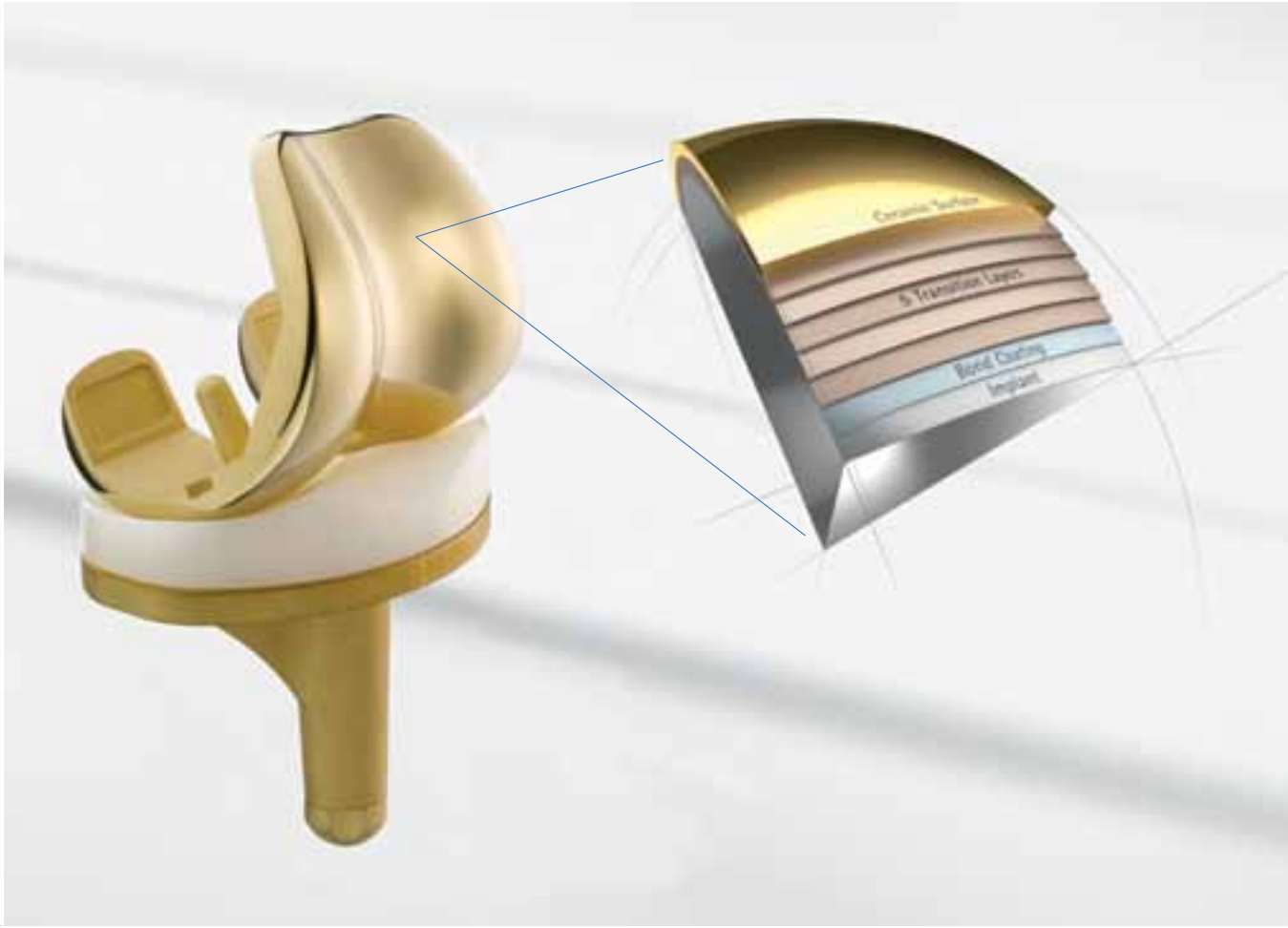
AS Advanced Surface Coating Technology

Coating Engineered for Performance



Aesculap Orthopaedics

AESCULAP®
Implant Systems

AS – Advanced Surface

Coating engineered for performance

Conventional monolayer coatings

Showed reduced resistance against mechanical ablation, which leads to a higher risk of third body wear followed by metal ion release.[1, 2]

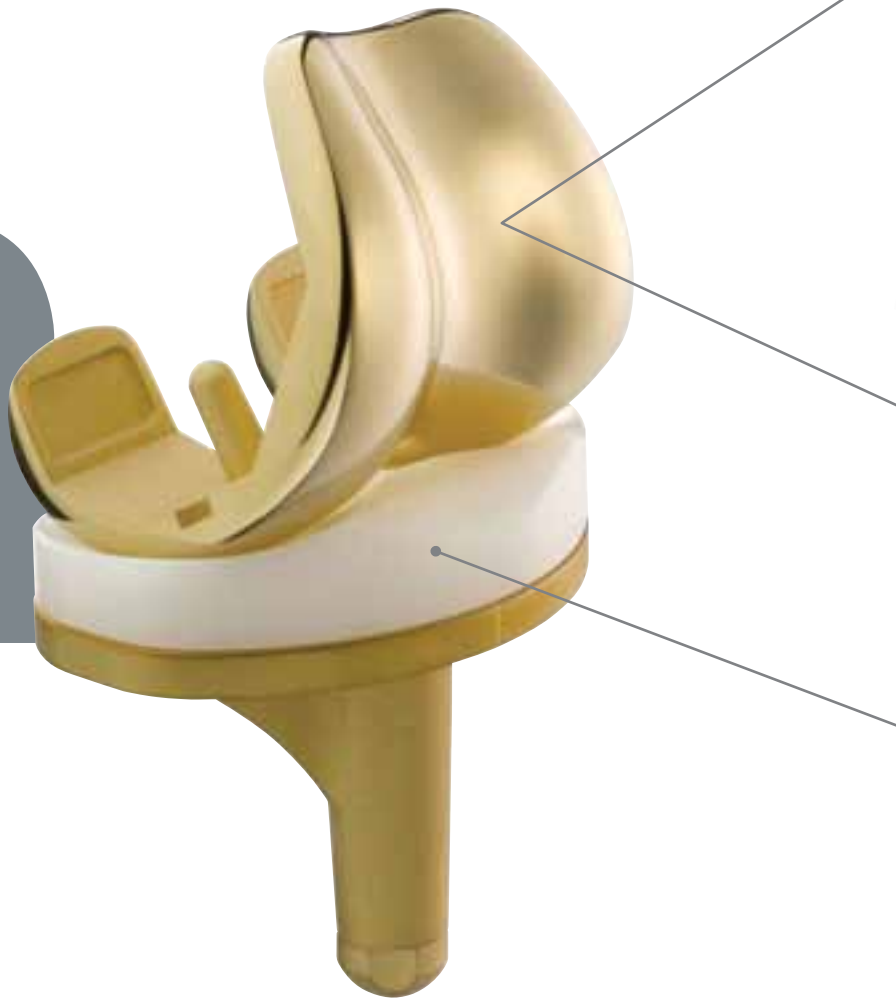
Multilayer coatings

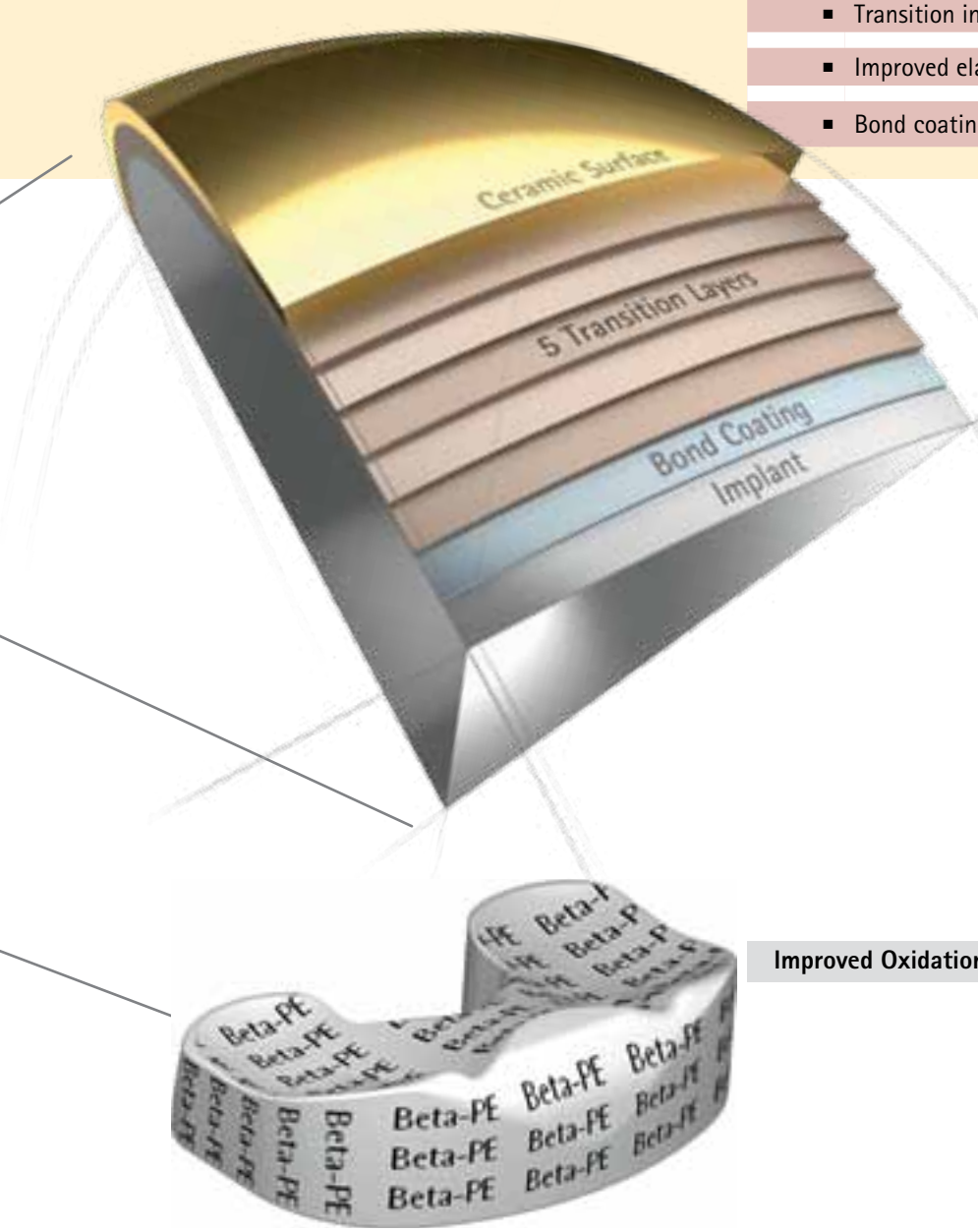
Can withstand corrosive environments, high stresses and strains which all artificial knees are exposed to in the human body. The AS multilayer coating consists of seven layers and is unique in the market.

AS – Advanced Surface

A 7-layer multilayer coating designed for performance and potentially reduces metal ion release.

Aesculap has the ONLY alternative coating technology that is applied to ALL surfaces.





Longevity – Ceramic Surface

Substantial reduction in wear

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

An AS coated knee prosthesis demonstrates a substantial reduction in wear when compared to a CoCr prosthesis.[3, 4]

Wear rate (mg/Mc)[11]

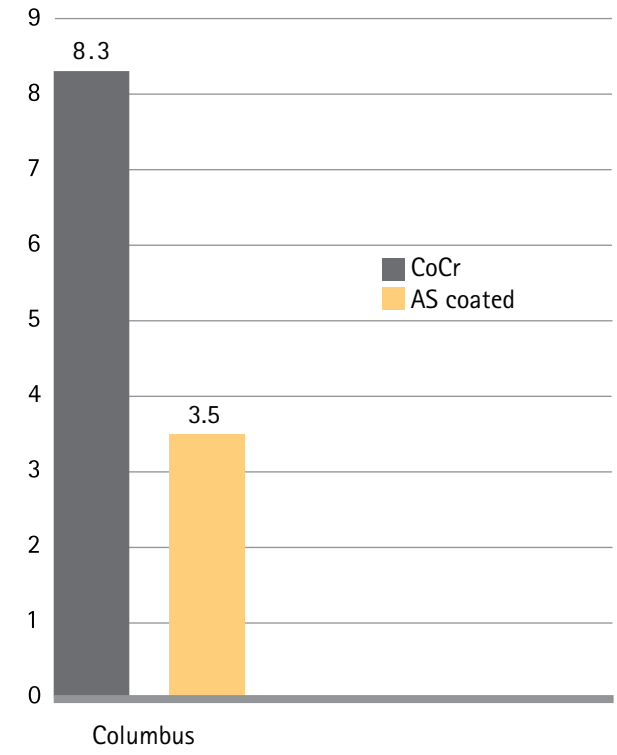


Fig. 1: Wear reduction with Columbus CR after 5 Mio cycles according ISO Standard 14243-1/3[3, 11]

DISCLAIMER: The results of in vitro wear simulation testing is not predictive of clinical performance and the results of in-vitro wear testing have not been proven to predict clinical performance.

Unmatched hardness

The ceramic surface layer can lead to improved scratch resistance and good wettability for better articulation between bearing surfaces.

Small scratches in CoCrMo implants are common and can lead to surface damage and higher PE wear.[15, 16]

The extremely hard ZrN ceramic surface:[11]
- Shows high resistance to scratches
- Demonstrates good wettability
- Leads to better articulation between polyethylene bearing surface and femoral components

The AS coated femoral implant was subject to extreme wear testing under the following conditions:
- Addition of cortical bone chips from 5 - 5.5 million cycles
- Addition of bone cement from 5.5 - 6 million cycles

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.[11]

Superior Surface Hardness

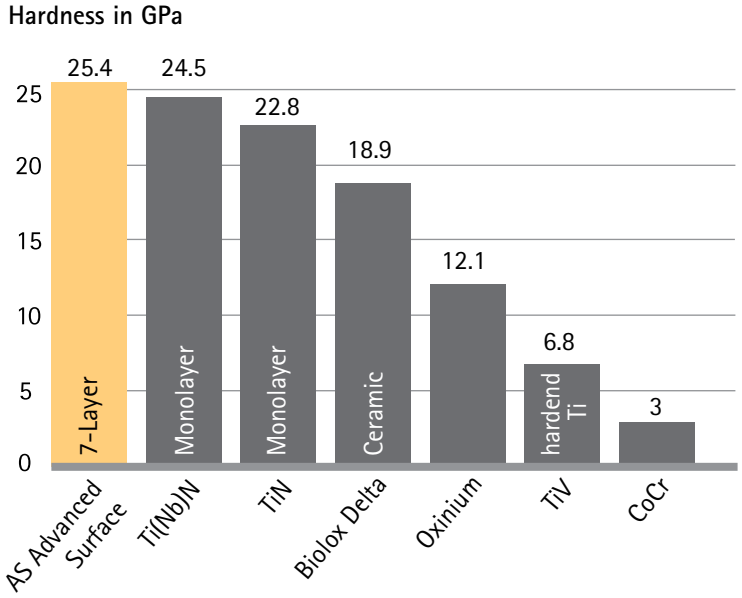


Fig. 2: Hardness of different types of surface treatments[5-10]

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

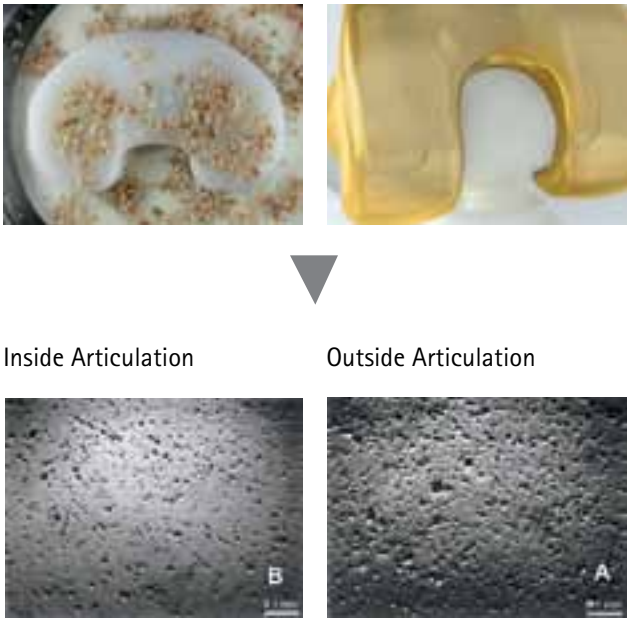


Fig. 3: Wear simulation under extreme conditions[11]

Potential Reasons for Early Revision

20% are unsatisfied after knee arthroplasty surgery.[17] What are the reasons for that?

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]

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 is 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 alternative coatings could minimize the risk of metal ion release.

Main reasons for early revision < 5 years

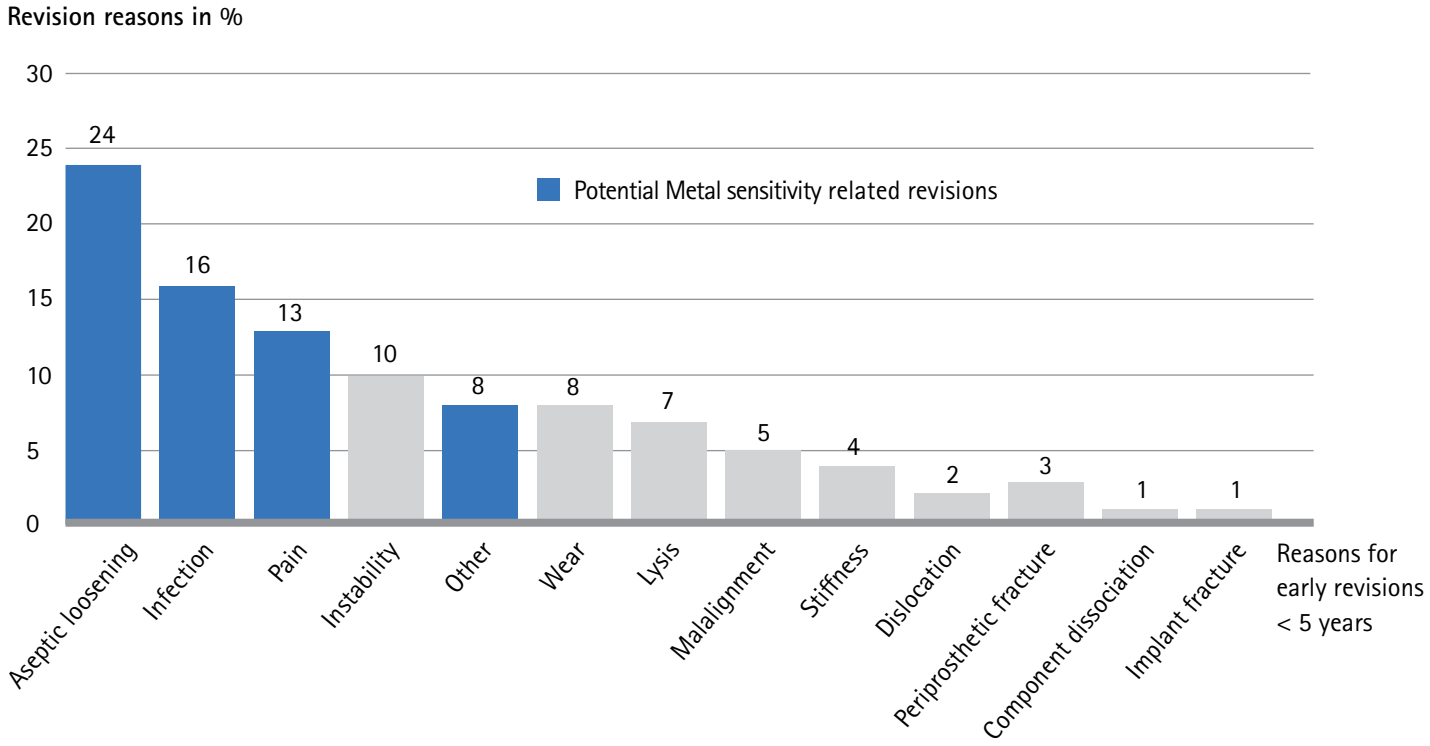


Fig. 5: National Joint Registry England and Wales 2010[21]

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 AS Coating. 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 6 times greater risk for developing metal sensitivity reaction[20]

- Lüetzner et al. could detect metal ions in the serum after conventional TKA.[22]
- Metal ions may cause local and systemic toxic effects, hypersensitivity reactions, and might even increase the risk for cancer.[22]

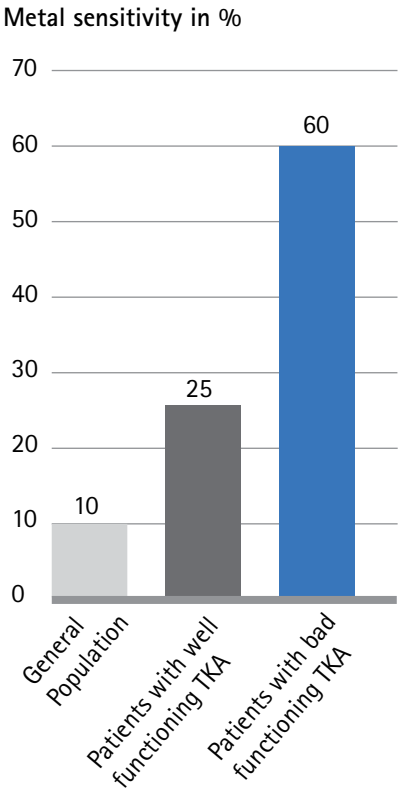


Fig. 6: Metal sensitivity after endoprosthesis in comparison to population.[19] Numbers are derived using a weighted average based on the number of subjects in each study.

Testing for Metal Hypersensitivity

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.[19]

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):

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

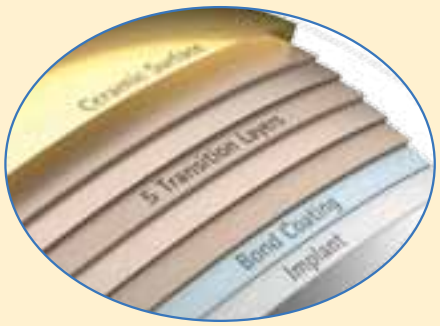
LTT is less popular than patch testing, but has been well established as a method for testing metal sensitivity in a variety of clinical settings.

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.

Reduced Potential for Metal Ion Release

Coating engineered for performance

The AS Coating acts as an effective barrier against the release of metal ions, such as molybdenum, nickel, cobalt, and chromium in laboratory (in-vitro) wear testing.



AS Advanced Surface is a real improvement in coating technologies.

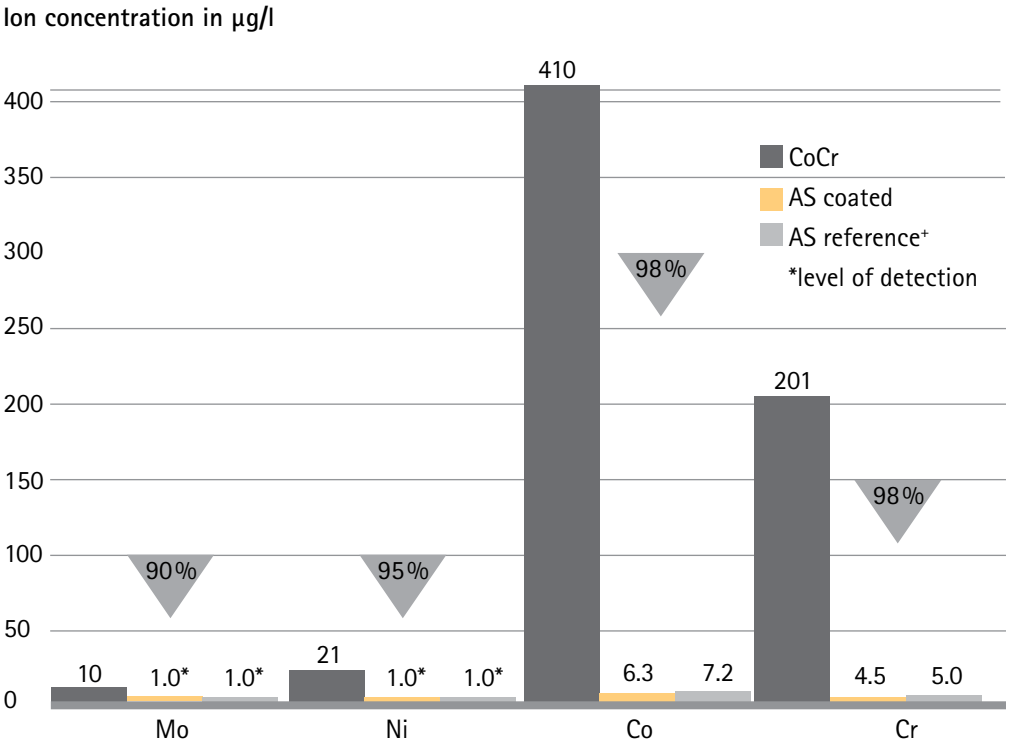


Fig. 7: Metal ion reduction[11]

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 AS Coating **significantly reduced** the release of metal ions (molybdenum, nickel, cobalt, and chromium) compared to non-coated implants. Testing also showed no significant difference in ion concentrations between the AS-coated-wear and AS-coated-reference samples, indicating that the effectiveness of the AS Coating was not compromised during the wear test. Full test protocol and results on file with Aesculap Implant Systems.

+ AS Reference is a wear simulation test with additional metal ion measurement using an AS 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.

Designed for Performance

Mechanical integrity of multilayers

Monolayer Coating

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).

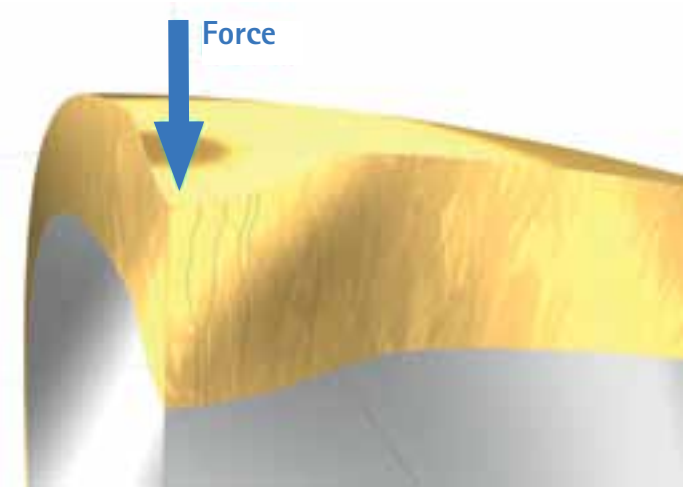
VS

Multilayer Coating

Transition Layers
The 7-layer coating is specifically designed to reduce the hardness from top to bottom in a gradient way (Fig. 8). The multilayer engineering in the transition layers leads to lower grain size and thus to an improved elastic modulus. This makes it extremely stable against mechanical stresses and strains and results in a more resilient product.[11, 25]

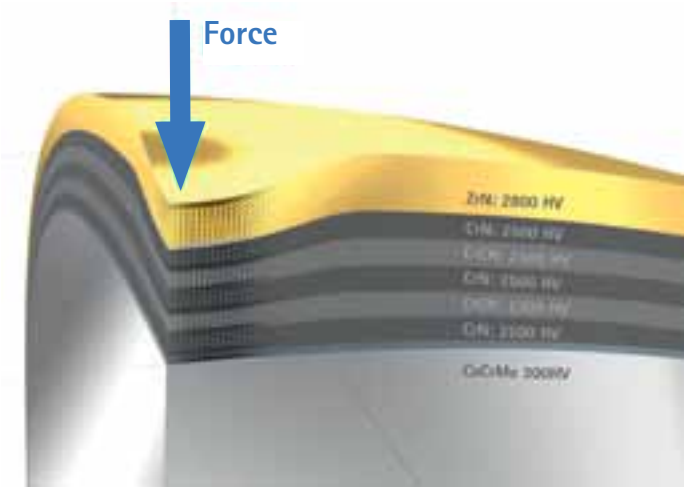
Bond Coating
A powerful bonding layer between the base material and subsequent layers forms an alloy compound that ensures strong adhesion.

Monolayer Coating



Column structure of crystallines

7-Layer Coating: improved elastic modulus



Small grain sizes

Fig. 8: Hardness gradient of the 7-layer coating

Beta Polyethylene Durability

Improved age resistance through beta-sterilization

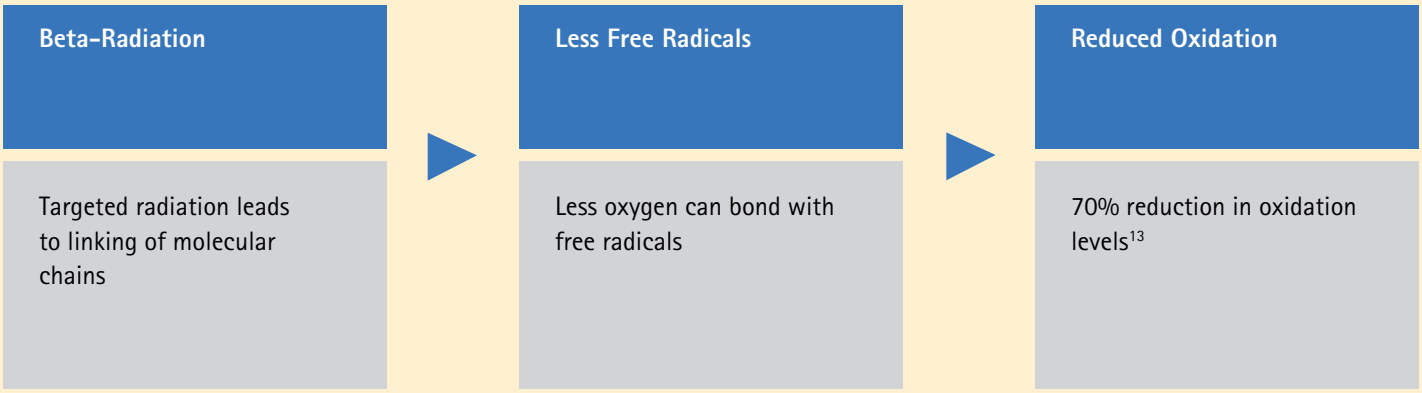
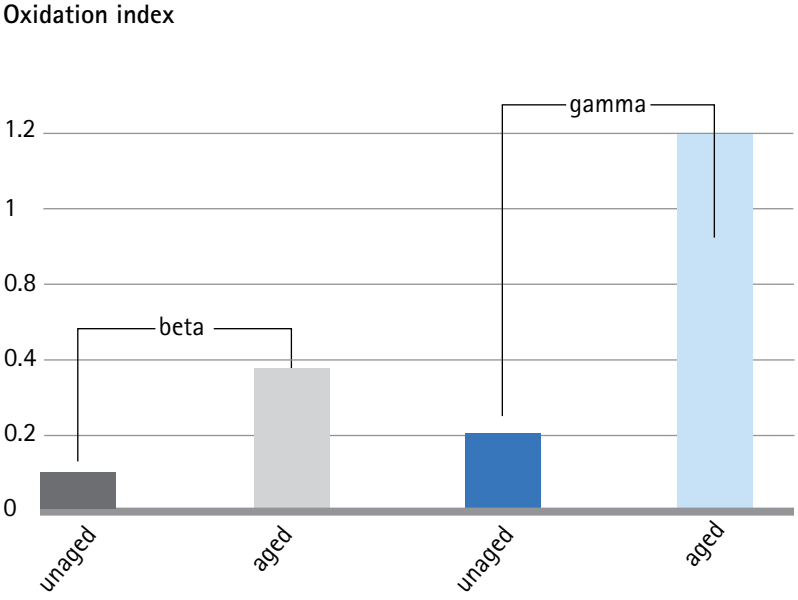


Fig. 9: Effects of Beta Sterilization

70% Reduction in oxidation levels[13]



ASTM F 2003: artificial aging of 10 years acc. to Kurtz et al.[12]: 14 days / 70°C / 5bar O_2

Fig. 10: Oxidation Level[13]

Decelerated Aging Process

Less oxidation means slower aging leading to optimized wear properties and less delamination[27]

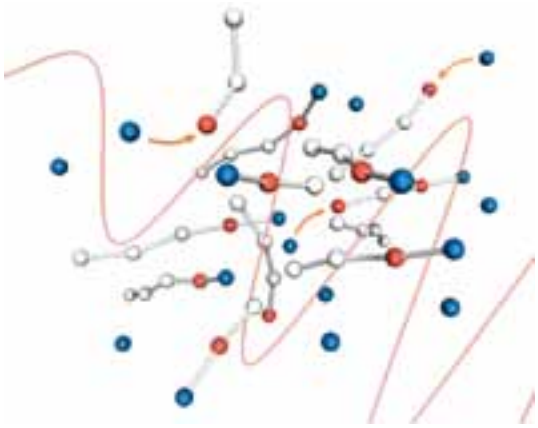
Beta PE + AS =

Advanced Bearing Technology

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

Columbus® AS knee

	Gamma Sterilization	Beta Sterilization
Radiation	Lower intensity, deeper higher penetration, doses: 2.5 Mrad – 4 Mrad	Higher intensity, concentrated, lower penetration, doses: 2.5 Mrad – 4 Mrad
Sterilization Time	Longer: 16 hours	Shorter: 15 seconds
Result	Higher content of residual free radicals leading to a higher risk of oxidation	Fewer residual free radicals after sterilization process causing less oxidation[27]



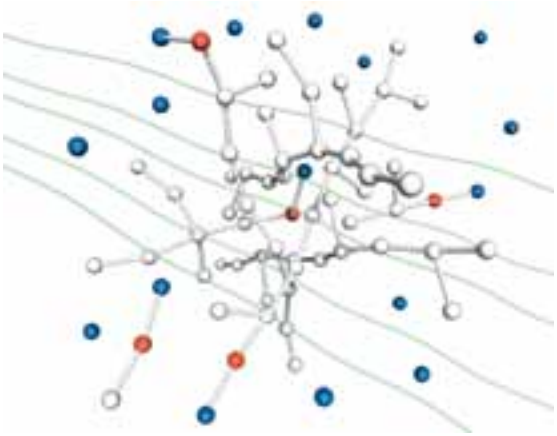


Fig. 11: Gamma vs. Beta Sterilization

Enhanced Performance

Beta PE + AS Advanced Surface

VEGA System®
PS knee system

Peter F. Sharkey, M.D. stated "*Improved polyethylene or alternative bearing surfaces can certainly diminish the failure rate after knee arthroplasty.*"[7]

As known from literature, highly crosslinked polyethylenes have reduced mechanical properties in terms of elasticity and impact strength. 28 Beta-PE combines the advantage of low wear with good mechanical properties of conventional polyethylenes.

Wear rates of CR bearing offerings (ISO 14243-1/3)

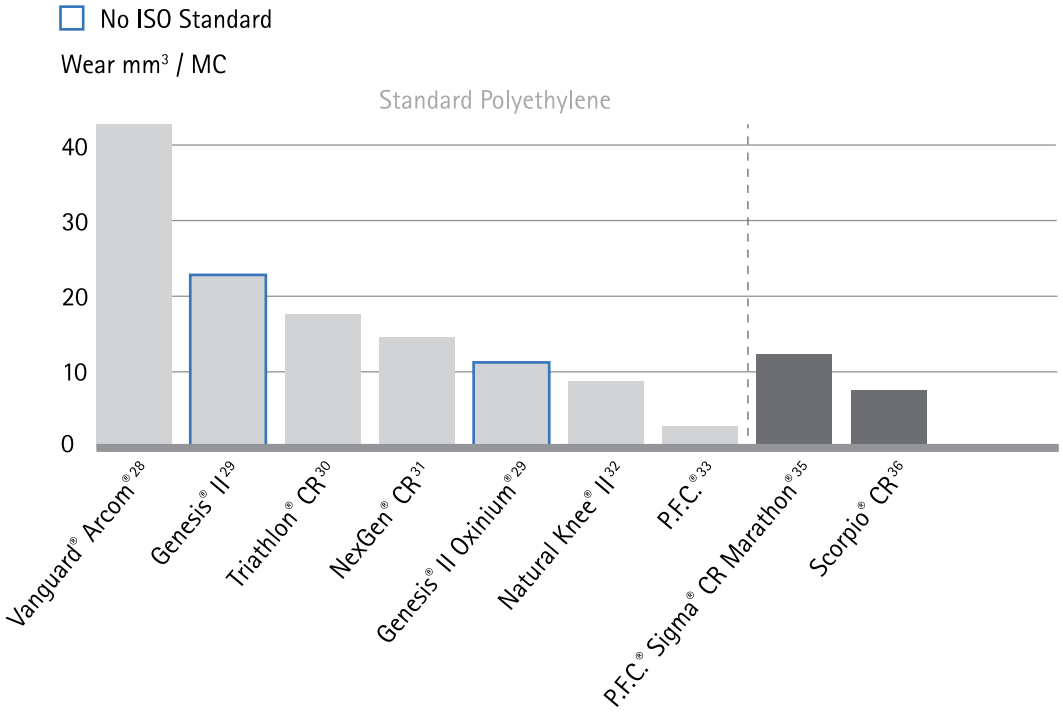


Fig. 12: Wear results of different knee replacement systems[11, 28-36]

Columbus® AS Revision knee

The AS coating in combination with Aesculap Knee Arthroplasty systems with Beta-PE yields excellent performance.

The AS coating is a real improvement in implant coating technology.

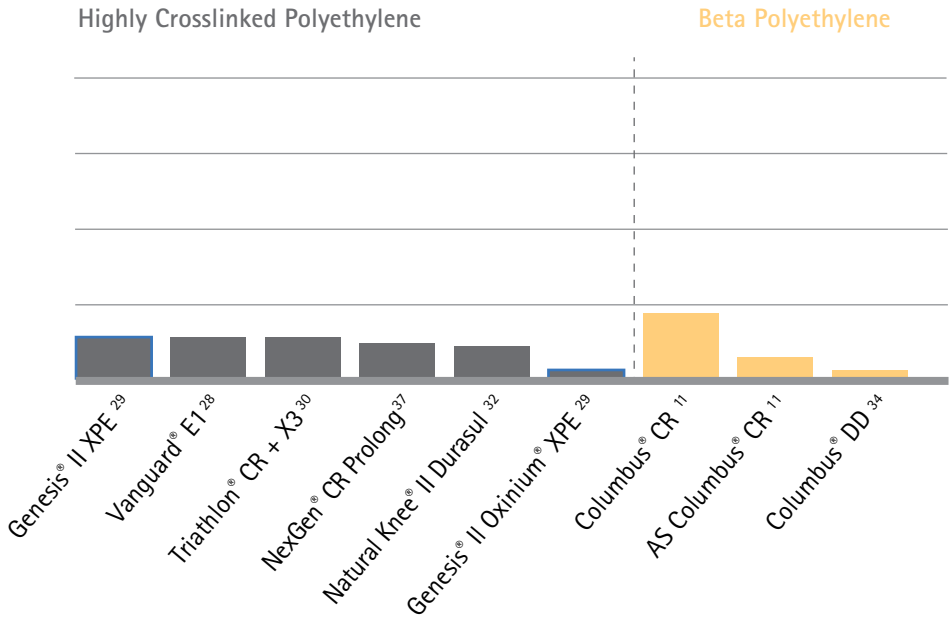


Fig. 13: Wear results of advanced knee replacement systems[11, 28-30, 32, 26-38]

Visit AesculapImplantSystems.com to view complete indications for use, contraindications, warnings and potential risks.

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