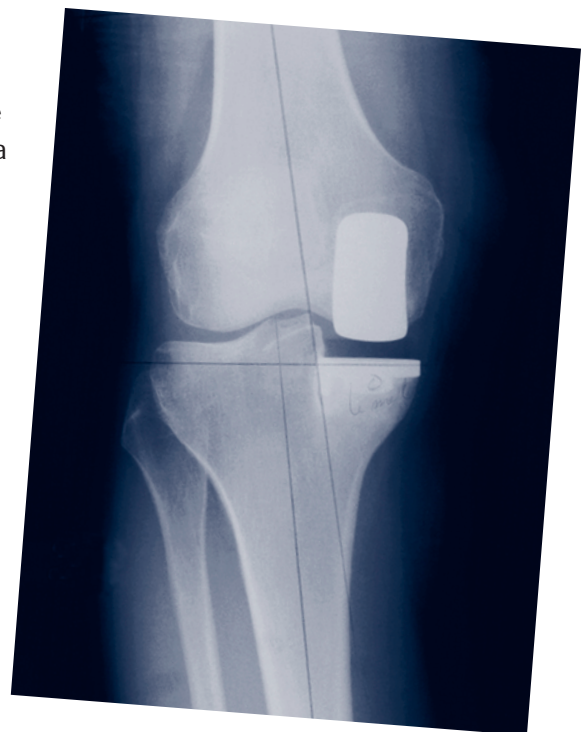




Minimally Invasive
Unicompartmental Knee System
Surgical Technique

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Nota Bene: The technique described herein is made available to the healthcare professional to illustrate a suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.



Surgical Technique Contributors:

Leo A. Pinczewski, M.D.
North Sydney Orthopaedic and Sports Medicine Centre
Sydney, Australia

William B. Smith, M.D.
Assistant Clinical Professor in Orthopaedic Surgery
Medical College of Wisconsin
Columbia Hospital
Milwaukee, Wisconsin

Genesis^{††} Unicompartmental Implants Designed in Conjunction With:

James R. Andrews, M.D.
Clinical Professor of Orthopaedics and Sports Medicine
University of Virginia Medical School
Orthopaedic Surgeon
Alabama Sports Medicine & Orthopaedic Center
Birmingham, Alabama

Philippe Cartier, M.D.
Orthopaedic Surgeon
Clinique des Lilas
Paris, France

Introduction

The Accuris[†] minimally invasive unicompartmental knee system is unique in that ligamentous balancing of the joint is achieved before bone cuts are made for implantation of the prosthesis. Once the joint has been balanced with the joint balancing shims, all bony resections are then referenced off the shim. This allows for accurate tibio-femoral resections. A unique femoral reaming system referencing off the cut surface of the tibia then resurfaces the distal femur as the knee is taken through its natural range of joint motion. Furthermore, the Accuris minimally invasive knee system is versatile, allowing surgeons to choose between an inlay or onlay surgical approach.



Through an anteromedial arthrotomy the joint is examined. Providing the gross degeneration change is limited to the medial compartment and the patient's cruciate ligaments are intact, it is possible to proceed with a unicompartmental knee replacement. In positioning the patient for surgery, the surgeon must be able to pass the knee through a range of motion from full extension through to approximately 110° of knee flexion.

Marginal osteophytes are resected from the medial femoral condyle and the medial femoral trochlear groove. The medial meniscus is resected and any large tibial osteophytes are removed. This should allow passive correction of the knee joint's varus deformity with normal tensioning to the medial collateral ligament. If the joint is unable to be passively corrected to a neutral alignment at this time then the surgeon must proceed to total knee replacement. If the joint alignment is satisfactory in extension then the Accuris system may be utilized.

Though the majority of UKA will affect the medial compartment of the knee joint, this technique is also suited for lateral compartment UKA. However, the lateral compartment is technically more challenging and should not be attempted until experience has been gained with medial compartment UKA.

The following technique may be used with either a cobalt chrome femoral component or an Oxinium[†] oxidized zirconium femoral component.

Tips Prior To Surgery

Implants:

- The Accuris System utilizes the Genesis Uni implants. A standard set configuration allows one to complete a single uni procedure. This generally means 1 each femoral size, 1 each metal-backed tibial base, and 2 each of the poly components. You will need to double this requirement for a bilateral uni case, but may only wish to have 3 each of the poly components.

Power equipment:

- The Accuris instruments require use of a drill, oscillating saw and reciprocating saw for the procedures. The cutting block is designed to work with the Profix narrow sawblade or the Genesis II narrow sawblade. The reciprocating sawblade needs to be about 3" long to work most effectively.
- The Accuris Power System will need to be reviewed by the Biomedical department prior to surgery, so plan on this ahead of the case.

Ordering other disposables for an Accuris case:

- The powered femoral and tibial cutters (tibial cutters are needed only for the Inlay Surgical Technique) in the Accuris System are shipped sterile and disposable. It is recommended that you have 2 of each cutter in your set.
- It is also recommend that you keep a range of fixation drills/pins in your Accuris set including: 3.2 mm x 3" trochar pins, short bone spikes, and 3.2 mm x 5" drills.

Onlay Surgical Technique

An anteromedial arthrotomy is made to the level of the tibial tubercle. A medial meniscectomy is performed, and the intercondylar notch must be clearly visualized. Part of the fat pad should be resected. All marginal osteophytes are resected from the affected femoral and tibial condyles to avoid "tenting" of the medial ligamentous structures and allow joint balancing.

NOTE: The surgical axiom is visualization, so extend the incision to the point that visualization is adequate.



1. Insert the appropriate Joint Balancing Shim (1,2,3 or 4 mm) allowing for normal physiological laxity in the medial compartment of the joint from 0-90°. If the shim prevents full flexion and the joint becomes too tight, then select a thinner shim. Once the joint is balanced with the shim, then the contact point of the shim superiorly represents the restored joint line.

NOTE: All retractors must be removed from the surgical site during the balancing procedure so that the stability of the knee can be properly assessed.

NOTE: Keep in mind that the Joint Balancing Shims are best used to assess the balance in extension and early flexion as most UKA patients have anterior-medial wear and often cartilage remains more posterior.



2. Flexing the knee joint to 90°, the appropriate Joint Balancing Shim is left in place. Slide the 8 mm Tibiofemoral Cutting Block over the Joint Balancing Shim through the middle slot until it touches the anterior aspect of the tibia.

NOTE: The 9 mm Tibiofemoral Cutting Block may be selected if more polyethylene thickness is desired.



3. Select the Onlay Alignment Connector with the desired posterior slope (3 and 7 degree options available). By inserting the extension guide of the Onlay Alignment Connector into the lower slot of the Tibiofemoral Cutting Block, a predefined amount of posterior slope is set.



4. Pre-assemble the Extramedullary Tibial Alignment System. Attach the system to the Onlay Alignment Connector through the slot above the varus/valgus guide. Once the desired varus/valgus position is achieved, pin the Cutting Block to the proximal tibia. One pin is placed in the hole guide closest to the tibial spine. A second pin is placed through the opposite oblique pinhole at the bottom of the Cutting Block. The Tibial Alignment System and Alignment Connector are then removed leaving the Joint Balancing Shim and Tibiofemoral Cutting Block pinned to the proximal tibia.

TIP: Before pinning the cutting block, place the reciprocating saw blade into the slot for the vertical tibial cut to provide a “line of sight” to the posterior aspect of the tibia. This will help the surgeon visualize the orientation of the cutting block to ensure it is not exhibiting too much internal or external rotation. It will also ensure that the tibial vertical cut does not hit the cruciate attachment.

TIP: Place a pin through the central slot of the Extramedullary Alignment System to dial in the appropriate varus/valgus slope.



5. With the knee flexed to 110°, resect the posterior femur through the superior slot of the Cutting Block.

NOTE: The Joint Balancing Shim remains in place during the posterior femoral resection process and tibial rotation should remain physiologic.

NOTE: The amount of femoral bone removed is about 5 mm.

TIP: In tight knees and large knees it may be desirable to cut on top of the cutting block which removes an additional 2-3 mm of femoral bone. This additional bone resection does not lead to flexion instability in UKA.



6a. Resect the proximal tibia through the inferior slot of the Cutting Block.

6b. Complete the tibial resection by using a reciprocating saw in the vertical cutting slot. Remove the Pins, Cutting Block and Shim.

NOTE: The amount of proximal tibia removed is the difference between the shim thickness and the block size. For instance, a 2 mm shim used with an 8 mm cutting block will remove about 6 mm of proximal tibia ($8 - 2 = 6$ mm). The thickness of the shim combined with the thickness of the proximal tibia resection will likely be equivalent to the total thickness of the tibial construct.

7. Remove the posterior femoral fragment and the proximal tibial fragment. Next, resect the posterior remnant of the medial meniscus.

TIP: Joint exposure can be assisted by inserting Taylor (or Hohmann) retractors into the distal most femoral trochlear groove and another about the medial aspect of the joint.



8. Place the appropriate size Tibial Onlay Base Trial on the resected proximal tibia and secure it in place with 2 small pins.

TIP: Before pinning the tibial base trial, make sure the proximal tibial cut bone is completely removed in the posterior region and completely flat. Some remaining bone/meniscus may be attached to the posterior/spine cut area. Cut/rasp any remaining bone to ensure proper seating of the tibia baseplate.

TIP: You may place the cut tibia section on top of the appropriate tibial trial to estimate the appropriate baseplate trial size.



9. Place the Tibial Trial Insert onto the Tibial Onlay Baseplate. Bring the knee into full extension. Scribe the “tide mark” at the point where the anterior edge of the femoral component will articulate with the insert in full extension.

NOTE: The Tibial Onlay Baseplate should be pinned flush on the tibia.

TIP: The center groove of the Tibial Trial Insert may also be scribed onto the distal femur to note the center of the femoral component.



10. Select the appropriate Femoral Reamer that corresponds to the compartment being replaced. Attach the Femoral Reamer to the Tibial Onlay Baseplate by aligning the dovetail on the bottom of the Femoral Reamer with the guide slot on the top of the Tibial Onlay Baseplate. Insert the Femoral Reamer until it reaches the most posterior aspect of the Tibial Baseplate trial.

NOTE: There are two types of Femoral Reamers, LM/RL (left medial/right lateral) and RM/LL (right medial/left lateral).



11. Set the Accuris Power System Control Unit to resect the appropriate compartment. The settings are LM/RL (left medial/right lateral) and RM/LL (right medial/left lateral) and should match the selected Femoral Reamer.



12. Position the knee such that the Femoral Reamer will begin resurfacing just anterior to the posterior femoral cut (no additional posterior femoral resection is necessary).

13. Step on the foot pedal connected to the power system. Allow the femoral reamer to reach full speed prior to distal resection.

14. Resurface the distal femur by slowly moving the knee from flexion to full extension, removing enough bone to provide a bed for the femoral component and ensure preservation of the joint line.

NOTE: The Femoral Reamer will remove about 3-4 mm of distal bone. The resection depth may be estimated by visualizing the path created by the Femoral Reamer with respect to the native femoral surface.

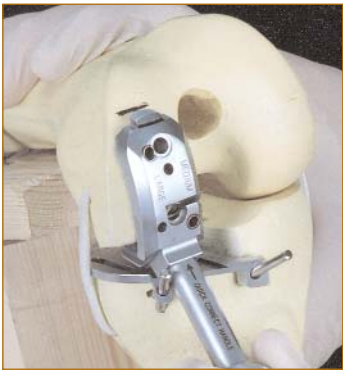
TIP: To facilitate preparation of the distal femur, use an oscillating saw or bone rasp to remove the posterior chamfer corner of the femur prior to engaging the femoral reamer.

TIP: To prevent the Femoral Reamer from “biting” into the femur, a slight valgus stress may be applied as the knee is extended. Multiple passes may be necessary in the case of particularly hard bone.

TIP: When using the Femoral Reamer, start reaming in flexion and extend the knee slowly. Do not rush the reaming process or bounce the cutter on the femur. Keep the cutter well irrigated by introducing saline solution. This allows the cutter to run cooler and keeps the joint free of debris. Apply suction to clear debris as needed.

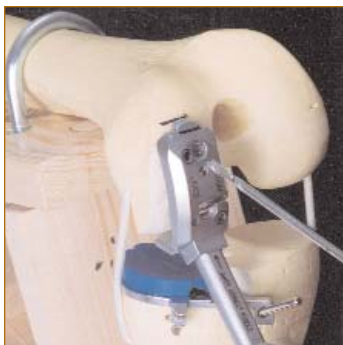
TIP: If the Femoral Reamer does not reach the anterior tide mark, proceed with the following steps:

- Stop femoral reaming.
- Slightly flex the knee and pull the Femoral Reamer slightly “anteriorly” in the dovetail slot.
- Extend the knee again until the Femoral Reamer reaches the tide mark.
- Resurface the remaining distal femur to the point of the tide mark.



15. Assemble the Quick Connect Handle to the Femoral Sizer/ Secondary Reamer Drill Guide. Place the sizing guide onto the distal femur with the posterior paddle flush with the cut posterior surface of the femoral condyle. The correct size is determined by matching the notch on the Femoral Sizer with the tide mark on the distal femur.

TIP: In some knees the quick connect handle may impinge on the tibia. In this case remove the handle and use a large mosquito to hold the Femoral Sizer/Secondary Reamer Drill Guide in place.

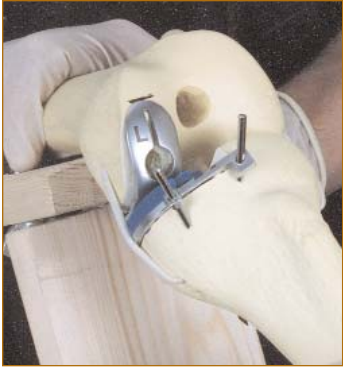


16. Prepare for the spikes on the Femoral Finishing Trials by drilling through the two offset laser etched holes on the Femoral Sizer/Secondary Reamer Drill Guide.

NOTE: The femoral trial spikes are located in the same position on the Femoral Finishing Trials, allowing upsizing or downsizing of the trials once the holes have been drilled. The only exceptions are the x-small/small trials.



17. The Tibial Onlay Insert Trial is placed on to the Tibial Onlay Baseplate. Attach the appropriate sized Femoral Finishing Trial to the Femoral Handle/Drill Guide and then impact the Femoral Finishing Trial onto the femur. Remove the Femoral Handle/Drill Guide leaving the femoral trial in place.



18. Perform a trial range of motion to assess proper knee function, alignment, and ligament balancing.

NOTE: All Genesis Uni femoral and tibial components are fully interchangeable.



19. Reattach the Femoral Handle/Drill Guide to the Femoral Trial and drill through the Femoral Handle/Drill Guide using the Femoral Lug Drill.

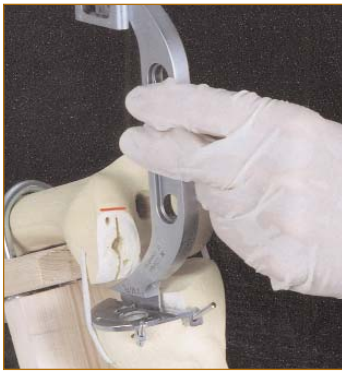


20. Cut a channel for the stabilizing fin of the prosthesis. The depth of the fin cut should mirror the depth of the fin on the femoral prosthesis.

21a. If an All-Poly Onlay Tibial component is to be used, proceed to step 22.



21b. With the knee flexed to 110-120° of flexion, place the Tibial Drill Guide over the Tibial Onlay Base Trial. Drill through the Tibial Drill Guide using the Tibial Boss Drill. When using a screw, drill with the Tibial Boss/Screw Drill; when using a peg, use the Tibial Boss/Peg Drill.



21c. Place the Tibial Fin Punch through the punch guide of the Tibial Onlay Base Trial and impact the fin punch to prepare for the fin of the final Tibial Baseplate.



22. The implants are then cemented in situ following the removal of the trial components. The wound is closed in the usual manner.

TIP: *Pre-assemble the tibial components prior to implantation.*

Inlay Surgical Technique

An anteromedial arthrotomy is made to the level of the tibial tubercle. A medial meniscectomy is performed, and the intercondylar notch must be clearly visualized. Part of the fat pad should be resected. All marginal osteophytes are resected from the affected femoral and tibial condyles to avoid “tenting” of the medial ligamentous structures and allow joint balancing.

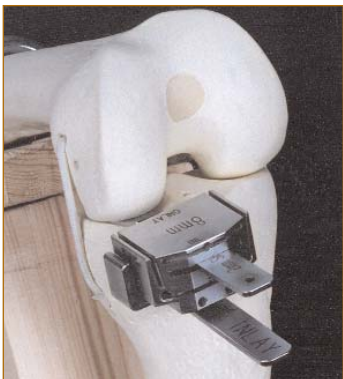
NOTE: The surgical axiom is visualization, so extend the incision to the point that visualization is adequate.



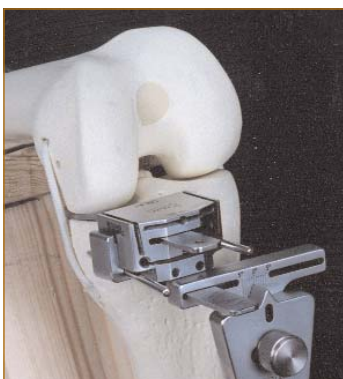
1. Insert the appropriate Joint Balancing Shim (1,2,3 or 4 mm) allowing for normal physiological laxity in the medial compartment of the joint from 0-90° of flexion. If the shim prevents full flexion and the joint becomes too tight, then select a thinner shim. Once the joint is balanced with the shim, then the contact point of the shim superiorly represents the true joint line.

NOTE: All retractors must be removed from the surgical site during the balancing procedure so that the stability of the knee can be properly assessed.

NOTE: Keep in mind that the Joint Balancing Shims are best used to assess the balance in extension and early flexion as most UKA patients have anterior-medial wear.

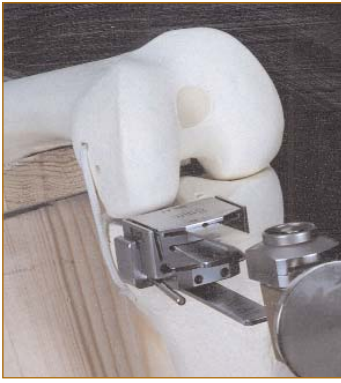


2. Select the Inlay Alignment Connector with the desired posterior slope (3 and 7 degree options available). By inserting the extension guide of the Inlay Alignment Connector into the lower slot of the Tibiofemoral Cutting Block, a predefined amount of posterior tibial slope is set. Slide the Inlay Alignment Connector/Tibiofemoral Cutting Block assembly onto the joint balancing shim through the middle slot of the block until it touches the anterior aspect of the tibia.



3. Pre-assemble the Extramedullary Tibial Alignment System. Attach the system to the Inlay Alignment Connector through the slot above the varus/valgus guide. Once the desired varus/valgus position is set, pin the Cutting Block to the proximal tibia. One pin is placed in the hole closest to the tibial spine. A second pin is placed through the opposite oblique pinhole at the bottom of the Inlay Alignment Connector. Remove the Extra Medullary Tibial Alignment System, leaving the Joint Balancing Shim, Tibiofemoral Cutting Block/Inlay Alignment Connector assembly pinned to the proximal tibia.

TIP: Place a pin through the central slot of the Extramedullary Alignment System to dial in the appropriate varus/valgus slope.



4. With the knee flexed to 110°, resect the posterior femur through the superior slot of the Cutting Block.

NOTE: The Joint Balancing Shim and Inlay Alignment Connector/Tibiofemoral Cutting Block assembly remain in place during the posterior femoral resection.

NOTE: The amount of femoral bone removed is about 5 mm.

TIP: In tight knees and large knees it may be desirable to cut on top of the cutting block which removes an additional 2-3 mm of femoral bone. This additional bone resection does not lead to flexion instability in UKA.



5. Remove the Joint Balancing Shim and Cutting Block, leaving the Inlay Alignment Connector pinned to the proximal tibia.



6. Place the Tibial Base Inlay Sizing Template on the tibia and mark the appropriate size.

TIP: A joint distractor may be used to improve visualization and access to the joint.



7. Connect the Tibial Inlay Cutter to the Accuris Power System Control Unit and press the button marked "Tibia".

8. Step on the foot pedal connected to the power system. Allow the Tibial Inlay Cutter to reach full speed before starting to resurface the proximal tibia.

9. Resect the proximal tibia using the Tibial Inlay Cutter and move the cutter within the confines of the marked area. Ream until the Tibial Inlay Cutter is flush against the Inlay Alignment Connector.

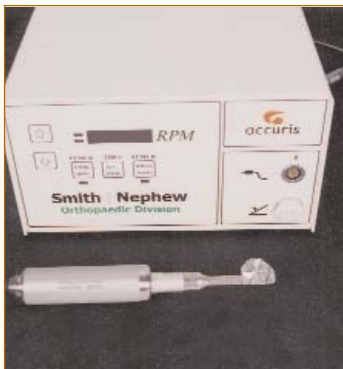


10. Place the appropriate size Tibial Inlay Insert Trial in the resected proximal tibia. Position the knee in full extension and scribe the "tide mark" onto the anterior aspect of the femoral condyle. The tide mark represents the anterior position of the femoral implant with the knee in full extension. Remove the Tibial Inlay Base Trial.

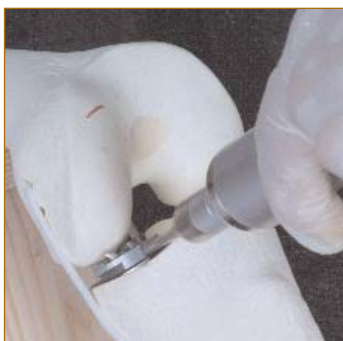


11. Select the appropriate Femoral Reamer that corresponds to the compartment being replaced. Attach the Femoral Reamer to the Tibial Inlay Base Trial by aligning the dovetail on the bottom of the Femoral Reamer with the guide slot on the top of the Tibial Inlay Base Trial. Insert the Femoral Reamer until it reaches the most posterior aspect of the Tibial Baseplate trial.

NOTE: There are two types of Femoral Reamers, LM/RL (left medial/right lateral) and RM/LL (right medial/left lateral).



12. Set the Accuris Power System Control Unit to resect the appropriate compartment. The settings are LM/RL (Left medial/right lateral) and RM/LL (right medial/left lateral), and should match the selected Femoral Reamer.



13. Place the Femoral Cutter/Tibial Inlay Base Trial assembly in the resected proximal tibia with the Inlay Base Trial resting flat against the floor of the tibial resection. Position the knee such that the Femoral Reamer will begin resurfacing just anterior to the posterior femoral cut (No additional posterior femoral resection is necessary).

14. Step on the foot pedal connected to the power system. Allow the Femoral Reamer to reach full speed before starting to resurface the femur.

15. Resurface the distal femur by slowly moving the knee from flexion to full extension, removing just enough bone to provide a bed for the femoral component and ensure preservation of the joint line.

NOTE: The Femoral Reamer will remove about 3-4 mm of distal bone. The resection depth may be estimated by visualizing the path created by the reamer with respect to the native femoral surface.

TIP: To facilitate preparation of the distal femur, an oscillating saw or bone rasp may be used to prepare a small posterior chamfer, prior to engaging the Femoral Reamer.

TIP: To prevent the Femoral Reamer from “biting” into the femur, a slight valgus stress may be applied as the knee is extended. Multiple passes may be necessary in the case of particularly hard bone.

TIP: When using the Femoral Reamer, start reaming in flexion and extend the knee slowly. Do not rush the reaming process or bounce the cutter on the femur. Keep the cutter well irrigated by introducing saline solution. This allows the cutter to run cooler and keeps the joint free of debris. Apply suction to clear debris as needed.

TIP: If the Femoral Reamer does not reach the anterior tide mark, proceed with the following steps:

- Stop femoral reaming.
- Slightly flex the knee and pull the Femoral Reamer slightly “anteriorly” in the dovetail slot.
- Extend the knee again until the Femoral Reamer reaches the tide mark.
- Resurface the remaining distal femur to the point of the tide mark.



16. Assemble the Quick Connect handle to the Femoral Sizer/Secondary Reamer Drill Guide. Place the sizing guide onto the distal femur with the posterior paddle flush with the cut posterior surface of the femoral condyle. The correct size is determined by matching the notch on the Femoral Sizer with the tide mark on the distal femur.

TIP: In some knees the quick connect Handle may impinge on the tibia. In this case remove the handle and use a large mosquito to hold the Femoral Sizer/Secondary Reamer Drill Guide in place.



17. Prepare for the spikes on the Femoral Finishing Trials by drilling through the two laser etched holes on the Femoral Sizer/Secondary Reamer Drill Guide.

NOTE: The femoral trial spikes are located in the same position on the femoral finishing trials, allowing upsizing or downsizing of the trials once the holes have been drilled. The only exceptions are the x-small/small trials.



18. Place the Tibial Inlay Trial on the tibia. Attach the appropriate sized Femoral Finishing Trial to the Femoral Handle/Drill Guide. Impact the Femoral Finishing Trial onto the distal femur. Remove the Femoral Handle/Drill Guide, leaving the femoral trial in place.



19. Perform a trial range of motion to assess proper knee function, alignment, and ligament balancing.

NOTE: All Genesis Uni femoral and tibial components are fully interchangeable.



20. Reattach the Femoral Handle/Drill Guide to the Femoral Finishing Trial, drill through the Femoral Handle/Drill Guide using the Femoral Lug Drill.



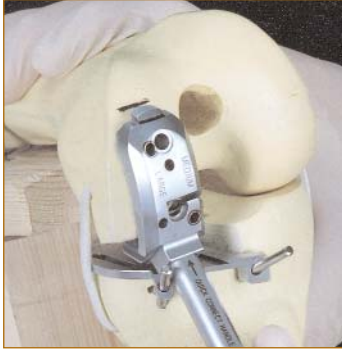
21. Cut a channel for the stabilizing fin of the prosthesis. The depth of the fin cut should mirror the depth of the fin on the femoral prosthesis.

22. The implants are then cemented in situ following the removal of the trial components. The wound is closed in the usual manner.

Alternate Reaming Surgical Technique

This technique may be used in lieu of the Accuris Power Control System.

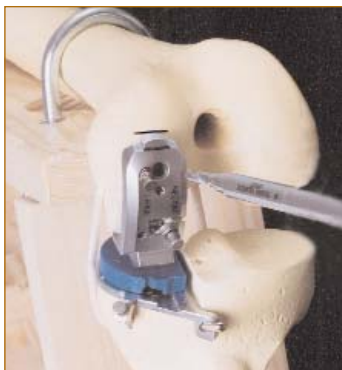
Proceed with steps 1-9 of the standard Onlay Surgical Technique.



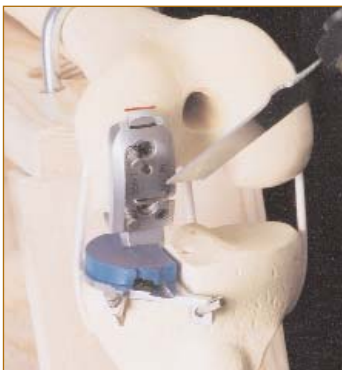
10. The appropriate size Femoral Sizer/Secondary Reamer Drill Guide is then pinned onto the distal femur with the posterior paddle flush with the cut posterior surface of the femoral condyle. The correctly sized femoral component is indicated by the anteriorly located notch on the Femoral Sizer/Secondary Reamer Drill Guide most closely corresponding with the “tide mark” on the distal femur.

TIP: In some knees the quick connect handle may impinge on the tibia. In this case remove the handle and use a large mosquito to hold the Femoral Sizer/Secondary Reamer Drill Guide in place.

TIP: Pin the Femoral Sizer/Secondary Reamer Drill Guide using the pin holes that match the spikes on the Femoral Finishing Trial.

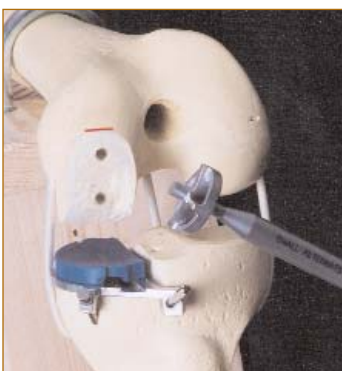


11. The Alternate Reamer Drill is then placed into the anterior and posterior center holes and advanced to prepare for the Alternate Reamer.



12. Resect the posterior chamfer through the slot on the Femoral Sizer/Secondary Reamer Drill Guide.

TIP: The posterior pin may need to be removed so as to not interfere with the posterior chamfer cut.



13. Select the appropriately sized Alternate Femoral Reamer and ream the distal femur anteriorly and posteriorly until the proper depth is achieved (3-4 mm of distal bone).

TIP: Care should be taken not to use excessive force when resurfacing the femoral condyle as this may result in over reaming, particularly in soft bone.

Continue with step 17 of the standard Onlay Surgical Technique.

MEDICAL INFORMATION

Smith & Nephew Knee Systems For Cemented Use Only

DESCRIPTION

Femoral components are cobalt chromium alloy or OxiniumTM oxidized zirconium alloy. Conversion modules are cobalt chromium alloy. Patellar components, all-polyethylene tibial components, tibial articular inserts, and Flex-Lok¹ pegs are ultra-high molecular weight polyethylene. Components that are made of only polyethylene may include x-ray marking wire made of stainless steel or cobalt chromium. Tibial trays, patellar bases, tibial and femoral wedges, tibial and femoral stems, screws, and pegs are titanium 6A1-4V alloy or cobalt chromium alloy. Porous coated cobalt chromium and titanium components feature a porous coating of cobalt chromium beads and unalloyed titanium beads, respectively. Hydroxylapatite (HA) coatings include HA 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.

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. Skeletal immaturity
8. Use of a supracondylar nail through intercondylar notch of Profix[†] primary femoral components
9. Use of slotted femoral and tibial stems with out adequate bone support.

Indications for Unicompartmental Knee Replacement

1. Noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
2. Correction of functional deformity
3. Revision procedures where other treatments or devices have failed; and
4. Treatment of fractures that are unmanageable using other techniques.

Contraindications for Unicompartmental Knee Replacement

The contraindications for Unicompartmental Knee Replacement include all of the contraindications listed for Total Knee Replacement.

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. Secondarily, 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. An implant should never be reused. While it may appear undamaged, imperfection may exist which would reduce the service life of the implant.
8. Use the Genesis¹ Torque Wrench to secure the distal femoral wedges and the conversion modules to the Genesis femoral component with femoral lugs. Use the Genesis II Torque Wrench to secure the distal femoral wedges and the conversion modules to the Genesis II femoral component with femoral lugs. The femoral lugs should be torqued to 70 in-lbs. Use the Mobile Bearing Rotation Peg Torque Wrench to secure the rotation peg to the Mobile Bearing Baseplate. The rotation peg should be torqued to 75 in-lbs.

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.
- For the United Kingdom, sterilization should be carried out in accordance with HTM 2010. The recommended prevacuum sterilization cycle is: Evacuation to 100mBar for 2-3 minutes, Negative Pressure pulsing (5): 800mBar-100mBar, Positive Pressure pulsing (5): 2.2Bar - 1.1 Bar, Sterilization exposure: 3 minutes at 134°-137°C, Drying vacuum 40mBar for 5-10 minutes.
Note: mBar absolute.
- Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum dwell time at temperature of 10 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
100% EtO	131°F (55°C)	40-80% (70% Target)	10 PSIA (689 millibars)	725 mg/l	60-180 minutes

Suggested initial starting point for aeration validation is 12 hours at 120°F (49°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.

Authorized EC Representative:

Smith & Nephew Orthopaedics GmbH, Tuttlingen, Germany

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

¹Trademark of Smith & Nephew, Reg. U.S. Pat. & Tm. Off. ¹¹Trademark of Smith & Nephew.

Manufacturing facilities and EC representative:

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Smith & Nephew, Inc.

1450 Brooks Road

Memphis, TN 38116 U.S.A.

1-800-821-5700 1-901-396-2121

For orders and order inquiries: 1-800-238-7538

www.smithnephew.com/orthopaedics

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