

Advanced Surface Technology

Why Take a Chance With Anything Else?



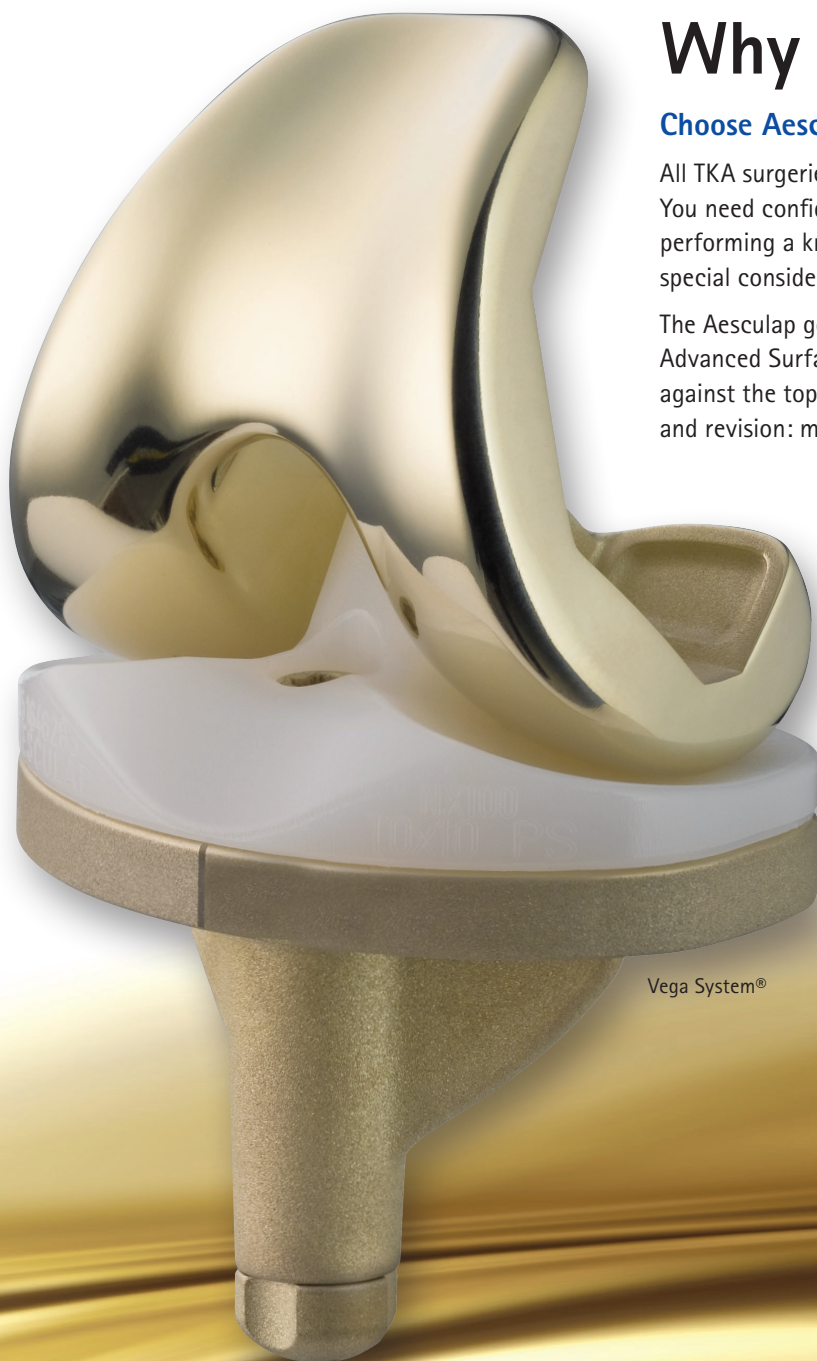
Aesculap Orthopaedics

AESCULAP
Implant Systems



By 2030 the demand

for total knee arthroplasty (TKA) in the United States is predicted to grow by 673%.^{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.³



Why Take a Chance?

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.*

Vega System®

* As evidenced by mechanical testing and literature review.

Prostheses–Related Causes of Implant Failure

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.⁴ The circulating byproducts of metal degradation may stimulate cells in the periprosthetic tissues, provoking joint dysfunction.



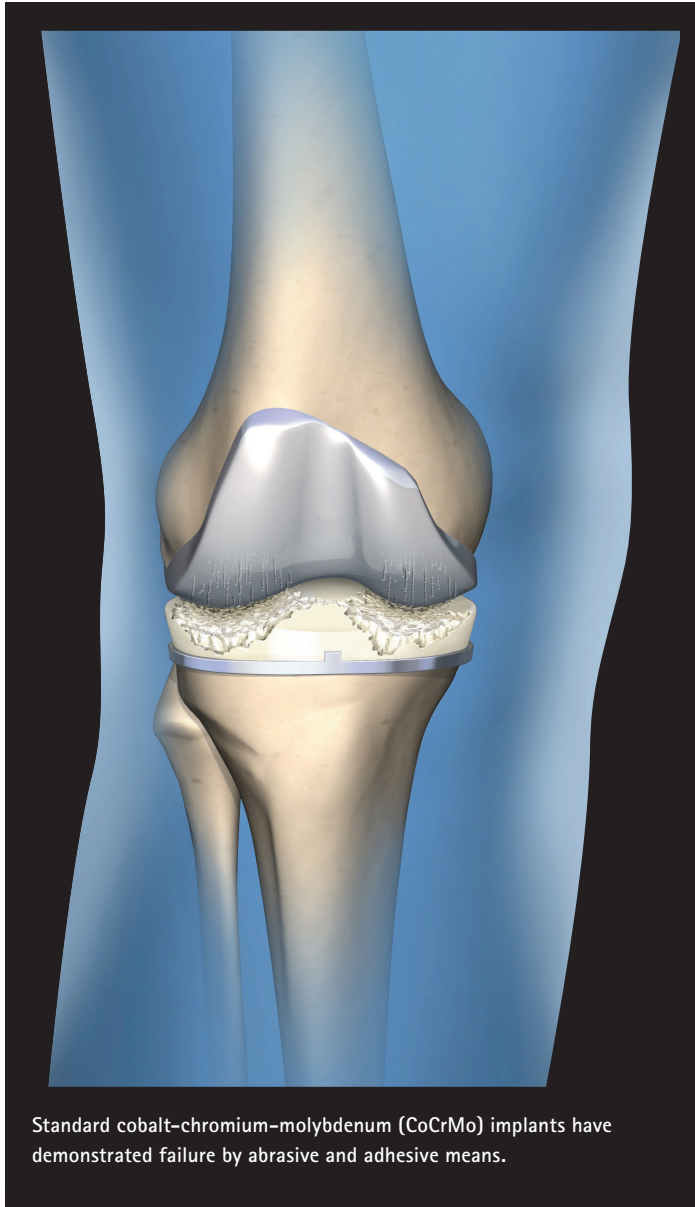
Metal ion release can present as chronic inflammation with no radiological evidence of joint dysfunction.



An eczematous reaction after standard cobalt-chromium-molybdenum total knee arthroplasty.

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.”⁵

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

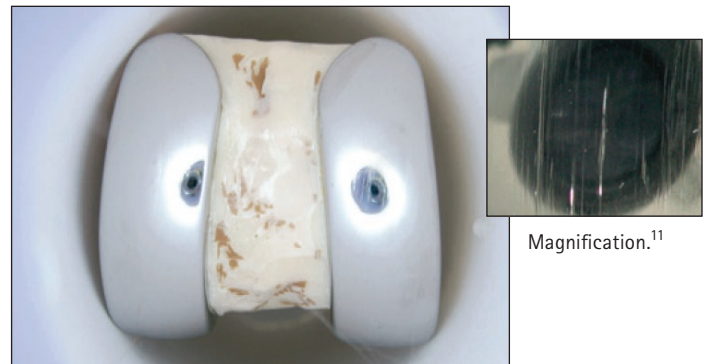


Implant Wear

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.



CoCrMo in TKA design with visible scratches after PE-wear simulation under bone cement particle contamination.¹¹

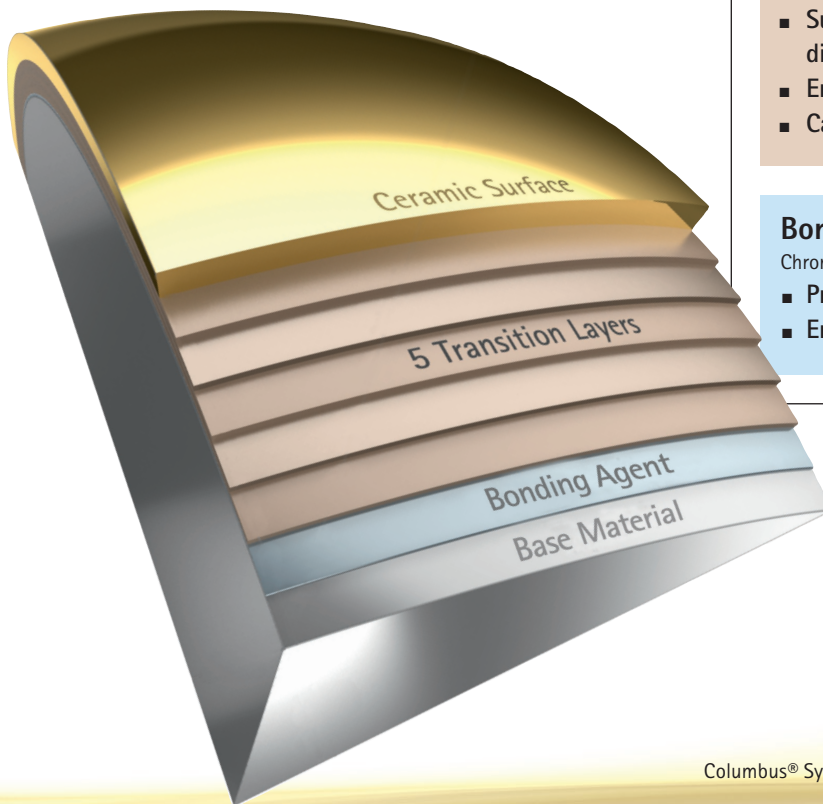
The Need for an Alternative

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 hardness^{12, 13, 14, 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



Columbus® System

*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



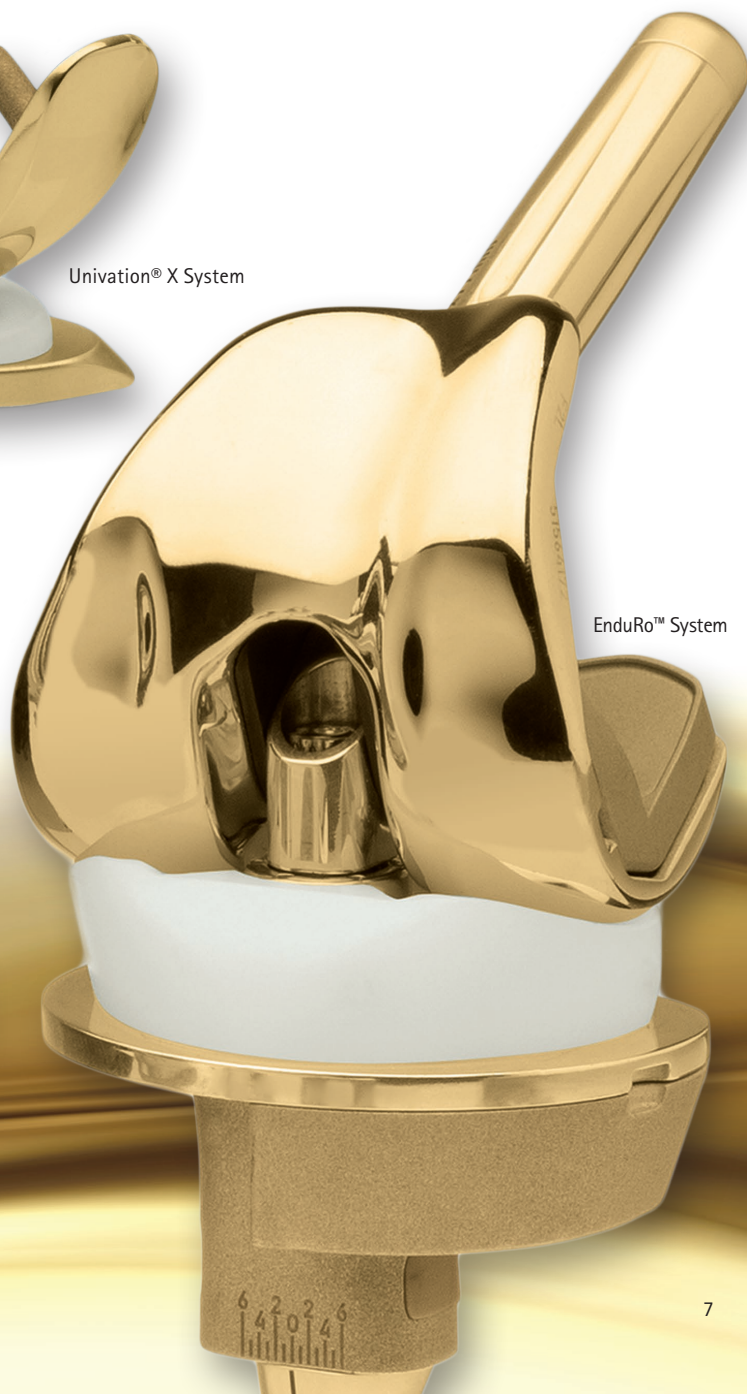
Columbus® Revision System



Univation® X System



Vega System®



Enduro™ System

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 ions^{18, 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*

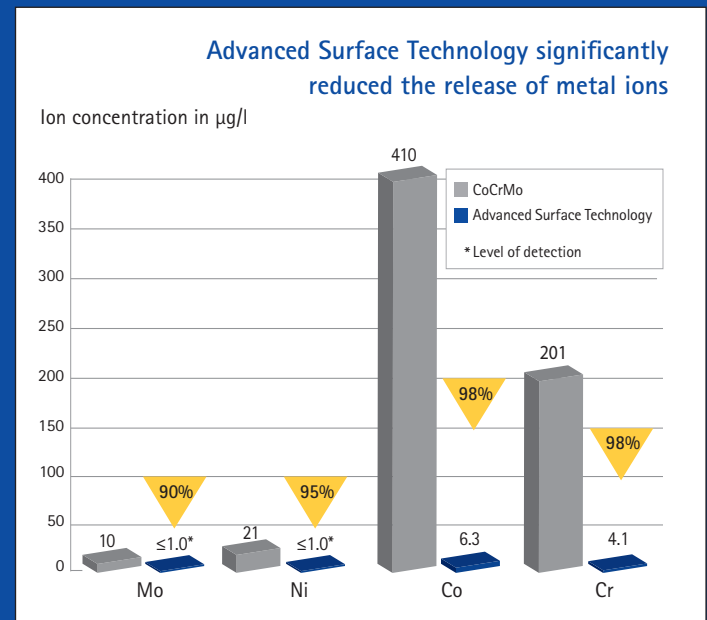


Figure 1: Serum ion release for Mo by 90%, for Ni by 95%, for Co by 98% and for Cr by 98%.⁴ Moreover, the ion concentrations for the Advanced Surface Technology reference sample that were axially loaded performed similar to those articulating in the wear simulator. The results confirm that even under 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

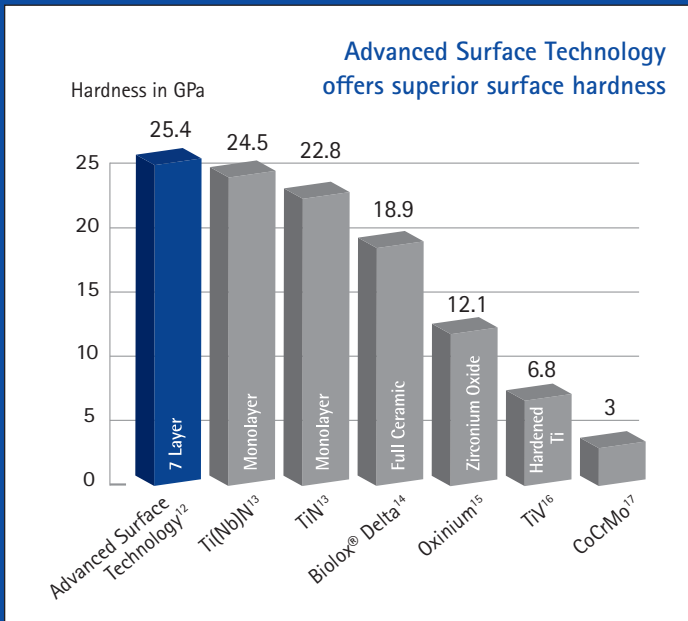


Figure 2: Advanced Surface Technology offers superior surface hardness to resist scratching by third-body debris.

Wear Simulation: Advanced Surface Technology vs. CoCrMo Implants

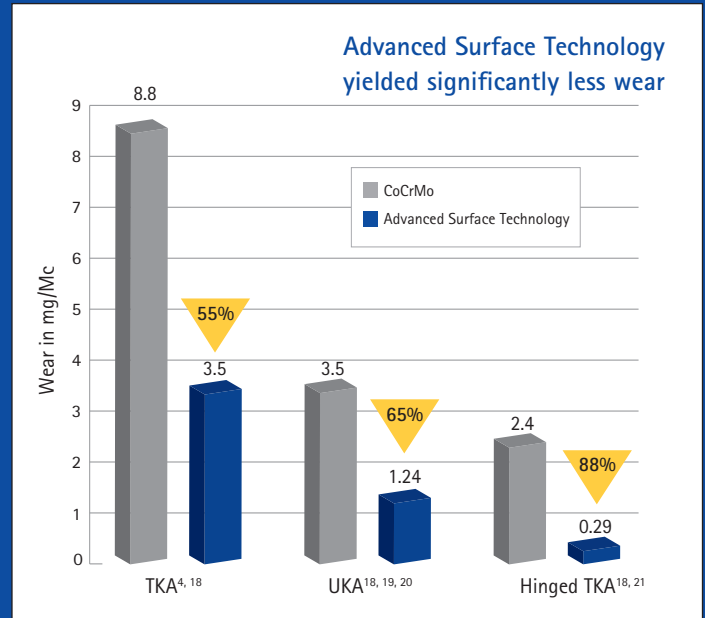
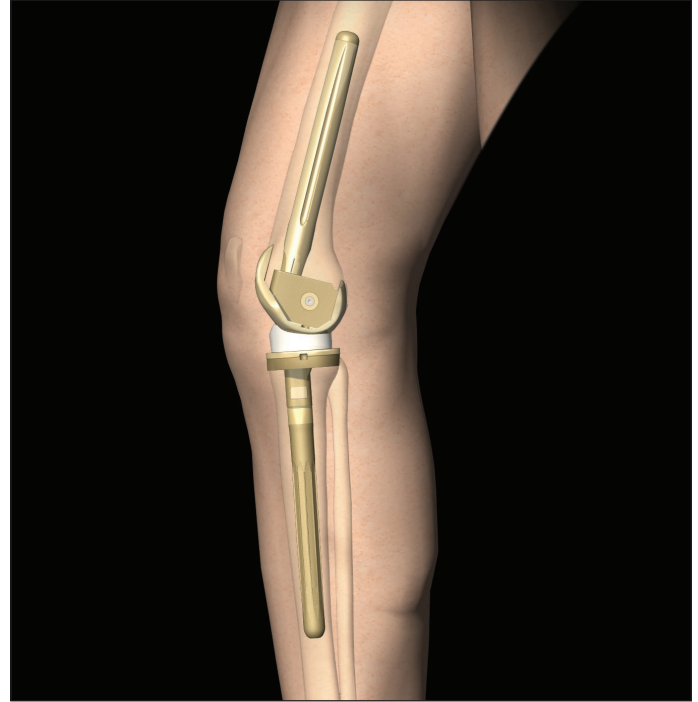


Figure 3: Advanced Surface Technology achieved a 55% wear reduction compared with standard CoCrMo in a TKA knee design, a 65% wear reduction when compared with standard CoCrMo in UKA design and an 88% reduction when compared with a standard CoCrMo in a hinged knee design.

Ask Aesculap for More



Complete revision cases can be particularly problematic. Aesculap's Enduro™ Rotating Hinge System, featuring Advanced Surface Technology, ensures your treatment plan for long-term success with high patient satisfaction.

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.

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