In this article the authors have explored the technical and historical basis for flash sterilization and focus on how standardization, knowledge and new technology can contribute to safe outcome.

Background

Originally flash sterilization was utilized on an emergency basis for a single dropped instrument. However, in recent years, more and more healthcare facilities are faced with an increasing volume of patients and less time between procedures to terminally sterilize instrument sets. Flash sterilization was not intended as an alternative to purchasing additional instrument sets or to save time or for reasons of convenience.

As the cost of instrumentation has risen, economic factors came into play. Sufficient instrument inventory has not kept up with the need. Thus the practice of rapidly re-processing in abbreviated cycles has increased. Today, flash sterilization is no longer used just for a single dropped instrument or only in an emergency situation, but is routinely used for full instrument sets.

“While there are a number of causes contributing to inefficient sterilization, the underlying factor responsible for the situation... is a widespread lack of understanding of the technical requirements involved.”

—John J. Perkins

Healthcare professionals must continually educate themselves to decontamination, preparation and sterilization—all of which are evolving technologies.
Definition

Steam sterilization is a product of heat plus moisture, under pressure. Moist heat in the form of saturated steam under pressure is the most dependable medium known for the destruction of all forms of microbial life. Items to be processed in a flash sterilization cycle have been unwrapped instruments in open pans, utilizing gravity displacement and sometimes pre-vacuum steam sterilization in abbreviated cycles.

In fact, according to AAMI ST37-1996, flash is defined as a “process designed for the steam sterilization of patient care items for immediate use.” Many factors and conditions have a bearing on the end result of the sterilization process. These include the thoroughness of the cleaning process as well as adequate time to safely process instrumentation. Flash sterilization utilizes the absolute minimum parameters for sterilization, presenting the potential for serious infection.

The Problem

Achievement of sterilization is a function of probability and the process influenced by the laws of chance.

Sterilization is a statistical concept. Adequate time is needed to properly sterilize medical devices. An abbreviated exposure time can compromise sterility. In other words, flash sterilization is an additional challenge in terms of safe and effective outcome. Many variables have a bearing on the end result of the flash sterilization process.

First, the hospital environment is in itself a community of ill people—people infected with infectious diseases and others who may be susceptible. All of the common modes of transmission of infection are present in the average healthcare facility. These include water, food, waste products as well as contaminated linen, dressings and surgical instruments requiring decontamination.

The transport of sterile items to point of use is a particular challenge especially when “sterile” instruments are transported through corridors in open pans and further when these items are wet, increasing the chance of contamination to the sterile field by the wet instruments. Flashing instruments in containers with the lid open position also poses a risk to re-contamination, as the lid must be closed after the sterilizer door is opened.

Second, as flash sterilization has been utilized in emergencies on a routine basis at minimum parameters, overkill may not be built into the process. This reduces the chance of achieving 106 SAL. In other words, there is less probability that a sterility
assurance level of less than one microbe in a million survival has occurred in an abbreviated process. Time is a factor in microbial death. An increase in exposure time results in increase in kill. Unless technology can be utilized to speed the efficiency of the process, the adage “greater the exposure time, the better the outcome” will prevail.

Third, proper cleaning is crucial for sterilization. If an item is not adequately cleaned, sterilization will not be achieved. According to AAMI ST37, the purpose of cleaning and rinsing is to remove visible soil and particulate matter and to reduce the number of microorganisms and the potential for pyrogens. Just rinsing items under running water will not provide for adequate microbial reduction. Remember, the number of organisms on the material and their resistance to the sterilizing agent, as well as protection of these organisms by extraneous matter such as blood, protein, tissue, and even soap, will have a bearing on the end result of the sterilization process. All steam sterilization is based on direct steam contact. The number of organisms dying per unit of time is proportional to the numbers present at the start. Inadequate cleaning will interfere with the ability of the steam to contact all surfaces.

Fourth is the condition of the sterilizer and the quality of the steam. Many autoclaves utilized for flashing are older models. A clearly defined daily maintenance schedule or service may be required. In many cases, if these units continue to be used for flashing, replacement to newer models designed for rapid cycles may be necessary. Some steam sterilizers are set for only gravity flash cycles, but others also capable of rapid pre-vacuum settings.

Basically, there are two distinct types of pressure steam sterilizers: the jacketed double wall type, which constitutes the almost universal standard for sterilization of surgical supplies, as opposed to the single wall, non-jacketed sterilizer, which is used in laboratories and a few in healthcare settings. The non-jacketed sterilizer will not adequately pre-condition the load in a flash sterilization process and must be run without load prior to processing to pre-heat the chamber.

The first essential requirement for an efficient steam sterilizer is that some means must be provided for the automatic removal of air and condensate from the chamber. To this end, it is generally true that all modern sterilizers are equipped with a thermostatic valve for the automatic control of air and condensate discharge. This results in the maximum possible temperature and can be obtained quickly.

The condition of the sterilizer must be controlled by routine maintenance, regular service and quality control procedures. Unfortunately many autoclaves near the OR are older models, set for gravity displacement steam sterilization with limited pre-conditioning time or limited mechanical means for air removal. Incomplete air removal from the sterilizer results in depressing the temperature and preventing sterilization.

There are significant differences between gravity displacement and pre-vacuum steam sterilizers. Gravity displacement sterilization relies on gravity to displace the air. It does not have mechanical means for air removal. When steam is admitted to a sterilizing chamber, the relatively cool air present is much heavier than the steam at the normal sterilizing temperature. This means that when steam is forced by pressure into the chamber containing air, steam will flow to the top of the chamber and will mix with and have absorbed part of the heat contained in the steam. The presence of air reduces the ultimate temperature of the steam below that of pure saturated steam and the pressure maintained.
According to Perkins (more than 30 years ago), “The high-vacuum sterilizer should replace many other types.” In pre-vacuum steam sterilization, the penetration time is greatly reduced as steam penetrates the load almost instantly.

Furthermore, superheated steam can diminish the effectiveness of moist heat and affect its microbial properties. The quality of steam may be defined as the weight of dry steam present in the mixture of dry saturated steam and entrained water. Gross impurities in the steam may occur as a result of an abnormally high water level in the boiler, excessive foam in the boiler, entrained water droplets. If the dryness factor should fall below 97 percent, the items may be soaked with excess moisture and subsequently offer difficulty in the drying of the load. In flash sterilization cycles where dry time is curtailed or eliminated entirely, wet loads are a common occurrence.

The Solution

Standardized procedures and products need to be established for safe flash sterilization that incorporates steps for cleaning, packaging, sterilization, transport and validation of sterile items. The products utilized for flashing need to be designed for its intended use with efficacy and efficiency factored into the equation.

Knowledge and Training

Decontamination, preparation, and sterilization are evolving technologies. As a result, it is a requirement that healthcare professionals keep up with current developments. Staff should have the specific knowledge and skills for reprocessing medical devices. In the case of flash sterilization, the OR staff needs to be trained as well as CS staff. Knowledge of standard operating procedures as well as quality control methodology will ensure that processes are followed. The basic science of sterilization should be incorporated into training programs and the variables of flash sterilization emphasized, so staff understand the importance of following established procedures including adequate record keeping when flash sterilization is used for instrument processing. And, OR staff must be knowledgeable about the operation and function of the sterilizers they are using for flash sterilization.

The Sterilizer

The best units must be selected for safe, and reliable flash sterilization cycles. The oldest units near the operating room need to be replaced. The labeling of the cycle must be clear to the user to avoid confusion over whether the cycle is gravity or pre-vacuum flash, whether it is for one or multiple items, whether lumened or porous items were validated. Proven parameters for use must be incorporated into the settings. If 10 minutes is required to process a full instrument set, then the three-minute cycle should be clearly defined for its limited use and explained as such in the labeling. New autoclaves need to incorporate quicker methods of air extraction for efficient sterilant penetration. Two minutes of dry time can greatly reduce surface condensate and avoid injury to healthcare workers due to burns. A minimal dry time can reduce the degree of wetness in instrument loads and, in some cases, eliminate it entirely.

The Decontamination Process

A thorough cleaning must be included in all flash protocols. This includes disassembling all devices whenever possible. Cleaning products with effective enzymes can speed the decontamination process and should be a requirement when flash sterilization cycles are to follow. The cleaning process can commence at point of use with enzymatic pre-soaks to save time and facilitate decontamination. A time-saving option is to utilize ready-to-use cleaners as they avoid the need to dilute and mix solutions and they are standardized.

Validation

Biological monitoring is recommended at least weekly, but it is endorsed that healthcare staff consider daily use of biological indicators in order to allow discovery of equipment malfunction and minimize the extent of patient surveillance. Utilizing newer biological indicators that are designed...
Central Sterile Management

It is imperative that we continue to find innovative solutions and products for safer and more effective outcome in lieu of the current practices in instrument processing.

Conclusions

Innovative solutions with technological advances are redefining and changing the way flash sterilization is being done today. Standardization of load, cycle parameters and product can contribute to a higher degree of assurance when utilizing flash sterilization for sterilization of surgical devices. Use sealed container systems designed for flashing to avoid recontamination. Use enzymatic cleaners at point of use to speed up the cleaning process. Buy take-apart devices that are easy to clean. Be sure that overkill is built into the sterilization process.

These options are available. New products can address some of the challenges; however, not all systems are the same. Ask the right questions. Review the documentation. And make the right choice. Consider sending contaminated items to your central service department for processing.

Flash sterilization continues to present an additional challenge for instrument processing staff, because of the many variables present. Rapidly sterilizing in abbreviated cycles requires greater vigilance in terms of safe and effective outcome. It is imperative that we continue to find innovative solutions and products for safer and more effective outcome in lieu of the current practices in instrument processing.

References


Footnotes

1. Perkins, p.125
2. ST37, p.2
3. Perkins, p. 156
4. ST37, p.7
5. Perkins, p.124
6. ST37, p.5

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