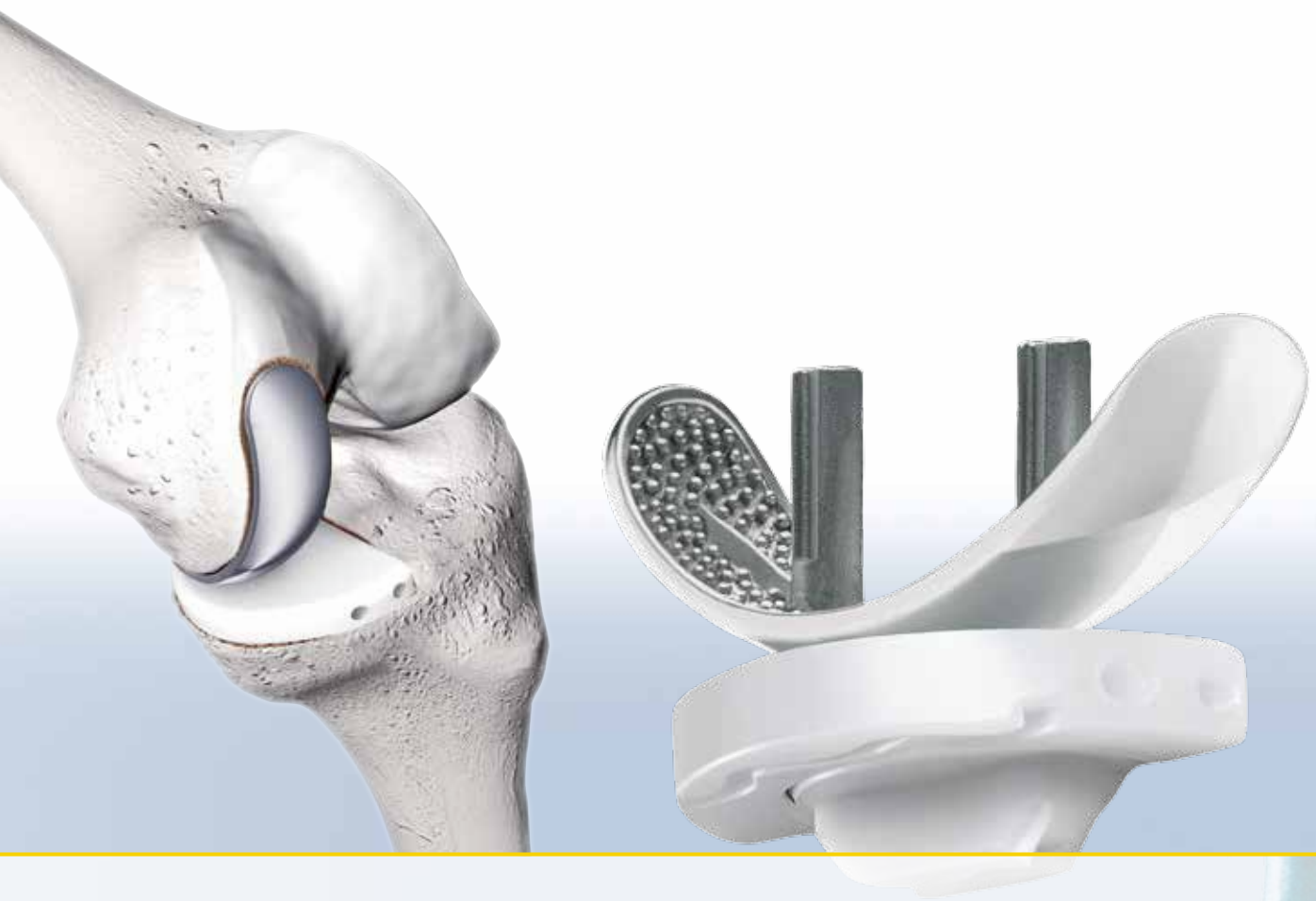

LINK® Sled Prosthesis

with MITUS® **ART** Instrument Set
Anatomic Reconstruction Technique

Surgical Technique

Presented by:

CE 0482

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LINK® Sled Prosthesis

with MITUS® **ART** Instrument Set
Anatomic Reconstruction Technique

This surgical technique guide was written in conjunction with:
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We would like to thank him for his valuable contribution.

LINK® Sled Prosthesis

Surgical Philosophy

”A resurfacing arthroplasty with minimal bone resection and maintenance of native anatomy”

The **LINK® Unicondylar Sled Prosthesis** was first implanted in 1969. Subsequent operative experience resulted in revisions to the initial prosthesis but the following basic design features have remained unchanged:

- This exceptional time frame and the outstanding clinical results are documented in numerous puplications *
- Polycentric femoral design – anatomically adapted shape
- Tapered superior femoral border – minimizing any risk of patella impingement
- 'Round-on-flat' design – allowing a high degree of initial freedom of movement and individual patient-specific motion after 'setting-in' phase
- Bone-preserving thanks to resurfacing philosophy

There have been no modifications since 1981 and it has been used successfully to treat both medial and lateral gonarthrosis.

The **LINK® Unicondylar Sled Prosthesis** only requires minimal bone resection, allowing cementation to the higher-quality bone stock which is vital for long-term secure fixation.

The technical guidance given below will ensure:

- A consistent, reliable technique
- Minimal bone resection
- Maintenance/restoration of bony (tibial slope) and soft tissue (cruciate/collateral) anatomy
- No 'edge loading' of the components
- An articulation with the centre of the plateau throughout the range of movement

* Annual Report: The Swedish Knee Arthroplasty Register 2013, http://www.myknee.se/en/.
Newman, J. et.al.: Unicompartmental or Total Knee Replacement, the 15-Years Results of a Prospective Randomised Controlled Trial; J Bone Joint Surg [Br] 2009; 91-B:52-7
Steele R.G. et.al.: Survivorship of the St. Georg® Sled Medial Unicompartmental Knee Replacement Beyond Ten Years; J Bone Joint Surg [Br] 2006; 89-B:1164-8

LINK® Sled Prosthesis

Femoral Components

The 'round-on-flat' articulation allows an initial high degree of movement with the joint motion being guided exclusively by the existing soft tissue constraints. Furthermore the design compensates for minor malposition without resulting in 'edge loading' of the component. The large surface radii serve to distribute the load over a larger area of the plateau than would be the case with smaller radii. The globular nature of the concave side of the femoral component provides optimal bonding between the implant and cement. The alignment and shape of the fixation pegs allow for easy positioning of the sled.

Note: Should revision be necessary the minimal resection of bone required to implant a LINK Sled Prosthesis will result in bone stock being preserved for the revision procedure resulting in a simpler procedure.

The femoral components are available in four sizes:

- Small (16 x 40 mm)
- Medium small (17 x 46 mm)
- Medium (18 x 52 mm)
- Large (20 x 60 mm)

Tibial Plateaus

As a result of their symmetrical shape the tibial plateaus can be used for both the medial and lateral tibial compartments. The sizing is adapted to the anatomical shape of the tibia.

- **All-poly Design**
  This design comes in four heights – 7, 9, 11 and 13 mm – and four diameters – 45, 50, 55 and 58 mm. The structured underside allows an excellent bone-cement interface.

- **Metal-backed Design**
  This design comes in four heights – 8, 9, 11 and 13 mm – and three diameters – 45, 50 and 55 mm. The globular undersurface of the plateau offers optimal bone-cement bonding.

LINK® Sled Prosthesis

LINK PorEx® (TiNbN = Titanium Niobium Nitride) Surface Modification – for patients who are hypersensitive to metal

The hypoallergenic LINK PorEx® surface modification leads to a ceramic-like surface, which significantly reduces the ion release of CoCrMo substrate. [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] Internal technical report: Study of the influence of TiNbN-coating on the ion release of CrCrMo-alloys in SBF buffer simulator testing

MITUS® ART Instrument Set

The instrument set is easy to use. All the instruments can be dismantled without tools and are stored on instrument trays in a clear and structured manner which ensures that they are sterile and ready-at-hand when needed. The use of these instruments should ensure:

- Conservation of bone stock
- Restoration of alignment and full control of tibial resection:
  - Posterior slope
  - Varus/valgus
  - Resection height
- Anatomically adapted femoral preparation
- Simple tibial preparation with milling system
- Possible application medial and lateral

The purpose of the LINK® Sled Prosthesis is to restore the damaged joint surfaces which will restore the original mechanical axis. Most patients will present with an underlying 'constitutional' varus and a slight 'undercorrection' of alignment can be achieved if desirable to reproduce this.

Patient Selection

Selection of the 'correct patient' is essential and as such consideration should be given to the indications / contraindications below:

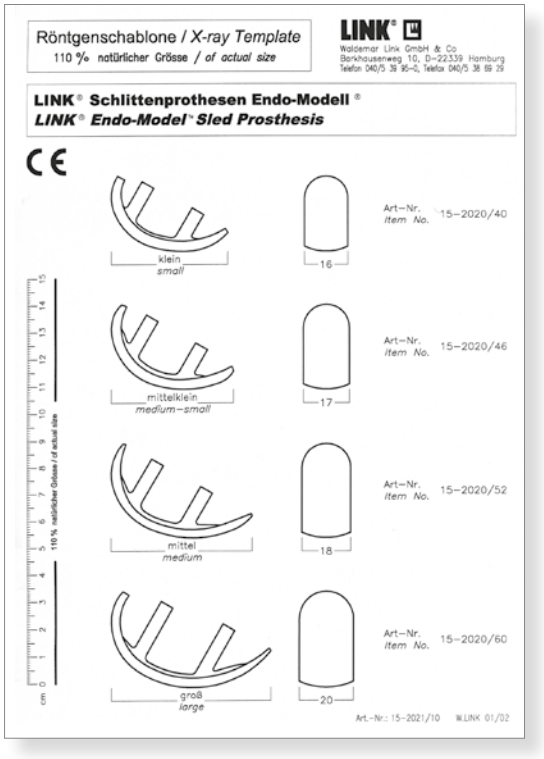
General Indications:

- Severe unicompartmental disease with limitation of mobility due to degenerative or post-traumatic arthrosis or arthritis.
- Unicompartmental arthrosis in a stable knee (intact ligaments including anterior and posterior cruciate ligaments) with correctable varus/valgus deformity (<10°)

Contraindications:

- Acute / chronic infections, local or systemic
- Hypersensitive to (implant) materials (LINK PorEx® indication)
- Neuro muscular disease affecting the limb which would put an arthroplasty 'at risk'
- Insufficient / inadequate bone stock preventing stable fixation of either prosthesis
- 'High' BMI
- Unstable knee (insufficient collateral ligaments)
- Non compliant patient

Patient Selection / Surgical Planning



Pre-operative planning is an essential part of the surgery. Weight bearing AP views taken in slight flexion are essential as is a good lateral image. There must be no compromise of the lateral compartment. These may be supplemented by stress views to ensure we are dealing with a correctable deformity.

X-ray templates of the individual components (femur and tibia) which are 110% the actual size are available. A note should be made of the natural tibial slope which will act as a guide during the tibial resection. These views may be supplemented by a long leg X-ray to determine the pre-operative weight bearing axis and any extra-articular deformity. We also support electronic computerized planning and cooperate with the leading manufacturers of electronic templating systems. We would be pleased to provide you with more information on request.

The MITUS® instruments are suitable both for the traditional approach and for a less invasive approach, producing less soft tissue damage. When the instruments are used as described below, the intervention can be performed with a small incision yet maximum precision.

Patient Positioning and Surgical Approach

Positioning

Following general/spinal anaesthesia and application of a tourniquet (optional), the patient is placed in the supine position and the flexion range of the knee joint is checked. It should be possible to flex the knee at least 120°. Coverage of the tibia and ankle should not be too thick in order to reliably determine the center of the ankle. The alignment instrument can then be set with the appropriate precision.

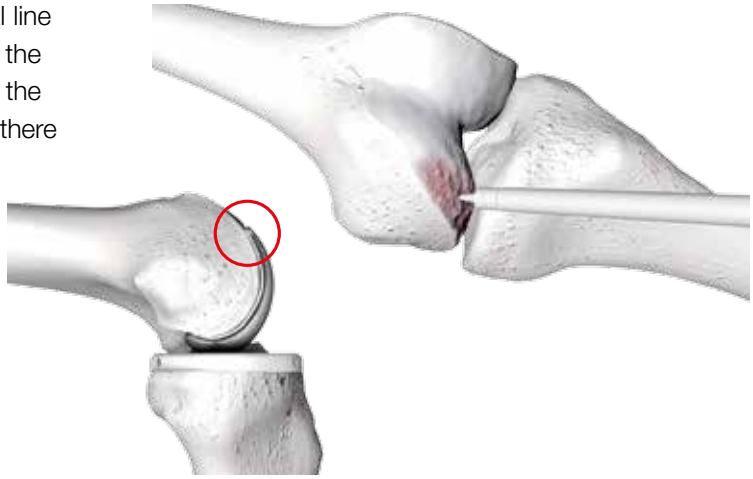
Suggested approach: Medial UKR

With the knee flexed 90°, a medial paramedian skin incision is made extending from a point 4 cm above the patella to a point midway between the tibial tuberosity and the joint line. A medial para patellar (omega) capsular incision is made which runs along the side of the patella tendon. This prevents later damage to the tendon when the reciprocating saw is used.

Following entry into the joint, the fat is partially excised from the medial side of the anterior compartment to allow direct visualization of the lateral wall of the medial femoral condyle.

A medial meniscectomy is performed but there is no requirement for any detachment of the medial collateral ligament. The osteophytes are then removed from the medial and lateral borders of the medial femoral condyle and the medial border of the tibial plateau to define the true borders.

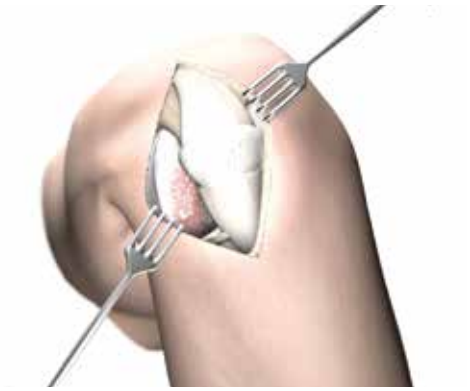
Finally the leg is fully extended and a horizontal line is marked on the femoral condyle to represent the future upper margin of the femoral prosthesis. If the femoral component projects beyond this mark, there is an increased risk of patellar impingement.



Tibial Resection

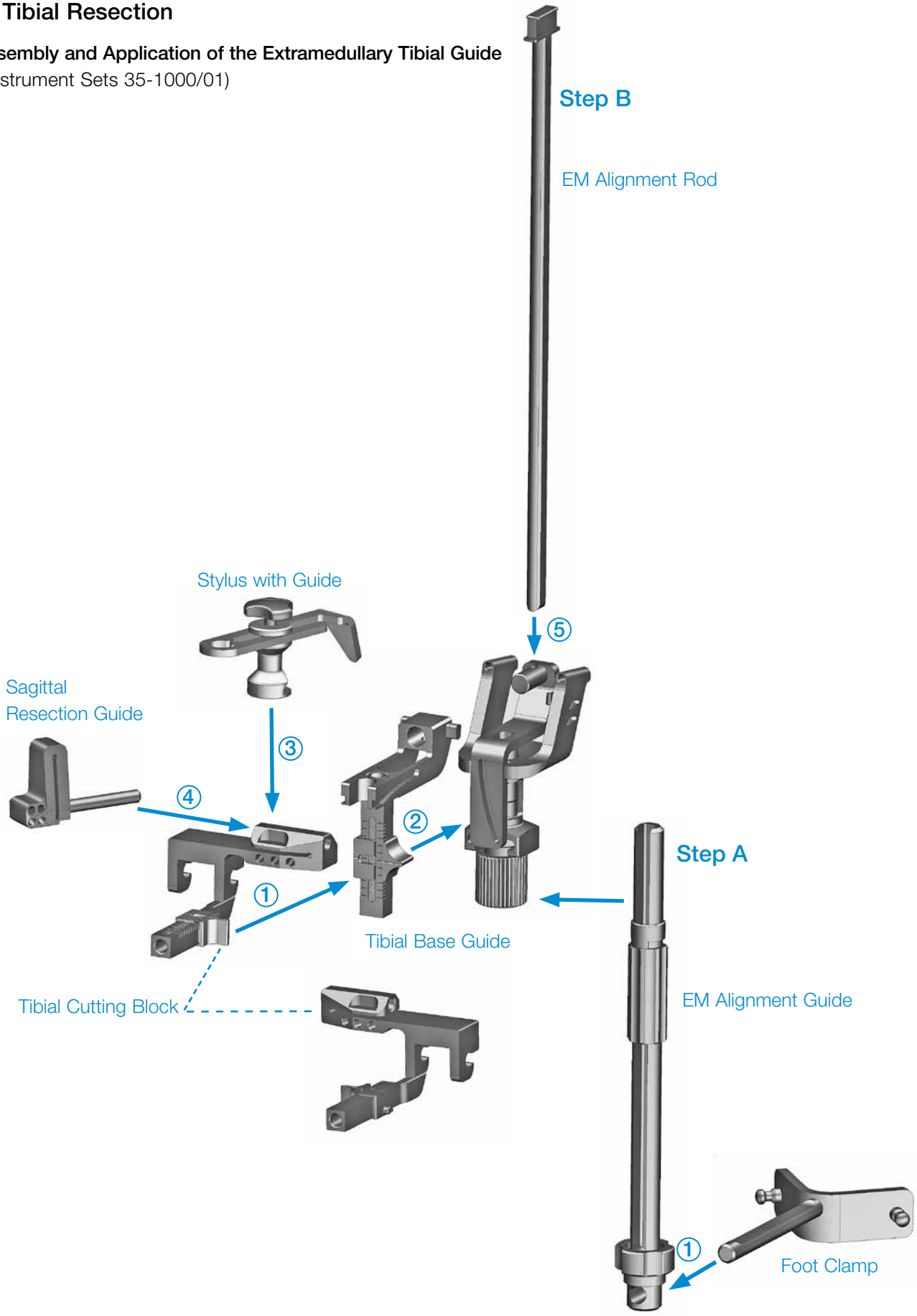
The front of the tibia is visualized in the distal area from the tuberosity to the margin of the plateau. Larger osteophytes are removed from the front of the tibia as these hinder positioning of the tibial saw guide.

The tibial saw guide enables the user to precisely set and maintain the desired resection height, varus/valgus alignment and posterior slope.



Tibial Resection

Assembly and Application of the Extramedullary Tibial Guide
(Instrument Sets 35-1000/01)



Tibial Resection

The following is the sequence for tibial resection:

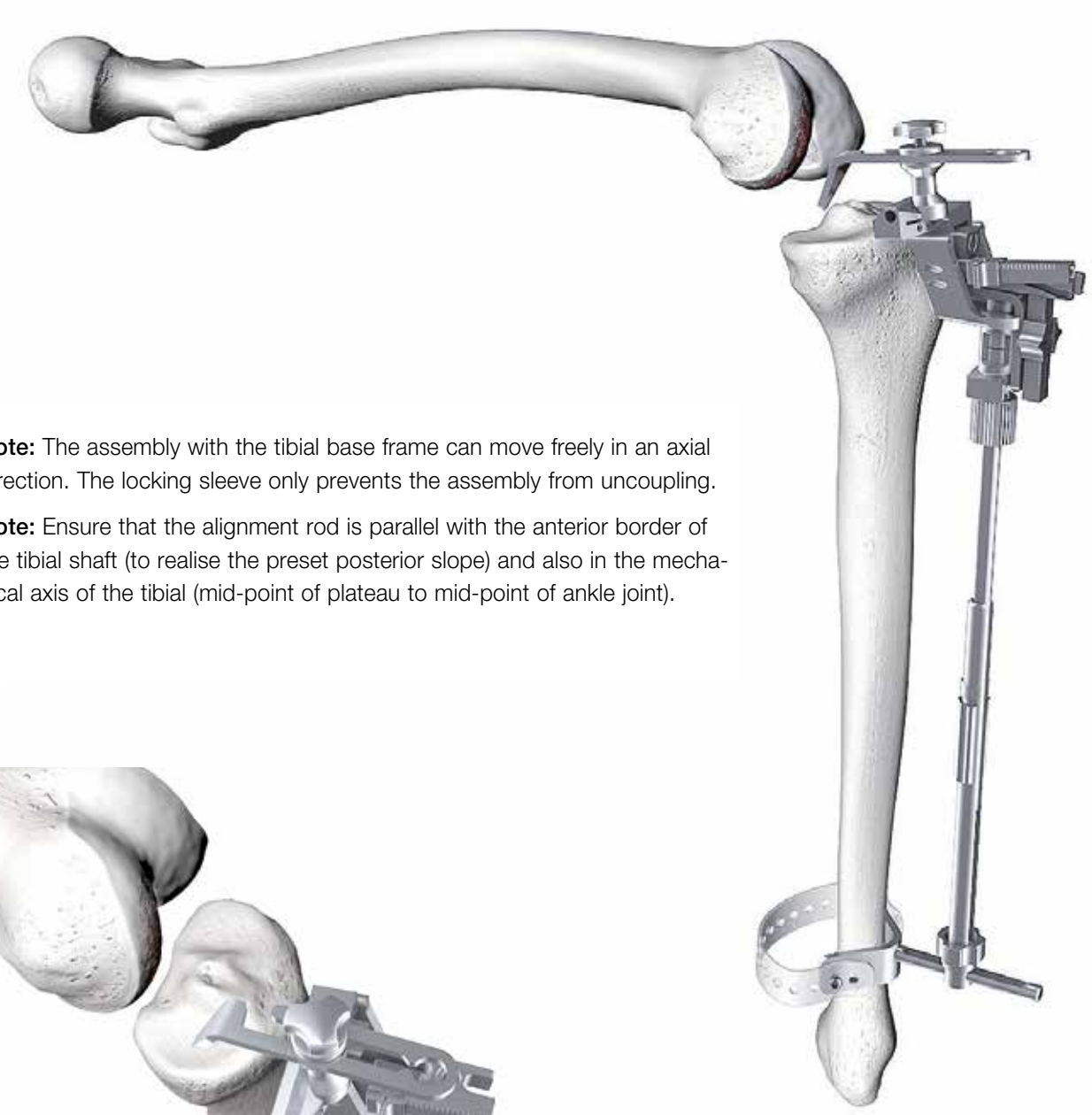
- Apply jig (with pre-set slope)
- Align jig
- Use stylus to calculate height of resection
- Fixation with pins
- Saggital cut with reciprocating saw
- AP cut with saggital saw
- Review tibial resection fragment (thickness/symmetry)
- Revise cut if required
- Ensure all bony fragments and post horn of meniscus is excised from the posterior aspect of the compartment

Fixation at the ankle is achieved either by the silicone strap or the optional spring clamp and is then assembled to the EM guide and positioned. The alignment guide is positioned parallel to the tibial shaft axis by releasing the set screw and pushing the EM guide in a anterior-posterior direction until the desired position is achieved. The set screw is then tightened again.

The appropiate tibial cutting block is positioned together with the mount for the tibial cutting block and assembled to the tibial base frame. The 5 mm stylus (optional 7 mm) is inserted in the guide and positioned on the tibial base frame. The EM alignment rod is pushed through the tibial base guide and secured using the locking sleeve.

Note: Set the height setting to ‘neutral’ in order to make subsequent fine adjustments.

Tibial Resection



Note: The assembly with the tibial base frame can move freely in an axial direction. The locking sleeve only prevents the assembly from uncoupling.

Note: Ensure that the alignment rod is parallel with the anterior border of the tibial shaft (to realise the preset posterior slope) and also in the mechanical axis of the tibial (mid-point of plateau to mid-point of ankle joint).

Tibial Resection

Determine the height of resection. The 5 mm stylus is used and should reference from the anterior margin/edge of the chondral defect. A good view must be ensured for this (if necessary open the joint slightly using a lamina spreader).

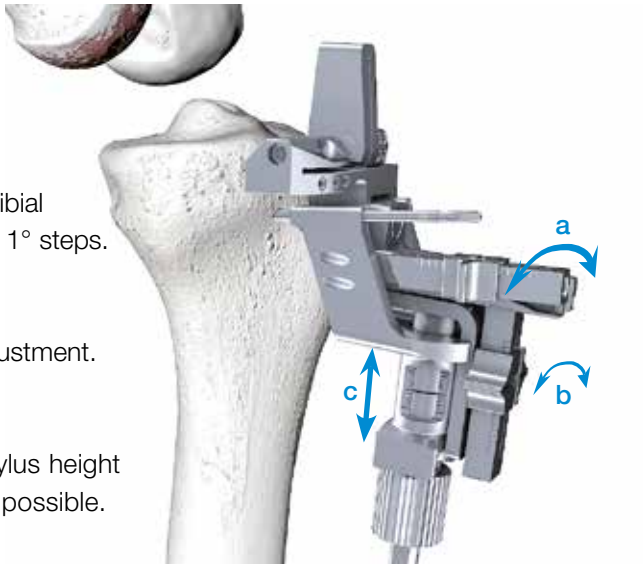
Note: The correct alignment and height of resection can be checked using the cutting template through the cut-tingslots for the saw.

The jig enables the user to precisely set and maintain the desired resection height, varus/valgus adjustment and setting for the posterior slope.

The tibial base frame initially is secured medially with a drill pin.

Note: Sufficient initial stability is usually achieved by the single pin and the foot clamp. If necessary an additional drill pin can be inserted medially (*).

The guide with stylus is removed. Fine adjustments can then made for precise tibial resection.



Fine adjustments for the tibial resection (if required)

Posterior slope (a)
The recommendation is to reproduce the pre-operative tibial slope. If an uneven cut is made it can be recut/adjusted in 1° steps.

Varus-valgus adjustment (b)
Precise varus or valgus alignment is possible with fine adjustment.

Tibial resection height (c)
After presetting the resection height with the selected stylus height fine adjustment of the resection height with the screw is possible.

Tibial Resection



After a final inspection of the proposed tibial resection, the tibial cutting block and (if desired) the sagittal resection guide are then fixed with a drill pin. The reciprocating saw is introduced through the vertical slot and should be in line with the lateral border of the medial femoral condyle. The cut should be in the AP direction. The sagittal saw is then introduced through the cutting slot. Care must be taken to ensure no damage is done to the superficial MCL, which may be protected with a retractor.

The drill pins for the tibial cutting block and the sagittal resection guide are removed and then the sagittal resection guide with the tibial cutting block are removed from the tibial base frame. If, later on, it becomes evident that the joint space is too small, the tibial cutting block can be simply repositioned and, after correcting the height setting, resection can be performed again.

The resected plateau is then inspected to assess its thickness and the evenness of the cut in the AP and medial/lateral planes. The plateau can then be sized by comparison with the tibial templates. It is important to ensure that all bony fragments/retained resection material and meniscal remnants are removed from the posterior aspect of the joint to allow easy positioning of the appropiate femoral drill guide.

It is important to ensure an adequate resection has been performed. A 7 mm trial is provided to insert onto the resected plateau which allows assessment throughout the range of motion.

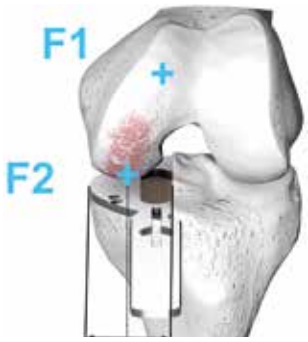
N.B. At this stage it is appropriate to visualise the femoral condyle as it articulates on the tibial plateau. In order to later guide the positioning of the femoral component an appreciation of the femoral condyle contact areas with the central aspect of the tibial plateau should be recorded. This is either with a marker pen or small drill holes.

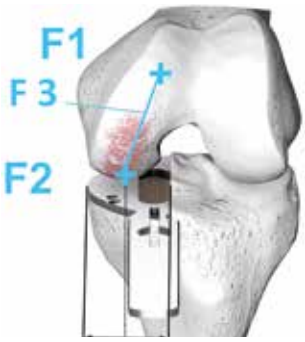
Femoral Component Positioning / Alignment

The positioning of an unicondylar prosthesis onto an anatomically unique femoral condyle will always involve a degree of compromise. However there are certain guidelines to aid in the positioning of the implant.

Femoral - tibial contact

In an attempt to prevent edge loading of the tibial component the femoral prosthesis should be positioned to contact in the centre of the tibial plateau. To aid this marks can be made on the femoral condyle before or after resection of the tibial plateau which correspond to the point of the femoral condyle which connects with the centre of the plateau in certain degrees of flexion.





Flexion / Extension

The drill guide should cover the femporal condyle in deep flexion and extend up to but not significantly beyond the ‚full extension line' previously marked. The selected femoral drill guide is positioned considering the previous indicated marks on the femoral condyle and fixed with drill pins. In doing so this will ensure total condylar coverage in flexion/extension and avoid any possibility of tibial component 'edge loading'.

Femoral Sizing

Note: Allowing a suitable sizing of the femoral component first the femoral cartilage has to be removed. Appropriate instruments are curette, sharp spoon, osteotome or burr.

Note: At this stage one should consider to remove the posterior osteophytes using a curved osteotome.

There are four sizes of the femoral component available (40, 46, 52 and 60 mm). The appropriate size is determined using the corresponding drill guides.

Femoral Preparation

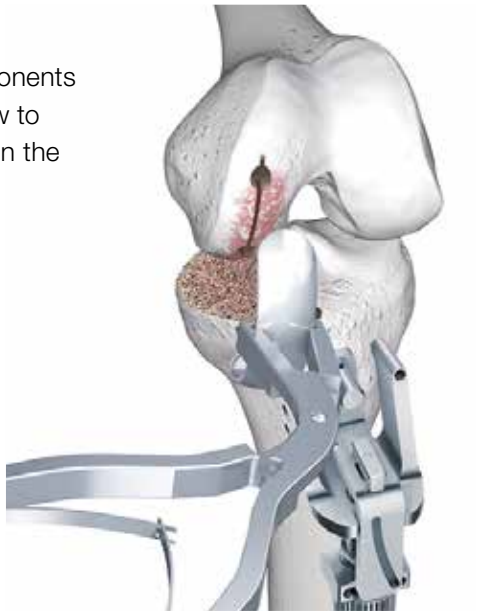
The fixation holes are drilled.

NOTE: The stop is to be unlocked using the corresponding hex head screwdriver (319-535/00). The stop is adjusted according to the implant size:

Small: S/MS
Medium-Small: S/MS
Medium: M
Large: La

Femoral Preparation

Corresponding to the femoral drill guides there are femoral trial components available. Prior to positioning the trial use a chisel or an oscillating saw to prepare a groove between the two fixation holes ensuring that the fin on the backside of the femoral component will fit.



To ensure adequate bony resection and 'balance' a trial reduction is performed. The trial sled prosthesis is placed on the prepared femoral condyle using the inserting forceps.

If the joint space it too small, the space can be corrected by refining the tibial cut in the appropriate way.

If the result is satisfactory, the tibial resection guide is taken off after removing the fixation pins and releasing the anchoring.

Tibial Preparation

The tibial preparation consists of:

- Sizing and aligning the tibial plateau
- Preparation of the tibial keel
- Shaping/final preparation of the tibial keel

Two options are available for the tibia: a metal-backed tibial component or an all-poly tibial component.

Due to the different profile of the backside of the implant the preparation required differs:

All-poly Tibial Component
Preparation can be done with either a milling system or a keel chisel and is concluded using a bone compressor.

Metal-backed Tibial Component
Here preparation is done exclusively with a keel chisel.

The tibial template used is based on the implant decision (metal-backed or all-poly):

All-poly Tbial Components	
Size (a/p) mm	Width (m/l) mm
45	22
50	27
55	29
58	31
Metal-backed Tibial Components	
Size (a/p) mm	Width (m/l) mm
45	22.5
50	25.0
55	27.5

Tibial Preparation: All-poly Component

The appropriately sized tibial template is put into place. It can be used left/right and medial/lateral. The ideal size (a/p) is determined by positioning the hook at the end of tibial template posterior of the intercondylar eminence. The template should be perfectly aligned with the anterior margin of the tibia. Do not undersize. The tibial template is secured using a screw **pin with stop** (drill pin with stop 319-566/00 or alternatively thread **pin with stop** 319-560/01).

Option: With soft bone, the tibial template can be additionally secured by the mill fixation adapter and further drill pins.

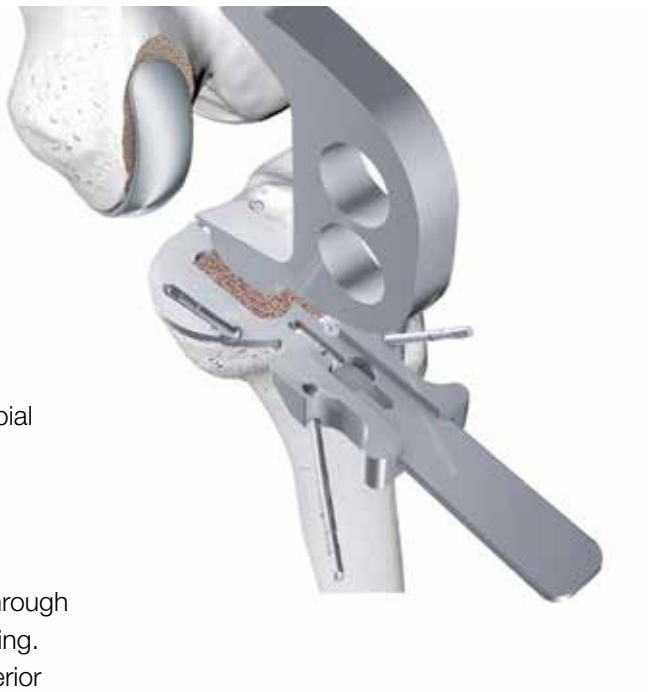
Tibial Preparation: All-poly Component

There are two options for preparing the keel.

1. Milling System
The tibial mill is selected according to the component size.

- The **tibial mill guide** is placed in the tibial template in anterior position.
- The **tibial cutter** is inserted and put into operation, milling is then performed up to the stop and the tibial cutter is subsequently removed.
- The **tibial mill guide** is pushed toward posterior and the mill is operated up to the stop. Then, with the mill operating, the tibial mill guide is moved toward anterior/posterior in order to prepare the box.

Once preparation is complete, the tibial cutter is removed followed by the tibial mill guide. For final preparation, the bone compressor which corresponds to the selected tibial size is chosen and inserted/impacted into the prepared box.



2. Keel Chisel
As an alternative to the milling system, the box for the tibial component can also be prepared with a keel chisel. As described above, the tibial template is fixed into place in order to determine both size and position (no fig.).

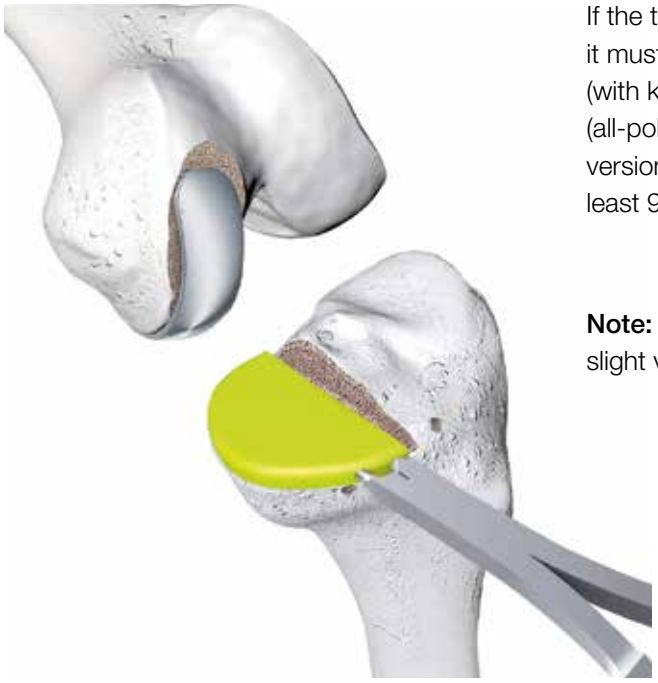
The tool of the corresponding size is selected, guided through the recess in the tibial template and then used for chiseling. The bone block is released by means of a posterior/anterior tilting motion and the keel chisel is removed (no fig.). The bone compressor can then be inserted.

Tibial Preparation: Metal-backed Component

For preparation of the keel for metal-backed tibial components there is the dedicated keel chisel to be used. As described above, the relevant tibial template is placed and fixed onto the tibia in order to determine both size and position.

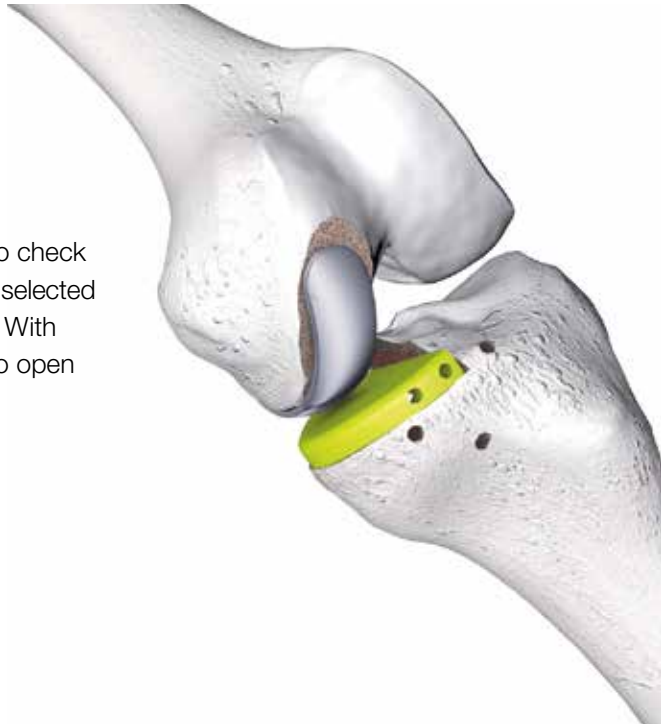
The tool of the corresponding size is selected, guided through the recess in the tibial template and then used for chiseling. As such, the bony structure is displaced, compressed and then the chisel is removed by tilting it posterior/anterior.

Trial Reduction



If the trial sled prosthesis has been removed in the interim, it must now be put back into place. The tibial trial prosthesis (with keel) is selected based on the treatment type chosen (all-poly or metal-backed) whereby, as a rule, the smallest version is used. For this, the knee joint should be flexed at least 90°.

Note: The tibial trial prosthesis is easier to put into place with slight valgus loading.



The knee is moved through its entire range of motion to check joint stability. The height of the tibial component is to be selected so that the natural tension of the ligaments is restored. With valgus loading of the knee joint, it should be possible to open the medial joint space 1-2 mm.

Implantation and Cementation

Note: Several holes are made using a small drill (drill pins may also be used) in order to improve penetration of the cement into the bone.

Note: The bone cement is prepared, taking account of the manufacturer's specific instructions.

Important: Ensure that excess bone cement is completely removed and no loose bone cement particles remain, especially in the posterior aspect of the joint.

Cementation is an essential part of the surgical procedure.

Tibial Component

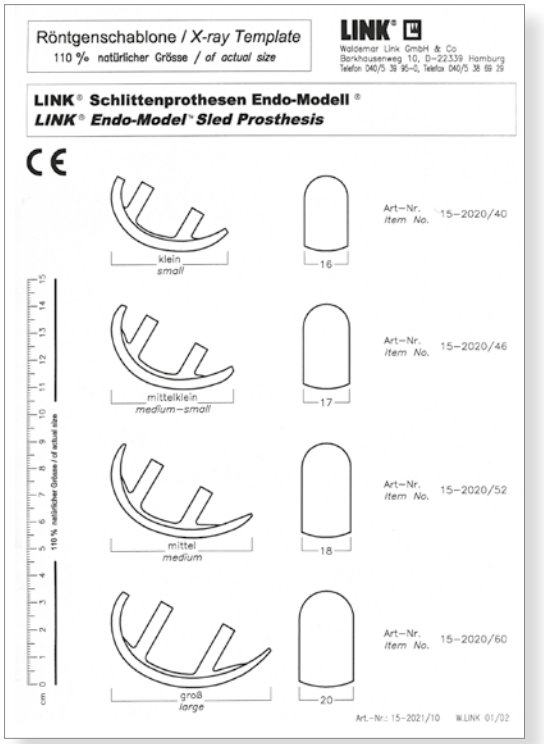
The bone cement is applied to the prepared bony surface and the underside of the implant. The tibial component is inserted posteriorly, then pushed downward and finally pushed in anteriorly.

Note: To facilitate placement, the knee is flexed and the tibia is externally rotated.

Femoral Component

The bone cement is applied to the back of the femoral component. In addition, both drill holes for the fixation pegs are filled with bone cement. The femoral component is positioned using grasping forceps and both pegs are to be inserted into the prepared drill holes. The femoral component is then finally driven on using the impactor.

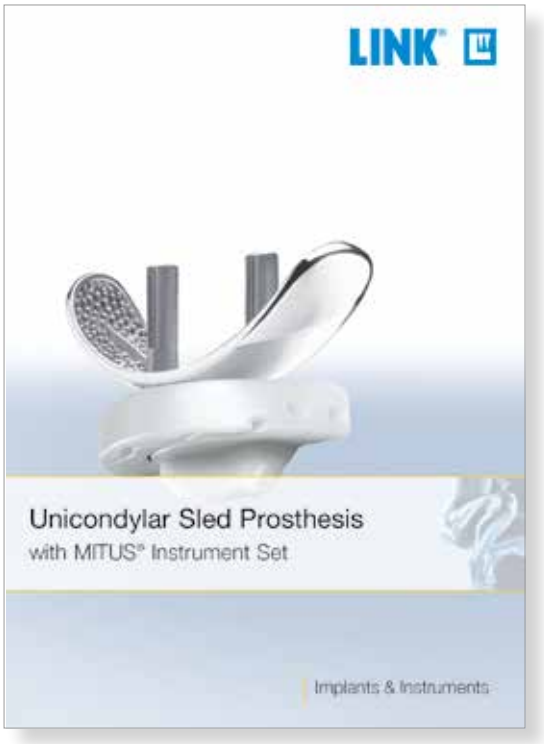
X-ray Templates



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

Item no.	Application
15-2021/10	for Unicondylar 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



Catalog:
Unicondylar LINK® Sled Prosthesis with MITUS® Instrument Set, Implants & Instruments
available on request.

Important Information

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 stresses.
   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 lifespan. 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. It cannot be compared to healthy bone!

5. **Unless otherwise indicated, the 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 up until the expiration date indicated on the packaging.
- Store implants in a permanent building.
- Protect against frost, dampness, direct sunlight and mechanical damage.
- Implants may be stored in their original packaging for up to 5 years from the date of manufacture. The expiration 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, Germany

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

Waldemar Link GmbH & Co. KG

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