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# **direct** Magazine for Arthroplasty

## »I really like it when a company can provide the whole portfolio«

Dr. Dirk Steinhagen, Head of the Clinic for Orthopedics at the Diakoneo Diak Clinic in Schwäbisch Hall, Germany

LINK Hip Revision Systems All the information on stems, femoral heads, acetabular cups, MobileLink inserts and TrabecuLink augments

#### Custom products from LINK

Here's how easy it is to order customized implant solutions from customLINK **MobileLink Acetabular Cup System** Case report of luxation-stable revision of a septically loosened acetabulum with inclining casing/insert adapters (Face Changer)



According to a study by the manufacturer HiPer Medical AG, LINK CeraDur has equivalent tribological and strength properties to other Zirconia-toughened alumina ceramics on the market, but does not contain chromium. Chromium compounds have no effect on the tribology and strength of femoral heads and inserts. The wear data are significantly more positive than the minimum values required by the U.S. Food and Drug Administration (FDA).



### Imprint

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### **Dear Readers!**

»No policy is better than the goals it sets.« That's what political scientist and former U.S. Secretary of State Henry A. Kissinger once said. The new Medical Device Regulation (MDR) shows that he is quite right. Dr. Bernd Buchholz (Free Democrats, FDP), former Minister of Economics in Schleswig-Holstein, Germany, gave us his view of the MDR during his visit.

Dr. Dirk Steinhagen also had a clear vision when he began seven years ago to develop the Orthopedics Clinic of the Diakoneo Diak Hospital in Schwäbisch Hall into a certified maximum-care arthroplasty center. In an interview, he talks about his long-standing relationship with us, his impressions of the Link OptiStem, and a development he is currently working on.

Part of LINK's mission is to find solutions for difficult cases. Our customLINK department develops reliable individual solutions that go beyond the successful standard implant systems for primary or revision care. Since the late 1960s, we have produced more than 40,000 custom implants. Now we have simplified the ordering process and laid it out on pages 16 and 17. The case of a young tumor patient who was implanted with a customLINK partial pelvic replacement in a 12-hour surgery can be found on pages 14 and 15.

I hope you enjoy these and many other topics in directLINK.

Yours, Helmut D. Link



# »I really like it when a company can provide the whole portfolio«

In seven years, Dr. Dirk Steinhagen has built up the Orthopedics Clinic of the Diakoneo Diak Hospital in Schwäbisch Hall, Germany, into a certified maximum-care arthroplasty center. In this interview, he talks about his relationship with LINK, his impressions of the Link OptiStem and a development he is currently working on.

## Dr. Steinhagen, what has changed since you took over the clinic seven years ago?

The Orthopedics Clinic did not exist like this seven years ago. My predecessor was a trauma surgeon and did basic arthroplasty as part of the trauma surgery department. We have rebuilt our clinic, formed a powerful team and got certified in 2017. Today, we are a maximum-care arthroplasty center, cooperate with the German Armed Forces Hospital in Ulm and receive patients from all over Germany – from Kiel to Stuttgart.

# When you took over the clinic, you changed your arthroplasty partner and are now essentially with LINK. What are your reasons?

I have a long-standing relationship with this company. LINK has also developed strongly, and I really like it when a company can deliver almost the entire portfolio. In addition, the collaboration is fun and I always feel well looked after at LINK. Last but not least, there are several world market leaders in our area who, like LINK, are family owned businesses. So it's a good fit.

#### You implanted the first Link OptiStems and one of the first LINK Embrace Shoulder Systems. What do you think about these implants?

With Embrace, I am particularly impressed by the versatility and high modularity of the system. The handling and feel of the instruments are more suitable for a hip surgeon like me than many other shoulder systems. For me, Embrace offers everything I need to customize a shoulder implant for a patient. Add to that the precision craftsmanship of LINK, and my decision to use Embrace was a logical one.

#### »We rebuilt our clinic, created a powerful team and got certified in 2017.«

#### Where do you see the greatest advantages of the OptiStem?

During revisions, delta or funnel-shaped defects often occur on the distal femur. Of course, we also use LINK's FlexiCones and MEGASYSTEM-C stems in such situations. But I am pleased that with the OptiStem there is an alternative which, due to its anatomical shape, anchors even better in the femur, is more rotationally stable, and allows me to offset the joint line with various adapters. We see more and more patients who have been implanted with a stem-anchored system during revision, which leaves large bone defects after removal. That is why it is very pleasant to work with the OptiStem, also because I like to do uncemented revisions. Many single-stage revisions we have done with the cementless OptiStem would have been difficult with a straight cemented stem. LINK has developed many cementless products in recent years with very good anchorage. I have been waiting for a stem like the



»We will soon be using the new digital portal from customLINK.« Dr. Dirk Steinhagen with nurse Christoph Sachs

OptiStem for a long time, as I already use LINK's Endo-Model family, which can be combined with the OptiStem.

#### Do you also use the cemented OptiStem?

Yes, because in the case of periprosthetic fractures, after removal of the old implant, you have a virtually virgin distal femur in front of you. Caution is advised with cementless implants, which can cause stem disruption. Especially for older patients with suboptimal bone quality, it is therefore important to also have a cemented version of the OptiStem available. For example, we had a very obese patient with a very thin femur into which the thinnest and longest OptiStem fit exactly. The patient is doing well today and can walk safely again. The previous implant had lasted only one year because it had no rotational stability.

## How do you proceed when there is no standard solution for a challenging case?

It's very simple: I send customLINK an e-mail with the necessary information and X-ray images, then we discuss the details for the custom design. I receive the planning by e-mail, I look at everything and confirm the order. Soon, we will be using customLINK's new digital portal for planning the custom-made products. We will be able to communicate directly with the engineer at LINK, by chat or in writing.

#### Together with LINK, you are developing an implant coating that you combine with an antibiotic. What's that all about?

The bone cement we have been using as an antibiotic carrier has a dose of about 100 times the mean inhibitory concentration (MIC) in the first few days. The new coating is a calcium-phosphateoil mixture that is highly fortified with gentamicin. However, it can be combined with other antibiotics according to antibiogram, because the substance does not get hot like bone cement and thus does not destroy the antibiotic. With gentamicin, which I use mostly with the new coating, the level is above 1,000 times the MIC for two days and then above 100 times the MIC for 30 days. At this dosage, over 90 percent of all germs are sensitive.

### How many patients have you used the coating on?

We have successfully performed more than 50 revisions with this procedure for periprosthetic infections existing for up to two years, of which about 20 were single-stage. The oil keeps the calcium phosphate in a paste-like consistency until it comes into contact with air or fluid, without interfering with prosthesis integration into the bone. I have only had to change one stem in my patients. However, this was undersized with an unfavorable medullary cavity shape and had therefore loosened. All the others are firmly integrated.

#### Can you describe a case for us?

We revised a patient with an infected distal femur fracture, with two plates



»I am pleased that with the OptiStem there is an alternative that anchors even better in the femur due to its anatomical shape.« Dr. Dirk Steinhagen

and pseudoarthrosis, to a distal femur replacement, applying the new coating to the OptiStem. The patient is now riding an e-bike again and is very satisfied. This was basically a one-stage revision into an infected tissue, but it worked well thanks to the new coating with gentamicin. However, surgical debridement is still the key in this procedure. The goal is that we no longer have to add intravenous antibiotics during revisions, because that is very stressful for patients.

»I have been waiting for a stem like the OptiStem for a long time, as I already use the Endo-Model family from LINK, which can be combined with the OptiStem.«

## How will you develop the clinic, where do you want to be in seven years?

Our hospital has a very large intensive care unit, a very capable anesthesia department, its own blood bank, cardiologists and a cardiac catheterization laboratory. So we can treat seriously ill patients. In orthopedics, however, we have more patients than surgical capacity. We want to change that. For example, we have already had fast-track treatment for two years and want to accelerate it further. Patients with hip and knee arthroplasties will then only have to stay with us as inpatients for one to two days. We are also bringing more affiliated physicians into the hospital and plan to outsource smaller surgeries to affiliated centers in order to have more room capacity for our larger surgeries. Last but not least, the construction of another operating room has been pending for a long time. Under Covid-19, everything has stagnated. But now things are finally set to move forward!

Dr. Steinhagen, thank you very much for the interview.



#### ABOUT

**Dr. Dirk Steinhagen, MD,** is Head of the Orthopedics Clinic at the Diakoneo Diak Klinikum in Schwäbisch Hall, Germany, a maximum-care arthroplasty center. He is restoring his Triumph GT6 MK1 from 1967 himself.

# Be adaptable.

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### LINK Hip Revision Systems Simplifying surgeons' lives

Intraoperative Flexibility · Great Variety Wide Range of Sizes · Selected Material Low Storage Need



# The LINK Hip Revision Systems at a glance

#### Stems

 LINK MP Reconstruction System Hip Stem (1) with proximal intermediate ring (2) and neck segments with suture holes (3) and neck segment standard (4):

The MP Reconstruction System (here the cementless version) combines all the advantages of a modular stem with the strong anchoring characteristics of a monoblock. Stem shape, elasticity and surface provide high osseointegration and strong primary stability. The modular connection is highly stable without proximal bone support, and the choice of anteversion, leg length correction and neck length is not dependent on distal fixation. More than 60,000 stems have been implanted since 1993, with a tenyear survival rate of 95.6 percent.

#### - LINK MP Monoblock Hip Stem (5):

The MP Monoblock is the shortest Wagner type revision stem on the market. The tapered stem (2 degrees) and wide rib geometry provide excellent axial stability with lower migration risk. The rough grid blasted Tilastane surface supports osseointegration and bone remodeling to provide long-term stability. The low risk of subsidence and the high offset version reduce the risk of dislocation to a minimum. The short taper and flattened neck provide a great range of motion.<sup>1, 2, 3</sup>

#### **Femoral Head**

 Femoral Head with LINK CeraDur (6) made of Zirconia-toughened alumina ceramics

#### MobileLink Acetabular Cup System

The MobileLink is available with a cluster-hole and a multi-hole pressfit cup (12). Both versions are available with a PlasmaLink coating, a TiCaP double coating and a TrabecuLink surface. The TiCaP dual coating combines a highly porous surface to achieve primary fixation and an osteoconductive HX<sup>\*\*</sup> calcium phosphate coating. The combination is designed to provide optimal primary and secondary stability through accelerated osseointegration.

#### **MobileLink Inserts**

In addition to ceramic and UHMWPE inserts, the MobileLink can be combined with modular offset and/or inclining casing/insert adapters (Face Changer). They allow the restoration of the anatomy and the necessary adjustments as well as the use of ceramic inserts for revisions. Dual Mobility Inserts made of EndoDur\*\*\* allow the MobileLink to be converted into a modular Dual Mobility System (DM), which reduces the risk of dislocation and increases the range of motion.<sup>4</sup> The DM insert can accommodate DM-Liners from the BiMobile Dual Mobility System made of polyethylene. Insert Standard\* (7):

- Casing/insert adapter (Face Changer), 4 mm offset, 20 gegree (8)
- Dual Mobility Inlay\* (9)
- Dual Mobility Insert (10)
- Insert luxation inhibiting\* (11)

#### **Acetabular Cups**

The acetabular cups are characterized by a secure fixation of the polyethylene inserts by a snap-lock mechanism as well as by conical coupling and antirotation tabs.

- TrabecuLink Cup, Multi-Hole (12):

The three-dimensional TrabecuLink structure provides excellent cell filling with its pore size, porosity and type of structure.<sup>5, 6</sup>

- TiCaP-Cup, Multi-Hole (13): The combination of rough titanium plasma plus HX coating<sup>\*\*</sup> promotes the bone ingrowth performance.<sup>7, 8</sup>

#### **TrabecuLink Augments**

The TrabecuLink Augments (14) offer an attractive solution for segmental acetabular defects as an alternative to structural allografts. The biocompatible material Tilastan-E and the TrabecuLink structure provide excellent conditions for stable and durable restoration of bone defects. In addition, the three-dimensional TrabecuLink structure with its pore size, porosity and structural depth has an excellent basis for promoting osseointegration and microvascularization taking into account the requirements of the structure-covering protein layer (fibronectin-vitronectin-fibrinogen).9,10 The augments can be combined with all LINK cups.

\*E-Dur: Highly cross-linked UHMWPE with added vitamin E \*HX: Rapidly soluble calcium phosphate \*\*E EndoDur: CoC/Mo / <sup>1-10</sup> Ilterature available by e-mailing to directlinkelinkhh.de



## MobileLink Acetabular Cup System with Face Changer: Dislocation-stable revision of a septically loosened acetabulum

In February 2021, a 72-year-old female patient, who had been fitted with hip arthroplasties on both sides since 2005, presented to the Hip Department of the Waldkliniken Eisenberg, Germany. The patient's medical history revealed increasing pain in the right hip joint, which had been limiting mobility for about two years. X-rays showed a loosening of the in situ screw cup on the right with migration of approximately 20 mm cranially and tilting to 85 degrees inclination as well as a destruction of the acetabular bearing dorsally by the screw cup. Microbiology of a puncture specimen from the hip joint revealed Staphylococcus epidermidis and confirmed the diagnosis of periprosthetic infection and septic loosened acetabulum.



The preoperative X-ray shows the total hip arthroplasties in situ on both sides; the migration of the screw cup on the right by approximately 20 mm to the cranial and tilting to 85 degrees inclination as well as the destruction of the acetabular bearing can be seen (1). The postoperative X-ray from March 2021 shows the spacer in situ on the right (2).

After complete removal of the right hip arthroplasty, surgical debridement and lavage in March 2021, a Girdlestone situation with spacer was created, according to in-house regimen in a two-stage procedure. The defect of the acetabulum was classified as Paprosky IIb.

Reimplantation of the hip arthroplasty with allogeneic spongiosaplasty to fill the defect cranially, performed in May 2021, confirmed a posterior acetabular wall destroyed dorsally by the screw cup. Because of possible impairment of the primary stability of the cup and to allow a press-fit, reimplantation was performed with 10-15 degrees of retroversion. A 20-degree Face Changer was implanted to set an anteversion to avoid an increased tendency to dislocation, resulting in an antetorsion of approximately 5-10 degrees. In addition, the revision cup was stabilized using two screws. The following components of the MobileLink Acetabular Cup System from LINK were used:

- MobileLink TiCaP Cluster Hole Size 62
- Face Changer 8 mm offset, 20° inclination
- Insert PE, Size E
- Screws 6.5/20 mm und 6.5/35mm

Postoperatively, the patient was partially loaded with 20 kg and gradually fully loaded after 6 weeks. The modular MobileLink Acetabular Cup System had made it possible to position the acetabulum securely and with stable luxation. Because the posterior acetabular rim was missing, implantation of the primary cup in slight retroversion was necessary to ensure stable anchorage of the cup. Thanks to the Face Changer, it was possible to set the inclination and anteversion within the anticipated »safe zone« according to Lewinnek. The result is reflected in the pain-free and safe mobilization of the patient. A control X-ray after 12 weeks showed a secure acetabular fit without secondary dislocation and clinically stable joint conditions.



Postoperative X-rays from May 2021 (3, 4) show the reimplanted total hip arthroplasty in situ; bottom: The postoperative X-rays of the 12-week follow-up show a fully bony integrated revision cup (5, 6).



»The MobileLink Acetabular Cup System from LINK offers the modularity we need intraoperatively to be able to respond to any situation. So I have the possibility to solve everything with one system — from the primary cup to the complex revision situation. What I particularly appreciate about the system is that I can use a dual-mobility insert in frequently unstable revision situations. This allows me to turn the primary or revision cup into a dual-mobility cup, which I can still screw and insert into larger defects.«



You can find a video about this case study via the QR code shown.



#### **ABOUT**

**Priv.-Doz. Dr. Steffen Brodt** is Senior Physician and Head of Hip Department at the German Center for Orthopedics at the Waldkliniken Eisenberg in Eisenberg, Germany.

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# »The results of our eight-year follow-up study show a 95.5% survival rate for the LINK Endo-Model.«

Dr. César Rocha has conducted a multicenter eight-year follow-up study of 45 primary rotating hinge total knee arthroplasties in a Latin American population using the LINK Endo-Model Rotating Hinge Knee. In this interview, he talks about the results of his study as well as his first implantation of a customLink OptiStem.

## Dr. Rocha, what exactly is your study about?

In Colombia, we have many elderly patients with valgus and varus deformities, some of whom have additional neurological disorders. The aim of our study was to present the results of a primary total knee arthroplasty (TKA) with a hinged prosthesis with a maximum follow-up of eight years and a minimum follow-up of one year.

#### How did you select patients for your study?

We included patients with a valgus deformity of more than 20 degrees or a varus deformity of more than 25 degrees who had a LINK Endo-Model Rotating Hinge implanted as the primary implantation. We also included patients with medial collateral ligament laxity, neurological disorders, and patients with functional problems, especially elderly patients. All patients were operated on by the same lead surgeon and according to a strict protocol.

#### What are the results of your study?

The results of our eight-year follow-up study showed a survival rate of 95.5% for the LINK Endo-Model. I think these are really good results for this type of product.

#### You also implanted the first customLink OptiStem in Latin America. Can you tell us something about this case?

The patient had a supracondylar femur fracture that was treated unsuccessfully with LINK's MEGASYSTEM-C, so a revision was required. We tried to implant a MEGASYSTEM-C with a long stem, but unfortunately that didn't work. Fortunately, we had the opportunity to contact colleagues in Europe who have a lot of experience, especially with tumor cases. They agreed with us on the use of the customLink OptiStem in this case. We then operated on the patient last November, and the result was excellent. Just 24 hours after surgery, the patient was pain-free. With the customLink OptiStem, the mechanical problems that had been the cause of his pain were gone.

## Why did you choose the customLink OptiStem?

When we were at LINK in Hamburg four years ago, Mr. Link introduced us to the OptiStem and what was special about this implant. Because of its conical shape, the OptiStem has not only single points for fixation, but whole areas. This significantly improves metaphyseal and diaphyseal fixation.





Figure 1 shows the demographics of the study



Figure 2 shows the functional results; OKS = Oxford Knee Score, APQ = Activity and Participation Questionnaire, KOOS-12 = Knee injury and Osteoarthritis Outcome Score-12. Right: System description of LINK Endo-Model Rotating Hinge Knee prosthesis

#### How is the patient doing today?

The patient is doing very well. The X-rays show no loosening. The man had been in excruciating pain for two years. Now he can walk again without pain. For a full evaluation of this case, of course, we have to wait up to a year after surgery, but for now the patient is doing well.

#### At the time of your patient's surgery, customLINK manufactured the OptiStem as a custom made product. How was your collaboration with customLINK?

It was really good. After we sent a panoramic image and a CT scan of the patient to customLINK, we received a preoperative 3D planning back. After the planning was approved, we got the customLink OptiStem. It's really great that customLINK offers the possibility to get patient-specific implants as a custom design.

## Dr. Rocha, thank you for the interview.



#### ABOUT

**Dr. César Rocha** is an orthopedic surgeon and traumatologist at the Fundación Cardio-Infantil and head of joint replacement at Los Cobos Medical Center in Bogotá, Colombia. He is also a past president of the Colombian Orthopedic Society.

## Successful interdisciplinary 12-hour surgery of young tumor patient with partial pelvic replacement from customLINK

The treatment of a 38-year-old female patient with an osteosarcoma in the area of the acetabulum, pelvic scapula and zones 2 and 1c of the sacrum required intraoperative collaboration between urology, gynecology, visceral surgery, orthopedics and trauma surgery. customLINK supplied a custom-made partial pelvic replacement with cementless stems for the 12-hour procedure at Leipzig University Hospital in Germany.

Initially, gynecological and urological procedures were performed. After subsequent gross dissection of the tumor, a vascular surgeon selected and separated the vessels affected by the tumor; the tumor could then be dissected free proximally and distally using custom-made resection templates.

In the next step, the partial pelvic replacement was attached to the caudal resection surface and screwed in place; all screws fit precisely based on digital surgical planning. The entire construct was then tilted laterally and placed against the superior resection surface. K-wires were then placed under radiographic control to temporarily fix the partial replacement in the desired tilt position. After placing a precisely fitting screw, the two ilium stem canals with diameters of 9 and 10 mm respectively were pre-drilled in a length of 115 mm under permanent X-ray control.

In the third and final step, the first and second stems were driven in, secured with the closure screws, and then a LINK BiMobile Dual Mobility Cup was cemented in place. According to the surgeon, this procedure achieved the best possible surgical result.



The preoperative 3D scans show the pelvic partial replacement projected by customLINK from the lateral (left), frontal (center) and dorsal (right) sides. A right partial pelvic replacement was planned, diameter 60/52 mm with TrabecuLink structure on the bone contact surfaces and cementless stems. The acetabulum has a diameter of 60/52 mm, the inlay 48 mm with a cement mantle of 2 mm; the inclination is approximately 45 degrees, the anteversion approximately 20 degrees.





Top left: Implant design (tabs, TrabecuLink structure on all bone contact surfaces): A = sacral connection, B = weight-saving connection; C = soft tissue connection holes (diameter 2 mm); D = foraminal hook; E = caudal connection; G/H = ilium screws; top right: F = polished recesses for nerve protection; bottom left: The implant was anchored in the sacrum with two ilium stems and cover screws and in the pelvic bones with cancellous bone screws: G = ilium stem, microporous, fin design, average 11 mm, length 120 mm including cover screw; H = ilium stem, microporous, fin design, average 9 mm, length 115 mm including cover screw; cancellous bone screws (orange), diameter 6.5 mm; bottom right: In planning, the center of rotation was cranialized by 20 mm to reduce the lever arm and allow caudal connection without further preparation.





# This is how easy it is to order a custom design from customLINK

customLINK develops reliable individual solutions that go beyond the successful standard implant systems for primary or revision care. Since the late 1960s, more than 40,000 custom implants have been manufactured, each of them carefully documented in an archive and thus fully traceable at any time. Based on many years of professional experience, customLINK finds effective solutions for each individual request. These include, for example, custom implants based on the LINK MP Hip Reconstruction System, the LINK Endo-Model Knee Prosthesis System or the LINK MEGASYSTEM-C Modular Tumor and Revision System, or custom pelvic partial replacement with components of the MobileLink Acetabular Cup System.

customLINK specialists work closely with ordering physicians and clinics to design, manufacture, sterile-package and ship the desired custom solutions. This quality-assured process typically takes four weeks from the time physician and clinic approval is received. See pages 14 and 15 for a report on the case of a 38-year-old tumor patient at Leipzig University Hospital for whom customLINK designed and manufactured a custom pelvic partial replacement. The custom design was planned by customLINK engineers based on the patient's CT data. To achieve this, they created 3-D models of the bone from the CT data through segmentation and designed the implant components based on this bone model. The ilium stem and custom pelvic component replacement were manufactured using additive 3-D



#### 5. Manufacturing

Your custom-made product is produced in a qualityassured manner, sterile packaged and sent to you.



printing after approval by the surgeons. Due to the large in-house manufacturing depth, customLINK was able to deliver the ordered implants four weeks after digital preparation of the design data and approval by the clinic's physician. Standard market delivery time is six to nine weeks. For more information on custom-LINK's additive manufacturing, scan the adjacent QR code with a smartphone.



enced medical device consultant.



LINK has several of these innovative systems for additive manufacturing (1). At the end of the production process, the powdery »cake« is removed from the machine (2). The freshly manufactured implants are exposed in a special blasting cabin (3).





### Politicians as guests at LINK

In the first half of 2022, Christine Aschenberg-Dugnus (FDP), member of the Bundestag and health policy spokeswoman for her parliamentary group, Andreas Rieckhof (Social Democratic Party of Germany SPD), State Councillor at the Hamburg Ministry of Economics and Innovation, and Dr. Bernd Buchholz (FDP), FDP Minister of Economics, Transport, Labor, Technology and Tourism of the State of Schleswig-Holstein, visited the LINK plant in Norderstedt. The politicians gained an impression of the production facilities and discussed the new MDR\* regulations with the management.



\* EU Regulation 2017/745 - Medical Device Regulation



# »Building bureaucracy against every rule of reason makes no sense«

Dr. Buchholz, what impressions will you take away from your visit to LINK? LINK is one of the »hidden champions« in the Schleswig-Holstein/Hamburg metropolitan region; a very exciting, expanding company with great dynamism. LINK has a considerable need for personnel; there are 89 vacancies, as I discovered today. This shows that many additional people could work here if it weren't for the shortage of skilled workers.

## What makes Schleswig-Holstein attractive for medical technology companies?

Together with Hamburg, we maintain the »Life Science Nord« cluster for medical technology, which attracts attention throughout Germany. In Germany's north with Schleswig-Holstein and Hamburg, out towards Lübeck and Oldenburg, there are many medical technology companies because they obviously find conditions that are very good for them.

## How do you assess the MDR and its impact on medical technology companies?

The regulation is a difficult European requirement. Especially for mediumsized companies, the recertification issue is a big hurdle. LINK has managed to a certain extent, even though it poses great problems to make the production of small batches economical despite the MDR requirements. What I take away from my visit is that politics must find other options. Especially when it comes to products that are only produced 50-100 times a year. Here, no large new scientific studies are worthwhile, and there must be simpler ways to obtain approval. Building up bureaucracy against every rule of reason makes no sense.

#### The development and market launch of arthroplasty products is shifting more and more to the U.S. because approval by the U.S. Food and Drug Administration, FDA, is easier to obtain. What is your opinion?

This is an obstacle to growth for Germany. The Berlin coalition agreement states that approval and planning procedures must be dramatically accelerated. If that doesn't succeed, entire industries will migrate abroad because the necessary permits are easier to obtain there.

#### Doing business with Iran is problematic: German banks are refusing to grant loans for fear of U.S. sanctions. Will that change in the foreseeable future?

There are several markets that are currently problematic for exporting companies, including sanction regulations against Russia. Of course, you can't do business with a country if it would create politically undesirable situations. In this respect, it is understandable that banks are critical of the risk of sales markets in a country like Iran. A more democratic regime would first have to be established there, and it would hardly be possible to do good business there before that. It would therefore be necessary to try to stabilize such countries.

Dr. Buchholz, thank you very much for the interview.



#### ABOUT

**Dr. Bernd Buchholz** (FDP) was FDP Minister of Economics, Transport, Labor, Technology and Tourism for the state of Schleswig-Holstein from June 2017 to July 2022; a doctor of law, he has been deputy state chairman of his party since 2013. In 2009, Buchholz was chairman of the executive board of Gruner + Jahr AG & Co. KG and was a member of the Bertelsmann AG Executive Board from 2009 to 2012.

# Live and on tape: »The Surgical World of LINK Embrace Shoulder System«

At the »Surgical World of LINK Embrace Shoulder System« on October 10 and 11, 2022 in Cologne, Germany, viewers were able to gain a detailed insight into the surgical technique of implanting a LINK Embrace Shoulder System in the TV studio and via livestream. In the subsequent »wetlab«, interested surgeons had the opportunity to implant a LINK Embrace Shoulder System in a human cadaver under the guidance of two experienced shoulder specialists.

The livestream was hosted by Dr. Ruiz Ibán (Madrid, Spain) and Dr. Martin Arbogast (Oberammergau, Germany). Shoulder specialists Dr. Pablo Cañete (Valencia, Spain) and Dr. Stefan Pietsch (Eisenberg, Germany) performed the surgery. For complete streaming of the event and dates of other events, visit www.linkademy.de.

Designed as a platform, the new LINK Embrace Shoulder System covers a wide range of indications: from elective procedures with anatomical prostheses to fracture and inversion procedures to conversion scenarios from anatomical to inverse or to rescue heads. The design takes into account many years of experience with successful implant systems and fixation concepts as well as the latest material and coating technologies.



For more information about the LINK Embrace shoulder system, please use the QR code or visit www.linkembrace.com.



# International events of LINKademy 2023

Since 2010, we have been promoting qualification in orthopedics and trauma surgery through high-quality continuing education and training under realistic conditions with the LINKademy. In order to intensify the dialogue between research and practice and to maintain the international network between medicine and industry, the LINKademy also organizes scientific symposia at which top-class speakers and trainers communicate current surgical techniques, clinical results and the latest standards.

Date	Content	Level	Product	Language
02/14–15	Level – Complex Knee Revision	Advanced	Endo-Model, FlexiCones	English
02/28-03/01	Level – Complex Hip Revision	Intermediate	MP, MobileLink	English
03/21–22	Level – Shoulder	Advanced	Embrace Shoulder System	English
04/04—05	Level – Uni to Total Knee	Excellence	SLED, LinkSymphoKnee	English
04/25–26	Rev:ease	Excellence	Revision Systems	German
06/23–24	LSK Care	Basic	LinKSymphoKnee	German
07/04–05	Level – Primary Knee	Advanced	LinkSymphoKnee	German
09/12–13	Level – Acetabular Replacements	Intermediate	MobileLink, BiMobile, Augments (LCU)	German
09/26–27	Training of Excellence Shoulder	Excellence	Embrace Shoulder System	English
10/10–11	Level – Primary Knee	Advanced	LinkSymphoKnee	English
11/10–11	Mega-C Care	Basic	MEGASYSTEM-C	German
11/14—15	Level – Shoulder	Advanced	Embrace Shoulder System	English
11/28–29	Level – Complex Hip Revision	Advanced	MP, MobileLink	English



For more information, visit www.linkorthopaedics.com or scan the QR code to the left. To register for a workshop, please contact your LINK medical device consultant or e-mail linkademy@link-ortho.com.









October 24 – 28, in Berlin



























The new LINK Embrace Shoulder System and the revision systems for complex cases were the central topics at the LINK booth at the German Congress for Orthopedics and Trauma Surgery DKOU in Berlin in October.

The new LINK Embrace Shoulder System is designed as a platform and covers a wide range of indications: from elective procedures with anatomical prostheses to fracture and inversion procedures to conversion scenarios from anatomical to inverse or to rescue heads. An insight into surgical techniques is provided by the internet livestream of the »Surgical World of LINK Embrace Shoulder System« recorded in October 2022 (see page 20). You can find the livestream on www.linkademy.de. For more information about the LINK Embrace Shoulder System, contact www.linkembrace.com.

Simplifying surgeons' lives – with its hip revision systems, LINK is taking on the promise of simplifying the lives of surgeons and surgical teams. With their intraoperative flexibility, great variety, wide range of sizes, selected material and low storage need, these systems represent an interesting portfolio for any orthopedic surgeon. For more information on the LINK revision systems for hip joints, please see pages 6 to 11 and visit www.link-hip.com.



At every DKOU, a popular place to go between lectures, seminars and workshops: Discussions among colleagues, with LINK medical device consultants and LINK management at the LINK booth in Hall 2.2, Messe Berlin.

NEWS

# Unbureaucratic and fast help from Poland for tumor patient from Ukraine

Shortly after the outbreak of war in Ukraine, customLINK was commissioned to manufacture an individual knee prosthesis based on the LINK Endo-Model for a 20-year-old Ukrainian tumor patient. The young woman had already received chemotherapy and was scheduled for immediate surgery. Unfortunately, once the implant had been completed, it was no longer possible to send it to the clinic in Ukraine.

Quick and unbureaucratic help then came from Rafal Skwirowski. The Sales Director of LINK distributor PCM Procardia Medical in Poland informed Dr. Jerzy Nazar, Instructor for the LINK MEGASYSTEM-C in Poland, and the management of the Heliodor Święcicki Clinic in Poznań, Poland, about the patient. They decided to treat her free of charge and let her go through the subsequent rehabilitation. Polish television reported on the case. You can access the article via the QR code on the right.









Pictures from the program »FAKTY« of the Polish TV channel TVE on April 10, 2022. Top left: The patient after her knee surgery; bottom left: Surgeon Dr. Jerzy Nazar; top right: the customLINK device used in the surgery.

### LINK and the Red Cross donate for Ukraine

A fundraising campaign for »Emergency Aid Ukraine« raised 5,100 euros via the LINK landing page of the German Red Cross. LINK employees set up an additional 13 collection boxes at the LINK Vacucast and DERU companies, collecting a further 500 euros. The management of the LINK Group doubled the total amount to 11,200 euros. Together with numerous donations in kind such as suitcases, drinking bottles, toys, hygiene articles and, baby carriages and baby carriages, the amount was handed over to the German Red Cross branch in Bad Segeberg, Germany.



Successful campaign by employees and management of the LINK Group: 11,200 euros and numerous donations in kind were collected for »Emergency Aid Ukraine«.

# New study: Twenty-year results of LINK C.F.P. Hip Prosthesis in primary total hip arthroplasty shows 94.9% Survivorship

Piakong, Pongsiri, et al. »Twenty-year results of a neck-preserving short-stem prosthesis in primary total hip arthroplasty.« Archives of Orthopaedic and Trauma Surgery (2022): 1-6.

Between January 1999 and December 2000, a total of 149 patients underwent A total hip arthroplasty procedure using the C.F.P. stem in a single institution.

At latest follow-up, 79 patients were available and were included in this study. The mean age of the cohort was 73.4 (range 44-92 years) with a mean follow-up of 20.7 years (range 20-21). Forty-six patients were lost to follow-up, while 24 patients were deceased due to other causes. The average age was 52.1 years at index procedure (range 21 -71 years). The most common indications were osteonecrosis (75.9%) and secondary osteoarthritis due to dysplasia (24.1%). The Kaplan-Meier survivorship free from revision for any cause at 5, 10 and 20 years was 93.2% (87.8% to 96.3%), 93.2% (87.8% to 96.3%) and 83.0% (75.7% to 88.3%), respectively. At 20 years follow-up, revision for any cause occurred in 26.6% (21 out of 79) of patients.

The most common causes for revision surgery were aseptic loosening, dislocation and polyethylene wear with 6.3% (5 out of 79), respectively. Peri-prosthetic fracture occurred in four patients (5.1%) followed by periprosthetic joint infection in two patients (2.5%). Among the 5 patients that underwent revision surgery due to aseptic loosening, all patients had loosening at the acetabular cup. The revision of the femoral stem was low, being seen in only four out of 79 patients (5.1%). The reasons for revision surgery of the stem were periprosthetic fracture and periprosthetic joint infection in two cases (2.5%), respectively. There was a statistically significant improvement of the Harris Hip Scores from 53 to 83.7 (range 56-91).

# Swedish Arthroplasty Register: LINK SPII has lowest revision risk and is reference system

The LINK SPII Hip Stem is named the reference system with the lowest revision risk compared to the other total hip prostheses on the market in the Swedish Arthroplasty Register's 2021 annual report\* (except BHR Upgrade (resurfacing prosthesis)). The LINK SPII stem is

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the most commonly used hip prosthesis stem in Sweden.

The Swedish Arthroplasty Register annually presents a ranking list that can be used to assess whether the revision risk of a particular system after surgery is at the expected level. This year, the registry presents an analysis for primary hip replacements performed for primary osteoarthritis with follow-up of five and ten years, respectively.

\* https://slr.registercentrum.se

### LINK products in the current scientific literature

Cohort analysis of two thousand nine hundred forty-three Link Lubinus SPII cemented total hip arthroplasties from a single hospital with surgeon stratification and twenty six thousand, nine hundred and eighty one component-years of follow-up Kropivšek L, Roškar S, Zore LA, Antoli V, Mavi B, Int Orthop. (2022 Apr), 46(4):797-804. DOI: 10.1007/s00264-022-05315, Epub 2022 Jan 25. PMID: 35076769

Distal femoral arthroplasty for native knee fractures – results from the Australian Orthopaedic Association National Joint Replacement Registry Aebischer AS, Hau R, de Steiger RN, Holder C, Wall CJ, Bone Joint J 2022;104-B(7):894–901

3D-printed porous Ti6Al4V alloys with silver coating combine osteocompatibility and antimicrobial properties Diez-Escudero A, Andersson B, Carlson E, Recker B, Link HD, Järhult JD, Hailer NP, Biomaterials Advances, DOI: 10.1016/j.msec.2021.112629

# LinkSymphoKnee

## Built on TRUST.



The LinkSymphoKnee System for primary implantations and revisions is characterized, among other things, by a broad size spectrum and high-end materials such as Cobalt Chrome. It is implanted with a slim, lightweight and ergonomic instrumentation that allows uncomplicated workflows and high reproducibility. The LinkSymphoKnee can be combined with LINK FlexiCones and with LINK PorEx components for metal hypersensitivity. For more information, please click on the QR code.