Improving implant performance through titanium anodizing



Titanium Anodizing Type II, DOTIZE®

Titanium Anodizing Type III, Coloring



Anodized surfaces for trauma, spinal fusion, joint replacement and dental components



The anodizing of titanium and its alloys are standard surface treatments for medical devices.

Anodizing Type II, DOTIZE® modifies the biological and biomechanical properties of devices.

Anodizing Type III, Coloring primarily impacts the cosmetic characteristics of the implants.

Anodizing Type II, DOTIZE®





Background

In searching for methods to improve the internal fixation characteristics of trauma implants, it was determined that the type II anodizing procedure, which had been originally developed for aerospace applications, provided excellent properties in the osteosynthesis environment.

Research and use of this coating has demonstrated the technology is biocompatible, decreases cold welding potential (e.g. between trauma nail and screw), improves fatigue strength, increases corrosion resistance, provides dry lubrication, and suppresses bone growth onto the implant.

User needs met

- Easier removal of implants after fracture healing
- Lower risk of device fracture through improved fatigue strength
- Reduction in cold welding potential

- Biocompatible surface, with reduced risk of ion release
- Potential for higher screw pre-loads in application
- Dark grey coloration can be used as an identifier.

Characteristics

The DOTIZE® procedure conforms to the standard AMS 2488 (Aerospace Material Specification).

Final Coating Thickness:	≤ 2 microns
Fatigue Strength:	~10% increases in fatigue strength reported
Corrosion Resistance:	~ 40% increase in corrosion resistance reported
Biocompatibility:	Good biocompatibility, with multiple predicates available

Technology

The DOTIZE® anodizing procedure developed by DOT, replaces the thin natural oxide film present at the implant surface, with a thick oxide coating. This is achieved through an electric spark discharge produced on the surface of the implant while it is immersed in an electrolytic bath containing a strong alkaline solution.

During the process the substrate is melted, while oxide forms and integrates into the surface eliminating micro cracks and pores. The result of the process is a smooth, corrosion resistant, anti-galling surface with minimal dimensional change.

Titanium and most of its alloys are suitable for the DOTIZE® anodizing process.

Anodizing Type III, Coloring







Background

The principal purpose of color anodizing is the positive identification of parts during a surgical procedure (e.g. sizes and mating pieces).

Applications cover dental, spinal, orthopedic, and trauma products.

User needs met

- Improves ease of use through color identification of component sizes and mating pieces
- Cosmetically appealing
- Biocompatible surface, with no dyes or pigments utilized

Characteristics

The anodizing type III coating is an extension of the naturally occurring oxide layer (20–200nm). Through precise control techniques, a wide selection of colors can be obtained, including but not limited to shades of brown, purple, blue, gold, pink, and green.

Technology

If necessary, a light exposure to an acid is performed to remove the native oxide and even out the finish without impacting dimension.

The implant is then installed as an anode in an electrolytic bath. The induced electric current splits the water molecules at the surface of the implant, and the oxygen generated reacts with

titanium to increase the thickness of the naturally occurring titanium oxide layer. The titanium oxide layer is partially transparent allowing light waves to reflect/refract off both the oxide and the substrate. The difference in the light wavelengths returning from the surface is perceived as color. Titanium and most of its alloys are suitable for the anodizing type III process.

DOT's Experience

Since 1998, DOT has successfully anodized (Type II and III) millions of implants and components used in medical applications world-wide.

DOT anodized products have been cleared or approved in technology applications in the US, Europe, and Asia

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DOT's Quality System

DOT America's anodizing 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.

