Case Medical

SteriTite® and MediTray® Instructions for Use

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IFU-CASEMEDICAL Rev.005

THE SteriTite® SYSTEM WARRANTY

Case Medical, Inc.'s SteriTite® product line ("Container") is guaranteed to be free of functional defects in workmanship and materials when used as directed for its intended purpose. All **SteriTite®** products are warranted only to the original purchaser and only against defects in workmanship or materials which under the intended use render the product inoperable. Case Medical, Inc.® at its sole option and without charge will either repair or replace any SteriTite® product determined to be defective in material or workmanship when used for its intended purpose. Lid gasket and filter ring gaskets are under warranty for three (3) full years from the date of purchase.

THE MediTray® SYSTEM WARRANTY

Case Medical, Inc.'s MediTray® product line is guaranteed to be free of functional defects in workmanship and materials when used as directed for its intended purpose. Case Medical, Inc.® will repair or replace, at their discretion, any MediTray® product found to have a manufacturing defect within three (3) years from the date of delivery at no charge to the customer. All MediTray® products are warranted only to the original purchaser and only against defects in workmanship or materials which under the intended use render the product inoperable.

The following exclusions apply to the MediTray® and SteriTite® product line replacement warranty:

• Damage due to the use of caustic or abrasive cleaning agents.
(Refer to Instructions for Use as to the proper specifications for the washing detergent. Case Medical recommends use of Case Solutions and SuperNova instrument cleaners or other pH neutral detergents).

• Excessive handling abuse to the Container bottom, Container lid or filter cover ring and improper opening techniques. (Refer to Instructions for Use as to the proper latch opening techniques).

• Damage from fire or other unpredictable event not under the control of Case Medical, Inc.®

CASE MEDICAL, INC.® RETURNED GOODS POLICY

Case Medical, Inc.® wants full customer satisfaction with its products, promptness, and customer service. Should you encounter a situation in which you wish to return a product, please contact our Customer Service Department at 1-888-227-CASE for proper authorization. All returns must be assigned an authorization number by Case Medical, Inc.® A completed Returned Goods Authorization (RGA) form must be affixed to the outside of all returned packages, showing prior cleaning and decontamination of returned merchandise. Issue of an RGA number should not be interpreted as a final credit to the customer account. Case Medical, Inc.® reserves the right to evaluate incoming returns prior to issuing any customer credit.

The following items are not returnable, except in the case of a manufacturing defect:

1. Products held longer than 60 days from the date of delivery.
2. Products that have been used.
3. Custom or modified products.
4. Discontinued products no longer carried on the current Case Medical Price List.
5. Products not properly packaged for returns.

Nonrefundable products received by Case Medical will be returned directly to the customer with a letter of explanation.

Merchandise must be returned within 60 days from date of delivery.

Product, which is not within the criteria of non-returnable merchandise, will be issued credit as follows: Credit will be issued for products returned in original packaging and resalable condition according to Terms and Conditions. Products returned after 30 days will be issued partial credit only.

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SteriTite®, the Container system of choice

DEVICE DESCRIPTION: The SteriTite® Container is a rigid, reusable, sealed medical sterilization packaging system that is compatible with all current sterilization modalities. Whenever a new packaging method is introduced into a health care facility, all procedures associated with its use should be carefully evaluated and adapted. For this reason, Case Medical Inc. recommends that each user of our products become familiar with the information contained in "Comprehensive guide to steam sterilization and sterility assurance in Health Care Facilities"[1] and "Containment devices for reusable medical device sterilization".[2]

References:
ISO/TC 198 Sterilization of Health Care Products
ANSI/AAMI ST79:2017 [1]
ANSI/AAMI ST77:2013 [2]
AAMI STANDARDS ORDER CODE: www.aami.org/publications/standards/index.html

INTENDED USE: The SteriTite® Container system is intended to be used for the sterilization of reusable surgical instruments and medical devices in health care facilities. The contents must be placed within an instrument basket or tray. The load may be distributed in layers using MediTray® baskets or trays. MediTray® products may be containerized or wrapped with an FDA cleared medical wrap. Please refer to the recommendations of your sterilizer manufacturer for specific processing instructions as well as recommendations from your medical device manufacturer for material compatibility.

The SteriTite® sealed Container and MediTray® products are a universal, reusable packaging system with FDA 510k and CE mark for sterilization, transport and storage of medical devices including flexible endoscopes according to manufacturer's instructions. The SteriTite® system has been validated for use in all current sterilization modalities, including prevacuum and gravity displacement steam, EtO, H2O2 sterilization including STERRAD 100, 100S, 200, NX, 100NX(Standard, Flex and DUO Cycle ALLCLEAR), Steris V-Pro 1, V-Pro 1 Plus, V-Pro maX, V-Pro maX 2(Lumen and Flex Cycle), V-Pro s2(Lumen and Flex Cycle), V-Pro 60(Lumen and Flex Cycle), TS03 STERIZONE® VP4, and sealed immediate use steam sterilization. The following table (Table 1) displays the SteriTite part numbers and the low temperature sterilizers they are compatible with.

Table 1. SteriTite Container Compatibility with Low Temperature Sterilizers

V-Pro s2/60 Lumen Flex	V-Pro 1 Lumen	V-Pro maX/maX 2 Lumen Flex	Sterizone VP4 Cycle 1	100NX Standard Flex DUO	100S/200 Standard	NX Advanced Standard	Steam Pre-vac Gravity IUSS
SC02MG	SC02MG	SC02MG	SC02M(G)*	SC02MG	SC02MG	SC02MG	SC02MG
SC03MG	SC03MG	SC03MG	SC03M(G)*	SC03MG	SC03MG	SC03MG	SC03MG
SC04MG	SC02NG	SC04MG	SC04M(G)*	SC04MG	SC04MG	SC04MG	SC04MG
SC02NG	SC03NG	SC02NG	SC02N(G)*	SC02NG	SC02NG	SC02NG	SC02NG
SC03NG	SC04FG	SC03NG	SC03N(G)*	SC03NG	SC03NG	SC03NG	SC03NG
SC04NLG	SC05FG	SC04NLG	SC04NL(G)*	SC04NLG	SC04NLG	SC04HG	SC04NLG
SC05NLG	SC06FG	SC05NLG	SC05NL(G)*	SC05NLG	SC05NLG	SC05HG	SC05NLG
SC04HG	SC08FG	SC04HG	SC04H(G)*	SC04HG	SC04HG	SC04QG	SC04HG
SC05HG	SC04HG	SC05HG	SC05H(G)*	SC05HG	SC05HG	SC05QG	SC05HG
SC04QG	SC05HG	SC06HG	SC06H(G)*	SC06HG	SC06HG	SC04FG	SC06HG
SC05QG	SC06HG	SC08HG	SC08H(G)*	SC08HG	SC08HG		SC08HG
SC04FG	SC08HG	SC04QG	SC04Q(G)*	SC04QG	SC04QG		SC04QG
	SC04QG	SC05QG	SC05Q(G)*	SC05QG	SC05QG		SC05QG
	SC05QG	SC06QG	SC06Q(G)*	SC06QG	SC06QG		SC06QG
	SC06QG	SC08QG	SC08Q(G)*	SC08QG	SC08QG		SC08QG
	SC08QG	SC04FG	SC04F(G)*	SC04FG	SC04FG		SC04FG
	SC04LG	SC05FG	SC04L(G)*	SC05FG	SC05FG		SC05FG
	SC06LG	SC06FG	SC06L(G)*	SC06FG	SC06FG		SC06FG
	SC05WG	SC08FG		SC08FG	SC08FG		SC08FG
		SC04LG		SC04LG			SC04LG
		SC06LG		SC06LG			SC06LG
		SC05WG		SC05WG			SC08LG
							SC05WG

The SteriTite containers with MediTray parts have demonstrated the ability to facilitate sterilization of narrow lumens in high and low temperature sterilization processes. The SteriTite container has been cleared for a low temperature sterilization lumen claim of ≥1mm x 1050mm for specific sterilizers, and a high temperature/steam sterilization lumen claim of ≥1mm x 400mm.
Please see Table 2 below.

Table 2. Steam and Low Temperature Lumen Claims

Sterilizer	Cycle	Lumen Sterilization Claims (I.D. x Length)	Validated Lumen Characteristics
STERIS V-Pro 60	Lumen	≥0.77mm x ≤527mm	Dual Channel
	Flexible	≥1mm x ≤990mm	Single or Dual Lumen
STERIS V-Pro s2	Lumen	≥0.77mm x ≤527mm	Dual Channel
	Flexible	≥1mm x ≤990mm	Single or Dual Lumen
STERIS V-Pro maX 2	Flexible	≥1mm x ≤1050mm	Single Lumen
	Lumen	≥0.77mm x ≤527mm	Dual Channel
STERIS V-Pro maX	Flexible	≥1mm x ≤1050mm	Single Lumen
	Lumen	≥0.77mm x ≤527mm	Dual Lumen
STERIS V-Pro 1	Lumen	≥3mm x ≤400mm	Single Lumen
STERRAD 100NX	DUO	≥1mm x ≤875mm	Single Lumen
	Standard	≥0.7mm x ≤500mm	Single Lumen
	Flex	≥1.2mm x ≤835mm	Single or Dual Lumen
STERRAD NX	Standard	≥2mm x ≤400mm	Stainless Steel Blades, Lumens and Mixed Loads
	Advanced	≥1mm x ≤500mm	Stainless Steel Blades, Lumens and Mixed Loads
		≥1mm x ≤850mm	Porous Lumens (Flexible Endoscope)
STERRAD 100/100S	Standard	≥3mm x ≤400mm	Single Lumen
STERRAD NX	Advanced	≥1mm x ≤500mm	Single Lumen
		≥1mm x ≤850mm	Flexible Lumen
Sterizone VP4	Cycle 1	≥1.2mm x≤1955mm	Flexible Lumen
		≥1.45mm x ≤3500mm	
		≥1mm x≤850mm	
		≥0.7mm x≤500mm	Rigid Lumen
Steam	Pre-Vac	≥1mm x ≤400mm	Flexible Lumen
		≥2mm x ≤400mm	Stainless Steel Lumen

The SteriTite® rigid Container system is available for both prevacuum and gravity displacement sterilizers. The perforated bottom Containers can be used in both prevacuum and gravity displacement sterilizers, as well as, STERRAD, Steris V-Pro sterilization and Sterizone sterilization. Solid bottom Containers can be used in pre-vacuum steam sterilization and TSO3 cycles only. The perforated bottom Containers are ideal for standardization as they are validated for all current sterilization methods. MediTray® baskets, trays and accessories are intended to organize, protect and secure devices during sterilization, transport and storage.

Case Medical has validated its MediTray® products to be compatible with all sterilization modalities. Stacking: External stacking of SteriTite® Containers is dependent on sterilization method. Refer to the section associated with the sterilization modality in the IFU. Up to 7 trays may be stacked internally in steam sterilization, up to 4 levels in all other modalities. Containers may be stacked for storage and transport.

Sterility Maintenance: SteriTite® Containers are event related and proven to maintain sterility during rotation, transport and multiple handling events. According to ANSI/AAMI ST79:2017 Section 11.1, “the shelf life of facility-sterilized items is event-related and should be based on the quality of the packaging material, the storage conditions, the methods and conditions of transport, and the amount and conditions of handling”. SteriTite® Containers have also been validated for one-year shelf life.

CONTRAINDICATIONS – not known

VALIDATION TESTING: Case Medical subscribes to the overkill principle. SteriTite® and MediTray® products are validated in independent laboratories under fractional and half cycle conditions. Health care personal need to perform testing to verify the effectiveness of the Container system in the hospital's sterilizer. Place biological indicators/integrators in opposing corners of each tray/basket within the Container for verification. Validation testing was performed per ANSI/AAMI ST77, ST79, TIR12, and EC Directive 93/42/EEC (Medical Devices Directive), CE Directions DIN 58952 and EN UNI 868 part 8.

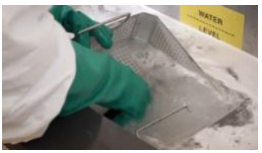
SteriTite® Containers and MediTray® products have FDA 510k as well as CE mark. The FDA 510k clearance demonstrates that the device is safe and effective for its intended use. The CE marking certifies that the product has met EU health, safety, and environmental standards and guidelines. All SteriTite® Containers display a unique device identification (UDI) barcode used to mark and identify medical devices within the healthcare supply chain. The UDI supports patient safety and supply chain security.

The following instructions for use provide guidance for proper care, handling, and processing of medical devices when SteriTite® Containers and MediTray® products are used.

SteriTite® and MediTray® Decontamination

The hospital is responsible for in-house procedures for the disassembly, reassembly, inspection and packaging of instrument sets including Container systems after they are thoroughly cleaned in a manner that will assure sterilant penetration and adequate drying. Prior to using the SteriTite® and MediTray® products follow the cleaning procedures in this IFU and perform a visual inspection of all parts. Case Medical recommends that Containers are reprocessed as soon as possible following use. Excess soil should be removed after use by rinsing or wiping the device prior to the cleaning procedure. Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices and equipment. PPE includes gown, mask, goggles or face shield, gloves and shoe covers. Thoroughly clean and decontaminate **MediTray®** products prior to first use and after each use with contaminated instruments (prior to sterilization). Details of proper cleaning procedures are as follows:

1. Disassemble all components. Unlatch and remove the lid of the **SteriTite®** rigid container. Remove filter retention plates from lid and base by turning the handle of the locking mechanism clockwise. Do not remove the gasket for the cleaning procedure. Remove filters and all other disposables and discard.
2. Remove the tray of contaminated instruments and prepare the instruments for decontamination following the recommendations of the instrument manufacturer.
3. Clean your **MediTray®** and **SteriTite®** products after each use with a pH neutral/enzymatic detergent and a soft, lint free cloth. Do not use abrasive cleaners, abrasive pads, or metal brushes. **MediTray®** baskets and trays can also be cleaned in an automatic washer. When using an automated washer, place filter retention plates in an instrument basket for cleaning.



Manual Cleaning:
SteriTite® Containers may be cleaned manually with a soft lint free cloth and a pH neutral detergent. Always follow with a thorough rinse to remove detergent residue. Use a soft lint free cloth to dry all components of the container. Avoid water collection by washing and drying the Container upside-down.

Recommendation: Case Solutions® and SuperNova® multi-enzymatic cleaners and detergents are ideal for cleaning medical devices and sterilization containers. In addition, single use enzymatic towelettes such as Penta Wipes can be used to decontaminate container components. Follow with

a rinse under the flow of water. Dry all surfaces and components. Alcohol Wipes can facilitate drying. Case Solutions® and SuperNova® cleaners, and instrument lubricant are U.S. EPA Safer Choice Awarded.

Automated Cleaning:

SteriTite® Containers may be cleaned in automated washers or cart washers when pH neutral detergents or enzymatic cleaners are used. Follow the recommended dosage of the detergent. If an automatic washer is used, secure all parts to avoid excess movement during cleaning. Make sure the Container latches are folded inward and the handles are tucked within the racks, so they don't protrude. Use utility or instrument cycles for automated cleaning in washer disinfectors and the Container cycle of the cart washer. Always follow the wash step with a thorough rinse to remove detergent residue.

Caution: Do not use alkaline detergents, acid neutralizers or scratch pads. Caustic detergents will oxidize the anodized aluminum surface of the Container and create discoloration and corrosion.

SteriTite® Inspection for Use

The recommended inspection criteria should be performed after each use, because of the variables associated with cleaning agents and equipment.

1. Perform a visual inspection of all parts prior to each use. Check that gaskets are properly secured and free of wear or damage. Latches should function properly. The case and lid should be free of dents that may interfere with the seal. The aluminum surface of the Container should have no noticeable corrosion or damage. Be sure filter retention plates or valve plates fit securely.
2. Verify that gaskets in the lid and in the filter retention plate(s) are pliable, without cracks or tears, and that they are all properly and firmly affixed.
3. Each retention plate should be flat and not warped or dented along the perimeter. The filter should be present covering each perforated vent. The retention plate should be securely latched when pressing down at center point. If the retention plate is not properly locked, the filter and retention plate can fall off onto the contents within the Container compromising the load. Some rotation of the circular retention plate is a natural occurrence when the filter is in place and will not affect the sterility maintenance of the contents.

Note: Case Medical does not recommend examining the filter at point of use because of our off-set vent pattern prevents strike-through and cross contamination. If your facility's policy is to examine the filter at point of use, the filters and retention plates should not be inspected over the container contents. This can result in filtrate particles falling from the exterior of the filter and lid and contaminating the sterile contents within the container.

4. Verify that the positioning pin in the lid and base, as well as the label holders on the front of the SteriTite® container are secure.
5. If the UDI direct mark is no longer readable, the product has reached the end of its useful life and should be taken out of service.

SteriTite® Assembly for Use

SteriTite® Containers require a disposable filter and filter retention plate as a microbial barrier. For Containers with a perforated base, place the appropriate filter over the perforations on the lid and base of the SteriTite® container and place the filter retention plate over the filter. Secure the filter retention plate by pushing downwards at center point (where indicated) and rotate the handle counter-clockwise to close.

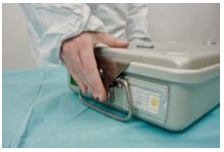
Note: Paper filters should be used only for steam and EO sterilization. Non-woven Polypro filters must be used for H2O2, STERRAD, STERIZONE and V-Pro sterilization, and may be used for pre-vacuum steam and EO sterilization.

Note: Prepare complex instruments according to the instrument maker's instructions. Use of nonabsorbent tray liners can cause condensate to pool. Do not use peel pouches within sealed containers, as they cannot be placed on their side for sterilization.

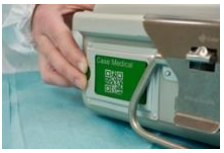
1. Select the appropriate size basket(s) or tray(s) according to Container size.
2. Arrange the clean instruments in the basket(s) according to hospital procedures. Review the recommendations provided by the device manufacturer.
Note: MediTray® partitions, brackets and posts are recommended for organization and protection of your delicate instruments. Place the prepared baskets into the base of the SteriTite® container. Do not exceed the height of the basket when placing instruments into the basket.
3. To determine container size, add one (1) inch of clearance for proper fit of contents, approximately 1/2 inch from the lid and 1/2 inch from the base. Case Medical has validated its SteriTite® Container system for stacking multiple layers within the container.

4. Place a process indicator or integrator in opposing corners of the instrument basket.

Note: Place the indicator in the area of the Container considered to be least accessible to sterilant penetration. The corners of the Container and the underside of the lid, away from the filters, are the most likely locations for air pockets.



5. Place the lid on top of the base. The edge of the base will fit in the lid channel creating a knife edge fit.
6. Secure the closure by latching the lid to the base. The top of the latch fits over the ridge in the lid. Push the bottom section of the latch over the lock holder. You will feel a solid click.
7. Place the appropriate metal ID tags in the label holders located on either side of the Container latches. The label holder on the right can accommodate a load card available from Case Medical, Inc®. Only clear ID tags can be used in H2O2 sterilization.



8. Thread the guide on the SteriTite® tamper- evident seal through the lock holder and secure. Repeat on both latches. Blue and red tamper evident seals are available for steam and gas. White tamper evident seals are recommended for H2O2/ STERRAD Sterilization.

Caution: Use of any non-approved tamper evident seal could damage the locking clip.

9. An external indicator or load card should be attached to the Container at this time. Case Medical provides external indicators for steam and EO, as well as H2O2 and gas plasma sterilization.

10. SteriTite Containers are designed to be dry after sterilization. Therefore, the use of absorbent liners is not recommended for use with the SteriTite® container.

SteriTite® Sterilization

1. Place the SteriTite® container flat on the shelf of the sterilizer cart. If needed, up to three (3) Containers may be stacked and processed in an autoclave.
2. If sterilized in a mix load, place Containers below wrapped or linen items.
3. Consult the recommendations of your sterilizer manufacturer to determine the correct parameters regarding temperature, weight load, dry time, instrument processing and pre-and post-conditioning cycles.

Note: To minimize the potential of condensate formation, crack the door of the autoclave for 10 to 15 mins.

4. Following the steam sterilization process, the cart should be removed from the autoclave and placed in cool down.

SteriTite® Labeling for Steam Sterilization

PRE-VACUUM STEAM TERMINAL STERILIZATION PARAMETERS FOR USE:
Use vented or solid base Container for pre-vacuum steam. Apply paper or polypropylene disposable filter for each use. Use MediTray® inserts in the Container to secure instrumentation. Recommended for sterilization of medical devices including, blades and metal lumens of 2mm minimum diameter up to 435mm in length and porous lumens 3mm minimum diameter up to 400mm in length.
Recommended exposure time: 4 minutes at 270°F.
Recommended dry times:
A minimum of 5 minutes for perforated bottom units
A minimum of 8 minutes for solid bottom units
20 minutes may be required for items stored for later use

Note: Case Medical recommends verification of these parameters in the health care facility given variations in equipment, steam quality and environmental conditions. To reduce condensate formation, crack the autoclave door for 10 to 15 minutes to allow gradual cool down.

Caution: Visible signs of moisture may be indicative of a sterilization process failure and may impact barrier performance of the container. If this occurs, it is recommended to repackage and re-sterilize with a longer dry time.

Limits of reuse: If visible signs of wear are present, such as cracking, peeling, rust/corrosion or discoloration, the Container should be discarded.
PRE-VACUUM IMMEDIATE USE STEAM STERILIZATION: Use vented or solid base Container for pre-vacuum steam “IUSS” sterilization. IUSS sterilization is for immediate use only. Moisture may occur in IUSS cycles.

Caution: Use a glove or towel when transporting hot items from the autoclave. Recommended exposure time: 4 minutes at 270°F (132°C) with 0-3 min dry time. User may add additional dry time for a drier outcome. Disposable paper filter SCF01 (7.5” diameter) and SCFM01 (10”X4”) are supplied nonsterile.

Note: The user should contact their device manufacturer for appropriate (extended) sterilization cycle conditions. (ANSI/AAMI ST 79:2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities).

TABLE TOP PRE-VACUUM STEAM STERILIZATION: SteriTite® Containers can be used in small table top sterilizers with dynamic air removal. Container sizes are limited due to the small chambers of the table top sterilizers.

GRAVITY DISPLACEMENT STEAM PARAMETERS FOR USE: Use **only perforated base** Containers for gravity displacement steam. Use MediTray basic trays. Select the appropriate exposure time based on load and size of container. Recommended minimum exposure time: 30 minutes at 250°F. Use of sealed Containers may require additional exposure time in gravity displacement steam.
Stack ability of SteriTite® Containers in Steam Sterilization: Up to three (3) Containers can be stacked and processed in the autoclave.

WARNING: Prepare complex instruments according to the instrument maker's instructions. Use of nonabsorbent tray liners can cause condensate to pool. Do not use peel pouches within sealed containers, as they cannot be placed on their side for sterilization.

SteriTite® Labeling for FlashTite®
DEVICE DESCRIPTION: The SteriTite® Container may be used as a filter-less sterilization packaging system when FlashTite valve plate(s) are utilized for steam sterilization. The FlashTite valve plate(s) are attachments to the SteriTite® rigid reusable sealed Container for pre-vacuum IUSS (flash) and gravity displacement IUSS (flash) steam sterilization cycles and are used in place of a disposable filter and its associated filter retention plate(s).
INTENDED USE: The SteriTite® sealed Container with FlashTite valve plate(s) is intended to be used for sterilization of one instrument or instrument set in immediate IUSS sterilization.
Note: Flashed items are for immediate use only, per AAMI guidance. Product was tested for sterility maintenance for 24-hour shelf life. The FlashTite valve is recommended for one (1) year of use or 400 cycles. Record date of first use for your records.
LOAD: The contents must be placed within an instrument basket or tray. FlashTite systems for gravity displacement steam sterilization require a load restricting basket designed to clear the FlashTite valves placed on the lid and on the base. Either perforated bottom or solid bottom SteriTite® Containers may be used with FlashTite valve plate in pre-vacuum IUSS sterilization. Use MediTray® basic trays for IUSS sterilization cycles. The SteriTite® solid bottom Containers including 4" high models may be used for IUSS sterilization with FlashTite valve plate(s) in lid.

FLASHTITE PARAMETERS FOR USE:
Pre-vacuum Immediate Use Steam Sterilization (IUSS): Use either vented or solid base Container with the same number of FlashTite valve plate(s) as the number of vents. Recommended parameters are 4 minutes exposure at 270°F (132°C). Recommended dry time for SteriTite® Container with FlashTite valve plate(s): 0- 3 minutes dry time in the autoclave for items processed in IUSS (flash) sterilization depending on the degree of dryness required. Clean with pH neutral detergent, rinse and dry after each use. To assemble FlashTite valve rotate the latch clockwise. To remove rotate latch counter clockwise.

Gravity Displacement IUSS Sterilization: Use only perforated bottom container. Attach FlashTite valve plate(s) over all vents. No filter is used. Recommended parameters are a minimum of 5 minutes exposure for non-porous items at 270°F (132°C) and minimum of 10 minutes exposure for porous items, lumens and mixed loads at 270°F (132° C). Recommended dry time: 0- 3 minutes dry time in the autoclave for items processed in flash sterilization depending on the degree of dryness required.

Note: Do not use the FlashTite valve with SteriTite® perforated bottom models SC04HG, SC04QG and SC04FG, because of height restrictions within these containers. Do not use solid bottom SteriTite® Container with FlashTite valve in gravity displacement IUSS sterilization.

FLASHTITE REPROCESSING INSTRUCTIONS:
After each use, disassemble and decontaminate the FlashTite valve plate with a multi-enzymatic, pH neutral detergent as you would any SteriTite® component part. Thoroughly rinse and dry.
Note: The copper module within the FlashTite valve mechanism will darken over time. This color change will not impact the safety and effectiveness of the device.

Refer to the sterilizer manufacturer's "Instructions for Use" for specific information as to the limitations of instrumentation, specifications and material compatibility. Complex instruments should be prepared and sterilized according to the instrument manufacturer's instructions. Contact the manufacturer of your endoscope or lumened devices when flashing.

Caution: When abbreviated dry time is implemented, moisture is present. Use a glove or towel when transporting hot items from the autoclave. Do not mix the FlashTite valve plate(s) with the filter retention plate(s) and disposable filter(s). Do not use the FlashTite valve plate(s) for EO or other low temperature sterilizers including gas plasma (STERRAD) sterilization.

Note: For low temperature sterilizers refer to the information provided below.

SteriTite® Labeling for Low Temperature Sterilization
Intended Use: Low temperature sterilization is utilized for moisture and temperature sensitive devices. Each sterilization modality has specific cycles and cleared for devices that are deemed compatible. Review the cycle parameters and compatibility statement from the sterilizer and device manufacturer. SteriTite Containers and MediTray products are universal reusable sterilization packaging systems validated for compatibility with low temperature sterilizers and for devices such as instrumentation including flexible endoscopes as follows:

STERRAD PARAMETERS FOR USE:
Use nonwoven polypropylene disposable filters: PolyPro filter # SCF02 (7.5" diameter) and SCFM02 (10"X4") are a disposable filter supplied non-sterile. In STERRAD 100, 100S & 200 process only stainless steel lumened instruments of 3mm diameter or larger and a length up to 400 mm. In STERRAD NX standard cycle, process stainless steel lumened instruments of 2mm diameter or larger and up to 400 mm in length. In STERRAD NX advanced cycle, process stainless steel lumened instruments of 1mm diameter or larger and up to 500 mm in length and porous lumens (flexible endoscope) of 1mm diameter or larger and up to 850 mm in length. In the STERRAD 100NX Standard cycle, process stainless steel lumened instruments of 0.7mm diameter or larger and up to 500mm in length. In STERRAD 100NX Flexible cycle, process flexible endoscopes, and lumened instruments of > 1.2mm x < 835 mm. STERRAD Systems have pre-programmed cycles for each unit.
Cycle time: The sterilizer manufacturer determines STERRAD® Sterilization cycle time.
Caution: In STERRAD® Sterilization do not use materials made of cellulose (paper filters and cotton) with SteriTite® containers.

Compatibility: In STERRAD® Sterilization use only compatible materials and instruments as stated in the Reference STERRAD® Operating Manual. Consult with your instrument manufacturer as to the compatibility of various materials in STERRAD ® Sterilization. Refer to STERRAD® System Operating Manual, instructions for use and labeling.

Internal Stacking: MediTray® baskets and trays may be stacked within the SteriTite® Container system as follows: In STERRAD NX up to two (2) instrument baskets or trays may be stacked within the SteriTite® container. In the STERRAD 200 up to four (4) instrument baskets or trays may be stacked. In STERRAD 200 & NX, the following MediTray baskets are not intended to be stacked: BSKF04, BSKF06, BSKH04, BSKQ04, and BSKQ06. In addition, MediTray® insert boxes are not intended to be stacked. Case Medical recommends that its Containers be placed flat on the sterilizer shelf.
External stacking was not tested. For STERRAD 100, 100S, 200 & 100NX: All models of SteriTite Containers can be placed on each of the two shelves within the STERRAD® 200. However, only one shelf can be used to accommodate an 8" high perforated base SteriTite® container, because of height restrictions within the sterilizer's chamber. For STERRAD NX only 2",3" and 4" high Containers will fit in the sterilizer chamber.

MediTray® Products including MediTray® inserts, instrument baskets, stacking trays, BackBone silicone brackets, stainless and aluminum brackets, posts and partitions may be used in STERRAD Sterilization, wrapped or containerized. Utilize white tamper evident seals, Polypro filters and load cards available from Case Medical for H2O2 sterilization.

Caution: Do not use nylon coated brackets or silicone mat. Do not use saline-based water softener for the final rinse as it causes corrosion and aborted cycles. Do not use alkaline cleaners to decontaminate the Container as it causes corrosion and aborted cycles.

EO PARAMETERS FOR USE:
EO Sterilization: SteriTite® Containers with disposable filter may be used in EO sterilization for sterilization of blades and lumens. Solid bottom Containers may be used in EO pre-vacuum sterilizers.
Residual analysis shows that EO and EC limits were found to be well below maximum limits after 12 hours post aeration at room temperature.
Recommended exposure time in 600 mg/liter EO gas mixture (90% CO2 / 10% EO) - 2 hours.
230 mg/liter EO gas mixture (91.5% CO2 / 8.5% EO) - 3 hours.
In EO sterilization, metal lumened devices of 2.2mm diameter or larger and length up to 457 mm and porous lumened devices of 3mm diameter or larger and length up to 400 mm may be processed. Contact your medical device manufacturer for specific processing information.
Stacking of SteriTite® Containers in EO sterilization: Up to three (3) SteriTite® Containers can be stacked and processed in the sterilizer.

Note: Polymeric and porous materials may require extended EO exposure time. Items with lumens should be thoroughly dried for EO sterilization.

TSO3 STERIZONE PARAMETERS FOR USE:
Use non-woven polypropylene disposable filters: Disposable nonwoven filter # SCF02 (7.5” diameter) and SCFM02 (10”X4”) are a single use disposable filter supplied nonsterile.
Use vented or solid base Container for STERIZONE® VP4 sterilization. Use MediTray® products in the Container to secure instrumentation. Recommended for sterilization of medical devices, including flexible endoscopes, full instrument sets and mixed loads, including general instrumentation (gliding mechanism, hinges & screws, stopcock, lure-lock), instruments with rigid lumens (no dead-end) and rigid non-lumened scopes. Sterilize instruments with diffusion restricted areas such as the hinged portion of forceps and scissors and medical devices, including single/multi-channel rigid endoscopes with an internal diameter of 0.7mm or larger and a length of 500mm or shorter (up to twelve rigid channels in the presence of other packaged medical devices). Sterilize up to three single channel surgical flexible endoscopes (one per container, three Containers per load) with an internal channel diameter of 1.0mm or larger and a length of 850mm or shorter.
Cycle time: The sterilizer manufacturer determines STERIZONE® VP4 Cycle 1 Sterilization cycle parameters. The cycle has a phase of hydrogen peroxide vapor exposure and one of hydrogen peroxide reduction using Ozone.
Internal Stacking: Testing was done with up to four (4) stacked trays or baskets inside the containers.
Compatibility: Use only compatible materials and instruments as stated in the STERIZONE® VP4 Operating Manual.

Compatibility: Consult with your instrument manufacturer as to the compatibility of various materials in STERIZONE® VP4 Sterilization. Refer to TSO3 System Operating Manual instructions for use and labeling.

Caution: Do not use saline-based water softener for the final rinse as it causes corrosion and aborted cycles. Do not use alkaline cleaners to decontaminate the Container as it causes corrosion and aborted cycles.

STERIS V-PRO PARAMETERS FOR USE: The SteriTite Container system is intended for use in Steris V-Pro1, V-Pro1 Plus, and V-Pro Max. The container system is validated for a maximum load of 31 lbs. including container and contents. Use non-woven polypropylene disposable filters: Disposable nonwoven filter # SCF02 (7.5" diameter) and SCFM02 (10"X4") are a single use disposable filter supplied nonsterile.

Sterilize only stainless steel lumened instruments of 3mm or larger and a length of 400mm or shorter for a maximum of 20 lumens per load in the Container.
Flexible endoscopes with load may be processed in Flex cycles when one flexible endoscope has an inside diameter of 1mm or larger and a length of 1050mm. Two flexible endoscopes may be sterilized if no additional load is present. Two shorter endoscopes may be processed at once, when one has an inside diameter of 1mm or larger, and a length of 998mm or shorter and the second one has an inside diameter of 1mm or larger and a length of 850mm or shorter.
Stacking of SteriTite® Containers in Steris V-PRO: MediTray® baskets and trays may be stacked within the SteriTite® Container system as follows: up to two (2) instrument baskets or four (4) trays may be stacked.

Caution: Stacking SteriTite® Containers stacking in Steris V-PRO is not recommended. All models of SteriTite® Containers can be placed on each of the two shelves within the V-PRO low temperature Sterilization System. However, only one shelf can be used to accommodate an 8" high perforated base SteriTite® container, because of height restrictions within the sterilizer's chamber.
MediTray® Products including MediTray® inserts, instrument baskets, stacking trays, BackBone silicone brackets, stainless and aluminum brackets, posts and partitions may be used in V-PRO Sterilization System.
Compatibility: In V-PRO sterilization use only compatible materials and instruments as stated in the V-PRO sterilization system operating manual. Consult with your instrument manufacturer for the compatibility of various materials in V-PRO Sterilization System. Refer to V-PRO Sterilization System Operating Manual, instructions for use and labeling.

Caution: Do not use nylon coated brackets or silicone mat. Do not use saline based water softener for the final rinse as it causes corrosion and aborted cycles. Do not use alkaline cleaners to decontaminate the Container as it causes corrosion and aborted cycles.

SteriTite® at Point of Use
1. Before opening the SteriTite® Container verify that: The tamper-evident seals are intact, the disposable filter is in place (visible through the perforations), the acceptability of the end point response of the external chemical indicator or load card, and that the correct set has been selected.
2. Break open the tamper evident seals, remove and discard.
3. Unlatch the Container by pulling upward to release. (The latches will fall away from the Container edge to avoid recontamination of contents.)
4. Remove the lid, using the rings on the top of the lid to avoid contaminating the contents of the container.
5. The scrub person should check the end point response of the chemical indicator to verify acceptable results.
6. The scrub person will then remove the basket or baskets of instruments in a straight upward position and then place in the sterile field.

Note: MediTray® baskets and inserts are designed for aseptic removal of contents.

7. At the completion of the procedure, the SteriTite® Container can be used to contain and transport contaminated instruments to the decontamination area.
Caution: Case Medical recommends that SteriTite® Containers sterilized in an outside contract facility should be double wrapped in plastic bags during transport.

Procedures for Checking Sterility Maintenance at Point of Use

1. Ensure that a filter has covered all perforation in lid and or base.
2. Check that filter retention plate is securely placed over filter.
3. Gasket should be engaged in its lid channel.
4. Container edge is free of dents or damage.
5. Check that the internal and external chemical indicator is present per hospital protocol.
6. Check that there is no residual moisture in the container.

Endpoint color change
The SteriTite® Container provides a location in the label holder for a chemical process indicator card to differentiate a processed from unprocessed load. For steam and EO sterilization, the tamper evident seal contains a process indicator. In steam sterilization, the color change is from cream to brown and in EO cream to orange. In STERRAD Sterilization, the color change on the load card is red to orange/yellow.

MediTray® Labeling
The MediTray® System combines unbeatable protection of sensitive instrumentation with maximum convenience. Use the inserts for the MediTray® system and the SteriTite® sealed Container system. MediTray® cases and covers must be wrapped or placed in a sealed Container for sterilization.

INTENDED USE: MediTray® is intended to be used for the sterilization of reusable surgical instruments and medical devices in health care facilities. MediTray® products may be containerized or wrapped with an FDA cleared medical wrap. Please refer to the recommendations of your sterilizer manufacturer for specific reprocessing instructions as well as recommendations from your medical device manufacturer for material compatibility and requirements for extended sterilization cycles. Note: MediTray® products may be used in steam, and low temperature sterilization, including EO, V-Pro, STERIZONE and H2O2 gas plasma (STERRAD) Sterilization.

REPROCESSING INSTRUCTIONS
Thoroughly clean and decontaminate MediTray® products prior to use. Use only pH neutral enzymatic cleaners and detergents. Abrasive cleaners, abrasive pads, or metal brushes cannot be used. MediTray® baskets and trays are recommended for automatic cleaning cycles. Be sure to follow all cleaning steps with a thorough rinse. Case Medical recommends its pH neutral Case Solutions and SuperNova cleaners for decontamination of medical devices including MediTray® and SteriTite® products. Dry product thoroughly before sterilization or further processing. A lint free cloth may be used for the drying process.

Warning: Use of a caustic cleaner can damage the anodized surface of aluminum devices and may cause corrosion. This practice will void the company's warranty.

ASSEMBLY: All MediTray® baskets, trays, and case-trays are designed with a unique patented grid pattern allowing for ease of assembly. BackBone® silicone brackets can be used to elevate and secure surgical instruments.

For delicate instruments which require a firm yet cushioning grip, use BackBone® silicone brackets with patented inner spine. BackBone® brackets have snap-in feet which attach securely to the base of your MediTray® basket, tray, or case-tray, without the need for tools. To remove a BackBone Bracket, push over with your fingers or palm to remove. If necessary, compress the snap-in feet on the underside with the MediTray® post tool or needle-nose pliers. MediTray® metal brackets, partitions, and posts are secured with threaded nuts.

Case Medical provides a full range of disposables for use with its SteriTite, universal container. To order the appropriate consumables, review the information below.

SCS01:SteriTite® Tamper-Evident Seals
Disposable plastic lock available in blue or red with chemical indicator dot for steam and EO. White seals are recommended for hydrogen peroxide and gas plasma.

SCF01:SteriTite® Disposable Paper Filters 7.5" round
100% Cellulose for steam sterilization

SCFM01:SteriTite® Disposable Paper Filters 10" X 4" Rectangular.
100% Cellulose for steam sterilization

SCF02:SteriTite® Polypro Disposable Filters 7.5" Round
Non-woven polypropylene for pre-vac steam, H2O2 and gas plasma sterilization

SCFM02:SteriTite® Polypro Disposable Filters 10" X 4" Rectangular
Non-woven polypropylene for pre-vac steam, H2O2 and gas plasma sterilization

SCL01:SteriTite® Dual Process Indicator Cards
ID card with a dual chemical indicator. Use for steam and EO sterilization

SCL02:SteriTite® Dual Indicator Cards, Small
ID card with a dual chemical indicator. Use for steam and EO sterilization

SCI001:SteriTite® Dual Process Indicators
ID card with a dual chemical indicator. Use for steam and EO sterilization

SCLH2023:SteriTite® H2O2 Load Cards
ID card with chemical indicator. Use for H2O2 and gas plasma sterilization

SCLH2024:SteriTite® H2O2 Load Cards, Small
ID card with chemical indicator. Use for H2O2 and gas plasma sterilization **SCKIT1BP:SteriTite® Steam and Gas Disposable Kit (Standard)** 3 pack paper filters, 1 pack seals, 1 pack load card

SCKIT2BP:SteriTite® Steam and Gas Disposable Kit
(Mini/Narrow) 1 pack paper filters, 1 pack seals, 1 pack load card

SCKIT1WN:SteriTite® H2O2 Disposable Kit (Standard) 3 pk Polypro filters, 1pk seals, 1pk load card

SCKIT2WN:SteriTite® H2O2 (Mini/Narrow) 1 pk Polypro filters, 1pk seals, 1pk load card

Best Practice Maintenance Procedures at Point of Use

1. All paper and polypropylene filters, tamper evident seals, and load cards are a one-time use item, use a new filter, seal and load card each time a SteriTite® container is placed into service. Please dispose of all one-time use items properly and in accordance with all local rules and regulations regarding medical waste recycling and/or disposal.

2. When placing a SteriTite® container into service, check that:
   A) All filter retention plates are securely placed over a NEW filter.
   B) Gasket should be engaged in its lid channel.
   C) Container edge is free of dents or damage.
   D) Container body and lid are free of mechanical damage and corrosion.
   E) All latches close securely with an audible click.

3. Containers whose protective anodized layer has been stripped by harsh chemical cleaning should be retired as "Not Repairable". Please dispose of all SteriTite® containers properly and in accordance with all local rules and regulations regarding medical waste recycling and/or disposal.

4. Containers whose mechanical latches no longer lock with an audible click should be returned for evaluation and repair as soon as possible. If deemed "Not Repairable", please dispose of all SteriTite® containers properly and in accordance with all local rules and regulations regarding medical waste recycling and/or disposal.

5. Containers which have sustained mechanical damage and denting should be returned for evaluation and repair as soon as possible. If deemed "Not Repairable", please dispose of all SteriTite® containers properly and in accordance with all local rules and regulations regarding medical waste recycling and/or disposal.

   Note: SteriTite® containers are made of highly recyclable aluminum and stainless steel but should always be disposed of in accordance with all local rules and regulations regarding medical waste recycling and/or disposal.

Case Medical

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