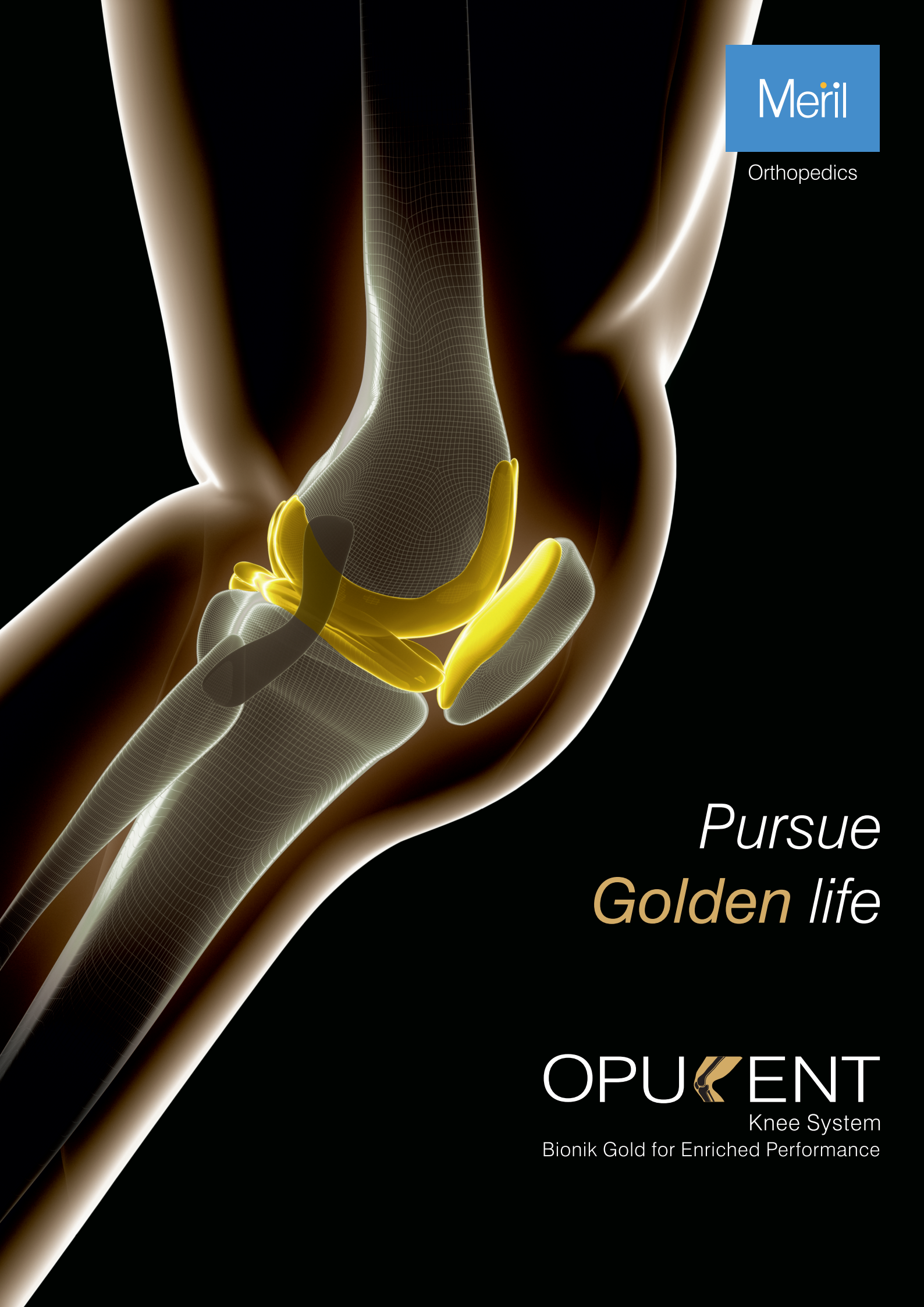


Meril

Orthopedics

Pursue

Golden life

OPUS ENT

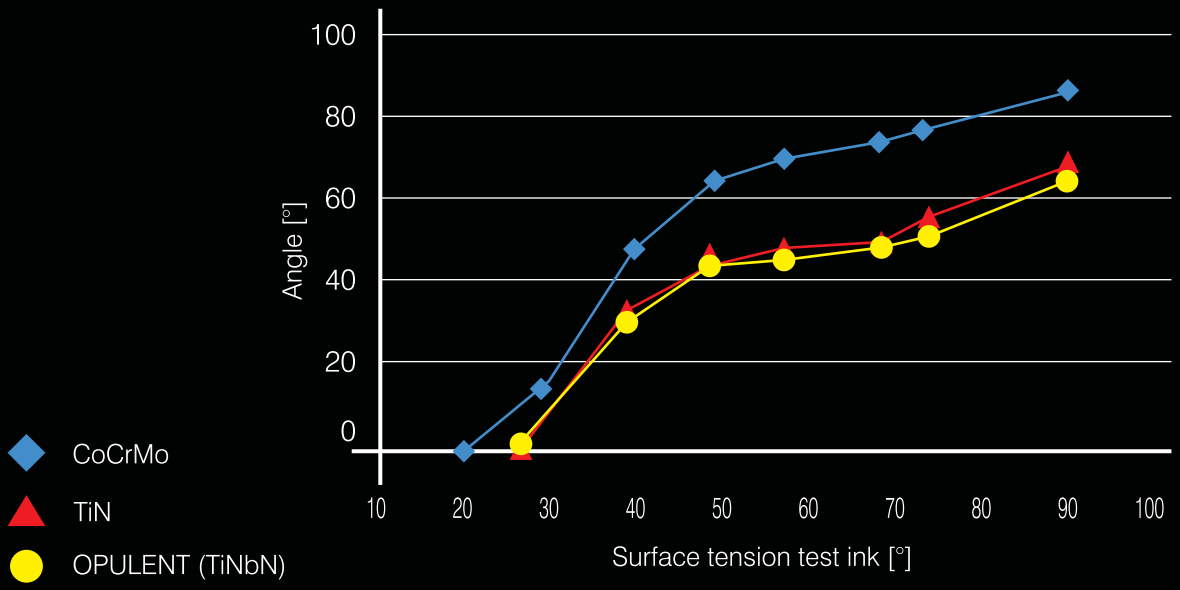
Knee System

Bionik Gold for Enriched Performance

Wetting angle

Coating with TiNbN reduces the wetting angle by 20°, resulting in improved wettability (greater hydrophili-city) of the implant surface for body fluids.

A better wettability will increase the lubrication, decreasing the coefficient of friction and this will help to reduce the wear.

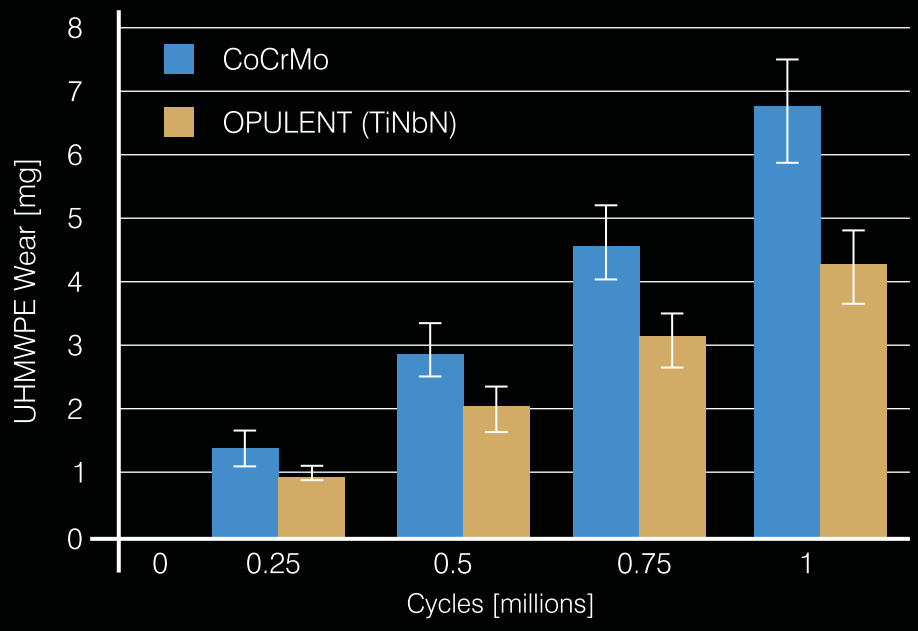


Reduction of the water contact angle with TiNbN coating (Source: DA M. Retzlaff)

UHMWPE Wear in “Pin-on-disc” Test

In a “Pin on disc” test with 1 million cycles the difference in wear of UHMWPE between uncoated and TiNbN-coated specimens was investigated. Whereas a wear of 6.72 mg was ascertained for the uncoated implants, the UHMWPE wear for the TiNbN-coated implants was just 4.25 mg. corresponding to a reduction in wear of almost 40%.

As a result of the hardness of the TiNbN coating and the ceramic like properties in terms of adhesion behavior and the wetting angle with liquids, the TiNbN coating shows an outstanding frictional coefficient in contact with UHMWPE.



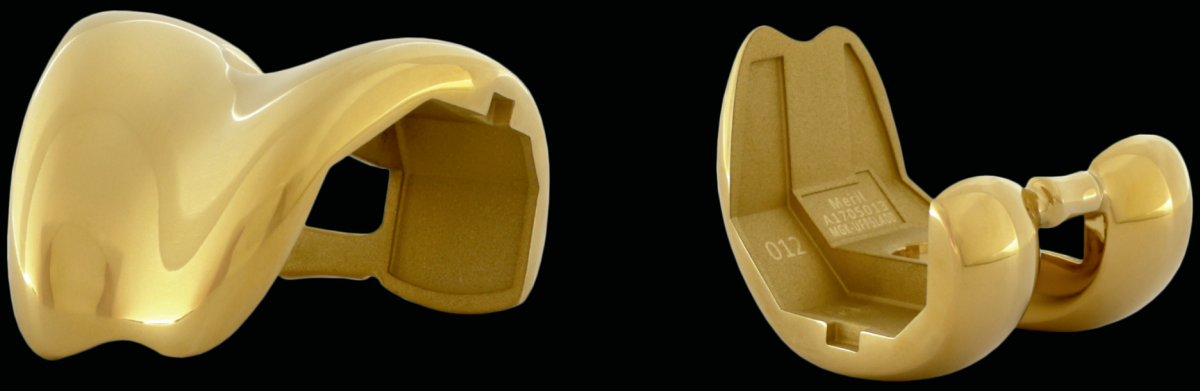
TiNbN (Titanium Niobium Nitride)

Background

Joint replacement implants, particularly knee and hip prostheses, are subject to a high degree of load and wear inducing movement that results in the release of abrasive particles. Wear and also the release of metal ions is caused by contact stress between the implant's polyethylene bearing surfaces and the metallic components. Wear debris and metal ions have been shown to be the main cause of inflammation, premature loosening and allergic reactions associated with joint replacement implants.

In comparison to other joint prostheses, knee replacement implants, which are mainly manufactured from cobalt/ chromium-based alloys, are required, for technical reasons to consist of up to 1 percent nickel traces. They also have a far larger bearing surface area than other joint prostheses. This can result in the continuous release of allergenic metal ions (nickel, chrome or cobalt) into the tissue surrounding the implant. Hence, the risk of post implantation adverse tissue reactions is particularly high in patients that are prone to allergy.

Additionally, one of the main development goals of modern manufacturing technologies, for new orthopaedic implants, is to improve their surfaces to avoid allergic reactions and wear debris caused by the articulating components.

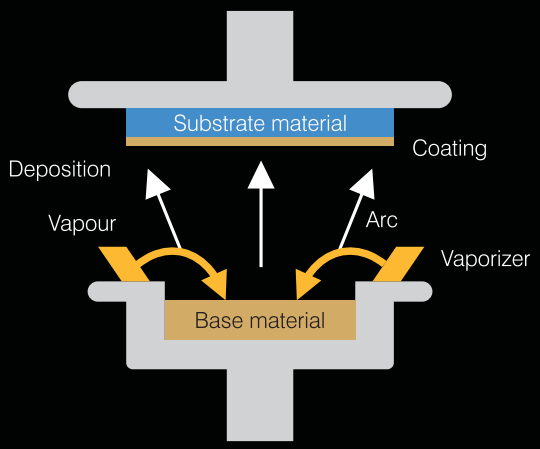


Technologies

A fully biocompatible titanium niobium nitride (TiNbN) ceramic surface coating on metallic implant components has a beneficial effect on reducing both allergic reactions and wear. **These ceramic coatings have been employed successfully in the U.S. Their use has been steadily increasing in Europe.**

The ceramic coating technique utilizes a technology known as PVD (physical vapor deposition), which involves coating the implant during the vapor phase in a high vacuum chamber to which nitrogen is added. The outstanding reproducibility of this computer controlled process produces coatings of consistently high quality.

In this manufacturing process, the coating is securely anchored in several atomic layers on the implant surface.



Bionik Gold Surface

The OPULENT Bionik Gold surface is for allergy and wear protection of knee implant. Macroscopically, the Bionik Gold surface presents a metallic, light golden yellow appearance whereby the coating forms an extremely strong bond with the implant.

The Bionik Gold surface prevents direct contact of the base material with the surrounding tissue and reduces the release of particles and ions due to wear.

Advantages at a glance

- Outstanding biocompatibility
- Allergy preventive
- Hardness superior to cobalt chromium-based alloys
- Higher wettability with synovial fluids
- Superior surface hardness
- Low friction articulation
- Long-term chemical stability
- Avoiding inflammation and endoprosthetic loosening
- Extreme adhesive strength

Reduction of Metal Ions

Chrome and nickel ions are undetectable and the release of cobalt ions is reduced by more than 90% with Opulent versus an uncoated, cobalt chrome substrate.

PVD coatings are useful over a broad range of implant and medical device applications

Properties of TiNbN

PROPERTY	RESULT
Color	Light golden yellow
Coating thickness	3-6 μm
Roughness	$\leq$ 0.05 μm
Adhesive strength (according to Rockwell indentation test)	HF 1-2
Coating hardness	ca. 2,400 HV (0.1 N)
Wear resistance	Very high wear resistance towards bone cement
Wear	Reduction of UHMWPE wear
Cytotoxicity	Not cytotoxic
Genotoxicity	Not genotoxic

PROPERTY	RESULT
Sensitization test ac-cording to 10993-1	No sensitization from TiNbN
Irritation test according to ISO 10993-1	No irritant reactions from TiNbN coating
Implantation according to DIN EN ISO 10993-6	No product-related tissue reactions
Friction against UHMWPE	0.04-0.07
Allergy potential	Release of ions was reduced to the detection limit
Liquid contact angle	Reduction of the liquid contact angle by 20%, result: improved wettability of the surface compared to uncoated CoCrMo surfaces

- Coatings modify surface properties only and have no effects on the substrate properties or biomechanical functionality of the coated device.
- Biocompatibility and corrosion resistance:
  The biocompatibility has been demonstrated in numerous published studies.

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Disclaimer: TiNbN = Bionik Gold