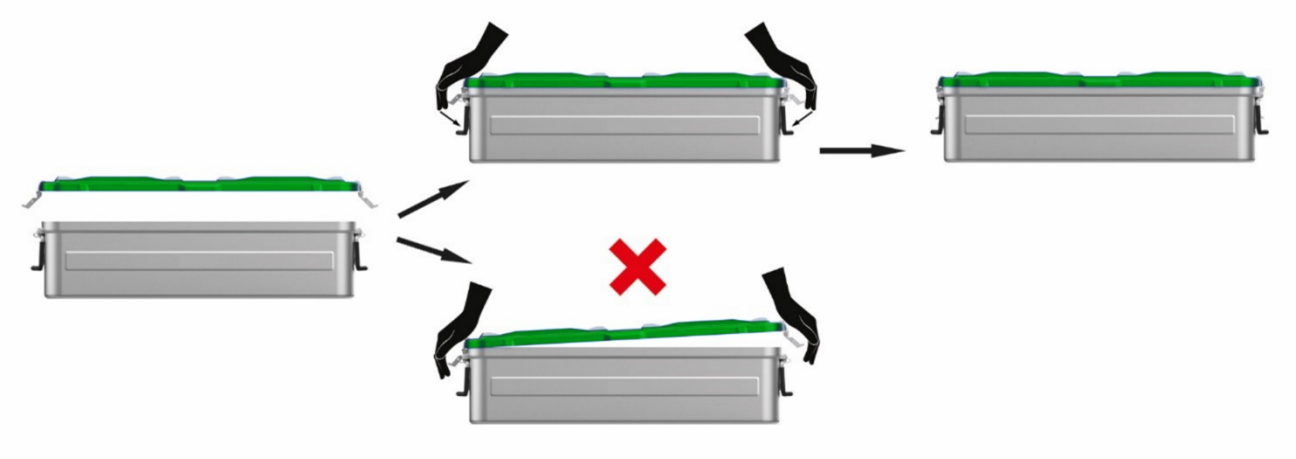
Make sure that the gasket is fully seated in the channel and that there is no gap in between.

5.2.2 Locking System Inspection

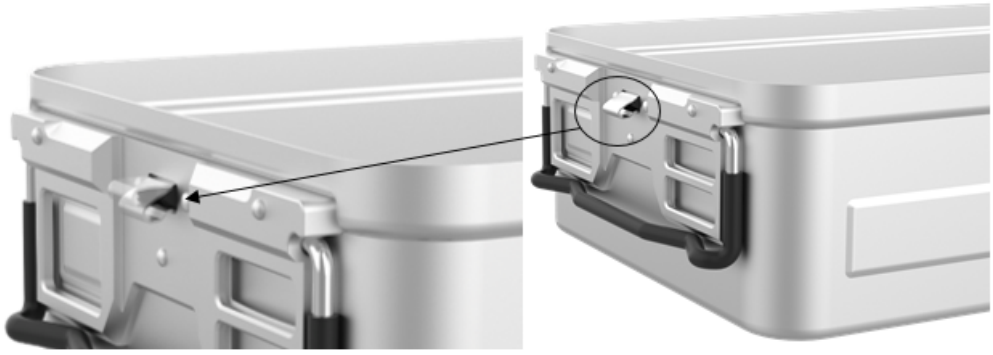
For the sterilization container system to function correctly, the lid must be securely seated and locked on the bottom. Otherwise, sterilization conditions will not be met, and the process will fail. Follow the steps to control the lock mechanism:

1. Inspect the locking mechanism prior to each use.
2. First, check the lock latch located in the middle of the faceplate. Ensure it is not excessively bent or broken.
3. Next, examine the locking mechanism located at the sides of the lid. The locking mechanism should be able to move freely up and down and show no signs of damage.
4. Once it is confirmed that there is no damage to the lock latch and/or the locking mechanism, place the lid onto the bottom and lock the system.

As shown in the illustration below, perform this process by simultaneously closing the locking mechanisms of the lid.



5. After the lid is locked to the bottom part, it should be secure, with no noticeable movement.
6. If the movement is to an unacceptable degree, adjustment needs to be made.
   a) Before making any adjustment, the container lid must be removed.
   b) If there is a level of play when the container lid is attached to the bottom, slightly bend the locking tabs on both sides downwards and reinstall the lid.
   c) Repeat this process until the lids are securely locked onto the bottom.

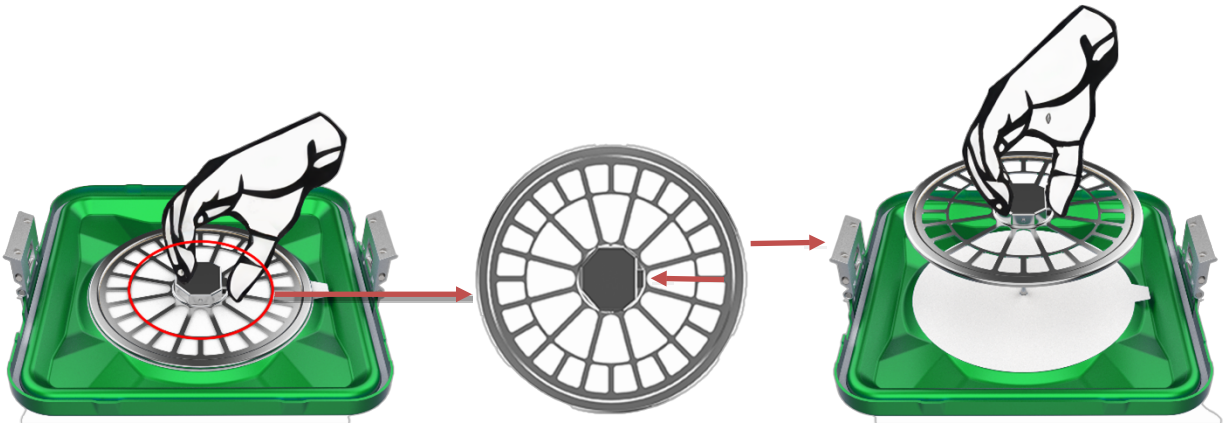


5.2.3 Filter Retainer Inspection

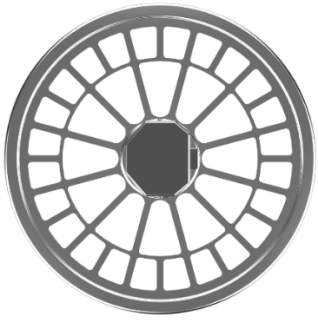
The filter retainer plays a crucial part in the sterilization process. If the filter retainer cannot fulfill its duty, the filter will not fit properly, and sterilization will be compromised. Therefore, the filter retainer must be checked before each use. Follow the steps below when inspecting the filter retainer:

1. To examine the filter retainer, it must first be separated from the lid. As shown in

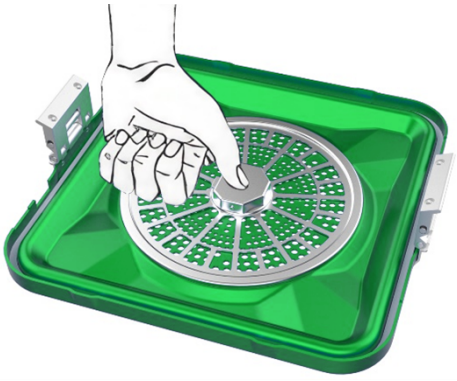
the illustration below, the filter retainer can be removed from the lid by pressing the latch on the filter retainer



2. Inspect the filter retainer for any visible damage such as rust, deformation or bending.
3. Turn the filter retainer upside down to ensure there are no tears, cuts, or similar damage on the silicone gaskets under it.



4. Finally, examine the filter retainer pin on the lid. In case of any loosening and bending of the filter retainer pin, the pin may not be able to fulfill its duty.
5. If any of the above situations is encountered, please contact a ContainMed authorized representative. The filter retainer should be replaced.
6. After confirming that the filter retainer is free from damage, place the filter retainer onto the filter retainer pin.



7. Try to rotate the filter retainer by hand. If the filter retainer does not rotate, this confirms that the mechanism is properly seated.

5.2.4 Basket Inspection Criteria

Baskets are used for the grouping of medical equipment, and they facilitate the set-up, washing, and sterilization. It is also used for the convenience of placing/removing the medical equipment from the container.

The baskets should be inspected prior to each use. Follow the steps below when inspecting the baskets:

1. Remove the basket from the container.
2. Ensure the basket does not have any dents, cracks, or breakage.
3. If the basket has stands, ensure they are not loose.
4. If the basket stands are damaged, please contact a ContainMed authorized representative.

5.2.5 Filter Inspection

Disposable paper filters provide effective protection by preventing microorganisms from entering the sealed container after sterilization. Therefore the filter must be inspected prior to each use. Followed the steps below when inspecting the filters:

1. After removing the filter retainer, discard the used single-use filter.
2. When placing a new filter, make sure that the filter has no holes, tears, or similar damage. If the filters are torn or damaged, sterilization will be compromised.
3. If such damage is detected, DO NOT use the filter, and discard it immediately.
4. Ensure that the filters completely cover the relevant perforations and are not torn.
5. If the filter does not completely cover the perforations, the container systems will not be able to maintain sterilization.
6. If the filters have no damage and completely cover the perforations, place the filter onto the inside of the lid.
7. After ensuring that the filter retainer is undamaged, place it onto the filter retainer pin and press your finger on the latch mechanism which is located in the middle of the filter retainer, until you hear the “click” sound.

Notes and Warnings:

- Removing and inserting the filter retainer harshly may damage the filter retainer pin.

6.0 Preparation and Assembly of ContainMed SteriPod™ Container System

Before reassembling ContainMed SteriPod™ Container Systems, the containers and their components must be inspected as described in Section 5. Refer to Section 5 for detailed information. Before the assembly, ensure that all the container components are completely dry.

Container bottoms should only be paired with lids specifically designed for that model. For detailed information about which bottoms and lids are compatible with which models, see Section 2. Refer to Section 7.2 to determine the correct bottom, lid, filter, filter holder and paper label to be used for the selected model.

Notes and Warnings:

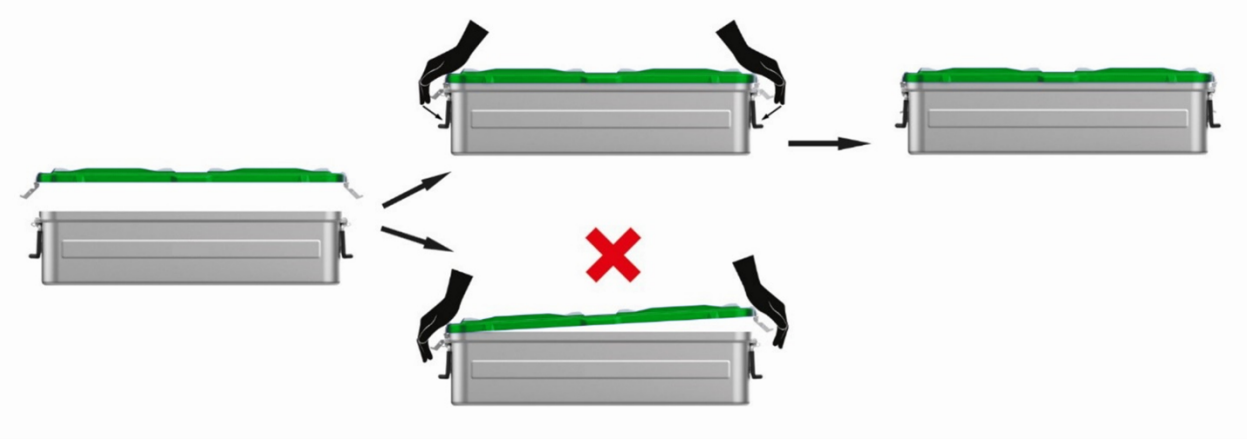
- Only OEM branded filters, filter retainers, paper labels and accessories should be used with ContainMed SteriPod™ Systems, otherwise the OEM cannot guarantee optimal efficiency.
- OEM container bottoms should not be paired with the lids of other brands.
- OEM filters are designed only for OEM Containers. They should not be used with other brands.

6.1 ContainMed SteriPod™ Container System Assembly

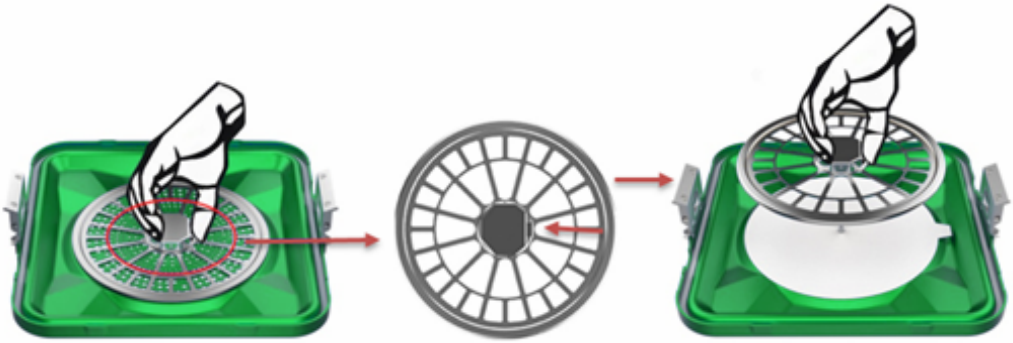
Before the assembly of ContainMed SteriPod™ Container Systems, the containers and their components must be thoroughly inspected. Refer to Section 5 for detailed information. Before the assembly, it is crucial to ensure that all the container components are completely dry. Follow the

steps below when assembling the ContainMed SteriPod™ Container Systems:

1. Ensure that the container bottoms are paired only with lids specifically designed for that model. See Section 7.2 to determine the correct bottom, lid, filter, filter holder and paper label to be used for the selected model.
2. Place the selected lid onto the appropriate bottom and secure the system by simultaneously closing the locking mechanisms of the lid.



3. Before installing the filter, remove the filter retainer. As shown in the figure below, the filter retainer attached to the lid can be removed by pressing the latch on the filter retainer



4. Place the selected filter over the perforated area. Refer to Table 14. Filters for Perforated Bottoms and Lids to find the appropriate filter. It is crucial to inspect the filter for holes, tears, or similar damages. Please refer to Section 5.2.4 for detailed information.
5. Place the filter retainer onto the filter retainer pin.

Notes and Warnings:

- Single use paper filters are not compatible with low temperature sterilizers.

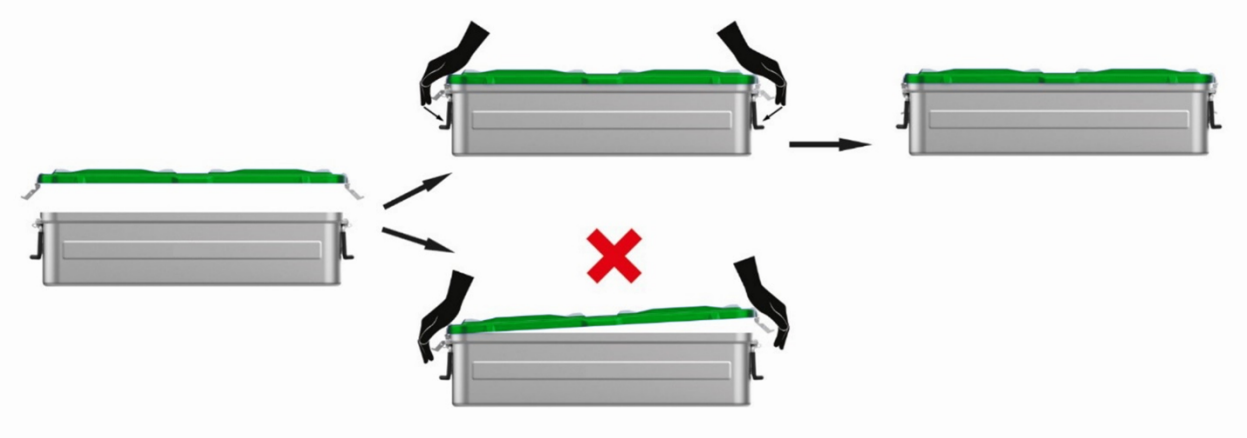
6.2 Assembly of Surgical Instrumentation

The medical devices and instruments to be placed into the container must be completely dry. The instruments should be sorted, cleaned, and assembled according to the hospital procedures and manufacturer's Instruction for Use (IFU).

6.3 Loading of Basket and/or Tray

The ContainMed SteriPod™ Container System can be used with a variety of baskets, trays, and platforms. The instruments to be placed into the basket should meet the following requirements:

1. The instruments must fit into the basket and container. There should be a gap of at least 2 inches between the lid and the load.
2. Otherwise, the perforations of the lid will be blocked, and the sterilization will fail. If the container perforations are closed, airflow during sterilization will be prevented and the container may be deformed under vacuum.
3. The instruments must be arranged in a way that allows for aseptic removal in the operation room.
4. The total weight of the container should not exceed the following limits: for Full and Three Quarter Size: 25 lbs., for Half Size 15 lbs. These limits comply with the AAMI ST79 Standard.
5. The instruments, which should be assembled according to the instrument manufacturers' Instructions for Use (IFU), are placed into the basket, lifting platform or tray.
6. After the baskets are placed into the appropriate bottom, the system is sealed by simultaneously closing the locking mechanisms of the lid.



Notes and Warnings:

- If the container perforations are closed, airflow during sterilization will be prevented and the container may be deformed.
- The medical devices and instruments must be arranged in accordance with the instrument manufacturers' Instruction for Use (IFU).
- Hospitals should adhere to the guidelines and weight limits as per AAMI and industry guidelines as well as the Instruction for Use (IFU).
- Baskets with stands can be used to reduce scratching and damage to the baskets.
- The ContainMed SteriPod™ Container System's Pre-Vac Steam validation studies were performed with a silicone mesh and a non -linting surgical towel placed under the instruments to model a "worst case" scenario. As per ANSI/AAMI ST79, "non-linting absorbent material may be placed in the tray to facilitate drying. It is important that the absorbent material does not produce lint, as lint can carry microorganisms to the surgical site as well as cause foreign-body reactions.

6.4 Chemical Process Indicators (CI)

6.4.1 Internal Chemical Indicators

One or more internal chemical indicators (FDA cleared only) should be placed within each package, tray, or rigid container. These indicators can be any type (Type 3, 4, 5, or 6) but preferably a Type 5 or Type 6 indicator as they provide more information on the critical steam sterilization parameters. All indicators should be used for the cycle(s) they are labeled for and in accordance with the manufacturer's written IFU.

Internal chemical indicators should be placed.
a. in such a way that one is visible to the person opening the package.
b. in the area or areas considered least accessible to steam penetration; and
c. in accordance with all applicable written IFU.

For further detailed information such as the placement, descriptions, and usage, refer to the AAMI ST79 Standard.

6.4.2 External Chemical Indicators

The AAMI ST79 Standard defines the purpose of the external process indicators as follows: "…an external process indicator (Type 1 CI) is to differentiate between processed and unprocessed items, not to establish whether the parameters for adequate sterilization were met."
The external CI should visually denote that the package has been exposed to a steam sterilization process. A user knowledgeable about the performance characteristics of the CI being used should examine the indicator after sterilization and before use of the item to verify that the item has been processed. If the color of the indicator has changed, this signifies that the system has reached the viable temperature for sterilization.
For further detailed information such as the descriptions and usage, refer to the AAMI ST79 Standard.

Notes and Warnings:
- The OEM does not validate containers with paper count sheets containing ink. It is the responsibility of the users to process count sheets.
- The external indicators should be stored in a cool, dry place and away from chemicals and direct sunlight.
- Do not use the external indicators if it has changed color before being processed.

6.5 Biological Process Indicators (BI)

Biological indicators (FDA cleared only) are the only sterilization process monitoring devices that provide a direct measure of the lethality of the process. Various types of BIs are available, each with different response characteristics and incubation requirements. To provide useful information about the lethality of the sterilization process, the appropriate BI must be chosen for the steam sterilization cycle being run and used correctly (in accordance with the manufacturer's written IFU).

Notes and Warnings:
- All BIs should be used in accordance with the BI manufacturer's written IFU.
- Health care personnel should select BIs that consist of spores of Geobacillus stearothermophilus, that comply with ANSI/AAMI/ISO 11138-3, and suitable for use in the specific sterilization cycle (see the written IFU of the BI manufacturer and the sterilizer manufacturer).
- For further detailed information such as the placement, descriptions, and usage, refer to the AAMI ST79 Standard.

6.6 Security Seals and Auto-Lock Mechanism

Medical devices and instruments inside sterilization containers remain sterile for up to 180 days if the lid remains unopened after sterilization. Security seals are accessories used to determine whether the container has been opened after sterilization.

Security seals are used to identify that the container, which should be locked before sterilization, remains unopened after sterilization by attaching it to the locking latch on both side of the container, and ensure the sterility of the medical device inside the container is not compromised. The security seals and auto-lock mechanism can be attached to all ContainMed SteriPod™

Container Models.

Notes and Warnings:

- The security seals should be stored in a cool, dry place and away from chemicals and direct sunlight.

6.7 Container Storage and Transportation

When placing ContainMed SteriPod™ Containers in the sterilizer, each container should not exceed the following weights: Full and Three Quarter Size: 25 lbs., Half Size: 15 lbs. Consult the rack manufacturer's IFU for guidance regarding the weight capacity of the racks on which the containers will be placed. For more information on weight considerations, refer to the AAMI ST79 and ASHRAE guidelines.

ContainMed SteriPod™ Containers can maintain the sterility of medical devices and instruments for 180 days after successful sterilization.

Sterilization containers containing sterile medical equipment should be stored in a clean, dry, and protected area. The deterioration of sterility is generally not solely based on time, but also on the transportation, storage, and handling of the container. Therefore, there is no comprehensive statement on storage times. Refer ISO 11607 -1, ANSI/AAMI ST79 for more details. The facility using the sterilization container should establish its own procedures regarding this.

Notes and Warnings:

- Sterile items, including those packaged in rigid sterilization container systems, should not be stored next to or under sinks, under exposed water or sewer pipes, or in any location where they could become wet.
- Storage period studies of ContainMed SteriPod™ Containers given in Table 10 were carried out in accordance with AAMI ST79 and ASHRAE standards.
- Refer to the AAMI ST79 guideline for transportation of the sterilization container systems.

7.0 ContainMed SteriPod™ Container System Sterilizer Cycle Parameters and Components

This section provides the configurations for paper filter, paper label and filter retainer for steam sterilization. The OEM has carried out validation studies for these configurations.

Each container bottom must only be paired with the specific lid designed for that model of container, and it should not be combined with other OEM or non-OEMproducts. For more information about ContainMed SteriPod™ Containers and bottom-lid configurations, see Section 2.

In cases where the medical device manufacturer's IFU and ContainMed IFU do not coincide, please refer to the AAMI ST79 standard.

7.1 Steam Sterilization Cycle Parameters

Table 10. OEM Accessories Compatible with Steam Sterilization Modalities

Accessories	Pre-Vac Steam
Paper Labels	Yes
Aluminum Identification Labels	Yes
Security Seals	Yes
Paper Filters	Yes
Filter Retainers	Yes
Silicone meshs	Yes
Silicone Mesh Mats	Yes
Silicone Gaskets	Yes
Silicone Fixation Systems	Yes
Holders	Yes
Dividers	Yes

Baskets	Yes
Safety Lid	No
Identification Label with or without Clip	Yes

7.1.1 Pre-Vac Steam Sterilization Cycle Parameters

- Sterilization Exposure Duration: 270°F/132°C for 4 minutes
- Minimum Drying Duration: 30 Minutes

Notes and Warnings:

- The given drying duration are the minimum requirements: The actual necessary drying duration may be longer, depending on the sterilizer properties, the medical instrument being sterilized, load density and water/steam quality.
- The sterilization exposure duration may vary in accordance with the load size.

7.2 Steam Sterilization Component and Accessories

This section provides the configurations for paper filter, paper label and filter retainer for steam sterilization. The OEM has carried out the validation studies of the given configurations.

7.2.1 SteriPod™ Container Systems – Validated Steam Sterilization Component and Accessories

Table 11. Validated SteriPod™ Components and Accessories for Steam Sterilization

Size	CM-10011 Model Bottoms	CM-10011 Model Lids	Accessories	Pre-Vac Steam Sterilization
1/1 Full Size	CM-10011-100	CM-10011-500	Paper Filter	CM-10011-851B
			Filter Retainer	CM-10011-850
3/4 Quarter Size	CM-10011-200	CM-10011-400	Paper Filter	CM-10011-851B
			Filter Retainer	CM-10011-850
Extra Long Size	CM-10011-300	CM-10011-600	Paper Filter	CM-10011-851B
			Filter Retainer	CM-10011-850

8.0 Aseptic Presentation

Hospital procedures and AORN guidelines should always be followed when handling the ContainMed SteriPod™ Container System. The recommended steps for aseptic presentation of an ContainMed SteriPod™ Container System containing a sterile medical device or instrument are as follows:

1. Non-scrubbed personnel should place the sterilization container on a separate, dry, flat surface at or slightly above the sterile field level.
2. Non-scrubbed personnel should visually inspect the sterilization container. There should be no damage to the external indicators located outside the container. Care must be taken to preserve the physical integrity of the container.
    a. External chemical indicators must show a color change after sterilization. Refer Section 6 for more detailed information.
    b. The security seal must remain intact. Refer Section 6.6 for more detailed information.
3. Non-scrubbed people should break safety seals by simultaneously opening the locking mechanisms. Before removing the lid, all broken pieces of the seals should be removed.
4. Non-scrubbed person should remove the lid from the bottom of the container by simultaneously opening the locking mechanisms of the lid. Non-scrubbed person removes the lid by holding on the locking mechanism, then puts the lid on the flat surface by filter retainer facing upwards.
5. Non-scrubbed person should inspect the filter for holes, tears, or other damage that could compromise by removing the filter retainer and conducting an examination. After confirming that there is no damage to the filter, the single use filter should be discarded, and the filter retainer(s) should be mounted again to the container lid.

6. Non-scrubbed person and/or scrubbed person should inspect internal indicator(s)
7. Scrubbed personnel should carefully remove the sterile medical device or instruments in the sterilization container together with the basket.
8. After completing all the checks, the scrubbed personnel can carry the sterile equipment by grasping both handles and lifting the tray/basket to the sterile area, ready for use in the operating room.

Notes and Warnings:

- Before the instruments are placed on the sterile field, the inside surface of the container should be inspected for debris, contamination, or damage as per AAMI ST79.
- Hospital procedures and AORN guidelines should always be followed when using and presenting the ContainMed SteriPod™ Container System.
- All personnel involved in the aseptic presentation must be adequately trained and competent in their roles.
- The components and accessories should be replaced in case of wear, age and/or damage. See Section "5. Inspection Prior to Use" for detailed information.
- After sterilization, the filter may exhibit a wavy appearance due to moisture. However, as long as the filter is secured in place by the filter retainer and has no holes, tears, or other damage and covers all the perforations, the sterilization will not be compromised.
- Refer to the table below when choosing sterilization modalities.
- All information and steps outlined in this IFU must be followed.

Table 12. Filters for Sterilization Modalities.

Filter Type	Model	ContainMed Code	Pre-Vac Steam
Paper Filter	CM-10011	CM-10011-851B	Yes

8.1 ContainMed SteriPod™ Container System Transportation to Decontamination

In case the container system becomes soiled, they must be thoroughly cleaned. Follow facility's policies, procedures, and AAMI ST79 recommended guidelines for the transportation of soiled instruments and containers.