Surgical Technique

Innovations in Minimally
Invasive Joint Surgery

smith&nephew

Minimally Invasive TKA
GENESIS® II Anterior Cut First

Instruments

Valgus Alignment
Guide Left
71441111

Valgus Alignment
Guide Right
71441112

Rotation Alignment
Paddles
71441163

Femoral Alignment
Template
71441141

Anterior Cutting
Guide Left
71441116

Anterior Cutting
Guide Right
71441117

Anterior Resection
Stylus
71441115

Distal Femoral
Cutting Block
71441118

Distal Resection
Stylus
71441161

Femoral Sizing Guide
71441113

4-in-1 Cutting Block
Size 1-71441119
Size 2-71441120
Size 3-71441121
Size 4-71441122
Size 5-71441123
Size 6-71441124
Size 7-71441125
Size 8-71441126

Housing Resection Block
Size 1-71441127
Size 2-71441128
Size 3-71441129
Size 4-71441130
Size 5-71441131
Size 6-71441132
Size 7-71441133
Size 8-71441134

Tibial Cutting
Block Left
71441136

Tibial Cutting
Block Right
71441137

Tibial Resection Stylus
71441135

Surgical technique described by Steven B. Haas, M.D., M.P.H.

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

Leg Position
Appropriate leg position is crucial when performing minimally invasive total knee arthroplasty. During the procedure, the knee is flexed to 70-90°. Hyperflexion is used only intermittently for specific portions of the case, such as insertion of the tibial component. To aid in holding the leg, a sandbag is placed across from the contralateral ankle when positioning the patient on the table.

Incision
With the leg fully extended, a longitudinal incision is made over the anterior aspect of the knee along the medial border of the patella.

Arthrotomy
Begin five millimeters medial to the tibial tubercle and extend dissection around the medial border of the patella. The arthrotomy is extended up to the proximal border of the patella.

The supra-patella pouch is identified, separated from the underside of the tendon and preserved.

The distal extent of the vastus medialis (VMO) is identified and the orientation of the fibers is determined. An oblique cut is made to the VMO and the muscle fibers are then spread bluntly for approximately 2 centimeters. *(Figure 1)*

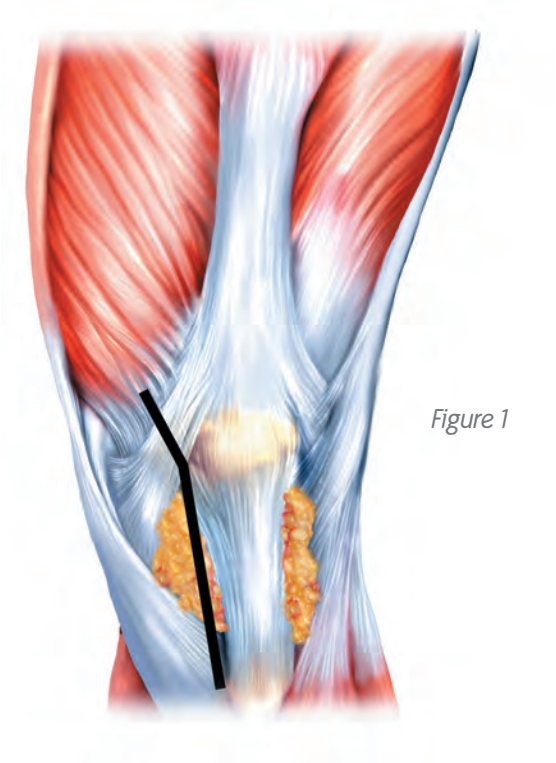


Figure 1

Exposure
With the leg extended, the patella is retracted. The fat pad is excised both medially and laterally leaving a small amount of fat deep under the patella tendon. The patella tendon proximal to the tubercle is dissected from the tibia. The anterior horn of the medial meniscus is divided and dissection is carried around the proximal medial tibia using electrocautery and a boxed osteotome.

A thin bent Hohmann retractor is placed on the proximal medial tibia. The proximal soft tissue attachments extending around the proximal medial tibia are released in the standard fashion. A small window is made along the anterior surface of the distal femur with the use of electrocautery to reference the anterior cortex.

Note: In patients with tight extensor mechanism (usually larger, muscular patients or those with abundant patella osteophytes), the patella is cut at this time (see page 9).

Femoral Preparation

Intramedullary Femoral Alignment

1. Flex the knee to 70-90°.
2. Place a thin bent Hohmann retractor laterally around the tibia and retract the patella.
3. Divide and excise the ACL and the anterior horn of the lateral meniscus.
4. Identify the rotational reference landmarks
   - A-P axis (as described by Whiteside)
   - Medial/lateral posterior femoral condyles
   - Epicondylar axis.
5. Open the femoral canal (generally just anterior to the PCL insertion) with the **9.5mm drill.**
6. Select the **valgus angle bushing/rod** based on preoperative measurements. Assemble the selected bushing to the **valgus alignment guide (left or right).** Make sure the **bushing** is positioned so that "left" is facing anteriorly when operating on a left knee and "right" is facing anteriorly when operating on a right knee. Attach a **quick connect handle** to the **valgus alignment guide.** *(Figure 2)*

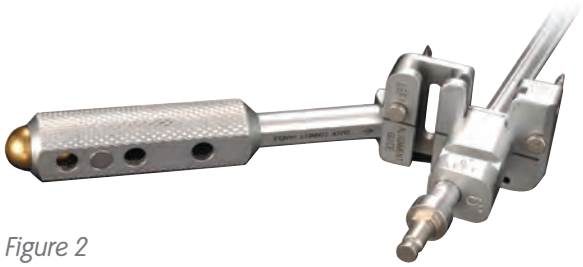


Figure 2

7. Insert the **intramedullary rod** into the canal. Position the **valgus guide** through the skin window until it contacts the distal femur. *(Figure 3)*

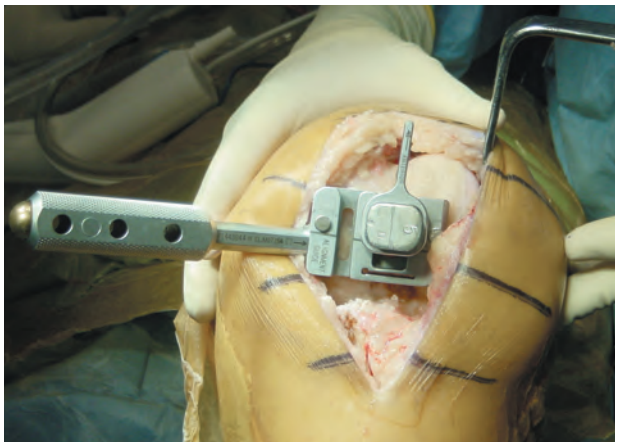


Figure 3

9.5mm Drill

Modular T-Handle

Valgus Angle Bushing

Intramedullary Rod

Quick Connect Handle

Femoral Rotational Alignment
Rotation of the **valgus alignment guide** is set neutral to the posterior femoral condyles by using the landmarks described above either with or without **rotational alignment paddles.**

Without Paddles

1. Flex the knee to 70-90°.
2. Align:
   (a.) The posterior aspect of the **valgus alignment guide** parallel to the posterior condyles.
   (b.) The line laser-etched across the distal surface of the valgus alignment guide parallel to the epicondylar axis. (The line on the valgus alignment guide is drawn such that placing it parallel to the epicondylar axis aligns the guide in neutral rotation.)
   (c.) The f**emoral alignment template** (Figure 5a) with the A-P axis. (The femoral alignment template is designed such that setting it parallel to the A-P axis aligns the valgus alignment guide in neutral rotation.)

Figure 4a

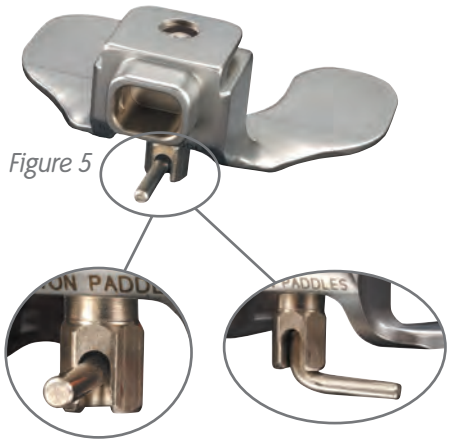
The **femoral alignment template** is placed over the **valgus angle bushing** to guide rotational alignment. Make sure that the template is positioned so that "left" is facing out when operating on a left knee and "right" is facing out when operating on a right knee. The **valgus alignment guide** is placed in neutral orientation by aligning the outrigger of the template with the A-P line.
(Figure 4b)

(Figure 4b)

With Paddles

1. Flex the knee to >100° when inserting the **valgus alignment guide** with the **modular paddles.**
2. Unlock the capture mechanism on the modular paddles. The arm on the paddles distracts posteriorly and rotates to either side to unlock so the anterior lip can engage the slot in the posterior aspect of the **valgus alignment guide.**
3. Insert the anterior lip of the **paddles** into the slot in the **valgus alignment guide**. Rotating the arm back centrally into the recess will lock the **paddles** onto the **valgus alignment guide**.
   (Figure 5)

Figure 5



Locked Unlocked

4. Position the paddles under the posterior condyles.

   Note: Posterior condylar referencing may be less reliable in knees with deficient posterior condyles (e.g.) severe valgus deformity). If the posterior condyles are deficient, the AP or epicondylar axis should be used.

Preliminary Anterior Femoral Resection

1. Secure the **valgus alignment guide** using the floating pins.
2. Release and remove the **modular paddles**.
3. Decrease knee flexion to 70-90°. (This allows the soft tissue window to be moved proximally for referencing of the anterior femoral cortex.)
4. Place the **anterior resection guide** into the **valgus alignment guide** and attach the **anterior stylus** to the **anterior resection guide** by sliding the foot into the cutting slot. Place the stylus tip on the lateral ridge of the anterior femoral cortex. *(Figure 6)*

   Note: The stylus is designed to insert the tip under the skin if necessary. The skin can be retracted to aid in placement of the stylus.

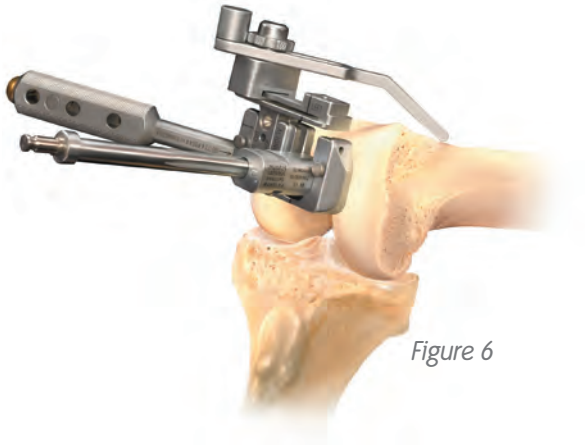


Figure 6

5. Pin the **anterior resection guide** with a 1/8" trocar pin and remove the **anterior stylus**.
6. Resect the anterior cortex. *(Figure 7)*

   Note: When making this cut, a retractor is used to retract the skin upward while the cut is made (the saw blade will cut under the skin). (Figure 7)

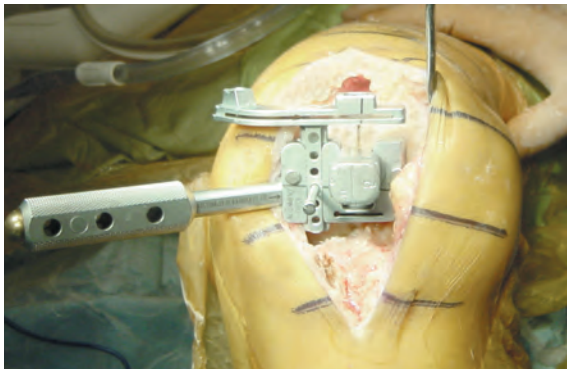


Figure 7

Distal Femoral Resection

1. Assemble the **distal femoral cutting block** with the **distal resection stylus** (the cutting block will slide distally until it hits a stop) and attach the assembly to the **anterior resection guide**.

   Generally, proximal retractors are not necessary.
2. Secure the **distal femoral cutting block** to the anterior cortex by impacting or drilling pins through the holes marked "o". *(Figure 8)*

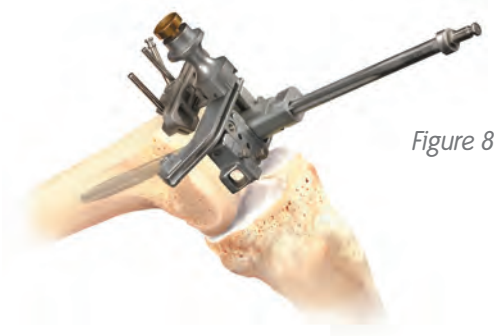


Figure 8

3. Attach the **slap hammer** to the **valgus bushing** and remove the **rod, distal resection stylus,** and **valgus alignment assembly**. *(Figure 9a)*

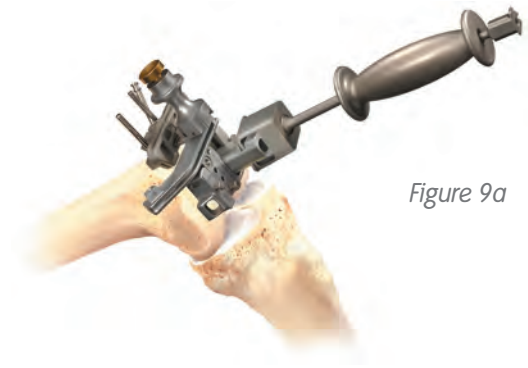


Figure 9a

Only the **distal femoral cutting block** should remain on the femur. *(Figure 9b)*

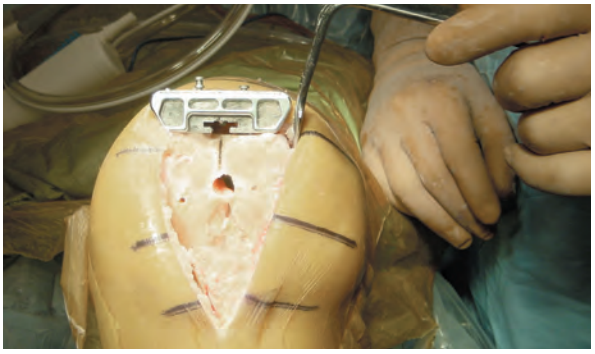


Figure 9b

4. Resect the distal femur and remove the **distal femoral cutting block**.

Femoral Preparation *(Continued)*

Femoral Sizing
Size the femur using the **femoral sizing guide**. It may be necessary to flex the knee to position the posterior paddles on the **sizing guide**. *(Figure 10)*

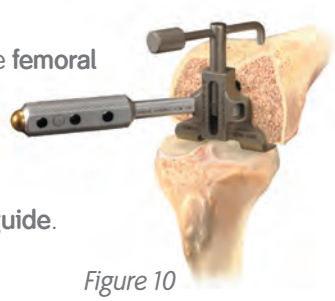


Figure 10

For the correct size assessment, place the stylus tip on the provisional anterior cut, read the size indicated by the line across the stylus shaft (not the retention pin) and choose the smaller size if between two sizes.

A-P Femoral Resections

1. Choose the correct size **A-P cutting block** and place it on the distal femur in a medialized position. The block is designed to allow for angling of the saw blade during the cuts. *(Figure 11)*

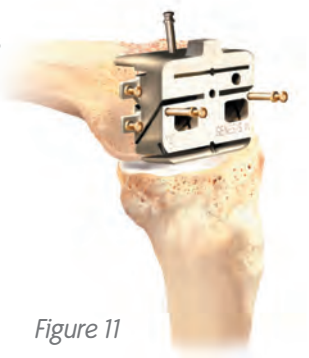


Figure 11

2. Secure the **A-P cutting block** first with a straight pin through either the medial, lateral or central pinhole in the distal block surface.
Pin through the angled holes in the ears on the medial and lateral sides of the block as bone quality dictates to achieve stability. *(Figure 12)*

*Note: The **A-P cutting block** should seat flush with the cut anterior and distal surfaces.*

One Recommended Sequence
- Pin through lateral hole in distal block and angled holes in posterior medial and lateral ears
- Posterior cut
- Medial anterior and posterior chamfer cuts
- Move pin in lateral hole in distal block to medial hole in distal block
- Lateral anterior and posterior chamfer cuts
- Anterior femoral cut

3. Complete the anterior, posterior and chamfer cuts. While cutting the posterior condyles, a thin bent Hohmann is placed beneath the MCL for retraction and for protection of the MCL.

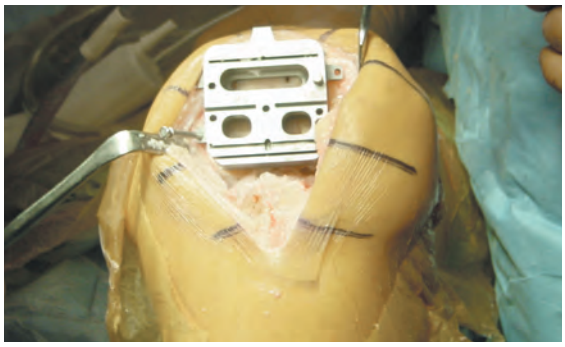


Figure 12

Note: If it is preferable to resect the chamfers over a block rather than through slots, a chamfer cutting block is available. To align the chamfer block on the distal femur, drill 1/8" pins through the medial and lateral holes in the distal surface of the A-P cutting blocks. These are used for the spikes on the primary chamfer cutting blocks.

Posterior Stabilized Femur Resection
Femoral preparation for Posterior Stabilized GENESIS® II is completed after Patella Preparation.
See page 10.

Tibial Preparation

Extramedullary or intramedullary alignment guides may be used. First, around the proximal medial tibia and retract the patella. Osteophytes are removed from the anteromedial and medial tibia.

Extramedullary Tibial Alignment

1. Assemble the **extramedullary tibial alignment guide** and place it onto the tibia. *(Figure 13)*

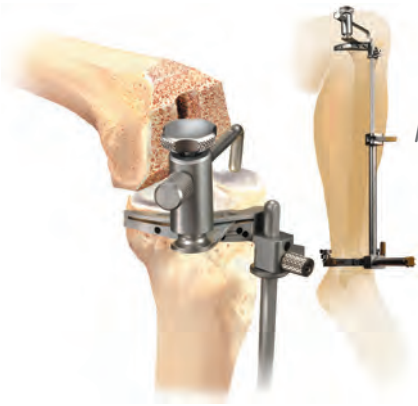


Figure 13

Ensure that the correct **left or right tibial cutting block** is chosen and that the **alignment guide** is correctly set distally for the left or right leg. The distal portion of the guide is adjusted over the center of the ankle and the proximal portion is aligned with the tibial crest.

2. Assess rotation of the alignment guide and slope of the cutting plane. Rotational alignment is critical due to the 3° posteriorly sloped cut. The goal is to align the **extramedullary alignment assembly** rotationally so that it aligns over the medial third of the tibial tubercle and over the second toe. The slope can be adjusted according to the patient's anatomy.

Note: 4° of slope is built into the articular insert and 3° of slope is built into the tibial cutting block. Neutral alignment should be used.

Intramedullary Tibial Alignment

1. Open the tibial canal (generally 5mm medial to the midline) with the 9.5mm drill. To determine correct placement, the hole can be made through the **tibial drill guide** with the **11mm tibial collet**. (A preliminary resection of the tibial spine may facilitate seating of the **tibial drill guide** onto the proximal tibia.)
2. Attach the correct left or right **tibial cutting block** to the **intramedullary tibial alignment assembly** and pass the **intramedullary rod** through the cannulated alignment sleeve on the alignment assembly.
3. Slowly insert the rod into the tibial canal.
4. Assess rotation of the **intramedullary tibial alignment guide**. Rotational alignment is critical due to the 3° posteriorly sloped cut. The alignment rod of the **intramedullary tibial alignment assembly** should align with the medial third of the tibial tubercle.
5. Impact the proximal end of the cannulated alignment sleeve to drive the distal spikes into the proximal tibia to lock rotation. *(Figure 14)*

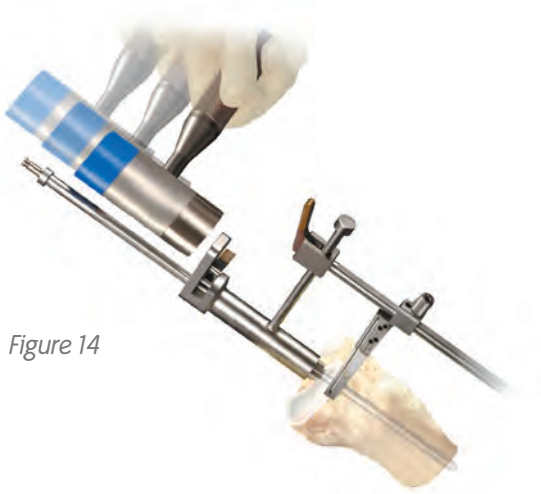


Figure 14

Extramedullary Tibial Alignment Guide

Intramedullary Tibial Alignment Guide

Tibial Preparation *(Continued)*

Tibial Resection

1. Attach the **tibial stylus** to the **tibial block** by inserting the stylus foot into the cutting slot.
2. Lower the **cutting block** until the **stylus** touches the less affected side of the tibia. This allows placement of the 9 mm articular insert. The stylus can also be used to adjust the depth of the tibia cut (adjustable to 9, 11 or 13 mm).
3. Pin the **tibial cutting block** to the tibia. Note that the cutting block sits along the medial half of the tibia. Insert pins first through the central holes. The medial hole may also be used to secure the **tibial cutting block**.
4. Remove the intramedullary alignment assembly leaving the cutting block on the anterior tibia. The extramedullary guide may be left in place.
5. Cut the tibia by first directing the blade in the posterior direction and then laterally.
6. Inspect the surface for any cortical ridges. The proximal tibia can be visualized by extending the leg, placing a laminar spreader, and retracting the patella.
7. Place the leg in 90° of flexion, insert a laminar spreader and remove remnants of the medial and lateral menisci and posterior osteophytes. *(Figure 15)*

8. Check alignment and balance with spacer block and rod. Balance ligaments in standard fashion.

Tibial Sizing

1. Determine the tibial implant size using the **tibial viewing template**.
2. Place the appropriate **tibial drill guide** or **stemless tibial trial** on the tibia.
3. Centralize and pin the **tibial drill guide** or **stemless trial**.
4. Drill through the **stemless trial** or place the **11mm tibial collet** in the **drill guide** and drill with the **11mm tibial drill**.
   If a 9.5mm drill has been used for the intramedullary tibial alignment assembly, only the **11mm tibial punch** is needed.
5. Punch with the **11mm tibial punch**. *(Figure 16)*

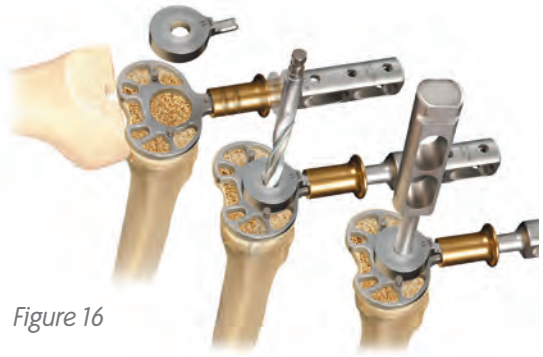


Figure 16

6. Remove the tibial drill guide if used and place the tibial trial onto the proximal tibia to assess coverage.

Tibial Viewing Template

Tibial Drill Guide

11 mm Tibial Collet

11 mm Tibial Drill

11mm Tibial Punch

Spacer Block

Patella Preparation

The easiest time to prepare the patella is after all tibial and femoral cuts are made, but prior to trial placement. In some cases, the patella is cut just after arthrotomy to facilitate exposure.

Measure its thickness, and determine the appropriate diameter implant.

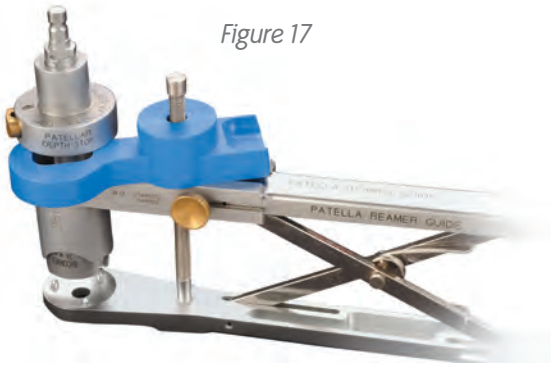
Resurfacing (Onlay) Patella

1. Place two Kocher clamps just proximal and distal to the patella to hold the patella's position.
2. Cut the patella using an oscillating saw.
3. Drill the peg holes using the drill guide.

Biconvex (Inset) Patella

1. Select the correct **patellar reamer collet** and slide it into place on the **patellar reamer guide**.
2. Attach the **patellar reamer guide** to the patella and tighten the reamer guide on the patella. *(Figure 17)*
3. Use the **calipers** to measure patella thickness.
4. Attach the **patellar depth gauge** for the selected patella design to the **reamer guide**.
   The reaming depth for each design is as follows:
   - Biconvex patellae: 13mm
   - Resurfacing patellae: 9mm
   - All-poly with FLEX-LOK® peg: 15mm
5. Attach the **patellar reamer dome** and **patellar depth stop** to the **patellar reamer shaft**. Before this assembly is attached to drill, lower it through the patellar reamer guide until the **reamer dome** contacts the patella.
6. Swing the **patellar depth gauge** around so that the "claw" surrounds the **patellar reamer shaft**.
7. Lower the **patellar depth stop** until it contacts the **patellar depth gauge** and automatically locks in place.
8. Remove the **depth gauge**.
9. Attach the patellar reamer assembly to power equipment. Ream the patella until the **depth stop** engages the **patellar reamer guide**.

Figure 17



Patellar Drill Guide | Patellar Drill Bit | Patellar Reamer Collet | Patellar Reamer Guide | Patellar Calipers | Patellar Depth Gauge | Patellar Reamer Dome | Patella Reamer Shaft

Posterior Stabilized Femur Resection

1. Flex the knee to approximately 90° and center the **P/S housing resection block** on the distal femur. (To assist, the housing resection blocks have the same M-L dimension as the implants.)

   Note: The only difference between the cruciate retaining and the posterior-stabilized femoral components is the addition of the housing for the cam mechanism. All other box dimensions are the same. The anterior and posterior chamfer resections can be made through the posterior stabilized housing resection block.

2. Secure with 1/8" trocar pins through the straight holes in the front of the block. If the chamfer cuts are made through this block, the angled holes in the sides of the block should be used.

3. Attach the **P/S housing resection collet** to the **housing resection block**. *(Figure 18)*

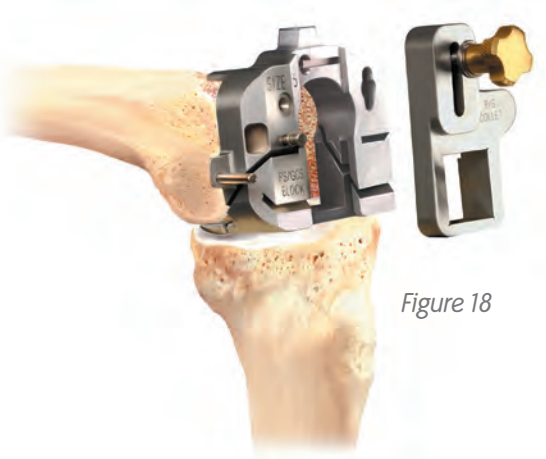


Figure 18

4. Attach the **housing reamer dome** and **P/S reamer sleeve** to the **patellar reamer shaft**.

5. Ream through the **housing resection collet** until the automatic depth stop contacts the **collet** and then move the reamer anterior and posterior until it contacts the automatic stops.

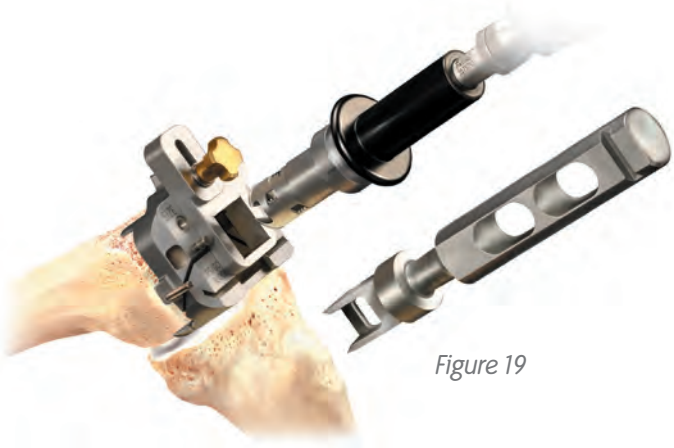


Figure 19

6. Impact the **housing box chisel** through the **housing resection collet** to square the corners of the housing. The **housing box chisel** should be used anteriorly and posteriorly to ensure that the full length of the box is prepared. *(Figure 19)*

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

P/S Housing Resection Collet

Housing Reamer Dome

Reamer Sleeve

Patella Reamer Shaft

Housing Box Chisel

Trial Placement

Femoral and Tibial Trialing

1. Insert thin bent Hohmanns laterally and medially (an Aufranc retractor can be placed posteriorly to sublux the tibia forward if necessary) and place the tibial trial.
2. Flex the knee to 90° and place the femoral trial.
3. Use the appropriate insert trial (begin with a 9mm trial) to determine stability and alignment.
4. Perform a trial range of motion. The alignment marks on the front of the femoral and tibial trials should line up. The **quick connect handle** may be attached to the tibial trial and used to set the appropriate rotational alignment.
5. Extend the knee fully with the handle attached to the tibial trial. Pass the extramedullary rod through the handle to assess full leg alignment. Mark correct tibial rotational alignment on the anterior tibia using a cautery knife. Alignment can be checked with the **spacer block**. Since the spacer block has one end for flexion and one for extension, ensure the appropriate end is used.
6. Determine whether a porous or nonporous tibial implant will be used. Select the appropriate **tibial fin punch** to prepare the fins and punch through the tibial trial.

   Note: If the tibial bone is sclerotic, begin the fin slot with a burr or thin saw blade before using the fin punch to prevent tibial fracture.

Patellar Trialing

1. Place the patellar trial into the prepared patella.
2. Perform a trial range of motion to assess patellar tracking. With cruciate retaining knees, medial lateral placement of the femoral trial can be adjusted to optimize patellar tracking.
3. For cruciate retaining femorals, drill the femoral lug holes through the femoral trial with the femoral lug drill.
4. Remove the tibial trial. Attach the end of the **universal extractor** to the femoral trial. Remove the femoral trial. Use a towel clip to remove the patellar trial.

Spacer Block

Tibial Fin Punch

Universal Extractor

Femoral Impactor

Articular Inserter/Extractor

Maximally flex the knee and place a thin bent Hohmann laterally and medially and an Aufranc retractor posteriorly to sublux the tibia forward.

Tibial Implantation

1. Apply cement on the proximal tibia and seat the tibial implant with the **tibial impactor**. Remove excess cement.
2. If using the porous tray and screws, orient the **tibial screw drill guide** over the holes and drill using the **tibial screw drill**. Determine the appropriate screw size using the **screw depth gauge**. Insert screws with alternating tightening to avoid liftoff.

Femoral Implantation

1. Flex the knee to 90° keeping the thin bent Hohmann laterally and removing the Aufranc retractor.
2. Apply cement only on the femoral component.
3. Place the femoral implant onto the femur and use the **femoral impactor** to fully seat the implant.
4. Remove excess cement. Extend the knee to remove cement anteriorly without retracting the proximal soft tissue.
5. Place the tibial insert trial onto the tibial implant and extend the leg to pressurize the cement.

Patellar Implantation

1. Assemble the **patellar cement clamp** to the **patellar reamer guide**.
2. Apply bone cement to the patella.
3. Place the patellar implant onto the patella and clamp into the bone. Remove excess cement.

Insert Placement

1. Determine the correct articular insert thickness.
2. Clear any debris from the locking mechanism and slide the insert into the tibial baseplate engaging the locking mechanism. For the P/S insert, begin insertion in flexion and extend the leg to engage the locking mechanism.
3. Attach the **articular inserter/extractor** to the tibial tray. Lift the **inserter** superiorly until the anterior lip of the articular insert is fully seated.

Closure

1. Close the arthrotomy by placing three O-Vicryl sutures at the superior border of the patella just distal to the VMO. A stitch is placed to close the VMO fascia. The remainder of the arthrotomy is closed in the standard fashion.
2. Perform routine subcutaneous and skin closure.

IMPORTANT MEDICAL INFORMATION Smith & Nephew Knee System

DESCRIPTION OF SYSTEM

Smith & Nephew Knee Systems consist of femoral components, tibial components, and accessories. The component material is provided on the outside carton label. Femoral and tibial components are available in porous and non-porous options. Non-porous components, PROFIX® porous coated no-hole tibial bases and POROUS PLUS® hydroxylapatite (HA) coated no-hole tibial bases* are to be used with cement. Semi-constrained porous coated devices, POROUS PLUS HA coated devices and HA coated devices of the PROFIX Total Knee System, GENESIS® II Total Knee System and LEGION® Knee System may be used without cement. The LEGION Revision Knee System and the LEGION Hinge Knee System are to be used with cement. Constrained tibial inserts may only be used with cemented femoral and cemented tibial components. Hydroxylapatite (HA) coatings include HA that is supplied either on a grit blasted or porous surface.

The JOURNEY® DEUCE® Knee Femoral Component is used to replace the medial condyle and patellofemoral regions of a femoral knee joint.

Note: HA on grit blasted knee components are not available in the US.

*Note: POROUS PLUS hydroxylapatite (HA) coated components intended for use with bone cement are not available in the US.

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.
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 incompetent.
6. Hinge 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 Unicompartmental Knee Replacement

Unicompartmental knee implants are indicated for restoring either compartment of a knee that has been affected by the following:

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.

Unicompartmental knee implants are single use only and are intended for implantation only with bone cement. HA coated unicompartmental knee implants are available outside the US for use without bone cement.

Contraindications for Unicompartmental Knee Replacement

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

Indications for Patello-Femoral Replacement

1. Degenerative arthritis in the distal femur and patella;
2. A history of patellar dislocation or patellar fracture; and
3. Failed previous surgery (arthroplasty, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

The Smith & Nephew Patello-Femoral Implants are intended for implantation with bone cement.

Contraindications for Patello-Femoral Replacement

The contraindications for Patello-Femoral Replacement include all of the contraindications listed for Total Knee Replacement.

Indications for JOURNEY DEUCE Knee Replacement and Combined Unicompartmental and Patello-Femoral Replacement

The JOURNEY DEUCE Components, and when used together, a JOURNEY Unicompartmental and Patello-Femoral implant device, are intended to be used for those patients whereby conditions exist that cannot be solely addressed by a device that treats a single compartment (i.e. Unicondylar or patellofemoral prosthesis) of the knee. Indications include:

1. Post-traumatic arthritis;
2. Degenerative arthritis; and
3. Failed osteotomies and unicompartmental replacement.

These indications will be used for the JOURNEY DEUCE Knee Components and the combined use of a JOURNEY Unicompartmental and Patello-Femoral implant device, whereby a single condyle and patellofemoral regions have been affected by one or more of these conditions. The Smith & Nephew JOURNEY DEUCE, Unicompartmental and Patello-Femoral Implants are intended for implantation with bone cement.

Contraindications for JOURNEY DEUCE Knee Replacement and Combined Unicompartmental and Patello-Femoral Replacement

The contraindications for JOURNEY DEUCE Knee Replacement and combined Unicompartmental and Patello-Femoral 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. Long hip stems and stemmed revision knee can all experience bone resorption in the area which sees stress shielding by the stem. This is especially true for larger diameter stems.
6. Tibia, femur, or patella fractures.
7. Acute post-surgical wound infection, late deep wound sepsis and/or low-grade synovitis.
8. 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.
9. Wound hematoma, thromboembolic diseases including venous thrombosis, pulmonary embolus, or myocardial infarction.
10. Myositis ossificans. Periarticular calcification or ossification, with or without impediment to joint mobility. Periarticular calcification can cause decreased range of motion.
11. Skin sloughs or delayed wound healing.
12. 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.
13. Damage to blood vessels.
14. Varus-valgus deformity.
15. 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. Single use devices should not be reused due to risks of breakage, failure or patient infection.
5. If a computer assisted surgery system is used, consult the applicable software and hardware reference manuals provided by the manufacturer to ensure proper operation of this equipment.

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 increase the risk to the patient and reduce the service life of the implant.
8. The GENESIS II Torque Wrench should be used for all LEGION femoral wedges, LEGION Hinge femoral wedges and LEGION tibial wedges. These lugs/screws should be torqued to a minimum of 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. Use the LEGION Hinge Torque Wrench to secure the hinge bolt to the tibial base. The bolt should be torqued to 150 in-lbs.
9. Caution: Failure to follow the Legion Hinge Knee Surgical Technique of "Torque post bolt to 150 in-lbs, impact post sleeve, and re-torque post bolt to 150 in-lbs" may result in the construct disassembling causing a need for a Revision Surgery.
10. Distal fixation lugs should be used with porous cruciate-retaining femoral components when implanted without cement. These lugs provide medial/lateral stability of the prosthesis.
11. For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g. bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and malpositioned implants.
12. The JOURNEY DEUCE Knee Implants are not to be used with the JOURNEY Patellar Components or Bi-Cruciate Stabilized (BCS) Patellar Components. They are to be used only with the GENESIS II Patellar Components.
13. The JOURNEY Patello-Femoral Joint (PFJ) Knee Implants are not to be used with the JOURNEY Patellar Components or Bi-Cruciate Stabilized (BCS) Patellar Components. They are to be used only with the GENESIS II Patellar Components.
14. JOURNEY Unicompartmental Knee System components are not intended to be used simultaneously on both the medial and lateral condyles of the knee.

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. Normal daily activity may be resumed at the physician's direction. Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.
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.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

Smith & Nephew knee systems have not been evaluated for safety and compatibility in the MR environment. Knee system components have not been tested for heating or migration in the MR environment.

PACKAGING AND LABELING

Implants 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, return the component to Smith & Nephew, Inc.

STERILIZATION

Implant components are supplied sterile to a Sterility Assurance Level (SAL) of 10-6. Implant components are supplied in protective packaging. Inspect packages for punctures or other damage prior to surgery. The method of sterilization is noted on the package label.

DO NOT REUSE OR RESTERILIZE implant components or single use disposable instruments. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components. If not specifically labeled sterile, instruments are supplied non-sterile and must be cleaned and sterilized prior to surgery. Please see also the document, "Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices", which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

RECOMMENDED STEAM STERILIZATION CYCLE PARAMETERS

- Dynamic Air Removal (Prevacuum) Steam Cycle: 132ºC (270ºF) for 4 minutes or 135ºC (275ºF) for 3 minutes and a minimum vacuum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C (270°F) for 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle (Reusable instruments only): 132°C (270°F) for 10 minutes in a Gravity Displacement Cycle or 4 minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle: 134° C (273°F) for 3 minutes and a minimum vacuum drying time of 30 minutes. (Note: Sterilization evacuation and pulsing should be carried out in accordance with HTM 2010).

Containment devices should be wrapped with a central supply wrap (CSR) or placed in a reusable rigid container for sterilization. Note to US Customers: FDA cleared sterilizers and wraps are to be used in your sterilization processes.

RETRIEVAL AND ANALYSIS OF REMOVED IMPLANTS

The most important part of surgical implant retrieval is preventing damage that would render scientific examination useless. Special care should be given to protect the implant from damage during handling and shipment. Follow internal hospital procedures for the retrieval and analysis of implants removed during surgery. When handling removed implants, use precautions to prevent spread of bloodborne pathogens.

If the implant will be returned to Smith & Nephew, Inc. for analysis, contact Customer Service using the phone numbers outlined in the Information section.

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.

Manufacturing facilities and EC representative:

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Tel.: 901-396-2121

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

– For cemented use only
– For uncemented use only

81074901 Rev. 0 2010-09

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Patent numbers: 4950298, 5047058, 5053037, 5100408, 5514140, 5354075, 5417694 and 5549688.

This system is intended for cemented use only.

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