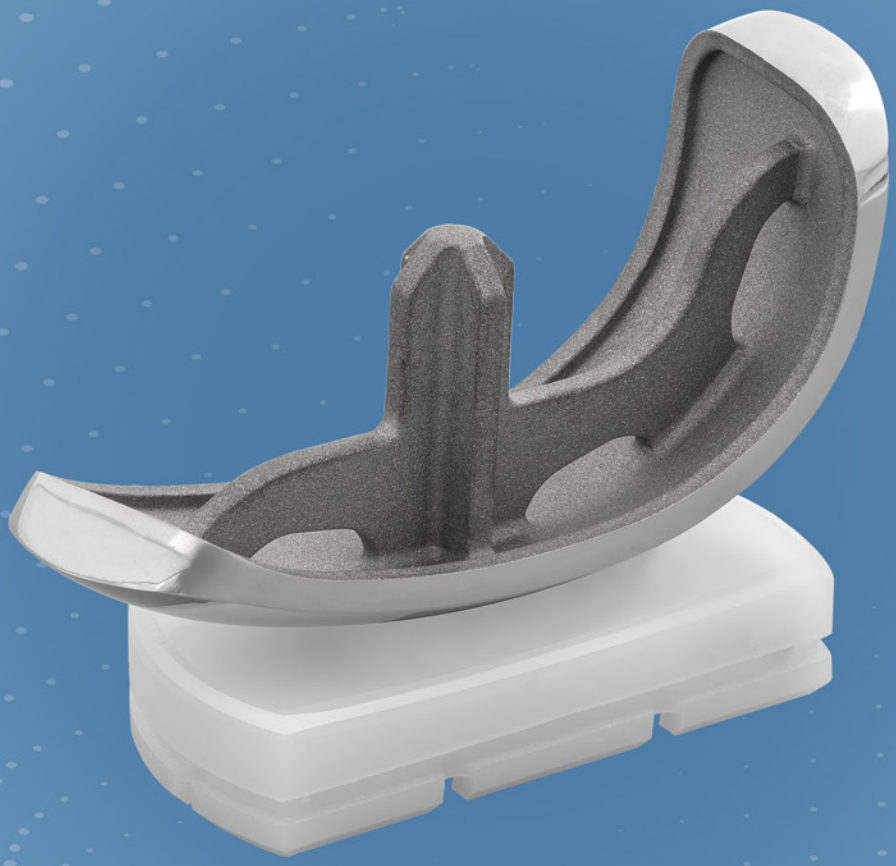
FREEDOM®

RENEW



PARTIAL KNEE

Surgical Technique

Pursue Life™

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OVERVIEW

The Freedom® Renew™ Partial Knee System (PKS) is a unicondylar knee arthroplasty (UKA) resurfacing prosthesis in which the design principle is to eliminate bone resections in an effort to preserve the patient's knee anatomy and alignment as it was before the arthritic process began. Many of the principles related to the finality of total knee arthroplasty (TKA) do not apply to this technique, such as large bone cuts, soft tissue balancing and increasing levels of built-in component constraint.

The Freedom® Partial Knee System surgical technique combines the use of cutting guides, high-speed burrs, a reciprocating rasp and freehand sculpting to prepare the bone surfaces, thus facilitating accurate prosthesis placement. Both components are designed for minimal bone sacrifice. The rounded, keeled femoral component fits without stress risers since there are no chamfered corners, which allows the metal to be thin without compromising strength. The inlaid tibial component resists rocking because it is cemented underneath and peripherally.

This surgical technique focuses on the following:

- Accurate tibial component placement maximizing coverage and alignment
- Proper femoral component placement centered on and guided by tibial component position
- Proper cementing technique to provide optimum fixation with resistance to aseptic loosening
- Varus/valgus restoration of the patient's pre-disease knee alignment (neutral to mild varus alignment)

The Freedom® Partial Knee System surgical technique was developed courtesy of Martin H. Redish, M.D.

OR SET-UP
Back-Table and Mayo Stand

The Freedom® Renew™ resurfacing PKS utilizes efficient back-table and Mayo stand set-up. The single instrument tray includes the following in left and right sides:

- Tibial Trials
- Tibial Rasp
- Femoral Jigs #1 & 2 (and screws)
- Femoral Trials
- Alignment Trials and Rod
- Femoral Post Reamer
- Inserter Handle
- Impactor

PATIENT POSITIONING

The patient is positioned to allow full flexion / extension mobility and applied varus / valgus stress of the operated knee.

- Begin with table in standard position.
- Move head piece to foot.
- Secure eggcrate to upper portion of bed with tape (to avoid patient sliding when the bed is put in Trendelenburg).
- Position patient supine with coccyx at edge of bed to allow maximum flexion.
- Place contralateral leg in an Allen stirrup.
- Apply tourniquet to thigh and place lateral offset post at tourniquet level.
- Remove headpiece and leg support from bed.

Final patient positioning should resemble lithotomy position with operative leg in arthroscopic position.

KNEE EXPOSURE

The incision is made for a medial arthrotomy, from the superior pole of the patella to just proximal to the tibial tubercle.

- The capsule is incised proximally just to the beginning of the vastus medialus muscle fibers.
- The anterior fat pad is excised.
- Patellar subluxation or dislocation is not necessary and should be avoided!
- The table is put into Trendelenburg and lowered to a comfortable position for the seated surgeon.

Final patient positioning should resemble lithotomy position with operative leg in arthroscopic position.

TECHNIQUE TIP

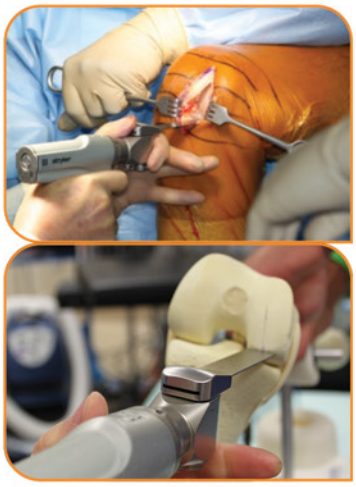
In some patients the tissue is tighter and it may be helpful to extend the capsulotomy into some muscle proximally. Also, if needed, minor releasing of the capsule from the anterior tibia can improve visualization.

Usually removing the medial edge of the patella is not necessary but using the burr to remove any medial patellar spurring is helpful for access in preparing the femoral surface and insertion of the femoral prosthesis.

RESECTION

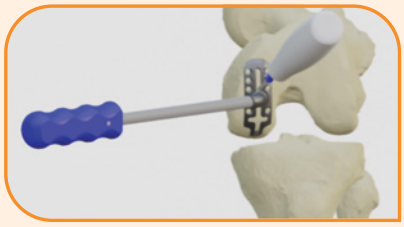
Posterior Femoral Condyle

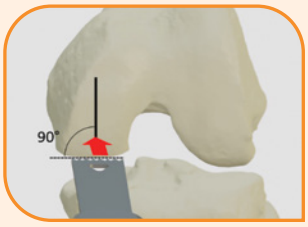
Flex the knee slightly past 90 degrees and confirm the anterior portion of the medial meniscus is excised. The posterior femoral condylar resection is performed freehand by passing the saw blade over the tibial surface and cutting in line in parallel with the femoral shaft. The cut bone is removed with an osteotome and is typically 8-12 mm in thickness.

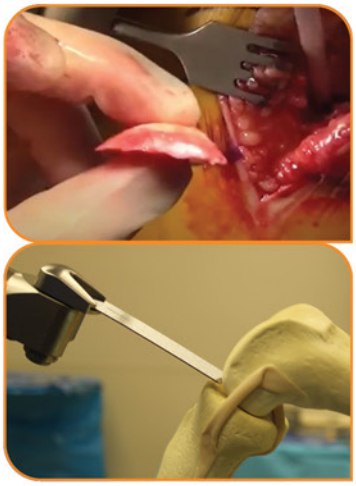


TECHNIQUE TIP

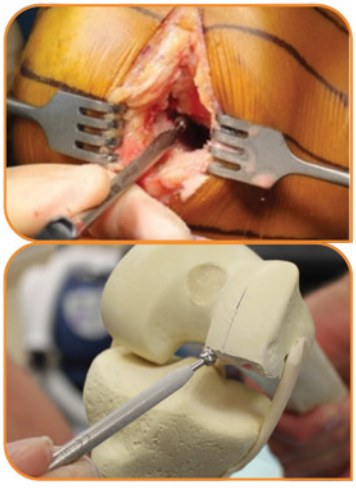
An optional step may be taken to avoid a grossly uneven cut in the coronal plane. Using the Femoral Keel Registration Template (#1 Femoral jig), mark through the central slit with a Bovie, this will help to maintain saw blade orientation during condylar resection. Guide the saw blade perpendicular to the marked line.







The resultant femoral cut edge is rounded with the high-speed spherical burr to allow better visualization of the tibia. The posterior condylar resection made is not the final femoral shaping. Burring of the femoral cut edge is helpful at this point to allow maximum visualization and access of the tibial surface.

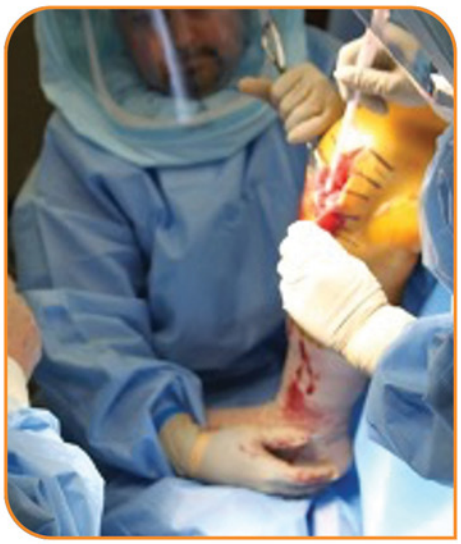


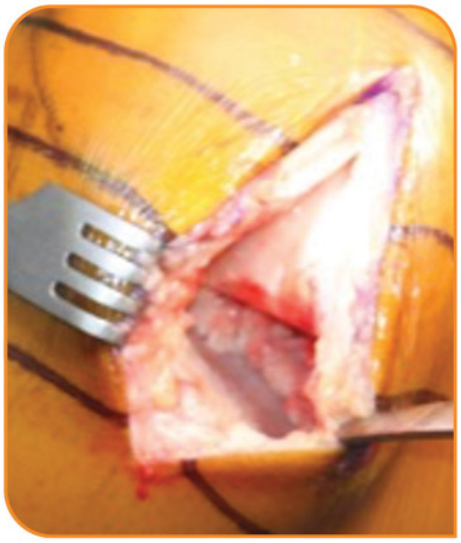
SOFT-TISSUE REMOVAL

Medial Tibial Plateau

With valgus stress applied to the knee, perform a medial meniscectomy starting anteriorly. As the meniscus is excised this will be facilitated by slipping a “baby” Hohman retractor over the medial edge of the plateau and having the assistant place the knee in maximum flexion and valgus stress.

Remove all soft tissues from the medial tibial surface so that the entire periphery of the plateau is seen. This allows for accurate placement of the tibial inlay and avoids the high-speed burrs from winding up soft tissue.



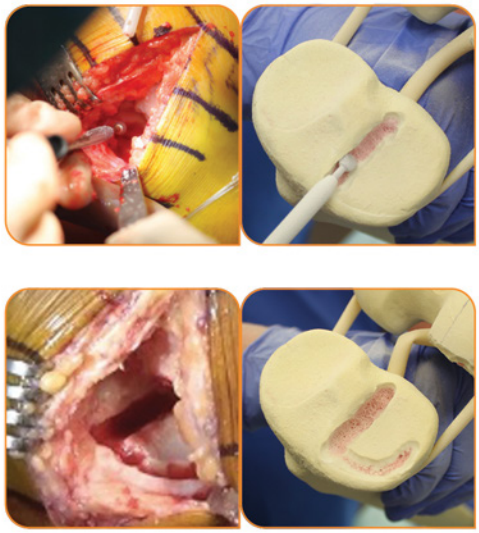


TIBIAL INLAY PREPARATION

The goal of the tibial preparation is to create a “pocket” to insert the tibial inlay approximately 2-5mm deep, depending on the degree of pre-operative varus.

Outlining the Tibial Plateau

Using the 6mm high-speed spherical burr, create a deep groove that parallels the intercondylar notch, slightly deeper than the burr diameter (NOTE: This is where the surface naturally rises towards the notch and must be cut in fairly deeply to avoid the tendency to place the implant into a varus inclination). The burr should outline the anterior half of the tibial pocket, keeping the burr a safe distance from the Hohman retractor, enough so that the retractor doesn’t break through.



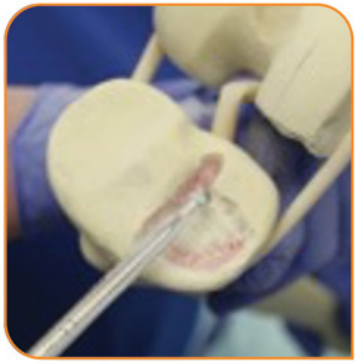
TECHNIQUE TIP

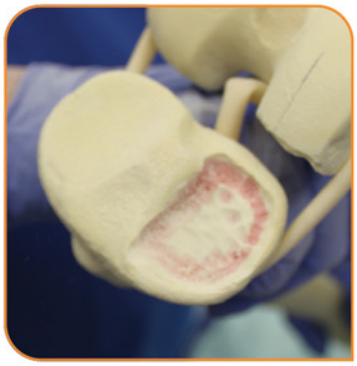
Avoid overstuffing the medial side by leaving the tibial implant sitting too proud. Typically, the medial edge sits up higher than by the notch. The alignment tibial jig can be utilized to check the slope of the inlay in the coronal plane.

TIBIAL INLAY PREPARATION

Utilizing a “back and forth” (medial-lateral) motion, work the spherical burr from the anterior plateau outline posteriorly approaching the posterior cortex carefully. With the defined exposure the surgeon should be able to easily access and feel the back edge of the surface with a finger, or a probe, to avoid penetration through the cortex.

It is acceptable to leave several millimeters of intact posterior surface. However, burring away the posterior cortex will allow for cement extrusion into the posterior recess making placement of trials, the tibial prosthesis and cement cleanup difficult. This back edge will serve as a wall to not allow the implant to advance posteriorly and may be as deep as the entire diameter of the 6mm spherical burr.





TECHNIQUE TIP

It is important to leave just a small amount of bone medially, and often the Hohman retractor is removed and a rake retractor is used instead medially. The depth of the cut is typically shallower at the medial edge dependent upon the amount of varus boney deformity present. If the medial edge is lost, it is not necessarily problematic.

TIBIAL INLAY PREPARATION

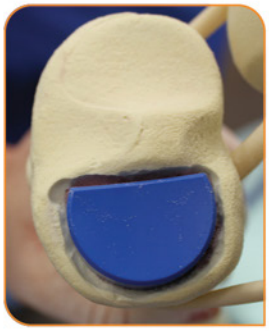
The appropriate (left / right) Tibial Finishing Rasp is used to flatten out the bottom surface, adjust depth and inclination of the tibial pocket.

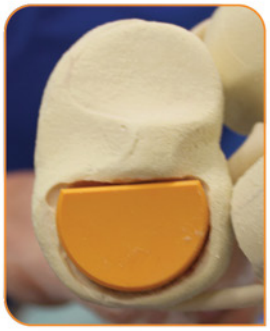
NOTE

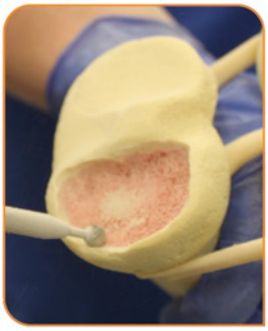
The Tibial Finishing Rasp is aggressive. Apply downward pressure as the rasp is moved side-to-side and from front-to back covering the entire tibial pocket. Frequently check the tibial pocket depth by inserting the 6.5mm tibial trial.

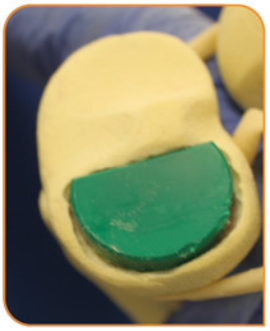
Tibial Trialing

Begin with smaller trials and work up to the largest one that will fit by enlarging the inlay surface area. If more width is needed and there is no more room medially, the notch can be undercut. It is important to get maximum coverage medial to lateral, not necessarily anterior to posterior. Use the 6.5 tibial trial initially, final determination of tibial implant thickness is done after the femoral trial is inserted.









FEMORAL PREPARATION

Accurate placement of the femoral component means having optimum contact and tracking with the central portion of the tibial component throughout flexion and extension. Since the femoral component is almost always placed up against the notch, it is only necessary to mark the medial extent of the prosthesis, as decortication will be done from that medial border to the notch. By establishing that medial border, this facilitates preparation of the stripe and curve that are necessary for femoral preparation.

Establishing the Medial Border

The 8.5 “slitted” tibial trial is placed into the prepared tibial pocket. Next, place the Bovie in the central “slit” and mark the femoral condyle in a vertical line as the knee is flexed and extended fully.

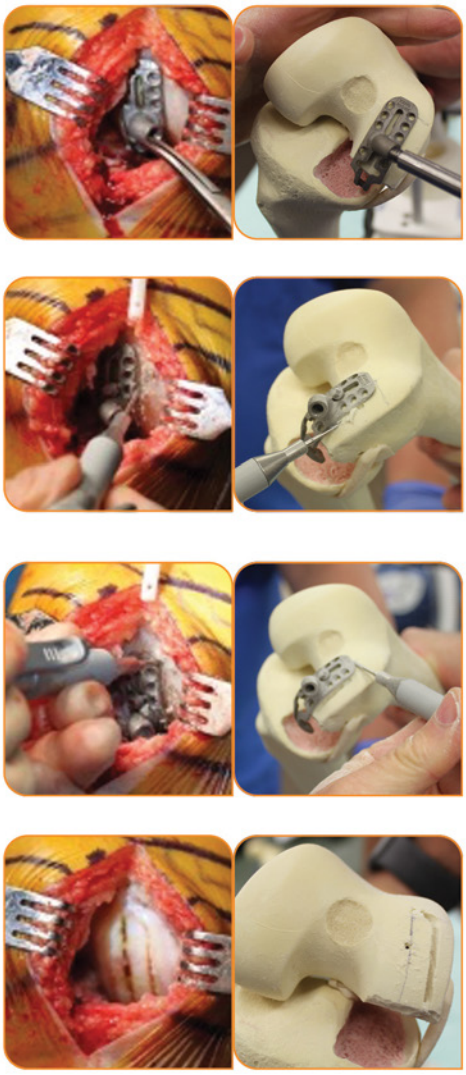
TECHNIQUE TIP

Often, a patellar spur is visible that obscures the femoral surface by the “notch”. Remove this with a 6mm burr to aid preparation and insertion of the femoral component.

FEMORAL PREPARATION

Outlining the Component on the Femoral Condyle

- Align the central slot of Femoral Keel Registration Template (femoral jig #1) with the previously marked line.
- Secure the jig with one or two lag screws.
- Pass the 2mm straight “pencil-tip” high-speed burr along the medial edge of the jig from the posterior edge to the anterior extent of the medial border (FIGS 13A-H).
- There is a medial slit in the 8.5 slitted tibial trial. This corresponds to the medial border on the femoral component. It can be used to mark a line on the femur similarly to the central line.



NOTE

The anterior edge of the femoral line marks where the anterior edge of the tibial trial contacts the femur in full extension. The anterior extent of the femoral component must be at or beyond that line. It is helpful to create a horizontal line to the medial edge of the femur for reference as the medial border is created, as the Femoral Keel Registration Template (femoral jig #1) often obscures that point.

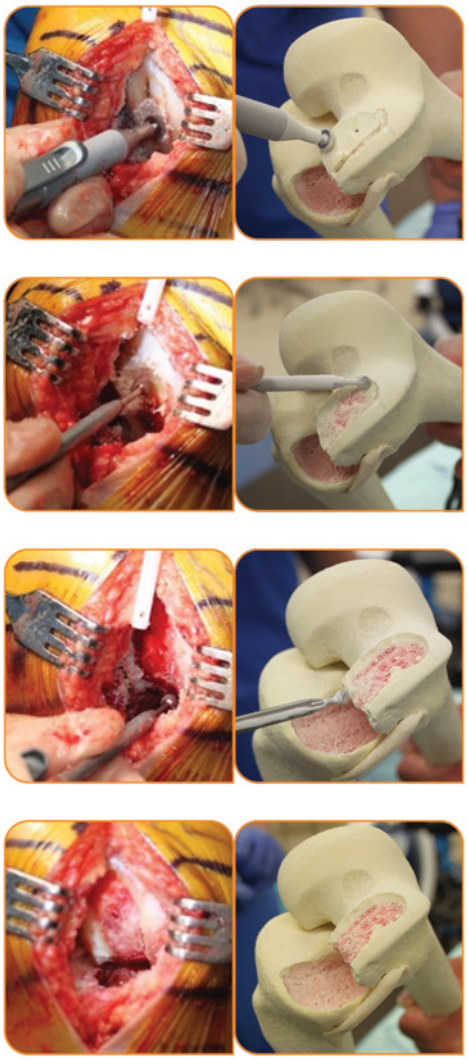
FEMORAL PREPARATION

Creating The “Stripe”

With the medial border established, both the flat femoral bit and round 6mm bit should be used to decorticate from the medial border to the notch. The depth is typically such that the 3 mm thick implant will be flush or slightly proud, depending on the amount of correction desired. The stripe extends at least to the anterior extent of what was marked on the femur or beyond if necessary.

Completing the Posterior Curve

The posterior curve is sculpted freehand as it is very difficult to place jigs into this space. This can be performed with side-to-side motions of the round burr. Since the round burr cuts on all sides, it can be safely placed posteriorly when the knee is flexed. The medial border serves as a guide to make the curve perpendicular to, since the entire stripe is not visible when the knee is flexed. Exact fit is not that important in this area as there is very little stress on this area and with the peg and keel the component will be very stable, so make sure and remove enough bone.

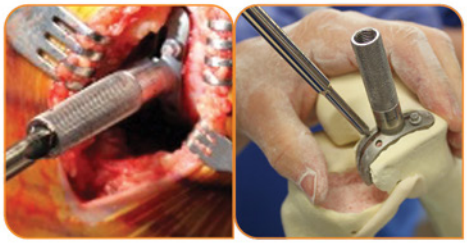


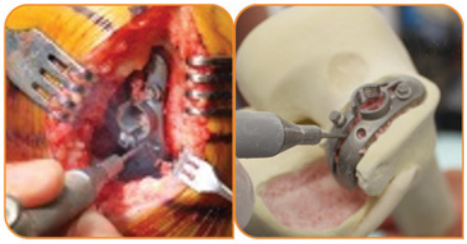
FEMORAL PREPARATION

Creating the Peg Hole and Keel Slot

Femoral Keel / Drill Guide (femoral jig #2) mimics the femoral component, so choose the appropriate size. Place the Femoral Keel / Drill Guide against the medial border and push anteriorly. Next, place the small lag screw into the anterior medial hole and a second small screw in the posterior lateral hole to secure the jig to the bone.

The hole can be drilled, and the drill guide unscrewed to allow the slot to be cut through the Femoral Keel / Drill Guide (femoral jig #2) with the 2 mm wire passing bit. Then the screws and jig are removed, and the components are ready to be trialed.





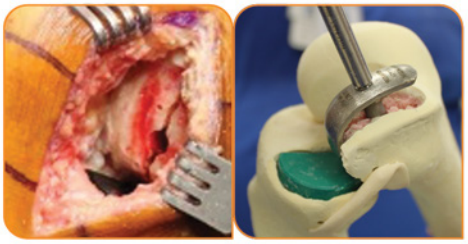
TECHNIQUE TIP

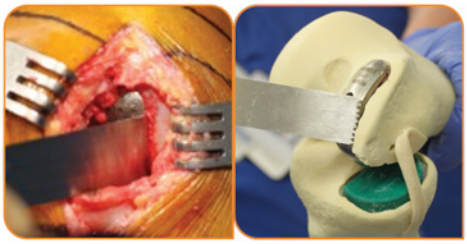
Be certain to burr adequate bone posterior so that the jig will seat properly. The anterior portion of the jig and implant is thickened so one must burr deeply anteriorly. If a more room is needed anteriorly, use the round burr to extend the “stripe.”

COMPONENT TRIALING

First place the tibial trial in the inlay. Then, using the inserter handle, the femoral trial corresponding to femoral Jig size 2 is inserted.

Flex the knee enough to get the peg in the hole, then rotate the component to align keel with the slot and seat with the mallet. Sometimes extending the knee is necessary to pass the anterior portion of the implant by the patella. With the femoral trial in place the medial femoral spur can be removed with the saw.





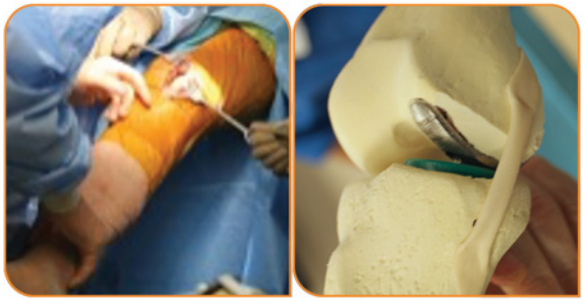
TECHNIQUE TIP

Femoral trial insertion is more easily performed with the knee semi-flexed and with applied valgus stress.

COMPONENT TRIALING

Assessing Range of Motion

Check that there is good metal to plastic contact throughout ROM. There can be a varying amount of flexion gap that should not be a problem unless the gap is too tight. Moving up to the 7.5 or 8.5 thickness can be done with a target of 0-3 degrees varus alignment. After selecting the desired thickness of the tibial implant, it is time to cement the final components in place.



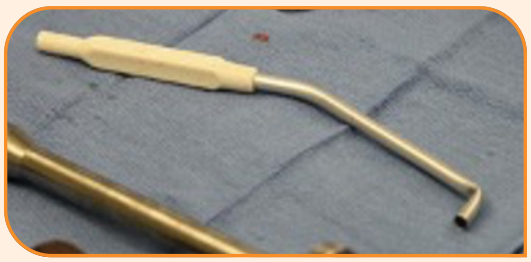
TECHNIQUE TIP

Overstuffing the joint will cause pain and valgus alignment is associated with disease progression, so leaving the knee a little looser is better. It is easy to tell if some height has been added to the medial side, we are trying to re-establish the patient's pre-disease state before the articular cartilage was worn down.

CEMENTATION OF IMPLANTS

As the cement is being mixed, prepare the tibial surface first with thorough pulse lavage and dry completely with a sponge. A large Fraizer endpiece with the tip bent at 90 degrees facilitates access and optimum marrow content removal of the prepared tibial. The standard pulsed lavalge hand piece is adequate for femoral marrow content removal and overall joint lavage.

TECHNIQUE TIP



Using the angled pulsed lavage tip, thoroughly clean out the marrow contents within the tibial pocket. Deeper cement penetration has been shown to better support the tibial inlay and resist aseptic loosening.

Medium viscosity cement in a cement gun is used typically for good cement penetration. Use when the cement stops being shiny and dripping from the gun. It is easier to clean up than high viscosity cement also. If the femoral component is cemented separately, High VIscosity cement may be used since it cures more quickly.

CEMENTATION OF IMPLANTS

Apply cement into the bed for the inlay and position the tibial implant into the inlay (it is not necessary to put cement on the implant surface). Slide the component posteriorly keeping downward pressure on the posterior portion so that it butts up against the posterior wall of the prepared inlay, then apply downward pressure to seat the implant fully. It should not be necessary to hold it in place, instead thoroughly removing excess cement should be undertaken. Wet Ray-Tec® sponges and special cement removing tools help this very important process.

TECHNIQUE TIP

Even a small piece of cement will float around the joint and cause problems necessitating arthroscopic removal, so prevention is the key. As the cement sets up pushing down again on the implant may sometimes extrude more cement out that needs to be removed.

Cementing the femoral component can be performed with the same batch of cement or separately. Pulse lavage the end of the femur and dry thoroughly, then place cement into the hole for the peg. The back of the femoral component should be covered with cement, not the peg. The femoral component is then seated, and excess cement is carefully removed.

KNEE CLOSURE

The knee is positioned in slight flexion and the wound is closed in layers after infiltration with local anesthetic.

PRODUCT SIZING TABLE
Tibial Component

TIBIAL COMPONENTS

SIZE	PN	DESCRIPTION	AP	HEIGHT
SMALL	311326	Partial All Poly Tibial Component, Small, 32mm, 6.5mm	32	6.5
	311327	Partial All Poly Tibial Component, Small, 32mm, 7.5mm		7.5
	311328	Partial All Poly Tibial Component, Small, 32mm, 8.5mm		8.5
SMALL-MEDIUM	311346	Partial All Poly Tibial Component, Sm-Med, 34mm, 6.5mm	34	6.5
	311347	Partial All Poly Tibial Component, Sm-Med, 34mm, 7.5mm		7.5
	311348	Partial All Poly Tibial Component, Sm-Med, 34mm, 8.5mm		8.5
MEDIUM	311366	Partial All Poly Tibial Component, Medium, 36mm, 6.5mm	36	6.5
	311367	Partial All Poly Tibial Component, Medium, 36mm, 7.5mm		7.5
	311368	Partial All Poly Tibial Component, Medium, 36mm, 8.5mm		8.5
MEDIUM-LARGE	311386	Partial All Poly Tibial Component, Med-Lrg, 38mm, 6.5mm	38	6.5
	311387	Partial All Poly Tibial Component, Med-Lrg, 38mm, 7.5mm		7.5
	311388	Partial All Poly Tibial Component, Med-Lrg, 38mm, 8.5mm		8.5
LARGE	311406	Partial All Poly Tibial Component, Large, 40mm, 6.5mm	40	6.5
	311407	Partial All Poly Tibial Component, Large, 40mm, 7.5mm		7.5
	311408	Partial All Poly Tibial Component, Large, 40mm, 8.5mm		8.5
EXTRA-LARGE	311426	Partial All Poly Tibial Component, Xlarge, 42mm, 6.5mm	42	6.5
	311627	Partial All Poly Tibial Component, Xlarge, 42mm, 7.5mm		7.5
	311428	Partial All Poly Tibial Component, Xlarge, 42mm, 8.5mm		8.5

PRODUCT SIZING TABLE
Femoral Component

FEMORAL COMPONENTS

SIZE	PN	DESCRIPTION	AP	ML	POST LENGTH
EXTRA SMALL	313421	Partial Femoral Component, Left, XSML, SZ 42x15	42	15	11
SMALL	313451	Partial Femoral Component, Left, SML, SZ 45x16	45	16	11
SMALL MEDIUM	313471	Partial Femoral Component, Left, SMED, SZ 47x17	47	17	11
MEDIUM	313501	Partial Femoral Component, Left, MED, SZ 50x18	50	18	11
LARGE	313541	Partial Femoral Component, Left, LRG, SZ 54x19	54	19	11
EXTRA SMALL	314421	Partial Femoral Component, Right, XSML, SZ 42x15	42	15	11
SMALL	314451	Partial Femoral Component, Right, SML, SZ 45x16	45	16	11
SMALL MEDIUM	314471	Partial Femoral Component, Right, SMED, SZ 47x17	47	17	11
MEDIUM	314501	Partial Femoral Component, Right, MED, SZ 50x18	50	18	11
LARGE	314541	Partial Femoral Component, Right, LRG, SZ 54x19	54	19	11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Pursue Life™

For more information about Freedom® Knee, please contact your local representative.

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Freedom Total Knee® System (Renew Resurfacing Unicondylar)

℞ only

Maxx Orthopedics, Inc.
2460 General Armistead Ave, Ste 100
Norristown, PA 19403 USA

Carefully read all instructions and be familiar with the surgical techniques prior to use.

Please see the package insert for complete device description, product selection information, indications, contraindications, precautions, adverse effects, warnings, materials, sterilization and patient guidance associated with the Freedom Total Knee® System.

CAUTION: THIS DEVICE IS RESTRICTED TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN

WARNING: THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY

Maxx Orthopedics Brochure No. MXO-MP00049-R01

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