ATTUNE® KNEE SYSTEM
INTUITION SOLO™ INSTRUMENTS
SURGICAL TECHNIQUE
Introduction

This surgical technique provides guidelines for the implantation of the ATTUNE® Knee System family of knee implants with the INTUITION SOLO™ Instrumentation. The INTUITION SOLO System is designed for single patient use only.

ATTUNE Knee System Implants are available in four configurations:
• Posterior Stabilized Fixed Bearing (PS FB),
• Posterior Stabilized Rotating Platform (PS RP),
• Cruciate Retaining Fixed Bearing (CR FB) and
• Cruciate Retaining Rotating Platform (CR RP)

The Cruciate Retaining (CR) configurations can also be used for Cruciate Sacrificing (CS) applications.

The INTUITION SOLO Instruments are available for ATTUNE Knee Sizes 3-8 only.

Information regarding optional Reusable INTUITION™ Instruments for use with INTUITION SOLO Instruments can be found throughout this surgical technique.

The INTUITION SOLO Instruments are designed to be used as a system but each pack can be used individually as part of an ATTUNE Knee System procedure with Reusable Instruments. While the surgical technique shows a specific workflow, the system allows the surgeon to choose to prepare the tibia or the femur first.
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Optional Reusable INTUITION Instruments

The INTUITION SOLO Instruments are designed to be used as a complete system to perform a complete surgical procedure.

The individual INTUITION SOLO Instruments are not interchangeable with the Reusable INTUITION Instruments unless noted.

This surgical technique details the situations where the Reusable INTUITION Instruments can be used to supplement the INTUITION SOLO Instruments procedure. The key Reusable INTUITION Instruments that are compatible with the INTUITION SOLO Instrument Kit are listed and described in more detail below and on the following pages.

Throughout the technique where this symbol is present, an alternative Reusable INTUITION Instrument can be used. Reference the ATTUNE Knee System Surgical Technique.

<table>
<thead>
<tr>
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### Optional Reusable INTUTION Instruments

Optional Reusable INTUTION Instruments that may be used with INTUTION SOLO Instruments.

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## Optional Reusable INTUITION Instruments

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Primary Pack Overview

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<td>B</td>
<td>Left Tibial Cutting Block</td>
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<td>C</td>
<td>Caliper</td>
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<tr>
<td>D</td>
<td>Tibial Sizing Guide</td>
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<td>Tibial Jig</td>
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<td>Measured Sizing and Rotation Guide</td>
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<td>H</td>
<td>3 Degree Foot, 0 and 5 Degree Foot</td>
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<td>I</td>
<td>Distal Femoral Jig</td>
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<td>J</td>
<td>IM Drill</td>
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<td>K</td>
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Sizing Pack Overview

A  Measured Sizer Stylus
B  Measured Sizing and Rotation Guide
C  3 Degree Foot
D  0 and 5 Degree Foot
E  Tibial Sizing Guide
Femur Pack Overview

The Femur (CR/PS) Packs are size specific for sizes 3-8.
### Tibia Pack Overview

The Tibia Packs are available for sizes 3-5 and 6-8 configurations.

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<td>Tibial Drill Tower</td>
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<td>G</td>
<td>Tibial Base Trials</td>
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Patella Pack Overview

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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
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
Incision and Exposure

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

Incision and exposure should be performed using the surgeon’s preferred technique.

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.

Accurate patella alignment is important for proper placement and tracking. It is recommended not to drill the patella lug holes prior to the trialing step so that correct rotation and position of the patella trial may be assessed.
Pinning

The ATTUNE Knee System has 3.15 mm diameter pins to increase the stability and functionality of the instruments. The INTUITION SOLO Instruments are designed to be used with either Pin Packs (2544-00-120 or 2544-00-121) that contain a Pin Driver, Threaded Headed Pins, and either Universal Pins or Threaded Non-Headed Pins.

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.

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

The Universal Pin can be drilled in or hammered in, and drilled out or pulled out using the INTUITION Pin Jack. Reference the ATTUNE Knee System Surgical Technique.

Steinmann Pins, if required, are compatible with all pin holes throughout the INTUITION SOLO Instruments.
Pinning Technique

Correct Pinning

Incorrect Pinning

Do not overtighten. Overtightening may change the angle or cause the pin to strip.

Headed Pins are best used to secure blocks against a flat surface such as cut bone. Non-Headed Pins are recommended for use with cutting blocks against a curved surface such as with the Distal Cut Block.

CAUTION

Caution should be taken to only drill pins under power through metal lined pin holes.
Distal Femoral Resection

Begin by opening the Primary Cuts and Sizing Pack.

With the knee in flexion, remove osteophytes from the intercondylar notch. Position the Drill to enter the intramedullary canal slightly superior and medial by 3 mm to the midline of the trochlea, 7 mm to 10 mm anterior to the origin of the Posterior Cruciate Ligament (PCL).

In the proper position, the IM Drill should pass easily into the femoral canal. Once the IM Drill has passed into the canal, the hole opening may be further enlarged by 3 mm as shown in the image.
**Distal Femoral Resection**

**Distal Femoral Jig Adjustment**

Method of Adjustment:

1. Rotate the Resection Knob to set the desired resection level.
2. Pull back Varus/Valgus Dial toward the handle then rotate to set desired Valgus angle.

Set the desired Valgus angle (left or right - 0 degrees to 7 degrees) on the Distal Femoral Jig by pulling the Varus/Valgus Dial toward the Femoral Handle, rotating it clockwise or counterclockwise to the appropriate setting.

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*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. 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.

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

CAUTION

Ensure that the Distal Cutting Block slides freely on the vertical uprights and that the block is resting on the anterior femur prior to pinning the block.
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. 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 by pressing the Red Cutting Block Clip. Pull the entire instrument distally.

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.

Information

Note that the IM Rod Handle can be used for leg alignment with the use of the Spacer Block which is contained in the Femur Pack.
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

Assemble the appropriate Cutting Block to the Tibial Proximal Uprod by pushing the proximal red trigger upward.

Right Tibial Cutting Block
Proximal Red Trigger
Extramedullary Tibial Ankle Clamp
Posterior Slope Adjustment
Height Adjustment Knob
A/P Adjustment Mechanism
Varus/Valgus Adjustment Mechanism
A/P Ratchet

Primary Pack

Cutting Block Options
Left Tibial Cutting Block
Right Tibial Cutting Block
Tibial Alignment and Resection

Set the tibial posterior slope as depicted on the Proximal Uprod of the Tibial Jig, according to the recommendations depending on the appropriate implant configuration.

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. The axis of the Proximal Uprod should be positioned with reference to the tibial axis.

Note that the figures on the Jig will only deliver that angle if the rest of the Jig is set up correctly as pictured here.

If the slope adjustment is changed after the Cutting Block is resting against bone, the surgeon should re-align the Uprod to be parallel to the tibial axis by moving the A/P adjustment mechanism.

The middle slot may be used for temporary fixation. It is recommended to use a Threaded Non-Headed or Universal Pin.

ATTUNE Knee Tibia Slope Recommendations: For a Posterior Stabilized (PS) configuration it is recommended to set the tibial posterior slope at 3 degrees. For a Cruciate Retaining or Cruciate Sacrificing (CRICS) configuration, a range of 5-7 degrees of tibial posterior slope is recommended, attempting to match the patient’s slope. In PCL-retaining TKA not adding adequate slope may limit the post-operative flexion.

Threaded Headed Pins are not recommended to be used in the temporary fixation pin slot.
Tibial Alignment and Resection

To make a fine tune adjustment of the resection height, the red adjustment wheel should be squeezed and rotated by the thumb and fingers. The fingers should be positioned in the middle of the slot not on the outer edges.

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.

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 Varus/Valgus Adjustment Mechanism until the second line from the lateral side of the ankle clamp lines up with the indicator line.

**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 achieve a 0 degree slope.*
Tibial Alignment and Resection

Attach the Stylus to the Cutting Block through the slot feature with either the 2 mm or 9 mm pointer towards the joint. Resection should always be made through the slot.

INFORMATION

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

REUSABLE INSTRUMENT ALTERNATIVE

The Adjustable Tibial Stylus may be used with the INTUITION SOLO Instruments. For description of the use of the Adjustable Tibial Stylus, with INTUITION SOLO Instruments, reference the ATTUNE Knee System Surgical Technique.
Tibial Alignment and Resection

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

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. If desired, the Cutting Block may be released from the Jig by pushing up on the red trigger.

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

To assess leg alignment, the Femoral Prep and Trials Pack needs to be opened to obtain the Spacer Block, which allows the Distal Femoral Jig IM Rod Handle to be inserted. Use the Femoral Sizing and Rotation Guide to determine which size of the Femoral Prep and Trials Pack to open.
Femoral Rotation and Balancing

Depending on the surgeon’s preference, rotation may be set with reference to either key anatomical landmarks via the measured resection approach or by balancing the soft tissues in flexion with the goal of generating a rectangular flexion gap. A secondary check to key anatomical landmarks should also be made to avoid malrotation of the femoral component.

The INTUITION Balanced Sizer may be used with the INTUITION SOLO Instruments. For description of the use of the Balanced Sizer, with INTUITION SOLO Instruments, reference the ATTUNE Knee System Surgical Technique.

Proper soft tissue balance is especially important in a Rotating Platform (RP) knee construct to reduce the risk of spin out of the tibial insert.
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 Cut 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 Sizing and Rotation Guide instrument is named to indicate its use for a Measured Resection surgical philosophy and is not a measurement device.
Measured Femoral Sizing and Rotation

Connect the appropriate Rotation Foot depending on rotation desired to the Measured Sizing and Rotation Guide. Ensure that the desired rotation angle is aligned to the R or L for a right or left knee.

Attach the Stylus to the top of the Measured Sizing and Rotation Guide using the pinch lever to fit the Stylus in the slots below the Sizer Locking Knob.
Measured Femoral Sizing and Rotation

Anatomic landmarks can be marked if desired.

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.

Adjust the degree of external rotation to be parallel to the epicondylar axis and perpendicular to Whiteside’s line by adjusting the assembly of the Sizer Feet. For angles greater than 5 degrees, utilize the Reusable Measured Sizer.

A provisional fixation pin may be used if desired.

The Measured Sizer is designed such that the anterior portion should not sit flush on the distal femur in order to allow the sizer body to slide for sizing. Pressure should be applied to the distal portion of the Measured Sizer, in the region of the epicondylar axis reference line. This will prevent tilting of the device.
Measured Femoral Sizing and Rotation

Slide the anterior section down.

Adjust the superior-inferior position of the Stylus to indicate the proper femoral component size. The position of the Stylus will have an effect on the femoral component sizing. Pick the M/L position of the Stylus to match the highest point of the anterior femur at the appropriate size indication on the Stylus scale. The position of the Stylus will then be located near the exit point of the Saw Blade. Read the scale from the black line on the top of the Sizer Guide.

Lock the size position by twisting the Size Locking Knob.

The line through the center of the Anterior Down Pin Holes indicates the size of the femur.

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

The Locking Knob only needs to be twisted to a position which prevents sliding of the sizer body, do not overtighten the Locking Knob.
Measured Femoral Sizing and Rotation

**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

**INFORMATION**

*Both pin holes should be positioned over bone. The Measured Sizer can be moved more medial or lateral to achieve this, providing the feet and posterior portion of the Measured Sizer remain in contact with the bone.*
Measured Femoral Sizing and Rotation

Removal of Sizer
Remove the Threaded Headed Pin, if utilized. Release the Knob by rotating counterclockwise.

Posterior Up Referencing
Remove the Measured Sizer, leaving the Universal or Non-Headed Pins in the distal femur.

Anterior Down Referencing
Squeeze the Stylus. Pull the Sizer off the bone while the Stylus stays in position until the pins have been cleared or the red knob aligns with the opening in the Stylus allowing the Stylus to first be removed.
Sizing the Tibia

Place the Tibial Sizer onto the resected tibial surface. Assess the size of the Tibial Base to maximize tibial coverage while avoiding overhang. For Fixed Bearing, the rotation of the Tibial Base Trial is typically centered on the junction between the medial and central third of the tibial tubercle.

Once the tibial size has been determined the appropriate Tibial Prep Pack may now be selected.

INFORMATION

The ATTUNE Knee System allows for a difference up to 2 sizes between the femoral component and tibial base.
Extension Gap Assessment and Balancing

Posterior Stabilized
For the PS technique, connect the Spacer Base and desired Shim to the Spacer Block to assess both the extension and flexion gaps.

Cruciate Retaining
For the CR technique, evaluate the CR extension gap using the Spacer Base and desired Shim connected to the Spacer Block. To assess the CR flexion gap connect the CR Flexion Base and desired Shim to the Spacer Block. The CR Flexion Base compensates for the 1 mm difference in thickness of the posterior condyles of the CR implant.

Shims (5, 6, 7, 8, 10, 12 mm) are provided 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.

If a larger Shim is required, please use the INTUITION Shims.
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 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 IM Rod from the Distal Femoral Jig 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.
Femoral Preparation

A/P Cut Block

The ATTUNE Knee System femoral components increase in size by a consistent 3 mm in the A/P direction. The A/P Cut Blocks allow the surgeon to adjust the A/P position of the femoral component by 1.5 mm in either direction. This creates the intra-operative flexibility to position the femoral component based on the surgeon’s assessment of the flexion gap and the desired posterior condylar offset.

Femoral cuts are made through an uncaptured saw surface except for the anterior cut.

The M/L width of the A/P Block represents the M/L width of the standard size femoral component. The cutout indicates the width of the narrow size of implants. 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 cuts are made through an uncaptured saw surface except for the anterior cut.

If the surgeon prefers closed cuts, the INTUITION A/P Chamfer Block can be used. Reference the ATTUNE Knee System Surgical Technique.
Femoral Preparation

A/P Cut Block

Place the Block over the two anterior or posterior Universal or Non-Headed Pins through the pin holes marked with a center line.

When using the anterior 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 Cut 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 A/P Cut Block can be moved 1.5 mm up or down (one hole location) to adjust the flexion gap, if necessary.

REUSABLE INSTRUMENT ALTERNATIVE

If a check of the planned anterior cut is desired, the INTUITION Angel Wing can be used. Reference the ATTUNE Knee System Surgical Technique.
Femoral Preparation

**CAUTION**

*Please note that if the A/P position of the A/P Cutting Block is not acceptable, adjustments should be made prior to pinning through the central fixation pin holes.*

**INFORMATION**

*Good pinning technique is critical to achieving accurate bone cuts during the anterior and posterior resections. The recommended technique is to avoid stripping the Threaded Headed Pins in the central fixation pin holes and to retain the pins during anterior and posterior resections for added stability.*

*It is recommended to use Threaded Headed Pins through the central fixation holes in the A/P Cut Block to provide sufficient stability against the distal femoral cut.*

Insert Threaded Headed Pins into the central fixation pin holes on the medial and lateral aspects of the A/P Cut Block.

These pin holes prepare the distal bone to accept the Chamfer Cutting Guide.

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

Once the A/P resections are made, remove the pins.
Femoral Preparation

**Femur Pack**

**Recommended Saw Blade is 1 inch width and 1.19 mm thick in order to ensure the Saw Blade does not flex easily. A/P and Chamfer Blocks were designed to ensure the femoral trial and implant seats fully on the distal femur by preparing the chamfer cuts with additional clearance.**

**CAUTION**

The anterior and posterior chamfer resections are made with the Chamfer Cutting Guide. Place the Chamfer Cutting Guide spikes into the pin holes in the middle of the resected distal femoral surface. Tap until flush against the distal bone cut.

The anterior and posterior chamfer resections are made with the Chamfer Cutting Guide. Place the Chamfer Cutting Guide spikes into the pin holes in the middle of the resected distal femoral surface. Tap until flush against the distal bone cut. The chamfer resections are made through an open cut. Ensure that the Saw Blade is flush against the Chamfer Cutting Guide surface.

**INFORMATION**

The Chamfer Cutting Guide must be oriented as shown, with the surfaces marked ‘ANTERIOR’ and ‘POSTERIOR’ being aligned to the anterior and posterior surfaces of the knee, respectively. When standing anterior to the knee, if the device is oriented incorrectly the text will appear upside down.

Therefore, a small “gap” may be observed between the femoral trial/implant and the chamfer cuts, particularly the anterior chamfer. This gap is intentional by design to ensure that fixation is achieved with the distal, anterior, and posterior surfaces. In this way, the position of the femoral component can be best controlled with regards to flexion and extension gaps.
CR Sulcus Cut

When implanting an ATTUNE Knee System CR component, the sulcus cut must be made with a freehand approach using a Saw Blade.

The width of the sulcus is indicated on the Chamfer Cutting Guide.

Alternatively, the INTUITION Femoral Finishing Guide (2544-00-023 through 2544-00-028) can be used. Or the INTUITION Rasp (2545-00-048). Reference the ATTUNE Knee System Surgical Technique.
Femoral Resection – PS Notch Cuts

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 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 Headed or Non-Headed Pins in all 3 holes to ensure stability of Guide.
Femoral Resection – PS Notch Cuts

Perform the notch cut.

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.

INFORMATION
A Reciprocating or Narrow (½ inch) Oscillating Saw Blade can be used to perform the PS notch cut.
When performing the resection ensure that the Saw Blade remains flat to the surface.
Femoral Trial Reduction

Position the appropriate Femoral Trial onto the femur by hand. Use the Impactor which is located in the Tibial Prep Pack to impact the trial as necessary.

**INFORMATION**

The Chamfer Cutting Guide prepares the chamfer cuts with an uncaptured cutting surface. Therefore, the ATTUNE Femoral Cut Assessment Tools are recommended to verify cut accuracy until familiarity with the open chamfer cuts can be obtained. Femoral Trial condyle breakage is a possibility if the bone cuts are not checked for accuracy. If the trial is not seating properly, the bone cuts may need to be rechecked. Excessive impaction required is a signal that undersection has occurred of the anterior, posterior, or chamfer cuts, or, in a PS configuration, the Notch Guide cuts or, in a CR configuration, the sulcus cut. Femur Trial M/L width of box is representative of implant and cement mantle. 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

Tibia Pack

Tibial Trial

Select 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.

For Fixed Bearing, the rotation of the Tibial Base Trial is typically centered on the junction between the medial and central third of the tibial tubercle. Insert the Evaluation Bullet into the cutout of the Base Trial by hand. The Evaluation Bullet is used when allowing rotation of the tibial component during a range of motion to dictate the optimal rotation of the tibial base. The bone can be marked for Base Trial orientation reference.

INFORMATION

Misalignment between the Tibial Drill and Tibial Drill Tower while drilling will cause polymer debris from the instruments. Care should be taken to ensure that bone and any possible polymer debris is removed from the drill cavity and wound site.

CAUTION

If irregular, sclerotic bone is encountered after proximal tibia resection, the ATTUNE INTUITION (Reusable) Tibial Prep Instrumentation may provide better function to avoid polymer wear and debris between the Tibial Drill and Tibial Tower (Tray Product Code: 2545-01-715/2545-01-702).

REUSABLE INSTRUMENT ALTERNATIVE

Either Rotating Platform or Fixed Bearing tibial components can be trialed before preparing the tibia. Reference the ATTUNE Knee System Surgical Technique.
Select the Tibial Articulation Surface Trial located in Femoral Prep and Trials Pack that matches the femoral size and style, and attach the corresponding size Shim of the appropriate thickness. Select the appropriate articulation surface for FB or RP.

Attach the selected shim thickness to the articulation surface. (Shim thickness options included are 5, 6, 7, 8, 10, 12 mm).

REUSABLE INSTRUMENT ALTERNATIVE

If additional Shim thicknesses are required, the Shims from the Reusable System may be used. Reference the ATTUNE Knee System Surgical Technique.
The Shims are reversible to accommodate both Rotating Platform and Fixed Bearing Implants. 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.

Removal of the Insert Trials on the Tibial Base Trial can be performed using an Osteotome or other general surgical instrument.

⚠️ CAUTION ⚠️

Care should be taken when disassembling the articulation surface from the Shim to avoid Bal Seal® damage. It is not advised to use a sharp instrument to separate the Shim and the articulation surface.
Trial Components

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.

INFORMATION

Removal of trial components should be performed by hand, by using the Impactor against the anterior femur.

REUSABLE INSTRUMENT ALTERNATIVE

If the surgeon prefers, the INTUITION Femoral Trial Gripper may be used for removal of the Femoral Trials instead of the Impactor. Reference the ATTUNE Knee System Surgical Technique.
Soft Tissue Considerations for Cruciate Retaining Application

As with any cruciate retaining total knee replacement, if the surgeon plans to preserve the posterior cruciate ligament (PCL), attention to PCL balance is extremely important for proper kinematics of the knee.¹

A knee that is tighter in flexion than extension may require one or a combination of the following: PCL release, increasing the amount of tibial slope, or downsizing the femoral component.¹

During trialing, the surgeon should select the trials that provide the greatest stability in flexion while still allowing full extension. Indications of an excessively tight flexion space may include one or more of the following:

- Femoral trial lifting off
- Tibial trial lift off or booking
- Excessive rollback of the femoral component on the tibia

If there is any indication of imbalance, it is not uncommon to perform a gradual release of the PCL.
Tibial Preparation

Tibia Pack

Remove trial components, keeping the Tibial Base Trial in place on the resected tibial surface. 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.

Drill Stop must be used to ensure appropriate depth is drilled.

Care should be taken not to protrude through the medial tibial cortex if pinning through the optional pin holes.

If irregular, sclerotic bone is encountered after proximal tibia resection, the ATTUNE Intuition (Reusable) Tibial Prep Instrumentation may provide better function to avoid polymer wear and debris between the Tibial Drill and Tibial Tower (Tray Product Code: 2545-01-715/2545-01-702).

Use the Tibial Drill and pre-assembled Drill Stop to ream the tibia to where the stop on the drill engages with the top surface of the tower. 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. Additionally, any tilt or side loading of the Tibial Drill through the Tibial Drill Tower while drilling will cause polymer debris from the instruments. Care should be taken to ensure that bone and any possible polymer debris is removed from the cavity and joint space.

If additional fixation is desired, the INTUITION Tibial Base Pins can be inserted through the two outside holes on the anterior aspect of the Base Trial. Reference the ATTUNE Knee System Surgical Technique.
Tibial Preparation

Attach the 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.

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

The Patella Prep Pack may now be opened.

Patella Drill Guide

Use the Caliper to estimate the thickness of the patella and evaluate the level of bone resection. 9.5 mm is the average thickness of the ATTUNE Knee System patella components.

Perform patella resection using a free-hand technique. The resection extends from the medial chondro-osseous junction to the lateral chondro-osseous junction.

If the surgeon prefers a Patella Resection Guide, the INTUITION Patella Resection Guide may be used. Reference the ATTUNE Knee System Surgical Technique.
Patella Lug Hole Preparation

Place the Patella Drill Guide on the resected patella to assess bone coverage. Use the size markings on the Patella Drill Guide to select the correct size of Patella Trial for maximum patella bone coverage. Verify the medial lateral location of the patella implant apex relative to the native anatomy ridge using the apex marking on the Patella Drill Guide. Firmly squeeze the Patella Handle to engage the Drill Guide onto the resected patella surface.

To check patella alignment, reduce the patella with the handle of the Patella Drill Guide overhanging the medial side of the leg. Flex the knee and verify the Patella Drill Guide remains perpendicular to the long axis of the leg and parallel to the prosthetic joint line.

When the correct alignment has been confirmed, drill the holes using the Patella/Femoral Lug Drill.
Patella Trialing

Patella Drill Trialing

Press the Patella Trial onto the resected bone with the lugs going into the previously drilled lug holes.

Medialized Dome Patella Drill Trial

If the surgeon prefers to use the ATTUNE Medialized Anatomic Patella, the Reusable INTUITION Medialized Anatomic Patella Trials can be used. Reference the ATTUNE Knee System Surgical Technique.
Drill the femoral lug holes through the Femoral Trial using the Patella Femoral Lug Drill. It is recommended to perform this step after patella trialing to ensure adequate medial/lateral placement.
Tibial Base Implantation

At this stage, thoroughly clean the joint using pulsatile lavage.

**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, taking care to dry the bone afterwards. Pack residual small cavity bone defects with cancellous autograft, allograft, or synthetic bone substitutes.

Apply a thick layer of cement to the bone, the implant surface or to both.

Cement should be applied to the cleaned and dried prepared tibial plateau. Also, it is critical to ensure that cement fully surrounds the cone of the tibial base implant.

⚠️ **CAUTION**

Blood lamination can reduce the mechanical properties of the cement; therefore, it is vital to choose cement that reaches its working phase quickly. If applying cement to both the implant and bone, implantation should be completed early in its dough state to ensure good cement-cement adhesion and reduce the risk of dry laminations; which can weaken the cement.
Tibial Base Implantation

Carefully insert the Tibial Base, avoiding malrotation.

With the Tibial Base inserted, impact it using an Impactor with several blows from the Mallet to the top of the Impactor in order to pressurize the cement. Then use a Curette to remove all extruded cement.

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

Care must be taken not to pull cement from under the edge of the implant in order to ensure the edges remain sealed.
Before insertion, place cement onto the femoral component and the femur. Place the femoral component onto the bone by hand.

Begin inserting the femoral component by engaging the Femoral Lugs in the lug holes of the distal femur.

Utilize the Impactor for final femoral component impaction.

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

If the surgeon prefers, the INTUITION Femoral Introducer may be used. Reference the ATTUNE Knee System Surgical Technique.
Tibial Insert Implantation

Once cement is cured, the trials can be used to verify stability throughout the range of motion. Refer to page 47 (Soft Tissue Considerations for CR Application).

Rotating Platform

For a Rotating Platform implant, place the RP Trial Post into the implanted base component. Then place the Insert Trial over the post and perform the trial reduction. Remove loose fragments or particulates from the Final Tibial Base.

Fixed Bearing

For Fixed Bearing components, place the Insert Trial on the Tibial Base. Remove loose fragments or particulates from the final Tibial Base.
Tibial Insert Implantation

Insert the tibial implant component.

For Fixed Bearing tibial components, angle the Tibial Insert posteriorly and slide the posterior tabs into the posterior undercuts of the Tibial Base. Insert slides back and then down. The Fixed Bearing Tibial Insert is impacted into place on the Tibial Base, using the Impactor as shown.

Position an 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 Impactor. Confirm seating by circumferential inspection. Move the leg into extension, and then lift the leg back into flexion for final removal of excess cement.

Care should be taken when flexing the knee past 45 degrees to avoid putting force on the posterior aspect of the tibial base while the cement is curing.

For Rotating Platform tibial components, insert the final Tibial Insert.

If the surgeon prefers, the INTUITION Fixed Bearing Insert Impactor may be used. Reference the ATTUNE Knee System Surgical Technique.
Cement Pressurization

Once all components are implanted, extending the leg will further pressurize the cement. The leg should then remain in extension until the cement hardens for the appropriate time depending on the cement type used.
Patella Component Implantation

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

Center the Cement Clamp Button over the articular surface of the implant and the backing plate against the anterior cortex of the patella, avoiding skin entrapment. Engage the Patella Drill Guide by repeatedly pressing the trigger to firmly hold the Patella Implant until polymerization is complete. Remove all extruded cement with a Curette.

Release the Clamp by pressing the release button to disengage from the patella.

Reduce the patella.
Closure

Close the knee in layers using the surgeon’s preferred technique.
## Flexion/Extension Gap Chart

<table>
<thead>
<tr>
<th>Loose Extension</th>
<th>Tight Extension</th>
<th>Stable Extension</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cause:</strong> Flexion and extension gaps are too large</td>
<td><strong>Cause:</strong> Flexion gap is larger than the extension gap</td>
<td><strong>Cause:</strong> Flexion gap is larger than extension gap</td>
</tr>
<tr>
<td><strong>Possible Solution(s):</strong></td>
<td><strong>Possible Solution(s):</strong></td>
<td><strong>Possible Solution(s):</strong></td>
</tr>
<tr>
<td>- Thicker tibial insert</td>
<td>- Recut distal femur and use thicker insert</td>
<td>- Decrease the tibial slope and use a thicker tibial insert</td>
</tr>
<tr>
<td></td>
<td>- Posterior capsular release</td>
<td>- Recut the distal femur and use a thicker tibial insert</td>
</tr>
<tr>
<td></td>
<td>- Posteriorize the femoral component by 1.5 mm</td>
<td>- Larger femoral component</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Posteriorize the femoral component by 1.5 mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tight Flexion</th>
<th><strong>Cause:</strong> Extension gap is larger than flexion gap</th>
<th><strong>Possible Solution(s):</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Check for osteophytes</td>
<td>- Thinner tibial insert</td>
</tr>
<tr>
<td></td>
<td>- Downsize femoral component and use thicker insert</td>
<td>- Resect additional tibia</td>
</tr>
<tr>
<td></td>
<td>- Increase tibial slope</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Recess PCL off of the femur</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stable Flexion</th>
<th><strong>Cause:</strong> Extension gap is too large</th>
<th><strong>Possible Solution(s):</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Downsize femoral component and increase insert thickness</td>
<td>- Recut distal femur</td>
</tr>
<tr>
<td></td>
<td>- Increase tibial slope and use thicker tibial insert</td>
<td>- Posterior capsular release</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Larger femoral component and thinner insert</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stable Flexion</th>
<th><strong>Cause:</strong> Extension gap is too small</th>
<th><strong>Possible Solution(s):</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Recut distal femur</td>
<td>- Decrease the tibial slope and use a thicker tibial insert</td>
</tr>
<tr>
<td></td>
<td>- Posterior capsular release</td>
<td>- Recut the distal femur and use a thicker tibial insert</td>
</tr>
<tr>
<td></td>
<td>- Larger femoral component</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Posteriorize the femoral component by 1.5 mm</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stable Flexion</th>
<th><strong>Cause:</strong> Balanced gaps</th>
<th><strong>Possible Solution(s):</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- No solution required</td>
<td></td>
</tr>
</tbody>
</table>
# Tibial Component Sizing Chart

Shim Depth and Final Insert Depth are equal

<table>
<thead>
<tr>
<th>Trial Insert and Shim Depth</th>
<th>Tibial Insert Depth</th>
<th>Tibial Base Depth</th>
<th>Implant Construct Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mm</td>
<td>5 mm</td>
<td>4 mm</td>
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</tr>
<tr>
<td>6 mm</td>
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<tr>
<td>10 mm</td>
<td>10 mm</td>
<td>4 mm</td>
<td>14 mm</td>
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<tr>
<td>12 mm</td>
<td>12 mm</td>
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<td>14 mm</td>
<td>14 mm</td>
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<tr>
<td>16 mm</td>
<td>16 mm</td>
<td>4 mm</td>
<td>20 mm</td>
</tr>
<tr>
<td>18 mm</td>
<td>18 mm</td>
<td>4 mm</td>
<td>22 mm</td>
</tr>
<tr>
<td>20 mm (PS only)</td>
<td>20 mm (PS only)</td>
<td>4 mm</td>
<td>24 mm (PS only)</td>
</tr>
</tbody>
</table>

Depth dimensions are all the same, whether using Cruciate Retaining (CR), Posterior Stabilized (PS) or Rotating Platform or Fixed Bearing combinations.

## REUSABLE INSTRUMENT ALTERNATIVE

Sizes 14 - 20 mm are not available for INTUITION SOLO Instruments. INTUITION Shims are required to be used for these thicknesses. Reference the ATTUNE Knee System Surgical Technique 0612-10-512.
### Compatibility Data

<table>
<thead>
<tr>
<th>SIZE</th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
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<td>Pink</td>
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<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
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Sizes 1, 2, 9 and 10 are not supported for INTUITION SOLO Instruments
## 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.

<table>
<thead>
<tr>
<th>Symbol or Text</th>
<th>Definition</th>
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<tbody>
<tr>
<td>􀑌</td>
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<tr>
<td>􀁒</td>
<td>Unlock</td>
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<td>Right</td>
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<tr>
<td>CR</td>
<td>ATTUNE Cruciate Retaining Implant</td>
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<tr>
<td>PS</td>
<td>ATTUNE Posterior Stabilized Implant</td>
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<td>RP</td>
<td>Rotating Platform</td>
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<tr>
<td>FB</td>
<td>Fixed Bearing</td>
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<tr>
<th>Symbol or Text</th>
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<td>Medial (for Patella Trials)</td>
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<tr>
<td>L</td>
<td>Lateral (for Patella Trials)</td>
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<td>DEG</td>
<td>Degrees</td>
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ATTUNE® CEMENTLESS 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
The ATTUNE® Cementless CR Femoral Components are intended for cementless use within the ATTUNE Total Knee Replacement System.

Candidates for total knee replacement include patients with a severely painful and/or severely disabled joint resulting from osteoarthritis, post-traumatic arthritis, or a failed previous implant (provided that adequate bone is present).

CONTRAINDICATIONS
The following conditions are contraindications for total knee replacement with a porous coated component:
1. Active local or systemic infection.
2. Loss of bone or muscle, inadequate bone quality (e.g. severe osteoporosis), neuromuscular compromise or vascular deficiency at the bone site in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures that could lead to implant instability, joint neuropathy).
3. Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity.
4. The inability to make bone cuts (e.g. inadequate bone stock) so as to assure correct component position, a firm press fit, and intimate apposition of the cut bone and prosthetic surfaces.
5. Porous coated components must not be used with bone cement.

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:
• The use of ATTUNE Cementless Knee components is a technically demanding surgical procedure that requires careful patient selection. In particular, it is necessary that there be a close bone/prosthesis interface for the components utilized during the operative procedure (see CONTRAINDICATIONS).
• ATTUNE CR Tibial Insert size should be the same size as the selected ATTUNE CR Femoral Component size. ATTUNE CR Tibial Inserts should be within 2 sizes of the ATTUNE Tibial Base.
• ATTUNE Patella component:
  • Sizes 38mm and 41mm may be used with all femoral component sizes.
  • Size 29mm may only be used with femoral component sizes 1 through 3.
  • Size 32mm may only be used with femoral component sizes 1 through 6.
  • 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.

NOTE: DePuy’s 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.
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 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.

MRI SAFETY INFORMATION
The ATTUNE Cementless Fixed Bearing Knee System has not been tested for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. Scanning a patient who has this device may result in patient injury.

The risks associated with other passive implants in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.
ATTUNE® CEMENTLESS ROTATING PLATFORM (RP) 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.

INDICATIONS FOR USE WITHOUT CEMENT
The porous coated ATTUNE® Rotating Platform (RP) Tibial Base is indicated for cementless use within the ATTUNE Total Knee Replacement System in skeletally mature individuals undergoing primary surgery for reconstructing knees damaged as a result of noninflammatory degenerative joint disease (NIDJD) or either of its composite diagnoses of osteoarthrits and post-traumatic arthritis pathologies.

The CR RP device configuration is indicated for use in knees whose posterior cruciate ligament is intact, absent, or in such condition as to justify its sacrifice.

CONTRAINDICATIONS FOR USE
The following conditions are contraindications for total knee replacement with a

- Loss of bone or musculature, inadequate bone quality (e.g. severe osteoporosis), neuromuscular compromise or vascular deficiency at the bone site in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculodialgamentous supporting structures that could lead to implant instability, joint neuropathy).
- Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity.
- The inability to make bone cuts (e.g. inadequate bone stock) so as to assure correct component position, a firm press fit, and intimate apposition of the cut bone and prosthetic surfaces.
- Porous coated components must not be used with bone cement.

The use of the RP Total Knee System is contraindicated in:
- the presence of osteomyelitis, pyogenic infection or other overt infection of the knee joint. Every effort should be made to rule out the possibility of pre-operative sepsis in a patient who has one or more of the following abnormalities:
  - fever or local inflammation;
  - rapid destruction or bone resorption apparent on x-rays;
  - elevation of the erythrocyte sedimentation rate or white blood cell count unexplained by other disease or a marked shift in the white blood cell differential count.
  - patients with any active infection at sites such as the genitourinary tract, pulmonary system, skin or any other site. Should a patient have any infection prior to implantation, the foci of the infection must be treated prior to, during and after implantation.
  - patients with loss of musculature or neuromuscular compromise leading to loss of function in the involved limb or in whom the requirements for its use would affect recommended rehabilitation procedures.
  - patients with severe osteoporosis or other metabolic bone diseases of the knee;
  - patients with any of the following conditions:
    - lesions of the supporting bone structures (e.g. aneurysmal or simple bone cysts, giant cell tumor or any malignant tumor),
    - systemic and metabolic disorders leading to progressive deterioration of solid bone support,
    - the presence of severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity, fixed deformities greater than 60° of flexion, 45° of genu varus or valgus,
    - known drug or alcohol addiction,
    - skeletally immature individuals and the presence of allergic reaction to implant metals or polyethylene are also contraindications for the use of all device configurations of the RP Total Knee System.

WARNINGS
- The correct selection as well as the correct seating/placement of the prosthetic implant is extremely important. During surgery, particular attention to tracking of the patella is also required for a successful result. Thus, failure to use the optimum size implant, failure to properly align/position the component, failure to adequately seat the component adjacent to adequate bone and failure to ensure that the component is stable may result in dislocation, subsidence, fracture, suboptimal extensor mechanism function, or loosening of the components. The proper size selection, the choice of and careful use of the components and the use of trial prostheses are imperative.
- The ATTUNE CR or PS RP Tibial Insert must be the same size as the selected ATTUNE CR Cemented or Cementless or ATTUNE PS Cemented Femoral Component. The ATTUNE CR or PS RP Tibial Inserts articulate with the ATTUNE RP Cemented or Cementless Tibial Bases. ATTUNE CR or PS RP Tibial Inserts must be within 2 sizes of the RP Tibial Base.
- ATTUNE RP Total Knee components, instruments and trial prostheses should not be used together with those of another manufacturer. Because dimensional compatibility cannot be assured, adverse outcomes can result from the use of components from different manufacturers.
- A post-operative management program is vital. It is recommended that the program be modified according to the condition of the patient and the extent of soft tissue and ligament reconstruction.
- The safety and effectiveness of the non-cemented use of the RP tibial base in patients under 50 years of age have not been established. The safety and effectiveness of the non-cemented use of porous coated components has not been established in patients undergoing revision procedures. The safety and effectiveness of the non-cemented use of the RP tibial base for indications other than noninflammatory degenerative joint disease (NIDJD) and in bilateral applications have not been established.
- The implantation of the RP tibial insert and femoral component will not in itself guarantee a high level of post-operative flexion. The degree of post-operative flexion is multi-factorial. These factors include, but are not limited to, surgical technique, patient build, pre-operative flexion and age.

MRI SAFETY INFORMATION
The ATTUNE Cementless Rotating Platform (RP) Total Knee System has not been tested for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. Scanning a patient who has this device may result in patient injury.

The risks associated with other passive implants in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.

PRECAUTIONS
The surgeon should discuss all physical and psychological limitations inherent to the use of this device with the patient pre-operatively. Particular discussion should be directed to the issues of premature weight bearing, activity levels and the necessity for periodic medical follow-up.

Surgeons should not begin the clinical use of any knee prosthesis before they have thoroughly familiarized themselves with its specific implantation technique. Certain methods may change with time as further clinical experience is gained. Such changes are presented at regularly scheduled surgical instruction courses for which periodic attendance is advised. Surgical technique brochures, course schedules, and course recordings are available from DePuy.

Particular attention should be paid to the handling of the components. Contact between the porous coated components and cloth or other fiber releasing materials should be avoided in order to minimize contamination of the porous surfaces with adherent fibers. (see HANDLING section for further information).
ATTUNE® 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:
• ATTUNE® CR Tibial Insert size should be the same size as the selected ATTUNE CR Femoral Component size. ATTUNE CR Tibial Inserts should be within 2 sizes of the ATTUNE Tibial Base.
• ATTUNE PS Tibial Insert size should be the same size as the selected ATTUNE PS Femoral Component size. ATTUNE PS Tibial Insert should be within 2 sizes of the ATTUNE Tibial Base.
• ATTUNE Patella Component:
  • Sizes 38 mm and 41 mm may be used with all femoral component sizes.
  • Size 29 mm may only be used with femoral component sizes 1 through 3.
  • Size 32 mm may only be used with femoral component sizes 1 through 6.
  • Size 35 mm 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.

NOTE: DePuy's 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.
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.

MRI SAFETY INFORMATION
The ATTUNE Fixed Bearing Knee System has not been tested for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment. Scanning a patient who has this device may result in patient injury.

The risks associated with other passive implants in an MR environment have been evaluated and are known to include heating, migration, and image artifacts at or near the implant site.
ATTUNE® KNEE SYSTEM – ROTATING PLATFORM

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
The Rotating Platform (RP) Total Knee System is indicated for cemented use in cases of osteoarthritis and rheumatoid arthritis. The rotating platform prosthesis is indicated for primary total knee arthroplasty or the revision of failed knee prostheses.

CONTRAINDICATIONS FOR USE
The use of the RP Total Knee System is contraindicated in:
- the presence of osteomyelitis, pyrogenic infection or other overt infection of the knee joint. Every effort should be made to rule out the possibility of preoperative sepsis in a patient who has one or more of the following abnormalities:
  - fever or local inflammation;
  - rapid destruction or bone resorption apparent on x-rays;
  - elevation of the erythrocyte sedimentation rate or white blood cell count unexplained by other disease or a marked shift in the white blood cell differential count.
- patients with any active infection at sites such as the genitourinary tract, pulmonary system, skin or any other site. Should a patient have any infection prior to implantation, the foci of the infection must be treated prior to, during and after implantation.
- patients with loss of musculature or neuromuscular compromise leading to loss of function in the involved limb or in whom the requirements for its use would affect recommended rehabilitation procedures.
- patients with severe osteoporosis or other metabolic bone diseases of the knee;
- patients with any of the following conditions:
  - lesions of the supporting bone structures (e.g. aneurysmal or simple bone cysts, giant cell tumor or any malignant tumor),
  - systemic and metabolic disorders leading to progressive deterioration of solid bone support,
  - the presence of severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity, fixed deformities greater than 60° of flexion, 45° of genu varus or valgus,
  - known drug or alcohol addiction,
  - skeletally immature individuals and the presence of allergic reaction to implant metals or polyethylene are also contraindications for the use of all device configurations of the RP Total Knee System.

WARNINGS
- The correct selection as well as the correct seating/placement of the prosthetic implant is extremely important. During surgery, particular attention to tracking of the patella is also required for a successful result. Thus, failure to use the optimum size implant, failure to adequately seat the component adjacent to adequate bone and failure to ensure that the component is stable may result in dislocation, subsidence, fracture or loosening of the components. The proper size selection, the choice of and careful use of the components and the use of trial prostheses are imperative.
- The RP inserts should be the same size as the selected CR or PS femoral component. The RP inserts articulate with the RP primary bases. RP tibial inserts should be within 2 sizes of the RP tibial base.
- RP Total Knee components, instruments and trial prostheses should not be used together with those of another manufacturer. Because dimensional compatibility cannot be assured, adverse outcomes can result from the use of components from different manufacturers.
- A postoperative management program is vital. It is recommended that the program be modified according to the condition of the patient and the extent of soft tissue and ligament reconstruction.
- The safety and effectiveness of the cemented use of the RP Total Knee in patients under 41 years of age have not been established.
- The implantation of the RP insert and femoral component will not in itself guarantee a high level of post-operative flexion. The degree of post-operative flexion is multi-factorial. These factors include, but are not limited to, surgical technique, patient build, pre-operative flexion and age.

These knee replacement prostheses have not been evaluated for safety and compatibility in the MRI environment. These knee replacement prostheses have not been tested for heating or migration in the MRI environment. The risks of exposure to MRI 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. Please refer to current local MR safety guidelines for additional investigation, patient monitoring and patient follow-up advice. DePuy 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’s 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.

PRECAUTIONS
The surgeon should discuss all physical and psychological limitations inherent to the use of this device with the patient preoperatively. Particular discussion should be directed to the issues of premature weight bearing, activity levels and the necessity for periodic medical follow-up.

Surgeons should not begin the clinical use of any knee prosthesis before they have thoroughly familiarized themselves with its specific implantation technique. Certain methods may change with time as further clinical experience is gained. Such changes are presented at regularly scheduled surgical instruction courses for which periodic attendance is advised. Surgical technique brochures, course schedules, and course recordings are available from DePuy.

Particular attention should be paid to the handling of the components. (see HANDLING section for further information).

NOTE: DePuy’s 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.
Reference