

MITUS[®]

Minimally Invasive Technique for
LINK[®] Unicondylar Sled Prosthesis

Presented by:



CE 0123

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MITUS[®]

Minimally Invasive Technique for LINK[®] Unicondylar Sled Prosthesis

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Important Information regarding the use of our implants

■ LINK® Unicondylar Sled Prosthesis



The successful design of LINK's Unicondylar Sled Prosthesis which was originated in 1969 has remained unchanged since its last modification in 1981. This extraordinary time period and the outstanding long-term clinical results have been reported in a number of publications*.

Further advantages:

- high joint mobility
- short recovery period

The design of the femoral component preserves bone substance and permits femoral resurfacing. This treatment is therefore available as a fall-back option.

The instruments and the surgical technique are regularly optimised to ensure ease of use and reliable implantation.

The LINK® Unicondylar Sled Prosthesis is available in four sizes.

*Exemplary: Annual Report, The Swedish Knee Arthroplasty Register, www.knee.nko.se



Femoral Components

The large radii of the femoral surface distributing the contact stress more homogeneously. The globular structure of the concave inner surface of the sled provides optimal bonding between implant and cement. The design incorporates two posts whose shape and alignment aid in positioning the sled. The implant is easy to remove should revision become necessary.



Tibial Plateaus

The tibial plateaus can be used medially as well as laterally owing to their symmetrical shape. The sizing is adapted to the anatomical shape of the head of the tibia. Two designs are available:

- **Type all-polyethylene** (non metal-backed)

This design is available in four heights and four diameters. The structured underside allows a very good interface between implant and bone cement.



- **Type metal-backed**

In this design, the tibial plateaus are available in three heights and three diameters. The globular structure on the underside of the plateau offers optimum bonding between the implant and bone cement.



PorEx® (TiNbN = Titan-Niob-Nitrid)

Surface modification

The hypoallergenic PorEx® surface modification leads to a ceramic-like surface, which significantly reduces the release of ions and can improve tolerance in patients who are sensitive to metal ¹⁾.

This surface is extremely hard and possesses abrasion properties similar to those of ceramics. These qualities and the wetting angle of the surface give it a low friction coefficient when in contact with fluids ¹⁾.

¹⁾ Study of the influence of TiNbN-coating on the ion release of CoCrMo-alloys in SBF buffer simulator testing.

■ **Rünow Minimally Invasive Surgical Technique**

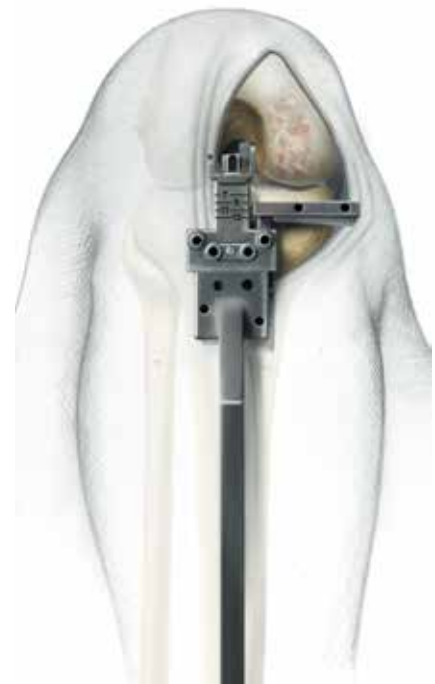
For implantation of a sled prostheses it is essential to select the correct indication. The concept is based on the fact that in early stages of knee osteoarthritis (OA) the cartilage damage is limited to a single compartment within the knee joint.

The design of the **LINK® Unicondylar Sled Prosthesis** ensures that only minimal bone resection is required when preparing the bone to receive the femoral and tibial components. This preserves high-quality bone, particularly the hard sub-chondral bone, which is important for secure long-term fixation of the implant.

The **Tibial Saw Guide** supports resection according to anatomical conditions and ensures precise, reproducible bone cuts.

The **MITUS® Instrument Set** offers distinct advantages to the surgeon:

- minimal bone resection
- full control over the level of tibial resection
- opportunity to try out different sizes using trial implants
- option to perform the surgery using either conventional or minimally invasive surgical techniques
- medial or lateral use of instruments possible

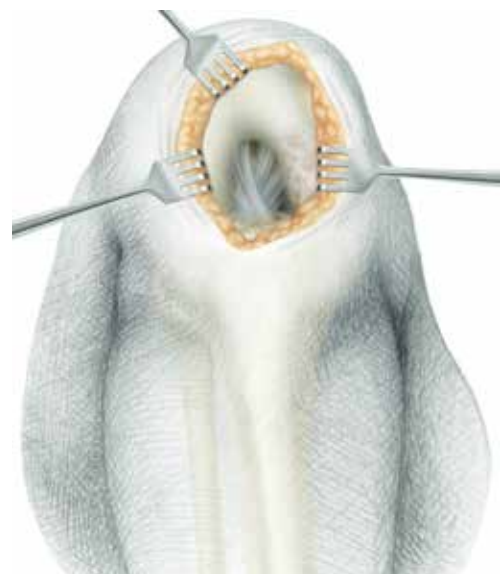


Two different forms of surgical approach can be used

Conventional Approach: through a midline or a medial parapatellar skin incision. The joint cavity is reached via a medial parapatellar incision and splitting of the quadriceps tendon. The patella is everted laterally.

Minimally Invasive Approach: through a short parapatellar skin incision. The capsular incision is also parapatellar allowing access to the joint with minimal disturbance of the extensor mechanism and without dislocating the patella.

The minimally invasive technique reduces complications and can be performed with great precision provided the LINK® instruments are used correctly.



■ Specified Indications and Contraindications

Product: LINK® Unicondylar Sled Prosthesis	LINK® Sled Prosthesis	additional with PorEx® (TiNbN) Surface Modification
General Indications		
<ul style="list-style-type: none"> Severe joint diseases with limitation of mobility due to degenerative, rheumatoid or post-traumatic arthrosis or arthritis. Joint fractures which disallow an osteosynthetic reconstruction. 	X	X
Indications		
<ul style="list-style-type: none"> Unicondylar arthrosis by intact ligaments including both cruciate ligaments. 	X	X
Differential Indications		
<ul style="list-style-type: none"> Valgus/Varus deformities <10° 	X	X
<ul style="list-style-type: none"> Sensitization against one or more components of used CoCrMo implant materials 		X
Contraindications		
<ul style="list-style-type: none"> Acute or chronic infections, local and systemic 	X	X
<ul style="list-style-type: none"> Hypersensitive to (implant) materials 	X	-
<ul style="list-style-type: none"> Distinctive muscular, nerve, vascular or other diseases which put the affected limb at risk. 	X	X
<ul style="list-style-type: none"> Insufficient / inadequate bone mass- or quality which prevents a stable anchor of the prosthesis. 	X	X
Relative Contraindications		
<ul style="list-style-type: none"> Adiposity 	X	X
<ul style="list-style-type: none"> Insufficient collateral ligaments 	X	X
<ul style="list-style-type: none"> Insufficient musculature 	X	X
<ul style="list-style-type: none"> Lacking or foreseeable not assured compliance 	X	X
<ul style="list-style-type: none"> Foreseeable overload of joint prosthesis 	X	X

■ Case Studies



1a

Male, age 75 years



1b



1c

Fig. 1a: Medial compartment OA, Ahlbäck Grade II, with pain after 15 minutes walking.

Fig. 1b,1c: Following minimally invasive technique of an LINK® Sled Prosthesis, postoperative X-rays show horizontal positioning of the Tibial Plateau in the coronal plane (Fig. 1b), a slight posterior slope of the plateau in the sagittal plane (Fig. 1c). RSA beads are issued in bone and implants. Two days after surgery, the patient was able to walk with crutches. His active ROM was 5 - 120°. At one week, he walked without crutches; at six weeks, he walked 5 km without any pain, and had ROM of 0 - 130°.



2a



2b

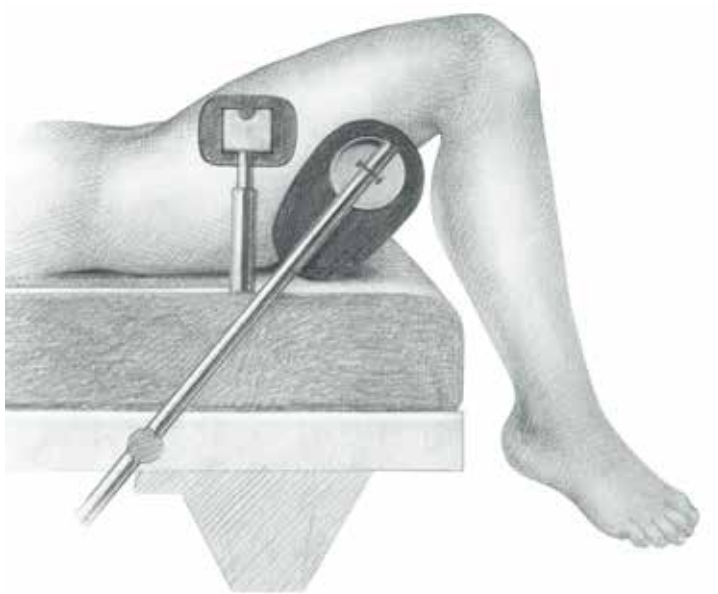
Female, age 62 years

Fig. 2a: Medial compartment OA, Ahlbäck Grade II, unable to walk without crutches, walking distance 500m.

Fig. 2b: Following minimally invasive technique of a LINK® Sled Prosthesis, good alignment and horizontal positioning of the Tibial Plateau was achieved. At four postoperative days, her ROM was 0 - 95°. By the end of the first month, the ROM was 0 - 115°.

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■ **Patient Positioning**

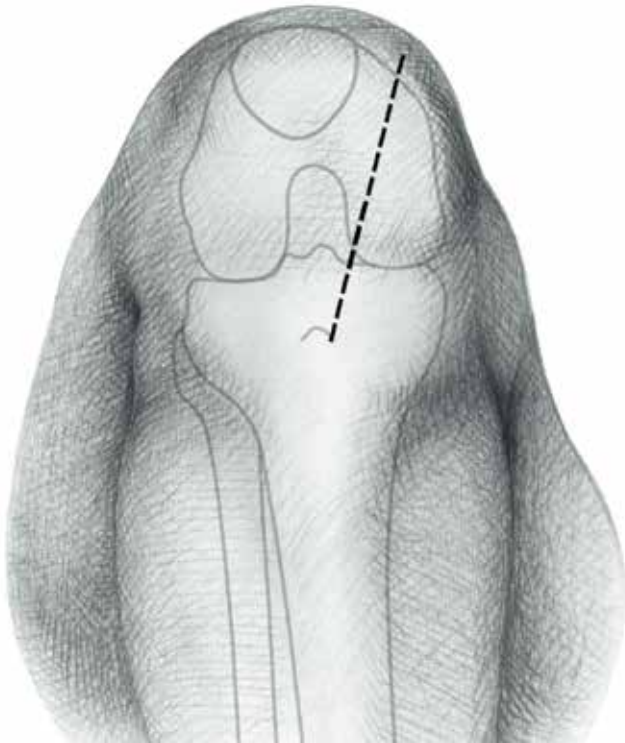


The limb is placed in a thigh support with 45° flexion of the hip. The leg is hanging down. It should be possible to flex the knee at least 120°. When using a medial incision a lateral thigh support is needed.



The operation is performed with the surgeon sitting in front of the flexed knee. The other leg is placed in a leg support leaving plenty of space for the surgeon and the assistant. The operation is performed in a bloodless field.

■ Patient Positioning



With the knee flexed 90°, a medial parapatellar incision is made starting at the margin of the vastus medialis 2–3 cm medial to the patella and extending distally and diagonally to the tibial tuberosity.

A medial parapatellar capsule incision is made. For better visualisation the incision is angulated in its proximal part. The vastus medialis is detached. The capsule is released from the tibia almost to the front of the medial collateral ligament. The meniscus is removed. Partial excision of the retropatellar fat pad is necessary to gain better exposure of the intercondylar notch.

A retractor is placed in the lateral recess, allowing inspection of this compartment. To examine the patellar articulation, the knee is extended. If there are any doubts preoperatively about the condition of the other compartments diagnostic arthroscopy or MRI can be performed prior to the operation. After inspection, the retractor is placed in the intercondylar notch and the curved retractor behind the femoral condyle, to get a full view of the medial compartment.

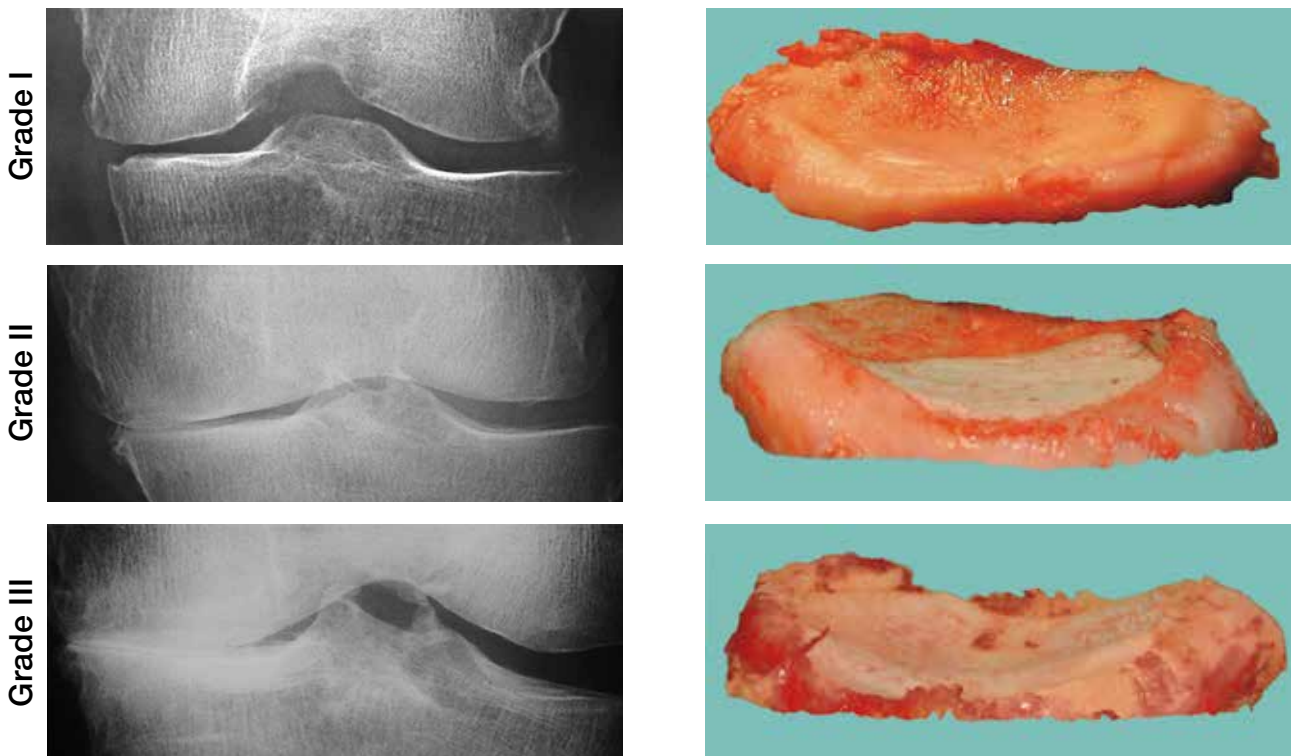
■ Tibial Resection



The purpose of the LINK® Unicondylar Sled Prosthesis is to restore the damaged joint surfaces and the mechanical axis; a slight under-correction is desirable.

The Tibial Saw Guide allows the surgeon to determine and achieve the desired cutting depth precisely and to control the cutting in the frontal and the sagittal planes. The Saw Guide can be used with either a minimally invasive technique or the traditional exposure.

■ Tibia Resection



In knee replacement surgery by the traditional technique, the deepest point and the most damaged area of the tibial plateau are taken as the basis for determining the depth of the tibial resection. The depth of the resection is then highly dependent on the surgeon's experience. Often further resection is needed or the height of the Tibial Plateau must be changed to obtain the desired alignment and stability of the knee. The best aid to determining the depth of the horizontal cut is weight-bearing radiographs of the knee and pre-operative observations of the degree of cartilage damage. These allow a slight undercorrection of only a few degrees of varus to be achieved. The analysis of the weight-bearing radiographs is based on the classification of Ahlbäck.

The proposed resection depths are based on the use of a 9-mm high Tibial Plateau.

Grade I The joint space is reduced by one-half. The cartilage of the tibial condyle is preserved but reduced in height. The Cutting Platform should be adjusted to 11 mm depth. The stylus is placed at the deepest point of the remaining cartilage of the tibial condyle.

Grade II Total loss of the cartilage on both the femoral and the tibial condyles. The Cutting Platform should be adjusted to 9 mm depth and the stylus placed at the deepest point of the exposed bone of the tibial condyle.

Grade III Half a centimeter bone attrition of the femoral and tibial condyles on the frontal view weightbearing radiograph. The Cutting Platform should be adjusted to 7 mm and the stylus placed at the border between the exposed and the eroded bone.

The stylus is not placed at the level of the planned surface of the Tibial Plateau. In Grade I the surface of the Tibial Plateau will be lower than the surface of the tibial condyle, and correspondingly in Grade III the surface of the Tibial Plateau will be higher than the surface of the damaged tibial condyle.

■ Tibial Resection

Height of Tibial Plateaus	Resection Height		
	Grade I	Grade II	Grade III
7 mm	9	7	–
9 mm	11	9	8
11 mm	13	11	9

Table 1:
Depth of the tibial resection (mm) in relation to the chosen height of the Tibial Plateau.

Resection Height	Height of Tibial Plateaus		
	Grade I	Grade II	Grade III
7 mm	–	7	9
9 mm	7	9	11
11 mm	9	11	13

Table 2:
Height of the Tibial Plateau (mm) in relation to the depth of the tibial cutting.

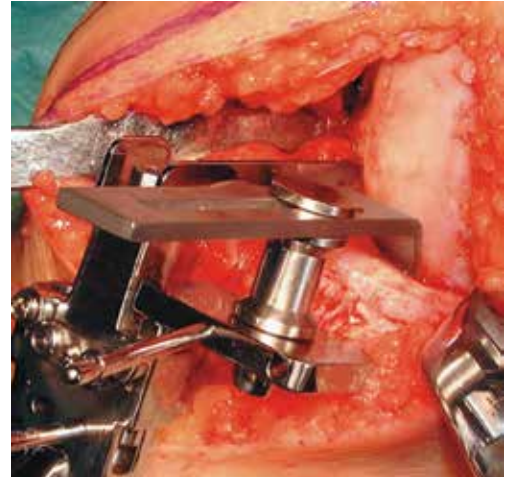


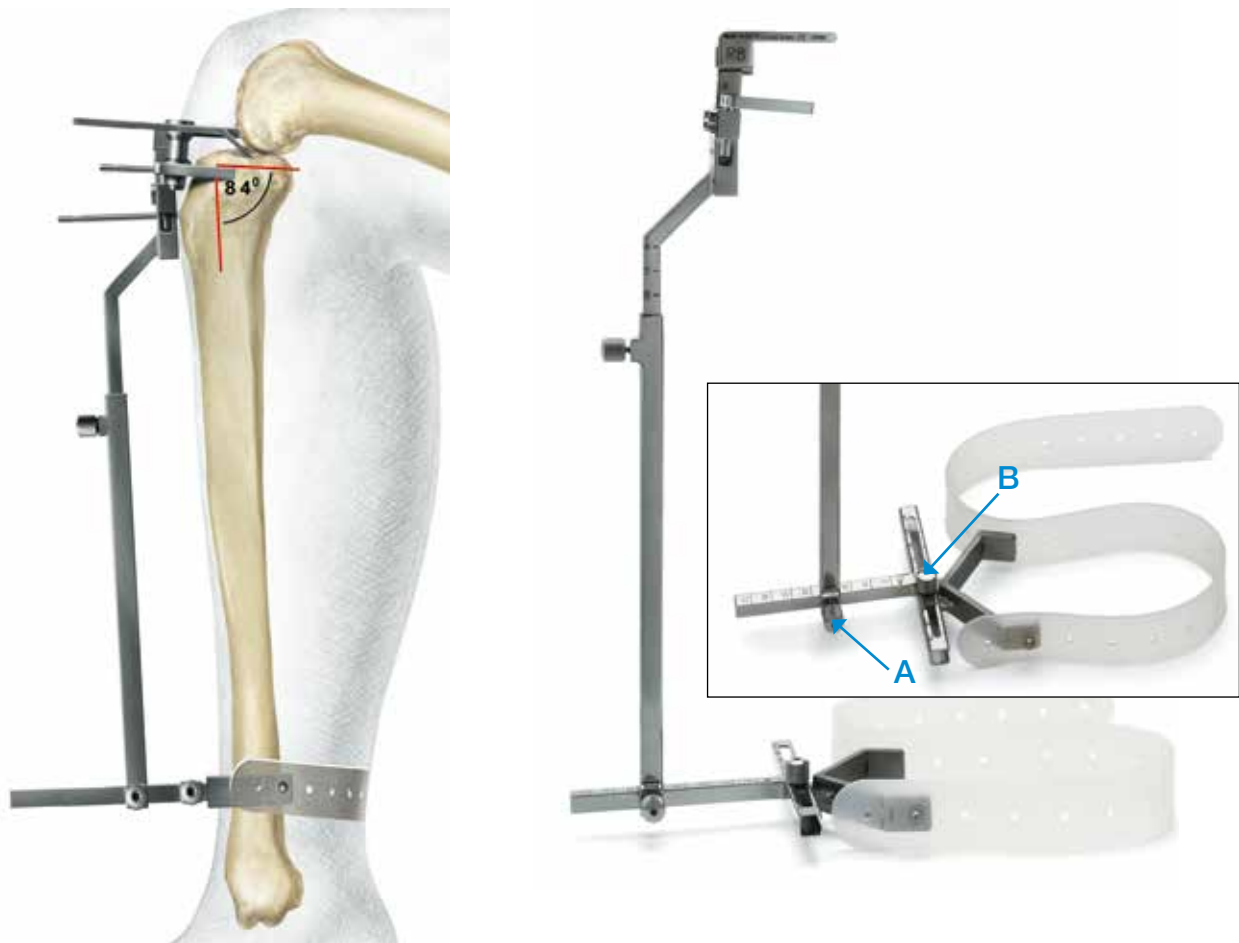
Table 1

When a 7-mm high Tibial Plateau is used, the tibial resection depth should be 9 mm in Grade I knees and 7 mm in Grade II knees. Because the construction of the Tibial Saw Guide does not permit less than 7 mm resection depth between the tip of the stylus and the Cutting Platform a 7-mm Tibial Plateau cannot be used in Grade III osteoarthrosis, and such knees must therefore be undercorrected. According to suggestions given above, the depth of the resection when using an 11-mm Tibial Plateau will be 13 mm in Grade I, 11 mm in Grade II, and 9 mm in Grade III. These resection depths will unnecessarily be too deep and will remove more bone than necessary.

Table 2

It is convenient to use the same resection depth independent of the degree of cartilage and bone damage. This means that a resection depth of 9 mm in relation to the tibial surface is needed in order to use a 7-mm Tibial Plateau in Grade I, a 9-mm Tibial Plateau in Grade II and an 11-mm Tibial Plateau in Grade III to achieve the same degree of alignment.

■ Tibial Resection



The clamp of the Tibial Saw Guide is placed at the level of the ankle directly proximal to the malleoli.

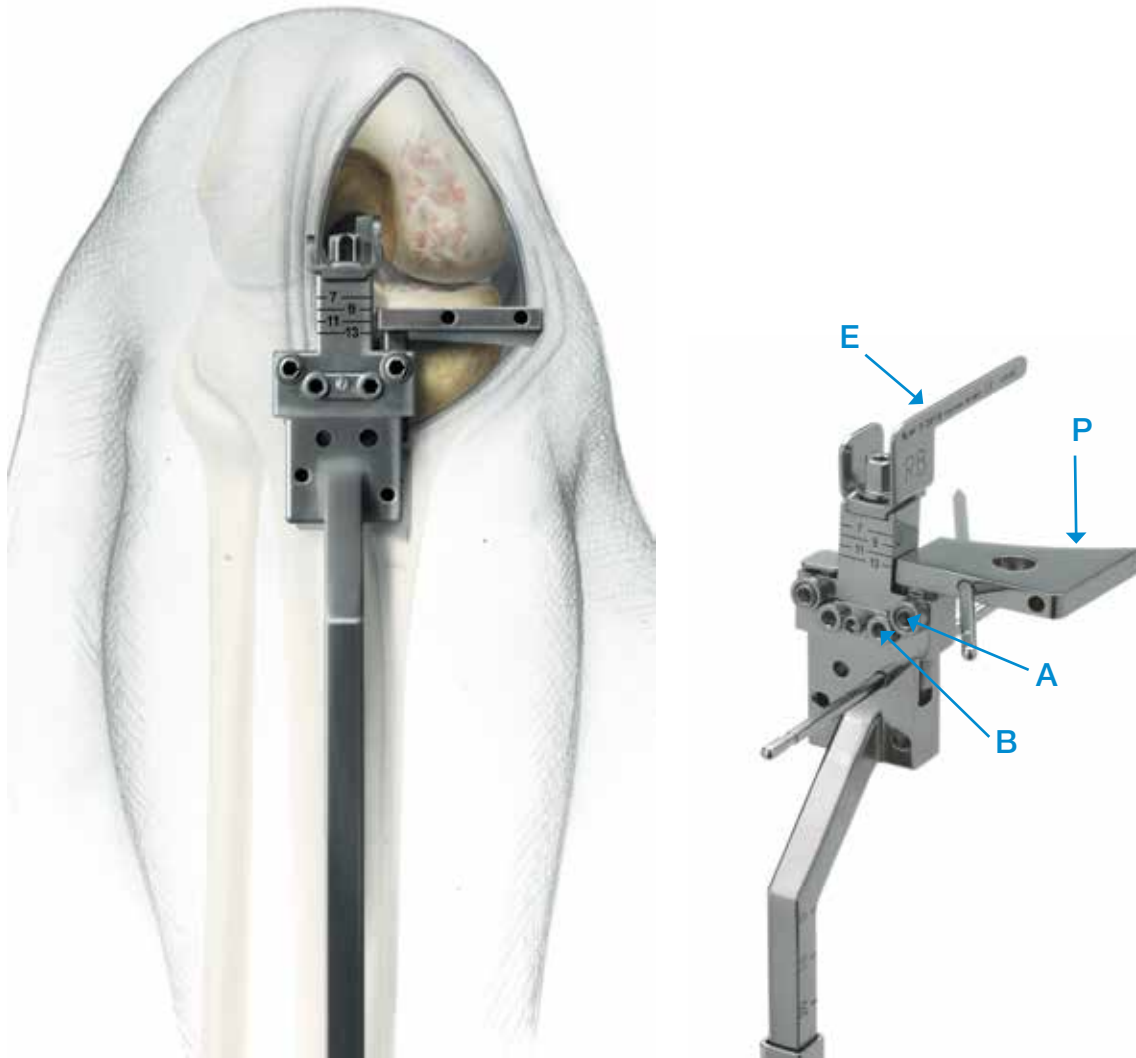
The posterior slope of the Tibial Component

Note that the Cutting Platform has a posterior slope of 6° in relation to the long axis of the Guide. The Tibial Saw Guide should be adjusted in the vertical plane parallel to the long axis of tibia by moving the vertical rod ventrally. In most cases the Guide needs to be moved 20–25 mm anteriorly to obtain the required posterior angle of a 6°. **Lock Screw A.**

The horizontal slope of the Tibial Component

The horizontal slope of the Tibial Component can be adjusted by placing the distal fixation of the long rod beneath the actual tibia condyle. In women the rod is moved approximately 20–25 mm and in men 25–30 mm from the centre to achieve a cutting surface perpendicular to the long axis of tibia. The horizontal slope is controlled with the Alignment Rod. **Lock Screw B.**

■ Tibial Resection

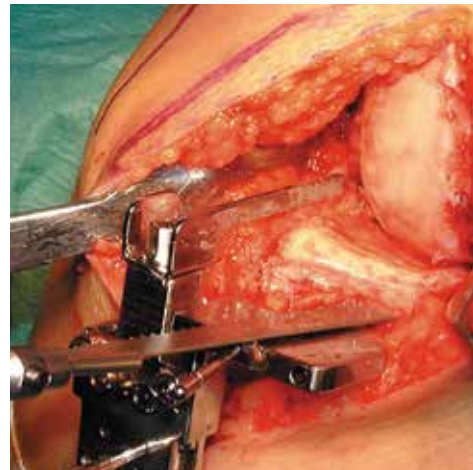


The **Eminentia Saw Guide (E)** is placed close and parallel to the eminentia along the planned sagittal cut.

There are **Cutting Platforms (P)** for the medial as well as the lateral compartments. The cutting depth can be set between 7 and 13 mm by using a Screwdriver in the adjustment **Hole (B)**. The Cutting Platform is secured and locked with **Screw (A)**.

The **Tibial Saw Guide** is fixed with a Fixation Pin in the central hole of the platform. The Pin is angulated centrally towards the eminentia. A second Fixation Pin is placed in the Tibial Saw Guide to secure the position.

■ Tibial Resection



Bone Cuts

The **vertical cut** is performed along the Eminentia Saw Guide. The **horizontal cut** is guided by the Cutting Platform.

The resected Tibial Plateau and remaining parts of the meniscus are then removed.

■ Tibial Resection



Templates for Tibial Plateaus all-Polyethylene (3 sizes: 45, 50, 55 mm)



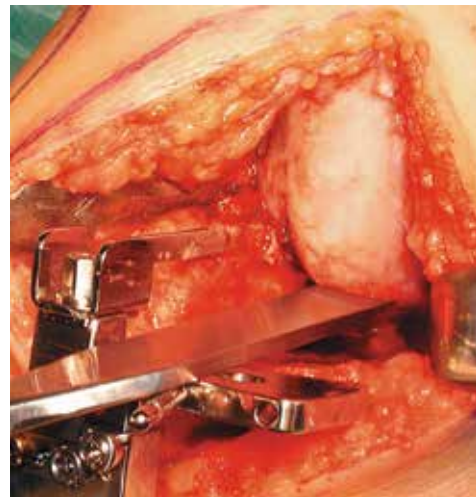
Templates for Tibial Plateaus metal-backed (3 sizes: 45, 50, 55 mm)

Depending on implant selection a **Template** is used for the sizing of the Tibial Plateau. Both are available in three sizes (45, 50 and 55 mm).

The size of the Tibial Plateau in the sagittal plane is determined by placing the hook of the Template behind the tibial condyle. If the anterior part of the Template is in alignment with the anterior border of the tibia, that is the right size.

The size must be checked medially to ensure there is no medial overhang.

■ Femur Resection

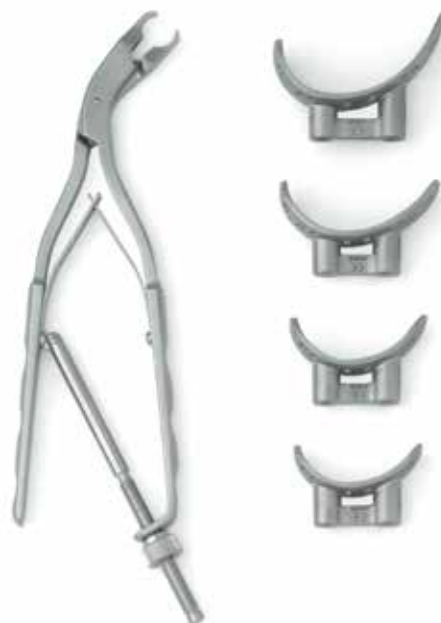
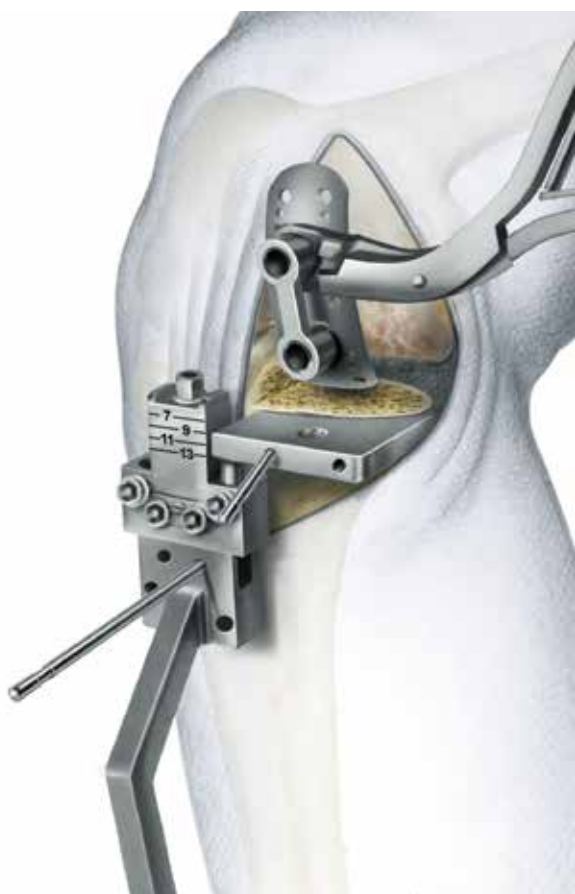


Do not remove the Tibial Saw Guide during the preparation for the Femoral Component.

Begin the preparation of the femoral condyle by cutting 3–5 mm of its posterior aspect to remove undamaged cartilage.

Resect central and medial osteophytes, with attention to osteophytes behind the medial collateral ligament.

■ Femur Resection



There are four sizes of the Femoral Components (40, 46, 52 and 60 mm) and corresponding Drill Guides to determine the correct size. The selected femoral Drill Guide is placed centrally on the femoral condyle and fixed with two short Fixation Pins.

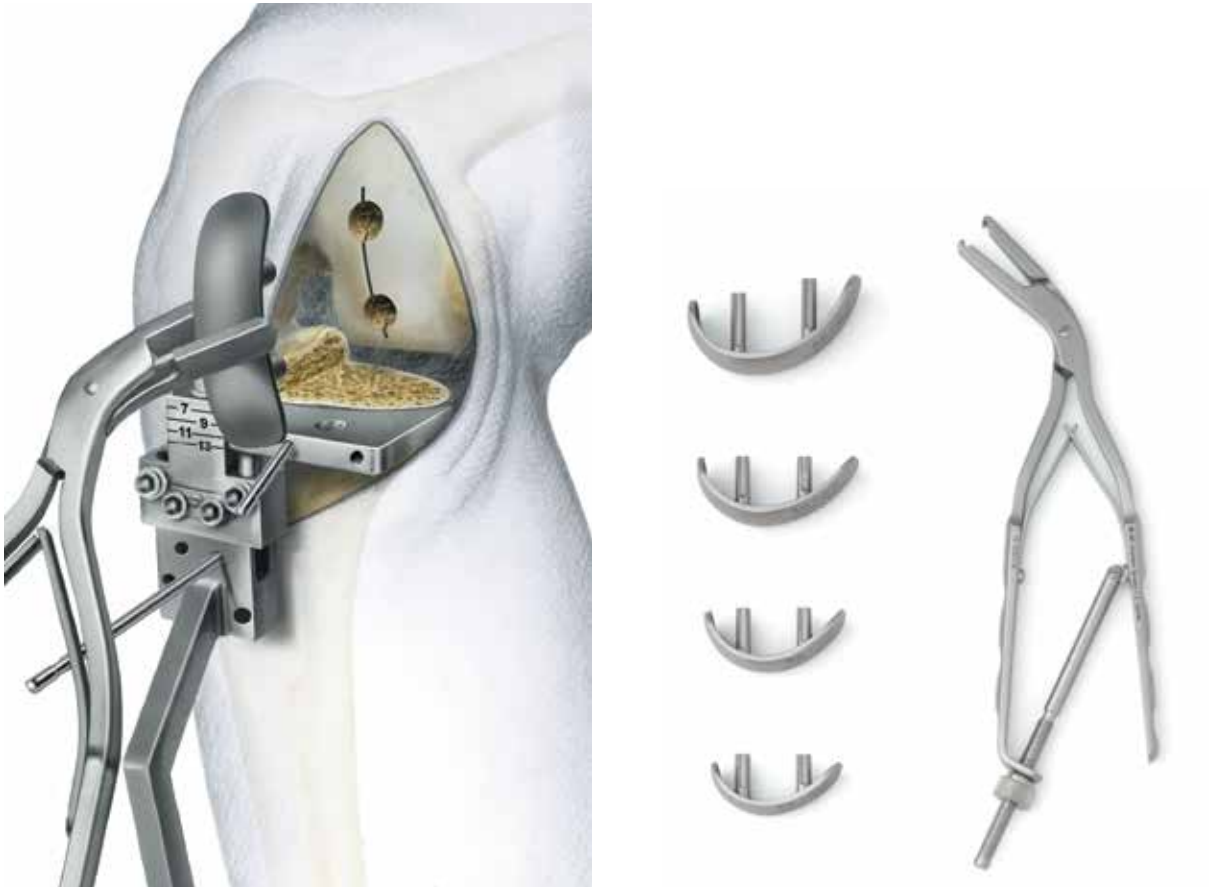
■ Trial Reduction



Drill the anchoring holes. If it is difficult to drill the lower hole at 100-110° of flexion of the knee, the Femoral Drill Guide is either too large or has been placed too far dorsally. Either change its position or chose a smaller Drill Guide.

Mark the borders of the Drill Guide. Remove any cartilage inside the area marked for the Femoral Component.

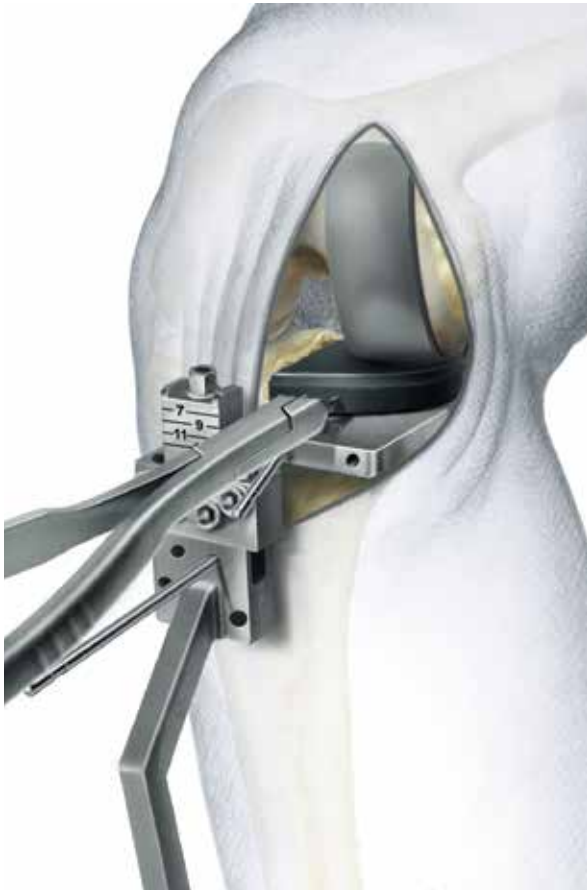
■ Trial Reduction



Corresponding to the Femoral Drill Guides are four **Femoral Trial Sled Prostheses**. Before trialing the chosen size, use a chisel or a saw to prepare a groove between the two anchoring holes. Place the Femoral Trial Sled Prosthesis using the **Inserting Forceps**.

Test knee flexion and extension to make certain that the Femoral Trial Sled Prosthesis does not make contact with the patella at any point during the movement. If it does, remove that part of the patella that made the contact.

■ Trial Reduction

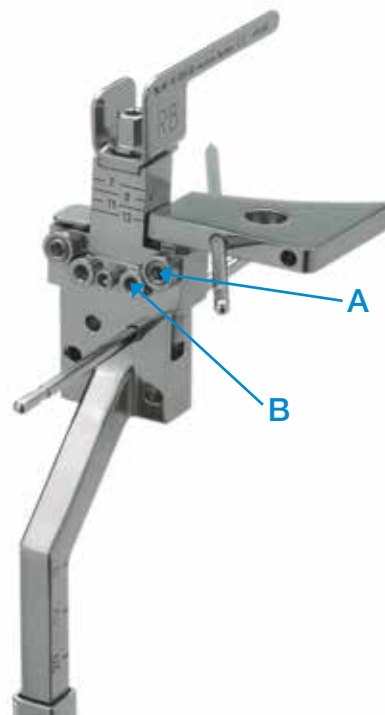


The **Tibial Plateaus** (all-polyethylene) are available in 4 heights (7, 9, 11 and 13 mm) and the Tibial Plateaus (metal-backed) in 3 heights (9, 11 and 13 mm).

With the Femoral Trial Sled Prosthesis in place, a 9-mm **Tibial Trial Plateau** is positioned. This is easiest when the knee is flexed at least 90°. Some valgus load may be needed. If the Tibial Component has a tendency to tilt anteriorly, the posterior angle of slope is too small. This can be corrected with a rasp.

Extend the knee to test the stability. In a normal knee there should be only a few millimeters' space between the components under valgus stress in a neutral position. If the gap is too wide change to a higher Tibial Component. In genu recurvatum, the gap is wider in the neutral position and the knee is stable only in hyperextension. Try to obtain the same degree of hyperextension of the knee as was present preoperatively, otherwise there is a risk that the knee will be overcorrected in valgus.

■ Trial Reduction

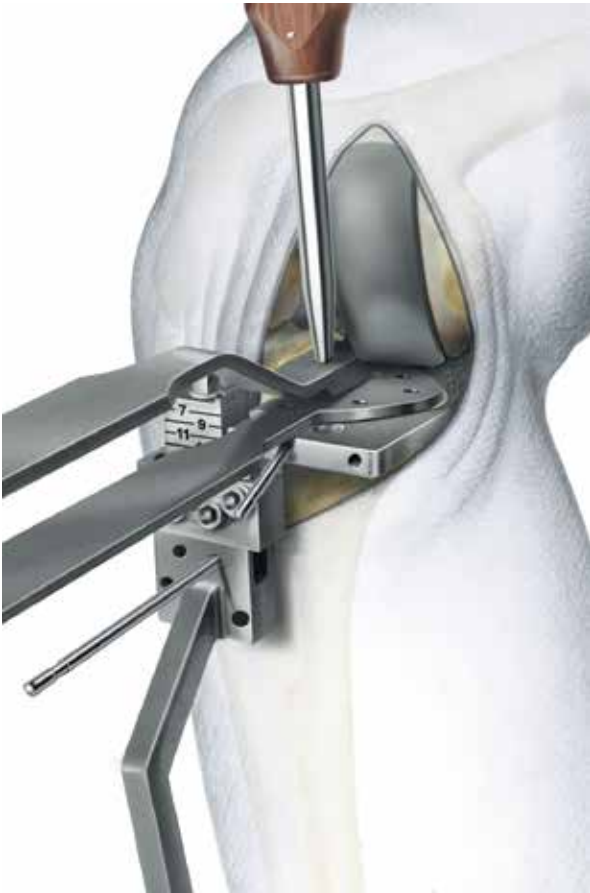


If the knee is too tight, remove the Tibial Trial Component and the Fixation Pin in the Cutting Platform and loosen **Screw (A)**. Deepen the resection by lowering the platform to the appropriate level by turning **Screw (B)** using a Screwdriver. As a rule 1-mm increase in resection depth increases varus angulation by 2 degrees.

Secure the Cutting Platform by tightening **Screw (A)** and stabilize it with a Fixation Pin through one of the unused holes in the Cutting Platform.

Perform the cut and repeat the trial by using the same height of the Tibial Trial Component.

■ Cementation

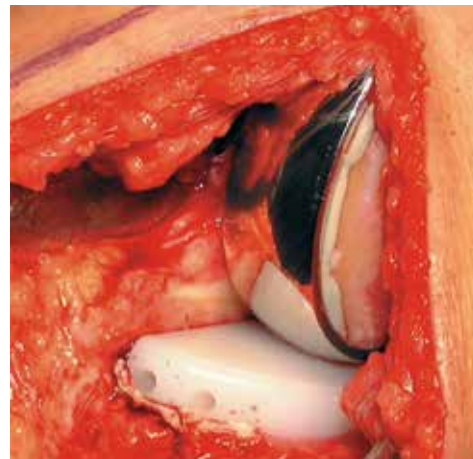


Prepare the space for the keel of the Tibial Plateau (metal-backed), place the head of the **Cancellous Bone Compressor** into the recess of the tibial Template and impact it using the **Impactor**.

The keel of the Tibial Plateau (all-polyethylene) is larger. To prevent fractures of the tibial condyle remove some bone with a chisel before impacting the Bone Compressor.

Whichever Tibial Plateau is being used, the tibial surface needs to be protected during the compression of the bone with the tibial Template, which is laid on the sawing platform. Test that the final choice of Tibial Plateau fits and can be placed easily. Some valgus stress will be needed. The keel slot may be extended anteriorly if necessary.

■ Cementation



Before cementing the prosthesis remove the Tibial Saw Guide.

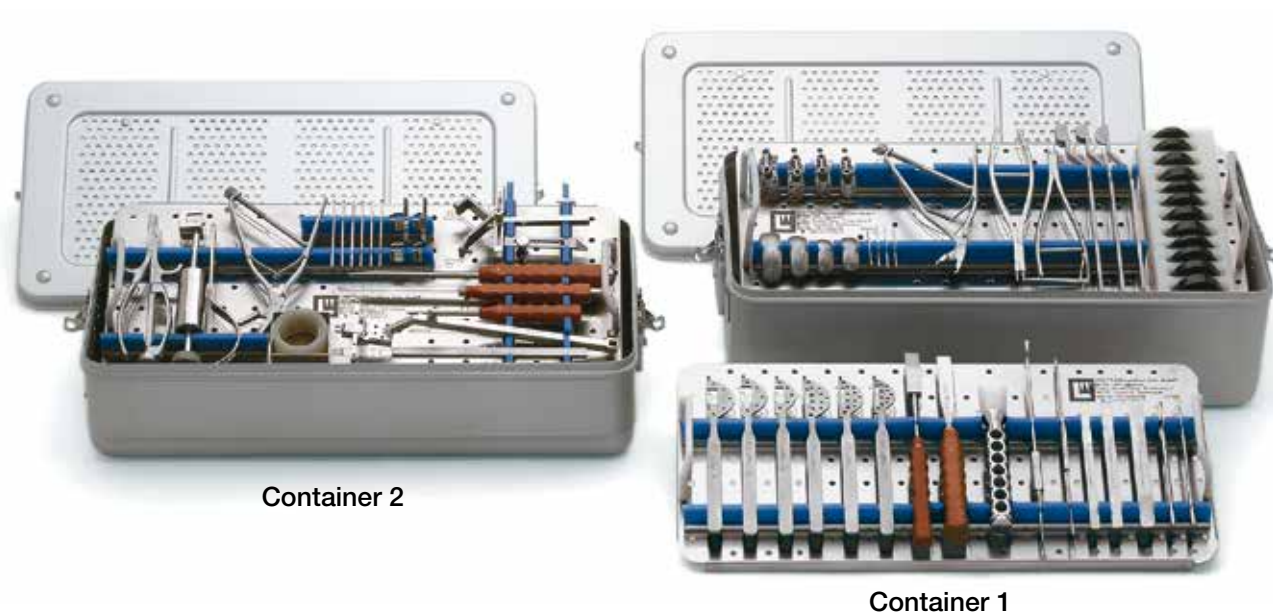
Prior to cementing inject 40 ml of 0.25 % Marcain® (Bupivacain) into the capsule to minimize postoperative pain and to facilitate the mobilization of the patient. Using an appropriate cementing technique, cement the Femoral Prosthesis first. Remove excess cement with the curette.

Extend the knee to a neutral position and allow the cement to harden. Remove any remaining excess cement.

Release the tourniquet and carry out careful hemostasis. The capsule and skin are sutured with the knee flexed at 90°.

■ **MITUS® Instrument Set**

for Minimally Invasive OP-Technique of the LINK® Unicondylar Sled Prosthesis



Container 2

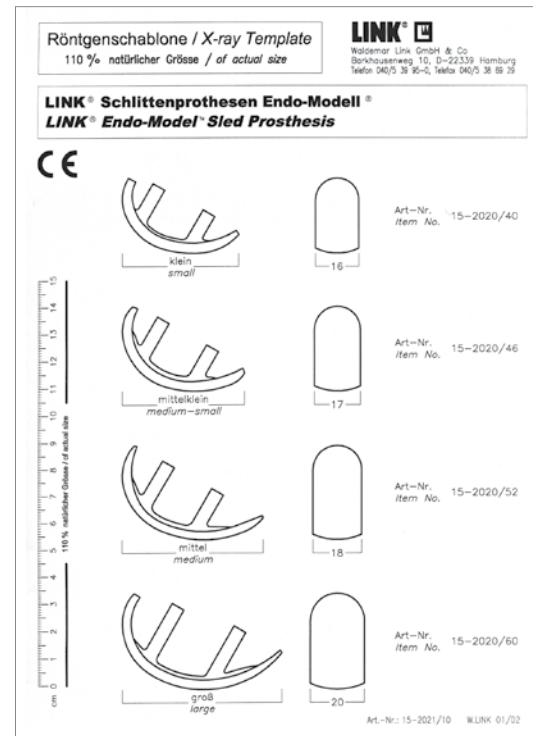
Container 1

Item no.	Instrument Set, complete (Container 1 and 2)	
15-2201/01	Set complete , in 2 standard containers, on 3 trays with storage inserts <u>Consisting of:</u>	
05-2001/03	N11 Standard Container , empty, 575 x 275 x 100 mm	1 ea.
05-2002/03	N21 Standard Container , empty, 575 x 275 x 130 mm	1 ea.
15-2200/02	Lower Tray (Container 1) , empty, stainless steel, 550 x 265 x 50 mm	1 ea.
15-2200/03	Upper tray (Container 1) , empty, stainless steel, 550 x 265 x 50 mm	1 ea.
15-2200/01	Tray (Container 2) , empty, stainless steel, 550 x 265 x 50 mm	1 ea.

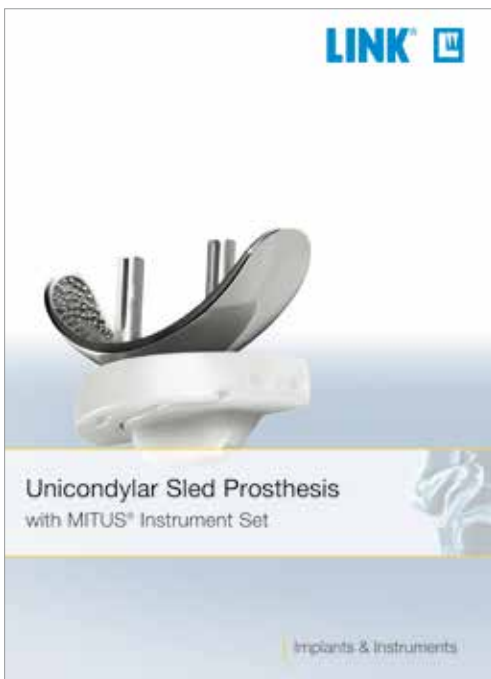
■ X-rays

X-ray Templates, 110% actual size, 1 sheet

Item no.	Application
15-2021/10	for Unicondylar LINK® Sled Prosthesis 15-2020/40 to 15-2020/60
15-2021/11	for Tibial Plateaus (metal-backed) 15-2030/01 to 15-2030/12
15-2021/13	for Tibial Plateaus (all-polyethylene) 15-2028/01 to 15-2028/12



■ Further Information



Catalogue:
**LINK® Unicondylar Sled Prosthesis
with MITUS® Instruments**
Implants & Instruments
available on request.

Please note the following regarding the use of our implants:

1. Choosing the right implant is very important.

The size and shape of the human bone determine the size and shape of the implant and also limit the load capacity. Implants are not designed to withstand unlimited physical stress. Demands should not exceed normal functional loads.

2. Correct handling of the implant is very important.

Under no circumstances should the shape of a finished implant be altered, as this shortens its life span. Our implants must not be combined with implants from other manufacturers.

The instruments indicated in the Surgical Technique must be used to ensure safe implantation of the components.

3. Implants must not be reused.

Implants are supplied sterile and are intended for single use only. Used implants must not be reused.

4. After-treatment is also very important.

The patient must be informed of the limitations of the implant. The load capacity of an implant cannot compare with that of healthy bone!

5. Unless otherwise indicated, implants are supplied in sterile packaging.

Note the following conditions for storage of packaged implants:

- Avoid extreme or sudden changes in temperature.
- Sterile implants in their original, intact protective packaging may be stored in permanent buildings up until the "Use by" date indicated on the packaging.
- They must not be exposed to frost, dampness or direct sunlight, or mechanical damage.
- Implants may be stored in their original packaging for up to 5 years after the date of manufacture. The "Use by" date is indicated on the product label.
- Do not use an implant if the packaging is damaged.

6. Traceability is important.

Please use the documentation stickers provided to ensure traceability.

7. Further information on the material composition is available on request from the manufacturer.

Follow the instructions for use!

Waldemar Link GmbH & Co. KG, Hamburg

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The Surgical Technique described has been written to the best of our knowledge and belief, but it does not relieve the surgeon of his/her responsibility to duly consider the particularities of each individual case.

Unless otherwise indicated, all instruments are made of surgical stainless steel.



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