

Advances and Intelligent Prospects in Veterinary Sterilization Equipment

Tom Jobe¹, Kedar Pai², Chris Timmons², Chris Bratcher²

¹BioInSpire LLC, Noble OK, USA
²Plasma Bionics, Stillwater, OK, USA

ABSTRACT

This paper describes the recent advances in the development of veterinary sterilization equipment. An analysis of autoclaves, dry-heat, chemical, and plasma sterilizers utilized in veterinary applications is performed to illustrate the state of available commercial instruments. The technical and commercial benefits of each technology are examined in the comparison, including the environmental impact. Prospects of sterilization using Artificial Intelligence tools are briefly discussed.

Keywords: Sterilization, Veterinary, Gas plasma, Air Plasma, Intelligent Sterilization Perspectives

I. A BRIEF HISTORY OF STERILIZATION EQUIPMENT

Sterilization is the process of killing all microorganisms, including bacterial spores. The history of sterilization dates as far back as the late 1600s, becoming a more common practice in the 1800s [1]. Due to the work of the French chemist Louis Pasteur and later the English surgeon Joseph Lister, antiseptics became more common in human surgery. Pasteur's pupil, Charles Chamberland, invented the first pressure steam sterilizer in 1876. In 1881, sterilization via boiling was introduced. Just before 1890, Goodyear Rubber introduced the first gloves for operating rooms. In the early 1900's, a company named Aesculap produced chrome-plated containers to transport sterile instruments. In 1929, ethylene oxide was first as a sterilizer for imported spices and furs. Commercial steam sterilizers first appeared in the US in the 1930s and became commonplace by 1940. The first textbook used as a standard for sterilizing medical instruments was published in 1956, *Principles and Methods of Sterilization in Health Care Sciences*, by J.J Perkins. A sterilizer based upon ozone was approved by the FDA in 1989, produced by Life Support, Inc. The FDA approved the plasma-based Sterrad sterilizer in 1993. Tuttnauer [2] introduced the first manual autoclave in 1929 and continues to be a leading supplier of both medical and veterinary sterilization equipment.

In the US, medical sterilizers are regulated by the FDA, while the CDC provides Guidelines for their use only in medical applications. Veterinary sterilizer manufacturers remain unregulated in terms of FDA approval, but operate under the umbrella of the National Institutes of Health (NIH); specifically the Office of Laboratory Animal Welfare (OLAW), where policies for veterinary care of animals are issued via the Institutional Animal Care and Use Committee (IACUS) [3]. IACUS has published *Accepted Methods & Monitoring guidelines* for the use of veterinary sterilization equipment and processes. Countries outside the US, such as New Zealand, have specific but similar guidelines for the use of veterinary

sterilization equipment [4]. In Europe, (EU) 2019/6 [5] will go into effect in early 2022, regulating all veterinary medicinal products, including sterilizers. Per the internationally recognized Spaulding Classification [12] method, sterilization is required whenever a device comes in contact with internal sterile tissue or the bloodstream, creating a "critical" risk of infection transmission, as opposed to disinfection methods for semi-critical or non-critical risks.

II. STERILIZERS UTILIZED FOR VETERINARY APPLICATIONS

A. Autoclaves

Steam sterilizers (autoclaves) are the most common and traditional form of sterilizer. Two types of steam sterilizers are common, the gravity autoclave and the high-speed autoclave. Most modern steam autoclaves are the high-speed type, with a cycle time of 4 minutes at 132 C or 30 mins at 121 C. In these sterilizers, a vacuum pump removes air to allow pressurized steam to replace it. Items are placed in vapor-permeable bags then typically placed on racks and subjected to steam and pressure. An example of this type of veterinary autoclave is the Tuttnauer tveiTM 11Ei [6]. The advantages of this type of sterilizer are that there are no toxic materials to be disposed of after the sterilization process, although the Bowie & Dick Test, which is used to confirm proper sterilizer function, does produce disposable towels. Another advantage of autoclaves is the purely physical mode of action; microorganisms are inactivated entirely by the high temperature. This allows liquids and a wide variety of heat-tolerant materials to be sterilized. Additionally, steam sterilization does not require direct contact with the steam to be effective as long as contaminated surfaces reach the high temperatures required for sterilization. A disadvantage of this type of sterilizer is that air elimination can be a stubborn opponent and lead to insufficient temperature and therefore incomplete sterilization. Also, several types of plastics cannot be autoclaved. Cycle times are also relatively long when cool-down times are included. From an energy management viewpoint, autoclaves are power-hungry, typically requiring a 230 VAC source with significant amperage requirements, even for units with relatively small interval volumes, such as the one referenced. Overall, steam autoclaves for veterinary applications provide a reliable sterilization solution but environmentally are a bit lacking due to the high power requirements.

B. Ethylene Oxide "gas" sterilizers (ETO)

Ethylene oxide sterilizers are utilized primarily for heat-sensitive instruments composed of certain plastics, metals, or electronic equipment. Approximately fifty percent of medical devices are sterilized with ETO [7]. ETO is carcinogenic and explosive and therefore has some clear disadvantages as an

environmentally friendly sterilization method. However, many delicate instruments and items made from various non-metal materials simply cannot be sterilized with traditional steam or dry-heat methods. The ETO sterilization process consists of the following steps: (1) air is evacuated from the sterilization chamber, (2) moisture is introduced to a pre-defined humidity level, (3) ETO gas is introduced and held for a specified exposure time, (4) initial evacuation of the ETO gas occurs, and finally (5) air circulation for several hours to remove any residual ETO gas. Ventilation of the expelled gases takes place in special ventilation system or may be converted to biodegradable compounds using a catalyst contained in a replaceable cartridge. An example of an ETO sterilizer for veterinary applications is the Anderson Anprolene AN74 [8]. This unit integrates two pieces of equipment, one for conditioning/exposure to the sterilant gases and one for abatement of the sterilant gas into a catalyst. Advantages are straightforward: (1) the process occurs at room temperature and without the need for steam, (2) it can be used for delicate instruments and non-metallic devices, (3) the ETO process enables reprocessing of expensive surgical devices. However, the disadvantages are also clear; (1) ETO utilizes ampoules of dangerous toxic gas, (2) sterilization times are very long (8-24 hours) and (3) it is comparatively expensive (\$10-\$20 per sterilization cycle). Given that there are few options for sterilizing some expensive veterinary surgical devices, ETO is clearly a viable alternative for use when no other sterilization method is practical. However, because it requires a hazardous gas and customer handling of replaceable ETO ampoules, it is not a desirable fit as an environmentally-friendly solution, especially given that ETO is a listed carcinogen.

C. Gas Plasma Sterilizers

Gas plasma has been used as a method of sterilization in the US since the 1990s. However, gas plasma does not refer to a specific sterilization method but rather a group of slightly different methods that each utilize vaporized hydrogen peroxide as the primary sterilant. In one type of "gas plasma" sterilization process, vaporized hydrogen peroxide is injected into the sterilization chamber, diffusing throughout the contents of the chamber to initiate destruction of any microorganisms. An electric field is then applied using radio frequency or microwave energy under deep vacuum to create a gas plasma. This creates hydroxyl and hydroperoxyl free radicals which act as the final sterilants. Other types of "gas plasma" sterilizers utilize the plasma production only as the final step of the process, converting the vaporized hydrogen peroxide into its byproducts of molecular oxygen (O_2) and water. Since the only byproducts of the process are simply water vapor and oxygen, it is a relatively more safe and "green" environmental solution. An example of a modern vaporized hydrogen peroxide "gas plasma" sterilizer intended for veterinary use is the Plasmapp STERLINK FPS instrument [9]. Utilizing a small pouch, this unit can complete a sterilization cycle in only 4 minutes, while using the full chamber of the instrument takes 36 minutes to complete. The disadvantages are few, one being that hydrogen peroxide packets must be purchased (as opposed to using free oxygen as in the Air Plasma sterilizer mentioned later) and there is no option for cloth sterilization, as sterilant gases cannot readily penetrate wrapping cloths for the items to be sterilized. Gas Plasma units operate at relatively low temperatures (57C) and as

a result use far less power than autoclaves. Operating costs are also much less than ETO units. Overall, the Gas Plasma type of sterilizer is very environmentally friendly but does utilize chemical consumables (H_2O_2).

D. Dry-heat Sterilizers

Dry-heat sterilizers are used when items might be damaged by moist heat or are impenetrable to moist heat. Two types of dry-heat units are available, the static-air type and the forced-air type. Static-air types heat from the bottom and are generally much slower while forced-air units are driven with a blower for circulation throughout the chamber. Sterilization occurs via oxidation of the microorganism cell structure. An example of a dry-heat sterilizer potentially suitable for the veterinary market is the STERICELL 22 [10]. This forced-air unit has a 22 liter volume and operates from 10C above ambient to a maximum of 250 C with 45 air exchanges per hour. At 180 C, the sterilization time is approximately only 20 minutes, or 60 minutes when the operating temperature is reduced to 160C. Advantages include: (1) a completely nontoxic process, (2) easy installation (3) low operating costs, and (4) low environmental impact. Disadvantages include: (1) numerous types of devices may be damaged or destroyed at high temperatures, (2) the sterilizer cycle is slow (especially when the cool down time is included) and (3) power consumption is relatively high. Overall, Dry-heat sterilizers fulfill just a small niche in the veterinary sterilization market, but do offer a reasonably environmentally-friendly profile except for power consumption. The smallest units are comparatively inexpensive also.

E. Air Plasma Sterilization (A new method)

A new type of commercial veterinary sterilizer has been recently introduced based upon "Air Plasma" sterilization. Air plasma sterilization differs from conventional gas plasma sterilization in that sterilant gases are produced using common air, no vacuum is required, and the sterilant gases are produced inside the sterilization chamber. This occurs when the air inside the chamber is converted by plasma into multiple reactive oxygen and nitrogen species, primarily ozone, nitrogen dioxide and hydroxyl radicals. The only available sterilizer of this type is the Plasma Bionics V10 Air Plasma Sterilizer [11], which operates at the low temperature of 40C. Preconditioning of the air in the sterilization chamber takes 15-20 mins, followed by a sterilization phase of 3 hours in which sterilant gases are produced by plasma generated on the surface of a replaceable and recyclable Plasma Sheet. Finally, during ventilation, the sterilant gases are pumped through a catalyst to convert them back into common air. The whole process takes about 4 hours, much longer than the gas plasma or standard steam autoclaves but much shorter than ETO sterilizers. One unique feature of the Plasma Bionics V10 Air Plasma sterilizer is that the user can use an accessory called the *Limitless Lumen*. This accessory provides the ability to move the sterilant gases through long lengths of narrow lumen such as an endoscope or a laparoscope, to sterilize the interior of the lumen. The Limitless Lumen is a battery-powered device can be placed inside a Tyvek pouch or SMS wrap along with the instrument connected to it being sterilized. Using a pump, the limitless lumen circulates the sterilant gases through the lumen during the sterilization cycle. This accessory provides the ability to truly sterilize long, narrow lumen, instead of just high-level disinfection, which has been

the accepted standard when using other gas or vapor-based sterilization methods. This patent-pending device enables lengths of tubing to be sterilized using Air Plasma when it would not be otherwise possible during the 3 hour sterilization time. Similar to Gas Plasma sterilizers, cloth sterilization is not practical with Air Plasma as the sterilant gases do not penetrate wrapping cloths. As with all gas or vapor-based sterilization methods, microorganism inactivation requires contact with the gas or vapor for a specific amount of time. On the advantages side, there are no external gases pumped into the sterilization chamber, no chemical disposables or consumables, the power requirements are the lowest of the methods discussed, and the unit operates at low temperature (40°C). Consequently, the Air Plasma technology presents itself as an environmentally friendly sterilization solution. Furthermore, the Air Plasma sterilizer has the lowest operating cost among the sterilizers intended for veterinary use. Overall, the Air Plasma technology excels as both a cost-effective and environmentally-friendly solution for the veterinary sterilization market.

F. Other sterilizer types considered

Gamma Radiation, Nitrogen Dioxide, and Peracetic Acid systems are potential alternatives to standard sterilization methods. However, all three are generally used for medical or pharmaceutical applications, as opposed to veterinary practice or clinics. As such, these methods are typically available as a “service” as opposed to a commercially available product for purchase by individual practices. The Gamma Radiation method is based upon the use of the radioisotope Cobalt 60, with the resultant photons acting as an effective sterilant. Gamma radiation is lethal to living beings and the relatively large size and substantial cost of the machines does not lend itself to veterinary use. Nitrogen dioxide also tends to be used at the biopharmaceutical level as opposed to veterinary practice for the same reasons; the size and cost of the equipment are prohibitive to veterinary practice, clinics and hospitals. Peracetic Acid forms by the reaction of acetic acid with hydrogen peroxide, which results in a highly biocidal sterilant. Peracetic acid solutions and Vaporized Peracetic Acid (VPA) components generally break down into carbon dioxide, oxygen and water and therefore can be drained or flushed normally. These systems are typically used on medical devices or pharmaceutical devices in large scale sterilization of bioabsorbable materials, and therefore are not included in the subsequent analysis of veterinary sterilizers.

G. Environmental Considerations of Veterinary Sterilizers

Veterinary sterilizers have marked differences when it comes to their power consumption and environmental considerations. Careful selection of a sterilizer can result in both full efficacy while preserving modern environmental considerations. While all five types of sterilizers have some unique niche in the veterinary market, Gas Plasma and Air Plasma have some advantages as being more “green” than the other three types. Air Plasma seemingly has an edge over Gas Plasma as it requires no hydrogen peroxide to begin the sterilization process, and therefore requires no disposable gas ampoule. The ampoules of hydrogen peroxide typically used in veterinary sterilizers use concentrations of H₂O₂ which are hazardous if misused or mishandled [13]. Therefore, Air Plasma is considered a safer and more “green” technology overall.

III. APPLICATIONS FOR VETERINARY STERILIZERS

Autoclaves are available in various sizes, enabling applications across the spectrum of small-to-large animal clinics and hospitals. Stainless steel instruments and gown packs are typical materials sterilized by the high temperature steam associated with autoclaves. If plastics or papers are to be sterilized, alternative methods must be utilized. ETO sterilizers are also found in small-large clinics and hospitals as traditionally ETO sterilization was the only practical alternative for heat sensitive instruments and materials until somewhat recently. However, as ETO utilizes a hazardous gas, environmental and safety concerns have made it a less popular selection as of late. Gas Plasma sterilizers have almost exclusively been used with heat sensitive instruments in small animal clinics and hospitals as the size of the sterilization chamber is conducive to small instruments and materials. Trends seem to indicate that Gas Plasma sterilization units are replacing ETO methods as it is safer and somewhat easier to use from an environmental standpoint, although since the Gas Plasma method is incompatible with many linens, gauze sponges and plastics, applications of this method are limited. Currently, only small animal clinics and hospitals utilize Air Plasma sterilizers, and primarily these are applications with heat sensitive instruments and materials, such as endoscopic, laparoscopic and Ligasure™ instruments. However, this method has the capability to be scaled in size for larger instruments, large-animal clinics and hospitals.

IV. FUTURE DEVELOPMENT - ARTIFICIAL INTELLIGENCE

A key consideration for future development of sterilizers is the need for improved efficacy in the area of infection control. The spread of drug-resistant pathogens such as Methicillin-resistant Staphylococcus Aureus (MRSA) in animals is partially attributable to the incomplete sterilization of materials used in surgical procedures [15]. In addition, there is a direct link between the spread of MRSA from animals to humans [16]. This serious concern requires further development of sterilization techniques toward the goal of 100% elimination of pathogens. One possible method to achieve this goal is the use of Artificial Intelligence (AI) techniques. In this case, the lowest form of AI, typically referred to as “weak” or “narrow” AI, should suffice. An example of this technique might involve the use of embedded microsensors to monitor the biological activity device during the sterilization process, linked via radio-frequency, similar to the technique used in RFID products. Another solution might employ the use of miniature digital cameras and viewing windows to monitor the same biological indicators. The sterilization control algorithms would then be modified to allow optimization of the process based upon actual biological sterilization, and not just a fixed protocol of time. The sterilizer could then essentially “learn” an optimized method of sterilization based upon actual and specific use, as opposed to factory settings based primarily upon time.

V. CONCLUSIONS

Veterinary sterilizers are available with varying features and based upon multiple sterilizing technologies [14]. Each has its

own advantages and disadvantages. As there are major differences in sterilizer technologies, these translate into differences in both personal safety and environmental risks. Autoclaves are still considered a gold standard in traditional veterinary surgical practice, while ETO sterilizers are common for heat sensitive materials. However, recent entrants such as Gas Plasma and Air Plasma sterilizers are finding niche applications and being increasingly adopted as they are environmentally friendly, easier to operate and safer to use for the veterinary technician. Per Table 1, Air Plasma has perhaps a slight advantage over Gas Plasma in terms of overall advantages out of the five basic technologies. However, each technology fulfills a substantial niche in the commercial veterinary sterilization market. A review of the portfolio of commercial veterinary sterilizers indicates that careful consideration of

requirements and features can result in both an effective sterilization method and an environmentally friendly solution for technicians involved in veterinary clinics.

Table 1. Advantages (+) vs. Disadvantages (-) of Sterilizer Technologies (N designates neither Advantage nor Disadvantage)

	Cycle Time	Toxic Materials used/Produced	Materials Compatibility	Environmental Impact	Operating Costs
Autoclaves	+	+	-	-	N
ETO	-	-	+	-	-
Gas Plasma	+	-	+	+	+
Dy Heat	-	+	-	+	+
Air Plasma	-	+	+	+	+

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