



# What do you need to know before purchasing a steam sterilizer?

by Kristina L. Pirolo with Ulrich J. Rosa

**H**ow educated are we when it comes to the sterilization process? Many people have the misconception that wiping an item with a disinfectant wipe renders a surface sterile. Wiping an item down with a disinfectant wipe is called disinfection.

Disinfection is the process of retarding the growth or destroying certain microorganisms. This process is effective for most organisms except large numbers of spores and viruses and is not equivalent to sterilization. Sterilization utilizing steam or low temperature sterilization is the only ways to achieve terminal sterilization. All reusable patient equipment must be appropriately decontaminated; cleaned, disinfected or terminally sterilized dependant on what the device will be used for. All critical devices that come in contact within the normally sterile sites of our skin must be terminally sterilized. Consider having surgery and the surgical instrumentation were used on a previous patient and were not cleaned and properly sterilized. The potential for infection or possibly death is mind-boggling. This is the reason why steam sterilizers play such an integral part in departments such as Sterile Processing where all the processes of decontamination, disinfection and sterilization take place.

When procuring a steam sterilizer for your Sterile Processing Department, what do you really need to know about it? Prior to discussing what a steam sterilizer should do and what we should consider before making a purchase, the following definitions will be helpful:

1. Sterilant - A sterilizing agent; for example, steam at certain temperature, ETO, parecetic acid.
2. Sterile - Free from all microorganisms.
3. Sterilization- Destruction of all living organisms by exposure to physical or chemical agents.
4. Sterilizer- A device in which physical or chemical agents are introduced into a chamber containing medical products for the purpose of destroying all living organisms.

Sterilization by steam requires three important factors. Temperature, time and moisture. Steam sterilizers must achieve high tempera-

tures ranging from 250 Fahrenheit for gravity displacement and 270 -275 Fahrenheit for flash and dynamic air removal sterilizers. These temperatures are normally pre-set by the sterilizer manufacturer. Sterilization times are based on manufacturer recommendations for different patient items. Adequate contact is also required for all types of sterilization. Sterilization time is measured utilizing a scientific factor called D-Value or decimal reduction time. This is the amount of time at the required temperature to kill 90% of micro-organisms. When an organism is reduced by 90% or 1 D, 10% of organisms remain. Each type of micro-organism will vary and therefore will have a different set of D-values. Within the steam sterilizer a spore or live bacteria called *Geobacillus Stearothermophilus* is used to challenge the steam sterilizer. Although highly resistant, this spore is considered non-pathogenic. This spore is used with every implantable item and used weekly to test the steam sterilizer as per ANSI/AAMI ST 79 recommendations. (AAMI is the Association for the Advancement of Medical Instrumentation. AAMI makes recommendations to promote sterility assurance and is used to guide healthcare personnel in the proper use and processing of patient equipment.) After the spore challenges the sterilizer, it is incubated for a period of time at a certain temperature to allow growth. Once the results are negative, there is no growth and all quarantined implants can be released. This spore has a D-Value of two minutes at 250 Fahrenheit or twenty seconds at 275 Fahrenheit. What does this mean? It will take two minutes at 250 Fahrenheit or twenty seconds at 275 Fahrenheit to kill 90% of the micro-organisms present. It is agreed that sterilization within a hospital approved sterilizer, six D-Values are sufficient enough to kill all pathogenic micro-organisms. The second D-value will reduce micro-organisms by another 90% bringing the reduction to 99%. A third D-Value will achieve a 99.9% reduction and six D-Values will render the item 99.9999% sterile. It is important to follow the manufacturer's recommendation. One tray may need a four minute cycle where another tray, much more complex may need a ten minute cycle.

Manufacturers base this process on a one half cycle. In other words, a 100% biological kill can be accomplished at one half of the recommended cycle. The manufacturer's recommendations should always be looked upon as the absolute minimum set. As important as sterilization is, the first step - cleaning is the most important step. If an item is not clean, it cannot be sterile. Remember you can clean without sterilization, but, you cannot sterilize without cleaning. It is impossible to sterilize proteins such as blood, feces, hair and tissue. Bacteria like to hide in nooks and crannies; therefore, all gross matter must be removed from all objects prior to the sterilization cycle. Proper manual or mechanical action is required to properly remove any gross matter.

Before purchasing a steam sterilizer you must understand how a sterilizer functions and what it is you will be utilizing this sterilizer for. An understanding of certain factors upon which the principles of steam are based is necessary. These include: Time, temperature, contact, pressure, moisture and what you are sterilizing.

Additionally, some questions you should ask include:

1. What kind of controls is the sterilizer equipped with?
2. Does it have a computer control system?
3. Is there an error alarm?
4. Can the sterilizer be manually operated in case of a power interruption?
5. Is there a tamper proof control that can be set by the operator?
6. Is it compatible with the peel pouches, wraps, and containerized systems currently used within your facility?
7. What is the maintenance fee per year of operation?
8. Is there a warranty and how long is the warranty?
9. What is covered under the warranty?
10. What is the cost of installation?

Finally, does the company have a local representative that can help you and be available for you when assistance is needed?

You must be certain the sterilizer you will purchase is the best choice for your facility and for what you will be utilizing

it for. A physical inventory of supplies and instrumentation should be conducted prior to making any purchase. Are these items steam compatible? Be aware certain scopes and instrumentation cannot withstand the high temperatures of steam sterilization. If this is the case you may want to look at the different options available to you utilizing low temperature sterilization. There are several to choose from such as ETO, Sterrad, Ozone and Parectic Acid for just in time sterilization. Manufacturers are

developing newer instrumentation and scopes compatible with the demands of high steam sterilization which is quick, inexpensive and safe when done correctly. Understanding steam sterilization will help all decision makers in the Procurement and Sterile Processing Departments make the best decision for their institution and their patients. HPN

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Resources:

1. EPA Regulation: 40 CFR 141.14:141.21
2. "Aseptic Processing vs. Terminal Sterilization-The Effects on Sterile Formulation Development." Proceeding of the PDA/PMA Sterilization Conference. Washington, DC. 1990.
3. FDA "Guideline on Sterile Drug Products Produced by Aseptic Processing." Center for Drugs and Biologics. Rockville, MD. June, 1987

Recommended Reading:

- Central Service Technical Manual, 6<sup>th</sup> Edition Chicago, IL
- AAMI ST 79
- Stanford Education 1997

## LETTERS

### Time to close the cracking door debate

**Dear Editor:**

I have read Linda Clement's article "Cracking the steam sterilizer door: Dispelling the myth," published in your May 2007 issue. I have also read Ray Taurasi's CS Questions on the subject, published in June 2007. As a sterilizer manufacturer, we agreed with Linda and recognize that Ray is representing the many healthcare users with equally valid comments. Users of healthcare sterilizers should not have to "crack the door" at the end of a vacuum steam sterilizer cycle. Having said that, we also understand that the many variables experienced at each location, from the quality of the steam supply to the sterilizer performance and finally wrapping and loading techniques (good and not so good).

The term "cracking the door" is dated. It goes back to the time when sterilizers had compression seal doors (Radial Arm Locking). Today's sterilizers have active gaskets that automatically seal via steam pressure and unseal/retract via water pressure. At the end of a cycle for today's sterilizer, there is a gap between the head ring and door plate that allows heated vapor to escape. In essence, the door "cracks" automatically.

The better term for the time inside the sterilizer would be called "Bake Time." Let's stop using the term "cracking the door" and start recognizing that if bake time is needed, it's because there is an issue with the steam, the sterilizer or loading techniques. All the things that are done to achieve a "dry" load are simply compensations for undiagnosed problems (i.e., wicking material on shelves, bake time, either pre-bake or post-bake).

Thank you, Linda and Ray, for bringing the subject up and creating user dialog and awareness. I would also suggest that the "cracking the door" topic be used as a springboard to discuss the need for a CS quality

initiative for repeatability for each load to include knowing that the steam meets certain performance standards, that the sterilizer has documented evidence it is maintained per the manufacturers instructions and that each load is produced the same and loaded the same. Repeatability is the foundation for all device manufacturers' quality systems. It should be no less for the production of sterile products for patient use.

*Thomas K. "Chip" Moore, Sales Manager  
Getinge Sourcing LLC, Rochester, NY*

**Dear Editor:**

As always, I read HPN from cover to cover. As evidence of that, I would like to comment on this issue on page 82 [July 2007, Letters to the Editor].

Those that object to 'cracking' seem to forget that the items in the load have been subjected to 250 degrees of heat. Although there is a cool down time in the cycle, it is far from being able to cool down the packages to a point that they can be safely handled. Furthermore, putting a hot item on a cool surface can cause undue condensation in the package rendering it to be viewed as non-sterile and not suitable for use. This condition is not seen in CS but rather when the package is opened at its point of use.

Recently, AAMI has published a new document on Sterility Assurance. One of the changes that has received attention is in reference to the use of rigid containers. According to the new standard, instrument sets that weigh as much as 25 lbs are permissible. From experience, I know that many CS personnel had problems coping with sets that weighed 16 lbs. Can you imagine how much more difficult it would be for them to handle hot containers weighing 25 lbs?

I don't believe that the answer to the problem should be left to the sterilizer manufacturer, but rather should be referred to one of the CS societies.

*Nathan L. Belkin, Ph. D*

**Dear Editor:**

I totally enjoy HPN and read it every month. However, I want to address the two questions that Ray Taurasi answered in the [May 2007 "CS Questions CS Answers" column].

First, in New Jersey the NJ State Department of Health and Senior Services requires that hospitals have to provide hospital-laundered scrubs for people who work in Central Service (CS) as well as other areas. So I would make sure that anyone who works in CS check with their home State to see if they are regulated.

Second, I want to clarify something about certification. In order to be certified you need to pass either the IAHCMM or CBSPD exam and maintain CEU's to recertify each year. As of now NJ is the only State that requires people working in CS to be certified. New York is implementing that in 2008, although I do not know if it will read the same. Yes, it is a cost depending on who pays for the CEU's, your facility or yourself. However, long term the rewards will be there. In New Jersey, certification has made a difference in many hospitals by giving an incentive for being or getting certified as well as increasing the starting pay for new employees not certified. Also, I believe if we are licensed we would be recognized more. The key to this is not only having a champion to fight for you in each facility but by having one National Organization that could help our cause.

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