Columbus® AS Revision Knee System

with Advanced Surface Technology

Aesculap Orthopaedics

AESCULAP®
Implant Systems

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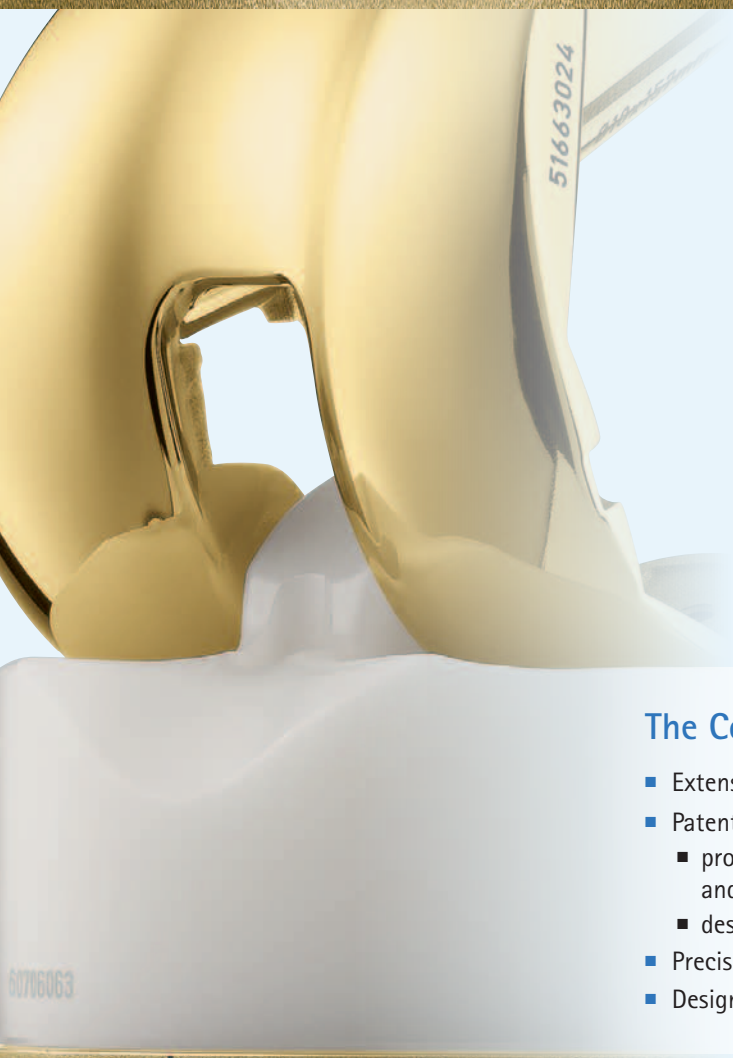


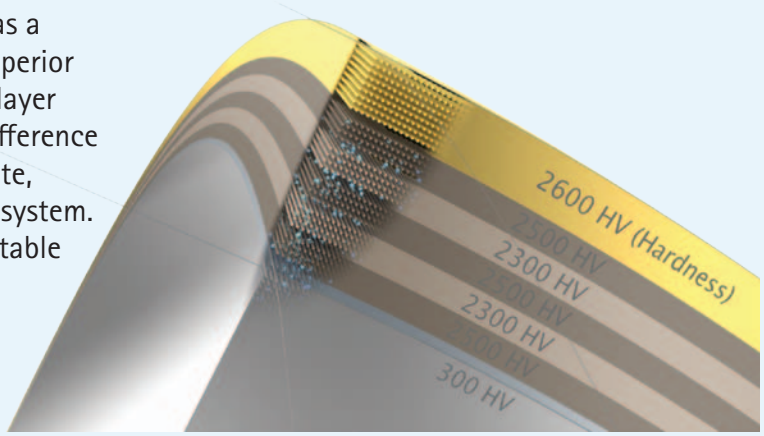
The patient's desire for a better quality of life has driven exponential demand in the knee replacement market and total knee revisions are projected to grow 601% between 2005 and 2030.[1] To address this increasing need, Aesculap Implant Systems offers the Columbus AS Revision Knee System that allows up to 130° of flexion and is based on the long standing technology of the Columbus Primary Knee System.

The Columbus AS Revision Knee System offers:

- Extensive portfolio of implant options for intraoperative flexibility
- Patented 7-layer Advanced Surface Technology:
  - provides substantial wear reduction, unmatched surface hardness and mechanical integrity.[2,3]
  - designed for performance and potentially reduces metal ion release
- Precision engineering allows for high productivity and good wear rates
- Designed for use with the computer assisted navigation system, OrthoPilot® TKR

ADVANCED SURFACE TECHNOLOGY

Each layer of the proprietary 7-layer coating has a specific function. The outer layer, ZrN yields superior surface hardness and reduces abrasion. The 7-layer coating is specifically designed to bridge the difference in hardness from the ZrN over the CoCr substrate, improving the molecular structure of a layered system. This makes the molecular structure extremely stable against mechanical stresses and strains and results in a more resilient implant. [11, 2]



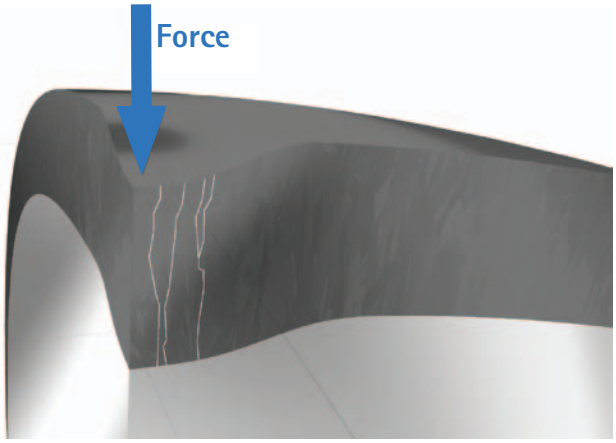
The 5 transition layers provide stability and acts to create a barrier to help prevent metal ion release. The adhesive layer bonds the substrate securely to the coated layers, creating a firm connection between implant and subsequent coated layers.

Monolayer Coating

VS

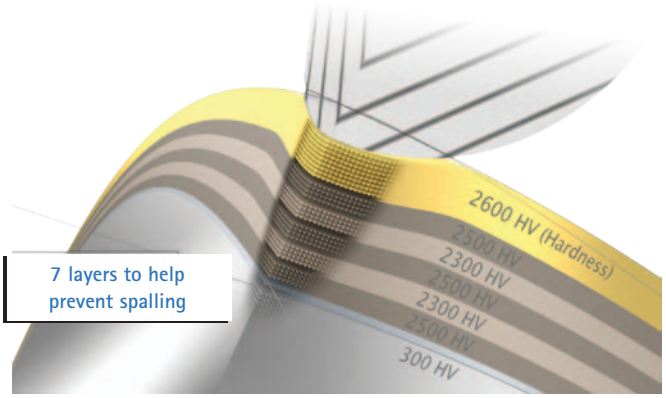
Multilayer Coating

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).



Column structure of crystallines

The multilayer engineering in the transition layers leads to lower grain size and thus an improved elastic modulus, which specifically reduces shock to the material.



Small grain sizes

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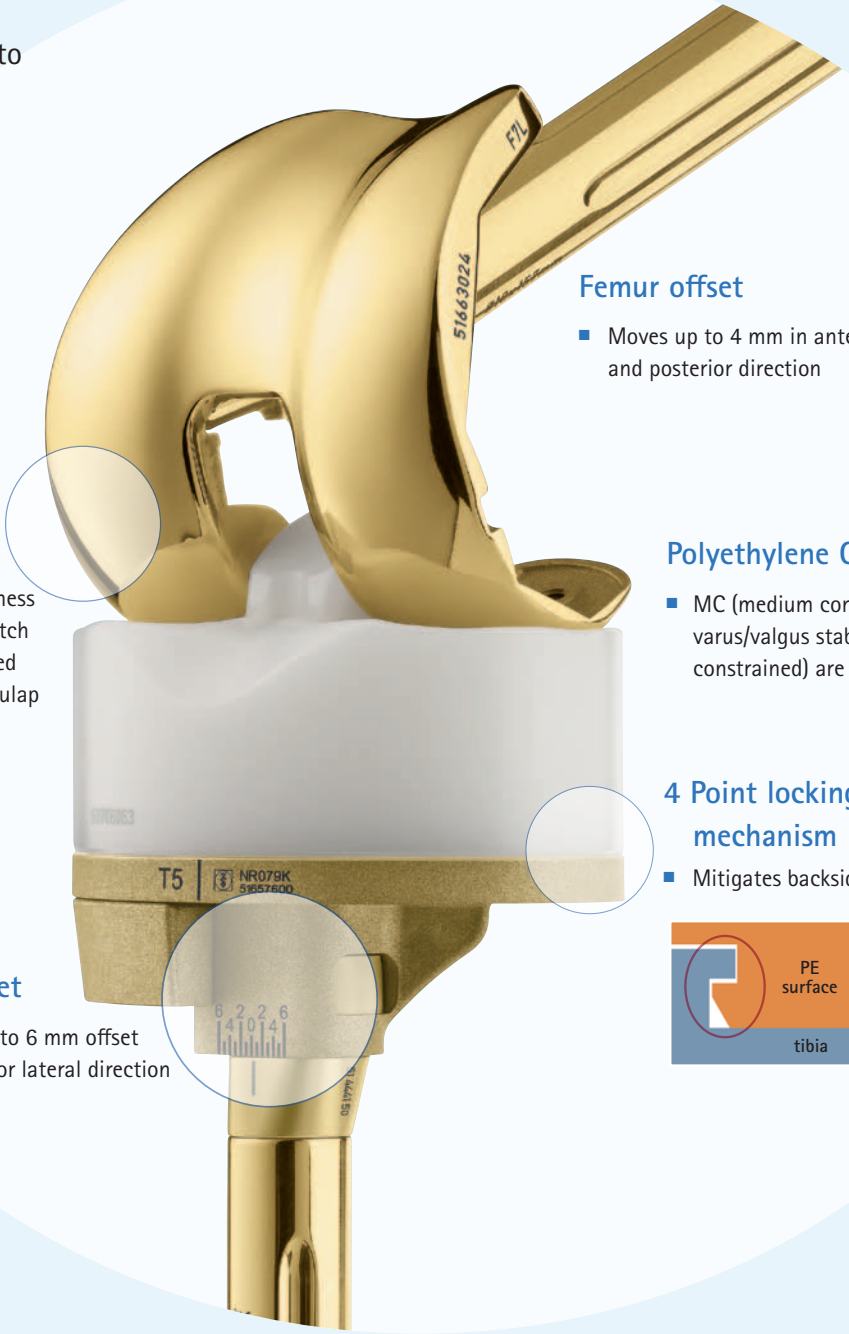
PRECISION ENGINEERING

Variable offset can be adjusted to adapt to the patient's anatomy.



Femur offset

- Moves up to 4 mm in anterior and posterior direction

Advanced Surface Technology

- 7-layer coating delivers unparalleled surface hardness and greatly improved scratch resistance, as demonstrated in testing with other Aesculap knee designs.[2,3]

Polyethylene Options

- MC (medium constrained) or varus/valgus stable HC (high constrained) are available.

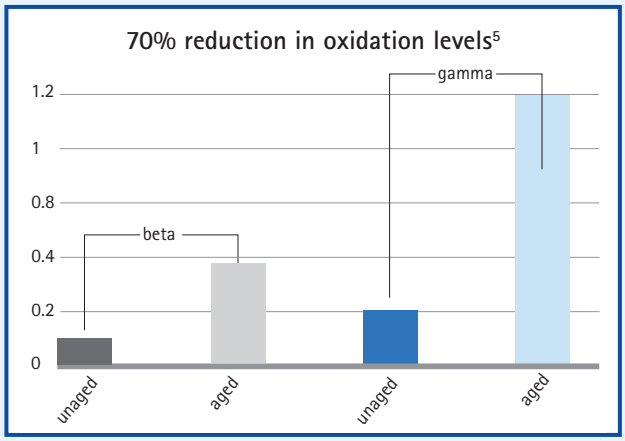
4 Point locking mechanism

- Mitigates backside wear

Tibia offset

- Moves up to 6 mm offset in medial or lateral direction

BETA POLYTHYLENE DURABILITY

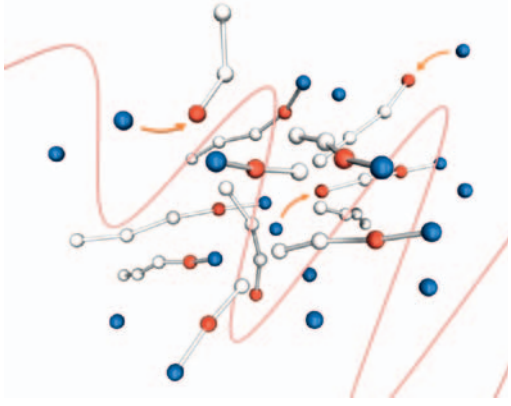


ASTM F 2003: artificial aging of 10 years acc. to Kurtz et al.[6] 14 days/70°C/5bar O_2 shown in BiCONTACT study.

Improved age-resistance through beta radiation sterilization

Beta-Radiation	Less Free Radicals	Reduced Oxidation	Decelerated Aging Process	**Beta PE + AS = Advanced Bearing Technology**
Targeted radiation leads to linking of molecular chains	Less oxygen can bond with free radicals	Reduction in oxidation levels	Less oxidation means slower aging leading to optimized wear properties and less delamination[3]	

	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]



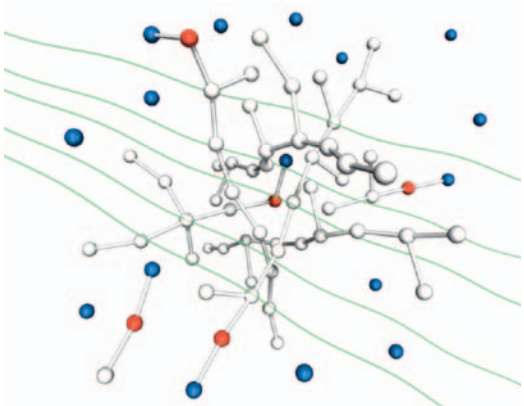


Fig. 11: Gamma vs. Beta Sterilization

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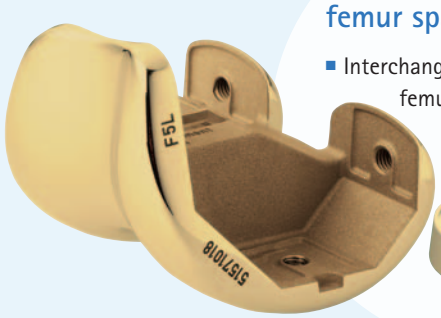
INTRAOPERATIVE FLEXIBILITY

A wide variety of implants provide broad options for the patient's anatomy

2 polyethylene gliding surfaces

- Medium and High-Constrained
- Size range from 10 mm to 32 mm

7 femur sizes

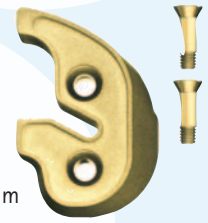


femur spacers

- Interchangeable distal and posterior femur augments in 5, 10, 15 mm

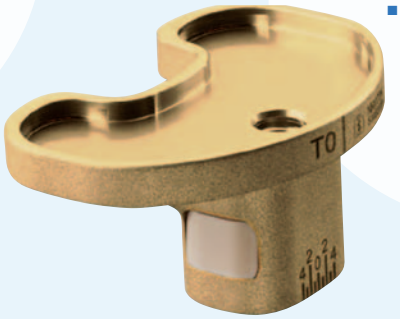
4 patella sizes

- Ø 27 x 7
- Ø 30 x 8
- Ø 33 x 9
- Ø 36 x 10



6 tibia sizes

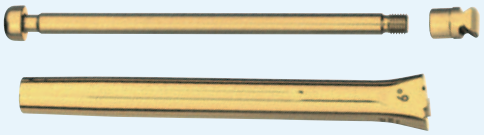
- Tibia hemi spacers in 5, 10, 15 mm
- Cemented and pressfit tibia stems in two lengths and seven sizes
  - Asymmetrical support flange for increased stability



Ø = diameter

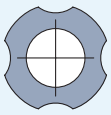
FEMUR STEM OPTIONS

Asymetrical support flange for increased stability

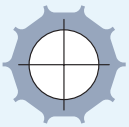


Cemented stem version

Pressfit stem version



4 longitudinal grooves to help avoid the risk of embolism



10 longitudinal grooves (Wagner Profile)

- **Femur extension stems**

  Cemented (6°): lengths 77 and 157 mm ø 12, 15 and 18 mm

  Pressfit (5°/ 7°): lengths 117 and 177 mm ø 12, 13, 14, 15, 16, 17, 18, 19 and 20 mm

TIBIA STEM OPTIONS

Cemented stem version

Pressfit stem version

- **Tibia extension stems**

  Cemented: lengths 52 and 92 mm ø 12, 15 and 18 mm

  Pressfit: lengths 92 and 132 mm ø 11, 12, 13, 14, 15, 16, 17, 18, 19 and 20 mm

Indication:

The Columbus® Revision Knee System is indicated for use in reconstruction of the diseased knee joint caused by osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, the need to revise failed arthroplasties or osteotomies where pain, deformity or dysfunction persist, and for patients suffering from correctable valgus or varus deformity and moderate flexion contracture.The Columbus Revision Knee System is designed for use with bone cement.

Contraindication:

Contraindications include, but are not limited to:

- Joint conditions that can be treated by reconstructive surgery (e.g. osteotomy)
- Acute or chronic infections near the joint, or systemic infections
- Secondary diseases that could influence joint implant functionality
- Systemic diseases and metabolic disorders
- Severe osteoporosis or osteomalacia
- Severely damaged bone structures that could prevent stable implantation of implant components
- Bone tumors in the region of implant fixation
- Bone malformations, axial misalignments or other bone conditions that rule out implantation of a prosthetic joint
- Predictable overload of the joint implant (e.g. due to adiposity)
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism
- Fever, infection or inflammation (systemic or local)
- Pregnancy
- Mental illness
- Severe osteopenia (or any other medical or surgical finding) that would preclude any benefit from the implants
- Combination with implant components from other manufacturers
- Inadequate patient compliance
- Foreign body sensitivity to the implant materials
- All cases listed under indications

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Please refer to instructions for use for important product information, including warnings, potential risks, precautions and possible adverse effects.

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