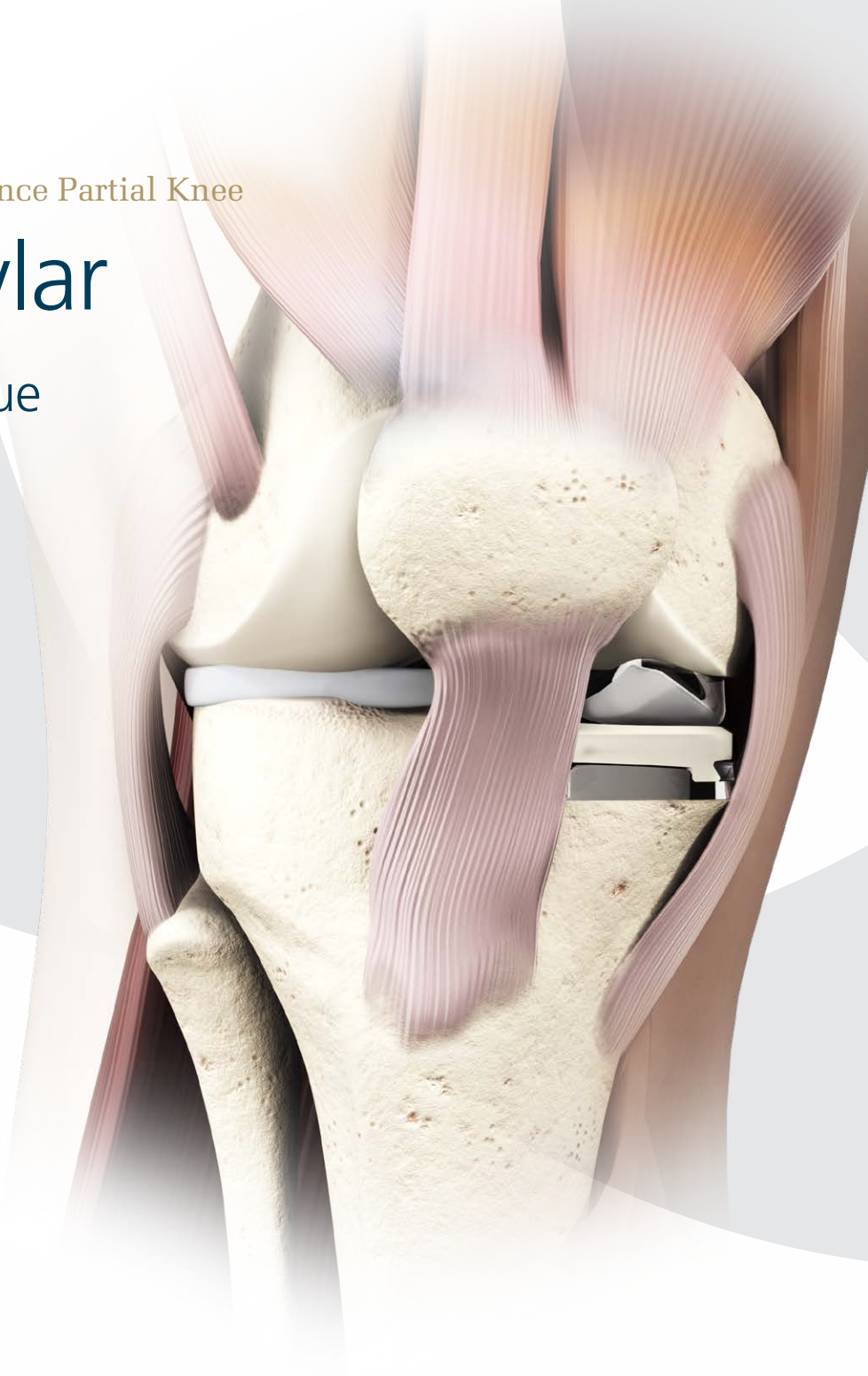
SIGMA® HIGH PERFORMANCE PARTIAL KNEE

SIGMA® High Performance Partial Knee

Unicondylar

Surgical Technique



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X-ray Templating

Anterior/Posterior (A/P) Template: Tibia

Goal: Use the A/P template to visualize and approximate the level of tibial resection to re-establish the pre-morbid articular cartilage joint line.

The tibial resection is planned at 90 degrees to the long axis of the tibia with a resection level that allows the desired thickness of tibial components to be used (Figure 1). The thinnest metal-backed tibial implant is 7 mm and the thinnest all-polyethylene tibial implant is 8 mm.

Lateral Template

Goal: Template the lateral X-ray to estimate femoral component size (Figure 2).

Position the template in the coronal plane at a right angle to the long axis of the femur. Align the template with the planned distal femoral cut. The template outline should be 2 mm larger than the bony margin of the X-ray to approximate the outline of the articular surface.

The posterior condyle of the prosthesis should not overlap the cartilage contour of the adjacent femoral posterior condyle by more than 2 mm.

Also measure the posterior slope of the proximal tibia on the lateral X-ray, with the goal to reproduce it during the surgery (Figure 3). The slope has been reported to vary from 0 degrees to greater than 15 degrees and may affect flexion space tightness.

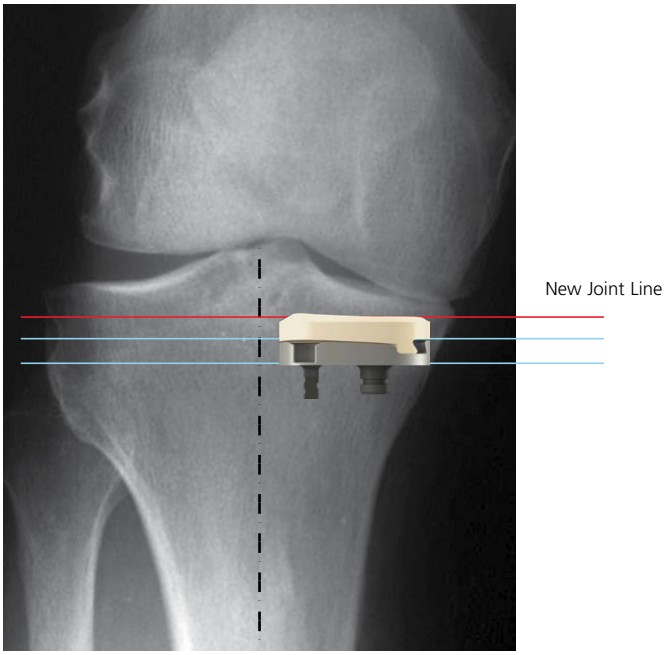

Figure 1: X-ray template with 7 mm tibial component.

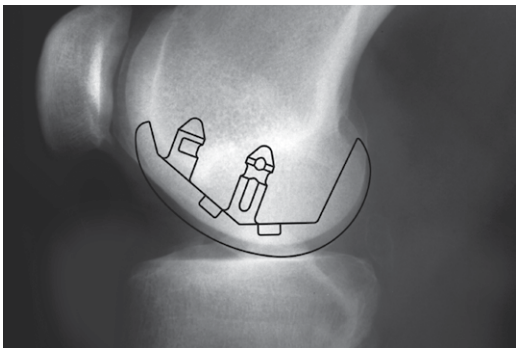

Figure 2: Femoral sizing on the lateral X-ray. Note the 105 degree posterior resection will not be parallel to the long axis.

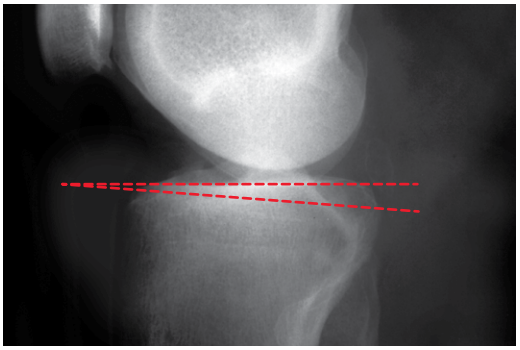

Figure 3: Posterior tibial slope on the lateral X-ray.

Approach and Exposure

Aim: Restore the patient's pre-morbid anatomy, alignment and ligament balance.

Achieving the aim may mean leaving the patient in slight varus (medial uni) or slight valgus (lateral uni) as determined by correct ligament tension. Alignment over-correction and over-tightening of the collateral ligament tension should be avoided.

The incision should be done per clinical practice to allow good exposure (Figure 4). An incision that is too small could compromise vision or component placement. A longer incision is advised when first starting to use the procedure or if the patient is obese.

After the joint is exposed, make a final assessment of the extent of arthritic damage in all three compartments and the suitability of the joint for this procedure. Ligaments, including the Anterior Cruciate Ligament (ACL), should also be assessed.

Carefully reflect the deep menisco-tibial layer of the medial or lateral capsule to provide good access to any tibial osteophytes. In order to reliably assess medial/lateral (M/L) alignment and joint stability, it is vital that all osteophytes are removed from the entire medial or lateral edges of the femur and tibia (Figure 5). Exposure can also be improved with excision of patellar osteophytes.

Excise any excess synovium to provide clear sight of the joint. If required, part of the fat pad may also be excised to improve exposure and allow inspection of the opposite compartment. Ligament releases should be avoided.

Clear intracondylar notch osteophytes.

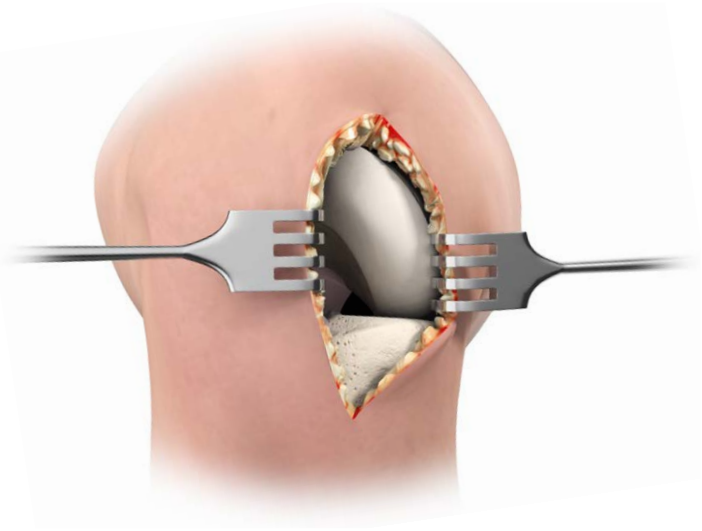

Figure 4

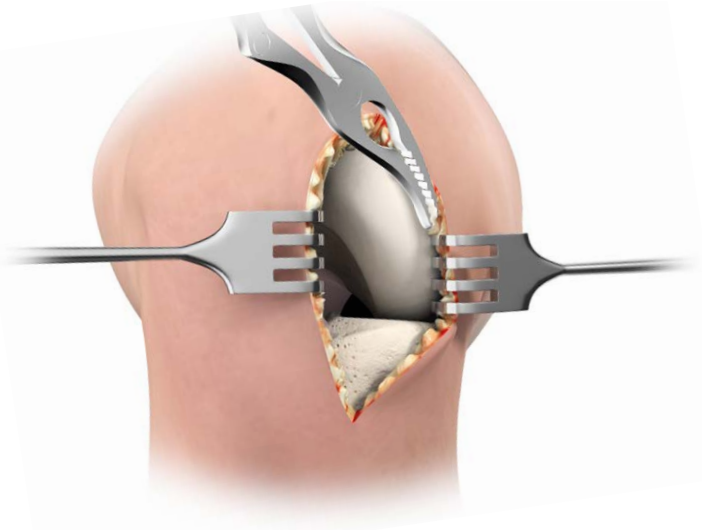

Figure 5: It is vital that all osteophytes are removed from the entire medial or lateral edges of the femur and tibia.

Proximal Tibial Resection

Tibial Jig Alignment

Aims: The Tibial Cutting Block is positioned to achieve varus/valgus alignment that is perpendicular to the mechanical axis of the tibia and for the tibial slope to match the patient's anatomy.

Place the knee in 90 degrees of flexion with the tibia translated anteriorly and stabilized. Place the Ankle Clamp proximal to the malleoli.

Assemble the Tibial Cutting Block onto the Tibial Jig Uprod.

Extend the uprod proximally to the approximate height of the intended resection.

Align the proximal central marking on the Tibial Cutting Block with the medial one third of the tibial tuberosity to set rotation.

The tibial resection should be perpendicular to the tibial mechanical axis.

The varus/valgus orientation of the tibial cut is adjusted by shifting the lower assembly of the Ankle Clamp from side-to-side. The lower assembly moves by pressing the varus/valgus wings. The lower assembly is typically translated 1–2 clicks medially to help avoid cutting the tibia in too much varus (Figure 7).

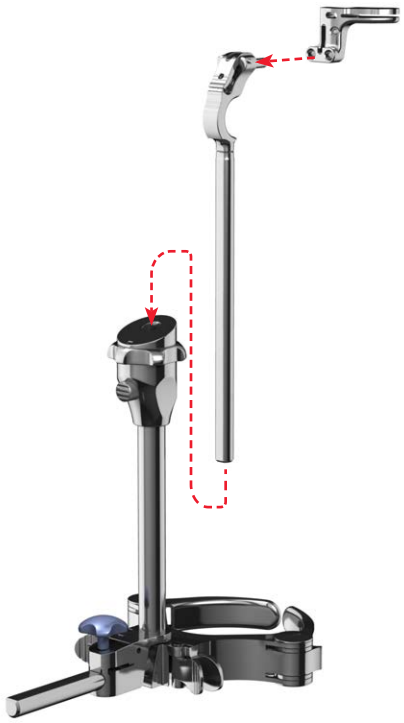

Figure 6

Figure 7

A/P Slope

Aim: The slope matches the patient's natural tibial slope. Select an unaffected portion of the affected plateau to estimate slope.

The Tibial Jig Uprod and Ankle Clamp are designed to prevent an adverse reverse slope. On an average size tibia this guide will give approximately a 0 degree tibial slope when the slope adjustment is translated posteriorly until it hits the stop (Figure 8).

The angle of the tibial slope can be adjusted to the patient's natural slope (Figure 9). First unlock the slide locking position and then translate the tibial slope adjuster anteriorly until the desired angle is reached.

Figure 8

Figure 9

Tibial Jig Alignment

Resection Level

Aim: Minimum amount of resection necessary to restore the joint line.

When using the cutting slot, position the foot of the Adjustable Tibial Stylus marked "slotted" into the slot of the Tibial Cutting Block (Figure 10). When resecting on top of the cutting block, place the foot marked "open" into the cutting slot (Figure 10, A). Bring the tip of the stylus to rest on the tibial plateau and set accordingly to achieve a resection that may accommodate at least a 7 mm tibial component.

The final resection level can be dialed in by rotating the fine-tune mechanism clockwise (upward adjustment) or counterclockwise (downward adjustment) (Figure 10, B). Care should be taken with severe valgus deformity not to over-resect the tibia.

After the height has been set, stabilize the block with one pin.

Note: When the resection level is in question, under-resect. A second tibial cut is preferable to an overly aggressive first cut.

Pin placement is per surgeon preference, but typically one pin is for alignment, one pin for stabilization after the resection level is determined and one pin for the L-cut. (Figure 11).

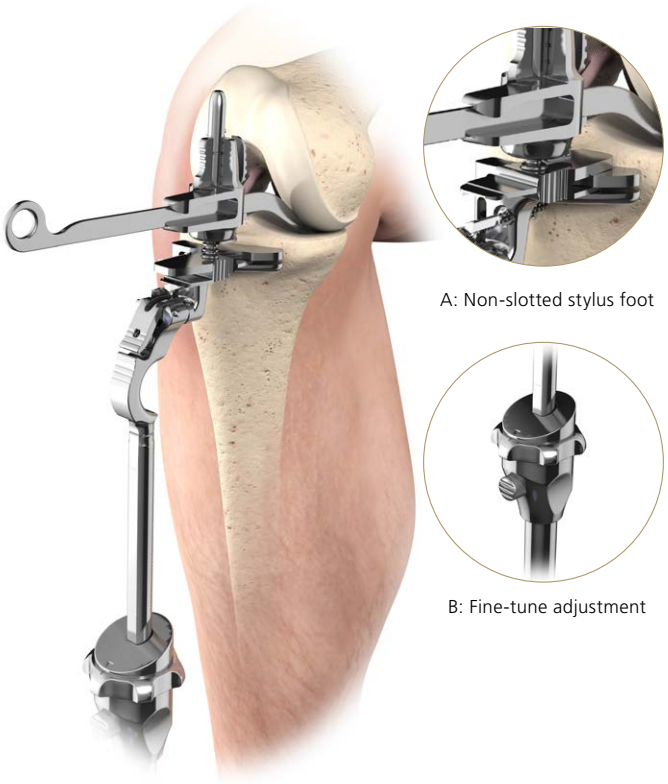

Figure 10

Figure 11

Resection

Make the sagittal or "L" cut using a reciprocating saw, using anatomic landmarks as reference points (Figure 12). Make the cut just central to the central border of the femoral condyle. Align the cut in the sagittal plane using the midpoint of the medial border of the insertion of the ACL as a landmark.

Tip: It may be advantageous to use a Threaded Pin to avoid pin motion.

Care must be taken to avoid making the "L" cut too deep and extending beyond the level of the proposed transverse cut (Figure 13).

Tip: The L-cut must be perfectly vertical to ensure insertion of the tibial insert into the metal-backed tibial tray.

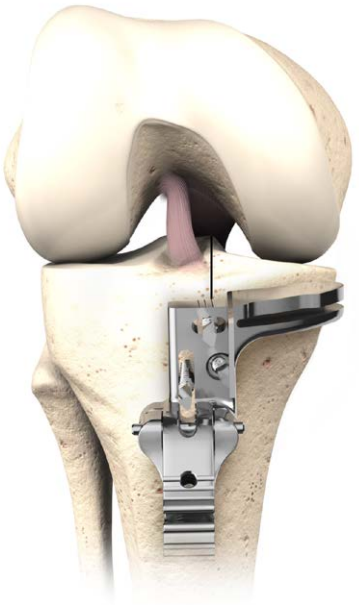

Figure 12

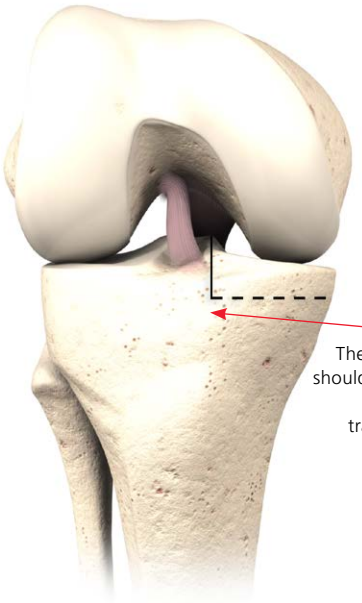

Figure 13

Tibial Jig Alignment

Make the transverse cut through the slot in the Tibial Cutting Guide or on the open cutting surface as determined prior to jig placement (Figure 14).

Note: **There is a 4.5 mm difference in depth of resection from the top surface of the cutting block to the slot.**

Tip: **Leave the Ankle Clamp in place during resection to aid stability.**

Tip: **Use retractors to protect all ligaments including the collateral ligaments.**

Remove the resected bone. The resected bone can be assessed to confirm reproduction of slope and compared with the Tibial Trial to confirm component size (Figure 15).

Tip: **Check the cut depth by flexing the knee to 90 degrees. The Tibial Trial should slip in and out without undue tension.**

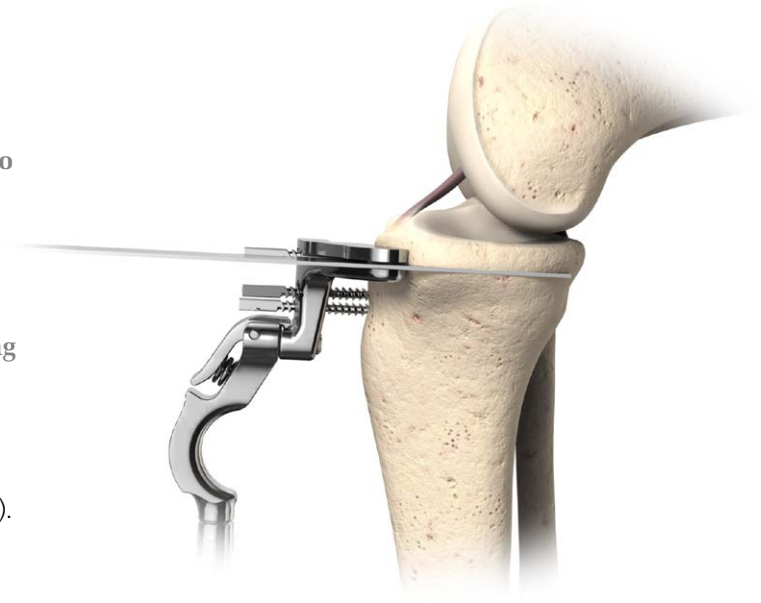

Figure 14

Figure 15

Tibial Sizing

Aim: Maximize tibial cortical coverage with no overhang.

Flex the knee to 90 degrees. Select a Tibial Trial corresponding to the thickness determined previously. Assess cortical bone coverage when placed on the tibia. The Tibial Sizing Arm can also be used to confirm sizing the anterior/posterior (A/P) dimension of the tibial plateau (Figure 16). This arm should be used along the L-cut surface. Markings on the arm correspond to the maximum A/P dimension.

Note: The system allows for ANY sizing mismatch between the femur and the tibia, to ensure the best coverage available.

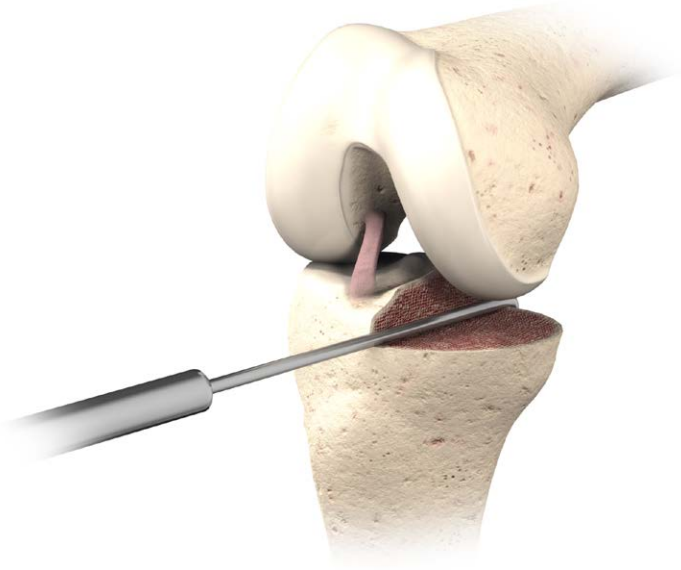

Figure 16

Balancing

Aim: Determine amount of distal femoral resection and tibial insert thickness to achieve equal extension and flexion gaps.

Check the flexion and extension gaps using the Tibial Trial of the desired size and thickness. Use the D-shaped end as the "spacer block." The D-shaped end has the same dimensions as the tibial implants. (The opposite end is used to introduce the metal-backed tibial tray into the joint space during cementing.) Composite thicknesses of the metal-backed tray and insert are 7 mm to 11 mm in one millimeter increments. All-polyethylene insert thicknesses are 8 mm to 11 mm in one millimeter increments.

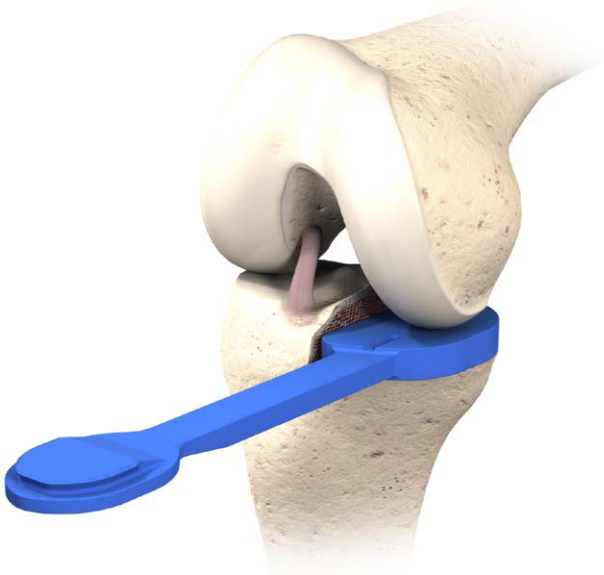

Figure 17

Flexion Gap Evaluation

Remove all retractors. Flex the knee to 90 degrees and check the flexion gap using the Tibial Trial of the desired thickness (Figure 17). If the flexion gap is tight, use caution before consideration of additional tibial resection. Evaluate the slope to ensure lack of slope is not contributing to a tight flexion gap.

Extension Gap Evaluation

Place the knee in extension and assess the extension gap with the Tibial Trial (Figure 18). The extension gap can be filled 1, 2 or 3 mm distally with use of a Femoral Defect Shim. If extension laxity exists relative to flexion, use a thicker trial in extension to get an idea of which Femoral Defect Shim should be used.

If both the flexion and extension gaps are loose, a thicker tibial component should be used.

At this stage the tibial implant thickness, extension gap, stability of the collateral ligaments, limb alignment and ability to achieve full extension can be verified.

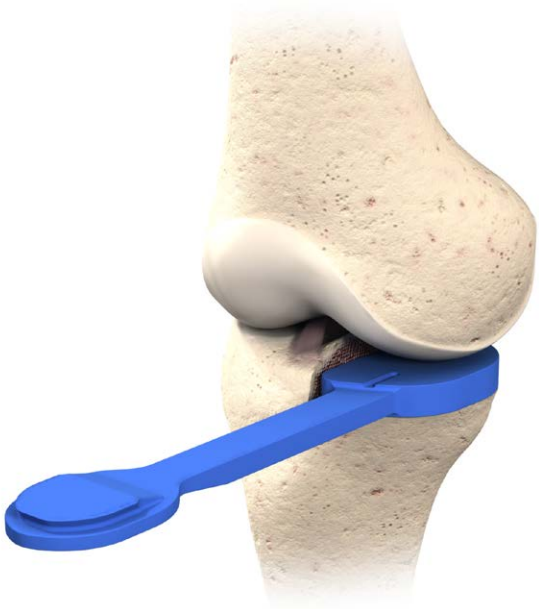

Figure 18

Note: **It may be desirable to leave up to 2 mm of laxity when subject to lateral stress at 20 degrees flexion.**

Tip: **Sizing and rotation of the femoral component can be enhanced with use of the Tibial Trial to create landmarks on the femur.**

Place the knee in extension and seat the Tibial Trial on the resected tibia. With a marking pen or electrocautery, make a vertical mark on the distal femur directly above the midpoint of the Tibial Trial to later help set the rotational alignment and anterior extent of the femoral component (the more anterior, the larger the femoral component) (Figure 19). By later aligning the tip of the Femoral Cutting Block to this line, the proper relationship between the femur and tibia in extension will be established.

A transverse mark along the anterior border of the Tibial Trial is made, and the femoral component should not extend anterior to this to avoid component impingement on the patello-femoral (PF) joint, whereas undersizing should also be avoided to prevent the tibial component from articulating with articular cartilage.

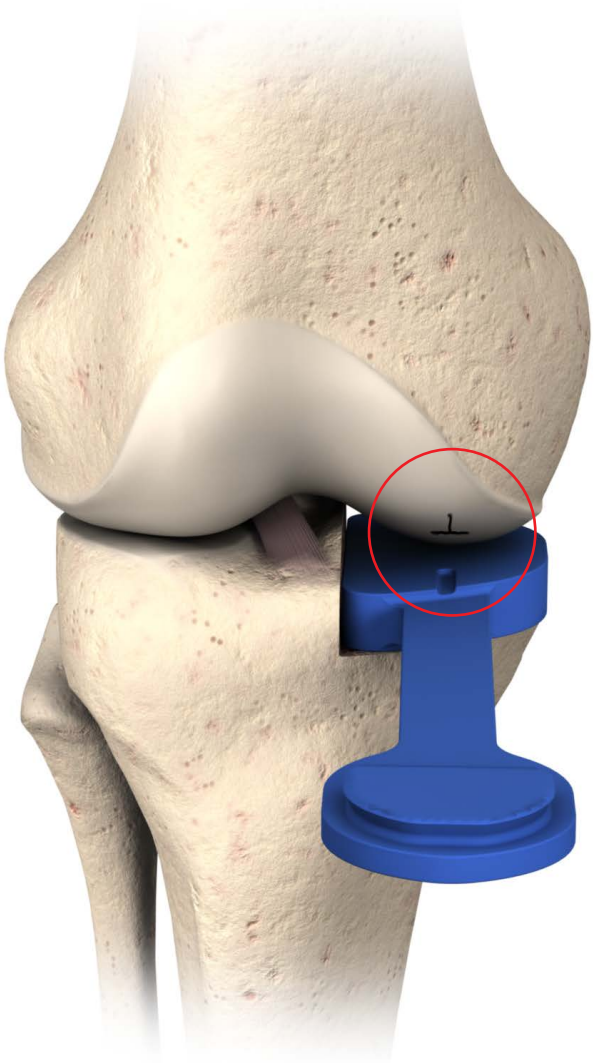

Figure 19

Distal Femoral Resection

Aim: Distal femoral resection parallel to the tibial resection, using shims where appropriate.

Shims

Use shims in the following scenarios where appropriate with the Distal Cutting Block (Figure 20).

Femoral Defect Shims (1 mm, 2 mm or 3 mm): if excessive extension laxity exists relative to flexion. Use of these Femoral Defect Shims will effectively under-resect the distal femur (removing less bone than is replaced by component thickness), tightening the extension gap in cases where distal femoral loss has occurred (Figure 21).

Tibial Shims (8 mm, 9 mm, 10 mm or 11 mm): If the 7 mm Tibial Trial was used in balancing, do not add any Tibial Shims to the tibial side of the Distal Cutting Block. If a thicker Tibial Trial was used, add the appropriate Tibial Shim to the tibial side of the Distal Cutting Block (Figure 22).

Figure 20

Figure 21: Femoral Shim added due to femoral defect.

Figure 22: Tibial Shim added for appropriate tibial insert thickness.

Placement and Alignment

With the knee in extension, introduce the Distal Cutting Block with any attached shims into the joint space using the System Handle (Figure 23).

With the leg in full extension, assemble the Femoral Alignment Guide and extramedullary Alignment Rod into the slot of the Distal Femoral Cutting Block to check local alignment, both varus/valgus and flexion/extension. To achieve proper femoral component position in the sagittal plane, flex the tibia until the Alignment Rod is parallel to the intramedullary axis of the femur (Figure 24).

The guide is used to:

1. Confirm varus/valgus of the tibial cut
2. Flexion/extension of the femoral cut

Use Drill Pins or pre-drill Steinmann pins to fix the Distal Cutting Block in place, confirming good position of the cutting block to the distal femur and proximal tibia. Resect the distal femoral bone using a saw blade.

Note: Without any Femoral Defect Shims in place, the Distal Cutting Block will resect 6.7 mm, the same thickness as the distal portion of the implant. Lack of distal femoral cartilage loss is rare medially but common laterally.

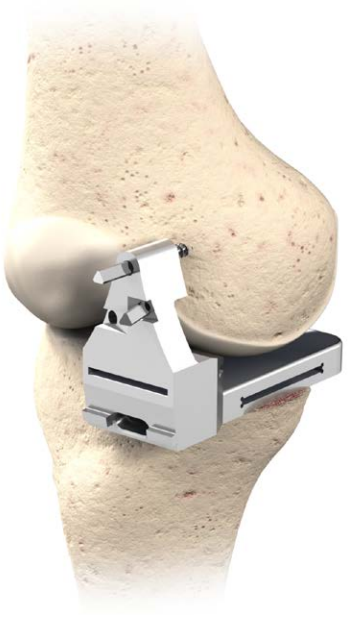

Figure 23

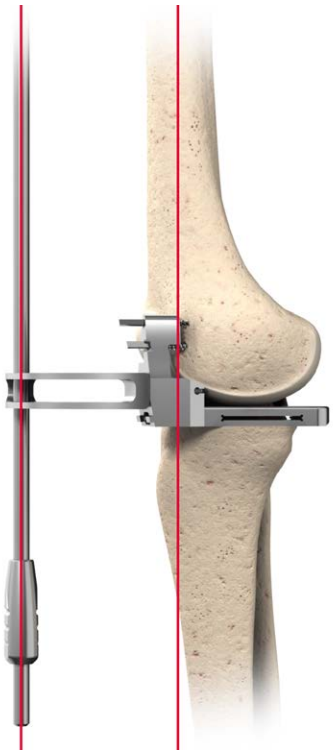

Figure 24

Using the Femoral Finishing Block

Aim: Establish appropriate femoral size and rotation.

Use the Femoral Finishing Blocks to establish the appropriate femoral size. The A/P size of the Femoral Finishing Block is the same as the final prosthesis, as is the M/L width posteriorly.

With the leg in full extension, place the Tibial Trial and make a mark on the femur referencing the cutout in the middle of the tibial trial (Figure 19). Move the knee to 90 degrees of flexion and make a similar mark. These marks establish the center of rotation at 0 and 90 degrees. With a marking pen, draw a line on the cut face of the distal femur connecting the marks (Figure 25). This line should be visible through the holes of the Femoral Finishing Block and match the sulcus proximally. This establishes rotation for the femoral component. Establish medial/lateral placement before pinning the block.

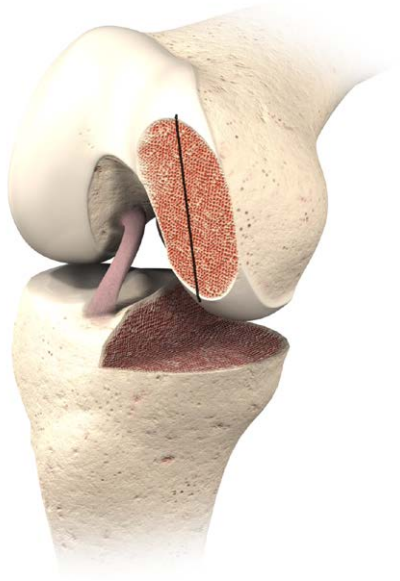

Figure 25

Place the leg in 90 degrees of flexion. Position the block size selected during templating under the posterior condyle to be flush with the resected distal femoral surface. Exchange a smaller or larger size to find the best fit.

Position the appropriately sized Femoral Finishing Block using the System Handle. The block may be rotated to assure the femoral component articulates over the center point of the tibial component throughout the range of motion. Use the marks previously made on the condyle (Figure 25) to confirm appropriate rotation and A/P Size. It is essential that the sulcus between the apexes of the block is aligned with the vertical line, and it should not extend superior to the horizontal line (Figure 26).

This will increase the likelihood that the tibial component will properly track with the femur in extension and prevent patello-femoral impingement. The medial/lateral position of the block is also established at this point.

Tip: **If between sizes, the smaller of the two is generally chosen.**

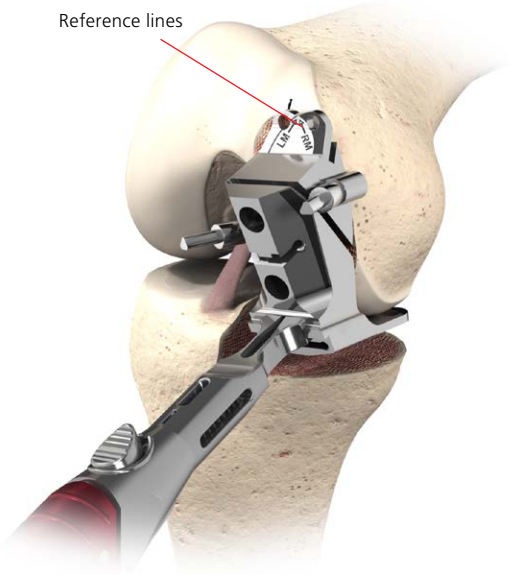

Figure 26

A Tibial Trial or the Femoral Spacer may be placed on the tibia to stabilize the block on the posterior condyle (Figure 27).

Figure 27

Using the Femoral Finishing Block

Secure the Femoral Finishing Block into place with pins.

Use the Curved Gouge to cut the profile of the proximal tip of the femoral prosthesis. Apply the gouge over the inner tip of the Femoral Finishing Guide and create a 3–5 mm deep gouge. This also will mark the extent of the anterior chamfer cut (Figure 28).

Resect the femoral bone in the following recommended order as shown in (Figure 29):

1. Posterior 105 degrees
2. Anterior cut (see note below)
3. Posterior chamfer cut (see tip below)
4. Drill the anterior and posterior peg holes with the Femoral Peg Drill

Tip: **Before each cut, check that the block is flush to the distal femoral cut.**

The System Handle can be used to help stabilize the block during chamfer resection. Remove the Spacer Block after the Femoral Finishing Block is pinned.

Note: **The Anterior Chisel may optionally be used in place of a saw cut. The chisel is required only in the track closest to the patella. For knees that do not achieve adequate fixation with the two outbound pins, an additional pin can be placed proximally. Pin the hole farthest away from the patella and use the Anterior Chisel in the track closest to the patella (Figure 30).**

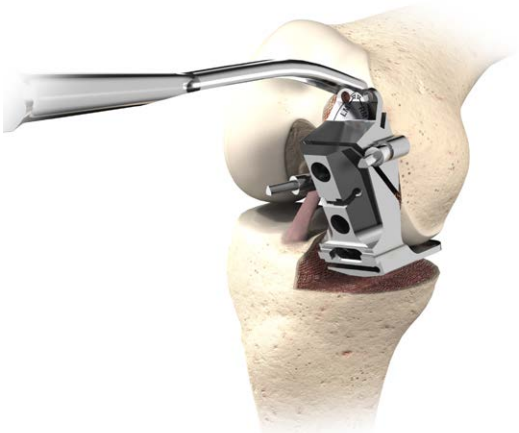

Figure 28

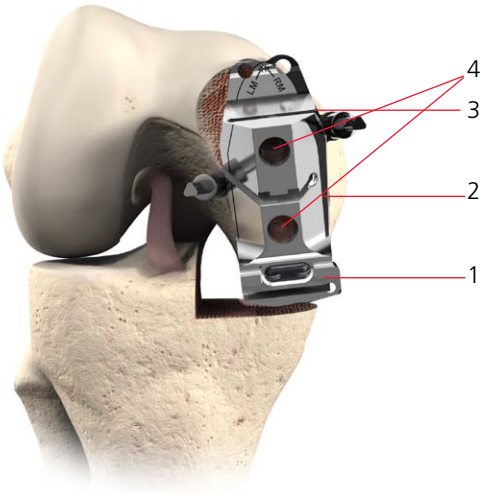

Figure 29

Figure 30

Trial Reduction

Aim: Assess soft tissue balance, range of motion and component-to-component relationship in flexion and extension.

Insert the selected sized Femoral Trial and Tibial Trial on the bone.

Move the knee through a full range of motion. Properly fitted and seated components will track smoothly throughout the entire range.

Confirm with the Tibial Trial that the L-cut is truly vertical. An L-cut inclined away from the midline may impede placement of the polyethylene insert or all-polyethylene tibial component.

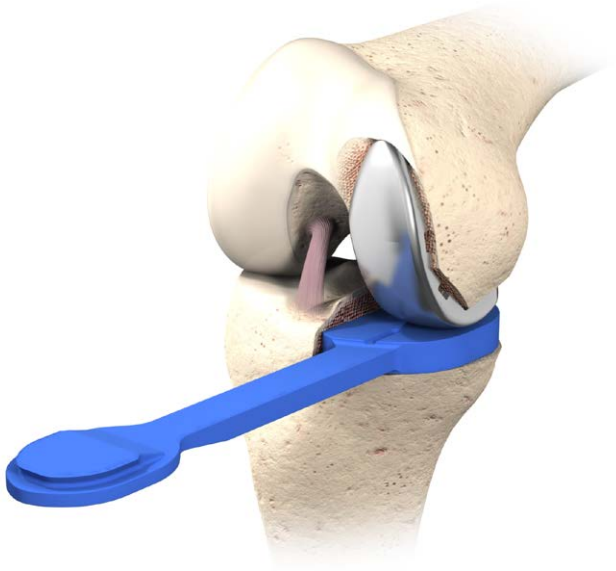

Figure 31

Figure 32

Tibial Preparation

Aim: Prepare tibia for keel and peg on posterior of tibial component.

Using the System Handle, insert the Tibial Template that matches the selected Tibial Trial (Figure 33). Tap this into place, ensuring proper position and orientation on the tibial plateau. Recheck sizing.

Use the Lamina Spreader to distract the joint to ease exposure and bone preparation (Figure 34).

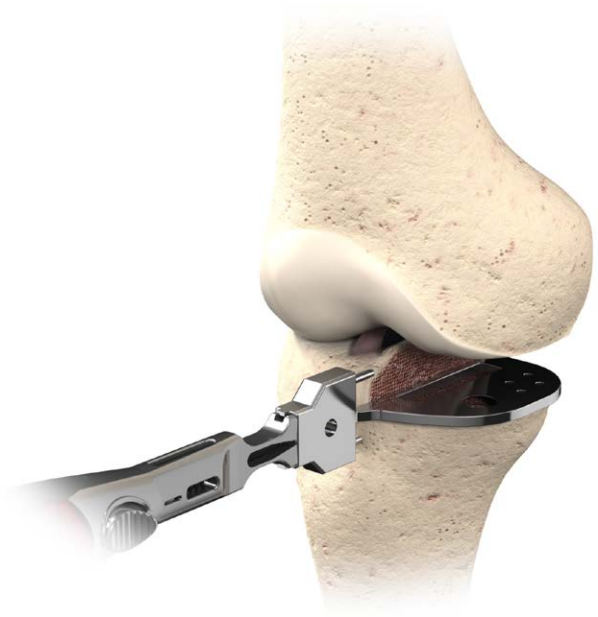

Figure 33

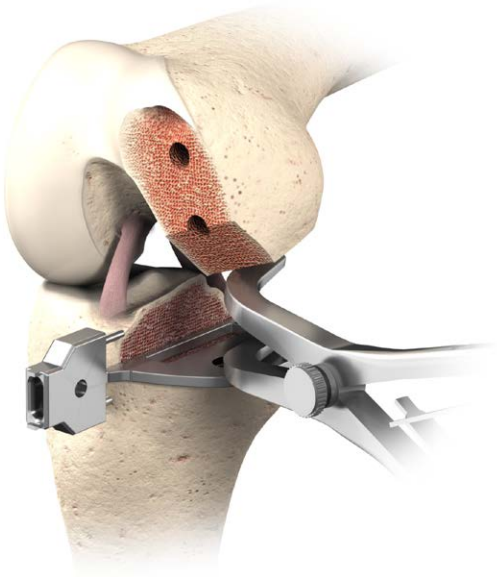

Figure 34

Use the Tibial Osteotome to gently remove the bone from the keel slot (Figure 35). Do not impact forcefully as this can cause a break of the posterior tibia.

Note: **The keel on metal-backed components is 2.5 mm wide and on all-polyethylene components is 5 mm wide (Figure 36). Ensure the correct osteotome is used to create the keel slot.**

Tip: **In sclerotic bone, use a reciprocating saw to prepare the keel in advance. Use caution not to cut too deep as the tibial component keel has a depth of 6 mm.**

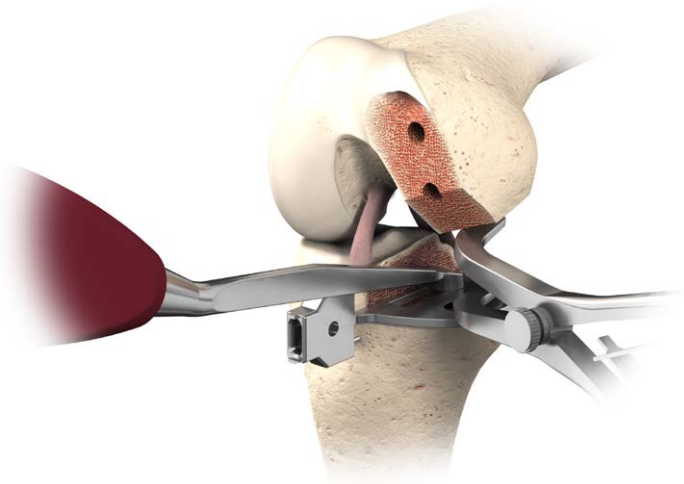

Figure 35

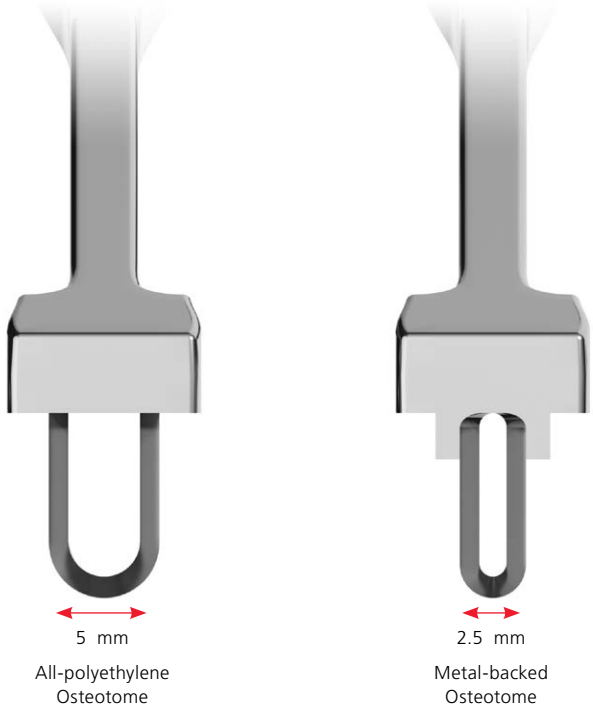

Figure 36

Tibial Preparation

Insert the Tibial Keel Trial through the slot into the cavity to confirm adequate bone has been removed (Figure 37).

Note: Due to the differences in keel width, there are separate Tibial Keel Trials for metal-backed and all-polyethylene (Figure 38). Ensure the correct trial is used to assess bone removal.

Use the Tibial Peg Drill to prepare the tibial peg. The peg hole should be drilled as close to perpendicular as possible (Figure 39). Externally rotating the tibia helps to gain perpendicular access to the peg hole.

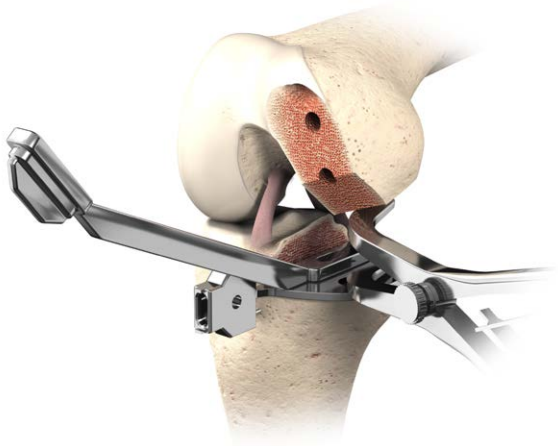

Figure 37

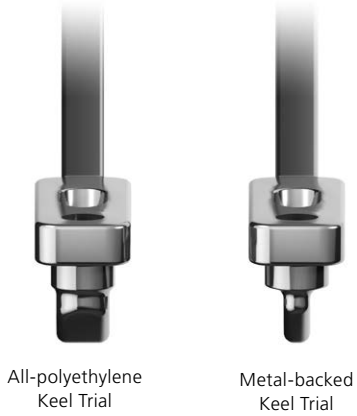

Figure 38

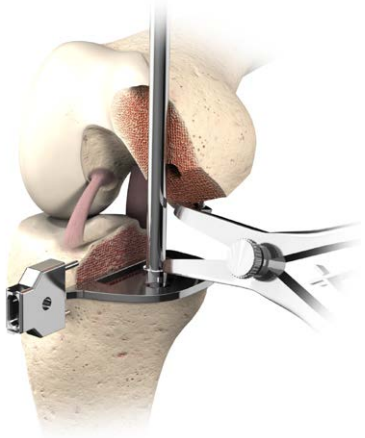

Figure 39

Component Implantation

When using a metal-backed tibial component the order of implantation is:

1. Metal-back tray
2. Femoral component
3. Tibial insert

When using an all-polyethylene tibial component the order of implantation is:

1. All-polyethylene tibia
2. Femoral component

Preparation for cementation

1. The tibial surface should be fully washed using pulse lavage or similar technique, ensuring that no residual particles of bone are present in the joint space.
2. Tibial surface should be fully dried using surgical sponges or similar material, ensuring the prepared surface is as dry as possible prior to cementing.
3. A sponge may be placed in the posterior aspect of the tibia prior to cementing to simplify cement removal.

Tip: If sclerotic bone is encountered, drill several small holes and fill with cement before placing the femoral and/or tibial component.

Cement Technique — Tibia

Apply cement to the prepared bone surface and pressurize digitally or with a flat instrument.

Insert a small cylindrically shaped piece of cement into the tibial keel slot and pressurize using the same technique.

Excess cement is cleared to leave approximately 1 mm of cement on the surface.

Metal-Backed Tibial Component

Engage the rounded end of the Tibial Trial of appropriate size and thickness with the tibial tray. Apply a layer of cement to the backside of the tray.

Stabilizing the trial and tray with a finger, introduce the tibial prosthesis at a 45 degree angle, engaging the most posterior aspect of the tibial keel to the prepared channel first (Figure 40). Lower the anterior of the prosthesis into position. This sequence promotes the flow of cement from posterior to anterior as the prosthesis is seated.

Use a mallet and the Tray Pressure Arm, per standard surgical technique, to complete the tibial insertion (Figure 41). Remove the Tibial Trial.

Clear residual cement with a sponge or cement removal tool such as a bent arthroscopy probe or nerve hook. Pay particular attention to the rim of the tibial tray.

If a sponge was used posteriorly, remove the sponge.

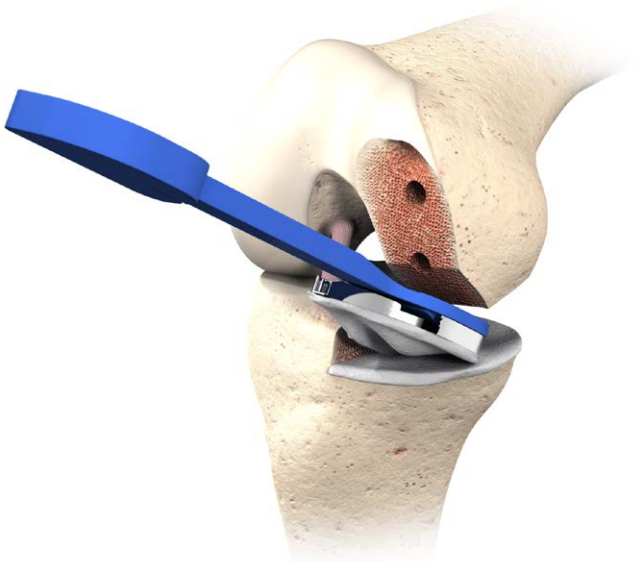

Figure 40

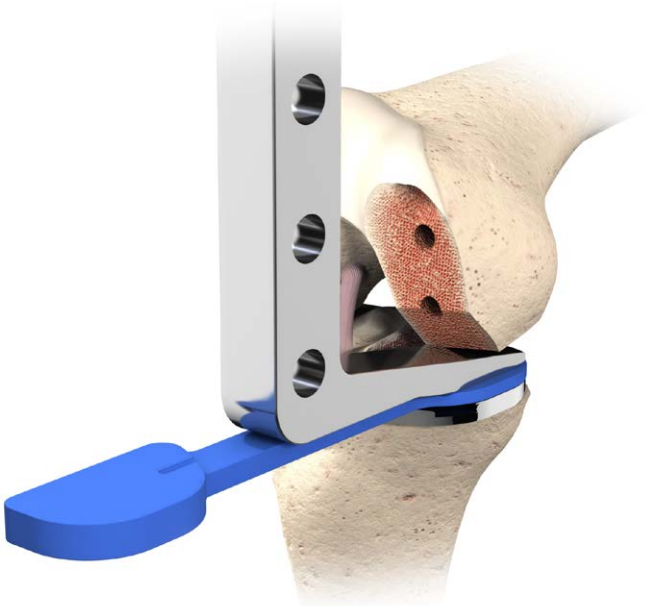

Figure 41

All-Polyethylene Tibial Component

Apply a layer of cement to the backside of the tibial prosthesis.

Introduce the prosthesis at a 45 degree angle, engaging the most posterior aspect of the tibial keel to the prepared channel first. Lower the anterior of the prosthesis into position. This sequence promotes the flow of cement from posterior to anterior as the prosthesis is seated.

Use the Tray Pressure Arm, per standard surgical technique, to complete the tibial insertion (Figure 42).

Clear residual cement with a sponge or cement removal tool such as a bent arthroscopy probe or nerve hook.

If a sponge was used posteriorly, remove the sponge.

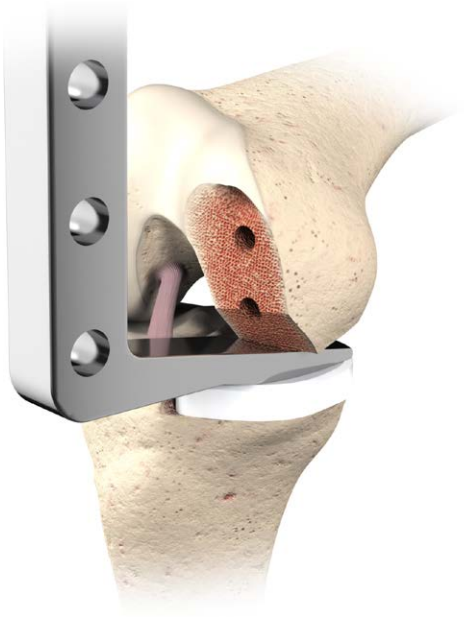

Figure 42

Femoral Component

Apply an even layer of cement on the femoral prosthesis, minimizing the amount applied posteriorly (Figure 43). Pressurize cement into the cut bone surface digitally or with a stiff flat surface with sufficient cement to pressurize cement into the femoral lug holes and any supplemental drill holes made in sclerotic bone.

Attach the femoral prosthesis to the Femoral Introducer. With the knee flexed to 100 – 110 degrees, seat the femoral prosthesis. The patella may need to be retracted to facilitate insertion. With a mallet, firmly tap the introducer onto the femur (Figure 44). Release the introducer from the femoral prosthesis and remove excess cement.

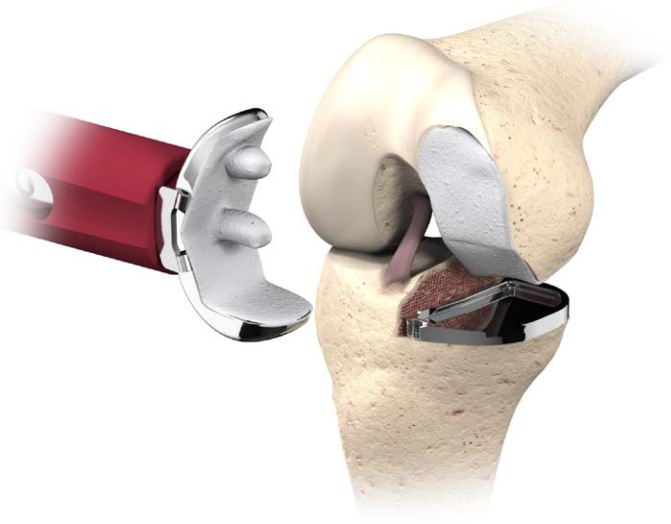

Figure 43

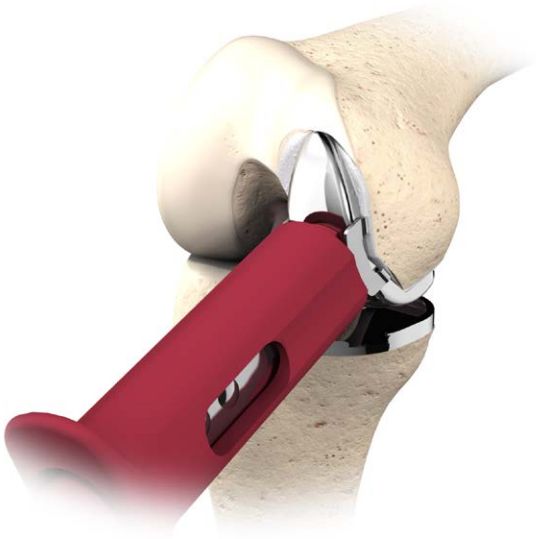

Figure 44

When using a metal-backed tibial component

As the tibial and femoral cement cures, re-engage the Tibial Trial with the tray and put the leg into extension. This will maintain compression and component position until the cement hardens. After the cement hardens, remove the Tibial Trial and introduce the final tibial insert (Figures 45 and 46).

The incision is closed in layers. Take care that all excess cement has been removed prior to closure.

Figure 45

Figure 46

Lateral Replacement Considerations

Aim: Restore the patient's pre-morbid anatomy and alignment.

This may mean:

- Patella retraction is more difficult than medial UKA because of the tuberosity position.
- Patellar tendon will typically be in line with the L-cut.
- As the patella tracks laterally in the intercondylar notch, care must be taken to avoid impingement of the femoral component with the patella.
- Ligament balancing is obviously different laterally than medially. As the lateral ligament complex is slightly more lax than medially in the normal knee and the lateral complex is easier to stretch, it is very important NOT to overstuff the lateral compartment.
- Plan retraction to avoid injury to the popliteus on the posterior chamfer cut. Use the 1.5 mm shim on Femoral Finishing Block if the posterior condyle is worn (Figure 47).
- Internal rotation of the tibial component at 90 degrees flexion may appear excessive at first, but this is a result of femoral roll-back and the lateral position of the tibial turberosity/patellar tendon. The cut is typically in line with the meniscal remnant horn attachment sites. The cut should be rechecked in extension.
- Femoral component is often perpendicular to tibia.
- L-cut will be different at 90 degrees than on medial. Check the cut in extension and recut in extension if not central enough.

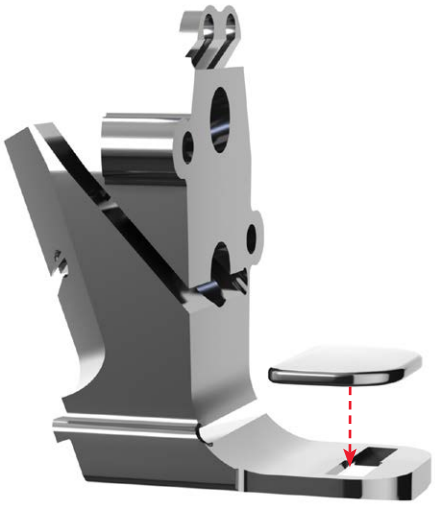

Figure 47

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

CAUTION: Federal Law restricts these devices to sale by or on the order of a physician.

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

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