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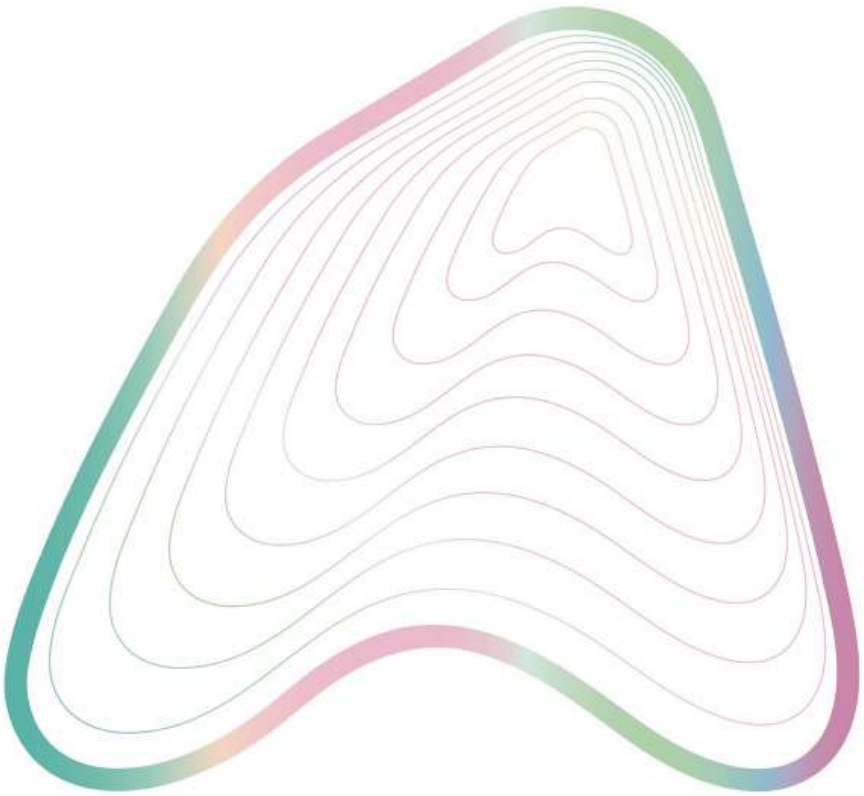
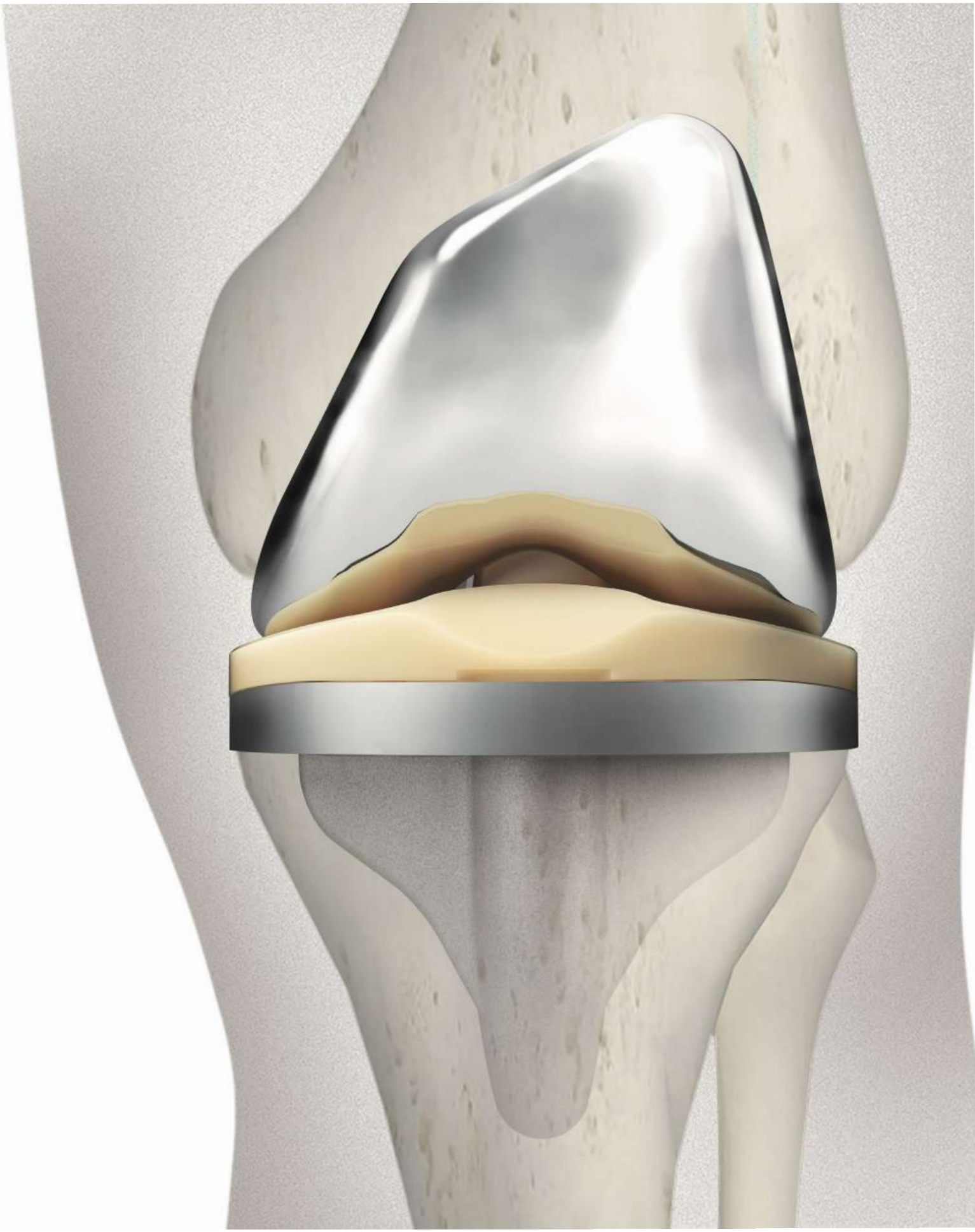


MOBIO™

Total Knee System

All in ONE

The MOBIO™ Total Knee System is an evolution of the 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 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.



MOBIO™ is the result of many years of clinical and engineering experience throughout the world. I strongly believe this system will represent the new "standard of care" in total knee reconstruction. The system incorporates the single radius design, which has proven its merits in the Rothman Institute and elsewhere over the past decade.

It will achieve a knee that provides enhanced stability, good range of motion, and superb function. In my experience, this knee design will have a "natural feel" and good longevity.

The manufacturing processes and standards have incorporated the highest level of quality control. The instruments are carefully designed and surgeon-friendly.

This should result in superior outcome for our patients, which is our universal goal.

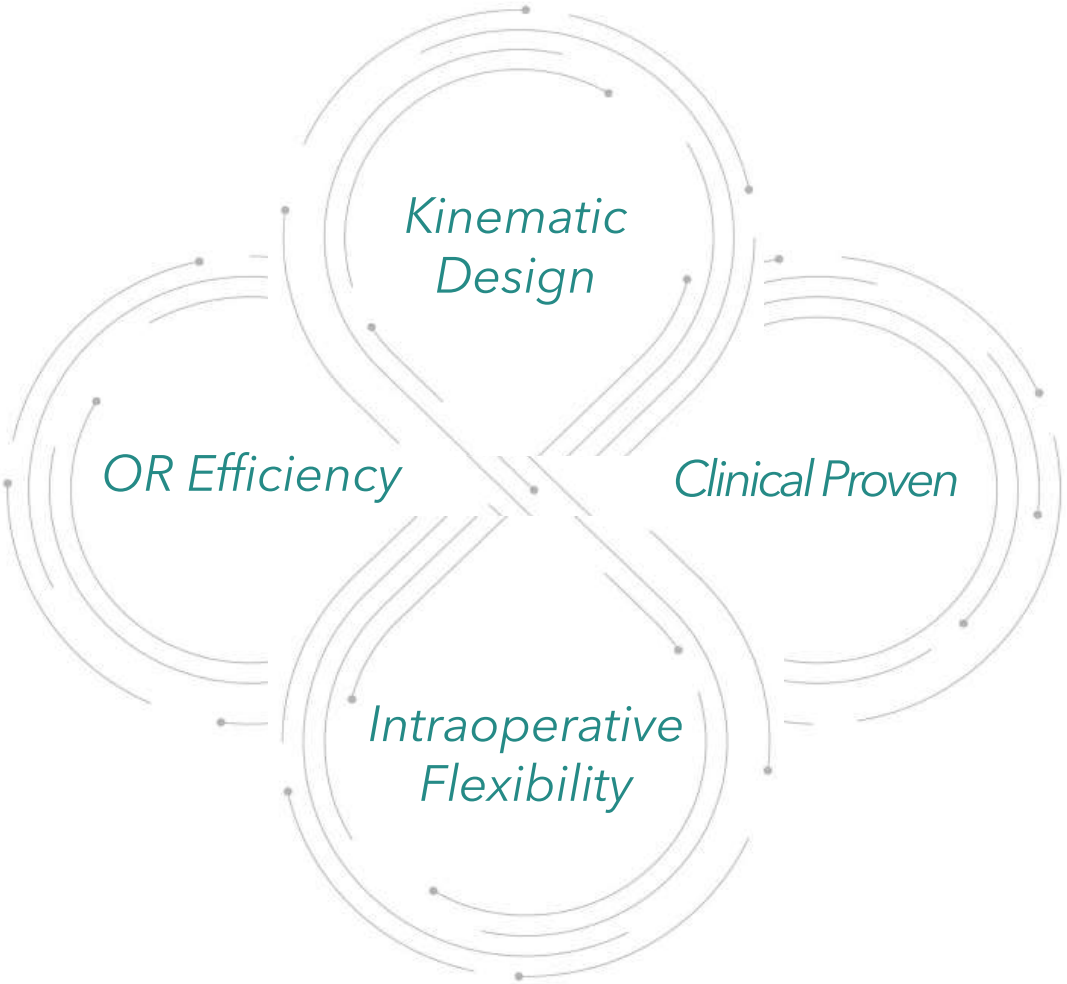
Richard Rothman, M.D., Ph.D.
Founder, The Rothman Institute

The **MOBIO**™ Total Knee System was designed by partnering experienced engineers with input from international surgeons. It is an evolution of the best features from the state of the art prosthetic systems available today. We listened to surgeons and patients to design a knee system that is versatile, easy to use, and will exceed patient needs.

Mark Kester, Ph.D.
Chief Scientific Officer

Imants Liepins
Vice President of Innovation Center

MOBIO™ Total Knee System
Design Goals



MOBIO™ Total Knee System
Key Design Features

BalanSEE™ single radius design

Fretella™ patellofemoral articulation

Bone-conserving PS box

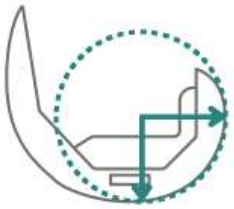
Robust tibial locking mechanism

Extensive tibiofemoral compatibility

Efficient instrumentation

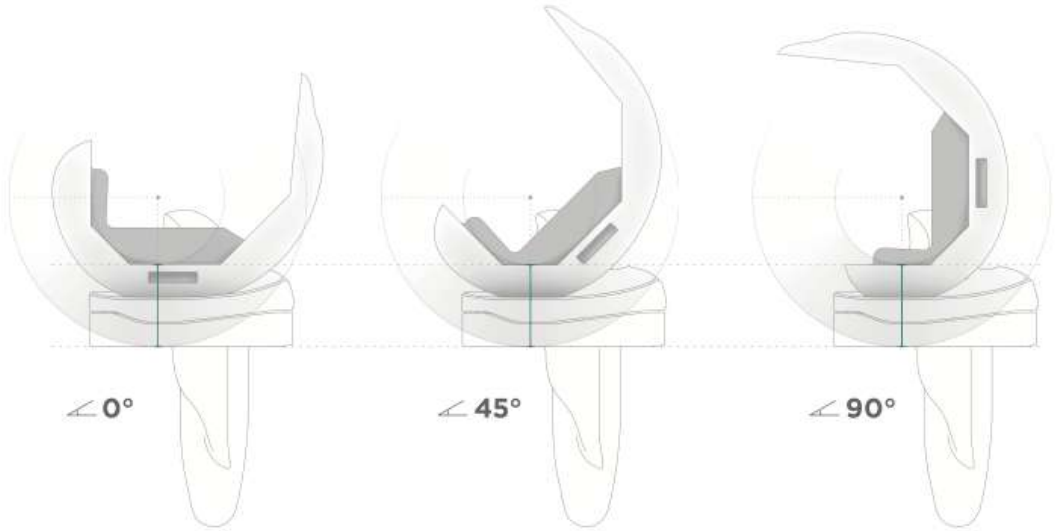
MOBIO™ Total Knee System

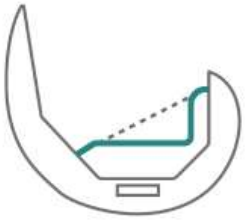
Kinematic Design Features



BalanSEE™ single radius design

- Single radius femoral design about the flexion-extension axis creates ligament isometry throughout the arc of motion.
- Equal distal and posterior resection means predictable and balanced resurfacing.





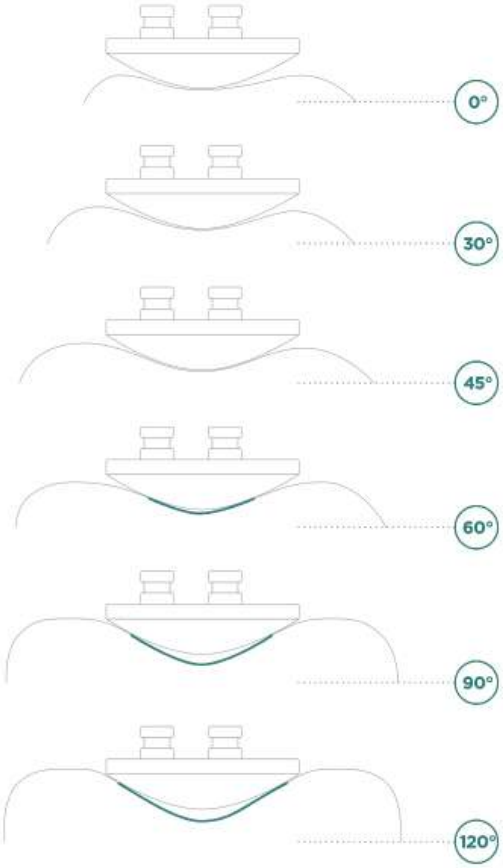
- Open shallow PS box tiered to femoral size to conserve bone.
- Accommodates both PS and PS Plus tibial inserts without the need for additional bony resection.
- Up to 30% more bone conserved when compared to leading competitive designs.

MOBIO™ Total Knee System

Kinematic Design Features

Fretella™ patellofemoral articulation

- Thin anterior flange with size-specific patella thicknesses help recreate native patellofemoral kinematics.
- Deepened transition zone from the trochlea to the intercondylar notch for smooth range of motion.



MOBIO™ Total Knee System

Performance Features

Robust tibial locking mechanism

- Full anterior, posterior, and central island locking fixation maximizes locking area and minimizes micromotion.
- Shortened central island allows for bearing placement at greater insertion angles.
- Unique peripheral ramp feature guides tibial insert into locking track of baseplate for ease of insertion.

Highly crosslinked polyethylene

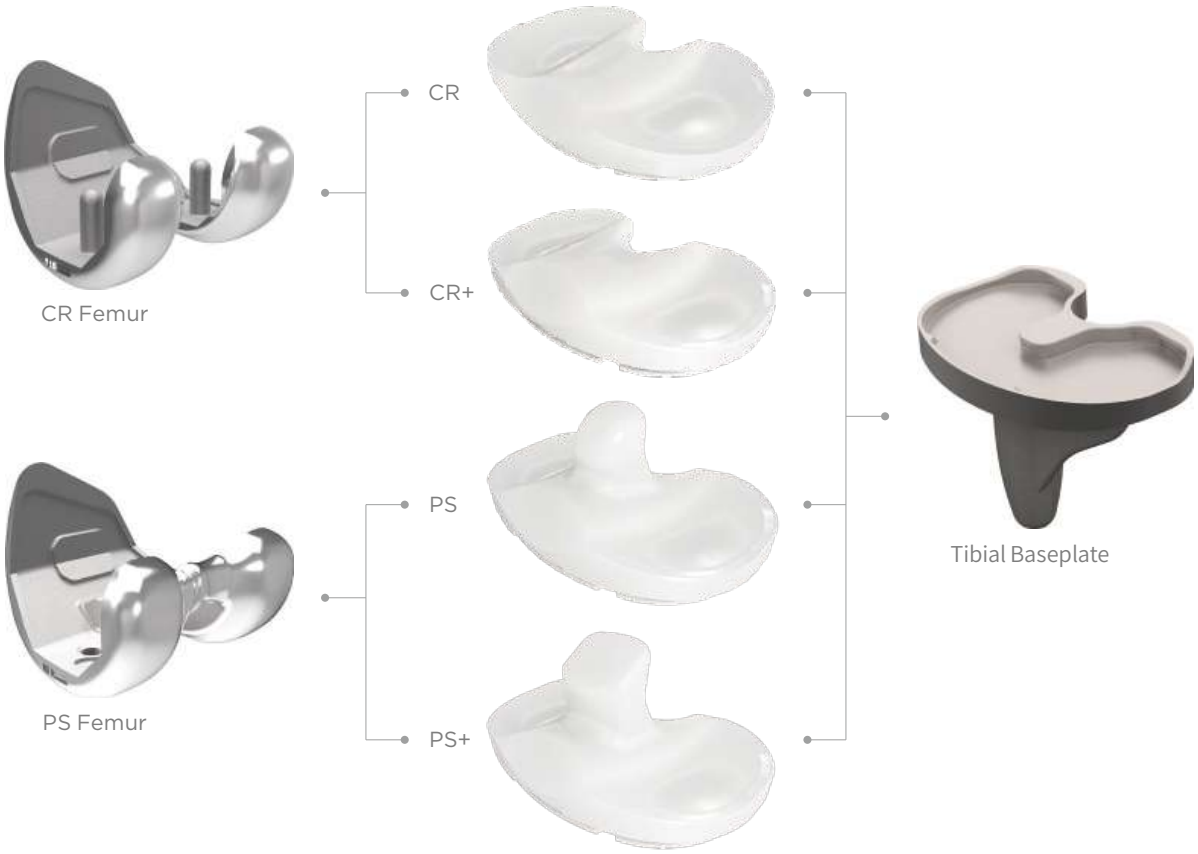
Demonstrates better wear characteristics than standard polyethylene bearings.

MOBIO™ Total Knee System

Intraoperative Flexibility

Wide range of implant sizes and constraint options allows for optimized component fit and soft tissue balancing.

- 13 femoral component sizes and 7 tibial component sizes.
- PS and PS PLUS Tibial Inserts in 5 thicknesses ranging from 9 to 16 mm.
- CR insert Provides ±15° of I/E rotation without V/V constraint whereas CR Plus insert provides ±6° to ±10° of I/E rotation without V/V constraint.
- CR Tibial Inserts preserves PCL which has important proprioceptive functions, allows for more natural rollback.
- CR Plus Provides more AP constraint and stability, substitutes for poorly balanced PCL, allows for preserving and substituting PCL.



MOBIO™ Total Knee System

Metaphyseal extension rod(*Improve tibial side fixation stability*)

The use of a metaphyseal extension rod (Diaphyseal Stem, short extension rod) to improve the fixation effect of the tibial prosthesis in the metaphysis has been widely used in revision surgery and has achieved good clinical results.

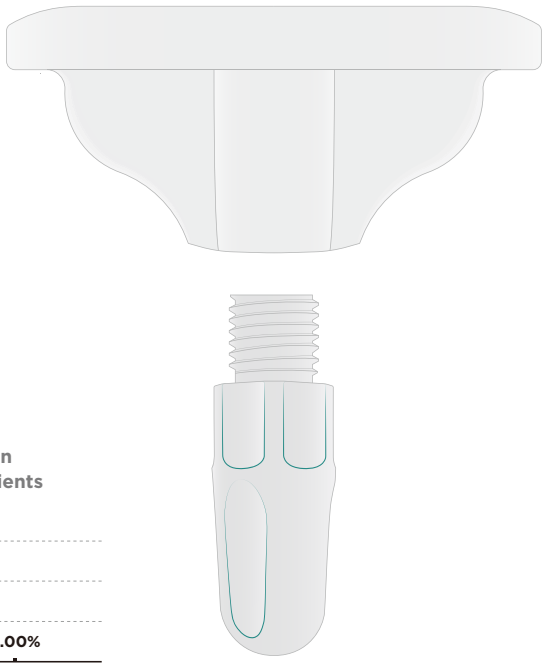
In recent years, as aseptic loosening has become the number one reason for knee revision, the research focus has shifted to how to rationally use extension rods to improve the efficiency of metaphyseal fixation, thereby reducing the incidence of aseptic loosening of the tibial tray.

- **Reduce shin pain and avoid osteolysis**
- **Extension rod reduces fretting and conducts stress more evenly**
- **No need to change the surgical form**

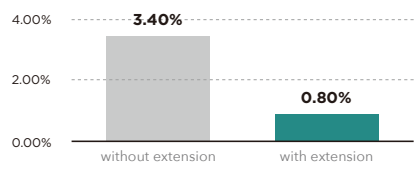
Metaphyseal extension rod significantly reduces the rate of tibial tray loosening

A study based on data from the American Joint Registry showed that during 10 years of follow-up, patients in the experimental group using metaphyseal extension rods had more severe preoperative symptoms. The revision rate due to aseptic loosening was significantly lower than that of the normal knee replacement case group.

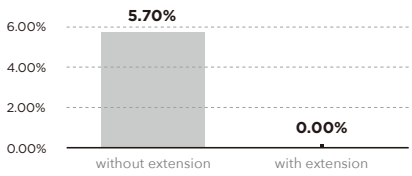
Park et al. followed up and compared 88 pairs of metaphyseal extension rods and common primary patients. During more than 8 years of follow-up, a group of patients who used metaphyseal extension rods did not have aseptic loosening of the tibial tray, while the control group was caused by aseptic loosening. The revision rate is close to 6%.



American Joint Registry Study, Comparison of Revision Rates at 10-Year Follow-up



Comparison of revision rates in 88 deformity patients



MOBIO™ Total Knee System

Efficient Instrumentation

The **MOBIO™** Total Knee System instrumentation is an intuitive platform that supports surgical efficiency with:

- Unique features that can eliminate extra surgical steps;
- Precise, robust cutting guides;
- Intuitive instrument kitting to accommodate differences in technical preferences;
- Sterilization trays that are rigid container compatible for easy wrap-to-rigid interchangeability.

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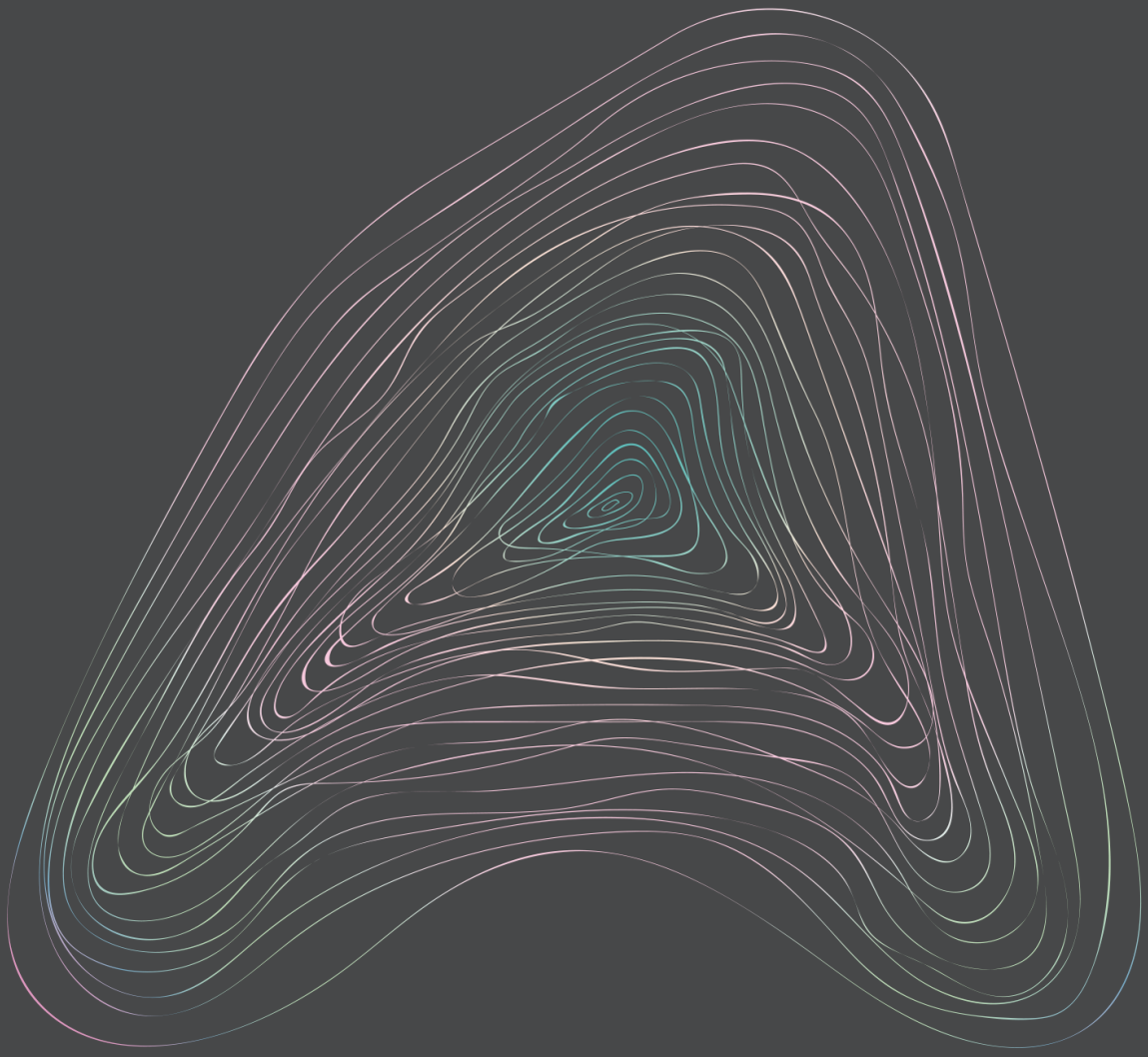


MOBIO® Total Knee System
Surgical Technique

for CR and CR Plus Implants

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.

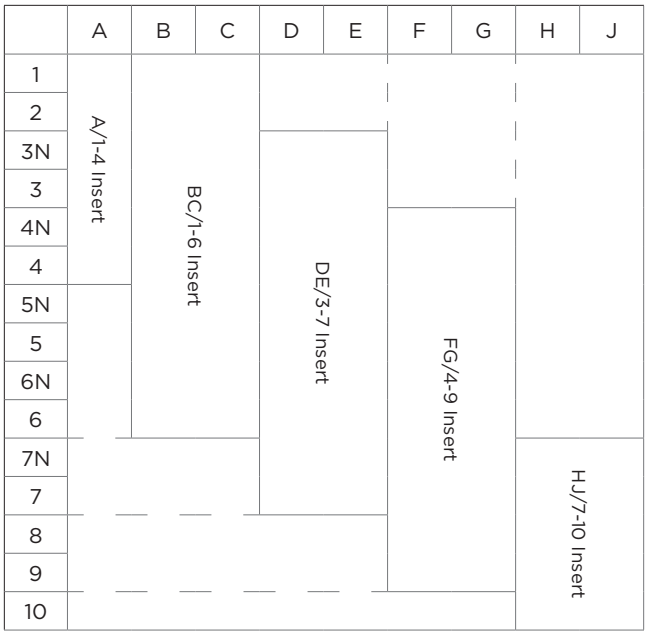
Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.

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.

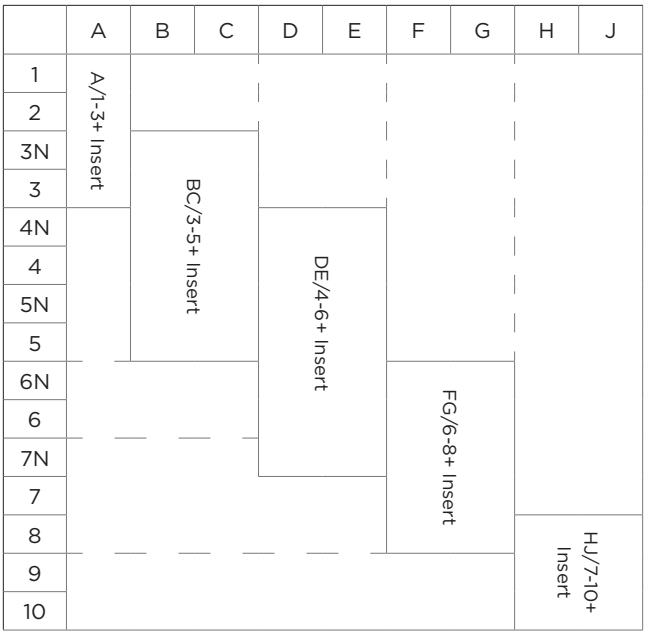
Any condition not described in the Indications for Use.

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.

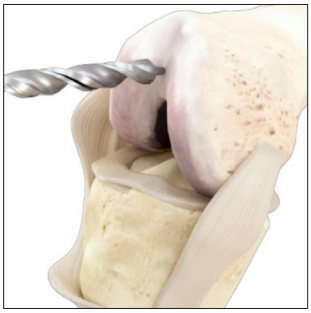
Pin/Screw	Description	Catalog Number	Compatible Driver/ Extractor	Description
	Threaded Headless Pin	8829005001/8829005000		Pin Driver
	Fluted Pin	8829012002/8829012000		Pin Puller/Pin Driver
	Tension Screws	8829004000		Pin Driver
	Headed Pin, 25 mm Headed Pin, 35 mm	8829006025/8829006250 8829006035/8829006350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

Pin Driver
8829011000

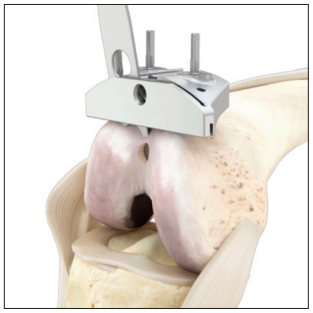
Pin Puller
8829003000

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

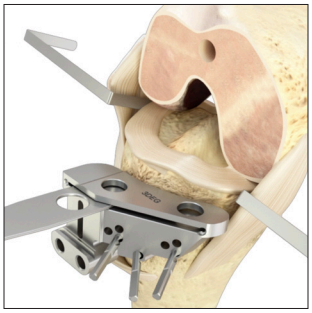
SURGICAL SNAP SHOTS



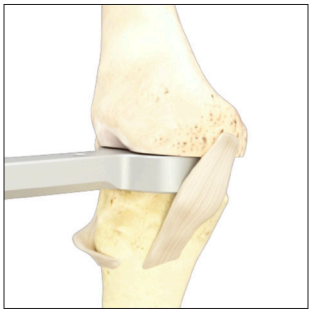
1 - Drill Femoral IM Canal



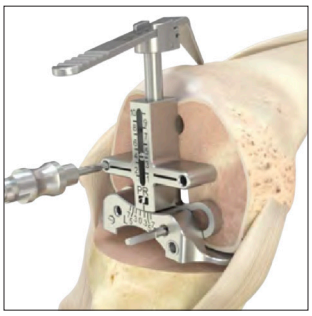
2 - Resect Distal Femur



3- Tibial resection, IM or EM Option

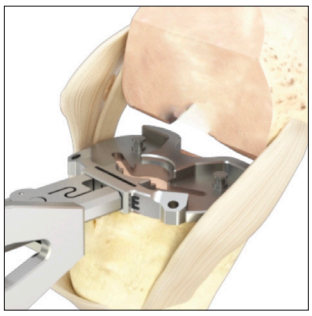


4- Assess Extension Gap and Tissue Balancing (Optional)

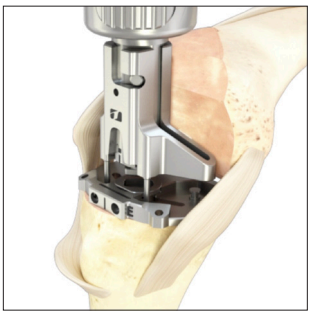


5 - Femoral Sizing & Rotation

6 - Femoral 4-in-1 Resection



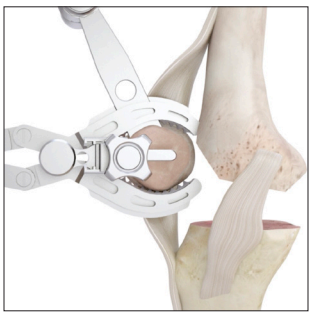
7 - Tibial Sizing Plate



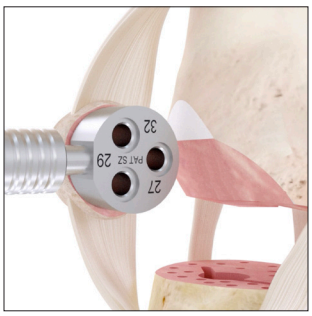
8 - Tibial Baseplate Preparation

9 - Tibial insert trial

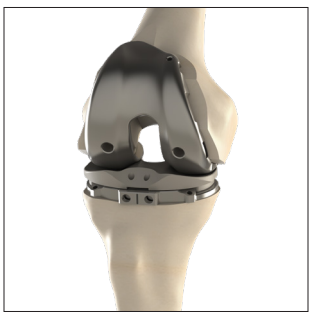
10 - Femoral Trial Placement



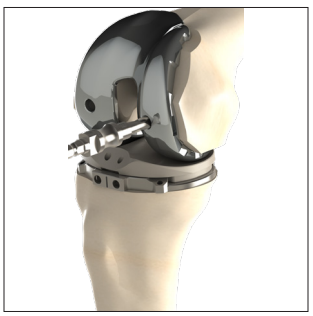
11-Patella Resection



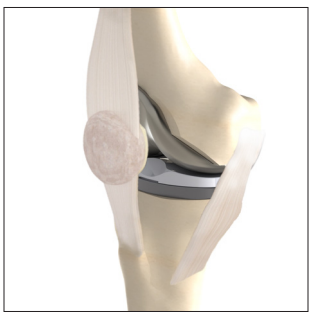
12 - Patella Sizing and Peg Drill



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

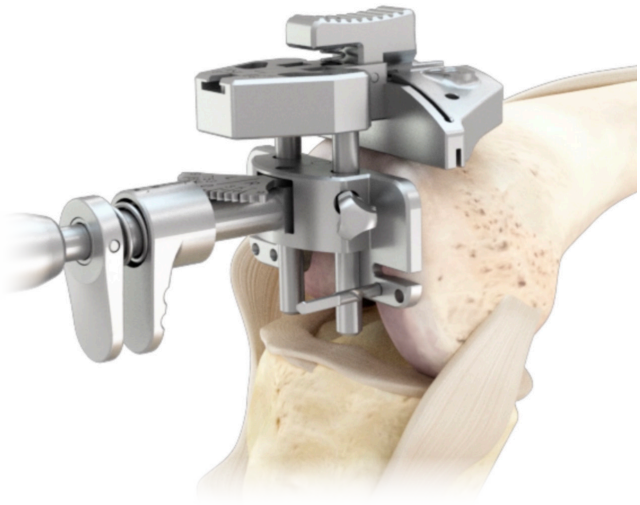
Attach the T-Handle to the IM Rod Insert the IM Rod into the Distal Femoral Alignment Guide Set the valgus angle on the appropriate Left or Right scale on the Alignment Guide by pulling back on the spring-loaded trigger and aligning the appropriate notch with the stop along the guide axis The angle options 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

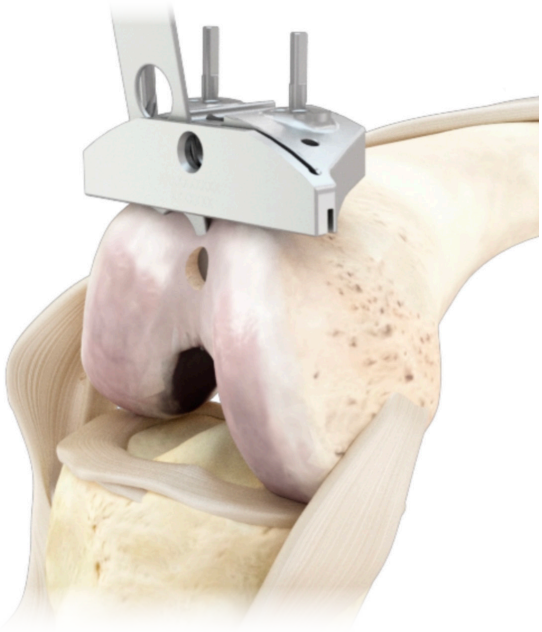


Distal Resection

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.

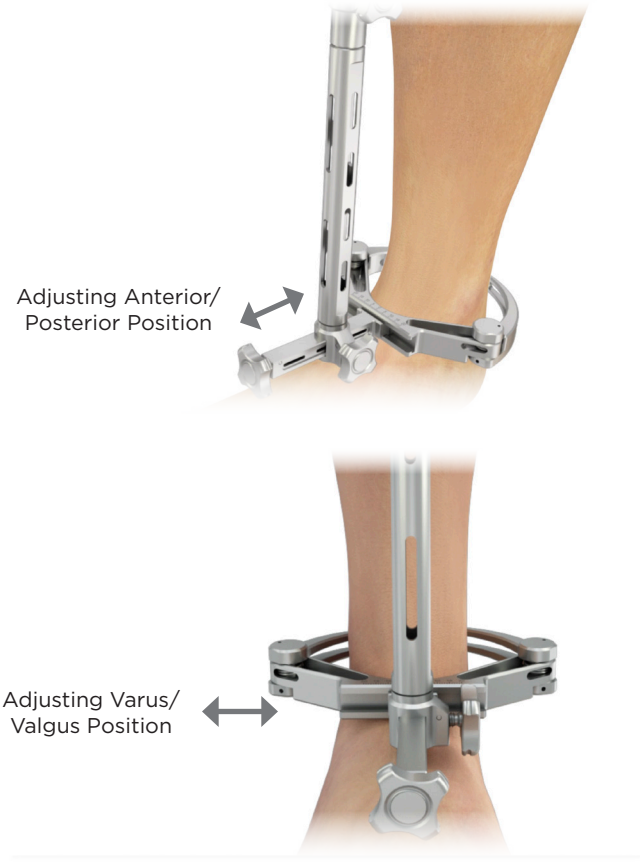
If using the Spiked Uprod, impact the long spike into the proximal tibia for adjustable stability.

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.



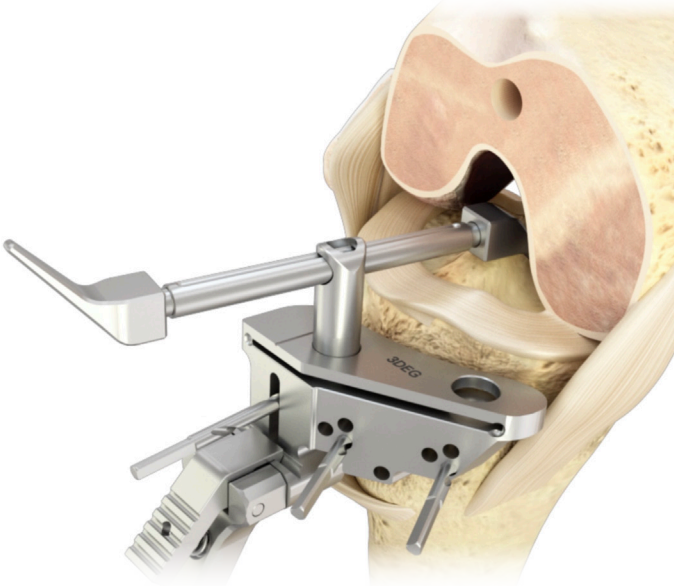
EM Tibial Alignment Guide Resection Level

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.

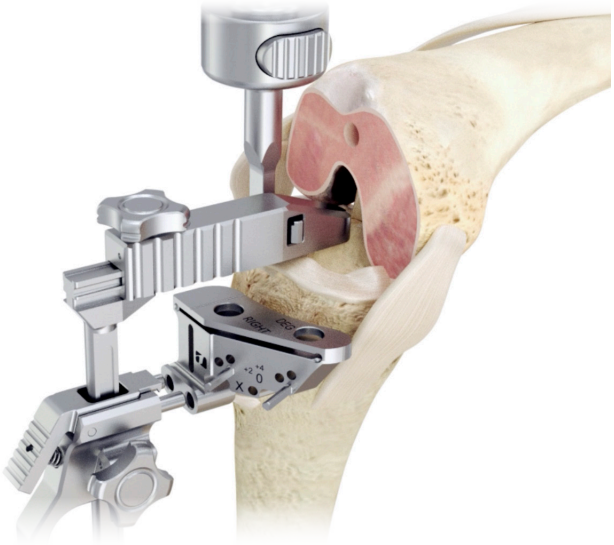


Spiked Uprod Removal

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

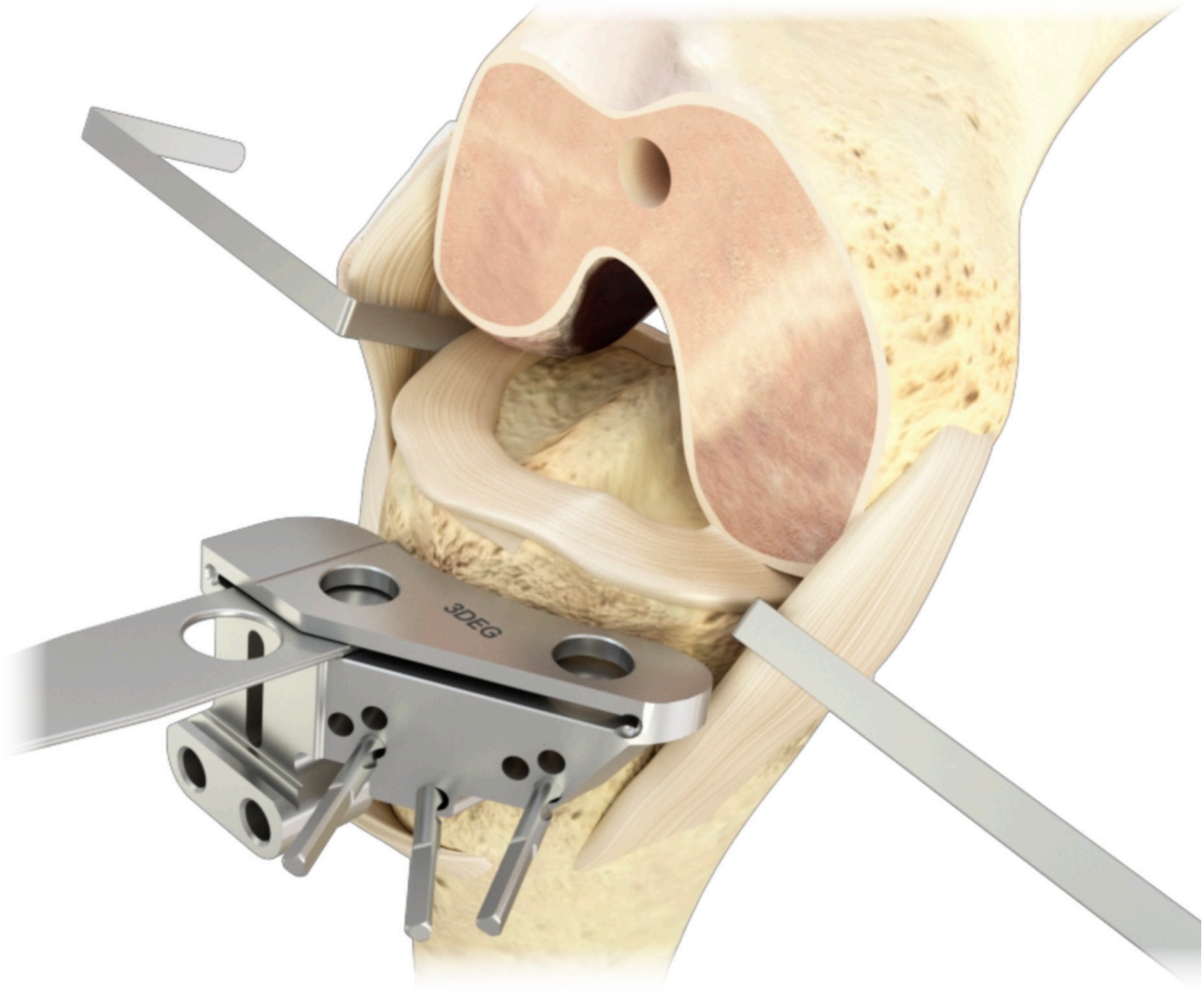
Remove all the Alignment Assembly instruments to leave the tibial block. For additional stability, place a headless pin through the angled hole, located below the “0” holes and indicated by an X mark, to serve as a crosspin.

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.



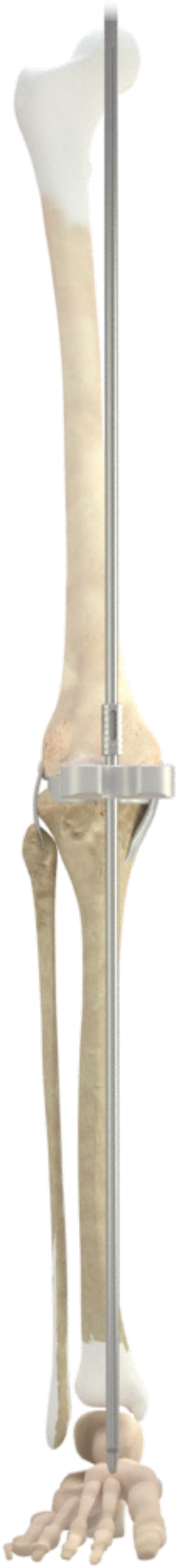
EXTENSION GAP ASSESSMENT

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.



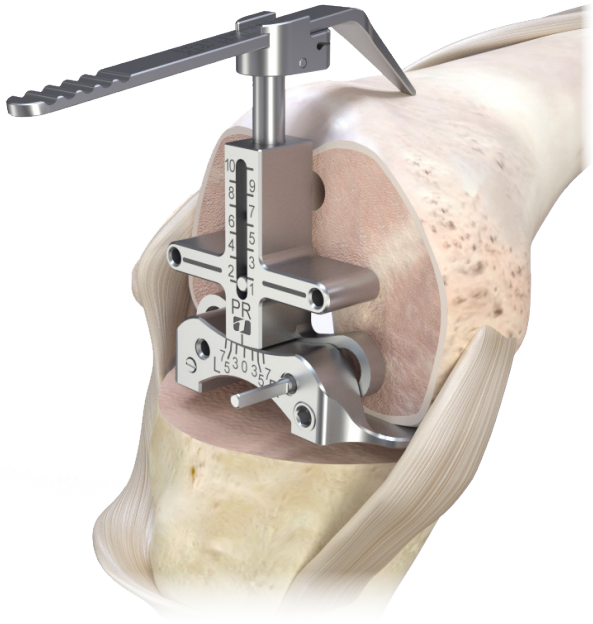
FEMORAL SIZING AND ROTATION - PR

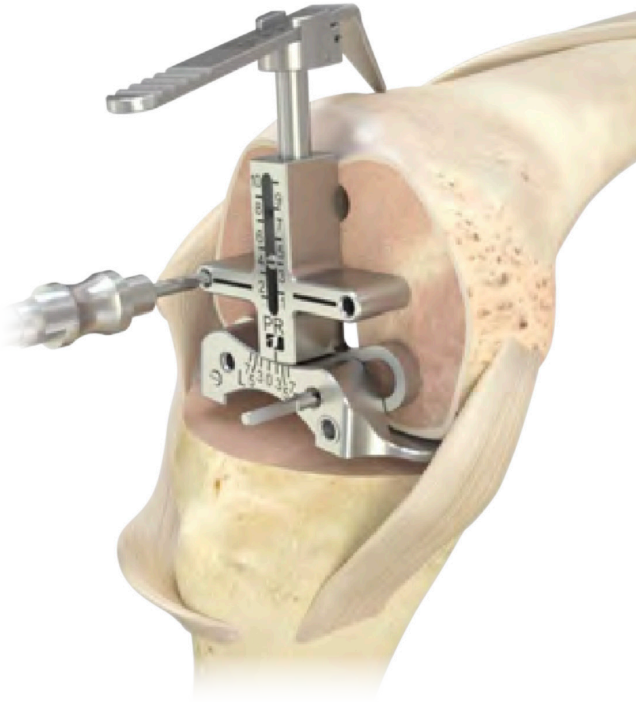
PR Femoral Sizing & Rotation

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.

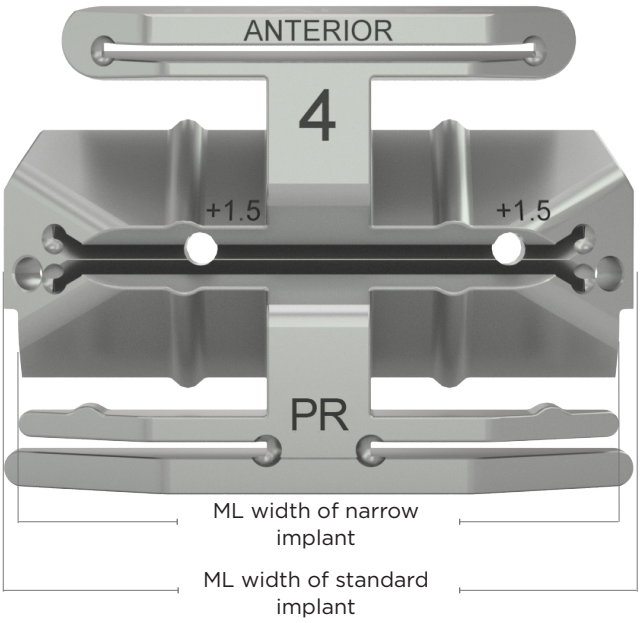
FEMORAL BONE CUTS - PR

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.

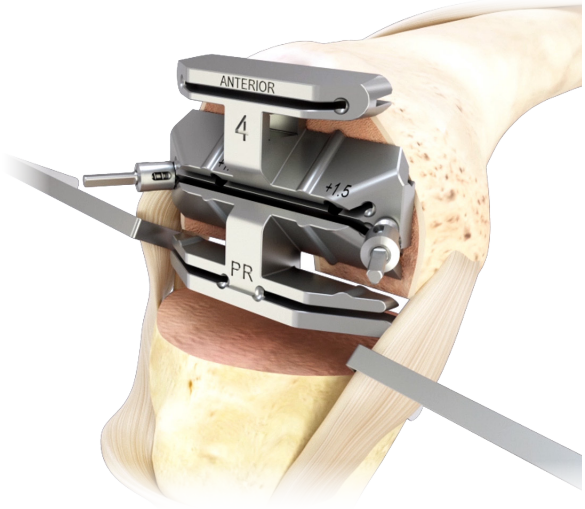
Note: the AP dimension increases 3mm per size.



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.

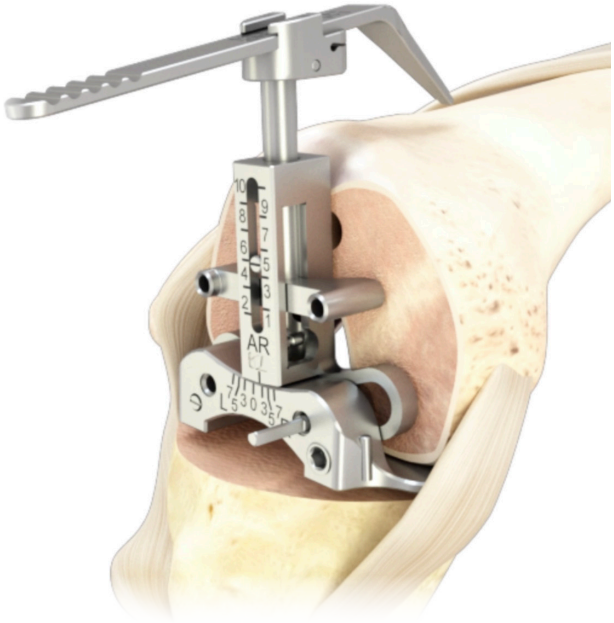
FEMORAL SIZING AND ROTATION - AR

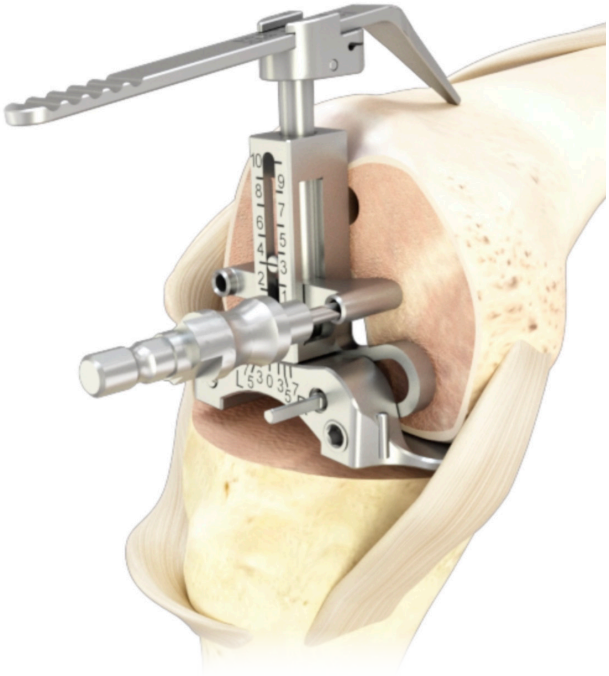
AR Femoral Sizing & Rotation

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.

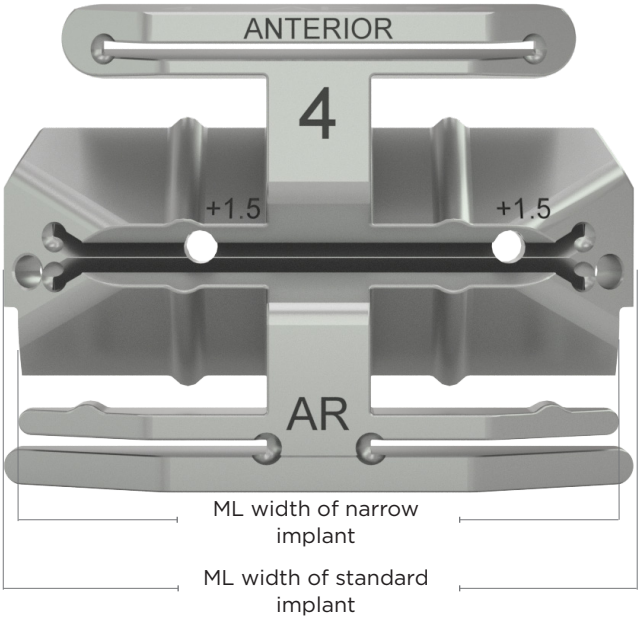
FEMORAL BONE CUTS - AR

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.

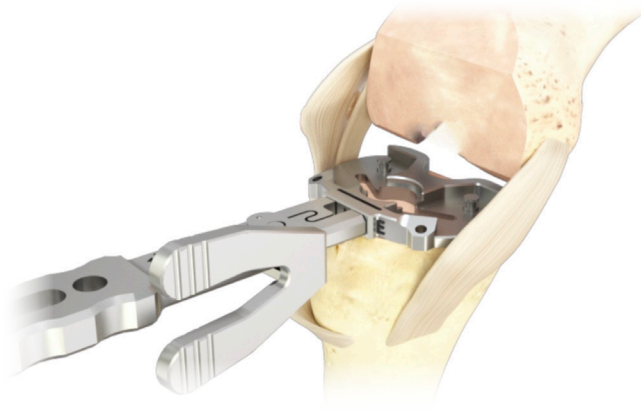
Alternativey, the posterior resection can be made, the block removed, and the flexion gap assessed. The block can be replaced in the described fashion and the remaining resections finished.

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.



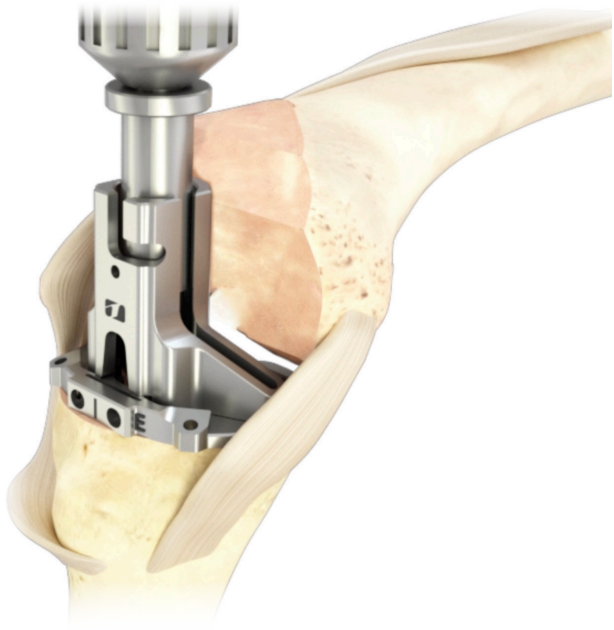
Keel Prep

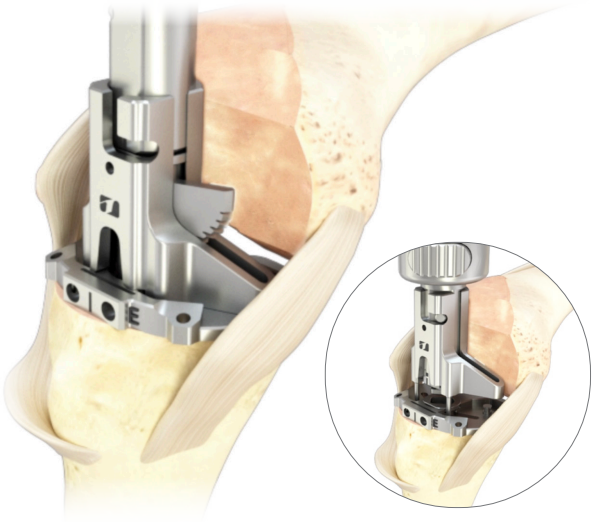
Assemble the Tibial Keel Punch Adaptor on to the Modular Handle. Then assemble the appropriate size Tibial Keel Punch onto the Adaptor based on tibial tray sizing. For example, use a size 4-7 keel punch on a size 5 tibial trial. Impact the Keel Punch through the Tibial Drill/Keel Guide until it bottoms 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.

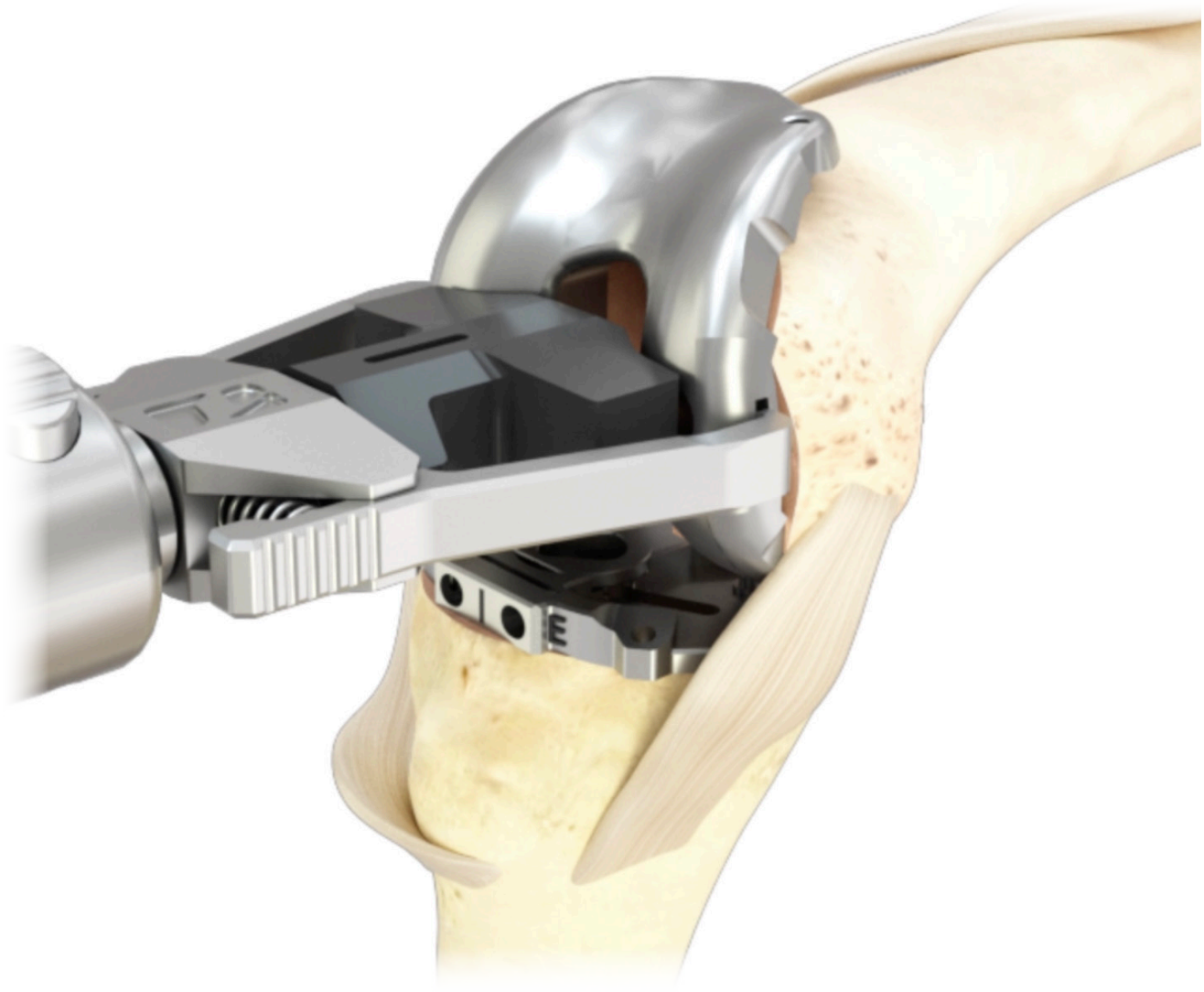
At this point, trial reduction with the femur, tibia, and insert can be performed, or proceed to the patella resection should patella resurfacing be desired.

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.

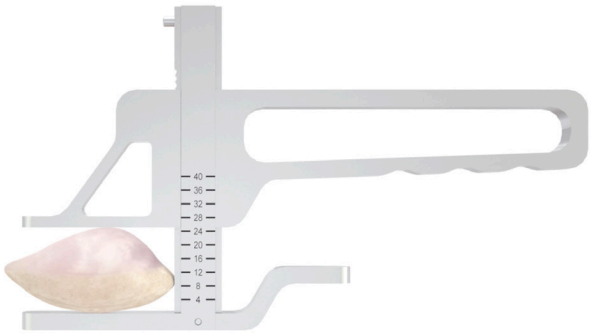
Note: The outer edge on all trials mimic the Standard femoral components. Femoral Trial sizes 3-7 have intermittent cutouts along the medial and lateral edges to indicate the edge of the Narrow femoral components.



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.

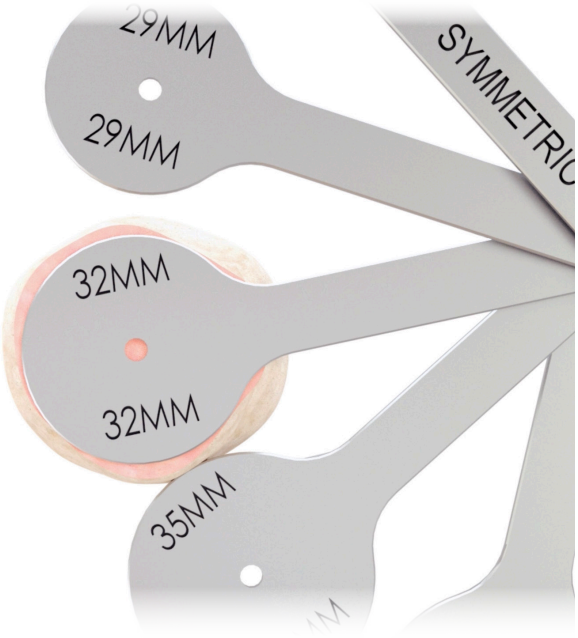
Remove the patella resection guide.

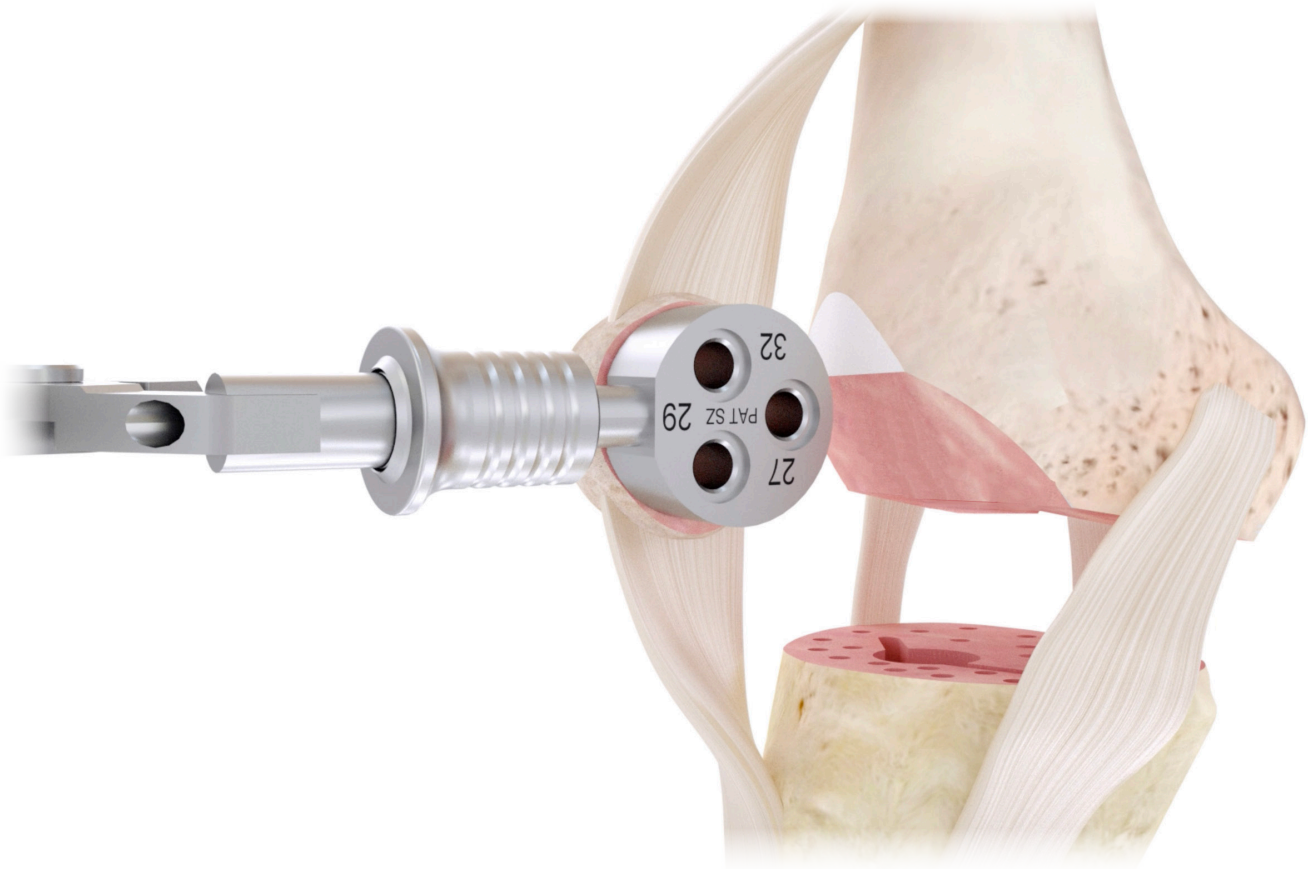
Patella Sizing and Peg Prep

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.



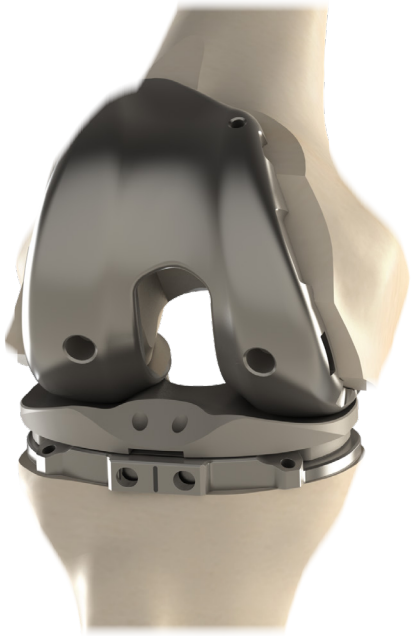


TRIAL REDUCTION

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.



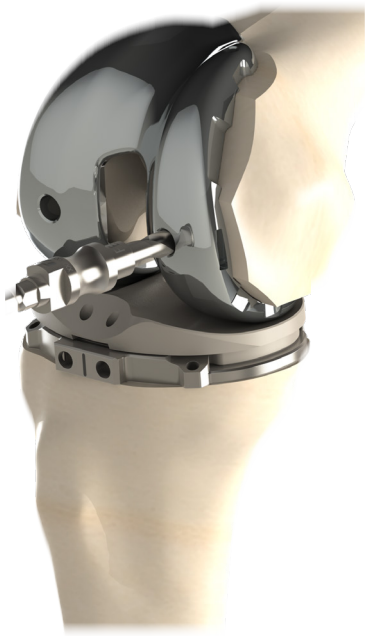
FEMORAL PEG PREPARATION

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.

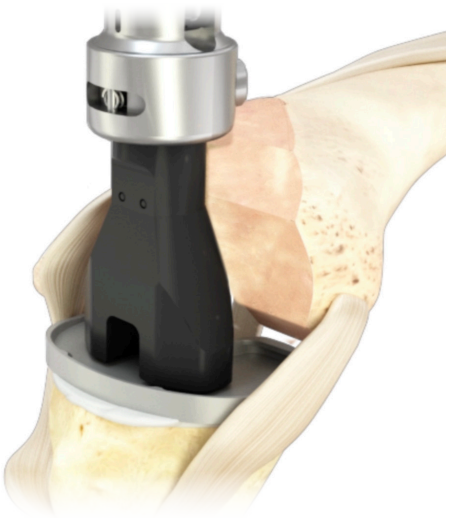
Avoid scratching any of the implants during handling.



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.

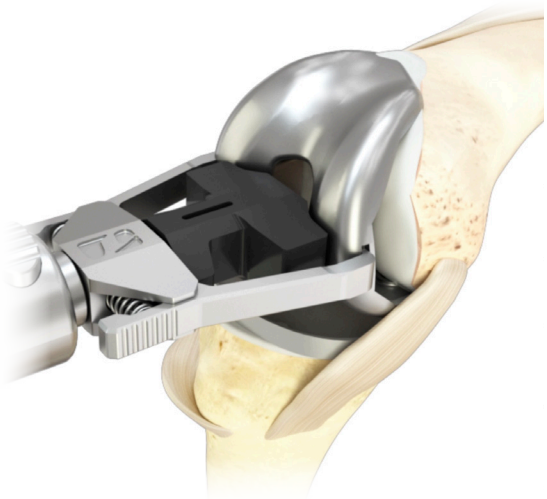


Femoral Component Implantation

Select the appropriate size femoral component.

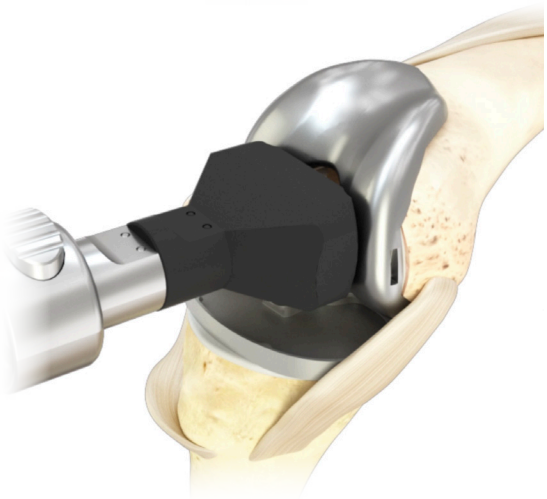
Assemble the Femoral Inserter-Extractor to the Modular Handle and assemble to the femoral prosthesis in the same manner as to the femoral trial.

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.

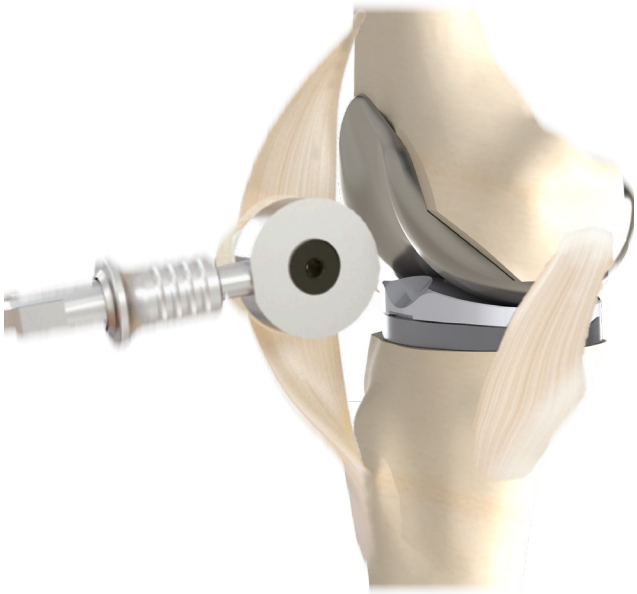


Tibial Insert Implantation

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.

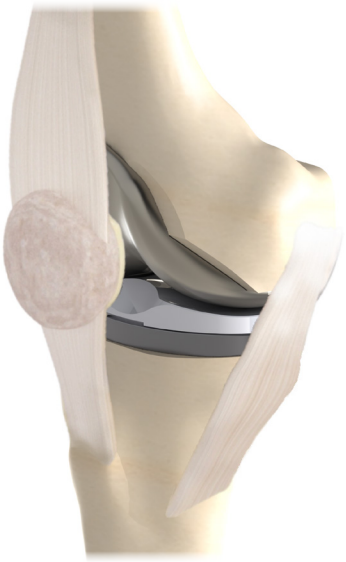
Patella Component Implantation

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

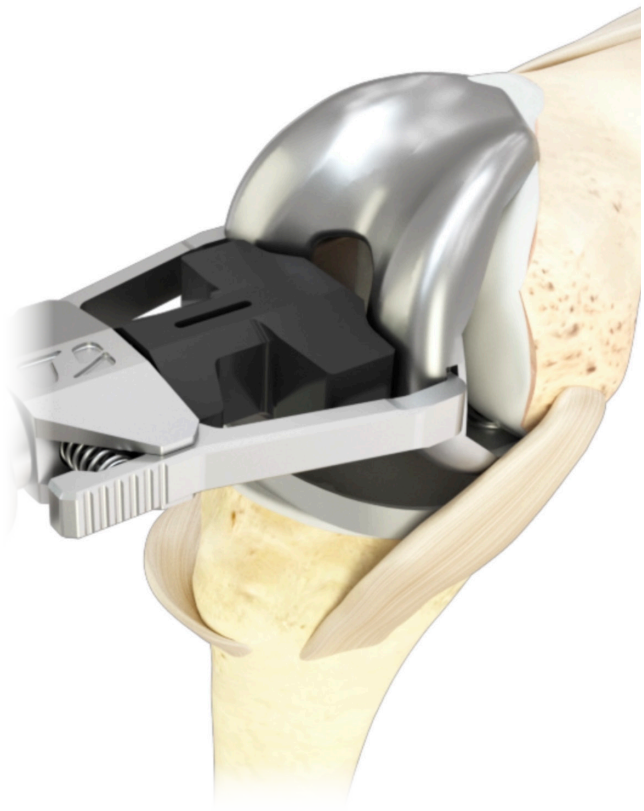
Standard techniques should be used to remove all cemented components.

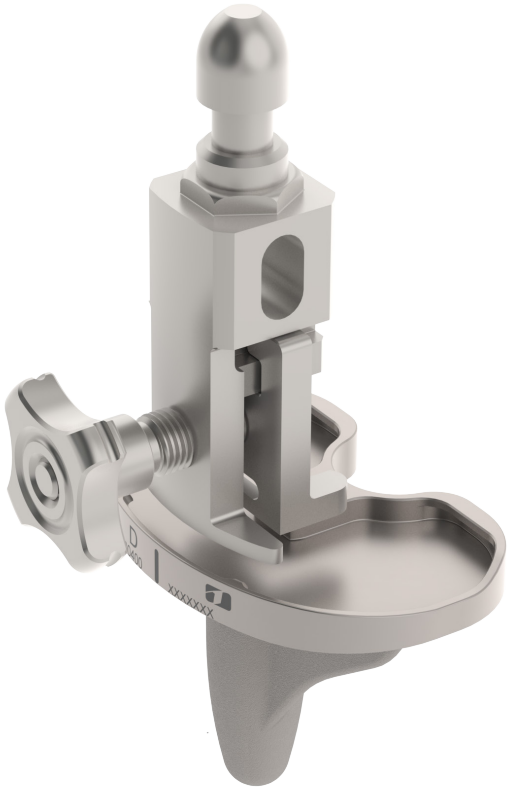
To remove the tibial insert, use a small osteotome in the central window between the tibial insert and the baseplate. Apply force to leverage the tibial insert from the baseplate. Note: Removal of the tibial insert will damage the tibial insert locking wire.

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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Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. The treating surgeon is responsible for determining the appropriate treatment, technique, and product(s) for each individual patient. b-ONE ORTHO does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

Contact your b-ONE representative if you have questions about the availability of b-ONE products in your area.

b1LIT-00050 MOBIO Total Knee System CR/CR Plus Surgical Technique Rev. A

b-ONE ORTHO

One Step Forward

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

www.b1.co

Total Hip System

b-ONE Bi-polar Heads

Adding Variety to Surgical Options

Reduces Wear

b-ONE Bi-polar heads reduces wear through proper distribution of the load stress.

Easy to Assemble

Femoral heads can be easily snapped into the Bi-polar insert during the surgery.

Accurate Fitting

b-ONE Bi-polar heads offer multiple size option for wide variety of patients.

In combination with the b-ONE femoral components and the surgeon's preferred Surgical Technique, the b-ONE Bi-polar can be a cost effective and efficient solution not only to patients with femoral neck fractures and avascular necrosis, but also to surgeons looking for good patient out-come.

b-ONE ORTHO

28.0mm Bi-polar System

Code	Product Description
3815001011	Bipolar Liner, ID 28mm, Size 1
3815002011	Bipolar Liner, ID 28mm, Size 2
3815003011	Bipolar Liner, ID 28mm, Size 3
3815004011	Bipolar Liner, ID 28mm, Size 4

Code	Product Description
3815390001	Bipolar Shell, OD 39mm, ID Size 1
3815400001	Bipolar Shell, OD 40mm, ID Size 1
3815410001	Bipolar Shell, OD 41mm, ID Size 1
3815420001	Bipolar Shell, OD 42mm, ID Size 1
3815430001	Bipolar Shell, OD 43mm, ID Size 2
3815440001	Bipolar Shell, OD 44mm, ID Size 2
3815450001	Bipolar Shell, OD 45mm, ID Size 2
3815460001	Bipolar Shell, OD 46mm, ID Size 3
3815480001	Bipolar Shell, OD 48mm, ID Size 3
3815500001	Bipolar Shell, OD 50mm, ID Size 3
3815520001	Bipolar Shell, OD 52mm, ID Size 4
3815540001	Bipolar Shell, OD 54mm, ID Size 4
3815560001	Bipolar Shell, OD 56mm, ID Size 4

Code	Product Description
7811128035	CoCr Head, 28mm-3.5
7811128000	CoCr Head, 28mm+0
7811128350	CoCr Head, 28mm+3.5
781112870S	CoCr Head, 28mm+7

Total Hip System

b-ONE Bi-polar Heads

Product Catalogue

Total Hip System

OFIT™ Hip System

Cost-Effective Solution for All

132° Neck Angle
Catered for Asian Anatomy

Modified Neck Geometry
Improves Neck Strength and Range of Motion

Proportional Neck Length
Logical Approach to Restoring Leg Length

Small Distal Tip
Easy to Insert, Reduces Thigh Pain

Constant Insertion Path
Easy to Insert and Easy to Assess Rotational Stability

Proximal Cross Section
Provides Rotational Stability and Self Locking

Distal Vertical Grooves
Improves Contact Area and Rotational Stability

Sand Blasting Technology
Improves Bony On-Growth

Total Hip System

OFIT®
Femoral Stem

Product Catalogue

Code	Product Description
7810110085	Femoral Stem, Proportional, 132°, Size 8.5
7810110009	Femoral Stem, Proportional, 132°, Size 9
7810110010	Femoral Stem, Proportional, 132°, Size 10
7810110011	Femoral Stem, Proportional, 132°, Size 11
7810110012	Femoral Stem, Proportional, 132°, Size 12
7810110013	Femoral Stem, Proportional, 132°, Size 13
7810110014	Femoral Stem, Proportional, 132°, Size 14
7810110015	Femoral Stem, Proportional, 132°, Size 15
7810110016	Femoral Stem, Proportional, 132°, Size 16

b-ONE ORTHO

Total Hip System

FUGU™ Acetabular System

Cost-Effective Solution for All

Firm Fixation

Macro Structures on the FUGU™ acetabular cup are oriented in two different directions for secure primary and secondary fixations.

Easy to Insert

Hemispherical design of the FUGU™ acetabular cup's main surface is design line to line with the reamer. Which facilitates the insertion of the cup.

Patented Locking

Patented locking mechanism of the FUGU™ cup is constitute of 12 asymmetric locking ear and tabs that provides secondary locking.

FUGUTM aims to improve clinically proven fixation technology, and incorporates patented secure locking mechanism to provide higher value for patients and surgeons world wide.

Total Hip System

FUGU®
Acetabular System

Product Catalogue

Code	Product Description
781331441C	Acetabular Shell, Code C, 44mm
781331461D	Acetabular Shell, Code D, 46mm
781331481E	Acetabular Shell, Code E, 48mm
781331501F	Acetabular Shell, Code F, 50mm
781331521G	Acetabular Shell, Code G, 52mm
781331541H	Acetabular Shell, Code H, 54mm
781331561I	Acetabular Shell, Code I, 56mm
781331581J	Acetabular Shell, Code J, 58mm
781331601K	Acetabular Shell, Code K, 60mm
781331621L	Acetabular Shell, Code L, 62mm
781331641L	Acetabular Shell, Code L, 64mm

Code	Product Description
781231281C	UHMWPE Liner, Hooded, Code C, 28mm
781231281D	UHMWPE Liner, Hooded, Code D, 28mm
781231281E	UHMWPE Liner, Hooded, Code E, 28mm
781231281F	UHMWPE Liner, Hooded, Code F, 28mm
781231281G	UHMWPE Liner, Hooded, Code G, 28mm
781231281H	UHMWPE Liner, Hooded, Code H, 28mm
781231281I	UHMWPE Liner, Hooded, Code I, 28mm
781231281J	UHMWPE Liner, Hooded, Code J, 28mm
781231281K	UHMWPE Liner, Hooded, Code K, 28mm
781231281L	UHMWPE Liner, Hooded, Code L, 28mm

Code	Product Description
7814106520	Shell Screw, 6.5×20mm
7814106525	Shell Screw, 6.5×25mm
7814106530	Shell Screw, 6.5×30mm
7814106535	Shell Screw, 6.5×35mm
7814106540	Shell Screw, 6.5×40mm

Primary Acetabular System

b-ONE ORTHO

The b-ONE Primary Acetabular System is a comprehensive platform that provides versatile solutions for surgeons and patients, focusing on high performance design implemented through simple intuitive instrumentation.

System Overview

The b-ONE™ Primary Acetabular System is a comprehensive platform that provides versatile solutions for surgeons and patients, focusing on high performance design implemented through simple intuitive instrumentation. The system is comprised of acetabular shells, acetabular liners, and acetabular screws.

The Primary Acetabular Shell is a true hemispherical design with an optimized head-to-shell diameter ratio. The shell is coated with a commercially-pure titanium porous plasma spray that features an optimal porosity and pore size to encourage osseointegration.[1,2] The shell is also available with a bioactive hydroxyapatite layer to accelerate bone remodeling and promote long-term fixation.[3,4] The innovative dual locking mechanism design secures the Vitamin E UHMWPE acetabular liners, which are available in neutral and hooded configurations.

The system is compatible with b-ONE™ 12/14 Taper Femoral heads, which are offered in BIOLOX® *delta* and CoCr.

REFERENCES:

1. b-ONE TM-00091

2. Bobyn JD, Pilliar RM, Cameron HU, Weatherby GC. The Optimum Pore Size for the Fixation of Porous-Surfaced Metal Implants by the Ingrowth of Bone. Clin Orthop. 1980, 150:263-70.

3. Frayssinet, P.; Hardy, D.; Hanker, J. S.; and Giammara, B. L. (1995) "Natural History of Bone Response to Hydroxyapatite-Coated Hip Prostheses Implanted in Humans," Cells and Materials: Vol. 5 : No. 2 , Article 2.

4. Herrera, et al., "Cementless Hydroxyapatite Coated Hip Prostheses," BioMed Research International, vol. 2015, Article ID 386461, 13 pages, 2015.

Indications & Contraindications

INDICATIONS

The b-ONE™ Total Hip System is intended for primary or revision total hip replacement in skeletally mature patients with a severely disabled hip joint and/or hip damage due to the following conditions:

Osteoarthritis, traumatic arthritis, avascular necrosis of the femoral head, noninflammatory degenerative joint disease (NIDJD), slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant. Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis and congenital dysplasia; treatments of nonunion, acute traumatic fracture of the femoral head or neck; failed endoprosthesis, femoral osteotomy, or Girdlestone resection; and fracture-dislocation of the hip.

The b-ONE™ Total Hip System is intended for cementless use only.
b-ONE™ Total Hip System components are not intended for use with other total hip systems.

CONTRAINDICATIONS

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implants materials.
- Severe osteoporosis or osteopenia may prevent adequate fixation and thus preclude the use of these or any other orthopedic implants.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or pregnancy are relative contraindications. The decision to use these devices in such conditions must be made by a physician taking into account the risks versus the benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during body healing and may be at a higher risk of implant failure.
- Using a BIOLOX®*delta* head in combination with a prosthesis stem left in situ in a revision surgery is contraindicated. A BIOLOX®*delta* head must only be used with a brand-new, unused, and undamaged stem taper.
- Any condition not described in the Indications for Use.

Refer to the package insert for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Surgical Technique

STEP ONE | PREOPERATIVE PLANNING

Templating

Preoperative planning supports the determination of appropriate implant style and size for the patient's anatomy and hip pathology. Qualitative and quantitative factors such as patient bone quality, density, and morphology should be considered to select the appropriate implant system for the patient. Preoperative templating should serve only as a guide.

Preoperative templating requires quality radiographs with known and correct magnification. The desired magnification for all imaging should be 20% magnification to correspond with the b-ONE™ x-ray templates, with x-ray magnification calibration used whenever possible. Generally, proper radiographs include a single anteroposterior (A/P) radiograph of the pelvis as well as A/P and lateral radiographs of the affected hip to show the proximal one-third of the femur. A/P views with the limbs in 15 degrees of internal rotation are preferred.

The following templating technique assumes the patient has a normal, symmetrical pelvis.

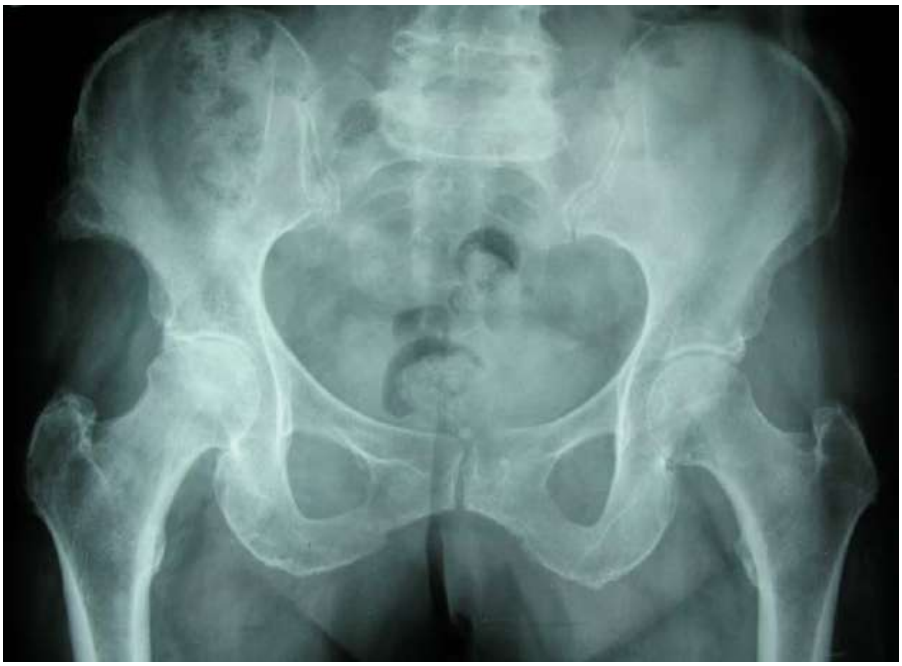


FIGURE 1: A/P RADIOGRAPH OF THE PELVIS

Surgical Technique

STEP ONE | PREOPERATIVE PLANNING

Template Acetabulum

The b-ONE™ Primary Acetabular System x-ray templates are oriented at a 45-degree angle. Using the A/P radiographs, overlay the acetabular template on the x-ray, positioning the cup with an abduction angle of 30-50 degrees. Ensure the medial border of the cup lies adjacent to the ilioischial line, and the inferior border of the cup is at the inferior aspect of the teardrop. The superolateral aspect of the cup should not be excessively uncovered. Mark the center of rotation (COR) of the acetabular component, as indicated by the "X" in **Figure 2**.

Take into consideration any anatomical anomalies, dysplasia, leg length discrepancies, or previous fractures. It may be helpful to assess the acetabular component on the lateral radiograph to provide a view of the subchondral bone.

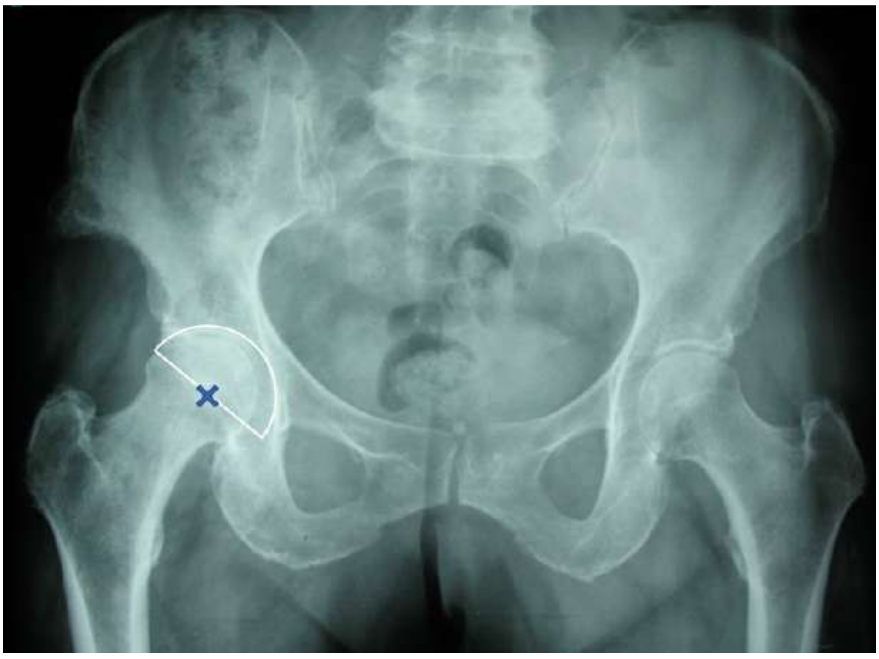


FIGURE 2: ACETABULAR TEMPLATE OVERLAY PLACED OVER X-RAY

Surgical Technique

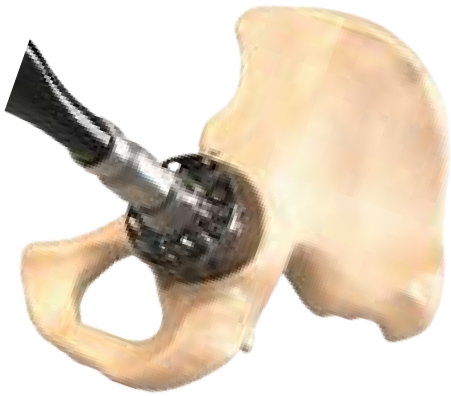
STEP TWO | ACETABULAR REAMING

Acetabular Reaming

The goal of acetabular reaming is to restore the center of the natural acetabulum. Select an acetabular reamer that is considerably smaller than the acetabular cup size determined in preoperative templating. Typically, a reamer 6-8mm smaller than the anticipated size is suitable to initiate reaming and deepen the acetabulum toward the medial wall.

Subsequent reaming should proceed in 1-2mm increments and be used to center and deepen the socket to create a true hemisphere. Take care to avoid eccentric reaming. To obtain optimal component positioning, ensure the reamers are positioned at approximately 30-50 degrees of abduction and 20 degrees of anteversion.

Note that the b-ONE™ Primary Acetabular Shell trials and implants are available in 2mm increments and are marked true to size. For example, a shell marked with size “52mm” measures 52mm in diameter at the rim. To obtain press-fit with the b-ONE™ Primary Acetabular Shell, the acetabulum can be under-reamed by 1mm to obtain 1mm of press-fit, dependent upon bone quality and acetabulum size.



INSTRUMENTS

8819056000
Reamer Driver, Straight

88190460XX
Acetabular Reamers

Surgical Technique

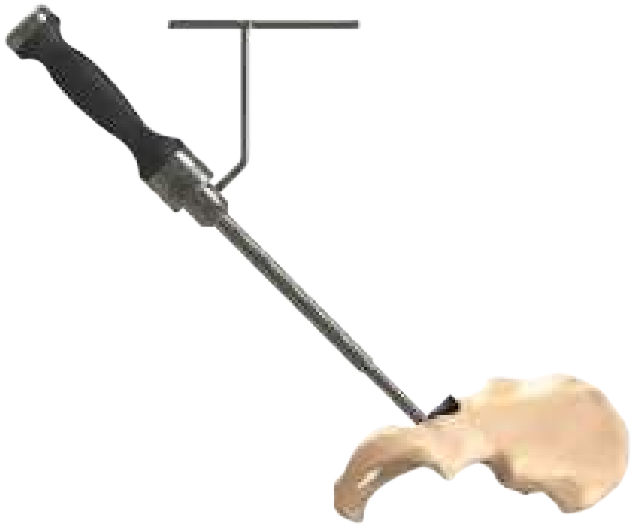
STEP THREE | ACETABULAR TRIALING

Acetabular Shell Trial

Select the appropriate acetabular Shell Trial based on the final reamer size and attach to the Shell Inserter. Note the Shell Trials are true to size.

The Abduction/Anteversion Guide is available to attach to the Shell Inserter to assist with component positioning in the acetabulum. It is important to remember that shell orientation in the patient depends on the patient position, and patient orientation can vary throughout the procedure. The Abduction/Anterversion Guide is designed for a traditional posterolateral approach with the patient positioned in the lateral decubitis position, and does not allow for variation in patient position with respect to the operating table.

Once assembled, position the Shell Trial in the reamed acetabulum. Raise the Shell Inserter handle until the vertical bar of the Abduction/ Anteversion Guide is perpendicular to the long axis of the body to achieve 45 degrees of abduction of the shell trial. Then rotate the Shell Inserter handle until the appropriate arm (left or right) of the Abduction/ Anteversion Guide is aligned with the long axis of the body of the patient to achieve 20 degrees of anteversion.



Once the desired positioning is achieved, impact the Shell Inserter with the Mallet to seat the Shell Trial. Assess the seating of the Shell Trial by viewing the acetabulum through the cutouts in the Shell Trial.

INSTRUMENTS

8819036000
Axial Handle

8819071000
Shell Inserter, Straight

8819072000
Abduction/Anteversion Guide

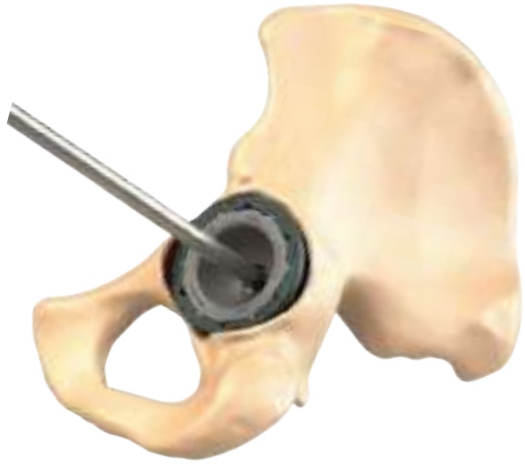
8819061XXX
Shell Trial

Surgical Technique

STEP THREE | ACETABULAR TRIALING

Acetabular Liner Trial

Upon satisfactory seating of the Shell Trial, remove the Shell Inserter and place the appropriately sized Acetabular Liner Trial into the Shell Trial. The Primary Acetabular System polyethylene liners and respective trials are available in neutral (0°) and hooded (10°) configurations. Acetabular Liner Trials are designed with tabs to facilitate alignment within the rim cutouts in the shell trial. Secure the liner trial to the shell trial by tightening the apical screw with the straight screwdriver assembled to the 1/4" Square Ratchet Handle.



INSTRUMENTS

881906XXXX
Acetabular Liner Trial

8819041000
1/4" Square Ratchet Handle

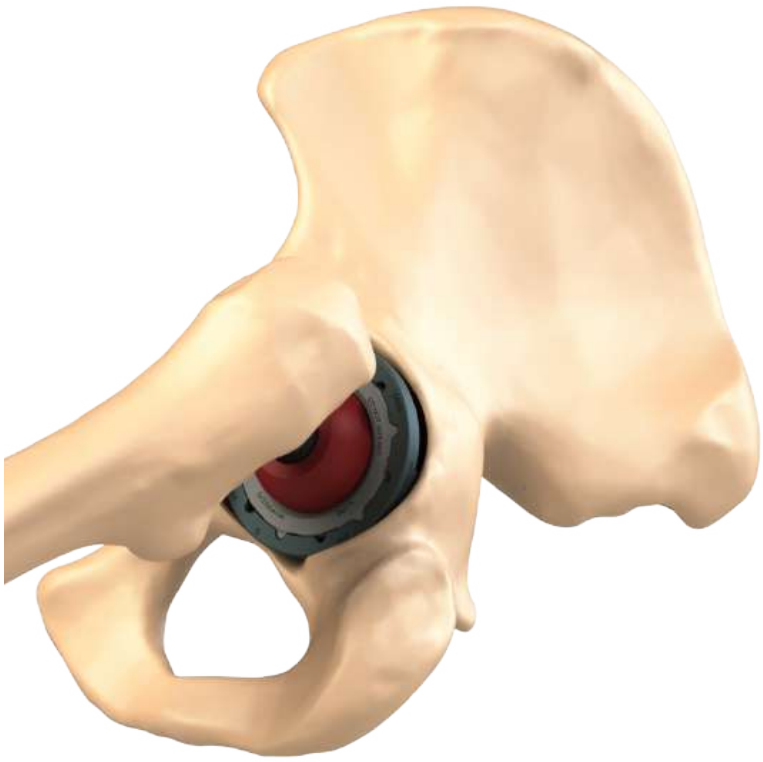
8819076000
Straight Screwdriver

Surgical Technique

STEP THREE | ACETABULAR TRIALING

Trial Reduction

With the femoral components in position, reduce the hip and assess stability and range of motion of the hip construct.



Surgical Technique

STEP FOUR | ACETABULAR SHELL IMPLANTATION

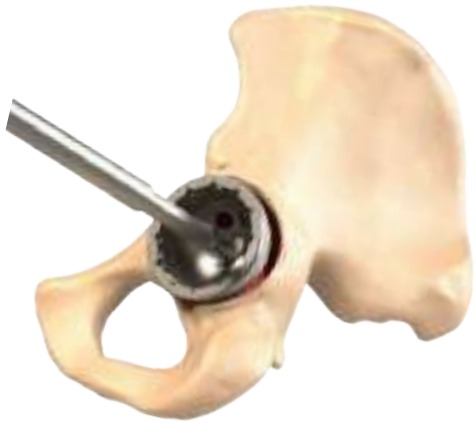
Select the appropriate acetabular shell prosthesis based on the size determined during trialing. Securely thread the acetabular shell implant onto the acetabular shell inserter.

Once assembled, position the acetabular shell in the reamed acetabulum using the same procedure described previously for the acetabular shell trial.

Note: If screw fixation is desired, be sure to orient the acetabular shell so that the screw holes will be positioned in the posterior-superior and/or posterior-inferior quadrants of the acetabulum. This will minimize the potential for neurologic and vascular injury.

Impact the acetabular Shell Inserter handle firmly with the mallet until the shell is fully seated. Gently toggle the acetabular Shell Inserter handle to assess the stability of the acetabular shell. Once satisfactory stability is confirmed, remove the Shell Inserter from the acetabular shell and confirm the acetabular shell is fully seated.

Visual inspection through the dome hole or screw holes, if applicable, can be used to help assess the seating of the shell in the acetabulum. If the shell is firmly seated, there should be no gap between the shell and the medial wall of the acetabulum and no apparent movement of the shell.



INSTRUMENTS

8819036000
Axial Handle

8819071000
Shell Inserter, Straight

8819072000
Abduction/Anteversion Guide

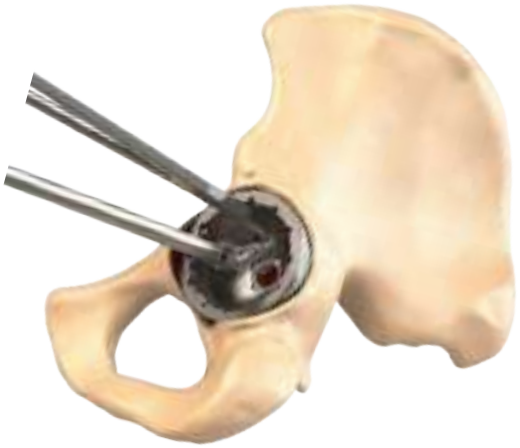
Surgical Technique

STEP FIVE | ACETABULAR SCREW IMPLANTATION

The b-ONE™ Primary Acetabular System includes cluster-hole and multi-hole acetabular shells to allow for screw fixation if screw placement is desired. The b-ONE™ Primary Acetabular System screws are 6.5mm self-tapping cancellous screws, available in various lengths, and must be predrilled with a 3.2mm drill bit.

To implant acetabular screws:

- Select screw holes that allow safe placement of acetabular screws. Typically, screws are placed in the posterior superior or posterior inferior acetabular quadrants to minimize potential neurological and/or vascular injury.
- Select the desired length 3.2mm modular drill bit and attach to the Modular Flexible Drill Shaft. The drill bits are available in 15mm, 30mm, 45mm, and 60mm lengths, and are marked according to the effective length of the drilled hole created when the drill bit is completely seated in the drill guide. For example, the 30mm Drill Bit will create a 30mm drilled hole when completely seated in the drill guide.
- Slide the drill bit through the Drill Guide and place the tip of the drill bit into the selected screw hole.
- Drill the bone using the Drill Guide to control the direction of the drill bit.
- After drilling, use the Depth Gauge to verify the appropriate screw length and select the corresponding screw implant.
- Assemble the U-Joint Screwdriver shaft to the 1/4" Square Ratchet Handle. Use the Screw Holder to hold the head of the screw and place the tip of the screwdriver into the hex of the screw.
- Introduce the screw into the predrilled hole and screw into place. Screws cannot be inserted into the dome hole.
- Ensure the head of the screw is fully seated so that it will not impinge the liner. After all screws are inserted, it is recommended to reconfirm that all screws are fully seated and completely tightened.



INSTRUMENTS

88190790XX
Modular Drill Bit

8819078X00
Flexible Modular Drill Shaft

8819023000
Drill Guide

8819024000
Depth Gauge

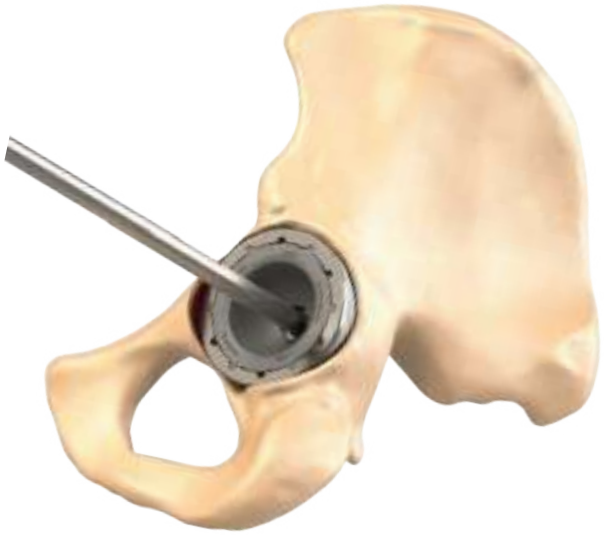
881902500X
U-Joint Screwdriver

8819041000
1/4" Square Ratchet Handle

Surgical Technique

STEP SIX | ACETABULAR LINER TRIAL

The Acetabular Liner Trial can be trialed in the implanted acetabular shell prosthesis if desired. Select the appropriate size Acetabular Liner Trial and place in the acetabular shell so that it is aligned correctly. If a hooded liner is being trialed, ensure the elevated hood is in the correct position. Secure the liner trial to the shell prosthesis by tightening the apical screw with the Straight Screwdriver assembled to the 1/4" Square Ratchet Handle.



Trial reduction should be performed with the trial femoral prosthesis and femoral head to assess range of motion, leg length, stability and offset. Once trial reduction is complete, remove the Acetabular Liner Trial.

INSTRUMENTS

881906XXXX
Acetabular Liner Trial

8819076000
Straight Screwdriver

8819041000
1/4" Square Ratchet Handle

Surgical Technique

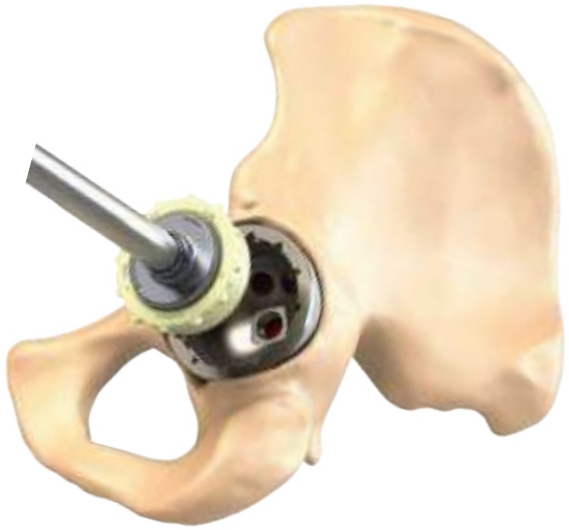
STEP SEVEN | ACETABULAR LINER IMPLANTATION

Select the appropriate size acetabular liner compatible with the implanted acetabular shell and determined by trialing. Prior to inserting the liner, thoroughly irrigate and clean the acetabular shell. It is important to check for any debris, ensure all screw heads are fully seated, and to remove any soft tissue at the face of the shell so that the seating of the liner will not be impeded.

The b-ONE™ Primary Acetabular System Liner is designed with 12 anti-rotation alignment tabs that mate with scallops in the rim of the acetabular shell. This allows the liner to be rotated in 30-degree increments during positioning of a hooded liner.

Select the liner Impactor Head that matches the inner diameter of the liner and assemble the Impactor Head to the Liner Impactor. Place the liner into the acetabular shell by hand and spin the liner so that the anti-rotation tabs are properly aligned and engaged with the scallops in the shell rim. If implanting a hooded liner, ensure the hood is in the desired location before impaction.

Press the liner impactor head into the liner and impact the liner impactor head with a mallet with several medium blows to fully seat the liner into the shell. Be sure to keep the liner impactor on axis with the shell to ensure proper seating of the liner. Impacting the liner along a tilted axis may prevent complete seating and proper locking of the shell.



INSTRUMENTS

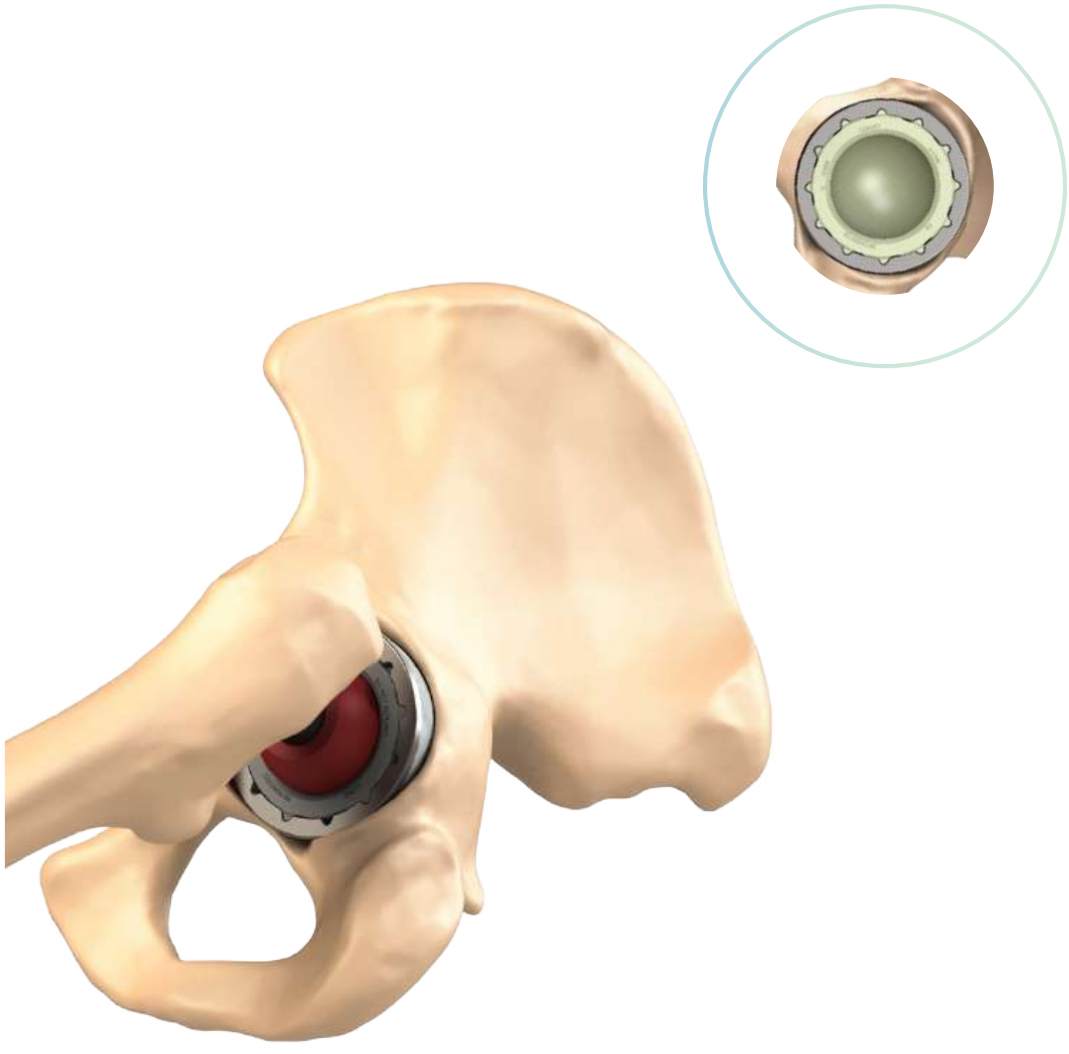
88190330XX
Poly Liner Impactor Head

8819020000
Liner Impactor, Straight

Surgical Technique

STEP SEVEN | ACETABULAR LINER IMPLANTATION

Inspect the acetabular liner and shell for proper seating of the liner. Seating is visually confirmed when the liner is flush with the face of the acetabular shell. Perform final reduction with the femoral prosthesis and femoral head.



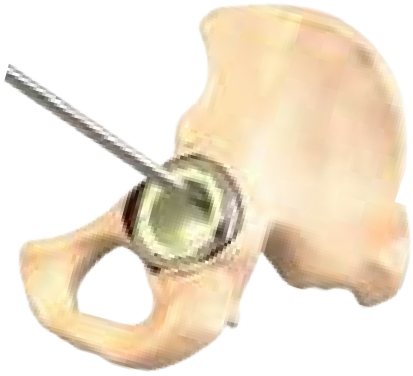
Surgical Technique

IMPLANT REMOVAL

Acetabular Liner Removal

To remove the acetabular liner, use the drill included in the set or any 3.2mm drill bit. Drill a pilot hole in the liner. Take care to drill in an area in which there are no screw holes located. By hand, screw the Liner remover tool, assembled to the 1/4" Square Ratchet Handle, into the pilot hole until the tip of the liner remover tool engages the acetabular shell and the acetabular liner is disengaged from the shell. Typically an audible snap can be heard as the locking mechanism is disengaged, and the liner can be seen lifting from out of the shell. It may be necessary to repeat this process in two or three opposing locations in the liner to completely disengage the locking mechanism and remove the liner.

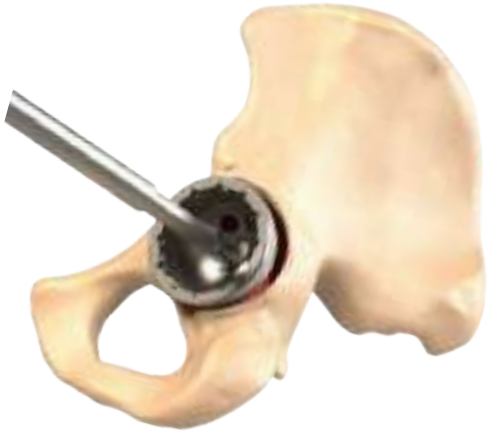
Once removed, the acetabular liner cannot be re-used. If the acetabular shell is to be left in place and a new liner is to be implanted, be sure to inspect the acetabular shell for damage. It is recommended to trial a liner before implanting another liner.



Shell Removal

Once the liner is removed, remove any acetabular screws in the shell using the u-joint screwdriver. The screws are compatible with a 3.5mm hex screwdriver.

Assemble the acetabular shell inserter to the Axial Handle. Thread the assembled acetabular Shell Inserter into the polar hole of the shell and remove the shell with reverse impaction to the handle with the mallet.



INSTRUMENTS

3.2mm drill bit

8819028000
Liner Remover

8819041000
1/4" Square
Ratchet Handle

8819025000
U-Joint
Screwdriver

8819071000
Shell Inserter

8819036000
Axial Handle

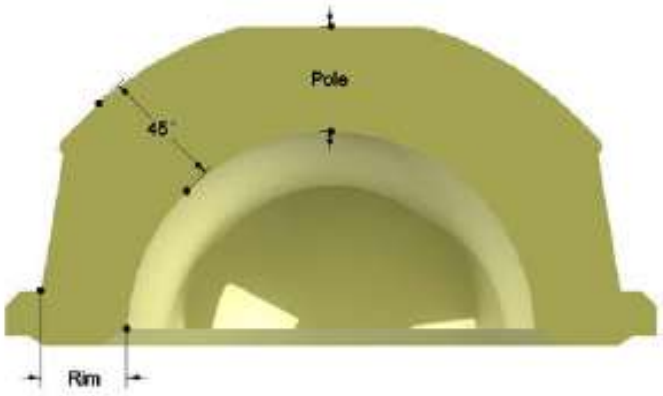
CHARTS | COMPATIBILITY

b-ONE Primary Acetabular System											
Shell & Liner Sizing Chart											
Shell Size (mm)	44	46	48	50	52	54	56	58	60	62	64
Liner Size	C	D	E	F	G	H	I	J	K	L	L
Vitamin E UHMWPE Liners	28mm Neutral/Hooded										
			32mm Neutral/Hooded								
					36mm Neutral/Hooded						

b-ONE Primary Acetabular System			
Poly Liner Thickness at 45 degrees			
Shell Size (mm)	Head Size		
	28	32	36
44 | C	5.9		
46 | D	6.6		
48 | E	7.3	5.3	
50 | F	8.6	6.6	
52 | G	9.3	7.3	5.3
54 | H	10.1	8.1	6.1
56 | I	10.8	8.8	6.8
58 | J	11.5	9.5	7.5
60 | K	12.2	10.2	8.2
62 | L	12.9	10.9	8.9
64 | L	13.6	11.6	9.6

b-ONE Primary Acetabular System			
Poly Liner Thickness at Pole			
Shell Size (mm)	Head Size		
	28	32	36
44 | C	4.6		
46 | D	5.3		
48 | E	6.0	4.0	
50 | F	7.2	5.2	
52 | G	8.0	6.0	4.0
54 | H	9.2	7.2	5.2
56 | I	10.5	8.5	6.5
58 | J	11.0	9.0	7.0
60 | K	12.0	10.0	8.0
62 | L	12.0	10.0	8.0
64 | L	13.0	11.0	9.0

b-ONE Primary Acetabular System			
Poly Liner Thickness at Rim			
Shell Size (mm)	Head Size		
	28	32	36
44 | C	3.6		
46 | D	4.6		
48 | E	5.6	3.6	
50 | F	6.6	4.6	
52 | G	7.6	5.6	3.6
54 | H	8.6	6.6	4.6
56 | I	9.6	7.6	5.6
58 | J	10.5	8.5	6.5
60 | K	11.5	9.5	7.5
62 | L	12.5	10.5	8.5
64 | L	13.5	11.5	9.5



ORDERING | IMPLANTS

Acetabular Shell
PPS + HA COATING

b-ONE Primary Acetabular System Acetabular Shell

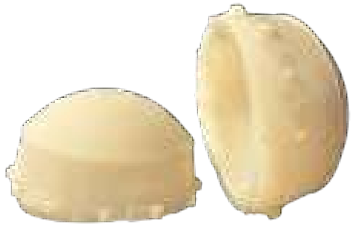
DESCRIPTION	PART #	O.D.	LINER SIZE
Primary Acetabular System Acetabular Shell Cluster Hole PPS + HA COATING	881311441C	44	C
	881311461D	46	D
	881311481E	48	E
	881311501F	50	F
	881311521G	52	G
	881311541H	54	H
	881311561I	56	I
	881311581J	58	J
	881311601K	60	K
	881311621L	62	L
	881311641L	64	L

Acetabular Shell Screw
6.5mm Diameter

b-ONE Primary Acetabular System Acetabular Shell Screw

DESCRIPTION	PART #	LENGTH
Primary Acetabular System Acetabular Shell Screw 6.5mm Diameter	8814006516	16mm
	8814006520	20mm
	8814006525	25mm
	8814006530	30mm
	8814006535	35mm
	8814006540	40mm
	8814006545	45mm
	8814006550	50mm
	8814006555	55mm
	8814006560	60mm

ORDERING | IMPLANTS



Vitamin E
UHMWPE Liners

b-ONE Primary Acetabular System Acetabular Liner			
PART #	DESCRIPTION	I.D.	LINER SIZE
881200281C	Primary Acetabular System Acetabular Liner Neutral, 0 Degree Vitamin E UHMWPE	28mm	C
881200281D			D
881200281E			E
881200281F			F
881200281G			G
881200321E		32mm	E
881200321F			F
881200321G			G
881200321H			H
881200321I			I
881200361G		36mm	G
881200361H			H
881200361I			I
881200361J			J
881200361K			K
881200361L			L
881201281C	Primary Acetabular System Acetabular Liner Hooded, 10 Degree Vitamin E UHMWPE	28mm	C
881201281D			D
881201281E			E
881201281F			F
881201281G			G
881201321E		32mm	E
881201321F			F
881201321G			G
881201321H			H
881201321I			I
881201361G		36mm	G
881201361H			H
881201361I			I
881201361J			J
881201361K			K
881201361L			L

ORDERING | INSTRUMENTS

PART #	DESCRIPTION
8819900000	**b-ONE™ Primary Acetabular System Sterilization Case Lid**
8819900200	**b-ONE™ Primary Acetabular System Sterilization Case** - *Includes 8819900201, 8819900202, 8819900203, 8819900204, & 8819900000*
8819900201	**b-ONE Primary Acetabular System Screw Instruments Sterilization Tray**
8819056000	Reamer Driver, Straight
8819078100	Cannulated Flex Modular Drill Shaft
8819076000	Straight Screwdriver
8819071000	Shell Inserter, Straight
8819072000	Abduction/Anterversion Guide
8819020000	Liner Impactor, Straight
8819023000	Drill Guide
8819024000	Depth Gauge
8819025000	U-Joint Screwdriver
8819027000	Screw Holder
8819028000	Liner Remover
8819033028	Poly Liner Impactor Head, 28mm
8819033032	Poly Liner Impactor Head, 32mm
8819033036	Poly Liner Impactor Head, 36mm
8819041000	1/4" Square Ratchet Handle
8819036000	Axial Handle
8819900203	**b-ONE Primary Acetabular System Modular Drill Bit Caddy Lid** - *Compatible with 8819900204*
8819900204	**b-ONE Primary Acetabular System Modular Drill Bit Caddy For Modular Drill Bits** - *16mm, 30mm, 45mm, 60mm*
8819079016	Modular Drill Bit, 16mm
8819079030	Modular Drill Bit, 30mm
8819079045	Modular Drill Bit, 45mm
8819079060	Modular Drill Bit, 60mm

PART #	DESCRIPTION
8819900202	**b-ONE Primary Acetabular System Shell & Liner Trials Sterilization Tray** *Compatible with Sterilization Case Lid 8819900000*
881906144C	Shell Trial, 44mm Outer Diameter x Liner Size C
881906146D	Shell Trial, 46mm Outer Diameter x Liner Size D
881906148E	Shell Trial, 48mm Outer Diameter x Liner Size E
881906150F	Shell Trial, 50mm Outer Diameter x Liner Size F
881906152G	Shell Trial, 52mm Outer Diameter x Liner Size G
881906154H	Shell Trial, 54mm Outer Diameter x Liner Size H
881906156I	Shell Trial, 56mm Outer Diameter x Liner Size I
881906158J	Shell Trial, 58mm Outer Diameter x Liner Size J
881906160K	Shell Trial, 60mm Outer Diameter x Liner Size K
881906162L	Shell Trial, 62mm Outer Diameter x Liner Size L
881906164L	Shell Trial, 64mm Outer Diameter x Liner Size L

ORDERING | INSTRUMENTS

PART #	DESCRIPTION
8819900202	**b-ONE Primary Acetabular System Shell & Liner Trials Sterilization Tray** *Compatible with Sterilization Case Lid 8819900000*
881906144C	Shell Trial, 44mm Outer Diameter x Liner Size C
881906146D	Shell Trial, 46mm Outer Diameter x Liner Size D
881906148E	Shell Trial, 48mm Outer Diameter x Liner Size E
881906150F	Shell Trial, 50mm Outer Diameter x Liner Size F
881906152G	Shell Trial, 52mm Outer Diameter x Liner Size G
881906154H	Shell Trial, 54mm Outer Diameter x Liner Size H
881906156I	Shell Trial, 56mm Outer Diameter x Liner Size I
881906158J	Shell Trial, 58mm Outer Diameter x Liner Size J
881906160K	Shell Trial, 60mm Outer Diameter x Liner Size K
881906162L	Shell Trial, 62mm Outer Diameter x Liner Size L
881906164L	Shell Trial, 64mm Outer Diameter x Liner Size L
881906028C	Acetabular Liner Trial, Neutral 0 Deg, Size C x 28mm I.D.
881906028D	Acetabular Liner Trial, Neutral 0 Deg, Size D x 28mm I.D.
881906028E	Acetabular Liner Trial, Neutral 0 Deg, Size E x 28mm I.D.
881906032E	Acetabular Liner Trial, Neutral 0 Deg, Size E x 32mm I.D.
881906028F	Acetabular Liner Trial, Neutral 0 Deg, Size F x 28mm I.D.
881906032F	Acetabular Liner Trial, Neutral 0 Deg, Size F x 32mm I.D.
881906028G	Acetabular Liner Trial, Neutral 0 Deg, Size G x 28mm I.D.
881906032G	Acetabular Liner Trial, Neutral 0 Deg, Size G x 32mm I.D.
881906036G	Acetabular Liner Trial, Neutral 0 Deg, Size G x 36mm I.D.
881906032H	Acetabular Liner Trial, Neutral 0 Deg, Size H x 32mm I.D.
881906036H	Acetabular Liner Trial, Neutral 0 Deg, Size H x 36mm I.D.

PART #	DESCRIPTION
881906032I	Acetabular Liner Trial, Neutral 0 Deg, Size I x 32mm I.D.
881906036I	Acetabular Liner Trial, Neutral 0 Deg, Size I x 36mm I.D.
881906036J	Acetabular Liner Trial, Neutral 0 Deg, Size J x 36mm I.D.
881906036K	Acetabular Liner Trial, Neutral 0 Deg, Size K x 36mm I.D.
881906036L	Acetabular Liner Trial, Neutral 0 Deg, Size L x 36mm I.D.
881906428C	Acetabular Liner Trial, Hooded 10 Deg, Size C x 28mm I.D.
881906428D	Acetabular Liner Trial, Hooded 10 Deg, Size D x 28mm I.D.
881906428E	Acetabular Liner Trial, Hooded 10 Deg, Size E x 28mm I.D.
881906432E	Acetabular Liner Trial, Hooded 10 Deg, Size E x 32mm I.D.
881906428F	Acetabular Liner Trial, Hooded 10 Deg, Size F x 28mm I.D.
881906432F	Acetabular Liner Trial, Hooded 10 Deg, Size F x 32mm I.D.
881906428G	Acetabular Liner Trial, Hooded 10 Deg, Size G x 28mm I.D.
881906432G	Acetabular Liner Trial, Hooded 10 Deg, Size G x 32mm I.D.
881906436G	Acetabular Liner Trial, Hooded 10 Deg, Size G x 36mm I.D.
881906432H	Acetabular Liner Trial, Hooded 10 Deg, Size H x 32mm I.D.
881906436H	Acetabular Liner Trial, Hooded 10 Deg, Size H x 36mm I.D.
881906432I	Acetabular Liner Trial, Hooded 10 Deg, Size I x 32mm I.D.
881906436I	Acetabular Liner Trial, Hooded 10 Deg, Size I x 36mm I.D.
881906436J	Acetabular Liner Trial, Hooded 10 Deg, Size J x 36mm I.D.
881906436K	Acetabular Liner Trial, Hooded 10 Deg, Size K x 36mm I.D.

ORDERING | INSTRUMENTS

PART #	DESCRIPTION
8819900300	**b-ONE Primary Acetabular System Reamers Sterilization Case -** *Includes 8819900301, 8819900303, & 8819900000*
8819900303	**b-ONE™ Primary Acetabular System Acetabular Reamers Inlay -** *For Reamers 38mm - 65mm*
8819900301	**b-ONE™ Primary Acetabular System Acetabular Reamers Sterilization Tray -** *Compatible with Sterilization Case Lid 881900000*
8819046038	Acetabular Reamer, 38mm
8819046039	Acetabular Reamer, 39mm
8819046040	Acetabular Reamer, 40mm
8819046041	Acetabular Reamer, 41mm
8819046042	Acetabular Reamer,42mm
8819046043	Acetabular Reamer, 43mm
8819046044	Acetabular Reamer, 44mm
8819046045	Acetabular Reamer, 45mm
8819046046	Acetabular Reamer, 46mm
8819046047	Acetabular Reamer, 47mm
8819046048	Acetabular Reamer, 48mm
8819046049	Acetabular Reamer, 49mm

PART #	DESCRIPTION
8819046050	Acetabular Reamer, 50mm
8819046051	Acetabular Reamer, 51mm
8819046052	Acetabular Reamer, 52mm
8819046053	Acetabular Reamer, 53mm
8819046054	Acetabular Reamer,54mm
8819046055	Acetabular Reamer, 55mm
8819046056	Acetabular Reamer, 56mm
8819046057	Acetabular Reamer, 57mm
8819046058	Acetabular Reamer, 58mm
8819046059	Acetabular Reamer,59mm
8819046060	Acetabular Reamer,60mm
8819046061	Acetabular Reamer, 61mm
8819046062	Acetabular Reamer, 62mm
8819046063	Acetabular Reamer, 63mm
8819046064	Acetabular Reamer, 64mm
8819046065	Acetabular Reamer, 65mm
8819056000	Reamer Driver, Straight

KOSMO® Femoral Hip System

Restore Activity

b-ONE ORTHO

Reduced Risk of Subsidence

Collared stem design options helps reduce the risk of stem subsidence, under-sizing and fracture[1].

Excellent Intramedullary Fixation

The stem body features tapered geometry on both the medial/lateral sides and anterior/posterior sides.

Optimized Mechanical Stability

Tapered geometry of the proximal body resists torsional stress. Horizontal and vertical grooves provide mechanical stability of the stem[2].

Induces Rapid Osteointegration

Fully HA coated stem induces rapid osteointegration which improves early and long term stability of the stem[3,4].

Reduces the Risk of Undersizing

Provide a more predictable intraoperative sizing experience and reduces the risk of under-sizing commonly seen in DAA procedures.

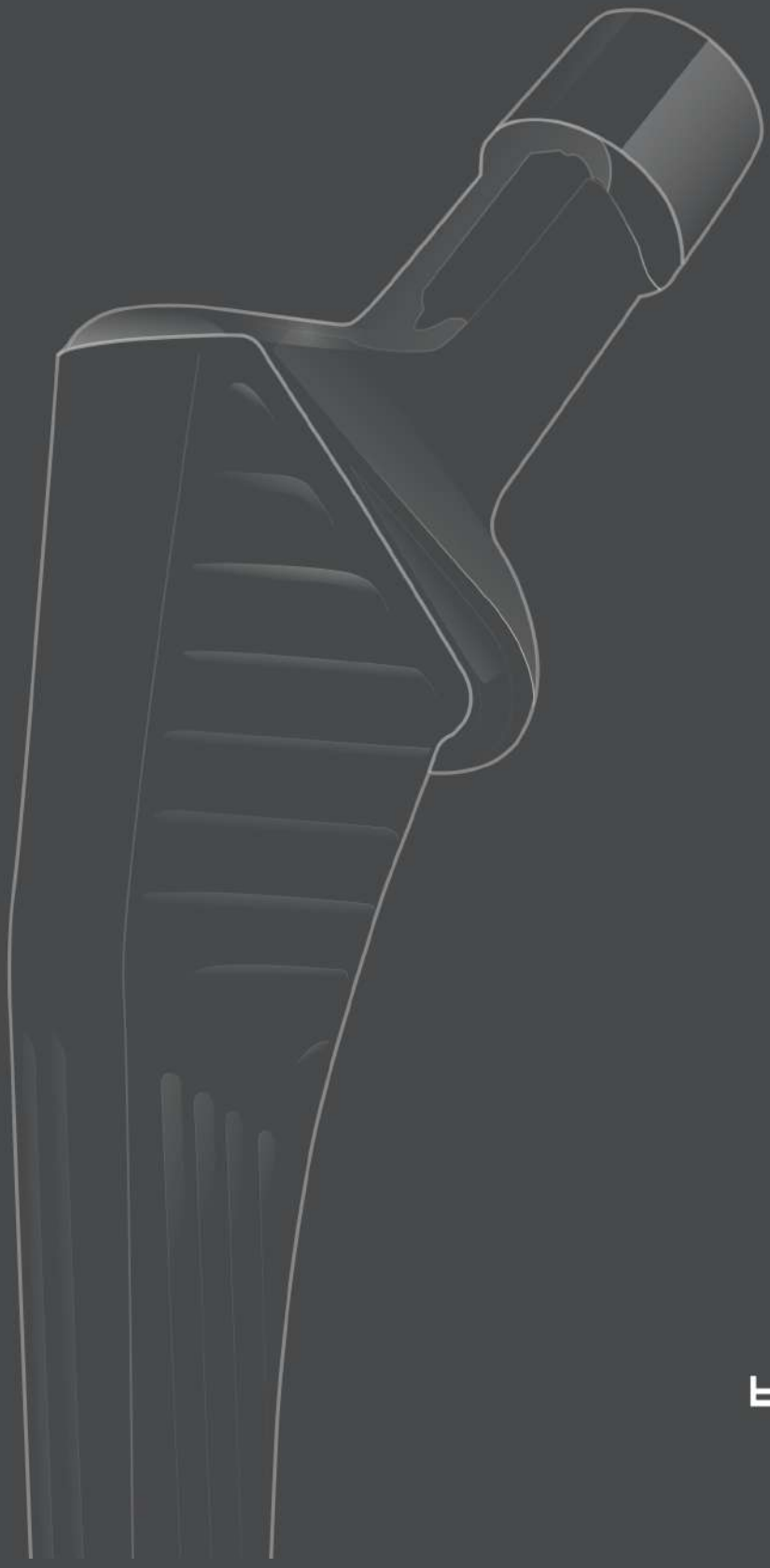
Reference

1. Panichkul P, Bavonratanavech S, Arirachakaran A, Kongtharvonskul J. Comparative outcomes between collared versus collarless and short versus long stem of direct anterior approach total hip arthroplasty: a systematic review and indirect meta-analysis. Eur J Orthop Surg Traumatol. 2019 Dec;29(8):1693-1704. doi: 10.1007/s00590-019-02516-1. Epub 2019 Jul 30. PMID: 31363848.fs
2. Vidalain JP. CORAIL Stem Long-Term Results Based upon the 15-Years ARTRO Group Experience. Fifteen Years of Clinical Experience with Hydroxyapatite Coatings in Joint Arthroplasty. Ed. Springer. 2004:217-224.
3. Frayssinet, Patrick & Hardy, D. & Hanker, J.S. & Giammara, B.L.. (1995). Natural history of bone response to hydroxyapatite-coated hip prostheses implanted in humans. Cells and Materials. 5. 125-138.
4. Vidalain JP. Twenty-year results of the cementless Corail stem. Int Orthop. 2011;35(2):189-194. doi:10.1007/s00264-010-1117-2

b1LIT-00057 Rev.A KOSMO Flyer

KOSMO® Femoral Stem System

Restore Activity



b-one ORTHO

This documentation is intended for health care professionals and the b-ONE ORTHO sales force.
Distribution to any other recipient is prohibited.

Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient. b-ONE ORTHO does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

Contact your b-ONE representative if you have questions about the availability of b-ONE products in your area.

Please refer to the following for compatible surgical techniques:
b1LIT-00001 Tapered Wedge Femoral Stem System Surgical Technique
b1LIT-00047 Direct Anterior Approach Surgical Technique

b1LIT-00051 KOSMO Bone Compacting Femoral Stem Surgical Technique Rev. B

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USA
www.b1.co

SYSTEM OVERVIEW

The KOSMO™ Femoral Hip System is a bone compacting femoral stem that is intended for Cementless and Cemented fixation. This hip stem is evolved from a traditional bone compacting design to optimize fit throughout a wide demographic of patient anatomies with a size-specific medial curvature geometry and fixed neck length design across the stem families.

The versatile stem design incorporates a reduced proximal lateral shoulder, a lateral distal relief, and an overall shorter stem length compared to traditional designs to allow ease of insertion in various surgical approaches.

The KOSMO™ Femoral Hip System is a broach-only system comprised of simple, intuitive instruments designed to optimize operative workflow and efficiency. Instrumentation carriers are designed to seamless stack into SterilContainers™ by Aesculap® or can be processed individually to accommodate hospital protocol or preference.

The KOSMO™ Hip System includes:

- Cementless HA coated stems offered in 6 families of collared and collarless design.
- Each of the collared and collarless options are offered in 3 different neck offsets,
  - Standard and High Offset (135° neck angle)
  - Coxa Vara (125° neck angle)
- Cemented stem offered in collarless design.
  - Standard (135° neck angle)
- 13 femoral stem sizes ranging from size 1 to 10 with half sizes of 6.5, 7.5 and 8.5 for each family.

The KOSMO™ hip stem is designed for use with b-ONE® 12/14 femoral heads and their compatible acetabular components. b-ONE® Femoral Head implants are available as cobalt chrome (CoCr) or BIOLOX® *delta* (ceramic). KOSMO™ Cementless Femoral Stems can be used with either CoCr or Ceramic heads options, while the KOSMO™ Cemented Femoral Stem can be used with Ceramic heads only.

INDICATIONS AND CONTRADICATIONS

INDICATIONS

The b-ONE® Total Hip System is intended for primary or revision total hip replacement in skeletally mature patients with a severely disabled hip joint and/or hip damage due to the following conditions:

Osteoarthritis, traumatic arthritis, avascular necrosis of the femoral head, noninflammatory degenerative joint disease (NIDJD), slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant. Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis and congenital dysplasia; treatments of nonunion, acute traumatic fracture of the femoral head or neck; failed endoprosthesis, femoral osteotomy, or Girdlestone resection; and fracture-dislocation of the hip.

The b-ONE® Total Hip System KOSMO™ HA coated stems are intended for cementless use only.

The b-ONE® Total Hip System KOSMO™ stainless steel stems are intended for cemented use only.

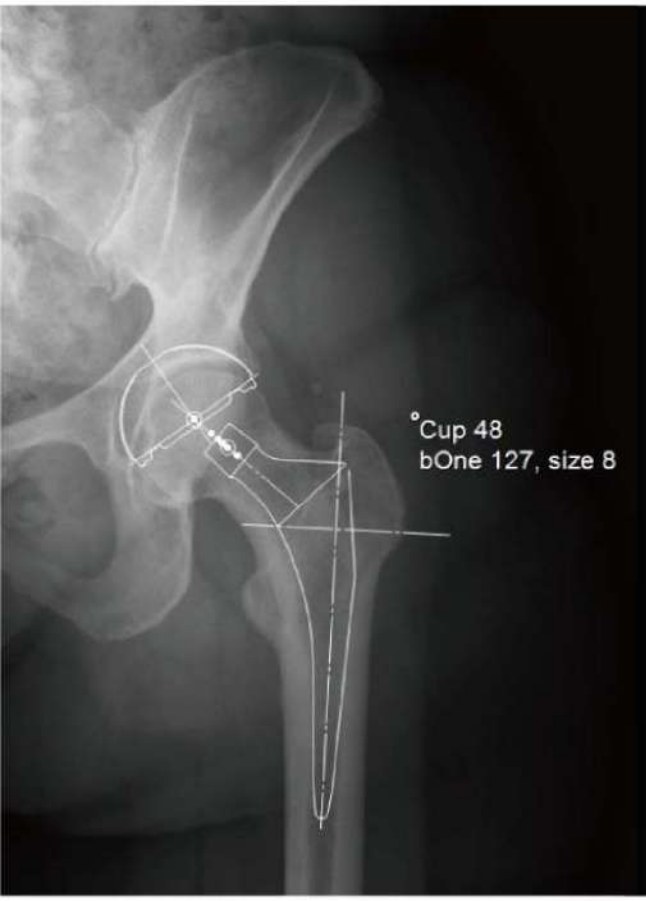
b-ONE® Total Hip System components are not intended for use with other total hip systems.

CONTRAINDICATIONS

- Use of this system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implants materials.
- Severe osteoporosis or osteopenia may prevent adequate fixation and thus preclude the use of these or any other orthopedic implants.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity, or pregnancy, are relative contraindications. The decision to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during body healing and may be at a higher risk of implant failure.
- Using a BIOLOX® *delta* head in combination with a prosthesis stem left in situ in a revision surgery is contraindicated. A BIOLOX® *delta* head must only be used with a brand-new, unused, and undamaged stem taper.

See package insert (b1INS-00004) for warnings, precautions, adverse effects, and other detailed product information.

PRE-OPERATIVE TEMPLATING



Preoperative planning supports the determination of appropriate stem style, size, level of femoral neck

Qualitative and quantitative factors such as patient bone quality, density, and morphology should be considered to select the appropriate implant system for the patient. Preoperative templating should serve only as a guide.

Preoperative templating requires quality radiographs with known and correct magnification. The desired magnification for all imaging should be 20% magnification to correspond with the b-ONE® x-ray templates,

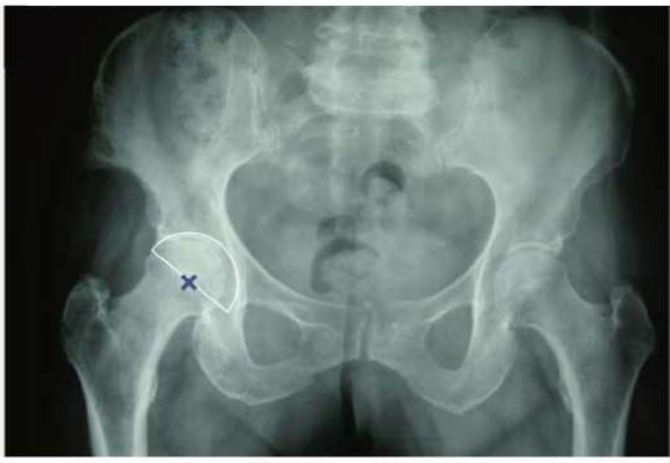
with x-ray magnification calibration used whenever possible. Generally, proper radiographs include a single anteroposterior (A/P) radiograph of the pelvis as well as A/P and lateral radiographs of the affected hip to show the proximal one-third of the femur. A/P views with the limbs in 15 degrees of internal rotation are preferred.

The following templating technique assumes the patient has a normal, symmetrical pelvis

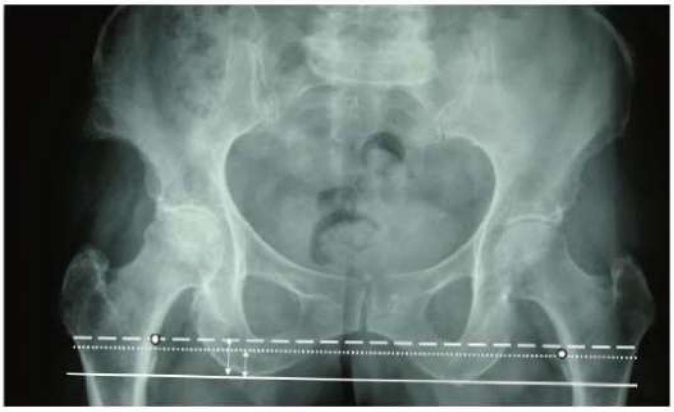
Template Acetabulum

Overlay the acetabular template on the x-ray, ensuring the medial border of the cup approximates the ilioischial line, and the inferior border of the cup is at the inferior aspect of the teardrop. The cup should be positioned with an abduction angle of 40-45 degrees. Mark the center of rotation of the acetabular component.

Check b1LIT-00002 for b-ONE Primary Acetabular Technique.



Assess Leg Length



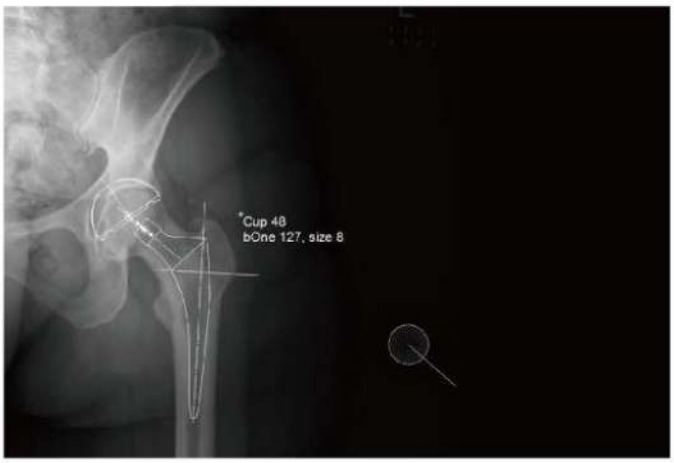
First note any possible hip flexion contracture which could make the leg appear short on x-ray. Use clinical evaluation with radiographic analysis to determine intraoperative leg length management.

Beginning with the A/P of the pelvis, draw a reference along the inferior border of the ischial tuberosities, ensuring the line extends beyond the medial cortices of the femurs. Alternatively, a reference line through the inferior aspect of the teardrop landmarks can be used. Then mark a reference point on each femur, such as the most proximal aspect of each lesser trochanter. Measure the distance between the reference line and each femoral reference point. Often, a line parallel to the reference line is drawn through each femoral reference point to assist with this measurement. The difference between the two measurements will indicate leg length discrepancy.

Template Femur

The KOSMO™ femoral stem has three offset options: the standard offset 135° neck angle, the high offset 135° neck angle and the Coxa Vara offset 125° neck angle. The KOSMO™ template has markings that indicate the center of the femoral head for the range of head options for each femoral neck offset option. Choose the appropriate stem size that achieves mediolateral cortical engagement at the proximal two-thirds of the stem and recreates the desired leg length and offset.

The relative positioning of the head center of rotation markings on the femoral template with respect to the acetabular center of rotation previously marked on the x-ray will predict the change in leg length and offset. For example, a given head center of rotation marking superior to the acetabular center of rotation mark will lengthen the limb, while a head center of rotation inferior to the acetabular center of rotation will shorten the limb. The desired change in leg length is determined by the radiographic leg length inequality and clinical evaluation previously determined. The predicted change in offset is also considered by comparing the relative medial/lateral position of the center of rotation markings of the femoral and acetabular components.



Mark the anticipated neck resection level. This will be used as a reference during neck resection.

FEMORAL NECK RESECTION

The neck resection level affects the final fit and placement of the stem.

The Neck Resection Guide can aid in marking the appropriate neck resection level by placing it on the anterior/posterior aspect of the exposed femur, with the centerline aligned with the axis of the femoral canal. Care should be taken to reference the anatomic landmarks determined during preoperative templating, as well as visual inspection in relation to the lesser trochanter prior to making the cut. After the femoral resection is marked, the resection is made with an oscillating saw.

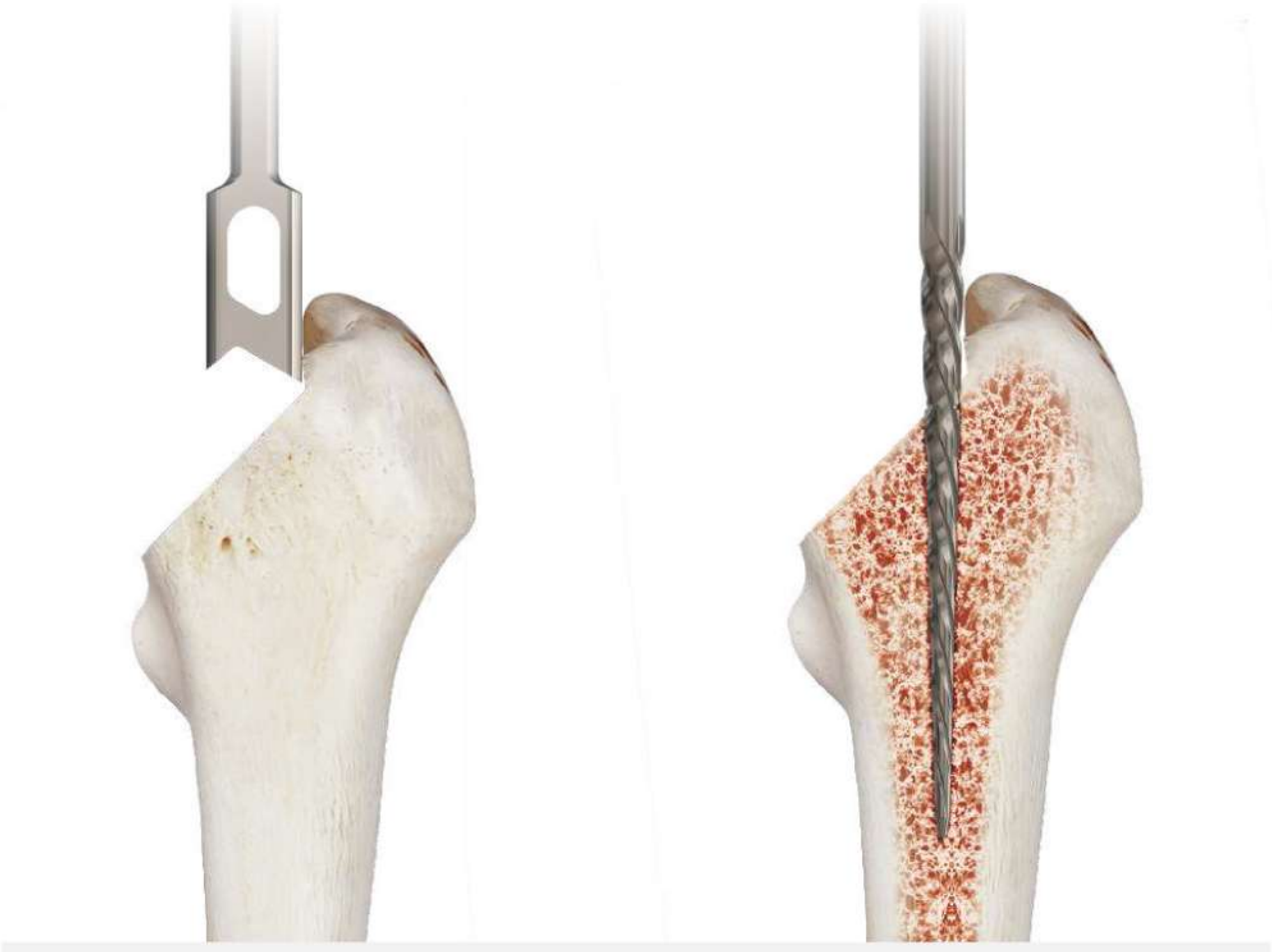
To remove the femoral head, a Modular Corkscrew is available and can be connected to the modular T-Handle or power. After the femoral head is removed, typically the acetabulum is prepared for the acetabular component (see b-ONE® Primary Acetabular Surgical Technique b1LIT-00002).

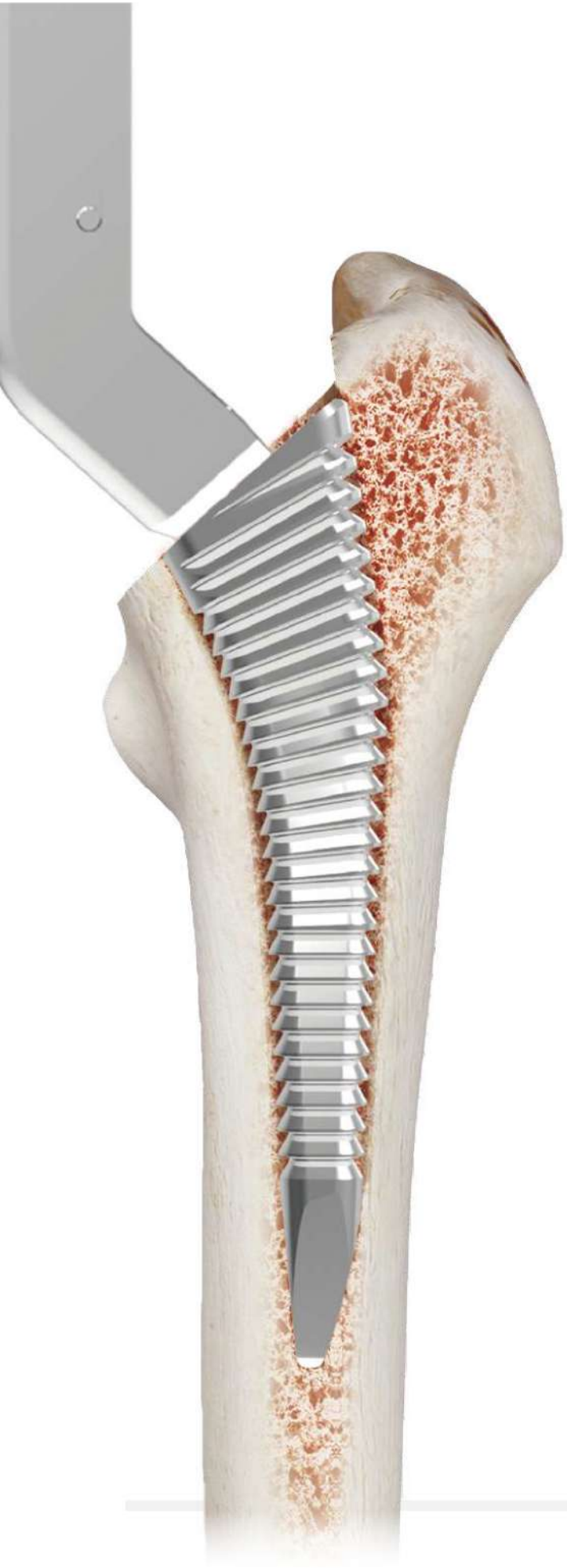
PREPARING THE FEMORAL CANAL

Access the Femoral Canal

Position the leg to provide the best exposure for preparation of the femoral canal. Use the Modular Box Osteotome, connected to the Modular Handle, and Mallet, to initiate entry into the femoral canal. Ensure the orientation of the Box Osteotome reflects the desired anteversion, which is typically 10-15 degrees.

Connect the Starter Reamer to the T-Handle or power and create a pathway into the medullary canal. To minimize the risk of varus placement or under-sizing of the femoral prosthesis, remove adequate bone from the lateral aspect of the canal with the Starter Reamer, Box Osteotome, or a rongeur.





BROACHING

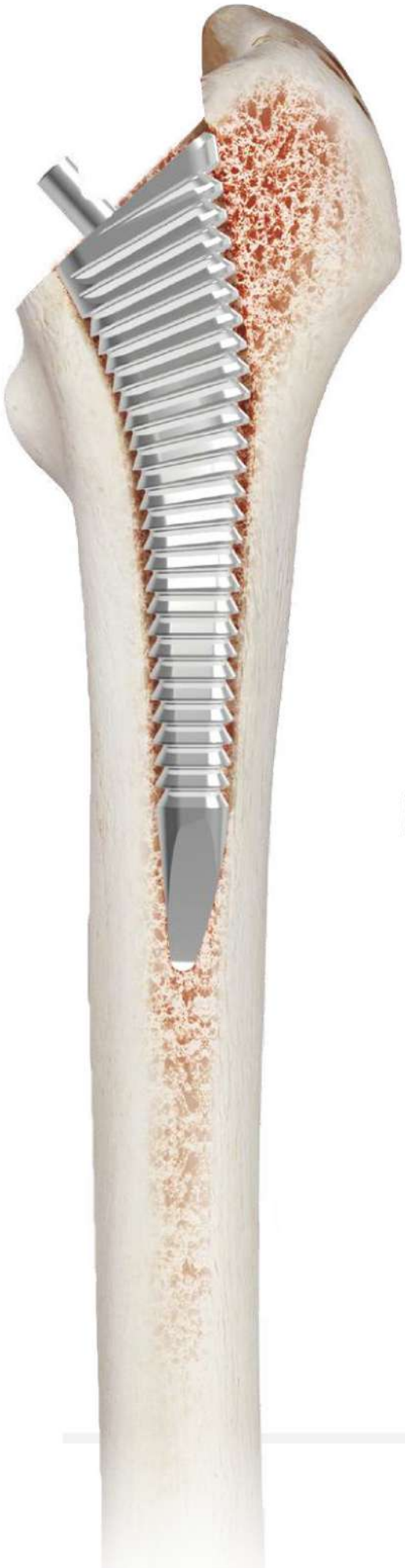
Begin broaching with the smallest available broach. The broach size can be identified on the broach.

The Broach Handle is designed for easy attachment to the broach by extending and closing the lever handle. Be sure to orient the broach in the correct version and pay special attention to the varus/valgus and anterior/posterior placement of the broach. With the Mallet, deliver solid impacts to the strike plate on the Broach Handle to advance the broach.

Sequentially increase the size of the Broach until adequate fill is achieved.

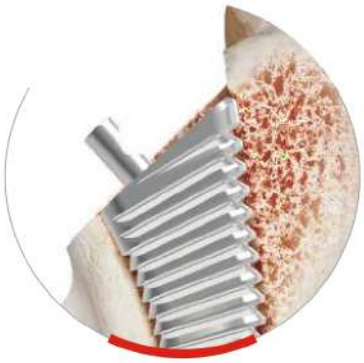
There are markings on the broach to identify its size.

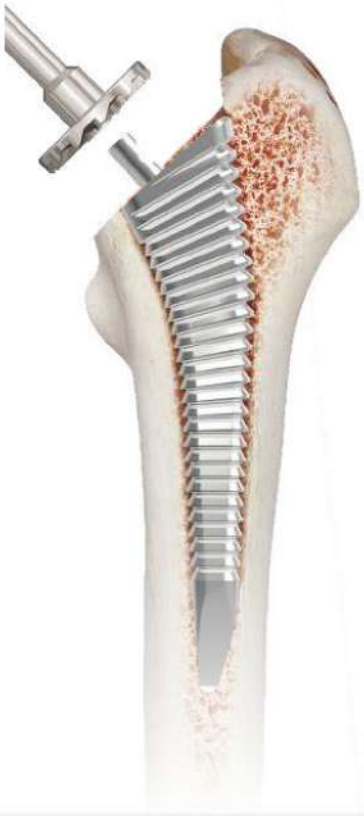
Starter Broach



The final Broach should sit firmly on medial and lateral cortical bone. Increased resistance to advancement and change in pitch during impaction serve as clues to achieving adequate size.

Broach can be advanced so that the medial aspect of broach is in line with resected bone.
Leave the final Broach in the femoral canal and remove the broach handle to proceed with calcar planning (optional) or trialing.





If calcar planning is desired, attach the Calcar Planer to power, ensuring the power setting is set to ream. Advance the Calcar Planer over the broach post, confirming alignment and stability. Power should be initiated prior to contacting bone. Slowly advance the Calcar Planar on continuous power until the stop engages the broach post and adequate bone is removed.

If the Calcar Planer cannot fully engage the broach post, remove the broach and recut the neck resection or consider the next larger broach.

TRIAL REDUCTION

Neck Trial

The KOSMO™ hip stem is designed with fixed neck length design across all stem sizes to provide an optimal patient fit. The neck trial options are:

- Standard Offset (135°)
- High Offset (135°)
- Coxa Vara (125°)

Choose the desired neck trial and assemble onto the broach.

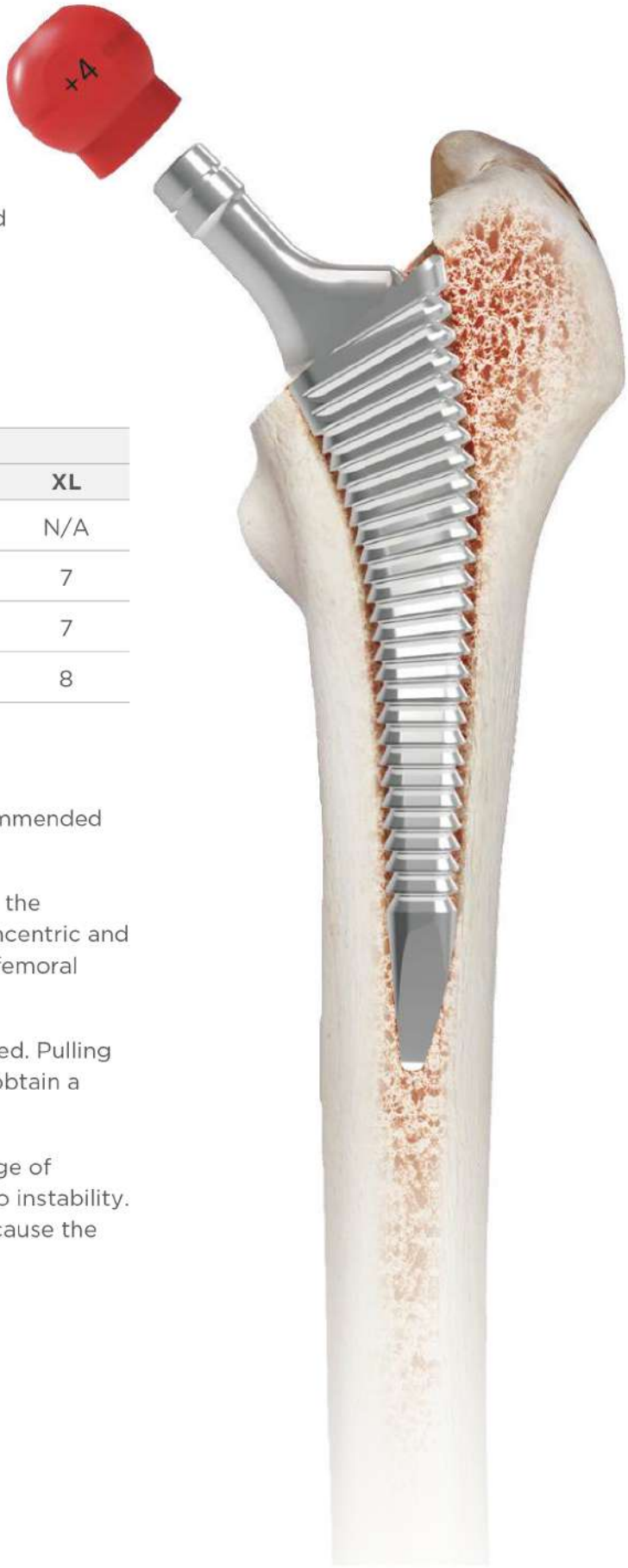
Standard offset
- Length: 39mm
- Neck angle: 135°

High offset
- Length: 43mm
- Neck angle: 135°

Coxa Vara
- Length: 40mm
- Neck angle: 125°

The neck lengths are shown in images above. The neck trials are labeled according to corresponding offset of the stem.

HEAD TRIAL



Insert the appropriate b-ONE® 12/14 taper head trial onto the neck trial. Note the femoral head offsets differ depending on the femoral head size as shown in the chart below:

HEAD DIAMETER	OFFSET			
	S	M	L	XL
22mm;22.2mm	0	2	4	N/A
28mm	-3.5	0	3.5	7
32mm	-4	0	4	7
36mm	-4	0	4	8

When performing the trial reduction, it is recommended to perform the following:

- Inspect the reduction of the femoral head in the acetabular cup. The reduction should be concentric and the appropriate amount of coverage of the femoral head achieved.
- Appropriate tissue tension should be assessed. Pulling the leg in a neutral position is important to obtain a true assessment of tissue tension.
- Assess stability through a full functional range of motion, checking any maneuvers that lead to instability. Note any acetabular osteophytes that may cause the hip to sublux out of the cup.
- Assess the leg lengths.

IMPLANTING THE STEM

Once the final construct is determined, remove all trial components from the body. Ensure that the selected stem size matches the broach and neck trial combination that was determined during the trial procedure.

Curved Inserter

Threaded Insertion

Scallop Impactor

The KOSMO™ Femoral Stem can be placed into the prepared canal by hand and seated with the femoral stem impactor.

To impact the stem, choose either the Scallop Impactor or Straight Stem Impactor and connect to the Modular Axial Handle.

Place the prosthesis in the femoral canal, ensuring the correct version prepared during femoral preparation. Position the assembled impactor/inserter into the impaction slot on the superior lateral aspect of the prosthesis. The Scallop Impactor allows for non-colinear impaction of the stem. Impact the assembled Femoral Impactor/inserter with the Mallet until the stem is fully seated.

NOTE: The Scallop Impactor or Straight Stem Impactor do not lock to the prosthesis. If a threaded insertion tool is preferred, the Stem Remover can be used. Attach the Stem Remover to the Modular Axial Handle and thread the Stem Remover into the threaded hole contained in the impaction slot of the prosthesis. Proceed with implantation as previously described.

FEMORAL HEAD

The KOSMO™ Cementless Femoral Stem is compatible with all b-ONE® 12/14 Taper Femoral Heads. b-ONE® Femoral Head implants are available as cobalt chrome (CoCr) or BIOLOX® *delta* (ceramic).

NOTE: The BIOLOX® *delta* ball head must only be used with a brand-new, unused, and undamaged stem taper. Prior to placement of the BIOLOX® *delta* head on the stem taper, the stem taper must be rinsed thoroughly and dried carefully. The stem taper and the inner taper of the BIOLOX® *delta* head must be inspected carefully, and any foreign bodies must be removed.

The image above shows the BIOLOX® *delta* head with the Primo™ Acetabular System

IMPLANTING THE FEMORAL HEAD

Remove the impactor/inserter. Perform the trial reduction steps with the trial head component on the femoral prosthesis to confirm the final femoral head implant neck length.

Once the final femoral head implant is selected and confirmed, remove the Femoral Head Trial and ensure the taper of the femoral prosthesis is clean and dry.

Assemble the Modular Head Impactor to the Modular Axial Handle. The final head implant is placed on the femoral taper. The BIOLOX® *delta* head must be fixed on the stem taper by using slight axial pressure and twisting at the same time.

Rest the plastic end of the assembled Head Impactor on the pole of the femoral head, ensuring the Head Impactor axis is aligned with the femoral stem neck axis, and with one or several moderate strikes of the Mallet, impact the Head Impactor to seat the femoral head.

Confirm the femoral head is secure on the femoral prosthesis by applying traction on the femoral head implant while confirming stability on the trunnion of the femoral stem.

Inspect the acetabulum for any bone or soft tissue interference and then reduce the hip. The hip biomechanics should be reassessed before closure.

Attention to detail during closure will improve stability and wound healing. Postoperative care is determined by surgical technique, patient factors, and surgeon preference and judgement.

Caution: The BIOLOX® *delta* head must never be struck with a mallet directly. Only the b-ONE® Modular Head Impactor should be used.

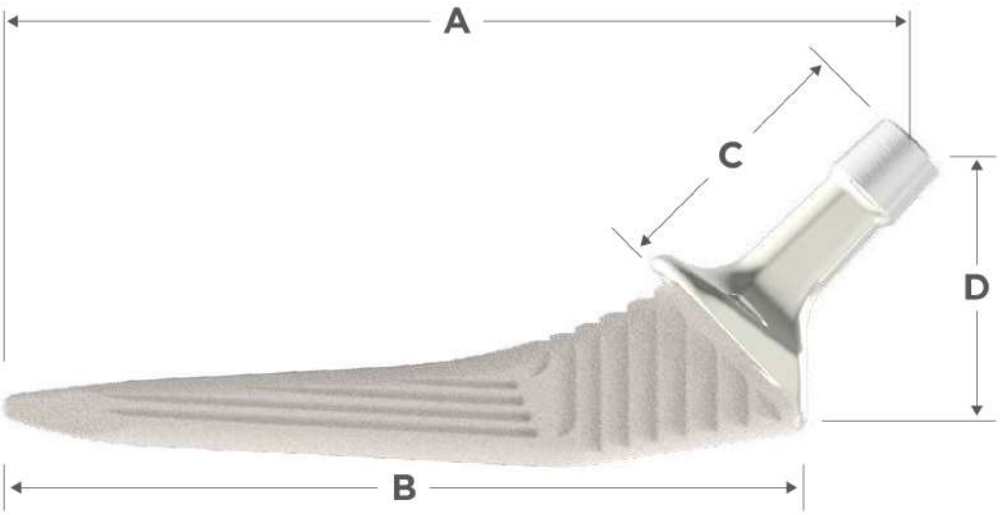
IMPLANT REMOVAL

If the stem must be removed, the impaction slot of the femoral prosthesis contains a threaded hole that mates with the Stem Remover. Clean the impaction slot and threaded hole thoroughly to ensure debris does not prevent engagement of the Stem Remover threads. Attach the Stem Remover to the Modular Axial Handle. Thread the assembled Stem Remover into the threaded hole of the prosthesis, being careful to avoid cross-threading

Proceed to reverse impact the stem remover handle with a mallet to remove the stem.

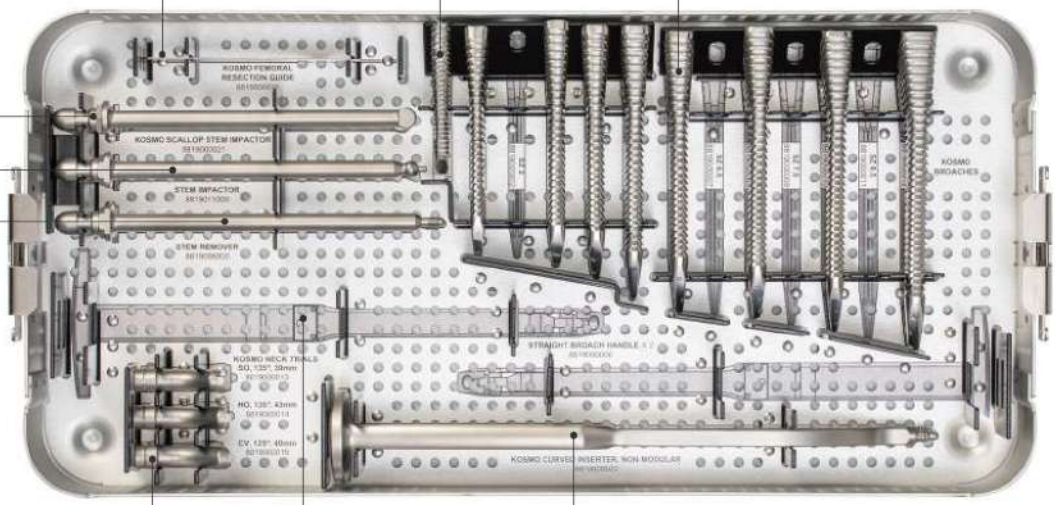
Reverse impact to remove the stem

IMPLANT INFORMATION



Size	Type	A	B	C	D
		Stem Length	Coating Length	Neck Length	Offset
1	Standard Offset 135°	134	120	39	39
2		139	125	39	40
3		144	130	39	40
4		149	135	39	41
5		159	145	39	42
6		164	150	39	42
7		169	155	39	43
8		174	160	39	44
9		184	170	39	45
1	High Offset 135°	129	120	43	46
2		134	125	43	46
3		139	130	43	46
4		144	135	43	47
5		154	145	43	48
6		159	150	43	49
7		164	155	43	50
8		169	160	43	51
9		179	170	43	52
1	Coxa Vera 125°	129	120	40	45
2		134	125	40	46
3		139	130	40	47
4		144	135	40	48
5		154	145	40	48
6		159	150	40	49
7		164	155	40	50
8		169	160	40	51
9		179	170	40	52

INSTRUMENTATION



Femoral Resection Guide
8819000016

Starter Broach
8819092100

BC KOSMO STEM, 1XX°, BROACH (SIZE: 1-9)
8819000001 - 8819000009

Scallop Stem Impactor
8819000021

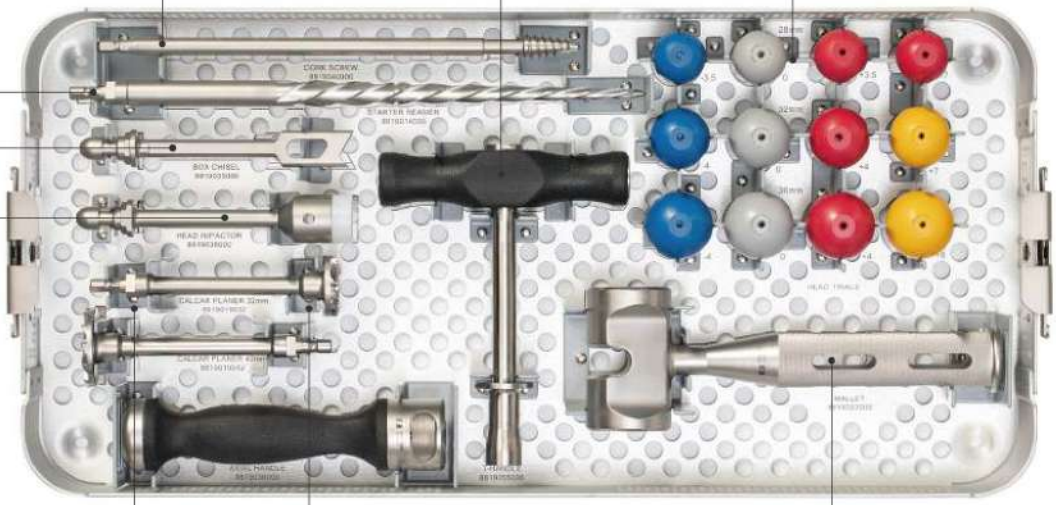
Stem Impactor
8819011000

Stem Remover
8819008000

NECK TRIAL, 1XX° KOSMO,XXMM (ANGLE: 125°,135° NECK LENGTHS: 39, 40, 43MM)
8819000013/14/15

BROACH HANDLE STRAIGHT
8819090000

CURVED INSERTER
8819000022



Cork Screw
8819040000

T-handle
8819055000

Head Trial (Od: 22, 28, 32, 36mm & Offset: -4, -3.5, 0, +2, +3.5, +4, +7, +8)
8819053xxx

Starter Reamer
8819014000

Box Chisel Modular
8819035000

Head Impactor Modular
8819038000

Calcar Planer (Od: 32, 42mm)
88190190xx

Axial Handle Modular
8819036000

Mallet
8819022000

Juveno™

Femoral Hip System

RESTORING MOBILITY

The Juveno™ femoral stem has evolved from a traditional tapered wedge design to one with size-specific medial curvature geometry and an anatomically proportional neck to optimize fit for each patient's native anatomy. At b-ONE™, we are committed to restoring mobility, elevating patients' quality of life, and exceeding expectations.

b-ONE ORTHO

Best-in-class
12/14 taper

Proportional neck lengths &
anatomic neck offsets to
optimize patient fit

Advanced Coating Technology

- Proximally circumferentially coated with a commercially pure titanium porous plasma spray that features an optimal porosity and pore size to encourage osseointegration[1,2,3]
- Enhanced with a bioactive hydroxyapatite layer to accelerate bone remodeling and promote long-term fixation[4,5,6]

Medial curvature designed to
be proportional to patient size

Stem length appropriate for
tissue-sparing approaches

Tapered distal relief to allow
for easy insertion

References:

1. b-ONE TM-00080
2. Kanuja et. Al. "Cementless Femoral Fixation in Total Hip Arthroplasty." The Journal of Bone & Joint Surgery. 93(5):500–509, Mar 2011.
3. Bobyn, J.D. et al. The Optimal Pore Size for the Fixation of Porous-surfaced Metal Implants by the Ingrowth of Bone. Clinical Orthopaedics and Related Research. (150): 263-70, 1980.
4. Chambers et al. "Hydroxyapatite-Coated Tapered Cementless Femoral Components in Total Hip Arthroplasty." The Journal of Arthroplasty. Vol. 22 No. 4 Suppl. 1 2007.
5. Frayssinet, P. et al. (1995) "Natural History of Bone Response to Hydroxyapatite-Coated Hip Prostheses Implanted in Humans," Cells and Materials: Vol. 5 : No. 2 , Article 2.
6. Herrera, A. et. Al. Clinical Study Cementless Hydroxyapatite Coated Hip Prosthesis," Biomed Research International, vol 2015.

Juveno™
Femoral Hip System
RESTORING MOBILITY

SURGICAL TECHNIQUE

b-ONE ORTHO

The Juveno™ Femoral Stem has evolved from a traditional tapered wedge design to one with size-specific medial curvature geometry and an anatomically proportional neck designed to optimize fit for each patient's native anatomy.[1,2,3]

System Overview

The Juveno™ Femoral Stem is a tapered wedge femoral stem that is intended for cementless, press-fit fixation. The Juveno™ femoral stem has evolved from a traditional tapered wedge design to one with size-specific medial curvature geometry and an anatomically proportional neck designed to allow the surgeon to optimize fit for each patient's native anatomy. [1,2,3]

The proximal geometry is circumferentially coated with a porous plasma spray technology that features an optimal porosity and pore size to encourage osseointegration.[4,5,6] The Juveno™ femoral stem is also available with a bioactive hydroxyapatite layer to accelerate bone remodeling and promote long-term fixation.[7,8,9]

The versatile stem design incorporates a reduced proximal lateral shoulder, a lateral distal relief, and an overall shorter stem length compared to traditional designs to allow for ease of insertion when performing various surgical approaches.

The Juveno™ Femoral Stem is prepared for using a broach-only system, comprised of simple, intuitive instruments designed to optimize operative workflow and efficiency. Instrumentation carriers are designed to seamlessly stack into rigid containers or can be processed individually to accommodate hospital protocol or preference.

THE JUVENO™ HIP SYSTEM INCLUDES:

- 11 femoral stem sizes ranging from size 1 to 11
- Standard offset (132°) and High offset (127°) neck options for each stem size.

The Juveno™ femoral stem is designed for use with b-ONE™ 12/14 Femoral Heads and their compatible acetabular components. b-ONE™ Femoral Head implants are available as cobalt chrome (CoCr) or BIOLOX® *delta* (ceramic).

REFERENCES:

1. Issa, K et al. Radiographic Fit and Fill Analysis of a New Second-Generation Proximally Coated Cementless Stem Compared to its Predicate Design. Journal of Arthroplasty (2013). http://dx.doi.org/10.1016/j.arth.2013.04.029
2. Wuestemann T, Bastian A, Parvizi J, Nessler J, Kolisek F. A novel tapered hip stem design optimized for femoral fit in a wide array of bone types. 2011 EFFORT.
3. Faizan et. al. "Development and Verification of a Cementless Novel Tapered Wedge Stem for Total Hip Arthroplasty." Journal of Arthroplasty 30 (2015) 235–240.
4. b-ONE TM-00080
5. Kanuja et. Al. "Cementless Femoral Fixation in Total Hip Arthroplasty." The Journal of Bone & Joint Surgery. 93(5):500-509, Mar 2011.
6. Bobyn, J.D. et al. The Optimal Pore Size for the Fixation of Porous-surfaced Metal Implants by the Ingrowth of Bone. Clinical Orthopaedics and Related Research. (150): 263-70, 1980.
7. Chambers et al. "Hydroxyapatite-Coated Tapered Cementless Femoral Components in Total Hip Arthroplasty." The Journal of Arthroplasty. Vol. 22 No. 4 Suppl. 1 2007.
8. Frayssinet, P. et al. (1995) "Natural History of Bone Response to Hydroxyapatite-Coated Hip Prostheses Implanted in Humans," Cells and Materials: Vol. 5 : No. 2 , Article 2.
9. Herrera, A. et. Al. (2015). Clinical Study: Cementless Hydroxyapatite Coated Hip Prostheses. BioMed Research International. 2015. 13 pages. 10.1155/2015/386461.

Indications & Contraindications

INDICATIONS

The b-ONE™ Total Hip System is intended for primary or revision total hip replacement in skeletally mature patients with a severely disabled hip joint and/or hip damage due to the following conditions:

Osteoarthritis, traumatic arthritis, avascular necrosis of the femoral head, noninflammatory degenerative joint disease (NIDJD), slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant. Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis and congenital dysplasia; treatments of nonunion, acute traumatic fracture of the femoral head or neck; failed endoprosthesis, femoral osteotomy, or Girdlestone resection; and fracture-dislocation of the hip.

The b-ONE™ Total Hip System is intended for cementless use only.
b-ONE™ Total Hip System components are not intended for use with other total hip systems.

CONTRAINDICATIONS

- Active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implants materials.
- Severe osteoporosis or osteopenia may prevent adequate fixation and thus preclude the use of these or any other orthopedic implants.
- Conditions that may place excessive stresses on bone and implants, such as severe obesity or pregnancy are relative contraindications. The decision to use these devices in such conditions must be made by a physician taking into account the risks versus the benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during body healing and may be at a higher risk of implant failure.
- Using a BIOLOX®delta head in combination with a prosthesis stem left in situ in a revision surgery is contraindicated. A BIOLOX®delta head must only be used with a brand-new, unused, and undamaged stem taper.
- Any condition not described in the Indications for Use.

Refer to the package insert for important product information, including, but not limited to, indications, contraindications, warnings, precautions, and adverse effects.

Surgical Technique

STEP ONE | PREOPERATIVE PLANNING

Templating

Preoperative planning supports the determination of appropriate stem style, size, level of femoral neck resection, and proper head and stem offset combination. Qualitative and quantitative factors such as patient bone quality, density, and morphology should be considered to select the appropriate implant system for the patient. Preoperative templating should serve only as a guide.

Preoperative templating requires quality radiographs with known and correct magnification. The desired magnification for all imaging should be 20% magnification to correspond with the b-ONE™ x-ray templates, with x-ray magnification calibration used whenever possible. Generally, proper radiographs include a single anteroposterior (A/P) radiograph of the pelvis as well as A/P and lateral radiographs of the affected hip to show the proximal one-third of the femur. A/P views with the limbs in 15 degrees of internal rotation are preferred.

The following templating technique assumes the patient has a normal, symmetrical pelvis.

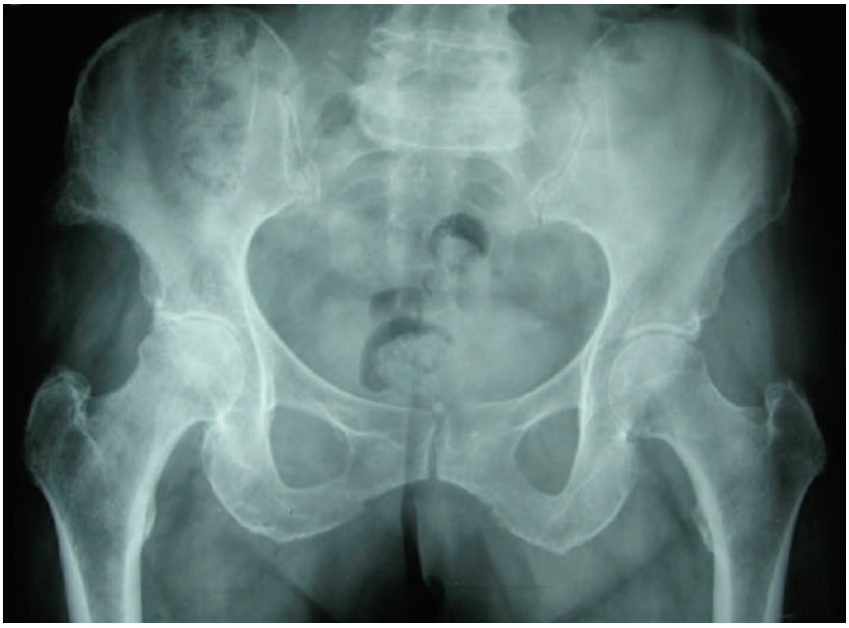


FIGURE 1: A/P RADIOGRAPH OF THE PELVIS

Surgical Technique

STEP ONE | PREOPERATIVE PLANNING

Assess Preoperative Leg Length

First note any possible hip flexion contracture which could make the leg appear short on x-ray. Use clinical evaluation with radiographic analysis to determine intraoperative leg length management.

Beginning with the A/P of the pelvis, draw a reference along the inferior border of the ischial tuberosities, ensuring the line extends beyond the medial cortices of the femurs. Alternatively, a reference line through the inferior aspect of the teardrop landmarks can be used. Then mark a reference point on each femur, such as the most proximal aspect of each lesser trochanter. Measure the distance between the reference line and each femoral reference point. The difference between the two measurements will indicate leg length discrepancy. Often, a line parallel to the reference line is drawn through each femoral reference point to assist with this measurement. This is shown below in Figure 2.

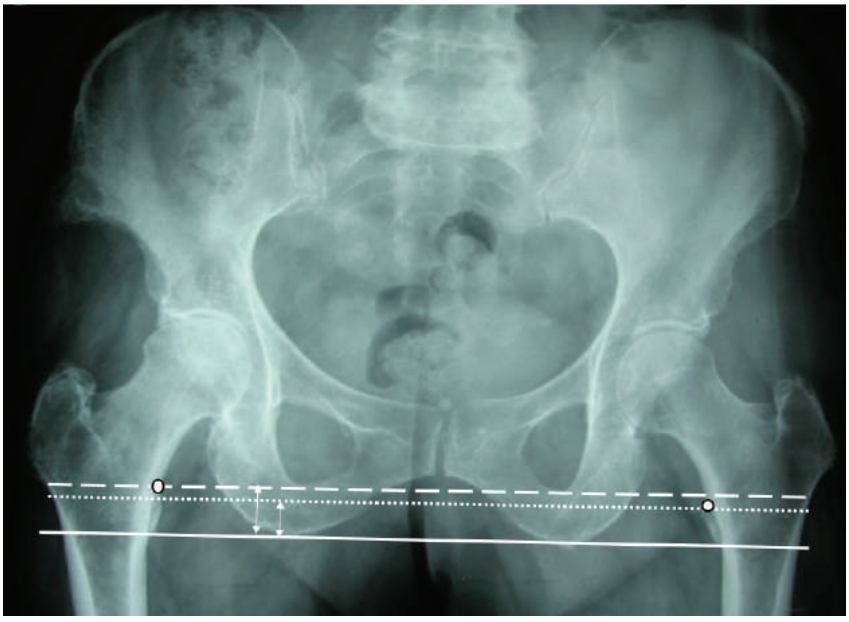


FIGURE 2: ASSESSING PREOPERATIVE LEG LENGTH

The solid line is the reference line connecting the inferior aspect of the ischial tuberosities.
The dashed line is parallel with the reference line and indicates the superior aspect of the right femoral lesser trochanter.
The dotted line is parallel with the reference line and indicates the superior aspect of the left femoral lesser trochanter.
The difference between the two measurements will indicate a leg length discrepancy. In this example, the right hip is 4mm shorter than the left hip.

Surgical Technique

STEP ONE | PREOPERATIVE PLANNING

Template Acetabulum

Overlay the acetabular template on the x-ray, ensuring that the medial border of the cup lies adjacent to the ilioischial line, and the inferior border of the cup is at the inferior aspect of the teardrop. The cup should be positioned with an abduction angle of 30-50 degrees. Mark the center of rotation (COR) of the acetabular component, as indicated by the "X" in **Figure 3**.

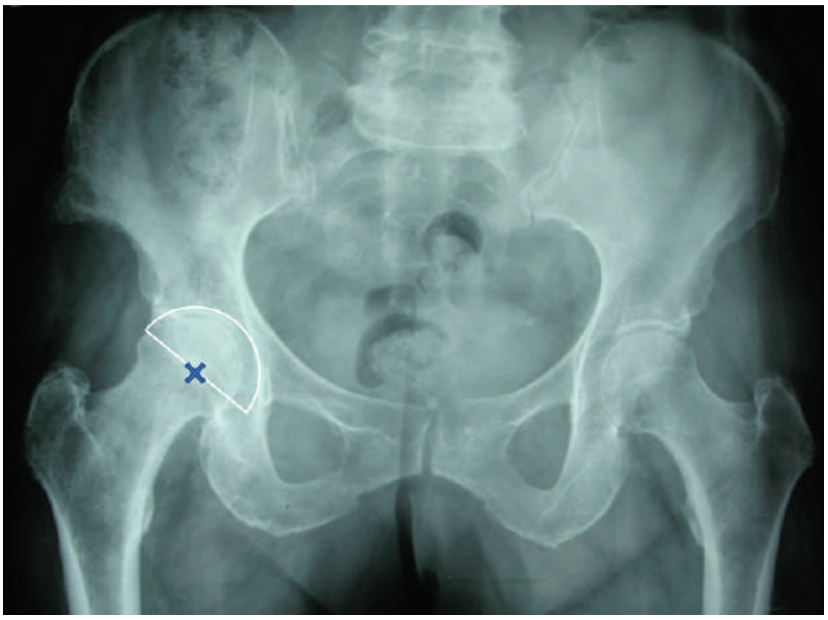


FIGURE 3: ACETABULAR TEMPLATE OVERLAY PLACED OVER X-RAY

Surgical Technique

STEP ONE | PREOPERATIVE PLANNING

Template Femur

The Juveno™ femoral stem has two offset options: the standard offset 132° neck angle and the high offset 127° neck angle. The Juveno™ template has markings that indicate the center of the femoral head for the range of head options for each femoral neck offset option. Choose the appropriate stem size that achieves mediolateral cortical engagement at the proximal two-thirds of the stem and recreates the desired leg length and offset.

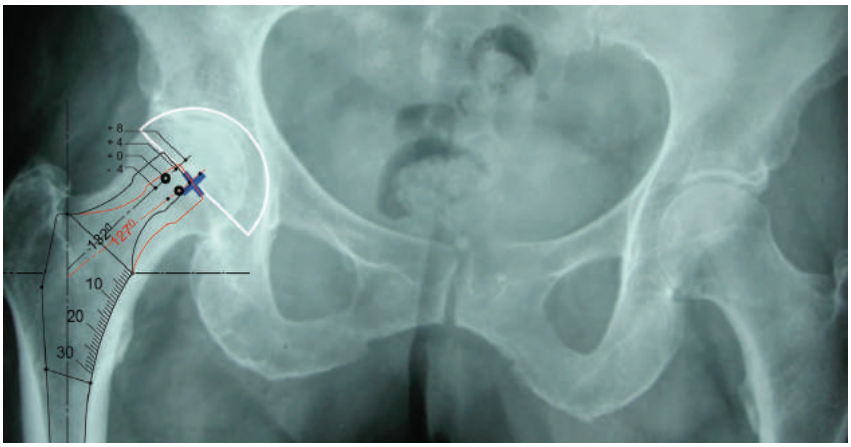


FIGURE 4: JUVENO™ FEMORAL STEM TEMPLATE

The change in leg length and offset will be predicted by the relative position of the femoral head center of rotation (COR), indicated on the Juveno™ femoral template, with respect to the acetabular COR previously marked (X) on the x-ray. For example, as shown in Figure 4, the +8mm femoral head COR for either stem offset lies superior to the acetabular COR (X), and thus will lengthen the limb. Selecting a femoral head COR that lies inferior to the acetabular COR (X) will predict a shortening of the limb. The change in offset is also predicted by comparing the relative medial/lateral position of the head COR and acetabular COR.

The desired change in leg length and offset is determined by the radiographic leg length inequality and clinical evaluation previously determined.

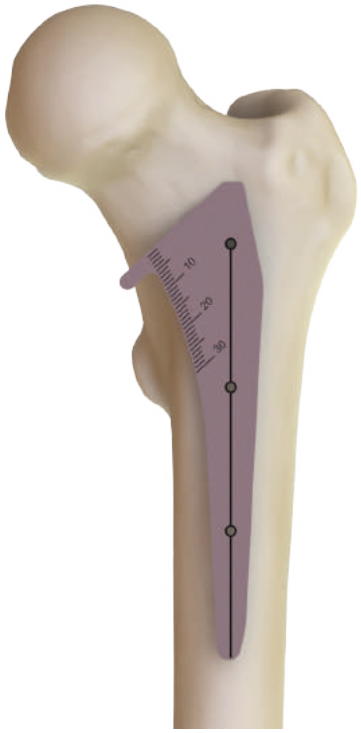
Once the stem size and offset that most closely meets this goal is determined, mark the anticipated neck resection level. This will be used as a reference during intra-operative neck resection.

Surgical Technique

STEP TWO | FEMORAL RESECTION

Resect the Femoral Neck

The neck resection level affects the final fit and placement of the stem. The Neck Resection Guide can aid in marking the appropriate neck resection level by placing it on the anterior/posterior aspect of the exposed femur, with the centerline aligned with the axis of the femoral canal. Care should be taken to reference the anatomic landmarks determined during preoperative templating, as well as visual inspection in relation to the lesser trochanter prior to making the cut. The neck resection will typically lie approximately 10mm above the lesser trochanter. After the femoral resection is marked, the resection is made with an oscillating saw. To remove the femoral head, a Corkscrew is available and can be connected to the modular T-Handle or power.



Typically after the femoral head is removed, the acetabulum Is prepared for the acetabular component before proceeding to the femoral preparation (see b-ONE Primary Acetabular System Surgical Technique, b1LIT-00002).

INSTRUMENTS

8819003000
Femoral Resection Guide

8819055000
T-Handle

8819040000
Corkscrew

Surgical Technique

STEP THREE | FEMORAL PREPARATION

Access the Femoral Canal

Position the leg to provide the best exposure for the preparation of the femoral canal. Connect the Modular Box Chisel to the Axial Handle, and impact with the Mallet to initiate entry into the femoral canal. Ensure the orientation of the Box Chisel reflects the desired anteversion which is typically 10-15 degrees.

Connect the Starter Reamer to the T-Handle, or power, and create a pathway into the medullary canal.

NOTE: To minimize the risk of varus stem placement or undersizing of the femoral prosthesis, remove adequate bone from the lateral aspect of the canal with the Starter Reamer, Box Chisel, or a rongeur.

INSTRUMENTS

8819035000
Modular Box Chisel

8819036000
Axial Handle

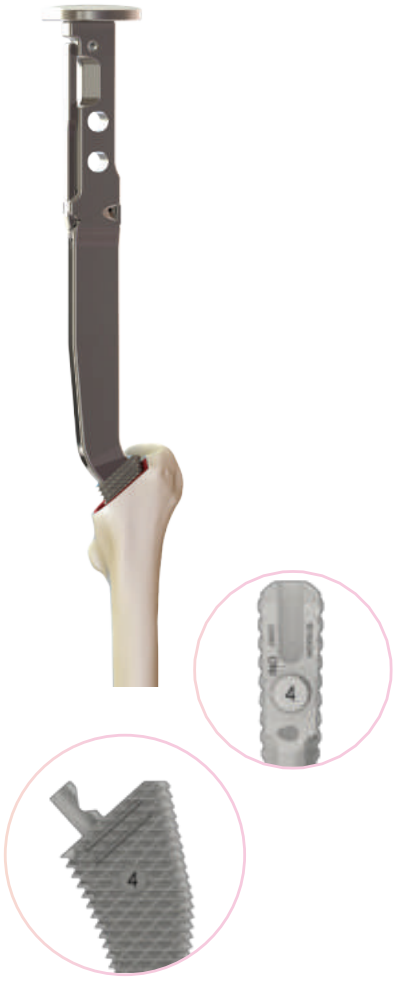
8819014000
Starter Reamer

8819055000
T-Handle

Surgical Technique

STEP THREE | FEMORAL PREPARATION

Broaching



Begin broaching with the smallest available Broach. The Broach size can be identified on the Broach.

The Broach Handle is designed for easy attachment to the Broach by extending and closing the lever handle. Be sure to orient the Broach in the correct version and pay special attention to the varus/valgus and anterior/posterior placement of the Broach. With the Mallet, deliver solid impacts to the strike plate on the Broach Handle to advance the Broach.

Sequentially increase the size of the Broach until adequate fill is achieved. The final Broach should sit firmly on medial and lateral cortical bone. Increased resistance to advancement and change in pitch during impaction serve as clues to achieving adequate size. In general, if the Broach sinks below the level of resection, advance to the next size unless the resection is deemed higher than desired.

Two grooves on the anterior and posterior aspect of the Broach act as reference marks to aid in visualizing the Broach advancing into the femur. The proximal groove approximates the level of advancement for standard bone, while the distal groove serves as a reference for poorer bone quality.

Leave the final Broach in the femoral canal and remove the Broach Handle to proceed with calcar planing (optional) or trialing.

INSTRUMENTS

88190420XX
Juveno Broaches

8819090000
Straight Broach Handle
OR

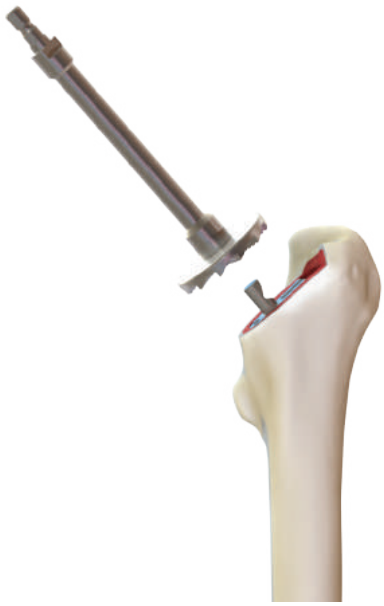
8819077000
Straight Broach Handle,
Trigger Style

8819022000
Mallet

Surgical Technique

STEP THREE | FEMORAL PREPARATION

Calcar Planing *(optional)*



Calcar planing may be performed but is not required as this is a collarless prosthesis. If calcar planning is desired, attach the Calcar Planer to power, ensuring the power setting is set to ream. Advance the Calcar Planer over the broach post, confirming alignment and stability. Power should be initiated prior to contacting bone. Slowly advance the Calcar Planer on continuous power until the stop engages the Broach post and adequate bone is removed.

If the Calcar Planer cannot fully engage the Broach post, remove the Broach and consider either a recut of the neck resection or proceeding to the next size Broach. Failure to follow these instructions could result in damage to the femur.

INSTRUMENTS

8819019032
Calcar Planer, 32mm

8819019042
Calcar Planer, 42mm

Surgical Technique

STEP FOUR | NECK TRIAL

Neck Trial

The Juveno™ femoral stem is designed with an anatomic proportional neck to optimize patient fit. The anatomic offset options are:

- Standard Offset (132° - silver trials)
- High Offset (127° - gold trials)

The neck length increases proportionally with femoral size, shown in **Chart A**. The neck trials are labeled according to corresponding femoral size.

Choose the Neck Trial with desired offset and correct size to match the final broach size, and assemble onto the broach.

STEM SIZE	NECK LENGTH
1	27mm
2, 3	30mm
4, 5, 6	35mm
7, 8, 9	37mm
10, 11	40mm

Chart A: Juveno™ Femoral Stem Size and Corresponding Neck Length

INSTRUMENTS

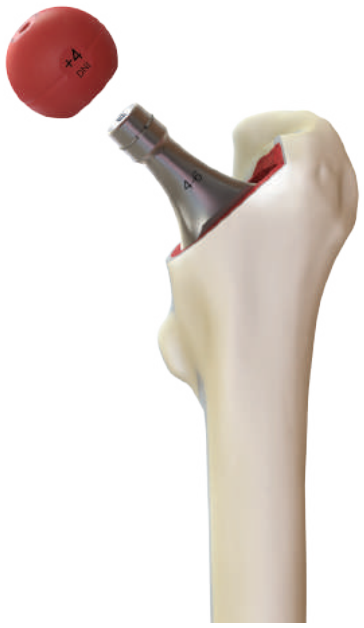
88190432XX
Standard Offset (132°)
Neck Trials

88190437XX
High Offset (127°)
Neck Trials

Surgical Technique

STEP FOUR | NECK TRIAL

Head Trial



Insert the appropriate b-ONE 12/14 Taper Head Trial onto the Neck Trial. Note the femoral head offsets differ depending on the femoral head size as shown in **Chart B**.

When performing the trial reduction, it is recommended to perform the following:

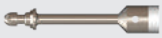
1. Inspect the reduction of the femoral head in the acetabular cup. The reduction should be concentric and the appropriate amount of coverage of the femoral head achieved.
2. Appropriate tissue tension should be assessed. Pulling the leg in a neutral position is important to obtain a true assessment of tissue tension.
3. Assess stability through a full functional range of motion, checking any maneuvers that lead to instability. Note any acetabular osteophytes that may cause the hip to sublux out of the cup.
4. Assess leg length.

HEAD DIAMETER (MM)	HEAD OFFSET (MM)
28	-3.5, 0, +3.5, +7*
32	-4, 0, +4, +7
36	-4, 0, +4, +8

Chart B. Femoral Head Offset Options. *28mm x +7mm not available in BIOLOX® *delta* ceramic.

INSTRUMENTS

8819053XXX
Head Trials



8819038000
Modular Head Impactor

8819036000
Axial Handle

Surgical Technique

STEP FIVE | IMPLANTATION

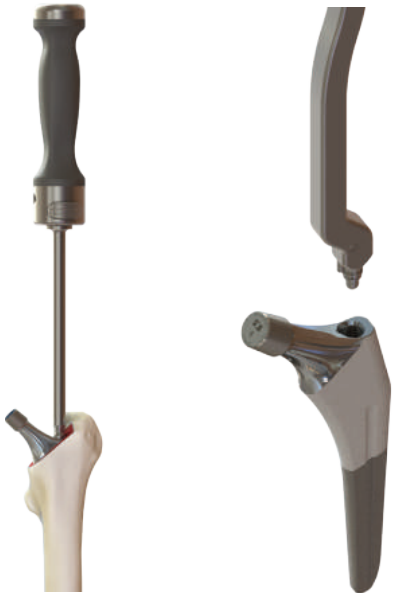
Once the final construct is determined, remove all trial components from the body. Ensure that the selected stem size matches the Broach and Neck Trial combination that was determined during the trial procedure.

The Juveno™ femoral stem can be placed into the prepared canal by hand and seated with the femoral stem impactor. Alternatively, if a threaded insertion tool is preferred, the Stem Remover can be assembled to the Axial Handle and used as a threaded inserter.

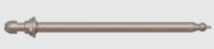
Assemble the Stem Impactor to the Axial Handle. The Stem Impactor is a straight instrument; should an offset impactor be desired, the Offset Stem Inserter can be assembled to the Axial Handle and used as an offset stem impactor.

Note: The Offset Stem Inserter has a version control tip that mates with an indexing feature found on the prosthesis' impaction slot for sizes 3-11 only. For sizes 1-2, the Stem Impactor (straight) must be used as these sizes do not contain the indexing feature on the impaction slot.

Position the assembled impactor/inserter into the impaction slot on the superior lateral aspect of the prosthesis. Impact the impactor/inserter with the Mallet until the stem is fully seated.



INSTRUMENTS



8819011000
Stem Impactor

8819010000
Offset Stem Inserter

8819008000
Stem Remover

8819022000
Mallet

8819036000
Axial Handle

Surgical Technique

STEP FIVE | IMPLANTATION

Femoral Head

Remove the Stem Impactor. Perform the trial reduction steps with the Head Trial component on the femoral prosthesis to confirm the final femoral head implant.

The Juveno™ Femoral Stem is compatible with all b-ONE™ 12/14 Taper Femoral Heads. b-ONE Femoral Head implants are available as cobalt chrome (CoCr) or BIOLOX® *delta* (ceramic).

Once the final femoral head implant is selected and confirmed, remove the Femoral Head Trial. Make sure the taper of the femoral prosthesis is clean and dry.

Note: The BIOLOX® *delta* head must only be used with a brand-new, unused, and undamaged stem taper. Prior to placement of the BIOLOX® *delta* head on the stem taper, the stem taper must be rinsed thoroughly and dried carefully. The stem taper and the inner taper of the BIOLOX® *delta* head must be inspected carefully, and any foreign bodies must be removed.

Assemble the Modular Head Impactor to the Axial Handle. The final head implant is placed on the femoral taper. The BIOLOX®*delta* head must be fixed on the stem taper by using slight axial pressure and twisting at the same time.

Rest the plastic end of the assembled Head Impactor against the femoral head, ensuring the Head Impactor axis is aligned with the femoral stem neck axis. Firmly impact the assembled Head Impactor with the Mallet to seat the femoral head.

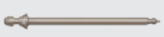
CAUTION: The BIOLOX®*delta* head must never be struck with a mallet directly. Only the plastic end of the b-ONE Modular Head Impactor should be used.

Confirm the femoral head is secure on the femoral prosthesis by applying traction on the femoral head while confirming stability on the trunnion.

Inspect the acetabulum for any bone or soft tissue interference and then reduce the hip. The hip biomechanics should be reassessed before closure.

Closure is performed. Attention to detail during closure will improve stability and wound healing. Postoperative care is determined by surgical technique, patient factors, and surgeon preference and judgment.

INSTRUMENTS

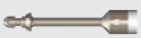


8819011000
Stem Impactor

8819010000
Stem Inserter, Offset

8819008000
Stem Remover

8819022000
Mallet



8819038000
Modular Head Impactor

8819036000
Axial Handle

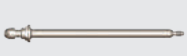
Surgical Technique

STEM REMOVAL

Stem Removal

If the stem must be removed, the impaction slot of the femoral prosthesis contains a threaded hole that mates with the Stem Remover. Clean the impaction slot and threaded hole thoroughly to ensure debris does not prevent engagement of the Stem Remover threads. Attach the Stem Remover to the Axial Handle. Thread the assembled Stem Remover into the threaded hole of the prosthesis, being careful to avoid cross-threading. Proceed to reverse impact the stem remover handle with a mallet to remove the stem.

INSTRUMENTS

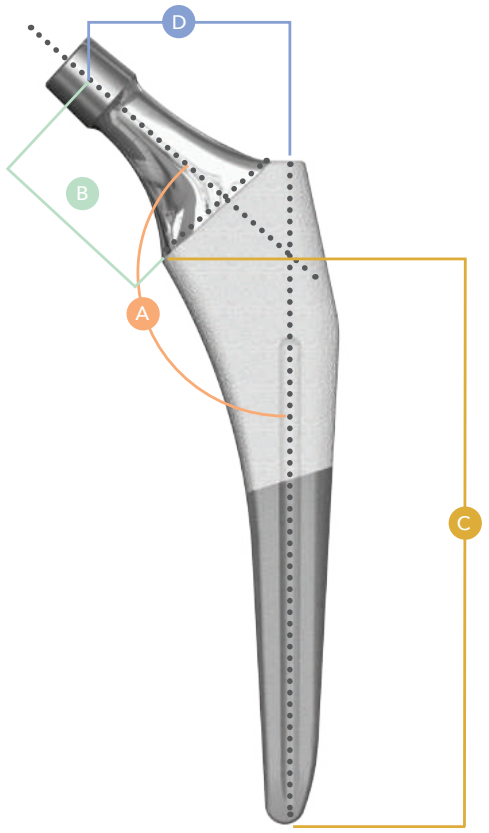


8819008000
Stem Remover

8819036000
Axial Handle

8819022000
Mallet

SIZING CHART | IMPLANTS



	A	B	C	D
SIZE	NECK ANGLE	NECK LENGTH	STEM LENGTH	OFFSET
1	132°	27mm	96mm	29mm
2		30mm	99mm	33mm
3		30mm	102mm	35mm
4		35mm	105mm	38mm
5		35mm	108mm	40mm
6		35mm	111mm	41mm
7		37mm	114mm	46mm
8		37mm	117mm	47mm
9		37mm	120mm	49mm
10		40mm	123mm	51mm
11		40mm	126mm	53mm

	A	B	C	D
SIZE	NECK ANGLE	NECK LENGTH	STEM LENGTH	OFFSET
1	127°	27mm	96mm	34mm
2		30mm	99mm	37mm
3		30mm	102mm	38mm
4		35mm	105mm	42mm
5		35mm	108mm	44mm
6		35mm	111mm	45mm
7		37mm	114mm	50mm
8		37mm	117mm	51mm
9		37mm	120mm	53mm
10		40mm	123mm	57mm
11		40mm	126mm	58mm

ORDERING | IMPLANTS

881000XXXX
Juveno™ Cementless
Femoral Stem with HA Coating

JUVENO™ Cementless Femoral Stem, Porous Plasma Spray + HA Coating		
SIZE	STANDARD OFFSET (132°) IMPLANT PART #	HIGH OFFSET (127°) IMPLANT PART #
1	8810003201	8810002701
2	8810003202	8810002702
3	8810003203	8810002703
4	8810003204	8810002704
5	8810003205	8810002705
6	8810003206	8810002706
7	8810003207	8810002707
8	8810003208	8810002708
9	8810003209	8810002709
10	8810003210	8810002710
11	8810003211	8810002711

ORDERING | IMPLANTS CONTINUED

88110XXXXX
CoCr Femoral Head

39717XXXXX
BIOLOX® *delta* Ceramic
Femoral Head

b-ONE™ 12/14 Taper Femoral Heads			
DIAME-TER	NECK LENGTH	BIOLOX®*delta* CERAMIC IMPLANT PART #	CoCr IMPLANT PART #
28mm	-3.5mm	397175445	8811028035
	+0mm	397175455	8811028000
	+3.5mm	397175465	8811028350
	+7mm	N/A	881102870S
32mm	-4mm	397175665	8811032040
	+0mm	397175675	8811032000
	+4mm	397175685	8811032400
	+7mm	3971796750	8811032700
36mm	-4mm	397179275	8811036040
	+0mm	397179285	8811036000
	+4mm	397179295	8811036400
	+8mm	397164795	8811036800

ORDERING | TRAYS

PART #	DESCRIPTION
8819900100	**Juveno™ Hip System Sterilization Case** *includes 8819900100, 8819900101, & 8819900102*
8819900000	**Sterilization Case, Lid**
8819900101	Juveno™ Hip System **Femoral General Tray**
8819014000	Starter Reamer
8819019032	Calcar Planer 32mm
8819019042	Calcar Planer 42mm
8819022000	Mallet
8819035000	Modular Box Chisel
8819036000	Axial Handle
8819038000	Modular Head Impactor
8819040000	Corkscrew
8819055000	T-Handle
8819053281	Head Trial - b-ONE™ 12/14 Taper *28mm Diameter, -3,5mm Neck Length*
8819053282	Head Trial - b-ONE™ 12/14 Taper *28mm Diameter, 0mm Neck Length*
8819053283	Head Trial - b-ONE™ 12/14 Taper *28mm Diameter, +3.5mm Neck Length*
8819053284	Head Trial - b-ONE™ 12/14 Taper *28mm Diameter, +7mm Neck Length*
8819053321	Head Trial - b-ONE™ 12/14 Taper *32mm Diameter, -4mm Neck Length*
8819053322	Head Trial - b-ONE™ 12/14 Taper *32mm Diameter, 0mm Neck Length*
8819053323	Head Trial - b-ONE™ 12/14 Taper *32mm Diameter, +4mm Neck Length*
8819053324	Head Trial - b-ONE™ 12/14 Taper *32mm Diameter, +7mm Neck Length*
8819053361	Head Trial - b-ONE™ 12/14 Taper *36mm Diameter, -4mm Neck Length*
8819053362	Head Trial - b-ONE™ 12/14 Taper *36mm Diameter, 0mm Neck Length*
8819053363	Head Trial - b-ONE™ 12/14 Taper *36mm Diameter, +4mm Neck Length*
8819053364	Head Trial - b-ONE™ 12/14 Taper *36mm Diameter, +8mm Neck Length*

PART #	DESCRIPTION
8819900102	Juveno™ Hip System **Femoral Broach Tray**
8819003000	Femoral Resection Guide
8819008000	Stem Remover
8819010000	Stem Inserter, Offset
8819011000	Stem Impactor
8819090000	Straight Broach Handle*
8819042001	Broach, Size 1
8819042002	Broach, Size 2
8819042003	Broach, Size 3
8819042004	Broach, Size 4
8819042005	Broach, Size 5
8819042006	Broach, Size 6
8819042007	Broach, Size 7
8819042008	Broach, Size 8
8819042009	Broach, Size 9
8819042010	Broach, Size 10
8819042011	Broach, Size 11
8819043227	Neck Trial *Standard Offset (132°), 27mm Length*
8819043230	Neck Trial *Standard Offset (132°), 30mm Length*
8819043235	Neck Trial *Standard Offset (132°), 35mm Length*
8819043237	Neck Trial *Standard Offset (132°), 37mm Length*
8819043240	Neck Trial *Standard Offset (132°), 40mm Length*
8819043727	Neck Trial *High Offset (127°), 27mm Length*
8819043730	Neck Trial *High Offset (127°), 30mm Length*
8819043735	Neck Trial *High Offset (127°), 35mm Length*
8819043737	Neck Trial *High Offset (127°), 37mm Length*
8819043740	Neck Trial *High Offset (127°), 40mm Length*

*Additional option available:
8819077000 Straight Broach Handle, Trigger Style

SURGICAL TECHNIQUE

Juveno™
Femoral Hip System
RESTORING MOBILITY

Disclaimer

This documentation is intended for health care professionals and the b-ONE ORTHO sales force. Distribution to any other recipient is prohibited.

Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient. b-ONE ORTHO does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

Contact your b-ONE representative if you have questions about the availability of b-ONE products in your area.

BIOLOX®delta is a trademark of CeramTec AG.

b1LIT-00001 Juveno™ Femoral Hip System Surgical Technique Rev B

b-ONE ORTHO Corp.
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Cedar Knolls, NJ 07927
USA
www.b1.co

b-ONE ORTHO

FDA

U.S. FOOD & DRUG ADMINISTRATION

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 4742-2-2023

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In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(15 Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer
B-ONE ORTHO, CORP.
3 Wing Drive Suite #259
Cedar Knolls, NJ USA 07927

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

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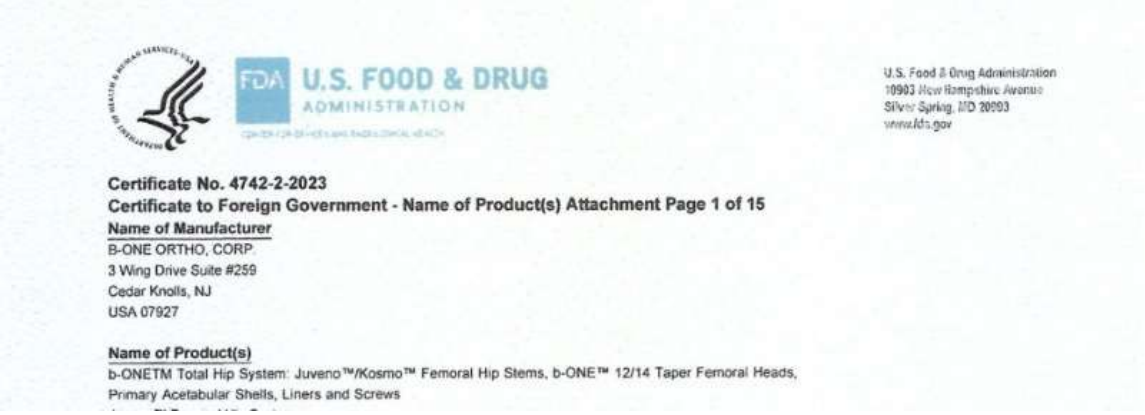

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U.S. Food & Drug Administration
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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 15

Name of Manufacturer
B-ONE ORTHO, CORP.
3 Wing Drive Suite #259
Cedar Knolls, NJ
USA 07927

Name of Product(s)
b-ONETM Total Hip System: Juveno™/Kosmo™ Femoral Hip Stems, b-ONE™ 12/14 Taper Femoral Heads, Primary Acetabular Shells, Liners and Screws

U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
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Silver Spring, MD 20993
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(17 Pages)

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Name of Manufacturer
B-ONE ORTHO, CORP.
3 Wing Drive Suite #259
Cedar Knolls, NJ USA 07927

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Certificate No. 4736-2-2023
Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 17
Name of Manufacturer
B-ONE ORTHO, CORP.
3 Wing Drive Suite #259
Cedar Knolls, NJ
USA 07927

Name of Product(s)
MOBIO™ Total Knee System Implants
8821131011 PS Femur, Size 1, LEFT, STANDARD, Cemented, CoCr


b-one
ORTHO