

Orthopaedics

Xcelerate® PR Surgical Protocol



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Xcelerate Instrumentation Surgical Technique for Duracon and Scorpio Total Knee Systems

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Legend:

Designates Duracon procedures only.

Scorpio

Designates Scorpio procedures only.

Duracon and Scorpio Total Knee Systems Surgical Protocol Using Xcelerate Knee Instruments

Acknowledgements

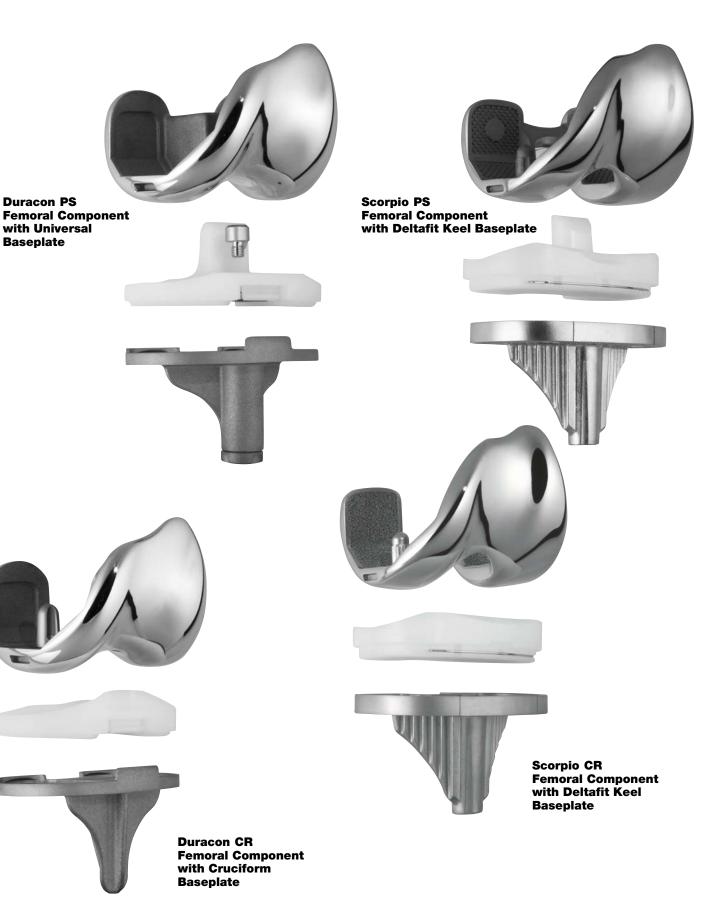
The following surgeons have contributed extensively to the development of the Scorpio prostheses:

James D'Antonio, MD Ormonde Mahoney, MD Lawrence Morawa, MD Thomas Schmalzried, MD

The following surgeons have contributed extensively to the development of the Duracon prostheses:

James V. Bono, MD
Lester S. Borden, MD
Edward T. Habermann, MD
Anthony K. Hedley, MD, FRCS
David S. Hungerford, MD
Kenneth A. Krackow, MD
Joseph McCarthy, MD

Howmedica Osteonics would also like to thank the many surgeons who contributed to the development of the Xcelerate Knee Instruments.

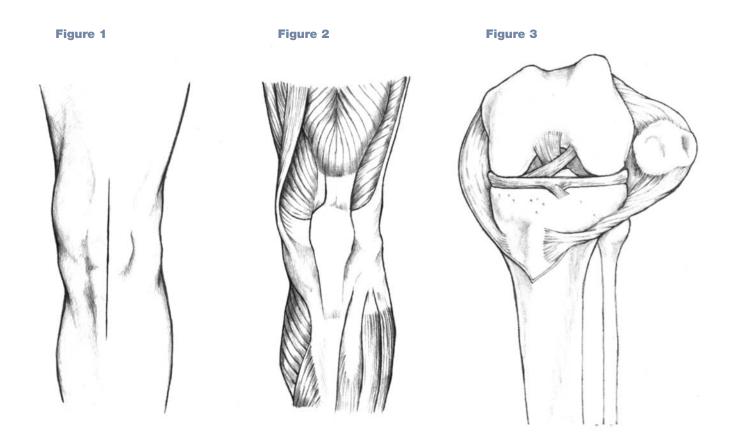


Exposure

Use a standard anterior mid-line incision (**Figure 1**). Previous incisions may be used or incorporated to decrease the risk of skin slough.

Enter capsule through a median parapatellar approach approximately 1cm from the medial border of the patella (Figure 2).

Incise the quadriceps mechanism longitudinally to allow adequate patellar eversion and sufficient knee flexion (Figure 3).



Femoral Preparation

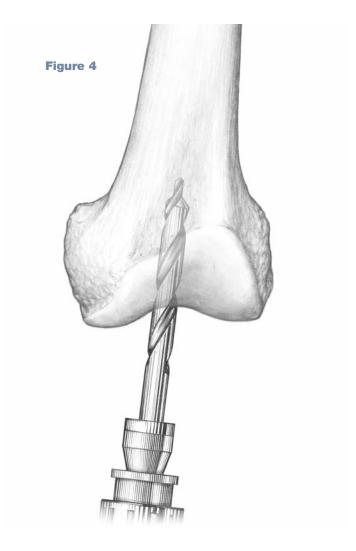
Femoral Intramedullary Alignment

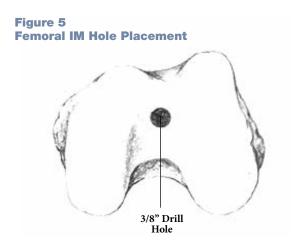
Use a 3/8" diameter drill to enter the intramedullary canal of the femur (**Figure 4**).

The drill hole is located approximately 1cm anterior to the femoral attachment of the posterior cruciate ligament and slightly medial to the mid-line of the distal femur (Figure 5).

Removal of osteophytes from the margins of the intercondylar notch may aid identification of landmarks.

It is recommended that the drill hole be slightly enlarged. This can be accomplished by toggling the drill, using a rongeur, or inserting an axial reamer.





Femoral Preparation

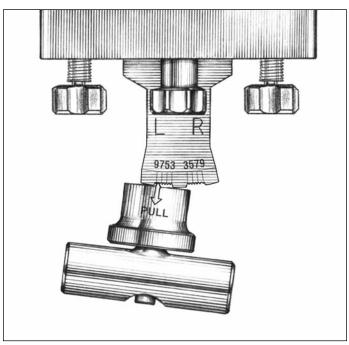
Femoral IM Alignment

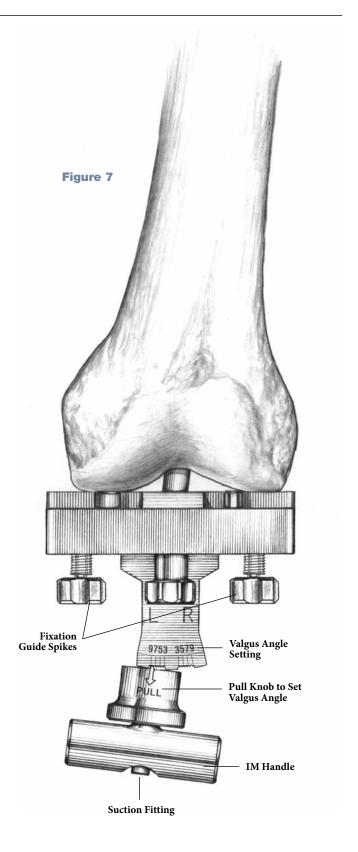
The Femoral Alignment Guide is designed for use on either the left or right knee and can be set at any valgus angle between 3° and 9°. Set the instrument to the desired angle by pulling the knob of the Femoral Alignment Guide and placing it in the appropriate notch (**Figure 6**). Handles may be attached to the sides of the guide to aid in alignment and stabilization.

Place the 5/16" T-Handle Rod through the Femoral Alignment Guide and insert the assembly into the intercondylar drill hole (**Figure 7**). Advance the rod slowly into the intramedullary canal. A suction source may be attached to the suction fitting on the rod to reduce the potential for excessive canal pressurization.

Place the Femoral Alignment Guide in contact with the more prominent distal femoral condyle and align the guide by referencing the posterior condyles or the epicondyles. The Femoral Alignment Guide can be partially stabilized by advancing the medial and/or lateral fixation spikes and gently impacting them into the distal bone.

Figure 6





Distal Femoral Resection Level

The Xcelerate System offers 8mm, 10mm, and 12mm Distal Femoral Resection Guides.

Select the appropriate Distal Femoral Resection Guide and assemble it to the Femoral Alignment Guide by positioning the Distal Femoral Resection Guide over the two pegs on the alignment guide. The resection guide is locked into place by pushing and turning the locking knob 1/4 turn clockwise (Figure 8).

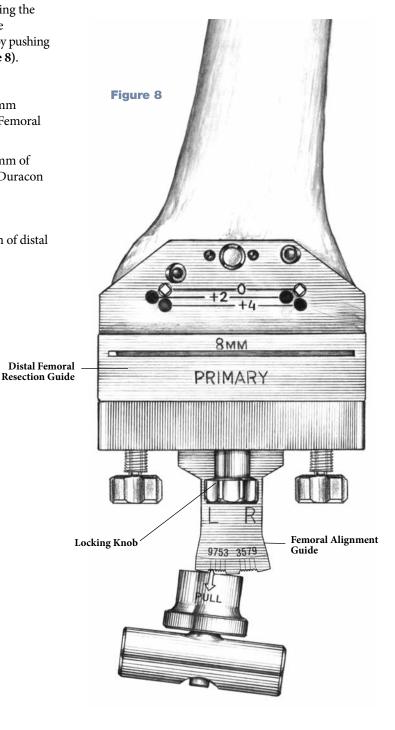
Duracon

Removing 10mm of distal bone corresponds to the 10mm of distal thickness of the small through large Duracon Femoral Components.

Removing 12mm of distal bone corresponds to the 12mm of distal thickness of the extra large and extra extra large Duracon Femoral Components.

Scorpio

Removing 8mm of distal bone corresponds to the 8mm of distal thickness of the Scorpio Femoral Components.

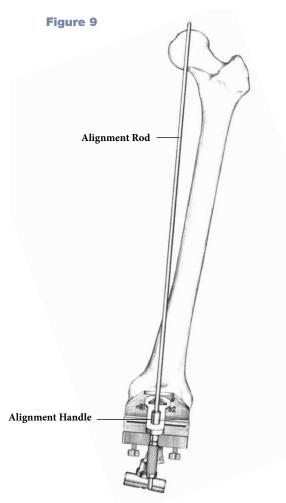


Femoral Preparation

Prior to pinning the Distal Femoral Resection Guide to the femur, an optional external alignment check may be performed. Attach the Alignment Handle to the Distal Femoral Resection Guide and insert the Alignment Rod into the handle (Figure 9). 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. Once acceptable alignment is confirmed, remove the handle and pin the Distal Femoral Resection Guide to the anterior femur using two 1/8" drill pins.

Note: The components shall be positioned to avoid excessive hyperextension. Excessive femoral flexion and tibial slope should be avoided when implanting the components. Implant positioning resulting in excessive hyperextension may result in premature wear and damage to the implant.

The Drill-Pin Driver can be attached directly to a reamer, drill fitting, or a Jacob's Chuck. The drill pins are loaded into the driver and drilled through the "0" set of holes on the resection guide. The pins are automatically released from the driver as it is pulled back.



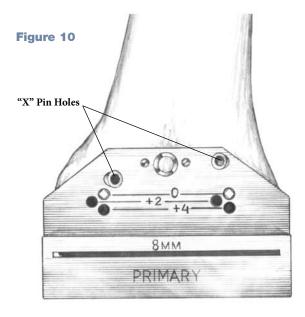
After the resection guide is pinned in place, the alignment guide is removed. Release the resection guide from the alignment guide by pushing and rotating the locking knob 1/4 turn counter-clockwise. Remove the IM rod, and the Distal Femoral Alignment Guide, leaving the Distal Femoral Resection Guide in place (Figure 10).

The level of distal femoral resection may be altered by repositioning the resection guide over the +2mm or +4mm pin holes to resect an additional 2mm or 4mm of bone respectively.

Pinning through the "X" Pin hole will aid in further securing the guide (**Figure 10**).

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

Note: A Blade Runner may be used to further assess the resection.



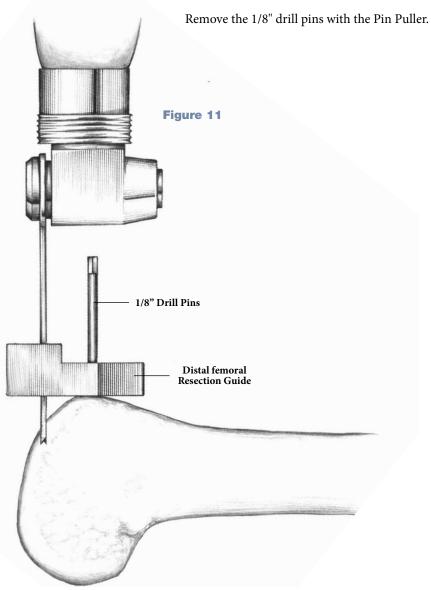
Note: Pins used with the size 3, 4 and 5 Notch Blocks should be used with no more than one pin per side to avoid the potential for the pins intersecting with each other. Pins should be used on the contra-lateral side from each other. For example, if a pin is placed through the medial anterior chamfer hole, a second pin should only be placed on the lateral side through either the chamfer or anterior flange hole. Towel clamps may be used for additional stability if necessary in the indicated holes on the distal plane.

Distal Femoral Resection

Once the resection level is determined, make the distal femoral resection (Figure 11).

Xcelerate Instruments are designed to provide precise control of the sawblade during bone resections. Using a .050" (1.27mm) thick saw blade produces the most accurate resections.

Once the distal femoral resection is complete, remove the guide and check the resection for flatness.



Femoral Preparation

Femoral A/P Sizing

The A/P Sizer is designed to set the desired external rotation and to provide adjustment of the anterior/posterior position when needed.

Attach the Modular Handles to the Sizer. Set the A/P adjustment indicator to "0" (Figure 12). Set the Sizer to the desired degree of external rotation and position the instrument flush on the flat distal femur, sliding the feet of the Sizer under the posterior condyles (Figure 13). Note that the medial lateral width of the implant can be assessed by referencing the width of the anterior portion of the sizer at each implant size. If desired, rotation can be further adjusted by using the Modular Handles to reference and parallel the epicondylar axis. Tighten the locking knob.

Note: It is important that the A/P adjustment indicator be set to zero prior to placing the A/P Sizer on the distal femur. Failure to set the indicator to zero may lead to incorrect sizing of the femur.

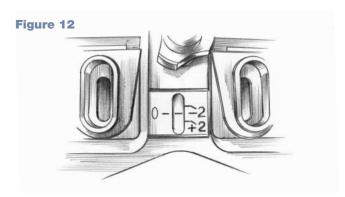
Snap the Femoral Stylus into position on the anterior surface of the Sizer. Using the Blade Runner, determine the implant size that gives the optimum anterior fit (**Figure 14**).

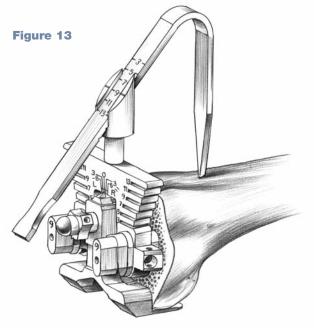
Duracon

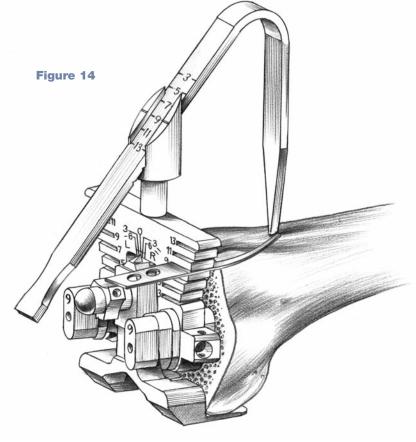
Use 3/16" peg drill to prepare the distal peg holes.

Scorpio

Place the appropriate size drill bushing into the A/P Sizer, taking care to ensure that it is properly oriented. Using an 1/8" drill pin, prepare the distal peg holes.







A/P Adjustment

Often the femur will size between two implant sizes. Preparing for the smaller size may potentially notch the femur. Preparing for the larger size prevents notching but may lead to overstuffing of the patello-femoral joint (**Figure 15**). The A/P Sizer has been designed to avoid both these situations by allowing the overall position of the drill holes to be adjusted to provide the optimum anterior resection.

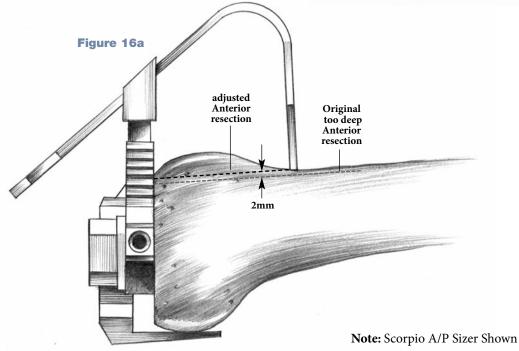
Anterior resection too proud

Anterior resection too deep

When an adjustment of the A/P sizer is necessary, loosen the locking knob and reposition the A/P adjustment indicator until it indicates the "-2" position (**Figure 16**). This will shift the position of the peg holes 2mm anteriorly, raising the level of the anterior resection and preventing notching of the anterior cortex (**Figure 16a**). However, it will remove an additional 2mm of bone from the posterior condyles, increasing the flexion gap. Care must be taken to properly balance the flexion and extension gaps in this situation.

When the A/P Sizer is adjusted to the +2mm mark, the level of the anterior resection is moved posteriorly 2mm. The amount of posterior bone removed is reduced. This is useful in cases where the flexion gap is particularly loose.





Femoral Preparation

Femoral Anterior, Posterior, and Chamfer Resections

Position the corresponding size Femoral Resection Guide on the distal femur. Locate the fixation lugs of the Femoral Resection Guide into the pin holes (Figure 17a) and impact until the guide is seated flush onto the distal femur (Figure 17b). Handles can be assembled to the Femoral Resection Guide to aid in both stabilization and removal. Towel clips may also be utilized for further stabilization.

Again, use of a .050" (1.27mm) thick saw blade is recommended.

Complete the remaining four femoral bone resections (Figures 18a and 18b).

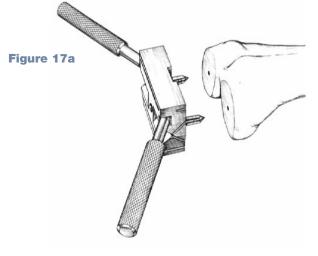
The order of bone resections is not critical, however, a recommended sequence is:

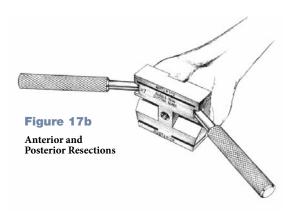
- 1. anterior cortex;
- 2. posterior condyles;
- 3. posterior chamfer;
- 4. anterior chamfer.

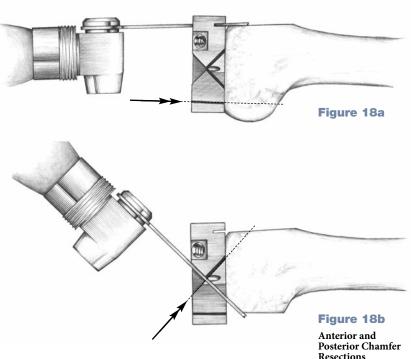
When performing the anterior chamfer resection, the sawblade should be passed over the mid-line of the femur so that the center portion of bone is resected.

Care should be taken not to bias the blade while resecting the bone, as it will cause excess friction between the blade and Femoral Resection Guide.

The Femoral Resection Guide is removed.







Duracon PS Box Preparation

Note: The posterior soft tissues must be directly visualized and protected with a retractor throughout this procedure.

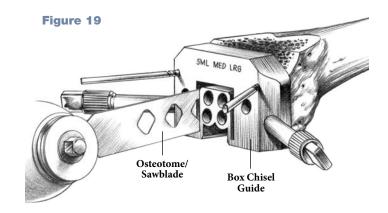
Attach the 3/16" fixation spikes to the appropriately sized box guide.

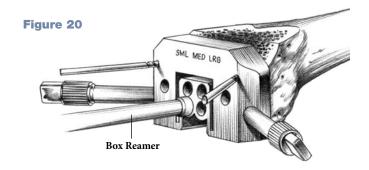
Place the box guide on the distal femur in the previously prepared holes. The box guide can be pinned in place using 3/16" auxiliary drill pins for added stability.

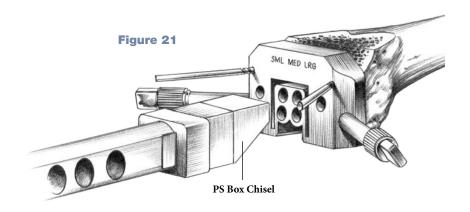
Use an oscillating saw, 1/4" or 1/2" osteotome in the anterior, medial, and lateral slots of the box chisel to initiate the box cut (**Figure 19**).

The majority of the intercondylar bone is removed by inserting the box reamer to full depth in the four holes located on the face of the box guide (**Figure 20**).

Insert the box chisel into the guide and impact to the full depth to ensure that the periphery of the box is fully defined (**Figure 21**). Use the optional slaphammer to remove the chisel if needed.







Duracon

Femoral Preparation

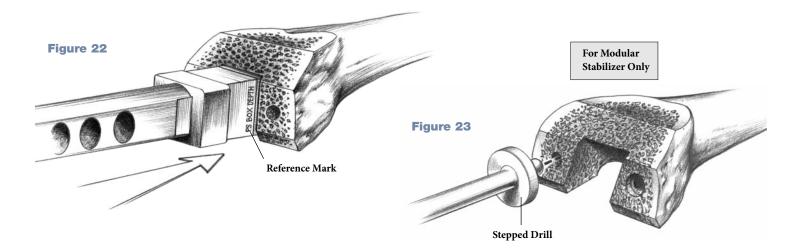
For Duracon Procedure Only... For Scorpio Procedure See Page 13

Duracon PS Box Preparation

Remove the box guide. Any remaining bone is removed with a small osteotome, a rongeur, or by inserting the box chisel until the reference mark is flush with the distal femoral cut (**Figure 22**). The bottom of the four previously reamed holes represents the correct depth of the box cavity and can be used as a depth guide when clearing out any remaining bone or tissue.

If using a <u>Modular</u> Stabilizer component, the stepped drill finishes the distal holes to make room for screws on the modular box (**Figure 23**).

Note: The mediolateral position of the box guide may be adjusted prior to completing the box preparation. Place the CR femoral trial on the resected femur and position it in the proper medial lateral location. Prepare the femoral peg holes using the 5/16" femoral drill. Remove the trial. Attach the 5/16" fixation pegs to the appropriately sized box guide and mount in the newly prepared holes.



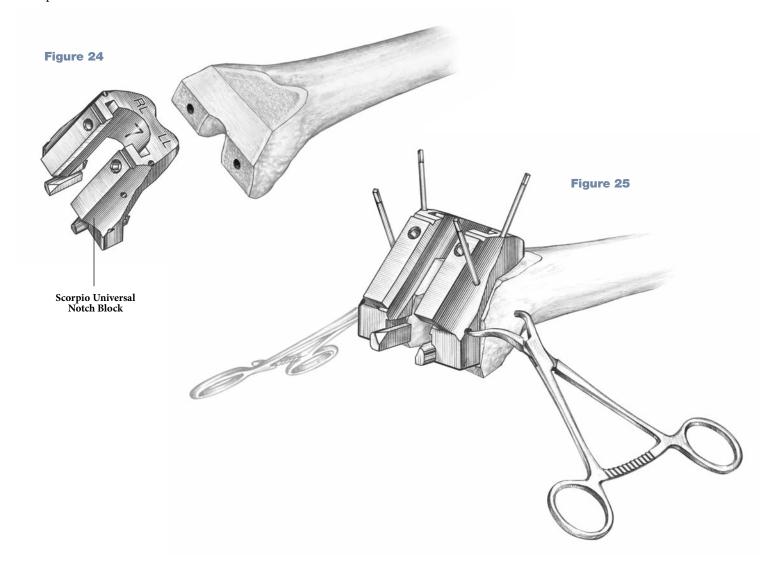
Scorpio Universal Preparation

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

• Select the appropriately sized Universal 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.

Note: Pins used with the size 3, 4 and 5 Notch Blocks should be used with no more than one pin per side to avoid the potential for the pins intersecting with each other. Pins should be used on the contra-lateral side from each other. For example, if a pin is placed through the medial anterior chamfer hole, a second pin should only be placed on the lateral side through either the chamfer or anterior flange hole. Towel clamps may be used for additional stability if necessary in the indicated holes on the distal plane.

- 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) (Figure 24). 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 surfacers of the block (4 "X" holes at 15°) (Figure 25).
- 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.



Scorpio

Femoral Preparation

For Scorpio Procedure Only... For Duracon Procedure See Page 11

For Posterior Stabilized Knees

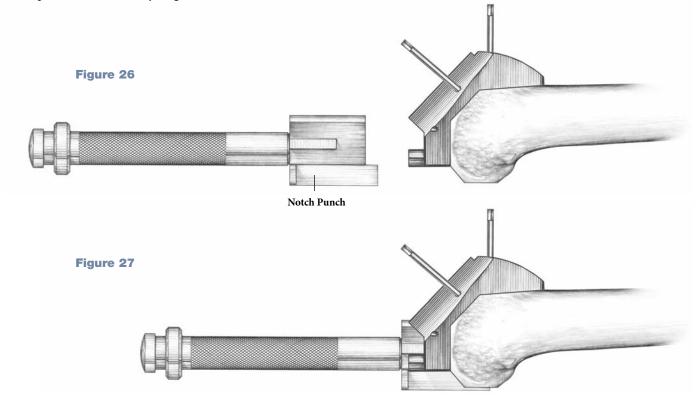
Notch Preparation Option 1: Punch Technique

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

- Assemble the appropriately sized Notch Punch to the punch handle.
- Guide the Notch Punch into the tracks on the distal face
 of the Notch Block (Figure 26). 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 (Figure 27). Remove the Punch from the tracks with a slaphammer if necessary (Figure 28).

Note: It is not uncommon for the area of bone being prepared for by the punch to remain inside and be removed by the punch at time of extraction. In this instance, it is still necessary to clean out remaining soft tissue and compact.

Note: Using a osteotome or rongeur, remove the margin of the 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 soft-tissue impingement.)

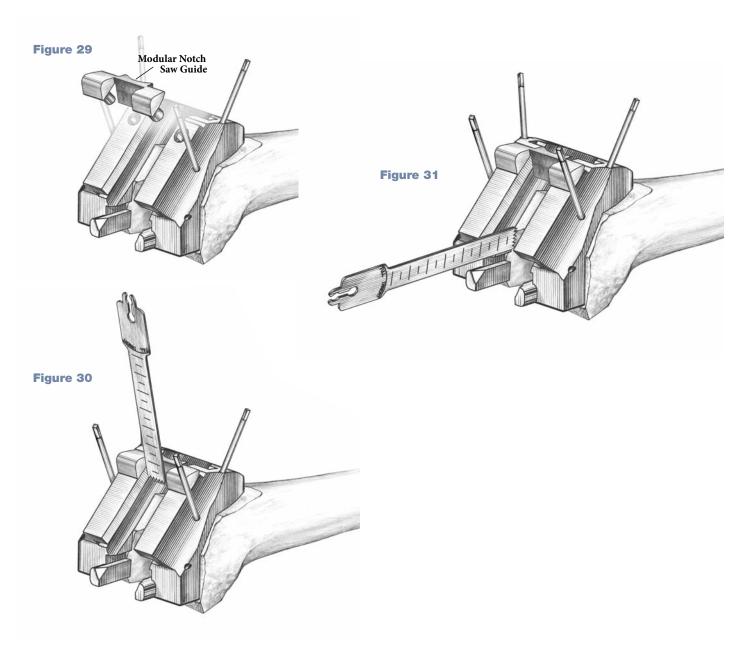


Slaphammer Slaphammer Fitting

Notch Preparation Option 2: Saw Technique

- Guide the pegs of the appropriately sized Notch Saw Guide into the anterior holes on the Notch Block (**Figure 29**).
- 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 (Figure 30).
- 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 (Figure 31).

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 the cam and post.



Scorpio

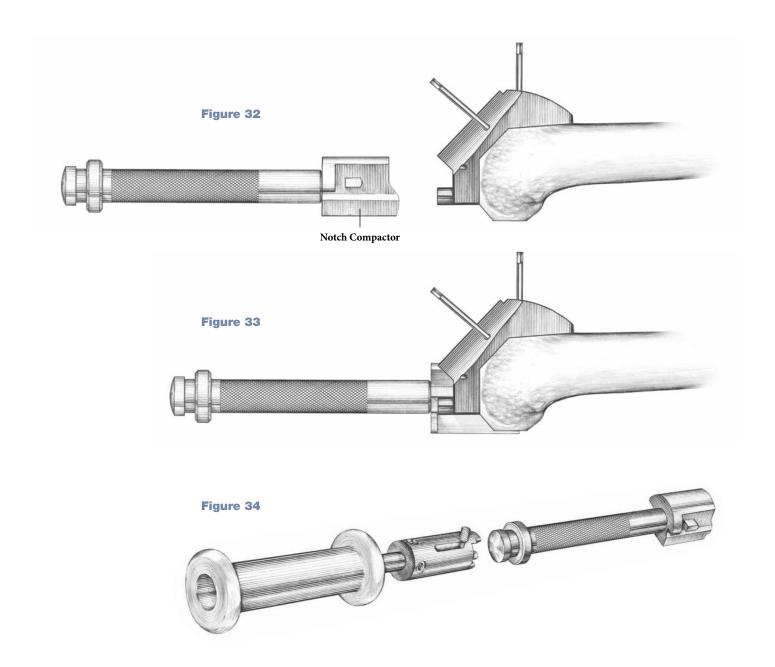
Femoral Preparation

For Scorpio Procedure Only... For Duracon Procedure See Page 11

For Posterior Stabilized Knees

Notch Compacting Preparation

- Assemble the appropriately sized Notch Compactor to the punch handle (Figure 32).
- 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.
- Using a Mallet, impact the Compactor until it reaches the end-stop and is fully seated in the Notch Block (Figure 33). Remove the Compactor from the tracks with a slaphammer if necessary (Figure 34).



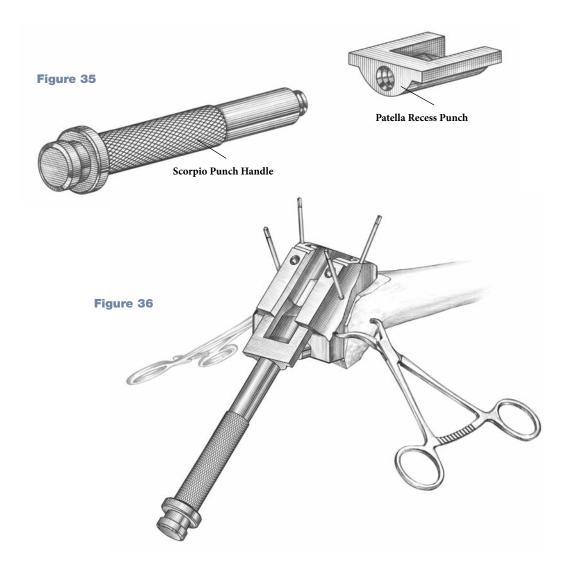
For Scorpio PS and Scorpio CR Knees

Patella Recess Preparation Option 1: Punch Technique

- Assemble the appropriately sized Patella Recess Punch to the punch handle (**Figure 35**).
- Insert the rails of the Patella recess Punch into the tracks at the distal end of the Notch Block. Start the cut from the distal surface and advance anterior/proximal (Figure 36).
- Tap the end of the Scorpio punch handle with the mallet to advance the punch.

Note: Take care that the handle is aligned with the track and rails that the punch passes through, so as to avoid jamming the instrument.

- One complete pass of the punch through the track and full length of the block will clear the necessary groove for the patella track. A secondary pass may be used, if desired, to confirm all tissue is removed.
- Remove the pins, towel clamps and the Universal Notch Block.



Scorpio

Femoral Preparation

For Scorpio Procedure Only... For Duracon Procedure See Page 11

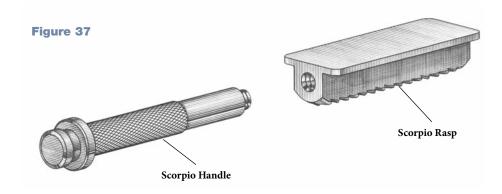
For Scorpio PS and Scorpio CR Knees

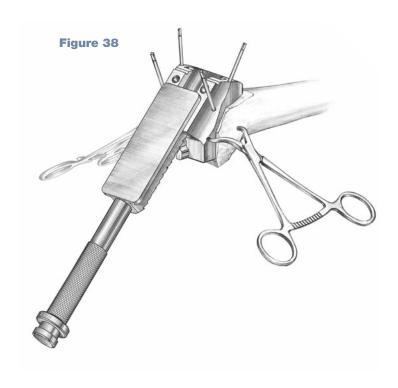
Patella Recess Preparation Option 2: Rasp Technique

- Assemble the Scorpio punch handle to the appropriately sized rasp (**Figure 37**).
- Start from the distal surface and advance to anterior/proximal so the entire rasp passes through the length of the block. The position of the rasp is constrained within the block.
- Continue cutting with the rasp until it rides flat on the top surface of the block. The groove is then completely prepared (Figure 38).

Note: The rasp only cuts in one direction.

• Remove the pins, towel clamps and the Universal Notch Block.



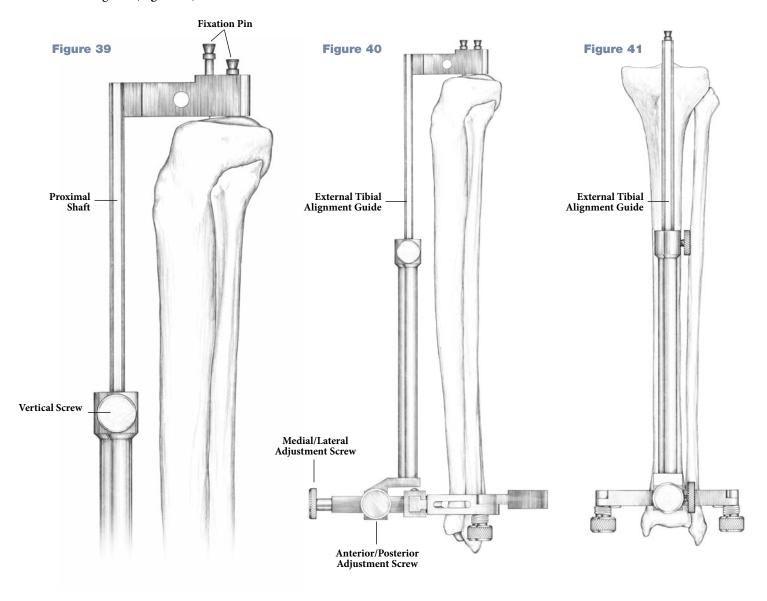


Tibial External Alignment Option

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 anterior/posterior 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 (**Figure 39**).

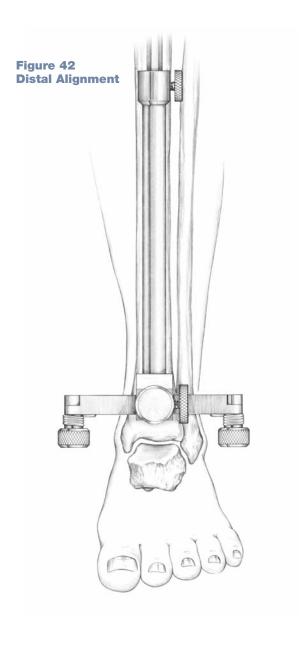
Axial alignment is achieved when the vertical shaft of the instrument parallels the long axis of the tibia in both the anterior/posterior and medial/lateral views. Use the anterior/posterior and medial/lateral adjustment thumbscrews to facilitate alignment (Figures 40 and 41).

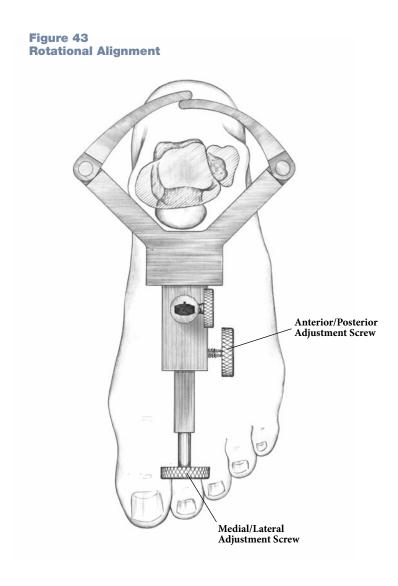


Landmarks often used to obtain correct axial alignment and rotation include:

- 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. 42).

Once axial alignment is established, tighten the anterior/posterior and medial/lateral adjustment thumbscrews (**Figure 43**).





Tibial Resection Level

The Xcelerate System offers Right and Left, 0°, 3°, and 5° Tibial Resection Guides.

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 holes on the top of the Tibial Resection Guide and releasing the button to lock the stylus into place (**Figure 44**).

Attach 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 (**Figure 45**).

Duracon

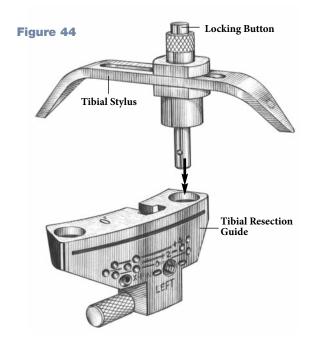
3° of posterior slope is recommended for use with the Duracon Total Knee System.

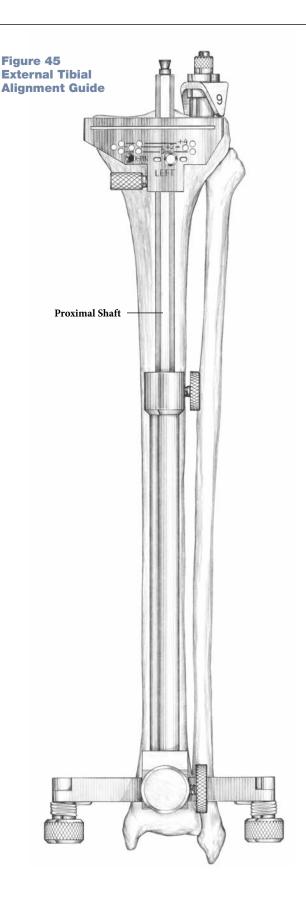
Scorpio

0° of posterior slope is recommended for use with the Scorpio PS Femoral Components.

5° of posterior slope is recommended for use with the Scorpio CR Femoral Components.

Note: The components shall be positioned to avoid excessive hyperextension. Excessive femoral flexion and tibial slope should be avoided when implanting the components. Implant positioning resulting in excessive hyperextension may result in premature wear and damage to the implant.





The Xcelerate System offers two Tibial styli each having two resection levels:

Duracon

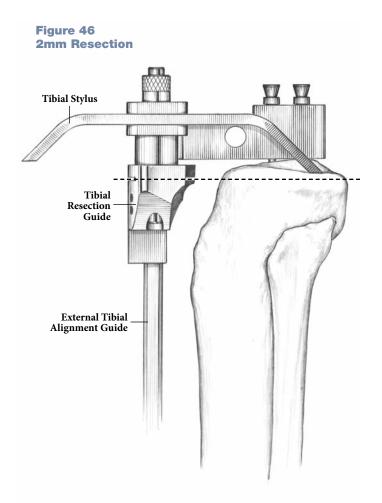
2mm and 9mm

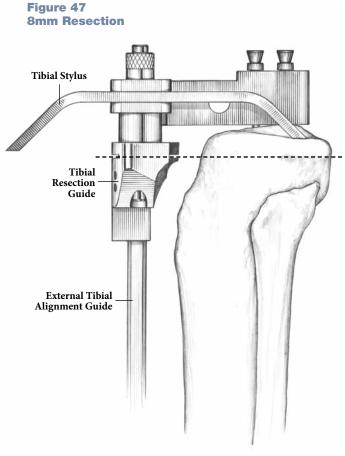
Scorpio

2mm and 8mm

The settings allow for a corresponding resection of bone below the point of the stylus (i.e., the 2mm setting allows for a 2mm resection below the point of the stylus.) (**Figures 46 and 47**).

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 Slaphammer, 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 (**Figure 48**).

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

Figure 48 Slide Proximal Shaft Up thRough Resection Guide **Tibial** Resection Guide Vertical ThumbScrew

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.

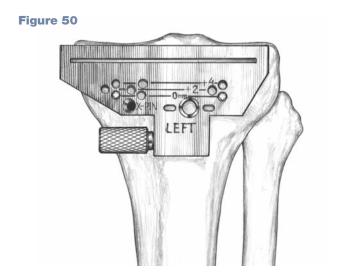
Resect the plateau using a .050" (1.27mm) saw blade (Figure 49).

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 (**Figure 50**).

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 49



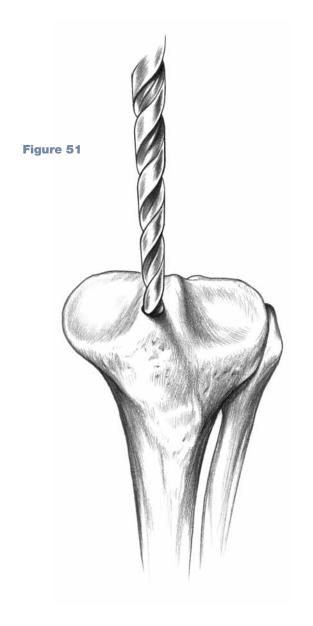
IM Rod Placement

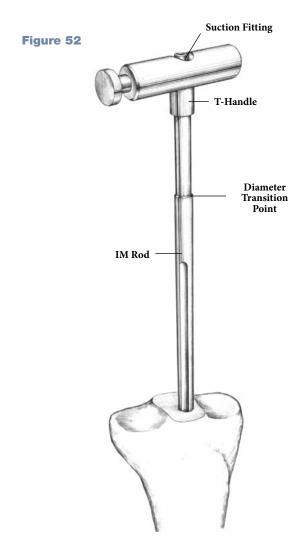
If the tibial eminence is pronounced, make an initial cut to flatten the tibial plateau and expose an area of cancellous bone. A 5/16" hole is drilled in the location determined by pre-operative X-rays (**Figure 51**).

Attach the pre-determined diameter IM Rod (1/4", 3/8", or 5/16") to the T-Handle by depressing the button, inserting the IM Rod fitting, and releasing the button to lock into place. Preoperative 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 (**Figure 52**).

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.

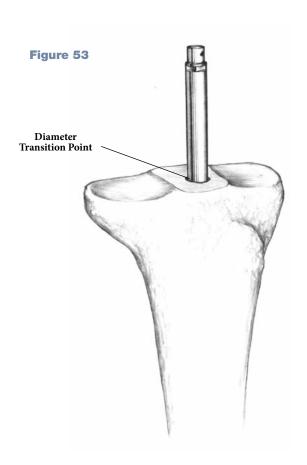


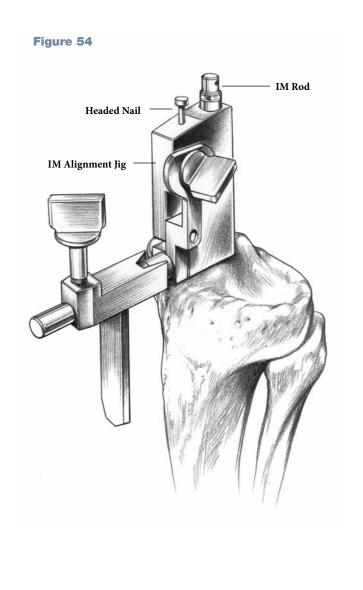


The proximal portion of both the 3/8" and 1/4" diameter IM Rods changes to 5/16" in diameter. It is necessary to insert those rods so that the diameter transition point is within the intramedullary canal. The 5/16" diameter IM Rod may be inserted to any depth up to the scribe mark on the proximal shaft. Once the IM Rod is positioned, remove the T-Handle (Figure 53).

Intra-operative X-rays may be obtained to confirm accurate position of the rod in the canal.

Slide the IM Alignment Guide over the Alignment Rod (Figure 54).



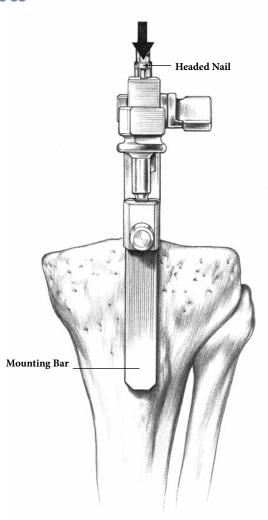


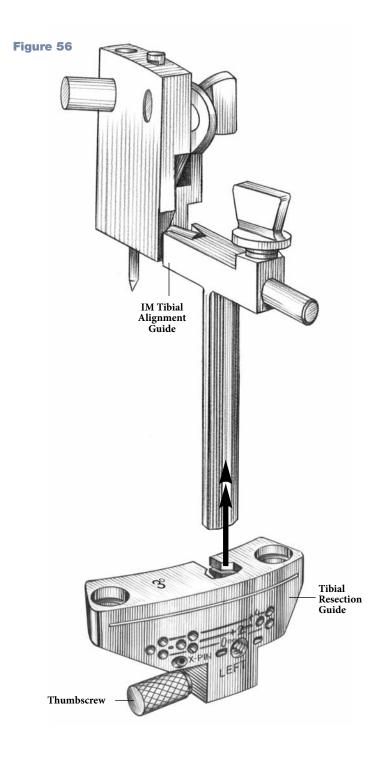
Rotational and Varus/Valgus Alignment

With the body of the IM jig resting on the proximal tibia, proper rotational alignment is achieved by rotating the instrument about the IM rod so that the tibial tubercle appears slightly lateral to the vertical mounting bar. The headed nail is impacted, fixing rotational alignment (**Figure 55**).

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 (**Figure 56**). Attach the alignment handle to the resection guide, and slide a long alignment rod into the alignment handle. When proper varus/valgus alignment is attained, the pin should be centered over the ankle (**Figure 57**).

Figure 55





If varus/valgus adjustment is needed, locking knob "1" is loosened. The mounting bar is pulled toward the surgeon, and the jig is rotated until proper varus/valgus orientation is achieved (Figure 58). Once the alignment rod is centered over the ankle, the locking knob is securely tightened.

Figure 57

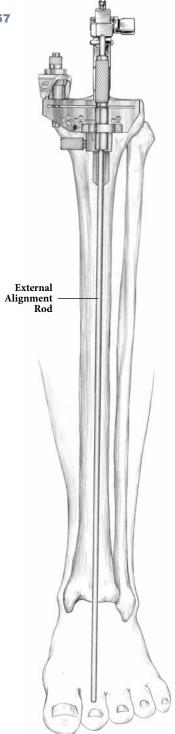
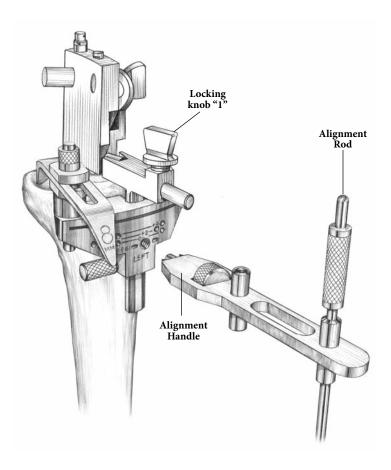


Figure 58



Flexion/Extension Alignment

If additional posterior slope is required, loosen locking knob "2" and set the slope. Once the correct slope is attained, securely tighten locking knob 2 to set the final position of the jig (Figure 59).

Increment markings have been added to the posterior slope adjustment FOR REFERENCE ONLY. Bear in mind that these are reference marks only and not indicative of an exact measurement of the posterior slope of the tibial resection. The true slope is dependent on many factors, including, but not limited to, tibial anatomy, the placement of the IM Rod, the position of the cutting block from the anterior portion of the tibia, etc.

Knob "2"

Tibial Resection Level

The Xcelerate System offers Right and Left, 0°, 3°, and 5° Tibial Resection Guides.

Duracon

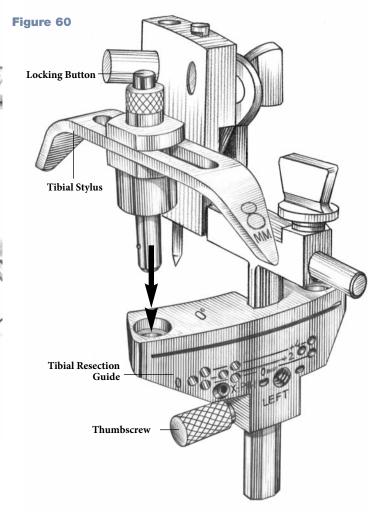
3° of posterior slope for use with the Duracon Total Knee System.

Scorpio

 0° and 5° of posterior slope for use with the Scorpio Total Knee System.

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 (**Figure 60**).

Note: The components shall be positioned to avoid excessive hyperextension. Excessive femoral flexion and tibial slope should be avoided when implanting the components. Implant positioning resulting in excessive hyperextension may result in premature wear and damage to the implant.



Loosen the thumbscrew and position the Tibial Stylus to reference the desired point on the tibial plateau. Secure the IM Tibial Alignment Guide to the Tibial IM Rod by re-tightening the thumbscrew.

The Xcelerate System offers two tibial styli each having two resection levels

Duracon 2mm and 9mm

Scorpio 2mm and 8mm

The settings allow for corresponding resection of bone below the point of the stylus (i.e. the 2mm setting allows for a 2mm resection below the point of the stylus) (**Figures 61 and 62**).

Figure 61 2mm Resection Level

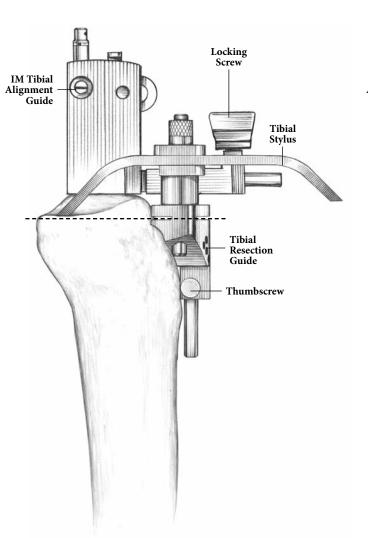
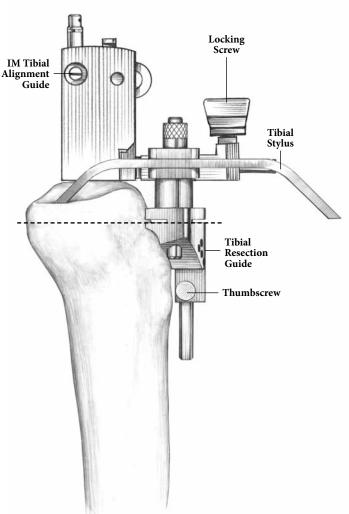


Figure 62 8mm Resection Level



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 (Figure 63).

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

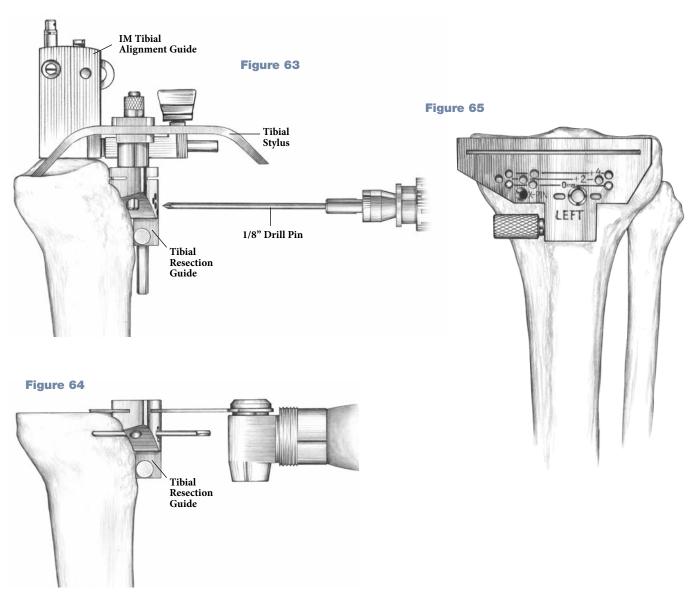
Release the IM Tibial Alignment Guide from the Tibial Resection Guide by loosening the thumbscrew on the resection guide. Re-attach the T-Handle to the IM Rod and extract both the IM Rod and IM Tibial Alignment Guide together, leaving the Tibial Resection Guide pinned in place. Resect the tibial

plateau through the slot in the Tibial Resection Guide. Use of a .050" (1.27mm) sawblade is recommended for an accurate resection (**Figure 64**).

Additional bone may be resected by repositioning the Tibial Resection Guide over the pins in the +2 or +4 holes to resect an additional 2mm or 4mm of bone respectively (**Figure 65**).

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.



Duracon

Tibial Baseplate Preparation

For Duracon Procedure Only... For Scorpio Procedure See Page 35

Duracon Cruciform and Universal Baseplates

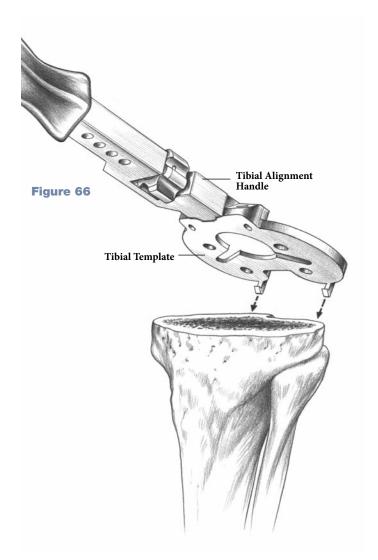
Maximally flex the knee and deliver the tibia forward.

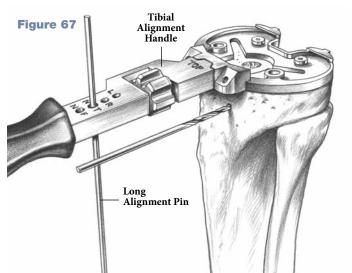
Assemble a Tibial Template to the Alignment Handle and place it on the resected tibial plateau. Choose the size that best covers the tibial plateau (**Figure 66**).

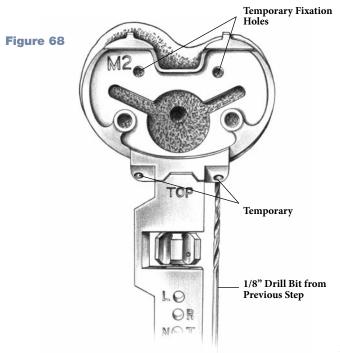
Verifying Alignment

The alignment handle verifies rotational, varus/valgus, and flexion/extension alignment (**Figure 67**). Rotational alignment is correct when the drill bit placed in a hole from the previous step parallels the handle (**Figure 68**). Varus/valgus and flexion/extension alignment are verified with a long alignment pin.

Holes are located on the anterior face and the posterior surface of the template. Headed nails or drills through these holes may be used to temporarily fix the template.







Duracon

Tibial Baseplate Preparation

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Duracon Trial Reduction

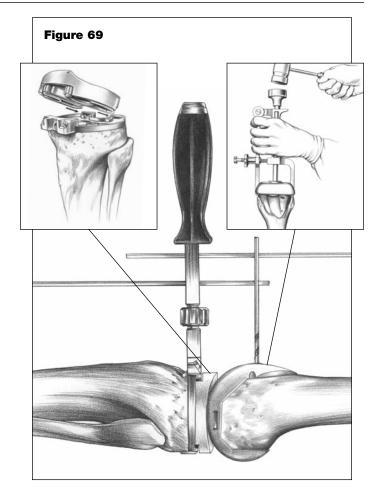
The proximal tibial template accepts trial inserts for a trial reduction. The alignment handle may be left in place and utilized for an open trial reduction, or the handle may be removed to allow the template to serve as a trial for a closed trial reduction. Trial baseplates are also available when the scenario dictates their use.

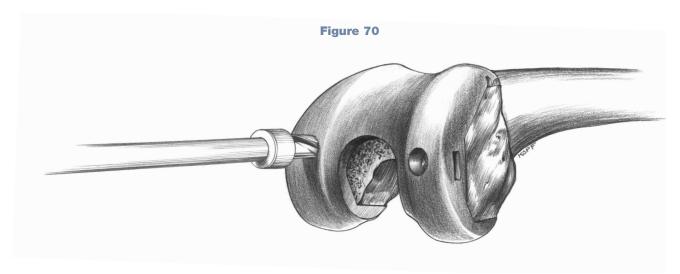
With the knee in 90° of flexion, carefully impact the trial femoral component on the distal femur. Carefully insert the appropriate tibial trial insert into the proximal tibial template. Insert the posterior portion of the insert first and then let it drop in place anteriorly. Forcing the trial spacer into place may cause it to break.

With the femoral trial component fully seated, carefully extend the knee, noting medial and lateral stability as well as overall alignment in the A/P and M/L planes (**Figure 69**).

When trial reduction has been completed, drill the femoral prosthesis finishing holes through the trial component with a 5/16" stepped drill (**Figure 70**).

Note: Trials are available for add-on components (Wedges, Stem Extenders, etc.), if required.





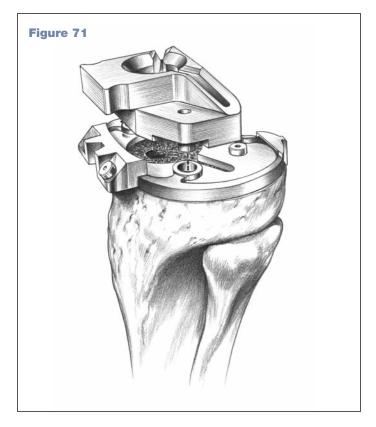
Duracon Universal Baseplate Preparation

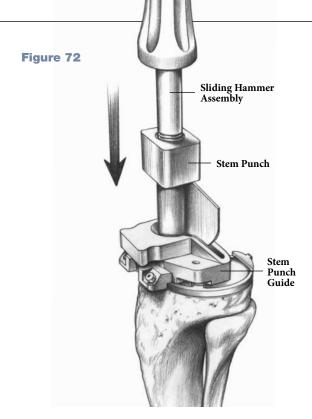
Place the stem punch guide in the corresponding locking holes in the tibial template (**Figure 71**). Attach the stem punch to the sliding hammer assembly. The stem punch fits into the cut-out on the guide.

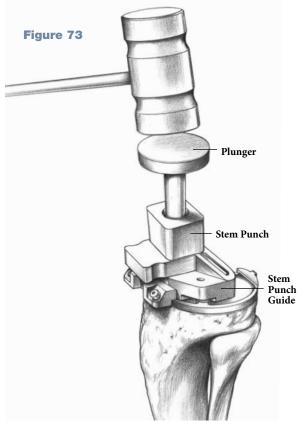
During insertion/impaction, the stem punch must be maintained perpendicular to the resected surface. Slowly impact the stem punch to allow expansion of the bone (**Figure 72**).

Insert the Universal stem punch plunger into the hole of the stem punch. Impaction of the plunger creates a bone plug at stem tip (Figure 73).

Remove the plunger and stem punch.







Duracon

Tibial Baseplate Preparation

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Duracon Cruciform Baseplate Preparation

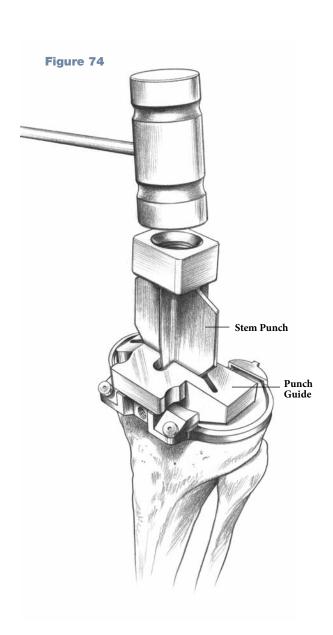
The Cruciform template, punch guide, and stem punch are used as described in "Universal Baseplate Preparation" (**Figure 74**). (The Cruciform Instruments are not the same catalog numbers as the Universal Instruments.)

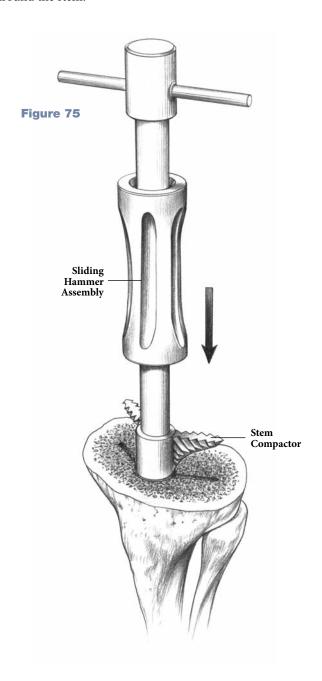
The Cruciform Baseplate has no stem plug plunger.

Duracon A/P Lipped All-Plastic Tibial Component

The tibia must first be prepared to accept the Universal Baseplate (**Figures 71, 72, and 73**) prior to preparation for the All-Plastic Component.

Use the all-polyethylene stem compactor to enlarge the cut-out for the stem (**Figure 75**). Alignment perpendicular to the tibia must be maintained. This provides space for a cement mantle around the stem.



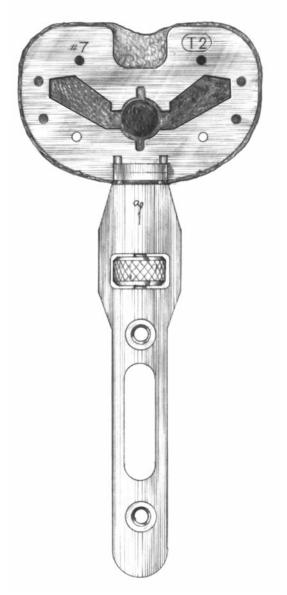


Scorpio Tibial Component Sizing

Maximally flex the knee and deliver the tibia forward.

Assemble a Tibial Trial Baseplate to the Alignment Handle and place it on the resected tibial plateau (**Figure 76**). Choose the size that best covers the tibial plateau. Slight overhang is preferable to undersizing.

Figure 76



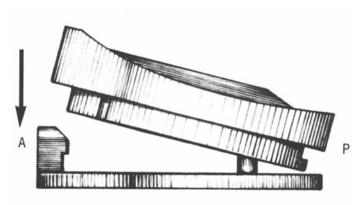
Tibial Component Alignment

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 (**Figure 77**). Reverse the steps to dis-assemble 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.

Figure 77



Scorpio

Tibial Baseplate Preparation

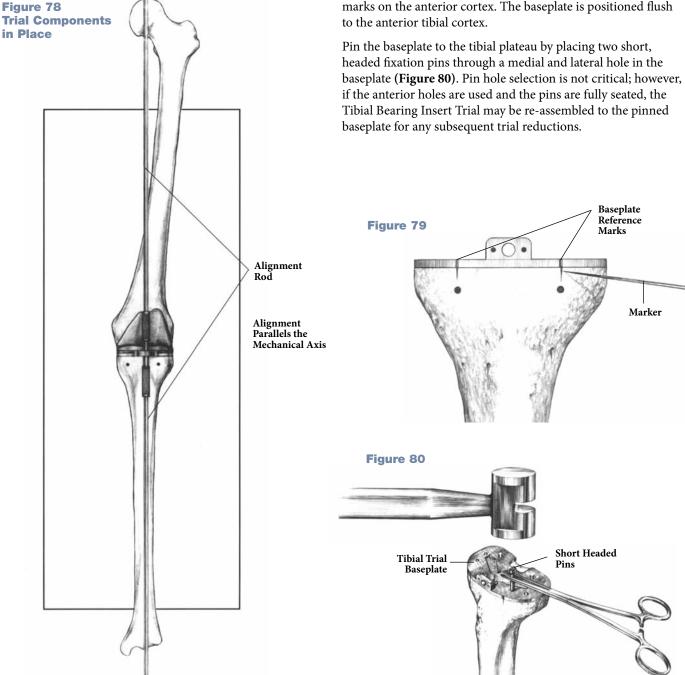
For Scorpio Procedure Only... For Duracon Procedure See Page 31

Tibial Component Alignment

Overall leg alignment may be assessed at this time. Re-attach 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 (Figure 78).

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 trial baseplate (Figure 79).

Remove the trial components and dis-assemble 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



Tibial Keel Punching

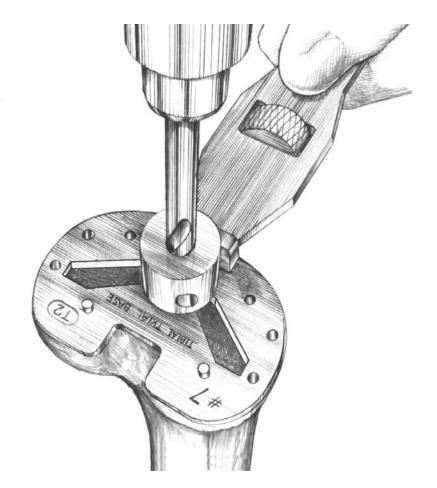
Tibial Punches are identified by keel size (3/5, 7/9, 11/13) and bone preparation ("Cement Keel" creates a cement mantle around the keel; "Press Fit Keel" creates an interference fit around the keel).

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 (Figure 81).

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.

Figure 81

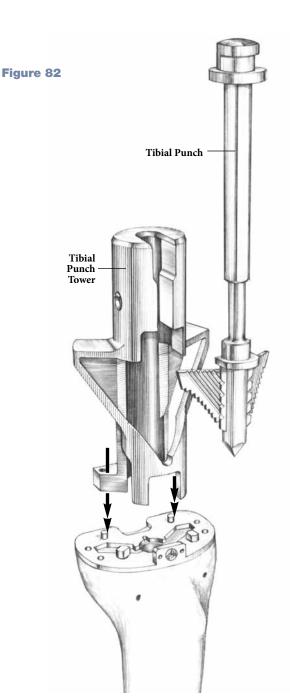


Tibial Baseplate Preparation

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Tibial Keel Punching

Fit the appropriate Tibial Punch into the Tibial Punch Tower (Figure 82). 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 (Figure 83). 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 (**Figure 84**).

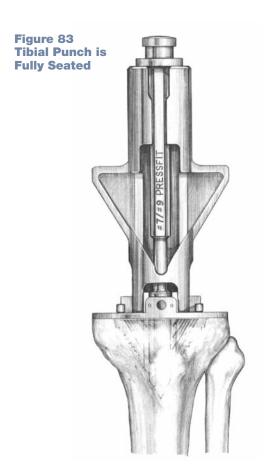
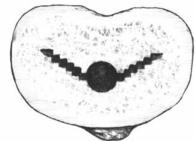


Figure 84
Completed Tibial
Preparation



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 40).

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.

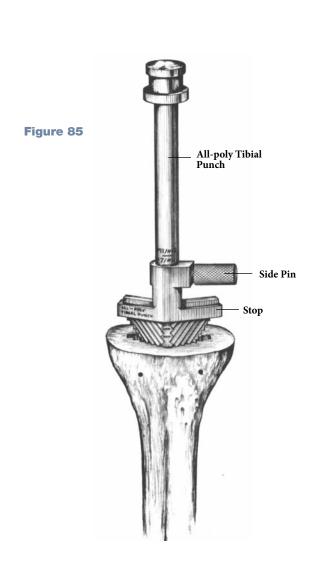
Set the All-Poly Tibial Punch to the pre-determined keel size (see below) by pulling the side pin out and sliding the stop up or down until the appropriate keel size is reached. Release the side pin to secure the punch position.

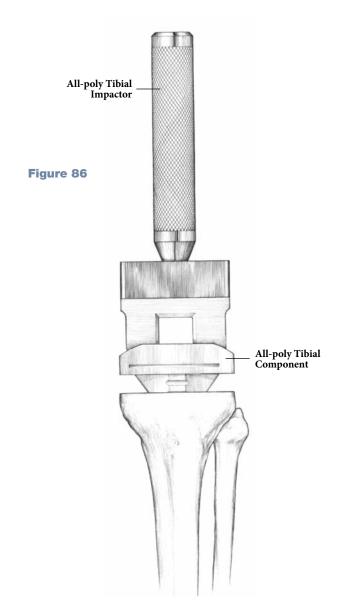
Impact the All-Poly Tibial Punch into the tibia using the punch slots produced from the previous punching sequence as a guide (Figure 85).

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 (**Figure 86**). After the cement is cured, the knee is thoroughly cleaned and lavaged.





Tibial Baseplate Preparation

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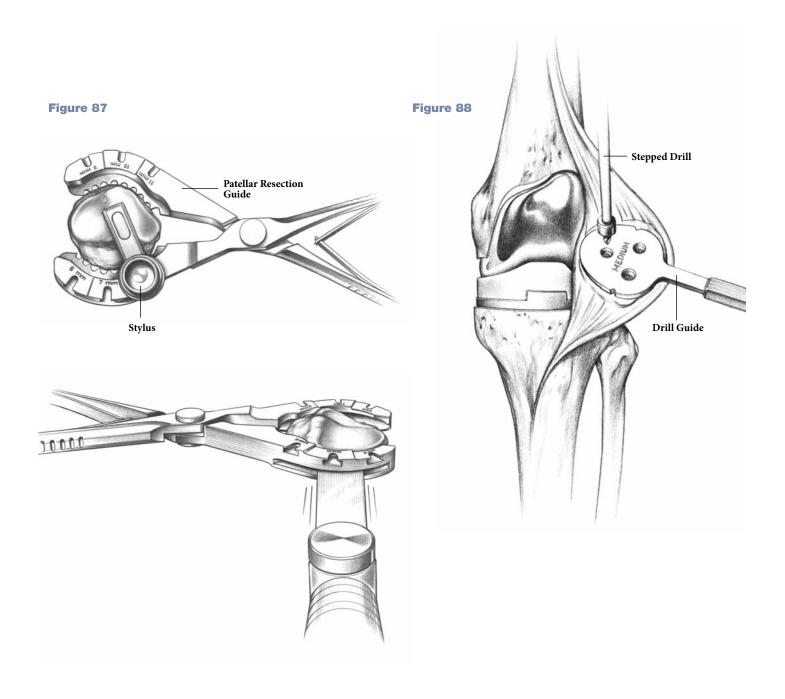
	Tibial Punching Sequence			
Implant Size	Press-Fit Keel	Cement Keel	All-Polyethylene Implant	
3	Press-Fit #3/#5	Press-Fit #3/#5 Cement #3/#5	Press-Fit #3/#5 Cement #3/#5 All-Poly #3/#5	
5	Press-Fit #3/#5	Press-Fit #3/#5 Cement #3/#5	Press-Fit #3/#5 Cement #3/#5 All-Poly #3/#5	
7	Press-Fit #3/#5 Press-Fit #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	

Patellar Preparation

Remove all osteophytes and synovial insertions around the patella, and measure thickness using a caliper. After determining the depth of the cut with a caliper, affix the stylus in the appropriate slot to the patellar resection guide, and capture the patella between the jaws of the saw guide. Using a .050" (1.27mm) non-offset sawblade, resect the patella (**Figure 87**).

Center the chosen patellar drill guide over the patella with the handle perpendicular to the trochlear groove. Drill three fixation holes with the appropriate stepped drill (**Figure 88**).

Prepare the resected bone surfaces for bone cement application.



Duracon Implantation

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Implantation of the Metal Tibial Component

If utilized, screw and tighten Stem Extenders to the Baseplate with the wrench instruments and torque to 60-80in/lb; cement Wedges to the Baseplate.

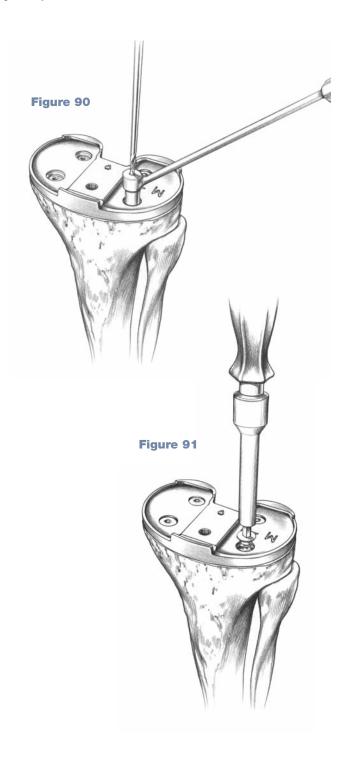
Lock the "feet" of the tibial impactor under the posterior lip of the component.

Turn the wing nut clockwise to secure the anterior lock.

Use the driver to impact the component. Ensure that the undersurface of the component always remains parallel to the cut surface of the tibia during insertion (**Figure 89**).

Tibial Impactor

If implanting the baseplate with 6.2mm cancellous screws, use a 1/8" drill bit and drill guide to create the pilot holes (**Figure 90**). Insert four screws of a pre-operatively determined length (**Figure 91**). Clear excess cement.



Tibial Bearing Insert Assembly

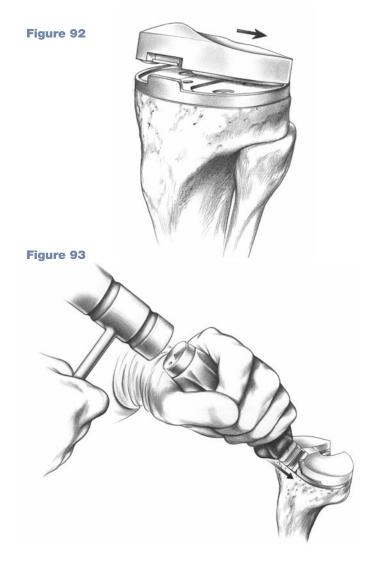
Note: Once assembled onto the Baseplate, the insert cannot be removed and re-assembled. One-time use only! To properly assemble the Tibial Insert to the Baseplate, slide the Insert fully posterior into the two posterior pockets of the Baseplate before attempting to snap down the anterior portion of the Insert.

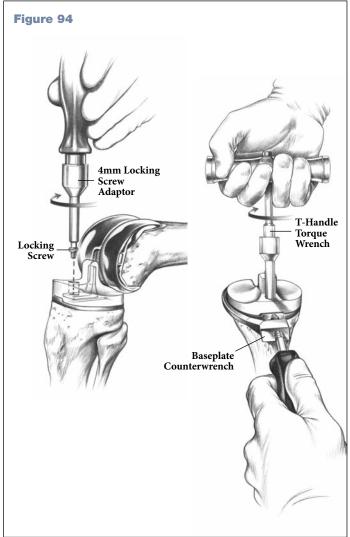
When the Insert is fully captured posteriorly, snap down the anterior locking tab by applying thumb pressure (**Figure 92**), or by light impaction with the tibial insert impactor (**Figure 93**). Make certain that pressure is applied in a distal-posterior direction. Once properly assembled to the Baseplate, the Insert should not be removed and re-seated.

Note: When using the Stabilizer insert, the locking screw must be tightened to 60-80in-lb of torque after the plastic insert has been snapped into the baseplate.

Insert and hand tighten the screw using the adaptor handle and the 4mm locking screw adaptor. Use the T-handle torque wrench to apply a torque in a clockwise direction until definitive drop in resistance is felt, signifying the pre-set torque level has been reached (between 60 and 80in-lb) (**Figure 94**). The baseplate counterwrench must be used if tightening the screw prior to the cement curing.

Note: Failure to tighten the locking screw to 60-80in-lb may result in screw loosening.



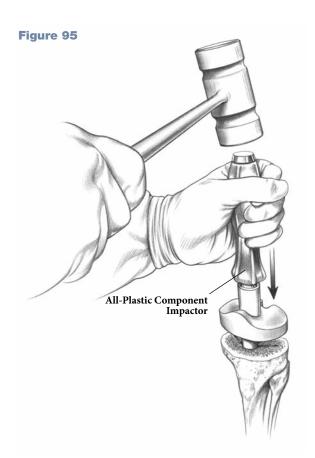


Duracon Implantation

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Implantation of the All-Plastic Tibial Component

Use the designated impactor to seat the All-Plastic Tibial Component (**Figure 95**).



Implantation of the Femoral Component

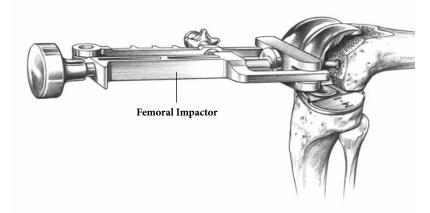
Modular Spacers, Stabilizer Boxes, and/or Stem Extenders are secured with fixation pegs or screws.

When using Modular femoral Components, prior to implantation, the modular fixation pegs or screws must be tightened to the recommended torque of 60in-lb minimum to 80in-lb maximum.

The femoral impactor guides the femoral component and ensures proper placement (Figure 96).

Note: The components shall be positioned to avoid excessive hyperextension. Excessive femoral flexion and tibial slope should be avoided when implanting the components. Implant positioning resulting in excessive hyperextension may result in premature wear and damage to the implant.

Figure 96



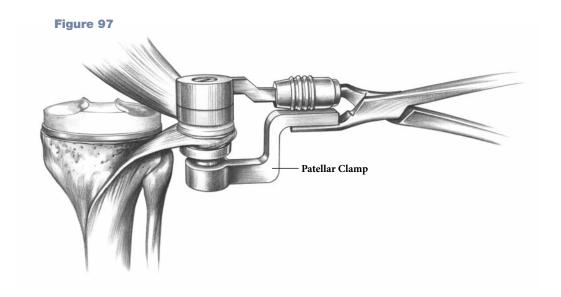
Closing

Implantation of the Patellar Component Closing

Cover the back surface of the implant (including the pocket) and the cut surface of the patella with a layer of cement. Cement should be interdigitated into the fixation holes on the cut patella and the pocket on the back of the all-plastic Symmetric Patellar Component.

The patellar clamp locks in place while the cement hardens (Figure 97).

The joint is copiously irrigated and closed in routine fashion over one or two wound suction drains.



Scorpio

Scorpio Implantation

For Scorpio Procedure Only... For Duracon Procedure See Page 42

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 (**Figure 98**).

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 (Figure 99).

Introduce the tibial tray into the prepared tibia and impact it until the tray is fully seated (**Figure 100**). Clear all excess bone cement while maintaining position of the implant.

To properly remove the tibial Impactor/Extactor loosen (counter-clockwise) the thumbscrew a minimum of four turns. Pull the slide lever up to release the instrument from the tibial tray.

Note: It is important to keep the central hole of the implant and the instrument "feet" clear of bone cement/debris upon assembly.

Figure 98

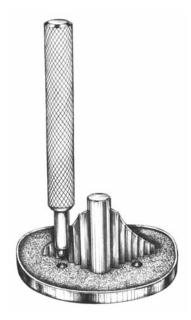
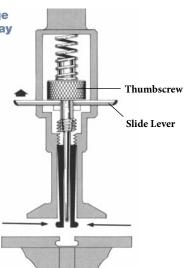
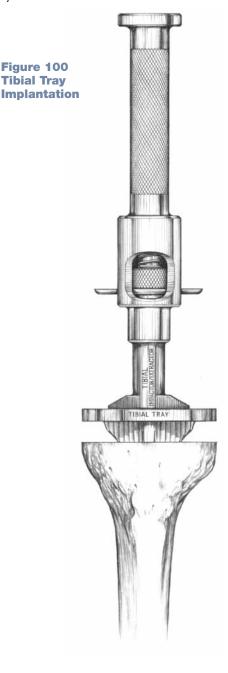


Figure 99
Retract Slide
Levers to Engage
Feet in Tibial Tray





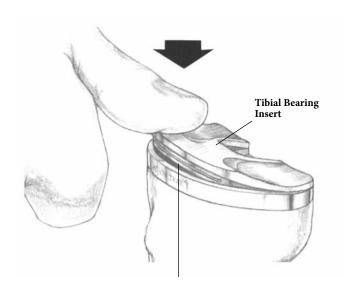
Tibial Bearing Insert Assembly

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.

Snap the insert in place anteriorly (**Figure 101**). 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.

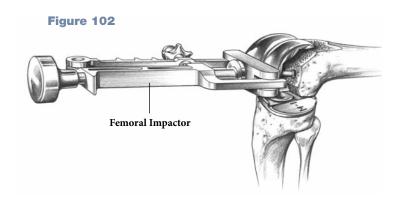
Figure 101



First Engage posteriorly, then snap into place anteriorly

Implantation of 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 (Figure 102). The Impactor/Extractor aids in maintaining accurate position of the implant during implantation.



Note: The components shall be positioned to avoid excessive hyperextension. Excessive femoral flexion and tibial slope should be avoided when implanting the components. Implant positioning resulting in excessive hyperextension may result in premature wear and damage to the implant.

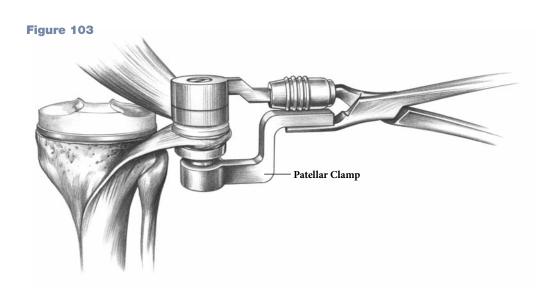
Closing

Implantation of the Patellar Component Closure

The back surface of the implant (including the pocket) and the cut surface of the patella are covered with a layer of cement. Cement should be interdigitated into the fixation holes on the cut patella and the pocket on the back of the all-plastic Symmetric Patellar Component.

The patellar clamp locks in place while the cement hardens (Figure 103).

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.



Indications and Contraindications

Duracon Indications

Indications

Indications for use of total knee replacement prostheses include:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis or avascular necrosis.
- · Rheumatoid arthritis.
- Correction of functional deformity.
- Revision procedures where other treatments or devices have failed.
- Post-traumatic loss of joint anatomy, particularly when there is patello-femoral erosion, dysfunction or prior patellectomy and,
- Irreparable fracture of the knee.

Contraindications

Absolute contraindications include:

- Overt infection.
- Distant foci of infections (which may cause hematogenous spread to the implant site).
- Rapid disease progression as manifested by joint destruction or bone absorption apparent on roentgenogram.
- Skeletally immature patients.
- Cases where there is poor bone stock which would make the procedure unjustifiable.

Conditions presenting increased risk of failure include:

- Un-cooperative patient or patient with neurological disorders who is incapable of following instructions.
- · Osteoporosis.
- Metabolic disorders which may impair bone formation.
- · Osteomalacia and,
- · Previous arthrodesis.

A higher incidence of implant failure has also occurred in paraplegics, cerebral palsy and patients with Parkinson's disease.

Warnings and Precautions

See package insert for warnings, precautions, adverse effects and other essential product information.

Scorpio Indications

Indications

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.

Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

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 post-operative 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.

Warnings and Precautions

See package insert for warnings, precautions, adverse effects and other essential product information.

Notes



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Literature Number: LSPK31 Rev. 1 MS/GS 11/11

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