BPK-S INTEGRATION

REVISION KNEE SYSTEM

SURGICAL TECHNIQUE

PETER BREHM
Die Präzision in Titan
für den Menschen

BPK-S Integration

The addition of new implant components has expanded the BPK-S Integration knee system into a comprehensive full system that provides solutions for nearly every initial setting in total knee arthroplasty. The use of stems is required for the fixation of the components of the Semi-Constrained (SC), Rotating Hinge (RH), and Total Hinge (TH) systems. This manual describes the intramedullary implantation technique for the Semi-Constrained (SC) components and for the Rotating Hinge and Total Hinge (RH and TH) components.

The existing Unconstrained (UC) version with the "Fix", "Mobile", and "Deep Dish" insert options has been expanded to include the Semi-Constrained (SC) design. The sizing of the intercondylar spine and cam mechanism provides posterior stabilization (PS) as well as varus/valgus stabilization.

Rotating or Total Hinge (RH, TH) designs are also available with two knee axis versions to address high-grade instability. Their coupling pin has a modular design that avoids the need to distract the joint during implantation and later removal should it become necessary. It is securely tightened to a defined torque of 25Nm during implantation. Appropriate instruments for separating the system components are available for implant removal.
It is the surgeon's responsibility to select the appropriate degree of constraint according to the initial ligament situation and joint stability.

In order to provide the surgeon with the greatest possible intraoperative flexibility, all femoral components (primary and revision) have been designed for a single uniform osteotomy and have a uniform outer contour.

This means that primary and revision components can be combined rather freely so as to adapt the system to the specific bone and soft-tissue situation.

A number of augment options are available for filling bone defects. Distal and/or posterior femoral defects of up to 10 mm can be managed with augments. Tibial augmentation up to a height of 15 mm is possible. Augments of different sizes can be freely combined. This enables to adapt the cortical bearing surface with a tapered, proximally widening structure.

A broad selection of stem designs ensures stable fixation in the bone:

- Cemented stems (Co28Cr6Mo) are available in diameters 10 - 22 mm (2 mm increments), each in the lengths 40, 80, and 140 mm.
- Cementless stems (Ti6Al4V) are available in diameter 13 - 22 mm (1 mm increments) in the lengths 40, 80, and 140 mm as well as stem diameters 23, 24 and 25 mm in the lengths 40 and 80 mm.
- All stems can be combined with both the tibial and femoral components.

The stems are connected with the aid of an adapter. A 4 mm offset and a 3° version are available in addition to the 0 mm adapter to adapt the implant to the patient's specific anatomy. Their alignment is continuously adjustable through 360°.

The screw connections between the femoral and tibial components and the adapter and stem are tightened to a defined torque of 25Nm.

Indications and Contraindications

Indications
- Congenital or acquired knee joint defects/deformation which necessitate the implantation of a knee joint replacement
- Defects or malfunction of the knee joint
- Degenerative, rheumatic, post-traumatic arthritis/arthrosis
- Symptomatic knee instability
- Reconstruction of flexibility

Additional indication for components of this system made of ceramic
- Patients with material hypersensitivity

Expanded range of indications for Semi-Constrained (SC) compared to the primary system
- Femoral and/or tibial bone loss (femoral up to 10 mm, tibial up to 15 mm)
- Insufficiency of the collateral ligament apparatus with severe leg-axis deformity and intact capsular structure
- Valgus malposition up to 25° with overstretching of the medial ligament structures
- Varus malposition up to 30° and flexing contractures up to 20°
- Extension/flexion gap ratio which cannot be ideally balanced

Additional indications for Rotating and Total Hinge (RH/TH)
- Loss of collateral ligaments
- Genu recurvatum
- Knee stiffening
- Severe deformities of the knee joint

Contra-indications
- Illnesses which can be treated without using a knee joint implant
- Acute or chronic infections near the implantation
- Systemic diseases and metabolic disorders
- Serious osteoporosis
- Serious damage to the bone and soft tissue structures which impedes stable anchoring and joint function
- Diseases that impair bone growth such as cancer, renal dialysis, osteopenia, etc.
- Bone tumors in the area of the implant anchoring
- Obesity or overweight of the patient
- Overload of the knee implant to be expected
- Abuse of medication, drug abuse, alcoholism or mental disease
- Lack of patient cooperation
- Sensitivity to foreign matter in the implant materials
- Pregnancy

Contra-indications for Semi-Constrained (SC)
- Loss of the collateral ligaments or non-intact capsular apparatus

Contra-indications for Rotating and Total Hinge (RH/TH)
- Insufficient capsular apparatus

In cases in which an implantation is considered medically necessary despite a contra-indication described above or in young and active patients, observe the following:
- The load capacity of the fixation and the materials used is limited
- Contra-indications must be reduced as far as possible

Overview

Preoperative Planning

Tibia: Alignment, Resection and Preparation

SC	Assembling the Trial Tibial Components	RH / TH
	Trial Tibial Augments	
	Assembling the Stem and Adapter for the Trial Tibial Components	
SC	Placing the Trial Tibial Components	RH / TH

Femur: Alignment and Resection

	Assembling the Trial Femoral Component	
	Assembling the Stem and Adapter for the Trial Femoral Component	
	Placing the Trial Femoral Component	
SC	Assembling/Disassembling the Trial Insert	RH / TH
SC	Placing the Trial Insert/Trial Reduction	RH / TH
SC	Removing the Trial Components	RH / TH

Assembling the Definitive Components

	Assembling the Stem and Adapter for the Final Tibial Component	
	Tightening the Tibial Component	
	Assembling the Tibial Impactor	
SC	Assembling the Final Femoral Components	RH / TH
	Final Femoral Augments	
	Assembling the Stem and Adapter for the Final Femoral Component	
	Tightening the Femoral Component	
	Assembling the Femoral Impactor	
SC	Placing the Final Implants	RH / TH

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I Preoperative Planning

Preoperative Planning

The most important goals in revision total knee arthroplasty are restoration of the desired alignment with the components in correct rotation, functional stability of the knee, preservation of the function of the extensor mechanism, 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 supplemented by a full-length standard view of the lower limb. Preoperative radiographs as well as radiographs of the contralateral side, which may not have had previous surgery, should also be consulted.

Allowing for correct axial alignment of the stem within the medullary canal, one can use the lateral radiographs to estimate the size of the femoral component for the reconstruction of the posterior femoral offset and to determine whether posterior augments are indicated for this size of component. Selecting a shorter stem and choosing a posterior point of entry into the medullary canal can shift the femoral component back from an overly anterior position and correct an excessively wide joint space in flexion. Planning the correct position of the femoral joint line is often difficult. The measurements relative to the various landmarks that are discussed in the literature have the obvious disadvantage of varying greatly depending on size and gender. Certain groups of authors have proposed formulas for calculating the distance from various landmarks to the joint line which have the advantage of allowing for size and gender-specific differences among patients. [1, 2]. The goal for restoring the joint line for the best possible functional results is specified in the literature as a range of ±4 mm [3]. Appropriate distal augments are available for restoring the joint line.

Similar information applies to planning the tibial component. Allowing for the axis of the stem, one can estimate the required component size and the necessity of an offset in both planes. The osteotomy planes can be planned and the necessity of medial and lateral augments to restore the tibial joint line can be estimated.

NOTE: In the tibia, one must allow for the thickness of the plateau (3 mm) and the minimal height of the insert (7 mm with UC or SC or 9 mm with RH or TH).

The distal thickness of the condyles of the BKS Integration (UC, SC und RH/TH) femoral components is 9 mm. Therefore a precut of about 9 mm is required in the femur when using an intramedullary technique in a primary procedure.

[1] Maderbacher G. et al.: Accuracy of bony landmarks for restoring the natural joint line in Revision Knee Surgery: an MRI Study. Int Orthop. 2014 Jun; 38(6): 1173-81
[2] Servien E et al. Reliability of bony landmarks for restoration of the joint line in revision knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2008 Mar; 16(3):263-9
[3] Hofmann AA et al.: Clinical and radiographic analysis of accurate restoration of the joint line in revision total knee arthroplasty. Clin Orthop Relat Res 2006

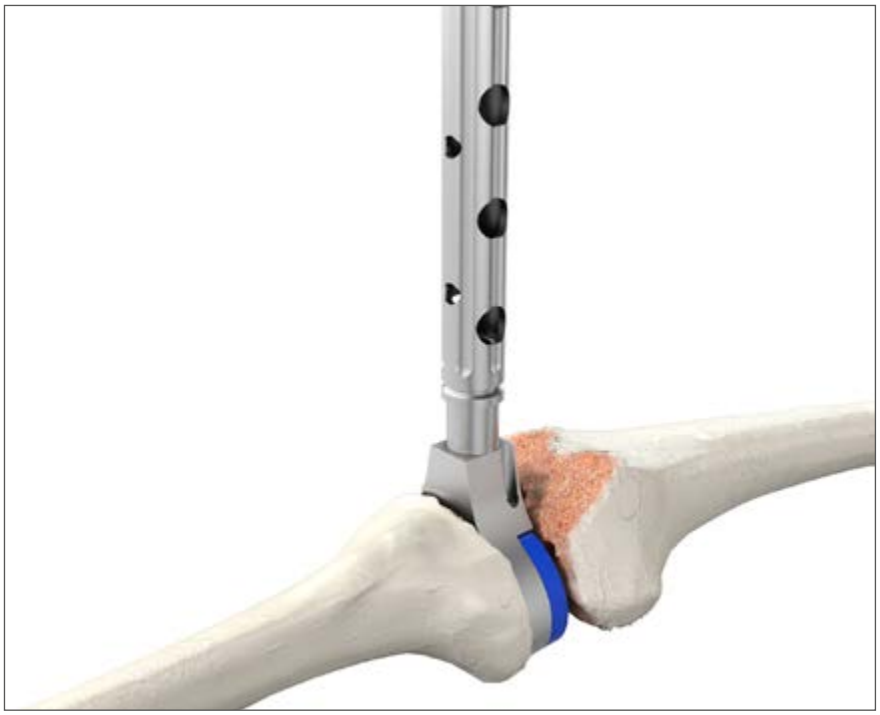
1.1 Determining the Joint Line

Evaluating Joint Space in Extension and Flexion

Before the implant components requiring revision are removed, a comparison can be made with the *Femoral Sizing Templates* or the *TRIAL FEMORAL Components SC/RH/TH* to determine the size of the femoral component.

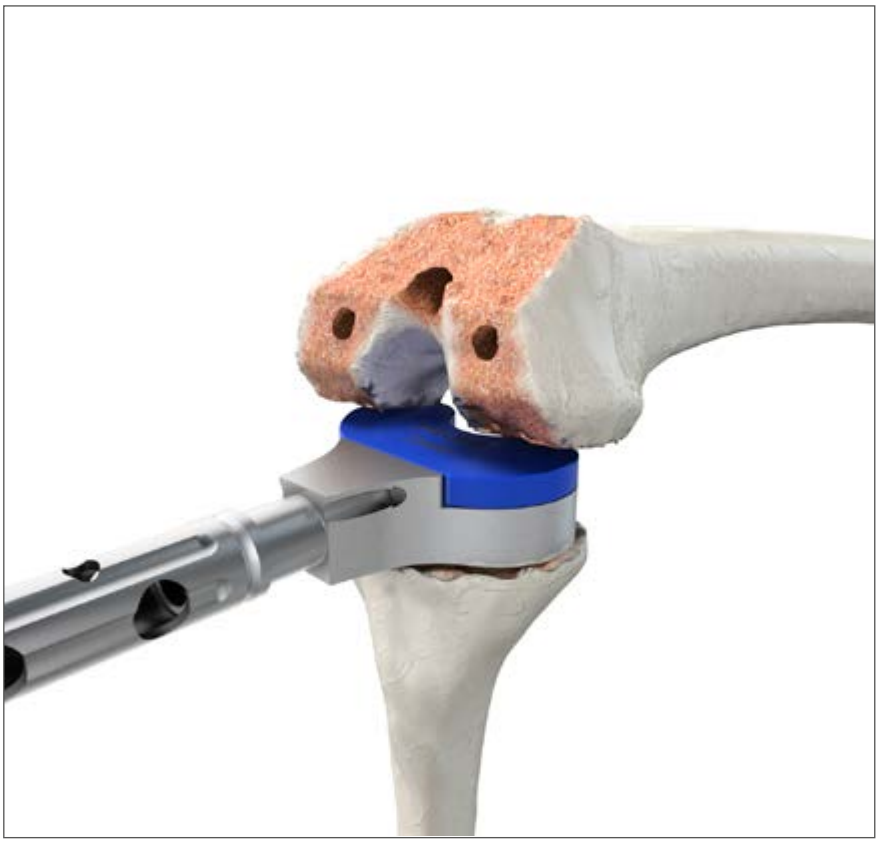
01

After the primary components have been removed, the surgeon estimates the required height of the entire implant construct (Tibial Component + Femoral Component + PE Insert) with the aid of spacer blocks and determines whether joint space in extension and flexion is poorly balanced.



! NOTE

Be sure to use the proper right or left version of the flexion spacer.



1.1 Determining the Joint Line

Opening the Tibia

02

The tibial medullary canal is opened in accordance with preoperative planning and reamed with *Rasps* of successively larger diameters until cortical bone is reached.

The *Rasps* are inserted with the *Handle* as far as the "L" marking; one may expect approximately 10 mm of tibial bone loss.

03

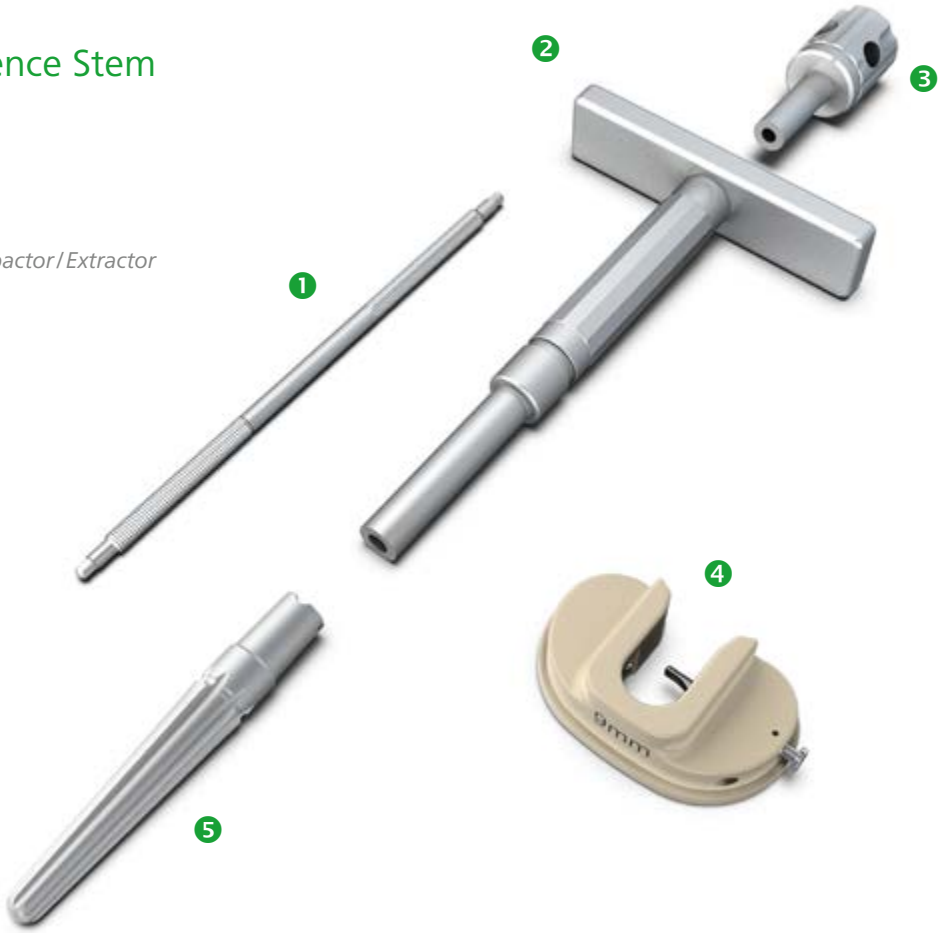
The *Rasps* are used to achieve stable seating for the *Reference Stem straight*. This stem is required for precise axial alignment.

1.1 Determining the Joint Line

Preparing the Reference Stem

04

1. *Guiding Rod*
2. *Handle of the Prosthesis Impactor / Extractor*
3. *Knurled Screw S*
4. *Tibial Joint Line Plate*
5. *Reference Stem straight*



05

Depth is measured using the pre-assembled *Tibial Reference Stem straight* .

Unsecured

Secured

1.1 Determining the Joint Line

Reconstructing the Tibial Joint Line

06

Next the *Reference Stem straight* is impacted with the *Tibial Joint Line Plate* so that the joint line is in the desired position. Where bone defects are present, there may be a gap between the joint line plate and the tibia.

The following reference points will aid in restoring the joint line:

- Approximately 15 - 20 mm proximal to the fibular head
- Plane of the tibial osteotomy for the previous prosthesis
- Level of the patella

Choosing a different stem diameter can change the position of the joint line.

! NOTE

A change of 1 mm in diameter corresponds to about a 1-2 cm change in position (height) depending on bone quality.

! NOTE

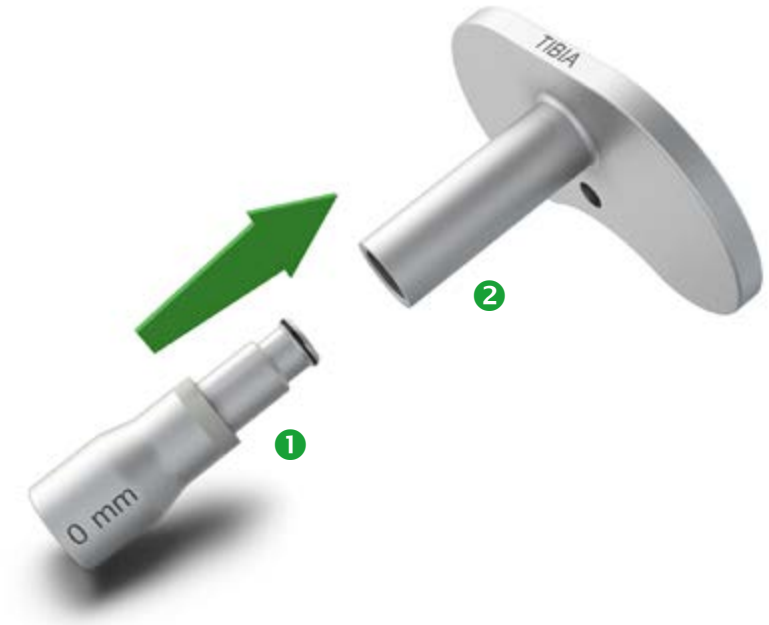
- Stable fixation of the stem is important
- Based on the natural anatomy, the implant system requires a tibial resection of 10 mm (SC) or 12 mm (RH) for the tibial plateau and insert (tibial plateau 3 mm, plus the insert height of 7 mm (SC) or 9 mm (RH)).

1.1 Determining the Joint Line

Assembling and Placing the Tibial Reference Plate

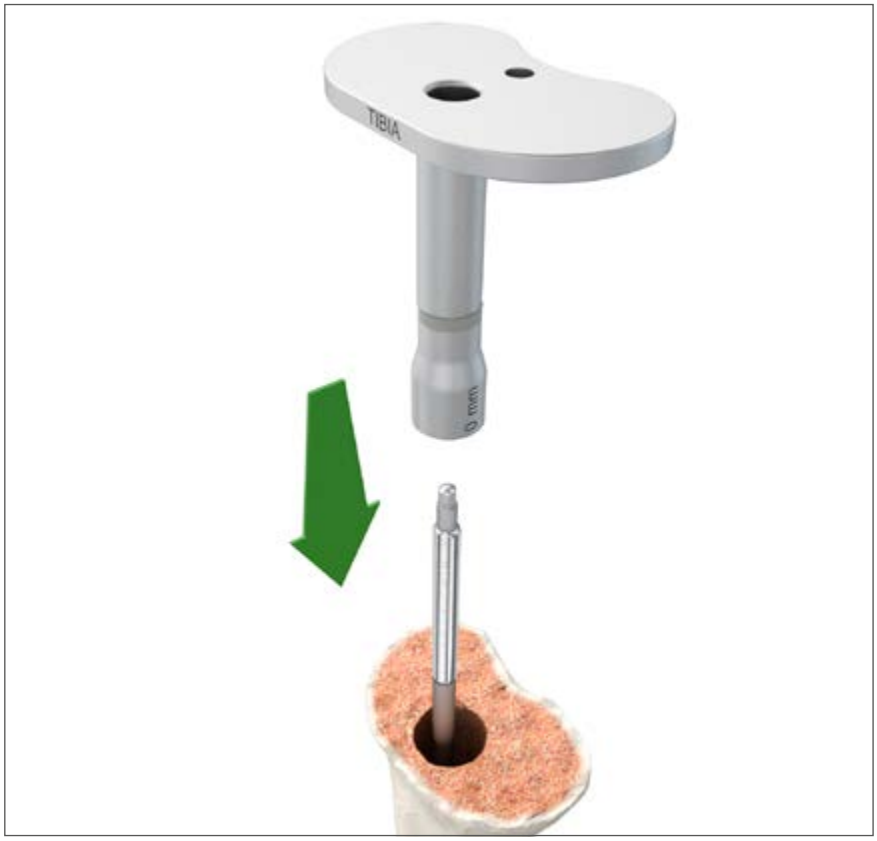
07

The first step is to assemble the *Tibial Reference Plate*. To do this, the *Extension Sleeve 0 mm* (❶) is screwed all the way into the *Tibial Reference Plate* (❷). The end of the threading must allow for some clearance.



08

Next the assembled *Tibial Reference Plate* is slid over the *Guiding Rod* onto the *Reference Stem straight*, and the *Guiding Rod* is then unscrewed with the *Socket Wrench SW3.5*.



1.1 Determining the Joint Line

Assembling and Placing the Tibial Reference Plate

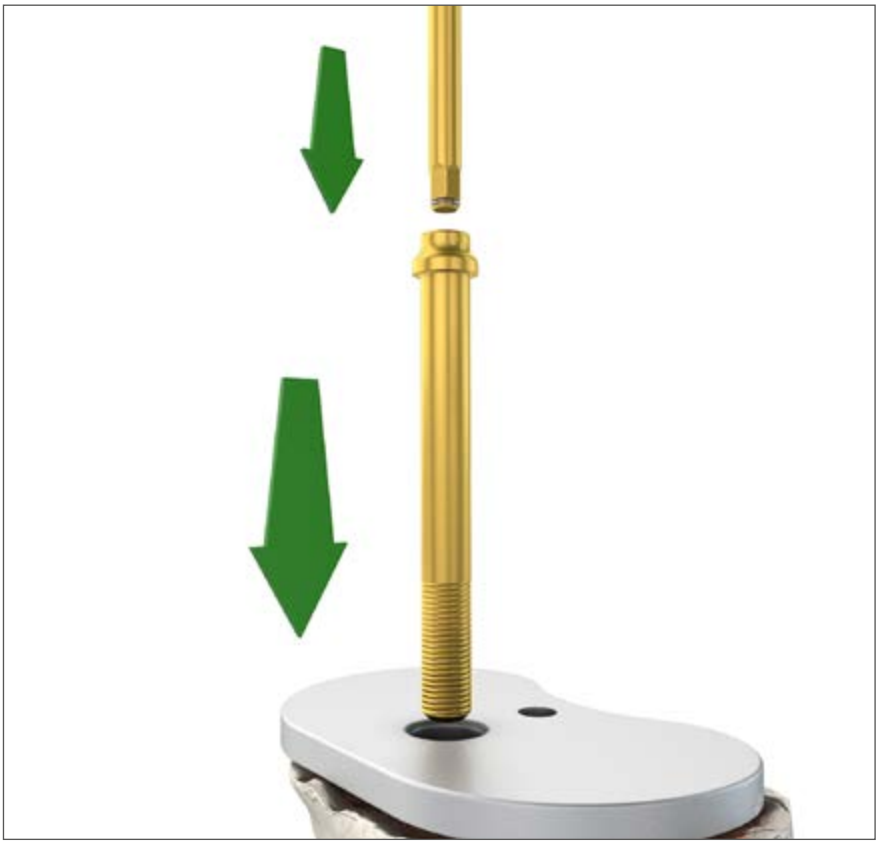
09

For correct position with respect to the joint line, the *Extension Sleeve 0 mm* must be seated on the taper of the *Reference Stem straight*.

10

The plateau is attached to the stem by hand tightening the *Clamp Screw M6/0mm*.

The rotational alignment of the plateau is unimportant at this stage.



1.1 Determining the Joint Line

Opening the Femur

11

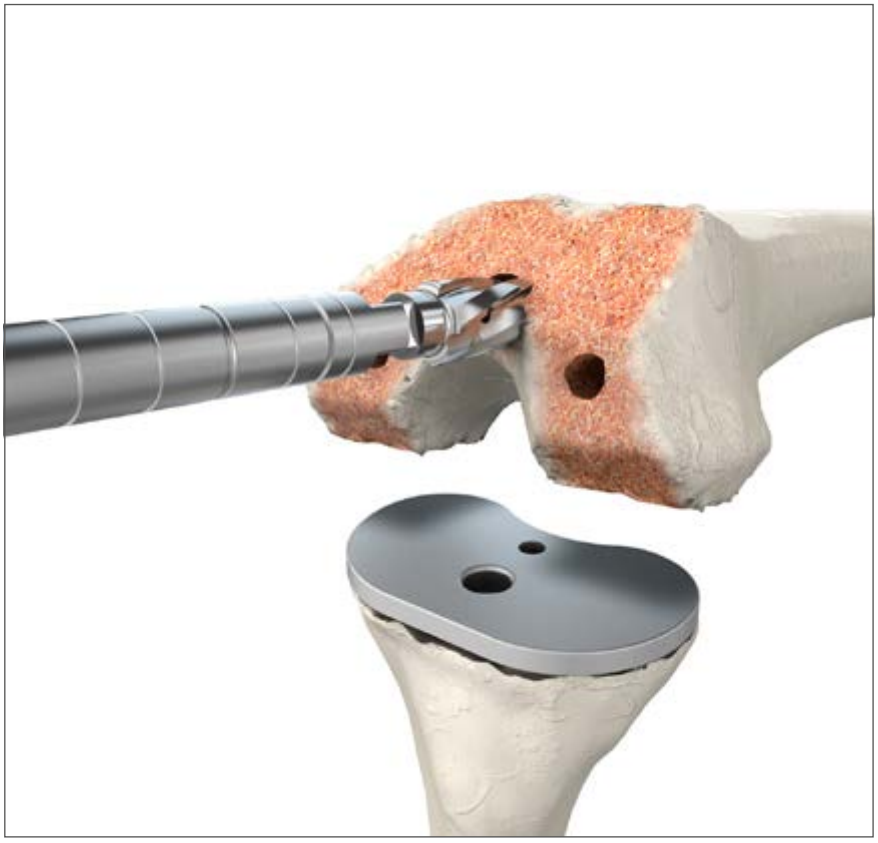
The distal femur is opened and reamed according to preoperative planning. Distinctive anatomic features such as the curvature of the femur must be taken into account.

The femoral canal is reamed with *Rasps* of successively larger diameters until cortical bone is reached.

The *Rasps* are inserted with the *Handle* as far as the "L" marking; one may expect approximately 10 mm of femoral bone loss.

12

The *Rasps* are used to achieve stable seating for the *Reference Stem straight*. This stem is required for precise axial alignment.



1.1 Determining the Joint Line

Opening the Femur

13

Depth is measured using the pre-assembled femoral *Reference Stem straight*.

WARNING

Transposing the right / left variants on / of instruments:

- Risk of implant failure!
- ➲ Observe the right/left variants.

14

After the *Femoral Joint Line Plate* is attached to the *Handle of the Prosthesis Impactor / Extractor*, it is secured with the pin.

Unsecured

Secured

The *Femoral Joint Line Plate* is turned on the *Handle of the Prosthesis Impactor / Extractor* so that the correct side label (R/L) is visible from above in the impacting position.

1.1 Determining the Joint Line

Reconstructing the Femoral Joint Line

15

Next the *Reference Stem straight* is placed with the *Femoral Joint Line Plate* so that the joint line is in the desired position. Where bone defects are present, there may be a gap between the *Joint Line Plate* and the femur.

The following reference points will aid in restoring the joint line:

- Approximately 25 - 30 mm distal to the medial epicondyle
- Allow for the thickness of the revision implant
- Level of the patella

Choosing a different stem diameter can change the position of the joint line.

! NOTE

A change of 1 mm in diameter corresponds to about a 1-2 cm change in position (height) depending on bone quality.

! NOTE

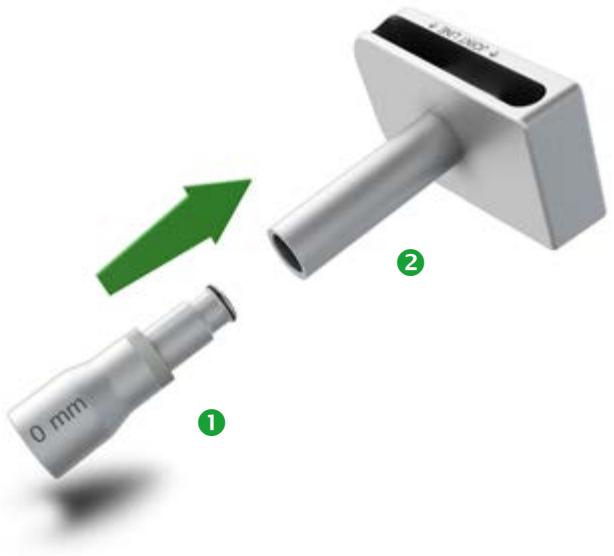
The distal vertex of the *Joint Line Plate* corresponds to the femoral joint line.

1.1 Determining the Joint Line

Assembling and Placing the Femoral Valgus Plate 6°

16

The *Femoral Valgus Plate 6°* is assembled in the same manner as the *Tibial Reference Plate*. To do this, the *Extension Sleeve 0 mm* (❶) is screwed all the way into the *Femoral Valgus Plate 6°* (❷). The end of the threading must allow for some clearance.



WARNING

Transposing the right / left variants on / of instruments:

- Risk of implant failure!
- ➲ Observe the right/left variants.

17

Next the assembled *Femoral Valgus Plate 6°* is slid over the *Guiding Rod* onto the *Refernce Stem straight*, and the *Guiding Rod* is then unscrewed with the *Socket Wrench SW3,5*.

! NOTE

I The upper edge must be parallel to the axis of the epicondyles.

For correct position with respect to the joint line, the *Extension Sleeve 0 mm* must be seated on the taper of the *Reference Steam straight*.

18

The *Femoral Valgus Plate 6°* is attached to the *Reference Steam straight* by hand tightening the *Clamp Screw M6/0mm*.

1.1 Determining the Joint Line

Evaluating Extension Space

19

Joint space in extension can be determined with the S*pacer (7 mm* (SC only), *9 -17 mm* (SC/RH/TH) *19 - 25 mm* (RH/TH only)).

! NOTE

- Extension space can be adjusted by up to ±4 mm during the further course of the surgical procedure to shift the femoral joint line.
- If extension space is too narrow, the position of the femoral and tibial stems must be evaluated and changed if necessary.

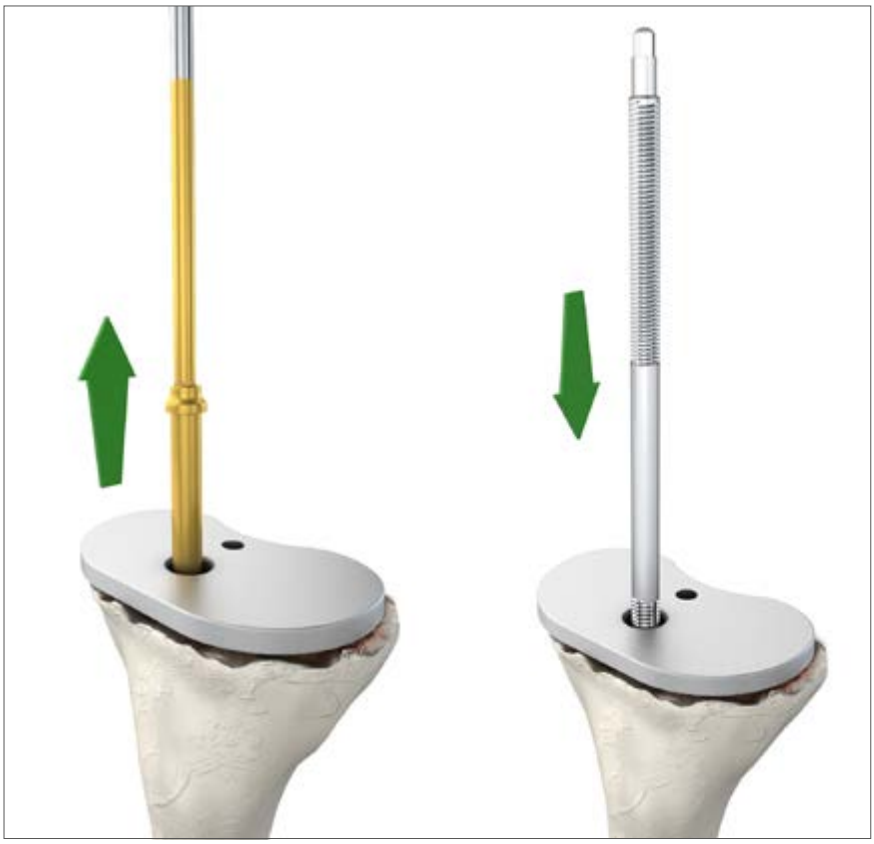
The joint line is located at the level of the marked edge on the *Femoral Valgus Plate 6°*.

2.1 Tibia: Alignment, Resection, and Preparation

Preparing the Tibial Resection

20

The *Tibial Reference Plate* must be removed before the tibial cutting block can be placed. This is done by unscrewing the gold *Clamp Screw M6/0 mm*. The *Guiding Rod* is screwed into the *Reference Stem straight* and the *Handle* is screwed into the *Tibial Reference Plate*. Then the *Tibial Reference Plate* can be removed.



The *Femoral Valgus Plate 6°* is removed as well. This requires unscrewing the *Clamp Screw M10 mm* with the *Socket Head Wrench SW5/SW3.5* and then removing the *Femoral Valgus Plate 6°*.

2.1 Tibia: Alignment, Resection, and Preparation

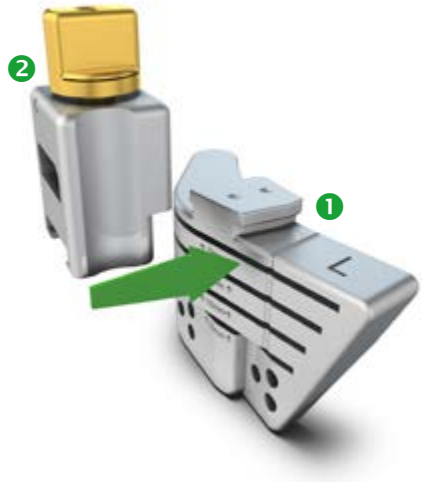
Assembling the Tibial Resection Guide

21

In order to attach the tibial cutting block conector, the *Extension Sleeve 0 mm* (❶) is screwed all the way into the *Outrigger for Tibial Resection Block Guide SC/RH/TH* (❷). The end of the threading must allow for some clearance.

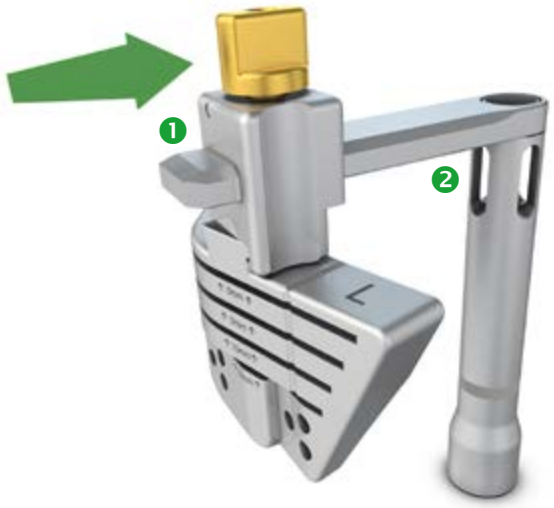
22

The *Tibial Cutting Block Adapter SC/RH/TH* (❷) is then attached to the *Tibial Cutting Block Adapter Anatomic SC/RH/TH* (right or left) (❶).



23

The assembled *Tibial Cutting Block Adapter Anatomic SC/RH/TH* (right or left) (❶) is slid onto the *Outrigger for Tibial Resection Block Guide SC/RH/TH* (❷). The position of the resection guide is then secured with the gold screw.



2.1 Tibia: Alignment, Resection, and Preparation

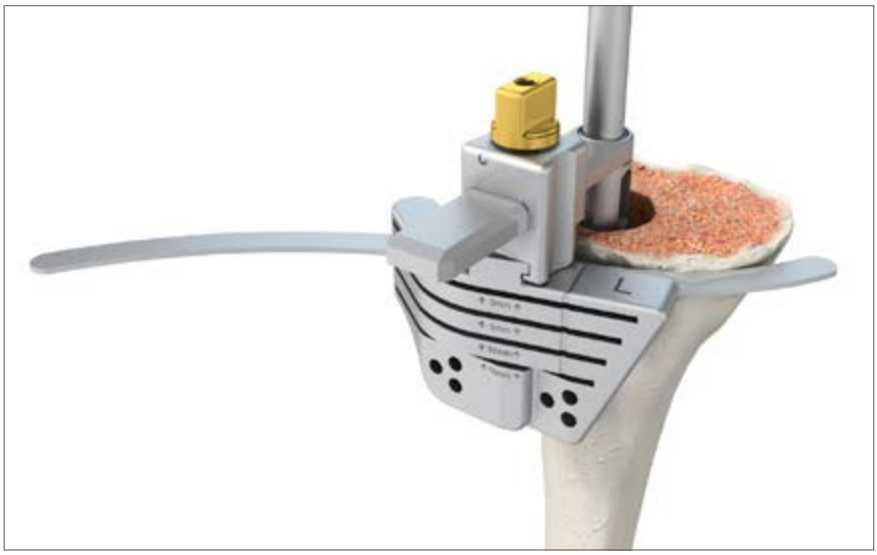
Placing the Resection Guide and Verifying the Osteotomies

24

Next the assembled *Cutting Block* is inserted over the *Guiding Rod* and secured with the *Clamp Sleeve* and *Clamp Screw*. The *Flat Wrench SW14* can be used for this purpose. Then slide the cutting block onto the bone and secure it with the gold screw.

25

The tibial osteotomy including any necessary augments is then verified using the *Visualisation Guide S*. The tibial slope is 0°.



! NOTE

The maximum tibial augmentation height of 15 mm can be achieved using 5 mm medial and lateral augments. Augments of different sizes can be combined as needed.

2.1 Tibia: Alignment, Resection, and Preparation

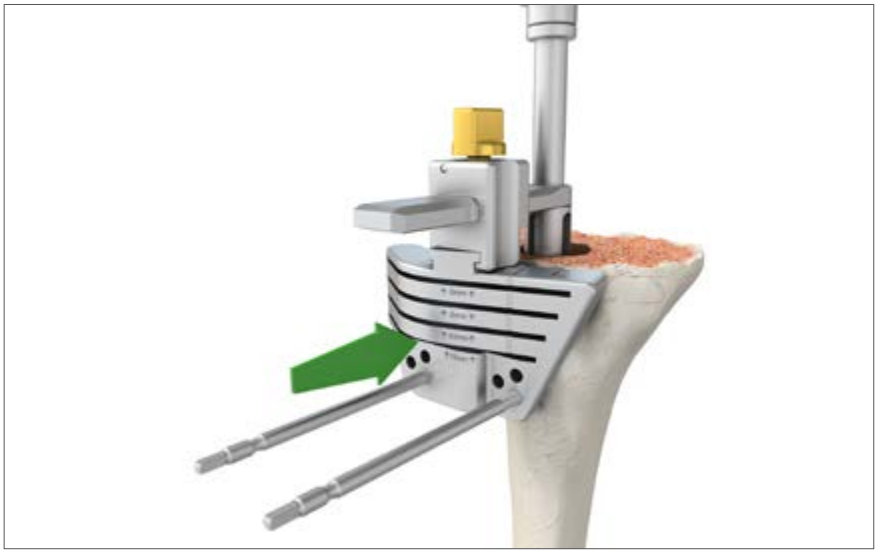
Fixing the Tibial Cutting Block, Performing the Resection

26

The *Tibial Cutting Block Anatomic SC/RH/TH* (right or left) is secured in the desired position by two par *Pins Ø 3.15 x 70 mm with Corticalis Thread.*

! NOTE

Using the lowest pair of holes will allow you to later change the position of the cutting block by 2.5 or 5 mm.

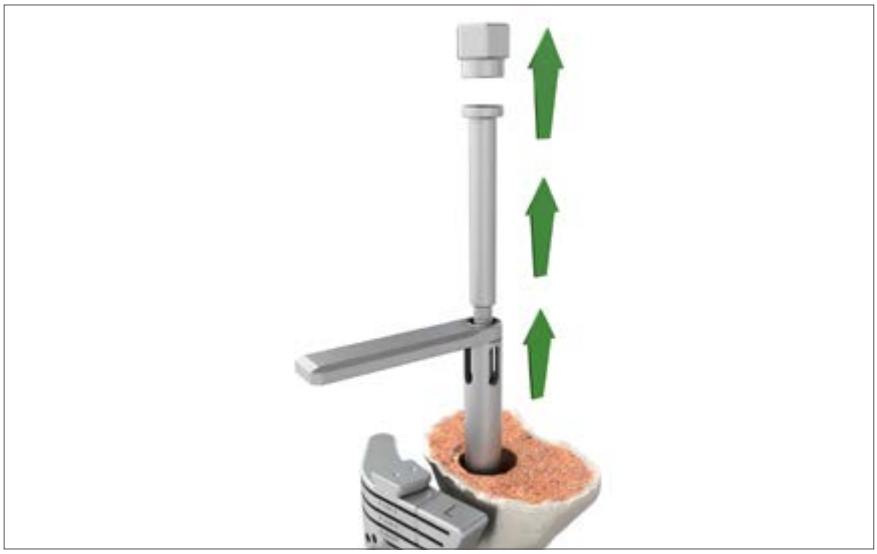


27

The *Clamping Screw* is unsecured and only the *Tibial Sawing Guide Adapter SC/RH/TH* is removed.

28

Then the *Clamp Screw* is unscrewed and removed. *Clamp Sleeve*, *Outrigger for Tibial Resection Block Guide SC/RH/TH* and *Guiding Rod* are then removed.



2.1 Tibia: Alignment, Resection, and Preparation

Fixing the Tibial Cutting Block, Performing the Resection

29

Now the osteotomy is performed. The *Reference Stem straight* can remain in the medullary cavity for this step.

! NOTE

Only saw blades from PETER BREHM GmbH with a thickness of 1.18 mm ±0.01 mm may be used for the osteotomy.

2.1 Tibia: Alignment, Resection, and Preparation

Determining the Size of the Tibial Component

30

The size can be determined by templating the *Tibial Base Plate*. The goal is to maximize cortical contact. If the resection allowed for augments, then *TRIAL AUGMENTS Tibial* must be attached to the underside of the *Tibial Base Plate* and secured with *Augment Locks*.

! NOTE

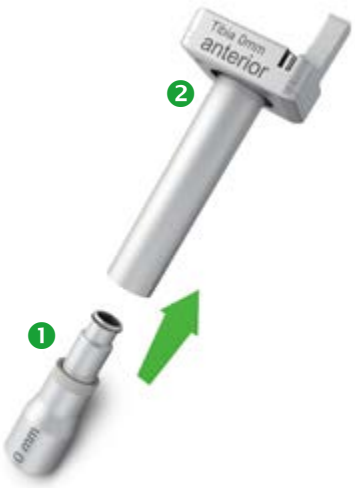
Augments can be combined as needed with any tibial components to achieve optimal cortical contact.

2.1 Tibia: Alignment, Resection, and Preparation

Assembling the Tibial Base Plate

31

The first step is to connect the *Tibial Adapter straight*/*Tibial Adapter 4 mm Offset* to the *Extension Sleeve 0 mm*. To do this, the *Extension Sleeve 0 mm* (❶) is screwed fully into the *Tibial Adapter straight* or *Tibial Adapter 4 mm Offset* (❷). The end of the threading must allow for some clearance.

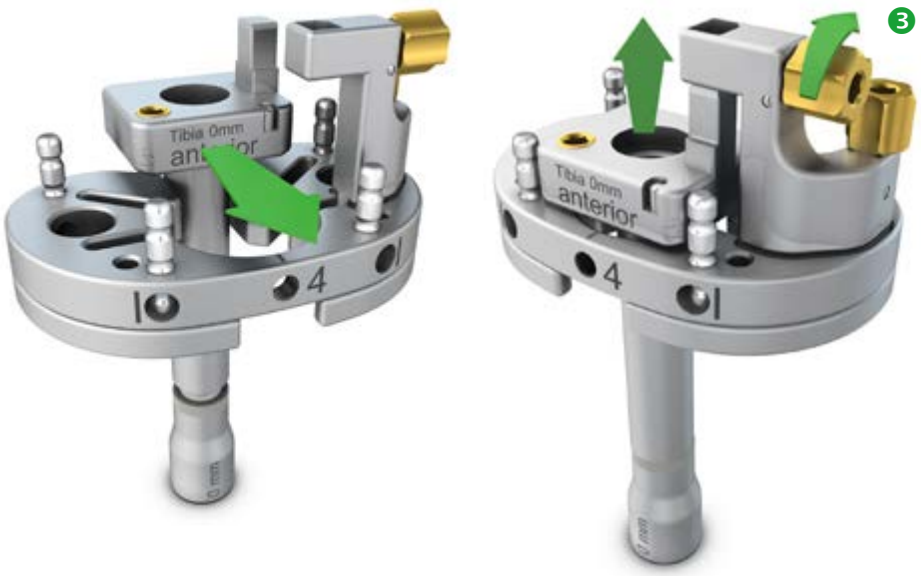


32

The *Adapter for Tibial Base Plate* is secured to the top of the *Tibial Base Plate*.

33

The last step is to insert the adapter into the *Tibial Base Plate* and secure it with the gold screw (❸) on the side.

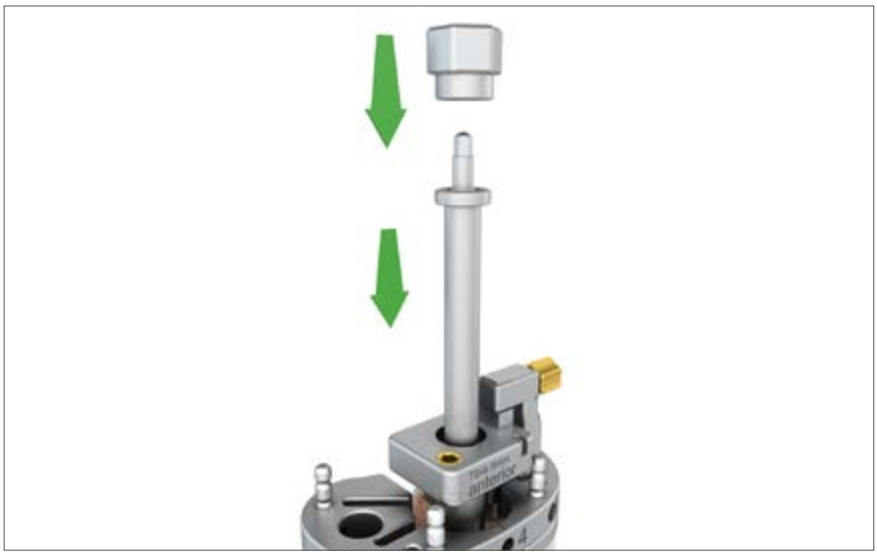


2.1 Tibia: Alignment, Resection, and Preparation

Placing the Tibial Base Plate

34

The assembled *Tibial Base Plate* is inserted over the screwed-in *Guiding Rod* and secured to the *Reference Stem straight* with the *Clamping Sleeve* and *Clamp Screw*.



35

❶ *Tibial Adapter straight*
❷ *Tibial Adapter 4 mm Offset*

! NOTE

If optimal cortical contact for the tibial plateau cannot be achieved with the *Tibial Adapter straight*, then the *Tibial Adapter 4 mm Offset* will have to be used instead.

2.1 Tibia: Alignment, Resection, and Preparation

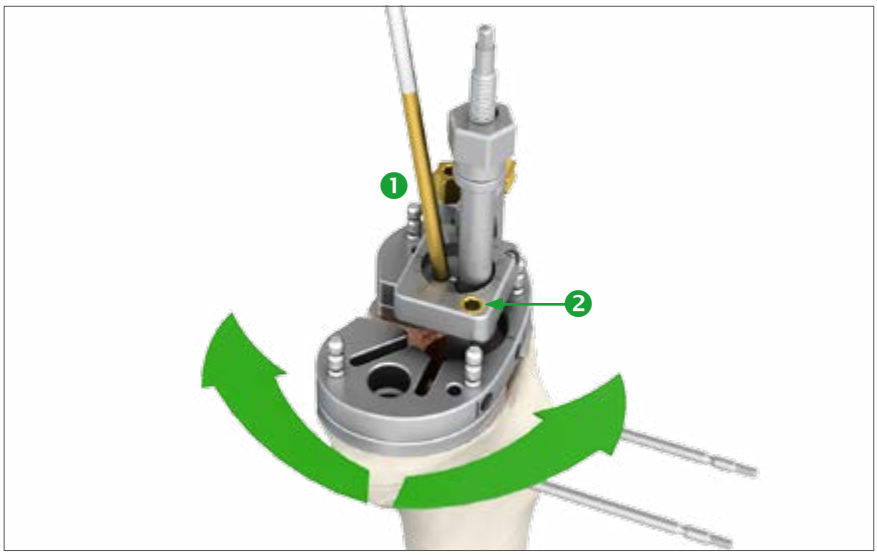
Adjusting the Tibial Adapter 4 mm Offset

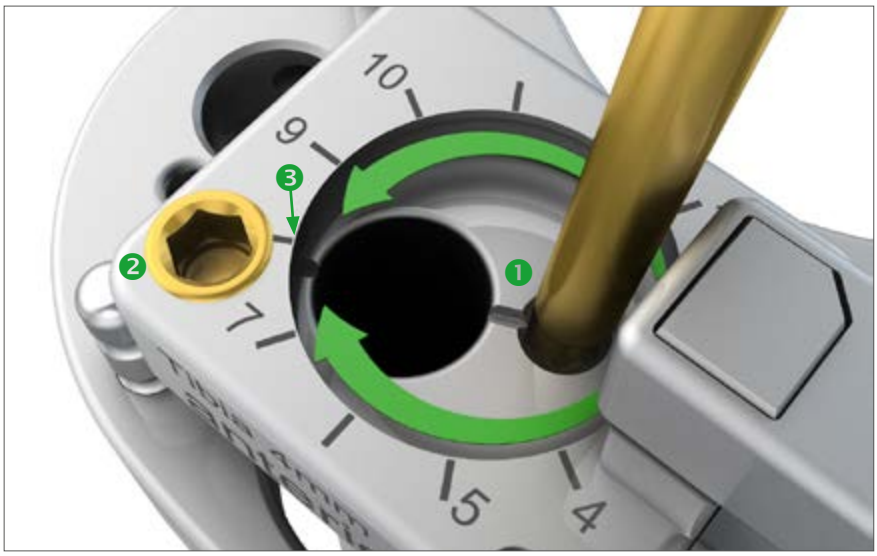
36

To change the position of the *Tibial Base Plate* when using the *Tibial Adapter 4 mm Offset*, use the gold *Socket Head Wrench SW3.5* to release the offset locking screw (❷).

Turn the rotational flange (❶) to bring the *Tibial Base Plate* into optimal alignment with the cortex. This position is locked by tightening the locking screw (❷).

The setting of the *Tibial Adapter 4 mm Offset* can be read from the marking (❸) and reliably transferred to the final implant later in the procedure.



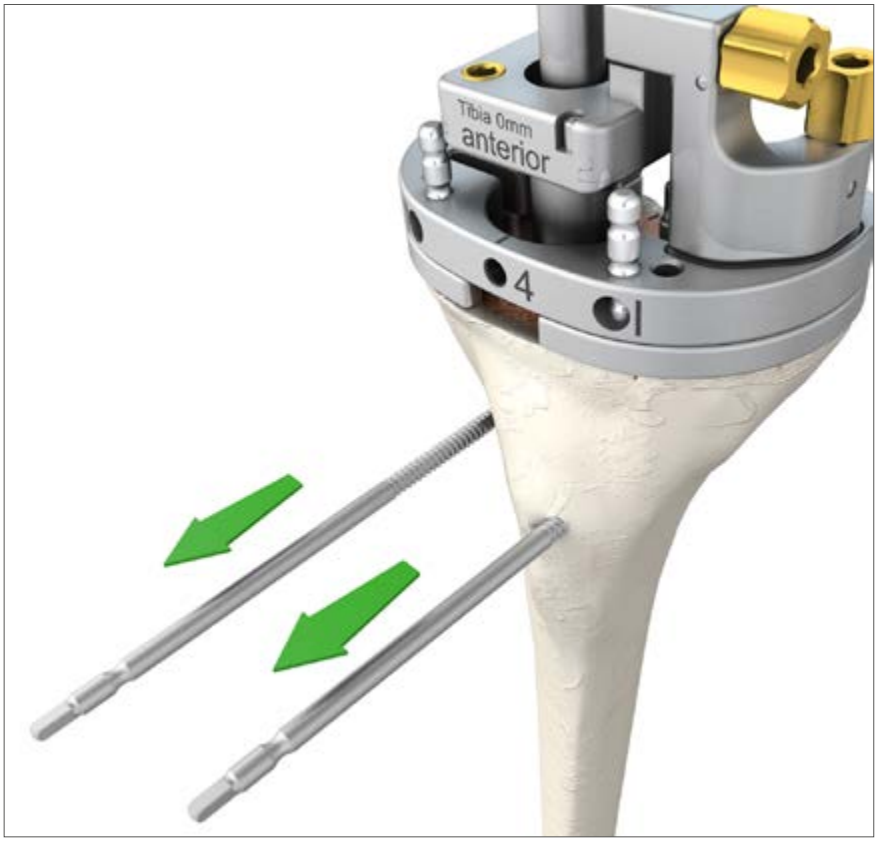


2.1 Tibia: Alignment, Resection, and Preparation

Fixation of the Tibial Base

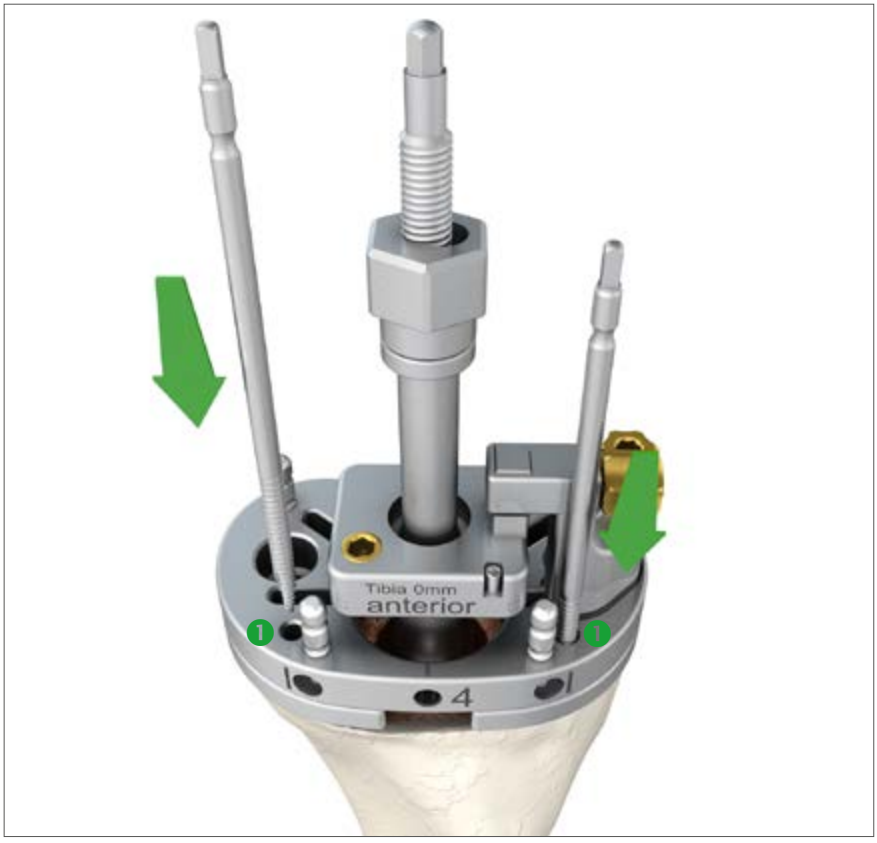
37

To secure the *Tibial Base Plate*, the pins of the tibial cutting block must first be removed.



38

Then two *Pins Ø 3.15 x 70 mm with Cortical Thread* are screwed trough the drill holes (❶) of the *Tibial Base Plate* to fix it.

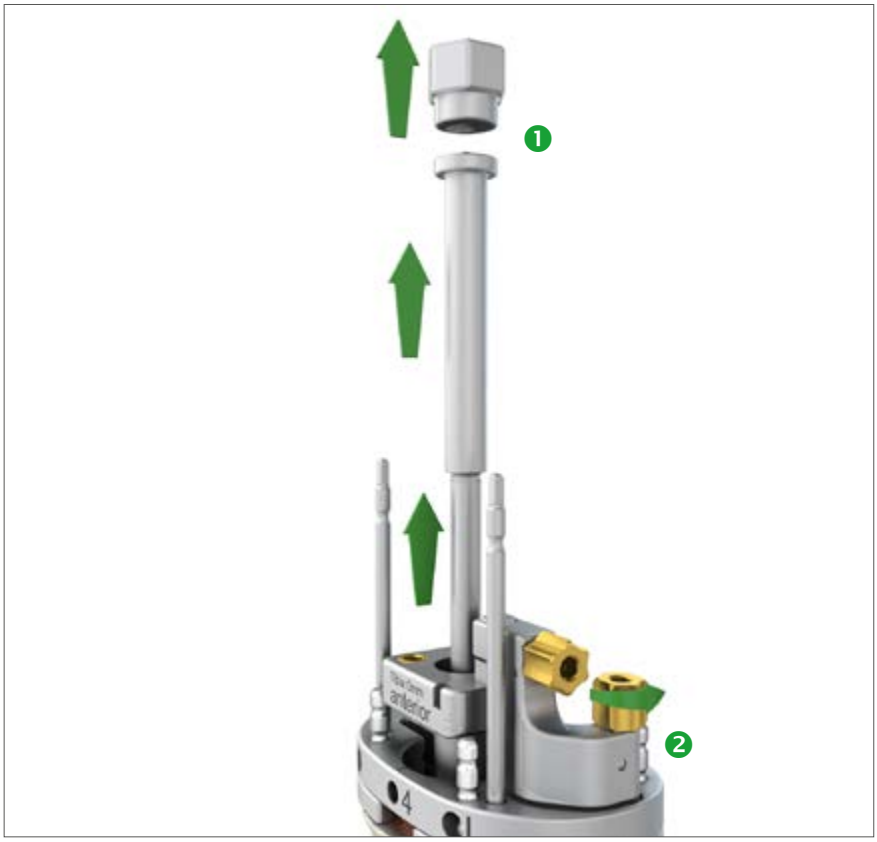


2.1 Tibia: Alignment, Resection, and Preparation

Disassembling the Adapter

39

After the *Tibial Base Plate* has been attached, the adapter must be removed. This is done by releasing the central clamp (❶)and the *Adapter for Tibial Base Plate* (❷).



Then the entire adapter can be withdrawn and the *Guiding Rod* can be removed.

2.1 Tibia: Alignment, Resection, and Preparation

Preparing the Tibial Implant Bed

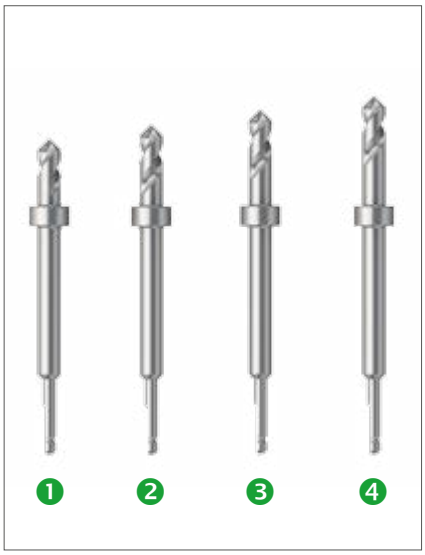
40

Precision preparation of the tibial implant bed begins with attaching the *Tibial Reaming Guide SC/RH/TH* to the *Tibial Base Plate*.

Then the *Tibia Reaming Guide SC/RH/TH* is secured with the gold screw.

41

The medial and lateral cavities of the proper depth are drilled using *Drill Bits* that match the total height of the augments (without tibial augments (❶), 5 mm (❷), 10 mm (❸), 15 mm (❹) augment).



42

The tibia is reamed to an inner taper with the *Tibial Revision Reamer SC/RH/TH* as far as it will go.

2.1 Tibia: Alignment, Resection, and Preparation

Preparing the Tibial Implant Bed

43

The *Tibial Punch SC/RH/TH* is used to punch the keel to determine the rotational alignment.

Make sure that the *Tibial Punch SC/RH/TH* is driven in as far as it will go (stop on the tibial base plate) to allow for the depth of the ribs.

44

Then all instruments and the *Reference Stem straight* are removed.

2.2 Assembling the Trial Tibial Components

Overview of Trial Components

45

The trial tibia is assembled from the *TRIAL TIBIAL Component*, *TRIAL ADAPTER for Tibial (0°, 3°, 4 mm) SC / RH / TH*, *TRIAL COUNTER NUT for Adapter*, and a *TRIAL ANCHORING STEM Straight* of the desired length.

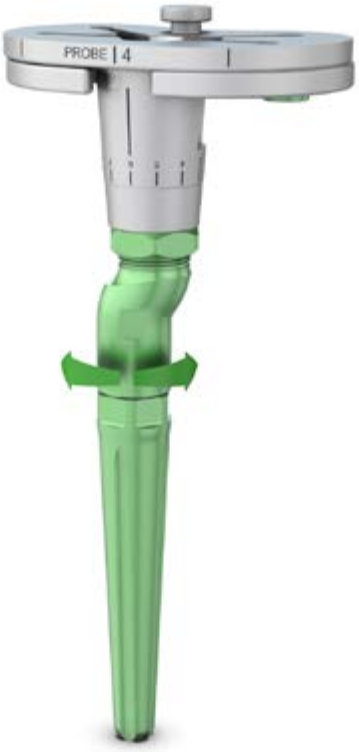
46

The adapters on the tibia are independent of the size of tibial component used.

The *TRIAL OFFSET ADAPTER 4 mm* allows the position of the offset to be continuously adjusted through 360° in both the femur and the tibia.

! NOTE

With the SC and RH or TH versions of the BPK-S Integration system, both the femoral and tibial stems must be used and connected using adapters determined intraoperatively.



2.2a Trial Tibial Component SC

Assembling the Trial Tibial Component – Assembly Block (SC)

47

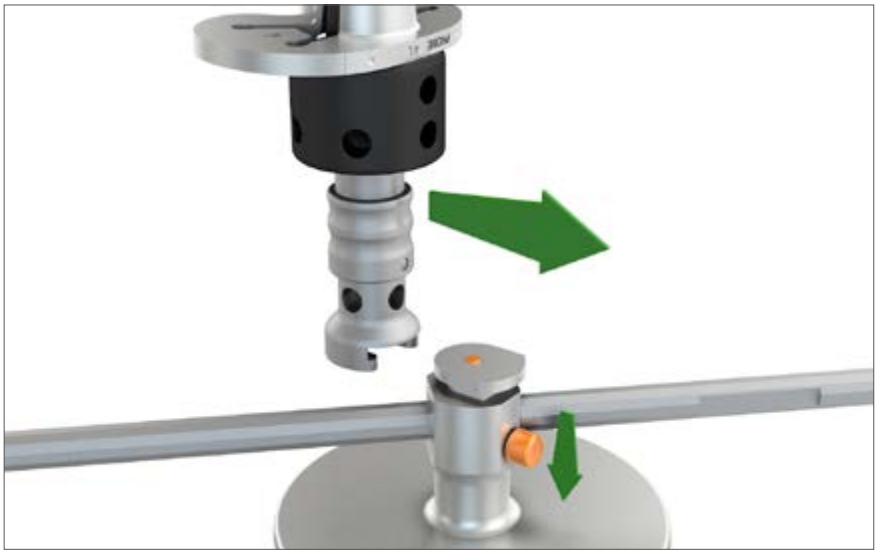
Two side *Handles* can be screwed on to the *Assembly Receiver* to help immobilize the assembly block when the construct is later tightened.

48

The tibial assembly block consists of the *Assembly Receiver* and the *Tibial Impactor/Extractor SC*. To secure the *TRIAL TIBIAL Component SC* on the *Tibial Impactor/Extractor SC*, the locking sleeve (1) is pressed and the *TRIAL TIBIAL Component* is pressed onto the *Tibial Impactor/Extractor SC*.

49

Pressing the locking button allows one to slide the *Tibial Impactor/Extractor SC* onto the *Assembly Receiver* and secure it.

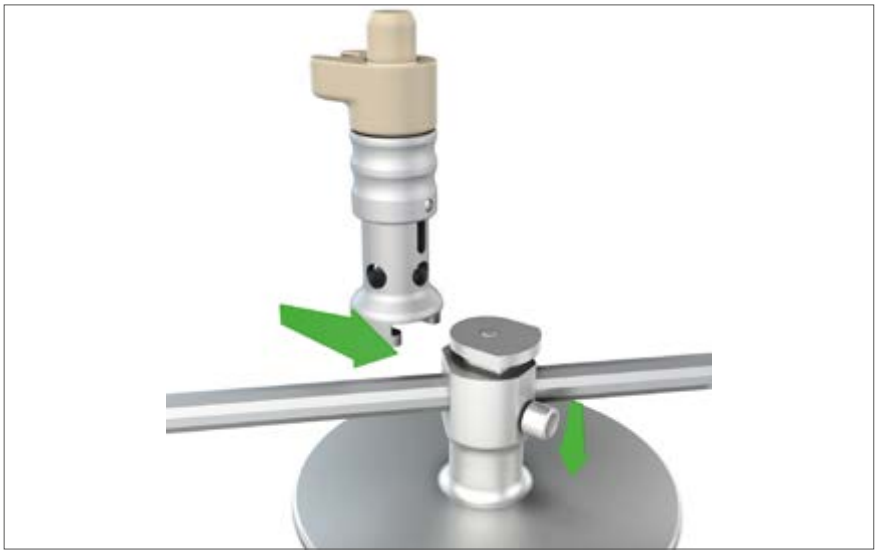


2.2b Trial Tibial Component RH / TH

Assembling the Trial Tibial Component – Assembly Block (RH, TH)

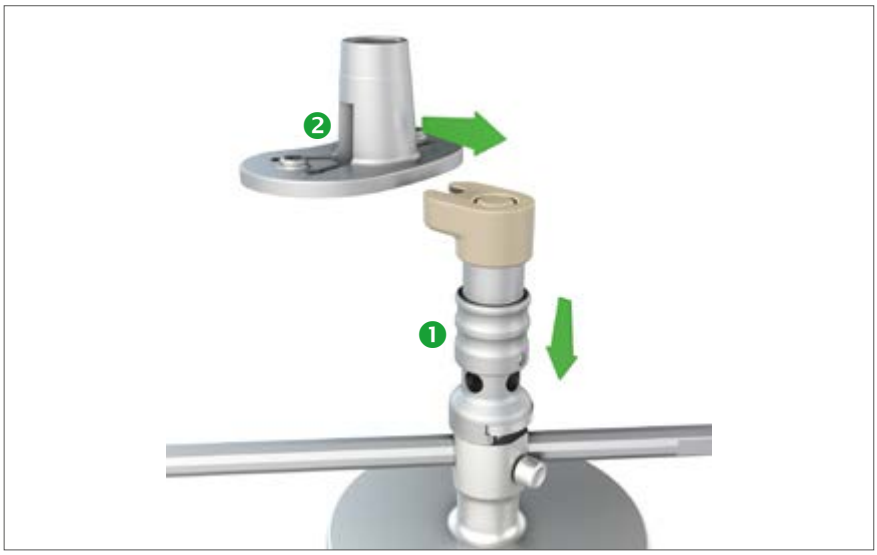
50

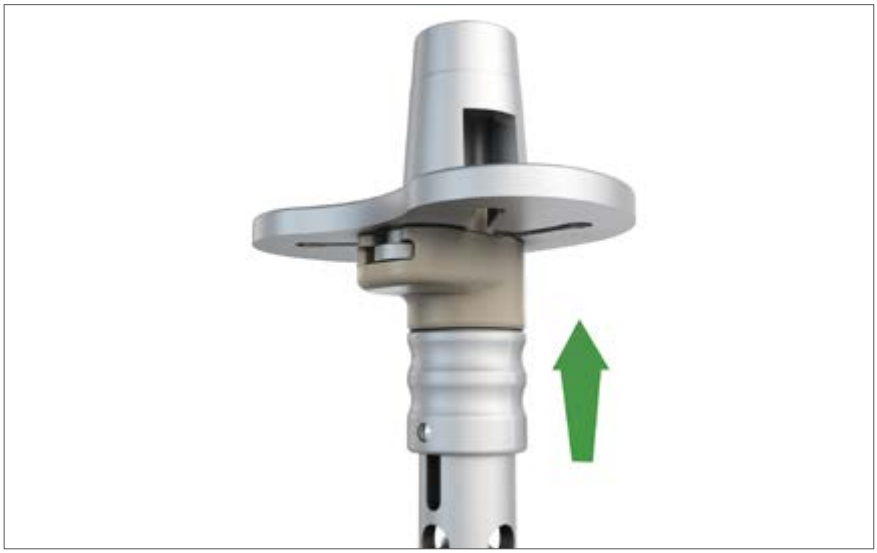
The tibial assembly block consists of the *Assembly Receiver* and the *Impactor / Extractor RH / TH*.



51

To secure the *TRIAL TIBIAL Component RH / TH* on the *Impactor / Extractor Tibial RH / TH*, the locking bolt (❶) is drawn back and the *TRIAL TIBIAL Component RH / TH* is slid onto the *Impactor / Extractor Tibial RH / TH* (❷). The *TRIAL TIBIAL Component RH / TH* is assembled on the *Impactor / Extractor Tibial RH / TH* with the locking bolt.





2.3 Trial Tibial Augments

Final Assembly of the Trial Tibial Component

52

If the resection allowed for augments, then the *TRIAL AUGMENTS Tibial* must be screwed on with the *TRIAL CLAMP SCREW for tibial Augments* of the appropriate length before attaching the stem.

The maximum tibial augmentation height of 15 mm can be achieved using 5 mm medial and lateral augments. Augments of different sizes can be combined as needed.

! NOTE

The length of the screw depends on the total height of the augments.

2.4 Assembling the Stem and Adapter for the Trial Tibial Component

Assembling the Trial Anchoring Stem Straight and Trial Tibial Adapter on the Tibia

53

A *TRIAL COUNTER NUT for Adapters* is screwed onto the preselected *TRIAL ADAPTER Tibial (0°, 3°, 4 mm)* all the way to the end of the threading.

54

Then the *TRIAL ANCHORING STEM straight* of the selected length is screwed into the *TRIAL ADAPTER Tibial (0°, 3°, 4 mm)* hand tight.

55

The gold *Socket Head Wrench SW3,5* can be used to screw it in.

2.4 Assembling the Stem and Adapter for the Trial Tibial Component

Assembling the Trial Anchoring Stem Straight and Trial Tibial Adapter on the Tibia

56

The *TRIAL ANCHORING STEM straight* together with the *TRIAL ADAPTER Tibial (0°, 3°, 4 mm)* is screwed all the way into the *TRIAL TIBIAL Component* with the gold *Socket Head Wrench SW3,5* and secured with the *TRIAL COUNTER NUT for Adapters*.

The T*RIAL ADAPTER Tibial* is independent of the size of tibial Component used.

2.4 Assembling the Stem and Adapter for the Trial Tibial Component

Assembling the Tibial Adapter 4 mm Offset

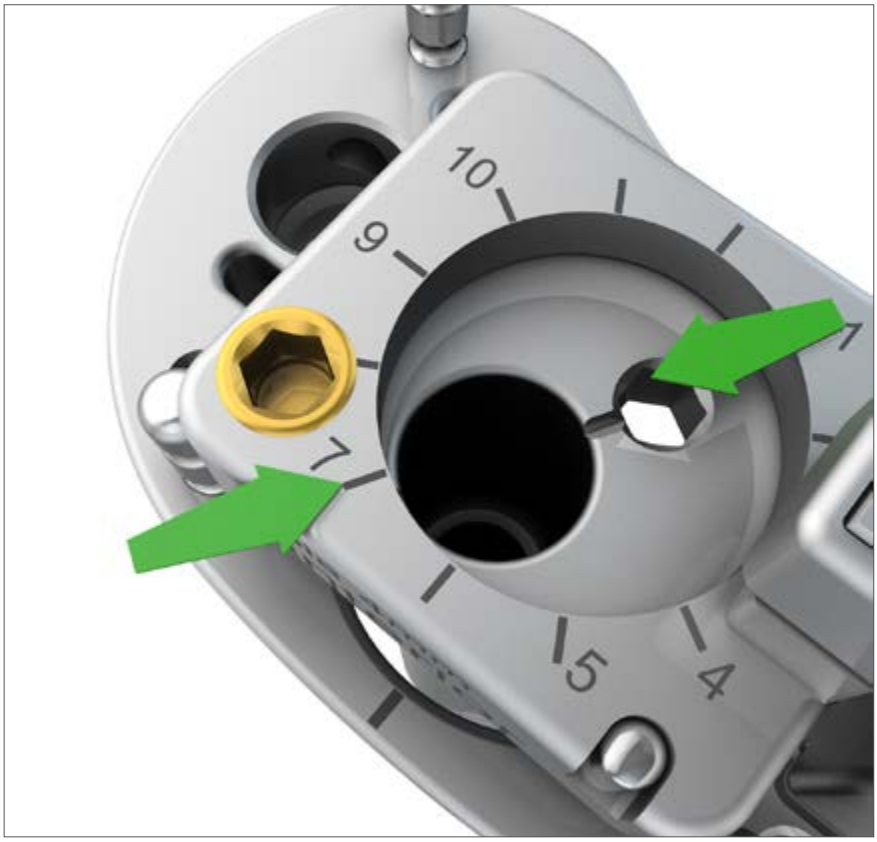
57

! NOTE

If a *Tibial Adapter 4 mm Offset* was used in positioning the *Tibial Base Plate*, then an offset adapter must also be used with the trial and the final implant. The setting is read off the *Tibial Adapter 4 mm Offset* and transferred.

The following rule should be observed when assembling the trial implants:

- All threaded connections must be screwed **tight**.
- When using a 4 mm offset or 3° adapter, the predetermined offset position must be set (within one backward turn) and secured with a hand tightened lock nut.



WARNING

Incorrect transfer of the offset position of the adapter:

- The implant may fail due to incorrect positioning!

➲ Ensure that the position of the offset adapter corresponds to the position which was previously read off when transferring it to the adapter.

2.5 Placing the Trial Tibial Component

Placing the Trial Tibial Component

58

To place Trial Components, the *Assembly Receiver* is removed and the *Handle of the Impactor / Extractor* is connected.

59

TRIAL TIBIBAL Component in situ.

3.1 Femur: Alignment and Resection

Determining the Size of the Femoral Component

60

The femoral osteotomies and the size of the femoral components should be determined using the *Femoral Sizing Templates.*

61

The dimensions of any previously removed implant will also be helpful in determining component size. They can be compared with the contralateral *TRIAL FEMORAL Components SC/RH/TH.*

3.1 Femur: Alignment and Resection

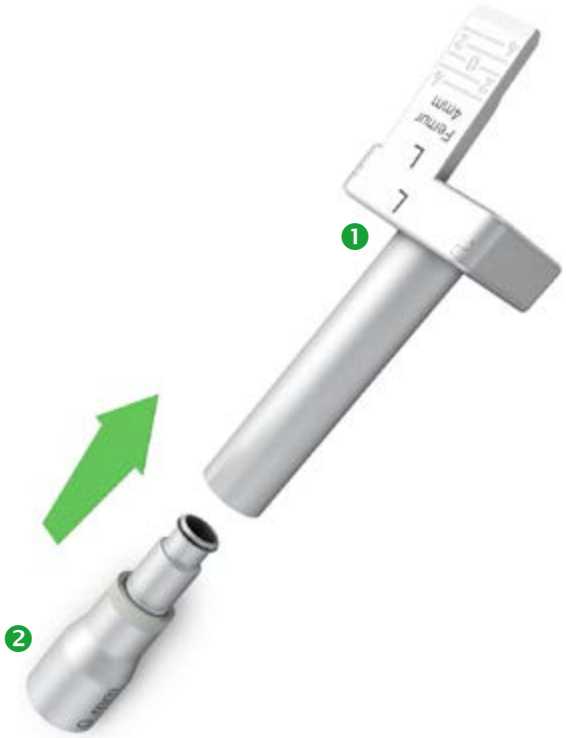
Assembling the Femoral Adapter

62

Before the *A/P Femoral Resection Guide SC/RH/TH* can be attached to the reference stem, the Femoral Adapter must first be preassembled. The system provides a choice between straight and 4 mm offset adapters. When setting the rotational alignment in the subsequent steps, one may find that an offset is required to achieve optimal positioning. In this case, the right or left *Femoral Adapter 4 mm Offset* must be used instead.

63

The *Extension Sleeve 0 mm* (❶) is screwed all the way into the femoral adapter (❷) until the *Extension Sleeve 0 mm* can be rotated freely.



WARNING

Incorrect postitioning of the implant due to selecting the wrong adapter (right/left):

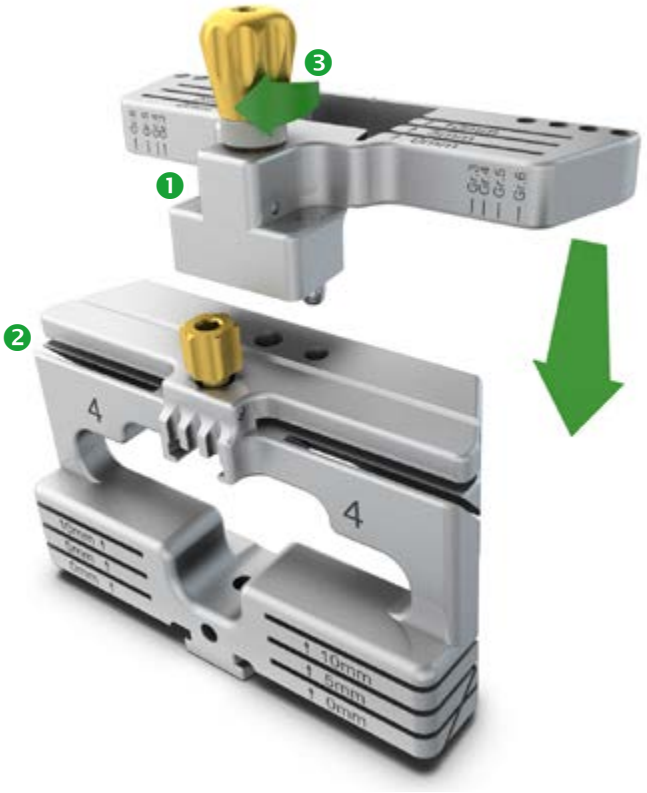
- The implant may fail!
- ➲ Observe the right/left variants.

3.1 Femur: Alignment and Resection

Assembling the All-in-One Femoral Resection Guide

64

The *Cutting Guide Femur distal SC/RH/TH* (❶) (same for all sizes) is attached to the *Cutting Block A/P Femur SC/RH/TH* (❷) of the selected femoral size and secured with the gold screw (❸). The *Socket Head Wrench W3,5* can be used for this purpose.



65

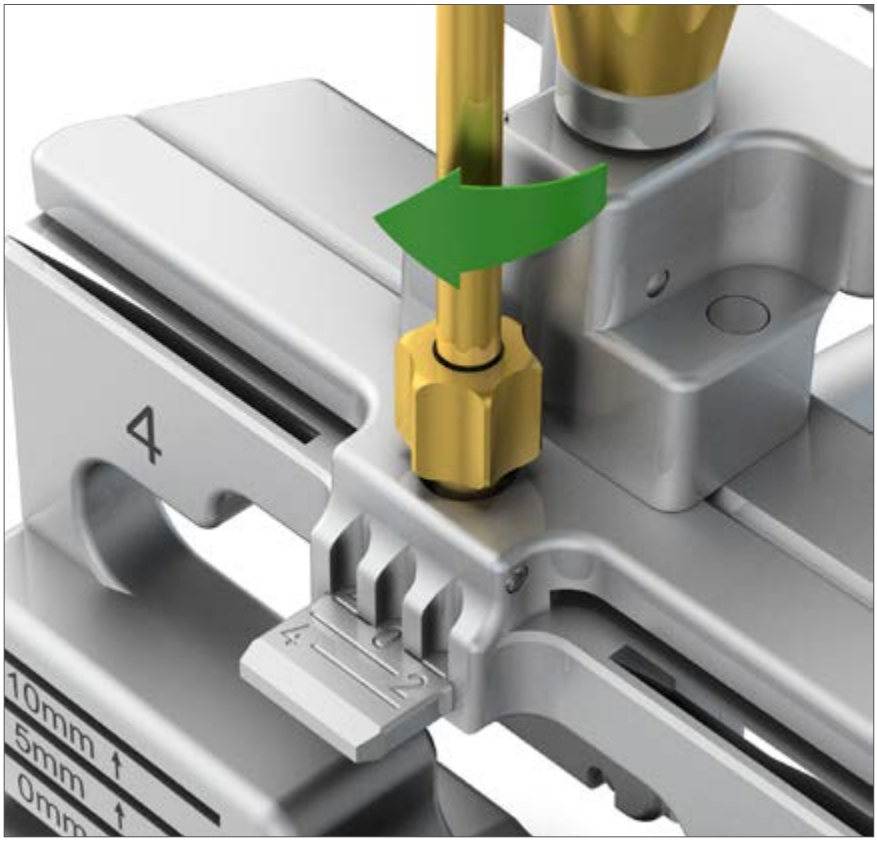
Then the femoral adapter is inserted into the *Cutting Block A/P Femur SC/RH/TH*.

3.1 Femur: Alignment and Resection

Assembling the All-in-One Femoral Resection Guide

66

The femoral adapter is secured in a neutral position (0 mm) with the gold screw.



67

Scale for proximal or distal adjustment of the joint line. Neutral position: "0".

! NOTE

All osteotomies can be simultaneously shifted distally or proximally to adjust extension space.

Straight adapter

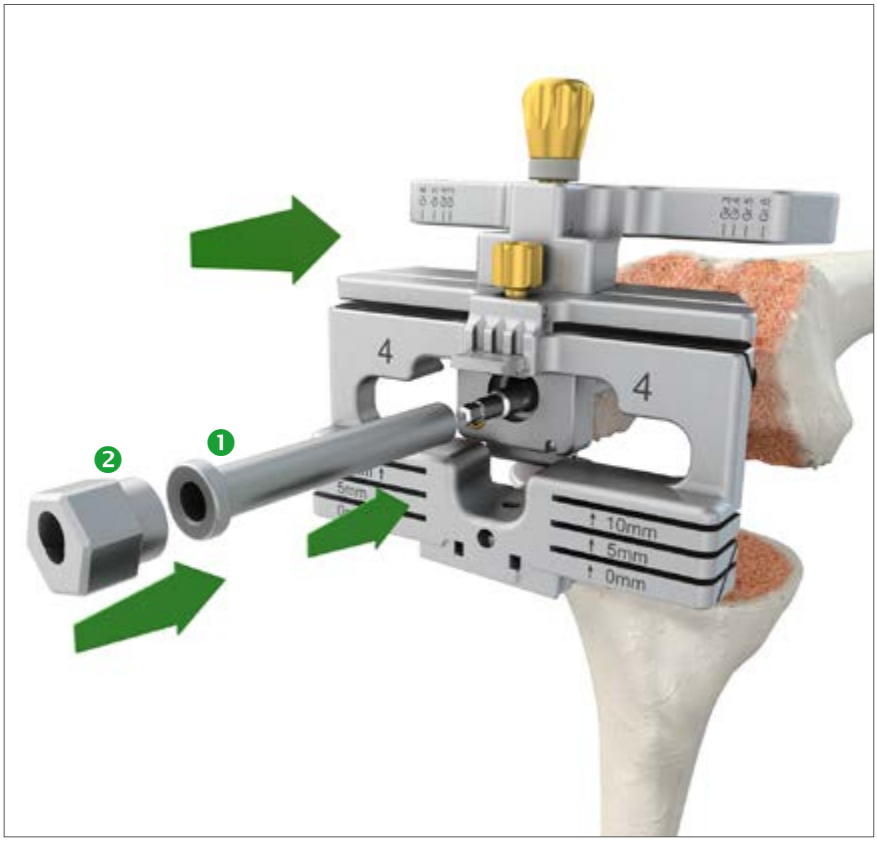
Adapter 4 mm Offset

3.1 Femur: Alignment and Resection

Rotational Alignment and Offset Adjustment of the Femoral Resection Guide

68

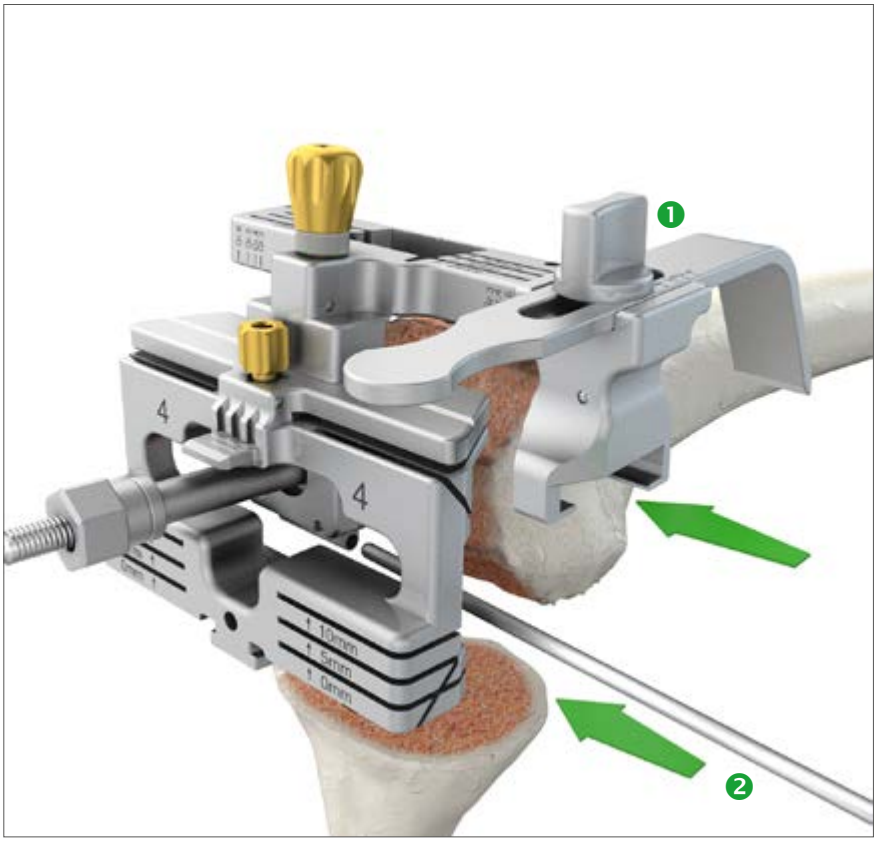
The first step is to screw the *Guiding Rod* into the *Reference Stem straight*. Then slide the assembled *Cutting Block A/P Femur SC/RH/TH* over it and use the *Clamp Sleeve* (❶) and the *Clamp Screw* (❷) to gently secure it to the Reference Stem.



69

Then the *Femoral Stylus* (❶) and the *Femoral Rotation Pointer* (❷) are inserted laterally.

Now the size of the femur is set on the *Femoral Stylus* (❶).

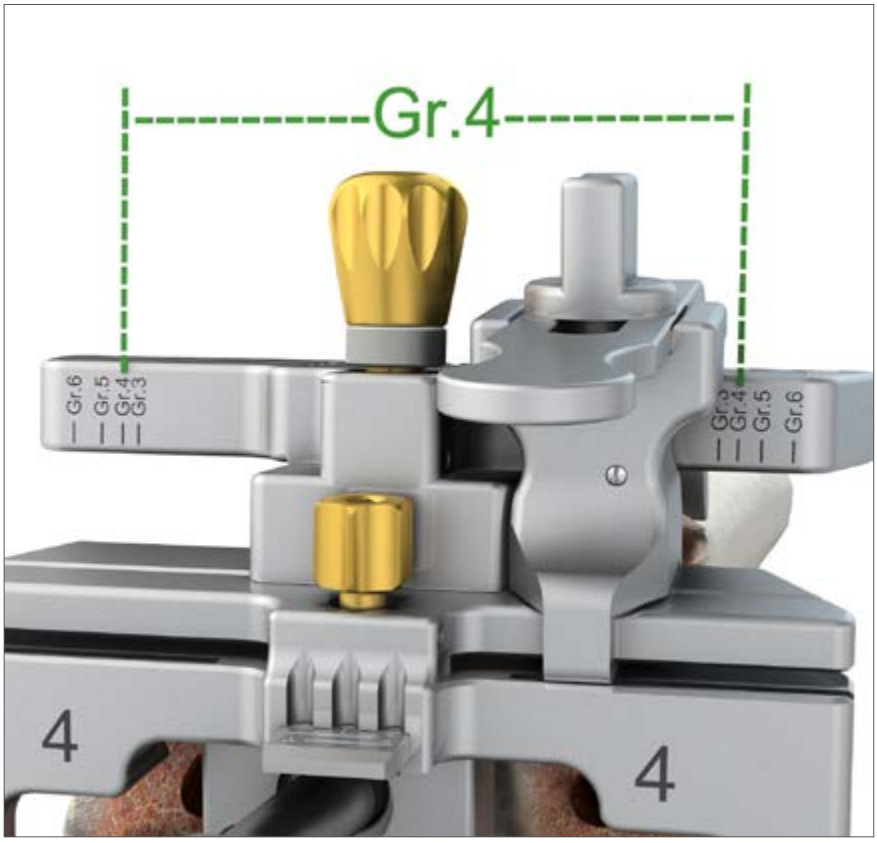


3.1 Femur: Alignment and Resection

Rotational Alignment and Offset Adjustment of the Femoral Resection Guide

70

The width of the femoral plate is visually evaluated using the width scale on the *Cutting Block Femur distal SC/RH/TH.*



71

Make sure the *Femoral Stylus* is precisely in contact with the anterior lateral cortex to avoid any overstuffing or notching.

3.1 Femur: Alignment and Resection

Rotational Alignment and Offset Adjustment of the Femoral Resection Guide

72

The *Femoral Rotation Pointer* (❶) is used to adjust the rotational alignment with respect to the epicondyles.

3.1 Femur: Alignment and Resection

Rotational Alignment and Offset Adjustment of the Femoral Resection Guide

73

At this point one may find that an offset is required to achieve optimal positioning of the femoral components (M/L and A/P). In this case, the *Femoral Adapter 4 mm Offset* must be used instead (see p. 43).

Use the *Socket Head Wrench SW3,5* to release the offset locking screw (❶) by turning the rotational flange (❷) of the femoral cutting block one can then achieve the optimal A/P or M/L alignment.

! NOTE

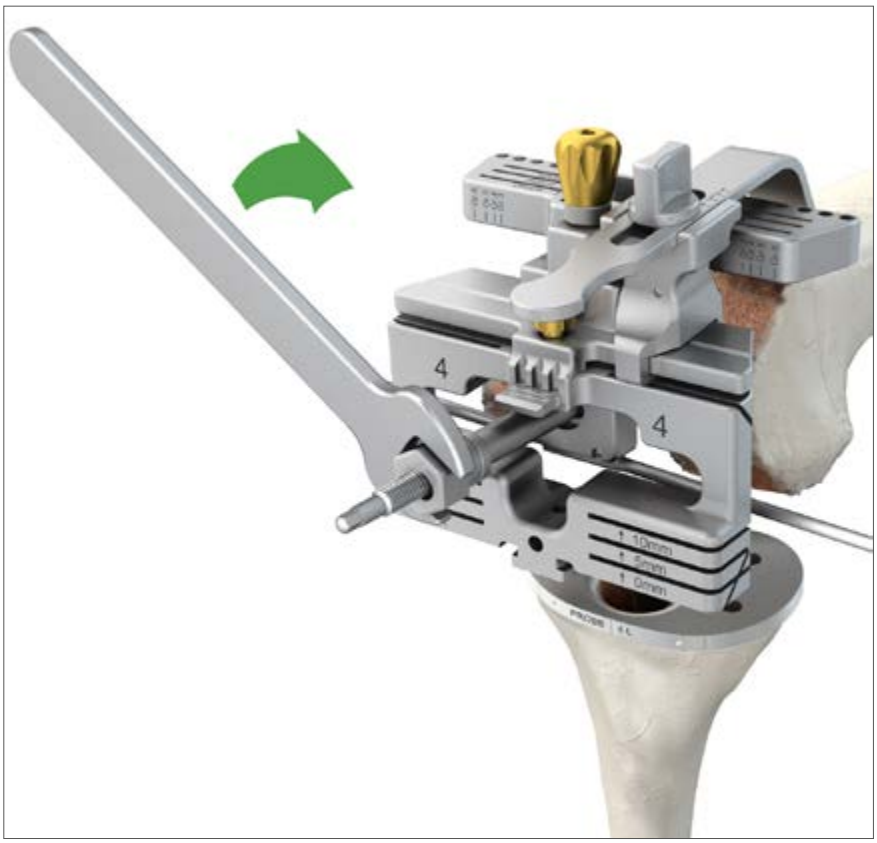
The setting of the *Tibial Adapter 4 mm Offset* can be read from the marking (❸) so that it can be reliably transferred to the final implant.

3.1 Femur: Alignment and Resection

Rotational Alignment and Offset Adjustment of the Femoral Resection Guide

74

After visual evaluation, the component is locked in the desired rotational alignment by tightening the *Clamp screw* with the *Flat Wrench SW14.*

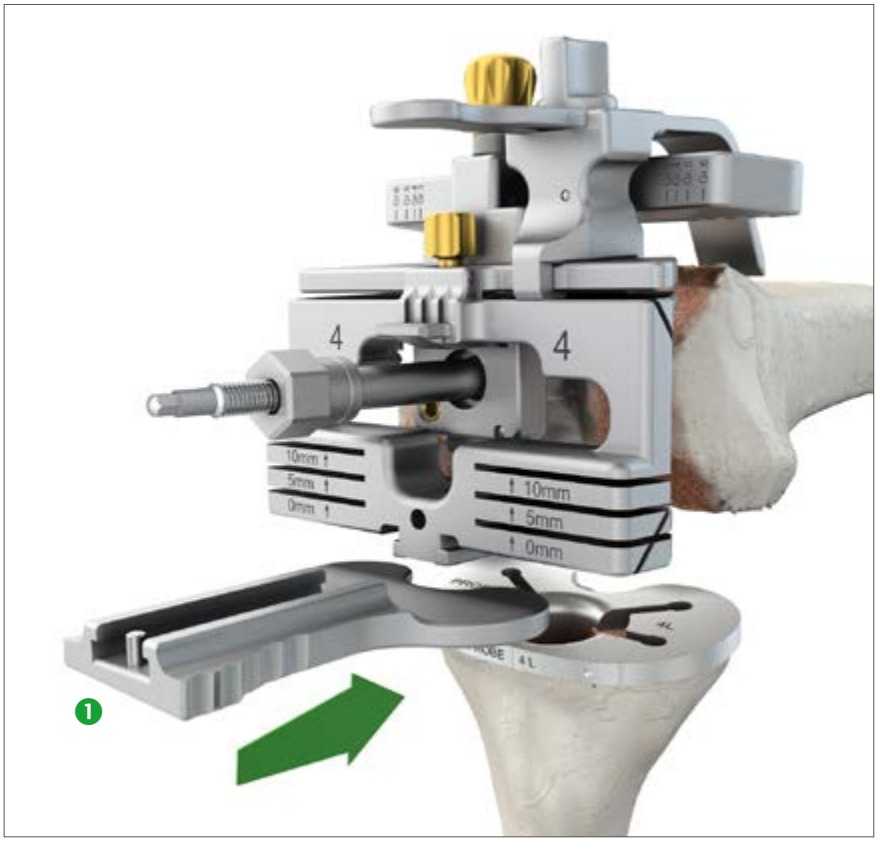


3.1 Femur: Alignment and Resection

Evaluating Flexion Space

75

The *shoe* (❶) for the respective side (right or left) is inserted to evaluate flexion space. Spacers measuring 7 mm (SC only), 9 mm - 17 mm (SC + RH/TH), and 19 mm - 25 mm (RH /TH only) (❷) are available for this purpose.



WARNING

Incorrect positioning of the implant by selecting the wrong instrument:

- The implant may fail!
- ➲ Observe the right/left variants.

76

Now one checks whether the lowest insert height of 7 mm (SC) or 9 mm (RH/TH) can be used and how much extension space differs from flexion space.

! NOTE

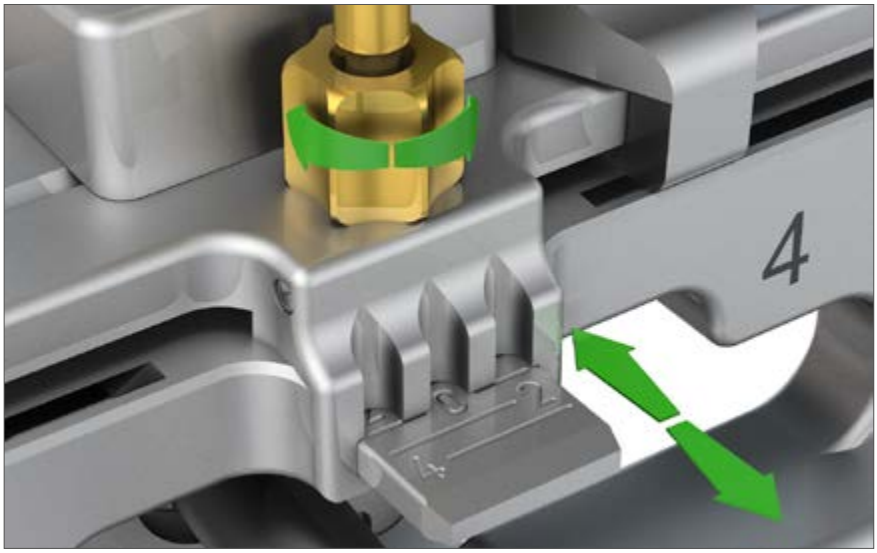
If a *TRIAL TIBIAL Component (RH/TH)* has been used, make sure that the *Shoe* or *Spacer* is not in contact with the rotation pin of the TRIAL TIBIAL.

3.1 Femur: Alignment and Resection

Adjusting Extension Space (Optional)

77

Once joint space in flexion has been evaluated, the required height of the insert in flexion and extension will be obvious. Extension space can be adjusted ±4 mm to match flexion space by shifting the all-in-one *Cutting Block A/P Femur SC/RH/TH* on the *Femoral Adapter straight* or the *Femoral Adapter 4 mm Offset*. This is done by releasing the gold screw and moving the *Cutting Block A/P Femur SC/RH/TH* into the desired position.



78

Maximum extension space increase of 4 mm

79

Maximum extension space decrease of 4 mm

3.1 Femur: Alignment and Resection

Verifying the Resections and Performing the Osteotomies

80

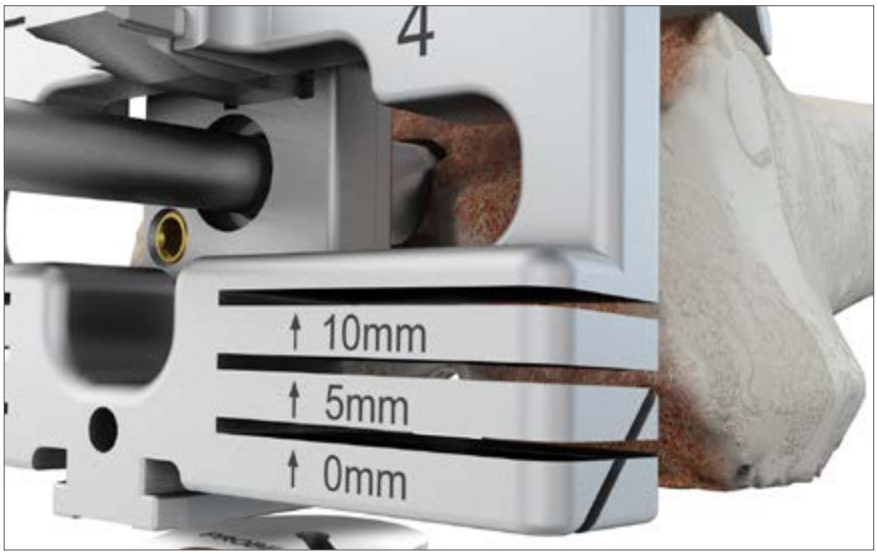
Before beginning the resection, all osteotomies including any necessary augments must be verified with the *Visualisation Guide S.*

81

Available femoral augments:

- Distal 5 mm, 10 mm
- Posterior 5 mm, 10 mm
- Combination of distal and posterior augments

Posterior resection guide 0 mm and for augmentation 5 mm and 10 mm



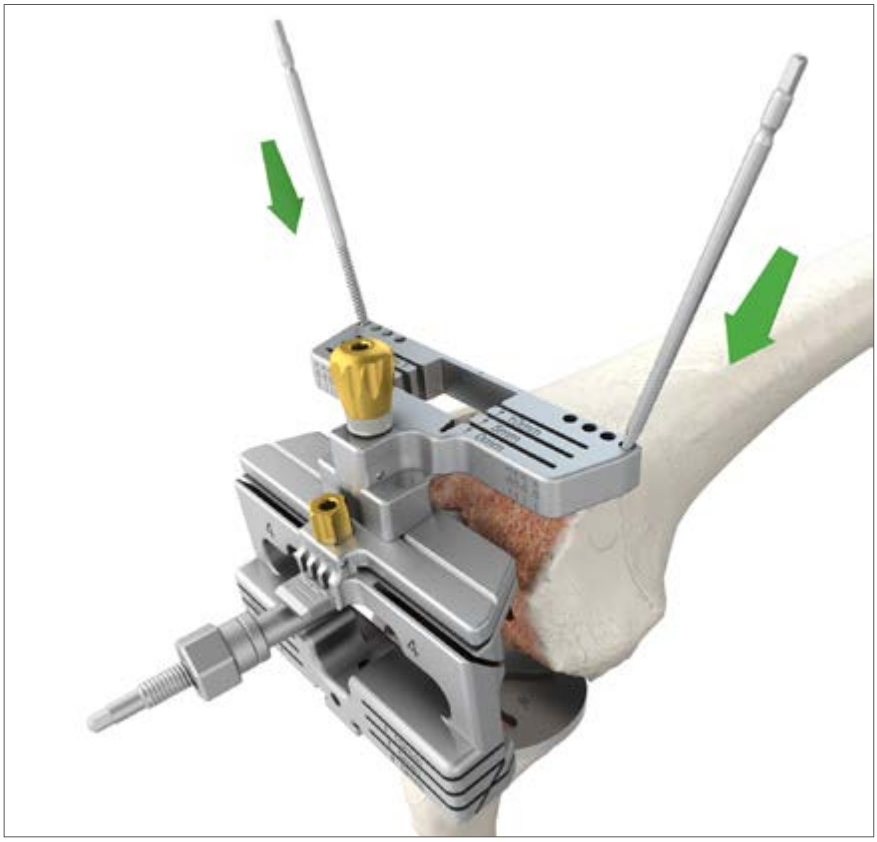
Distal cutting guide 0 mm and for augmentation 5 mm and 10 mm.

3.1 Femur: Alignment and Resection

Performing the Femoral Osteotomies

82

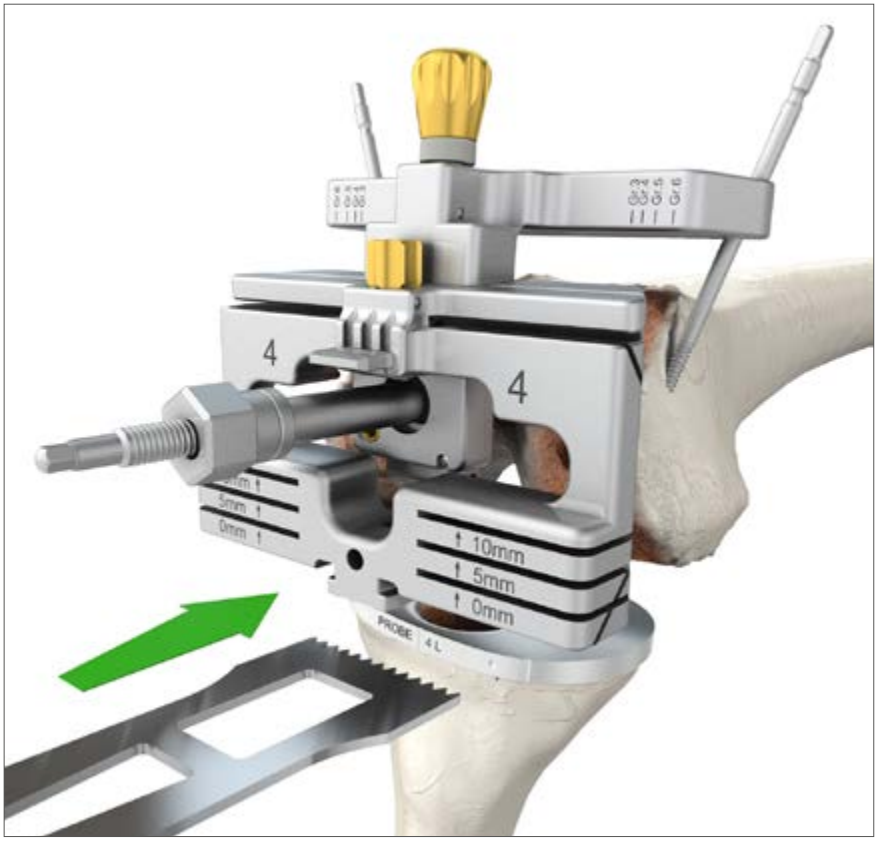
Then the *Femoral Stylus* is removed and the cutting guide is additionally secured with *Pins Ø 3.15 x 70 mm with Corticalis Thread*. These pins can be screwed in with the *Four-Square Wrench SW2*. The threaded pins should only be placed medially and laterally so as not to interfere with performing the osteotomy.



83

! NOTE

Only saw blades from PETER BREHM GmbH with a thickness of 1.18 mm ±0.01 mm may be used for the osteotomy.

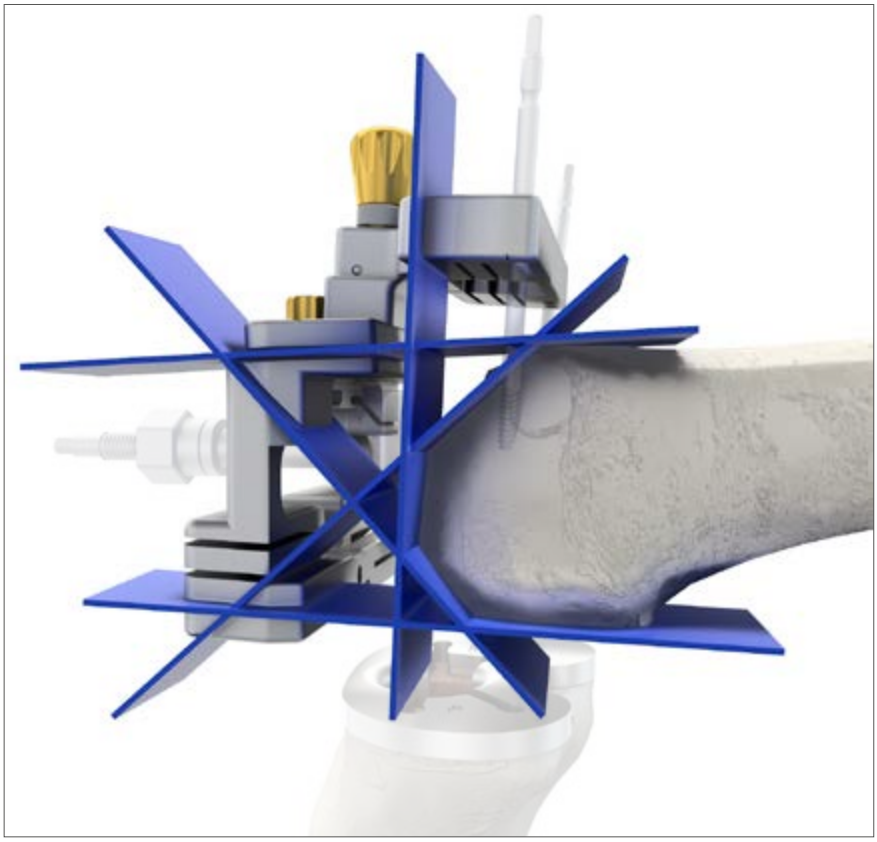


3.1 **Femur: Alignment and Resection**

Performing the Femoral Osteotomies

84

The cutting block system allows all resections to be performed in a single step.



3.1 Femur: Alignment and Resection

Preparing the Box preparation on the Femur

85

To ensure precise axial alignment of the instruments for preparing the femoral box, a mark is made on the bone with the aid of the *Pointer for Box Positioning* (1), after the femoral osteotomies have been performed.

WARNING

Incorrect positioning of the box preparation due to a false transfer of the marking:

- The bone may be fractured if the implant components are positioned incorrectly!

➲ Determine and mark the position of the box preparation using the *Pointer for Box Postitioning*.

Then all instruments are removed except for the *Reference Stem straight*.

3.1 Femur: Alignment and Resection

Assembling and Placing the Box preparation

86

If the resection allowed for augments, then the appropriate *TRIAL AUGMENTS Femoral SC/RH/TH* must be inserted into the *Box Preparation*. The guide must have optimal contact with the osteotomy surfaces.

87

The following *TRIAL AUGMENTS Femoral SC/RH/TH* are available:

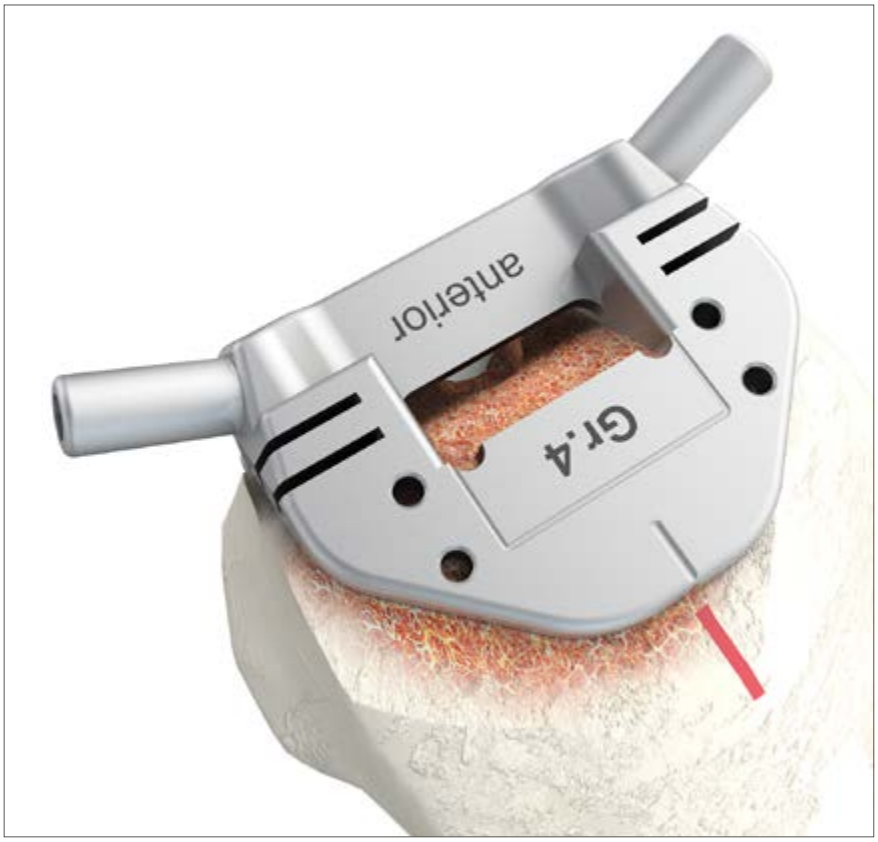
- Posterior: 5 mm; 10 mm
- Distal: 5 mm; 10 mm
- Distal und posterior combined: 5 mm / 10 mm; 10 mm / 10 mm; 10 mm / 5 mm

3.1 Femur: Alignment and Resection

Assembling and Placing the Box Osteotomy Guide

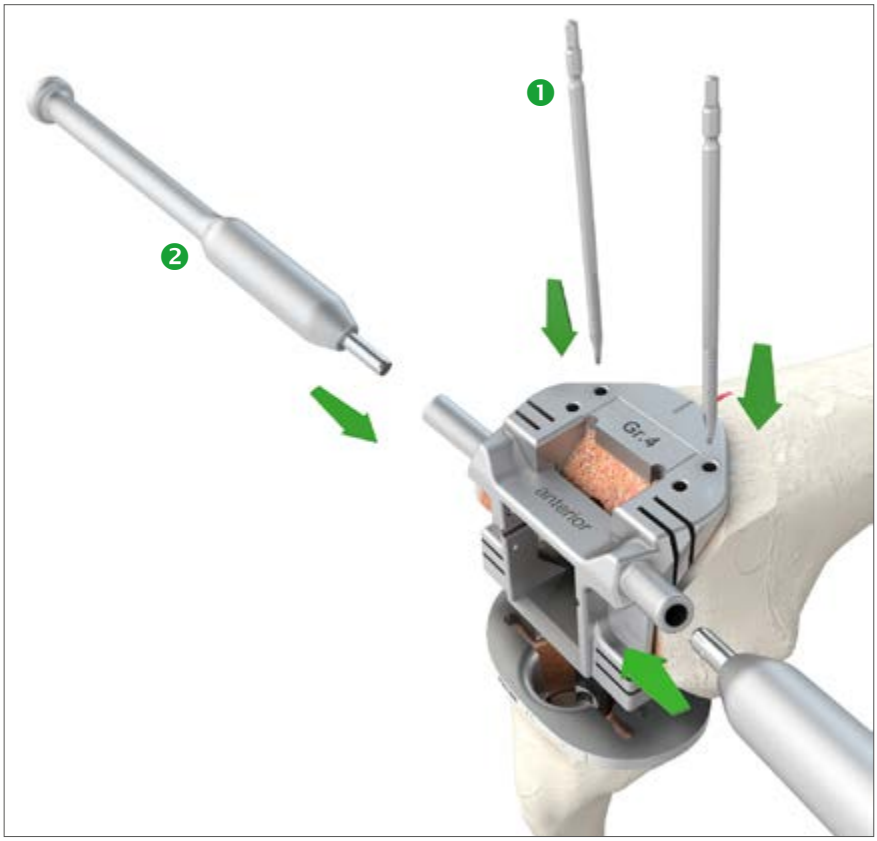
88

The bone marking must correspond to the instrument marking to ensure precise axial alignment.



89

The *Box Preparation* must also be secured with two *Pins Ø 3.15 x 70 mm with Corticalis Thread* (❶) or *Handles* (❷).



3.1 Femur: Alignment and Resection

Preparing the Femoral Box

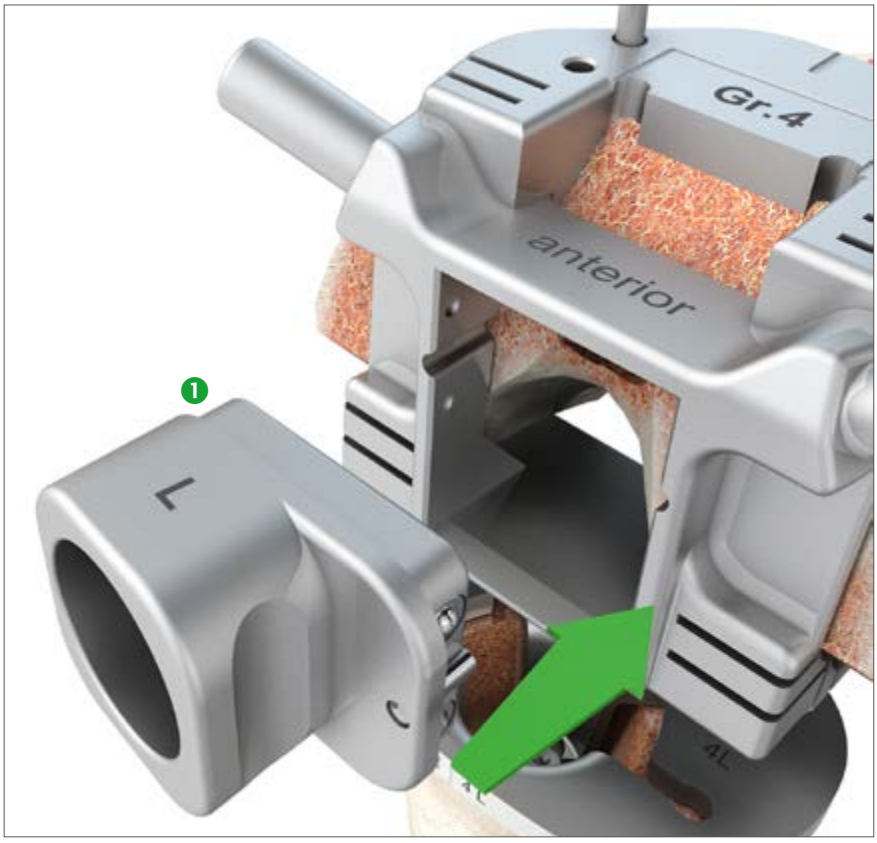
90

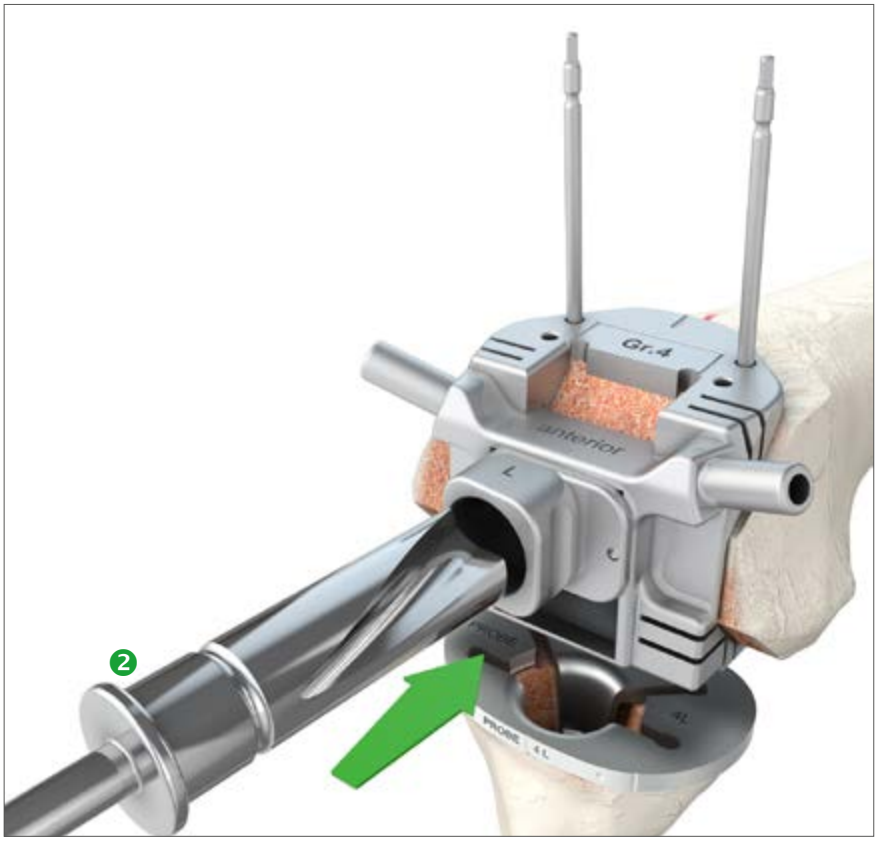
The *19 mm Drill* (❷) and *19 mm Drill Sleeve* (❶) are used at the beginning of the preparation. Be sure to use the proper right "R" or left "L" position. The label on the instrument indicating the side must be visible anteriorly.

WARNING

Non-axial drill hole due to transposing the right/left variant of the drill guide:

- Risk of bone fracture!
- ➲ Observe the right/left variants.



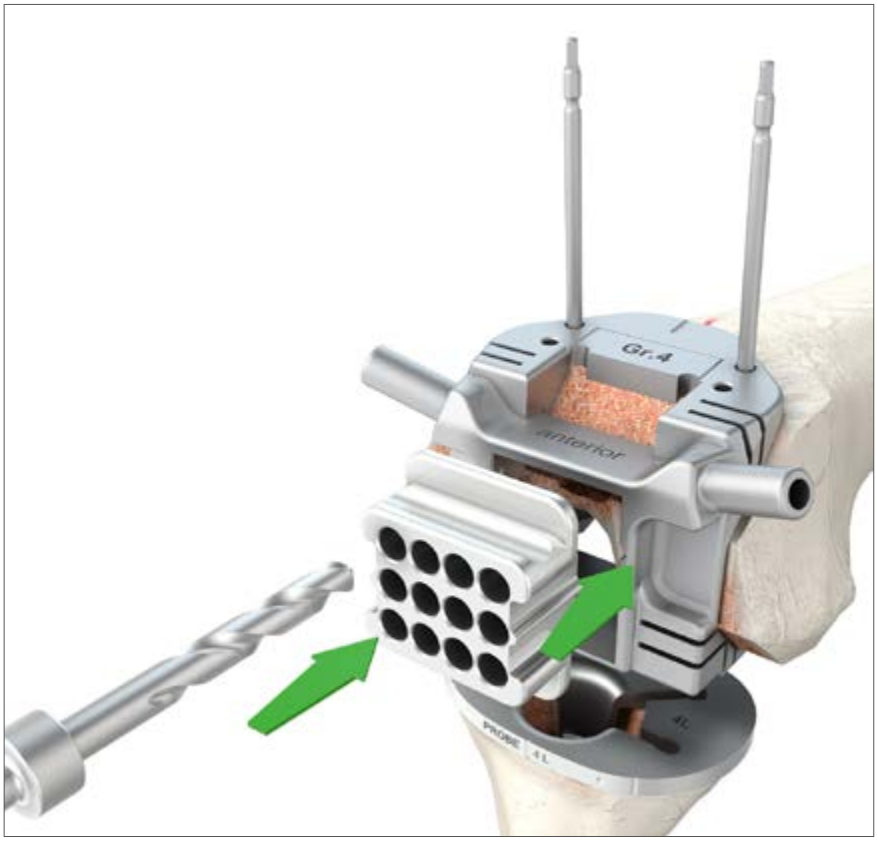


3.1 Femur: Alignment and Resection

Preparing the Femoral Box

91

The *Drill Guide Ø 6 mm* and the *Ø 6 mm Drill with AO Coupling* can be used to remove excess bone in the corners of the box. The edges of the box can be created with a narrow osteotome or saw blade.



92

The *Box Osteotome* can also be impacted, taking care to preserve the posterior structures. The *Handle of the Impactor/Extractor* is attached to the *Box Osteotom* for this purpose.

WARNING

Incorrect use of the Box Chisel for box preparation:

- Risk of injury to dorsal or intercondylar structures!
- ➲ Ensure that the "anterior" lettering on the *Box Osteotom* can be read from above.

3.1 Femur: Alignment and Resection

Alternate Method of Preparing the Femoral Box

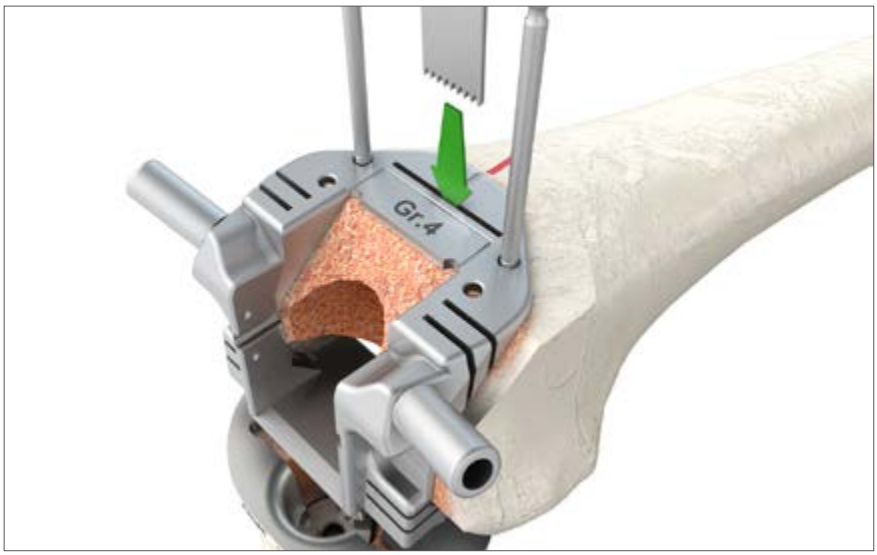
93

Special alternate *Box Preparation* are available for creating the box with the oscillating saw. First the distal resection is performed through the anterior slot in the *Box Preparation for Saw*.

WARNING

Incorrect use during incision:

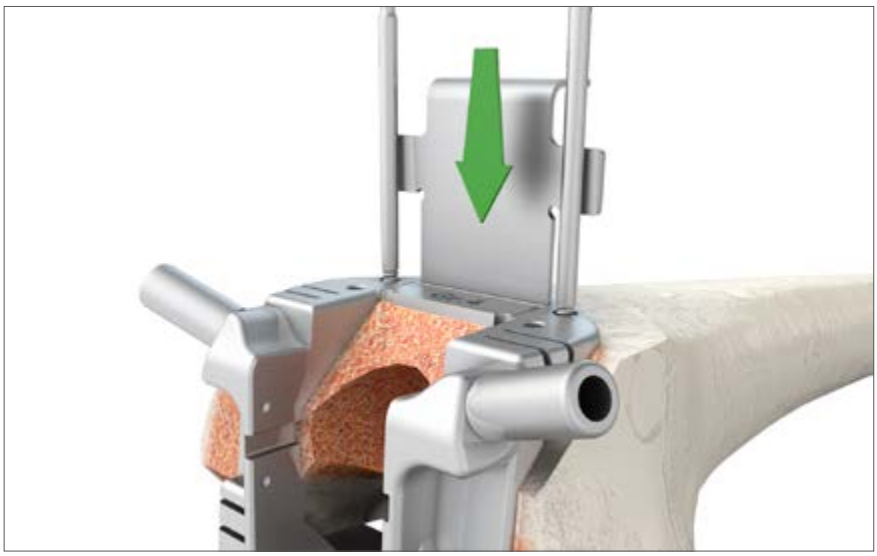
- Risk of fissures and fractures!
- ➲ Ensure that the saw blade is guided axially.

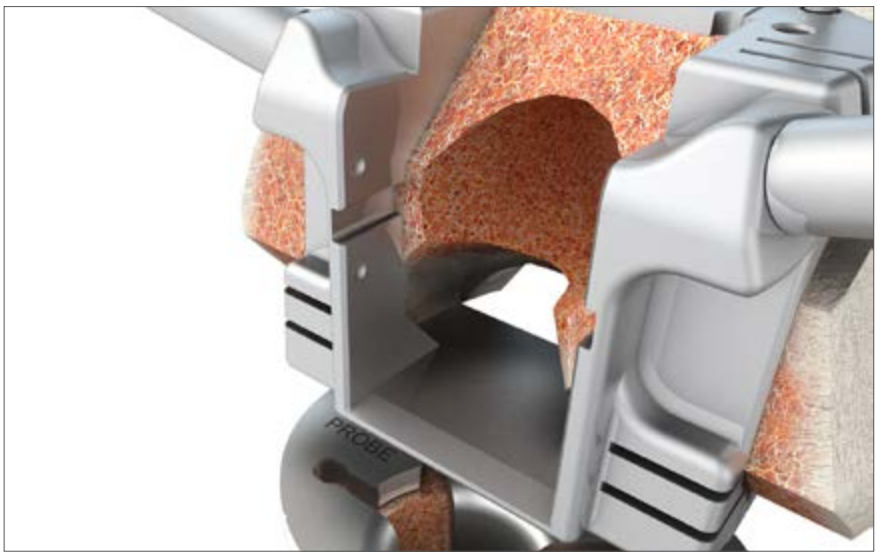


After the stop plate of the *Box Preparation* has been inserted, a distal osteotomy is carried as far as the *stop plate of the Box Preparation* to mobilize the block of bone.

! NOTE

Only saw blades from PETER BREHM GmbH with a thickness of 1.18 mm ±0.01 mm may be used for the osteotomy.



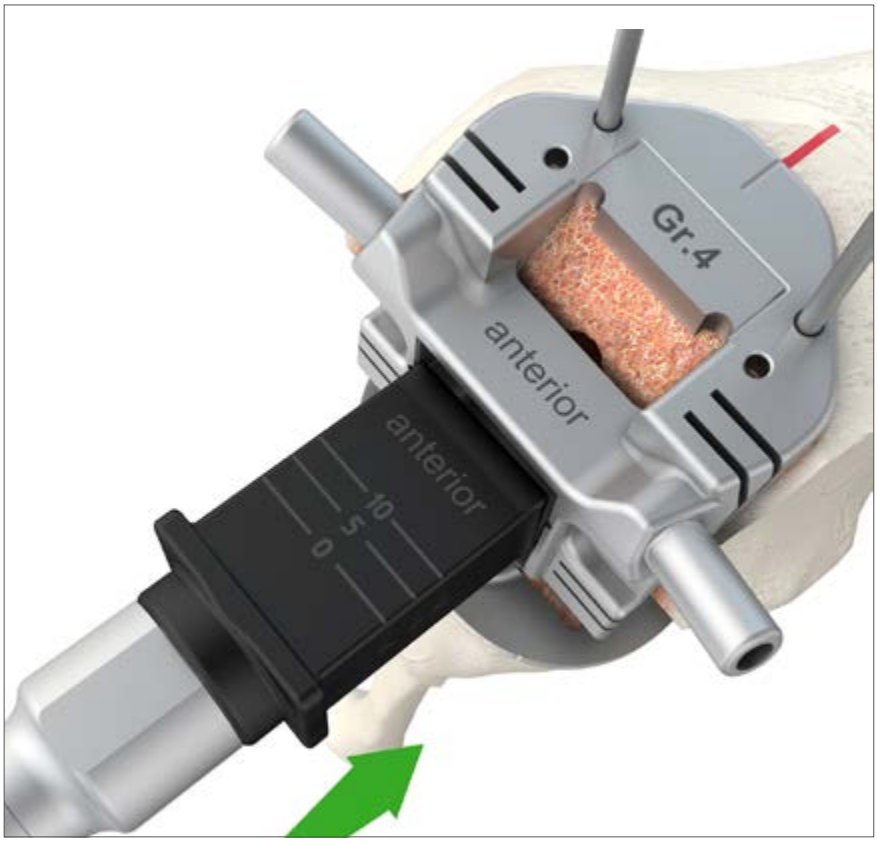


3.1 Femur: Alignment and Resection

Checking the Femoral Resection

94

The *Box Preparation Depth Gauge* is used to determine the width and depth of the prepared box.



3.1 Femur: Alignment and Resection

Evaluating the Femoral Resection

95

All instruments are now removed except for the *Reference Stem straight*. The *TRIAL FEMORAL Component SC/RH/TH* can then be placed to evaluate the osteotomies and the femoral box.

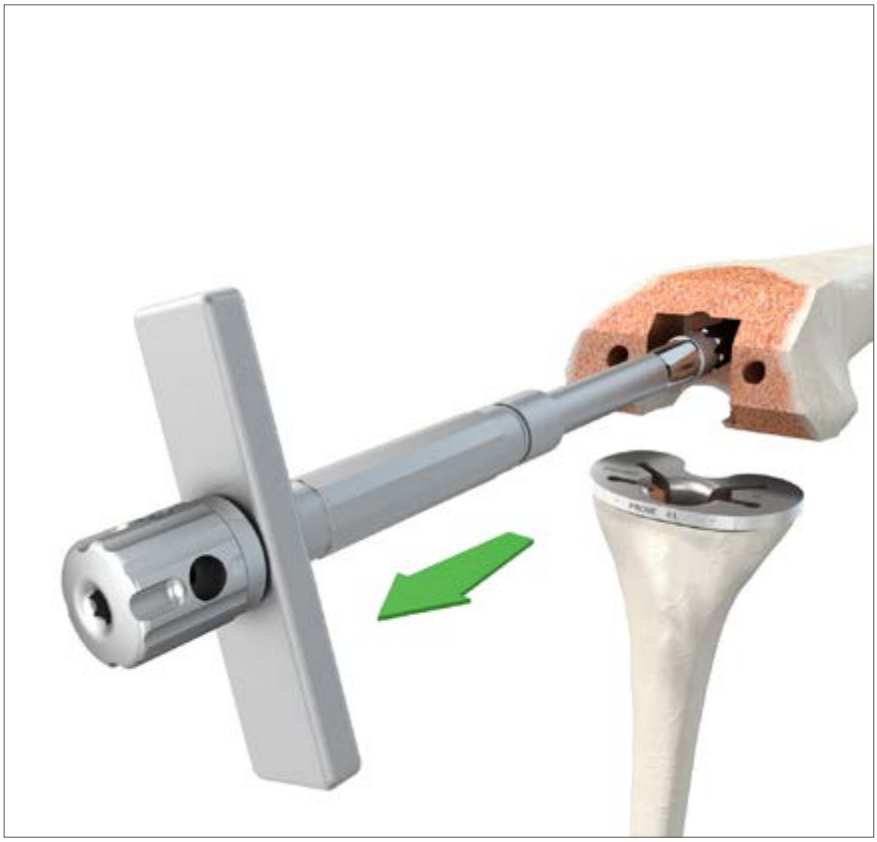
If the resection allowed for *TRIAL AUGMENTS Femur SC/RH/TH*, then they must first be inserted into the *TRIAL FEMORAL Component SC/RH/TH*.

! NOTE

The size of the augment depends on the size of the femur.

96

Once proper results have been verified, the *Guiding Rod* is screwed into the *Reference Stem straight*, and the *Handle of the prosthesis Impactor/Extractor* is slid over it and secured with the *Knurled Screw S*. Then the *Reference Stem straight* can be extracted.



3.2 Assembling the Trial Femoral Components

Assembling the Trial Femoral Component RH/TH

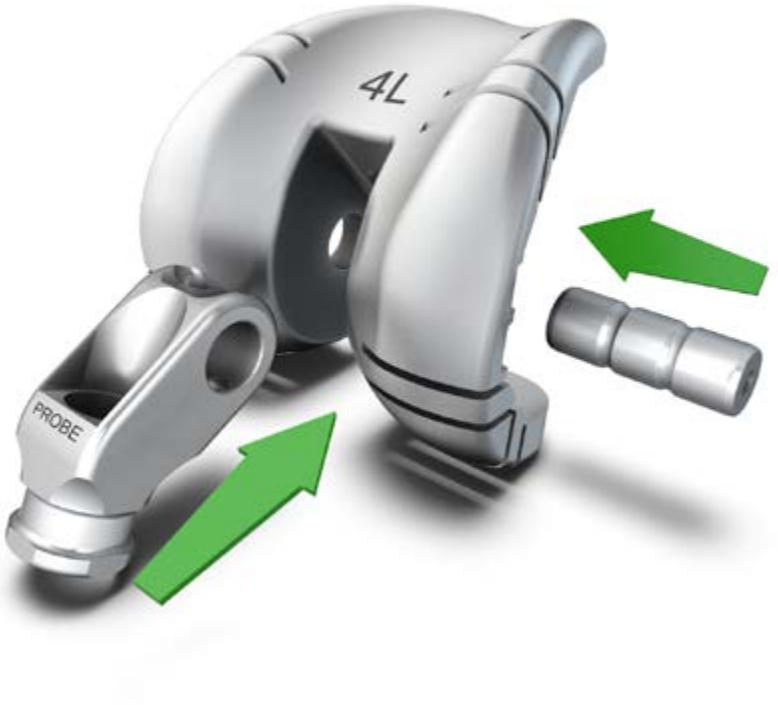
97

The *TRIAL FEMORAL Component SC/RH/TH* is assembled by inserting the *TRIAL YOKE NECK for Femur RH/TH* into the intercondylar box.

The axis holes on the *TRIAL FEMORAL Components SC/RH/TH* and *TRIAL YOKE NECK for Femur RH/TH* are aligned and the *TRIAL HINGE* is inserted.

! NOTE

The size of the Yoke Neck depends on the size of the femoral component.



3.2 Assembling the Trial Femoral Components

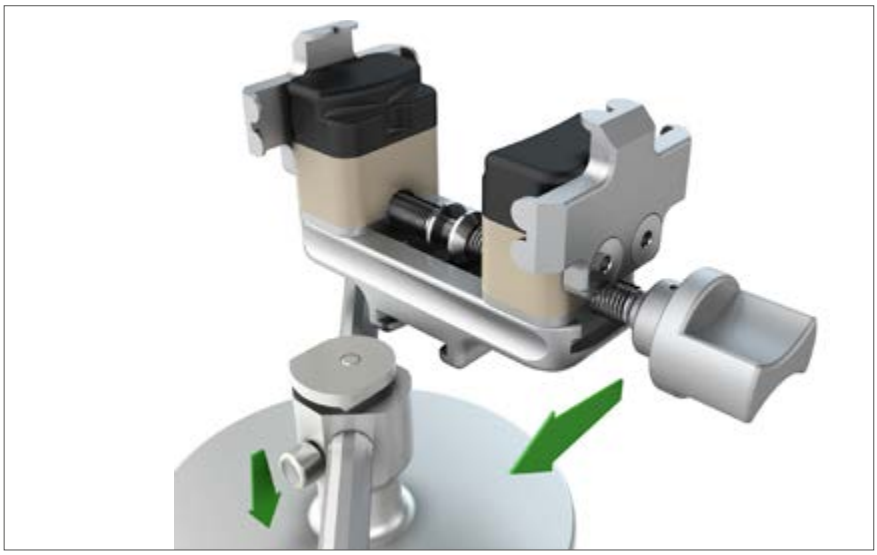
Attaching the Trial Femoral Component SC and RH/TH to the Assembly Block and Placing Augments

98

Two *side Handles* can also be screwed on to the *Femoral Assembly Receiver* to help immobilize the assembly block when the construct is later tightened.

99

The femoral assembly block consists of the *Femoral Assembly Receiver* and the *Femoral Impactor/Extractor*. Pressing the locking button allows one to slide the *Femoral Impactor/Extractor* onto the *Femoral Assembly Receiver* and secure it.



100

The *TRIAL FEMORAL Component SC* and *RH/TH* is fixed on the *Femoral Impactor/Extractor* for assembling.

! NOTE

If the resection allowed for augments, then the *TRIAL AUGMENTS* must be inserted into the *TRIAL FEMORAL Component.*

3.3 Assembling the Stem and Adapter for the Trial Femoral Components

Assembling the Trial Anchoring Stem and Trial Femoral Adapter

101

To assemble the *TRIAL ANCHORING STEM*, a *TRIAL COUNTER NUT for Adapter* is screwed onto the preselected *TRIAL ADAPTER for Femoral SC/RH/TH* (0°, 3°, or 4 mm Offset) all the way to the end of the threading.

! NOTE

The size of the femoral adapter depends on the size of the femoral component used.

102

Now the *TRIAL ANCHORING STEM* of the selected length is screwed into the *TRIAL ADAPTER for Femoral SC/RH/TH* hand tight.

3.3 Assembling the Stem and Adapter for the Trial Femoral Components

Assembling the Trial Anchoring Stem and Trial Femoral Adapter

103

The gold *Socket Head Wrench SW3.5* can be used for fixation.

104

The *TRIAL ANCHORING STEM* together with the *TRIAL ADAPTER Femur SC/RH/TH* is screwed all the way into the *TRIAL FEMORAL Component* with the gold *Socket Head Wrench SW3.5* and secured with the *TRIAL COUNTER NUT for Adapters*.

3.3 Assembling the Stem and Adapter for the Trial Femoral Components

Trial Femural Adapter 4 mm Offset SC and RH/TH

105

If an offset was used with the femoral resection guide, then the *TRIAL ADAPTER 4 mm Offset* for *Femur SC/RH/TH* of the size corresponding to the femoral component must also be used.

The following rule should be observed when assembling the trial implants:

- All threaded connections must be screwed tight.
- When using an offset or 3° adapter, the predetermined offset position must be set (within one backward turn) and secured with the hand tightened *TRIAL COUNTER NUT for Adapters*.

WARNING

False Transfer of the Offset position:

- Implant failure due to malpositioning!

➲ Ensure offset position is in line with position evaluated within the tibial preparation.

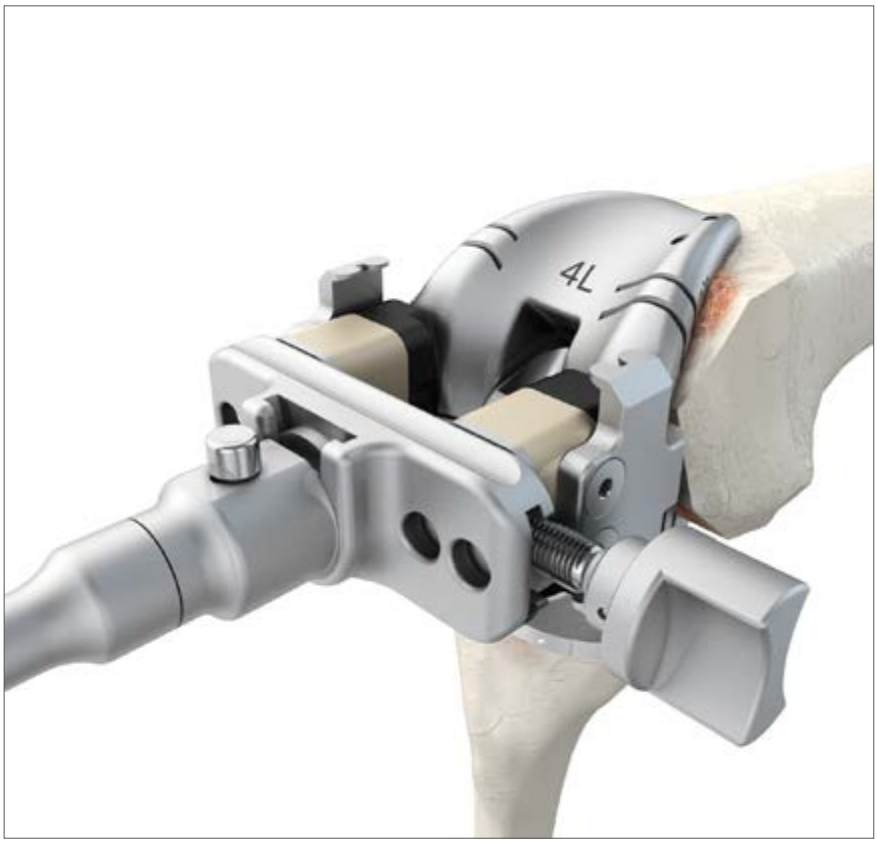
3.4 Placing the Trial Femoral Component

Placing the Trial Femoral Components

106

To place trial implants, the *Femoral Assembly Receiver* is removed and the *Handle of the Impactor / Extractor* is connected.

TRIAL FEMORAL Component SC / RH / TH in situ.



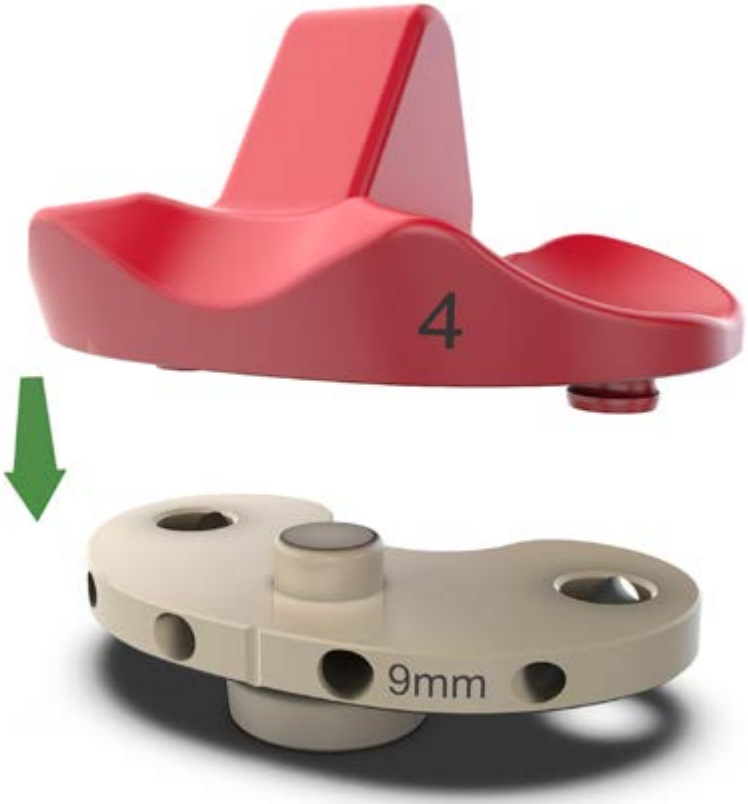
4.1 Assembling the Trial Insert

Assembling the Trial Insert

107

The trial insert consists of the *TRIAL INSERT receiver (SC mobile* or *RH/TH)* and the *TRIAL INSERT (SC* or *RH/TH)*.

The size of the *TRIAL INSERT (SC* or *RH/TH)* should be selected according to the size of the femoral component. The *TRIAL INSERT receiver (SC mobile* or *RH/TH)* is selected according to the insert height determined by evaluating joint space in flexion and extension. The two components are pressed together for the trial reduction.



Assembling the TRIAL INSERT SC

108

The *TRIAL INSERT receiver (SC mobile* or *RH/TH)* is independent of the size. The following heights are available: 7 mm (SC only), 9 mm - 17 mm (SC/RH/TH), 19 mm - 25 mm (RH/TH only).

! NOTE

The size of the *TRIAL INSERT (SC* or *RH/TH)* depends on the size of the femur.

Assembling the TRIAL INSERT RH/TH

4.2 Placing the Trial Insert / Trial Reduction

Placing the Trial Insert SC

109

The *Trial Insert Holder* is used to introduce the assembled trial insert into the joint space.

110

The joint can now be moved through its range of motion to evaluate stability and function.

WARNING

Implantation of trial implants:

- Risk of injury due to trial implant breakage!
- ➲ Use trial implants to select the suitable permanent implants only.
- ➲ Ensure that trial implants are not permanently implanted.

4.2 Placing the Trial Insert / Trial Reduction

Placing the Trial Insert and Trial Yoke RH

111

The trial insert is slid over the pin of the *TRIAL TIBIAL Component RH / TH*.

4.2 Placing the Trial Insert / Trial Reduction

Placing the Trial Insert and Trial Yoke RH

112

The *Yoke sling* is screwed into the *TRIAL YOKE RH*, which is chosen to match the selected insert height. The *Yoke Assembling Device* can be used for this purpose.

113

When placing the *TRIAL YOKE RH* make sure that the eye faces forward.

! NOTE

The *Yoke sling* may not be bent or damaged.

The *TRIAL YOKE RH* should be selected according to the height of the polyethylene insert.

4.2 Placing the Trial Insert / Trial Reduction

Connecting the Trial Yoke RH

114

The eye of the *Yoke sling* is now visible through the *TRIAL YOKE NECK for Femur RH / TH* (Fig. 115).

Moving the knee through its range of motion makes it easier to center the *TRIAL YOKE NECK* above the *TRIAL YOKE*.

115

The hook of the *Yoke Assembling Device* is hooked into the eye.

4.2 Placing the Trial Insert / Trial Reduction

Coupling the Trial Components (RH/TH)

116

To pull the *TRIAL YOKE RH* into the *TRIAL YOKE NECK for Femur RH/TH* you must now use the *Yoke Assembling Device* as a lever to pry the *Yoke sling* upwards.

117

The *Yoke sling* is unscrewed with the *Yoke Assembling Device*.

4.2 Placing the Trial Insert / Trial Reduction

Coupling the Trial Components (RH / TH)

118

The last step is to remove the *Yoke sling.*

4.2 Placing the Trial Insert / Trial Reduction

Coupling the Trial Components (RH/TH)

119

The *TRIAL COUPLING PIN (RH)* is secured in the *TRAIL YOKE Femoral (RH, TH)* with an additional *TRIAL CLAMPING SCREW M6 0,5 mm* which is tightened with the *Socket Head Wrensch 5 mm*.

120

The joint can now be moved through its range of motion to evaluate stability and function.

4.3 Removing the Trial Components

Removing the Trial Components SC

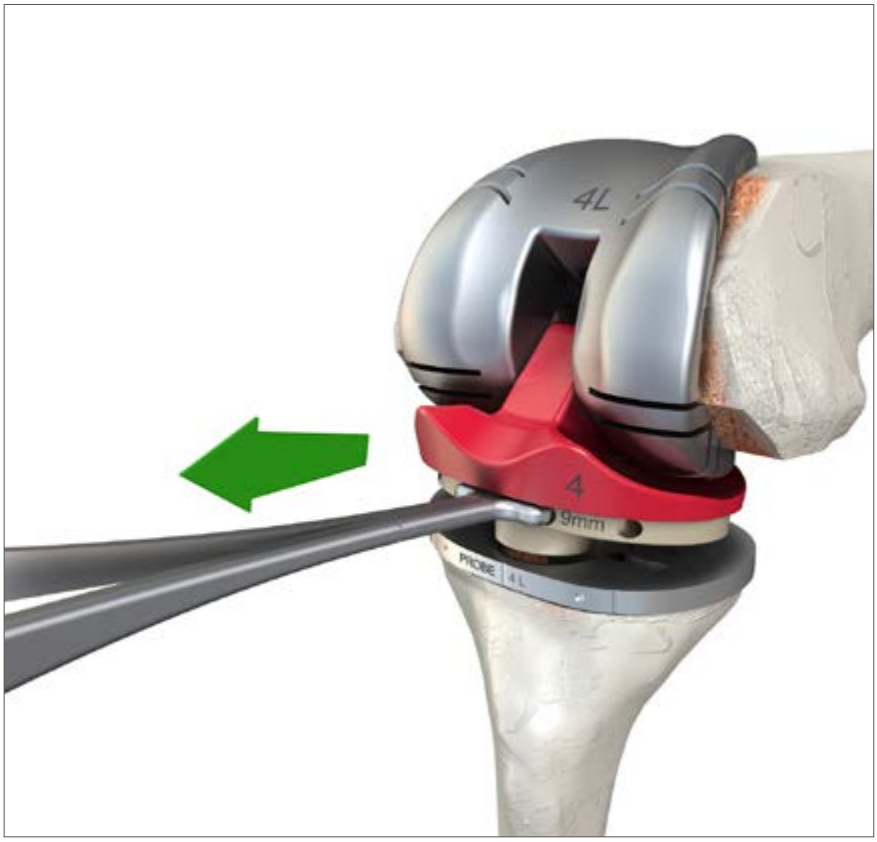
WARNING

Implantation of trial implants:

- Risk of injury due to trial implant breakage!
- ➲ Use trial implants to select the suitable permanent implants only.
- ➲ Ensure that trial implants are not permanently implanted.

121

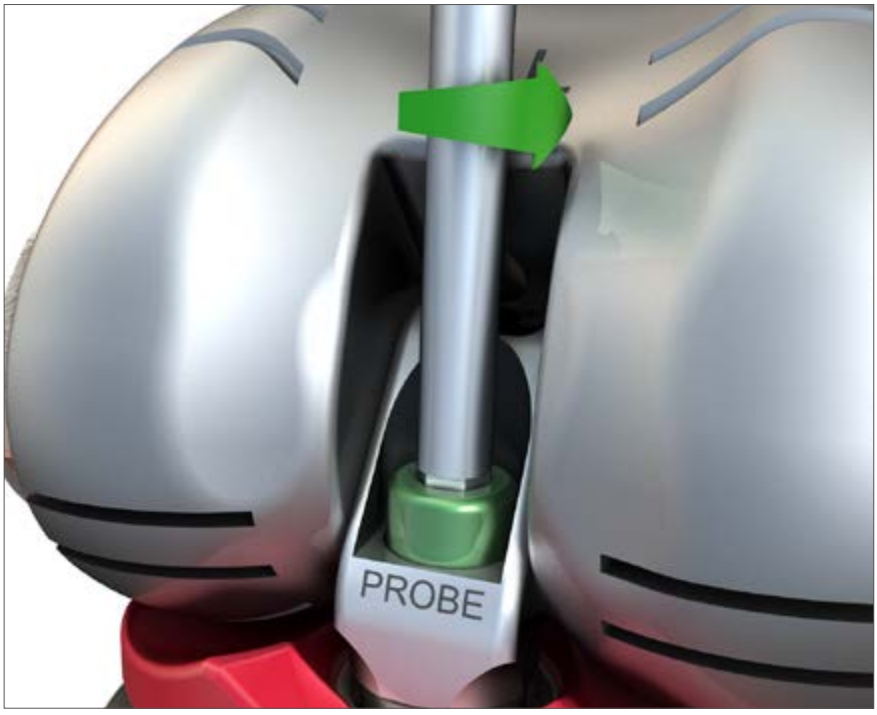
The trial insert is lifted with the *Trial Insert Holder* so that it can be pulled out anteriorly.



Disconnecting the Trial Yoke (RH/TH)

122

The trial assembly is disconnected by unscrewing the *TRIAL CLAMP SCREW M6x0.5* with the *Socket Head Wrench SW5*.

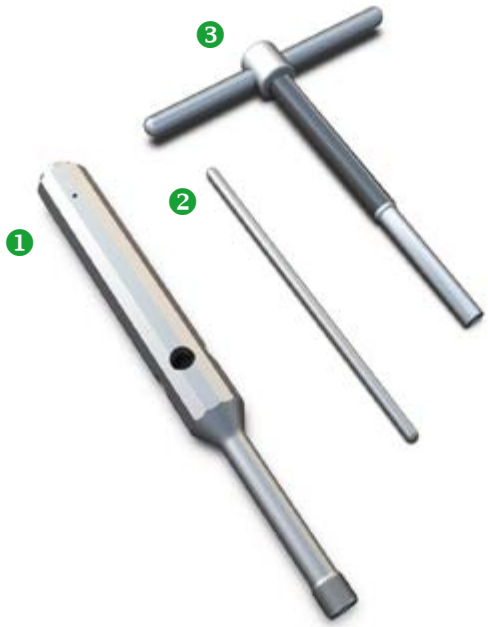


4.3 Removing the Trial Components

Disconnecting the Trial Yoke (RH/TH)

123

Next the *Removing Handle RH/TH* (❶) is screwed into the *TRIAL YOKE NECK for Femur RH/TH* and the *Removing Rod* (❷) is inserted from above. Then the *Removing Mandril RH/TH* (❸) is screwed into the *Removing Handle RH/TH* and turned clockwise until the taper connection separates.

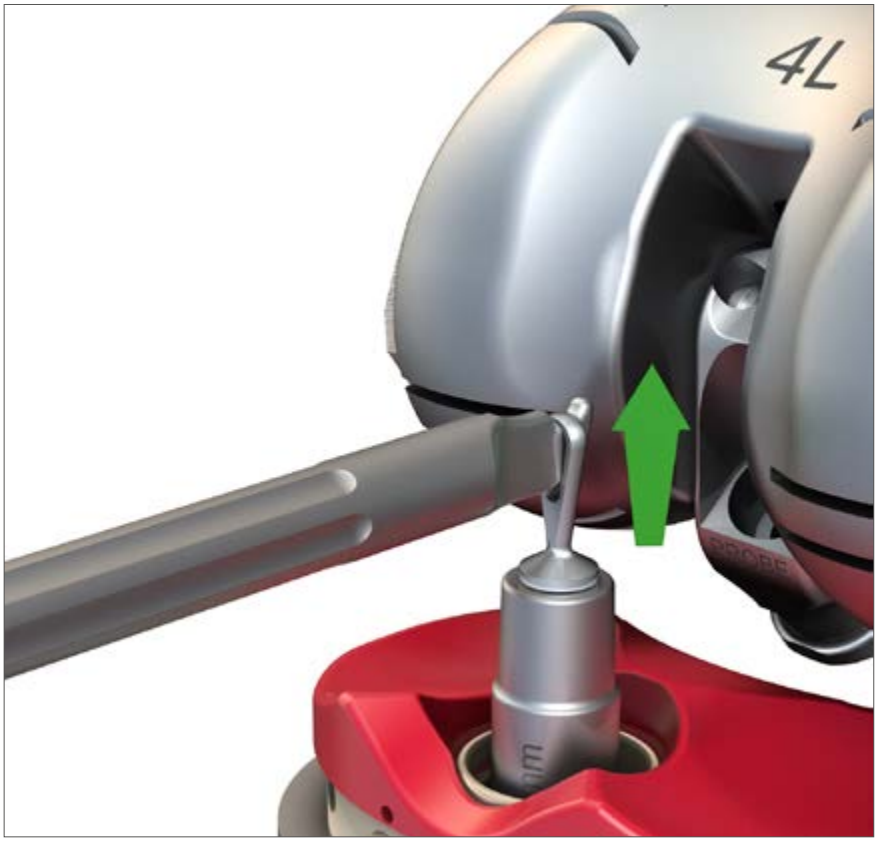


4.3 Removing the Trial Components

Removing the Trial Yoke (RH/TH)

124

To remove the *TRIAL YOKE RH/TH*, now screw in and pull out the *Yoke sling* using the *Yoke Assembling Device*.



125

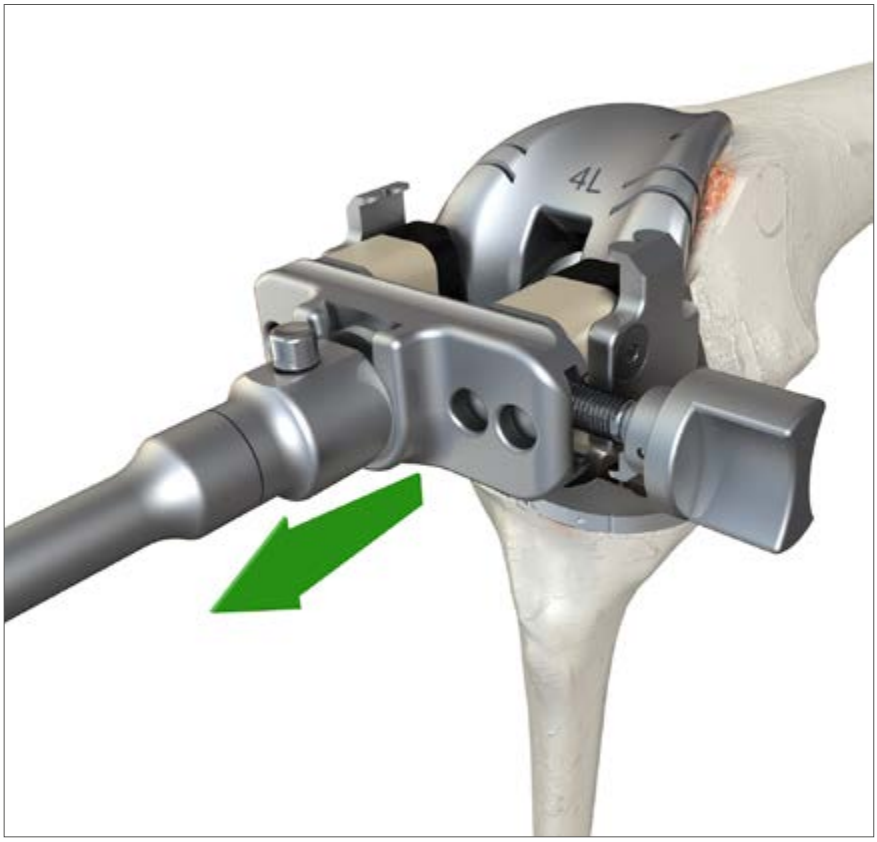
The trial insert is removed anteriorly.

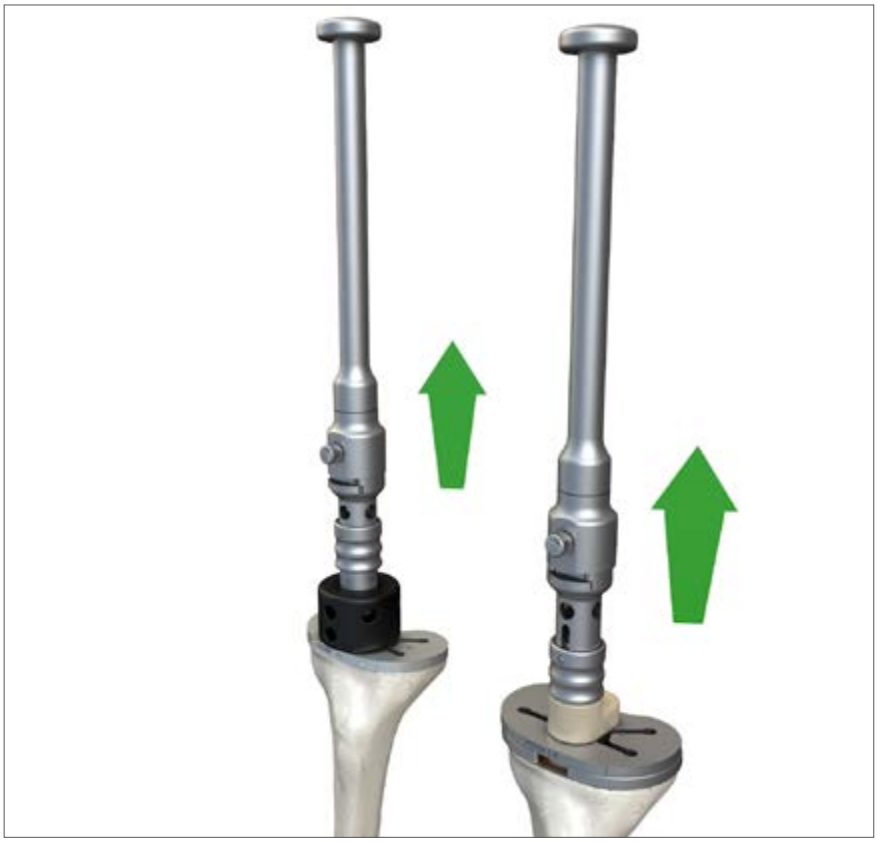
4.3 Removing the Trial Components

Removing the Femoral and Tibial Trial Implants

126

The *Impactor / Extractor Femoral* and *Impactor / Extractor Tibial* are attached to the trial components and the components are then extracted.





5.1 Assembling the Final Tibial Components

Assembling the Tibial Augments

127

The final tibial plateau is clamped in the *Impactor/Extractor Tibial SC* in the same manner as the trial (see p. 35-37). The final augments are screwed onto the tibial component with the *Socket Head Wrench SW3.5* and hand tightened.

The maximum augmentation height of 15 mm can be achieved using 5 mm medial and lateral augments. Augments of different sizes can be combined as needed.

! NOTE

The length of the locking screw depends on the height of the respective compartment.

5.1 Assembling the Final Tibial Components

Assembling the Stem Adapter for the Tibial Components

128

The final stem and final adapter are assembled in the same manner as for the trial components (see p. 38-40).

Offset Adapter Tibia SC/RH/TH

129

When an offset adapter is used, the offset is adjusted in the same manner as for the trial components (see p. 40).

5.1 Assembling the Final Tibial Components

Tightening the Implant Components – Tibia

130

1. Tightening the stem and adapter

The *Torque Key 25 Nm* is fitted with a *Flat Wrench SW14 for Torque Key* and placed on the tibial stem. A *Flat Wrench SW14* placed on the adapter acts as a brace. Then the two components are tightened until the audible click occurs.

2. Tightening the Counter Nut

The *Torque Key 25 Nm* is fitted with a *Flat Wrench SW17 for Torque Key* and placed on the Counter Nut. A *Flat Wrench SW14* placed on the adapter acts as a brace. The offset position is again verified. Then the Counter Nut is tightened and the correct position of the stem is again verified.

5.1 Assembling the Final Tibial Components

Tightening the Implant Components - Tibia

WARNING

Components which are tensioned and secured insufficiently:

- Risk of implant failure!
- ➲ Observe the correct handling of the implant components and instruments.
- ➲ Ensure that the *Torque Key 25Nm* is guided with the right hand and the torque scale can be read from above.
- ➲ Ensure that a click is clearly audible during tensioning.

CAUTION

Using the torque wrench to loosen screws:

- The instrument may be damaged!
- ➲ Do not use the *Torque Key 25Nm* to loosen screws.
- ➲ The instrument can be damaged if the *Torque Key 25Nm* is used to loosen screws, meaning that it would no longer apply the required torque during a subsequent implantation.

5.1 Assembling the Final Tibial Components

Assembling the Tibial Impactor

131

After the tibial implant has been removed from the *Assembly Receiver*, the *Handle* of the *Impactor / Extractor Tibial* is connected.

5.2 Assembling the Final Femoral Components

Placing the Cementing Seal for Femur SC

132

The *Cementing Seal for Femur SC* must now be placed for cementing the component. The *Trial Insert Holder* (❶) can be used for this purpose.

WARNING

Incorrect positioning of the cementation protection:

- Risk of implant failure!
- ➲ Ensure that the cementation protection completely seals the open femur box.

Correctly positioned Cementing Seal

Incorrectly positioned Cementing Seal

5.2 Assembling the Final Femoral Components

Placing the Cementing Seal for Femur RH/TH

133

The *Cementing Seal for Femur RH/TH* must now be placed to protect the femoral box. The *Trial Insert Holder* (❶) can be used for this purpose. Then a forceps is used to pull the cementing seal down over the Yoke Neck RH/TH, which is in extension.

WARNING

Incorrect positioning of the cementation protection:

- Risk of implant failure!
- ➲ Ensure that the cementation protection completely seals the open femur box.

Correctly positioned Cementing Seal

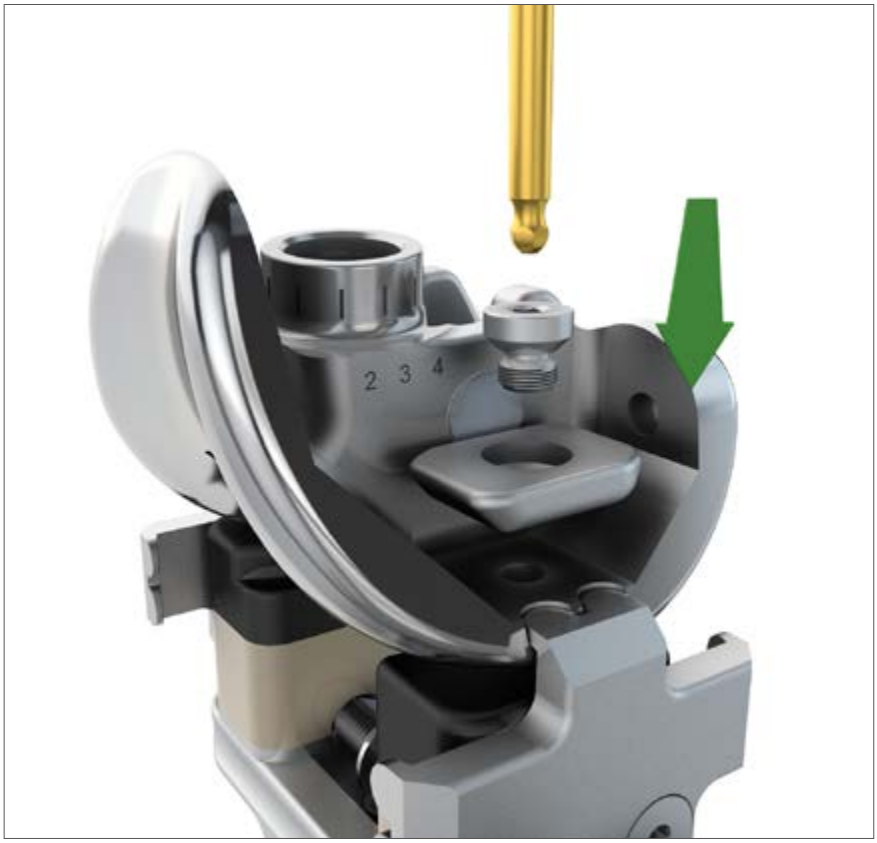
Incorrectly positioned Cementing Seal

5.2 Assembling the Final Femoral Components

Assembling the Femoral Augments

134

The final femoral component is clamped in the assembly aid in the same manner as the trial (see p. 65). The final augments are screwed onto the femoral component with the *Cardan Screw Driver SW3.5* or the *Socket Head Wrench SW3.5* and hand tightened.



! NOTE

The size of the augment depends on the size of the femoral component.

Assembling the Femoral Stem and Adapter

135

The final stem and final adapter are assembled in the same manner as for the trial components (see p. 66-68).

5.2 Assembling the Final Femoral Components

Femoral Offset SC/RH/TH

136

When the Femoral Offset Adapter SC/RH/TH is used, the offset is adjusted in the same manner as for the trial components (see p. 68).

! NOTE

If an offset adapter was used in the trial construct, then an offset adapter must also be used with the final implant. The setting is read off the Femoral Offset Adapter SC/RH/TH and transferred.

WARNING

False Transfer of the Offset position:

- Implant failure due to incorrect positioning!

➲ Ensure offset position is in line with position evaluated within the tibial preparation.

! NOTE

The size of the femoral adapter depends on the size of the femoral component used.

5.2 Assembling the Final Femoral Components

Femoral Offset SC/RH/TH

137

The final implant is tightened in the same manner as the tibial components (see p. 84, 85).

1. Tightening the stem and adapter

Components which are tensioned and secured insufficiently:

- Risk of implant failure!
- ➲ Observe the correct handling of the implant components and instruments.
- ➲ Ensure that the *Torque Key 25Nm* is guided with the right hand and the torque scale can be read from above.
- ➲ Ensure that a click is clearly audible during tensioning.

WARNING

2. Tightening the Counter Nut (see p. 84, 85)

Using the torque wrench to loosen screws:

- The instrument may be damaged!
- ➲ Do not use the *Torque Key 25Nm* to loosen screws.
- ➲ The instrument can be damaged if the *Torque Key 25Nm* is used to loosen screws, meaning that it would no longer apply the required torque during a subsequent implantation

CAUTION

5.2 Assembling the Final Femoral Components

Assembling the Femoral Impactor

138

Then the *Femoral Impactor / Extractor* is disconnected from the *Assembly Receiver* and connected to the *Handle* of the *Impactor / Extractor Femoral*.

5.3 Placing the Final Implants

Placing the Cement Restrictor

The BPK-S Integration system does not provide standard equipment for placing cement restrictors. When third-party systems are used, it is important to compare the length of the Impactor to the length of the implant.

Follow the instructions in the manufacturer's manual.

Those portions of the bone where cement will be used to fix implants are carefully cleaned of contaminants such as residues from reaming, blood, and medullary fat using suitable irrigation instruments (brush, jet lavage) and then dried. The cleaner the surface is, the farther the bone cement can penetrate into the cancellous bone. Drying prevents formation of a parting layer of liquid between the cement and cancellous bone.

After preparation of the bone cement, the femoral canal is filled in retrograde fashion with the aid of a cement syringe.

Placing the Implant Components SC

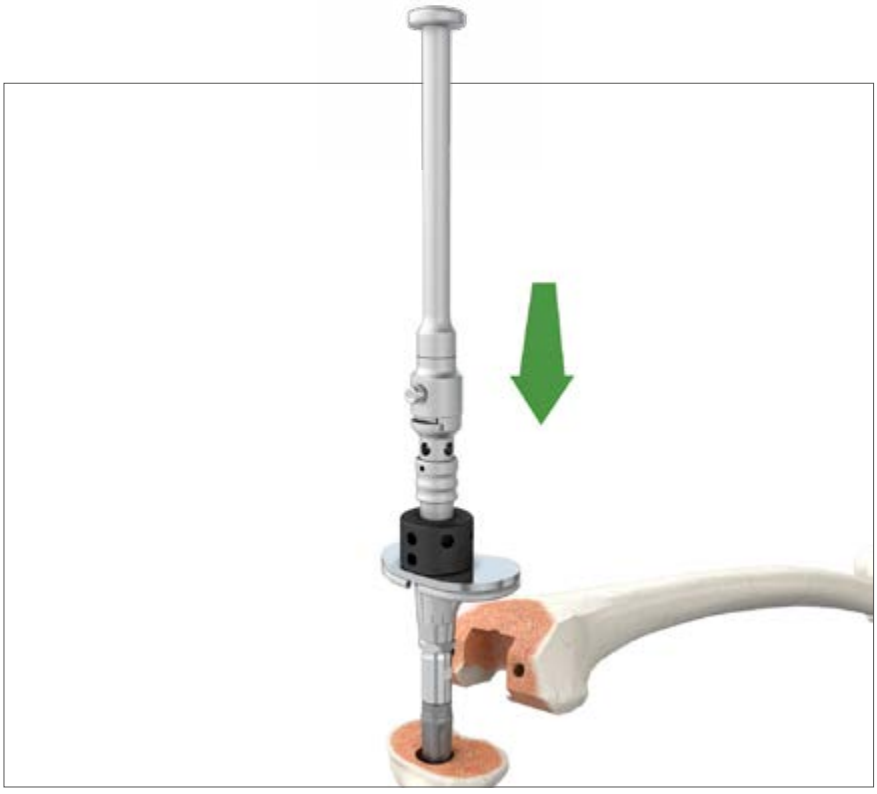
Order of Implantation
1. TIBIAL Component
2. FEMORAL Component
3. Polyethylene Insert
4. Secure Polyethylene Insert with Locking Bolt

All components of the implant system must be cemented except the cementless stems. They must be dry and clean when placed.

Placing the Tibial Plateau SC

139

The tibial plateau SC is inserted with the *Tibial Impactor/Extractor SC*.



5.3 Placing the Final Implants

Placing the Femoral Component SC

140

Placing the FEMORAL Component SC.

! NOTE

For greater clarity, the following figures do not show the bone cement.

141

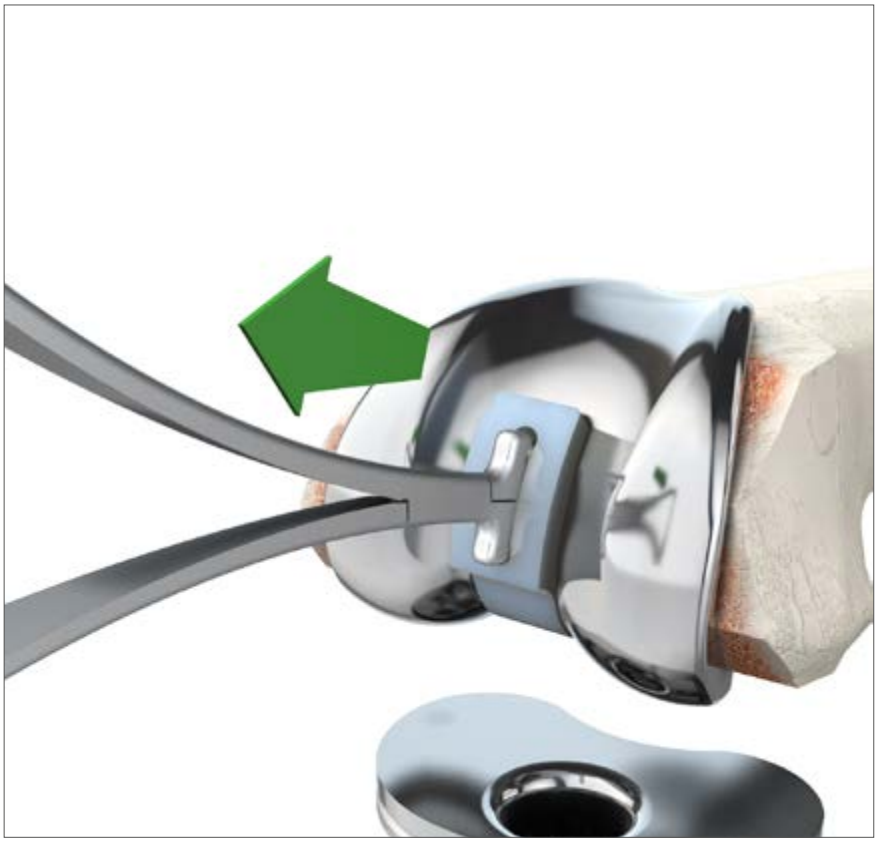
After the prosthesis has been placed, the cementing seal and any residual cement must be removed. Particular attention should be paid to the open femoral box.

WARNING

Foreign objects (e.g. excess cement, tissue, bone) between the implant components:

- Risk of injury due to implant failure!

➲ Clean the implant components thoroughly.



5.3 Placing the Final Implants

Placing the PE Insert SC mobile

142

Once the cement has hardened, the final polyethylene insert is placed.

5.3 Placing the Final Implants

Placing the PE Insert SC mobile

143

The *Impactor for Locking Bolt* is screwed onto the Locking Bolt.

144

The Locking Bolt is driven in with the *Hammer 700 g*.

WARNING

Insufficiently secured components:

- Risk of implant failure!
- ➲ Make sure that the Locking Bolt snaps into place within the tibial component.

Finally, the knee is closed in the usual manner.

5.3 Placing the Final Implants

Placing the Implant Components RH/TH

The implantation procedure is the same as for the SC implant components (see p. 93-94).

All components of the implant system must be cemented except the cementless stems. They must be dry and clean when placed.

Placing the Femoral Component RH/TH

145

The Cementing Seal is pushed away posteriorly by the femoral component.

When removing residual cement, take care to ensure that no cement interferes with or blocks the Yoke Neck.

WARNING

Foreign objects (e.g. excess cement, tissue, bone) between the implant components:

- Risk of injury due to implant failure!

➲ Clean the implant components thoroughly.

5.3 Placing the Final Implants

Placing the Implant Components (PE Insert and Yoke) RH

146

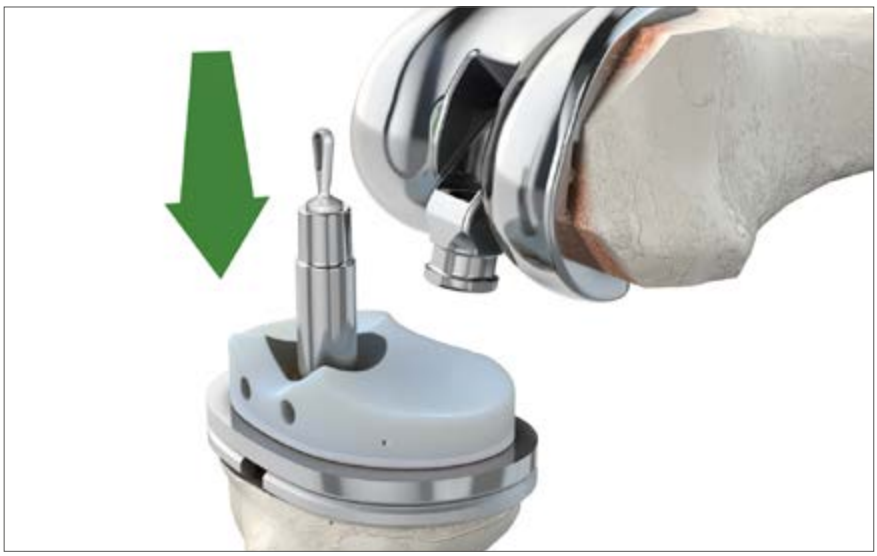
The final PE INSERT RH/TH of the selected height is slid over the pin of the tibial component.

147

The *Yoke sling* is screwed into the Yoke, which is then inserted into the tibial component.

148

When placing the *Yoke* make sure that the eye faces forward.



! NOTE

The *Yoke sling* may not be bent or damaged.

The coupling pin should be selected according to the height of the polyethylene insert.

5.3 Placing the Final Implants

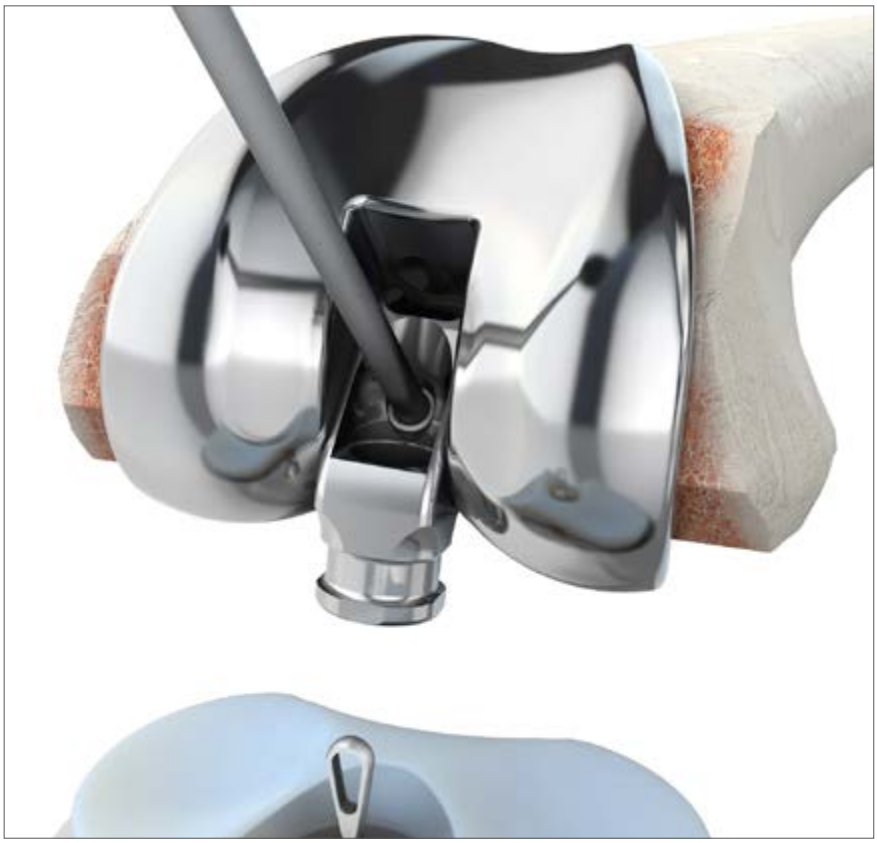
Disassembling the Axis Lock

149

Before the Yoke Neck RH/TH and Yoke RH for Insert can be connected, the axis lock must be temporarily removed from the preassembled femoral plate. The *Socket Head Wrench SW5/SW3.5* with snap ring can be used for this purpose.

150

This screw is reinserted to secure the axis once the components have been joined together and tightened (see p. 104).



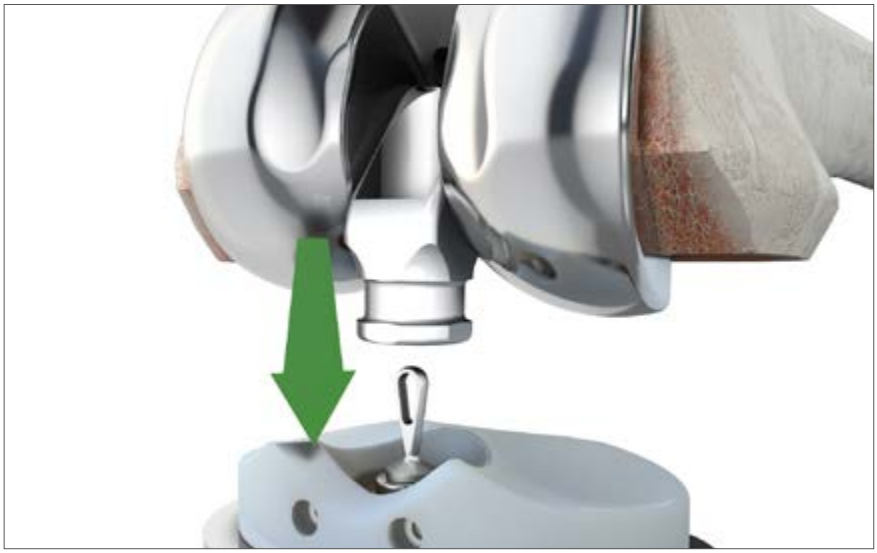
5.3 Placing the Final Implants

Connecting the Yoke RH/TH

151

The Femoral Component is positioned above the insert so that the Yoke Neck RH/TH is centered over the Yoke RH/TH for PE Insert.

Moving the knee through its range of motion makes it easier to center the Yoke Neck above the Yoke.

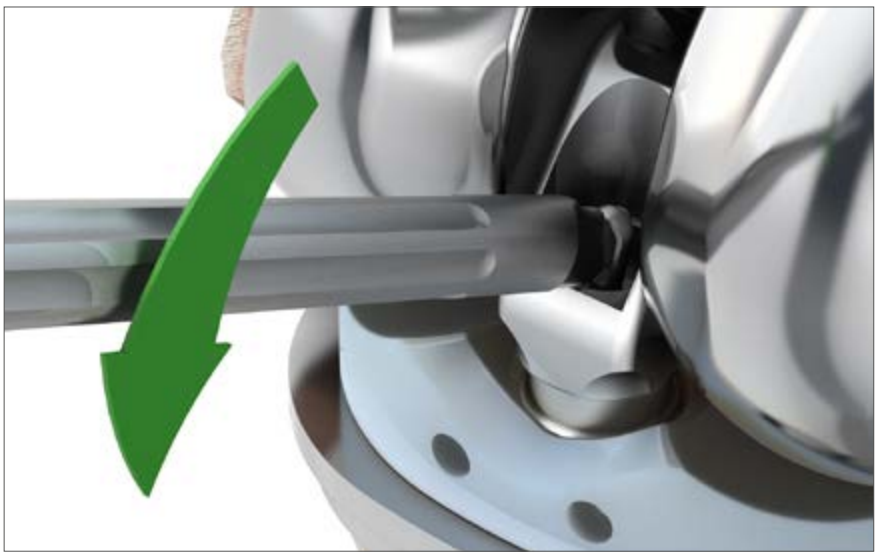


152

The eye of the *Yoke sling* will now be visible.

153

To pull the Yoke RH/TH for PE Insert into the Yoke Neck RH/TH you must now use the *Yoke Assembling Device* as a lever to pry the *Yoke sling* upwards.



5.3 Placing the Final Implants

Removing the Yoke sling

154

After the connection is made, the *Yoke sling* is unscrewed with the *Yoke Assembling Device* and removed.

5.3 Placing the Final Implants

Fixing and Tightening the Yoke RH

155

The Yoke RH for PE Insert is secured in the Yoke Neck RH/TH with the Clamping Screw which is screwed in and tightened with the *Socket Head Wrench SW5*.

5.3 Placing the Final Implants

Fixing and Tightening the Yoke RH

156

To tighten the Clamping Screw the *Impactor/Extractor* is placed on the femoral plate as a brace. The *Socket Head Wrench SW5* (with the hex key flange) is placed in the Clamping Screw. The *Torque Limiter 25±1 Nm* and the *Tommy Bar f. Socket Head Wrench SW6* are attached to the Socket Head Wrench. Then the Clamping Screw is tightened to a defined torque with the *Torque Limiter 25±1 Nm*.

WARNING

Insufficiently tensioned components:

- Risk of implant failure!
- ➲ Observe the correct handling of the implant components and instruments.
- ➲ Secure the Clamp Screw using the *Torque Limiter 25±1Nm*.
- ➲ Ensure that the limiting mechanism of the *Torque Limiter 25±1Nm* releases.

WARNING

Bone fracture due to failing to use a counter holder:

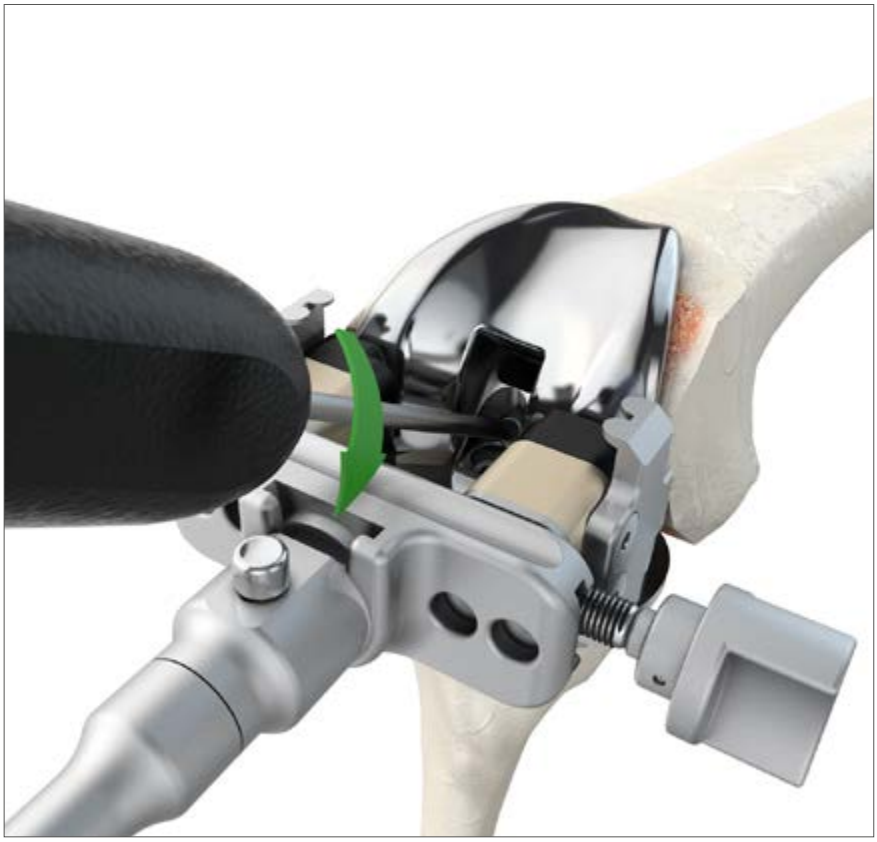
- Risk of injury due to implant loosening!
- ➲ Use the *Torque Limiter 25±1Nm* only with the *Femoral Impactor/Extractor* as a counter holder to prevent the rotational forces from being transferred to the bone.

5.3 Placing the Final Implants

Assembling the Axis Lock

157

The Axis Lock that was removed previously is reinserted once the components have been joined together and tightened (see p. 99). The *Socket Head Wrench SW5/SW3.5* with snap ring can be used for this purpose. The screw is hand tightened. Then the *Femoral Impactor/Extractor* can be withdrawn again.

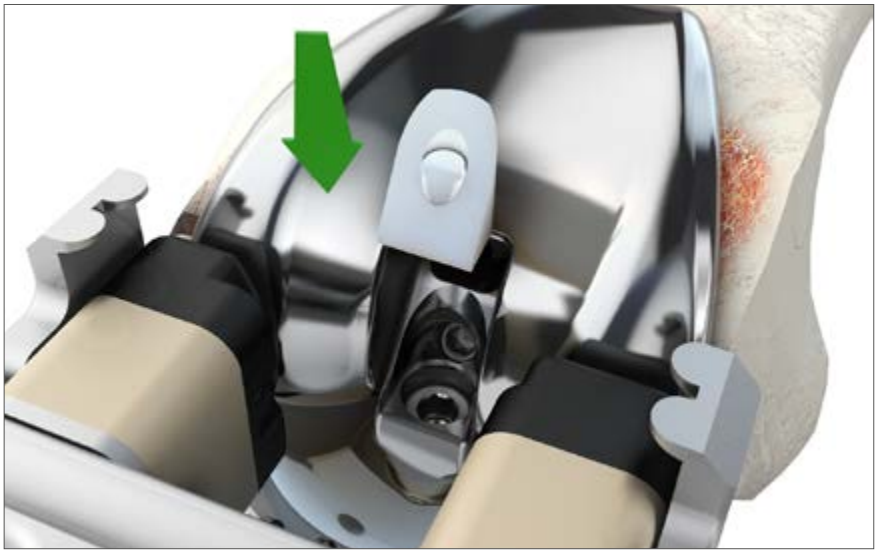


5.3 Placing the Final Implants

Fixing and Tightening the femoral Hyperextension Stop RH/TH

158

Finally the Femoral Hyperextension Stop RH/TH is placed by hand.



The Femoral Hyperextension Stop RH/TH is pressed in and locked with the narrow side of the *Socket Head Wrench SW5/SW3.5*.

Wrong

Right

159

Finally, the knee is closed.

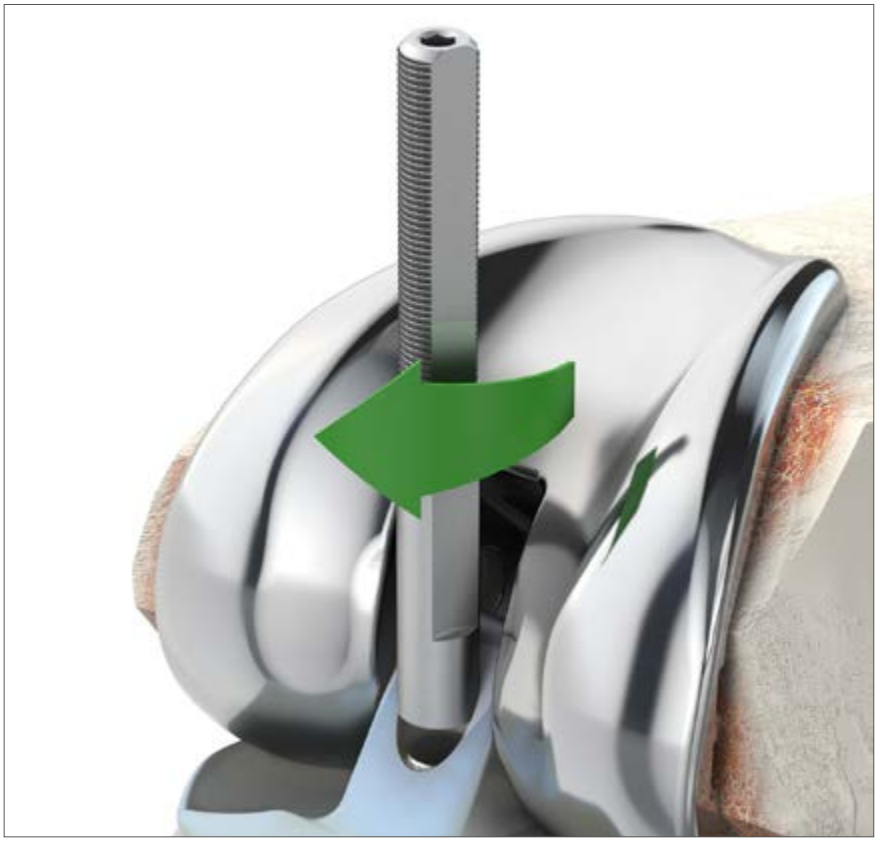
6.1 BPK-S Integration Appendix A

Replacing the PE Insert SC mobile

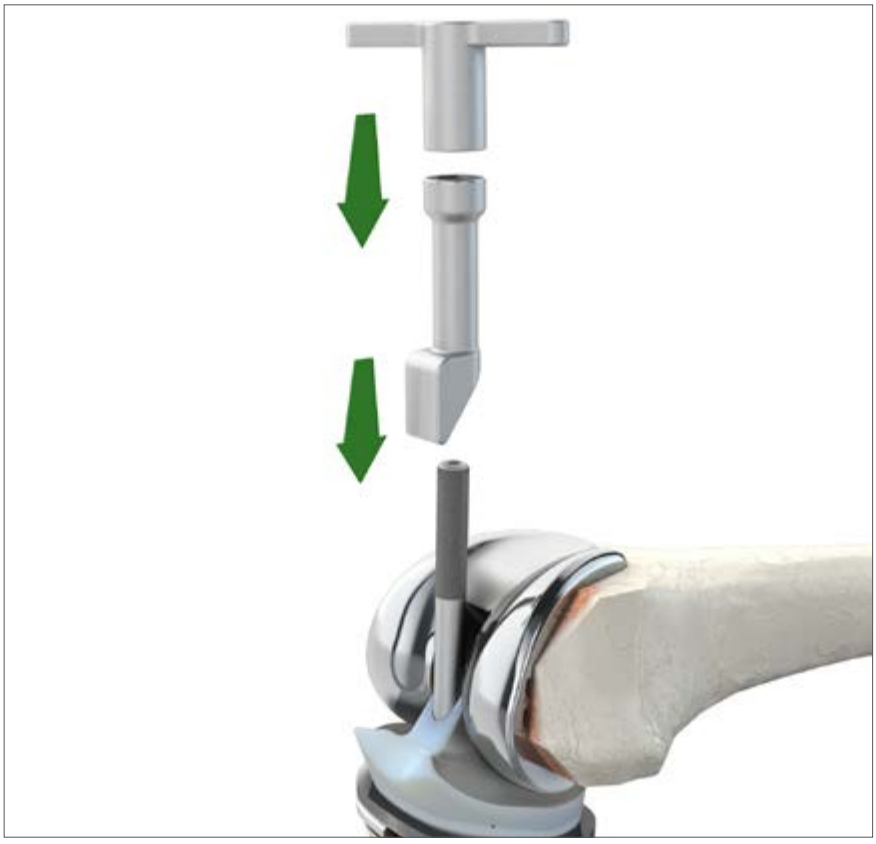
160

In order to replace the PE Insert SC mobile, the Locking Bolt must be removed with the removal device.

The *Extractor for Locking Bolt (inner)* is first screwed onto the Locking Bolt.



The *Extractor for Locking Bolt (outer)* is slid over it. Then the *Extractor for Locking Bolt (Knob)* is attached.



6.1 BPK-S Integration Appendix A

Replacing the PE Insert SC mobile

161

The locking pin can then be removed by turning it clockwise.

162

A new Locking Bolt must be used whenever the PE Insert is replaced.

WARNING

Use of previously used implants:

- Risk of injury due to implant failure!
- May lead to sepsis!

➲ The implants are intended for single use only; do not reuse them.

6.2 BPK-S Integration Appendix B
Disconnecting the Yoke

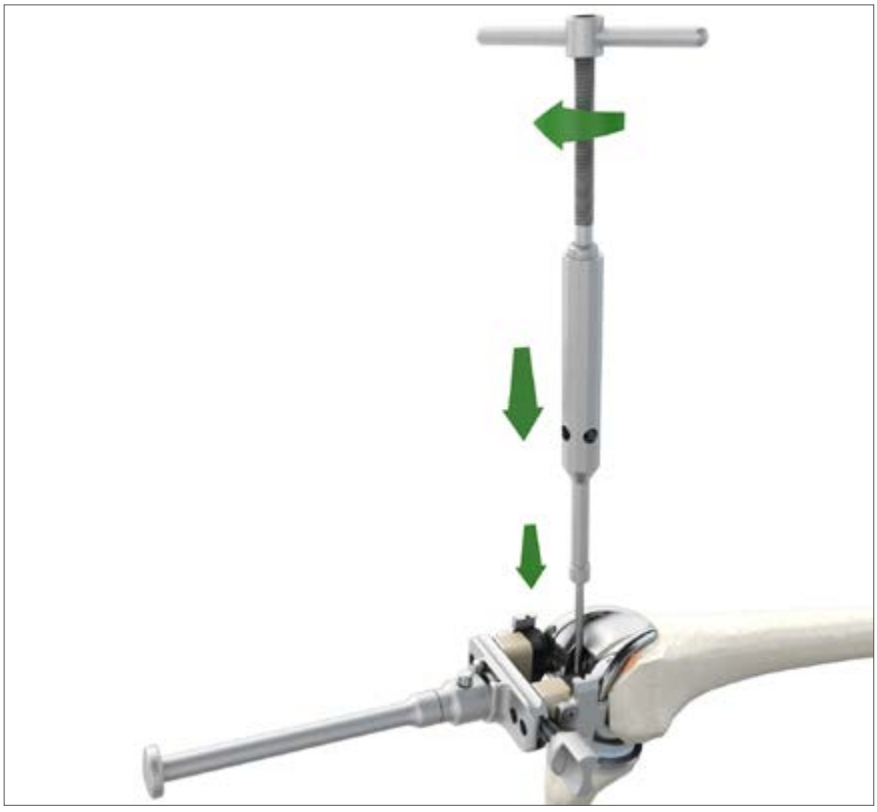
To disconnect the coupling pin, first remove the Femoral Hyperextension Stop RH/TH using a flat instrument like an osteotome. Then the Axis Lock is unscrewed using the *Socket Head Wrench SW5/SW3.5*.

163

To remove the Clamp Screw, attach the *Socket Head Wrench SW5* and the *Tommy Bar f. Socket Head Wrench SW6* and unscrew the screw.

164

To release the Yoke from the taper connection, the *Removing Handle RH/TH* is screwed into the Yoke Neck RH/TH, the *Removing Rod* is inserted, and the *Removing Mandril RH/TH* is screwed in until the taper connection separates.



6.2 BPK-S Integration Appendix B

Removing the Yoke and PE Insert

165

After the separating instrument has been removed, the coupling pin can be removed from the tibial component with the aid of a clamp and the PE Insert (RH/TH) can be pushed off anteriorly.

WARNING

Use of previously used implants:

- Risk of injury due to implant failure!
- May lead to sepsis!
- ➲ The implants are intended for single use only; do not reuse them.

6.3 BPK-S Integration Appendix C

Size Combinations for Femoral/Tibial Components

		Tibia Gr./Sz.					
		3	4	5	6	7[1]	8[1]
Femur Gr./Sz.	3	■	■	■			
	4	■	■	■	■		
	5		■	■	■	■	
	6				■	■	■

[1] The tibial components in sizes 7 and 8 are only available as UC/SC (not augmentable, 3° tibial slope) and SC versions.

Please note the information about the available sizes of the various components in Appendix D. The length of the locking pin (SC) or the coupling pin (RH/TH) depends on the height of the tibial insert.

Sizing of the following implants is according to the size of the femoral Component:

- Patella
- Tibial insert
- Cement guard
- Adapter (femoral) for connecting stems
- Axis lock screw
- Hyperextension stop
- Yoke
- Femoral augments

Size Combinations for Femoral/Patellar Components

	Patella	Durchmesser			
		24	28	32	36
Femur Gr./Sz.	3	■	■	■	
	4	■	■	■	■
	5		■	■	■
	6		■	■	■

6.4 BPK-S Integration Appendix D

UC/SC Components

1 FEMORAL COMPONENT SC cemented
- Size 3, 4, 5, 6 left and right

2 Femoral AUGMENT SC/RH/TH
- Distal 5 mm, 10 mm
- Posterior 5 mm, 10 mm
- Distal / posterior 5 mm, 10 mm

3 Femoral adapter
- 0°, 3°, 4 mm offset

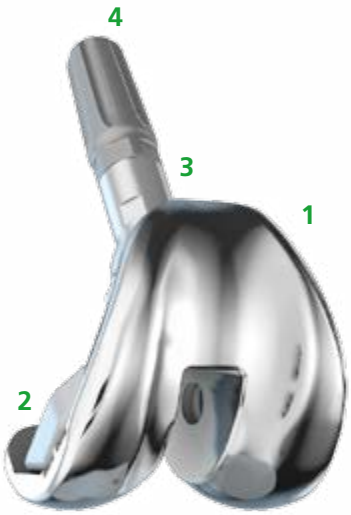
4 Straight STEM
- Cementless
  - Dia. 13 …. 22 mm (length 40, 80, 140 mm)
  - Dia. 23 …. 25 mm (length 40, 80 mm)
- Cemented
  - Length 40 mm, 80 mm, 140 mm
    Dia. 10, 12, 14, 16, 18, 20, 22 mm

5 PE INSERT SC mobil
- Height 7 mm -17 mm (2 mm steps)

6 TIBIAL COMPONENT UC/SC cemented
- Size 3, 4, 5, 6, 7, 8 left and right
- Asymmetrical tibial componen
- 3° posterior slope
- NOT augmentable

7 Tibial ADAPTER
- 0°, 3°, 4 mm offset

8 Patella
- Size 3, 4, 5, 6
- Dia. 24/8 mm, 28/8 mm, 32/8 mm, 36/8 mm



6.4 BPK-S Integration Appendix D

SC Components

1 FEMORAL COMPONENT SC cemented
- Size 3, 4, 5, 6 left and right

2 Femoral AUGMENT SC / RH / TH
- Distal 5 mm, 10 mm
- Posterior 5 mm, 10 mm
- Distal / posterior 5 mm, 10 mm

3 Femoral adapter
- 0°, 3°, 4 mm offset

4 Straight STEM
- Cementless
  - Dia. 13 …. 22 mm (1 mm steps)length 40, 80, 140 mm
  - Dia. 23 …. 25 mm length (1 mm steps) 40, 80 mm
- Cemented
  - Length 40 mm, 80 mm, 140 mm

  Dia. 10, …., 22 mm (2mm steps) length 40, 80, 140 mm

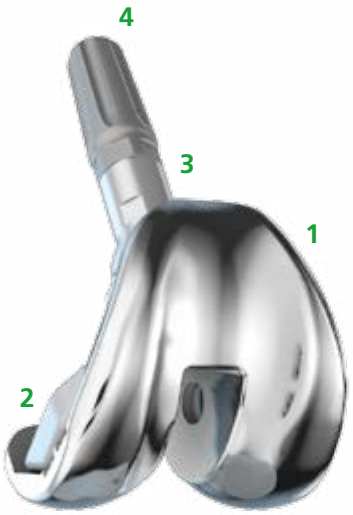
5 PE INSERT SC mobil
- Height 7 mm - , 17 mm (2mm steps)

6 TIBIAL COMPONENT SC cemented
- Size 3, 4, 5, 6, 7, 8 left and right
- Symmetrical tibial component
- 0° posterior slope
- Augmentable

7 Tibial AUGMENTS SC
- Medial 5 mm, 10 mm, 15 mm
- Lateral 5 mm, 10 mm, 15 mm

8 Tibial ADAPTER
- 0°, 3°, 4 mm offset

9 Patella
- Size 3, 4, 5, 6
- Dia. 24/8 mm, 28/8 mm, 32/8 mm, 36/8 mm



6.4 BPK-S Integration Appendix D

RH/TH Components

1 FEMORAL component RH/TH cemented
- Size 3, 4, 5, 6 left and right

2 Femoral AUGMENTS SC/RH/TH
- Distal 5 mm, 10 mm
- Posterior 5 mm, 10 mm
- Distal / posterior 5 mm, 10 mm

3 Femoral adapter
- 0°, 3°, 4 mm offset

4 Straight STEM
- Cementless
  - Dia. 13 …. 22 mm (1 mm steps)length 40, 80, 140 mm
  - Dia. 23 …. 25 mm length (1 mm steps) 40, 80 mm
- Cemented
  - Dia. 10, …., 22 mm (2mm steps) length 40, 80, 140 mm

5 PE INSERT RH/TH
- Height 9 mm - 25 mm (2mm steps)

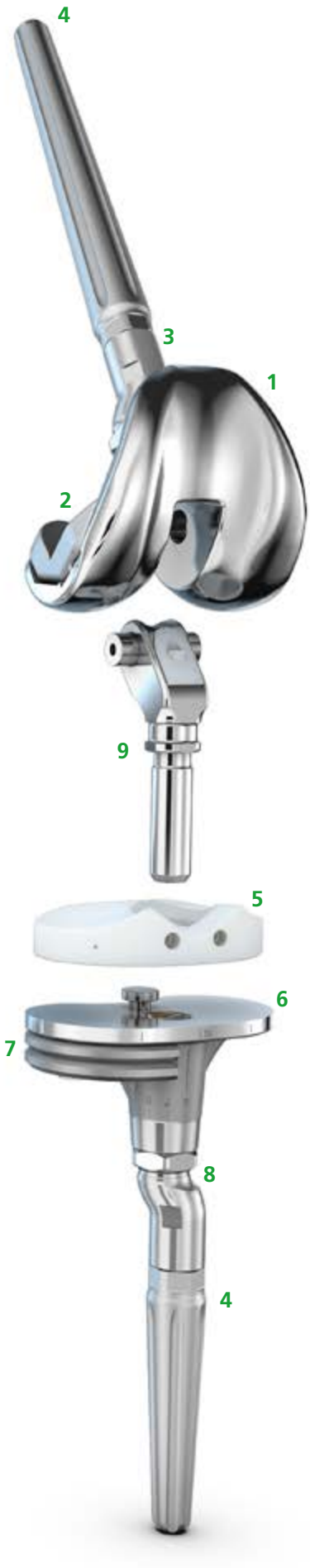
6 TIBIAL COMPONENT RH/TH cemented
- Size 3, 4, 5, 6
- Symmetrical tibial component
- 0° posterior slope
- Augmentable

7 Tibial AUGMENTS RH/TH
- Medial 5 mm, 10 mm, 15 mm
- Lateral 5 mm, 10 mm, 15 mm

8 Tibial ADAPTER
- 0°, 3°, 4 mm offset

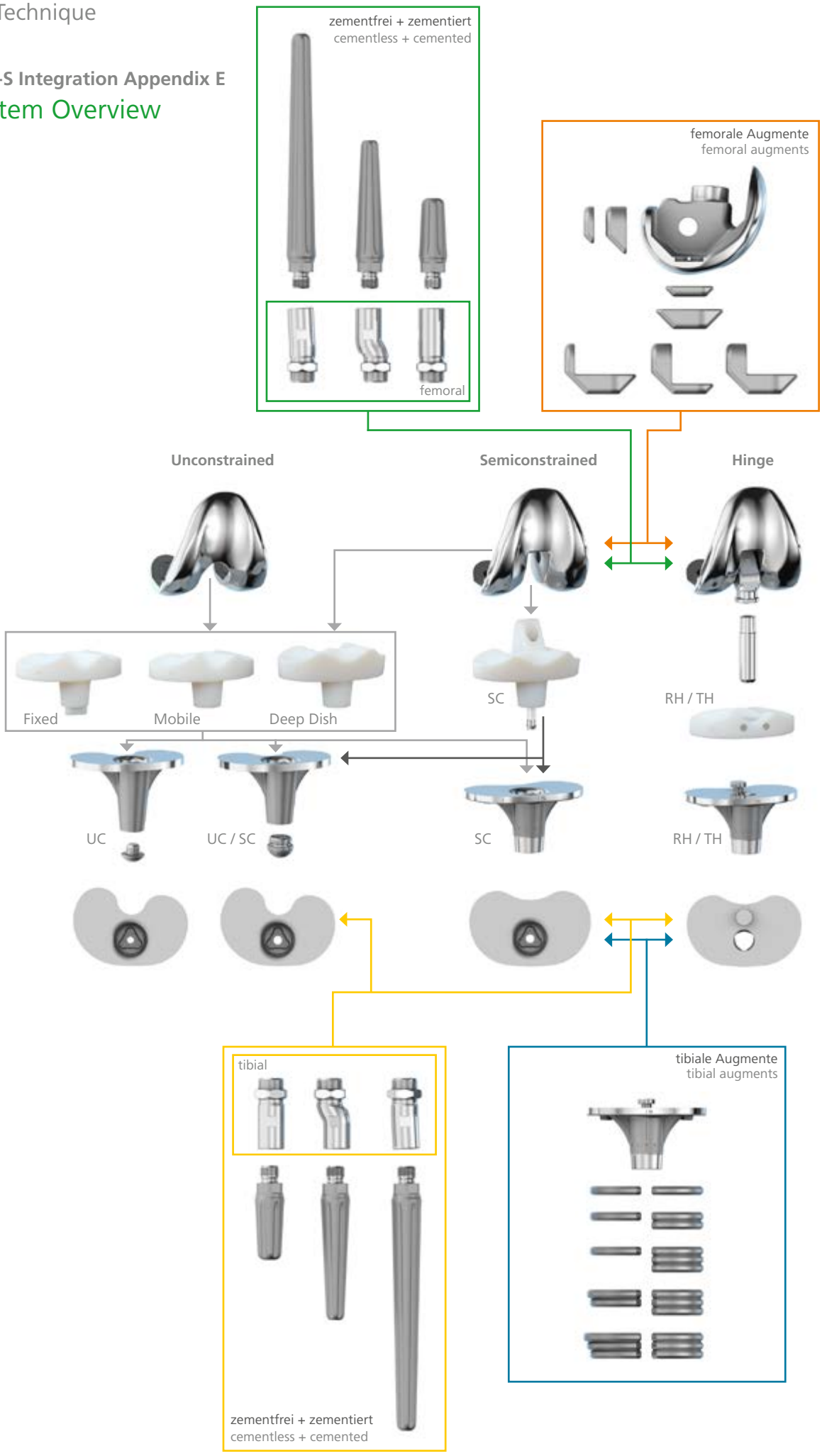
9 COUPLING PIN RH for PE Insert
- Height 9 mm - 25 mm (2mm steps)

10 Patella
- Size 3, 4, 5, 6
- Dia. 24/8 mm, 28/8 mm, 32/8 mm, 36/8 mm



6.5 BPK-S Integration Appendix E

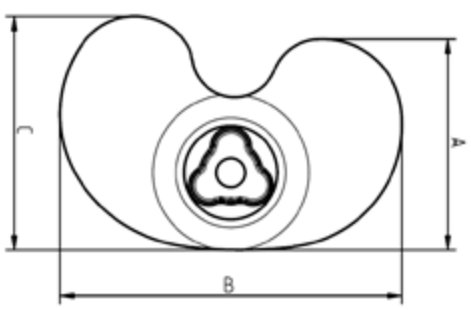
System Overview



6.6 BPK-S Integration Appendix F

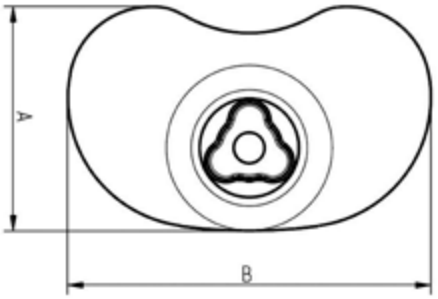
Dimensions - Tibial Components (All Measurements Rounded)

UC / SC



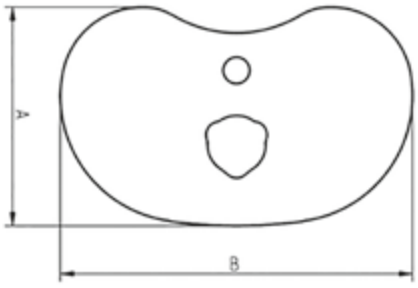
Size	A [mm]	B [mm]	C [mm]
1	36,9	60	40,9
2	38,8	63,2	43
3	41,1	66,5	45,3
4	43,3	70	47,7
5	45,9	74,2	50,5
6	48,6	78,7	53,5
7	51,6	83,4	56,8
8	54,7	88,4	60,2

SC

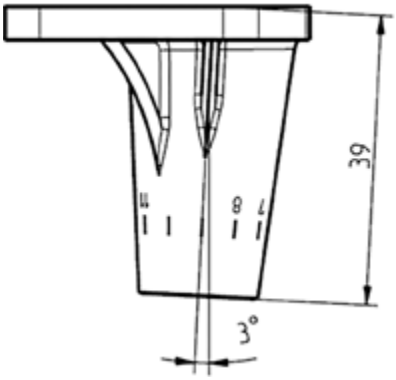


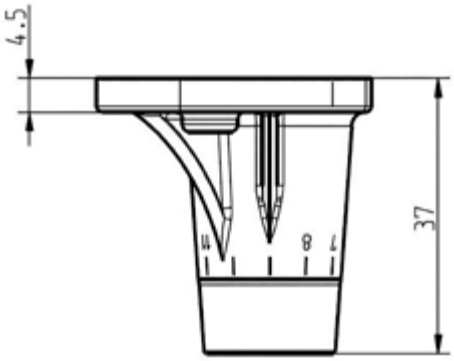
Size	A [mm]	B [mm]
3	41,1	66,5
4	43,3	70
5	45,9	74,2
6	48,6	78,7
7	51,6	83,4
8	54,7	88,4

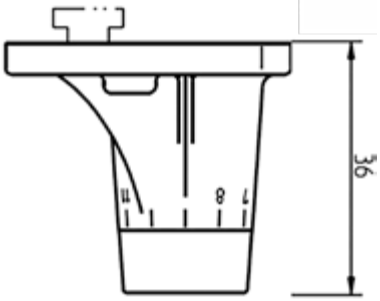
RH / TH



Size	A [mm]	B [mm]
3	41,1	66,5
4	43,3	70
5	45,9	74,2
6	48,6	78,7



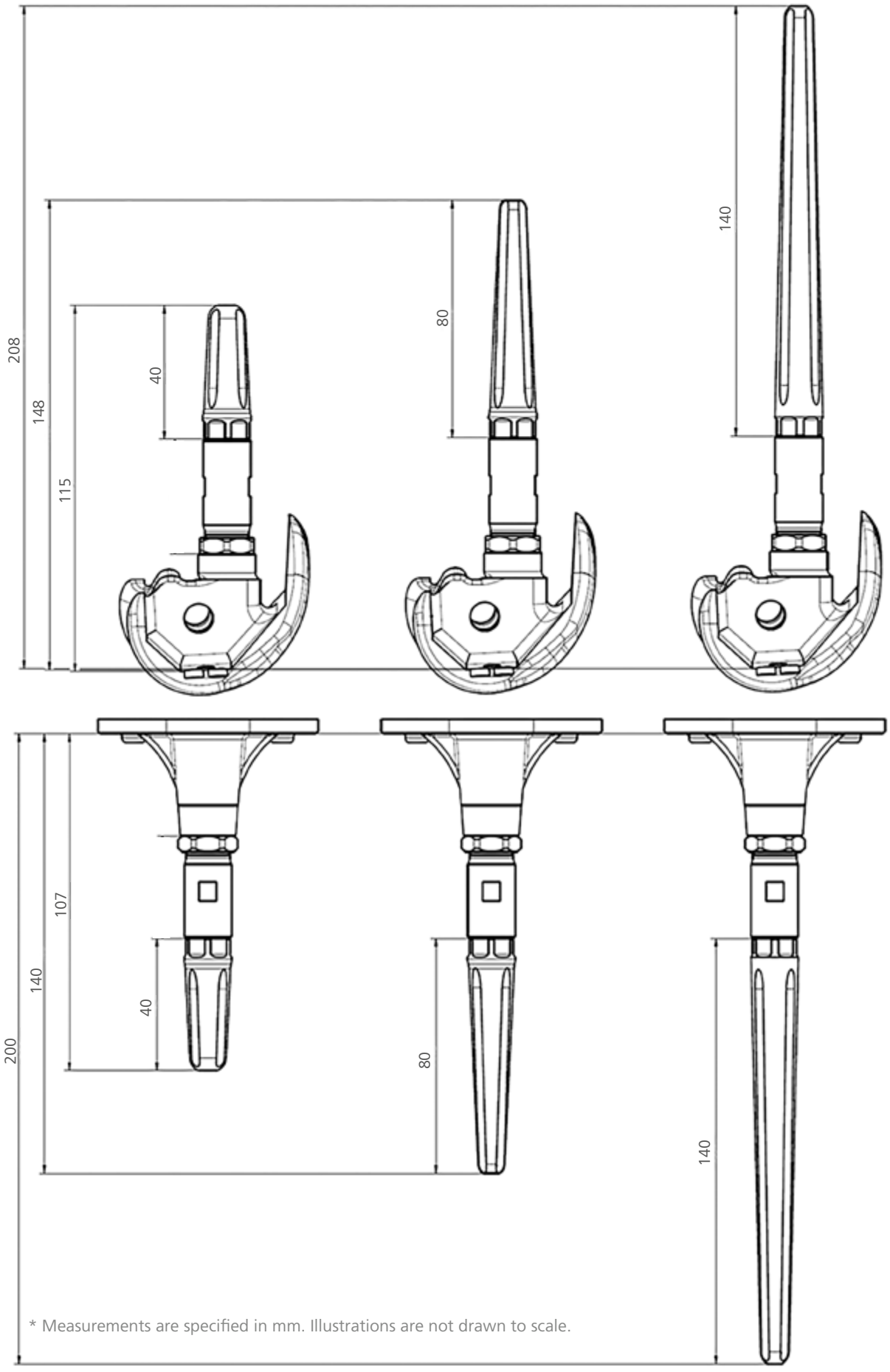




*Measurements are specified in mm. Illustrations are not drawn to scale.

6.6 BPK-S Integration Appendix F

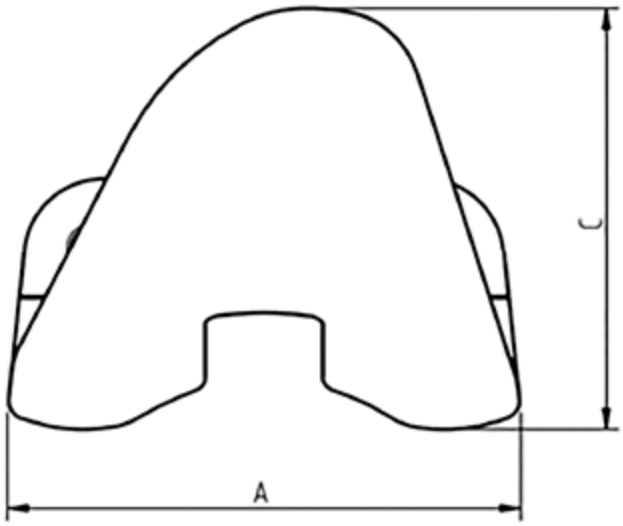
Construct Lengths (All Measurements Rounded)

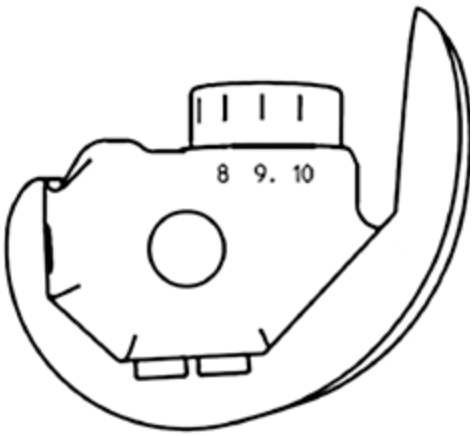


* Measurements are specified in mm. Illustrations are not drawn to scale.

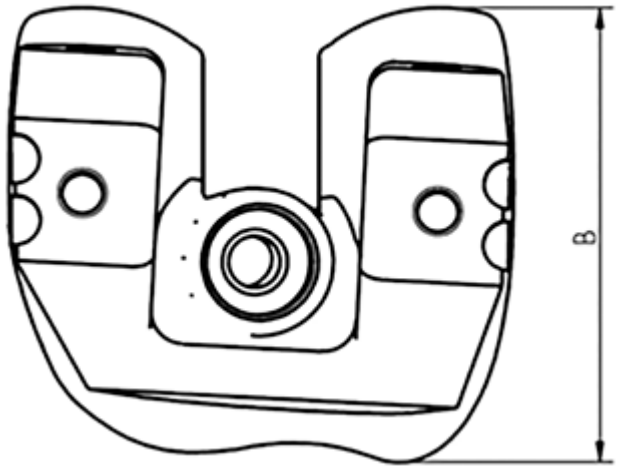
6.6 BPK-S Integration Appendix F

Femoral Components SC and RH/TH (All Measurements Rounded)





Size	A [mm]	B [mm]	C [mm]
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



* Measurements are specified in mm. Illustrations are not drawn to scale.

! NOTE

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