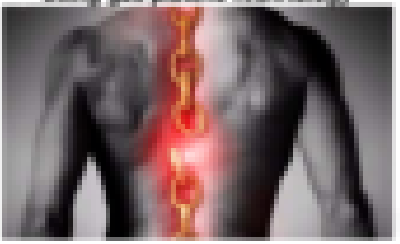
Precision cleaning, sterilization and surface activation of spinal implants using gas plasma technology



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

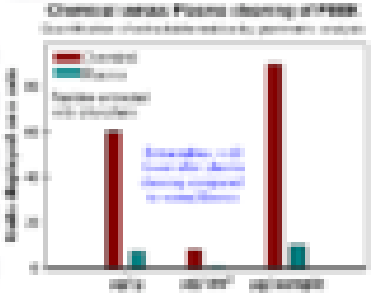
Decontamination	Surface chemistry
Sterilizes	Promotes cell adhesion
Removes organic	
residues	
Removes endotoxins	
Micrologic inactivation	

Plasma removes organic contamination at the molecular level following machining, tooling and wet chemical processing steps. The decontamination is confirmed 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.

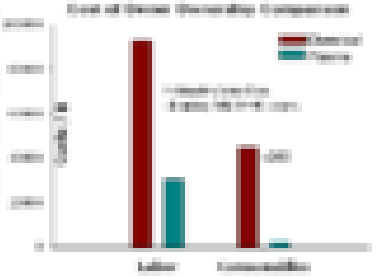
Plasma precision cleaning of PEEK

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% detergent).

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/SP) 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 healthcare 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