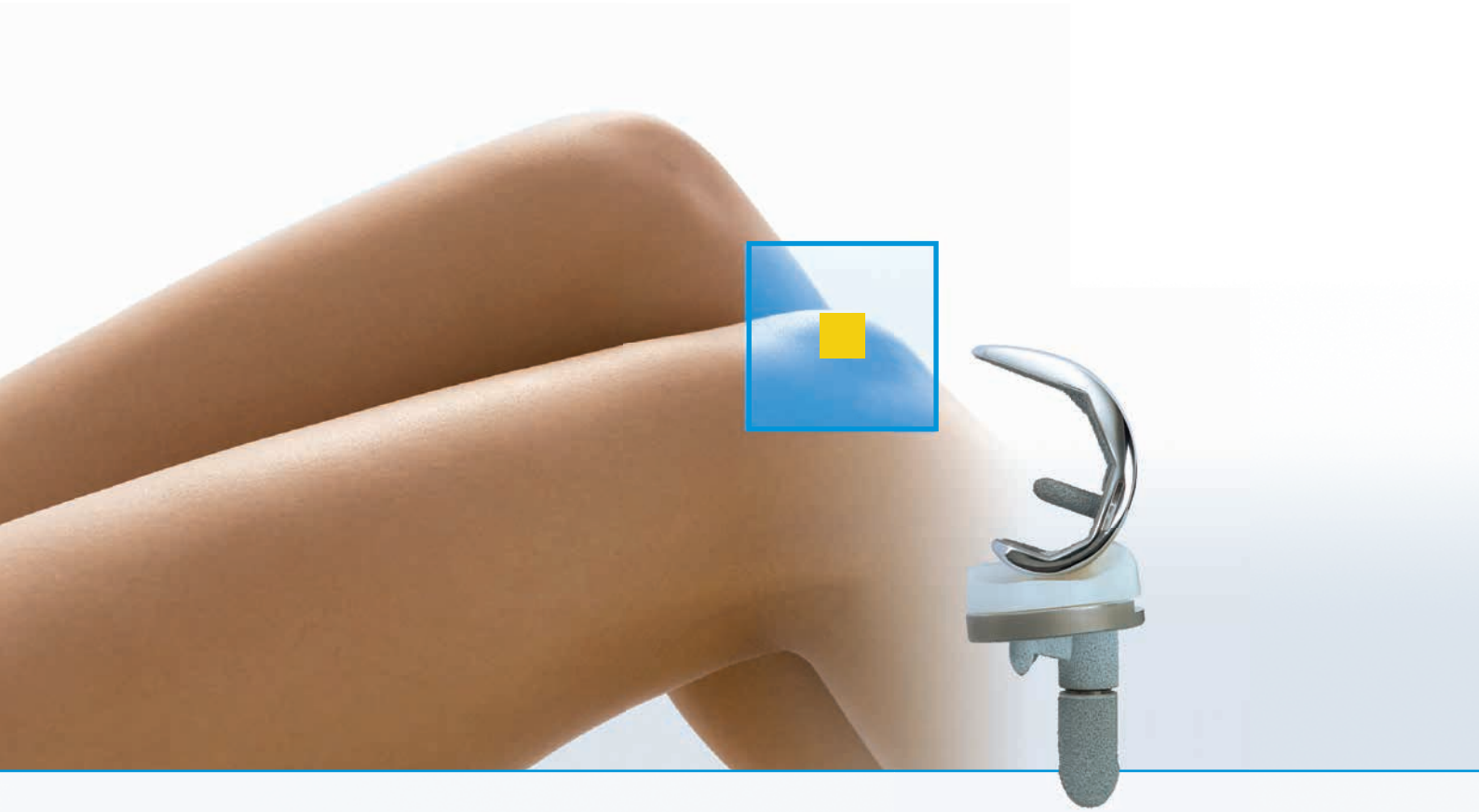
LINK®



MIT-K Minimally Invasive Technique – Knee

for GEMINI SL Total Knee Replacement

Mobile Bearing | Fixed Bearing | Fixed Bearing PS | LINK PorEx Technology

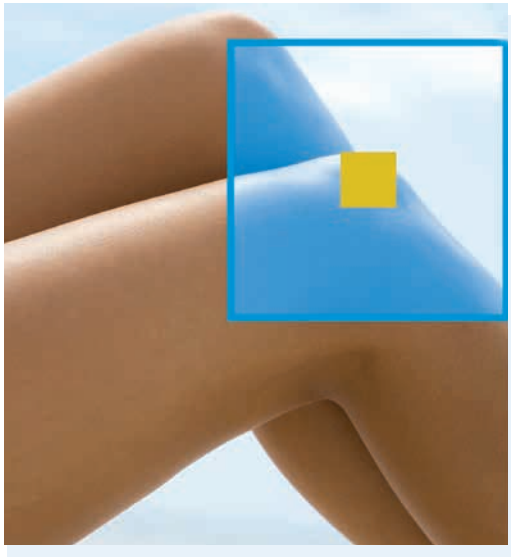
Surgical Technique

CE 0482

Explanation of Pictograms			
	Manufacturer	REF	Article number
MAT	Material (number)	CE	Product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking.

MIT-K Minimally Invasive Technique – Knee for GEMINI SL Total Knee Replacement

MIT-K Minimally Invasive Technique - Knee



- **Accurate and preserving**
- **Precise, tissue-sparing implantation**

The success of total knee arthroplasty depends upon:

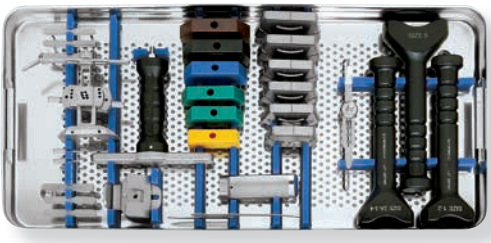
- **Correct alignment** of the leg axis
- **Good soft-tissue balancing**
- **Stable primary fixation** of the implant

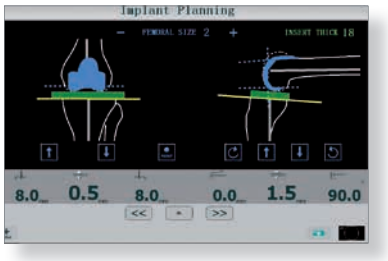
The **MIT-K M**inimally **I**nvasive **T**echnique – **K**nee presents a tissue-sparing surgical technique for implanting the GEMINI SL prosthesis via a small incision. This leads to less blood loss, both during and after surgery, while preserving muscles, tendons and ligaments. The risk of infection and embolism is reduced; wound healing is improved and the patient recovers faster.

Navigation

The newly developed, state-of-the-art instrument set and the optional **computer-assisted navigation system BLU-IGS** (from Orthokey) facilitate precise alignment of the axes and positioning of the resection guides. The instruments are compact, so they do not impinge on surrounding soft tissue.

These features enable the surgeon to ensure that the patient gets the maximum life from the artificial joint, optimal implant function, and the minimally invasive technique provides short convalescence.





GEMINI SL Total Knee Replacement

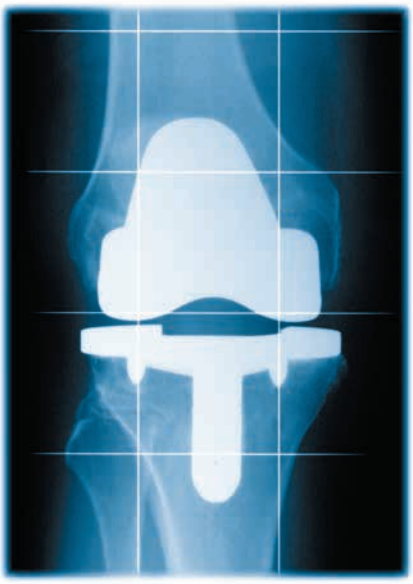
The **LINK GEMINI Total Knee Replacement**, including implants and system-specific instruments, is part of the **LINK SL Knee Family concept**.

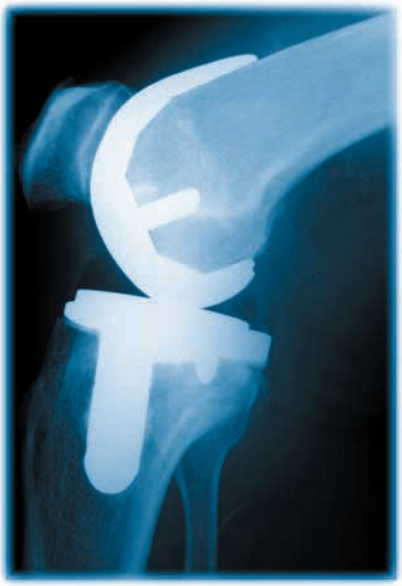
SL stands for **S**ystem-integrated So**L**ution

- **One implant system for standard implantation and revision**

Essential criteria for obtaining good results in knee arthroplasty are long-term fixation, anatomically correct implant components and a reproducible implantation technique. The LINK GEMINI SL knee implant for **cemented or cementless primary replacement** of damaged knees combines tried-and-tested and innovative principles of design.

The design of the femoral and tibial components and a wide choice of sizes ensure **primary stability**. The tibial components are available with either a mobile bearing or a fixed bearing. The optimal surface texture and our **TiCaP double coating** – Titan (Ti)/Calcium Phosphate (CaP) provide secondary fixation for cementless implantation.





GEMINI SL Total Knee Replacement

Flexibility

The resections made for GEMINI SL Total Knee Replacement allow the surgeon **to switch intraoperatively to the SL rotating hinge or hinged knee implants** and to use the MEGASYSTEM-C variants if indicated, with the aid of just a few additional instruments, because each knee system within the SL Knee Family is compatible with the very same bone resection (see page 7).

Modularity

The GEMINI SL product range guarantees optimal compatibility and is an excellent treatment option for the patient. A uniform femoral component for fixed bearing and mobile bearing and a different femoral component for fixed bearing PS (Posterior Stabilized) are available. A compatible PE articulating surface must be selected in each case. This gives the surgeon great intraoperative flexibility. The GEMINI SL system caters to a range of femoral and tibial dimensions – in general, the femoral component of the same size or one size smaller than the tibial component used.

Femoral components

A major contributing factor to the long-lasting function of the GEMINI SL system is the frictional connection between the fixation surfaces and the resected femoral condyles, and also the external form of the femoral component, which is designed to replicate the anatomy of the knee and implant function. The high patella shield prevents the patella from “clicking” in cases of patella alta. The anatomically shaped patellar groove provides for physiological tracking of the bony patella or patella resurfacing component in all positions.

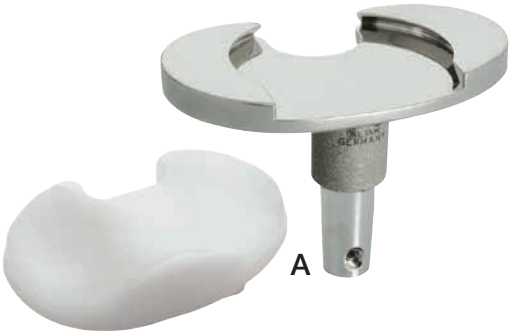
The femoral component comes in two variants for cemented or cementless fixation.

The **PS (Posterior Stabilized)** design with its secure coupling mechanism prevents femoral ventral subluxation in flexion in the absence of the posterior cruciate ligament. This design consists of a posterior (post) on the tibia and a stabilizing bar (cam) on the femoral component. The special design of the intracondylar box geometry in the femoral component allows for bone-sparing resection.

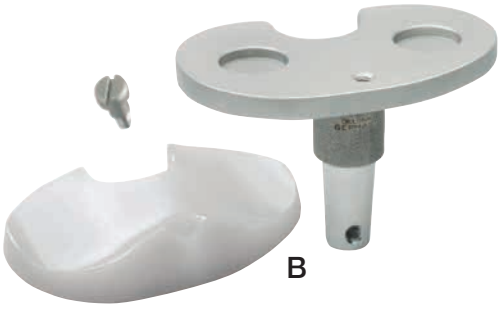
Tibial components

The GEMINI SL tibial components are adapted to the anatomy of the tibial head, and left and right variants are available. The central taper and the bars radiating out toward dorsal have been shown in various tests* to protect against shear forces, rotation and, above all, the alternating varus/valgus loads that cause loosening. The tapered pegs at the ends of the bars transmit forces laterally into the load-bearing cortical bone.

The concave surface of mobile bearing tibial plateau (**A**) provides congruency of the articulating surfaces in extension while allowing the femoral condyles to glide in increasing flexion. Distribution of the load over a large area reduces polyethylene wear. The rotating articulating surface separates function from movement in the articulating areas, enabling the soft tissue structures to take over motion control, which makes for natural kinematics. In addition, the implant fixation is spared. **The deep trough in the tibial plateau stabilizes the knee, even in cases of posterior cruciate ligament deficiency.****



In cases of good joint stability, where the ligaments and capsule are intact, a tibial tray with a replaceable fixed bearing PE articulating surface is available (**B**).



Note: The size of the tibial plateau determined primarily by the femoral component.

* Fabriciani C. et al.: "Total Knee Arthroplasty, Tibial Components: Design and Surfaces", Cementless Arthroplasty, M. D'Arienzo, R. Civinni, B. Pavolini, Aulo Gaggi Editore, Bologna

Crownshiled R.D., Murase K., Pedersen D.R.: "An analysis of tibial component design in total knee arthroplasty". Presented at the 28th Annual ORS, New Orleans, Jan 19-21, 1982

Walker P.S. et al.: "Fixation of Tibial Components of Knee Prostheses", JBJS 63-A, No.2, 1981, pp. 258-267

Walker P.S., Hu-Ping Hsu, Zimmermann R.A.: "A comparative study of uncemented tibial components", J. of Arthrop., Vol. 5, No. 3, 1990, pp. 248

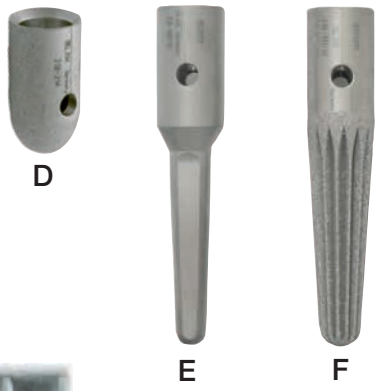
** Christine S. Heim,BSc, Paul D. Postak, BSc, Nicholas A. Plaxton, MS, A. Seth Greenwald, DPhil (Oxon): "Classification of Mobile-Bearing Knee Designs: Mobility and Contraint", The JBJS (American) 83:S32-37 (2001)

GEMINI SL Total Knee Replacement

In the absence of the posterior cruciate ligament, function is assured by the post coupling mechanism. This induces mechanical rollback while preventing dorsal subluxation of the tibia. Ventrally, the PS (posterior stabilized) polyethylene articulating surface (**C**) has a deep cutout to give the extension apparatus enough space in flexion.

Taper cap/prosthesis stems

The taper below the tibial metal tray can be fitted with a taper cap (**D**). In cases of instability or insufficient bone quality, in particular, this taper allows a cemented (**E**) or cementless (**F**) stem to be connected.

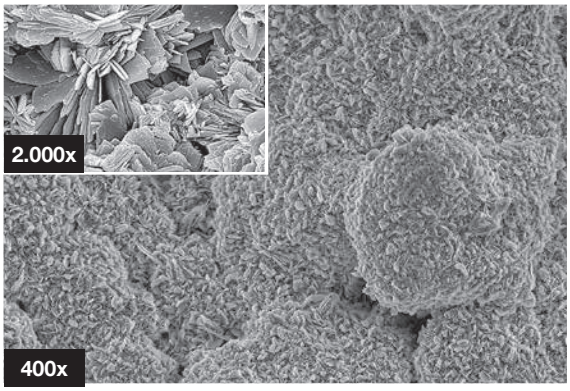


Anchorage

The bone contact surfaces on the tibial and femoral components have an **SMS** (Squarical Monobloc Structure) honeycomb macrostructure for cementable fixation. For cementless fixation, implants with **TiCaP double coating** – Titan (Ti)/Calcium Phosphate (CaP) are available.

TiCaP double coating: Titan (Ti)/Calcium Phosphate (CaP)

The TiCaP coating is applied to implants by firstly spraying a highly porous layer of titanium approximately 200 µm* thick onto the surface of the implant using vacuum plasma technology. On top of this porous surface, an approx. 20 µm** thick layer of extremely mechanically stable calcium phosphate is deposited in an electrochemical process, which promotes ingrowth into the open-cell titanium layer. Animalexperiments have demonstrated ingrowth on 47.9% of the implant surface.**



* The thickness of the titanium layers varies in different types of implant.

** Cunningham B W et al.: "General Principles of Total Disc Replacement Arthroplasty", Spine, Vol 28, No 20 Suppl, 2003

LINK PorEx (TiNbN = Titanium Niobium Nitride) Surface modification

The LINK PorEx hypoallergenic 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.

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]

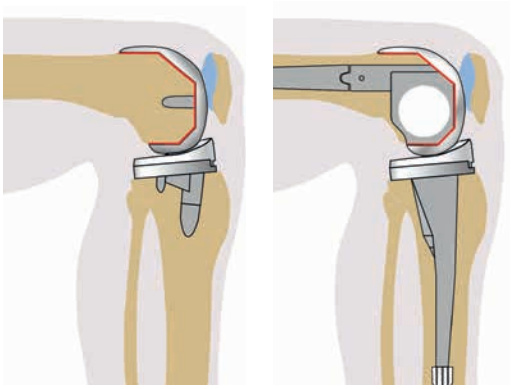
[1] Internal technical report.

Resections compatible with Endo-Model SL rotating and hinge knee

The tibial and femoral resections for sizes 2, 3 and 4 of the LINK GEMINI SL Total Knee Replacement are identical to those required for the corresponding sizes of Endo-Model SL rotating hinge knee:

Size **2 GEMINI SL** corresponds to size **small Endo-Model SL**
Size **3 GEMINI SL** corresponds to size **medium Endo-Model SL**
Size **4 GEMINI SL** corresponds to size **large Endo-Model SL**

After resection of the femur (for which the additional instrument set 16-0001/02, Endo-Model SL rotating knee is necessary), it is possible to switch intraoperatively or revise with the SL constrained total knee system.

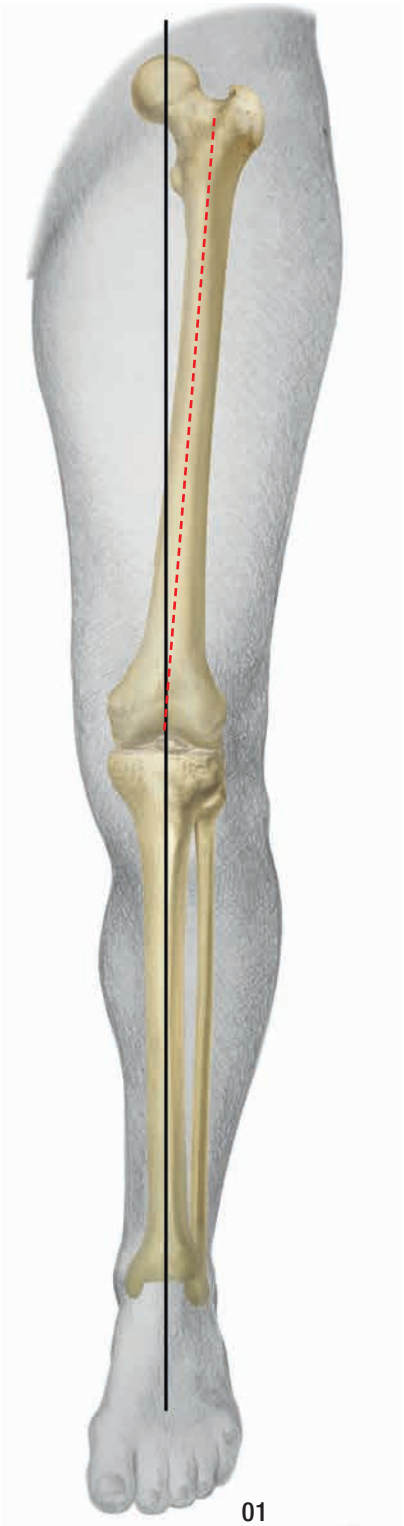


GEMINI SL **Endo-Model SL**

Indications/Contraindications

Note:
Specified indications/contraindications see page 35.

1 Preoperative Planning



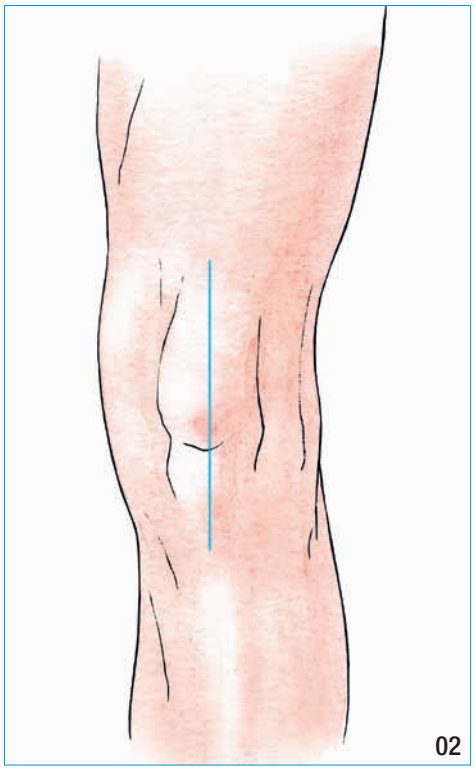
01

Full-leg standing radiographs of the healthy and diseased side are obtained for preoperative identification of the anatomic landmarks in the knee. The angle between the anatomic axis (center of the knee – intramedullary canal) and the mechanical axis (center of the femoral head – center of the knee – center of the ankle to the 2nd toe ray) defines the valgus angle (**01**).

These angles should be determined for both knees. The valgus angle of a healthy knee is 5° to 7°. This angle must be determined before per-forming the distal femoral resection by comparison with the healthy joint in order to restore this valgus angle in the diseased joint.

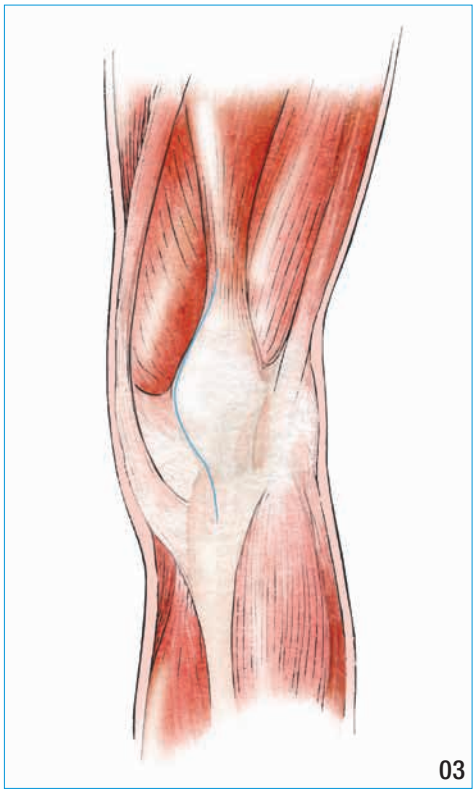
The appropriate implant size can be ascertained preoperatively using X-ray templates. (X-ray templates: See catalog GEMINI SL Total Knee Replacement). The implant size dictates the resections required.

2 Approach



02

In slight flexion, a straight incision is made above the patella to the tibial tuberosity.



03

A medial parapatellar incision is made through the patellar retina-culum, the capsule and the synovial membrane.

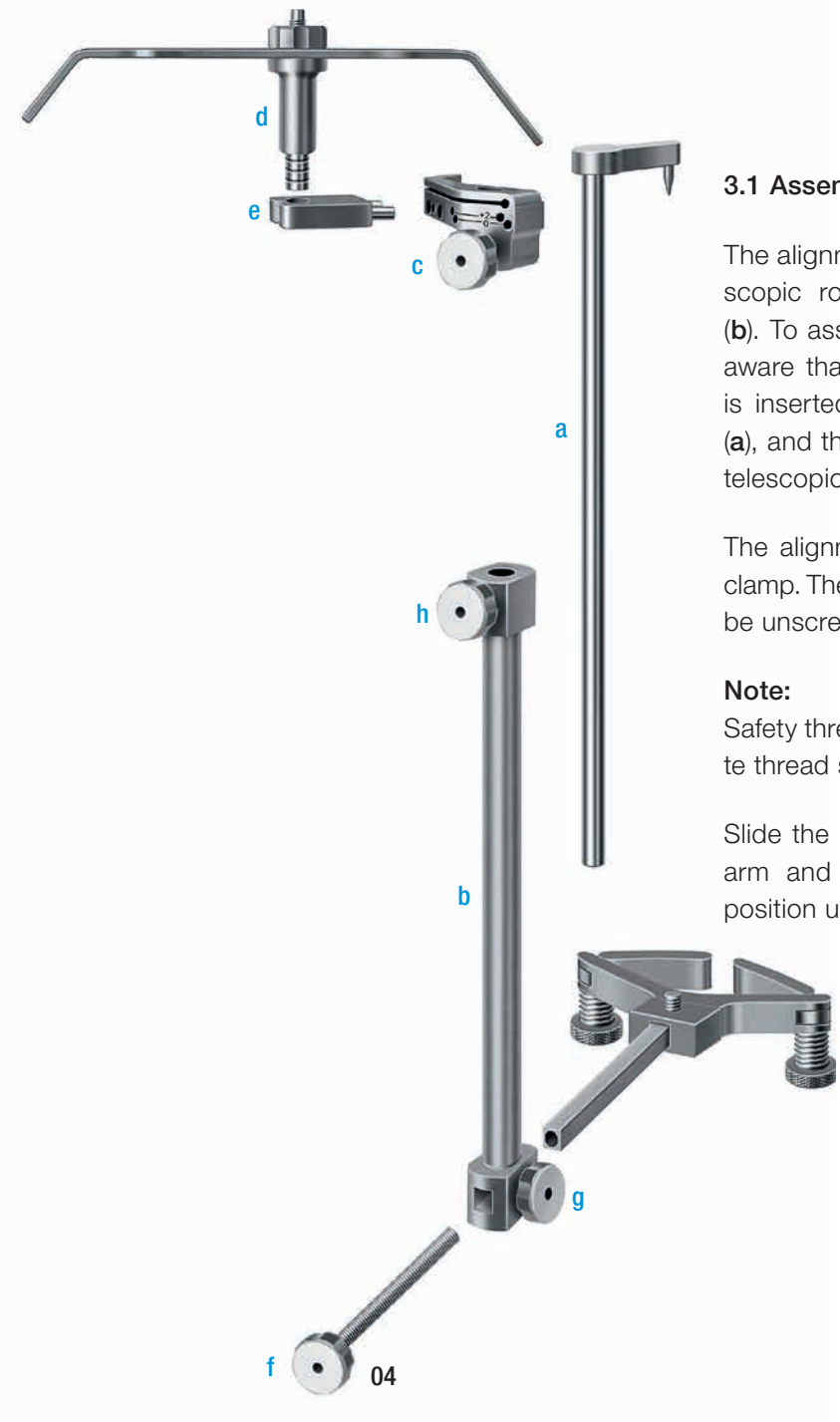
When making the parapatellar incision the patella is displaced laterally to expose the femoropatellar joint. Access is gained to the medial, lateral and intracondylar parts of the joint by removing the hypertrophic synovium and parts of the fat pad.

To prevent post-operative impingement and adhesions, excess synovia should be removed. Some surgeons prefer complete synovectomy.

3 Preparation Tibia Plateau – Extramedullary Alignment

Osteophytes on the femur and tibia are removed, especially those around the collateral ligaments, as they could affect soft-tissue balancing. Approx. 2.5 cm of the proximal tibia is exposed ventral and medial. With the knee in 90° flexion, the tibia can be additionally rotated for better visualization.

For external alignment of the tibial resection, the extramedullary guide is assembled and preset to the length of the tibia.



04

3.1 Assembling the extramedullary guide

The alignment rod consists of proximal telescopic rod (**a**) and distal telescopic tube (**b**). To assemble, the tibial saw guide (**c**) (be aware that there are right and left versions) is inserted into the proximal telescopic rod (**a**), and then both are inserted into the distal telescopic tube (**b**).

The alignment rod is connected to the foot clamp. The set screw (**f**) on the foot clamp must be unscrewed and removed.

Note:
Safety thread! To undo, there are two separate thread sections.

Slide the alignment rod onto the positioning arm and provisionally secure in a neutral position using set screw (**g**).

3.2 Positioning the guide

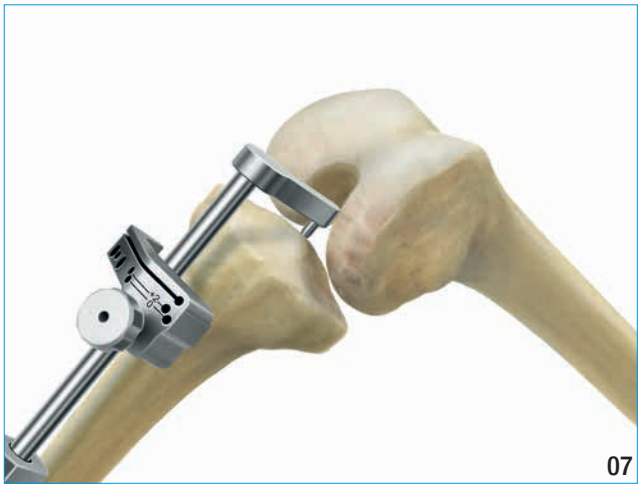
The assembled extramedullary guide (**05**) is now placed on the tibia.

The alignment instrument is attached to the ankle with the foot clamp, with the tip of the alignment instrument initially resting around the insertion of the anterior cruciate ligament, approximately central to the intercondylar eminence on the tibial plateau (**06**).

Then the tip is driven in with a hammer. The guide instrument can still be rotated (**07**).

05

06



07

3.3 Rotational and axis alignment

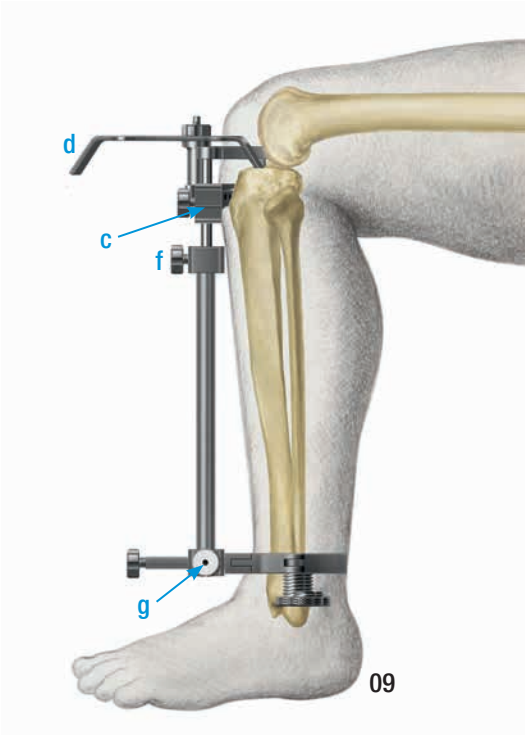
To determine the correct rotational alignment and the varus/valgus position, the instrument is aligned centrally along the tibial shaft axis and extending a line projected to the second toe (**08**). To assist, the center of the tibia, the tibial tuberosity and the second toe ray can be marked with a sterile marker.

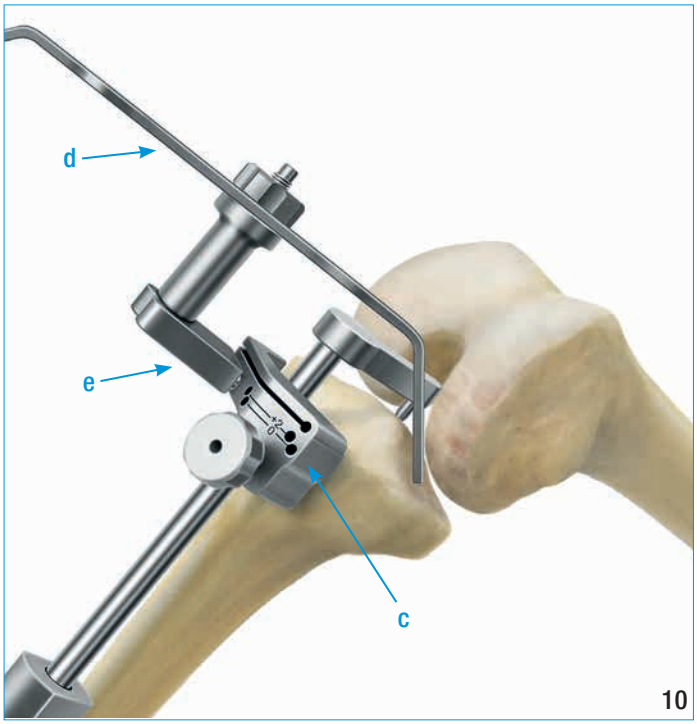
When the tibial alignment rod looks parallel to the ventral tibia, when viewed from the side, the saw guide is neutral, i.e. without dorsal slope.

The recommended dorsal slope is 5°. After undoing the distal set screw (**g**) the alignment instrument can be tilted by moving the alignment rod, and thereby set to the desired dorsal slope of 5°. Once in the correct position, the set screw (**g**) and the fixation screw (**f**) on the distal telescopic tube can be tightened (**09**).

Note:
To secure rotational and axis alignment, the instrument can be fixed in the tibial plateau with a fixation pin.

To determine the resection level, the stylus (**d**) for the tibial saw guide is placed on the saw guide (**c**).





10

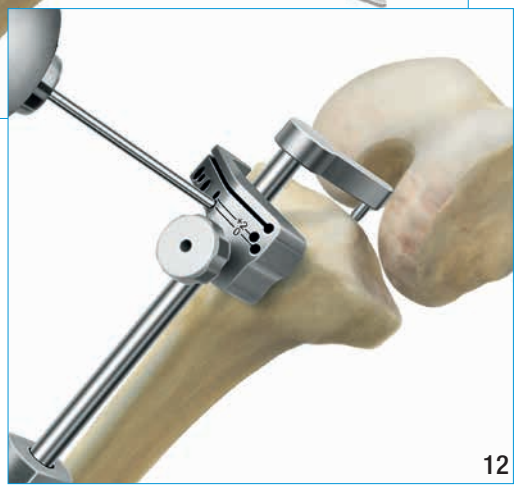
3.4 Determining the tibial resection level

The stylus facilitates two different settings for standard resection and re-resection. Standard resection ("10") is generally used. In the event that re-resection is necessary, but cannot be set by repositioning the saw guide, setting „2" (re-re-section) must be set.

The stylus (**d**) and mount (**e**) are together inserted into the saw guide (**c**). The stylus is aligned with the highest point of the best-preserved area of the tibial plateau. The resection level is determined in consideration of the metal tray with the thin-nest PE articulating surface.


11

The course of tibial resection can be checked with the cutting template (**11**). Any corrections of the position can be carried out at this point. Subsequently, the tibial saw guide is secured by means of two pins inserted into the ventral, parallel holes marked „0" (**12+13**).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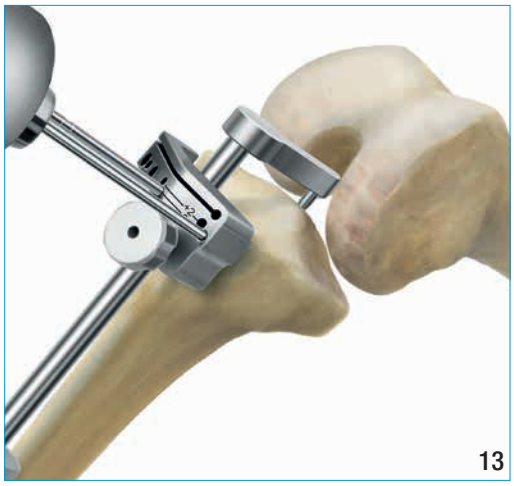
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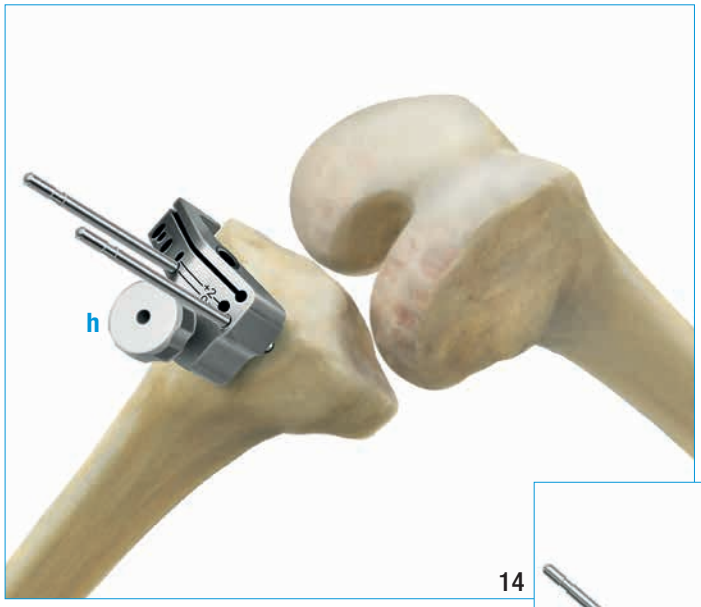

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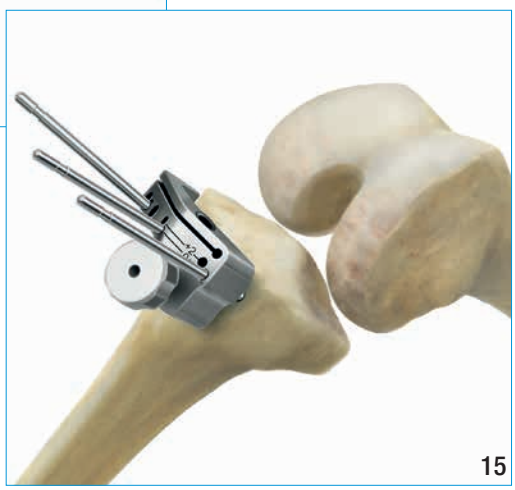
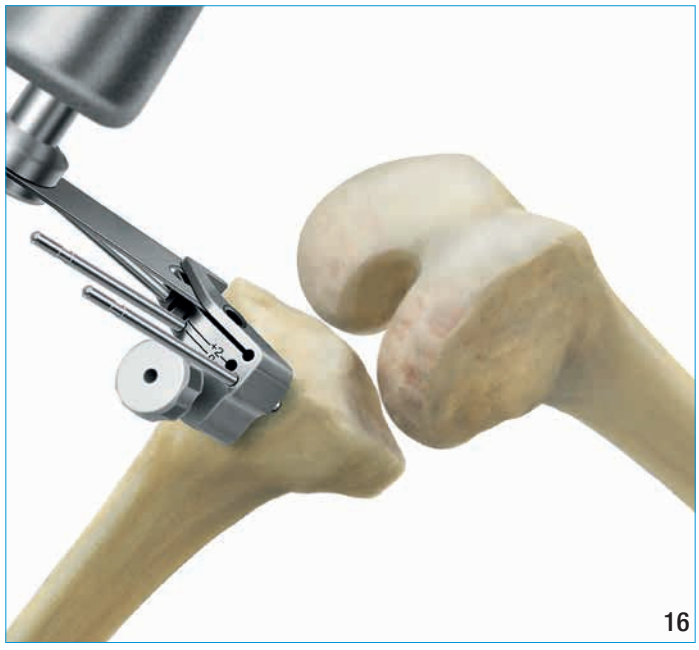

15

3.5 Resection of the tibia

The stylus is taken off and the fixation screw (**h**) is un-screwed to carefully remove the tibial alignment rod and the foot clamp. The tibial saw guide is pushed as far as it will go against the ventral tibial cortical bone (**14+15**).


16

Correct alignment can be checked by attaching a control rod.

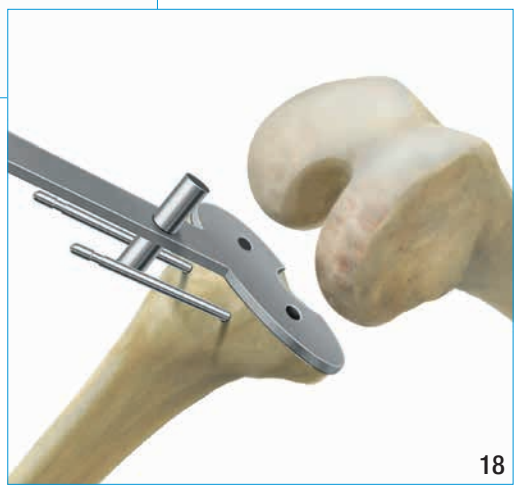
The tibial saw guide is medially fixed with a third pin (**15**) and resection is performed (**16**).


17

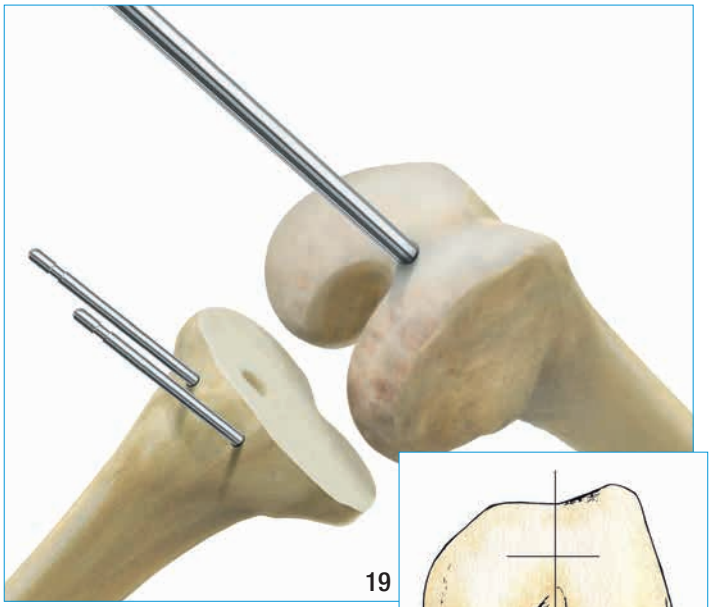
3.6 Sizing the tibia

After resection, the third pin and the tibial saw guide are removed. The anterior pins are left in place (**17**).

The tibial implant size can be determined by putting in place the suitable tibia sizer. The instrument must optimally cover the cortical bone without protruding (**18**) The tibial implant size can also be used as an indicator of femoral implant size.


18

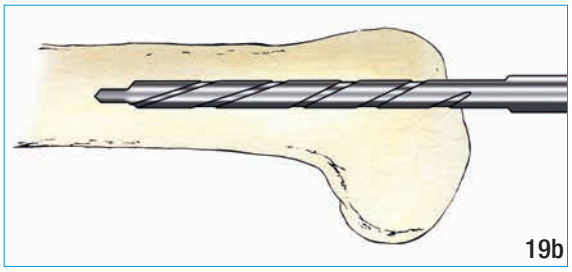
4 Preparation of the femur – Distal resection (extension gap)

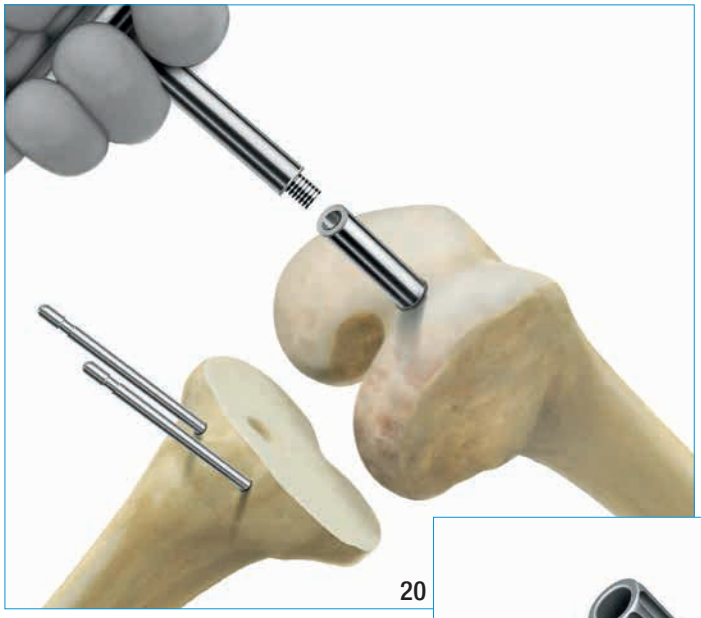

19

4.1 Opening the femoral medullary cavity

To prepare the femur, the knee is placed in 90° flexion. To determine the entry point (point of intersection of Whiteside's line and the trans-epicondylar axis) for opening the femur, this can be marked with the electric scalpel. It generally lies approx. 3 to 5 mm to medial above the intercondylar fossa. After marking with the bone awl, the medullary cavity is opened with a twist drill of 8 mm diameter (**05, 19a+19b**).

19a


19b



20

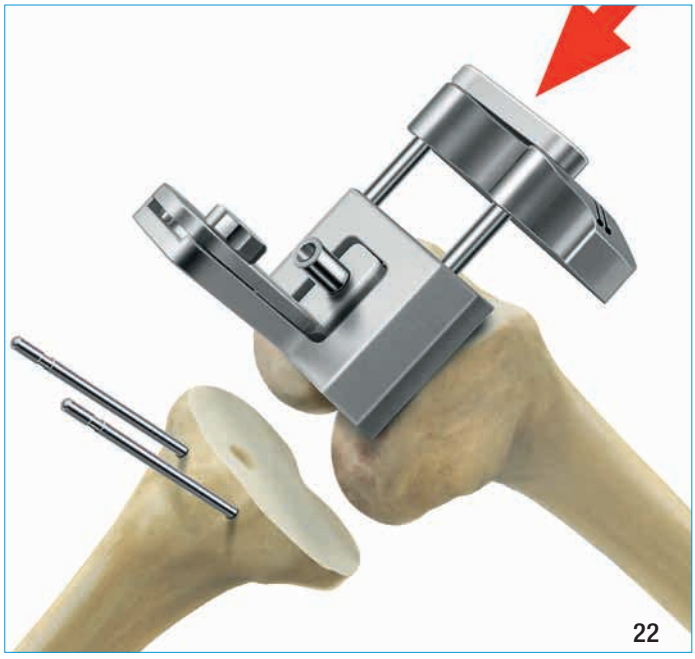
4.2 Sizing the femur

The intramedullary guide rod is introduced and the T-handle unscrewed (**20**). The femoral sizer is inserted. Point the stylus to lateral to the ventral cortical bone. The dorsal plate must touch the dorsal condyles (**21**).

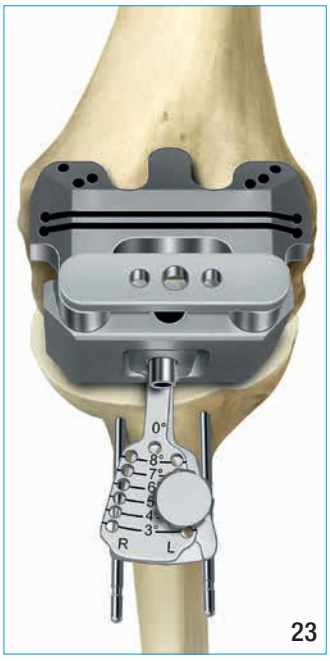
Note:
It is imperative to avoid soft tissue between the stylus and the cortical bone, as this will distort sizing. The implant size can be read off the instrument's scale. For in-between sizes, the smaller of the two must be chosen.

21

This measure determines the femoral component fit in the a/p dimension. To check the m/l fit of the chosen component, the corresponding trial femoral component can be used.



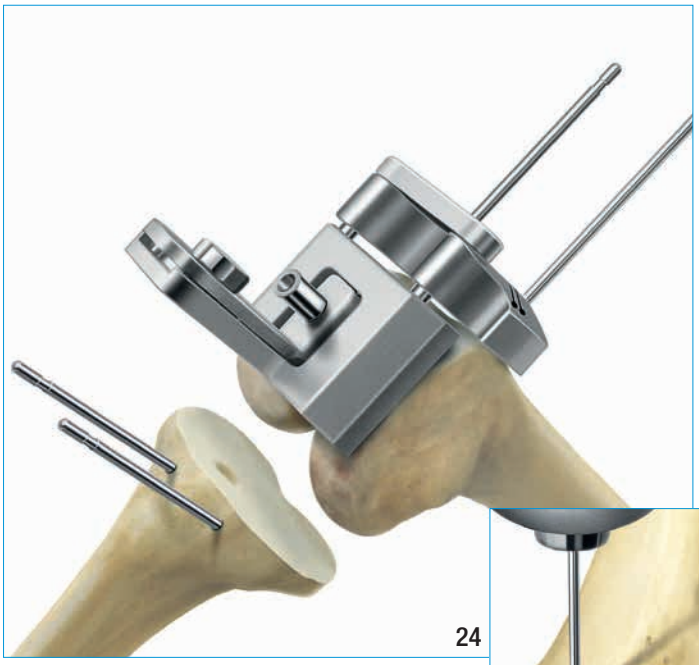
22



23

4.3 Distal femoral resection (extension gap)

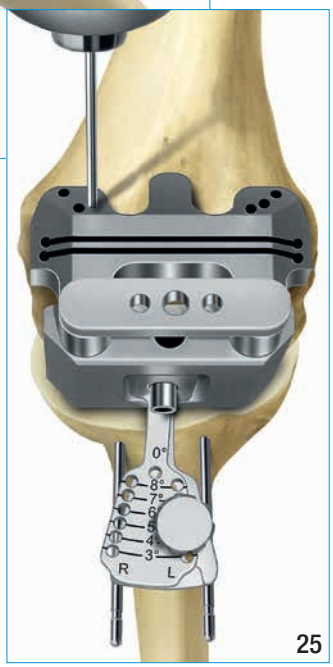
The distal cutting block corresponding to the pre-selecte femur size is connected to the alignment instrument for valgus angle (**22**). Subsequently, the valgus angle determined pre-operatively is set and the instrument is placed on the intramedullary guide rod (**23**).



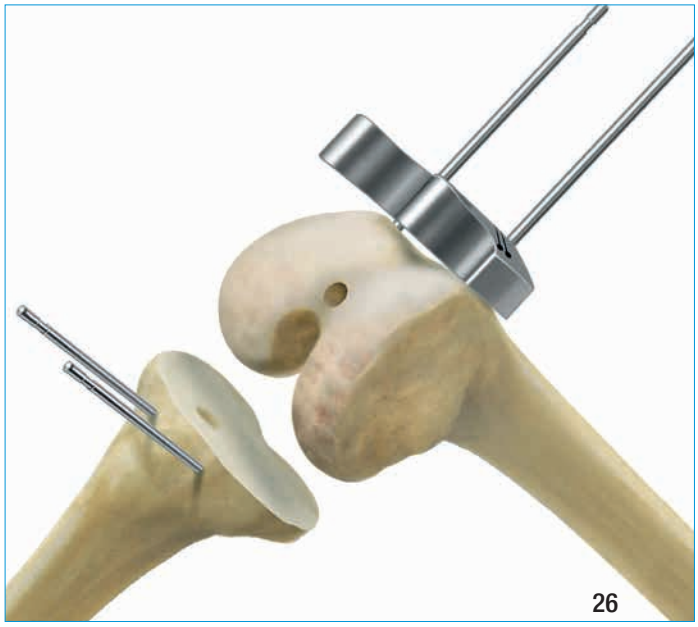
24

Before fixing the distal cutting block by means of two pins, it must be ensured that at least one condyle is in contact with the alignment instrument and the valgus angle of the correct side has been set.

The two pins are introduced into the holes marked “0” (**24+25**).

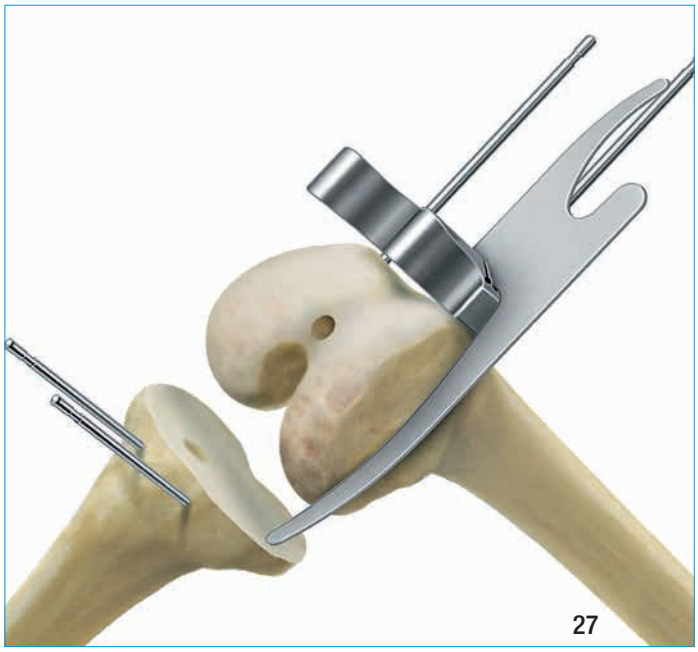


25

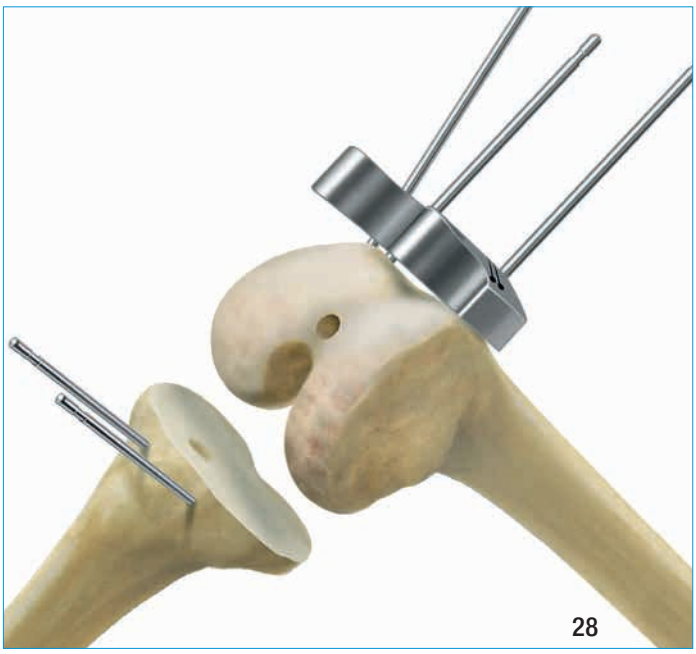


26

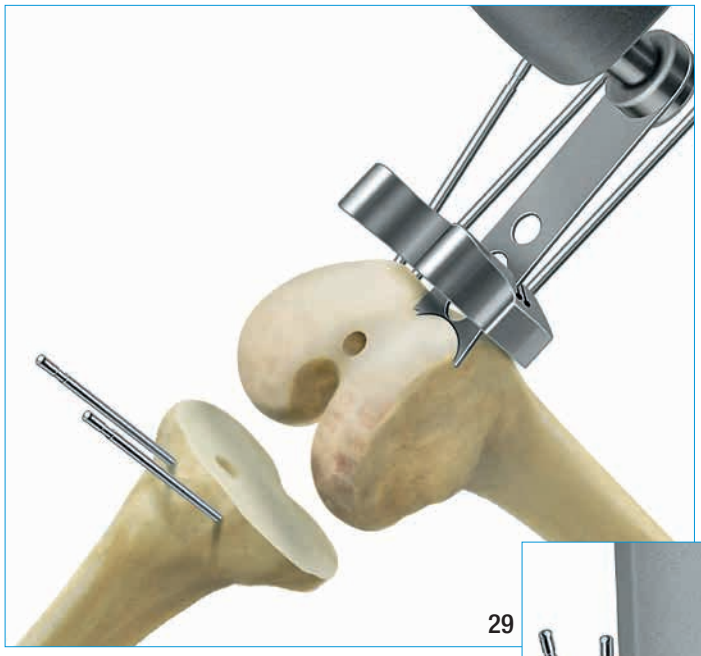
Subsequently, the alignment instrument for valgus angle is taken off the distal cutting block. The intra-medullary guide rod is also removed.



The course of distal resection can be checked with the cutting template.

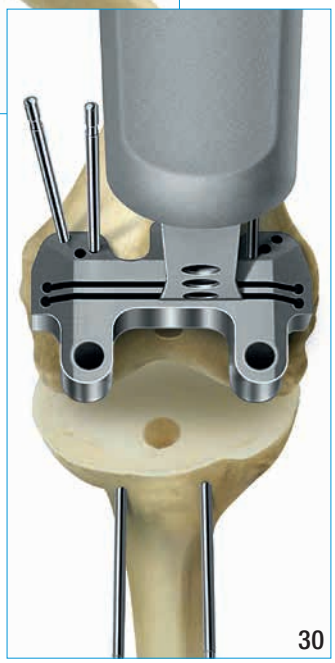


To improve stability of the instrument a third pin is fixed in the unmarked oblique hole.

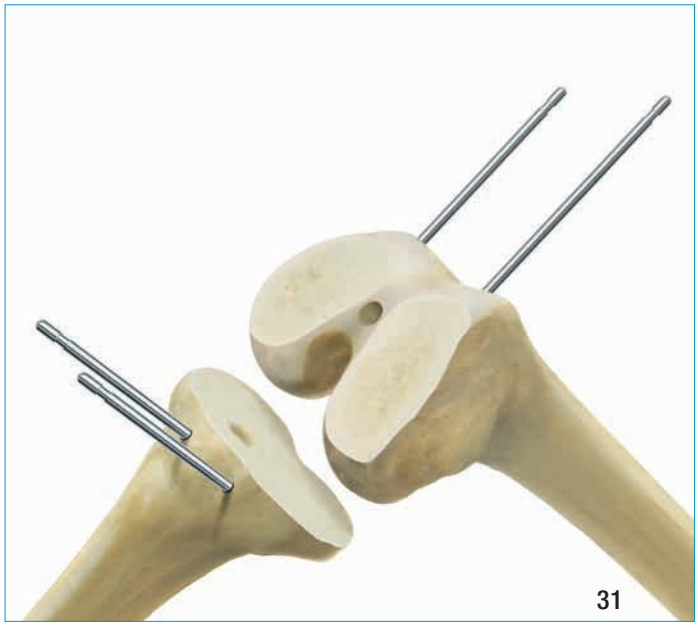


29

In 90° flexion, the distal resection is performed (**29+30**) and then the cutting block is taken off.



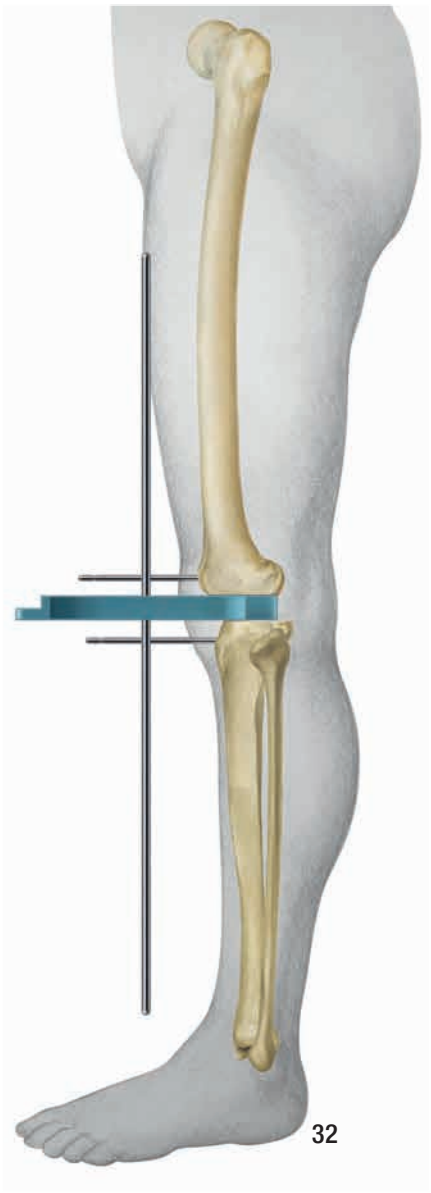
30



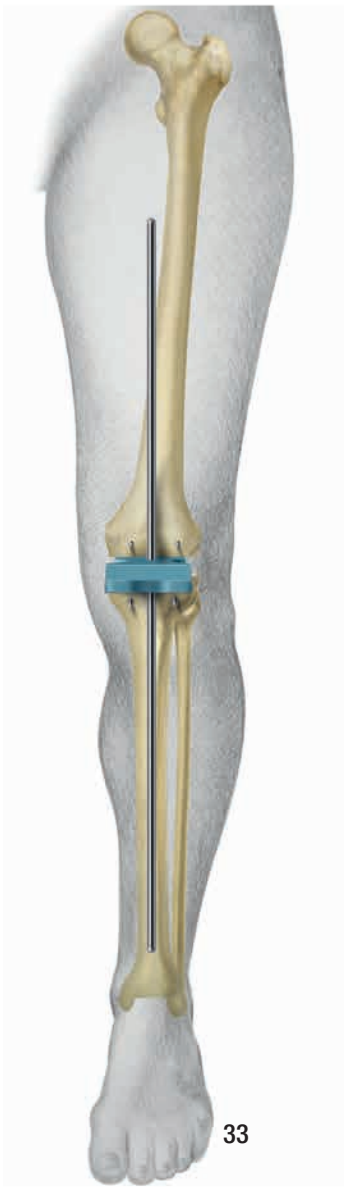
31

The parallel pins are left in place.

5 Examining Extension Gap and Axes



32

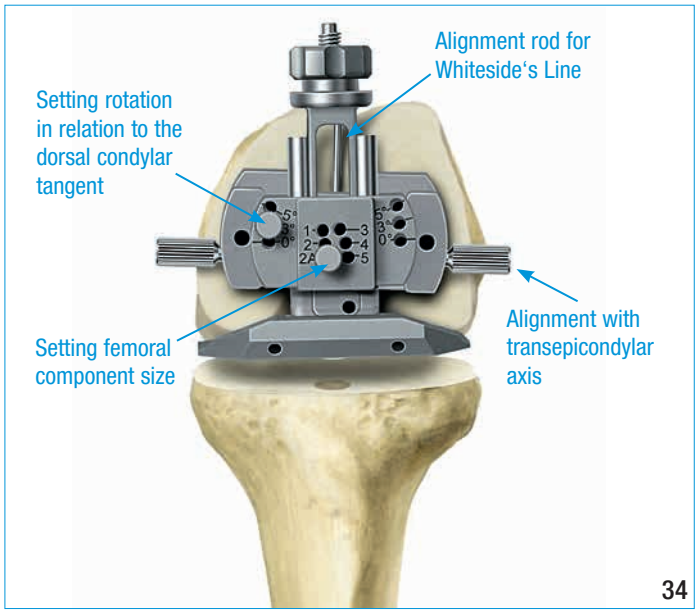


33

After careful cleaning of the soft tissue, the spacer corresponding to the femoral component size is inserted and the axis alignment and stability of the joint in extension is checked (**32+33**).

If no further resection is necessary, the femoral and tibial pins can now be removed.

6 Final Preparation of the Femur



34

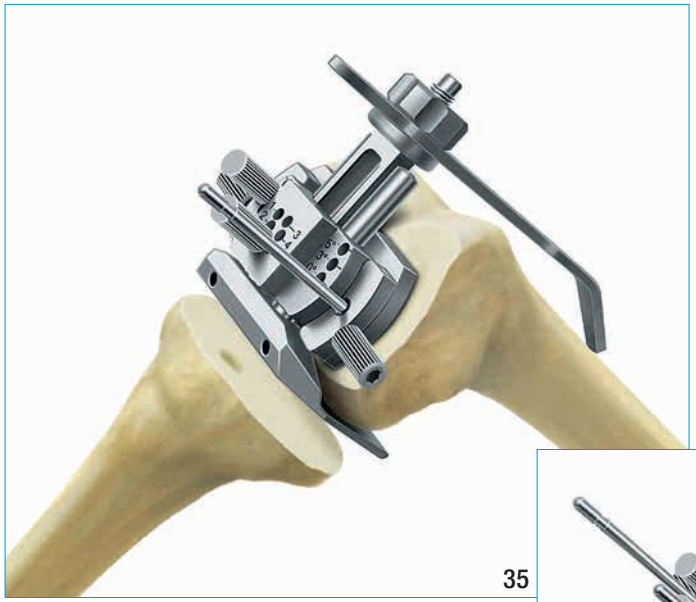
6.1 Setting femoral rotation

On the alignment instrument for external rotation, the selected femoral component size is set and secured with a pin (**34**).

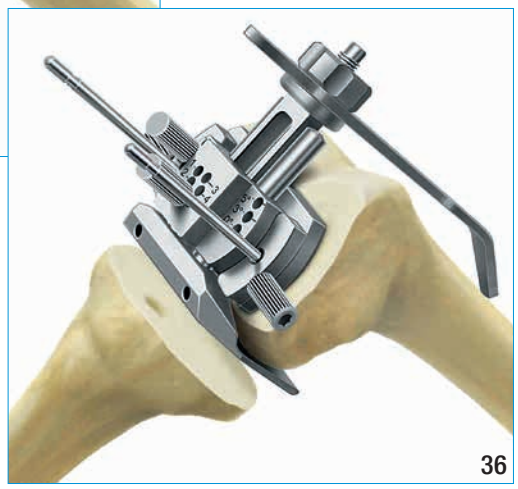
The alignment instrument allows 0°, 3° and 5° external rotation to be set in reference to the dorsal condylar tangent.

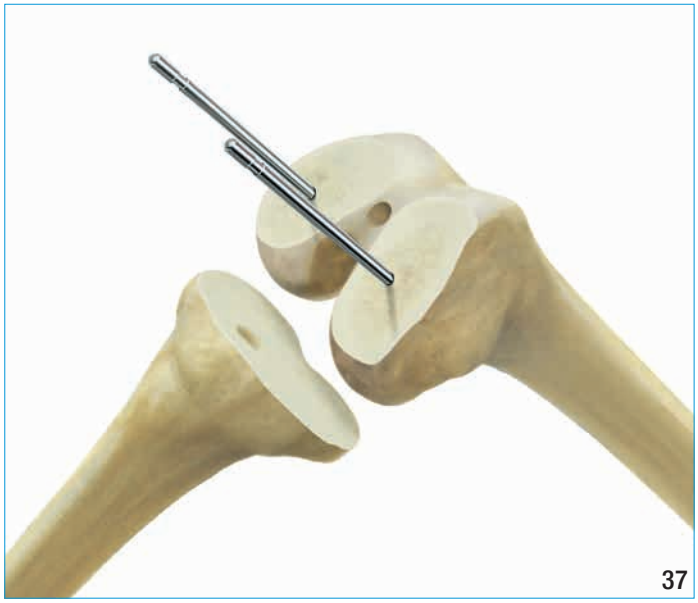
Alternatively, external rotation can be set using Whiteside's Line with the small alignment rod in the center of the instrument.

For alignment with the transepicondylar line, small alignment rods can be secured medial and lateral.


35

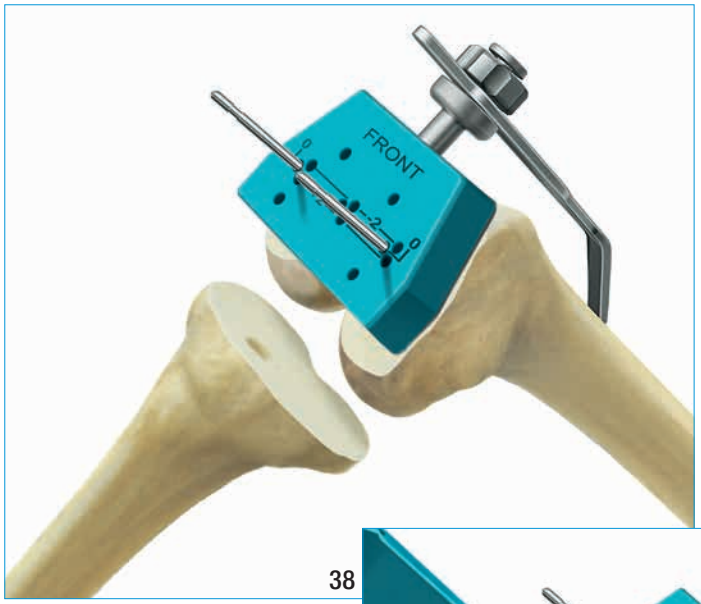
Once the correct rotation is set, the instrument is secured by inserting two pins into the medial and lateral holes (**35+36**).


36



37

The alignment instrument is removed, but the two pins are left in the bone.



38

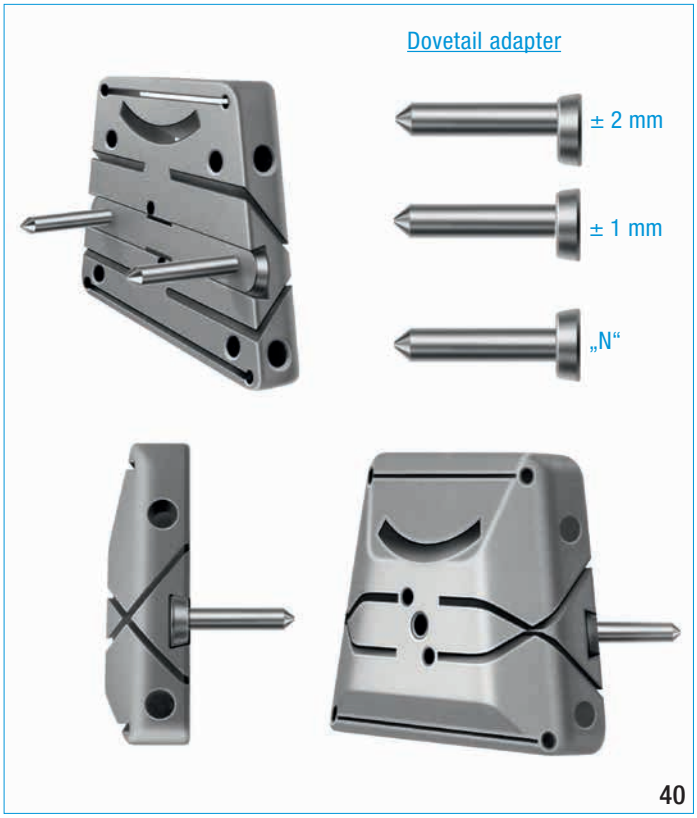
6.2 Examining the flexion gap

The femoral control block of appropriate size is placed over the pins at markings „0“. The knee is in 90° flexion. The ventral resection can be checked once the stylus is attached (**38**).

The stepped end of the spacer of appropriate size is now placed underneath the control block with the higher side abutting the control block (**39**).

It is possible to vary the simulation of the flexion gap by +/- 2 mm by moving the control block, that is, the control block can be moved 2 mm to ventral or dorsal.

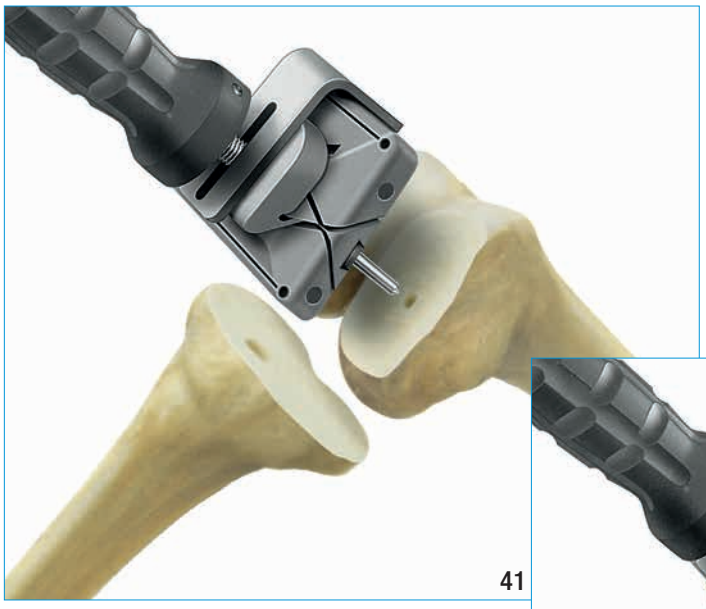
39



40

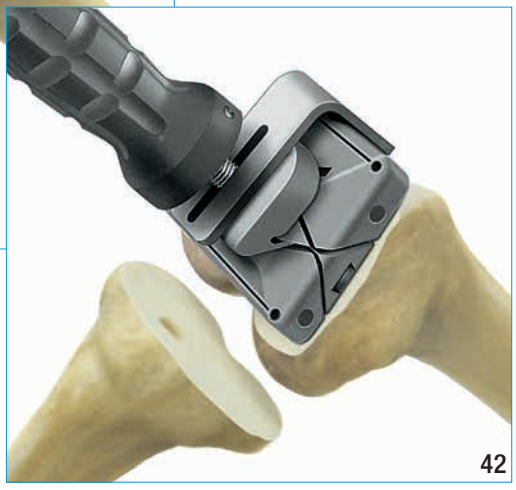
6.3 a/p resection of the femur and facets

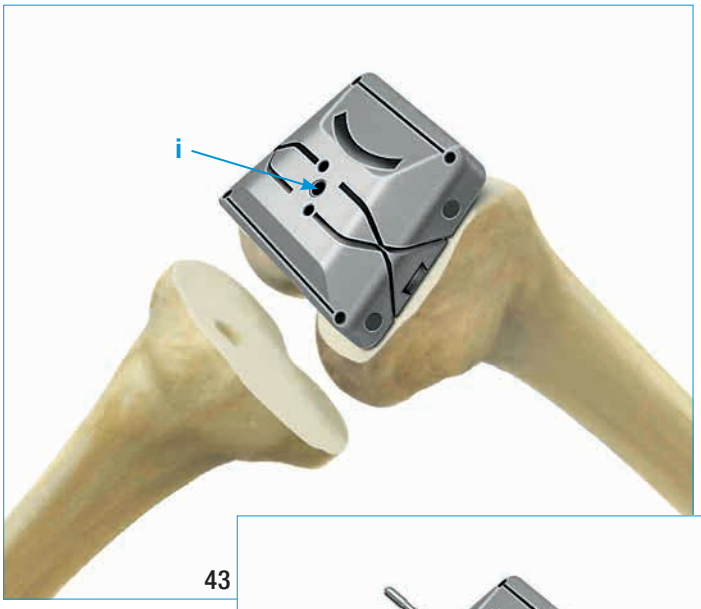
The femoral control block including pins is removed. The dovetail adapter for femoral cutting block is placed on the femoral cutting block, where it moves freely. The dovetail adapter for the femoral cutting block offers three options: setting of standard height or corrections of +/- 2 mm or +/- 1 mm. The setting is dictated by the setting previously made on the femoral control block, which takes account of the ventral resection (avoid notching).


41

The cutting block is grasped with the handle and femoral cutting block inserter, and positioned (**41+42**).

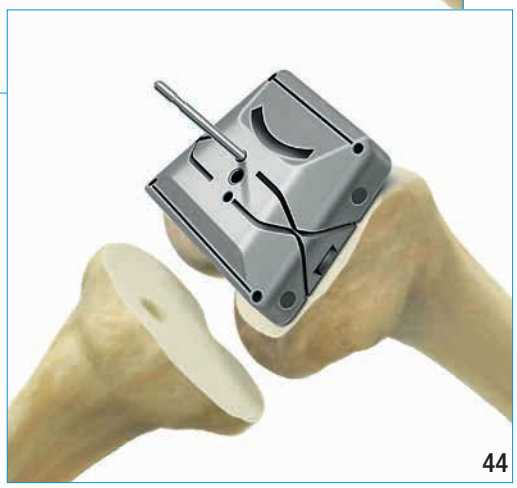
Note:
The course of individual resections, but especially the ventral cut, can be checked with the cutting template.


42

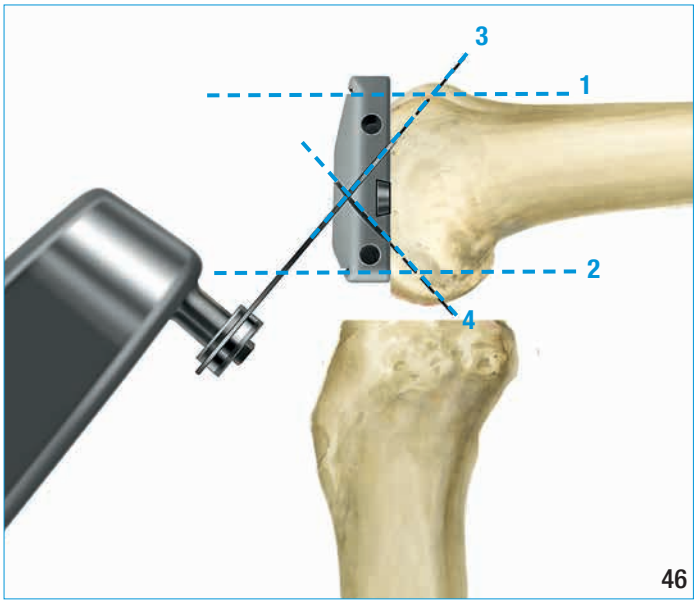


43

The cutting block can be placed on the dovetail adapter so that it moves freely, or fixed by tightening the central socket head screw (**i**) and driving in two pins (**15, 44+45**).

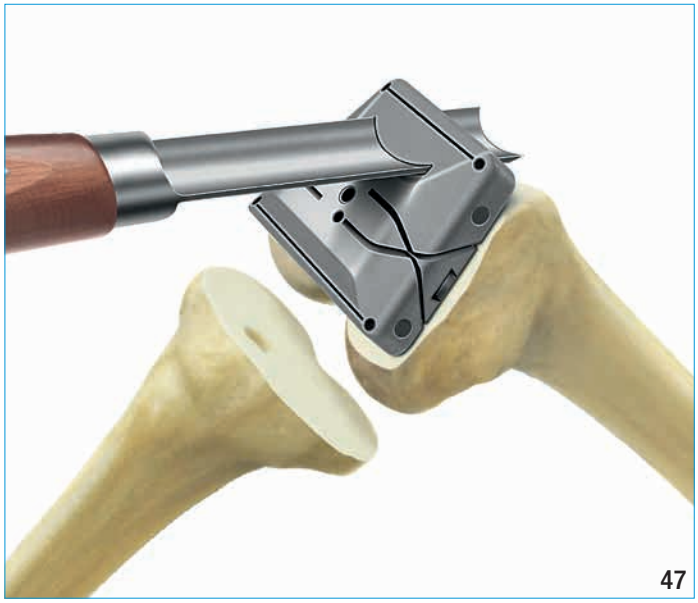

44


45



46

First the ventral, next the dorsal, and then the anterior and posterior oblique cuts are made.



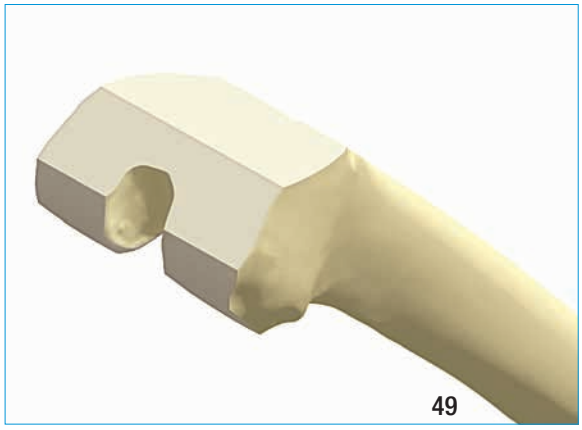
47

Before the trochlea is resected with the chisel for patellar intercondylar groove, the femoral cutting block is aligned a little lateral of center.

Then the trochlea is resected with the chisel.

48

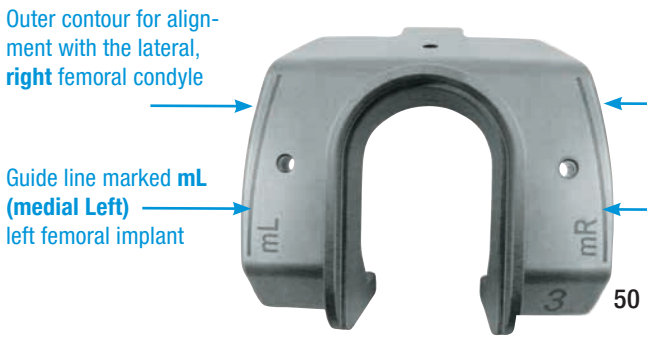
Alternatively, it can be prepared with the rasp.


49

Procedure using GEMINI PS

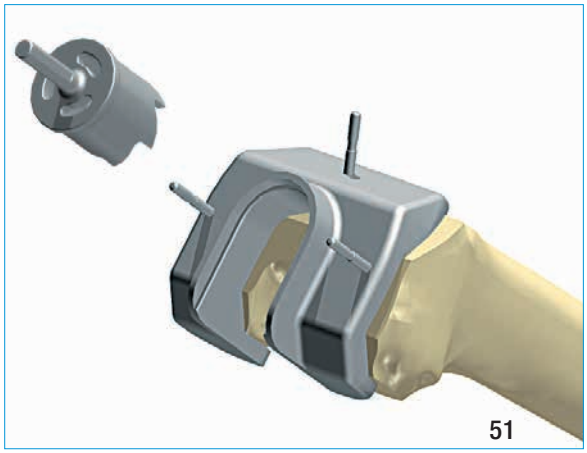
The box guide is selected according to the size of the femoral component, positioned, and aligned with the pre-prepared trochlea (**49**).

Note:
Alignment and orientation guide lines (**50**).
The box guide is symmetrical to permit its universal use.



50

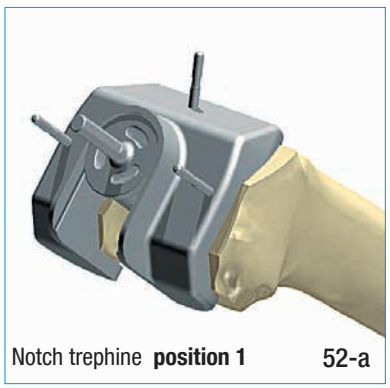
Application:
As well as notch alignment, the box guide can be aligned with the outer contour of the femoral condyle. The guide lines (marked **mL** and **mR**) indicate the medial end of the implant for orientation purposes.

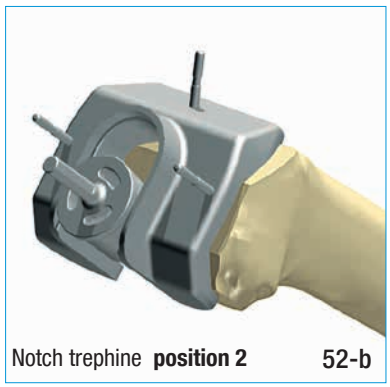

51

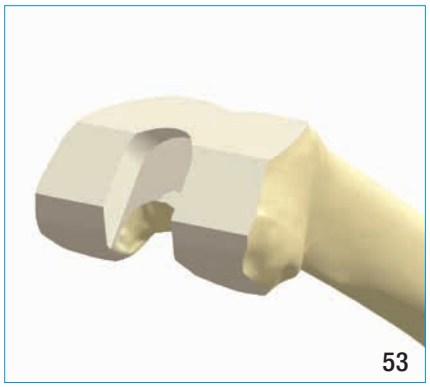
The box guide is fixed with no fewer than two and up to three pins (**51**). The notch is prepared using the notch trephine:

1. Drilling in **position 1** (**52-a**)
2. Drilling in **position 2** (**52-b**)
3. Smoothing the prepared surface by guiding the notch trephine from **position 1** to **position 2**

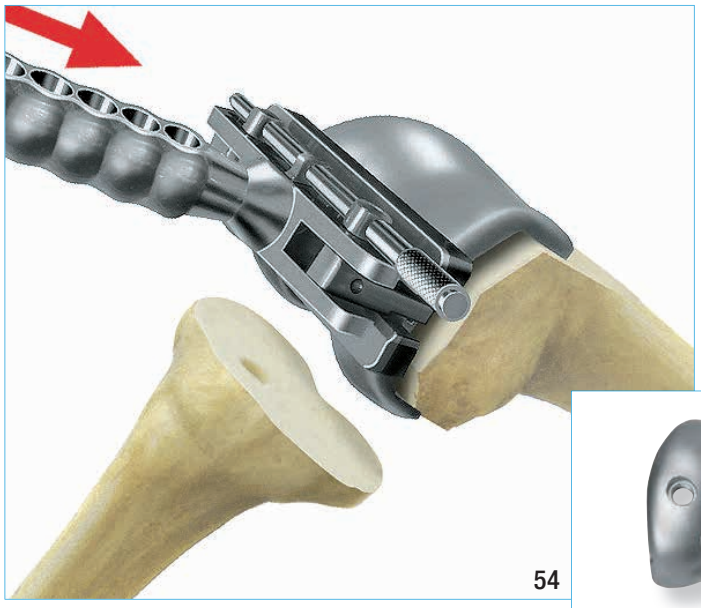
Option
The guide surfaces can be prepared with a chisel. Figure 53 shows the femoral bone after resection is complete.


Notch trephine **position 1** 52-a


Notch trephine **position 2** 52-b


53

7 Trial Reduction and Checking Function

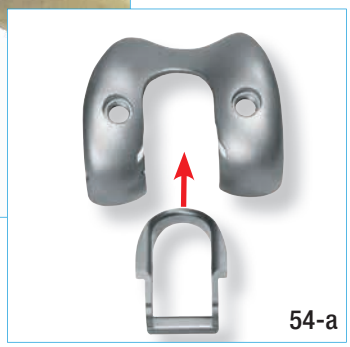


54

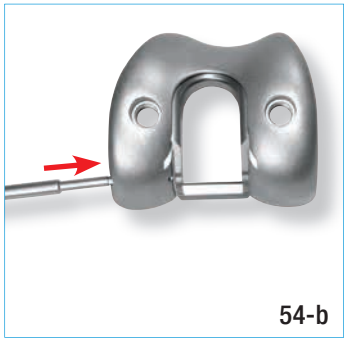
The corresponding trial femoral component is positioned with the inserter/extractor.

Procedure with GEMINI® PS

The PS femoral box trial is placed in the trial femoral component (**54-a**) and fixed with the locking screw (**54-b**) Then the trial implant is positioned with the inserter/extractor.



54-a



54-b

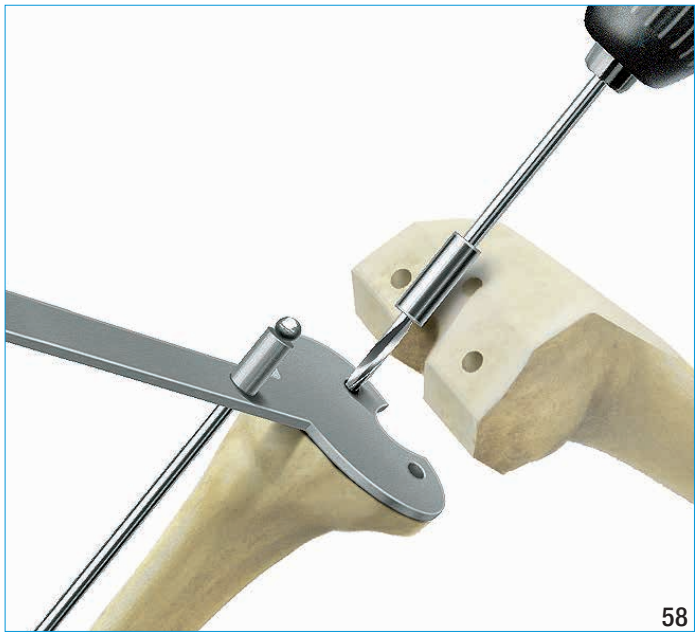
55

In addition, the trial implant can be put in the final position with the impactor (**55+56**).

Subsequently, the two drill guides are placed and the fixation holes drilled with the twist drill of 5.5 mm diameter (**57**).

56

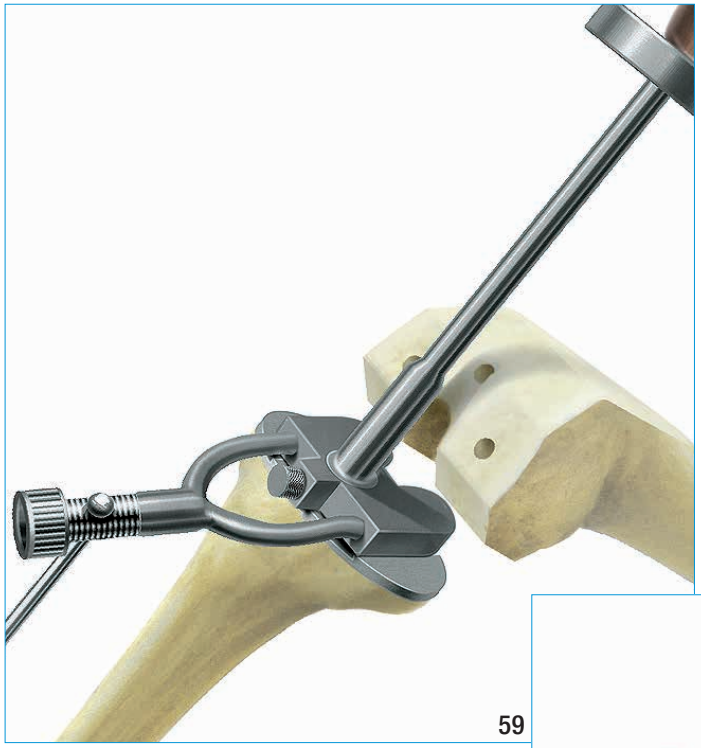
57


58

The trial femoral implant is then removed.

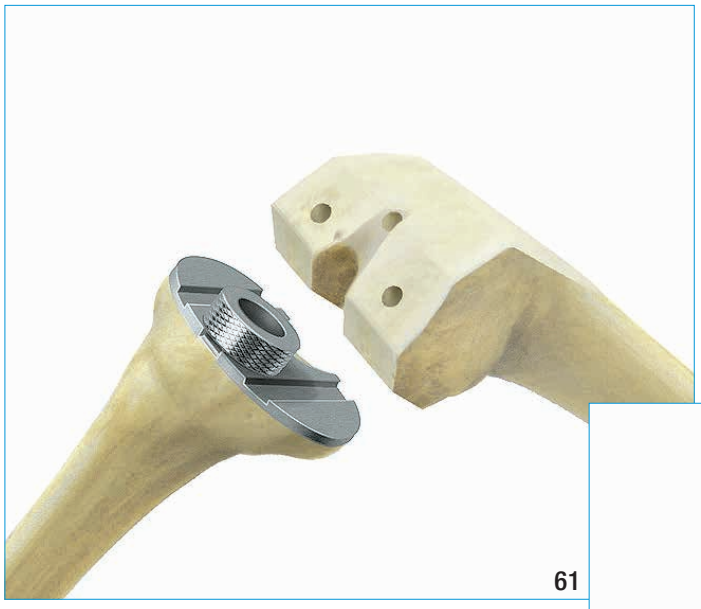
The suitable tibial sizer is placed, and rotational alignment is done with the aid of the extramedullary alignment rod, before the two holes are pre-drilled with the twist drill (**58**).

Caution:
Drill only a few millimeters, and not to the limit, or alternatively, mark using a bone awl.


59


60

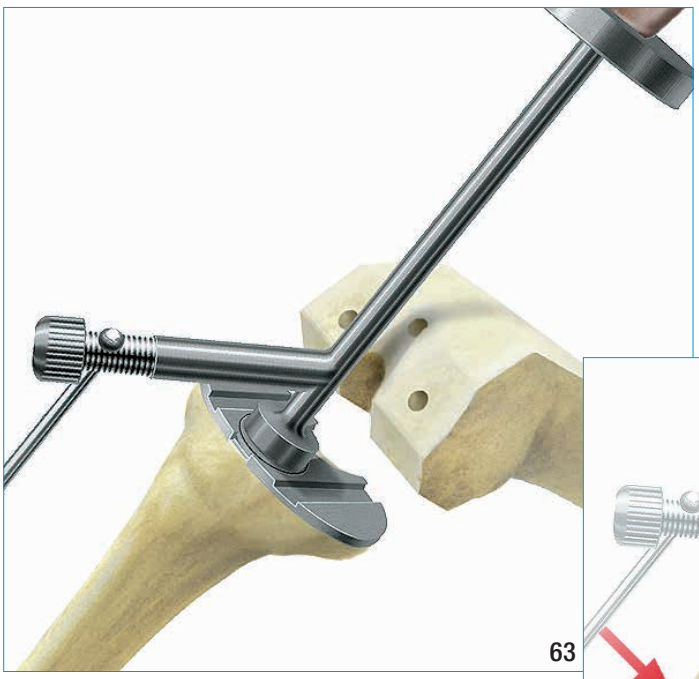
The suitable trial tibial baseplate is driven in with the impaction instrument incl. alignment rod (**59+60**).



61

After the impaction instrument is removed, the drill guide is inserted (**61**) and a bone dowel is milled out with the trephine (**62**).

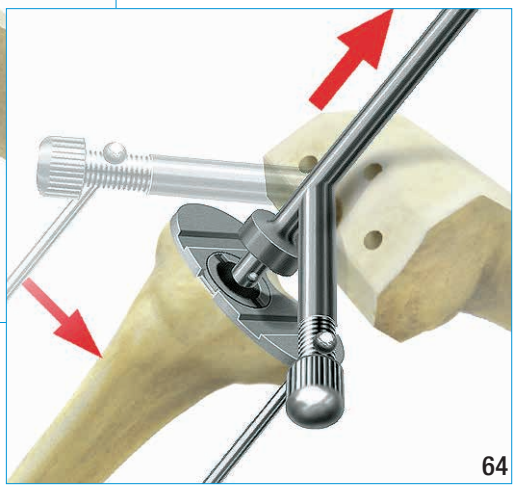
62



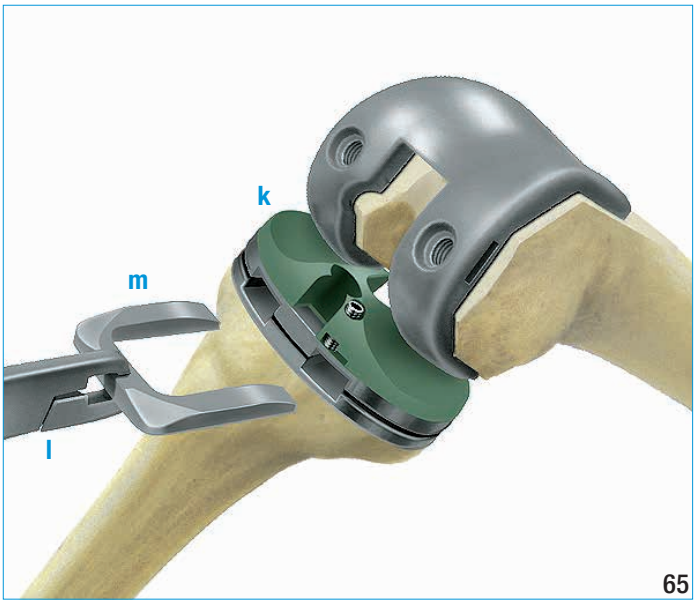
63

The sleeve for compressing the cancellous bone block is driven into the hole with the cancellous bone compressor incl. alignment rod (**63**).

The cancellous bone compressor is removed by turning it to the right – the sleeve remains in place (**64**).



64



65

The trial femoral component can be fitted with two threaded pins. Then the trial implant is placed and the corresponding trial plateau (**k**) is inserted. The slimmest shim (**m**) is introduced with the insertion forceps (**l**) (**65**). Next comes trial reduction, with extension, flexion of the knee, and ligature tension is checked.

Note:
Ensure that no osseous structures (e.g. osteophytes) or soft tissue interfere with the kinetics. If necessary, the area around the notch, and especially at the dorsal condyles, must the reworked with a small curved chisel.

The trials are then removed.

8 Implantation

8.1 Tibial components

Overview of combinations:

66

Optionally, a taper cap (cementable or cementless) can be placed on the tibial component. Furthermore, there is the option of stem extensions (cementable or cementless) in the case of instabilities or insufficient bone.

Compatibility: Femoral / Tibial Components

Tibial Components	Femoral Components / Polyethylene Plateaus						
	1	2	2A	2B	3	4	5
1	X	X	–	–	–	–	–
2	X	X	X	X	X	–	–
3	X	X	X	X	X	X	–
4	X	X	X	X	X	X	X
5	X	X	X	X	X	X	X

X = unrestricted compatibility
X = reduced compatibility, depending on the situation
– = no combination

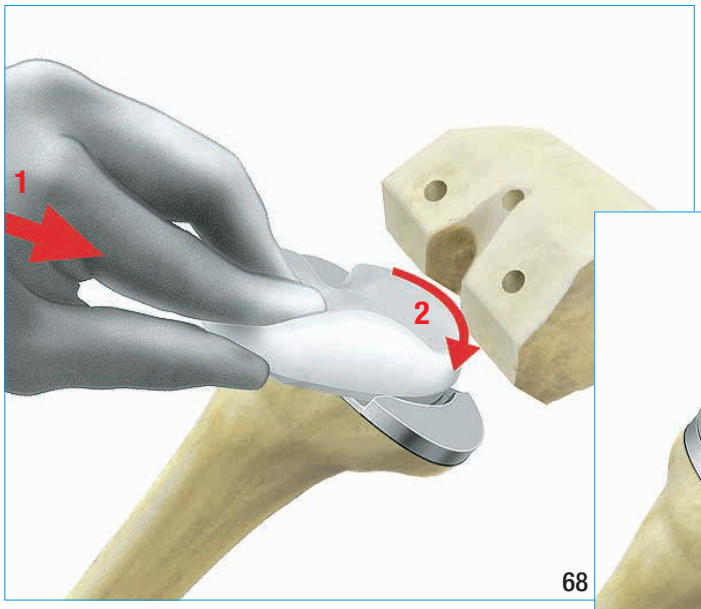

67

Cementable metal tibial component
The bone cement is prepared as directed by the specific manufacturer and applied to the bottom of the metal tibial component, which is then introduced into the resected tibia and impacted with the driver (**67**).

Caution!
Ensure that excess bone cement is completely removed and that no loose particles of bone cement are left in the joint.

Cementless metal tibial component
The cementless metal tibial tray is placed and impacted directly into the resected tibia.

Note:
Use only the appropriate implants as marked for the type of fixation in question (cementable/ cementless).



68

The polyethylene articulating surface is introduced lengthwise (**1**) and then rotated clockwise 90° into the final position (**2**) (**68+69**).

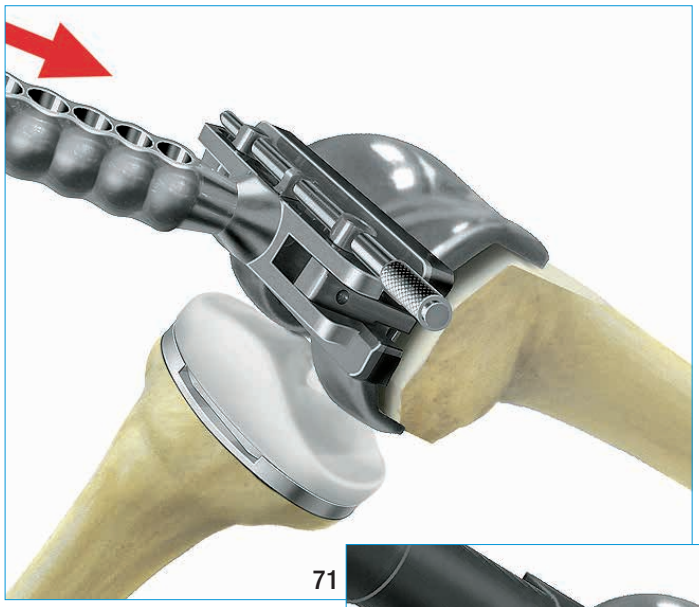

69


70

Optionally, the metal tibial component and the premounted polyethylene articulating surfaces can be impacted together. To do so, the impactor for metal component incl. PE articulating surface (Mobile Bearing) is used.

Note on FIXED and PS versions
After implantation of the tibial metal tray (Fixed Bearing), the polyethylene articulating surface (Fixed or PS) corresponding to the femoral component is placed. Ensure that the two posts on the bottom are positioned in the recesses in the metal tray. Finally, the polyethylene articulating surface is fixed with the safety bolt (enclosed with the metal tray).

8.2 Femoral component


71

Cementable femoral component
The femoral component is placed with the impactor handle. After applying the bone cement previously prepared as directed by the specific manufacturer, the femoral component is implanted. The final femoral component is impacted with the impactor handle (**71**).

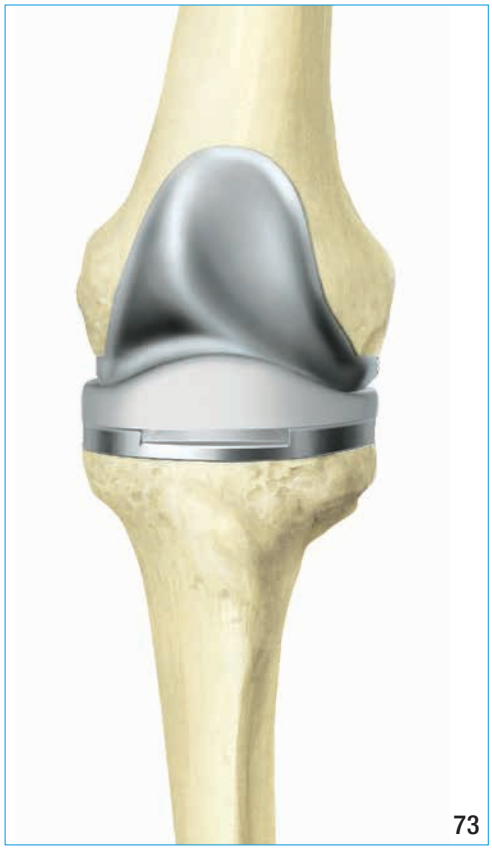
Subsequently, the impactor can be used to finish impacting the femoral component (**72**).

Caution!
Ensure that excess bone cement is completely removed and that no loose particles of bone cement are left in the joint.


72

Cementless femoral component
As described for the cementable variant, the cementless femoral component is placed in a similar way using the impactor handle. The femoral component is positioned and implanted with a couple of delicate yet effectual strikes of a hammer.

9 Functional Test



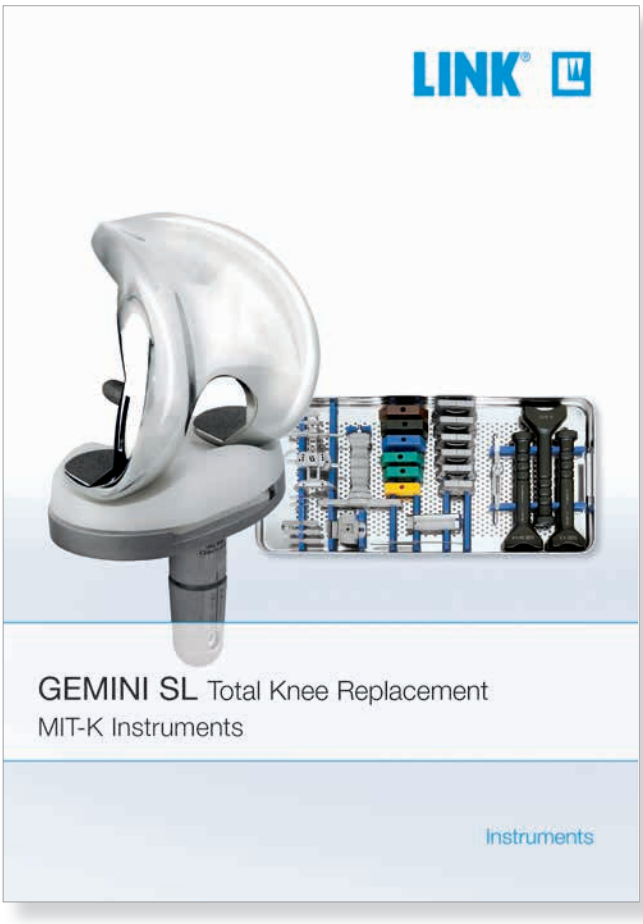
73

74

Implanted femoral and tibial components in situ (**73+74**).

Functional test

A final check is done to completely verify the correct position of the components in extension, in flexion, and ligament tension.



GEMINI SL Total Knee Replacement
MIT-K (Minimally Invasive Technique - Knee) Instruments

LINK PorEx Technology
(TiNbN = Titanium-Niobium-Nitrid)
for metal sensitive patients

Patella Components
for LINK Knee Prosthesis Systems

For more information please register for our LINK Media Library (linkorthopaedics.com)

Specified indications and contraindications: GEMINI SL Total Knee Replacement — Product	Mobile Bearing	Fixed Bearing	Fixed Bearing PS Posterior Stabilized	with LINK PorEx (TiNbN) Surface Modification
General Indications				
• 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	X	X
Indications				
• Bone necroses	X	X	X	X
• Bicondylar arthrosis by intact ligaments including the posterior ligament	X	X	–	X*
• Bicondylar arthrosis by intact collateral ligaments and absence of cruciate ligament function	X	–	X	X*
Differential Indications				
• Arthrosis of patella flange	X	X	X	X
• Valgus/Varus deformities <10°	X	X	X	X
• Valgus/Varus deformities 10 -15°	X	X	X	X
• Sensitization against one or more components of used CoCrMo implant materials	–	–	–	X
Contraindications				
• Acute or chronic infections, local and systemic	X	X	X	X
• Allergies due to (implant) materials	X	X	X	–
• Distinctive muscular, nerve, vascular or other diseases which put the affected limb at risk	X	X	X	X
• Insufficient / inadequate bone mass- or quality which pre vents a stable anchor of the prosthesis	X	X	X	X
Relative Contraindications				
• Adiposity	X	X	X	X
• Insufficient collateral ligaments	X	X	X	X
• Insufficient musculature	X	X	X	X
• Lacking or foreseeable not assured compliance	X	X	X	X
• Foreseeable overload of joint prosthesis	X	X	X	X

* dependent on the implant variant

These indications/contraindications refer to standard cases. The ultimate decision on whether or not an implant is suitable for a patient must be made by the surgeon based on his/her individual analysis and his/her experience.

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 determines the size and shape of the implant and also limits 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 used again.

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!

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