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FREEDOM® KNEE

Pursue Life™

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

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

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FREEDOM® KNEE

Surgical Technique

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Introduction

The Freedom Total Knee System was developed using advanced design engineering technologies and extensive clinical experience to address the anatomical, physiological and lifestyle needs of today's patients. The system's significant design advances allow patients to achieve optimal high flexion motion regardless of whether the all poly or metal-backed tibial component is chosen. This approach provides surgeon with unique component options that deliver successful, predictable and reproducible results.

The Freedom Knee system offers the widest range of interchangeable component size combinations on the market today.

Freedom Knee Instrumentation was designed to address the requirements of all total-knee replacement procedures, to fully assure precise and dependable resection of the host bone and to serve a variety of surgical options.

Criteria for Successful TKR

- Accurate Sizing of Components
- Precise Component Alignment
- Soft Tissue Balancing
- Accurate Patello-Femoral Tracking
- Good Cement Fixation

Pre-Operative Planning

Full-length extremity X-Rays are obtained and the mechanical and anatomic axes are identified.

OR

In order to assess bone quality, potential ligament instability and the anatomical axis, a 36" long standing AP X-Ray is recommended. Be careful of misleading angles in knees with a flexion contracture or rotated lower extremities.

Radiographic templates are overlaid on the films to estimate the appropriate size of the prosthesis. Estimate the femoral component size preoperatively by using lateral view X- ray and radiographic templates. The A/P size is critical to the restoration of normal kinematics and quadriceps function.

Patient Preparation

Tourniquet:

The extremity is appropriately prepared and draped. A tourniquet is applied and following application of an Esmarch bandage, inflated.

Surgical Approach:

Freedom total knee Instruments are designed for used with both traditional surgical methods as well as minimally invasive techniques.

Three common approaches can be used for total knee arthroplasty are -

Medial Parapatellar

Sub Vastus Approach

Mid Vastus

Surgical Technique

Exposure

I) Femoral Preparation:

The medullary canal is entered at the midline of the femoral trochlea 7–10 mm anterior to the origin of the PCL to a depth of about 5–7 cm using a 8 mm Step Drill. Make sure that the drill is parallel to the shaft of the femur in both the Antero-Posterior and Lateral projections.

The step on the drill will enlarge the entry hole on the femur to 12 mm to reduce intra-medullary pressure during subsequent IM guides. Suction the medullary contents prior to insertion of the Distal Femoral Cutting Guide (DFCG) to reduce the potential of fat embolism. Distal femoral shaft is palpated (Figure 1) as the drill is advanced to avoid the cortices.

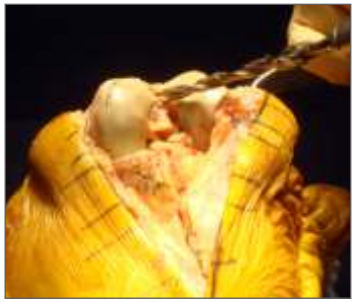

Figure 1

The Modular IM alignment guide is available with two IM rods to choose from 30 cm or 40 cm length as per pateint's anatomical axis.

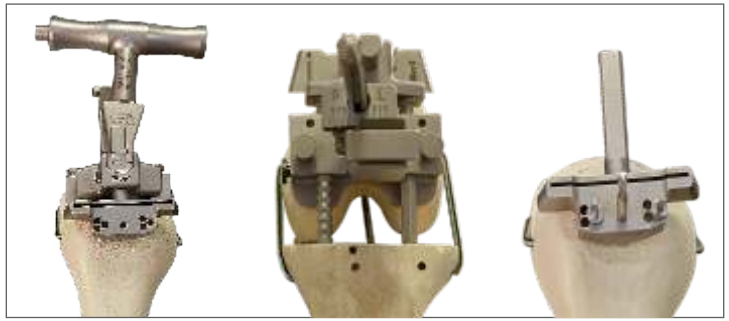

Figure 2

Secure the distal femoral cutting jig with appropriate valgus angle adaptor (0-10 deg options) along with the calibration guide to set the appropriate resection depth for distal femur resection (1-13 mm).

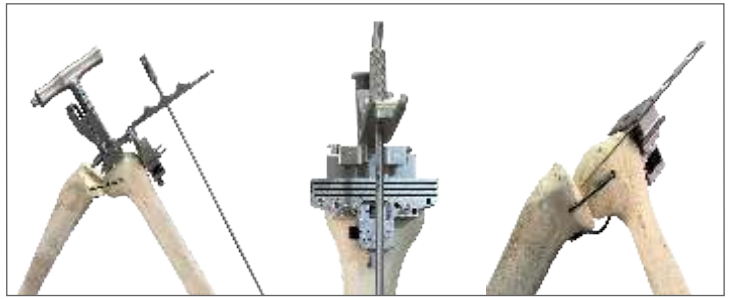

Figure 3

Pin the distal femur cutting (DFC) jig and extract the assembly using slap hammer after unlocking the DFC jig button.

The distal femoral cutting jig cuts the distal femur in a measured resection, standard cut being 9 mm (pins in neutral Holes).

Optional cutting slots are designated at 13 & 17 mm for circumstances that require additional femoral resection. Provision of +2, 0 and -2 is available on the jig for facilitating 11, 9 and 7 mm measured resection respectively.

Femoral mechanical axis is checked with the help of alignment tower and rod. Perform the distal femoral cut by using oscillating saw (Figure 4).

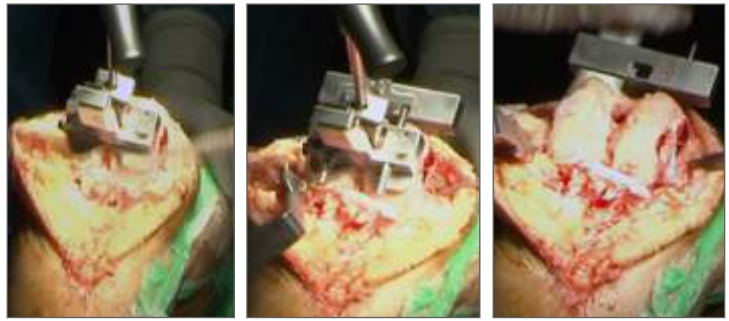

Figure 4

II) Extramedullary Tibial Resection:

The knee is placed in maximal flexion with the tibia subluaxated anteriorly and stabilised, place the ankle clamp around the distal tibia just above the malleoli. At this time, confirm parallel alignment of the tibial cutting jig to the mechanical axis in both planes. Use the fine adjustment knob at the proximal end of the tibial cutting jig to adjust the height of the cutting slot. The tibial cutting jig (0, 3 and 5 Degree Posterior Slope) is raised to the condyles using the gross alignment knob (Figure 5).

Align the tibial cutting jig with the mechanical axis of the tibia in the coronal and sagittal plane. Secure the guide with pins in neutral holes marked with box. The stylus determines the level of resection on the proximal tibia. The side with 2 prongs adopt to the tibial cutting jig and the resection depth can be selected (0-13 mm). There is a 4 mm difference between the top surface and the slot in the tibial cutting jig.

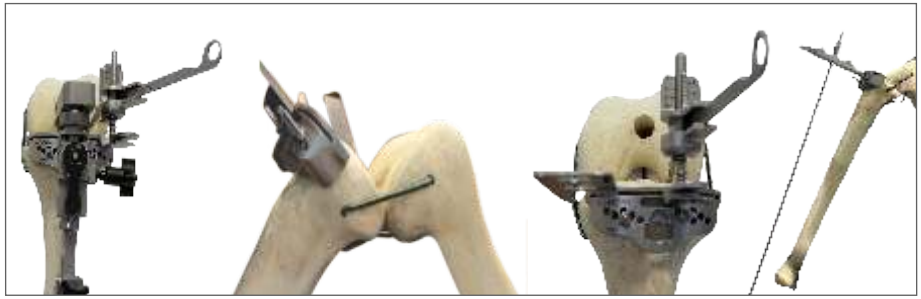

Figure 5

A level of 9 mm is suggested where resection is based on less involved condyle & 2 mm resection is recommended where more involved condyle is referenced.

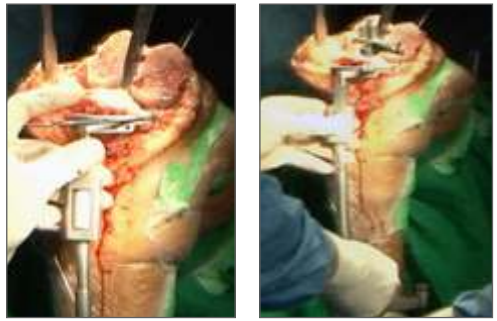

Figure 6

III) Extension Gap Assessment & Balancing :

Place the knee in full extension and insert spacer block (9, 11, 14, 17 mm) to check for rectangular extension gap. If the extension gap is trapezoidal the soft tissues must be balanced to obtain a rectangular gap (Figure 7a & b).

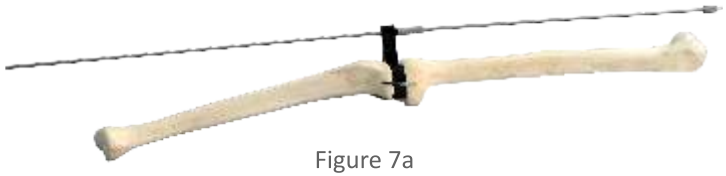

Figure 7a

Figure 7b

A set of spacer blocks measures the gap and indicates the appropriate thickness of the tibial insert, subject to reevaluation at trial reduction.

IV) Femoral Sizing & Rotation:

Place the AP sizing guide flush against the resected distal femur with the posterior condyles touching on posterior saddles of the sizing guide (Figure 8a & b). Place the sizing guide stylus on the anterior femur with the tip positioned at the intended exit point on the anterior cortex to avoid any potential notching of the femur.

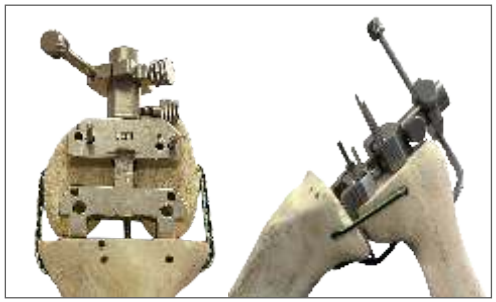

Figure 8a

The Femoral A/P sizing guide is a single unit, reversible modular instrument. It allows for sizing of both the RT and LT femur based on the orientation of the guide. It also allows the surgeon to set the femur in the 3 degree, 4.5 degree or 6 degree of external rotation, based on the posterior condylar axis. Intra-operatively, the rotation can be verified using the AP axis (Whiteside Line) or the surgical trans epi-condylar axis of the femur.

Once adjusted, place headless pins into the two 3 degree external rotation slots and read the sizing indicator. If in between sizes up or down size as appropriate. Leave the sizing pins on the distal femur & remove the sizer.

Undersizing will cause looseness in flexion and possible notching of the anterior femoral cortex. Oversizing will cause tightness in flexion and increased tension in the quadriceps mechanism.

Figure 8b

V) Flexion Gap Assessment:

Flex the knee and check ligament balance and joint alignment in flexion (Figure 9a).

Use of 6 mm or 8 mm spacer blocks is recommended for checking 9 mm or 11 mm flexion gap with 5 in 1 jig in situ. (Figure 9b).

If the tension is significantly less in extension than in flexion, either downsize the femur or perform additional ligament releases.

Figure 9a

Figure 9b

VI) Femoral 5 in 1 Resection:

Anterior Referencing Technique -

Select the correct size of 5 in 1 block as determined by femoral AP sizing guide. Position the 5 in 1 cutting jig by sliding it on headless pins through the rectangular slot on the distal femur. Secure the 5 in 1 cutting block to the distal femur using threaded/ headed pins in the medial and lateral pin holes.

For additional stability use the 6.5 mm cancellous screws in the peg holes using power screw driver. Confirm that the anterior cut will not notch the anterior cortex of the femur (Figure 10a & b). Remove the headless pins.

Use the appropriate narrow oscillating saw blade to cut the femoral profile in the following order :

1)Anterior Cut 2) Posterior Cut 3) Superior Champher Cut

4) Inferior Champher Cut 5) Trochlear Cut

The cuts can be made in any order though the sequence of femoral cuts has been provided. Use narrow saw blade to cut the base and score the edges of the trochlear recess. The width of the 5 in 1 cutting jig replicates the width of the freedom femoral component.

If positioned in external rotation correctly on the distal face of the femur, then more postero medial femoral condyle would be removed compared to postero lateral femoral condyle. Be careful not to transect the attachment of the medial co-lateral ligament (MCL) during the resection of the posterior condyles.

Figure 10a

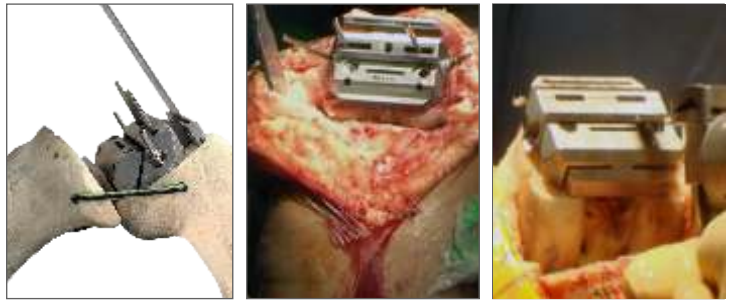

Figure 10b

Figure 11

To reassess the flexion gap, flex at 90 degree and insert 9 or 11 mm spacer block with alignment rod in place (Figure 11).

Femoral Notch/Box Cut (For PS Knee only)-

Flex the knee in 90 degree and secure the Notch Guide to the femur distally with two short 3.2 mm headed pins. Use a reciprocating saw to cut the sides & base of the intercondylar box. Protect the tibia with a wide osteotome (Figure 12).

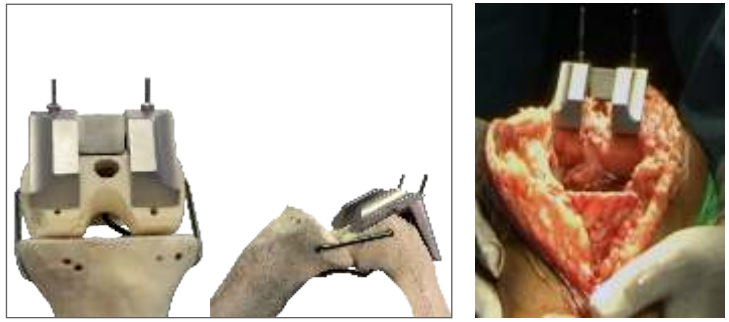

Figure 12

Femoral Trial Component-

Mount the specific trial femoral component (PS/CR) on the femoral impactor/extractor.

Carefully introduce femoral component on the prepared femoral surface aligning the peg holes. Perform the gentle impaction with a mallet till the femoral component sits flush on the prepared femoral bone.

Perform the extraction of the femoral component using same impactor/extractor with the slap hammer gently (Figure 13).

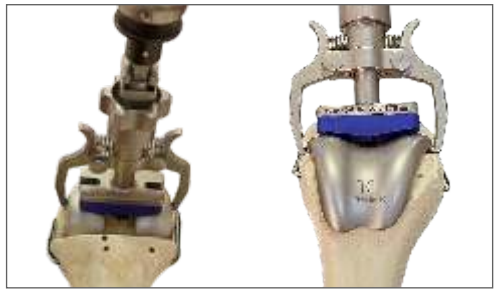

Figure 13

VII) Tibial Sizing and Preparation:

Flex the knee maximum and stabilize it. The size of the base plate is matched to the ML of the cut tibia surface. Definite trial tibial base plate to be introduced and secured on proximal tibial surface using short headed pins.

Check the rotation and alignment using extramedullary alignment rod through round holes on tibial handle. Place the tibial broach housing on the trial tibial base plate.

Using the 17 mm tibial entry reamer, gently ream the proximal tibia until the stop on the reamer reaches the top of the tibial broach housing.

If the All Poly tibial tray is been used, go to " broaching the tibia" using smaller broach (Figure 14a, 14b & 14c).

Tibial sizing

Figure 14a

Tibial drilling

Figure 14b

Tibial broaching

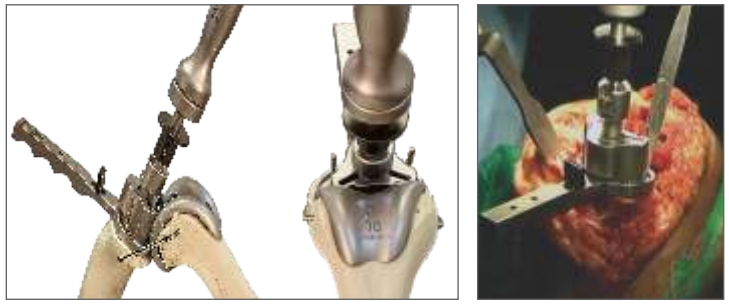

Figure 14c

VIII) Trial Reduction:

In this step a trial reduction is performed to check femoral trial component position, patellar tracking, range of motion, alignment, varus-valgus stability, antero-posterior stability and over all joint stability.

Ensure that the trial femur (CR/PS) component is placed, with appropriate size of trial tibial base plate & corresponding insert trial (CR/PS) (Figure 15).

With all trial prostheses in place, the knee is carefully and fully extended, noting medial and lateral stability and overall alignment in the A/P and M/L plane. Where there is any indication of instability, the next greater size tibial insert is substituted and reduction repeated.

The insert that gives the greatest stability in flexion and extension and allows full extension is selected. Where there is a tendency for lateral subluxation or patellar tilt in the absence of medial patellar influence (thumb pressure), lateral retinacular release is indicated.

Rotational alignment of the tibial tray is adjusted with the knee in full extension, using the alignment handle to rotate the tray and trial insert into congruency with the femoral trial.

Figure 15

IX) Patella Preparation:

The preparation of the patella should be done with the patella everted and the knee flexed to 30°. The minimum thickness of the resected patella should be 8 mm. Over stuffing the patella-femoral joint may lead to flexion loss, while leaving a thin patella may lead to fracture or early loosening. Use a caliper to help decide the amount of resection that is required.

Once the patellar surface is resected, use the patellar drill guide to assess the size of the patella. Using the patellar drill guide and the peg drill , drill three holes in the remaining patellar bone. Place the patella trial onto the resurfaced patella and begin range of motion to evaluate patellar tracking (Figure 16).

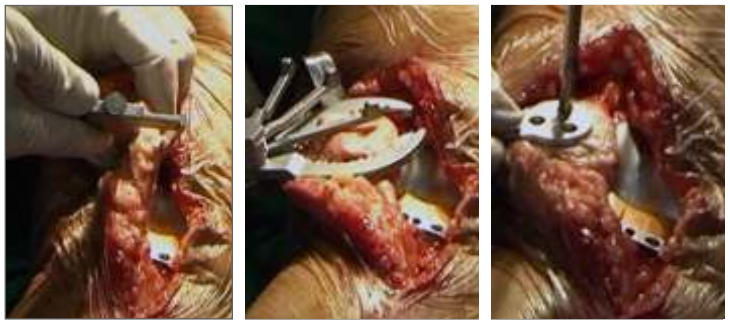

Figure 16

X) Implantation:

Using the standard mixing protocol for the bone cement, mix and prepare the bone cement for cementing the implants.

We recommend the following order of implantation.

1. Tibial component
2. Femoral component
3. Patellar component
4. Tibial articulating surface

Prior to cementing, irrigate the bone surfaces and drill sclerotic areas with a 1⁄8" drill bit to a depth of approximately 1⁄8". Firmly press cement into the bone surfaces, including the reamed keel entry hole, to allow for adequate interdigitation. Place cement on the undersurface of the tibial component and firmly impact the tibial component into place using the tibial impactor. Remove excess cement.

Hyperflex the knee and dry the distal femoral bone cuts. Finger pressurize the posterior condyles with cement. Apply bone cement to the undersurface of the femoral component. Firmly impact the femoral component into place using the femoral impactor. Remove excess cement.

If the metal-backed tibial tray is being used, irrigate the surface of the tray and remove any excess debris to clear the locking mechanism. Firmly impact the selected articular surface liner into place and check to see that the locking mechanism is engaged (Figure 17).

Figure 17

Figure 18

Reduce the knee and place into extension. Evert the patella. Dry the bony surface of the patella. Place cement into the bone surfaces. Apply bone cement to the undersurface of the patella implant. Place the patella implant in the resected bone. Use the patella clamp to secure the patella implant. Trim excess osteophytes and remove excess cement (Figure 18).

Closure:

Closure is performed (Figure 19)

Figure 19