Case Medical

SteriTite® and MediTray® Instructions for Use

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 IFU-CASEMED-IRISH ENGLISH Rev.004

Product Warranty

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 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 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 authorisation. All returns must be assigned an authorisation number by Case Medical, Inc.® A completed Returned Goods Authorisation (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.

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.

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SteriTite®, the Container system of choice

DEVICE DESCRIPTION: The SteriTite® Container is a rigid, reusable, sealed medical sterilisation packaging system that is compatible with all current sterilisation 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 the "Comprehensive Guide to Steam Sterilisation and Sterility Assurance in Health Care Facilities"[1] and "Containment Devices for Reusable Medical Device Sterilisation".[2]

References:
ISO/TC 198 Sterilisation 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 sterilisation 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 placed in containers or wrapped with an FDA approved medical wrap. Please refer to the recommendations of your steriliser 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 sterilisation, transport and storage of medical devices including flexible endoscopes according to the manufacturer's instructions. The SteriTite® system has been validated for use in all current sterilisation modalities, including pre-vacuum and gravity displacement steam, EtO, H_2O_2 sterilisation including STERRAD 100, 100S, 200, NX, 100NX, Steris V-Pro 1, V-Pro 1 Plus, V-Pro maX, TS03 STERIZONE® VP4, and sealed immediate use steam sterilisation.

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

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

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-sterilised 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 steriliser. 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.

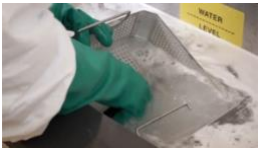
SteriTite® Containers and MediTray® products have FDA 510k as well as CE marking. The FDA 510k clearance demonstrates that the device is safe and effective for its intended use. The CE marking certifies that the product has met EU health, safety, and environmental standards and guidelines. All SteriTite® 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 the 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 sterilisation). 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 sterilisation containers. In addition, single use enzymatic sheets such as Penta Wipes can be used to decontaminate container components. Follow this with a rinse under running 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 neutralisers or scratch pads. Caustic detergents will oxidise the anodised aluminium surface of the container and cause 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.

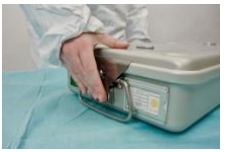
1. Perform a visual inspection of all parts prior to each use. Check that gaskets are properly secured and free of wear or damage. Latches should function properly. The case and lid should be free of dents that may interfere with the seal. The aluminium surface of the container should have no noticeable 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 the centre. If the retention plate is not properly locked, the filter and retention plate can fall off onto the contents within the container compromising the contents.
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. 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

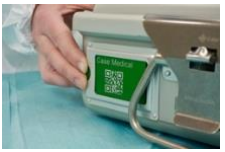
SteriTite® Containers require a disposable filter and filter retention plate as a microbial barrier. For containers with a perforated base**,** place the appropriate filter over the perforations on the lid and base of the SteriTite® Container and place the filter retention plate over the filter. Secure the filter retention plate by pushing downwards at the centre (where indicated) and rotate the handle counter-clockwise to close.
Note: Paper filters should be used only for steam and EO sterilisation. Non-woven Polypro filters must be used for H2O2, STERRAD, STERIZONE and V-Pro sterilisation, and may be used for pre-vacuum steam and EO sterilisation.

Note: Prepare complex instruments according to the instrument maker's instructions. Use of non-absorbent tray liners can cause condensate to pool. Do not use peel pouches within sealed containers, as they cannot be placed on their side for sterilisation.
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 organisation 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 2.5 cm (1 inch) of clearance for proper fit of contents, approximately 1.3 cm (1/2 inch) from the lid and 1.3 cm (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 forceful 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 H_2O_2 sterilisation.



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 H_2O_2/ STERRAD sterilisation.
Caution: Use of any unapproved 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 H_2O_2 and gas plasma sterilisation.
10. SteriTite Containers are designed to be dry after sterilisation. Therefore, the use of absorbent liners is not recommended for use with the SteriTite® Container.

SteriTite® Sterilisation

1. Place the SteriTite® Container flat on the shelf of the steriliser cart. If needed, up to 3 containers may be stacked and processed in an autoclave.
2. If sterilised in a mix load, place containers below wrapped or linen items.
3. Consult the recommendations of your steriliser manufacturer to determine the correct parameters regarding temperature, weight load, drying 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 min.

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

SteriTite® Labelling for Steam Sterilisation

PRE-VACUUM STEAM TERMINAL STERILISATION PARAMETERS FOR USE:
Use vented or solid base containers for pre-vacuum steam. Apply paper or polypropylene disposable filter for each use. Use MediTray® inserts in the container to secure instrumentation. Recommended for sterilisation of medical devices including, blades and metal lumens of 2 mm minimum diameter up to 435 mm in length and porous lumens 3 mm minimum diameter up to 400 mm in length.
Recommended exposure time: 4 minutes at 132°C (270°F).
Recommended drying 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 condensation, leave the autoclave door slightly ajar for 10 to 15 minutes to allow gradual cool down.
Caution: Visible signs of moisture may be indicative of a sterilisation process failure and may impact barrier performance of the container. If this occurs, it is recommended to repackage and re-sterilise with a longer drying 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 STERILISATION: Use vented or solid base container for pre-vacuum steam "IUSS" sterilisation. IUSS sterilisation 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 132°C (270°F) with 0 to 3 min dry time. User may add additional dry time for a drier outcome. Disposable paper filter SCF01 (19 cm / 7.5" diameter) and SCFM01 (25.4X10.2 cm / 10"X4") are supplied non-sterile.
Note: The user should contact their device manufacturer for appropriate (extended) sterilisation cycle conditions. (ANSI/AAMI ST 79:2006 – Comprehensive Guide to Steam Sterilisation and Sterility Assurance in Health Care Facilities).

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

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 the contents and size of the container. Recommended minimum exposure time: 30 minutes at 121°C (250°F). The use of sealed containers may require additional exposure time in gravity displacement steam.
Stack ability of SteriTite® Containers in Steam Sterilisation: Up to 3 containers can be stacked and processed in an autoclave.
WARNING: Prepare complex instruments according to the instrument maker's instructions. Use of non-absorbent tray liners can cause condensate to pool. Do not use peel pouches within sealed containers, as they cannot be placed on their side for sterilisation.

SteriTite® Labelling for FlashTite®
DEVICE DESCRIPTION: The SteriTite® Container may be used as a filter-less sterilisation packaging system when FlashTite valve plate(s) are utilised for steam sterilisation. 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 sterilisation 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 sterilisation of one instrument or instrument set in immediate IUSS sterilisation.

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 1 year of use or 400 cycles. Record the 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 sterilisation 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 sterilisation. Use MediTray® basic trays for IUSS sterilisation cycles. The SteriTite® solid bottom containers including 10.2 cm (4") high models may be used for IUSS sterilisation with FlashTite valve plate(s) in the lid.

FLASHTITE PARAMETERS FOR USE:

Pre-vacuum Immediate Use Steam Sterilisation (IUSS): Use either a 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 132°C (270°F). Recommended drying time for SteriTite® Container with FlashTite valve plate(s): 0 to 3 minutes drying time in the autoclave for items processed in IUSS (flash) sterilisation 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 Sterilisation: Use only perforated bottom containers. 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 132°C (270°F) and a minimum of 10 minutes exposure for porous items, lumens and mixed loads at 132°C (270°F). Recommended dry time: 0 to 3 minutes dry time in the autoclave for items processed in flash sterilisation 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® Containers with FlashTite valve in gravity displacement IUSS sterilisation.

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 colour change will not impact the safety and effectiveness of the device.
Refer to the steriliser manufacturer's "Instructions for Use" for specific information as to the limitations of instrumentation, specifications and material compatibility. Complex instruments should be prepared and sterilised according to the instrument manufacturer's instructions. Contact the manufacturer of your endoscope or lumened devices when flashing.
Caution: When abbreviated drying 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 sterilisers including gas plasma (STERRAD) sterilisation.
Note: For low temperature sterilisers refer to the information provided below.

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

STERRAD PARAMETERS FOR USE:
Use non-woven polypropylene disposable filters: PolyPro Filter # SCF02 (19 cm / 7.5" diameter) and SCFM02 (25.4X10.2 cm / 10"X4") are disposable filters supplied non-sterile. In STERRAD 100, 100S & 200 process only stainless steel lumened instruments of 3 mm diameter or larger and a length up to 400 mm. In STERRAD NX standard cycle, process stainless steel lumened instruments of 2 mm diameter or larger and up to 400 mm in length. In STERRAD NX advanced cycle, process stainless steel lumened instruments of 1 mm diameter or larger and up to 500 mm in length and porous lumens (flexible endoscope) of 1 mm diameter or larger and up to 850 mm in length. In the STERRAD 100NX Standard cycle, process stainless steel lumened instruments of 0.7 mm diameter or larger and up to 500 mm in length. In STERRAD 100NX Flexible cycle, process flexible endoscopes, and lumened instruments of > 1.2 mm X < 835 mm. STERRAD Systems have pre-programmed cycles for each unit.
Cycle time: The steriliser manufacturer determines STERRAD® Sterilisation cycle time.
Caution: In STERRAD® Sterilisation do not use materials made of cellulose (paper filters and cotton) with SteriTite® Containers.
Compatibility: In STERRAD® Sterilisation 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 ® Sterilisation. Refer to STERRAD® System Operating Manual, instructions for use and labelling.
Internal Stacking: MediTray® baskets and trays may be stacked within the SteriTite® Container system as follows: In STERRAD NX up to 2 instrument baskets or trays may be stacked within the SteriTite® container. In the STERRAD 200 up to 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 steriliser shelf.
External stacking was not tested. For STERRAD 100, 100S, 200 & 100NX: All models of SteriTite Containers can be placed on each of the 2 shelves within the STERRAD® 200. However, only one shelf can be used to accommodate an 20.3 cm (8") high perforated base SteriTite® container, because of height restrictions within the steriliser's chamber. For STERRAD NX only 5, 7.6, and 10.2 cm (2", 3", and 4") high containers will fit in the steriliser chamber.

MediTray® Products including MediTray® inserts, instrument baskets, stacking trays, BackBone silicone brackets, stainless and aluminium brackets, posts and partitions may be used in STERRAD Sterilisation, wrapped or placed in containers. Use white tamper evident seals, Polypro filters and load cards available from Case Medical for H_2O_2 sterilisation.

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 Sterilisation: SteriTite® Containers with disposable filters may be used in EO sterilisation for sterilisation of blades and lumens. Solid bottom containers may be used in EO pre-vacuum sterilisers.
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/litre EO gas mixture (90% CO_2 / 10% EO) - 2 hours.
230 mg/litre EO gas mixture (91.5% CO_2 / 8.5% EO) - 3 hours.
In EO sterilisation, metal lumened devices of 2.2 mm diameter or larger and length up to 457 mm and porous lumened devices of 3 mm 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 sterilisation: Up to 3 SteriTite® Containers can be stacked and processed in the steriliser.

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

TSO3 STERIZONE PARAMETERS FOR USE:
Use non-woven polypropylene disposable filters: Disposable nonwoven filter # SCF02 (19 cm / 7.5" diameter) and SCFM02 (25.4X10.2 cm / 10"X4") are a single use disposable filter supplied non-sterile.
Use vented or solid base containers for STERIZONE® VP4 sterilisation. Use MediTray® products in the container to secure instrumentation. Recommended for sterilisation 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. Sterilise 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 0.7 mm or larger and a length of 500 mm or shorter (up to twelve rigid channels in the presence of other packaged medical devices). Sterilise up to three single channel surgical flexible endoscopes (1 per container, 3 containers per load) with an internal channel diameter of 1.0 mm or larger and a length of 850 mm or shorter.
Cycle time: The steriliser manufacturer determines STERIZONE® VP4 Cycle 1 Sterilisation cycle parameters. The cycle has a phase of hydrogen peroxide vapour exposure and one of hydrogen peroxide reduction using Ozone.
Internal Stacking: Testing was done with up to 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 Sterilisation. Refer to TSO3 System Operating Manual instructions for use and labelling.
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 14.1 kg (31 lbs), including container and contents. Use non-woven polypropylene disposable filters: Disposable non-woven filter # SCF02 (19 cm / 7.5" diameter) and SCFM02 (25.4X10.2 cm / 10"X4") are a single use disposable filter supplied non-sterile.
Sterilise only stainless steel lumened instruments of 3 mm or larger and a length of 400 mm 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 1 mm or larger and a length of 1050 mm. Two flexible endoscopes may be sterilised if no additional load is present. Two shorter endoscopes may be processed at once, when one has an inside diameter of 1 mm or larger, and a length of 998 mm or shorter and the second one has an inside diameter of 1 mm or larger and a length of 850 mm 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 2 instrument baskets or 4 trays may be stacked.
Caution: Stacking SteriTite® Containers 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 Sterilisation System. However, only one shelf can be used to accommodate a 20.3 cm (8") high perforated base SteriTite® container, because of height restrictions within the steriliser's chamber.
MediTray® products including MediTray® inserts, instrument baskets, stacking trays, BackBone silicone brackets, stainless and aluminium brackets, posts and partitions may be used in V-PRO Sterilisation System.
Compatibility: In V-PRO sterilisation, use only compatible materials and instruments as stated in the V-PRO sterilisation system operating manual. Consult with your instrument manufacturer for the compatibility of various materials in V-PRO Sterilisation System. Refer to V-PRO Sterilisation System Operating Manual instructions for use and labelling.

Caution: Do not use nylon coated brackets or silicone mats. 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. After 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 sterilised 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 colour 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 sterilisation, the tamper-evident seal contains a process indicator. In steam sterilisation, the colour change is from cream to brown and in EO cream to orange. In STERRAD Sterilisation, the colour change on the load card is red to orange/yellow.

MediTray® Labelling
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 sterilisation.

INTENDED USE: MediTray® is intended to be used for the sterilisation of reusable surgical instruments and medical devices in health care facilities. MediTray® products may be placed in containers or wrapped with an FDA cleared medical wrap. Please refer to the recommendations of your steriliser manufacturer for specific reprocessing instructions as well as recommendations from your medical device manufacturer for material compatibility and requirements for extended sterilisation cycles.

Note: MediTray® products may be used in steam, and low temperature sterilisation, including EO, V-Pro, STERIZONE and H_2O_2 gas plasma (STERRAD) sterilisation.

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 the product thoroughly before sterilisation or further processing. A lint free cloth may be used for drying.

Warning: Use of a caustic cleaner can damage the anodised surface of aluminium 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
(1000 per case) 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 19 cm (7.5") Circular
(1000 per case) 100% Cellulose for steam sterilisation

SCFM01: SteriTite® Disposable Paper Filters 25.4X10.2 cm (10" × 4") Rectangular.
(1000 per case) 100% Cellulose for steam sterilisation

SCF02: SteriTite® Polypro Disposable Filters 19 cm (7.5") Circular
(1000 per case) Non-woven polypropylene for pre-vac steam, H_2O_2 and gas plasma sterilisation

SCFM02: SteriTite® Polypro Disposable Filters 25.4X10.2 cm (10" × 4") Rectangular
(1000 per case) Non-woven polypropylene for pre-vac steam, H_2O_2 and gas plasma sterilisation

SCL01: SteriTite® Dual Process Indicator Cards
(1000 per case) ID card with a dual chemical indicator. Use for steam and EO sterilisation

SCL02: SteriTite® Dual Indicator Cards, Small
(1000 per case) ID card with a dual chemical indicator. Use for steam and EO sterilisation

SCI001: SteriTite® Dual Process Indicators
(1000 per case) ID card with a dual chemical indicator. Use for steam and EO sterilisation

SCLH2023: SteriTite® H_2O_2 Load Cards
(1000 per case) ID card with chemical indicator. Use for H_2O_2 and gas plasma sterilisation

SCLH2024: SteriTite® H_2O_2 Load Cards, Small
(1000 per case) ID card with chemical indicator. Use for H_2O_2 and gas plasma sterilisation

SCKIT1BP: SteriTite® Steam and Gas Disposable Kit (Standard) 3 pack 1000 each paper filters, 1 pack seals, 1 pack load card

SCKIT2BP: SteriTite® Steam and Gas Disposable Kit
(Mini/Narrow) 1 pack 1000 each paper filters, 1 pack seals, 1 pack load card

SCKIT1WN:SteriTite® H_2O_2 Disposable Kit (Standard) 3 pack 1000 each Polypro filters, 1 pack seals, 1 pack load card

SCKIT2WN:SteriTite® H_2O_2 (Mini/Narrow) 1 pack 1000 each Polypro filters, 1 pack seals, 1 pack load card

Case Medical

If you have any questions regarding Case Medical products
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