



Innex™ Knee System Primary



Flexibility through Modularity

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Innex™ – The Knee Prosthesis System

The Knee Prosthesis System that enables unique intra-operative flexibility for all bicondylar implantations

Mobile Bearing



Innex™ CR Type

Mobile Bearing
(Cruciate Retaining)
In case of retention of the posterior cruciate ligament



Innex™ UCOR Type

Mobile Bearing
(Ultra Congruent Only Rotating)
In case of loss of the posterior cruciate ligament

Fixed Bearing



Innex™ FIXCR Type

Fixed Bearing
(Cruciate Retaining)
In case of retention of the posterior cruciate ligament



Innex™ FIXUC Type

Fixed Bearing
(Ultra Congruent)
In case of loss of the posterior cruciate ligament

The introduction of the Innex™ system (Innex™ stands for «Innovation Nexus Next Generation») in 2001 was an important step in the understanding of the demanding problems connected with the endoprosthetic treatment of degenerative diseases of the knee joint. Re-establishment of the natural anatomical relationships between the femur, tibia and patella, together with physiological axis alignment, is a decisive factor if patients are to be treated successfully with predictable and reproducible results.

At the same time, optimum anchoring principles and the Cancellous Structured Titanium™ (CSTi™) porous coating have set a so far unequalled standard for the cementless fixation of knee prostheses.

The aim of the Innex™ system is to cover as many indications as possible in the field of total knee endoprosthetics. This is possible with a minimum of components. Both mobile (Mobile Bearing) and fixed (Fixed Bearing) meniscus components can be used.

The whole Innex™ knee system is based on one single surgical technique. This means that the instrument set can be kept compact and limited in range.

Thanks to the modular structure of the Innex™ knee system, the instrument set is far smaller than that of other systems.

Anatomically shaped implants, coupled with the logical and extremely precise instrument set, enable conservative treatment of degenerative diseases with bone-sparing resections as well as extensive restoration of the natural kinematics of the knee joint.

The multi-centre study has shown that very good results are achieved through a combination of newly developed and proven design principles.

Advantages

Thanks to the combination of all these criteria, the Innex™ knee system offers four key advantages in times of rising healthcare costs and heavy cuts in healthcare budgets:

- High level of patient satisfaction and return to almost normal conditions of life.
- Shorter times for surgery thanks to the efficient and logical instruments.
- Significant savings in terms of hospital inventory thanks to the possibility of combining the implant components according to individual requirements and the wide range of indications that can be treated with this system
- Instrument trays developed and simplified with the close co-operation of surgeons and theatre nurses, so as to make the work of the surgical staff much easier.

Component	Property	Mobile Bearing		Fix Bearing	
		*CR Cruciate Retaining	UCOR Ultra Congruent Only Rotating	FIXCR Cruciate Retaining	FIXUC Ultra Congruent
Femur	cementless	■	■	■	■
Femur	cemented	■	■	■	■
Tibia	cementless	■	■		
Tibia	cemented	■	■	■	■

**The Mobile Bearing type CR is manufactured according to the principle patented by André-R. Baehler.*

Indications and Contraindications

Idiopathic or post-traumatic deforming arthrosis and rheumatoid arthritis are the most frequent causes of painful destruction of the knee joint.

The **indication** for implanting an Innex™ knee prosthesis exists when the arthrotic pain cannot be relieved using the conservative methods that are available today, so that the patient's suffering becomes unbearable and the joint-retaining surgical methods offer no prospect of longterm improvement.

Implanting a knee prosthesis is not simply a matter of improving the patient's quality of life, it often includes maintaining of social independence and self-sufficiency. Age plays a rather secondary role in the decision-making process.

Given the wide variety of options available in the modular Innex™ knee system, the question soon arises as to which type of Innex™ prosthesis should be used for which situation.

The surgeon should decide, on the basis of his own experience and knowledge, which type of Innex™ prosthesis will be used. The objective is the optimal treatment of the knee pathology in question.

In addition to correct positioning and stable fixation, the physiological leg axes and ligament stability during both flexion and extension, and the maximum range of movement should be restored.

These are the prerequisites for painfree functioning of the knee joint and a lasting long-term result.

The following general guidelines may be used to determine which type of prosthesis is used:

Innex™ CR type

Mobile bearing (Cruciate Retaining)

Suitable for:

- Gonarthrosis with intact and viable posterior cruciate ligament
- Mild or non-fixed varus or valgus malpositioning
- No severe loss of extension capacity
- Relatively younger patient
- Good quality of the ligamentous apparatus
- Well-balanced pre-operative extension and flexion gaps
- Poor bone quality, patient relatively old = cemented
- Good bone quality, patient relatively young = uncemented
- The surgeon prefers to use the mobile meniscal bearing

Innex™ FIXCR type

Fixed bearing (Cruciate Retaining)

Suitable for:

- Same as for Innex™ CR Type
- The surgeon prefers to use the fixed meniscal bearing

Innex™ UCOR type

Mobile Bearing (Ultra Congruent Only Rotating)

Suitable for:

- Gonarthrosis and rheumatoid arthritis with insufficient posterior cruciate ligament
- Medium and to some extent also fixed varus or valgus malpositioning
- Genu flexum in the range from 10° to 20°
- Patient relatively old, but this does not exclude using the Innex™ UCOR type in younger patients!
- Especially with a good quality collateral ligamentous apparatus
- Well-balanced extension and flexion gaps
- Poor bone quality, patient relatively old = cemented
- Good bone quality, patient relatively young = uncemented
- The surgeon prefers to use the mobile meniscal bearing

Innex™ FIXUC type

Fixed bearing (Ultra Congruent)

Suitable for:

- Same as for the Innex™ UCOR type
- The surgeon prefers to use the fixed meniscus bearing

Innex™ FIXSC type

Fixed Bearing (Semi-Constrained) (see separate Surgical Technique Manual)

Suitable for:

- Severest forms of gonarthrosis and rheumatoid arthritis
- Moderately difficult to difficult revision (prosthesis-replacement surgery)
- The age of the patient is less important than the local condition and the findings in the knee joint
- Insufficiency of the ligamentous apparatus
- Extension and flexion gaps not optimally balanced
- Use of cement, intramedullary anchoring stem, and prosthetic spacers essential

A contraindication for the implantation of an Innex™ knee prosthesis is a florid bacterial or inflammatory process in the region of the knee concerned. Particular caution is indicated with neuromuscular disorders such as, for example, status following poliomyelitis, Parkinson's disease, multiple sclerosis and polyneuropathy or when there is an insufficiency of the extensor apparatus.

Mobile Bearing Type CR/UCOR Fixed Bearing Type FIXCR/FIXUC

The Innex™ Mobile and Fixed Bearing knee system has proved to be an optimum solution, both enabling the restoration of natural anatomical relationships and also successfully tackling one of the greatest potential problems in the field of knee endoprosthesis, the likely abrasion of polyethylene particles due to friction. With the new design of the femur-condyle and surface radii of the tibia inlays, further improvement of the maximum contact surface has been achieved, with as little specific surface pressure as possible. The congruence of the single components offers a significant contribution towards the durability of the knee prosthesis.



Cemented femur

Femur component

- The resection in stages of the anterior facets and the patellar groove, deeper on the implant side, reconstruct the run of the patella in a natural manner, thus ensuring an improved range of motion.
- The fact that the anterior radius is moved backwards takes the load off the anatomical extensor mechanism, which also improves the range of motion.
- the lateral oblique edge minimises the need for release of the lateral patellar retinaculum.
- the cementless version of the asymmetrical cobalt-chromium component has a porous coating (CSTi™) on the whole bone side, thus enabling excellent bone in-growth together with optimum articulation against the polyethylene sliding partner.
- This component is available in five sizes (right/left) each in the cementless and the cemented versions.



Cementless femur

Tibia component

- The entirely symmetrical shape of the base-plate enables almost complete cortical covering of the proximal tibia.
- Tibia base-plates are available in seven different sizes. The best possible coverage of the proximal tibia is ensured thanks to the small increments from one size to the next.
- The arrangement of the small stabilising pegs increases the primary stability of the implant.
- The design of the stem (conical, with three ribs) spares bone tissue and increases the rotational stability of the implant. The integrated PMMA protecting plug prevents the entry of bone cement.
- The tibia base-plate is available either as a cementless component (mobile version) with a complete porous coating (CSTi™), or as a component for cementing (fixed and mobile), with cement pockets (with or without stem and plug).

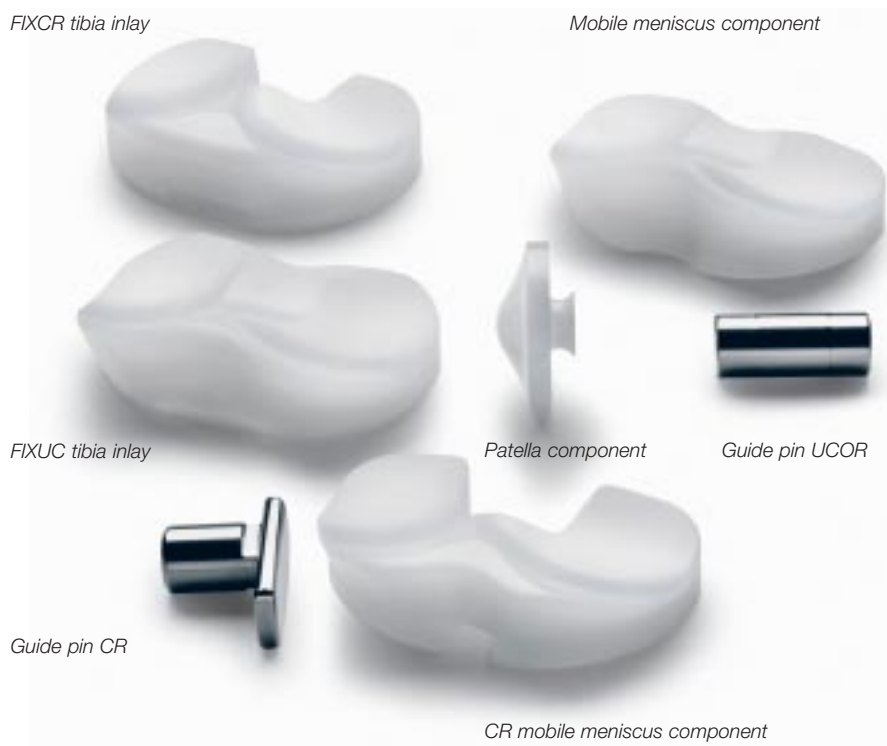


Spacer

A special feature of the tibia spacer is that it is offered as a single piece, which has to be separated into parts at the points provided only after the indications and its use have been defined. It can, however, also be used as a whole unit.

The tibia spacers are available with three different proximal thicknesses. This ensures that the surgeon can use the spacers with great flexibility, inserting them on the basis of the individual indications.





PE Meniscus Inlay

- The inlays, made of milled high-density polyethylene and available in the «congruent» and «ultracongruent» versions, provide intra-operative flexibility in that the posterior cruciate ligament can be retained or, in the event of instability, replaced. Both types are available in a finely graded range of heights from 10 mm to 17.5 mm.
- The ultra-congruent variants provide safety against luxation, thanks to the raised anterior lips. The congruent variants have an anatomically shaped recess at the rear for the posterior cruciate ligament.
- The front recess for the abundant fat pads ensures pain-free results for the patients. This ensures that little or no «fat pad impingement» can occur.
- The snap-in mechanism enables stable anchoring of the inlay in the base-plate for Fixed-Bearing implants.

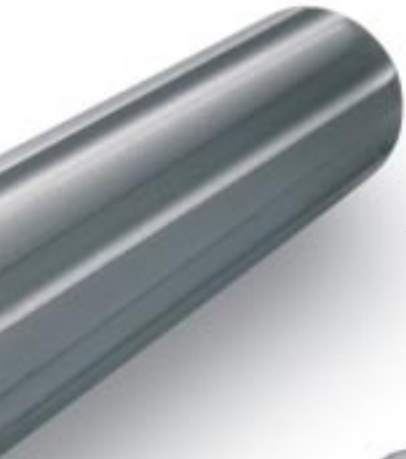
Patella component

- The patella component is available in four sizes, as a cemented 100% PE component.
- Thanks to its adapted dome-shaped geometry, a high degree of congruence with the femoro-patellar joint is achieved.
- Because of the dome-shaped geometry of the patella, problem-free setting of the rotational position is possible, without any shifting occurring.
- The single centred rotanally symmetrical peg ensures good primary stability

Anchoring Stem

An integral component of the Innex™ knee system, range of stems is designed to meet surgeons' needs and to suit the possible indications in the best possible way. With the very precise and structured instrument set, it is possible to achieve predictable and reproducible results.





*Anchoring stem
Conical size 50*



*Anchoring stem
Conical size 100*

Stems

- Two conical straight stems are included as standard items in the range of primary variants.
- Cylindrical stems are part of the revision range. These are available in various lengths and diameters.
- The cylindrical stems can be straight, with an angle or with an offset.
- Thanks to the 2° angle of the cylindrical stems, it is possible to set two additional valgus angles.
- The variable (progressive) design of the offset stem ensures the possibility of intramedullary and thus optimum anatomical fit on the cortical bone.
- Finely graded increases in diameter of 2 mm steps enable the surgeon to achieve optimum bone anchoring.

Instruments and Tray

The Innex™ instrument set, made of stainless steel, is modular and was developed to meet the high quality demands of surgeons. It consists of a small number of logically structured instrument trays made of synthetic material. The way in which the trays are divided up was planned in close co-operation with surgeons and surgical staff. This is a significant advantage of the Innex™ knee system. The trays are designed on the basis of the same logical sequence as the surgical technique. In developing the instruments, special attention was paid to simplicity of use and the ergonomic requirements of the user. This is why almost all the parts of those instruments that need assembly are equipped with quick-fitting mechanisms rather than screws.



*Femur-setting instrument with
a cementless femur*



Instruments

- It is possible to check alignment at any time during the operation, using the alignment rod.
- The very precise bone cuts provide optimum matches between the implants and the cuts.
- It is possible to switch between the single implant systems at any time during surgery, and this can be done without bringing significant changes into the surgical technique.
- Users have at their disposal a convenient range of logically and ergonomically structured trays made of synthetic material.
- Accurate and exact performance of the operation is the result of the precise, top-quality manufacture of the instruments.



*Modular handle with tibia template
and trial tibia inlay*

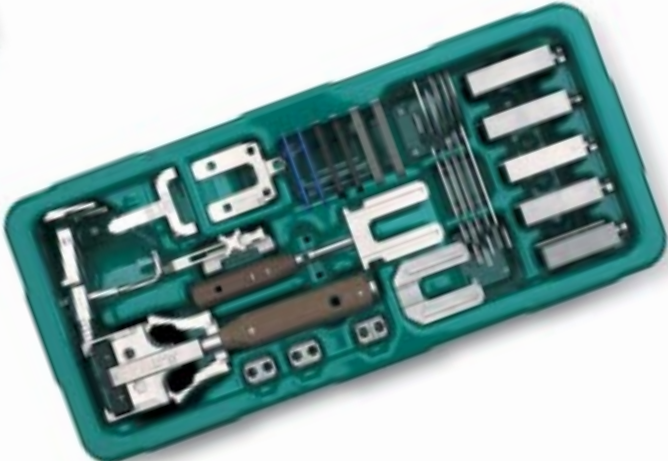
Overview of Trays



Universal Tray



Tibia Tray



Femur Tray CR/UCOR/FIX/SC



Femur Tray CR/UCOR/FIX



Patella/Stem Tray



Femur/Tibia Tray CR/UCOR/FIX

Product Safety through Physiological Testing

Fatigue tests are carried out in our in-house laboratory. The implant components to be tested are subjected to an alternating continuous load for 10 million loading cycles.



Mechanical resistance theory states that the probability of a fracture in metal materials after 10 million loading cycle is negligible.

This means that fatigue testing of our implant with 10 million loading cycles offers patients lifelong mechanical safety of their implants.

Determination of the contact surface and of the related stresses between the femur component and the meniscus replacement provides information about the durability of the polyethylene insert. The relevant material parameters of the polyethylene represent the standard values that should not be exceeded in a knee-joint replacement. Otherwise, delamination and increased wear must be expected.

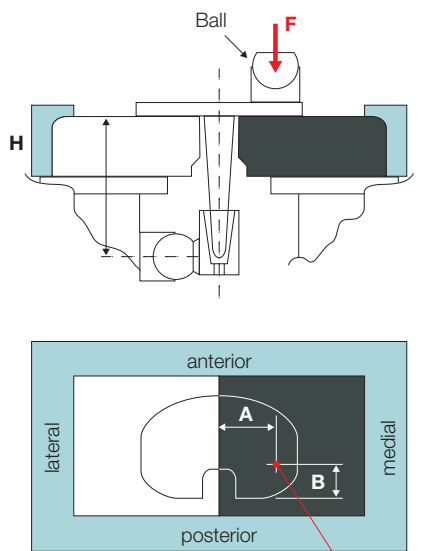
To determine these parameters, the knee-joint components are loaded in a static testing set-up with a pressure-sensitive film inside the joint. Then, with the help of image-processing programs and calibration curves, the contact surface can be calculated in square millimetres, and the stress in MPa.



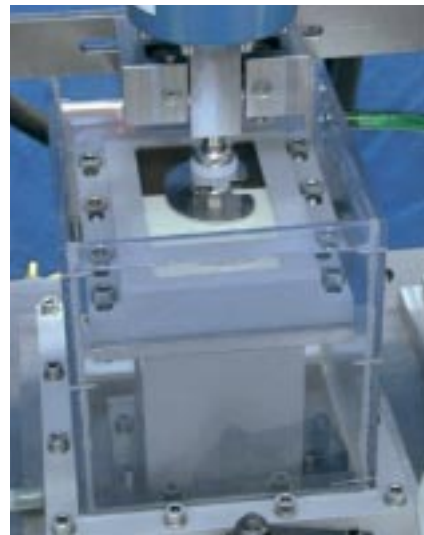
The «physiological tibia test» simulates an extreme in vivo load situation. In this test, a varus misalignment that has led to the collapse of the medial compartment is assumed. For this reason the tibia component is impinged on only medially with a load that amounts to about 6 times the body weight.

The implant is supported from underneath by two blocks made of synthetic material. If the implant has an intra-medullary anchoring stem, this is made to impinge on its distal end with a pressure bearing on it laterally.

Using this test method, it is possible to test the fatigue strength both of the tibia metal-backing and of the anchoring stem, as well as the strength of the bond between the two components, in a single test set-up



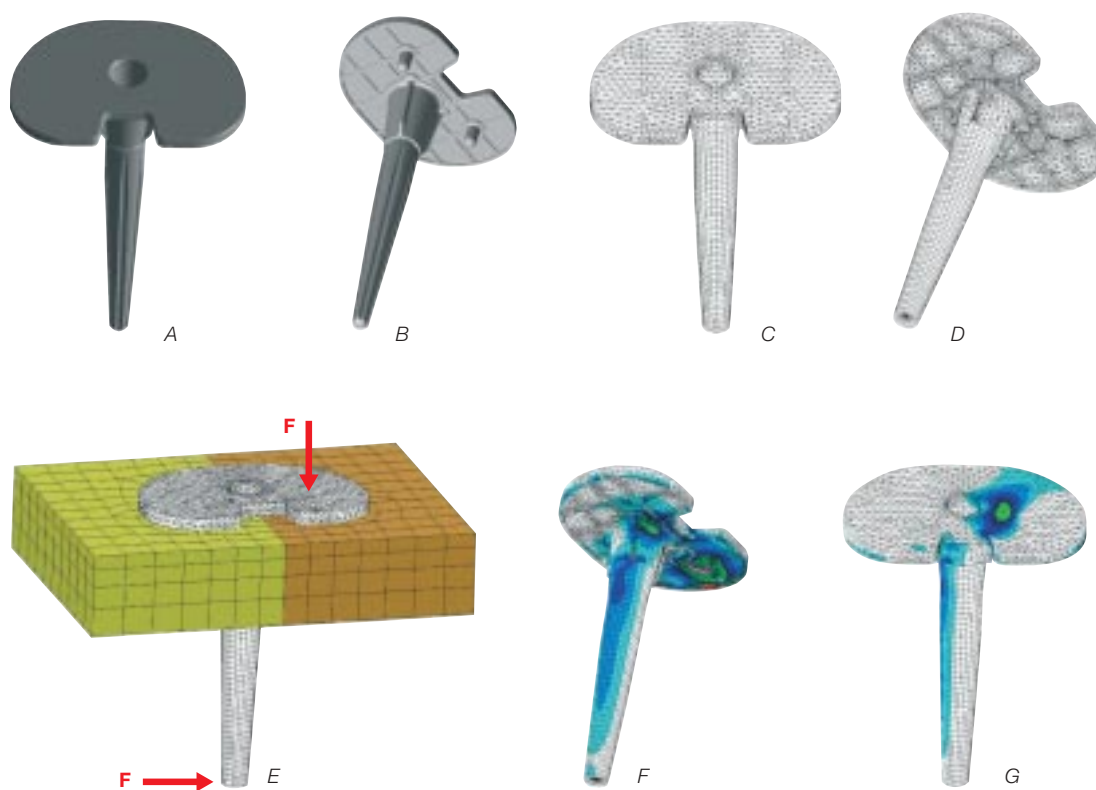
Application of the force



Computer-aided calculation methods, such as finite-element analysis (FEA), are used as a standard for testing implants for their resistance.

The greatest advantage of these methods is that no physical models need to be prepared. Starting out from a three-dimensional CAD model Figures A/B, crosslinking Figures C/D of the component is carried out with the aid of the FEA software.

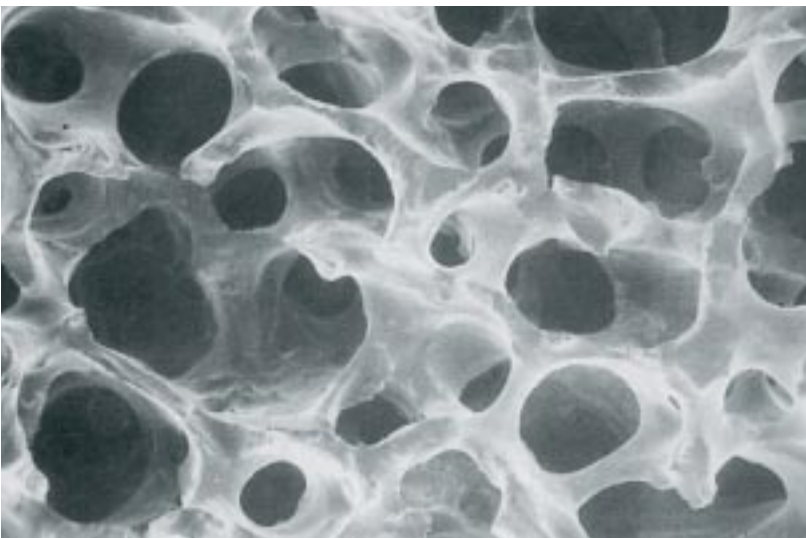
Then the boundary conditions (forces, friction conditions, etc.) Figure E and the experimental set-up of the mechanical test are added. At this point, the FE program is able to calculate the strain occurring in the implant component as a result of this load situation Figures F/G. The graphic representation enables possible critical areas to be identified with the help of a colour scale.



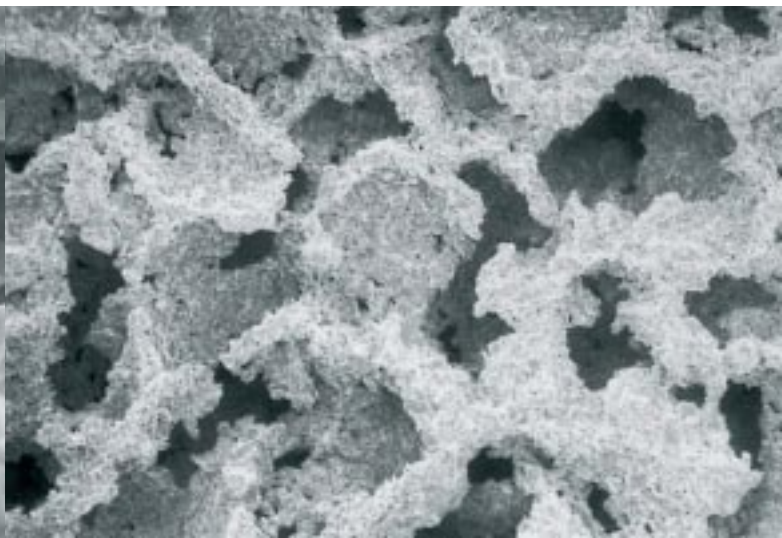
A Milestone in Material Technology – SinterLock CSTi™

As early as 1983 Sulzer Orthopedics Inc. had earned a place as a leading company in orthopedic material technology with the development of their porous coatings with Cancellous-Structured Titanium™ (CSTi™). The morphology of cancellous-structured titanium is more similar to human cancellous bone tissue than any other porous coating available on the market. Its variable pore size of about 500 µm and its porosity (60%) promote fixation of the implant through exceptional bone in-growth or with bone cement, while the shear forces on the anchoring surfaces are minimised.





Cancellous tissue



CSTi™

SinterLock CSTi™

The introduction of Sinterlock CSTi™, in the course of technological progress, constituted yet another milestone in the field of composite materials. Sinterlock CSTi™ was developed by Sulzer Orthopedics Inc. and is the result of progress in metallurgy achieved by means of a patented sintering process. This process bonds the porous CSTi™ coating firmly with the cobalt-chromium base material.

This combination couples the good resistance to wear of CoCrMo alloys with the well-known biocompatibility of titanium.

By comparison with conventional porous coatings, the SinterLock CSTi™ process offers outstanding static shear and

tensile strength values, as well as fatigue strength. In addition, electrochemical tests have shown that this combination of materials is resistant to corrosion inside the body.

Thus, the coupling of cobalt-chromium and cancellous-structured titanium in SinterLock CSTi™ forms an ideal combination of metals and provides an important contribution towards the durability of orthopedic implants.

Packaging, Safety and Quality

Sterility and Packaging

- All the metal components are sterilised exclusively with gamma-rays and packaged in such a way that environmental impact is kept as low as possible.
- All components made of high-density polyethylene – SULENE™-PE (UHMWPE) – are also gamma-ray sterilised in an oxygen-free atmosphere.
- This process increases the cross-linking and decreases the material's tendency to become brittle, with a positive effect on its resistance to wear and Delamination.



Safety and Quality

Zimmer GmbH and our suppliers have SQS and TÜV quality certification of conformity with ISO 9001/EN 29001/EN 46001.

A high quality standard means safety for the patients and is a solid foundation for successful surgery.



Sample Cases

Innex™, Mobile UCOR
Cemented tibia
Cementless femur
No patellar rear-surface replacement

Pre-operative mobility in extension/ flexion was 0°–10°–110° (10° fixed flexion of the knee).

Re-establishment of the physiological axis of the leg following the operation can be seen.

The knee was treated by means of an UCOR type implant. Retention of the posterior cruciate ligament was not advisable due to the fixed varus and flexum deformity.



Pre-operative

Post-operative

Innex™, Mobile UCOR
Cemented tibia
Cemented femur
Cemented patellar rear-surface replacement

The initial condition was post-traumatic gonarthrosis of the left knee-joint with posterior and postero-lateral instability following a complex knee injury involving the ligaments many years earlier.

The knee was treated by means of an UCOR type implant with patellar rear-surface replacement, without retaining the posterior cruciate ligament.

Pre-operative mobility in terms of extension/flexion amounted to 0°–0°–120°.

Re-establishment of the physiological axis of the leg following the operation can be seen



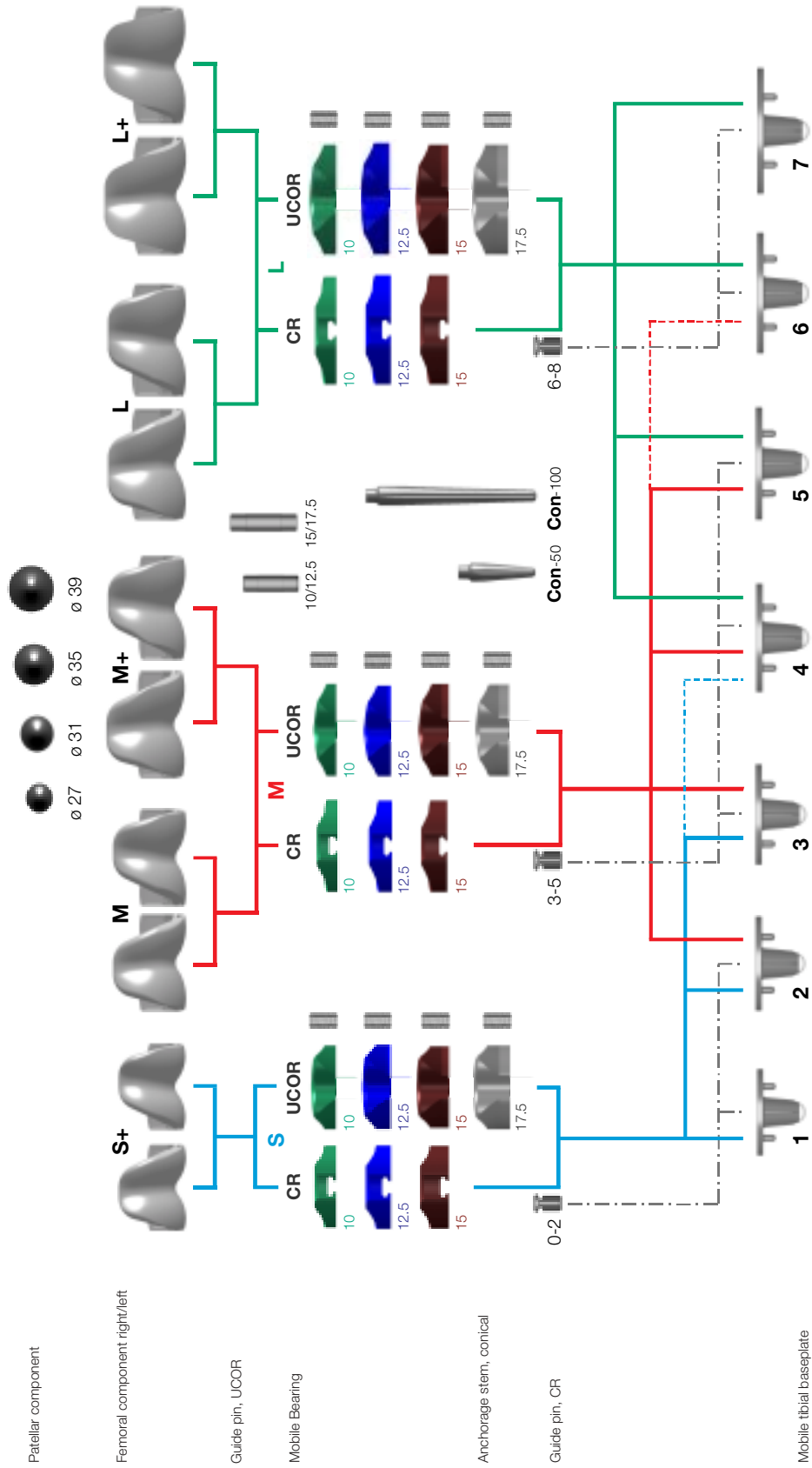
Pre-operative

Post-operative

Innex™ Knee System

Tables of Combinations (Mobile Meniscus Components)

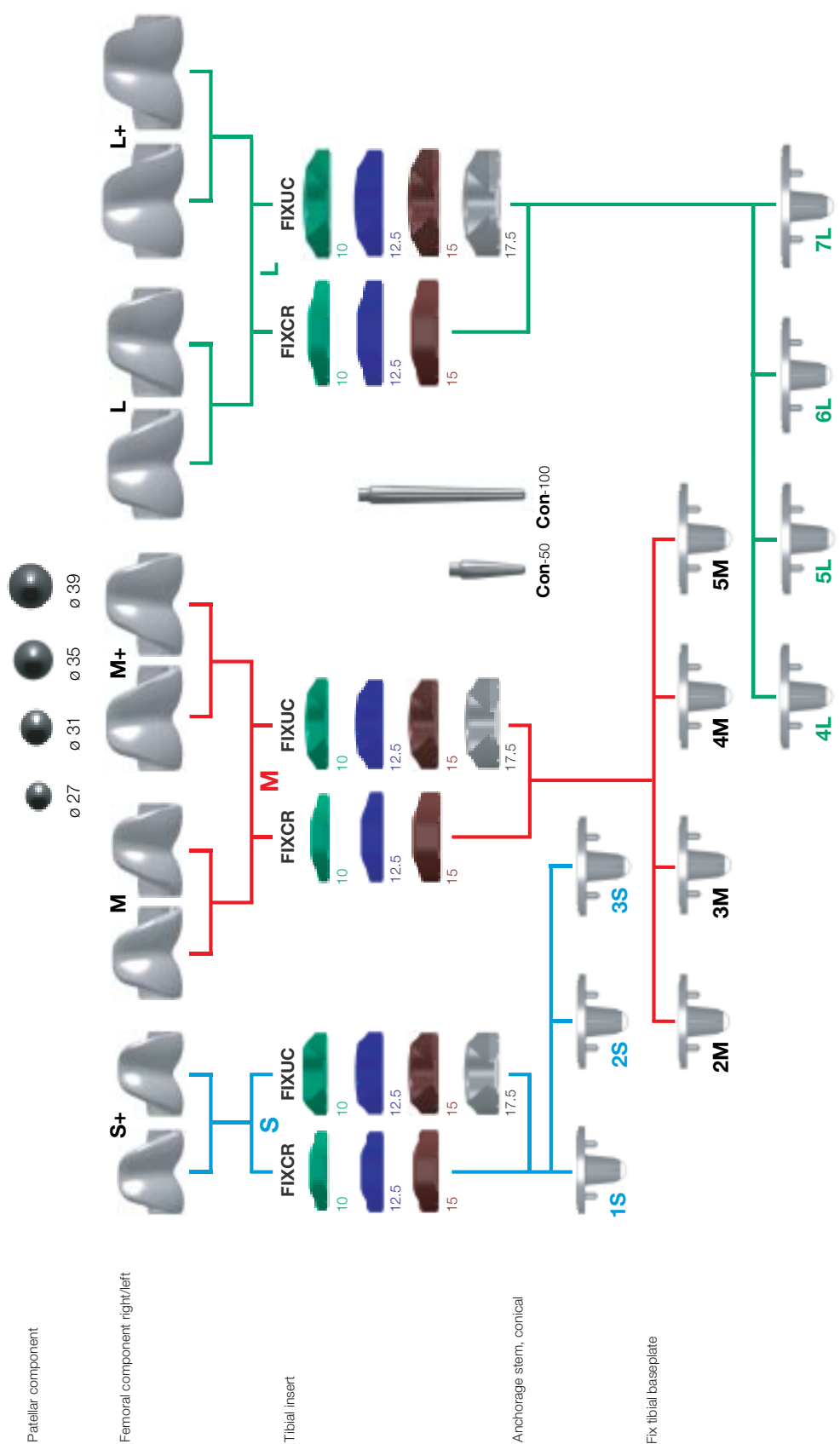
CR (Cruciate Retaining) With retention of the cruciate ligaments
UCOR (Ultra Congruent Only rotating) With replacement of the cruciate ligaments



Innex™ Knee System

Tables of Combinations (Fixed Meniscus Components)

FIXCR (Cruciate Retaining) With retention of the cruciate ligaments
FIXUC (Ultra Congruent) With replacement of the cruciate ligaments



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Lit.-Nr. 06.00915.012x – Ed. 03/2005 WL



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