

GENESIS® II

TOTAL KNEE SYSTEM

Revision Surgical Technique

GENESIS II

Revision Surgical Technique

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Nota Bene:

The technique description herein is made available to the healthcare professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.

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 patented intramedullary reference guide for the femoral cuts makes even the most difficult revision case a little easier. The angled/stepped hemi-wedge guide takes the

guesswork out of making wedge cuts with guides for 20° and 30° angled wedges and 10 mm and 15 mm stepped wedges. Trial stems and wedges attach directly to the femoral finishing block to provide the most accurate cuts possible and optimize implant fit. The same stem and wedge trials mate with the corresponding implant trial so that fit can be confirmed prior to cementing.

While it has been the designer's 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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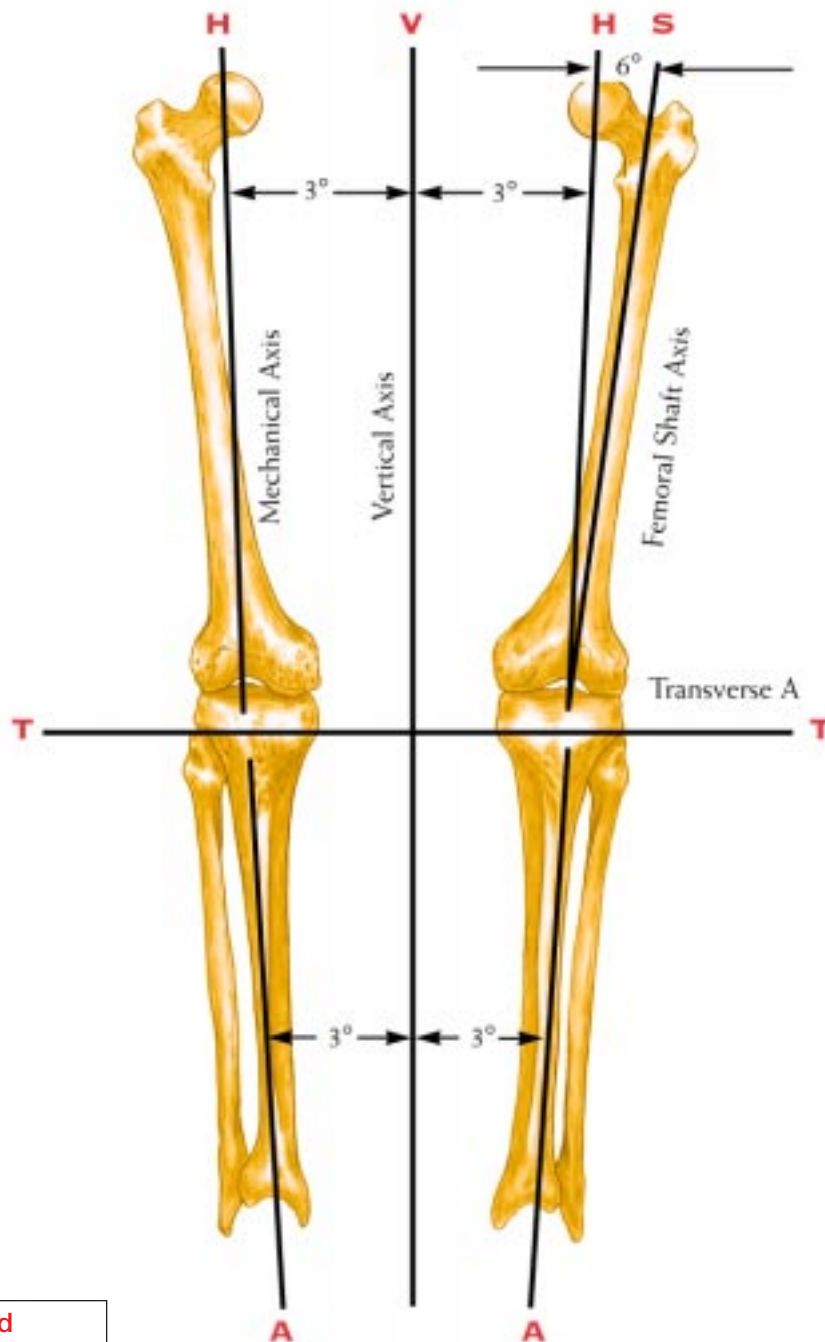
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Determine the approximate size of the femoral and tibial components as well as the length and diameter of any long stems to be used. Bone defects can also be templated to determine approximate

size needed. This can be accomplished by using long standing A-P and lateral X-rays of both the involved and uninvolved extremities with radiographic markers for magnification.



**Recommended
GENESIS II Sawblade:**

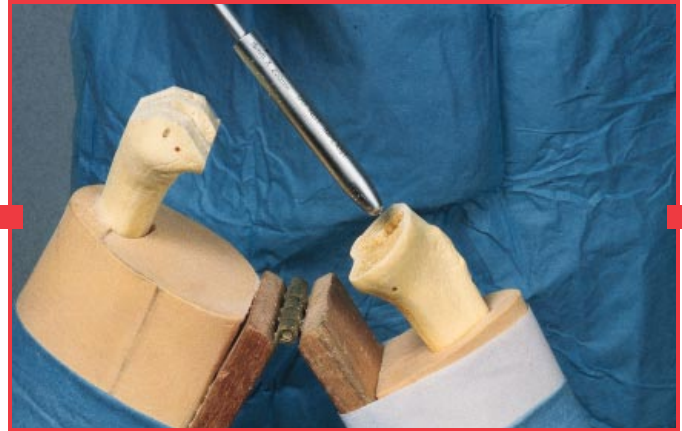
7144-0374 3M
7144-0376 Stryker
7144-0378 Amsco-Hall
7144-0375 New Stryker
or a .050" or 1.27 mm
Thickness Sawblade

SHORT TECHNIQUE

Note: The insert shown is for illustration purposes only. Actual implants will vary.



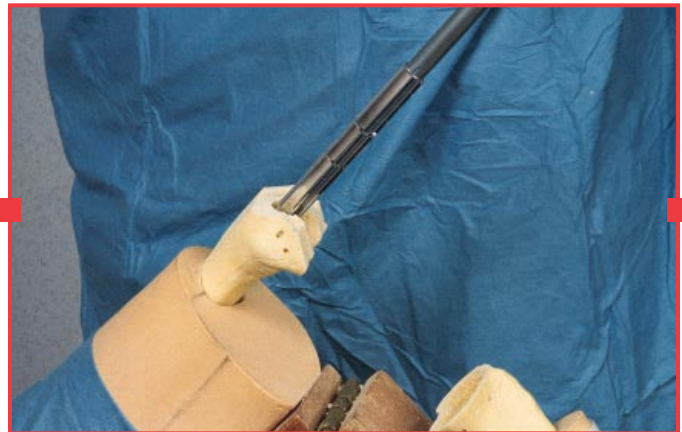
1 After making the pilot hole into the tibial canal, ream the canal until cortical contact is achieved using progressively larger diameter long-stem reamers.



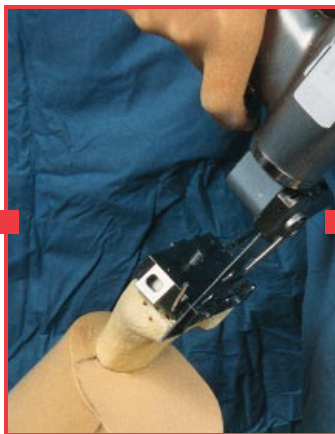
2 Attach the long-stem extractor rod to the appropriate tibial trial stem (same diameter as last reamer used) and insert into the tibial intramedullary canal.



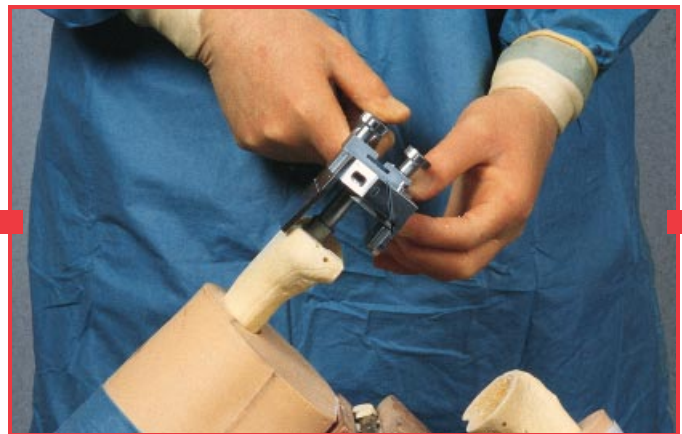
5 After assessing the level of resection, resect the proximal tibia.



6 After opening the femoral intramedullary canal, ream the canal until cortical contact is achieved using progressively larger diameter stem reamers.



9 Pin the Revision A-P cutting block to the distal femur. Remove the revision distal femoral cutting block from the revision A-P cutting block and resect the posterior and anterior condyles over the surface of the cutting block.



10 Attach the femoral trial stem adapter to the correctly sized housing resection block. Attach the correct trial stem to the adapter. Add any distal or posterior wedges to the housing resection block.



3 Attach the correct left or right tibial cutting block to the intramedullary tibial alignment guide and place the I/M alignment guide over the long-stem extractor rod.



4 Attach the revision tibial stylus to the tibial cutting block. Lower the cutting block until the stylus touches the side of the proximal tibia with the least amount of bone loss. Pin the cutting block to the tibia.



7 Add the revision cutting block stem adapter to the correctly sized revision A-P cutting block. Attach the correct trial stem to the stem adapter and insert the trial into the intramedullary canal.



8 The revision distal femoral cutting block is attached to the revision A-P cutting block. Place the revision A-P cutting block in the correct neutral rotational alignment and pin the revision distal femoral cutting block to the anterior cortex. Now the distal femoral resection is performed.



11 After pinning the housing resection block to the distal femur, remove the trial stem adapter and stem trial from the intramedullary canal.



12 Attach the revision housing resection collet to the housing resection block. Attach the housing reamer dome to the patellar reamer shaft and ream through the appropriate collet.

SHORT TECHNIQUE



13 Impact the housing box chisel/sizer through the appropriate collet until the stop hits the collet.



14 Perform the anterior and posterior chamfer resections through the chamfer slots in the housing resection block.



17 Properly position the appropriate tibial wedge resection block against the anterior tibia.



18 Pin the resection block to the tibia and remove the modular handle and tibial trial assembly. Resect the proximal tibia to accept the appropriate wedge.



21 Insert cement onto the distal surface of the femur and onto the posterior aspect of the femoral prosthesis. Insert the femoral implant into position.



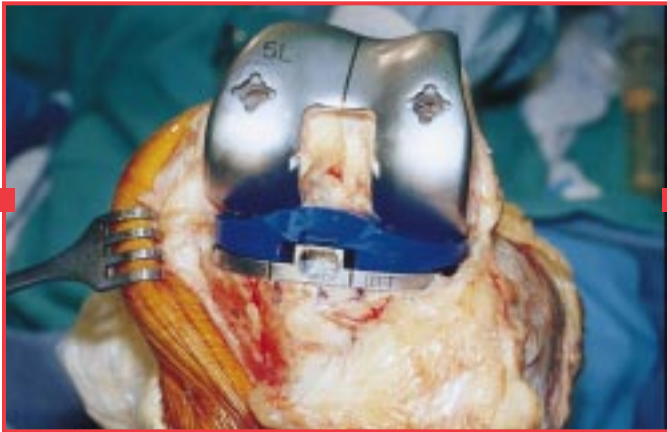
22 Using the tibial insertion tool, fully seat the tibial articular insert.



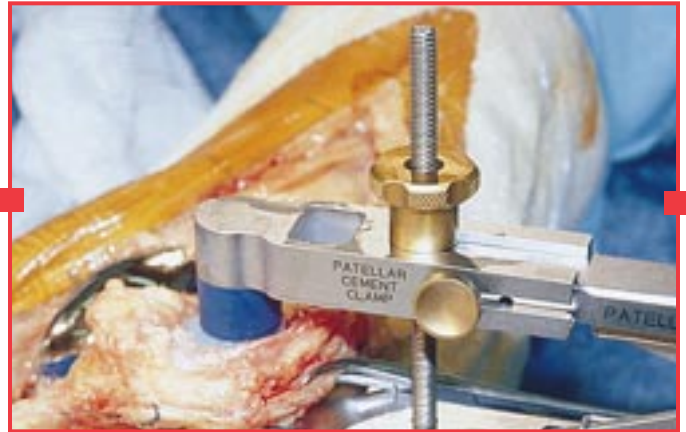
15 Measure the patellar thickness and determine correct patellar implant. Attach the correct patellar reamer to the patellar reamer shaft. Ream the patella until an adequate bed is prepared. Be careful not to over ream!



16 Assemble the appropriate tibial trials and seat this assembly onto the proximal tibia.



19 After inserting the appropriate femoral, tibial, and patellar trials, gently perform a trial range of motion to ascertain proper joint tension and patellar tracking.



20 After cementing the tibial baseplate in place, cement the patellar implant onto the prepared surface of the patella.

STEP 1: TIBIAL ALIGNMENT

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

The following describes the technique for intramedullary tibial alignment, which is recommended for long-stem surgery. If extramedullary tibial alignment is preferred, the extramedullary tibial alignment technique follows on page 10.



Figure 1

OPTION A: INTRAMEDULLARY TIBIAL ALIGNMENT

- 1** Make a 9.5 mm pilot hole into the tibial canal. This can be made through the tibial drill guide with the “IM” tibial collet in place to ascertain correct placement (*Figure 1*).
- 2** Using progressively larger diameter long-stem reamers, ream the tibial canal until cortical contact is achieved. Long-stems are offered in 100, 150, and 200 mm lengths. Each reamer is marked with these different lengths (*Figure 2*).
- 3** Attach the long-stem extractor rod to the appropriate tibial trial stem (same diameter as last reamer used) and insert into the tibial intramedullary canal (*Figure 3*).



Figure 2



Figure 3



Figure 4

4 The cannulated alignment sleeve of the intramedullary tibial alignment assembly is placed over the long-stem extractor rod. The intramedullary tibial alignment assembly is rotated until the alignment rod is centered over the medial third of the tibial tubercle. **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 rotational orientation is locked in place by impacting the proximal end of the cannulated alignment sleeve to drive the distal spikes into the proximal tibia (*Figure 4*).



Figure 5

5 Attach the correct left or right tibial cutting block to the intramedullary tibial alignment guide (*Figure 5*).

OPTION B: EXTRAMEDULLARY TIBIAL ALIGNMENT

- 1** Assemble the extramedullary tibial alignment guide and place the guide onto the tibia (*Figure 6*). 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 center of the ankle. The slope can be adjusted according to the patient's anatomy. However, if a long-stem is needed, the extramedullary rod should be parallel to the tibial shaft.
Note: 4° of slope is built into the articular insert and 3° of slope is built into the tibial cutting block.

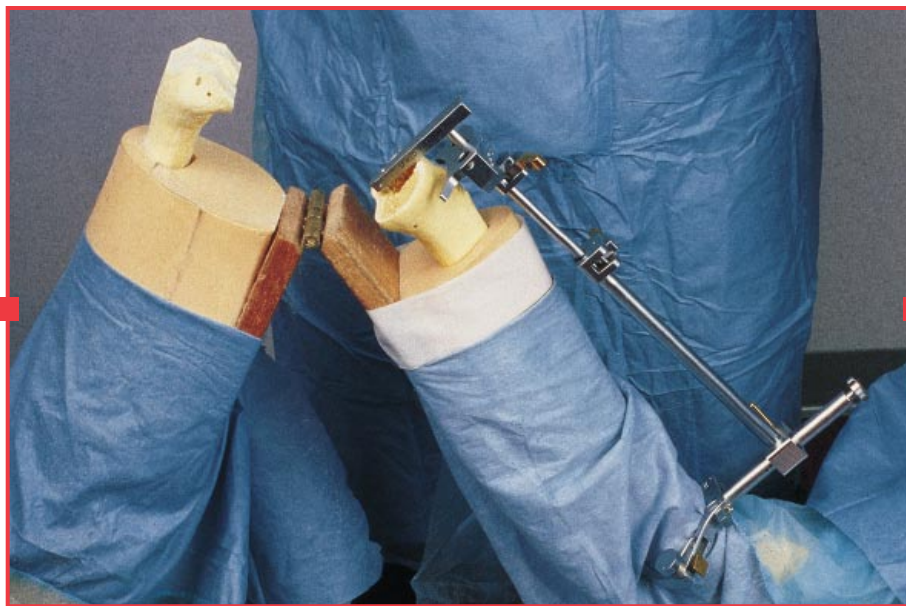


Figure 6

STEP 2: TIBIAL RESECTION

Objective—Resect a minimal amount of bone from the proximal tibia while providing a good foundation for implant fixation.

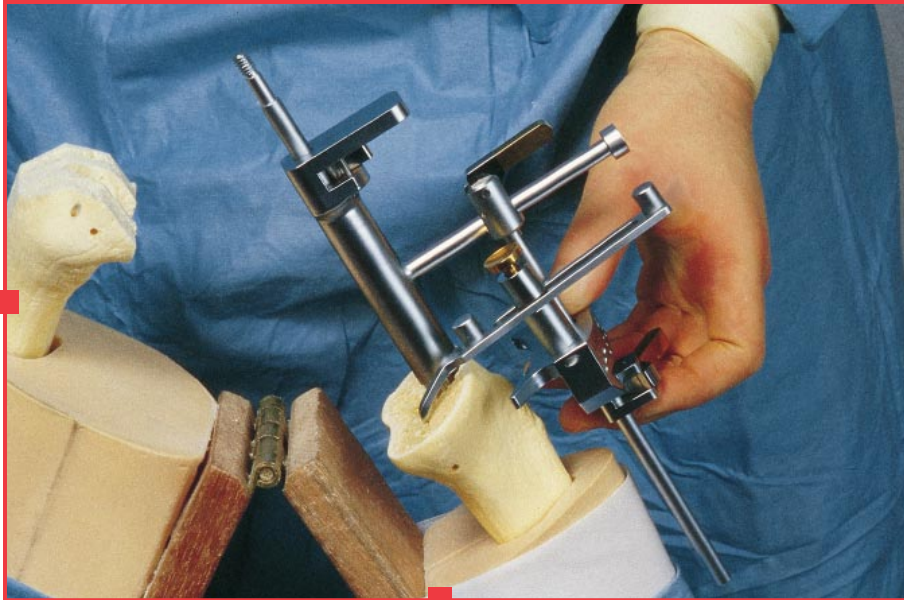


Figure 7



Figure 8

- 1** Attach the revision tibial stylus to the tibial cutting block. Lower the cutting block until the stylus touches the side of the proximal tibia with the least amount of bone loss (*Figure 7*). The revision stylus will remove 1 mm from this point. In case of bony defects, it may be necessary to adjust the cutting level proximal to or above the level of maximum bone loss and to subsequently bone graft the defect or use an augmentation wedge.
- 2** Insert pins through the central holes to secure the tibial cutting block to the tibia (*Figure 8*).
- 3** Remove the alignment assembly leaving the tibial cutting block on the anterior tibia (*Figure 9*).



Figure 9

TIBIAL PREPARATION

4 Attach the quick connect handle to the tibial cutting block. Pass the alignment rod through the hole in the handle to check tibial alignment (Figure 10).

5 Resect the proximal tibia with a GENESIS II Sawblade with a GENESIS II Sawblade (Figure 11). *Note: A modular slot can be added to the non-slotted tibial cutting block or permanently slotted tibial cutting blocks are available. The GENESIS II Sawblades are specifically manufactured to fit these slots so as to provide a more precise resection.*



Figure 10

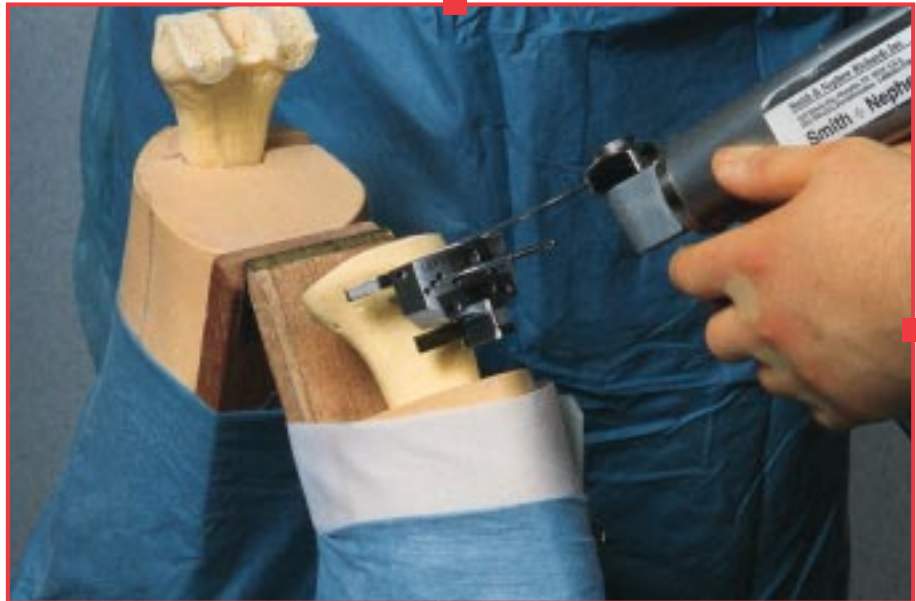


Figure 11

STEP 3: TIBIAL SIZING

Objective—Select the appropriate size tibial implant and prepare for long-stem if extramedullary alignment was used.



Figure 12



Figure 13

- 1** Use the tibial viewing template to determine the tibial implant size that best fits the proximal tibia (Figure 12).

Note: If extramedullary tibial alignment has been used, proceed with the following steps. If intramedullary tibial alignment has been used, proceed to Step 4.

- 2** Select the appropriate tibial drill guide and place it on the proximal tibia. Once the tibial drill guide has been centralized on the proximal tibia, pin the drill guide in place. Ream the tibial intramedullary canal using progressively larger diameter tibial collets and reamers until cortical contact is made. Long-stems are available in 100, 150, and 200 mm lengths. Each reamer is marked with these lengths (Figure 13).
- 3** Remove the tibial drill guide.
- 4** Perform a trial seating of the tibial trial with the tibial trial stem attached (same size as last reamer used) to be sure that the implant will seat correctly.

STEP 1: INTRAMEDULLARY FEMORAL ALIGNMENT

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

1 If necessary, open the femoral intramedullary canal using the 9.5 mm femoral drill (*Figure 14*).

2 Using progressively larger diameter stem reamers, ream the femoral intramedullary canal until cortical contact is achieved (*Figure 15*). Stems are available in 100, 150, and 200 mm lengths. Each reamer is marked with these lengths. *Note: Because of the internal dimensions, each size femoral component has a maximum allowable diameter of femoral stem that can be used. The limitations are as follows:*

Femoral Component Size	Maximum Stem Diameter
1	14
2	16
3	18
4	20
5	22
6	24
7	24
8	24

Remove the reamer and note diameter and length.

3 Add the revision cutting block stem adapter to the correctly sized revision A-P cutting block. The revision A-P cutting blocks are the same size M-L as the implants. Make sure that the distal end of the stem adapter points to the correct indication for a left or right knee. Attach the correct trial stem to the stem adapter (*Figure 16*). Handles may be connected to the revision cutting block, if necessary. Insert the trial stem into the intramedullary canal until the revision A-P cutting block touches the distal femur. Do not affix the cutting block to bone at this time.



Figure 14



Figure 15



Figure 16

STEP 2: DISTAL FEMORAL RESECTION

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

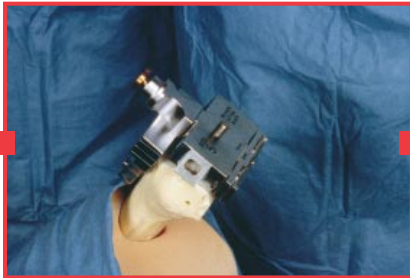


Figure 17

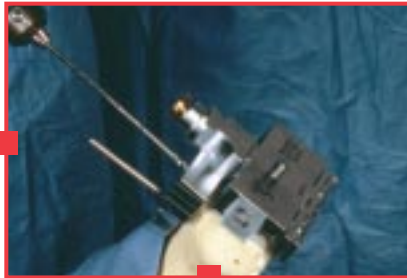


Figure 18



Figure 19

- 1** Attach the revision distal femoral cutting block to the anterior surface of the revision A-P cutting block (Figure 17).
- 2** Place the revision A-P cutting block in the correct neutral rotational alignment using the cut proximal tibia, the epicondyles, and the patellar groove as references. The revision distal femoral cutting block is pinned to the anterior cortex of the femur locking the rotational alignment of the cutting assembly (Figure 18). The resection check can be used on top of the anterior surface of the revision A-P cutting block to make sure that the anterior cortex will not be notched.
- 3** Make the distal femoral resection. If the distal slot is used, 1.5 mm of bone will be removed from the distal femur. If a distal femoral wedge is needed to fill a bony defect, two more proximal slots are available for 5 and 10 mm distal femoral wedges (Figure 19).

STEP 3: ANTERIOR/POSTERIOR FEMORAL FINISHING RESECTIONS

Objective—Perform final anterior and posterior resections to prepare the femur for the femoral implant.



Figure 20

1 Before the pins are removed from the revision distal femoral cutting block, pin the revision A-P cutting block to the distal femur. This will ensure that the rotational orientation and level of resection does not change (Figure 20).

2 Remove the revision distal femoral cutting block from the revision A-P cutting block.

3 Resect the posterior condyles over the posterior surface of the revision A-P cutting block. If wedges are needed to fill bony defects, two more posterior slots are available for 5 and 10 mm augmentation wedges (Figure 21).

4 Perform the anterior cut (Figure 22).



Figure 21

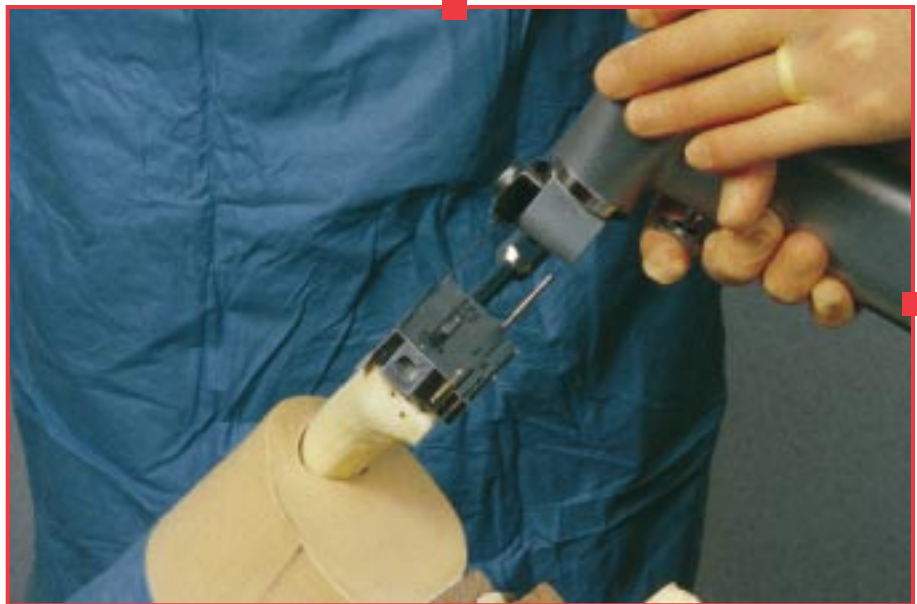


Figure 22

STEP 4: FEMORAL HOUSING AND CHAMFER RESECTIONS

Objective—Perform the housing and chamfer resections for either the posterior stabilized or constrained femoral implants.

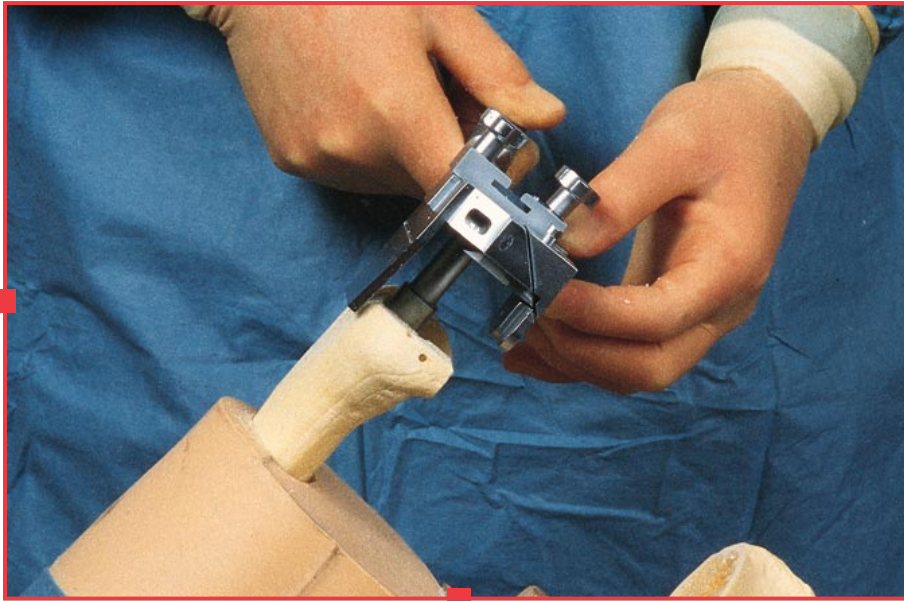


Figure 23



Figure 24



Figure 25

- 1** If a stem is to be used, attach the femoral trial stem adapter to the correspondingly sized housing resection block. The correct trial stem is connected to the femoral trial stem adapter. Any distal or posterior wedges that have been prepared should also be added to the housing resection block to ensure proper reaming depth for housing. The wedges are magnetized and automatically adhere to the cutting block (Figure 23).
- 2** Insert the trial stem into the femoral intramedullary canal and impact the housing resection block until it contacts the distal aspect of the femur. The housing resection block can be anchored to the femur with drill bits or bone spikes (Figure 24).
- 3** Remove the femoral trial stem adapter and trial stem from the housing resection block and the femoral intramedullary canal after the housing resection block is pinned into place. This can be accomplished by loosening the screw attachment of the femoral trial stem adapter and extracting the trial stem from the intramedullary canal with the universal extractor (Figure 25).

FEMORAL PREPARATION

4 Attach the revision housing resection collet to the housing resection block by sliding the collet into the block from the posterior aspect of the central opening. This collet will prepare for a posterior stabilized with stem or a constrained femoral implant (*Figure 26*). Note: If a stem will not be needed and a primary posterior stabilized implant will be used, the primary posterior stabilized collet should be used in place of the revision housing collet.

5 Attach the housing reamer dome to the patellar reamer shaft. The reamer dome is both an end-cutting and a side-cutting reamer.

6 Ream through the appropriate collet (*Figure 27*). Ream until the automatic depth stop contacts the collet. Then move the reamer anterior and posterior until it contacts the automatic stop (*Figure 28*).

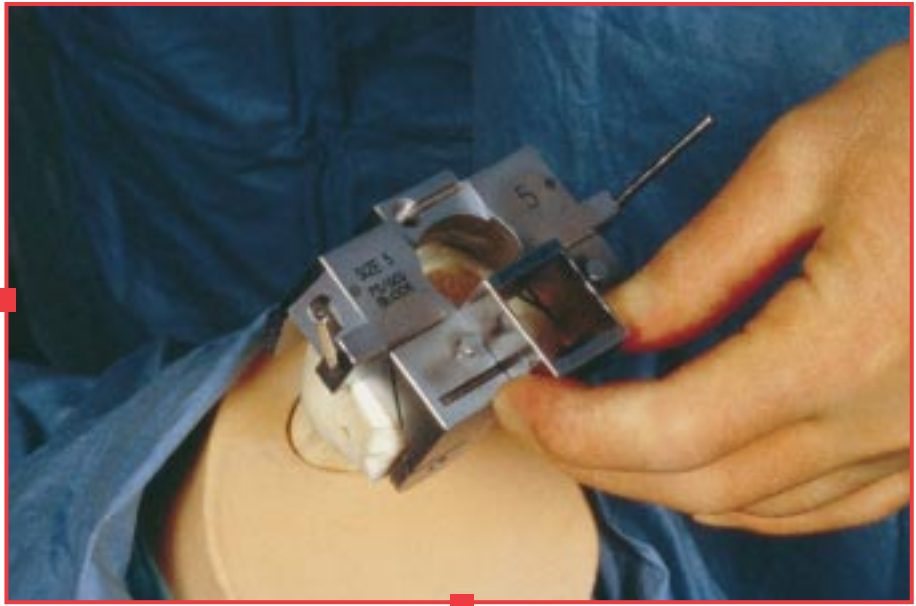


Figure 26

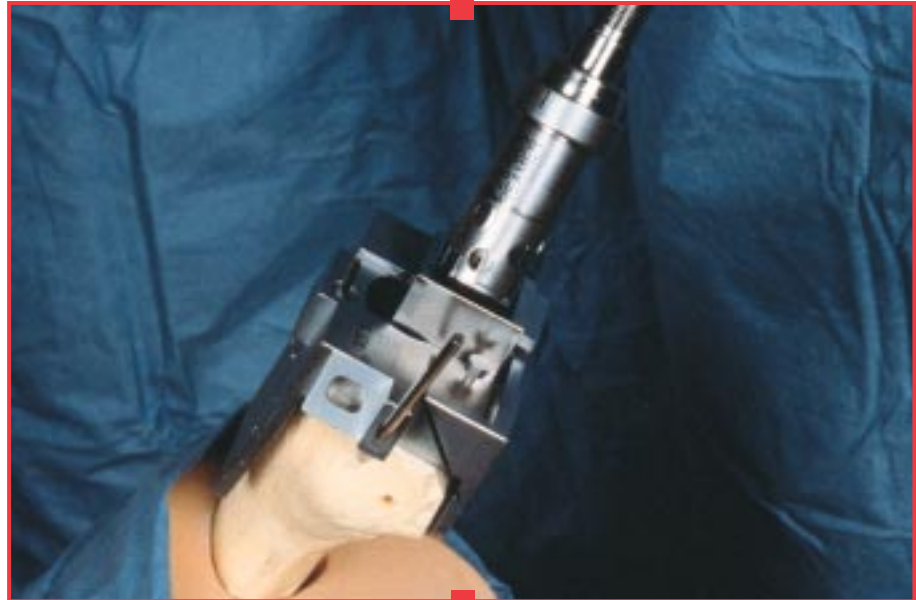


Figure 27

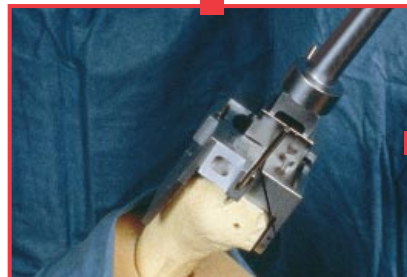


Figure 28

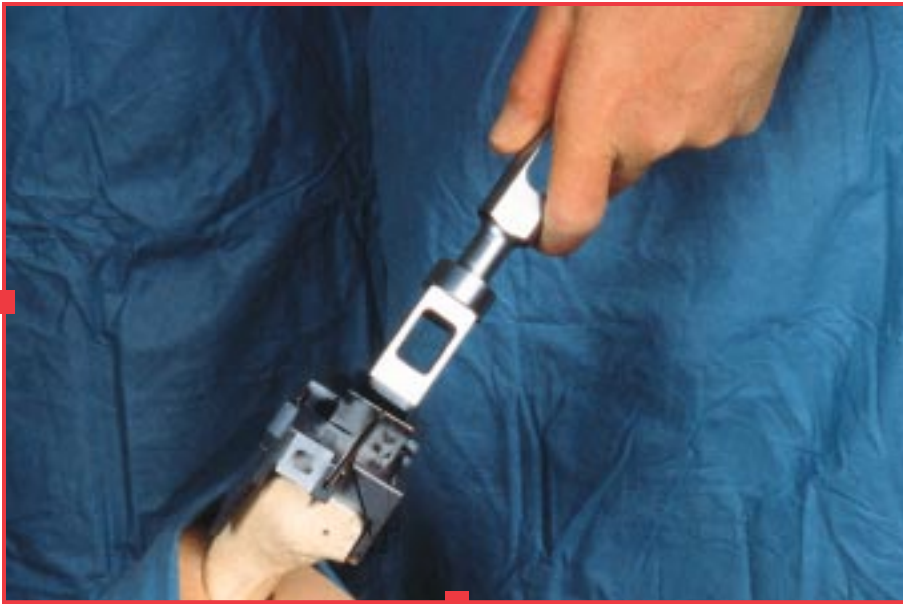


Figure 29

7 Impact the housing box chisel/sizer through the appropriate collet until the stop hits the collet. Depending upon implant size, this step might be needed twice in order to cover the full A-P dimension of the implant box. This will square off the corners of the housing (*Figure 29*).

8 Perform the anterior and posterior chamfer resections through the chamfer slots in the housing resection block (*Figure 30*).



Figure 30

9 Remove the housing resection block from the distal femur.

STEP 1: PATELLAR RESECTION

Objective—Prepare the patella for the patellar implant ensuring that the original thickness of the patella is restored.

1 Measure patellar thickness with the patellar calipers. Determine the correct design and diameter of patellar implant to be used. A resurfacing, Biconvex, or Revision Biconvex patellar implant may be chosen. The resurfacing patella is 9 mm thick and a sawblade or reamer can be chosen as a means of bony preparation. The Biconvex patella is 13 mm thick and the Revision Biconvex patella is 17 mm thick. A reamer is used to prepare for both Biconvex patellae.

2 Select the correct diameter of patellar reamer collet and slide it into place on the patellar reamer guide.

3 Attach the patellar reamer guide to the patella. Secure the patellar reamer guide on the patella by tightening the set screw (*Figure 31*).

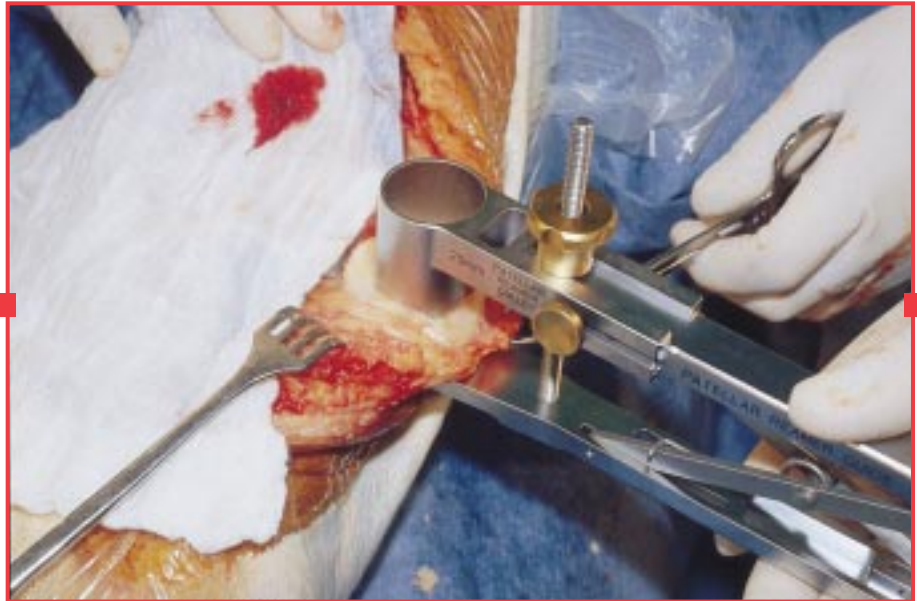


Figure 31

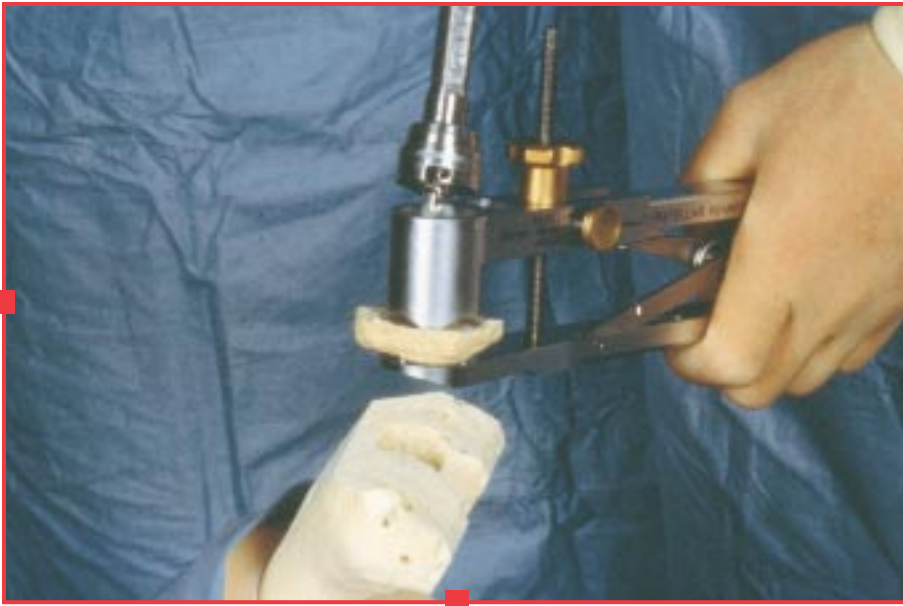


Figure 32



Figure 33

- 4** Attach the correct patellar reamer to the patellar reamer shaft. Lower the assembly through the patellar reamer guide until the reamer dome contacts the patella (Figure 32). *Note: The patellar reamer stop can be used to avoid over reaming. Once the patellar reamer is placed against the patella, the depth stop is dropped until it contacts the surface of the patellar reamer guide. The depth stop can then be backed off a couple of millimeters to allow for minimal reaming.*
- 5** Ream the patella until an adequate bed is prepared for the implant.
- 6** After reaming is complete, remove the reamer guide and place the appropriate trial patellar button in the recess to check position and total thickness. If necessary, use a rongeur to remove any prominent patellar surface.
- 7** If a resurfacing patellar prosthesis has been used, drill the three fixation holes at this time using the correctly sized resurfacing drill guide and resurfacing drill.
- 8** Place the patellar trial and measure the thickness of the composite (Figure 33).

STEP 1: FEMORAL TRIAL ASSEMBLY AND POSITIONING

Objective—Correctly assemble the femoral trial and confirm proper fit on the femur.

- 1** Select the appropriately sized femoral trial. If a long-stemmed conversion module is to be used, place it onto the posterior stabilized or cruciate retaining femoral trial at this time. The conversion module trial is held in place with augmentation lugs. These are placed through the distal aspect of the conversion module trial and threaded into the femoral trial.
- 2** If distal and/or posterior femoral wedge trials are to be used, the trial wedges are magnetized and can be simply placed onto the femoral trial.
- 3** Lastly, screw the correct trial stem onto the femoral trial.
- 4** Impact the femoral trial onto the distal femur (*Figure 34*).



Figure 34

STEP 2: TIBIAL TRIAL PLACEMENT AND TIBIAL WEDGE RESECTION

Objective—Prepare for any tibial wedge augmentation and ensure proper fit of the tibial trial.



Figure 35



Figure 36

- 1** Place a towel or lap against the distal aspect of the femoral trial. Using a Hohmann or similar retractor, sublux the tibia anteriorly.
- 2** Select the appropriate trial tibial base. If a tibial long-stem is to be used, screw it onto the tibial trial at this time. Seat this assembly onto the proximal tibia (Figure 35). The tibial trial should be rotationally symmetric with the femoral trial in full extension with the extensor mechanism reduced. Make sure that the rotational marks on the femoral trial and the articular insert trial are aligned. Mark the rotation on the tibia and remove the articular insert trial. Use spikes through the tibial trial into the proximal tibia to lock the rotational orientation of the tibial trial (Figure 36).

COMPONENT IMPLANTATION

- 3** If tibial wedges will be used, select either the full tibial wedge or the angled/stepped tibial wedge resection block. Position the appropriate tibial wedge resection block and run a modular handle through the most proximal hole of the block and into the anterior portion of the tibial trial. This will properly position the tibial wedge resection block against the anterior tibia (*Figure 37*).
- 4** Stabilize the tibial wedge resection block by placing pins through the block and into the tibia. The modular handle and tibial trial assembly are removed. Resect the proximal tibia over the surface of the tibial wedge resection block to prepare the bone for placement of a tibial wedge (*Figure 38*).
- 5** Place the appropriate tibial wedge(s) onto the distal aspect of the tibial trial. Again, the trial wedges are magnetized so that they can be simply seated onto the trials. Replace the tibial trial assembly onto the proximal tibia.
- 6** Replace any pins needed for stability and, using the appropriately sized fin punch, punch for the tibial fins (*Figure 39*).



Figure 37



Figure 38



Figure 39

STEP 3: FINAL TRIAL SEATING/CHECK

Objective—Confirm implant fit and function.

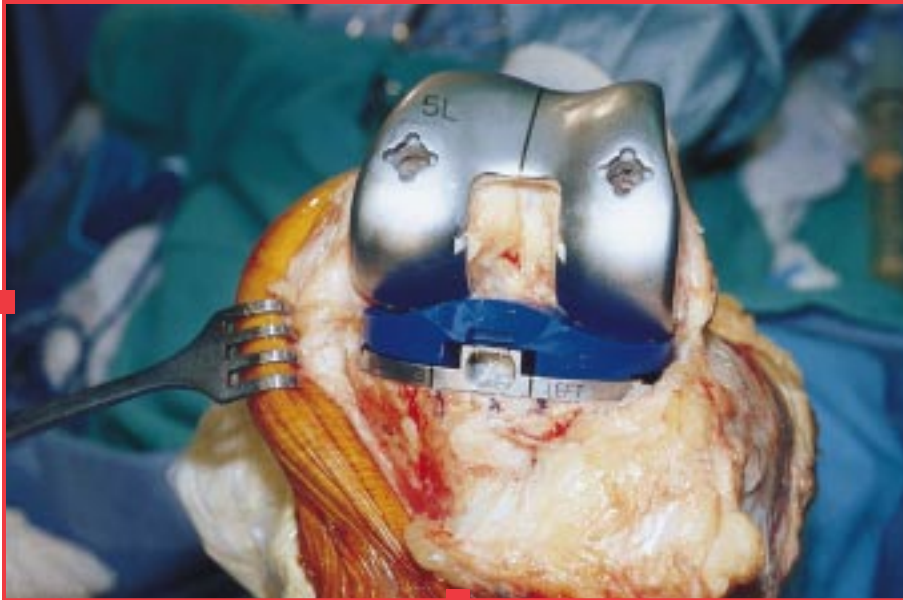


Figure 40

- 1** Place the correct tibial trial articular insert onto the tibial trial. *Note: If a constrained prosthesis is to be used, it may be necessary to lock the constrained tibial articular insert trial to the trial baseplate using one of the constrained tibial articular trial screws provided. This will ensure a stable construct when assessing joint stability.*
- 2** Place the correct patellar trial onto the patella.
- 3** With the trials in place, gently perform a trial range of motion to ascertain proper joint tension and patellar tracking (Figure 40). *Note: If the joint is loose in flexion, it may be necessary to use the next larger size of femoral trial, adding posterior augmentation to fill the flexion space. If this is necessary, a narrower diameter stem may be needed to allow proper placement of the femoral trial onto the anterior cortex. If the joint is loose in extension, distal augmentation may be added to the femoral trial to fill the extension space.*

- 4** Add a modular handle onto the anterior surface of the tibial trial. With the knee in full extension, check the mechanical axis of the limb using the long alignment rod (Figure 41).
- 5** Remove the trials. *Note: Hold onto the side of the trials to help prevent the trial wedges from disassembly during removal extraction.*



Figure 41

STEP 4: IMPLANT ASSEMBLY

Objective—Properly assemble all implants so that they will properly fit the bony resections made.

- 1** Choose the correctly sized femoral component, conversion module, wedges, stem, and patellar implant. Assemble them in the same manner that the trial was assembled. If distal wedges are chosen, use the lug that is packaged sterile along with the implant wedge. It is important to turn the torque wrench until you feel a “break” when tightening the femoral fixation lugs in place (Figure 42).

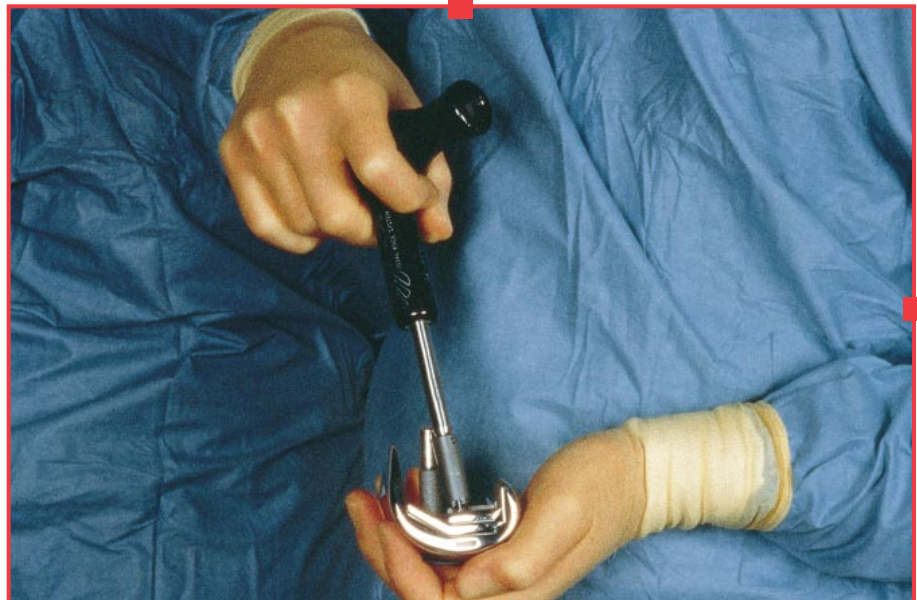


Figure 42



Figure 43

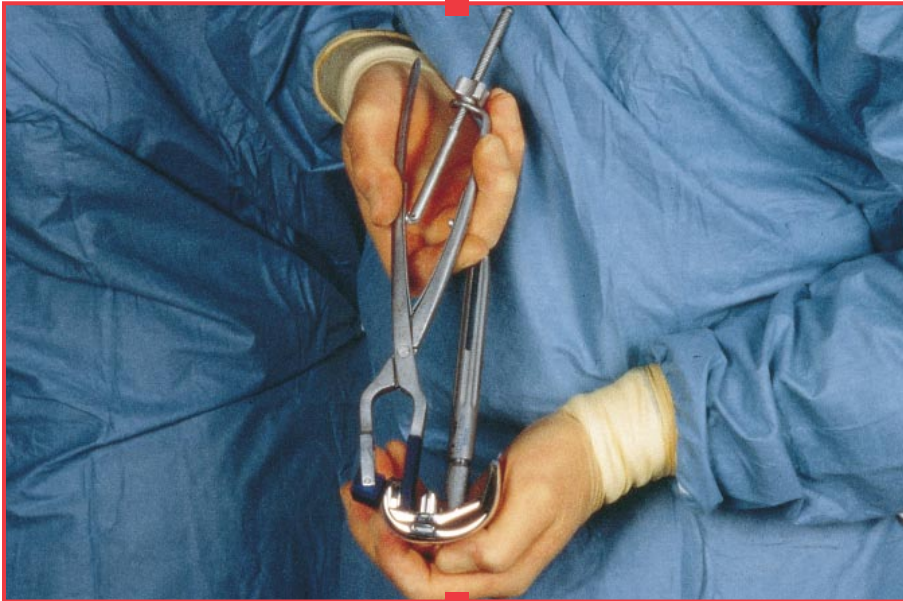


Figure 44

- 2** The femoral stem is attached to the femoral component via a Morse-type taper. If using a slotted stem, make sure that the rotational mark on the stem lines up with the rotational mark on the Morse-taper of the femoral implant. The stem should be impacted at least twice on a stable surface to ensure that the lock has been properly engaged (*Figure 43*).
- 3** If posterior wedges are used, these will be cemented to the femoral component. The wedge cement clamp is used to hold the wedges in place until the cement has hardened (*Figure 44*). *Note: All of the posterior femoral wedges, the tibial wedges, and the patellar implant can be cemented simultaneously to avoid wasting time and cement.*
- 4** Select the correctly sized tibial baseplate, tibial wedges, and stem. The tibial stem and wedges are assembled in the same manner as the femoral stem and posterior wedges.

STEP 5: IMPLANTATION

Objective—Place all implants into position so as to optimize implant function.

1 Sublux the tibia anteriorly using a Hohmann or similar retractor. Place cement onto the proximal tibia. Insert the tibial implant onto the proximal tibia and remove any excess cement. Place the correct trial tibial articular insert into the tibial baseplate and hold the limb in full extension until all cement hardens.

2 Place cement onto the distal surface of the femur and onto the posterior aspect of the femoral prosthesis. Insert the femoral implant into position (*Figure 45*). Remove any excess cement. *Note: It is important to remove all excess cement from the housing of the posterior stabilized or constrained implant.*



Figure 45

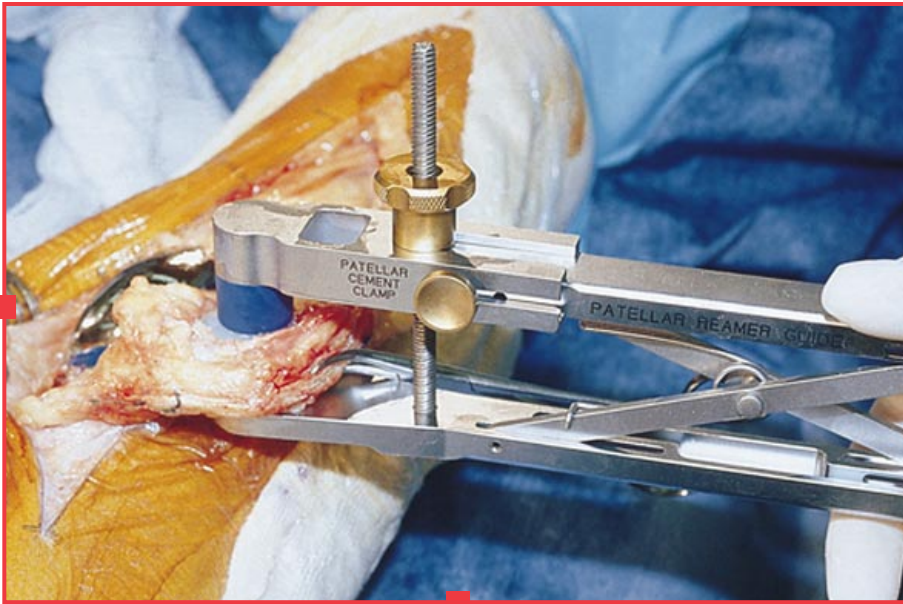


Figure 46



Figure 47

3 If the patellar implant has not yet been cemented, do so at this time. Assemble the patellar cement clamp adapter to the patellar reamer guide. Apply bone cement to the patella. Place the patellar implant onto the prepared surface of the patella. *Note: If using a resurfacing patellar implant, it is helpful to identify the three fixation holes drilled prior to positioning the patellar implant. This will help you to identify the correct rotational orientation of the implant.* Clamp the patellar implant onto the bone and remove the extruded cement (Figure 46).

4 Slide the tibial articular insert into the tibial base-plate as far posteriorly as possible, engaging the peripheral locking mechanism. Attach the tibial insertion tool to the tibial tray. Rotate the tool superiorly until the anterior lip of the articular insert is fully seated (Figure 47). *Note: A mallet should not be used when inserting the polyethylene. A mallet can cause damage to the insert's locking mechanism.*

CLOSURE

Close in the usual manner.



IMPORTANT MEDICAL INFORMATION

SMITH & NEPHEW KNEE SYSTEMS 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 6A1-4V 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 organisms 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-PTM 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 preempt 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 contra-indicated 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 RESTERILIZE 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	Maximum Pressure	Concentration	Exposure Time
10% EtO 90% HCFC	130°F (55°C)	40-60%	28 PSIA (1930 millibars)	550-650 mg/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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Additional patents pending. GENESIS, Flex-Lok and Tricon are trademarks of Smith & Nephew, Inc.
This system is intended for cemented use only.