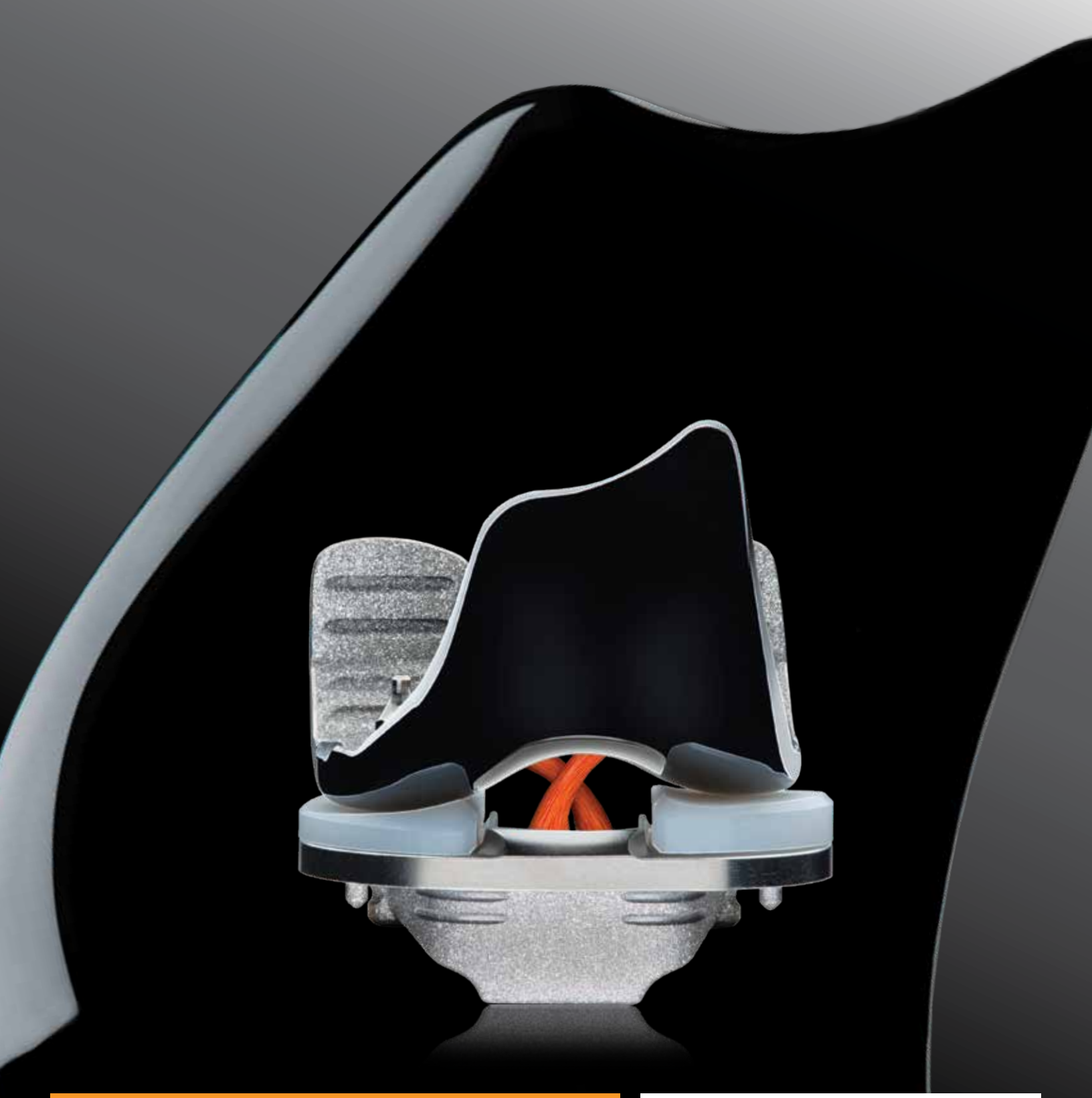

Design Rationale

smith&nephew

JOURNEY® II XR®

Bi-Cruciate Retaining
Knee System

Supporting healthcare professionals

JOURNEY® II XR®
Bi-Cruciate Retaining Knee System Design Rationale
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Introduction

While literature reports good outcomes for many current knee systems,[1] clinical scores do not necessarily reflect patient satisfaction, with up to 20% of knee patients dissatisfied with their knee replacement.[2,3] While this dissatisfaction could be attributed to abnormal motion, such as paradoxical motion and AP instability,[4] 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 designed to address those limitations.

The JOURNEY BCS Bi-Cruciate Stabilized Knee System successfully replicates both the PCL and ACL function, promotes recovery of normal muscle activity, accommodates deep flexion, includes normal tibiofemoral axial rotation and provides proper patellar tracking throughout the entire range of flexion.[5-19] 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.

Building upon this success, Smith & Nephew set out to develop a bi-cruciate retaining knee system, to no longer replicate, but retain all of the normal, healthy ligaments of the knee. The literature shows that the ACL is paramount in providing normal stability and kinematics throughout the range of motions, as well as proprioception.[20,22,23]

Promising solution for dissatisfied patients

One potential option to address dissatisfied patients is bi-cruciate retaining (BCR) total knee arthroplasty (TKA). BCR TKA has been shown to be preferred by patients with bilateral TKA where one knee was a traditional CR or PS knee, and one knee was a BCR implant.[20] BCR TKA also has motion patterns more similar to normal knee than most other TKA.[21-23] Additionally, BCR TKA has had good long-term survivorship for implant designs that have low conformity tibial inserts and metal backed tibias.[24,25] The literature is very clear that patients who maintain their ACL/PCL through a partial knee replacement have significantly higher satisfaction compared to TKA patients.[58] Data suggests that maintaining the ACL might play a large role in partial knee replacement's relative satisfaction compared to TKA. All of this data suggests that BCR TKA could help reduce the rate of dissatisfied patients. JOURNEY® II XR® was designed to capture the patient satisfaction of a partial knee replacement combined with the long term survivorship and principles of a TKA.

BioPro/Townley

Cloutier

Geometric

LCS

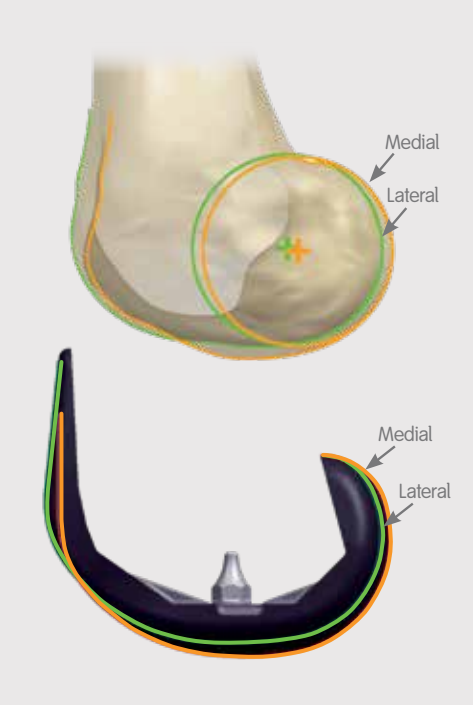
Limitations of bi-cruciate retaining TKA

While there were some positive results with certain BCR designs, other designs had some clinical outcomes that led to limited use. A review of published literature, FDA Maude database*, and retrieved BCR tibial implants found the following areas of concern:

- Flexion (< 105° or manipulations) was limited as a result of constrained polyethylene and non-anatomic implant designs[24,26-30]
- Tibia fixation in all-poly and metal backed BCR implants as a result of polyethylene constraint and poor fixation features[24,27,30-38]
- Tibia implant strength as a result of poor materials or fatigue strength design[33,38,39]
- Tibia insert lock issues[38]
- Tibia polyethylene wear[24,25,38]
- Difficult surgical technique also contributed to the limited use of BCR TKA and some of the poor clinical outcomes[25,40-43]

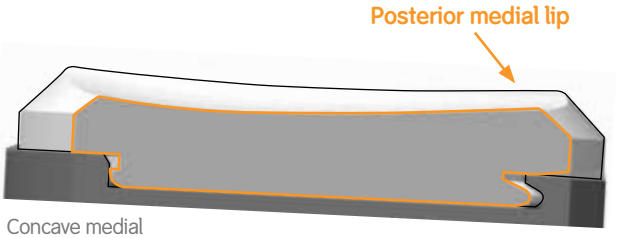
* MDR data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices. Confirming whether a device actually caused a specific event can be difficult based solely on information provided in a given report.

JOURNEY® II XR® is designed to solve past BCR limitations

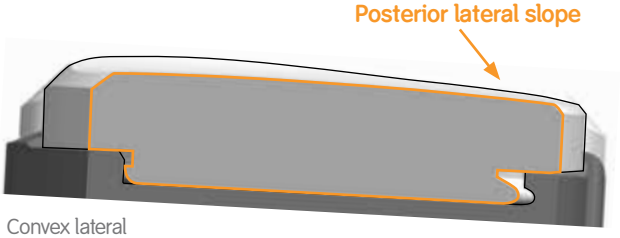


Flexion and ligament balance

JOURNEY II XR is designed with asymmetric femoral condyles and low constraint concave medial and convex lateral articular surfaces to improve range of motion and aid ligament balancing. The normal knee has asymmetric femoral condyles which affect the tension profile of the medial and lateral soft tissues differently. By having asymmetric femoral condyles, JOURNEY II XR is designed to replicate the different medial and lateral tension profiles. Ligaments that attach anterior or posterior on the tibia like the cruciates are affected by anterior-posterior position of the femur, so low constraint articular surfaces with asymmetric medial and lateral profiles like the native anatomy encourage normal femur positions while allowing the ligaments to influence motion and avoid tightness that could restrict flexion.

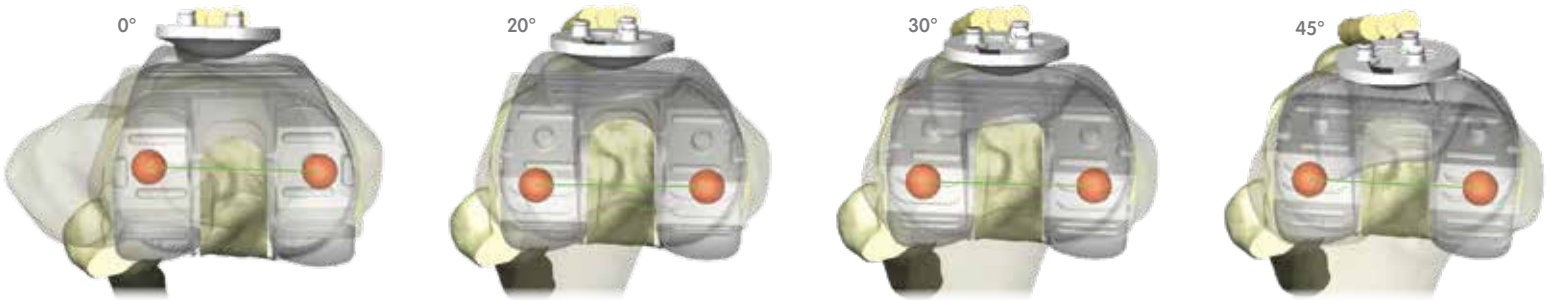


Concave medial



Convex lateral

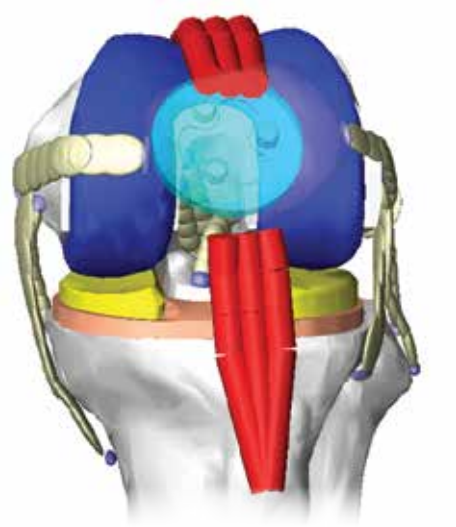
Coronal conformity central and flat peripheral



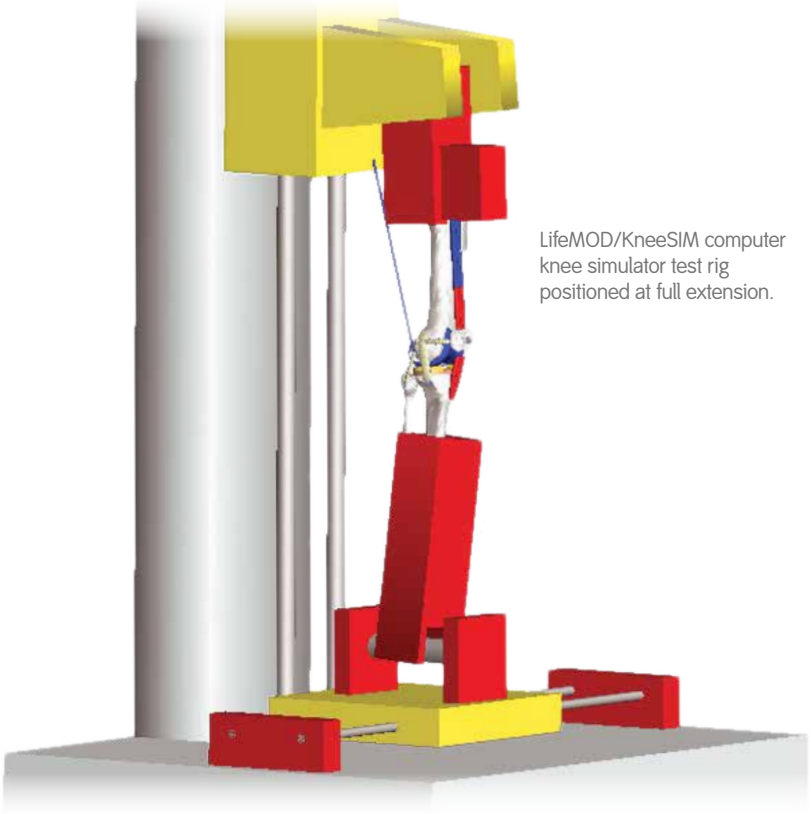
LifeMOD

Proprietary LifeMOD Design Software

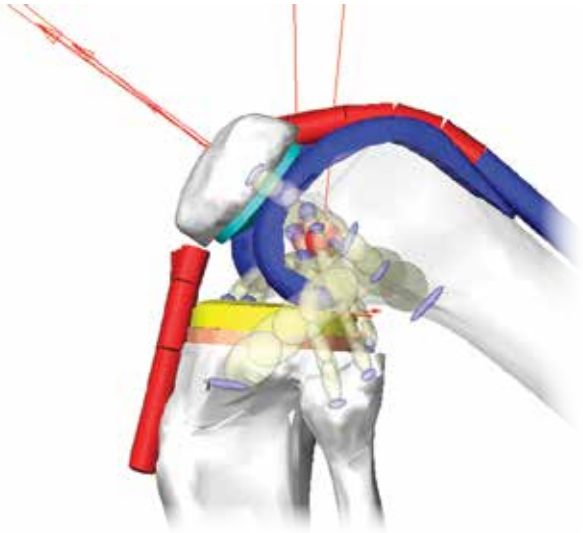
JOURNEY® II XR® was designed using state-of-the-art computer simulation techniques. Parametrically controlled CAD models were virtually implanted in an advanced computer knee simulator (proprietary, enhanced version of LifeMOD/KneeSIM®) and analyzed during multiple activities including deep knee bend and gait. Key measures including kinematics and ligament strain, which have been correlated to in vivo[5] and in vitro data[44] respectively, were collected throughout flexion to characterize the biomechanic performance of the design under ideal conditions and when accounting for surgical variability.



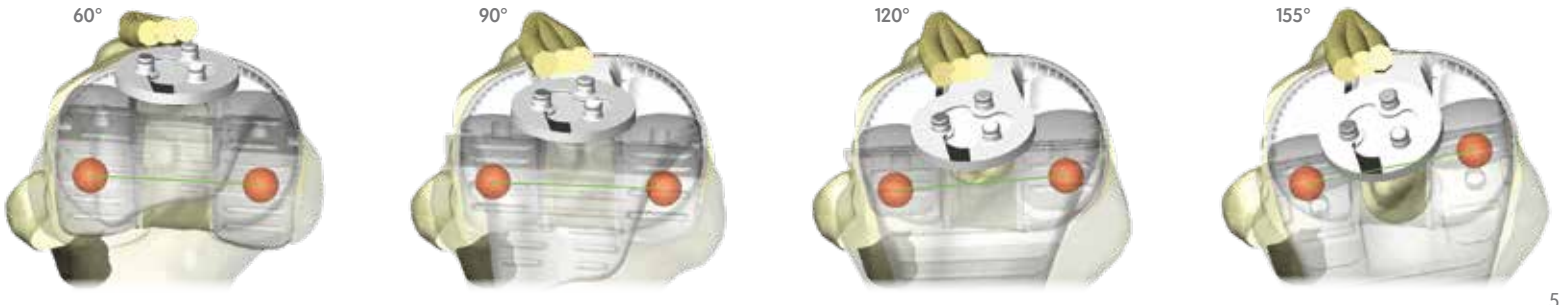
Anterior view of JOURNEY II XR during simulated flexion in LifeMOD/KneeSIM



LifeMOD/KneeSIM computer knee simulator test rig positioned at full extension.

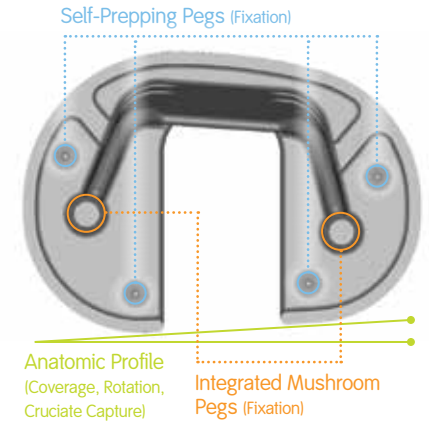


Lateral view of JOURNEY II XR during simulated flexion in LifeMOD/KneeSIM



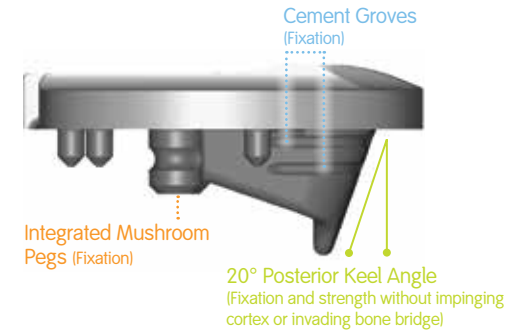
Tibia fixation

The JOURNEY® II XR® tibial baseplate has the same proven asymmetric perimeter shape as the GENESIS® II tibial baseplate,[45,46] which is designed to have maximal coverage and bony support to reduce loosening. Additionally, it features an asymmetric notch, with a more anterior position medially to accept a well fixated ACL footprint. A keel was designed to match the anatomy of the anterior tibia with four corners intended to replicate the good tibia fixation of previous four peg tibia designs.[47-49]



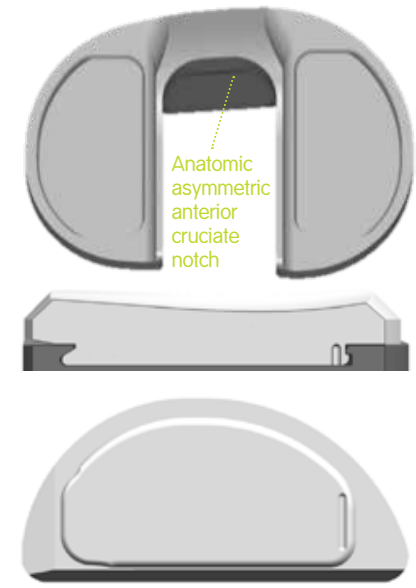
Tibia implant strength

The JOURNEY II XR tibial baseplate has a continuous keel and optimized anterior bridge to provide strength, which was designed to eliminate historical design concerns related to anterior implant fractures.[33,38,39] The keel is angled posteriorly to allow depth without hitting anterior cortex or undermining ACL. The anterior bridge is shaped to have a gradual transition from the increased thickness surrounding the cruciate notch. The baseplate material is forged Ti-6Al-4V, and has lower stiffness than CoCr,[55] reducing the risk of bone resorption from stress shielding. The resulting tibial baseplate design completed fatigue testing at 500 lbs for 10 million cycles with the loaded half of the baseplate unsupported according to ASTM F1800-07,[56] which is more than double the 202 lbf minimum load recommended by ASTM F 2083-08 and 225 lbf documented in the Zimmer Biomet™ literature around VANGUARD XP's fatigue strength.[57]



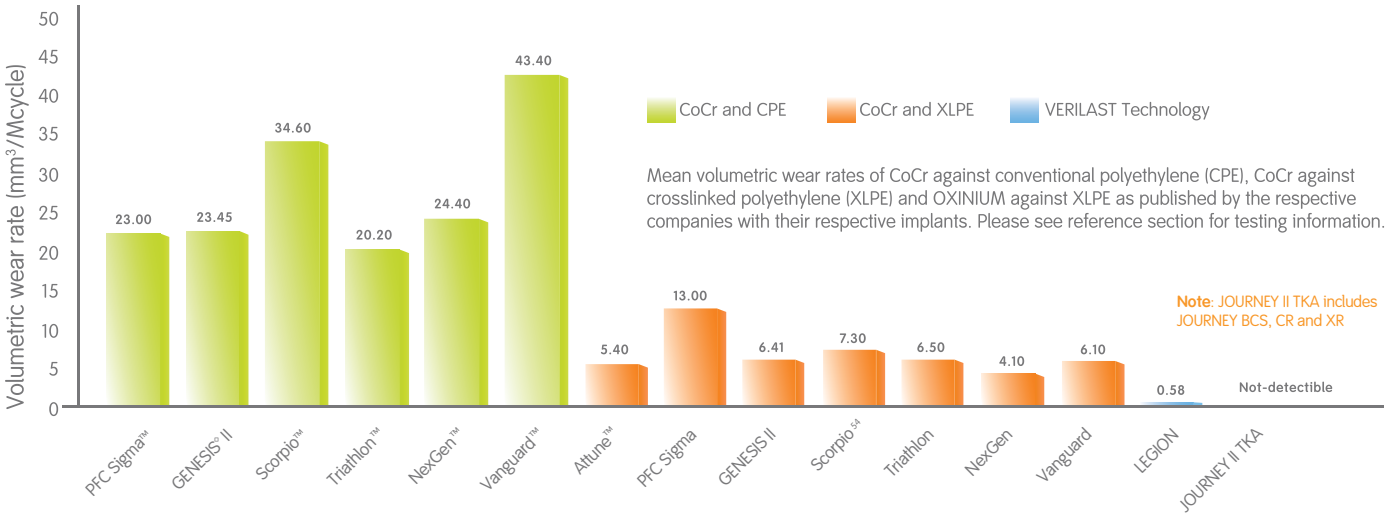
Tibia insert lock

The JOURNEY II XR tibial design has a fully captured lock detail with posterior and anterior locking interfaces. When tested to determine resistance to anterior lift-off caused by an extension moment, the lock for each insert is as strong as an entire TKA lock detail.[50] A narrow pocket is located behind the anterior lock to increase flexibility during insertion, which allows the insert to be assembled to the baseplate with less force than reasonable thumb pressure.[51,52]



Tibia polyethylene wear

The JOURNEY II XR tibial inserts are manufactured from highly cross-linked polyethylene (XLPE) which combines with the OXINIUM® femoral to form VERILAST® Technology a highly durable bearing combination shown to have low wear rates during simulator testing.[53] JOURNEY II XR's wear simulator results show no measurable wear at 5 million cycles.



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.

Note: JOURNEY II TKA includes JOURNEY BCS, CR and XR

Surgical technique

The JOURNEY® II XR® instruments have been designed to facilitate a surgical technique that continuously provides feedback for efficient, safe, and effective preservation of the anterior and posterior cruciate ligaments.

- Joint line preservation is important when retaining ligaments because the relationship between the articular surface and ligament attachments affects ligament function. The Distal Femoral Gage checks extension gap with posterior condyles in place to maintain tension on posterior capsule and avoid false sense of extension laxity. This allows for a precise approach to the distal femoral resection because immediate feedback is available to correct for an insufficient resection before any other steps are completed. Without this step, there is a higher risk of full extension tightness leading to tibia eminence fracture or joint line elevation leading to ligament imbalance throughout flexion.
- Preserving the ACL attachment causes the tibial resections to determine tibial implant position, which adds complexity compared to a typical total knee arthroplasty. The added complexity is mitigated by instrumentation such that tibial alignment is performed in the following independent steps. These steps build upon each other eliminating the need to redo a step based on a subsequent step.

Setting initial rotation

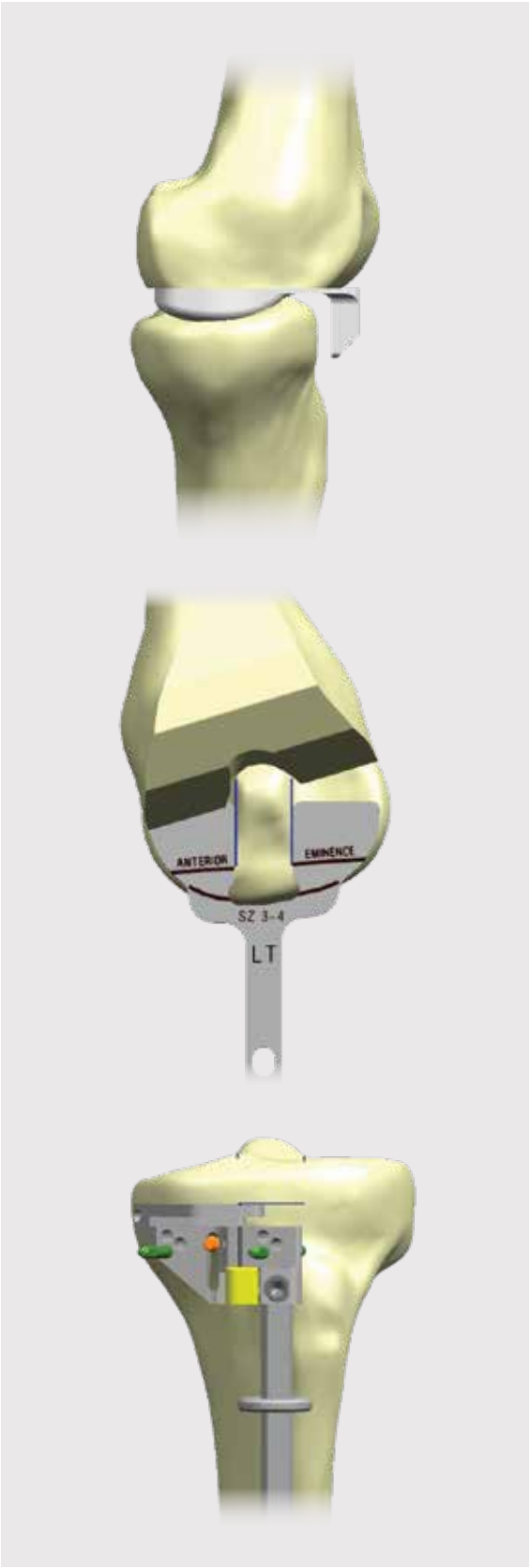
Use the Tibial Orientation Template to visualize and mark placement of the eminence resections.

- Tibia cortical support and cruciate retention are top priorities.
- The JOURNEY II XR implants have low constraint, so tibia baseplate rotation has little effect on knee function as defined by tibiofemoral kinematics, patella tracking, and ligament strain.

Initial tibial alignment and resection depth

Position the extramedullary alignment tube and set tibial varus-valgus by pinning the 3° Datum Block through the vertical slot, allowing for hands free refinement of depth, varus/valgus, slope and rotation adjustments in subsequent steps.

Use the Depth Stylus and check sagittal alignment before pinning through parallel holes in the Datum Block to set tibial depth and posterior slope.



Surgical technique *continued*

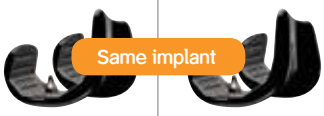
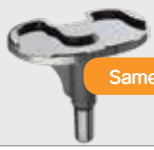
Tibial resections and balancing

Mate the Tibial Orientation Stylus to the Datum Block and align the guide arms to the eminence marks, provisionally lock with the lever, and drill/pin through the eminence holes. The freedom to adjust Tibial Orientation Stylus placement eliminates the need for perfect Datum Block placement.

- Medial and lateral tibial resections are completed using separate cutting guides locked to same platform which is intended to provide the accuracy of a single cutting guide with two smaller cutting guides.
- The tibial eminence is protected during all tibial resections. Drills or pins are used in the Tibial Orientation Stylus to protect the resection corners. The Lateral Saw Capture has an integral pin providing protection and medial access to the saw. The Anterior Eminence Chisel locks into the Anterior Eminence Chisel Guide to block the saw during the anterior resection.
- All trialing is completed with all resected bone space filled to avoid a false sense of laxity. Trialing with the full femoral trial and medial tibial trial prior to lateral tibial resection is a good predictor of balance after all resections are completed, so any recuts can be isolated to the more accessible medial tibia.
- The anterior cut is last after all trialing is completed (ACL technique). This allows any tightness throughout the range of motion to be identified while the tibial eminence is still connected to the anterior cortex protecting the eminence connection to the tibia in case the ACL is too tight. If the anterior cut was not last, there would be a significantly higher chance of a bone bridge fracture.
- A well balanced knee is important with a low constraint design that relies on the ligaments for stability, so JOURNEY® II XR® includes more options to enable balancing. During medial balancing if the knee is too tight with the minimum thickness or tighter in flexion than extension, insert trials simulating a depth and/or slope recut can be used to evaluate the effects of a recut before committing. If the knee is looser in flexion than extension at any point in the surgery, tibial trials corresponding to tibial implants can be used to effectively reduce the tibial slope. With these balancing options, the surgeon can have a higher level of confidence of achieving a balanced joint throughout the range of motion, and only require a recut when the joint is too tight.

	Tight	OK	Loose
Extension	6mm, 0° 	8mm, 0° 	9 – 12mm, 0° 
Flexion	2° trial, 2mm, 2° recut 	0° trial, 2mm recut 	2mm recut. Then use – 2° Insert
Flexion	8mm, 2° recut 	8mm 	8mm, -2° Insert 
Flexion	9 – 12mm, 2° Insert 	9 – 12mm 	9 – 12mm, -2° Insert 

- If at any point during a JOURNEY® II XR® surgery the patient is no longer a good candidate for a bi-cruciate retaining knee, it is an easy intra-operative conversion to a JOURNEY II CR, DD, BCS or Constrained knee. JOURNEY II XR uses the same femoral trial, so with removal of the ACL and tibial eminence bone and preparation of the PS box for BCS or Constrained, the knee can be completed as usual.

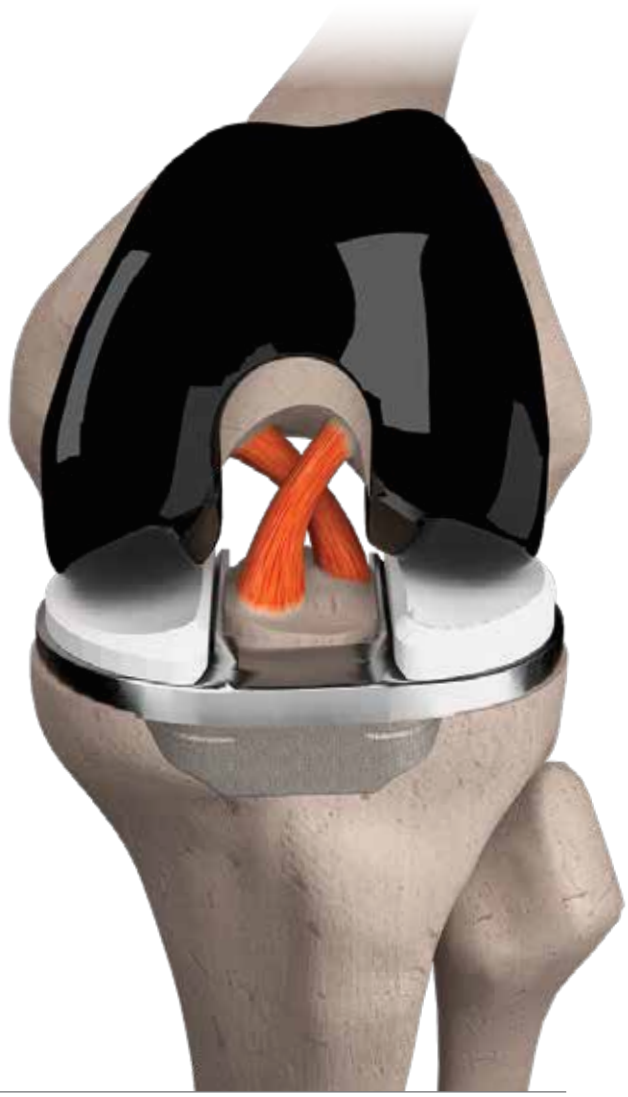
	JOURNEY II XR	JOURNEY II CR	JOURNEY II BCS	
				
				Kinematic options
				Constraint options
				
JOURNEY Early Intervention				LEGION® Revision

JOURNEY II XR brings it all together

There is a clear need and demand to improve patient satisfaction in knees. While most companies are just now talking about this issue, Smith & Nephew has been addressing this need for over a decade by replacing and replicating the cruciates with JOURNEY's physiological matching shapes.

JOURNEY II XR is the next step in this evolution to change the discussion around TKA, by retaining rather than substituting for the ACL and PCL. The ultimate design intent was to provide the patient satisfaction of a partial knee replacement with the long term survivorship and reproducible principles of TKA. JOURNEY II XR accomplishes this by eliminating the past concerns of BCR knee through:

- Retaining the ACL and replacing the affected joint with a completely asymmetric and anatomic joint designed to move like a normal knee.
- Advanced simulation and testing to create baseplate features that allow the optimal fixation and fatigue strength characteristics
- Advanced bearing materials of VERILAST® Technology to provide lasting survivorship
- A robust technique to allow reproducible outcomes



This design rationale is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients.

For detailed product information, including indications for use, contraindications, effects, precautions and warnings, please consult the product's Instructions for Use (IFU) prior to use.

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