BAHADIR STERILIZATION CONTAINERS- (STERRAD/Steris V-PRO Sterilization)

INSTRUCTIONS OF USE

Indications for Use:

Bahadir Sterilization Containers are reusable, metal, sterilization containers. They are designed for holding operating room instruments and/or textiles during low temperature hydrogen peroxide sterilization procedures and for maintaining sterility during storage and transport under proper hospital conditions. This container system is compatible for use with the following low temperature sterilizers and the cycles identified below:

*STERIS V-PRO maX/maX2 - Lumen, Non-Lumen and Flexible Cycles *STERIS V-PRO s2/60 - Lumen, Non-Lumen and Flexible Cycles *STERRAD 100NX - Duo, Express, Standard and Flex Cycles *STERRAD NX - Standard and Advanced Cycles

Bahadir USA Container Lumen Configurations

Sterilization Cycle	Container Size	Compatible Lumens
STERIS VPRO maX/maX2	Full Size	 ≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel) ≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid non-metallic lumen) x ≤424mm (rigid non-metallic lumen)
Lumen Cycle	Three-Quarter Size	 ≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel) ≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid nonmetallic lumen) ≥4mm x ≤424mm (rigid nonmetallic lumen)
	Half Size	 ≥0.77mm x ≤527mm (single, dual or triple channel) ≥0.8mm x ≤542mm (single, dual or triple channel) ≥0.48mm x ≤100mm (single, dual or triple channel) ≥1.3mm x ≤73mm (dead end lumen) ≥3mm x ≤298mm (rigid non- metallic lumen) ≥4mm x ≤424mm (rigid non- metallic lumen)

STERIS VPRO maX/maX2	Full Size	 (2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm Or (1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device
Flexible Cycle	Three-Quarter Size	device(2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load.The flexible endoscopes may contain Single or Dual channel lumens ≥1mm x ≤1050mm Or(1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥1mm x ≤1050mm. Additional single, dual or triple channel stainless steel lumen device that is ≥0.48mm x ≤100mm OR non-lumen device
	Half Size	device(2) flexible endoscopes with light cord (if not integral to endoscope) and mat with no additional load.The flexible endoscopes may contain Single or Dual channel lumens ≥ 1 mm x ≤ 1050 mm Or(1) flexible endoscope with light cord (if not integral to endoscope), endoscope accessories, mat and additional instruments. The flexible endoscope may contain Single or dual channel lumens that are ≥ 1 mm x ≤ 1050 mm. Additional single, dual or triple channel stainless steel lumen device that is ≥ 0.48 mm x ≤ 100 mm OR non-lumen device

STERIS VPRO maX/maX2	Full Size	-Non lumened instruments
Non-Lumen Cycle	Three-Quarter Size	-Non lumened instruments
	Half Size	-Non lumened instruments
	Full Size	 ≥0.77mm x ≤410mm (single or dual channel) ≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel)
STERIS VPRO s2/60		≥2.8mm x ≤317mm (triple channel)
Lumen cycle	Three-Quarter Size	 ≥0.77mm x ≤410mm (single or dual channel) ≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel) ≥2.8mm x ≤317mm (triple channel)
	Half Size	 ≥0.77mm x ≤410mm (single or dual channel) ≥1.8mm x ≤542mm (single or dual channel) ≥1.2mm x ≤275mm (triple channel) ≥1.8mm x ≤310mm (triple channel) ≥2.8mm x ≤317mm (triple channel)
STERIS VPRO s2/60	Full Size	 -Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or
		dual lumen device with lumens that are ≥1mm x ≤990mm
Flexible Cycle	Three-Quarter Size	 -Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm
	Half Size	 -Non-lumened instruments and instruments with diffusion restricted spaces (such as the hinged portion of forceps and scissors) -(1) surgical flexible endoscope or bronchoscope with light cord (if not integral to the endoscope). The

		flexible endoscope may be single or dual lumen device with lumens that are ≥1mm x ≤990mm
STERIS VPRO s2/60	Full Size	-Non lumened instruments
Non-Lumen Cycle	Three-Quarter Size	-Non lumened instruments
	Half Size	-Non lumened instruments
STERRAD NX	Full Size	(5) SS lumens 1mm I.D. x 150mm L (5) SS lumens 2mm I.D. x 400mm L
Standard Cycle	Three-Quarter Size	(10) SS lumens 1mm I.D. x 150mm L
	Half Size	(10) SS lumens 1mm I.D. x 150mm L
STERRAD NX	Full Size	(10) SS lumens 2mm I.D. x 500mm L
Advanced Cycle	Three-Quarter Size	(6) SS lumens 1mm I.D. x 350mm L
	Half Size	(10) SS lumens 1mm I.D. x 200mm
STERRAD 100NX	Full Size	(5) SS lumens 1mm I.D. x 500mm L
Standard Cycle	Three-Quarter Size	(5) SS lumens 1mm I.D. x 350mm L
	Half Size	(5) SS lumens 0.7mm I.D. x 200mm L
STERRAD 100NX	Full Size	Non lumened SS instruments
Express Cycle	Three-Quarter Size	Non lumened SS instruments
	Half Size	Non lumened SS instruments
STERRAD 100NX	Full Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
Duo Cycle	Three-Quarter Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
	Half Size	(1)PTFE tubing 1.5 mm I.D. x 850mm L
STERRAD 100 NX	Full Size	(1) Scope lumen 1mm I.D. x 850mm L
Flexible Cycle	Three-Quarter Size	(1) Scope lumen 1mm I.D. x 850mm L
	Half Size	(1)PTFE tubing 1mm I.D. x 850mm L

Bahadir USA Container Configurations

Bahadir USA Contain		Container News	Total Loaded Cantainan (Ita)
Sterilization Cycle	Container Size	Container Name	Total Loaded Container (lbs)
	Full Size 4 1/8"	Y111.10	19.65
	Full Size 5 ¼"	Y111.13	19.65
	Full Size 5 %"	Y111.15	19.65
	Full Size 7 ¾"	Y111.20	19.65
	Full Size 10 ¼ "	Y111.26	19.65
	Full Size 7 ¾"	Y111.70	19.65
STERIS VPRO	Three-Quarter Size 4 1/8"	Y211.10	19.65
maX/maX2	Three-Quarter Size 5 ¼"	Y211.13	19.65
Lumen Cycle	Three-Quarter Size 5 ⁷ / ₈ "	Y211.15	19.65
	Three-Quarter Size 7 ¾"	Y211.20	19.65
	Half Size 4 ¹ / ₈ "	Y311.10	15
	Half Size 5 ¼"	Y311.13	15
	Half Size 5 [™]	Y311.15	15
	Half Size 7 ¾"	Y311.20	15
	Half Size 10 ¼"	Y311.26	15
	Full Size 4 1/8"	Y111.10	21
	Full Size 5 ¼"	Y111.13	21
	Full Size 5 [™]	Y111.15	21
	Full Size 7 ¾"	Y111.20	21
	Full Size 10 ¼ "	Y111.26	21
	Full Size 7 ¾"	Y111.70	21
STERIS VPRO	Three-Quarter Size 4 1/8"	Y211.10	21
maX/maX2	Three-Quarter Size 5 ¼"	Y211.13	21
Flexible Cycle	Three-Quarter Size 5 ⁷ / ₈ "	Y211.15	21
	Three-Quarter Size 7 ¾"	Y211.20	21
	Half Size 4 ¹ / ₈ "	Y311.10	21
	Half Size 5 ¼"	Y311.13	21
	Half Size 5 [™]	Y311.15	21
	Half Size 7 ¾″	Y311.20	21
	Half Size 10 ¼"	Y311.26	21
	Full Size 4 1/8"	Y111.10	26
	Full Size 5 ¼"	Y111.13	26
	Full Size 5 [™]	Y111.15	26
	Full Size 7 ¾"	Y111.20	26
	Full Size 10 ¼ "	Y111.26	26
	Full Size 7 ¾"	Y111.70	26
STERIS VPRO	Three-Quarter Size 4 1/8"	Y211.10	26
maX/maX2	Three-Quarter Size 5 ¼"	Y211.13	26
Non-Lumen Cycle	Three-Quarter Size 5 %"	Y211.15	26
	Three-Quarter Size 7 ¾"	Y211.20	26
	Half Size 4 1/8"	Y311.10	19
	Half Size 5 ¼"	Y311.13	19
	Half Size 5 %"	Y311.15	19
	Half Size 7 ¾"	Y311.20	19
	Half Size 10 ¼"	Y311.26	19
	Full Size 4 ¹ / ₈ "	Y111.10	11
	Full Size 5 ¼"		

Full S			Y111.15	11
Full S			Y111.20	11
Full S			Y111.26	11
Full S			Y111.70	11
		↓ ½″	Y211.10	11
		5 ¼″	Y211.13	11
Lumen Cycle Three	e-Quarter Size 5	5 7%"	Y211.15	11
Three	e-Quarter Size 7	7 ¾"	Y211.20	11
Halfs	Size 4 1⁄8"		Y311.10	11
Half	Size 5 ¼"		Y311.13	11
Half	Size 5 %"		Y311.15	11
Halfs	Size 7¾"		Y311.20	11
Half	Size 10 ¼"		Y311.26	11
Full S			Y111.10	11
Full S	ize 5 ¼"		Y111.13	11
Full S	ize 5 %"		Y111.15	11
Full S	ize 7 ¾"		Y111.20	11
Full S	ize 10 ¼ "		Y111.26	11
Full S	ize 7 ¾"		Y111.70	11
		↓ ½″	Y211.10	11
		5 1/4"	Y211.13	11
		5 7/8"	Y211.15	11
		7 3⁄4″	Y211.20	11
Halfs		74	Y311.10	11
Half			Y311.13	11
Half			Y311.15	11
Half			Y311.20	11
Half			Y311.26	11
	512C 10 74		1311.20	
Full S	ize 4 ½"		Y111.10	19
Full S			Y111.13	19
Full S			Y111.15	19
Full S			Y111.15	19
Full S			Y111.20	19
		1 1/11	Y111.70	19
		1 ½″	Y211.10	19
		5 1/4"	Y211.13	19
	-	5 7/8"	Y211.15	19
		7 ¾″	Y211.20	19
Halfs			Y311.10	12.5
Halfs			Y311.13	12.5
Half			Y311.15	12.5
Half			Y311.20	12.5
Half	Size 10 ¼"		Y311.26	12.5
Full S			Y111.10	10.7
Full S			Y111.13	10.7
Full S			Y111.15	10.7
Full S			Y111.20	10.7
	101/ "		Y111.26	10.7
Full S			1111.20	10.7
Full S			Y111.70	10.7
Full S	ize 7 ¾"	l ⅓"		

		2011.15	40.7
Standard Cycle	Three-Quarter Size 5 ⁷ / ₈ "	Y211.15	10.7
	Three-Quarter Size 7 ³ ⁄ ₄ "	Y211.20	10.7
	Half Size 4 1/8"	Y311.10	10.7
	Half Size 5 ¼"	Y311.13	10.7
	Half Size 5 ⅔"	Y311.15	10.7
	Half Size 7 ¾"	Y311.20	10.7
	Half Size 10 ¼"	Y311.26	10.7
	Full Size 4 1⁄8"	Y111.10	10.7
	Full Size 5 ¼"	Y111.13	10.7
	Full Size 5 [™]	Y111.15	10.7
	Full Size 7 ¾"	Y111.20	10.7
	Full Size 10 ¼ "	Y111.26	10.7
	Full Size 7 ¾"	Y111.70	10.7
STERRAD NX	Three-Quarter Size 4 1/8"	Y211.10	13.85
	Three-Quarter Size 5 ¼"	Y211.13	13.85
Advanced Cycle	Three-Quarter Size 5 %"	Y211.15	13.85
	Three-Quarter Size 7 ¾"	Y211.20	13.85
	Half Size 4 ¹ / ₈ "	Y311.10	10.7
	Half Size 5 ¼"	Y311.13	10.7
	Half Size 5 ⁷ / ₈ "	Y311.15	10.7
	Half Size 7 ¾"	Y311.20	10.7
	Half Size 10 ¼"	Y311.26	10.7
	Full Size 4 ¹ / ₈ "	Y111.10	21.4
	Full Size 5 ¼"	Y111.13	21.4
	Full Size 5 %"	Y111.15	21.4
	Full Size 7 ¾"	Y111.20	21.4
	Full Size 10 ¼ "	Y111.26	21.4
	Full Size 7 ¾"	Y111.70	21.4
STERRAD 100NX	Three-Quarter Size 4 1/8"	Y211.10	13.85
STERIAD LOUNA	Three-Quarter Size 5 ¼"	Y211.13	13.85
Standard Cycle	Three-Quarter Size 5 ³ / ₄	Y211.15	13.85
Standard Cycle	Three-Quarter Size 7 ³ / ₄ "	Y211.20	13.85
	Half Size 4 1/8"	Y311.10	13.85
	Half Size 5 ¼" Half Size 5 %"	Y311.13 Y311.15	13.85 13.85
	Half Size $7 \frac{3}{4}''$	Y311.20	13.85
	Half Size 10 ¼"	Y311.26	13.85
	Eull Sizo 4 1/"	V111 10	21.4
	Full Size 4 1/8"	Y111.10	21.4
	Full Size 5 ¼"	Y111.13	21.4
	Full Size 5 %"	Y111.15	21.4
	Full Size 7 ¾"	Y111.20	21.4
	Full Size 10 ¼ "	Y111.26	21.4
	Full Size 7 ¾"	Y111.70	21.4
STERRAD 100NX	Three-Quarter Size 4 ¹ / ₈ "	Y211.10	13.85
	Three-Quarter Size 5 ¼"	Y211.13	13.85
Express Cycle	Three-Quarter Size 5 ⁷ / ₈ "	Y211.15	13.85
	Three-Quarter Size 7 ¾"	Y211.20	13.85
	Half Size 4 1/3"	Y311.10	13.85
	Half Size 5 ¼"	Y311.13	13.85
	Half Size 5 ⁷ ‰"	Y311.15	13.85
	Half Size 7 ¾"	Y311.20	13.85

	Half Size 10 ¼"	Y311.26	13.85
	Full Size 4 1/8"	Y111.10	13.2
	Full Size 5 ¼"	Y111.13	13.2
	Full Size 5 ⁷ ‰"	Y111.15	13.2
	Full Size 7 ¾"	Y111.20	13.2
	Full Size 10 ¼ "	Y111.26	13.2
	Full Size 7 ¾"	Y111.70	13.2
STERRAD 100NX	Three-Quarter Size 4 1/8"	Y211.10	13.2
	Three-Quarter Size 5 ¼"	Y211.13	13.2
DUO Cycle	Three-Quarter Size 5 %"	Y211.15	13.2
	Three-Quarter Size 7 ¾"	Y211.20	13.2
	Half Size 4 ¹ ∕₃"	Y311.10	7.2
	Half Size 5 ¼"	Y311.13	7.2
	Half Size 5 [™]	Y311.15	7.2
	Half Size 7 ¾"	Y311.20	7.2
	Half Size 10 ¼"	Y311.26	7.2
	Full Size 4 [™]	Y111.10	12.59
	Full Size 5 ¼"	Y111.13	12.59
	Full Size 5 [™]	Y111.15	12.59
	Full Size 7 ¾"	Y111.20	12.59
	Full Size 10 ¼ "	Y111.26	12.59
	Full Size 7 ¾"	Y111.70	12.59
STERRAD 100NX	Three-Quarter Size 4 ¹ / ₈ "	Y211.10	13.85
	Three-Quarter Size 5 ¼"	Y211.13	13.85
Flexible Cycle	Three-Quarter Size 5 ⁷ 8"	Y211.15	13.85
	Three-Quarter Size 7 ¾"	Y211.20	13.85
	Half Size 4 ¹ ∕₃"	Y311.10	13.85
	Half Size 5 ¼"	Y311.13	13.85
	Half Size 5 ⁷ ‰"	Y311.15	13.85
	Half Size 7 ¾"	Y311.20	13.85
	Half Size 10 ¼"	Y311.26	13.85

Bahadir USA containers may be used with Bahadir USA accessories according to the table below:

Cycle	Baskets including holding pins, holding clamps, silicone holders, partition sheets, tamper evident locks	Silicone Mats
Steris VPRO 60/s2	YES	YES
Lumen, Non-Lumen, Flex		
Steris VPRO maX/maX2	YES	YES
Lumen, Non-Lumen, Flex		
STERRAD NX – Standard	YES	NO
STERRAD NX – Advanced	YES	NO
STERRAD 100NX – Standard	YES	NO
STERRAD 100NX – Duo	YES	NO
STERRAD 100NX – Flex	YES	NO
STERRAD 100NX - Express	YES	YES

DIRECTIONS FOR USE

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 <u>info@bahadirusa.com</u> 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

Table 2: Mechanical Washer Cycle Parameters:

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

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. If any of the above issues exist, contact manufacturer.

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:

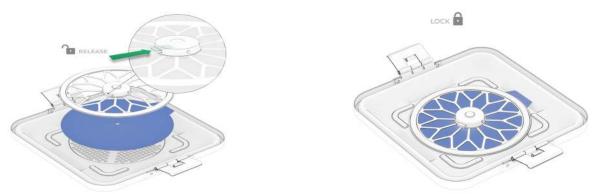
- ✓ Select surgical instrument set for sterilization.
- \checkmark Be sure all the components are completely dry.
- ✓ Select appropriate size baskets and containers.

Bahadir Sterilization Containers are designed to be used with single-use <u>Polypropylene</u> filters validated for use with the containers (BAHADIR USA item number Y801.01).

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). User must ensure that only the approved polypropylene filter is used.
- 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.

*Ensure the filter retention plates are seated properly and securely locked tight in position



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. 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.

SPECIAL Note: Devices placed within the container are not to be separately enclosed in sterile barriers because inadvertent use of such secondary packaging by users has the potential to cause failures in the recommended sterilization cycles and raises the risk of infections for patients due to reduced sterility assurance levels.

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. 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 NOT permitted in the chamber during the sterilization

PROCESSING

The loading instructions of the sterilizer manufacturer should be observed

CAUTION: In order to avoid post-sterilization against accidents Containers need to remain on the container cart, in draft free area until cool enough to handle

Page 12 of 14

Sterilization Cycle Parameters and Configurations for the Bahadir Container System by Modality – See Indications for Use at beginning of manual.

SHELF LIFE

In protected storage (temperature, humidity, air filtration etc. controlled hospital storage room conditions) containers can store sterilized medical devices for up to 180 days, provided the integrity of the container is not compromised (Tamper-evident security seal (Y819.00) remains intact). Facilities should follow industry guidelines and establish processes and procedures related to shelf-life and storage.

Note: Bahadir Sterilization Containers can be stacked during storage, one on top of another. Be sure that heavier container is placed at the bottom.

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

Label Symbols Key:







Product is non-sterile

Consult Instructions for Use

Caution



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