stryker

Orthopaedics

Scorpio® NRG® CR & PS
Single Radius Primary Knee System Surgical Protocol

PR

Posterior Referencing

This document is intended to be used by healthcare professionals only.

Scorpio NRG

PR Single Radius Primary Knee System Surgical Protocol

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Xcelerate Instrumentation Surgical Technique
For Scorpio NRG Single Radius Primary Knee System

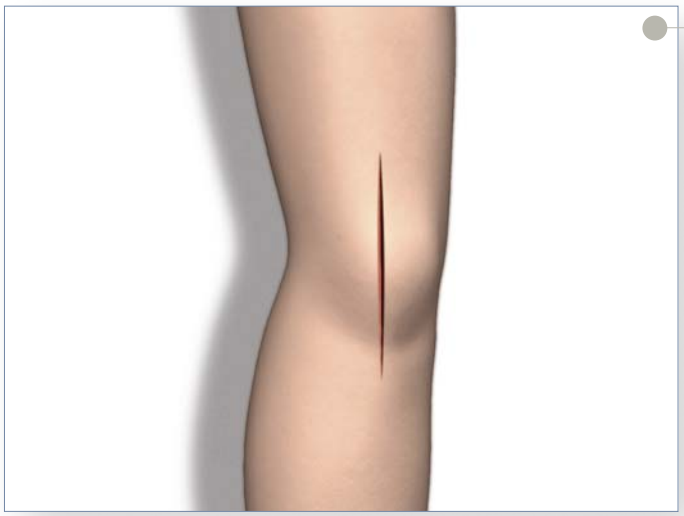


Figure 1

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 the capsule through a medial parapatellar approach approximately 1cm from the medial border of the patella.

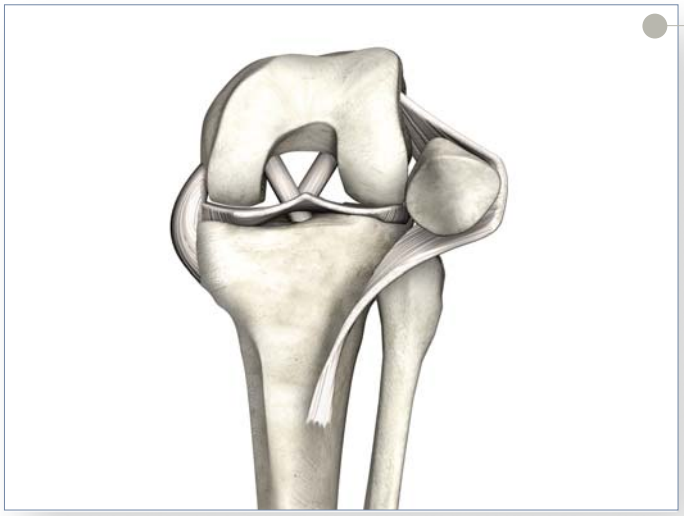


Figure 2

- Incise the quadriceps mechanism longitudinally to allow adequate patellar eversion and sufficient knee flexion **(Figure 2)**.

Figure 3

Femoral Preparation

Femoral Intramedullary Alignment

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

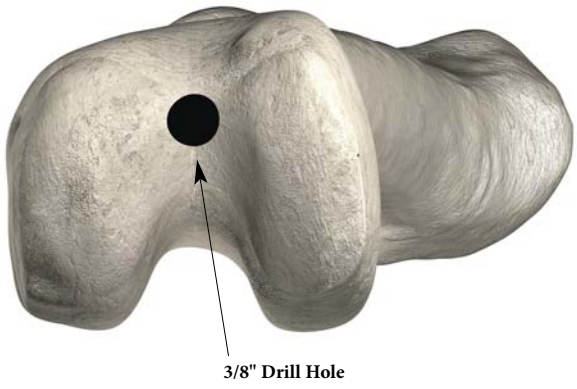


Figure 4

- 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 4)**.
- 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.

Figure 5

- Place the 5/16" T-Handle Rod through the Femoral Alignment Guide and insert the assembly into the intercondylar drill hole **(Figure 5).** 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 distal bone.

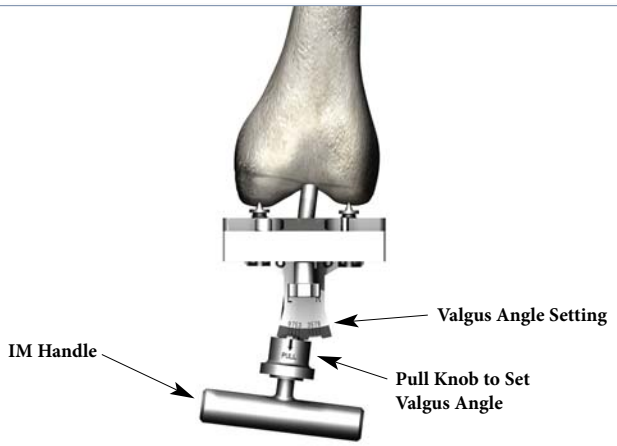


Figure 6

- 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.

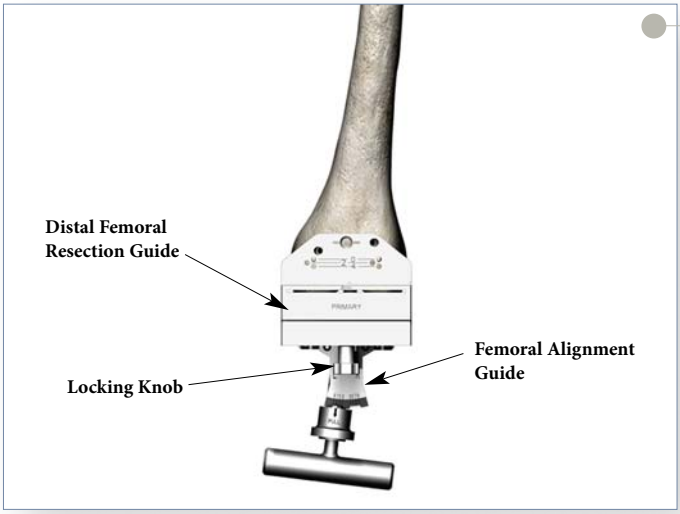


Figure 7

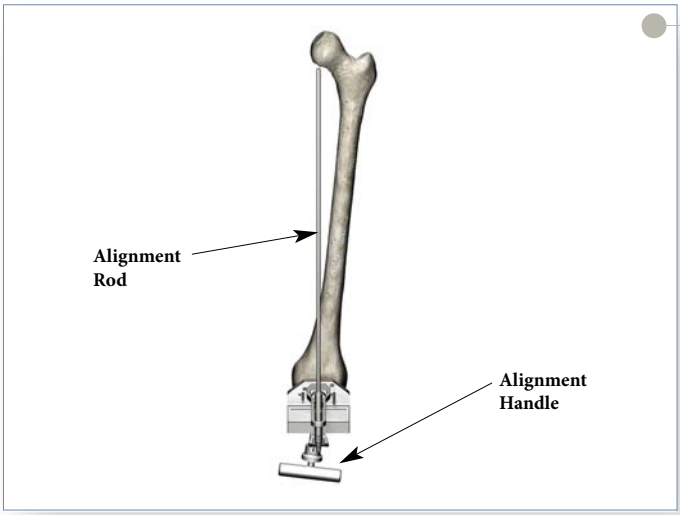


Figure 8

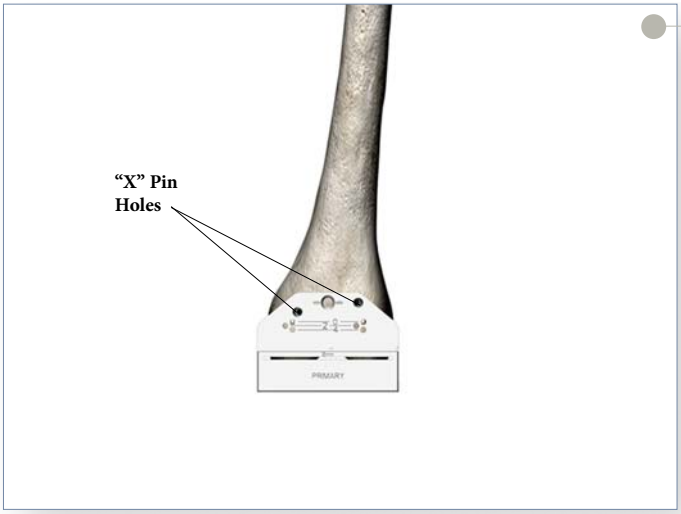


Figure 9

Distal Femoral Resection Level

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

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

- Select the appropriate Distal Femoral Resection Guide and assemble it to the Femoral Alignment Guide by positioning the 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 7)**.

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.

- 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 8)**. 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.

- The Drill-Pin Driver can be attached directly to the 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 9)**.

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.

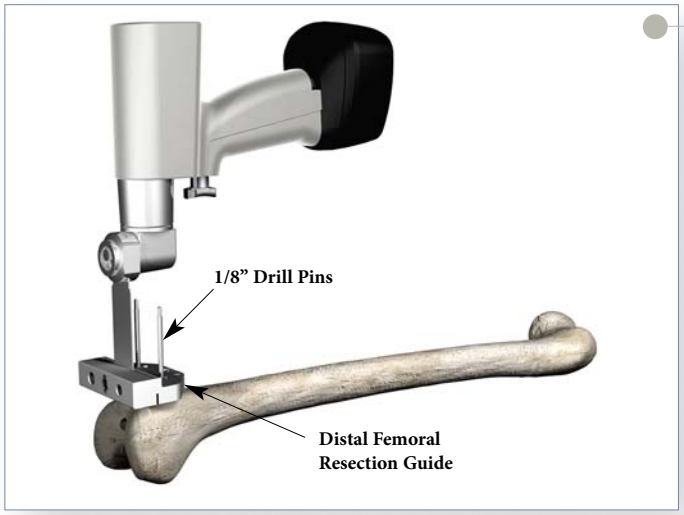


Figure 10

Distal Femoral Resection

- Once the resection level is determined, make the distal femoral resection **(Figure 10)**.
- Xcelerate Instruments are designed to provide precise control of the sawblade during bone resections. Using a 0.05" (1.27mm) thick saw blade produces the most accurate resections.
- Once the distal femoral resection is complete, remove the guide and check the cut is smooth and flat.
- Remove the 1/8" drill pins with the Pin Puller.

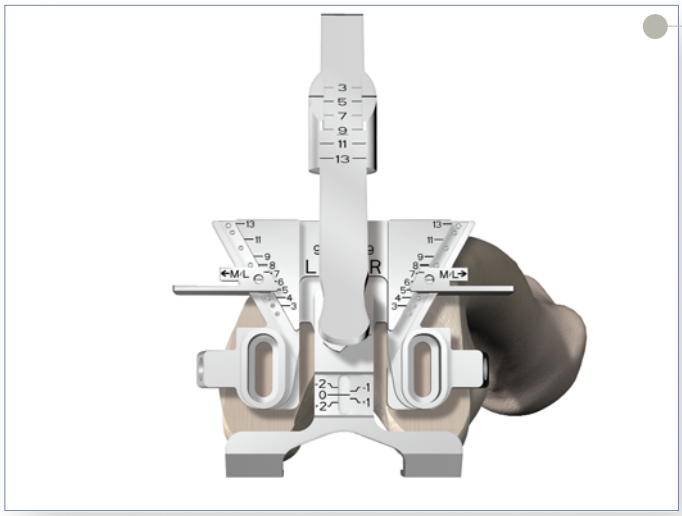


Figure 11

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 Sizer. Set the A/P adjustment indicator to "0" **(Figure 11)**.

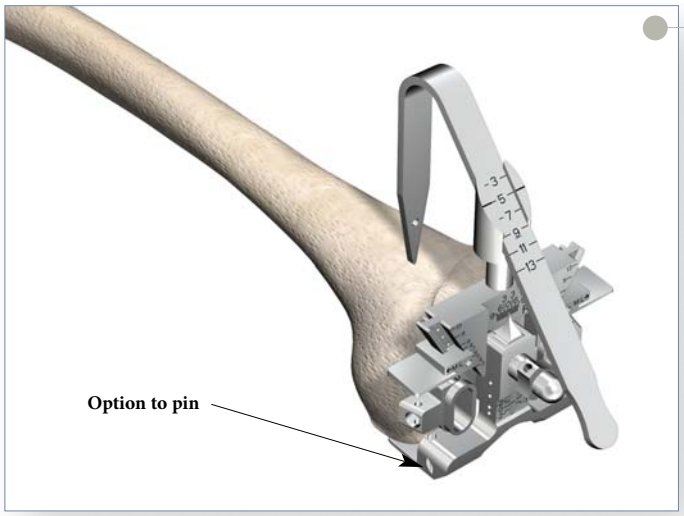


Figure 12

- Adjust 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 12)**. 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.

Note: Option to pin **(Figure 12)**.

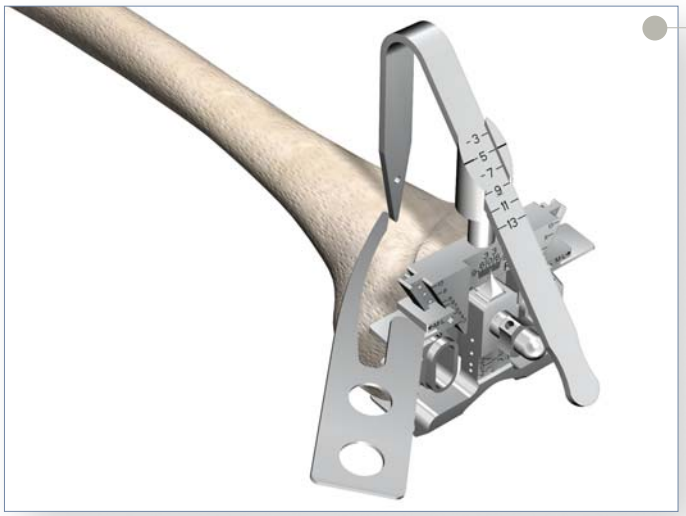


Figure 13

- 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 13)**.
- Place the appropriate size drill bushing into the A/P Sizer, taking care to ensure it is correctly oriented. Using a 1/8" drill pin, prepare the distal peg holes.

Note: If you plan to use the Scorpio Universal Notch block with lugs you can check your position in the medial lateral with the A/P sizer.

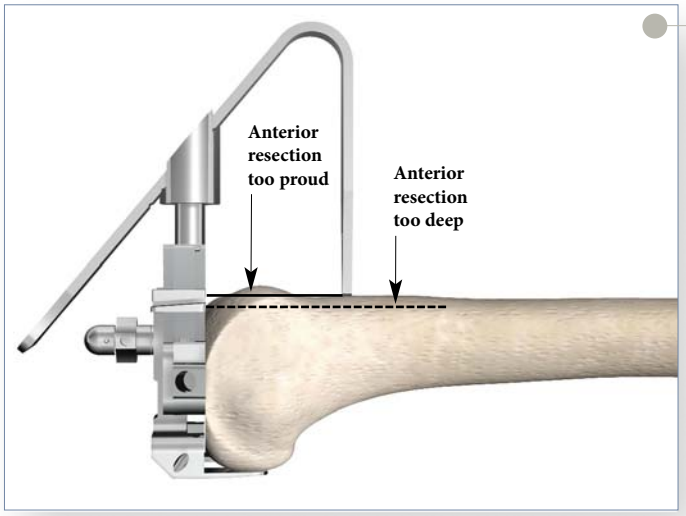


Figure 14

A/P Adjustment

- On occasion the femur will fall 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 14)**. 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.

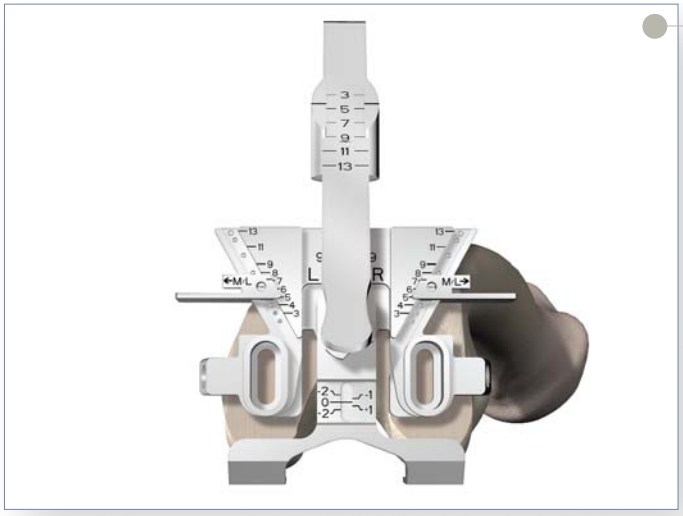


Figure 15

- 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 15)**.

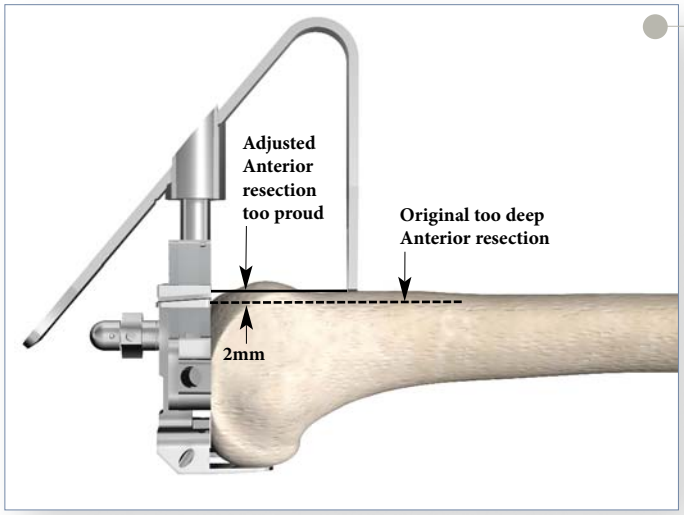


Figure 16

- 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 16**). 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.

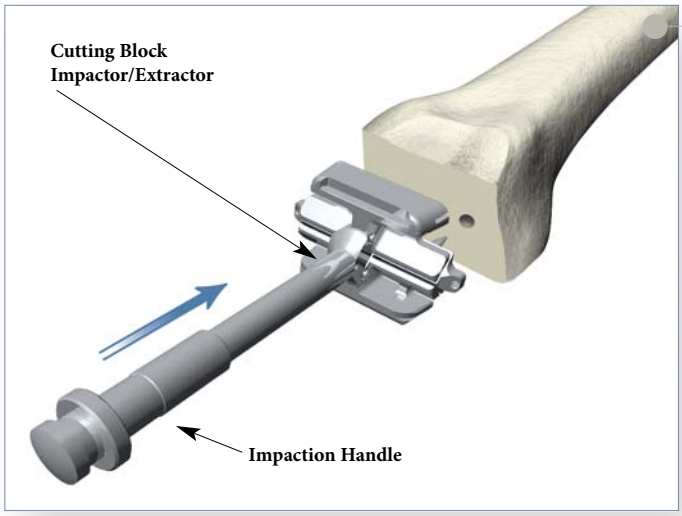


Figure 17

A/P and Chamfer Bone Cuts

- Assemble the Cutting Block Impactor/Extractor to the Impaction Handle.
- Insert the two prongs of the Cutting Block Impactor/Extractor into the two distal holes on the cutting guide.
- Position the corresponding Femoral 4:1 Cutting Block into the pin holes and impact until the block is seated flush on to the distal femur. Additional fixation can be achieved by pinning the Femoral 4:1 Cutting Block to the bone.
- Impact the Cutting Block Impactor/Extractor using a mallet while guiding alignment of the Femoral 4:1 Cutting Block with the other hand.

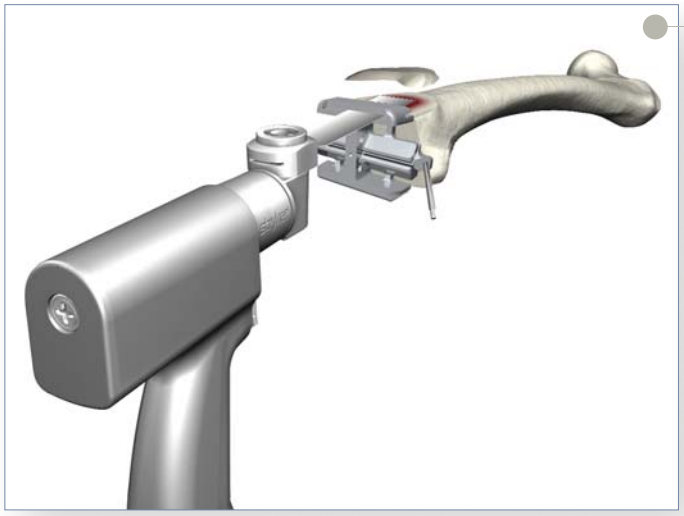


Figure 18

- Use of a 0.05" (1.27mm) thick, 18mm wide saw blade is recommended
- Complete the remaining four bone resections
- The recommended bone resection sequence for the Femoral 4:1 Cutting Block is:
  1. Anterior Cortex
  2. Posterior Condyles
  3. Posterior Chamfer
  4. Anterior Chamfer
- Extract the Femoral Cutting Guide by using the Cutting Guide Impactor/Extractor
- Do not remove the Femoral 4:1 Cutting Block from the bone by impacting on the backside of block.

Extraction with the Cutting Block Impactor/Extractor

- Assemble the Cutting Block Impactor/Extractor to the Impaction Handle.
- Insert the two prongs of the Impactor/Extractor into the two distal holes on the Femoral 4:1 Cutting Block.
- Extraction can be achieved by pulling on the attached handle. If additional force is needed, the Slaphammer may be attached to the end of the Impaction Handle.

Note: Additional fixation support should be provided for the cutting block to ensure block stability during disengagement of the adapter when used on osteoporotic bone.

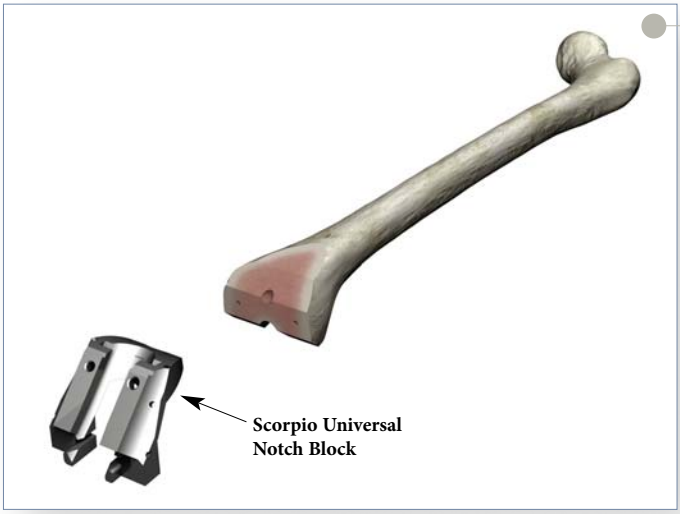


Figure 19

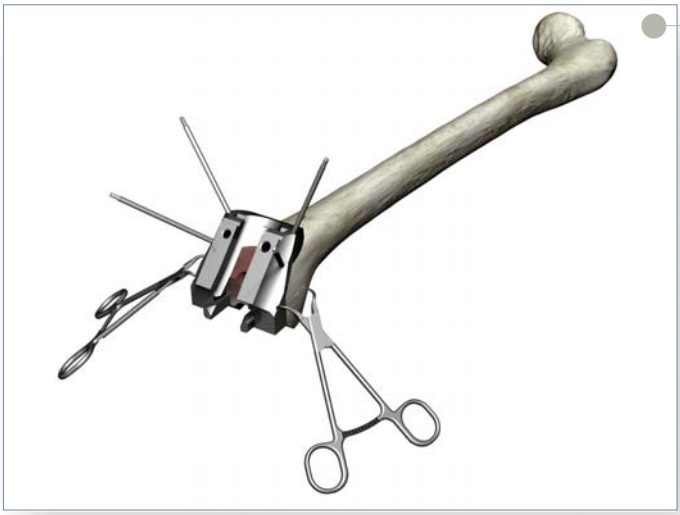


Figure 20

Notch Preparation for Scorpio PS

- 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.
- 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 the mallet **(Figure 19)**. To further aid the positioning, if using pegless blocks, note that the block is also the same width as the implant of its respective size.

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.

- 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 (there are 4 "X" holes each at 15°) **(Figure 20)**.
- 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.
- Stryker recommends the following instructions be used when using the Size 3 Notch Preparation Guide:

  Size 3 Notch Block Notch Preparation
  Pins used with the size 3 Notch Block should only be placed in through the anterior ***chamfer*** to avoid hitting the notch punch.

  Do not place pins through the anterior ***flange***.

  Towel clamps may be used for additional stability if necessary, in the indicated holes on the distal plane.

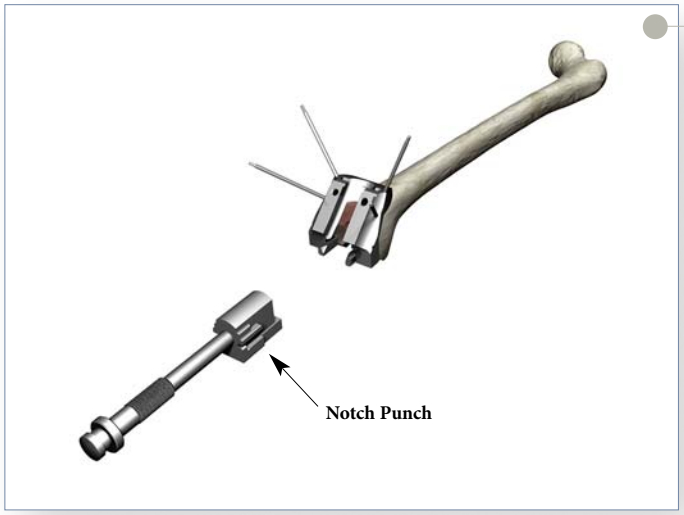


Figure 21

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 21)**. The rails on the sides of the cutting edge fit into the tracks on the inside walls of the block.

Figure 22

- Using a mallet, impact the Punch until it reaches the end-stop and is fully seated in the Notch Block **(Figure 22).**

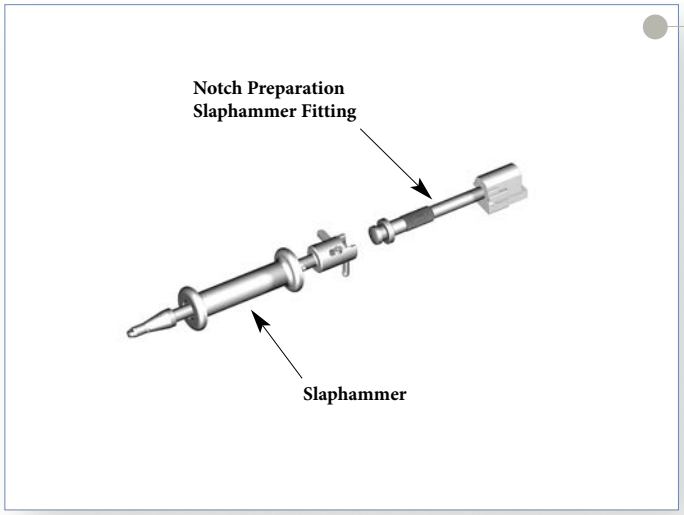


Figure 23

- Remove the Punch from the tracks with a Slaphammer if necessary **(Figure 23).**

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

Note: Using an 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 the femoral notch prior to compacting bone to avoid future potential soft-tissue impingement).

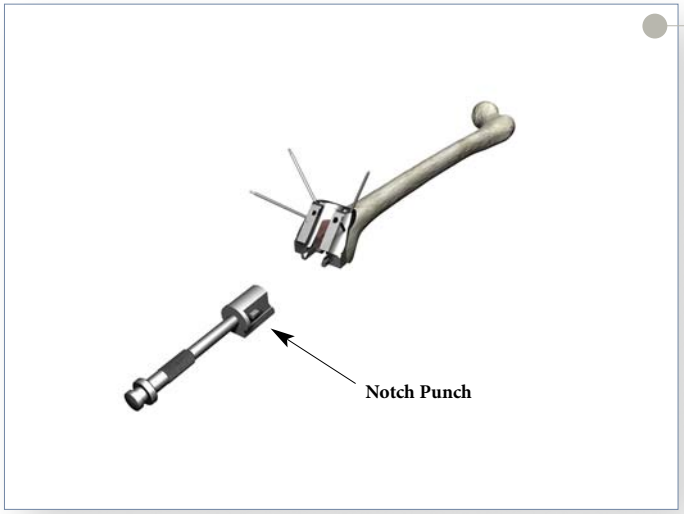


Figure 24

Compacting Technique

- Assemble the appropriately sized Notch Compactor to the punch handle **(Figure 24)**.
- Guide the Notch Compactor into the tracks on the distal face of the Notch Block.

Figure 25

- Using a mallet impact the compactor until it reaches the end-stop and is fully seated in the Notch Block **(Figure 25).**

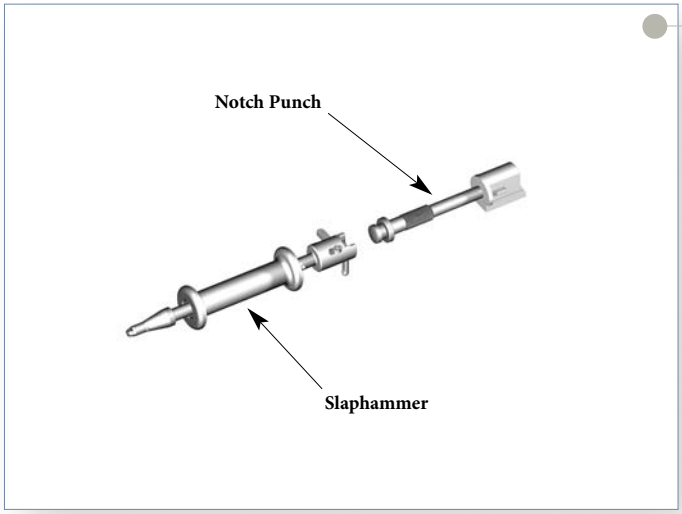


Figure 26

- Remove the Compactor from the tracks with a Slaphammer if necessary **(Figure 26)**.

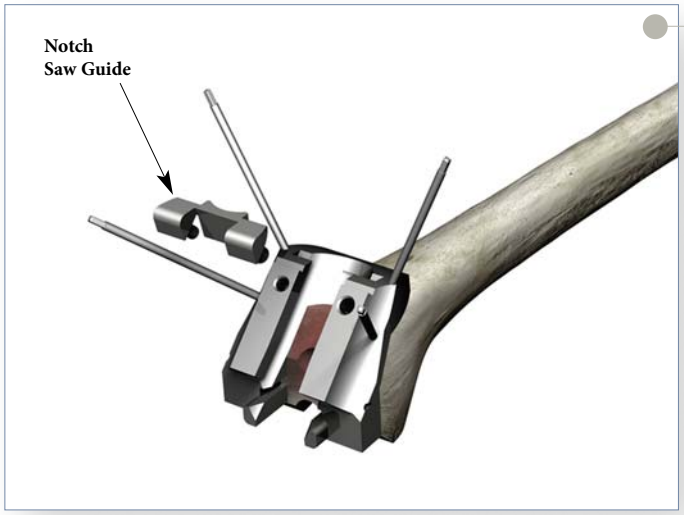


Figure 27

Option 2: Saw Technique

- Guide the pegs of the appropriately sized Notch Saw Guide into the anterior holes on the Notch Block **(Figure 27)**.

Figure 28

- 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 28)**.

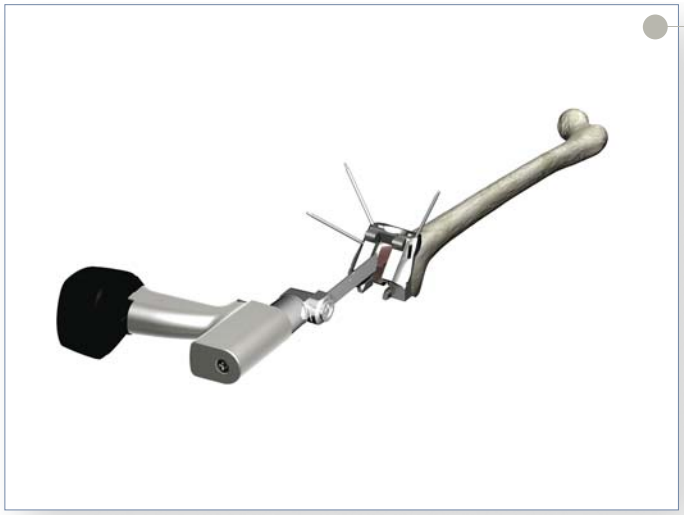


Figure 29

- 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 29)**.

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.

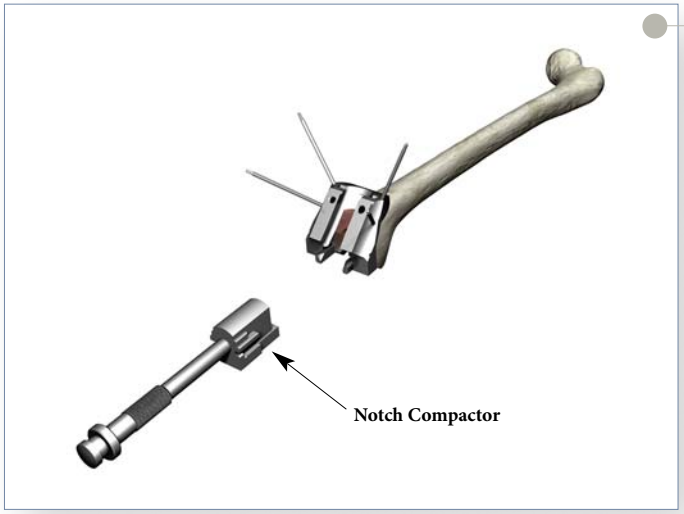


Figure 30

Compacting Technique

- Assemble the appropriately sized Notch Compactor to the punch handle **(Figure 30)**.
- 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.

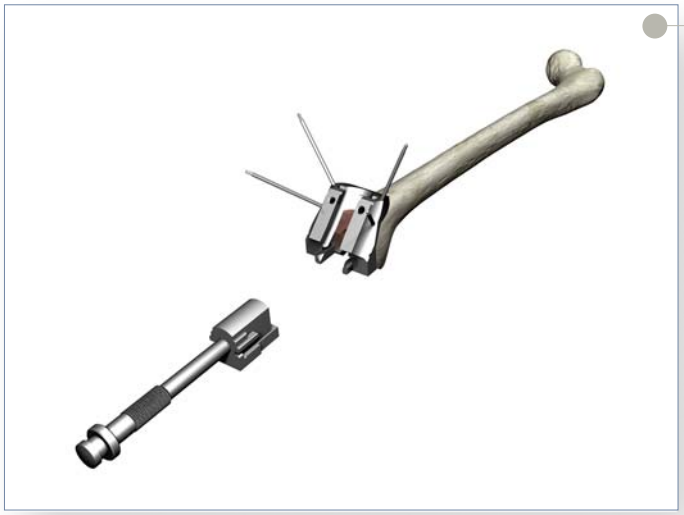


Figure 31

- Using a Mallet, impact the Compactor until it reaches the end-stop and is fully seated in the Notch Block **(Figure 31)**.

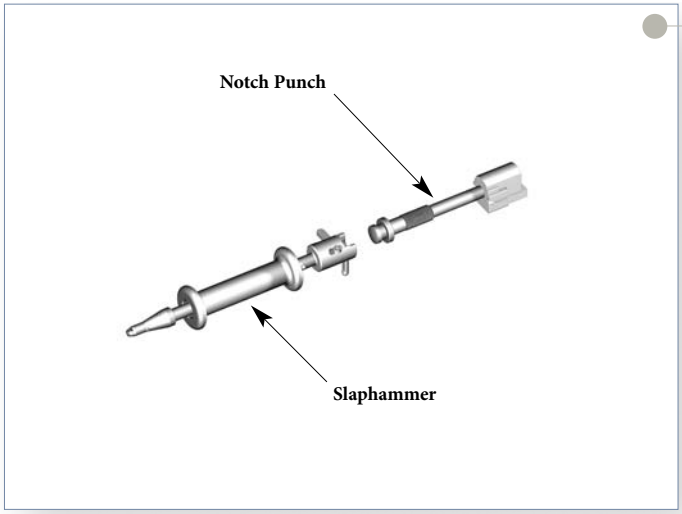


Figure 32

- Remove the Compactor from the tracks with a Slaphammer if necessary **(Figure 32)**.

Figure 33

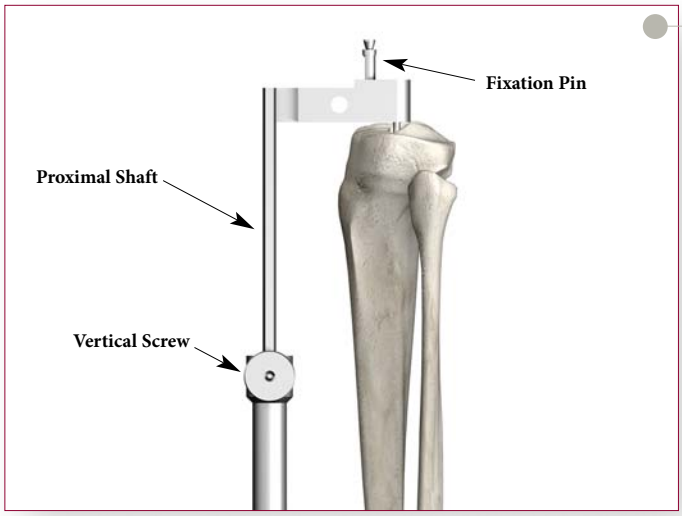


Figure 34

Femoral Trial Assessment

- Assemble the appropriate size and side (Left/Right) PS or CR Femoral Trial to the Femoral Impactor/ Extractor.
- Impact the PS or CR Femoral Trial onto the prepared distal femur ensuring the Femoral trial is aligned with the distal plane.
- Remove the Femoral Impactor/Extractor and assess the fit of the PS or CR Femoral Trial. Care must be taken to ensure that all of the osteophytes beyond the end of the posterior femoral condyles are removed.
  - **Cruciate Retaining Knee:** Attach the 1/4" Peg Drill to the Universal Driver and create the Femoral Distal Fixation Peg holes if using the Pegless Trials. Use a 1/8" drill for size 3 and 4 femoral Trial. **Option:** After removing size 3 or 4 Femoral Trial, follow-up with 1/4 in Peg Drill.
  - **Posterior Stabilized Knee:** If the Peg Holes were not prepared by using the Pegged Notch Block, attach the 1/4" Peg Drill to the Universal Driver and create the Femoral Distal Fixation Peg holes. Use a 1/8" drill for size 3 and 4 femoral Trial. **Option:** After removing size 3 or 4 Femoral Trial, follow-up with 1/4" Peg Drill.

Tibial Preparation

Option 1: Extramedullary Technique

- 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 Proximal Rod 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 34)**.

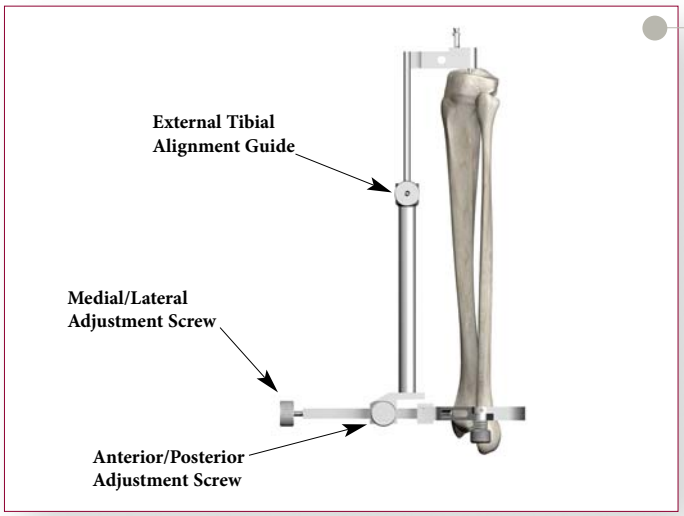


Figure 35

- 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 adjustment thumbscrews to facilitate alignment **(Figures 35 and 36).**

Figure 36

Figure 37

- 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 **(Figure 37)**.

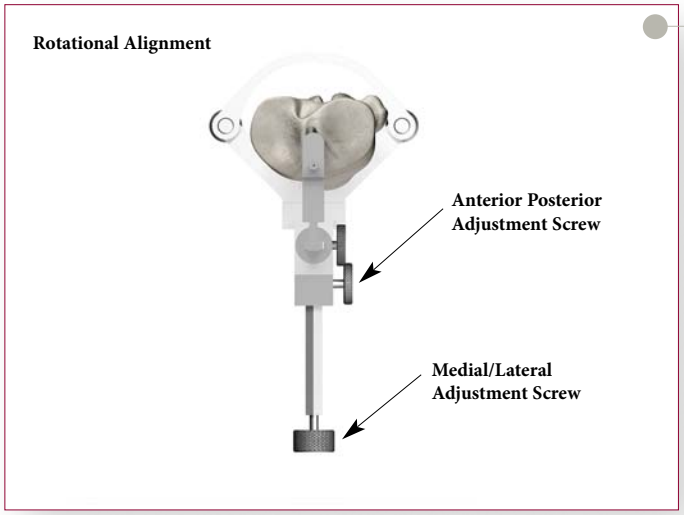


Figure 38

- Once axial alignment is established, tighten the anterior/posterior and medial/lateral adjustment thumbscrews **(Figure 38).**

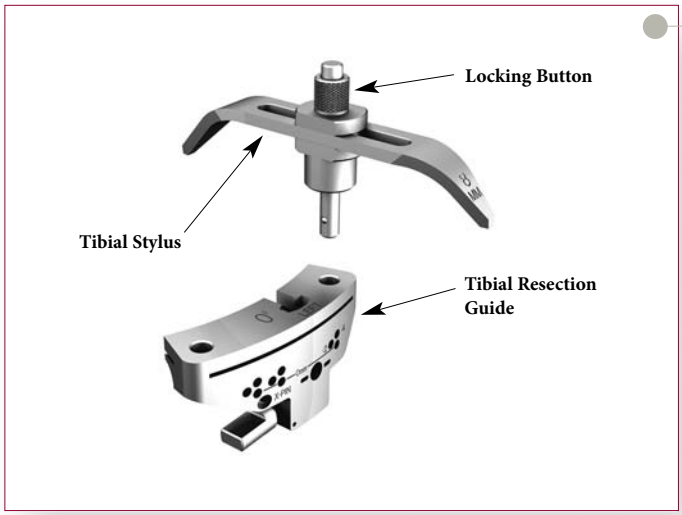


Figure 39

Tibial Resection Level

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

Note:
0 degrees of posterior slope is recommended for use with the Scorpio PS femoral components.

5 degrees of posterior slope is recommended for use with the Scorpio CR femoral components.

- Assemble the tibial stylus onto 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 39)**.

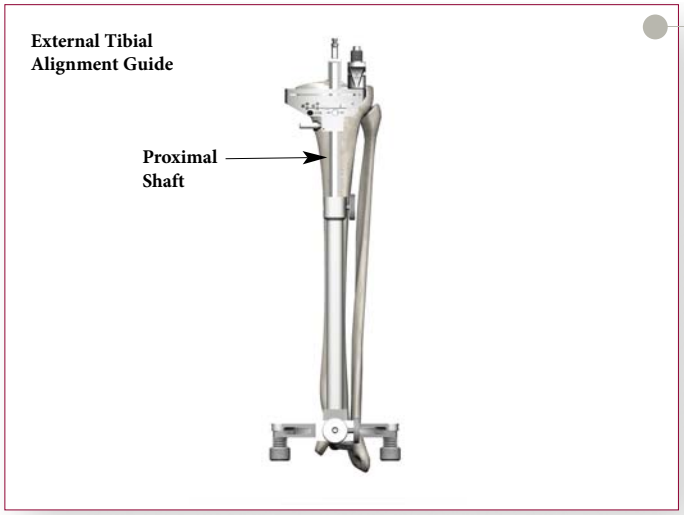


Figure 40

- 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 40).**

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.

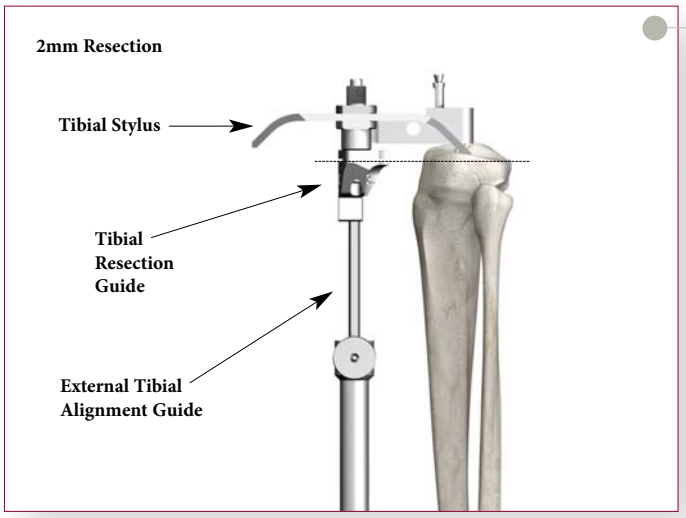


Figure 41

- The Xcelerate System offers two Tibial styli each having two resection levels; 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 41 and 42)**.

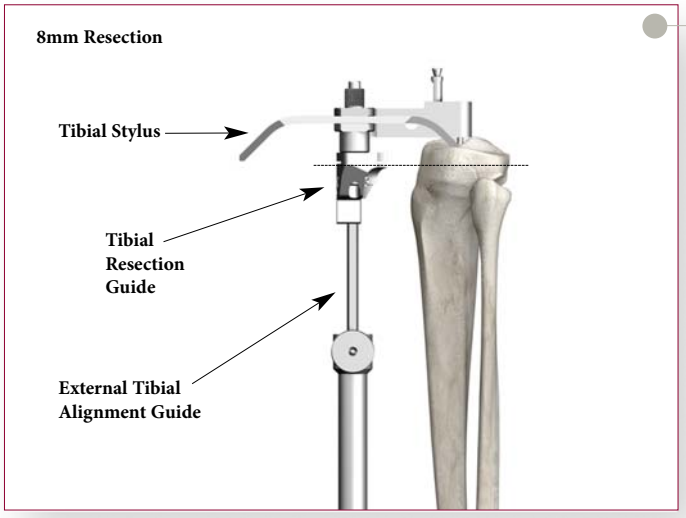


Figure 42

- 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.

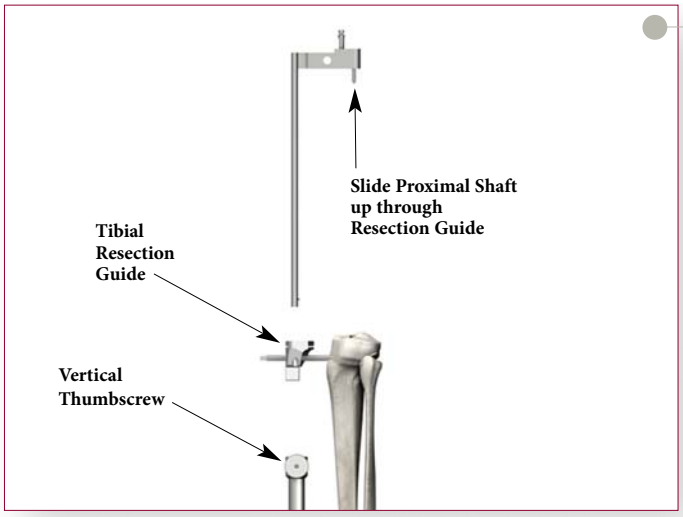


Figure 43

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 43)**.

Figure 44

- 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 0.05" (1.27mm) saw blade **(Figure 44)**.

Figure 45

- 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 45)**.
- The Tibial Resection Guide is removed by first sliding the guide off 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 46

Option 2: Intramedullary Technique
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 46)**.
- Attach the pre-determined diameter IM Rod (1/4", 3/8", or 5/16") to the T-Handle by depressing the button to lock into place. Pre-operative X-Ray templating will aid in the determination of the IM Rod diameter.

Figure 47

- Introduce the IM Rod into the entry hole and gradually advance it down the intramedullary canal **(Figure 47)**. 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.

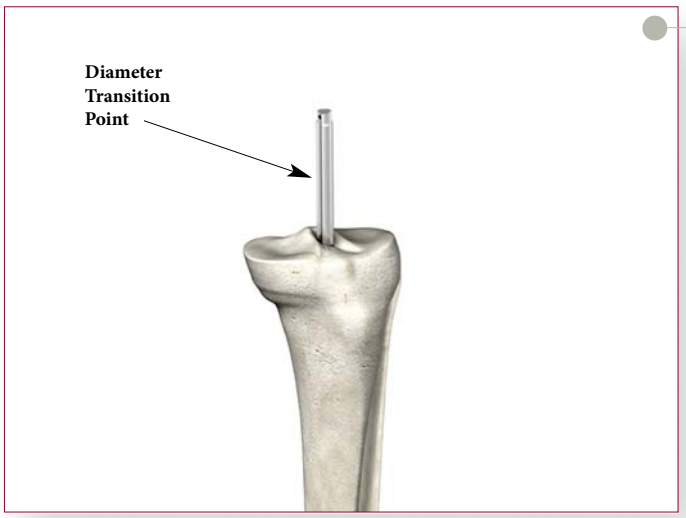


Figure 48

- The proximal portion of both the 1/4" and 3/8" 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 48)**.

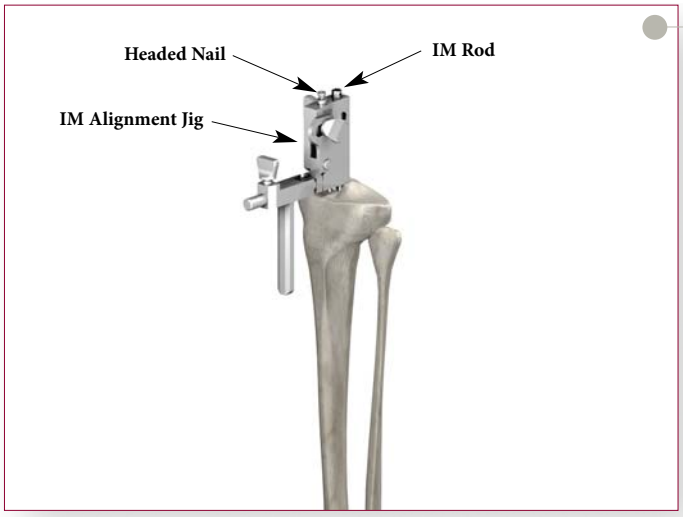


Figure 49

- 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 49)**.

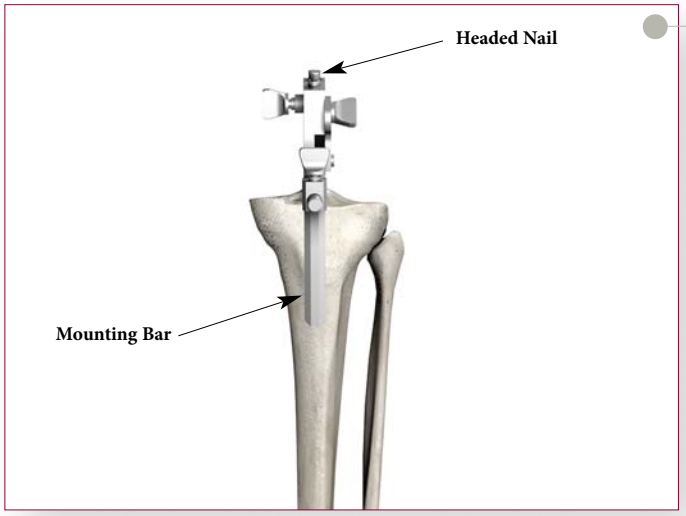


Figure 50

Rotation and Varus/Valgus Alignment

- With the body of the IM jig resting on the proximal tibia, correct 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 50)**.

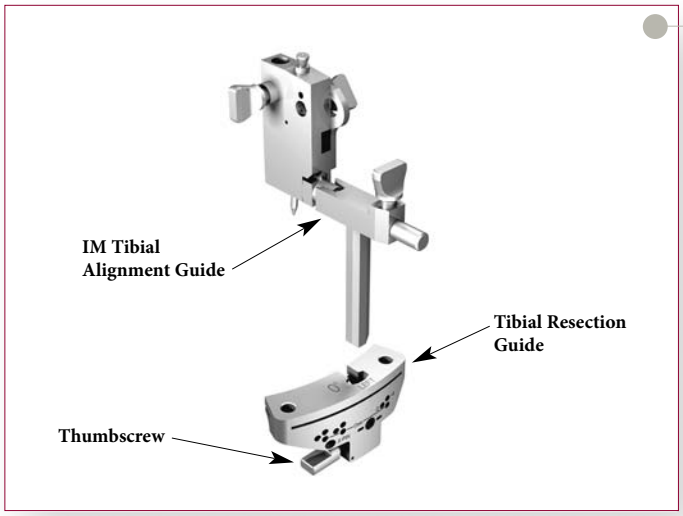


Figure 51

- 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 51)**.

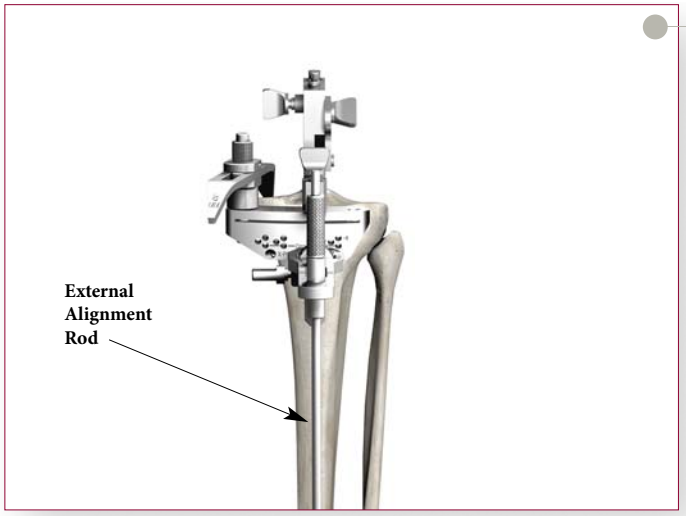


Figure 52

- Attach the alignment handle to the resection guide, and slide a long alignment rod into the alignment handle. When correct varus/valgus alignment is attained, the pin should be centered over the ankle **(Figure 52).**

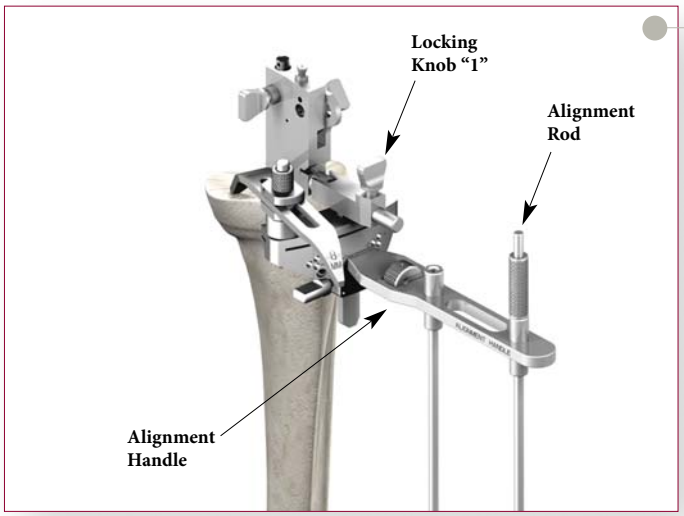


Figure 53

- 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 53)**. Once the alignment rod is centered over the ankle, the Locking Knob is securely tightened.

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 54)**.

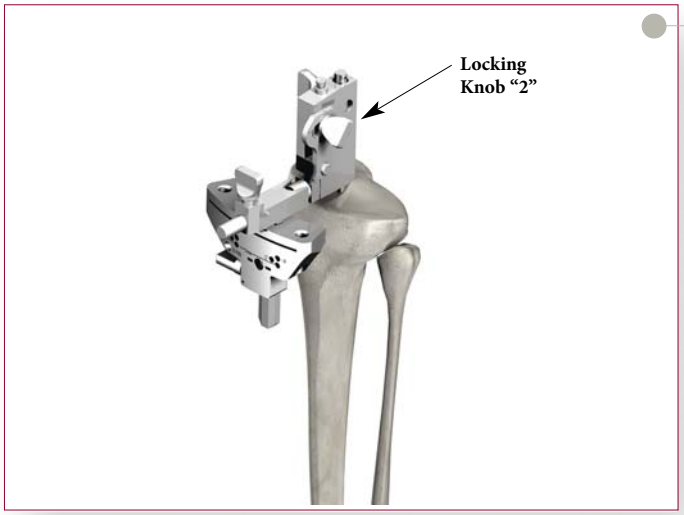


Figure 54

- 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.

Tibial Resection Level

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

Note:
0 degrees of posterior slope is recommended for use with the Scorpio PS femoral components.

5 degrees of posterior slope is recommended for use with the Scorpio CR femoral components.

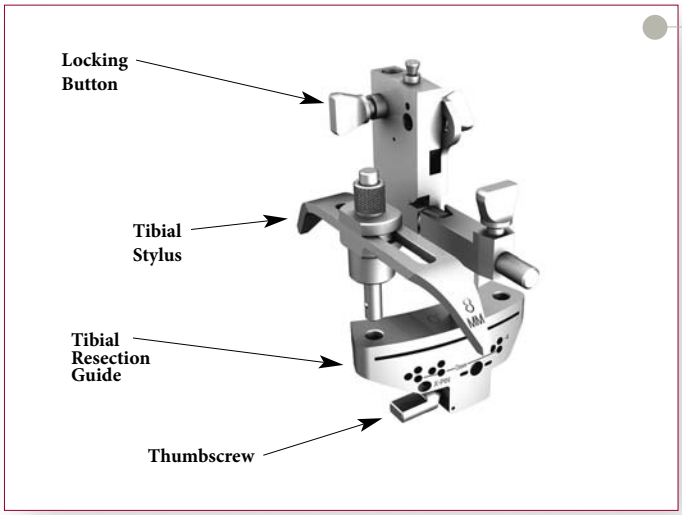


Figure 55

- Assemble the Tibial Stylus onto 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 55)**.

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.

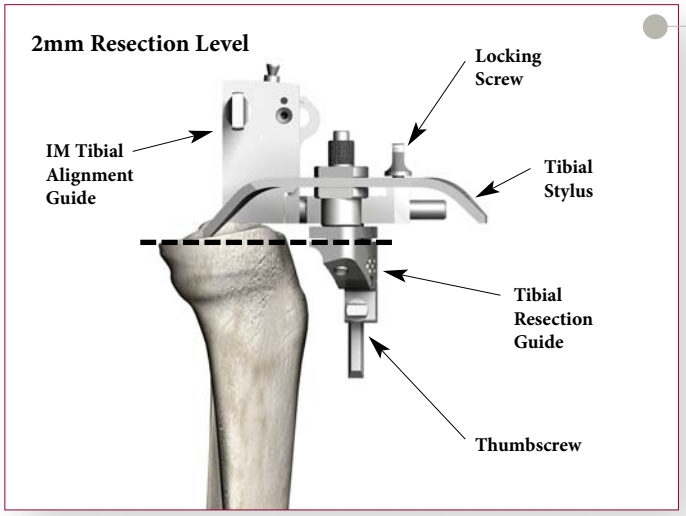


Figure 56

- 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 thumb-screw.
- The Xcelerate System offers two Tibial styli each having two resection levels; 2mm and 8mm.

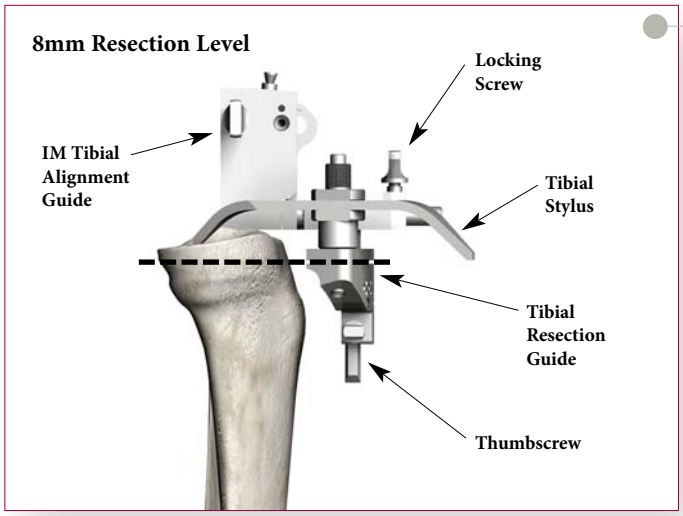


Figure 57

- 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 56 and 57)**.

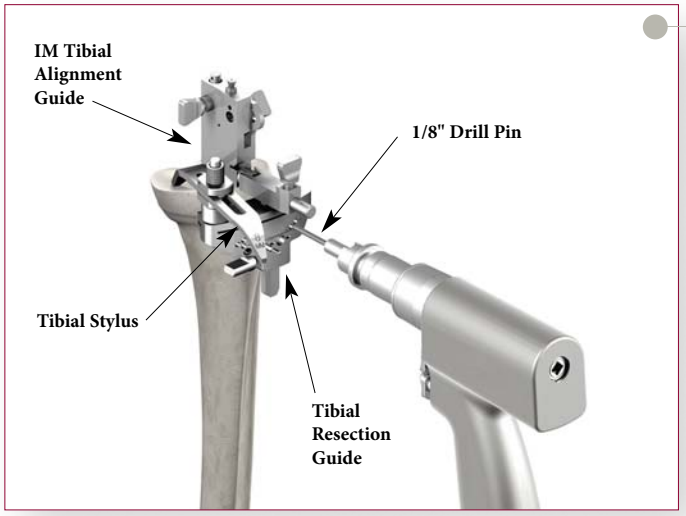


Figure 58

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 58)**.

Figure 59

- 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 0.05" (1.27mm) sawblade is recommended for an accurate resection **(Figure 59)**.

Figure 60

- 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 60)**.
- The Tibial Resection Guide is removed by first sliding the guide off 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 61

Tibial Baseplate Preparation

Scorpio NRG Tibial Component Sizing

- Maximally flex the knee and deliver the tibia forward. Assemble a Tibial Trial Baseplate onto the Alignment Handle and place it on the resected tibial plateau **(Figure 61)**. Choose the size that best covers the tibial plateau.

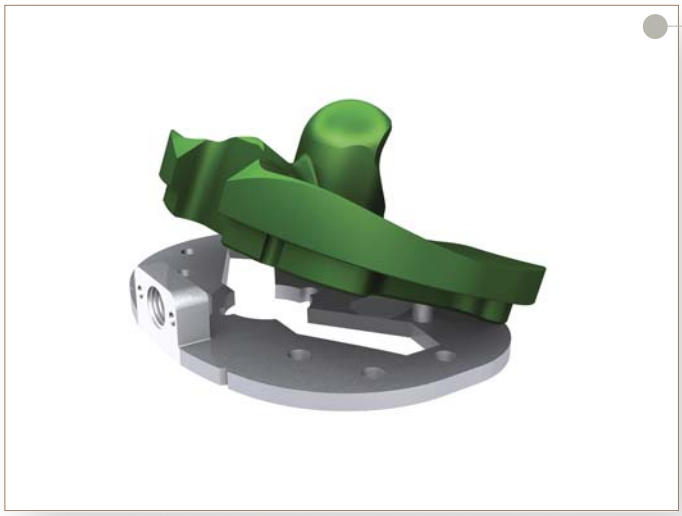


Figure 62

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 62)**. 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.

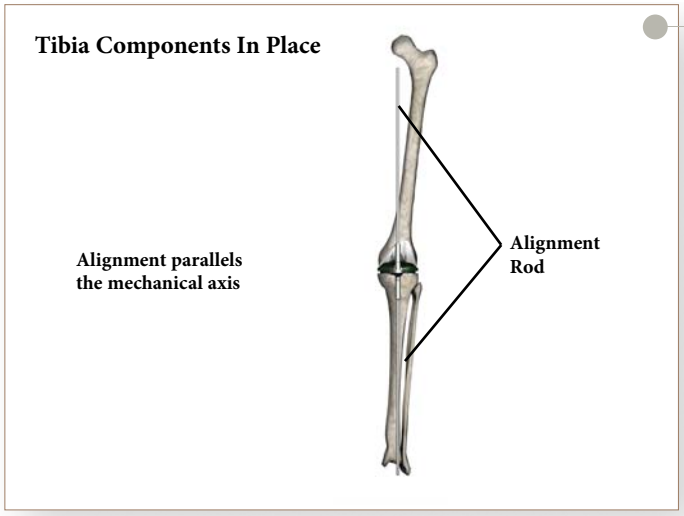


Figure 63

- 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.
- 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 63)**.

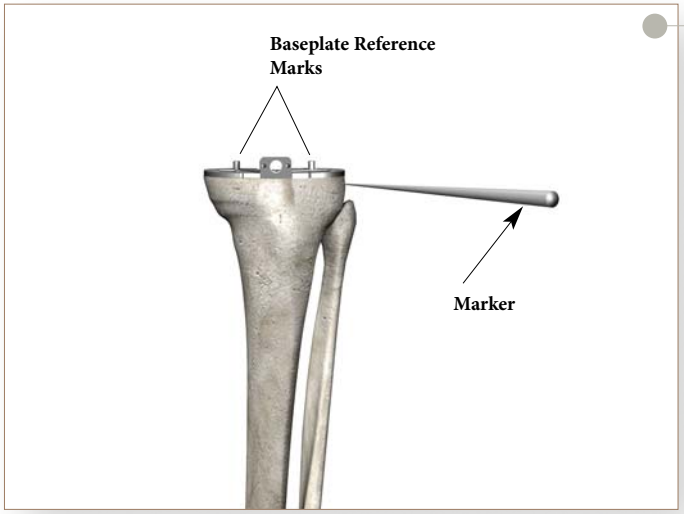


Figure 64

- 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 64)**.
- 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 to the anterior tibial cortex.

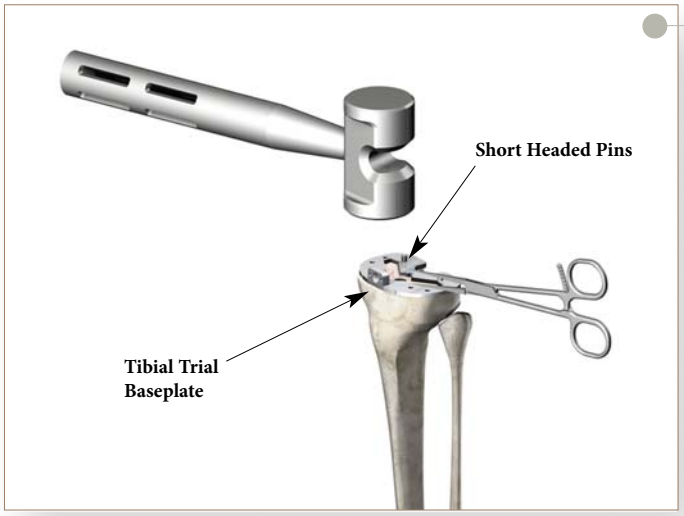


Figure 65

- Pin the baseplate to the tibial plateau by placing two short, headed fixation pins through a medial and lateral hole in the baseplate **(Figure 65)**. 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 re-assembled to the pinned baseplate for any subsequent trial reductions.

Figure 66

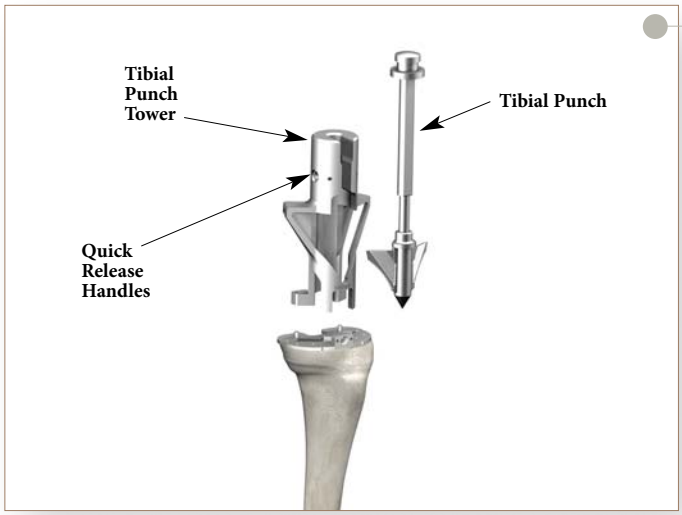


Figure 67

Figure 68

Tibial Keel Punching

- Tibial Punches are identified by keel size (3/5, 7/9, 11/13) and bone preparation ("Cement 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 tibia 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 66).**
- 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 **(Figure 67)**. See Appendix 1 - Baseplate Preparation Table. 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 68)**. During extraction, take care to avoid toggle or angulation of the punch as this may distort the bone preparation. The Quick Release Slaphammer connects to the punches for extraction.

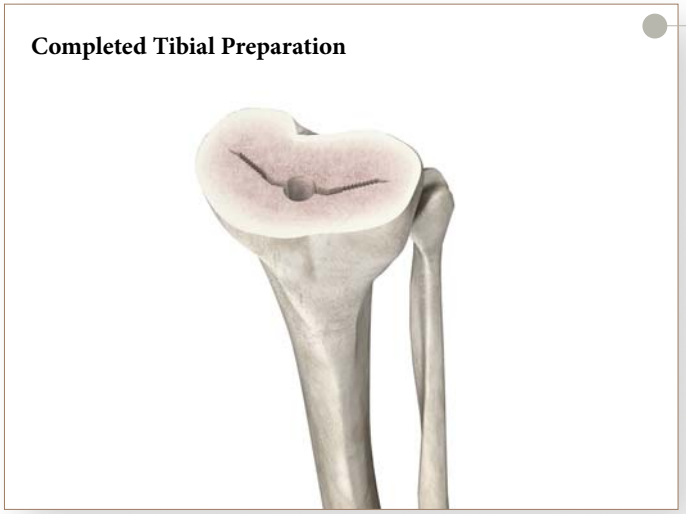


Figure 69

- Once the final punch has been seated, tibial preparation is complete **(Figure 69)**.

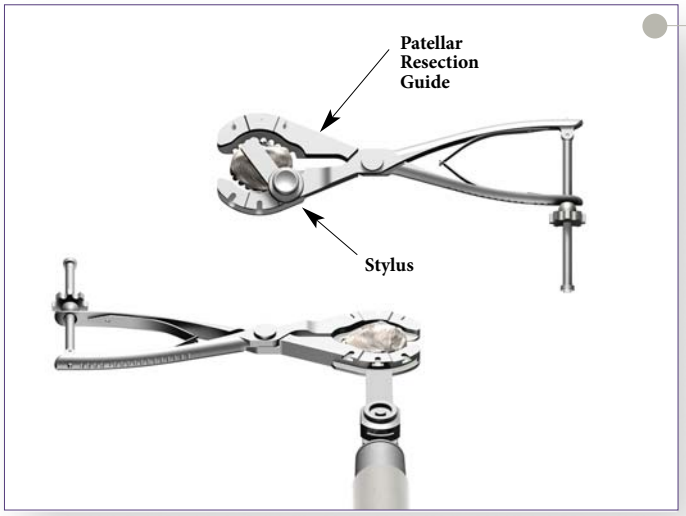


Figure 70

Patella 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, fix the stylus in the appropriate slot to the patellar resection guide, and capture the patella between the jaws of the saw guide. Using a 0.05" (1.27mm) non-offset sawblade, resect the patella **(Figure 70)**.

Patella Trial Assessment

- Remove any residual cartilage and wash away all debris. Place correct size Patella Trial onto the prepared patella.
- Replace all Trials and assess patellar tracking by taking the knee through a ROM. The patella should track normally through the ROM without tendency for tilting or lateral subluxation.

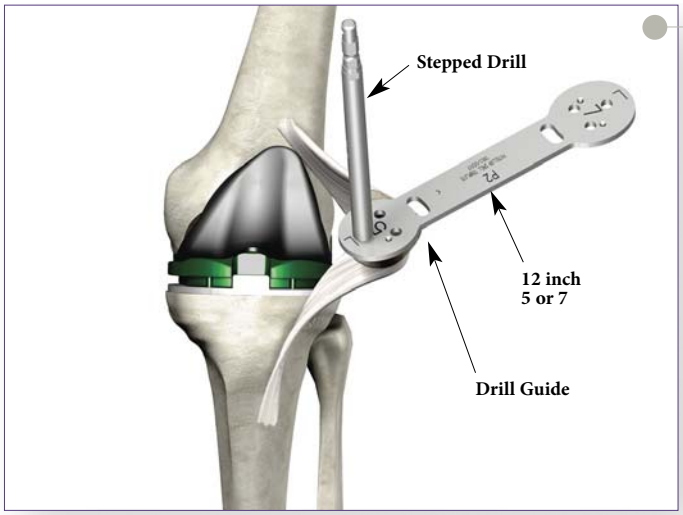


Figure 71

- 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 71)**.
- Prepare the resected bone surfaces for bone cement application. **See page 29 for cementing with the Patellar Clamp.**

Figure 72

Implantation

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 72)**.

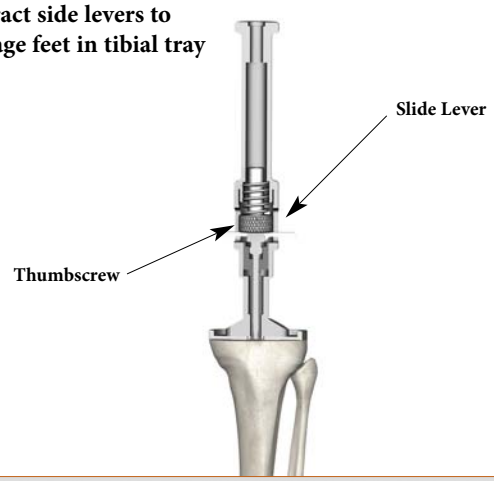


Figure 73

- 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 73)**.

Figure 74

- Introduce the tibial tray into the prepared tibia and impact it until the tray is fully seated **(Figure 74).** Remove the instrument from the tray before polymerization. Clear all excess bone cement without disturbing the position of the implant.

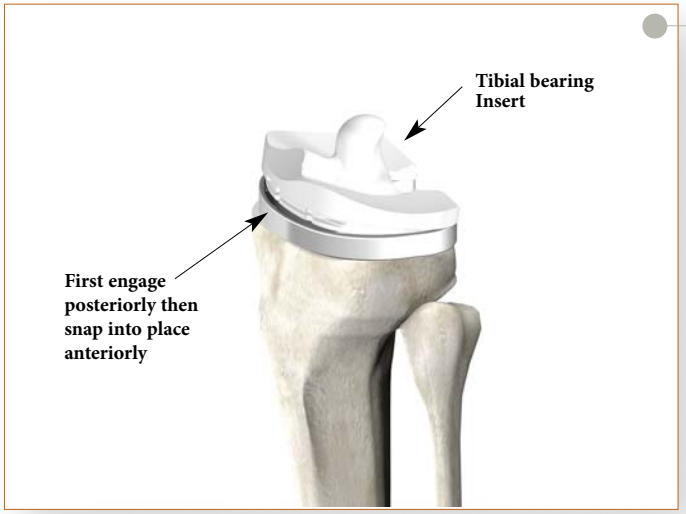


Figure 75

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 75)**. 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 wall.

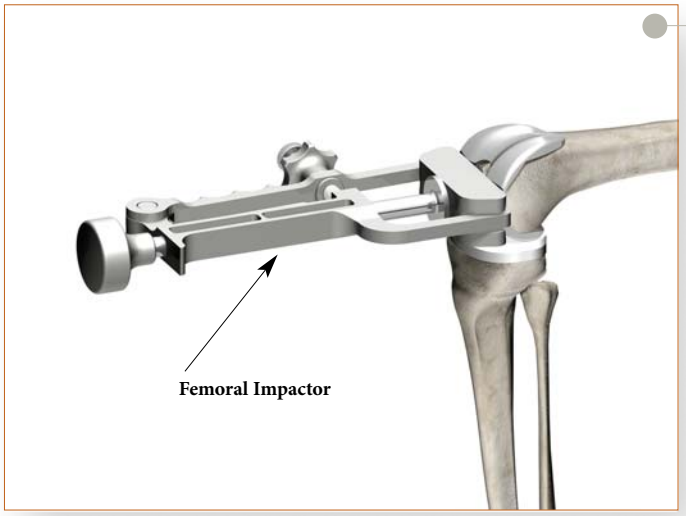


Figure 76

Implantation of Femoral Component

- Assemble the appropriate size of left or right femoral implant onto the Femoral Impactor/Extractor in the same manner as the femoral trial. See Appendix 2 for Scorpio NRG PS/CR interchangeability chart. Place the implant on the prepared femur and impact it until fully seated **(Figure 76)**. The Impactor/Extractor maintains 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.

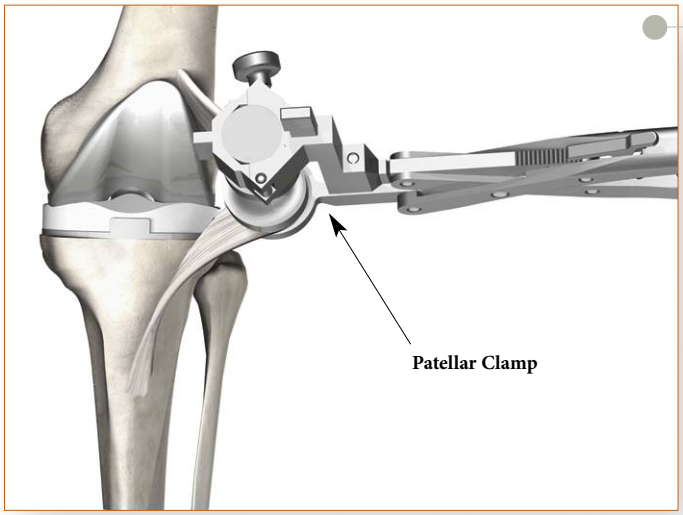


Figure 77

Implantation of the Patellar Component

- 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 Patellae Components.
- The patellar clamp locks in place while the cement hardens **(Figure 77)**.

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.

Appendix 1

Scorpio NRG Tibial Punching Sequence

Implant Size	Press-Fit Keel	Cement Keel
3	Press-Fit #3/#5	Press-Fit #3/#5
		Cement #3/#5
4	Press-Fit #3/#5	Press-Fit #3/#5
		Cement #3/#5
5	Press-Fit #3/#5	Press-Fit #3/#5
		Cement #3/#5
6	Press-Fit #3/#5	Press-Fit #3/#5
		Cement #3/#5
7	Press-Fit #3/#5 Press-Fit #7/#9	Press-Fit #3/#5
		Press-Fit #7/#9
		Cement #7/#9
9	Press-Fit #3/#5 Press-Fit #7/#9	Press-Fit #3/#5
		Press-Fit #7/#9
		Cement #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
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

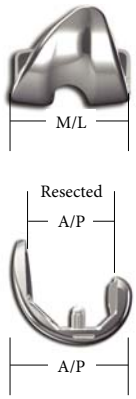
Appendix 2

Scorpio NRG Sizing Guide

Femoral Component	Tibial Tray	Tibial Insert	PS Notch & Compactor
3	3, 4	3	3/5
	5, 6	5	3/5
4	3, 4	3	3/5
	5, 6	5	3/5
5	3, 4	3	3/5
	5, 6	5	3/5
	7	7	3/5
6	5, 6	5	7/9
	7	7	7/9
7	5, 6	5	7/9
	7	7	7/9
	9	9	7/9
8	7	7	7/9
	9	9	7/9
9	7	7	7/9
	9	9	7/9
	11, 13	11	7/9
11	9	9	11/13
	11, 13	11	11/13
13	11, 13	11	11/13

Tibial Component	Tibial Tray Punch	IC Notch (mm)
3	3/5	18
4	3/5	18
5	3/5	18
6	3/5	20.1
7	7/9	20.1
9	7/9	20.1
11	11/13	22.3
13	11/13	22.3

Appendix 3



Scorpio NRG PS Femoral Component

Catalog # Left Knee	Catalog # Right Knee	Size	A/P	M/L	Resected A/P	
81-4403L	81-4403R	#3	51mm	57mm	35mm	Non-LFIT Waffle w/Lugs
81-4404L	81-4404R	#4	54mm	60mm	37mm	
81-4405L	81-4405R	#5	56mm	62mm	39mm	
81-4406L	81-4406R	#6	58mm	65mm	42mm	
81-4407L	81-4407R	#7	61mm	67mm	44mm	
81-4408L	81-4408R	#8	63mm	70mm	46mm	
81-4409L	81-4409R	#9	65mm	72mm	49mm	
81-4411L	81-4411R	#11	70mm	77mm	53mm	
81-4413L	81-4413R	#13	75mm	82mm	58mm	

Scorpio NRG PS Tibial Insert - N2Vac

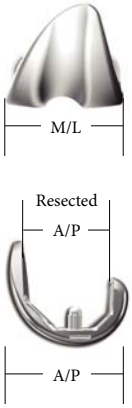
Catalog # Size #3	Catalog # Size #5	Catalog # Size #7	Catalog # Size #9	Catalog # Size #11	Thickness
82-3-0308	82-3-0508	82-3-0708	82-3-0908	82-3-1108	8mm
82-3-0310	82-3-0510	82-3-0710	82-3-0910	82-3-1110	10mm
82-3-0312	82-3-0512	82-3-0712	82-3-0912	82-3-1112	12mm
82-3-0315	82-3-0515	82-3-0715	82-3-0915	82-3-1115	15mm
82-3-0318	82-3-0518	82-3-0718	82-3-0918	82-3-1118	18mm
82-3-0321	82-3-0521	82-3-0721	82-3-0921	82-3-1121	21mm
82-3-0324	82-3-0524	82-3-0724	82-3-0924	82-3-1124	24mm

Scorpio NRG PS Tibial Insert - X3

Catalog # Size #3	Catalog # Size #5	Catalog # Size #7	Catalog # Size #9	Catalog # Size #11	Thickness
82-7-0308	82-7-0508	82-7-0708	82-7-0908	82-7-1108	8mm
82-7-0310	82-7-0510	82-7-0710	82-7-0910	82-7-1110	10mm
82-7-0312	82-7-0512	82-7-0712	82-7-0912	82-7-1112	12mm
82-7-0315	82-7-0515	82-7-0715	82-7-0915	82-7-1115	15mm
82-7-0318	82-7-0518	82-7-0718	82-7-0918	82-7-1118	18mm
82-7-0321	82-7-0521	82-7-0721	82-7-0921	82-7-1121	21mm
82-7-0324	82-7-0524	82-7-0724	82-7-0924	82-7-1124	24mm

Appendix 4

Scorpio NRG CR Femoral Component



Catalog # Left Knee	Catalog # Right Knee	Size	A/P	M/L	Resected A/P	
80-4403L	80-4403R	#3	51mm	57mm	35mm	Non-LFIT Waffle w/Lugs
80-4404L	80-4404R	#4	53mm	60mm	37mm	
80-4405L	80-4405R	#5	55mm	62mm	39mm	
80-4406L	80-4406R	#6	57mm	65mm	42mm	
80-4407L	80-4407R	#7	60mm	67mm	44mm	
80-4408L	80-4408R	#8	62mm	70mm	46mm	
80-4409L	80-4409R	#9	64mm	72mm	49mm	
80-4411L	80-4411R	#11	69mm	77mm	53mm	
80-4413L	80-4413R	#13	74mm	82mm	58mm	

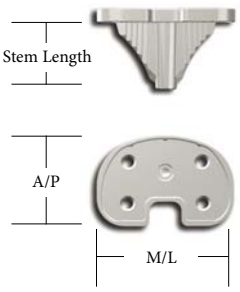
Scorpio NRG CR Tibial Insert - N2Vac

Catalog # Size #3	Catalog # Size #5	Catalog # Size #7	Catalog # Size #9	Catalog # Size #11	Thickness
82-2-0308	82-2-0508	82-2-0708	82-2-0908	82-2-1108	8mm
82-2-0310	82-2-0510	82-2-0710	82-2-0910	82-2-1110	10mm
82-2-0312	82-2-0512	82-2-0712	82-2-0912	82-2-1112	12mm
82-2-0315	82-2-0515	82-2-0715	82-2-0915	82-2-1115	15mm
82-2-0318	82-2-0518	82-2-0718	82-2-0918	82-2-1118	18mm
82-2-0321	82-2-0521	82-2-0721	82-2-0921	82-2-1121	21mm
82-2-0324	82-2-0524	82-2-0724	82-2-0924	82-2-1124	24mm

Scorpio NRG CR Tibial Insert - X3

Catalog # Size #3	Catalog # Size #5	Catalog # Size #7	Catalog # Size #9	Catalog # Size #11	Thickness
82-6-0308	82-6-0508	82-6-0708	82-6-0908	82-6-1108	8mm
82-6-0310	82-6-0510	82-6-0710	82-6-0910	82-6-1110	10mm
82-6-0312	82-6-0512	82-6-0712	82-6-0912	82-6-1112	12mm
82-6-0315	82-6-0515	82-6-0715	82-6-0915	82-6-1115	15mm
82-6-0318	82-6-0518	82-6-0718	82-6-0918	82-6-1118	18mm
82-6-0321	82-6-0521	82-6-0721	82-6-0921	82-6-1121	21mm
82-6-0324	82-6-0524	82-6-0724	82-6-0924	82-6-1124	24mm

Appendix 5



Tibial Component Baseplate

Deltafit Series PA with Screw Holes	Deltafit Series Microstructured with Screw Holes	Deltafit Series 7000 Waffle No Screw Holes	Size	A/P	M/L	Stem
7145-0003	7125-0003	7115-0003	#3	40mm	61mm	30mm
	7125-0004	7115-0004	#4	42mm	63mm	30mm
7145-0005	7125-0005	7115-0005	#5	44mm	66mm	30mm
	7125-0006	7115-0006	#6	45mm	68mm	30mm
7145-0007	7125-0007	7115-0007	#7	47mm	71mm	35mm
7145-0009	7125-0009	7115-0009	#9	51mm	77mm	35mm
7145-0011	7125-0011	7115-0011	#11	54mm	82mm	40mm
7145-0013	7125-0013	7115-0013	#13	58mm	88mm	40mm
Use screw 2030-6530-1 2030-6535-1	Use screw 2030-6530-1 2030-6535-1					

Patella Component - N2Vac

Scorpio Medialized Dome Patella	Scorpio Concentric Dome Patella	Size	S/I*	M/L	Thickness
73-0510	73-2510	#5	32mm	35mm	10mm
73-0710	73-2710	#7	34mm	38mm	10mm
73-0910	73-2910	#9	36mm	41mm	10mm
73-0110	73-2110	#11	38mm	44mm	10mm

Patella Component - N2Vac

Universal Dome Patella	Size	Dia.	Thickness
73-3308	#3	30mm	8mm
73-3508	#5	32mm	8mm
73-3708	#7	34mm	8mm
73-3710	#7	34mm	10mm
73-3910	#9	36mm	10mm
73-3110	#11	38mm	10mm

Patella Component - X3

Scorpio Medialized Dome Patella	Scorpio Concentric Dome Patella	Size	S/I*	M/L	Thickness
73-20-0510	73-20-2510	#5	32mm	35mm	10mm
73-20-0710	73-20-2710	#7	34mm	38mm	10mm
73-20-0910	73-20-2910	#9	36mm	41mm	10mm
73-20-0110	73-20-2110	#11	38mm	44mm	10mm

Patella Component - X3

Universal Dome Patella	Size	Dia.	Thickness
73-20-3308	#3	30mm	8mm
73-20-3508	#5	32mm	8mm
73-20-3708	#7	34mm	8mm
73-20-3710	#7	34mm	10mm
73-20-3910	#9	36mm	10mm
73-20-3110	#11	38mm	10mm

*S/I = Superior/Inferior

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.

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.

Warnings and Precautions:

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

Notes

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