# pfc Sigma RP

Rotating Platform Knee System Surgical Technique with M.B.T. Tray An Addendum to Cat. No. SP2-007



#### **Designed in Conjunction with:**

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The surgeon design team and DePuy Orthopaedics, Inc. wishes to thank the following International Surgeon Evaluation Team for their valuable contributions to the development of the P.F.C. Sigma RP System.

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The P.F.C. Sigma surgical procedure is followed to the point of proximal tibial resection.

#### INTRODUCTION

Total knee replacement is performed on a wide range of patients with various pathologies and anatomical anomalies. Since no single arthroplastic approach is appropriate for every knee, the surgeon must be prepared, as the situation indicates, to preserve, sacrifice or substitute for the posterior cruciate ligament. Regardless of the approach used, it is essential that the balance in flexion and extension be confirmed.

The P.F.C. Sigma Knee System incorporates both mobile-bearing and fixed-bearing options into one integrated system. (The P.F.C. Sigma Rotating Platform (RP) tibial products articulate with existing P.F.C. Sigma femoral and patellar components.) The Specialist® 2 Instruments, which are a single integrated set of instruments, are designed to make fully accurate bone resection and to accommodate most surgical techniques and contingencies.

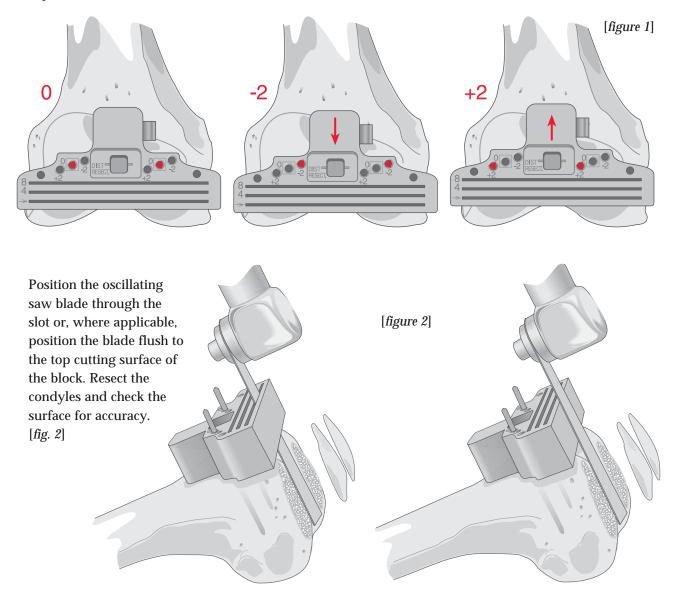
Soft tissue releases should be performed during the initial exposure to facilitate implantation of the P.F.C. Sigma RP devices. In order to deliver the tibia forward relative to the femur, the medial capsular structures must be released from anterior to posterior, at least to the mid sagittal plane. **Special attention should also be taken to ensure flexion and extension gaps are equal and all soft tissues are subsequently balanced.** 

Please note that the posterior stabilized version of the P.F.C. Sigma RP prosthesis requires a proximal tibial resection with a 0 degree posterior slope. For the curved version, the proximal tibial resection should match the patients normal anatomy (0-5 degrees). As part of the Specialist 2 System, several approaches to surgery are available. Either prepare the femur first then proceed to the tibia, or prepare the tibia first and proceed to the femur. Regardless, it is important for the ligaments to be balanced correctly. This can be assessed by using spacer blocks, laminar spreaders or the trial components themselves. This technique will begin with the distal femoral cut first, followed by the proximal tibia cut to balance the extension gap.

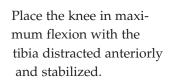
### DISTAL FEMORAL CUT

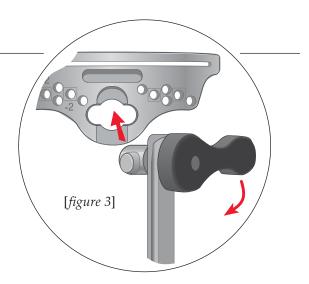
Note: Distal femoral resection or proximal tibial resection can be done in any order.

Resect the distal femur using the chosen resection level. The distal thickness of the Sigma femoral implant is 9 mm (10 mm on size 6). The holes on the block are designated -2, 0 and +2, indicating in millimeters the amount of bone resection each will yield supplemental to that indicated on the calibrated outrigger. [*fig.* 1]



# TIBIAL ALIGNMENT





Assemble the upper cutting platform [*fig.* 3] and secure it onto the proximal uprod of the tibial alignment device. Choose a 0 degree cutting block. [*fig.* 4]



Position the malleolar clamp of the tibial alignment device immediately proximal to the malleoli. Raise the platform to the level of the condyles. [*fig.* 5]

[figure 5]

## TIBIAL ALIGNMENT

Translate the lower assembly anteroposteriorly to align it parallel to the tibial axis. [*fig. 6*]

The posterior slope must be perpendicular to the tibial axis for the stabilized RP insert (0 degree posterior slope).

When using a curved insert, the posterior slope should match the patients normal anatomy (0-5 degrees).

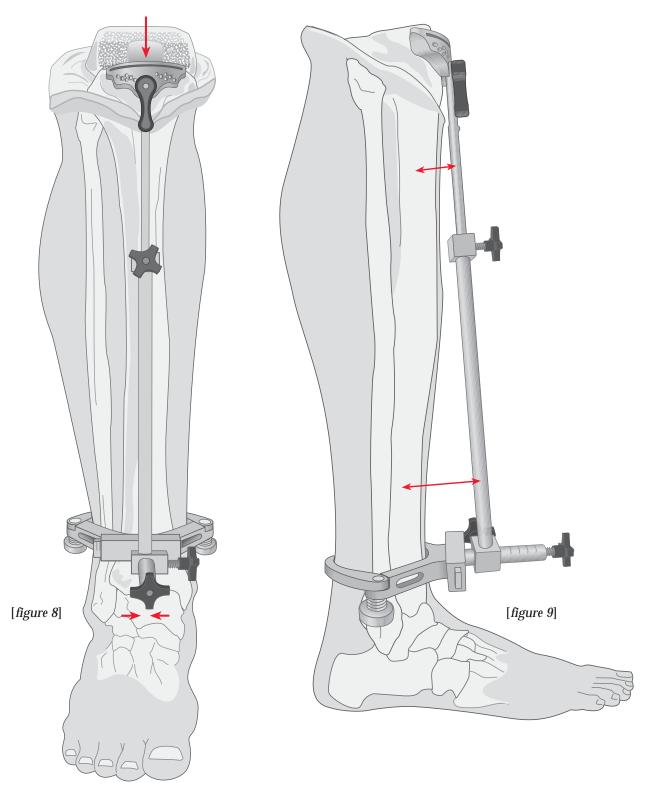
[figure 6]

[figure 7]

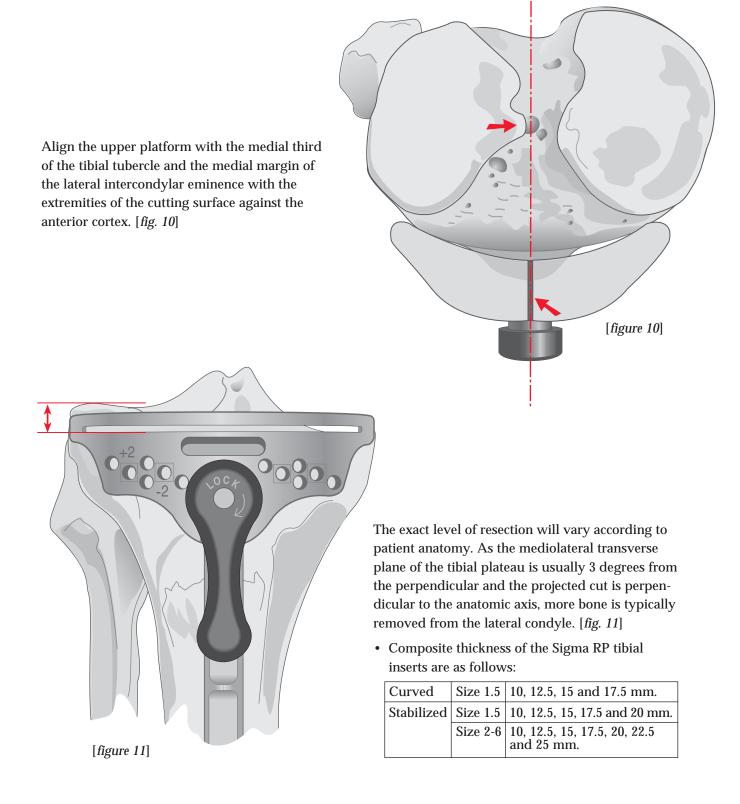
Mediolateral alignment is approximately parallel to the tibial axis, but as the lateral malleolus is more prominent, bisecting the transmalleolar axis will prejudice the cut into varus. The midline of the tibia is approximately 3-5 mm medial to the transaxial midline. Translate the lower assembly medially to the palpable anterior crest of the tibia, usually somewhere between the first and second vertical mark. There are scribe marks at 3 and 6 mm for reference. If the platform is medially displaced, make an adjustment at the lower assembly. [*fig. 7*] The distal portion of the long arm of the tibial alignment device should align with the center of the talus. [*fig. 8*]

Lateral alignment is similarly confirmed. [fig. 9]

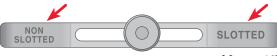
Note: Where indicated, make varus/valgus corrections by sliding the distal portion of the tibial alignment to the appropriate location.



## UPPER PLATFORM



The stylus determines the exact level of resection.



<sup>[</sup>figure 12]

The outrigger of the stylus is marked nonslotted and slotted at either end. [*fig. 12*] When the tibial resection is performed from the surface of the block, choose the *nonslotted* end of the outrigger; conversely, when the resection is performed through the slots, choose the *slotted* end of the outrigger. There is a 4 mm difference between the top surface and the slot.

Insert the cylinder foot into the slot of the cutting block [*fig.* 13] and adjust to the appropriate level. It is calibrated in 2 mm increments, indicating the amount of bone and residual cartilage to be resected. [*fig.* 14]

A level of 10 mm is suggested when resection is based on the less involved condyle. Adjust the block so that the stylus rests on the center of the condyle and the cutting block is secured by the large anterior set screw. figure 14

Select level 0 when resection is based on the more involved condyle and does not result in excessive contralateral resection. [*fig. 15*] Secure the cutting block by the large anterior set screw.

Note: When this indicates greater than 10 mm of resection from the contralateral condyle, a higher level is indicated. Augment the deficiency with cement or bone graft as the situation dictates.

[figure 15]

O DEG

## SECURING THE PLATFORM AND TIBIAL RESECTION

Introduce Steinmann pins or 1/8 in. drill bits through the central holes into the tibia, stopping well short of the posterior cortex. [*fig.* 16] The tibial alignment device can either be removed by unlocking the cutting block or left in place for additional stability.

Cut an entry slot with a narrow oscillating saw into the intercondylar eminence anterior to the attachment of the PCL. Position an osteotome to shield the ligament. [*fig.* 17]

[figure 17]

Resection is made either through the slot or on the top surface, depending upon the stylus reference used. A 1.19 mm saw blade is recommended when cutting through the slots.

[figure 16]

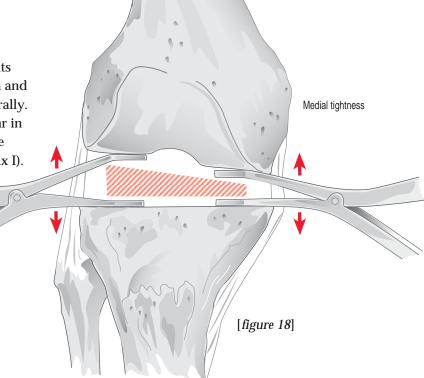
# EVALUATION OF EXTENSION GAP



With the distal femoral and proximal tibial cuts accomplished, place the knee in full extension and apply the lamina spreaders medially and laterally. [*fig. 18*] The extension gap must be rectangular in configuration. The bilateral soft tissue must be balanced where it is trapezoidal (see Appendix I). Bone cuts are not altered. [*fig. 19*]

Balanced

[figure 19]

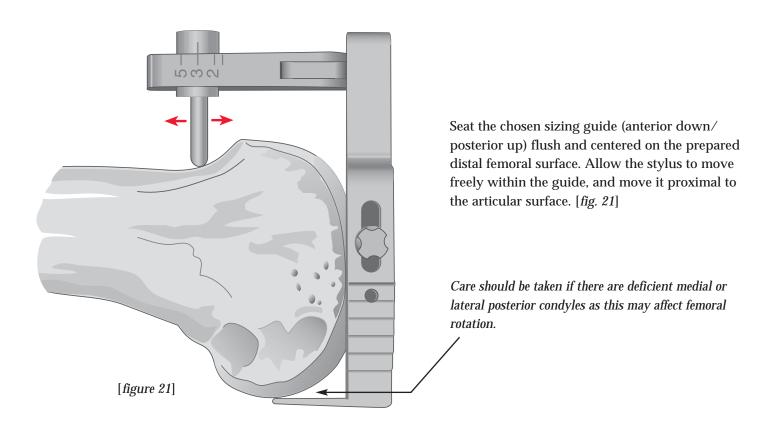


A set of RP spacer blocks are available to measure the gap and indicate the appropriate thickness of the tibial insert and the distal femoral implant, subject to reevaluation at trial reduction. [*fig. 20*]

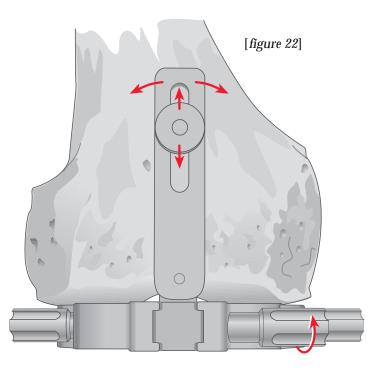
When using blocks to assess flexion and extension

gaps, use a 1 mm shim for the extension gap. Remove the spacer when assessing the flexion gap. This will compensate for the 1 mm difference between the distal and posterior resection levels.





Pass the stylus over the anterior cortex immediately proximal to the articular surface. At the appropriate level where the stylus is not impeded, turn the stylus locking knob clockwise until it is tight to fix its position. [*fig. 22*]



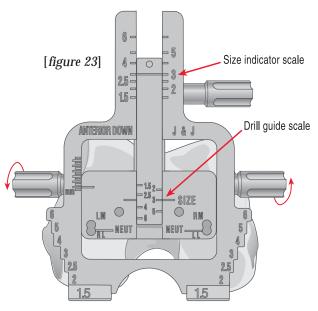
# Two Femoral Sizing Guides are Available:

- ANTERIOR REFERENCE (ANTERIOR DOWN)
- POSTERIOR REFERENCE (POSTERIOR UP)

The two sizing guides assure a consistent posterior cut or a consistent anterior cut and the ability to accommodate femurs, which fall between whole sizes.

## ANTERIOR DOWN

Use the sizing guide to position the femoral A/P chamfer cutting block so the anterior flange of the prosthesis will fit flush with the anterior cortex of the femur. When the sizing device indicates a whole size, 8 mm will be resected from the posterior condyles, corresponding to the posterior condyle thickness of the prosthesis. The serrated edges of the drill guide show the M/L dimension of the femoral component. [*fig. 23*]

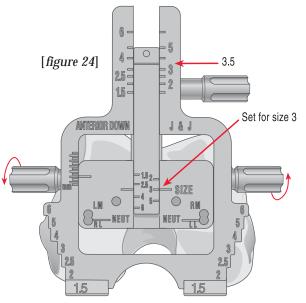


The Anterior Reference Femoral Sizing Guide

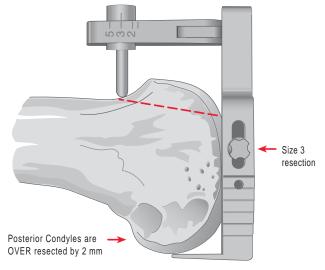
Decide whether to up or downsize based on where the femur measures between sizes (e.g. 3.5).

#### **OPTION 1 – DOWNSIZE**

If choosing to **downsize** when the upper scale reads 3.5, set the sizing guide (lower scale) to size 3 and use a size 3 A/P cutting block. [*fig. 24*] Because the guide uses the anterior cortex as the reference, the anterior cut level remains constant and more bone will be resected from the posterior condyles.



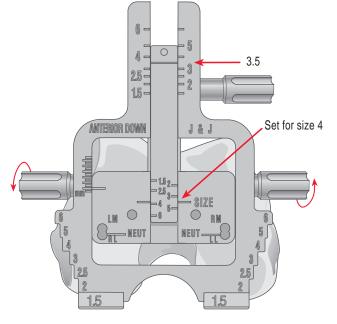
The extra posterior resection increases the size of the flexion gap. If, at trial reduction, there is marked laxity in flexion, remove more distal femur and use a thicker tibial insert. [*fig. 25*]



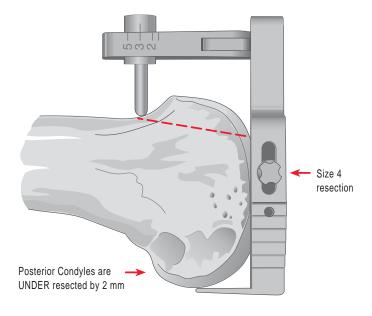
#### **OPTION 2 – UPSIZE**

When electing to **upsize** the femur, set the sizing guide (lower scale) to size 4 and use a size 4 A/P cutting block. [*fig. 26*] The anterior cut remains constant and less bone is removed from the posterior condyles.

The under resection of the posterior condyles will decrease the size of the flexion gap. [*fig. 27*] Decreasing the tibial insert thickness may cause instability in extension. To maintain balance, it is generally better to downsize and accept an over resection posteriorly.



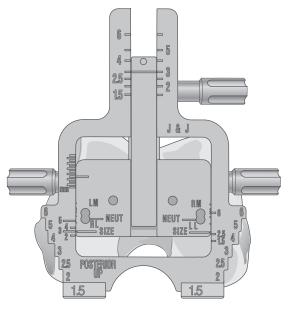
[figure 26]



[figure 27]

## POSTERIOR UP

The posterior up sizing guide measures the femur in the same way as the anterior down guide. [*fig. 28*] The sizing guide will position the femoral A/P chamfer cutting block so 8 mm will be resected from the posterior condyles, corresponding to the posterior condyle thickness of prosthesis.



[figure 28]

The Posterior Reference Femoral Sizing Guide

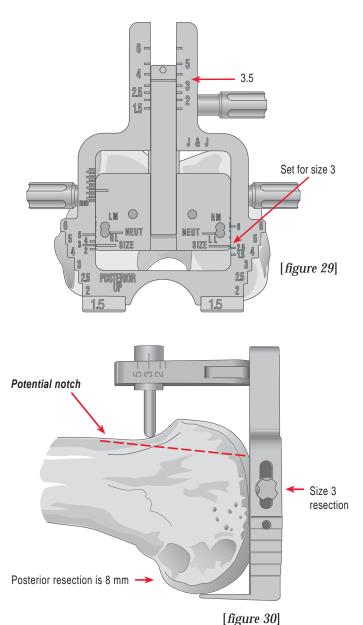
When the femur measures between sizes (e.g. 3.5), choose one of the three technique options.

#### **OPTION 1 – DOWNSIZE**

**Downsize** by setting the sizing guide (lower scale) to size 3 and using a size 3 cutting block. [*fig. 29*]

This will give an 8 mm posterior resection but will cause a larger anterior resection. [*fig. 30*]

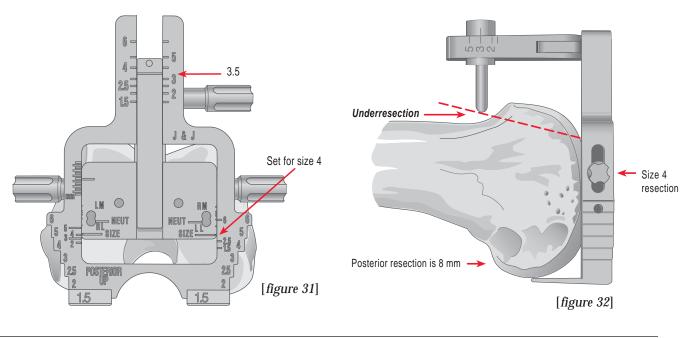
Increased anterior resection may notch the anterior cortex of the femur. Femoral shaft notching should be avoided, since there is an associated risk for fracture.



#### **OPTION 2 – UPSIZE**

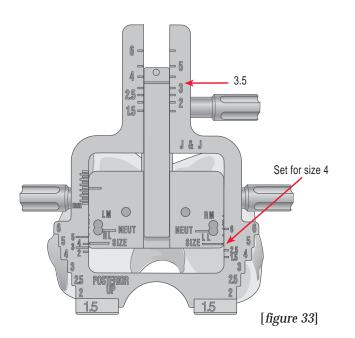
**Upsize** by setting the sizing guide (lower scale) to size 4 and using a size 4 cutting block. [*fig. 31*] This again will resect 8 mm from the posterior condyles but less anteriorly. [*fig. 32*]

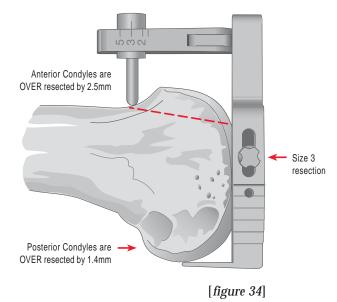
The underresection of the anterior surface can have a significant effect on the patella. It may cause tightness of the joint and high forces to be transmitted to the patella since the anterior articular surface would be too anterior.



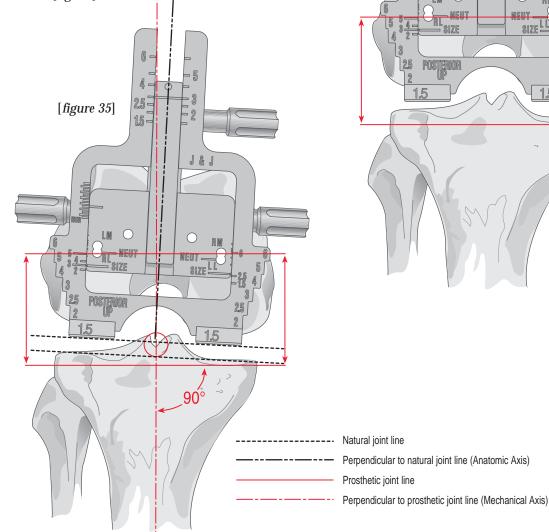
#### **OPTION 3 – "SPLIT THE DIFFERENCE"**

**Divide** the extra bone resection involved in downsizing between the anterior and posterior cuts by setting the sizing guide (lower scale) to size 4 and using the size 3 cutting block. [*fig. 33*] This increases the posterior resection by 1.4 mm and the anterior by 2.5 mm. [*fig. 34*]

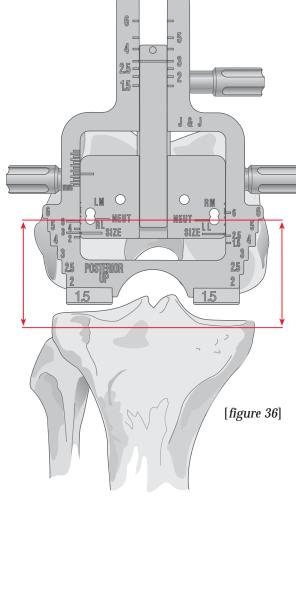




Control internal/external rotation of the A/P cuts by resting the skids of the sizing guide on the posterior condyles. The natural joint line lies medially oblique by approximately three degrees. The tibial resection at 90 degrees to the tibial mechanical axis effectively rotates to prosthetic joint line three degrees laterally (external rotation). The anterior and posterior cuts must be externally rotated in order for the flexion gap to be a parallel/rectangular space. Follow the legend on the sizing guide, which places the medial pin in the upper hole and the lateral pin in the lower hole. Offsetting the holes produces a three degree external rotation of the cutting block. [*fig. 35*]



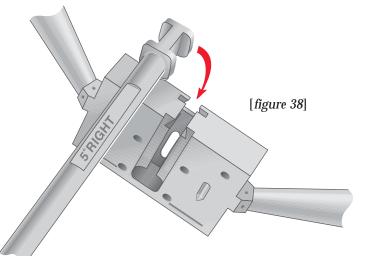
No rotation is achieved if the posterior "neutral" holes are used. [*fig. 36*]



## ALTERNATIVE METHOD: THE FEMORAL A/P SIZING AND CUTTING BLOCK

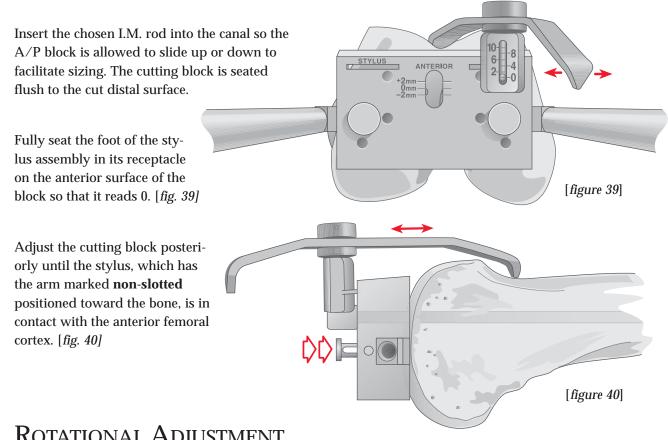
Select the appropriate rod [*fig. 37*] and assemble it to the appropriately sized femoral A/P cutting block with the appropriate RIGHT/LEFT designation toward the anterior. [*fig. 38*] Retract the pins.



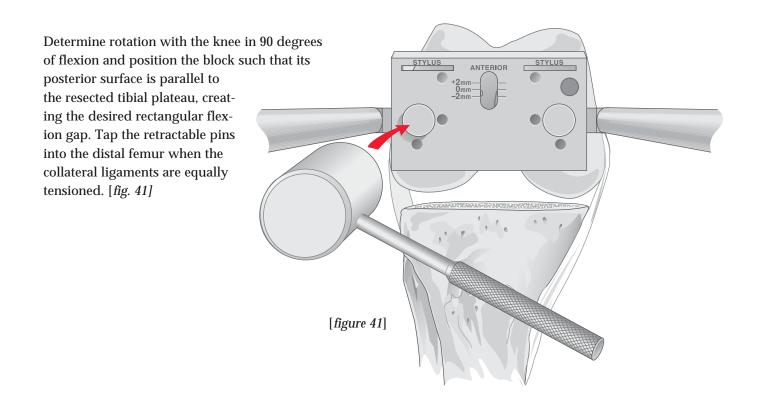


Note: Alternatively, the femoral sizing guide can be used to position and size the component (see pages 11-16). With positioning established, use the appropriately sized A/P cutting block.

# **POSITIONING THE CUTTING BLOCK**



## **ROTATIONAL ADJUSTMENT**



# EVALUATING THE FLEXION GAP

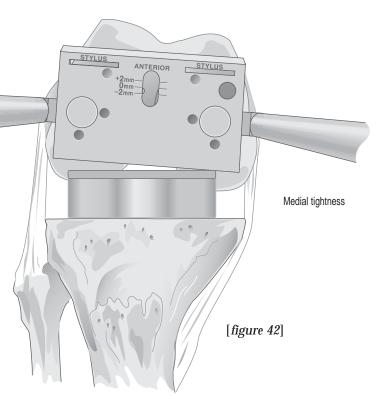
Position a properly sized spacer block between the resected proximal tibial surface and the posterior surface of the block. [*figs. 42 and 43*]

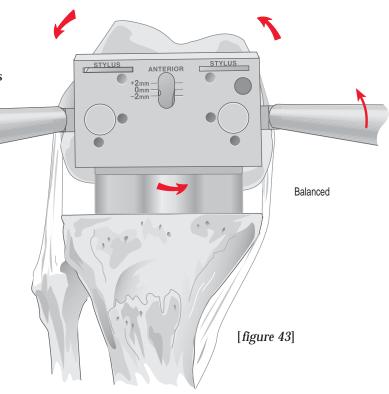
Note: Further ligamentous release is not recommended at this stage.

The goal is a rectangular flexion gap with the collateral ligaments equally tensioned.

The following guidelines are available for the determination of rotation of the A/P cutting block:

- 1. Place the A/P cutting block parallel to the trans-epicondylar axis.
- 2. Place the anterior margin of the block perpendicular to the anteroposterior axis (femoral sulcus).
- 3. Position the block parallel to the resected proximal tibia (with the knee at 90 degrees flexion and collateral ligaments equally tensioned).





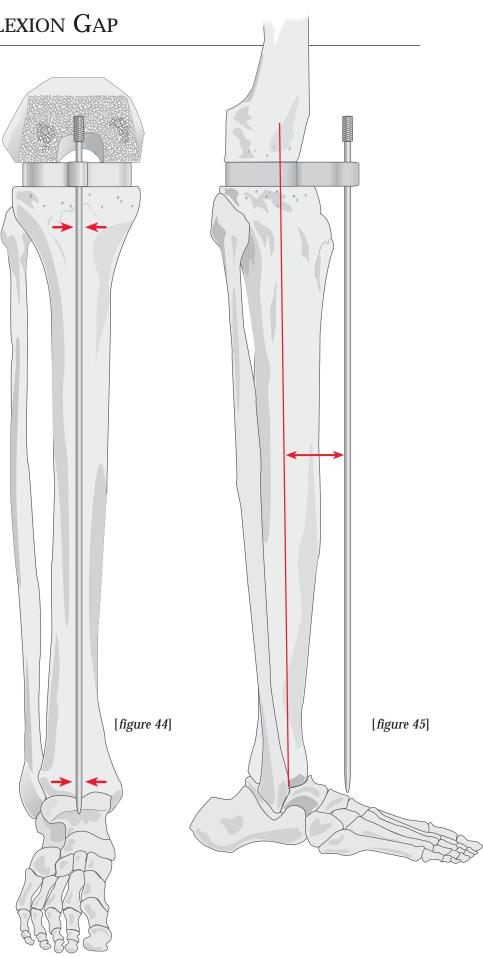
Use spacer blocks to measure the gap at 90 degrees of flexion. When using blocks to assess flexion and extension gaps, use a 1 mm shim for the extension gap. Remove it when assessing the flexion gap. This will compensate for the 1 mm difference between the distal and posterior resection levels.

Where further distal femoral resection is required to establish equivalent flexion and extension gaps, return the Steinmann pins to their original position in the anterior femoral cortex and the distal femoral cortex. Reposition the distal femoral cutting block using the holes designated +2 and +4 as indicated.

The long alignment rod should pass through the center of the talus [*fig.* 44] and lie parallel to the lateral tibial axis. [*fig.* 45]

Femoral and proximal tibial cuts are now completed. Ligament balance has been achieved.

Note: With a size 6, there is a 2 mm difference between flexion and extension on the femoral component.



Prior to final preparation of the proximal tibia, the surgeon may assess whether to implant a fixed or mobile-bearing prosthesis.

#### TRIAL REDUCTION WITH M.B.T. **EVALUATION BULLET**

Position the appropriately sized femoral trial onto the femur and place the appropriately sized M.B.T. tray trial onto the resected tibial surface using the tibial tray alignment handle.

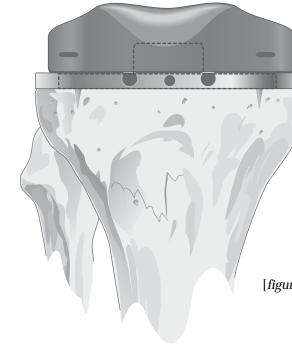
Assess the position of the M.B.T tray trial for maximum tibial coverage. The rotation of the M.B.T. tray is usually centered on the junction between the medial and central one-third of the tibial tubercle. Mark the appropriate position with electrocautery on the anterior tibial cortex.

Note: Excessive malrotation of the tibial tray, relative to the femoral component, can result in excessive poly overhang and impingement with soft tissues.

Position the M.B.T. evaluation bullet into the cutout of the M.B.T. tray trial and tap down lightly to secure the tray trial to the proximal tibia. [fig. 46]

M.B.T. evaluation bullet

[figure 46]

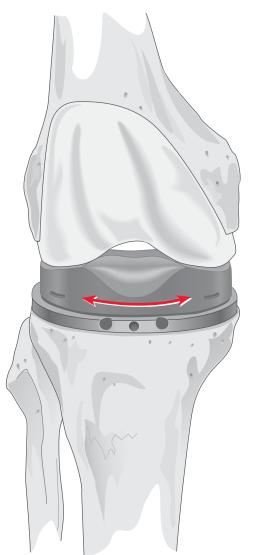


Select the appropriate style and thickness (RP curved or RP stabilized) tibial insert trial that matches the chosen femoral size and type, and place it onto the M.B.T. tray trial. [fig. 47]

[figure 47]

Remove the tibial tray alignment handle. With the trial prosthesis in place, extend and flex the knee carefully, noting the anteroposterior stability, medial/lateral stability and overall alignment in the A/P and M/L planes throughout a full range of motion. [*fig. 48*] Assess insert rotation and patellofemoral tracking. Optionally, confirm overall alignment using the two-part alignment rod, by attaching them to the tibial tray alignment handle. If there is any indication of instability, substitute a tibial insert trial with the next greater thickness and repeat reduction. Select the insert which gives the greatest stability in flexion and extension while still allowing full extension. Confirm tray rotation and position and mark with electrocautery if this has not already been done.

At this stage it is possible to prepare the proximal tibia for a P.F.C. Sigma fixed-bearing tibial tray and insert if this is the preferred option. (Please refer to the P.F.C. Sigma Knee System primary cruciate-retaining and cruciate-substituting procedure Cat. No. SP2-007).



[figure 48]

# PLATEAU PREPARATION

## BUILD-A-TRIAL TIBIAL PREPARATION

With the knee in full flexion and the tibia subluxed anteriorly, assemble the alignment handle onto the M.B.T. tray trial.

Connect the tibial tray alignment handle to the M.B.T. tray trial by retracting the lever, inserting the two pins into the anterior portion of the tray trial and releasing the lever. [*fig. 49*] Place the tray trial onto the resected tibial surface. Take care to maximize the coverage of the M.B.T. tray trial on the proximal tibia. [*fig. 50*]

Note: Excessive malrotation of the tibial tray, relative to the femoral component, can result in excessive poly overhang and impingement with soft tissue.

Secure the tray with two fixation pins inserted through the recessed holes. Mark rotational alignment of the M.B.T. tray trial with electrocautery on the anterior tibial cortex to aid in the permanent tibial tray implantation. [*fig. 51*]

Note: The rotation of the tibial tray is usually centered on the junction between the medial and central one-third of the tibial tubercle.

M.B.T. Tray Trial

[figure 51]

[figure 49]

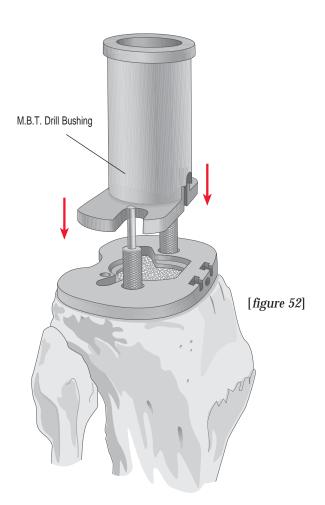
[figure 50]

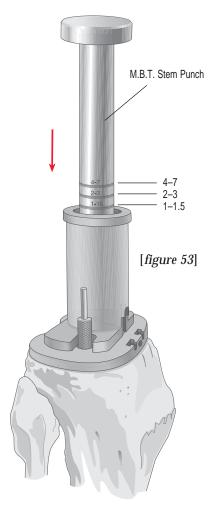
Seat the M.B.T. drill bushing into the tibial tray trial by lightly tapping the top of the drill bushing. [*fig. 52*]

In cases where the proximal tibial bone is sclerotic, use a Steinmann pin to drill two small holes posteriorly to facilitate the placement of the spikes on the drill bushing onto the tray trial.

#### FOR NON-CEMENTED APPLICATION:

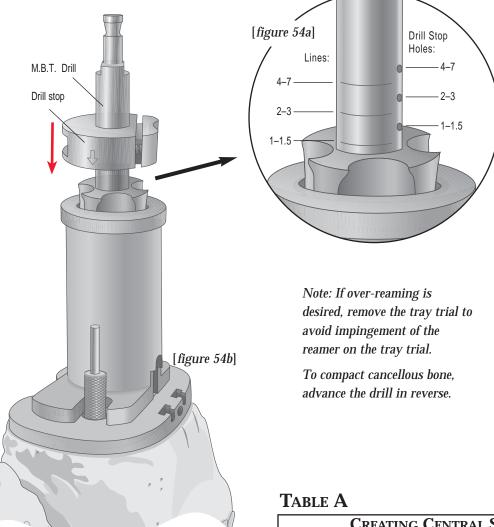
Advance the M.B.T. stem punch into the drill bushing and impact into the cancellous bone until the appropriate tray size marking is reached. [*fig. 53*]

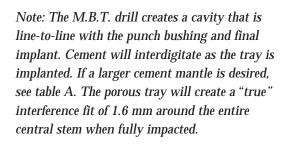




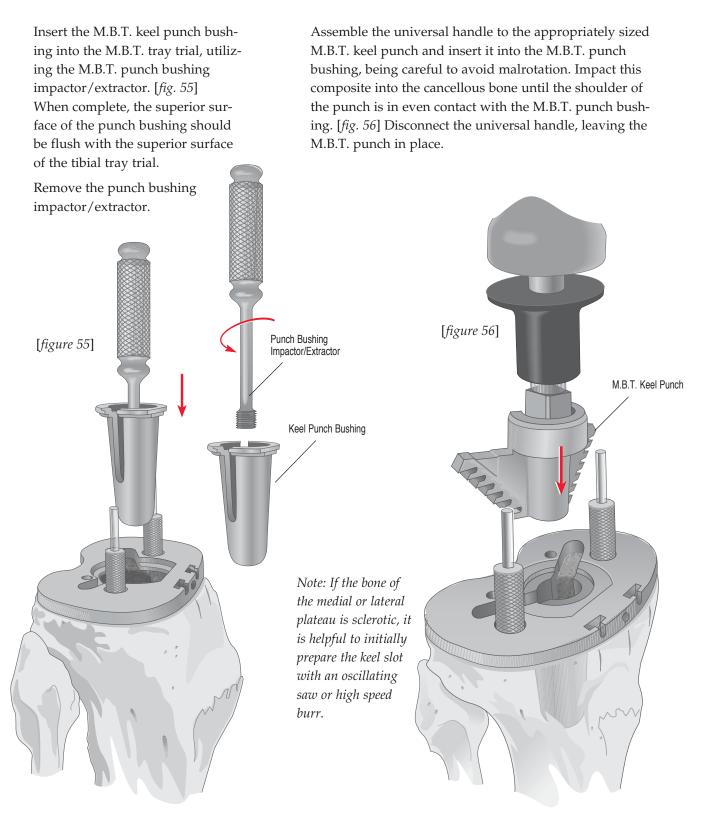
## FOR CEMENTED APPLICATION:

Assemble the drill stop onto the M.B.T. drill and position at the selected tray size. [*fig. 54a*] Advance the M.B.T. drill through the M.B.T. drill bushing and into the cancellous bone, until it hits the drill stop. [*fig. 54b*]



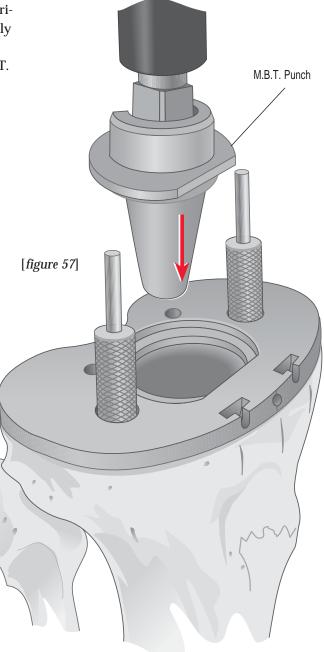


# CREATING CENTRAL STEM MANTLETray SizeDrill Stop SettingCement Mantle1-1.52-3.5 mm per side/4 mm distal2-34-7.5 mm per side/4 mm distal4-7drill "bottoms out"<br/>on tray trial.5 mm per side/4 mm distal

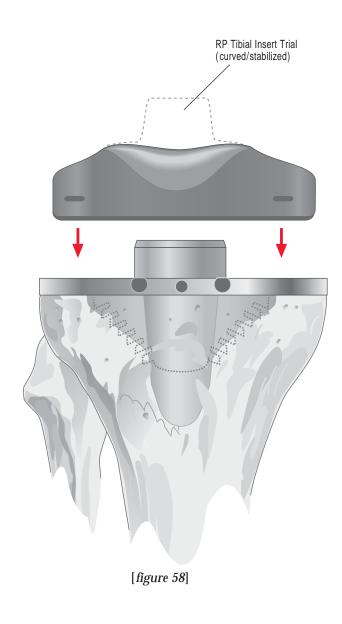


Note: The illustrated keel punch and punch bushings provide a line-to-line fit. If a cement mantle is desired, select the appropriate sized cemented keel punch and cemented keel punch bushing. These will provide a 1 mm cement mantle per side of the keel.

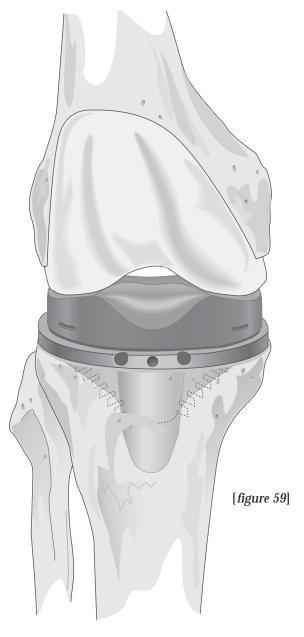
Assemble the universal handle to the appropriately sized M.B.T. punch. Impact this assembly into the cancellous bone until the shoulder of the punch is in even contact with the M.B.T. tray trial. Disconnect the universal handle, leaving the M.B.T. punch in place. [*fig. 57*]



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. [*fig. 58*]



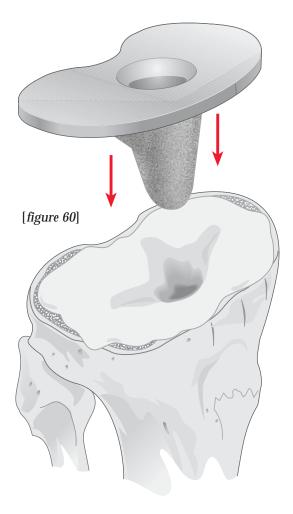
With the trial prostheses in place, fully extend the knee carefully [*fig. 59*], noting the anteroposterior stability, medial/lateral stability and overall alignment in the A/P and M/L plane. If there is any indication of instability, substitute a tibial insert trial with the next greater thickness and repeat reduction. Select the insert that gives the greatest stability in flexion and extension while still allowing full extension.

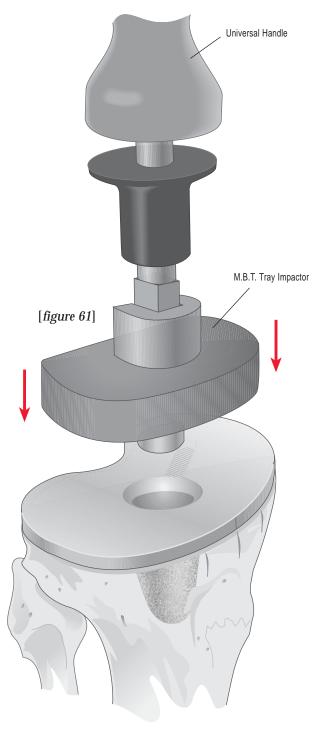


#### THE TIBIAL COMPONENT

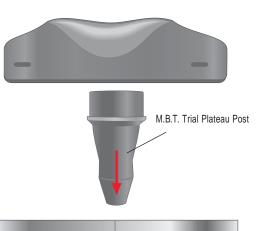
Thoroughly cleanse the entire site with pulsatile lavage. Prepare bone cement and apply it by syringe or with digital pressure in its low viscous state to assure maximal penetration into the trabecular bone. [*fig. 60*]

Assemble the universal handle onto the M.B.T. tray impactor and carefully insert the tibial tray, avoiding malrotation. When fully inserted, deliver several mallet blows to the top of the universal handle. [*fig.* 61]

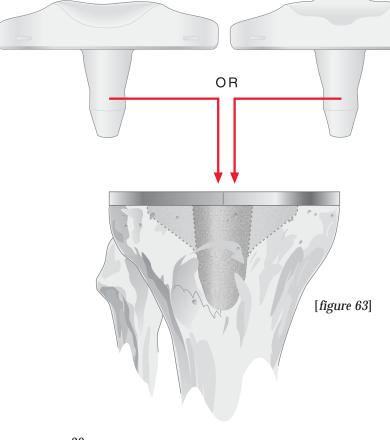




As the cement polymerizes, position a trial femoral component on the prepared femur and place a tibial insert trial on the tibial component. To avoid an abnormally high anterior moment on the tray implant while the cement polymerizes, do not use the M.B.T. trial plateau post. Take care to avoid scratching the proximal surface of the tibial tray. Place the knee in full extension and maintain equal pressure at the bone/tibial implant interface. When the cement has set, place the knee in flexion and remove the trial femoral component. Carefully remove all extruded cement with special attention to the posterior compartment and entire periphery. To perform a trial reduction with an insert trial, place the M.B.T. Trial Plateau Post into the tibial tray component and place the insert trial over this post and proceed with the trial reduction. [*fig. 62*]



[figure 62]



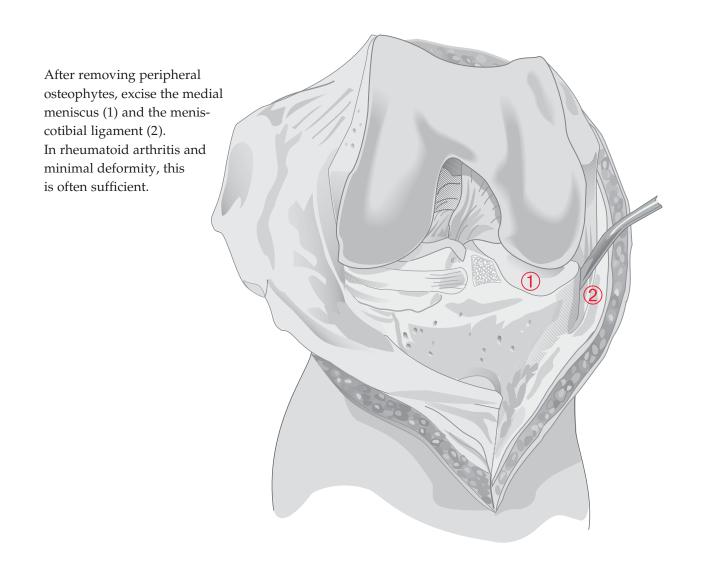
## THE TIBIAL INSERT

Carefully clear/remove any loose fragments or particulates from the permanent tibial tray. Insert the appropriate permanent tibial insert at any time during the cementing procedure. [fig. 63]

When using a curved insert only and the flexion gap is snug, implant the permanent insert prior to cementing the femoral component. Following is the suggested sequence of ligamentous releases to correct varus or valgus deformity and quadriceps-mechanism imbalance. There is no general agreement on the order; however, there is on principles:

- Perform preliminary soft tissue release at the start of surgery based upon preoperative evaluation.
- Establish balance by eliminating soft tissue contractures, not by modifying the bone cuts.
- Establish final correction at trial reduction.

# MEDIAL LIGAMENTOUS RELEASE FOR FIXED VARUS DEFORMITY



If further release is indicated, release the posterior expansion of the deep medial collateral ligament from its tibial attachment (3) using a curved osteotome.

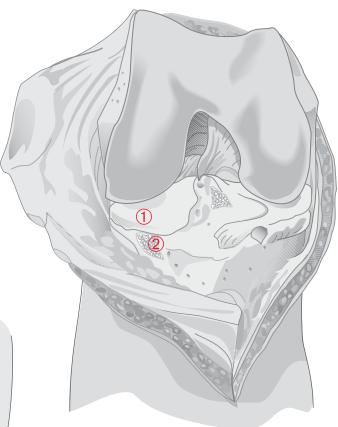
If further release is still indicated, denude the medial tibial subperiosteally (4).

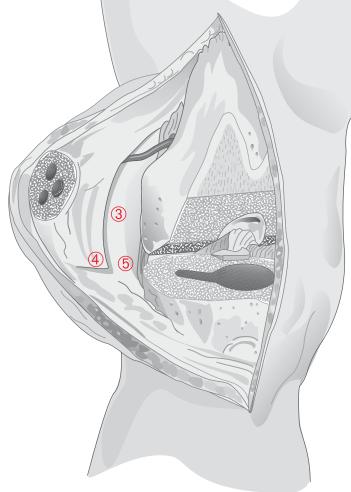
Release the superficial portion of the medial collateral ligament from its tibial attachment (5) if further release is still indicated. Generally, this is indicated only in severe deformity associated with significant flexion contracture.

5

(3)

Following removal of peripheral osteophytes, initial release comprises lateral meniscectomy (1) and release of the iliotibial band from its tibial insertion (2). A lateral quadriceps retinacular release is indicated when there is poor patellar tracking at trial reduction.





Perform lateral retinacular release on the internal surface in the longitudinal plane. Take care that the lateral superior genicular artery is protected. Isolate it at the intermuscular septum as it penetrates the retinaculum superficially. Then, retract it proximally as the retinacular incision is carried to the level of the joint line and distally as the incision is extended superiorly to the intermuscular septum (3).

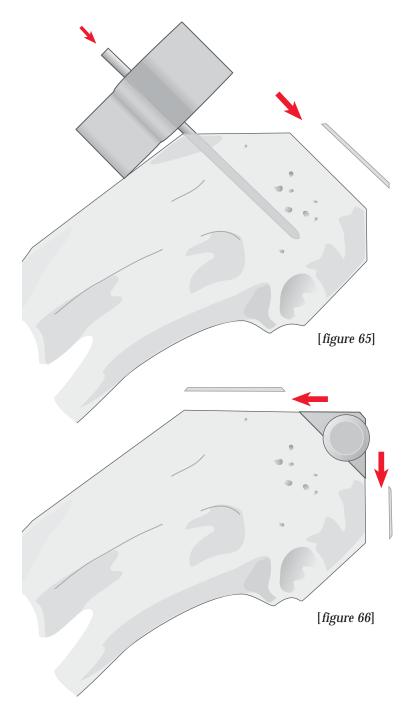
If indicated, further release is effected by extending the distal terminus of the incision transversely to the lateral margin of the patellar tendon (4) and posteriorly to the lateral collateral ligament (5). If further release is once again indicated, release the lateral collateral ligament and popliteus tendon from the femoral epicondyle, allowing them to slide posteriorly (6).

If further release is indicated, evaluate the posterior cruciate ligament and, if necessary, sacrifice it (7).

*Note: Priority of steps 6 and 7 is a matter of preference.* 

If balance requires still further release, extend the dissection posteriorly, freeing the intermuscular septum (8) and the lateral head of the gastrocnemius (9).

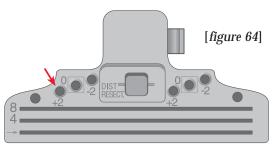
Take care that the posterolateral neurovascular structures are preserved and that the insertion of the *biceps femoris*, which overlies the common peroneal nerve, remains intact. If the joint line is maintained, flexion and extension gaps are usually balanced at trial reduction, but where there is preoperative deformity and contracture, imbalance may be present.



#### **Residual Flexion Contracture**

Where there is restriction in extension but not in flexion, remove additional bone from the distal femur. This affects the extension gap but not the flexion gap. Where contracture persists, following appropriate retinacular release and removal of posterior osteophytes and scar tissue, depending on severity, remove an additional 2-4 mm of distal femur.

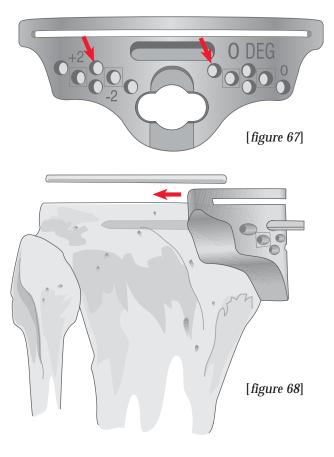
Return the Steinmann pins to their original position in the anterior femur and return the distal femoral cutting block to the pins using the holes designated +2 as the degree of contracture indicates. Revise the distal cut accordingly. [figs 64 and 65]



Chamfers are subsequently revised to maintain the correct configuration; [*fig. 66*] anterior and posterior cuts are not. This affects ligamentous tension in extension but not in flexion.

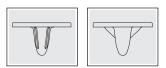
## **Residual Tightness in Flexion AND Extension**

A thinner tibial insert or additional tibial resection is indicated, as either will affect both flexion and extension gaps. If resection is selected, it is recommended that 2 mm of proximal tibia be removed. Return the Steinmann pins to their drill holes in the anterior tibial cortex, and reposition the cutting block on the pins using the holes designated +2. [*fig.* 67] Accordingly revise the cut. [*fig.* 68]



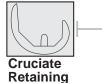
## ROTATING PLATFORM KNEE SYSTEM TIBIAL INSERT & TIBIAL TRAY COMPATIBILITY

#### ROTATING PLATFORM TIBIAL INSERTS MATCH FEMORAL COMPONENTS SIZE-TO-SIZE



MOBILE BEARING TIBIAL (M.B.T.) TRAY SIZING • AP/ML (mm)

			<b>1</b> 39/59	<b>1.5</b> 41/62	<b>2</b> 43/65	<b>2.5</b> 44/67	<b>3</b> 46/70	<b>4</b> 49/75	<b>5</b> 53/81	6 57/87	<b>7</b> 60/92
	1.5 37/58	CURVED									
P.F.C. SIGMA RP TIBIAL INSERTS SIZING • AP/ML (mm)		STABILIZED									
	<b>2</b> 39/61	Curved									
		STABILIZED									
	2.5 40/64	Curved									
		STABILIZED									
	<b>3</b> 42/66	CURVED									
		STABILIZED									
	<b>4</b> 44/69	CURVED									
		STABILIZED									
	5 47/74	CURVED									
		STABILIZED									
	6	Curved									
Р.Н.С	50/79	STABILIZED									





Sigma RP Curved Sizes 1.5-6 10,12.5,15,17.5 (mm)





Cruciate Substituting Sigma RP StabilizedSizes 1.510,12.5,15,17.5,20 (mm)Sizes 2-610,12.5,15,17.5,20,22.5,25 (mm)




#### LCS<sup>®</sup> COMPLETE<sup>™</sup> – P.F.C.<sup>®</sup> SIGMA<sup>™</sup> RP MOBILE BEARING TOTAL KNEE SYSTEM

#### 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

#### CEMENTED USE

The LCS<sup>®</sup> Complete<sup>™</sup> – P.F.C.<sup>®</sup> Sigma<sup>™</sup> RP Mobile Bearing Total Knee System is indicated for cemented use in cases of osteoarthritis and rheumatoid arthritis. The RPF insert and femoral component are indicated where a higher than normal degree of post-operative flexion is required. The rotating platform prosthesis and modular revision components are indicated for revision of failed knee prostheses.

#### UNCEMENTED USE

The porous coated Keeled and Non Keeled M.B.T.<sup>M</sup> (Mobile Bearing Tibial) Tray configurations of the LCS Total Knee System are indicated for noncemented use in skeletally mature individuals undergoing primary surgery for reconstructing knees damaged as a result of noninflammatory degenerative joint disease (NIDJD) or either of its composite diagnoses of osteoarthritis and post-traumatic arthritis pathologies. The Rotating Platform device configuration is indicated for use in knees whose anterior and posterior cruciate ligaments are absent or are in such condition as to justify their sacrifice. The P.F.C. Sigma RP Curved bearings when used with the P.F.C. Sigma Cruciate Retaining Femoral Component can be used in posterior cruciate ligament retaining procedures.

#### CONTRAINDICATIONS

The use of the LCS Complete - P.F.C. Sigma RP Mobile Bearing Total Knee System is contraindicated in:

- the presence of osteomyelitis, pyrogenic infection or other overt infection of the knee joint;
- patients with any active infection at sites such as the genitourinary tract, pulmonary system, skin or any other site. Should a patient have any infection prior to implantation, the foci of the infection must be treated prior to, during and after implantation.
- patients with loss of musculature or neuromuscular compromise leading to loss of function in the involved limb or in whom the requirements for its use would affect recommended rehabilitation procedures.
- patients with severe osteoporosis or other metabolic bone diseases of the knee.
- patients with any of the following conditions:
- · lesions of the supporting bone structures (e.g. aneurysmal or simple bone cysts, giant cell tumor or any malignant tumor),
- systemic and metabolic disorders leading to progressive deterioration of solid bone support,
- the presence of severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity, fixed deformities greater than 60° of flexion, 45° of genu varus or valgus,
- · known drug or alcohol addiction,
- skeletally immature individuals and the presence of allergic reaction to implant metals or polyethylene are also contraindications for the noncemented, porous coated, M.B.T. and LCS Complete P.F.C. Sigma RP Mobile Bearing device configurations, and for the cemented use of all device configurations of the LCS Complete P.F.C. Sigma RP Mobile Bearing Total Knee System.

#### CONTRAINDICATIONS FOR USE WITHOUT CEMENT

Noncemented use of the Porous Coated Keeled or Non-Keeled M.B.T. Tray device configurations is contraindicated in patients with sufficient loss in quantity or quality of bone stock (as determined on x-ray) such that successful noncemented fixation is unlikely. Additional contraindications may become apparent at the time of surgery. These include:

- vascular deficiency at the bone site;
- inadequate bone stock to assure both a firm press fit and close apposition of the cut bone surfaces to the prosthesis;
- the inability to make bone cuts so as to assure both correct component position and intimate apposition of bone and prosthetic surfaces;
- inadequate bone quality (e.g. severe osteoporosis) and lack of stability of the implanted components.

In the presence of any of the above conditions the components should be fixed with cement.

#### 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. The P.F.C. stem extensions can only be used with M.B.T. revision trays and LCS Complete Revision and Modular femoral components.

#### ADVERSE EVENTS

The following are the most frequent adverse events after knee arthroplasty: change in position of the components, loosening, 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.

For more information about the P.F.C. Sigma RP, visit our web site at www.mobilebearingknees.com.



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