

 **Attune™**
Knee System

intuition™
INSTRUMENTS

Surgical Technique



 **DePuy Synthes** *People inspired™*
JOINT RECONSTRUCTION
COMPANIES OF *Johnson & Johnson*

Introduction

This surgical technique provides guidelines for the implantation of the ATTUNE™ Knee System family of fixed bearing knees with the ATTUNE™ INTUITION™ Instrumentation.

The ATTUNE INTUITION Instrumentation is intended for use with the ATTUNE Knee System Implants only and should not be considered interchangeable with any other instrumentation unless specifically noted in the surgical technique.

ATTUNE Knee System Implants are available in one configuration which allows for cruciate retaining (CR) or cruciate sacrificing (CS) applications and another configuration which allows for posterior stabilized (PS) applications.

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Surgical Technique

The ATTUNE™ INTUITION™ Instrumentation is unique in its ability to combine the surgical process with the implant options to allow the surgeon to balance the soft tissue and precisely control the implant position and fit for each patient. These instruments are intuitive to use and reduce steps throughout the surgical process, providing reduced effort to the entire OR team.

Precise Control

Intuitive instrumentation combined with a comprehensive range of sizes gives you precise control over the implant fit and position.

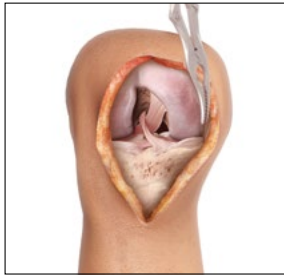
Designed Clarity

Reduced learning curve, more certainty. Design features like red actuators, high-contrast markings and quick set/release functions make ATTUNE™ INTUITION™ Instruments clear and easy to use from the moment you pick them up.

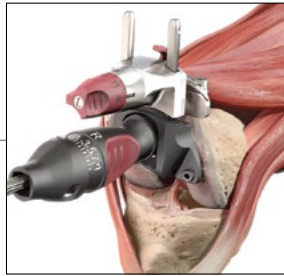
Efficient Path

Single layer trays, lightweight, and fewer instruments are just a few efficiencies that reduce your effort from start to finish.

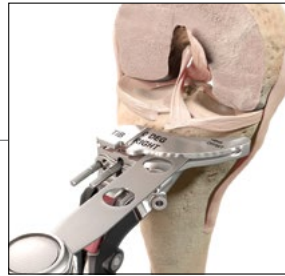
Key Surgical Steps Summary



Incision and Exposure



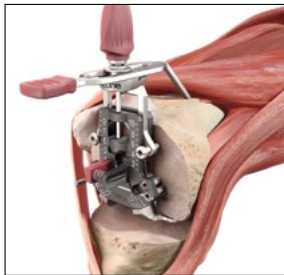
Femoral Alignment and Distal Resection



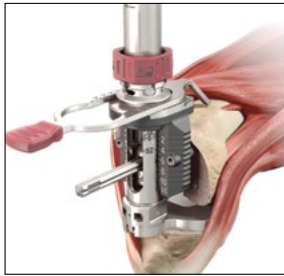
Tibial Alignment and Proximal Resection



Extension Gap Assessment and Balancing



Measured Femoral Sizing and Rotation



Balanced Femoral Sizing and Rotation



Femoral Preparation



Trial Reduction



Tibial Preparation



Femoral Lug Hole Preparation



Patella Resection and Final Patella Preparation



Final Component Implantation

Note: All resections are done using a 1.19 mm Saw Blade to maximize accuracy through the Slotted Cutting Guides.

Incision and Exposure

The ATTUNE INTUITION Instruments are designed for both standard open and minimally invasive approaches to the knee.

Incision and exposure should be done using the surgeon's preferred technique.



INFORMATION

Excise any hypertrophic synovium and a portion of the infrapatellar fat pad to allow access to the medial, lateral, and intercondylar spaces. Before proceeding, consider removing prominent osteophytes, particularly medial and lateral osteophytes, as they can affect soft tissue balancing.

Many of the instruments on the following pages are made of polymer materials. As with any composite or polymer-based instrument, it is important to allow adequate drying time after cleaning.

Pinning

The ATTUNE Knee System has specifically designed pins to increase the stability and functionality of the instruments. The ATTUNE INTUITION Instruments are designed to be used with the Single-Use Pin Pack (2544-00-111) that contains Universal Pins and Threaded Headed Pins.



Universal Pin

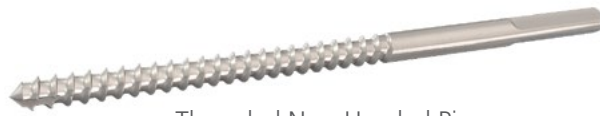
The Universal Pin* can be drilled in or hammered in, and drilled out or pulled out using the Pin Jack.



Threaded Headed Pin

The Threaded Headed Pin* is designed to be inserted and removed with a Power Drill. These pins are best used to secure blocks against a flat surface such as cut bone.

*Included in the Pin Pack



Threaded Non-Headed Pin

The Threaded Non-Headed Pin is also available and is designed to be inserted and removed with a Power Drill.

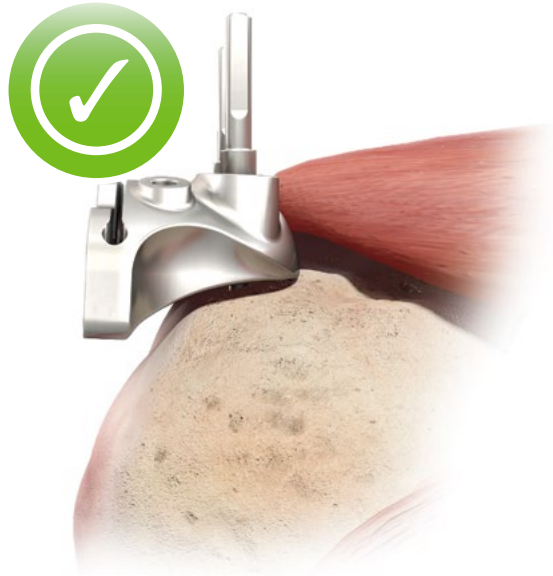


Pin Jack



Power Driver

Pinning Technique



Correct Pinning



Incorrect Pinning

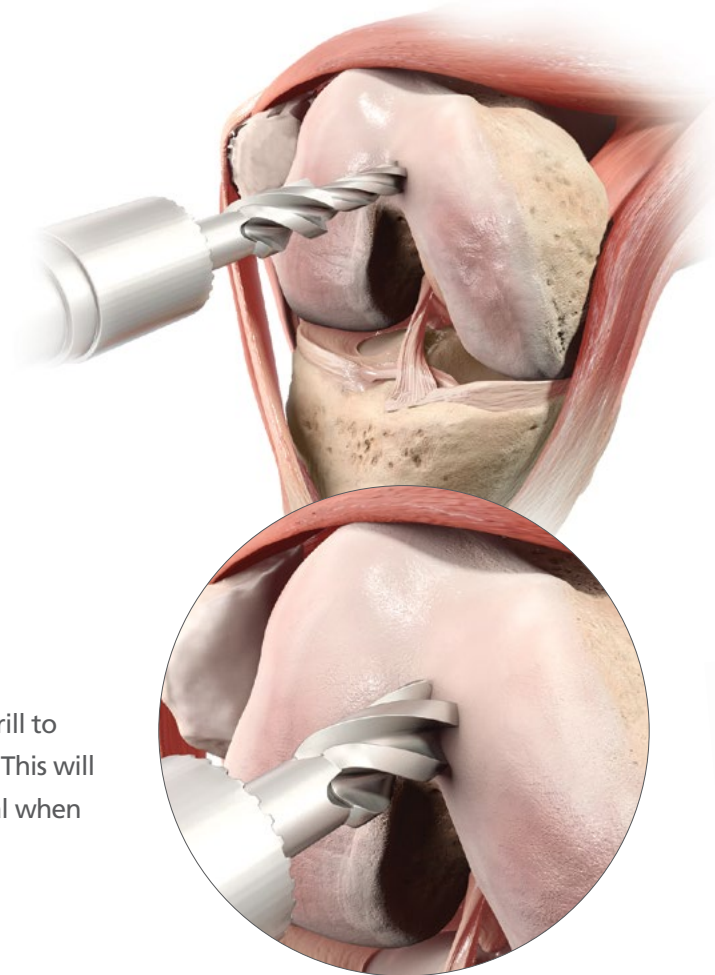
Headed pins are best used to secure blocks against a flat surface such as cut bone, however, if used on uncut bone with a curved surface, be careful that the Headed Pins are not overtightened as this can lead to tilting and malalignment of the block.

Distal Femoral Resection

With the knee in flexion, remove osteophytes from the intercondylar notch. Position the Step Drill to enter the intramedullary canal slightly superior and medial to the midline of the trochlea, 7 mm to 10 mm anterior to the origin of the PCL.

In the proper position, the Step Drill should pass easily into the femoral canal.

Use the step feature of the Step Drill to increase the diameter of the hole. This will allow depressurization of the canal when the IM Rod is inserted.



Distal Femoral Resection – Instrument Assembly

Distal Femoral Jig Assembly

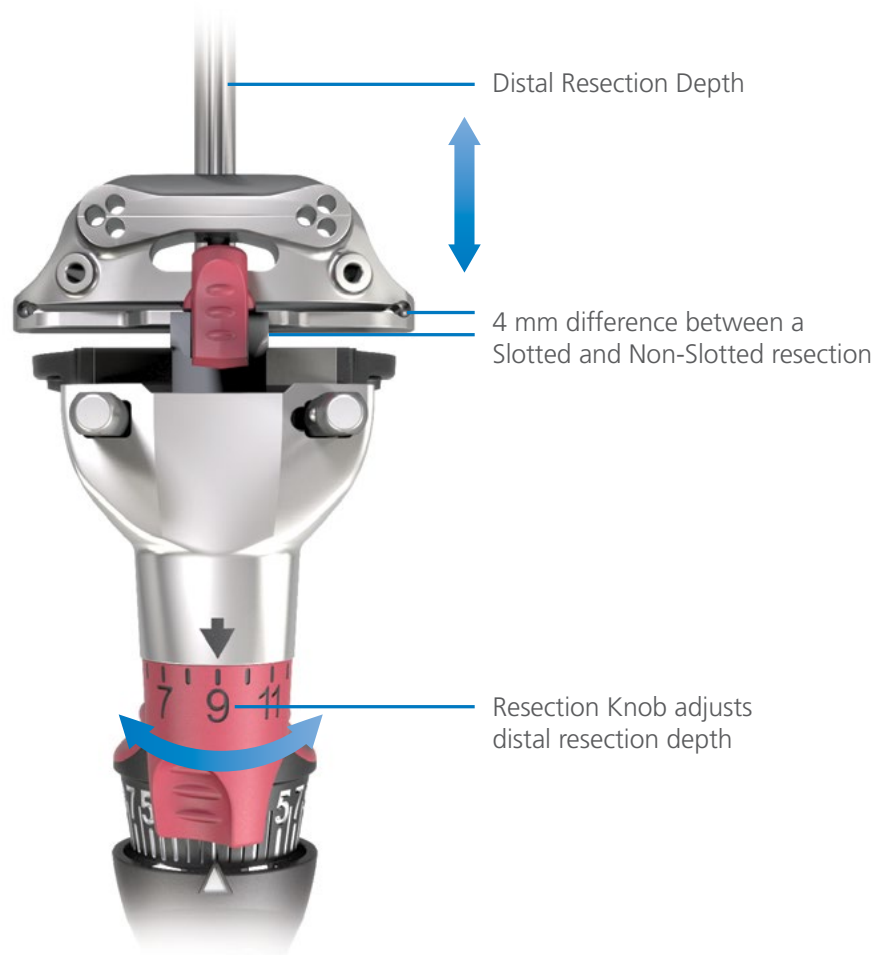
Order of Assembly:

1. Rotate the Resection Knob of the Outrigger counterclockwise until the padlock symbol is aligned with the arrow.
2. Insert the Outrigger Slide into the Outrigger.
3. Rotate the Resection Knob clockwise to set the desired resection level.
4. Engage the Distal Femoral Cutting Block with the Outrigger Slide and the Cutting Block Clip.



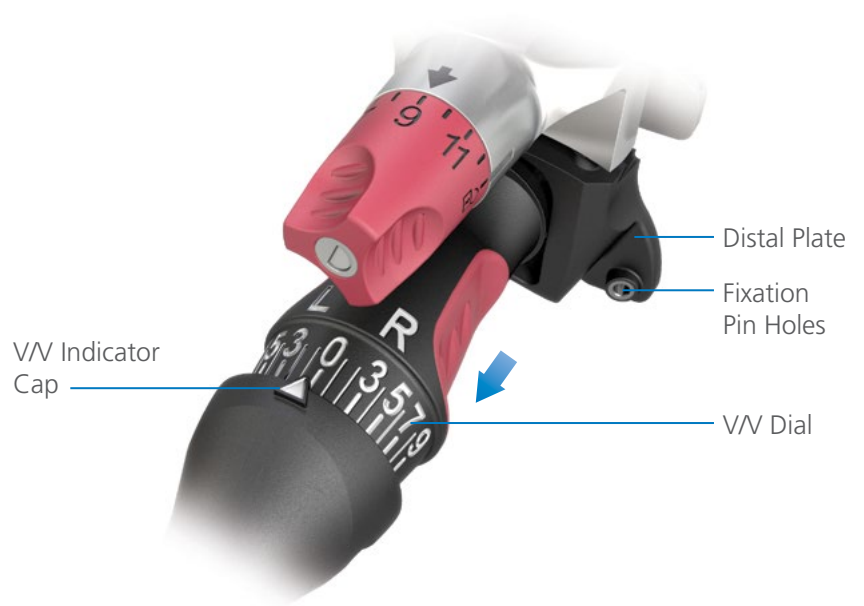
Distal Femoral Resection – Instrument Assembly

A 9 mm resection will match the thickness of the implant. The arrow on the Outrigger, near the Resection Knob, indicates the resection level when using the Cutting Slot. Each click moves the Distal Femoral Cutting Block 1 mm proximal or distal.



Distal Femoral Resection

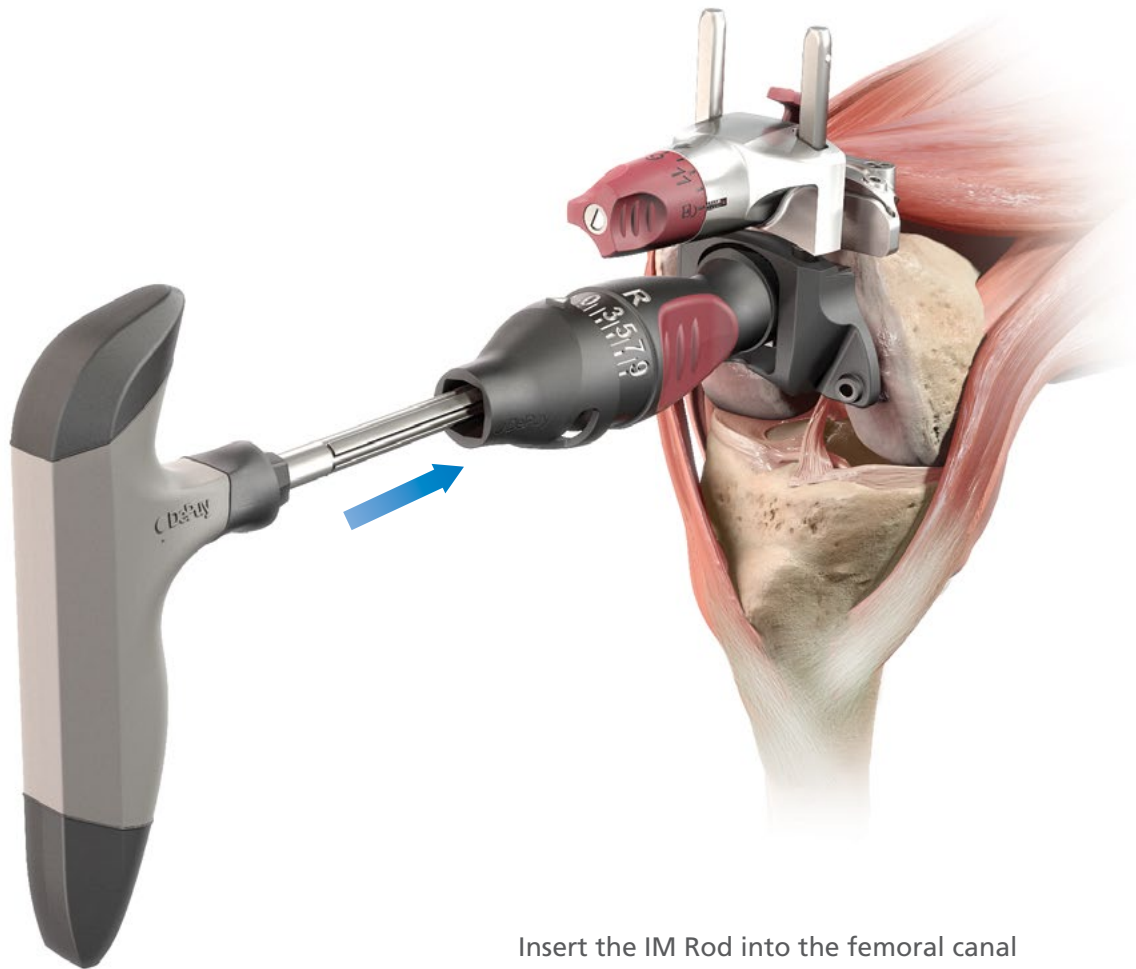
Set the desired valgus angle (left or right - 0 degrees to 9 degrees) on the Distal Femoral Jig by pulling the V/V Dial toward the Femoral Handle, rotating it clockwise or counterclockwise to the appropriate setting.



INFORMATION

Be sure that the Varus/Valgus Dial is FULLY disengaged by sliding it back from the Distal Plate before rotating it.

Distal Femoral Resection

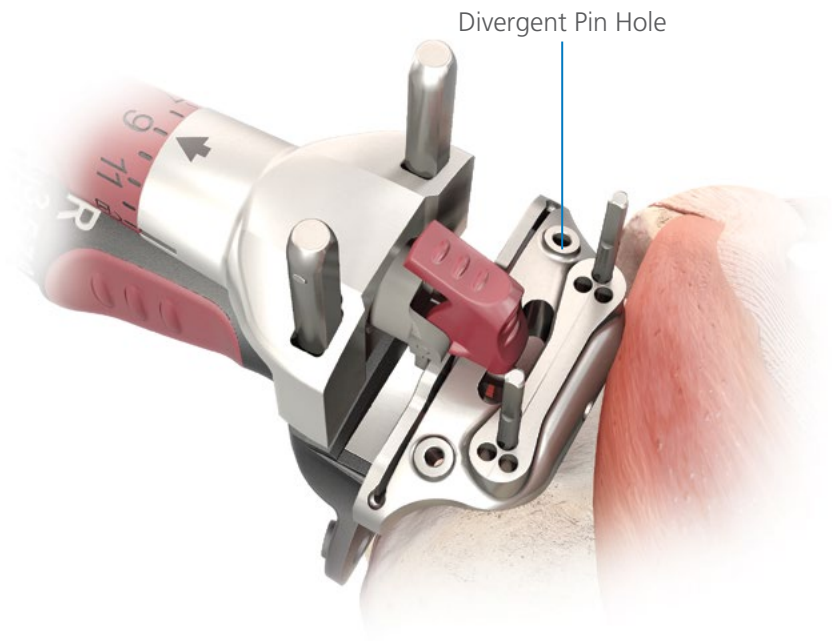


Insert the IM Rod into the femoral canal to the level of the isthmus. Disengage the Distal Femoral Jig from the Handle by pushing on the V/V Indicator Cap and slide the Jig toward the femur until the distal plate contacts the distal femur. The jig may be pinned temporarily using pin holes in the distal resection plate.

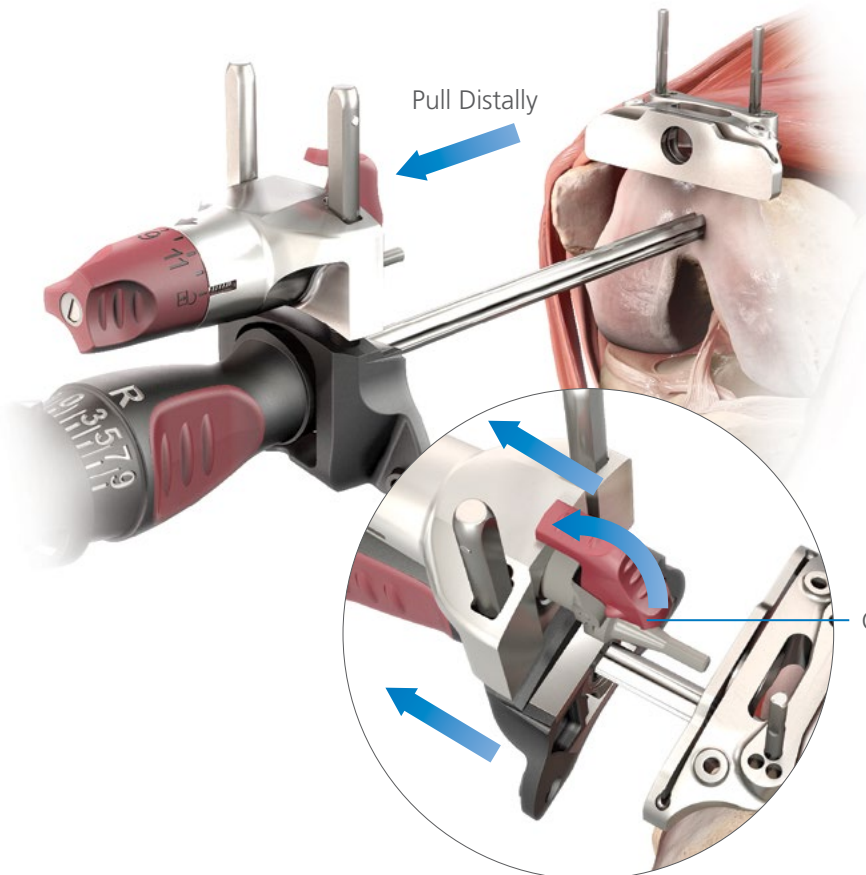
Position the Distal Femoral Cutting Block on the anterior femur by rotating it until it is seated on the anterior condyles.

Distal Femoral Resection

Secure the Cutting Block to the femur with two Universal or Non-Headed Pins through the holes marked with a center line. To further adjust the distal resection depth once the Distal Femoral Jig is removed, use the distal or proximal pin holes, that move the block 2 mm in either direction. If necessary for additional stability, insert a Universal or Non-Headed Pin through one of the divergent pin holes on the Cutting Block.

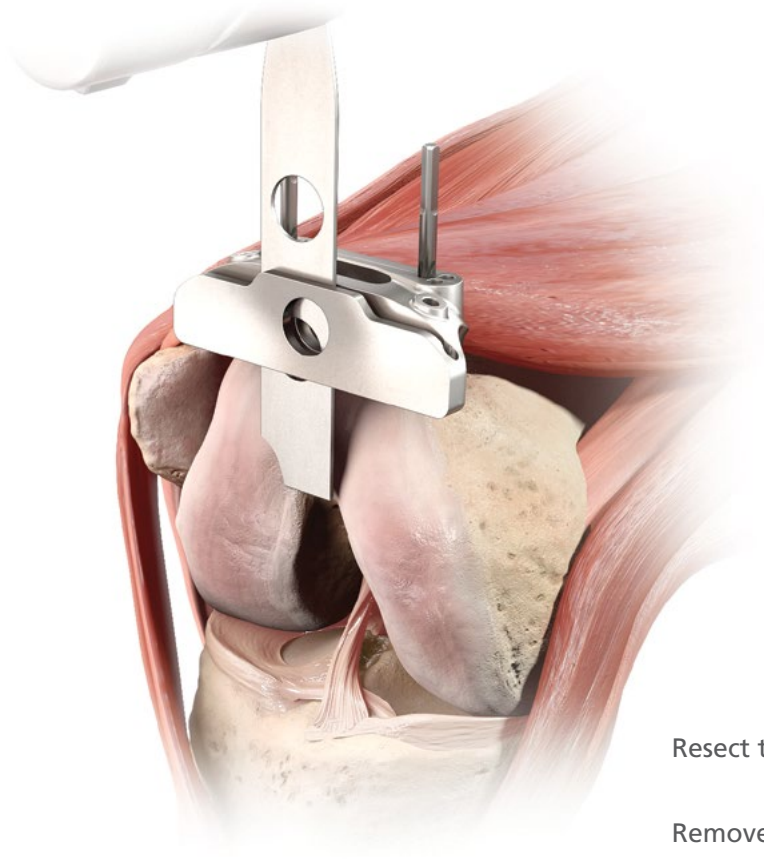


Removal of the Distal Femoral Jig



Disengage the Distal Femoral Cutting Block from the Outrigger Slide by pressing the Red Cutting Block Clip. Pull the entire instrument distally.

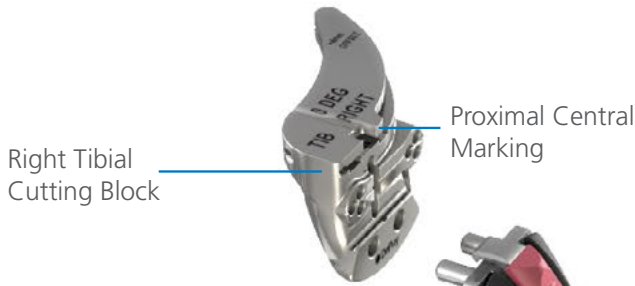
Distal Femoral Resection



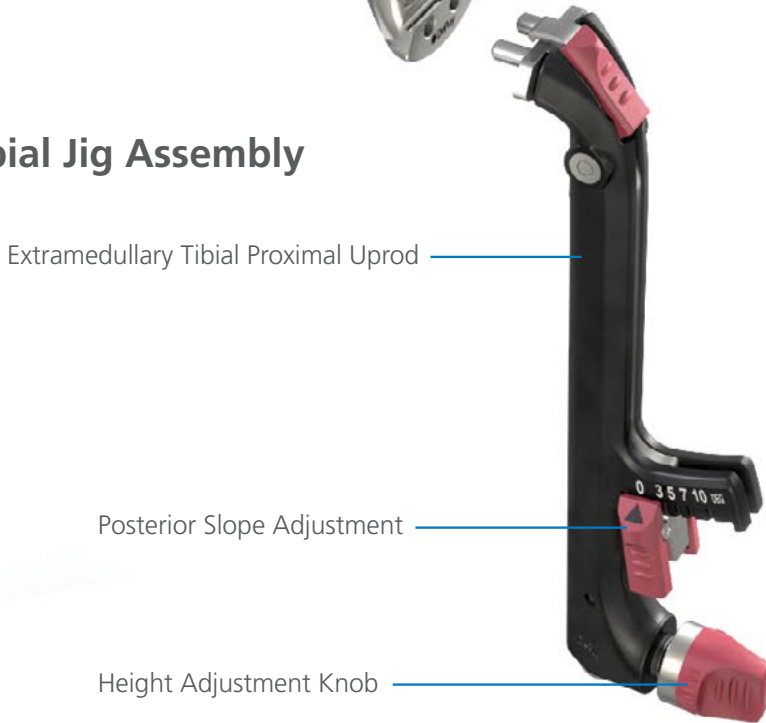
Resect the distal femur.

Remove the Distal Femoral Cutting Block. Depending on surgeon preference, the Pins may be removed or left in place to allow for a recut if required.

Tibial Alignment and Resection – Instrument Assembly



Tibial Jig Assembly



With the Height Adjustment Knob fully unscrewed on the Tibial Proximal Uprod, attach the Tibial Distal Uprod to the Proximal Uprod. Then attach the Tibial Ankle Clamp to the Distal Uprod. Assemble the appropriate Cutting Block to the Tibial Proximal Uprod.

Cutting Block Options



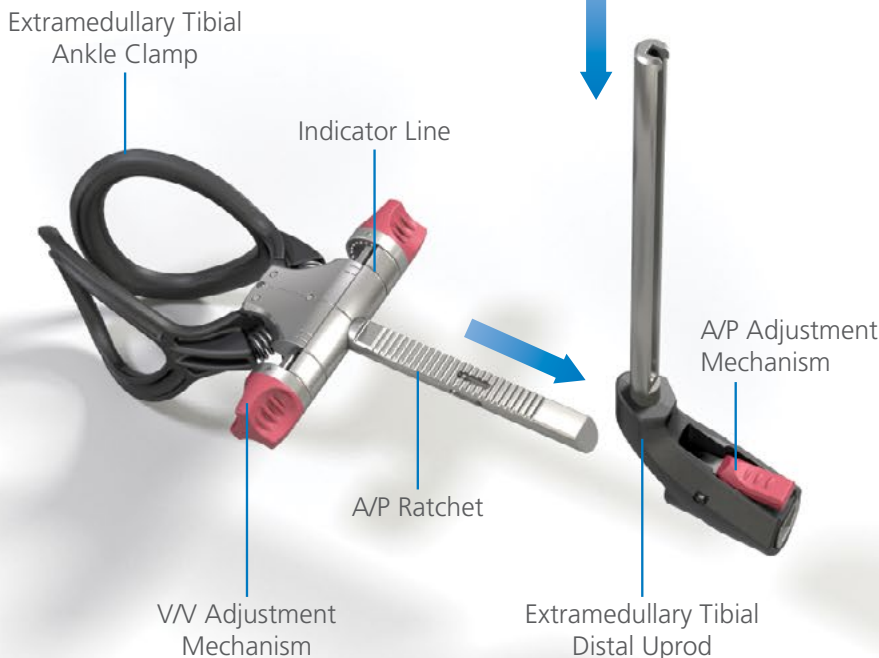
Left Tibial Cutting Block



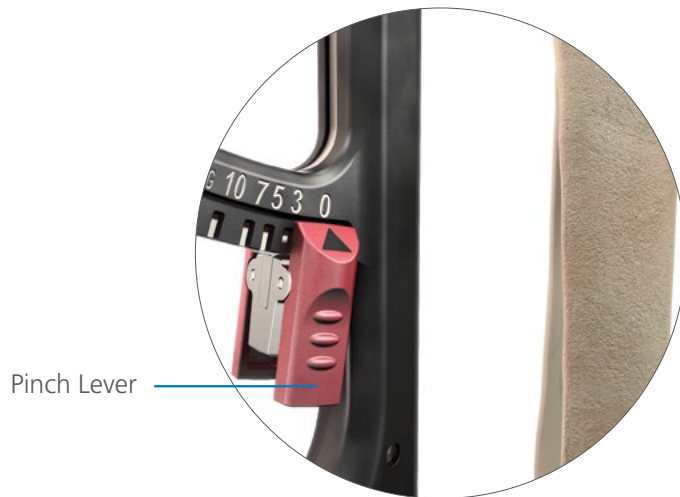
Right Tibial Cutting Block



Symmetrical Cutting Block

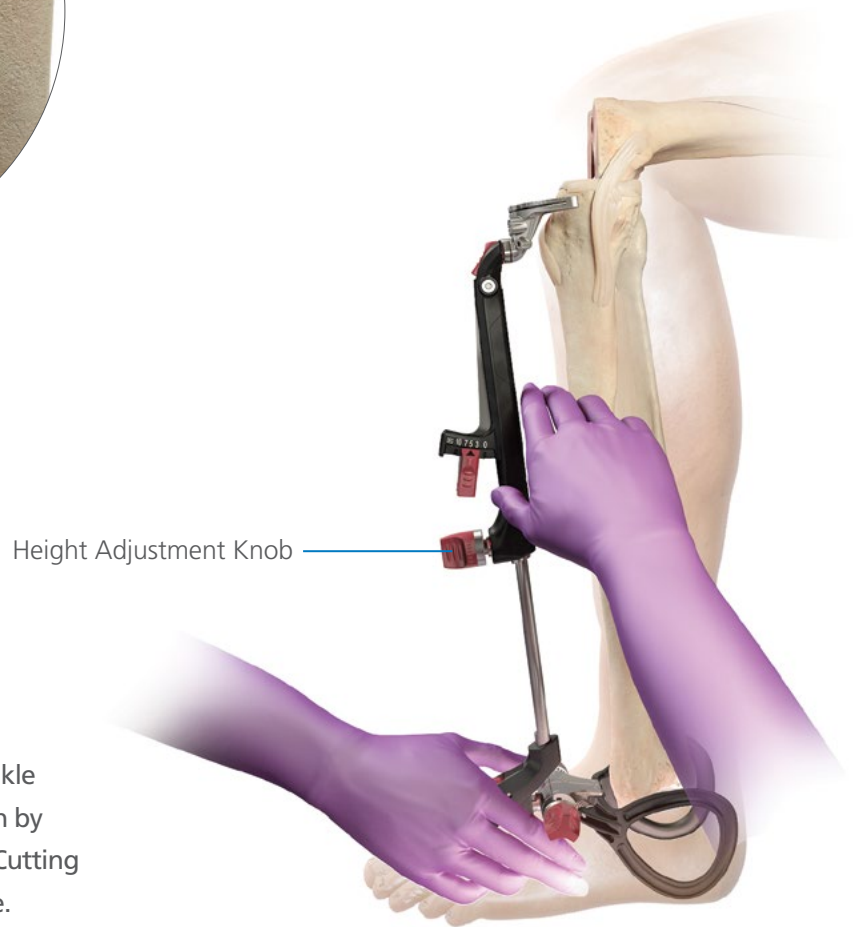


Tibial Alignment and Resection



Pinch Lever

Set the desired tibial posterior slope prior to attaching to the leg, which is indicated on the Proximal Uprod, by using the two pinch levers on the adjustment.



Height Adjustment Knob

Place the knee in 90 degrees of flexion. Place the Ankle Clamp around the malleoli. Set Varus/Valgus rotation by aligning the proximal central marking on the Tibial Cutting Block with the medial one third of the tibial tubercle.

Position the Tibial Distal Uprod so that it is parallel with the axis of the tibia using the A/P Ratchet at the ankle. An approximation of this can be done by running 2 fingers between the uprod and the anterior face of the tibia.




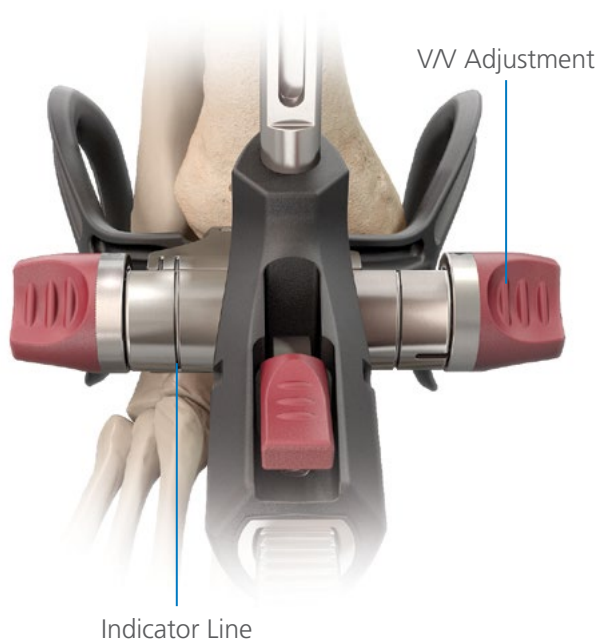
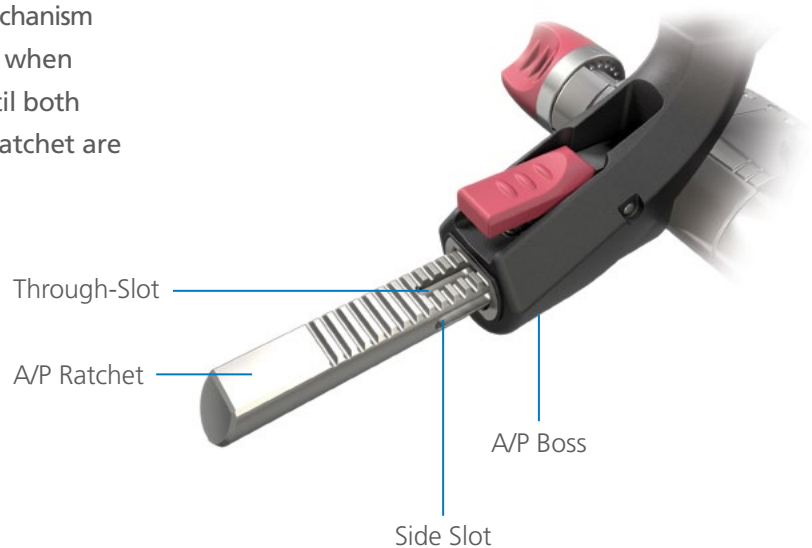
INFORMATION

For a posterior stabilized (PS) design, a 0-3 degree posterior slope is recommended. For a cruciate retaining (CR) design, match the patient slope up to 7 degrees.

Optional: Insert a Threaded Headed Pin through the center of the vertical slot in the Cutting Block to aid stability.

Tibial Alignment and Resection

On an average size tibia, the A/P adjustment mechanism provides approximately 0 degrees of tibial slope when the A/P adjustment is translated anteriorly until both the Through-Slot and the Side Slot in the A/P Ratchet are covered. 



Use the Varus/Valgus Adjustment Mechanism to align the Tibial Proximal Uprod parallel to the long axis of the tibia. For many patients, this involves translating the V/V Adjustment Mechanism until the second line from the lateral side of the ankle clamp lines up with the indicator line.



CAUTION

When checking and setting the sagittal alignment, be careful to prevent anterior slope. This could happen if the A/P Boss on the Distal Uprod is translated too far towards the ankle, exposing the Through-Slot. Posterior slope adjustment is the equivalent to using Cutting Blocks with slope built into them.



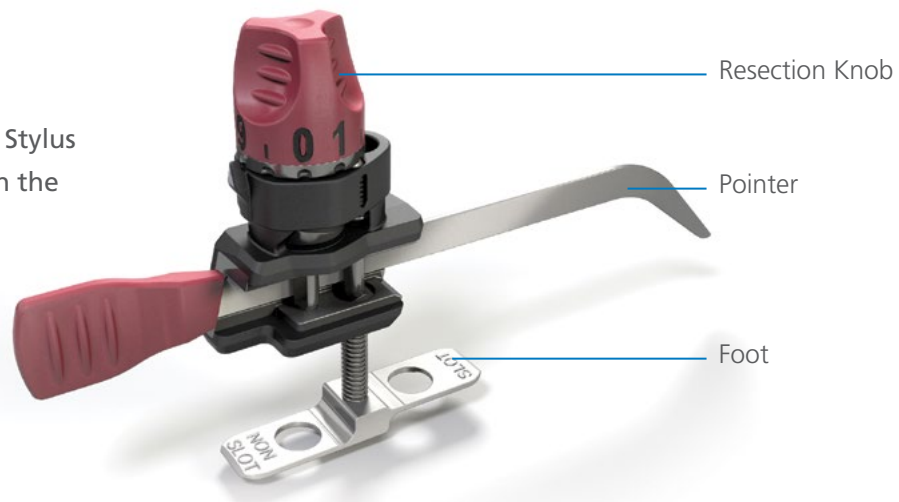
INFORMATION

In ankles with a large soft tissue envelope in which the soft tissue prevents achieving 0 degrees of alignment at the neutral position, the Distal Uprod can be moved posterior to reveal the Through-Slot to achieve a 0 degree slope.

Tibial Alignment and Resection

Stylus Attachment

Attach the Adjustable Tibial Stylus to the Cutting Block through the slot feature.



Resection through the Slot

If planning to resect through the slot, position the foot of the Stylus marked "slot" into the Slot Feature of the Cutting Block.



Resection on top of the Cutting Slot

If planning to resect on top of the Cutting Block, place the foot marked "non-slot" into the Slot Feature.

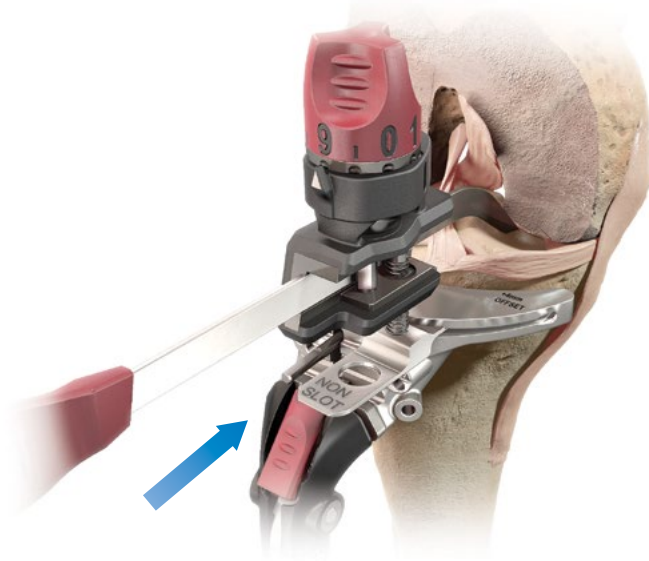
i INFORMATION

The minimum composite thickness of the tibial implant (4 mm base +5 mm insert) is 9 mm.

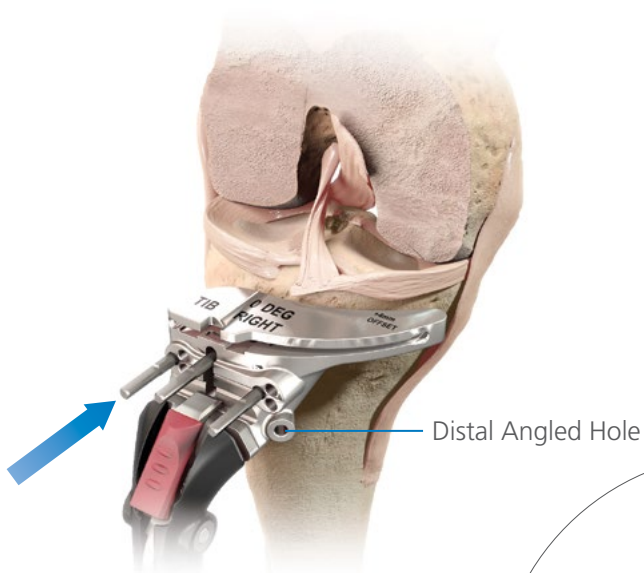
Rotate the Resection Knob to set the resection level on the Stylus (0 to 10). Each number corresponds to a resection amount in millimeters.

Rest the pointer of the Adjustable Tibial Stylus on the lowest point of the tibial plateau. Then lock the Height Adjustment Knob on the Proximal Upod.

Tibial Alignment and Resection



After the height has been set, pin the block through the holes marked by a center line using two Universal Pins.



If necessary, remove the Stylus for better access, ensuring that the Height Adjustment Knob is locked. The resection level can be adjusted by using the distal or proximal pin holes, which move the block 2 mm in either direction. If desired, the Cutting Block can be more securely fixed with an additional Universal or Non-Headed Pin placed through the distal angled hole.

Distal Angled Hole

Temporary Fixation Pin Slot

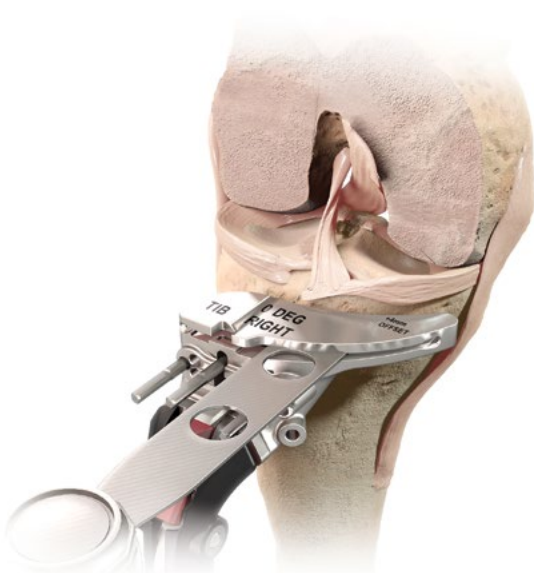


Tibial Alignment and Resection



Optional: To assess long leg alignment, place the Alignment Handle into the Slot Feature of the Cutting Block, and insert the Alignment Rod. Alignment can be checked by ensuring that the Alignment Rod remains parallel with the tibial axis.

In addition, a second Alignment Rod may be inserted through the Alignment Handle in the M/L plane to help ensure that the tibia is not cut in Varus or Valgus.



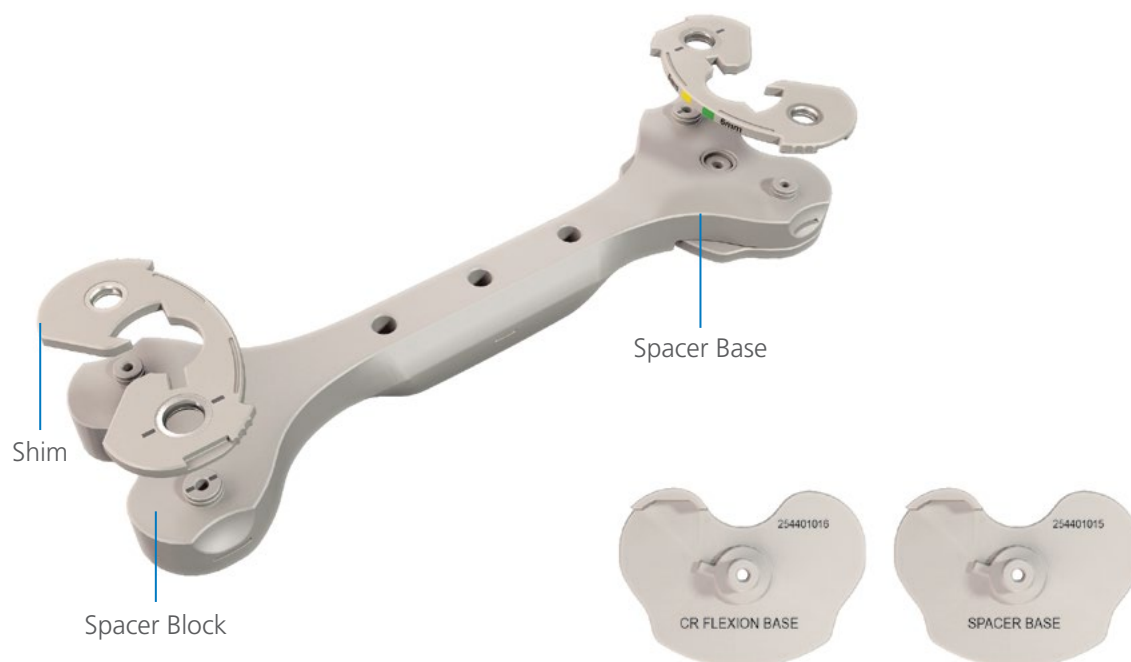
Resect the tibia.



INFORMATION

Place retractors to protect the PCL and collateral ligaments during tibial resection.

Extension Gap Assessment and Balancing



Posterior Stabilized

For the PS technique, connect the ATTUNE Knee System Spacer Base and desired Shim to the Spacer Block to assess both the extension and flexion gaps. When the ATTUNE Spacer Base is attached, both ends of the Spacer Block are equal thicknesses and can each be connected to a different Shim to allow successive evaluation of multiple thicknesses. As an example, if the surgeon is unsure as to whether the gap will correspond to a 5 mm or 6 mm insert, the 5 mm Shim can be connected to one end and the 6 mm Shim to the other.

Cruciate Retaining

For the CR technique, evaluate the CR extension gap as described in the previous paragraph. To assess the CR flexion gap connect the CR Flexion Base and desired Shim to one end of the Spacer Block. The CR Flexion Base compensates for the 1 mm difference in thickness of the posterior condyles of the CR implant.

	PS	CR
Distal Condyle Thickness	9	9
Posterior Condyle Thickness	9	8



INFORMATION

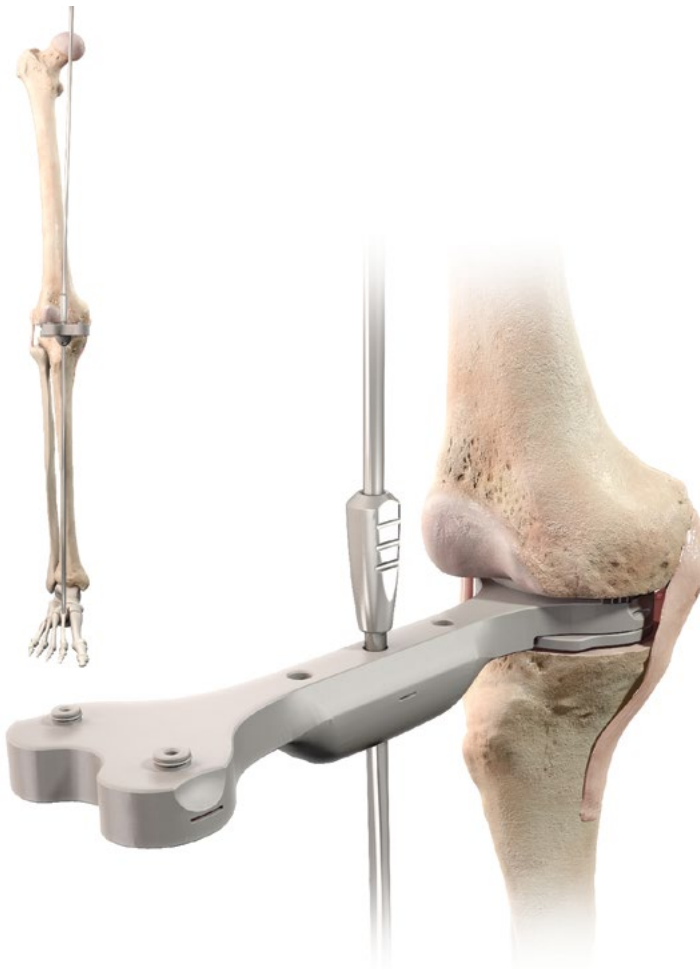
The Spacer Block is designed to accommodate both CR and PS techniques. In the PS implant the distal and posterior condyles are the same thickness, resulting in no compensation required for extension and flexion balancing. In the CR implant the posterior condyle is 1 mm thinner than the distal condyles. The Spacer Block connects to Shims on both ends to evaluate multiple

thicknesses. The labels on the Shims indicate the thickness of the insert they represent when assembled to the Spacer Block, and can be read off the top of the Shim when it is attached to the Spacer Block. Although any size Shim will assemble to the Spacer Block, the size 5/6 Shim is recommended as it most closely matches the shape of the Spacer Block.

Extension Gap Assessment and Balancing

To check the extension gap, fully extend the leg and place the appropriate end of the Spacer Block between the two resected surfaces. The Block should fit snugly in the extension space. The Block should fit snugly in the extension space. The extension gap should be rectangular with the leg in full extension. If the extension gap is not balanced, adjust the angle of either the tibial or the femoral cut, or perform appropriate soft-tissue releases to achieve balance.

If desired, perform a gentle Varus/Valgus stress test with the Spacer Block in place. Typically 1 mm to 3 mm of opening both medially and laterally is desirable.

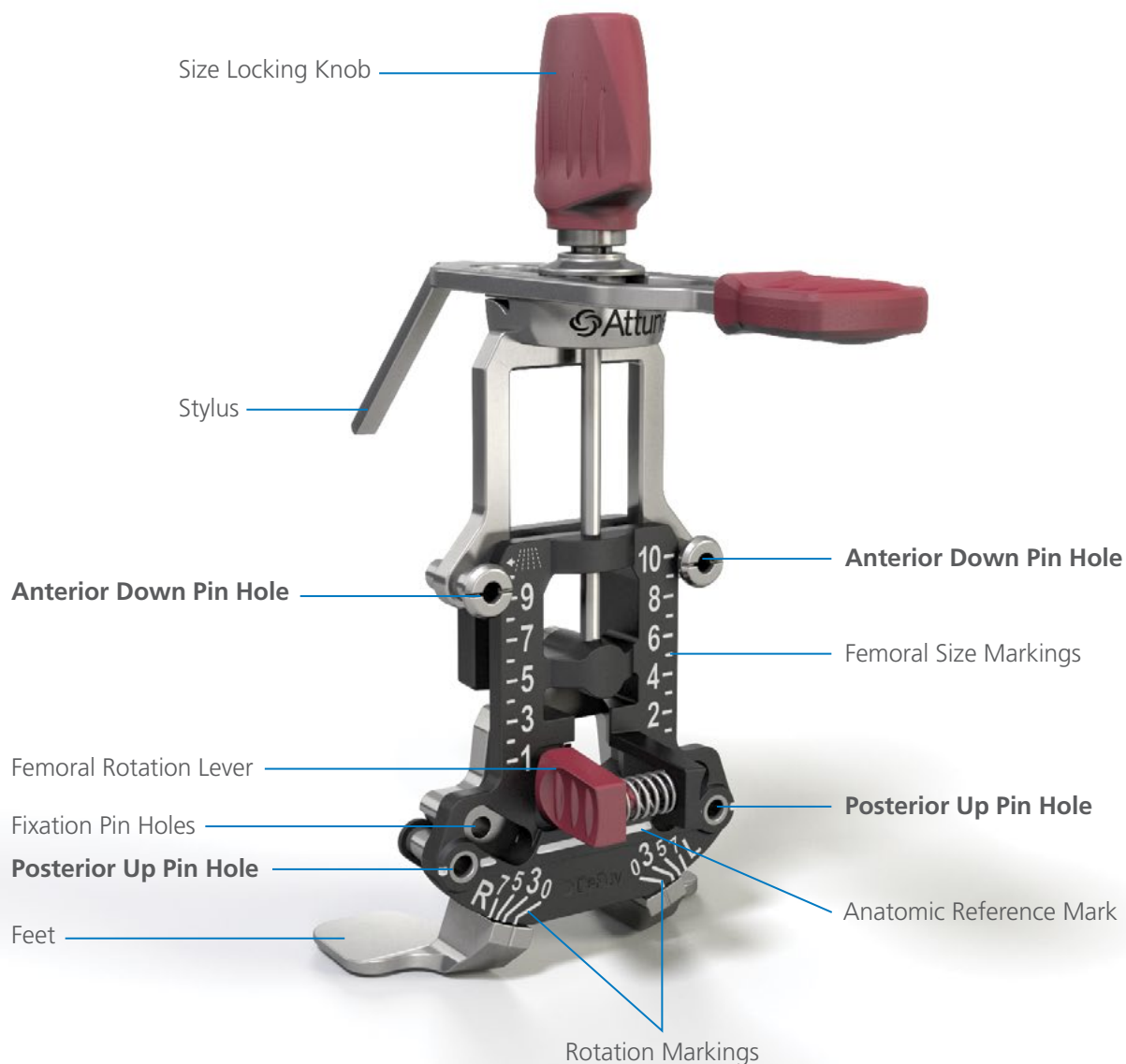


If desired, the two piece Alignment Rod can be inserted into the Spacer Block to assess alignment.

The Spacer Block can also be used to assess the flexion gap after resecting the posterior femoral condyles.

Measured Femoral Sizing and Rotation

Measured Sizing and Rotation Guide



INFORMATION

Choosing the anterior down pin holes will provide a fixed anterior reference with a constant anterior cut, regardless of the size of the A/P Chamfer Block. All variability in bone cuts from size to size will occur on the posterior cut.

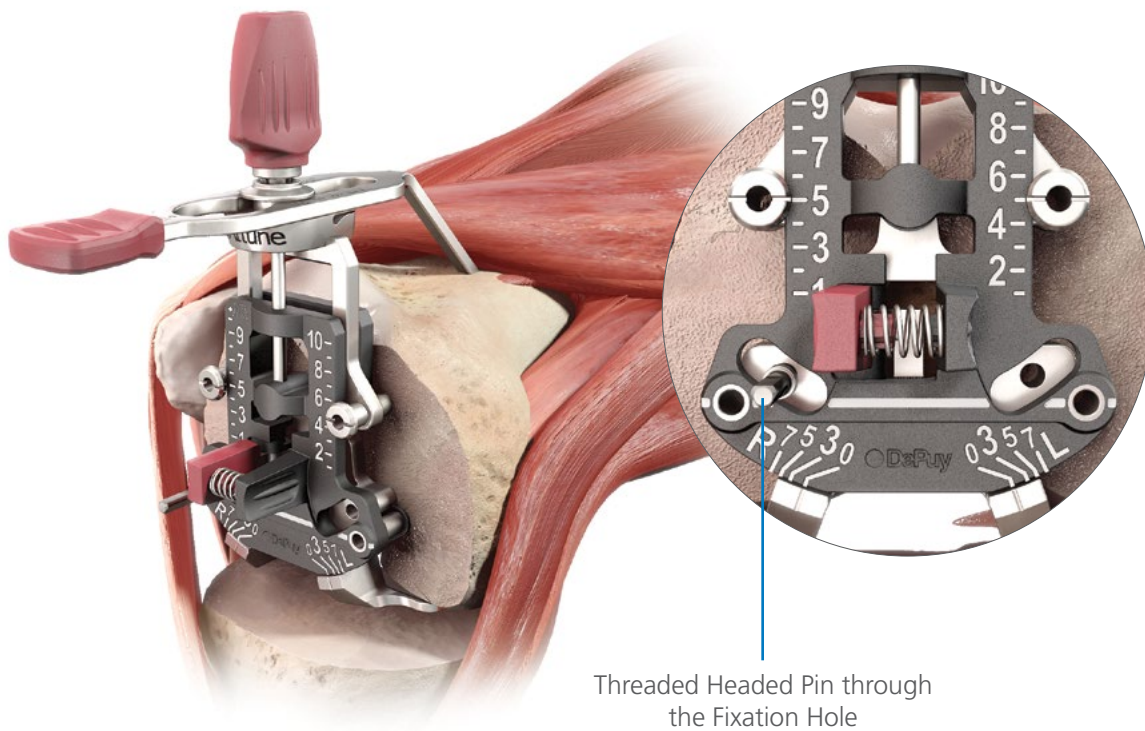
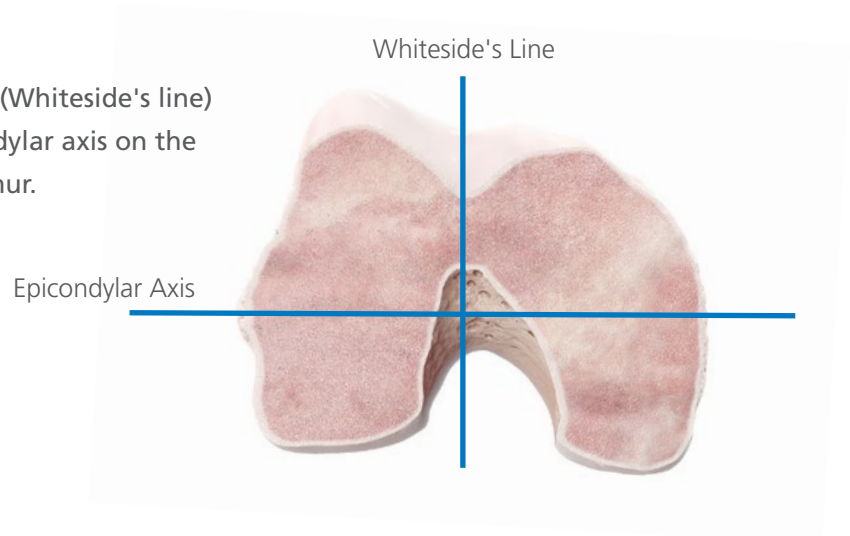
Conversely, choosing the posterior up pin holes will provide a fixed posterior reference with a fixed posterior cut. All variability in bone cuts from size to size will occur on the anterior cut.

The Measured Sizer instrument is named to indicate its use for a Measured Resection surgical philosophy and is not a measurement device.

Measured Femoral Sizing and Rotation

Placement of Sizing Guide

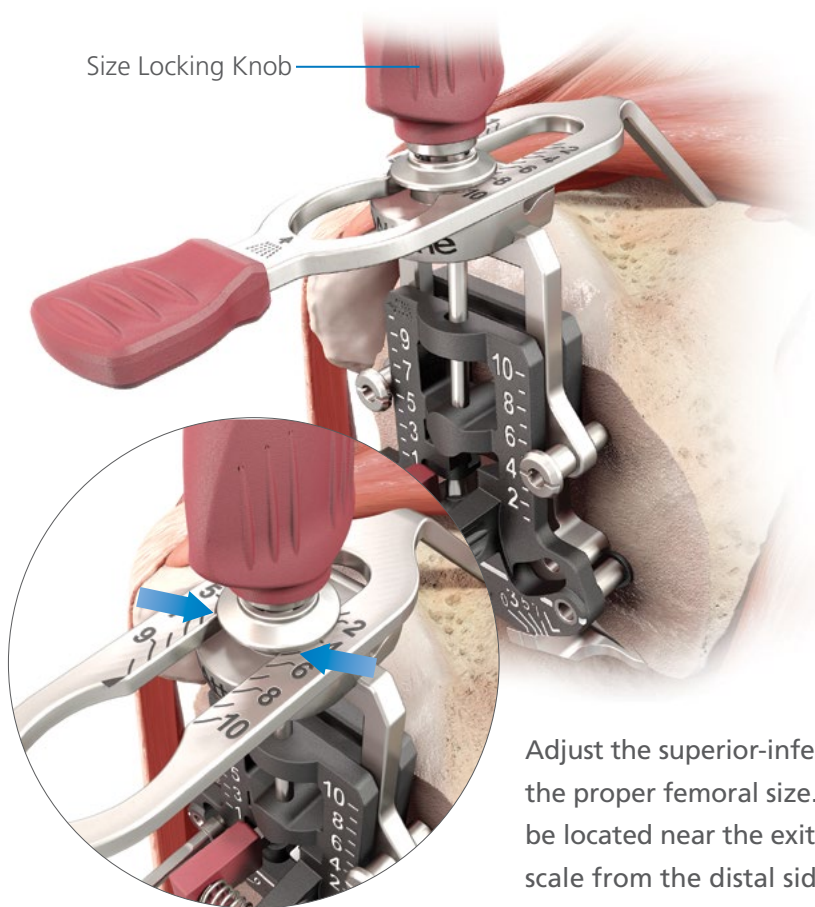
Mark the A/P Axis (Whiteside's line) and/or the epicondylar axis on the resected distal femur.



Place the Measured Sizing and Rotation Guide against the resected surface of the distal femur with the posterior feet of the guide contacting the posterior condyles. If desired, secure the Guide with a Threaded Headed Pin through the fixation hole.

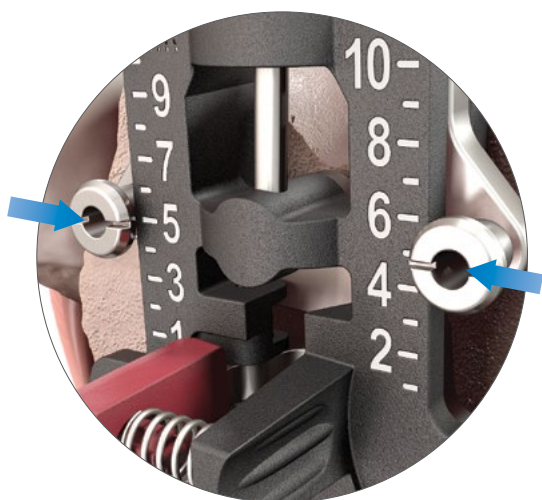
Measured Femoral Sizing and Rotation

Size Locking Knob



Slide the anterior section down and position the Stylus so the tip just contacts the desired point on the anterior femur.

Adjust the superior-inferior position of the scale to indicate the proper femoral size. The position of the Stylus will then be located near the exit point of the Saw Blade. Read the scale from the distal side of the Size Locking Knob.



The line through the center of the Anterior Down Pin Holes indicates the size of the femur. Lock the size position by twisting the Size Locking Knob.

Anterior Down Pin Holes indicating Size 5

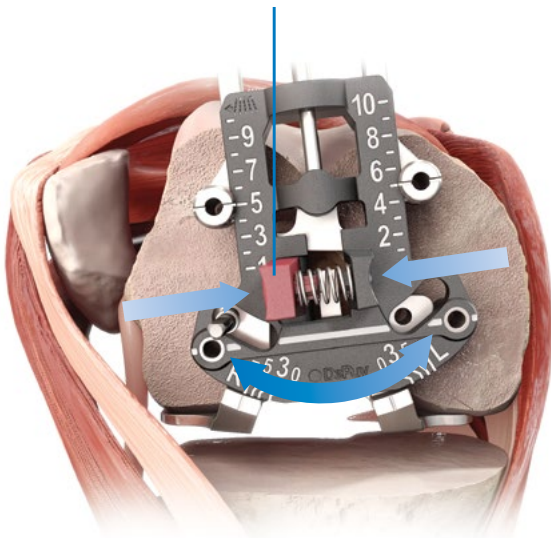


CAUTION

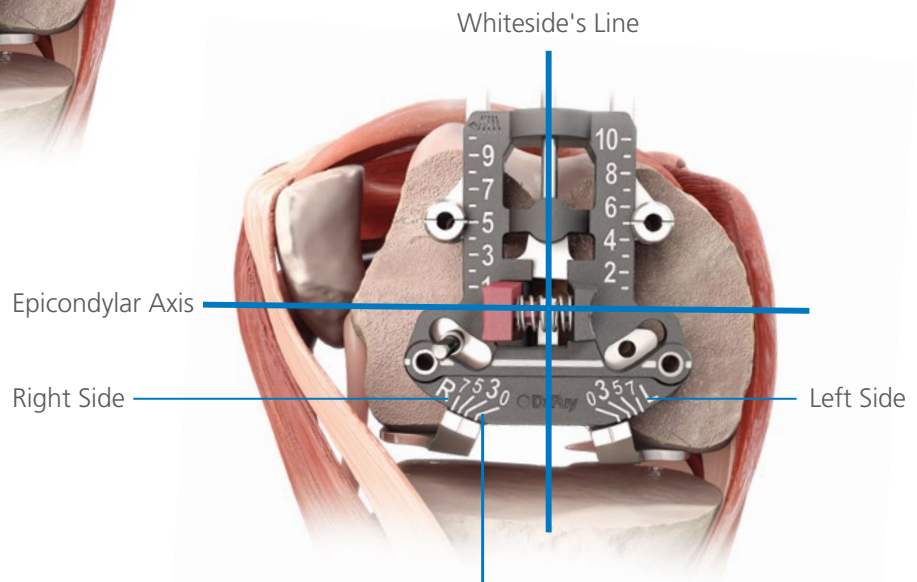
Be very careful not to apply a large force when contacting the anterior femur with the Stylus, avoiding excessive deflection of Stylus which may bias the sizing.

Measured Femoral Sizing and Rotation

Squeeze the Lever and simultaneously rotate



Adjust the degree of external rotation to be parallel the epicondylar axis and perpendicular to Whiteside's line by squeezing the Femoral Rotation Lever and rotating the anterior section while holding the feet of the device against the posterior condyles.



The rotation markings indicate the degree of external femoral rotation with reference to the posterior condyles

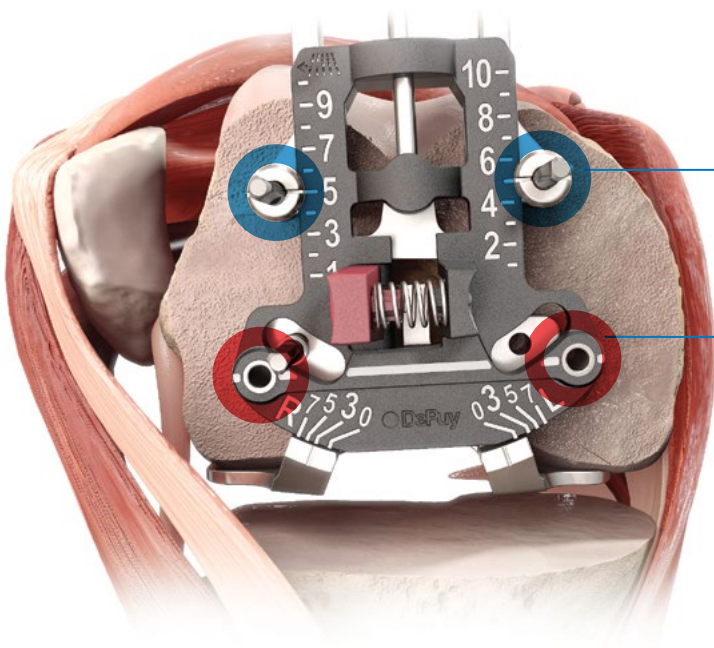
Pin Insertion

Insert Universal or Non-Headed Pins through the top pin holes for **anterior down** referencing

OR

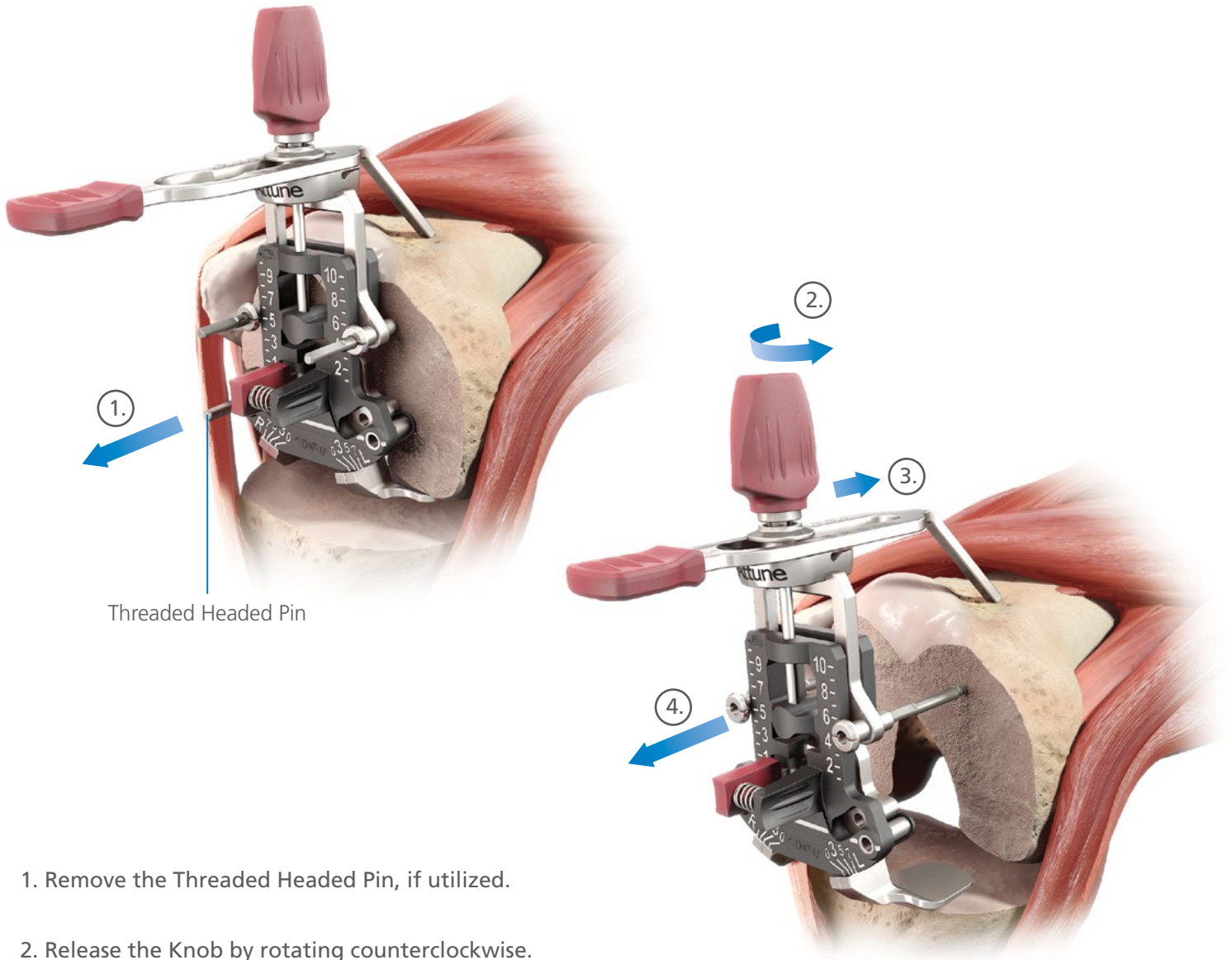
Insert Universal or Non-Headed Pins through the bottom pin holes for **posterior up** referencing

(For further information see page 23).



Measured Femoral Sizing and Rotation

Removal of Sizer

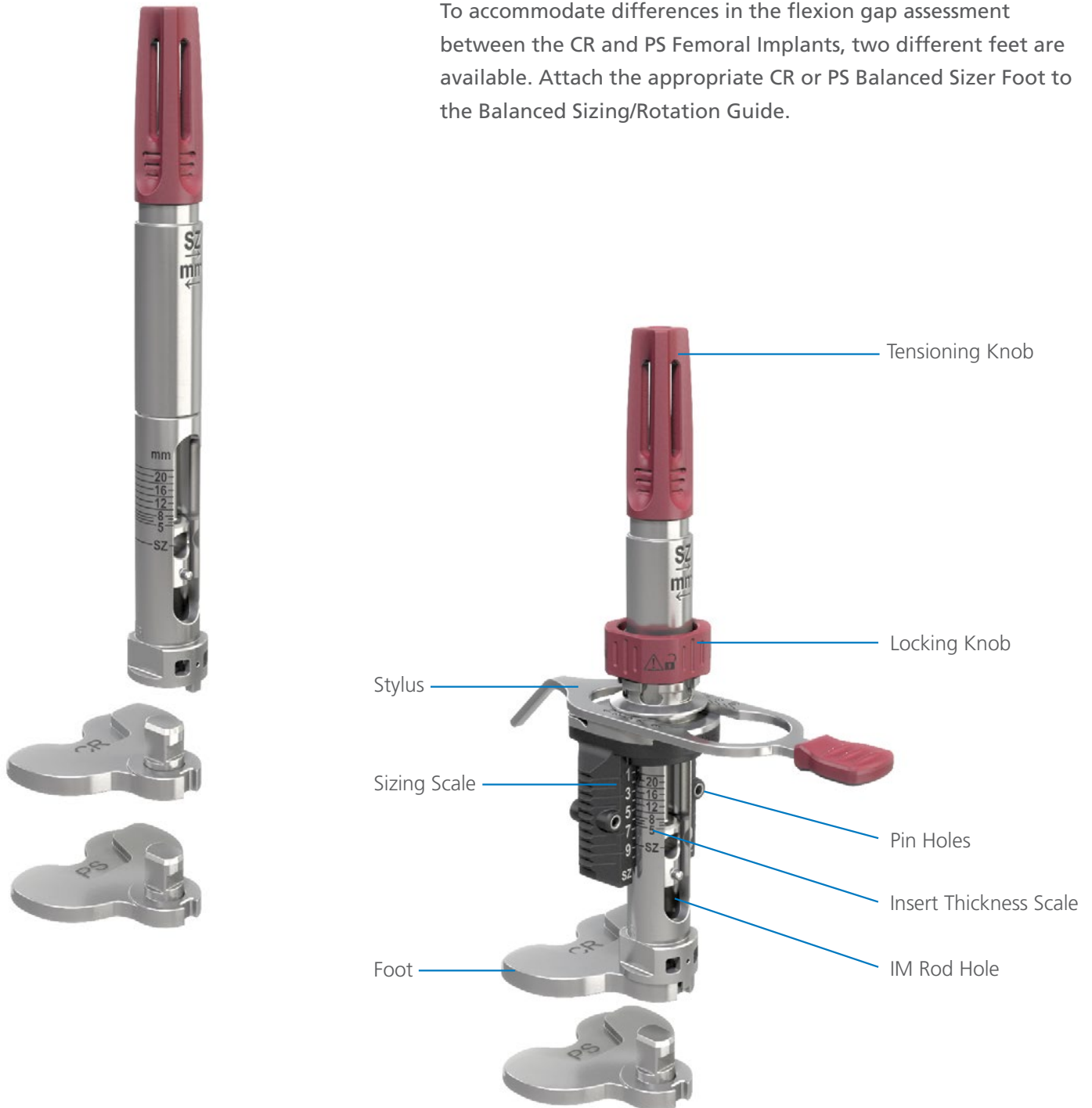


1. Remove the Threaded Headed Pin, if utilized.
2. Release the Knob by rotating counterclockwise.
3. The Stylus is loosened, then pushed forward on the anterior face of the femur so that it is no longer contacting the bone surface (as the anterior surface slopes downward). The Sizer is pulled off the femur and the 2 components removed together.
4. Remove the Sizing/Rotation Guide, leaving the Universal or Non-Headed Pins in the distal femur.

Balanced Femoral Sizing and Rotation

Balanced Sizing/Rotation Guide Assembly

To accommodate differences in the flexion gap assessment between the CR and PS Femoral Implants, two different feet are available. Attach the appropriate CR or PS Balanced Sizer Foot to the Balanced Sizing/Rotation Guide.



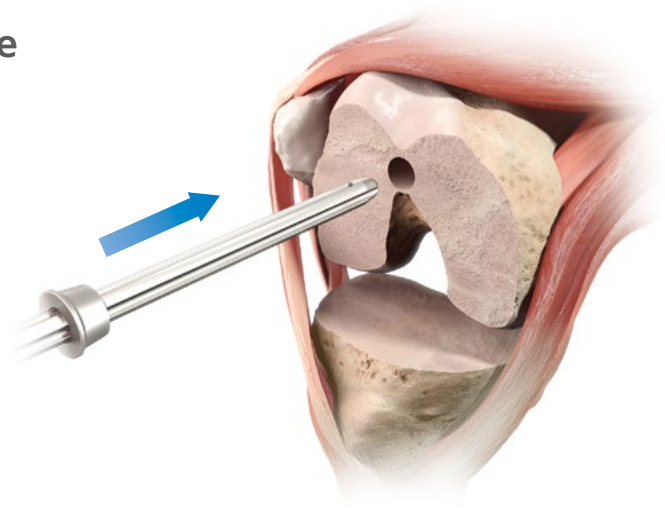
Balanced Femoral Sizing and Rotation

Balanced Sizing and Rotation Guide

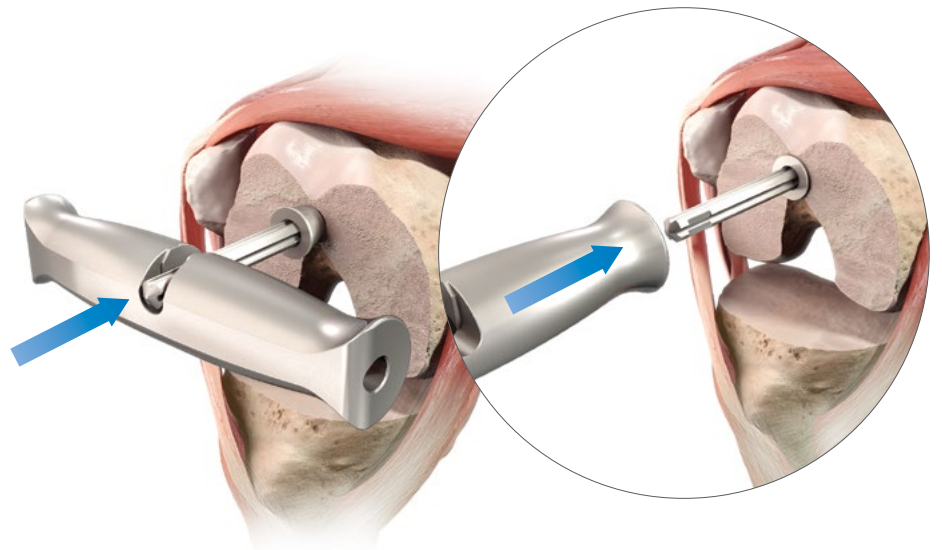
The Balanced Sizer performs several key functions:

1. Sizes the femur
2. Sets rotation of the femur based on ligament tension
3. Enables assessment of the flexion gap in comparison to the previously determined extension gap

Before using the Balanced Sizer, measure the extension gap using the Spacer Block as outlined on page 22. After making the primary cuts and measuring the extension gap, record the insert thickness that corresponds to the extension gap for future reference.



Attach the IM Rod Handle to the Balanced Sizer IM Rod and insert the Rod into the intramedullary canal.



Use the handle as a Slap Hammer to secure the Tapered Plug and stabilize the IM Rod. The Tapered Plug may not fit flush against the bone, but should be tight.



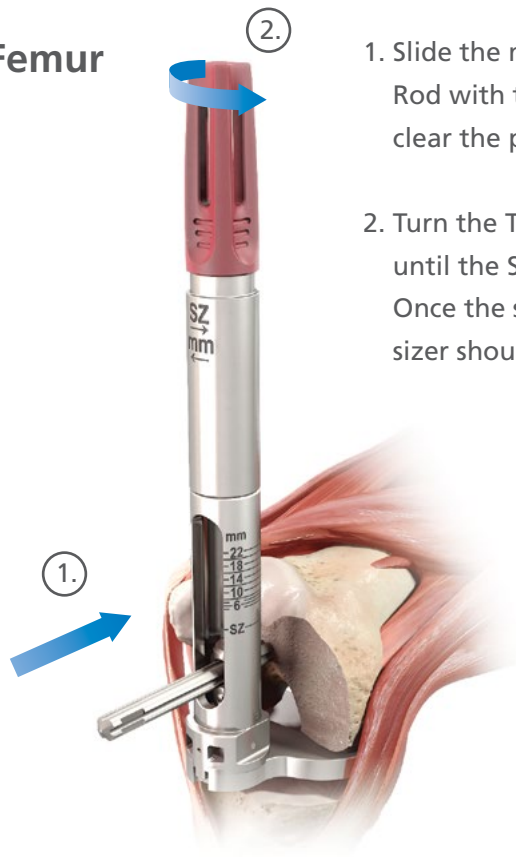
INFORMATION

The Balanced Sizer technique is anterior referencing only.

The Tapered Plug may not fit flush against the bone, but should be tight.

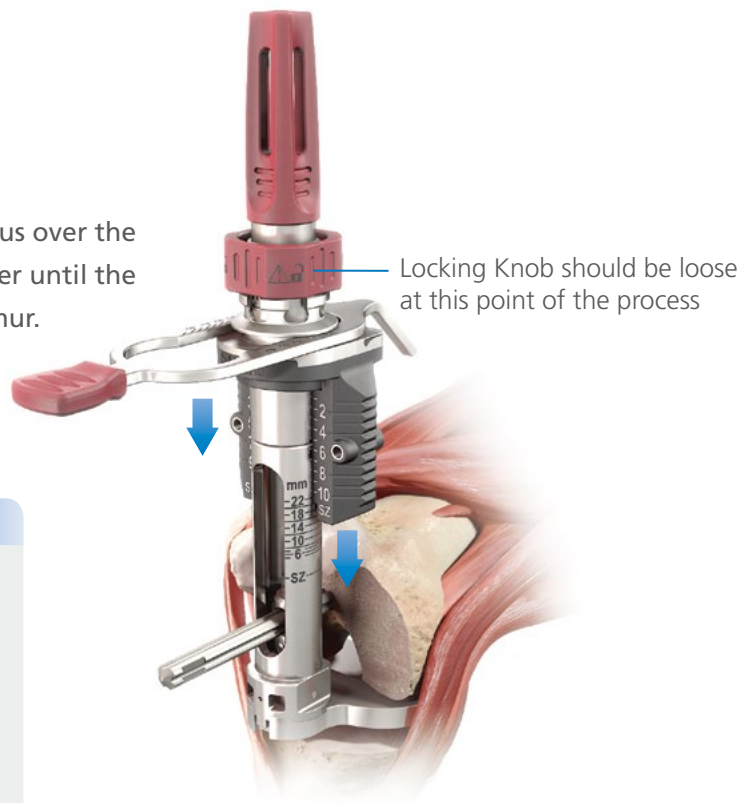
Balanced Femoral Sizing and Rotation

Sizing the Femur



1. Slide the main body and foot of the Balanced Sizer onto the IM Rod with the knee flexed at 90 degrees, ensuring that the feet clear the posterior condyles.
2. Turn the Tensioning Knob in a counterclockwise (SZ) direction until the Sizer Foot contacts the posterior femoral condyles. Once the sizer foot contacts the posterior femoral condyles the sizer should not be able to rotate about the IM Rod.

Slide the Sizing Guide and Stylus over the main body of the Balanced Sizer until the Stylus touches the anterior femur.



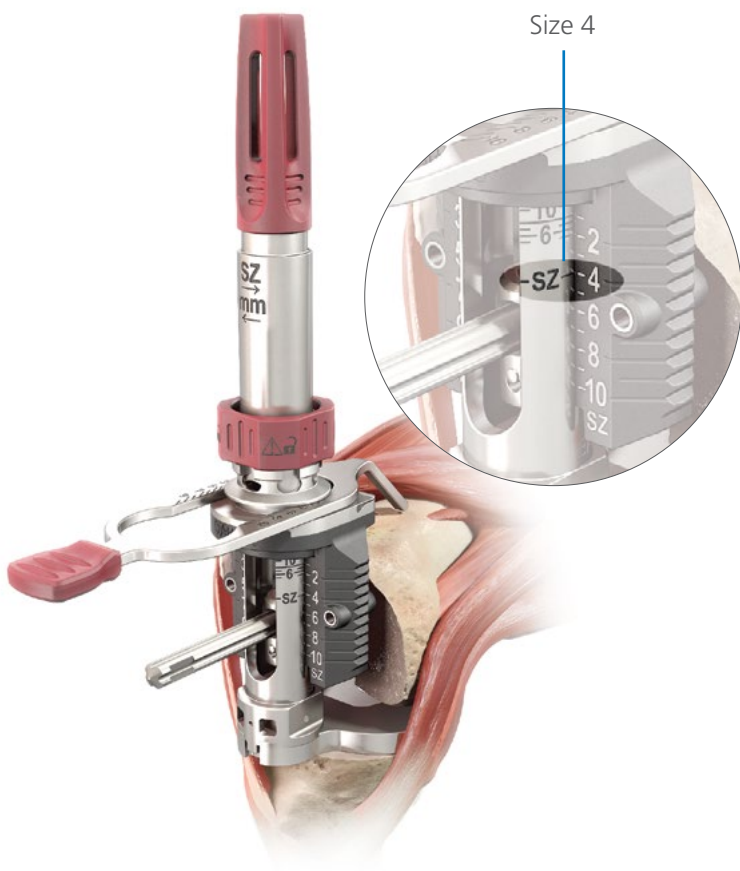
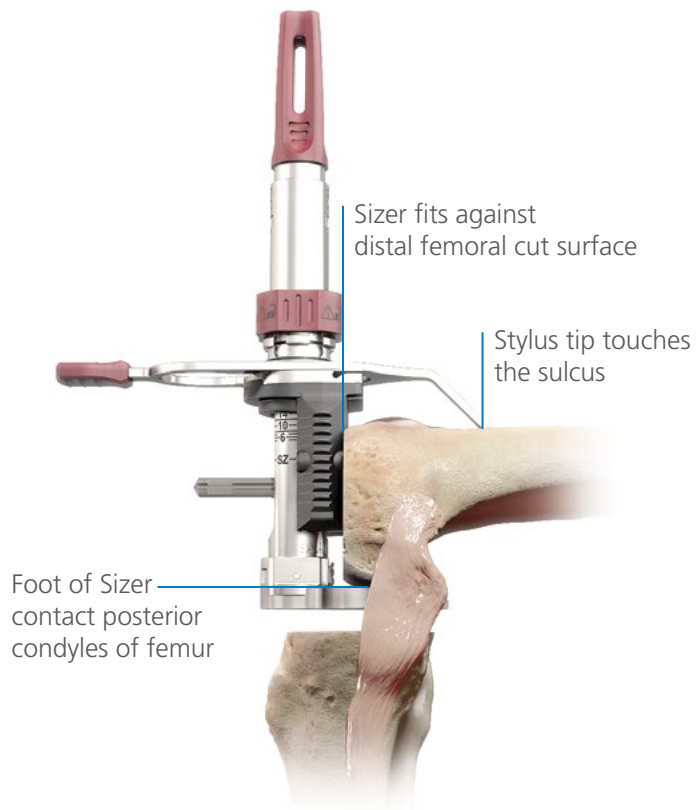
INFORMATION

Once the Foot of the Balanced Sizer have contacted the posterior femoral condyles, be careful not to excessively rotate the Tensioning Knob in the SZ direction as this could result in disassembling the device.

Balanced Femoral Sizing and Rotation

Confirm that the Guide is firmly placed against the distal femoral cut with the knee flexed at 90 degrees.

Adjust the superior-inferior position of the Stylus to indicate the proper femoral size. The position of the Stylus will then be located near the exit point of the Saw Blade.



Then read the femoral size at the "SZ" line of the Guide.



CAUTION

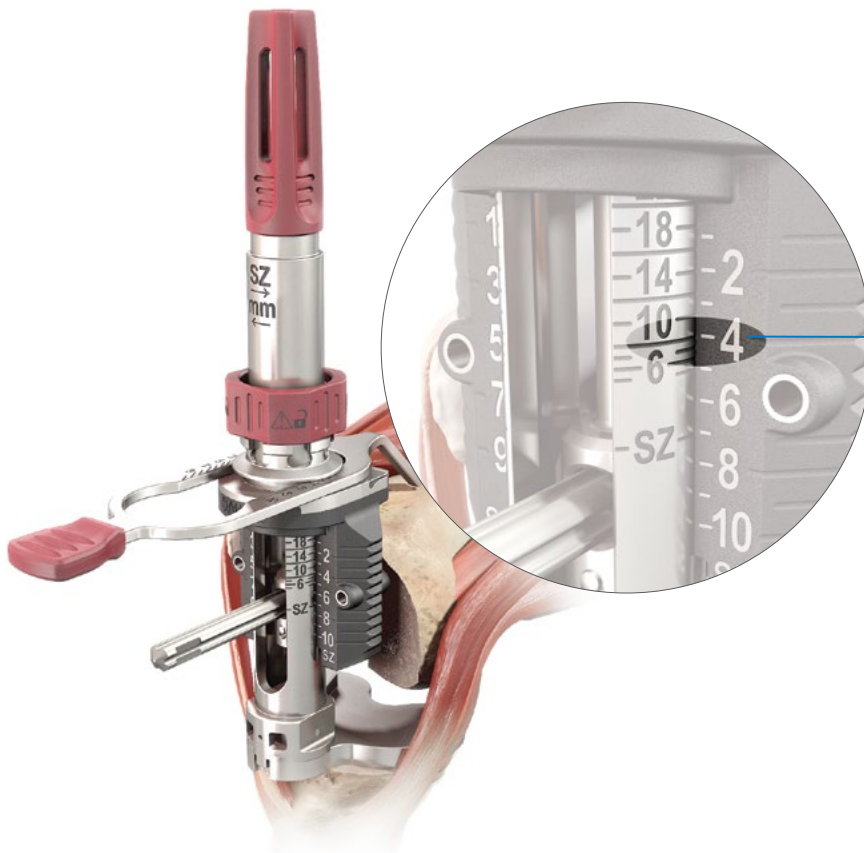
Be very careful not to apply a large force when contacting the anterior femur with the Stylus.

At this point in the procedure do NOT lock the assembly by turning the Locking Knob. The Locking Knob should only be turned to lock the assembly after completion of balancing and in preparation of pin placement.

Balanced Femoral Sizing and Rotation

Setting Femoral Rotation

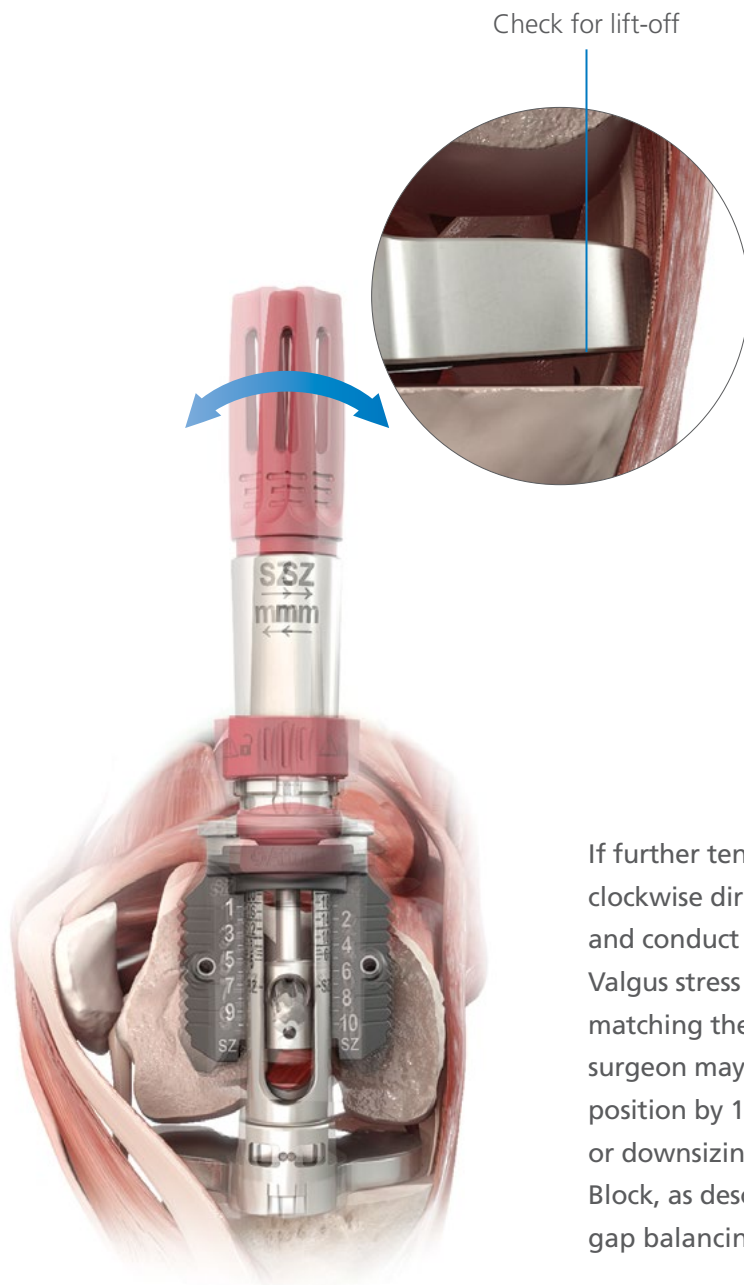
Turn the Tensioning Knob in a clockwise (MM) direction until the gap in flexion (Insert Thickness Measurement) matches the previously measured extension gap.



8 mm tibial insert thickness
for a size 4 femoral component

To determine the tibial insert thickness read the insert thickness scale across from the previously determined femoral size indication. e.g. This image indicates an 8 mm Tibial Insert for a size 4 Femoral component.

Balanced Femoral Sizing and Rotation



To assess the tension, hold the tibia firmly and use the Tensioning Knob to apply a Varus/Valgus stress whilst observing lift off between the Sizer Foot and the tibial cut.

If further tension is required, turn the Tensioning Knob in a clockwise direction until the next thickness of insert is reached and conduct a further assessment of the ligaments using a Varus/Valgus stress test. If the predicted insert thickness in flexion is not matching the previously measured extension thickness, then the surgeon may need to consider moving the femoral component position by 1.5 mm in an anterior or posterior direction, or upsizing or downsizing the femoral component, using the 4-in-1 Cutting Block, as described on page 35. Refer to page 67 for further gap balancing information.

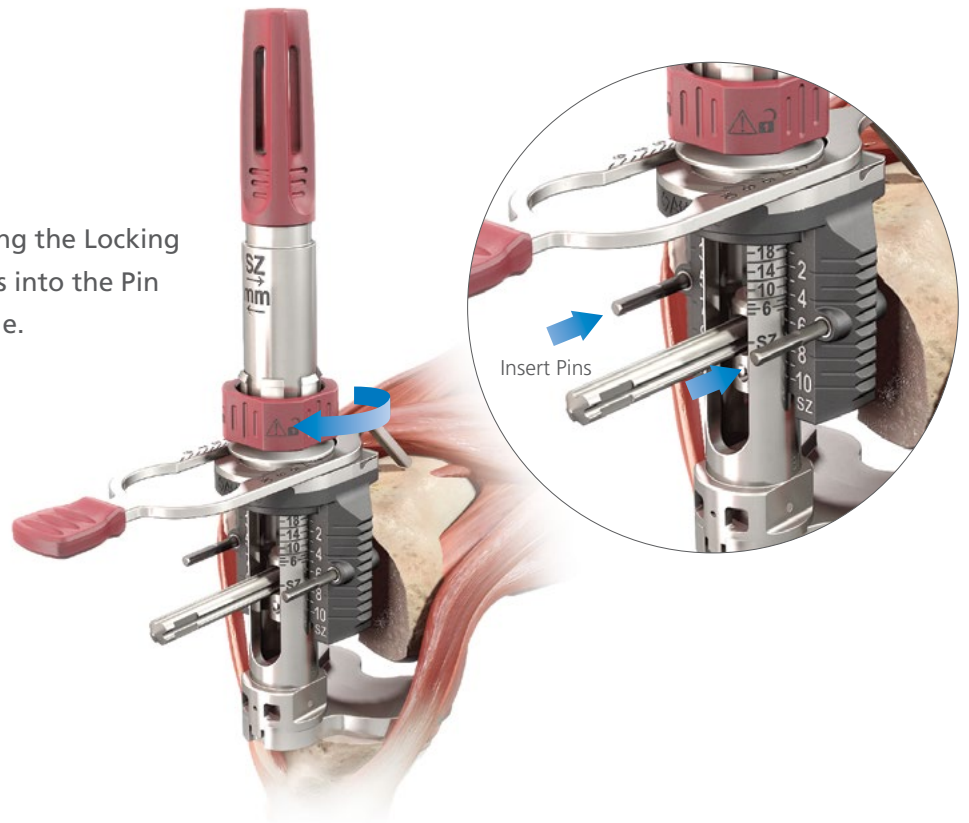


CAUTION

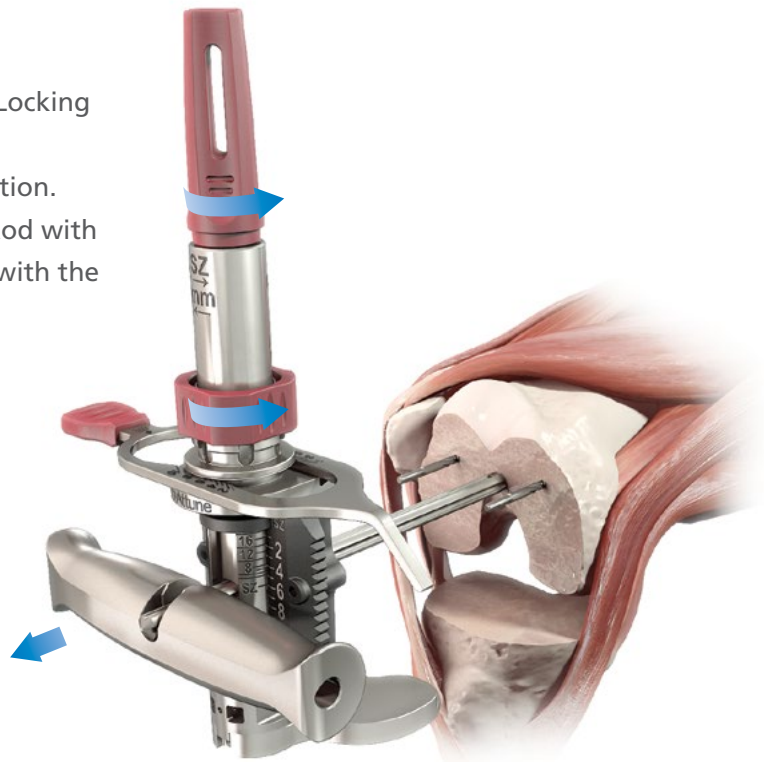
Over-rotation of the lateral condyle in the anterior direction could result in excessive femoral component external rotation and could be an indication of over-tightening.

Balanced Femoral Sizing and Rotation

Lock the assembly in place by rotating the Locking Knob clockwise. Insert Universal Pins into the Pin Holes on each side of the Sizing Scale.

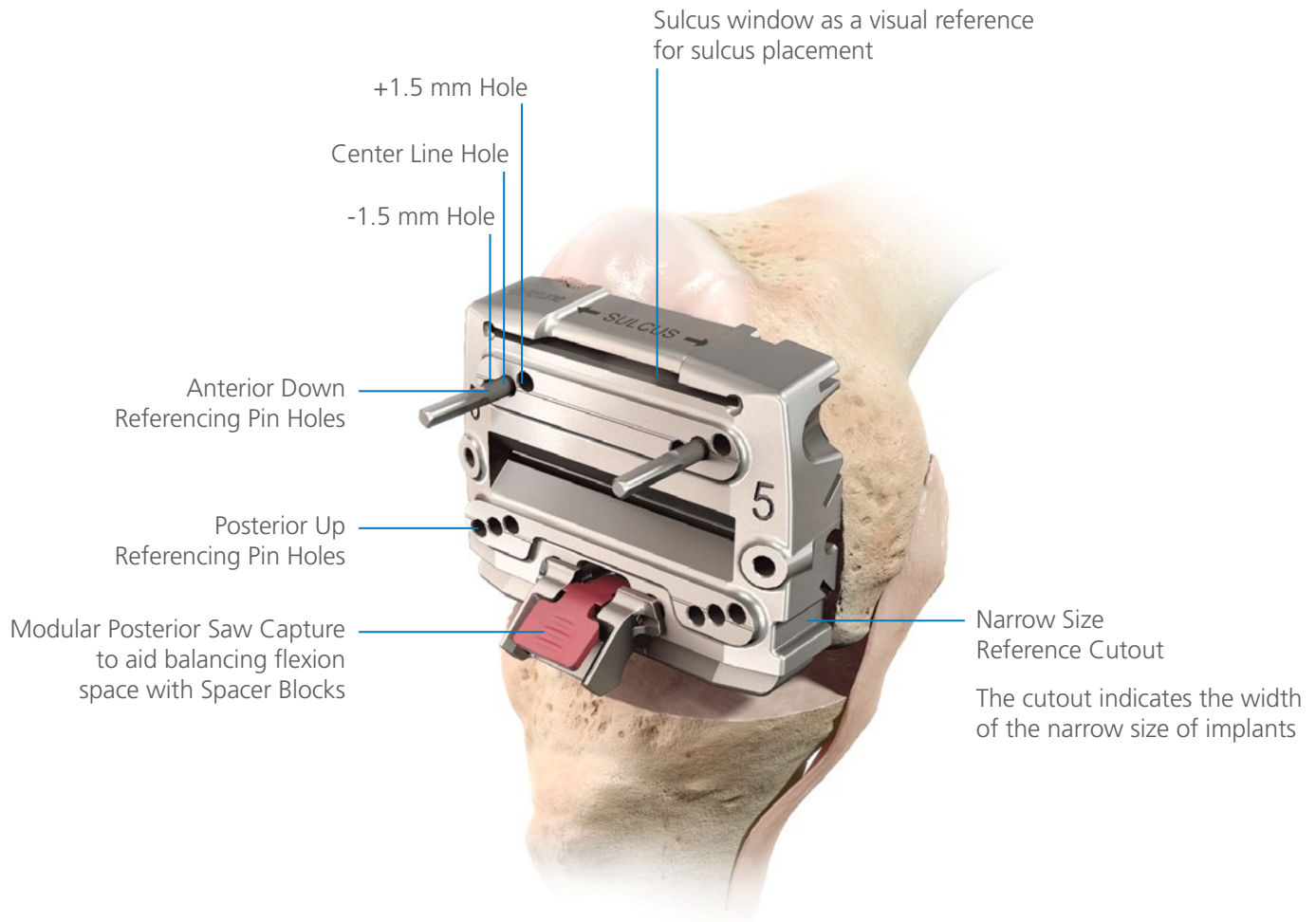


Remove the Balanced Sizer. First unlock the Locking Knob and release the tension by turning the Tensioning Knob in a counterclockwise direction. Attach the Rod Handle and remove the IM Rod with the Tapered Plug, engage the Tapered Plug with the guide to remove it from the bone.



Femoral Preparation

4-in-1 Cutting Block

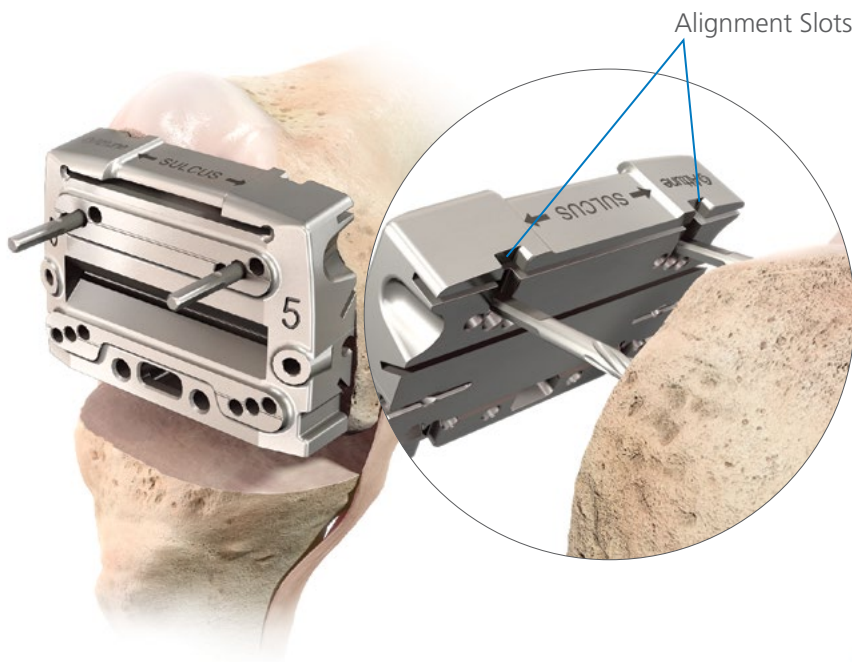


INFORMATION

The ATTUNE Knee System femoral components increase in size by a consistent 3 mm in the A/P direction. The Intuition A/P Cutting Blocks allow the surgeon to adjust the A/P position of the femoral component by 1.5 mm in either direction.

This creates the intraoperative flexibility to position the femoral component based on the surgeon's assessment of the flexion gap and the desired posterior condylar offset. See page 67 for more information on gap balancing.

Femoral Preparation



A/P and Chamfer Cuts

Select the A/P Chamfer Block that matches the femur size. Place the Block over the two anterior or posterior Universal or Non-Headed Pins through the pin holes marked with a center line.

The flexion space can be checked by using a Spacer Block placed below the A/P Chamfer Block with the Modular Posterior Saw Capture removed.



INFORMATION

When using the anterior offset pin holes, changing the size of the femoral component will alter the posterior femoral condyle resection.

To evaluate femoral size adjustments without altering the posterior femoral cut, place the A/P Chamfer Block onto the anterior Universal Pins and insert two additional pins through the posterior-up holes on the Block.

Then remove the anterior reference pins. This enables the femoral implant size to be adjusted without altering the flexion gap.

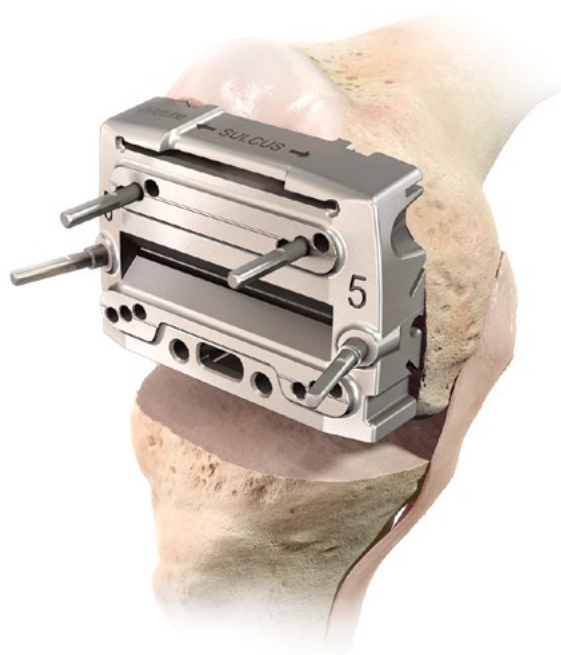
Alternatively, the Block can be moved 1.5 mm up or down (one hole location) to adjust the flexion gap, if necessary.

Femoral Preparation



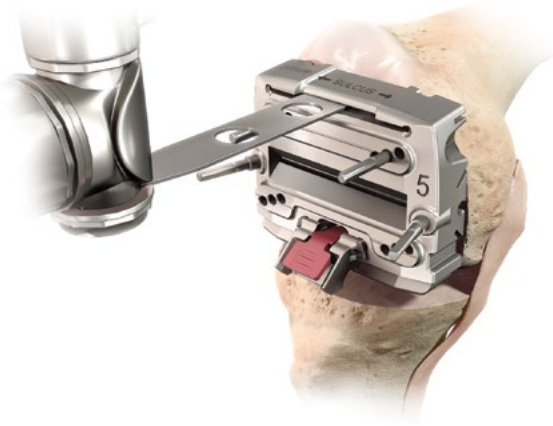
Angel Wing

Use the Angel Wing to confirm the location of the cut and the degree of rotation. The Block can also be used at this stage to assess the M/L width of the implant size for both the standard or narrow sizes.

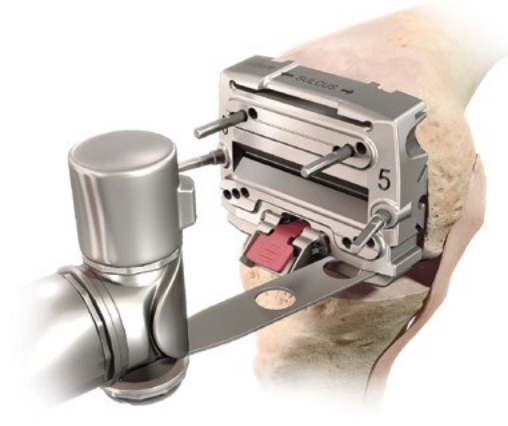


Insert Threaded Headed Pins into the divergent pin holes on the medial and lateral aspects of the A/P Chamfer Block.

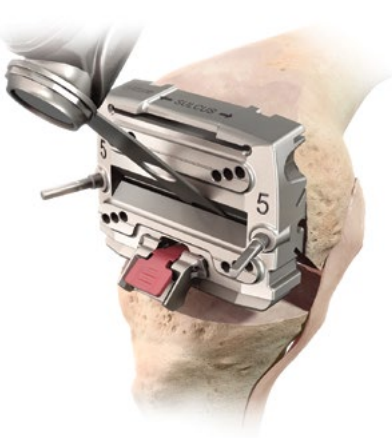
Femoral Preparation



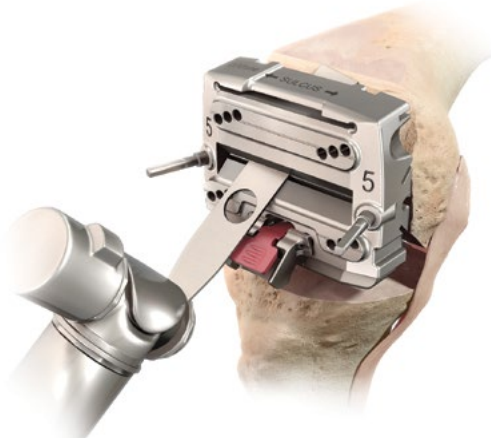
Recommended: Re-attach the appropriate size Modular Posterior Saw Capture to the A/P Chamfer Block to provide for capture guidance on all cuts.



Place Retractors to protect the medial and lateral collateral ligaments and the popliteal tendon. Then resect the anterior and posterior femur.



Remove the Universal or Non-Headed Pins and cut the anterior and posterior chamfers. Remove the Threaded Headed Pins and the A/P Chamfer Block.

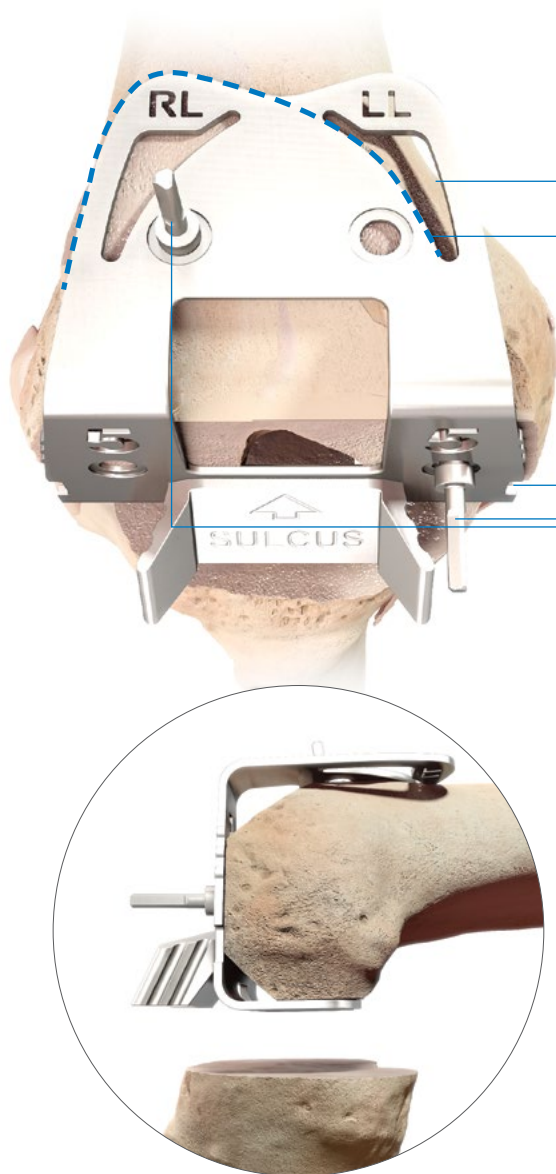


INFORMATION

The posterior Saw Captures are open medially and laterally to accommodate complete saw cuts. To reduce the risk of inadvertent Saw Blade kickout, point the Blade slightly toward the midline before starting the Saw.

Posterior Condyle Preparation

Removal of Excess Bone



Reference Window

Dotted lines indicate the outer edges of the final component

Cutouts indicate narrow size

For optimal stability, place Base Pins as shown

To avoid impingement in flexion, remove any excess bone between the posterior tibial implant and the posterior femoral condyles in flexion. To aid in osteophyte and excess bone removal, select the Femoral Finishing Guide that corresponds to the femoral trial component size. Push the instrument onto the resected distal femur and position mediolaterally, using the lateral anterior profile of the instrument as a guide. The inner surface of the windows represents the anterior medial aspect of the implant and the outside profile of the anterior face represents the anterior lateral aspect of the implant.

Fix the instrument flush to the distal cut using Base Pins.



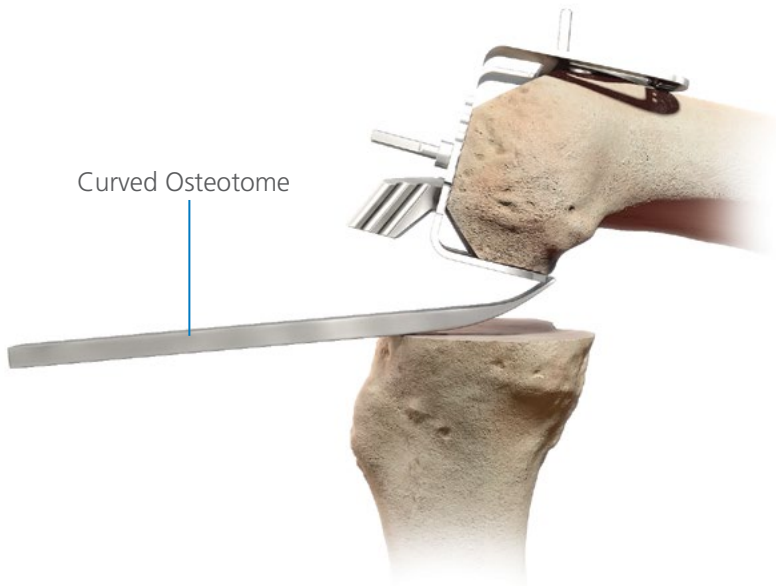
INFORMATION

The cutouts on the sides of the Femoral Finishing Guide show where the outer edge of the narrow component is located. If there is no cutout, a narrow component is not available for that size. Narrow components are available for sizes 3, 4, 5 and 6.



Base Pin

Posterior Condyle Preparation



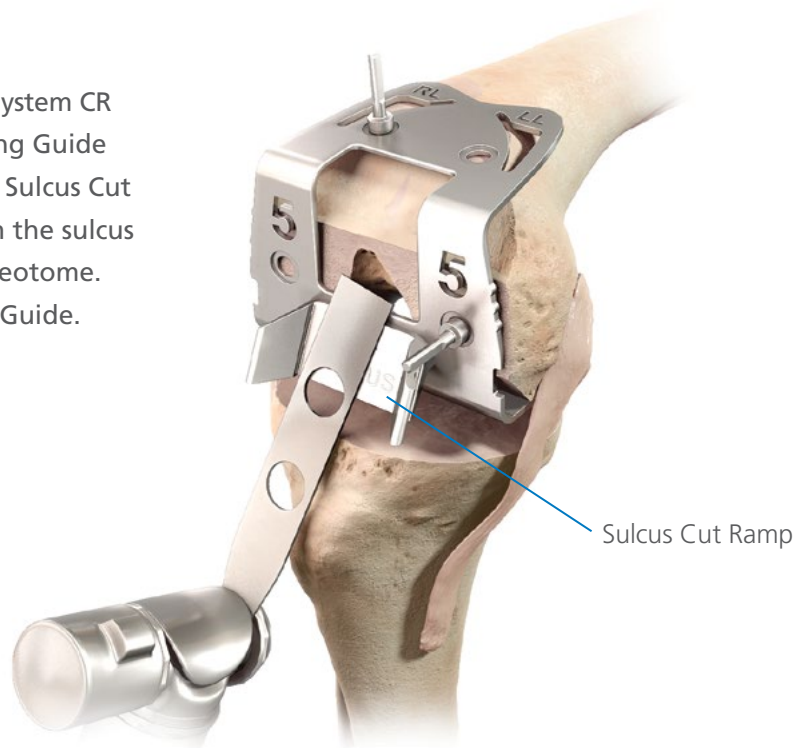
Removal of Excess Bone (Cont.)

With the Femoral Finishing Guide in place, verify that any excess bone or residual osteophytes in the posterior recesses have been removed. If not, use a Curved Osteotome or Gouge to remove any remaining bone that can be seen beyond the end of the Femoral Finishing Guide feet.

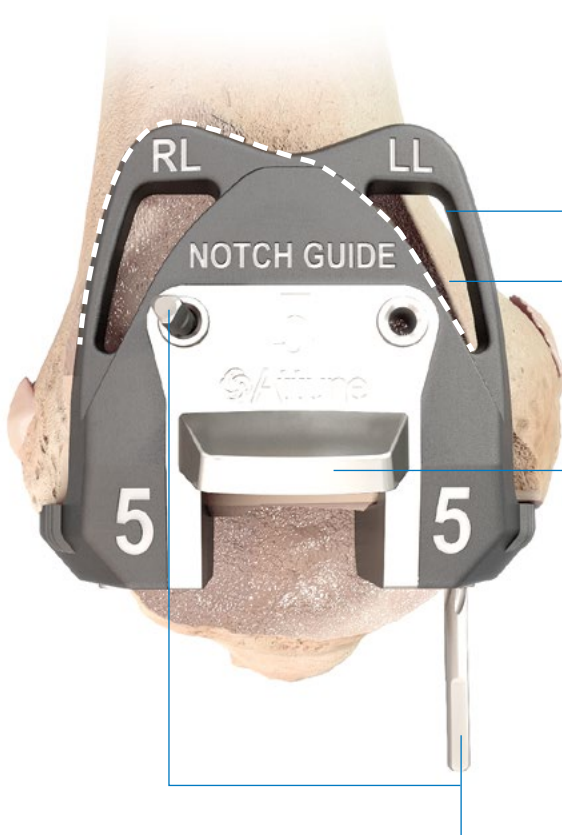
Always work carefully under direct vision to avoid damage to the neurovascular structures in the popliteal fossa.

CR Sulcus Preparation

When implanting an ATTUNE Knee System CR component, use the Femoral Finishing Guide to perform the sulcus cut. Using the Sulcus Cut Ramp as a guide, remove bone from the sulcus with the Rasp, a 0.5 inch Saw or Osteotome. Then remove the Femoral Finishing Guide.



Femoral Resection – PS Notch Cuts



Reference Window

Dotted lines indicate the outer edges of the final component

The tongue of the Notch Guide is extended to provide a long cutting surface for an 18 degree cut

For optimal stability, place Threaded Headed Pins as shown

When implanting an ATTUNE Knee System PS component, use the Notch Guide to perform the notch cut. The profile of the Notch Guide provides anterior and distal references to the width of the implant. In addition, windows in the Notch Guide provide additional reference.

The inner surface of the windows represents the anterior medial aspect of the implant and the outside profile of the Notch Guide represents the anterior lateral aspect of the implant. The references are designed to confirm optimal component size and position. The tongue of the Notch Guide is extended to provide a long cutting surface for an 18 degree cut.


Position the Notch Guide on the resected anterior and distal surfaces of the femur as far laterally as possible while assuring that the lateral border of the implant does not overhang the lateral femoral cortex. Pin the Guide in place using the Threaded Headed Pins.



INFORMATION

The cutouts on the sides of the Notch Guide show where the outer edge of the narrow component is located. If there is no cutout, a narrow component is not available for that size. Narrow components are available for sizes 3, 4, 5 and 6.

Femoral Resection – PS Notch Cuts

Perform the notch cut. 

18 Degree Cut

Reference Window

Width Reference

Narrow Size
Reference Cutout



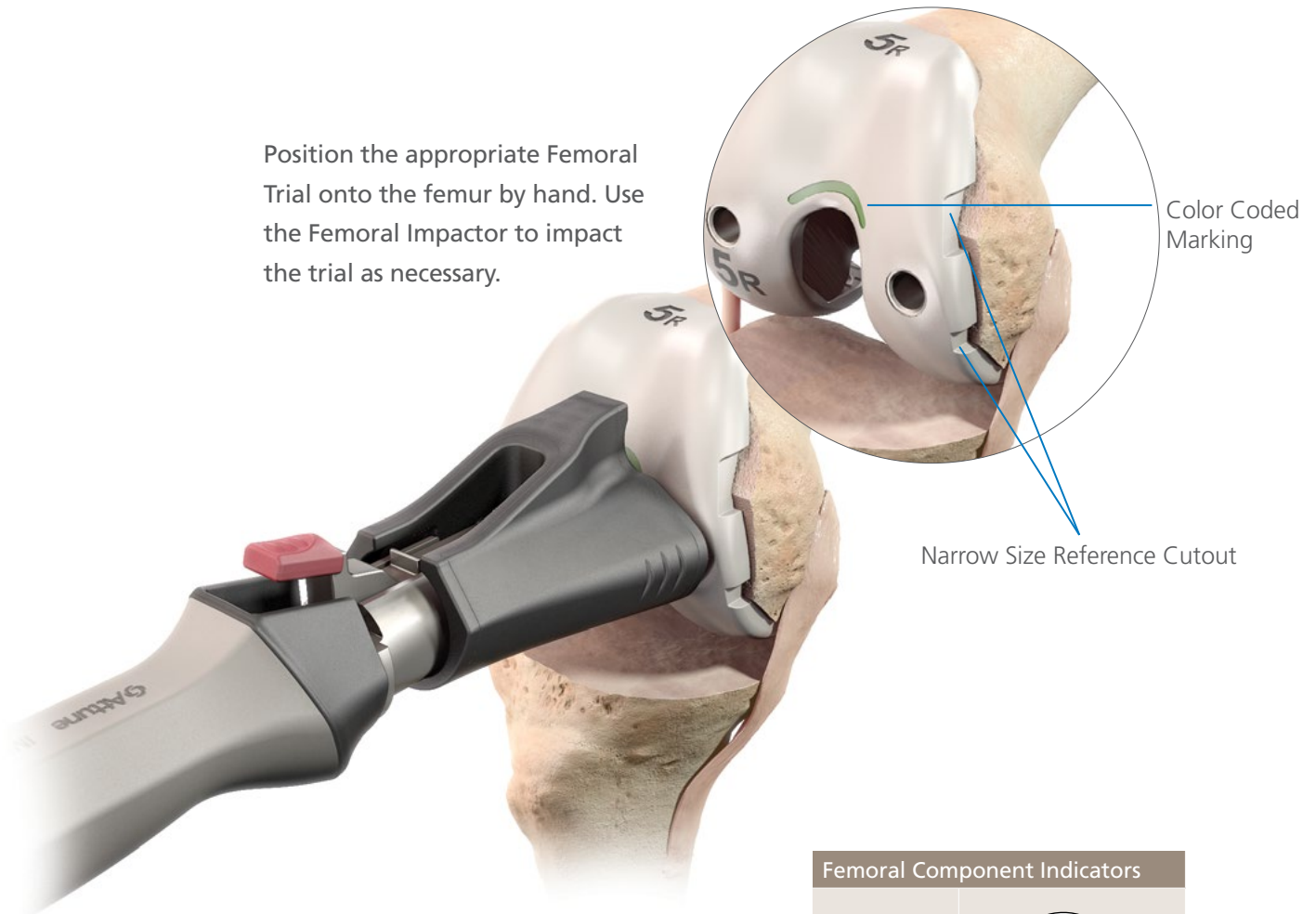
CAUTION

When completing the notch cut, be careful to avoid excessive angulation of the Saw Blade or penetration past the posterior femoral cortex to avoid injury to the neurovascular structures.

Avoid undercutting the condyles.

Trial Reduction

Position the appropriate Femoral Trial onto the femur by hand. Use the Femoral Impactor to impact the trial as necessary.



Femoral Component Indicators	
CR	
PS	



INFORMATION

If the trial is not seating properly, the bone cuts may need to be rechecked. The Femoral Trial should be fully seated prior to joint reduction.



INFORMATION

The cutouts on the sides of the Femoral Trial show where the outer edge of the narrow component is located. If there is no cutout, a narrow component is not available for that size. Narrow components are available for sizes 3, 4, 5 and 6.

Trial Components

Tibial Trial

Attach the Alignment Handle to the appropriate size Tibial Base Trial and place onto the resected tibial surface. Assess the position of the base to maximize tibial coverage while avoiding overhang. The rotation of the Tibial Base Trial is typically centered on the junction between the medial and central third of the tibial tubercle.



Fixed Bearing

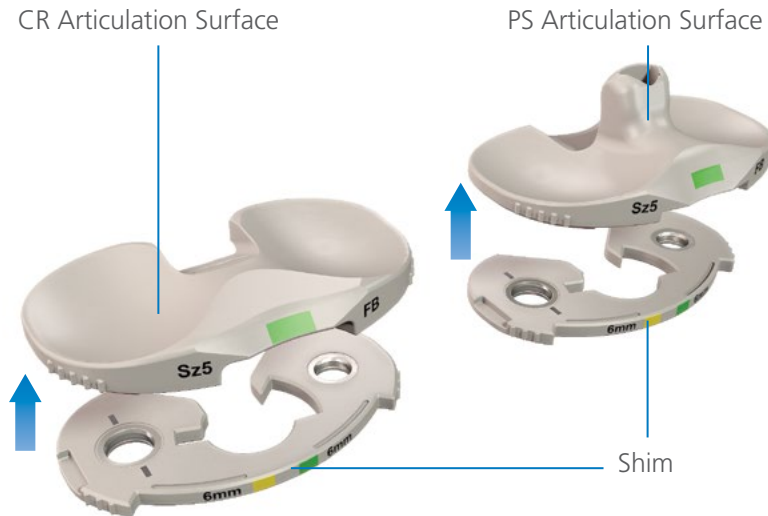
For fixed bearing tibial components, insert the Non-Spiked Evaluation Bullet into the cutout of the Base Trial by hand. The Non-Spiked Evaluation Bullet is used when allowing normal internal/external rotation of the tibial component during a range of motion to dictate the optimal placement of the tibial base. The bone can be marked for Base Trial orientation reference.



INFORMATION

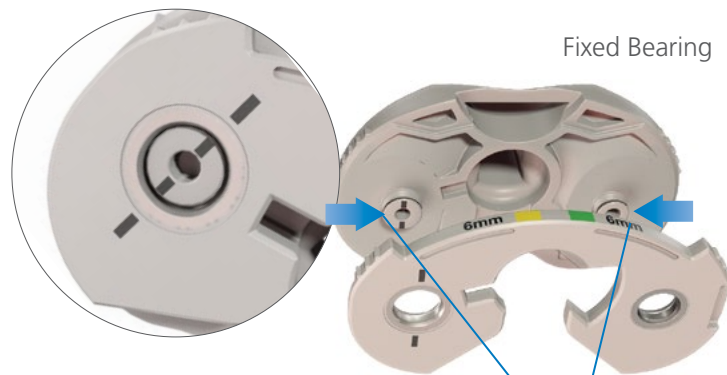
Tibial components can be trialed before preparing the tibia.

Trial Components



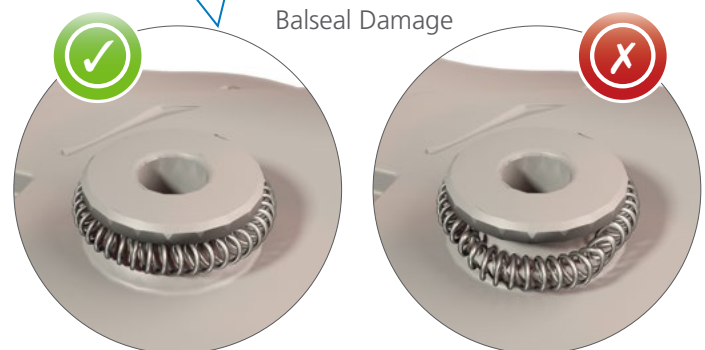
Select the Tibial Articulation Surface Trial that matches the femoral size and style (CR or PS fixed bearing), and attach the corresponding size Shim of the appropriate thickness (5 mm, 6 mm, 7 mm, 8 mm, 10 mm, 12 mm,

14 mm and 16 mm for CR and PS, and in addition 18 mm for PS, for core sizes 3-8). **The thickness markings on the insert trials and the final insert implant indicate the insert thickness without the base thickness included.**



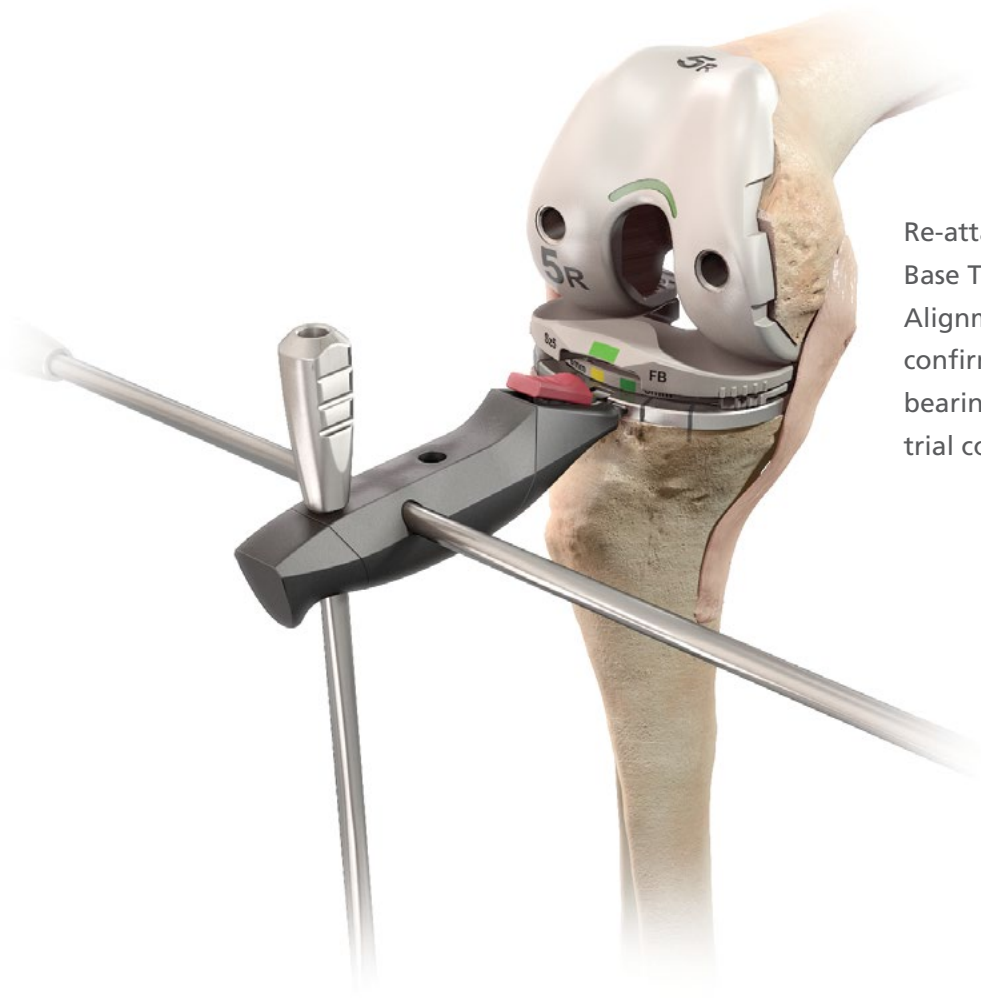
Ensure that the Articulation Surface Trial and Shim are securely engaged, as these two components make up the Insert Trial. Attach the assembly into the Tibial Base Trial.

Check for Balseal damage. If damage is observed, replace the damaged component.



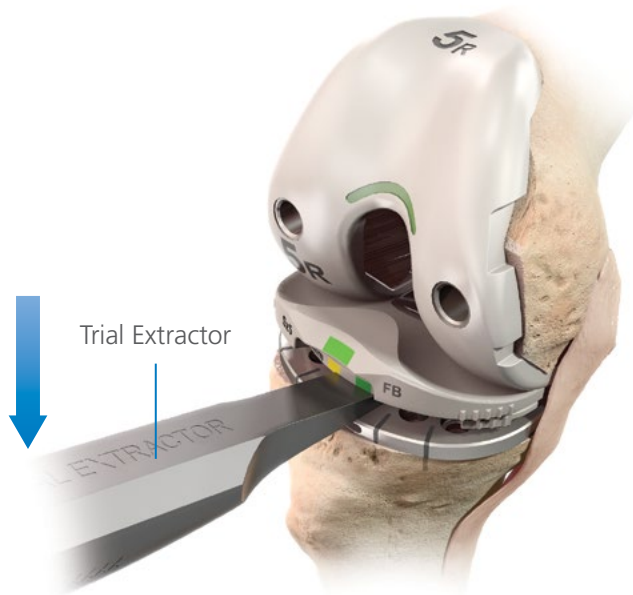
Trial Components

Remove the Alignment Handle from the Tibial Base Trial and, with the trial prosthesis in place, extend the knee carefully, noting the anteroposterior and mediolateral stability, and the overall alignment in the A/P and M/L planes. If there is any indication of instability, use the next thicker Shim and repeat the check. Select the trial assembly that provides the greatest stability in flexion while still allowing full extension. Verify that the posterior femoral condyles are sufficiently prepared to prevent impingement on the tibial insert in deep flexion.



Re-attach the Alignment Handle to the Tibial Base Trial and then attach the two-part Alignment Rod to the Alignment Handle and confirm the overall alignment. For a fixed bearing component, mark the position of the trial component on the anterior tibial cortex.

Trial Components



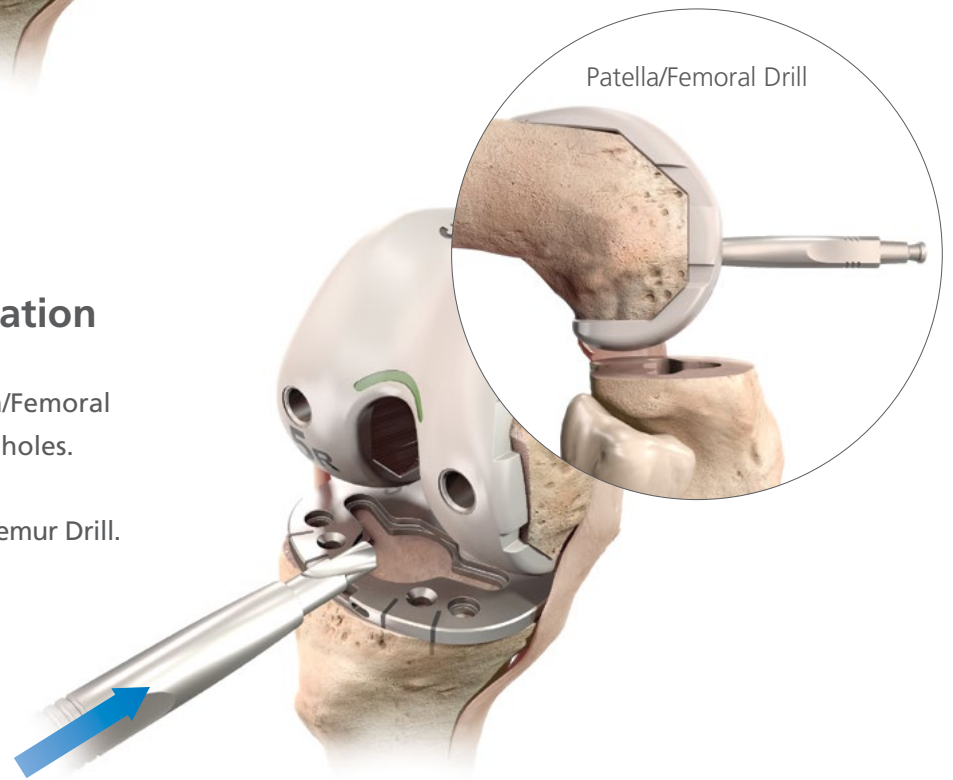
Fully flex the knee, and remove the Insert Trial. The Trial Extractor can be used to aid in removal of Insert Trials.

Insert the Trial Extractor between the Tibial Base Trial and the Shim and lever the handle towards the foot in order to remove the Insert Trial.

Femoral Lug Hole Preparation

For implant sizes 3-10, use the Patella/Femoral Drill to drill through the appropriate holes.

For implant sizes 1-2, use the size 1-2 Femur Drill.



INFORMATION

Do not insert the Trial Extractor between the Shim and the articulation surface to prevent damage to the connection feature.

The Trial Extractor can also be used to remove the Femoral Trial.

When removing the Tibial Trials with the Trial Extractor, avoid engaging the Keel Punch to prevent damage to the Trial Extractor.

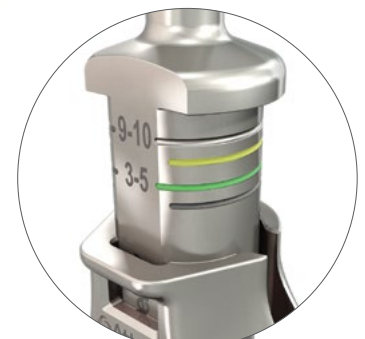
Tibial Preparation

Re-attach the Handle to the Tibial Base Trial and re-insert it on the resected tibial surface, (aligning it with the mark on the bone for a Fixed Bearing Tibial Construct).

Attach the Tibial Drill Tower to the Tibial Base Trial by inserting the spikes on the underside of the Tower through the two inside holes on the anterior aspect of the base trial. The spikes provide fixation for both the Drill Tower and the Base Trial. If additional fixation is desired, place Base Pins through the two outside holes on the anterior aspect of the Base Trial.



Base Pins



Use the Tibial Drill to ream the tibia to where the line marked on the side of the Drill aligns to the top surface of the tower. The Line marking corresponds to the Tibial Base size. Bone debris from drilling could prevent the Keel Punch from seating completely in the Base Trial. To prevent this, flush out the cavity after drilling.



CAUTION

Care should be taken not to protrude through the medial tibial cortex if using the medial Base Pin.

Care should be taken not to overdrill. An optional Drill Stop is available.



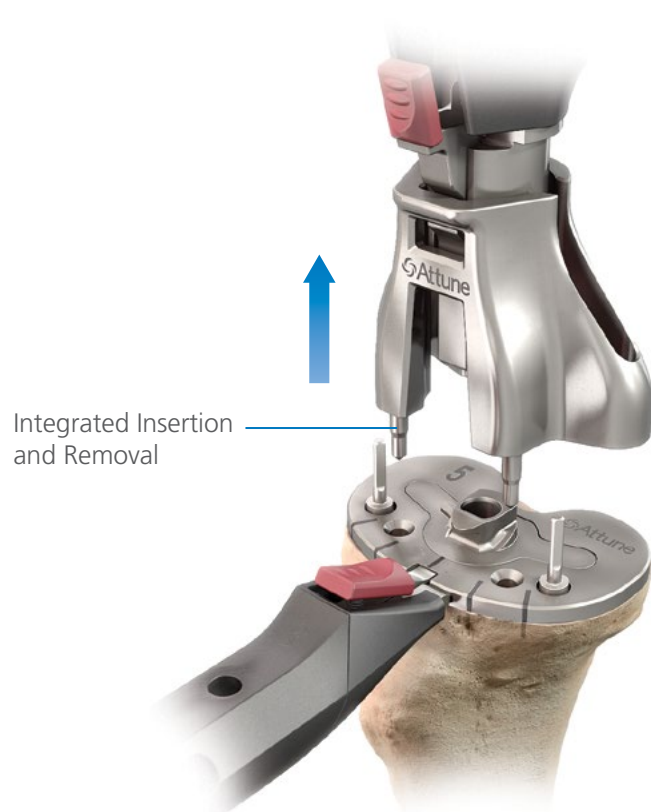
Tibial Preparation



Keel Punch

Attach the correct size Keel Punch to the Impaction Handle, and insert the assembly into the Tibial Drill Tower. Impact the assembly into the cancellous bone until the Keel Punch is seated flush on the Tibial Base Trial.

Use the anterior window in the tower to monitor the progress of the Keel Punch while impacting.



When the Keel Punch is fully seated, the Impaction Handle will automatically disengage from the Keel Punch, allowing the Impaction Handle and the Tibial Drill Tower to be removed together.

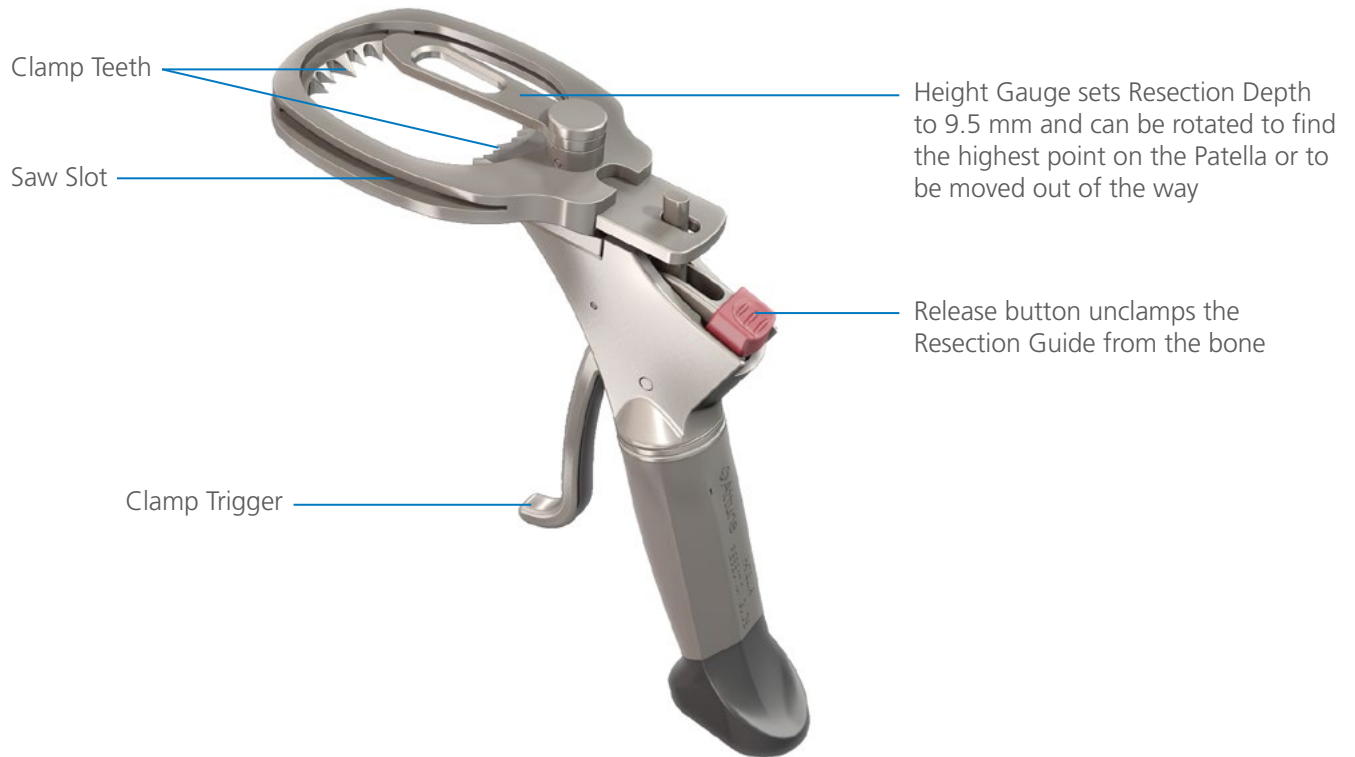


INFORMATION

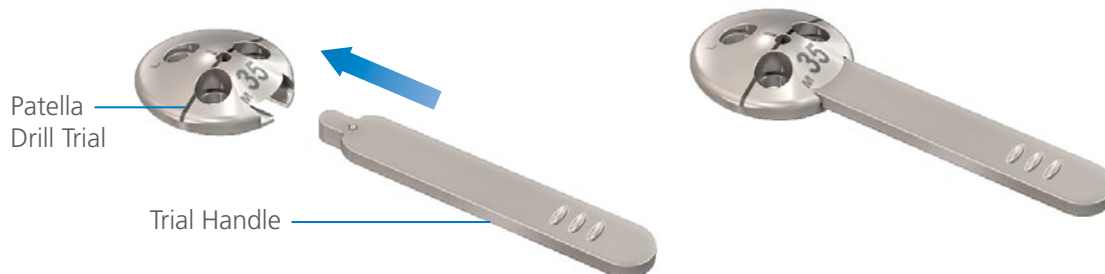
Optional: If desired, perform a final trial reduction by inserting the appropriate trial components and repeating the previous trial evaluation.

Patella Resection and Preparation – Instrument Assembly

Patella Resection Guide



Patella Drill Trials



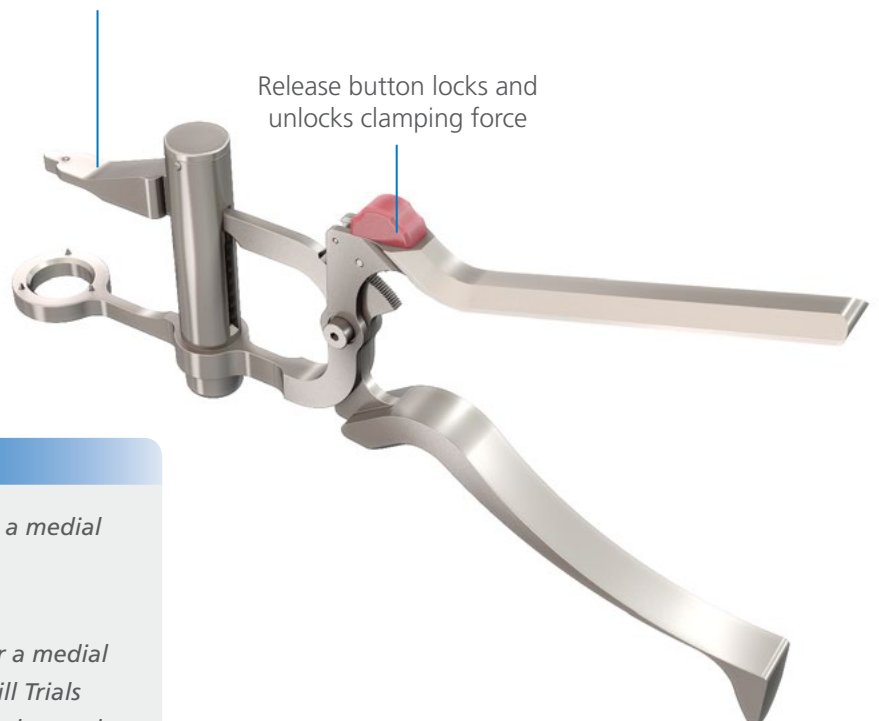
Assemble by inserting the Trial Handle into the slot on the Drill Trial until it clicks into place

Patella Resection and Preparation – Instrument Assembly

Patella Modular Clamp



Clamp Connection Post attaches to either the Drill Trials or Clamp Ring with a snap-on mechanism




INFORMATION

The patella instrumentation is designed for a medial approach only.

The clamp and trial handle are designed for a medial approach only. The Resection Guide and Drill Trials (used as stand alone without the clamp) can be used for a medial or lateral approach.

Patella Resection



Use the Caliper to estimate the thickness of the patella and evaluate the level of bone resection. The Height Gauge on the Patella Resection Guide accounts for a resection of 9.5 mm of bone, which is the average thickness of the ATTUNE Knee System Patella components. 



Place the leg in extension and evert the patella.

Position the Patella Resection Guide so the Height Gauge is against the articular surface of the patella. Align the serrated jaws at the medial and lateral margins of the articular surface. Engage the largest tooth on the lateral side then engage the largest tooth on the opposite side to temporarily secure the clamp while allowing for rotation of the patella until the inferior and superior orientation is achieved and clamp fully.



CAUTION

If the patellar thickness is less than 21.5 mm, the thickness of the bone remaining after resection would be less than 12 mm and resecting less bone should be considered.

If less resection is required, the Patella Guide Shim is available which reduces the depth of the resection to 7.5 mm.



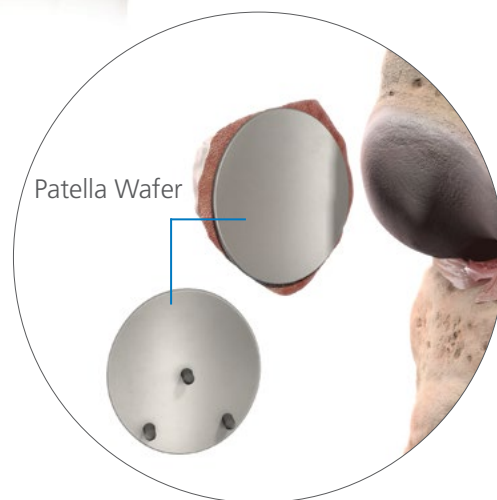
INFORMATION

The resection progresses from the medial chondro-osseous junction to the lateral chondro-osseous junction.

Patella Resection



Perform the resection using an Oscillating Saw through the Saw Capture.



If desired, place a Patella Wafer on the resected surface by hand to protect the patellar bone bed.



INFORMATION

When resecting the patella, care should be taken to avoid Saw Blade excursion into the Femoral Trials or Implants.

Patella Preparation

Patella Implant Options



Anatomic Patella



Medialized Dome Patella

Patella Size Chart	
Size	Thickness
29	8.5 mm
32	9 mm
35	9.5 mm
38	10 mm
41	10.5 mm

Two patella options are available; the Medialized Dome Patella or the Anatomic Patella.

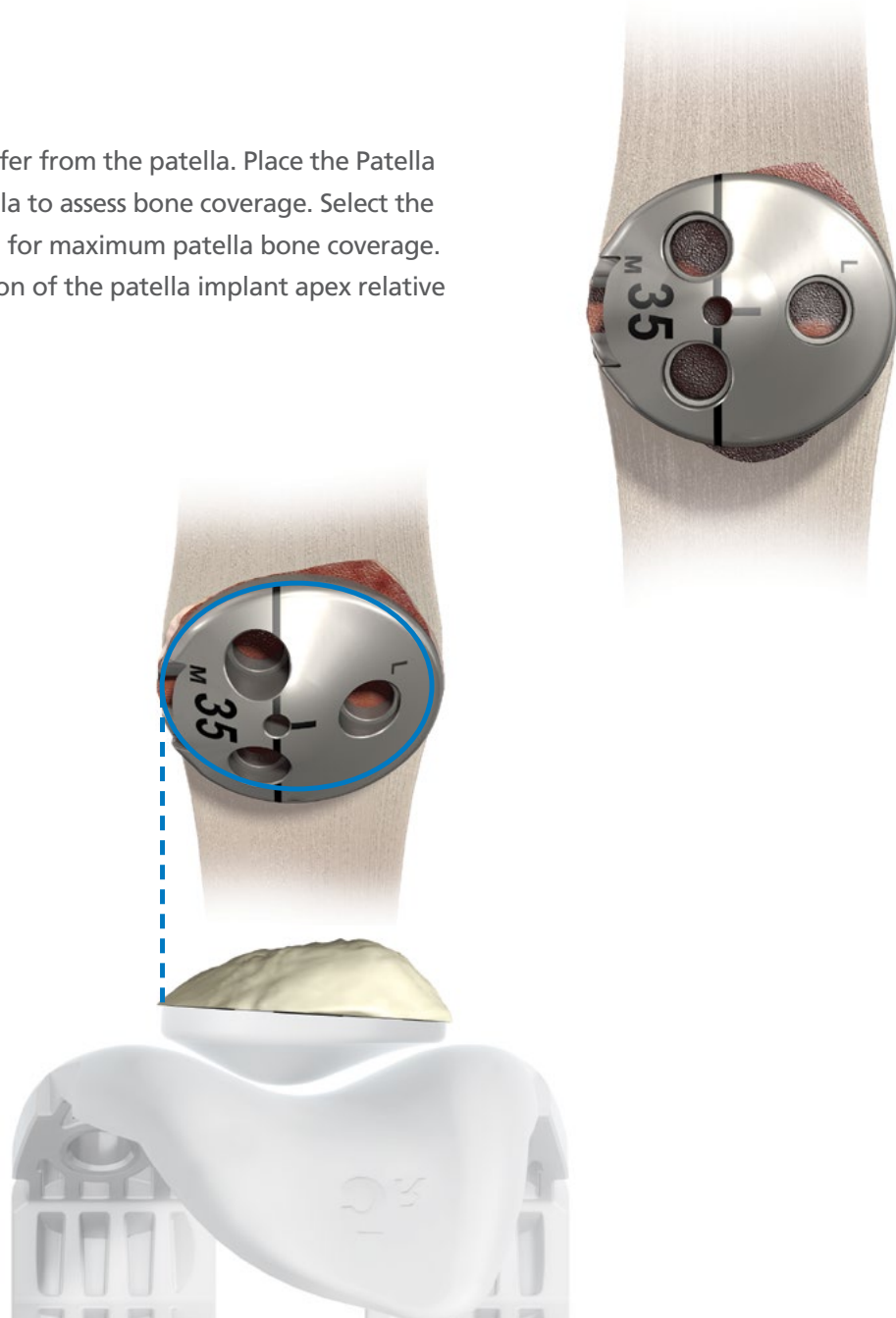
The Anatomic Patella is designed to be conforming with the femoral component and has a built in range of +/- 15 degrees freedom of rotation from its optimal position. Therefore, accurate alignment of the Patella Drill Trial is important for proper patella placement and tracking.

The following steps will aid in accurate alignment of both patella designs, but is particularly critical for the Anatomic Patella.

Patella Preparation

Patella Drill Trialing

If used, remove the Patella Wafer from the patella. Place the Patella Drill Trial on the resected patella to assess bone coverage. Select the correct size of Patella Drill Trial for maximum patella bone coverage. Verify the medial lateral location of the patella implant apex relative to the native anatomy ridge.



INFORMATION

Optional Technique:

Prior to resecting the patella a small hole can be drilled through the apex of the native patella bone (1-2 mm deeper than the intended amount of resection). Once the patella has been resected the remainder of the hole will be present on the resected bone surface. The Drill Trial has a small hole through the center of the apex, representing the peak of the patella implant.

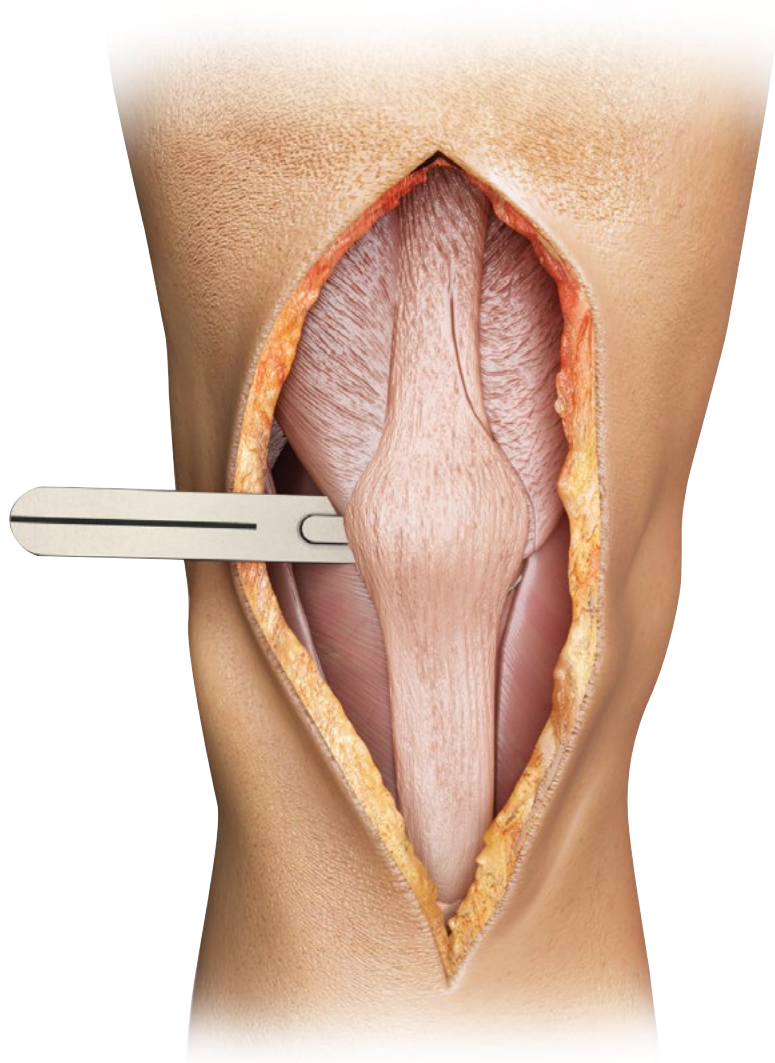
This hole can be visually aligned with the pre-drilled hole on the resected patella surface to aid in anatomic placement of the trial.

Patella Preparation

Patella Drill Trialing

Press the trial onto the bone manually or with the Patella Modular Clamp and Clamp Ring to engage spikes.

The Drill Trials have one larger central spike to allow engagement of only the central spike so that the Drill Trial may be rotated about the central axis to aid in assessment of its optimal position prior to being fully seated on bone.



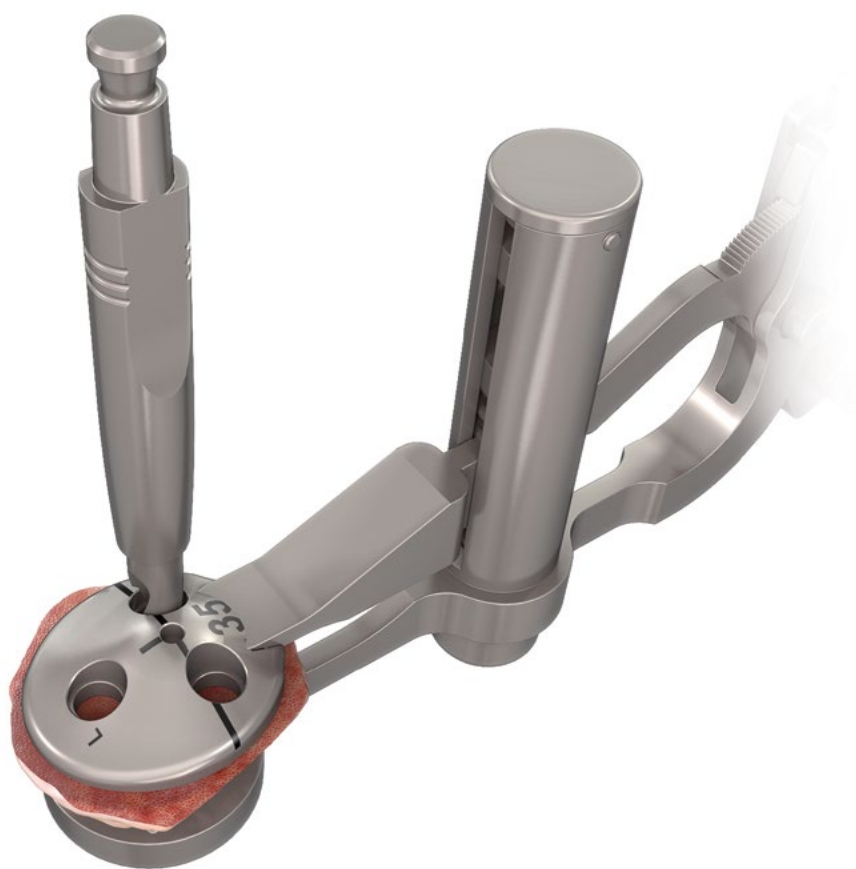
The Trial Handle may be used to aid in determining optimal position.

Reduce the patella with the Drill Trial in place and Trial Handle attached. When properly aligned, the Trial Handle should be perpendicular to the long axis of the leg and parallel to the prosthetic joint line.

If the Drill Trial/Trial Handle appears to be misaligned to the long axis or joint line, the trial should be removed from the patella and reset until proper alignment is achieved.

Patella Preparation

Use the Patella Modular Clamp to secure the Drill Trial if desired. Drill the holes using the Patella/Femoral Lug Drill.



CAUTION

If the surgeon is not satisfied with alignment or tracking of the Anatomic Patella Trial after drilling the peg holes, it is recommended to use a Medialized Dome Patella.

Tibial Base Implantation

Cementing Technique



During cementing of implants, movement of the components should be minimized while the cement is curing.

Prepare the sclerotic bone to ensure a continuous cement mantle with good cement interdigitation of 2 mm - 4 mm. This can be done by drilling holes and cleansing the bone with Pulsatile Lavage. Pack residual small cavity bone defects with cancellous autograft, allograft, or synthetic bone substitutes.

Base Protector



Place a layer of cement on the bone, the implant, or both.



CAUTION

Blood lamination can reduce the mechanical properties of the cement; therefore, it is vital to choose cement that reaches its working phase quickly.

Tibial Base Implantation



Carefully insert the Tibial Base, avoiding malrotation. Select the fixed bearing Tibial Impactor.



FB Tibial Impactor



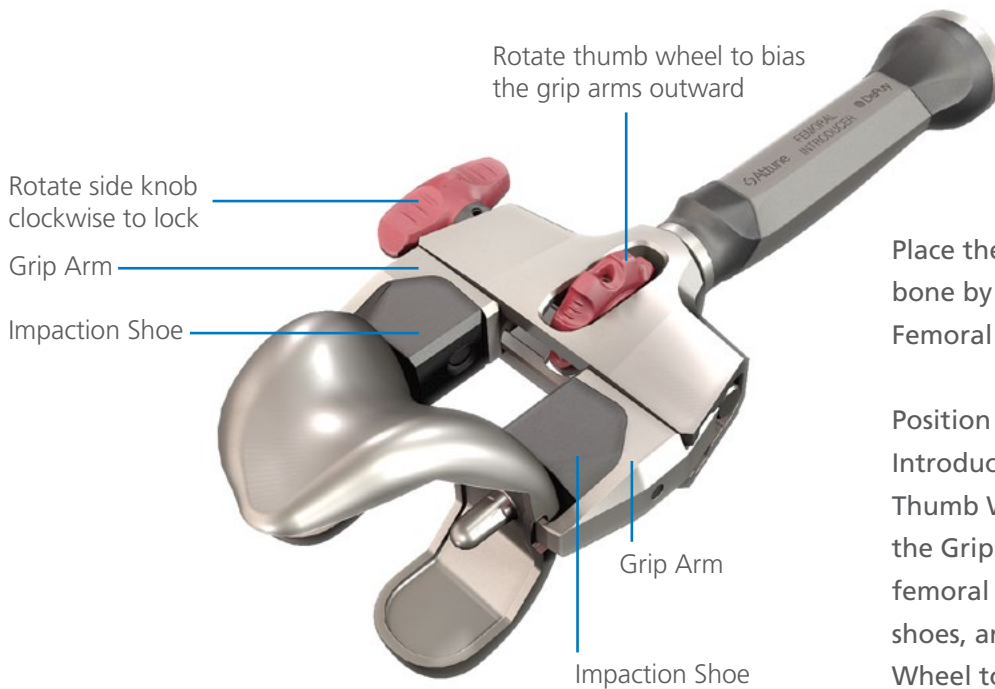
With the base inserted, impact it with several blows from a Mallet to the top of the Impactor. Then use a Curette to remove all extruded cement.



CAUTION

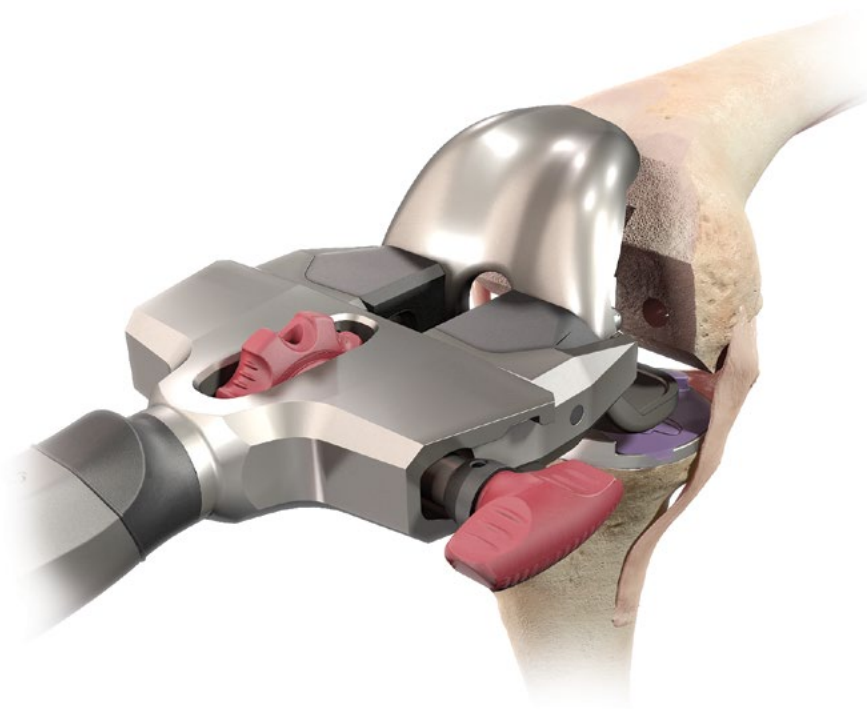
To prevent damage to the bearing surface, do not remove the Base Protector before impacting the base.

Femoral Component Implantation



Place the femoral component onto the bone by hand or, if preferred, use the Femoral Introducer.

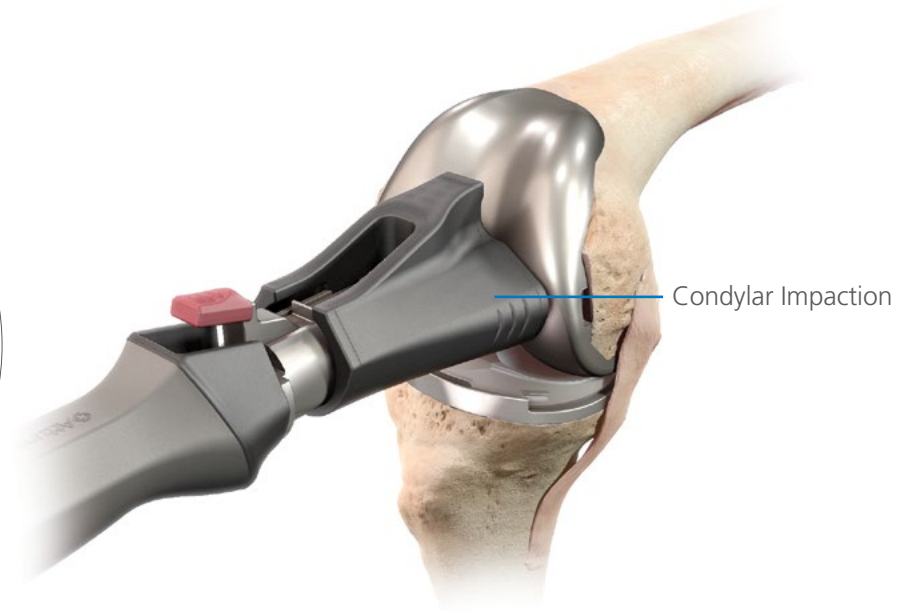
Position the femoral component on the Introducer by rotating the red Central Thumb Wheel on the Introducer to move the Grip Arms outward. Then push the femoral component against the impaction shoes, and rotate the Central Thumb Wheel to move the Grip Arms inward so that the arms engage in the slots on the femoral component. Rotate the Side Knob clockwise to lock and secure the implant.



Begin inserting the femoral component by engaging the Femoral Lugs in the lug holes of the distal femur, and deliver several Mallet blows to the Introducer.

To release the Femoral Introducer, rotate the Side Knob counterclockwise and rotate the red Central Thumb Wheel to move the Grip Arms outward.

Femoral Component Implantation



For final femoral component impaction, attach the Impaction Handle to the Femoral Impactor head.

Use a combination of condylar and notch impaction to seat the femoral component. Then use a Curette to remove all extruded cement.



INFORMATION

The Femoral Introducer is not designed for nor intended to be used for femoral component removal.



Tibial Insert Implantation

A trial reduction may be performed using Insert Trials.

Fixed Bearing

For fixed bearing components, place the Insert Trial on the Tibial Base. Verify that the Insert Trial does not tilt up off the front of the base during the range of motion test. This could indicate that the PCL is too tight.

Remove loose fragments or particulates from the Final Tibial Base.

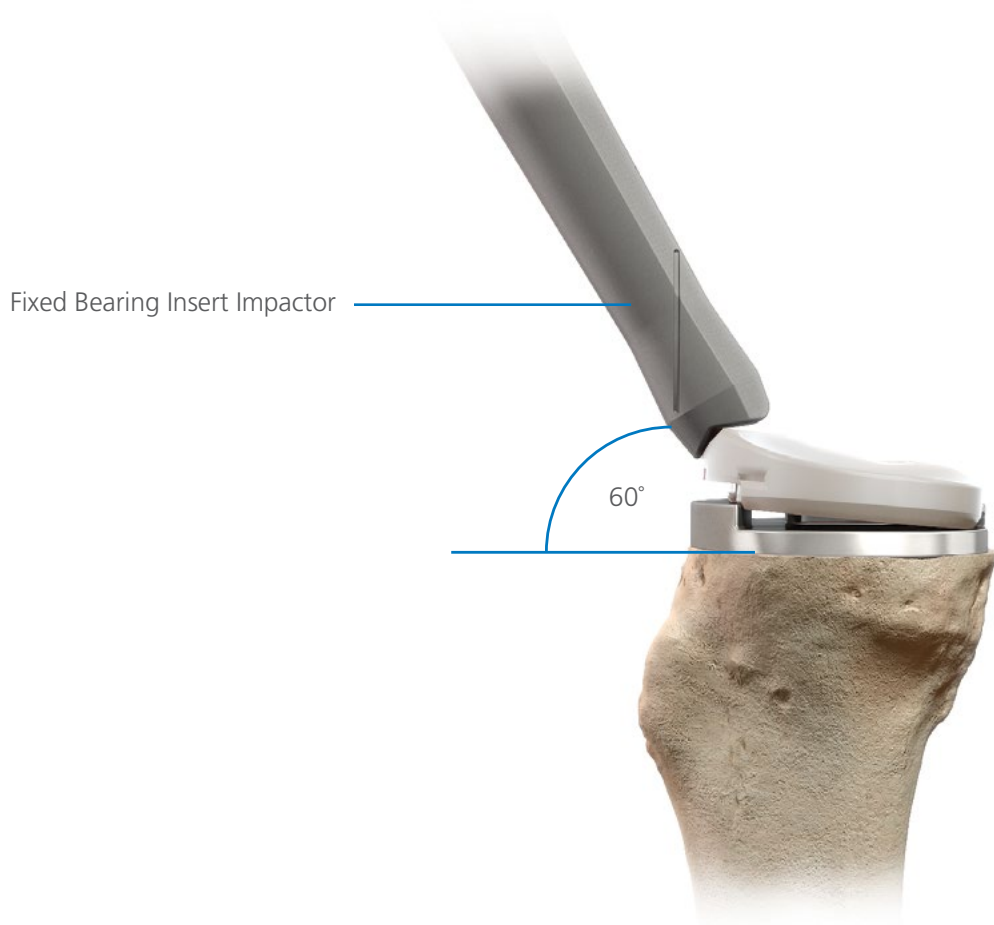
For fixed bearing tibial components, angle the Tibial Insert posteriorly and slide the posterior tabs into the posterior undercuts of the Tibial Base.



CAUTION

The Base Protector should be kept in place during trialing, then it MUST be removed before assembling the final Tibial Insert.

Tibial Insert Implantation



The Fixed Bearing Tibial Insert is impacted into place on the Tibial Base, using the Fixed Bearing Insert Impactor.

Position the Impactor at approximately 60 degrees on the insert so that the notch rests on the anterior edge of the center of the insert. Use a Mallet to strike the Fixed Bearing Insert Impactor. Confirm seating by circumferential inspection.

Final Patella Preparation



Apply cement to the patella implant. Thoroughly clean the cut surface of the patella with pulsatile lavage. Apply cement to the surface of the patella and insert the component.



Connect the Clamp Ring to the Patella Modular Clamp.

Patella Component Implantation

The Clamp Ring is designed to fully seat and stabilize the implant as the cement polymerizes.

Center the Clamp Ring over the articular surface of the implant and the metal backing plate against the anterior cortex of the patella, avoiding skin entrapment.

Engage the Patella Clamp Handle to firmly hold the Patella Implant until polymerization is complete. Remove all extruded cement with a Curette.

Release the Clamp by unlocking the Locking-Switch on the handle and slightly squeezing the Clamp Handles to disengage the locking mechanism.



Reduce the patella.

Closure




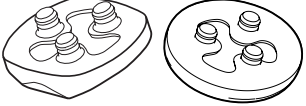


Close the knee in layers using the surgeon's preferred technique.

Flexion/Extension Gap Chart





	Loose Extension	Tight Extension	Stable Extension
Loose Flexion	<p>Cause: Flexion and extension gaps are too large</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • Thicker tibial insert 	<p>Cause: Flexion gap is larger than the extension gap</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • Recut distal femur and use thicker insert • Posterior capsular release • Posteriorise the femoral component by 1.5 mm 	<p>Cause: Flexion gap is larger than extension gap</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • Decrease the tibial slope and use a thicker tibial insert • Recut the distal femur and use a thicker tibial insert • Larger femoral component • Posteriorise the femoral component by 1.5 mm
Tight Flexion	<p>Cause: Extension gap is larger than flexion gap</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • Check for osteophytes • Downsize femoral component and use thicker insert • Increase tibial slope • Recess PCL off of femur or tibia 	<p>Cause: Flexion and extension gaps are too small</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • Thinner tibial insert • Resect additional tibia 	<p>Cause: Flexion gap is too small</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • Check for osteophytes • Downsize femoral component • Anteriorize the femoral component by 1.5 mm • Increase tibial slope • Recess PCL off of femur or tibia
Stable Flexion	<p>Cause: Extension gap is too large</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • Downsize femoral component and increase insert thickness • Increase tibial slope and use thicker tibial insert 	<p>Cause: Extension gap is too small</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • Recut distal femur • Posterior capsular release • Larger femoral component and thinner insert 	<p>Cause: Balanced gaps</p> <p>Possible Solution(s):</p> <ul style="list-style-type: none"> • No solution required


Compatibility Data

SIZE SZ																			
Pink	1	1	1	2	3										29	32	35	38	41
Dark Blue	2	2	1	2	3	4									29	32	35	38	41
Grey	3/3N	3	1	2	3	4	5								29	32	35	38	41
Black	4/4N	4		2	3	4	5	6								32	35	38	41
Green	5/5N	5			3	4	5	6	7							32	35	38	41
Yellow	6/6N	6				4	5	6	7	8					32	35	38	41	
Light Blue	7	7					5	6	7	8	9					35	38	41	
Red	8	8						6	7	8	9	10				35	38	41	
Purple	9	9							7	8	9	10					38	41	
Brown	10	10								8	9	10					38	41	

Symbols on Surgical Instruments

Some of the instruments have markings on them for guidance.
The interpretation of these markings is as detailed in the table below.

Symbol or Text	Definition
	Cleaning position here
	Dismantle for cleaning
	Unlock
	Lock
L	Left
R	Right
LEFT	Left
RIGHT	Right
CR	Attune Cruciate Retaining Implant
PS	Attune Posterior Stabilised Implant
FB	Fixed Bearing

Symbol or Text	Definition
L	Lateral
M	Medial
LL	Left Lateral
RL	Right Lateral
SULCUS	Sulcus
FLEXION	Flexion
EXTENSION	Extension
SZ	Size
TIB	Tibia
	Refer to Accompanying Documents
DEG	Degrees

ATTUNE™ KNEE SYSTEM FIXED BEARING KNEE

IMPORTANT

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INTENDED USE

Total knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total knee replacement may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for total knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured. This includes severely crippled patients with multiple joint involvement for whom a gain in knee mobility may lead to an expectation of significant improvement in the quality of their lives.

INDICATIONS

Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, or a failed previous implant.

CONTRAINDICATIONS

The following conditions are contraindications for total knee replacement:

1. Active local or systemic infection.
2. Loss of bone or musculature, osteoporosis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).
3. Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity.

NOTE:

Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound healing, etc., the physician should carefully consider the advisability of knee replacement in the severely diabetic patient.

WARNINGS AND PRECAUTIONS

CAUTION:

- Tibial insert size should be the same size as the selected femoral component size. Tibial inserts should be within 2 sizes of the tibial base.
- Patella component sizes 38mm and 41mm may be used with all femoral component sizes. Patella component size 29mm may only be used with femoral component sizes 1 through 3. Patella component size 32mm may only be used with femoral component sizes 1 through 6. Patella component size 35mm may only be used with femoral component sizes 1 through 8.
- Implants and trial components from different manufacturers or implant systems should never be used together.
- Knee prosthesis components should never be reimplanted. Even though the implant appears undamaged, the implant may have developed microscopic imperfections which could lead to failure.
- Always use a trial prosthesis for trial purposes. Trials should not be assembled with any components intended for permanent implantation. Trials must have the same configuration size, as the corresponding components to be permanently implanted.
- Do not alter or modify implants in any way.
- Avoid drilling multiple pin holes in the proximal tibia which may affect the compressive strength of the tibia.
- When used with multiple components of a total knee replacement system, the MR compatibility and safety of the entire system of implants has not been evaluated and the entire system of implants has not been tested together for heating or migration in the MR environment. The risks of exposure to MR include heating and/or displacement of a metallic implant. Image artifacts including dead zones and distortion may occur, especially in the immediate area around the implant, requiring optimization of imaging parameters. In line with the recommendations of the American College of Radiology, DePuy Orthopaedics, Inc. recommends that a professional familiar with the specific MRI apparatus to be used, assess the patient prior to any MRI examination or therapy.

NOTE:

DePuy Orthopaedics' Single Use devices have not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. Reuse can potentially compromise device performance and patient safety.

CAUTION:

The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity thereby placing the patient at higher risk of failure of the knee replacement:

1. Obesity or excessive patient weight.
2. Manual labor.
3. Active sports participation.
4. High levels of patient activity.
5. Likelihood of falls.
6. Alcohol or drug addiction.
7. Other disabilities, as appropriate.

In addition to the above, the following physical conditions, singularly or concurrently, tend to adversely affect the fixation of knee replacement implants:

1. Marked osteoporosis or poor bone stock.
2. Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.).
3. History of general or local infections.
4. Severe deformities leading to impaired fixation or improper positioning of the implant.
5. Tumors of the supporting bone structures.
6. Allergic reactions to implant materials (e.g. bone cement, metal, polyethylene).
7. Tissue reactions to implant corrosion or implant wear debris.
8. Disabilities of other joints (i.e., hips or ankles).

A higher incidence of implant failure has been reported in paraplegics and in patients with cerebral palsy or Parkinson's Disease.

WHEN THE SURGEON DETERMINES THAT KNEE REPLACEMENT IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS OR WHO IS SIMPLY YOUNG AND ACTIVE, IT IS IMPERATIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR FIXATION AND THE RESULTANT NEED TO SUBSTANTIALLY REDUCE OR ELIMINATE ANY OF THE ABOVE CONDITIONS.

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure.

Excessive physical activity or trauma to the replaced joint may contribute to premature failure of the knee replacement by causing a change in position, fracture, and/or wear of the implants. **The functional life expectancy of prosthetic knee implants is, at present, not clearly established.** The patient should be informed that factors such as weight and activity levels may significantly affect wear.

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (800) 366 8143



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