BPK-S INTEGRATION

BREHM PRECISION KNEE SYSTEM

SURGICAL TECHNIQUE

PETER BREHM
Die Präzision in Titan
für den Menschen

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PRODUCT DESCRIPTION

BPK-S INTEGRATION

A single system for every indication

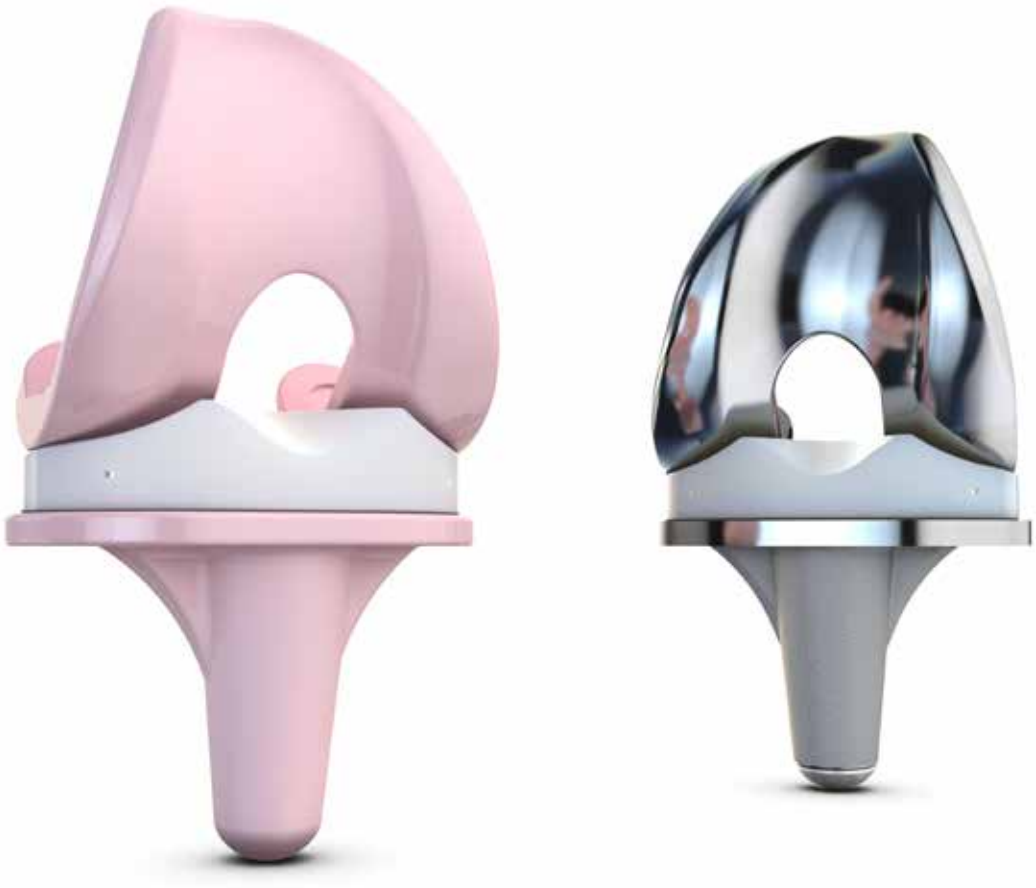
Introduction

In 1999 an interdisciplinary research group of orthopaedists, trauma surgeons, and material scientists set itself the goal of developing an implant system for total knee arthroplasty characterized by minimized particulate wear, sensible soft-tissue management, and optimized patella tracking.

The years that followed saw the development of a modern, comprehensive total system that provides a solution for nearly every initial situation in total knee arthroplasty. Moreover, it addresses the challenges posed today by demographic developments and changes in patient behaviour. The BPK-S Integration knee system offers new and unique solutions for enhanced protection against instability, aseptic loosening, and material-related complications.

The last decade has witnessed a significant reduction in postoperative instability and aseptic loosening following total arthroplasty. Yet this has been accompanied by increasing numbers of periprosthetic infections and reactions due to metal incompatibility.[1]

BPK-S Integration is the first knee system in the world to offer a completely metal-free treatment option. While the use of the metal-free implants requires cement, the femoral and tibial metal components are offered as cemented and cementless versions. The bone side surfaces of the cementless implants are coated with titanium grade 4 (Titanium Rough Coated (TiCR)). Rough surfaces are realised by a titanium-plasma-process.



[1] Lombardi AV, Berend KR, Adams JB: Why knee replacements fail in 2013: Patient, Surgeon, or Implant. CCJR Supplement to the Bone Joint J, 96-B (11 Suppl A) 101-4, 2014

Introduction

PETER BREHM GmbH supplies the implants of the BPK-S Integration system in a sterile condition. Sterile products are gamma sterilized in the final packaging.

! NOTE

- Do not use implants or instruments whose packaging is damaged.
- Do not use implants or instruments whose use-by date is exceeded.
- Check the use-by-date and the integrity of the sterile packaging.
- Do not resterilize and/or repack implants or instruments delivered sterile.
- Return products with expired use-by date to PETER BREHM GmbH.
- The implants and Single-Use Instruments are approved for single use only, do not re-use!

Preoperative planning

The most important goals in total knee arthroplasty besides pain relief are restoration of the desired alignment with the components in correct rotation, functional stability of the knee, preservation of the function of the knee extenders, permanent stable fixation of the implant components, and restoration of the joint line. As in all arthroplasties, preoperative planning is essential. This is done using A/P and M/L radiographs and, if applicable, supplemented by a full-length view of the lower limb obtained with the patient standing.

Considering correct leg position, one can use the lateral radiographs to estimate the femoral size for the reconstruction of the posterior femoral offset and determine the component size. Correct reconstruction of the joint line is usually achieved by performing the resections at levels corresponding to the thickness of the implants.

When using the TIBIA Component UC/SC or UC Ceramic, the minimum resection thickness for the tibia results from the sum of the thickness of the tibial plateau of at least 3 mm and the smallest height of PE-INSERT of 7 mm. The distal resection thickness for the BPK-S Integration FEMUR Component UC is 9 mm.

! NOTE

- The selection of the correct implant type is extremely important for the medical success of a treatment. The use of an implant type disproportionate for the specific situation may result in accelerated clinical failure, such as implant loosening, crack formation and fracture of the implant and/or bone.
- The BPK-S Integration knee system can only be combined with products approved by PETER BREHM GmbH.

Approaches

! NOTE

No special positioning of the patient and no special access for the implant is required. The surgeon is free to choose his preferred access, but must follow the given surgical steps for implantation and modify them for his selected access.

Surgical technique

In the surgical technique described here, at the beginning of the bony preparation the tibial resection is adjusted extramedullary. The tibial resection subsequently serves as a reference for the soft tissue-guided axial orientation of the femoral component. After selecting the valgus angle, the axial femoral rotation is set and the femoral size is determined in relation to the flexion gap and the posterior resection level. In the next step, the extension gap is measured, compared with the flexion gap and, if given, adjusted to it. The anterior and posterior femoral resection is then performed. After checking and, if necessary, correcting the distal resection, the final tibial and femoral preparations are made.

! NOTE

- Observe correct handling of implant components and instruments.
- Do not use implants/trial implants/instruments with visible damage.
- Instruments and trial implants must be checked for fatigue fretting and correct handling/function prior to surgery.
- Use only implants/trial implants/instruments without visible contamination.
- Handle implants/trial implants/instruments exclusively with sterile surgical gloves.
- In the interest of reliable instrumentation, avoid placing shear forces on instruments during the entire operation. Lateral forces can damage instruments or impair their function - in particular on torque limiters.
- Avoid surface damage such as scratches and impact points that could be caused by chisels, hammers, luers, clamps, etc., as well as contact or sparks from electrosurgical instruments.
- Do not touch rough surfaces with cloths or any linting materials.
- Observe the right/left variants.

Surgical technique

To perform the bone cuts, surgically invasive disposable *Saw blades* from PETER BREHM GmbH are connected to an active medical device (oscillating saw). To ensure usability, the *Saw blades* have common machine connections. All *Saw blades* are to be used only in the appropriate and suitable handpieces/drives according to the instructions of the handpiece/drive manufacturers.

! NOTE

Only use PETER BREHM GmbH Saw blades for bone resection, the thickness of the Saw blades is 1.18 ± 0.01 mm:

- *Saw blades* must only be used with the designated and properly fitting hand pieces/drives in accordance with the hand- piece/drive manufacturers' Instructions for Use.
- Make sure the *Saw blades* are only mounted in technically and hygienically well-maintained and cleaned hand pieces/drives.
- To avoid damaging the instrument or causing injury to the patient/user and third parties, make sure that the *Saw blades* are always correctly inserted and tightened in accordance with the device manufacturer's instructions.
- The *Saw blades* must be activated before making any contact with the bone.
- The *Saw blades* must only be activated after its insertion into the resection guides. Strictly avoid tilting, levering or bending the *Saw blade* (risk of fracture) during the sawing process with the aid of resection guides.
- Excessive pressure forces on the *Saw blades* may lead to thermal necrosis, undesirable rough surfaces, shorten the lifespan or even fracture the *Saw blades*.
- Contact of the *Saw blade* cutting edge with the resection guide or other metallic objects must be strictly avoided. Any contact with such objects will result in damage to the instrument or resection guide.
- Damaged cutting teeth or chipped edges may also cause inadvertent injury to bones and surrounding tissue or fracture the *Saw blade*.
- Always keep appropriate *Saw blades* in reserve in order to avoid any delays during an ongoing surgery.
- Vulnerable patient areas must be protected adequately.
- To prevent the unwanted generation of heat, ensure sufficient cooling with a commercially available isotonic saline solution (NaCl) and suction.
- *Saw blades* with worn cutting teeth and/or blunt, bent or chipped teeth must not be used any further. Such devices may cause excessive generation of heat due to insufficient removal of bone leading to irreversible damage to bone tissue (thermal necrosis), fractured *Saw blades* and danger to the patient, user and third parties.
- The user and operating staff must use appropriate eye protection when using the *Saw blades*.
- Protect the patient's surrounding tissue during the operation.
- Dispose used *Saw blades* in accordance with the procedures commonly used at the hospital.

BPK-S INTEGRATION

SURGICAL TECHNIQUE

1 Extramedullary alignment and tibial resection

01

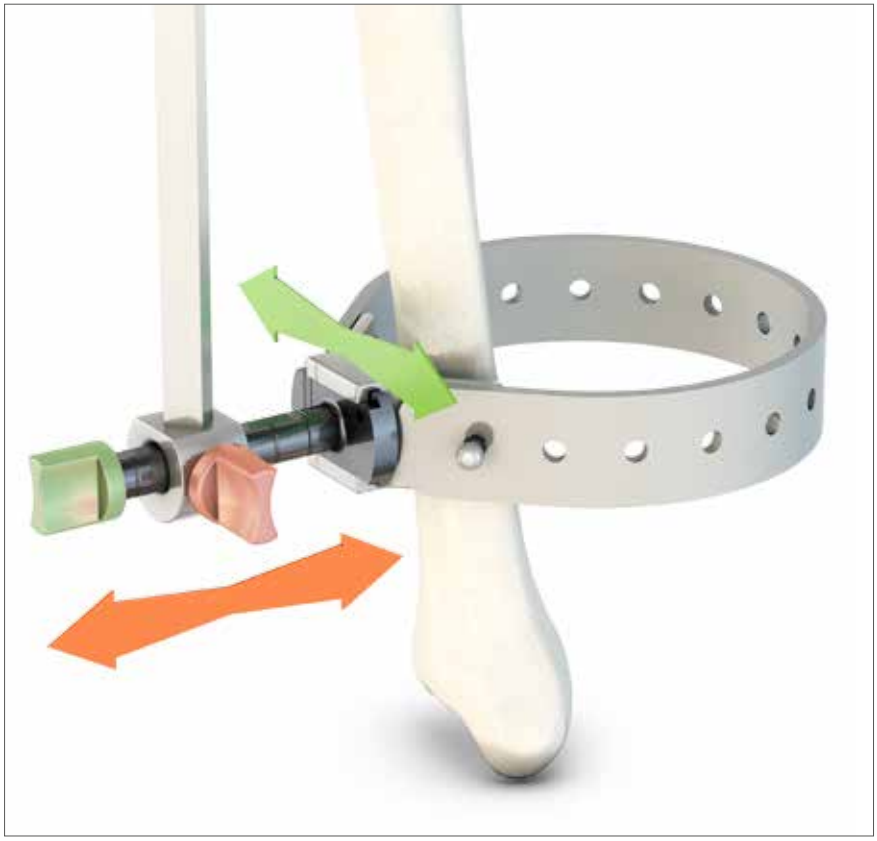
Extramedullary Alignment Guide

The *Tibia Extramedullary Alignment Guide* is secured with a *Headed Pin Ø 3,15 x 70 mm* in the intercondylar eminence. The pin is impacted through the guide sleeve of the tibial bracket so that it allows rotation of the instrument. The *Tibia Extramedullary Alignment Guide* is adjusted to the length of the tibia of the specific patient and secured with the clamping screw.

Tibia Extramedullary Alignment Guide and *Tibial Resection block anatomic*

Assembling the *Tibia Extramedullary Alignment Guide*

Tibia Extramedullary Alignment Guide and *Tibial Cutting Block adjustable*



02

Varus/valgus and tibial slope adjustments

Varus/valgus and slope adjustments are made with the clamping screws on the lower section of the *Tibia Extramedullary Alignment Guide*.
Posterior Slope
Varus/Valgus

Alignment parallel to the axis of the tibial rim corresponds to a posterior slope of the tibial plateau of 3°.

1 Extramedullary Alignment and Tibial Resection

03

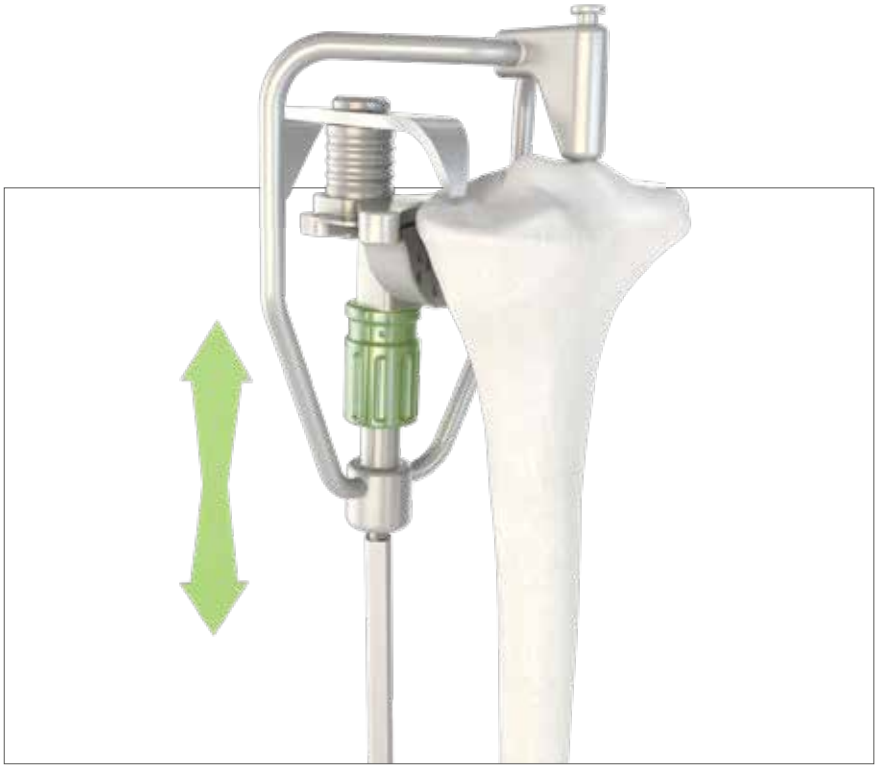
Assembling the Tibial Stylus

The *Tibial Stylus* can be mounted on the *Tibial Resection block anatomic* and *Tibial Cutting Block adjustable*.

The implant system requires a minimal resection of 10 mm to restore the natural anatomy (tibial plateau 3 mm, plus the minimal insert height of 7 mm).

Tibial Resection block anatomic

Tibial Cutting Block adjustable



04

Setting the tibial resection depth

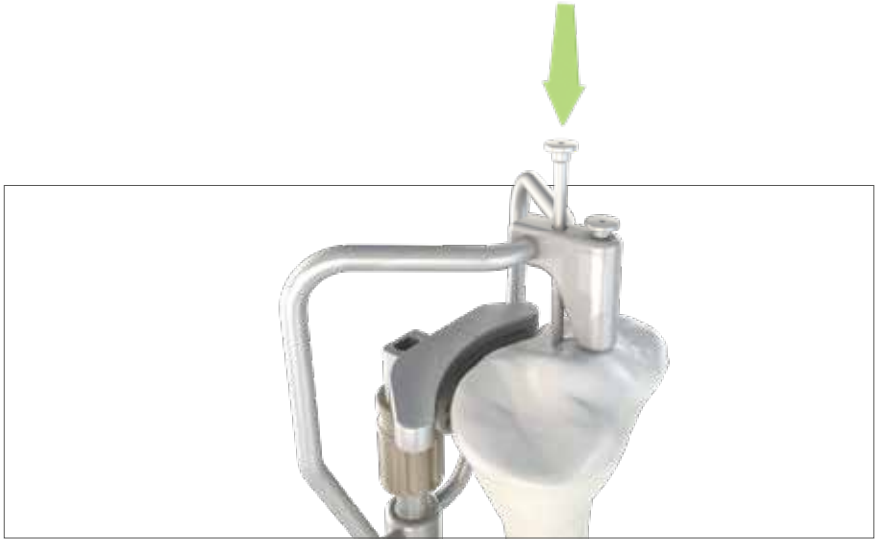
After the *Tibial Resection block anatomic* has been attached, the *Tibial Stylus extra long* is lowered to the level of the articular surface with the adjusting screw.

One turn of the adjusting screw corresponds to a change in depth of 2 mm.

2 mm --- Resection setting --- 10 mm

Side with greater destruction

Side with lesser destruction



05

Securing the tibia Extramedullary Alignment Guide

The guide is secured with a *Headed Pin Ø 3,15 x 70 mm*.

06

Checking resection depth

The selected resection plane and slope can be checked with the *Visualisation Guide S*.

1 Extramedullary alignment and tibial resection

07

Securing the Tibial Resection or Cutting Block

The *Tibial Resection block anatomic* is secured at the selected resection depth setting with two pins. This requires drilling a pilot hole in the cortex with the *Drill AO Coupling Size: Ø 2,5 mm*. To spare the tendon, the guide should be secured laterally through the patellar ligament with a *Pin with Trocar Ø 3,2 x 85 mm*.

❶ Adjustments: *Tibial Resection block anatomic*

Moving the resection block
Δh = 2.5 mm

Moving the resection block
Δh = 5 mm

❷ Adjustments: *Tibial Cutting Block adjustable*

Moving the cutting block
Δh = 2.5 mm

Alternatively, the *Tibial Cutting Block adjustable* can be secured with *Screws self-tapping Size: Ø 5 mm.*

08

Removing the Extramedullary Alignment Guide

The *Tibia Extramedullary Alignment Guide* is now removed except for the *Tibial Cutting* or *Resection Block* which remains in situ. The silicone belt above the ankle is removed. The two *Headed Pins Ø 3,15 x 70 mm* must be extracted from the guide sleeve of the tibia bracket using the *Headed Pin Extractor with Slap Hammer*. Then the *Tibia Extramedullary Alignment Guide* is withdrawn from *Tibial Cutting or Resection Block*.

09

Checking alignment

Varus or valgus position and rotation of the *Tibial Resection* or *Cutting block* are again checked with the *Alignment Rod*. When inserted into the selected *Tibial Resection* or *Cutting block*, the tip of the *Alignment Rod* must point to the anterior margin of the tibia or the extensor hallucis longus, respectively.

1 Extramedullary alignment and tibial resection

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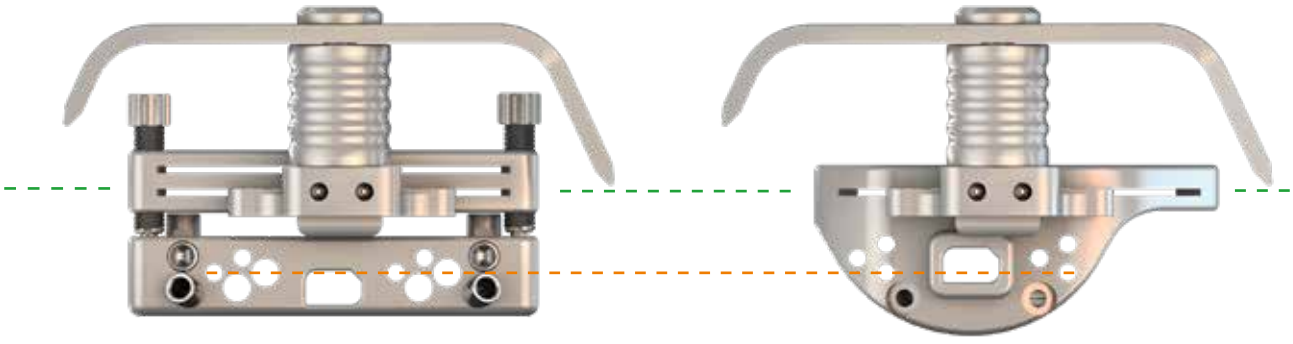
Correcting tibial alignment

If the tip of the *Alignment Rod* does not point to the extensor hallucis longus, the line of the resection can be corrected with the *Tibial Cutting Block adjustable*.

The *Tibial Cutting Block adjustable* is adjusted to correctly transfer the resection depth of the *Tibial Resection block anatomic*. To do this, the *Spacer 7 mm* is inserted into the *Tibial Cutting Block adjustable*. The adjustable section is then lowered onto the *Spacer 7 mm* with the adjustment screws.

Turn the left and right screws alternately to avoid jamming the mechanism.

When the adjustment is complete, the second resection slot corresponds to the resection depth of the *Tibial Resection block anatomic* (when using the same seating position).



Now the *Tibial Cutting Block adjustable* is slid into position over the *Pin with Trocar Ø 3,2 x 85 mm*. The same pilot holes as before must be used again. Then the *Alignment Rod* is inserted and aligned with the second toe using the adjustment screws. Once the desired alignment is achieved, the device is locked in this position.

The two screws are then tightened to lock the adjustable alignment of the tibial resection plane.

Now the resection may be performed.

1 Extramedullary alignment and tibial resection

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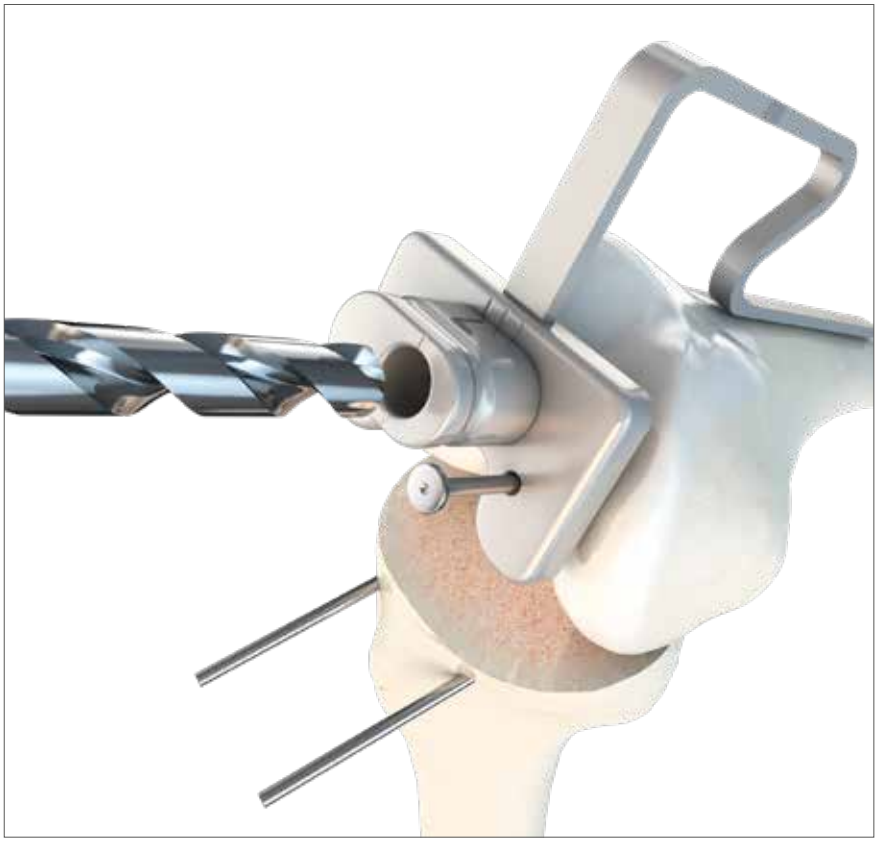
Performing the resection

The *Tibial Resection block anatomic* or the *Tibial Cutting Block adjustable* is removed after the tibial resection has been made. The *Pins with Trocar Ø 3,2 x 85 mm* or the *Screws self-tapping Size: Ø 5 mm* are left in situ for possible additional adjustments in a later stage of the surgery.

Tibial Resection block anatomic

Tibial Cutting Block adjustable

2 Preparing the femur



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Preparing the Intramedullary Guide

The point of entry is determined using the *Femoral Drill Guide*. The narrow part of the guide is placed on the distal femur and the plate is centered in the intercondylar notch and secured with a *Headed Pin Ø 3,15 x 30 mm*. Then the medullary canal is accessed as far as the marking on the *Drill for Intermedullary Guide Size: Ø 11 mm*.

! NOTE

The drill guide must be inserted into the femoral drilling jig ensuring that the correct marking points upwards (L = Left and R = Right). Check the drill holes by observing the anatomical landmarks.

13

Assembling and inserting the Intramedullary Guide

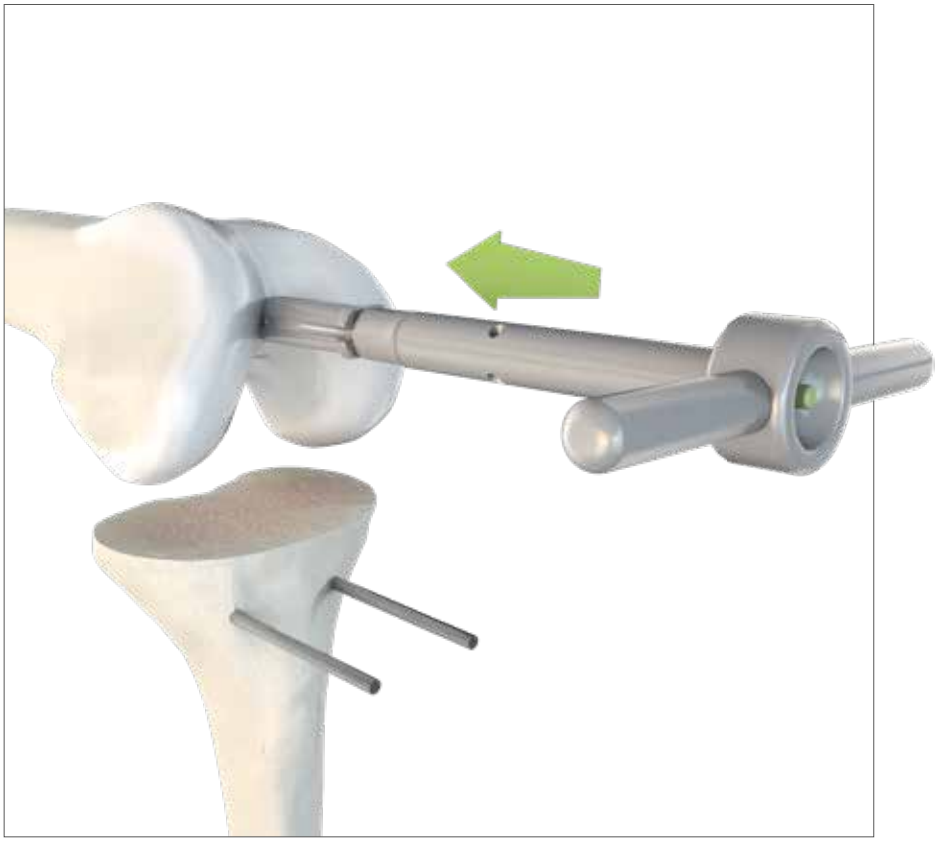
The push button on the *T-Handle Intramedullary Guide* must be depressed when assembling the guide.

! NOTE

The *Intramedullary Guide* is available in 120 mm, 220 mm, and 320 mm lengths.

2 Preparing the femur

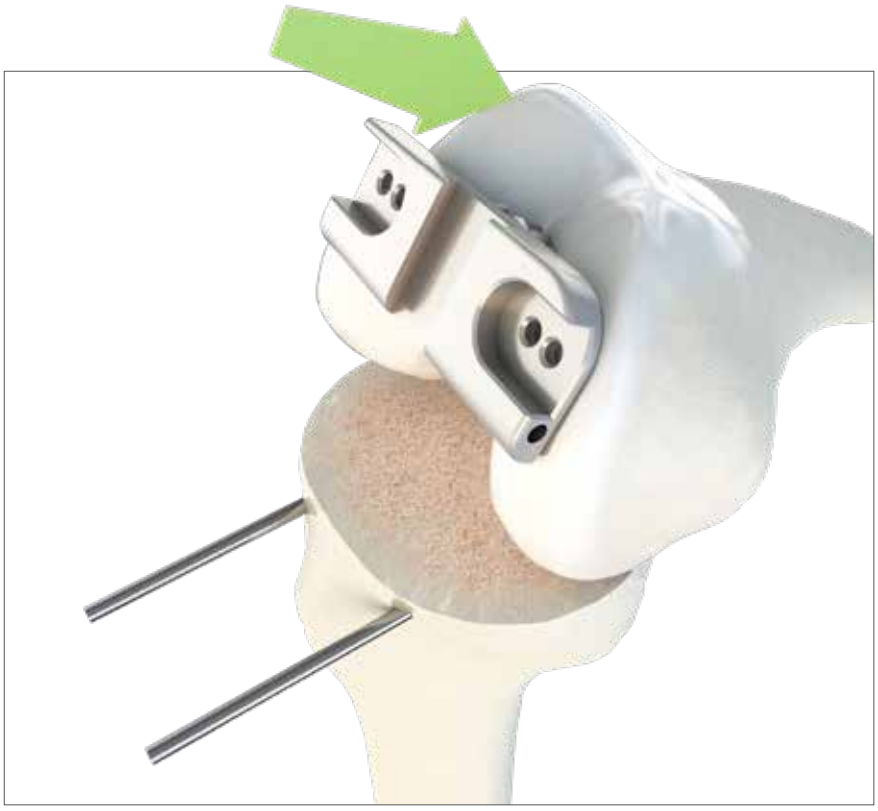
The *Intramedullary Guide* is inserted with the *T-Handle Intramedullary Guide* as far as possible.



14

Determining the approximate size of the FEMUR Component

The *Femoral Sizing Template* is used to determine the approximate size of the femoral component.



15

Placing the Valgus Plate

The preoperatively selected right or left *Valgus Plate* (1°, 3°, 5°, 6°, 7°, 8°, or 9°) is placed onto the *Intramedullary Guide*. The *Valgus Plate* must be in contact with the bone on at least one side.

16

Ligamentous axis control

After replication of the mechanical axis by attaching the selected *valgus plate left* or *right,* the ligamentous stability must be checked. For this purpose, the collateral ligaments are tensioned by the aid of the *valgus plate left* or *right* and a *Spacer* of suitable thickness. In case of inacceptable instability, a compromise between mechanical and ligamentary axis correction should be sought.
If necessary, the situation can be corrected by a soft tissue release in favour of the mechanical axis.

2 Preparing the femur

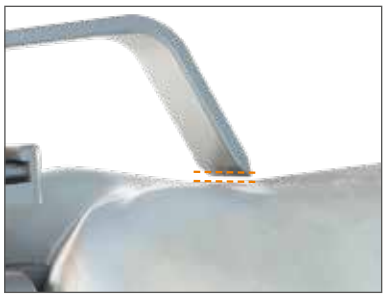
17

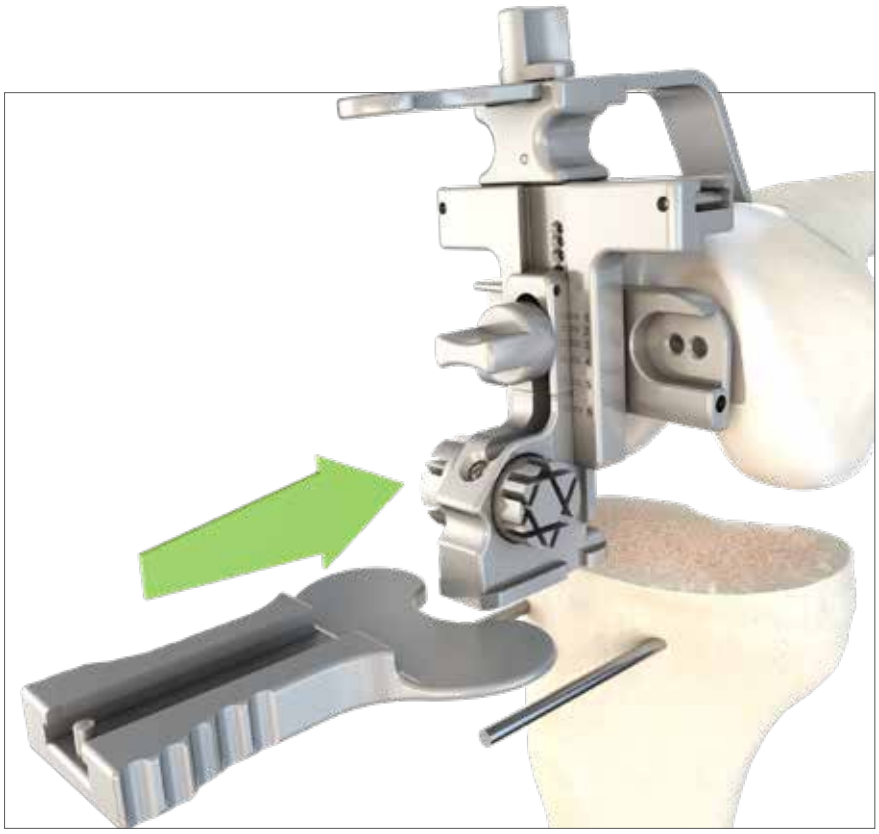
Adjusting rotation

The *Flexion Measuring Device* is placed on the *Valgus Plate left* or *right* to adjust rotation.

The stylus of the *Flexion Measuring Device* must not be in contact with the bone to allow correction of rotation.

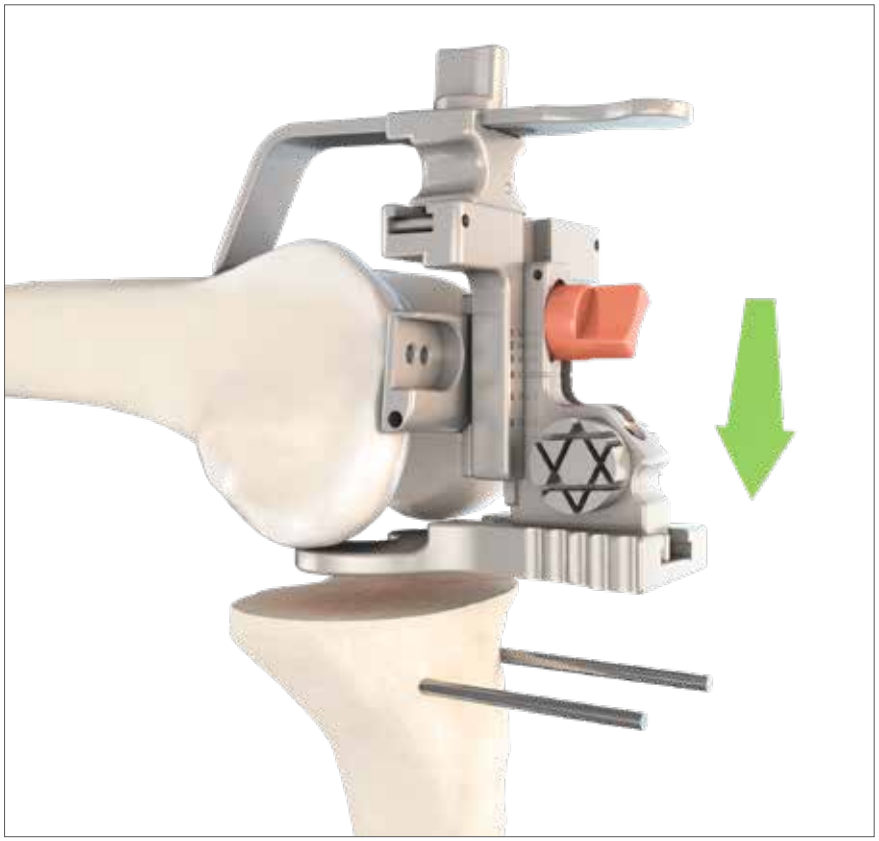
Lock the *Flexion Measuring Device* on the *Valgus Plate left* or *right* with the central clamping screw so that there are about 3 to 5 mm of clearance between the stylus and the cortex.





Slide the *Shoe* over the adjustable base with the knee flexed 90°.

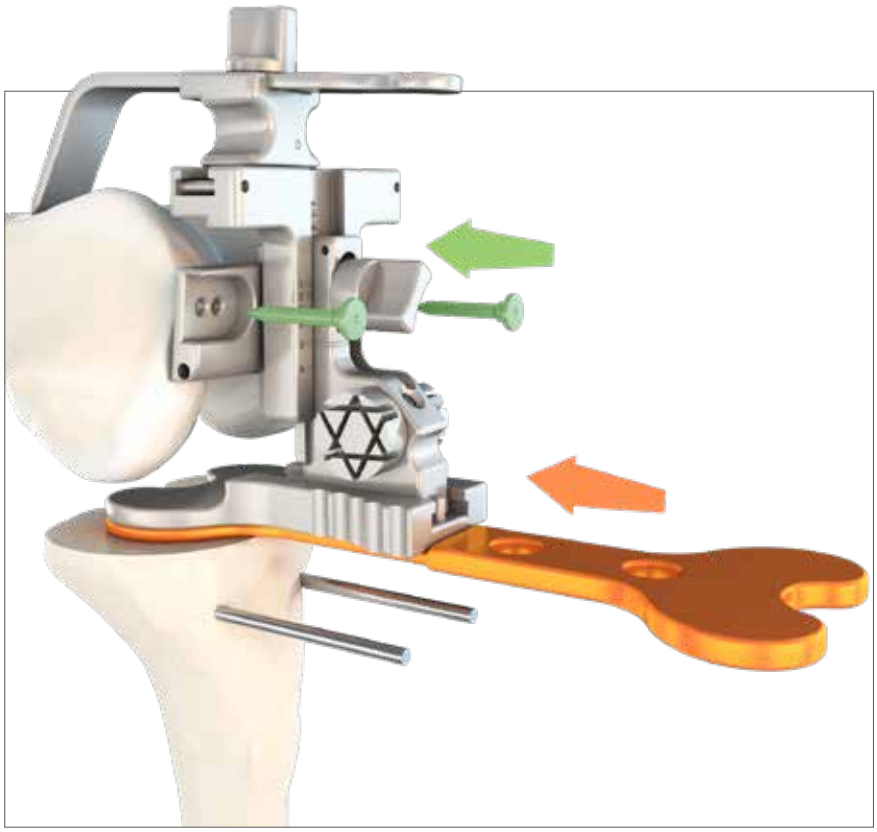
The central clamping screw for locking the *Flexion Measuring Device* can only be operated in the adjustable base positions for sizes 3-6.



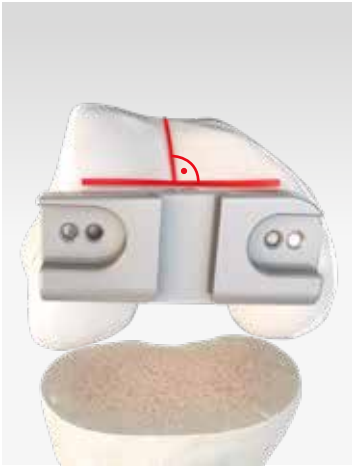
Lower the *Shoe* onto the surface of the tibial osteotomy as far as possible and then secure it with the clamping screw.

2 Preparing the femur

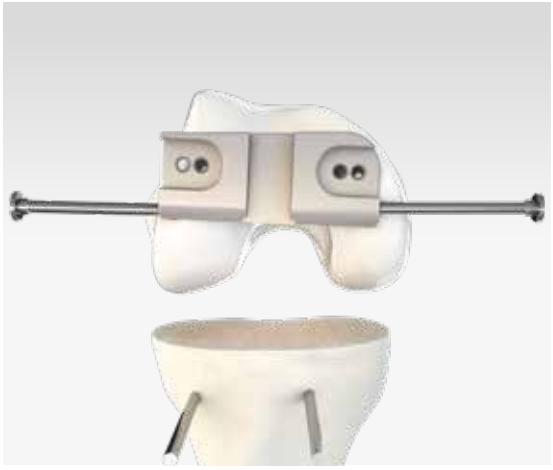
Next the ligaments are tensioned using the various *Spacers*, and anatomic rotational alignment is secured with the aid of two *Headed Pins Ø 3,15 x 30 mm* in the *Valgus Plate left* or *right*.



Additional alignment options for adjusting the rotation of the valgus plate:

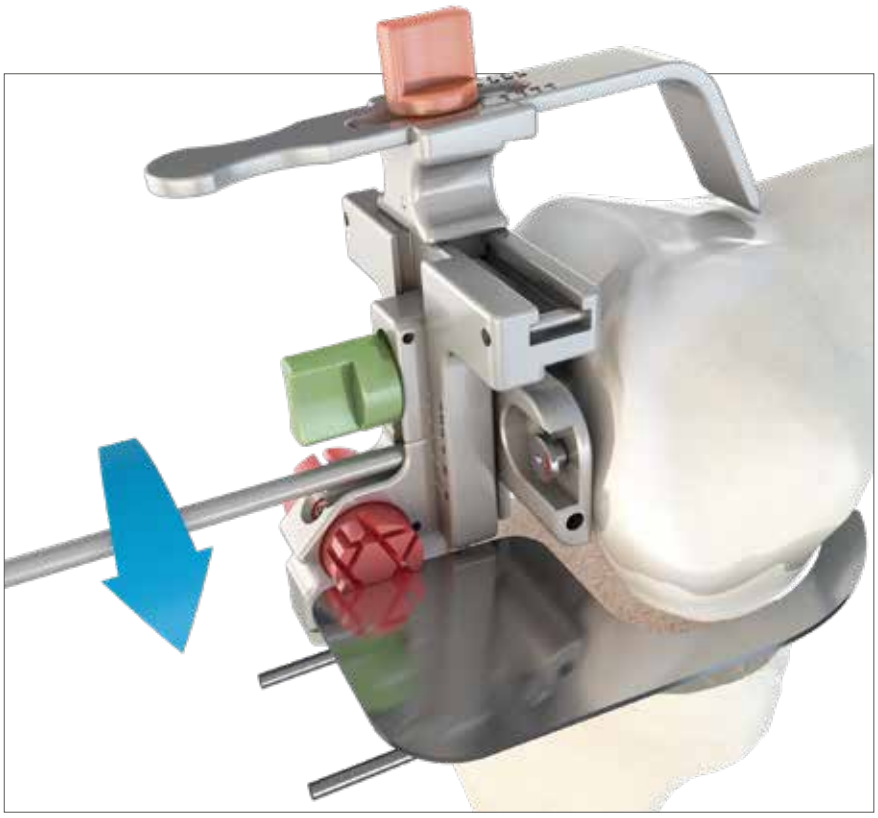


❶ Whiteside line



❷ Epicondylar axis

❸ Posterior condyles



18

Determining the size of the FEMUR Component

❶ Set the stylus to the appropriate size, secure it with the screw, and lower it to the highest point of the anterolateral cortex.

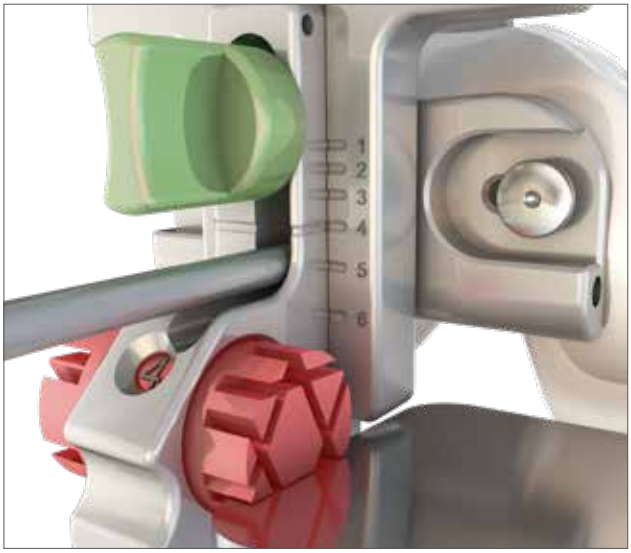
❷ Tighten the central clamping screw with the screw driver.

❸ Set the adjustable base to the approximate size and secure it with the clamping screw.

❹ Set the resection gauge to the approximate size.

❺ Check the posterior osteotomy with the *Visualisation Guide* and set it to the new size if necessary.

Size adjustment screw on stylus



Clamping screw and resection gauge

The central clamping screw for locking the *Flexion Measuring Device* can only be operated in the adjustable base positions for sizes 3 - 6.

3 Checking flexion and extension space

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Checking flexion space

After checking size, the *Shoe* is again slid over the adjustable base and the *Spacers* (7 - 17 mm) are used to evaluate flexion space and stability with the knee flexed 90°.

The *Spacers* simulate the height of the PE-INSERTS.

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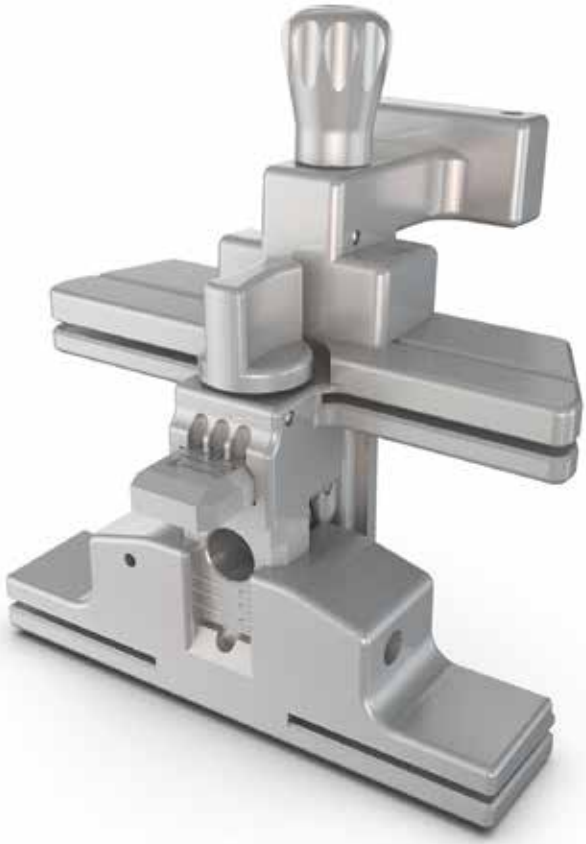
Checking extension space

Once the *Flexion Measuring Device* has been withdrawn, the *Spacer* (7 - 17 mm) is used to evaluate extension space.

! NOTE

- The extension space can be adjusted to the flexion space up to +/-4 mm as the operation proceeds.
- If the flexion and extension spaces are too narrow, the tibia should be resected once more.
- If just the flexion space is too narrow, a smaller femoral size may also be considered.

4 Femoral resection



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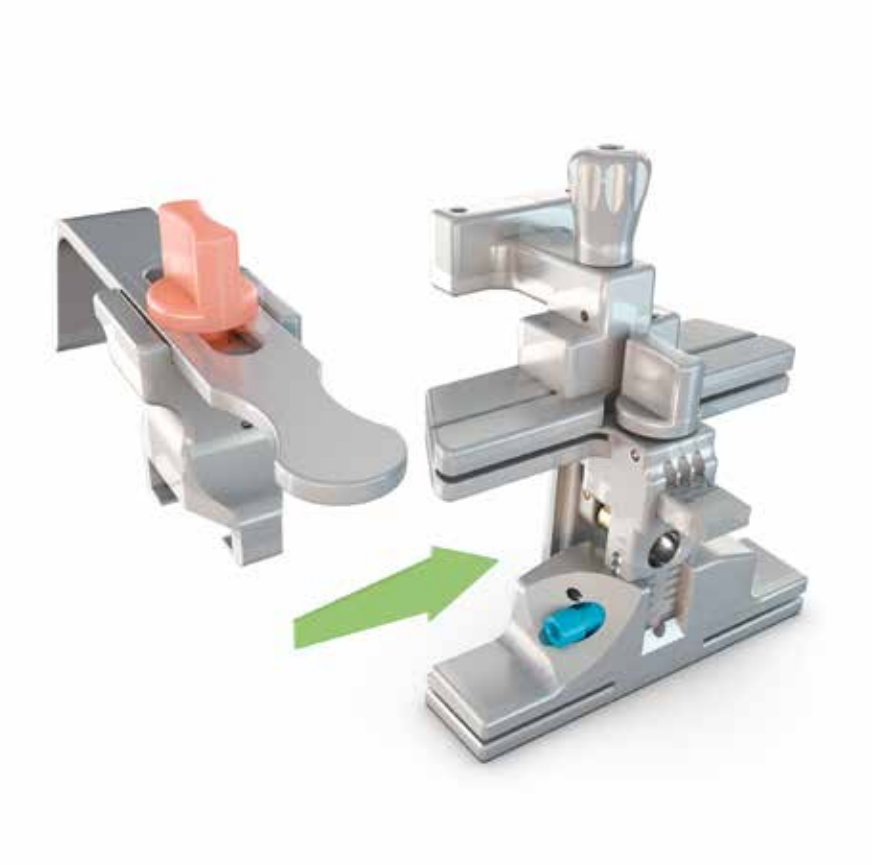
Assembling, attaching, and aligning the Femoral A/P Resection Guide

Adjustments on the *Femoral A/P Resection Guide*.

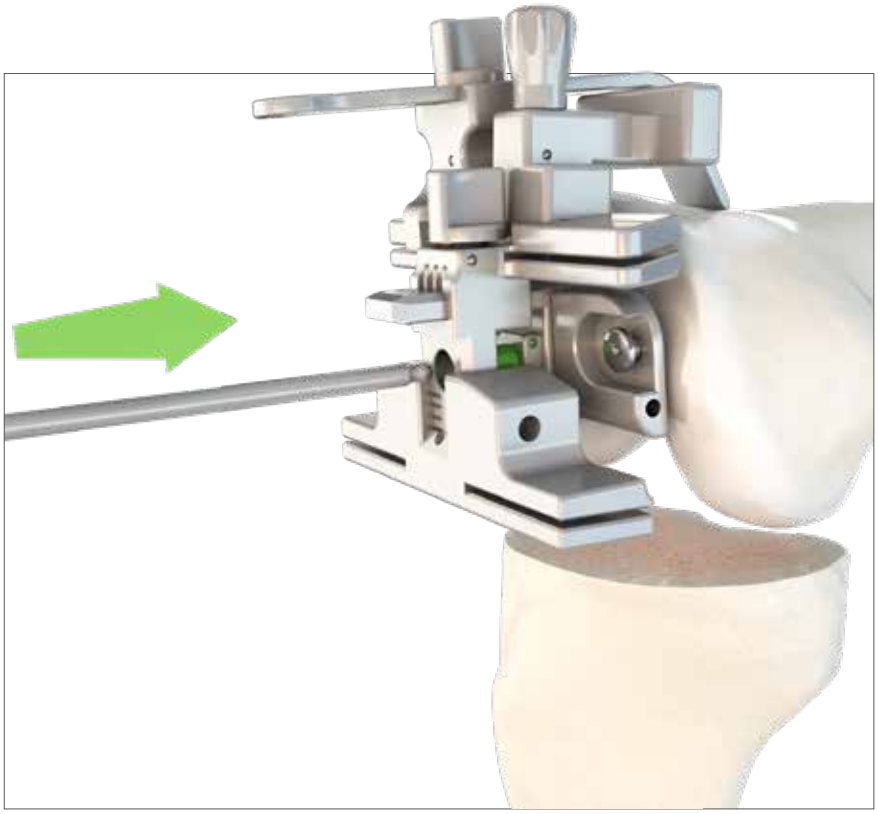
Extension space can be widened or narrowed by setting the guide to ± 2 or ± 4 mm.

4 Femoral resection

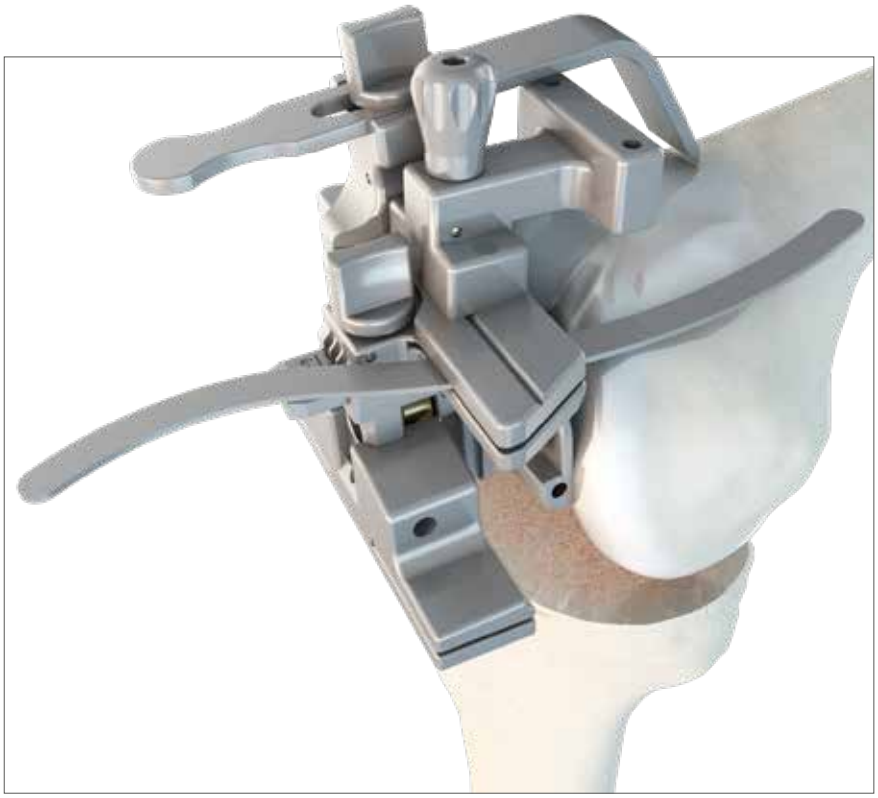
Set the measured femur size on the *Femoral Stylus* and the *Femoral A / P Resection Guide*. The settings are secured with the clamping screw and fixation screw.



The *Femoral A / P Resection Guide* is placed on the *Valgus Plate left* or *right*. Lower the *Femoral Stylus* to the highest point of the anterolateral cortex.



Tighten the central clamping screw to secure the assembly.



Check the osteotomy surfaces with the *Visualisation Guide S*.

4 Femoral resection

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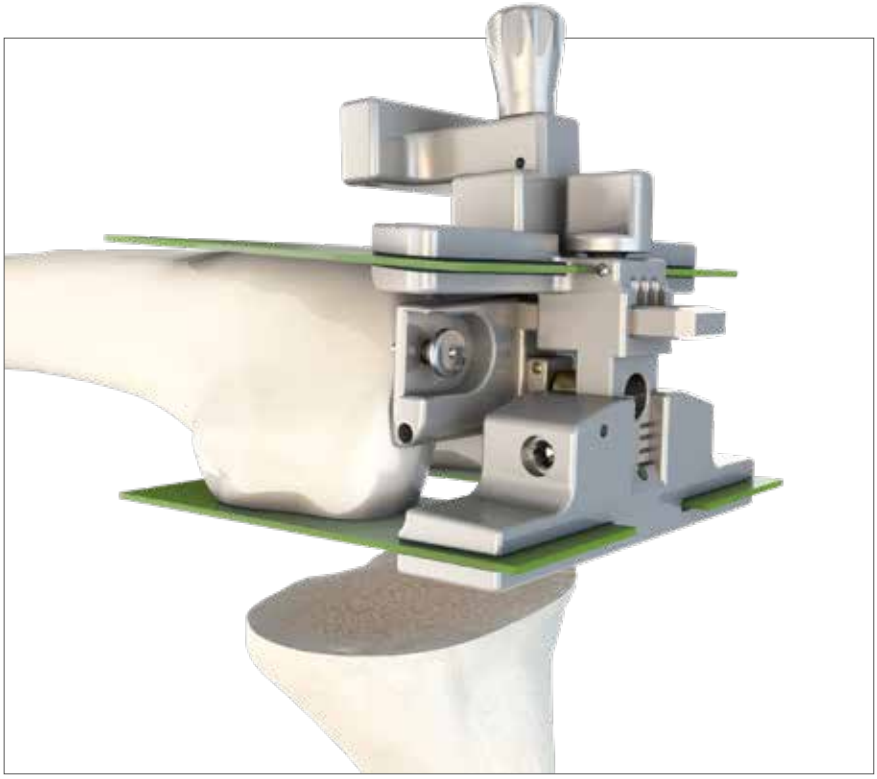
Performing the anterior and posterior osteotomies

The *Femoral Stylus* is removed and the anterior and posterior osteotomies are performed.



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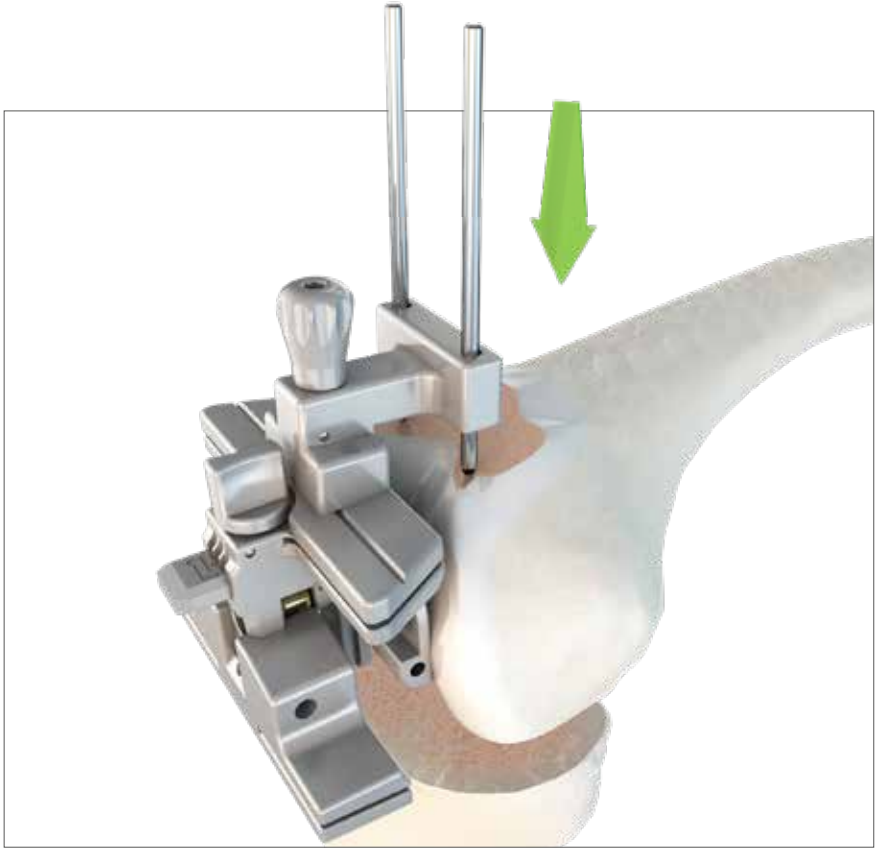
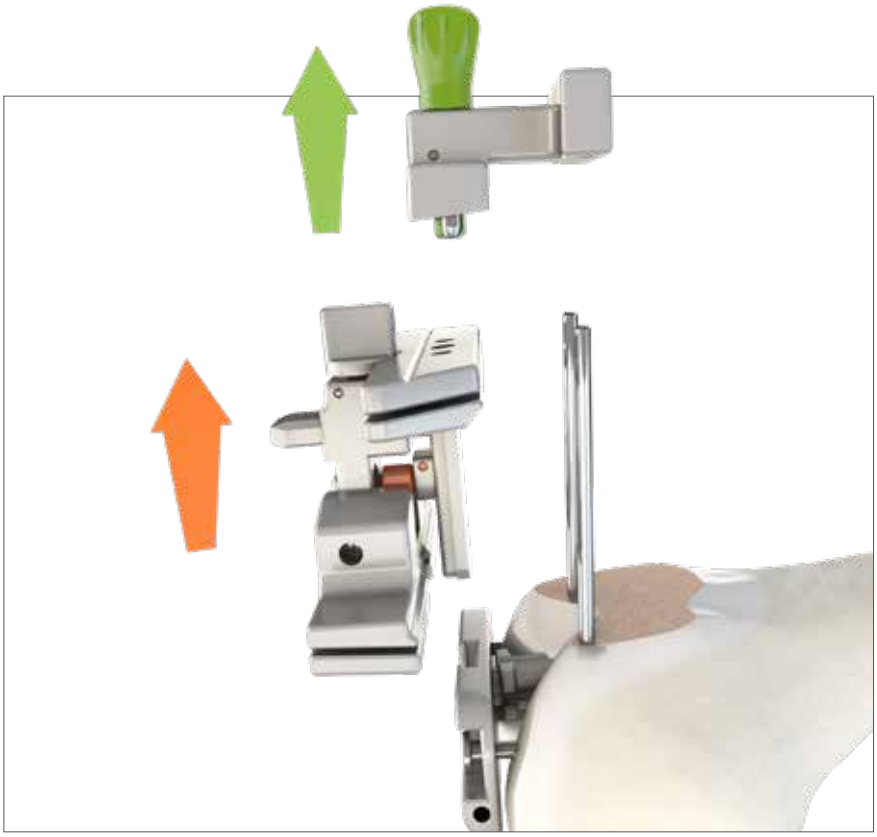
Placing the Pins and disassembling the device

Two *Pins with Trocar Ø 3,2 x 85 mm* are inserted through the *Pin Setting Guide*.





❶ The clamping screw is released and the *Pin Setting guide* is removed.

❷ The central clamping screw is released and the *Femoreal A/P Resection Guide* is removed.

❸ The *Valgus Plate left* or *right* is removed using the *Headed Pin Extractor with the Slap Hammer*.

❹ The *Intramedullary Guide* is removed.

4 Femoral resection

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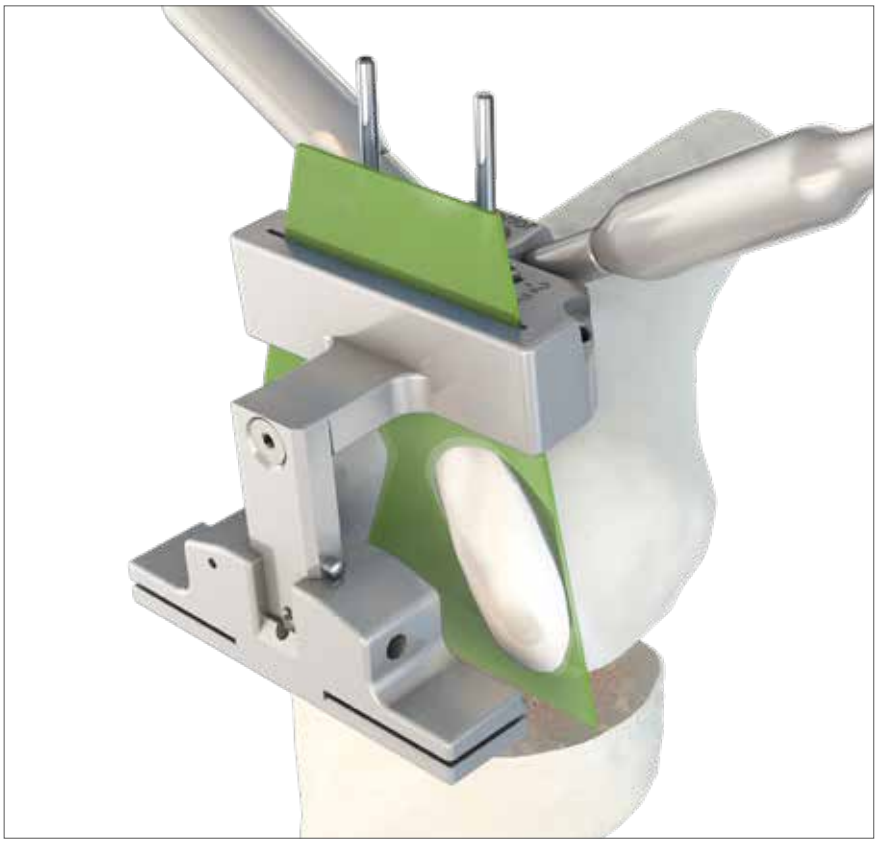
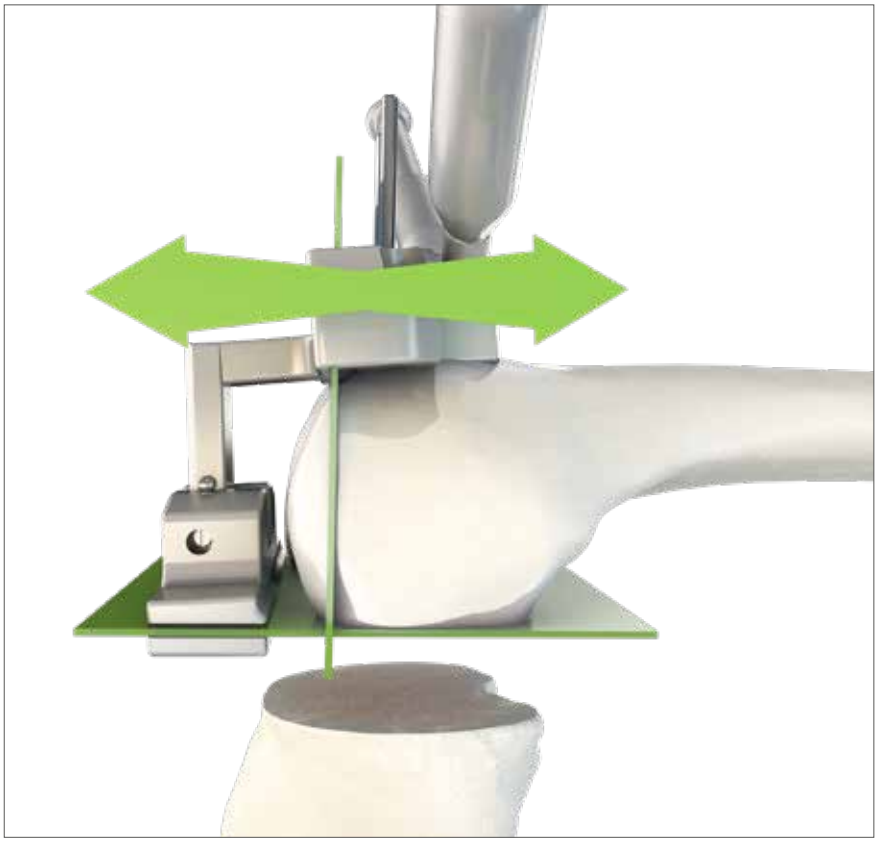
Distal resection

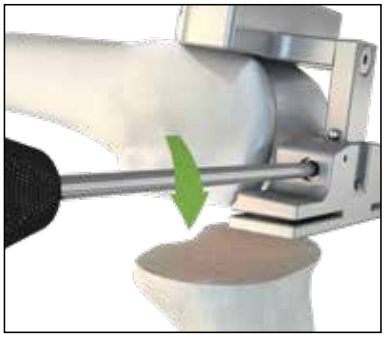
The *Distal Resection Guide* is placed using the drill holes for a neutral osteotomy with the "0" marking. To fix the *Distal Resection Guide*, pins or handles can be attached to the instrument.



The other drill holes can be used to vary the distal resection and thus influence extension space.



In case of distal resection > 0, resection of the posterior condyles is necessary. For this purpose the *Posterior Resection Guide* is attached to the *Distal Resection Guide* and secured laterally with the *Combined Key AF 3,5 / Clamping Screw.*



4 Femoral resection

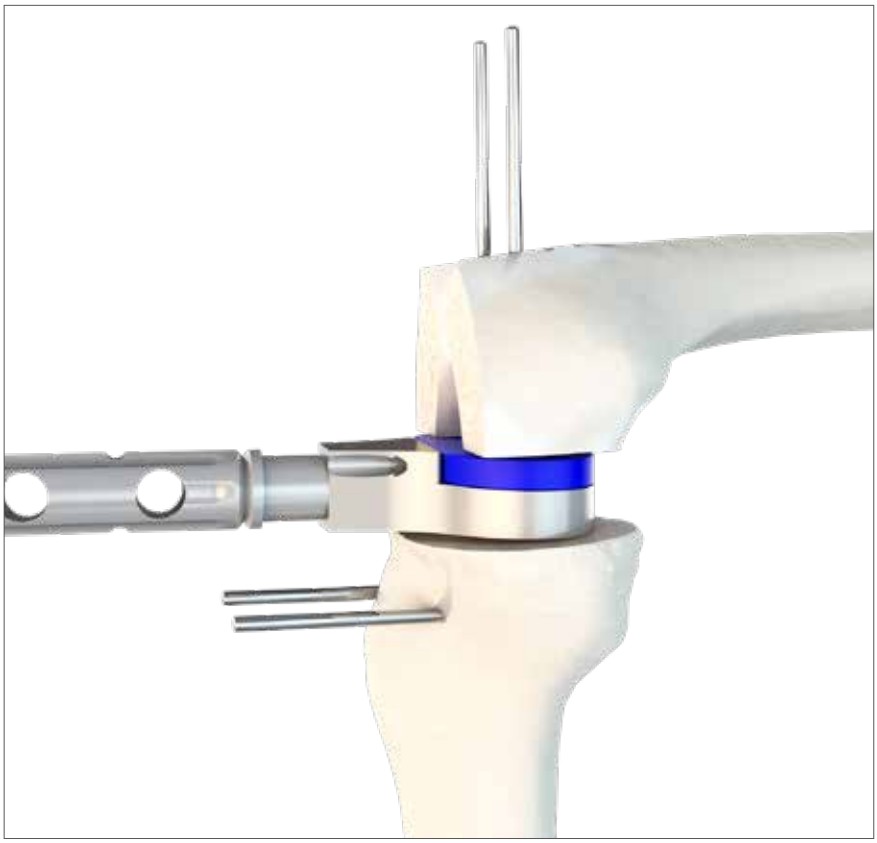
25

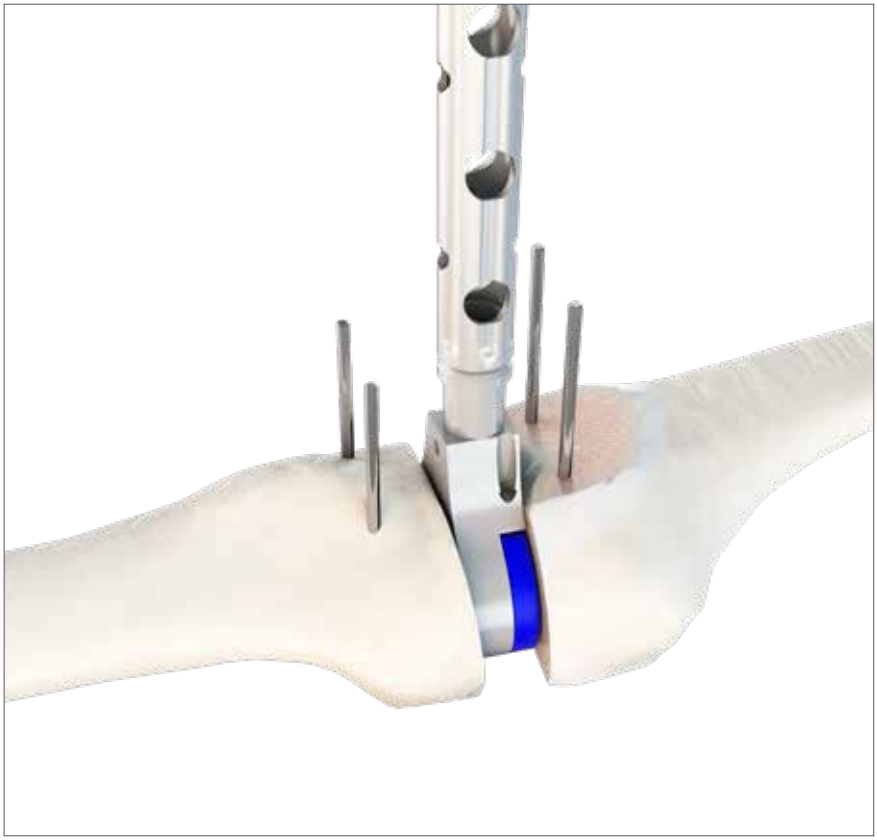
Re-checking flexion and extension space

After the anterior, posterior, and distal osteotomies have been performed, the surgeon can again use the *Spacers Flexion* and *Spacer Extension* to check flexion and extension space. The height of the *Spacer* used is identical to the height of the definitive insert.

Observe correct indication Flexion (left / right) or Extension:

Corrections can still be made if the surgeon now finds that flexion space and extension space vary or extension space is too narrow. This is done using the *Pins with Trocar Ø 3,2 x 85 mm* left in situ in the femur or tibia. For a secondary osteotomy the cutting blocks (*Tibial Cutting* or *Resection block*, *Distal Resection Guide*) are placed at a lower level (see item 07 ff. and item 23).





26

Oblique osteotomies

After the *Pins with Trocar Ø 3,2 x 85 mm* have been removed, the *Chamfer Cut Resection Guide* is placed on the distal osteotomy surface. The *Chamfer Cut Resection Guide* can be secured with handles or pins.

Performing the two oblique osteotomies.

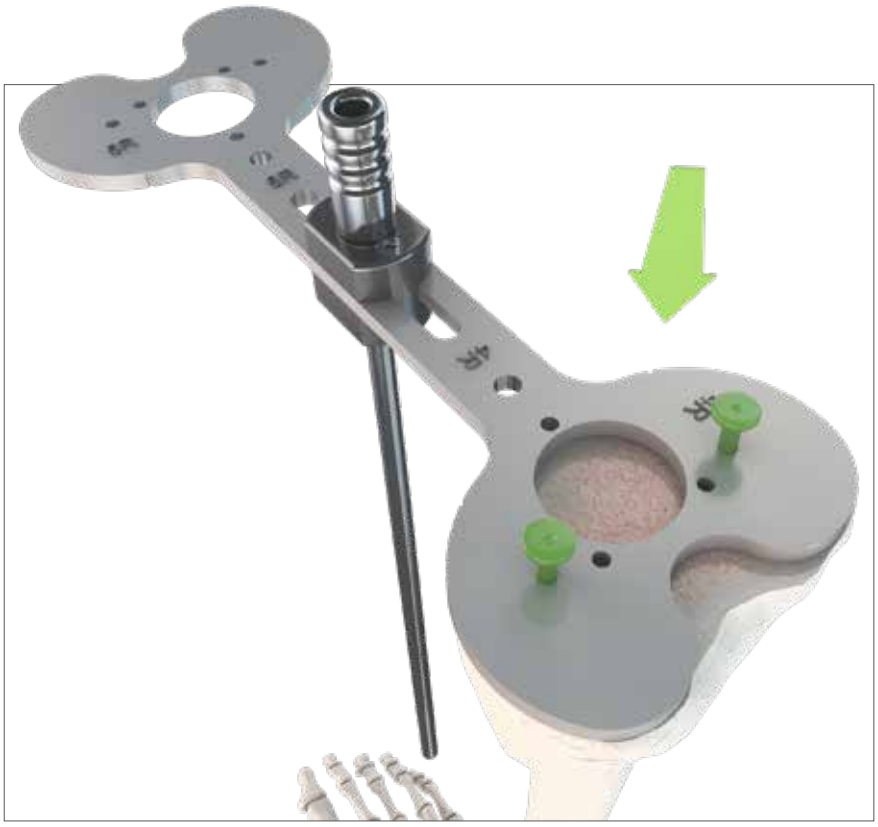
5 Finalisation tibia

27

Determining the size of the TIBIA Component

The size of the tibial component is determined using the *Tibial Template*. The size for best cortical support is selected. Rotation is also checked using the *Aiming Rod*.

When using the *Tibial Template* observe left-/right variants.



The *Tibial Template* is secured with the *Headed Pins Ø 3,15 x 30 mm* in the outer holes.

28

Resecting cancellous bone from the tibial head

Attach and secure the *Cancellous Bone Punch Sleeve*. Then cancellous bone is harvested from the tibial head with the *Cancellous Bone Punch Ø 15 mm*.

5 Finalisation tibia

The tibia is reamed with the *Tibial Cone Reamer* as far as possible. Then the *Tibial Template* and all its attachments are removed.

29

Placing the TRIAL TIBIAL Component

The *TRIAL TIBIAL Component UC/SC* of the measured size is implanted with the *Tibial Impactor UC/SC*. Press the central pin to attach and detach the *Tibial Impactor UC/SC*.

6 Finalisation femur

30

Sealing the femoral canal
The cancellous bone harvested from the tibial head with the *Tibial Cancellous Bone Punch* is now used to close intramedulary femoral canal.

31

Placing the TRIAL FEMORAL Component

7 Checking and correcting rotation of PE-INSERT UC fix

32

Placing the TRIAL INSERT UC mobile

The size of the *TRIAL INSERT UC mobile* corresponds to the size of the *TRIAL FEMORAL Component UC*. The height is determined by evaluating flexion space and extension space (see chapter 3).

The insert is placed with the *Trial Insert Holder.*

! NOTE

- Use trial Implants exclusively for the selection of corresponding final implants.
- Ensure that trial Implants are not implanted.

33

Checking rotation of the TIBIA Component

After the knee is moved through its range of motion several times, the rotation of the *TRIAL INSERT UC mobile* is marked on the anterior tibia.

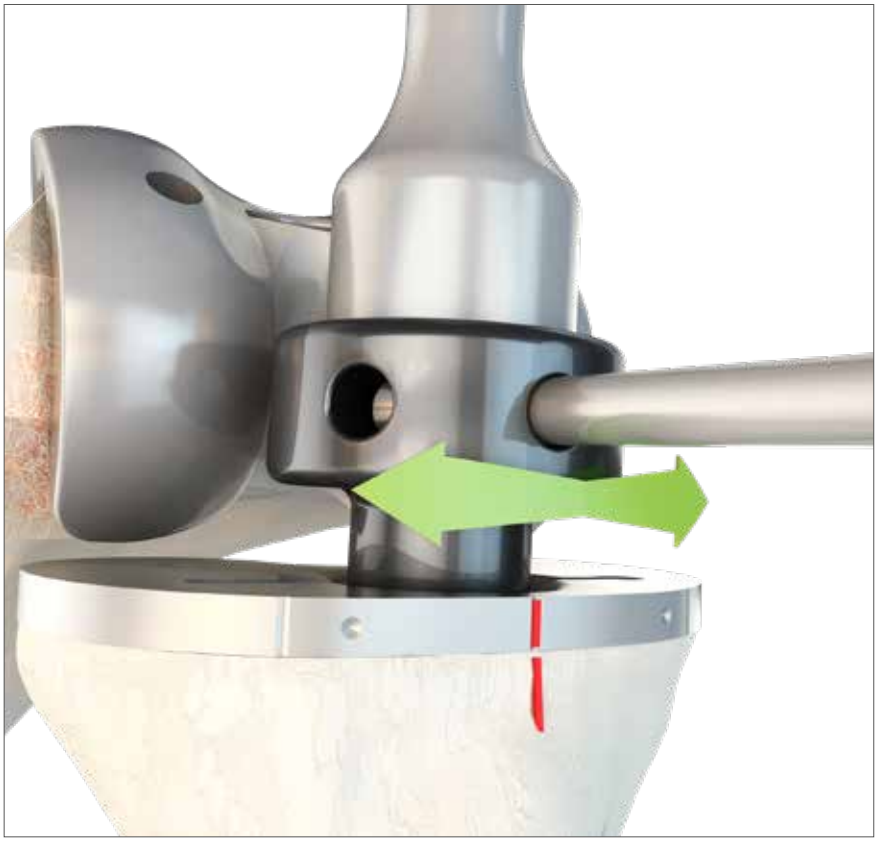
7 Checking and correcting rotation of PE-INSERT UC fix

34

Correcting rotation of the TIBIA Component

When a fixed insert is used, the *TRIAL TIBIAL Component UC / SC* is rotated on the tibia according to the marking

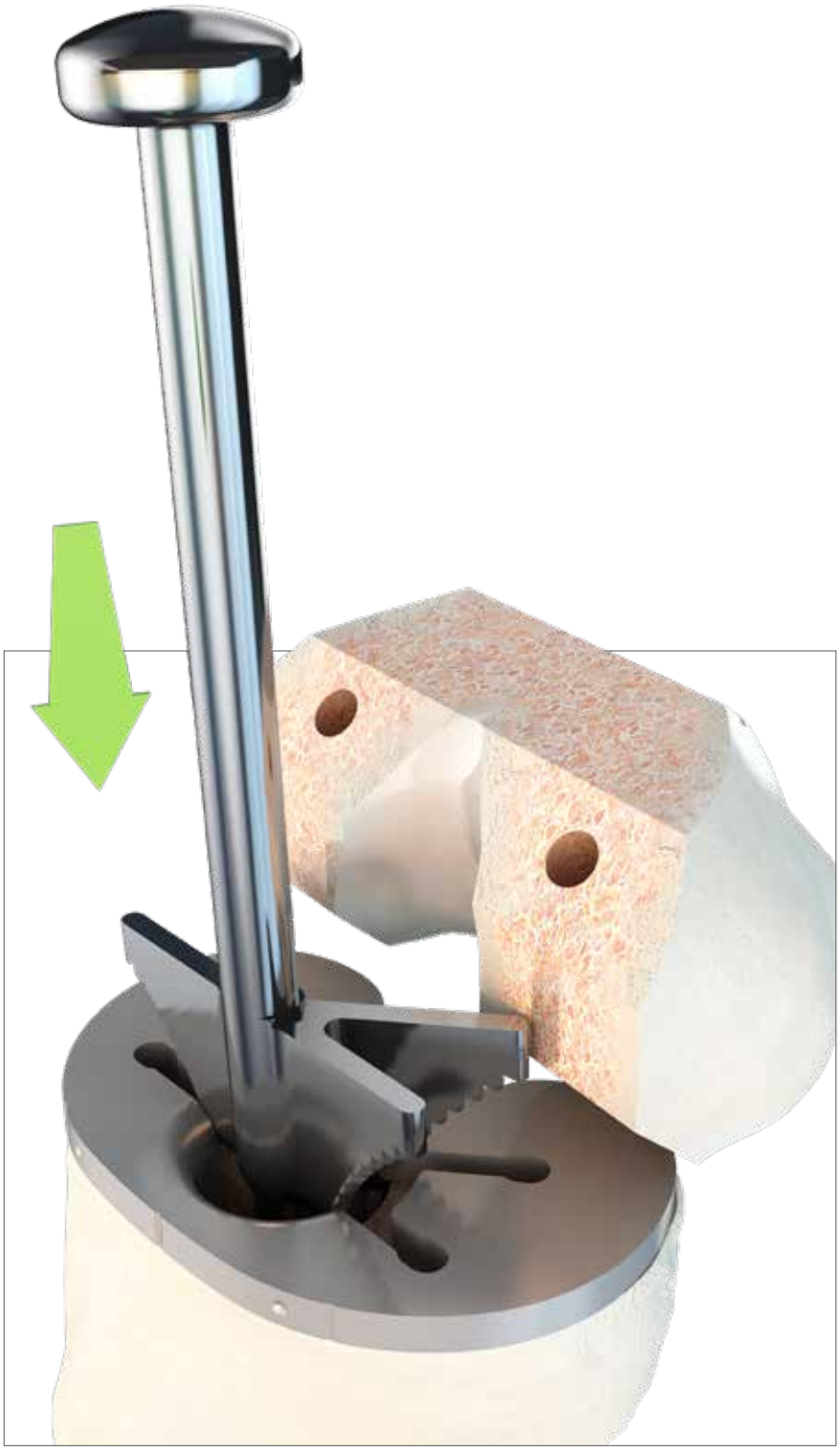
Note the possible combinations listed in the appendix.



35

Drilling the fixation holes

The holes for the lugs of the femoral component are drilled through the 6 mm holes of the *TRIAL FEMORAL Component UC*. The *Drill for femoral Lugs AO Coupling Size: Ø 6 mm* is used for this.



36

Impacting the Cancellous Pusher

The cancellous bone is compressed with the *Cancellous Pusher*. A fine drill is used in sclerotic areas. The *Tibial Impactor UC/SC* is used to remove *TRIAL TIBIAL Component UC/SC*.

! NOTE

Strike in the *Cancellous Pusher* to the stop.

8 Placing the implants

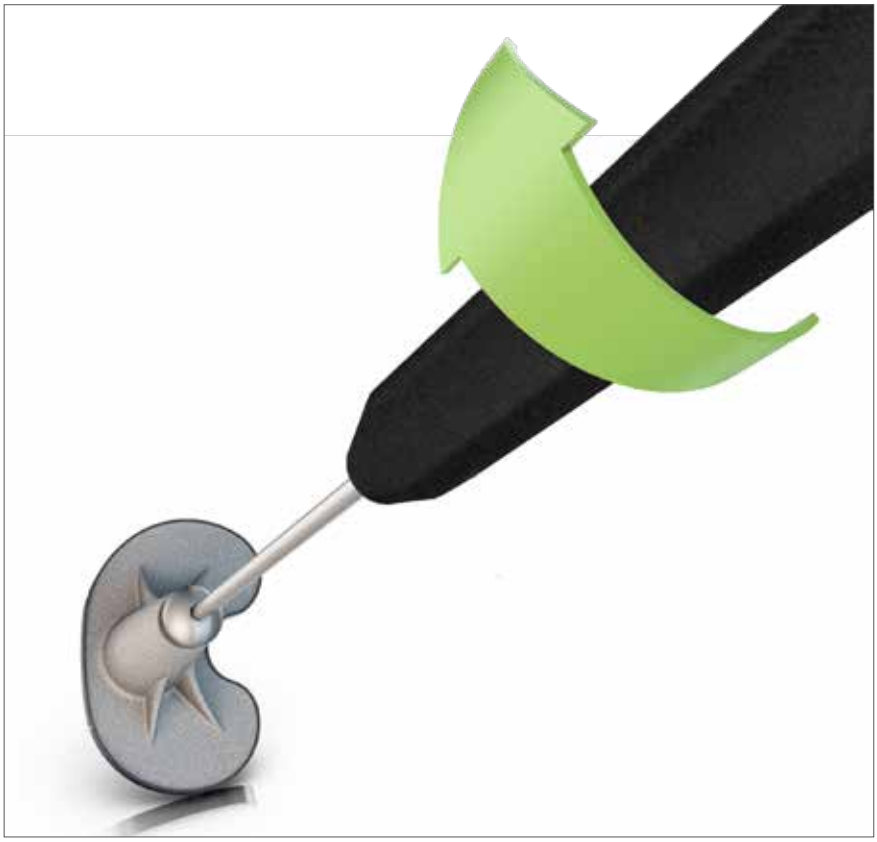
37

Placing the TIBIA Component

Before the definitive tibial component is placed, it must be sealed with the SEALING SCREW Femur/Tibia UC or UC/SC. There is no sealing screw for the BPK-S Integration Ceramic tibial component.

! NOTE

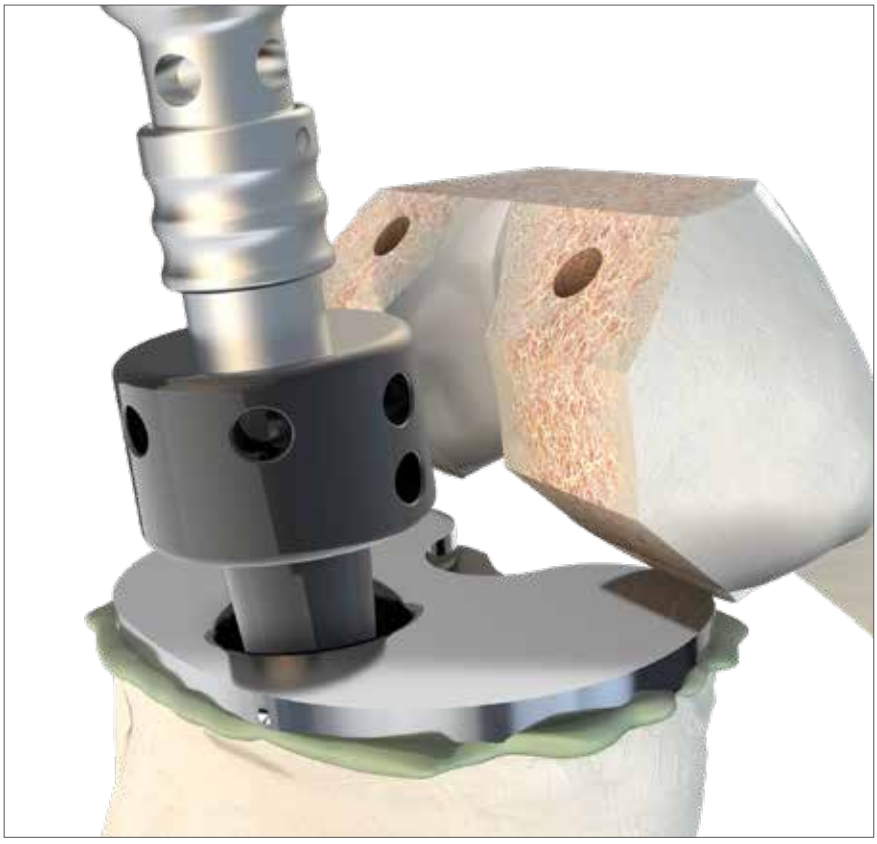
TIBIA Component UC/SC Cementless is to be used with SEALING SCREW only.



Placing the tibial component with the *Tibial Impactor UC/SC*. Please note that there are separate cemented and cementless versions.

! NOTE

When using bone cement, user information of the cement manufacturer must be observed. Ensure, the bony implant site is fully cemented and the surface of the implant is dry and clean.



38

Placing the FEMUR Component UC

Cemented and cementless versions of the metallic FEMUR Components UC are available.

When impacting the FEMUR Component UC it is important to exert upward pressure with the assembled *Femoral Impactor / Extractor.*

! NOTE

The FEMUR Component UC can also be applied after the PE-INSERT UC or DD. Care must be taken to carefully remove excessive cement.

39

Placing the PE-INSERT UC or DD

The definitive PE-Insert UC or DD is placed once the cement has hardened. The size of the PE-Insert UC or DD corresponds to the size of the FEMUR Component UC.

! NOTE

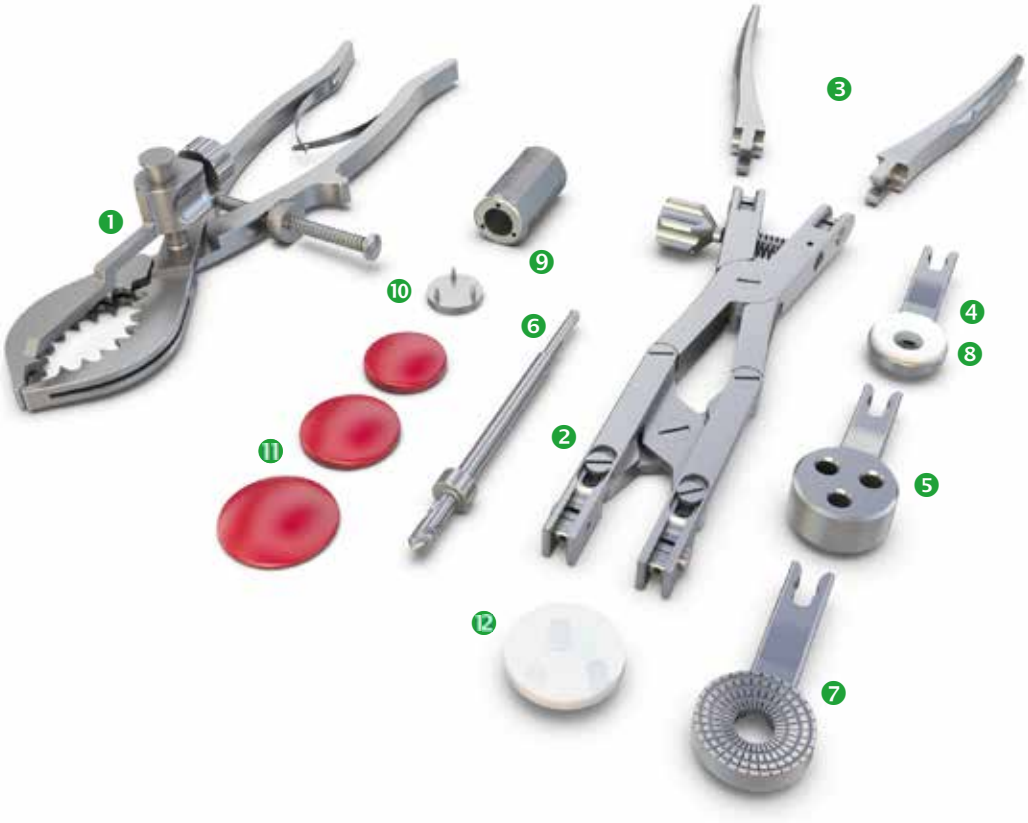
PETER BREHM GmbH recommends determining the correct positioning of the implant with intraoperative X-rays as well as discovering any fractures with immediate treatment options if necessary.

9 Patella preparation

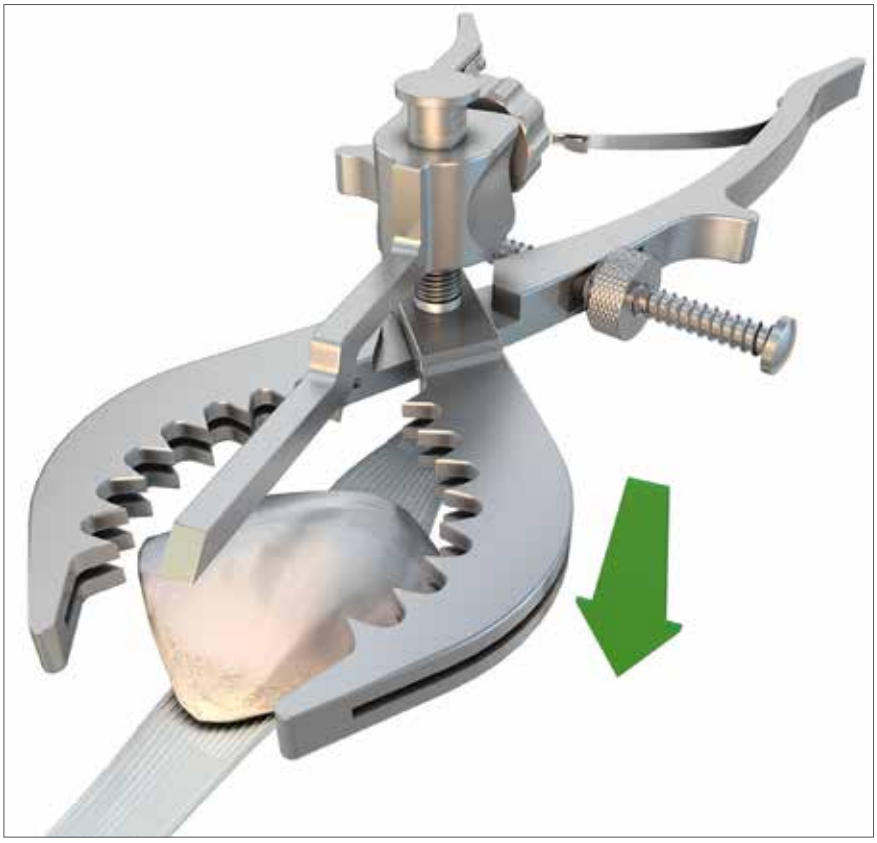
40

Preparation and osteotomy of the patella

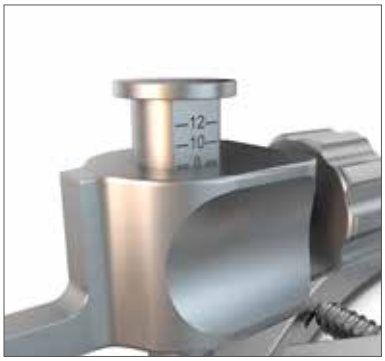
1. *Patella Gripper*
2. *Parallel compression foreceps modular*
3. *Handle for modular parallel forceps - short*
4. *Patella Pusher*
5. *Drilling Jig*
6. *Drill for femoral Lugs AO Coupling Size: Ø 6 mm*
7. *Patella Holder*
8. *Teflon Shell*
9. *Patella Chimney*
10. *TRIAL Patella Base Plate*
11. *TRIAL Patella*
12. *PATELLA cemented*



Measuring the thickness of the patella with the *Patella Caliper*. The residual thickness of the patella after resection must be at least 10 mm.



Set the feeler gauge on the clamping screw to a resection depth of 8 mm and lock it, if a residual thickness of 10 mm is maintained. If the residual thickness is calculated to be less than 10 mm, the resection depth must be adjusted accordingly.



Apply the *Patella Gripper* posterior to the patella with the patient's leg extended.

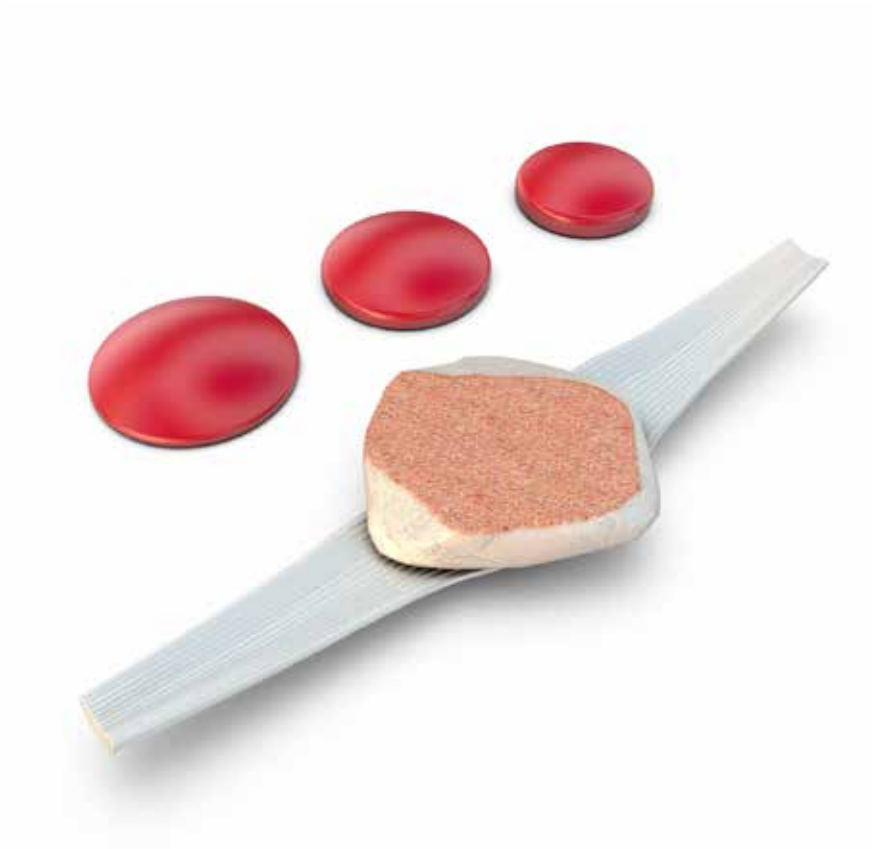
Then place the depth guide on the highest point of the patella, secure it with the locking screw, and perform the patellar osteotomy.

9 Patella preparation

41

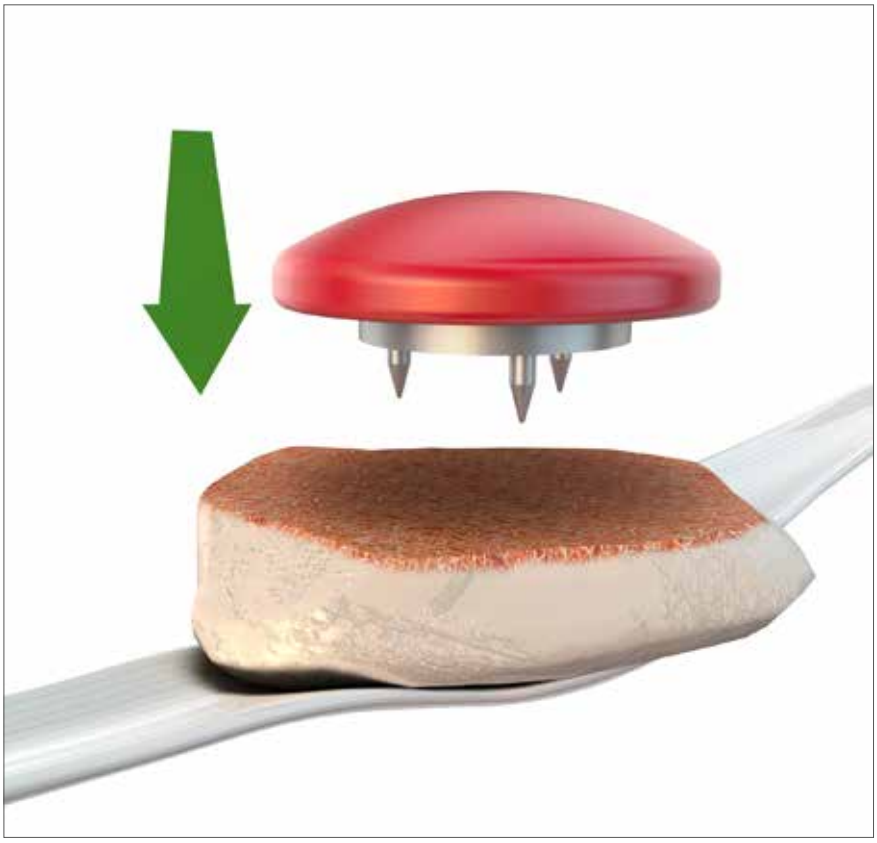
Determining the size and placing the TRIAL Patella

The *TRIAL Patella* is placed on the osteotomy surface to determine the diameter of the PATELLA Cemented. The *TRIAL Patella* that best matches the osteotomy surface is selected for trial implantation. The size of the PATELLA Cemented corresponds to the size of the FEMUR Component.



The *TRIAL Patella Base Plate* is placed on the *Patella Chimney*.

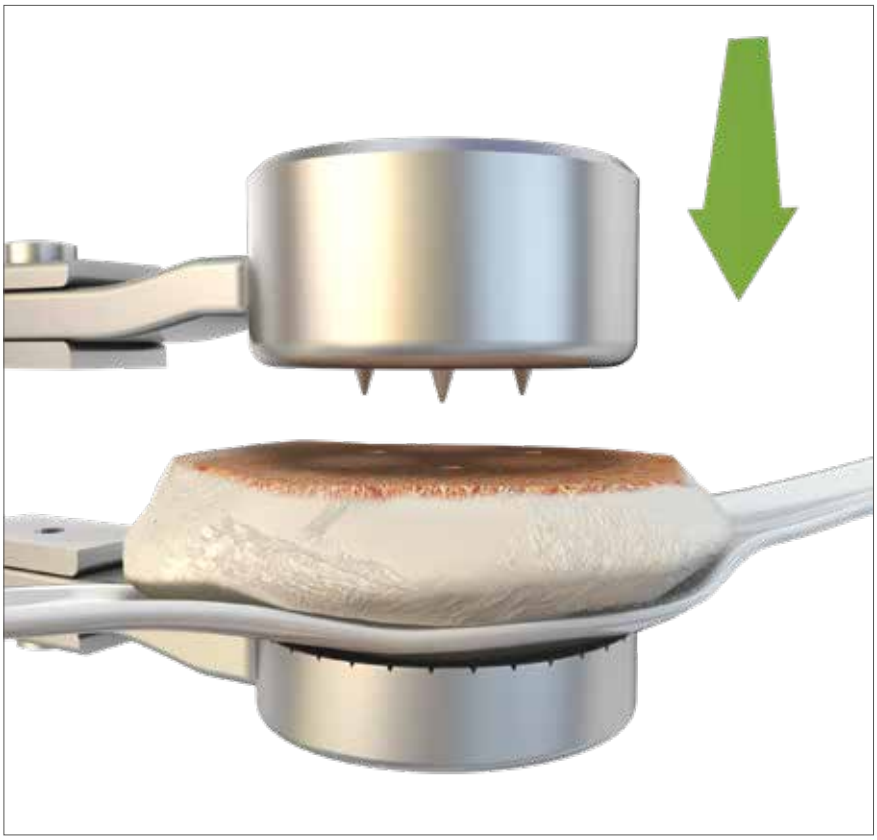
Then the desired *TRIAL Patella* is screwed onto the *TRIAL Patella Base Plate*.



42

Aligning the TRIAL Patella and drilling the fixation holes

The *TRIAL Patella* is aligned on the osteotomy surface of the patella with the *TRIAL Patella Base Plate* and the spikes are pressed into the bone.

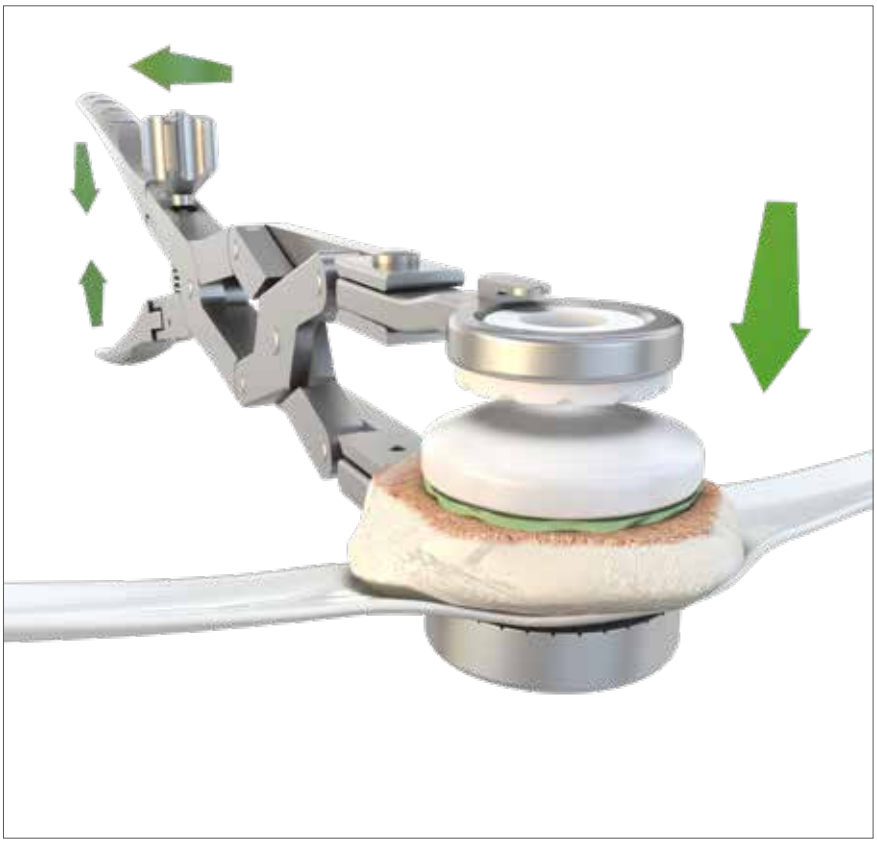


The spikes of the *Drill Jig* are aligned at the same potition as those of the *TRIAL Patella Base Plate.*

9 Patella preparation

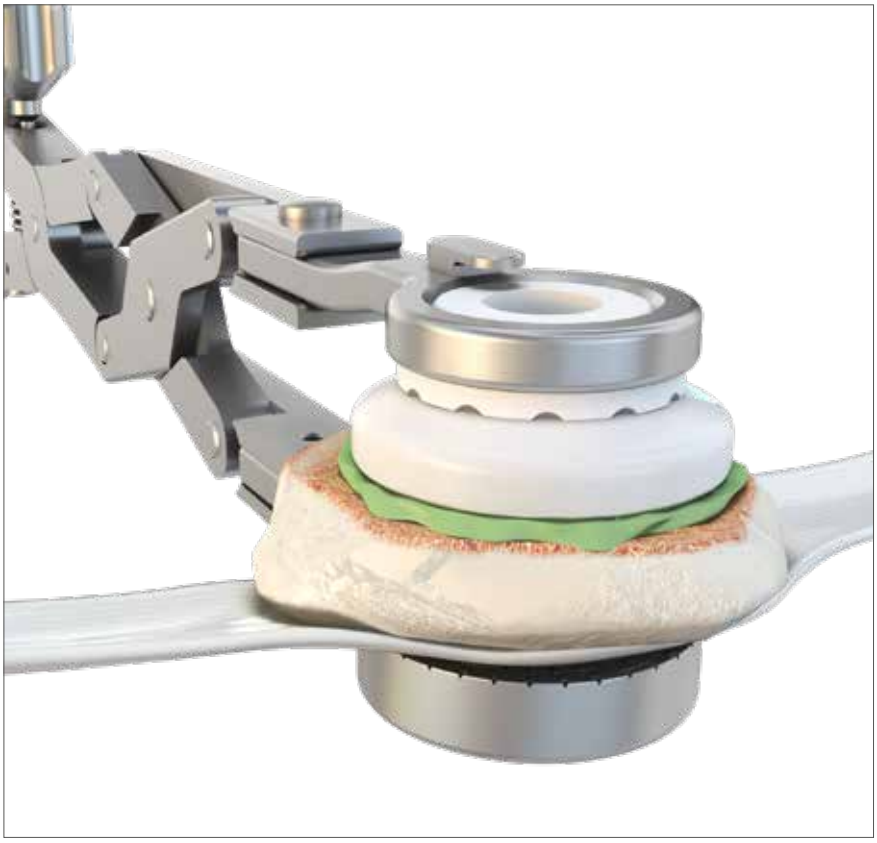
The holes for the pegs of the PATELLA Cemented are prepared with the *Drill for femoral Lugs AO Coupling Size: Ø 6 mm.*

43



Implanting the PATELLA Cemented

The PATELLA Cemented is pressed together with the anterior surface of the patella with the *Parallel compression foreceps modular* and secured with the knurled screw. The patellar implants for the BPK-S Integration system are available for cemented use only.



Any excess cement is removed, and the *Parallel compression foreceps modular* is removed after the cement has hardened.

10 Appendix

BPK-S Integration Ceramic

The ceramic implants of the BPK-S Integration system may be used **only with cement**.

! NOTE

When using bone cement, user information of the cement manufacturer must be observed. Ensure, the implant is fully cemented at the bony site.

Only PE-INSERTS UC Mobile and DD can be used with BPK-S Integration Ceramic. PE-INSERTS UC Fix and SC are not compatible with the CERAMIC TIBIA component.

To avoid metal deposition on ceramic components resulting in third-body wear, ensure that no metal instruments or other metal objects get in contact with the ceramic implants. No metal instruments (forceps, scalpels) may be used to remove excess bone cement.

! NOTE

- When handling ceramic implants, ensure that there is no contact with metallic surgical instruments.
- For the implantation of ceramic implants, only use the special *Impactor/Extractor Ceramic Femoral Component* with mounted *Protectors Impactor/Extractor* or *Impactor Ceramic Tibial Component*.
- Only perform revisions after ceramic-implant-failure with all-ceramic implants.
- If secure anchorage of the all-ceramic implants and/or ligament stable care is not possible, knee arthrodesis may have to be considered.

44

Special Impactor/Extractor CERAMIC FEMUR Component UC

A special *Impactor/Extractor Ceramic Femoral Component* with "Safecoat" coating and applied *Protectors Impactor/Extractor Ceramic Femoral Component* are used to implant the CERAMIC FEMUR Component UC.

Make sure that the FEMUR Component is not oblique in the *Impactor/Extractor Ceramic Femoral Component*, that the jaws are fully engaging the FEMUR Component, and that the screw is hand tight. Before and after every use, inspect the *Impactor/Extractor Ceramic Femoral Component* and verify that its "Safecoat" coating is intact. Residual cement must be removed immediately with a soft (plastic-)instrument. Avoid using sharp instruments for cleaning!

10 Appendix

45

Special Impactor CERAMIC TIBIA Component UC

Use a special *Impactor Ceramic Tibial Component* to implant the CERAMIC TIBIA Component UC.

The sealing ring must be inspected after each operation and before each use.

! NOTE

Ensure to cement the entire TIBIA Component in total, including the distal portion.

Seating the CERAMIC TIBIA Component UC with the *Impactor Ceramic Tibial Component*

Removing the CERAMIC TIBIA Component UC with the *Extractor Ceramic Tibial Component*

Size combinations for FEMUR and TIBIA Components (Primary)

		Tibia size							
		1	2	3	4	5	6	7	8
Femur size	1	■	■	■					
	2	■	■	■	■				
	3		■	■	■	■			
	4			■	■	■	■		
	5				■	■	■	■	
	6						■	■	■
	7						■	■	■

Size combinations for FEMUR Components and PATELLA (Primary)

	Patella	Diameter			
		24	28	32	36
Femur size	1	■	■		
	2	■	■		
	3	■	■	■	
	4	■	■	■	■
	5		■	■	■
	6		■	■	■
	7		■	■	■

! NOTE

Observe possible size combinations of FEMUR/TIBIA/PE-INSERT and PATELLA.

UC and UC/SC implants

1 FEMORAL Component UC Cemented / Cementless
- Sizes 1, 2, 3, 4, 5, 6, 7 left and right

FEMORAL Component UC Ceramic Cemented
- Sizes 3, 4, 5, 6 left and right

2 PE-INSERT UC Fix
- Height 7-17 mm (2 mm increments)

PE-INSERT UC Mobile
- Height 7-17 mm (2 mm increments)

PE-INSERT DD Mobile
- Height 7-17 mm (2 mm increments)

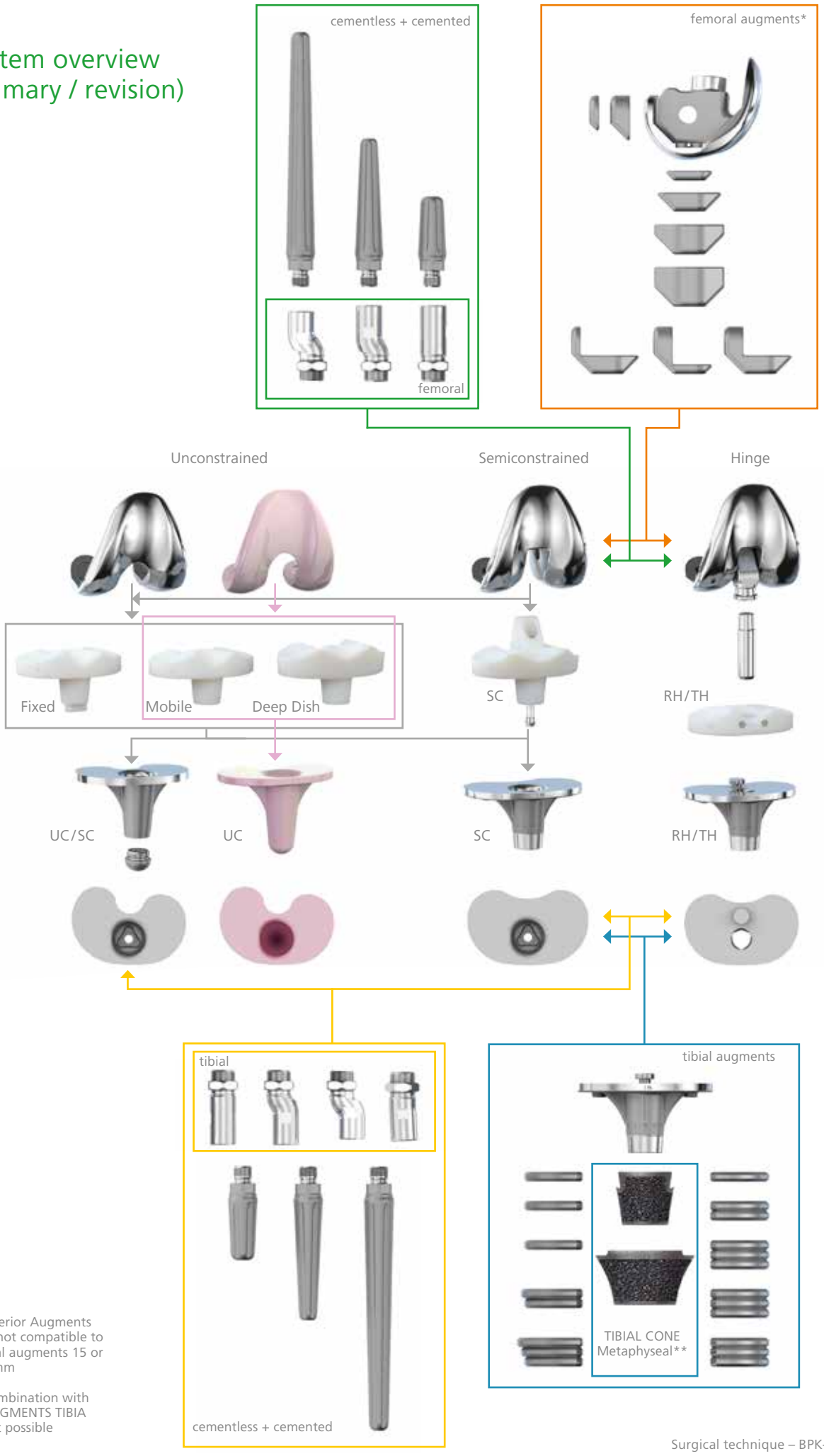
3 TIBIAL Component UC / SC Cemented
- Sizes 1, 2, 3, 4, 5, 6, 7, 8 left and right
- Asymmetrical tibial component
- 3° posterior slope
- With stem coupling

TIBIAL Component UC / SC Cementless
- Sizes 1, 2, 3, 4, 5, 6, 7, 8 left and right
- Asymmetrical tibial component
- 3° posterior slope
- With stem coupling

TIBIAL Component UC Ceramic Cemented
- Sizes 3, 4, 5, 6, 7, 8 left and right
- Asymmetrical tibial component
- 3° posterior slope

4 PATELLA cemented
- Sizes 1, 2, 3, 4, 5, 6, 7
- Ø 24/8 mm, 28/8 mm, 32/8 mm, 36/8 mm

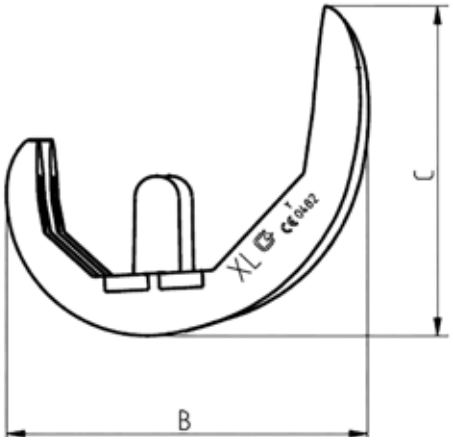
System overview (primary / revision)



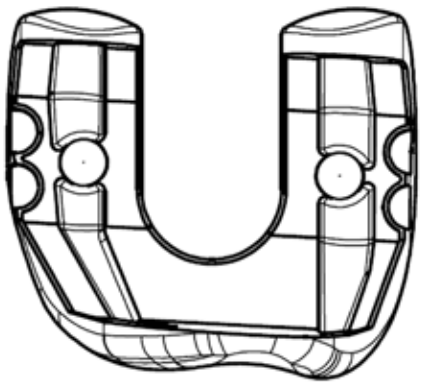
* Posterior Augments are not compatible to distal augments 15 or 20 mm

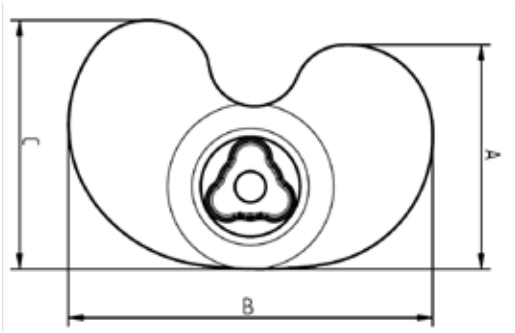
** Combination with AUGMENTS TIBIA not possible

Dimensions – FEMOR and TIBIA Components

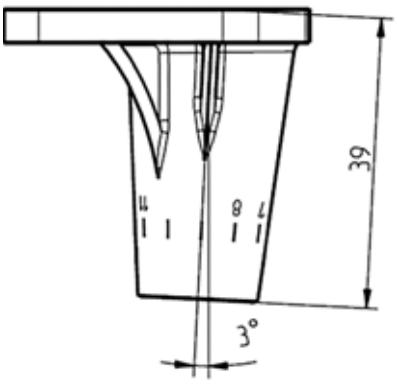


Size	A [mm]	B [mm]	C [mm]
1	55.6	50	45.6
2	58.5	52.6	48
3	61.5	55.4	50.4
4	65.5	59.4	53.6
5	70.8	64.2	57.9
6	77.2	70.2	63
7	83.8	76.5	69





Size	A [mm]	B [mm]	C [mm]
1	36.9	60	40.9
2	38.8	63.2	43
3	41.1	66.5	45.3
4	43.3	70	47.7
5	45.9	74.2	50.5
6	48.6	78.7	53.5
7	51.6	83.4	56.8
8	54.7	88.4	60.2



! NOTE

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