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Introduction

While literature reports good outcomes for many current knee systems, clinical scores do not necessarily reflect patient satisfaction. While this dissatisfaction could be attributed to abnormal motion, such as paradoxical motion and AP instability, today’s active patients simply expect more out of their knee replacements than ever before. These expectations are not being met by the current generation of knee replacement designs.

To replicate normal knee function, Smith & Nephew conducted in-depth analyses of the geometry, kinetics, kinematics and ligament behavior of the normal knee and conventional TKA systems. These analyses created a better understanding of how the normal knee works and the limitations inherent in current knee designs. The knowledge gained through this research fueled the creation of a knee system to address those limitations.

The JOURNEY™ Bi-Cruciate Stabilized Knee System was designed to replicate both the PCL and ACL function, promote recovery of normal muscle activity, accommodate deep flexion, induce normal tibiofemoral axial rotation and provide proper patellar tracking throughout the entire range of flexion. Building upon that history, the JOURNEY II Total Knee System has refined the design and expanded the system to include cruciate retaining, deep dished, and constrained posterior stabilized options.

The knee system was designed to achieve PHYSIOLOGICAL MATCHING™ Technology through Function, Motion and Durability, Smith & Nephew has created a platform that hopes to empower patients to regain satisfaction while returning to their active lifestyle.

Indications

Indications for use include rheumatoid arthritis; post-traumatic arthritis, osteoarthritis or degenerative arthritis; failed osteotomies or unicompartmental replacement. This system is designed for use in patients in primary total knee replacement surgery, where the anterior and posterior cruciate ligaments are incompetent and the collateral ligaments remain intact.

To replicate normal knee motion, the JOURNEY II BCS and JOURNEY II CR prosthesis provides more mobility in the lateral compartment than other total knee systems. For patients that present with significant varus or valgus deformities (> 15º), morbid obesity or deficient collateral ligaments consider whether additional implant constraint is more appropriate. If patients with the above mentioned conditions are scheduled for a JOURNEY II BCS or JOURNEY II CR then assess the flexion space under full ligament tension (eg, laminar spreaders) with the patella reduced and consider having a constrained implant option on hand.
The guiding principle behind the design of the JOURNEY™ II Total Knee System was to achieve near normal function and motion while maintaining excellent durability and having the robustness to accommodate surgical and patient variability.

How to achieve PHYSIOLOGICAL MATCHING

Function
- Stability – Replicate the function of the native anatomy to yield normal laxity throughout the range of motion
- Strength – More normal neuromuscular firing patterns resulting from more normal anatomic tibiofemoral alignment and motion
- Satisfaction – Patients feel confident while performing activities of daily living due to more normal stability, neuromuscular firing patterns, and ligament behavior

Motion
- Tibiofemoral kinematics – Replicate the normal pattern of tibiofemoral motion throughout the range of motion
- Patellofemoral kinematics – More anatomic femoral condyles lateralize the patella groove in flexion to encourage more normal patella tracking
- Flexion – More normal kinematics and restored posterior femoral offset result in superior high flexion

Durability/Robustness
- Wear – VERILAST™ Technology combines OXINIUM™ and XLPE to form a highly durable and long-lasting bearing combination
- OXINIUM Oxidized Zirconium, exclusively from Smith & Nephew, contains <0.0035% nickel content compared to 0.5% in cobalt chrome.
- Surgical robustness – All the benefits of improved function and motion with similar sensitivity to surgical and patient variability as conventional knee systems.

PHYSIOLOGICAL MATCHING

Conventional TKA
Sizing and fit
To design the JOURNEY™ II Total Knee System, statistical data from over 250 femurs and tibias was used to characterize articular shapes and resected profiles in an effort to optimize four types of fit:
• **Coverage fit** – coverage of resected bone
• **Resection fit** – resection required to attach implants to bone
• **Interface fit** – implant/bone interface stability
• **Biomechanic fit** – restoration of functional surfaces

This wealth of data showed clear dimensional and size differences across a variety of unique patient anatomy that required a non-linear progression of more anatomic and personalized implant dimensions throughout the size range as seen below:
• Bone coverage was optimized by providing asymmetric baseplates and 10 (non-scaled) femoral sizes
• Bone resections were minimized by angling the PS box and posterior resection for all sizes
• Interface fit was improved through a unique femoral ‘hooking’ implantation method that helps pressurize the cement and lock the implant to the femur
• Biomechanic fit was improved by restoring the sagittal profiles, trochlear depth and jointline
The result is a system that is anthropometrically optimized.

Virtual simulation
The JOURNEY II Total Knee System was designed using state-of-the-art computer simulation and optimization techniques. Parametrically controlled CAD models were virtually implanted in an advanced computer knee simulator (proprietary, enhanced version of LifeMOD/KneeSIM™) and analyzed during multiple activities including deep knee bend and gait. Key measures including kinematics and ligament strain, which have been correlated to in vivo⁵ and in vitro data²⁰ respectively, were collected throughout flexion to characterize the biomechanic performance of the design. This allowed targeted advancements over previous total knee designs including JOURNEY BCS to further close the gap between total knee arthroplasty and normal healthy knees. Output from LifeMOD/KneeSIM was processed using the following:
• **Characterize:** Design of Experiments to characterize implant behavior and identify the most influential design parameters
• **Optimize:** Response Surface Methodology to optimize the implant shapes
• **Analyze:** Monte Carlo Simulations to evaluate surgical sensitivity on multiple patients compared to conventional knee designs

During development of the JOURNEY II Total Knee System, hundreds of thousands of combinations³⁴ of implant designs, patient anatomy, and surgical positioning were simulated, which is impossible to accomplish using conventional implant design methods. The resulting optimized design maintains the anatomic shapes of the original JOURNEY BCS design and uses subtle enhancements to expand the benefits of PHYSIOLOGICAL MATCHING™ Technology to more surgeons and patients.
Normal knee function

Shape

Joint line
• Medial condyle more distal than lateral condyle
• 3° physiological joint line

Femur
• Distal lateral condyle less round than the medial condyle
• Lateral posterior offset less than medial
• Posterior condyles circular in shape

Tibia
• Medial concave surface
• Medial sulcus near AP midline
• Lateral convex surface

AP stability
• ACL provides anterior stability and limits anterior translation of the tibia (femoral posterior translation)
• PCL provides posterior stability and limits posterior translation of the tibia (femoral anterior translation)
• Medial sulcus causes the medial posterior femoral condyle to sit nearly flush with the posterior tibia
• In this anterior position, the force environment causes femoral rollback during flexion
Extension

0° – Screw-home, anterior AP position
• Tibial tubercle approximately 10mm lateral to the ML midline
• Femur internally rotated 5° “screw-home” creating a Q-angle of 14-17°
• Sulcus of medial side and ACL cause the femur to sit nearly flush with the posterior tibia

Mid-flexion

0 – 90° – Rollback medial pivot
• Because of the anterior position of the femur, forces during flexion direct the femur to roll back
• During flexion, the quadriceps mechanism attempts to straighten and applies external rotation torque to the femur through the patella
• Femur external axial rotation is aided by the downhill force of the convex lateral compartment
• Axial rotation occurs due to greater lateral than medial rollback until the quadriceps mechanism is straight and the Q-angle is minimized
• Rollback combined with femoral external axial rotation yields a medial pivot
• MCL strain is near constant 0-60° before starting to slacken
• LCL strain gradually decreases with flexion
• PCL strain increases with flexion aiding femoral rollback

Deep-flexion

90 – 155° – Posterior translation
• Femur translates further posteriorly
• Femoral axial rotation continues due to lateral rollback while medial rollback has small changes and may decrease
• MCL continues to become looser with flexion
• PCL strain reaches its peak without becoming overly tight and limiting flexion

Functional flexion
• Lateral posterior offset is less, so femoral external axial rotation and convex lateral compartment are necessary for lateral condyle to clear tibia
• Medial condyle is more anterior than the lateral condyle, therefore, large posterior offset is needed to clear tibia
• Femoral external axial rotation and lateralized patella groove minimizes patellofemoral ML shear force, which optimizes quadriceps mechanism function
Conventional TKA function

Shape

Joint line
- Medial and lateral condyles equal thickness
- Non-physiological 0° joint line

Femur
- Symmetric distal condyles identical in thickness and shape
- Symmetric posterior condyles identical in thickness and shape

Tibia
- Symmetric insert identical in thickness and shape, creating a bi-concave design
- Sulcus located in posterior 1/3 of insert
- Symmetric baseplate does not provide anatomic coverage

AP stability
- Lack of ACL replicating feature causes anterior instability, especially in early gait while small tibial insert posterior lips further limits anterior stability
- Posterior cam or PCL provides posterior stability and limits anterior translation of the femoral component
- Insert sulcus causes the posterior femoral condyles to overhang the tibia posteriorly
- In this posterior position, the force environment causes femoral paradoxical anterior translation during flexion
Kinematics and ligament behavior

Extension

0° – No screw-home, posterior overhang
• Symmetric insert causes femoral component/femur to be directed anteriorly
• This results in no screw-home, reducing Q-angle
• Posterior sulcus and lack of an ACL cause the femur to overhang the tibia posteriorly
• This may require continuous use of the quadriceps muscle to stand, causing fatigue

Mid-flexion

0° – 90° – Paradoxical motion, lateral pivot
• Because of the posterior position of the femoral component, forces during flexion direct the femur to paradoxically translate anteriorly
• During flexion, the quadriceps mechanism attempts to straighten and applies external rotation torque to the femur through the patella
• Femoral external axial rotation resisted by insert bi-concave conformity
• Q-angle is not minimized, causing patellofemoral ML shear force
• Paradoxical anterior translation combined with limited femoral external axial rotation yields a lateral pivot
• MCL strain remains near constant 0-90° which could result in more tension than normal in some conventional designs. In others the MCL becomes slack in mid-flexion before regaining tension by 90°, which could contribute to mid-flexion instability.
• LCL strain is likely looser than normal in extension because femur sits more posterior.
• When the PCL is retained, its strain increases with flexion aiding femoral rollback, but it is likely looser than normal in extension because the femur sits more posterior, which could reduce early flexion stability

Deep-flexion

90° – Max flexion – Posterior translation, abnormal rotation
• Posterior cam causes femoral posterior translation
• Insert bi-concave conformity exceeds external torque applied by the quadriceps mechanism
• Femoral component abnormally rotates internally and aligns with symmetric insert
• Posterior translation combined with femoral abnormal internal rotation yields a lateral pivot
• Q-angle is increased, causing significant patellofemoral ML shear force
• MCL strain continues to remain constant which could restrict flexion
• When the PCL is retained, its strain reaches its peak but is often tighter than the normal knee\(^2\) which could inhibit high flexion

Functional flexion

• Lateral posterior offset is less, so femoral internal axial rotation and concave lip of lateral insert may cause early bone impingement, limiting flexion
• Large patellofemoral ML shear force may cause anterior knee pain, which can limit functional flexion
JOURNEY° II
Total Knee System function

Shape

Joint line
- Medial condyle more distal than lateral condyle
- 3° physiological joint line created

Femur
- Lateral distal condyle less thick than medial femoral condyle
- Posterior offset of medial and lateral condyles maintained
- Posterior condyles circular in shape

Tibia
- Concave medial surface
- Medial sulcus near AP midline
- Lateral compartment thicker than the medial compartment
- Convex lateral surface in sagittal plane creates a slight posterior slope

Stability throughout a range of motion
Kinematics and ligament behavior

Extension
0° – Screw-home, anterior AP position
- Insert arcuate path allows for 5° of screw-home
- Sulcus of medial side causes the femur to sit nearly flush with the posterior tibia
- Normal Q-angle and AP position created in extension

Mid-flexion
0° – 90° – Rollback medial pivot
- Because of the anterior position of the femur, forces during flexion direct the femur to roll back
- During flexion, the quadriceps mechanism attempts to straighten and applies external rotation torque to the femur through the patella
- Femur external axial rotation is aided by the downhill force of the convex lateral compartment
- Rotation continues until the quadriceps mechanism is straight and the Q-angle is minimized
- Rollback combined with femoral external axial rotation yields a medial pivot
- MCL strain is near constant 0-60° before starting to slacken
- LCL strain gradually decreases with flexion
- When the PCL is retained, its strain increases with flexion aiding femoral rollback plus the PCL is under some tension in extension due to the anatomic anterior position of the femur, which provides early flexion stability

Deep-flexion
90° – 155° – Posterior translation
- Femur translates posteriorly
- MCL continues to become looser with flexion which allows for high flexion
- When the PCL is retained, its strain reaches its peak but less tight than conventional knees, which allows for high flexion

Functional flexion
- 15° flexed cut extends articular surfaces by 4mm while minimizing bone resection
- Lateral posterior offset is less, so femoral external axial rotation and convex lateral compartment are necessary for lateral condyle to clear tibia
- Medial condyle is more anterior than the lateral condyle, therefore, large posterior offset is needed to clear tibia
- Femoral external axial rotation and lateralized patella groove from anatomic asymmetric femoral condyles minimizes patellofemoral ML shear force, which optimizes quadriceps mechanism function
Function summary

**Shape – Normal knee**
- Concave medial surface
- Sulcus near AP midline
- Convex lateral surface
- 3° physiological joint line

**Shape – Conventional TKA**
- Symmetric concave medial and lateral surfaces
- Sulcus located in posterior 1/3
- 0° unnatural joint line

**Shape – JOURNEY™ II Total Knee System**
- Concave medial surface
- Sulcus near AP midline
- Convex lateral surface
- 3° physiological joint line

**AP stability – Normal knee**
- ACL provides anterior stability
- PCL provides posterior stability
- Anterior AP position causes femoral rollback

**AP stability – Conventional TKA**
- Lack of anterior stability (ACL function)
- Posterior overhang causes femoral paradoxical anterior translation
- Anterior and mid-flexion instability

**AP stability – JOURNEY™ II Total Knee System**
- Anterior cam and posterior medial lip provide anterior stability
- Anterior AP position causes rollback
- ACL function and femoral rollback provide anterior and mid-flexion stability

### Conventional TKA function

<table>
<thead>
<tr>
<th>Flexion</th>
<th>Ant. instability</th>
<th>Mid-flexion instability</th>
<th>Posterior stability/Over tension or reduced stability</th>
</tr>
</thead>
<tbody>
<tr>
<td>-5</td>
<td>(No ACL function)</td>
<td>(Paradoxical motion)</td>
<td>(Posterior cam/PCL or PCL release)</td>
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<tr>
<td>0</td>
<td>No screw-home</td>
<td>Lateral pivot</td>
<td>Posterior translation</td>
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<tr>
<td>10</td>
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<td>(Paradoxical motion and limited axial rotation)</td>
<td>@Posterior cam/PCL</td>
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<tr>
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<td>150</td>
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</table>

- Adequate quadriceps efficiency
- Patellofemoral ML shear stresses increase
Kinematics – Normal knee
- 0° – Screw-home, anterior AP position
- 0° – 90° – Rollback plus femoral external axial rotation yields medial pivot
- 90° – 155° – Posterior femoral translation

Kinematics – Conventional TKA
- 0° – No screw-home, posterior overhang
- 0° – 90° – Paradoxical motion plus limited axial rotation yields lateral pivot
- 90° – 155° – Abnormal femoral internal axial rotation

Kinematics – JOURNEY™ II Total Knee System
- 0° – Screw-home, anterior AP position
- 0° – 90° – Rollback plus femoral external axial rotation yields medial pivot
- 90° – 155° – Posterior femoral translation

Flexion – Normal knee
- External axial rotation of femur allows lateral condyle to clear posterior tibia
- Large posterior offset allows medial condyle to clear posterior tibia
- Patellofemoral ML shear force minimized

Flexion – Conventional TKA
- Abnormal internal axial rotation causes early bone impingement, limiting flexion
- Internal axial rotation and centralized distal patella track causes significant patellofemoral ML shear force

Flexion – JOURNEY™ II Total Knee System
- External axial rotation of femur allows lateral condyle to clear posterior tibia
- Large posterior offset allows medial condyle to clear posterior tibia
- Patellofemoral ML shear force minimized

JOURNEY II Total Knee System function

<table>
<thead>
<tr>
<th>AP stability</th>
<th>Ant. stability (Anterior cam)</th>
<th>Mid-flexion stability (Concave medial surface)</th>
<th>Posterior stability (Asymmetric posterior cam/PCL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screw-home</td>
<td>Medial pivot (Convex lateral and concave medial)</td>
<td>Posterior translation (Asymmetric posterior cam/PCL)</td>
<td>Minimized patellofemoral ML shear stress</td>
</tr>
<tr>
<td>Enhanced quadriceps efficiency</td>
<td></td>
<td></td>
<td>Extended articular surfaces</td>
</tr>
</tbody>
</table>

Flexion

-5 0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 155
Ligament behavior

Ligament behavior – Normal knee
- Asymmetric femoral condyles affect tension profile of medial and lateral soft tissues differently
- MCL strain is near constant 0-60° before starting to slacken
- LCL strain gradually decreases with flexion
- PCL strain increases with flexion up to its peak in deep flexion without being overly tight

Ligament behavior – Conventional TKA
- Symmetric femoral condyles can not replicate normal tension profile of medial and lateral soft tissues without femoral malalignment
- MCL strain is typically near constant throughout flexion which could restrict deep flexion or loose in mid-flexion which could cause instability
- LCL strain is likely looser than normal in extension because femoral sits posterior
- PCL strain is looser in extension which could affect knee stability and tighter in deep flexion which could restrict deep flexion

Ligament behavior – JOURNEY™ II Total Knee System
- Asymmetric femoral condyles allow replication of normal tension profiles of both medial and lateral soft tissues
- MCL strain is near constant 0-60° before starting to slacken
- LCL strain gradually decreases with flexion
- PCL strain increases with flexion up to its peak in deep flexion without being overly tight

Ligament behavior comparison - MCL strain
Ligament behavior comparison - LCL strain
Ligament behavior comparison - PCL strain
**Conventional TKA wear**
- Paradoxical motion during flexion may increase sliding distance/wear\(^4\)
- Concave lateral insert conformity increases the wear footprint (the total amount of area that the femoral traverses during the entire ROM), which may increase wear

**Conventional TKA post contact**
- Unintended femoral contact with the post causes severe post stresses
- Surpassing fatigue stress can cause post breakage
- Non-rounded posts and cams can cause edge loading during femoral external axial rotation, increasing stresses on the post

**Conventional TKA patellofemoral shear forces**
- Limited and abnormal femoral axial rotation increases patellofemoral ML shear forces
- Excessive shear force may cause anterior knee pain, premature articular wear and/or peg breakage

**Conventional TKA materials**
- CoCr is less abrasion resistant and is less lubricious than OXINIUM\textsuperscript{TM} Oxidized Zirconium, increasing both adhesive and abrasive wear\(^36, 37, 38\)
- Non-polished baseplates produce more backside wear than polished baseplates

**Conventional TKA locking mechanism**
- Competitive insert/baseplate locking mechanisms require a screw or bolt augment through the insert to prevent insert disassociation

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**Patella tracking comparison**\(^{35}\)

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**Durability**

**JOURNEY II TKA**
JOURNEY™ II Bi-Cruciate Stabilized Knee System wear

- Wear tested to five million cycles
- Predominant wear feature on the insert articular surface was burnishing
- There were no signs of fatigue wear or delamination
- Volumetric wear was less than previously published wear for conventional TKA25-33
- Medial pivot and rollback cause the lateral side to roll more and slide less and virtual elimination of paradoxical sliding as the knee flexes should maintain the normal cycles of the femur across the polyethylene leading to reduced wear compared to conventional designs
- Convex lateral insert compartment reduces wear footprint

JOURNEY II BCS Knee System post contact

- Large, rounded anterior cam reduces contact stresses and eliminates edge loading
- Asymmetric, rounded posterior cam maintains congruent contact during femoral axial rotation, eliminating edge loading and minimizing stress

JOURNEY II TKA patellofemoral ML shear forces

- Femoral external axial rotation and patella groove lateralized by asymmetric femoral condyles minimizes patellofemoral ML shear forces
- Risk of premature wear, peg breakage and anterior knee pain reduced

JOURNEY II TKA materials

- OXINIUM® Oxidized Zirconium reduces abrasive and adhesive wear
- Highly cross-linked polyethylene (XLPE) combines with OXINIUM to form VERILAST Technology a highly durable bearing combination shown have low wear rates during simulator testing26
- ETO sterilization does not produce free radicals, which reduces the risk of oxidation and subsequent delamination39
- Polished tibial baseplate reduces backside wear

JOURNEY II TKA locking mechanism

- Strategic interference designed to reduce micromotion
- Insertion tool provides confidence of proper assembly
- Large dovetail interface area eliminates the need for additional locking mechanisms (i.e. screws, clips)
- Deep flexion possible

The implants identified below were tested by their manufacturers using different testing protocols and, therefore, the results are not directly comparable.

Mean volumetric wear rates of CoCr against conventional polyethylene (CPE), CoCr against crosslinked polyethylene (XLPE) and OXINIUM against XLPE as published by the respective companies with their respective implants. Please see reference section for testing information.
Surgical sensitivity analysis
- Used to determine how sensitive JOURNEY™ II Total Knee System is when not implanted in optimal alignment
- Response Surface Methodology was used to create a model of the effects of deviations from ideal surgical alignment
- Distributions, based on literature, were assigned to the surgical deviations. Then, Monte Carlo Analysis simulated a patient performing a deep knee bend after 100,000 random surgeries to identify the effects on knee joint loads, ligament strain, and kinematics for JOURNEY II and compared them to conventional TKA.

The distribution of outcomes from the surgical sensitivity analysis showed JOURNEY II system has:
- Lower worst case patella shear
- Similar or lower likelihood of overly tight ligaments
- More normal kinematics even when malaligned than a conventional TKA design

Robustness

Variation in patella shear due to surgical variation.
Left, more negative number, is higher shear force.

Variation in kinematics due to surgical variation.

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<thead>
<tr>
<th>Surgical Variable</th>
<th>Max. Value</th>
<th>Min. Value</th>
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<td>Femoral Joint Line</td>
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<td>Femoral Internal-External</td>
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<td>Tibia Varus-Valgus</td>
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<td>Extension Gap</td>
<td>4 mm gap</td>
<td>2 mm interference</td>
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System overview

Femoral component dimensions (mm)

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Note: Stem sloped 3° posteriorly. Stem length is 50mm on all nonporous sizes.

Tibial baseplate dimensions (mm)

<table>
<thead>
<tr>
<th>Size</th>
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Note: Stem sloped 3° posteriorly. Stem length is 50mm on all nonporous sizes.
Articular insert dimensions (mm)

Minimum polyethylene thickness for a 9mm metal-backed component is 6.7mm on the medial side.

* Baseplate thickness included.

**JOURNEY™ II CR insert compatibility**

Completely interchangeable with all size femoral components
Tibial insert dimensions (mm)

### JOURNEY™ II BCS constrained insert

![Image of JOURNEY™ II BCS constrained insert]

### JOURNEY™ II CR deep dish insert

![Image of JOURNEY™ II CR deep dish insert]

**9mm Constrained Insert**

<table>
<thead>
<tr>
<th>Insert Size</th>
<th>A</th>
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<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
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</table>

Minimum polyethylene thickness for a 9mm metal-backed component is 6.7mm on the medial side.  
* Baseplate thickness included.

**9mm Deep Dished Insert**

<table>
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<th>Insert Size</th>
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<th>D</th>
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<td>Sz 1-2</td>
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</table>

Minimum polyethylene thickness for a 9mm metal-backed component is 6.7mm on the medial side.  
* Baseplate thickness included.

### Insert offering / compatibility (BCS, Constrained, Deep Dished)

<table>
<thead>
<tr>
<th>Femoral Size</th>
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<tr>
<td>3-4</td>
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<tr>
<td>7-8</td>
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</tbody>
</table>

**JOURNEY™ II CR insert compatibility**

Completely interchangeable with all size femoral components
The JOURNEY™ II Total Knee System is the next step for a knee system designed to restore normal function in that it maintains the tenets of restoring normal knee AP stability, kinematics and deep flexion while adding a Cruciate Retaining version, more stable Constrained PS and Deep Dished options, and enhancing the Bi-Cruciate Stabilized design. Smith & Nephew has continually improved the technologies used to better understand the behavior of the knee from the kinematics to the soft tissue function to further advance the science behind knee arthroplasty design. With a design based on natural anatomy, the JOURNEY II Total Knee System addresses many of the problems associated with conventional systems, while maximizing durability and minimizing sensitivity to malpositioning.

The JOURNEY II Total Knee System achieves function, motion and durability without sacrificing robustness required to work in the real world.