b-ONE ORTHO

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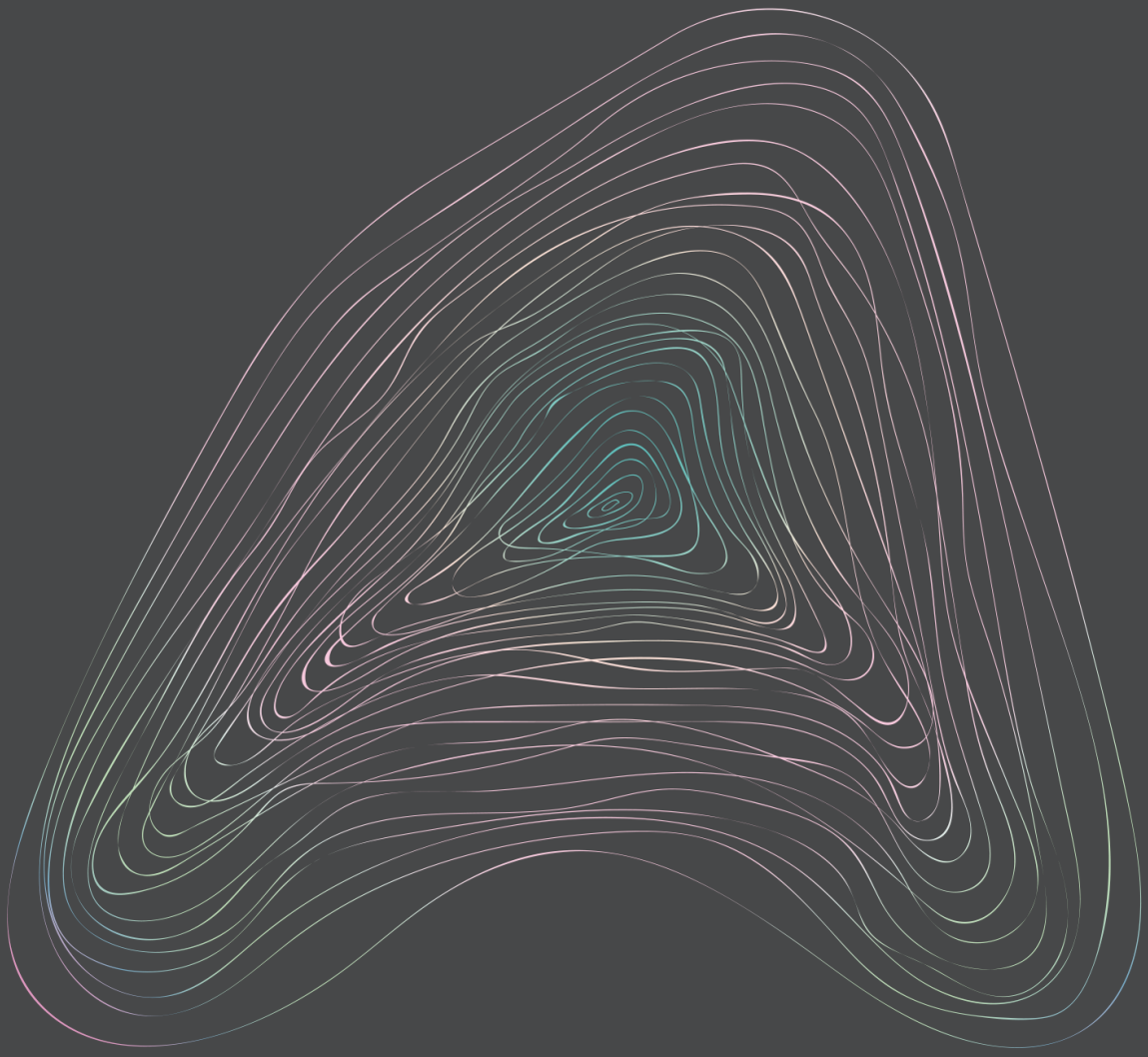


MOBIO® Total Knee System
Surgical Technique

for CR and CR Plus Implants

TABLE OF CONTENTS

Cruciate retaining (CR) knee designs allow preservation of the PCL and avoid sacrificing bone for an intercondylar box. However, these knee designs allow for some anterior translation of the femur on the tibia especially in early flexion, where Condylar Stabilizing (CR+ plus) inserts provide anterior posterior stability without the need for a posterior cam.

Condylar Stabilizing (CR+ Plus) inserts have an elevated anterior and deep dish trough creating more congruency between the femur and polyethylene insert. This improved congruency serves to prevent anterior subluxation of the femoral condyles during flexion.

SYSTEM OVERVIEW

The b-ONE® Total Knee System is a comprehensive total knee prosthesis system designed by top R&D, surgeons, and clinicians.

This surgical technique describes use of the cruciate retaining (CR) and condylar stabilizing (CR Plus) articulations for total knee replacements.

Streamlined, intuitive, sensible instrumentation options designed for surgical preference are available in the following configurations. Please confirm with your local representative the desired configuration to have available for surgery.

» Femoral resection options:

    - posterior referencing

    - anterior referencing

» Intramedullary or extramedullary tibial resection

Femoral components are available in sizes 1-10, with narrow size options also available for sizes 3-7. They are designed to accomodate CR and CR Plus inserts.

Tibial baseplate components are available in 9 sizes described as A, B, C, D, E, F, G, H , J.

Symmetric patella components are available in standard. Sizes include diameters (mm): 26*, 27, 29, 32, 35, 38, and 41 with incremental thickness increases. *Size 26 is only compatible with femoral sizes 1 and 2.

Polyethylene inserts are available in standard polyethylene. Sizes include Size A, Size B/C, Size D/E, Size F/G, Size H/J with thickness (mm) ranging from 9, 10, 11, 12, 13, 14, 16, 19, 22, 25

*The following content presents the surgical technique of the MOBIO® CR and CR Plus Knee devices. This surgical technique serves as a guideline when using these instruments but the choice of appropriate steps to follow are ultimately the responsibility of the surgeon performing the operation.

INDICATIONS AND CONTRADICATIONS

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.

- Posttraumatic 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.

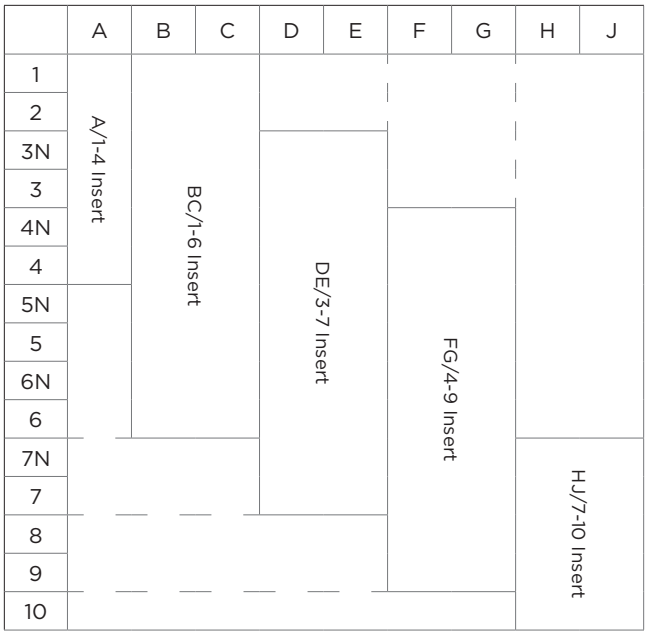
Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.

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.

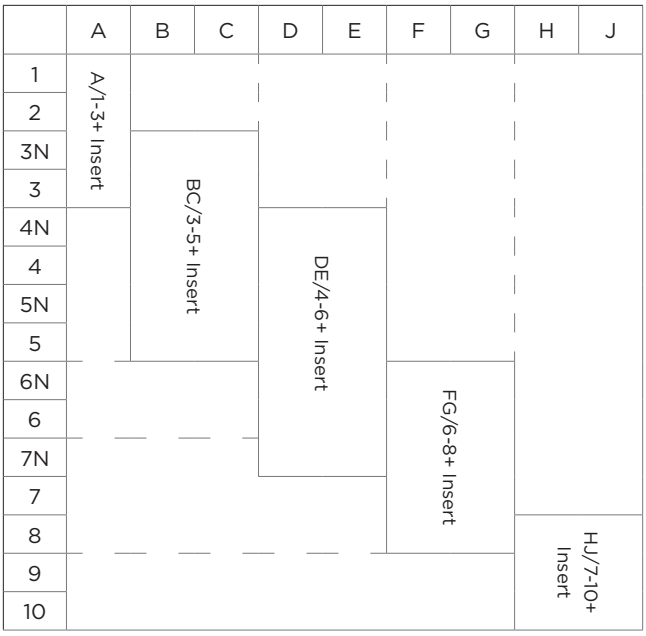
Any condition not described in the Indications for Use.

COMPATIBILITY CHARTS

CR Interchangeability Chart



CR+ Interchangeability Chart



Femoral and Patellar Compatibility Chart (mm)

	1	2	3N	3	4N	4	5N	5	6N	6	7N	7	8	9	10
26	X	X													
27	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
29	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
32	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
35	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
38	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
41	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Femoral Component Dimensions (mm)

	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
AP	48	50	53	53	56	56	59	59	62	62	65	65	68	71	74

Tibial Component Dimensions (mm)

	A	B	C	D	E	F	G	H	J
ML	58	61	64	67	70	74	77	80	85
AP	38	40	42	44	46	49	52	55	59

PIN/SCREW INFORMATION

The chart below contains relevant information on the pins and screws that are compatible with this system.

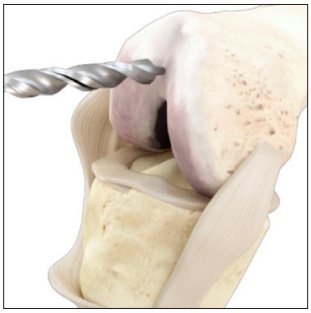
Pin/Screw	Description	Catalog Number	Compatible Driver/ Extractor	Description
	Threaded Headless Pin	8829005001/8829005000		Pin Driver
	Fluted Pin	8829012002/8829012000		Pin Puller/Pin Driver
	Tension Screws	8829004000		Pin Driver
	Headed Pin, 25 mm Headed Pin, 35 mm	8829006025/8829006250 8829006035/8829006350		Pin Puller
	Headed Screw, 32mm Headed Screw, 22mm	8829016320 8829016220		Pin Driver

Pin Driver
8829011000

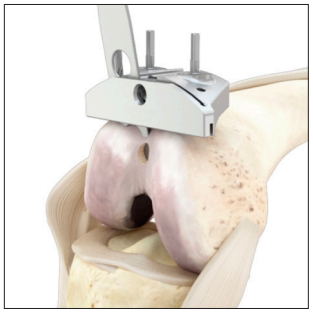
Pin Puller
8829003000

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

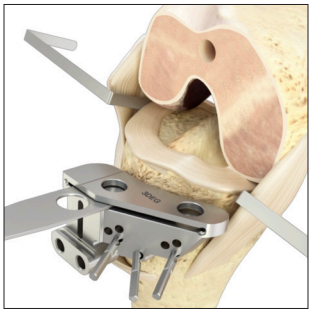
SURGICAL SNAP SHOTS



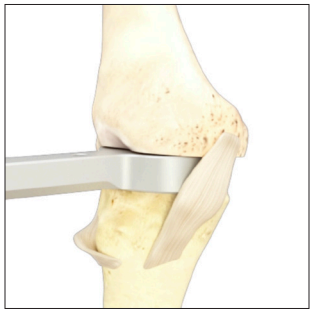
1 - Drill Femoral IM Canal



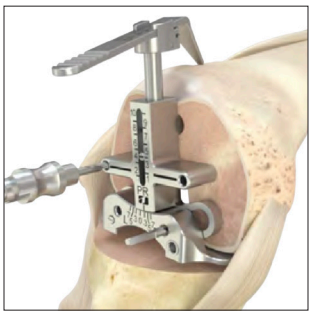
2 - Resect Distal Femur



3- Tibial resection, IM or EM Option

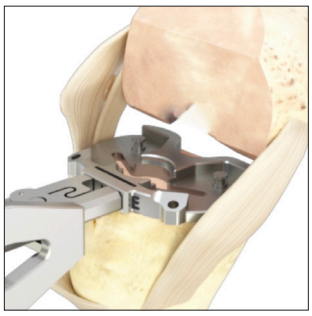


4- Assess Extension Gap and Tissue Balancing (Optional)

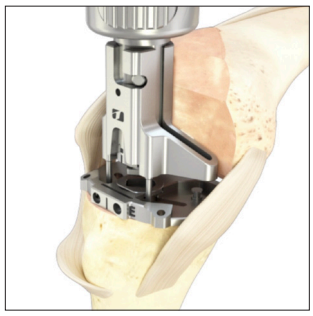


5 - Femoral Sizing & Rotation

6 - Femoral 4-in-1 Resection



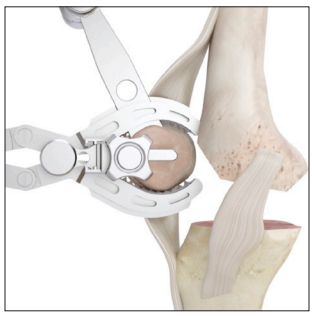
7 - Tibial Sizing Plate



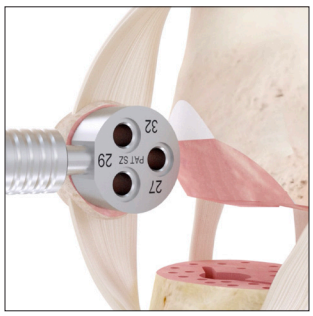
8 - Tibial Baseplate Preparation

9 - Tibial insert trial

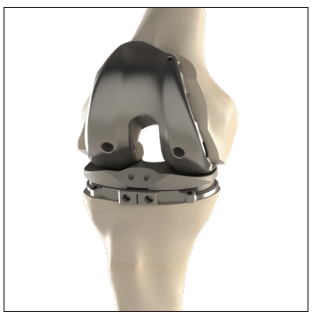
10 - Femoral Trial Placement



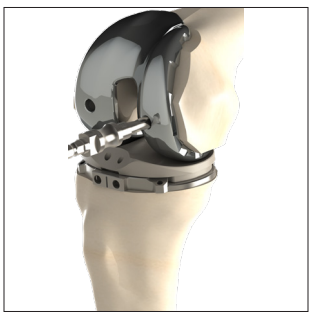
11-Patella Resection



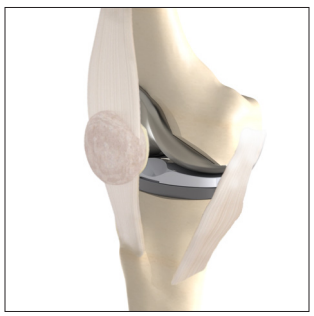
12 - Patella Sizing and Peg Drill



13 - Patella trial and Trial Reduction



14 - Drill Femoral Peg holes



15 - Final Implantation and Closure

RESECT DISTAL FEMUR

Femoral Canal Exposure

Using the IM Drill, drill a hole into the intramedullary femoral canal. The canal is approximately 10mm anterior to the origin of the PCL and slightly medial to the mid-line of the trochlea. The inferior aspect of the hole should be approximately 1-2mm anterior to the intercondylar notch.

To make the hole larger for depressurization of the canal, toggle the bit at the entrance. The tapered feature of the IM Drill assists with this. Irrigate and suction the canal to further decrease the risk of fat embolism

Femoral Alignment

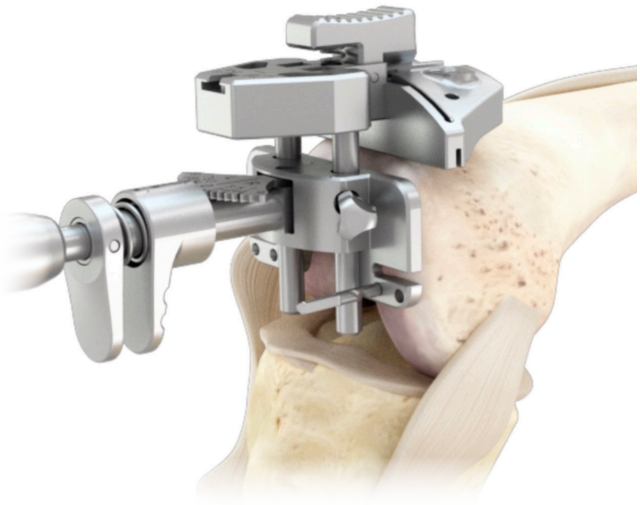
Attach the T-Handle to the IM Rod Insert the IM Rod into the Distal Femoral Alignment Guide Set the valgus angle on the appropriate Left or Right scale on the Alignment Guide by pulling back on the spring-loaded trigger and aligning the appropriate notch with the stop along the guide axis The angle options range from 0° to 9° valgus Typical angles range from 4° to 6° Insert the IM Rod into the femoral IM canal until the alignment guide plate contacts the distal femur

For additional fixation, place pins along the medial or lateral sides of the Femoral Distal Alignment Guide to secure it in place

Assemble the selected Distal Resection Guide Tower to the Distal Resection Block (DRB) Insert the posts of the Guide Tower into the two anterior holes of the Distal Femoral Alignment Guide to position the DRB on the anterior femur Confirm the Distal Femoral Alignment Guide is flush with the most prominent distal femoral condyle to ensure accurate placement of the DRB and accurate resection, then fix the DRB position to the bone with two headless pins through the “0” holes The Adjustable Distal Femoral Guide Tower allows resection adjustment from 8mm-11mm in 1mm increments.

Remove the Distal Femoral Alignment assembly by first removing the IM Rod Press the button to disengage the Guide Tower from the DRB and remove the Distal Femoral Alignment Guide with the Guide Tower

Additional resection can be set in 2mm increments by sliding the Distal Resection Block off the smooth pins and re-aligning the pins with the holes marked “+2” or “+4”, increasing resection by 2mm or 4mm respectively

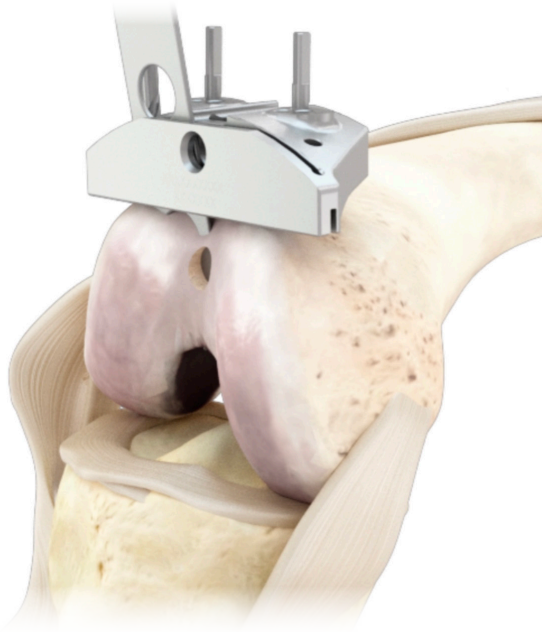


Distal Resection

Once the Distal Resection Block depth is satisfactory, for additional fixation, place headless pins through the divergent holes.

Using a .050” (1.27mm) blade, resect the distal femur.

Remove all pins and the distal block.



RESECT PROXIMAL TIBIA - EXTRAMEDULLARY TECHNIQUE

To assemble the EM Tibial Alignment Guide, choose either the Tibial Ankle Clamp or Ankle Rest, depending on surgeon preference. Slide the chosen option into the distal end of the Base Assembly.

The EM Tibial Alignment Guide Assembly can be assembled with or without a Spiked Uprod, depending on surgeon preference.

EM Tibial Alignment Guide without spiked Uprod

Attach the desired Tibial Resection Block (Left or Right, 0°, 3° or 5° posterior slope) to the EM Tibial Non-spiked Uprod, and slide the EM Tibial Non-spiked Uprod into the proximal end of the EM Tibial Base Tube.

EM Tibial Alignment Guide with Spiked Uprod

Attach the desired Tibial Resection Block (Left or Right, 0°, 3° or 5° posterior slope) to the Tibial Cut Block Adapter.

Slide the Tibial Cut Block Adapter/Resection Block Assembly onto the tube of the Spiked Uprod as shown in the image above; note the flat end of the Spiked Uprod tube will align with the flattened aspect of the Tibial Cut Block Adapter hole.

Then slide the distal end of the Spiked Uprod tube into the proximal end of the Base Assembly tube.

EM Tibial Alignment Guide Alignment

If using the Ankle Clamp option, place the ankle clamp arms around the ankle. Adjust the length of the EM Tibial Alignment Guide to position the Resection Block near the proximal tibia.

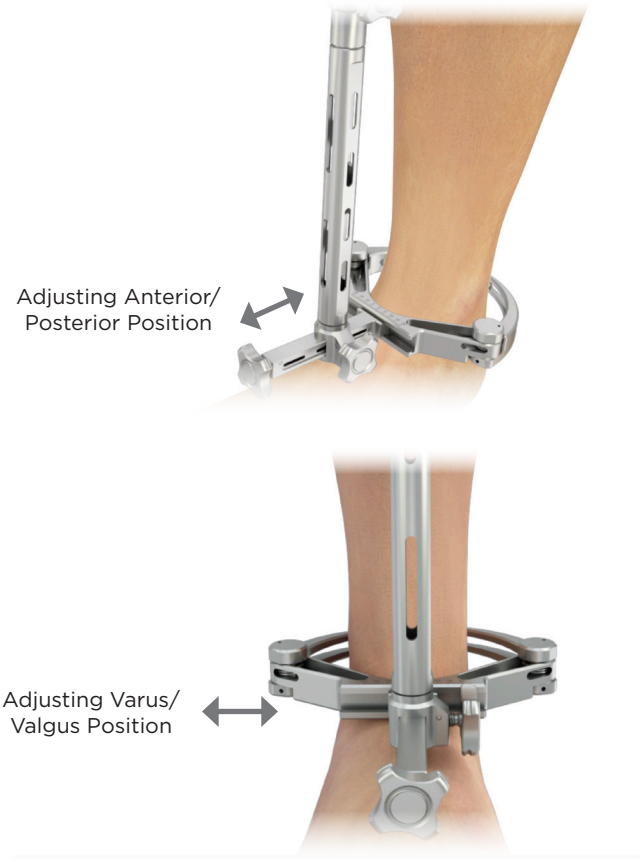
If using the Spiked Uprod, impact the long spike into the proximal tibia for adjustable stability.

The M/L position of the Guide can be adjusted by loosening the knob at the ankle, on the front of the assembly, and sliding the assembly along the capture of the ankle clamp.

The slope can be adjusted by loosening the second knob by the ankle, and sliding the Guide along the ankle post.

The goal is to align the EM Alignment Guide so that it aligns over the medial third of the tibial tubercle and second toe.

If using the Spiked Uprod, impact the second spike to secure the assembly.



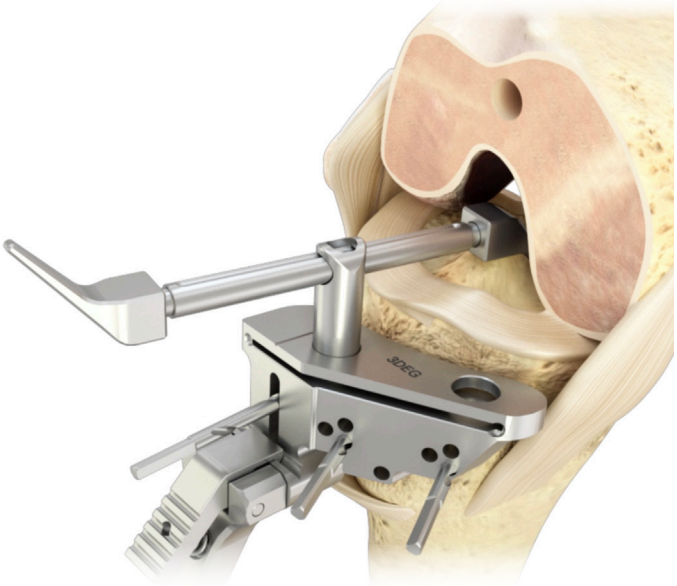
EM Tibial Alignment Guide Resection Level

Attach the Tibial Depth Resection Stylus on to the Tibial Resection Block. It is recommended that the 2mm tip rest on the lowest point of the damaged compartment or the 9mm tip rest on the least damaged compartment.

The Tibial Resection block can be pinned through the center slot to provide M/L stability. Slope and micro superior/inferior adjustments of the EM Tibial Alignment Guide can be made.

Use the Angel Wing to verify the desired resection level and slope. Once the desired level/slope is determined, tighten the knobs on Alignment Assembly.

Fix the position of the tibial block with two headless pins through the “0” holes.

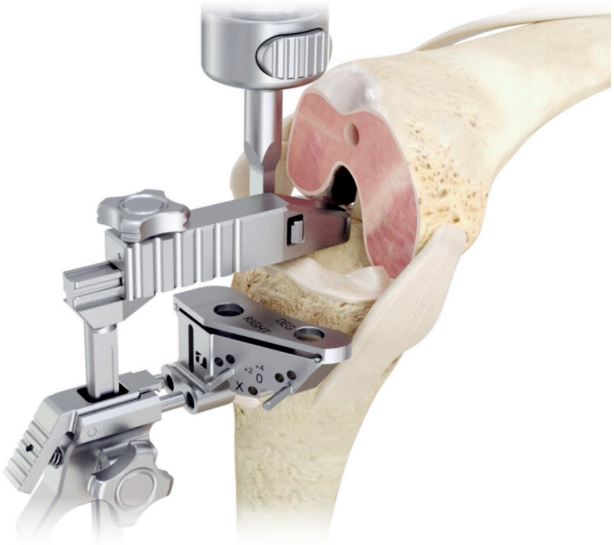


Spiked Uprod Removal

To remove the Spiked Uprod Assembly, loosen the top knob of the Spiked Uprod and detach the Cut Block Adapter from the Resection Block by depressing the button on the Adapter.

Slide the Extraction Hook, attached to the Slaphammer, into the hole on the Spiked Uprod as shown in the image to the right.

Be sure to disengage the Cut Block Adapter from the Cut Block before applying force to the Slaphammer.



RESECT PROXIMAL TIBIA - INTRAMEDULLARY TECHNIQUE

Tibial IM Canal Exposure and Alignment

Using the IM Drill, locate and drill a hole into the intramedullary tibial canal. Define the correct rotational tibia axis referring to the condylar axis, medial 1/3 of the tibia tubercle and the center of the ankle.

Attach the T-Handle to the IM Rod and insert into the drilled canal. Remove the T-Handle, leaving the IM Rod in the canal.

Assemble the desired Tibial Resection Block (left or right, 0°, 3° or 5° posterior slope) to the IM Tibial Alignment Guide, and slide the IM Tibial Alignment Guide Assembly onto the IM Rod. Attach the Tibial Depth Resection Stylus on to the Tibial Resection Block. It is recommended that the 2mm tip rest on the lowest point of the damaged compartment or the 9mm tip rest on the least damaged compartment. Once the desired resection level is determined, tighten the knobs on Alignment Assembly. Use the Angel Wing to verify the desired level and slope of the resection.

Fix the position of the tibial block with two headless pins through the “0” holes.

Proximal Resection

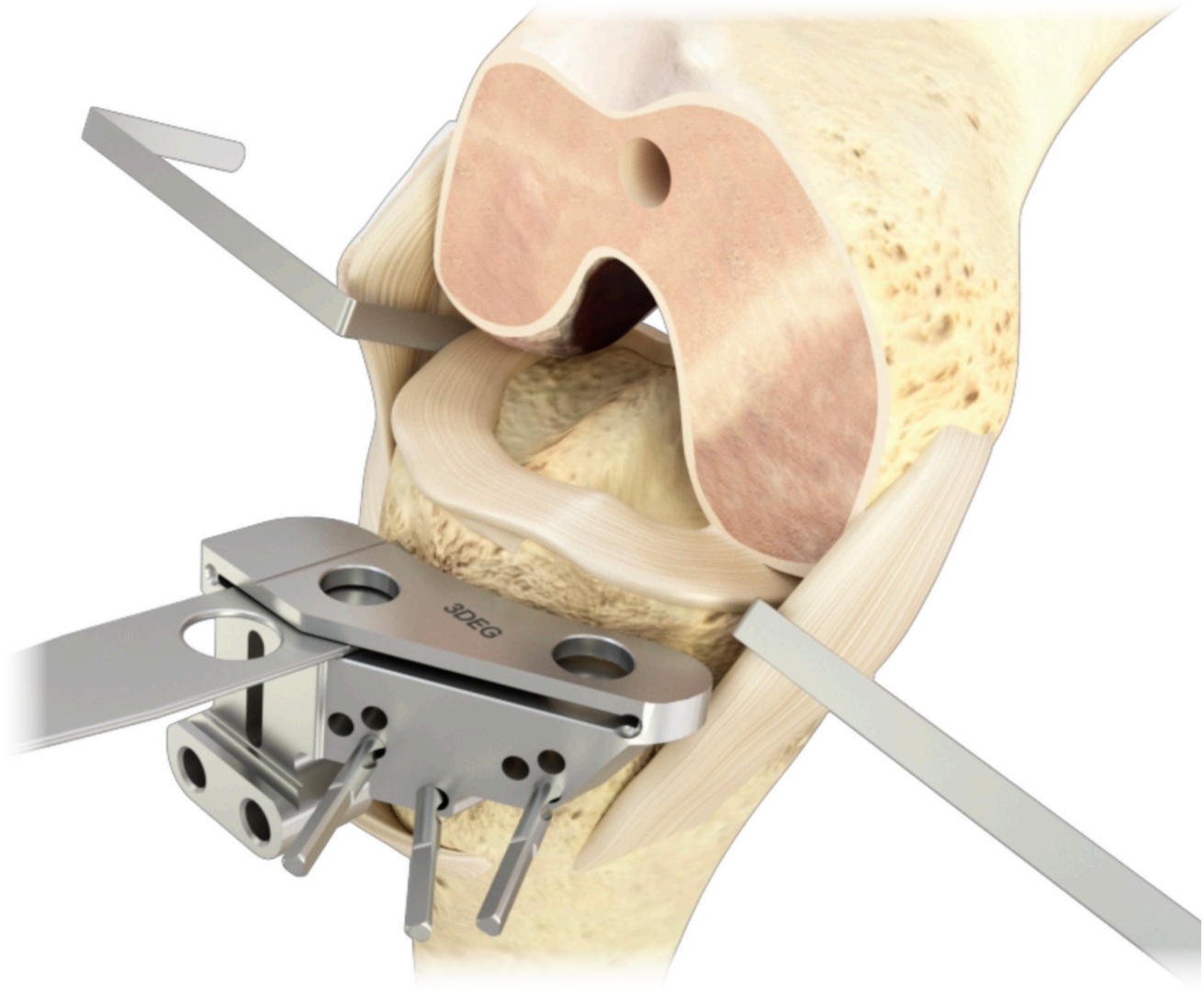
Remove all the Alignment Assembly instruments to leave the tibial block. For additional stability, place a headless pin through the angled hole, located below the “0” holes and indicated by an X mark, to serve as a crosspin.

To check the varus/valgus position of the resection block, place the flat end of the alignment rod adapter into the resection slot of the Tibial Resection Block. Slide the Alignment Rod through the hole of the Alignment Rod Adapter. The Alignment Rod should be parallel with the tibial axis.

Resect the tibia using a .050” (1.27mm) oscilating saw blade through the captured slot.

Additional resection can be set in 2mm increments by removing the crosspin and sliding the Resection Block off the smooth pins and re-aligning the pins with the holes marked “+2” or “+4”, increasing resection by 2mm or 4mm, resepectively.

Remove all pins and the Tibial Resection Block.



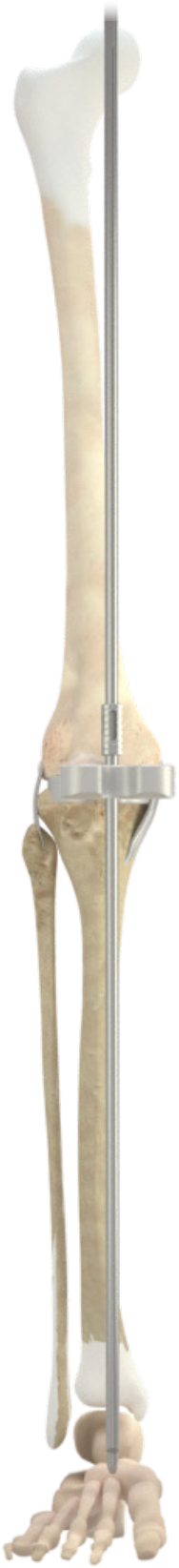
EXTENSION GAP ASSESSMENT

Gap Assesment

To check the extension gap, fully extend the leg and place the appropriate size Spacer Block between the resected 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.

If the extension gap is not balanced, reassess resection amount and angle, or perform appropriate soft-tissue releases to achieve balance.

The Alignment Rods with couplers can be inserted into the Spacer Block to assess alignment of the leg.



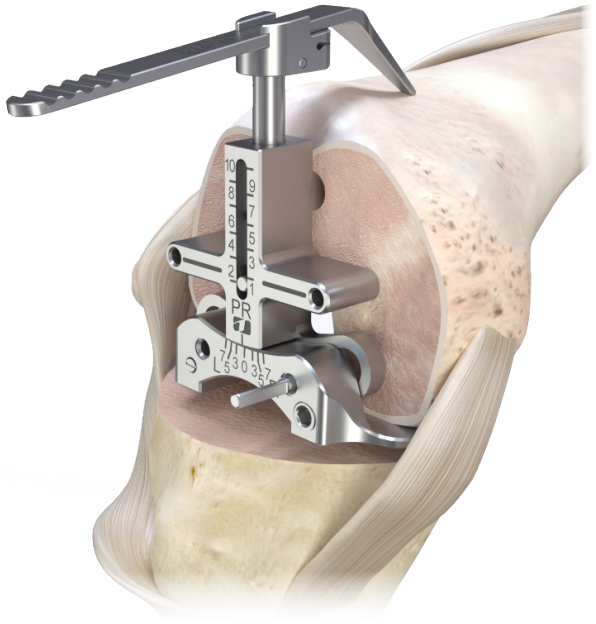
FEMORAL SIZING AND ROTATION - PR

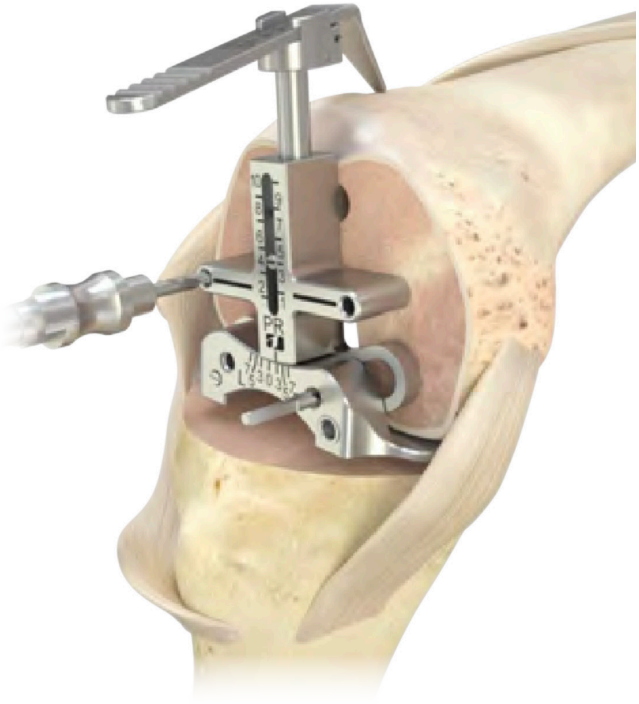
PR Femoral Sizing & Rotation

Mount the PR Rotational Sizer against the distal resected surface and the sizer feet flush against the posterior condyles. Adjust to the desired amount of external rotation, from 0° to 7°, for Left or Right leg setting. The sizer center slot should be positioned to be in line with Whiteside's line for M/L drill hole optimization.

If necessary, secure the sizer feet to the femur using headless pins. The external rotation can be locked into place by tightening the 3.5mm hex located on the face of the right foot of the sizer, below the optional pin hole.

Position the stylus tip on the highest point of the anterior cortex of the femur while adjusting the sizer stylus to indicate the proper femoral component size. The stylus will then be near the exit point of the resecting saw blade.



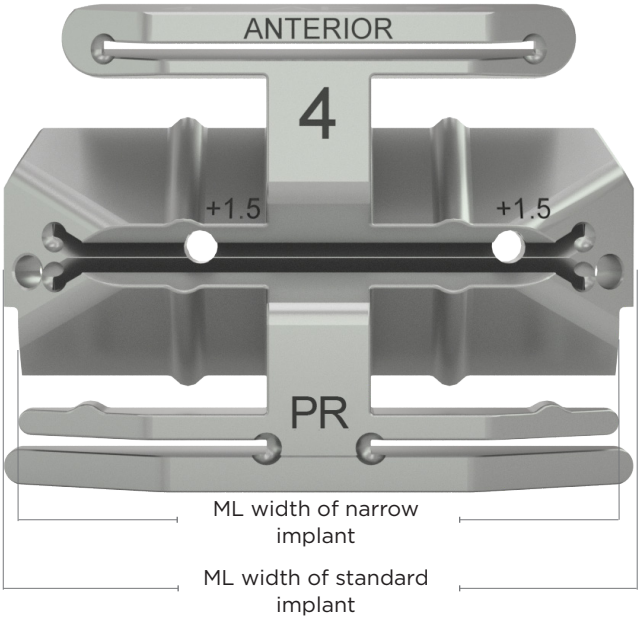


After the PR Sizer is appropriately positioned on the femur, flush against the distal femoral resection, the femoral component size is determined, and correct external rotation is confirmed, use the 3.2mm Drill through the M/L holes on the PR Sizer to pre-drill the holes for the pegs on the PR 4-in-1 Cut Block.

Remove all pins and the PR Sizer.

FEMORAL BONE CUTS - PR

Femoral 4-in-1 Resections

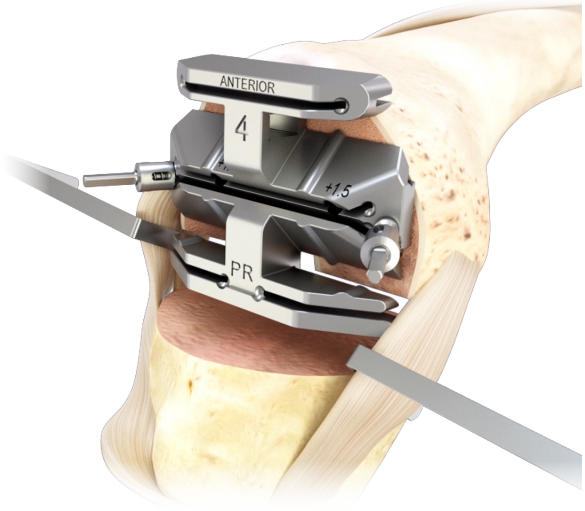


Select the appropriate size PR 4-in-1 Cut block.

The PR 4-in-1 Cut Block allows visualization of the M/L boundary of the final implant components: the outer width of the cut block represents the M/L boundary of the Standard femoral components. The cut-out edge represents the M/L boundary of the narrow femoral components.

Note: the AP dimension increases 3mm per size.

Place the PR 4-in-1 Cut block on the distal femur, aligning the backside pegs into the drill holes determined by the PR Sizer. The Tibial Tray Trial Inserter can be used to insert the PR 4-in-1 Cut block and struck with a mallet to ensure the block is flush with the bone.



Use the Angel Wing through the resection slots to visualize the resections.

For additional fixation of the 4-in-1 Cut Block, use headless pins or Tension Screws through the M/L holes. Once the block is stabilized, proceed with bone resection cuts using an oscillating sawblade of .050" (1.27mm) thickness.

Remove all pins/screws. If needed, the Slaphammer can be used to extract the 4-in-1 Cut Block by sliding the extraction hook into the hole under the anterior cut slot of the Cut Block.

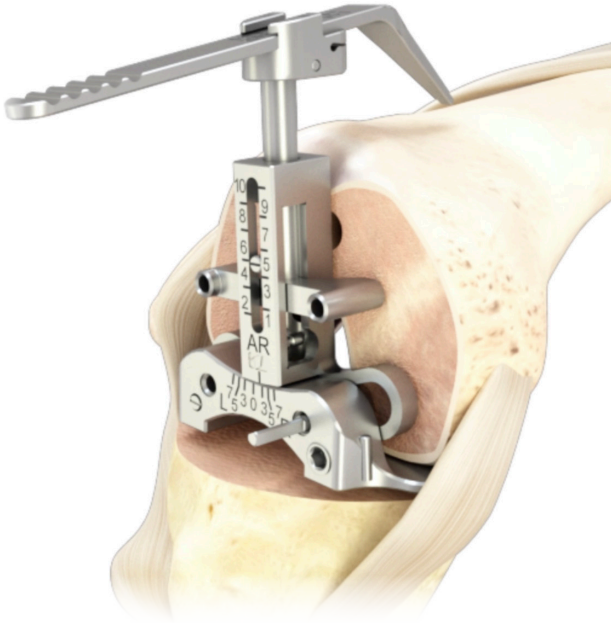
FEMORAL SIZING AND ROTATION - AR

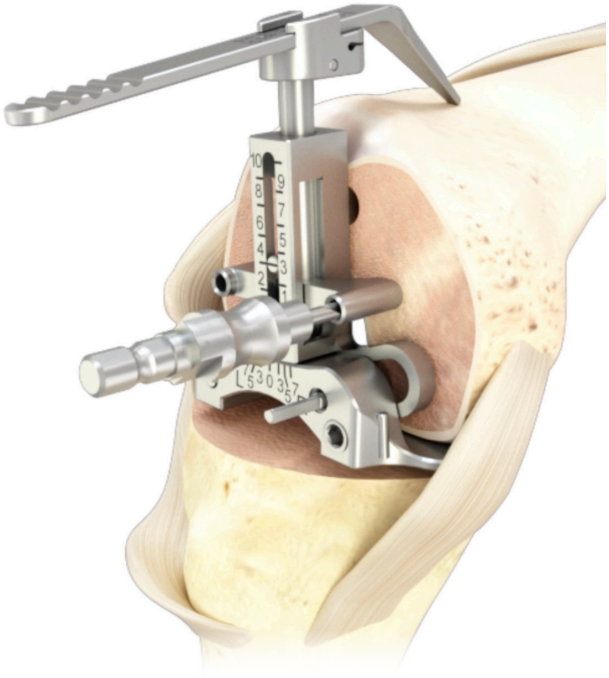
AR Femoral Sizing & Rotation

Mount the AR Rotational Sizer against the distal resected surface and the sizer feet flush against the posterior condyles. Adjust to the desired amount of external rotation, from 0° to 7°, for Left or Right leg setting. The sizer center slot should be positioned to be in line with Whiteside's line for M/L drill hole optimization.

If necessary, secure the sizer feet to the femur using headless pins. . The external rotation can be locked into place by tightening the 3.5mm hex located on the face of the right foot of the sizer, below the optional pin hole.

Position the stylus tip on the highest point of the anterior cortex of the femur while adjusting the sizer stylus to indicate the proper femoral component size. The stylus will then be near the exit point of the resecting saw blade.





After the AR Sizer is appropriately positioned on the femur, flush against the distal femoral resection, the femoral component size is determined, and correct external rotation is confirmed, use the 3.2mm Drill through the M/L holes on the AR Sizer to pre-drill the holes for the pegs on the AR 4-in-1 Cut Block.

Note that the A/P location of these holes will change with the size, so be sure to hold the sizer so that it does not move while drilling.

Alternatively, use smooth pins to pin one hole to hold the sizer in place, and then proceed to drilling the second hole. Remove all pins and the AR Sizer.

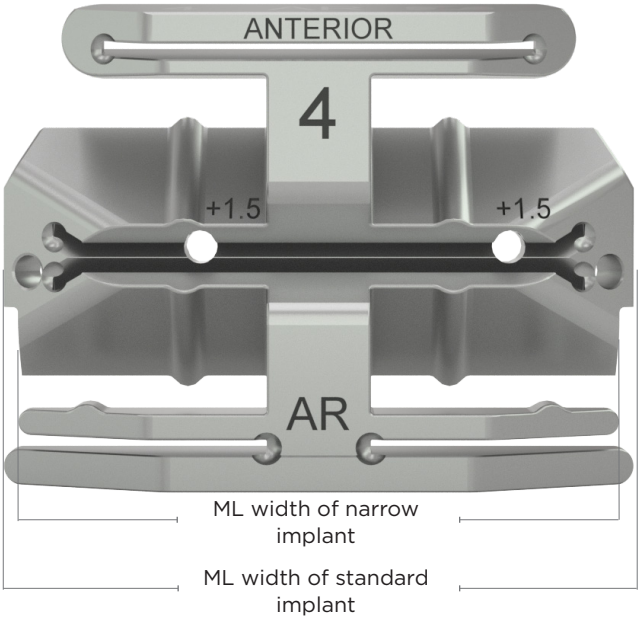
FEMORAL BONE CUTS - AR

Femoral 4-in-1 Resections

Select the appropriate size AR 4-in-1 Cut block.

The AR 4-in-1 Cut Block allows visualization of the M/L boundary of the final implant components: the outer width of the cut block represents the M/L boundary of the Standard femoral components. The cut-out edge represents the M/L boundary of the narrow femoral components.

Note: the AP dimension increases 3mm per size.



Place the AR 4-in-1 Cut block on the distal femur, aligning the backside pegs into the drill holes determined by the AR Sizer. The Tibial Tray Trial Inserter can be used to insert the AR 4-in-1 Cut block and struck with a mallet to ensure the block is flush with the bone.

Use the Angel Wing through the resection slots to visualize the resections.

For additional fixation of the 4-in-1 Cut Block, use headless pins or Tension Screws through the M/L holes. Once the block is stabilized, proceed with bone resection cuts using an oscillating sawblade of .050" (1.27mm) thickness.

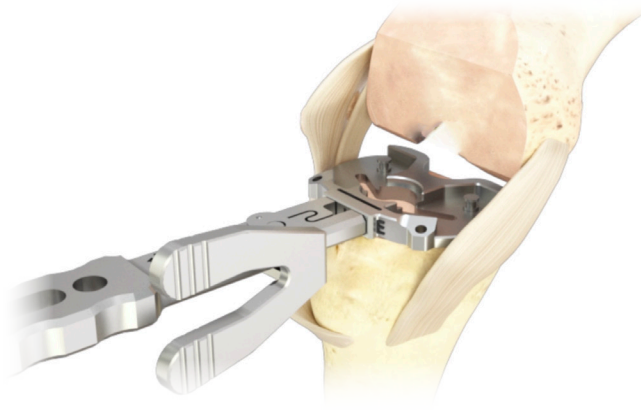
Alternativey, the posterior resection can be made, the block removed, and the flexion gap assessed. The block can be replaced in the described fashion and the remaining resections finished.

Remove all pins/screws. If needed, the Slaphammer can be used to extract the 4-in-1 Cut Block by sliding one of the legs into any side of the AR 4-in-1 cut block and backslapping.

TIBIAL SIZING AND KEEL PREPARATION

Tibial Sizing and Rotation

Attach the Trial Inserter Handle to the appropriate size Tibial Tray Trial that provides desired tibial coverage without overhang in the proper rotation. Refer to the sizing charts for femorotibial compatibility. The Alignment Rod with coupler may be inserted through the hole or slot on the Trial Inserter Handle to confirm the overall alignment and slope. Secure the Tibial Tray Trial with Headed Pins in the two holes near the PCL cutout. There are also two pin holes on the anterior rim for additional stability.



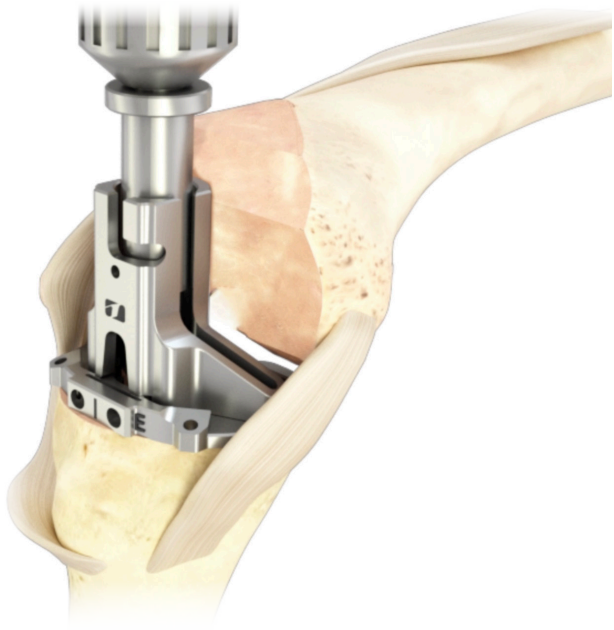
Keel Prep

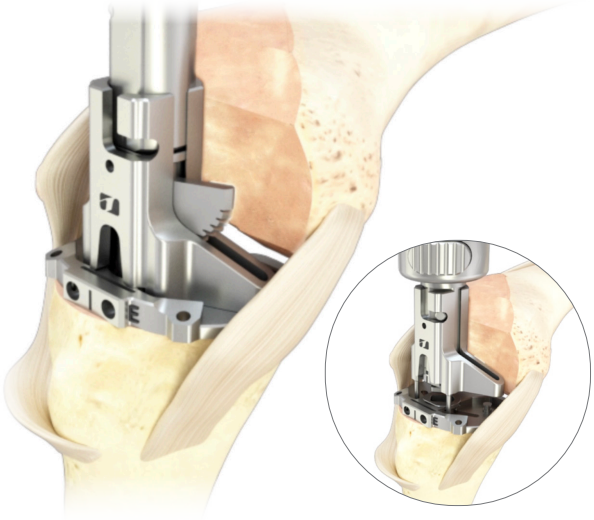
Assemble the Tibial Keel Punch Adaptor on to the Modular Handle. Then assemble the appropriate size Tibial Keel Punch onto the Adaptor based on tibial tray sizing. For example, use a size 4-7 keel punch on a size 5 tibial trial. Impact the Keel Punch through the Tibial Drill/Keel Guide until it bottoms out on the Guide. The Keel Punch is fully seated when the boss on the adaptor is flush with the top of the Tibial Keel Punch Guide. To leave the Keel Punch in for trialing, turn the Modular handle counter-clockwise to disengage the Keel Punch. This will also engage the peg of the punch adaptor with the Guide to remove the Modular Handle/Adapter assembly with the Guide together.

Tibial Post Prep

Attach the Tibial Drill/Keel Guide to the Tibial Tray Trial by inserting the underside spikes into the two anterior M/L holes on the Tray.

Ensuring the Guide is fully seated, drill through the center of the Guide with the Tibial Post Drill on power until the drill bottoms out.





TIBIAL INSERT TRIAL ASSESMENT

Select the preferred thickness of the Tibial Insert Trial and slide it posteriorly onto the Tibial Tray Trial until it falls flush into place.

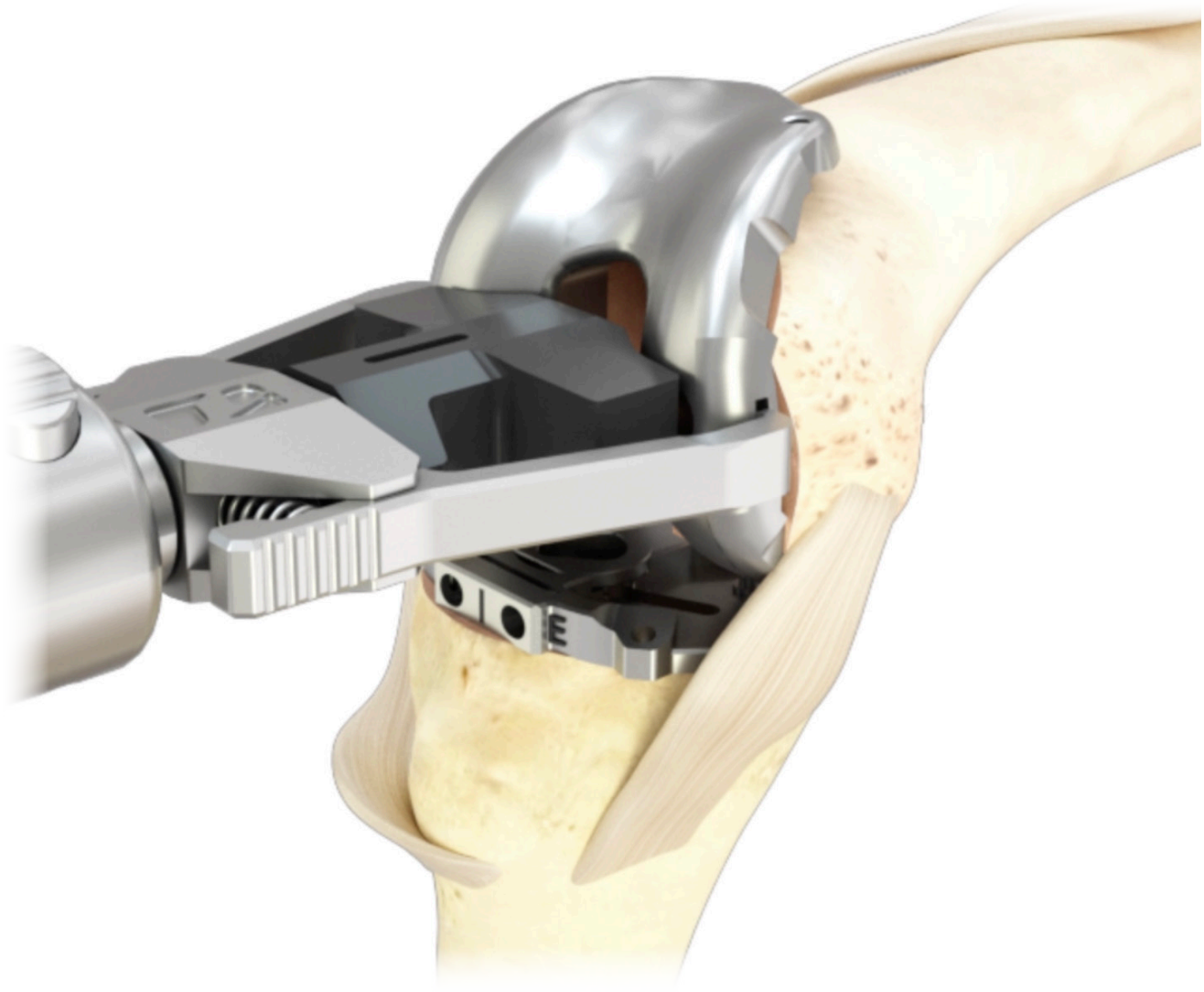
At this point, trial reduction with the femur, tibia, and insert can be performed, or proceed to the patella resection should patella resurfacing be desired.

FEMORAL TRIAL ASSESMENT

Assemble the appropriate size Femoral Trial to the Femoral Inserter- Extractor claws, attached to the Modular Handle. Rotate the handle until adequate grip on the trial is obtained. Impact the Femoral Trial onto the prepared distal femur. Alternatively, position the trial onto the distal femur by hand and use the Femoral Finishing Impactor to impact the femoral trial until seated.

Remove the Femoral Inserter-Extractor by loosening the handle and disengaging the claws. Remove any problematic osteophytes. Assess fit.

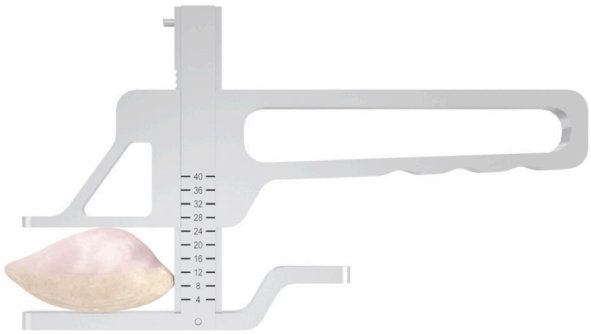
Note: The outer edge on all trials mimic the Standard femoral components. Femoral Trial sizes 3-7 have intermittent cutouts along the medial and lateral edges to indicate the edge of the Narrow femoral components.



PATELLA PREPARATION

Patella Resection

Measure the most prominent anterior-posterior thickness of the patella using the Caliper.



Set the bone resection amount on the Patella Resection Guide by turning the knob until the line on the gauge indicates the desired resection. Refer to the patella-femoral sizing chart for patella implant thickness. Note the resection amount will be from where the stylus rests. Grip the patella with the Patella Resection Guide jaws with the stylus touching the most prominent point on the bone. The ratchet along the Patella Resection Guide handle should secure the jaws in place. Tighten the knob tight against the handle for secure hold.

Patella Resection Guide

Using a .050” (1.27mm) oscillating saw blade, resect the patella through the slot.

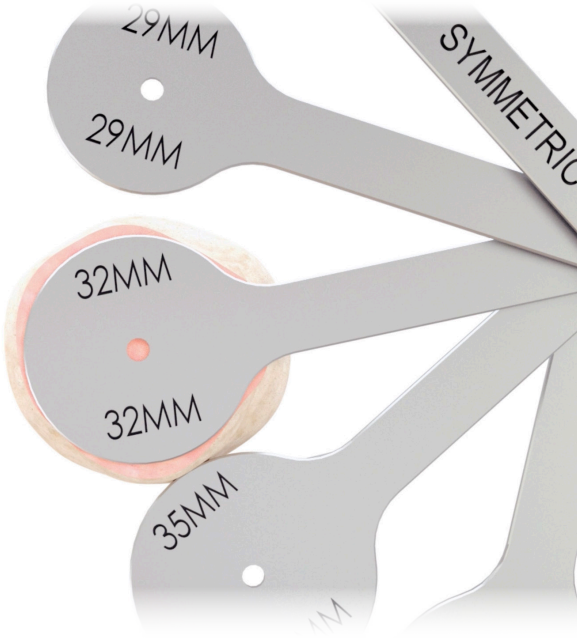
Remove the patella resection guide.

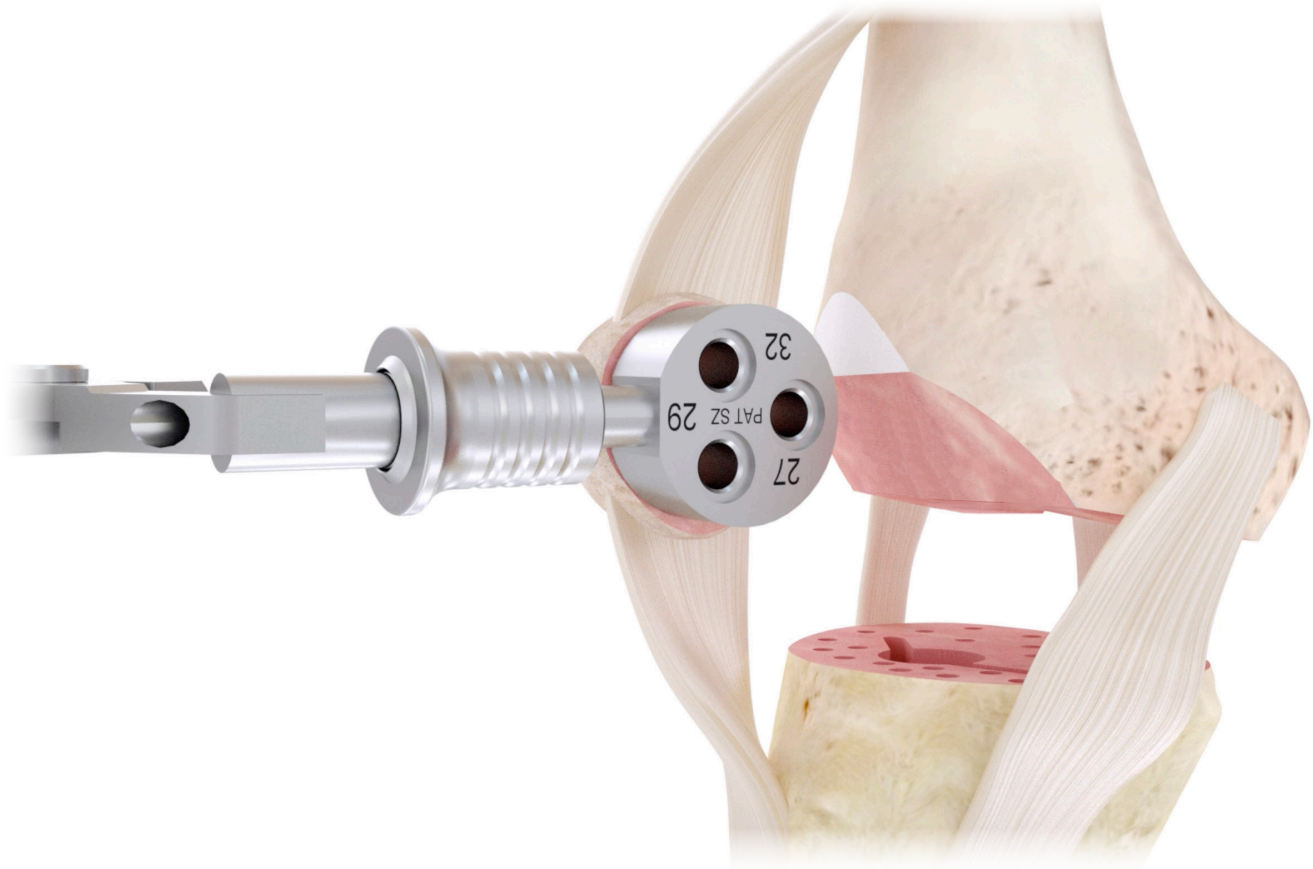
Patella Sizing and Peg Prep

Use the Patella Sizing Guide to select the largest patella diameter that does not overhang the bone.

Connect the appropriate size Patella Drill Guide to the Patella Clamp Handle and clamp the drill guide flush and centered to the resected patella bone surface. Use the Patella Peg Drill to drill all 3 peg holes on the drill guide. The drill will bottom out on the Drill Guide.

Remove the Patella Clamp Handle Assembly, and insert the corresponding Patella Trial into the drilled bone.



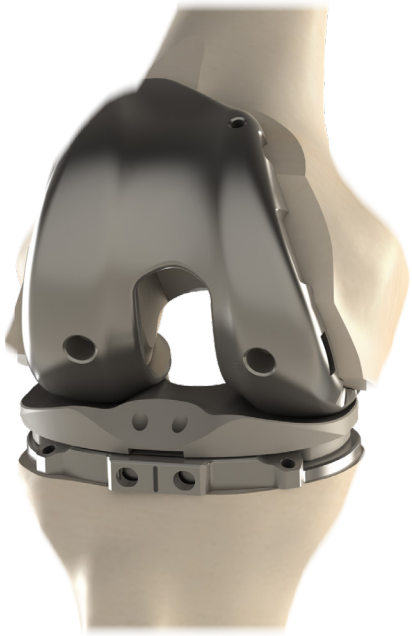


TRIAL REDUCTION

Once the adequate tibial insert thickness is selected, perform a ROM to check component position and joint stability. Perform a ROM to check the patellar tracking. For additional fixation of the femoral component during ROM, place a pin through the anterior surface hole.

If the flexion/extension gap imbalance exist, refer back to gap balancing.

If on the patella, tilting or subluxation occurs, rotation and alignment of the trials should be checked or if they are positioned correctly, then lateral retinacular release should be considered.



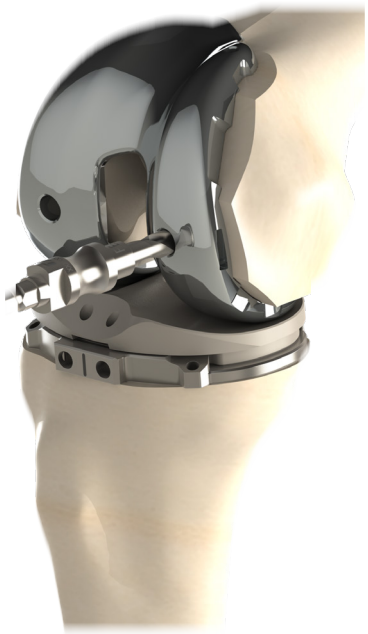
FEMORAL PEG PREPARATION

Once the trial reduction is complete and the femoral trial is at the desired M/L position, using the Femoral Peg Drill, drill through the two peg holes located distally on the femur until the drill bottoms out.

Remove all trial components accordingly. Use the Cement Removal Tool to hook into the insert trial anterior notch cut slot for extraction.

On the next steps to follow, it's up to the surgeon preference for implantation order.

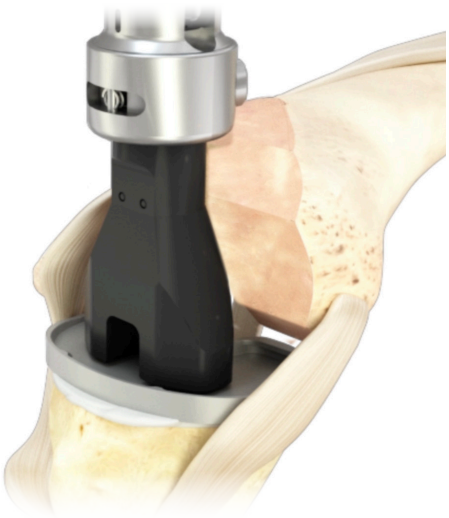
Avoid scratching any of the implants during handling.



IMPLANTATION

Tibial Component Implantation

Select the appropriate size tibial baseplate. Mix a batch of cement and coat the underside of the tibial baseplate, around the keel area, on the proximal tibial resected surface and in the tibial IM canal. Assemble the Tibial Tray Finishing Impactor to the Modular Handle. Position the tibial implant over the tibial resected bone surface, and use the impactor to fully seat the implant flush to the surface. Remove any excess cement using the Cement Removal Tool.

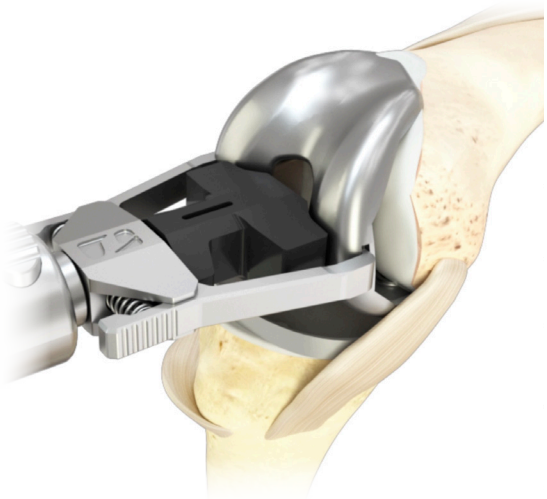


Femoral Component Implantation

Select the appropriate size femoral component.

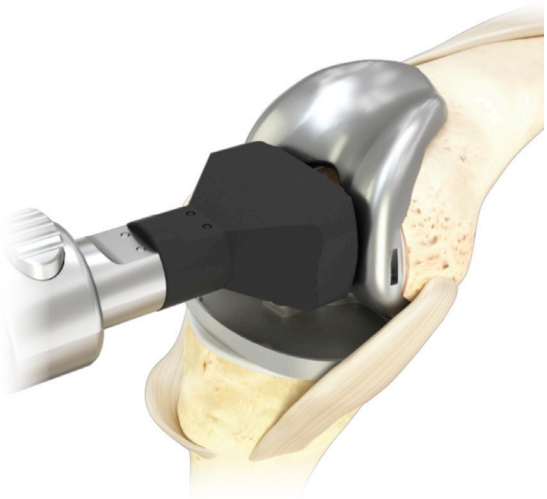
Assemble the Femoral Inserter-Extractor to the Modular Handle and assemble to the femoral prosthesis in the same manner as to the femoral trial.

Mix a batch of cement and coat the underside of the femoral component, and in the drilled peg holes on the distal femur.



Position the femoral component onto the distal femur, aligning the pegs to the drilled holes, if applicable. Impact the femoral inserter-extractor, removing excess cement with the Cement Removal Tool or curettes as appropriate. Once the prosthesis is flush, remove the Inserter-Extractor.

Assess the seating of the femoral component. If additional impaction is necessary, Impactor assembled to the Modular Handle can be used. Remove any excess cement using the Cement Removal Tool.

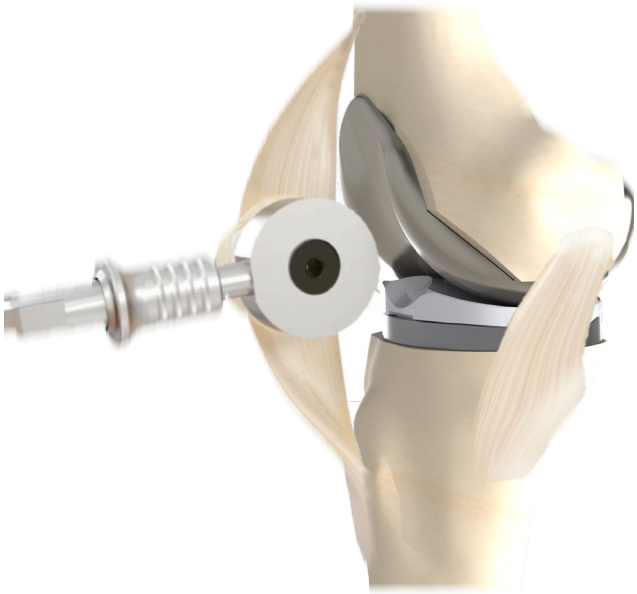


Tibial Insert Implantation

Select the appropriate tibial insert based on size, constraint, and thickness as determined by the trial ROM. Place the tibial insert implant onto the tibial tray and apply pressure on the anterior edge to engage the insert in the tibial tray. Assemble the Tibial Insert Finishing Impactor to the Modular Handle. Align the impactor over the insert trochlear groove, and impact to fully seat the implant flush to the tray. When fully seated, the anterior wire in the insert would of engaged behind the anterior lip of the tray.

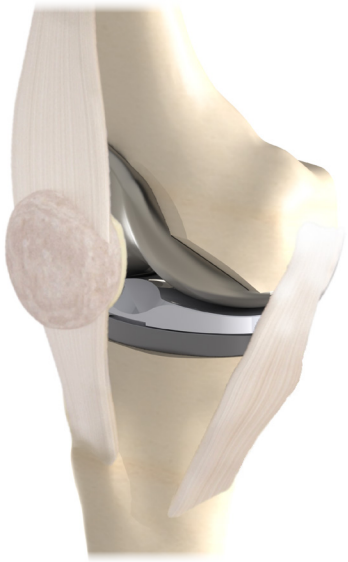
Patella Component Implantation

Select the appropriate size patella implant. Mix a batch of cement and coat the underside of the patella component, including the pegs, and in the drilled peg holes on the patella bone. Assemble the Patella Cement Clamp Insert to the Patella Cement Clamp Handle and with it, locate the drilled peg holes and secure the patella implant tightly to the patella bone. Remove any excess cement using the Cement Removal Tool. Release the patella clamp once the cement is hard.



CLOSURE

Reduce the knee and perform ROM where all aspects are checked. Once everything is confirmed, the knee can be closed in layers using the surgeon's preferred technique. Refer to package insert for complete product information, warnings, precautions, adverse effects, and including contraindications.



PROSTHESIS REMOVAL/EXTRACTION

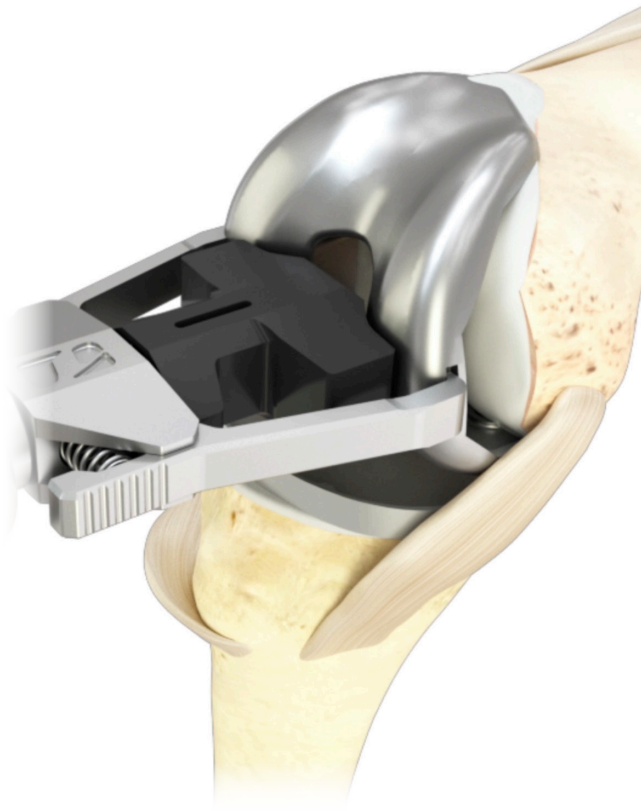
Standard techniques should be used to remove all cemented components.

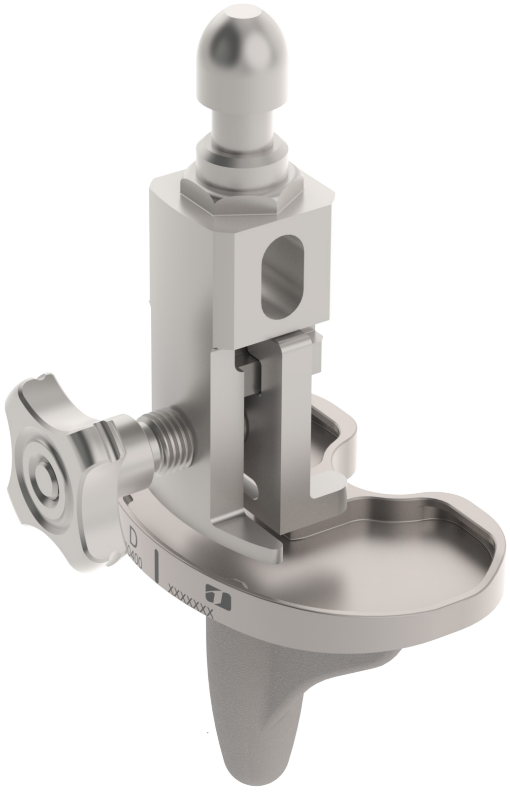
To remove the tibial insert, use a small osteotome in the central window between the tibial insert and the baseplate. Apply force to leverage the tibial insert from the baseplate. Note: Removal of the tibial insert will damage the tibial insert locking wire.

To remove the tibial baseplate, slide the feet of the Tibial Baseplate Extractor around the central island of the baseplate, as shown in below figure. 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 Unviversal 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 as shown in below figure.

Components must not be reused once removed.





IMPLANT ORDERING INFORMATION

CR Femur

Part Numbers	Desciption
8821121011	Size 1, Left
8821121012	Size 1, Right
8821121021	Size 2, Left
8821121022	Size 2, Right
8821121031	Size 3, Left
8821121032	Size 3, Right
8821122031	Size 3 Narrow, Left
8821122032	Size 3 Narrow, Right
8821121041	Size 4, Left
8821121042	Size 4, Right
8821122041	Size 4 Narrow, Left
8821122042	Size 4 Narrow, Right
8821121051	Size 5, Left
8821121052	Size 5, Right
8821122051	Size 5 Narrow, Left

Part Numbers	Desciption
8821122052	Size 5 Narrow, Right
8821121061	Size 6, Left
8821121062	Size 6, Right
8821122061	Size 6 Narrow, Left
8821122062	Size 6 Narrow, Right
8821121071	Size 7, Left
8821121072	Size 7, Right
8821122071	Size 7 Narrow, Left
8821122072	Size 7 Narrow, Right
8821121081	Size 8, Left
8821121082	Size 8, Right
8821121091	Size 9, Left
8821121092	Size 9, Right
8821121101	Size 10, Left
8821121102	Size 10, Right

CR Tibial Insert

Part Numbers	Desciption
8821321009	Size A/1-4, 9 mm
8821321010	Size A/1-4, 10 mm
8821321011	Size A/1-4, 11 mm
8821321012	Size A/1-4, 12 mm
8821321013	Size A/1-4, 13 mm
8821321014	Size A/1-4, 14 mm
8821321016	Size A/1-4, 16 mm
8821321019	Size A/1-4, 19 mm
8821321022	Size A/1-4, 22 mm
8821321025	Size A/1-4, 25 mm
8821321109	Size BC/1-6, 9 mm
8821321110	Size BC/1-6, 10 mm
8821321111	Size BC/1-6, 11 mm
8821321112	Size BC/1-6, 12 mm
8821321113	Size BC/1-6, 13 mm
8821321114	Size BC/1-6, 14 mm
8821321116	Size BC/1-6, 16 mm
8821321119	Size BC/1-6, 19 mm
8821321122	Size BC/1-6, 22 mm
8821321125	Size BC/1-6, 25 mm
8821321309	Size DE/3-7, 9 mm
8821321310	Size DE/3-7, 10 mm
8821321311	Size DE/3-7, 11 mm
8821321312	Size DE/3-7, 12 mm
8821321313	Size DE/3-7, 13 mm

Part Numbers	Desciption
8821321314	Size DE/3-7, 14 mm
8821321316	Size DE/3-7, 16 mm
8821321319	Size DE/3-7, 19 mm
8821321322	Size DE/3-7, 22 mm
8821321325	Size DE/3-7, 25 mm
8821321509	Size FG/4-9, 9 mm
8821321510	Size FG/4-9, 10 mm
8821321511	Size FG/4-9, 11 mm
8821321512	Size FG/4-9, 12 mm
8821321513	Size FG/4-9, 13 mm
8821321514	Size FG/4-9, 14 mm
8821321516	Size FG/4-9, 16 mm
8821321519	Size FG/4-9, 19 mm
8821321522	Size FG/4-9, 22 mm
8821321525	Size FG/4-9, 25 mm
8821321709	Size HJ/7-10, 9 mm
8821321710	Size HJ/7-10, 10 mm
8821321711	Size HJ/7-10, 11 mm
8821321712	Size HJ/7-10, 12 mm
8821321713	Size HJ/7-10, 13 mm
8821321714	Size HJ/7-10, 14 mm
8821321716	Size HJ/7-10, 16 mm
8821321719	Size HJ/7-10, 19 mm
8821321722	Size HJ/7-10, 22 mm
8821321725	Size HJ/7-10, 25 mm

CR PLUS Tibial Insert

Part Numbers	Description
8821311009	Size A/1-3+, 9 mm
8821311010	Size A/1-3+, 10 mm
8821311011	Size A/1-3+, 11 mm
8821311012	Size A/1-3+, 12 mm
8821311013	Size A/1-3+, 13 mm
8821311014	Size A/1-3+, 14 mm
8821311016	Size A/1-3+, 16 mm
8821311019	Size A/1-3+, 19 mm
8821311022	Size A/1-3+, 22 mm
8821311025	Size A/1-3+, 25 mm
8821311109	Size BC/3-5+, 9 mm
8821311110	Size BC/3-5+, 10 mm
8821311111	Size BC/3-5+, 11 mm
8821311112	Size BC/3-5+, 12 mm
8821311113	Size BC/3-5+, 13 mm
8821311114	Size BC/3-5+, 14 mm
8821311116	Size BC/3-5+, 16 mm
8821311119	Size BC/3-5+, 19 mm
8821311122	Size BC/3-5+, 22 mm
8821311125	Size BC/3-5+, 25 mm
8821311309	Size DE/4-6+, 9 mm
8821311310	Size DE/4-6+, 10 mm
8821311311	Size DE/4-6+, 11 mm
8821311312	Size DE/4-6+, 12 mm
8821311313	Size DE/4-6+, 13 mm

Part Numbers	Description
8821311314	Size DE/4-6+, 14 mm
8821311316	Size DE/4-6+, 16 mm
8821311319	Size DE/4-6+, 19 mm
8821311322	Size DE/4-6+, 22 mm
8821311325	Size DE/4-6+, 25 mm
8821311509	Size FG/6-8+, 9 mm
8821311510	Size FG/6-8+, 10 mm
8821311511	Size FG/6-8+, 11 mm
8821311512	Size FG/6-8+, 12 mm
8821311513	Size FG/6-8+, 13 mm
8821311514	Size FG/6-8+, 14 mm
8821311516	Size FG/6-8+, 16 mm
8821311519	Size FG/6-8+, 19 mm
8821311522	Size FG/6-8+, 22 mm
8821311525	Size FG/6-8+, 25 mm
8821311709	Size HJ/8-10+, 9 mm
8821311710	Size HJ/8-10+, 10 mm
8821311711	Size HJ/8-10+, 11 mm
8821311712	Size HJ/8-10+, 12 mm
8821311713	Size HJ/8-10+, 13 mm
8821311714	Size HJ/8-10+, 14 mm
8821311716	Size HJ/8-10+, 16 mm
8821311719	Size HJ/8-10+, 19 mm
8821311722	Size HJ/8-10+, 22 mm
8821311725	Size HJ/8-10+, 25 mm

INSTRUMENT ORDERING INFORMATION

CR Femur Trials

Part Numbers	Description
8829111011	Size 1, Left
8829111012	Size 1, Right
8829111021	Size 2, Left
8829111022	Size 2, Right
8829111031	Size 3, 3N, Left
8829111032	Size 3, 3N, Right
8829111041	Size 4, 4N, Left
8829111042	Size 4, 4N, Right
8829111051	Size 5, 5N, Left
8829111052	Size 5, 5N, Right
8829111061	Size 6, 6N, Left
8829111062	Size 6, 6N, Right
8829111071	Size 7, 7N, Left
8829111072	Size 7, 7N, Right
8829111081	Size 8, Left
8829111082	Size 8, Right
8829111091	Size 9, Left
8829111092	Size 9, Right
8829111101	Size 10, Left
8829111102	Size 10, Right

Part Numbers	Description
8829111111	Size 1, Left
8829111112	Size 1, Right
8829111121	Size 2, Left
8829111122	Size 2, Right
8829111131	Size 3, 3N, Left
8829111132	Size 3, 3N, Right
8829111141	Size 4, 4N, Left
8829111142	Size 4, 4N, Right
8829111151	Size 5, 5N, Left
8829111152	Size 5, 5N, Right
8829111161	Size 6, 6N, Left
8829111162	Size 6, 6N, Right
8829111171	Size 7, 7N, Left
8829111172	Size 7, 7N, Right
8829111181	Size 8, Left
8829111182	Size 8, Right
8829111191	Size 9, Left
8829111192	Size 9, Right
8829111201	Size 10, Left
8829111202	Size 10, Right

CR Tibial Insert Trials

Part Numbers	Description
8829301109	Size A/1-4, 9mm
8829301110	Size A/1-4, 10mm
8829301111	Size A/1-4, 11mm
8829301112	Size A/1-4, 12mm
8829301113	Size A/1-4, 13mm
8829301114	Size A/1-4, 14mm
8829301116	Size A/1-4, 16mm
8829301119	Size A/1-4, 19mm
8829301122	Size A/1-4, 22mm
8829301125	Size A/1-4, 25mm
8829303109	Size BC/1-6, 9mm
8829303110	Size BC/1-6, 10mm
8829303111	Size BC/1-6, 11mm
8829303112	Size BC/1-6, 12mm
8829303113	Size BC/1-6, 13mm
8829303114	Size BC/1-6, 14mm
8829303116	Size BC/1-6, 16mm
8829303119	Size BC/1-6, 19mm
8829303122	Size BC/1-6, 22mm
8829303125	Size BC/1-6, 25mm
8829304109	Size DE/3-7, 9mm
8829304110	Size DE/3-7, 10mm
8829304111	Size DE/3-7, 11mm
8829304112	Size DE/3-7, 12mm
8829304113	Size DE/3-7, 13mm

Part Numbers	Description
8829304114	Size DE/3-7, 14mm
8829304116	Size DE/3-7, 16mm
8829304119	Size DE/3-7, 19mm
8829304122	Size DE/3-7, 22mm
8829304125	Size DE/3-7, 25mm
8829305109	Size FG/4-9, 9mm
8829305110	Size FG/4-9, 10mm
8829305111	Size FG/4-9, 11mm
8829305112	Size FG/4-9, 12mm
8829305113	Size FG/4-9, 13mm
8829305114	Size FG/4-9, 14mm
8829305116	Size FG/4-9, 16mm
8829305119	Size FG/4-9, 19mm
8829305122	Size FG/4-9, 22mm
8829305125	Size FG/4-9, 25mm
8829306109	Size HJ/7-10, 9mm
8829306110	Size HJ/7-10, 10mm
8829306111	Size HJ/7-10, 11mm
8829306112	Size HJ/7-10, 12mm
8829306113	Size HJ/7-10, 13mm
8829306114	Size HJ/7-10, 14mm
8829306116	Size HJ/7-10, 16mm
8829306119	Size HJ/7-10, 19mm
8829306122	Size HJ/7-10, 22mm
8829306125	Size HJ/7-10, 25mm

CR PLUS Tibial Insert Trials

Part Numbers	Description
8829301209	Size A/1-3+, 9mm
8829301210	Size A/1-3+, 10mm
8829301211	Size A/1-3+, 11mm
8829301212	Size A/1-3+, 12mm
8829301213	Size A/1-3+, 13mm
8829301214	Size A/1-3+, 14mm
8829301216	Size A/1-3+, 16mm
8829301219	Size A/1-3+, 19mm
8829301222	Size A/1-3+, 22mm
8829301225	Size A/1-3+, 25mm
8829303209	Size BC/3-5+, 9mm
8829303210	Size BC/3-5+, 10mm
8829303211	Size BC/3-5+, 11mm
8829303212	Size BC/3-5+, 12mm
8829303213	Size BC/3-5+, 13mm
8829303214	Size BC/3-5+, 14mm
8829303216	Size BC/3-5+, 16mm
8829303219	Size BC/3-5+, 19mm
8829303222	Size BC/3-5+, 22mm
8829303225	Size BC/3-5+, 25mm
8829304209	Size DE/4-6+, 9mm
8829304210	Size DE/4-6+, 10mm
8829304211	Size DE/4-6+, 11mm
8829304212	Size DE/4-6+, 12mm
8829304213	Size DE/4-6+, 13mm

Part Numbers	Description
8829304214	Size DE/4-6+, 14mm
8829304216	Size DE/4-6+, 16mm
8829304219	Size DE/4-6+, 19mm
8829304222	Size DE/4-6+, 22mm
8829304225	Size DE/4-6+, 25mm
8829305209	Size FG/6-8+, 9mm
8829305210	Size FG/6-8+, 10mm
8829305211	Size FG/6-8+, 11mm
8829305212	Size FG/6-8+, 12mm
8829305213	Size FG/6-8+, 13mm
8829305214	Size FG/6-8+, 14mm
8829305216	Size FG/6-8+, 16mm
8829305219	Size FG/6-8+, 19mm
8829305222	Size FG/6-8+, 22mm
8829305225	Size FG/6-8+, 25mm
8829306209	Size HJ/8-10+, 9mm
8829306210	Size HJ/8-10+, 10mm
8829306211	Size HJ/8-10+, 11mm
8829306212	Size HJ/8-10+, 12mm
8829306213	Size HJ/8-10+, 13mm
8829306214	Size HJ/8-10+, 14mm
8829306216	Size HJ/8-10+, 16mm
8829306219	Size HJ/8-10+, 19mm
8829306222	Size HJ/8-10+, 22mm
8829306225	Size HJ/8-10+, 25mm

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b-ONE ORTHO, Corp. 3 Wing Drive, Suite 259 Cedar Knolls, NJ 07927 USA

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