



Clear-Line®; (SteriTite®) Sterilization Container IFU

1. Disassemble all components. Unlatch and remove the lid of the SteriTite® rigid container. Inspect the gasket in the lid for accurate fit and undamaged surface. There is no reason to remove the gasket for the cleaning procedure.

2. Remove the tray of instruments and prepare the instruments for decontamination following the recommendations of the instrument manufacturer.

3. Remove the filter retention plate(s) by turning the handle of the locking mechanism clockwise. Inspect the gaskets in each filter plate. Place the filter retention plate in a basket for cleaning.

Note: SteriTite® solid bottom containers have filters in their lid. The SteriTite® container with perforated base has filters in both the lid and base.

Note: In order to properly decontaminate the container, be sure to remove the filter retention plate(s) from the container lid and base and place into a basket for cleaning.

4. Remove filter(s) and discard. Remove all other disposables including indicators, load cards and seals and discard.

Caution: **Filters installed on delivery are not meant for the sterilization process. Filters are disposable and limited to single use only.**

5. The SteriTite® Container components should be cleaned in an automatic washer/decontaminator. Always use a pH-neutral detergent and follow the washer manufacturer's instructions concerning correct use and secure positioning of the items. If necessary, you may clean SteriTite® Container components manually with a soft lint free cloth and a pH neutral detergent. Case Solutions® multi-enzymatic cleaners are ideal for medical devices and sterilization containers. Make sure to remove all detergent agent with a thorough rinsing. Detergent residues can affect coloration and the appearance of the container's surface. Lubricate latching mechanism for smooth functioning. Try to avoid water collections by washing and drying the container upside-down. Use a soft lint free cloth to dry all components of the container.

CAUTION: Do not use alkaline detergents, as they will oxidize the aluminum of the container. There will be no warranty for components damaged by non-neutral pH detergents or by the use of scratch pads.

Assembly:

1. Recommended inspection criteria: 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. If the retention plate is loose, adjust the tension by pressing downward along the perimeter of the round plate, and upward or downward at the tabs located at the ends of the rectangular plate.

Verify that the filter retention post(s) in the lid and label holders on the front of the SteriTite® Container is secure.

Note: Testing has been completed by Case Medical, Inc® that verified correct gasket operation after 1000 gravity displacement steam cycles and 100 cycles in STERRAD® Sterilization. The recommended inspection criteria should be performed after each use, because of the variables associated with cleaning agents and equipment.

2. For SteriTite® Perforated Bottom Container:

Place the appropriate filter over the perforations in the 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 counterclockwise to close.

Use SCF01, SCFM01 or SCF02, SCFM02 filters for steam, ETO, and Sterizone®125L sterilization.

Use paper filters SCF01, SCFM01 for prevacuum flash.

Use PolyPro filters SCF02, SCFM02 for STERRAD®
STERRAD® is a registered trademark of ASP, a division of Ethicon
Sterizone® 125L is a registered trademark of TSO3

Note: Components of the filter retention plate are spot welded together. An orange discoloration mark at the site of the weld is a normal reaction to spot welded stainless steel.

3. Arrange the clean instruments in the basket(s) according to hospital procedures. Follow the recommendations provided by the instrument manufacturer. MediTray® partitions, brackets and posts are recommended for easy loading and unloading as well as protection of your delicate instruments. Place the prepared baskets into the base of the SteriTite® Container.

4. Place a chemical indicator in the corner of the instrument basket. An internal chemical indicator should be used within each container. It should be placed in the area of the container considered to be least accessible to sterilant penetration...the corners of the container and the underside of the lid, away from the filters, are the likeliest locations for air pockets.

5. Place the appropriate filter over the perforations in the lid 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 the clicking sound.

6. Place the lid on top of the base. The edge of the base will fit in the lid channel.

7. 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.

8. Place the appropriate metal ID tags in the label holders located to either side of the container latches. The label holder on the right can accommodate a load card.

Note: The SteriTite container system with disposable filter is compatible with all current sterilization methods including prevacuum steam flash.

9. Thread the guide on the SteriTite® tamper evident seal through the lock holder and secure. Repeat on both latches. An external indicator should be attached to the container at this time. 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.

10. Consult the recommendations of your sterilizer manufacturer in order to determine the correct parameters regarding temperature, weight load, dry time, instrument processing and pre- and post conditioning cycles.

CAUTION: Use of the SteriTite container in gravity displacement steam may increase exposure time.

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

11. Following the sterilization process, the cart should be removed from the sterilizer and placed in cool down.

NOTE: To minimize the potential of condensate formation in solid bottom containers, crack the door of the autoclave for 15 minutes. Then remove for cool down.

At Point of Use:

1. Before opening the SteriTite® Container always verify that:

-The tamper-evident seals are intact.
-The acceptability of the end point response of the external chemical indicator.

-The correct set has been selected.

2. Break open the seals, remove and discard.

3. Unlatch the container.

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 will check the end point response of the chemical indicator to verify acceptable end point response.

6. The scrub person will then remove the basket of instruments and place it in the sterile field.

NOTE: 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 SteriTite® Containers sterilized in an outside contract facility should be double wrapped in plastic bags during transport.