LINK®

GEMINI® SL®

Total Knee Replacement

Surgical Technique

Presented by:

CE 0482

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GEMINI® SL®
Total Knee Replacement

GEMINI® SL® Total Knee Replacement

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 design principles.

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** – Titanium (Ti) / Calcium Phosphate (CaP) provide secondary fixation for cementless implantation.

Mobile Bearing

with congruent tibial plateau surface

- Congruence of the articular surfaces in extension
- Articulating femoral condyle as flexion increases, giving greater freedom of flexion and relieving strain on the patella
- High congruence stabilizes the joint, also in the absence of the posterior cruciate ligament [1]

Fixed Bearing

on tibial component

- For use with intact ligaments and capsule and adequate joint stability
- The same femoral component for fixed and mobile bearings
- The same tibial component for fixed bearing and fixed bearing PS

Fixed Bearing PS

with mechanical stop

- Post on the tibia and stabilizing cam on the femoral component as coupling mechanism
- Guided tibial “rollback” with dorsal subluxation stop
- Joint function stabilised in the absence of the posterior cruciate ligament

1 Christine S. Heim, BSc, Paul D. Postak, BSc, Nicolas A. Playton, MS, A. Seth Greenwald, DPhil (Oxon): „Classification of Mobile-Bearing Knee Designs: Mobility and Contraint“, The JBJS (American) 83:S32-37 (2001)

Specified indications and contraindications: GEMINI® SL® Total Knee Replacement Product	Mobile Bearing	Fixed Bearing	Fixed Bearing PS Posterior Stabilized	with 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

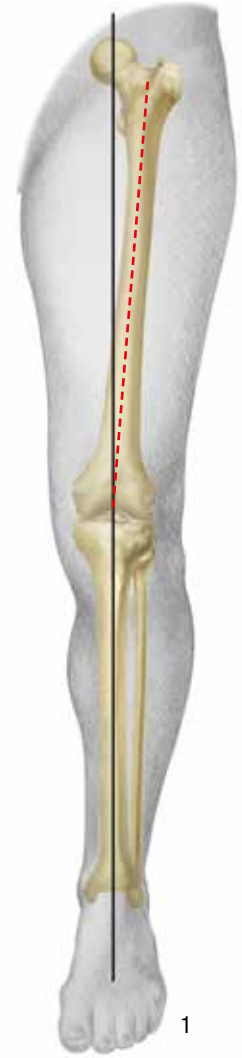
These indications/contraindications refer to standard cases. The ultimate decision on whether or not an implant is suitable for a patient must be made by the surgeon based on his/her individual analysis and his/her experience.

Preoperative Planning

The anatomic landmarks in the knee joint are defined preoperatively by imaging the whole leg on the healthy and the affected side in the standing position. The angle between the anatomic axis (center of knee joint – intramedullary canal) and the mechanical axis (center of femoral head – center of knee joint – center of ankle to the second toe) determines the valgus angle (1).

These angles should be determined for both knees. The valgus angle of a healthy knee joint is 5°–7°. In comparison with the healthy side, and for the purpose of reconstructing the corresponding valgus angle in the affected knee joint, this angle must be determined before carrying out the distal femoral resection.

The appropriate implant size can be selected preoperatively with X-ray templates (see GEMINI® SL® Implants & Instruments brochure for X-ray templates). The necessary resections are determined by the size of the implant.



1

Approach

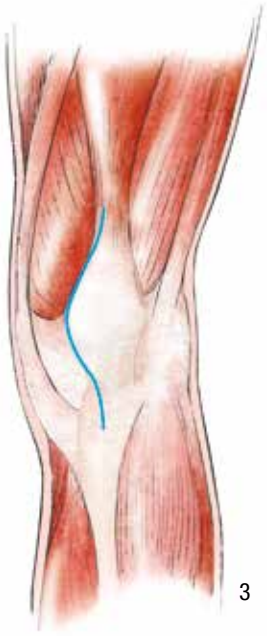
With the knee in slight flexion, a straight incision is made over the patella, as far as the tibial tuberosity (2).

2

A medial parapatellar incision is made through the patellar retinaculum, capsule and synovial membrane (3).

When making the parapatellar incision, the patella is pushed to one side to visualize the femoropatellar joint. Removal of the hypertrophic synovial membrane and parts of the fat pad allow access to the medial, lateral and intracondylar parts of the joint.

Excess synovia should be removed in order to avoid postoperative impingement and adhesions. Some surgeons prefer total synovectomy.



3

Tibial Plateau Resection

Osteophytes are removed from the femur and tibia, especially those located in the region of the collateral ligaments. These could impair soft-tissue balancing. Approx. 2.5 cm of the proximal tibia is visualized ventrally and medially. With the knee flexed to 90°, the tibia can be additionally rotated for better visualization.

Extramedullary alignment

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

Assembling the extramedullary guide

The extramedullary guide comprises the following components:

- EM orientation rod with fixation arm (4.1)
- Foot clamp with positioning guide (4.2-a)
  = alternative version (4.2-b)
- Stylus with guide (4.3)
  The stylus comes in the following versions:
  - "12" for GEMINI SL Mobile
  - "10" for GEMINI SL Fixed and Fixed PS
  - "2" for GEMINI SL defect referencing
- Cutting block with tibial base guide (4.4)
  The cutting block comes in the following versions:
  - Symmetrical
  - Asymmetrical (approach from medial), left
  - Asymmetrical (approach from medial), right

Alignment is carried out in reference to the anterior edge of the tibia. When the orientation rod is parallel to the anterior edge of the tibia, the resection is 90°, which means 0° dorsal slope.

The dorsal slope, varus/valgus alignment and tibial resection height are set on the tibia base guide.

Tibial Plateau Resection

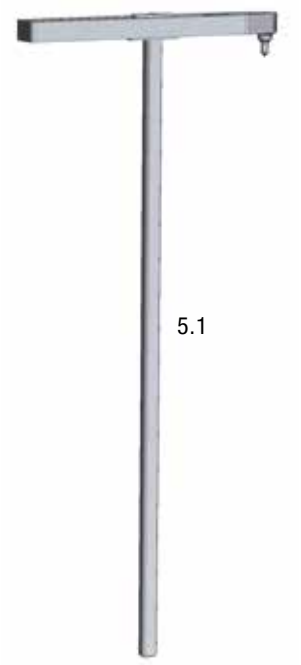
The requisite components are assembled:

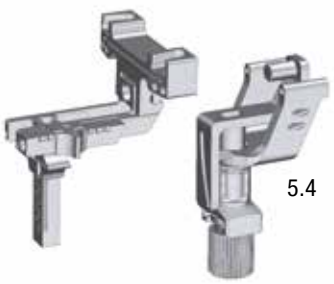
5.1 EM orientation rod with fixation arm

5.2 Foot clamp with positioning guide

5.3 Stylus with guide

5.4 Cutting block with tibial base guide





Tibial Plateau Resection

6.1

6.2-a

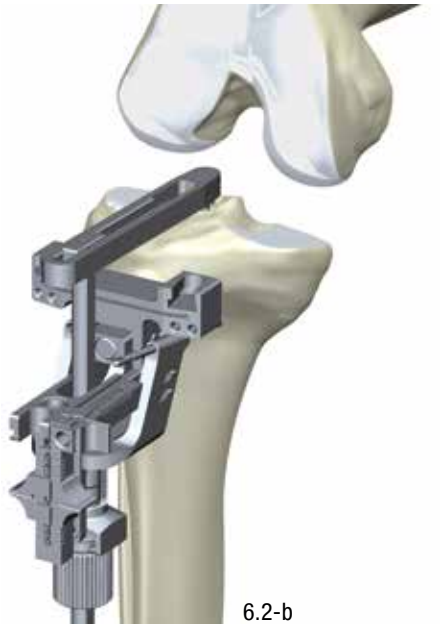
Positioning the alignment

Note:
- Varus/valgus position setting in Neutral "0"
- Dorsal slope setting at 5°

6.1 The foot clamp is attached to the ankle and t ightened using the handle.

6.2 The EM orientation rod with the fixation arm is inserted through the tibial base guide and into the distal guide tube, and is secured with the connecting sleeve.

In the proximal region, the tip of the fixation arm initially rests in the area of the point of attachment of the anterior cruciate ligament, roughly centrally in the region of the intercondylar eminence on the tibial plateau (6.2-a, 6.2-b). Then the tip is knocked in with a hammer. The alignment instrument can still be rotated.



6.2-b

Tibial Plateau Resection

Rotation definition and axial alignment

To determine the correct alignment of the rotation, the alignment instrument is aligned centrally along the tibial shaft axis and in extension of a line onto the second toe (7.1).

Note:
To secure the rotation setting, the alignment instrument can be fixed in the tibial plateau by means of a fixation pin. For assistance, the center of the tibia, the tibial tuberosity and the second toe can be marked with a sterile marker pen.

When the alignment instrument, viewed from the side, is parallel to the ventral tibia, this means that the saw guide is set in the previously selected dorsal slope. Fine adjustment is possible following alignment (7.2).

7.1

7.2

Tibial Plateau Resection

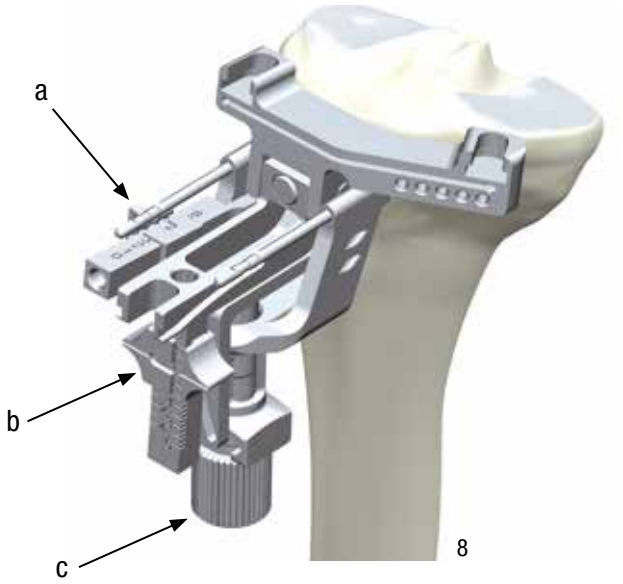
Resection adjustment

Fine adjustment for the tibial resection
The tibial saw guide is now pushed against the ventral tibial cortical bone as far as the limit stop. Correct alignment can be checked by attaching a check rod.

Dorsal slope
The recommended dorsal slope is 5°. It can be adjusted in 1° steps with the fine adjustment (a) (8).

Varus-valgus adjustment
The fine adjustment (b) allows precise correction of the varus or valgus alignment (8).

Tibial resection height
After presetting the resection height with the selected stylus version, the surgeon can now carry out fine adjustment of the resection height with the screw (c) (8).



8

Tibial Plateau Resection

Tibial resection

The cutting template can be used to check the alignment of the tibial resection (9). Any necessary corrections to the position can be carried out at this point.

9

Then the tibial cutting block is fixed with a fixation pin (10) and the resection is performed (11).

10

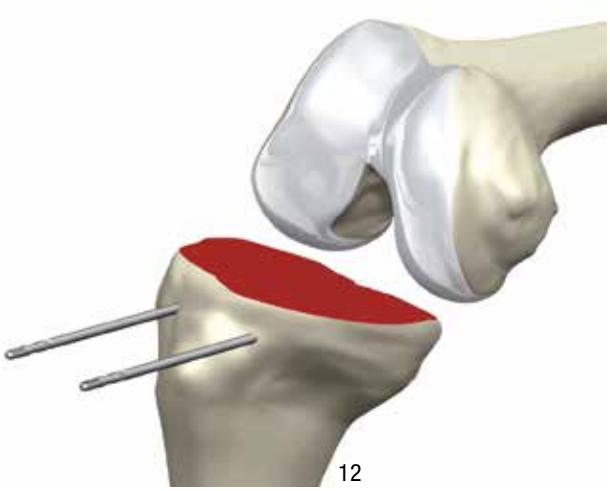
11

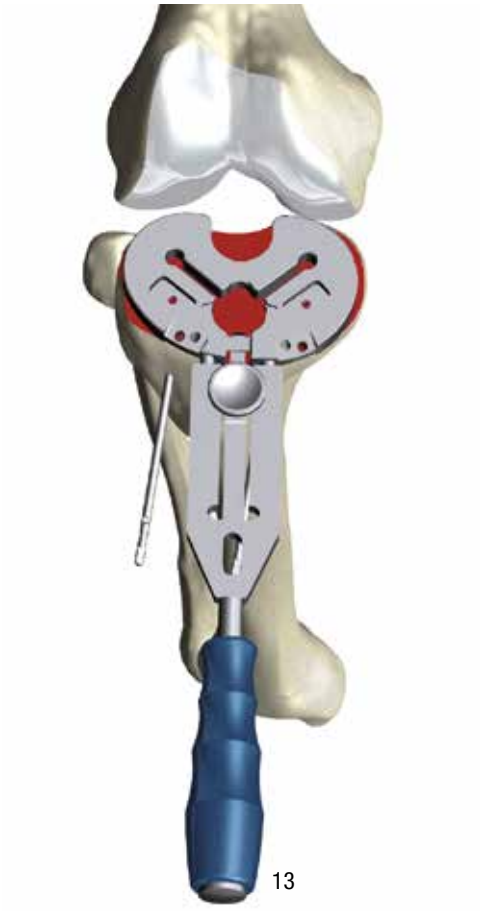
Tibial Plateau Resection

Determining the tibial size

Following the resection, the third fixation pin and the tibial saw guide are removed. The anterior fixation pins remain in position (12).

The tibial implant size can now be determined by applying the appropriate tibial sizer. The instrument must cover the cortical bone optimally, without projecting beyond it (13). The tibial implant size can also serve as an indicator for the femoral implant size if the femoral measurement is between two sizes.

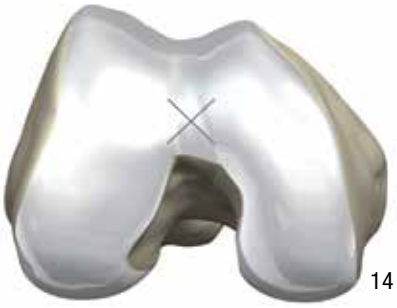

12


13

Femoral Resection – Distal Resection (extension gap)

Opening the femoral medullary space

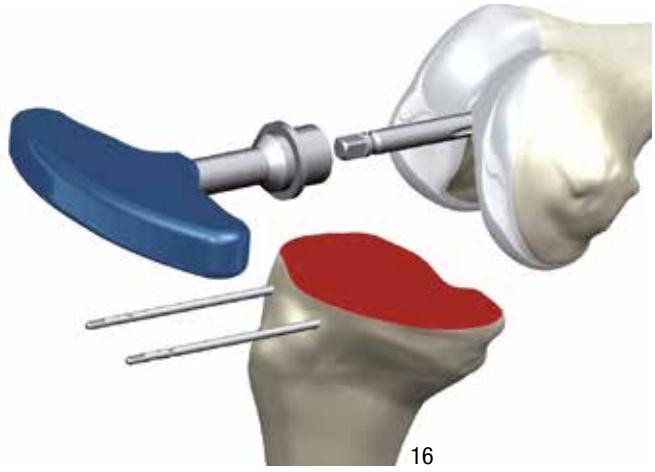
The knee is flexed to 90° in order to resect the femur. To determine the entry point (intersection of Whiteside and Insall lines) for opening the femur, this can be marked with the electrocautery. It is usually located approx. 3–5 mm medially above the intercondylar fossa (14). The medullary space is opened with the step drill (15).


14


15

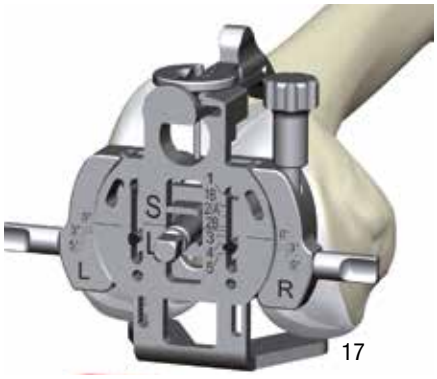
Predetermining the femoral size

The intramedullary guide rod is inserted and the T-handle is removed (16).


16

The femur measuring instrument is attached, aligning the stylus laterally
on the ventral cortical bone. The dorsal plate must rest against the dorsal condyles (17).

Note:
Soft tissue between the stylus and the cortical bone will falsify the size measurement, so it is essential to avoid this.



17

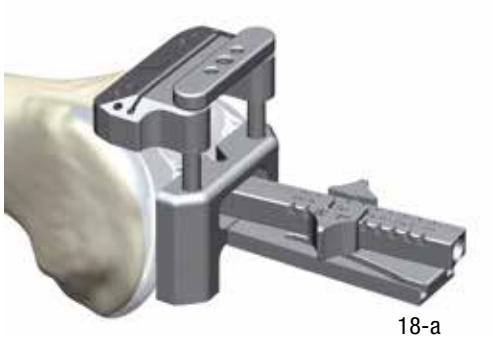
At this point, a first predetermination of the femoral size is carried out in order to select the appropriate distal femoral resection guide. The implants are divided into the groups small (S) and large (L).
Small (S): sizes 1, 1B, 2, 2A and 2B
Large (L): sizes 3, 4, and 5

This predetermination of the joint prosthesis size is read off the instrument scale, on the left (17).

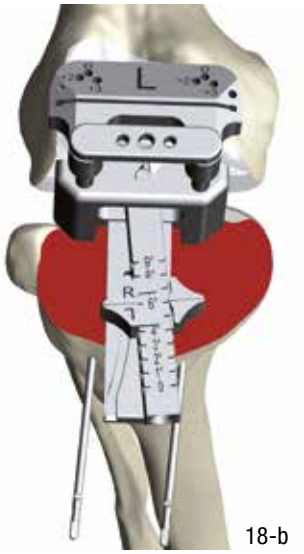
Femoral Resection – Distal Resection (extension gap)

Distal femoral cut (extension gap)

According to the previously selected femoral size (small "S" or large "L"), the distal cutting block is connected to the alignment instrument for valgus angle. Then, the preoperatively determined valgus angle is set, and the instrument is attached to the intramedullary guide rod (18-a, 18-b).



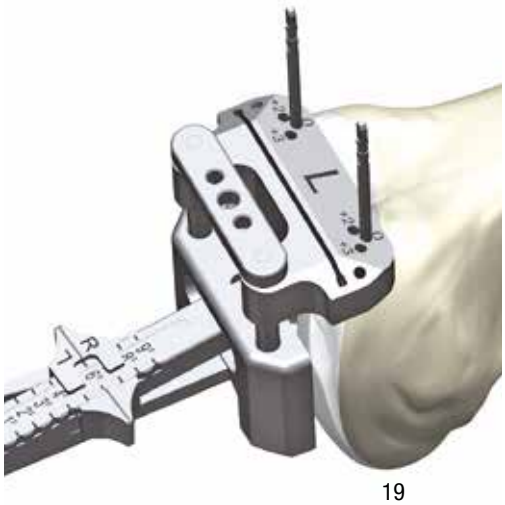
18-a



18-b

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

The two fixation pins are inserted through the holes labeled "0" (19).



19

Then the alignment instrument for valgus angle is separated from the distal cutting block and removed. The intramedullary guide rod is removed (20).

20

Femoral Resection – Distal Resection (extension gap)

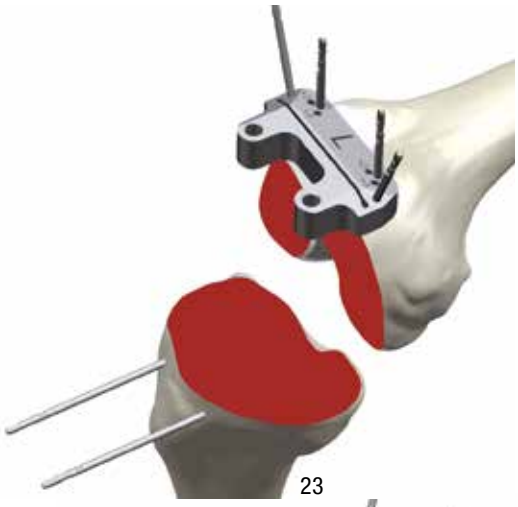
The cutting template can be used to check the alignment of the distal resection (21).


21

To make the instrument more stable, a third fixation pin is fixed into the outer diagonal hole. There is the option of inserting a fourth fixation pin (22).

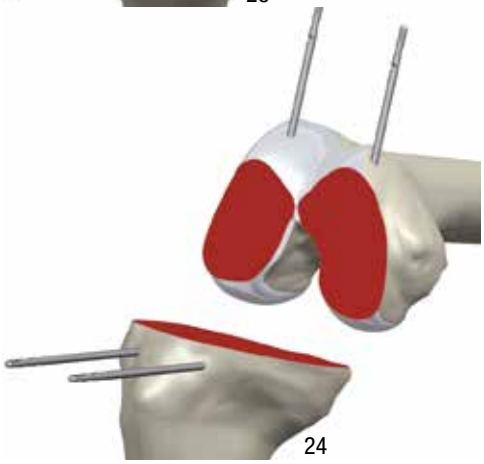

22

The distal saw cut is made at 90° flexion (23). Then the cutting block is removed.


23

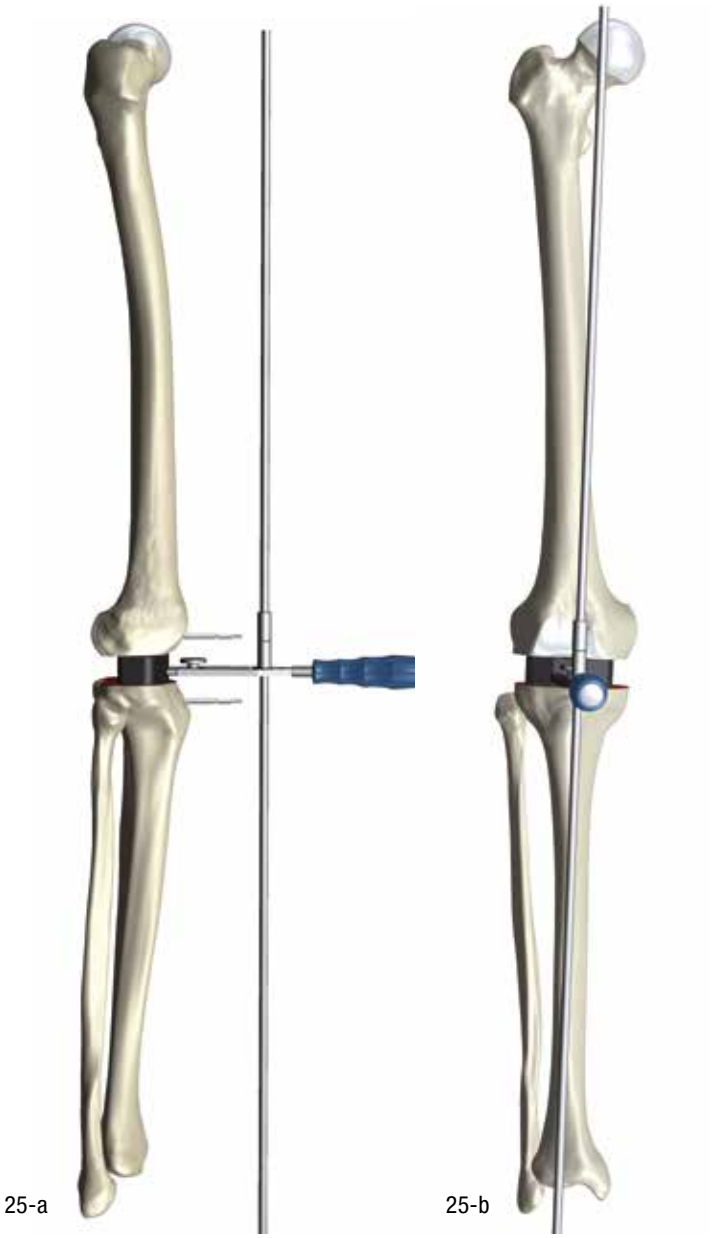
The parallel fixation pins remain in position (24).

Note: It is possible to set the extension gap by means of post-resection.


24

Checking the Extension Gap and Axes

After careful cleaning of the soft tissues, the spacer is inserted, according to the femoral size, and both the axial alignment and the stability of the joint in extension are checked (25-a, 25-b).



25-a

25-b

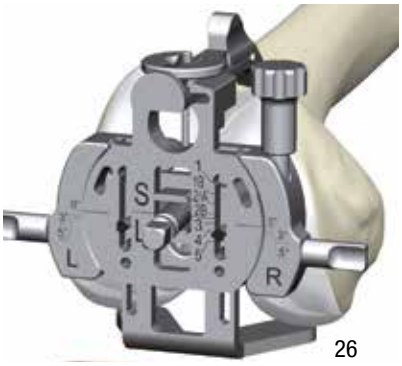
If no further resections are required, the femoral and tibial fixation pins can now be removed.

Final Femoral Resection

Determining the femoral size

For final femoral resection, the next step is to determine the definitive femoral size. The femur measuring instrument is applied to the distal femoral resection surface.

Note: The femur measuring instrument can be applied over the intra-medullary guide rod to ensure stable positioning. This measurement determines the adaptation of the femoral implant size to the A/P dimension. To check the M/L dimension of the selected size, the appropriate femur trial can be held against it. The femoral size is read off from the right side (26).



26

Two fixation pins are used to fix the size and, at the same time, to fix the frame of the measuring instrument to the distal resection surface (27).

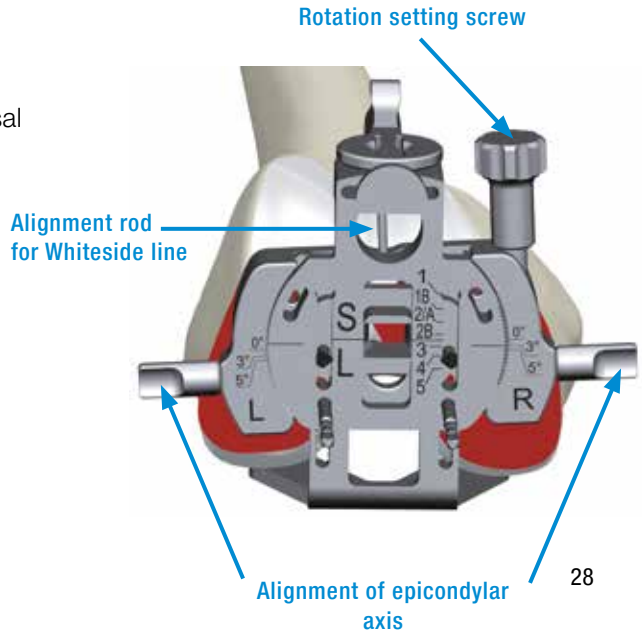
27

Rotation setting

The alignment instrument allows stepless adjustment from 0° to 5° external rotation in reference to the dorsal condyle tangent (28).

Alternatively, the external rotation can be aligned using the Whiteside line, with the alignment rod in the center of the instrument (28).

Alignment pins are provided medially and laterally for aligning on the epicondylar line (Insall line) (28).



28

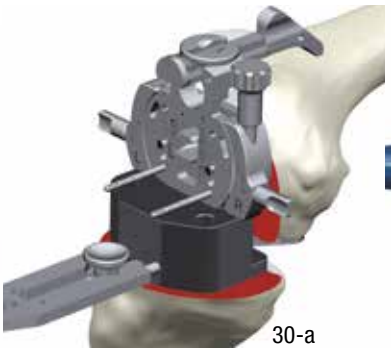
Final Femoral Resection

Rotation setting

Note: Checking the flexion gap
The flexion gap can be checked before finally defining the rotation setting and the femoral resection.

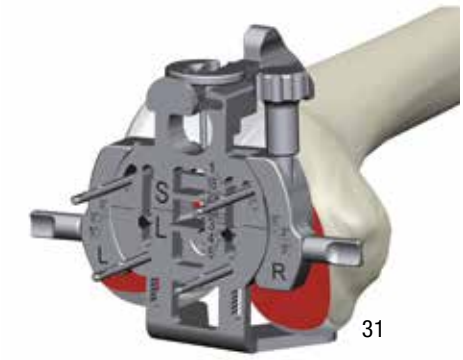
Flex the knee joint 90°. The stepped end of the spacer for the selected size (29) is now slid under the control block so that the higher end rests against the control block (30-a, 30-b). The stepped design means that the condyles are exposed.

29


30-a

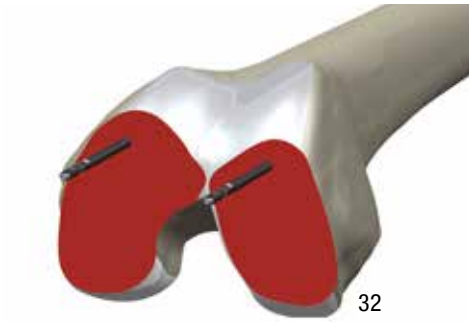

30-b

Once the correct rotation has been set, the instrument is fixed with two fixation pins through the medial and lateral holes (31). These fixation pins are the guide reference for the position of the femoral cutting block.



31

The alignment instrument is removed, but the two fixation pins remain fixed in the bone (32).

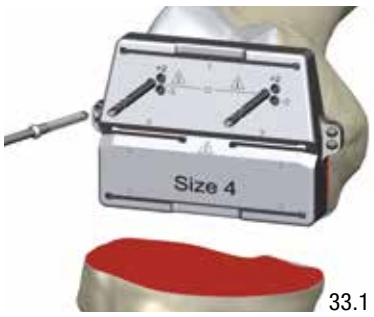

32

Final Femoral Resection

A/P femoral resection and facet surfaces

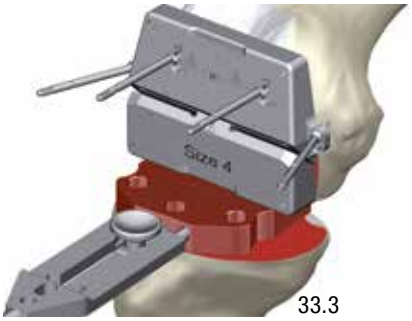
The femoral cutting block is attached over the fixation pins and fixed with screw pins (33.1, 33.2). Optional, it is possible to use fixation pins (Ø 3,5 mm) with stop for the fixation of the femoral cutting block.

The flexion gap can be checked or corrected by using the spacer in combination with femoral cutting block.The spacer is with his stepped side pushed as far as under the block, until it rests on the highest point under the femoral cutting block. The flexion gap can be adjusted by the reaction of the femoral cutting block prior to the final resection (33.3).



33.1

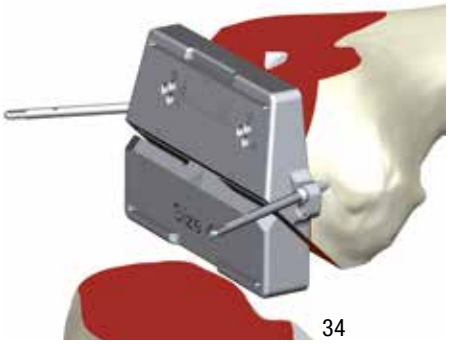
33.2



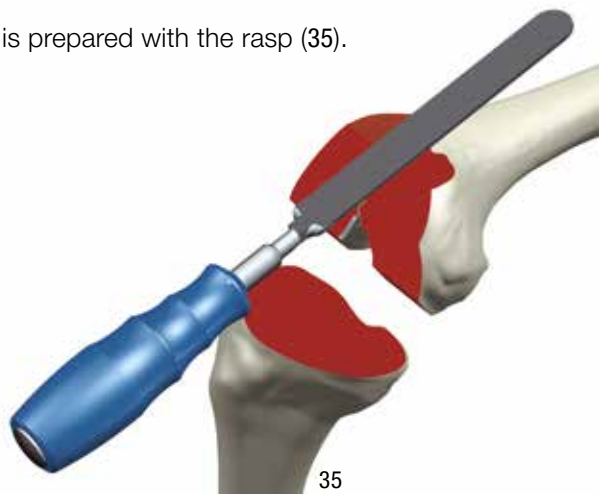
33.3

Note:
The cutting template can be used to check the alignment of the individual resections, especially the ventral cut.

The ventral cut is carried out first, followed by the dorsal, then the anterior and posterior facet cuts (34).


34

After that, the trochlea is prepared with the rasp (35).


35

Final Femoral Resection

FIXED Bearing PS (Fixed Bearing Posterior Stabilized)

Procedure with GEMINI® SL® PS

The box guide is selected according to the size of the femur and is positioned on the resected end of the femur. Alignment is performed on the notch and the m/l dimension (36).


36

Note:
The box guide is symmetrically designed to permit universal use. Marking guide lines enable orientation and alignment (37).

37

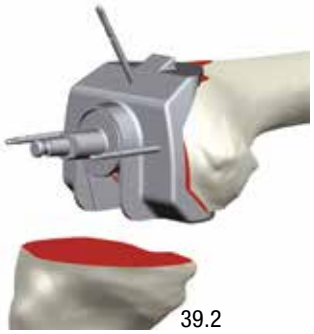
The box guide is fixed with at least two fixation pins, or with three if preferred (38).

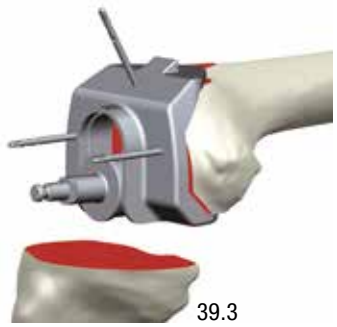

38

The notch trephine is used to prepare the box:

1 Drill in Position 1 (39.1+2)
2 Drill in Position 2 (39.3)
3 Smooth the resection by passing the notch trephine from Position 1 to Position 2


39.1


39.2


39.3

Femur bone after completion of resection (40).


40

Tibial Preparation

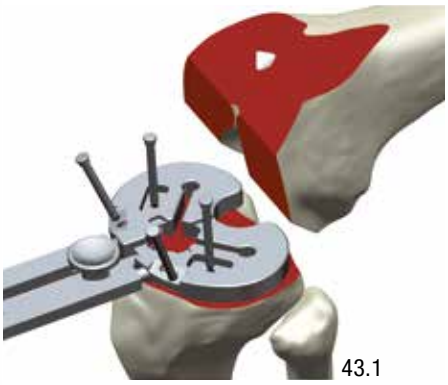
Tibial size determination

The tibial implant size can now be determined by applying the appropriate tibial resection plate. The instrument must cover the cortical bone optimally, without projecting beyond it (41).

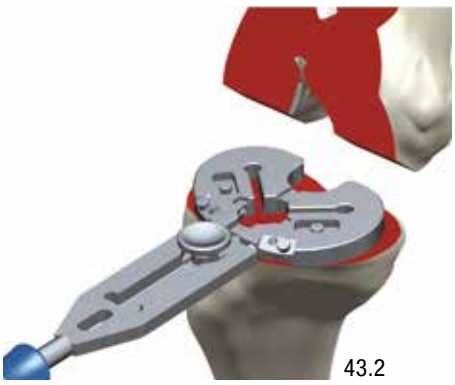
41

After applying the appropriate tibial sizer and aligning the rotation with the aid of the extramedullary alignment rod, (42) the last step is to fix the tibial resection plate with 4 head pins (43.1, 43.2).

42



43.1



43.2

Tibial Preparation

Preparation the tibial stem

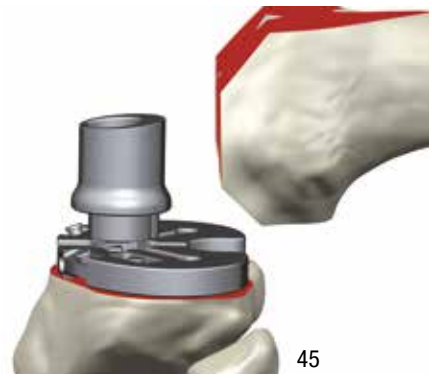
The blade chisel is used to prepare the two guides and the anchoring holes for the fixation pins for the tibia base plate (**44.1**, **44.2**).


44.1

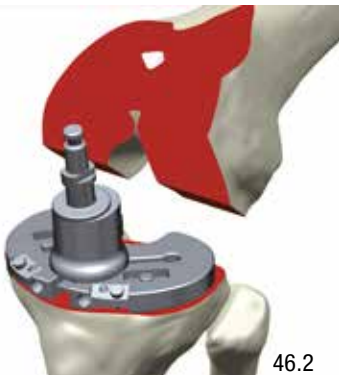

44.2

Then the guide sleeve is inserted (**45**) and the taper guide is resected (**46.1**, **46.2**).

Note:
The choice of reamer depends on which treatment option is selected: tibial taper cap or stem extension.

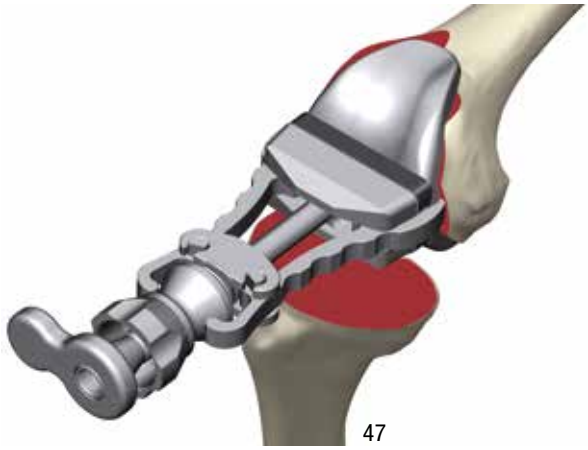

45


46.1


46.2

Trial Reduction and Functional Test

The femur trial is selected according to the resected femoral size and is positioned with the attachable handle and impactor (47).

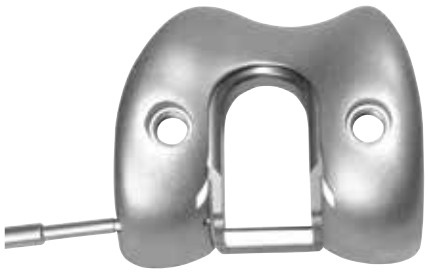


47

Procedure for GEMINI® PS

The femur trial box PS is inserted into the femur trial (48.1) and fixed with the securing screw (48.2). Then the trial is positioned with the attachable handle and impactor.

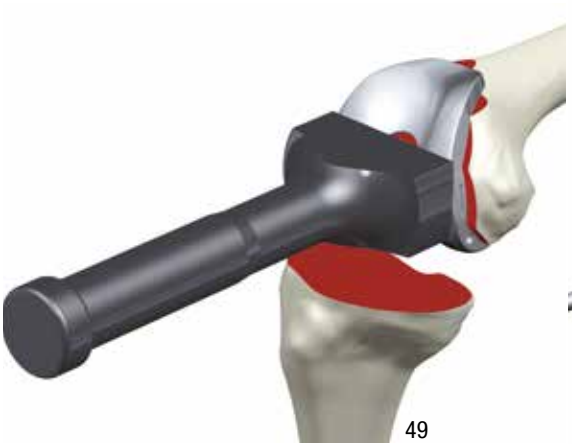
48.1



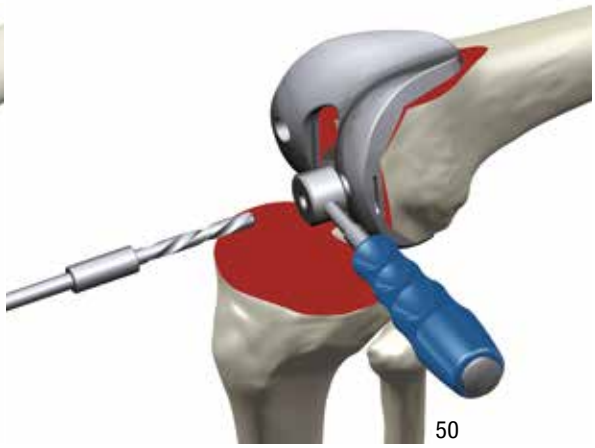
48.2

In addition, the trial can be inserted into its final position using the driver (49).

Then the securing holes are drilled with the 5.5 mm twist drill (50). A drill guide is applied for guiding the twist drill.



49



50

Trial Reduction and Functional Test

The trial plateau is selected and used according to which type of prosthesis is chosen (Fixed Bearing, Fixed Bearing PS or Mobile Bearing). The different heights are set by means of the shim (51).


51

Procedure:

Fixed Bearing / Fixed Bearing PS

1. Assembled shim with trial plateau is inserted into tibia preparation plate.
2. Femoral trial prosthesis is positioned.

Mobile Bearing

1. Femoral trial prosthesis is positioned.
2. Assemled shim with trial plateau is inserted into tibia preparation plate.

Then trial reduction is performed with the knee joint in extension and flexion, and the ligament tension is checked (52).

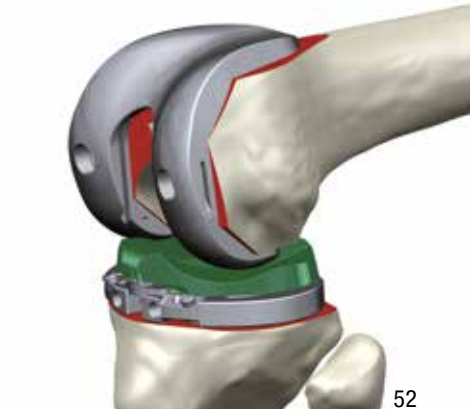
Height correction:

Fixed Bearing / Fixed Bearing PS

For adjusting the height the trial plateau with shim were removed. Then the shim is changed accordingly.

Mobile Bearing

For correction of pure plateau height at lying femoral trial prosthesis, the trial plateau must be used for Fixed Bearing.


52

Note:

Make sure that no bony structures (e.g., osteophytes) or tissue parts interfere with the movement. If necessary, rework the bone in the notch area, but especially on the dorsal condyles, using a small curved chisel.

The trial implants are then removed again.

Implantation

Compatibility table

The following table (53) shows possible size combinations.

Compatibility: Femoral/tibial components

		Femoral components							
		1	1B	2	2A	2B	3	4	5
PE articulating surfaces		1	1B	2	2A/B		3	4	5
Tibial components	1	X	X	X	–	–	–	–	–
	2	X	X	X	X	X	X	–	–
	3	X	X	X	X	X	X	X	–
	4	X	X	X	X	X	X	X	X
	5	X	X	X	X	X	X	X	X

X = unrestricted compatibility

X = restricted compatibility, depending on the patient's soft tissue situation in relation to the articulating surface

– = prohibited combination

53

Implantation sequence

Mobile Bearing

1 1.1 Implantation of tibial component
1.2 Implantation of femoral component
1.3 Insertion of PE articulating surface (refer to the compatibility table)
2 2.1 Assembly of Mobile PE articulating surface (refer to the compatibility table) with Mobile tibial component
2.2 Implantation of tibial component complete with PE articulating surface (refer to the compatibility table)
2.3 Implantation of femoral component

Fixed Bearing / Fixed Bearing PS

1.1 Implantation of Fixed tibial component
1.2 Implantation of femoral component
1.3 Insertion of Fixed or Fixed PS PE articulating surface (refer to the compatibility table)

Implantation

Tibia implant overview:

Optionally, a taper cap or stem extensions can be placed on the taper and fixed with a screw. The taper cap and the stem extensions are available in cemented and cementless versions (54).

Note:
If the tibial component with stem extension is used, ensure that the tibial medullary canal is suitably resected prior to placement.

Note:
Installing taper cap or stem extension. The taper cap or stem extension is fixed primarily by taper clamping, and doubly secured with a second securing screw.

Important!
A first securing screw (grub screw with point (56) is already in place in the taper hole. The second securing screw is supplied, in sterile packaging, together with the tibial component.

After resection of the tibia, the taper cap or stem extension is selected according to the planned type of treatment, and is placed on the taper of the tibial component. When doing this, align the mark on the taper cap or stem extension with the mark on the taper of the tibial component. Then fix with a hammer blow (55).

Note: Place gauze over the surface to protect it from the hammer blow.

Screw in the first securing screw (grub screw with point) (56-a –1) and tighten it strongly by hand. Then screw in the second securing screw (56-a –2) with flat point for double securing.

Implantation

Mobile Bearing

Cemented tibial component
The bone cement is prepared following the specific manufacturer's instructions, and applied to the bottom surface of the tibial component. The tibial component is then inserted into the resected tibia, and driven onto the resection surface of the tibial head with the driver (57).

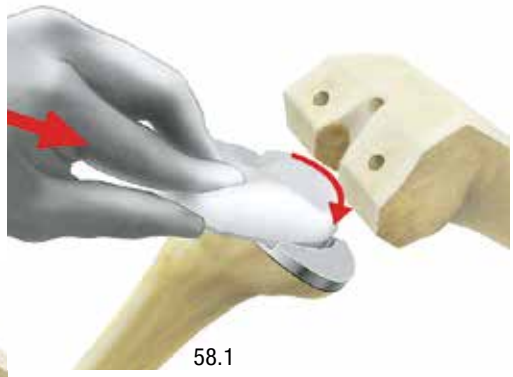

57

Important!
Ensure that excess bone cement is completely removed and no loose bone cement particles remain, especially in the dorsal joint region.

Cementless tibial component
The cementless tibial component is introduced directly into the resected tibia and driven onto the resection surface of the tibial head with the impactor.

Note:
For each type of fixation (cemented/cementless), only use the correspondingly marked implants.

Insert the PE articulating surface (Mobile Bearing) sideways in longitudinal direction (58.1) and turn 90° clockwise to locate it in its final position (58.2).


58.1


58.2

Optionally, the tibial component can be driven on together with the previously mounted PE articulating surface. The instrument used for this purpose is the impactor (Mobile Bearing) adapted for the plastic articulating surface (59).


59

Implantation

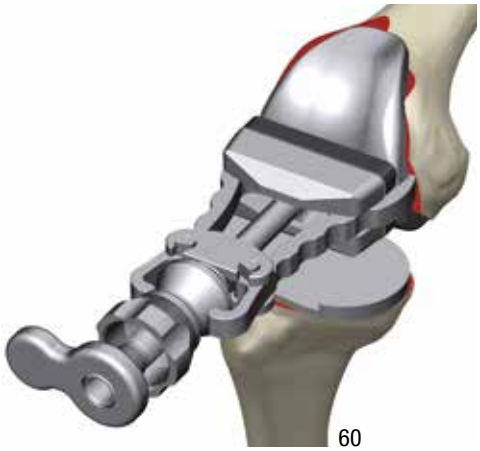
Mobile Bearing

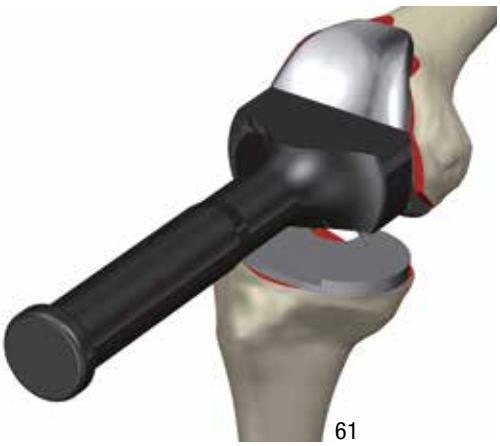
Femoral component

Cemented femoral component

The femoral component is coupled with the attachable handle and impactor. After applying the bone cement, prepared according to the specific manufacturer‘s instructions, the femoral component is implanted. It is driven on with the attachable handle and impactor (60).

To finish, the femoral component can be re-driven with the plastic impactor (61).


60


61

Important!
Ensure that excess bone cement is completely removed and no loose bone cement particles remain, especially in the dorsal joint section.

Cementless femoral component

The cementless femoral component is coupled in the same way as described above for the cementable version, using the attachable handle and impactor. Positioning of the femoral component and implantation are performed with several measured but forceful hammer blows.

Implantation

Fixed Bearing and Fixed Bearing PS

Cemented tibial component

Important!
The retaining screw for fixing the UHMWPE articulating surface has been screwed into the tibial component. It must not be removed for cementing.

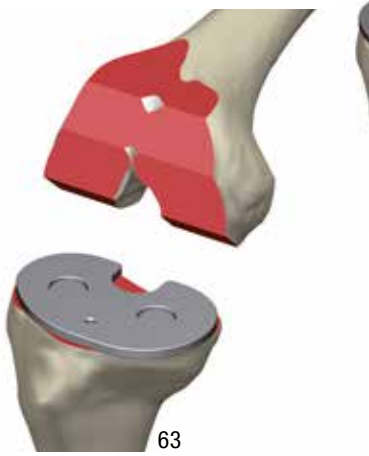
The bone cement is prepared following the specific manufacturer's instructions, and applied to the bottom surface of the tibial component. The tibial component is then inserted into the resected tibia, and struck onto the resection surface of the tibial head and driven on with the driver (62).


62

Important!
Ensure that excess bone cement is completely removed and no loose bone cement particles remain, especially in the dorsal joint section (63).

Cementless tibial component

The cementless tibial component is introduced directly into the resected tibia and driven on.

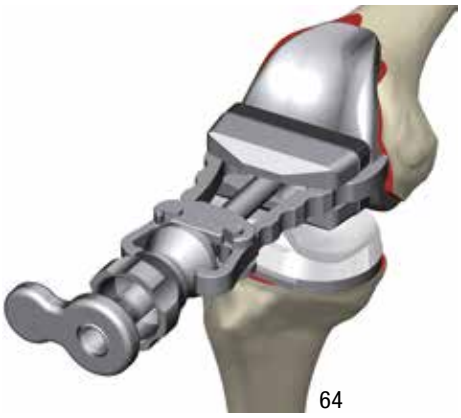

63

Femoral component

Cemented femoral component

The femoral component is coupled with the attachable handle and impactor. After applying the bone cement, prepared according to the specific manufacturer's instructions, the femoral component is implanted. It is driven on with the attachable handle and impactor (64).

To finish, the femoral component can be re-driven with the plastic impactor (65).


64

Important!
Ensure that excess bone cement is completely removed and no loose bone cement particles remain, especially in the dorsal joint section.


65

Implantation

Fixed Bearing and Fixed Bearing PS

Cementless femoral component

The cementless femoral component is coupled in the same way as described above for the cemented version, using the attachable handle and impactor. Positioning of the femoral component and implantation are performed with several measured but forceful hammer blows.

PE articulating surface

The PE articulating surface (Fixed or PS) corresponding to the femoral component is selected and inserted. Ensure that the two securing pins on the bottom surface of the articulating surface are positioned in the recesses of the component.

To finish, the PE articulating surface is fixed to the component using the retaining screw supplied together with the component.

Implantation

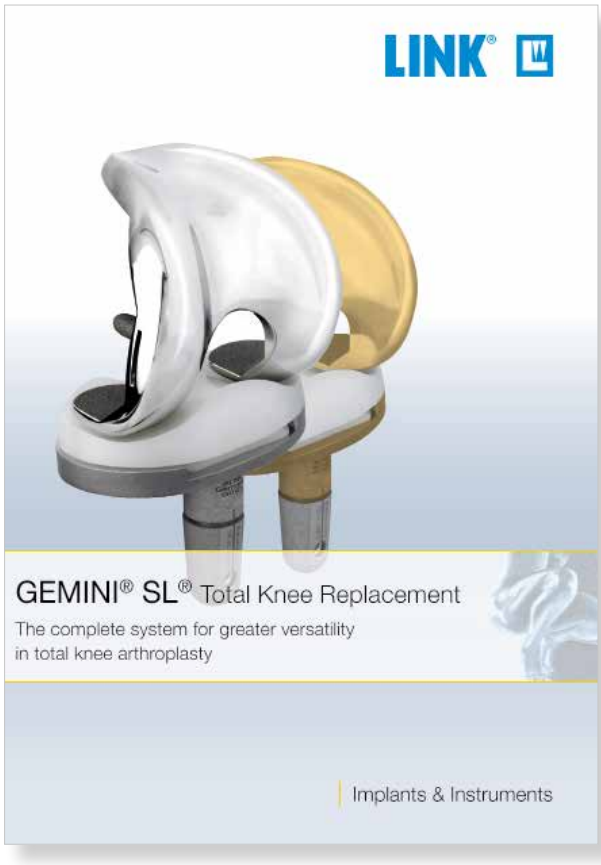
Functional test

Implanted femoral and tibial components (66-a, 66-b).

The concluding functional test is designed to check that the components are correctly positioned in extension and flexion of the knee joint, and also to check for correct ligament tension.

66-a

66-b



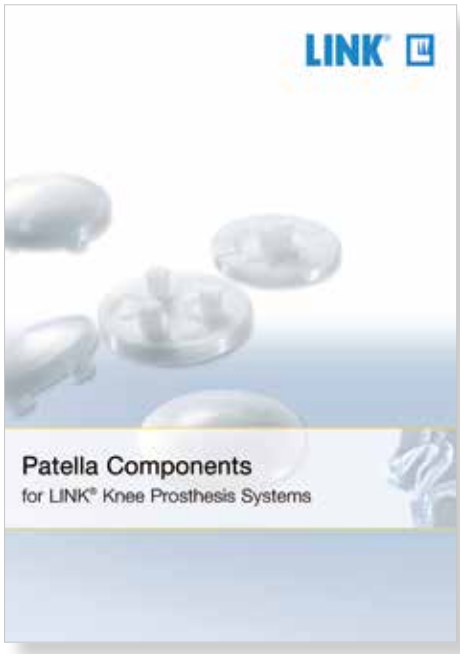
Further information on GEMINI® SL®

- **GEMINI® SL® Total Knee Replacement**
  Catalog: Implants & Instruments

  Available on request.

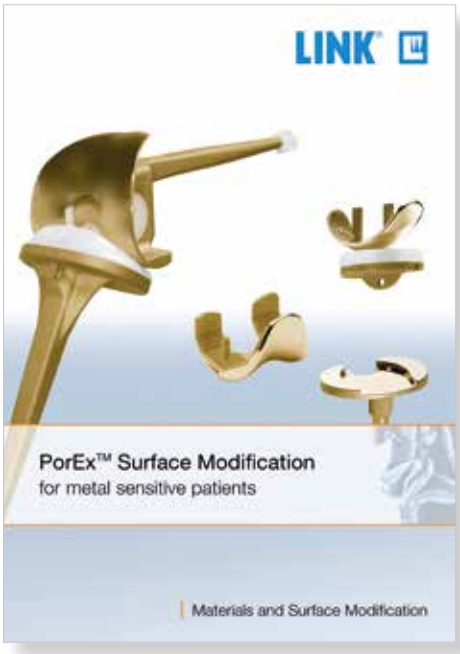
Further information on:

- **Patella Components for LINK® Knee Prosthesis Systems**
  Available on request.



Further information on:

- **PorEx® (TiNbN = Titanium Niobium Nitride) Surface Modification** for metal sensitive patients
  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

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.

Waldemar Link GmbH & Co. KG

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