b-ONE ORTHO



MOBIO™

Total Knee System

All in ONE

SURGICAL TECHNIQUE

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INTRODUCTION

The **MOBIO**™ All-in-ONE Total Knee System is an evolution of the most successful and clinically-proven prosthetic designs in primary total knee reconstruction. Inspired by the core motivation to develop an inclusive system with the best features to ultimately improve patient satisfaction, a team of renowned surgeons, top engineers, and accomplished scientists came together to develop the **MOBIO**™ All-in-ONE Total Knee System. The following design goals were established:

- focus on kinematic design and anatomic design;
- provide premium materials and design to advance implant performance and durability;
- ensure intraoperative flexibility to reduce compromise;
- enhance OR efficiency with intuitive, streamlined instrumentation.

Successful total knee replacement depends on several factors, including, but not limited to, appropriate prosthesis selection, the re-establishment of neutral alignment of the leg, proper implant orientation, secure implant fixation to bone, and soft tissue balancing. The **MOBIO**™ Total Knee System is designed to help surgeons achieve these goals through its wide range implant options and intuitive, streamlined instrumentation.

The key design features of the **MOBIO**™ Total Knee System are:

- BalanSEE™ single radius design with equal distal and posterior femoral resection to promote ligament isometry and balanced resurfacing;
- Kinematic patellofemoral design;
- Open, shallow PS box tiered to femoral size to conserve bone;
- Multiple constraint options without the need for additional bone resection;
- Extensive range of tibiofemoral compatibility to allow for better patient fit;
- Robust omnidirectional tibial insert locking mechanism;
- Vitamin E highly crosslinked polyethylene/Standard UHMWPE.



SYSTEM OVERVIEW

The **MOBIO**™ Total Knee System offers extensive sizing options to optimize fit and soft tissue balancing:

- 15 Femur sizes, including ten Standard Widths and five Narrow Widths for core sizes 3 through 7;
- 9 Tibial Baseplate Sizes;
- PS and PS PLUS Tibial Inserts in 8 thicknesses ranging from 9-25mm;
- 6 Patella sizes;
- Optional femoral pegs for additional femoral fixation.

Refer to Appendix D for sizing compatibility.

MOBIO™ femoral implants and femoral peg implants are cast CoCr alloy. Tibial Baseplates are composed of Titanium (Ti-6Al-4V) alloy, and all size of polyethylene components are provided in 2 materials options: Vitamin E highly crosslinked polyethylene and Standard UHMWPE. All components are indicated for cemented use only.

TKS instrumentation is offered in both posterior referencing (PR) and anterior referencing (AR) platforms. Be sure to confirm instrument availability prior to surgery.

CONSTRAINT OPTIONS

The **MOBIO**™ Total Knee System currently offers two bearing options with different degrees of constraint. The PS Tibial Insert and the PS PLUS (PS+) Tibial Insert can be used when the PCL is deficient, absent, or removed, and are compatible with the cemented **MOBIO**™ Primary Tibial Baseplate and the cemented **MOBIO**™ PS Femoral Component.

The PS Tibial Insert can be used for moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.

The PS PLUS (PS+) Tibial Inserts have a wider taller post than the PS Tibial Inserts and are indicated when increased constraint is required due to ligamentous instability and/or severe anteroposterior instability. The PS PLUS Tibial Inserts are designed to provide +/- 3.5 degrees of varus/valgus constraint and +/- 5 degrees of internal/external rotational constraint.

When greater varus/valgus constraint is needed and/or stems or augments are required, the surgeon should consider using a revision implant system.

The constraint of the bearing can be planned based on surgeon preference and patient requirements depending on the degree of the deformity, the stability of the ligaments, and the quality of the bone. The surgeon is responsible for assessing whether a more constraining implant/system or revision implant/ system is necessary.

Please refer to the package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.



PS UHMWPE | PS HXLPE VE | PS PLUS UHMWPE | PS PLUS HXLPE VE

INDICATIONS

The **MOBIO**™ Total Knee System is intended for total knee arthroplasty due to the following conditions:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), 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.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture- management techniques.

Additional indications for Posterior Stabilized (PS) and Posterior Stabilized Plus (PS+) components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or nonfunctioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.

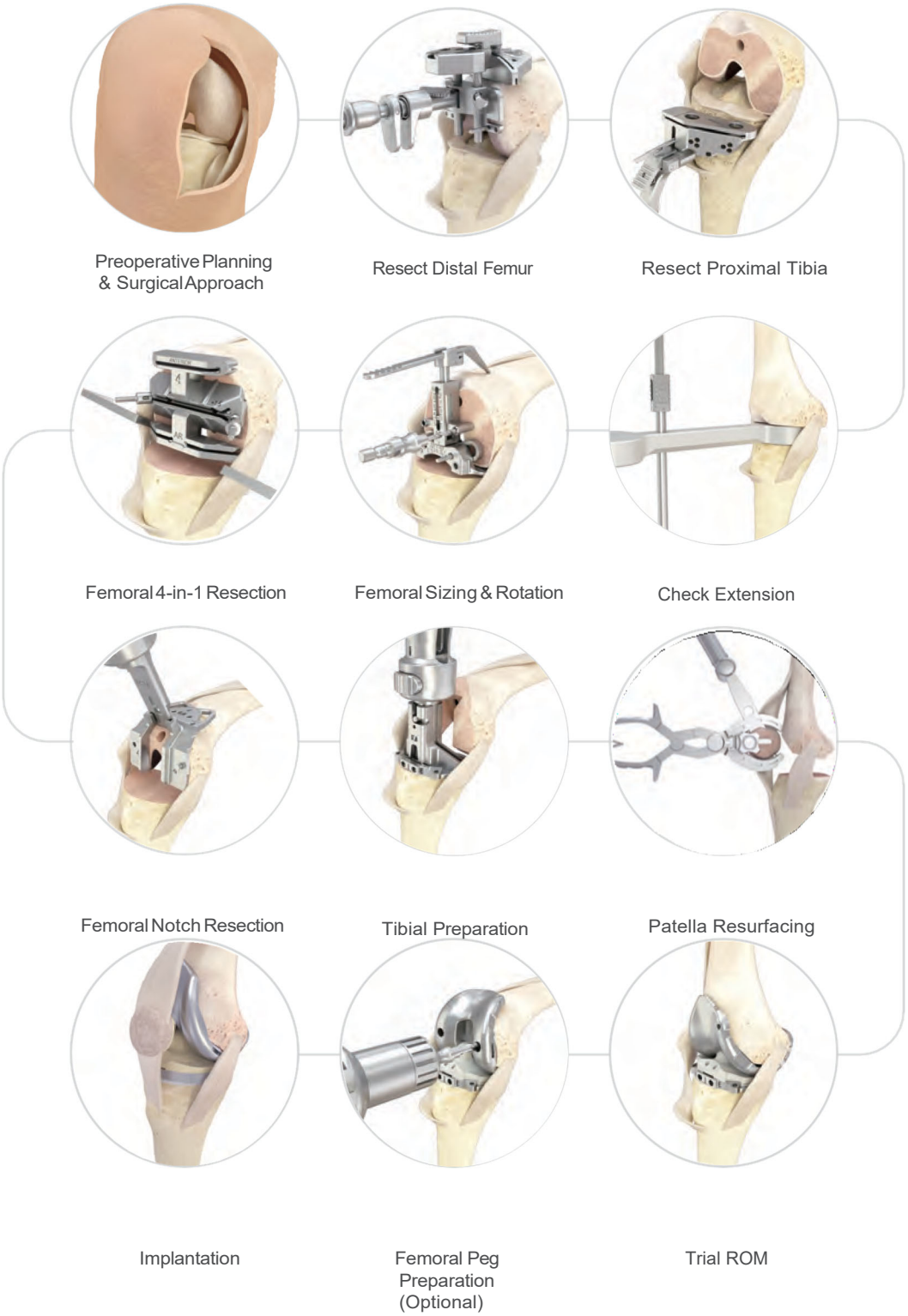
The **MOBIO**™ Total Knee System is intended for implantation with bone cement only.
MOBIO™ Total Knee System components are not intended for use with other knee systems.

CONTRAINDICATIONS

- Any active or suspected latent infection of the knee joint, or distant foci of infection, or any systemic infection.
- Allergy or foreign body sensitivity to any of the implants materials.
- Skeletal immaturity.
- Any conditions which may prevent adequate fixation or support and thus preclude the use of these or any other orthopedic implants, such as severe osteoporosis or osteopenia, osteomalacia or any metabolic disorders which may impair bone formation, vascular insufficiency, muscular atrophy, neuromuscular disease, and/or incomplete or deficient soft tissue surrounding the knee.
- Conditions that may place excessive stresses on bone and implants, such as obesity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Use in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and instructions.
- Any condition not described in the Indications for Use.

Please refer to the package insert for complete product information, including contraindications, warnings, precautions, and adverse effects.

Surgical Steps



Fixation Pin Chart

Pin/Screw	Description/Part Number	Compatible Driver
	**Fluted Pin** 8829012002/8829012000	 **OR**  **Pin Driver** 8829011000 **Pin Puller** 8829003000
	**Threaded Headless Pin** 8829005001/8829005000	 **Pin Driver** 8829011000
	**Tension Screw** 8829004000	 **Pin Driver** 8829011000
	**Headed Screw, 22mm** 8829016220 **Headed Screw, 32mm** 8829016320	 **Pin Driver** 8829011000
	**Headed Pin, 25mm** 8829006025/8829006250 **Headed Pin, 35mm** 8829006035/8829006350	 **Pin Puller** 8829003000

Note

All pins/screws are 3.2mm diameter. Screws are provided non-sterile and pins are provided non-sterile or sterile within the instrumentation set.

Preoperative Planning

Obtain standing (weight-bearing) anteroposterior and lateral radiographs of the operative leg, as well as a sunrise view of the patella. It is important to visualize the entire femur in order to rule out any structural anatomic abnormalities or implants from prior surgeries. The instrumentation in this technique uses an intramedullary rod in the femur to determine the distal femoral resection. Measure the angle between the anatomic axis of the femur and the mechanical axis. This angle will be reproduced intraoperatively when preparing the valgus angle for femoral alignment. Preoperative determination of this measurement helps the surgeon ensure that the distal femur will be cut perpendicular to the mechanical axis and parallel to the resected surface of the proximal tibia. Use the **MOBIO**™ Total Knee System X-ray templates (b1LIT-00018 and b1LIT-00019) to determine the anticipated size of the implant components.

Surgical Approach

The **MOBIO**™ Total Knee System instrumentation is suitable for standard total knee replacement techniques. The surgeon can use a midvastus approach, a subvastus approach, or a parapatellar medial arthrotomy. Depending on surgeon preference, the patella can be either everted or subluxed. The femur, tibia, and patella are prepared independently, and can be resected in the surgeon s preferred sequence.

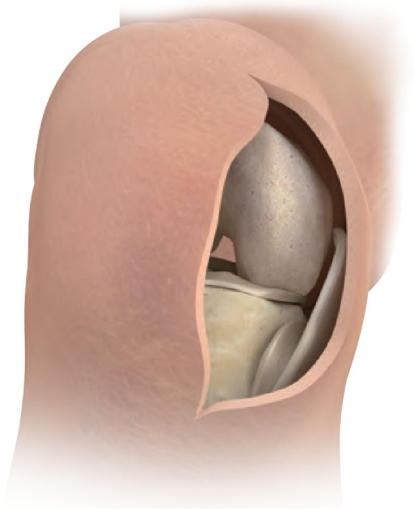


Figure 1

Distal Femoral Resection

Drill IM Canal

Flex the knee to access the distal femur and locate the entry point to the femoral intramedullary (IM) canal. Typically, the entry point is approximately 1cm anterior to the femoral attachment of the posterior cruciate ligament (PCL) and slightly medial to the mid-line of the distal femur. Firmly place the sharp tip of the 9mm IM Drill on the entry point location so that the drill will not slip when in use. Alternatively, use a small awl to create a starter hole. Drill the canal using the 9mm IM drill. Use suction to remove the intramedullarycontents.

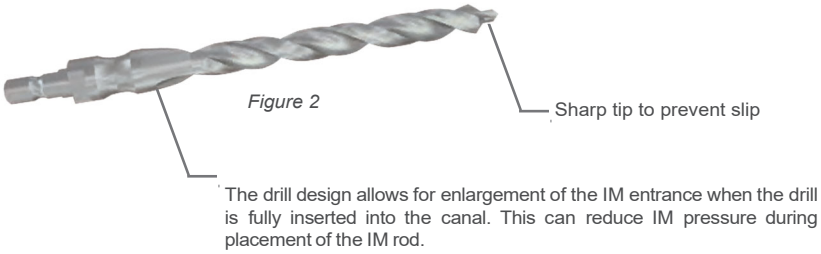


Figure 2

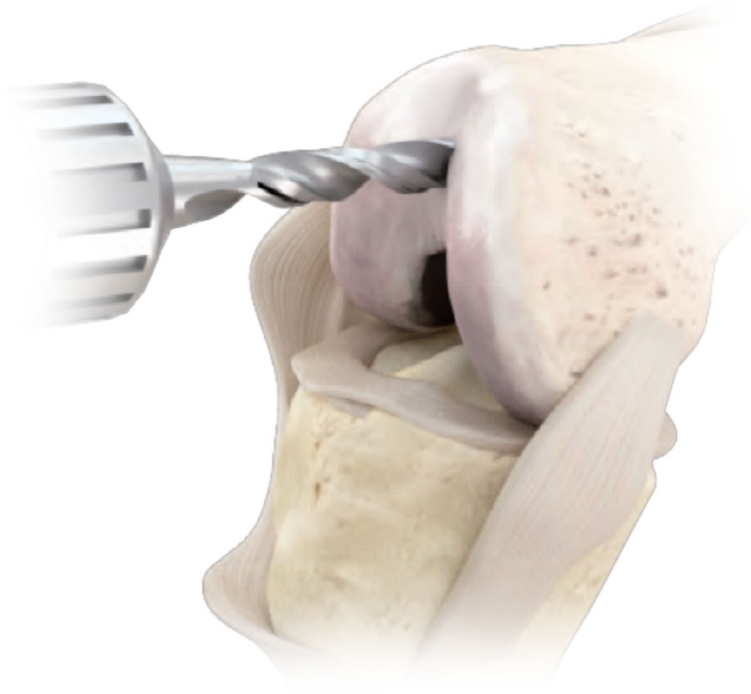


Figure 3

Distal Femoral Resection

Distal Femoral Alignment Guide Assembly

Assemble the IM Rod to the T-Handle. Pull the T-Handle collet while connecting the IM Rod and release to lock. Slide the Distal Femoral Alignment Guide over the IM Rod, trigger first, so that the flat face of the guide is facing away from the T-Handle. Squeeze the valgus trigger to release the lock on the valgus scale, and swivel the scale to set the valgus angle to the appropriate laterality and desired degree. The central tooth on the top of the trigger aligns with the set valgus angle of the Distal Femoral Alignment Guide, which allows 0^0 - 9^0 in 1 degree increments.

Connect the Distal Resection Block to the Adjustable Distal Resection Guide Tower by inserting the peg into the connection hole on the block while pressing the capture button. Release the button to capture the block. Insert the two posts of the Guide Tower into the Distal Femoral Alignment Guide. Tighten the locking knob to secure the tower.

Note

The Distal Femoral Alignment Guide/IM Rod assembly can be inserted into the femoral canal prior to placing the Adjustable Distal Resection Guide Tower/DRB assembly onto the guide if preferred.

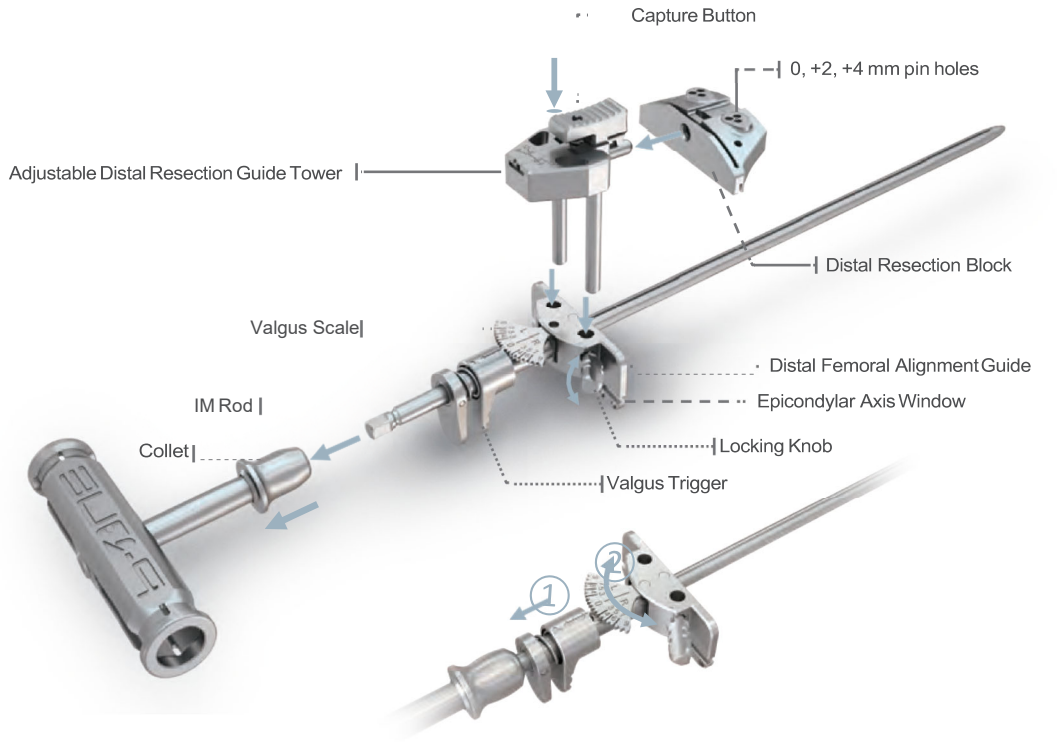


Figure 4

Distal Femoral Resection

Set Distal Resection

The standard distal femoral resection for the **MOBIO**™ TKS is 9mm. If necessary, the Adjustable Distal Resection Guide Tower allows the resection to be adjusted to 8, 9, 10, or 11mm prior to cutting. Move the Slide to align the centerline with the desired resection amount, indicated by the scale on the tower. There is a small prominence on the slide to allow deliberate resection adjustment.

Additionally, the **MOBIO**™ Distal Resection Block provides +2mm and +4mm adjustment pin holes.

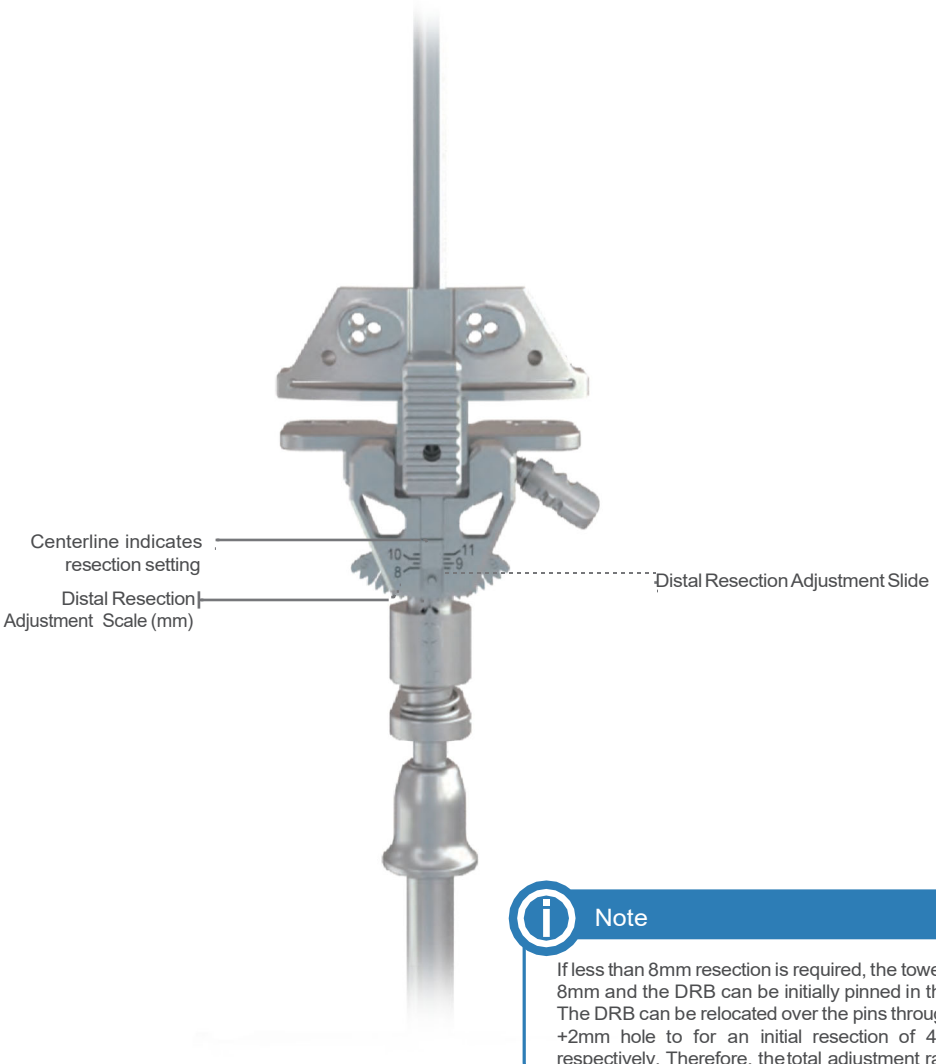


Figure 5

Note

If less than 8mm resection is required, the tower can be set to 8mm and the DRB can be initially pinned in the +4mm hole. The DRB can be relocated over the pins through the 0mm or +2mm hole to for an initial resection of 4mm or 6mm, respectively. Therefore, the total adjustment range capability of the system is 4-15mm.

Distal Femoral Resection

Resect Distal Femur

The Epicondylar Guide can be used to visualize the epicondylar axis prior to inserting the Distal Femoral Alignment Guide. The axis can be marked on the bone through the windows in the guide.



Figure 6

Slowly advance the IM Rod assembled to the Distal Femoral Alignment Guide into the femoral canal far enough to ensure the anatomic axis is replicated by the guide. Slide the Distal Femoral Alignment Guide against the femur so that it is flush with the most prominent distal femoral condyle. The epicondylar axis can be visualized through the epicondylar axis windows on the guide and should align with the epicondylar axis marking on bone.

Check the valgus setting on the guide is correct. Once confirmed, the guide can be stabilized by pinning the face of the guide to the distal femur with a fluted pin (Figure 7).

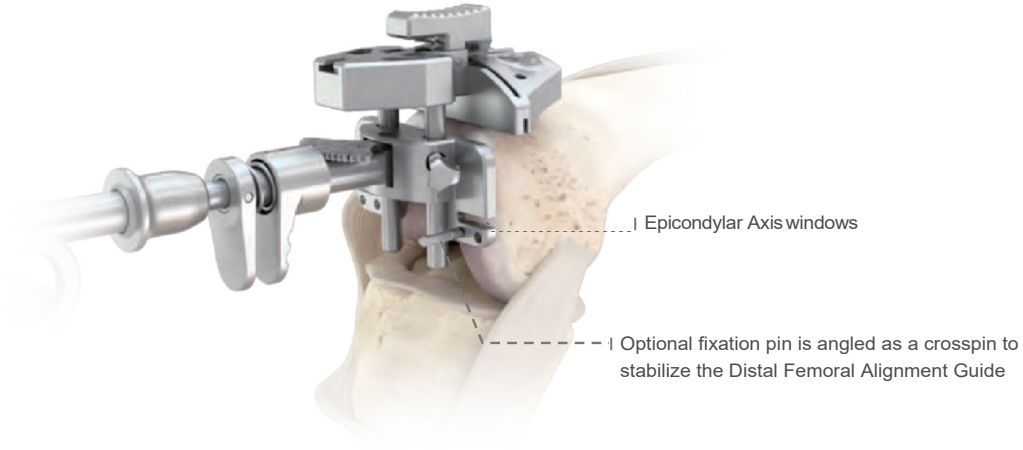


Figure 7



Figure 8

Confirm the distal resection setting is correct. Ensure the face of the Distal Femoral Alignment Guide is flush with at least one distal femoral condyle, then insert two fluted pins through the 0mm holes on the Distal Resection Block to pin the block to the anterior cortex of the femur.

Distal Femoral Resection

Resect Distal Femur *continued*

Remove the Distal Femoral Alignment Guide assembly to leave the Distal Resection Block pinned to the anterior cortex of the femur by pressing the capture button on the Tower (Figure 9, step 1) and pulling the guide axially to disengage (Figure 9, step 2). If any fixation pins were used to stabilize the guide to the distal femur, be sure to remove these prior to removing the assembly.

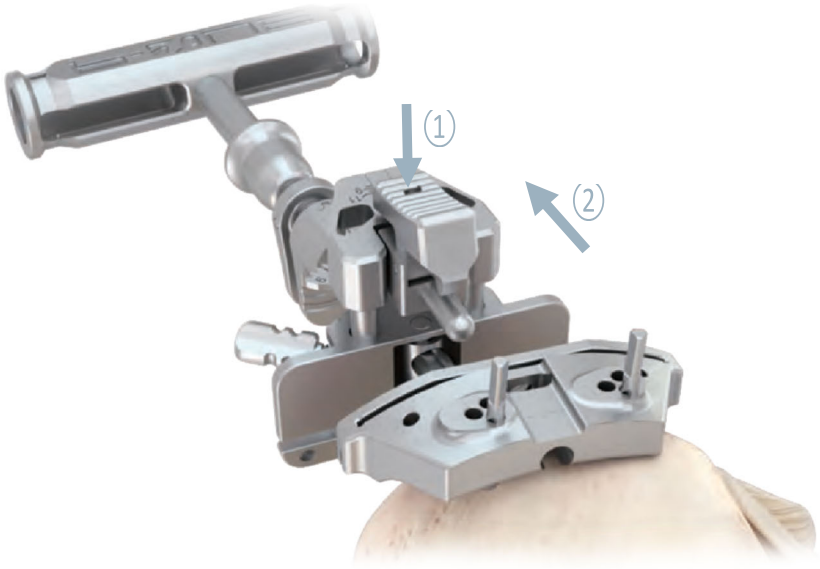
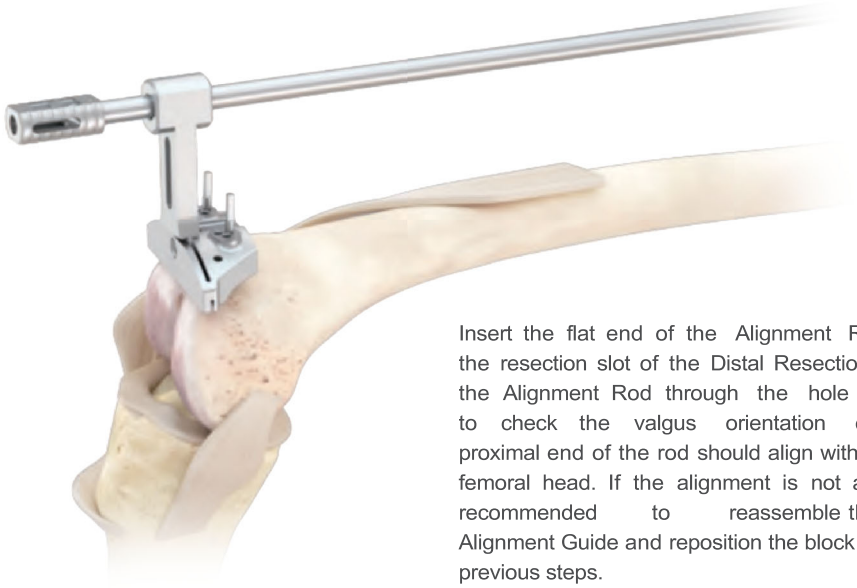


Figure 9



Insert the flat end of the Alignment Rod Adapter into the resection slot of the Distal Resection Block and slide the Alignment Rod through the hole in the Adapter to check the valgus orientation of the block. The proximal end of the rod should align with the center of the femoral head. If the alignment is not accurate, it is recommended to reassemble the Distal Femoral Alignment Guide and reposition the block as outlined in the previous steps.

Figure 10

Distal Femoral Resection

Resect Distal Femur

Use the Angel Wing through the resection slot to visualize the amount of distal femoral bone to be resected. If more bone removal is required, reposition the block by sliding it over the two fluted pins through the +2mm or +4mm holes for an additional 2 or 4mm of bone resection, respectively.

If the preoperative plan requires less than the standard bone resection, place the fluted pins through the +2mm or +4mm hole initially. Then move the resection block to the 0mm hole to achieve a -2mm or -4mm resection, respectively.

Once the appropriate resection is confirmed, insert a third fluted pin through the angled fixation hole to stabilize the block.

Tip

The Angel Wing is double sided and provides a long wing for ease of use on the femur.

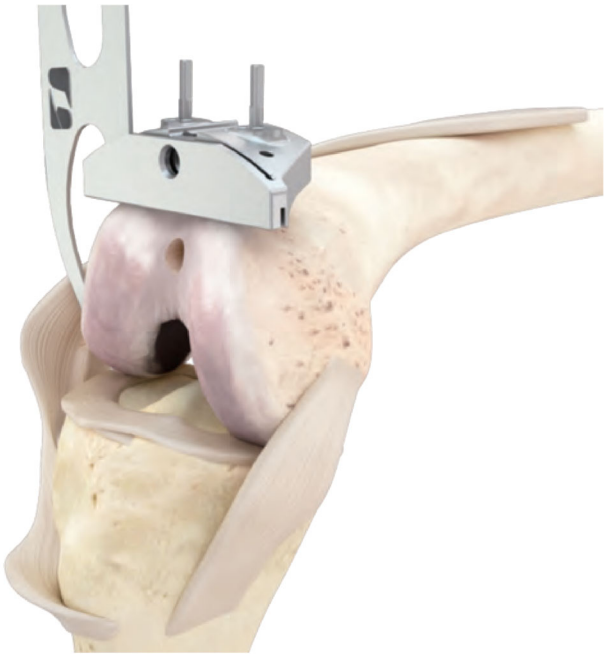


Figure 11

0mm hole



Figure 12a

+2mm hole



Figure 12b

+4mm hole



Figure 12c

Distal Femoral Resection

Resect Distal Femur

Use a 1.27mm (0.050in) oscillating saw blade through the captured slot on the Distal Resection Block to resect the distal femur. Protect the surrounding soft tissues.

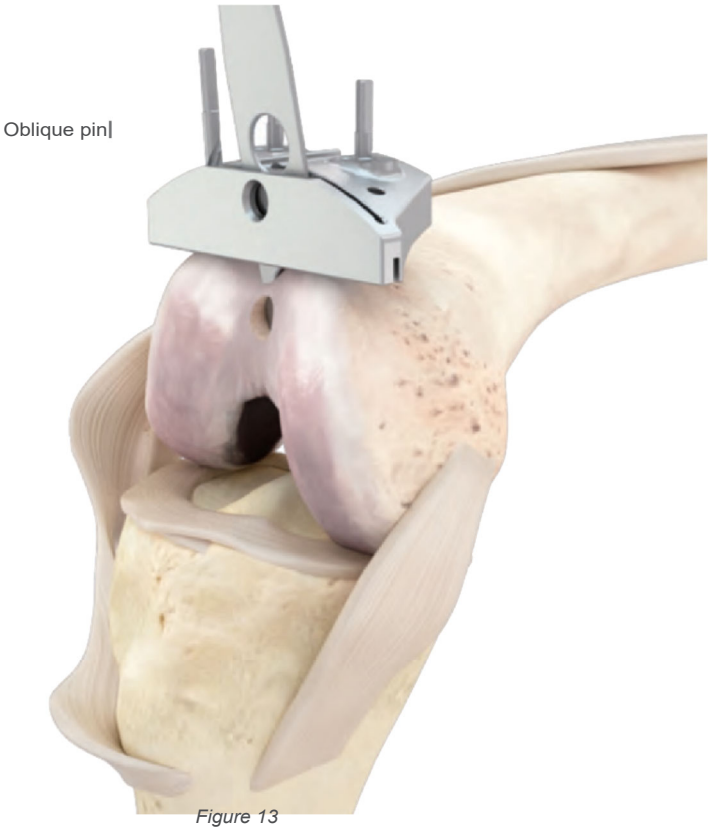


Figure 13

Alternatively, the bone resection can be made from the distal surface of the Distal Resection Guide instead of through the capture slot. The distal surface of the guide is 4mm from the capture slot, therefore if this technique is preferred, the guide must be repositioned to resect the desired amount of bone. Prior to inserting the oblique fixation pin, move the guide from the two fluted pins through the 0mm holes and reinsert the guide over the two pins through the +4mm holes. Insert a third fluted pin through the oblique hole to stabilize the guide. Resect the bone on the most distal surface of the guide using a 1.27mm (0.050in) oscillating saw blade. Protect the surrounding soft tissue.

Once bone resection is complete, remove the pins and the Distal Resection Guide. Ensure the bone cut is flat.

Proximal Tibial Resection

EM Tibial Alignment Guide Overview

The **MOBIO™** TKS offers two styles of Extramedullary (EM) Tibial Alignment Guides (TAGs). The surgeon may choose either the Non-Spiked or Spiked style according to preference. For tibial resection using the Spiked EM TAG, refer to **Appendix B**.



Figure 14a



Figure 14b

Proximal Tibial Resection: Non-Spiked EM TAG

Instrument Assembly

To assemble the Non-Spiked EM TAG Assembly, choose either the Ankle Clamp or Ankle Rest per surgeon preference. Slide the selected option onto the rail on the distal end of the EM TAG Base. Secure by tightening the varus/valgus adjustment knob. Slide the Non-Spiked Uprod into the proximal end of the EM TAG Base and secure by tightening the EM TAG height adjustment knob.

Attach the Tibial Resection Block (Left or Right, 0^0, 3^0 or 5^0 posterior slope) to the EM TAG Non-Spiked Uprod by pressing the button at the proximal end of the Uprod while sliding the two pegs into the two connector holes on the Tibial Resection Block. Release the button to capture the Tibial Resection Block. Confirm the block is locked to Non-Spiked Uprod.

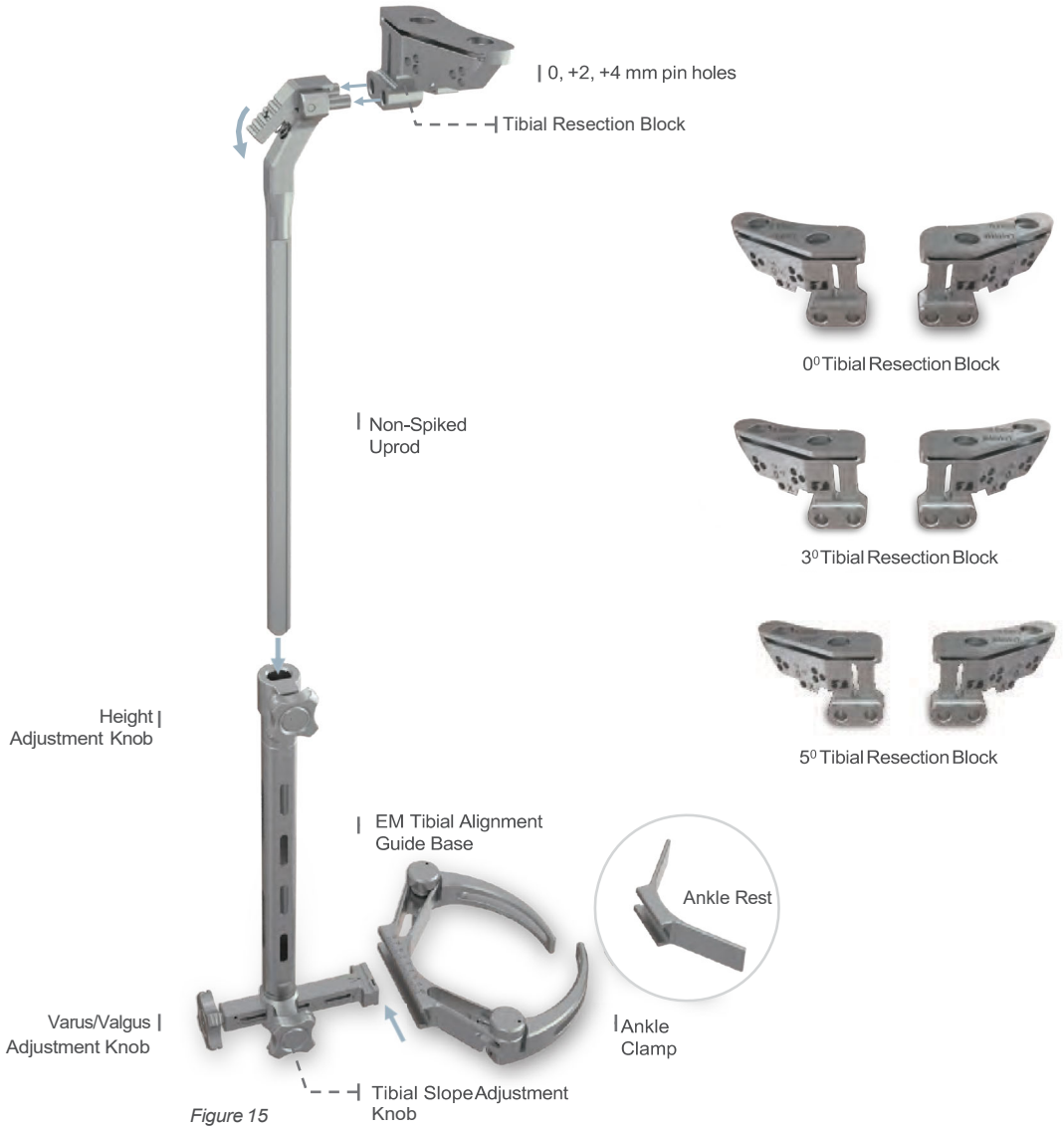


Figure 15

Proximal Tibial Resection: Non-Spiked EM TAG

Establish Tibial Alignment

Ensure adequate exposure of the tibial surface by flexing the knee and retracting the tibia anteriorly. The goal is to align the EM TAG with the mechanical axis of the tibia. Adjust the EM TAG to the approximate length of the tibia. Proximally, the guide should align over the medial third of the tibial tubercle, and distally, the guide should be positioned over the second toe. If using the EM TAG Ankle Clamp, place the arms of the Ankle Clamp around the ankle, proximal to the malleoli.



Figure 16

Tip

The **MOBIO™** TKS is equipped with a Torque Knob that can be placed over the system's locking knobs to facilitate final tightening if needed.



Figure 17

Position the Tibial Resection Block (TRB) to the approximate desired location, proximal to the tibial tubercle. Align the vertical slot in the TRB with the medial third of the tibial tubercle. The engraved line on the top of the TRB can also be used to align the block in the M/L position and should align with the intercondylar eminence.

Insert a fluted pin through the 12mm vertical slot on the TRB to set the desired medial/lateral position of the block and provide stability to the guide while making final adjustments. The block will be able to move distally and/or proximally within the range of the slot.

Proximal Tibial Resection: Non-Spiked EM TAG

Establish Tibial Alignment

With the varus/valgus adjustment knob in the loose position, slide the EM TAG Base so that the guide is aligned with the long axis of the tibia. This will typically position the EM TAG Base over the second metatarsal, or approximately 5-10mm medial to the midpoint between the maleoli. The markings on the ankle clamp indicate 1mm increments.



Figure 18

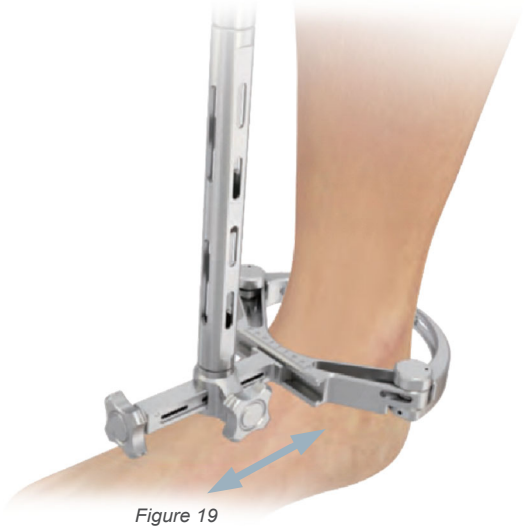


Figure 19

Adjust the EM TAG in the sagittal plane by loosening the tibial slope adjustment knob at the base of the guide and slide the base of the guide to the appropriate position. The goal is to align the long axis of the EM TAG so that the posterior slope of the resection will be parallel with the tibial surface or so that it provides the desired posterior slope. It is recommended to achieve 3 degrees of posterior slope in the tibial cut for the **MOBIO**™ PS or PS PLUS construct. Note that tibial bowing or excess soft tissue may make external referencing unreliable.

Proximal Tibial Resection: Non-Spiked EM TAG

Set Tibial Resection Level

Place the Tibial Resection Stylus, 2/9 into the hole on the top surface of the TRB. The stylus is designed with a magnetic lock for easy and secure assembly to the block. Each tip of the stylus is labeled according to the corresponding resection level. The 2mm tip is used to establish the resection level from the most affected side of the tibial plateau for a minimal resection. The 9mm tip is used to establish the resection level from the least affected side of the tibial plateau.

Place the 2mm tip of the stylus on the lowest point of the affected side of the tibia, or place the 9mm tip on the lowest point of the less affected side. After determining the amount of resection, securely tighten the height adjustment knob on the EM TAG. Remove the Stylus. Insert two fluted pins into the 0mm holes of the TRB to secure it to the proximal tibia. Use the Angel Wing through the resection slot of the TRB to visualize the bone resection.

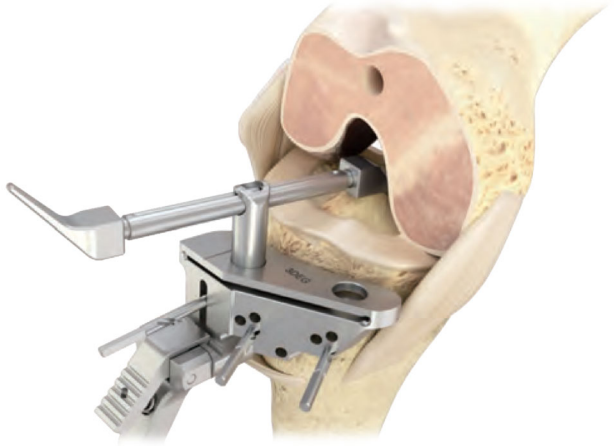


Figure 20

To confirm the alignment of the TRB, insert the Alignment Rod Adapter into the resection slot of the TRB, and slide the Alignment Rod through the circular hole on the Adapter. Confirm varus/valgus and posterior slope. If adjustment is needed, remove the pins and adjust accordingly.

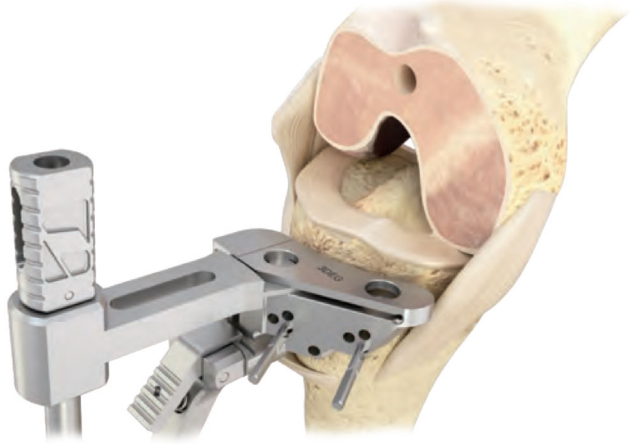


Figure 21

Proximal Tibial Resection: Non-Spiked EM TAG

Resect Proximal Tibia

The EM TAG can be removed to proceed with resection. Alternatively, the EM TAG can be left in place for additional stability during resection if desired.

To remove the EM TAG, press the button at the proximal end of the guide to disengage from the TRB. Remove the EM TAG. Check the final position of the TRB using the Alignment Rod and Adapter to ensure the block did not move. Use the Angel Wing through the TRB resection slot to visualize the bone resection.

If the EM TAG has been removed, an additional 2mm or 4mm adjustment to the original resection level can be made by repositioning TRB over the fluted pins through the sets of holes marked
+2 or +4, respectively. If a pin or screw was inserted into the 12mm vertical slot, it must be removed prior to shifting the TRB.

Once the final resection level is confirmed, insert a fluted pin into the oblique hole of the TRB for additional stability.

Tip

The Angel Wing is double sided and provides a short wing for ease of use on the tibia.



Figure 22

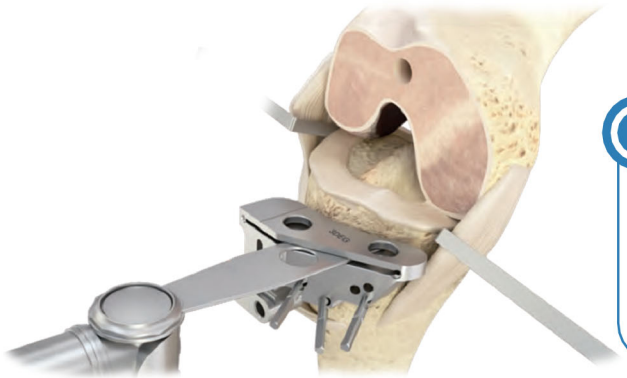


Figure 23

Tip

If desired, the resection can be made from the top surface of the TRB instead of through the captured resection slot. The top surface is 4mm above the resection slot, so the TRB must be shifted to the
+4mm holes (from the 0mm holes) to maintain the desired resection level.

Use a 1.27mm (0.050in) thick oscillating saw blade to resect the proximal tibia through the resection slot of the TRB.

After resection, check the flatness of the cut. Upon satisfactory completion of the cut, remove the pins and TRB.

Check Extension

To check the extension gap, fully extend the leg and place the appropriate size Spacer Block between the resected distal femur and proximal tibia surfaces. The Spacer Block represents the total combined thickness of the baseplate, insert, and femoral component. The labeled size refers to the corresponding insert thickness. For example, a 9mm spacer block represents the total construct thickness of a baseplate, femoral component, and 9mm insert.

To assess the alignment, assemble the Alignment Rod with Coupler and slide through the hole in the Spacer Block handle, from proximal to distal, as shown in the image. The coupled Alignment Rods should align with the mechanical axis of the femur.

If the extension gap is not balanced, assess the soft tissues and the resection planes. Determine if additional resection is needed to achieve a balanced extension gap.



Figure 24

Note

The **MOBIO™** Total Knee System has a minimum tibial insert thickness of 9 mm. The thickness of the tibial insert indicated by the Spacer Block is for reference only, and the final thickness of the tibial insert will be determined by final trialing.

Femoral Sizing and Rotation

PR Sizing and Rotation Guide Overview

The **MOBIO**™ TKS offers both posterior referencing instrumentation and anterior referencing instrumentation. These instrumentation sets are provided separately and must be ordered prior to surgery, according to surgeon preference. Confirm instrumentation availability prior to surgery.

This technique describes the posterior referencing instrumentation. For anterior referencing, refer to **Appendix A**.

PR Sizer and Rotation Guide

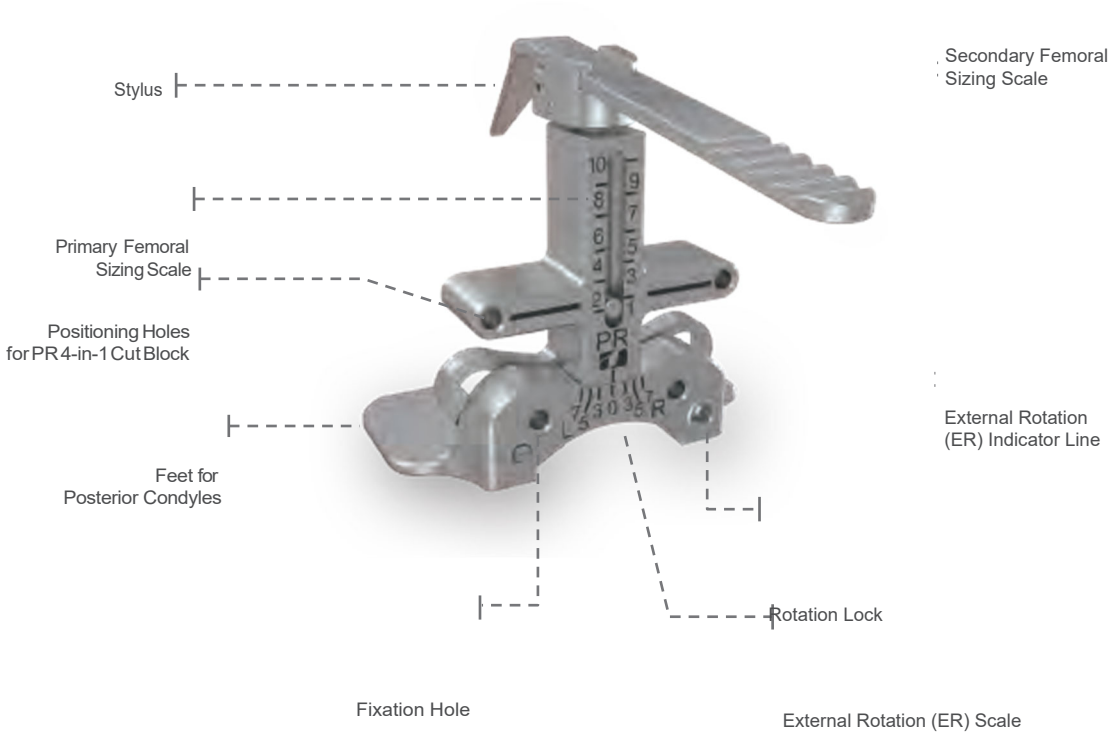


Figure 25

Tip

Posterior Referencing uses the posterior condyles to set the A/P placement of the femoral component. The **MOBIO**™ PR SIzer and Rotation Guide sets the position of the femoral component by setting the A/P placement of the PR 4-in-1 Cut Block through the Positioning Holes, which are a fixed position from the posterior condyles regardless of femoral size. The anterior resection is variable. The A/P dimension of the **MOBIO**™ femoral prosthesis changes 3mm per size.

Femoral Sizing and Rotation (PR)

PR Sizing and Rotation Guide Placement

Place the PR Sizer & Rotation Guide so that it is flush against the resected surface of the distal femur and the posterior feet are flush against the posterior femoral condyles (Figure 26). Center the guide mediolaterally. If necessary, insert a headed screw or pin into one or both of the Fixation Holes on the posterior aspect of the guide to draw the guide flush with the resected surface and to provide additional stability.

Use a headed screw or pin to ensure the guide is flush and stable.

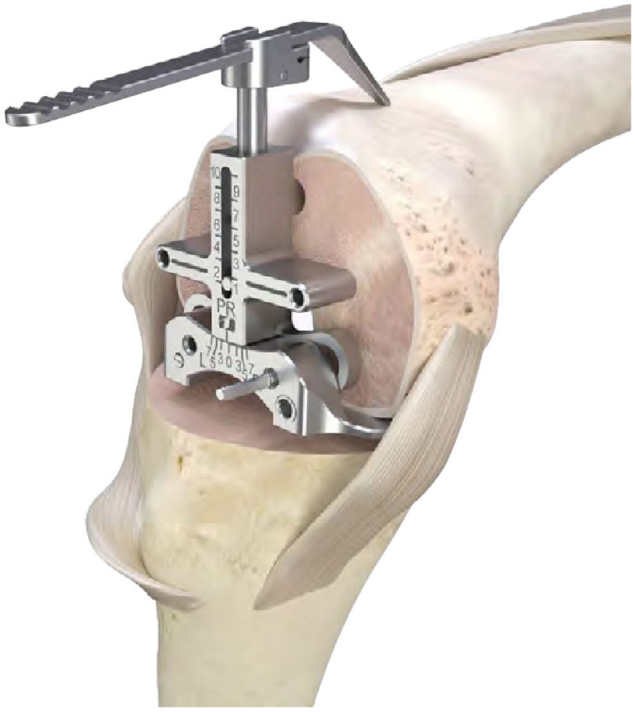


Figure 26

Femoral Sizing and Rotation (PR)

Set External Rotation

Establish the external rotation by axially pivoting the body of the guide in relation to the posterior feet. Both the horizontal and vertical aspects of the guide provide visual cues for reference to the epicondylar and AP axes, respectively.

The ER Indicator Line will align with the tick marks of the ER Scale to indicate the external rotation setting of the guide. Ensure the external rotation setting indicates the correct laterality by referencing the L or R on the ER Scale.

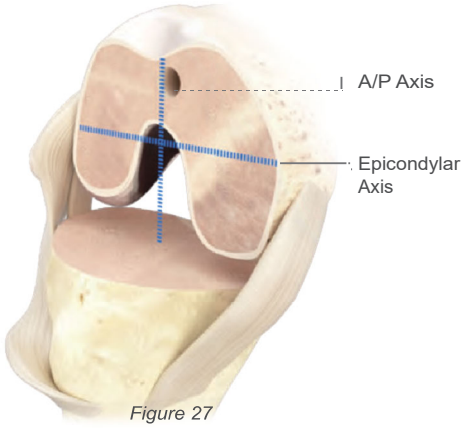


Figure 27

The PR Sizing & Rotation Guide allows for 0^0, 3^0, 5^0 and 7^0 of external rotation to be set. In Figure 28a, the guide is set to 3 degrees of external rotation for a right femur.

Once the desired external rotation is confirmed, use the Hex Driver assembled to the T-Handle to tighten the Rotary Lock on the PR Sizing & Rotation Guide. This will secure the external rotation angle of the guide.

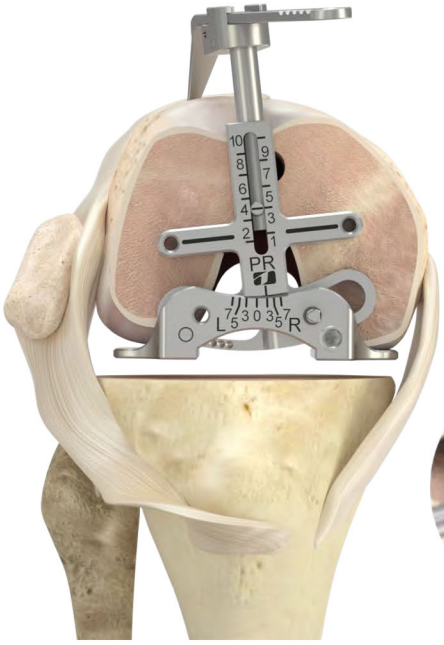


Figure 28a



Figure 28b

Use the 3.2mm drill to drill through the positioning holes on the PR Sizer and Rotation Guide. This prepares for the pegs on the 4-in-1 Cut Block and will set the A/P placement and external rotation of the 4-in-1 Cut Block and femoral prosthesis.

Note: Because the A/P placement of the 4-in-1 Cut Guide pegs is a fixed distance from the posterior condyles regardless of femoral size, this step can be done prior to measuring the femoral size.

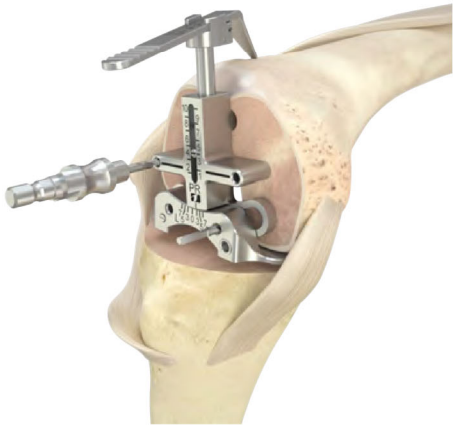


Figure 29

Femoral Sizing and Rotation (PR)

Measure Femoral Size

Ensure adequate exposure of the anterior cortex by slightly extending the knee and retracting soft tissue. The position of the stylus tip is designed to approximate the proximal position of the anterior flange of the femoral component. Likewise, the stylus tip approximates the exit point of the saw blade for the anterior chamfer resection. Therefore, to lessen the likelihood of notching, position the stylus tip laterally and on the high point of the anterior cortex. Once the stylus tip is in the proper position, the size of the femur must be read from the primary femoral sizing scale on the body of the guide. The secondary femoral sizing scale on the stylus should be used to ensure close approximation with the primary scale reading.

With PR instrumentation, if the sizing scale reads between sizes, it is recommended to choose the larger size to avoid over resection of the anterior cortex.

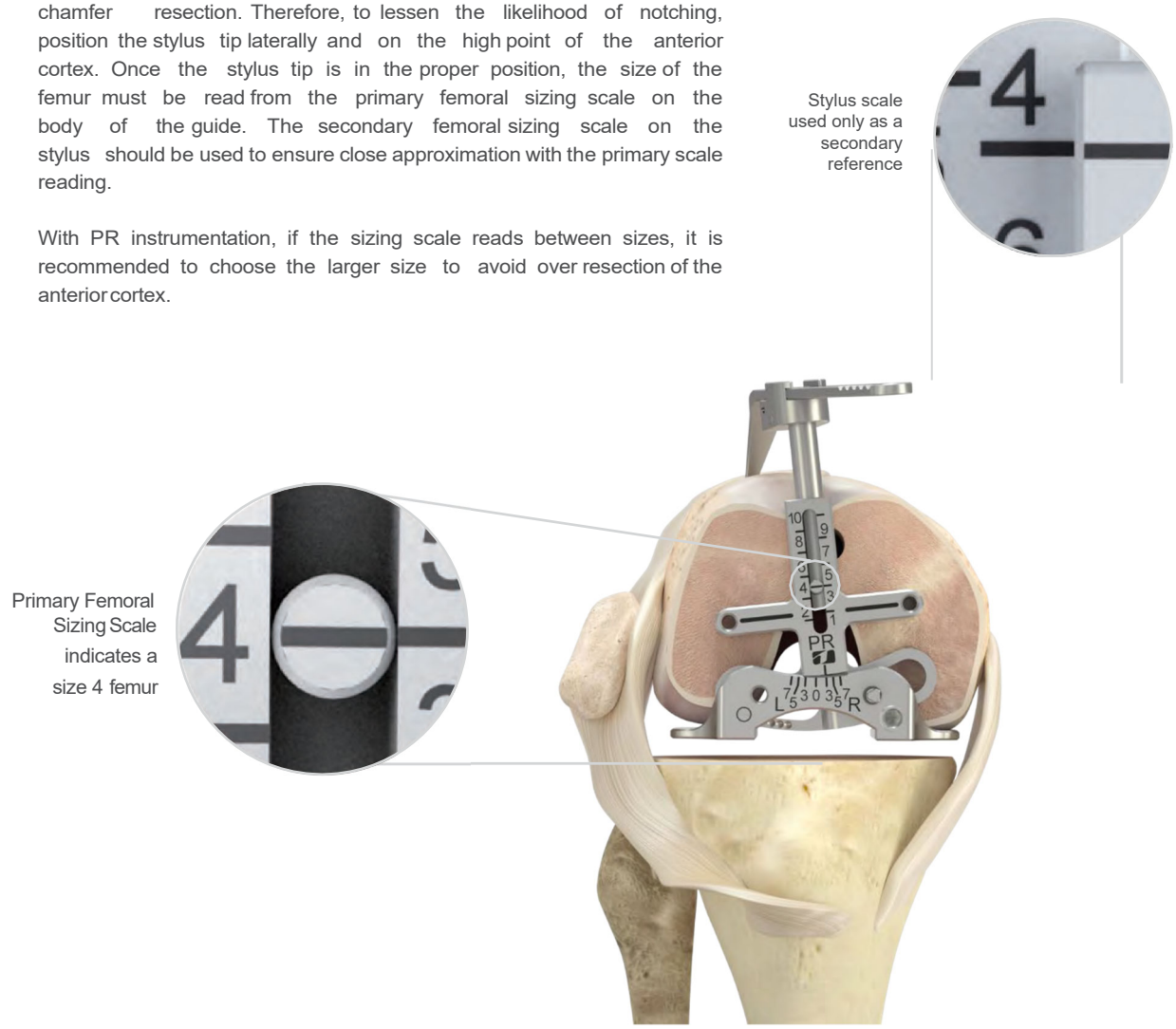


Figure 30

Note

Excessive force should not be applied to the stylus tip. Excessive force to the stylus tip can potentially deform the stylus and affect the femoral size reading.

Femoral Preparation

PR 4-in-1 Cut Block Overview

The **MOBIO**™ 4-in-1 Cut Blocks are specific to the referencing system used. Ensure that for posterior referencing, the PR 4-in-1 cut blocks are used.

The **MOBIO**™ TKS offers both Standard and Narrow width femoral prosthesis. The Narrow widths are available for sizes 3 through 7. The M/L width of the distal femoral prostheses can be referenced on the **MOBIO**™ 4-in-1 Cut Blocks as shown in Figure 31.

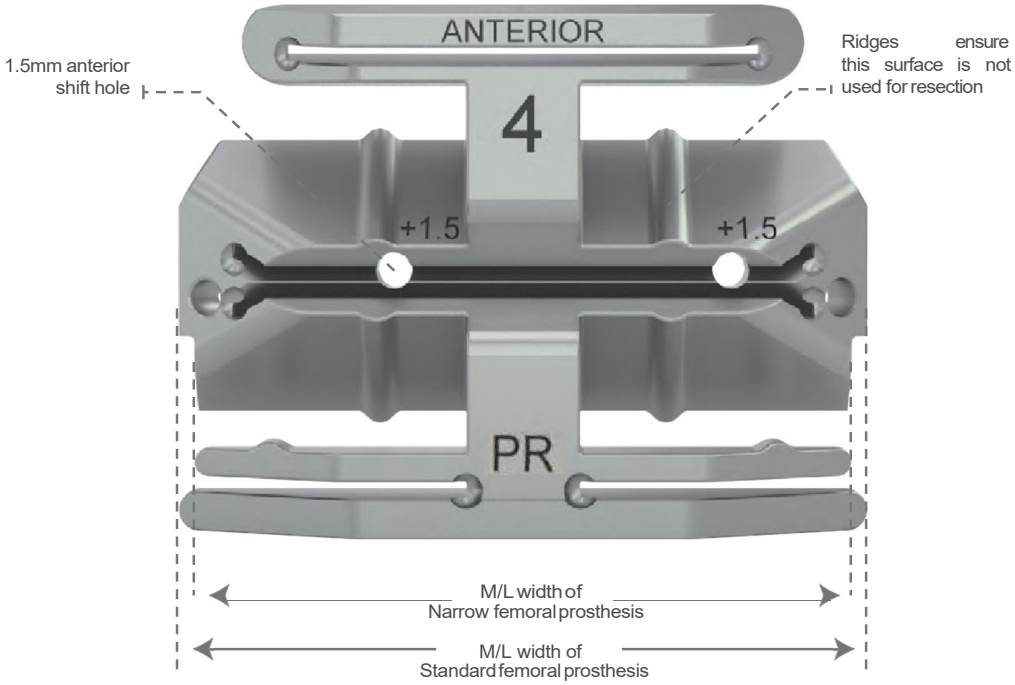


Figure 31

Tip

Posterior Referencing uses the posterior condyles to set the A/P placement of the femoral component. The **MOBIO**™ PR 4-in-1 Cut Block fixation pegs on the back surface are the same distance from the posterior resection slot regardless of femoral size, corresponding with the positioning holes on the PR Sizer and Rotation Guide. The anterior resection on the PR 4-in-1 Cut Block is variable by 3mm per size.

Femoral Preparation

PR 4-in-1 Cut Block Positioning

Select the PR 4-in-1 Cut Block that corresponds with the femoral size measured by the PR Sizer and Rotation Guide. By hand, place the PR 4-in-1 Cut Block on the distal femur by aligning the two pegs on the back of the block with the prepared positioning holes (drilled through the PR Sizing and Rotation Guide). Impact the face of the block until the block is flush with the femur. Use the Angel Wing through the cut block resection slots to visualize the resection and confirm the position of the PR 4-in-1 Cut Block (Figure 32). Confirm the appropriate external rotation.



Figure 32

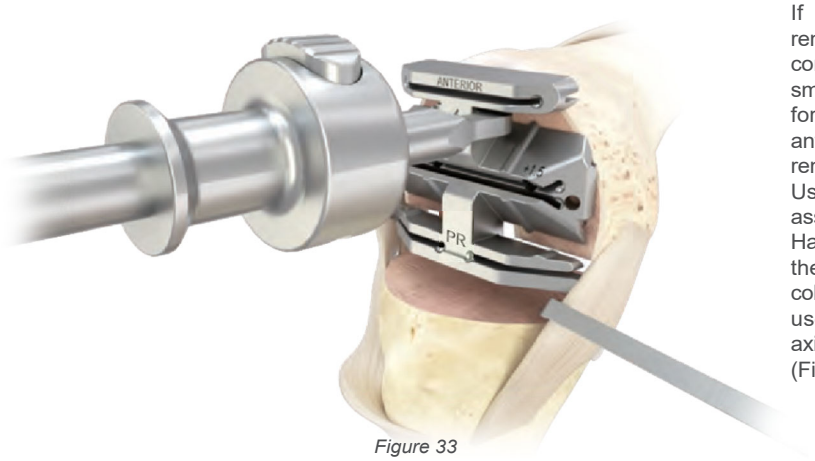


Figure 33

If inadequate bone will be removed from the anterior cortex, use the next size smaller PR 4-in-1 Cut Block for an additional 3mm of anterior bone resection. First remove the current cut block. Use the Extractor Hook assembled to the Slap Hammer. Slide the hook into the cutout on the central column of the cut block and use the Slap Hammer to axially remove the cut block (Figure 33).

Femoral Preparation

PR 4-in-1 Cut Block Positioning *continued*

If there is risk of unacceptable notching of the anterior cortex, evaluate the necessary repositioning of the 4-in-1 Cut Guide. Depending on the desired outcome, there are two options to reduce the amount of anterior resection using the **MOBIO**™ Posterior Referencing instrumentation, outlined in Chart A.

Option 1: To simply upsize the 4-in-1 Cut Block, remove the cut block from the distal femur with the Extraction Hook assembled to the Slap Hammer. Slide the hook into the notch on the central column of the cut block and use the Slap Hammer to axially remove the block (Figure 33). Place the next size 4-in-1 Cut Block into the same positioning holes in the distal femur. Use the Angel Wing to visualize the resection and confirm positioning.

Option 2: Alternatively, a 1.5mm anterior shift can be achieved by drilling the 3.2mm drill through the two +1.5mm shift holes in the 4-in-1 Cut Block. Remove the block with the Extraction Hook assembled to the Slap Hammer. Place the same block into the newly drilled positioning holes.

	Option	Result
1	Upsize the PR 4-in-1 Cut Block by one size	• reduces anterior resection by 3mm; • no impact to posterior resection (no impact to flexion space)
2	Shift PR 4-in-1 Cut Block 1.5mm anterior	• reduces anterior resection by 1.5mm; • increases posterior resection by 1.5mm (increases the flexion space)

Chart A: Options to reduce anterior resection using **MOBIO**™ PR Instruments.

Femoral Preparation

Femoral Resection (PR)

Once the final position of the selected PR 4-in-1 Cut Block has been confirmed, use the Pin Driver to insert two Tension Screws through the oblique holes of the cut block.



Figure 34

Use a 1.27mm (0.050 in.) thick oscillating saw blade to perform the anterior, posterior, posterior chamfer, and anterior chamfer cuts through the resection slots of the cut guide.

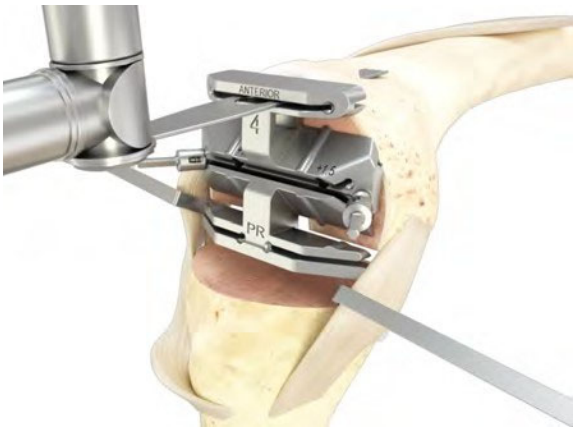


Figure 35

Upon completion of the bone cuts, use the Pin Driver to remove the Tension Screws. Use the Extractor Hook assembled to the Slap Hammer to axially remove the cut block.



Figure 36

Femoral Preparation

PS Femoral Notch Preparation

The **MOBIO**™ PS Femoral Notch Prep Guide is designed to allow visualization of the position of the femoral prosthesis, as shown in Figure 37. This allows for the proper M/L position of the femoral component to be confirmed prior to resecting the PS femoral notch.

The anterolateral border of the anterior flange of the prosthesis is referenced by the anterolateral contour of the Notch Resection Guide. The anteromedial border of the prosthesis flange can be visualized through the reference window as shown by the dotted line in the image.

The distal medial and lateral edges of the Notch Resection Guide indicate the medial and lateral edges of the standard femoral component. In addition to standard femoral widths, the **MOBIO**™ femoral prostheses are available in narrow widths for sizes 3 through 7. The width of the narrow prosthesis is indicated by the notch cutouts on the distal medial and lateral edges of the Notch Resection Guide.

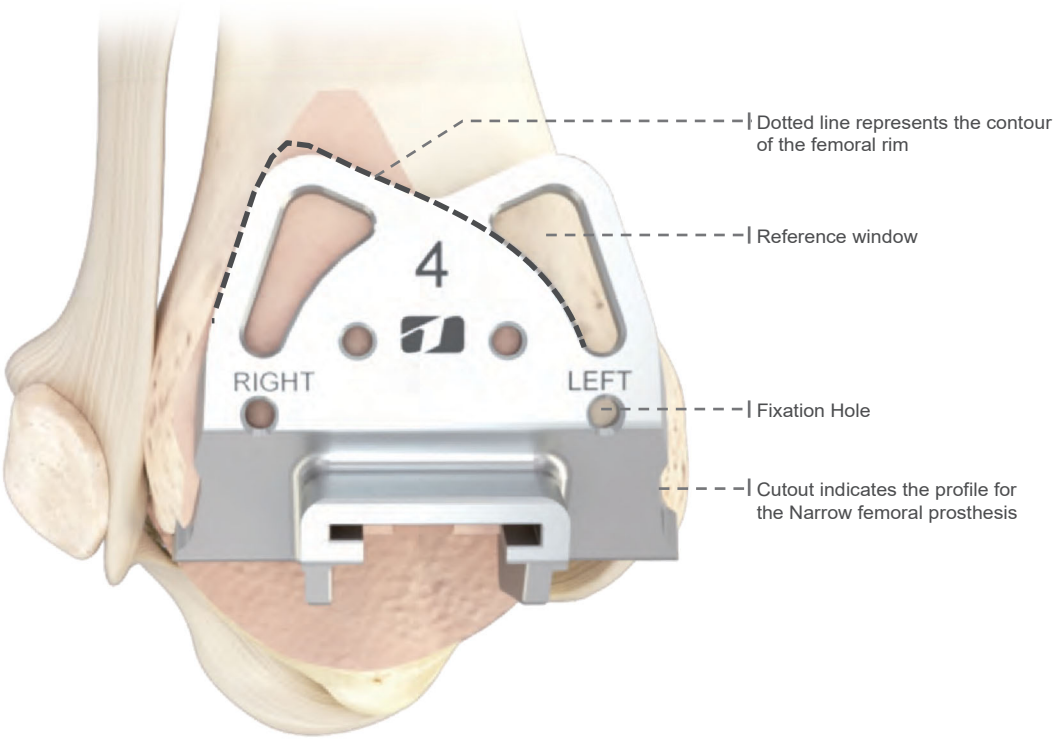


Figure 37

Femoral Preparation

PS Femoral Notch Preparation

Select the PS Femoral Notch Prep Guide of the same size as the 4-in-1 Cut Block, and place the Notch Prep Guide on the resected surfaces of the femur by hand. The M/L position of the Notch Prep Guide is determined by visualizing the final femoral prosthesis placement and appropriate position of the intercondylar notch. Avoid placement that results in lateral overhang of the femoral prosthesis.

Ensuring the Notch Prep Guide is flush with the resected surfaces of the femur, secure the guide using headed pins. Insert one headed pin into the anterolateral fixation hole to ensure the anterior flange of the guide is flush with the anterior resection. This will also aid in preventing a flexed position of the guide. Insert a second pin in the distal medial fixation hole. Place a third pin in the distal lateral fixation hole for rotational stability.

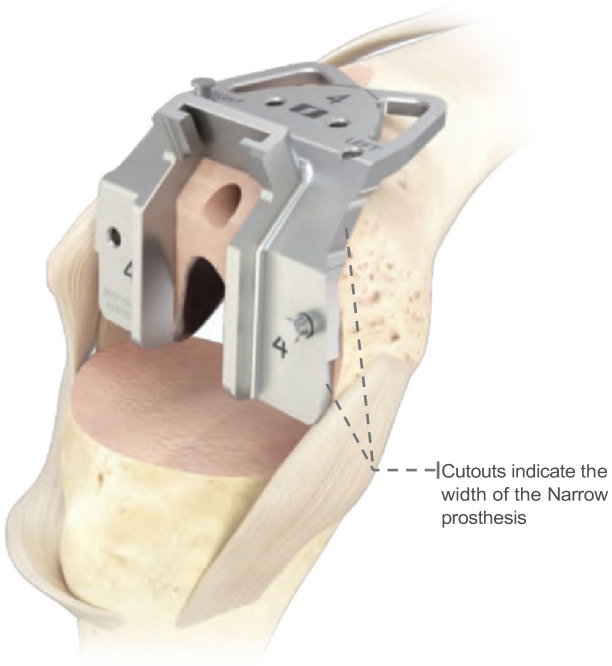


Figure 38

Femoral Preparation

PS Femoral Notch Preparation

For the **MOBIO**™ PS Femoral Notch Preparation, the PS Femoral Notch Punch instrument is provided to initiate the notch preparation. A narrow oscillating or reciprocating saw will also be required to complete the medial and lateral walls of the notch resection.

Select the appropriate size PS Femoral Notch Punch and assemble to the Universal Handle. The Notch Punch is designed so that it can only be assembled to the Universal Handle in one direction. The distal face is marked according to compatible femoral sizes and includes a lasermark line to provide a visual cue to the final resection depth. The reverse side includes a positive stop feature that controls the final resection depth. The Notch Punch will stop against the PS Notch Guide when resection is complete.



Figure 39

\

Femoral Preparation

PS Femoral Notch Preparation

Use a narrow oscillating saw or reciprocating saw to cut the cortical rim on both sides of the most posterior portion of the intercondylar notch.

Insert the assembled Notch Punch into the captured slot on the Notch Guide so that the laser marking faces distally and the positive stop faces proximally. Impact with Mallet until seated. Leave the Notch Punch in place to serve as a reference during the remaining bone resection.

Use a narrow oscillating or reciprocating saw to complete the medial and lateral sides of the notch resection. Ensure the blade remains within the planes of the guide notch walls to maximize bone conservation.

Tip

The Protector Plate can be used to protect the proximal tibia resection surface during notch preparation.

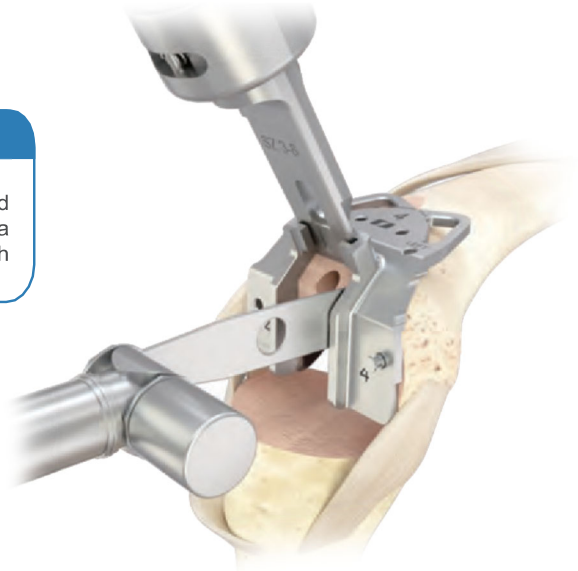


Figure 40

After notch resection is complete, remove the Notch Guide by using the pin removal side of the Slap Hammer to easily extract the headed pins.

Check the notch is properly prepared. Remove any remaining bone from the prepared notch prior to femoral trialing.

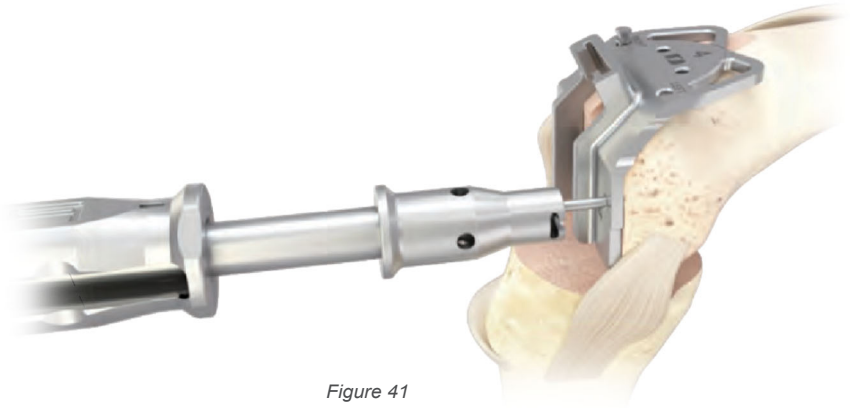


Figure 41

Tibial Preparation

Tibial Sizing and Rotation

Remove all osteophytes. Select an appropriate Tibial Trial Plate that will provide appropriate tibial coverage without any overhang. Oversizing of the tibia and subsequent overhang can lead to soft tissue impingement and potential pain for the patient.

MOBIO™ tibial baseplates and trial plates are available in 9 sizes: A, B, C, D, E, F, G, H, J. Refer to the Tibiofemoral Compatibility Chart in **Appendix D** to confirm compatibility with the selected femoral size.

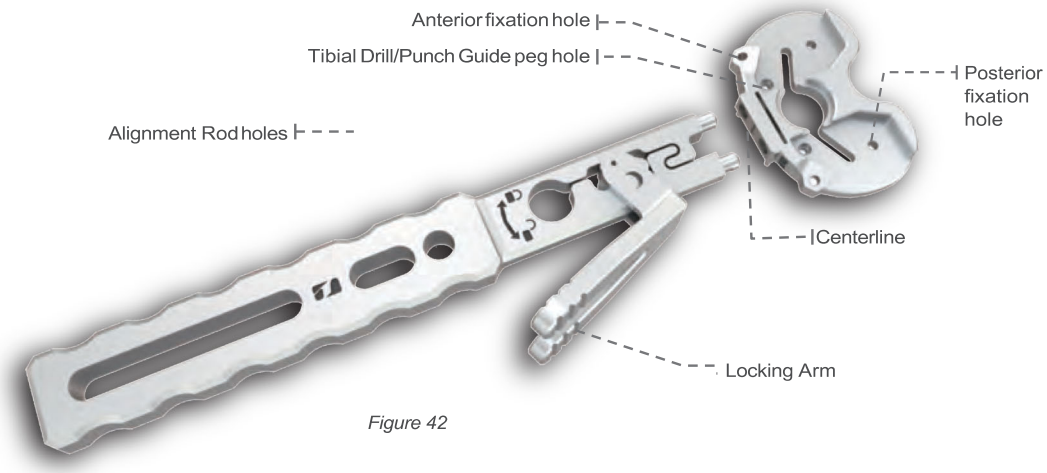


Figure 42

With the Tibial Trial Plate Handle locking arm in the unlocked position, insert the two pegs of the Tibial Trial Plate Handle into the two holes on the anterior face of the Trial Plate. Press the Locking Arm into the locked position to secure. Place the Tibial Trial Plate onto the proximal tibial resection.

Establish the proper position and rotation of the trial plate. The lasermarked centerline on the Trial Plate can be used to aid in achieving the desired alignment. Typically the rotational alignment should be within 5 degrees of the A/P axis created by the medial 1/3 of the tibial tubercle and the PCL attachment point.

Once the posítion ís determíned, ínsert two headed pins into the posterior fixation holes.

Place the Alignment Rod with Coupler through the alignment rod hole on the Tibial Trial Plate Handle to confirm the alignment of the Trial Plate.

If desired, insert a headed pin or 22mm headed screw into the anterior fixation hole for additional stability.

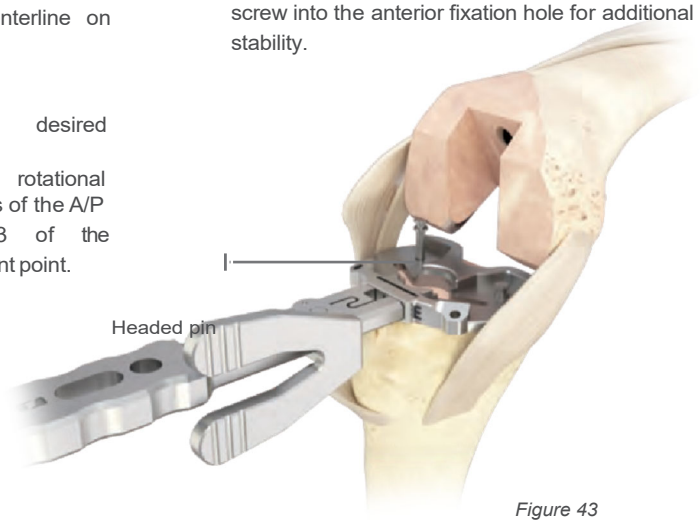


Figure 43

Tibial Preparation

Tibial Drill

Place the Tibial Drill/Punch Guide onto the Tibial Trial Plate by inserting the guide alignment pegs into the guide peg holes on the plate (Figure 44). Ensure the Guide is flush with the trial plate.

The Tibial/Drill Punch Guide can be used with all sizes of the **MOBIO**™ tibia.

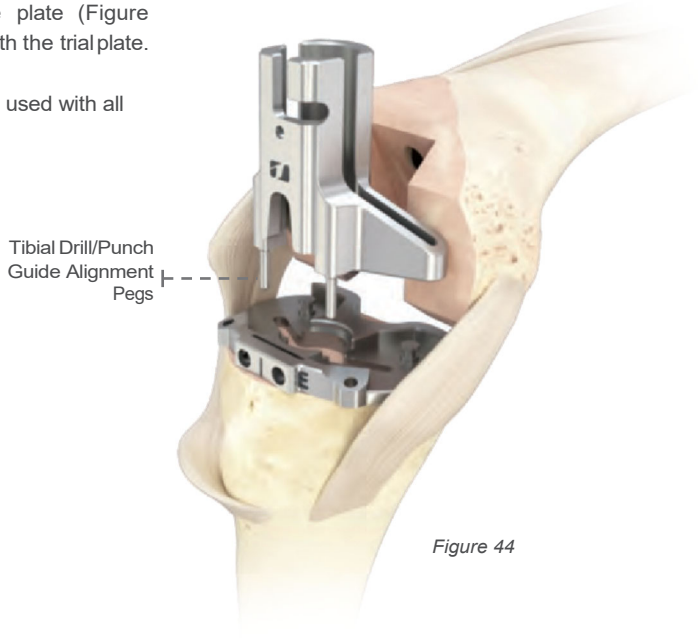


Figure 44

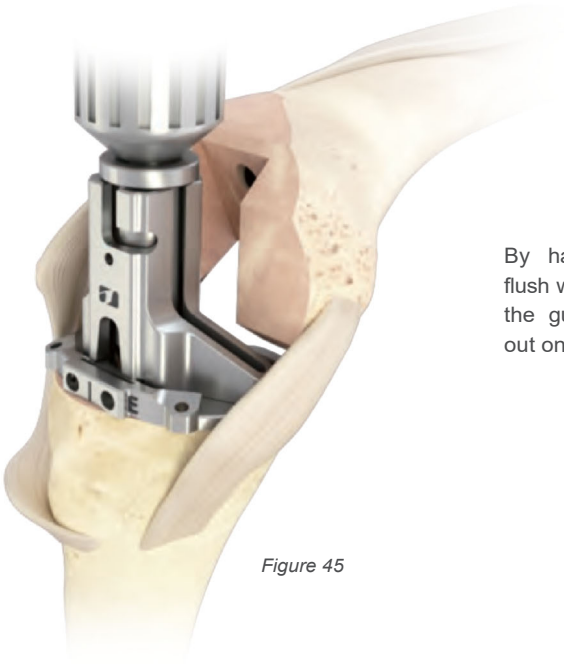


Figure 45

By hand, hold the Tibial Drill/Punch Guide flush while introducing the Tibial Post Drill into the guide. Drill on power until the drill bottoms out on the top of the guide (Figure 45).

Tibial Preparation

Tibial Keel Punch

Assemble the Tibial Keel Punch Adapter to the Universal Handle. Select the Tibial Keel Punch size that corresponds to the Tibial Trial Plate size affixed to the tibia. The Tibial Keel Punch is marked with the compatible Tibial Trial Plate size range (Figure 46).

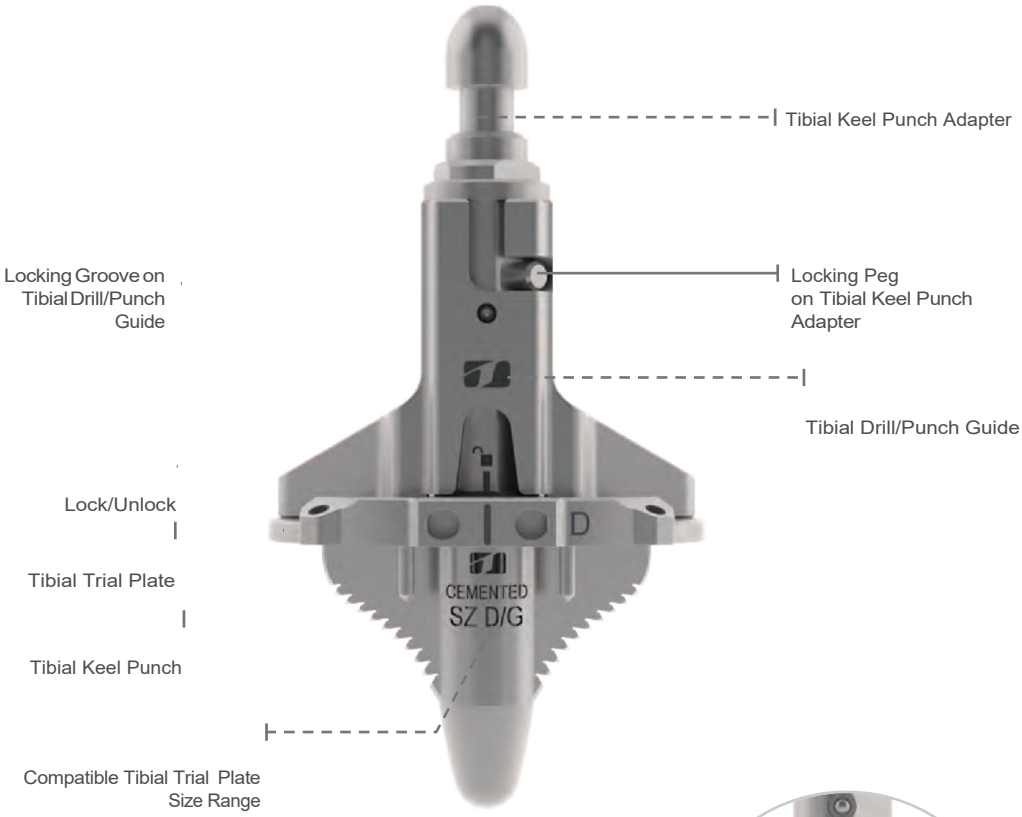
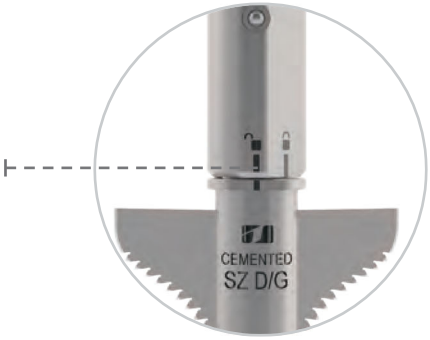


Figure 46a



To assemble the Tibial Keel Punch Adapter with the Keel Punch, align the centermark with the Unlock symbol. Rotate the Adapter 1/8 turn clockwise to engage into the Lock position.

Figure 46b

Tibial Preparation

Tibial Keel Punch *continued*

Insert the Tibial Keel Punch assembly into the Tibial Drill/Punch Guide (Figure 47a). Carefully impact the assembly with a mallet to progress the Keel Punch into cancellous bone until the punch is flush with the Tibial Trial Plate. The locking peg on the anterior column of the Keel Punch Adapter will bottom out in the L-shaped locking groove of the Drill/Punch Guide (Figure 47b).

Upon final seating, the Keel Punch may be left in place to serve as the trial keel. While assembled, rotate the Universal Handle 1/8 turn counterclockwise, sliding the locking peg into the locking groove to disengage the Keel Punch Adapter from the Keel Punch. Confirm the Keel Punch is disengaged from the Keel Punch Adapter by visualizing the Unlock symbol centralized in the anterior window of the Guide. Once confirmed, the Tibial Drill/Punch Guide, Keel Punch Adapter, and Universal Handle can be easily removed as one construct (Figure 48a).

Leave the Tibial Trial Plate and Keel Punch in place for the trial reduction.

Alternatively, the Keel Punch can be removed to trial with the Tibial Trial Plate alone. Reverse impact the Universal Handle to remove the Keel Punch and Tibial Drill/Punch Guide after final seating (Figure 48b).

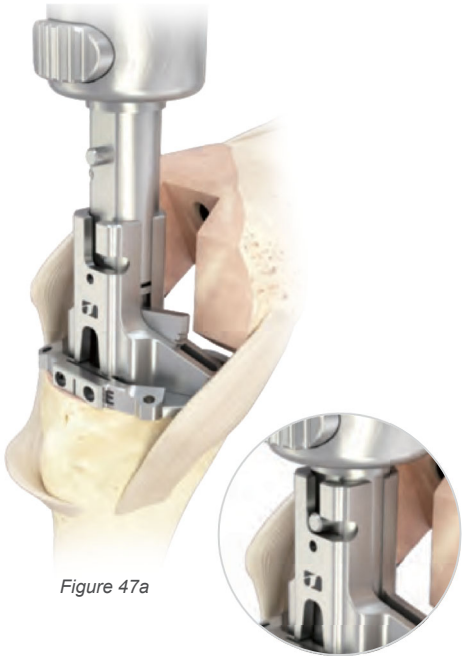


Figure 47a

Figure 47b

Note

The Tibial Keel Punch must be flush with the Tibial Trial Plate for adequate bony preparation and to allow for the Tibial Insert Trial.



Figure 48a

OR



Figure 48b

Patella Resurfacing

Patella Resection Guide

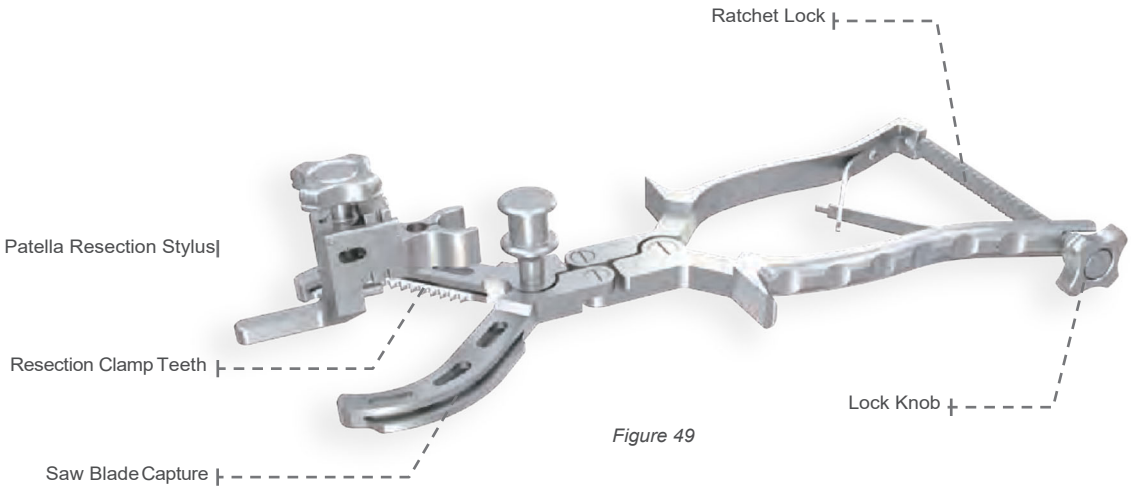
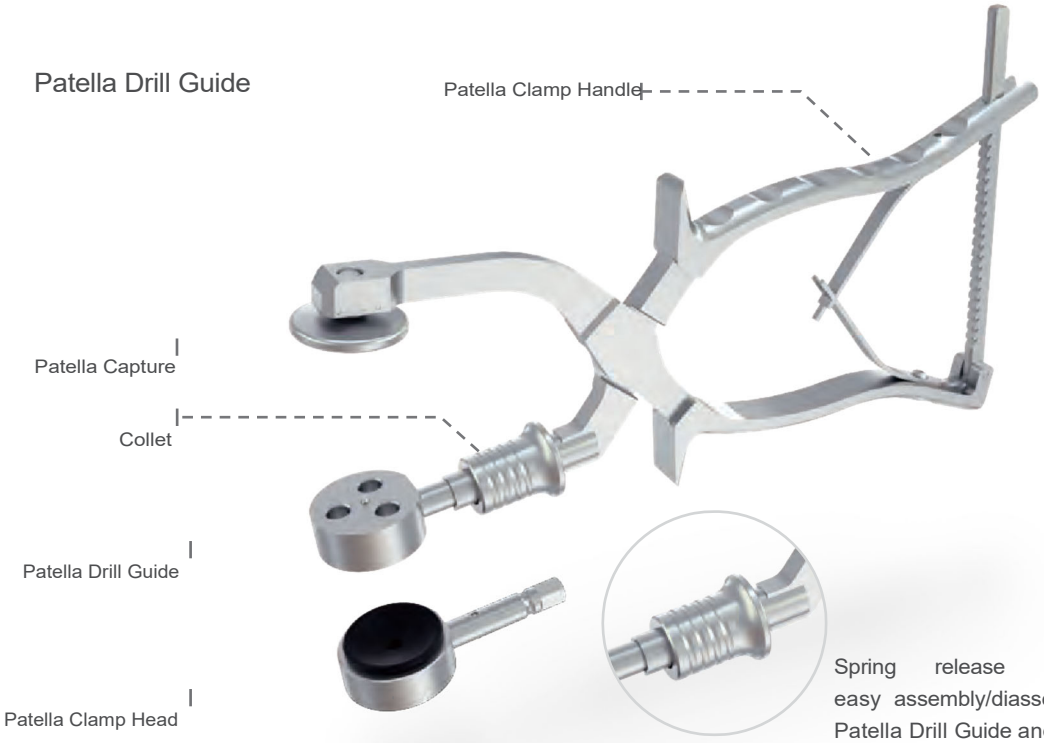


Figure 49

Patella Drill Guide



Spring release Collet for easy assembly/diassembly of Patella Drill Guide and Patella Clamp Head to handle

Figure 50

Patella Resurfacing

Determine the Resection

If the surgeon determines the condition of the native patella is satisfactory, it is not necessary to resurface the patella when using the **MOBIO**™ TKS.

If resurfacing is desired, place the leg in full extension and evert the patella to at least 90 degrees to access the articular surface. Use two towel clips to stabilize the patella. Proper patellar exposure and appropriate removal of surrounding soft tissues will allow for better visualization and judgment of the cutting level.

Using the Caliper, measure the most prominent A/P dimension of the patella bone to determine the thickness of the patella.

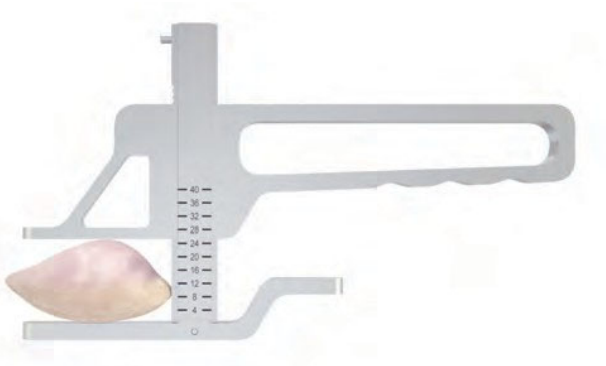


Figure 51



Figure 52

Assemble the Patella Resection Stylus to the Patella Resection Guide.

Set the desired amount of resection by turning the knob on the Patella Resection Stylus to adjust the height of the stylus. Reference the scale which indicates the amount of bone (mm) that will be removed by resecting through the cut slot. If the patella is very worn, resect less bone.

Refer to the Chart B for the dimensions of the **MOBIO**™ patella. The **MOBIO**™ patella is a symmetric patella design.

Note

The scale on the Patella Resection Stylus refers to the amount of bone to be removed.

Diameter	Thickness
29	7.5 mm
32	8.5 mm
35	9.0 mm
38	9.5 mm
41	10 mm

Chart B: Patella dimensions.

Patella Resurfacing

Resect the Patella

Prior to resection, it is recommended to use a small drill (2.0mm - 3.2mm) to drill the highest point of the medial facet (medial sagittal ridge perpendicular to the articular surface). This mark will serve as a guide for proper medialization of the patella after resection. Drill approximately 12mm deep to ensure the mark will still be visible after resection.

Capture the patella in the jaws of the Patella Resection Guide. Squeeze the handle to capture the patella in the clamp teeth, making sure the guide is applied with the jaws parallel to the dorsal surface of the patella. Ensure the Patella Resection Stylus is positioned on the most prominent point of the patella, referencing the same location from which the patella thickness was measured. Tighten the Lock Knob on the Patella Resection Guide handle to secure the setting of the guide.

Using a 1.27mm (0.050 in.) thick oscillating saw blade, resect the patella articular surface through the saw blade capture on the guide. Take care to avoid damage to surrounding tissues, trials, or prostheses.

When completed, ensure the resected surface is flat.

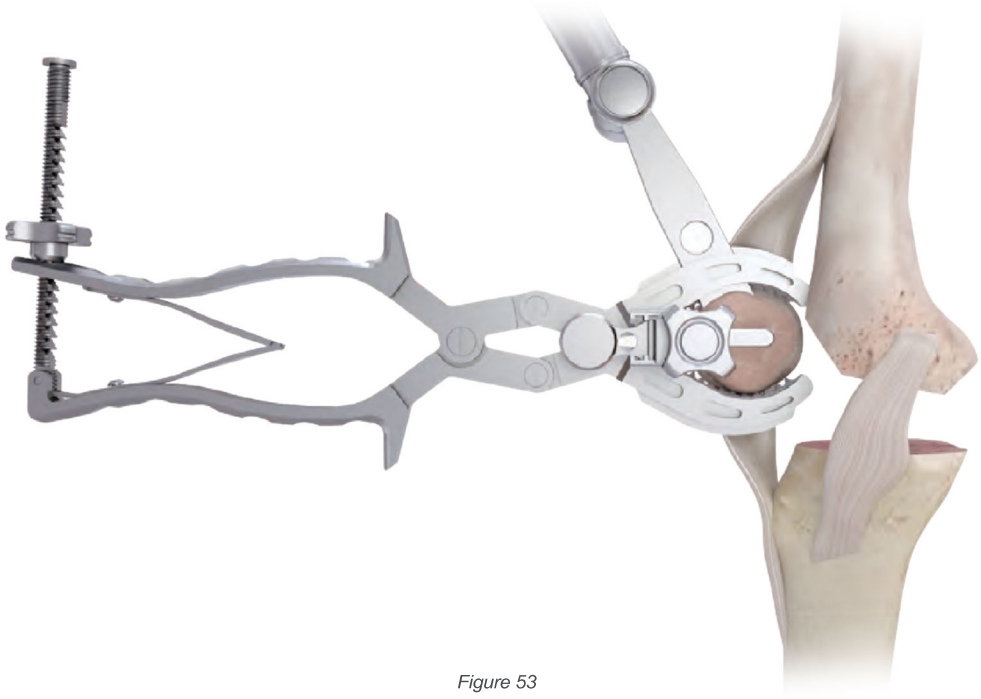


Figure 53

Patella Resurfacing

Size and Drill Peg Holes

Place the Patella Sizer on the resected surface, aligning the central hole with the mark created by the drill prior to resection, or approximately 3-4mm medial of the center of the resection plane to ensure proper medialization.

Select the size that allows for adequate coverage without overhang.

Assemble the appropriate size Patella Drill Guide to the Patella Clamp Handle. There are two size drill guides that correspond to the peg geometry of the patella size.

Place the Drill Guide against the resected surface, centering over the hole created previously or approximately 3-4mm medial to the center of the resection plane. Slight medialization of the patella component allows for better patellofemoral tracking.

After confirming the position, squeeze the Patella Clamp Handle to engage the patella bone, confirming the Drill Guide is flush with the resected surface. This will ensure adequate bone is removed to accommodate the patella pegs.

Drill the Patella Peg Drill through each of the three peg holes until the drill bottoms out on the guide.



Figure 54

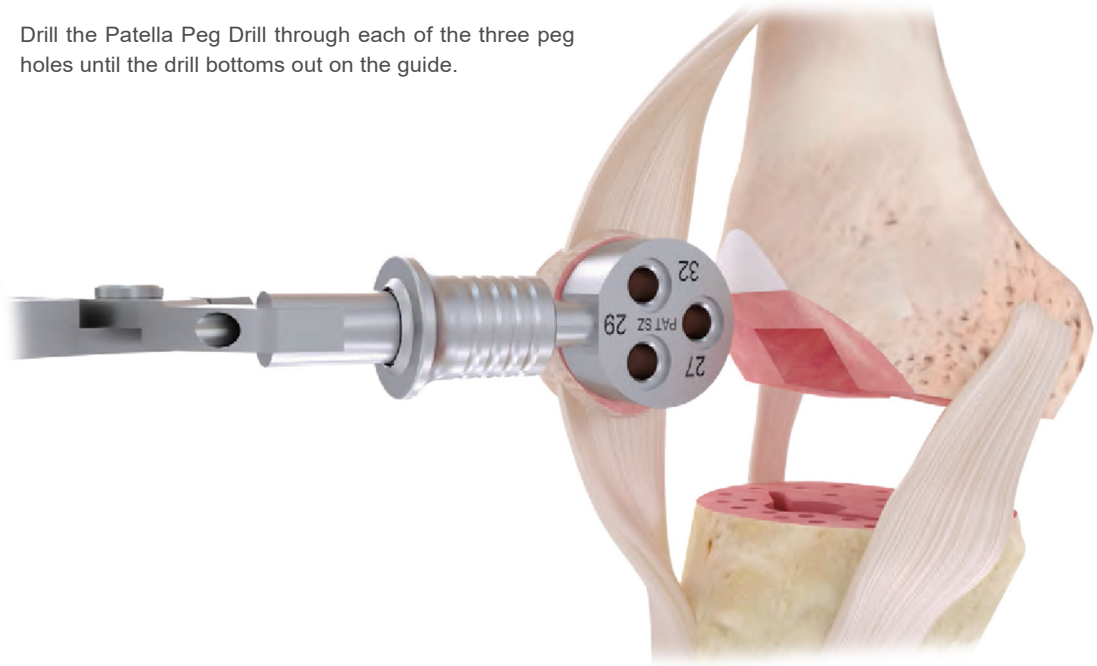
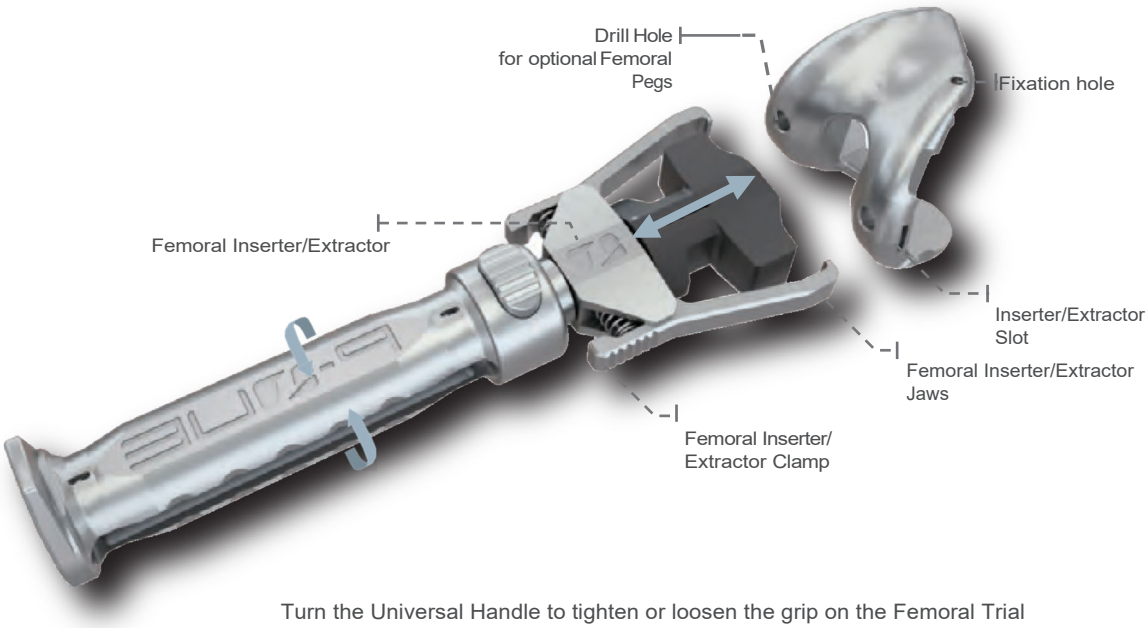


Figure 55

Trial Reduction

Femoral Trial

Assemble the Femoral Inserter/Extractor to the Universal Handle. Select the Femoral Trial size that matches the size prepared with the femoral preparation instruments. To place the trial on the Inserter/ Extractor, squeeze the clamp to open the jaws and grasp the slots on the distal medial and lateral edges of the Femoral Trial. While holding the trial, rotate the Universal Handle clockwise to tighten and secure the hold of the Femoral Trial.



Turn the Universal Handle to tighten or loosen the grip on the Femoral Trial

Figure 56

Trial Reduction

Femoral Trial *continued*

Remove any posterior osteophytes or overhanging bone prior to inserting the Femoral Trial. While assembled to the Femoral Inserter/Extractor, place the Femoral Trial onto the resected femur, pressing the Femoral Trial into place for initial positioning and fit. Once the position is confirmed, impact the Universal Handle with a mallet until the Femoral Trial is fully seated. Use the secondary Femoral Impactor assembled to Universal Handle for final seating if desired.

If the Femoral Trial does not fully seat, remove the trial, check for osteophytes and examine the bone resections. If necessary, use the same 4-in1 Cut Block and/or Notch Prep Guide used previously to ensure the resections are accurate.

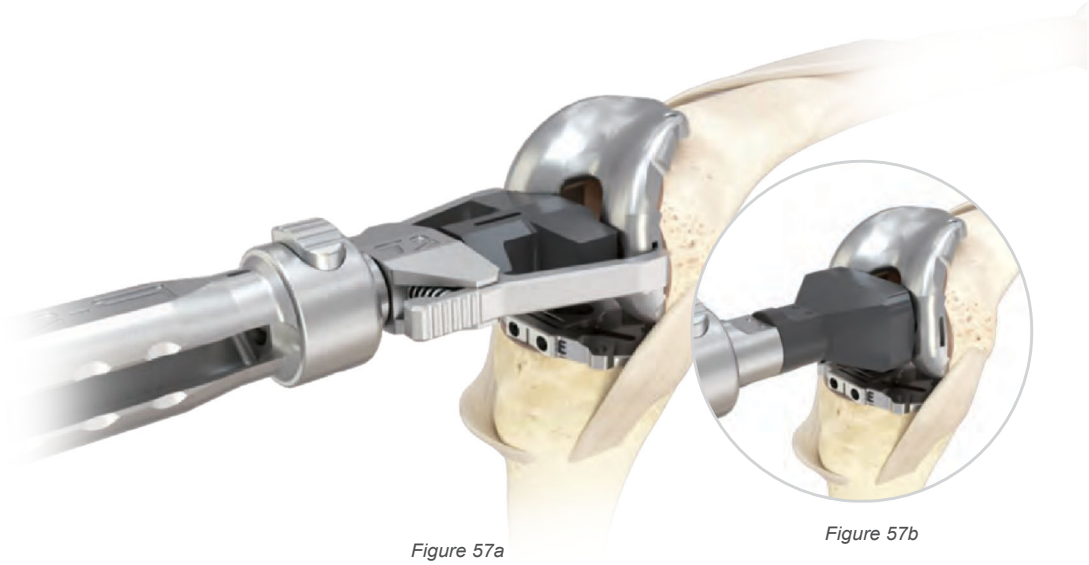


Figure 57a

Figure 57b

Once the Femoral Trial is fully seated, assess bone coverage.

The **MOBIO**™ femoral component offers additional Narrow width femoral options for core sizes 3 through 7. The Narrow width can be visualized on the corresponding Femoral Trial by the cutouts along the medial and lateral border of the trial.

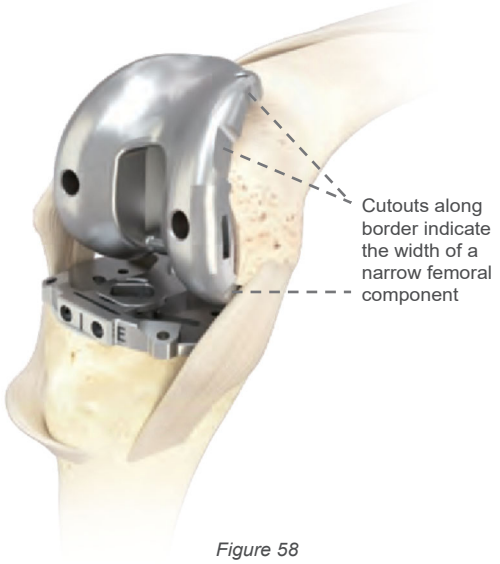


Figure 58

Trial Reduction

PS Tibial Insert Trial

With the Tibial Trial Plate in place, select the appropriate size and thickness of the PS or PS PLUS Tibial Insert Trial and place it on the Tibial Trial Plate. The insert trial should sit flush on the trial plate.

The PS PLUS Tibial Inserts have a wider taller post than the PS Tibial Inserts and should be used when the collateral ligaments are insufficient or additional stability is required.

The PS PLUS Tibial Inserts are designed to provide +/- 3.5 degrees of varus/valgus constraint and +/- 5 degrees of internal/external rotational constraint.

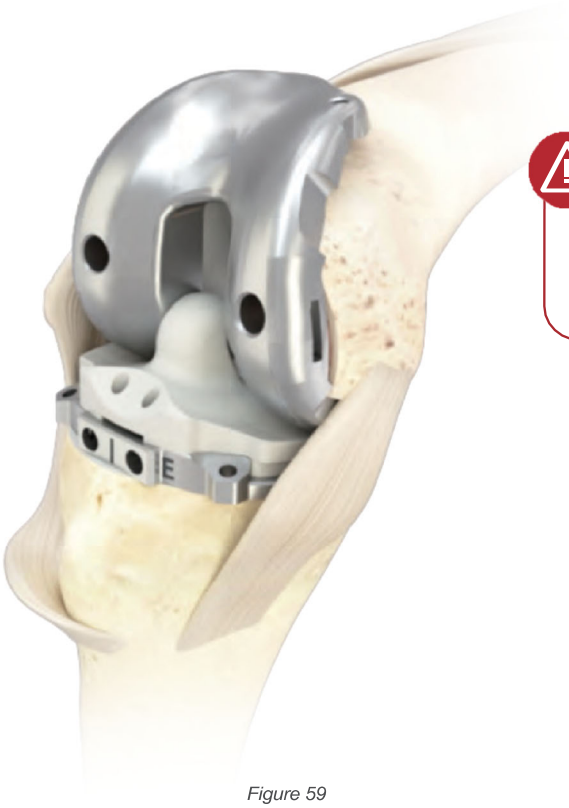


Figure 59

Note

For size A Tibial Baseplate, the femoral compatibility differs between the PS Tibial Insert and the PS PLUS Tibial Insert. Refer to the tibiofemoral compatibility charts in Appendix D for details.

Primary Tibial Baseplate	Color
A	BLUE
B	YELLOW
C	
D	GRAY
E	
F	IVORY
G	
H	BLACK
J	

Chart C: Tibial Insert Trial color scheme.

The PS and PS PLUS Tibial Insert Trial is marked on the anterior surface by tibiofemoral compatibility and thickness. The compatibility is indicated first by baseplate compatibility, followed by femoral compatibility. For example, DE/3-7 indicates that the Tibial Insert Trial is compatible with tibial sizes D and E, and compatible with femoral sizes 3 through 7 (including both Standard and Narrow widths). The PS and PS PLUS Tibial Insert Trials are color coded to allow easy visualization of baseplate compatibility. See Chart C for details.

Trial Reduction

Perform a trial range of motion. Assess ligament stability throughout the range of motion, being sure to check stability at 0, 30, 60, and 90 degrees of flexion. In hyperflexion, confirm the PS Insert Trial post engages the cam.

If the patella was resurfaced, insert the Patella Trial onto the resected patella surface that matches the size prepared for during patella preparation. Perform a trial range of motion to check patella tracking.

When all of the component positions have been checked and joint stability confirmed through ROM, the trial components can be removed. If femoral pegs are desired, leave the Femoral Trial in place for peg preparation (next page).



Figure 60



Tip

The hooked end on the double-ended Cement Removal Tool is designed for easy removal of the Tibial Trial Insert

Figure 61

Femoral Peg Preparation (Optional)

If desired, femoral pegs are available to augment fixation. Ensure the Femoral Trial is fully seated on bone prior to drilling. Drill through the two distal holes on the Femoral Trial with the Femoral Peg Drill until the drill bottoms out on the trial.

Remove the Femoral Trial with the Femoral Inserter/Extractor.



Figure 62

Note

Note: the femoral peg implants are packaged separately from the femoral prosthesis.

Implantation

The **MOBIO**™ TKS offers cemented components. Prior to cementing implants, remove all trials. Use pulse lavage to clear unwanted debris from the joint. Ensure all resected bone surfaces are clean and dry prior to cementing. It is recommended to use two batches of bone cement. If the resected surfaces of the tibia and/or femur are sclerotic, drill multiple holes with a small drill (2.0mm-3.2mm) to improve cementinterdigitation.

Confirm all implants are correct size, laterality, and compatibility.

Prepare the bone cement per the manufacturer's guidelines.

Tip

Prior to removing the Tibial Trial Plate, create a mark on the bone to reference the centerline on the plate. This can be used to check final component positioning.



Figure 63

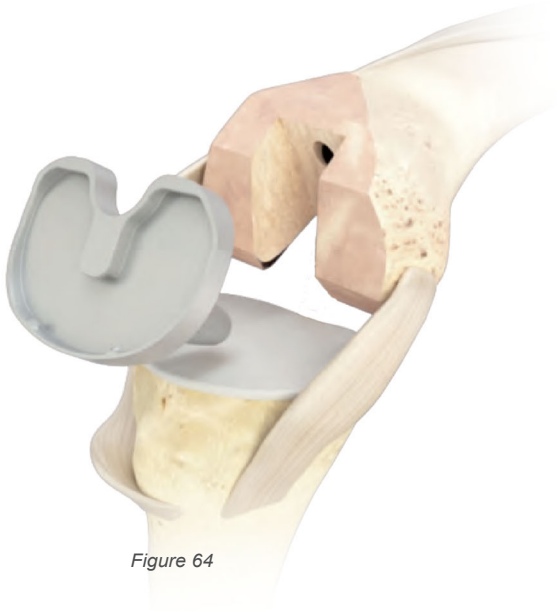


Figure 64

Tibial Implant

To provide for adequate clearance to implant the tibial baseplate into the prepared bone, sublux the tibia anteriorly. Be sure the prosthesis remains clean and free of debris prior to applying the bone cement. Place a layer of cement on the underside of the tibial baseplate and around the keel. Place cement on the resected tibial surface and in the prepared tibial intramedullary canal.

Prosthesis Implantation

Tibial Implant *continued*

Assemble the Tibial Baseplate Impactor to the Universal Handle.

By hand, carefully place the tibial baseplate onto the prepared tibia. Confirm proper rotation and position. Using a mallet, firmly impact the assembled Tibial Baseplate Impactor to seat the tibial baseplate flush with the resected tibial surface.



Figure 65



Figure 66

Use the Cement Removal Tool or a small curette to thorougly remove excess bone cement. Confirm the tibial baseplate is flush and in the proper position. Allow the cement to fully cure before performing a trial ROM or implanting the tibial insert.

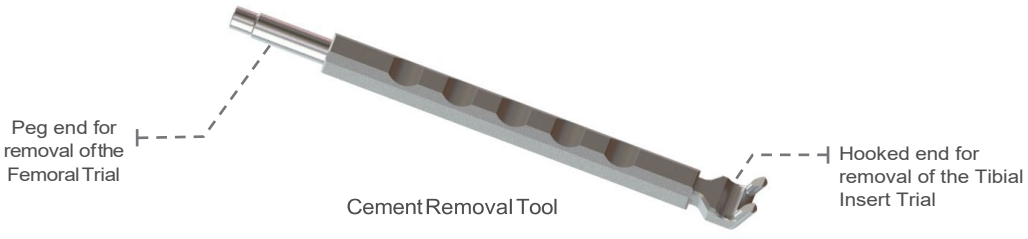


Figure 67

Prosthesis Implantation

Femoral Component

If femoral pegs are to be used, assemble the femoral pegs to the femoral prosthesis by screwing them into the threaded peg holes on the underside of the prosthesis using the Hex Driver assembled to the T-Handle. Tighten.

Attach the Femoral Inserter/Extractor to the femoral prosthesis in the same manner as the Femoral Trial. Adjust the grip on the femoral prosthesis by turning the Universal Handle if necessary. Place cement on the underside of the femoral prosthesis.

With the knee in a flexed position, apply bone cement to the resected femoral surfaces and in the drilled peg holes if prepared.

Use the assembled Femoral Inserter/Extractor to place the femoral prosthesis onto the prepared femur. Impact the end of the Universal Handle to apply axial force to seat the femoral component. While impacting, confirm the prosthesis is seating in the proper position. Use the Cement Removal Tool or a small curette to thoroughly remove bone cement.

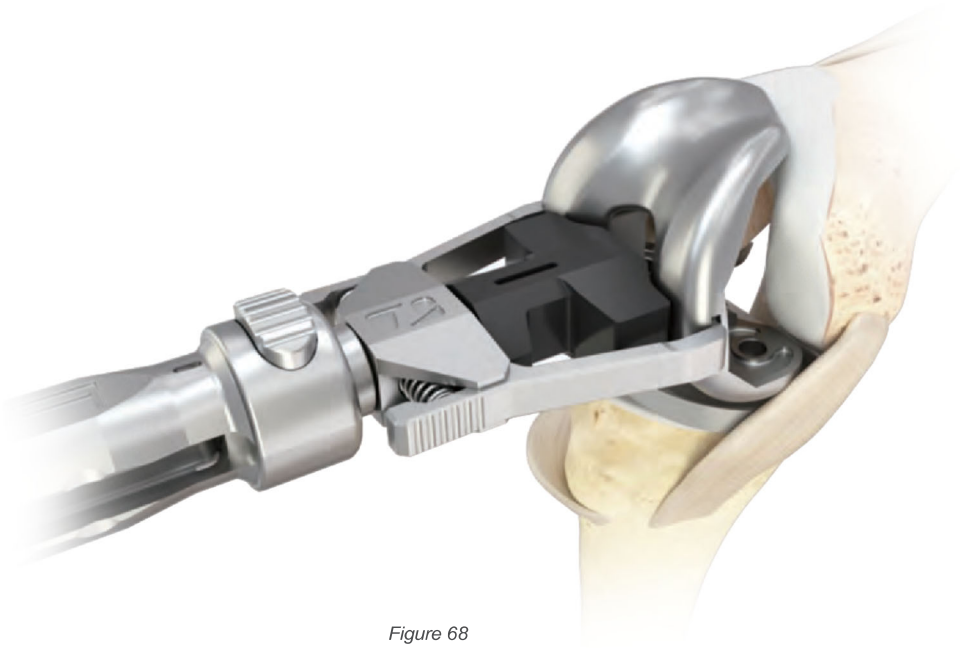


Figure 68

Prosthesis Implantation

Femoral Component *continued*

Once the femoral component is positioned and firmly seated, disengage the Femoral Inserter/Extractor from the femoral component by squeezing the clamp to release the jaws. Assemble the Femoral Impactor head to the Universal Handle and use this impactor to fully seat the femoral prosthesis. Confirm the implant is fully seated by checking distally on both the medial and lateral sides, and ensure the position of the component is correct. Thoroughly remove any excess bone cement.

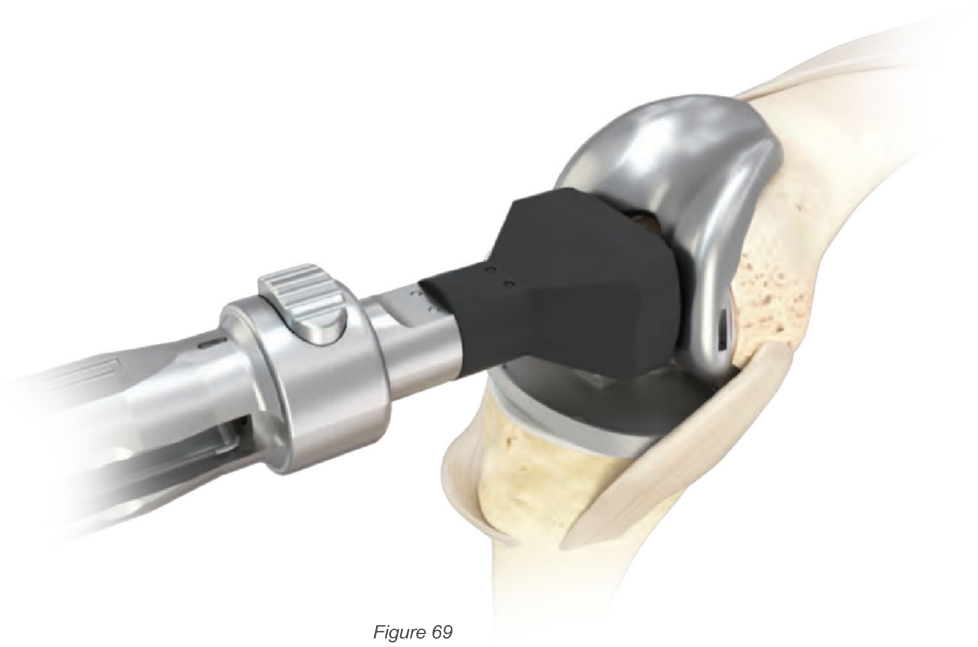


Figure 69

Prosthesis Implantation

Tibial Insert

Once the bone cement has fully cured, the Tibial Insert can be implanted. Prior to implanting the final Tibial Insert, the Tibial Insert Trial may be placed on the Primary Tibial Baseplate to perform an additional check of stability and ROM.

Confirm the tibiofemoral compatibility and thickness of the insert is correct. Check the tibial baseplate surface and circumferential periphery to ensure there is no debris and/or soft tissue that could impede the seating and proper locking of the insert to the baseplate.

Distract the joint to provide adequate access to the posterior aspect of the baseplate. The **MOBIO**™ Primary Tibial Baseplate is designed with a shortened central anti-rotation island and medial/lateral peripheral insertion ramps to allow the surgeon to insert the bearing at a greater angle.

By hand, place the tibial insert onto the tibial baseplate by angling the insert posteriorly and sliding the posterior end toward the posterior rim of the baseplate. The posterior tab of the Tibial Insert must fit beneath the posterior lip of the Primary Tibial Baseplate rim.



Figure 70



Figure 71

Attach the Tibial Insert Impactor to the Universal Handle. Place the impactor head on the anterior aspect of the Tibial Insert, resting the impactor groove on the insert patella relief. Use a mallet to impact the handle and fully seat the insert. The Tibial Insert is fully seated once the anterior locking wire is captured under the anterior tabs of the baseplate.

Note

The Tibial Insert can only be inserted into the Primary Tibial Baseplate once. Should the insert need to be removed, it cannot be reinserted nor reused.

Prothesis Implantation

Patella Component

Assemble the Patella Clamp Head to the Patella Clamp Handle.

Apply bone cement to the anterior surface and pegs of the **MOBIO**™ patellar component. Evert the patella to access the resected patella. By hand, align the patella component pegs into the drilled peg holes in the bone.

Fully open the assembled Patella Clamp, placing the three teeth of the Patella Capture on the anterior surface of the patella and aligning the Patella Clamp Head over the posterior dome of the patella implant. Squeeze the Patella Clamp Handle to press the patella component onto the prepared bone. Apply enough pressure to fully seat the implant on the patellar surface. Use the Cement Removal Tool or a small curette to thoroughly remove excess cement.

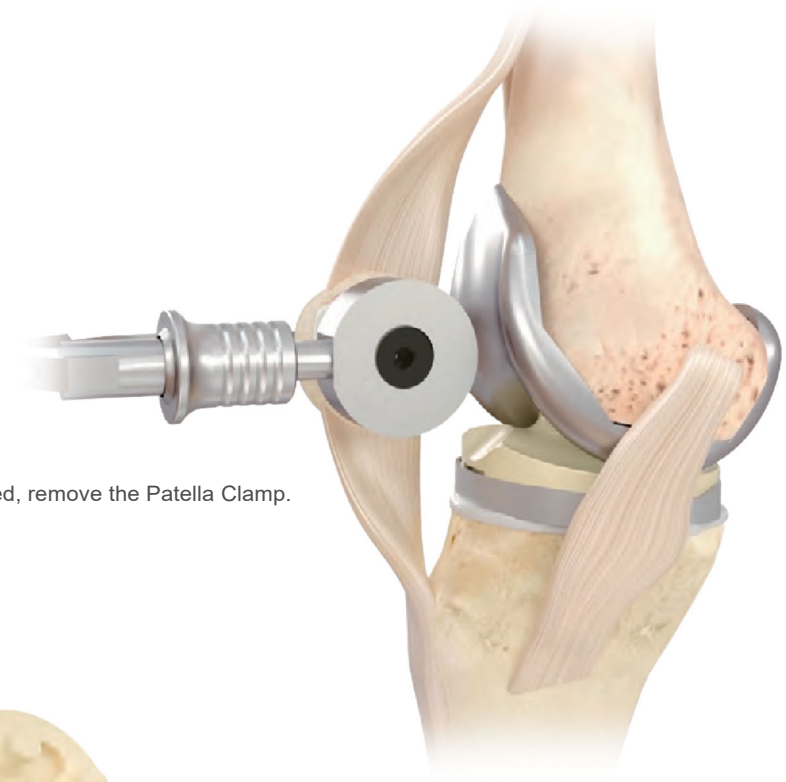


Figure 72

Once the cement has cured, remove the Patella Clamp.



Figure 73

The **MOBIO™** patella is designed with a dovetail cement pocket to maximize cement mantle interlock.

Closure

After the cement is fully cured, thoroughly irrigate and debride the joint. Apply a drain intracapsularly if desired. Close the soft tissues according to normal protocol. Refer to the package insert for complete product information, including indications, contraindications, warnings, precautions, and adverse effects.



Figure 74

Prosthesis Removal/Extraction

Standard techniques should be used to remove all cemented components.

To remove the tibial insert, use a small osteotome in the central window between the tibial insert and the baseplate. Apply force to leverage the tibial insert from the baseplate. Note removal of the the tibial insert will damage the tibial insert locking wire.

To remove the tibial baseplate, slide the feet of the Tibial Baseplate Extractor around the central island of the baseplate, as shown in Figure 75. Turn the lock knob clockwise to expand the extractor and engage the anterior rim of the baseplate. The Torque Knob can be used to securely tighten the lock knob.

Attach the Slap Hammer to the Tibial Extractor. Alternatively, the Universal Handle can be used. Back slap the assembly until the baseplate is removed.

To remove the femoral component, the Femoral Inserter/Extractor can be used.

Components must not be reused once removed.



Figure 75

APPENDIX A

Femoral Sizing and Rotation

AR Sizing and Rotation Guide Overview

The **MOBIO™** TKS offers both posterior referencing instrumentation and anterior referencing instrumentation. These instrumentation sets are provided separately and must be ordered prior to surgery, according to surgeon preference. Confirm instrumentation availability prior to surgery.

AR Sizer and Rotation Guide

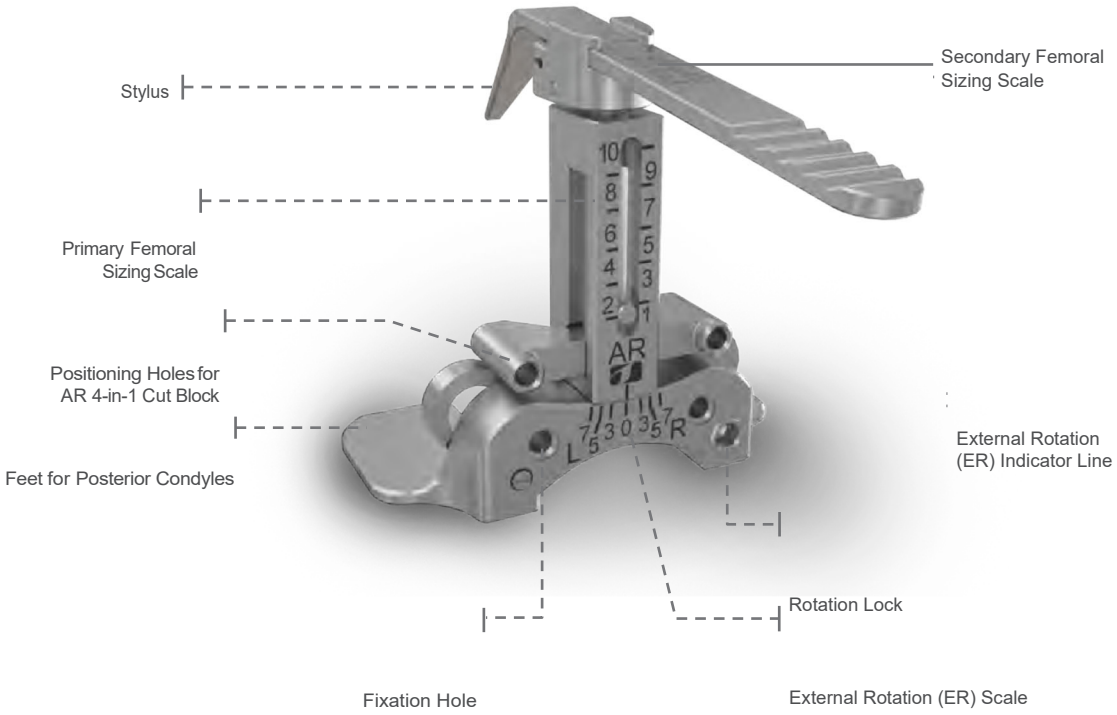


Figure 76

Tip

Anterior Referencing uses the anterior femur to set the A/P placement of the femoral component. Unlike traditional anterior referencing which requires an additional step to create a skim resection plane to reference, the **MOBIO™** AR Sizer and Rotation Guide uses the stylus to reference the anterior cortex and set the A/P location of the positioning holes for the placement of the AR 4-in1 Cut Block. Because the positioning holes on the Guide move anterior/posterior with respect to the stylus, it is critical that the size is measured carefully and accurately, and that the guide does not move during the drilling of the positioning holes.

Femoral Sizing and Rotation

AR Sizing and Rotation Guide Placement

Place the AR Sizer & Rotation Guide so that it is flush against the resected surface of the distal femur and the posterior feet are flush against the posterior femoral condyles (Figure 77). Center the guide mediolaterally. If necessary, insert a headed screw or pin into one or both of the fixation holes on the posterior aspect of the guide to draw the guide flush with the resected surface and to provide additional stability.

Use a headed screw or pin to ensure the guide is flush and stable.



Figure 77

Femoral Sizing and Rotation

Set External Rotation

Establish the external rotation by axially pivoting the body of the guide in relation to the posterior feet. Both the horizontal and vertical aspects of the guide provide visual cues for reference to the epicondylar and AP axes, respectively.

The ER Indicator Line will align with the tick marks of the ER Scale to indicate the external rotation setting of the guide. Ensure the external rotation setting indicates the correct laterality by referencing the L or R on the ER Scale.

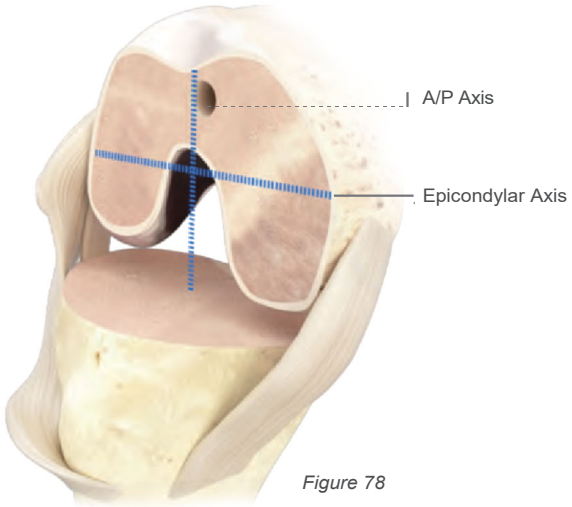


Figure 78

The AR Sizing & Rotation Guide allows for 0^0, 3^0, 5^0 and 7^0 of external rotation to be set. In Figure 79, the guide is set to 3 degrees of external rotation for a right femur. Once the desired external rotation is confirmed, use the Hex Driver assembled to the T-Handle to tighten the Rotary Lock on the AR Sizing & Rotation Guide. This will secure the external rotation angle of the guide.

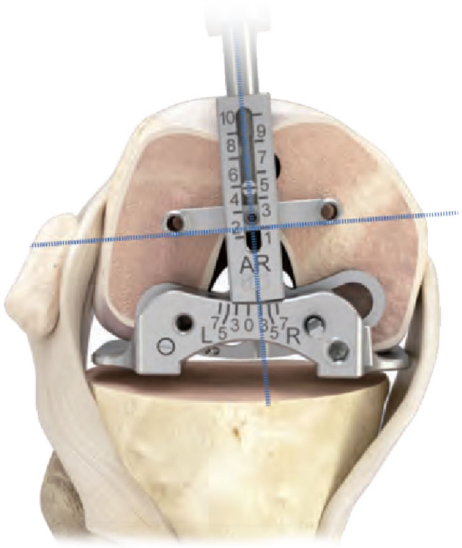


Figure 79a



Figure 79b

Femoral Sizing and Rotation

Measure Femoral Size

Ensure adequate exposure of the anterior cortex by slightly extending the knee and retracting soft tissue. The position of the stylus tip is designed to approximate the proximal position of the anterior flange of the femoral component. Likewise, the stylus tip approximates the exit point of the saw blade for the anterior chamfer resection. To lessen the likelihood of notching the anterior femur, position the stylus tip laterally and on the high point of the anterior cortex. Once the stylus tip is in the proper position, the size of the femur must be read from the primary femoral sizing scale on the body of the guide. The secondary femoral sizing scale on the stylus should be used to ensure close approximation with the primary scale reading.



Figure 80

Note

Excessive force should not be applied to the stylus tip. Excessive force to the stylus tip can potentially deform the stylus and affect the femoral size reading.

Once the proper femoral size is determined, the positioning holes can be drilled to prepare for the pegs on the AR 4-in-1 Cut Block. The positioning holes move anterior/posterior as the sizer moves. The placement of these holes will set the A/P placement and external rotation of the 4-in-1 Cut Block and femoral prosthesis. Therefore, care must be taken to ensure the sizer remains firmly in place at the appropriate size. Use the 3.2mm drill through the positioning holes on the AR Sizer and Rotation Guide to drill the holes.

Alternatively, a fluted pin can be used to drill the first positioning hole and left in place to stabilize the guide while the second hold is drilled.

Femoral Preparation

AR 4-in-1 Cut Block Overview

The **MOBIO**™ 4-in-1 Cut Blocks are specific to the referencing system used. Ensure that for anterior referencing, the AR 4-in-1 cut blocks are used.

The **MOBIO**™ TKS offers both Standard and Narrow width femoral prosthesis. The Narrow widths are available for sizes 3 through 7. The M/L width of the distal femoral prostheses can be referenced on the **MOBIO**™ 4-in-1 Cut Blocks as shown in Figure 81.

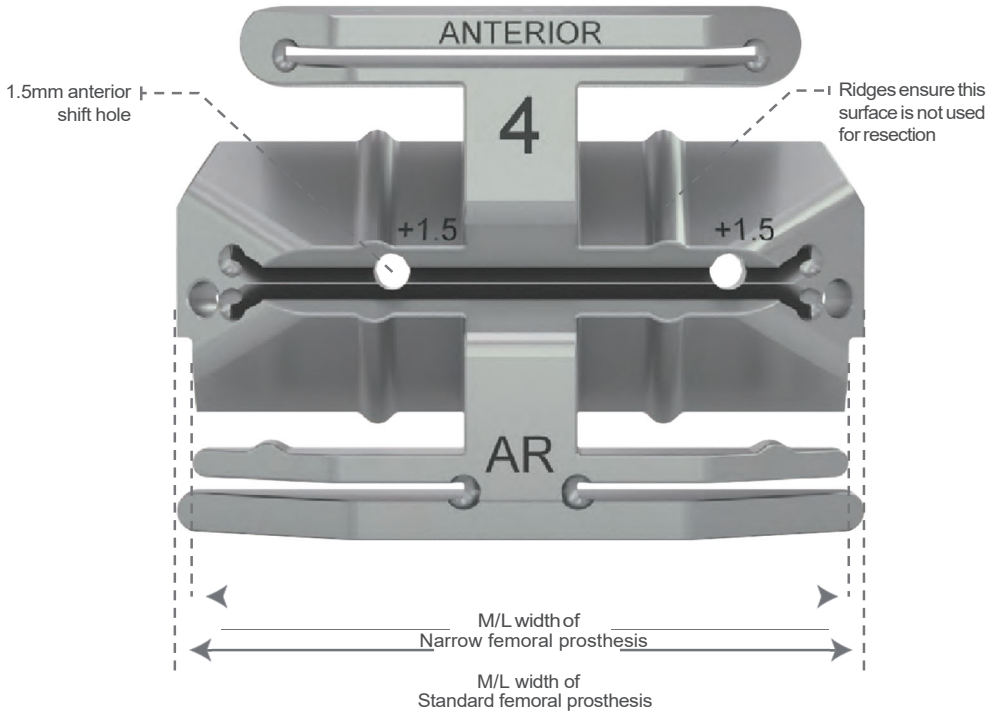


Figure 81

Tip

Anterior Referencing uses the anterior femur to set the A/P placement of the femoral component. The **MOBIO**™ AR 4-in-1 Cut Block fixation pegs on the back surface are the same distance from the anterior resection slot regardless of femoral size. The posterior resection is variable.

Femoral Preparation

AR 4-in-1 Cut Block Positioning

Select the AR 4-in-1 Cut Block that corresponds with the femoral size measured by the AR Sizer and Rotation Guide. By hand, place the AR 4-in-1 Cut Block on the distal femur by aligning the two pegs on the back of the block with the prepared positioning holes (drilled through the AR Sizing and Rotation Guide). Impact the face of the block until the block is flush with the femur. Use the Angel Wing through the resection slots of the cut block to visualize the resections. Check the position of the AR 4-in-1 Cut Block (Figure 82) and confirm the appropriate external rotation.

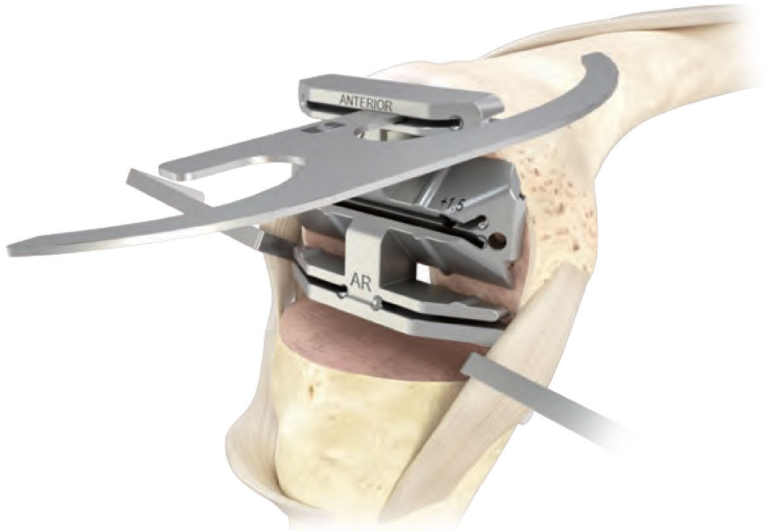


Figure 82

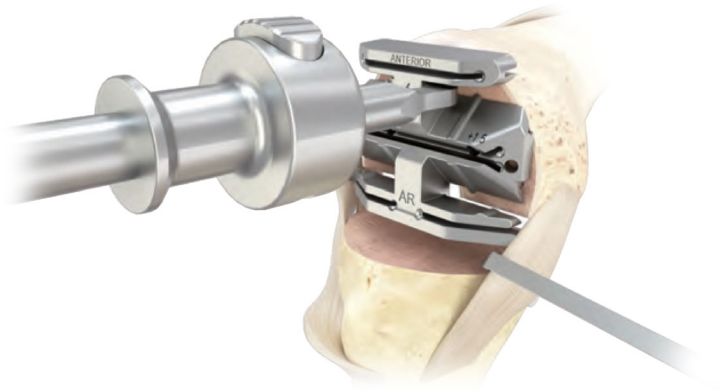


Figure 83

If inadequate bone will be removed from the posterior condyles, use the next size smaller AR 4-in-1 Cut Block in the same positioning holes for an additional 3mm of posterior condyle resection. First remove the current cut block. Use the Extractor Hook assembled to the Slap Hammer. Slide the hook into the cutout on the central column of the cut block and use the Slap Hammer to axially remove the cut block (Figure 83).

Femoral Preparation

AR 4-in-1 Cut Block Positioning *continued*

If there is risk of unacceptable notching of the anterior cortex, evaluate the necessary repositioning of the AR 4-in-1 Cut Guide. It may be necessary to re-measure the femur and prepare one size larger than originally measured. Alternatively, the **MOBIO**™ AR 4-in-1 Cut Blocks are designed with 1.5mm shift holes. Refer to Chart D for two options using the AR 4-in1 Cut Block 1.5mm shift holes to reduce the amount of anterior resection.

Option 1:: Use the 3.2mm drill to drill through the two +1.5mm shift holes in the AR 4-in-1 Cut Block. Remove the block with the Extraction Hook assembled to the Slap Hammer and place the same block into the newly drilled peg holes. This will reduce the anterior resection by 1.5mm and increase the posterior resection by 1.5mm.

Option 2: Use the 3.2mm drill to drill through the two +1.5mm shift holes in the AR 4-in-1 Cut Block. Remove the block with the Extraction Hook assembled to the Slap Hammer and place the next size larger block into the newly drilled positioning holes. This will reduce both the anterior resection and posterior by 1.5mm (thereby tightening the flexion space by 1.5mm).

	Option	Result
1	Shift the AR 4-in-1 Cut Block 1.5mm anterior	• reduces anterior resection by 1.5mm; • increases posterior resection by 1.5mm (makes flexion space looser by 1.5mm)
2	Shift the AR 4-in-1 Cut Block 1.5mm anterior AND Upsize the 4-in-1 Cut Block by one size	• reduces anterior resection by 1.5mm; • reduces posterior resection by 1.5mm (makes the flexion space tighter by 1.5mm)

Chart D: Options to reduce anterior resection using **MOBIO**™ AR Instruments.

Femoral Preparation

Femoral Resection (AR)

Once the final position of the selected AR 4-in1 Cut Block has been confirmed, use the Pin Driver to insert two Tension Screws through the oblique holes of the cut block.

Use a 1.27mm (0.050 in.) thick oscillating saw blade to perform the anterior, posterior, posterior chamfer, and anterior chamfer cuts through the resection slots of the cut guide.

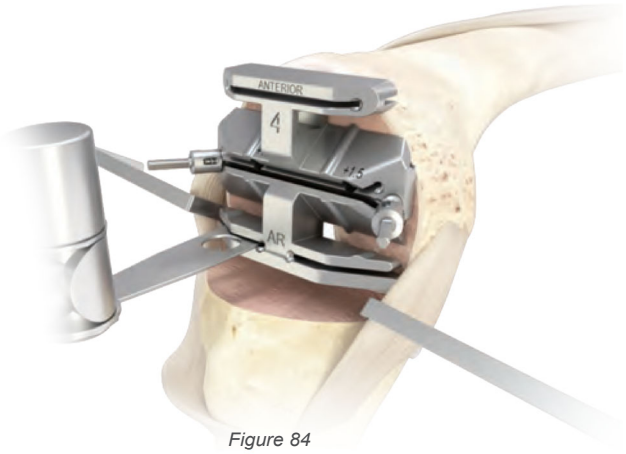


Figure 84

Upon completion of the bone cuts, use the Pin Driver to remove the Tension Screws. Use the Extractor Hook assembled to the Slap Hammer to axially remove the cut block.



Figure 85

Use the Spacer Block to assess the flexion gap spacing and confirm balance with extension gap.

Proceed to PS Femoral Notch Preparation step described in the Surgical Technique.

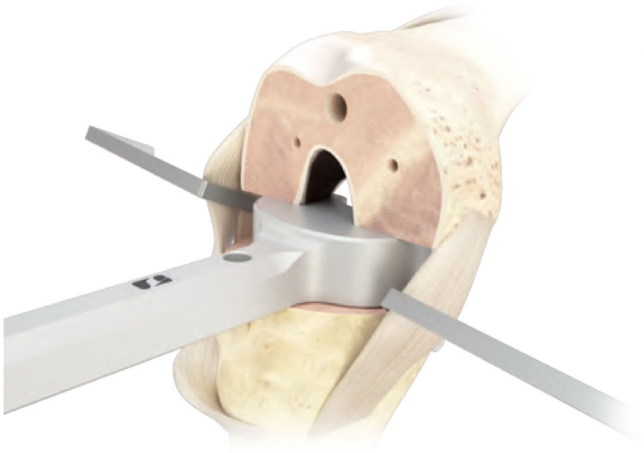


Figure 86

APPENDIXB

Proximal Tibial Resection: Spiked EM TAG

Instrument Assembly

To assemble the Spiked EM TAG Assembly, choose either the Ankle Clamp or Ankle Rest per surgeon preference. Slide the selected option onto the rail on the distal end of the EM TAG Base. Secure by tightening the varus/valgus adjustment knob.

Slide the Tibial Resection Block Adapter onto the Spiked Uprod as shown in Figure 88. Tighten the Adapter knob to secure in place. Slide the Spiked Uprod into the proximal end of the EM TAG Base and secure by tightening the EM TAG height adjustment knob.

Attach the Tibial Resection Block (Left or Right, 0^0, 3^0 or 5^0 posterior slope) to the Tibial Resection Block Adapter by pressing the button on the Adapter while sliding the two pegs into the two connector holes on the Tibial Resection Block. Release the button to capture the Tibial Resection Block. Confirm the block is locked to the Adapter.



Figure 87

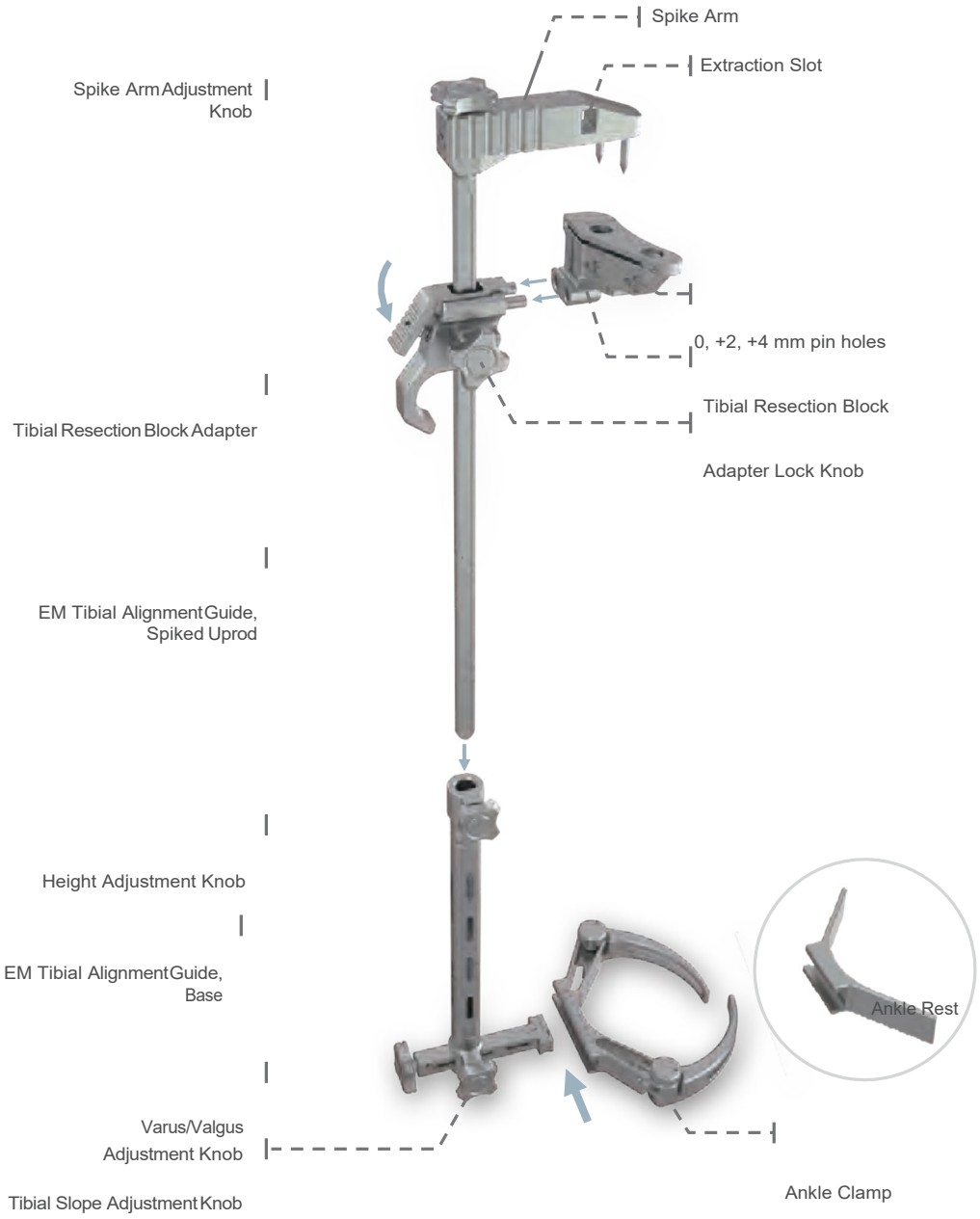

Spike Arm
Extraction Slot
Spike Arm Adjustment Knob
0, +2, +4 mm pin holes
Tibial Resection Block
Tibial Resection Block Adapter
Adapter Lock Knob
EM Tibial Alignment Guide, Spiked Uprod
Height Adjustment Knob
EM Tibial Alignment Guide, Base
Ankle Rest
Varus/Valgus Adjustment Knob
Tibial Slope Adjustment Knob
Ankle Clamp

Figure 88

Proximal Tibial Resection: Spiked EM TAG

Establish Tibial Alignment

Ensure adequate exposure of the tibial surface by flexing the knee and retracting the tibia anteriorly. The goal is to align the EM TAG with the mechanical axis of the tibia. Adjust the EM TAG to the approximate length of the tibia. Proximally, the guide should align over the medial third of the tibial tubercle, and distally, the guide should be positioned over the second toe. If using the EM TAG Ankle Clamp, place the arms of the Ankle Clamp around the ankle, proximal to the malleoli.

Loosen the spike arm adjustment knob to position the long spike on the proximal tibial surface, anterior to the tibial spine and centered mediolaterally. This should align the proximal portion of the EM TAG with the medial third of the tibial tubercle so that the guide is aligned with the long axis of the tibia.

When alignment is confirmed, gently tap the spike arm so that only the tip of the long spike engages with bone. Do not drive the spike in too deep. This will provide initial stability of the EM Tag while further adjustments are made.

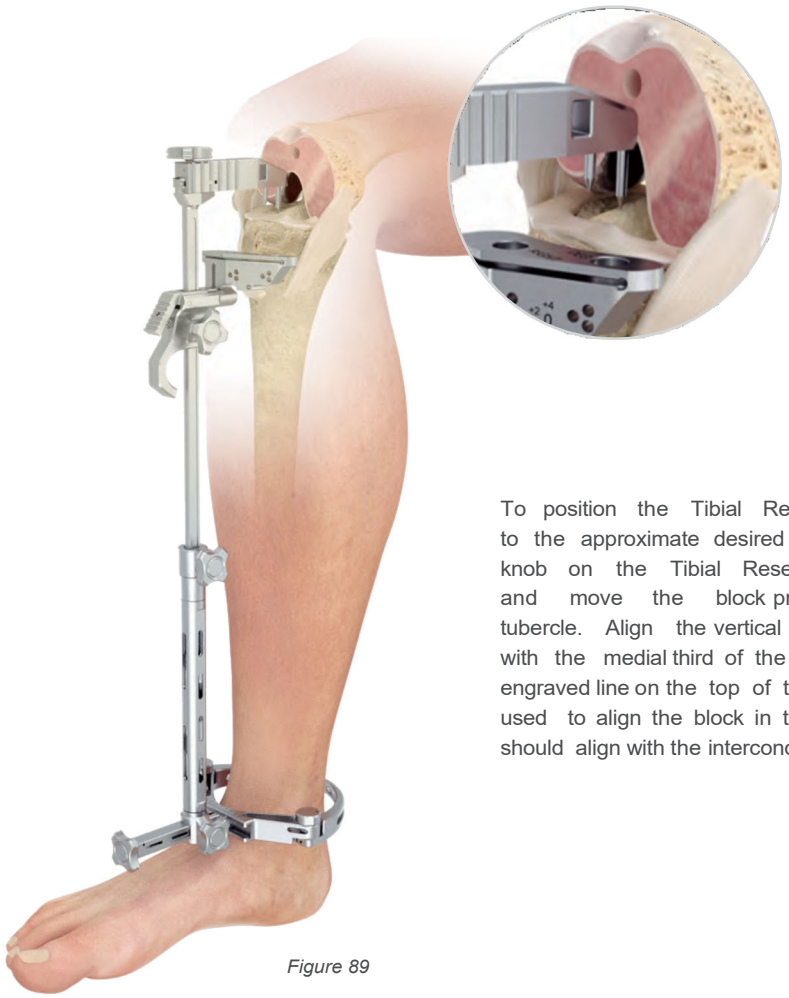


Figure 89

To position the Tibial Resection Block (TRB) to the approximate desired location, loosen the knob on the Tibial Resection Block Adapter and move the block proximal to the tibial tubercle. Align the vertical slot in the TRB with the medial third of the tibial tubercle. The engraved line on the top of the TRB can also be used to align the block in the M/L position and should align with the intercondylar eminence.

Proximal Tibial Resection: Non-Spiked EM TAG

Establish Tibial Alignment

With the varus/valgus adjustment knob in the loose position, slide the EM TAG Base so that the guide is aligned with the long axis of the tibia. This will typically position the EM TAG Base over the second metatarsal, or approximately 5-10mm medial to the midpoint between the maleoli. The markings on the ankle clamp indicate 1mm increments.



Figure 90



Figure 91

Adjust the EM TAG in the sagittal plane by loosening the tibial slope adjustment knob at the base of the guide and slide the base of the guide to the appropriate position. The goal is to align the long axis of the EM TAG so that the posterior slope of the resection will be parallel with the tibial surface or so that it provides the desired posterior slope. It is recommended to achieve 3 degrees of posterior slope in the tibial cut for the **MOBIO**™ PS or PS PLUS construct. Note that tibial bowing or excess soft tissue may make external referencing unreliable.

Proximal Tibial Resection: Spiked EM TAG

Set Tibial Resection Level

Set the final position of the EM TAG assembly by tapping the spike arm until both the long and short spikes are fully engaged with tibial bone. Tighten the height adjustment knob of the EM TAG assembly to lock the position of the Uprod with the Base. Use the Torque Knob over the adjustment knobs for final tightening if needed.

Place the Tibial Resection Stylus, 2/9 into the hole on the top surface of the TRB. The stylus is designed with a magnetic lock for easy and secure assembly to the block. Each tip of the stylus is labeled according to the corresponding resection level. The 2mm tip is used to establish the resection level from the most affected side of the tibial plateau for a minimal resection. The 9mm tip is used to establish the resection level from the least affected side of the tibial plateau.

Place the 2mm tip of the stylus on the lowest point of the affected side of the tibia, or place the 9mm tip on the lowest point of the less affected side. After determining the amount of resection, securely tighten the lock knob on the TRB Adapter. Remove the Stylus. Insert two fluted pins into the 0mm holes of the TRB to secure it to the proximal tibia. Use the Angel Wing through the resection slot of the TRB to visualize the bone resection.

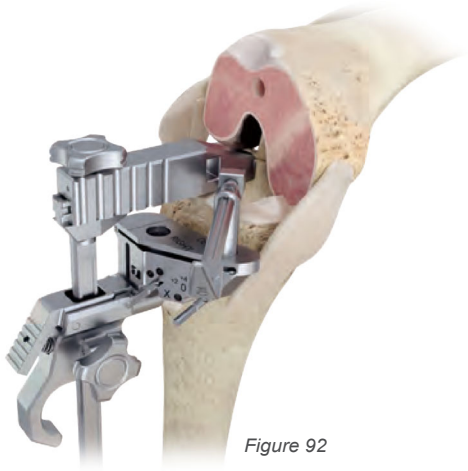


Figure 92

Tip

The Angel Wing is double sided and provides a short wing for ease of use on the tibia.

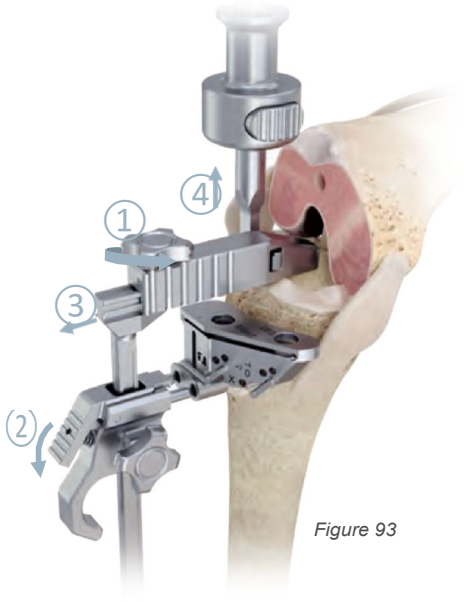


Figure 93

Once the TRB is fixed to bone, the Spiked EM TAG can be removed. First loosen the spike arm adjustment knob. Then press the release button on the Tibial Resection Block Adapter to disengage the EM TAG from the TRB. Gently pull the EM Tag assembly away from the tibia and apart from the spike arm. Use the Extractor Hook assembled to the Slap Hammer to remove the spike arm from the proximal tibial bone.

Proximal Tibial Resection: Spiked EM TAG

Resect Proximal Tibia

To confirm the alignment of the TRB, insert the Alignment Rod Adapter into the resection slot of the TRB, and slide the Alignment Rod through the circular hole on the Adapter. Confirm varus/valgus and posterior slope. If adjustment is needed, remove the pins and adjust accordingly.

An additional 2mm or 4mm resection can be made by repositioning the TRB over the fluted pins through the sets of holes marked +2 or +4, respectively. Once the final resection level is confirmed, insert a fluted pin into the oblique hole of the TRB for additional stability.

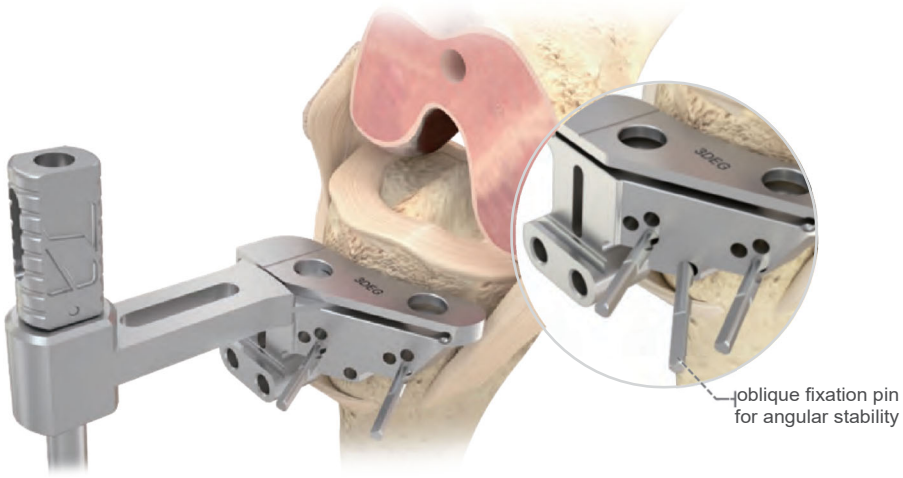
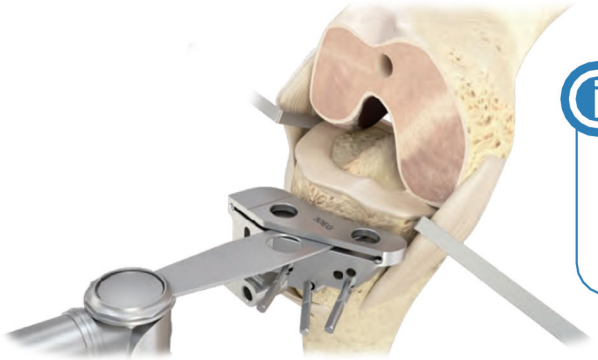


Figure 94



Tip

If desired, the resection can be made from the top surface of the TRB instead of through the captured resection slot. The top surface is 4mm above the resection slot, so the TRB must be shifted to the +4mm holes (from the 0mm holes) to maintain the desired resection level.

Figure 95

Use a 1.27mm (0.050in) thick oscillating saw blade to resect the proximal tibia through the resection slot of the TRB. After resection, check the flatness of the cut. Upon satisfactory completion of the cut, remove the pins and TRB.

APPENDIX C

Proximal Tibial Resection: Intramedullary (IM) Guide

Instrument Assembly

The Intramedullary Guide Assembly uses the intramedullary canal of the tibia to reference the mechanical axis of the tibia and prepare the proximal tibia resection. A preoperative radiograph of the tibia is necessary to ensure the tibial shaft is straight and will accept the IM Rod. The IM Guide cannot be used if the tibia is bowed or has too small of a canal to accept the IM Rod. The IM Rod is 8mm in diameter.

The IM Guide Assembly is shown in Figure 96. Assemble the desired Tibial Resection Block to the Tibial Resection Block Adapter. Slide the IM Tibial Alignment Guide rod through the hole on the TRB Adapter and secure by tightening the Adapter Lock Knob.

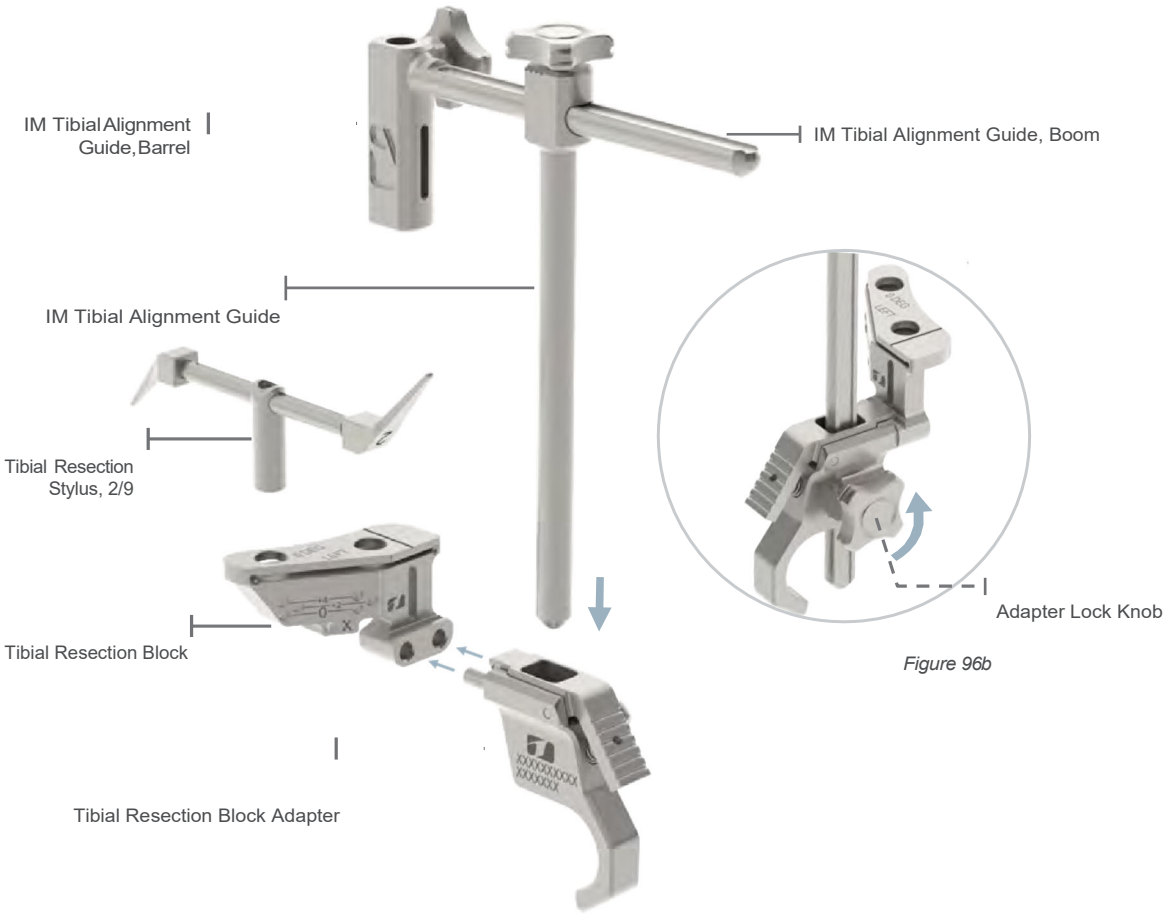


Figure 96b

Figure 96a

Proximal Tibial Resection: Intramedullary Guide

Resect Proximal Tibia

Use the 9mm IM Drill to create a pilot hole for entry to the tibial canal. Position the drill anterior to the ACL insertion and just medial to the tibial crest (3-5mm medial to midline) to ensure straight entry into the canal. Drill the hole. Slowly insert the IM Rod assembled to the T- handle. Remove the T-Handle, leaving the IM Rod in the tibia.

Slide the barrel of the IM Guide Assembly over the IM rod. Tighten the barrel adjustment knob to secure the assembly to the IM Rod. The boom lock knob and the TRB Adapter adjustment knobs can be used for positioning of the TRB. To check varus/valgus alignment, insert the thin end of the Alignment Rod Adapter into the resection slot of the Tibial Resection Block and slide the Alignment Rod through the adapter hole from proximal to distal. The rod should point toward the second toe. Slight varus/valgus adjustment can be made by loosening the boom knob and adjusting the assembly if needed.

Use the Tibial Resection Stylus, 2/9 to determine the depth of tibial resection. The stylus is designed with a magnetic lock for easy and secure assembly to the block. Each tip of the stylus is labeled according to the corresponding resection level. The 2mm tip is used to establish the resection level from the most affected side of the tibial plateau for a minimal resection. The 9mm tip is used to establish the resection level from the least affected side of the tibial plateau.

Place the 2mm tip of the stylus on the lowest point of the affected side of the tibia, or place the 9mm tip on the lowest point of the less affected side. After determining the amount of resection, securely tighten the lock knob on the TRB Adapter. Remove the Stylus. Insert two fluted pins into the 0mm holes of the block to secure it to the proximal tibia. Use the Angel Wing through the resection slot of the TRB to visualize the resection.



Figure 97

Tip

The Angel Wing is double sided and provides a short wing for ease of use on the tibia.

Proximal Tibial Resection: IM Guide

Tibial Resection

Remove the IM Tibial Alignment Guide by loosening the boom lock knob and disengaging the TRB Adapter from the TRB to allow the assembly to be gently pulled away from the block. Loosen the barrel lock knob and remove the assembly from the IM Rod. Use the T-handle to remove the IM Rod from the tibia.

Confirm position of the block. An additional 2mm or 4mm resection can be made by repositioning the TRB over the fluted pins through the sets of holes marked +2 or +4, respectively. Once the final resection level is confirmed, insert a fluted pin into the oblique hole of the TRB for additional stability.

Use a 1.27mm (0.050in) thick oscillating saw blade to resect the proximal tibia through the resection slot of the TRB.

After resection, check the flatness of the cut. Upon satisfactory completion of the cut, remove the pins and TRB. Proceed to Check Extension and femoral and tibial preparation as described in the Surgical Technique.

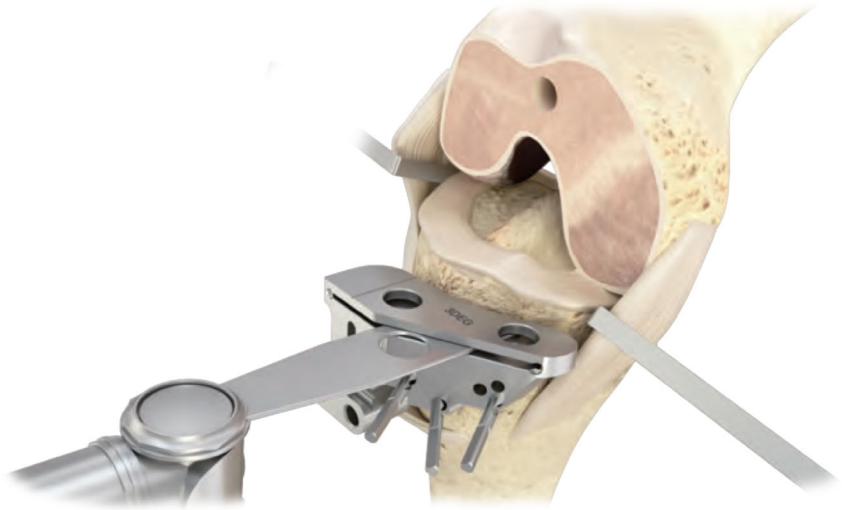


Figure 98

Tip

If desired, the resection can be made from the top surface of the TRB instead of through the captured resection slot. The top surface is 4mm above the resection slot, so the TRB must be shifted to the +4mm holes (from the 0mm holes) to maintain the desired resection level.

APPENDIX D

Tibiofemoral Compatibility Charts



PS Compatibility (*Units=mm*)			PS Femoral Component															
			Size	1	2	3N	3	4N	4	5N	5	6N	6	7N	7	8	9	10
			ML	55	57	57	59	59	62	62	65	65	68	68	71	74	77	80
Tibial Baseplate	Size	ML	AP	48	50	53	53	56	56	59	59	62	62	65	65	68	71	74
	A	58	38	A/1-4														
	B	61	40	BC/1-2		BC/3-6												
	C	64	42															
	D	67	44			DE/3-7												
	E	70	46															
	F	74	49					FG/4-9										
	G	77	52															
	H	80	55											HJ/7-10				
	J	85	59															
				PS Tibial Inserts														



PS PLUS Compatibility (*Units=mm*)			PS Femoral Component															
			Size	1	2	3N	3	4N	4	5N	5	6N	6	7N	7	8	9	10
			ML	55	57	57	59	59	62	62	65	65	68	68	71	74	77	80
Tibial Baseplate	Size	ML	AP	48	50	53	53	56	56	59	59	62	62	65	65	68	71	74
	A	58	38	A/1-2 +		A/3-4 +												
	B	61	40	BC/1-2 +		BC/3-6 +												
	C	64	42															
	D	67	44			DE/3-7 +												
	E	70	46															
	F	74	49					FG/4-9 +										
	G	77	52															
	H	80	55											HJ/7-10 +				
	J	85	59															
				PS+ Tibial Inserts														

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