



Balanced
Surgical Technique



Contemporary total knee arthroplasty demands high performance instrumentation that provides enhanced efficiency, precision, and flexibility. Through a program of continuous development DePuy now offers a single system of High Performance instruments that supports your approach to knee replacement surgery.

This surgical technique provides instruction on the implantation of the Sigma® family of fixed bearing and rotating platform knees utilizing the Balanced resection instrumentation.

There are several approach options available to the surgeon, the most common are; medial parapatellar, mini-midvastus and mini-subvastus.

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Surgical Summary



Step 1: Incision and exposure



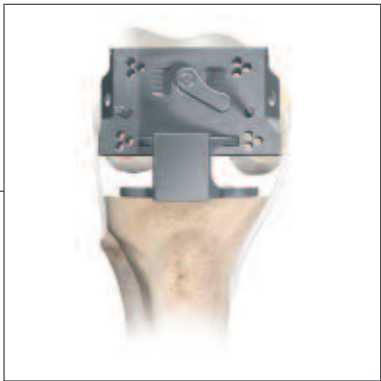
Step 2: Patellar resection



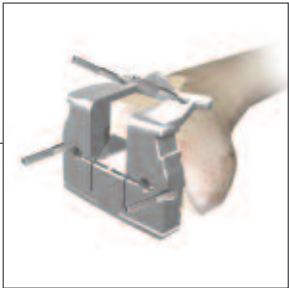
Step 3: Lower leg alignment



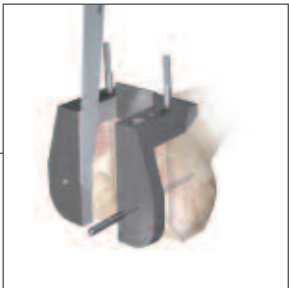
Step 7: Soft tissue balancing



Step 8: Femoral rotation



Step 9: Femoral preparation



Step 9: Femoral resection notch cuts (alternative)



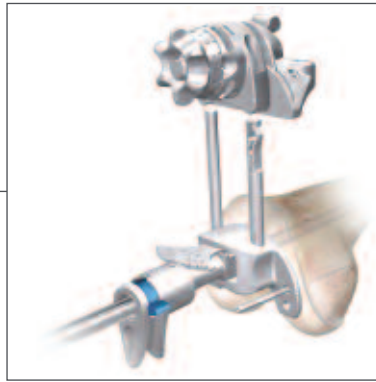
Step 13: Final patella preparation



Step 14: Final component implantation



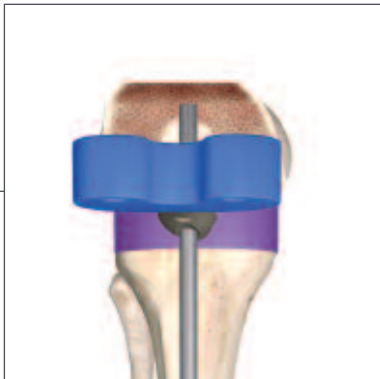
Step 4: Tibial resection



Step 5: Femoral alignment



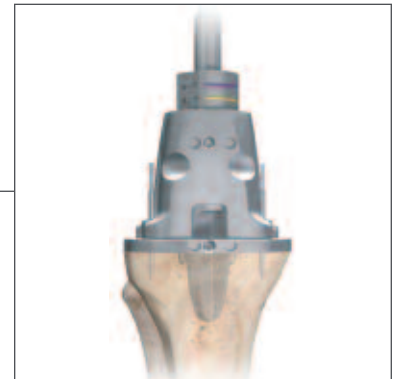
Step 6: Distal femoral resection



Step 10: Measuring flexion gap



Step 11: Trial reduction



Step 12: Tibial preparation

Incision and Exposure

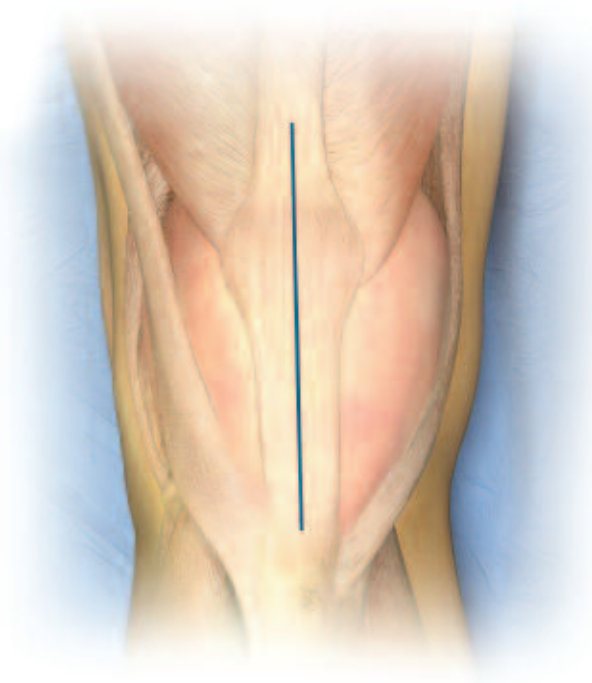


Figure 1

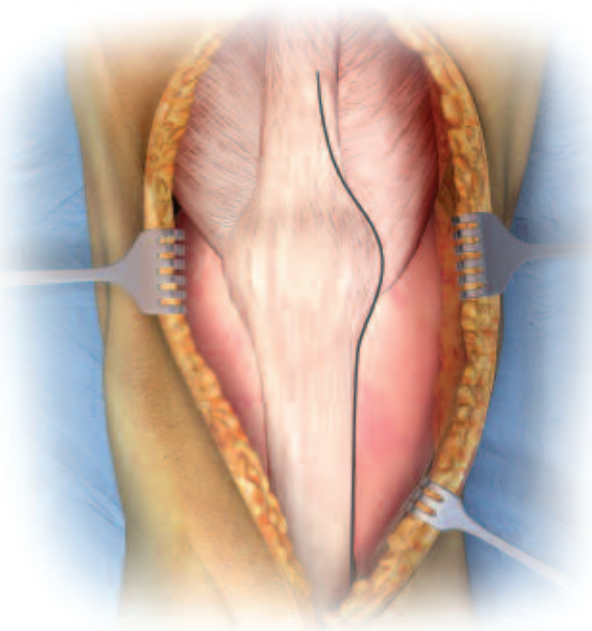


Figure 2

The Sigma® High Performance instrumentation is designed for use with and without Ci™ computer assisted surgery, for both open and minimal invasive approaches to the knee.

Make a straight midline skin incision starting from 2 to 4 cm above the patella, passing over the patella, and ending at the tibial tubercle (Figure 1).

There are three approach options available for the surgeon: medial parapatellar, mini-midvastus, and mini-subvastus.

For surgeons choosing the medial parapatellar (Figure 2):

Make a medial parapatellar incision through the retinaculum, the capsule and the synovium, with neutral alignment or with varus deformity. The medial parapatellar incision starts proximal (4 cm) to the patella, incising the rectus femoris tendon longitudinally, and continues distally around the medial aspect of the patella and ligamentum patella stopping just medial to the tibial tubercle (Figure 2). Following this incision, either evert or luxate the patella laterally to expose the entire tibio-femoral joint.

Incision and Exposure

For surgeons choosing the mini midvastus option (Figure 3):

The midvastus approach starts 3-4 cm in the middle of the Vastus Medialis Obliquus (VMO), running distal and lateral to the muscle fibers towards the rectus femoris, splitting the VMO.

Continue the incision distally around the medial aspect of the patella and ligamentum patella stopping just medial to the tibial tubercle (Figure 3). Following this incision, luxate the patella laterally to expose the entire tibio-femoral joint.

For surgeons choosing the subvastus option:

The subvastus approach starts by lifting the VMO with a 90 degree stomp hook. A 3-4 cm incision is made in the capsule underneath the VMO, running horizontal from medial to lateral towards the mid portion of the patella. The incision continues distally around the medial aspect of the patella and ligamentum patella stopping just medial to the tibial tubercle (Figure 4). Following this incision, luxate the patella laterally to expose the entire tibio-femoral joint.

Note: When having difficulties in correctly placing the Sigma High Performance instruments in any of these approaches, the incision should be further extended to avoid over-retraction of the soft tissues.

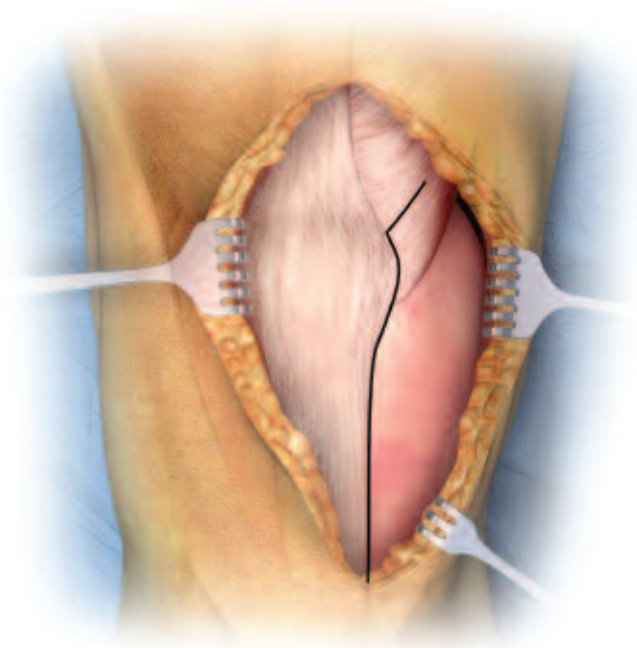


Figure 3

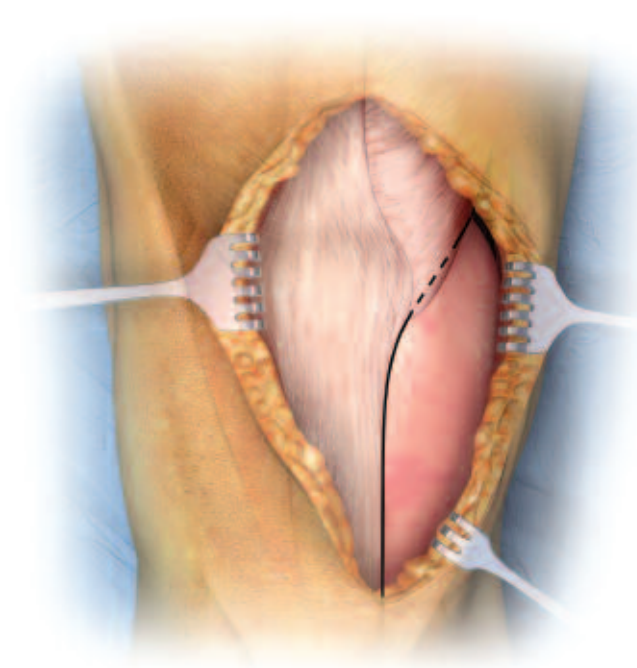


Figure 4

Incision and Exposure



Figure 5

Excise hypertrophic synovium if present and a portion of the infrapatella fat pad to allow access to the medial, lateral and intercondylar spaces.

Remove all osteophytes at this stage as they can affect soft tissue balancing (Figure 5).

Note: Particular attention should be given to posterior osteophytes as they may affect flexion contracture or femoral rotation.

Evaluate the condition of the posterior cruciate ligament (PCL) to determine the appropriate Sigma component to use. Resect the PCL if required.

Patella Resection

Resection and preparation of the patella can be performed sequentially or separately, as desired, and can be performed at any time during surgery.

Measure the thickness of the patella and calculate the level of bone resection (Figure 6). The thickness of the resurfaced patella should be the same as the natural patella. There should be equal amounts of bone remaining in the medial/lateral and superior/inferior portions of the patella.

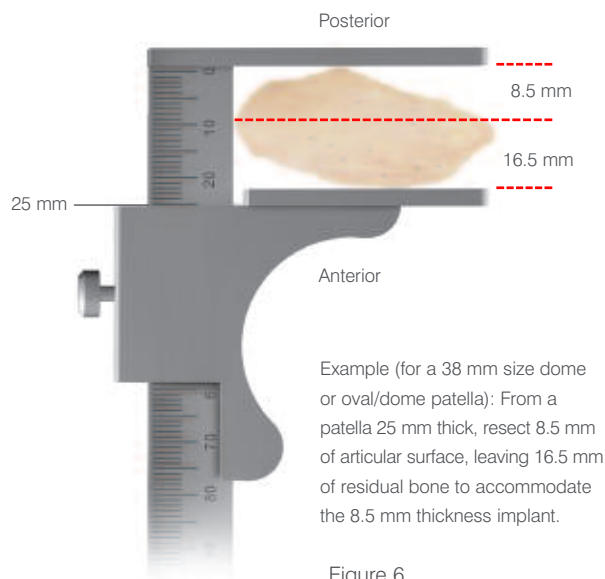


Figure 6

Select a patella stylus that matches the thickness of the implant to be used. The minimum depth of the patella resection should be no less than 8.5 mm (Figure 7).

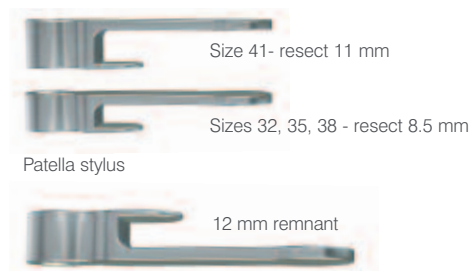


Figure 7

However, when the patella is small, a minimal residual thickness of 12 mm should be maintained to avoid fracture.

A 12 mm remnant stylus can be attached to the resection guide resting on the **anterior** surface of the patella, to avoid overresection (Figure 8).

Place the leg in extension and position the patella resection guide with the sizing stylus against the **posterior** cortex of the patella with the serrated jaws at the superior and inferior margins of the articular surface. Close the jaws to firmly engage the patella (Figure 9).



Figure 8

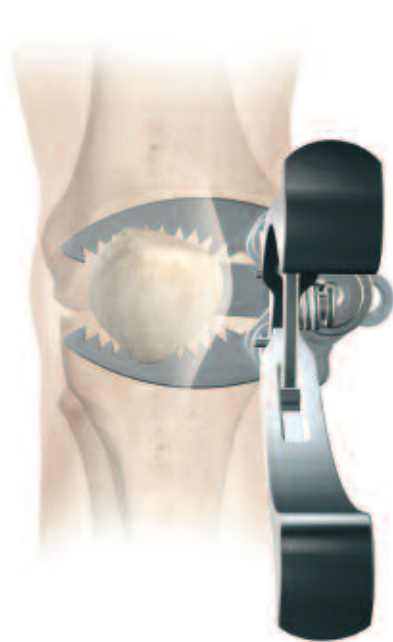


Figure 9

Patella Resection

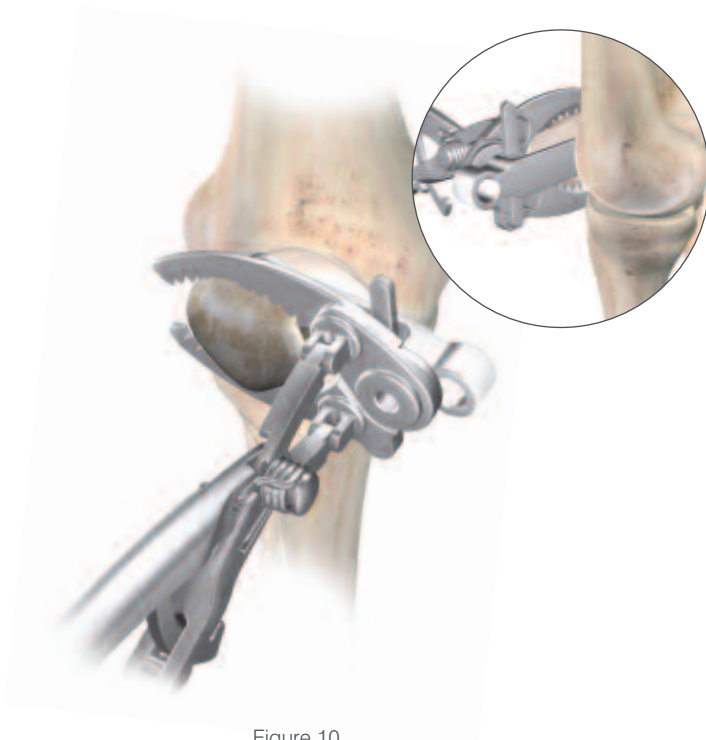


Figure 10

Tilt the patella to an angle of 40 to 60 degrees (Figure 10).



Patella wafer

Figure 11

Remove the stylus and perform the resection using an oscillating saw through the saw capture and flush to the cutting surface (Figure 11).

A patella wafer can be hand placed on the resected surface if required to protect the patella bone bed.

Tibial Jig Assembly

The tibia can now be resected to create more room in the joint space.

Assemble the appropriate 0-3 degree, left/right or symmetrical cutting block to the tibial jig uprod. Slide the tibial jig uprod into the ankle clamp assembly (Figure 12).

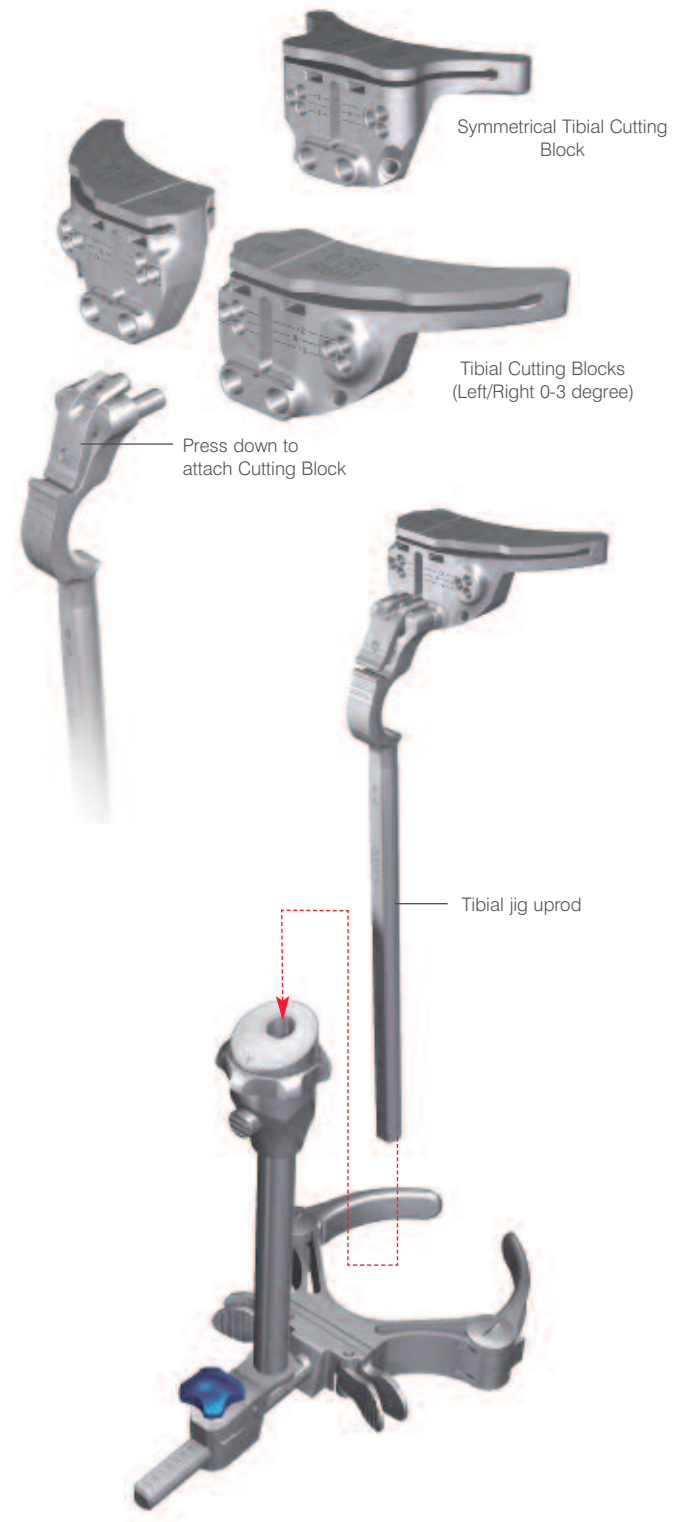


Figure 12

Lower Leg Alignment



Figure 13

Place the knee in 90 degrees of flexion with the tibia translated anteriorly and stabilized. Place the ankle clamp proximal to the malleoli (Figure 13). Align the proximal central marking on the tibia cutting block with the medial one third of the tibial tubercle to set rotation. To provide stability, insert a central pin through the vertical slot in the cutting block to aid stability (Figure 13). Push the quick release button to set the approximate resection level.

Varus/Valgus

Align the tibial Jig ankle clamp parallel to the transmalleolar axis to establish rotational alignment (Figure 14). The midline of the tibia is approximately 3 mm medial to the transaxial midline. Translate the lower assembly medially (usually to the second vertical mark), by pushing the varus/valgus adjustment wings (Figure 15). There are vertical scribe marks for reference aligning to the middle of the talus.

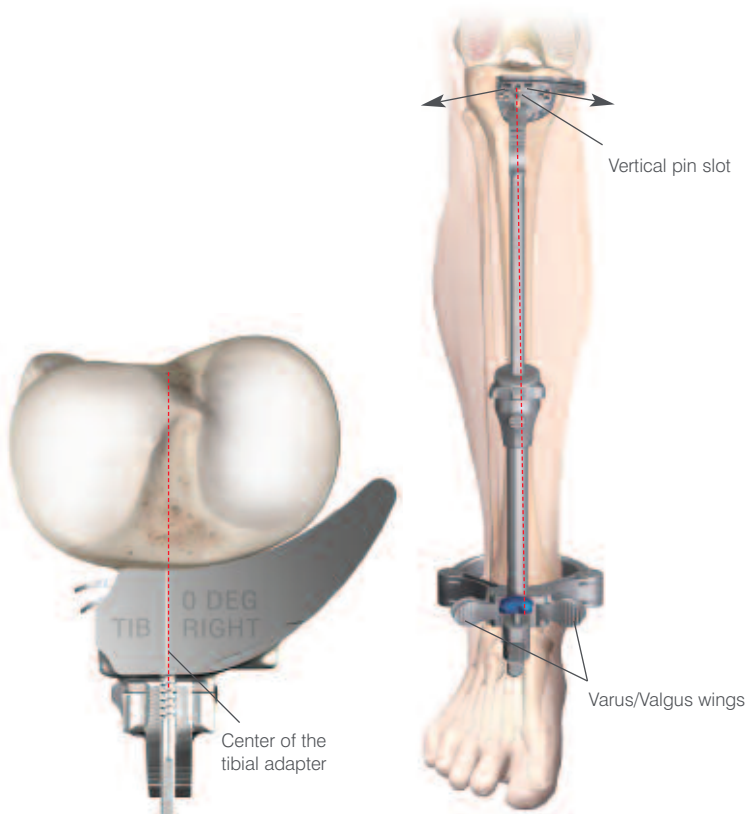


Figure 14

Figure 15

Slope

The tibial jig uprod and ankle clamp are designed to prevent an adverse anterior slope. On an average size tibia this guide gives approximately a 0 degree (Figure 16) tibial slope when the slope adjustment is translated anteriorly until it hits the stop. In some cases, a slight amount of slope will remain (1-2 degrees) (Figure 17).

Lower Leg Alignment

Increase the angle of the tibial slope to greater than 0 degrees if the patient has a greater natural slope (Figure 16). First, unlock the slide locking position and then translate the tibial slope adjuster anteriorly until the desired angle is reached. For a Cruciate Substituting (CS) design, a 0 degree posterior slope is recommended.

As each patient's anatomy varies, the EM tibial uprod can be used for both smaller and larger patients. The length of the tibia influences the amount of slope when translating the adapter anteriorly. The 0 degree default position can be overridden by moving the slope adjustment closer to the ankle.

On the uprod 5, 6 and 7 zones are present, which correspond to the length of the tibia. These markings can be used to fine tune the amount of slope. When the uprod shows a larger zone (7) marking, this indicates that when the lower assembly is translated 7 mm anterior, it will give an additional 1 degree of posterior slope (Figure 17).

Height

When measuring from the less damaged side of the tibial plateau set the stylus to 8 mm or 10 mm. If the stylus is placed on the more damaged side of the tibial plateau, set the stylus to 0 mm or 2 mm. Adjustment of resection height on the stylus should be done outside the joint space before locating the stylus in the cutting block.

If planning to resect through the slot, position the foot of the tibial stylus marked "slotted" into the slot of the tibial cutting block (Figure 18). If planning to resect on top of the cutting block, place the foot marked "non-slotted" into the cutting slot.

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

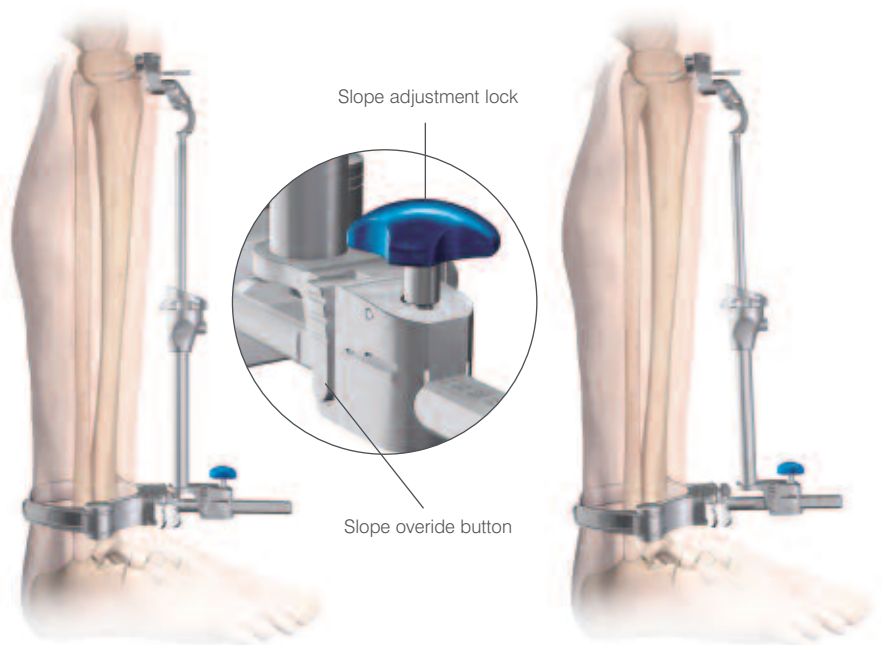


Figure 16

Figure 17

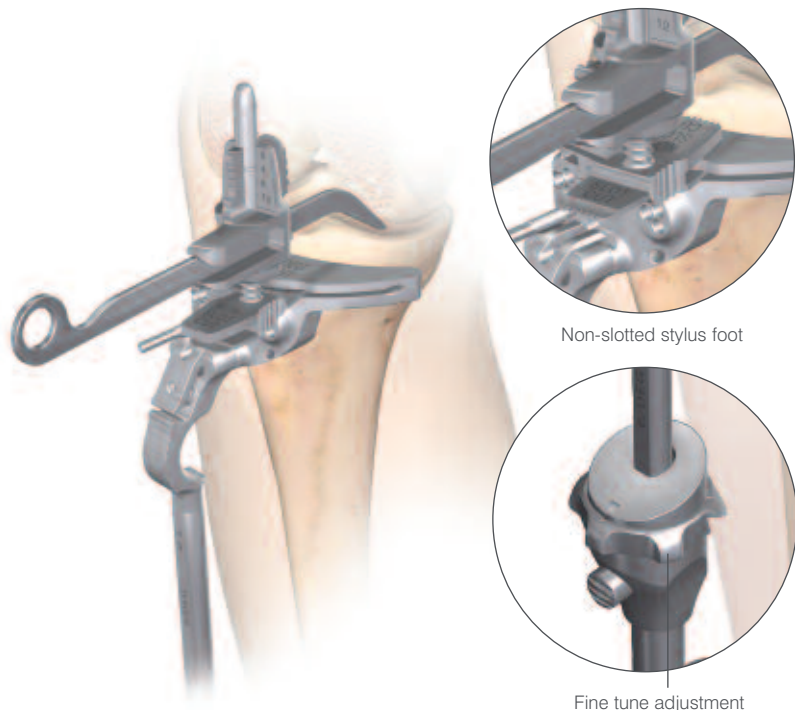


Figure 18

Tibial Resection



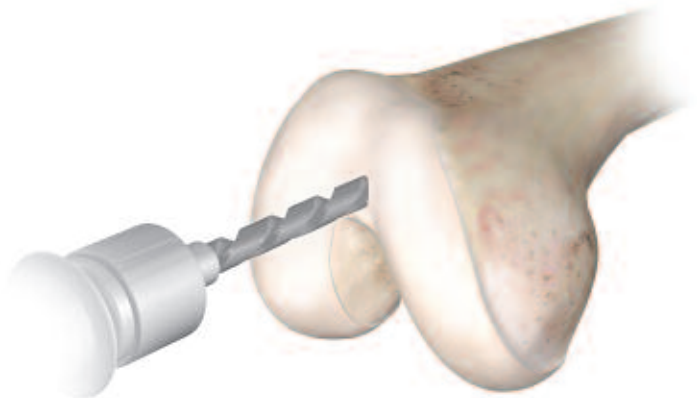
Figure 19

After the height has been set, pin the block through the 0 mm set of holes (the stylus may need to be removed for access). ± 2 mm pinholes are available on the resection blocks to further adjust the resection level where needed.

The block can be securely fixed with a convergent pin (Figure 19).

Femoral Alignment

Enter the medullary canal at the midline of the trochlea, 7 mm to 10 mm anterior to the origin of the PCL. Drill to a depth of approximately 5 mm to 7 mm. Take care to avoid the cortices (Figure 20).



Note: Correct location of the medullary canal is critical to avoid malposition of the femoral component.

Figure 20

Position the drill anteromedially to allow unobstructed passage of the I.M. rod in the femoral canal (Figure 21).

Attach the T-handle to the I.M. rod and slowly introduce the rod into the medullary canal, to the level of the isthmus (Figure 22).

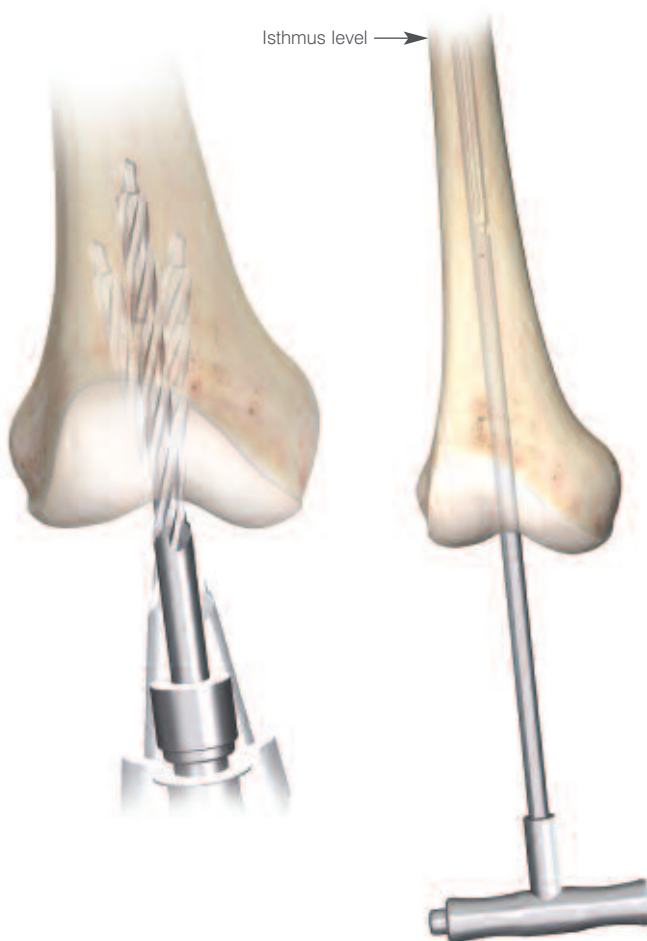


Figure 21

Figure 22

Femoral Alignment

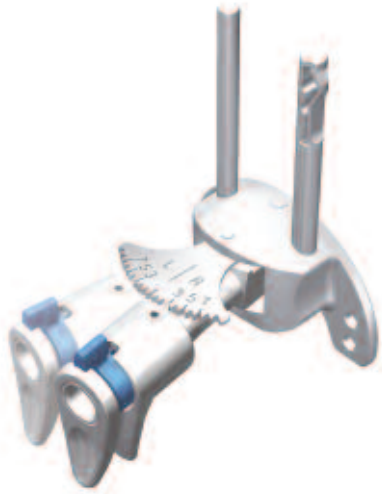


Figure 23

Use preoperative radiographs to define the angle between the femoral, anatomical and mechanical axis. Set the valgus angle (left or right - 0 degrees to 9 degrees) on the femoral alignment guide by compressing the two triggers and lock in place by rotating the blue locking lever clockwise (Figure 23).

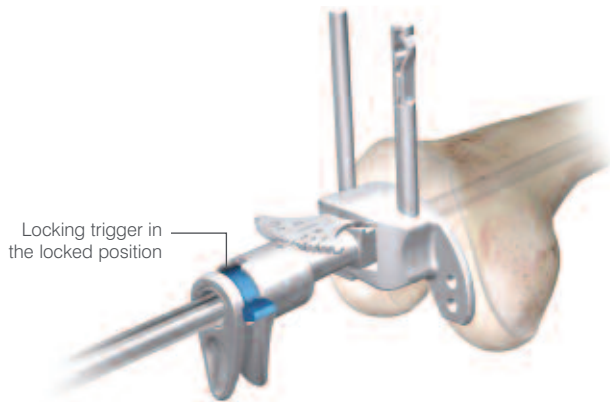


Figure 24

Remove the T-handle and place the femoral alignment guide on the I.M. rod and seat against the distal femur (Figure 24).

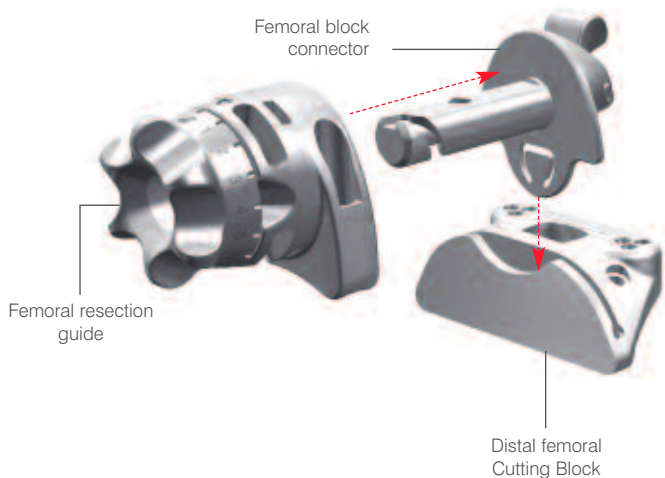


Figure 25

Rotate the knob on the resection guide until the arrow is pointing to the padlock symbol. Slide the femoral cutting block in the femoral block connector. Rotate the knob clockwise to set the desired resection level. Every click moves the femoral cutting block 1 mm proximal or distal and represents a slotted resection. An open resection will resect 4 mm less distal femur, so when an open resection is desired, the dial should be set to take an increased 4 mm of femur. Place the block connector in the femoral resection guide so that the tang on the connector slides in to the cutting slot on the cutting block. The trigger should engage in the hole behind the slot (Figure 25).

Femoral Alignment

Position the resection guide over the two legs of the distal femoral alignment guide until the distal cutting block touches the anterior femur (Figure 26).

Optional

Adjust the internal/external rotation of the alignment guide with reference to the trochlear groove. When rotation is correct, secure the alignment guide by inserting one threaded pin through the medial hole.

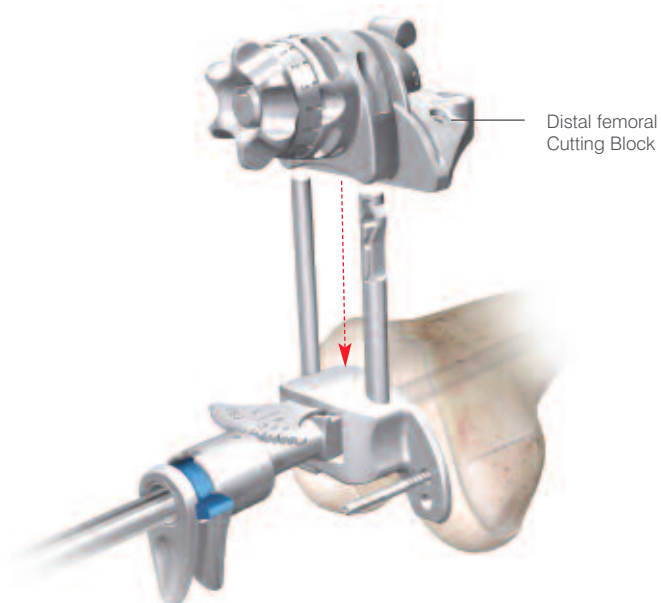


Figure 26

Adjust the medial-lateral placement of the resection block as desired and rotate until firmly seated on the anterior condyles.

Secure the cutting block to the femur with two threaded pins through the holes marked with a square. Make sure the pins are engaging the posterior condyles. This will allow a +2 or -2 mm adjustment to be made.

Resect at least 9 mm of distal femoral bone from the most prominent condyle (Figure 27).

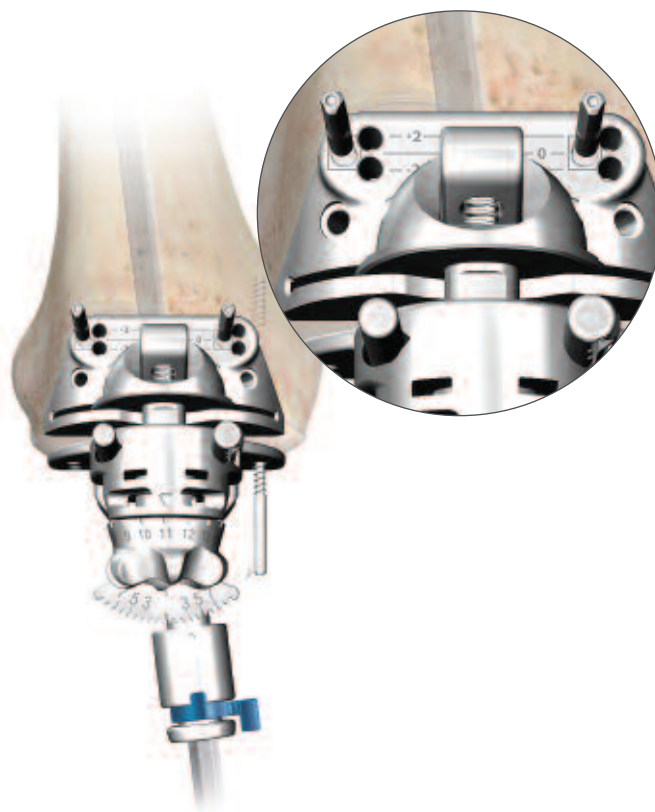


Figure 27

Distal Femoral Resection

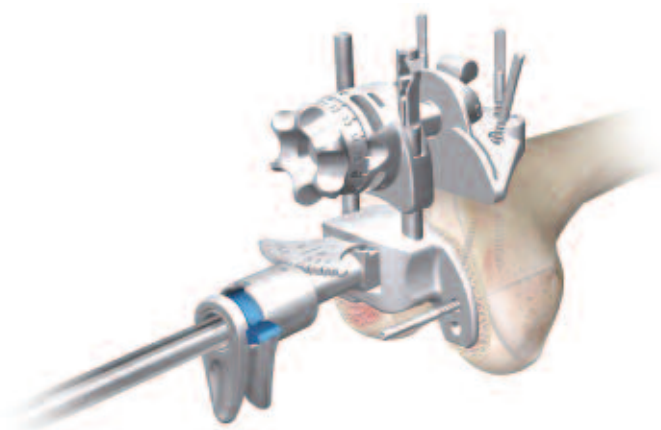


Figure 28

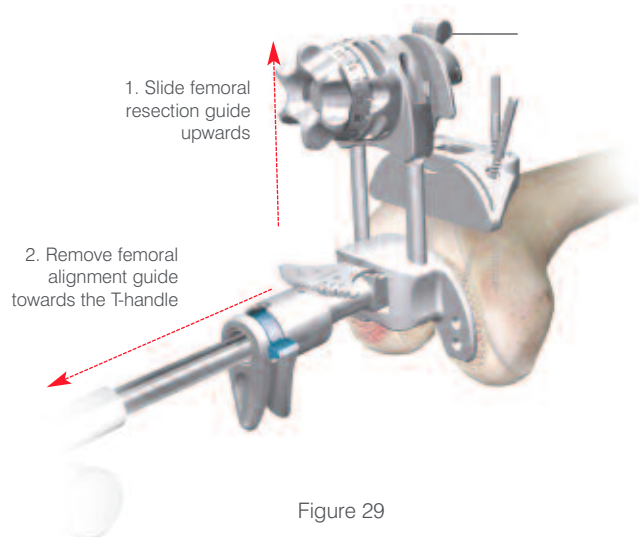


Figure 29



Figure 30

After the correct amount of resection is set, add a convergent pin through the medial hole in the block to aid stability (Figure 28).

Removal of the Femoral Alignment Guide

First attach the T-handle to the I.M. guide. Then unlock the cutting block from the block connector, using your thumb and index finger to release the attachment. Slide the femoral resection guide upwards over the legs until the block connector disengages the cutting block and in one motion remove the femoral alignment guide by pulling the instruments distally in the direction of the T-handle (Figure 29).

Perform the distal femoral resection (Figure 30).

Extension Gap Assessment and Balancing

Place the knee in full extension and apply lamina spreaders medially and laterally. The extension gap must be rectangular in configuration with the leg in full extension. If the gap is not rectangular, the extension gap is not balanced and appropriate soft tissue balancing must be performed (Figure 31).

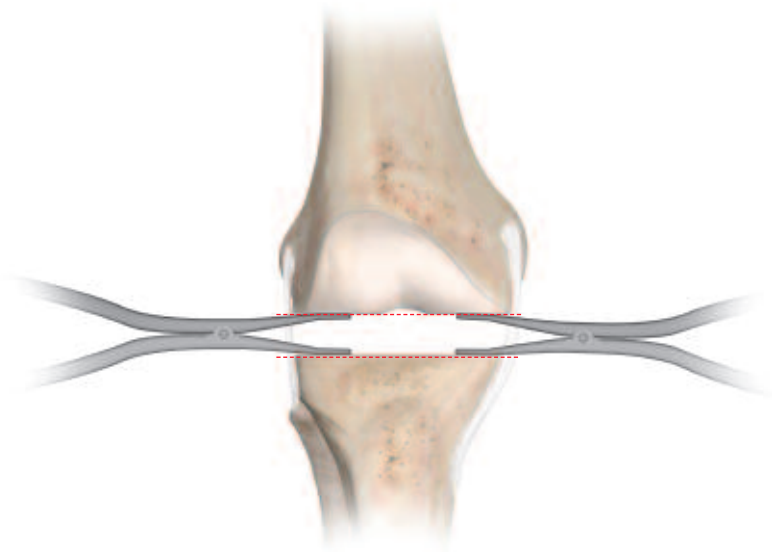


Figure 31

A set of specific fixed bearing and mobile bearing spacer blocks are available. Every spacer block has two ends, one for measuring the extension gap and one for the flexion gap. The extension gap side of the spacer block can be used to determine the appropriate thickness of the tibial insert and to validate the soft tissue balance (Figure 32).

Introduce the alignment rod through the spacer block. This may be helpful in assessing alignment (Figure 33).

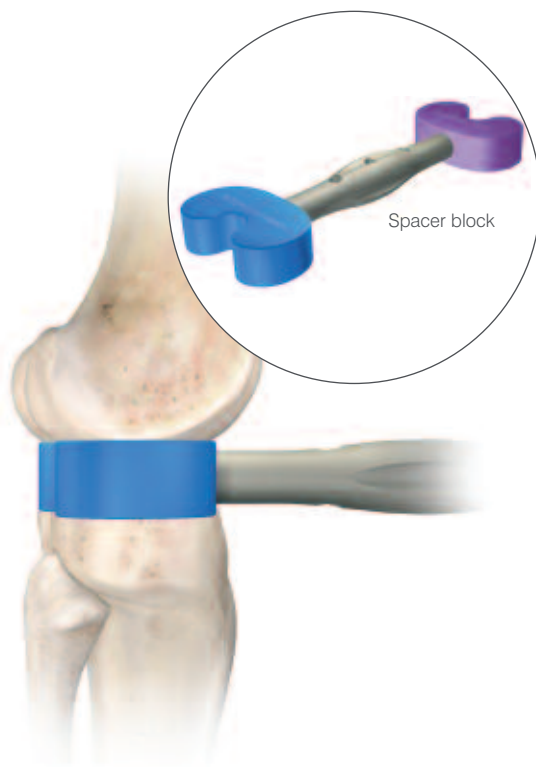


Figure 32



Figure 33

Femoral Sizing (Optional)



Figure 34

Place the Fixed Reference sizing guide against the resected distal surface of the femur, with the posterior condyles resting on the posterior plate of the guide. Secure with threaded headed pins (optional) (Figure 34).

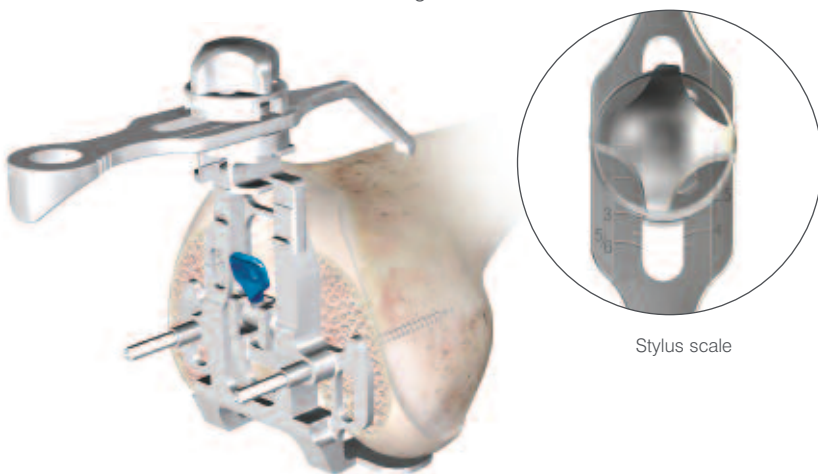


Figure 35

Place the sizing guide stylus on the anterior femur with the tip positioned at the intended exit point on the anterior cortex to avoid any potential notching of the femur. A scale on the surface of the stylus indicates the exit point on the anterior cortex for each size of femur. The scale is read from the distal side of the lock knob (Figure 35).

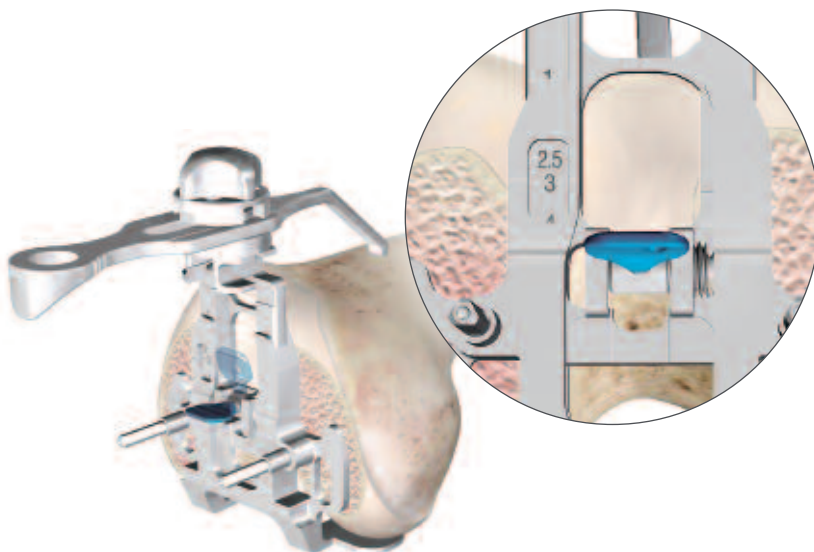


Figure 36

Tighten the locking lever downward and read the size from the sizing window (Figure 36).

Femoral Rotation

Select the appropriate I.M. rod (3 or 5 degrees) with the left/right designation to anterior, as determined during preoperative x-ray analysis. Slide the rod in the Sigma or RPF balanced resection block. Insert the I.M. rod into the distal femoral I.M. canal taking care to avoid over-pressurisation (Figure 37).

Note: The RP-F and standard Sigma blocks are visually very similar. To help differentiate them, the RP-F block has the letters "RP-F" engraved on it, and a series of grooves rising from the posterior cut face.

Assemble the femoral stylus to the anterior slot of the balanced Sigma or RP-F femoral block and tighten it by turning the knurled screw clockwise (Figure 38).

Ensure the A/P resection block is unlocked and lower the assembly onto the I.M. plate. Translate the block posteriorly until the anterior femoral stylus contacts the anterior cortex of the femur. The stylus should rest on the anterior femur at the approximate exit point of the anterior cut. Fix the position of the balanced femur block by turning the locking mechanism clockwise. Final rotation has not been fixed at this stage. Remove the anterior femoral stylus (Figure 39).

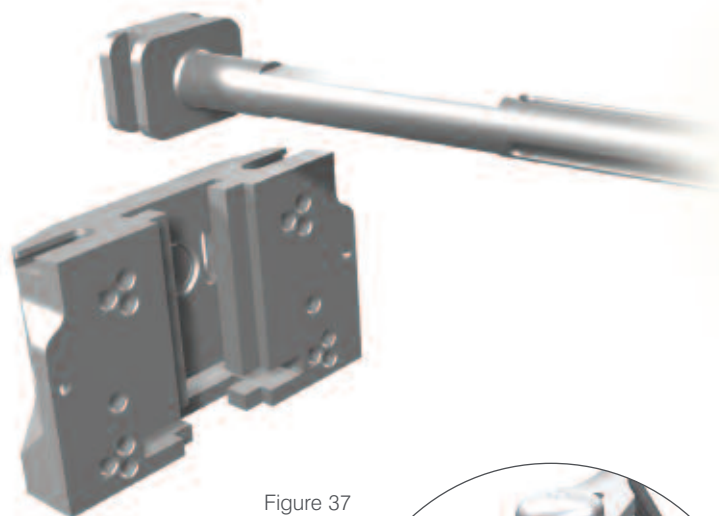


Figure 37

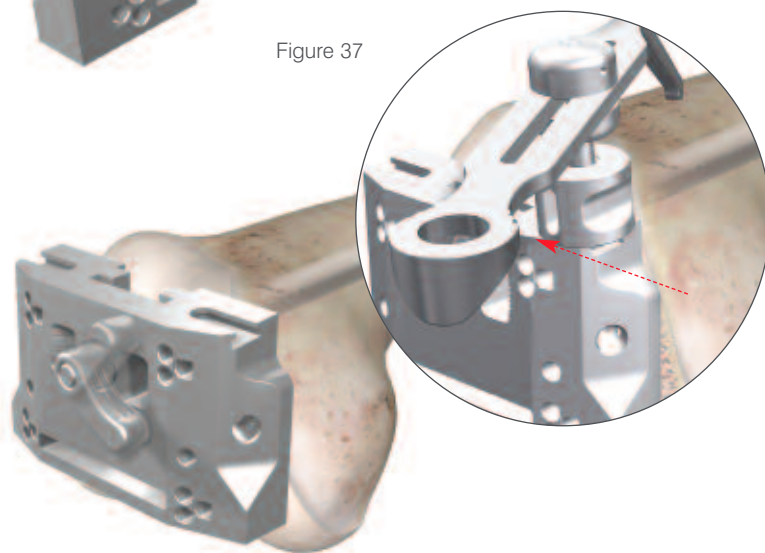


Figure 38

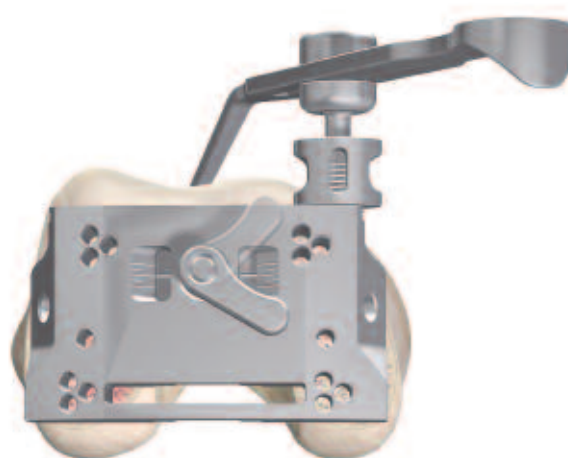


Figure 39

Femoral Rotation



Figure 40

Two handles can be attached to the balanced cutting block to help in visualizing the degree of rotation of the balanced cutting block in respect to the trans-epicondylar axis (Figure 40).

Rotation is determined with the knee in 90 degrees of flexion such that the posterior surface is parallel to the resected tibial plateau. Introduce the femoral guide positioner, (with the appropriate tibial shim added) into the joint space engaging the posterior slot of the balanced resection guide (Figure 41).

The femoral guide positioner should mirror the extension gap previously measured with the spacer block.

The knee may be slightly flexed or extended until the positioner lies flat on the previously resected proximal tibia.

Alternatively lamina spreaders or spacer blocks (Figure 41) can be used.

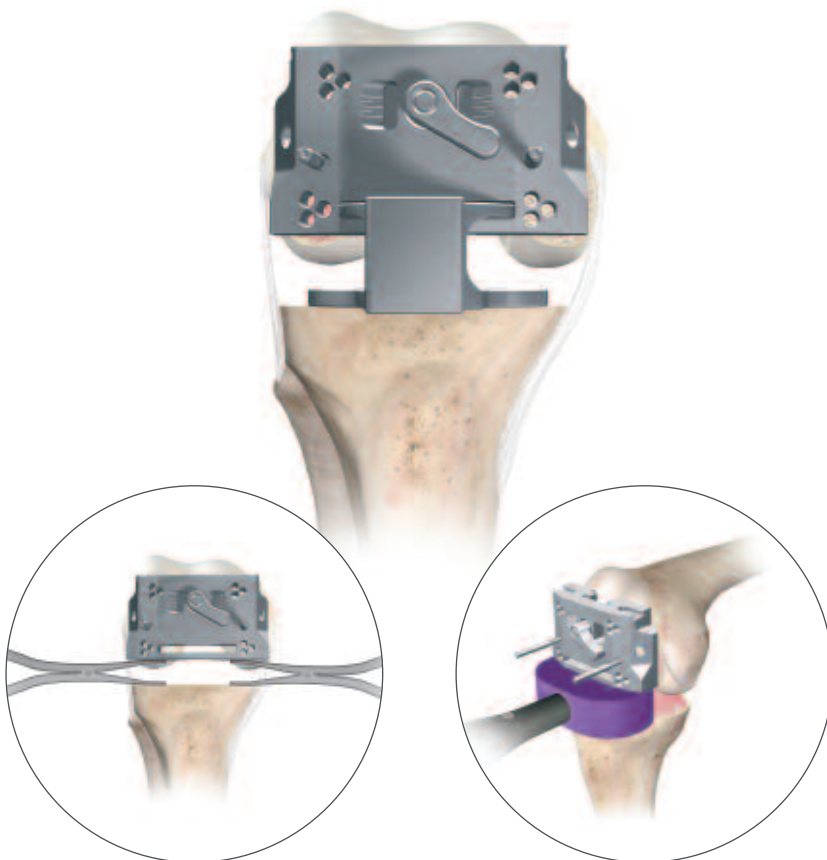


Figure 41

Femoral Rotation

If the flexion gap is too lax, tibial shims may be added to ensure that the positioner fits snugly (Figure 42).

Note: If the flexion gap no longer matches the extension gap, the distal cut will need to be revisited.

Re-evaluate the tibial alignment using the external alignment rod passed through the hole in the femoral guide positioner.

The femoral rotation is set by the femoral guide positioner and is based on the principle of equal compartment tension and balanced collateral ligaments. Using the femoral guide positioner this balance should automatically occur, because the femur can freely rotate around the I.M. plate.

Conduct a final check of the anterior resection level with the visualization wing. All adjustments should be made prior to pinning the block. Pin the A/P resection block to the distal femur using the two neutral central holes (marked with a square) before cutting. Remove the Femoral Guide positioner (Figures 42 and 43).

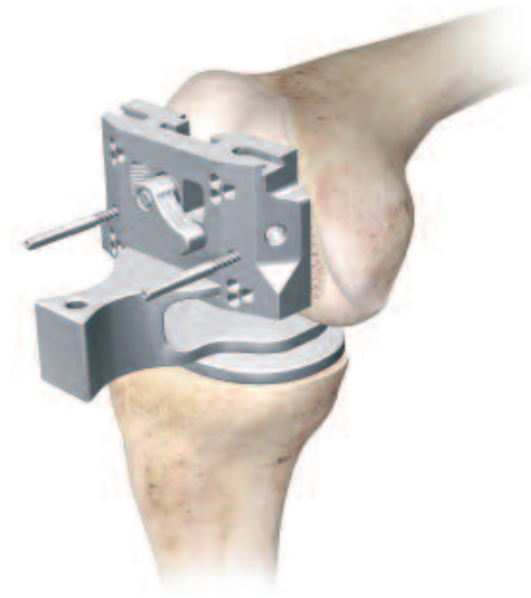


Figure 42

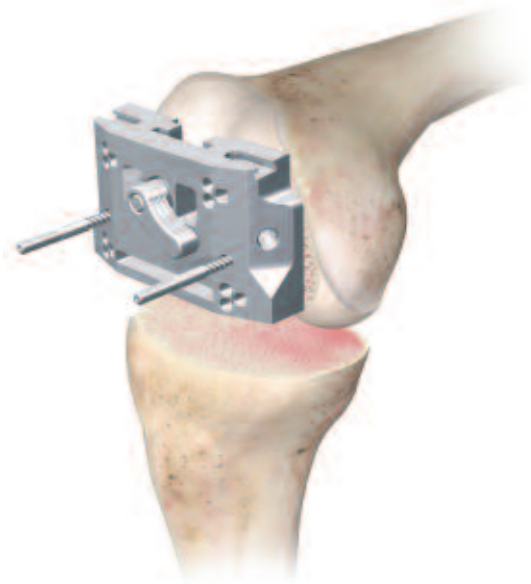


Figure 43

Femoral Finishing

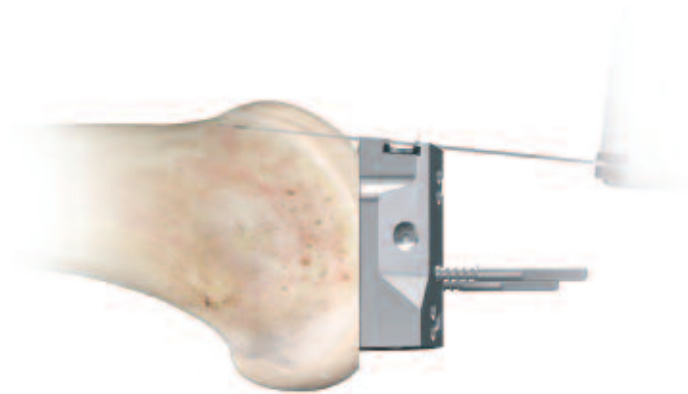


Figure 44

Resect the anterior cortex using the balanced femoral cutting block. Remove the resected bone (Figure 44).

Select the appropriate sized Sigma or Sigma RP-F femoral finishing block and position the block on the resected anterior and distal surfaces of the femur.

Note: The posterior aspect of the block corresponds exactly to the M/L dimension of the final implant and can be used to visualize the correct M/L position. In addition, the anterior flange on the cutting block represents the medial flange of the implant, with the proximal anterior protrusions representing the lateral implant flange (Figure 45).

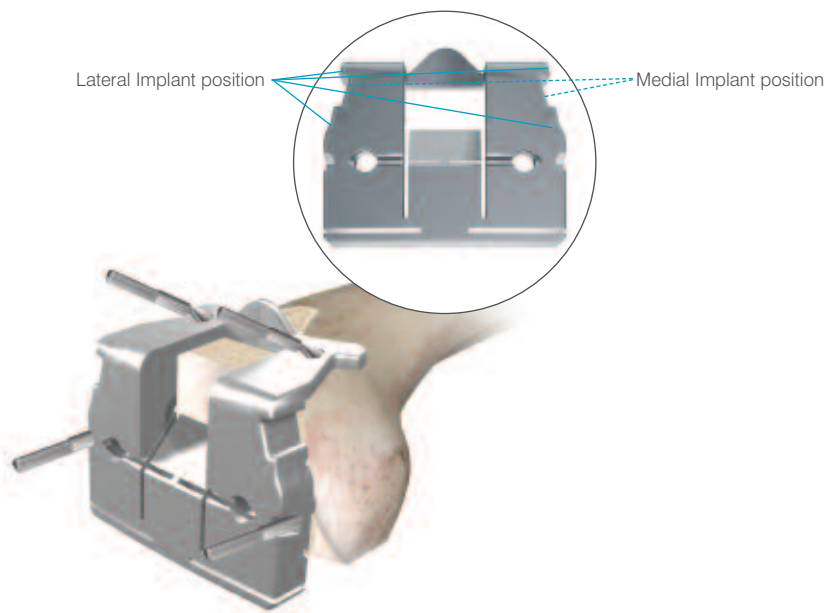


Figure 45

Pin the block in place through the fixation pinholes with at least three threaded pins before any bone cuts are made. Perform the final resections: posterior resection, notch cut, anterior and posterior chamfer resections (Figure 45).

Femoral Finishing (Alternative)

Alternatively, position the appropriate sized Sigma or Sigma RP-F A/P chamfer block in the pre-drilled medial and lateral holes.

Secure and stabilize the Sigma or Sigma RP-F classic A/P chamfer block by drilling a headed drill pin through the central pinhole. Alternatively, medial and lateral pins can be placed. Place retractors to protect the MCL medially and the popliteal tendon laterally.

After securely fixing the femoral chamfer block, resect the anterior cortex, the posterior condyles and the anterior/posterior chamfers (Figure 46).

Note: On both the classic A/P chamfer block and the femoral finishing block, the RP-F and standard Sigma blocks look very similar. To easily identify them, the RP-F block has the letters “RP-F” on the distal face, and the area above the posterior cut has several grooves.

When using a stabilized Sigma or Sigma RP-F component, select and attach the appropriate femoral notch guide.

The Sigma RP-F and standard Sigma notch guides look very similar. Care should be taken not to confuse the blocks as this will result in under-or-over resection of the box.

Note: The RP-F guide can be identified through the letters “RP-F” on the anterior face, and a series of grooves along the notch distal anterior corner.

Position the notch guide on the resected anterior and distal surfaces of the femur. Pin the block in place through the fixation pin holes with at least three pins before any bone cuts are made. Make notch cuts with a small saw blade (Figures 47 and 48).

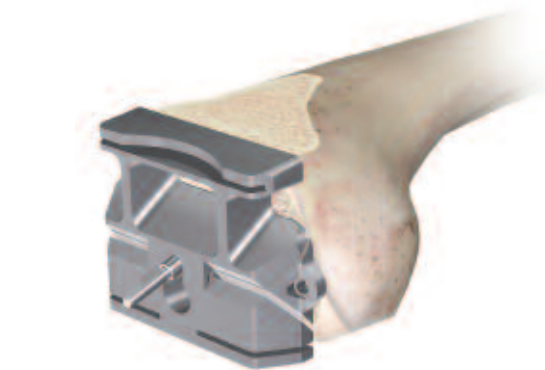


Figure 46



Figure 47

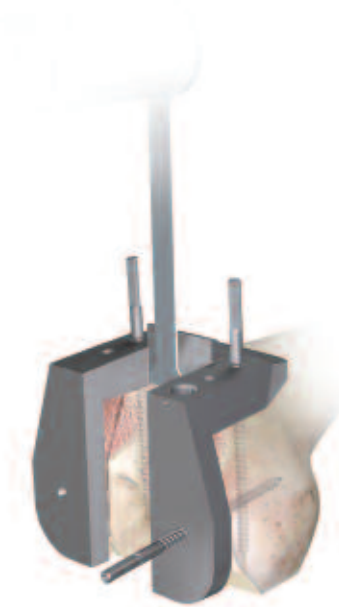


Figure 48

Measuring the Flexion Gap



The flexion side of the spacer block is used to evaluate the flexion gap. Where RP-F spacer blocks are used, flexion shims will need to be added.

An alignment rod assembled to the spacer block should pass through the center of the talus and lie parallel to the lateral tibial axis (Figure 49).

Figure 49

Trial Components (For Fixed Bearing, see Appendix A)

Note: Either M.B.T. or Fixed Bearing tibial components can be trialed prior to performing the tibial preparation step.

Femoral Trial

Attach the slap hammer or universal handle to the femoral inserter/extractor. Position the appropriately sized femoral trial on the inserter by depressing the two triggers to separate the arms and push the trial against the conforming polyethylene surface.

Release the triggers so that the arms engage in the slots on the femur, and rotate the handle clockwise to lock. Position the trial onto the femur, impacting, as necessary. To detach the inserter from the femur, rotate the handle counterclockwise and push the two triggers with thumb and index finger. Position the femoral trial onto the femur (Figure 50).



Figure 50

Tibial Trial

Place the appropriate sized M.B.T. tray trial onto the resected tibial surface. Position the evaluation bullet into the cut-out of the M.B.T. tray trial (Figure 51).

There are two options available to assess the knee during trial reduction. One or both may be used.

1) Trial reduction with trial bearing in non-rotation mode

This option is useful when the tibial tray component size is smaller than the femoral size.

*Note: Mobile bearing tibial insert size **MUST** match femoral component size.*

With equivalent sizes, the bearing rotation allowance is 8 degrees for Sigma and 20 degrees for Sigma RP-F. For a tibial tray one size smaller than the femoral component, this bearing rotation allowance reduces to 5 degrees. In this situation, finding the neutral position with respect to the femur is therefore more important in order to prevent bearing overhang and soft tissue impingement. Position the evaluation bullet into the cut-out of the M.B.T. tray trial.



Figure 51

Trial Components (For Fixed Bearing, see Appendix A)

2) Trial reduction with trial bearing free to rotate

This trial reduction can be done instead or in addition to the one described before.

Place the appropriately sized M.B.T. trial tray onto the resected tibial surface (Figure 52).



Figure 52

Assess the position of the tray to achieve maximal tibial coverage (align the tibial tray handle with the electrocautery marks if procedure described in tibial trial 1 has been followed). The rotation of the M.B.T. tray trial is usually centered on the junction between the medial and central one-third of the tibial tubercle. Secure the keel punch impactor to the spiked evaluation bullet and position into the cut-out of the M.B.T. tray trial. Tap down lightly to secure the tray to the proximal tibia (Figure 53).



Figure 53

Trial Components (For Fixed Bearing, see Appendix A)

Select the tibial insert trial that matches the chosen femoral size and style, curved or stabilized, and insert it onto the M.B.T. tray trial (Figure 54). Carefully remove the tibial tray handle and, with the trial prosthesis in place, extend the knee carefully, noting the anterior/posterior stability, medial/lateral stability and overall alignment in the A/P and M/L plane. If there is any indication of instability, substitute a tibial insert trial with the next greater thickness and repeat the reduction.



Figure 54

Select the tibial insert trial that gives the greatest stability in flexion and extension while still allowing full extension (Figure 55).

Adjust rotational alignment of the M.B.T. tray trial with the knee in full extension, using the tibial tray handle to rotate the tray and trial insert into congruency with the femoral trial. The rotation of the M.B.T. tray trial is usually centered on the junction between the medial and central one-third of the tibial tubercle. Overall alignment can be confirmed using the two-part alignment rod, attaching it to the tibial alignment handle (Figure 56). The appropriate position is marked with electro-cautery on the anterior tibial cortex. Fully flex the knee, and remove the trial components.

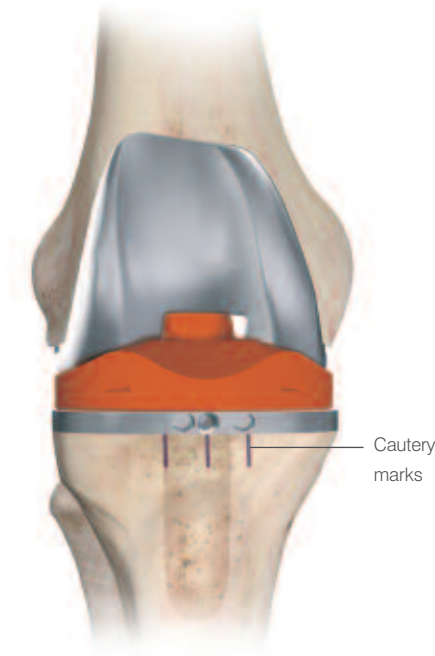


Figure 55



Figure 56

Tibial Preparation - M.B.T.

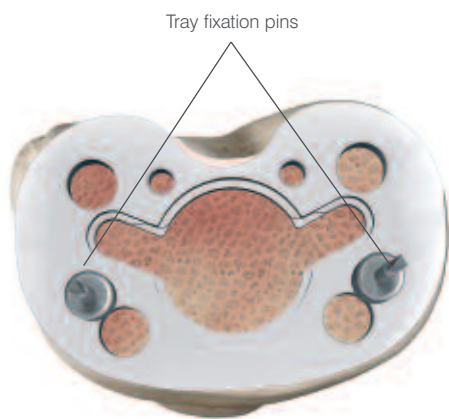


Figure 57

Tibial Preparation

Align the tibial trial to fit with the tibia for maximum coverage or, if electrocautery marks are present, use these for alignment. Pin the trial with two pins. The tray trial allows for standard and M.B.T. keeled (Figure 57). Attach the M.B.T. drill tower to the tray trial. Control the tibial reaming depth by inserting the reamer to the appropriate colored line (Figures 58 and 59). An optional Modular Drill Stop is available to provide a hard stop when reaming. See table for appropriate size.

Tray Size	Line Color
1-1.5	Green
2-3	Yellow
4-7	Blue



Figure 58



Figure 59

Note: For cemented preparation, select the “Cemented” instruments, and for non-cemented or line-to-line preparation, select the “Non-Cemented” tibial instruments. The Cemented instruments will prepare for a 1 mm cement mantle around the periphery of the implant.

Tibial Preparation - M.B.T.

Keeled Tray Option

If a keeled M.B.T. tray is to be employed and the bone of the medial or lateral plateau is sclerotic, it is helpful to initially prepare the keel slot with an oscillating saw or high speed burr. Assemble the M.B.T. keel punch impactor to the appropriately-sized M.B.T. keel punch by pressing the side button and aligning the vertical marks on both impactor and keel punch (Figure 60). Insert assembly into the M.B.T. Drill Tower, taking care to avoid malrotation. Impact the assembly into the cancellous bone until the shoulder of the keel punch impactor is in even contact with the M.B.T. Drill Tower (Figure 61).



Figure 60



Figure 61

Non-Keeled Tray Option

For a non-keeled tray option, attach the M.B.T. punch and follow the same routine (Figure 62).

Final Trialing Option

A secondary and final trialing step can be performed after tibial preparation. Remove the keel punch impactor from the keel punch by pressing the side button and remove the drill tower as well. Place the trial femoral component on the distal femur. Place the appropriate tibial insert trial onto the tray trial and repeat previous trial evaluation.



Figure 62

Final Patella Preparation

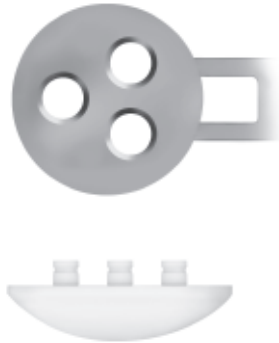


Figure 63



Figure 64

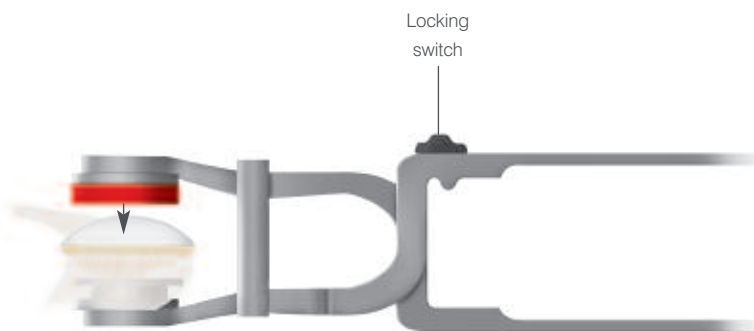


Figure 65



Figure 66

Select a template that most adequately covers the resected surface without overhang (Figure 63). If used, remove the patella wafer from the patella. Position the template handle on the medial side of the everted patella. Firmly engage the template to the resected surface and drill the holes with the appropriate drill bit (Figure 64).

Cement the patellar implant. Thoroughly cleanse the cut surface with pulsatile lavage. Apply cement to the surface and insert the component. The patellar clamp is designed to fully seat and stabilize the implant as the cement polymerizes. Center the silicon O-ring over the articular surface of the implant and the metal backing plate against the anterior cortex, avoiding skin entrapment. When snug, close the handles and hold by the ratchet until polymerization is complete. Remove all extruded cement with a curette. Release the clamp by unlocking the locking switch and squeezing the handle together (Figure 65).

Reduce the patella and evaluate the patella implant. Unrestricted range of motion, free bearing movement and proper patellar tracking should be evident (Figure 66).

Cementing Technique

Prepare the sclerotic bone to ensure a continuous cement mantle with good cement interdigitation. This can be done by drilling holes and cleansing the bone by pulsatile lavage (Figure 67). Any residual small cavity bone defects should be packed with cancellous autograft, allograft or synthetic bone substitutes such as Conduit™ TCP.

Note: Blood lamination can reduce the mechanical stability of the cement, therefore it is vital to choose a cement which reaches its working phase early.

Whether mixed by the SmartMix™ Vacuum Mixing Bowl or the SmartMix™ Cemvac® Vacuum Mixing System, SmartSet® GHV Bone Cement offers convenient handling characteristics for the knee cementation process.

A thick layer of cement can be placed either on the bone (Figure 68) or on the implant itself.



Figure 67



Figure 68

Final Component Implantation



Figure 69

Tibial Implantation

Attach the M.B.T. tibial impactor by inserting the plastic cone into the implant and tighten by rotating the lock knob clockwise. Carefully insert the tibial tray avoiding malrotation (Figure 69). When fully inserted, several mallet blows may be delivered to the top of the tray inserter. Remove all extruded cement using a curette.

Polyethylene Implantation

Remove loose fragments or particulates from the permanent tibial tray. The appropriate permanent tibial insert can be inserted.



Figure 70

Femoral Implantation

Hyperflex the femur and sublux the tibia forward. Attach the slap hammer or universal handle to the femoral inserter/extractor. Position the appropriately sized femoral component on the inserter/extractor by depressing the two triggers to separate the arms and push the femoral component against the conforming polyethylene. Release the triggers so that the arms engage in the slots on the femoral component and rotate the handle clockwise to lock (Figure 70).



Figure 71

Extend the knee to approximately 90 degrees for final impaction. Release the inserter/extractor by rotating the handle counterclockwise and push the two triggers with thumb and index finger. For final femur impaction use the femoral notch impactor to seat the femur component. In Sigma CS and Sigma RP-F (not Sigma CR) cases the impactor can be used in the notch to prevent adverse flexion positioning (Figure 71). Clear any extruded cement using a curette.

Closure



Figure 72

Release the tourniquet and control bleeding by electrocautery. Place a closed-wound suction drain in the suprapatellar pouch and bring out through the lateral retinaculum. Reapproximate the fat pad, quadriceps mechanism, patella tendon and medial retinaculum with interrupted sutures.

Fully rotate the knee from full extension to full flexion to confirm patellar tracking and the integrity of the capsular closing (Figure 72). Note the final flexion against gravity for post-operative rehabilitation. Reapproximate subcutaneous tissue and close the skin with sutures or staple.

Appendix A: Fixed Bearing Modular Tibial Preparation



Figure 73

Femoral Trial

Attach the slap hammer or universal handle to the femoral inserter/extractor. Position the appropriately sized femoral trial on the inserter by depressing the two triggers to separate the arms and push the trial against the conforming polyethylene surface. Release the triggers so that the arms engage in the slots on the femur, and rotate the handle clockwise to lock. Position the trial onto the femur, impacting as necessary. To detach the inserter from the femur, rotate the handle counterclockwise and push the two triggers with thumb and index finger. Position the femoral trial onto the femur (Figure 73).

There are two options available to assess the knee during trial reduction. One or both may be used.

1. Trial reduction with trial insert and tray in rotation, or free floating mode.

This option is useful when allowing normal internal/external extension of the tibial components during flexion/extension to dictate optimal placement of the tibial tray.

Select the trial bearing size determined during implant planning and insert onto the tray trial. Place the knee in approximately 90 to 100 degrees of flexion. With the knee in full flexion and the tibia subluxed anteriorly, attach the alignment handle to the tray trial by retracting the lever. Position the tray trial on the resected tibial surface, taking care to maximize the coverage of the tray trial on the proximal tibia (Figure 74).



Figure 74

Appendix A: Fixed Bearing Modular Tibial Preparation

With the trial prostheses in place, the knee is carefully and fully extended, noting medial and lateral stability and overall alignment in the A/P and M/L plane. Where there is any indication of instability substitute the next greater size tibial insert and repeat reduction. Select the insert that gives the greatest stability in flexion and extension and allows full extension. Where there is a tendency for lateral subluxation or patellar tilt in the absence of medial patellar influence (thumb pressure), lateral retinacular release is indicated.

Adjust rotational alignment of the tibial tray with the knee in full extension, using the alignment handle to rotate the tray and trial insert into congruency with the femoral trial. The appropriate position is marked with electrocautery on the anterior tibial cortex. (Figures 75 and 76).

2. Trial reduction with trial insert and tray in fixed, non-rotation mode.

Assess the position of the tray to achieve maximal tibial coverage (align the tibial tray handle with the electrocautery marks, if procedure described in 1 has been followed). The rotation of the tray trial is usually centered on the junction between the medial and central one-third of the tibial tubercle. Secure the fixed bearing keel punch impactor to the evaluation bullet and position into the cut-out of the tray trial. Tap down lightly to secure the tray to the proximal tibia (Figure 77).

Carefully remove the tibial tray handle and repeat the trial reduction step from Step 1.

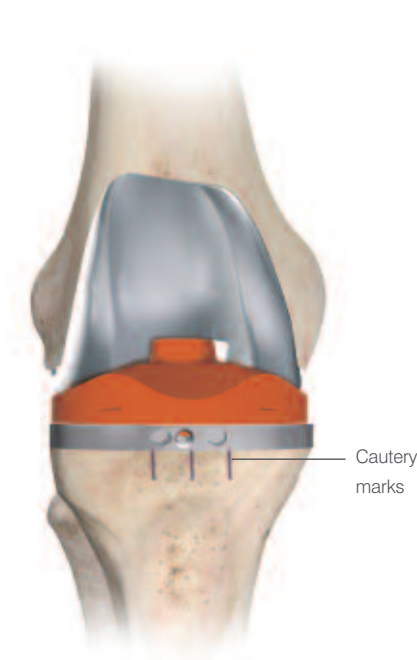


Figure 75



Figure 76



Figure 77

Appendix A: Fixed Bearing Modular Tibial Preparation



Figure 78

Sigma Modular & UHMWPE Tray:

Select the appropriate fixed bearing drill tower, drill bushing, drill and modular keel punch system. Pin the trial with two pins. Remove the alignment handle from the tray trial and assemble the fixed bearing drill tower onto the tray trial (Figure 78).

Fully advance the matching drill through the drill tower into the cancellous bone (Figure 79) to the appropriate line shown in Table below.

Tray Size	Line Color
1.5-3	Green
4-5	Yellow
6	Purple

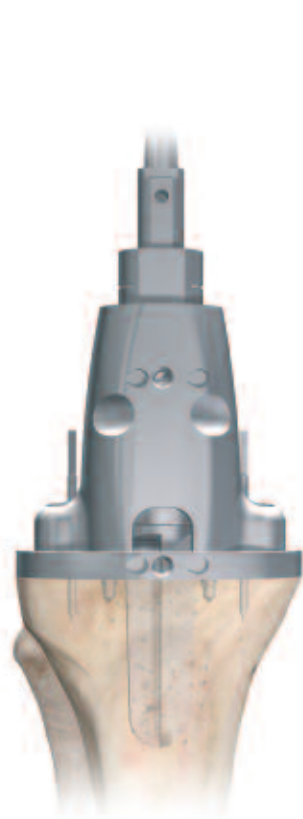


Figure 79



Figure 80

Note: For cemented preparation, select the “Cemented” instruments, and for non-cemented or line-to-line preparation, select the “Non-Cemented” tibial instruments. The Cemented instruments will prepare for a 1 mm cement mantle around the periphery of the implant.

Insert the fixed bearing keel punch impactor and keel punch through the drill tower and impact until the shoulder of the punch is in contact with the guide (Figure 80). Remove the keel punch impactor by pressing the side button taking care that the punch configuration is preserved.

Appendix B: Tibial I.M. Jig Alignment



Figure 83



Figure 84

The entry point for the intramedullary alignment rod is a critical starting point for accurate alignment of the intramedullary alignment system.

In most cases, this point will be centered on the tibial spine in both medial/lateral and anterior/posterior aspect. In some cases, it may be slightly eccentric.

Flex the knee maximally, insert the tibial retractor over the posterior cruciate ligament and the sublux tibia anteriorly. All soft tissue is cleared from the intercondylar area. Resect the tibial spine to the highest level of the least affected tibial condyle.

Position the correct size fixed bearing or M.B.T. tray trial on the proximal tibia to aid in establishing a drill point. Drill a hole through the tray trial to open the tibia intramedullary canal with the I.M. step drill (Figure 83).

The intramedullary rod is passed down through the medullary canal until the isthmus is firmly engaged (Figure 84).

Appendix B: Tibial I.M. Jig Alignment

Remove the handle and place the I.M. rotation guide over the I.M. rod to define the correct rotational tibia axis, referring to the condylar axis, medial 1/3 of the tibia tubercle and the center of the ankle (Figure 85).

The angle can also be checked relative to the posterior condylar axis by moving the slider forward and rotating it until it is aligned with the posterior condyles. The marks on the rotation guide are in 2 degree increments and give an indication of the angle between the posterior condylar axis and the chosen rotation.

The rotation can then be marked through the slot on the rotation guide. The rotation guide can then be removed. After the correct rotation has been marked, slide the I.M. tibial jig over the I.M. rod and rotate the I.M. jig until the rotation line on the jig lines up with the line previously marked using the rotation guide.

Assemble the appropriate 3 degree Sigma HP handed (left/right) or symmetrical tibia cutting block to the HP I.M. tibial jig in line with the marked rotation (Figure 86).

A 3-degree cutting block is recommended to compensate for the anterior angled I.M. rod position in the I.M. canal. This will prevent an adverse anterior slope position. This results in an overall 0 degree position, which is recommended for the Sigma Cruciate Substituting components. Additional posterior slope can be added through the slope adjustment knob, when using Sigma cruciate retaining components.

Note: The number in the window indicates the amount of **ADDITIONAL SLOPE** that has been added.



Figure 85

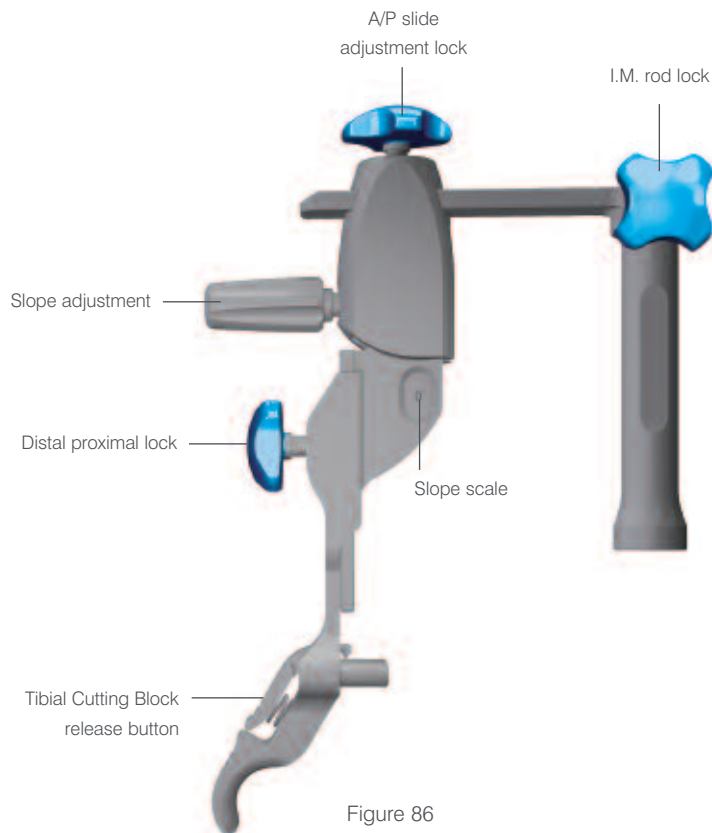


Figure 86

Appendix B: Tibial I.M. Jig Alignment



Figure 87

Slide the appropriate fixed or adjustable stylus in the HP tibial cutting block slot. When measuring from the less damaged side of the tibia plateau set the stylus to 8 mm or 10 mm. If the stylus is placed on the more damaged side of the tibia plateau, set the stylus to 0 mm or 2 mm (Figure 87).

Slide the total construct as close as possible towards the proximal tibia and lock this position.

Adjust the correct degree of slope by rotating the slope adjustment screw. For Sigma Cruciate Retaining components, a 3-5 degree slope is recommended. For Sigma Cruciate Substituting components a 0 degree slope is recommended as previously described. Ensure that the slope scale reads zero.

Obtain the correct block height by unlocking the distal proximal lock and lowering the bottom half of the block until the stylus is resting on the desired part of the tibia. Lock the device, by turning the distal proximal locking screw, when the correct position has been reached.

After the height has been set, insert two pins through the 0 mm set of holes in the block (the stylus may need to be removed for access). The block can be securely fixed with one extra convergent pin.

+ and -2 mm pinholes are available on the cutting blocks to further adjust the resection level where needed.

Check the position of the resection block with an external alignment guide before making any cut. Unlock the intramedullary alignment device from the cutting block and remove the I.M. rod (Figure 88).

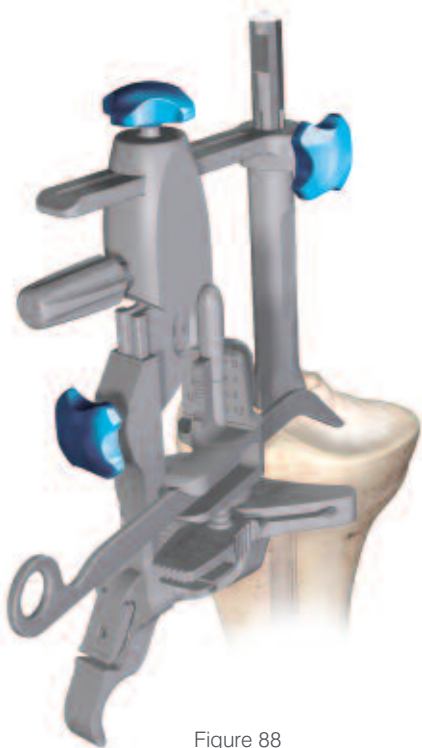


Figure 88

Appendix C: Spiked Uprod

Assemble the appropriate 0-3 degree, left/right or symmetrical cutting block to the spiked uprod. Slide the spiked uprod into the ankle clamp assembly.

Place the knee in 90 degrees of flexion with the tibia translated anteriorly and stabilized. Place the ankle clamp proximal to the malleoli and insert the larger of the two proximal spikes in the center of the tibial eminence to stabilize the EM alignment device.

Loosen the A/P locking knob and position the cutting block roughly against the proximal tibia and lock the knob. Position the cutting block at a rough level of resection and tighten the proximal/distal-sliding knob (Figure 89).



Figure 89

Varus/Valgus

Establish rotational alignment by aligning the tibial Jig ankle clamp parallel to the transmalleolar axis. The midline of the tibia is approximately 3 mm medial to the transaxial midline.

Translate the lower assembly medially (usually to the second vertical mark) by pushing the varus/valgus adjustment wings.

There are vertical scribe marks for reference aligning to the middle of the talus (Figure 90).



Figure 90

Appendix C: Spiked Uprod



Figure 91



Figure 92

Slope

The spiked uprod and ankle clamp are designed to prevent an adverse anterior slope. On an average size tibia, this guide will give approximately a 0 degree tibial slope when the slope adjustment is translated anteriorly until it hits the stop. In some cases, a slight amount of slope will remain (1-2 degrees).

The angle of the tibial slope can be increased to greater than 0 degrees should the patient have a greater natural slope (Figure 91). First, unlock the slide locking position and then translate the tibial slope adjuster anteriorly until the desired angle is reached. For a Cruciate Substituting (CS) design, a 0 degree posterior slope is recommended.

As each patient's anatomy varies, the spiked uprod can be used for both smaller and larger patients. The length of the tibia influences the amount of slope when translating the adapter anteriorly. The 0 degree default position can be overridden by moving the slope adjustment closer to the ankle.

On the spiked uprod 5, 6 and 7 zones are present, which correspond to the length of the tibia. These markings can be used to fine tune the amount of slope.

When the spiked uprod shows a larger zone (7) marking, this indicates that when the lower assembly is translated 7 mm anterior, it will give an additional 1 degree of posterior slope (Figure 92).

Appendix C: Spiked Uprod

Height

Loosen the proximal/distal sliding knob, insert the adjustable tibial stylus into the cutting block, and adjust to the correct level of resection.

When measuring from the less damaged side of the tibial plateau, set the stylus to 8 mm or 10 mm. If the stylus is placed on the more damaged side of the tibial plateau, set the stylus to 0 mm or 2 mm. Adjustment of resection height on the stylus should be done outside the joint space before locating the stylus in the cutting block.

If planning to resect through the slot, position the foot of the tibial stylus marked “slotted” into the slot of the tibial cutting block (Figure 93). If planning to resect on top of the cutting block, place the foot marked “non-slotted” into the cutting slot. Drop the block and stylus assembly so that the stylus touches the desired point on the tibia. Care should be taken with severe valgus deformity, not to over resect the tibia.

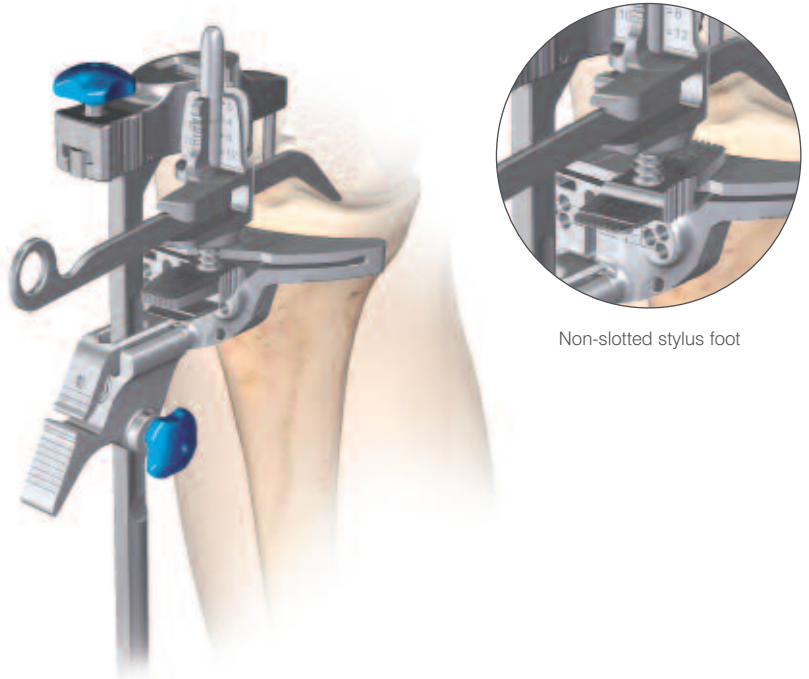


Figure 93

Tibial Resection

After the height has been set, lock the proximal/distal sliding knob and pin the block through the 0 mm set of holes (the stylus may need to be removed for access). ± 2 mm pinholes are available on the resection blocks to further adjust the resection level where needed.

The block can be securely fixed with one extra convergent pin.

Spiked Uprod Removal

Loosen the A/P locking knob. Press the cutting block release button and translate the spiked uprod anterior to disengage from the cutting block.

Connect the slap hammer to the top of the spiked uprod and disengage the spikes from the proximal tibia. Remove the tibial jig and perform the appropriate resection (Figure 94).

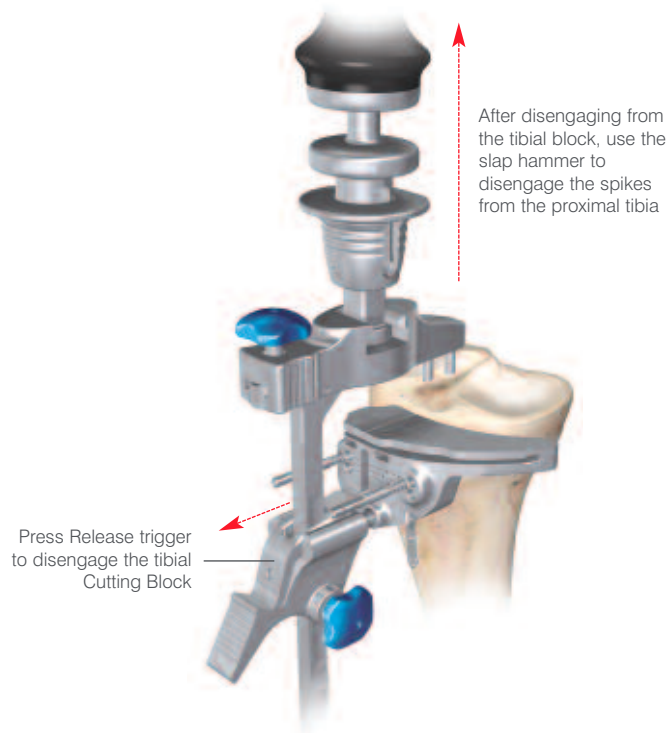


Figure 94

Ordering Information

Product Code Description

Tibia Resection

950501228	HP EM Tibial Jig Uprod
950501229	HP EM Tibial Jig Ankle Clamp
950501202	HP IM Tibia Rotation Guide
950501203	HP IM Tibia Jig
950501204	Sigma HP 0 degrees Symmetrical Cut Block
950501222	Sigma HP 0 degrees Left Cut Block
950501223	Sigma HP 0 degrees Right Cut Block
950501205	Sigma HP 3 degrees Symmetrical Cut Block
950501224	Sigma HP 3 degrees Left Cut Block
950501225	Sigma HP 3 degrees Right Cut Block
950501209	Sigma HP Adj Tibial Stylus

Femoral Resection

992011	IM Rod Handle
966121	IM Rod 300 mm
950502079	HP Step IM Reamer
950501234	Sigma HP Distal Femoral Align Guide
950501235	Sigma HP Distal Femoral Resect Guide
950501238	Sigma HP Distal Femoral Connector
950501236	Sigma HP Distal Femoral Block
950501307	HP Alignment Tower
950501207	HP Alignment Rod
966530	Reference Guide

Balanced Femoral Sizing

950501263	HP Fixed Reference Femoral Sizer
950501268	HP Fixed Reference Anterior Rot Guide 0 Degrees
950501269	HP Fixed Reference Anterior Rot Guide 3 Degrees
950501270	HP Fixed Reference Anterior Rot Guide 5 Degrees
950501271	HP Fixed Reference Anterior Rot Guide 7 Degrees

Femoral Resection

950502126	Sigma HP Balanced A/P Block Size 1.5
950502127	Sigma HP Balanced A/P Block Size 2
950502128	Sigma HP Balanced A/P Block Size 2.5
950502129	Sigma HP Balanced A/P Block Size 3
950502130	Sigma HP Balanced A/P Block Size 4
950502131	Sigma HP Balanced A/P Block Size 5
950502132	Sigma HP Balanced A/P Block Size 6
950502141	Sigma HP Balanced A/P Block Stylus

Femoral Resection

950502142	Sigma HP Balanced IM Rod 5 Degrees
950502143	Sigma HP Balanced IM Rod 3 Degrees
950502144	Sigma HP Balanced RP Femoral Positioner
950502145	Sigma HP Balanced FB Femoral Positioner
950502146	Sigma HP Balanced Femoral Positioner Shim 10 mm
950502147	Sigma HP Balanced Femoral Positioner Shim 12.5 mm
950502148	Sigma HP Balanced Femoral Positioner Shim 15 mm
950502149	Sigma HP Balanced Femoral Positioner Shim 17.5 mm
966147	Removable Handles (Pack Of 2)
950501279	Sigma HP Femoral Finish Block Size 1.5
950501280	Sigma HP Femoral Finish Block Size 2
950501281	Sigma HP Femoral Finish Block Size 2.5
950501282	Sigma HP Femoral Finish Block Size 3
950501283	Sigma HP Femoral Finish Block Size 4
950501284	Sigma HP Femoral Finish Block Size 5
950501285	Sigma HP Femoral Finish Block Size 6
950502133	RP-F HP Balanced A/P Block Size 1
950502134	RP-F HP Balanced A/P Block Size 1.5
950502135	RP-F HP Balanced A/P Block Size 2
950502136	RP-F HP Balanced A/P Block Size 2.5
950502137	RP-F HP Balanced A/P Block Size 3
950502138	RP-F HP Balanced A/P Block Size 4
950502139	RP-F HP Balanced A/P Block Size 5
950502140	RP-F HP Balanced A/P Block Size 6
950501286	Sigma RP-F HP Femoral Finish Block Size 1
950501287	Sigma RP-F HP Femoral Finish Block Size 1.5
950501288	Sigma RP-F HP Femoral Finish Block Size 2
950501289	Sigma RP-F HP Femoral Finish Block Size 2.5
950501290	Sigma RP-F HP Femoral Finish Block Size 3
950501291	Sigma RP-F HP Femoral Finish Block Size 4
950501292	Sigma RP-F HP Femoral Finish Block Size 5
950501293	Sigma RP-F HP Femoral Finish Block Size 6
966278	PFC Chamfer Guides Size 1.5
966272	PFC Chamfer Guides Size 2
966279	PFC Chamfer Guides Size 2.5
966273	PFC Chamfer Guides Size 3
966274	PFC Chamfer Guides Size 4
966275	PFC Chamfer Guides Size 5
966277	PFC Chamfer Guides Size 6

Ordering Information

Fixed Bearing Preparation

950502040	Sigma HP FBT Tray Trial Size 1.5
950502041	Sigma HP FBT Tray Trial Size 2
950502042	Sigma HP FBT Tray Trial Size 2.5
950502043	Sigma HP FBT Tray Trial Size 3
950502044	Sigma HP FBT Tray Trial Size 4
950502045	Sigma HP FBT Tray Trial Size 5
950502046	Sigma HP FBT Tray Trial Size 6
950502053	Sigma HP FBT Evaluation Bullet Size 1.5-3
950502054	Sigma HP FBT Evaluation Bullet Size 4-6
950502055	Sigma HP FBT Keel Punch Impact
950502060	Sigma HP FBT Drill Tower
217830123	M.B.T. Tray Fixation Pins
950502028	HP Tibial Tray Handle
950502068	FBT Modular Drill Stop

Standard Tray Preparation

950502061	HP FBT Standard Tibial Punch Guide Size 1.5-4
950502062	HP FBT Standard Tibial Punch Guide Size 5-6
950502063	HP FBT Standard Tibial Punch Size 1.5-2
950502064	HP FBT Standard Tibial Punch Size 2.5-4
950502065	HP FBT Standard Tibial Punch Size 5-6
950502066	HP FBT Standard Cemented Tibial Punch Size 1.5-2
950502067	HP FBT Standard Cemented Tibial Punch Size 2.5-6

Modular Tray Preparation

950502047	HP FBT Cemented Keel Punch Size 1.5-3
950502048	HP FBT Cemented Keel Punch Size 4-5
950502049	HP FBT Cemented Keel Punch Size 6
950502056	Sigma HP FBT Cemented Drill Size 1.5-3
950502057	Sigma HP FBT Cemented Drill Size 4-6
950502050	HP FBT Non Cemented Keeled Punch Size 1.5-3
950502051	HP FBT Non Cemented Keeled Punch Size 4-5
950502058	HP FBT Non Cemented Drill Size 1.5-3
950502059	HP FBT Non Cemented Drill Size 4-6
950502052	HP FBT Non Cemented Keeled Punch Size 6

Fixed Bearing Preparation

950502000	HP M.B.T. Tray Trial Size 1
950502001	HP M.B.T. Tray Trial Size 1.5
950502002	HP M.B.T. Tray Trial Size 2
950502003	HP M.B.T. Tray Trial Size 2.5
950502004	HP M.B.T. Tray Trial Size 3
950502006	HP M.B.T. Tray Trial Size 4
950502007	HP M.B.T. Tray Trial Size 5
950502008	HP M.B.T. Tray Trial Size 6
950502009	HP M.B.T. Tray Trial Size 7
950502022	HP M.B.T. Spiked Evaluation Bullet Size 1-3
950502023	HP M.B.T. Spiked Evaluation Bullet Size 4-7
950502099	HP M.B.T. Evaluation Bullet Size 1-3
950502098	HP M.B.T. Evaluation Bullet Size 4-7
950502027	HP M.B.T. Drill Tower
950502024	HP M.B.T. Keel Punch Impact
217830123	M.B.T. Tray Fixation Pins
950502028	HP Tibial Tray Handle
950502029	M.B.T. Modular Drill Stop
950502038	M.B.T. Central Stem Punch
217830137	M.B.T. RP Trial Button

M.B.T. Keeled Preparation

950502025	HP M.B.T. Cemented Central Drill
950502010	HP M.B.T. Cemented Keel Punch Size 1-1.5
950502011	HP M.B.T. Cemented Keel Punch Size 2-3
950502012	HP M.B.T. Cemented Keel Punch Size 4-7
950502026	HP M.B.T. Non Cemented Central Drill
950502013	HP M.B.T. Non Cemented Keeled Punch Size 1-1.5
950502014	HP M.B.T. Non Cemented Keeled Punch Size 2-3
950502015	HP M.B.T. Non Cemented Keeled Punch Size 4-7

M.B.T. Non Keeled Preparation

950502025	HP M.B.T. Cemented Central Drill
950502016	HP M.B.T. Cemented Punch Size 1-1.5
950502017	HP M.B.T. Cemented Punch Size 2-3
950502018	HP M.B.T. Cemented Punch Size 4-7
950502026	HP M.B.T. Non Cemented Central Drill
950502019	HP M.B.T. Non Cemented Punch Size 1-1.5
950502020	HP M.B.T. Non Cemented Punch Size 2-3
950502021	HP M.B.T. Non Cemented Punch Size 4-7

Ordering Information

M.B.T. DuoFix Preparation

950502030	HP DuoFix Tibial Bullet Size 1-1.5
950502031	HP DuoFix Tibial Bullet Size 2-3.5
950502032	HP DuoFix Tibial Bullet Size 4-7
950502034	HP DuoFix Tibial Central Drill
950502005	HP M.B.T. Tray Trial Size 3.5
950502039	HP M.B.T. Tray Trial Size 4.5
900335000	DuoFix Peg Drill

Femoral Trials

961007	Sigma Femur Cruciate Retaining Femur Trial Size 1.5 Left
961002	Sigma Femur Cruciate Retaining Femur Trial Size 2 Left
961008	Sigma Femur Cruciate Retaining Femur Trial Size 2.5 Left
961003	Sigma Femur Cruciate Retaining Femur Trial Size 3 Left
961004	Sigma Femur Cruciate Retaining Femur Trial Size 4 Left
961005	Sigma Femur Cruciate Retaining Femur Trial Size 5 Left
961006	Sigma Femur Cruciate Retaining Femur Trial Size 6 Left
961017	Sigma Femur Cruciate Retaining Femur Trial Size 1.5 Right
961012	Sigma Femur Cruciate Retaining Femur Trial Size 2 Right
961018	Sigma Femur Cruciate Retaining Femur Trial Size 2.5 Right
961013	Sigma Femur Cruciate Retaining Femur Trial Size 3 Right
961014	Sigma Femur Cruciate Retaining Femur Trial Size 4 Right
961015	Sigma Femur Cruciate Retaining Femur Trial Size 5 Right
961016	Sigma Femur Cruciate Retaining Femur Trial Size 6 Right
966200	Distal Femoral Lug Drill
961047	Sigma Femur Cruciate Substituting Box Trial Size 1.5
961042	Sigma Femur Cruciate Substituting Box Trial Size 2
961048	Sigma Femur Cruciate Substituting Box Trial Size 2.5
961043	Sigma Femur Cruciate Substituting Box Trial Size 3
961044	Sigma Femur Cruciate Substituting Box Trial Size 4
961045	Sigma Femur Cruciate Substituting Box Trial Size 5
961046	Sigma Femur Cruciate Substituting Box Trial Size 6
966295	SP2 Femur Box Trial Screwdriver

RP-F Femoral Trials

954210	RP-F Trial Femur Size 1 Left
954211	RP-F Trial Femur Size 1.5 Left
954212	RP-F Trial Femur Size 2 Left
954213	RP-F Trial Femur Size 2.5 Left
954214	RP-F Trial Femur Size 3 Left
954215	RP-F Trial Femur Size 4 Left
954216	RP-F Trial Femur Size 5 Left
954217	RP-F Trial Femur Size 6 Left
954220	RP-F Trial Femur Size 1 Right

RP-F Femoral Trials

954221	RP-F Trial Femur Size 1.5 Right
954222	RP-F Trial Femur Size 2 Right
954223	RP-F Trial Femur Size 2.5 Right
954224	RP-F Trial Femur Size 3 Right
954225	RP-F Trial Femur Size 4 Right
954226	RP-F Trial Femur Size 5 Right
954227	RP-F Trial Femur Size 6 Right

Fixed Bearing Insert Trials

Posterior Lipped

961210	Sigma PLI Tibial Insert Trial Size 1.5 8 mm
961211	Sigma PLI Tibial Insert Trial Size 1.5 10 mm
961212	Sigma PLI Tibial Insert Trial Size 1.5 12.5 mm
961213	Sigma PLI Tibial Insert Trial Size 1.5 15 mm
961214	Sigma PLI Tibial Insert Trial Size 1.5 17.5 mm
961215	Sigma PLI Tibial Insert Trial Size 1.5 20 mm
961220	Sigma PLI Tibial Insert Trial Size 2 8 mm
961221	Sigma PLI Tibial Insert Trial Size 2 10 mm
961222	Sigma PLI Tibial Insert Trial Size 2 12.5 mm
961223	Sigma PLI Tibial Insert Trial Size 2 15 mm
961224	Sigma PLI Tibial Insert Trial Size 2 17.5 mm
961225	Sigma PLI Tibial Insert Trial Size 2 20 mm
961230	Sigma PLI Tibial Insert Trial Size 2.5 8 mm
961231	Sigma PLI Tibial Insert Trial Size 2.5 10 mm
961232	Sigma PLI Tibial Insert Trial Size 2.5 12.5 mm
961233	Sigma PLI Tibial Insert Trial Size 2.5 15 mm
961234	Sigma PLI Tibial Insert Trial Size 2.5 17.5 mm
961235	Sigma PLI Tibial Insert Trial Size 2.5 20 mm
961240	Sigma PLI Tibial Insert Trial Size 3 8 mm
961241	Sigma PLI Tibial Insert Trial Size 3 10 mm
961242	Sigma PLI Tibial Insert Trial Size 3 12.5 mm
961243	Sigma PLI Tibial Insert Trial Size 3 15 mm
961244	Sigma PLI Tibial Insert Trial Size 3 17.5 mm
961245	Sigma PLI Tibial Insert Trial Size 3 20 mm
961250	Sigma PLI Tibial Insert Trial Size 4 8 mm
961251	Sigma PLI Tibial Insert Trial Size 4 10 mm
961252	Sigma PLI Tibial Insert Trial Size 4 12.5 mm
961253	Sigma PLI Tibial Insert Trial Size 4 15 mm
961254	Sigma PLI Tibial Insert Trial Size 4 17.5 mm
961255	Sigma PLI Tibial Insert Trial Size 4 20 mm
961260	Sigma PLI Tibial Insert Trial Size 5 8 mm
961261	Sigma PLI Tibial Insert Trial Size 5 10 mm
961262	Sigma PLI Tibial Insert Trial Size 5 12.5 mm

Ordering Information

Posterior Lipped

961263	Sigma PLI Tibial Insert Trial Size 5 15 mm
961264	Sigma PLI Tibial Insert Trial Size 5 17.5 mm
961265	Sigma PLI Tibial Insert Trial Size 5 20 mm
961270	Sigma PLI Tibial Insert Trial Size 6 8 mm
961271	Sigma PLI Tibial Insert Trial Size 6 10 mm
961272	Sigma PLI Tibial Insert Trial Size 6 12.5 mm
961273	Sigma PLI Tibial Insert Trial Size 6 15 mm
961274	Sigma PLI Tibial Insert Trial Size 6 17.5 mm
961275	Sigma PLI Tibial Insert Trial Size 6 20 mm

Curved

961320	Sigma Curved Tibial Insert Trial Size 1.5 8 mm
961321	Sigma Curved Tibial Insert Trial Size 1.5 10 mm
961322	Sigma Curved Tibial Insert Trial Size 1.5 12.5 mm
961323	Sigma Curved Tibial Insert Trial Size 1.5 15 mm
961324	Sigma Curved Tibial Insert Trial Size 1.5 17.5 mm
961325	Sigma Curved Tibial Insert Trial Size 1.5 20 mm
961330	Sigma Curved Tibial Insert Trial Size 2 8 mm
961331	Sigma Curved Tibial Insert Trial Size 2 10 mm
961332	Sigma Curved Tibial Insert Trial Size 2 12.5 mm
961333	Sigma Curved Tibial Insert Trial Size 2 15 mm
961334	Sigma Curved Tibial Insert Trial Size 2 17.5 mm
961335	Sigma Curved Tibial Insert Trial Size 2 20 mm
961340	Sigma Curved Tibial Insert Trial Size 2.5 8 mm
961341	Sigma Curved Tibial Insert Trial Size 2.5 10 mm
961342	Sigma Curved Tibial Insert Trial Size 2.5 12.5 mm
961343	Sigma Curved Tibial Insert Trial Size 2.5 15 mm
961344	Sigma Curved Tibial Insert Trial Size 2.5 17.5 mm
961345	Sigma Curved Tibial Insert Trial Size 2.5 20 mm
961350	Sigma Curved Tibial Insert Trial Size 3 8 mm
961351	Sigma Curved Tibial Insert Trial Size 3 10 mm
961352	Sigma Curved Tibial Insert Trial Size 3 12.5 mm
961353	Sigma Curved Tibial Insert Trial Size 3 15 mm
961354	Sigma Curved Tibial Insert Trial Size 3 17.5 mm
961355	Sigma Curved Tibial Insert Trial Size 3 20 mm
961360	Sigma Curved Tibial Insert Trial Size 4 8 mm
961361	Sigma Curved Tibial Insert Trial Size 4 10 mm
961362	Sigma Curved Tibial Insert Trial Size 4 12.5 mm
961363	Sigma Curved Tibial Insert Trial Size 4 15 mm
961364	Sigma Curved Tibial Insert Trial Size 4 17.5 mm
961365	Sigma Curved Tibial Insert Trial Size 4 20 mm
961370	Sigma Curved Tibial Insert Trial Size 5 8 mm
961371	Sigma Curved Tibial Insert Trial Size 5 10 mm

Curved

961372	Sigma Curved Tibial Insert Trial Size 5 12.5 mm
961373	Sigma Curved Tibial Insert Trial Size 5 15 mm
961374	Sigma Curved Tibial Insert Trial Size 5 17.5 mm
961375	Sigma Curved Tibial Insert Trial Size 5 20 mm
961380	Sigma Curved Tibial Insert Trial Size 6 8 mm
961381	Sigma Curved Tibial Insert Trial Size 6 10 mm
961382	Sigma Curved Tibial Insert Trial Size 6 12.5 mm
961383	Sigma Curved Tibial Insert Trial Size 6 15 mm
961384	Sigma Curved Tibial Insert Trial Size 6 17.5 mm
961385	Sigma Curved Tibial Insert Trial Size 6 20 mm

Stabilized

961410	Sigma Stabilized Tibial Insert Trial Size 1.5 8 mm
961411	Sigma Stabilized Tibial Insert Trial Size 1.5 10 mm
961412	Sigma Stabilized Tibial Insert Trial Size 1.5 12.5 mm
961413	Sigma Stabilized Tibial Insert Trial Size 1.5 15 mm
961414	Sigma Stabilized Tibial Insert Trial Size 1.5 17.5 mm
961420	Sigma Stabilized Tibial Insert Trial Size 2 8 mm
961421	Sigma Stabilized Tibial Insert Trial Size 2 10 mm
961422	Sigma Stabilized Tibial Insert Trial Size 2 12.5 mm
961423	Sigma Stabilized Tibial Insert Trial Size 2 15 mm
961424	Sigma Stabilized Tibial Insert Trial Size 2 17.5 mm
961425	Sigma Stabilized Tibial Insert Trial Size 2 20 mm
961426	Sigma Stabilized Tibial Insert Trial Size 2 22.5 mm
961427	Sigma Stabilized Tibial Insert Trial Size 2 25 mm
961430	Sigma Stabilized Tibial Insert Trial Size 2.5 8 mm
961431	Sigma Stabilized Tibial Insert Trial Size 2.5 10 mm
961432	Sigma Stabilized Tibial Insert Trial Size 2.5 12.5 mm
961433	Sigma Stabilized Tibial Insert Trial Size 2.5 15 mm
961434	Sigma Stabilized Tibial Insert Trial Size 2.5 17.5 mm
961435	Sigma Stabilized Tibial Insert Trial Size 2.5 20 mm
961436	Sigma Stabilized Tibial Insert Trial Size 2.5 22.5 mm
961437	Sigma Stabilized Tibial Insert Trial Size 2.5 25 mm
961440	Sigma Stabilized Tibial Insert Trial Size 3 8 mm
961441	Sigma Stabilized Tibial Insert Trial Size 3 10 mm
961442	Sigma Stabilized Tibial Insert Trial Size 3 12.5 mm
961443	Sigma Stabilized Tibial Insert Trial Size 3 15 mm
961444	Sigma Stabilized Tibial Insert Trial Size 3 17.5 mm
961445	Sigma Stabilized Tibial Insert Trial Size 3 20 mm
961446	Sigma Stabilized Tibial Insert Trial Size 3 22.5 mm
961447	Sigma Stabilized Tibial Insert Trial Size 3 25 mm
961450	Sigma Stabilized Tibial Insert Trial Size 4 8 mm
961451	Sigma Stabilized Tibial Insert Trial Size 4 10 mm

Ordering Information

Stabilized

961452	Sigma Stabilized Tibial Insert Trial Size 4 12.5 mm
961453	Sigma Stabilized Tibial Insert Trial Size 4 15 mm
961454	Sigma Stabilized Tibial Insert Trial Size 4 17.5 mm
961455	Sigma Stabilized Tibial Insert Trial Size 4 20 mm
961456	Sigma Stabilized Tibial Insert Trial Size 4 22.5 mm
961457	Sigma Stabilized Tibial Insert Trial Size 4 25 mm
961460	Sigma Stabilized Tibial Insert Trial Size 5 8 mm
961461	Sigma Stabilized Tibial Insert Trial Size 5 10 mm
961462	Sigma Stabilized Tibial Insert Trial Size 5 12.5 mm
961463	Sigma Stabilized Tibial Insert Trial Size 5 15 mm
961464	Sigma Stabilized Tibial Insert Trial Size 5 17.5 mm
961465	Sigma Stabilized Tibial Insert Trial Size 5 20 mm
961466	Sigma Stabilized Tibial Insert Trial Size 5 22.5 mm
961467	Sigma Stabilized Tibial Insert Trial Size 5 25 mm
961470	Sigma Stabilized Tibial Insert Trial Size 6 8 mm
961471	Sigma Stabilized Tibial Insert Trial Size 6 10 mm
961472	Sigma Stabilized Tibial Insert Trial Size 6 12.5 mm
961473	Sigma Stabilized Tibial Insert Trial Size 6 15 mm
961474	Sigma Stabilized Tibial Insert Trial Size 6 17.5 mm
961475	Sigma Stabilized Tibial Insert Trial Size 6 20 mm
961476	Sigma Stabilized Tibial Insert Trial Size 6 22.5 mm
961477	Sigma Stabilized Tibial Insert Trial Size 6 25 mm

Mobile Bearing Insert Trials

RP Curved

973001	Sigma RP Curved Tibial Insert Trial Size 1.5 10 mm
973002	Sigma RP Curved Tibial Insert Trial Size 1.5 12.5 mm
973003	Sigma RP Curved Tibial Insert Trial Size 1.5 15.0 mm
973004	Sigma RP Curved Tibial Insert Trial Size 1.5 17.5 mm
963011	Sigma RP Curved Tibial Insert Trial Size 2 10 mm
963012	Sigma RP Curved Tibial Insert Trial Size 2 12.5 mm
963013	Sigma RP Curved Tibial Insert Trial Size 2 15.0 mm
963014	Sigma RP Curved Tibial Insert Trial Size 2 17.5 mm
963021	Sigma RP Curved Tibial Insert Trial Size 2.5 10 mm
963022	Sigma RP Curved Tibial Insert Trial Size 2.5 12.5 mm
963023	Sigma RP Curved Tibial Insert Trial Size 2.5 15.0 mm
963024	Sigma RP Curved Tibial Insert Trial Size 2.5 17.5 mm
963031	Sigma RP Curved Tibial Insert Trial Size 3 10 mm
963032	Sigma RP Curved Tibial Insert Trial Size 3 12.5 mm
963033	Sigma RP Curved Tibial Insert Trial Size 3 15.0 mm
963034	Sigma RP Curved Tibial Insert Trial Size 3 17.5 mm
963041	Sigma RP Curved Tibial Insert Trial Size 4 10 mm

RP Curved

963042	Sigma RP Curved Tibial Insert Trial Size 4 12.5 mm
963043	Sigma RP Curved Tibial Insert Trial Size 4 15.0 mm
963044	Sigma RP Curved Tibial Insert Trial Size 4 17.5 mm
963051	Sigma RP Curved Tibial Insert Trial Size 5 10 mm
963052	Sigma RP Curved Tibial Insert Trial Size 5 12.5 mm
963053	Sigma RP Curved Tibial Insert Trial Size 5 15.0 mm
963054	Sigma RP Curved Tibial Insert Trial Size 5 17.5 mm
963061	Sigma RP Curved Tibial Insert Trial Size 6 10 mm
963062	Sigma RP Curved Tibial Insert Trial Size 6 12.5 mm
963063	Sigma RP Curved Tibial Insert Trial Size 6 15.0 mm
963064	Sigma RP Curved Tibial Insert Trial Size 6 17.5 mm

RP Stabilized

973101	Sigma RP Stabilized Tibial Insert Trial Size 1.5 10.0 mm
973102	Sigma RP Stabilized Tibial Insert Trial Size 1.5 12.5 mm
973103	Sigma RP Stabilized Tibial Insert Trial Size 1.5 15.0 mm
973104	Sigma RP Stabilized Tibial Insert Trial Size 1.5 17.5 mm
963105	Sigma RP Stabilized Tibial Insert Trial Size 1.5 20.0 mm
963111	Sigma RP Stabilized Tibial Insert Trial Size 2 10.0 mm
963112	Sigma RP Stabilized Tibial Insert Trial Size 2 12.5 mm
963113	Sigma RP Stabilized Tibial Insert Trial Size 2 15.0 mm
963114	Sigma RP Stabilized Tibial Insert Trial Size 2 17.5 mm
963115	Sigma RP Stabilized Tibial Insert Trial Size 2 20.0 mm
963116	Sigma RP Stabilized Tibial Insert Trial Size 2 22.5 mm
963117	Sigma RP Stabilized Tibial Insert Trial Size 2 25 mm
963121	Sigma RP Stabilized Tibial Insert Trial Size 2.5 10.0 mm
963122	Sigma RP Stabilized Tibial Insert Trial Size 2.5 12.5 mm
963123	Sigma RP Stabilized Tibial Insert Trial Size 2.5 15.0 mm
963124	Sigma RP Stabilized Tibial Insert Trial Size 2.5 17.5 mm
963125	Sigma RP Stabilized Tibial Insert Trial Size 2.5 20.0 mm
963126	Sigma RP Stabilized Tibial Insert Trial Size 2.5 22.5 mm
963127	Sigma RP Stabilized Tibial Insert Trial Size 2.5 25 mm
963131	Sigma RP Stabilized Tibial Insert Trial Size 3 10.0 mm
963132	Sigma RP Stabilized Tibial Insert Trial Size 3 12.5 mm
963133	Sigma RP Stabilized Tibial Insert Trial Size 3 15.0 mm
963134	Sigma RP Stabilized Tibial Insert Trial Size 3 17.5 mm
963135	Sigma RP Stabilized Tibial Insert Trial Size 3 20.0 mm
963136	Sigma RP Stabilized Tibial Insert Trial Size 3 22.5 mm
963137	Sigma RP Stabilized Tibial Insert Trial Size 3 25 mm
963141	Sigma RP Stabilized Tibial Insert Trial Size 4 10.0 mm
963142	Sigma RP Stabilized Tibial Insert Trial Size 4 12.5 mm
963143	Sigma RP Stabilized Tibial Insert Trial Size 4 15.0 mm

Ordering Information

RP Stabilized

963144	Sigma RP Stabilized Tibial Insert Trial Size 4 17.5 mm
963145	Sigma RP Stabilized Tibial Insert Trial Size 4 20.0 mm
963146	Sigma RP Stabilized Tibial Insert Trial Size 4 22.5. mm
963147	Sigma RP Stabilized Tibial Insert Trial Size 4 25 mm
963151	Sigma RP Stabilized Tibial Insert Trial Size 5 10.0 mm
963152	Sigma RP Stabilized Tibial Insert Trial Size 5 12.5 mm
963153	Sigma RP Stabilized Tibial Insert Trial Size 5 15.0 mm
963154	Sigma RP Stabilized Tibial Insert Trial Size 5 17.5 mm
963155	Sigma RP Stabilized Tibial Insert Trial Size 5 20.0 mm
963156	Sigma RP Stabilized Tibial Insert Trial Size 5 22.5. mm
963157	Sigma RP Stabilized Tibial Insert Trial Size 5 25 mm
963161	Sigma RP Stabilized Tibial Insert Trial Size 6 10.0 mm
963162	Sigma RP Stabilized Tibial Insert Trial Size 6 12.5 mm
963163	Sigma RP Stabilized Tibial Insert Trial Size 6 15.0 mm
963164	Sigma RP Stabilized Tibial Insert Trial Size 6 17.5 mm
963165	Sigma RP Stabilized Tibial Insert Trial Size 6 20.0 mm
963166	Sigma RP Stabilized Tibial Insert Trial Size 6 22.5. mm
963167	Sigma RP Stabilized Tibial Insert Trial Size 6 25 mm

RP-F

954110	RP-F Tibial Insert Trial 10 mm Size 1
954111	RP-F Tibial Insert Trial 12.5 mm Size 1
954112	RP-F Tibial Insert Trial 15 mm Size 1
954113	RP-F Tibial Insert Trial 17.5 mm Size 1
954114	RP-F Tibial Insert Trial 10 mm Size 1.5
954115	RP-F Tibial Insert Trial 12.5 mm Size 1.5
954116	RP-F Tibial Insert Trial 15 mm Size 1.5
954117	RP-F Tibial Insert Trial 17.5 mm Size 1.5
954120	RP-F Tibial Insert Trial 10 mm Size 2
954121	RP-F Tibial Insert Trial 12.5 mm Size 2
954122	RP-F Tibial Insert Trial 15 mm Size 2
954123	RP-F Tibial Insert Trial 17.5 mm Size 2
954125	RP-F Tibial Insert Trial 10 mm Size 2.5
954126	RP-F Tibial Insert Trial 12.5 mm Size 2.5
954127	RP-F Tibial Insert Trial 15 mm Size 2.5
954128	RP-F Tibial Insert Trial 17.5 mm Size 2.5
954130	RP-F Tibial Insert Trial 10 mm Size 3
954131	RP-F Tibial Insert Trial 12.5 mm Size 3
954132	RP-F Tibial Insert Trial 15 mm Size 3
954133	RP-F Tibial Insert Trial 17.5 mm Size 3
954140	RP-F Tibial Insert Trial 10 mm Size 4
954141	RP-F Tibial Insert Trial 12.5 mm Size 4

RP-F

954142	RP-F Tibial Insert Trial 15 mm Size 4
954143	RP-F Tibial Insert Trial 17.5 mm Size 4
954150	RP-F Tibial Insert Trial 10 mm Size 5
954151	RP-F Tibial Insert Trial 12.5 mm Size 5
954152	RP-F Tibial Insert Trial 15 mm Size 5
954153	RP-F Tibial Insert Trial 17.5 mm Size 5
954160	RP-F Tibial Insert Trial 10 mm Size 6
654161	RP-F Tibial Insert Trial 12.5 mm Size 6
954162	RP-F Tibial Insert Trial 15 mm Size 6
954163	RP-F Tibial Insert Trial 17 mm Size 6

Patella Resection

950501121	Sigma HP Patella Resection Guide
950501242	Sigma HP Patella Resection Stylus 32-38 mm
950501243	Sigma HP Patella Resection Stylus 41 mm
950501247	Sigma HP Patella Resection Stylus 12mm Remnant
950501923	HP Patella Wafer Small
950501623	HP Patella Wafer Large
869188	Patella Calliper
865035	Patella Clamp
868800	Oval Patellar Drill-Single End
961100	PFC*Sigma Oval/Dome Patella Trial 3 Peg 32 mm
961101	PFC*Sigma Oval/Dome Patella Trial 3 Peg 35 mm
961102	PFC*Sigma Oval/Dome Patella Trial 3 Peg 38 mm
961103	PFC*Sigma Oval/Dome Patella Trial 3 Peg 41 mm
966601	Patellar Drill Guide 38 mm & 41 mm
966602	Patellar Drill Guide 32 mm & 35 mm

Spacer blocks

Fixed Bearing

950502105	Sigma HP FBT Spacer Block 8 mm
950502106	Sigma HP FBT Spacer Block 10 mm
950502107	Sigma HP FBT Spacer Block 12.5 mm
950502108	Sigma HP FBT Spacer Block 15 mm
950502109	Sigma HP FBT Spacer Block 17.5 mm
950502110	Sigma HP FBT Spacer Block 20 mm
950502111	Sigma HP FBT Spacer Block 22.5 mm
950502112	Sigma HP FBT Spacer Block 25 mm
950502113	Sigma HP FBT Spacer Block 30 mm
950502193	Flexion/Extension Cap Size 6

Ordering Information

Mobile Bearing

950502114	HP M.B.T. Spacer Block 10 mm
950502115	HP M.B.T. Spacer Block 12.5 mm
950502116	HP M.B.T. Spacer Block 15 mm
950502117	HP M.B.T. Spacer Block 17.5 mm
950502118	HP M.B.T. Spacer Block 20 mm
950502119	HP M.B.T. Spacer Block 22.5 mm
950502120	HP M.B.T. Spacer Block 25 mm
950502121	HP M.B.T. Spacer Block 30 mm
950502193	Flexion/Extension Cap Size 6

RP-F

950502122	Sigma HP Hifx Size 1 SP Block 10 mm
950502123	Sigma HP Hifx Size 1 SP Block 12.5 mm
950502124	Sigma HP Hifx Size 1 SP Block 15 mm
950502125	Sigma HP Hifx Size 1 SP Block 17.5 mm
950502104	Sigma RP-F HP Flex Shim Size 1
950502100	Sigma RP-F HP Flex Shim Size 1 .5
950502101	Sigma RP-F HP Flex Shim Size 2
950502102	Sigma RP-F HP Flex Shim Size 2.5-5
950502103	Sigma RP-F HP Flex Shim Size 6
950502193	Flexion/Extension Cap Size 6

Pinning

950502070	HP Pin Impactor/Extractor
950502071	HP Power Pin Driver
950502072	HP Quick Pin Drills
950502073	HP Quick Pin Drills Headed
950502088	HP Threaded Pins
950502089	HP Threaded Pins Headed
226712000	Smooth 3 Inch Pins (5 Pack)

Insertion

Femur

950501218	Sigma HP Femoral Notch Impactor
950501171	HP Femoral Imp/Ext
950501308	HP Slap Hammer
950501305	HP Universal Handle

Mobile Bearing Tibia

950501558	M.B.T. Tibial Impactor
965383	M.B.T. Tray Impactor

Fixed Bearing Tibia

950501306	Sigma FB Tibial Impactor
2581-11-000	FBT Tray Insert
966385	FBT Poly PS

Instrument Trays

General

950502800	HP Base Femur & Tibia
950502802	Sigma HP Spacer Blocks
950502808	Sigma HP Patella & Insertion Instruments
950502840	Sigma HP Insertion Instruments

Femoral Sizing & Resection

950502801	Sigma HP Fixed Reference Femur Preparation
950502803	Sigma HP RP-F Fixed Reference Femur Preparation
950502810	Sigma HP Classic Reference Femur Preparation
950502809	Sigma HP RP-F Classic Reference Femur Preparation
950502811	Sigma HP Balanced Femur Preparation
950502816	Sigma HP RP-F Balanced Femur Preparation
950502820	Sigma HP Femoral Finishing Blocks

Fixed Bearing Preparation & Trials

950502812	Sigma HP FB Tibial Preparation
950502837	Sigma HP Standard Tibial Guides & Punches
950502835	Sigma HP FB PLI Insert Trials
950502813	Sigma HP Curved Insert Trials
950502814	Sigma HP Stabilized Insert Trials

Mobile Bearing Preparation & Trials

950502806	Sigma HP M.B.T. Tibia Preparation
950502836	Sigma HP DuoFix
950502807	Sigma HP RP Insert Trial

Femoral Trials

950502804	Sigma HP Femoral Trials
950502815	Sigma HP RP-F Trials

Miscellaneous

950502817	HP CAS
950502841	Sigma HP Quick Kit FB Case

Total and Unicompartmental Knee Prostheses

Important

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

Indications

Total Knee Arthroplasty (TKA) and Unicompartmental Knee Replacement are intended to provide increased patient mobility and reduce pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. The Sigma C/R Porocoat Femoral Components are intended for cemented or cementless use as the femoral component of a Total Knee Replacement System. TKA is indicated for: a severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or a failed previous implant. Unicompartmental knee replacement is indicated in these conditions if only one side of the joint (medial or lateral) is affected.

Contra-indications

TKA and Unicompartmental knee replacement are contraindicated in cases of: active local or systemic infection; loss of musculature, osteoporosis, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable. Unicompartmental knee replacement is contraindicated in patients with over 30 degrees of fixed varus or valgus deformity.

Warnings and Precautions

Components labeled for "Cemented Use Only" are to be implanted only with bone cement. The following conditions tend to adversely affect knee replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, disabilities of other joints.

Adverse Events

The following are the most frequent adverse events after knee arthroplasty: change in position of the components, loosening, tibial subsidence, bending, cracking, fracture, deformation or wear of one or more of the components, infection, tissue reaction to implant materials or wear debris; pain, dislocation, subluxation, flexion contracture, decreased range of motion, lengthening or shortening of leg caused by improper positioning, looseness or wear of components; fractures of the femur or tibia.



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