Precision cleaning, sterilization and surface activation of spinal implants using gas plasma technology

Materials used for orthopaedic implants are typically inert metals/alloys, ceramics and polymers. Their surface properties are engineered to encourage osteo-integration, while surface cleanliness and sterility are critical for avoiding inflammatory responses after implantation. Indeed, for implanted medical devices achieving and maintaining surface cleanliness at the molecular level demands careful attention and exhaustive procedures.

Plasma

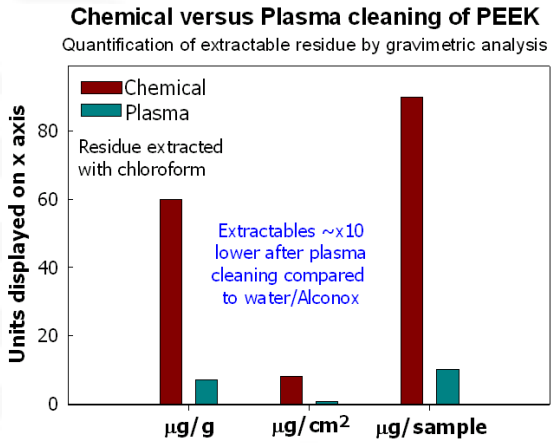
Decontamination	Surface chemistry
Sterilizes	Promotes cell adhesion
Removes organic residues	
Removes bioburdens	
Minimizes leachables	

Plasma removes organic contamination at the molecular level following machining, tooling and wet chemical processing steps. The decontamination is conformal not only for substrates of complex geometries but also on textured surfaces with “rough” topographies. Plasma has also been shown to increase surface bioactivity, promoting attachment.

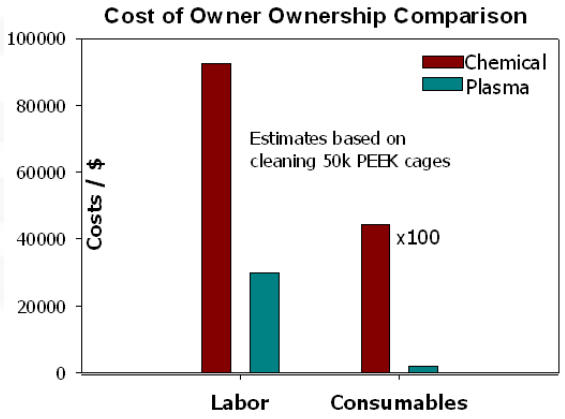
Plasma precision cleaning of PEEK

Polyetheretherketone (PEEK) is a preferred material for vertebral implants due to its biocompatibility, physical properties, and above all its radiolucency. It is a semi-crystalline thermoplastic and therefore prone to absorption of cleaning solvents (0.5wt.% of water by test method ISO 62). This can cause the material to swell and its bulk to become contaminated. Obvious concerns are therefore raised over the choice of cleaning method used for implantable applications (traditionally 99% DI water+1% Alconox).

Since plasma is a dry, gaseous process under low vacuum there are none of the liabilities associated with wet chemistry. After plasma cleaning PEEK the total aerobic bio-burden count (CFU/SIP) was <1 and the quantification of extractable residues by chloroform using gravimetric analysis is compared with standard cleaning methods (see graph below).



When comparing cost of ownership between plasma and chemical cleaning equipment, again plasma looks very favorable. The table below compares the most significant costs; labor and consumables.



Plasma sterilization

The increasing importance of infection control in lifescience industries is placing greater focus on sterilization technologies. New regulatory forces are generating industry specific criteria. This, coupled with the need for fast turnaround and economical sterilization methods, is defining

sterilization technologies for specific market applications.

Advantages of Plasma Sterilization

Process	Method
Low Temperature <55C	No special building requirements
No polymer damage	No licensing process gases
Non-hazardous	Processes validated by DIN EN ISO 14937
Tubing up to 5m meters	Low cost of ownership
Short process times	Turnkey systems
No risk of corrosion	Cost ~ $75 US dollars per cycle
No discoloration or embrittlement	Low setup costs

The germicidal affects of plasma have been known for a long time. PVA TePla America offers a sterilization solution for in-house manufacturing, targeting implantable medical devices in orthopaedics and cardiac rhythm systems. Our Steriplas offers up to 2000 litres capacity, and TUV certified for H_2O_2 / plasma sterilization.

PVA TePla's large plasma sterilization system

What is plasma?

Plasma is a gas energized to a state of electrical conductivity. Chemically it is a highly reactive environment that is used to change the properties of surfaces without affecting the bulk material. Plasma is a powerful tool in solving surface preparation problems. It provides a reliable, consistent, and environmentally friendly method of conditioning culture plates and cellular matrices to maximizing cell attachment.

PVA TePla's IoN40 system

What does PVA TePla America offer?

At PVA TePla America we offer a full line of vacuum and atmospheric gas plasma systems including systems for plasma assisted H_2O_2 sterilization. Our reliable, easy-to-operate products deliver some of the most advanced and innovative solutions in the world for a wide variety of industrial applications. We also offer clean area contract processing services with ISO 9001:2000 certification. We are experienced conducting FDA trials and developing CFR Part 11 compliant software.

Additionally, we offer free proof of processing as an incentive to evaluate our plasma technology. This allows you to access gas plasma technology without up front capital expenditure on labor and/or facilities.

Contract plasma lab. at PVA TePla in California

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