This paper is intended to be a quick reference on the topic of Flash sterilization, designed specifically for internal use by STERIS. The information has been gathered from the standards and recommended practices indicated in the text. It is important that our customers/clients be encouraged to purchase the full documents, for their continual reference, from the organizations indicated. Providing a copy of this information for our customers is not permitted because it would put us in violation of our agreement with AAMI, who authorized STERIS to quote and illustrate their material, for our convenience.

What is FLASH sterilization?

From a historical perspective, FLASH sterilization has been most commonly known as steam sterilization using the unwrapped method. It was first performed using small Gravity displacement steam sterilizers in the operating room. Today, Flash sterilization is also accomplished using the Prevacuum and EXPRESS cycles, as well as with various rigid containment methods.

Why is it called “FLASH” sterilization?

Probably because someone said one day, “I’ll get it to you in a FLASH.”

When is it intended to be used?

It was originally intended to be used for the emergent need and immediate use of an instrument(s) that was dropped on the floor (particularly a one of a kind instrument), as well as for those instruments that were forgotten or unanticipated. Another scenario: the physicians’ own instruments that traveled with them from hospital to hospital. In fact, these reasons for the use of FLASH sterilization remain the same today, as well as several others, including the frowned upon FLASH sterilization of surgical implants.

The Association of Perioperative Registered Nurses (AORN) states that “Flash (steam) sterilization should be used only in carefully selected situations to meet special clinical situations when certain parameters are not met.” AORN recognizes that Flash Sterilization is a safe and effective process for medical devices intended to come in contact with compromised tissue and the vascular system when performed correctly.

- Work practices dictating proper decontamination, inspection and arrangement of instruments in the sterilizing tray or containers are followed.

- Department/work area physical configuration provides for direct delivery of sterilized item to point-of-use.

- Defined procedures for aseptic handling and personnel safety are followed during transfer of sterile item to point-of-use.

Flash sterilization should be used only when time does not permit the preferred wrapped sterilization method as performed by Central Service. AORN recognizes that Flash sterilization is a safe and effective process for medical devices intended to come in contact with compromised tissue and the vascular system, when performed correctly.

Why is it recommended that Surgical Implants are not to be Flash sterilized, and by whom?

The Centers for Disease Control and Prevention (CDC), made a recommendation in 1985 in their document Guideline for Handwashing and Hospital Environmental Control, Section 2: Cleaning, Disinfecting, and Sterilizing Patient-Care Equipment, that continues to be referenced by various organizations. It indicates that wrapped packs containing implantable objects need to be clearly labeled, and to guarantee a wide margin of safety a spore test is to be included in the load. The wrapped sterilized implantable item is not to be released for use until a negative biological test result. Flash sterilization is not recommended.
Implantable medical devices should not be flash sterilized because of possible patient complications. Careful planning, appropriate packaging and inventory management in cooperation with suppliers can eliminate the need to flash sterilize implantable medical devices.

The Association for the Advancement of Medical Instrumentation (AAMI) document, “Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use,” ANSI/AAMI ST 37-1996 says essentially the same thing as AORN but also states that, “Although the risk of an unrecognized sterilization failure can be minimized if the physical parameters of time, temperature, and pressure are monitored, recorded, and examined for each cycle, it is recommended that healthcare personnel quarantine implantable devices and await the outcome of biological monitoring of the cycle before releasing these items for use.”

These organizations appear to agree that “Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can eliminate the need to Flash sterilize implantable items.” All healthcare facilities should strive to achieve this goal.

Healthcare personnel are encouraged to wrap and process implantable medical devices and await biological results.

**Is FLASH sterilization as efficacious as the steam sterilization process used for wrapped goods?**

YES, FLASH sterilization temperature and exposure times “are capable of producing appropriate lethality, as compared to the exposure times used to sterilize wrapped items” (AAMI, 1996). It must be remembered however, that in each case, sterilization is a probability that is dependent upon:

- properly decontaminating the medical devices
- careful inspection of the items for cleanliness during the inspection/clean preparation process
- opening and/or disassembling instruments so that steam can reach all of the areas that you intend to sterilize, remembering that steam will only sterilize the surface that it can touch
- flushing lumened items such as needles for injection or biopsy, suctions, and tubing with sterile or distilled water because the water will become steam during the sterilization process and help to move air out of the lumen for steam contact
- proper application of the method used to contain the instruments for FLASH sterilization, e.g., the conventional unwrapped perforated tray, a rigid sterilization container designed and tested by its manufacturer as appropriate for FLASH, or FLASH sterilization using a single wrapper with the EXPRESS cycle
- the sterilizer being in good working order
- choosing and using the appropriate FLASH sterilization cycle and cycle parameters

**Who is AAMI and what does it have to do with sterilization?**

AAMI or the Association for the Advancement of Medical Instrumentation was founded in 1967, creating a unique alliance of engineering, medicine, nursing, industry, and government professionals. The common goal was and still is to increase the understanding and beneficial use of medical instrumentation. To directly quote the organization, “AAMI’s mission is to assist in the development, evaluation, acquisition, use, and maintenance of medical devices and instrumentation. The association fulfills this mission through continuing education conferences, certification of healthcare technical specialists, and the publication of periodicals, technical documents, books, and software.”
AAMI is accredited by the American National Standards Institute and is well known as one of the principal voluntary, standards organizations in the United States. AAMI provides a forum for over 60 technical committees, subcommittees, and working groups that write consensus voluntary standards for medical devices, technical information reports, and recommended practices. These documents are respected around the world and are used as models and references nationally and internationally. STERIS, as an active corporate member, takes part in writing documents regarding decontamination and sterilization processing.

The FLASH sterilization document cited earlier is a recommended practice. It does not address sterilizer performance but instead discusses:

- design considerations: traffic control, physical facilities in relation to decontamination, preparation and sterilization areas, hand washing, and housekeeping
- personnel considerations: qualifications for supervision and sterile processing personnel, training and continuing education, health and personal hygiene, attire (general, for decontamination and sterilization areas)
- processing recommendations: transfer of contaminated items to the decontamination area, decontamination using cleaning and microbicidal processes
- open tray sterilization of routine porous and nonporous loads: preparation, loading the sterilizer, sterilization cycle parameters, monitoring and unloading the sterilizer
- flash sterilization with single wrappers: preparation of items, sterilization cycle parameters, monitoring, unloading the sterilizer
- sterilization container systems
- specialty instruments
- care and maintenance of sterilizers
- quality control: policies and procedures, record keeping, physical/chemical/biological monitoring, sterilizer efficacy, testing, prevacuum sterilizer air leak test, product testing
- process performance: the quality process

The AAMI Flash recommendations were developed to assist healthcare facilities achieve “optimum performance in the processing of medical devices sterilized by the FLASH method.” The recommendations in the document may not be “applicable to all circumstances,” and they “might not be immediately achievable,” but they can be used by healthcare professionals as a guide “towards desirable performance objectives,” using their “professional judgment and experience.” Department managers can review the information and adapt it to the needs of their particular institution.

Note that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) references this well as other AAMI documents for best practice information regarding sterilization, etc.

STERIS routinely refers employees and customers to AAMI documents for guidance, particularly regarding sterilization cycles and process monitoring. Healthcare professionals are encouraged to purchase all of the AAMI documents that regard their routine practices of decontamination, steam, ethylene oxide, and chemical sterilization.
Why did the AAMI Steam Sterilization Hospital Practices Working Group write the document “Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use”?

Very simply, because AAMI recognized that the real problems regarding Flash Sterilization involved:

- inadequate handling, cleaning/decontamination, and worker safety practices
- lack of Flash sterilization cycle documentation (should be consistent with practices used for documenting wrapped goods steam sterilization, e.g., contents of the load, etc.)
- inadequate aseptic transfer practices (getting the sterilized product safely from the sterilizer to the point of use)

Consequently, the document focuses on work practices, physical plan/layout for reprocessing and aseptic procedures, and much more, as cited earlier in the paragraph on what is contained in the Flash document.

**Cycle parameters used for Flash sterilization:**

The following cycles (Gravity-displacement, Prevacuum, and Express) are all recognized as appropriate means of accomplishing Flash sterilization by AAMI and AORN. Note that these organizations refer to the Express cycle as a “Flash cycle with a single wrapper” to avoid any company specific name.

<table>
<thead>
<tr>
<th>Cycle Parameters</th>
<th>Temperature</th>
<th>Exposure Time</th>
<th>Dry Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity</td>
<td>270° F (132° C)</td>
<td>3 minutes (Non-porous items) 10 minutes (Porous items)</td>
<td>0*</td>
</tr>
<tr>
<td>Prevacuum</td>
<td>270° F (132° C)</td>
<td>3 minutes (Non-porous items) 4 minutes (Porous items)</td>
<td>1** minute</td>
</tr>
<tr>
<td>Express Cycle</td>
<td>270° F (132° C)</td>
<td>4 minutes (Non-porous items, except wrapper)</td>
<td>3*** minutes</td>
</tr>
</tbody>
</table>

*Gravity Flash does not typically utilize drytime.

**Prevacuum Flash drytime used to help decrease steam in chamber at door opening.

***Wrapper may be dry but contents of tray may be wet depending on the amount of metal mass. This is acceptable as long as proper aseptic transfer technique is used.

- **GRAVITY-DISPLACEMENT CYCLE** - the original means of Flash sterilization where steam displaces the air in the chamber by gravity. DRY time is not used.

Non-porous items such as simple, routine instruments (forceps, needle holders, scissors, clamps, retractors) that require surface sterilization only are processed unwrapped, using this cycle.

PARAMETERS - 3 MINUTES Exposure time at 270° F (132° C).
Porous items such as towels (though not preferred to be used in the tray), rubber, plastic, silastic, silicone sheets or tubing, as well as needles for injection or diagnosis, suctions, and instruments with sliding parts (that may cover a surface and prevent ease of sterilant contact) require longer time at temperature. **PARAMETERS - 10 MINUTES** Exposure time at 270° F (132° C).

- **PREVACUUM CYCLE*** - air is removed from the chamber and steam is injected using mechanical air removal assistance. The prevacuum cycle normally used for wrapped goods sterilization can be altered and used for Flash sterilization. **IMPORTANT** to remember that if this cycle is altered to Flash sterilize items, the operator must be certain to readjust the parameters before wrapped goods (that will be stored after sterilization) are processed. One Minute DRY time is sometimes used.

Non-porous items, same as indicated for Gravity cycle: **PARAMETERS - 3 MINUTES** Exposure time at 270° F (132° C).

Porous items as indicated in Gravity cycle: **PARAMETERS - 4 MINUTES** Exposure time at 270° F (123° C).

- **GRAVITY & PREVACUUM CYCLE** unloading and aseptic transfer techniques are determined by each health care facility.

- **EXPRESS CYCLE** - Cycle parameters are preset: 4 MINUTE Exposure time at 270°F with a 3 MINUTE DRY time.

**EXPRESS CYCLE - IMPORTANT THINGS TO REMEMBER:**

- Instruments with lumens or channels cannot be processed in this cycle. If the client finds this unsatisfactory, remind them that they have the 10 minute Gravity Flash and 4 minute Prevacuum Flash cycles that can be used for these porous items.

- Complex medical devices, like power equipment, cannot be processed in this cycle unless validated by the manufacturer of the device.

- A single reusable or disposable flat wrapper is applied to the instrument tray prior to sterilization, to facilitate protection of the items after processing, for transportation to the point of use.

- Paper/plastic peel pouches are not acceptable because they were not used in cycle development/research.

- Kimberly Clark “ONE STEP” wrapper is a two ply wrapper and can only be used if that company or other suppliers of a like product have validated the product in the EXPRESS cycle.

- Rigid sterilization containers that are a substitute for a wrapper and protective organizing boxes cannot be used in this or any other Flash cycle unless the manufacturer of same has validated their use in each cycle. Note that if a container is validated it may require longer exposure times at temperature than those minimums indicated by STERIS, but they should never be shorter.
EXPRESS cycle unloading technique:

- Items Flash sterilized using the EXPRESS cycle are intended for immediate use as with any other Flash cycle.

- Handle the tray as though it had no wrapper.

- Wear sterile gloves and use sterile towels as potholders to contact the tray.

- Place the wrapped tray on a sterile impervious surface, separate from the working sterile field, to open.

- The same person who transported the tray carefully opens the wrapper, and the sterile contents are removed from the tray by the sterile or “scrubbed” person.

- The sterilized wrapped tray must never be placed on an unsterile surface (counter or shelf) because the tray may contain moisture that could strike through the wrapper, AND CONTAMINATE THE TRAY.

MONITORING Flash cycles:

- **PHYSICAL monitoring** - clients should be encouraged to observe the real-time assessment round charts, computer printouts, and gauges before a new cycle is initiated, during the cycle, and before the load is released for use.

- **CHEMICAL monitoring** - a chemical indicator or integrator is used in each tray. They are not considered a porous item and so the porous cycle parameters are not used. Consider that a chemical integrator will respond to all necessary parameters of a sterilization cycle and is a more reliable measure of a successful cycle.

- **BIOLOGICAL monitoring** - a successful biological test indicates the efficacy of the sterilization cycle parameters used by killing the test microorganism, *geobacillus stearothermophilus*. It does not prove that the items were sterilized, but that the cycle was sufficient to kill. (Microorganisms may not be killed if something prohibits the sterilant from contacting a surface, e.g., when instruments are not disassembled.)

Use a biological test product that is appropriate for the type of Flash cycle being used. Some are specifically designed for Gravity, others for Prevacuum and still others may be appropriate for both. Encourage the client to read biological manufacturer's instructions carefully to use the product properly, and avoid false positives or negatives.

FREQUENCY of Biological Testing:

- **UPON INSTALLATION & AFTER MAJOR REPAIR**- run three consecutive biological tests and release sterilizer for use upon three negative results. Client and service representative determine what constitutes a major repair (a repair that could directly affect the efficacy of the sterilization cycle for instance a repair outside the scope of normal maintenance, such as weld repairs of the pressure vessel, replacement of chamber door or a major assembly, or rebuilding or upgrading of controls.; a repair not only to the sterilizer but also the steam source).

- Any load containing IMPLANTABLE devices.

- **ROUTINELY** - at least weekly, preferably daily. Each type of Flash cycle used must be tested. Each type of tray configuration [e.g. open tray, single-wrapped tray, rigid sterilization container, organizing case] routinely used should be tested separately.
BIOLICAL TEST TRAY composition and placement.

- One or more biological indicators (one is usually used) and one chemical indicator are placed in the tray configuration to be tested. The tray should be otherwise empty, no instruments. (If clients are testing rigid sterilization containers they should consult the AAMI document, Guidelines for Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide and Steam Sterilization in Health Care Facilities.

Instruments are not included because performing the test in an otherwise empty chamber is a more rigorous biological challenge to sterilizer performance than is a filled tray. This condition minimizes heat-up time because there is little metal to absorb the heat. Therefore the lethality of the process is minimized creating a greater challenge to the biological monitor. If we can kill the biological test organism under these conditions we are most likely to achieve kill under routine sterilization of instruments because these items (the addition of metal mass) increase lethality.

- PLACE THE TRAY in the sterilizer positioned so that the biological indicator and chemical indicator are near the sterilizer drain, the coolest part of the chamber, to present the greatest challenge.

BIOLICAL TEST CYCLE:

- Choose the NON-Porous load cycle time to run the Gravity and Pre-vacuum Flash tests

- The Express cycle is run as is.

- If rigid containers are tested, the manufacturer may require increased time at temperature for any of the cycles mentioned.

- The use of Drytime will not compromise the test.

BIOLICAL TEST CYCLE ACCEPTANCE criteria:

If a POSITIVE biological test result is reported, indicating that the *geobacillus stearothermophilus* was presumably not killed during sterilization, the supervisor must be notified.

- The supervisor, facility maintenance, and sterilizer service personnel will attempt to determine the cause of the Positive result.

- The sterilizer should be retested and all information concerning the sterilization cycle in question must be examined. That would include all physical monitors [round charts or printouts and chemical indicators]. Historical data on the sterilizer performance from previous cycles should be reexamined and a decision made on whether to quarantine the sterilizer until satisfactory biological results are achieved.

- The laboratory should be instructed to do a presumptive identification of the biological specimen to assure that it is *geobacillus stearothermophilus* that is growing and not a contaminant.

**IMPORTANT NOTE:** If the open tray Flash test results are NEGATIVE, this indicates that the sterilization cycle parameters are sufficient to kill the test microorganisms under normal operating circumstances. If on that same day in the same sterilizer, the test using the rigid container for flash is POSITIVE it is likely that the container may not be functioning properly in the cycle, for adequate air removal and sterilant contact to take place.
A DAILY AIR REMOVAL TEST should be performed on both the Prevacuum and EXPRESS cycles. These cycles should be tested three times upon installation and after any major repair. Following that, the test should be performed routinely each day before these cycles are used.

**How long should Flash sterilization records be kept?**

AAMI and AORN both indicate that the records shall be maintained for as long as is required by state and local statutes. It is suggested that the persons involved in setting policy for same include the OR and CS managers, Risk Management, Infection Control, and the healthcare facility’s legal counsel and insurance carrier.
This paper is not intended to be comprehensive or to replace the information provided by AAMI or AORN recommended practices. It is provided as a quick reference to STERIS employees who are assisting our customers. STERIS employees are encouraged to access and read the full documents and asked to encourage our clients to do the same.

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