Technical Data on the Orthopedic TPS Coating

Orchid Detroit, 23149 Commerce Drive, Farmington Hills, MI 48335
Phone (248) 352-4570 Fax (248) 352-5543
sales@orchid-ortho.com

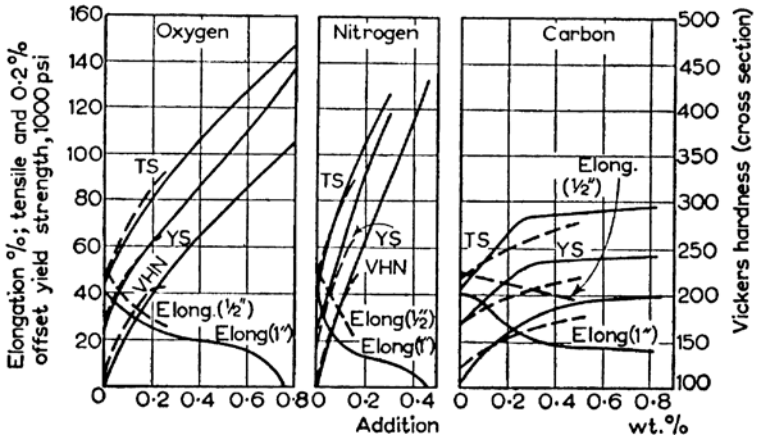
ISO 13485 Registered

Background

The high chemical reactivity of titanium, especially in its powder form, makes it a challenge to plasma spray correctly. The most protective environment for spraying titanium is a vacuum. Bio-Coat has been vacuum plasma spraying titanium for dental applications for 7 years. We have succeeded in developing a vacuum titanium plasma sprayed (TPS) coating for orthopedic applications, using the same technology and equipment used by the aerospace industry for critical engine applications. (1)

Vacuum Plasma Spray Verses Argon Plasma Spray Technology

The most significant advantage to spraying in a vacuum is the dramatic reduction in the formation of brittle ceramic titanium compounds such as TiC, TiN, TiO2, and TiH. While these compounds may be useful for wear resistance, they lack ductility and will create cracking and inclusions in a plasma sprayed coating. The figure below demonstrates that as little as 0.8 wt % of either, oxygen, nitrogen or carbon create a marked increase in the brittleness of titanium. (2)



Inert argon plasma spray technology is limited in its ability to minimize the above compounds.

Another significant advantage to vacuum plasma spraying is the ability to alter the velocity of the powder particles being sprayed. In general, the higher the velocity, the stronger will be the bond between the coating and the substrate. The formation of a metallurgical bond (i.e. / the substrate and the coating become continuous) using plasma spray technology can only be achieved using a vacuum. Conventional argon spray systems are not capable of forming an “as

sprayed" metallurgical bond.

The Bio-Coat vacuum plasma spray system is equipped with 5 axes of robotic motion. The use of a "CNC type" controller enables the creation of reproducible programs, which guarantee the same coating each time. Argon spray systems rarely use robotics and rely heavily on the art of "hand spraying".

The Bio-Coat Vacuum Plasma Sprayed Coating Has Been Developed Using The New FDA Guidelines

In lieu of post-market surveillance, the FDA has issued new stringent guidelines for plasma sprayed coatings. (3) The following represent the guidelines as well as how the Bio-Coat titanium coating compares to these guidelines on both Ti-6Al-4V and Co-Cr-Mo substrates.

Taber Abrasion Resistance (grams loss at 100 cycles)

Substrate	C.P. Titanium	Ti-6Al-4V	FDA Guidelines
Ti-6Al-4V	0.031 ± 0.012	0.026 ± 0.003	0.065, max.
Co-Cr-Mo	0.031 ± 0.012		

Static Tensile Strength (psi.)

Substrate	C.P. Titanium	Ti-6Al-4V	FDA Guidelines
Ti-6Al-4V	9957 ± 1452	11497 ± 296	3190, min.
Co-Cr-Mo	7746 ± 1517		3190, min.

Static Shear Strength (psi.)

Substrate	C.P. Titanium	Ti-6Al-4V	FDA Guidelines
Ti-6Al-4V	5932 ± 240	6860 ± 60	2900, min.
Co-Cr-Mo	6224 ± 1335		2900, min.

Shear Fatigue Endurance Limit (psi. @ 107 cycles)

Substrate	C.P. Titanium	Ti-6Al-4V	FDA Guidelines
Ti-6Al-4V	2240	2500	NONE
Co-Cr-Mo	2160		NONE

Microstructural Analysis

The figures below show a light micrograph of the Bio-Coat coating in cross-section (right) and an SEM micrograph of the coating surface (left). The coating was found to be metallurgically bonded and crack-free.

Availability

The Bio-Coat TPS coating is currently available on both titanium and Co-Cr-Mo substrates. Master Device File MAF-1085 has been established at the FDA for the coating.

References

1) Electro-Plasma, Inc., LPPS ® Production Systems, Meyer, P.J. and Hawley, D.; Proceeding of the Fourth National Thermal Spray Conference, May 1991

2) Relationships of Properties and Processes, from Titanium A Technical Guide; Edited by Matthew J. Donachie, Jr., ASM International, 1988.

3) Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements; CDRH, FDA, January 4, 2000.