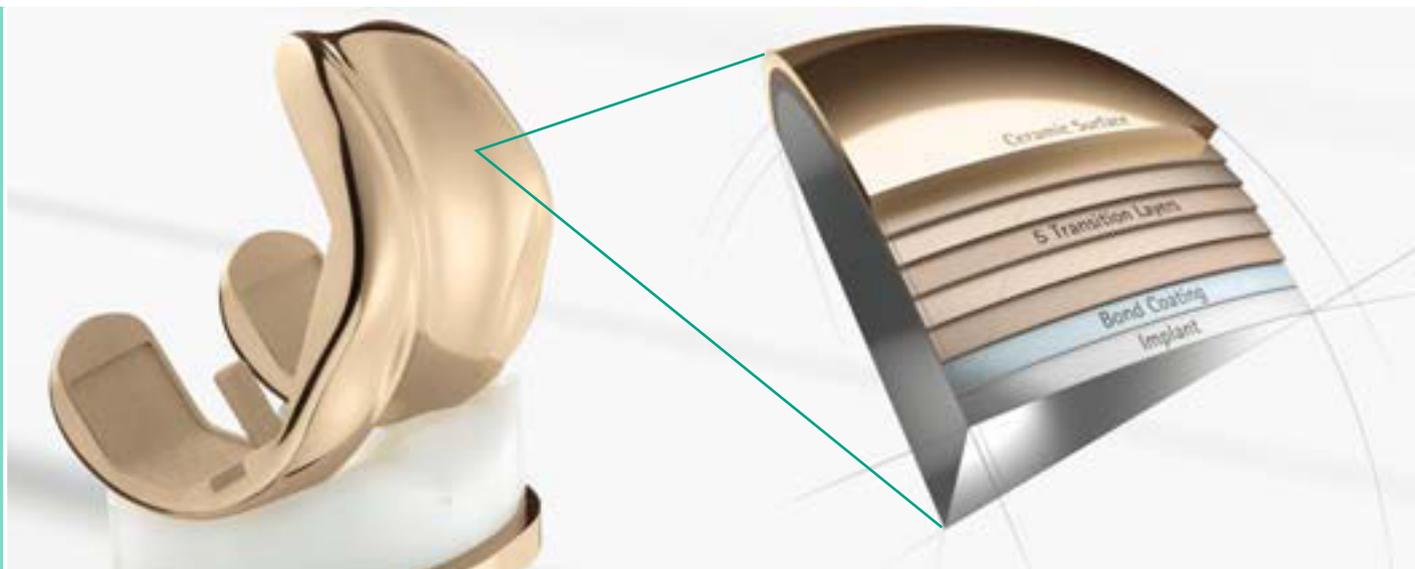


Aesculap[®] AS Advanced Surface

7 Layers to Protect You



Aesculap Orthopaedics

Aesculap® AS Advanced Surface

7 Layers to Protect You



Conventional monolayer coatings

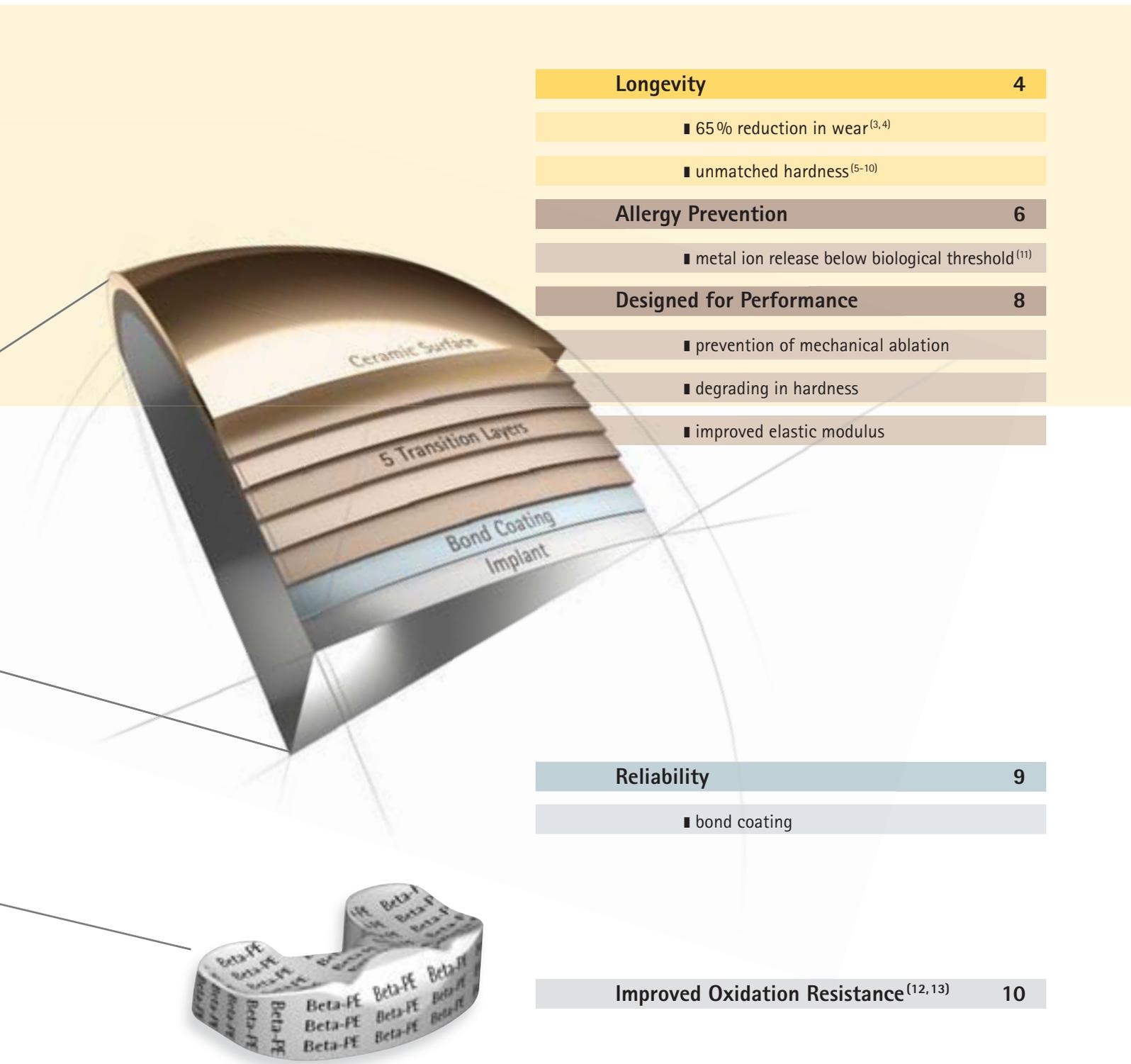
showed reduced resistance against mechanical ablation, which leads to a higher risk of third body wear followed by metal ion release.^(1,2)

Multilayer coatings

can withstand corrosive environment high stresses and strains all artificial knees are exposed to in the human body. This multilayer coating consisting of seven layers is unique in the market.



7-Layer Coating + Beta PE



Longevity 4

- 65% reduction in wear^(3,4)
- unmatched hardness⁽⁵⁻¹⁰⁾

Allergy Prevention 6

- metal ion release below biological threshold⁽¹¹⁾

Designed for Performance 8

- prevention of mechanical ablation
- degrading in hardness
- improved elastic modulus

Reliability 9

- bond coating

Improved Oxidation Resistance^(12,13) 10

Longevity – Ceramic Surface

65% Reduction in Wear

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

AS knee demonstrates 65% reduction in wear when compared to a CoCrMo prosthesis.^(3,4)



Wear rate (mg/Mc)

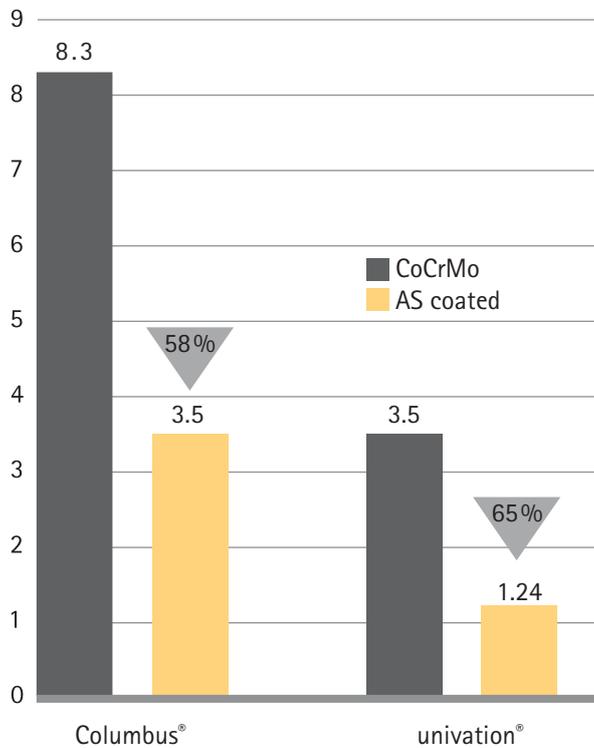


Fig.1: Wear reduction with Columbus[®] CR and univation[®] M after 5 Mio cycles according ISO standard 14243-1/3^(3,4,11)

Unmatched Hardness

Ceramic surface with a superior hardness can improve scratch resistance and implant bearing articulation.

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

A hard ceramic surface improves scratch resistance.⁽¹¹⁾

The extremely hard surface shows a high resistance to scratches and also good wettability, which leads to better articulation between the polyethylene bearing surface and the femoral component. Even with the addition of cortical bone chips and bone cement particles after 5 and 5.5 million cycles (Fig. 3), no damages (scratches, nicks, etc.) could be seen on the condyle surfaces. Third body wear and the risk for mechanical ablation can be minimized this way.⁽¹¹⁾

Superior surface hardness

Hardness in GPa

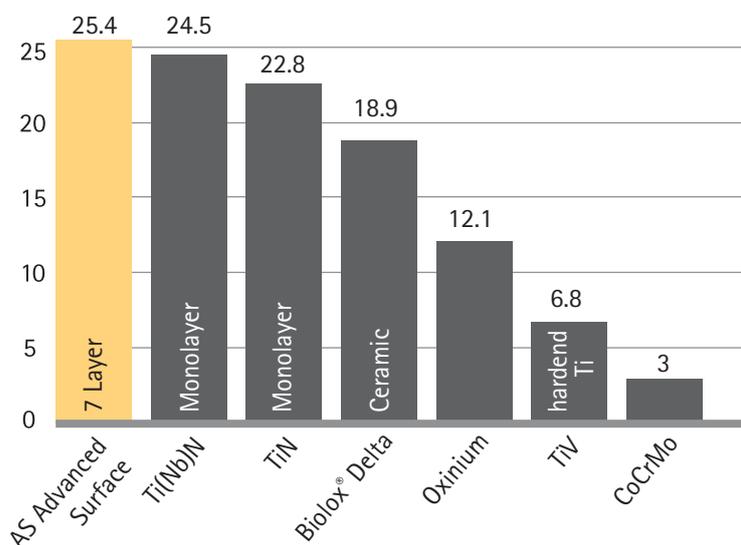


Fig. 2: Hardness of different kind of surfaces⁽⁵⁻¹⁰⁾

No damage after extreme wear test with bone and cement particles

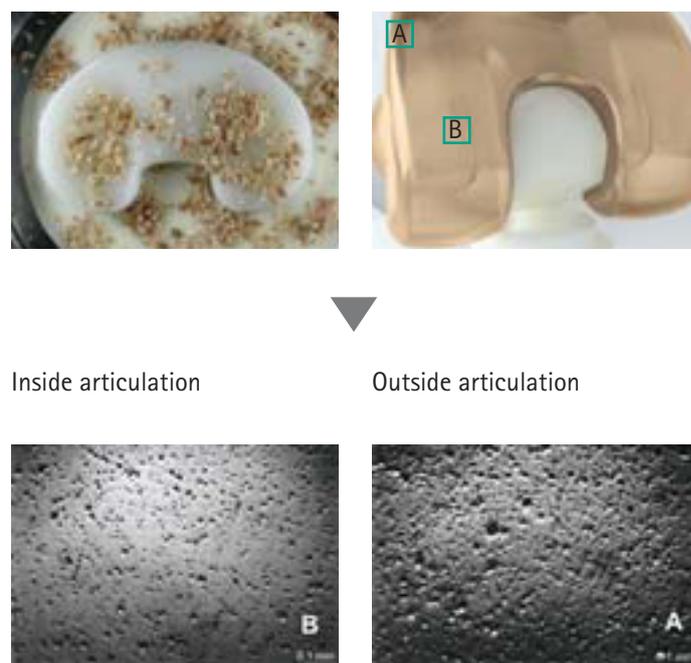


Fig. 3: Wear simulation under extreme conditions⁽¹¹⁾

Allergy Prevention – Transition Layers

20% are unsatisfied after Knee Arthroplasty Surgery.⁽¹⁷⁾

What are the Reasons for early Revision?

Patients with problems after total knee replacement have a higher level of chromium ions ($p=0.001$).⁽¹⁸⁾

60% of patients with poorly functionary total knees are sensitive to metal ions on the skin⁽¹⁹⁾, suggesting that the metal sensitivity is acquired through the primary arthroplasty.

Main reasons for early revision are aseptic loosening, infection and pain (Fig. 5).

How many of these could be originated in a hypersensitivity reaction?

- In a study with 1335 patients only 30% with an allergic history were detected and documented⁽²⁰⁾, which shows that metal allergies still are getting very low attention.
- Lützner et al could detect metal ions in the serum after conventional TKA.⁽²²⁾
- Metal ions may cause local and systemic toxic effects and hypersensitivity reactions.⁽²²⁾
- The metal allergy prevalence among the general population is relatively high at 13%.⁽²³⁾ The number of patients who

Main reasons for early revision < 5 years

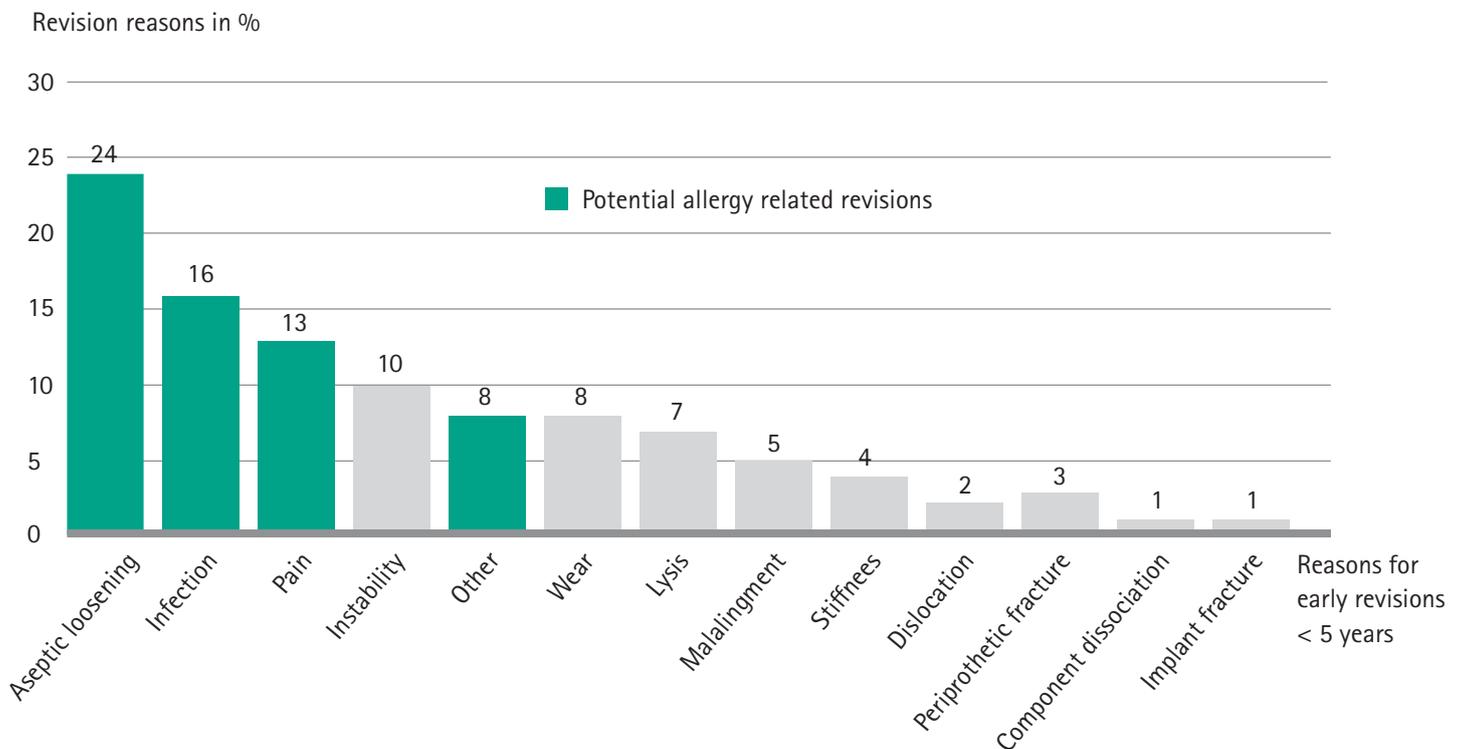


Fig. 5: National Joint Registry England and Wales 2010⁽²¹⁾

Metal ion Release below Biological Threshold

develop hypersensitivity against implant materials is estimated to 4%.⁽²⁴⁾

With AS, metal ion concentration is near the level of detection and below biological threshold.⁽¹¹⁾ (Fig. 7)

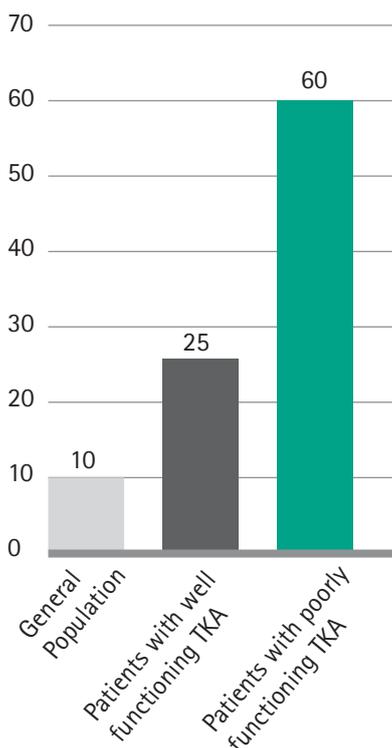
The higher risk of a hypersensitive reaction could be reduced by using an AS coated implant for all revision patients.



AS Enduro

Patients in need of revision are at 6 times greater risk for developing an allergic reaction⁽²⁰⁾

Metal sensitivity in %



Ion concentration in µg/l

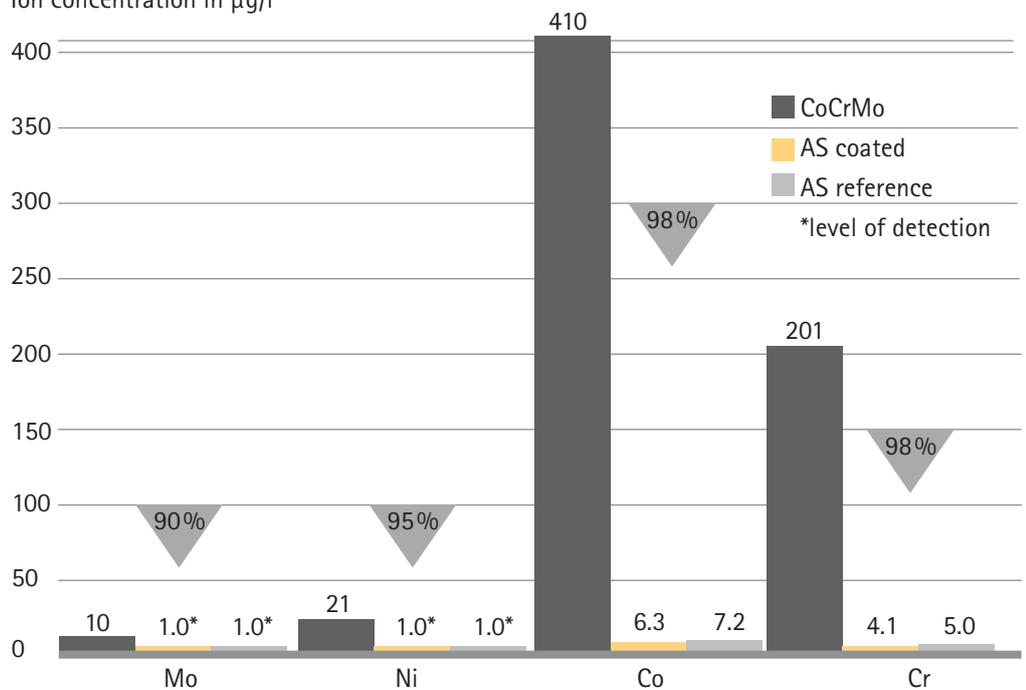


Fig. 6: Metal sensitivity after endoprosthesis in comparison to population⁽¹⁹⁾

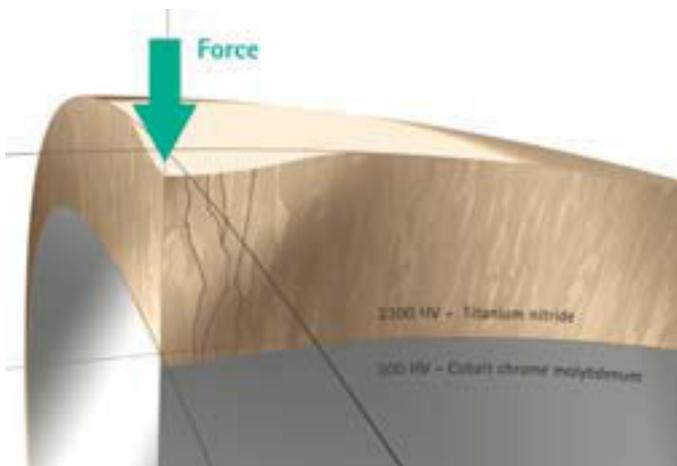
Fig. 7: Metal ion reduction with AS coated implants⁽¹¹⁾

Prevention of Mechanical Ablation

A quite hard surface on the relatively soft base material (CoCrMo) might lead to an egg shell effect. Monolayer coatings showed reduced resistance against mechanical ablation.^(1,2)

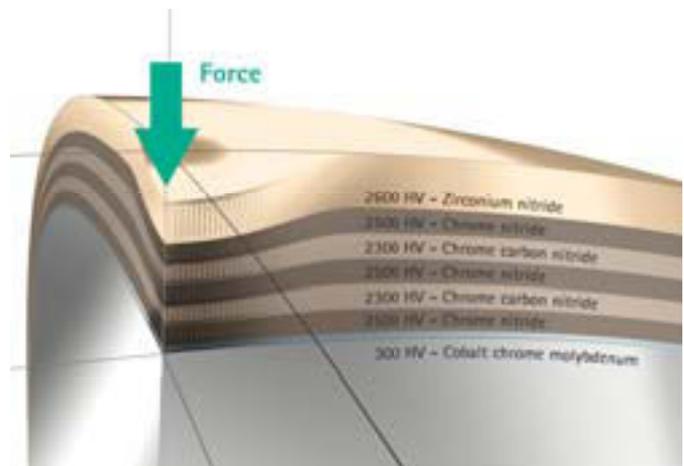
The 7-layer coating is built in a way to reduce the hardness from top to bottom in a gradient way (Fig. 8). The multilayer engineering results in a very dense crystalline structure with high capacity for plastic deformation favorable to withstand corrosive environment and high stresses and strains.^(11,25)

Monolayer coating



Column structure with big elongated grains
(low density coating)

7-layer coating: improved elastic modulus



Small grain sizes (high density coating)

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

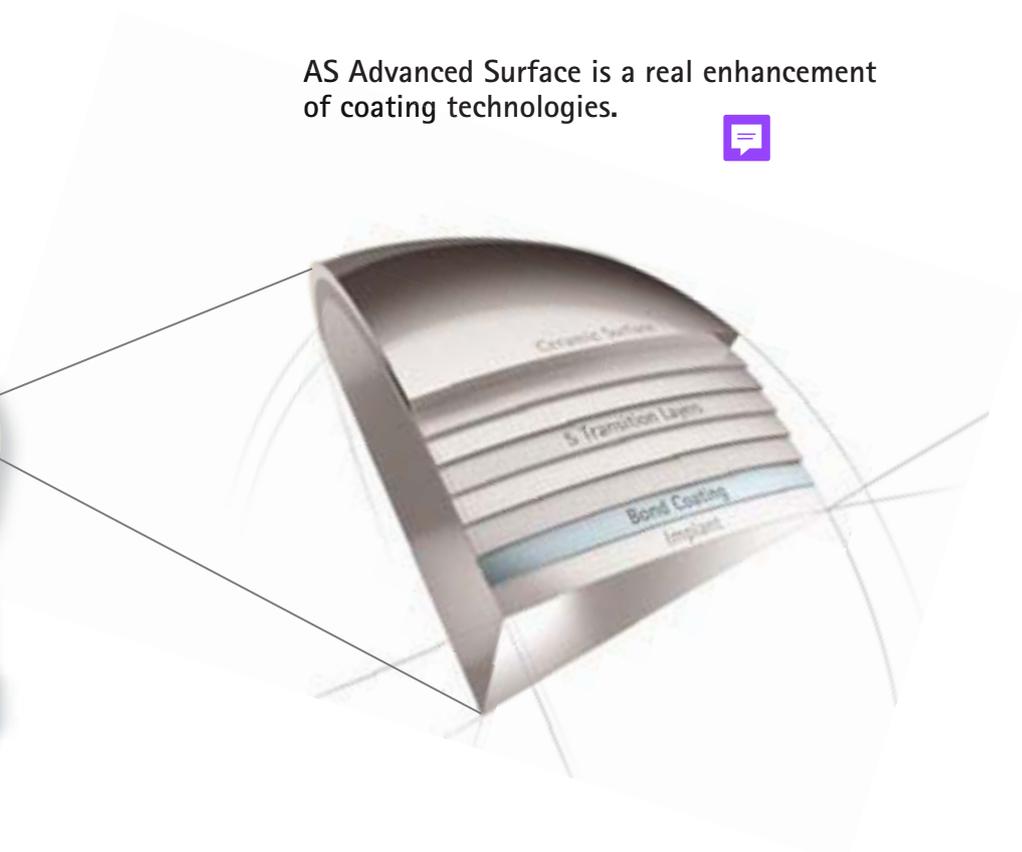
Bond Coating

7 Layers to Protect You



The bonding layer between CoCrMo and transition coating forms an alloy compound with the base material promoting superior adhesion.

AS Advanced Surface is a real enhancement of coating technologies.



Beta Polyethylene Durability

Improved Age Resistance through Beta Sterilization

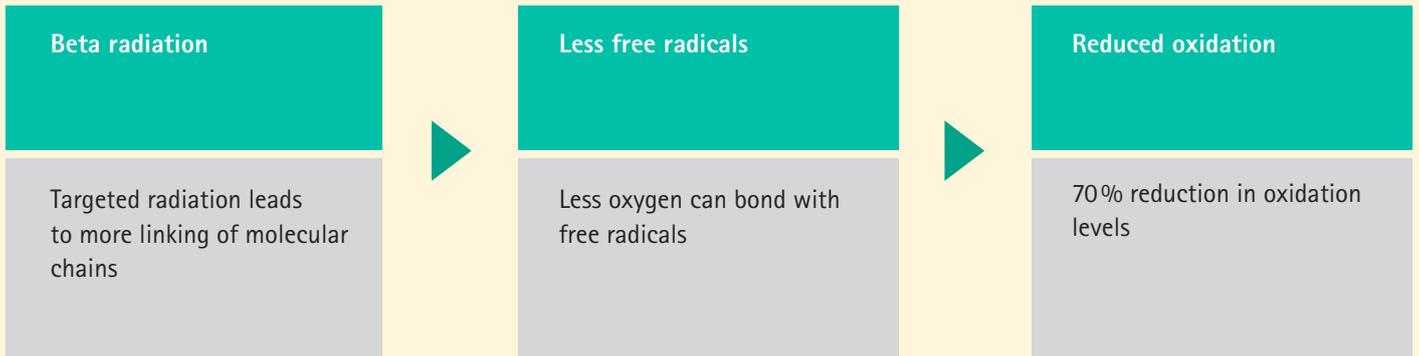
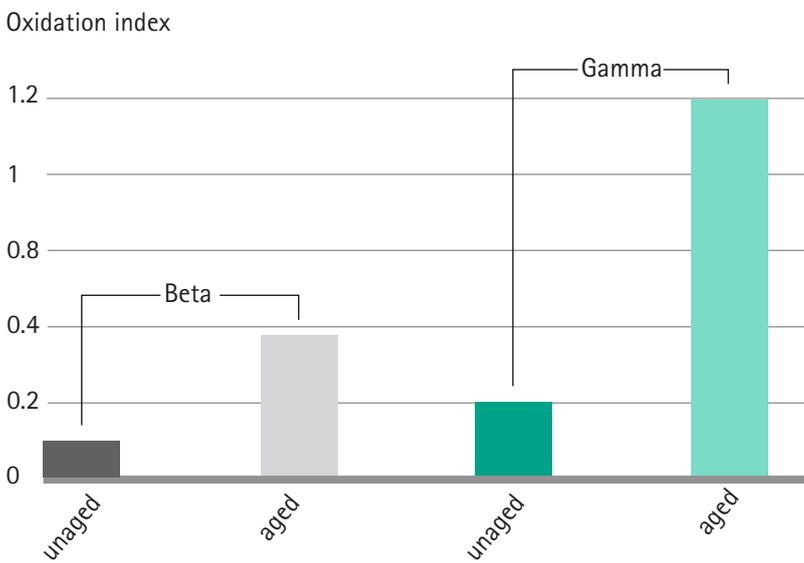


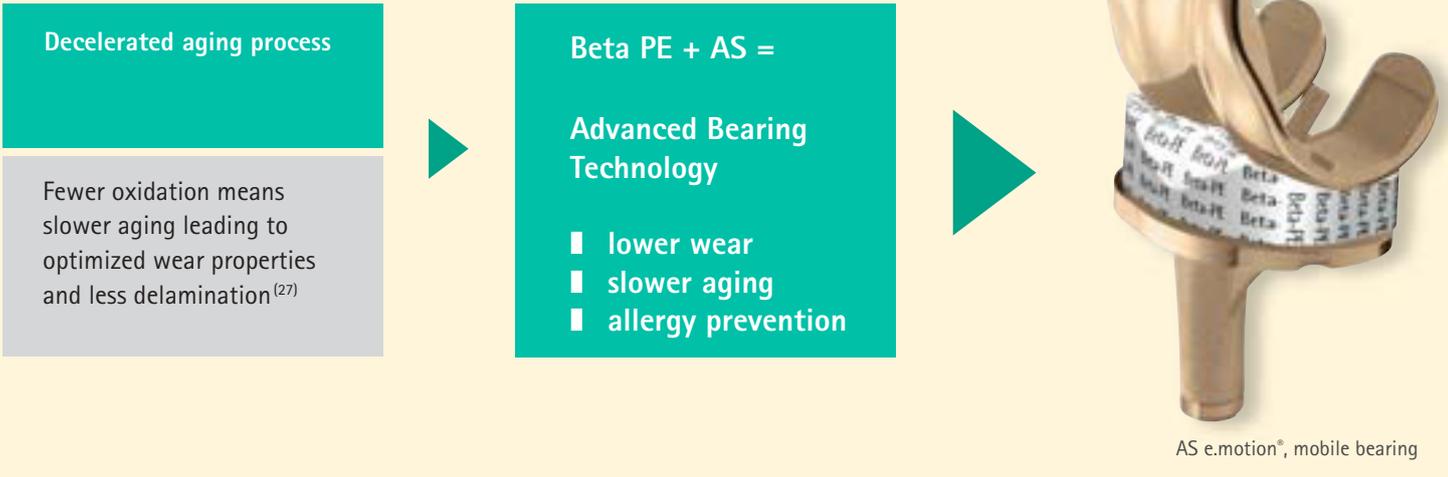
Fig. 9: Effects of Beta sterilization

70% reduction in oxidation levels⁽¹³⁾



ASTM F 2003: artificial aging of 10 years acc. to Kurtz et al.⁽¹²⁾: 14 days / 70°C / 5 bar O₂

Fig. 10: Oxidation level⁽¹³⁾



Feature	Gamma sterilization	Beta sterilization
Radiation	Lower intensity, deeper higher penetration, dosage: 2.5 Mrad – 4 Mrad	Higher intensity, concentrated, lower penetration, dosage: 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 free residual radicals after sterilization process causing less oxidation ⁽²⁷⁾

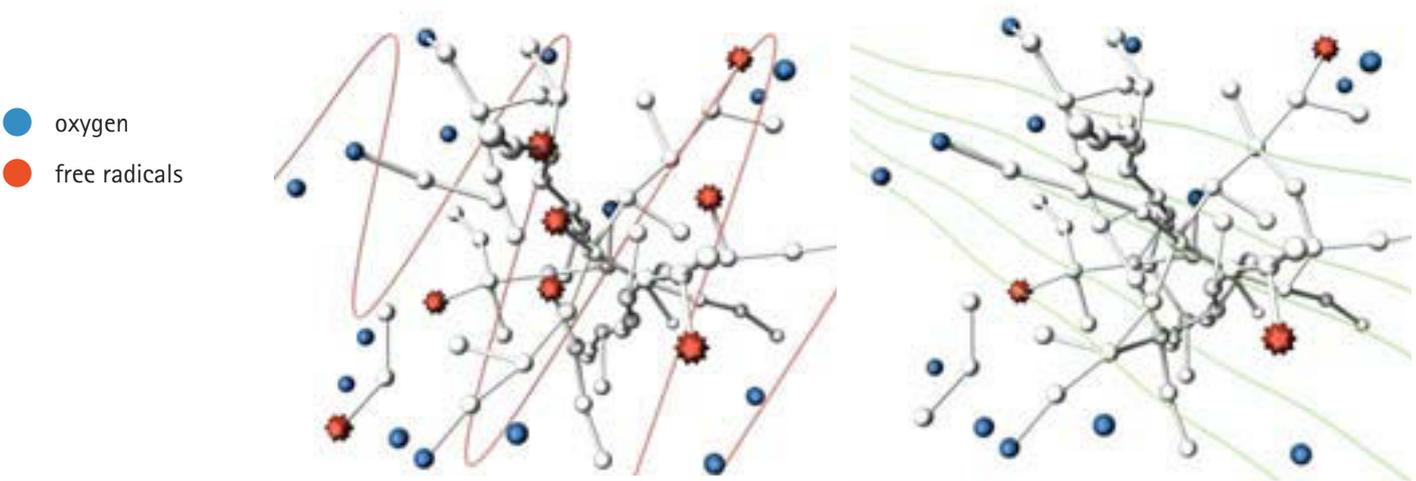


Fig. 11: Gamma vs. Beta sterilization

Enhanced Performance

Beta PE + AS Advanced Surface

Sharkey ,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.⁽²⁷⁾

Beta PE combines the advantage of low wear with good mechanical properties of conventional polyethylenes.



AS VEGA System®, PS

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

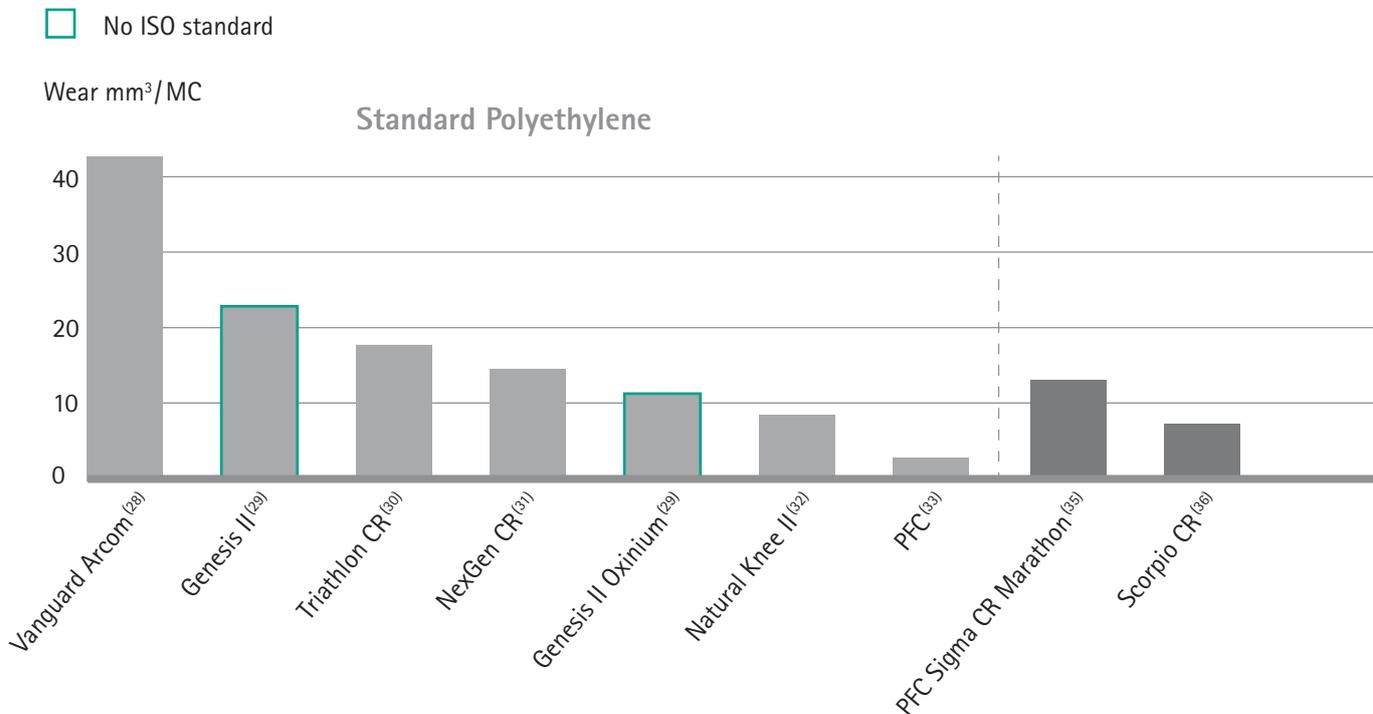


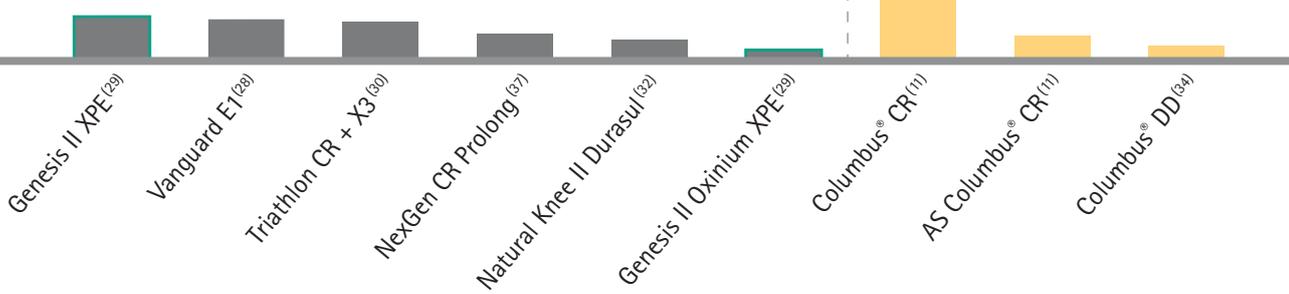
Fig. 12: Wear results of CR knee systems^(11,28-37)

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



Highly Crosslinked Polyethylene

Beta Polyethylene



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