FREEDOM® PCK

ADDENDUM TO
Freedom PCK® Revision Knee Surgical Technique

OFFSETTING THE FEMORAL COMPONENT

Follow the Freedom Knee Revision Surgical Technique. At Step 4 ("Anterior and Posterior Cuts"), use the *following procedure to offset the PCK femoral component with respect to the IM canal.*

NOTE
The reamed depth of the IM canal increases if the femoral component is to be offset, see Table A. If the need to offset the femoral is undetermined at this time, the additional depth can be reamed later.

TABLE A
FEMORAL IM CANAL REAMING DEPTH REQUIREMENTS

STEM LENGTH	REAMER DEPTH MARKING	
	No Offset	With Offset
40mm	65	100
75mm	100	130
100mm	130	155
150mm	175	205

STEP 4: Anterior and Posterior Cuts

Refine the anterior and posterior femoral cuts, including posterior augmentation cuts, if necessary. Assess the need for offsetting the femoral component with respect to the IM canal.

STEP 4a: Positioning the Femoral Anterior/Posterior Cutting Block

Reintroduce the ***distal reamer*** into the IM canal if it was removed to perform the distal femoral resection. Select the size of ***femoral A/P positioning guide*** that matches the implant size. The medial/lateral width of each guide is equal to the medial/lateral width of its corresponding femoral component. If the distal face was prepared for augmentation in the previous step, ***femoral augments*** can be attached to the ***femoral A/P positioning guide*** to increase the stability of the guide on the distal face (Fig. F1). Medial and/or lateral side and thickness of augments should match the previously made femoral distal augment cuts. Femoral augments are supplied in two footprints, small and large. The size B, C and E positioning guides use the small femoral augments. The size F, G and H positioning guides require the large augments. Each set contains thicknesses of 5, 10 and 15mm.

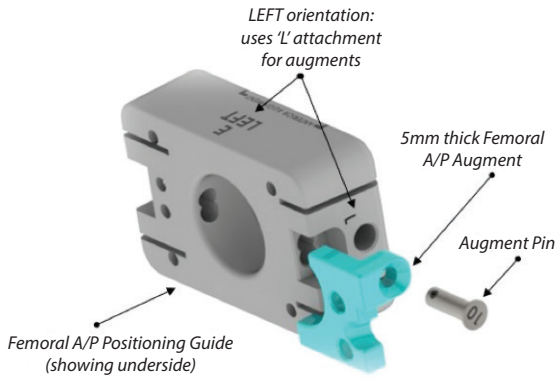

Fig. F1: Assembling Femoral A/P Positioning Guide and Augments

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Using the ***10mm trial augment pin***, attach the appropriate size and thickness of ***augment(s)*** to the ***positioning guide*** through the holes on the sides of the guide according to operative side (holes marked "L" for a left knee and "R" for a right knee). The augments will not obstruct the anterior alignment slot and there are clearance holes in the augments that align with the straight pinning holes in the positioning guide.

Drop the ***femoral A/P positioning guide*** over the ***distal reamer***, orienting it for the correct operative side and resting it on the previously resected distal face of the femur. Slide the ***"0" dial*** over the ***distal reamer*** and fit it into the recess of the ***femoral A/P positioning guide***. Use an ***angel wing*** through the anterior slot in the positioning guide to check its alignment with the existing anterior cut. If this central location of the positioning guide does not result in correct alignment of the anterior slot with the previous anterior cut or the medial/lateral position is not acceptable, then an offset placement of the femoral should be evaluated. Remember, the width and current position of the ***femoral A/P positioning guide*** mimic those of the same size femoral implant. To assess offsetting, replace the ***"0" dial*** with the ***"left"*** or ***"right" femoral 4mm offset dial***, according to operative side. Rotate the dial around the distal reamer to reposition the guide in an acceptable anterior/posterior and medial/lateral location. Again, use an ***angel wing*** through the anterior slot as a guide, understanding that this indicates the final position of the anterior surface of the PCK femoral implant (Fig. F2).

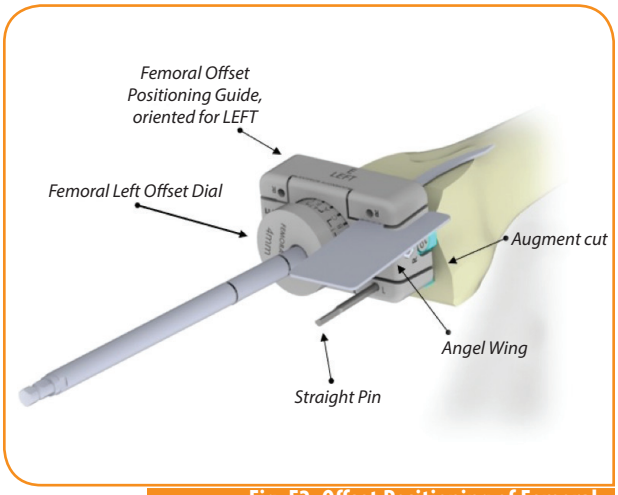

Fig. F2: Offset Positioning of Femoral

There are three holes available per operative side for pinning the ***femoral A/P positioning guide*** on the distal cut face of the femur. Insert ***long straight pins*** through at least 2 of the 3 holes; marked as "L" for a left knee or "R" for a right knee (Fig. F3). Remove the ***femoral offset dial*** and the ***femoral A/P positioning guide***, leaving behind the ***distal reamer*** and ***straight pins***.

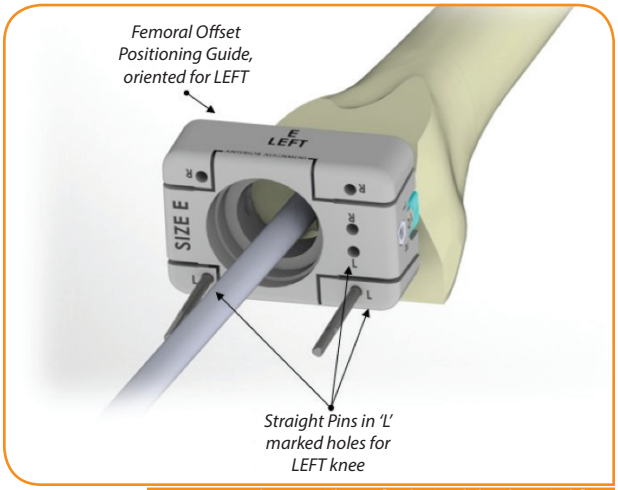

Fig. F3: Pinned A/P Positioning Guide

Prepare the appropriate size ***femoral A/P cutting block*** with the same ***femoral augments*** used on the ***femoral A/P positioning guide*** (Fig. F4). Attachment of the ***femoral augments*** is done through holes in the sides of the ***A/P cutting block*** using the same ***10mm trial augment pins***. Each cutting block has 4 straight pinning holes in the exact configuration as its corresponding femoral A/P positioning guide (which has 3 of these 4 holes). Slide the ***femoral A/P cutting block*** over the ***straight pins*** through the appropriate pinning holes, resting it on the cut distal face of the femur (Fig. F4). Reaffirm the location of the anterior cut using an ***angel wing*** through the anterior cut slot, ensuring that the anterior cut is not too deep as to notch the anterior cortex of the femur. Reaffirm the medial/lateral position of the cutting block for optimal coverage, understanding that the width and location of the cutting block will exactly match the width and location of the femoral PCK implant. Secure the ***femoral A/P cutting block*** to the bone with ***threaded headed pins*** through its oblique holes.

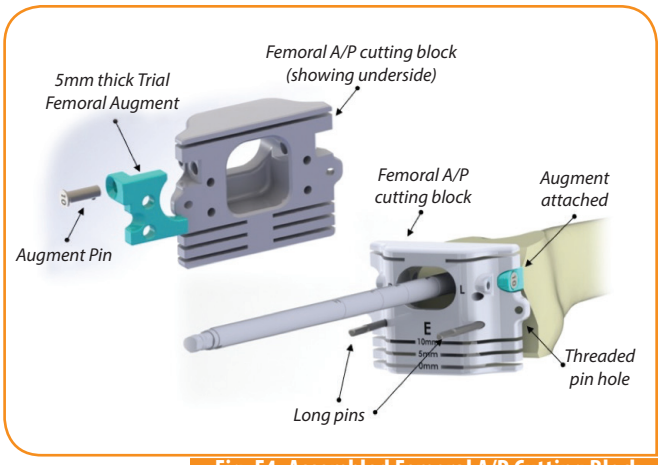

Fig. F4: Assembled Femoral A/P Cutting Block

STEP 4b: Performing anterior and posterior cuts including augment cuts

Make the anterior and posterior cuts using an oscillating saw through the appropriate cutting slots in the ***femoral A/P cutting block***. For the posterior cuts, use the '0mm' slots if no augmentation is needed or use the '5mm' or '10mm' augment slots to remove bone for 1 or 2 posterior augments, respectively, as required. The maximum number of posterior augments per side is two.

NOTE

The maximum number of distal and posterior augments combined per side is four. Therefore, two posterior augments may be used on a particular side only if two or fewer distal augments are used on that same side; again, adding up to a combined maximum number of four augments per side.

Remove the ***femoral A/P cutting block*** and ***pins*** and proceed with Step 5: 'Intercondylar Box Preparation'.

STEP 5: Intercondylar Box Preparation

Remove intercondylar bone to accommodate the femoral offset component and the boss and intercondylar box of the PCK femoral implant.

STEP 5a: Opening IM Canal to Accept Femoral Offset Component

If the IM canal is reamed to a diameter smaller than Ø17mm, additional reaming is necessary to prepare the femur to accept the proximal portion of the offset junction in line with the IM canal. If not, proceed directly to STEP 5b.

Remove all instrumentation including the current ***distal reamer***. Using the ***Ø17mm distal reamer*** and following the previously reamed IM canal, ream until the 65mm mark on the reamer is flush with the distal face of the femur. (Be sure to reduce this reaming depth accordingly for any augment cuts already performed on this distal face).

STEP 5b: Positioning the Box Cut Guide

Reintroduce the original ***distal reamer*** into the IM canal if it was previously removed (diameter which matches the stem to be implanted). Select the size of ***femoral PCK box cut guide (BCG)*** that matches the implant size. The medial/lateral width of each guide is equal to the medial/lateral width of its corresponding femoral component. If the distal face was prepared for augmentation, ***distal femoral augments*** can be attached to the ***BCG*** to increase the stability of the guide on the distal face. Medial and/or lateral position and thickness of augments should match the previously made femoral distal augment cuts. There is one ***distal femoral augment*** for all sizes of box cut guides available in thickness of 5, 10 or 15mm. The proper orientation of the ***distal femoral augments*** will ensure no interference with the subsequent box and chamfer cuts. Attach the appropriate thickness augment to the distal face of the ***BCG*** using the corresponding length of ***trial augment pin*** (Fig. F5).

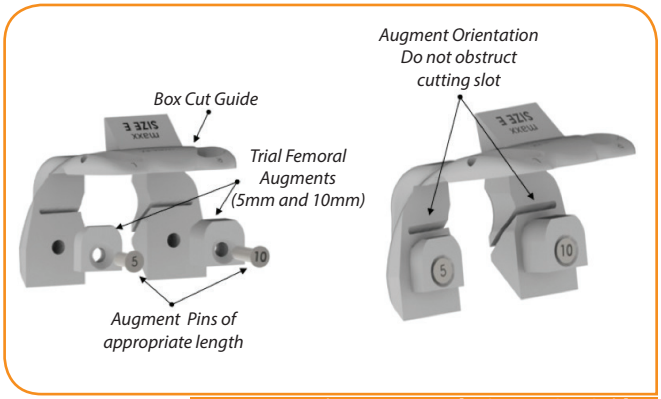

Fig. F5: Femoral PCK Box Cut Guide with Augments

Depending on implant size, attach the small (B-E) or large (F-H) ***femoral BCG offset plate*** to the ***BCG***, oriented according to the correct operative side (Fig. F6).

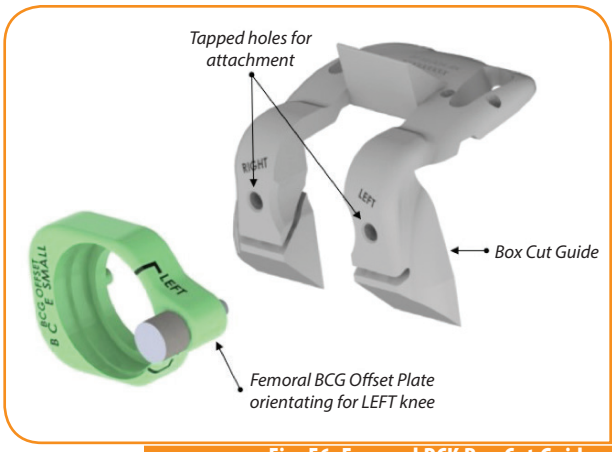

Fig. F6: Femoral PCK Box Cut Guide with Femoral BCG Offset Plate

Drop the ***BCG*** assembly over the ***distal reamer***. Initially, allow the internal anterior face of the ***BCG*** to rest on the anterior cut of the femur and the distal surface of the ***BCG*** to rest on the distal cut of the femur. Next, slide the appropriate ***"left" or "right" femoral offset dial*** over the ***distal reamer*** and fit it into the recess of the ***femoral BCG offset plate*** (Fig F7). Check to confirm that the medial/lateral placement of the ***BCG*** accurately represents the desired final location of the PCK femoral. If it does not, rotate the ***offset dial*** around the ***distal reamer*** to reposition the ***BCG*** accordingly. Two situations can occur:

1. Ideally, the internal anterior face of the ***BCG*** rests on the anterior cut of the femur and its medial/lateral placement is good. Recall that in positioning the ***femoral A/P cutting block*** to make the anterior and posterior cuts, this medial/lateral position was assessed and therefore should be correct.

OR

2. The internal anterior face of the ***BCG*** is not resting on the anterior cut of the femur, but rather is floating off the bone. In this case, offsetting of the femoral is most likely anterior with respect to the IM canal. This can happen if the explanted femoral was placed too far posterior and/or too much anterior bone was resected during the previous surgery. Understand that if you desire to finalize the position of the ***BCG*** as such, you will need to recut the posterior face of the femur accordingly, as well as fill this resulting anterior gap with bone cement.

Pin the ***BCG*** with ***long straight pins*** through the straight anterior pinning holes. Be mindful to avoid pinning holes that may interfere with the reamer, especially in situations where offsetting is primarily in the medial or lateral direction. The oblique pinning holes can be used later for further fixation. Record which marking on the ***offset dial*** is aligned with the corresponding mark on the ***femoral BCG offset plate*** (Fig. F7).

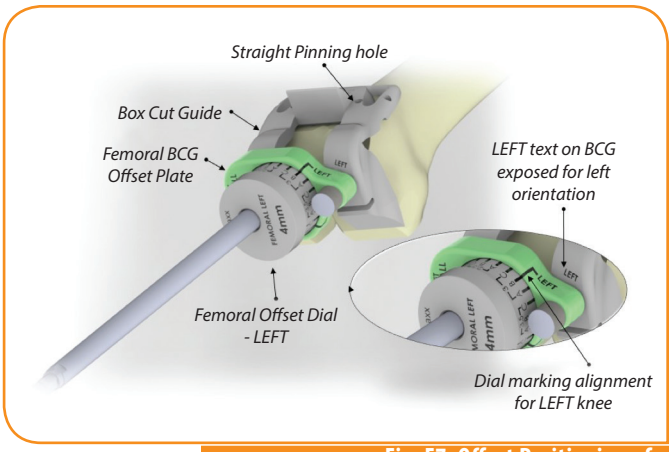

Fig. F7: Offset Positioning of Femoral PCK Box Cut Guide

NOTE

Recording the offset dial marking that aligns with the marking on the BCG offset plate (in this case, '3B') aids in later assembling the trial and implant components correctly.

Disassemble the instrumentation as follows. First, remove the ***femoral offset dial*** and ***BCG offset plate***. Prior to extracting the ***distal reamer***, temporarily remove the ***BCG*** from the ***pin*** or ***pins*** securing it. Extract the ***distal reamer*** and then replace the ***BCG*** on the ***pin(s)***.

NOTE

If the ***distal reamer*** diameter exceeds those listed in Table B corresponding to the femoral implant size, it is necessary to temporarily remove the ***BCG*** from the ***pins*** prior to extracting the ***distal reamer***. After removing the ***distal reamer***, reassemble the ***BCG*** onto the ***pins*** before proceeding.

TABLE B. MAXIMUM REAMER Ø VS. FEMORAL IMPLANT SIZE

FEMORAL IMPLANT SIZE	REAMER Ø
B	Ø17.5mm
C	Ø18.0mm
E	Ø18.0mm
F	Ø22.0mm
G	Ø22.0mm
H	Ø22.0mm

After extracting the ***distal reamer***, additional ***pins*** can be used through the oblique holes to further secure the ***BCG***. With only the pinned ***BCG*** remaining, proceed directly to Step 5c: 'Performing Central Boss Reaming and Intercondylar Box Cuts'.

STEP 5c: Central boss reaming and intercondylar box cuts

NOTE

Central boss reaming is always needed in cases where the femoral is offset.

Prepare the femur to accept not only the central boss of the PCK femoral component, but also the distal portion of the offset junction component. Attach the appropriate size ***femoral drill guide housing*** [small (B-E) or large (F-H)] to the pinned ***BCG***, oriented according to the correct operative side (Fig. F8). Additional ***pins*** can be introduced through the oblique set of holes in the ***BCG*** for further fixation.

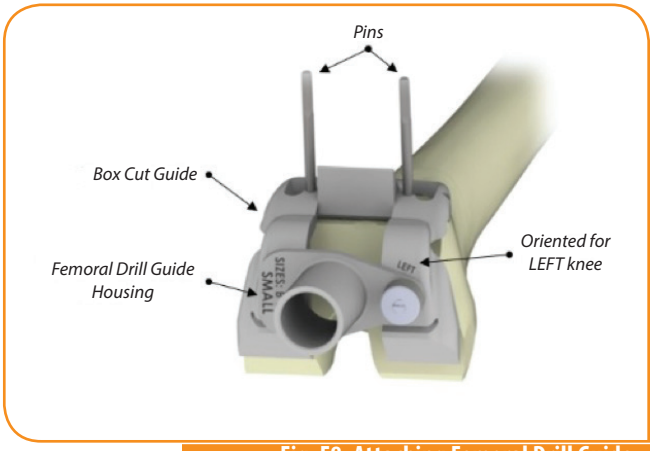

Fig. F8: Attaching Femoral Drill Guide Housing to the Box Cut Guide

Advance the ***Ø17mm distal reamer*** through the ***femoral drill guide housing***, reaming until the 100mm groove reaches the top of the ***femoral drill guide housing*** (Fig. F9). Remove the ***femoral drill guide housing***, leaving the ***BCG*** in place for the subsequent box and chamfer cuts.

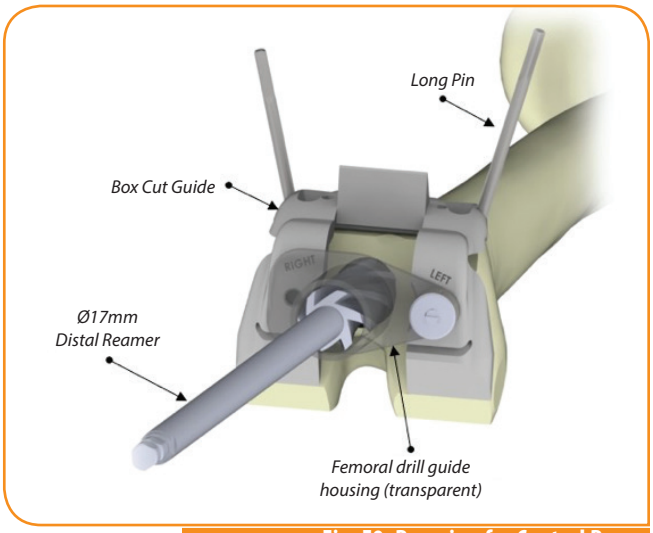

Fig. F9: Reaming for Central Boss of PCK Femoral

STEP 5d: Intercondylar box cuts

For this step, ensure that the pinned ***BCG*** is the only instrumentation present. With a ***reciprocating saw***, use the three centralized surfaces of the ***BCG*** to aid in making the box cuts on the distal femur (Fig. F10). Be careful not to risk fracture by undermining the medial or lateral condyles. Use an ***oscillating saw*** through the cutting slot in the ***BCG*** to perform the anterior chamfer resection. Guide the saw along the posterior angled faces of the ***BCG*** to perform the posterior chamfer resection.

Remove all instrumentation in preparation for trialing.

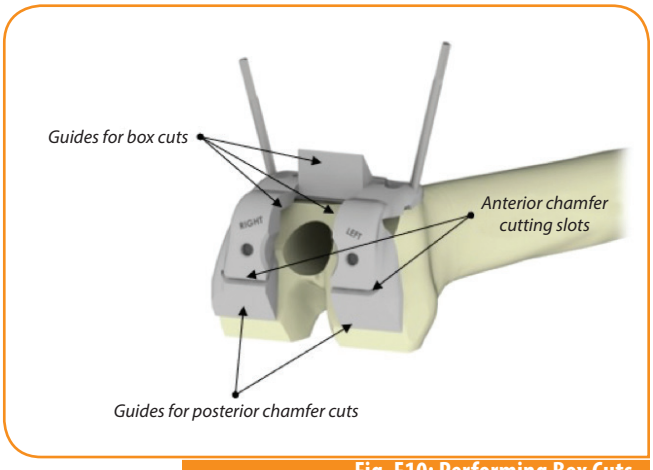

Fig. F10: Performing Box Cuts

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PREPARING THE PCK FEMORAL TRIAL COMPONENTS

Select the size of ***femoral trial*** and ***stem extension trial*** that match the sizes to be implanted. Additional trial components include the ***4mm offset junction trial*** and any needed ***femoral augment trials***.

If needed, attach the appropriate size and thickness of ***femoral trial augment(s)*** with the appropriate length ***augment pins(s)*** to the ***femoral trial*** (Fig. I1). The thickness and placement of the ***femoral trial augment(s)*** is dictated by the femoral distal and posterior augment cuts previously made.

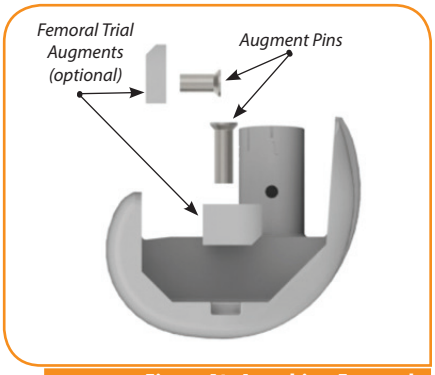

Figure I1: Attaching Femoral Trial Augments

Thread and hand tighten the appropriate diameter and length ***stem extension trial*** into the ***4mm offset junction trial***. Thread the ***offset junction trial*** into the central boss of the ***femoral trial*** until the ***offset junction trial*** can spin freely (Fig. I2).

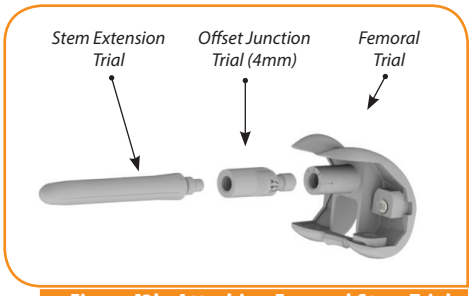

Figure I2b: Attaching Femoral Stem Trial and Offset Junction Trial

Align the ***femoral trial*** and ***offset junction trial*** markings according to the rotational position recorded earlier between the ***femoral BCG offset plate*** and the ***femoral offset dial*** (refer to step 5b and Fig. F7, under "Positioning the BCG"). Secure this orientation by inserting the ***PCK junction screw*** through the hole in the ***femoral trial*** and threading it into the ***offset junction trial*** (Fig. I3).

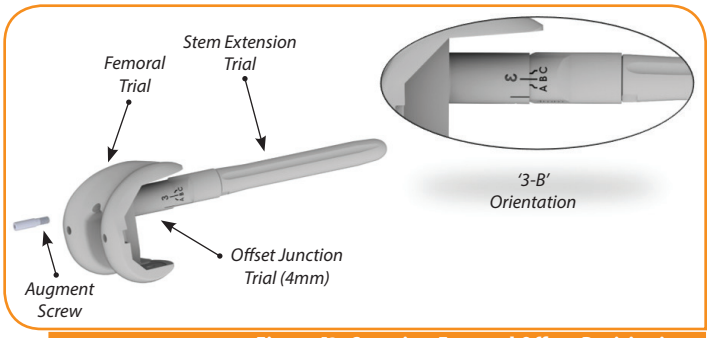

Figure I3: Securing Femoral Offset Positioning

Alternatively, the trial assembly of the femoral, offset junction and stem can first be impacted in place, prior to inserting the screw. This allows the offset junction to rotate freely and the assembly to find its natural position in the prepared bone. For this alternative method, as the last step, lock the orientation of the assembly by inserting the ***PCK junction screw*** as previously mentioned. After extracting the trial assembly, be sure to record the marking value that aligns the offset junction to the femoral trial. ***This value is imperative to assemble the implant components in the same orientation as the trial components.***

NOTE

The femoral trial has the numbers '1', '2' and '3' laser etched on the circumference of the boss with corresponding laser etched lines respectively for 1, 1.5, 2, 2.5 and 3. Regardless of whether the femoral is a LEFT or a RIGHT component, the '1' is located on the medial side of the boss and the '3' is on the lateral side of the boss.

NOTE

The laser etched lines respectively for 3.5, 4 and 4.5 are located on the flat distal face of the boss. No numbers accompany these three lines (Fig. I4). Note the locations of these markings on the LEFT and RIGHT femorals shown here.

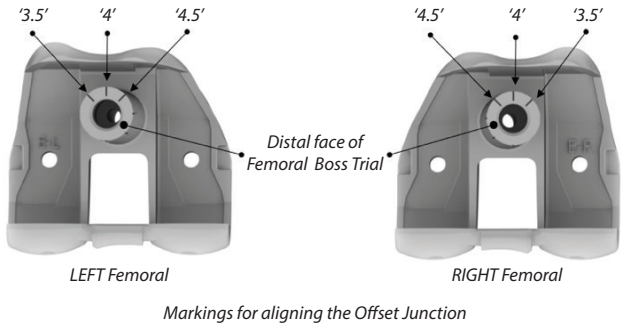

Figure I4: Femoral Trial Offset Markings

Place and impact the ***femoral trial assembly*** into the prepared femur using a ***femoral impactor***. Using a ***tibial alignment guide***, reduce the knee to estimate the tibial liner thickness (Fig. I5).

CONTINUE FOLLOWING THE ***FREEDOM KNEE REVISION® SURGICAL TECHNIQUE***, PROCEEDING TO PREPARE THE TRIAL STEMMED TIBIAL COMPONENTS.

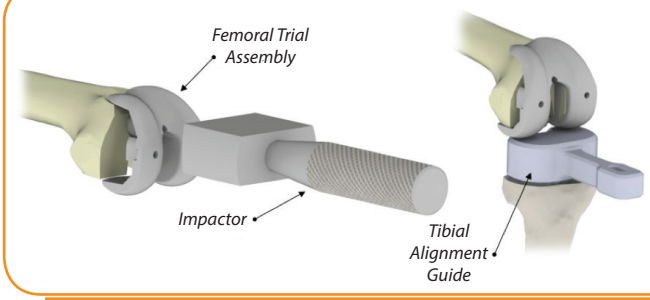

Figure I5: Impacting Femoral Trial and Estimating Tibial Liner Thickness

PREPARING THE PCK FEMORAL IMPLANT ASSEMBLY

The ***femoral implant***, ***stem extension*** and ***offset junction*** have Morse-type taper locking mechanisms with ***set screws*** (Fig. I6). The ***set screws*** are included with their respective components, packaged separately in their own pouches. Seat the ***stem extension*** firmly within the proximal end of the ***offset junction***. Properly orient the ***offset junction*** with respect to the ***PCK femoral***, replicating the alignment markings determined during trialing, and firmly seat its distal end into the female taper of the ***PCK boss***. Protect the articulating surface of the ***femoral***; support it against the surface of the surgical cart, and while protecting the ***stem extension***, strike it solidly once with a two-pound mallet. Use the ***2mm hex key*** to thread and hand tighten the ***set screws*** through the holes in the side of the ***PCK boss*** and the ***offset junction***. Attach ***posterior femoral augment(s)*** and ***distal femoral augment(s)*** with the appropriate length ***augment screw(s)*** as required. The number and type of augments should replicate that of the trial assembly.

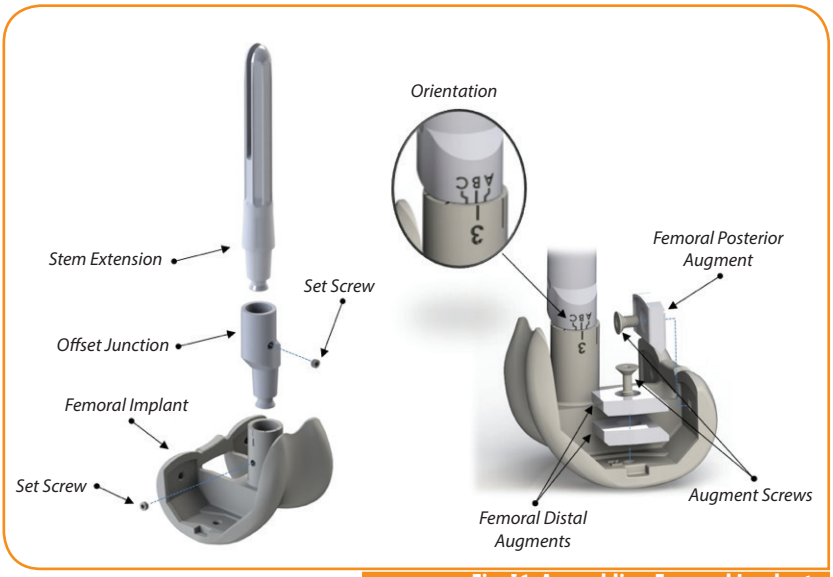

Fig. I6: Assembling Femoral Implant Components (showing '3B' orientation)

NOTE

Striking the stem more than once to engage the taper may loosen the taper connection.

CONTINUE FOLLOWING THE ***FREEDOM KNEE REVISION® SURGICAL TECHNIQUE***, PROCEEDING TO PREPARE THE STEMMED TIBIAL IMPLANT COMPONENTS.

Freedom Total Knee® System (CR and PS)

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Please see the package insert for complete device description, product selection information, indications, contraindications, precautions, adverse effects, warnings, materials, sterilization and patient guidance associated with the Freedom Total Knee® System.

CAUTION: THIS DEVICE IS RESTRICTED TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

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