directLINK®

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The Orthopedicus of Florence

Visiting Professor Rodolfo Capanna at his workplace, the Centro Traumatologico Ortopedico in Florence, Italy

CaP: Calcium phosphate coatings are ideal for biological cementless fixation of joint prostheses

Custom-made implant: Total femur and tibia push-through prosthesis with medial tibia stem offset

Wax models for casting

The VACUCAST® automatic transportation system carries wax models for the investment casting process to the next manufacturing stage. Dipping in ceramic slurry creates a covering layer which is fired to produce the final mold. VACUCAST®, a leading investment casting foundry specializing in vacuum casting, is a member of the LINK group.

Dear reader,

Now that we are all networked and satellites show us where we've parked our cars, the idea of »nearness« has taken on a completely different meaning. If I go from our administrative center in Hamburg to our factory for a short meeting, that may seem old fashioned, but - for me - that's what »nearness« is all about. Personal contact.
When Prof. Rodolfo Capanna made his career choice, medicine was nearer to his heart than architecture, as he reveals in our interview.
If Rimini had not been so near to Bologna we would have one less distinguished tumor surgeon, and LINK's Megasystem-C® would not exist.
Nearness is also important where surface treatments for cementless joint prostheses are concerned, though this time it is the nearness to the body's own tissue that is relevant. In our report we explain why LINK uses calcium phosphate coatings and why they are superior to other surface coatings.
The article on LINK custom-made products presents a highly complex prosthesis made for a patient at the Mayo Clinic. The prosthesis replaces all bones from the hip through to the ankle, but is variable nonetheless. In my father's day, this young man's leg would have had to be amputated. In the current issue we see just what nearness means for LINK - commitment, creativity and top quality results.

I hope you enjoy this issue of direct**LINK**,

Helmut D. Link

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The Orthopedicus of Florence

Anyone who visits Professor Rodolfo Capanna at his workplace, the Centro Traumatologico Ortopedico in Florence, Italy, will learn a lot, and not just about his current work. The man who developed LINK's Megasystem-C® almost chose a quite different profession.

No spacious senior consultant's office - a desk in a walk-through room on the ward has to suffice. »One half of the hospital is being renovated at the moment« explains Prof. Capanna by way of apology. No problem, we don't mind sitting closer together. Next door, in one of the rooms, a patient listens to pop on a smartphone and sings along. Nobody minds. People are more relaxed about a lot of things in Italy.

That the student, Rodolfo Capanna, went on to become a world-famous orthopedic cancer surgeon is thanks to the town of Bologna, about 100 km north of Rimini, where he was born. Bologna, whose streets make you feel as though you're strolling through the 8th century, has since the late Middle Ages been home to one of Italy's best universities. »My second passion is the ancient world. That's why I wanted to study architecture at first,« explained Prof. Capanna, »but the good reputation of the medical faculty at Bologna made me decide to go for medicine.«

Good teachers at the Istituto Ortopedico Rizzoli di Bologna

Luckily for tumor surgery, and for Italy as well. At the end of the 1970s orthopedics had poor standing as a specialty, but the Istituto Ortopedico Rizzoli in Bologna looked ahead. Prof. Capanna described his time as a junior doctor. »I had a good teacher there straight away, the oncological pathologist Prof. Campanacci.« Prof. Mario Campanacci is rated as one of the fathers of today's classification of bone and soft tissue tumors.

Years passed. Orthopedics became increasingly popular as a specialty, the survival time for bone

»The creative side is what I like so much about my work« – **Prof. Rodolfo Capanna** heads the Department of Orthopedic Oncology and Reconstructive Surgery at the Centro Traumatologico Ortopedico in Florence

tumors grew longer and the Istituto Ortopedico Rizzoli established a bone tumor center. At its basis was an impressive collection of tissue samples and x-rays, some of them dating back to the 18th century. »Soon patients were coming to us from all over Italy to have their bone tumors classified« said Prof. Capanna. »That meant an enormous wealth of experience for us.« Instead of amputating the affected limb, the doctors at the Rizzoli Orthopedic Institute started to reconstruct the bone. »We always tried to rescue the affected leg, sometimes with the aid of an joint prosthesis« explained Prof. Capanna. »I learnt the necessary techniques at the Mayo Clinic in the USA.«

A task calling for creativity and skill

Just like any other doctor, Prof. Rodolfo Capanna is motivated by the challenges of trying new methods and thinking up ways to solve medical problems. »I tried out a great many different kinds of reconstruction in that period,« said Prof. Capanna, remembering his early years as a tumor surgeon, »first just with joint prostheses and then with allografts as well.« There was no shortage of patients. At that time, 90 percent of all the bone tumor cases in Italy ended up at the Istituto Ortopedico Rizzoli. »We compared many different joint prostheses and techniques« said Prof. Capanna. »That way we learnt which prosthesis is best for which patient.« Even then, operations could last seven hours and involve the loss of more than 12 centimeters of bone, demanding all the tumor surgeon's creativity and skill. »The creative side is what I like so much about my work« said Prof. Capanna.

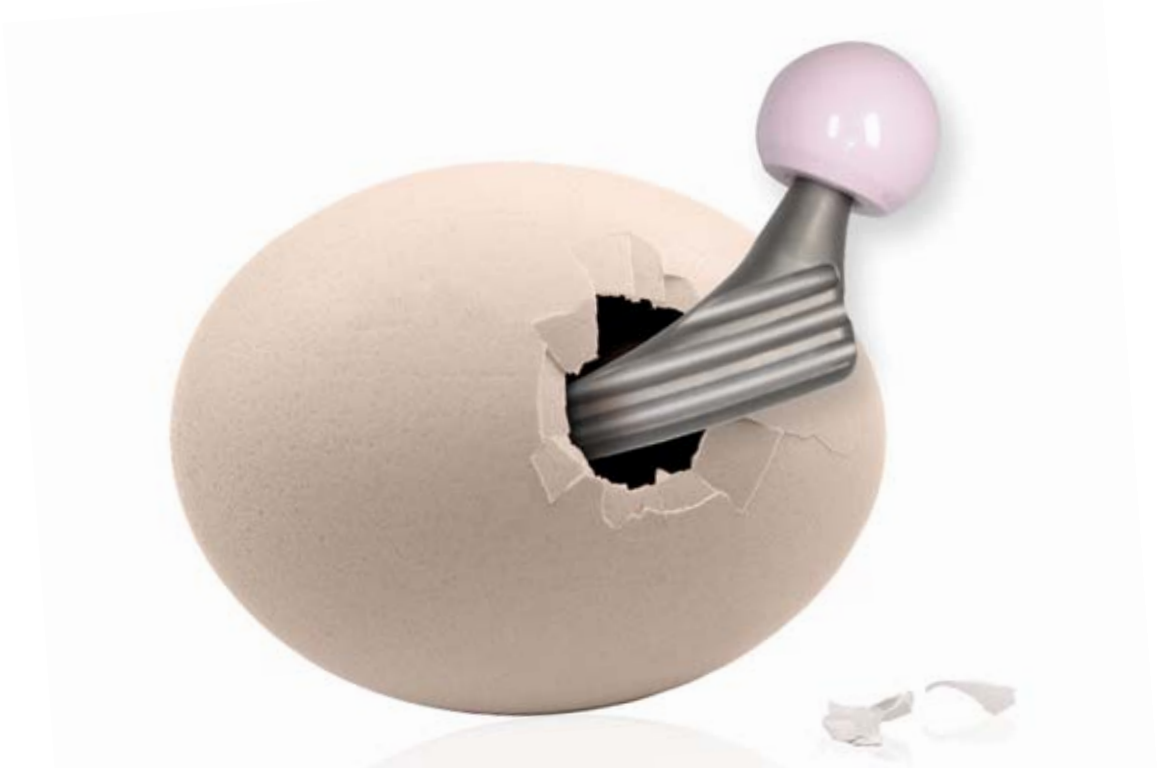
At last, in 1993, Prof. Capanna took over the Department of Orthopedic Surgery at the Centro Traumatologico Ortopedico in Florence and developed it into a Department of Orthopedic Oncology and Reconstructive Surgery. As Prof. Capanna explained, »At that time we were starting from zero because our specialty just didn't exist. The bone bank that we began back then is now one of the biggest in Italy.«

While developing the new department his contact with LINK, which had existed since his Bologna days, became more intensive. »The LINK rotational knee joint was superior to our knee prostheses at that time so we were, naturally, very interested in it« remembered Prof. Capanna. Later on, Prof. Capanna worked with LINK to develop a modular tumor and revision system called Megasystem-C®. Prof. Capanna described its advantages: »With Megasystem-C® we now have a system of implants for tumors and revision that can be combined with an allograft« he said. At present Megasystem-C® is still only available for the lower extremities. But, as Prof. Capanna added, »We are working with LINK to develop something similar for the shoulder-elbow area as well«.

»We all move closer together« – **Prof. Capanna** and his team of surgeons on the ward

»Hatching ideas takes time«

It can take five years for an idea to develop into a fully licensed prosthesis. Dr. Hans-Joachim Fischer and Dr. Thomas Mehler discuss what it takes to develop new products. Dr. Fischer is head of development at LINK's development company, DERU GmbH, and Dr. Mehler is head of quality management at LINK.



It is sometimes said that the ideas of well-known developers start out as sketches on paper napkins. Where does a LINK prosthesis begin its life?
Dr. Mehler: Many developments result from the structured product development processes that we use to work on feedback from our clients. But our medical product advisers and marketing and product management departments give us ideas and suggestions for improvements, too. Helmut Link also provides a lot of ideas himself because he is in close contact with our key clients.

Once an idea is born, what happens then?
Dr. Fischer: If the idea fits in our product range and is economically feasible, we discuss it with selected doctors and experts. The development process is complex. From the first calculations, the risk analysis, and the choice of materials right up to prototyping, everything is regulated down to the smallest detail. That means a process like this can take between 6 months and several years.

Exactly what makes the development process so long?
Dr. Fischer: The enormous complexity of the projects. For instance, a project to create a straight stem prosthesis could be expected to take about one month, on the basis of existing clinical experience. But with larger projects, like the tumor prosthesis system for the upper extremities, we can hardly refer to existing data at all, so it takes longer for the product to reach the licensing stage.
Dr. Mehler: A great deal of time goes into putting customers' requests into action and carrying out

licensing tests. After that, we hand over a detailed product file to the »notified body«. In our case this is TÜV, the German technical monitoring body, in Munich. Their evaluation process can take over 6 months but it's an essential requirement for licensing approval. Where innovations like new implant surfaces are concerned, the evaluators ask very wide-ranging questions.

Can the evaluators' questions still affect the development process?
Dr. Mehler: Yes, because the evaluators are our partners. They pose important questions which provide us with useful clues about the testing strategy and the clinical evaluation of our products.

Why are there still quality failures in arthroplasty products, in spite of the great care that is taken?
Dr. Fischer: Even the smallest changes - in production conditions, for instance - can have major effects. It's also the case that the failure of an implant usually becomes apparent only after about three years in situ. There just aren't any lab criteria for simulating the long term behavior of new materials or design constructions in vivo, or for taking into account all imaginable stresses and strains over such a long period.
Dr. Mehler: That's why we take so much care with analyzing the risks of the design, the production process and actual use. We involve all the necessary experts so that patient safety and product performance are as good as possible when a product reaches the market. To achieve this safety we may take a bit longer than the others to hatch our ideas fully, but LINK has always put a great deal of effort into development and has considered past experiences in the process.

Important though it is, doesn't the long development period hinder innovation?
Dr. Fischer: Yes and no. Anyone who wants to develop something innovative is forced to distance themself from the standard, and therefore from a normal licensing phase for the product. But this is where a long development period makes real sense, because you don't want to be doing your development work on the patient.
Dr. Mehler: We demand such high quality because patient safety and impeccable product performance are always top priorities. For LINK, »Quality without compromise« comes before »Innovation«. Our products are in Class III, the highest risk class. So the stringent requirements that govern the development process are justified, even though they can be a burden for LINK as a midsize company.

How could the licensing process be improved?
Dr. Fischer: For new products to be authorized, we can count on competent people who have been working in this sector for many years. But we would welcome a more extensive exchange of specialist knowledge between the »notified body« and industry.

Dr. Fischer, Dr. Mehler, thank you very much for talking to us.

Development of medical technology depends on complex processes« – **Dr. Hans-Joachim Fischer** heads the R & D department at DERU GmbH, LINK's R & D company.

»For LINK, »Quality without compromise« comes before innovation.« – **Dr. Thomas Mehler** is head of quality management at LINK.

CaP: Naturally well connected

Calcium phosphate (CaP) coatings are ideal for biological cementless fixation of joint prostheses because they promote exchange between bone and implant better than other surfaces. LINK uses several variants of these coatings.

Cementless implants derive their stability from a combination of mechanical primary fixation and biological secondary fixation. In the case of hip prostheses, mechanical primary fixation is achieved mainly with macrostructures such as ribs on the stem and/or by means of meta- or diaphyseal press-fit.
But it is the microstructures – porous rough titanium surfaces, plasma sprayed surfaces and CaP coatings – which promote the adherence of bone on the surface of the implant. The more osteoconductive the surface is, the more stable will be the bone that is subsequently adhered and therefore the long-term biological fixation of the prosthesis itself. Calcium phosphate coatings give better results than surfaces that have been grit-blasted or coated with titanium alone.
Several authors have included CaP coated im plants in comparative studies and have confirmed that these coatings resulted in faster biological fixation of the implants. [2,3,4]

CaP coating promotes exchange between bone and implant

The biological reaction of the bone environment to the implant is dictated by the roughness, the electrical charge and the chemical composition of the surface. A newly formed protein layer on the implant surface acts as a substrate to which cells can adhere. This biological exchange process between the bone environment and the implant surface involves three stages:

- the microsctructure of the implant surface triggers fibrin absorption and activates thrombocytes
- osteoblasts settle and begin to synthesize bone on the implant surface
- osseointegration takes place

Coating the implant with CaP reinforces this biological exchange process between bone environment and implant surface. The formation of bone on the implant surface (osteoconduction) involves the following steps:

- lowering of surrounding pH
- partial dissolution of the CaP coating in the surrounding medium
- increase in concentrations of calcium and phosphorus ions
- exchange of ions with surroundings
- resettlement of crystals with inclusion of proteins
- inclusion of extracellular ions in apatite crystals
- formation of collagen matrix and new bone
- increase in concentration of calcium and phosphorus ions stimulates chemotaxis

LINK combines two surface structures with different characteristics

The macrostructure of the implant and the microstructure of its surface both influence the stability of the coating and the quality of fixation, as does the mechanical stress exerted on the implant during implantation.

Stressed implants fix four times better than unstressed implants[5]. The surface of a coated implant, in particular, must meet a number of criteria in order for the implant to withstand stresses as effectively as possible. The structure of the surface must

- allow bone formation (osteoconduction)
- bond optimally with the implant, or else consist of the substrate surface itself, for the best possible adhesion
- be highly biocompatible
- allow osseointegration, and preferably possess osteogenic properties itself
- be strong enough for long term transmission of forces

One surface structure alone cannot meet all these requirements, so LINK combines two surface structures with different, but complementary, characteristics:

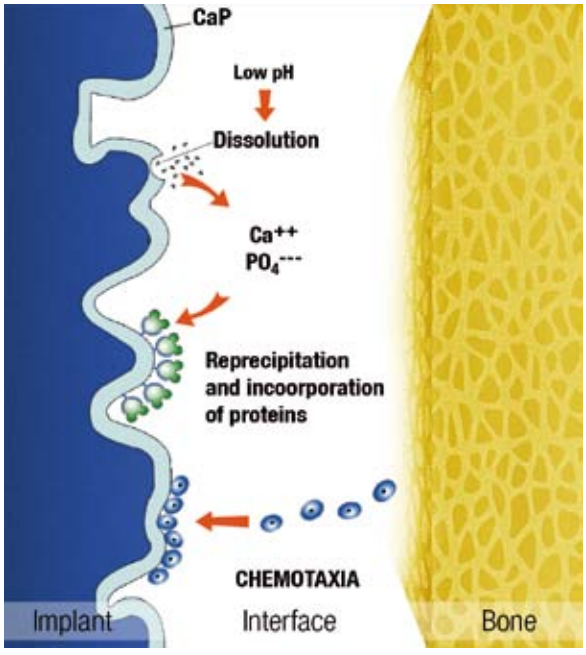
I. The first structure
(base structure, may include coating)

- provides the geometry for good macrostructural bone fixation
- ensures a positive bond with the implant or belongs to the implant itself
- has appropriate structural strength

II. The second structure (coating)

- is highly biocompatible
- promotes osteoconductivity
- adheres firmly

The LINK® TiCaP® double coating and the LINK® HX™ coating both possess the relevant characteristics. Like all materials used in LINK prostheses, their biocompatibility has been proven. They also possess good mechanical strength and high absorption capacity in the CaP area. They are manufactured in a tried and tested electrochemical coating process.



Osteoconduction process with CaP[1]

LINK Calcium Phosphate Coatings

LINK prostheses with HX™ coating

The hard HX™ coating used by LINK in the C.F.P. hip stem, for example, is 15 µm thin. It combines a corundum-blasted titanium substrate, whose structure is basically porous, with a CaP-coated surface to encourage optimal bone ongrowth. That means

- no need for an additional layer requiring firm fixation
- no additional chemical application to interfere with bone formation
- prosthesis stems are not exposed to heat which could reduce the quality of the substrate material
- the porous structure can be predetermined

What's more, LINK's HX™ coating is microcrystalline and, unlike plasma sprayed hydroxyapatite coatings, does not consist of monolithic structures. That means the HX™ coating achieves highly stable adhesion to the substrate, is very thin and – above all – dissolves rapidly to start osteoconduction. There is no danger of the delamination which can occur with hydroxyapatite coatings.

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Product name	Description	Application
PoroLink®	Coarsely blasted titanium surface Ra > 7 µm	Cementless fixation of titanium implants
PlasmaLink®	TPS, substrate coated with pure titanium	Highly porous pure titanium surfaces similar to TiCaP-coating but without the CaP outer layer
HX™	CaP directly on substrate	Calcium phosphate coating for cementless fixation of components in bone
TiCaP®	TiCaP = titanium plasma + calcium phosphate coating on substrate	Cementless fixation of titanium or cobalt-chromium components of different porosity. Pore size and number can be altered to suit the site of use, e.g. acetabular cup or ankle joint

»Whatever is said must have real substance« – **Prof. Christoph Lohmann** is director of the Otto von Guericke University Orthopaedic Hospital in Magdeburg, Germany.

»The thinking isn't nearly over yet!«

Prof. Lohmann, how have you settled into Magdeburg?
Very well! Magdeburg is a beautiful town of immense cultural historical importance. A lot of people here have made my arrival easier and supported me right from the start.

What were your reasons for taking up this position?
My predecessor, Prof. Wolfram Neumann, left behind a hospital spanning the whole of orthopedics. For instance, over 1,000 operations involving joint prostheses are carried out here per year. The fact that we provide medical care for the Saxony-Anhalt Olympic Support Center is also a major attraction.

What tasks does a professor have in orthopedics, as well as caring for the patients?
The Chair means overall representation of the specialty in research and teaching. It also means responsibility for the employees and leadership of the department as a business. I studied agriculture as a parallel subject, and in the process I learnt a lot of business things that I can apply here.

How do you plan your research projects?
I'm particularly interested in the biological reactions to implant materials and infections. We have established a study center that works with the study doctors to organize follow-up examinations and work-up clinical data. That has brought big improvements in data quality and in the way studies are organized. That's very important to me because, as a doctor and a scientist, I'd like everything to have real substance and to be presented that way too. That is only possible with scientific evidence.

How important to you is cooperation with manufacturers?
Very important, because many innovations can only be realized in cooperation with partners from the industry. Just recently, for example, we worked with LINK on further development of acetabular cups for revision. With the result that the new acetabular cups are now smaller than LINK's previous cups for large defects.

What is going to be the focus of arthroplasty over the next few years?
I think innovative surgical techniques and instruments will be the main focus. The idea of restoring the body's former geometry when a joint is replaced will also undergo a rethink. For instance, large femoral heads give the patient an ideal sensation when walking. But we have to admit that the results are not all that positive. There's also a lot of potential in relation to implant surfaces. We need factors that improve the adherence of bone. But here, too, the thinking isn't nearly over yet.

Prof. Lohmann, thank you very much for talking to us.

Total femur and tibia push-through prosthesis with medial tibia offset stem

Taking away people's pain, getting them moving again after a long illness and improving quality of life. At LINK we see these tasks as both our calling and our duty. If none of the prostheses in our product range will do the job, LINK develops and produces a custom-made implant of top technical quality. LINK archives all documentation, making it possible to adjust a custom-made prosthesis at any time if further revision is called for. We'd like to describe one particularly interesting case to you here.

Diagnosis

34 year-old male patient at the Mayo Clinic, Rochester, Minnesota with polyostotic fibrous dysplasia affecting the right pelvis, femur, tibia, fibula and foot. Intramedullary nails and bone screws had already been inserted to stabilize the femur and tibia.

Specifications

The aim was to improve stabilization of the femur and tibia and to ensure transmission of forces from the foot right up to the hip. The patient was therefore to receive right total hip and knee prostheses with long connected stems.

Treatment

The patient received a LINK custom-made prosthesis consisting of a total hip joint with push-through femoral stem connecting it to a total knee joint. This, in turn, was equipped with a push-through tibia stem reaching to the ankle joint with the option of ankle joint replacement.

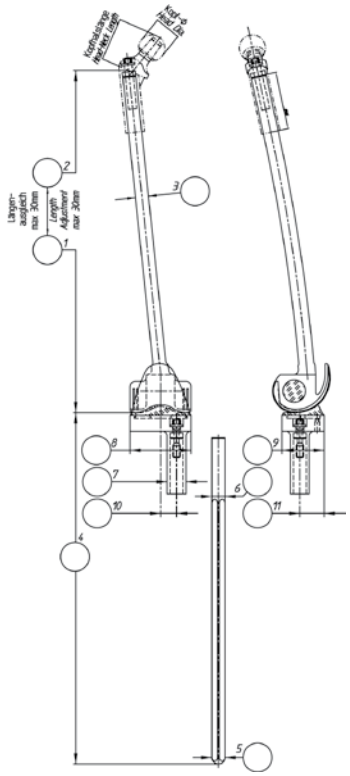
Further details of the custom-made implant:

- tibia casing with medial stem offset
- tibia stem can be inserted from proximal tibia; connection as for MP® prosthesis with sleeve and expansion bolt
- spacer rings allow stems (femoral and/or tibial) to be lengthened by up to 30 mm

Conclusion

LINK created an individual custom prosthesis to improve the quality of life of a 34 year-old man with polyostotic fibrous dysplasia of the right lower extremity. With this custom prosthesis it was possible to restore the stability of the affected extremity.

Preoperative: polystotic fibrous dysplasia; intramedullary nails and bone screws in situ for stabilization



LINK planning form for custom-made products: Push-through total femur and push-through total tibia with medial offset of tibia stem and bone screws for stabilization; ankle joint can be attached if required

LINK custom-made prosthesis: Push-through total femur and push-through total tibia with medial offset of tibia stem, can be extended during surgery by up to 30 mm

X-ray with planning superimposed: Push-through total femur and push-through total tibia with medial offset of tibia stem

Postoperative: Push-through total femur with rotating knee and proximally attachable tibia stem, which can be lengthened

Revision experts from 23 countries attend LINK International Revision Symposium

The LINK International Revision Symposium in Berlin was an exceptionally informative event thanks to its wide-ranging scientific program, top-class speakers and participants from 23 countries around the world.

Core topics at this event were an overview of techniques for knee and hip revision, the best approaches to reconstruction, the management of infections and the latest clinical results for revision prostheses and megaprostheses. The symposium, which was held at the Grand Hotel Esplanade in Berlin, was sold out in spite of wonderful weather. Both speakers and participants launched eagerly into discussions. All agreed that revision is becoming increasingly important for patients and doctors. The feeling among participants was that revision can bring unforeseen intraoperative situations calling for deviation from the surgical plan in many cases. With a steadily growing caseload, revision operations therefore demand a great deal, both from surgeons and from materials. Up-to-date strategies and clear guidelines for dealing with complex revisions are essential in order that safety and quality can be ensured at all times.

More revisions because of implant loosening and infections with cemented revision hip stems

Prof. Johann Kärrholm (Sweden) compared data from the Swedish hip register on cemented and non-cemented long stems in first revisions. He reported that the rate of revision for the whole country had remained constant over the past decade at just over 10 percent, with cementless revision hip stems being used with increasing frequency. »In 2010, modular stems were implanted in around two thirds of the cementless revisions in Sweden. LINK's MP® Revision stem was used in about one third of these cases« said Kärrholm. »We compared 1,073 cemented revision stems made by different manufacturers with 812 LINK MP® Revision stems. More re-revisions were needed because of implant loosening and infections among the cemented hip stems than among the cementless hip stems« said Prof. Kärrholm.

A survival rate of 98 percent after five years is achieved

Rüdiger Weiss MD PhD from Sweden presented the results of his 5 year follow-up study on the use of cementless modular conical stems in hip revision. As Weiss said when explaining the rationale for this study, »Immediate axial and rotational stability in the distal thigh bone is very important for the service life of the prosthesis.« In his study Weiss looked at 90 cases in which LINK cementless MP® Revision stems had been implanted. »The data show that, with the MP® Revision stem, a survival rate of 98 percent after five years is achieved.« Weiss also emphasized that the MP® Revision stem offers great variability of neck geometry and that the different lengths and diameters of the stems mean they can be chosen to fit the individual.

90 percent of all periprosthetic infections can be cured

Associate Professor Dr. Andrej Trampuz from Switzerland provided the participants with another interesting presentation. Speaking on the topic of »Hip revision in a septic environment«, Trampuz saw periprosthetic infections as being among the »simplest« of the complications occurring in hip revision. »Periprosthetic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infections respond well to a combination of surgical and antibiotic measures« said Trampuz, »as long as one goes about combating the infection in the right way.« According to Trampuz, this requires an understanding of how the biofilm is created, correct classification of the microorganisms involved, appropriate treatment and close cooperation between surgeons and infection specialists. As Trampuz said, »If these conditions are fulfilled, over 90 percent of all periprosthetic infections can be cured«. The implant can be retained provided that it is seated firmly in the bone, the symptoms do not persist for more than three weeks and neither fistulas nor resistant microorganisms are present. »In all other cases of periprosthetic infection, the implant must be removed« said Associate Professor Dr. Trampuz.

Metal allergy or low-grade infection?

In his talk on »Differential diagnosis in cases of implant allergy« Prof. Peter Thomas from Munich noted that the subject of metal implants and allergies is still controversial. At present it is still not clear which patients with metal allergies also develop complications associated with the implant. »Before an allergy is considered, other common causes of complications should be excluded, such as implant loosening, malposition of the implant and - above all - low grade infections« said Thomas. A reaction to the bone cement used is also a possibility. The clinical state, examination findings and medical history should then be considered and evaluated together. »But we need more follow-up studies to further verify the latest findings« concluded Prof. Thomas.

Gold-plated prosthesis for NATON

at the COA congress in China

To mark the 15th anniversary of Chinese partner company NATON, LINK's owner Helmut D. Link and CEO Norbert Ostwald presented their NATON colleagues with a gold plated prosthesis bouquet. The bouquet was made especially for the event by employees at the LINK factory in Norderstedt, Germany. NATON held a gala dinner for 3,500 invited guests at the 6th international congress of the Chinese Orthopaedic Association (COA) in Beijing.
In its sixth year the COA congress hit a new record with 15,000 participants, 9,500 abstracts submitted and 240 exhibitors. The satellite symposia on LINK products Megasystem-C® and the MP® Reconstruction hip stem attracted particular interest among participants and were almost fully booked. The congress was opened by COA chairman Prof. Yan Wang accompanied by guest of honor Helmut D. Link. Together with Chinese partners NATON, LINK was represented at the Congress as one of three Double-Diamond sponsors with 1,080 m2 of exhibition space.

The next COA congress will be held in Beijing on November 12 – 15, 2012.

»In China, too, people buy us for our Quality«

LINK is among China's market leaders in the imported joint prosthesis sector. We talked to LINK CEO Norbert Ostwald and CFO Peter Willenborg about German premium products, Chinese partners and interesting tasks for German surgeons in China.

What is LINK doing in China?
Peter Willenborg: We have two areas of activity in China. Firstly, we distribute LINK premium products very successfully via our Chinese partners. Secondly, we recently started a joint venture with our partners to produce high quality implants for the Chinese market.

How successful has this been?
Norbert Ostwald: None of the other markets we serve has shown such a persistently high level of growth as that in China. We're well into two figures there. In the mid-1990s, when we first got to know our present partners, we were one of the first importers of arthroplasty products in the

country. For us, China was just one export market among many. From the year 2000 onwards our turnover increased sharply.

What position does LINK occupy on the Chinese market today?
Peter Willenborg: We're running a permanent neck-and-neck race with our big American competitors for the position of China's number one importer. But the market is growing strongly. That's why we are extending our sales network further and further into China's large provincial towns. The increasing prosperity there enables people to spend more money on high quality.

What do you see as the reason for your lasting success in China?
Norbert Ostwald: We have never changed our Chinese partners. That way, we know each other very well. Our clients also perceive us as a reliable company with consistent quality. If you also have the good luck to attract and keep outstandingly talented people in marketing and distribution, then sooner or later you land up where we are now.

And what's the competition doing?
Peter Willenborg: The competition situation in China is the same as in the rest of the world, except that LINK is one of the market leaders. Our market share is around 25 percent and we're continuing to grow more strongly than the market as a whole.

Will LINK abandon its usual high standard in order to gain a greater share of the market with cheaper products?
Peter Willenborg: In China, too, LINK will never abandon its high quality standard. Our products are premium products worldwide. Because of the way they are made and the production standards we apply, they are not at the lower end of the price scale in any of our markets around the world.

What role is played by personal bonds in business activities in China?
Peter Willenborg: They play a very large role, which is why we place great emphasis on intensive academic exchanges with China and promote it with several events per year. For example, the LINK® Academic Sino-German Friendship Symposium will take place this year for the twelfth time.

»None of the other markets we serve has shown such a persistently high level of growth as that in China.«

What exactly is the Academic Sino-German Friendship Symposium?
Peter Willenborg: Every year we invite up to 70 Chinese doctors to come to Germany for a week. The Friendship Symposium takes place in three German towns and hospitals and includes lectures, workshops and live surgeries. During the symposium, German surgeons share with their Chinese colleagues surgical techniques and special treatments such as the management of infections. We also organize three other symposia including one for surgeons from China's provinces who don't yet speak English so well. In all, we play host to around 300 Chinese surgeons every year.
Norbert Ostwald: Our good contact with the academic world helps us to introduce new products. Many of the surgeons who visited us in Germany for the first time 15 years ago now occupy very important positions in universities and large hospitals in China. That makes us a little bit proud, too.

But you encourage exchange in the other direction too?
Norbert Ostwald: There is an unbelievably great need for good training in arthroplasty

in China. So we often travel to China with LINK users from Germany and other countries who train their colleagues in working with our products. This exchange is going to be considerably increased in the future. Anyone who is interested in taking part in the one-week program is welcome to contact LINK.

»In China, too, LINK will never abandon its high quality standard.«

Isn't too much German know-how being exported to China with the LINK products?
Peter Willenborg: Of course joint prostheses can generally be copied. The production details of the LINK products, and especially our unique know-how on the casting of implants, ensure that we achieve outstanding results in terms of long-term hardness and fracture resistance. These complex technologies can only be copied with very great difficulty.
Norbert Ostwald: In China, too, people buy us for our quality. You can't prevent know-how from being transferred in the process. In the joint venture with our Chinese partners we also develop and produce prostheses in China. With the most up-to-date technology, of course. We prefer to do it right straight away, together with our partners. That way, the know-how that we want to share gets used in the right place and in the interests of LINK.

What role do cultural differences play in business dealings with China?
Norbert Ostwald: I'm pleasantly surprised at just how similar we are. Negotiations can take longer. Language can be a barrier, too, when an interpreter has to translate everything. But after 15 years we understand each other extremely well and there's a high level of trust on both sides.

Do you notice the financial crisis in China too?
Peter Willenborg: Quite the contrary. In some European markets the effects of the financial crisis on the health care market are clearly noticeable. But China is a reliable partner for us in this phase, with continual growth and no negative impact on sales.

Can LINK's success in China be carried over to other markets?
Norbert Ostwald: We are very successful in China because we have very good partners and because we took certain risks that are now paying off. When you build up a market with distributors, a lot is bound to depend on your partners. It's similar in other markets. In that way our success in China can certainly be carried over.

Left: Peter Willenborg, middle: Prof. Yan Wang, chairman of the Chinese Orthopaedic Association (COA), in conversation with LINK directors, right: Norbert Ostwald:

How often are you both in China, personally?
Peter Willenborg: To be successful in China you have to have a one hundred percent trusting relationship with your Chinese partners and you have to live it on a personal level too. So we go to China regularly and meet with our partners in person at least once every three months. And of course we attend the important orthopedic events as well, like the international congress of the Chinese Orthopaedic Association (COA), which is held every year.

»We often travel to China with LINK users who train their colleagues in working with our products.«

To sum up, what are the most important factors for doing successful business in China?
Norbert Ostwald: Trust, courage and steadfastness in one's business relationships. The work that LINK has invested over the last 15 years is paying off, anyway. If we hadn't taken so much trouble at the beginning, there wouldn't be so many options open to us now. But that doesn't mean our work in China is sunshine all the way. We've also had years when things didn't go so well. So we're very conscious that we can't be successful all the time.

Norbert Ostwald, Peter Willenborg, thank you very much for talking to us.

Norbert Ostwald (below right) studied chemistry and worked in this area for a short time before moving over to business. After working as head of sales, European manager and sales director for American companies, he joined Waldemar Link GmbH & Co. KG in 2004. Since 2008 he has been CEO of Waldemar Link GmbH & Co. KG, investment casting foundry VACUCAST Feinguss GmbH & Co. Metall KG in Berlin and development company DERU GmbH. Norbert Ostwald is one of the directors of the joint venture in China.

Peter Willenborg (below left) is a business administration graduate. After a stint at PriceWaterhouse Coopers as Management Consultant Finance & Controlling, he took on leading positions in midsized consulting companies. He joined LINK in 2009, initially as business director for finance, controlling, IT, supply chain management and customer service. Since July 2011 Peter Willenborg has held the position of Chief Financial Officer (CFO), one of the three managing directors of Waldemar Link GmbH & Co. KG. He is on the board of several LINK group companies outside Germany and has responsibility for the finances of 15 LINK enterprises in Germany and abroad.

»The PET results for the **MP® Revision Stem** are very good«

Prof. Ullmark, in a pilot study you analyzed the formation of new bone following hip revision, mainly involving MP® stems by LINK. How did you go about this?
We wanted to know whether the body will form new bone even without a bone graft following a revision due to osteolysis or prosthetic loosening. So we used fluoride PET scans to measure bone metabolic activity around the hip prosthesis at various points in time following implantation. In addition, we also determined bone mineral density using dual x-ray absorptiometry (DXA). We used the contralateral femur of each patient as the reference value.

What were the results for the MP® revision stem by LINK?
The clinical and radiological results for the MP® stem by LINK are very good. The fluoride PET scan showed an increase in new bone formation of about 253 percent in the proximal osteolytic area one week following the operation. New bone formation also remained above normal even a year following the procedure.

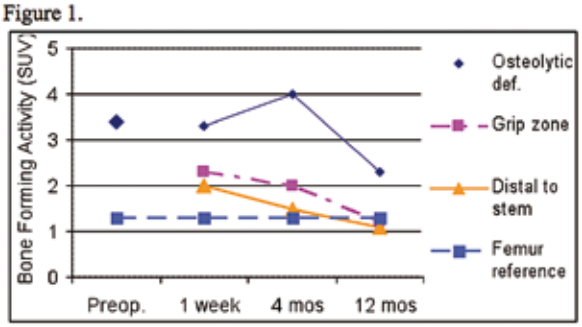
»We wanted to know whether the body will form new bone even without a bone graft following a revision.« **Prof. Gösta Ullmark**, Centre for Research & Development at Uppsala University/Sweden, is President-elect of the European HIP Society (EHS). He also invented the Ullmark instrument set for knee and hip osteoplasty.

And the distal region?
Bone metabolic activity in that area was about twice the normal value one week following the operation. New bone formation then returned to normal after one year. In all of the cases we studied the MP® stems were biologically stable and well-anchored in the bone.

What did the DXA analysis reveal?
Despite above-average new bone formation, the DXA bone density analysis revealed a net loss of bone material around the implanted hip prosthesis at 6 and 24 months post-op. Nevertheless, osteolytic defects decreased starting in the fourth month following surgery. After twelve months the defects were significantly below their respective values at the time of the revision.

What are your conclusions based on the study?
Using fluoride PET scans we were able to identify an increase in bone metabolic activity in the cases we studied - despite osteolysis and prosthesis loosening - which continued following revision. Of particular interest here is the fact that the increase in bone metabolic activity was found throughout the entire proximal region around the stem and not merely in the areas where the prosthetis stem had contact with the cortex.

Figure 1.



PET analyses: Bone forming activity in osteolytic zone and in grip zone adjacent to the stem. [1]

Do the PET scans involve a lot of effort and expense?
The level of effort and expense for each individual fluoride PET scan is very high. The patients have to be brought in for each scan and then returned to their hospital ward. At US$2,000 per scan, the associated expense is also considerable because it is necessary to run about 3 scans per patient. Our pilot study included 21 patients who were in need of a revision because of either osteolysis or prosthesis loosening. In total, we ran over 100 fluoride PET scans for this pilot study.

Thank you very much for talking with us, Prof. Ullmark.

Source:

[1] Ullmark G., Kärrholm J., Sörensen J.: "Bone metabolism analyzed by PET and DXA following revision THA using a distally fixed stem. A pilot study.", Hip Int. 2011 Jan-Mar;21(1):30-8.

Fine tools for surgeons

Sixty years ago, when company founder Waldemar Link developed the first of his own surgical instruments, his top priority was to find high quality solutions that were reliable and well thought-through. Today, LINK employees in the surgical instrument department carry on this tradition.

You can't overtake anyone if you just follow in other people's footsteps. Theo F. Huber is driven by the same realization that motivated film director François Truffaut to create his much-acclaimed works. For the head of LINK's Surgical Instruments business unit, the best possible surgical instruments are the result of craftsmanship that has been refined more and more over the generations. »We look at the instruments currently being used in operating theaters and we think how their functionality can be improved and their handling made easier.«

Long-lasting individual solutions for specialized surgeons

Ideally the result is a new prototype instrument. If the prototype proves satisfactory in daily use, it is turned into a product – or even a product family – for shoulder, hand, foot or spinal surgery. LINK's clients themselves show just

»I know a lot of experienced surgeons who have passed on their favorite LINK instrument to their successor after many years' use« – **Theo F. Huber** is head of the Surgical Instruments business unit.

how long-lasting these individual solutions often are. »I know a lot of experienced surgeons who have passed on their favorite LINK instrument to their successors after years of use« said Theo F. Huber.

Details make the difference

The precision workmanship involved in making good surgical instruments is fascinating. A new specification in spine surgery shows how important high quality details can be. »It became almost impossible to clean rongeurs to meet today's hygiene standards« explained Huber, »so the mechanics of the rongeur were altered. The instruments can now be opened, cleaned and closed again without tools, even during an operation.« The design is impressive. The rongeur is comfortable to hold and is available in a variety of forms. A color coded titanium screw indicates jaw size. »We specialize in difficult cases. That makes us typically LINK.« explained product manager Wolfgang Hilgert. »Surgeons can develop their own personal scissors with us.«

Surgeons are increasingly asking for complete solutions

It is not generally known that the Surgical Instruments department was the true origin of LINK as a company. »We're conscious of this history and tradition and we plan to demonstrate our competence in this market more intensively in future. In particular, we want to convince clients with our innovative solutions« said Theo F. Huber. »Surgeons are increasingly asking for complete solutions. As well as the instrument kit for the prosthesis, they want instruments for creating surgical access that will suit their own personal operating technique.« New developments now being made in surgery also call for newly designed instruments. They need to be smaller and finer and to be made from titanium or plastics so that they can be used in open MRI. They also need to be easy to clean thoroughly. Because cleaning agents for surgical instruments are becoming more and more aggressive, alloys are currently being developed which stand up better to cleaning cycles.

Made in Germany

LINK's surgical instruments are produced in Germany even though manufacturing costs are considerably higher than in countries with low wage rates. This is the only way to ensure reliable monitoring of material and manufacturing quality. The surface of a product can easily be made to look smooth on a macroscopic level. Only a microscope can show up any small holes in which germs can settle. »And so we demand high grade workmanship and quality right from the start« said Huber. »That's typically LINK too.«

»Surgeons can work with us to develop their own personal scissors.« – **Product Manager Wolfgang Hilgert** is a certified surgical instrument maker.

Ultramodern VC HIP unit

goes into service at VACUCAST®

VACUCAST® – a member of the LINK group – brought a new HIP unit into service in September 2011 to increase the long-term hardness of prostheses and make them more fracture-resistant. The ultramodern hot isostatic press has brought another marked improvement in the material properties of precision cast blanks. These blanks, which are made from alloys of metals such as cobalt-chrome-molybdenum and titanium, are hot-pressed and redensified under argon gas in a chamber at over 1,000 °C and pressure of more than 1,000 bars. This process eliminates even the finest pores. The special temperature management in the new HIP plant has a favorable effect on the amount, form and distribution of the structural components. The new process technology also ensures that downstream thermal treatments give even better results. Investment casting blanks produced in this way are fine-structured and homogeneous. The new HIP unit thus further improves the mechanical properties of LINK's casted items.

LINK extends and invests

New cleanroom and more production space for the LINK factory

In September 2011, after a year of planning, a new cleanroom was brought into service at the LINK factory in Norderstedt. The cleanroom qualifies as class C, meeting the requirements for producing implants in risk class III, the highest of the risk classes. All implant assembly work and quality control checks will be carried out in the new facility under cleanroom conditions. The factory was extended in October 2011, creating a further 800 m^2 of production area. Ultramodern processing centers are now being used there for the production of prostheses.

Firing the molds

Ceramic molds are fired in a **push-through furnace** which gives the molds their strength. The molds are then used to cast titanium, CoCrMo or stainless steel parts. VACUCAST® has specialized in manufacturing implant and instrument blanks for the medical sector since the 1970s.

Working on cast parts

Investment cast parts are irradiated, checked for cracks and HIPped (subjected to hot isostatic pressing). This gives the material important properties such as fracture resistance and freedom from pores. When making implants VACUCAST® uses only high-purity base alloys of titanium and cobalt-chrome whose chemical purity exceeds the requirements of the relevant standards.