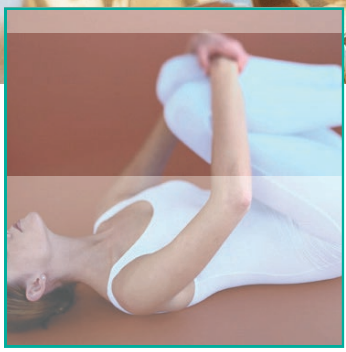
Optimized Protection Against Allergic Reactions and Wear by Using Durable Ceramic Coatings



medical implant solutions

Principles

Joint replacement implants, particularly knee and hip prostheses, are subjected to a high degree of load and wear-inducing movement. Abrasive particle release is generally known to be the reported outcome of the arthroplasty.
Wear and metal-ion release is caused by contact stress between the polyethylene bearing surfaces and the implant's metallic components. Wear as well as the release of particles and metal ions in the artificial joint have been implicated as the main cause of inflammation, premature loosening and allergic reactions associated with joint replacement implants.
Knee replacement implants, which are manufactured from cobalt-chromium-molybdenum and contain 1% nickel as a result of production-related influences, are known to have a significantly larger friction surface when compared with other joint prostheses.
Studies have shown that consequently, permanent allergenic metal ions (nickel, chromium or cobalt) are released into the tissue adjacent to the prosthesis. Hence, patients sensitive to metals run the risk of allergy incidence after metal device implantation.
Besides promoting the application of modern manufacturing technologies, research efforts are geared towards the development of new implant surfaces that significantly reduce the occurrence of wear debris and allergic reactions.

Technology

A fully biocompatible titanium nitride (TiN) or titanium niobium nitride (TiNbN) ceramic surface is coated onto a metallic implant component to facilitate its wear performance and to minimize ion release.

It is thus used to drastically reduce the incidence risk of allergic reactions and to minimize inflammation.
Ceramic coatings have been successfully employed in the U.S. and in Europe since the early 1980s and 1990s, respectively.
They are produced by using a special arc-evaporation technique (PVD coating process), which involves coating the implant during the vapor phase in a high-vacuum chamber to which nitrogen is added. A high degree of reproducibility and coating stability is achieved with this computer-controlled process which is essentially an additive manufacturing procedure with which the coating is securely anchored in several atomic layers of the implant surface.

Advantages

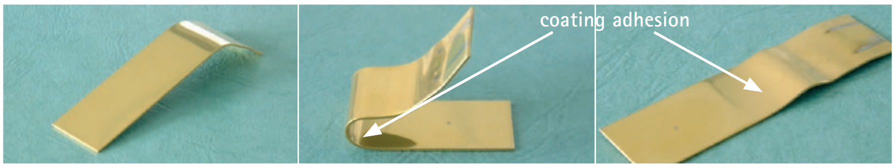
- Outstanding biocompatibility
- Reduction of ion release
- Hardness superior to cobalt-chromium-molybdenum-based alloys
- Higher wettability with synovial fluids
- Low friction articulation
- Long-term chemical stability

Properties

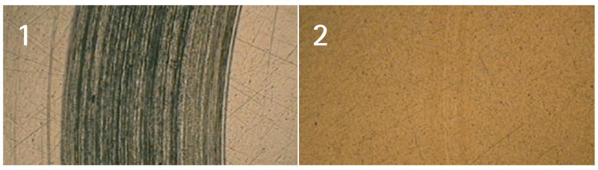
Ti(Nb)N coatings only modify surface properties and do not affect the substrate properties or the biomechanical functionality of the implant.

Coating thickness	0.5-7 µm Coating thickness is measured using a calotte grinding test, on test pieces that are coated alongside each implant batch.
Hardness	Ca. 2,400 HV (0.1N) Hardness is measured using a micro-hardness test. The hardness of CoCrMo alloys is only 550 HV (0.1N) auf.
Adhesive strength	HF 1-2 Adhesive strength is tested in accordance with VDI guideline 3824 using the Rockwell HRC test. In addition, a thorn bending test is carried out using a Scratch test plate. These tests have demonstrated that the coating has outstanding adhesive properties.
Roughness	Ra <0.05 µm Roughness determined with the profile method in accordance with DIN EN ISO 4287. These roughness values are in compliance with the DIN EN ISO 21534.
Tribology / wear resistance	Low friction coefficient in contact with UHMWPE; ion release is suppressed upon exposure to frictional fretting. A significantly higher degree of surface scratch resistance.
Biocompatibility	The biocompatibity of Ti(Nb)N has been demonstrated in numerous published studies based on the standard series DIN EN ISO 10993..

Adhesive strength of Ti(Nb)N coatings in bending tests



Ti(Nb)N coating wear resistance as shown by pin-on-disc test compared to bone cement



1. Titanium alloy wear resistance as shown by pin-on-disc test compared to bone cement
2. Ti(Nb)N wear resistance as shown by pin-on-disc test compared to bone cement

Broad range of applications
Outstanding wear resistance is a key parameter for quality assessment that is not only limited to the field of orthopedic implants. Ceramic hard-surface coatings are increasingly being used to develop and manufacture surgical instruments as well as rotary dental instruments.
Diamond-Like Carbon (DLC) and Zirconium Nitride (ZrN) coatings are (in addition to TiN and TiNbN) additional options for special hard-surface coatings that DOT offers in this sector.

Clinical results

DOT has coated more than 900,000 joint replacement implants with Ti(Nb)N for German and international OEM's since 1995. Incidents stemming from implant that were caused by a coating failure have not been reported to-date. Studies have shown that Ti(Nb)N coatings provide better polyethylene wear resistance and more effective friction coefficient reduction than cobalt/chromium/molybdenum-based alloy coatings. Medium term clinical trial results have confirmed the durability of Ti(Nb)N coatings.

Literature

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We look forward to talking with you!

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DOT – coating specialist for orthopedic and dental implants

DOT is one of Europe's leading providers of medical coating solutions for orthopedic and dental implants and instruments and also their cleanroom packaging.

Our comprehensive supply chain concept makes us an ideal medical technology partner. Our activities help restore the health of patients worldwide and thus make a major contribution to the improvement of their quality of life.

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