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Cirect LinkSymphoKnee

INSIDE

What surgeons in the U.S. are saying about the new LinkSymphoKnee



Imprint

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HARMONY IN FORM AND FUNCTION

The new LinkSymphoKnee for primary implantation or revision is available in 14 femur sizes and 10 tibia sizes. All configurations are approved for 2-up, 2-down size compatibility. LINK TrabecuLink FlexiCone sizes S, M, L and 2-zone neutral and proximal are compatible with the LinkSymphoKnee. E-DUR (highly cross-linked PE with antioxidant vitamin E) is available for the articular surfaces and patella, as is LINK



PorEx* surface modification for each configuration. The photo shows the LinkSymphoKnee in LINK PorEx with offset stem. Read more about the new LinkSymphoKnee in this special edition: click or scan the QR code.

* LINK PorEx: TiNbN = Titanium-Niobium-Nitride; surface modification (gold color)



Dear Readers,

A lot has happened since my father founded our family business in 1948. At the time, Link was no more than a specialty dealer for hospital supplies in Hamburg, Germany. Revolutionary implants such as the first German total hip joint prosthesis in 1963 and the Endo-Model knee joint prosthesis in 1979 were trendsetting in arthroplasty and paved the way for further groundbreaking LINK products. Today, 75 years and many new innovations later, LINK enjoys the trust of surgeons in many countries worldwide, including the USA.

This year, LINK launched a new implant system for primary knee arthroplasty, the LinkSymphoKnee. It is a complete and comprehensive knee system, based on many features and learnings from our very successful long history, including our Unicondylar Sled Prosthesis presented as early as 1968 and our Endo-Model Rotational Knee. The LinkSymphoKnee system is additionally available with a LINK PorEx surface modification and can be combined with the LINK FlexiCones.

In this special edition of our directLINK Magazine for Arthroplasty, you will find product information on the LinkSymphoKnee as well as interviews with U.S. surgeons who will report on their first experiences with the LinkSymphoKnee.

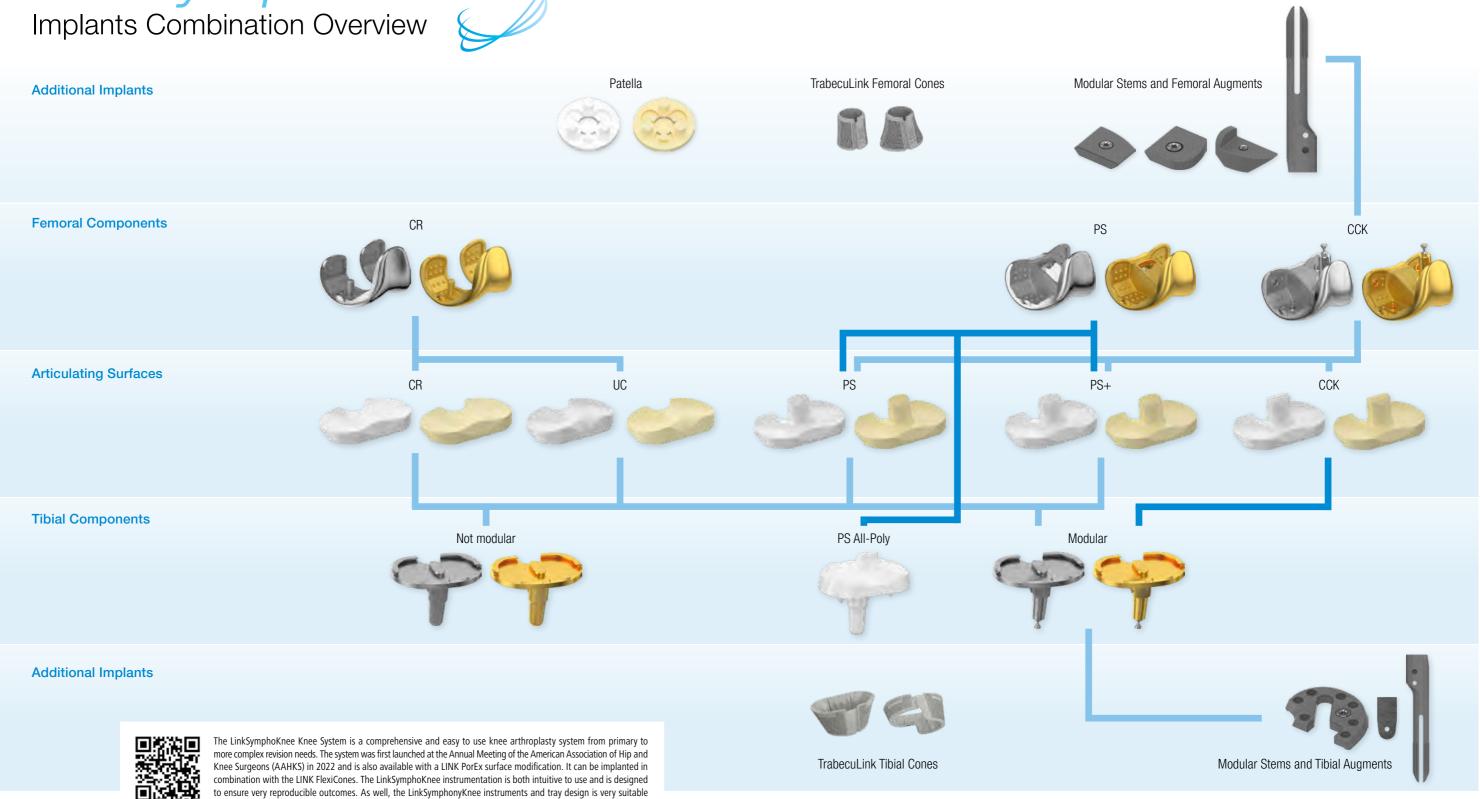
I hope you enjoy these and many other topics in direct $\ensuremath{\mathsf{LINK}}$.

Yours, Helmut D. Link

LinkSymphoKnee Implants Combination Overview

for smaller settings such as ambulatory surgical systems. Click or scan the QR code for more information about the

LinkSymphoKnee.







From left: Dr. Brett R. Levine and Dr. Alejandro G. Della Valle at the LINK booth at the Annual Meeting of the American Association of Hip and Knee Surgeons 2022 (AAHKS 2022)

»The LinkSymphoKnee optimizes the workflow and minimizes surgical time«

Members of the development group for the new LinkSymphoKnee include US surgeons Dr. Alejandro Della Valle and Dr. Brett Levine. In this interview they discuss instrumentation, workflow and early clinical results.

Dr. Della Valle, Dr. Levine, what is special about the LinkSymphoKnee? Dr. Alejandro Della Valle:

I think the LinkSymphoKnee has a number of features that are very attractive. The first is really the instrumentation, which was designed by a group of very experienced arthroplasty surgeons. Our goal was to provide precision and versatility in a relatively small number of instruments so that the surgeon does not waste time during surgery with unnecessary gestures related to instrumentation, sizing, positioning and rotation of components. The LinkSymphoKnee was designed to optimize workflow and minimize operative time. And that is what we have accomplished. *Dr. Brett Levine:*

The instruments are actually very good and I think they're pretty easy to use. They also offer some advantages over the ones that surgeons in the U.S. probably use for every other system they have, just with some nice little advantages on some of the guides. The 4-in-1 cutting block, for example, is very nice. Overall, though, the instruments give me the ability to go from CR to PS, PS+ or CCK without having to change anything in my workflow. Switching from CR to CCK doesn't take much effort either. This greatly simplifies the entire workflow when implanting a total knee arthroplasty. I think the instruments are one of the reasons why the LinkSymphoKnee delivers very good, reproducible results.

Dr. Della Valle:

When we developed the instruments, we went through a process called alpha launch. This means that the same surgeons review the first cases to make sure that the instruments are what the designers and the company wanted. We are still making small adjustments.

The LinkSymphoKnee has a relatively narrow femoral component. How important is this for your work? *Dr. Della Valle:*

In fact, another real beauty of the LinkSymphoKnee is that it is designed with a relatively narrow femoral component. The morphology between a male and female distal femur looks the same, but is different. In fact, the female distal femur is narrower and taller, which can sometimes result in a significant overhang of the femoral component in female knees. When the overhang is significant, patients complain of problems, including pain. That's why a number of orthopedic companies are struggling with excess inventory. The LinkSymphoKnee was designed with this in mind and is intentionally made a little narrower to fit both male and female anatomy perfectly. Also, some people have a relatively large femur in relation to the tibia and vice versa. With the LinkSymphoKnee you have upward and downward compatibility, so you can adapt the knee replacement perfectly to the patient's anatomy. It is even possible to connect a larger femur to a smaller tibia and vice versa.

Have you had patients where the LinkSymphoKnee has helped overcome difficult arthroplasty challenges? Dr. Levine:

With some other implants, we have had a number of revisions where the metal of the prosthesis in situ had separated from the cement. So, of course, the removal of the cement has created a hole in the tibia or femur. In this situation, it is good to know that the LinkSymphoKnee system is compatible with LINK's TrabecuLink FlexiCones. They are very easy to use and a great help in filling the defects so that the implant bonds with the cement and stays with the patient for a really long time.



The LinkSymphoKnee is available in 14 femoral and 10 tibial sizes. All configurations are approved for 2-up, 2-down size compatibility. E-DUR (highly cross-linked PE with antioxidant vitamin E) is available for the articular surfaces and the patella. The picture shows the CR version with LINK PorEx* surface modification.

 * LINK PorEx: TiNbN = Titanium-Niobium-Nitride; surface modification (gold color)





»With the LinkSymphoKnee, you have upward and downward compatibility, so you can perfectly adapt the knee joint replacement to the patient's anatomy.«

Dr. Alejandro Della Valle, MD

Dr. Della Valle:

As for the FlexiCones, I find them very attractive because they are so thin. Another wonderful feature of the LinkSymphoKnee is the easy transition between cruciate ligament-preserving posterior stabilization and posterior stabilization with a PS+ insert. This allows the best possible choice to be made for each patient, either preoperatively or during surgery. Sometimes a posterior cruciate ligament defect is found intraoperatively when you planned cruciate ligament preserving surgery. With the LinkSymphoKnee, you can quickly switch from a planned CR surgery to a PS surgery.

Transition to a PS could lead to ligament defects or an inability to balance the knee perfectly.

Dr. Della Valle:

In these circumstances, you can easily use a PS+ or semi-constraint insert to provide the stability that the slightly deficient ligaments cannot. This transition from cruciate ligament preservation to a constrained implant is built into the LinkSymphoKnee platform. It gives surgeons great confidence.

Dr. Levine:

We also had a lot of these cases with chronic instability of the knee joint. We were able to use a PS or a PS+ without changing anything and get a little bit more stability just by changing the polyethylene and not changing anything else in the workflow.

How was the transition from your previous knee replacement system to the LinkSymphoKnee? Dr. Levine:

I have used a number of different systems from different companies over the years. This has probably been the easiest of the transitions. I think the fact that I was involved in the development of some of the instrumentation made me feel more familiar with the system. But all in all, I would say it took maybe four or five implantations to get back to the same surgical speed and the same good reproducible results that I had with previous knee systems.

Dr. Della Valle:

With any new system there is a learning curve. With the LinkSymphoKnee, I had a head start because I was involved in the development of the system. But



LinkSymphoKnee CCK version with LINK PorEx* (available for each configuration).

* LINK PorEx: TiNbN = Titanium-Niobium-Nitride; surface modification (gold color)

my surgical technicians and nurses were not involved in the development of the implant or the instruments, and they just love it. They find the system very easy to use and have quickly adapted to the new instruments. And let me tell you, my operating times are comparable to what I've experienced with implants I've used for many years.

How does the system perform in your workday in terms of space requirements, cost efficiency?

Dr. Della Valle:

This is a very important point. The LinkSymphoKnee is designed to be used by surgeons who have different philosophies on how to perform a total knee replacement. This means that some surgeons will prefer certain instruments over others. What I have done in my hospital is to condense the wide range of LinkSymphoKnee instruments into a small number of trays that allow me to perform the surgery with the minimum



The LinkSymphoKnee is a complete system for primary and revision solutions. The picture shows the PS version with LINK PorEx* (available for each configuration).

* LINK PorEx: TiNbN = Titanium-Niobium-Nitride; surface modification (gold color)

»The LinkSymphoKnee system is very space efficient. There's also not a lot of turnover. It's very easy to move between cases, and you can do a lot of cases in one day if you want to.« Dr. Brett R. Levine, MD, MS

number of instruments required. Fewer trays means a happier nurse, less sterilization costs, less lifting, less draping and less shipping costs for LINK. Especially in an Ambulatory Surgical Center, a small number of trays is certainly advantageous, as they significantly increase efficiency in terms of turnaround time, sterilization and cost. Dr. Levine:

We create a lot of templates for our cases prior to surgery, which usually limits the implant selection to two or three sizes. So when we come into the OR, we only have about three trays that we need for the procedure. The LinkSymphoKnee system is very space efficient. The OR team is also happy because they only need a few trays and they take up less space overall. It also helps that the trays are not very heavy.

How are your clinical results? Dr. Della Valle:

I have done about 150 primary knees in the last year. The clinical results have been excellent for both PS and CR. Especially in terms of early ROM. The rate of stiffness or patients requiring manipulation under anesthesia was also extremely low. And to my surprise, they were lower than with other knee replacements I've used for so many years. Dr. Levine:

As a designer on the team, you are always a little worried because it is







The articulating surface of the LinkSymphoKnee All-Poly is identical to the PS insert.



LINK TrabecuLink FlexiCone sizes S, M, L and 2-zone neutral and proximal are compatible with the LinkSymphoKnee.

your baby they are working on. But we have been pleasantly surprised that the patients are doing very well. Right now, for example, my patients' range of motion is very good and they seem to be recovering very quickly. It is hard to say because we do not have the research behind it at the moment, but it seems that the patient's ROM is better than with my previous implants.

Younger people who need a knee replacement want to return to an active lifestyle after surgery. Can they achieve this goal with the LinkSymphoKnee?

Dr. Della Valle:

This is another important point. The LinkSymphoKnee was designed not only to try to replicate the shape of the bones. But it was also designed to try to replicate the way the human knee moves. And that is essentially the key to providing a range of motion and function that is similar to a non-arthritic knee in terms of being able to bend, straighten, rotate, translate and all those types of movements that you use for activities of daily living. Some activities are simple, like walking on a level surface. Other activities are much more complex. For example, swinging a golf club, playing tennis or dancing. And the LinkSymphoKnee is designed to perform not only the simple activities of daily living, but also the more complex activities, particularly those related to sports and recreational activities that involve so much rotation and complex motion. And I think that's one of the reasons why our patients are so happy with the LinkSymphoKnee.

What do you tell your patients about the type of implant they're getting? Dr. Levine:

For a standard knee replacement, I don't go into too much detail other than showing the patient the implant. We have a full plastic model that I show them that shows the different parts of the knee replacement. But I don't go into the intricacies of the implant itself. When patients bring up the subject of metal allergies, I explain the use of the LINK PorEx material.

Dr. Della Valle:

I don't necessarily go into the details of the brand or the design. I do get into the details when I see a patient who has a clear metal allergy or concern. And I generally discuss whether I'm going to preserve the posterior cruciate ligament or sacrifice it, but I personally don't get into that too much.

I think LINK has done a wonderful job. In terms of making sure that all the designers were working in a collegial environment, making sure that our voices were heard, taking our comments into consideration, following up on the actual things that we would highlight, and probably it was the attention to detail and the commitment to listening to the advice of the designers that resulted in such an excellent product. They put together a fantastic team of designers, engineers, administrators, it was a fantastic project.

Dr. Della Valle, Dr. Levine, thank you very much for the interview.

- High congruence - Cruciate retention option - 5-degree posterior slope Tissue-conserving design **1** = Posterior cruciate ligament (PCL) recess 2 = Patella recess

Symmetrical design

The LinkSymphoKnee Fixed Bearing Ultracongruent (FB UC)* The LinkSymphoKnee offers different articular surfaces dependent ing on the configuration: FB CR, FB UC, FB PS/PS+ and CCK. All surfaces have a dovetail locking mechanism on the posterior underside that engages with the tibial component through the corresponding recess. Final engagement with the tibial component is achieved by a snap-lock mechanism between the anterior aspects of the articulating surface and the tibial component. Additional rotational stability is provided by engagement between a central recess in the articulating surface and an antirotational island in the tibial component.

*510k pending



Dr. Alejandro Gonzalez Della Valle, MD,

is a hip and knee surgeon at HSS | Hospital for Special Surgery in New York, specializing in minimally invasive hip and knee replacement surgery, and arthroscopic

Dr. Brett R. Levine, MD, MS

ABOUT

surgery of the knee.

and replacement.

is an associate professor of medicine at Rush University Medical Center in Chicago and a service line director at Elmhurst Memorial Healthcare in Illinois. Dr. Levine specializes in hip and knee reconstruction



LinkSymphoKnee

Commentary from US surgeons about LinkSymphoKnee and the LINK company



Dr. Russel Russo, MD, is an orthopedic surgeon in New Orleans, Louisiana. While in Houston, he was a team physician for the Houston Texans, Houston Astros, Houston Rockets, and Houston Dynamo FC. He also served as a physician for NASA at the Johnson Space Center.

»With LINK I don't feel like just another user.

I feel like I'm really getting service. If there's something that frustrates me or that I think could be better, that's passed on immediately and I get feedback and results. They help me coordinate feedback and results from other surgeons to see where we have common ground. You don't get that kind of relationship with other companies.«

»There's a few parts of the instrumentation which help you skip steps that are unnecessary.

Such as drilling pins to hold it in place because of the precision of the instruments. Once you put it into position, it'll just stay there while you're making your cuts. All in all, the speed and efficiency is definitely improved from previous systems.«

»I think the PorEx option is advantageous for the system.

I had a patient who had another company's knee on one side but had some questionable pain that we could not really wrap our heads around what the issue was. When we did her other side, we use the LinkSymphoKnee and we used LINK PorEx surface modification. And the patient did well, had no issues. That was a case where you had a side-by-side comparison and the LinkSymphoKnee outperformed the competitor.«



Dr. Venkat R. Rapuri, MD, MS, FRCS (Edinburgh), FAAOS, is a total joint replacement surgeon in Arlington, Texas. He also is Medical Director of the Total Joint Replacement. Program

»How the LinkSymphoKnee has impacted on my workday is one of the reasons why it has become my standard knee replacement. So, if I'm doing a knee replacement, it is booked as a LinkSymphoKnee and not something else. It is my go-to basically, and that's how I book my cases. And I do close to 450 joints, of which a significant number of them are knee replacements and the majority of them are all LinkSymphoKnee systems.«

»If you fall behind the four degrees of variance of what the patient's anatomy is dictating, then you have a higher chance of failure obviously.

What LinkSymphoKnee does for me is that it addresses the degree of variance and keeps it closer to the neutral variance of patient's anatomy or at least within four degrees of patient's anatomy. It offers a platform, not just by PS alone, but a PS+. The PS+ will bring it back even if your cuts are slightly fractionally on the varus side or the valgus side, sufficient to put you back under four degrees, and keeps it closer to the neutral variance of patient's anatomy or at least within four degrees of patient's anatomy«

»A third of my patients are done as a same-day surgery.

That includes the Medicare elderly patient population all the way up to 75 years and older. They're able to get up, walk, go home the same day after the surgery. So not even requiring a hospital stay.«



Dr. Russel G. Benuck, MD, is an orthopedist in Chicago, Illinois. He is affiliated with multiple hospitals in the area, including Swedish Hospital and Northwest Community Hospital. »Being one of the early adopters, it's been remarkable to work with the group, to give and receive feedback and have discussions with them. We use a certain instrument and I say maybe it would be better if we did it this way or that way. And immediately they get back to me to talk to the engineers and come up with workflows, solutions or workarounds. Whenever we run into an obstacle, they're right there. And by the next meeting, they've already come up with two or three solutions to work around or overcome those obstacles.«

»I work in a community hospital. With that comes a unique patient population as well as unique staffing issues.

One of the things I like about this system is that it's a quick learning curve, not only for the surgeon but for the staff as well. With the LinkSymphoKnee device, I found that the learning curve is very steep and quick for both sides.«

»One of the things I worry about most in my patient population is them getting their flexion.

It's a challenge in my population sometimes getting in with physical therapy and being compliant with the home exercises. If I can eliminate at least one variable from that problem list, that's ideal. And I really think the LinkSymphoKnee does that so quite nicely.«

»The first patient I did the LinkSymphoKnee on came in at two weeks with no walker, no cane.

It was just remarkable how well she was doing just two weeks out. So far, the early postoperative results have been very satisfactory as far as patient satisfaction and just clinical results.«





»The LINK staff is very responsive and very thorough in addressing our questions. When we need implants for special cases, they are very good at getting them.«

Dr. Brett Levine, MD, is an associate professor at Rush University Medical Center in Chicago, and services line director at Elmhurst Memorial Healthcare in Illinois.



Dr. Russel T. Nevins, MD, Is an Orthopedic Surgeon in Las Vegas, Nevada

»All my guys are an A+. I couldn't be more pleased with them. They are there for me 24 hours a day, 7 days a week if I need anything. I'm just so thankful for the team, and I really think it has to do with the culture of LINK and

that it's a family business. It's very different than the orthopedic companies I've worked with before.«



Will McDonald, Co-Owner at Southern Medical Solutions in upstate Alabama, a medical device distributorship that specializes in Orthopedics and General/Vascular surgery

»I picked up LINK about two and a half years ago and it is definitely one of the best business decisions we've ever made,«

Will McDonald said in Kevin Brown's podcast »Device Nation« in May 2022. »They have been fantastic for us. Everyone at the company from logistics, to operations, to product management, their whole goal is to do anything they can to help us grow our business.«



Click or scan the QR code to go directly to the episode with Will McDonald



Meetings and professional discussions at the LINK booth at AAHKS 2022.

Over the past five years LINK has grown from a simple 10x5 foot tabletop display exhibitor to one of the marquee industry partners of the Annual Meeting of the American Association of Hip and Knee Surgeons (AAHKS) with over 2,000 attending surgeons, residents, and fellows.

Our massive footprint and impressive booth display has expanded to a 20x20 foot space with outstanding product displays and digital messaging for LINK products. Likewise, over the past two years the LINK team in the US has engaged our key opinion leaders in side events focused on TrabecuLink Cones, Complex Revision and our newest portfolio offering LinkSymphoKnee (primary and revision options). In 2023 LINK will continue its partnership with AAHKS and again to promote our global suite of products at this very important congress.

AAHKS was established in 1991 with a mission to advance hip and knee patient care through education, advocacy, research and outreach. AAHKS addresses a broad array of scientific topics such as implant design, outcomes, surgical techniques and complications of primary and revision total joint arthroplasty (TJA) for hip and knee surgeons. The meeting addresses the latest socioeconomic issues in health care.

Special courses are also offered for residents, non-physician team members and surgeon administrators. Held in Dallas in November each year, the Annual Meeting typically attracts around 4,600 clinical and industry attendees. While most of the faculty and attendees are from the United States, there are attendees and faculty who join scientific panels from Canada, the UK, Europe, Australia and Latina America.



Click or scan the QR code to go directly to the homepage of the AAHKS.

LINK PorEx* surface modification is available for all LinkSymphoKnee configurations

The LINK PorEx surface modification has been shown to significantly reduce chrome and nickel ion release.^{2,4} Here is what you need to know about LINK PorEx.

LINK PorEx is a titanium niobium nitride (TiNbN) surface modification that has been used in Europe for over 25 years. The LINK PorEx surface modification contains the elements titanium and niobium but no chromium or nickel.

LINK PorEx has a lower coefficient of friction^{2, 3, 4} compared to polyethylene (UHMWPE) due to its outstanding hardness, ceramic-like abrasion behavior and optimal wetting angle when in contact with fluids. Implants with LINK PorEx surface modification exhibit optimized sliding and friction properties.

The LinkSymphoKnee is a complete knee new system from primary to revision. The picture shows the LinkSymphoKnee CR with LINK PorEx surface modification (available for each configuration).

* LINK PorEx: TiNbN = Titanium-Niobium-Nitride; surface modification (gold colour)



In addition to its great hardness, biocompatibility^{5, 6, 7}, high corrosion resistance^{8, 9} and wear protection, LINK PorEx also features pronounced adhesive strength and high fatigue resistance¹⁰. The thickness is around 4.5 \pm 1.5 µm. In terms of hardness, LINK PorEx reaches values of approximately 2400 HV (0.1 N), compared to approximately 550 HV (0.1 N) for CoCrMo alloys.

> LINK PorEx is available for all configurations of the LinkSymphoKnee system in addition to LINK products such as the Unicondylar Sled prosthesis and the Endo-Model Knee Prosthesis System.

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»Today, with the risks of infection and sleep deprivation in the hospital and improved post-operative pain control, patients are requesting the ASC setting.« Dr. Keith Pitchford

»Reducing the overall labor, material and reduce burden on staff is a critical component to the success of the ASC«

Ambulatory Surgical Centers (ASCs) are a growing facility for U.S. physicians. However, as shareholders of ASCs, physicians face cost pressures. LINK offers the LinkSymphoKnee, a particularly interesting product for ASCs. Keith Pitchford, MD., specializes in knee conditions at Great Lakes Orthopedics and Sports Medicine, P.C., in St. John, Indiana, which he founded. In this interview, he talks about what makes LinkSymphoKnee so useful for ASCs.

Dr. Pitchford, what are you looking for in a knee system when considering a TKA at your surgery center?

The knee system for an ASC setting needs to have a manageable number of trays, which means 2-3 per surgery at the most. Obviously, enough to get the job done, but not too many to slow down the reprocessing workflow. This makes turnover easier. There also needs to be an efficient and consistent process to allow for efficiency of the procedure and not too complicated to confuse the staff. Not an onerous learning curve for the staff assisting during the procedure.

How has the instrument design been beneficial in the ASC setting?

The Link system is beneficial in the ASC setting because it provides an efficient use of trays that does not overwhelm the sterile processing in the ASC. Also, the actual instrumentation is designed so that the multiple use of instruments reduces the number of instruments required and makes the procedure more efficient. ASCs are extremely selfsufficient but have somewhat limited storage space, washers, and sterilizers compared to an acute care hospital. Therefore, from an implant partner's

perspective, reducing the overall labor, material and residue burden on staff is a critical component to the success of the ASC.

Is there peace of mind in having LINK PorEx or PS+ options when doing surgery in the ASC setting?

The system also provides for an easy transition from a posterior cruciate ligament saving procedure to a sacrificing procedure with the same kit and very few additional steps. This facilitates the ability to obtain accurate and efficient ligament balancing.

What are the main reasons total joint replacements in ASCs will continue to grow over time?

The future of total knee arthroplasty in the ASC setting is and should continue to grow for the foreseeable future because of many efficiencies. The public is becoming more aware of outpatient joint replacement. Complication rates for ASCs are lower because patients' medical conditions are optimized prior to surgery. The collaboration between surgeon and anesthesiologist is facilitated by more efficient communication and medical control in the preoperative setting. This optimization of the patient's medical condition is paramount to a successful ASC joint program.

How do patients benefit from the site of service change from traditional hospitals to ASC?

The patient benefits with the venue change as their perspective shift from a passive participant to an active one is the big change. The change provides the confidence that the surgery will be performed efficiently with medical optimization, and the confidence that their pain will be managed and their functional ability to ambulate and perform activities of daily living will be preserved means that patients will seek out the ASC setting for their joint replacement. The other big issue is the reduced risk of infection from COVID and nosocomial pathogens, which has been researched and proven time and time again.

Do you think that commercial payers will continue to encourage surgeons to look at the total cost of care in order to participate in their payer networks? Do you believe that these payers will continue to build their provider networks based on this cost? The cost structure is a significant feature of outpatient total knee arthroplasty. The providers are tracking the cost efficiency of the ASC and each surgeon's

cost profile, and as the paradigm continues to evolve over time the push for cost containment and improved outcomes provides value for all parties involved. The patient has a more efficient surgery and recovery, the physician has more control over the procedure and the insurance carrier has a value proposition.

In your mind, do patients generally have a better experience in an ASC format or in a traditional hospital setting?

The patients of an ASC clearly have a better experience than in the traditional setting. The disruption to their life and lifestyle is reduced, the pain control measures for outpatient surgery are improved and longer lasting, which leads to improved satisfaction and more efficient recovery. The LinkSymphoKnee has been a big part of the improvement for me because the stability gives the patient confidence to walk and do outpatient physical therapy, which hastens their recovery.

What is your primary driver in determining the best site of service for a patient?

The primary driver in determining the site of service is the patient. Their overall health and motivation and whether they have had surgery in an ASC before. Today, with the risks of infection and sleep deprivation in the hospital and improved post-operative pain control, patients are requesting the ASC setting. As long as the patient is in reasonable health (optimized preoperatively) and motivated with home assistance for at least a few days to two weeks, they are a perfect candidate for an outpatient total knee arthroplasty.

Dr. Pitchford, many thanks for the interview.





ABOUT

Dr. Keith Pitchford is the founder. president and CEO of Great Lakes Orthopedics & Sports Medicine, P.C., in St. John, Indiana. He is also an Adjunct Assistant Professor of Orthopedic Surgery at Midwestern University and is affiliated with several other area hospitals. Dr. Pitchford specializes in hip conditions and reconstruction, knee conditions and sports medicine.

Primary and revision cases with the LinkSymphoKnee

CASE I: Aseptic loosening of a total knee arthroplasty left (revision) by Dr. Brett Levine

A 61-year-old female patient presented to Midwest Rush Orthopedics at Rush University Medical Center because her left knee pain had increased over the past decade, especially in the past six months. The patient was limping and her quality of life was diminished.



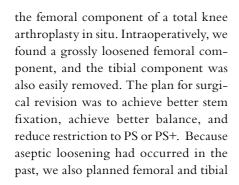
Top left to right: X-rays from 2012, 2018, and 2022 show gradual aseptic loosening of the femoral component. Bottom left: Preoperative plan included achieving better balance, reducing restriction to PS or PS+, and femoral and tibial cones; middle and right: LinkSymphoKnee with LINK tibial and femoral LINK FlexiCones in situ.



The patient had no significant past medical history. Examination on admission revealed a range of motion (ROM) of 0-115 degrees and recurrent effusions; C-reactive protein (CRP), serum erythrocyte sedimentation rate (ESR), and aspiration were negative.

X-rays from 2012, 2018, and 2022 showed gradual aseptic loosening of





tapers. At surgery, we restored the poste-

rior condylar offset, maintained the joint line, and improved stability by using a LinkSymphoKnee PS+, with LINK FlexiCones on both sides, and a bypass for the loosening site.

At the first follow-up three weeks after surgery, the patient had a ROM of 3-110 degrees.

CASE II: Varus case (primary) by Dr. Brett Levine

A 76-year-old female patient presented with left knee pain that had been present for five years and had worsened, especially over the past six months. The patient was limping and her quality of life was diminished.



Top left to right: Preoperative X-rays show significant degenerative joint disease. Bottom left and middle: Postoperative X-rays show the LinkSymphoKnee in situ.; right: X-rays at one-year follow-up.

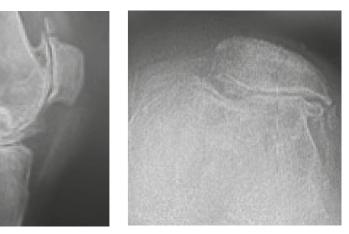


Preoperative X-rays show significant degenerative joint disease in all three compartments. Intraoperatively, significant medial bone loss was noted. We performed an 8-mm resection on the medial side and a 10-mm tibial incision on the lateral side, restored the posterior condylar offset, maintained the joint line, and implanted a LinkSymphoKnee CR. No intraoperative complications

occurred. The mechanical axis was neutral, and tracking was excellent.

At one-year follow-up, a very satisfied patient reported no pain; ROM in the knee joint was 0-120 degrees.













Dr. Brett Levine, MD, is an associate professor at Rush University Medical Center in Chicago, and Services Line Director at Elmhurst Memorial Healthcare in Illinois.



CASE III: Severe valgus deformity (primary) by Dr. Venkat R. Rapuri

A 65-year-old female patient with severe valgus deformity of the right knee, a CCK prosthesis in situ on the left side, and chronic instability of both knees presented to Texas Health Arlington Memorial Hospital. The patient also had a history of hypertension and type 2 diabetes mellitus.



Top left and right: Preoperative X-rays show a CCK in situ in the left knee, a severe valgus deformity of the right knee (15 degrees), and gradual aseptic loosening of the femoral component. Postoperative X-rays bottom: LinkSymphoKnee in situ



On admission, the patient stated that she had been suffering from knee pain for at least five years, and that it had gotten worse in the last two years. She also limped and felt that her knee joints were very unstable when she walked. Despite the use of a walker, the patient had fallen several times.

Her orthopedic examination revealed a severe valgus deformity of the right knee (15 degrees). There was a gradual aseptic loosening of the femoral component.



Her knee had a range of motion (ROM) of 5-90 with no extensor lag, less than 2 mm of A/P instability, and more than 4-6 mm of M/L opening in the varus/ valgus plane.

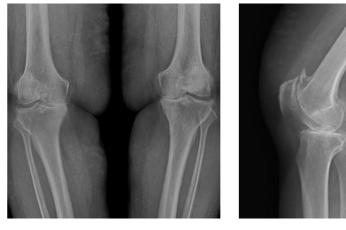
During surgery, we corrected the severe valgus deformity and performed soft tissue corrections to achieve a well-balanced knee. Although this sometimes requires the use of a semi-constrained knee replacement, we were able to provide the patient with a LinkSymphoKnee



PS+ poly with a capped tibial plate. Postoperatively, the patient no longer limped and stated that the feeling of knee instability had disappeared.

The patient's postoperative ROM is 0-120 and her knees feel very stable in the A/P and M/L planes.

CASE IV: Significant degenerative joint disease left and right (primary) by Dr. Venkat R. Rapuri A 64-year-old female patient with severe obesity (BMI > 40) and right > left knee pain for more than one year presented to Texas Health Arlington Memorial Hospital. She had a medical history of congestive heart failure, atrial fibrillation, and type 2 diabetes mellitus.



Top left and right: Preoperative X-rays show significant degenerative joint disease. Bottom: Postoperative X-rays show the LinkSymphoKnee on both sides.



The patient's main concern was her weight. She reported that she wanted to lose weight but was unable to exercise sufficiently due to severe pain and knee deformity. Despite her best efforts, she continued to gain weight.

Her problems had worsened over the past two years. Examination revealed a ROM of 10-90 without extension lag, less than 2 mm A/P. During surgery, we implanted a LinkSymphoKnee bilaterally. While the current trend by most of the adult reconstruction surgeons in America is to stem the tibial complement when the patients BMI crosses more than 40, we were able to use a capped tibial plate, which essentially acts as a stemmed tibial component, giving her the added stability and fixation.

Postoperatively, the patient has a ROM of 0-120 and her knee feels very stable in both A/P and M/L. Radiographs show that she no longer has severe knee flexion. She is now able to walk









straighter and at a good steady pace, take long walks, exercise, eat healthily and be on a diet to lose weight significantly. She has already lost nearly 15 kilos.



Dr. Venkat R. Rapuri, MD, MS, FRCS (Edinburgh) FAAOS, is a total joint replacement surgeon in Arlington, Texas. He also is Medical Director of the Total Joint Replacement. Program



CASE V: Severe valgus deformity (primary) by Dr. Russel G. Benuck

An 81-year-old female patient presented with severely deformed valgus osteoarthritis of the left knee. Her BMI raised concerns that she would require a tibial-sided stem. It was suspected that a monobase and stem-cap-only approach would not meet the patient's desire for a more active lifestyle with appropriate activities in the long term.

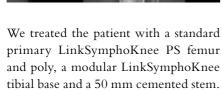


Top row: Preoperative X-rays show a severely deformed valgus osteoarthritis of the left knee. Bottom: Postoperative X-rays show the LinkSymphoKnee with the cemented tibial 50mm stem in situ.









Postoperatively, the patient is active, pain free and doing very well. She is looking forward to having her right knee replaced once she is fully recovered.



Dr. Russel G. Benuck, MD, is an orthopedist in Chicago, Illinois. He is affiliated with multiple hospitals in the area, including Swedish Hospital and Northwest Community Hospital.

CASE VI: Significant degenerative joint disease left and right (primary) by Dr. Russel Russo

A 61-year-old muscular male patient presented about 1 year ago with osteoarthritis of the medial knee compartment. Previous therapies had failed to improve the patient's pain and had prevented him from performing activities of daily living.



Top: Preoperative X-rays show significant degenerative joint disease. Bottom: Postoperative X-rays show the LinkSymphoKnee A/P and lateral.





On examination, the patient's bone was of good quality and the posterior cruciate ligament was fully intact and compliant. Prior to surgery, we felt that the patient may require a lateral retinacular release, but the patella behaved normally in the trochanteric groove after resurfacing.

The patient received a LinkSymphoKnee primary component and is pain free to date.





Dr. Russel Russo, MD,

is an orthopedic surgeon in New Orleans, Louisiana. While in Houston, he was a team physician for the Houston Texans, Houston Astros, Houston Rockets, and Houston Dynamo FC. He also served as a physician for NASA at the Johnson Space Center.



»I expect most patients to come in at about two weeks with a pain level of about three, which is very, very low.« Dr. Russel T. Nevins, MD

»After six weeks, patients walk in as if nothing had happened«

Late last summer, Dr. Russell T. Nevins visited the LINK factory in Norderstedt near Hamburg. An interview about the new LinkSymphoKnee and what cookies have to do with it.

Dr Nevins, when asked what is special about the new LinkSymphoKnee, the first thing your colleagues mention is that the instruments are very easy to use. How do they affect the workflow? Every instrument, for example the distal femoral cutting gauge, is fantastic, the sizing gauge is very accurate, the alignment rods are also great. But there are two places where the instruments affect my workflow. One is in the operating room and the other is in the clinic. In the operating room, the fact that the instruments are very easy to set up plays a big role. We have a routine because I run two rooms and have a technician who follows me. The hospital staff set everything up the way they like it and

then the assistant comes in, takes over and hands over the instruments. So I always have the same person handing me the instruments. But because it's such a simple set of instruments, it's very reproducible for the hospital staff to set up the instruments. That means there are fewer delays and fewer problems in making sure the instruments are in the right place. That's why the LinkSymphoKnee has changed my workflow in the OR.

How does the LinkSymphoKnee affect your clinic workflow?

I no longer have to spend a lot of time explaining to patients why they are still in pain and why it will take time for them to get better. Instead, I have time to treat more patients, who have a better quality of life and stay in my practice for less time. So the LinkSymphoKnee makes a big difference in the operating room and in my clinic.

Does the design of the LinkSymphoKnee itself affect the workflow?

I am a firm believer in all-poly. Today, probably 50% of my cases are all-poly, which was not the case before. So the fact that the LinkSymphoKnee is available in an all-poly version has had an impact on my workflow. My workflow has also changed dramatically because harder knees are easier to do. They are better balanced. So I don't have to go to a higher level of constraint and do tricks, whether it's recessing some of the medial bone in a bad varus deformity, or whether it's going to a high level of constraint in a valgus deformity. And it saves a lot of time. The LinkSymphoKnee is a very reproducible knee. It's also very forgiving. The margin of safety to get a well-balanced knee is huge, much larger than any other knee system I've ever implanted.

How was the transition from your previous knee replacement system?

There was no learning curve at all. All the instruments were super easy to use and they were well labeled. It was a very quick transition. Also, the balance is so good with this knee system, and I use the PS version, that I didn't have to worry about the transition and understanding the balance of the soft tissue. The fact is that the patients I have implanted with a LinkSymphoKnee do better. I've implanted over 300 LinkSymphoKnees, and when I compare 100 of those knee systems to 100 Medial-Pivot knee systems and 100 DePuy knee systems, I find that in those cohorts of patients, the pain with the DePuy and Medial-Pivot knee systems was almost exactly the



The articulating surface of the LinkSymphoKnee All-Poly is identical to the PS insert.

same at two weeks, six weeks, and three months. And the amount of morphine equivalents or prescribed narcotics that they were taking in tablet form was almost exactly the same. The LinkSymphoKnee system was 50% better in every way. Patients had less pain and used fewer narcotics.

For which indications would you switch from the LinkSymphoKnee to the LINK Endo-Model Rotating Hinge Knee Prosthesis?

It depends on the balance of the ligaments. If the patient can't balance flexion, the knee is unstable. So I would start with a traditional knee replacement. If I cannot balance the flexion, or I have to add so much polyethylene that I have a patella baja, then I know I have to go to a higher level of constraint. At that point I'll go to a CCK, and if the CCK still doesn't allow the knee to be properly balanced because the medial collateral ligament is basically incompetent, I would go to the Endo-Model. This prosthesis is fascinating and so well made. For example, last week I had a severe valgus deformity of 45 degrees in an 85-year-old woman. In 35 minutes I implanted a hinge prosthesis and today she has a straight leg and she's fully weight bearing. The Endo-Model hinge prosthesis is so good and so quick to use for safety that the benefits clearly outweigh the risks in a patient like this. So I went straight for the hinge.

To what extent does explaining the type of knee replacement to the patient affect the outcome of the operation?

Patient expectations are very high and understanding the procedure is very important. So I would be honest about what a patient should expect. With the knee systems I've used, they'd hate me for the first three days after surgery, they'd



start to like me after six weeks, and they'd bring me cookies after three months. With LinkSymphoKnee, my expectations are very different. I expect most patients to come in at about two weeks with a pain level of about three, which is very, very low. After six weeks, patients walk in as if nothing had happened.

Dr. Nevins, many thanks for the interview.



ABOUT

Dr. Russell T. Nevins, MD,

is an orthopedic surgeon in Las Vegas, Nevada, and is affiliated with several area hospitals, including Valley Health Specialty Hospital which is a fully dedicated orthopedic care hospital. Dr. Nevins specializes in hip and knee replacements and revision surgery (above with Helmut D. Link at the LINK Factory in Norderstedt near Hamburg, Germany).



Back row from left: Malte Köster da Veiga (Technical Purchasing), Melanie Bünning (Specialist Clinical Affairs – Clinical Evaluation), Amos Balzarini (Senior R&D Engineer), Marco Iredi (Head of Research and Development), Lars Timm (Production Planning), Hans-Henning Buhmann (Team Leader Production Unit CAM Programming/Industrial Engineering), Dario Lupo (Head of Marketing); front row from left: Nico Schmidt (Technical Purchasing), Leonie Butenschön (Team Leader Project Management R&D), Andreas Regenstein (Manager Quality Assurance Implant), Eugen Martens (Inspection Planning)

»We develop evolutions for patients, not revolutions just for marketing«

A conversation with the team leaders of the LinkSymphoKnee development group Leonie Butenschön and Dario Lupo about visions, the selection of developers and the success factors of a product development.

Ms. Butenschön, Mr. Lupo, how does the development of a new LINK product begin?

Dario Lupo: I think the success of a project depends on the vision. The LinkSymphoKnee was Mr. Link's vision; he wanted to develop a completely new system, but above all a better, more complete system. The LINK company assembled the best possible team of project managers, engineers, surgeons and many other experts to achieve this. That was in 2014. In June 2021, Mr. Link's vision became reality with the first implantation of the LinkSymphoKnee in Europe.

Leonie Butenschön: Right from the start, we wanted to have a system that would meet the needs of populations around the world with their differing anatomies. That's why we put together a global team with surgeons from almost every continent.

The LinkSymphoKnee is based on the proven LINK implants such as the LINK **GEMINI SL Total Knee Replacement** and the Endo-Model Knee System. What is new about it?

Dario Lupo: The LinkSymphoKnee embodies LINK's slogan: Trust. Innovation. Progress. The LinkSymphoKnee is based on decades of experience and very successful existing products. We have retained the good features of these products and made small optimizations in all areas. For example, we achieved more robust kinematics and very good fixation of the components. We have also introduced innovative materials such as the surface modification LINK PorEx and the E-DUR technology. The LinkSymphoKnee is a statement: We develop evolutions for patients, not revolutions just for marketing.

What were the next steps in the development process?

Leonie Butenschön: After analyzing whether the project would be cleared for the US market by the Food and Drug Administration (FDA), our production department checked whether the new functions would be feasible from a manufacturing point of view. Our purchasing department took care of having the instruments manufactured by different suppliers. Our clinical department knows all the literature on knee arthroplasty and told us what else we need to consider for the new product.

Dario Lupo: One of many important aspects is the collaboration with the production department. LINK produces everything from raw material to the finished implant from a single source. When we develop a system like the LinkSymphoKnee, this also allows us to keep an eye on the efficiency of the individual production steps.

How was the collaboration with the surgeons in the development group?

Leonie Butenschön: We had many meetings with the surgeons - for the LinkSymphoKnee it was three per year. For each meeting, we manufacture prototypes that are reviewed and often tried out by the surgeons. After that, we discuss what needs to be changed. Also at this point, we talk with production or other departments to find a good solution or compromise. For example, if the surgeons say that a detail of the design needs to be slimmer or more stable. we present our solution at the next meeting with a new prototype.

Dario Lupo: The LinkSymphoKnee includes a large number of configurations as well as primary and revision instruments, so it required many prototypes and many sessions. In total, it took us only seven years to develop a complete knee prosthesis system for primary and revision care. Not many companies are able to do that.

Is the design affected by the fact that the surgeons come from different countries?

Leonie Butenschön: The Americans, for example, have been the driving force behind the simplicity and efficiency of the instruments. For this reason, LinkSymphoKnee instruments are simple and easy to use. The European surgeons wanted a very thin femur, and the Asian surgeons wanted a fine-tuning mechanism, very small dimensions and many adjustment options. So there were different philosophies, but we finally found the best compromise together.

How are the surgeons selected for the development group?

Dario Lupo: We always try to put together the best possible group of surgeons. With LinkSymphoKnee, we didn't look for surgeons who only use LINK products, quite the opposite. We wanted to have surgeons with different experiences and backgrounds who have a different philosophy when it comes to implanting knee prostheses. That they have a scientific background was also important to us.

When is a product development completed?

Leonie Butenschön: That's the moment we call design freeze, when the surgeons say, "This is the way to go." But after that, the work continues. The most important next step is to get the product approved. We also have to have mechanical tests done in a certified lab. Some tests take up to three months. And if the results are not good, we have to rework. Finally, once we get a CE Mark and FDA clearance for the product, everything is ready for the launch phase and user training.

What is the main success factor in the development of the LinkSymphoKnee? Dario Lupo: The development of the LinkSymphoKnee was a great team



effort because everyone was committed to the project and there was a very pleasant atmosphere between all team members. I am convinced that such a development would not have been possible without this great team of people who worked with a lot of passion and dedication and were willing to invest many hours in the success of the project. Leonie Butenschön: We had the opportunity to turn ideas into prototypes and finally into a great product. And when you then see this product in patients, it's a very good feeling.

Ms. Butenschön, Mr. Lupo, many thanks for the interview.



ABOUT

Leonie Butenschön, MSc, is a development engineer and Team Leader Project Management R&D at LINK.

Dario Lupo is a biomedical engineer and Head of Marketing at LINK.

»No single feature of the LinkSymphoKnee is more important than the others«

Prof. Bernardo Innocenti is a member of the international development group for the new LinkSymphoKnee. As a professor of biomechanics, he played a leading role in analyzing the prosthesis mechanics. In this interview, he explains how the new LINK implant system works.

Prof. Innocenti, what is the basic idea behind the new LinkSymphoKnee?

The main idea was to create a system as close as possible to the needs of the patients. We wanted to develop something new, of course, but above all something better. Because, when a prosthesis replaces the knee joint, the patient should be pain-free and fully mobile again and not feel the difference from a natural joint.

The LinkSymphoKnee builds in important features on existing structures and thus builds on the history of LINK products from the Sled Prosthesis to the Endo-Model Knee System. Why?

We have taken the best structures from these and tuned the individual parameters so that they work together in the best possible way. Each feature has its own history, but in the LinkSymphoKnee, no single feature is more important than the others.

How were the mechanics of the LinkSymphoKnee developed?

First, we took a close look at the design of the existing LINK knee prostheses. We analyzed how they work in detail and which of their parameters could possibly be optimized. We also listened carefully to what surgeons expect from a new implant and tried to see the mechanics of them from their point of view. The information we obtained in this way is very close to real-world data.

You have also carried out numerous laboratory tests. What did you focus on?

We evaluated various options and design features and tested kinematics, mechanical stability and congruency, among other things. For example, we analyzed the biomechanics of walking and squatting to find out where a knee joint has its performance limits. From a biomechanical point of view, walking

is important, even though it is not a very demanding activity. Squatting is much more demanding. In it, you flex the knee joint a lot, and the force acting in the joint increases significantly with flexion. We then used the biomechanical data of the knee joint during walking and squatting to develop the biomechanics of the LinkSymphoKnee.

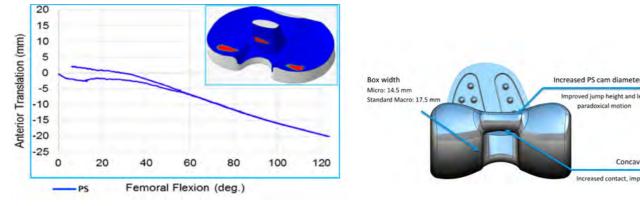
The femoral design of the LinkSymphoKnee has a gradually decreasing flexion radius, uniform distal and posterior thickness, and graduated depth of the trochlear groove. What do these design features accomplish?

One development goal was to equally consider and optimize the performance of all three joints in the knee - the medial tibiofemoral, lateral tibiofemoral and patellofemoral joints. We developed the gradually decreasing flexion radius to

oved jump height and less

Concave cam

eased contact, improved kinematics



Left: Improved deep flexion performance of the LinkSymphoKnee; right: Improved post an cam

reduce instability in mid-flexion. The uniform distal and posterior thickness is designed to facilitate extension and flexion gap consistency, and the graduated depth of the trochlear groove reduces the risk of patellofemoral joint overstuffing and ligament strain. The latter endows the LinkSymphoKnee with an extension mechanism where patellar flexion, internal/external rotation or tilt can be as close as possible to physiological values.

Early users of the LinkSymphoKnee refer to it as the gentle flexing knee. What does that mean?

When the knee is flexed, the articulating surfaces in the joint become significantly smaller. This is at the expense of stability. Our idea was therefore to keep the articulating surfaces as large as possible over the entire range of motion and thus to develop a knee implant that functions perfectly in full extension without losing stability in flexion. An increased tibiofemoral contact area also reduces contact stress in the joint. This is what we have achieved with the high congruency. I think that's what is meant by the gentle flexing knee.

In the development group for the LinkSymphoKnee, you worked with surgeons from different countries. How was the cooperation?

It was unusual at first to interact with each other and speak the same language, but we eventually managed. Each member of the development group had their own ideas about the LinkSymphoKnee, although the goal was the same for everyone. The strong interaction between us was really a keypoint, and I think that makes the difference. Most of the time, after all, the development of a new implant is done internally, without the involvement of external clinical experts. We did it differently and in the end everyone agreed with the result because everyone could see the significant improvements compared to other implants on the market. With the

LinkSymphoKnee, we wanted to design a system that was as close as possible to the needs of patients and surgeons, and I think we succeeded very well.

Prof. Innocenti, thank you for the interview.



ABOUT

Bernardo Innocenti, Ph.D., is Professor of Biomechanics in the BEAMS Department, Université Libre de Bruxelles, École Polytechnique de Bruxelles in Belgium. He is also the founder and first president of CAOS-Belgium, the Belgian Society for Computer Assisted Orthopedic Surgery, and guest professor at KU Leuven in Belgium.





75 years ago, Waldemar Link forged a powerful bond with orthopedic surgeons from Germany and together they engineered new solutions for the problems their patients faced. Today, LINK is a global player, with a comprehensive portfolio of primary and complex revision products. As a full-line supplier, our trust in clinicians remains as strong as ever – and our innovations remain of world-class quality.

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