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PLASMA BIONICS

WHAT IS AIR PLASMA STERILIZATION®?

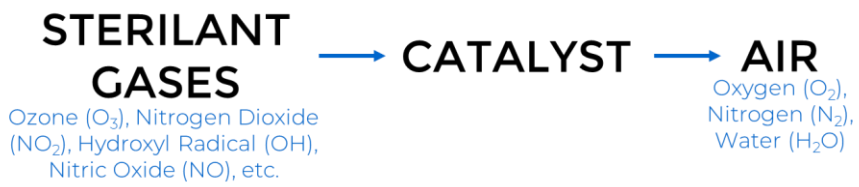
"Air Plasma Sterilization" is a term coined by Plasma Bionics LLC to differentiate the proprietary non-thermal plasma (a.k.a. cold plasma) sterilization system from other plasma, gas, or vapor-based sterilization systems. "Plasma" in this context refers to ionized gas, the fourth and most energized state of matter. The gas used in Air Plasma Sterilization® is air, composed of approximately 78% nitrogen (N_2), 20% oxygen (O_2), 2% other trace gases, and a variable amount of dispersed water vapor (the relative humidity). When plasma is produced along the surface of the Plasma Bionics Plasma Sheets inside a gas tight sterilization chamber, a high concentration of reactive oxygen and nitrogen species accumulate and rapidly destroy microorganisms on veterinary instrument surfaces.

The Air Plasma Sterilization® process uses just air and electricity to produce a mixture of sterilant gases through the generation of air plasma.

Air Plasma Sterilization® is very different from other so-called "gas plasma" sterilizers. What is often referred to as "gas plasma" sterilization should more accurately be referred to as vaporized hydrogen peroxide sterilization. These sterilization systems usually only use plasma under vacuum conditions as a short step within the sterilization cycle or as part of the ventilation step, converting vaporized hydrogen peroxide into oxygen and water. Thus, in vaporized hydrogen peroxide sterilizers, the plasma production step usually plays a minor to no role in the actual sterilization of instruments.

In contrast, during the Air Plasma Sterilization® process, plasma is produced from air within the sterilization chamber and is the sole source of sterilant generation, with air and electricity being the only inputs for the sterilization process. **Multiple ions, charged particles, and reactive oxygen and nitrogen species (such as ozone, nitrogen dioxide, hydroxyl radicals, and nitric oxide, among many others), are produced during the sterilization process.** This feature provides a multi-pronged approach for efficiently eliminating microorganisms from the surfaces of sensitive veterinary instruments.

After sterilization is complete, the sterilant gases are passed through a catalyst and adsorbent material that converts them back into air.



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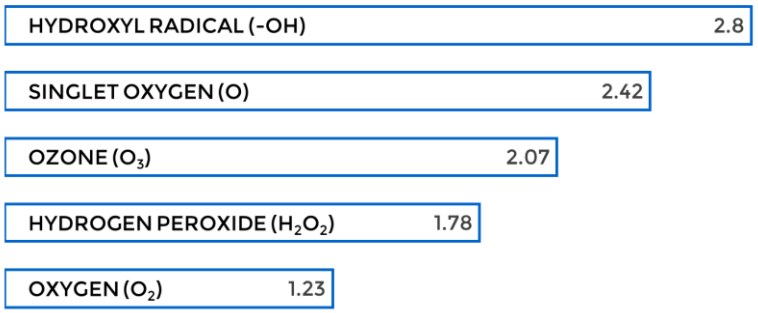
HOW DOES AIR PLASMA STERILIZATION® WORK?

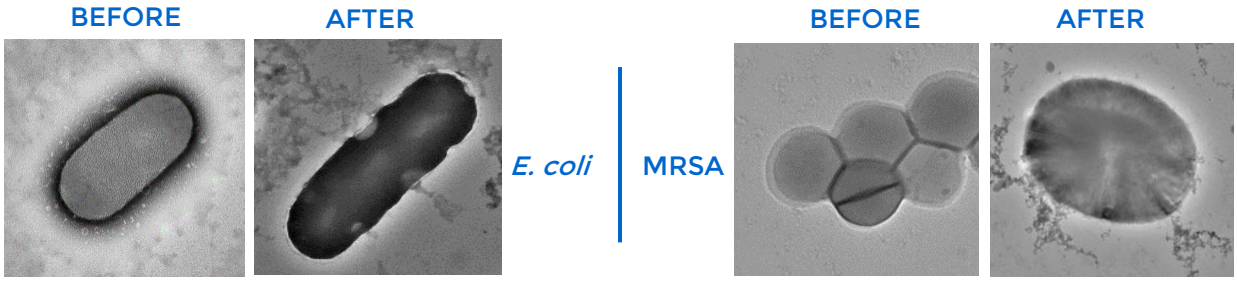
The reactive oxygen and nitrogen species produced by Air Plasma Sterilization® are highly oxidative, meaning that they readily react with other molecules by either losing an oxygen atom or gaining an electron. When this molecular reaction occurs with microorganisms it results in physical damage to microbial cell structure and DNA. The process of oxidation is a natural and very efficient method for killing unwanted microorganisms. The human immune system uses some of the same reactive oxygen species to kill microbial pathogens. The reactive species produced by Air Plasma have some of the highest oxidative potentials possible.

Ozone in particular is produced in high concentrations by the Air Plasma Sterilization® process and plays an important role in the sterilization efficiency. Singlet oxygen and hydroxyl radicals, both of which are also produced by Air Plasma, are the only reactive oxygen species that have a higher oxidation potential.

Oxidation potentials of common reactive oxygen species.



Transmission electron micrographs of *Escherichia coli* (*E. coli*) and Methicillin-resistant *Staphylococcus aureus* (MRSA) exposed to the Air Plasma sterilants show mechanical damage to the cell structure, with the cell contents visibly leaking out.



Biological indicators were used to develop the parameters of the Air Plasma Sterilization® process and to determine the necessary length of the sterilization cycle. Biological indicators are inoculated with at least 10^6 (one million) spores of *Geobacillus stearothermophilus*, the most resistant known organism to Air Plasma Sterilization®. A sterility assurance level (SAL) of 10^{-6} is achieved by taking the time required to kill 10^6 spores (10^{-3} SAL) and doubling it. This is the standard practice for all sterilization methods, often referred to as the overkill method of sterilization (ISO 14937: 2009), and provides the necessary one in one million probability (10^{-6} SAL) that a product is not sterile after going through the sterilization process.

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AIR PLASMA STERILIZATION® PROCESS

Air Plasma Sterilization® is a 3-part process consisting of 1) Preconditioning, 2) Sterilizing, and 3) Ventilating

PART 1:

PRECONDITONING

The preconditioning step conditions the air inside the sterilization chamber to a specific pressure, temperature, and humidity. This is essential for reliable and repeatable performance despite differences in environments, geographic locations, and altitudes. Preconditioning takes between 15 and 20 minutes, depending upon ambient conditions when the process is started.

PART 2:

STERILIZING

During the sterilizing step, air inside of the sterilization chamber is converted by plasma into multiple reactive oxygen and nitrogen species. The amount of time required for the sterilizing step is defined as twice the amount of time required to kill 10^6 cells of the most resistant know organism to the process, in this case *Geobacillus stearothermophilus* spores. This provides a sterility assurance level (SAL) of 10^{-6}.

PART 3:

VENTILATING

During the ventilating step, sterilant gases are pumped through a catalyst that converts the sterilant gases back into air. The amount of time required for the ventilating step is twice the amount of time required to reduce the ozone concentration to 0.1 parts per million (ppm). Ozone concentration is a good measure for the effectiveness of the ventilation step since it is one of the longest-lived of the reactive species produced by air plasma.

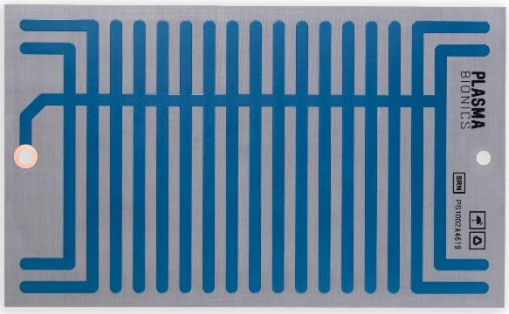
PLASMA SHEETS

THE CORE OF AIR PLASMA STERILIZATION®

The key component to the Air Plasma Sterilization® process is the proprietary Plasma Sheet.

Plasma is produced on the surface of the plasma sheet inside the sterilization chamber, converting air into highly oxidative sterilant gases.

Plasma sheets wear out over time and must be periodically replaced. This robust, durable consumable has an indefinite shelf life, has no disposal restrictions, and can be recycled.



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ADVANTAGES OF AIR PLASMA STERILIZATION®

- ✓ **LOW TEMPERATURE:** The Air Plasma Sterilization® process takes place at 40 °C (104 °F). This is well below the 60 °C (140 °F) required to be classified as a low temperature sterilization method. Heat-sensitive complex instruments composed of plastics and housing sensitive electronics or optics will not be damaged by Air Plasma Sterilization®.

- ✓ **LOW PRESSURE:** The Air Plasma Sterilization® process occurs at atmospheric pressure. It does not require high pressure like a steam autoclave or a deep vacuum like an ethylene oxide sterilizer. Only a slight variation in pressure (±1 psi) occurs inside the sterilization chamber as the plasma is being produced, which helps push the sterilant gases into hard-to-reach instrument crevices. The minor pressure changes allow even the most delicate instruments to be sterilized without physical damage.

- ✓ **LOW COST PER CYCLE:** The cost per cycle for Air Plasma Sterilization® ranges between $3 and $5, depending on environmental conditions. This is less than a third the cost per cycle for ethylene oxide.

- ✓ **LOW MAINTENANCE:** Maintenance of an Air Plasma sterilizer is minimal, consisting of simply wiping down the sterilization chamber with a damp cloth followed by a dry cloth every 15 sterilization cycles.

- ✓ **LOW POWER REQUIREMENTS:** An Air Plasma sterilizer requires only a standard single-phase electrical outlet rated for 110-120 VAC and draws a maximum current of 6.5 amps. Two Air Plasma sterilizers can easily be run from a single power outlet. The total power draw is about one fourth that of a similarly sized steam autoclave.

- ✓ **NO CHEMICAL CONSUMABLES:** The Air Plasma Sterilization® process uses just air and electricity. No chemicals are required.

- ✓ **NO HARMFUL BYPRODUCTS:** After a sterilization cycle is complete, the Air Plasma sterilant gases are passed through a catalyst that converts them back into air, producing no byproducts.

- ✓ **NO INSTALLATION COSTS:** Unlike ethylene oxide sterilizers which often require modifications to a facility to exhaust the gases outside of the building, an Air Plasma sterilizer has no installation costs and can simply be plugged into a properly rated power outlet and is ready for use.

- ✓ **BROAD MATERIAL COMPATIBILITY:** The Air Plasma sterilant gases are compatible with a wide variety of plastics, elastomers, and medical grade metals.

- ✓ **INDEFINITE CONSUMABLE SHELF LIFE:** None of the Air Plasma Sterilization® consumables (plasma sheets, desiccant canister, and catalyst canister) have an expiration date. They can be stored indefinitely in the original packaging.

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V10 AIR PLASMA STERILIZER

The only low temperature sterilizer that utilizes proprietary Air Plasma Sterilization®

STERILIZE CRITICAL INSTRUMENTS

- ✓ surgical electronics
- ✓ lumen
- ✓ optics

REDUCE OPERATING COSTS

- ✓ no installation cost
- ✓ low cost per cycle
- ✓ low maintenance

ELIMINATE HARMFUL CHEMICALS

- ✓ no chemical consumables
- ✓ environmentally friendly
- ✓ zero emissions

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CERTIFIED