



SKLARLITE™

Rigid Sterilization Container System

DIRECTIONS FOR USE,
CARE & HANDLING



SklarLite™ Rigid Sterilization Container System

Directions for Use and Care & Handling

The SklarLite™ Rigid Sterilization Container System is a reusable rigid container made from anodized aluminum alloy. These lightweight yet durable containers are designed to be used for the packaging, transportation and storage of surgical instruments before, during and after steam sterilization and come in a variety of sizes and colors to meet your needs.

CLEANING & HANDLING

The SklarLite™ Rigid Sterilization Container should be handled by qualified personnel who are trained in the use of sterilization containers, hospital hygiene and sterilization technology. This will prevent damage to the containers, fasteners, seals and filters during use. Properly cared for, the SklarLite™ containers provide years of instrument protection and sterility assurance.

DO NOT use any abrasive cleaners, material or stainless steel brushes or pads to clean the SklarLite™ Containers as this may cause chemical or physical corrosion resulting in permanent damage to the aluminum surface. Use of abrasive products will void all manufacturer warranties.

Recommended Cleaners: Use only mild alkaline, sodium carbonate-free, neutral pH (7) detergents, such as Sklar Kleen™ Liquid Detergent, to clean effectively without causing damage to the anodized layer of aluminum. Containers must be thoroughly cleaned and dried prior to use.

PRE-CLEANING PREPARATION:

1. Remove lid from the container bottom.
2. Separate the safety lid from the container lid if using the SklarLite™ Safe Model.
3. Remove the basket(s) and any instructions from the container.
4. Remove the filter retention plate(s) from the lid.
5. Remove the filter retention plate(s) from the bottom, if using perforated container bottoms.
6. Remove and discard the disposable filter(s).
7. Remove all indicator cards and disposable locks.

MANUAL CLEANING:

- Use a soft sponge and mild, pH(7) neutral detergent (such as Sklar Kleen™ Liquid Detergent) to thoroughly wash the entire container and all accessories in water (at room temperature).
- The container and its parts must be rinsed thoroughly in demineralized (if possible) water (at room temperature) until all cleaning solution and detergent residue is removed.
- Visually inspect the container for soil residues. If present, reprocess per the steps above.
- Dry thoroughly by hand with a soft cloth or air dry. Store in a clean, dry environment.

MECHANICAL CLEANING:

- Securely place the container bottom (open side) face down in the washer. Handles should be folded down.
- Securely place the container lid (open side) face down in the washer.
- Place retention plates securely in the washer manufacturer basket, away from washer jets to avoid damage during the washing cycle.
- Follow the washer manufacturer instructions for cleaning of aluminum containers using a neutral pH(7) detergent approved for machine washing. Use demineralized (if possible) water (at room temperature) for final rinsing. Salt in the saline/water may cause future deterioration to the surface of the device.
- Visually inspect the container for soil residues. If present, reprocess per the steps above.
- After cleaning, dry thoroughly with a soft cloth or air dry and store in a clean, dry environment.

For more information concerning the inspection and cleaning of closed sterilization containers, please see Sections 5.2.3 and 7.5.9 of AMSI/AAMI ST79 Standard.

ASSEMBLY FOR USE

PRE-ASSEMBLY INSPECTION AND PREPARATION: _____

- Verify that all components are thoroughly dry before assembling.
- Select surgical instruments for sterilization.
- SklarLite™ Containers are intended for use with (non-porous) surgical instruments.
- Complex instruments such as air-powered instruments, endoscopes and instruments with lumens or channels, should be prepared and sterilized according to the instrument manufacturer's instructions. The Full and Mid-size containers are validated for sterilization of up to two instruments with lumens no smaller than 2.4mm in diameter and no longer than 380mm in length. The Half-size container is validated for sterilization of up to two instruments with lumens no smaller than 1.0mm in diameter and no longer than 250mm in length.
- Select appropriate size container and basket(s).
- Visually check container bottoms and lids to ensure they are free from peeling, cracking, dents or other deformations. Such deterioration could indicate age and should not be used
- Inspect the inside channel of the lid to ensure that the silicone gasket is in good condition and free from cracks. A cracked gasket could indicate age and / or deterioration and should not be used.

An optional silicon mat (one per basket) can be used to prevent instrument slippage during sterilization, transport and storage.

FILTER ASSEMBLY: _____

- Place one new sheet of filter paper over each perforated section on the inside of the container lid and / or bottom, making sure it is centered on the protruding pin.
- Secure the filter with the retention plate by pressing the plate onto the protruding pin until you hear an audible click, which indicates that locking has been realized.
- Repeat process until all filters have been secured.

The filters validated for use with the containers are SklarLite™ Filters item #10-4910. Filters are 7.5" in diameter and intended for single use only. A new filter is required for each processing cycle.

INSTRUMENT AND CONTAINER ASSEMBLY: _____

- Arrange clean and dry instruments into the wire baskets according to the established facility procedures. Containers have been validated for stacking of up to two (2) internal baskets.
- Place instrument basket(s) into the prepared container bottom.
- Place lid on the container bottom, aligning handles on bottom with latches on lid.
- Simultaneously close both locking latches on the lid.

Instruments should be arranged to allow for uniform exposure to sterilization agents. Leave a minimum of one inch clearance between the instruments and the inside of the container lid for effective processing.

DO NOT exceed a combined maximum weight limit (container and contents) of 25lbs.

PROCESSING ASSEMBLY: _____

- Select a SklarLite™ Indicator Card and place it into the holding bracket(s) on the outside of the container. A tab at one end of the indicator card will facilitate insertion and removal.
- Insert color-code SklarLite™ Identification Cards selected by the user into the holding bracket(s) on the outside of the container.
- Insert a plastic tamper-proof seal into the locking channel on each end of the container.
- Secure and lock.

Use of internal and external indicators should be in accord with the facility's protocol, determined by the user.

The process indicator cards validated for use with the containers are SklarLite™ Indicator Cards, item #10-4900. These disposable indicators are designed for use in steam sterilizers.

LOADING THE STERILIZER:

- For effective sterilization, always place the SklarLite™ Rigid Sterilization Container flat / level.
- The container should be positioned on the autoclave cart below wrapped items for optimum sterilization and drying conditions.

DO NOT cover filter perforated sections with paper wrapped instruments or any other objects that could obstruct the way air and steam flow. This obstruction may cause permanent damage to the container.

Stacking: Both solid and perforated bottom containers, no deeper than 150mm each, have been validated for stacking of up to three (3) containers high. Stacking should not exceed three (3) containers to ensure effective air removal and adequate steam penetration.

PROCESSING

Run the loaded sterilizer according to the manufacturer's instructions with the following parameters:

HIGH VACUUM (pre-vacuum, three pulse, standard) STEAM CYCLE

Temperature: 270° F

Exposure Time: 4 minutes (minimum)

Cycle Dry Time: 30 minutes (minimum)

Cool Time: Varies according to load contents

CAUTION: The container needs to remain on the container cart until cool enough to handle. Cool drafts from air ducts or other air currents should be avoided during the cooling phase to avoid post-sterilization moisture caused by rapid cooling syndrome. If condensation on the inside of containers comes in contact with outside contaminants, sterility may be compromised. Condensation inside containers may cause rust to form on some instruments.

Snap safety lids onto the container lid following sterilization and cooling to protect filters during transportation and storage. Containers can be stacked during storage, placing the heavier containers on the bottom. The SklarLite™ Containers with either perforated or non-perforated bottoms, can store high-vacuum (pre-vacuum) sterilized medical devices for a maximum of 180-days, so long as the container integrity has not been compromised.

WARRANTY

Sklar hereby warrants all SklarLite™ Rigid Sterilization Containers and components of the system purchased through the Sklar Instruments supply chain in accordance with the following conditions:

SklarLite™ Rigid Sterilization Containers are guaranteed to be free from defects in design, workmanship, and materials when used for their intended purpose. Any SklarLite™ container that proves defective in design, workmanship, or material will either be repaired or replaced at Sklar's discretion and without charge during the warranty period.

The warranty period for SklarLite™ containers and gaskets is two (2) years from the date of purchase.

Containers not purchased from an authorized source may not be authentic or meet Sklar's quality standards, and are NOT covered by this warranty.

Periodic inspection and maintenance is suggested to ensure all parts are in good working order.

REPAIR OR REPLACEMENT

Under this warranty, and at its discretion, Sklar will repair or replace any products found to be defective in design, workmanship or material.

Sklar will determine at its discretion the cause and nature of any defect, the necessity and manner of repair or replacement, and all other matters pertaining to the condition of the SklarLite™ Rigid Sterilization Containers.

Sklar's standard Return Policy applies to all returned items.

EXCLUSIONS

The SklarLite™ Rigid Sterilization Container Warranty does not cover conditions or damage resulting from negligence, misuse, improper handling, improper cleaning, improper opening techniques, or unauthorized repair work including but not limited to:

- Incidents of abuse such as denting of the SklarLite™ Container by dropping or other mechanically applied pressure.
- Damage determined to be related to caustic or abrasive cleaning agents.
- Items modified by the customer.
- Items modified or customized by Sklar at the request of the customer.
- Damage from fire, flood and other occurrences beyond the control of Sklar.

PRODUCT LINE

SklarLite™ Rigid Sterilization Containers* with Filter System <small>*All Container Lids are available in your choice of Silver, Yellow, Red, Blue, Green or Black.</small>	MODEL	Perforations	Dimensions	Load Limit	Stacking Max.
	Full Size Containers Basic/Safe Models	Perforated Lid and Non Perforated Bottom	580 x 280 x 100	25 lbs.	3
			580 x 280 x 135	25 lbs.	3
			580 x 280 x 150	25 lbs.	3
			580 x 280 x 200	25 lbs.	N/A
			580 x 280 x 260	25 lbs.	N/A
		Perforated Lid and Perforated Bottom	580 x 280 x 100	25 lbs.	3
			580 x 280 x 135	25 lbs.	3
			580 x 280 x 150	25 lbs.	3
			580 x 280 x 200	25 lbs.	N/A
			580 x 280 x 260	25 lbs.	N/A
		Full Size Wire Baskets	540 x 255 x 30mm	N/A	2
			540 x 255 x 50mm		2
			540 x 255 x 70mm		2
			540 x 255 x 100mm		2
	Mid Size Containers Basic/Safe Models	Perforated Lid and Non Perforated Bottom	465 x 280 x 100	25 lbs.	3
			465 x 280 x 135	25 lbs.	3
			465 x 280 x 150	25 lbs.	3
		Perforated Lid and Perforated Bottom	465 x 280 x 100	25 lbs.	3
			465 x 280 x 135	25 lbs.	3
			465 x 280 x 150	25 lbs.	3
	Half Size Containers Basic/Safe Models	Mid-Size Wire Baskets	405 x 255 x 30mm	N/A	2
			405 x 255 x 50mm		2
			405 x 255 x 70mm		2
			405 x 255 x 100mm		2
		Perforated Lid and Non Perforated Bottom	285 x 280 x 100	25 lbs.	3
			285 x 280 x 135	25 lbs.	3
			285 x 280 x 150	25 lbs.	3
			285 x 280 x 200	25 lbs.	N/A
			285 x 280 x 260	25 lbs.	N/A
		Perforated Lid and Perforated Bottom	285 x 280 x 100	25 lbs.	3
			285 x 280 x 135	25 lbs.	3
			285 x 280 x 150	25 lbs.	3
			285 x 280 x 200	25 lbs.	N/A
			285 x 280 x 260	25 lbs.	N/A
	Accessories	Half-Size Wire Baskets	255 x 245 x 30mm	N/A	2
			255 x 245 x 50mm		2
			255 x 245 x 70mm		2
			255 x 245 x 100mm		2
		Silicone Mats	230 x 240mm	N/A	N/A
			395 x 240mm		N/A
			530 x 240mm		N/A
		Disposable Filters	White	N/A	N/A
		Custom Identification Cards	Silver, Yellow, Red, Blue, Green, Black	N/A	N/A
		Indicator Cards	N/A	N/A	N/A
		Security Locks	N/A	N/A	N/A

Please direct your questions or comments about this product to:



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