

AMSCO[®]
STERILIZATION CONTAINER SYSTEM
User's Guide



AMSCO® STERILIZATION CONTAINER SYSTEM User's Guide

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Product and packaging are latex free

1. UNPACKING

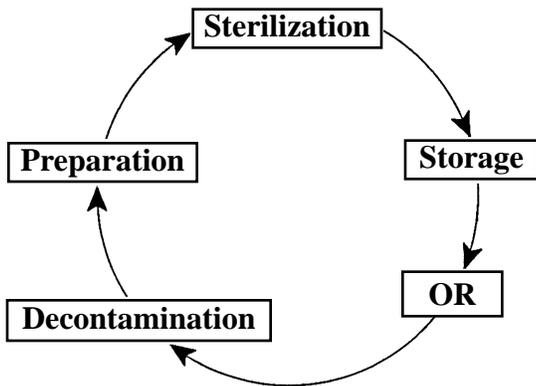
For aseptic reasons it is recommended that unpacking of the container system be done in an area other than where they will be used.

1. Open corrugated carton and carefully remove the container system and/or components.
2. Remove any plastic bags and twist ties on the side clamps of the container. Also remove and read package inserts.
3. Inspect the container system for nicks, gouges, or damage that may have occurred during shipping. (If there is damage, notify your STERIS Customer Service Representative.)
4. Check contents of the bag against the packing list.
5. Transport container system and/or components to decontamination area.

2. CONTAINER TRANSPORT AND HANDLING

To effectively handle the weight of the containers, you should:

- Understand container flow through your institution.
- Predetermine how the container is to be transported.
- Train all personnel to ensure the correct methods for handling and transport are being followed.



1. Minimize or eliminate hand carrying. Utilize carts when possible. (Photos 1 & 2)



CAUTION: Do not lift the container using the side clamps; use the handles located at the ends of the container.

2. Slide containers when possible to avoid lifting.
3. Store heaviest containers on open wire racks at a height between the mid-chest to mid-thigh area. (Photo 3)



4. Ensure that an appropriate location is available for container staging in the Operating Room. A prep stand is preferable over a mayo or ring stand. (Photo 4)
5. Remove the container lid and/or base from the room prior to entry of the patient, to avoid having to decontaminate these components. Containers and components should be routinely cleaned following facility established policies and guidelines.

3. GENERAL CLEANING, DECONTAMINATION, AND INSPECTION

CAUTION: Do not use boiler additives such as cyclohexylamine or morphine in steam in excess of FDA limits.

1. Process disassembled lid, tray, base, and retainer rings in automated washing equipment, a washer disinfectant, or another approved institutional protocol for cleaning.
2. Clean ceramic filters frequently to prevent clogging. Remove any excessive foreign material by soaking the filter in water until the foreign material is loose, then brush, and rinse. Flush the filter from the backside with running water. The filter may also be processed in an ultrasonic cleaner.
3. Use heat resistant protection on the hands or allow components to cool prior to removal from washing equipment.
4. Visually inspect each component to ensure that it is clean and that there is no damage to the component. For ceramic filters, crack lines on the top surface of the filter are considered evidence of damage and the ceramic filter should not be used. If components or filters show evidence of damage, do not use.
5. Transport components to preparation area.

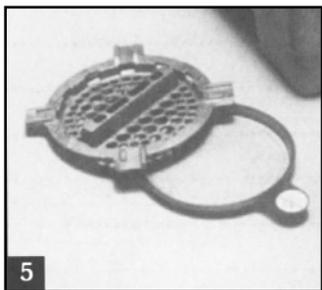
4. UNIT ASSEMBLY

Select the Appropriate Filter System

There are three different filter systems. Select a filter system that is appropriate for the sterilization cycle to be used. (Refer to the text and the chart below for guidance.)

A. Cartridge Filter System

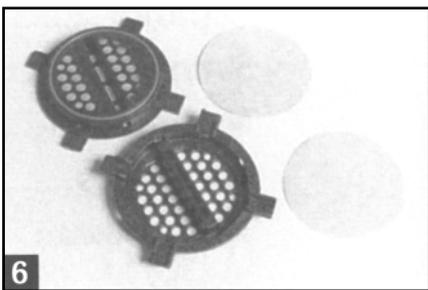
- 1) The cartridge is made of plastic with the filter media permanently attached. Every cartridge filter has an internal chemical indicator attached to the handle which will indicate exposure to a specific sterilization process. The cartridge is for single use only. (Photo 5)



- 2) The reusable retainer ring is made of composite material.

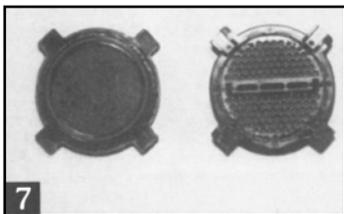
B. Disc Filter System

- 1) The disc filter consists of filter media without an attached plastic cartridge. The disc system does not have an attached internal chemical indicator. It is for single use only.
- 2) The reusable retainer ring is made of a composite material. A silicone gasket circles the retainer ring filter sealing surface. (Photo 6)



C. Ceramic Filter System

- 1) The reusable ceramic filter system does not have an internal chemical indicator.
- 2) The ceramic filter is encased in a retainer ring. A silicone gasket circles the retainer ring filter sealing system. (Photo 7)



GUIDANCE FOR FILTER SELECTION

FILTER SYSTEM	STERILIZATION CYCLE			
	PREVAC STEAM	GRAVITY STEAM	FLASH*	EO GAS
CARTRIDGE - (Steam-Enhanced for Drying)	Yes	Yes	Yes	N/A
CARTRIDGE (EO)	N/A	N/A	N/A	Yes
DISC - (Steam-Enhanced for Drying)	Yes	Yes	Yes	N/A
DISC (EO)	N/A	N/A	N/A	Yes
CERAMIC	Yes	No	Yes	Yes

*Gravity or prevac

Load Filters

- A. Gently place new disposable filters (cartridge or disc) in all filter access ports located in the lid and base units. Place a retainer ring on top of each filter and rotate clockwise until it has been totally engaged. Ensure that all filter access ports in the lid and base units are enclosed with a filter.
- B. The ceramic filter is encased by a retainer ring. Place a ceramic filter in each filter access port and rotate clockwise until it has been totally engaged. Ensure that all filter access ports are enclosed with a filter.

Load Tray

- A. It is not recommended to place any absorbent material in the tray. This type of material may hold water (condensation) and extend the drying time.
- B. Load inner tray, making sure instruments are arranged in such a way as to not interfere with the lid when closing.
- C. As appropriate, place chemicals and/or biological indicators in the tray following AAMI Recommended Practices for Steam Sterilization and Sterility Assurance.
- D. Place loaded instrument tray into container base. Use the chart below as the guideline for maximum weights to be loaded. Instruments, especially complex ones such as air powered drills, multi-hinged instruments, or multi-part instruments must be prepared and sterilized according to the recommendations of the instrument manufacturer.

RECOMMENDED MAX INSTRUMENT LOAD WT

CONTAINER SIZE	PREVAC STEAM	GRAVITY STEAM	FLASH	EO
22.50cmx35.56cm				
9" x 14"	6 lbs. (2.7 kg)	6 lbs. (2.7 kg)	2 lbs. (0.9 kg)	6 lbs. (2.7 kg)
22.50cmx71.12cm				
9" x 28"	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)	NA**	16 lbs. (7.3 kg)
27.94cmx40.64cm				
11" x 16"	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)
27.94cmx48.26cm				
11" x 19"	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)
30.48cmx30.48cm				
12" x 12"	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)
30.48cmx58.42cm				
12" x 23"	26 lbs. (11.8 kg)	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)	16 lbs. (7.3 kg)

**the 9" x 28" container should not be used in flash sterilization.

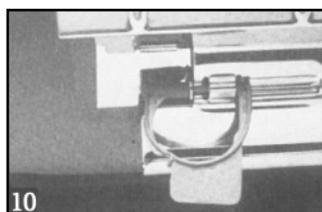
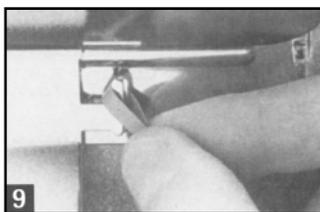
Install Lid

- A. Put lid on container. If lid does not seat properly, check to see if instruments are preventing closure.
- B. Engage and close container side clamps, after making sure there are no restrictions. (Photo 8)



Install Tamper Evident Security System

- A. For steam sterilization, place tamper evident bands on each side clamp. Make sure the band is on both the front and back parts of the side clamp. (Photo 9)



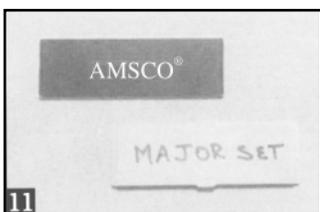
NOTE: After steam sterilization, the tamper evident bands will shrink and have to be broken to disengage the side clamp.

- B. For ethylene oxide sterilization, place tamper evident locking tags on each side clamp. Make sure each device is placed through both parts of the side clamp and locked into place. (Photo 10)

NOTE: To remove tamper evident locking tags and disengage side clamps, turn tag firmly clockwise to snap it off.

Install Identification System

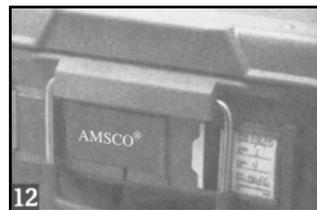
- A. Two nameplates are available.
 - 1) Customized aluminum engraved nameplates in a variety of colors.
 - 2) Plastic nameplates, which can be marked with a permanent marker. (Photo 11)



- B. Nameplate placement and removal.
 - 1) Either type of nameplate can be easily inserted or removed.
 - 2) Push the small center tab on the nameplate holder, and the nameplate can be easily inserted by sliding up, or removed by sliding down.

Install Information Data Card/Chemical Indicator

- A. Data card is slid into place in the data card holder. (Photo 12)



- B. Pertinent sterilization information should be recorded on the external data card per institutional protocol. The data card includes an external chemical indicator that will change color with exposure to the respective steam or ethylene oxide sterilization processes.

NOTE: Do not attach any type of tape or adhesive backed labels to the container. Such adhesives will bake on and are difficult to remove.

5. STERILIZATION

Load Sterilization Containers

- A. Remove all toweling material or loose linen from sterilizer rack to aid in steam penetration and accelerated drying.
- B. Load prepared containers onto sterilizer carriage in the horizontal position.
- C. The 23" or longer containers may require placement lengthwise on the sterilizer carriage to avoid touching the wall of the sterilizer jacket. Check before loading.
- D. Testing confirms that containers may be stacked five high on a sterilizer carriage. However, it is recommended that containers be stacked no more than two high.

NOTE: Same size containers only may be stacked on top of each other.

Determine Sterilization Cycle Parameters

- A. Sterilize containers using instructions provided by the manufacturer of instruments/devices to be processed within the parameters recommended by the manufacturer of the sterilizer and container, and institutional protocol.
- B. The following chart recommends cycles that have been validated for use with Amsco containers. Verification that selected cycles are operating properly following AAMI standards is required. Each sterilization cycle must be verified using chemical and/or biological indicators according to your institutional policies, standards, and

RECOMMENDED PARAMETERS FOR STEAM STERILIZATION CYCLES

(Unless otherwise specified by the manufacturer of the sterilizer and/or instrument)

Steam Sterilization Loads
< 16 lbs. (7.3kg) of Instruments

Steam Sterilization Loads
≥ 16 lbs. (7.3kg) of Instruments

a. Prevacuum Cycle			a. Prevacuum Cycle		
Temperature	Exposure Recommended Minimum	Dry Time Recommended Minimum	Temperature	Exposure Recommended Minimum	Dry Time Recommended Minimum
270-274°F (132-134°C)	4 minutes	20 minutes	270-274°F (132-134°C)	4 minutes	30 minutes
Gravity Cycle			Gravity Cycle		
Temperature	Exposure Recommended Minimum	Dry Time Recommended Minimum	Temperature	Exposure Recommended Minimum	Dry Time Recommended Minimum
270-274°F (132-134°C)	20 minutes	30 minutes	270-274°F (132-134°C)	20 minutes	45 minutes
250-254°F (121-123°C)	45 minutes	30 minutes	250-254°F (121-123°C)	45 minutes	45 minutes

procedures. This should be done for each sterilizer in your facility since the sterilization process can be affected by work practices, sterilizer performance, and the utilities supplying the sterilizer. Users of the container system also have the responsibility to ensure items placed in a container are suitable for the sterilization process to be employed.

C. Following sterilization, remove containers from the sterilizer and place in cool-down area away from drafts.

D. After containers have cooled, they may be placed in storage.

6. DRYING

There are a number of factors that can contribute to achieving a consistently dry container and instrument set. Listed below are the factors that may influence drying with suggested recommendations to ensure dry instruments.

1. Loading Containers

AMSCO containers are designed to be used without absorbent material inside the container. Absorbent materials hold condensation, which increases drying time and may cause condensation on the instruments. Instruments should be arranged so that the sterilant will contact all instrument surfaces. Overloading instrument trays may inhibit drying.

2. Loading Sterilizer Carriage

A. Dedicated loads, that is, loads consisting of only AMSCO containers, are recommended. If it is necessary to sterilize a load of containers with wrapped or packaged items, place the containers on the bottom of the sterilizer carriage. The filter access ports of the containers must not be blocked by wrapped or packaged items. (Photo 13)



It is recommended that containers be stacked no more than two high.

B. Place containers flat on the sterilizer carriage. AMSCO containers will not function properly if turned on their sides or ends. Containers may be stacked on top of each other, but it is recommended that same size containers be stacked no more than two high.

C. The sterilizer must be kept free of towels and drapes, which may impede radiant heat transfer from sterilizer walls to containers, preventing thorough drying.

NOTE: Same size containers only may be stacked on top of each other.

Recommended Sterilization Cycle

3. Prevacuum steam sterilization is the preferred steam sterilization cycle.
4. Weight Load
Increased instrument weight load may require increased drying time.
5. Instrument Dry Time
An increased dry time may remove condensate from instruments.
6. Instrument Processing
Instruments should be dry prior to entering the sterilizer. Wet instruments will increase the moisture content within the sterilizer.
7. Sterilizer Function
Observe preventative maintenance schedule for the sterilizer as recommended by the sterilizer manufacturer.
8. Pre- and Post-Conditioning
Use a pre-conditioning or a post-conditioning time. Pre-conditioning warms the instruments

prior to sterilizing helping to lessen excess moisture. Post-conditioning results in a slower cool down time, allowing radiant heat from the walls of the sterilizer to help dry the instruments.

9. Quality of Steam

Steam that arrives at the sterilizer should be at least 97% vapor quality steam.¹ This is a critical factor for having consistently dry loads. Clogged sterilizer and steam line filter traps can be a source of low quality steam.

10. Environmental Considerations

This includes the temperature, humidity, and air exchange rate of the cool-down area. Refer to the AAMI Steam Sterilization/Sterility Assurance in Healthcare Facilities document for environmental guidelines.

11. Use a Vacuum Steam Sterilizer

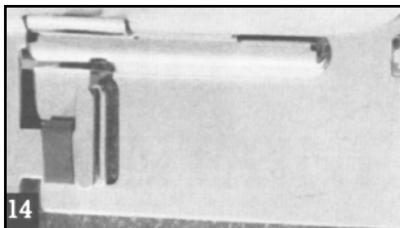
With the exception of flash sterilization, all containers should be consistently dry upon completion of a cycle.

¹American National Standards Institute, Inc. Association for Advancement of Medical Instrumentation - ANSI/AAMI 46:2002 - Steam Sterilization and Sterility Assurance in Healthcare Facilities, 3.3.4.2, p. 10.

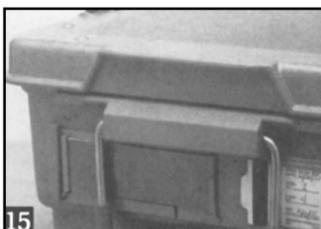
7. OPERATING ROOM HANDLING

1. Circulating Nurse

- A. Place sterilized container on convenient surface that helps facilitate aseptic opening. The table surface should be stable and of the proper height.
- B. Check that all tamper evident bands/devices are intact. If they are not, contents should be considered contaminated and should not be used. (Photo 14)



- C. Confirm external indicator has turned the appropriate color and sterilization information is correct. (See “How to Evaluate Chemical Indicators.”) (Photo 15)



- D. To disengage side clamps, hold side clamps firmly and pull the bottom out, away from the container base. Disengage side clamps from lid and open to its full extended position. Make sure all side clamps are completely open and extended before lid removal. (Photo 16)



- E. Aseptically remove the lid from the base by placing fingers directly on the lid removal tabs. Place thumb directly on the lid itself. Lift lid up and away from the container toward your body. (Photo 17)



- F. If cartridge filter is used, visually confirm internal chemical indicator has turned the appropriate color. (See “How to Evaluate Chemical Indicators.”)
- G. Check to be certain that filters have been used in all filter access ports and that the filters are securely in place.

2. Scrub Nurse

- A. Remove inner tray by firmly grasping the inner tray handles, pulling the inner tray up in one continuous motion until clear of container. CAUTION: Avoid touching the outer part of the container base with gloves or sterile attire. (Photo 18)



- B. If using a cartridge filter and/or internal chemical indicator, visually confirm that the internal indicator has turned the appropriate color prior to adding instrument tray to the sterile field. (See “How to Evaluate Chemical Indicators.”) Process biological indicators per institutional protocol.

8. SPECIAL INSTRUCTIONS FOR USE IN FLASH STERILIZATION

1. Circulating Nurse or Operating Room Technician

- Place new disposable filters and their appropriate retainer rings in all filter access ports or ensure the permanent ceramic filters are in place.
- Load inner tray, making sure instruments are not arranged in such a way as to interfere with the lid sliding shut.
- Place loaded instrument tray into base.
- Set the lid of the container on the base and slide the lid open approximately three inches. (Photo 19)



- Place the container in the sterilizer with the lid extending toward the operator. (Photo 20)



- For gravity displacement cycles, a minimum of 10 minutes of steam exposure is required for flash sterilization. For pre-vacuum cycles, a minimum of three minutes of steam exposure is required for flash sterilization. More complex instruments (e.g., with lumens), or porous items, require four minutes of steam exposure.
- Sterilize per AAMI recommended practices and institutional protocol using the maximum load weights in the following chart.
- After sterilization, open sterilizer door and slide the container lid closed with appropriate device to prevent burning (e.g. a heat resistant glove).
- To prevent burns, caution should be used when removing container and instruments from flash sterilization cycles. Carefully remove hot container, using a heat resistant glove, from

sterilizer utilizing the handles at ends of container, and place on transport cart or transfer directly to where it will be opened.

CONTAINER SIZE	FLASH STERILIZATION: MAX INSTRUMENT LOAD WEIGHTS
22.50cm x 35.56cm 9" x 14"	2 lbs. (0.9 kg)
22.50cm x 71.12cm 9" x 28"	Not For Flash
27.94cm x 40.64cm 11" x 16"	16 lbs. (7.3 kg)
27.94cm x 48.26cm 11" x 19"	16 lbs. (7.3 kg)
30.48cm x 30.48cm 12" x 12"	16 lbs. (7.3 kg)
30.48cm x 58.42cm 12" x 23"	16 lbs. (7.3 kg)

9. DECONTAMINATION AFTER USE

- Workers should wear appropriate personal protective equipment (e.g. gowns, masks, eye protection, gloves, head coverings and shoe covers) according to institutional protocol.
- Open the side clamps and remove lid from container.
- Remove all filter retainer rings.
- Rotate retainer ring counterclockwise and lift.
- Remove and discard all disposable filters.
- Remove and inspect ceramic filters.
- Refer to Section on General Cleaning, Disinfection and Inspection for processing instructions.
- Keep all retainer rings.
- Remove inner tray with the instruments and process according to institutional protocol.
- Remove and discard all pieces of tamper evident bands/locks from side clamps. Do not remove clear plastic tab cover on back part of side clamp.
- Remove external data card.
- Unit is now ready for decontamination. Refer to General Cleaning, Decontamination and Inspection Section.
- Following decontamination, periodic inspection of the unit is suggested to ensure that all parts are in good working order.

10. CHEMICAL/BIOLOGICAL INDICATORS

1. Biological Indicators

Biological indicators should be used in accordance with AAMI Guidelines and institutional protocols. Only biological indicators can determine if sterilization has taken place.

2. Chemical Indicators

Chemical indicators DO NOT verify sterility. They provide the user with a visual indication that the parameters for the sterilization process exist.

11. HOW TO EVALUATE CHEMICAL INDICATORS (For External Data Cards And Internal Filter Cartridge Indicators)

1. Steam Sterilization Indicators

Steam indicators are a cream color in their unexposed state, turning to a shade of dark brown after processing. Ensure that the indicator has changed to the appropriate color as directed on the legend of the indicator. The indicator must be completely turned across the bar and must be a shade of dark brown.

NOTE: In a failure mode, ink turns no darker than tan.

2. Ethylene Oxide (EO) Sterilization Indicators

EO Indicators are a shade of cream in their unexposed state, turning to a shade of orange after processing. The indicator must be completely turned across the bar and must be a shade of orange.

NOTE: In a failure mode, ink turns to light yellow.

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Technologies to Prevent Infection and Contamination™

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