Smith & Nephew has a rich history in the medical field dating back over 150 years. The company has produced many products that demonstrate proven performance. Built upon the world-class GENESIS II design and its nearly 20 years of clinical data, the LEGION Total Knee System is carrying on the legacy.

LEGION Primary Knee System - Safety and Efficacy Clinical Study

- A ten year study spanning five sites and 138 patients.
- Two year interim results show just two revisions; one for infection and one for patella clunk.
- LEGION Primary demonstrated excellent implant survivorship of 98.6%.

While the study shown above is based on two year interim results, the LEGION Total Knee System has a rich heritage based on the GENESIS II Design.

LEGION and GENESIS II achieve equivalent articulation but do so via different surgical approaches to femoral external rotation.

GENESIS II offers built-in external rotation by having asymmetric posterior condyles whereas LEGION offers surgeon-directed external rotation with symmetric posterior condyles. The differing techniques produce identical implant tibio-femoral kinematics and wear performance.

When GENESIS II was introduced in 1995, the built-in external rotation was a unique concept and design. It simplified the procedure and surgical technique for primary total knees.

Over time, the need to simplify more complex primary and revision procedures has grown. To address this the implant was modified so that the surgeon could set the external rotation based on patient anatomy, resulting in symmetric posterior condyles. At the same time, the instruments were simplified and a seamless transition to a revision procedure was created leading to the evolution of GENESIS II into the LEGION Total Knee System.

LEGION has symmetric posterior condyles while GENESIS II has a thinner medial posterior condyle due to the built-in external rotation.
What do the clinical results look like?


Kaplan-Meier Estimated Cumulative % Probability of Revision at Ten Years

**At 13 years, the cumulative percent revision of primary total knee replacement undertaken for osteoarthritis is 6.8%.**

Table KT10: Cumulative Percent Revision of Primary Total Knee Replacement with Cement Fixation

<table>
<thead>
<tr>
<th>Femoral Component</th>
<th>Tibial Component</th>
<th>N Revised</th>
<th>N Total</th>
<th>1 Year</th>
<th>3 Years</th>
<th>5 Years</th>
<th>7 Years</th>
<th>10 Years</th>
<th>13 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genesis II CR</td>
<td>Genesis II</td>
<td>338</td>
<td>11253</td>
<td>0.9 (0.7, 1.1)</td>
<td>2.5 (2.2, 2.8)</td>
<td>3.2 (2.9, 3.6)</td>
<td>4.0 (3.6, 4.5)</td>
<td>4.3 (3.8, 4.8)</td>
<td>4.6 (4.0, 5.3)</td>
</tr>
</tbody>
</table>

At 13 years, the cumulative percent revision of primary total knee replacement undertaken for osteoarthritis is 6.8%.

Table KT11: Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA)

<table>
<thead>
<tr>
<th>Knee Class</th>
<th>N Revised</th>
<th>N Total</th>
<th>1 Year</th>
<th>3 Years</th>
<th>5 Years</th>
<th>7 Years</th>
<th>10 Years</th>
<th>13 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Knee</td>
<td>13277</td>
<td>386242</td>
<td>1.0 (1.0, 1.1)</td>
<td>2.8 (2.7, 2.9)</td>
<td>3.8 (3.7, 3.8)</td>
<td>4.5 (4.4, 4.6)</td>
<td>5.6 (5.4, 5.7)</td>
<td>6.8 (6.6, 7.0)</td>
</tr>
</tbody>
</table>

*TRIATHALON and VANGUARD % Probability at eight years only (from 2013 report).*
**15 – 17 year GENESIS® II Clinical Results**

- “Excellent” survivorship of 98.1% at a minimum follow-up of 15 years
- 89 consecutive GENESIS II knee procedures were studied
- “Minimum 15-year follow-up reports after TKA are not abundant”

**GENESIS II Total Knee Arthroplasty: Five-to-Eight Year Results**

- 98 TKAs with oxidized zirconium femoral component
- “Excellent” survival rate of 97.8% at 10 years
- “Excellent” survivorship of 98.8% at nine years

**5 Year Follow-up of First 100 cases**

- Survivorship 98.8% at 5 years
- Mean flexion 118°
- 100% “excellent” or “good” results post-op Knee Society Score

**5-year Results of an Oxidized Zirconium Femoral Component for TKA**

- Survival rate of 98.7% at 7 years
- 98 TKAs with oxidized zirconium femoral component
- Mean post-op knee society score of 89

**Oxidized zirconium femoral component for TKA: A follow-up note of a previous report at a minimum of 10 years**

- 98 TKAs with oxidized zirconium femoral component
- “Excellent” survival rate of 97.8% at 10 years
- “Good clinical and radiological outcomes”

**Minimum 10 Year Follow-up**

- “Excellent” survival rate of 97.8% at 10 years
- 98 TKAs with oxidized zirconium femoral component
- “Good clinical and radiological outcomes”
Why do LEGION° and GENESIS° II have such good results?

The clinical results of LEGION and GENESIS II can in large part be attributed to unique design features working together to produce a world class knee implant.

**Lateralized and deepened trochlear groove**
Femoral components have an “S-curve” trochlear groove that, like the natural femur, gently moves the patella from a lateral position in extension towards the midline in flexion. This has shown to reduce lateral release rates to ~3%\(^{12}\) compared to ~14%\(^{13}\) for competitive systems. The patella groove has been distally extended to provide full patellofemoral contact throughout the ROM.

**Bone Conserving PS Box**
Less bone is removed with the femoral components compared to competitive systems\(^{14}\), leaving the critical anterior bone bridge intact for stability and strength.

**Asymmetric baseplate for better tibial coverage**
The asymmetric shape matches the anatomy of the tibia,\(^{15}\) eliminating the need to undersize which can lead to uncovered bone or oversize which can lead to baseplate overhang. Additionally, maximizing tibial coverage through asymmetric baseplate has also been shown to minimize tibia rotational errors.\(^{16}\)

**VERILAST° Technology for wear reduction**
VERILAST Technology is the bearing couple of OXINIUM\(^{°}\) Oxidized Zirconium and XLPE which has completed wear testing 9 times the industry standard\(^{17}\) and shown exceptional wear performance. VERILAST Technology incorporates proprietary OXINIUM alloy. Compared to cobalt chrome, OXINIUM alloy has much less cobalt (<0.002%), chromium (<0.02%) and nickel (<0.0035%) content.

**Highly polished baseplate for backside wear reduction**
LEGION baseplates have a proven locking mechanism with an anterior and posterior dovetail to reduce micromotion and are composed of highly polished titanium to decrease backside wear.\(^{18}\)

**Flexion friendly**
Tightly radiused posterior condyles allow for deeper flexion without the risk of edge loading or excessive collateral ligament tension. The PS and CR High Flex inserts support flexion up to 155°. One study by Dr. Laskin showed a mean ROM of 118° five years postoperatively.\(^{19}\)
LEGION encompasses the same design features that have demonstrated long-term survivorship with GENESIS™ II. LEGION CR and PS knees provide the same kinematic motion and articulation as GENESIS II with the addition of updated instrumentation and a seamless total knee system able to handle all stages of knee reconstruction.2

LEGION is not only offered with updated traditional instrumentation but also with a more cost-effective and simplified approach to total knee arthroplasty. VISIONAIRE® FASTPak includes VISIONAIRE Cutting Guides and size-specific disposable instruments.

The surgeon has confidence that he will have new, sterile instruments specific for each patient and the OR staff can have confidence that setup, surgery and cleanup will be simple with minimal time commitment.20
LEGION® offers peace of mind

LEGION has the flexibility to address diverse surgical challenges and simplify decision making interoperatively. The LEGION instrumentation gives you the ability to move from a cruciate retaining implant all the way to a hinged component.

Today’s orthopaedic environment demands simple solutions with proven clinical history. With the durability of VERILAST® Technology, inter-operative flexibility of both implants and instrumentation, and a rich clinical heritage – the LEGION Total Knee System gives surgeons peace of mind not only in the OR but with the knowledge that their patients will successfully return to their active lifestyles.
References

1. LEGION® Primary Knee System: A Prospective, Multi-Center, Non-Randomized, Safety and Efficacy Clinical Study of the LEGION Primary Knee System for Primary Total Knee Replacement in Subjects with Degenerative Knee Disease. 10-K300-95301, 29 April 2014. Version 1.0.
3. National Joint Registry for England, Wales, and Northern Ireland, 11th Annual Report, 2014, Table 3.22: Kaplan-Meier estimated cumulative percentage probability of first revision (95% CI) of a primary total knee replacement by main type of implant brand at the indicated number of years after primary operation.
5. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. Adelaide: AOA, 2014 Table KT11: Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA)
8. S&N literature 40422802 02/06.
17. ISO 14243-3