FREEDOM® KNEE

maxx medical

Freedom Knee Surgical Technique

Pursue Life™

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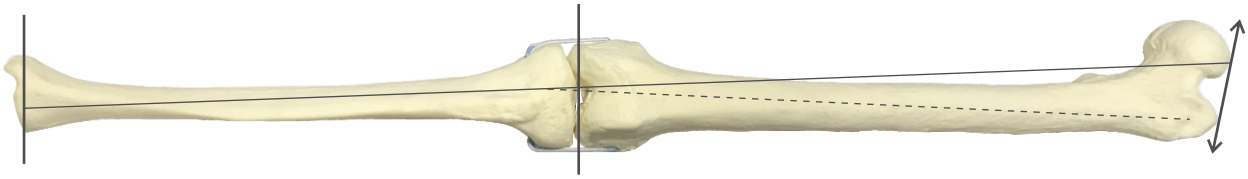


Pre-Operative Planning

As a standard protocol, a thorough physical examination of the knee should be performed to evaluate the patient's overall knee function. Functional stability, muscle tone, ligamentous/capsular laxity and/or contractures and potential boneloss-all need to be considered during this step.

AP and Lateral standing radiographs along with a Skyline view in a known magnification should be obtained and evaluated. Radiographs of the non-operative limb may also be considered to provide an additional reference.

Additionally, the surgeon may elect to obtain AP whole leg radiographs for both limbs to determine the current hip/knee/ankle centers, anatomical & mechanical axis to allow for additional pre-operative planning of the intended corrective osteotomies and resultant alignment/implant positioning.

If intra-medullary alignment instrumentation is intended for use, the shape and diameter of femoral and tibial canals should be evaluated to help assure its successful use and the passage of intra-medullary alignment devices into respective bone canals.

The intended implant size must also be evaluated on both AP and lateral radiographs by using the Meril Radiographic overlay templates. The magnification percentage of the templates used should approximate the known magnification of the radiographs.

Patient Preparation

The extremity to be operated is appropriately prepared and draped before applying tourniquet following application of an Esmarch Bandage and inflated.

Surgical Incision

Freedom knee Instruments are designed for use with the traditional surgical methods and also for minimal invasive techniques.

Three common used methods for surgical incision are [Fig. 1]:

- Medial Parapatellar Approach Fig. 1(a)
- Mid Vastus Approach Fig. 1(b)
- Sub Vastus Approach Fig. 1(c)

The surgeon may select either of these standard exposure methods to perform skin and capsular incision. If the medial parapatellar approach is selected, a straight midline skin incision, extending above and below the patella is made to begin the exposure. The capsular exposure is then approached by utilizing a longitudinal medial parapatellar incision, typically extending upward to a level of one third of the rectus femoris or vastus medialis and downward to the medial side of the origin of patellar tendon on the tibial tuberosity.

Once the exposure is completed, the patella is everted in a standard fashion [Fig. 2], and the knee joint is inspected. Cautious assessment and removal of the osteophytes should be undertaken. ROM, patellar tracking and soft tissue stability/instability should be evaluated again. It may be the preference of the surgeon to conduct a preliminary soft tissue release of the fixed contracted structures. Once completed, the knee is flexed to 90 degrees to perform the initial femoral pilot hole for the intra-medullary alignment.

Medial Parapatellar Approach
(a)

Mid Vastus Approach
(b)

Sub Vastus Approach
(c)

Fig. 1

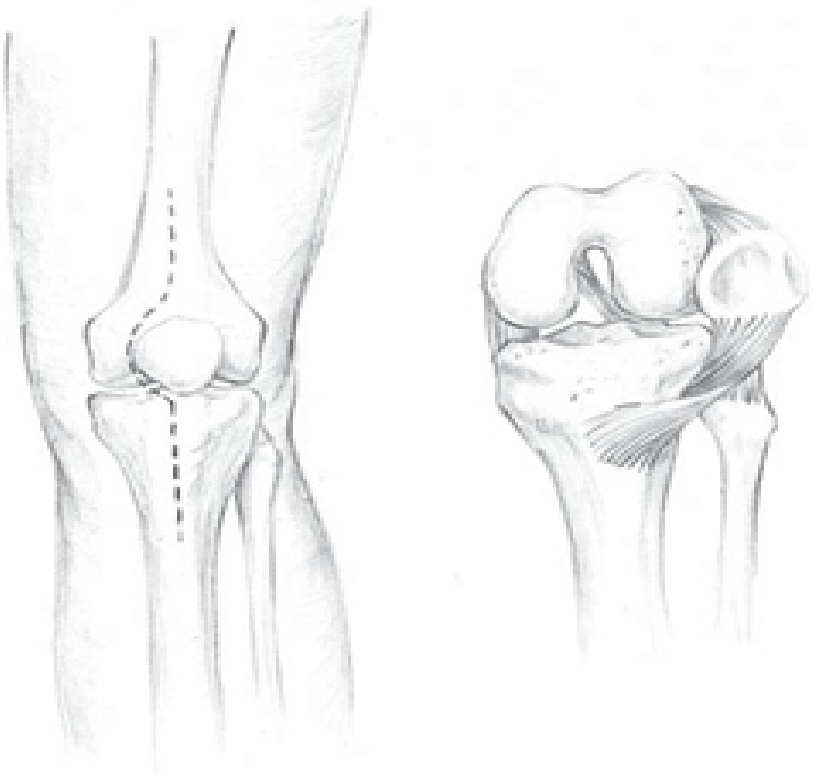


Fig. 2

A.Tibial Preparation

A1. Tibial Extra-medullary Alignment Method

The knee is placed in maximal flexion with a subluxated tibia that is anteriorly stabilised.

Assemble the Tibial Extra-medullary Alignment Guide to the selected Proximal Tibial Cutting Jig. The surgeon may select this from available MIS Left or right or standard 0, 3 or 5 degrees posterior slope.

With the knee, in fully flexed position, the distal portion of the Tibial EM Alignment Guide is placed on the anterior ankle joint with its supramalleolar spring tabs. Position the proximal portion of the Tibial EM alignment guide by impacting the spikes of the Tibial EM Alignment Guide onto the central portion of the proximal tibial plateau. While aligning the tibial EM alignment guide, ensure that it aligns with patient's 2nd toe (of operating leg). At this time, confirm parallel alignment of the EM assembly-Fig. 3(b) to the mechanical axis in both coronal & sagittal planes. Use the fine adjustment knob at the proximal end of the tibial cutting guide to make finer adjustments to the desired bone resection level.

Important Note : The tip of the stylus must be placed on the lowest point on the unaffected/healthy side of the tibial plateau. Fig. 3(a)

(a) (b)

Fig. 3

A2. Tibial Cutting Jig Positioning and Tibial Resection

Once the desired resection level is achieved, 2 long headless pins can be drilled into square holes marked zero to secure the tibial resection guide, Fig. 4(a). Additional pins may also be drilled to secure the guide during tibial resection.
Once the Tibial Cutting Guide is securely positioned, Tibial EM Alignment Guide is now removed by disengaging the spike using a Tibial EM Guide Extractor. Resection of the tibial plateau is now performed by using a 1.24 mm oscillating saw blade.Fig. 4(b)

Important Note : Prior to resection, if the surgeon wishes to increase or decrease the tibial resection thickness the "+2" or "-2" holes are to be utilized to reposition the Tibial Cutting Jig.

(a) (b)

Fig. 4

B. Femoral Preparation

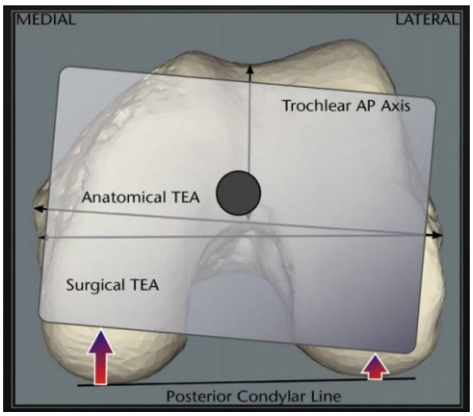
B1. Preparing Femoral Pilot Hole

With the ACL removed, the typical femoral entry point is slightly medial to the center of the intercondylar notch and approximately 5-7 mm anterior to the anterior insertion of the PCL into the femur.

Important Note : As both varus and valgus deformities are commonly encountered in the patient, cautious evaluation of the possible AP and ML curvature of the femoral shaft should be undertaken to consider shifting the initial entry hole to a more appropriate location for each specific patient.

A surgical marker is used to mark the hole location; the proper entry point at the distal femur should be 2 mm to 3 mm medial and 2 mm to 3 mm superior to the top of the femoral intercondylar notch, Fig. 5(a) followed by an 8 mm step Drill to create an opening in the femoral canal. The drill is typically inserted to a depth of approximately 100 mm within the femoral canal. Ensure that the drill is parallel to the shaft of femur in both AP & lateral projections. Fig. 5(b)

After removal of the drill, intra-medullary fluid along with bone debris may be flushed out of femur to avoid any fat embolism.



(a)

(b)

Fig. 5

B2. Femoral Valgus Angle Confirmation

Once an access to the canal is created, adjust the locating device (range ± 10 degree) to the pre-operatively estimated valgus angle and load it on the appropriate length of the Femoral IM Rod (with T-Handle) manually insert the Femoral IM Rod into the femoral canal. Fix the locating device on the femur with spike to ensure that the device is in firm contact with the distal femur.[Fig. 6]

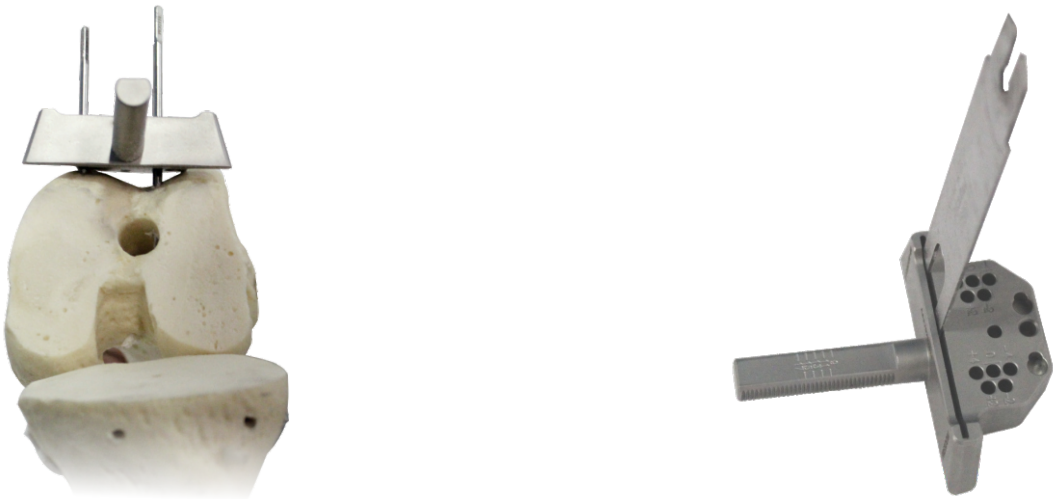
Important Note : Use a long IM rod (40 cm) for tall patients or a small IM rod (30 cm) for average height patients.

Fig. 6

B3. Distal Femur Bone Besection

Adjust the out trigger to desired distal femur cut level (the standard suggested distal femur cut is 9 mm) and attach the distal femur cutting jig to the out trigger. Connect this assembly to the locating device. Fig. 7(a)

To secure the DFCG (Distal Femoral Cutting Guide), firmly to anterior femur, drill non-headed long pins in the square marked zero holes. Once the entire instrument assembly is secured, the angel wing is used to assess the depth of distal femur cut and if necessary appropriate adjustments are recommended to adjust the DFCG to pre-operative desired level. Press the hook available on the out trigger to release the DFCG jig from entire assembly by pulling the IM rod using T handle leaving behind only the DFCG fixed with pins.



(a) (b)

Fig. 7

Important Note : "+-2 mm" guide holes on the DFCG provides options to allow additional resection if desired. Once the distal femur resection is assessed and adjusted to desired level, distal femur resection is performed through the cutting slot using a 25 mm wide oscillating saw blade with 1.24 mm thickness.

C. Extension Gap Confirmation

The flexion and extension joint space gaps may be evaluated at this time with the spacer block (the 9 mm spacer block initially selected) to assess both the flexion and extension joint space.

If a thicker gap is observed, try additional spacer block (available in 11, 14 & 17 mm) with different thickness and test again for rectangular extension gap.

A set of spacer blocks measures the gap and indicates the appropriate thickness of tibial insert. (subject to be re-evaluated at the time of trial reduction)

Important Note : The flexion gap can also be measured before performing the 5 femoral cuts with 5-in-1 cutting guide in-situ. Use of 6 mm or 8 mm is recommended at this stage to pre-assess the flexion gap.

The alignment rod is inserted through the spacer block handle to assess the extra-medullary alignment in extension. [Fig. 8]

Extension Gap Confirmation

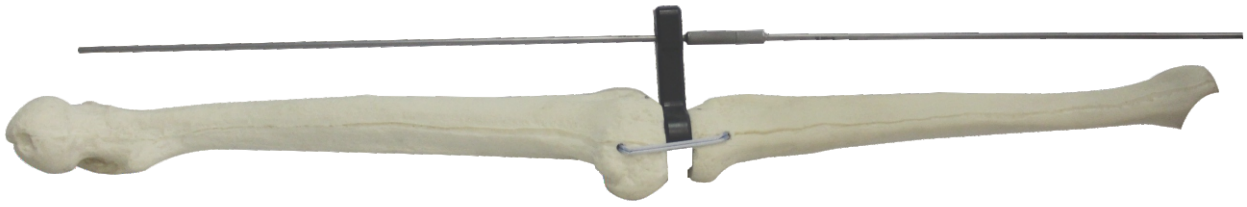


Fig. 8

D. Femoral Component Sizing

Extract the non-headed long pins using pin extractor instrument and remove the DFCG after distal femur resection.

Orient the AP sizing guide to the desired side of the knee being operated upon by rotating it. Place the AP sizing guide flat against the resected distal femur with its two posterior saddles rested flushed against the posterior femoral condyles and ensure tip of stylus touches the highest point of the lateral anterior femoral cortex to avoid any potential notching of femur, Fig. 9(a). The estimated size is indicated on the front of AP sizing guide and tighten the nut to ascertain the correct size of femur.

Important Note : Use the 'LARGE' marked distal component of AP sizing guide for bigger bones and 'SMALL' marked one for smaller bones. Fig. 9(b)

(a) (b)

Fig. 9

Important Note : The Freedom Knee system is anterior referencing system. In case, the estimated size lies in between two sizes, it is recommended to choose the smaller/lower size. Any additional bone resection will be removed from posterior condyles. Under-sizing causes loosening in flexion and possible notching of anterior femoral cortex while over-sizing causes tightness in flexion and increased tension in quadriceps mechanism.

To establish the external rotation, drill the non-headed long pins in desired holes, the AP sizing guide has provision for 3 degree and 6 degree external rotation. In case desired external rotation is 3 degree, drill pins in 3 degree holes, drill both the pins in 6 degree holes to achieve 6 degree external rotation. There is additional option of achieving 4.5 degree external rotation by placing one pin in 3 degree on the lateral side and 6 degree on the medial side.

E. 5-in-1 Femur Resection

Remove the AP sizing guide leaving the long non-headed pins in place & position the estimated size of 5-in-1 cutting guide as determined by the AP sizing guide, on the predrilled pins on distal femur by sliding on pins through rectangular slot.

Important Note : The 5-in-1 cutting guide should be flush seated on the distal femur.

At this step, there is the option of reconfirming the estimated size again by attaching optional stylus to the 5-in-1 cutting guide and ensure its stylus touches the highest point of the lateral anterior femoral cortex and using a 6 mm or 8 mm spacer to pre-assess anterior notching and flexion gap, before the five femoral cuts are performed. The M/L width of 5-in-1 cutting guide matches with the corresponding M/L width of the Freedom Knee Femoral component. The M/L rectangular slots, on the 5-in-1 cutting guide facilitate medial-lateral positioning of the guide and therefore the final femoral implant.

Drill lug screws in lug holes of 5-in-1 guide using power system to flush seat them completely. Use additional cancellous pins in lateral & medial holes to enhance stability during resection and check resection thickness using angel wing in anterior and posterior resection slots, Fig. 10(a). Next, complete the Anterior, Posterior, Anterior Chamfer and Posterior Chamfer resections using a 25 mm wide oscillating saw blade with 1.24 mm thickness through appropriate slots in 5-in-1 cutting guide, Fig. 10(b). Use 10 mm wide reciprocating saw blade with 1.24 mm thickness to complete the trochlear groove resection using the trochlear groove slot in 5-in-1 cutting guide.

(a)

(b)

Fig. 10

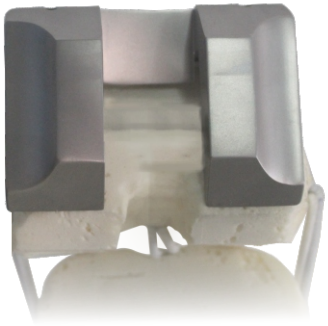
Important Note : If positioned in external rotation correctly on the distal face of the femur, then more of posterior medial femoral condyle would be resected as compared to posterior lateral femoral condyle. Be careful not to transect the attachment of the medial collateral ligament (MCL) during the resection of posterior condyles. To reassess the flexion gap, flex the knee at 90 degree and insert the 9 mm or 11 mm spacer blocks with alignment rod.

At this point the femoral resection for Cruciate Retaining (CR) femoral component is complete.

F. Femoral Notch/Box Cut (For Freedomknee and PS design knee only)

Flex the knee at 90 degree and secure the femoral Notch/Box cut guide to the distal femur with two headed pins, Fig.11(a). Use a reciprocating saw to cut the sides and base of intercondylar box while protecting tibia. A visual assessment of complete clearance of resected bone is advised. Fig.11(b)

(a)



(b)

Fig.11

G. Trial with Provisional Tibial Base Plate

Try the different tibial base plate provisional options available from size 1 to 8 on the resected tibial surface, Fig.12(c) select the one which offers maximum bone coverage in ML of resected tibia, without any implant overhang in the A/P and M/L dimensions to obtain the desired tibial tray size. Fig.12(a)

Important Note : Check the rotation and alignment using the alignment rod (through the hole on the tibial tray holder). Fig.12(b & d)

(a)

(b)

(c)

(d)

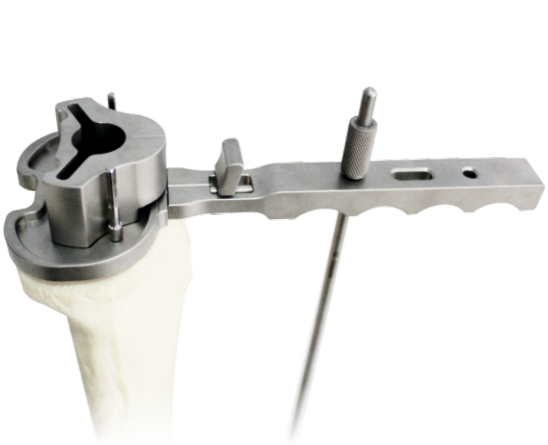
Fig.12

H. Creating Keel Space for Tibial Base Plate

Fix the desired Tibial Base Plate provisional on the tibia with short headed pins, Fig. 13(a). Attach the Tibial broach housing to it and ream gently an opening with the 17 mm Tibial reamer, Fig. 13(f) until the STOP on the reamer reaches the top of the tibial broach housing, Fig. 13(b). The 17 mm reamer creates space for a 30 mm keel. Select the appropriate Tibial broach (use tibial metal back broach for metal backed tibia, Fig. 13(e) & the all poly broach, Fig. 13(d) for all poly tibia) and attach it to slap hammer.

Position the Tibial broach to the guide hole on the Tibial broach housing and ensure that the broach hits precisely and vertically into the tibial canal creating space for the wings of tibia base plate. Fig. 13(c)

Remove all the instruments leaving behind the tibial tray provisional for further trial reduction. Insert the keel stabilizer in the space created in the tibial tray provisional with appropriate size of provisional insert. Now, the tibia is ready for a trial reduction.



(a)

(b)

(c)

(d)

(e)

(f)

Fig. 13

I . Final Trial Reduction Preparation

I1. Provisional Femoral Insertion

Assemble the PS femoral provisional to the femoral Impactor-Extractor. Cautiously introduce femoral provisional on the prepared femoral surface aligning the lug holes with lugs on the femoral provisional and perform gentle impactions with the femoral impactor till the femoral provisional sits flush on the resected femoral surface.

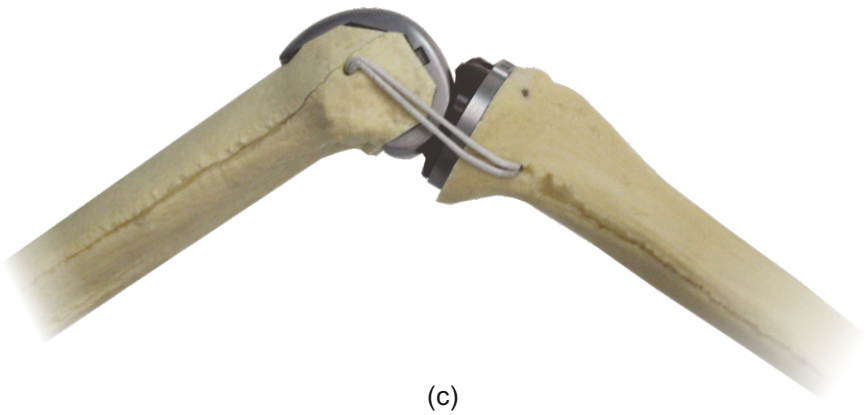
I2.Provisional Tibial Base Plate Insertion

As the Freedom Knee system allows inter-changeability of femoral and tibial implant sizes select the tibial base plate provisional that best provides maximum coverage of the proximal tibia.

Once selected, attach the tibial base plate provisional with keel stabilizer in it, to the handle and reposition this assembly onto the tibia. The alignment rod may be inserted into the tibial base plate provisional handle to further evaluate the positioning of the tibial base plate provisional. Remove the tibial base plate provisional handle and insert a PS tibial insert provisional of desired thickness.

(a)

(b)



(c)

Fig. 14

J. Patella Preparation

J1. Patellar Resection Measurement

Evert the patella and remove excessive osteophytes. Use a calliper, measure and assess the thickness of the anterior - posterior dimension of the patella.

Important Note : To plan the resection thickness, it is recommended to retain a 12 mm or 14 mm minimum thickness of patella bone to support the implant structure. By 'Overstuffing' the patella, femoral joint can lead to flexion loss while leaving a thin patella can lead to fracture or early loosening of patella.

J2. Patellar Resection

The patellar resection guide is used to determine the desired patellar diameter and position. Typically the guide is positioned over the highest point of the articulation and the centre position is marked with an electrocautery or surgical marker. Once the patella surface is resected, use the corresponding patella drill guide, Fig. 15(b, d, f) to assess the dimensional size of patella. Using the 'patella lug drill' guide drill 3 holes in remaining patella bone, Fig. 15(c). Place the patella provisional on to the resurfaced patella and begin range of motion evaluation of patellar tracking.

Patella Calliper

(a)

Patella Drill Guide 25/28 mm

(b)

Femoral/Patellar Lug Hole Bit

(c)

Patella Drill Guide 31/34 mm

(d)

Patella Resection Guide

(e)

Patella Drill Guide 37/40 mm

(f)

Fig. 15

K. Implant Preparation

K1. Bone Cement Preparation

After satisfactory final trial reduction, remove all provisional and clean the resected bones of all tissue debris. Using the standard mixing protocol for the bone cement, mix and prepare the bone cement for cementing the implants.

K2. Cementing & Fixing Implants

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 bone cement into the bone surfaces, including the reamed keel entry hole to allow for adequate indigitation. Place bone cement on the under surface of tibial definitive implant and on the resected proximal tibia. Firmly impact it on the prepared tibia using the tibial impactor. Remove excess bone cement.

Hyperflex the knee and dry the distal femoral bone cuts. Finger pressurise the posterior condyles with the bone cement. Apply the bone cement to the under surface of the femoral component and the resected distal femur. Firmly impact the femoral component in to place using femoral impactor, Fig. 16(a). Remove excess bone 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. Use the tibial liner impactor, Fig. 16(c) to firmly impact the articulating surface liner into place and check to see that the locking mechanism is engaged.

Reduce the knee and place it into extension. Evert the patella, dry the bony surface of patella and place bone cement into the bone surface, apply bone cement underneath the patella implant. Place the patella implant on the resected bone. Use patella pressuriser clamp, Fig. 16(f) to secure the patella implant. Trim excess osteophytes and remove excess bone cement.

Femoral Impactor

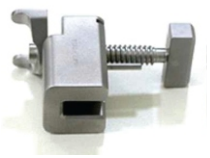
(a)

Tibial Implant

(b)

Tibial Liner Impactor

(c)



Tibial Implant Holder

(d)

Slap Hammer

(g)

Femoral Impactor-Extractor

(e)

Patellar Nip Cement Pressurizer

(f)

Fig. 16

L. Closure

Capsule and Skin closure is performed following standard closure technique.

M. Tips & Pearls :

	Tight in Flexion (cannot fully flex)	Balanced in Flexion	Loose in Flexion (large drawer test)
Tight in Extension (can not fully extend)	Tight in Extension, Tight in Flexion **Problem:** Did not cut enough tibia **Solution:** Cut more proximal tibia	Tight in Extension, Balanced in Flexion **Problem:** Did not cut enough distal femur or did not release enough posterior capsule **Solution:** 1) Release posterior capsule 2) Cut more distal femur	Tight in Extension, Loose in Flexion **Problem:** Distal femur too long. **Solution:** 1) Resect more distal femur or use thinner distal femoral augmentation wedge (revision scenario) 2) Upsize femoral component
Balanced in Extension	Balanced in Extension, Tight in Flexion **Problem:** Did not cut enough posterior femur, PCL scarred and too tight. **Solution:** 1) Decrease size of femoral component 2) Recess & release PCL 3) Resect posterior slope in tibia 4) Resect more posterior femoral condyle 5) Release posterior capsule	Balanced in extension, Balanced in Flexion (Perfect)	Balanced in Extension, Loose in Flexion **Problem:** Cut too much posterior femur. **Solution:** 1) Increase size of femoral component (AP only) 2) Posterior femoral component (augment posterior femur)
Loose in Extension (recurvatum)	Loose in Extension, Tight in Flexion **Solution:** 1) Downsize femur and use thicker tibial insert until balanced	Loose in Extension, Balanced in Flexion **Problem:** Cut too much distal femur. **Solution:** 1) Augment distal femur	Loose in Extension, Loose in Flexion **Problem:** Cut too much tibia. **Solution:** 1) Use thicker tibia PE 2) Use thicker tibial metal insert

FREEDOM® KNEE

Global shape and sizing

Optimal AP- ML ratios for global patients

CR & PS Femurs (L & R)

	A	B	C	D	E	F	G	H
M/L	54.00	58.00	62.00	64.00	66.00	70.00	74.00	78.00
A/P	51.00	54.00	58.00	60.00	62.00	66.00	70.00	74.00

Patella Dia.

25, 28, 31, 34, 37 & 40 mm

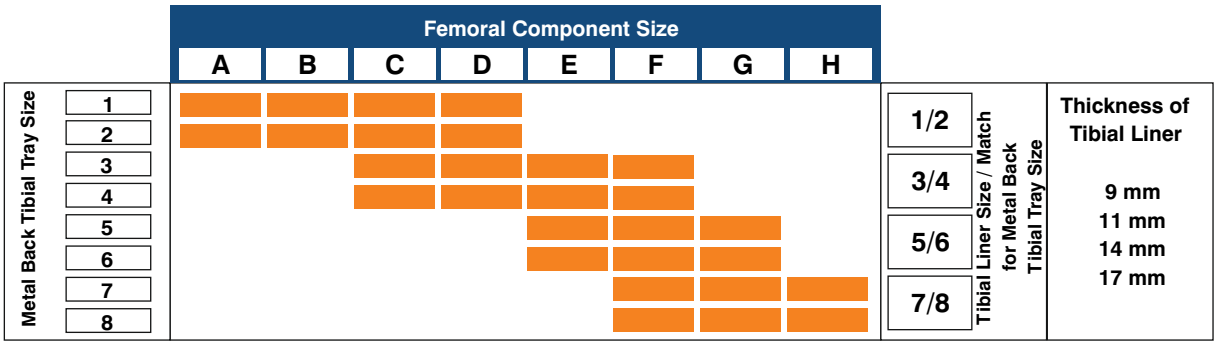
Transitional size 'D'

Metal Back Tibial Trays

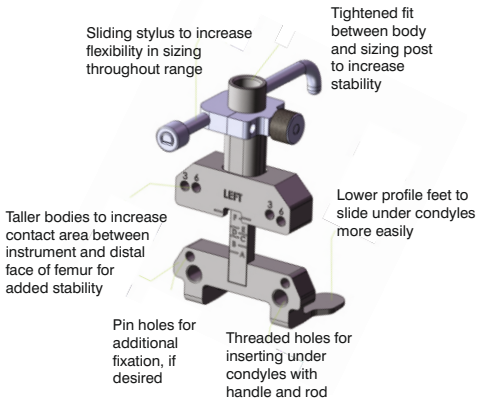
	1	2	3	4	5	6	7	8
M/L	59	62	66	66	71	72	76	78
A/P	40	40	42	46	48	50	52	54

Modularity of sizes along with compatibility of 2 size mix & match in critical sizes

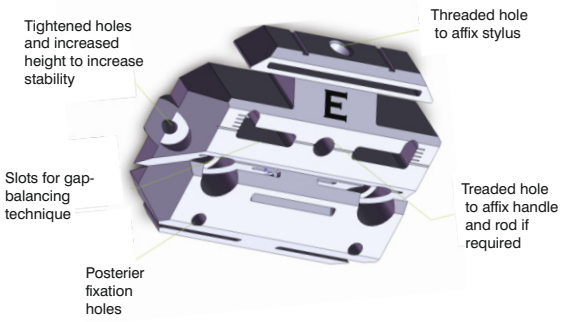
Component modularity CR & PS femur, metal-backed tibia trays & inserts



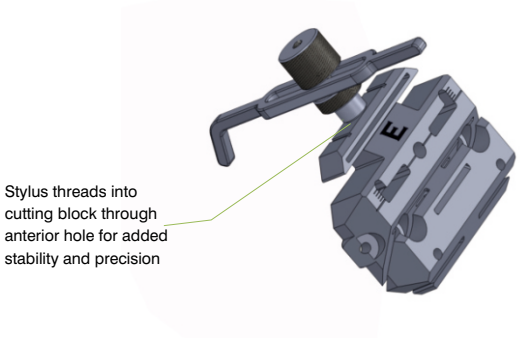
Femoral A-P Sizing Guide



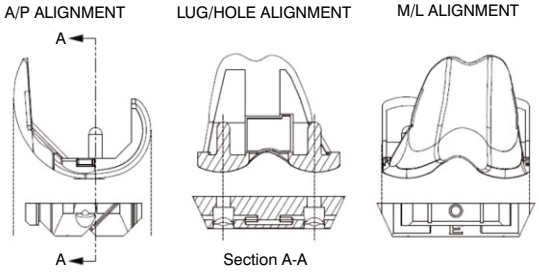
5-1 A-P Cutting Block



5-1 A-P Cutting Blocks with Stylus



5-1 A-P Cutting Block Line to Line with Femur



Notes :