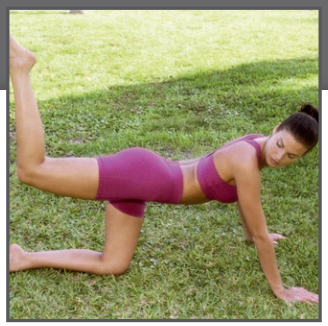
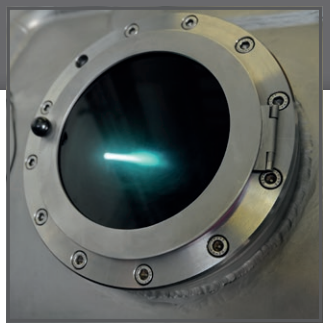
Firm fixation by using porous plasma-sprayed titanium coatings





Titanium Plasma Spray (TPS)

DOT America
medical implant solutions

Porous coated surfaces aid optimal osseointegration

Background

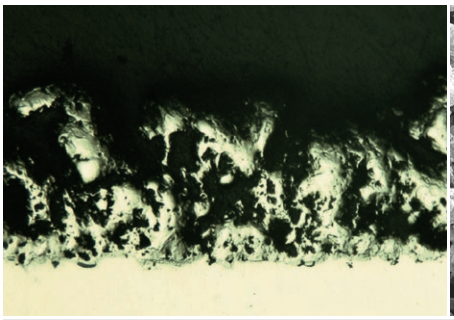
The demand for uncemented joint replacements has been steadily increasing since the 1970s.
This is because less bone loss is known to occur with an uncemented replacement prosthesis when compared to a cemented prostheses. Cement-free implants are particularly beneficial to younger patients whose chances of requiring revision surgery are higher. The key to the success of this procedure is stable osseointegration which is mainly determined by surface structure, surface chemistry, as well as good primary implant stability. Bone cells are known grow directly onto biocompatible materials such as titanium and its alloys provided with a structured surface with a favorable pore size. There are different techniques for implant surface structuring that provide surfaces with bone ongrowth characteristics. These techniques have not been able to achieve the required levels of fatigue strength.
These processes include:
(a) sintered titanium beads whose thermal effect can reduce the fatigue resistance of titanium alloy implants by about one third;
(b) corundum-blasted implants whose micro-cracks can reduce fatigue resistance by up to two-thirds.

Technologies

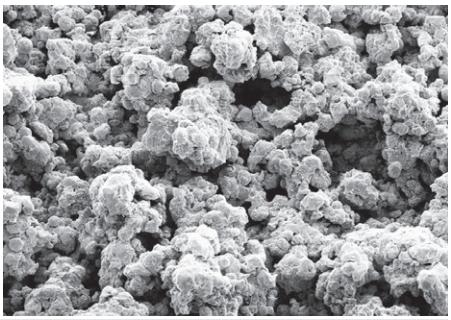
Unlike sintering or corundum blasting, the process of producing porous structures using the Titanium Plasma Spray (TPS) process reduces the fatigue resistance to acceptable limits. In this procedure, a pure titanium coating is bonded to the implant, thus providing the bone with a surface that promotes osseointegration and bone growth.
TPS was first developed in the U.S. in the 1980s and has become particularly important because of the superior osseointegration provided by this type of thermal spray coating. DOT produces TPS coatings on implants in a vacuum chamber. An inert gas mixture (argon) is ionised in an ultra high temperature plasma flame. The gas heats up and expands rapidly after being expelled at high speed through a nozzle shaped anode. At the same time, titanium powder is injected into the plasma flame and it begins to melt. Propelled at a highspeed, the molten titanium particles strike the substrate surface, cool down rapidly and fuse to the implant surface. The resultant porous layer is comprised of multiple layers of particles.

Properties

The robot controlled Titanium Plasma Spray (TPS) process creates a highly reproducible porous coating. DOT's TPS coating complies with FDA guidelines for plasma sprayed coatings on orthopedic implants.



TPS coating, cross section



TPS SEM picture

Coating thickness	30 - 800 µm The thickness of the porous structure affects the adhesion strength. Coatings that are more than 500 µm thick are not known to significantly improve the adhesion strength.
Static tensile strength	40 - 100 MPa This parameter is measured in accordance with ASTM F 1147. Static tensile strength of at least 22 MPa is required in accordance with FDA guidelines.
Roughness	Ra 3.5 - 80 µm A minimum roughness of Ra = 3.5 µm is needed in order to achieve adequate primary fixation. Roughness of up to Ra = 80 µm is technically feasible.
Biocompatibility	The coating raw material is ISO 5832-2 compliant, and therefore approved for manufacturing surgical implants.
Pore size	75 - 300 µm This pore size is known to achieve a good level of mineralised bone ingrowth into the implant surface structure. Vascularisation accompanied by the formation of non-mineralised bone has been observed in pores ranging in size from 75-100 µm.
Porosity	20 - 40 % Porosities of less than 20 % do not allow for bone ingrowth and vascularisation, whereas porosities exceeding 60 % provide only incomplete bone ingrowth.
Titanium coating powder	Grade 4 pure titanium in accordance with ISO 5832-2 and titanium alloy in accordance with ISO 5832-3.

User needs met

- Outstanding biocompatibility
- Enlarged surface without any significant thermally induced structural changes in the substrate material
- Implant fatigue resistance superior to sintered porous surfaces
- Outstanding primary stability from the surface roughness.
- Long term implant stability following osseointegration in the porous titanium coating

DOT's Experience

DOT has coated more than 2.3 million orthopedic and dental implants for implant manufacturers in Germany and worldwide using the Titanium Plasma Spray (TPS) process since 1997.

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DOT's Quality System

DOT America's TPS processes are validated and its quality system is ISO13485:2016 certified by the BSI Group America.

DOT America operates under US FDA facility registration #3011461101.

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