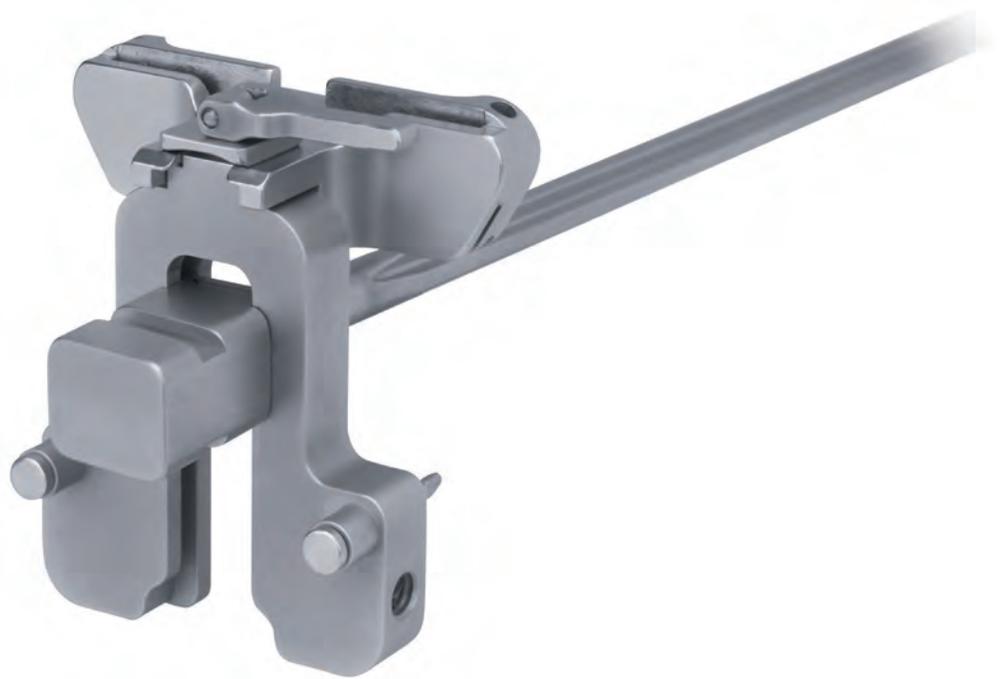


Minimally Invasive TKA
GENESIS[®] II Distal Cut First



Instruments



Valgus Alignment Guide
7144-1144



A-P Cutting Block
 Size 1 7144-1149 Size 6 7144-1154
 Size 2 7144-1150 Size 7 7144-1155
 Size 3 7144-1151 Size 8 7144-1156
 Size 4 7144-1152
 Size 5 7144-1153



Femoral Alignment
Viewing Template
7144-1141



P-S Housing Resection Block
 Size 1 7144-1127 Size 6 7144-1132
 Size 2 7144-1128 Size 7 7144-1133
 Size 3 7144-1129 Size 8 7144-1134
 Size 4 7144-1130
 Size 5 7144-1131



Distal Femoral
Cutting Block
7144-1147



Tibial Cutting Block (Left)
7144-1136



Distal Femoral
Sizing Guide
7144-1233



Tibial Cutting Block (Right)
7144-1137



Femoral Sizing
Guide Stylus
7144-1140



Tibial Resection Stylus
7144-1135



Shims
 1mm 7144-1164
 2mm 7144-1165
 3mm 7144-1166
 4mm 7144-1167
 5mm 7144-1168

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Kace A. Ezzet, MD
Attending Orthopaedic Surgeon
Scripps Clinic and Research Foundation
La Jolla, CA

David Harwood, MD
Associate Professor
UMDNJ Robert John Wood Medical School
New Brunswick, NJ

Nota Bene:

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

Introduction

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. If significant tension is noted at the skin edges, the incision should be extended to minimize risk of wound edge necrosis.

Arthrotomy

The procedure can be performed using a “mini-patellar” capsulotomy or a “mini-mid-vastus” capsulotomy. The mid-vastus may offer some advantages for quicker recovery of extensor function postoperatively. However, in cases where the extensor mechanism is stiff or the patient is heavily muscled, the parapatellar capsulotomy may allow easier mobilization of the patella. Either type of arthrotomy can be extended to conventional length if exposure is problematic.

For the mini-mid-vastus approach, begin 5mm 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.

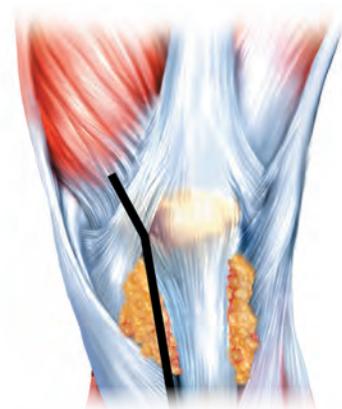


Figure 1

The suprapatellar 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 2cm (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 patellar tendon. The patellar tendon proximal to the tubercle is dissected from the tibia. The release of the anterior horn of the lateral meniscus at this point will facilitate reflection of the extensor mechanism and exposure to the lateral side. The anterior horn of the medial meniscus is divided and dissection is carried around the proximal medial tibia using electrocautery and a box osteotome.

A thin bent Hohmann is placed into the lateral side to hold the patella while a second Hohmann or a Z-retractor is placed along the medial border of the proximal tibia to protect the medial collateral ligament.

Tip: Excessive tension on the retractors is not necessary and can sometimes hamper the exposure.

The proximal soft tissue attachments extending around the proximal medial tibia are released in the standard fashion. Finally, divide and excise the anterior cruciate ligament.

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

Femoral Preparation

Intramedullary Femoral Alignment

1. Flex the knee 70-90°. Open the femoral canal with a 9.5mm intramedullary drill.
2. Insert the intramedullary rod through the appropriate valgus angle bushing (5°, 6°, 7°).
3. Attach the selected valgus angle bushing to the valgus alignment guide.

Check the bushing position to ensure that “left” is facing anteriorly when operating on a left knee and “right” is facing anteriorly when operating on a right knee.

4. Assemble the distal femoral cutting block onto the valgus alignment guide and lock by pressing the lever in a horizontal position. Ensure the cutting block is positioned at the ‘primary’ resection.

Tip: If desired, the distal femoral cutting block may be set to resect +2, +5 or +7mm.

Tip: Positioning the distal cutting block at the “primary” resection will ensure the cut will equal the distal thickness of the femoral prosthesis.

5. Slide the assembly with the intramedullary rod into the femoral canal until the alignment guide contacts the distal femur (Figure 3).
6. Orient rotation of the assembly neutral to the posterior condyles and impact the floating spikes into the distal femur.



Figure 3

Distal Femoral Resection

1. Pin the distal femoral cutting block to the anterior femur using the holes marked “0”.
2. Once pinned, the distal resection can be increased by shifting the block proximally to the +2mm or +4mm levels.

Tip: Once adequate distal femoral resection is noted, an additional headed pin can be placed obliquely to provide additional security.



Figure 4

3. Unlock the lever on the valgus alignment guide, remove the intramedullary rod and the valgus alignment assembly using the universal extractor (Figure 4). Only the distal femoral cutting block should remain on the femur.
4. Resect the distal femur.
5. Remove the distal femoral cutting block.

Tip: If the distal femoral resection is not adequate, remove the oblique headed pin, shift the block proximally to the desired level and finish resection.



9.5mm Drill



Modular T-Handle



Valgus Angle Bushing



Intramedullary Rod



Universal Extractor

Femoral Preparation

Femoral Sizing Guide Preparation

The unique feature of the sizing guide for this system is that it may be used in an anterior referencing or a traditional posterior referencing manner. It includes an anterior surface (Figure 5a) located on the sizing guide which is adjustable by the hex screw mechanism (b), and is internally attached to the drill guide used to set the drill holes (c) for placement of the A-P cutting blocks.

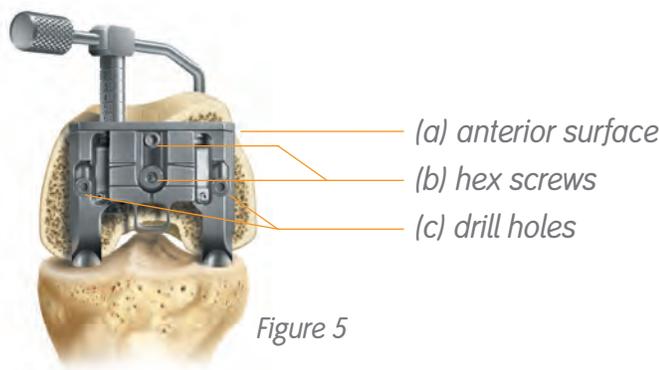


Figure 5

Anterior Referencing

An anterior referencing technique is based on the anterior cortex, which serves as the primary reference point. The anterior resection is fixed while the posterior resection varies with size. Because the component will be flush against the anterior cortex, this will enable the reapproximation of the patellofemoral joint. When the sizing guide indicates the femoral implant is between two sizes, the smaller size should be selected. Choosing the smaller size results in more bone resection from the posterior condyles thereby increasing the flexion space.

| Anterior Referencing | |
|--|------------------------------|
| Advantages | Disadvantages |
| Reapproximation of the patellofemoral joint | Knee may be loose in flexion |
| Reduced chance of notching the anterior cortex | |

To use the guide in this manner, femoral size is read from the graduations on the stylus arm relative to the anterior surface.

By adjusting the lower hex screw, the anterior surface can be raised from the lowest position (Figure 6a) to read the next smaller size on the stylus. In raising the anterior surface, the drill holes are also raised by the same amount (Figure 6b).

As a result, the anterior surface is shifted anteriorly by a distance equal to the amount the A-P dimension of the femur is from the next smaller implant size. Additional resection of the same amount is made from the posterior condyles. Once the appropriate size is determined, the drill holes and anterior surface are locked in place by adjusting the upper hex screw.

Posterior Referencing

A posterior referencing technique is based on the posterior femoral condyles which serve as the reference point. The posterior resection remains constant while the anterior resection varies with respect to the anterior cortex. Therefore, the posterior resection will equal the posterior thickness of the prosthesis, resulting in a balanced flexion-extension space. When the sizing guide indicates the femoral implant is between two sizes, the larger size should be chosen. Even though there is a slight chance in overstuffing the patellofemoral joint with a larger size, there is a reduced risk in notching the anterior cortex of the femur.

To use the sizing guide in this manner, the femoral size is read from the graduations on the stylus arm relative to the anterior surface. If the anterior surface is positioned in between sizes on the stylus shaft, the larger of the two sizes should be chosen.

| Posterior Referencing | |
|---------------------------------------|--|
| Advantages | Disadvantages |
| Balanced flexion and extension spaces | Chance of notching the anterior cortex |
| | May overstuff the patellofemoral joint |

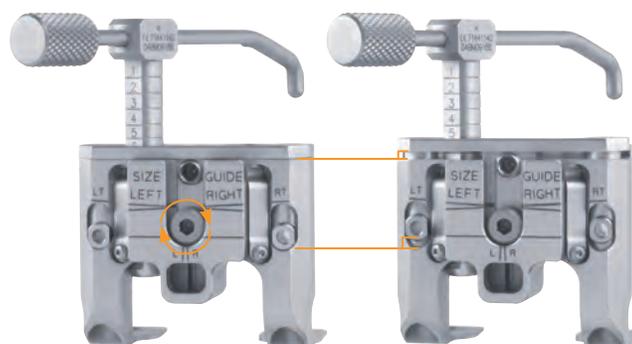


Figure 6a

Figure 6b

Sizing Guide Procedure

1. Flex the knee, approximately 90°, so the posterior condyles are accessible.
2. Position the femoral sizing guide flush against the distal femur, while ensuring the posterior paddles are contacting the underside of both posterior condyles.

Tip: It is not necessary that the guide be centered on the femur, as long as the paddles adequately reference both posterior condyles. Positioning the guide somewhat medial to the midline minimizes interference with the patella and extensor mechanisms.

3. Adjustable shims (1-5mm) may be attached to the posterior paddles of the sizing guide in the event rotational alignment is not appropriate due to deficient posterior condyles.



Figure 7

Sizing Procedure: Anterior Referencing (Fixed Anterior Resection)

1. Ensure the anterior surface of the sizing guide is in the lowest level position (Figure 7).
2. Position the sizing guide stylus so that it contacts the lateral ridge of the anterior femoral cortex (highest point on the anterior cortex of the femur).
3. Determine the size of the component from the graduations on the shaft of the stylus (Figure 7).
4. If the indicated size is in-between sizes, turn the lower hex screw to raise the anterior surface to the next smaller size (Figure 8). Once the appropriate size is selected, turn the upper hex screw to lock the anterior surface and drill holes in position.



Figure 8

5. Drill the holes to mark the location holes for the A-P cutting block then remove the sizing guide.

Sizing Procedure: Posterior Referencing (Fixed Posterior Resection):

1. Ensure the anterior surface of the sizing guide is in the lowest level position (Figure 7).
2. Drill and insert two pins through the holes of the sizing guide to secure the guide and prepare holes for the A-P cutting block.
3. Position the sizing guide stylus so that it contacts the lateral ridge of the anterior femoral cortex (highest point on the anterior cortex of the femur).

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

4. Determine the size of the component from the graduations on the shaft of the stylus.
5. If the femur is between sizes, choose the larger size.
6. Remove the pins and sizing guide.

Femoral Preparation

A-P Femoral Resections

1. Position the fixed spikes on the A-P cutting block into the pre-drilled holes.

Tip: It is not necessary that the block be centered M-L on the distal femur.

Tip: Positioning the cutting block medial to the midline is preferred so the patella and extensor mechanisms do not interfere.

2. Ensure that the cutting block is flush with the resected distal femur. Several holes in the A-P block allow fixation of the block. Place one or two pins centrally through the middle holes, near the quick connect attachment. For additional stability, a pin may be placed through the holes on the medial or lateral side of the block (Figure 9).

Tip: While cutting the posterior condyles, a thin bent Hohmann retractor is placed medially to retract and protect the MCL.

Tip: When making the anterior cut, a retractor is used to retract the skin upward while the cut is made (the saw blade will cut under the skin).

3. Complete the anterior, posterior, and chamfer cuts. The block is designed to allow for angling of the saw blade during the cuts.

Tip: A narrow shaft or fan-tip saw blade is recommended for cutting with the MIS A-P cutting block.

Posterior-Stabilized Femoral Resection

Femoral preparation for Posterior-Stabilized GENESIS[®] II is completed after Patellar Preparation. See page 10.

Figure 9



Tibial Preparation

Extramedullary or intramedullary alignment guides may be used. A thin bent Hohmann or a Z-retractor is placed around the proximal medial tibia to protect the MCL. A thin bent Hohmann is placed over the lateral tibial plateau to retract the patella, and protect the patellar tendon. A PCL retractor or standard Hohmann may be placed posterior to the tibia to sublux the tibia anteriorly, if needed. The menisci may be removed at this time, if desired. 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 10).



Figure 10

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.

Tip: 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.

Tip: To determine correct placement, the hole can be made through the tibial drill guide with the 11mm tibial collet.

Tip: 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 11).



Figure 11

Tibial Preparation

Tibial Resection

The MCL, lateral capsule, patellar tendon and posterior structures are vulnerable to injury. Confirmation of medial and lateral retractor position should be performed.

1. Attach the tibial stylus to the tibial cutting 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. The stylus can be adjusted for a 9, 11 or 13mm tibial resection.
3. Pin the tibial cutting block to the tibia by inserting pins first through the central holes; then the medial hole.

Tip: Positioning the cutting block along the medial half of the tibia is preferred so that the patella and extensor mechanisms do not interfere.

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 proximal tibial surface for any cortical ridges by extending the leg, placing a laminar spreader, and retracting the patella.
7. Flex the leg to 90°, insert a laminar spreader and remove remnants of the medial and lateral menisci and posterior osteophytes.
8. Check alignment and balance with spacer block and rod. Balance ligaments in standard fashion.

Tibial Sizing

Determine the tibial implant size using the tibial viewing template.

Stemmed Tibial Sizing

1. Place the appropriate tibial drill guide on the tibia, centralize and pin.
 2. Place the 11mm tibial collet into the drill guide, drill with the 11mm tibial drill and punch with the 11mm tibial punch (*Figure 12*).
- Tip: If a 9.5mm drill has been used for intramedullary tibial alignment assembly, only the 11mm tibial punch is needed.*
3. Remove the tibial drill guide and place the stemmed tibial trial onto the proximal tibia to assess coverage.

Stemless Tibial Sizing

1. Attach the quick connect handle to the stemless trial, centralize and pin.
2. Drill with the 11mm tibial drill and punch with the 11mm tibial punch.

Tip: Rotational alignment, using the tibial fin punches, may be set now or at the time of trial placement. See page 11.



Figure 12



Patellar 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 and 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 13).
3. Use the calipers to measure patellar thickness.

4. Attach the patellar depth gauge for the selected patellar 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.

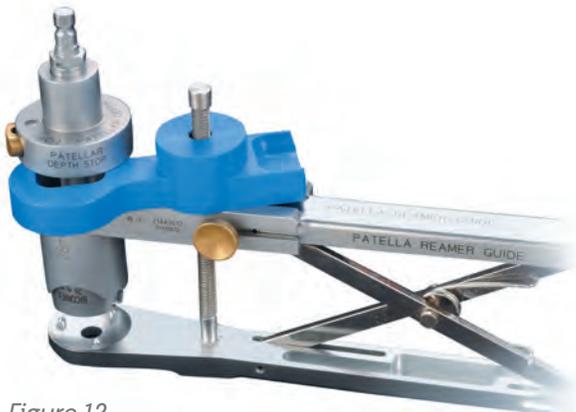


Figure 13



Posterior-Stabilized Femoral Resection

1. Flex the knee to approximately 90°.

2. The P-S housing resection block must be centered on the femur, as this will determine component position.

Tip: The housing resection blocks have the same M-L dimension as the implants.

Tip: 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.

3. 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.

4. Attach the P-S housing resection collet to the housing resection block (Figure 14).

5. Attach the housing reamer dome and the P-S reamer sleeve to the patellar reamer shaft.

6. 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.

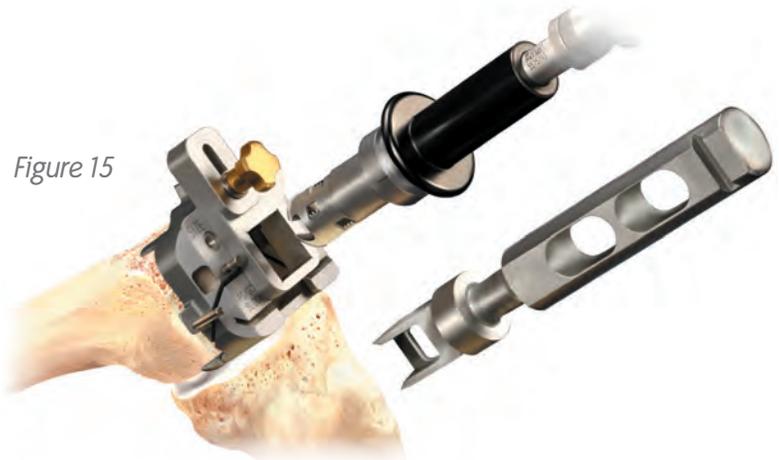


Figure 15

7. 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 15).

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



Figure 14



P-S Housing Resection Collet



Housing Reamer Dome



Reamer Sleeve



Patellar 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 subluxe the tibia forward if necessary) and insert the tibial trial.
2. Flex the knee to 90° and insert 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.

Tip: 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.

Tip: 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

Implantation and Closure

Maximally flex the knee and place a thin bent Hohmann laterally and medially and an Aufranc retractor posteriorly to subluc 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. Mix and prepare bone cement for femoral component and distal femur.
Tip: Care should be taken to avoid excess cement on the posterior aspect of the femur and femoral component. Excess cement that extrudes posteriorly is difficult to remove.
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. 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, loosening 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 impeding 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.

IMPORTANT MEDICAL INFORMATION Smith & Nephew Knee System

WARNINGS AND PRECAUTIONS

Intraoperative *continued*

- 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.
- 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.
- JOURNEY Unicompartmental Knee System components are not intended to be used simultaneously on both the medial and lateral condyles of the knee.

Postoperative

- 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.
- Use extreme care in patient handling.
- Postoperative therapy should be structured to prevent excessive loading of the operative knee and to encourage bone healing.
- 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:** 132°C (270°F) for four minutes or 135°C (275°F) for three 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 four minutes in a Dynamic Air Removal (Prevacuum) Cycle.
- United Kingdom Steam Cycle:** 134°C (273°F) for three 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:

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116 (USA)
Tel.: 901-396-2121

Smith & Nephew Orthopaedics GmbH
Alemannenstrasse 14
78532 Tuttlingen, Germany
Tel.: 07462/208-0
Fax: 07462/208-135

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

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Smith & Nephew, Inc.
7135 Goodlett Farms Parkway
Cordova, TN 38016
USA

www.smith-nephew.com

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

