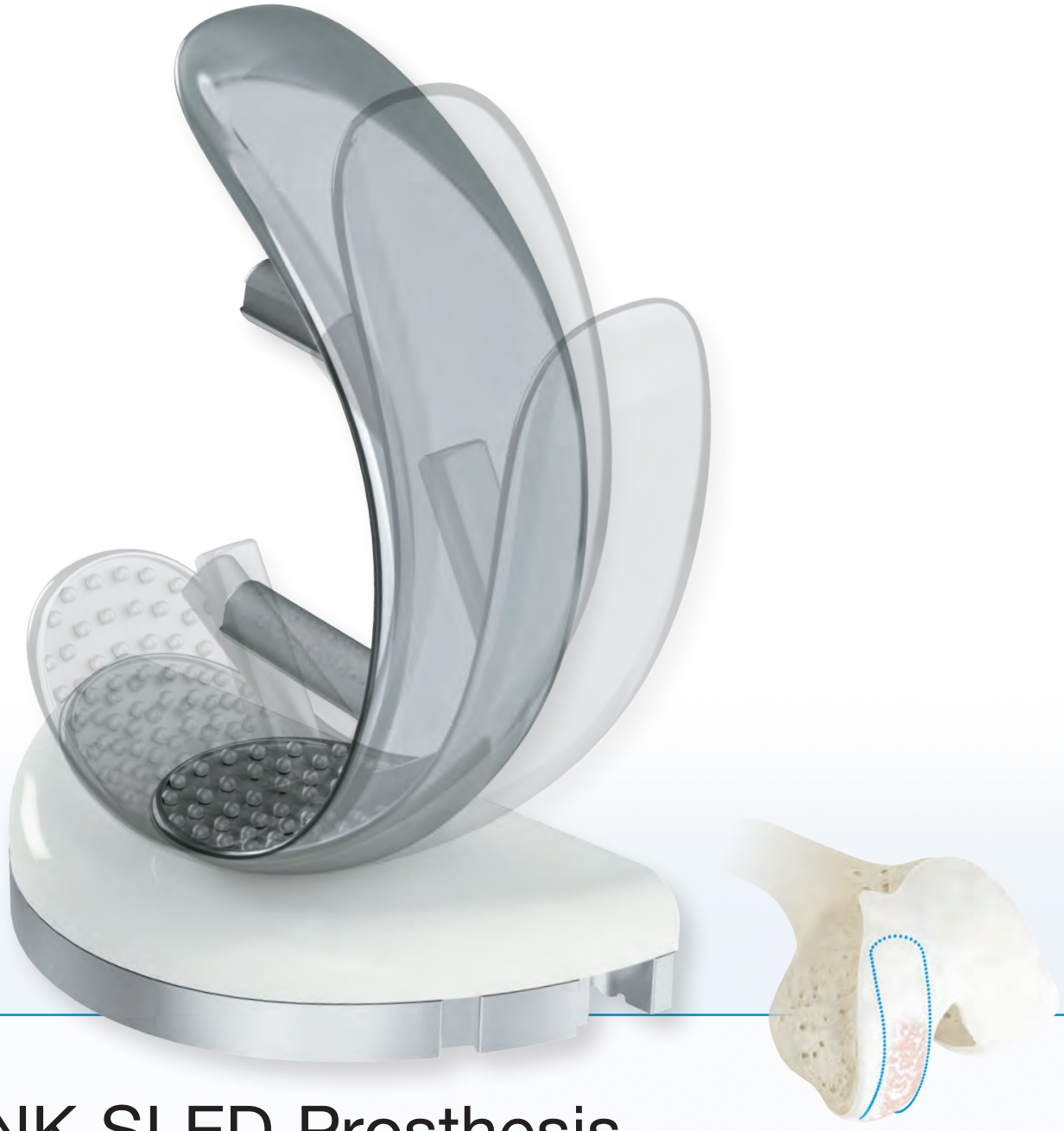


LINK SLED Prosthesis

with MITUS **ART** Instrument Set

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.

LINK SLED Prosthesis
with MITUS **ART** Instrument Set

This surgical technique guide was written in conjunction with:
Mr. Sean O'Leary FRCS (TR & Orth), Department of Trauma and Orthopaedics,
Royal Berkshire NHS Foundation Trust, Reading UK, www.readingkneeunit.co.uk
We would like to thank him for his valuable contribution.

LINK SLED Prosthesis

Femoral Components

The “round-on-flat” articulation allows a large degree of freedom and the joint motion is guided exclusively by the existing soft tissue constraints. Furthermore the design compensates for minor mal-position 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 alignment and shape of the fixation pegs allow for easy positioning of the femoral component. The implant is easy to remove should revision become necessary.

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.

- **Metal-backed Design**
  This design comes in four heights: 8, 9, 11 and 13 mm and three diameters: 45, 50 and 55 mm.

LINK PorEx Technology – Surface Modification

(TiNbN = Titanium Niobium Nitride)

The LINK PorEx Surface Modification leads to a ceramic-like surface, which significantly reduces the release of ions and can improve tolerance in patients who are sensitive to metal[1].

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

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

MITUS ART Instrument Set (Anatomic Reconstruction Technique)

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 **A**natomic **R**econstruction **T**echnique allows for a patient individual femoral preparation. It ensures a pure removal of cartilage thus preserving maximal femoral bone stock.

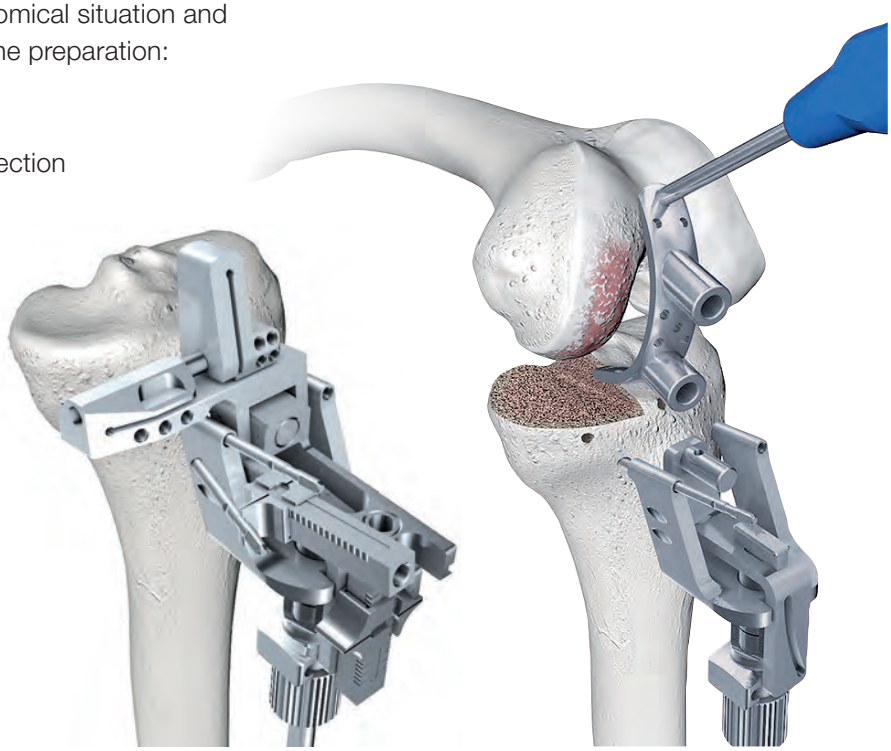
The **MITUS Instrument Set** offers a good number of advantages:

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

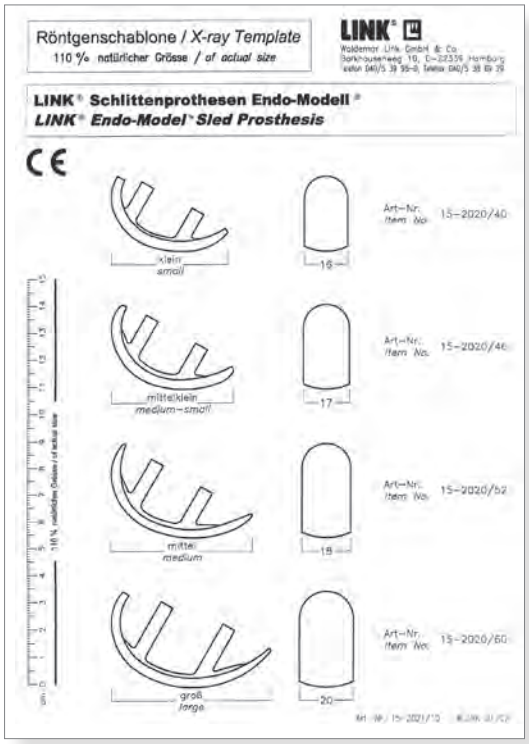
The purpose of the LINK SLED Prosthesis is to restore the damaged joint surfaces which will restore the original mechanical axis. Most patients will present with an underlying ‚constitutional' varus and a slight, undercorrection of alignment can be achieved if desirable to reproduce this.

The **Tibial Saw Guide** is used for resection, ensuring accurate reproduction of the anatomical situation and enabling precise, reproducible bone preparation:

- Setting of the posterior slope
- Adjustment of varus/valgus correction
- Precise adjustment of the resection height



Patient Selection and Surgical Planning



Imaging:
Pre-operative planning is an essential part of the surgery.

The following baseline radiographs are recommended; Weight bearing AP views or Rosenberg PA view taken in slight flexion are essential These may be supplemented by varus/valgus stress views and Rosenberg view to ensure a correctable deformity.True lateral (femoral condyles overlapping) to assess for posterior tibial plateau erosion seen with chronic ACL deficiency Skyline PFJ view.

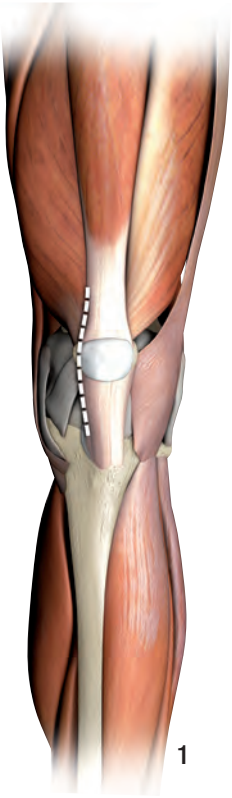
X-ray Templates of the individual components (femur and tibia) which are 110% the actual size are available. A note should be made of the natural tibial slope which will act as a guide during the tibial resection. These views may be supplemented by a long leg X-ray to determine the pre-operative weight 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 ART 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 p erformed 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 for later application of the tibial jig.



1

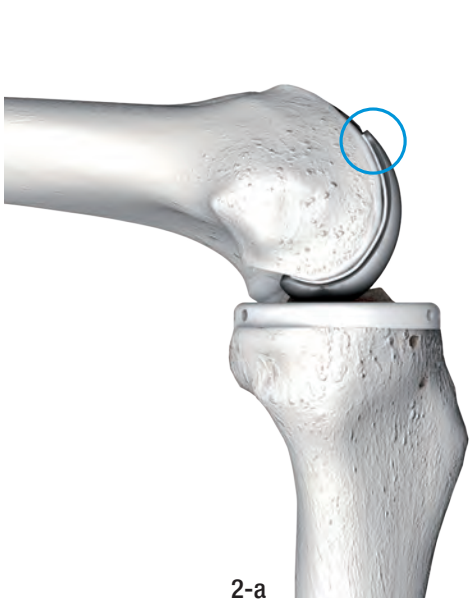
Suggested Approach: Medial UKR

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 (1).

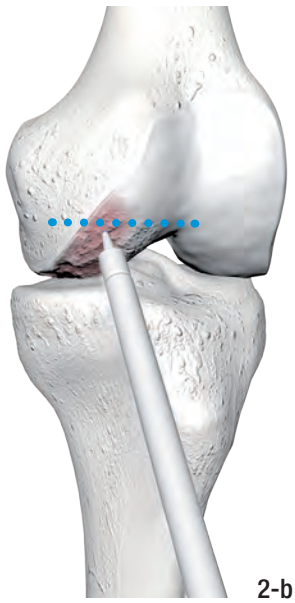
We reccomend partial excision of the fat pad to allow direct visualization of the lateral wall of the medial femoral condyle.

A medial meniscectomy is performed taking care to protect the superficial meniscal attachment to 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 demarcate the future anterior margin of the femoral prosthesis (**2-a**). If the femoral component projects beyond this mark, there is an increased risk of patellar impingement (**2-b**).

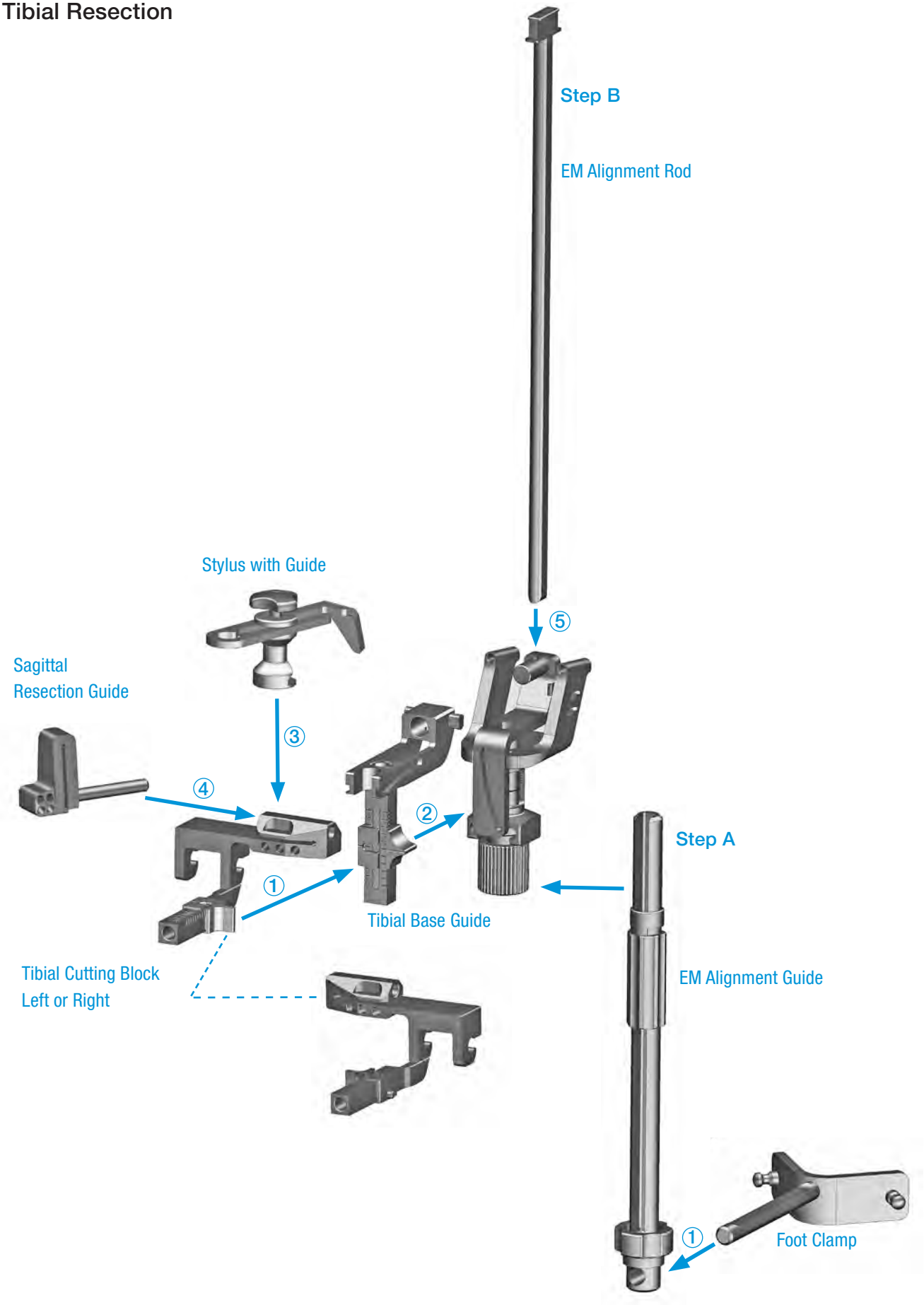


2-a



2-b

Tibial Resection

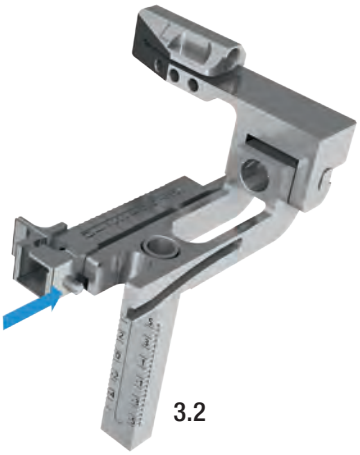


Assembly and Application of the Extramedullary Tibial Guide

(Instrument Sets 35-1000/01)

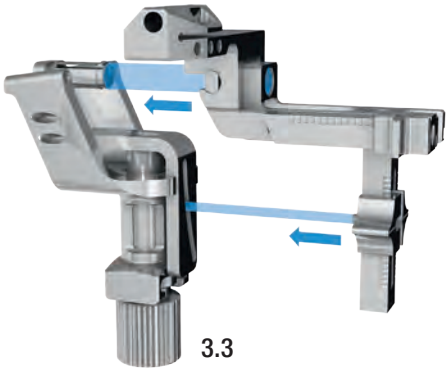
3.1

Slide the Tibial Cutting Block (Left or Right) 90° onto the proximal end of the Tibial Base Guide (**3.1**).



3.2

Insert the Posterior Slope Selector onto the Tibial Cutting Block and position it at “0” (**3.2**).
Be sure that the Selector Pin is inserted into the slot of the Tibial Base Guide.

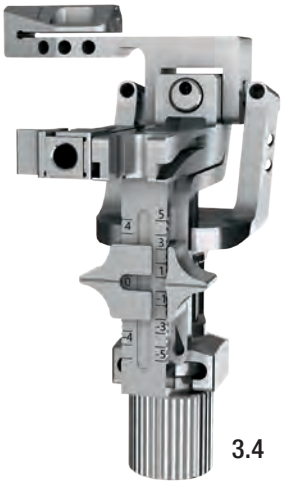


3.3

Slide the Tibial Cutting Block Assembly into the Tibial Base Guide.

Be sure that the big peg of the Tibial Base Guide is aligned with the hole on the proximal end of the Tibial Cutting Block Assembly (**3.3**).

Note:
Set the resection micro adjustment to ‘neutral’.



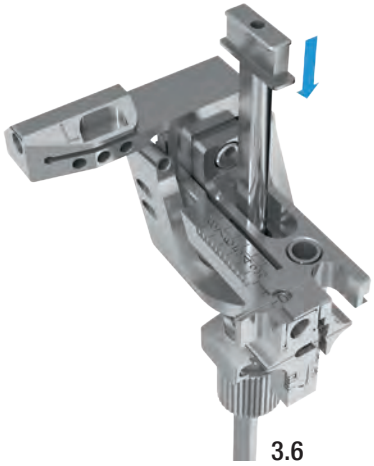
3.4

Tibial Cutting Block Assembly (**3.4**).

Position all Selectors (posterior slope and varus/valgus adjustment) at “0”.

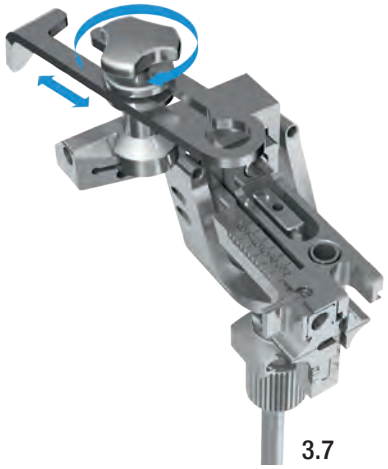
3.5

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 (**3.5**).



3.6

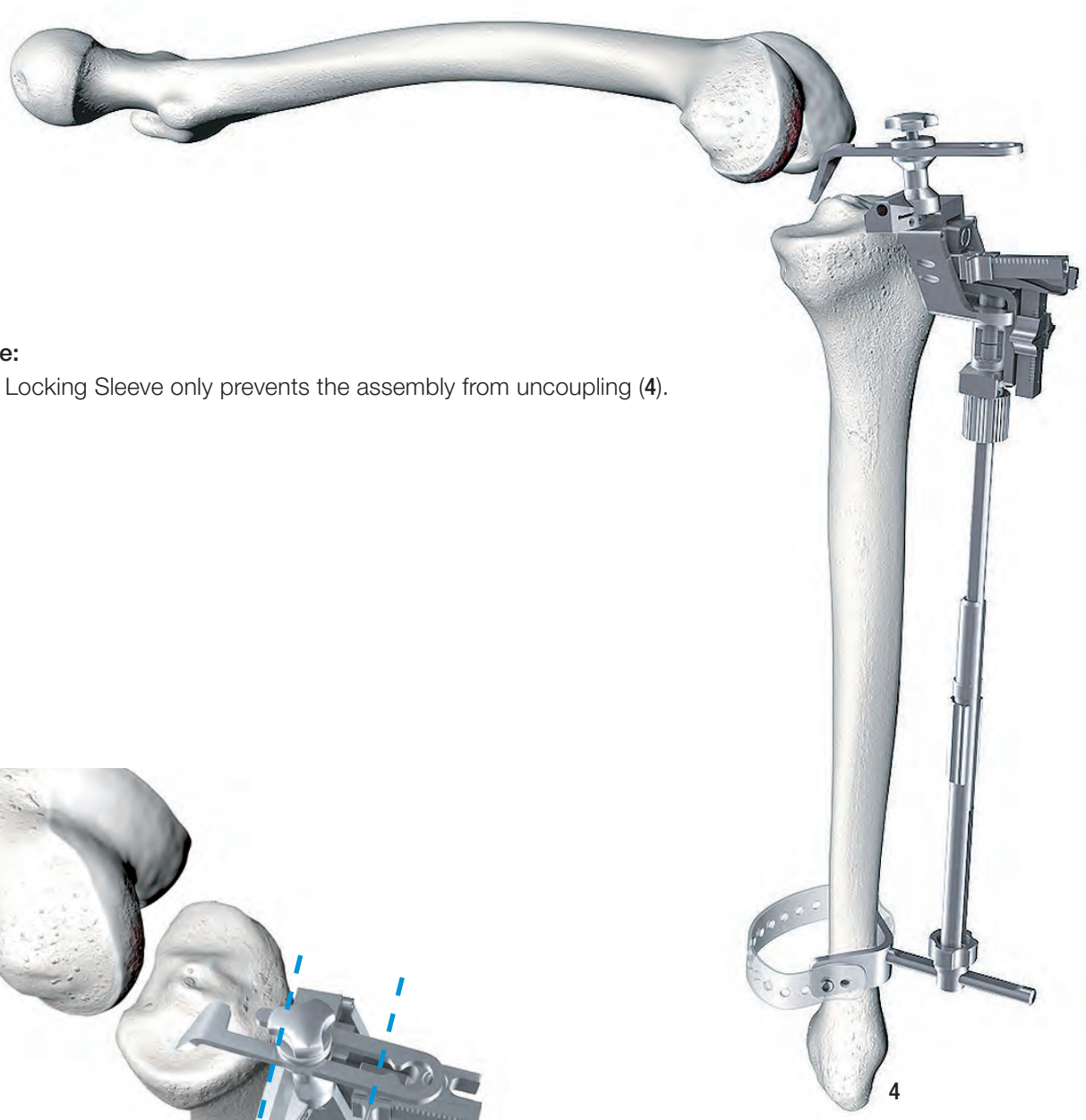
The EM Alignment Rod is pushed through the Tibial Cutting Block Assembly (**3.6**).



3.7

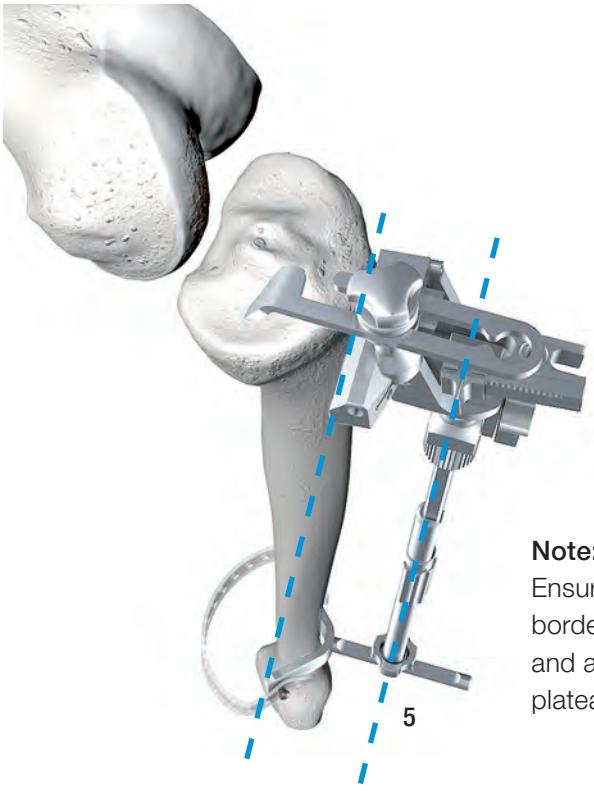
The 5-mm Stylus (optional 7 mm) is inserted in the Guide and positioned on the Tibial Base Frame. We recommend measuring an inital 5 mm initial bony cut from the anterior aspect of the tibial defect. This allows for the use of a 7-mm Component
(5 mm bone + 2 mm cartilage) (**3.7**).

Note:
The Stylus know is locking the Stylus assembly to the Tibial Cutting Block Assembly.



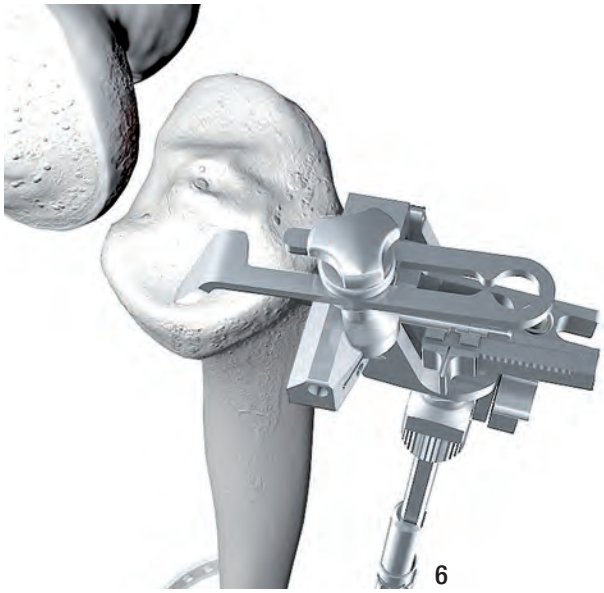
4

Note:
The Locking Sleeve only prevents the assembly from uncoupling (**4**).

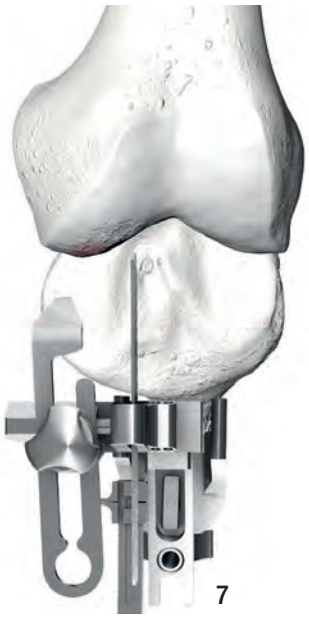


5

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 tibia (mid-point of plateau to mid-point of ankle joint) (**5**).


6

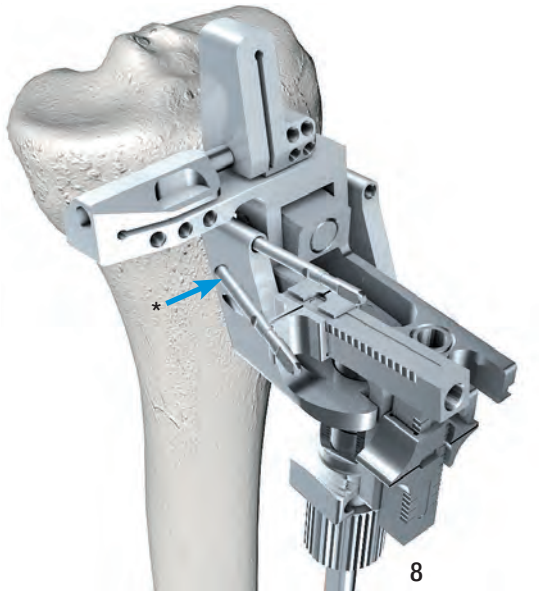
Determine the height of resection. The 5-mm Stylus is used and should reference from the anterior margin/ edge of the chondral defect. A good view must be ensured for this (if necessary open the joint slightly using a lamina spreader) (**6**).


7

Note:
The correct alignment and height of resection can be checked using the Cutting Template through the cutting slots for the saw (**7**).

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 (*).

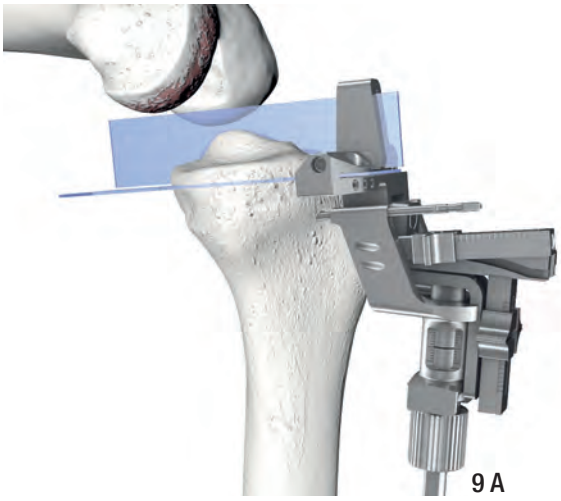
The Guide with Stylus is removed. Fine adjustments can then made for precise tibial resection (**8**).



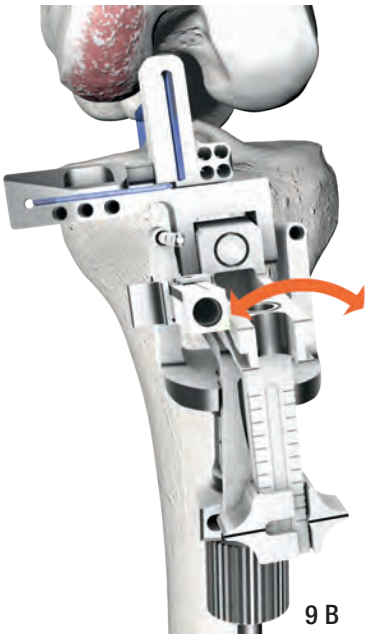
8

Optional: Fine adjustments for the tibial resection

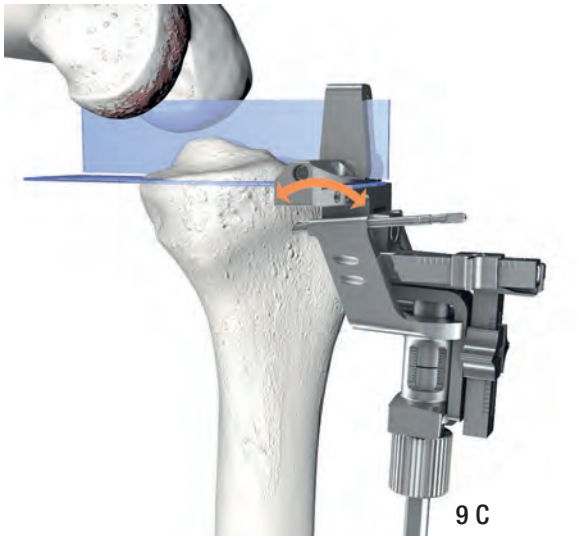
Posterior Slope (A)
The recommendation is to reproduce the pre-operative tibial slope. If an uneven cut is made it can be recut/ adjusted in 1° steps.

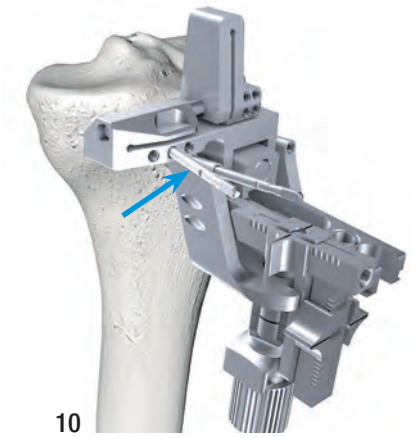

9 A

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

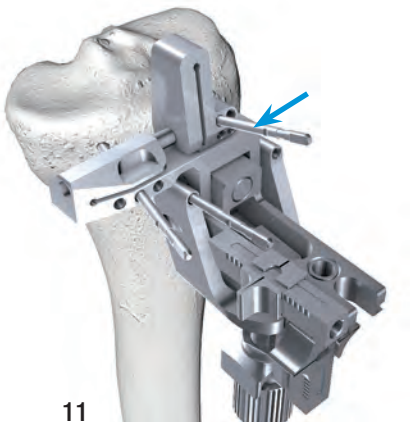

9 B

Tibial Resection Height (C)
Fine-tune of the resection height is possible by acting on the micro adjustment screw.

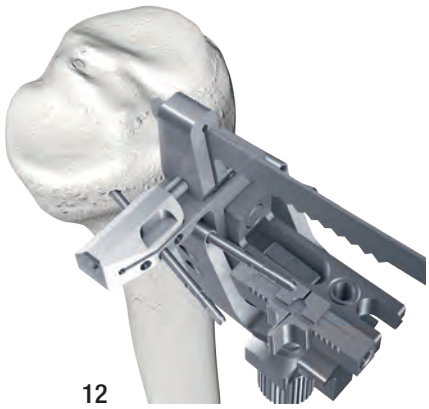

9 C



10

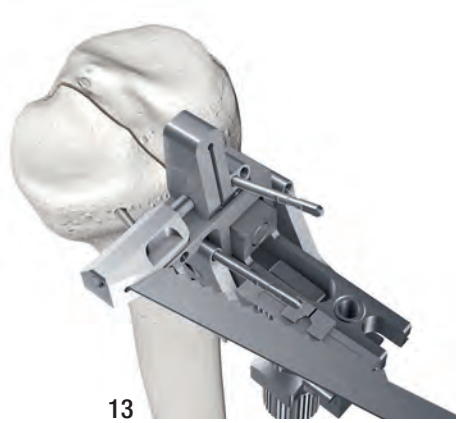


11



12

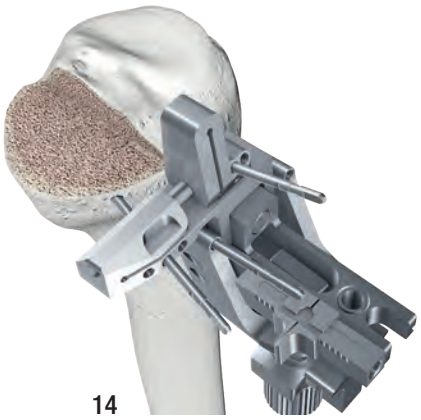
After a final inspection of the proposed tibial resection, the Tibial Cutting Block (**10**) and (if desired) the Sagittal Resection Guide are then fixed with a Drill Pin (**11**). The reciprocating Saw is introduced through the vertical slot and should be in line with the lateral border of the medial femoral condyle (**12**). The cut should be in the AP direction. The sagittal Saw is then introduced through the cutting slot (**13**). Care must be taken to ensure no damage is done to the superficial MCL, which may be protected with a Retractor.



13

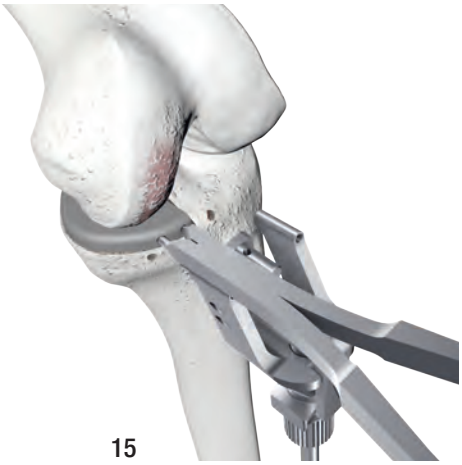
The Drill Pins for the Tibial Cutting Block and the Sagittal Resection Guide are removed and then the Sagittal Resection Guide with the Tibial Cutting Block are removed from the Tibial Base Frame (**14**). If, later on, it becomes evident that the joint space is too small, the Tibial Cutting Block can 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.



14

A 7-mm Trial is provided to insert onto the resected Plateau which allows assessment throughout the range of motion (**15**).



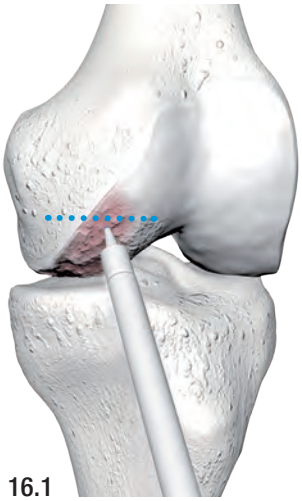
15

Femoral Component Positioning / Alignment

The positioning of a Unicondylar Sled 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.

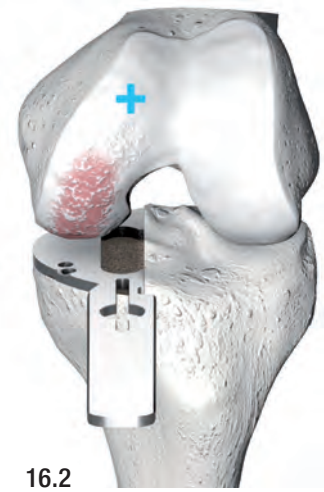
Femoral – Tibial Contact

In an attempt to prevent edge loading of the Tibial Component the femoral prosthesis should be positioned in order to be in contact with the center of the Tibial Plateau. Marks can be made on the femoral condyle during cyclical flexion/extension which correspond to the contact point of the femoral condyle with the centre of the Plateau throughout flexion.



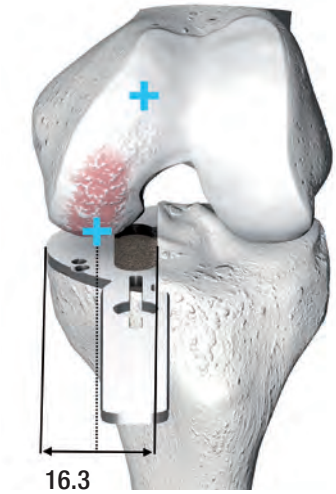
16.1

Step 1
Marking of the anterior margin of the femoral prosthesis with the knee in extension.



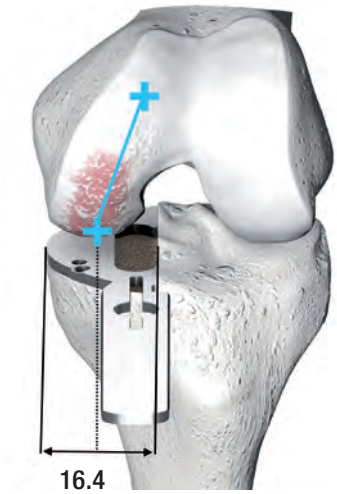
16.2

Step 2
Knee in flexion.



16.3

Step 3
Marking of center of the condyle in flexion.

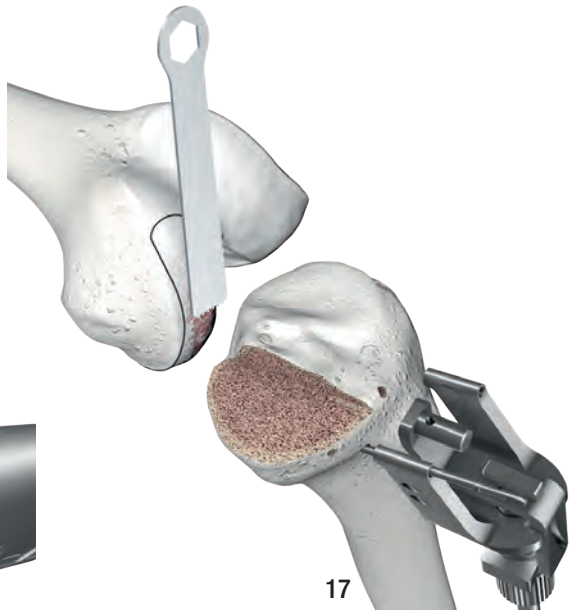


16.4

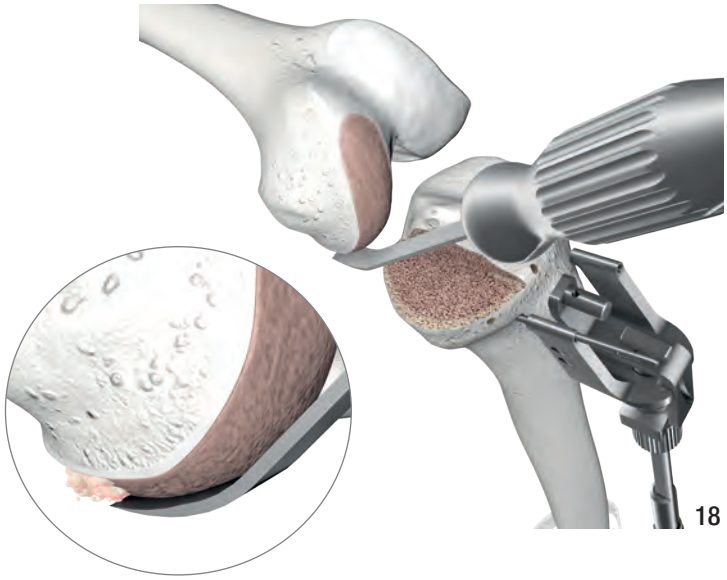
Step 4
Connecting of the two markings. This describes the femoral component alignment.

Femoral Cartilage Removal

Suitable sizing of the Femoral Component required the femoral cartilage to be removed (**17**). Appropriate inst-ru-ments for cartilage removal include the burr, Curette, Sharp Spoon or Sawblade. At this stage remove any posterior osteophytes using a curved Osteotome (**18**).



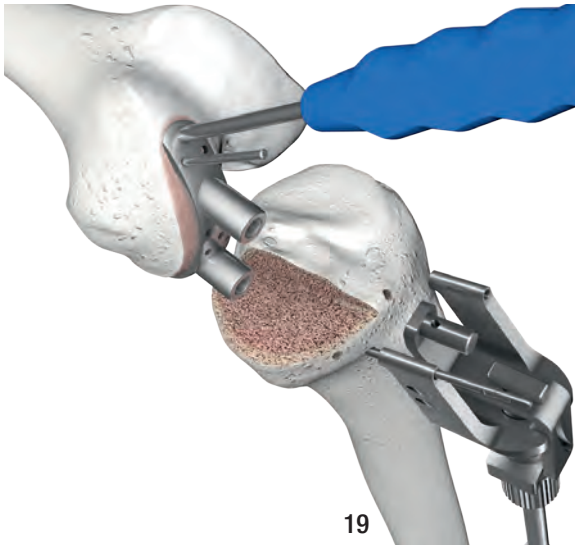
17



18

The Drill Guides match the component geometries and can be used as a surrogate sizing device. The Drill Guide should cover the femoral condyle to allow tibio femoral contact in deep flexion and extend up to but not significantly beyond the anterior mark made during the approach and avoid any possibility of Tibial Component ‘edge loading’. The selected Femoral Drill Guide is fixed with Drill Pins (**19**).

There are four sizes of the Femoral Component available (40, 46, 52 and 60 mm). The appropriate size is selected using a best fit philosophy.

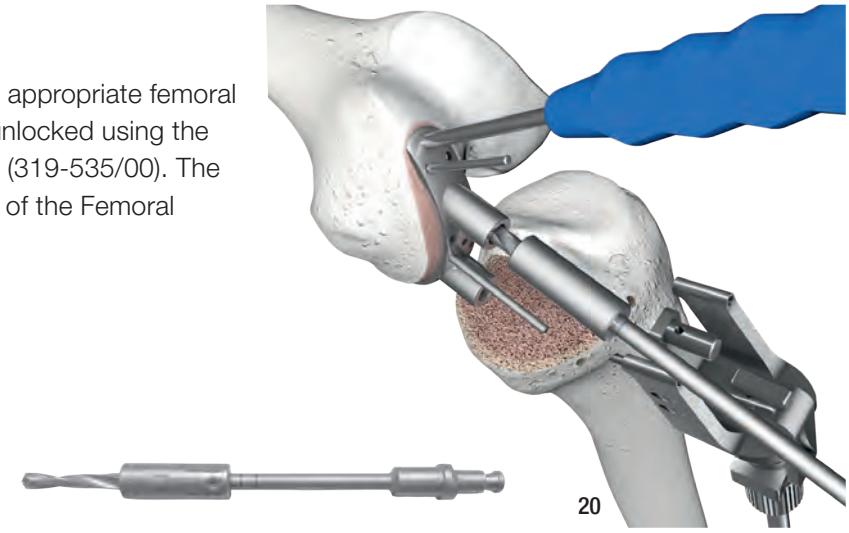


19

Femoral Preparation

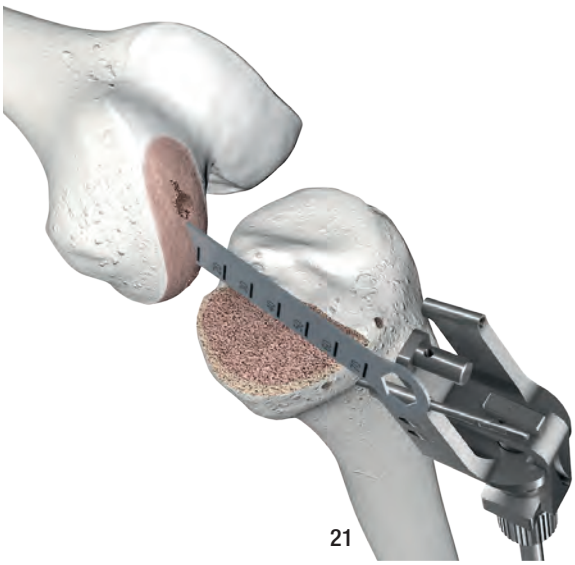
The fixation holes are drilled using the appropriate femoral drill length (**20**).The drill stop is to be unlocked using the corresponding Hex Head Screwdriver (319-535/00). The stop is adjusted according to the size of the Femoral Component:

Femoral Size	
Small	S/MS/M
Medium-small	S/MS/M
Medium	S/MS/M
Large	L



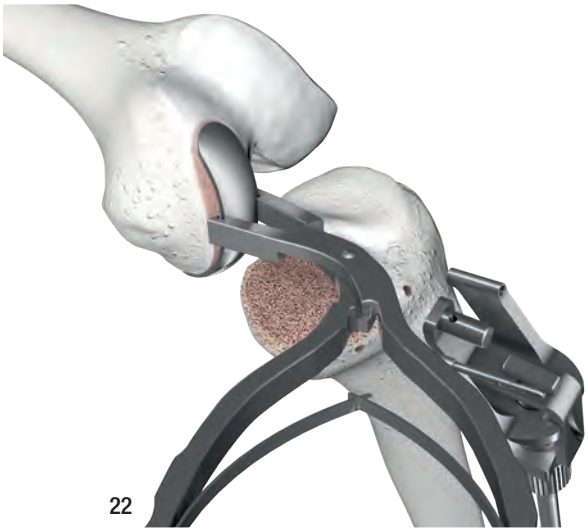
20

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 (**21**).



21

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 (**22**).

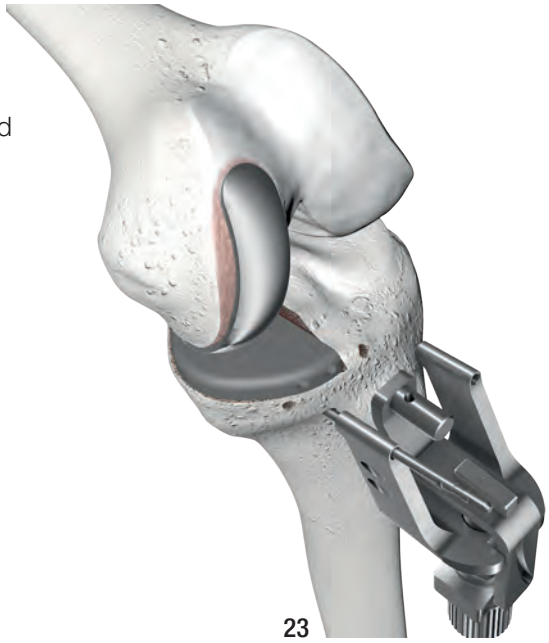


22

Tibial Spacer Blocks are avaiable in the Instrument Set for evaluating the joint space (**23**).

If the joint space is too small, the space can be corrected by re-cutting the tibial surface following re-application of the Tibial Jig over the Guide Pin.

If the result is satisfactory, the Tibial Resection Guide is taken off.



23

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

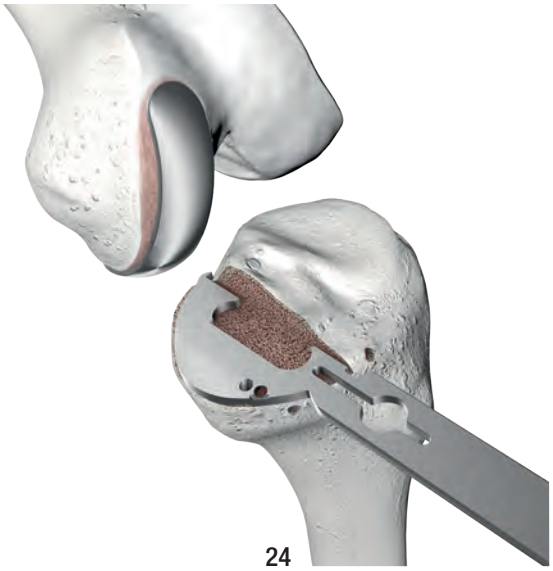
Size (A/P) mm	Width (M/L) mm
45	22
50	27
55	29
58	31

Metal-backed Tibial Components

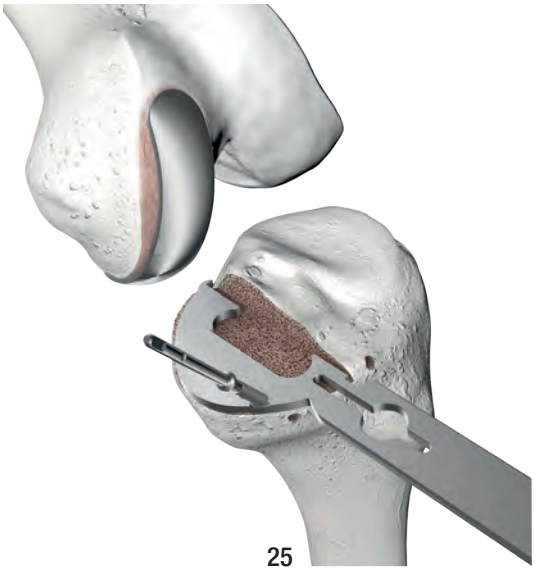
Size (A/P) mm	Width (M/L) mm
45	22.5
50	25.0
55	27.5

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 (**24**). The Tibial Template is secured using a **Pin with stop** (Drill Pin with stop 319-566/00 or alternatively Thread Pin with stop 319-560/01) (**25**).

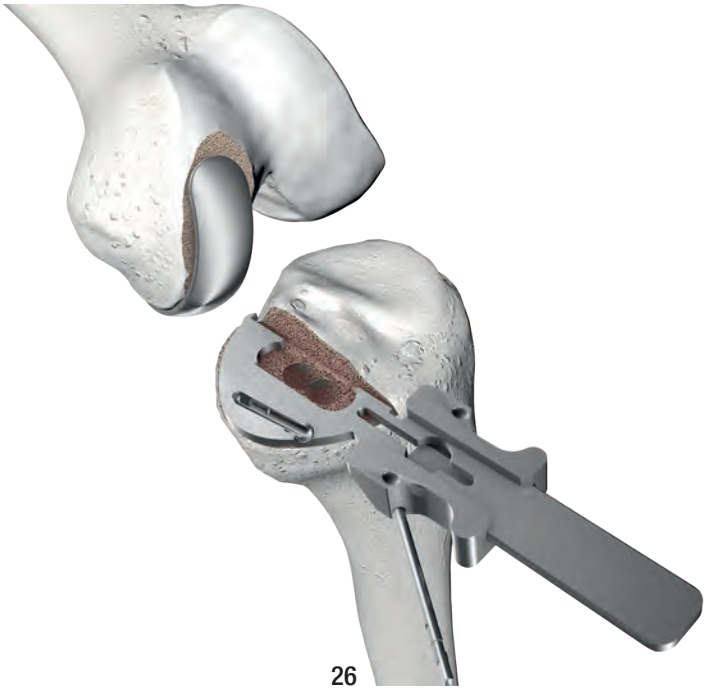


24



25

Optional: In case of insufficient stability or poor bone quality, the Tibial Template can be additionally secured by the Mill Fixation Adapter and further Drill Pins (**26**).

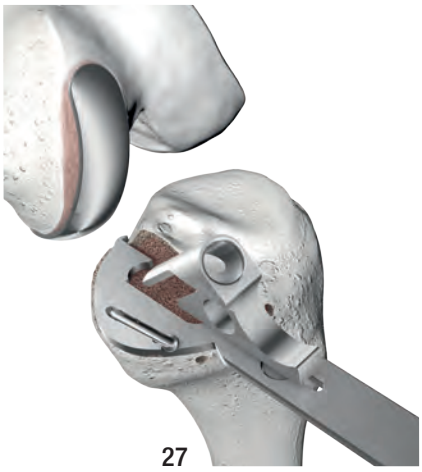


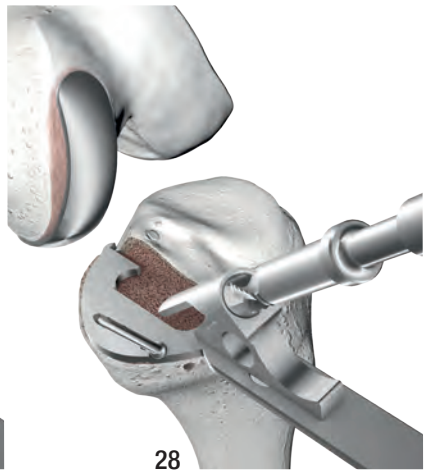
26

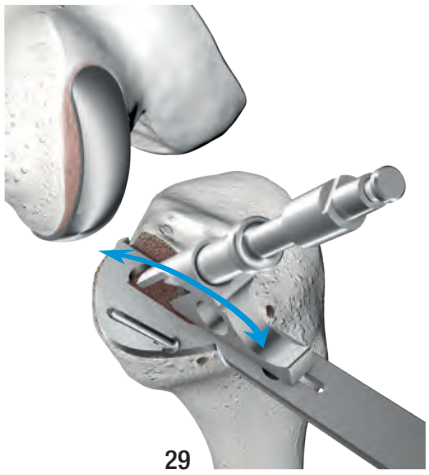
There are two options for preparing the keel.

1. Milling System
The tibial mill limits the depth and AP excursion of the mill and is selected according to the component size.

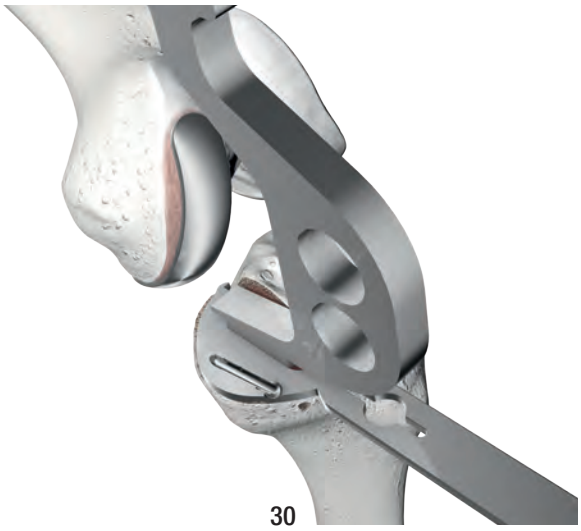
- The **Tibial Mill Guide** is placed in the Tibial Template in anterior position (**27**).
- The **Tibial Cutter** is inserted and put into operation, milling is then performed up to the stop and the Tibial Cutter is subsequently removed (**28**).
- The **Tibial Mill Guide** is pushed toward posterior 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 (**29**).


27


28


29

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 (**30**).

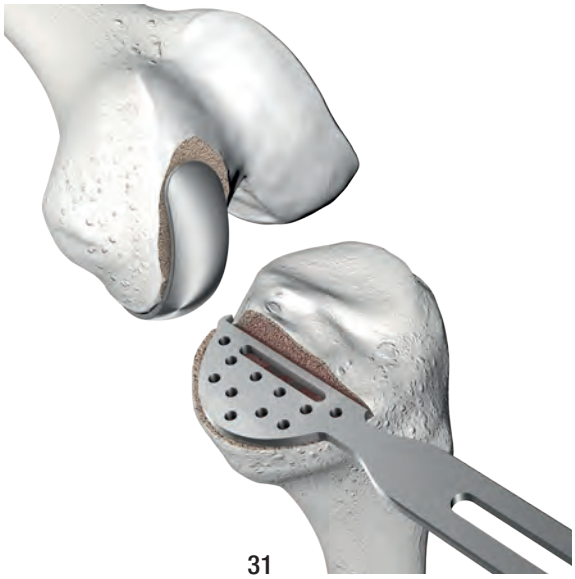

30

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.

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. The Bone Compressor can then be inserted.

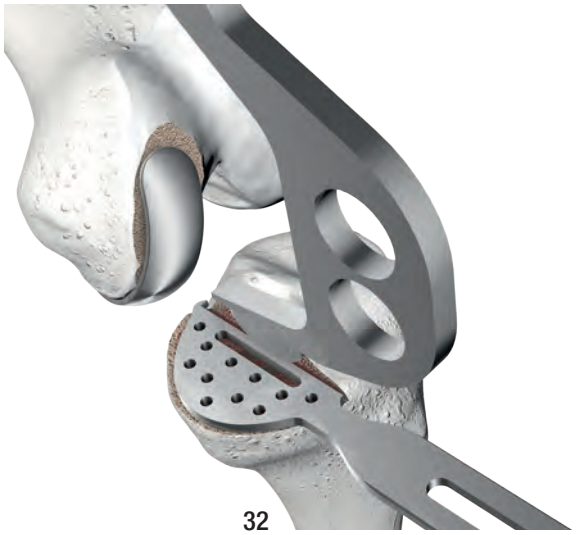
Tibial Preparation: Metal-backed Component

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 (**31**).



31

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 (**32**).

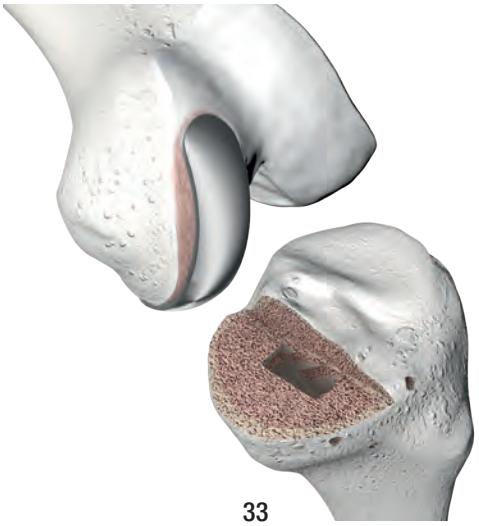


32

Trial Reduction

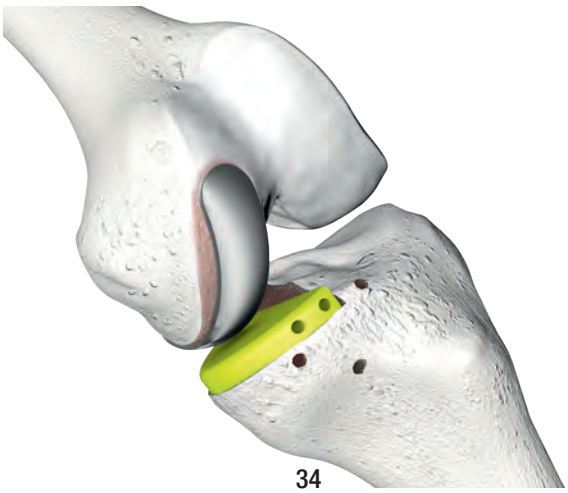
The Tibial Trial Prosthesis (with keel) is selected – All-poly (yellow) or Metal-backed (red). As a rule, the smallest Trial Component is used. For this, the knee joint should be flexed at least 90° (**33**).

Note:
The Tibial Trial Prosthesis is easier to put into place with slight valgus loading.



33

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 (**34**).



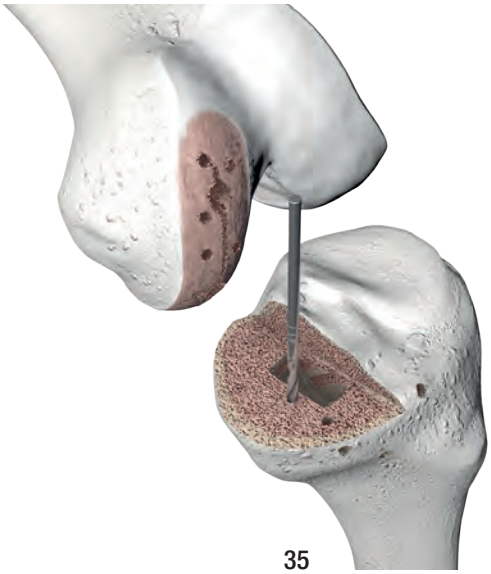
34

Implantation and Cementation

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 (**35**) 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.



35

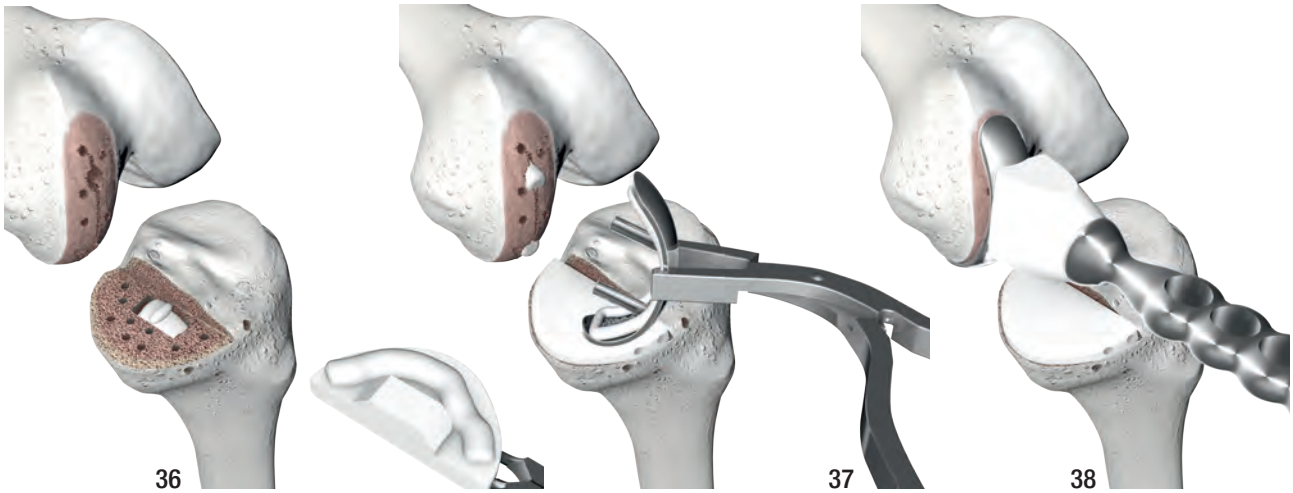
Tibial Component

The Bone Cement is applied to the prepared bony surface and the underside of the implant. The Tibial Component is inserted posteriorly initially, then pushed downward and finally pushed in anteriorly (**36**).

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

Femoral Component

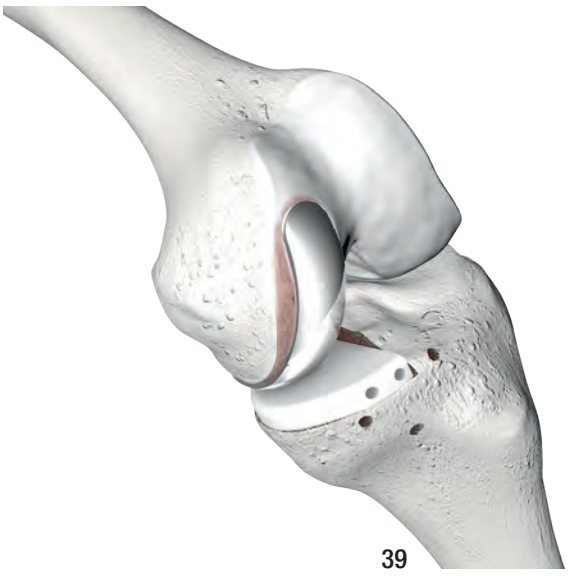
The Bone Cement is applied to the back of the Femoral Component. In addition, both drill holes for the fixation pegs are filled with Bone Cement. The Femoral Component is positioned using Inserting Forceps and both pegs are to be inserted into the prepared drill holes (**37**). The Femoral Component is then finally driven on using the Femoral Impactor (**38**).



36 37 38

Final Reduction

The leg is held in extension for the remainder of the cement curing process (**39**).



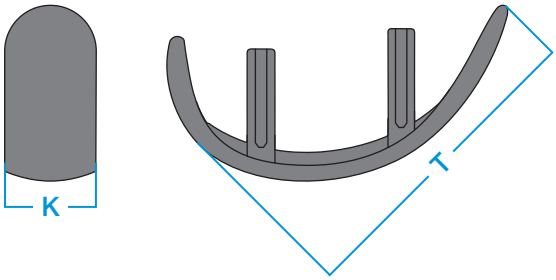
39

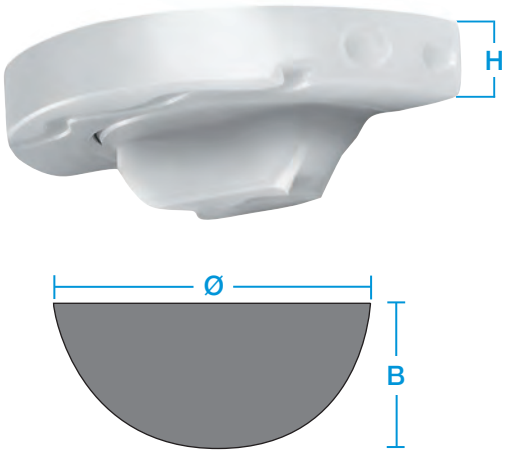
Femoral Components

MAT CoCrMo or CoCrMo/LINK PorEx *

REF MAT CoCrMo	REF MAT CoCrMo/ LINK PorEx*	Size	Width (K) mm	Length (T) mm
15-2020/40	15-2220/40	small	16	40
15-2020/46	15-2220/46	medium small	17	46
15-2020/52	15-2220/52	medium	18	52
15-2020/60	15-2220/60	large	20	60

* LINK PorEx: TiNbN = Titanium Niobium Nitride; hypoallergenic coating (gold colour).





Tibial Plateaus – All-polyethylene

MAT UHMWPE

REF MAT UHMWPE	Height (H) mm	Ø mm	Width mm
15-2028/01	7	45	22
15-2028/02	9	45	22
15-2028/03	11	45	22
15-2028/04	13	45	22
15-2028/05	7	50	27
15-2028/06	9	50	27
15-2028/07	11	50	27
15-2028/08	13	50	27
15-2028/09	7	55	29
15-2028/10	9	55	29
15-2028/11	11	55	29
15-2028/12	13	55	29
15-2028/13	7	58	31
15-2028/14	9	58	31
15-2028/15	11	58	31
15-2028/16	13	58	31

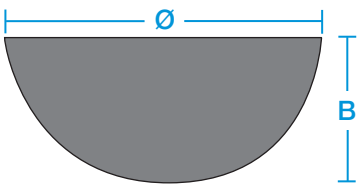
Important information:
Tibial Components of 7-mm hight offer the advantage of particular bone preservation and allow for a good range of motion. The suitability of these particular components have to be medically indicated. The Tibial Components of 7-mm hight are not suitable for obese or very active patients.

Tibial Plateaus – metal-backed

MAT CoCrMo or CoCrMo/LINK PorEx *, UHMWPE

REF MAT CoCrMo	REF MAT CoCrMo/ LINK PorEx*	Height (H) mm	Ø mm	Width (B) mm
15-2030/13	15-2230/13	8	45	22.5
15-2030/02	15-2230/02	9	45	22.5
15-2030/03	15-2230/03	11	45	22.5
15-2030/04	15-2230/04	13	45	22.5
15-2030/14	15-2230/14	8	50	25.0
15-2030/06	15-2230/06	9	50	25.0
15-2030/07	15-2230/07	11	50	25.0
15-2030/08	15-2230/08	13	50	25.0
15-2030/15	15-2230/15	8	55	27.5
15-2030/10	15-2230/10	9	55	27.5
15-2030/11	15-2230/11	11	55	27.5
15-2030/12	15-2230/12	13	55	27.5

* LINK PorEx: TiNbN = Titanium Niobium Nitride; hypoallergenic coating (gold colour).



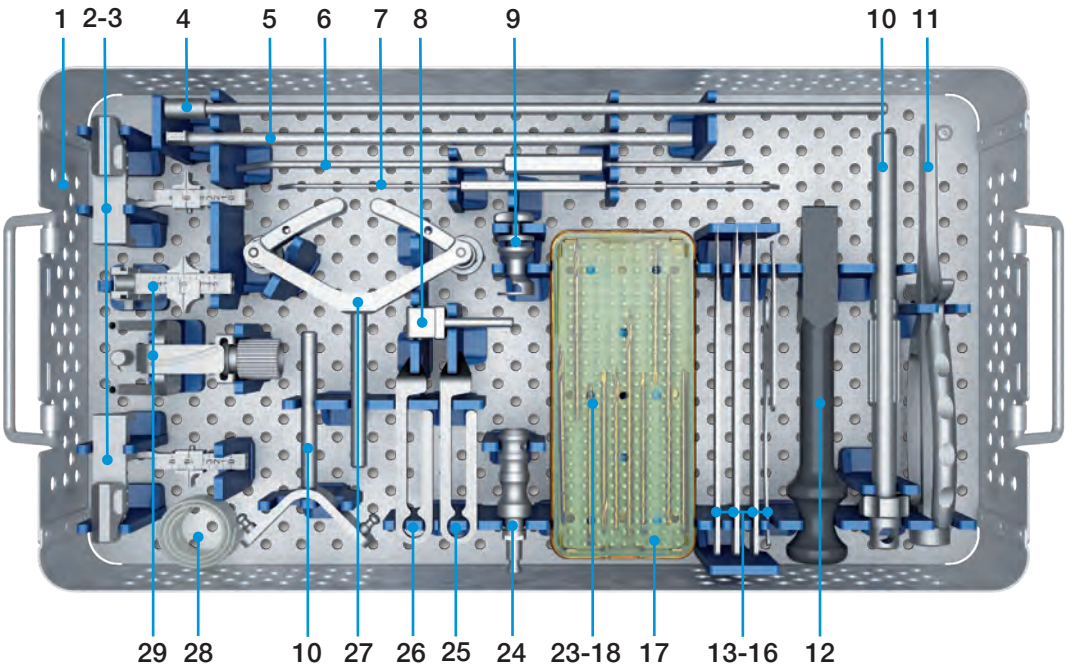
MITUS ART Instrument Set (Anatomic Reconstruction Technique)

Greater Safety and Higher Precision

- Instrument Set for optimal alignment and soft tissue adjustment with reproducible results
- The Instruments are arranged on the Trays in the correct surgical sequence
- All the Instruments can be dismantled without tools and are quick and easy to reassemble

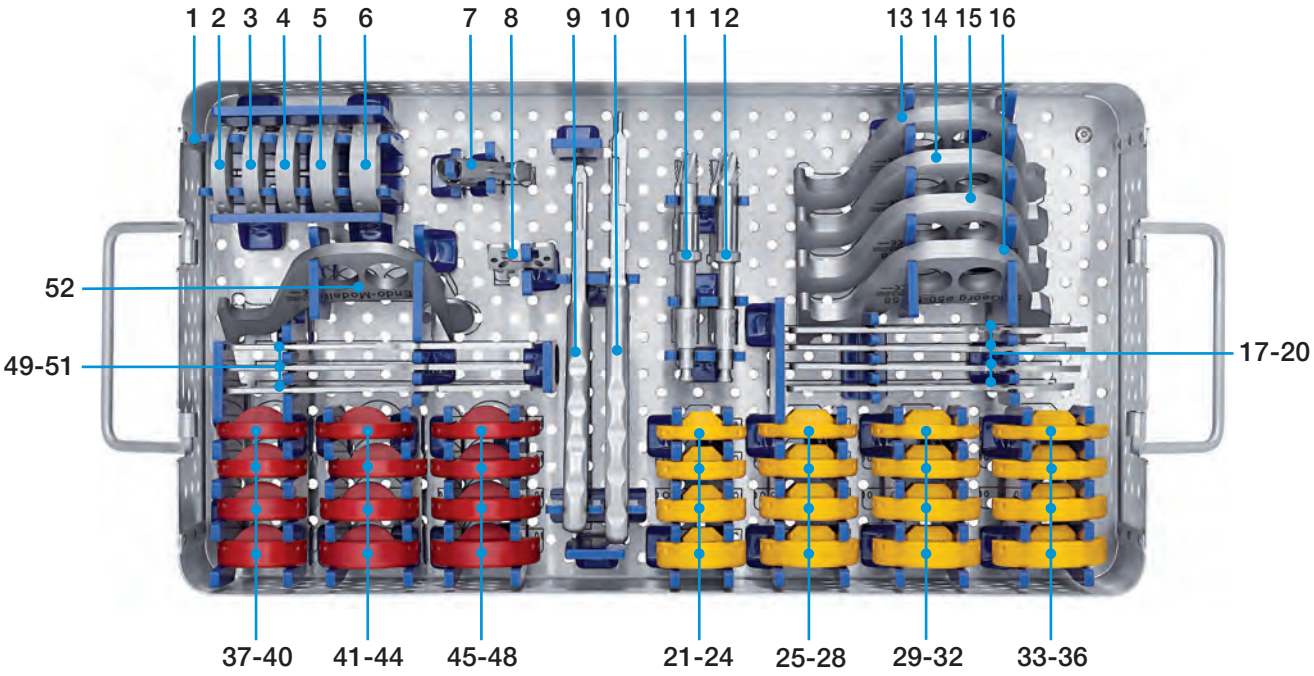
REF	MITUS ART Instrument Set
35-1000/01	Case – Tibia Resection
35-1100/00	Case – Tibia Preparation
35-2100/00	Case – Femur Preparation

35-1000/01 Case – Tibia Resection



1	35-0100/01	**Instruments Tray – Tibia Resection,** empty, 485 x 253 x 80 mm
2	35-1002/00	**Tibial Saw Guide,** asymmetrical, right
3	35-1001/00	**Tibial Saw Guide,** asymmetrical, left
4	319-520/01	**Alignment Rod,** extramedullary
5	319-110/01	**EM Alignment Rod,** for tibia alignment
6	15-2201/70	**Curette** to remove excess cement
7	15-2201/71	**Spatula,** double end, to remove excess cement
8	35-1003/00	**Tibial Sagittal Resection Guide**
9	35-1004/00	**Guide** for stylus
10	319-160/00	**Foot Clamp,** EM tibial alignment (2 parts)
11	317-586	**Inserter/Extraction Forceps,** for fixation pins Ø 3 mm
12	35-1017/00	**Tibial Impactor**
13	317-802/53	**Cutting Template**
14	15-2102/03	**Lambotte Osteotome,** width 15 mm
15	15-2201/17	**Lambotte Osteotome,** width 11 mm
16	15-2201/16	**Lambotte Osteotome,** width 9 mm
17	319-602/30	**Sterilizing Box** with base, silicon mat and top consisting of:
18	319-560/01	**Thread Pin,** Ø 3.5 mm, 70 mm (2 pieces)
19	319-566/00	**Drill Pin** with stop, Ø 3.0/3.5 mm, 85 mm (2 pieces)
20	319-581/00	**Drill Pin,** Ø 3 mm, 80 mm (3 pieces)
21	319-582/00	**Drill Pin,** Ø 3 mm, 110 mm (2 pieces)
22	35-1020/08	**Self-tapping Fixation Pin,** Ø 3 mm, 80 mm (3 pieces)
23	35-1021/00	**Locking Socket,** for tibia alignment rod (1 piece)
24	16-3287/00B	**Adapter,** LINK power tool snap lock adapter
25	35-1005/00	**Stylus,** height 5 mm
26	35-1007/00	**Stylus,** height 7 mm
27	319-183/00	**Flexible Belt,** spring fixation
28	317-538/01	**Plastic Connector,** 495 mm
29	319-140/01	**Tibial Base Guide** (2 parts)

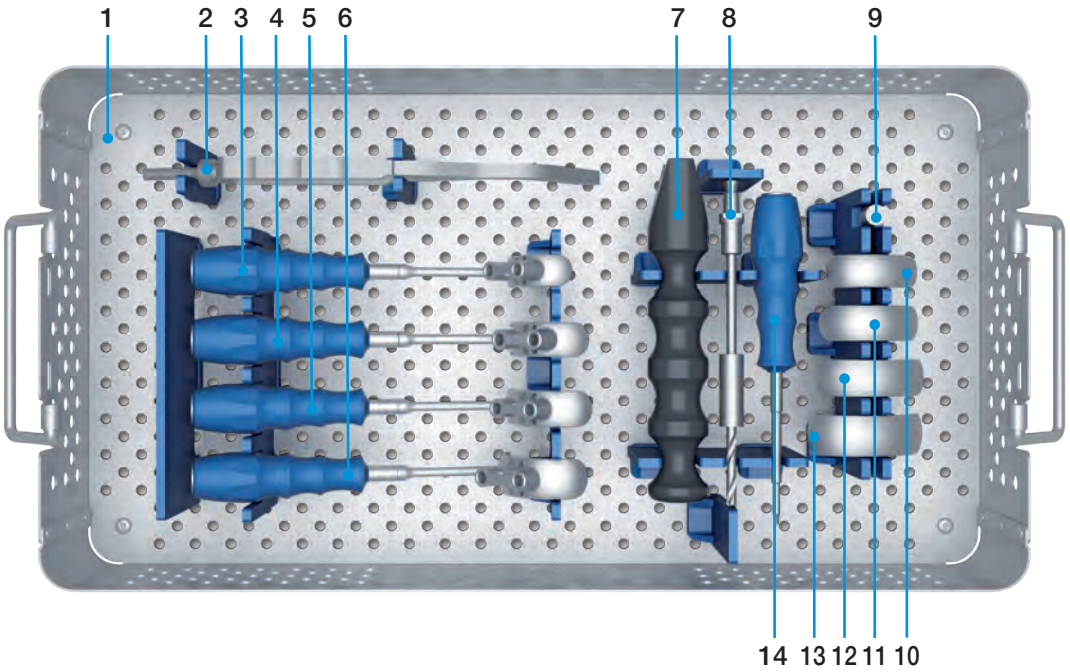
35-1100/00 Case – Tibia Preparation



1	35-0110/00	**Instruments Tray – Tibia Preparation,** empty, 485 x 253 x 80 mm
		Tibial Trial Plates, Ø 45 mm
2	35-1012/07	Height 7 mm
3	35-1012/08	Height 8 mm
4	35-1012/09	Height 9 mm
5	35-1012/11	Height 11 mm
6	35-1012/13	Height 13 mm
7	35-1010/00	**Tibia Milling Guide**
8	35-1011/00	**Milling Fixation Block**
9	15-2040/09	**Plateau Holding and Inserting Forceps,** for tibial plateaus (metal-backed)
10	15-2042	**Inserting Forceps,** for tibial trial prosthesis (all-poly) and tibial plateaus (all-poly)
11	35-1008/00	**Tibial Cutter,** small, for tibial plateaus (all-poly) Ø 45 mm
12	35-1009/00	**Tibial Cutter,** large, for tibial plateaus (all-poly) Ø 50, 55, 58 mm
13	35-1013/00	**Keel Chisel,** for tibial plateaus (all-poly), Ø 45 mm
14	35-1015/00	**Bone Compressor,** for tibial plateaus (all-poly), Ø 45 mm
15	35-1014/00	**Keel Chisel,** for tibial plateaus (all-poly), Ø 50, 55, 58 mm
16	35-1016/00	**Bone Compressor,** for tibial plateaus (all-poly), Ø 50, 55, 58 mm
		Tibial Templates for tibial plateaus (all-poly)
17	35-1158/00	Ø 58 mm
18	35-1155/00	Ø 55 mm
19	35-1150/00	Ø 50 mm
20	35-1145/00	Ø 45 mm

		Tibial Trial Prostheses, for tibial plateaus (all-poly)
21	35-1145/07	Ø 45 mm, Height 7 mm
22	35-1145/09	Ø 45 mm, Height 9 mm
23	35-1145/11	Ø 45 mm, Height 11 mm
24	35-1145/13	Ø 45 mm, Height 13 mm
25	35-1150/07	Ø 50 mm, Height 7 mm
26	35-1150/09	Ø 50 mm, Height 9 mm
27	35-1150/11	Ø 50 mm, Height 11 mm
28	35-1150/13	Ø 50 mm, Height 13 mm
29	35-1155/07	Ø 55 mm, Height 7 mm
30	35-1155/09	Ø 55 mm, Height 9 mm
31	35-1155/11	Ø 55 mm, Height 11 mm
32	35-1155/13	Ø 55 mm, Height 13 mm
33	35-1158/07	Ø 58 mm, Height 7 mm
34	35-1158/09	Ø 58 mm, Height 9 mm
35	35-1158/11	Ø 58 mm, Height 11 mm
36	35-1158/13	Ø 58 mm, Height 13 mm
		Tibial Trial Prostheses, for tibial plateaus (metal-backed)
37	35-1045/08	Ø 45 mm, Height 8 mm
38	35-1045/09	Ø 45 mm, Height 9 mm
39	35-1045/11	Ø 45 mm, Height 11 mm
40	35-1045/13	Ø 45 mm, Height 13 mm
41	35-1050/08	Ø 50 mm, Height 8 mm
42	35-1050/09	Ø 50 mm, Height 9 mm
43	35-1050/11	Ø 50 mm, Height 11 mm
44	35-1050/13	Ø 50 mm, Height 13 mm
45	35-1055/08	Ø 55 mm, Height 8 mm
46	35-1055/09	Ø 55 mm, Height 9 mm
47	35-1055/11	Ø 55 mm, Height 11 mm
48	35-1055/13	Ø 55 mm, Height 13 mm
		Tibial Templates, for tibial plateaus (metal-backed)
49	35-1055/00	Ø 55 mm
50	35-1050/00	Ø 50 mm
51	35-1045/00	Ø 45 mm
52	35-1012/00	**Keel Chisel,** for tibial plateaus (metal-backed)

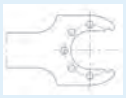
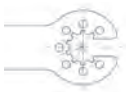
35-2100/00 Case – Femur Preparation



1	35-0201/00	**Instruments Tray – Femur Preparation,** empty, 485 x 253 x 80 mm
2	15-2201/10	**Inserting Forceps,** for trial sled prostheses
		Drill Guides
3	15-2040/40	small
4	15-2040/46	medium-small
5	15-2040/52	medium
6	15-2040/60	large
7	35-2002/00	**Femoral Impactor**
8	15-2040/03B	**Twist Drill** with stop, Ø 5.5 mm, 160 mm, with B Hudson fitting
9	15-2201/53	**Fixation Pin** for stabilization of drill guide
		Trial Sled Prostheses
10	35-2340/00	small
11	35-2346/00	medium-small
12	35-2352/00	medium
13	35-2360/00	large
14	319-535/00	**Screwdriver,** hex 2.5 mm

Additional Instruments

Sawblades,
without offset teeth, 1.24 mm thick

Width (**A**) 25 mm	Width (**A**) 13 mm	Fitting	
317-654/10	317-656/10	Synthes	
317-654/11	317-656/11	Aesculap Combi	
317-654/13	317-656/13	Zimmer/Hall Combi	
317-654/14	317-656/14	Stryker System 4	

15-2040/08
Set of Trial Plateaus on storage tray,
Ø 45, 50, 55 mm, heights: 7, 9, 11, 13 mm (12 ea.)

15-2048/04
Storage Tray, separate
for all-polyethylene trial tibial plateaus, Ø 58 mm

15-2048/05
Storage Tray, separate
for trial tibial plateaus height 8 mm

15-2201/11
Retractor

Important Information for X-ray Investigations

X-ray investigations
X-ray images can be used to evaluate implant positioning post-operatively.
Images taken from certain angles can create the impression that the implant has broken.

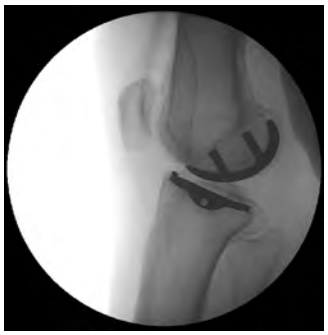


Fig. 1: Post-operative X-ray 1

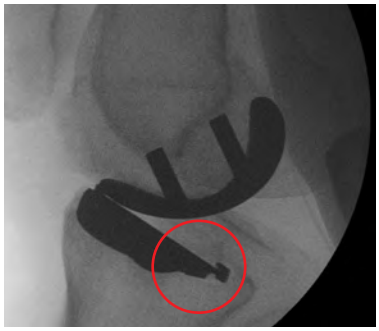


Fig. 2: Post-operative X-ray 2

Note
The LINK Tibial Plateau metal-backed is delivered as one piece, i.e. the Polyethylene Component and the Metal Component are pre-assembled as a single unit. The manufacturing process of the components has never been changed. For secure connection the polyethylene engages with a mechanical coupling device.

These technical specifications can lead X-ray images taken from certain angles to appear distorted, which may give the impression that the Tibial Plateau is broken. Examples of such distorted images are shown below:

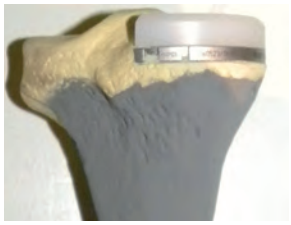


Fig. 3a: Photograph of externally rotated tibia

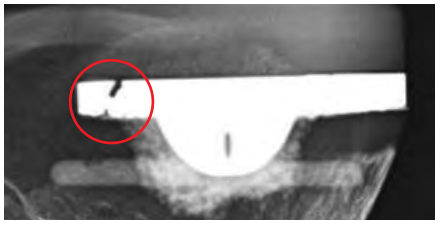


Fig. 3b: X-ray image of figure 3a

As a broken Tibial Plateau is most unlikely, the diagnosis should be verified with additional X-ray images.
Verification: Rotation of the tibia ensuring strictly lateral alignment for the follow-up X-ray.

Fig. 4a: Photograph of tibia from a strictly lateral position

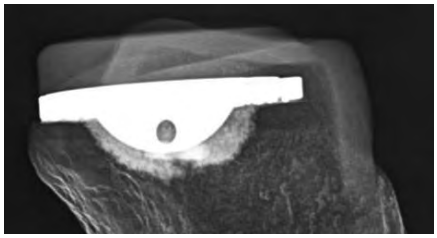
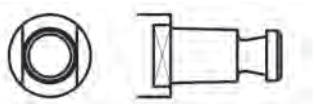


Fig. 4b: X-ray image of figure 4a

Adapter for Power Tool Chuck
Different adapters are available to ensure compatibility to allow various connections:

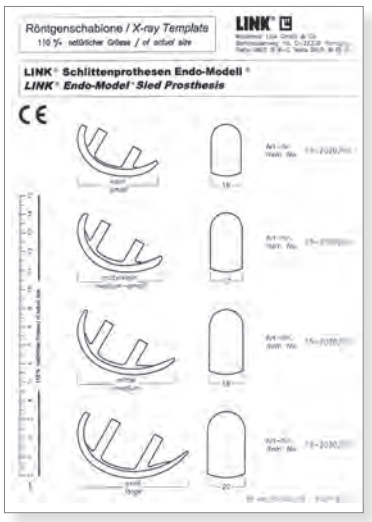
Item no.	Attachment	
16-3283/01	Jakobs-Fitting (E)	
16-3284/00	AO-Fitting (D)	
16-3285/00	Harris-Fitting (C)	

Hudson-Fitting
Standard tool connection.



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

REF	Application
15-2021/10	for Unicondylar Sled Prosthesis 15-2020/40 to 15-2020/60
15-2021/14	for Tibial Plateaus, metal-backed 15-2030/02 to 15-2030/13 and 15-2230/02 to 15-2230/13
15-2021/13	for Tibial Plateaus, all-polyethylene 15-2028/01 to 15-2028/16



Further Information

LINK PorEx Technology
(TiNbN = Titanium-Niob-Nitride) Surface Modification for metal sensitive patients

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

Specified indications and contraindications:	LINK Sled	LINK Sled with PorEx*
General Indications:		
Severe unicompartmental disease with limitation of mobility due to degenerative or post-traumatic arthrosis/arthritis.	X	X
Unicompartmental arthrosis in a stable knee (intact ligaments including anterior and posterior cruciate ligaments) with a correctable varus / valgus deformity (<10°).	X	X
Contraindications (absolute):		
Acute / chronic infections, local or systemic – insofar as they compromise the successful implantation of a unicondylar Sled prosthesis.	X	X
Any neuro-muscular disease affecting the limb which would put an arthroplasty 'at risk'.	X	X
Insufficient / inadequate bone stock preventing stable fixation of either prosthesis.	X	X
Unstable knee (Insufficient crucial and/or collateral ligaments).	X	X
Non-compliant patient.	X	X
Contraindications (relative):		
Hypersensitivity to (implant) materials (LINK PorEx indication).	X	–

* LINK PorEx: TiNbN = Titanium Niobium Nitride; hypoallergenic coating (gold colour).

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!

Waldemar Link GmbH & Co. KG, Hamburg

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