Murder in the 10th Degree - Are Your Items Sterile?

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****This in-service has been Approved by the CBSPD, Inc. for 1.5 CEUs.**

Objectives:

- To review the parameters for steam sterilization
- To discuss the AAMI minimum steam sterilization cycle parameters
- To review wet packs and their impact on sterility maintenance
- To discuss the recommended quality assurance testing of steam sterilizers

The Enemies – are the various microbes we face on a daily basis. The danger is that we cannot see them so we tend to ignore or forget about them. We are at war with the enemies!

Warfare requires a systematic approach. Everyone must be prepared and fully trained. Everyone must have the needed equipment. We need to know and understand the enemy so we can "take them out". If we do not do our job, the enemy prevails which can lead to a patient's death! **We must work as a team**…if even one person does not do their job; it reflects and can affect all others including co-workers and patients!

A noted Microbiologist, Dr. Bertha Litsky used to start many of her Seminars with the statement that "An unsterile item……is as dangerous as a loaded gun! And she was correct!

What is murder? According to Webster's Dictionary, one of the definitions of murder is to: "put an end to". Warfare is defined as: "activity that is done as part of a struggle between competing groups, companies, etc." So, SPD (our group) is fighting microorganisms.

What are our weapons?

- Effective cleaning
- Effective sterilization
  - Steam, ETO, gas plasma, vapor phase peroxide, etc.
- Effective high level disinfection

Why do we delude ourselves to BELIEVE that STERILIZATION will COMPENSATE for POOR OR INADEQUATE CLEANING??????? **Why do we allow this to happen in "our facility?" We MUST change this!**

People dramatically impact on warfare. The weapons DO NOT work unless we use them correctly. We must ALWAYS follow the device manufacturer's written instructions. We must ALWAYS follow the sterilizer or disinfectant manufacturer's instructions. Failure to do so will permit the enemy to prevail in our most vulnerable patients; the elderly, the sick and children.

Training and Competency - are our soldiers in SPD trained correctly? Are competencies verified for all tasks? Are annual competencies performed? Remember, certification **DOES NOT** ensure competency.

General Information – "Artillery" – this is the equipment we use to wage warfare.

Sterilizers are usually located in the preparation and packaging area adjacent to the sterile storage area. The Association for the Advancement of Medical Instrumentation (AAMI) recommends that the temperature in the sterilization area be 68ºF to 73ºF (20ºC to 23ºC) and that the relative humidity is 35% to 60%. The ideal humidity level is 50%. The temperature and humidity should be documented daily (ANSI/AAMI ST-79). The recommended ventilation is 10 air exchanges per hour under positive pressure.

Sterility is defined as the absence of all forms of microbial life, including bacterial spores. Sterility is described in terms of probability. An item is considered sterile if there is less than a one-in-a-million chance that a viable microorganism has survived the sterilization process; that is, its "sterility assurance level" (SAL) is $10^{-6.}$ Steam sterilization and other sterilization processes are generally designed to kill one million bacterial spores. As the sterilization process progresses, the bacterial population decreases. A one-log reduction means that 90% of the spores have been killed. Each successive log reduction results in an additional 90% kill until there is less than one microorganism surviving. **This is why the cleaning and decontamination process is so vital to good sterilization outcomes.** Removing as many microorganisms as possible before the sterilization process enhances the probability of bacterial kill.

How to Commit Murder - Steam sterilization is accomplished by saturated steam under pressure, a process similar to what happens in a pressure cooker. Steam under pressure sterilizes devices quickly and efficiently by denaturing (coagulating) the protein. Because it is fast, efficient, low in cost, readily available, and non-toxic, steam sterilization is the most common form of sterilization used in healthcare facilities for items that are heat- and moisture-tolerant. Steam sterilization should always be the preferred method of sterilization unless otherwise directed by the manufacturer of the device. You should always follow the sterilizer manufacturer's directions for operating the sterilizer. Remember that items must first be scrupulously cleaned! Follow the device manufacturer's instructions for cleaning procedures.

All personnel using sterilization equipment should be thoroughly trained with competencies verified.

Parameters for Steam Cycles – there are three parameters:

- Time - Temperature and Pressure

The exposure time varies with the temperature. The lower the temperature the longer the exposure time.

The phases of the steam sterilization cycle include:

- Come-up time - time to heat-up the load
- Exposure time – time the load is held at the stated temperature
- Come-down time - steam exhausted
- Dry cycle

Steam Quality – AAMI recommends 97% saturated steam with 3% entrained water. Steam quality can be a cause of wet packs so we need to make sure we have good quality steam. The steam quality is the responsibility of the Maintenance Department.

Steam Cycles - There are two types of steam cycles. Most steam sterilizers in use today are pre-vacuum steam; they usually have the capacity to also be used as gravity displacement.

Pre-vacuum cycles can operate at a temperature of 270^{o}F with a minimum 4 minute exposure time at 28-30 psi (pressure) or 275^{o}F with a minimum exposure time of 3 minutes at 28-30 psi. These parameters are for wrapped cycles. Drying time is dependent on the environmental conditions in your department, the type of packaging being used, the age and condition of your sterilizer, the weight and configuration of your sets, how the sterilizer was loaded and the load contents. In a pre-vacuum cycle, drying takes place through HEPA filtered air.

Gravity displacement cycles have a minimum exposure time of 30 minutes at 250^{o}F, with 15-17 psi. This is for wrapped items. Generally, drying is more difficult in gravity displacement cycles because drying takes place by evaporation through chamber walls.

The differences between pre-vacuum and gravity displacement cycles are:

- Pre-vacuum depends on mechanical removal of air from chamber and packs
- Gravity displacement – the air is displaced by steam with gravity as the force pushing the air out

The greatest resistance to steam sterilization is removal of air! If the air is not removed from the chamber and each pack, steam cannot enter.

The phases of the pre-vacuum sterilization cycle (wrapped items) consist of:

- Conditioning phase – the sterilizer goes through alternating pressure and vacuum pulses. The length of this phase varies with the load content. However excessively long conditioning phases could indicate a potential problem.

- Sterilization phase – this is the phase where there is exposure of the devices to the pre-set temperature. As the sterilizer operator, you should verify that the sterilizer maintained the set temperature, exposure time and pressure.

- Exhaust – the sterilizer draws a vacuum to remove all the steam and draws in HEPA filtered air.

The phases for wrapped gravity displacement cycles are the same phases as pre-vacuum.

You should always follow the sterilizer manufacturer's directions for cycle times/temperatures. However, you then need to follow the device manufacturer's instructions for cycle time and temperature which may vary (e.g. extended cycles).

The AAMI standard for the **MINIMUM** Cycle Parameters – wrapped items in a pre-vacuum steam sterilizer are:

- Temperature 270^{o}F – 4 minutes minimum

- Temperature 275 ^{o}F – 3 minutes minimum

For a gravity displacement wrapped cycle:

- Temperature 250 ^{o}F - 30 minutes minimum

Do you follow these? Do you check the manufacturer's instructions? Are you exceeding the recommended cycle time recommended by the sterilizer manufacturer? Remember, these are the minimum cycle times; you cannot go below these parameters. Also, some manufactures instructions for use specify temperatures of 272, 273, 274 degrees F. These temperatures are not recognized in the U.S.

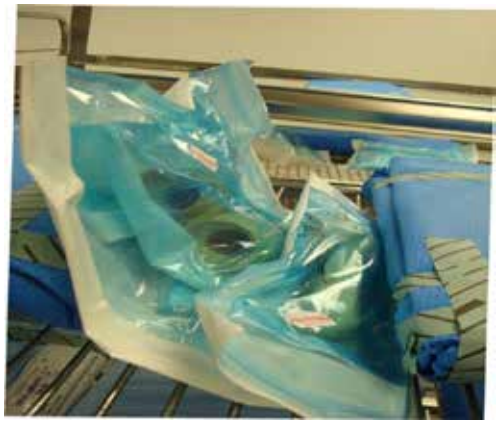
Drying - For effective drying in wrapped cycles, select the drying time per the sterilizer manufacturer's instructions. However, you may have to amend the time base upon conditions in your facility. Relative humidity, packaging (e.g. rigid containers) and loading techniques all can affect drying.

Preparation of Devices – How items are prepared can also affect sterilization. The following list demonstrates how many processes can affect sterilization:

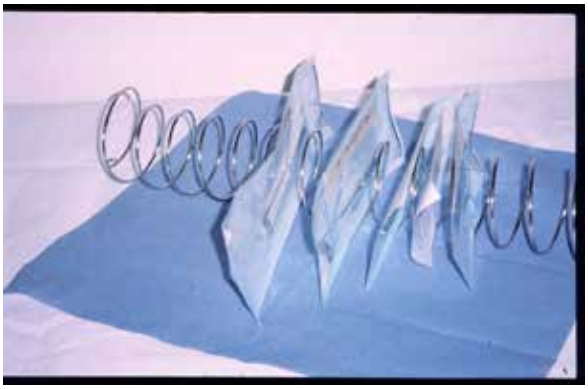
- Rigid containers will affect dry time
- Properly cleaned and inspected instruments
- Prepared in accordance with manufacturers' IFUs
- All hinged instruments completely open
- Multi-part items disassembled
- Lumens verified for cleanliness
- Select chemical indicator based upon sterilization process
- All items able to make direct contact with steam (no bowls/cups over instruments)

Loading Sterilizers - Load items loosely; you should not stack or overlay any packages. Rigid containers should only be stacked if recommended by the container manufacturer. Metal items should be placed

beneath linens or paper-plastic pouches. Paper-plastic pouches should be placed on their side and in separator.



INCORRECT loading – note how the paper-plastic pouches are crushed on the cart



CORRECT -Paper-Plastic Pouches in a Pouch Separator

Basins, solid trays or anything that can collect water should be placed on their sides. Metal mesh baskets should be placed flat.

If you have many similar items - can you put your fist between the packs? If not, they are loaded too tightly. You should leave at least a 1" space between the sterilizer cart and the autoclave walls. It is important to leave space for the air and steam to circulate around all the items.

INCORRECT loading of sterilizer; trays stacked, items too close.

Cooling of Items - Items being cooled should be in a low traffic area - no air conditioners or other cold-air vents near-by. The time for cooling should be based on professional judgment, experience and the environmental conditions of the area. It is not necessary for the load to remain inside the sterilizer with the door cracked; however if desired, it is acceptable to leave the load inside with the door open for a 5-10 minute period of time. Wrapped items being cooled after removal from the sterilizer must remain on the sterilizer cart, **untouched**, during the cooling period which can last as long as 2 hours or more. Today, many facilities use an infrared thermometer device to determine the actual temperature of each package before touching it. Follow the manufacturer's instructions for use. At this time the recommended temperature for release is ambient temperature (70-72^{o} F).

Infrared thermometer gun to determine the temperature of packs before handling

Removal of Items From the Sterilizer - Items/packs removed from the sterilizer should be visibly dry. Avoid directly touching items while hot. Steam vapor remaining in packs can cause condensate to form so it is not recommended to place hot items on cool surfaces; condensate will form. Allow all items to thoroughly cool before handling.

Handling/Inspection - Never handle sterile items before they are cool. Handle them as little as possible thereafter. All packages should be visually inspected for integrity and dryness. Do not use any packs

which appear torn, wet, compressed or punctured, appear to have been opened or to have breached seals or any item which drops to the floor. All such items should be completely re-processed.

Physical Monitoring – This includes time, temperature and pressure-recording devices and gauges. The sterilizer operator should label charts/printouts with sterilizer number and date. At end of each cycle, and before items are removed, the operator must examine the record and verify all the cycle parameters met. Then initial the printout.

Chemical Monitors should be used with each package (inside and outside). These monitors are designed to detect problems associated with incorrect packaging, incorrect loading or malfunction. They are not a sterility test. Always use indicators designed for the cycles you are using. Check the manufacturer's instructions for use for storage and interpretation. Always check the expiration date before use.

Chemical Indicators are classified into 6 categories

- Class 1 – process indicators (e.g. tape)
- Class 2 – Bowie-Dick type tests
- Class 3 – single parameter indicators
- Class 4 – multi parameter indicators
- Class 5 – integrators (parallel a BI)
- Class 6 – emulating indicators

Process Indicators **(Class 1)** - e.g. sterilizer tape - differentiates processed from non-processed devices and keeps packages closed. Indicators for specific tests **(Class 2)** include the Bowie-Dick test. Single parameter indicators **(Class 3)** are designed to react to one of the critical parameters and to indicate exposure to a sterilization cycle at a stated value of the chosen parameter. Multi-parameter indicators **(Class 4)** are designed to react to 2 or more critical parameters of the cycle. Integrating Indicators **(Class 5)** are designed to react to all critical parameters over a specified range of sterilization cycles. Their performance is correlated to the performance of a biological test (BI) under the same conditions of use. Class 6 emulating indicators are cycle verification indicators which are designed to react to all critical variables for specified sterilization cycles. They are specific to a cycle type (gravity or pre-vac), temperature and exposure time; that is, they should be used only in the specific cycles for which they are labeled. The response of a Class 6 emulating indicator does not necessarily correlate to a Biological Indicator, so the indicator cannot be used as an additional monitoring tool to release loads that contain implants.

A Bowie-Dick test is required daily for all pre-vacuum sterilizers. It tests the ability of the sterilizer to remove air from the chamber and the packs. This test must be performed according to the test pack manufacturer's instructions for use (IFU). The test pack should be placed over drain line, flat, facing up. The test is performed daily as the first cycle or at same time each day if the steam is left on 24 hours a day.

Biological Monitors are intended to demonstrate whether or not the conditions in the sterilizer were adequate to achieve sterilization. **A negative BI does not prove that all items in the load were sterile or all exposed to adequate sterilization conditions.** You need a control vial for verification of test results.

Steam cycles are tested using the spore *geo bacillus stearothermophilus*. Obtain the BI manufacturer's instructions for use, storage, handling and incubation. Verify the temperature of your incubator (if it has one) daily and document. BI Test packs are now called Process Challenge Devices (PCDs).

The frequency of BI testing as recommended by AAMI is to test at least weekly for each cycle type used (e.g. gravity and pre-vac) and all loads containing implantable devices. Implantable devices should be quarantined until the BI results are known. Verify that the control and test vials are from the same lot number. For implantable devices, AAMI recommends a BI test pack that contains a Class 5 integrator inside.

After any major repair of your sterilizer (defined as a repair outside the scope of normal maintenance such as weld repairs, repairs of pressure vessel, replacement of chamber door or major piping assembly; rebuilds or upgrades of controls") qualification testing of the sterilizer is recommended (AAMI). Qualification testing is also recommended when a new sterilizer is installed or relocated. The testing consists of performing three (3) BI tests, back-to-back, in an empty sterilizer for each type of cycle in use (e.g. gravity and pre-vac). Follow with three (3) Bowie-Dick tests back-to-back. The sterilizer should not be used until all the BI tests are negative and the Bowie-Dick tests pass. It is not required to test special cycles (e.g. extended cycles) for this testing.

Most facilities use a manufacturer's test packs containing a biological indicator. For routine testing, always use a BI test pack in a fully loaded sterilizer. Position the BI test pack in the "coldest" part of the sterilizer which is usually over the drain line. The BI test pack should be placed flat, facing up and should be placed on the cart first to make sure it is in the correct location and positioned correctly.

Document all installation and routine testing by date. Verify the results of the BI and control vials. When a positive BI occurs, all items processed since the last known negative test must be considered non-sterile, retrieved, if possible and re-processed.

Sterilization Logs - All items processed in wrapped cycles should be documented. The record should be neat and legible. List items by quantity, description and department to facilitate retrieval in the event of a recall. Keep the records neat. If a mistake is made, do not use whiteout or similar product. Draw a line through the incorrect information and initial.

Recall Policy – There should be a Recall Policy in the event of a recall. The Policy should include information about follow-up of patients for recalled items.

Documentation - Save all sterilizer print-outs, BI testing records and Bowie-Dick tests. Check with your facility's legal advisor how long you must save your sterilization records.

SUMMARY - Sterilization requires all parameters be met. Operators of sterilizers must monitor cycles and verify proper conditions. Only trained and competent personnel should operate sterilizers. Proper handling of packs after sterilization is critical to prevent re-contamination. Proper cleaning is an essential component in effective sterilization. **Either an item is sterile, or it is not.** We cannot rush the

process - especially the decontamination! Dr. John Perkins, a noted sterilization expert said "Speed is a militant force against effective sterilization". How true that is!

There is a legal liability with producing sterile items. Are your sterilization practices effective? Do you really produce sterile devices?

Our war will never end. Microbes are getting smarter and more resistant. We must never let our guard down. We are all in this together. All of us must do our jobs recognizing someone's life depends on us.

QUIZ – Murder in the 10th Degree - Are Your Items Sterile?

Please click on the link below to take the quiz.

https://www.spdceus.com/ceus/are_your_items_sterile_quiz.htm

Good Luck!