B BRAUN
SHARING EXPERTISE

WHY TAKE A CHANCE WITH ANYTHING ELSE?

AESCULAP® ORTHOPAEDICS

ADVANCED SURFACE TECHNOLOGY

By 2035 the demand for Total Knee Arthoplasty (TKA) in the UK is predicted to grow by 160%.[1] 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.[2]

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 procedure 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 reviews

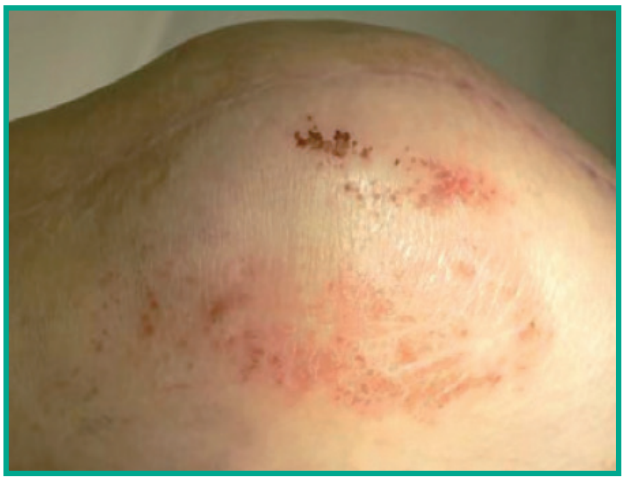
PROSTHESES-RELATED CAUSES OF IMPLANT FAILURE

METAL ION RELEASE

All metals can corode inside the body. When metals such as Nickel (Ni), Cobalt (Co) and Chromium (Cr), used in orthopaedic prostheses corrode, they can release metal ions that can trigger a cascade of adverse reactions in certain patients.[3]

The circulating by-products of metal degradation may stimulate cells in the peri-prosthetic tissues, provoking a localised reaction.

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 arthoplasty.

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".[4]

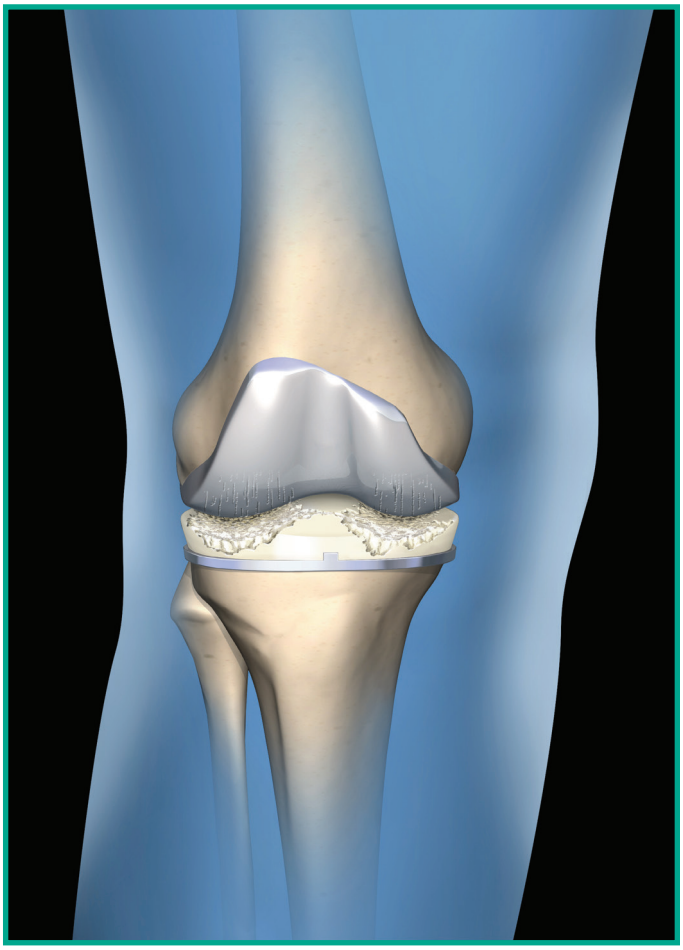
As the observed assocation between standard cobalt-chromium-molybdenum implants and patient dissatisfaction increases, implant materials warrant case-by-case consideration.

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.[5,6] 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.[5,6]

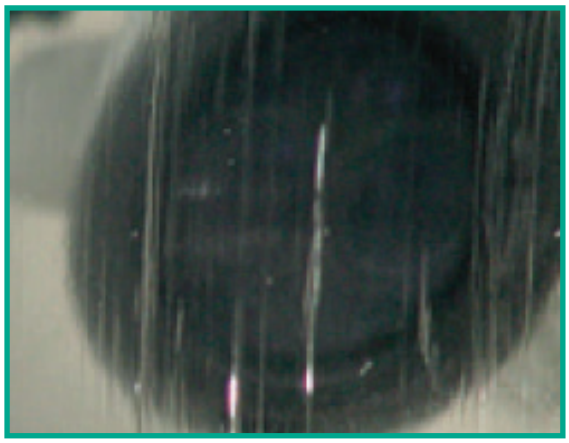
Monolayer coatings over metal can delaminate.[7,8] All-ceramic components are brittle and subject to fracture.[11]

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.[10]



Magnification.[10]

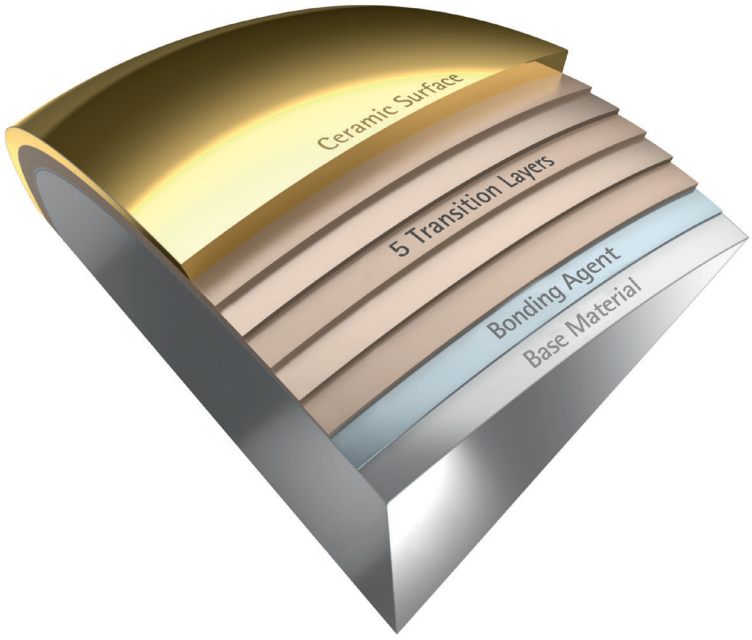
NEED FOR AN ALTERNATIVE

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 vapour deposition (PVD) to ensure effective adhesion of each layer.[10]



SEVEN-LAYER ADVANCED SURFACE TECHNOLOGY

Each layer provides special functionality to benefit your patients.

Ceramic Surface - ZrN Layer
Zirconium Nitride

- Delivers favourable biocompatibility compared with standard CoCrMo
- Imparts superior surface hardness[11,12,13,14,15,16]
- Resists roughening and mechanical breakdown[3]
- Improves wear rates*[3,17,18,19,20]

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 ductility[21]
- 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 unkown. A clinical evalution 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 encapsulasted metal knee prostheses.[22]

TECHNOLOGY LIKE NO OTHER

UNMATCHED TESTING

An extensive review of competitive literature reveals the unmatched testing of Advanced Surface Technology.[22] Through in vitro wear simulation, Advance Surface Technology has been tested to determine the release of nickel, cobalt, chromium and molybdenum ions[17,23] and to evaluate wear characteristics of unicondylar, primary and revision knee systems.*[3,17,18,19,20]

FAVOURABLE 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.*[3](Figure 1)
- Is the hardest material used in orthopaedic devices today - two times as hard as Oxinium® (Smith & Nephew, Memphis, TN) and more then eight times as hard as traditional CoCr.[11,14,16] (Figure 2)
- Provides superior resistence to wear, including substantial polyethylene wear resistence, compared with CoCrMo.*[5,17,18,19,20](Figure 3)
- Ensures mechanical integrity by providing ductility that permits the overall structure to deform slightly without cracking.[21]
- Encourages excellent wettability for a low-friction counterface that resists roughening and supports the expectation of prolonged prosthses survival.

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

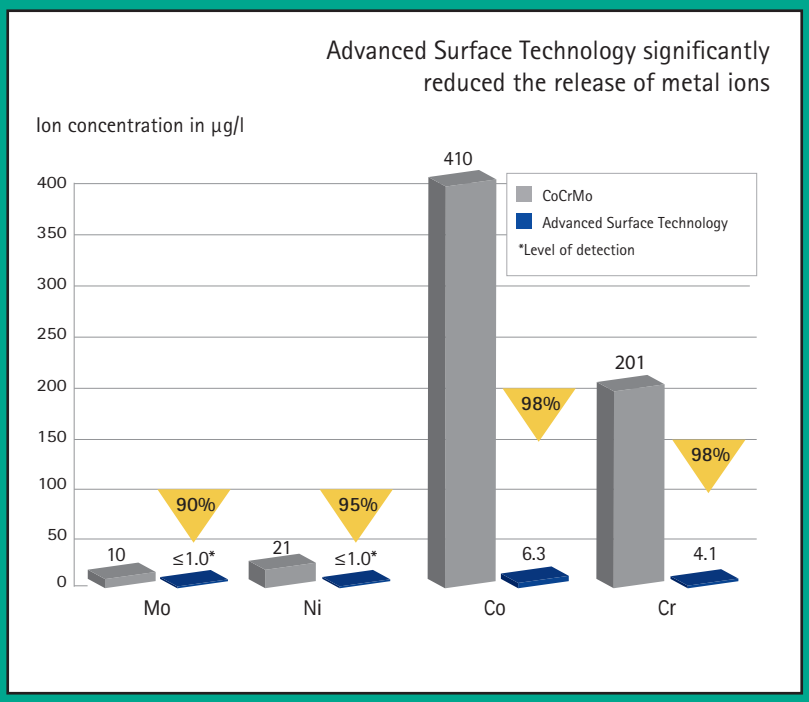


Figure 1: Serum Ion release for Mo by 90%, for Ni by 95%, for Co by 98% and for Cr by 98%.[4] Morever, the ion concentrations for the Advanced Surface technology reference sample that were axially loaded performed similar to those articulating the wear simulator. The results confirm that even under extreme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

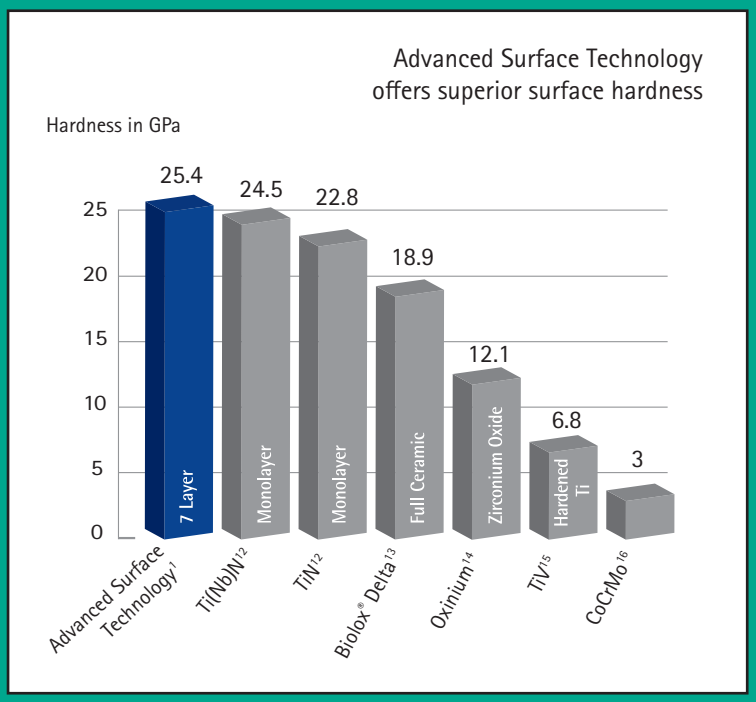


Figure 2: Advanced Surface Technology offers superior surface hardness to resist sratching by third-body debris.

Wear Simulation:
Advanced Surface Technology vs CoCrMo Implants

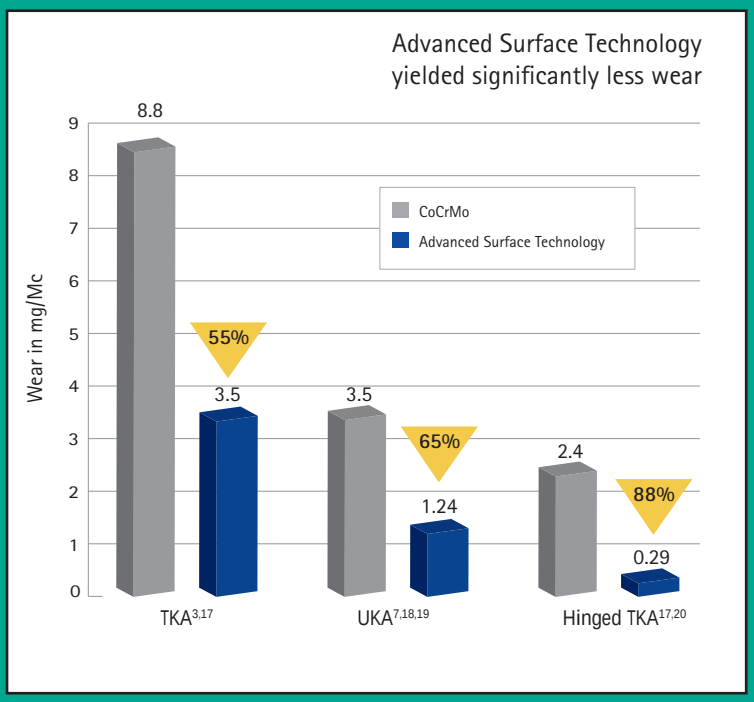


Figure 3: Advanced Surface Technology achieved a 55% wear reduction compared with standard CoCrMo in a TKA knee design, a 65% wear reduction when compared with standard CoCrMo in UKA design and an 88% reduction when compared with a standard CoCrMo in a hinged knee design.

PERFORMANCE LIKE NO OTHER

FUNCTION OF INTERLEUKINS

An enormously important but seldom considered aspect of TKR, is the meaning of the Interleukins (IL) regarding the health of the patient. IL are cytokines that are secreted by body-own cells to control immunous processes. IL-10 acts as an anti-inflammatory in an early stage of infections and IL-8 acts as an inflammatory mediator. The presence of higher concentrations of both interleukins may be interpreted as a result from ongoing inflammation, as reported in a recent publication on metal-on metal inflammatory pseudotumors.

RELATION BETWEEN INTERLEUKINS AND RADIOLUCENCY

In 2007, the AS surface was introduced and has been used in excess of 100,000 cases worldwide. A recent comparison study at 5 years has shown a significant reduction in the serum levels of both interleukins 8 and 10, as well as a reduction in radiolucencies over the standard CoCr implants, indicating a possible association between the two factors.[23 24 25]

	Coated TKA	Uncoated TKA	p-value
IL-8 (pg/ml)	1.15 (2.1)	36.60 (5..6)	<0.001
IL-10 (pg/ml)	0.25 (0.5)	3.58 (0.9)	<0.001
Revisions	3*	4*	0.680
Radiolucent lines of more than 1 mm (n) I Femur I Tibia	 2 0	 11 16	 0.019 <0.0001

NATIONAL JOINT REGISTRY REPORT

The National Joint Registry (NJR) has produced a report analysing the usage and outcomes with the AS Columbus Cemented knee, based on data collected by the NJR. The data used is from the first recorded usage, on 6th July 2009, up to the last recorded usage on the 5th March 2018.

The report found that the AS Columbus has a cumulative revision rate of 1.74% after 5 years. In comparison, all other TKR registered by the NJR have a cumulative revision rate of 2.658%.

The evidence from the NJR at 5 years shows that the AS Columbus has better reported outcomes compared to the market leading implants.[26]

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.

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