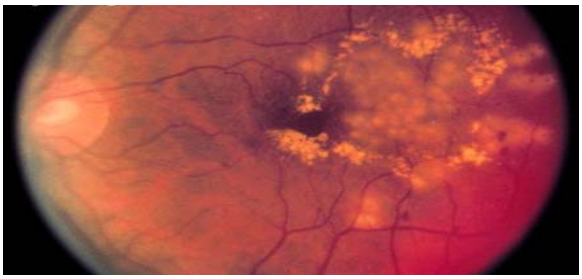
# Endotoxin Decontamination of Intraocular Lenses and Surgical Instruments using Gas Plasma

*By Demetrius Chrysostomou, PhD., Director of Technology, PVA TePla America*



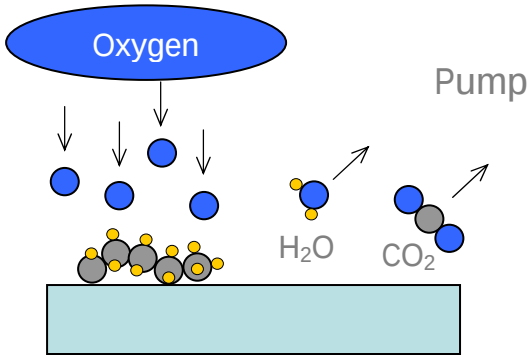
Toxic Anterior Segment Syndrome (TASS) following cataract surgery is an acknowledged concern of the American Society of Cataract and Refractive Surgery (ASCRS). Characterized by postoperative inflammation to intraocular structures, TASS has been attributed to noninfectious agents accessing the anterior chamber of the eye. Most likely sources of contamination are from inadequate cleaning of surgical instruments and of the implanted IOL. Of particular concern are surface adsorbed pyrogens that are difficult to detect and notoriously difficult to remove, particularly from heat sensitive substrates.

Gas plasma is a powerful and safe method of significantly reducing the presence of surface bound endotoxins. Low temperature (<60°C) plasma discharge has demonstrated >3 log count reductions of surface immobilized endotoxin bioactivity. Plasma is a dry process that eliminates the liabilities of wet cleaning and is a technique that can be easily implemented in cleaning practices for intraocular devices and related surgical instruments.

**What is plasma?**

Plasma is a gas energized to a state of electrical conductivity. An applied electric field accelerates electrons that ultimately collide with gases that are fed into the chamber. Upon collision these gases are chemically activated creating a highly reactive environment that is used to change the properties of surfaces without affecting the bulk material. For example plasma activated oxygen reacts with surface bound hydrocarbons converting them mostly to $CO_2$ and $H_2O$.

Plasma is a powerful tool in solving surface preparation problems. It provides a reliable, consistent, and environmentally friendly method of critically cleaning surfaces from organic contamination at the molecular level.




**Mechanism of plasma depyrogenation**

There are three fundamental components of a plasma that influence the surface properties of materials; chemical, physical and irradiative.

a. *The Chemical Component*

The rate of removal of surface immobilized endotoxins has a strong dependence on the presence of plasma activated oxygen. Detection of $C_xO_y$, $N_xO_y$ and $OH_x$ products in the plasma strongly suggest that surface contaminants are oxidized, volatizing into these products. These volatile products are then removed from the plasma system by the pump.

b. *The Physical Component*

In a radio frequency generated plasma, ions and electrons can be accelerated towards the surface of the substrate. Upon impact energy is imparted to the surface that can ultimately break open surface bonds or even induce some contaminants to desorb. This physical component of the plasma has a great synergistic effect with the chemical component as bonds broken on the surface are more accessible to oxidation by the plasma activated oxygen.

c. *Irradiation*

Plasma can emit strong UV light in the 200-300nm range. While this is very effective at destroying the DNA of bacterial spores it has little or no effect on the decomposition of pyrogens or proteins.

**Advantages of plasma depyrogenation**

1. Highly effective; particularly on surface immobilized endotoxins
2. Easy to implement and facilitize; plasma systems have small footprint, low power consumption and simple connections to feed gases
3. Low temperature; non-equilibrium plasmas are highly effective at temperatures < 60$^{o}$C
4. Low risk; reactant gases (oxygen and argon) are non-toxic posing minimal environmental impact and personnel safety concerns
5. No liabilities of wet cleaning; since plasma is a gas phase treatment process there are no residues from solvents or precipitation of salts from solution
6. Low cost; cost of ownership is very low amounting to less than $1/hour of use
7. Plasma is an isotropic process; this means there are no line-of-sight issues
8. Highly reproducible processes; process gases are continuously fed into the chamber and reactant gases continuously pumped away. All parameters are computer controlled and monitored by a sophisticated alarm protocol

**What does PVA TePla America offer?**

At PVA TePla America we offer a full line of vacuum gas plasma systems. Our reliable, easy-to-operate products deliver some of the most advanced and innovative solutions for a wide variety of lifescience applications. The sophisticated software control package is written to CFR Title 21 Part 11 standards.


We also offer clean area contract processing services with ISO 9001:2008 certification. This allows you to access gas plasma technology without up front capital expenditure on labor and/or facilities. Additionally, we offer free proof of process as an incentive to evaluate our plasma technology.

**PVA TePla America Inc. Headquarters**

References:
1) L. Werner *et. al.* J. Cataract. Surg. 35 (2009) 1273
2) F. Rossi *et. al.* New Journal of Physics 11 (2009) 115017

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251 Corporate Terrace
Corona, CA 92879-6000
**www.pvateplaamerica.com**
*business:* 951.371.2500
*sales:* 800.527.5667
*fax:* 951.371.9792