

Minimally Invasive
Surgical Technique

 **smith&nephew**
ACCURIS[®]
Uni Knee System



ACCURIS[®] Uni-Compartmental Knee System

Minimally Invasive Surgical Technique

Contents

Introduction	4
Tips Prior to Surgery	5
Frequently Asked Questions	7
Using the ACCURIS Power Reaming System	9
Onlay Surgical Technique	10
Inlay Surgical Technique	16
Alternate Reaming Surgical Technique	21
Medical Information	22

Surgical Technique Contributors:

Joseph E. Burkhardt, DO

Great Lakes Bone and Joint Center
Battle Creek Michigan

Stephen Davenport, MD

Orthopedic Associates
Oklahoma City, Oklahoma

Keith Frederick, DO

Frederick Knee Center
Phelps County Regional Medical Center
Rolla, Missouri

Craig Levitz, MD

South Nassau University Hospital
Oceanside, NY

Leo A. Pinczewski, MD

North Sydney Orthopaedic and
Sports Medicine Centre
Sydney, Australia

William B. Smith, MD

Assistant Clinical Professor in Orthopaedic Surgery
Medical College of Wisconsin
Columbia Hospital
Milwaukee, Wisconsin

Mark Snyder, MD

Wellington Ortho & Sports Medicine
Cincinnati, Ohio

GENESIS[®] Uni-Compartmental Implants Designed in Conjunction with:

James R. Andrews, MD

Clinical Professor of Orthopaedics and
Sports Medicine
University of Virginia Medical School
Orthopaedic Surgeon
Alabama Sports Medicine & Orthopaedic Center
Birmingham, Alabama

Philippe Cartier, MD

Orthopaedic Surgeon
Hartman Knee Institute
Clinique Hartman
Paris, France

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.

Introduction

The ACCURIS® minimally invasive uni-compartmental 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 tibiofemoral 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.

An important part of the pre-operative assessment of a patient for a Unicompartamental replacement includes an assessment of the mechanical axis. Most authors in the orthopedic literature agree that for a medial uni replacement, the knee should be slightly under-corrected, that is the post-operative mechanical axis should be in slight varus. This is necessary since over-correction (into valgus for a medial Uni) has been shown to cause accelerated wear of the native cartilage of the lateral side. Just as it is not desirable to end up with over-correction, it is also not desirable to end up with excessive under-correction, since this can lead to accelerated poly wear and loosening. Therefore, when assessing the knee pre-operatively, the surgeon should consider what the mechanical axis is likely to be at the end of the procedure. Since at this time ligament releases are not routinely used during a Uni replacement, a useful assessment of this angle can be accomplished pre-operatively. This can be done clinically by observing the correction achieved by the application of a valgus force with the knee in 15° flexion. By this method, a surgeon can identify pre-operatively those patients that are likely to be over-corrected if a Uni is done as well as those that would remain excessively under-corrected and can therefore choose another treatment option for those patients.

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 uni-compartmental 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.

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 saw blade or the Genesis II narrow sawblade. The reciprocating saw blade 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.
- The ACCURIS Motor Handpiece is labeled “do not immerse” - it can, however, be sterilized. Just follow these guidelines.

Sterilize the motor assembly using one of the following options:

Prevacuum Flash Cycle: 4 pulses (Maximum = 2.8 bars) & Minimum = 10.0 in Hg (339 millibars) with a minimum exposure time of 4 minutes at 270°F to 275°F (132°C to 135°C), followed by a 1 minute purge.

High Temperature Gravity Cycle: 270°F to 275°F (132°C to 135°C) with a minimum exposure time of 10 minutes, followed by a 1 minute purge and at least 15 minutes of vacuum drying.

Prevacuum Cycle: 4 pulses (Maximum = 26.0 psig (2.8 bars) & Minimum = 10.0 in Hg (339 millibars) with a minimum exposure 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.

Recommended Uk Sterilization Parameters

Prevacuum Cycle: Evacuation to 100 mBar for 2-3 minutes, Negative Pressure Pulsing (5): 800 mBar-100 mBar, Positive Pressure pulsing (5): 2.2 Bar - 1.1 Bar, Sterilization Exposure: 3 minutes at 134°-137°C, Drying Vacuum 40 mBar for 5-10 minutes. Note: mBar absolute.”

Ordering other disposables for an ACCURIS[°] case:

- The “one use only” 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.

Tips Prior to Surgery *continued*

- It is also recommend that you keep a range of fixation drills/pins in your ACCURIS set including: 3.2 mm x 3" trocar pins, short bone spikes, and 3.2 mm x 5" drills.
- If utilizing the femoral sizer drill guides (a.k.a. "spikeless trials"), it is recommended that you make sure you have a hemostat or other surgical tool that effectively holds these trials.
- Ensure that the hospital has a reciprocating saw. Make sure to have the appropriate reciprocating blades. Here are some that are recommended:
 - 1) Stryker # 277-96-300. 78 mm. This is the thinnest that will work.
 - 2) 277-96-325 Angled down - ok.
 - 3) 277-96-350 Best, angled down and thick.

Frequently Asked Questions

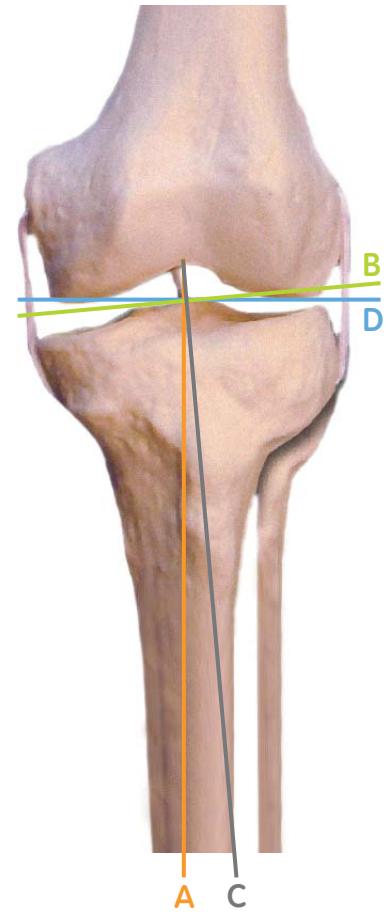
Q: Why does the Accuris system have a varus angle option for the tibial component?

A: Most uni knee systems force a 90° horizontal tibial cut, the same is with a TKA. Accuris allows the surgeon to choose either a 90° horizontal tibial cut or to dial in a degree of varus through the use of the mechanism on the extramedullary guide.

In a TKA, the tibial component is placed perpendicular to the tibial mechanical axis. The weight bearing line will be straight through the center of the knee so that there will be no shear stress on the components.

Some uni surgeons, such as Dr. Philippe Cartier, advise that a uni should not be treated as half of a total knee. With a uni, the weight bearing line lies medial to the center of the knee, and therefore a line perpendicular to the weight bearing line will be in slight varus, because the knee is in slight varus (mandatory undercorrection). Therefore, in order to avoid shear stress on the components in a uni, the components need to be placed perpendicular to the weight bearing line, not perpendicular to the tibial mechanical axis.

The varus angle corresponding to the authentic tibial bow is the angle between A and C. When the angle is more than 5° the UCA arthroplasty is contraindicated. It corresponds to the Accuris extramedullary alignment guide and is typically 1-5°. Incidentally, a line drawn perpendicular to the weight bearing line (from center of the ankle to center of the hip) in a valgus stress view coincides with the line drawn parallel to the joint line that is used to produce the varus angle.

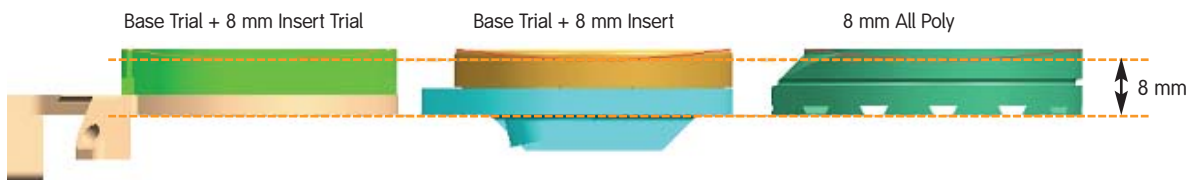


- A** - Tibial mechanical axis: center of the knee to the middle of the ankle
- B** - Line tangential to the external tibial plateau
- C** - Line perpendicular to the B line
- D** - Line perpendicular to the A line

Frequently Asked Questions *continued*

Q: If a plastic trial insert is 8 mm, doesn't the trial metal baseplate add to the total thickness, therefore affecting the trial range of motion?

A: The insert takes into account the thickness of the baseplate. For example, what is marked as an 8 mm insert is actually 5 mm thick to account for the 3 mm thick baseplate. The total construct will be 8 mm. The same goes for the implants, though the dimensions are different. For an 8 mm metal backed baseplate and insert combination, you will pick up an insert labeled "8 mm" when in fact it is 6 mm to account for the 2 mm baseplate implant. The diagram below illustrates this concept. Keep in mind that the implant baseplate has a perimeter so that you can't see the true 2 mm thickness once the insert is snapped in.



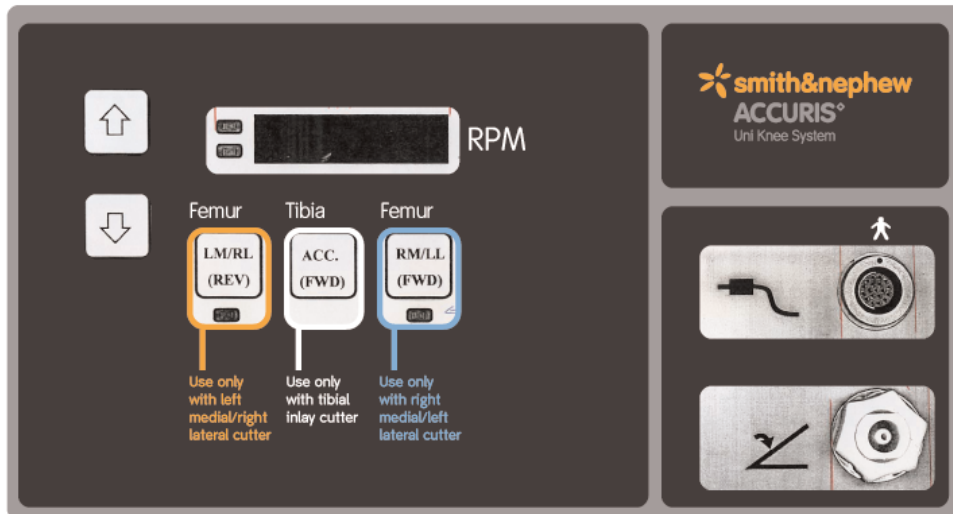
Q: Since there is only one size of the range of motion reamer, how do you account for the seven different femoral sizes?

A: The medial/lateral difference between the sizes is small. The total difference between an XS and MG+ is 7 mm. The reamer cuts a track that is ideal for the midrange sizes. For an XS, there will be a mm or two on either side of the implant, and for a MG+ it will be necessary to trim the edges with a Rongeur to seat the implant.

Q: How interchangeable are the sizes on the femur and tibia?

A: Any size femur with any size tibia. With a "round-on-flat" design, any size femur will mate with any size tibia. The tibia is actually almost flat - every size has a five inch radius, making it spherical but nearly flat, and the femoral components are rounded, so the design is nearly non-constrained. In most cases, the sizes will not vary by more than one size up or one size down.

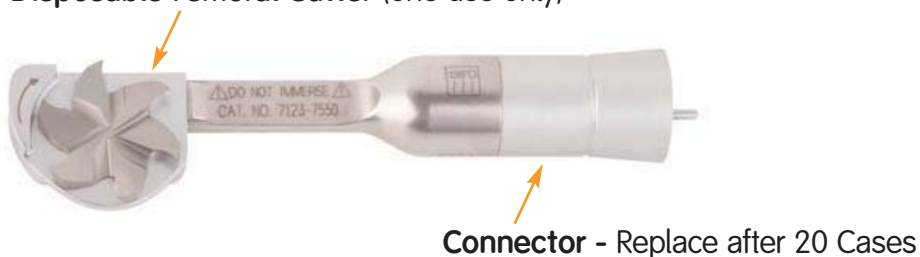
Using the ACCURIS[®] Power Reaming System



ACCURIS Power Box Front Cover

1. The Accuris power system is designed to run the RM/LL disposable femoral cutters in a counter-clockwise direction, and the LM/RL cutters in a clockwise direction.
2. You must make sure to press the button and check the indicator on the power system so that it matches the intended cutter.
3. A mismatch can result in intra-operative breakage.
4. The cutters are single-use only. Once used, they cannot be re-sterilized.
5. The connector piece can be sterilized and re-used, but it should be replaced periodically, approximately after every 20th case.
6. The handpiece motor and cord should not be immersed in water, but can be wiped with antiseptic cloth and gas sterilized.
7. The power box is outside the sterile field and should be wiped with an antiseptic cloth.
8. The foot pedal is outside the sterile field and should be wiped with an antiseptic cloth.
9. Periodic maintenance and calibration. The Accuris power console is an electronic piece of equipment and requires no periodic maintenance or calibration. If there are any problems with the console or handpiece motor, it will be sent to Smith & Nephew and replaced.

Disposable Femoral Cutter (one use only)



Onlay Surgical Technique

This technique primarily describes a proposed treatment for varus knees. 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 with an adequate opening. 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.” Further preparation may include the release of the tibial arm of the semi-membranosus tendon. This allows for external tibial rotation during jig placement and implant insertion, as well as posterior cement removal.

The intercondylar notch has to be open and osteophytes taken out. If an anterior bony block is present in front of the ACL, it has to be removed.”

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

1. Make a freehand vertical tibial cut with a reciprocating saw. This cut determines the rotation and medial-lateral position of the implant. Leave the blade embedded in the bone. It will serve as a reference for aligning the cutting block. This cut does not have to be too deep; you can complete the cut later through the vertical slot in the cutting block (**Figure 1**).
2. 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. If there is a dished tibial surface, the anterior bony block may have to be resected to allow the shim to sit properly (**Figure 2**).

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.

3. 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 (**Figure 3**).

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

4. Select the Onlay Alignment Connector with the desired posterior slope. The 3 degree slope is more often indicated than the 7. The 7° slope connector is exceptional and used only for specifically indicated anatomy and should not be used if the ACL is present but of poor quality. 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 (**Figure 4**).

Leave reciprocating saw blade embedded in bone.

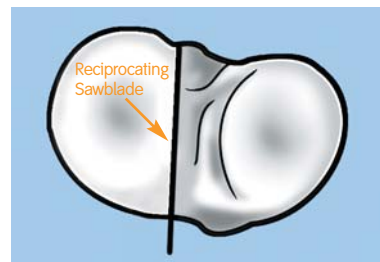


Figure 1

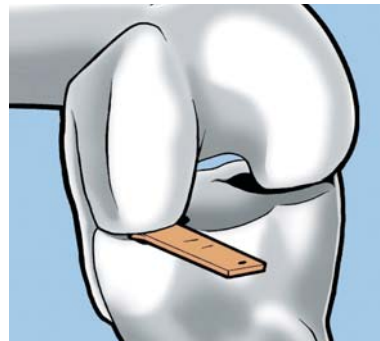


Figure 2

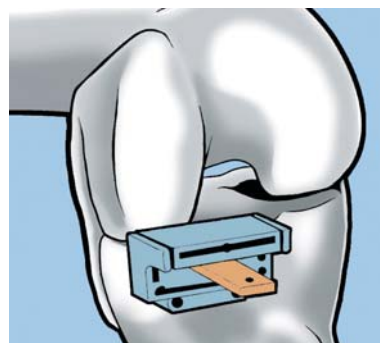


Figure 3

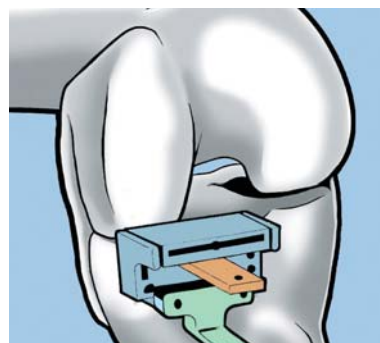


Figure 4

- The long axis of the extramedullary alignment guide should be placed parallel to the tibia. Once this is established, the desired degree of varus or valgus can be dialed in using the mechanism at the top of the guide. Two schools of thought on tibial alignment include: 1) neutral alignment (perpendicular to the tibial axis) or 2) medial slope away from the tibial spine, parallel to the joint line, as espoused by Dr. Philippe Cartier. This angle is typically about 3 degrees. It is crucial to make sure that the ankle clamp is firmly fixed and parallel to the tibia either by hand or with a spring before pinning the block. Once the preferred slope is achieved, lock the guide into place and insert the pins. Pins are inserted medially and laterally into the tibiofemoral cutting block. In a medial uni, the medial pinhole is straight and at the top of the block, while the lateral pinhole is at the bottom of the block at an oblique angle. Once pinned, remove the connector and alignment guide (**Figure 5**).

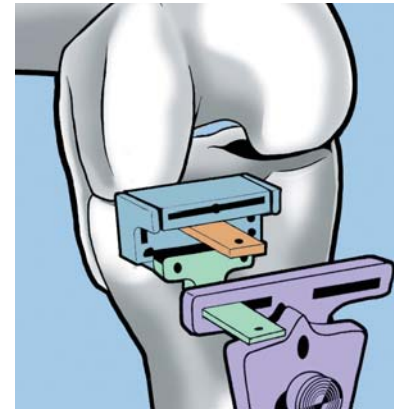


Figure 5

- With the knee flexed to 110°, resect the posterior femur through the superior slot of the Cutting Block (**Figure 6**).

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.

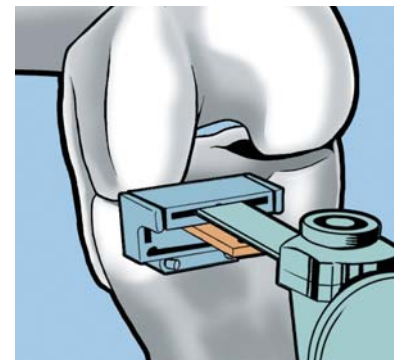


Figure 6

- Resect the proximal tibia through the inferior slot of the Cutting Block.

Complete the tibial resection by using a reciprocating saw in the vertical cutting slot. Remove the Pins, Cutting Block and Shim (**Figure 7**).

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 ($8 - 2 = 6\text{mm}$). 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.

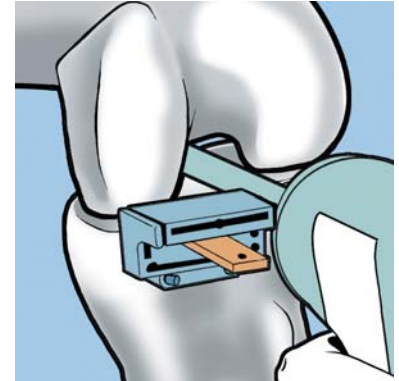


Figure 7

- 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.

- Place the appropriate size Tibial Onlay Base Trial on the resected proximal tibia and secure it in place with 2 small pins (**Figure 9**).

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.



Figure 9

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

Onlay Surgical Technique *continued*

10. 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 (**Figure 10**).

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.

11. 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 (**Figure 11**).

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 (**Figure 12**).

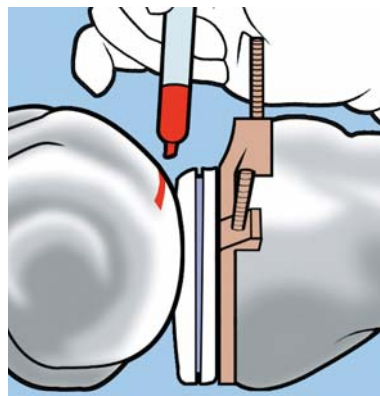


Figure 10

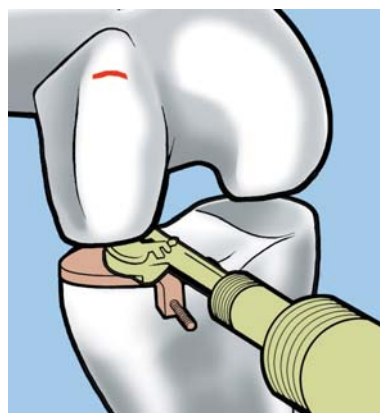


Figure 11

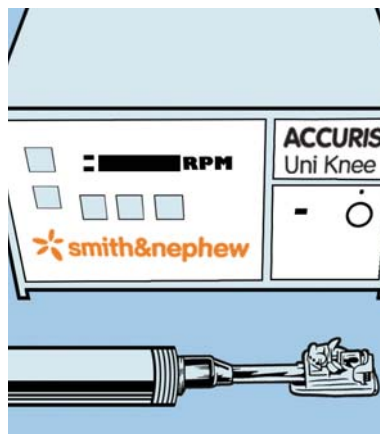


Figure 12

13. Make a chamfer cut of 2-3 millimeters at 45 degrees to the posterior cut. This can be done either freehand or with the sizer guide block. Make sure to preserve this chamfer cut. Position the knee such that the femoral reamer will begin resurfacing just anterior to the chamfer cut. No resurfacing of the chamfer cut is necessary.
14. Step on the foot pedal connected to the power system. Allow the femoral reamer to reach full speed prior to distal resection.
15. 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. An assistant can hold the reamer while the surgeon focuses on the patient's physiology (**Figure 15**).

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.

16. Hold one of the seven femoral sizer drill guides (a.k.a spikeless trials) with a hemostat or other preferred instrument. Use the holes marked “hold” (**Figure 16a**). Determine the size of the femoral component by making sure the posterior portion of the component is flush with the posterior cut, and that the anterior taper reaches the tide mark. Align for rotation using the vertical mark. Drill for the spikes. A pin can be placed in the first hole before drilling the second hole to make sure the holes line up correctly (**Figure 16b**).

TIP: There is also another option for sizing the femur - see the femoral sizer/secondary reamer drill guide appendix.

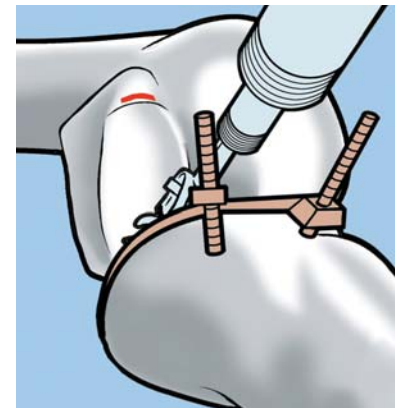
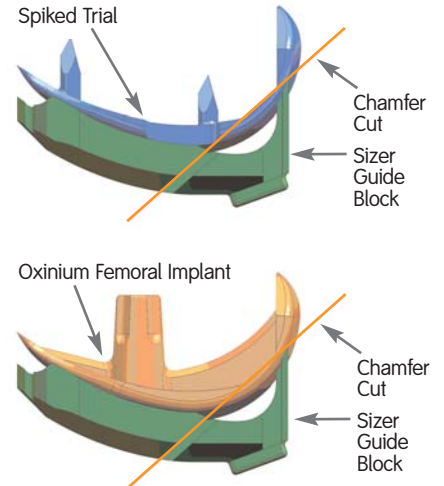


Figure 15

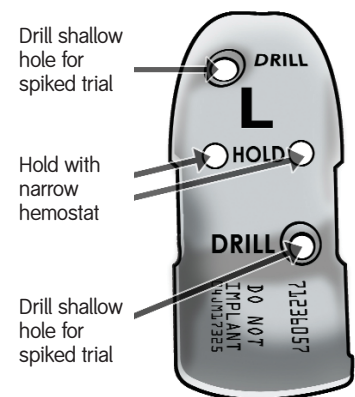


Figure 16a



Figure 16b

Onlay Surgical Technique *continued*

- Align the trial and drill through the offset holes for the spikes in the spiked trials. In an XL, MG or MG+ it may be necessary to slightly widen the track with a Rongeur.

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.

- Instructions for loading femoral trials on the trial holder:
Loosen the thread nut with minimal force. Pull the outer handle towards the nut until it snaps. The two wings will be pressed inward, allowing the trial to be loaded. Load a spiked femoral trial on the holder. Note that the posterior side is marked "P" and the anterior "A." Push the outer handle towards the trial so that the wings snap outward, locking in the trial. Tighten the threaded nut with minimal force. Place the femoral trial on the femur (**Figure 18**).
- Perform a trial range of motion to assess proper knee function, alignment, and ligament balancing (**Figure 19**). It is a good practice to remove all fixation pins, and trial with the components still in place, unfixed. With proper alignment, you will observe no tibial plateau tilting, no rocking, and slight laxity at 15° of flexion."
NOTE: All GENESIS® Uni femoral and tibial components are fully interchangeable.
- Reattach the Femoral Handle/Drill Guide to the Femoral Trial and drill through the Femoral Handle/Drill Guide using the Femoral Lug Drill (**Figure 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 (**Figure 21**).

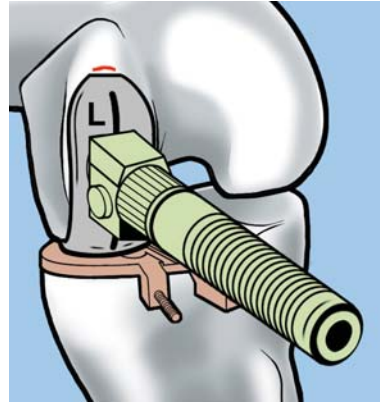


Figure 18

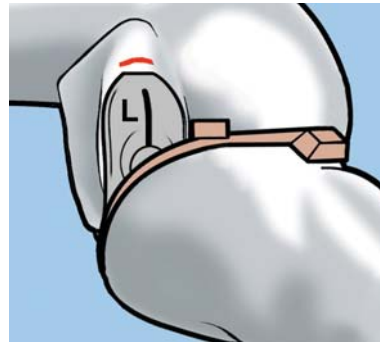


Figure 19

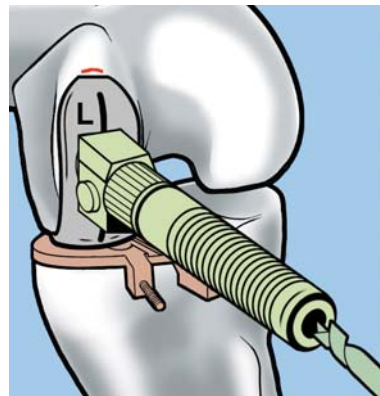


Figure 20

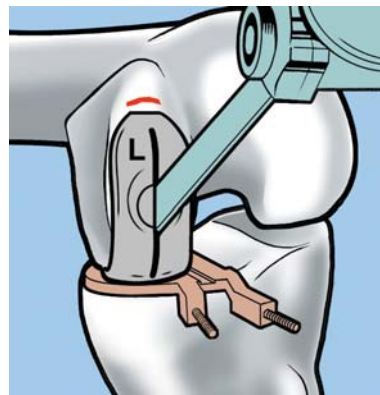


Figure 21

22. If an All-Poly Onlay Tibial component is to be used, proceed to step 23.

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 (**Figure 22a**).

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 (**Figure 22b**).

23. The implants are then cemented in situ following the removal of the trial components. The wound is closed in the usual manner (**Figure 23**).

TIP: Pre-assemble the tibial components prior to implantation. If you are using a metal backed tibial implant, please take care when assembling the two components. The straight edge of the poly must seat underneath the lip on the baseplate first. Then the curved side can be snapped in. Make sure there is no debris on either component, which could impair assembly.

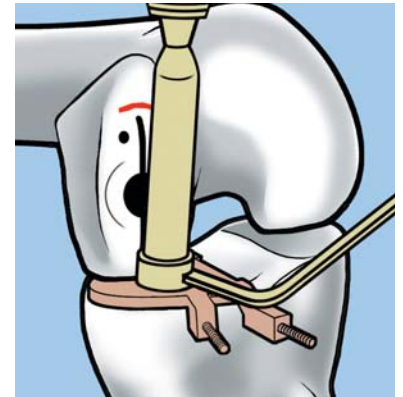
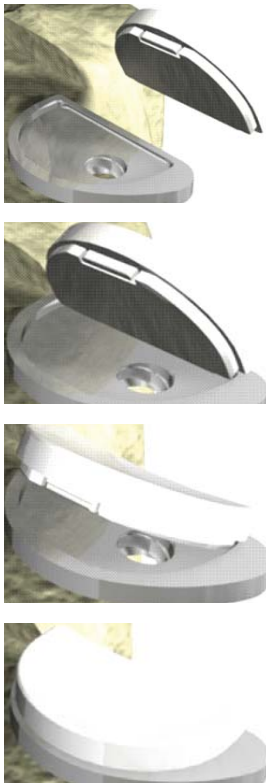


Figure 22a



Figure 22b



Figure 23

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. If there is a dished tibial surface, the anterior bony block may have to be resected to allow the shim to sit properly (**Figure 1**).

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 (**Figure 2**).
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 (**Figure 3**).

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

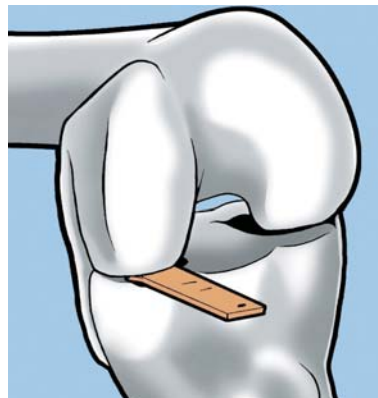


Figure 1

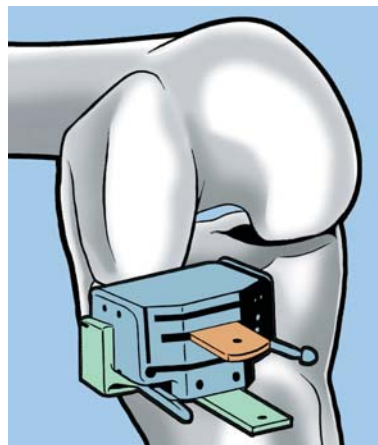


Figure 2

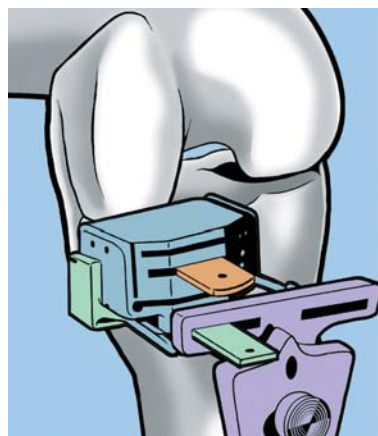


Figure 3

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

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 (**Figure 5**).
6. Place the Tibial Base Inlay Sizing Template on the tibia and mark the appropriate size (**Figure 6**).

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

TIP: Some surgeons prefer to clear the main portion of bone with a larger debulking burr then proceed to use the ACCURIS® 90 degree cutter to finish the implantation site.

7. Connect the Tibial Inlay Cutter to the ACCURIS Power System Control Unit and press the button marked "Tibia" (**Figure 7**).
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.

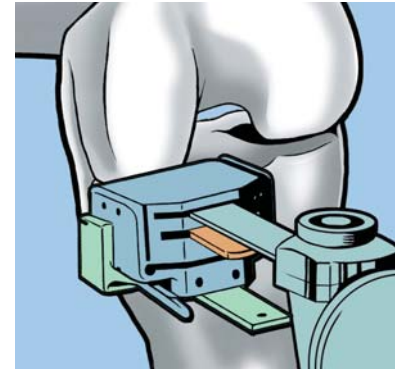


Figure 4

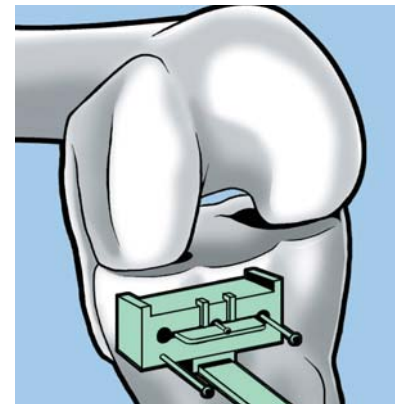


Figure 5

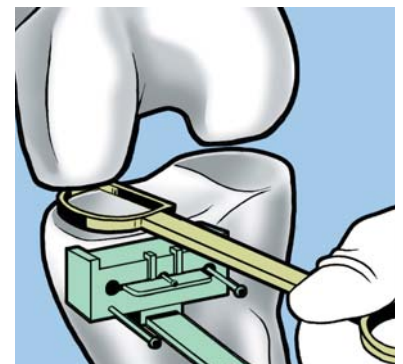


Figure 6

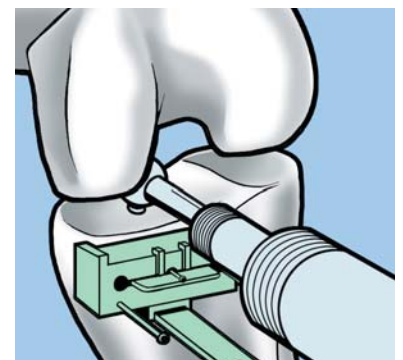


Figure 7

Inlay Surgical Technique *continued*

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 (**Figure 10**).



Figure 10

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 (**Figure 11**).

TIP: Cut a channel in the cortical rim adjacent to the tibial spine with the tibial reamer to allow room for the neck of the femoral reamer. This allows the femoral reamer to sit in the floor of the tibial implantation site.

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

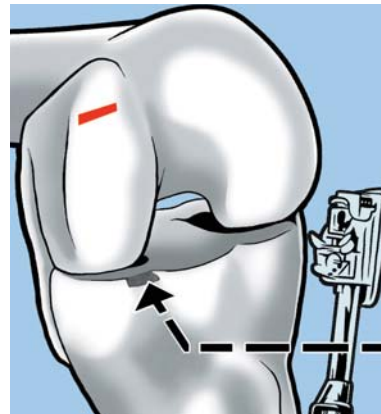


Figure 11

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 (**Figure 12**).

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) (**Figure 13**).

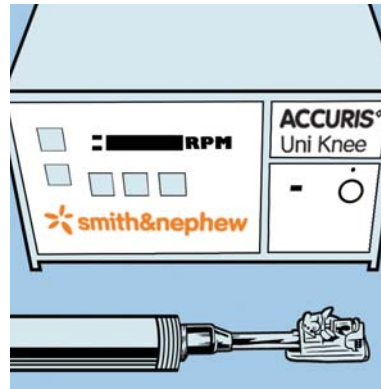


Figure 12

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.

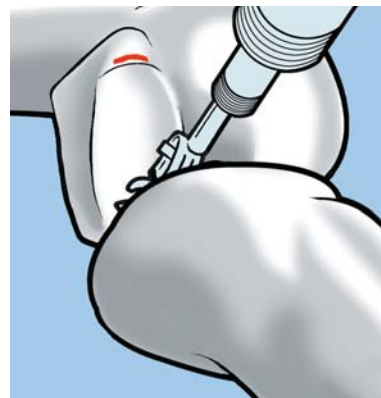


Figure 13

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. Hold one of the seven femoral size drill guides (a.k.a. spikeless trials) with a hemostat or other preferred instrument. Use the holes marked “hold” (**Figure 16a**). Determine the size of the femoral component by making sure the posterior portion of the component is flush with the posterior cut, and the anterior taper reaches the tide mark. Align for rotation using the vertical mark. Drill for the spikes. A pin can be placed in the first hole before drilling the second hole to make sure the holes line up correctly (**Figure 16b**).

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. 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 (**Figure 17**).

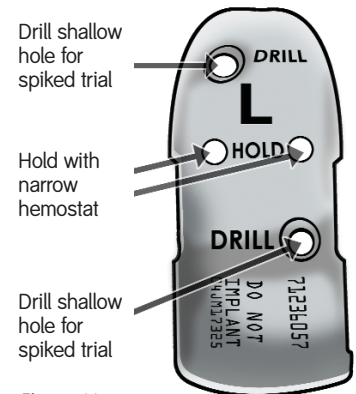


Figure 16a



Figure 16b

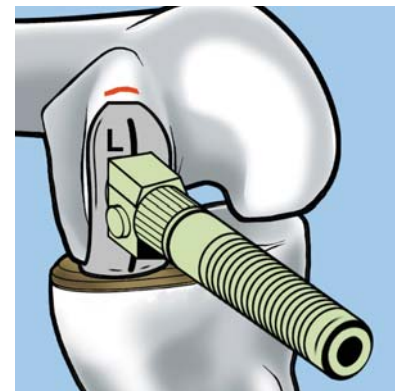


Figure 17

Inlay Surgical Technique *continued*

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

NOTE: All GENESIS[®] Uni femoral and tibial components are fully interchangeable.

19. Reattach the Femoral Handle/Drill Guide to the Femoral Finishing Trial, drill through the Femoral Handle/Drill Guide using the Femoral Lug Drill (**Figure 19**).

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.

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

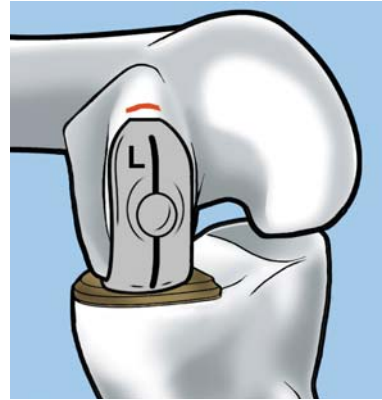


Figure 18

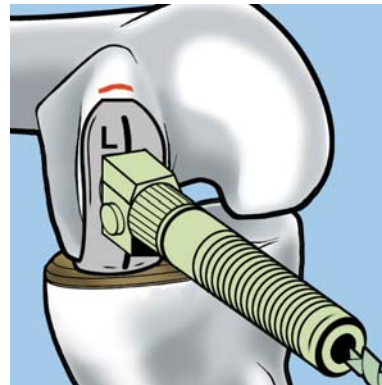


Figure 19



Figure 20

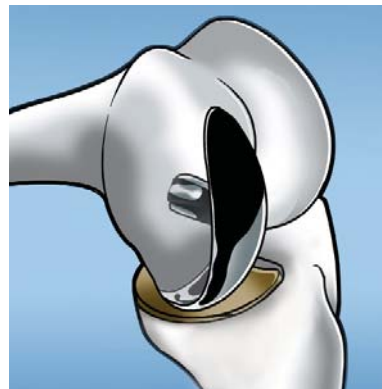


Figure 21

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 hemostat 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.



Figure 10



Figure 11



Figure 12



Figure 13

Description

Femoral components are cobalt chromium alloy or OXINIUM[®] oxidized zirconium alloy. Conversion modules are cobalt chromium alloy. Patellar components, all-polyethylene tibial components, tibial articular inserts, and FLEX-LOK[®] 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 6Al-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 orthopaedic 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, uni-compartmental 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 without adequate bone support.

Indications for Uni-compartmental Knee Replacement

1. Non-inflammatory 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 Uni-compartmental Knee Replacement

The contraindications for Uni-compartmental 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. 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. 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 GENESIS[®] 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

Non-porous 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:

- a) 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.
- b) 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.

- c) 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	Concentrations	Exposure Time
100%EO	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.

Manufacturing facilities and EC representative:

81006811 Rev. 10/05

Orthopaedic Reconstruction

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

www.smith-nephew.com

Telephone: 1-901-396-2121
Information: 1-800-821-5700
Orders/Inquiries: 1-800-238-7538