TiN -Titanium Nitride





Gold Standard the strong coating...



TiN - Titanium Nitrid

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Implants coated with TiN

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ic coating that has many advantages

increased wettability LOT 0946189116 Gr.3 REF 4201082 extreme hardness cemented and cementless components high wear-resistancy LOT 111911M283 reduced ion release excellent adhesive strength minimized polyethylene wear reliable coating more than 20 years of experience more than 300.000 implants without flaking



TiN - Titanium Nitride

Reliable coating

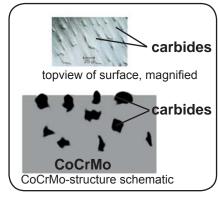
For more than 20 years titanium nitride (TiN)-coatings have been applied to prosthesis to prevent implant allergies and to reduce wear in total knee arthroplasty. TiN-coated implants have been established successfully in the market.^{1, 2, 3, 20} Ideal hygienic conditions in the manufacturing environment as well as the correct coating type and process management ensure constant product safety. Implantcast GmbH cooperates with DOT GmbH, Rostock (Germany) a company specialized on coatings with more than 20 years of experience in coating medical implants.⁴ Every implant coating is 100% inspected ensuring the highest possible quality standards. More than 300.000 TiN-coated cemented and cementless implants have been clinically successfully applied to date.

Base material

Base for a coating with titanium nitride is a finished implant with a highly polished articulating surface. The implant components of the ACS®- system are manufactured from implavit®, a cobalt-chromium-molybdenum (CoCrMo)-alloy according to ISO 5832-4. In the process of manufacturing carbides (bondings of metal and carbon) develop, which are characterized by extreme hardness and these carbides partly protrude from the surface of the finished implant at a microscopic level. These protruding carbides cause wear of the softer articulating bearing surface - in this case polyethylene.

element	cut-off grade % (weight per- cent)
Chromium	26,5-30
Molybdenum	4,5-7
Nickel	max. 1,0
Iron	max. 1,0
Carbon	max. 0,35
Manganese	max. 1,0
Silicium	max. 1,0
Cobalt	rest

CoCrMo-alloy chemical composition acc. to ISO 5832-4



Structure of a highly polished noncoated component

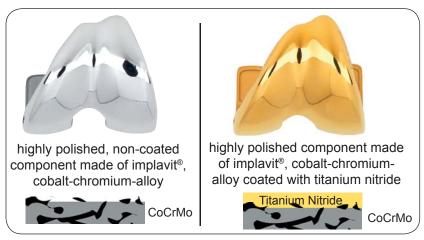
cemented CoCrMo-component coated with TiN

TiN covers carbides

A limiting factor for the life time of a knee replacement is its cyclic and load dependent wear of the softer polyethylene after implantation which produces a significant release of wear debris. The carbides that protrude at the implant surface, which are mainly responsible for wear of the polyethylene, are covered by the much harder TiN-coating. This results in severely reduced wear of the softer articulating partner.⁵

Technology

For manufacturing of the ceramic TiN-coating a specific arc vaporization technique (PVD-coating, physical vapour deposition) is applied. Nitrogen supply is added to the implants as they are coated in an evacuated vacuum chamber in the vapor phase. The computer-controlled process leads to a high reproducibility and coating uniformity. The process anchors the coating safe in several layers of atoms to the implant surface. Therefore only the implant surface is modified. The material properties of the base material (CoCrMo-alloy) as well as its biomechanical functionality remain unaltered.



highly polished non-coated component versus coated component

cementless CoCrMo-component coated with TiN



TiN - key advantages

OT 111911M283

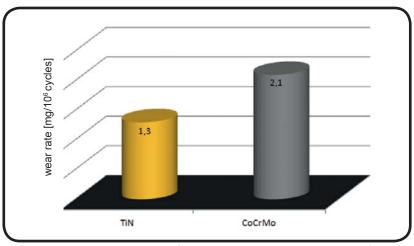
Reduced wear

Wear of the polyethylene is in the longterm one of the main causes for failure of knee endoprosthesis. Aseptic implant loosening can result due to the process of abrasion and wear and consequently revision surgery becomes inevitable.

The TiN-coating reduces wear to a minimum. In in-vitro wear tests on a knee simulator according to ISO

14243 standard the high wear-resistancy of the hard TiN-coating was proven over CoCrMo.¹ The wear rate with TiN-coated components was 38% of the wear rate of the non-coated CoCrMo-components.6

This demonstrates that the TiN coating has superior bearing qualities to CoCrMo.



Wear rates of the ACS® knee system after 5 Mio cycles®

In wear tests the ceramic TiN-coating demonstrates a higher resistancy against scratching. Particles of bone cement are temporarily tolerated in the tribological pairing because extremely hard foreign particles merely generate striae. Thus the potential risk of third body wear is minimized. On the contrary at a non-coated implant third bodies can induce small scratches in the surface, which lead to increased wear of the polyethylene.





Surfaces after Pin-on-Disc-Test with bone cement, TiN (left), non-coated titanium (right)

Minimized ion release

All metallic implant components release ions to their environment over time. In some patients such ions can elicit allergic reactions. Nickel, cobalt and chromium, which are elements of the base material of the articulating implant components, are considered the most frequently allergy eliciting metals.¹⁹



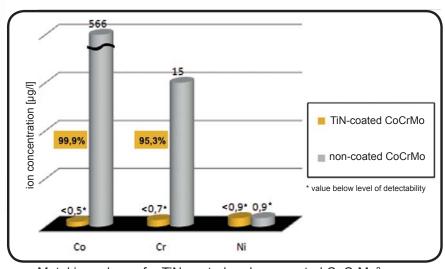
The TiN-coating is biocompatible and acts like a barrier; the potential release of allergy eliciting ions of the base material is reduced to a minimum.⁷ The ceramic coating itself is inert in the human body.

In in-vitro tests TiN-coated CoCrMo was suspended and after a defined time of exposure the ion concentration of the solution was analyzed with regard to Co-, Cr- and Ni-ions. This was compared to the data from non-coated CoCrMo. There was a significant difference in metal ion release in favour of TiN coating.

The ion release is so minimal in the TiN coated components that it is below the limit of detectability.8

Also in clinical practice there have never been any evidence of allergic reactions with implants that have been TiN-coated showing an intact surface.³

Therefore the TiN-coating on implant components is especially suitable for patients with sensitivity to nickel, chromium or cobalt.^{3, 8}



Metal ion release for TiN-coated and non-coated CoCrMo⁸



TiN and its properties

Adhesive strength

The adhesive strength is one of the most important parameters for the quality of a coating coupled with how well it adheres to the base material. The coating is classified into adhesive strength categories (HF), in which HF1 means an excellent adhesive strength and HF6 an insufficient adhesive strength that produce flaking of the coating from the base material.

TiN-coating onto a CoCrMo base material has an adhesive strength of HF1.9

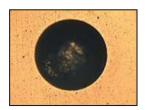
In in-vitro tests there is no evidence of the TiN-coating flaking (delaminating) from the base material. The adhesive strength of the TiN-coating is technologically ruled. Optimal hygienic conditions in the manufacturing environment as well as the correct type of coating and process management ensure a constant product safety.

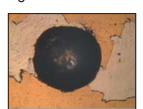
Previous studies have proven that the adhesvie strength of TiN-coatings on CoCrMo meets the top requirements and it is rated higher than the adhesive strength of a zirconium oxide diffusion layer (Oxinium) on a ZrNb-alloy (HF1 vs. HF3).¹⁰

In the past it has been reported that some clinical partial failure of the coating occurred on femoral heads. 11,12 The so-called "eggshell effect" was held responsible for that. This means that the coating should flake of the soft base material when interacting with third bodies (particles) in the presence of high punctual loads (bearing pressure).

However on closer examination of these failed cases in specific regard to coating adhesion strength, it was found that they were manufactured by an inferior manufacturing process that was widely adopted at that time. As a consequence they exhibited an insufficient adhesive strength and partial failure occurred.^{1, 8} The manufacturing process pioneered by DOT GmbH has never had a reported case of delemination.

DOT GmbH have more than 15 years without any report on adhesion failures. The adhesive strength of the coating is so strong that even particles of bone cement are tolerated without problems in the tribological pairing. Extreme hard foreign particles merely generate striae on the surface, which however do not result in delamination of the coating.⁴



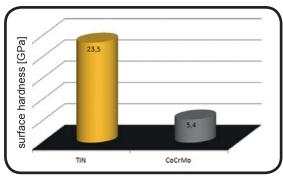


Rockwell-Test according to DIN 50103: A diamond pin is pushed in the base material with a defined load. Afterwards the coating of the boundary is optically classified in the adhesive strength categories HF1-HF6 according to scratches and flaking of the coating.

Determination of the adhesive strength: HF1 (left) and "eggshell effect" HF6 (right)

Surface hardness

The hardness of the surface plays an important factor in the resistance against wear. The surface hardness of the TiN-coating is 23,5 GPa. This is 5 times higher than that of a non-coated CoCrMo-component.

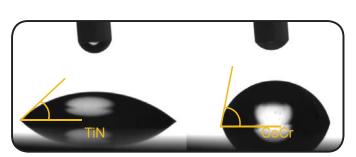


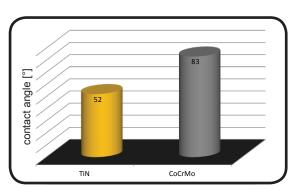
Hardness of different surfaces 1,13

Wettability

When a water droplet is placed on given material the contact angle shows the wettability of a surface which directly correlates to the gliding properties and surface lubrication of a material. The smaller the contact angle between surface and fluid, the better is the wettability and the hydrophilic property of the surface.

A drop of fluid on a TiN-coated implant covers a larger surface area compared to a drop of fluid on a non-coated CoCrMo-component. This increased wettability of a TiN-coated surface when in-vivo surrounded by synovial fluid reduces the friction between femoral component and PE-insert and therefore reduces the wear of the PE-insert.

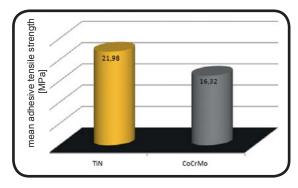


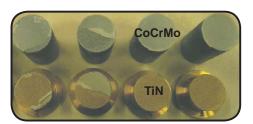


Wettability of a TiN-coated and non-coated CoCr-component with bovine serum9

Adhesive strength of bone cement on TiN

In-vitro tests have proved that TiN coating has a superior adhesion strength of bone cement over CoCrMo. The tests demonstrated a significant increase of one third of the adhesive strength of bone cement on TiN-coated surfaces compared to non-coated surfaces.²¹





Adhesvie strength of bone cement on different surfaces²¹



TiN in comparison...

...to other implant surfaces

There are alternative modified surfaces of endoprosthesis in the market, which also have been designed to overcome abrasive wear as well as minimized ion release. These include amongst others multi-layer ceramic coatings (AS-coating, Aesculap) and an oxidized surface of the implant (Oxinium, Smith and Nephew).

TiN



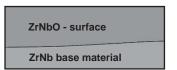
- monolayer coating
- ceramic
- coating thickness app. 5,5µm
- surface hardness 23,5GPa
- coating colour golden

AS¹



- multilayer coating (7 layers)
- ceramic
- coating thickness total app. 4,5µm
- surface hardness 25GPa
- coating colour golden

Oxinium 13, 14, 15



- zirconium-niobium-metal alloy with oxidized surface
- ceramic
- no coating
- thickness oxidized surface app. 5µm
- surface hardness 12GPa
- colour black

The mean coating thickness of the TiN-coating (app. 5,5µm) is greater than the thickness of the multilayer AS-coating.¹³ This increased coating thickness ensures increased safety against wear in case of emerging third body wear by particles of bone cement for instance.

In regard to Oxinium - if the oxidized surface fails by wear (e.g. third body wear by particles of cement), there will be just soft zirconium metal as articulating partner. Zirconium is approximately as soft as pure titanium and thus not suitable as a bearing surface as pure material.¹⁰

The multilayer architecture of the AS-surface requires demanding process management. Thus its manufacturing process is more prone to small technological failures, which eventually could have an influence on the quality of the coating, compared to the established TiN-coating. An increased adhesive strength by the multilayer structure could not be proven in a publication to date.

The surface hardness of the TiN- and AS-coating is comparable, whereas Oxinium exhibits 50% of the surface hardness of TiN and AS.¹³ This makes the Oxinium surface potentially more sensitive to scratch formation and wear.

All 3 surfaces minimize the ion release of the relevant metals Co, Cr, Ni in in-vitro tests to or below the limit of detectability. 16, 13, 17, 18 Nevertheless it needs to be noted that the AS-coating even contains chromium as chromium nitride, thus a potentially allergenic metal, in its coating architecture.

Furthermore all 3 surfaces reduce PE-wear compared to a non-coated CoCrMo-component.^{6, 13, 14, 15, 16, 17} But a direct comparison of wear rates of different manufacturers needs to be considered critical due to different implant designs, implant materials and testing conditions.

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implantcast GmbH Lüneburger Schanze 26 D-21614 Buxtehude Germany

phone: +49 4161 744-0 fax: +49 4161 744-200 e-mail: info@implantcast.de (60482

internet: www.implantcast.de

Your local distributor:

