Exceptional Durability
How many knee systems have been lab-tested to 30 years of simulated wear?

Just one: LEGION™ Primary Knee System with VERILAST™ Technology

‡ The LEGION™ Primary Knee System with VERILAST™ Technology is expected to provide wear performance sufficient for 30 years of actual use under typical conditions, based on in-vitro wear simulation testing. The results of in-vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance. Also, a reduction in total polyethylene wear volume or wear rate alone may not result in an improved clinical outcome as wear particle size and morphology are also critical factors in the evaluation of the potential for wear mediated osteolysis and associated aseptic implant loosening. Particle size and morphology were not evaluated as part of the testing.
Wear performance

As today’s patients seek more active lifestyles than traditional patients, knee implants will be expected to endure more stress without succumbing to wear. However, the functional lifetime demand of younger and active patients is 10-fold greater than the estimated functional lifetime of traditional polyethylene. VERILAST™ Technology from Smith & Nephew is the only bearing technology with published results of 45 Million Cycles of knee in-vitro wear simulation testing with the LEGION Primary Knee System. This means the replacement may be expected to provide improved wear performance. More importantly, if implanted earlier, it may restore patients to their active lifestyles sooner.

VERILAST Technology in the LEGION Primary Knee System demonstrates superior wear performance in 5 and 45 million cycle testing.

Comparison of the mean volumetric wear of the CoCr/CPE and VERILAST couples after simulating 5 Mc.

Comparison of the mean volumetric wear of CoCr/CPE after simulating 5 Mc of use and VERILAST after simulating 45 Mc respectively.
**Wear performance**

VERILAST™ Technology is the bearing combination of OXINIUM® alloy and highly cross-linked polyethylene (XLPE). By combining the biocompatible, proprietary OXINIUM alloy with XLPE, Smith & Nephew’s VERILAST Technology in the LEGION® Knee System allows surgeons to address their patient’s knee pain earlier.

When comparing Smith & Nephew’s conventional technology to its XLPE technology, the XLPE technology provides an expected, significant reduction in wear rates. Moreover, when comparing Smith & Nephew’s XLPE technology to VERILAST Technology, there is another significant reduction in wear rates. Understanding these tests were conducted using pristine components, the differences in these wear rates would be even more pronounced with roughened components due to the resistance to micro-scratches of the VERILAST couple. (see chart below)

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

The 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 references for testing information.
Clinical wear performance

Oxidized Zirconium vs. Cobalt-Chromium TKA: Surface roughness of retrieved femoral components. A matched pair retrieval analysis showed the following results:

- Scratching visible on CoCr retrievals, while little scratching is seen on retrieved OxZr components (Figure 1a & 1b)
- The CoCr implants roughened significantly more in vivo than the OxZr components
- The average surface roughness for the retrieved CoCr was 83% greater than the OxZr retrieved components

3D surface profiles of Oxidized Zirconium and Cobalt-Chromium femoral components

* Median values reported for roughness parameters. All values in μm.
Metal sensitivity

Just as metal ions are a well described problem for many hip replacement patients, cobalt, chromium and nickel are commonly cited allergens for knee replacement patients. In several cases, sensitivity to one or more of the allergens has resulted in revisions for these patients.\textsuperscript{10-13}

Surgeons should be aware that all metal implants contain varying amounts of cobalt, chromium, and nickel. When selecting the appropriate implant, surgeons should consider the composition of each implant before use. To help with this decision, VERILAST\textsuperscript{®} Technology incorporates proprietary OXINUM\textsuperscript{®} alloy. Unlike cobalt chrome, OXINUM alloy has <0.002% cobalt, <0.02% chromium and <0.0035% nickel content.

Metal content of implants\textsuperscript{14}

<table>
<thead>
<tr>
<th>Maximum nickel content</th>
<th>Maximum cobalt content</th>
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<tbody>
<tr>
<td>OXINUM</td>
<td>&lt;0.0035%</td>
</tr>
<tr>
<td>Titanium</td>
<td>0.1%</td>
</tr>
<tr>
<td>Cobalt Chrome</td>
<td>0.5%</td>
</tr>
<tr>
<td>OXINUM</td>
<td>&lt;0.002%</td>
</tr>
<tr>
<td>Titanium</td>
<td>&lt;0.01%</td>
</tr>
<tr>
<td>Cobalt Chrome</td>
<td>58-68%</td>
</tr>
</tbody>
</table>

Clinical studies\textsuperscript{15}

<table>
<thead>
<tr>
<th>Prevalence of patients demonstrating metal sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>General population</td>
</tr>
<tr>
<td>Patients with well-functioning implants</td>
</tr>
<tr>
<td>Patients with poorly functioning implants</td>
</tr>
</tbody>
</table>

% Metal sensitive
References


7. Biomet publication, FDA Cleared Claims for E1 Antioxidant Infused Technology

8. Ref: DePuy Attune 310 K Document K101433 Dec 10, 2010


