# directLINK®

Special issue December 2013

# Metal allergies under control

## »in focus!«

A conversation with Prof. Peter Thomas about metal allergies, special consultations and predictive tests.

**PorEx® Surface Modification**
More information at **porex.linkorthopaedics.com**
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**Clinical experiences:** PD Dr. med. Andreas L. Oberholzer on the subject of tissue-friendly materials and allergy screening | **BiPorEx®:** Solution for metal-sensitive hip patients

## Dual control principle

No implant leaves LINK's production plant without a final inspection by two Quality Control technicians - because two pairs of eyes are better than one. The photograph shows inspection of femoral components of the LINK® GEMINI® SL® Total Knee Replacement with PorEx® surface modification for cemented implantation in metal-sensitive patients.

# Dear Readers:

The Duchess of Cambridge cannot get to close to horses, Lionel Ritchie has to steer clear of dairy products, and Tiger Woods avoids exposure to pollen. Allergies are very common, but with a little luck and knowhow, we can easily avoid the substances that trigger »our« particular intolerances. On the other hand, if you require a joint prosthesis and you have a metal allergy, that is more of a problem. More and more people suffer from contact allergies to metals such as silver or nickel.

The problem is not new, and it is on the increase, as you can discover in this issue of direct**LINK**. Consequently, we at LINK have been investigating suitable biocompatible alternatives for years now. Find out about our products for patients with metal and cement allergies, and read about the special surface modification that we have developed for metal-sensitive hip patients.

The word »allergy« comes from the Greek, meaning to »act differently«. When a patient's body acts differently to how it should, one can regard it as a challenge. After all, it is often by attempting to solve a problem that we make new discoveries.

Enjoy this issue of direct**LINK**. Regards.

## Publication details

**Published by:** Waldemar Link GmbH & Co. KG · Helmut D. Link
**Editor:** Heike Urbschat · Tel.: +49 40 53995-0 · E-mail: redaktiondirectLINK@linkhh.de
**Editing/Design/Production:** medienärzte Gesundheitskommunikation · Hamburg · www.medienaerzte.de
**Photography/Graphics:** Albrecht (back cover) · LINK (outside/inside front cover, pages 1, 5–7, 9) · medienärzte (pages 3, 8) · fotolia (front cover)
**Disclaimer:** The opinions of the interviewees do not necessarily reflect the views of the publisher.

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# »Implant allergies are increasingly the focus of attention!«

How important are implant allergies? Prof. Dr. med. Peter Thomas on the subject of natural latex gloves, special consultations and predictive tests.

**Prof. Thomas, there's a six-week wait for an appointment at your special consultation for patients with a suspected implant allergy. Does this mean that implant allergies are more common than we thought?**
We don't have absolute numbers just yet, so I can't give you a scientific answer to your question. But that does not make implant allergy any less medically important. This subject reminds me of the story with natural rubber latex allergy 25 years ago.

**Back then, powdered latex gloves triggered asthma in surgeons and patients. But it took years before anyone made the connection.**
The latex allergy demonstrates that phenomena can be explained if you devote enough attention to them. At first, the problem was scarcely perceived, but today it's perfectly clear: natural rubber latex gloves must be unpowdered because otherwise the air in the room will be contaminated with latex allergens carried in the powder.

»Nowadays ›metal sensitivity‹ appears in registers as a reason for revision or implant failure.«

**Inadequate data is one reason why opinions differ about the significance of implant allergies. What is the current situation?**
There is a lack of comprehensive data collection, but for decades now we have been receiving information from numerous countries obtained from small cohorts of patients. Nowadays ›metal sensitivity‹ appears in registers as a reason for revisions or implant failure, the first record being in the Australian register. There, a hypersensitivity-related failure rate of 0.9 percent[1] is cited for shoulder prostheses, and up to 5.7 percent[2] for metal-on-metal hip implants.

**You have also set up a register for implant allergies.**
Each month, the data from around 25 patients who attend our special consultations goes into a register[3]. In the meantime, we have built up a relatively large database, and we are always pleased to receive more feedback.

**Can a metal allergy have an impact on implant survival?**
I believe it can. Some working groups, including one headed by my colleague Donatella Granchi[4] in Bologna, are able to make a general statement, based on the studies they have conducted, that implant survival is lower in those patients who have an implant allergy.

**So should it be made obligatory to use hypoallergenic implants?**
The regulatory aspect is a critical point. You cannot know in advance which patients are going to develop an allergy to their implant. However, allergy sufferers should be informed about alternative materials before a joint prosthesis is implanted. For example, »You are allergic to cobalt, so this or that particular implant would be most suitable for you.«

**Your special consultancy is the only one of its kind in Germany. Could you describe the work you do?**
We conduct clinical examinations and laboratory analyses in order to establish whether a patient has an implant allergy. It involves a lot of time and effort, but it is valuable because, of course, a

patient with an implant allergy stands to benefit greatly if he receives an implant with an anti-allergenic coating when he undergoes a revision procedure. Unfortunately, our work does not pay for itself. But to provide appropriate funding, the relevant bodies demand more scientific data.

**Would it make sense to carry out allergy screening before implant surgery?**
The purpose of an allergy test is to help identify an existing problem, such as a drug allergy, after a skin rash occurs. A predictive test for a metal allergy prior to surgery is not the answer. What would be advantageous is preoperative tests on patients who have problems with jewelry or their watch-strap, for example, or who have experienced persistent wound healing impairment after osteosynthesis.

»A predictive test for a metal allergy prior to surgery is not the answer.«

**How will the topic of implant allergy develop in the future?**
Increasing attention is being focused on implant allergies. In North America, for example, there are a growing number of scientific working groups investigating metal ion effects and hypersensitive reactions. In Germany, too, the majority of general and orthopedic surgeons have an open mind on this subject.

**What direction is research taking today?**
We are currently engaged on a research project to identify genetic factors which trigger excessive reactions. In general, we are trying to establish whether there are individual characteristics which cause patients to react hypersensitively to implant materials. Ideally, this work will enable us to create predictive tests or biomarkers for at-risk patients. But in the final analysis, we need materials and material modifications which prevent hypersensitivity reactions from occurring. That is the job of the manufacturers.

**Prof. Thomas, many thanks for talking to us.**

[1]Registry AOANJR. Annual Report. 2012.
[2]Registry AOANJR. Annual Report. 2012.
[3]www.allergomat.klinikum.uni-muenchen.de.
[4]Granchi D, Cenni E, Trisolino G et al. Sensitivity to implant materials in patients undergoing total hip replacement. J Biomed Mater Res B Appl Biomater. 2006;77(2):257-264.

»We need materials which prevent hypersensitivity reactions from occurring« – **Prof. Dr. med. Peter Thomas** is senior physician at the Department of Dermatology and Allergology at the Ludwig Maximilian University Hospital in Munich, Germany, and head of the implant allergy register: www.allergomat.klinikum.uni-muenchen.de

# »Golden age«
## for metal-sensitive patients

**The hypoallergenic surface modification PorEx® is the ideal solution for patients with suspected metal hypersensitivity. PorEx® reduces the release of allergenic ions by around 95 percent[1]. In addition, it has a lower coefficient of friction[2, 3, 4] vis-à-vis polyethylene (UHMWPE) due to its outstanding hardness, ceramic-like abrasion behavior, and optimal wetting angle in contact with liquids. Prosthetic joints with PorEx® surface modification display optimized sliding and friction properties with a considerable reduction in wear.**

PorEx® is a titanium niobium nitride (TiNbN) surface modification which has been in use in Europe for over ten years to offer protection against wear and allergies in orthopedic applications. PorEx® surface modification only contains the hypoallergenic elements titanium and niobium, and no chrome or nickel.

### Pronounced adhesive strength, high fatigue strength

In addition to its great hardness, biocompatibility[5, 6, 7], high corrosion resistance[8, 9] and wear protection, PorEx® is also characterized by pronounced adhesive strength and high fatigue strength[10]. The thickness of the PorEx® surface modification is normally 4.5 ± 1.5 $\mu$m. In terms of hardness, PorEx® achieves values of approx. 2400 HV (0.1 N), compared to around 550 HV (0.1 N) for CoCrMo alloys.

### Cementless versions are available as custom-made implants

PorEx® surface modification is available for the LINK® GEMINI® SL® Total Knee Replacement, the Unicondylar Sled Prosthesis, and the Endo-Model® Knee Prosthesis. In addition, the LINK® Arthrodesis Nail can be customized with PorEx®. For patients who react hypersensitively to bone cement, LINK also offers a custom-made cementless version.

[1] Untersuchung zum Einfluss von TiNbN-Beschichtungen auf die Ionenausgabe von CoCrMo-Legierungen in SBF-Puffer nach Simulatorversuch.

[2] R. M. Streicher, Möglichkeiten der Optimierung von Gleitpaarungen gegen UHMWPE für künstliche Gelenke, Biomed. Technik, Volume 35, Issue 4/1990.

[3] M. J. Pappas, Titanium Nitride Ceramic Film against Polyethylene, Clinical Orthopedics Vol. 317,1995.

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[5] R. Thull, K.-D. Handke, E.J. Karle, Examination of Titanium coated with (Ti,Nb)ON and (Ti,Zr)O in an Animal Experiment, Biomedizinische Technik, Volume 40, Issue 10/1995.

[6] J. Eulert, R. Thull, Standardised Testing of Bone/Implant Interfaces using an Osteoblast Cell Culture system, Biomedizinische Technik, Volume 45, Issue 12/2000

[7] Test report Bioserv AG, Analysis of TiNbN in accordance with ISO 10993-5, 2006.

[8] R. Thull, Corrosion behavior of dental alloys coated with Titanium Niobium Oxinitride, Deutsche Zahnärztliche Zeitschrift, Nov. 1991, University of Würzburg.

[9] Test report DOT GmbH and Nordum GmbH, Examination of influence of PVD coatings to the ion release of CoCrMo-alloys in SBF buffer, 2006.

[10] A. Wilson, A comparison of the wear and fatigue properties of PVD TiN, CrN and duplex coatings on Ti-6Al-4V, International Conference of Metallurgical Coatings and Thin Films, San Diego 1993.

# Cement allergy? TiCaP®/PorEx®!

**A large proportion of implanted joint prostheses – especially knee prostheses – are cemented and are well tolerated. However, in the field of orthopedic surgery, dental surgery and cosmetic applications[1, 2] there have been occasional reports of inflammatory reactions attributable to sensitivity to bone cement.[3] This allergy to polymethyl methacrylate (PMMA) bone cement and its constituents is relatively unusual, but does have implications for the choice of joint prosthesis.**

Although »cement allergy« is a rare phenomenon, the potential for inflammatory reactions and the possibility of pain and loosening of the prosthesis must be clarified prior to arthroplasty. When the patient is admitted, a full history should be taken, including the individual allergy risk and also take into account any previous sensitivity to contact with metals and dental materials.

### TiCaP® enables long-term fixation

If the patient is sensitive to polymethyl methacrylate bone cement or its constituents, this is a contraindication for the use of a cemented joint prosthesis.[4] In such cases of hypersensitivity to constituents of bone cement, joint prostheses are usually implanted without cement. LINK offers the GEMINI® SL® Total Knee Replacement as a cementless version with TiCaP®/PorEx®.

TiCaP® is a microfine coating in which high-porosity titanium and calcium phosphate are applied in a double layer. This promotes the ingrowth of bone into the surface structures, thus enabling long-term fixation. The GEMINI® SL® Total Knee Replacement, shown opposite, with its implants and system-specific instruments is part of the LINK SL® knee family: an implant system for primary and revision arthroplasties.

[1]Johnson DR, Mathis CGT. Case report: a dentist with allergic contact dermatitis caused by ethylene glycol dimethacrylate. Am J Contact Dermat 1993; 4:90.
[2]Fisher AA. Paresthesia on the fingers accompanying dermatitis due to methylmethacrylate bone cement. Contact Dermatitis 1979; 5:55.
[3]Thomas P, Schuh A, Eben R, Thomsen M., Allergie auf Knochenzementbestandteile, Orthopäde 2008, 37:117-120.
[4]Kaplan K, Della Valle CJ, Haines K, Zuckerman JD. Preoperative identification of a bone-cement allergy in a patient undergoing total knee arthroplasty. J Arthroplasty 2002; 17:788-791.

Cementless version of the GEMINI® SL® Total Knee Replacement with TiCaP® coating (light grey) and PorEx® surface modification (gold)

# The »Golden Five« from LINK

## All products with hypoallergenic surface modifications and coatings

| Product name | LINK® GEMINI® SL® Total Knee Replacement | LINK® Unicondylar Sled Prosthesis |
|---|---|---|
| **Material/ surface modification** | Cemented: CoCrMo/PorEx®1<br>Cementless: CoCrMo/PorEx®1/TiCaP®2 | Cemented: CoCrMo/PorEx®1 |
| **Key features** | • Cemented or cementless anchorage<br>• Extended range of indications and compatibility with other systems thanks to integrated SL® knee family concept<br>• Physiological patella movement and patella self-tracking by means of raised patella shield and optimized patellar articulating groove<br>• Optimal physiological freedom of movement with high flexion enables special femur design<br>• Extreme tibial precision of fit ensured by anatomically designed tibial metal tray<br>• Blades and fixation pegs ensure secure tibial anchorage against rotational and shear forces<br>• Cemented and cementless stems ensure stability when bone structure is insufficient<br>• Optimal alignment and soft tissue adjustment by means of easy-to-use instrument set | • 1st place, benchmark for minimal revision risk, The Swedish Knee Arthroplasty Register, 2012* (without PorEx®)<br>• Bone-conserving design<br>• Full range of movement<br>• Short rehabilitation time<br>• Optimal implant-cement bond produced by globular macrostructure on the inner surfaces of the prosthesis<br>• Tibial plateaus made of UHMWPE with and without metal base<br>• Minimally invasive or conventional implantation technique is possible<br>• Patella-friendly thin design<br>*Annual Report 2012, The Swedish Knee Arthroplasty Register, page 35, www.knee.nko.se |

| LINK® Endo-Model® Rotational and Hinge Knee Prosthesis | LINK® Endo-Model® Arthrodesis Nail | T.O.P.® Acetabular Cup with zirconium nitride-CaP coating for patients with titanium allergy |
|---|---|---|
| Cemented:<br>CoCrMo/PorEx®[1] | Cemented:<br>CoCrMo/PorEx®[1] | Cementless:<br>Zirconium nitride-calcium phosphate (ZrNCaP) |

**Endo-Model® Rotational Knee Prosthesis**

- Strong diaphyseal prosthesis anchorage for weak ligaments
- Minimal bone resection during primary implantation
- Conservation of valuable bone tissue
- Natural gait thanks to physiological pivot point and axial rotation
- Anti-luxation device

**Endo-Model® Hinge Knee Prosthesis**

- For cases of major loss of bone tissue, ligament instability and extreme muscular insufficiency

- Available as custom-made implant
- Cemented or cementless anchorage
- Special coupling for stable connection of femoral and tibial components
- Minimal longitudinal movement (approx. 3 mm) of the nail components relative to each other is necessary for coupling
- This makes intraoperative joining possible
- Shape of the nail components enables stable, frictional connection
- Final securing of the connection between the two components by means of two screws

- Custom-made: Tilastan®[3] titanium alloy with ZrN[4] and HX®[5] coating
- Standard version: Tilastan®[3] titaniumalloy with HX®[5] coating
- Press-fit fixation with maximumbone conservation
- Medioventral recess (femoralisprotective rim) allows wider range of movement and protects the psoas tendon and femoralis nerve
- Equatorial fixation for primary stability
- Optional additional fixation with fixation screws
- Snap lock mechanism ensures secure connection between metal casing and UHMWPE insert
- Standard acetabular cup insert for normal cup entrance angle
- Use of anti-luxationcup insert prevents femoral headluxation when the metal casing is at a steep cup entrance angle
- For X-LINKed®[6] UHMWPE and standard polyethylene inserts
- Wide rangeof sizesfrom 40 mm to 68 mm Ø (15 sizes)

[1]PorEx®: TiNbN = titanium niobium nitride surface modification.
[2]TiCaP® double coating: titanium/calcium phosphate.
[3]Tilastan®: TiAl6V4, forged titanium alloy.
[4]ZrN: zirconium nitride.
[5]HX®: calcium phosphate coating (CaP).
[6]X-LINKed®: highly crosslinked UHMWPE.

»Titanium niobium nitride is the most tissue-friendly material available today« – **PD Dr. med. Andreas L. Oberholzer** moved, in 2006, from Berlin's Charité to the Pyramide hospital in Zürich, Switzerland, where he is head of the Centre for Joint and Sport Surgery

# »The **allergy risk** must be minimized as far as we possibly can!«

What experiences of implant allergies are reported by arthroplasty surgeons at Zürich's Pyramide hospital in Switzerland? directLINK put five questions to PD Dr. med. Andreas L. Oberholzer.

**Dr. Oberholzer, for some years now, you have exclusively used prostheses coated with titanium niobium nitride when performing primary arthroplasties and revisions. Why is that?**
Titanium niobium nitride is the most tissue-friendly material available today for joint prostheses. It may be assumed that complications such as implant loosening are also attributable to allergies to metal ions or cement constituents. It is vital to minimize the risk as far as we possibly can, especially for revisions – that's why I use a particularly well tolerated material. Cementless prostheses coated with titanium niobium nitride are the best choice in this respect.

**What complications can an implant allergy cause?**
A metal allergy irritates the tissue and makes it proliferate, with the result that it gets pinched in the prosthesis, causing stabbing pains. In the past I encountered this problem with around 5 percent of my knee prosthesis patients. But since I started implanting only titanium niobium nitride coated prostheses, the number of problem cases is virtually zero.

**What other symptoms did your patients complain of?**
Many complained of a burning sensation, and erythema (reddening of the skin) also appeared over time. We would then carry out allergy tests for metal and cement constituents, and if the results were positive, we implanted a cementless titanium niobium nitride coated knee prosthesis. That solved the problem.

## »Cementless prostheses coated with titanium niobium nitride are the best choice.«

**Is the subject of metal allergy growing in importance in clinical practice?**
Overall, the number of allergies is growing! Implanting a knee prosthesis means replacing a large surface in the body with metal, and consequently metal ions are released by abrasion. This increases the likelihood of allergies occurring in people who already have an allergic disposition.

**So should preoperative allergy screening become standard practice?**
Not really at the present time. The body as a system reacts differently from mucous membranes. I have had patients in whom the skin test was negative, yet they still developed a metal allergy. We do not yet have a method of screening that can tell us with certainty that a hypoallergenic prosthesis needs to be used in one case but not another. Nevertheless, screening is a useful tool for eliminating risk as far as possible.

**Dr. Oberholzer, many thanks for giving us this interview.**

# BiPorEx®
## for metal-sensitive hip patients

**Metal-sensitive hip patients require special implants in order to minimize the risk of an allergic reaction. Essentially, titanium is a very good choice because it is highly biocompatible and corrosion-resistant in the aggressive environment of the human body. However, it performs less well in terms of wear and rigidity, and is therefore unsuitable for cemented hip prosthesis stems.**

For this reason, LINK has developed the BiPorEx® (TiNb) surface modifications. BiPorEx® performs the same function as PorEx®, namely to prevent the release of cobalt-chrome ions from implants[1] such as the SP II® Hip Prosthesis Stem (see illustration). In addition, BiPorEx® enables the use of a ceramic acetabular head on the taper. The layer thickness is > 4 µm.

**BiPorEx® displays high tensile strength and fracture resistance, amongst other characteristics**

BiPorEx® equates to titanium niobium (TiNb), an alloy which combines good corrosion resistance with high tensile strength and fracture resistance. The elements titanium (Ti) and niobium (Nb) are biocompatible and have been used for more than a quarter of a century in joint implants in the EU and the USA.

For metal-sensitive hip patients, BiPorEx® surface-modified hip prosthesis stems are available as custom-made implants.

»Prevents the release of cobalt-chrome ions and offers high tensile strength and fracture resistance« – **SP® II Hip Prosthesis Stem with BiPorEx® surface modification**

[1]LINK elution test: Reduction of at least 97.3 percent in release of metal ions. No release of metal ions detectable up to the detection limit

# Might trigger an allergic reaction.

# The solution for your allergic patient.

**PorEx® – Knee replacement systems with surface modification against hypersensitivities to metal.**

LINK® knee replacement systems with PorEx® are the ideal solution for patients where a suspicion of hypersensitivity to metal exists. Due to the special surface modification, the release of allergy-causing ions is reduced by 95 %* and wear characteristics are optimized at the same time.

More than 40 years of LINK experience in joint replacement stand for excellence and reliability.

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Unitech House · Unit B1 & B2 Bond Close · Kingsland Business Park · Basingstoke · Hampshire · RG24 8PZ · Phone 0 12 56 365 480

*Study on the influence of TiNbN coatings on the release of CoCrMo alloy ions in an SBF buffer following trial simulation

LINK®

Regaining Quality of Life.