



Gas plasma hydrogen peroxide (H₂O₂) sterilization

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Cite this study: Usta, E. O., & Ayaz, F. (2022). Gas plasma hydrogen peroxide (H₂O₂) sterilization. 3rd Advanced Engineering Days, 54-56

Keywords

Sterilization
Hydrogen Peroxide- Sterilization
Low temperature
Sterilization methods

Abstract

Sterilization is a critical process and its effectiveness is vital. For this reason, the most important feature to be considered when determining the correct and effective sterilization method is determining the appropriate sterilization management for the appropriate material and ensuring the continuity. The inadequacy of High Temperature Sterilization methods has created an urge for the development of alternative methods. With the Gas Plasma Hydrogen Peroxide (H₂O₂) sterilization method, effective and reliable sterilization performance is provided for materials with lumen, and sterilization efficiency can be evaluated with lumen tests. The lumen materials used in these tests and sterilized medical devices (endoscope, bronchoscope, etc.) are simulated. Inner diameter of Sterrad 100NX and Sterrad 100S sterilization devices min. Single channel stainless steel lumens with 0.7 mm and maximum length of 500 mm were tested using different numbers of loads. It is difficult for the sterilization agent to reach the hollow part of the device and compared to other methods, Gas Plasma Hydrogen Peroxide (H₂O₂) Sterilization is preferred because of its effectiveness. In addition to these advantages, Gas Plasma Hydrogen Peroxide (H₂O₂) Sterilization is not suitable for the sterilization of the materials containing cellulose.

Introduction

Sterilization is the process of purifying surfaces from microorganisms, and its effectiveness is very important [1]. For this reason, it is necessary to determine the appropriate sterilization management and test the effectiveness of the determined method. The inadequacy of the High Temperature Sterilization methods, which were used in the 1950s, supported the development of alternative methods. We can divide the hospital-type sterilization methods into two main groups as low temperature sterilization and high temperature sterilization. High Heat Sterilization methods were started to be used in the 1950s. These methods are; Dry Temperature Sterilization Method is Pressurized Steam Sterilization Method. However, High Temperature Sterilization methods are not suitable for sterilization due to the long sterilization period, very high heat requirement, unsuitable for fabric and rubber materials, the development of laparoscopic surgical instruments and the increase in the use of lumen materials in these surgeries. The need for new sterilization methods arose due to reasons such as Low Temperature Sterilization methods have gained diversity in order to meet these needs. The most common Low Temperature Sterilization Methods can be grouped as follows a) Ethylene Oxide (EO) Sterilization, b) Formaldehyde Sterilization, c) Gamma (Irradiation) Sterilization, d) Gas Plasma Hydrogen Peroxide (H₂O₂) Sterilization, Ozone Sterilization [2]. Among these methods, Gas Plasma Hydrogen Peroxide (H₂O₂) Sterilization comes to the fore in the sterilization of heat and humidity sensitive materials. With the H₂O₂ sterilization method, effective and reliable sterilization performance is provided for lumen materials, and it is easy to install, easy to use, short sterilization time, environmentally friendly due to no toxic residue, has no corrosive effect, and provides

safe use for users [3]. Hydrogen Peroxide (H₂O₂), which is used as a sterilization agent, is injected into the environment by the sterilization device after it is placed in the area in the sterilization unit by the user, and the Hydrogen Peroxide (H₂O₂) is evaporated and dispersed in the vacuum environment. Hydrogen Peroxide (H₂O₂), which is a biocide, enters the diffusion stage and has a lethal effect on microorganisms. With the applied radio frequency (RF) energy, a plasma is created that will react with microorganisms and stop their vital functions. With the effect of plasma unit in sterilization systems, the amount of residue is below 1PPM TLV. It is also defined as an environmentally friendly method [4-5]. The steps of the H₂O₂ Sterilization cycle (45 min at 45 °C on average) in five successive phases; Vacuum Phase, H₂O₂ Injection Phase, Diffusion Phase, Gas Plasma Phase, Verification Phase are taking place [4].

Results

With the Gas Plasma (H₂O₂) Sterilization method, all devices sensitive to heat and humidity can be sterilized and serious economic gains are achieved. It is one of the most preferred methods, especially in the sterilization of lumen materials. With Table-1, Steam Sterilization is evaluated in terms of Ethylene Oxide (EO) Sterilization and Gas Plasma Hydrogen Peroxide (H₂O₂) Sterilization advantages and its advantages are included [6-7].

Table 1. Steam Sterilization, Ethylene Oxide (EO) Sterilization and Gas Plasma (H₂O₂) Sterilization Comparison Chart

TYPE	Steam Sterilization	Ethylene Oxide (EO) Sterilization	Gas Plasma (H ₂ O ₂) Sterilization
Sterilization Method	High temperature, pressure, steam	Injection of EO(ethylene oxide) gas	Injection of Hydrogen Peroxide (H ₂ O ₂) gas
Sterilization Time	Sterilization time: 10 min.-1 hour Ventilation time: Use after cooling	Duration: 2-3 hours Ventilation time: 7-10 hours Can only be used once a day	Duration: 30-60 min. Ventilation time: 0
Sterilization Agent	Steam created from high-temperature water	EO gas + CFC (Freon) or CO ₂	Hydrogen Peroxide (H ₂ O ₂)
Security	Special precautions must be taken to create high pressures and high temperatures.	Harmful to User/Patient Not environmentally friendly	No harm to the user/patient environmentally friendly
Setup	Electricity/ Water Supply/ Gas Pipe/ High pressure resistant boiler	Electricity/ Water Supply/ Gas Pipe/ Gas tank	Plug & Play
Effect on MIS Device	Serious damages and abrasions caused by 120-135°C high temperature and high pressure	55-60°C damage and wear from low heat and high pressure	Very limited wear effect in 50-55°C low temperature and vacuum environment

Lumen tests of the Gas Plasma Hydrogen Peroxide (H₂O₂) Sterilization method for Serrad NX and Sterrad 100S devices are summarized in Table-2, lumen material sterilization with Sterrad NX [7] and Table -3, lumen material sterilization with Sterrad 100S [7]. It has been determined that effective sterilization is performed in the loading made according to Table-2 and Table-3, which includes the length, diameter and load amount of the lumen material.

Table 2. Lumen sterilization with Sterrad NX [7]

Load Characteristic	Duration	Lumen	Length	Suggestion
	Diameter			
Metal lumen materials	28min.	≥ 1mm	≤ 150 mm	It can be sterilized, provided that it does not exceed 10 in a normal load.
	28min.	≥ 2mm	≤ 400 mm	
	38min.	≥ 1 mm	≤ 500 mm	
In non-metal lumens (polyethylene and teflon)	28 min.	≥ 1 mm	≤350mm	Without any other load, 10 can be sterilized at a time.
	38min.	≥ 1 mm	≤1000mm	
Flexible Endoscope	38 min.	≥1 mm	≤850 mm	1 single-channel flexible endoscope can be sterilized. There should be no other burdens.

Table 3. Lumen sterilization with Sterrad 100S [7]

Load Characteristic	Lumen Diameter	Length	Suggestion
Metal Lumen Materials	≥1 mm	≤125 mm	It recommends sterilization in short or long cycles without the use of boosters/adapters.
	≥2 mm	≤250 mm	
	≥3 mm	≤400 mm	
Metal Lumen Materials	≥1 mm	>125/≤500mm	It recommends sterilization by adding booster/adaptor in short or long cycle.
	≥2 mm	>250mm/≤500mm	
	≥3 mm	>400 mm/≤500mm	
In copper and similar alloy lumens	≥3 mm	≤500mm	It recommends sterilization by adding booster/adaptor in short or long cycle.
In non-metal lumens (polyethylene or Teflon)	≥1 mm	≤1000mm	It recommends sterilization in short or long cycles without the use of boosters/adapters.
	≥1 mm	≤1000mm/≤2000mm	
Flexible Endoscope	≥1 mm	≤500mm	It recommends sterilization by adding booster/adaptor in short or long cycle.
	≥1 mm	≥500mm/2000mm	
Multi-lumen Flexible Endoscope	≥1 mm	≥500mm/2000mm	In the long cycle, it recommends sterilization by adding a booster/adaptor to each lumen.

Discussion

Medical devices (e.g., endoscopes) used in Minimally Invasive Surgical Operations (MIS), which are preferred instead of traditional open surgical operations, can be safely sterilized by Gas Plasma (H₂O₂) Sterilization method, which is one of the low-temperature sterilization methods, due to its much more expensive, complex and sensitive structure. Steam and ethylene oxide sterilization methods, which are widely used in this study, are not replaced by hydrogen peroxide sterilization devices due to high installation and operating costs, and the chemicals used pose serious risks to human health and the environment. The Gas Plasma (H₂O₂) Sterilizer, which has low operating costs and high sterilization efficiency, is user-friendly and environmentally friendly, and is preferred because of its performance in lumen material tests. However, this method should not be used for the sterilization of the materials containing cellulose.

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