



# GENESIS II<sup>®</sup>

Prótesis total de Rodilla

The GENESIS II Total Knee System has been designed to offer the orthopaedic surgeon solutions to address intraoperative situations. Implant function is directly related to accurate surgical technique. The GENESIS II instrumentation has been developed to be an easy-to-use system that will assist the surgeon in obtaining accurate and reproducible knee alignment. The use of patent pending locking cams and quick connects will save time and allow the surgeon to easily align cutting blocks and assemble instrumentation. The intraoperative option of anterior or posterior femoral referencing offers the surgeon the ability to select the femoral implant size that best fits the patient.

The tibial instrumentation is designed to adjust for tibia variation by offering a movable medial offset at the ankle. Left and right tibial cutting blocks avoid impingement with the patellar tendon and allow the surgeon to affix the block more intimately with the anterior proximal tibia. As determined by anatomical restrictions or surgeon preference, both intramedullary and extramedullary tibial alignment options are available. While it has been the designers' objective to develop accurate, easy-to-use instrumentation, each surgeon must evaluate the appropriateness of the following technique based on his or her medical training, experience, and patient evaluation.

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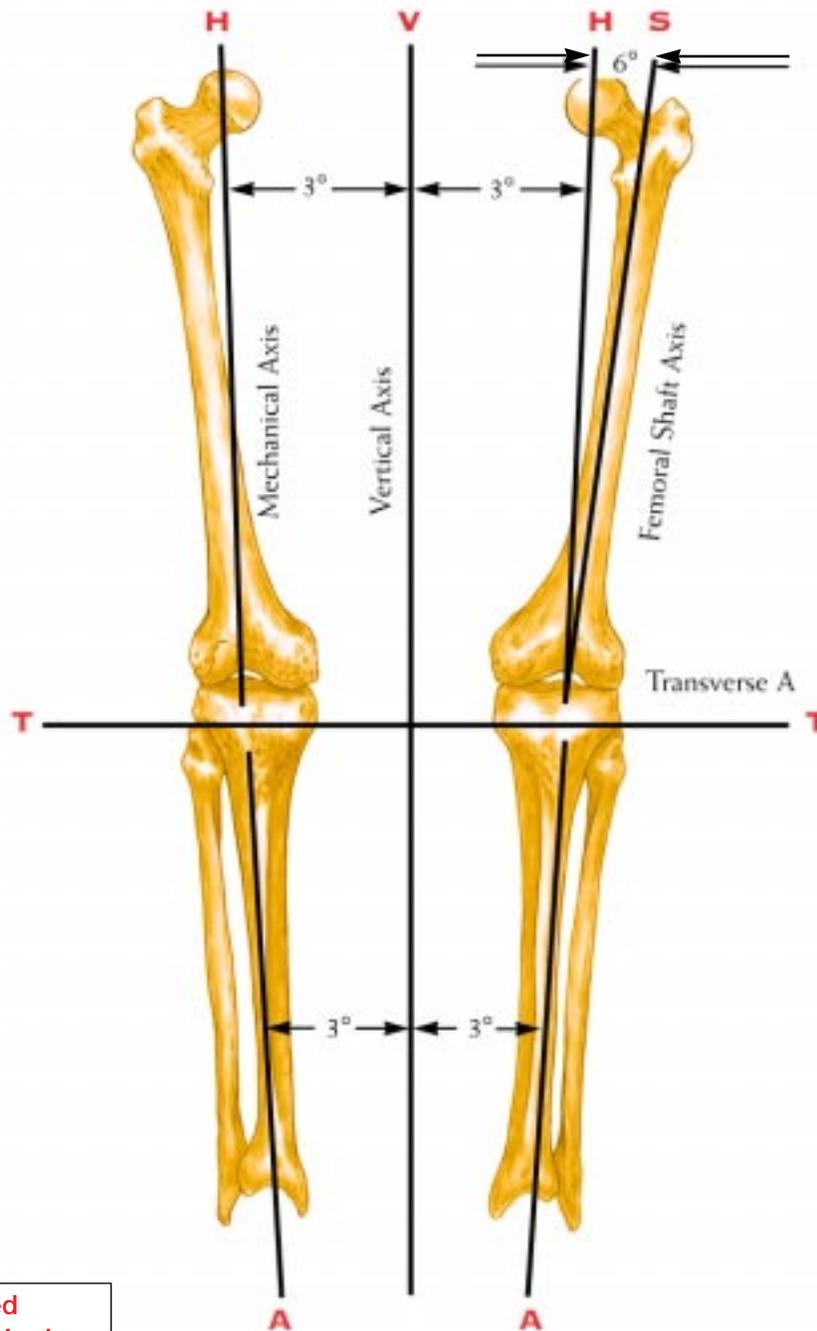
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Determine the angle between the anatomical and the mechanical axes. This measurement will be used intraoperatively to select the appropriate valgus angle so that correct limb alignment is restored.

Beware of misleading angles in knees with a flexion contracture or rotated lower extremities. The T-template provided as part of the GENESIS II templates will help in this determination.



**Recommended  
GENESIS II Sawblade:**

7144-0374 3M  
 7144-0376 Stryker  
 7144-0378 Amsco-Hall  
 7144-0375 New Stryker  
 or any .050" or 1.27 mm  
 Thickness Sawblade

# Primary Surgical Technique



**1** Use the 9.5 mm femoral drill to open the femoral canal.



**2** Slide the femoral valgus alignment assembly up the intramedullary rod until it contacts the distal femur.



**3** For anterior referencing, attach the femoral sizing stylus to the anterior referencing (gold color) femoral sizing guide. Attach the guide to the valgus alignment assembly. If indicated size is between two sizes, select the smaller size.



**4** For posterior referencing, attach the femoral sizing stylus to the posterior referencing (silver color) femoral sizing guide. Attach the guide to the valgus alignment assembly. If indicated size is between two sizes, select the larger size.



**7** Remove the valgus alignment assembly and distal femoral resection stylus from the distal femoral cutting block. Resect the distal femur.



**8** Place the femoral A-P cutting block onto the distal femur and secure with angled pins through the sides of the block. Resect the femur.



**9** For extramedullary tibial alignment, assemble the extramedullary tibial alignment guide and place the guide onto the tibia. Rotate so that it aligns over the medial third of the tibial tubercle.



**10** For intramedullary tibial alignment, place the intramedullary tibial alignment assembly onto the tibia. Rotate so that it aligns over the medial third of the tibial tubercle.



**13** Select the appropriate tibial drill guide and place it on the proximal tibia; pin in place.



**14** With the 11 mm tibial collet in place, drill with the 11 mm tibial drill and punch with the 11 mm tibial punch.



**15** Place femoral, tibial, and articular insert trials in position and perform a trial range of motion. Alignment marks on the front of the trials should match up.



**16** Determine whether a porous or nonporous tibial implant will be used. Select the appropriate tibial fin punch and punch through the tibial trial.



**19** After trialing the patella, drill for the femoral lugs through the femoral trial. Remove femoral, tibial, and patellar trials.



**20** Implant tibial component.



**21** Implant femoral component.



**22** Implant articular insert.

## Posterior-Stabilized



**5** Resect the anterior cortex.



**6** Attach the distal femoral resection stylus and cutting block to the anterior or posterior referencing femoral sizing guide. Pin the distal cutting block to the anterior cortex.



**11** Attach the primary tibial stylus to the tibial cutting block. Insert pins through the central holes to secure.



**12** Remove the tibial alignment assembly leaving the cutting block on the anterior tibia. Resect the proximal tibia.



**17** Determine the appropriate diameter patellar implant. Select correct patellar reamer collet. Attach the patellar reamer guide to the patella.



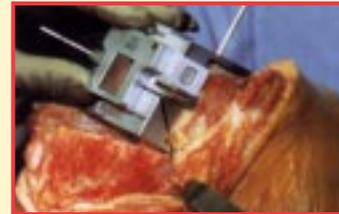
**18** Attach patellar depth stop and reamer dome to reamer shaft. Attach the patellar depth gauge to the reamer guide. Lower patellar depth stop until it contacts the depth gauge. Remove gauge. Ream the patella.



**23** Implant patellar component.



**1** Place the appropriate size housing resection block on the distal femur. Secure with 1/8" trocar pins through the angled holes in the sides of the block.



**2** Attach the posterior-stabilized housing resection collet to the housing resection block.



**3** Attach the housing reamer dome to the patellar reamer shaft. Ream through the posterior-stabilized housing resection collet. Ream until the automatic depth stop contacts the collet.



**4** Impact the housing box chisel/sizer through the posterior-stabilized housing resection collet to square off the corners of the housing.



**5** If the chamfer resections have not been made, they can now be made by cutting through the chamfer slots in the housing resection block.

## STEP 1: INTRAMEDULLARY FEMORAL ALIGNMENT

*Objective*—Align the distal femoral resection at the correct valgus angle using the femoral canal as a reference.



Figure 1

**1** Use the 9.5 mm femoral drill to open the femoral canal (Figure 1).

**2** Select the appropriate valgus angle bushing based upon preoperative measurements. Assemble the selected bushing to the femoral valgus alignment guide. Make sure the bushing is positioned so that either “left” or “right” (based on the operative knee) is facing anteriorly. When operating on the left knee, “left” should face anteriorly. When operating on the right knee, “right” should face anteriorly. Attach quick connect handles to the valgus alignment guide, if necessary.

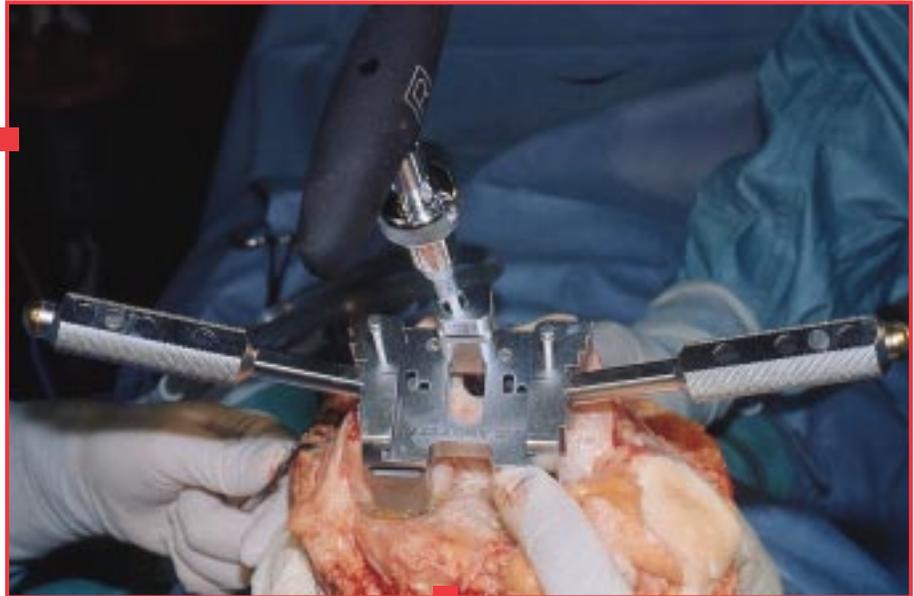


Figure 2



Figure 3

**3** Attach the modular T-handle to the intramedullary rod. Insert the intramedullary rod through the valgus angle bushing and into the medullary canal. Slide the valgus alignment assembly up the intramedullary rod until it contacts the distal femur. The posterior paddles on the valgus alignment assembly should contact the posterior condyles (Figure 2).

*Note: If the posterior condyles are deficient, the femoral rotational alignment guide can be placed over the valgus angle bushing to aid in proper rotational alignment (Figure 3). Make sure that the guide is positioned so that either “left” or “right” (based on the operative knee) is facing distally. When operating on the left knee, “left” should face distally. When operating on the right knee, “right” should face distally. The valgus alignment guide can be placed in a neutral orientation by aligning the outriggers of the femoral rotational alignment guide with the epicondyles and the trochlear reference line on the distal surface of the femoral rotational alignment guide with the trochlear groove.*

**4** Remove the modular T-handle from the intramedullary rod.

**5** Secure the valgus alignment assembly to the distal femur by impacting the floating pins.

## STEP 2: FEMORAL SIZING AND PRELIMINARY ANTERIOR RESECTION

*Objective* — Determine the correct size femoral implant and resect the anterior cortex to provide a reference for the femoral A-P cutting block.

The following describes the anterior referencing technique. The posterior referencing technique begins on page 10.

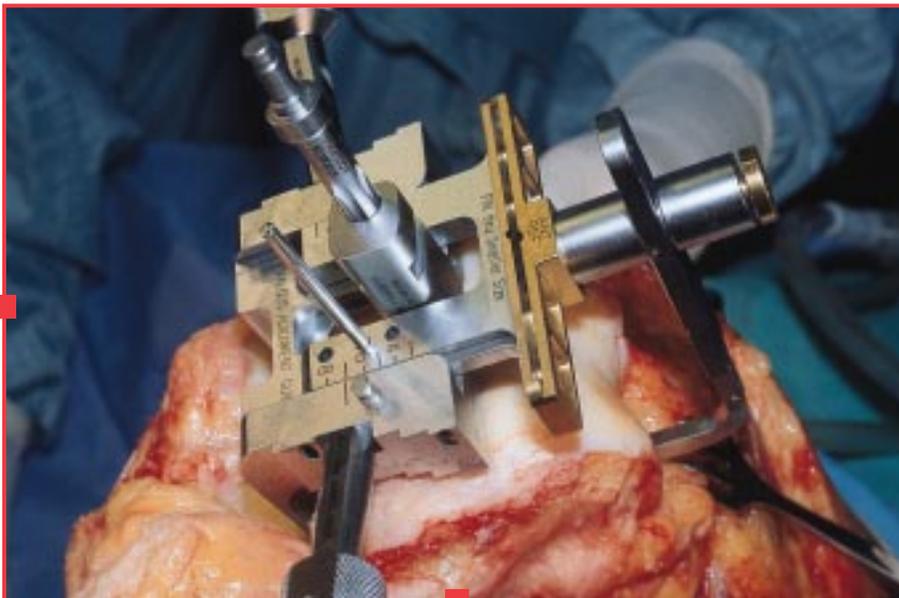


Figure 4

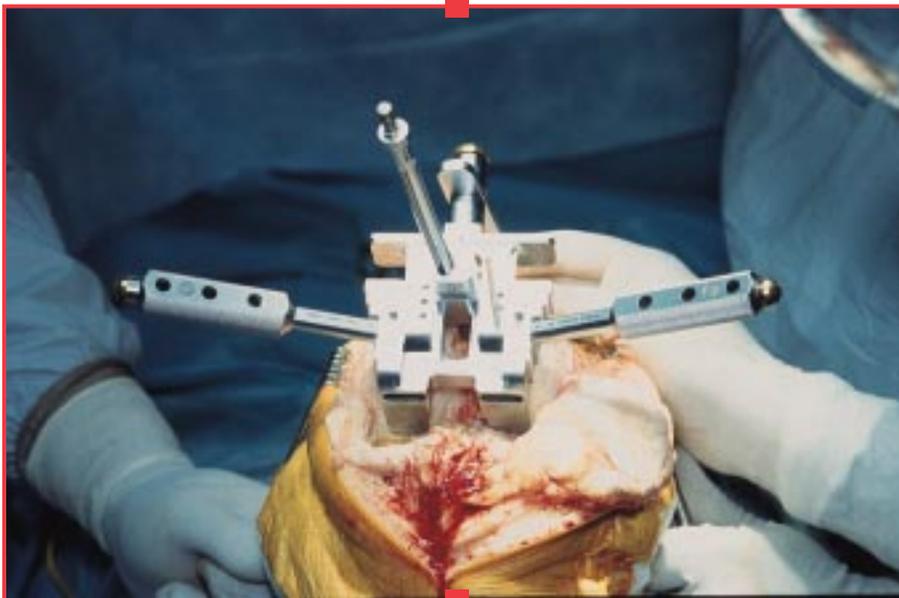


Figure 5

### OPTION A: ANTERIOR REFERENCING

Anterior Referencing Femoral Instrumentation ensures restoration of the patellofemoral joint. If the indicated size falls between two sizes, the smaller size is chosen to avoid overstuffing of the flexion space.

- 1** Attach the femoral sizing stylus to the anterior referencing femoral sizing guide (gold color).
- 2** Attach the anterior referencing femoral sizing guide to the valgus alignment assembly (Figure 4).
- 3** Lower the stylus to the lateral anterior cortex and note the indicated size. If you are between two sizes, pin the sizing guide through the hole of the smaller size without moving the sizing guide. (Figure 5).

(If the indicated size is closer to the larger size, you have the option of switching, intraoperatively, to the posterior referencing femoral technique to select the larger size. [For a complete explanation of this patented technique option, see appendix.]

## FEMORAL PREPARATION

- Secure this resection level by impacting a 1/8" trocar pin through the hole adjacent to the selected femoral size.
- Remove the anterior femoral sizing stylus from the anterior referencing femoral sizing guide by depressing the gold release button on the anterior femoral sizing stylus.
- Resect the anterior cortex (Figure 6).

### OPTION B: POSTERIOR REFERENCING

Posterior referencing instrumentation ensures that the flexion and extension spaces remain balanced. If the indicated size is between two sizes, the larger size is chosen to avoid notching the anterior cortex.

- Attach the femoral sizing stylus to the posterior referencing femoral sizing guide (silver color).
- Attach the posterior referencing femoral sizing guide to the valgus alignment assembly.
- Lower the stylus to the lateral anterior cortex and note the indicated size (Figure 7). If you are between two sizes, move the resection level anteriorly to align the selected size with the sizing hash mark. This will guard against notching the anterior cortex.

[If the indicated size is closer to the smaller size, you have the option of switching, intraoperatively, to the anterior referencing femoral technique to select the smaller size. (For a complete explanation of this patented technique option, see appendix.)]

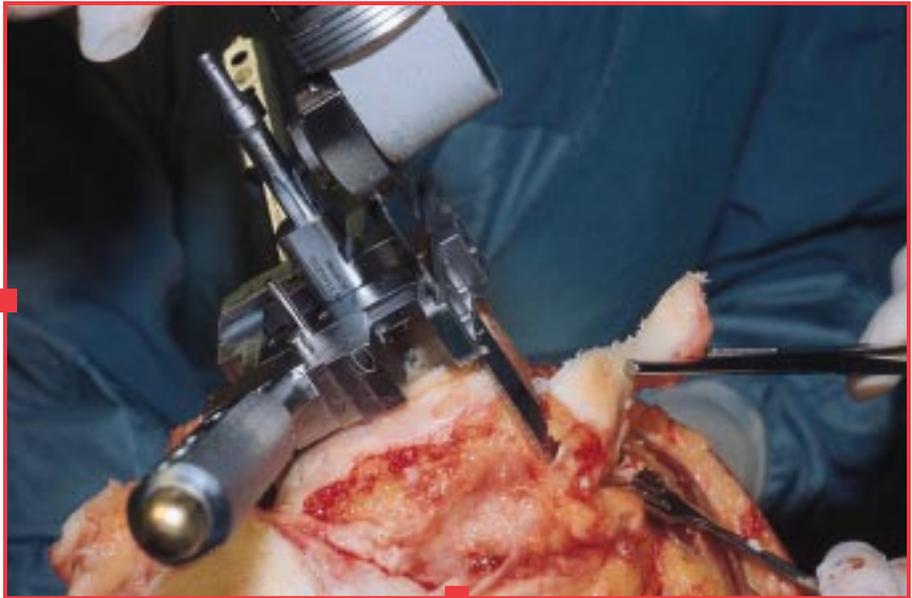


Figure 6

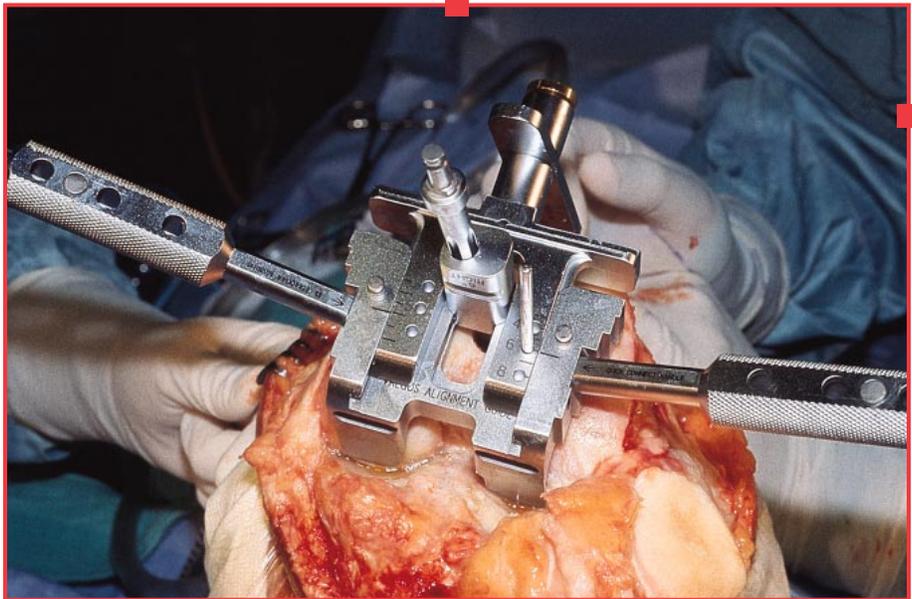


Figure 7

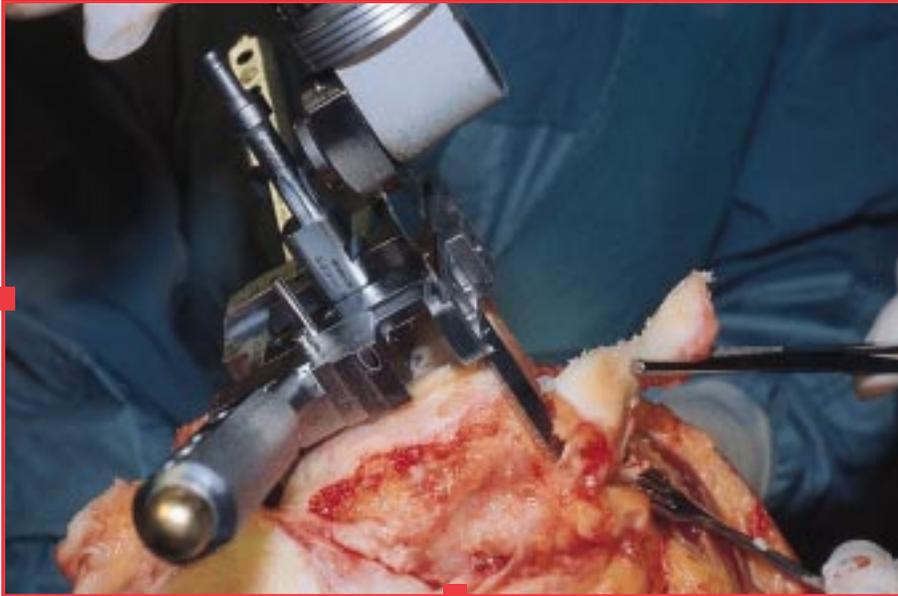


Figure 8

- 4** Secure the posterior referencing femoral sizing guide to the valgus alignment assembly by impacting a 1/8" trocar pin through the hole adjacent to the selected femoral size.
- 5** Remove the femoral sizing stylus from the posterior referencing femoral sizing guide by depressing the gold release button on the anterior femoral sizing stylus.
- 6** Resect the anterior cortex (Figure 8).

## STEP 3: DISTAL FEMORAL RESECTION

*Objective* — Resect the distal femur at the correct valgus angle.

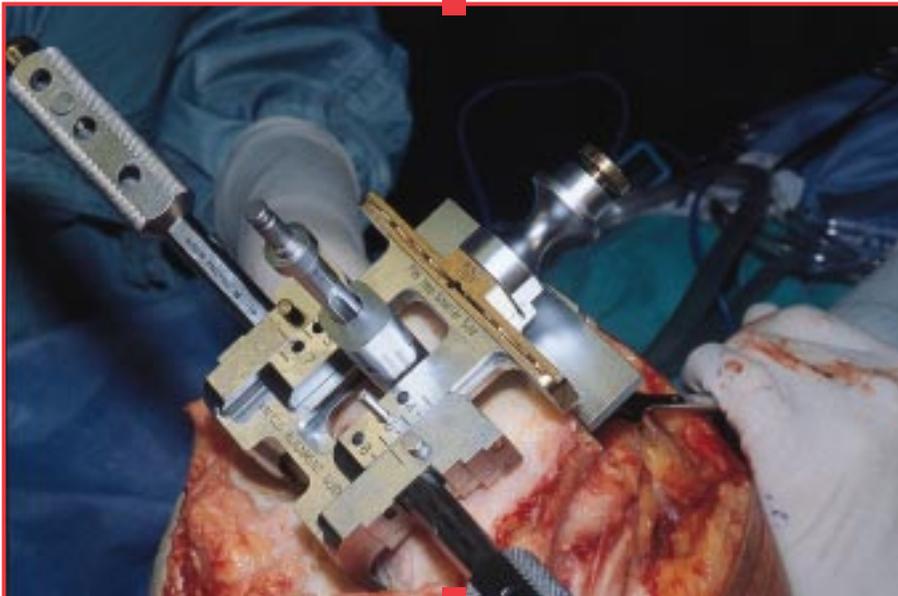


Figure 9

- 1** Attach the distal femoral resection stylus and cutting block to the anterior or posterior referencing femoral sizing guide (Figure 9). The distal femoral cutting block will slide distally until it hits a stop. The cutting block can be locked in this position by engaging the cam mechanism.

## FEMORAL PREPARATION

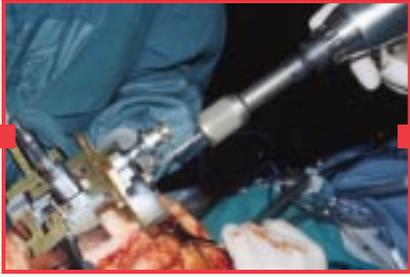


Figure 10

**2** Secure the distal femoral cutting block to the anterior cortex by impacting or drilling pins through the holes marked “primary” (Figure 10).

**3** Attach the modular T-handle to the intramedullary rod and remove the rod.

**4** Disengage the cam on the distal femoral cutting block and remove the valgus alignment assembly and distal femoral resection stylus from the distal femoral cutting block (Figure 11).

**5** Only the distal femoral cutting block should remain on the femur. Resect the distal femur (Figure 12).

*For a guided resection, attach the modular femoral slot to the distal femoral cutting block or use the slotted block.*

**6** Remove the distal femoral cutting block.

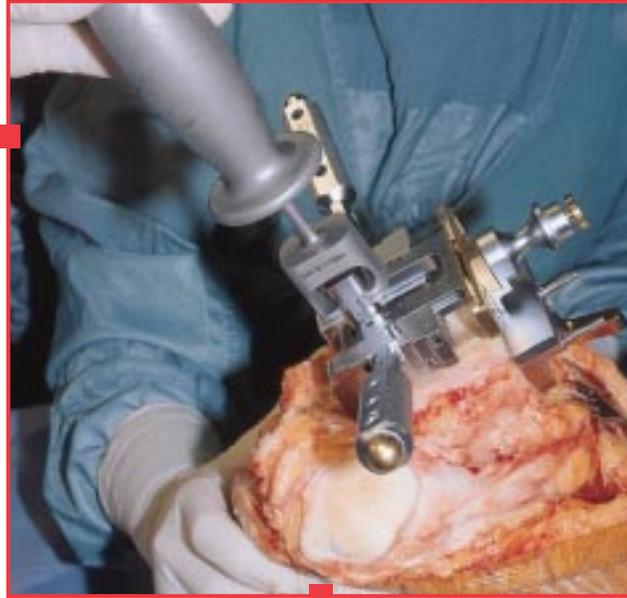


Figure 11



Figure 12

## STEP 4: FINISHING FEMORAL RESECTION

*O*bjective—Perform the final posterior, anterior, and chamfer resections to prepare the femur for the femoral implant.

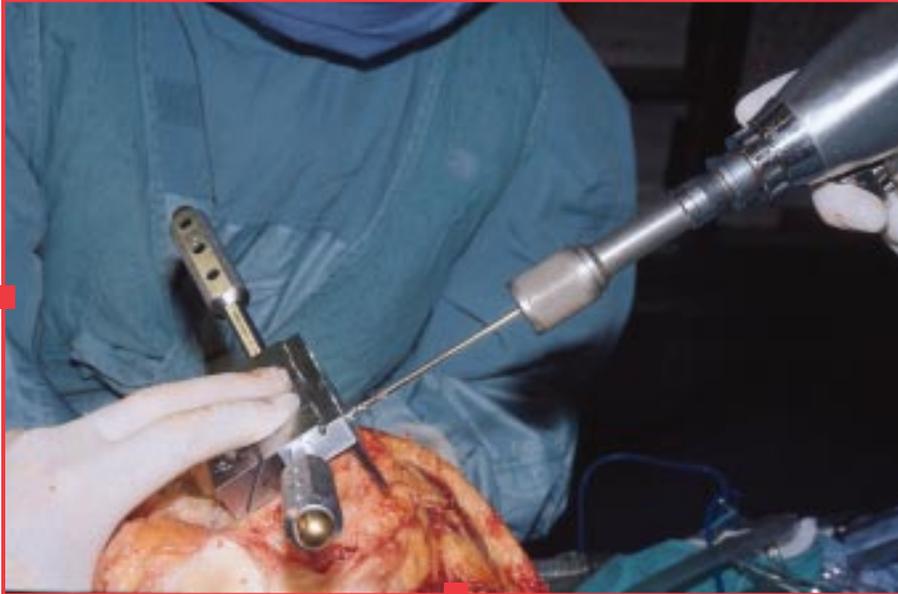


Figure 13

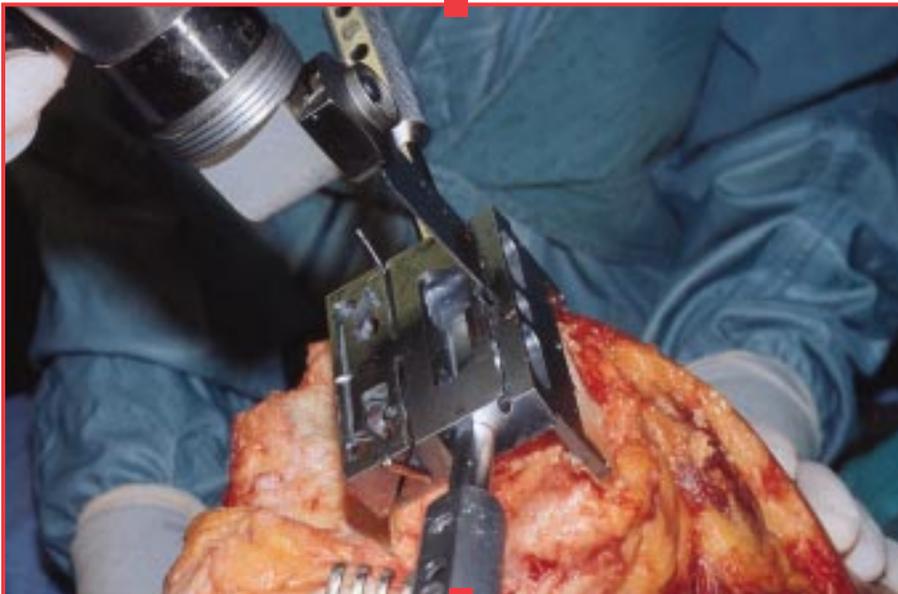


Figure 14

- 1** Add quick connect handles as necessary to the appropriate femoral A-P cutting block.

Place the femoral A-P cutting block onto the distal femur and secure with angled pins through the sides of the block (Figure 13). If additional fixation is necessary, the angled anterior holes may also be used.

The A-P cutting block should seat flush with the cut anterior and distal surface.

- 2** Resect the femur (Figure 14) in the following order:

1. Posterior resection

*To help guide the saw blade during the posterior resection, attach the modular femoral slot to the A-P cutting block.*

**Note: Remove the modular femoral slot before any other cuts are made.**

2. Posterior chamfer
3. Anterior resection
4. Anterior chamfer

## FEMORAL PREPARATION

**3** Remove the femoral A-P cutting block.

[If it is preferable to resect the chamfers over a block rather than through slots, an optional chamfer cutting block is available. To correctly align the chamfer cutting block on the distal femur, drill 1/8" pins through the holes on the distal face of the A-P cutting block (Figure 15). These pins are used as marker holes for the spikes on the chamfer cutting block.]

### option:

Impact the spikes of the chamfer cutting block into the previously drilled holes until the chamfer cutting block is seated on the distal femur. Check to make sure the chamfer cutting block is flush on the flat distal femur. Resect anterior and posterior chamfers (Figure 16).



Figure 15

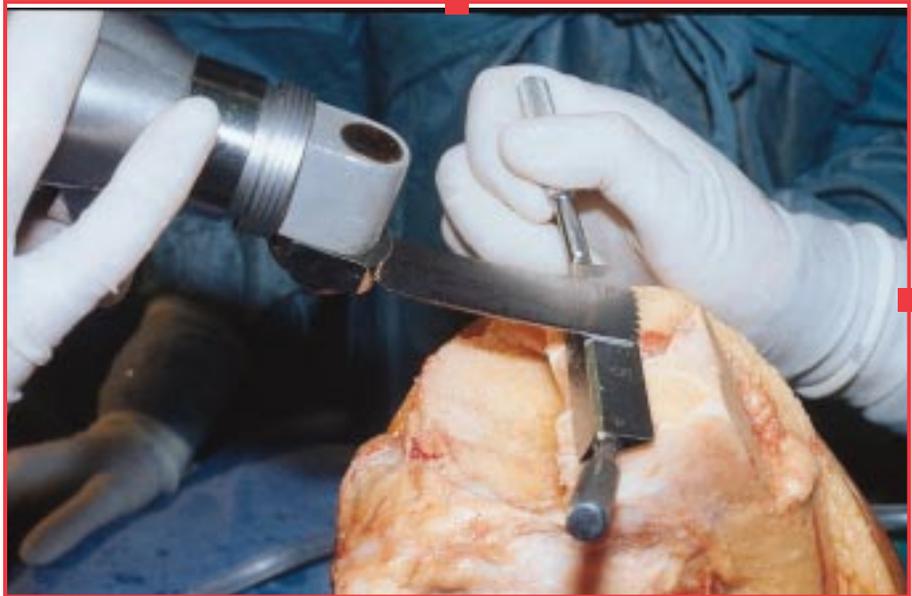


Figure 16

## STEP 5: FINISHING POSTERIOR-STABILIZED FEMORAL RESECTION

*Objective*—Perform the final chamfer resections and prepare for the posterior stabilized implant.

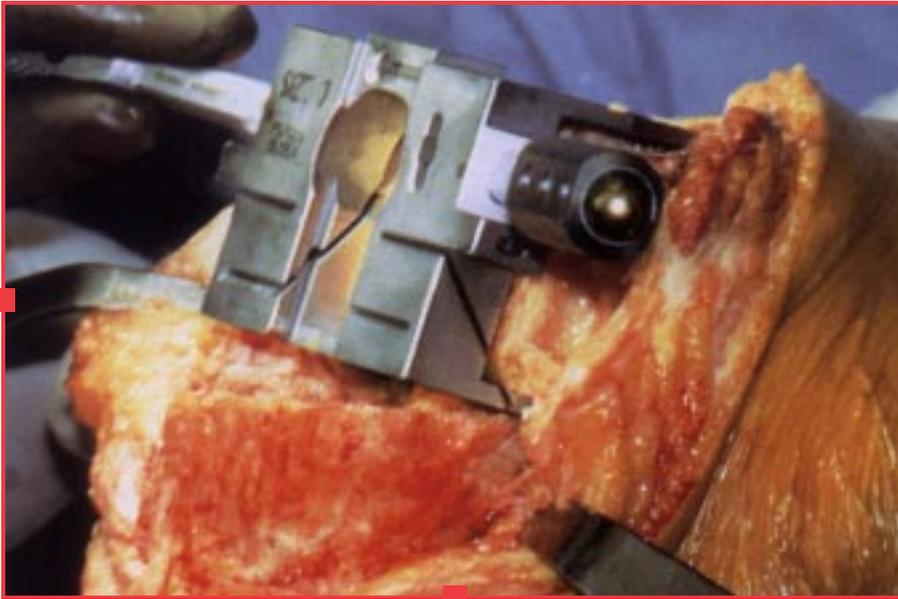


Figure 17

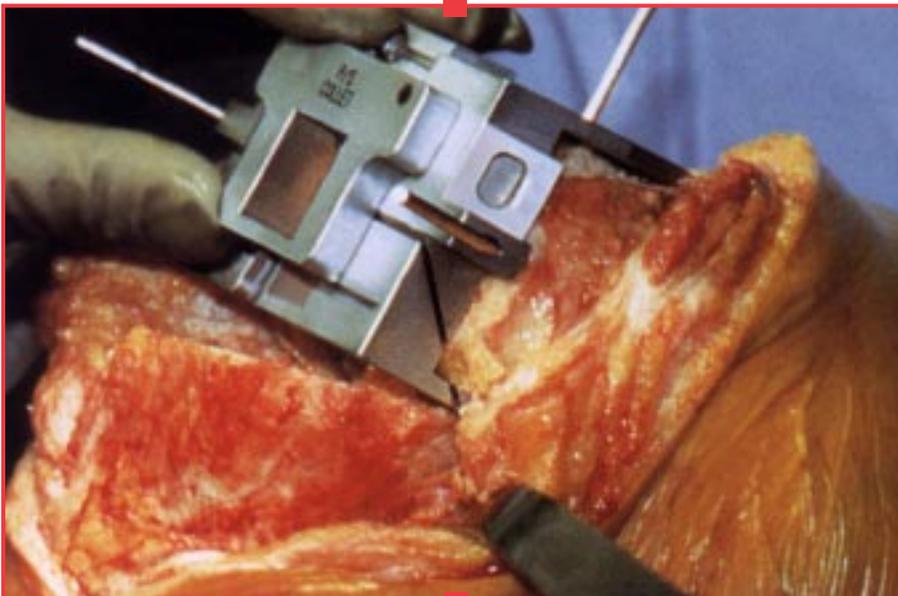


Figure 18

### POSTERIOR-STABILIZED TECHNIQUE

The only difference between the cruciate retaining femoral component and the posterior-stabilized femoral component is the addition of the housing for the cam mechanism. All other inner box dimensions are the same. The posterior-stabilized housing is prepared after the anterior and posterior resections are complete. However, the anterior and posterior chamfer resections can be finished before or after preparing for the posterior stabilized housing.

- 1** Before preparing for the posterior-stabilized housing, place the appropriate size housing resection block on the distal femur. Make sure the block is centered on the distal femur. (To help with centering, the housing resection blocks have the same M-L dimension as the implants.) Secure with 1/8" trocar pins through the angled holes in the sides of the block (*Figure 17*).
- 2** Attach the posterior-stabilized housing resection collet to the housing resection block (*Figure 18*).

## FEMORAL PREPARATION

- 3** Attach the housing reamer dome and posterior stabilized reamer sleeve to the patellar reamer shaft. The reamer dome is both an end-cutting and a side-cutting reamer.
- 4** Ream through the posterior stabilized housing resection collet (*Figure 19*). Ream until the automatic depth stop contacts the collet. Then move the reamer anterior and posterior until it contacts the automatic stop.
- 5** Impact the housing box chisel/sizer through the posterior stabilized housing resection collet to square off the corners of the housing (*Figure 20*). The housing box chisel/sizer may have to be impacted twice to ensure that the full length of the box is prepared.
- 6** If the chamfer resections have not been made, they can now be made by cutting through the chamfer slots in the housing resection block (*Figure 21*).

*Note: if a nonslotted chamfer resection is preferred, you may attach the chamfer cutting block to the distal femur to perform the chamfer resections.*

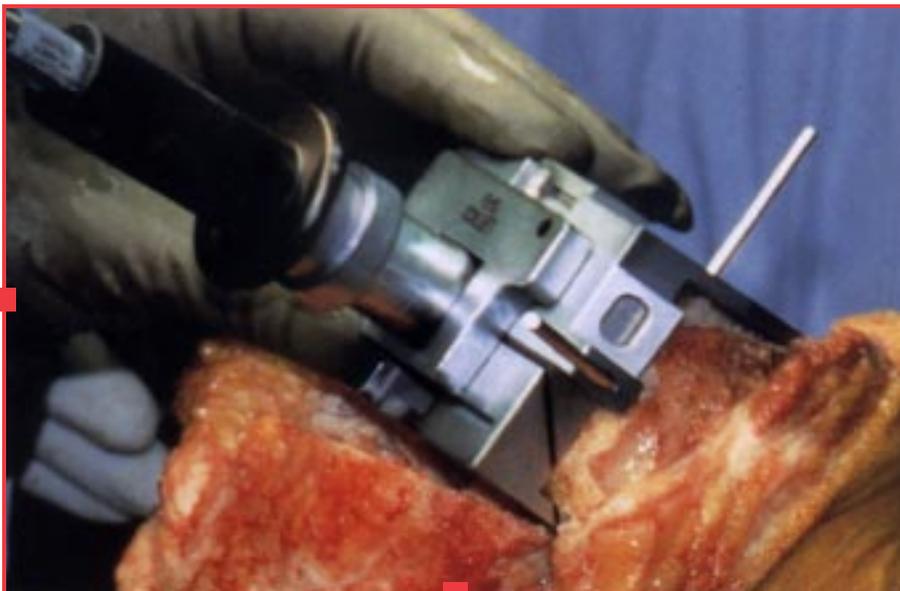


Figure 19

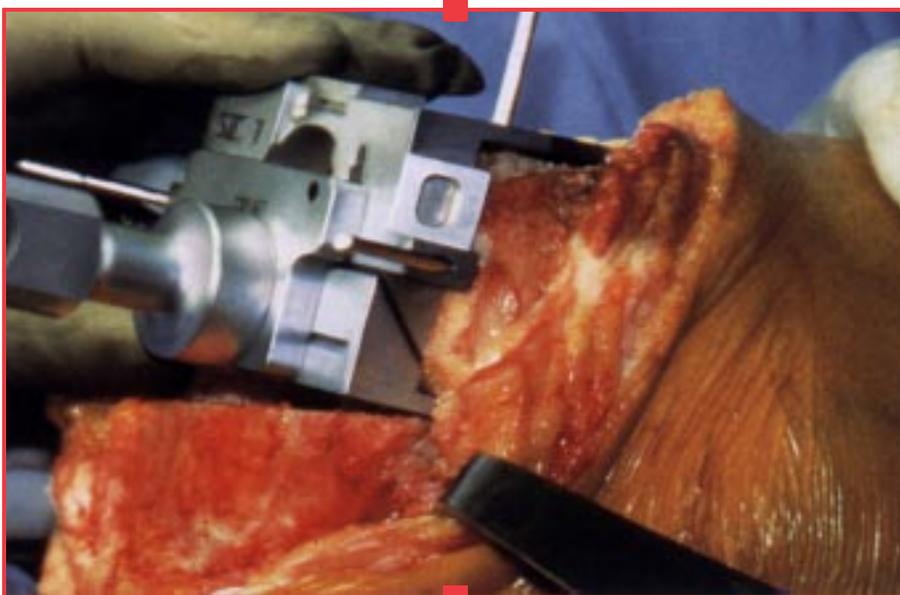


Figure 20



Figure 21

## STEP 1: TIBIAL ALIGNMENT

*Objective* — Align the resection for the tibial baseplate perpendicular to the mechanical axis.

The following describes the technique for extramedullary tibial alignment. If intramedullary tibial alignment is preferred, the intramedullary tibial alignment technique follows on page 18.



Figure 22

### OPTION A: EXTRAMEDULLARY TIBIAL ALIGNMENT

- 1** Assemble the extramedullary tibial alignment guide and place the guide onto the tibia (Figure 22). Make sure that the correct left or right tibial cutting block is chosen and that the alignment guide is correctly set distally for the left or right leg.
- 2** Impact the longer spike of the spiked fixation rod into the proximal tibia.
- 3** Assess rotation of the alignment guide and slope of the cutting plane and impact the second spike to secure the assembly. Rotational alignment is critical due to the 3° posterior sloped cut. The center of the cutting block will also be the center of the tibial tray and articular surface. The goal is to align the extramedullary alignment assembly rotationally so that it aligns over the medial third of the tibial tubercle and over the second toe. The slope can be adjusted according to the patient's anatomy.

*Note: 4° of slope is built into the articular insert and 3° of slope is built into the tibial cutting block. A neutral or slightly sloped alignment should be chosen.*

### OPTION B: INTRAMEDULLARY TIBIAL ALIGNMENT

- 1** Make a 9.5 mm pilot hole into the tibial canal (*Figure 23*). This can be made through the tibial drill guide with the "I/M" tibial collet in place to ascertain correct placement. (Note: a preliminary resection of the tibial spine may facilitate seating of the tibial drill guide onto the proximal tibia.)
- 2** Attach the correct left or right tibial cutting block to the intramedullary tibial alignment assembly and pass the intramedullary rod through the cannulated alignment sleeve on the alignment assembly.
- 3** Slowly insert the rod into the tibial canal (*Figure 24*).
- 4** Assess rotation of the intramedullary tibial alignment guide. Rotational alignment is critical due to the 3° posterior sloped cut. The alignment rod of the intramedullary tibial alignment assembly should align with the medial third of the tibial tubercle.
- 5** Impact the proximal end of the cannulated alignment sleeve to drive the distal spikes into the proximal tibia to lock rotational alignment (*Figure 25*).

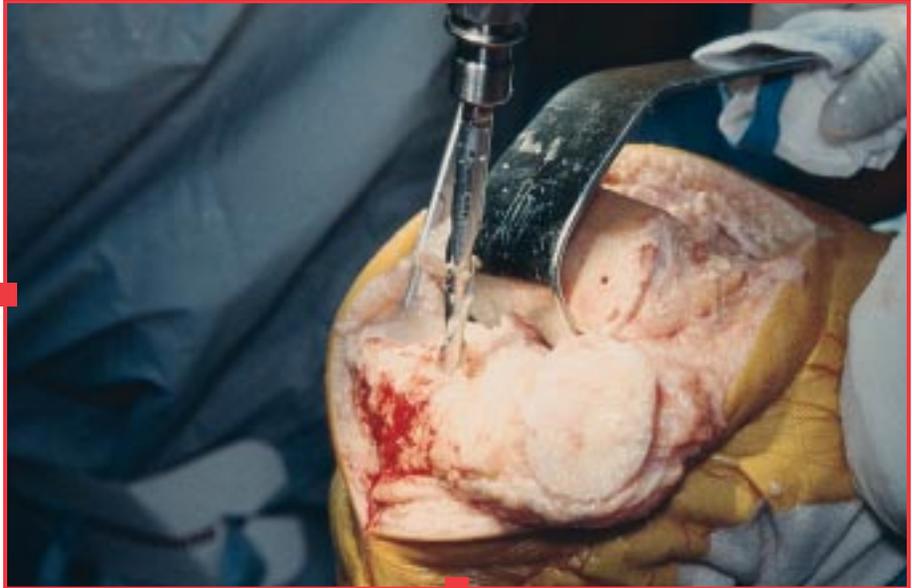


Figure 23



Figure 24

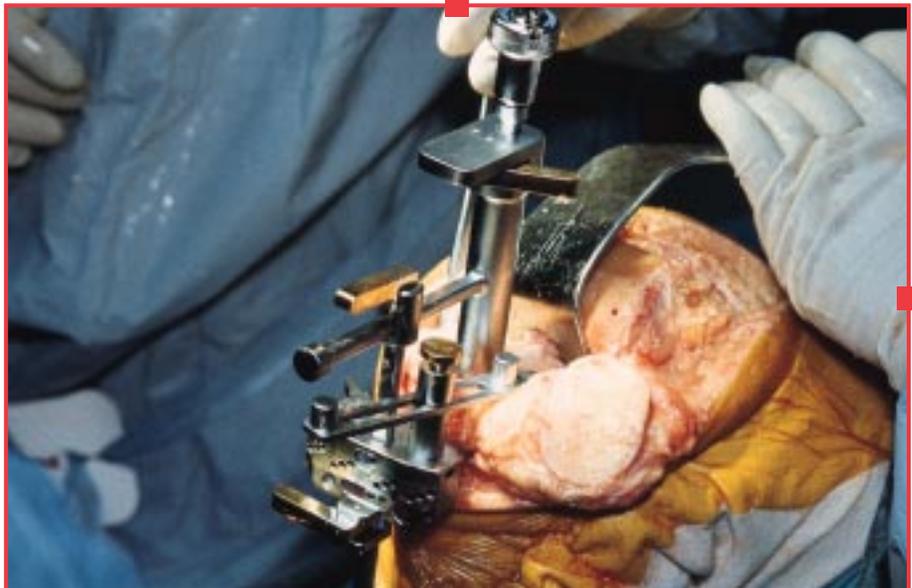


Figure 25

## STEP 2: TIBIAL RESECTION

*Objective*—Resect the proper amount of tibia for the tibial implant.

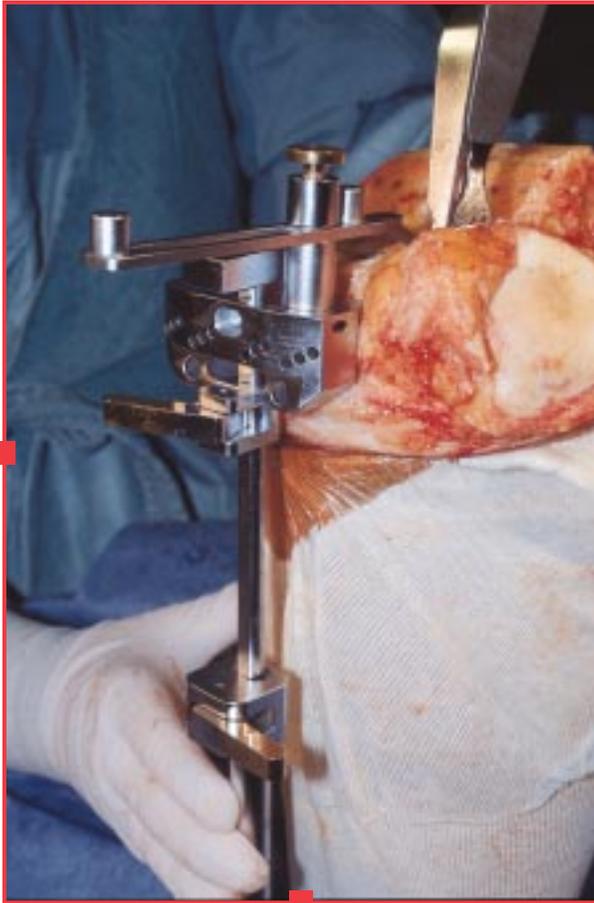


Figure 26

- 1** Attach the primary tibial stylus to the tibial cutting block. Lower the cutting block until the stylus touches the less affected (less worn) side of the tibia (*Figure 26*). (This technique should allow the placement of the 9 mm articular insert [6.7 mm of UHMWPE].)
- 2** Insert pins through the central holes to secure the tibial cutting block to the tibia (*Figure 27*).

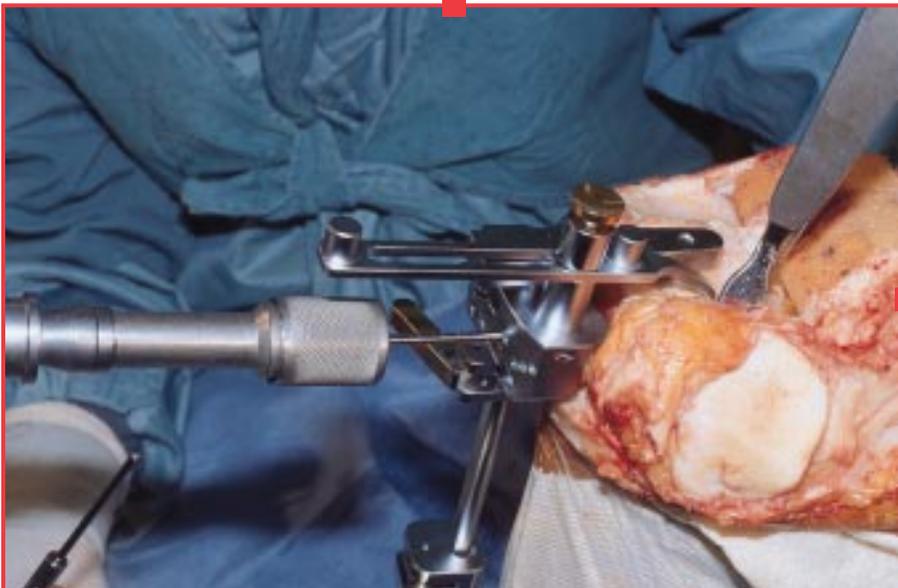


Figure 27

## TIBIAL PREPARATION



Figure 28

**3** Remove the alignment assembly leaving the tibial cutting block on the anterior tibia (Figure 28).

**4** Attach the quick connect handle to the tibial cutting block. Pass the extramedullary rod through the hole in the handle to check tibial alignment (Figure 29).

**5** Use the appropriate GENESIS II sawblade to resect the proximal tibia (Figure 30).

*For a guided resection, attach the modular tibial slot to the tibial cutting block or use the slotted block.*

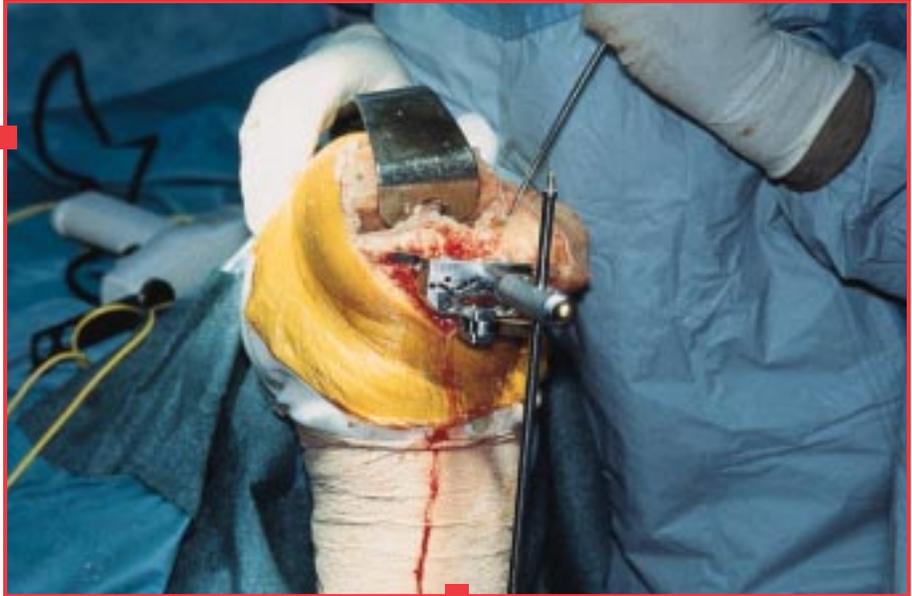


Figure 29

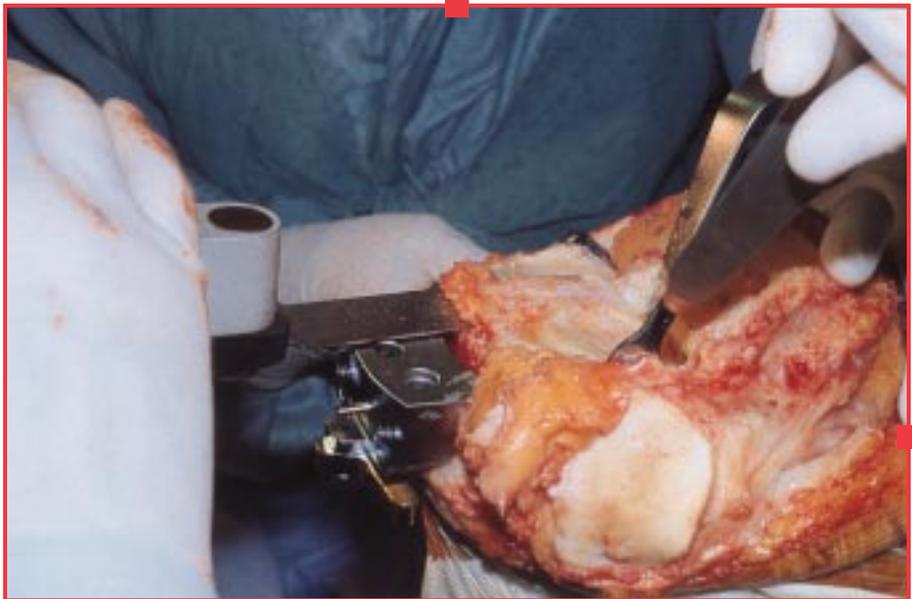


Figure 30

## STEP 3: TIBIAL SIZING

*Objective*—Select the appropriate size tibial implant and prepare for the tibial stem.



Figure 31



Figure 32



Figure 33

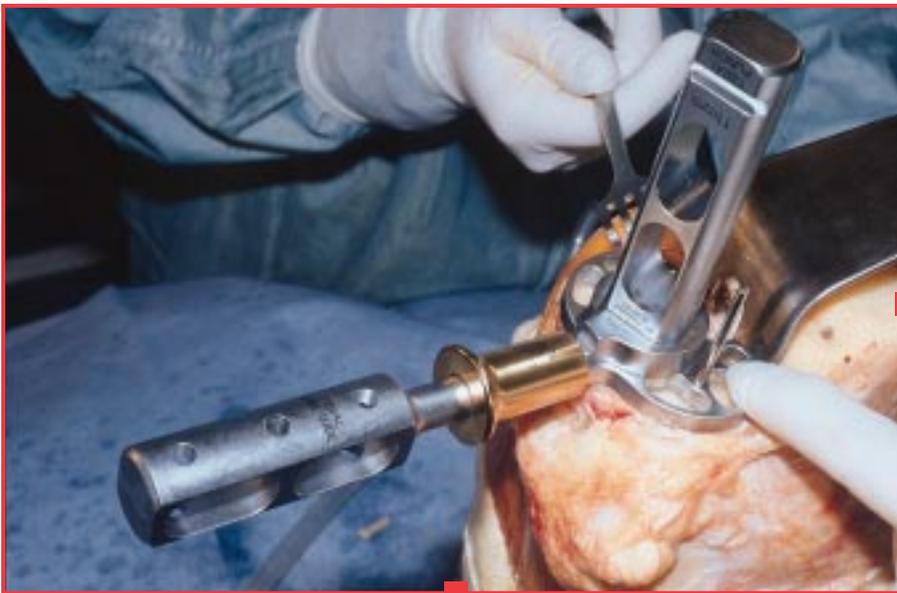


Figure 34



Figure 35

- 1** Use the tibial viewing template to determine the tibial implant size that best fits the proximal tibia (*Figure 31*).
- 2** Select the appropriate tibial drill guide and place it on the proximal tibia.
- 3** Once the tibial drill guide has been centralized on the proximal tibia, pin the drill guide in place (*Figure 32*).
- 4** With the 11 mm tibial collet in place, drill with the 11 mm tibial drill (*Figure 33*) and punch with the 11 mm tibial punch (*Figure 34*). If a 9.5 mm hole has already been made for use of the intramedullary tibial alignment assembly, you only need to utilize the 11 mm tibial punch at this time.
- 5** Remove the tibial drill guide.
- 6** Place the tibial trial onto the proximal tibia and assess coverage (*Figure 35*).

# FEMORAL AND TIBIAL TRIALING

*Objective*— Confirm that implant fit and tibial rotation are correct and determine the appropriate insert thickness.

- 1** If femoral or tibial trials are not positioned, replace them at this time.
- 2** Use the appropriate insert trial to determine leg stability and alignment. Start with the 9 mm insert trial (Figure 36).
- 3** Perform a trial range of motion. The alignment marks on the front of the femoral and tibial trials should line up (Figure 37). The quick connect handle may be attached to the tibial trial and used to rotate the tibial trial to the appropriate rotational alignment.

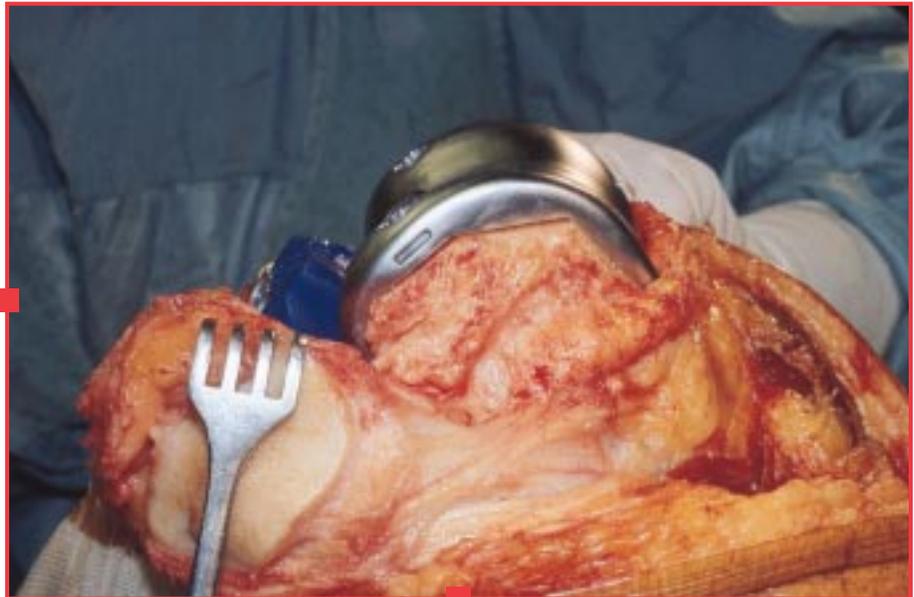


Figure 36

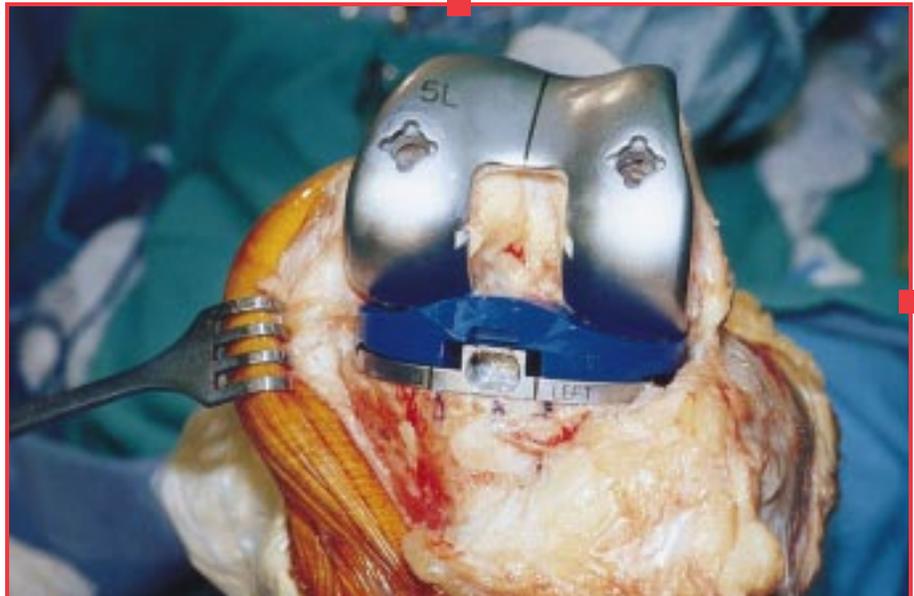


Figure 37



Figure 38

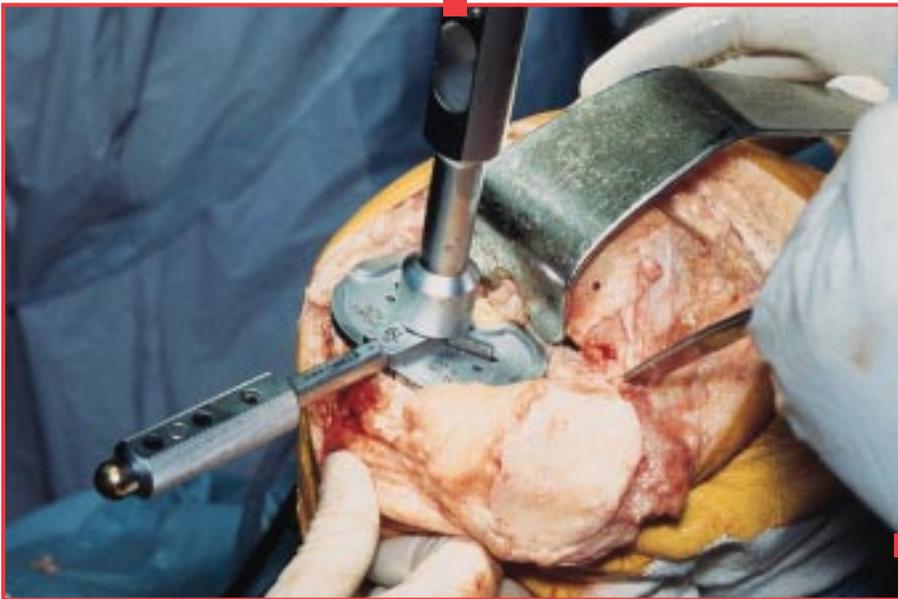


Figure 39

**4** With the handle attached to the tibial trial, take the knee into full extension. Pass the extramedullary rod through the handle to assess full leg alignment. Once correct tibial alignment has been selected, a rotational alignment mark can be made on the anterior tibia using a cautery knife. If it is preferable to use a spacer block to check alignment, insert the block into the joint (*Figure 38*). Since the spacer block has two different ends, one for flexion and one for extension, check to make sure the appropriate end of the block is used.

**5** Determine whether a porous or nonporous tibial implant will be used. Select the appropriate tibial fin punch to prepare the fins and punch through the tibial trial (*Figure 39*). **If the tibial bone is sclerotic, begin the fin slot with a burr or thin saw blade to prevent tibial fracture before using the fin punch.**

## STEP 1: PATELLAR SIZING

*O*bjective—Determine proper placement for the patellar implant.

- 1** Determine the appropriate diameter patellar implant.
- 2** Select the correct patellar reamer collet and slide it into place on the patellar reamer guide.
- 3** Attach the patellar reamer guide to the patella. Tighten the patellar reamer guide on the patella (*Figure 40*).

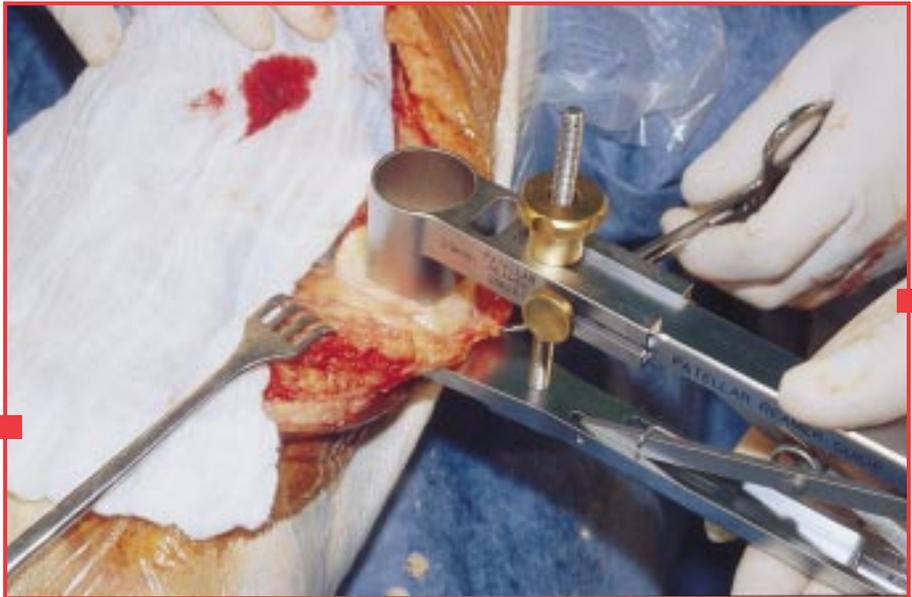


Figure 40

## STEP 2: REAM THE PATELLA

*Objective*—Determine proper reaming depth and prepare the patella to ensure the original patellar thickness has been restored.



Figure 41

- 1** Use the patellar calipers to measure the thickness of the patella (*Figure 41*).
- 2** Attach the patellar depth gauge to the reamer guide based on the selected patellar design. Every patellar design has its own depth gauge. The depth of reaming for each design is as follows:  
Biconvex patellae: 13 mm  
Resurfacing patellae: 9 mm  
All-poly with Flex-Lok® peg: 15 mm

## PATELLAR PREPARATION

- 3** Attach the patellar reamer dome and patellar depth stop to the patellar reamer shaft. Before the patellar reamer assembly is attached to power equipment, lower the assembly through the patellar reamer guide until the reamer dome contacts the patella (*Figure 42*).
- 4** Swing the patellar depth gauge around so that the “claw” surrounds the patellar reamer shaft.
- 5** Lower the patellar depth stop until it contacts the patellar depth gauge. The patellar depth stop will automatically lock in place (*Figure 43*).
- 6** Remove the depth gauge.
- 7** Attach the patellar reamer assembly to power equipment, making sure that the position of the patellar depth stop has not changed.
- 8** Ream the patella until the depth stop engages the patellar reamer guide.

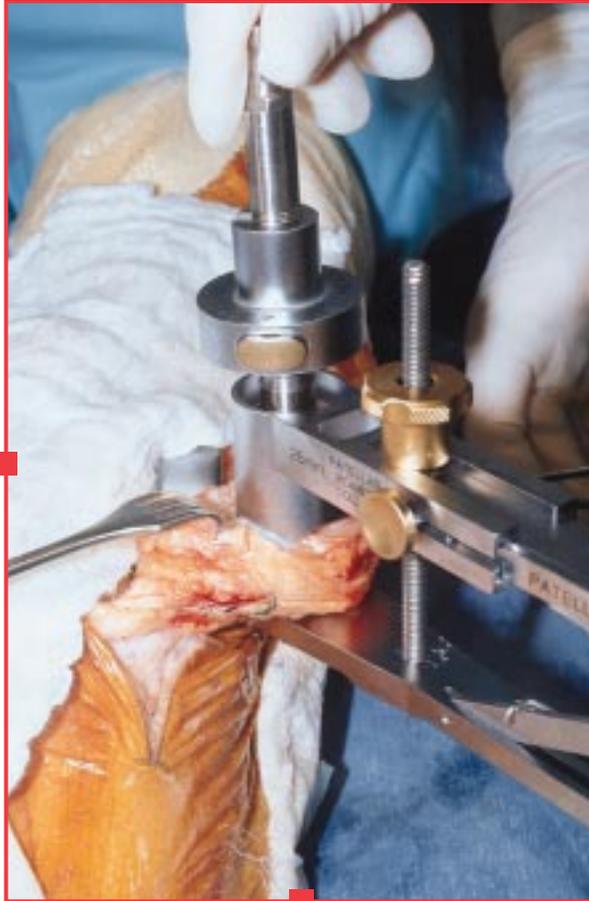


Figure 42

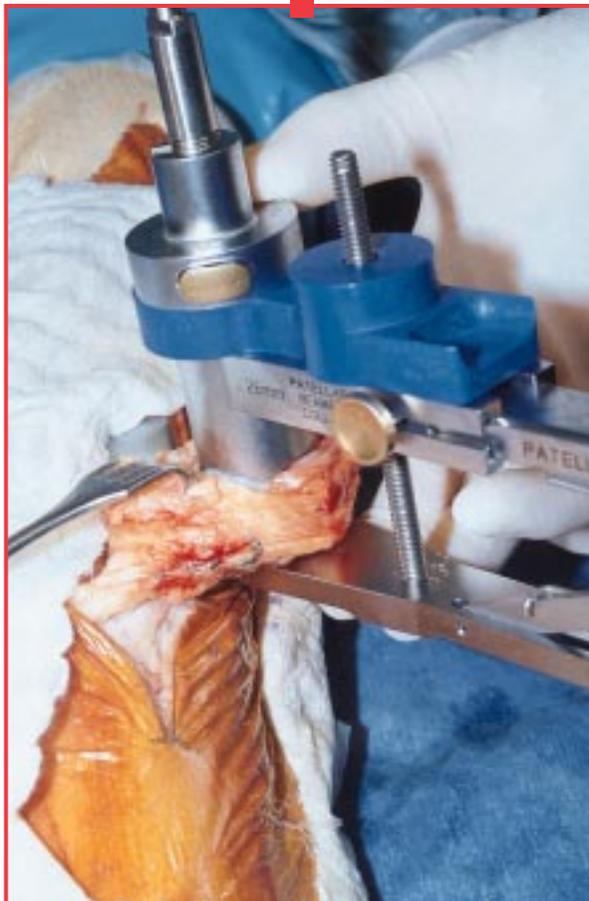


Figure 43

## STEP 3: PATELLAR TRIALING

*Objective*— Confirm correct tracking of the patellar implant.

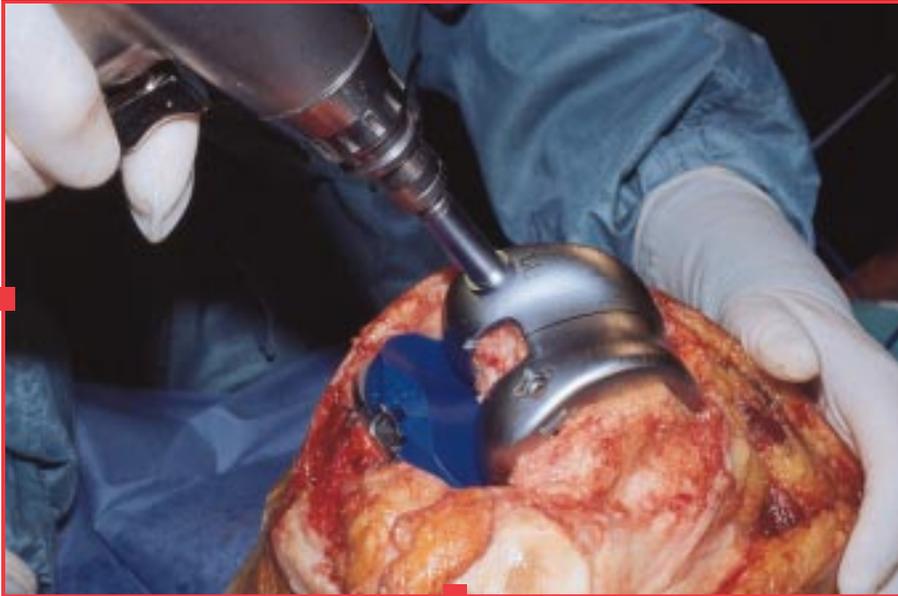


Figure 44



Figure 45

- 1** With the patellar reamer guide still in position, place the patellar trial into the prepared patella.
- 2** Use the patellar calipers to remeasure the composite thickness of bone and trial.
- 3** Remove the patellar reamer guide.
- 4** Perform a trial range of motion and assess patellar tracking. Medial-lateral placement of the femoral trial can be adjusted to maximize patellar tracking.
- 5** Drill for the femoral lugs through the femoral trial with the femoral lug drill (Figure 44).
- 6** Remove the tibial trial. Attach the T-shaped end of the universal extractor to the femoral trial (Figure 45). Remove the femoral trial. Use a towel clip to remove the patellar trial.

## STEP 1: TIBIAL IMPLANTATION

- 1** Mix and prepare cement for placement on the proximal tibia.
- 2** Use the tibial baseplate impactor to seat the tibial implant onto the prepared tibial surface (*Figure 46*).
- 3** If the porous tray and screws will be used, orient the tibial screw drill guide over each screw hole and drill using the tibial screw drill. The screws may be angled up to 10° to reach the cortex if desired.
- 4** Using the screw depth gauge, determine the depth of each screw hole to select the appropriate size screw. Insert and tighten screws of the tibial implant, alternating to avoid liftoff.
- 5** Remove excess cement.



Figure 46

## STEP 2: FEMORAL IMPLANTATION

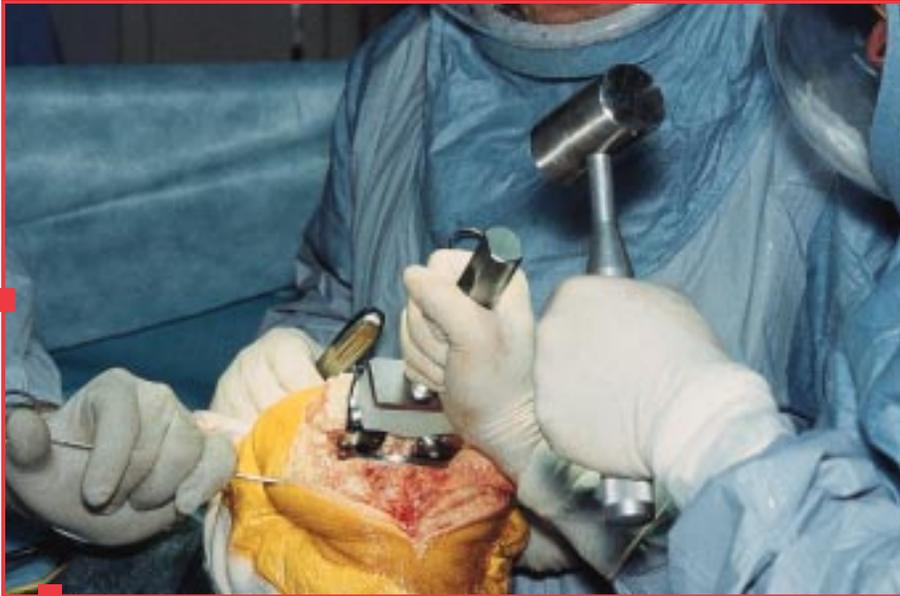


Figure 47

- 1** Mix and prepare bone cement for placement on the femoral component and distal femur.
- 2** Place the femoral implant onto the prepared femur.
- 3** Use the femoral impactor to fully seat the implant (Figure 47).
- 4** Remove excess cement.
- 5** Place the appropriate size tibial insert trial onto the tibial implant and take the leg into extension to pressurize the cement.

## STEP 3: PATELLAR IMPLANTATION

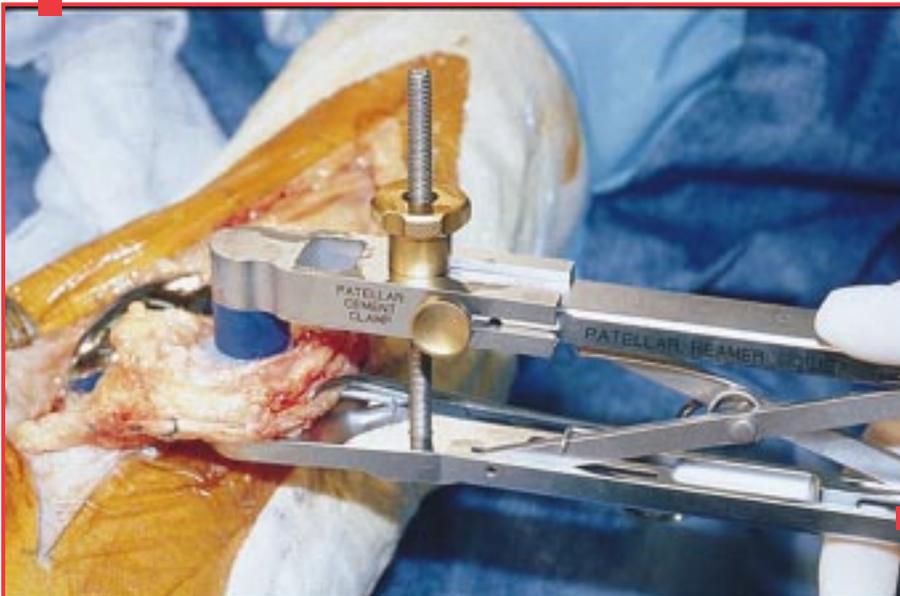


Figure 48

- 1** Assemble the patellar cement clamp to the patellar reamer guide.
- 2** Apply bone cement to the reamed patella.
- 3** Place the patellar implant onto the prepared patella.
- 4** Clamp the patellar implant into the bone and remove the extruded cement (Figure 48).

## STEP 4: INSERT PLACEMENT

**1** After determining the correct thickness of the articular insert, slide the insert into the tibial baseplate as far as possible, engaging the peripheral locking mechanism.

**2** Attach the articular inserter/extractor to the tibial tray. Lift the articular inserter/extractor superiorly until the anterior lip of the articular insert is fully seated (Figure 49). *Note: A mallet should not be used when inserting the polyethylene. A mallet can cause damage to the insert's locking mechanism.*



Figure 49

## CLOSURE

Close in the usual manner.

# USING ANTERIOR AND POSTERIOR REFERENCING INSTRUMENTATION IN CONCERT TO OPTIMIZE FEMORAL SIZING

Anterior referencing and posterior referencing femoral instrument philosophies differ in their primary reference point and, therefore, the anterior-posterior placement of the femoral implant. These basic differences have

inherent advantages and disadvantages. The system you select must be chosen based upon surgeon familiarity and patient indications.

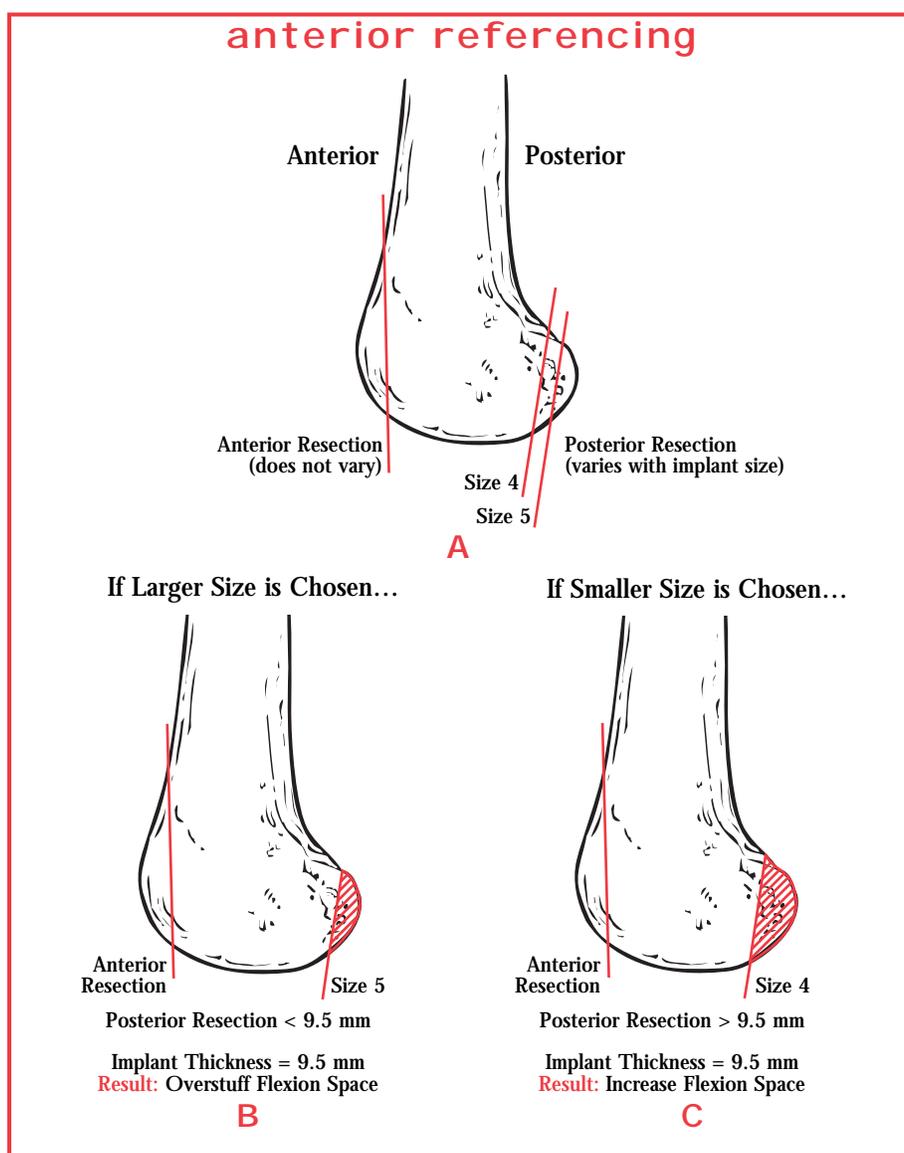


Figure 1

## Anterior Referencing

Anterior-posterior placement of the femoral component is based on the anterior cortex which serves as the primary point of reference. The anterior resection level remains constant and flush with the anterior cortex so that the patellofemoral joint can be most accurately reconstructed. The posterior resection level varies (based on implant size) with respect to the posterior condyles (Figure 1A). The selected femoral implant will be placed flush with the anterior cortex and, therefore, reapproximate the original patellofemoral joint.

When the sizing guide indicates a femoral implant size that is between two sizes, the smaller size should be selected. If the larger size is selected, the amount of bone resected from the posterior condyles will be less than the thickness of the posterior condyles of the femoral implant (Figure 1B). Therefore, the flexion space will be overstuffed. The result of selecting the smaller size implant is the amount of bone resected from the posterior condyles will be greater than the thickness of the posterior condyles of the femoral implant (Figure 1C). Therefore, the flexion space will be greater than the extension space.

Advantages	Disadvantages
Reapproximation of the patellofemoral joint. Reduced chance of notching the anterior cortex.	The knee may be loose in flexion.

## Posterior Referencing

Anterior-posterior placement of the femoral component is based on the posterior femoral condyles which serves as the primary point of reference. The posterior resection level remains constant with the posterior condyles. The anterior resection level varies (based on implant size) with respect to the anterior cortex (Figure 2A). The amount of bone resected from the posterior condyles will equal the thickness of the posterior condyles on the femoral implant. Because the distal femoral resection is equal to the thickness of the distal femoral implant, the flexion and extension space will be balanced. When the sizing guide indicates a femoral implant size that is between two sizes, the larger size should be selected. If the smaller size is selected, there is a strong chance of notching the anterior cortex (Figure 2B). However, the consequence of selecting the larger size is that the patellofemoral joint may be raised and overstuffing, thereby reducing the amount of flexion achieved (Figure 2C).

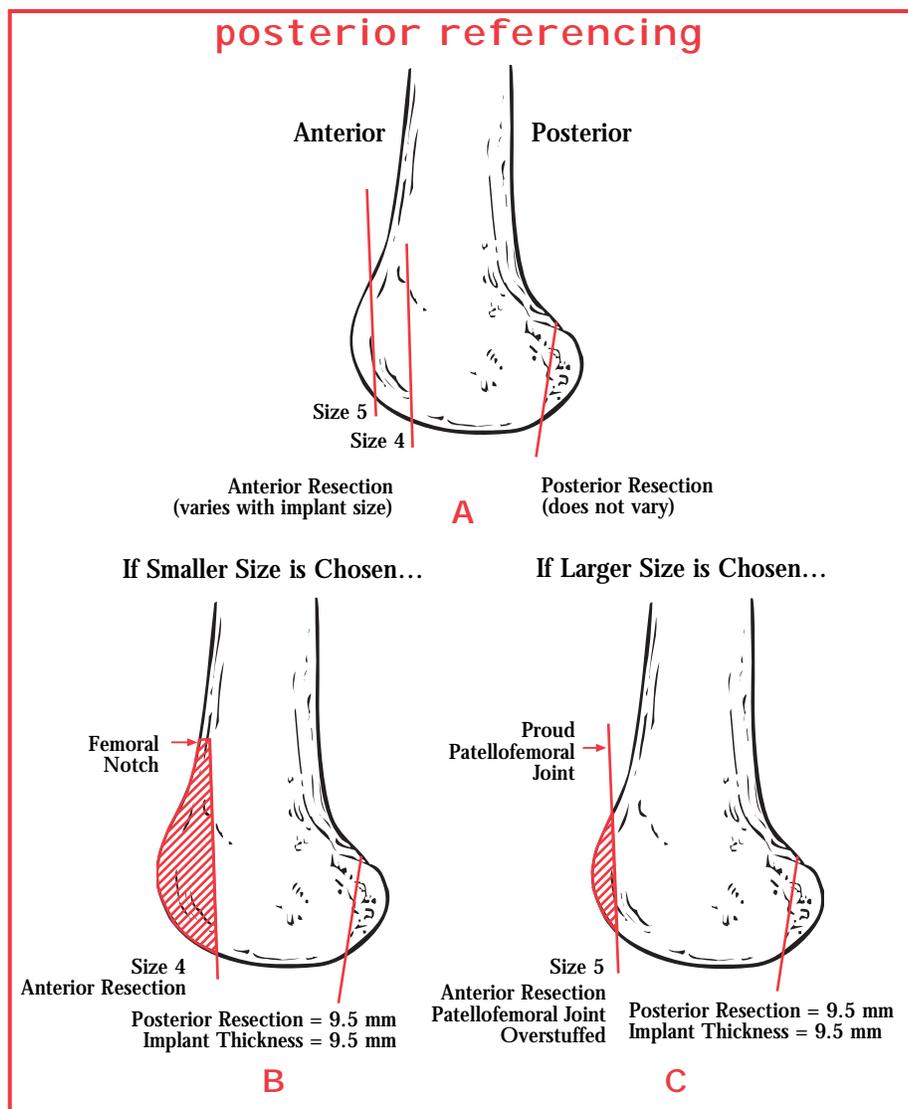


Figure 2

Advantages	Disadvantages
Balanced flexion and extension spaces.	Chance of notching the anterior cortex. May overstuff the patellofemoral joint.

## How does the patented GENESIS II femoral instrumentation and surgical technique improve on the above situation?

Ideally, you could intraoperatively choose which referencing system (anterior or posterior) best fits each individual patient. For example, consider the following two scenarios:

1. You use a posterior referencing femoral instrument system. When sizing the femur, your sizing guide falls between two sizes but you are much closer to the smaller size. Presently, you would be forced to choose the larger size so as to avoid notching the

anterior cortex. By choosing the larger size, you are overstuffing the patellar joint by up to 3.5 mm. Since the femoral sizer is indicating that a smaller size would fit this particular patient's femur better, why not pull out an anterior referencing instrument system for this patient? By making this switch, you would reapproximate the patellofemoral joint and enlarge the flexion gap by 0.5 mm. A much better compromise!

2. You use an anterior referencing femoral instrument system. When sizing the femur, your sizing guide falls between two sizes but you are much closer to the larger size. Presently, you would be forced to choose the smaller size so you do not overstuff the flexion space. By choosing the smaller size, you are enlarging the flexion space by as much as 3.5 mm. Since the femoral sizer is indicating that a larger size would fit this particular patient's femur better, why not pull out a posterior referencing instrument system for this patient? By making this switch, you would reapproximate the flexion space and overstuff the patellofemoral joint by 0.5 mm. Again, a much better compromise!

The option of being able to intraoperatively switch from one femoral referencing system to another allows you to better match the patient's natural femoral anatomy. GENESIS II not only offers eight femoral sizes, it also lets you choose the best of two femoral placement options, thus doubling your femoral sizing options. With GENESIS II, the switch from one femoral referencing system to another is as easy as switching from one instrument to another right there on the table. Both the anterior and the posterior referencing sizing guides are in the sterilization tray and available to you at every surgery.



# IMPORTANT MEDICAL INFORMATION

## SMITH & NEPHEW KNEE SYSTEM

### FOR CEMENTED USE ONLY

#### DESCRIPTION

Femoral components are cobalt chromium alloy (ASTM F 75 and ISO 5832/4) or oxidized zirconium alloy. Conversion modules are cobalt chromium alloy (ASTM F 75 and ISO 5832/4).

Patellar components, all-polyethylene tibial components, tibial articular inserts, and Flex-Lok® pegs are ultra-high molecular weight polyethylene (ASTM F 648). Components that are made of only polyethylene may include X-ray marking wire made of stainless steel (ASTM F 138 and ISO 5832/1) or cobalt chromium (ASTM F 90).

Tibial trays, patellar bases, tibial and femoral wedges, tibial and femoral stems, screws, and pegs are titanium 6Al-4V alloy (ISO 5832/3) or cobalt chromium alloy (ASTM F 75 and/or ISO 5832/4) or (ASTM F 1537 and ISO 5832-12).

Porous-coated cobalt chromium and titanium components feature a porous coating of cobalt chromium beads (ASTM F 75 and ISO 5832/4) and unalloyed titanium beads (ASTM F 67 and ISO 5832/2), respectively. Hydroxylapatite (HA) coatings include HA (ASTM F1185) that is supplied either on a grit-blasted or porous surface.

NOTE: HA coated knee implants are not available in the USA.

Description of the component material is provided on the outside carton label.

Each total knee system is designed as a system and does not allow the substitution of components from other systems or manufacturers. All implantable devices are designed for single use only.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such phenomenon, in spite of the millions of implants in use.

#### INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS

The general principles of good patient selection and sound surgical judgment apply to the total knee procedure. Preoperative planning and meticulous surgical technique are essential to achieve optimum results. Considerations of anatomic loading, soft-tissue condition, and component placement are critical to minimize a variety of postoperative complications.

##### Indications for Total Knee Replacement

1. Rheumatoid arthritis.
2. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result.
3. Failed osteotomies, unicompartmental replacement, or total knee replacement.
4. Posterior-stabilized knee systems are designed for use in patients in primary and revision surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.
5. Constrained knee systems are designed for use in patients in primary and revision surgery, where the posterior cruciate ligament and one or both of the collateral ligaments (i.e. medial collateral and/or lateral collateral ligament) are absent or incompetent.
6. The Tricon-M® and Tricon-P™ Total Knee System can be implanted with or without cement; the Flex-Lok pegs are driven into cancellous bone to secure the components in place.

##### Contraindications for Total Knee Replacement

1. Cases where there is poor bone stock which would make the procedure unjustifiable
2. Active, local infection or previous intra-articular infections
3. Mental or neurologic conditions that tend to pre-empt the patient's ability or willingness to restrict activities
4. Neuropathic (Charcot) joint
5. Conditions that tend to place increased loads on implants such as age, weight, and activity level, which are incompatible with a satisfactory long-term result
6. Collateral ligament insufficiency (except in cases where a constrained knee system is indicated and used)
7. Cementless applications for the Tricon-M and Tricon-P Total Knee Systems is contraindicated with non-correctable ligamentous laxity of the affected knee
8. Skeletal immaturity
9. Use of a supracondylar nail through intercondylar notch of Profix® primary femoral components
10. Use of slotted femoral and tibial stems without adequate bone support.

##### Indications for Unicompartmental Knee Replacement

1. Post-traumatic arthritis, osteoarthritis, or degenerative arthritis in older patients whose age, weight, and activity level are compatible with an adequate long-term result
2. Failed osteotomies

##### Contraindications for Unicompartmental Knee Replacement

The contraindications for Unicompartmental Knee Replacement include all of the contraindications listed for Total Knee Replacement and also inflammatory arthritis, such as rheumatoid arthritis, gout, lupus, etc.

#### Possible Adverse Effects

1. Wear of the polyethylene articulating surfaces of knee replacement components has been reported following total knee replacement. Higher rates of wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis, and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondly, particles may also be generated by third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocation, subluxation, excessive rotation, flexion contracture, decreased range of motion, lengthening or shortening of the leg, looseness of components, unusual stress concentrations, and extraneous bone can result from trauma, improper implant selection, improper implant positioning, improper fixation, and/or migration of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
5. Tibia, femur, or patella fractures.
6. Acute post-surgical wound infection, late deep wound sepsis and/or low-grade synovitis.
7. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may be a result of surgical trauma. Temporary or permanent nerve damage can result in pain or numbness of the affected limb.
8. Wound hematoma, thromboembolic diseases including venous thrombosis, pulmonary embolus, or myocardial infarction.
9. Myositis ossificans. Periarticular calcification or ossification, with or without impediment to joint mobility. Periarticular calcification can cause decreased range of motion.
10. Skin sloughs or delayed wound healing.
11. Although rare, metal sensitivity or allergic reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in histological reactions involving macrophages and fibroblasts.
12. Damage to blood vessels.
13. Varus-valgus deformity.
14. Failure of the porous coating/substrate interface or hydroxylapatite coating/porous coating bonding may result in bead/HA separation.

#### WARNINGS AND PRECAUTIONS

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, and that the implant can break or become damaged as a result of strenuous activity or trauma, and has a finite expected service life and may need to be replaced in the future.

##### Preoperative

1. Use care in handling and storing of implant components. Cutting, bending, or scratching the surfaces of components can significantly reduce the strength, fatigue resistance and/or wear characteristics of the implant system. These in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Do not allow the porous surfaces to come in contact with cloth or other fiber releasing materials.
2. Surgical information is available upon request. The surgeon should be familiar with the technique.
3. An adequate inventory of implant sizes should be available at the time of surgery.
4. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear and damage prior to surgery.

##### Intraoperative

1. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum size component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Modular components must be assembled securely to prevent disassociation. Avoid repeated assembly and disassembly of the modular components which could compromise a critical locking action of the components. Surgical debris must be cleaned from components before assembly. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure.
3. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of cement, care should be taken to prevent movement of the implant components.

4. Fixation screws, when used, should be fully seated to assure stable fixation, and to avoid interference with the proper seating of components. Use only screws recommended by the manufacturer for the specific prosthesis to avoid improper fit, and to avoid improper mixing of metals.
5. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, extraneous cement, ectopic bone, etc. Foreign particles at the metal and/or plastic interface may cause excessive wear and/or friction.
6. Posterior stabilized knee systems, constrained knee systems, and systems with a deep articular surface should not be utilized without significant adjunctive fixation (stems, screws, etc.).
7. It is essential that the patient's bone stock be of sufficient quality to support the plastic and metallic fixation pegs in the Tricon-M and Tricon-P Total Knee Systems.
8. An implant should never be reused. While it may appear undamaged, imperfection may exist which would reduce the service life of the implant.
9. Use the Richards Torque Wrench to secure the distal femoral wedges and the conversion modules to the Genesis® femoral component. The femoral lugs should be torqued to 70 in-lbs. The Richards Torque Wrench is also used to secure the rotation peg to a Mobile Bearing Baseplate.

#### Postoperative

1. Postoperative patient care and directions and warnings to patients by physicians are extremely important. Protected weight bearing with external support is recommended for a period of time to allow healing.
2. Use extreme care in patient handling.
3. Postoperative therapy should be structured to prevent excessive loading of the operative knee and to encourage bone healing.
4. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

#### Packaging and Labeling

Knee implants are sterilized products and should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, refer to the Sterilization/Resterilization section below.

#### STERILIZATION/RESTERILIZATION

Most implants are supplied sterile and have been packaged in protective trays. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation. If not specifically labeled sterile, the implants and instruments are supplied non-sterile and must be sterilized prior to use. Inspect packages for punctures or other damage prior to surgery.

#### Metal Components

Nonporous or non-HA coated metal components may be resterilized, if necessary, by steam autoclaving in appropriate protective wrapping, after removal of all original packaging and labeling. Protect the devices, particularly mating surfaces, from contact with metal or other hard objects which could damage the product. The following process parameters are recommended for these devices:

\* Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 inHg (339 millibars)) with a minimum dwell time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

\* Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 15 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying at 10 inHg (339 millibars) minimum.

Smith & Nephew does not recommend the use of low temperature gravity cycles or flash sterilization on implants.

If porous-coated or HA-coated implants are inadvertently contaminated, return the unsoiled prosthesis to Smith & Nephew for resterilization. DO NOT RSTERILIZE porous coated or HA coated implants. The coating requires special cleaning procedures.

#### Plastic Components

Plastic components may be resterilized by ethylene oxide gas. The following parameters are recommended as starting points for cycle validation by the health care facility:

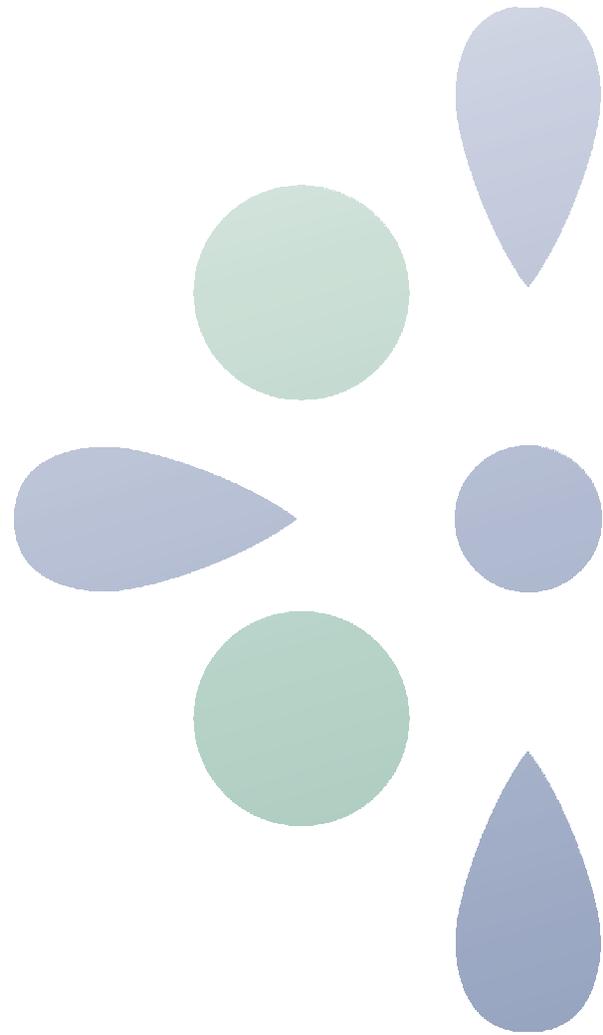
Sterilant	Temp.	Humidity	Max. Pressure	Concentration	Exposure Time
10% EtO 90% HCFC	130°F (55°C)	40-60%	28 PSIA (1930 millibars)	550-650mg/L	120 minutes
10% EtO 90% HCFC	100°F (38°C)	40-60%	28 PSIA (1930 millibars)	550-650 mg/L	6 hours
100% EtO	131°F (55°C)	30-60%	10 PSIA (689 millibars)	736 mg/L	30 minutes

Suggested initial starting point for aeration validation is 12 hours at 122°F (50°C) with power aeration. Consult aerator manufacturer for more specific instructions.

#### INFORMATION

For further information, please contact Customer Service at (800)-238-7538 for all calls within the continental USA and (901) 396-2121 for all international calls.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.



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