FLASH PAK® STERILIZATION CONTAINER SYSTEM

INSTRUCTIONS FOR USE

Description

The Flash Pak® Sterilization Container System consists of a family of rigid reusable containers that provide an effective sterilization packaging method for surgical instruments requiring immediate-use steam sterilization. Each Flash Pak® system is comprised of an upper lid that seals by means of a silicone gasket and latches to a lower base creating a totally enclosed environment. A stainless steel wire basket is utilized inside the container to facilitate handling of sterilized items. The lid and base incorporate pressure actuated valves that open to allow sterilant to enter the container during the pressurization portion of the sterilization cycle and then close to seal the container once the cycle is over so the container and its contents can be removed from the sterilizer and immediately transported to the point of use without the risk of recontamination.

Intended Use

Flash Pak® is a reusable rigid container system to be used during immediate use steam sterilization (IUSS) by hospitals and healthcare facilities. It is intended to enable sterilization of the enclosed devices and prevent recontamination during immediate transport to the point of use. The container is compatible with gravity-displacement steam sterilization using a 10 minute cycle at 132° C for porous items and items with lumens or a 3 minute cycle at 132° C for nonporous items like routine metal instruments. The container is also compatible with pre-vacuum steam sterilization using a 4 minute cycle at 132° C for porous items and items with lumens or a 3 minute cycle for nonporous items like routine metal instruments. Flash Pak® is recommended for sterilization of lumens with the following limits: gravity-displacement (5.5mm inner diameter or larger and up to 184mm in length), pre-vacuum (1mm inner diameter or larger and up to 203mm in length).

⚠ WARNINGS AND PRECAUTIONS

Warnings

- Read these instructions completely before using the device.
- Flash Pak® is designed and intended for immediate-use steam sterilization.
- Care should be taken when removing Flash Pak® after sterilization because it will be hot.

Precautions

- This product is packaged and shipped non-sterile. It must be cleaned with a neutral pH detergent prior to use.
- Do not use a Flash Pak® container that is chipped, cracked or has a damaged lid gasket, valve seal or vent button.
- Do not stack the Flash Pak® containers in the sterilizer as this may inhibit sterilant access.
- Flash Pak® is recommended for use with an approved multi-parameter chemical integrator (CI). Always verify proper multi-parameter chemical integrator (CI) exposure after every sterilization cycle.
- After sterilization the valves must seat against silicone seals to prevent possible recontamination. Always visually verify full seal contact after every sterilization cycle.
- Immediate-use (flash) steam sterilization does not include dry times so condensation in the container is expected. Care should be taken when transporting the container and when removing the container lid and contents.
- Unless otherwise recommended by the device manufacturer's instructions, do not use Flash Pak® for sterilization of batteries, motorized, electric or electronic devices.
- The Flash Pak® valves and pressure balance element (i.e. metal micro filter) must be periodically replaced in order to ensure continued effectiveness. Replacement of parts should only be performed by trained personnel.

CLEANING

Manual Cleaning

1. Remove lid and instrument basket from the Flask Pak® base. Expose all components to a neutral pH low-sudsing enzymatic cleaning solution (e.g. Steris Prolystica 2X Concentrate Enzymatic Cleaner or equivalent) prepared and administered according to manufacturer directions.

2. During exposure to the cleaning solution, wash components thoroughly inside and out using a soft bristle brush or sponge. Pay careful attention to the handles and latches.
3. Thoroughly rinse the components in warm running tap water for a minimum of 1 minute.
4. Visually inspect each component for any remaining soil or cleaning material residue. If soil or residue is observed then repeat the cleaning process.
5. Dry the Flash Pak® thoroughly using clean lint free absorbent towels and/or clean pressurized air.

Automated Cleaning

1. Remove lid and instrument basket from the Flask Pak® base. Follow the automated washer / disinfector equipment manufacturer directions for placement of all three components within the unit. Place the lid and base inside the washer with the inside surface of the components facing down to prevent water from collecting in them.
2. Follow the washer / disinfector manufacturer directions for set up and preparation of the washer. Use a low-sudsing neutral pH enzymatic cleaning solution (e.g. Steris Prolystica 2X Enzymatic Cleaner or equivalent) for the first wash cycle and a low-sudsing neutral pH detergent solution (e.g. Steris Prolystica 2X Concentrate Neutral Detergent or equivalent) for the second wash cycle. Follow the cleanser manufacturer directions to prepare the solutions. The following minimum wash cycle parameters are recommended.

Step	Description
1	4 minute enzyme wash with hot water or equivalent 2 minute prewash with cold tap water followed by 2 minute enzyme soak and wash with hot tap water at 63 – 67 °C (145 – 152 °F)
2	30 second cold tap water rinse
3	2 minute detergent wash with hot tap water, 63 – 67 °C (145 – 152 °F)
4	2 minute thermal rinse at 80 – 95 °C (176 – 203 °F)
5	15 minute hot air dry at 80 – 116 °C (176 – 240 °F)

3. Remove the Flash Pak® components from the washer equipment and visually inspect for any remaining soil or cleaning material residue. If soil or residue is observed then repeat the cleaning process.
6. Verify the components are dry before storing the Flash Pak®. If moisture is observed, dry the unit using clean lint free absorbent towels and/or clean pressurized air. Excessive moisture may require a longer dry cycle.

MAINTENANCE

Daily Activities

1. Clean Flash Pak® before first use when visibly soiled, and daily according to the recommended directions above. Flash Pak® may be washed manually or in automated washers.

2. Visually inspect the entire container with each use and daily to assure there are no chips or cracks. Visually inspect the silicone lid gasket, silicone valve seals in the lid and base and the silicone lid vent to assure there are no cuts, tears or other damage.

Valve seals under mounting plate (not visible)
See Picture for Sterilization Step 1
Lid gasket

CAUTION: Do not use a Flash Pak® that is chipped, cracked or has damaged gaskets, seals or lid vent button. Remove the affected unit from service and replace damaged or worn parts before re-using.

Periodic Activities

- Replace both pressure actuated valves, in the lid and base, at least once per year.
- For Flash Pak® containers used exclusively for gravity-displacement sterilization replace the valves after approximately 1500 uses.
- For Flash Pak® containers used exclusively for dynamic-air-removal (pre-vacuum) sterilization replace the valves after approximately 500 uses.
- Replace the lid vent button if it becomes damaged.
- Replace the pressure balance element (or metal micro filter) at least once per year or when it becomes discolored. The micro filter allows the internal container pressure to reach equilibrium with the outside ambient pressure while the valves are closed. Over time it will become clogged with particles from the steam and will appear discolored (e.g. rust spots). Quality of the steam will affect the element life.

CAUTION: Replacement of parts should only be performed by trained personnel. The local Flash Pak® sales representative can provide in-service training to hospital personnel or perform a variety of maintenance services or non-warranty repairs.

Sterilization Process

1. Visually verify that the valve plate fully engages the silicone valve seals around its entire circumference of both the lid and base valve assemblies.

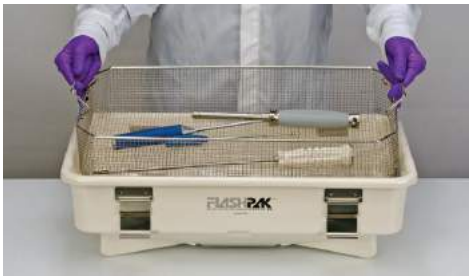
2. Read and follow the device manufacturer's Instructions for Use (IFU) regarding immediate-use steam sterilization. Clean and decontaminate instruments and devices per the manufacturer's instructions prior to sterilization. Disassemble instruments and devices as required per the manufacturer's instructions prior to sterilization.
3. Do not attempt to sterilize lumens of smaller diameter, longer length or in greater numbers than shown in the table.

Lumen Size Recommendations					
Gravity			Pre-Vacuum		
ID	Length	Qty	ID	Length	Qty
5.5 mm	184 mm	3	1 mm	203 mm	5

4. See chart below for recommended instrument weight per Flash Pak® model. Recommended weights are based upon limiting the total loaded container weight to approximately 25 lbs. (11.4 kg) per ANSI/AAMI ST77:2013, Containment Devices for Reusable Medical Devices. Instruments should be uniformly distributed across the wire basket. Ensure that instruments are properly loaded so that they do not contact the valve or interfere with closing the lid. Hinged devices should be in an open position when placed in the Flash Pak®.

	Maximum Instrument Load Weight Recommendation	
Flash Pak® Model	Gravity	Pre-Vacuum
9020 w/ 9020-08 Basket	3 pounds (1.36 Kg)	3 pounds (1.36 Kg)
9030 w/ 9030-08 Basket	10 pounds (4.55 Kg)	10 pounds (4.55 Kg)
9040 w/ 9040-08 Basket	14 pounds (6.35 Kg)	14 pounds (6.35 Kg)
9050 w/ 9050-08 Basket	16 pounds (7.27 Kg)	16 pounds (7.27 Kg)

5. Place the wire basket containing the instruments inside Flash Pak®. Instruments may be placed directly into the Flash Pak® without using the wire basket but care must be taken to ensure the instruments do not contact the valve plate. Contact with the valve plate may interfere with or damage the valve and sterilization efficacy may be affected.



6. Place an approved multi-parameter chemical integrator (CI) in the center of the basket for process monitoring. Additional multi-parameter chemical integrators (CI) may be added as required by hospital procedures and recommended practices.

7. Place the lid on top of the base and secure the four latches.

8. Routine biological testing should be performed in accordance with hospital policy and procedures.
9. Place Flash Pak® in sterilizer chamber ensuring that its feet sit level and flat on the rack.

CAUTION: Do not stack on top of another container or another Flash Pak®

10. Select the appropriate sterilization parameters from the table below:

Instrument/device type	Minimum Steam Exposure Time (minutes) At Minimum Temperature 132°C (270°F)	
	Pre-Vacuum Sterilizers	Gravity Displacement Sterilizers
Non-porous	3	3
Porous or mixed (porous & non-porous)	4	10

CAUTION: Read and follow the device manufacturer's immediate-use steam sterilization instructions for specialty items such as complex devices, power equipment, and batteries before sterilizing them in Flash Pak®. Failure to follow the manufacturer's instructions may result in irreparable damage to the device or in the device not being sterilized.

11. Initiate the sterilization cycle.

12. After the sterilization cycle ends, open the sterilizer door and remove Flash Pak®

WARNING: The container will be hot. Flash Pak® Gloves 9000-14 or towels may be necessary to prevent minor burns. Do not handle or carry Flash Pak® by the lid.

13. Transfer the container to the Flash Pak® Delivery Cart Product Code 9111 or other suitable cart for transport to the point of use. As a result of its closed system design and the raised integral feet Flash Pak® may be placed on non-sterile surfaces.

CAUTION: Condensate may have formed inside the Flash Pak® so use care when transporting.

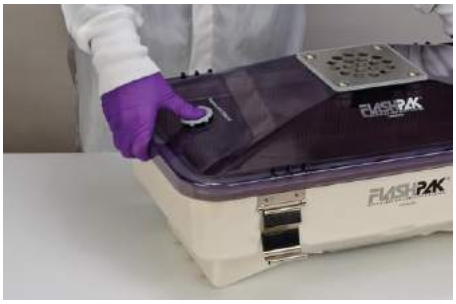
CAUTION: Never touch or probe the valve plate after sterilization as this may breach the sterile barrier and render the contents non-sterile.

CAUTION: Never touch or probe the pressure relief button prior to opening the case at the point of use as this may breach the sterile barrier and render the contents non-sterile.

14. Place Flash Pak® on a table near the point of use and visually verify that the valve plate in the lid fully engages the silicone seal around its entire circumference. See picture for sterilization step 1 lid gasket.

CAUTION: If the valve appears to be open or is not fully engaged with the silicone seal assume the instruments are contaminated and reprocess accordingly.

15. Unlatch the lid. Depress the pressure relief button and remove the lid.

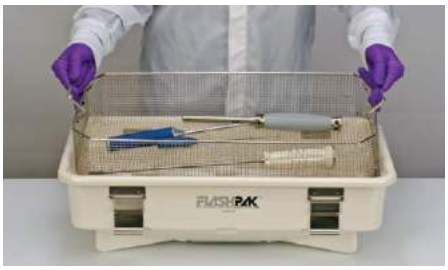


16. Grasping the lid on diagonally opposite corners while lifting may aid lid removal.

17. Verify that the multi-parameter chemical integrator (CI) indicates acceptable exposure. As the terminology used varies by CI brand, follow the CI instructions to verify that sufficient exposure for sterilization has occurred.

CAUTION: Do not use the instruments if the multi-parameter chemical integrator (CI) does not verify acceptable exposure. Incomplete change in the multi-parameter integrator (CI) indicates that the sterilization process was incomplete or interrupted. Troubleshoot the process according to established procedures and after resolving the problem, repeat these instructions beginning at step 6.

18. Aseptically remove the basket and contents in accordance with hospital policy and procedures.



19. Visually verify that the base valve plate fully engages the silicone seal around its entire circumference before the basket or its contents are placed on the sterile field. See picture for sterilization step 1 lid gasket.

CAUTION: If the valve appears to be open or is not fully engaged with the silicone seal assume the instruments are contaminated and reprocess accordingly. Do not touch the valve during this examination.

20. Residual water condensate is typical after immediate-use steam sterilization cycles and may be present in the bottom of the container.
    Remove any liquid water from the Flash Pak® and dry the container before using it again.

Valve Replacement Instructions:

1. Examine packaging containing replacement valves. Packages damaged during shipping should not be accepted and a claim should be filed with the carrier. Remove the replacement valve from its packaging and examine it for any obvious signs of damage. Valves with obvious damage such as breakage, holes or crushed, bent or distorted parts should not be used.
2. Remove the existing valves from Flash Pak® base and lid by removing the four (4) retaining nuts for each valve. **Note: Both valves should be replaced at the same time**.
3. If replacing an existing Flash Pak® Evolution valve with another Evolution valve, skip to step 6.
4. If replacing legacy diaphragm valves (#9020-09) use one Evolution Valve Replacement Kit (#9090 -90), two 9090-92 Retaining Nuts (8 pack) and two 9090-93 Carriage Bolts (4 pack). Remove and discard the legacy mounting hardware including the sheet metal Valve Mount bracket. Flash Pak®. **Keep the perforated valve guard and silicone valve gasket.**

Perforated Valve Guard

Silicone Valve Gasket

5. Use the 9090-92 and 9090-93 hardware to install the new Evolution valve. This hardware is required to convert from legacy polymer valves to Evolution valves in all Flash Pak® models (Le. 9020, 9030, 9040 and 9050).
    a. Insert the four (4) stainless steel carriage bolts (#9090-93) from the kit through the perforated top plate first, then the silicone valve gasket and finally through the lid or base. **Be sure that the silicone valve gasket flange is directed toward the inside of the lid or base**.

b. Thread and firmly hand-tighten four plastic retaining nuts (#9090-92) onto the carriage bolts; do not use any tools to tighten.
c. The new valve is now ready to assembly. Go to step 6 to complete the valve replacement.

6. Align the four holes in the replacement valve with the four stainless steel carriage bolts and push into place. Thread and hand-tighten the four (4) plastic retaining nuts. Repeat this process for both valves.

Replacement Parts:

Numerous replacement parts are available to maximize Flash Pak® in-service time. Refer to the replacement parts chart below. To use the chart, first locate the item that requires replacement and then the model number of the Flash Pak® itself. The catalog number at the intersection of the appropriate row and column is that of the required part.

Please contact your local sales representative for assistance selecting replacement parts or repairing Flash Pak®.

	Fits Flash Pak® Model Number			
Replacement Part	**9020**	**9030**	**9040**	**9050**
Evolution Valve Replacement Kit	9090-90	9090-90	9090-90	9090-90
Valve Gasket	9020-10	9020-10	9020-10	9020-10
Valve Guard	9020-18	9020-18	9020-18	9020-18
Retaining Nuts (set of 8)	9090-92	9090-92	9090-92	9090-92
Carriage Bolts (set of 4)	9090-93	9090-93	9090-93	9090-93
Pressure Balance Element (PBE)	9020-11	9020-11	9020-11	9020-11
PBE Gasket	9020-12	9020-12	9020-12	9020-12
Pressure Relief Button	9020-16M	9020-16M	9020-16M	9020-16L
Base Only. No valve or PBE	9020-01	9030-01	9040-01	9050-01
Base w/PBE & Gasket No Valve	9020-13	9030-13	9040-13	9050-13
Lid Only w/Gasket. No Valve	9020-02	9030-02	9040-02	9050-02
Wire Basket	9020-08	9030-08	9040-08	9050-08
Silicone Pin Mat for Basket	9020-04	9030-04	9040-04	9050-04
Flash Pak® Gloves (Pair)	9000-14	9000-14	9000-14	9000-14
Flash Pak® Delivery Cart	9111	9111	9111	9111

Symbol Definitions:

 Symbol for Manufacturer; the name and address of the Manufacturer is next to this symbol

 Caution-Consult accompanying documents

Lot number or batch number

Catalog number

 Consult instructions for use

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