Advanced Surface Technology
Engineered for Performance

Aesculap Orthopaedics
Advanced Surface Technology
Engineered for performance

Advanced Surface 7-layer Technology
Aesculap’s proprietary Advanced Surface Technology can withstand corrosive environments, high stresses and strains which all artificial knees are exposed to in the human body. The Advanced Surface Technology consists of seven layers and is unique in the market.

Advanced Surface Technology Compared to Conventional Monolayer Coatings
Advanced Surface Technology helps to reduce mechanical ablation. Mechanical ablation leads to a higher risk of third body wear followed by metal ion release.¹,²

Patented Advanced Surface Technology
This 7-layer surface technology is designed for performance and creates a potential barrier to help prevent metal ion release.

Each layer of the proprietary 7-layer technology has a specific function. The outer layer, ZrN, yields superior surface hardness and reduces abrasion. The 7-layer technology is specifically designed to bridge the difference in hardness from the ZrN over the CoCr substrate, improving the molecular structure of a layered system. This technology makes the molecular structure extremely stable against mechanical stresses and strains and results in a more resilient implant.³,¹⁰

Advanced Surface Technology is proprietary to Aesculap and is applied to all metal surfaces of the implant.
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Longevity – Ceramic Surface

Substantial reduction in wear

Wear is the number one reason for revision in the long term.14

A knee prosthesis with Advanced Surface Technology demonstrates a substantial reduction in wear when compared to a CoCr prosthesis.3, 4

![Graph showing wear rate comparison between CoCr and Advanced Surface Technology](image)

Fig. 1: Wear reduction with Columbus CR after 5 Mio cycles according ISO Standard 14243-1/3.11

**DISCLAIMER:** The results of in vitro wear simulation testing are not predictive of clinical performance, and the results of in-vitro wear testing have not been proven to predict clinical performance.
Unmatched hardness

The outer layer is made from zirconium nitride (ZrN). This ceramic surface can lead to improved scratch resistance and good wettability for better articulation between bearing surfaces.

Small scratches in CoCr implants are common and can lead to surface damage and higher PE wear.\textsuperscript{15, 16} The extremely hard ZrN ceramic surface:\textsuperscript{11}
\begin{itemize}
  \item Shows high resistance to scratches
  \item Demonstrates good wettability
  \item Leads to better articulation between polyethylene bearing surface and femoral components
\end{itemize}

The femoral implant with Advanced Surface Technology was exposed to extreme wear testing under the following conditions:
\begin{itemize}
  \item Addition of cortical bone chips from 5 - 5.5 million cycles
  \item Addition of bone cement from 5.5 - 6 million cycles
\end{itemize}

\textbf{RESULT:} In the wear simulator (Fig. 3), no damage (scratches and nicks) could visibly be seen on the condyle surfaces. Third body wear and the risk for mechanical ablation can be minimized this way.\textsuperscript{11}

**Superior Surface Hardness**

<table>
<thead>
<tr>
<th>Hardness in GPa</th>
<th>25.4</th>
<th>24.5</th>
<th>22.8</th>
<th>18.9</th>
<th>12.1</th>
<th>6.8</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Surface Technology</td>
<td>TiWbN</td>
<td>TiN</td>
<td>Biolox Delta</td>
<td>Oxinium</td>
<td>hardened Ti</td>
<td>TiV</td>
<td>CoCr</td>
</tr>
</tbody>
</table>

Fig. 2: Hardness of different types of surface treatments\textsuperscript{5-10}

No damage after extreme wear test with bone and cement particles!

Fig. 3: Wear simulation under extreme conditions\textsuperscript{11}
Data from the peer reviewed literature demonstrates that metal ions released from implants, such as nickel, cobalt and chromium, can trigger an adverse reaction in certain patients with metal sensitivity and can lead to the need for implant revision.

Patients with reported problems after knee replacement have a higher level of chromium ions \( p=0.001 \) in their blood serum.\(^{18}\)

60% of patients experiencing problems with a knee replacement show a sensitivity to metal ions.\(^{19}\)

### Potential Reasons for Early Revision

20% of all TKA patients are unsatisfied after knee arthroplasty surgery.\(^{17}\) What are the reasons for that?

Could early revision be a result of metal ion release?

As the number of early revision surgeries increase, metal ions and the potential effects on patients are slowly gaining more attention by surgeons. Rau C et al. found in a study with 1,335 patients, only 30% with a history of allergies were detected and documented.

The higher risk of a hypersensitive reaction could be reduced by using an alternative implant material for appropriate revision patients.

When revision surgery is required, selecting implants with an alternative surface technology could minimize the risk of metal ion release.

### Main reasons for early revision < 5 years

<table>
<thead>
<tr>
<th>Reason</th>
<th>% of Revisions</th>
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<tr>
<td>Aseptic loosening</td>
<td>24</td>
</tr>
<tr>
<td>Infection</td>
<td>16</td>
</tr>
<tr>
<td>Pain</td>
<td>13</td>
</tr>
<tr>
<td>Instability</td>
<td>10</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
</tr>
<tr>
<td>Wear</td>
<td>8</td>
</tr>
<tr>
<td>Lysis</td>
<td>7</td>
</tr>
<tr>
<td>Malalignment</td>
<td>5</td>
</tr>
<tr>
<td>Stiffness</td>
<td>4</td>
</tr>
<tr>
<td>Dislocation</td>
<td>2</td>
</tr>
<tr>
<td>Periprosthetic fracture</td>
<td>3</td>
</tr>
<tr>
<td>Component dissociation</td>
<td>1</td>
</tr>
<tr>
<td>Implant fracture</td>
<td>1</td>
</tr>
</tbody>
</table>

**Fig. 5: National Joint Registry England and Wales 2010\(^{21}\)**

**DISCLAIMER:** The absolute ion concentration that can trigger a hypersensitivity reaction against metal ions is not known. A clinical evaluation of metal sensitivity was not performed with respect to the Advanced Surface Technology. The laboratory testing performed is not necessarily indicative of clinical performance and the results of in-vitro wear testing have not been proven to predict clinical performance.
Revision patients are at a 6 times greater risk for developing metal sensitivity reaction. Lüetzner et al. could detect metal ions in the serum after conventional TKA. Metal ions may cause local and systemic toxic effects, hypersensitivity reactions and may even increase the risk for cancer.

Currently, there is no generally accepted test for the clinical determination of metal hypersensitivity to implanted devices. Historically, testing for delayed-type hypersensitivity (DTH) has been conducted in vivo by skin testing and in vitro by lymphocyte transformation testing (LTT) and leukocyte migration inhibition (LMI) testing.

**Testing for Metal Hypersensitivity**

Tests Available

**Patch Test**
Patch testing involves incorporating an antigen in a carrier and exposing this to dermal tissue by means of an affixed bandage for 48-96 hours. There are concerns about the applicability of skin testing to the study of immune responses to implants. One concern is the short length of the test because typical reports of eczemic reactions to orthopaedic implants occur after weeks to months of constant exposure. There are also concerns that patch testing could possibly be affected by immunological tolerance or by impaired host immune response, and the testing could induce hypersensitivity in the patient.

**Lymphocyte Transformation Test (LTT)**
LTT is a measure of the proliferative response of lymphocytes following activation. A radioactive marker is added to isolated lymphocytes along with the desired challenge agent. On the sixth day, radioisotope uptake is measured with use of liquid scintillation. The proliferation factor, or stimulation index, is calculated with use of measured radiation counts per minute (cpm):

\[
\text{proliferation factor} = \frac{\text{mean cpm with treatment}}{\text{mean cpm without treatment}}
\]

LTT is less popular than patch testing, but has been well established as a method for testing metal sensitivity in a variety of clinical settings.

**Leukocyte Migration Inhibition (LMI) Test**
LMI testing involves the measurement of mixed-population leukocyte migration activity. Leukocytes in culture actively migrate in a random pattern, but they can be attracted preferentially to chemoattractants. In the presence of a sensitizing antigen, leukocytes migrate more slowly, losing the ability to recognize chemoattractants and are said to be migration-inhibited. Migration testing may lack the sensitivity for detecting a DTH response at certain times over the course of a hypersensitivity reaction.

![Fig. 6: Metal sensitivity after endoprosthesis in comparison to population. Numbers are derived using a weighted average based on the number of subjects in each study.](image)
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Reduced potential for metal ion release

Advanced Surface

The 5 transition layers provide stability and act to create a potential barrier to help prevent metal ion release. The bonding agent is a layer which adheres the substrate to the different layers, creating a firm connection between implant and subsequent layers.

Reduced Metal Ion Concentration

Metal Ion concentration in µg/l

![Graph showing reduced metal ion concentration](image)

Fig. 7: Metal ion reduction

+ AS Reference is a wear simulation test with additional metal ion measurement using an Advanced Surface implant and limiting motion. The test is designed to measure the diffusion of fluid into the PE.

DISCLAIMER: The results of in vitro wear simulation testing have not been proven to quantitatively predict clinical wear performance. Wear testing was conducted out to 5 million cycles on a knee simulator on identical coated and uncoated CoCrMo alloy knee implants of the Columbus® Total CR Knee System in accordance with ISO standard 14243-1:2002(E). Cumulative metal ion concentration of lubricant from the wear stations was performed in accordance with ISO standard 11885 out to 1 million cycles. The post-wear samples demonstrate that the Advanced Surface Technology significantly reduced the release of metal ions (molybdenum, nickel, cobalt, and chromium) compared to implants without this technology. Testing also showed no significant difference in ion concentrations between the Advanced Surface Technology-wear and reference samples, indicating that the effectiveness of the technology was not compromised during the wear test. Full test protocol and results on file with Aesculap AG (Tuttlingen, Germany).
Mechanical Integrity of 7-Layer Technology

Designed for performance

Monolayer Coating vs. Advanced Surface Technology

A hard surface on the relatively soft base material (CoCr) may lead to a higher risk of breakage of the surface, as it has been seen with monolayer coatings (eggshell effect).

Transition Layers

The 7-layer technology is specifically designed to bridge the difference in the hardness from the ZrN to the CoCr substrate, improving the modular structure of the layer system (Fig. 8). This makes the modular structure extremely stable against mechanical stresses and strains and results in a more resilient product.\textsuperscript{11,25}

Bonding Agent

A powerful bonding agent is applied between the base material and subsequent layers to form an alloy compound that ensures strong adhesion.

Monolayer Coating

- Force

Column structure of crystallines

Fig. 8: Monolayer and 7-layer Technology

7-Layer Technology: Improved Elastic Modulus

- Force

Blue circles represent metal ions being trapped within 7 layers

Small grain sizes
Beta (E-beam) Polyethylene Durability

Improved age resistance through beta-sterilization

**Beta-Radiation**
Targeted radiation leads to linking of molecular chains

**Less Free Radicals**
Less oxygen can bond with free radicals

**Reduced Oxidation**
70% reduction in oxidation index

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**Fig. 9: Effects of Beta Sterilization**

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**70% Reduction in oxidation levels**

Oxidation index

![Graph showing oxidation levels](image)

**Fig. 10: Oxidation Level**

ASTM F 2003: artificial aging of 10 years acc. to Kurtz et al.: 14 days / 70°C / 5bar O₂
Decelerated Aging Process

Less oxidation means slower aging leading to optimized wear properties and less delamination

Beta PE + Advanced Surface Technology = Advanced Bearing Technology

- lower wear
- slower aging
- potential reduction in metal ion release

Gamma Sterilization

Radiation
Lower intensity, deeper higher penetration, doses: 2.5 Mrad – 4 Mrad

Sterilization Time
Longer: 16 hours

Result
Higher content of residual free radicals leading to a higher risk of oxidation

Beta Sterilization

Higher intensity, concentrated, lower penetration, doses: 2.5 Mrad – 4 Mrad

Shorter: 15 seconds

Fewer residual free radicals after sterilization process causing less oxidation

Fig. 11: Gamma vs. Beta Sterilization
References


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Notes