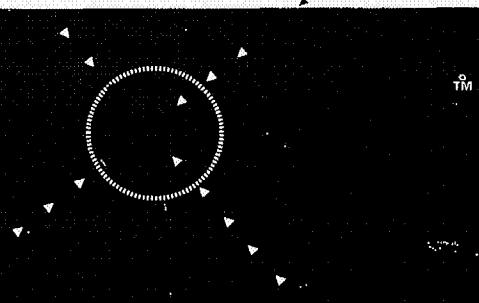


Scorpio¹

SINGLE AXIS TOTAL KNEE SYSTEM



Passport A.R.
Surgical Technique

stryker
Howmedica
OSTEONICS

S&N 1009

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Acknowledgments:

Osteonics Corporation wishes to thank the following orthopedic surgeons for their expertise in the development of the Passport A/R Instrumentation System:

John T. Andronico, MD
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INTRODUCTION

Introduction

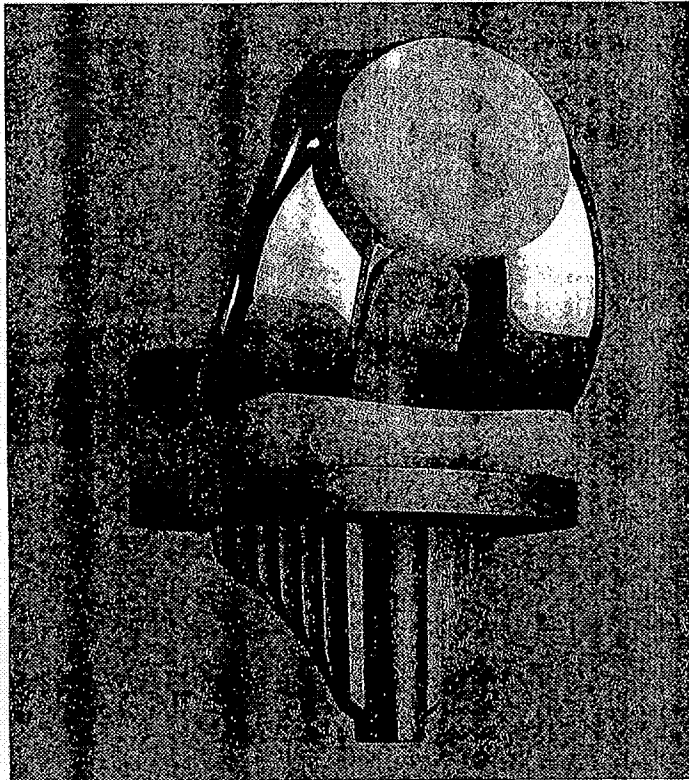
Osteonics Passport A/R Instrumentation is designed for the surgeon who prefers anteriorly based femoral resections.

Passport A/R Instruments are an organized and flexible set of surgical instruments designed to address patient variables and individual surgeon preferences. Femoral alignment is based on intramedullary referencing. Tibial alignment may be carried out in either an extramedullary or intramedullary fashion. The order of femoral and tibial preparation is not critical. This surgical protocol depicts femoral preparation first, followed by tibial preparation. This order may be changed to address patient indications or to satisfy surgeon preference.

The Passport A/R system allows the surgeon the flexibility to choose preoperatively or intraoperatively between a cruciate retaining or cruciate substituting component while using one core set of instrumentation. Passport A/R Instruments can be used with the Series 7000 Total Knee System or the Scorpio Total Knee System. Consult the respective PS Protocol Addendum for either Series 7000 Primary Posterior Stabilized Knee or Scorpio Notch Preparations.

Passport A/R Instruments provide a highly accurate and predictable method for resecting bone. At various stages throughout the procedure optional alignment checks may be carried out to confirm instrument position, component orientation, and overall limb alignment.

Finally, several orthopaedic surgeons have added valuable input and guidance to the creation of these instruments and this surgical protocol. Their contributions significantly enhance the information found in this document.



Scorpio® Total Knee

SUMMARY

FEMORAL PREPARATION

1. Distal Alignment
2. Anterior Skim Cut
3. Distal Resection
4. Sizing
5. A/P and Chamfer Resections
6. Trial
7. Femoral Notch Preparation
(For PPSK or Scorpio Knee Only)
8. Implant

TIBIAL PREPARATION

1. Tibial Alignment
2. Proximal Tibial Resection
3. Trial
4. Trial Broaches and
Alignment Tower
5. Implant

EXPOSURE

Exposure

A standard anterior midline incision is preferable (Fig. 1); however, any previous incisions can be used or incorporated to decrease the risk of skin slough.

The capsule is entered through a medial parapatellar approach approximately 1 cm from the medial border of the patella. (Fig. 2)

The quadriceps mechanism is incised longitudinally to allow adequate patellar eversion and sufficient knee flexion. (Fig. 3)

Figure 1

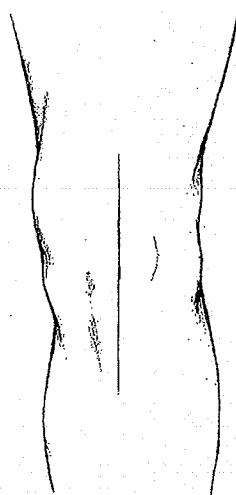


Figure 2

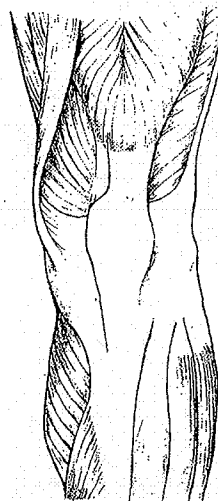
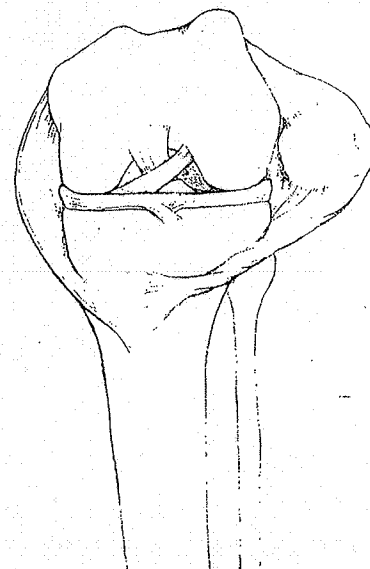


Figure 3



FEMORAL PREPARATION

Femoral Preparation

The intramedullary canal is accessed by drilling a hole in the center of the intercondylar notch using the Passport 3/8" diameter starter drill. (Figs. 4, 5)

Figure 4

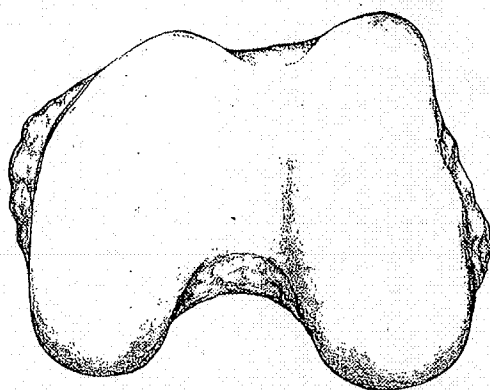
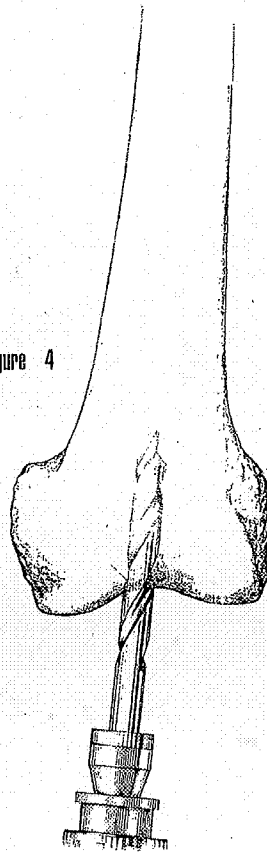


Figure 5

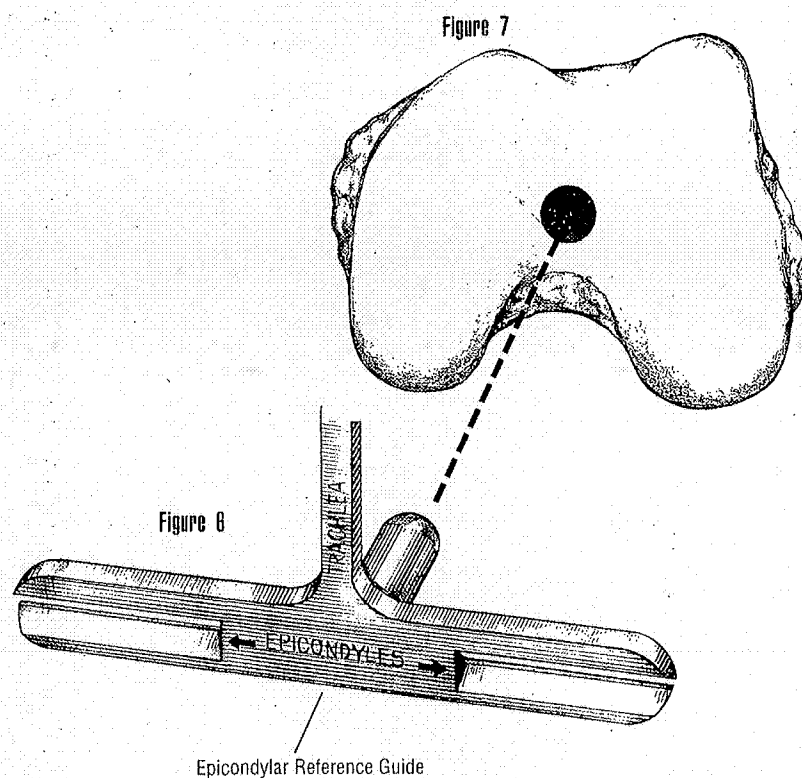
Rotational Alignment can be determined in one of two ways:

Option 1 - Femoral IM Alignment with Epicondylar Referencing

Place the epicondylar referencing guide (Fig. 6) into the intercondylar notch hole (Fig. 7) and reference either:

- 1) the trochlear groove using the vertical bar; or
- 2) the epicondyles using the horizontal slotted bar.

Either of the above methods will result in a line parallel to the epicondylar axis.



Once rotation is set appropriately, mark the epicondylar axis through the slots provided using electrocautery or an osteotome. (Fig. 8) Remove the guide.

The Femoral Alignment Guide is designed for use on either the left or right knee and can be set at 5 or 7 degrees of valgus. Place the 5/16" Passport T-Handle Rod through the back of the Femoral Alignment Guide and set the instrument to the preoperatively determined angle by pulling the knob on the Femoral Alignment Guide and locking it in the appropriate notch.

Insert the Femoral Alignment Guide into the intramedullary hole (Fig. 9), lining up the marks on the distal femur with the slots on the Femoral Alignment Guide. (Fig. 10) Use two 1/8" diameter pins through the distal holes to secure the Femoral Alignment Guide to the distal femur.

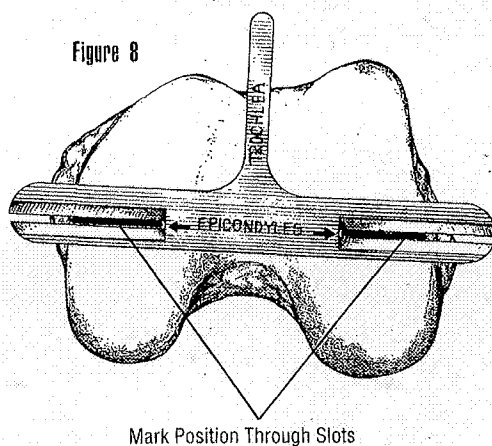


Figure 8

Figure 10

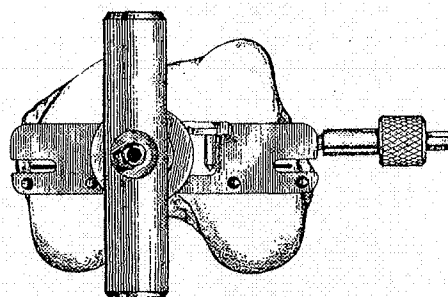
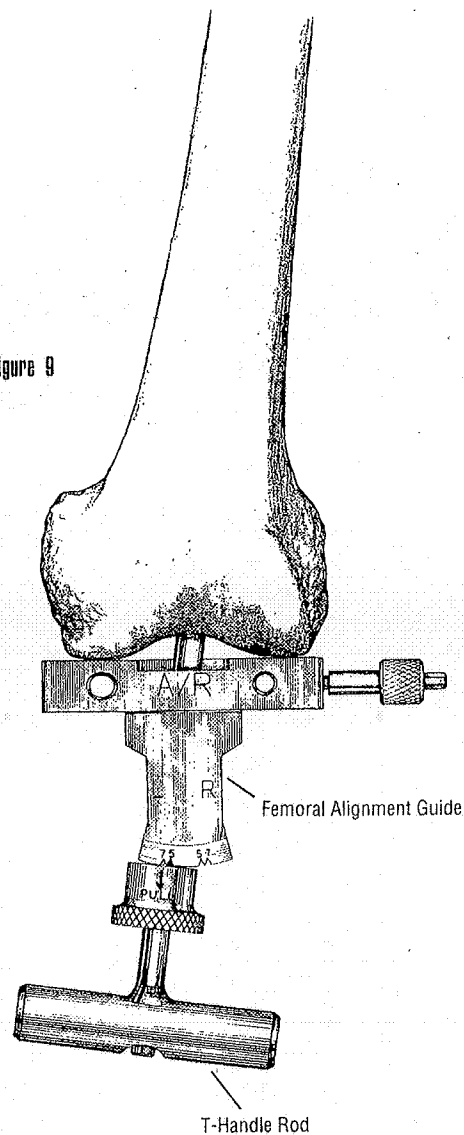


Figure 9



Option 2 - Femoral IM Alignment with 3° External Rotation Guide

Insert the Femoral Alignment Guide into the intramedullary hole. (Figs. 11,12)

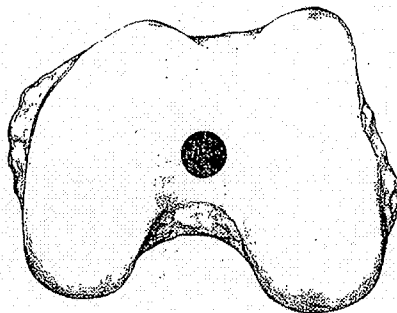


Figure 11

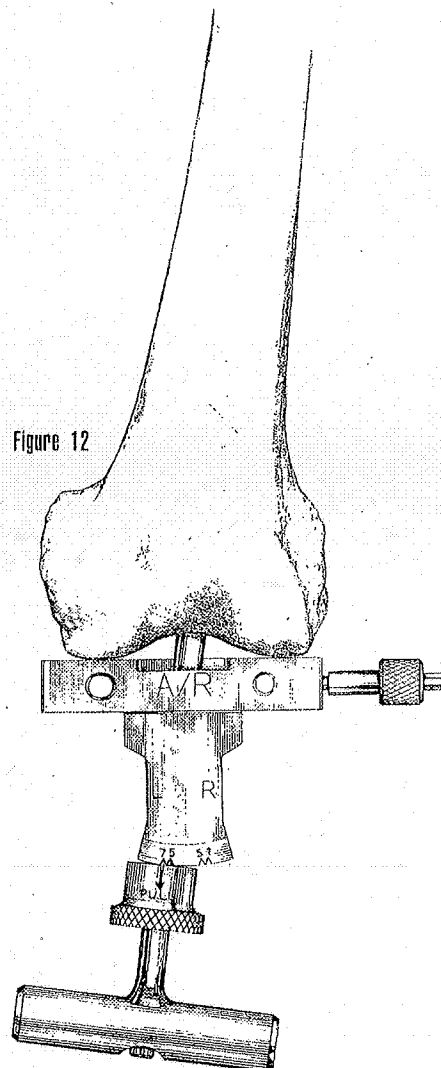
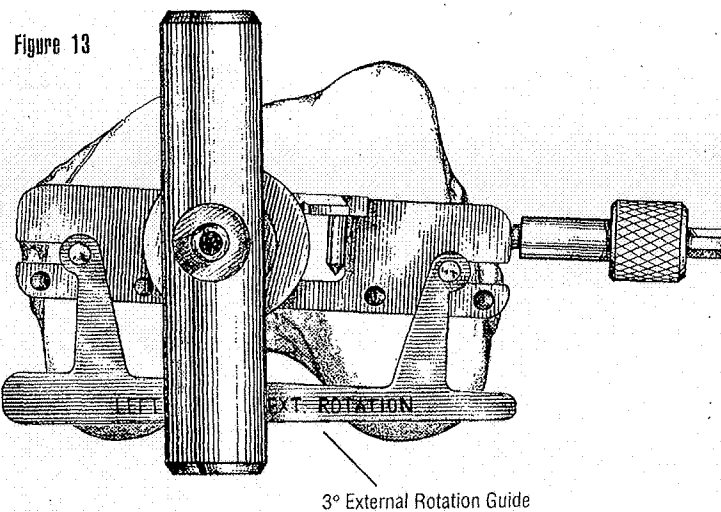


Figure 12

Place the 3 degree External Rotation Guide into the slots of the Femoral Alignment Guide taking care to assemble the guide in the appropriate left or right orientation. Use this guide to judge equal amounts of medial and lateral posterior condyle. (Fig. 13) If the posterior condyles are a deficient reference due to a bone deformity, the guide should be aligned with the epicondyle using the epicondylar referencing guide.

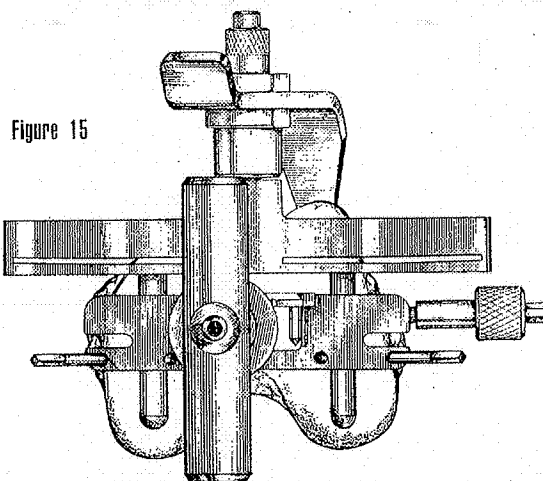
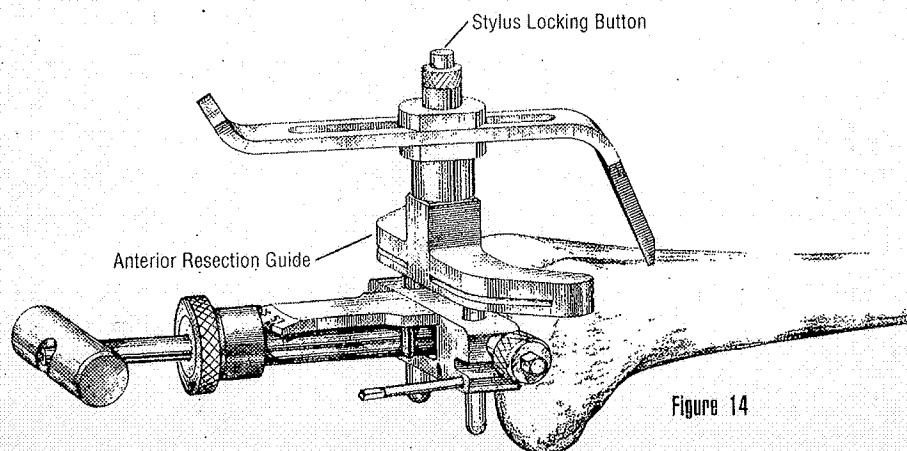
Use two 1/8" diameter pins through the distal holes to secure the Femoral Alignment Guide to the distal femur. The External Rotation Guide may be removed.

Two sets of holes are provide for use with small or large knees.



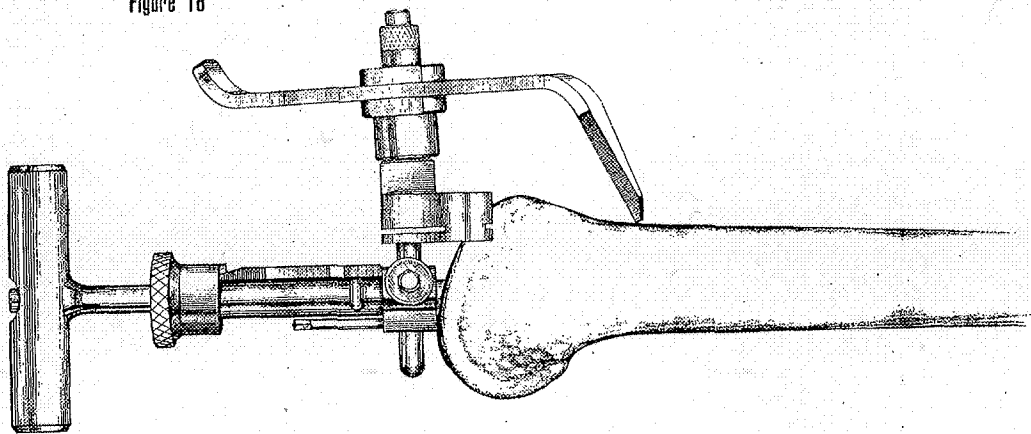
Anterior Skim Cut

Assemble the Stylus to the Anterior Resection Guide by depressing the button on the stylus and fully seating it into the hole on the Anterior Resection Guide. Release the button to lock the stylus in place. Insert the Anterior Resection Guide into the two anterior holes on the Femoral Alignment Guide. (Figs. 14, 15)



The length of the stylus may be easily adjusted by sliding it to the appropriate point. The tip of the stylus indicates the exit point of the sawblade when the final femoral resections are made. Adjusting the tip of the stylus to reference off the high point of the anterior lateral cortex will result in a conservative anterior cut, eliminating the risk of notching the cortex. (Fig. 16)

Figure 16



Prior to resection, check the saw exit level around the superomedial and superolateral sides of the anterior cortex with a sawblade or an Osteonics Bladerunner. (Fig. 17) Tighten the side screw with the hex wrench to lock the resection guide in place. (Fig. 18) The stylus can be removed before the resection is made. Use a .050" thick sawblade to make the resection. (Fig. 19)

After the resection is completed, loosen the side screw and remove the Anterior Skim Resection Guide, leaving the Femoral Alignment Guide pinned in place.

"Because more lateral bone than medial bone will be resected from the anterior femur, cut the medial side first - it should be a relatively small wafer of bone. If it is a large medial resection, double check that the guide is properly externally rotated."

Stephen Incavo, MD

Figure 17

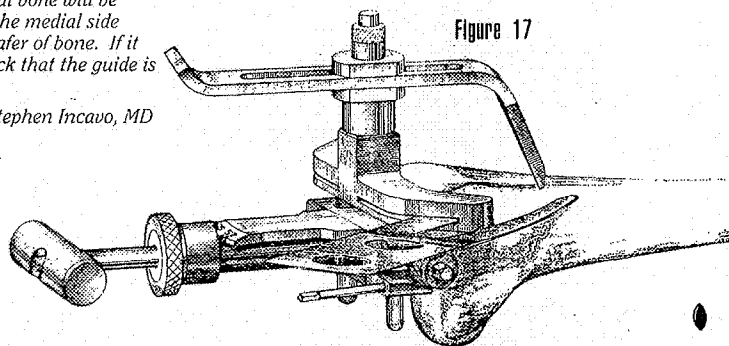


Figure 18

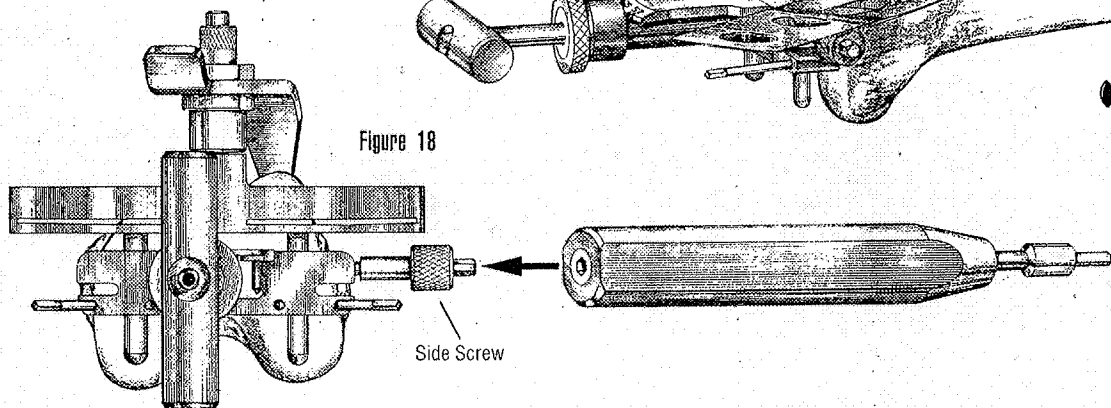
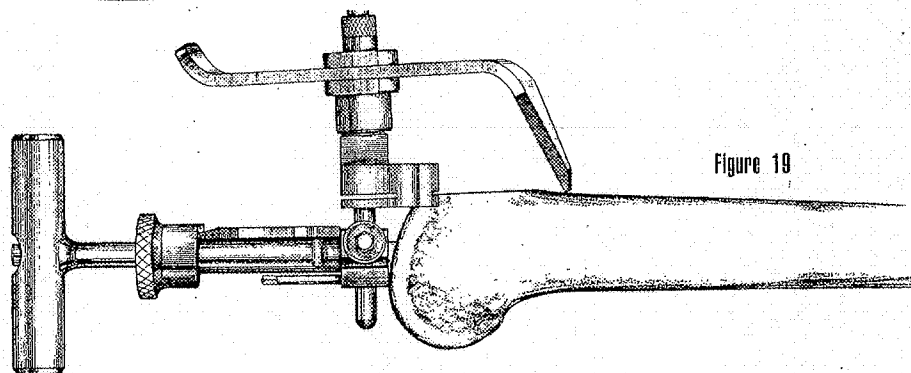


Figure 19



Distal Femoral Resection

Assemble the 8mm or 10mm Distal Resection Guide to the Distal Resection Guide Stand by placing the Guide over the pegs. These guides are magnetized to assure correct assembly. The resection guide may then be locked into place by pushing in and turning the locking knob 1/4 turn clockwise. (Fig. 20)

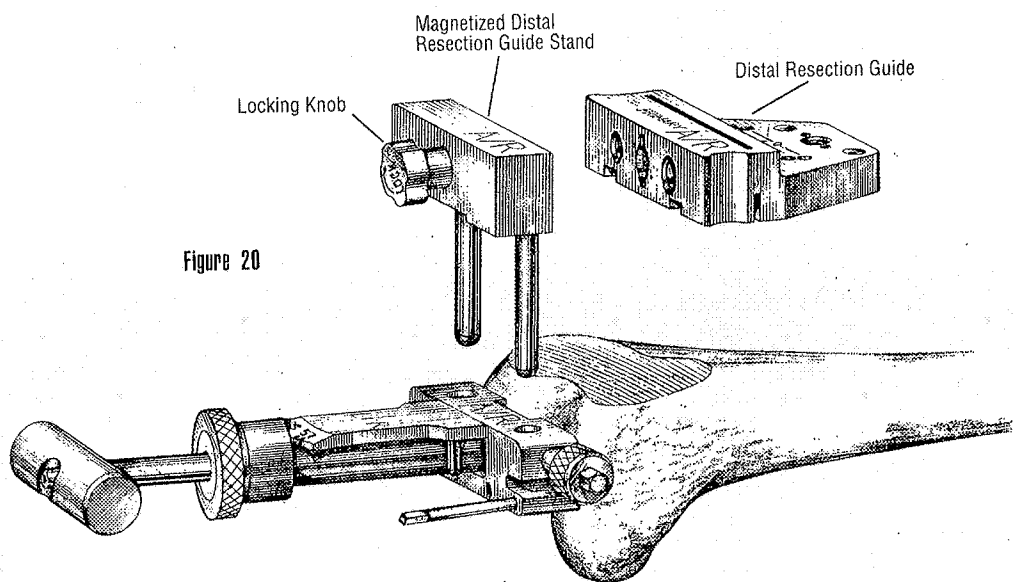
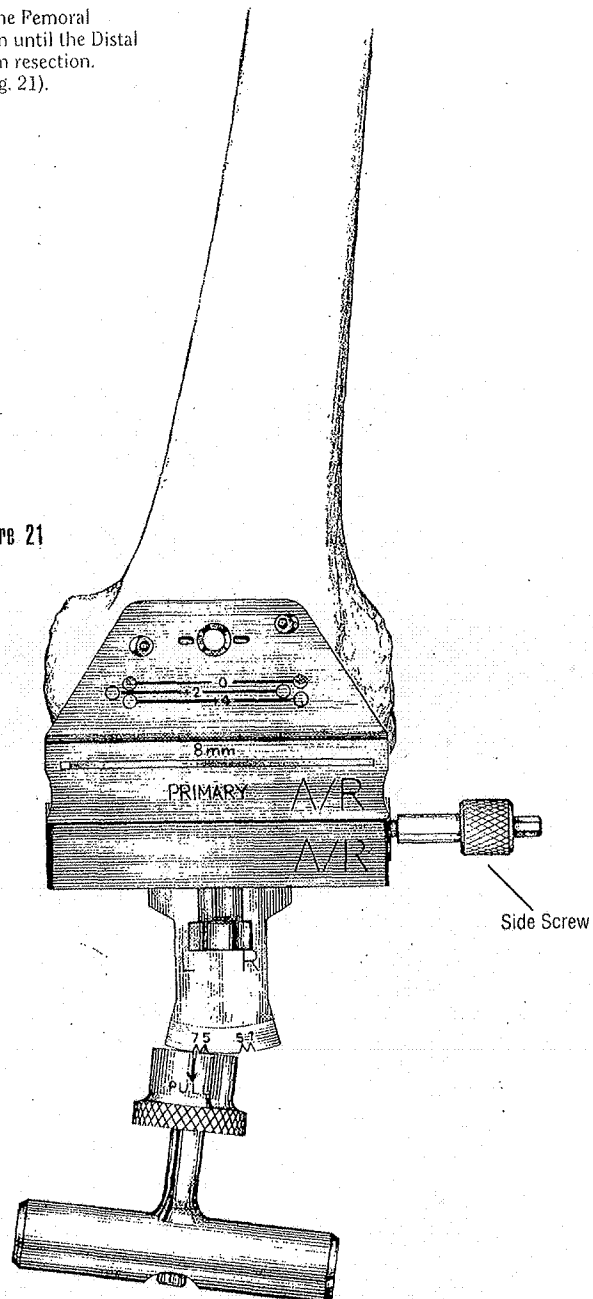


Figure 20

Slide the assembly into the anterior holes of the Femoral Alignment Guide and lower the assembly down until the Distal Resection Guide sits flush on the anterior skin resection. Tighten the side screw to secure the guide (Fig. 21).

Figure 21



Prior to pinning the Distal Femoral Resection Guide to the femur, an optional external alignment check may be carried out. Attach the Alignment Guide Handle to the Distal Femoral Resection Guide and insert an External Alignment Rod into the handle. Alignment is correct when the rod intersects the center of the femoral head and roughly parallels the axis of the femur in the lateral view. (Fig. 22)

Drive two 1/8" headless pins into the holes marked "0". (Fig. 23) The Distal Resection Guide comes in 8mm or 10mm Resection configurations and allows 8mm or 10mm of bone to be removed from the distal femur. Pinning through the "X" pin hole will aid in further securing the guide.

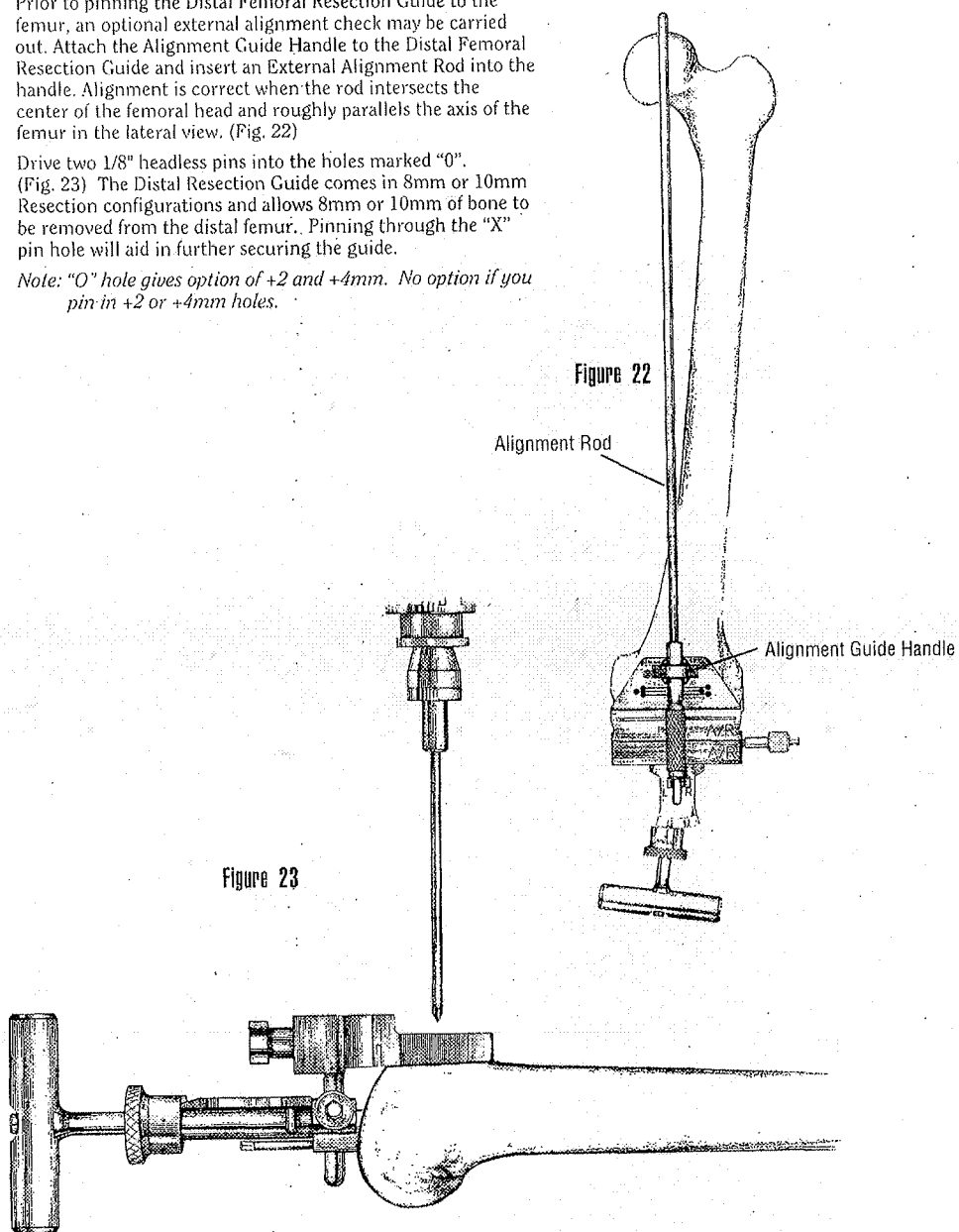
Note: "O" hole gives option of +2 and +4mm. No option if you pin in +2 or +4mm holes.

Figure 22

Alignment Rod

Alignment Guide Handle

Figure 23



Once secured (Fig. 24) remove the Distal Femoral Alignment Guide by first removing the 1/8" pins in the distal femur. Remove the IM Rod, then slide out the Distal Femoral Alignment Guide and Distal Resection Guide Stand, leaving only the Distal Resection Guide in place.

Make the distal resection using a .050" thick sawblade and remove the resection guide. (Fig. 25)

An additional 2mm or 4mm of distal femur may be resected by sliding the Distal Resection Guide up off the headless pins and placing it back on so that the pins go through either the "+2" or "+4" holes. Resect the remaining bone.

Note: If the "X" pin hole is used, this pin must be removed prior to repositioning or removing the Distal Resection Guide.

Figure 24

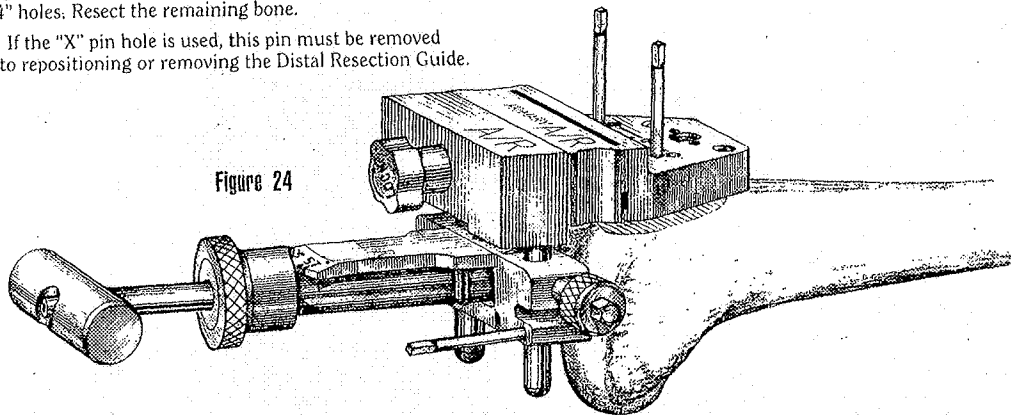
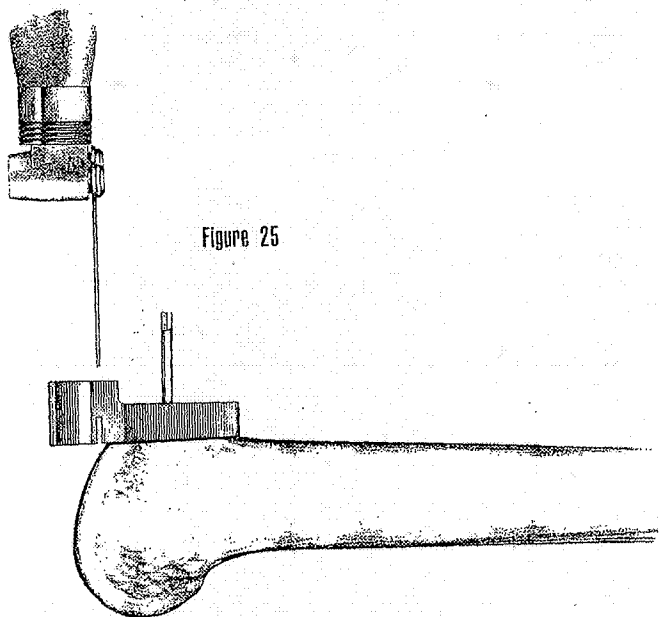


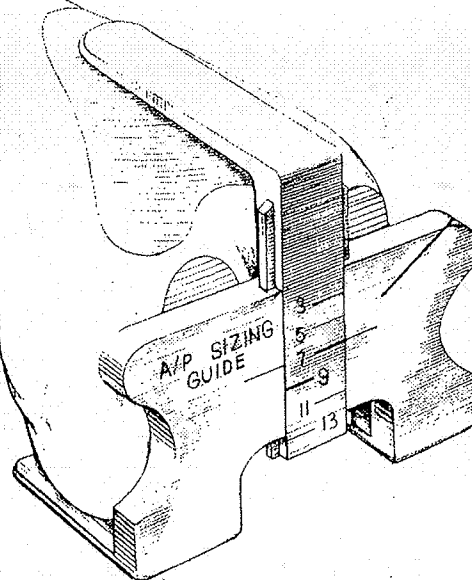
Figure 25



Femoral Sizing

The sizing guide should be used to determine the appropriate size cutting block and femoral component. The size can be determined by placing the feet of the guide under the posterior femoral condyles. The top bar should be collapsed until it seats flush on the anterior skin resection. In the event of in-between sizing, the smaller size should be selected. (Fig. 26)

Figure 26



Femoral Anterior, Posterior and Chamfer Resections

Position the Femoral Cutting Guide on the distal femur. The anterior lip of the block should sit flush against the resected anterior femur. (Fig. 27) Using the pin driver and a mallet, drive the two serrated pins into the femur. (Fig. 28) Additional stability may be achieved by using towel clamps on the side of the blocks.

▶ "If the bone is sclerotic, pre-drill the hole with a 1/8" drill bit."

David Markell, MD

Figure 27

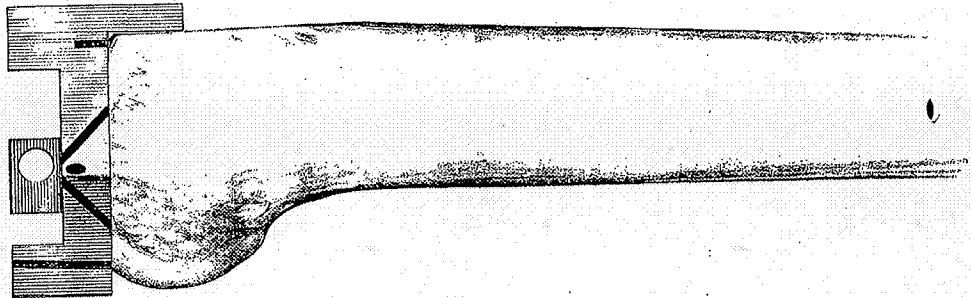
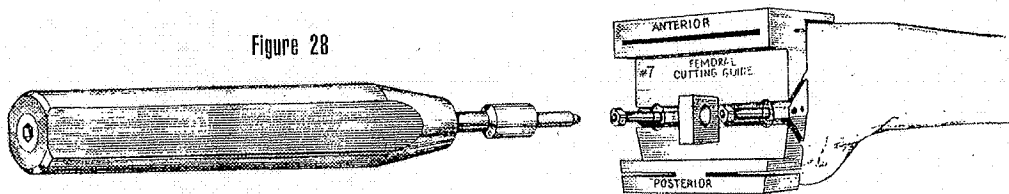


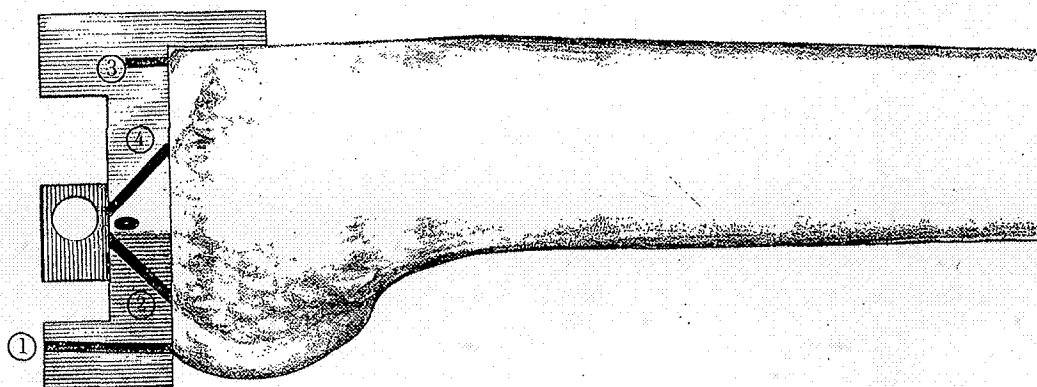
Figure 28



Complete the remaining four femoral bone resections.
(Fig. 29) The order of the resections is critical;
the sequence is:

1. posterior condyles
2. posterior chamfer
3. anterior cortex
4. anterior chamfer.

Figure 29



SCORPIO® UNIVERSAL PREPARATION BLOCK

The SCORPIO® Universal Preparation Block Instrument is used after completion of the five femoral bone cuts.

- Select the desired size Femoral Notch Block. The block sits on the anterior, anterior chamfer and distal cuts. The anterior geometry represents the left and right lateral flanges of the implant of the same size. The sides are marked LL and RL for left lateral and right lateral, respectively.
- Position the Notch Block on the prepared distal femur, aligning the lugs with the holes made by the Femoral Cutting Guide (tap into place with mallet)

(Fig. 30). To further aid the positioning, note that the block is also the same width as the implant of its respective size.

- Once the Notch Block is seated flush against the anterior, anterior chamfer and distal cuts of the femur, drill 1/8" headless pins through the angled holes ("X") on the anterior and/or anterior chamfer surfaces of the block (4 "X" holes at 15° (Fig. 31)).

- Towel clamps may be used on the medial and lateral sides of the distal portion of the block. It is recommended to use at least the 2 anterior pin holes, even if towel clamps are used.

Figure 30

Scorpio® Universal
Notch Block

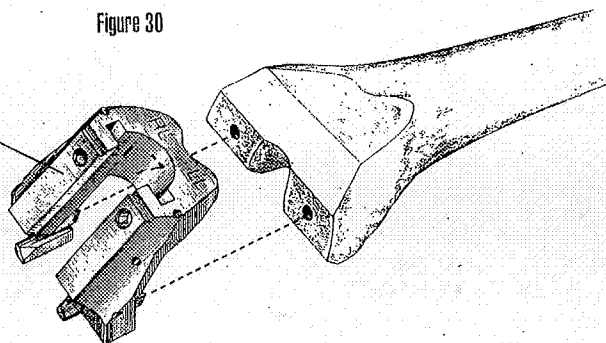
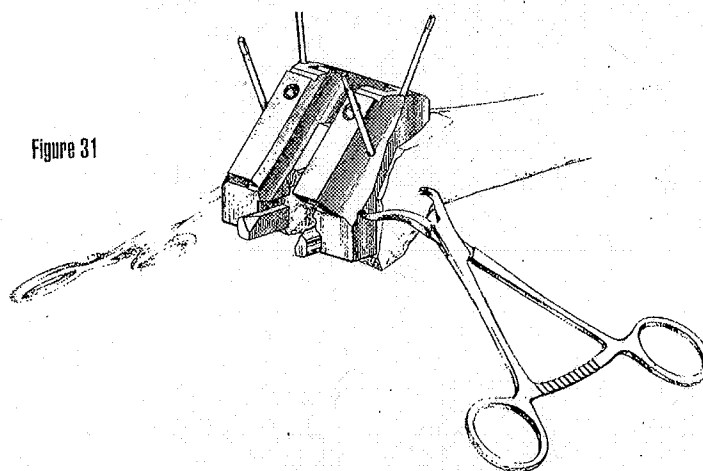


Figure 31



For Posterior Stabilized Knees

Choose one of the following options to prepare the femoral notch:

Notch Preparation Option 1: Punch Technique

Note: If the femoral bone is sclerotic, Option 2 (Saw Technique) should be used for the notch preparation.

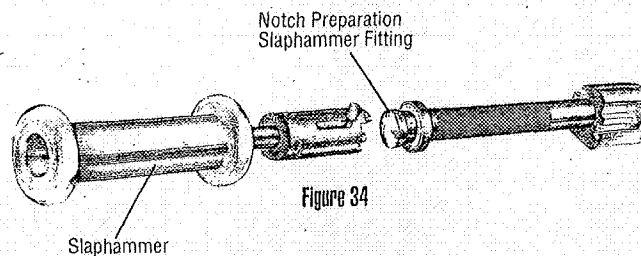
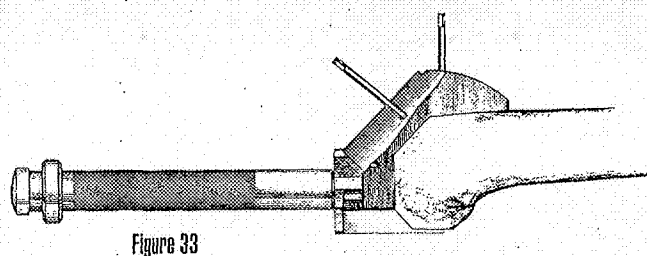
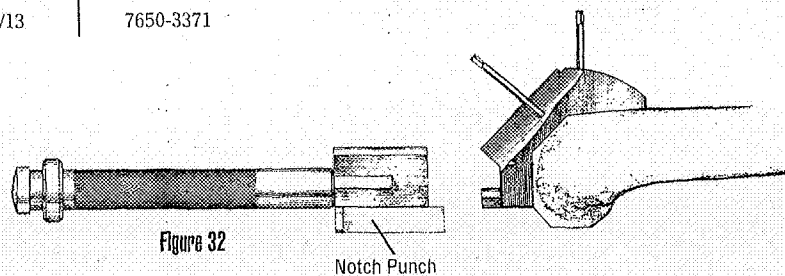
- Assemble the appropriate size Notch Punch to the punch handle.

| Notch Punch Size | Part # |
|------------------|-----------|
| 3/5 | 7650-3373 |
| 7/9 | 7650-3377 |
| 11/13 | 7650-3371 |

- Guide the Notch Punch into the tracks on the distal face of the Notch Block (Fig. 32). The rails on the sides of the cutting edge fit into the tracks on the inside walls of the block.

- Using a mallet, impact the Punch until it reaches the end-stop and is fully seated in the Notch Block (Fig. 33). Remove the Punch from the tracks with a slaphammer if necessary (Fig. 34).

Note: Using an osteotome or rongeur, remove the margin of intercondylar bone necessary to ensure that all soft tissue is cleared from the intercondylar area of the femur. (It is important to remove all soft tissue in femoral notch prior to compacting bone to avoid future potential for soft-tissue impingement.)



Notch Preparation Option 2:

Saw Technique

- Guide the pegs of the modular Notch Saw Guide into the anterior holes on the Notch Block (Fig. 35)

- Use a narrow saw blade, osteotome, or double-edged reciprocating saw blade and the Notch Saw Guide as a guide to saw or cut distally through the entire depth of the intercondylar notch (Fig. 36).

- Using the inner walls of the Universal Notch Guide as a saw guide, lay the saw blade flat against the cutting guide and saw on it through the intercondylar notch both medially and laterally until the cut is complete (Fig. 37).

Note: Even if the saw technique is used, you must still perform the Notch Compacting step to confirm that enough bone was removed to accommodate for the cam and post.

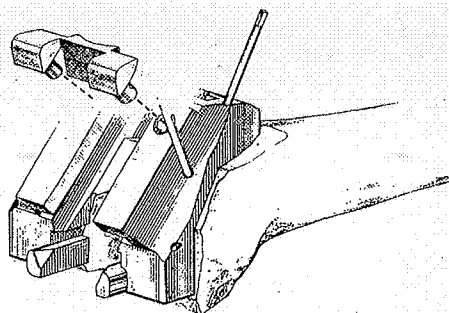


Figure 35

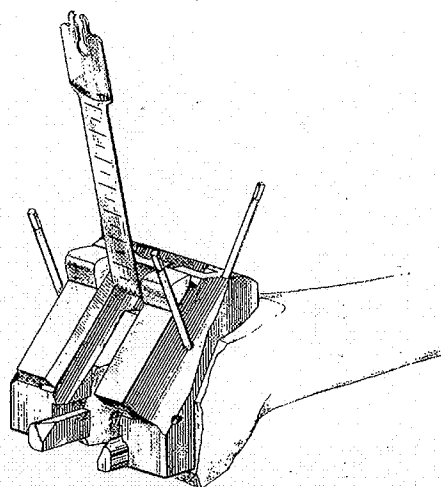


Figure 36

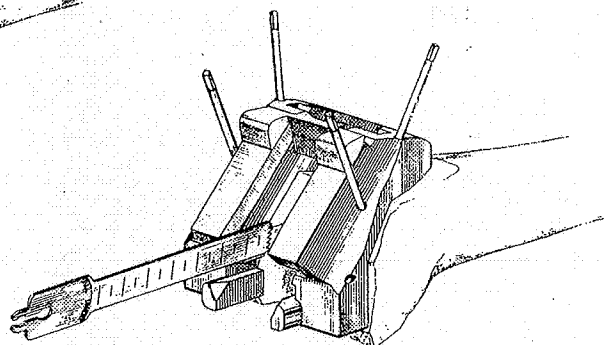


Figure 37

Notch Compacting Preparation

- Assemble the appropriate size Notch Compactor to the punch handle (Fig. 38).

| Notch Compactor Sizes | Part # |
|-----------------------|-----------|
| 3/5 | 7650-3383 |
| 7/9 | 7650-3387 |
| 11/13 | 7650-3381 |

- Using a Mallet, impact the Compactor until it reaches the end-stop and is fully seated in the Notch Block (Fig. 39). Remove the Compactor from the tracks using a slaphammer if necessary (Fig. 40).

- Guide the Notch Compactor into the tracks on the distal face of the Notch Block. The rails on the sides of the cutting edge fit into the tracks on the inside walls of the block.

Figure 38

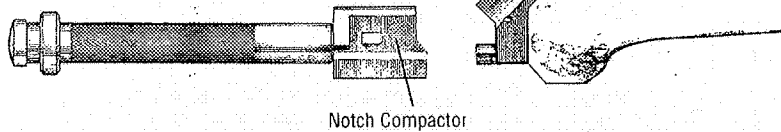


Figure 39

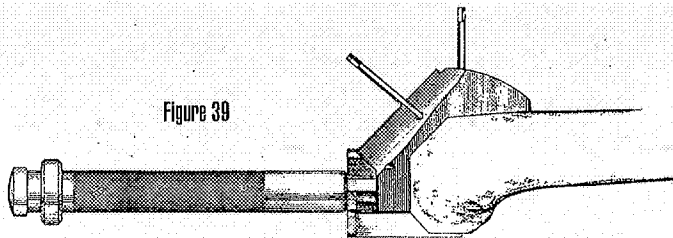
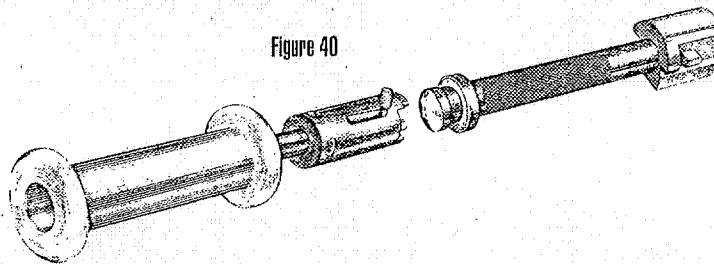


Figure 40



This order of cuts will optimize the stability of the femoral cutting block. Making the posterior chamfer cut before the anterior chamfer maintains a larger surface of bone upon which to support the Femoral-Cutting Guide. The resection slots are designed so all of the resections can be completed without having to remove the block.

After the femur has been cut, release the towel clamps, if they were used. Remove the guide by inserting the removal pin on the Slide Hammer into the extraction hole on the block (Fig. 41) and use the Slide Hammer Extractor to pull the guide off distal femur. (Fig. 42)

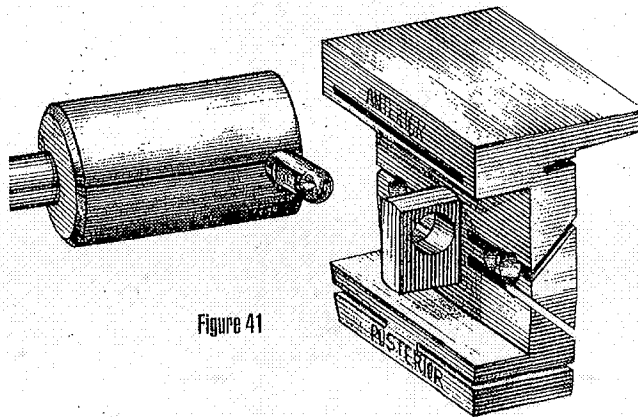


Figure 41

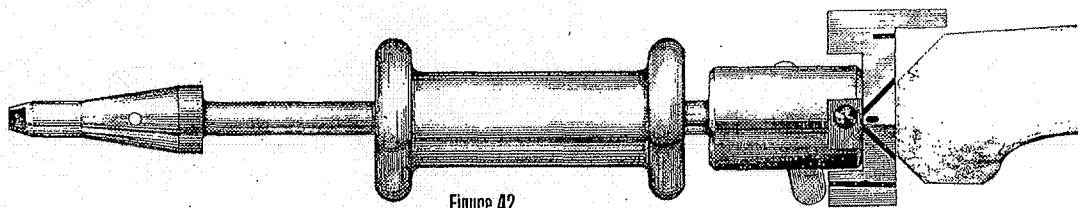


Figure 42

Optional Flexion/Extension Check

If an optional check for flexion/extension equality is desired, the Femoral Cutting Guide must be removed after the posterior resection was made and the tibial resection must be completed. (For tibial resection instructions, please see the "Tibial Preparation" section of this protocol). Place the knee in flexion and using the proper size and thickness Osteonics Flexion/Extension Blocks, measure the gap between the posterior femoral condyles and the proximal tibia. (Fig. 43) Then, bring the knee into extension and measure the gap between the distal femoral condyles and the proximal tibia. (Fig. 44) This check should give a good indication of flexion/extension equality.

Figure 43

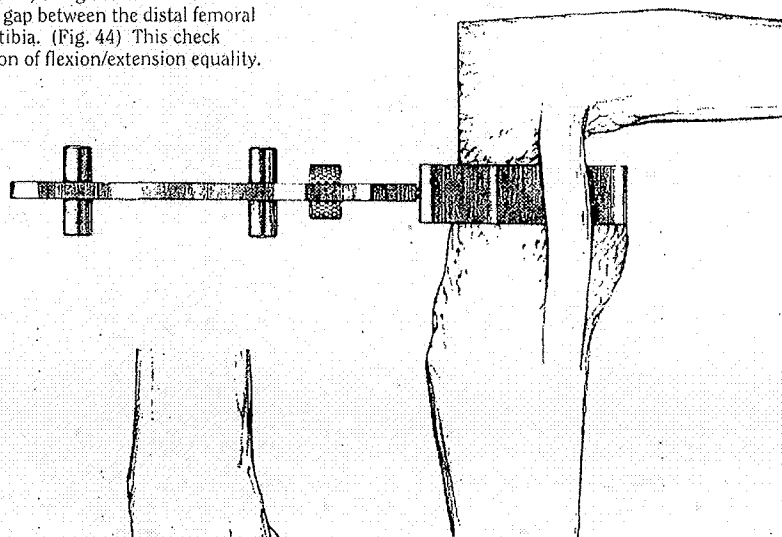
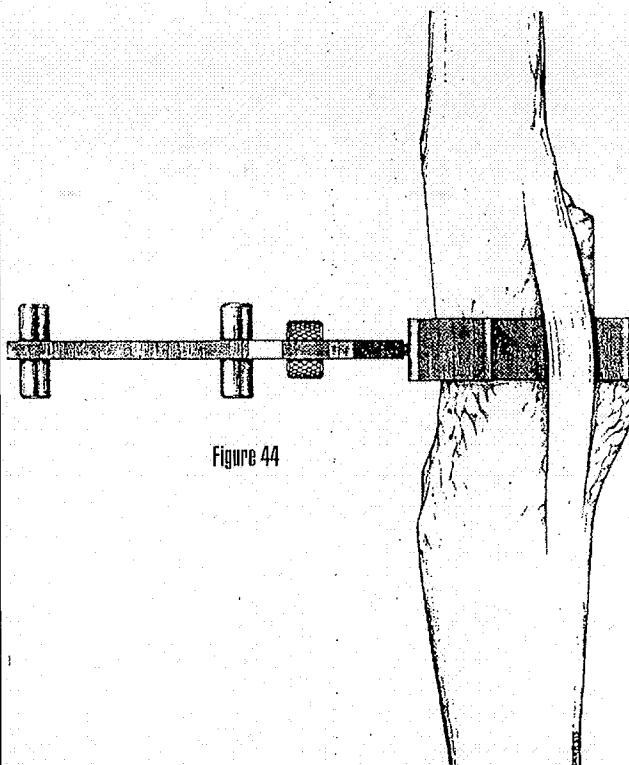


Figure 44



Assessment of Fit

Assemble the appropriate Femoral Trial to the Femoral Impactor/Extractor. This is done by first rotating the center knob counter-clockwise in order to lower the plastic head of the instrument. Taking note of the proper orientation of the instrument, (LEFT MEDIAL or RIGHT MEDIAL), align the jaws with the medial/lateral recesses in the Femoral Trial and turn the side adjustment knob until the jaws tighten into the recesses.

Rotate the center knob clockwise until the plastic head contacts the Femoral Trial. (Figs. 45) This secure assembly helps maintain correct medial/lateral and flexion/extension position of the trial while seating.

Impact the trial onto the prepared distal femur.

Remove the Femoral Impactor/Extractor and assess the fit of the trial component. Fixation lug holes are created by drilling through the trial femur with a 1/4" diameter lug drill with stop.

Note: Size #3 femoral trials only accept an 1/8" diameter drill. The drill hole diameter is increased to 1/4" after removal of the trial.

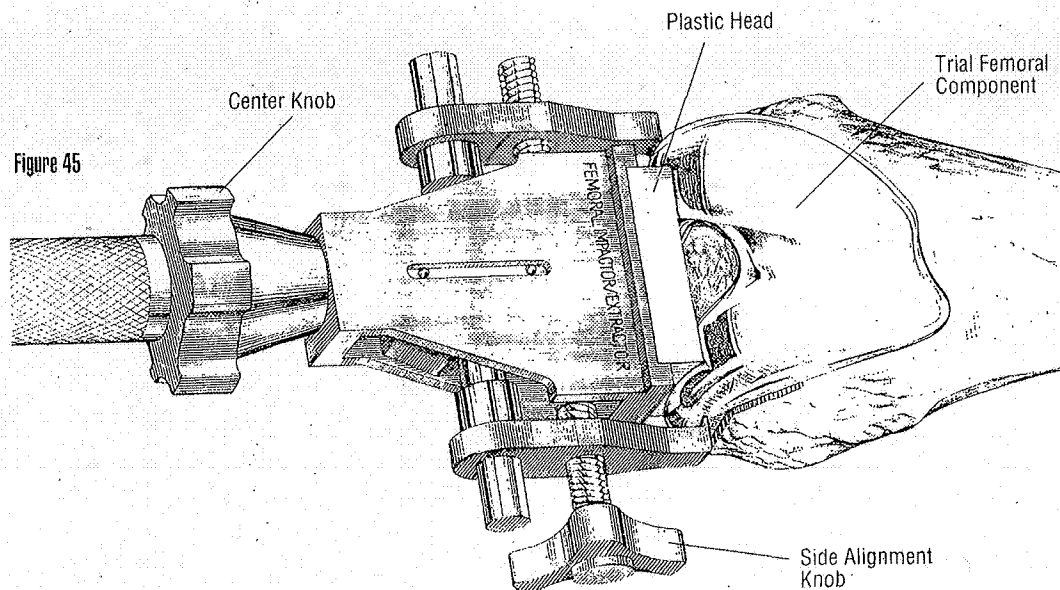


Figure 45

Downsizing the Femur

If a smaller femoral component is desired after the femur has already been cut for a specific size, simply assemble the next smaller size femoral cutting guide to the femur by driving the serrated pins into the same fixation holes used with the previous cutting guide. Towel clamps should be used to secure the block to the femur. Repeat the posterior, posterior chamfer, anterior and anterior chamfer resections.



"Watch for excess lateral overhang."

Peter Bonutti, MD

Posteriorly Stabilized Option

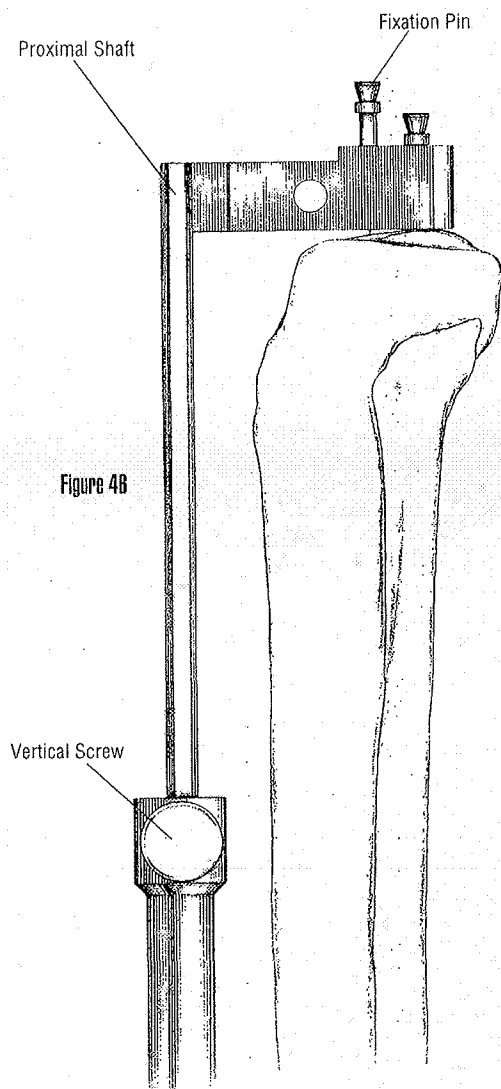
See the appropriate Series 7000 Primary Posterior Stabilized Knee or Scorpio PS Protocols.

TIBIAL PREPARATION

Tibial External Alignment Option

With the knee flexed, place the External Tibial Alignment Guide on the tibial shaft. Place the spring-loaded clamp around the distal tibia just above the malleoli.

Place the head of the instrument over the tibial eminence. There should be a finger's breadth clearance between the proximal shaft of the alignment guide and the anterior cortex when the head is positioned properly. Center the proximal fixation pins over the tibial eminence and tap in the most posterior pin first to fix the A/P location of the head. Rotation is now adjusted, and then set, by anchoring the second pin. Tighten the vertical screw to secure the proximal shaft of the guide (Fig. 46).



Axial alignment is achieved when the vertical shaft of the instrument parallels the long axis of the tibia in both the A/P and M/L views. Use the A/P and M/L adjustment thumbscrews to facilitate alignment (Figs. 47, 48).

► "Prior to placement of the tibial alignment guide, either extra or intramedullary, it is helpful to sublax the tibia anteriorly. This is most easily done by placing a curved Hohmann retractor in front of the posterior cruciate ligament from beneath the resected femur."

"If the PCL has become abnormally adherent to the posterior aspect of the tibial spine, this will cause booking open of the knee in flexion. The PCL may be very gently released in a subperiosteal fashion using a 3/8" curved osteotome or similar elevator. Do not release or recess the PCL below the level of the intended tibial cut."

Hugh Morris, M.D.

Figure 47

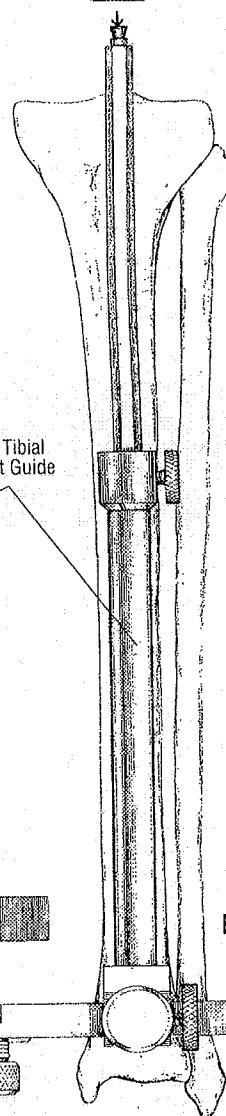
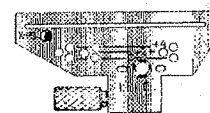
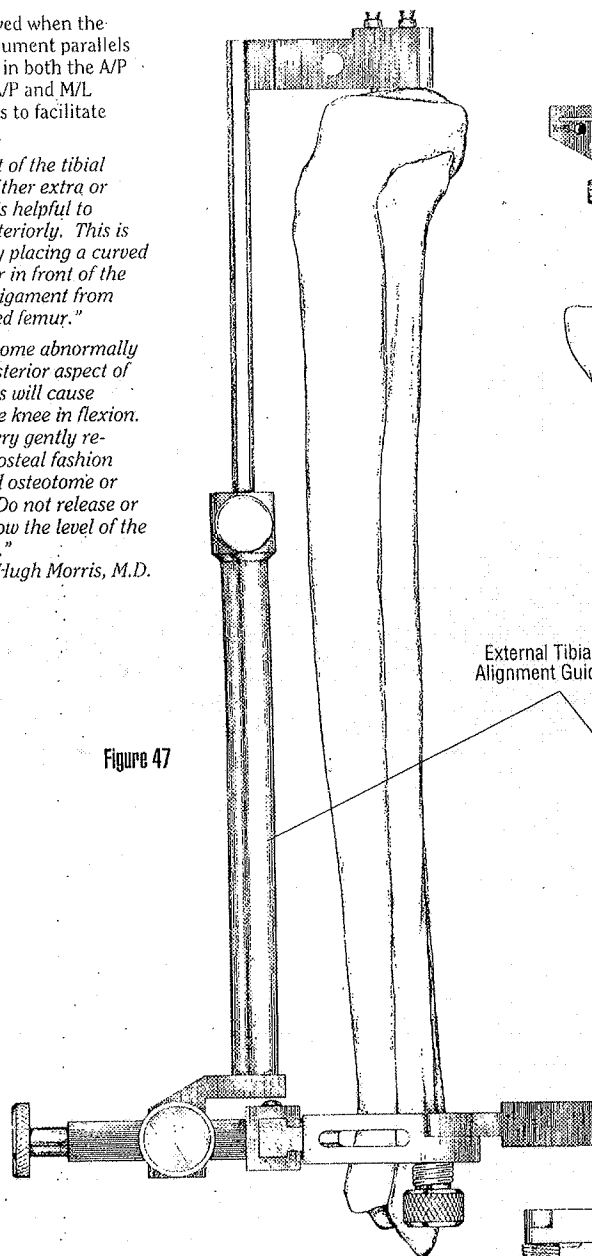


Figure 48

Landmarks often used to obtain correct axial alignment and rotation include:

1. Tibial Tubercle - The alignment rod usually lies over the medial third of the tibial tubercle.
2. Second Metatarsal - The second metatarsal generally is in line with the center of the ankle. (Fig. 49)

Once axial alignment is established, tighten the A/P and M/L adjustment thumbscrews. (Fig. 50)

Figure 48
Distal Alignment

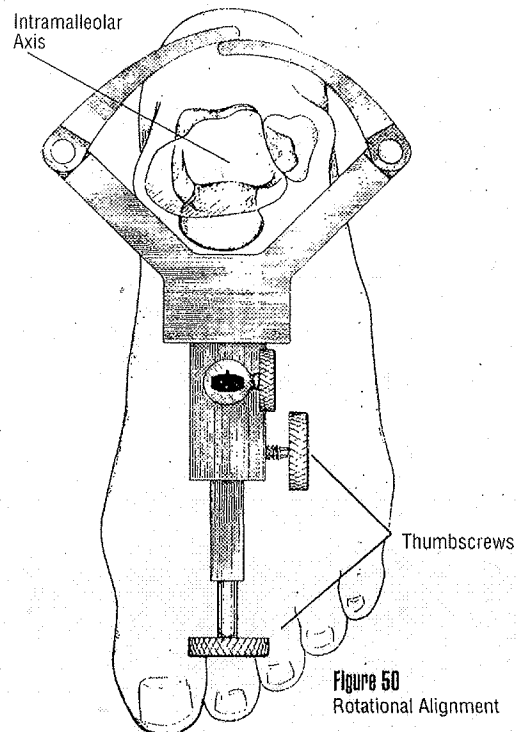
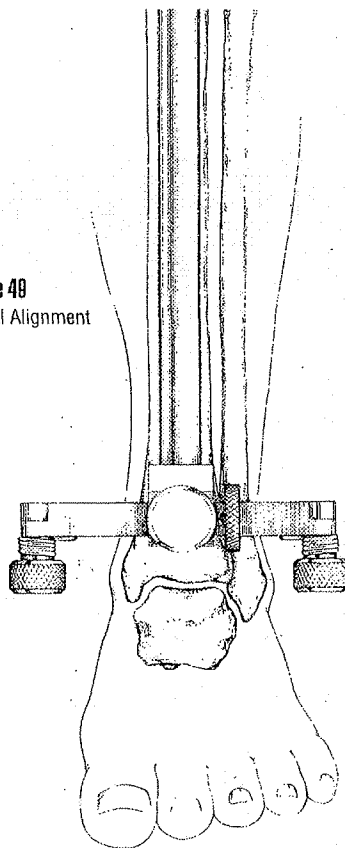


Figure 50
Rotational Alignment

“By external rotation of the foot and anterior translation of the tibia, the tibial plateau can be subluxed into the field, enhancing visualization. Medial and lateral menisci are excised and posterior menisco-femoral ligaments are released.”

Steven Zelicof, M.D., Ph.D.

Tibial Resection Level

The Passport System offers Right and Left, 0 and 5 degree Tibial Resection Guides.

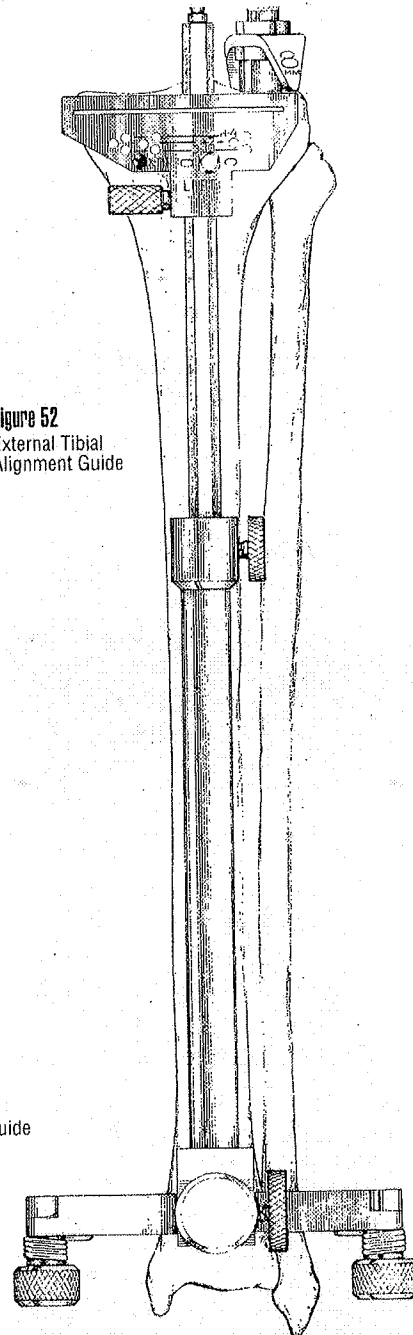
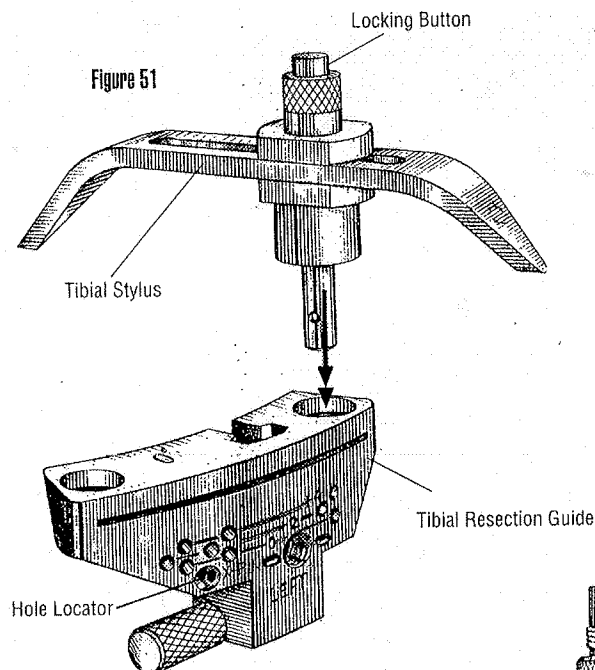
The Tibial Stylus is assembled to the appropriate Tibial Resection Guide by depressing the button on the Tibial Stylus and then fully seating it in either the medial or lateral hole on the top of the resection guide. Release the button to lock the stylus in place. (Fig. 51)

Assemble the Tibial Resection Guide/Tibial Stylus assembly to the External Tibial Alignment Guide by sliding it over the top of the proximal shaft, adjusting the stylus to reference the desired point on the tibial plateau. (Fig. 52)

► *"The posterior inclination of the tibial resection may be adjusted slightly by moving the distal end of the alignment jig anteriorly."*

James Scott, M.D.

Figure 52
External Tibial
Alignment Guide

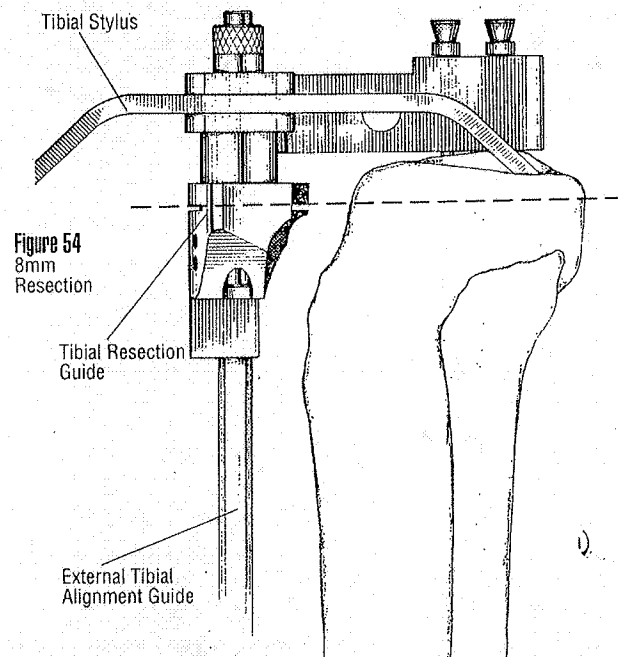
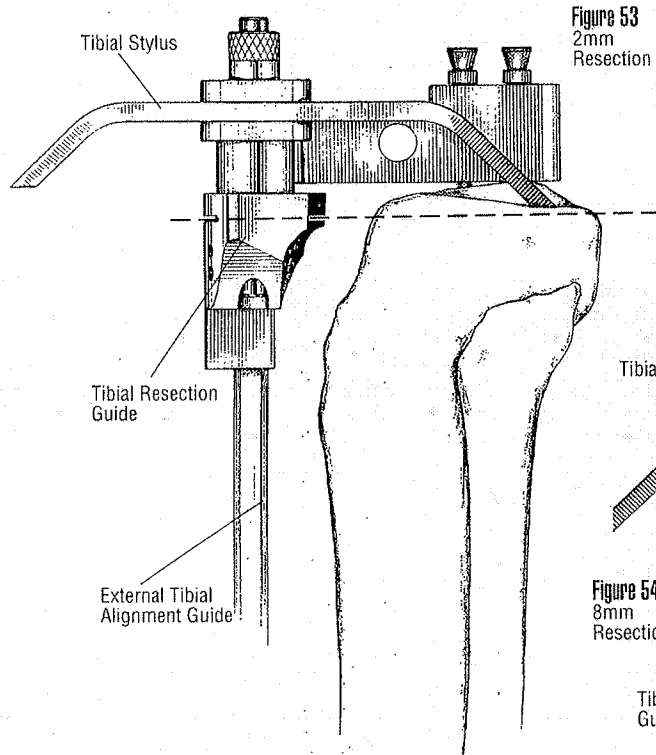


The Tibial Stylus offers both 2mm and 8mm resection levels.

The 2mm setting will allow for a resection of 2mm of bone below the point of the stylus. (Fig. 53)

The 8mm setting will allow for a resection of 8mm of bone below the point of the stylus. (Fig. 54)

Once the resection level is established, tighten the thumbscrew on the Tibial Resection Guide. The Tibial Stylus is removed by depressing the button and pulling it out.



Proximal Tibial Resection

Secure the Tibial Resection Guide to the proximal tibia using two 1/8" Drill-Pins, drilling through the "0" holes.

Loosen the thumbscrew that holds the Tibial Resection Guide to the External Tibial Alignment Guide.

Loosen the vertical adjustment thumbscrew on the shaft of the alignment guide.

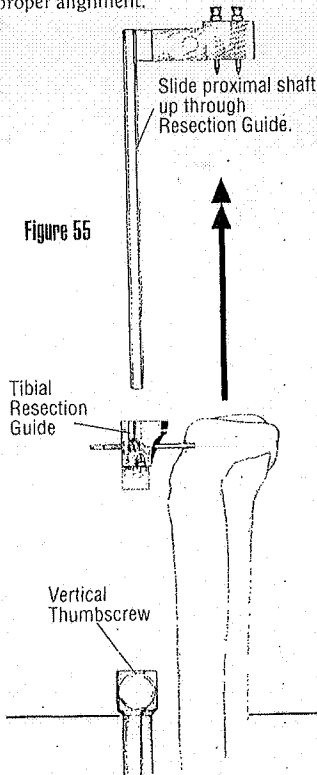
Using the Pin Puller, extract the two headed fixation pins on the top of the alignment guide from the proximal tibia.

Remove the proximal shaft of the alignment guide by sliding it up through the top of the resection guide. (Fig. 55)

Slide the Tibial Resection Guide posteriorly until it comes in contact with the anterior tibia.

Placing a 1/8" Drill-Pin through the "X" pin hole will further secure the resection guide to the tibia.

The Alignment Handle may be used with an Alignment Rod, referencing the same landmarks as outlined previously to verify proper alignment.



Resect the plateau using a .050" (1.25mm) saw blade. (Fig. 56)

The Tibial Resection Guide is removed by first sliding the guide off over the two 1/8" Drill-Pins and then removing the pins with the Pin Puller.

If desired, 2mm or 4mm of additional bone may be resected by repositioning the guide over the pins through the +2 or +4 holes respectively. (Fig. 57)

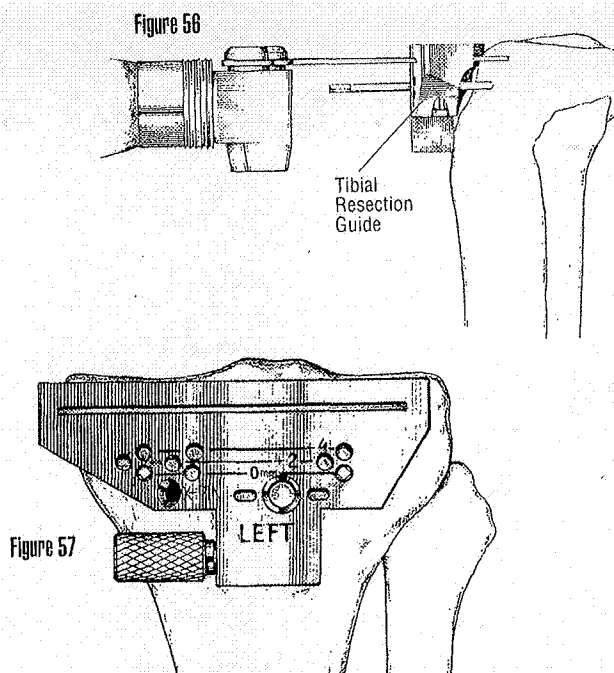
Note: If the "X" Pin hole is used, this pin must be removed prior to repositioning or removing the Tibial Resection Guide.

▶ "Placing the body of a Hohmann retractor or a pin in front of the PCL will help protect it while making the tibial cut."

Hugh Morris, M.D.

▶ "Care should be taken to protect the medial and lateral collateral ligaments and the patellar tendon. A Hohmann retractor is effective along the lateral compartment to protect the patellar tendon."

Steven Zelicof, M.D., Ph.D.



Tibial Intramedullary Alignment Option

Pre-op A/P and M/L x-rays of the tibial shaft should be obtained to determine the shape and size of the intramedullary canal. If the canal is excessively bowed or otherwise deformed (previous fracture, etc.) preventing proper placement of an IM rod, external alignment may be indicated.

Entry Hole and IM Rod Position

The Passport IM Tibial Alignment Instruments provide 1/4", 5/16", and 3/8" diameter cannulated IM Rods.

If the tibial eminence is pronounced, make an initial cut to flatten the tibial plateau and expose an area of cancellous bone.

Remove all soft tissue, including remnants of the ACL, from the intercondylar area of the tibial plateau.

Make an entry hole for access into the intramedullary canal using a 3/8" drill. It is generally agreed that a point on the tibial plateau approximately mid-line in the medio-lateral plane and at the approximate junction of the anterior and middle 1/3 of the plateau in the A/P plane will be in line with the tibial intramedullary canal. (Fig. 58)

The entry hole may also be prepared by utilizing the 3/8" Guide Bushing which has been assembled to the predetermined size Tibial Trial Baseplate and positioned on the resected plateau. (Fig. 59)

Proper alignment is confirmed by attaching the Alignment Handle and Alignment Rod to the Tibial Trial Baseplate so that the rod is parallel to the tibial axis in both the M/L and A/P planes.

Use a 3/8" diameter drill bit to create the entry hole. Advance the 3/8" drill bit only so far enough to gain access to the IM canal. Toggling the drill will create a slightly oversized hole which will aid in self-centering of the IM Rod and will allow for extrusion of marrow and fat during rod placement.

Figure 58

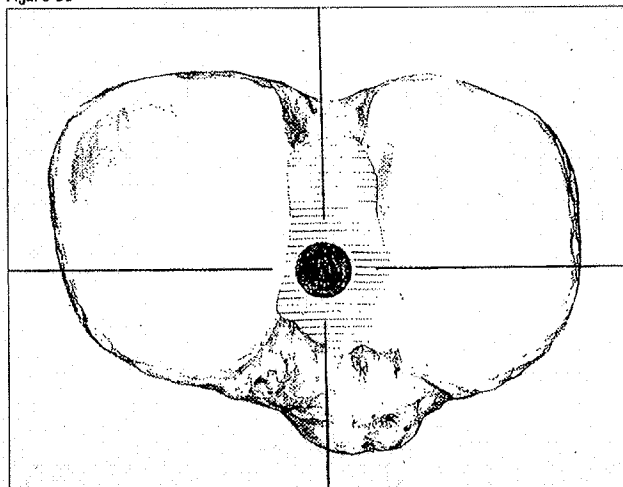
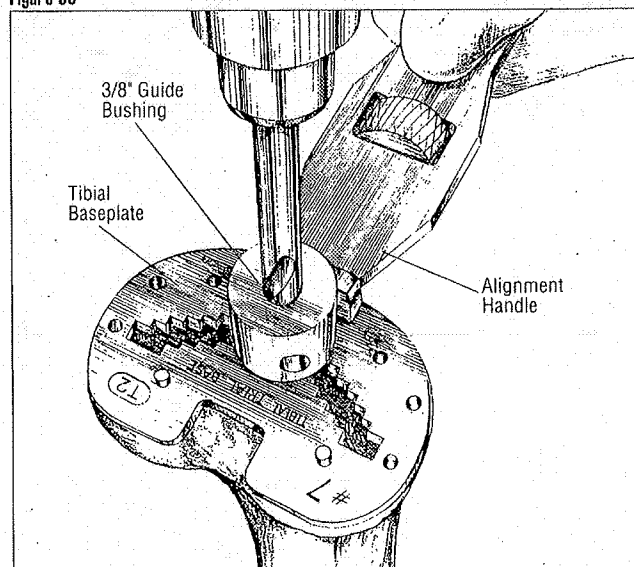


Figure 59



IM Rod Placement

Attach the predetermined diameter IM Rod to the T-Handle by depressing the button, inserting the IM Rod fitting, and releasing the button to lock into place. Pre-operative x-ray templating will aid in the determination of the IM Rod diameter. Introduce the IM Rod into the entry hole and gradually advance it down the intramedullary canal. (Fig. 60)

Several steps may be taken to avoid an increase in intramedullary pressure:

- A. Advance the IM Rod slowly;
- B. Rotate the IM Rod within the canal during advancement;
- C. Apply suction to the fitting on the end of the cannulated IM Rod.

The proximal portion of both the 3/8" and 1/4" diameter IM Rods changes to 5/16" in diameter. It is necessary to insert those rods so that the diameter transition point is within the intramedullary canal. The 5/16" diameter IM Rod may be inserted to any depth up to the scribe mark on the proximal shaft. Once the IM Rod is positioned, remove the T-Handle. (Fig. 61)

Intraoperative x-rays may be obtained to confirm accurate position of the rod in the canal.

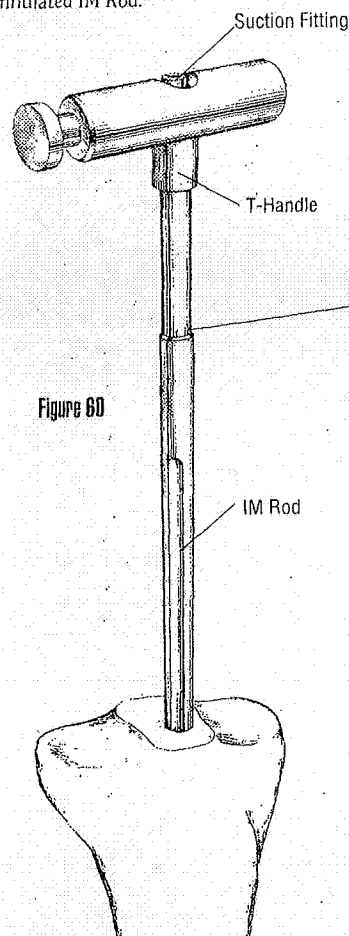


Figure 60

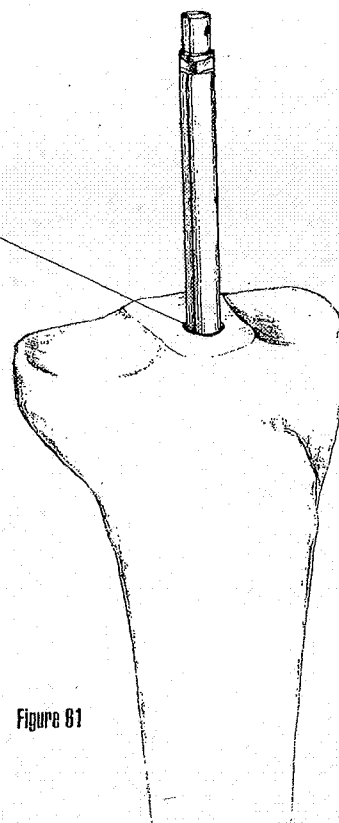


Figure 61

TIBIAL PREPARATION

Tibial Resection Level

The Passport System offers Right and Left, 0 and 5 degree Tibial Resection Guides.

Assemble the appropriate Tibial Resection Guide to the IM Tibial Alignment Guide by sliding the Tibial Resection Guide onto the rail of the alignment guide and tightening the thumbscrew on the resection guide. (Fig. 62)

Assemble the Tibial Stylus to the Tibial Resection Guide by depressing the button on the top of the Tibial Stylus, inserting the stylus into either the medial or lateral hole on the top of the Tibial Resection Guide, and releasing the button to lock the stylus into place. (Fig. 63)

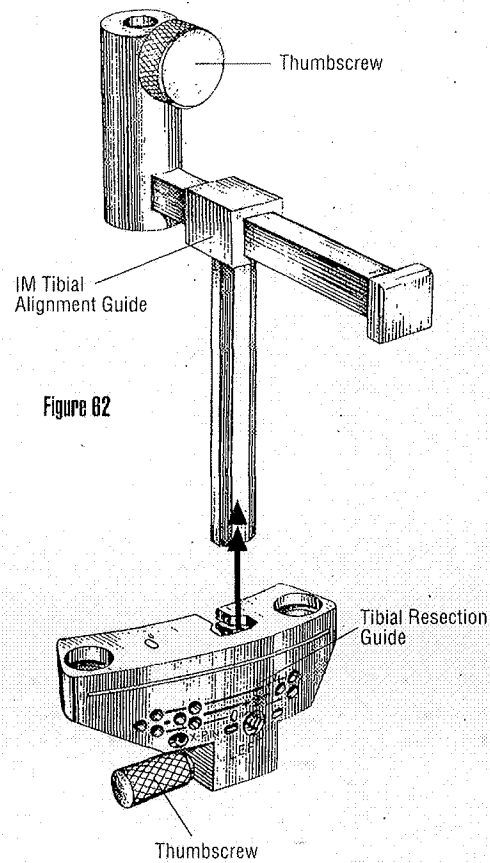


Figure 62

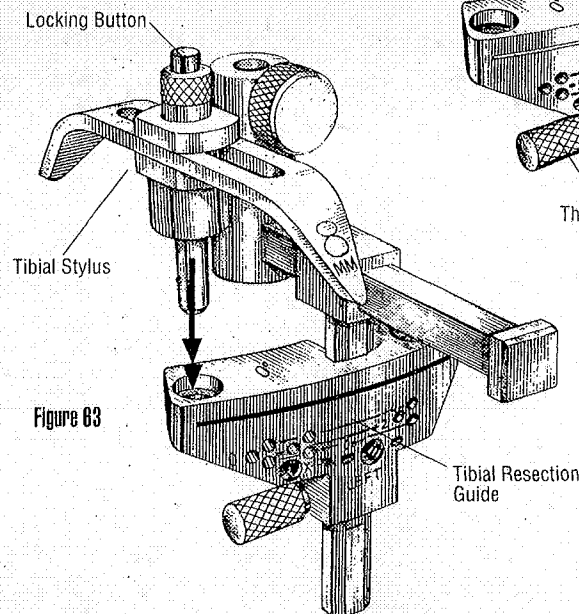


Figure 63

Slide the assembly over the Tibial IM Rod, positioning the Tibial Stylus to reference the desired point on the tibial plateau. Secure the IM Tibial Alignment Guide to the Tibial IM Rod by tightening the thumbscrew. Slide the Tibial Resection Guide posteriorly until it comes in contact with the anterior tibia. Further adjustments to the resection level may be made by loosening the thumbscrew on the Tibial Resection Guide and positioning it accordingly.

The Tibial Stylus offers both 2mm and 8mm resection levels.

The 2mm option will allow for a resection of 2mm of bone below the point of the stylus. (Fig. 64)

The 8mm option will allow for a resection of 8mm of bone below the point of the stylus. (Fig. 65)

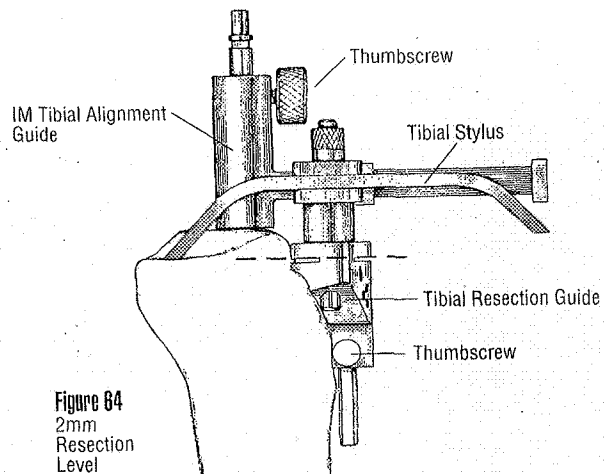


Figure 64
2mm
Resection
Level

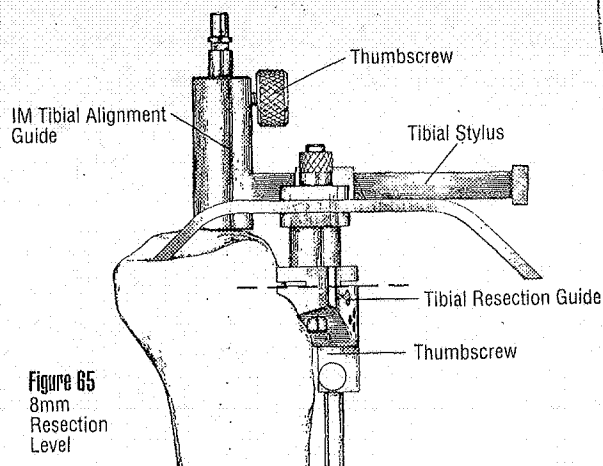


Figure 65
8mm
Resection
Level

Both the 0 and 5 degree Tibial Resection Guides may be used with the IM Tibial Alignment Guide. When the 0 degree Tibial Resection Guide is used, the A/P direction of the guide is not critical. However, when the 5 degree Tibial Resection Guide is used, care must be taken to direct the resection directly from anterior to posterior. Any mal-rotation of the resection may result in an inadvertent varus or valgus plane of resection.

Accurate rotational position of the Tibial Resection Guide may be assessed by attaching the Alignment Handle to the front of the resection guide and inserting an Alignment Rod through the handle (Fig. 66)

Several alignment references may be used to determine correct rotational position:

- A. The external rod will usually lie over the medial third of the tibial tubercle.
- B. The external rod should intersect the center of the talus, slightly medial to the mid-intermalleolar space.
- C. The external rod should be in line with the second metatarsal (provided no foot or lower leg abnormalities exist) (Fig. 67)

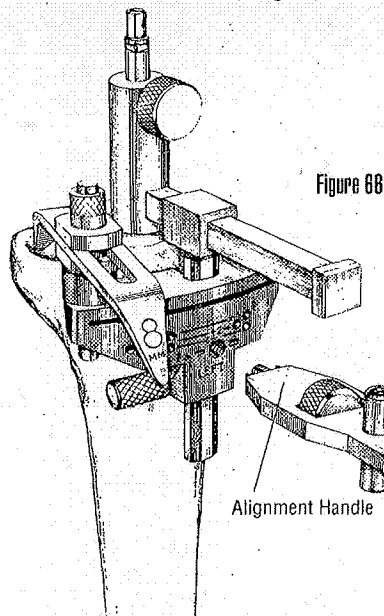


Figure 66

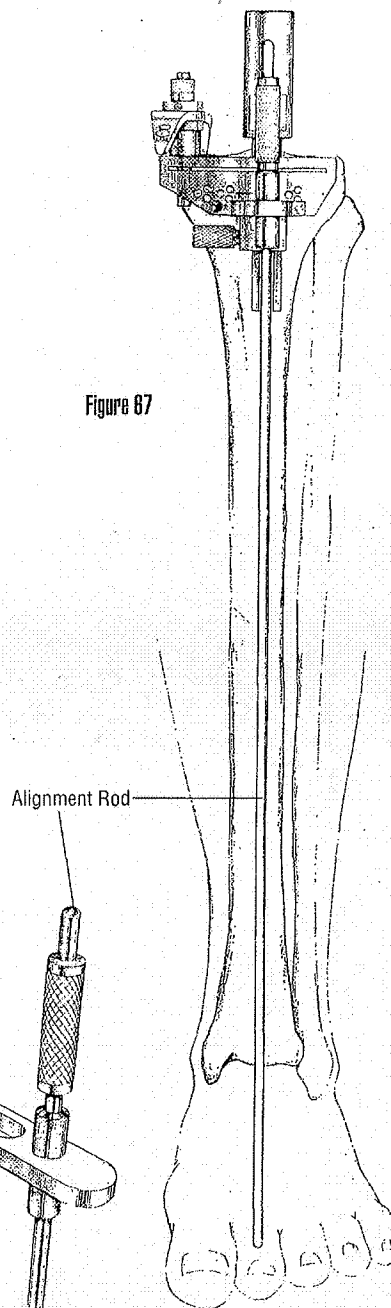


Figure 67

Proximal Tibial Resection

Once the resection level is established, secure the Tibial Resection Guide to the anterior tibia using the 1/8" Drill-Pins, drilling through the "0" holes. Pinning through the "X" Pin hole will further secure the Tibial Resection Guide to the tibia. (Fig. 68)

Remove the Tibial Stylus by depressing the button and pulling the stylus out.

Release the IM Tibial Alignment Guide from the Tibial Resection Guide by loosening the thumbscrew on the resection guide. Reattach the T-Handle to the IM Rod and extract both the IM Rod and IM Tibial Alignment Guide together, leaving the Tibial Resection Guide pinned in place. Resect the tibial plateau through the slot in the Tibial Resection Guide. Use of a .050" (1.25mm) sawblade is recommended for an accurate resection. (Fig. 69)

Additional bone may be resected by repositioning the Tibial Resection Guide over the pins in the +2 or +4 holes. This will resect an additional 2mm or 4mm of bone respectively. (Fig. 70)

The Tibial Resection Guide is removed by first sliding the guide off over the two 1/8" Drill-Pins and then removing the pins with the Pin Puller.

Note: If the "X" Pin hole is used, this pin must be removed prior to repositioning or removing the Tibial Resection Guide.

Figure 68

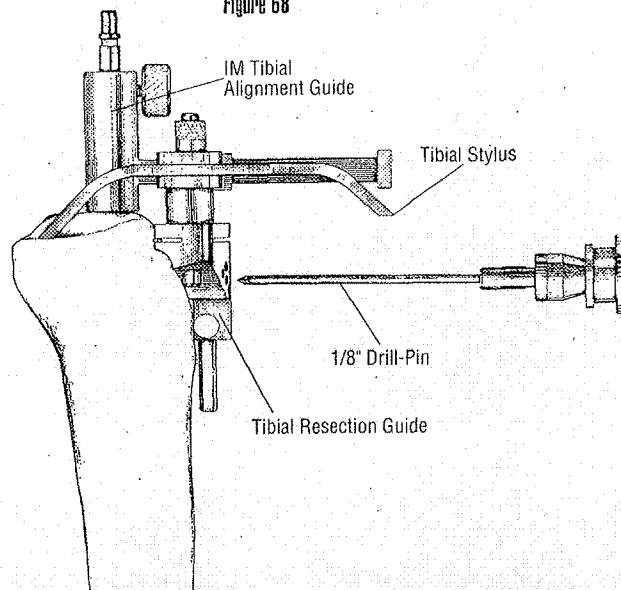


Figure 69

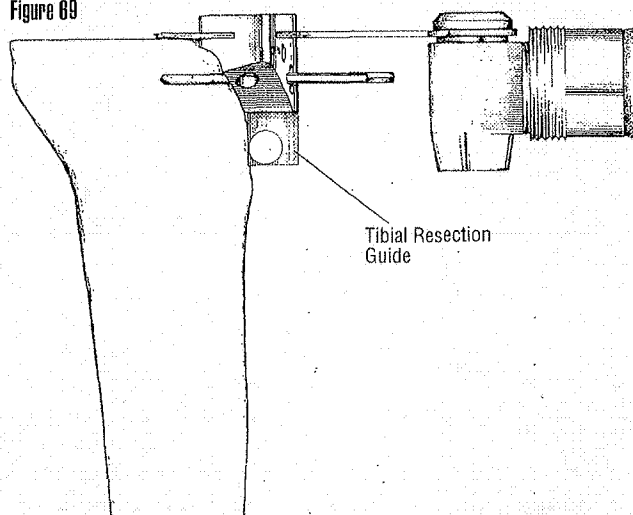
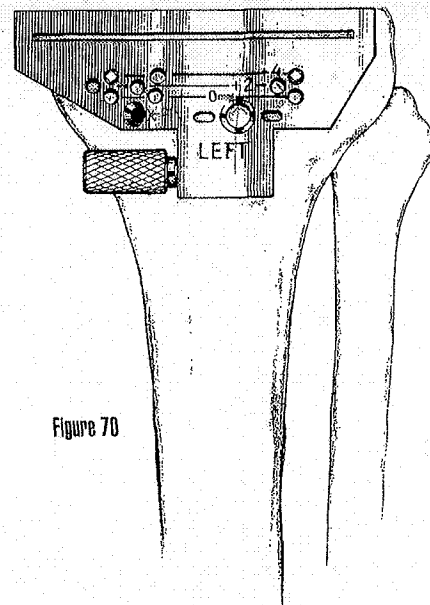


Figure 70



DELTA FIT KEEL PREPARATION

Tibial Component Sizing

Maximally flex the knee and deliver the tibia forward.

- ▶ "To facilitate exposure of the tibial plateau, a limited release may be performed and extended as required to compensate for angular deformities. Medial osteophytes are removed to facilitate the medial release. The lateral fat pad is freed from the infrapatellar bursa to allow superior lateral visualization."

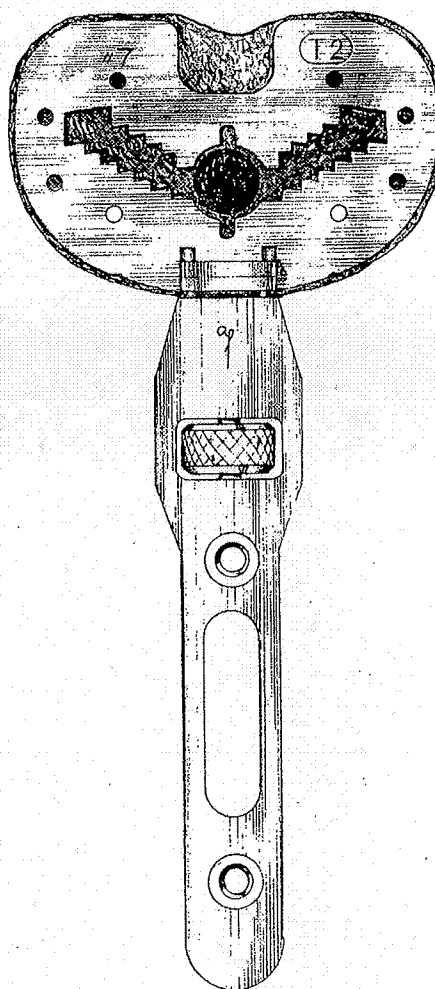
Steven Zelicof, M.D., Ph.D.

Assemble a Tibial Trial Baseplate to the Alignment Handle and place it on the resected tibial plateau (Fig. 71). Choose the size that best covers the tibial plateau. Slight overhang is preferable to undersizing.

- ▶ "If slight medial or lateral overhang is necessary for adequate anterior-posterior cover, the overhang will be better tolerated laterally rather than medially. Medial overhang is associated with pain secondary to soft tissue impingement on the tray."

Richard Fingerioth, M.D.

Figure 71



Tibial Component Alignment

Replace the Trial Femoral Component on the femur. Assemble a Tibial Bearing Insert Trial to the Tibial Trial Baseplate by first positioning it posteriorly on the baseplate and then fully seating it anteriorly. (Fig. 72) Reverse the steps to disassemble the insert trial from the baseplate.

Position the assembled insert and baseplate on the tibial plateau and carry out a trial reduction. Assess overall component fit, ligament stability, and joint range of motion.

As the joint is taken through flexion and extension, the femoral trial component helps position the tibial baseplate. Final position of the tibial trial is achieved when tibiofemoral articular contact is most congruent. This is best assessed when the knee is in extension.

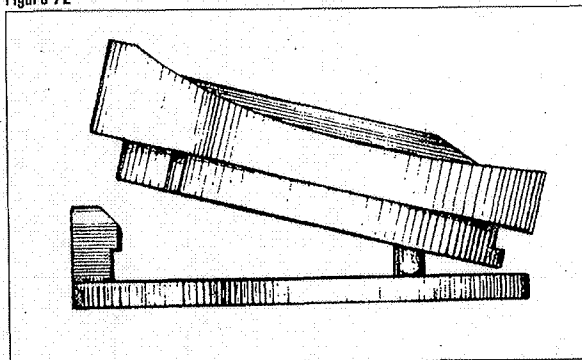
▶ *"It is important to note that when taking the knee through range of motion, the patella should be in its normal position. If the knee is ranged while the patella is everted, it will abnormally externally rotate the tibia and give a false impression of the correct rotational orientation for the tibial baseplate."*

Hugh Morris, M.D.

▶ *"With the patella reduced, soft tissue balancing can also be evaluated at this time. If there is excessive tightness on one side, the tibial tray will lift off on the contralateral side as the knee is flexed and extended. Appropriate releases can then be performed until the tray remains flat through a full range of motion. Furthermore, if the PCL is too tight, the anterior tray will lift up as the knee is flexed. This can be corrected with PCL recession."*

Richard Fingerioth, M.D.

Figure 72

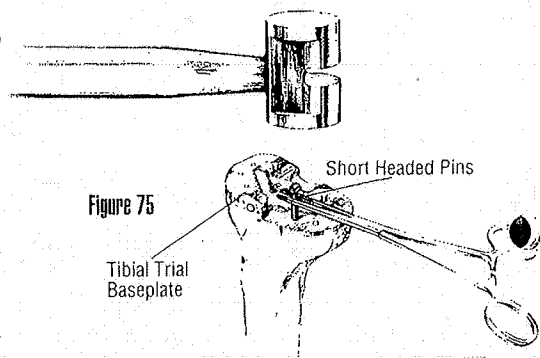
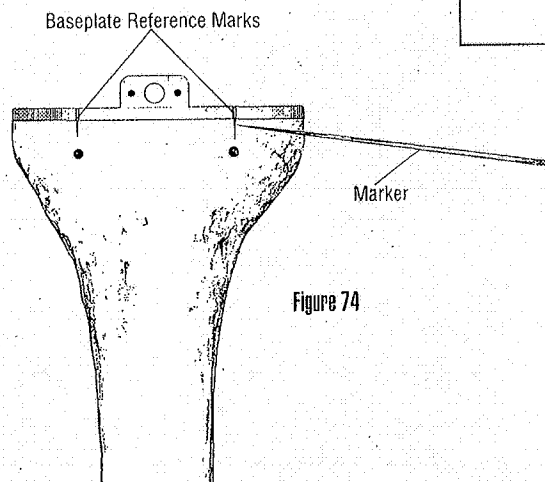
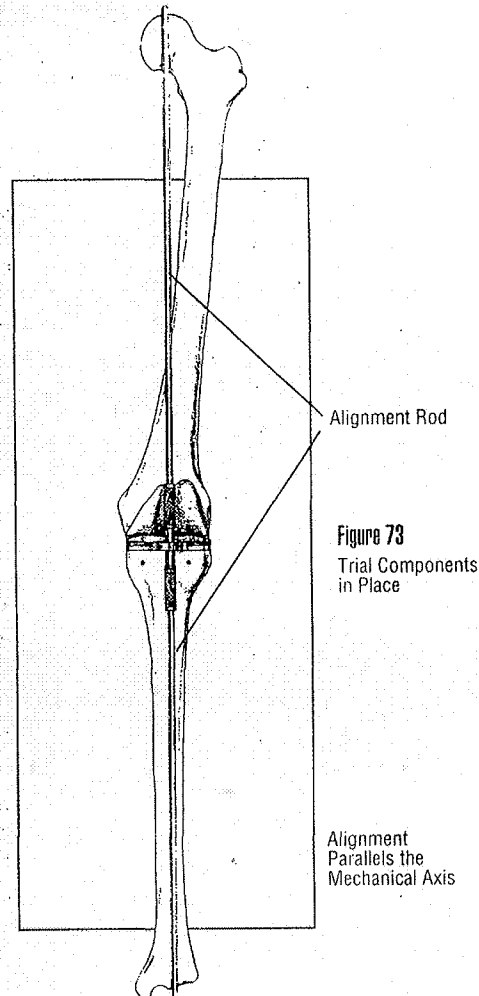


Overall leg alignment may be assessed at this time. Reattach the Alignment Handle to the trial baseplate and insert two Alignment Rods into the handle. The rods should parallel the mechanical axis of the leg in both the coronal (A/P) and sagittal (M/L) views. (Fig. 73)

Once satisfactory alignment and tibial component orientation is achieved, mark the anterior tibial cortex in line with the reference marks on the anterior border of the baseplate. (Fig. 74)

Remove the trial components and disassemble the trial insert from the baseplate. Reposition the Tibial Trial Baseplate aligning the anterior reference marks on the baseplate with the reference marks on the anterior cortex. The baseplate is positioned flush to the anterior tibial cortex.

Pin the baseplate to the tibial plateau by placing two short, headed fixation pins through a medial and lateral hole in the baseplate. (Fig. 75) Pin hole selection is not critical; however, if the anterior holes are used and the pins are fully seated, the Tibial Bearing Insert Trial may be reassembled to the pinned baseplate for any subsequent trial reductions.

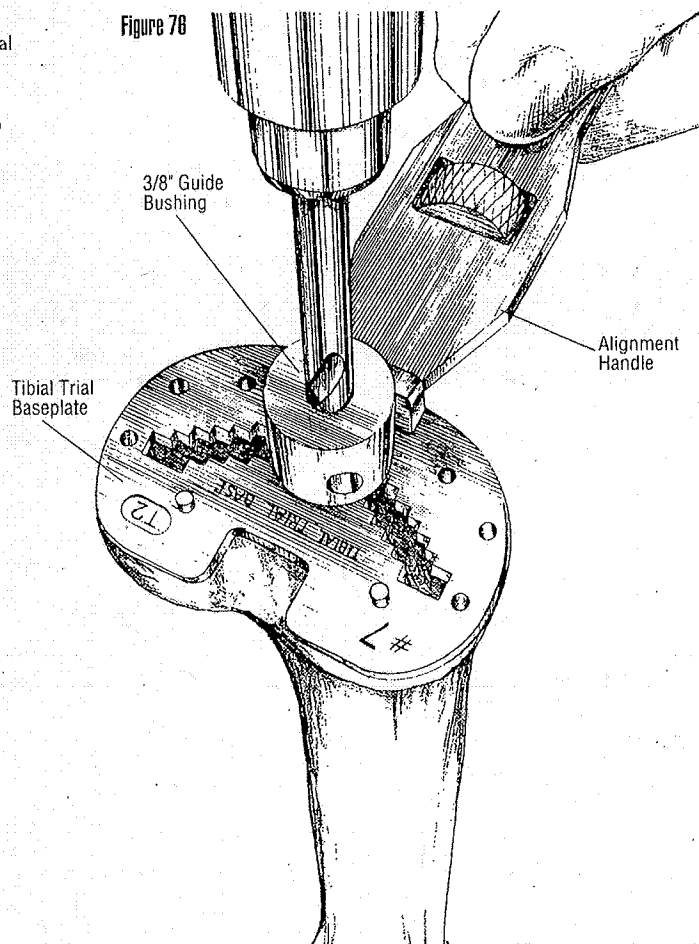


Tibial Keel Punching

Tibial Punches are identified by keel size (3/5, 7/9, 11/13) and bone preparation ("Cement Keel" creates a cement mantle around the keel; "Press Fit Keel" creates an interference fit around the keel).

The sequence of steps necessary to prepare the tibia for the Deltafit Keel may vary depending on the bone quality of the proximal tibia. In relatively soft bone (i.e., rheumatoid) only one punching step with the final tibial size/preparation punch may be required. In normal bone, it is recommended that a smaller "Press Fit Keel" punch be used first, followed by the final size/preparation punch.

In denser bone, several intermediate punching steps may be required prior to final punching. If sequential punching is undertaken, only "Press Fit Punches" should be utilized until the final size is reached. If extremely dense bone is encountered, a 3/8" Guide Bushing may be assembled to the baseplate and a pilot hole drilled prior to tibial punching (Fig. 76).



Assemble the Tibial Punch Tower to the baseplate by placing the tower onto the two small locating pins on top of the baseplate. During the subsequent tibial punching, the tower will maintain correct position of the punches.

Fit the appropriate Tibial Punch into the Tibial Punch Tower. (Fig. 77) Handles may be assembled to the tower to aid in maintaining position and stability of the tower/baseplate assembly during punching. A mallet may be used to impact the punch.

Advance the punch until it seats fully on the baseplate. (Fig. 78) During extraction, take care to avoid toggle or angulation of the punch as this may distort the bone preparation. The Quick Release Slide Hammer connects to the punches for extraction.

Once the final punch has been seated, tibial preparation is complete. (Fig. 79)

▶ *"In good quality bone, I will often cement the tibial tray but press fit the Deltafit Keel. As a rough test to determine bone quality, I lift the tower by its handles with the press fit punch in place. If the punch does not pull out of the bone, I press fit the keel."*
Richard Fingerioth, M.D.

Figure 78
Tibial Punch is Fully Seated

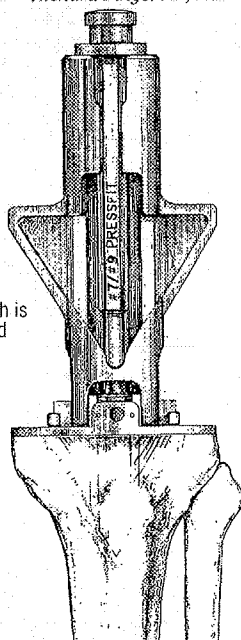


Figure 77

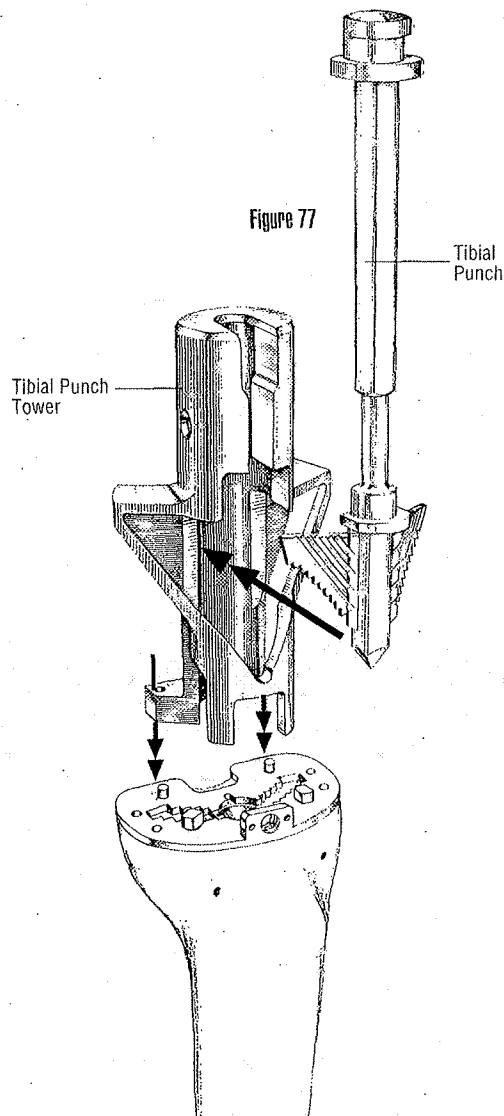
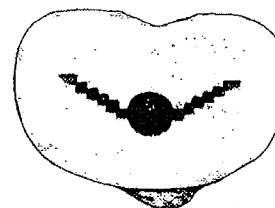


Figure 79
Completed Tibial Preparation



All-Poly Tibial Punching

To prepare for an All-Poly Tibial Component, the tibia must first be prepared with the appropriate size Cement Punch as shown in the Tibial Punching Sequence Chart. (Page 45)

Note: If sequential punching is undertaken, only "Press Fit Punches" should be utilized until the final size is reached.

Remove all instruments from the tibia, including the Tibial Punch, Punch Tower, Trial Baseplate, and Fixation Pins.

Set the All-Poly Tibial Punch to the pre-determined keel size (see below) by pulling the side pin out and sliding the stop up or down until the appropriate keel size is reached. Release the side pin to secure the punch position.

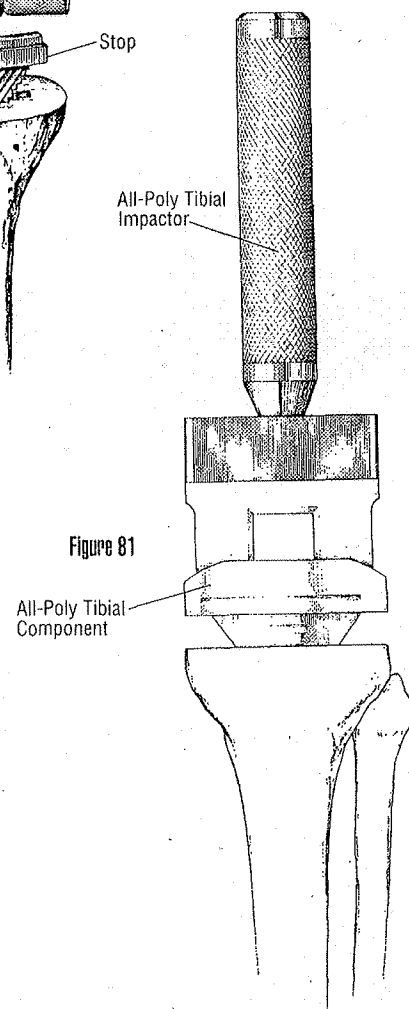
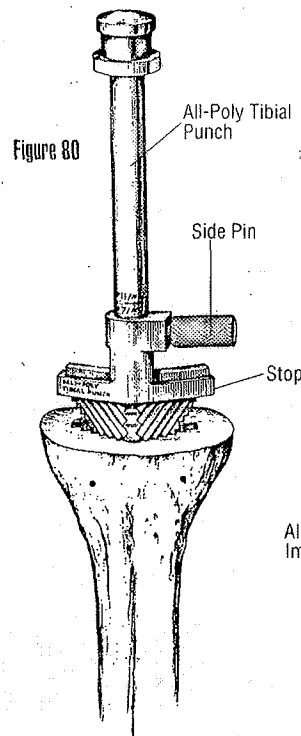
| Tibial Tray Size | Stop Location |
|------------------|---------------|
| #3 | #3/#5 |
| #5 | #3/#5 |
| #7 | #7/#9 |
| #9 | #7/#9 |
| #11 | #11/#13 |
| #13 | #11/#13 |

Impact the All-Poly Tibial Punch into the tibia using the punch slots produced from the previous punching sequence as a guide. (Fig. 80)

Continue impaction until the stop contacts the proximal tibia. It is important that the All-Poly Tibial Punch be held straight during impaction.

Once the punch has been seated, remove it with a mallet or the Quick Release Slap Hammer. The resected and punched surfaces are prepared for bone cement in the usual fashion.

After the preferred cementing technique has been performed, place the All-Poly Tibial Component into the prepared tibia. Seating is accomplished by first positioning and partially seating the component by hand, followed by final seating with the All-Poly Tibial Impactor. (Fig. 81) After the cement is cured, the knee is thoroughly cleaned and lavaged.



| IMPLANT SIZE | TIBIAL PUNCHING SEQUENCE | | |
|-------------------------|---|---|---|
| | PRESS FIT KEEL | CEMENT KEEL | ALL-POLYETHYLENE IMPLANT |
| 3 | PRESS-FIT #3/#5 | PRESS-FIT #3/#5 CEMENT #3/#5 | PRESS-FIT #3/#5 CEMENT #3/#5 ALL-POLY #3/#5 |
| 5 | PRESS-FIT #3/#5 | PRESS-FIT #3/#5 CEMENT #3/#5 | PRESS-FIT #3/#5 CEMENT #3/#5 ALL-POLY #3/#5 |
| 7 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 CEMENT #7/#9 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 CEMENT #7/#9 ALL-POLY #7/#9 |
| 9 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 CEMENT #7/#9 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 CEMENT #7/#9 ALL-POLY #7/#9 |
| 11 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 PRESS-FIT #11/#13 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 PRESS-FIT #11/#13 CEMENT #11/#13 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 PRESS-FIT #11/#13 CEMENT #11/#13 ALL-POLY #11/#13 |
| 13 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 PRESS-FIT #11/#13 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 PRESS-FIT #11/#13 CEMENT #11/#13 | PRESS-FIT #3/#5 PRESS-FIT #7/#9 PRESS-FIT #11/#13 CEMENT #11/#13 ALL-POLY #11/#13 |

Tibial Component

If tibial fixation is to be augmented by bone screws, remove the polyethylene plugs in the tibial tray screw holes prior to implantation. (Fig. 82)

Assemble the Tibial Component Impactor/Extractor to the implant. To assemble, retract the slide rod levers and insert the "feet" into the central hole in the tibial tray. Release the levers and tighten the knurled thumbscrew by hand to securely engage the impactor/extractor to the implant. (Fig. 83)

Introduce the tibial tray into the prepared tibia and impact it until the tray is fully seated. (Fig. 84) Clear all excess bone cement while maintaining position of the implant.

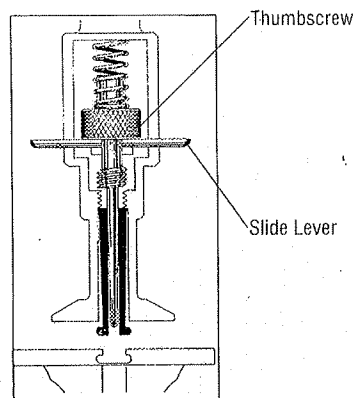


Figure 83
Retract Slide Levers to Engage Feet in Tibial Tray

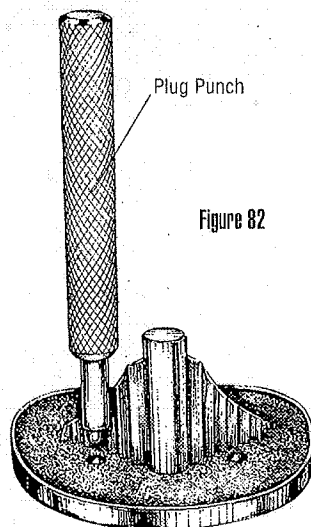
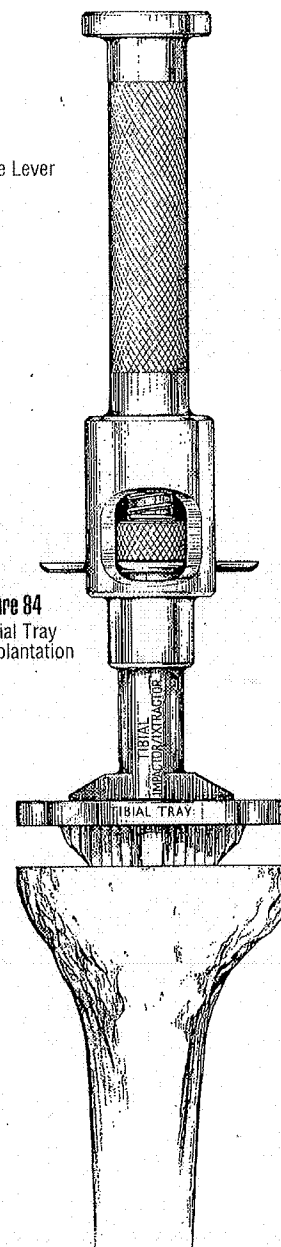


Figure 84
Tibial Tray Implantation



Tibial Bearing Insert Assembly

Prior to assembly of the prosthetic UHMWPE bearing insert, the trial insert may be placed in the tibial tray to once more assess joint stability and range of motion.

To assemble the prosthetic bearing insert, distract the joint and angle the insert posteriorly into the tray. The posterior lips of the bearing insert must fit beneath the lips on the interior, posterior tray wall.

"Placement of the final polyethylene insert after hemostasis is obtained facilitates accessibility to posterior bleeding points and cement."

Steven Zelicof, M.D., Ph.D.

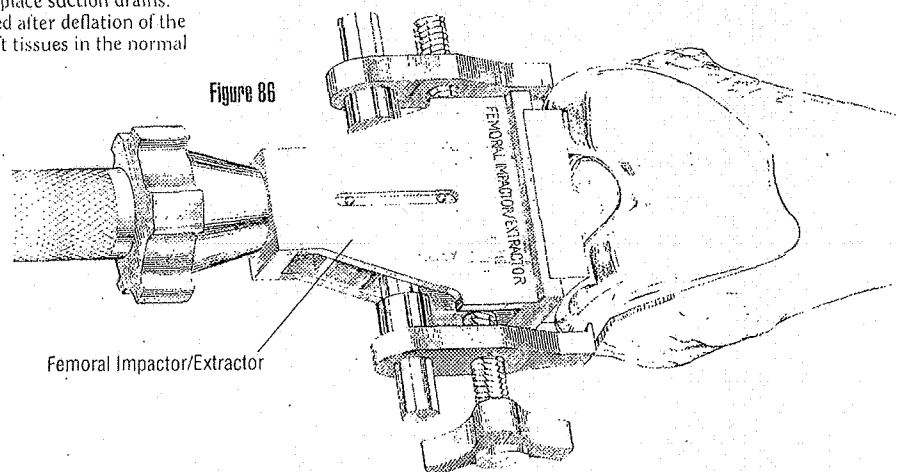
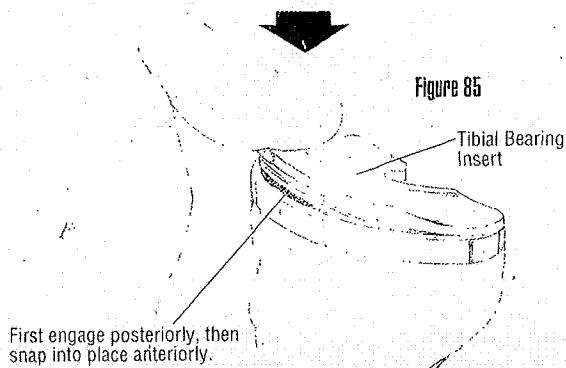
Then snap the insert in place anteriorly. (Fig. 85) Hand pressure or a light tap with a mallet is required. The tibial bearing insert is fully seated once the metal retaining wire locks under the barbs on the anterior, interior surface of the tray wall.

Femoral Component

Assemble the appropriate size and side femoral implant to the Femoral Impactor/Extractor in the same manner as the femoral trial. Place the implant on the prepared femur and impact it until fully seated. (Fig. 86) The Impactor/Extractor aids in maintaining accurate position of the implant during implantation.

Closure

After cement polymerization, thoroughly irrigate the joint and place suction drains. Hemostasis is achieved after deflation of the tourniquet. Close soft tissues in the normal layered fashion.



POSTOPERATIVE CARE, INDICATIONS, CONTRAINDICATIONS AND WARNINGS

Description

Osteonics' Total Knee Systems include femoral, patellar, tibial tray, tibial bearing insert and bone augmentation components which are designed to be used together to achieve total reconstructive replacement of the knee joint. The characteristics specific to each device are detailed on the product label. Generally, these components are available in a variety of fixation surface alternatives including MicroStructured® porous coating, waffled pattern and grit blasted. MicroStructured and waffled fixation surfaces are not applied to the stems, keels or fixation posts of the components. All components are intended for cemented fixation and are to be implanted on the prepared distal femur, proximal tibial or posterior patella, as appropriate.

Femoral Components: The femoral components are designed in right and left configurations and are available in standard and posterior stabilized designs. The standard component is available with or without an intramedullary stem. The posterior stabilized component, which provides supplemental intrinsic prosthetic constraint, is available in a primary design without a stem, as well as in fixed and modular intramedullary stem designs. Femoral components are available with nitrogen ion surface treatment (Low Friction Ion Treated (LFIT™)).

Tibial Components: The tibial tray components are available in standard length, extended length and modular intramedullary stem versions. A tibial bearing insert is assembled preoperatively or intraoperatively to the tibial tray. These inserts are available in a series of thicknesses and range of constraints as follows:

- Standard non-constrained bearing surface (e.g. Series I)
- Increased anterior and posterior bearing geometry surfaces for additional stability against subluxation (e.g. Series II)
- Raised tibial eminence for increased anterior and posterior constraint and resistance to posterior subluxation (e.g. Series P/S I)
 - Used only with primary posterior stabilized femoral components
- Raised tibial eminence for increased anterior and posterior constraint and resistance to posterior subluxation (e.g. Series P/S II)
 - Requires associated reinforcing pin
 - Used only with stemmed posterior stabilized femoral components
- Raised tibial eminence for increased anterior and posterior constraint, resistance to posterior subluxation and varus/valgus stability (e.g. Series P/S III)
 - Requires associated reinforcing pin
 - Used only with stemmed posterior stabilized femoral components

Patellar Components: The patellar components are available in resurfacing and recessed configurations as well as all-plastic and metal-backed designs. Dome and single medial-lateral radius configurations of the patellar components include concentric, modified and superior modified offset designs.

Bone Augmentation Components: The bone augmentation components are available in wedge and block configurations to fill bone defects encountered during total knee reconstruction. The components are initially cemented to the appropriate femoral or tibial component of the corresponding total knee design and then the assembly is cemented to the prepared underlying bone.

Modular Stem Extensions: The modular stem extensions are available in a variety of stem lengths and diameters. After removal of the cement plug from the appropriate femoral or tibial component, the stem extension is assembled via the locking taper to the component and is secured with the associated locking screw utilizing torque wrench and screw driver.

Materials:

- | | |
|--|--|
| • ASTM F-75 cobalt chromium alloy | Femoral component, tibial tray, bone augmentation wedge, patellar component metal backing, MicroStructuring (sintered beads) |
| • ASTM F-1537 wrought cobalt chromium alloy | Reinforcing pins, modular stem extension, extension locking screw, locking wire |
| • ASTM F-648 ultra-high molecular weight polyethylene (UHMWPE) | Tibial bearing insert, tibial screw hole plug, patellar component body, all-polyethylene tibial component |
| • Polymethylmethacrylate (PMMA) | Cement plug |

Additional Indications for Posteriorly Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- For Series P/S III Inserts Only: Severe anteroposterior and medial/lateral instability of the knee joint. Indications for Bone Augmentation Wedges:

Indications for Bone Augmentation Wedges:

- Painful, disabling joint disease of the knee secondary to: degenerative arthritis, rheumatoid arthritis, or post-traumatic arthritis, complicated by the presence of bone loss.
- Salvage of previous unsuccessful total knee replacement or other surgical procedure, accompanied by bone loss.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Obesity. An overweight or obese patient can produce loads on the prosthesis which can lead to failure of the fixation of the device or to failure of the device itself.

Additional Contraindication for Bone Augmentation Wedges:

Bone stock which is sufficient for the adequate fixation of the total knee component without augmentation wedges.

Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Patients should be instructed in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly.
- Appropriate selection, placement and fixation of the total knee components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanical and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
- Care must be taken to protect the components and any polished bearing surfaces from being marred, nicked or notched as a result of contact with metal or abrasive objects.

Utilization and Implantation

- The recommended trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- The UHMWPE plugs may be removed from the screw holes, and bone screws may be used for additional fixation. The PMMA plug must be removed from the modular tibial tray in situations where a modular stem extension is utilized.

- The Osteonics Surgical Protocols provide additional procedural information.
- Consult the product label for specific product compatibility. Generally, the following applies:
 - Osteonics Omnifit Primary Posterior Stabilized Femoral Components are not designed for use with the Series P/S I Tibial Bearing Inserts.
 - Series P/S II and P/S III Tibial Bearing Inserts are not designed for use with Osteonics Omnifit Tibial Trays.
 - Osteonics Omnifit Series III and IV Tibial Bearing Inserts are not designed for use with Series 7000 Tibial Trays.
 - Series 7000 Primary Posterior Stabilized Femoral Components are not designed for use with Osteonics Omnifit Series III or IV Tibial Bearing Inserts or Series 7000 P/S II or P/S II Tibial Bearing Inserts.
 - Series 7000 Modular Femoral Components are not designed for use with Series P/S I Tibial Bearing Inserts.
 - Series 7000 Patellar Components are not designed for use with any Osteonics Omnifit Femoral Components.

Warnings

- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.
- Polished bearing areas must not come in contact with hard or abrasive surfaces.
- Bearing areas must always be clean and free of debris prior to assembly.
- Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
- The metal retaining wire on the insert should not be handled or removed, as it is critical to the security of the assembly. Discard any tibial bearing insert if the metal retaining wire appears damaged or mishandled. Tampering with this assembly can result in improper function of the retaining mechanism.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.
- Osteonics strongly advises against the use of another manufacturer's total knee component with any Osteonics total knee component. Any such use will negate the responsibility of Osteonics for the performance of the resulting mixed component implant.
- Osteonics strongly advises against the use of another manufacturer's bone screws with any Osteonics total knee component, due to variations which exist between screw head and screw seat configurations.
- Intentional removal of a total knee component can be accomplished by careful

use of cutting burrs, thin and narrow osteotomes and cautious extraction forces

- Intentional removal of the plastic tibial insert after its assembly into the metal tray results in the destruction of the plastic insert. Care should be taken not to nick or notch the surface of the tibial tray during insert removal.
- Removal of an unloosened MicroStructured implant may require the use of special instruments to disrupt the interface at the implant surface.
- Return all packages with flaws in the sterile barrier to the supplier. Do not resterilize.

Adverse Effects

- Dislocation of the femoral, tibial, or patellar prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
- Loosening of total knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fatigue fracture of total knee components, including tibial, femoral and patellar components, has occurred in a small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, and/or amputation of the limb.

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THE OSTEONICS TOTAL KNEE COMPONENTS TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.

WARNING: OSTEONICS TOTAL KNEE COMPONENTS ARE NOT INTENDED AND HAVE NOT BEEN APPROVED FOR NONCEMENTED APPLICATION IN THE U.S.A.

Notes

Notes

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