Advanced Surface Technology
Why Take a Chance With Anything Else?
By 2030 the demand for total knee arthroplasty (TKA) in the United States is predicted to grow by 673%.\textsuperscript{1,2} As the overall incidence of TKA procedures accelerates, prostheses-related issues are becoming more evident. Approximately 20% of all TKA patients report dissatisfaction with their knee replacements.\textsuperscript{3}
Choose Aesculap Advanced Surface Technology

All TKA surgeries present some degree of outcome uncertainty. You need confidence in your treatment plan. Whether you are performing a knee revision or a primary surgery that requires special consideration, why take a chance?

The Aesculap gold knee, with its patented seven-layer Advanced Surface Technology, offers enhanced protection against the top prostheses-related reasons for implant failure and revision: metal ion release and wear.*

* As evidenced by mechanical testing and literature review.
Metal Ion Release

Inside the body, all metals corrode. When metals such as nickel (Ni), cobalt (Co) and chromium (Cr) used in orthopaedic prostheses corrode, they release metal ions that can trigger a cascade of adverse reactions in certain patients. The circulating byproducts of metal degradation may stimulate cells in the periprosthetic tissues, provoking joint dysfunction.

An adverse reaction due to metal ions can be deceptive; it can present as subtly as chronic inflammation and persistent pain without radiological evidence of mechanical failure or as markedly as aseptic loosening with subsequent implant failure. Adding to these concerns, the National Institutes of Health in its 14th RoC cited the release of cobalt ions in vivo as “reasonably anticipated to be a human carcinogen.”

As the observed association between standard cobalt-chromium-molybdenum implants and patient dissatisfaction increases, implant materials warrant case-by-case consideration.
Implant Wear

Metals such as cobalt-chromium (CoCr) alloy and titanium (Ti) alloy, which still serve as the standard for femoral and tibial components, have demonstrated surface roughening that can substantially increase polyethylene wear between articulating components and generate metal debris.6, 7 Research has verified that the physiological response to this wear debris is a key contributor to periprosthetic osteolysis and subsequent implant loosening—a primary cause of TKA revisions.6, 7

Monolayer coatings over metal can delaminate.8, 9 All-ceramic components are brittle and subject to fracture.10 The longer life expectancy and higher activity level of younger patients necessitate implants that can endure greater stress without succumbing to wear-related problems.

Standard cobalt-chromium-molybdenum (CoCrMo) implants have demonstrated failure by abrasive and adhesive means.

CoCrMo in TKA design with visible scratches after PE-wear simulation under bone cement particle contamination.11
The Need for an Alternative

The Aesculap Answer
Aesculap Advanced Surface Technology is designed to provide a strong barrier to the potential release of metal ions, such as nickel, cobalt and chromium, with exceptional resistance to wear.*

Multilayer, Fully Encapsulated Components
Advanced Surface Technology starts with a cobalt–chromium–molybdenum (CoCrMo) substrate for toughness and encases it in a ceramic bearing surface comprising seven layers: a thin adhesive chromium agent; five intermediate layers alternating between chromium nitride (CrN) and chromium carbon nitride (CrCN); and a final, highly biocompatible shielding ceramic surface composed of zirconium nitride (ZrN). Advanced Surface Technology is applied via physical vapor deposition (PVD) to ensure effective adhesion of each layer.11

Seven-Layer Advanced Surface Technology
Each layer provides special functionality to benefit your patients.

Ceramic Surface – ZrN Layer
Zirconium Nitride
- Delivers favorable biocompatibility compared with standard CoCrMo
- Imparts superior surface hardness12, 13, 15, 16, 17
- Resists roughening and mechanical breakdown4
- Improves wear rates*4, 18, 19, 20, 21

5 Transition Layers – CrN–CrCN–CrN–CrCN–CrN
Chromium Nitride / Chromium Carbon Nitride / Chromium Nitride / Chromium Carbon Nitride / Chromium Nitride
- Supply multiple grain boundaries to arrest ion diffusion
- Ensure mechanical integrity by providing ductility22
- Capture diffusion ions interstitially to limit leaching

Bonding Agent – Cr Layer
Chromium
- Provides reliability
- Ensures effective bonding

*The results of in vitro testing have not been proven to quantitatively predict clinical performance with regard to implant wear or metal ion release. The absolute ion concentration that can trigger a hypersensitivity reaction to metal ions is unknown. A clinical evaluation of metal sensitivity was not performed with respect to Advanced Surface Technology.
A Complete Product Portfolio

Exceptionally strong, highly stable multilayer Advanced Surface Technology is applied to all metal implant components—femur, tibia, stems and augments. Aesculap is the only manufacturer that offers a complete portfolio of fully encapsulated metal knee prostheses.23
Technology Like No Other

Unmatched Testing
An extensive review of competitive literature reveals the unmatched testing of Advanced Surface Technology.23 Through in vitro wear simulation, Advanced Surface Technology has been tested to determine the release of nickel, cobalt, chromium and molybdenum ions18, 24 and to evaluate wear characteristics of unicondylar, primary and revision knee systems.* 4, 18, 19, 20, 21

Favorable Biocompatibility and Longevity
Research shows that Aesculap’s patented seven-layer Advanced Surface Technology:
- Demonstrates significantly reduced metal ion release across the most concerning medical device metals (Ni, Co, Cr and Mo) compared with implants without this technology.*4 (Figure 1)
- Is the hardest material used in orthopaedic devices today—two times (2x) as hard as Oxinium® (Smith & Nephew, Memphis, TN) and more than eight times (8x) as hard as traditional CoCr.12, 15, 17 (Figure 2)
- Provides superior resistance to wear, including substantial polyethylene wear resistance, compared with CoCrMo.*4, 18, 19, 20, 21 (Figure 3)
- Ensures mechanical integrity by providing ductility that permits the overall structure to deform slightly without cracking.22
- Encourages excellent wettability for a low-friction counterface that resists roughening and supports the expectation of prolonged prostheses survival.

Metal Ion Diffusion:
Advanced Surface Technology vs. CoCrMo Implants*

![Graph showing reduced metal ion release with Advanced Surface Technology](image)

Figure 1: Serum ion release for Mo by 90%, for Ni by 95%, for Co by 98% and for Cr by 98%.* Moreover, the ion concentrations for the Advanced Surface Technology reference sample that were axially loaded performed similar to those articulating in the wear simulator. The results confirm that even under extreme wear stress, Advanced Surface Technology constitutes an effective barrier against the potential diffusion of metal ions from the base material.

*The results of in vitro testing have not been proven to quantitatively predict clinical performance with regard to implant wear or metal ion release. The absolute ion concentration that can trigger a hypersensitivity reaction to metal ions is unknown. A clinical evaluation of metal sensitivity was not performed with respect to Advanced Surface Technology.
**Surface Hardness:**
Advanced Surface Technology vs. Competitive Material Options

**Advanced Surface Technology offers superior surface hardness to resist scratching by third-body debris.**

<table>
<thead>
<tr>
<th>Material</th>
<th>Hardness in GPa</th>
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</thead>
<tbody>
<tr>
<td>Ti(Nb)N</td>
<td>25.4</td>
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<tr>
<td>TiN</td>
<td>24.5</td>
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<tr>
<td>Molybdenum</td>
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<tr>
<td>Hafnium</td>
<td>6.8</td>
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<tr>
<td>CoCrMo</td>
<td>3</td>
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**Wear Simulation:**
Advanced Surface Technology vs. CoCrMo Implants

**Advanced Surface Technology yielded significantly less wear**

**Figure 2:**
- **Advanced Surface Technology** achieved 55% wear reduction in a TKA knee design, 65% wear reduction in UKA design and 88% reduction in a hinged knee design.

**Figure 3:**
- Advanced Surface Technology achieved 55% wear reduction compared with standard CoCrMo in a TKA knee design, a 65% wear reduction when compared with standard CoCrMo in UKA design and an 88% reduction when compared with a standard CoCrMo in a hinged knee design.
Ask Aesculap for More

More Confidence

When knee arthroplasty requires special considerations, why take a chance? Talk to your Aesculap representative for more detailed technical information about the benefits of Advanced Surface Technology versus competitive materials. Aesculap offers a comprehensive array of Advanced Surface Technology products in a range of sizes for knee arthroplasty, along with the unsurpassed operating room expertise to help your procedures advance most effectively.

About Aesculap

U.S.-based Aesculap Implant Systems, LLC is a B. Braun company with a global reputation backed by nearly two centuries of market-leading innovation. Headquartered in Melsungen, Germany, B. Braun is a world-leading manufacturer and provider of healthcare solutions.
References

15. Oxinium®: Made for Life Image brochure S8tN.
23. Based on an extensive review of publicly available literature and promotional information accessed by 2/22/17.