

BAHADIR STERILIZATION CONTAINERS-(Pre-Vac Sterilization W Series Container Systems)

INSTRUCTIONS OF USE

Bahadir Sterilization Containers are reusable, metal, sterilization containers. They are designed for holding operating room instruments and/or textiles during vacuum-steam sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions.

This user manual describes important instructions on the proper usage and maintenance of Bahadir Sterilization Containers, and possible hazards that could result from failure to observe the instructions.

- In order to prevent damage to the containers during usage it is important that the containers be handled by fully trained and qualified personnel in all areas of sterilization containers, hospital hygiene and sterilization technology.
- * Thoroughly clean prior to first use. Items are shipped Non-Sterile

PRE-CLEANING

- ✓ Remove lid and basket with instruments from the container.
- ✓ Separate the safety lid from the container lid, (if using safety lid)
- √ Remove filter retainer plate(s). (If bottom perforated, also remove retainer plates)
- Remove indicators and disposable security seals and disposable paper filter.

CLEANING AND DISINFECTION

Requirements according DIN 58953/9; Users have to specify by means of disinfection and cleaning plan, when and how the sterilization containers have to be cleaned and/or disinfected. Containers that are used for waste disposal have to be cleaned and disinfected each time after use.



Do not use metal brushes or any abrasive cleaning material. Never use bleach or other corrosive chemicals to clean Bahadir Sterilization Containers. Abrasive products may cause chemical and physical corrosions that will void all manufacturer warranties.

For more information concerning the inspection and cleaning of closed sterilization containers, please see Sections 5.2.3 and 7.5.9 of ANSI/AAMI ST79 Standard, if available, or contact Bahadir USA at info@bahadirusa.com or call 856-517-3080.

MANUAL CLEANING

See Table 1 for Manual Washing Parameters

- 1. Remove all remaining external process indicators and disposable locks
- 2. Remove lid from bottom of container
- 3. Remove the basket and any instruments from the container
- 4. Single-use Filter
 - a. Remove the Retention plate(s)
 - b. Remove filter(s) and discard (if present)
- 5. Rinse visible debris from all container components for at least 2 minutes under cold tap water
 - a. If debris remains, repeat rinsing
- 6. Prepare a bath of cleaning solution using STERIS® Prolystica® 2x Concentrate Neutral Cleaner according to manufacturer's instructions.
- 7. Fully immerse the container components in cleaning solution and soak for minimum of 5 minutes.
- 8. Use a soft bristled brush or sponge and scrub each component for approximately 5 minutes
- 9. Rinse all the parts under cold deionized water for 2 minutes without leaving any stain or residue on them.
- 10. Thoroughly dry with soft lint-free cloth or compressed filtered air and store in clean and dry environment.

Table 1: Manual Washing Parameters:

Cleaning Process Steps	Instructions
Prepare container for cleaning	Remove any indicators and locks, remove basket and any instruments, separate base from lid, remove filter retention plates, discard filters if present
Rinse	Using cold tap water, rinse all visible debris from components for at least 2 minutes.
Cleaning Solution	STERIS® Prolystica® 2x Neutral Cleaner, prepare bath according to manufacturer directions
Soak	Fully immerse components for minimum for5 minutes

Cleaning/Brushing	Scrub with soft sponge or brush to clean components for approximately 5 minutes	
Final Rinse	Thoroughly rinse for 2 minutes under cold deionized water to remove all detergent residues	
Dry	Dry using a lint free cloth or filtered compressed air	
Inspect	After cleaning visually inspect and repeat the cleaning process if a visually clean endpoint has not been achieved	

MECHANICAL CLEANING

Mechanical cleaning of the containers is preferred to manual cleaning provided that the washing machine is designed for cleaning sterilization containers. This applies in particular to ensure secure placement in the washing baskets and arrangement of the spray jets and arms. Washer must also have a special washing program for aluminum containers. See Table 2 for Mechanical Washing Parameters



Do not use any cleaning solutions that contain soda or caustic acid. Do not use additional acidic neutralizers.

- 1. Remove all remaining external process indicators and disposable locks
- 2. Remove lid from bottom of container
- 3. Remove the basket and any instruments from the container
- 4. Single-use Filter
 - a. Remove the Retention plate(s)
 - b. Remove filter(s) and discard (if present)
 - c. Rinse visible debris from the retention plates
- 5. Rinse visible debris from all container components
 - a. Demineralized water is recommended for the final rinse and steam generation to avoid discoloration or damage resulting from minerals found in utility water
 - b. Make sure no residues from the Pre-cleaning process remain on the lid or bottom
 - c. If debris remains, repeat rinsing
- 6. Place components on washer rack facing down to avoid water collection
 - a. Retention plates should be placed in a separate washing basket
 - b. Use a neutral pH enzymatic cleaning solution in accordance with the manufacturer's instructions
- 7. After mechanical cleaning cycle thoroughly dry (either with a soft, dry cloth or air dry) all components, including retention plate(s) before proceeding to assembly

Treatment	Time (mm:ss)	Temperature	Cleaning Solution	
Pre-Rinse	01:30	Cold Tap	N/A	
Wash	05:00	55°C	STERIS® Prolystica® 2X	
			Concentrate Neutral Cleaner	
Final Rinse	01:45	Deinonized Water 90°C	N/A	
Dry	07:30	90°C	N/A	

Table 2: Mechanical Washer Cycle Parameters:

ASSEMBLY FOR USE

Bahadir Sterilization Containers must be checked visually before each usage. Inspect the container bottoms, container lids and the surfaces where seals sit must be free of dents, visible deformations and anything else that might appear out of the ordinary.

Users are responsible for pre-inspection prior to assembly for use of containment devices to verify that the gaskets in the lid and filter retention plates are in good working order, the plates properly seal over the vented area of the container lid and base, and that no rust or corrosion are present on any surfaces. Furthermore, the gasket should be intact and the edge of

the container base nest properly within the container lid. Dents and deformations can affect the seal of the container compromising the integrity of the containment device.



Do not use spray oil or solvents on the lid seals. The seal in the inner lid must be completely inserted and undamaged. If there is any kind of damage detected, lids should not be used.

PRE-ASSEMBLY INSPECTION AND PREPARATION:

- ✓ Select surgical instrument set for sterilization.
- ✓ Be sure all the components are completely dry.
- ✓ Select appropriate size baskets and containers.

Bahadir Sterilization Containers are designed to be used with single-use paper filters validated for use with the containers (BAHADIR USA item number Y800.00).

FILTER ASSEMBLY:

- 1. Place one sheet of filter over each perforated section on the inside of Bahadir Sterilization Containers. (Make sure it covers all the perforation holes properly).
- 2. Make sure that filters and filter retainers are placed properly. 'Click' sound should be heard while placing filter retainers by pressing on them which indicates locking is realized.

For <u>perforated bottoms</u>; place one filter over the perforated section in the bottom of the container. Make sure you hear the click sound while pressing onto the protruding pin. <u>Solid Bottoms</u>; There is no perforated section for this model and does not require a filter or retention plate.

CAUTION:

Filters and filter retainers must show no visual deformations. These parts must be checked visually and for their functionality before usage.

INSTRUMENT AND CONTAINER ASSEMBLY

Place thoroughly cleaned and dried instruments into the instrument basket(s) according to established hospital procedures. Complex instruments, such as air-powered instruments have to be prepared and sterilized according to the instrument manufacturer's instructions. Small baskets, trays and other types of accessories, especially with covers and lids, should only be used with the sterilization container which has been specifically designed for that purpose. The Containers have been validated for sterilization of up to 2 instruments with lumens no smaller than 1 mm in diameter and no longer than 300 mm in length for the Full Size, ¾ Size, and Wide Body Containers. Place instrument basket(s) into the prepared container bottom. Place assembled lid onto the container bottom, aligning handles on bottom with latches on lid. Simultaneously close both locking latches on the lid.

CAUTION: Leave one inch of free space between the instruments and the inside of the container lid for effective processing.

PROCESSING ASSEMBLY

- 1. Select the appropriate indicator card and insert into the holding brackets on the outside of the container.
- 2. Insert the security seals (Y819.00).
- 3. Secure and Lock.

Bahadir Sterilization Containers are protected by disposable plastic security seals which once attached can be opened only by breaking which prevents inadvertent opening of the containers, and ensures that it is evident whether or not the sterility of the contents has been compromised. 2) Use of internal and external indicators should be in accordance with in-house protocol that is determined by the user.

LOADING THE STERILIZER:

Bahadir Sterilization Containers should be placed horizontally in the sterilizer for effective sterilization and drying.

STACKING:

Stacking permitted in the chamber during the sterilization process provided the following criteria are met:

- Each container's maximum load weight, including baskets, accessories & instruments, is not exceeded.
- The largest/heaviest container must be on the bottom.
- Pre Vacuum sterilization containers may be stacked <u>up to 18 inches</u> during the sterilization process with <u>no more than THREE containers</u> as part of the <u>18" maximum</u> configuration.

 Containers are labeled with height on handle face side of container. Please see picture diagram below. If mark is worn or illegible, please measure height of the tray.



- 3 containers MAXIMUM can be stacked.
- UNDER NO CIRCUMSTANCES SHOULD STACKED CONTAINERS EXCEED 18 INCHES IN HEIGHT

PROCESSING

The loading instructions of the sterilizer manufacturer should be observed. High vacuum (pre-vacuum, three pulse, standard) Temp: 270° Exposure Time: 4 minutes (minimum) Cycle Dry Time: 20 Minutes (minimum) Cool Time: Varies according to load contents.

CAUTION: In order to avoid post-sterilization moisture caused by rapid cooling syndrome, cool drafts from air ducts or other air currents should be avoided. Do not place the container on cold surfaces or expose to a cold draft. To safeguard against accidents (burns, dropping, etc.), containers that are still hot should never be handled with bare hands. Containers need to remain on the container cart, in draft free area until cool enough to handle.

SHELF LIFE

In protected storage (temperature, humidity, air filtration etc. controlled hospital storage room conditions) containers can store high-vacuum (pre-vacuum) sterilized medical devices for up to 12 months, provided the integrity of the container is not compromised.(Tamper-evident security seal (Y819.00) remains intact) Note: Bahadir Sterilization Containers can be stacked during storage, one on top of another. Be sure that heavier container is placed at the bottom. Immediate Use sterilized devices cannot be stored.

BAHADIR USA CONTAINER SYSTEM WARRANTY

BAHADIR USA hereby warranties all products carrying the registered trademark and logo of BAHADIR USA purchased directly from BAHADIR USA or an authorized dealer in accordance with the following terms and conditions: The warranty period of Bahadir Sterilization Containers is two years from the date of purchase. Bahadir Sterilization Containers are guaranteed to be free from defects in material and workmanship when used for its intended purpose. Containers that prove defective in material or workmanship will either be repaired/replaced free of charge during the warranty period. Containers that are not purchased from BAHADIR USA or an authorized source may not meet BAHADIR USA quality standards. Repair or Replacement: Under warranty, BAHADIR USA will repair or replace any parts and determine the nature of any defect, the necessity and manner of repair or replacement, all other matters pertaining to the conditions of the Bahadir Sterilization Container Systems. All devices returned for repair or replacement are assessed on an individualized basis, and may result in either repair or replacement upon thorough inspection and evaluation with the safety and integrity of the device as our foremost concern. Repair will be limited to components which would not affect the performance of the containers with regards to sterilization, such as handles. Containers which have damage to the frame or seal areas which could affect the integrity of the system will be replaced.

Exclusions

This warranty shall not apply to any condition(s) or damage resulting from misuse, improper cleaning, improper handling, negligence, improper opening or unauthorized repair work including but not limited to: Incidents of abuse such as denting of Bahadir Sterilization Container due to dropping or other instances of mechanically applied pressure. Damage determined to be related to caustic or abrasive cleaning agents, items modified by the customer, items modified or customized by BAHADIR USA at the request of the customer, damage from fire, flood and other occurrences not under the control of BAHADIR USA.

Please direct your questions regarding this warranty to:

BAHADIR USA

431 South Pennsville Auburn Road Carney's Point, NJ 08069 Tel: (856) 514-3080 Fax: (856) 514-3081

www.bahadirusa.com

Maximum Recommended Load (including basket and contents)

Maximum Recommended Load Model	Dimensions (mm)	LBS.
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	580X280X100	24.75
1/1 Size	580X280X135	24.75
	580X280X150	24.75
Container	580X280X200	24.75
	580X280X260	24.75
3/4 Size	465x280x100	12.5
	465x280x135	12.5
Container	465x280x150	12.5
	465x280x200	12.5
	285x280x100	9.25
1/2 Size	285x280x135	9.25
	285x280x150	9.25
Container	285x280x200	9.25
	285x280x260	9.25
Wide Body	600x400x120	24.75
Container	600x400x180	24.75
Long Body Container	790x330x190	24.75
Flat	285x280x55	9.25
Container	285x280x85	9.25
Mini	300x140x40	6.0
	300x140x70	6.0
Container	300x140x100	6.0
Dental	310x190x40	9.25
Dentai	310x190x65	9.25
Container	310x190x130	9.25