SteriTite® and MediTray® Instructions for Use

Manufacturer: Case Medical, Inc.®
50 West Street, Bloomfield, NJ 07003
Phone: (201) 313-1999 Fax: (201) 373-9090
www.casemed.com

MDSS Gmbh
Schiffgraben 41
30175 Hannover
Germany
EC REP

MDSS CH Gmbh
Laurenzenvorstadt 61
5000 Aarau
Switzerland
CH REP

MDSS-UK RP Ltd.
6 Wilmslow Road, Rusholme
Manchester M14 5TP
United Kingdom

IFU-CASEMEDICAL Rev.008.1

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 three (3) full years from the date of purchase.

THE MediTray® SYSTEM WARRANTY

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

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

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

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

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

CASE MEDICAL, INC.® RETURNED GOODS POLICY

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

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

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

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

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

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

Contact information: Case Medical, Inc.® 50 West Street, Bloomfield, NJ 07003
Phone: (201) 313-1999 Fax: (201) 373-9090 info@casemed.com

SteriTite®, the Container system of choice

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

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

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

The SteriTite container and MediTray products are a universal, reusable packaging system with CE mark and FDA 510k for sterilization, transport and storage of medical devices including flexible endoscopes according to manufacturer's instructions. The SteriTite® system has been validated for use in all current sterilization modalities, including prevacuum and gravity displacement steam, EtO, and H2O2 sterilization. The following table (Table 1) displays the SteriTite part numbers and the sterilizers with which they are compatible.

Table 1. SteriTite Container Compatibility with Low Temperature Sterilizers

V-Pro s2/60 Lumen Flex	V-Pro 1 Lumen	V-Pro maX/maX2 Lumen Flex Non-Lumen	100NX Standard Flex	100NX** DUO Express	100S/200 Standard	NX Advanced Standard	Sterizone VP4 Cycle 1	Steam Pre-Vac IUSS
SC02MG	SC02MG	SC02MG	SC02MG	SC02MG	SC02MG	SC02MG	SC02M(G)*	SC02M(G)***
SC03MG	SC03MG	SC03MG	SCO3MG	SCO3MG	SC03MG	SC03MG	SC03M(G)*	SC03M(G)***
SC04MG	SC02NG	SC02NG	SCO4MG	SCO4MG	SC04MG	SC04MG	SC02N(G)*	SC02N(G)***
SC02NG	SC03NG	SC03NG	SC02NG	SC02NG	SC02NG	SC02NG	SC03N(G)*	SC03N(G)***
SC03NG	SC04NLG	SC04NLG	SC03NG	SC03NG	SC03NG	SC03NG	SC04NL(G)*	SC03NL(G)***
SC04NLG	SC05NLG	SC05NLG	SC03NLG	SC04NLG	SC04NLG	SC04HG	SC05NL(G)*	SC04NL(G)***
SC05NLG	SC04FG	SC04FG	SC04NLG	SC05NLG	SC05NLG	SC05HG	SC04F(G)*	SC05NL(G)***
SC04HG	SC05FG	SC05FG	SC05NLG	SC04HG	SC04FG	SC04QG	SC05F(G)*	SC04F(G)***
SC05HG	SC06FG	SC06FG	SC04HG	SC05HG	SC05FG	SC05QG	SC06F(G)*	SC05F(G)***
SC04QG	SC08FG	SC08FG	SC05HG	SC06HG	SC06FG	SC04FG	SC08F(G)*	SC06F(G)***
SC05QG	SC04HG	SC04HG	SC06HG	SC08HG	SC08FG		SC04H(G)*	SC08F(G)***
SC04FG	SC05HG	SC05HG	SC08HG	SC04QG	SC04HG		SC05H(G)*	SC04H(G)***
	SC06HG	SC06HG	SC04QG	SC05QG	SC05HG		SC06H(G)*	SC05H(G)***
	SC08HG	SC08HG	SC05QG	SC06QG	SC06HG		SC08H(G)*	SC06H(G)***
	SC04QG	SC04QG	SC06QG	SC04FG	SC08HG		SC04Q(G)*	SC08H(G)***
	SC05QG	SC05QG	SC08QG	SC05FG	SC04QG		SC05Q(G)*	SC04Q(G)***
	SC06QG	SC06QG	SC04FG	SC06FG	SC05QG		SC06Q(G)*	SC05Q(G)***
	SC08QG	SC08QG	SC05FG	SC08FG	SC06QG		SC08Q(G)*	SC06Q(G)***
	SC04LG	SC04LG	SC06FG	SC04LG	SC08QG		SC04L(G)*	SC08Q(G)***
	SC06LG	SC06LG	SC08FG	SC06LG			SC06L(G)*	SC04L(G)***
	SC05WG	SC05WG	SC04LG	SC05WG			SC05W(G)*	SC06L(G)***
			SC06LG					SC08L(G)***
			SC05WG					SC05W(G)***

The items in **Table 1 (above) identify the containers that are associated with the specific sterilizer claims.*
***For the STERRAD 100NX Express and DUO cycle, load containers on the bottom shelf and one container at a time.*
****Parenthesis* (G) means that both solid bottom and perforated bottom containers have been cleared for this sterilization modality. Solid bottom containers have been cleared for pre-vacuum steam sterilization. G alone means that the perforated bottom container should be used.

The SteriTite containers with MediTray parts have demonstrated the ability to facilitate sterilization of narrow lumens in high and low temperature sterilization processes. The SteriTite container has been cleared for the following lumen claims presented in Table 2 below.

Table 2. Steam and Low Temperature Lumen Claims

Sterilizer	Cycle	Lumen Sterilization (I.D. x Length)
STERIS V-Pro 60	Lumen	≥0.77mm x ≤527mm (Dual Channel)
	Flexible	≥1mm x ≤990mm (Single or Dual Channel)
STERIS V-Pro s2	Lumen	≥0.77mm x ≤527mm (Dual Channel)
	Flexible	≥1mm x ≤990mm (Single or Dual Channel)
STERIS V-Pro maX 2	Lumen	≥0.77mm x ≤527mm (Dual Channel)
	Flexible	≥1mm x ≤1050mm (Single Lumen)
STERIS V-Pro maX	Lumen	≥0.77mm x ≤527mm (Dual Channel)
	Flexible	≥1mm x ≤1050mm (Single Lumen)
STERRAD 100NX	DUO	≥1mm x ≤875mm (Single Lumen)
Sterizone VP4	Cycle 1	≥1.2mm x ≤1955mm (Flexible Lumen)
	Cycle 1	≥1.45mm x ≤3500mm (Flexible Lumen)
Steam	Pre-Vac	≥1.2mm x ≤400mm (Flexible Lumen)
		≥1mm x ≤400mm (Stainless Steel Lumen)

Table 3. MediTray Products Sterilizer Compatibility Table

MediTray Product	V-Pro maX/2	V-Pro 1	V-Pro s2/60	STERRAD 100NX	STERRAD 100S/200	STERRAD NX	STERIZONE VP4	Steam
Baskets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trays	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Insert Boxes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Metal Brackets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Metal Partitions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Posts	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Silicone Brackets	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Racks	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Stringers	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The following table identifies which SteriTite accessories are compatible with low temperature sterilizers and steam sterilization:

Table 4. SteriTite Accessories Sterilizer Compatibility Table

SteriTite Accessories	V-Pro maX/2	V-Pro 1	V-Pro s2/60	STERRAD 100NX	STERRAD 100S/200	STERRAD NX	STERIZONE VP4	Steam
SCF02 Round filter	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCFM02 Rectangular filter	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCS01W Tamper Evident Seals	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCLH2O23 Load Card Large	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SCLH2O24 Load Card Small	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

The following tables (5-11) identify the sterilizer maximum load weight recommendations with the SteriTite containers:

Table 5. SteriTite Container in V-Pro s2 and V-Pro 60 Manufacturer's Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in V-Pro s2/60 Lumen Cycle	Total Load Weight in V-Pro s2/60 Flexible Cycle
SC02MG	25lbs	11lbs
SC03MG	25lbs	11lbs
SC04MG	25lbs	11lbs
SC02NG	25lbs	11lbs
SC03NG	25lbs	11lbs
SC04NLG	25lbs	11lbs
SC05NLG	25lbs	11lbs
SC04HG	25lbs	11lbs
SC05HG	25lbs	11lbs
SC04QG	25lbs	11lbs
SC05QG	25lbs	11lbs
SC04FG	25lbs	11lbs
Weight Validated	**25lbs**	**13.3lbs**

Table 6. SteriTite Container in STERRAD NX Manufacturer's Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in NX Standard Cycle	Total Load Weight in NX Advanced Cycle
SC02MG	10.7lbs	10.7lbs
SC03MG	10.7lbs	10.7lbs
SC04MG	10.7lbs	10.7lbs
SC02NG	10.7lbs	10.7lbs
SC03NG	10.7lbs	10.7lbs
SC04HG	10.7lbs	10.7lbs
SC05HG	10.7lbs	10.7lbs
SC04QG	10.7lbs	10.7lbs
SC05QG	10.7lbs	10.7lbs
SC04FG	10.7lbs	10.7lbs
Weight Validated by Manufacturer	**10.7lbs**	**20.13lbs**

Table 7. SteriTite Container in V-Pro 1 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in V-Pro 1 Lumen Cycle	Total Load Weight in V-Pro 1 Non-Lumen Cycle
SC02MG	19.65lbs	19.65lbs
SC03MG	19.65lbs	19.65lbs
SC02NG	19.65lbs	19.65lbs
SC03NG	19.65lbs	19.65lbs
SC04FG	19.65lbs	19.65lbs
SC05FG	19.65lbs	19.65lbs
SC06FG	19.65lbs	19.65lbs
SC08FG	19.65lbs	19.65lbs
SC04HG	19.65lbs	19.65lbs
SC05HG	19.65lbs	19.65lbs
SC06HG	19.65lbs	19.65lbs
SC08HG	19.65lbs	19.65lbs
SC04QG	19.65lbs	19.65lbs
SC05QG	19.65lbs	19.65lbs
SC06QG	19.65lbs	19.65lbs
SC08QG	19.65lbs	19.65lbs
SC04LG	19.65lbs	19.65lbs
SC06LG	19.65lbs	19.65lbs
SC08LG	19.65lbs	19.65lbs
SC05WG	19.65lbs	19.65lbs
Weight Validated	**19.65lbs**	**21.5lbs**

Table 8. SteriTite Container in STERRAD 100s/200 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in the STERRAD 100s/200 Standard Cycle
SC02MG	22lbs
SC03MG	22lbs
SC04MG	22lbs
SC02NG	22lbs
SC03NG	22lbs
SC04NLG	22lbs
SC05NLG	22lbs
SC04HG	22lbs
SC05HG	22lbs
SC06HG	22lbs
SC08HG	22lbs
SC04QG	22lbs
SC05QG	22lbs
SC06QG	22lbs
SC08QG	22lbs
SC04FG	22lbs
SC05FG	22lbs
SC06FG	22lbs
SC08FG	22lbs
Weight Validated	**22lbs**

Table 9. SteriTite Container in 100NX Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Weight in 100NX Standard Cycle	Total Weight in 100NX Flexible Cycle	Total Weight in 100NX DUO Cycle	Total Weight in 100NX Express Cycle
SC02MG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC03MG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC04MG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC02NG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC03NG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC03NLG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC04NLG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC05NLG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC04HG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC05HG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC06HG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC08HG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC04QG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC05QG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC06QG	21.4lbs	21.4lbs	N/A	N/A
SC08QG	21.4lbs	21.4lbs	N/A	N/A
SC04FG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC05FG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC06FG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC08FG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC04LG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC06LG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC08LG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
SC05WG	21.4lbs	21.4lbs	13.2lbs	10.7lbs
Weight Validated by Manufacturer	**22lbs**	**21.4lbs**	**14.8lbs**	**22.4lbs**

Table 10. SteriTite Container in V-Pro maX/maX 2 Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in V-Pro maX/maX2 Lumen Cycle	Total Load Weight in V-Pro maX/maX2 Flex Cycle	Total Load Weight in V-Pro maX/maX2 Non-Lumen Cycle
SC02MG	19.65lbs	24lbs	50lbs
SC03MG	19.65lbs	24lbs	50lbs
SC04MG	19.65lbs	24lbs	50lbs

SC02NG	19.65lbs	24lbs	50lbs
SC03NG	19.65lbs	24lbs	50lbs
SC04NLG	19.65lbs	24lbs	50lbs
SC05NLG	19.65lbs	24lbs	50lbs
SC04HG	19.65lbs	24lbs	50lbs
SC05HG	19.65lbs	24lbs	50lbs
SC06HG	19.65lbs	24lbs	50lbs
SC08HG	19.65lbs	24lbs	50lbs
SC04QG	19.65lbs	24lbs	50lbs
SC05QG	19.65lbs	24lbs	50lbs
SC06QG	19.65lbs	24lbs	50lbs
SC08QG	19.65lbs	24lbs	50lbs
SC04FG	19.65lbs	24lbs	50lbs
SC05FG	19.65lbs	24lbs	50lbs
SC06FG	19.65lbs	24lbs	50lbs
SC08FG	19.65lbs	24lbs	50lbs
SC04LG	19.65lbs	24lbs	50lbs
SC06LG	19.65lbs	24lbs	50lbs
SC08LG	19.65lbs	24lbs	50lbs
SC05WG	19.65lbs	24lbs	50lbs
Weight Validated	**19.65lbs**	**24lbs**	**50lbs**

Table 11. SteriTite Container in Steam Sterilization/IUSS Maximum Load Weight Recommendations Including Weight of Container

Part Number	Total Load Weight in Steam Sterilization Pre-Vacuum Cycle	Total Load Weight in Steam Sterilization Gravity Cycle
SC02MG	35lbs	35lbs
SC03MG	35lbs	35lbs
SC04MG	35lbs	35lbs
SC02NG	35lbs	35lbs
SC03NG	35lbs	35lbs
SC04NLG	35lbs	35lbs
SC05NLG	35lbs	35lbs
SC04HG	35lbs	35lbs
SC05HG	35lbs	35lbs
SC06HG	35lbs	35lbs
SC08HG	35lbs	35lbs
SC04QG	35lbs	35lbs
SC05QG	35lbs	35lbs
SC06QG	35lbs	35lbs
SC08QG	35lbs	35lbs
SC04FG	35lbs	35lbs
SC05FG	35lbs	35lbs
SC06FG	35lbs	35lbs
SC08FG	35lbs	35lbs
SC04LG	35lbs	35lbs
SC06LG	35lbs	35lbs
SC08LG	35lbs	35lbs
SC05WG	35lbs	35lbs
Weight Validated	35lbs	35lbs

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

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

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

CONTRAINDICATIONS – not known

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

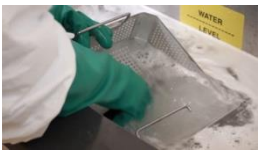
SteriTite® Containers and MediTray® products have FDA 510k as well as CE mark. The FDA 510k clearance demonstrates that the device is safe and effective for its intended use. The CE marking certifies that the product has met EU health, safety, and environmental standards and guidelines. All SteriTite®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

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

SteriTite® and MediTray® Decontamination

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

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



Manual Cleaning:
SteriTite® Containers may be cleaned manually with a soft lint free cloth and a pH neutral detergent or enzymatic detergent (pH 6 to < 9). Always follow with a thorough rinse to remove detergent residue. Use a soft lint free cloth to dry all components of the container. Avoid water collection by washing and drying the Container upside-down.

Recommendation: Case Solutions® and SuperNova® multi-enzymatic cleaners and detergents are ideal for cleaning medical devices and sterilization containers. In addition, single use enzymatic towelettes such as Penta Wipes can be used to decontaminate Container components. Follow with a rinse under the flow of water. Dry all surfaces and components. 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 (pH 6 to < 9) or enzymatic cleaners are used. Always disassemble and remove the filter retention plate for the cleaning process. Case Medical provides a rack to organize and secure filter retention plates during automated cleaning. Follow the recommended dosage of the detergent. If an automatic washer is used, secure all parts to avoid excess movement during cleaning. Make sure the Container latches are folded inward and the handles are tucked within the racks, so they don't protrude. Use utility or instrument cycles for automated cleaning in washer disinfectors and the Container cycle of the cart washer. Always follow the wash step with a thorough rinse to remove detergent residue.

Caution: Do not use alkaline detergents, acid neutralizers, or drying or sheeting agents. Caustic detergents will oxidize the anodized aluminum surface of the container and create discoloration and corrosion. Do not use recycled water in the cart washer for rinsing the container as it will add excess chemical agents to the surface.

SteriTite® Inspection for Use

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

1. Perform a visual inspection of all parts prior to each use. Check that gaskets are properly secured and free of wear or damage. Latches should function properly. The case and lid should be free of dents that may interfere with the seal. The aluminum surface of the Container should have no noticeable corrosion or damage. Be sure filter retention plates or valve plates fit securely.
2. Verify that gaskets in the lid and in the filter retention plate(s) are pliable, without cracks or tears, and that they are all properly and firmly affixed.
3. Each retention plate should be flat and not warped or dented along the perimeter. The filter should be present covering each perforated vent. The retention plate should be securely latched when pressing down at center point. If the retention plate is not properly locked, the filter and retention plate can fall off onto the contents within the Container compromising the load.
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.
6. If discoloration and deep scratches are observed, check the anodized surface. Utilize a permanent marker and our CSR ink and adhesive remover to test. Any remaining mark after removing the ink indicates that the surface has been compromised.
7. If white powder residue is observed, this may have been caused by an alkaline cleaning solution or inadequate rinsing. Check the pH level of the cleaner and water. If sterilized in vaporized hydrogen peroxide, white powder could be peroxide residue or an indication of surface corrosion.

SteriTite® Useful Life

1. SteriTite® containers used in steam sterilization are validated for 1001 steam sterilization cycles. However, they can last up to 10 years or more when pH neutral detergents like Supernova and Case Solutions enzymatic and non-enzymatic detergents are used.
2. SteriTite® containers used in hydrogen peroxide sterilizers have been validated for 501 cycles. Given the frequency of use, and the acidic nature of the sterilant, the useful life is reduced despite the excellent compatibility of aluminum and hydrogen peroxide.

SteriTite® Assembly for Use

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

Note: Prepare complex instruments according to the instrument maker's instructions. Use of nonabsorbent tray liners can cause condensate to pool. Do not use peel pouches within sealed containers, as they cannot be placed on their side for sterilization.
1. Select the appropriate size basket(s) or tray(s) according to Container size.
2. Arrange the clean instruments in the basket(s) according to hospital procedures. Review the recommendations provided by the device manufacturer.
Note: MediTray® partitions, brackets and posts are recommended for organization and protection of your delicate instruments. Place the prepared baskets into the base of the SteriTite® container. Do not exceed the height of the basket when placing instruments into the basket.
3. To determine container size, add one (1) inch of clearance for proper fit of contents, approximately 1/2 inch from the lid and 1/2 inch from the base. Case Medical has validated its SteriTite® Container system for stacking multiple layers within the container.

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

5. Place the lid on top of the base. The edge of the base will fit in the lid channel creating a knife edge fit.
6. Secure the closure by latching the lid to the base. The top of the latch fits over the ridge in the lid. Push the bottom section of the latch over the lock holder. You will feel a solid click.

7. Place the appropriate metal ID tags in the label holders located on either side of the Container latches. The label holder on the right can accommodate a load card available from Case Medical, Inc®. Only clear ID tags can be used in H2O2 sterilization.
8. Thread the guide on the SteriTite® tamper- evident seal through the lock holder and secure. Repeat on both latches. Blue and red tamper evident seals are available for steam and gas. White tamper evident seals are recommended for H2O2/ STERRAD Sterilization.
Caution: Use of any non-approved tamper evident seal could damage the locking clip.

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

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

SteriTite® Sterilization

1. Place the SteriTite® container flat on the shelf of the sterilizer cart. If needed, up to three (3) Containers may be stacked and processed in an autoclave.
2. If sterilized in a mix load, place Containers below wrapped or linen items.
3. Consult the recommendations of your sterilizer manufacturer to determine the correct parameters regarding temperature, weight load, dry time, instrument processing and pre-and post-conditioning cycles.
Note: To minimize the potential of condensate formation, crack the door of the autoclave for 10 to 15 mins.

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

SteriTite® Labeling for Steam Sterilization

PRE-VACUUM STEAM TERMINAL STERILIZATION PARAMETERS FOR USE:
Use vented or solid base Container for pre-vacuum steam. Apply paper or polypropylene disposable filter for each use. Use MediTray® inserts in the Container to secure instrumentation. Recommended for sterilization of medical devices including, blades and metal and porous lumens, see Table 1 through Table 11 for specific information.
Recommended exposure time: 4 minutes at 270°F.
Recommended dry times:
A minimum of 5 minutes for perforated bottom units
A minimum of 8 minutes for solid bottom units
20 minutes may be required for items stored for later use
Note: Case Medical recommends verification of these parameters in the health care facility given variations in equipment, steam quality and environmental conditions. To reduce condensate formation, crack the autoclave door for 10 to 15 minutes to allow gradual cool down.
Caution: Visible signs of moisture may be indicative of a sterilization process failure and may impact barrier performance of the container. If this occurs, it is recommended to repackage and re-sterilize with a longer dry time.
Limits of reuse: If visible signs of wear are present, such as cracking, peeling, rust/corrosion or discoloration, the Container should be discarded.

PRE-VACUUM IMMEDIATE USE STEAM STERILIZATION: Use vented or solid base Container for pre-vacuum steam "IUSS" sterilization. IUSS sterilization is for immediate use only. Moisture may occur in IUSS cycles.
Caution: Use a glove or towel when transporting hot items from the autoclave. Recommended exposure time: 4 minutes at 270°F (132°C) with 0-3 min dry time. User may add additional dry time for a drier outcome. Disposable paper filter SCF01 (7.5" diameter) and SCFM01 (10"X4") are supplied nonsterile.
Note: The user should contact their device manufacturer for appropriate (extended) sterilization cycle conditions. (ANSI/AAMI ST 79:2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities).

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

GRAVITY DISPLACEMENT STEAM PARAMETERS FOR USE: Use **only perforated base** Containers for gravity displacement steam. Use MediTray basic trays. Select the appropriate exposure time based on load and size of container. Recommended minimum exposure time: 30 minutes at 250°F. Use of sealed Containers may require additional exposure time in gravity displacement steam.
Stack ability of SteriTite® Containers in Steam Sterilization: Up to three (3) Containers can be stacked and processed in the autoclave.
WARNING: Prepare complex instruments according to the instrument maker's instructions. Use of nonabsorbent tray liners can cause condensate to pool. Do not use peel pouches within sealed containers, as they cannot be placed on their side for sterilization.

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

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

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

Gravity Displacement IUSS Sterilization: Use only perforated bottom container. Attach FlashTite valve plate(s) over all vents. No filter is used. Recommended parameters are a minimum of 5 minutes exposure for non-porous items at 270°F (132°C) and minimum of 10 minutes exposure for porous items, lumens and mixed loads at 270°F (132° C). Recommended dry time: 0- 3 minutes dry time in the autoclave for items processed in flash sterilization depending on the degree of dryness required.
Note: Do not use the FlashTite valve with SteriTite® perforated bottom models SC04HG, SC04QG and SC04FG, because of height restrictions within these containers. Do not use solid bottom SteriTite® Container with FlashTite valve in gravity displacement IUSS sterilization.

FLASHTITE REPROCESSING INSTRUCTIONS:
After each use, disassemble and decontaminate the FlashTite valve plate with a multi-enzymatic, pH neutral detergent as you would any SteriTite® component part. Thoroughly rinse and dry.
Note: The copper module within the FlashTite valve mechanism will darken over time. This color change will not impact the safety and effectiveness of the device.
Refer to the sterilizer manufacturer's "Instructions for Use" for specific information as to the limitations of instrumentation, specifications and material compatibility. Complex instruments should be prepared and sterilized according to the instrument manufacturer's instructions. Contact the manufacturer of your endoscope or lumened devices when flashing.
Caution: When an abbreviated dry time is implemented, moisture can be present. Use a glove or towel when transporting hot items from the autoclave. Do not mix the FlashTite valve plate(s) with the filter retention plate(s) and disposable filter(s). Do not use the FlashTite valve plate(s) for EO or other low temperature sterilizers including gas plasma (STERRAD) sterilization.
Note: For low temperature sterilizers refer to the information provided below.

SteriTite® Labeling for Low Temperature Sterilization
Intended Use: Low temperature sterilization is utilized for moisture and temperature sensitive devices. Each sterilization modality has specific cycles and cleared for devices that are deemed compatible. Review the cycle parameters and compatibility statement from the sterilizer and device manufacturer. SteriTite Containers and MediTray products are universal reusable sterilization packaging systems validated for compatibility with low temperature sterilizers and for devices such as instrumentation including flexible endoscopes as follows:
STERRAD PARAMETERS FOR USE:
Use nonwoven polypropylene disposable filters: PolyPro filter # SCF02 (7.5" diameter) and SCFM02 (10"X4") are a disposable filter supplied non-sterile. For compatibility in the various low temperature sterilizers see Table 1 through Table 11.
Caution: In STERRAD® Sterilization do not use materials made of cellulose (paper filters and cotton) with SteriTite® containers.
Compatibility: In STERRAD® Sterilization use only compatible materials and instruments as stated in the Reference STERRAD® Operating Manual. Consult with your instrument manufacturer as to the compatibility of various materials in STERRAD ® Sterilization. Refer to STERRAD® System Operating Manual, instructions for use and labeling.
Internal Stacking: MediTray® baskets and trays may be stacked within the SteriTite® Container system as follows: In STERRAD NX up to two (2) instrument baskets or trays may be stacked within the SteriTite® container. In the STERRAD 200 up to four (4) instrument baskets or trays may be stacked. In STERRAD 200 & NX, the following MediTray baskets are not intended to be stacked: BSKF04, BSKF06, BSKH04, BSKQ04, and BSKQ06. In addition, MediTray® insert boxes are not intended to be stacked. Case Medical recommends that its Containers be placed flat on the sterilizer shelf.
External stacking was not tested. For STERRAD 100, 100S, 200 & 100NX: All models of SteriTite Containers can be placed on each of the two shelves within the STERRAD® 200. However, only one shelf can be used to accommodate an 8" high perforated base SteriTite® container, because of height restrictions within the sterilizer's chamber. For STERRAD NX only 2",3" and 4" high Containers will fit in the sterilizer chamber.

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

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

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

TSO3 STERIZONE PARAMETERS FOR USE:
Use non-woven polypropylene disposable filters: Disposable nonwoven filter # SCF02 (7.5" diameter) and SCFM02 (10"X4") are a single use disposable filter supplied nonsterile.
Use vented or solid base Container for STERIZONE® VP4 sterilization. Use MediTray® products in the Container to secure instrumentation. Recommended for sterilization of medical devices,

including flexible endoscopes, full instrument sets and mixed loads, including general instrumentation (gliding mechanism, hinges & screws, stopcock, lure-lock), instruments with rigid lumens (no dead-end) and rigid non-lumened scopes. For compatibility in the various low temperature sterilizers see Table 1 through Table 11.
Cycle time: The sterilizer manufacturer determines STERIZONE® VP4 Cycle 1 Sterilization cycle parameters. The cycle has a phase of hydrogen peroxide vapor exposure and one of hydrogen peroxide reduction using Ozone.
Internal Stacking: Testing was done with up to four (4) stacked trays or baskets inside the containers.
Compatibility: Use only compatible materials and instruments as stated in the STERIZONE® VP4 Operating Manual.
Compatibility: Consult with your instrument manufacturer as to the compatibility of various materials in STERIZONE® VP4 Sterilization. Refer to TSO3 System Operating Manual instructions for use and labeling.
Caution: Do not use saline based water softener for the final rinse as it causes corrosion and aborted cycles. Do not use alkaline cleaners to decontaminate the Container as it causes corrosion and aborted cycles.

STERIS V-PRO PARAMETERS FOR USE: The SteriTite Container system is intended for use in Steris V-PRO sterilizers. See Table 1 through Table 11 for compatibility and specific lumen claims. Use non-woven polypropylene disposable filters: Disposable nonwoven filter # SCF02 (7.5" diameter) and SCFM02 (10"X4") are a single use disposable filter supplied nonsterile.
Stacking of SteriTite® Containers in Steris V-PRO: MediTray® baskets and trays may be stacked within the SteriTite® Container system as follows: up to two (2) instrument baskets or four (4) trays may be stacked.
Caution: Stacking SteriTite® Containers stacking in Steris V-PRO is not recommended. All models of SteriTite® Containers can be placed on each of the two shelves within the V-PRO low temperature Sterilization System. However, only one shelf can be used to accommodate an 8" high perforated base SteriTite® container, because of height restrictions within the sterilizer's chamber.
MediTray® Products including MediTray® inserts, instrument baskets, stacking trays, BackBone silicone brackets, stainless and aluminum brackets, posts and partitions may be used in V-PRO Sterilization System.
Compatibility: In V-PRO sterilization use only compatible materials and instruments as stated in the V-PRO sterilization system operating manual. Consult with your instrument manufacturer for the compatibility of various materials in V-PRO Sterilization System. Refer to V-PRO Sterilization System Operating Manual, instructions for use and labeling.

Caution: Do not use nylon coated brackets or silicone mat. Do not use saline based water softener for the final rinse as it causes corrosion and aborted cycles. Do not use alkaline cleaners to decontaminate the Container as it causes corrosion, white powder residue, and contributes to aborted cycles. If a white powder residue is observed after sterilization in vaporized hydrogen peroxide do not use, until residue is removed using a pH neutral detergent followed by a thorough rinse. Avoid using solvents such as acetone or benzene which are commonly found in drying agents. Such solvents can cause irreparable damage to the Container and even void the warranty.

SteriTite® at Point of Use

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

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

Procedures for Checking Sterility Maintenance at Point of Use

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

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

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

INTENDED USE: MediTray® is intended to be used for the sterilization of reusable surgical instruments and medical devices in health care facilities. MediTray® products may be containerized or wrapped with an FDA cleared medical wrap. Please refer to the recommendations of your sterilizer

manufacturer for specific reprocessing instructions as well as recommendations from your medical device manufacturer for material compatibility and requirements for extended sterilization cycles. Note: MediTray® products may be used in steam, and low temperature sterilization, including EO, V-Pro, STERIZONE and H2O2 gas plasma (STERRAD) Sterilization.

REPROCESSING INSTRUCTIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SCLH2024:SteriTite® H2O2 Load Cards, Small
ID card with chemical indicator. Use for H2O2 and gas plasma sterilization

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

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

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

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

Best Practice Maintenance Procedures at Point of Use

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

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

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

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

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

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

If you have any questions regarding Case Medical products
Please contact us at:
Phone: (201) 313-1999 Fax: (201) 373-9090
info@casemed.com www.casemed.com

MDSS Gmbh
Schiffgraben 41
30175 Hannover
Germany
EC REP

MDSS CH Gmbh
Laurenzenvorstadt 61
5000 Aarau
Switzerland
CH REP

MDSS-UK RP Ltd.
6 Wilmslow Road, Rusholme
Manchester M14 5TP
United Kingdom