INDICATIONS AND USAGE

The CONSENSUS® KNEE SYSTEM Primary Knee is designed as a system and is not intended for substitution of components from other systems.

The indications for use are:

A. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, or degenerative arthritis.
B. Failed osteotomy or unicompartmental replacements.
C. Replacement of unsatisfactory cemented or press-fit knee components when sufficient bone stock exists.
D. The non-porous (uncoated and coated with CoCr beads without Titanium) components may only be used with cement.
E. The porous coated (CoCr beads with Titanium) components may be used with or without cement.
Consensus® Knee System
Surgical Technique

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Design Rationale

The Consensus® Knee is designed to restore near normal anatomy, alignment and kinematics, as well as improve implant fixation. Anatomy is restored by referencing the intact portion of the distal femur, proximal tibia and the apex of the patella. Bone resections are followed by equal amounts of prosthetic replacement which contributes to the maintenance of the anatomic joint line and replication of the knee kinematics.

Reduced Lateral Profile (RLP) Femoral components offer additional sizing options in the anterior mediolateral dimension. Intraoperative measurements of patients having total knee replacements were taken by a Consensus Knee surgeon. These studies found that many patients needed a component narrower in the medial-lateral plane on the anterior portion. These measurements guided the RLP Femoral components’ design to provide additional sizing options and reduce component overhang in some patients (Figure 1).

The tibial resection parallels the posterior slope in the sagittal plane which helps prevent camming or laxity in flexion. Reproduction of the normal posterior slope maintains the load bearing capacity of the proximal tibia and resists anterior subsidence of the tibial component. The depth of the trochlear groove of the distal femur is restored to its anatomical level by the use of a recessed anterior chamfer cut. This enhances joint stability while decreasing patello-femoral compressive forces.

The tibial stem is offset medially to better support medial loads and avoid impingement on the lateral cortex. It is also positioned anteriorly and contoured to avoid impingement on the posterior cortex. Each tibial insert is compatible with multiple femoral components (Table 1).

The alignment rationale is based on the supposition that “normal” alignment is considered to be 6° of tibio-femoral valgus (Figure 2). This is achieved by cutting the tibia perpendicular in the coronal plane and by cutting the distal femur in 6° valgus in reference to the femoral canal. However, cutting blocks allow the resection to be modified intra-operatively to 4° or 8° of valgus if necessary.

<table>
<thead>
<tr>
<th>Size Compatibility</th>
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<tr>
<td>Tibial Insert</td>
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<td>Femoral Component</td>
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Table 1
Surgical Approach

The preferred anterior approaches to the knee are represented in Figure 3. After entering the synovium, elevating a subperiosteal flap off the medial plane of the tibia, and freeing the patellar tendon, the knee is maximally flexed. The medial capsule is released to the posteromedial corner to allow subluxation of the tibia anterior to the femur. This will allow complete visualization of the proximal tibia.

All osteophytes are removed from the distal femur to expose the true shape of the condylar surfaces. At this point, the meniscal remnants and the anterior and posterior cruciates should be removed to improve exposure and instrumentation access throughout the case. Additional ligament releases may be necessary for alignment correction or exposure.

Both standard and reduced incision approaches are complemented by our instrument systems. These lower-profile and medial-oriented instruments provide accurate resections and reproducible cuts for either technique.

The Consensus® Knee System requires attention to soft tissue balance and flexion-extension gap equality. Incision size should never limit appropriate implant position or alignment, or soft tissue balance.

As in all total knee techniques, a primary goal is to achieve balanced flexion and extension gaps. An additional objective is to provide equal medial and lateral soft tissue balance. These goals can assure consistent contact between the tibial insert and femoral component and
also prevent insert dislocation or subluxation.

**Femoral Preparation**

*Distal Femoral Resection*

An 8mm hole is made in line with the femoral shaft and medial edge of the intercondylar notch (Figure 4). The **T-handle** is attached to the (8mm) **I.M. Rod**. The I.M. Rod is then inserted through the **Femoral Alignment Guide**, which is assembled with the **Distal Femoral Cutting Block** (Figure 5). Prior to bone insertion, the **Femoral Alignment Guide** should be configured for a right or left knee by pulling and rotating the center “knob” to the left or right position. Both cannulated stabilizing screws should be fully retracted. The **I.M. Rod** is then inserted into the femoral canal until the guide contacts the distal femur. Should one of the condyles have a defect, the appropriate stabilizing screw can be adjusted to compensate for the lost cartilage and stabilize the instrument. The **T-Handle** can be removed to allow better access for installing fixation pins or screws.

Rotational alignment is determined by adjusting the posterior portion of the **Femoral Alignment Guide** so that it is parallel to the posterior femoral condyles. The rotation is then locked in place by drilling through either of the cannulated stabilizing screws with a 3.2mm drill bit and filling it with a like-size smooth pin (Figure 6). Alignment (6º valgus) can be confirmed with the **Alignment Tower** and **Rod** which should point through the center of the femoral head. Minor varus/valgus adjustments can be made by adjusting the stabilizing screws.
The **Distal Femoral Cutting Block** is affixed to the distal femur by drilling through the “0” marked holes and filling them with smooth pins. This will position the **Cutting Block** to make a 10mm resection which is the distal thickness of the femoral component (Figure 7 and 8).

All cutting blocks require a saw blade thickness of either 1.27mm or 1.37mm depending on the amount of clearance desired. Thermal injury to the bone can be controlled by using new blades and intermittently irrigating the saw blade when making bone cuts. With the **Cutting Block** affixed to the distal femur, the **Femoral Alignment Guide** is removed by releasing the thumb screw from the **Cutting Block**. An additional 3mm can be resected from the distal femur using the additional slot. The amount of bone resected can also be adjusted by moving the saw guide either proximally or distally in the holes provided for this purpose. These options for increased resection can help with the correction of flexion-contractures and assist in flexion-extension discrepancies. As a general guide, the sawblade should just contact or barely resect the femoral sulcus (Figure 9).
Femoral Sizing/Rotational Alignment

There are two types of Femoral Drill Guides: Standard and 2mm Anterior Shift. Each Drill Guide can be used in a neutral or 3º external rotation configuration (Note: The 3º external rotation configuration is left and right specific). This provides more anatomic patellar tracking and aids in preventing patellar subluxation and tracking problems later. The selected Drill Guide is placed into the Femoral Sizer (Figure 10).

With the knee maximally flexed, the Femoral Drill Guide/Sizer is centered in the M/L plane on the distal femur with the posterior feet referencing the posterior condyles. This position can be checked by making sure that the intercondylar notch aligns with the notch on the Femoral Sizer. The two captured stabilizing pins are then impacted. (If one of the condyles is defective, impact the stabilizing pin on the unaffected side and rotate the Femoral Sizer to compensate for lost cartilage. The second stabilizing pin can then be impacted.)

The sliding stylus along with the size markings on the Femoral Drill Guide are used to determine the correct Femoral Component size.

The two distal femoral holes are then drilled with the Distal Femoral Drill (Figure 11).
Femoral Resections

The **4-in-1 Cutting Block** is impacted in place and secured using the gold-headed fixation pins. The femoral resection check guide is then placed parallel to the **4-in-1 Cutting Block** to verify the femur will not be notched. If it appears this will notch the femur, the surgeon needs to move the block 2mm anterior and drill again or move to the next size block. The anterior, posterior, anterior chamfer and posterior chamfer resections are then made (Figure 12). Handles can be screwed into the blocks if needed for additional stability. When making the posterior cuts, **Retractors** should be positioned to protect the collateral ligaments.

The gold pins are then removed using the **Slap Hammer/Extractor**.

At this point the posterior osteophytes and loose bodies may be removed by lifting up the femur through the intramedullary hole previously placed or utilizing laminar spreaders.

Trial is placed on the femur and positioned in the medial-lateral plane. Drill holes are then drilled for the femoral implant posts. Once the trial is removed the trochlear groove can be prepared for the final implant. (Figure 13)

The trochlear notch is prepared using the **Trochlear Notch Cutting Guide**. With the properly sized guide placed in the holes on the distal femur, a 1” saw blade can be used to resect the trochlear notch on the anterior femur (Figure 14). (If the bone is soft enough, the blunt end of the Chisel and a mallet may be used to create the recessed chamfer by compressing the bone).

Tibial Preparation

The **Tibial Alignment Guide** can be used as an extramedullary or intramedullary guide. In either mode, the **Tibial Cutting Block** is preassembled to the medial side of the **Tibial Alignment Guide** which should be dialed to its
most proximal position. The technique chosen is based on surgeon preference. Once the alignment guide is set, either extramedullary or intramedullary, then the alignment guide procedure is the same.

**Extramedullary Alignment Guide**

The spines of the proximal tibia can be removed with a saw to allow accurate placement of the guide. Resect the spines level with the tibial plateau making a gross cut with the saw. The posterior pin on the proximal guide is impacted into the center of the tibial plateau. The ankle cradle is then opened and allowed to engage the tibia and fibula just above the malleoli. The adjustable shaft seeks the proper length when its lever is in the up position. When the desired length is established, the shaft is locked in place by pushing the lever down. Do not put excessive force on the locking arm.

The guide shaft is then adjusted to the interval between the tibialis anterior and exterior digitorum longus (center of the talus) at the ankle by dialing either of the knobs on the distal portion of the ankle cradle (Figure 15).

**Intramedullary Alignment Guide**

The intramedullary technique uses the 8mm fluted *Intramedullary Rod* (*I.M. Rod*) and *T-handle* passing through the proximal portion of the *Tibial Alignment Guide* (Figure 16). A reference hole is drilled with the 8mm drill bit referencing the tibial spine and between the middle and anterior one-third of the tibial plateau. It is critical that the drill hole not be placed in the center, as the *Tibial Alignment Guide* will impinge into the patellar tendon (Figure 17). The assembled *I.M. Rod* and *Tibial Alignment Guide* is then slowly introduced into the medullary canal and the assembly is positioned on the proximal tibia. The *T-handle* can be removed from the *I.M. Rod* if needed.

After placement of the *Tibial Alignment Guide* by either extramedullary or intramedullary methods, the tibial alignment guide technique then continues the same for each.
Tibial Alignment Guide Technique

Rotation

Position the alignment guide just medial of the tibial tuberosity and impact the stabilizing pins.

Note: For the intramedullary technique, the alignment guide can be rotated as desired.

Posterior Slope

The Stylus “pin” is placed into the hole on the superior surface of the Cutting Block that corresponds with the least defective side. The tip of the Stylus marked “slope” references the posterior slope of the tibial plateau. The thumb screw marked “slope” is then adjusted until the foot of the Stylus is parallel to the proximal tibial plateau. It is easiest to dial down from an elevated position superior to the tibia replicating slope (Figure 18). Under most circumstances this should be approximately 7° posterior slope.

Level of Resection

The Stylus is then picked up and rotated 180° so that the end marked “depth” is positioned over the least involved, or most normal non-deficient, portion of the tibial plateau. The Stylus is then lowered by turning the thumbscrew marked “depth” until the Stylus tip contacts the tibia (Figure 19). This will adjust the block for a 10mm resection which corresponds to the thinnest baseplate/insert combination. Caution should be noted, as the Stylus is flexible at the block connection. Be sure to confirm the Stylus is in its neutral position when adjusting the resection level. Holes are provided in the Cutting Block so that adjustments can be made by moving it up or down in 2mm increments if the surgeon feels there is too much or too little being resected.

The Cutting Block is affixed to the proximal tibia by filling the “0” marked holes with smooth fixation pins. The Stylus may be left in place to confirm accurate Cutting Block placement. The Cutting Block is released
using the top thumb screw and the *Tibial Alignment Guide* is removed with the *Slap Hammer/Extractor*.

Alignment can be checked by attaching the *Alignment Tower* to the saw guide. The *Alignment Rod* is then inserted in the stationary or pivoting hole of the tower. The tip of the rod should lie over the center of the talus to ensure a perpendicular cut. The proximal tibia is then resected (Figure 20).

Once a satisfactory cut is achieved, the *Cutting Block* is removed leaving one or both pins in place as a rotational guide. At this point, the osteophytes from the posterior femur should be removed with a curved osteotome.

**Sizing of the Proximal Tibia**

*Tibial Prep Guides* are used to size the tibia. They also serve as a guide for the *Tibial Stem Punch* and are used as trial baseplates.

The *Tibial Prep Guide Handle* is assembled to the *Tibial Prep Guide*. The guides are then fitted to the tibial plateau until the appropriate size is determined. Proper positioning is accomplished by aligning the *Prep Guide Handle* medial to the tibial tuberosity and centering the *Tibial Prep Guide* so there is no overhang. Once the desired position is obtained, the guide is fixed with two gold headed fixation pins (Figure 21). The *Alignment Rod* is used to verify axial alignment and is inserted through the *Tibial Prep Guide Handle*. The four peripheral peg holes are then drilled with the 3.2mm drill bit. *If sclerotic bone is present, re-drill these peripheral holes after the Tibial Baseplate is removed, using the patella stop drill bit.*

If a stemmed baseplate is to be used, the appropriate size *Tibial Stem Punch* is selected and positioned over the stabilizing pins. The punch is then fully impacted with a mallet (Figure 22) and removed using the *Slap Hammer/Extractor*. The *Tibial Prep Guide* is left in place and serves as the *Tibial Baseplate Trial*. 

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**Figure 21**

*Figure 22*
Patellar Preparation

The patella thickness is measured with the *Patellar Caliper* to provide a baseline dimension prior to the osteotomy.

A free-hand patella resection can be made or the *Patellar Osteotomy Guide* can be positioned vertically in the coronal plane with the jaws at the osteochondral juncture medially and laterally. The stylus is positioned over the apex of the patella. The resection is made through the saw capture (Figure 23). The *Patellar Drill Guide* is placed over the cut surface to determine the appropriate size *Patellar Component* (Figure 24).

The *Patellar Component* drill holes are drilled with the *Patellar Stop Drill Bit* (Figure 25). The *Patellar Trial* is then fully seated for trial reduction.

### Round Patella/Femur Compatibility Chart

<table>
<thead>
<tr>
<th>Patellas</th>
<th>Femur Sizes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Size 0 7.5mm</td>
<td>✓</td>
</tr>
<tr>
<td>Size 1 2.5mm &amp; 10mm</td>
<td>✓</td>
</tr>
<tr>
<td>Size 2 7.5mm &amp; 10mm</td>
<td>✓</td>
</tr>
<tr>
<td>Size 3 10mm</td>
<td>✓</td>
</tr>
</tbody>
</table>

*All oval patellas may be used with all femoral components*

Table 2

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Figure 23

Figure 24

Figure 25
**Trial Reduction**

A trial reduction is performed to assess soft tissue balancing, patellar tracking and range of motion. The *Tibial Prep Guide* serves as the tibial baseplate trial and should be left in position on the proximal tibial plateau. The appropriate size *Trial Femoral Component* is positioned using the *Femoral/Tibial Impactor*. *Trial Tibial Inserts* for either congruent or PCL substituting can then be inserted. The knee is then extended and overall alignment checked (Figure 26). If excessive varus or valgus exists, the alignment of the tibia is checked with an *Alignment Rod* through the *Prep Guide Handle*. If tibial correction is necessary, the trials are removed and the Varus/Valgus Saw Guide is used to correct the tibia. If the tibia alignment is correct, the malalignment is in the femur. The components are removed and the two pins are reinserted into the holes for the distal femoral cut. The Varus/Valgus Saw Guide is attached and the distal femur is recut to correct the deformity. The anterior, posterior, and recessed chamfer cuts must also be recut. If a flexion contracture exists with the 10mm spacer in place, the distal femur may be resected in 2mm increments to achieve adequate extension. Ligament balance is then checked. There must be equal laxity medially and laterally to assure even wear and proper kinematics. Finally, patellar tracking is assessed. A final trial reduction must be carried out to make sure that any balancing of soft tissues did not influence the size of the tibial insert.

The Trial Components are then removed with the Slap Hammer/Extractor.
Cemented Component Implantation

Prior to cement application, additional small holes may be placed in sclerotic or cancellous bone surfaces to aid in intrusion of cement and interdigititation.

Patella

The VitalitE Patellar Component is implanted first. The cut surface is thoroughly cleansed with pulsatile lavage. Cement is applied to the surface and the component is pressed into position using the Patellar Clamp and Inserter (Figure 27). All extruded cement is removed and attention turned to the tibia.

Tibia

The tibia is subluxed anteriorly with retractors posteriorly to the tibia. The tibial plateau is then thoroughly cleansed with pulsating lavage. Cement is applied to the tibial surface and forced into the trabecular bone with digital pressure or gun injection to attain 3-5mm penetration. The Tibial Baseplate Component is then pressed into place and fully seated using the Femoral/Tibial Impactor (Figure 28). Prior to hardening, excess cement is removed.

The appropriate size and thickness VitalitE Tibial Insert Component is then positioned into place by engaging the dovetail locking feature of the insert/baseplate anteriorly and pushing posteriorly until the insert is seated flush on the tibial tray (Figure 29).

Femur

The femur is cleaned thoroughly with pulsating lavage. Cement is applied to the resected surfaces and forced into trabecular bone with digital pressure or gun injection. The Femoral Component is positioned and fully seated into place using the Femoral/Tibial Impactor (Figure 30). Prior to hardening, excess cement is removed.
Porous Component Implantation

Tibia

The tibia is subluxed anteriorly with retractors posteriorly to the tibia. The tibial plateau is then thoroughly cleansed with pulsating lavage. The Tibial Baseplate Component is then pressed into place and fully seated using the Femoral/Tibial Impactor (Figure 28).

A 3.5mm Drill is positioned and a screw hole is drilled. The porous Tibial Baseplate allows a 22° angulation for screws. The selected 6.5 cancellous screw is then inserted until fully seated. Confirm screw is fully seated to assure there is no contact with the Tibial Insert.

The appropriate size and thickness VitalitE Tibial Insert Component is then positioned into place by engaging the dovetail locking feature of the insert/baseplate anteriorly and pushing posteriorly until the insert is seated flush on the tibial tray (Figure 29).

Femur

The femur is cleaned thoroughly with pulsating lavage. The Femoral Component is positioned and fully seated into place using the Femoral/Tibial Impactor (Figure 30).
PS Femoral Box Preparation (for PS type Femoral Implant use only)

To prepare the femur to accept a PS Femoral component with the pocketed central housing, the appropriately sized **PS Resection Guide** (Figure 31) is mounted onto the femur utilizing multiple Headed, or Smooth Pins to secure the **PS Resection Guide**. The **PS Resection Guide** A/P dimensions are the same as the implant to allow positioning and visual sizing confirmation.

*Note: If the femoral peg holes have been previously drilled, the PS Resection Guide holes are centered over the previous drilled peg holes.*

*Note: A single Peg Drill may be used momentarily in one of the PS Resection Guide holes, to align the Guide with the previously drilled peg holes in the femur.*

The femoral bone is removed by guiding a saw blade against the two vertical side wall surfaces of the Guide (Figure 32). Care is taken to direct the saw blade on a flat and parallel plane so as to avoid excess bone removal.

A saw is then used to make a plunge cut that is guided by the proximal anterior tab portion of the **PS Resection Guide**. (Figure 33)

Check to confirm posterior condyle bone is removed within the posterior cut outs of the **PS Resection Guide**. (Figure 34)

**Make the above resections in the following order:**

#1 Cuts - Two vertical A/P interior cuts  
#2 Cut - Plunge cut  
#3 Cuts - Posterior cut-outs

Inspection of cuts and confirmation of completeness and accuracy is critical to assure no possibility of impingement.
Once all cuts are completed, a Distal Femoral Drill is drilled into the holes of the PS Resection Guide to prepare for the Femoral Component Lugs (Figure 35).

The **PS Resection Guide** is removed, by pulling the Gold-Headed, or Smooth Pins.

The appropriately sized **Trochlear Notch Cutting Block** (Figure 36) is placed in the lug-holes to confirm the bone within the notch has been fully resected and if not, complete this resection using a chisel or a saw to resect the remaining bone. The PS Femoral Trial is positioned on the femur to assess accurate fit. The Trial is then removed.

**Determination of the Tibial Resection Slope Angle for P/S:**

**Posterior Slope:**

Utilizing the “Slope” adjustment knob, the target resection posterior slope should not exceed 3-4 degrees. This can be adjusted by using the Graduated Angle Guide on the **Tibial alignment Guide** (Figure 37), or visualization with the tibial stylus. This can be assessed to produce the required total slope of 3-4 degrees.
Cemented Component Implantation

Femur
The femur is cleaned thoroughly with pulsating lavage. Cement is applied to the resected surfaces and forced into trabecular bone with digital pressure or gun injection. The PS Femoral Component is positioned and fully seated into place using the Femoral/Tibial Impactor (Figure 38). Prior to hardening, excess cement is removed.

Tibia
The tibia is subluxed anteriorly with retractors posteriorly to the tibia. The tibial plateau is then thoroughly cleansed with pulsating lavage. Cement is applied to the tibial surface and forced into the trabecular bone with digital pressure or gun injection to attain 3-5mm penetration. The Tibial Baseplate Component is then pressed into place and fully seated using the Femoral/Tibial Impactor (Figure 39). Prior to hardening, excess cement is removed.

The appropriate size and thickness Tibial Insert Component is then positioned into place by engaging the dovetail locking feature of the insert/baseplate anteriorly and pushing posteriorly until the insert is seated flush on the tibial tray.

Using the Insert Impactor positioned on the anterior ridge at 45°, lightly tap the Insert Impactor to ensure complete seating of the PS Tibial Insert (Figure 40).

Note: If seating is not achieved by lightly striking the PS Tibial Insert, remove the Insert and inspect the tibial baseplate for any possible impingements.