

THE BASICS OF STERILIZATION

Objectives:

State the importance of sterilization to patient care

Review three key essentials of the sterilization process

Describe sterilization methods used, application, limitations, and risks of each

Discuss the parameters associated with each method of sterilization

Review monitoring and record keeping requirements

Introduction

The proper sterilization of medical devices, surgical instruments, supplies and equipment utilized in direct patient care and surgery is a critical aspect of the modern health care delivery system and directly impacts patient safety.

The Association for the Advancement of Medical Instrumentation (AAMI) defines sterilization as: *A process designed to remove or destroy all viable forms of microbial life, including bacterial spores, to achieve an acceptable sterility assurance level.* Sterility is measured by probability expressed as sterility assurance level (SAL). It is generally accepted that a sterility assurance level (SAL) of 10^{-6} is appropriate for items intended to come into contact with compromised tissue, which has lost the integrity of natural body barriers. This would include sterile body cavities, tissues and vascular system. A sterility assurance level (SAL) of 10^{-6} means that there is less than or equal to one chance in a million that a particular item is contaminated or unsterile following a sterilization process.

Reusable medical devices, including surgical instruments that enter normally sterile tissue or the vascular system require sterilization before each use. Improperly sterilized or contaminated medical devices utilized in patient care can contribute to surgical site infection and pose a serious risk to the patient's safety and welfare and can result in a serious life threatening infection or even death.

Sterilization is a complex process. It is imperative that healthcare workers and technicians involved in the reprocessing and sterilization of medical devices have a thorough knowledge and understanding of the scientific principles and methods of sterilization utilized in today's health care settings.

The same standards and principles apply and are a critical component of infection control regardless of where patient care is provided, be it an acute care hospital, ambulatory surgical center, out patient facility, dental or physician's office.

Key Essentials of Sterilization Process

The efficacy of any sterilization process is contingent on the following three essentials:

- 1) Conditions must be present to effectively destroy living organisms. In other words, the sterilant and sterilizing equipment must be validated and appropriate in design and operation to achieve the correct combination of temperature and sterilant combination to be lethal to microorganisms.
- 2) Devices to be sterilized must be thoroughly cleaned to reduce bioburden (soil) in order to ensure the effectiveness of the sterilization process. The higher the bioburden the greater the challenge to the sterilization process. If bioburden is too great the established sterilization parameters may not be adequate rendering the sterilization process ineffective.
- 3) There must be intimate and adequate contact between the sterilant and all surfaces and crevices of the device to be sterilized.

Achieving sterilization is not only contingent on achieving these three essentials but it is also important that medical devices are properly inspected, assembled, packaged, and loaded into the sterilizer in accordance with established procedures and techniques. It is imperative to obtain and follow all manufacturers instructions for use and reprocessing of medical devices. This includes patient care equipment, instruments, sterilants, sterilization systems and sterilizers.

All methods of sterilization are intended to kill microorganisms; therefore, one must be mindful that sterilants and sterilizing equipment can be hazardous to the health care worker. The inherent risks associated with various sterilants and equipment can be greatly minimized through staff education, observing appropriate precautions, adhering to established policies and procedures and following the manufacturers instructions for use.

Sterilization Methods and Parameters

Sterilization involves the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial spores. The major sterilizing agents commonly used in healthcare facilities today are a) saturated steam, b) ethylene oxide gas, c) hydrogen peroxide gas plasma, and d) liquid chemicals. Dry heat is also used, although less commonly. And a new sterilizing agent, ozone, has recently become available for use in the US.

Steam

Saturated steam under pressure is the oldest and most widely used, economical, effective and reliable method of sterilization available to health care facilities. The steam sterilizer consists of a pressurized chamber, increasing the pressure in the chamber elevates and holds the temperature. The sterilizer chamber and all contents must be free of any air entrapment to ensure direct contact of the steam to all surfaces to be sterilized. Steam sterilizers are designed to eliminate all air

from the chamber during the conditioning phase in the sterilization cycle. Steam is vaporized water and serves as the conduit to rapidly permeate packaging delivering high temperature moist heat to all contents and destroying microorganisms. Steam kills microorganisms by coagulating and denaturing the cell protein. Due to the very high temperatures and moisture associated with steam sterilization it may only be used with heat and moisture stable medical devices, instruments and compatible materials.

The different types of steam sterilization processes include:

Dynamic air removal process, also known as pre-vacuum, high-vacuum, or mechanical air removal. Dynamic air removal steam sterilizers utilize a mechanical vacuum pump to suck air from the sterilizer chamber during the condition phase of the sterilization cycle. Since the removal of air is mechanical the total cycle time is less than that of a gravity cycle.

Gravity, downward air displacement process, relies on gravity to remove air from the sterilizer chamber. Since steam is lighter than air, as it enters the sterilizer chamber it rises to the top. As the chamber fills with steam, the steam forces the air down and out of the chamber drain.

An abbreviated steam sterilization cycle, known as flash, can be accomplished in either a pre-vacuum or gravity displacement sterilizer. Flash sterilization is intended for emergency use when instrumentation is urgently needed and time does not allow for routine processing. Flash sterilized items are intended for immediate use.

Steam Parameters

The essential conditions for steam sterilization are temperature, saturated steam, time and pressure.

Recommended minimum sterilization times for wrapped instruments:

- Prevacuum: 270°F 4 min exposure; 30 min drying time
- Gravity displacement: 250°F 30 min exposure; 45 min drying time

Recommended minimum “flash” sterilization times for unwrapped metal or non-porous items only (i.e., no lumens)

- Prevacuum: 270°F 3 min exposure; no drying time
- High-speed gravity 270°F 3 min exposure; no drying time

Recommended minimum “flash” sterilization times for unwrapped metal items with lumens and porous items (e.g., rubber, plastic) sterilized together

- Prevacuum: 270°F 4 min exposure; no drying time

- High-speed gravity 270°F 10 min exposure; no drying time

When sealed containers are used for flash sterilization, the manufacturer's written instructions for exposure times and drying times should be followed as the times may be extended.

Ethylene Oxide

Ethylene Oxide (EO) is a low temperature sterilization method that has been used for many years. The low temperature process makes it suitable for the sterilization of heat and moisture sensitive medical devices that cannot tolerate the high temperatures and moisture associated with steam sterilization. EO is a colorless gas, which destroys microorganisms by a process called alkylation. The EO penetrates the cells membrane and reacts with the nuclear material rendering it unable to metabolize and reproduce.

EO does have some disadvantages including a relatively long sterilization cycle and the need for aeration for a specified amount of time. EO is toxic and porous materials exposed to EO will absorb the toxic gas requiring aeration following the sterilization process to allow the residue to escape from the medical devices before they are handled and used.

EO is extremely flammable in its pure form and requires that special precautions be taken in its storage and use. Furthermore, EO is also a known carcinogen. EO presents a work place hazard and the Occupational Safety and Health Administration (OSHA) has developed permissible exposure limits and requires continuous monitoring of the work area and personnel. The Environmental Protection Agency (EPA) has also established regulations to protect the environment from EO. Sterilizers must be designed to address certain requirements for ventilation and exhaust and users must monitor the process to ensure that safety and environmental standards are adhered to.

Ethylene Oxide Parameters

There are four primary conditions/requirements to effectively sterilize with EO (1) gas concentration (2) humidity, (3) temperature and (4) time. A change in any one of these conditions will require an adjustment of other conditions. For example if the temperature is decreased the exposure time must be extended. Because of the vast differences in the configuration, density, design and permeability of products routinely sterilized in the hospital setting standard cycle parameters have been established to accommodate the most challenging of circumstances. EO sterilizers are designed and programmed to operate at the required concentration and humidity levels for the established routine hospital cycles parameters.

- Relative humidity 50 – 75% (items should be completely dried prior to packaging and being placed in sterilizer)
- Temperatures range from 85-145°F depending on cycle chosen, chamber size, and gas blends (manufacturers instructions to be followed)

- Exposure Time is usually 2 hours or longer depending on load capacity, density and porosity
- Aeration times and temperatures; 8 hours at 140°F and 12 hours at 122 °F.

Hydrogen Peroxide Gas Plasma

Gas Plasma is a low temperature sterilization alternative that has been available for several years and is suitable for many heat sensitive and moisture sensitive or moisture stable medical devices. Unlike EO sterilization, gas plasma sterilization is devoid of the occupational, environmental and patient safety concerns. Gas plasma is also less expensive and total cycle times are significantly less than EO. Medical devices are ready for use following sterilization without the need for aeration. This method disperses a hydrogen peroxide solution in a vacuum chamber, creating a plasma cloud, reactive species are generated from the hydrogen peroxide that are reactive with microorganisms. Gas Plasma sterilizes by oxidizing key cellular components of the microorganisms, which inactivates and destroys them. There are some restrictions on lumen devices validated for sterilization by this method based on gauge and length of the device. Users should obtain documentation from the manufacturer for appropriate use and restrictions. Gas plasma is not compatible with highly porous absorbers, such as cellulose, and paper products and cannot be utilized to process liquids.

Hydrogen Peroxide Gas Plasma Parameters

- Temperature range varies but is maintained between 104-131°F
- Total cycle time will range between 28 - 75 minutes depending on the sterilizer model and size.

Liquid Chemical Sterilization

Liquid chemical sterilization is utilized for the sterilization of heat sensitive devices that can be immersed. This method employs the use of a germicidal solution and requires the complete immersion of items in the solution for a prescribed period of time to kill microorganisms.

Peracetic acid is a liquid chemical sterilant used in conjunction with a self-contained automated processor designed for this method of sterilization. It is commonly used for flexible endoscopes and components. Devices that are sterilized by this method are intended for just-in-time use and have no shelf life.

Glutaraldehyde is also a liquid chemical sterilant when used according to the manufacturer's directions for sterilization; however, it is usually used as a high-level disinfectant. There are several disadvantages of using glutaraldehyde as a sterilant. These include toxic fumes, long exposure time, potential for contamination of sterile devices during rinsing and transfer to the area of use, and no method to biologically monitor the sterilization process. A well-ventilated work environment is required and personal protective equipment such as gloves,

goggles, masks, aprons and gowns are necessary to protect the staff performing the process.

Chemical sterilants can pose a risk to health care workers and patients, if they come in contact with tissue, skin, mucous membrane or eyes.

Liquid Chemical Sterilization Parameters

- Items must be totally immersed in the chemical, allowing direct contact to all surfaces for a prescribed period of time to achieve sterilization.
- Peracetic acid comes in a single use, sealed container at a precise concentration.
- Peracetic acid requires 12 minutes of exposure and the temperature range is between 122°F to 130°F.
- Glutaraldehyde is activated once a container is opened, by adding the pre-measured activating chemical, which comes with each bottle.
- Glutaraldehyde requires 10 hours of exposure.

Dry Heat

Dry heat sterilization should be used to sterilize anhydrous (waterless) items that can withstand high temperatures. Dry heat sterilizers are not commonly found in healthcare facilities today. If used, it is generally to sterilize talcum powder for surgical procedures.

Dry heat sterilization may be used to sterilize sharp instruments, such as dental instruments, burrs, and reusable needles that would be damaged by the moisture of steam.

Dry heat sterilization is accomplished by conduction where heat is transferred from molecule to molecule or from the exterior surface of an item to its internal parts. The destruction of organisms occurs by oxidation, which is a slow burning up process of coagulating the cells protein. It is a long sterilization process due to the length of time it takes for objects to reach required temperatures; unlike steam sterilization there is no moisture present, which speeds up heat penetration.

Dry Heat Parameters

There are great variations in times and temperatures based on volume, density, packaging and sterilization apparatus. It is essential to follow the manufacturer's instructions for the items being sterilized and the sterilizer being utilized.

- Settings range from 30-minute exposure at 356° F to 6-hour exposure at 250°F. These are the exposure times only and do not include the time required for all parts to reach the desired temperature.

Ozone

Ozone sterilization is the newest low-temperature sterilization method recently introduced in the US and is suitable for many heat sensitive and moisture sensitive or moisture stable medical devices. Ozone is a strong oxidizer and is generated within the sterilizer using medical grade oxygen, water and electricity. Ozone is inexpensive, non-toxic and environmentally friendly.

Ozone sterilization is compatible with stainless steel instruments, however there are some lumen restrictions. Currently, ozone sterilization is not cleared to process flexible endoscopes, glass or plastic ampoules, liquids or implants. Information regarding device compatibility should be obtained from the manufacturer of the device and the sterilizer manufacturer.

Packaging materials that can be used for ozone sterilization include anodized aluminum containers using noncellulose disposable filters, polyethylene pouches and uncoated nonwoven wrap.

Ozone Parameters

- The cycle time is approximately 4.5 hours, at a temperature of 85 ° F - 94 ° F.

Quality Assurance

A high degree of sterility assurance is of critical importance for the sterilization process. For safe, effective sterilization practice it is essential that staff performing the sterilization function have an in-depth-knowledge and understanding of the scientific principles and methods of sterilization, parameters, applications, and risks associated with each method. Staff must be adequately trained to perform the sterilization function and demonstrate their competency.

Process controls including the healthcare facility's policies and procedures for sterilization and the sterilizer manufacturer's written instructions for sterilizer operation should be readily available and consistently followed.

Each sterilization cycle should be monitored with mechanical, chemical, and biological indicators to verify that parameters required for sterilization have been met. Mechanical indicators such as recording charts and computerized printouts show the conditions of the sterilizer during the cycle. An air removal test (Bowie-Dick Test) of prevacuum steam sterilizers should be performed daily in an empty chamber. The appropriate chemical indicators should be placed on the outside of packages to be sterilized to provide evidence of sterilization process completion. Chemical indicators or integrators should be placed inside of each package being sterilized, to provide results after sterilization as to whether the condition(s) measured for sterilization were met on a pack-to-pack basis.

The appropriate biological indicator should be used in steam, ethylene oxide, hydrogen peroxide gas plasma, dry heat, peracetic acid, and ozone sterilizers.

The spore, *Geobacillus Stearothermophilus* should be used for testing steam, gas plasma, paracetic acid, and ozone sterilizers. *Bacillus atrophaeus* should be used for ethylene oxide and dry heat sterilizers. A negative BI result is indicative that conditions for sterilization to occur were met. The frequency of biological monitoring should be based on current regulations, recommended practices and the sterilizer manufacturers recommendations:

- Steam sterilizers at least weekly and preferably daily
- Gas plasma, paracetic acid, dry heat, and ozone - daily
- Ethylene oxide and implants – every load

Additionally, record keeping is required to document essential information such as testing, cycles run, load contents, chemical and biological indicator results, and the sterilizer operator. This information is typically recorded in a sterilization log. Record keeping is the key to accountability and provide an audit trail. Sterilization records are necessary if there is a recall of items sterilized in-house or if sterilization records are subpoenaed for a lawsuit.

Summary

Knowing and understanding the scientific principles and various sterilization methods and their proper applications, as well as the monitoring and record keeping requirements can help to ensure effective sterilization, patient safety, and cost-effectiveness.

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