**SteriTite® - The Container System of Choice**

**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**
  (1000 per case) Disposable plastic “pad” lock available in blue with chemical indicator dot for steam and EtO, and red for flash sterilization. White seals are recommended for hydrogen peroxide, STERRAD, V-Pro and Sterizone.

- **SCF01: SteriTite Disposable Paper Filters**
  (1000 per case) 100% Cellulose and water repellent. For steam sterilization. 7.5” round with positioning hole.

- **SCFM01: SteriTite Disposable Paper Filters**
  (1000 per case) 100% Cellulose and water repellent. 10” X 4” Rectangular. For steam sterilization.

- **SCF02: SteriTite Polypro Disposable Filters**
  (1000 per case) Hydrophobic non-woven polypropylene, highly recommended for use for pre-vac steam, gas, hydrogen peroxide and STERRAD sterilization. 7.5” Round.

- **SCFM02: SteriTite Polypro Disposable Filters**
  (1000 per case) Hydrophobic non-woven polypropylene, highly recommended for use for use for pre-vac steam, gas, hydrogen peroxide and STERRAD sterilization. 10” X 4” Rectangular.

- **SCL01: SteriTite Dual Process Indicator Cards**
  (1000 per case) ID card with a dual chemical indicator. For steam and EO sterilization.

- **SCL02: SteriTite Dual Indicator Cards, Small**
  (1000 per case) ID card with a dual chemical indicator. Use with SC02,3,4M(G), SC02,3N(G) & to lock MediTray case trays. Use for steam and EO sterilization.

- **SC1001: SteriTite Dual Process Indicators**
  (1000 per case) A dual process indicator strip with room for process identification. Use for steam and EO sterilization. 8” Long with perforation may be reconfigured to two 4” long indicator strips. Place in opposing corners of inner tray.

- **SCHL2023: SteriTite H2O2 Load Cards**
  (1000 per case) ID card with chemical indicator. Use for STERRAD and V-Pro Sterilization and Sterizone.

- **SCHL2024: SteriTite H2O2 Load Cards, Small**
  (1000 per case) ID card with chemical indicator. Use for STERRAD and V-Pro Sterilization and Sterizone. Use with SC02,3,4M(G), SC02,3N(G), & to lock MediTray case trays.

- **SCKIT1BP: SteriTite Disposable Kit**
  Steam and Gas Disposable Kit (Standard) 3 pk paper filters, 1 pk seals, 1 pk load card

- **SCKIT2BP: SteriTite Disposable Kit**
  Steam and Gas Disposable Kit (Mini/Narrow) 2 pk paper filters, 1 pk seals, 1 pk load card

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

- **SCKIT2WN: SteriTite Disposable Kit**
  H2O2 Disposable Kit (Mini/Narrow) 2 pk Polypro filters, 1 pk seals, 1 pk load card

If you have any questions regarding Case Medical products, please contact us at Phone: (201)-313-1999 Fax: (201) 373-9090
Info@casemed.com or www.casemed.com
19 Empire Blvd, South Hackensack, NJ. 07606
Product Warranty

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.

THE SteriTite® SYSTEM WARRANTY

Case Medical, Inc.’s SteriTite® product line 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 following exclusions apply to the MediTray® and SteriTite® product line replacement warranty:

• Damage due to the use of caustic or abrasive cleaning agents.
(Rrefer 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.
(Rrefer 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 or product complaint:
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.

Non-refundable 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.

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.

THE MediTray® SYSTEM WARRANTY

Case Medical’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 years from the date of delivery at no charge to the customer.

DEVICE DESCRIPTION: MediTray® is a rigid, reusable, medical sterilization packaging system validated for steam and low temperature sterilization systems.

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 a 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, ETO, ozone, V-Pro and H2O2 gas plasma (STERRAD) Sterilization. Caution: Nylon coated parts, color anodized parts and silicone mats are not recommended for STERRAD Sterilization.

REPROCESSING INSTRUCTIONS

Thorougly clean and decontaminate MediTray® products prior to use. Use only pH neutral 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.

All MediTray® baskets, trays, and case-trays are designed with a unique patented grid pattern allowing for easy interchanging all inserts. 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 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.

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If you have any questions regarding Case Medical products, contact us at info@casemed.com or call (201) 313-1999
**SteriTite® - The Container System of Choice**

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” and “Containment devices for reusable medical device sterilization”.


AAMI STANDARDS ORDER CODE: www.aami.org/publications/standards/index.html

The SteriTite sealed container and MediTray products are a universal, reusable packaging system with FDA 10k 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, EO, H2O2 sterilization including STERRAD 100, 100S, 200, NX, 100NX, AMSCO V-Pro 1, V-Pro 1 Plus, V-Pro maX, as well as STERIZONE® 12L, and sealed immediate use steam sterilization. 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 TS03 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.

**SteriTite® Labeling for Amsco V-PRO Low Temperature Sterilization System**

DEVICE DESCRIPTION: The SteriTite® container is a rigid, reusable, sealed medical sterilization packaging system.

INTENDED USE: The SteriTite universal container system with MediTray products is a reusable sterilization container system used to enclose other medical devices, which are to be sterilized, transported and stored by a health care provider. The SteriTite container system is intended for use in Steris Amsco V-Pro1, V-Pro1 Plus and V-Pro maX low temperature sterilization system. Please refer to the recommendations of the sterilizer manufacturer for specific processing instructions and to your medical device manufacturer for material compatibility.

LOAD: The contents must be placed within an instrument basket or tray. Leave 1” of clearance in container. (for example 3” high basket may be placed within a 4” high container). Case Medical validated maximum load of 31.36lbs including container and contents. AAMI recommends a maximum of 25lbs total weight.

Note: All containers for Steris Amsco V-PRO low temperature Sterilization System are perforated bottom containers, which must be used with the single-use non-woven Polypropylene filter. All MediTray products excluding nylon coated brackets and silicone mats are compatible with V-PRO H2O2 sterilization.

PARAMETERS FOR USE:

Use nonwoven polypropylene disposable filters: Disposable nonwoven Filter @ SCF02 (7.5” diameter) and SCFM02 (10”X4”) are a single use disposable medical device supplied nonsterile. In Non-lumen cycles, validation testing was performed with non-lumened instruments including non-lumened rigid endoscopes and non-lumened hinged instruments like forceps or scissors. In Lumen cycles, validation testing was performed with blades and lumens. Only stainless steel lumened instruments of 1mm or larger and a length of 400mm or shorter for a maximum of 20 lumens per load should be processed. In Flexible cycle, validation testing was performed with single or dual lumen surgical flexible endoscopes in either of two load configurations (per sterilizer manufacturer instruction): a. Two flexible endoscopes and no additional load, each having either a single lumen with a minimum inside diameter of 1mm and a maximum length of 1050mm; two lumens with one having an inside diameter of 1mm or larger and a length of 998mm or shorter and the second one an inside diameter of 1mm or larger and a length of 850mm or shorter.

b. One flexible endoscope and load, each having either: a single lumen with an inside diameter of 1mm or larger and a length of 1050mm or shorter two lumens with one having an inside diameter of 1mm or larger and a length of 998mm or shorter and the second one an inside diameter of 1mm or larger and a length of 850mm or shorter.

Adequate sterilant penetration and barrier properties were demonstrated using the SteriTite® rigid reusable container system and MediTray products in the Steris Amsco V-PRO low temperature Sterilization System under half cycle and fractional studies.

**Stackability of SteriTite® Containers in Steris Amsco 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: External stacking was not tested. Stacking SteriTite containers on top of each other in Steris Amsco V-PRO is not recommended. Placement of SteriTite® Containers in V-PRO low temperature Sterilization System: Case Medical recommends that its containers be placed flat on the sterilizer shelf. 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.

Caution: 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 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® 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 for the first time follow the cleaning procedures in this IFU and perform a visual inspection of all parts.

Cleaning and Decontamination

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 automated washer. When using an automated washer, place filter retention plates in an instrument basket for cleaning.

4. Remove all detergent residue with a thorough rinse. If visible moisture is present, dry with a lint free cloth.

5. Examine each component for cleanliness.

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. Try to avoid water collection by washing and drying the container upside-down.

Recommendation: Case Solutions or SuperNova multi-enzyme cleaners are ideal for medical devices and sterilization containers. In addition, single use enzymatic towelettes such as Penta Wipes can be used to decontaminate container components and Alcohol Wipes facilitate drying.

Automated Cleaning:

SteriTite containers may be cleaned in automated washers or cart washers when pH neutral detergents or enzymatic cleaners are used. Always follow with a thorough rinse to remove detergent residue. 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.

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

SteriTite® Labeling

for SteriTite with disposable filter in TSO3 Sterilizers

DEVICE DESCRIPTION: The SteriTite® container is a rigid, reusable, sealed medical sterilization packaging system.

INTENDED USE: The SteriTite® container system is intended for use in TSO3’s STERIZONE® VP4 sterilizer and 125L Ozone Sterilizer for sterilization of reusable surgical instruments and medical devices in health care facilities. MediTray® containers may be wrapped or sterilized in STERIZONE® VP4 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.

LOAD: The contents must be placed within an instrument basket or tray. Load may be distributed in layers using MediTray baskets and trays. Leave 1” of clearance in container. Case Medical validated maximum load of 25 lbs in STERIZONE® VP4 and 22 lbs in 125 Ozone sterilizer (load included container and contents). AAMI recommends a maximum of 25 lbs total weight.

STERIZONE® VP4 Cycle 1 sterilization:

PARAMETER FOR USE: Use vented or solid base container for STERIZONE® VP4 Cycle 1 sterilization. Use MediTray products in the container to secure instrumentation. Recommended for sterilization of medical devices, including full instrument sets and mixed loads:

- 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 par 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. Use nonwoven polypropylene disposable filters (#SCFO2 (7.5” dia) and SCFM02 (10”X4”) supplied non-sterile).
- Internal Stacking: Testing was done with up to four (4) stacked trays or baskets inside the containers. Adequate sterilant penetration and barrier properties were demonstrated using the SteriTite® rigid reusable container system and MediTray products in the STERIZONE® VP4 Sterilization System under half cycle.

125L Ozone Sterilization

PARAMETER FOR USE: Use vented or solid base container for 125L Ozone sterilization. Use MediTray products in the container to secure instrumentation. Recommended for sterilization of medical devices, including blades, and stainless steel lumened instruments of 3mm diameter or larger and a length up to 470 mm. Do not use silicone mats as it was not designed for this purpose. Slight discoloration with our device may occur in 125L Ozone sterilization. Use paper or nonwoven disposable filters for 125L Ozone sterilization.

- Steralize instrum ents 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 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. Use nonwoven polypropylene disposable filters (#SCFO2 (7.5” dia) and SCFM02 (10”X4’)) and propylene filters (#SCFO2 (7.5” dia) and SCFM02 (10”X4’)) are disposable medical device supplied non-sterile.
- Stackability of SteriTite® Containers in 125L Ozone Sterilization:
  - External Stacking: Up to three (3) containers can be stacked and processed in the 125L Ozone Sterilizer.
  - Internal Stacking: Testing was done with up to three (3) stacked trays or baskets inside the containers. Adequate sterilant penetration and barrier properties were demonstrated using the SteriTite® rigid reusable container system and MediTray products in the 125L Ozone Sterilization System under half cycle and fractional studies.

EVENT RELATED STERILITY MAINTENANCE DATA: SteriTite containers are event related and maintain sterility during transport and multiple handling events provided that the integrity of the seal is not broken. The SteriTite containers sterilized in STERIZONE® VP4 sterilization (Cycle 1) maintained sterility after a six month (180 days) real time with handling events. Note: The user should contact their device manufacturer for appropriate sterilization cycle conditions (ANSI/AAMI ST 79:2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities).

Caution: use only compatible materials and instruments as stated in the STERIZONE® VP4 and Ozone 125L Operating Manual. Specifically: Consult with your instrument manufacturer as to the compatibility of various materials in STERIZONE® VP4 and Ozone 125L Sterilization. Refer to TSO3 System Operating Manual instructions for use and labeling. MediTray Products including MediTray inserts, instrument baskets, stacking trays, BackBone silicone brackets, stainless and aluminum brackets, posts and partitions may be used in 125L Ozone Sterilization. Caution: Do not use nylon coated brackets or silicone mat in STERIZONE® VP4 hydrogen peroxide and 125L ozone sterilization.

VALIDATION TESTING: Case Medical subscribes to the overkill principle. SteriTite and MediTray products are validated under fractional and half cycle conditions.
**SteriTite® Labeling**

**for EO Sterilization using disposable filter**

**DEVICE DESCRIPTION:** The SteriTite® container is a rigid, reusable, sealed medical sterilization packaging system.

**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. MediTray product may be containerized or wrapped with a 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.

**LOAD:** The contents must be placed within an instrument basket or tray. Load may be distributed in layers using MediTray basic trays. Leave 1” of clearance in container. Case Medical validated maximum load of 22lbs including container and contents. AAMI recommends a maximum of 25lbs total weight.

**PARAMETERS FOR USE:**

**EO Sterilization:** SteriTite containers 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. Polymeric and porous materials may require extended EO exposure time.

Items with lumens should be thoroughly dried for EO sterilization. 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.

**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.

**Stackability of SteriTite® Containers in EO sterilization:** Up to three (3) SteriTite containers can be stacked and processed in the sterilizer.

**VALIDATION TESTING:** Case Medical subscribes to the overkill principle. SteriTite and MediTray products are validated in independent laboratories under fractional and half cycle conditions.

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**SteriTite Assembly 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.

**Note:** Testing has been completed by Case Medical, Inc® that verified gasket function after 501 cycles in STERRAD® 100NX® Sterilizer and 1000 cycles in steam sterilization.

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.

**Note:** Some rotation of the circular retention plate is a natural occurrence when the filter is in place.

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. For SteriTite® Universal 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 EtO sterilization. Non-woven Polyprop filters must be used for H2O2 STERRAD and V-Pro sterilization.

6. Select the appropriate size basket(s) or tray(s) according to container size. Arrange the clean instruments in the basket(s) according to hospital procedures. Review the recommendations provided by the device manufacturer. MediTray® partitions, brackets and posts are recommended for easy loading and unloading as well as protection of your delicate instruments. Place the prepared baskets into the base of the SteriTite® container.

**Note:** Do not exceed the height of the basket when placing instruments into the basket. 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 validated its SteriTite container system for stacking multiple layers within the container. The use of absorbent liners are not recommended for use with the SteriTite container.

7. Place a process indicator or integrator in the corner of the instrument basket.

**Note:** An internal process indicator should be used within each container. It should be placed 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 likeliest locations for air pockets.

**Note:** Rectangular filters should only be used for the rectangular filter retention plates. The round filters should be used for the round filter retention plates.
**SteriTite® Assembly for Use:**

8. Place the lid on top of the base. The edge of the base will fit in the lid channel creating a knife edge fit.

9. 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.

10. 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.

11. 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.

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 (STERRAD and V-Pro) sterilization. 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. If sterilized in a mix load, place containers below wrapped or linen items.

12. 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 in containers, crack the door of the autoclave for 15 mins.

**Caution:** Use of the SteriTite container in gravity displacement steam sterilization may increase exposure time for 15 mins. Then remove for cool down.

13. Following the steam sterilization process, the cart should be removed from the autoclave and placed in cool down. For low temperature sterilization modalities remove the container from the sterilizer and place in the storage area.

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**SteriTite® Labeling for Immediate Use Sterilization using FlashTite valve plate(s)**

**DEVICE DESCRIPTION:** The FlashTite valve plate(s) are attachments to the SteriTite rigid reusable sealed container for pre-vacuum flash and gravity displacement flash steam sterilization cycles.

**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 flash sterilization.

**NOTE:** Flash 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. Use MediTray basic trays for flash sterilization cycles. The SteriTite solid bottom containers including 4” high models may be used for flash sterilization with FlashTite valve plate(s) in lid.

**PARAMETERS FOR USE:**

**Pre-vacuum Immediate Use Sterilization:** 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 flash sterilization depending on the degree of dryness required.

**Gravity Displacement IUSS Sterilization:** Use only perforated bottom container. Attach FlashTite valve plate(s) over all vents. 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, SC04G and SC04FG, because of height restrictions within these containers. Do not use solid bottom SteriTite container with FlashTite valve in gravity displacement IUSS sterilization.

**Important:** Clean after each use with pH neutral detergent.

**Note:** “The evaluation of the container/sterilizer combination is especially important in gravity displacement steam sterilization because of the relative inefficiency of air removal in this sterilization process. The user must review the data upon which the container manufacturer bases the recommended cycle time and must verify those results in the hospital’s sterilizer.” ANSI/AAMI ST79: 2010/2011.

**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 gas plasma (STERRAD) sterilization.

**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.

**Case Medical recommends that:** A chemical indicator or integrator should be placed in every container for processing. Within the sealed container, place indicator in opposing corners. Case Medical recommends use of the 3M rapid read out biological indicator for verification.

**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.

**VALIDATION TESTING:** Case Medical subscribes to the overkill principle. SteriTite and MediTray products are validated in independent laboratories under fractional and half cycle conditions.
SteriTite® Labeling for STERRAD Sterilization using disposable PolyPro filter

DEVICE DESCRIPTION: The SteriTite® container is a rigid, reusable, sealed medical sterilization packaging system.

INTENDED USE: The SteriTite® container system is intended for use in STERRAD 100, 100S, 200, STERRAD NX and 100NX sterilizers for the sterilization of reusable surgical instruments (blades and lumens) and for medical devices in health care facilities. MediTray products may be containerized or wrapped with a FDA cleared medical wrap. Please refer to the recommendations of your sterilizer manufacturer for specific processing instructions and to your medical device manufacturer for material compatibility.

LOAD: The contents must be placed within an instrument basket or tray. Leave one (1) inch of clearance in container. Case Medical recommends a maximum of 31.95 lbs including container and contents. AAMI recommends a maximum of 25lbs total weight. For STERRAD 100, 100S, 200, NX and 100NX use only perforated base SteriTite® containers with polypropylene filter.

Note: For STERRAD 100, 100S, 200, 100NX all models of SteriTite perforated bottom sealed containers may be used except for the SC05WG, SC04MG and SC06LG which does not fit the STERRAD chamber. For STERRAD NX Sterilization only the SC02MG, SC03MG, SC04MG, SC02NG, SC03NG, SC04HG, SC04QG and SC04FG containers can be used due to STERRAD NX size.

PARAMETERS FOR USE:

Use nonwoven polypropylene disposable filters: PolyPro filter # SCF02 (7.5” diameter) and SCFM02 (10”X4”) a medical device supplied nonsterile. 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. 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, PU/PTFE 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.

Caution: In STERRAD® Sterilization use only compatible materials and instruments as stated in the STERRAD® Operating Manual. Consult with your instrument manufacturer as to the compatibility of various materials in STERRAD® Sterilization. Refer to ASP’s 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, BSFK06, BSKF10, BSKQ04, and BSQ06. In addition, MediTray insert boxes are not intended to be stacked, Case Medical recommends that its containers be placed 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®. However, only one shelf can be used to accommodate an 8” high perforated base SteriTite® container, because of height restrictions within the sterilizer 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.

Caution: Do not use nylon coated brackets or silicone mat.

VALIDATION TESTING: Adequate sterilant penetration and barrier properties were demonstrated using the SteriTite® rigid reusable container system and MediTray® products in the STERRAD® Sterilization Systems (100S, 200, NX®, and 100NX®) under half cycle and fractional studies. STERRAD® Systems have preprogrammed cycles for each unit.

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.

SteriTite® At Point of Use:

1. Before opening the SteriTite® Container always verify that:
   - The tamper-evident seals are intact.
   - The disposable filter is visible through the perforations.
   - The acceptability of the end point response of the external chemical indicator or load card.
   - 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.

Sterility Maintenance Procedures

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

The SteriTite container system and MediTray products are universal reusable packaging systems for medical devices to be used for sterilization including STERRAD 100S, 200, NX, 100NX, steam, EtO, Sterizone and V-Pro sterilization.

A SteriTite containment system with a solid lid and solid base is available for soaking and transporting contaminated instruments to the decontamination area.
**SteriTite® Labeling**

**Reprocessing Instructions and Inspection Criteria**

**DEVICE DESCRIPTION:** The SteriTite® container is a rigid, reusable, sealed medical sterilization packaging system.

**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. MediTray products may be containerized or wrapped with a 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.


**Contraindications:** Dry heat and Formaldehyde sterilization.

**REPROCESSING INSTRUCTIONS AND INSPECTION CRITERIA**

1. **Clean after each use.** Disassemble all container components. Clean manually using a soft, lint free cloth or process in an automated washer. In addition, single use enzymatic towelettes such as Penta Wipes can be used to decontaminate container components and Alcohol Wipes facilitate drying. If an automated washer is used, secure parts to avoid excess movement during processing. Make sure container latches are folded inward and handles are tucked within the racks and not protruding. The filter retention plate should be removed and placed in a basket for the cleaning process.

2. Always use a pH neutral detergent, recommended for use on aluminum. Multi-enzymatic cleaners may be used if they are pH neutral. **Caution:** Do not use abrasive cleaners, alkaline or acidic detergents, metal brushes or abrasive pads.

3. Rinse all components to prevent detergent residue. Dry thoroughly.

4. Do a visual inspection of all parts. Check that gaskets are properly secured and free of wear or damage. Latches should function properly. Case and lid should be free of dents, which may interfere with the seal. Be sure filter retention plate or valve plate fits securely.

5. Verify the integrity of gaskets and other component parts.

6. Remove the filter retention plate(s) by turning the handle of the locking mechanism clockwise. Adjust filter retention plate by bending down along the edge to modify the tension.

7. Replace the disposable filter after each use.

8. Secure the filter by turning handle counter clockwise.

9. Load the container with DRY surgical instruments.

10. Place chemical indicators or indicators on each level of surgical instrument tray. For SteriTite® sealed containers place chemical indicators, integrators or biological indicators in corners of the basket or tray within the sealed container.

11. Secure the container by latching the lid to the base. The top of the latch fits over the ridge in the lid of the container. Push bottom section of the latch over the lock hold (clip). Thread a disposable tamper evident seal through the latching mechanism.

12. Place the proper load cards with complete information in the label holder on the right side of container latches. If the containers are sterilized in an outside contract facility, they should be double wrapped in double plastic bags during transport.

13. Check with your sterilizer manufacturer for additional information on reprocessing sterilization containers in their sterilizer.

**Recommendations:** Always use a pH neutral detergent for cleaning anodized aluminum sterilization containers and trays. Case Medical highly recommends its validated pH neutral Case Solutions and SuperNova instrument cleaners for decontamination of the SteriTite container system and other sealed container systems. **Warning:** Use of a caustic cleaner will damage the anodized surface of aluminum devices and can cause corrosion. This practice will void the company’s warranty on its container system. Final rinse with softened water can cause corrosion when processed in H2O2.

Any questions about preparation and assembly should be directed to:

Case Medical, Inc at 19 Empire Blvd, South Hackensack NJ 07606
Phone: 1-(888)-227-CASE or (201)-313-1999. Fax: 201-373-9090
To access our website, visit [www.casemed.com](http://www.casemed.com)

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**SteriTite® Labeling**

**for Steam Sterilization using disposable filter**

**DEVICE DESCRIPTION:** The SteriTite® container is a rigid, reusable, sealed medical sterilization packaging system.

**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. MediTray products may be containerized or wrapped with a 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.

**LOAD:** The contents must be placed within an instrument basket or tray. The load may be distributed in layers using MediTray baskets or trays. When stacking trays, leave 1” of clearance in container. Case Medical validated maximum load of 35lbs including container and contents. AAMI recommends a maximum of 25lbs total weight.

**Note:** The SteriTite container with paper filter may be used for immediate use pre-vacuum steam sterilization cycles.

**PARAMETERS FOR USE:**

- **Pre-vacuum steam sterilization:** 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 20 minutes 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.

- **Pre-vacuum steam immediate use (flash) sterilization:** Use vented or solid base container for pre-vacuum steam “IUS” sterilization. IUS sterilization is for immediate use only. Moisture may occur in IUS sterilization 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 SCF10 (7.5” diameter) and SCFM10 (10”X4”) are disposable medical device 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).

- **Gravity displacement steam:** Use only perforated base containers for gravity displacement steam. Use MediTray basic trays in container. Select the appropriate exposure time based on load and size of container. Validation testing demonstrated kill in 15 to 25 minutes. Recommended minimum exposure time: 30 minutes at 250°F. Minimum recommended dry time 30 minutes. Use of sealed containers may require additional exposure time in gravity displacement steam.

- **Stackability 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.

**Note:** To reduce condensate formation, crack the autoclave door for 10 to 15 minutes to allow gradual cool down.

**VALIDATION TESTING:** Case Medical subscribes to the overkill principle. SteriTite and MediTray products are validated in independent laboratories under fractional and half cycle conditions.