LINK PorEx® Technology

for metal sensitive patients

Materials and Surface Modification

LINK PorEx® Technology

For the past 24 years Titanium Niobium Nitride (TiNbN) has been used in European medical products as a surface treatment to protect implant alloys against wear and reduce their allergenic potential.*

Orthopaedic and dental products with TiNbN-treated surfaces have been available for 20 years.
Around 150,000 implants have already been successfully modified with this form of PVD treatment. TiNbN surface modification of implant alloys is carried out using the PVD arc process which is characterised by high ion density and efficiency and excellent process stability.*


PVD surface modification equipement

These ceramic-like surface modification systems possess important properties making them suitable for this purpose. They are biocompatible, adhere well to the implant material and have a positive impact on the fatigue strength of the modified alloy. Last but not least it must be ensured that a surface modification meets the requirements for gliding components with regard to polish quality.

These properties are ensured by means of thorough testing of the modified surface that is conducted during production in order to meet the requirements concerning product safety of surface-modified implants

The high quality of our LINK PorEx® coating results from our proprietary, validated process parameters.

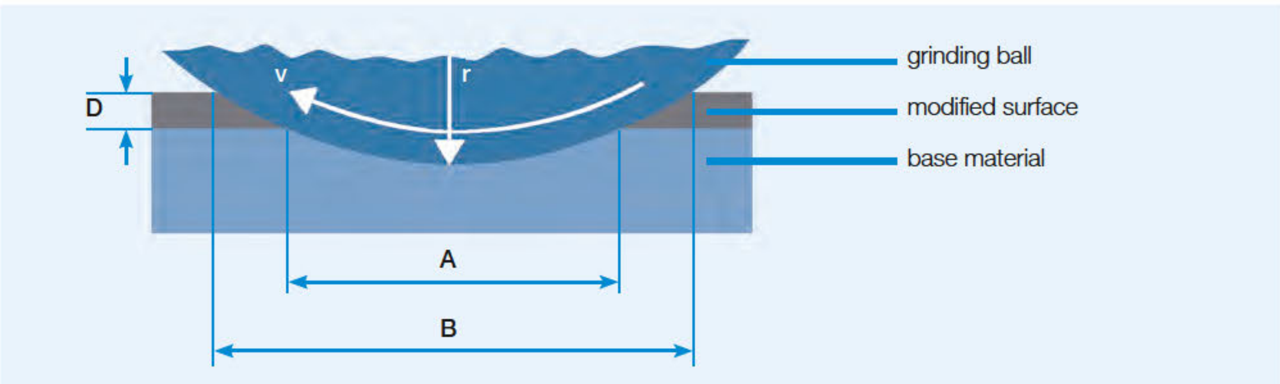
*OMT/IMT GmbH, Lübeck, Germany

Specific properties of LINK PorEx® and testing of the modified surface

Material

The material used for surface modification is a LINK PorEx® alloy with a chemical composition of Ti/Nb 70/30 wt %.
Regarding trace elements the requirements of ISO 5832-2 are fulfilled.

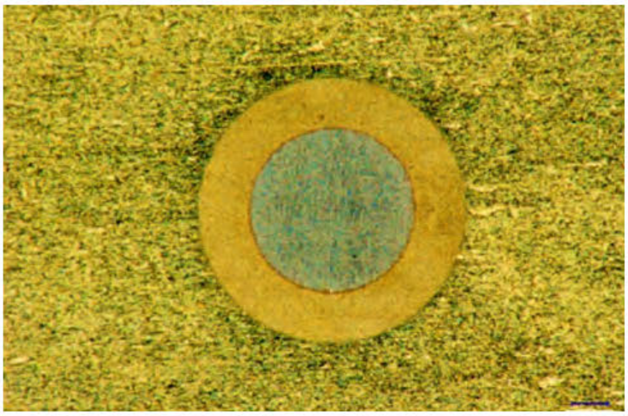
The nitrogen in the surface modification gas has a purity of 99.999%. Trace elements are therefore negligible in comparison to surface modification material.



Micrographic measurement of thickness of LINK PorEx®-treated surface

Specifications

Thickness of modified surface of LINK PorEx®

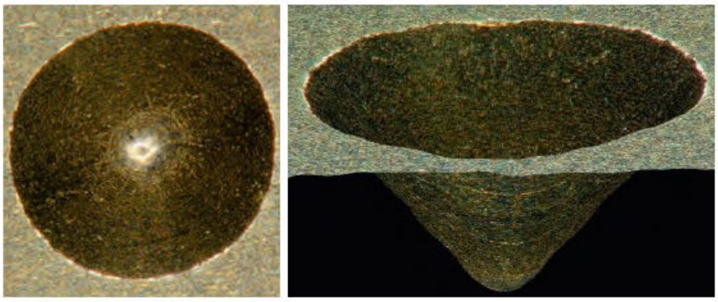


The thickness of LINK PorEx® layers is determined by means of a calotte grinding procedure performed on test sheets which are treated in a surface modification run along with the implants. The calotte grinding procedure is a destructive measuring procedure and thus only applicable to test samples.
However a fixed arrangement of the test samples and a co-ordinated procedure ensure that the layer thicknesses can be optimally reproduced.

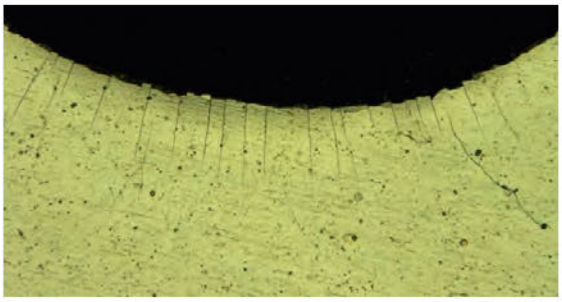
For the modification of implant surfaces with TiNbN a maximum layer thickness of 6 µm is recommended. This is best for surface properties such as corrosion resistance, protection against wear and adhesive strength of the layer. The typical thickness of the LINK PorEx® modified surface is 4.5 ± 1.5 µm.
Calotte grinding is evaluated with software support, in order to minimize the subjective factor.

Adhesive strength of LINK PorEx®

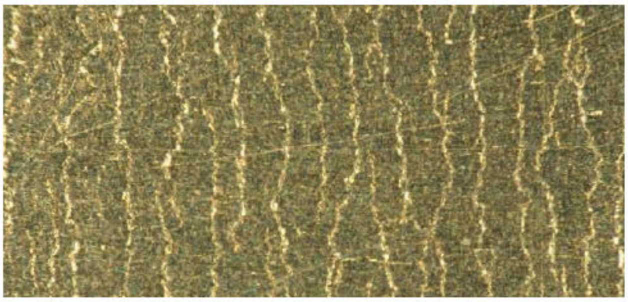
The adhesive strength of LINK PorEx® is evaluated qualitatively using the Rockwell HRC test in accordance with VDI guideline 3198. After indentation of a Rockwell diamond with a load of 1500 N, the edge of the indentation is examined with an optical microscope and the damage is classified in adhesive strength grades. A firmly adhering layer only shows slight cracking and no layer flaking at the deformed edge.



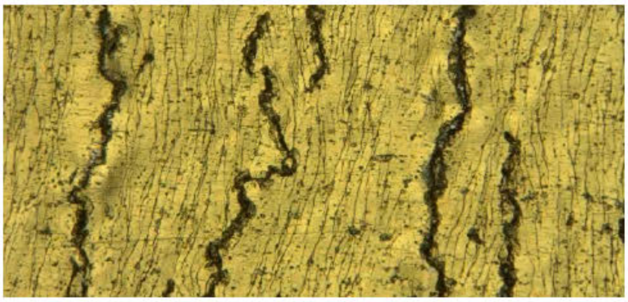
Surface treated with LINK PorEx® after Rockwell test
Adhesive strength grade HF1, 100x



Surface treated with LINK PorEx® after Rockwell test
Adhesive strength grade HF1, 500x

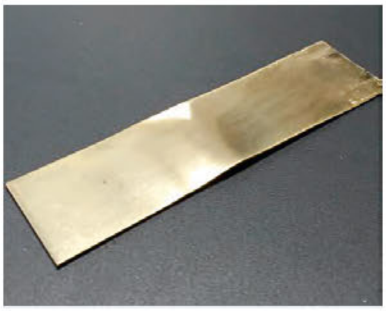


Surface treated with LINK PorEx® after bending test
No delamination of layer, 100x



Surface treated with LINK PorEx® after bending test
No delamination of layer, 500x





Adhesion strength of LINK PorEx® – bending test

An additional test sheet for the bending test is treated with each batch. In this test a test sheet is bent through a 10 mm pin and then bent back.

The adhesive strength can be determined from the cracks in the layer. The adhesive strength is high if the layer does not flake off between the cracks.

Hardness of LINK PorEx®

The hardness of LINK PorEx® is determined by means of microhardness measurement. In this procedure the test load is gradually applied and at the same time the associated penetration depth is measured. The microhardness can be determined in this way for each load step.

Microhardness and Vickers hardness can be displayed as a function of the layer thickness. With LINK PorEx® layers hardness values of approximately 2400 HV (0.1N) are achieved, whereas CoCrMo alloys exhibit a hardness of approximately 550 HV (0,1N).

Test results*		HM	HIT	HV
		N/mm^2	N/mm^2	
Mean value	X.	13944.03	25650.32	2423.96
Confidence level	q	217.29	519.48	49.09
Standard deviation	s	477.23	1140.95	107.82
Variation coefficient	V/%	3.42	4.45	4.45
Number of measured values	n	21	21	21
Smallest value	Min.	13077.6	23544.6	2225.0
Greatest value	Max.	14690.3	27424.8	2591.6
Range	R	1612.69	3880.26	366.68
Range	R/%	11.57	15.13	15.13

*The test results are shown as examples in a production run, with the characteristic values from batch to batch fluctuating through production.

HM = Martens hardness
HIT = Indentation hardness
HV = Vickers hardness

Roughness of LINK PorEx®

The roughness of a LINK PorEx® layer is determined using the Profile method, as specified by to DIN EN ISO 4287, with a Hommel tester T 1000.
From a measured primary profile the roughness is determined by means of filtering. The measurement of roughness is non destructive and thus also applicable to implants.
Surfaces treated with TiNbN achieve roughness values, which are below the levels required by DIN EN ISO 21534.

Friction behavior and abrasion resistance of LINK PorEx®

Because of their hardness, their ceramic-like abrasion properties and their wetting angle on contact with liquids, surfaces treated with LINK PorEx® exhibit a low friction-coefficient when in contact with UHMWPE. Since the LINK PorEx® treated surface has almost no measureable wear, the emission of ions from the implant surface due to fretting corrosion is strongly suppressed.
A variety of publications have reported a decrease in polyethylene wear of PVD-treated surfaces when compared to untreated cobalt-based alloys [2, 8, 9].

Biocompability and corrosion resistance of LINK PorEx®

The biocompatibility of TiNbN has been examined and proven in, as reported in a variety of publications [7,11,13]. Further studies by different authors have confirmed the increase in corrosion resistance of different substrates after surface modification with TiNbN [4,10].
The corrosion resistance of TiNbN-treated surfaces was investigated for CoCrMo alloys in particular. A decrease in ion release of up to 90% was measured in the static condition. Under the influence of fretting corrosion the difference becomes substantially more significant, because no friction contact occurs at the TiNbN-treated surface of the CoCrMo alloy. The examination of TiNbN in accordance with ISO 10993-5 gave no indication of cytotoxicity [14].

Influence on the fatigue strength

Studies were carried out at IMA Dresden regarding the influence of TiN surface modification on the fatigue strength of CoCrMo. In the rotating bend test a 5% increase in the fatigue strength of coated components was measured. These results are comparable with findings reported by Wilson [6], who found that the fatigue strength of TiAl6V4 increased by approximately 10% with TiN surface modification.

This effect is due primarily to pressure-related residual stresses, which result from the surface modification and which reduce the effective maximum bending stress in the border region. These effects are also to be expected with TiNbN surface modifications.

Typical Parameter of LINK PorEx® Coating

Surface modification process	PVD – ARC
Surface modification	TiNbN (Titan-Niob-Nitrid)
Thickness of modified surface	4,5 ± 1,5 µm on the reference strip
Hardness of modified surface	2300 - 2500 $HV_{0,1}$
Adhesion strength VDI 3198	HF 1 - HF 2
Adhesion strength (Thorn bending test)	no delamination between the cracks
Roughness	Ra <0,05 µm
Biocompatibility	Not cytotoxic acc. to ISO 10993-5

Titan Sensitivity

For titanium hypersensitve patients we offer our PorEx-Z® (zirconium nitride coating) as a custom-made product

Literature

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