V.Mueller™

Genesis™ Reusable Rigid Sterilization Container System Operator's Manual

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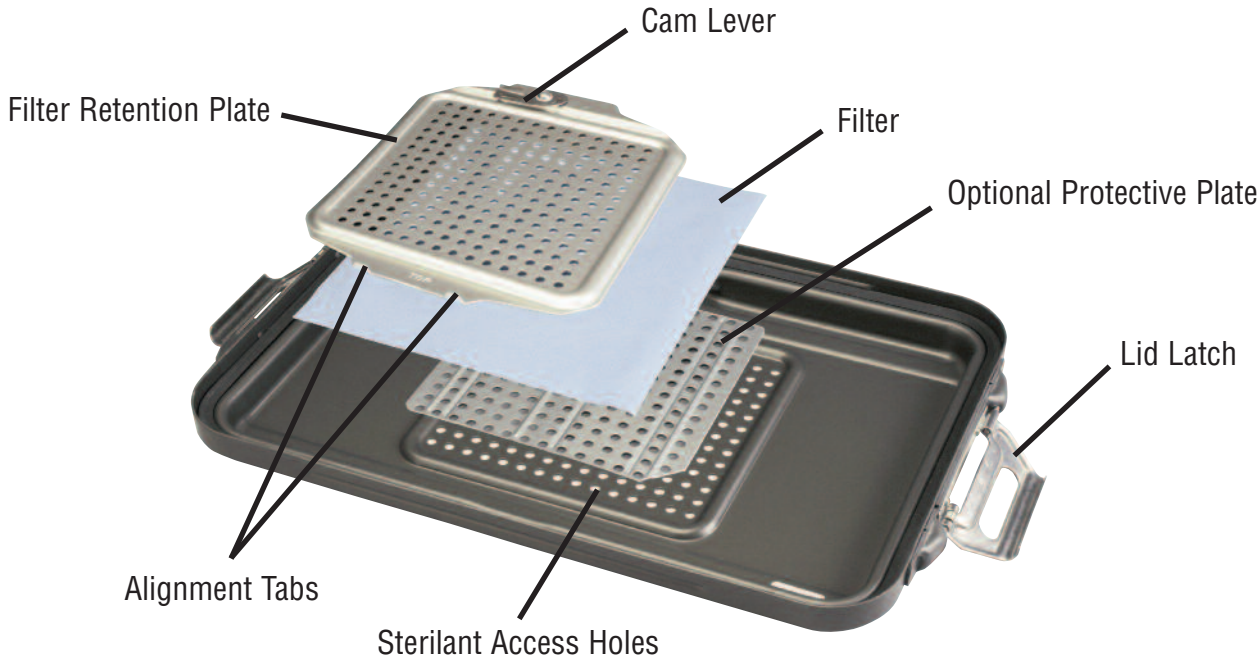
CF36-1778B • 2015-05

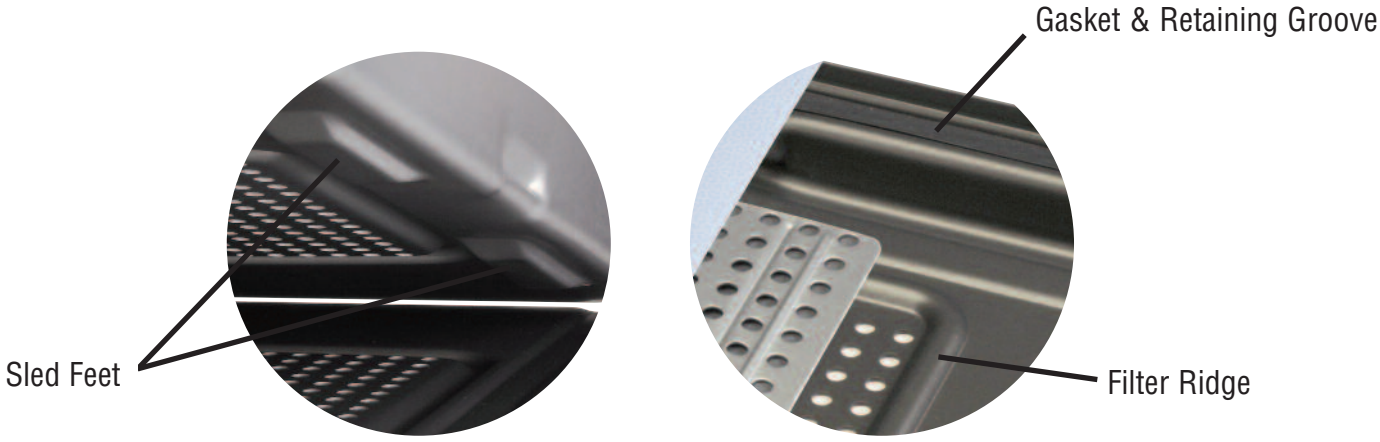
LATEX

Not made with natural rubber latex.

CareFusion

Container Component Breakdown





Instructions for Use

These instructions provide information on how to set up, use, troubleshoot, and maintain the Genesis reusable rigid sterilization container system. It does not cover service and repair procedures. For information about the product that is not covered in this document, contact your local sales representative or call customer service at 1-800-227-3220.

Intended Use

The Genesis reusable rigid sterilization container system is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used.

Baskets and accessory items are intended to organize and secure enclosed medical devices during sterilization, transport, and storage of the container.

Note: For detailed information regarding usage of specific containers, accessories, materials, weight limits, and supported sterilization challenges for indicated sterilization modalities, refer to the **Modality Specific Recommendations for Accessories and Containers** chart on pages 10-12.

Initial Receiving

Inspect, thoroughly clean, and rinse all reusable components (container, basket, and accessories) before placing into service. Not properly preparing your Genesis sterilization containers may adversely affect the protective anodized finish.

General Precautions

Cleaning

- Use only properly diluted, enzymatic / neutral pH detergent solution recommended for safe use on anodized aluminum. Use of highly acidic or highly alkaline detergents could permanently damage the protective finish of the container.
- Alcohol is not recommended for manual cleaning or wiping down. All cleaning agents should be thoroughly rinsed off prior to any sterilization process to remove all residual chemicals which could damage the protective anodized finish.
- Do not use abrasive cleaners, abrasive cleaning pads, or metal brushes on container surfaces. Use of these abrasive materials will permanently damage the protective anodized finish of the container.
- Do not clean the anodized container or container components (bottom, lid, retention plate, optional protective plate) in an ultrasonic washer.
- Ultrasonic cleaning (cavitation) processes may loosen threaded accessories such as pins, dividers, etc. Routine inspection of threaded accessories may require tightening to secure them after ultrasonic processing.

Processing

- Do not obstruct the sterilant access holes. These holes allow the exchange of air and penetration of sterilant into and out of the container. When these access holes are blocked it can impede this exchange process. Under pre-vacuum steam, this blockage can cause the container to collapse.
- Do not use adhesive tape on the container.
- The use of basket liners may cause condensate to pool.
- The DST series filter recommended for use with Genesis reusable rigid sterilization containers is for single use only. One filter sheet, or thickness, should be used underneath each retention plate per process. Using more than one thickness of the recommended filter (DST series) has not been validated for efficacy. Each sterilant access (perforated) area requires one filter.
- When sterilizing mixed loads, containers must be placed below absorbent, wrapped items on the autoclave cart to avoid excess condensation dripping onto wrapped goods below the container.
- Sterilize container and contents using hospital protocol. Since sterilizers vary in design and performance characteristics, it is strongly recommended that the user verify the cycle parameters for the specific sterilizer and types of instruments being sterilized prior to use.
- Always practice safe lifting and handling of heavy objects. Do not stack containers more than three (3) high in pre-vacuum sterilization cycles, per recommended dry time parameters. Stacking is only recommended in pre-vacuum steam cycles.
- Be sure to choose the correct data card material for the sterilization process used. Cellulose materials are compatible with steam and ethylene oxide (EO) processes. Cellulose materials are not compatible with the STERRAD processes.
  Steam/100% EO: MD1-1 cellulose data card.
  STERRAD 50 and 100S: MH1-1 non-cellulose data card.
- It is important that each facility verify the manufacturer's written sterilization instructions (Instructions for Use) to verify that the conditions in their particular facility (i.e. steam quality, equipment, protocols) achieve the same results as the manufacturer. If not, the container manufacturer, as well as the equipment manufacturer, should be consulted to identify potential causes and remedies.
- Only Genesis filters, arrows, data cards, baskets, accessories, and repair parts are validated for use with the Genesis reusable rigid sterilization container system. Do not use unauthorized single use accessories or container components.
- If using pre-vacuum steam immediate use steam sterilization (IUSS), container contents will be wet upon removal from the sterilizer.

Warnings

- Do not use filter materials in the presence of flammable anesthesia. A safety hazard may occur.

Cautions

- Complex instruments, such as air powered instruments, endoscopes or instruments with lumens or channels should be sterilized according to the instrument manufacturer's instructions.
- Only the following lumen devices have been validated for use in the pre-vacuum steam modalities:
  - ≥ 2.68 mm in inner diameter and ≤ 450 mm in length
  - ≥ 1.37 mm in inner diameter and ≤ 242 mm in length
- Lumen devices exceeding 400 mm in length or less than 3.0 mm in inner diameter have not been validated for use in the 100% Ethylene Oxide, STERRAD 50, or STERRAD 100S modalities.

- The stacking basket configuration has not been validated for use in the 100% Ethylene Oxide sterilization modality.
- A basket or lifting platform must always be used when sterilizing in a perforated bottom container model.
- The optional protective plate has not been validated for use in 100% Ethylene Oxide, STERRAD 50 or STERRAD 100S modalities.
- Solid bottom containers have not been validated for use in the 100% ethylene oxide modality.
- Containers have not been validated for stacking in STERRAD 50, STERRAD 100S, or 100% ethylene oxide modalities.
- Silicone mat devices have not been validated for use in 100% Ethylene Oxide, STERRAD 50 or STERRAD 100S modalities.
- Container models other than the Genesis STERRAD model containers have not been validated for use in the STERRAD modalities.
- Perforated container model number CD2-10BDL has not been validated for use in the 100% Ethylene Oxide Sterilization modality.
- Filter materials other than the Genesis DST series filters have not been validated for use with the Genesis sterilization containers.
- The optional protective plate has not been validated for use in the Genesis container bottom.
- Devices entailing surfaces that are completely obstructed (air-tight occluded challenges) have not been validated for use with the Genesis reusable rigid sterilization container system.
- Threaded connections that cannot be loosened prior to cleaning have not been validated for use with the Genesis reusable rigid sterilization container system.
- Materials other than metals, composites, and polymers have not been validated for use with the pre-vacuum steam sterilization modality.
- Materials other than stainless steel, aluminum, Radel, and silicone elastomers have not been validated for use with the 100% ethylene oxide sterilization modality.
- Materials other than stainless steel, aluminum, and silicone elastomers have not been validated for use with STERRAD 50 and STERRAD 100S modalities.
- Only container models designated as STERRAD compatible are indicated for use in the STERRAD 50 and 100S modalities. The STERRAD compatible reusable rigid container system can be identified by the following features: Pink (fuchsia) gasket in lid, light aluminum color on lid and bottom, pink (fuchsia) end plate with container description, pink (fuchsia) grips on the carrying handles, catalog numbers ending in ST, and pink (fuchsia) tamper evident arrows are all STERRAD compatible.
- The color anodized lids and standard dark gray lids have not been validated for use in the STERRAD 50 or 100S modalities.

Cooling

- Do not remove containers from the carrier until cool to touch or place warm containers on cold tabletops. Proper cool down is necessary to prevent wet sets or re-condensation from forming.
- Eliminate drastic temperature differences by keeping the containers away from cool ventilation ducts or cool drafts. Rapid cooling can cause recondensation to form resulting in wet sets.
- Do not place processed containers into the sterile storage area until they reach room temperature.

Returns

- Thoroughly clean and sterilize containers per these instructions for use before returning for service or repair. See Return/Repair Policy.

Recommended Sterilization Cycle Parameters

The following recommendations may include sterilization temperature/exposure parameters and maximum loads different than those which your institution commonly uses. Since individual sterilizers may perform differently it is important to conduct individual sterilizer testing of containerized instrument sets using biological and chemical indicators to verify exposure times and to determine adequate sterilizing parameters in your particular facility.

These recommendations represent specific validated settings, but are not inclusive of all possible combinations of settings and variables which could produce acceptable results. The recommendations below were generated to cover a worst case Genesis reusable rigid sterilization container with typical load contents. The end user is ultimately responsible for establishing and following protocols to ensure properly sterilized and dried sets.

Note: Total weight is defined as the total container system weight when fully assembled with baskets, instruments/devices, and organizing accessories. Refer to the **Modality Specific Recommendations for Accessories and Containers** chart on pages 10-12 for detailed information regarding modality specific use.

Sterilizers vary in design and performance characteristics. It is strongly recommended that the user verify the cycle parameters for the specific sterilizer prior to use. It is important to verify the parameters in conjunction with the sterilizer, load contents and any other processing accessories that may be used. Adjusted cycle times or dry times may be required to properly sterilize and dry desired loads.

Color anodized lids and standard dark gray lids have been approved for use using only the pre-vacuum steam, gravity-displacement steam, and 100% Ethylene Oxide sterilization modalities.

Specific Recommendations for Accessories and Containers

Pre-vacuum Steam Sterilization Cycle for all Perforated and Solid Bottom Containers

Exposure Temperature 270ºF (132ºC)

Preconditioning Pulses 3

Exposure Time 4 minutes

Dry Time Cycle with total weight of 25 lbs (11.36 kg) 30 minutes

Cracked door time 15 minutes and cool time 60 minutes (may vary according to load contents)

Pre-vacuum Steam Sterilization Cycle for all Perforated and Solid Bottom Containers (Immediate Use Steam Sterilization - IUSS)

Exposure Temperature 270ºF (132ºC)

Preconditioning Pulses 3

Exposure Time 4 minutes

Maximum Total Weight 25 lbs (11.36 kg)

Devices must be used immediately and cannot be stored for later use

100% Ethylene Oxide (EO) Sterilization Cycle for only Select Size Perforated Bottom Containers

EO Sterilant Concentration 100% EO, 725mg/L

Preconditioning Time 30 minutes

Exposure Temperature 130ºF (55ºC)

Exposure Time 60 minutes

Relative Humidity 50-80%

Aeration 8 hours at 110ºF (43ºC)

Total Weight 15 lbs (6.82 kg)

STERRAD 50 Sterilization Cycle for STERRAD Compatible Containers

STERRAD 50 is a preset cycle. For the maximum total weight allowed for each compatible container model refer to the **Modality Specific Recommendations for Accessories and Containers** chart (page 12).

STERRAD 100S Sterilization Cycle for STERRAD Compatible Containers

STERRAD 100S is a preset cycle. For the maximum total weight allowed for each compatible container model refer to the **Modality Specific Recommendations for Accessories and Containers** chart (page 12).

180-Day Event-Related Shelf-Life Study

Genesis test containers were sterilized under indicated modalities. The fully loaded containers were transferred to wire storage shelves and held for 180 days. Genesis reusable rigid sterilization containers were periodically rotated to simulate normal handling and to provide an equal challenge to all units. After 180 days, the units were assessed for sterility. The contents of all containers were sterile, indicating that sterility was maintained for the indicated event-related shelf life duration.

Genesis Container Cleaning and Processing

After each use, Genesis reusable rigid sterilization containers, baskets, and accessories should be washed with a properly diluted, enzymatic / neutral pH detergent solution recommended for use on anodized aluminum. A neutral pH is defined as 7. The post-dilution pH level should not be below 5.5 or exceed 8.5.

Caution: A detergent with a highly acidic or highly alkaline pH could permanently damage the anodized finish of the container. Alcohol is not recommended for manual cleaning or wiping down. All cleaning agents should be thoroughly rinsed off prior to any sterilization process to remove all residual chemicals which could damage the protective anodized finish.

Genesis accessories are used inside the baskets to organize and secure the instruments being sterilized and should be routinely inspected for proper attachment and cleanliness. When applicable (soiled), silicone mats and other accessories should be scrubbed with a soft brush to reach hard-to-clean areas such as between the fingers on a silicone mat, attached surfaces of pins and dividers in the basket, and inside the holes of silicone bars.

Surgical instruments should be reprocessed according to the instrument manufacturer's instructions for use (IFU) prior to organizing in Genesis container baskets.

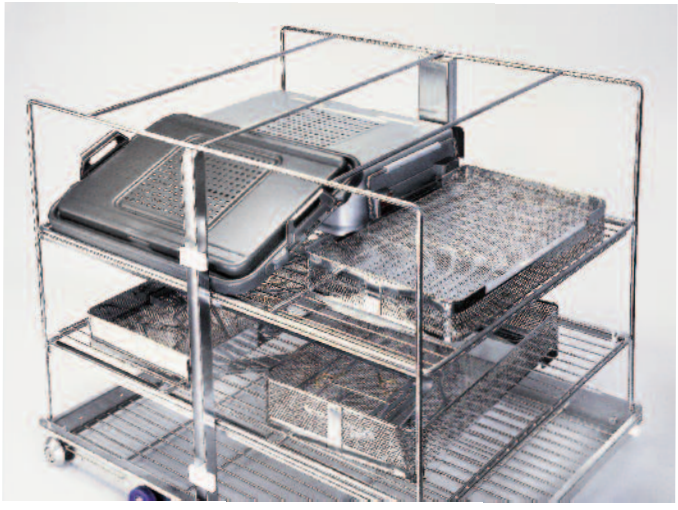
Components may be processed in a mechanical washer, cart washer or processed by hand. Do not clean the anodized container or container components (bottom, lid, retention plate, or optional protective plate) in an ultrasonic washer.

Pre-processing Instructions

It is recommended that containers are reprocessed as soon as is reasonably practical following use. Containers should be transported via the institutions established transport procedure.

Excess gross soil should be removed as soon as possible after use by rinsing or wiping the device.

All containers must be processed in the completely open and disassembled (i.e. taken-apart) configuration. Disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.) unless otherwise indicated.



Manual Cleaning

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Containers and accessories must be cleaned in the completely open and disassembled (i.e. taken-apart) configuration. Note that applicable device disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.) unless otherwise indicated.
3. Prepare the enzymatic / neutral pH detergent solution, utilizing tap water with a temperature range of 81°F to 111°F (27°C to 44°C), per manufacturer's instructions.
4. Place containers in the open/relaxed position, and completely immerse in the detergent solution and allow container to soak for a minimum of 5 minutes. Actuate all movable parts during the initiation of the soak time.
5. Using a soft bristled brush, remove all visible soil from the container. Actuate all movable parts of container while brushing, paying particular attention to hinges, crevices and other difficult to clean areas.

Note: It is recommended that the detergent solution is changed when it becomes grossly contaminated (bloody and/or turbid).

6. Rinse the container by completely immersing in tap water with a temperature range of 81°F to 111°F (27°C to 44°C), for a minimum of 30 seconds to remove any residual detergent or debris.
7. Dry the container with a clean, lint-free towel.
8. Visually examine each container and accessory device for cleanliness.
9. If visible soil remains, repeat cleaning procedure.

Automated Cleaning

If you wish to use automatic cleaning for these devices, you must follow the washer manufacturer's recommendations pertaining to the accessories required to clean these types of devices. Most washer manufacturers have specific washing equipment accessories for these types of devices.

1. Ensure all pre-processing instructions are followed prior to cleaning.
2. Containers and accessories must be cleaned in the completely open and disassembled (i.e. taken-apart) configuration. Note that applicable device disassembly should not require any mechanical tooling (i.e. screwdriver, pliers etc.) unless otherwise indicated.
3. Clean the containers and accessories via the Automatic cleaning parameters below.

Phase	Minimum Recirculation time (minutes)	Water Temperature	Detergent Type and Concentration (If Applicable)
Pre-Wash 1	00:15	Cold tap water 33° F – 60° F (1° C – 16° C)	N/A
Enzyme Wash	01:00	Hot tap water 110° F – 179° F (43° C – 82° C)	• Detergent: Enzol™ (pH-neutral/enzymatic detergent) • Concentration: Per the detergent manufacturer's recommendations
Wash 1	02:00	Tap water 110° F – 179° F (43° C – 82° C)	• Detergent: NpH-KlenzR (pH-neutral cleanser) • Concentration: Per the detergent manufacturer's recommendations
Rinse 1	00:15	Tap water 110° F – 179° F (43° C – 82° C)	N/A
Pure Rinse	00:10	Purified water 110° F – 179° F (43° C – 82° C)	N/A
Drying	00:00	N/A	N/A

4. Manipulate the containers and accessories to allow rinse water to drain.
5. If visible moisture is present dry the instrument with a clean, lint-free towel.
6. Visually examine each instrument for cleanliness.
7. If visible soil remains, repeat cleaning procedure

Note: Do not use ultrasonic cleaning for anodized aluminum devices.

Genesis Container Assembly

The Genesis reusable rigid sterilization container system should be routinely inspected for damage which could result in the product not functioning as intended, such as not closing properly or failing to maintain closure. Routine inspection of the gasket and lid will alert you to potential repair or replacement issues. Whenever you have questions about the proper functionality of the Genesis reusable rigid sterilization container system you should contact your local sales representative or call customer service at 1-800-227-3220.

Note: The container should never be overloaded with instruments. Ensure that instruments are well placed inside the basket, not protruding over the top and interfering with proper closure. Refer to **Instrument Assembly**.

Whenever possible, break up the overall density of the contents to achieve better drying results. The use of stacking baskets and accessories to divide and separate the set contents is intended to assist in this process.

It may be necessary to adjust your set assembly practices to comply with current weight recommendations and guidelines. This adjustment may require you to break up overweight sets and reconfigure them into multiple container sets.

The DST series filter recommended for use with Genesis reusable rigid sterilization containers is for single use only. One filter sheet, or thickness, should be used underneath each retention plate per process. Using more than one thickness or reusing the recommended filter (DST series) has not been validated for efficacy.

Consult with the device manufacturer to ensure the instruments you are processing are compatible with the chosen sterilization process.

Routine Inspection

- The container lid should demonstrate a noticeable bounce upon opening due to the downward compression created by the interlocking handles when closing. An absence of a noticeable bounce may indicate the need for gasket replacement or further handle inspection.
- Inspect the edges of the container lid and bottom to ensure there are no sharp burrs or dents that may affect the gasket seal or proper lid closure.
- Inspect the gasket to ensure that it is free of cracks and tears, and that it is properly seated in its retaining groove.
- Inspect gasket for visible compression indentation formed by the upper lip of the container bottom. The compression indentation should be uniform and continuous around the entire gasket length.
- Routinely inspect retention plates to ensure proper locking mechanism function.

Preventative Maintenance Checklist

Discontinue use of the Genesis™ Reusable Rigid Sterilization Container System if visible signs of damage or excessive wear are present that could compromise maintenance of sterile barrier or the use of sterile contents, such as cracking, peeling or flaking of the internal anodized layer of the container or the lid gasket.

The following should be routinely checked for proper container performance. A Genesis container is **not** in good working order if the following is observed in any of the areas indicated:

Lid

- Latch is bent.
- Latch cannot swing up and down freely.
- Latch spring is bent or protruding.
- Latch bracket is separated from lid.
- Gasket contains cuts or holes or is shredding.
- The seams of the gasket are separating.
- Gasket is not properly seated in retaining groove.
- Gasket exhibits visible degradation or color change.
- Dents, which could affect the gasket's sealing capabilities.

Bottom

- Latch is loose or separating from container.
- Identification tag is missing.
- Handle sleeve is cracked or torn.
- Dents on upper lip of container, which comes in contact with the gasket.

Retention Plates

- Distorted shape.
- Bent lever.
- Lever does not secure plate properly under indent.
- Inadequate spring or compression.

Instrument Assembly

Density

- Select appropriate size basket(s) according to container size and sterilization modality.

Note: Do not exceed the height of the basket when assembling the instruments. Overloading the baskets can cause the instruments to touch the lid of the container and interfere with proper closure of the lid. This could potentially cause instrument damage or unintentionally dislodge the filter retention plate.

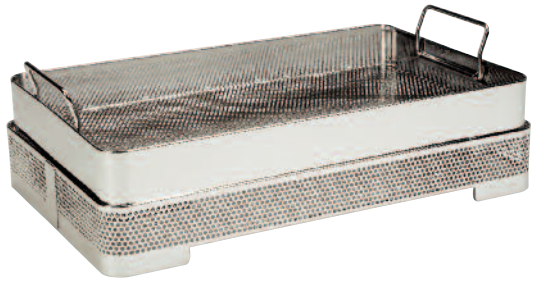
Basket Liners

The use of absorbent or non-absorbent basket liners has not been validated in Genesis reusable rigid sterilization containers. Genesis containers have been validated for efficacy and dryness without the use of any basket liners, indicating that the use of basket liners is not necessary to achieve a dry set when processing according to our sterilization parameter recommendations.

Stacking Baskets

There should be a 2" (5.1 cm) clearance between the height of a standard ("A" or "V" suffix) basket(s) and the overall height of the container for proper closure. To maintain this recommended clearance, keep your instruments below the rim of the basket when fully assembled.

If a stacking basket is used ("AS" or "VS" suffix) in a stacking configuration, only a 1" (2.5 cm) clearance is required because the stacking basket clears the lid when closed and still provides space to protect the filter retention plate from instrument contact.



Weight

A validated total weight of 25 lbs (11.36 kg) has been demonstrated for pre-vacuum steam and 15 lbs (6.82 kg) for 100% Ethylene Oxide using the most challenging Genesis container from a sterilant penetration perspective.

Refer to the **Modality Specific Recommendations for Accessories and Containers** chart (pages 10-12) for additional information on modality specific use of particular containers, accessories, and load contents. Refer to **Table 1** on page 13 for the maximum weight validated for use in the STERRAD 50 and 100S modalities.

Filter Assembly

The same filter material (DST series) is used in all models of Genesis reusable rigid sterilization containers and is suitable for pre-vacuum steam, STERRAD 50, STERRAD 100S, and 100% EO sterilization.

Caution: Filters are for single use only and must be discarded after each process. Do not use more than one thickness of filter material. Each sterilant access (perforated hole) area requires one filter.

Choose the Correct Filter Material for the Selected Sterilization Process

The same filter material (DST series) is used for all sterilization modalities. Select the appropriate filter such that it completely covers each retention plate area.

- DST-3 Filter: FULL, MID, HALF, XL, and RETRACTOR size containers
- DST-2 Filter: LARGE NARROW, SMALL NARROW, and QUARTER size containers
- DST-1 Filter: MINI containers.

Optional Protective Plate

An optional protective plate is available for use with the pre-vacuum steam sterilization modality only. Use of this plate is not supported in 100% Ethylene Oxide, STERRAD 50, or STERRAD 100S modalities. Within indicated modalities, validated lethality and shelf life are achieved independent of optional protective plate use (i.e. use of this plate does not have an impact on shelf life.) While the offset perforations of the Genesis lid and retention plate provide additional protection to the filter material, the use of the optional protective plate helps prevent direct contact of the filter material from external objects.

Note: The optional protective plate is not provided with the mini container.

Warning: Use of the optional protective plate is not supported in 100% Ethylene Oxide, STERRAD 50 or STERRAD 100S modalities.

If the optional protective plate is used in the lid:

1. Place the optional protective plate directly over the perforations (sterilant access holes).

2. Place a new filter on top of the optional protective plate.
3. Place the retention plate on top of the filter.
4. Rotate the retention plate lever to secure the filter.

Caution: The filter must be placed between the optional protective plate and the retention plate.

If the Optional Protective Plate is Not Used in the Lid:

1. Place a new filter directly over the perforations (sterilant access holes).
2. Place the retention plate on top of the filter.
3. Rotate the retention plate lever to secure the filter.

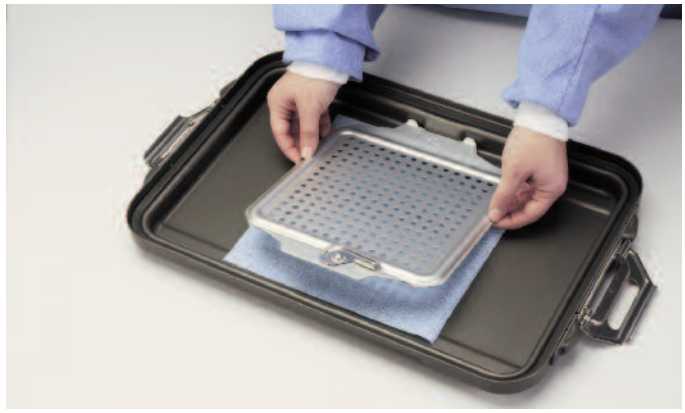
Filter Material Placement

Place one filter over the entire filter ridge surrounding each sterilant access hole area in the container lid or bottom. The filter material should overlap the filter ridge on all four sides and will be secured between the filter retention plate and the lid or bottom when assembled.

Caution: Make sure filter does not overlap itself or become wrinkled or creased. (folded over onto itself)

Retention Plate Placement

1. Place the filter retention plate over the filter material. Use the two alignment tabs on the filter retention plate to properly position it under the indentations. Make sure the retention plate is firmly seated under the indentation in the container.



Note: The filter retention plates are stamped “Bottom” or “Top” as a guide for appropriate placement.

2. To secure the filter retention plate, apply downward pressure to the plate near the lever.
3. Simultaneously rotate the lever toward the indentation protruding from the side of the container. Make sure the lever is rotated completely to the side of the container and the retention plate is locked firmly in place.

Processing Data Card

The purpose of the data card is to record processing information such as load, date processed and expiry date, according to your facility's protocols. The data cards are inserted into the data blocks located on the left side of each bottom container latch for easy visual access during storage and transport.

Caution: Be sure to choose the correct data card material for the sterilization process used. Cellulose materials are compatible with steam and ethylene oxide (EO) processes. Cellulose materials are **not** compatible with the STERRAD 50 or 100S processes.

Steam/EO: MD1-1 Cellulose Data Card.

STERRAD 50 and 100S: MH1-1 Non-Cellulose Data Card.

Note: Insert data card prior to attaching the lid. Always use a data card to record processing information. Do not reuse data cards.

Organizational Accessories

Select the desired accessories (such as posts or pins, aluminum brackets and silicone bars) needed to properly accommodate the instruments being sterilized. Refer to the **Modality Specific Recommendations for Accessories and Containers** chart (pages 10-12) for details on acceptable use.

Instrument pins, dividers and bottom and side mounting brackets are secured in instrument baskets according to the following:

Threaded Style

1. Insert the threaded end of the accessory through one of the basket holes so that the threaded end is on the underside of the basket.
2. Apply the square washer over the end of the desired accessory.
3. Using the wrench supplied, secure the square washer with the wide end of the wrench, and tighten the washer firmly against the bottom of the basket.
4. Apply the hex nut onto the square washer.
5. Using the small end of the wrench supplied, tighten the hex nut against the square washer until secure. Do not over-tighten, as this could damage the threads.

Quick-Disconnect Style Post and Clips

1. Insert a post through the hole on either end of the bracket and position in the Genesis basket at the desired location.
2. Holding the post in place, turn the basket over and position the quick-disconnect clip over the tip of the post. Slide the clip until the post is locked securely in place.
3. To release, apply pressure while sliding the quick-disconnect away from the post.

Silicone Bars and Brackets

1. Slide a silicone bar into the bracket.

Note: Instrument lubricant may be used to lubricate the aluminum bracket for easy installation of the silicone bar.

Identification Tags

1. To remove the identification tag, slide the tag up and out while pushing the metal clip or tongue toward the container body.
2. To insert the new identification tag, slide the tag down into data block located on right side of bottom latch while pushing the metal clip or tongue toward the container body.

Container Assembly

1. Confirm that the lid (and bottom, if perforated) has the appropriate filters and retention plates in place.
2. Place appropriately sized and assembled basket with instruments into the container bottom.
3. When placing the filled instrument basket(s) into the container bottom, ensure that the basket handles are facing properly:
   - "A" or "AS" style handle- toward the center of the basket.
   - "V" or "VS" style handle - in the down position.
4. Place an internal processing indicator, or integrator, in the set according to hospital protocols and policies.
5. Place assembled lid on container bottom, properly seating it on the container bottom.

Lock the Container

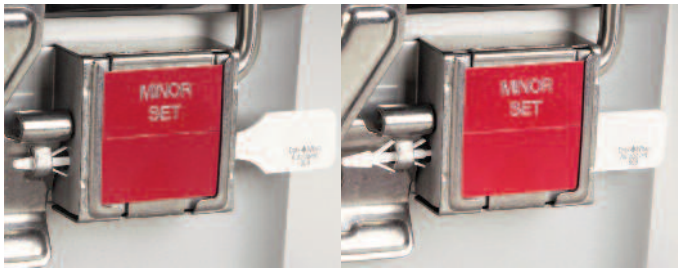
1. Interlock lid-latch component with bottom-latch component on both sides.

2. Press down with smooth continuous pressure until an audible snap is heard, confirming the latch is secured.

Insert the Tamper-Evident Arrows

1. Select the proper tamper-evident arrow. See **Modality Specific Recommendations for Accessories and Containers** chart (pages 10-12) for proper arrow selection.
2. Move the carrying handle to an upright position.
3. Orient the arrow so that the chemical indicator dot is facing outward.
4. Insert one arrow into the open channel found under the data block that holds the identification tags (right side of container).

5. Advance the arrow until both sets of tabs have completely passed through the channel and are visible. When fully inserted, the tail portion of the arrow should be flush with the channel.



NOT FULLY INSERTED **FULLY INSERTED**

6. Grasp the arrow end with the indicator dot and gently pull back on the arrow to ensure that it is correctly placed and secure.
7. Repeat steps 3 through 6 for the other end of the container.

When completed, the container should have two fully inserted and secured tamper- evident arrows in place.

Genesis Sterilization Loading and Cooling

When fully assembled, the Genesis container is ready for sterile processing by loading it onto the autoclave cart. Special attention should be taken to ensure that the container and its processing supplies are appropriately matched to the chosen sterilization method.

Genesis sterilization containers should be positioned flat on the cart and not placed on their sides or upside down. Stacking is appropriate in some sterilization methods and not recommended in others.

Refer to the **Modality Specific Recommendations for Accessories and Containers** chart (pages 10-12) for detailed information. Always place Containers on shelves under wrapped items.

Caution: Make sure sterilant access holes (perforations) on the containers are not obstructed with items such as wrapped goods, other container systems that obstruct air flow, or internal products and items such as count sheets.

Caution: Always practice safe lifting and handling of heavy objects. Do not stack containers more than three (3) high in pre-vacuum sterilization cycles, per recommended dry time parameters. Stacking is only recommended in pre-vacuum steam cycles.

Cart Loading Guidelines

Always place containers flat on shelves.

Containers may be sterilized in dedicated loads or in mixed loads with wrapped and other peel-pouched items.

If sterilizing in a mixed load, place containers below absorbent wrapped items. An absorbent liner may be used on the autoclave cart; however, if wet containers are a problem, the liner should be removed and the containers should be placed on unlined autoclave shelves for best drying results.

Genesis Aseptic Presentation

The Genesis reusable rigid sterilization container system provides the operating room personnel with an exterior tamper-evident arrow to help visually communicate that the container has been subjected to a sterilization process and has not been tampered with (opened) prior to its intentional opening at the point of use.

Chemical and/or biological indicators may be incorporated into the assembly process and provide critical information to the end user to establish whether the internal contents are safe to use. Which indicator is used is the decision of the hospital based on individual hospital protocol and current guidelines.

Inspection should also be conducted at the point of use to ensure that the filter has been inserted properly, that the retention plate is secure and there is no visible damage to the gasket found in the lid and that contents are dry. If the filter is missing, the retention plate is not secure, the gasket is visibly damaged, the arrow is missing or broken, or the dot hasn't changed color the container should be considered contaminated and not used.

Inspecting these external and internal devices is important prior to placing any basket on the sterile field. The container itself is not to be placed on a sterile field because the container exterior is not sterile.

In general, the baskets are removed by carefully lifting them up and away from the container bottom edge (lip) and placed on the sterile field. Multiple baskets are removed using the same protocol.

Sterility Maintenance Guidelines

The contents of a Genesis container should **not** be considered sterile if any of the following conditions are present:

- A filter is missing from any of the perforated areas.
- A retention plate is dislodged or not fully engaged.
- A filter does not cover the raised edges (filter ridge) surrounding the perforated areas on the lid or bottom.
- A filter is wet.
- A filter is damaged, torn, ripped, punctured, or creased. (folded over onto itself)
- More than one filter is used for processing or the filter material has been folded forming more than one layer over the perforations.
- The filter has already been used before.
- A tamper-evident arrow is missing or broken in either of the two locks.
- The indicator dot is missing from the tamper-evident arrow at the time of opening.
- The indicator dot does not indicate a noticeable color change.
- There is no internal chemical indicator found in the basket when opened. (if hospital protocol dictates that one should be present)
- The internal chemical indicator (if present, per hospital protocol) does not indicate the item has been processed when used according to the manufacturers' recommendations for use.
- The gasket is either damaged or separated from its retaining groove.
- The bottom lip is damaged or dented causing a gap or break in the compression indentation in the gasket.
- There is residual water or condensation within the container at the point of use.

Preparing for Opening

Place the container on a level surface that facilitates aseptic opening.

External Inspection

1. Inspect the container per the **Sterility Maintenance Guidelines** before opening.
2. Check for the appropriate color change of the chemical indicator located on the tamper-evident arrow:
   - The indicator on the white (steam) arrow changes color in the half circle to a dark gray or black.
   - The indicator on the yellow (EO) arrow turns green.
   - The indicator on the pink (STERRAD) arrow turns blue.

Note: A chemical indicator that has changed color differentiates a processed container from an unprocessed one. As long as there is a noticeable color change, the indicator has reacted sufficiently to indicate the container has been processed. The chemical indicators on the tamper-evident arrows are not an indicator of sterility.

Tamper-Evident Arrows

3. Check for the physical integrity of both tamper-evident arrows.
4. Grasp the arrow on the chemical indicator dot end and gently pull. If the arrow slips out of the channel, consider the contents of the container not sterile.

Inspect Filter Placement and Integrity

Inspect to ensure filter(s) is in place.

- The filter color will show through the sterilant access holes (perforations) on the lid of the container and container bottom (if a perforated container bottom is used).
- If the optional protective plate was used in assembly of the lid, the filter color will show through a single corner of the sterilant access area.

Inspect Identification Tags

Verify that the correct instrument set has been selected.

Inspect the Data Card

Check for expiration date. Do not use if beyond expiration date.

Opening the Container (Non-scrubbed Personnel)

1. Rest base of thumbs against the upper latch plates for support.
2. Place fingers under bottom latch on both ends of the container.
3. Gently pull upward and outward on bottom latch.

Simultaneously open both latches or open one side at a time. This disengages the lid from the bottom and breaks the tamper-evident arrow to enable opening of the container.

The lid handles will move to the full upright position.

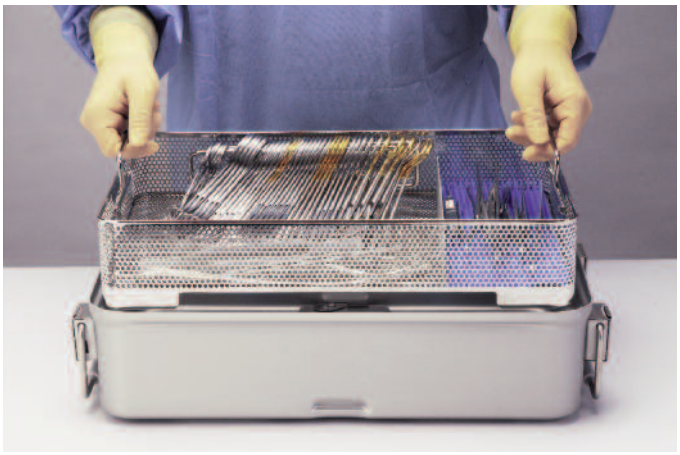
Removing the Lid

1. Place fingers into the opening on each of the lid handles. Lift lid vertically up and off the container bottom. After removing, inspect the container lid.

2. Inspect gasket to ensure there is no damage or separation from the retaining groove.
3. Inspect gasket to make sure the compression indentation is uniform around the gasket perimeter.
4. Inspect the filter(s) and retention plate(s) in the lid for correct placement.
5. Inspect the filter for any visible tears or punctures.

Removing the Basket (Scrubbed Personnel)

1. Check the internal chemical indicator (CI) for acceptable results (if present, per hospital protocol).
2. Remove the instrument basket from the container.
3. Securely grasp the basket handles, making sure the sterile gown and gloves do not touch the outside of the container, the container edge (lip) or table.
4. Lift the basket in a straight upward direction. Any additional baskets within the container are removed in the same manner.



5. Discard filters and tamper-evident arrows.

Soiled Return

A closed containment system is offered by CareFusion which allows soiled instruments to safely soak and be transported to the decontamination area for processing:

- CR1-6, CR2-6, CR3-6 Red Lids with bio hazard label.

Genesis Disassembly

All container components should undergo a complete decontamination process after each use. In preparation for thorough cleaning, the container should be fully disassembled and decontaminated either mechanically or manually. See **Genesis Container Cleaning and Processing** (Page 3) for complete cleaning recommendations.

Open the lid

1. Rest base of thumbs against the upper latch plates for support.
2. Place fingers under bottom latch plates on both ends of the container.
3. Gently pull upward and outward on bottom latch plates. Simultaneously open both latches. This disengages the lid from the bottom.

4. With the handles in the upright position, lift lid from the bottom.

Remove Retention Plates from container lid and bottom (if applicable)

1. Apply downward pressure on the retention plate near the lever.
2. Simultaneously rotate the cam lever away from the indentation protruding from the side of the lid.

3. Discard the used filter. **Do not reuse.**
4. Remove the optional protective plate from the lid, if applicable.

Remove remaining single use accessories

1. Inspect for arrow fragments that might be remaining under the handles in the arrow space on both sides of the container bottom. Discard fragments.

Note: The data card may be kept as a record.

Modality Specific Recommendations for Accessories and Containers

		Sterilization Modality			
Solid Bottom Container	**Contents / Configuration**	**Pre-Vacuum Steam**	**100% Ethylene Oxide**	**STERRAD® 50**	**STERRAD® 100S**
CD0-3C CD0-4C CD1-4C CD1-5C CD1-6C CD1-7CDL CD1-8CDL CD2-4C CD2-5C CD2-6C CD2-8C CD2-7CDL CD2-10CDL CD3-4C CD3-5C CD3-6C CD3-7C CD3-8CDL CD3-9CDL CD4-3C CD4-5C CD5-3C CD5-61C CD6-6C CD7-5C CD7-6C CD7-9C **Note:** These specific recommendations also apply to container configurations assembled using the color anodized lids.	Baskets	YES	NO	NO	NO
	Stacking Baskets	YES	NO	NO	NO
	Lumen: 2.68 mm (ID) x 450 mm (L) (see Lumen)	YES Qty. 16	NO	NO	NO
	Lumen: 1.37 mm (ID) x 242 mm (L) (see Lumen)	YES Qty. 10	NO	NO	NO
	Lumen: 3.0 mm (ID) x 400 mm (L) (see Lumen)	YES Qty. 2	NO	NO	NO
	Occluded/Mated Challenge (see Occluded/Mated)	YES	NO	NO	NO
	Silicone Support Bars	YES	NO	NO	NO
	Silicone Mat	YES	NO	NO	NO
	Laparoscopic Rack	YES	NO	NO	NO
	Optional Protective Plate	YES	NO	NO	NO
	Filter	DST series	NO	NO	NO
	Data Card	MD1-1	NO	NO	NO
	Tamper-Evident Arrow	White AS series	NO	NO	NO
	Stack Height	3 containers	NO	NO	NO
	Materials	Metals Polymers Composites	NO	NO	NO
	Maximum total Container system weight	25 lbs (11.36 kg)	NO	NO	NO

Modality Specific Recommendations for Accessories and Containers

		Sterilization Modality			
Perforated Bottom Container	**Contents / Configuration**	**Pre-Vacuum Steam**	**100% Ethylene Oxide**	**STERRAD® 50**	**STERRAD® 100S**
CD0-3B CD0-4B CD1-4B CD1-5B CD1-6B CD1-7BDL CD1-8BDL CD2-4B CD2-5B CD2-6B CD2-8B CD2-7BDL CD2-10BDL CD3-4B CD3-5B CD3-6B CD3-7B CD3-8BDL CD3-9BDL CD4-3B CD4-5B CD5-3B CD5-61B CD6-6B CD7-5B CD7-6B CD7-9B **Note:** The CD2-10BDL container model is not validated for use in 100% Ethylene Oxide sterilization **Note:** These specific recommendations also apply to container configurations assembled using the color anodized lids.	Baskets	YES	YES	NO	NO
	Stacking Baskets	YES	NO	NO	NO
	Lumen: 2.68 mm (ID) x 450 mm (L) (see Lumen)	YES Qty. 16	NO	NO	NO
	Lumen: 1.37 mm (ID) x 242 mm (L) (see Lumen)	YES Qty. 10	NO	NO	NO
	Lumen: 3.0 mm (ID) x 400 mm (L) (see Lumen)	YES Qty. 2	YES Qty. 5	NO	NO
	Occluded/Mated Challenge (see Occluded/Mated)	YES	YES	NO	NO
	Silicone Support Bars	YES	YES	NO	NO
	Silicone Mat	YES	NO	NO	NO
	Laparoscopic Rack	YES	YES	NO	NO
	Optional Protective Plate	YES	NO	NO	NO
	Filter	DST series	DST series	NO	NO
	Data Card	MD1-1	MD1-1	NO	NO
	Tamper-Evident Arrow	White AS series	Yellow AG series	NO	NO
	Stack Height	3 containers	No Stacking	NO	NO
	Materials	Metals Polymers Composites	Radel Stainless Steel Aluminum Silicone	NO	NO
	Maximum total Container system weight	25 lbs (11.36 kg)	15 lbs (6.82 kg)	NO	NO

Modality Specific Recommendations for Accessories and Containers

		Sterilization Modality			
STERRAD Container	**Contents / Configuration**	**Pre-Vacuum Steam**	**100% Ethylene Oxide**	**STERRAD® 50**	**STERRAD® 100S**
CD0-3ST CD0-4ST CD1-4ST CD1-5ST CD1-6ST CD2-4ST CD2-5ST CD2-6ST CD2-8ST CD3-4ST CD3-5ST CD3-6ST CD3-7ST CD4-3ST CD4-5ST CD5-3ST CD5-61ST	Baskets	YES	YES	YES	YES
	Stacking Baskets	YES	NO	YES	YES
	Lumen: 2.68 mm (ID) x 450 mm (L) (see Lumen)	YES Qty. 16	NO	NO	NO
	Lumen: 1.37 mm (ID) x 242 mm (L) (see Lumen)	YES Qty. 10	NO	NO	NO
	Lumen: 3.0 mm (ID) x 400 mm (L) (see Lumen)	YES Qty. 2	YES Qty. 5	YES	YES
	Occluded/Mated Challenge (see Occluded/Mated)	YES	YES	YES	YES
	Silicone Support Bars	YES	YES	YES	YES
	Silicone Mat	YES	NO	NO	NO
	Laparoscopic Rack	YES	YES	YES	YES
	Optional Protective Plate	YES	NO	NO	NO
	Filter	DST series	DST series	DST series	DST series
	Data Card	MD1-1	MD1-1	MH1-1	MH1-1
	Tamper-Evident Arrow	White AS series	Yellow AG series	Pink AH series	Pink AH series
	Stack Height	3 containers	No Stacking	No Stacking	No Stacking
	Materials	Metals Polymers Composites	Radel Stainless Steel Aluminum Silicone	Stainless Steel Aluminum Silicone	Stainless Steel Aluminum Silicone
	Maximum total Container system weight	25 lbs (11.36 kg)	15 lbs (6.82 kg)	See Table 1 on page 13	See Table 1 on page 13

Table 1: STERRAD 50 and 100S Maximum Load (Excluding Container)

Model Number	Genesis Container Model Description	STERRAD® Maximum Load (Excluding Container)
CD0-3ST	Genesis Mini Container, STERRAD Compatible	1.5 lbs (0.68 kg)
CD0-4ST	Genesis Quarter Length Container, STERRAD Compatible	2.5 lbs (1.14 kg)
CD1-4ST	Genesis Half Length Container, 10 cm (4 in) Deep, STERRAD Compatible	3.4 lbs (1.55 kg)
CD1-5ST	Genesis Half Length Container, 12.7 cm (5 in) Deep, STERRAD Compatible	4.4 lbs (2.00 kg)
CD1-6ST	Genesis Half Length Container, 15.2 cm (6 in) Deep, STERRAD Compatible	5.2 lbs (2.36 kg)
CD2-4ST	Genesis Mid Length Container, 10 cm (4 in) Deep, STERRAD Compatible	6.0 lbs (2.73 kg)
CD2-5ST	Genesis Mid Length Container, 12.7 cm (5 in) Deep, STERRAD Compatible	7.6 lbs (3.45 kg)
CD2-6ST	Genesis Mid Length Container, 15.2 cm (6 in) Deep, STERRAD Compatible	9.1 lbs (4.14 kg)
CD2-8ST	Genesis Mid Length Container, 20.3 cm (8 in) Deep, STERRAD Compatible	12.2 lbs (5.55 kg)
CD3-4ST	Genesis Full Length Container, 10 cm (4 in) Deep, STERRAD Compatible	7.2 lbs (3.27 kg)
CD3-5ST	Genesis Full Length Container, 12.7 cm (5 in) Deep, STERRAD Compatible	9.2 lbs (4.18 kg)
CD3-6ST	Genesis Full Length Container, 15.2 cm (6 in) Deep, STERRAD Compatible	11.0 lbs (5.00 kg)
CD3-7ST	Genesis Full Length Container, 17.8 cm (7 in) Deep, STERRAD Compatible	12.2 lbs (5.55 kg)
CD4-3ST	Genesis Small Shallow Container, 7.6 cm (3 in) Deep, STERRAD Compatible	2.9 lbs (1.32 kg)
CD4-5ST	Genesis Small Container, 14 cm (5 1/2 in) Deep, STERRAD Compatible	5.4 lbs (2.45 kg)
CD5-3ST	Genesis Large Shallow Container, 7.6 cm (3 in) Deep, STERRAD Compatible	7.6 lbs (3.45 kg)
CD5-61ST	Genesis Large Container, 15.2cm (6in) Deep, STERRAD Compatible	12.2 lbs (5.55 kg)

Lethality Challenge Types

Lumen

A stainless steel tube of indicated inner diameter (ID) and length (L). The longest length and smallest inner diameter lumens validated for use in the pre-vacuum steam sterilization modality are 2.68 mm (ID) x 450 mm (L) and 1.37 mm (ID) x 242 mm (L). The longest length and smallest inner diameter lumens validated for use in 100% Ethylene Oxide, STERRAD 50, and STERRAD 100S modalities are 3.0 mm (ID) x 400 mm (L). Lumens with smaller ID and/or longer length than those indicated have **not** been validated for use.

Occluded/Mated

A device that has conjoined surfaces or surfaces which meet, touch, or unite.

Examples include: a lumen secured to a silicone bar, an instrument placed on a silicone mat, a double action instrument with the mated parts held open.

Specific instruments types covered by this challenge include the following (assuming sterilization in the disassembled or open position): scissors, forceps/clamps (including double action), hand held & self retaining retractors, needle holders, osteotomes/chisels, rongeurs, kerrison rongeurs, specula.

Note: Air-tight occluded challenges—devices with surfaces that are completely obstructed—have **not** been validated for use.

Materials

Metals, Polymers, Composites – Intrinsically stable metals. Composites, thermoplastics, and thermosetting polymers with constant use temperatures above 135°C.

Examples of intrinsically stable metals include stainless steel, titanium (CP and alloys), and aluminum. Examples of thermoplastic polymers are PEEK, PEKK, PEI (Ultem), Acetal (Delrin), Radel (PPSU), Nylon, PTFE, Polypropylene, ABS (Acrylonitrile/Butadiene/Styrene) and POM (Polyoxymethylene). Examples of thermosetting polymers are phenolic and silicone. Examples of composites include carbon fiber reinforced epoxy (CFRE).

Warranty

We guarantee every surgical device bearing the V. Mueller® Genesis brand name to be free of functional defects in workmanship and materials when used normally for its intended purpose. Any V. Mueller Genesis device proving to be defective will be replaced or repaired at no charge.

Gaskets are warranted by CareFusion for three (3) years from date of sale to be free of functional defects in both materials and workmanship.

CareFusion does not warrant the steadfastness of the colored anodizing of the Genesis colored lid product offering. Over time, the color may fade due to processing.

Repairs or modifications performed by unauthorized personnel may void all product warranties and could affect performance and efficacy of device.

Repair Policy

Contact your local sales representative or call customer service at 1-800-227-3220.

Prior to returning any items for repair, authorization by CareFusion is required. Pack containers securely to avoid damage during shipment. When shipping multiple containers in one carton, avoid metal-to-metal contact. Determination of credit amount or warranty repair/replacement will be made at the Genesis facility.

IMPORTANT: All devices being returned for maintenance, repair, etc. must be cleaned and sterilized per these instructions for use prior to shipment.

Product Return for Repair Information

- Parts that are faulty due to defects in material or workmanship will be repaired or replaced at no charge.
- Parts that have been misused or mishandled are not covered under warranty.
- Authorization is required before returning any item for repair or warranty replacement. Please contact your local sales representative or call customer service at 1-800-227-3220 for a Return Goods Authorization number.
- Used or processed items may not be returned for credit.
- Clean and sterilize used components per these instructions for use before returning for repair or replacement. Questionable items will be returned to sender.
- Wrap baskets in protective foam before placing in the container to avoid internal shipping damage. Avoid metal-to-metal contact by securing retention plates and separating containers with cardboard dividers or similar protection.
- Lock the lid to the container bottom for shipment.
- Place container in plastic bag. Use protective packaging such as packing paper or foam to cushion the bottom of the box. Gaps around containers should be protected with packing to avoid internal movement.
- Do not use foam peanuts, newspaper or inflatable air packs.

If you are in need of proper shipping material, contact your local sales representative or call customer service at 1-800-227-3220.