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LOW TEMPERATURE HYDROGEN PEROXIDE GAS PLASMA STERILIZATION SYSTEM - AN INNOVATION IN STERILIZATION PRACTICE.

Medical Science

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ABSTRACT

Plasma sterilization is fast evolving as an alternative to standard sterilizing techniques. Research on plasma sterilization started way back in 1960. Since then, extensive research has been performed in plasma sterilization. The first sterilizer came in the market in 1997 in Europe. Improvement of this technology of the initial product is going on and this trend is going to continue.

Hydrogen peroxide plasma sterilization process offers several advantages for sterilization of heat sensitive medical devices, thanks to the relatively short cycle duration and the fact that there is no problem with residues. On, closer scrutiny, one sees there are only few medical devices for which ethylene oxide sterilization is deemed to be the method of choice (e.g; electronic components, coated boards, extremely long medical devices such as gastroscopes and colonoscopes). It cannot be ruled out that in the future hydrogen peroxide based processes will not replace steam sterilization in certain areas (surgical practices, out patient surgery, use in natural disaster). First there is a growing interest among users and second more suppliers are appearing in the market.

KEYWORDS:

Introduction

Plasma is the fourth state of matter in addition to solids, liquids and gases. Without going into the intricacies, simply put, plasma sterilization uses a triphasic technique. Plasma is basically ionized gas. When we apply an electric field to a gas, it gets ionized into electrons and ions. When plasma is turned on, it generates a whole lot of particles-uv photons, electrons, ions and neutral particles. The electrons and ions just swim around. It is the uv photons and radicals that do all the hard work. The spores are basically made up of simple atoms like C, O, N, H and the like. The radicals react with these atoms to form simple compounds like CO_2 which can subsequently be flushed out. When the organism loses such atoms that are intrinsic to its survival, it dies.[1]

The items to be sterilized are placed in chamber, the door is closed and evacuation begins. When a sufficiently low pressure is achieved in the vacuum stage, a low temperature air plasma is generated to aid in the removal of residual moisture from the instruments being sterilized. At the end of the pre-exposure plasma stage, the system is vented to atmospheric pressure by the introduction of filtered air. This constitutes the end of the pretreatment drying phase, and the sterilization process then begins. The pressure in the sterilizer is reduced and an aqueous solution of hydrogen peroxide is injected and vaporized into the chamber. The hydrogen peroxide diffuses throughout the chamber, surrounding the items to be sterilized, and inactivates microorganisms. The pressure in the system is first increased and then after a subsequent pressure reduction, a low temperature plasma is generated by applying RF energy to create an electric field that initiates the generation of the plasma. This constitutes the first half of the total sterilization process, which is then completed by repeating the preceding steps with the exception of the pretreatment of drying phase. [2]

At the end of the cycle, the remaining active components recombine to form oxygen and vaporized water. It uses low temperature hydrogen peroxide gas plasma technology to rapidly sterilize a wide range of medical instruments. It produces dry, wrapped, sterile items ready for immediate use or sterile storage.

Scope

- High speed.
- 55 min. cycle time (short cycle).
- Optional 72 min-cycle for flexible endoscopes (long cycle).
- Rapid turn around of instruments and lesser inventory costs.
- Non-toxic (unlike Ethylene Oxide gas or low temperature steam formal-dehyde)
- Water vapour and oxygen are the primary end products.
- Sterilized instruments are free from toxic residue.
- Sterilized instruments are available for immediate-use, no aeration required.
- Ensures patients and health care workers safety.
- Instruments Safe.
- Ensures longevity of surgical instruments and sharp micro-surgical instruments.
- Metal instruments are less prone to corrosion.
- Sharp micro-surgical instruments retain their integrity and instrument life is extended.
- The process is usually at room temperature and hence poses no danger associated with high temperature (unlike autoclaves).
- Instrument costs and replacement cost is reduced.

Low Temperature Sterilization of Medical Devices:

With the many advances in minimum invasive surgical techniques, the instruments used have become more and more complex, with integrated electronics, robotic control and precise operating mechanisms. Most of them are temperature sensitive materials and can not be exposed to steam or heat sterilization techniques. Low temperature sterilization for such items is increasingly becoming the desired process, as it is device compatible and sterilization takes place in a safe way.

Steam and dry heat sterilization are the most widely used methods but are restricted to temperature resistant materials and instruments. In the case of steam, the overall cost of installation, correct operation, maintenance and validation can be expensive considering water purity, steam generation and its quality, and drainage requirements.

The low Temperature Ethylene oxide sterilization (ETO) and steam with formaldehyde (LTSF) is being replaced in hospitals due to long cycle time, gas aeration and health concerns. There are recent developments in low temperature like hydrogen peroxide gas plasma technology, humidified ozone, liquid chemical, peracetic acid technology **with** plasma generation.[3]

There are a number of new systems recently developed that all use hydrogen peroxide for low temperature sterilization. Those that use plasma as a part of the process and those that use only hydrogen peroxide (non plasma) with four injections. All these systems expose loads to be sterilized under vacuum to the gas, in the presence or absence of plasma. Plasma is an excited gas and is produced by adding energy (in the form of heat or an electromagnetic field). An aqueous solution of hydrogen peroxide is vaporized within the chamber surrounding the items to be sterilized. Radiofrequency induced electrical field accelerates electrons and other particles, which collide with each other, generating free radicals and other species in the plasma which destroys micro-organisms. Oxygen and vaporized water are the primary end products of the system.

Using this method, the entire sterilization process is split into two consecutive, equal phases. The process parameters in each phase are identical. A 6-log reduction of the resistant bacterial spores used to validate the process is demonstrated with the first phase. Because the second injection phase is equal to the first (i;e all the process parameters are identical) , an additional 6-log reduction is obtained at the end of the second phase, and the total process provides SAL of 10^{-6} (4)

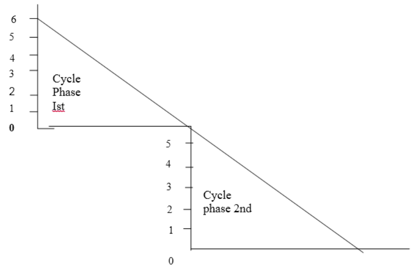

Fig 1: Full cycle in hydrogen peroxide plasma sterilizer

Hydrogen peroxide is one of the most widely used biocides for various antiseptic, disinfectant and sterilization application. When in the gas phase hydrogen peroxide also known as vaporized hydrogen peroxide (VHP) demonstrates greater antimicrobial efficacy and compatibility than in the liquid form. This may be due to the more reactive nature of the gas but recent evidence would also suggest that the mechanism of action of the gas is different than the liquid. Hydrogen peroxide in gas state has been confirmed to have broad spectrum antimicrobial activity with confirmed virucidal, bactericidal, fungicidal, mycobactericidal, cysticidal and sporicidal activity.

In gas form, hydrogen peroxide has been shown to have compatibility with the commonly used metals and plastics and even are compatible with electrical components.

The gas can be safely contained, easily degraded/removed during the process and rapidly degrades into water and oxygen, providing an important environmental benefit when utilized under vacuum conditions. Practically these systems require little installation requirement (electricity only) in comparison to other low and high temperature alternatives, with no extended aeration requirements as traditionally needed with ethylene oxide and LTSF sterilization. (5)

Advantages

This newer system is particularly intended for the terminal sterilization of cleaned, rinsed and dried reusable metal and non-metal medical devices used in health care facilities. The sterilization cycle consists of three phases: conditioning, sterilization, and aeration. The overall process is conducted under vacuum to ensure air removal and steriliants gas penetration, but is also safety feature containing the gas during the process for operation, liquid hydrogen peroxide (at 59% in water) is provided in a sealed container and used to generate the gas within the sterilization chamber. At completion of the cycle, the load is removed and can be immediately used or stored for use. An average concentration of 0.22% by weight of hydrogen peroxide remains the only chemical residual which is within the accepted American Association for Advancement of Medical Instrumentation limits.(5)

Limitations

- Medical devices to be sterilized must be dry.
- The process cannot be used for liquids, cellulose based materials viz. paper and lenin etc.
- The metal devices must not touch the chamber walls (plasma drum).

Cleaning

Before reprocessing medical devices, they must be cleaned properly in automatic washer disinfector or ultrasonic washers. If these equipments are not available, then the devices/instruments should be cleaned manually by three sink method. Either neutral pH multi enzyme detergent be used or mild alkaline detergent of a reputed manufacturing company certified by international standards.

In 1971 Dr. E.F. Spaulding devised an approach to disinfect and sterilize patient care items or equipment on basis of their intended use. It has proved to be so clear and logical that it has been used by the infection control professionals since then.

Depending in the intended use of an item, medical and surgical equipment may be required to undergo the following processes between uses on different patients:

- Cleaning followed by sterilization.
- Cleaning followed by high or intermediate level of disinfection.
- Cleaning alone.

Classification	Item use	Goal	Appropriate process
Critical items	Items entering sterile tissue, the body cavity, the vascular system and non intact mucous membranes e.g surgical instruments	Objects must be sterile (free of all micro-organisms including bacterial spore)	Sterilization (or use of single-use sterile product) • Steam sterilization. • Low temperature methods (ethylene oxide, peracetic acid, hydrogen peroxide plasma)
Semi-critical items	Items that make contact, directly or indirectly, with intact mucous membranes or non intact skin. e.g endoscopes, anaesthetic equipment.	Objects must be free of all microorganisms with the exception of high numbers of bacterial spores.	High level disinfection • Thermal disinfection • Chemical disinfection (glutaraldehyde, OPA) • It is always preferable to sterilize semi-critical items whenever they are compatible with available sterilization processes
Non-critical items	Objects that come into contact with intact skin but not mucous membranes e.g crutches, BP cuffs, tabletops.	Objects must be clean	Low level disinfection • Cleaning (manual or mechanical)

Device compatibility varies with each low temperature sterilization method. The user should obtain written functional compatibility information from the device manufacturer and sterilizer efficacy information from the sterilizer manufacturer before processing costly devices by this method.

Conclusion

We are in an era where speed and safety has become the primary sterilization process selection criteria. The devices sterilized by hydrogen peroxide plasma sterilization system are safe for the patients. The end products are eco-friendly. There are no environmental concerns.

Today a variety of different models of hydrogen peroxide plasma sterilizers have become available for use in healthcare, manufactured by number of reputed companies. But in coming days large sized next generation equipments are coming in the market for industrial use.

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