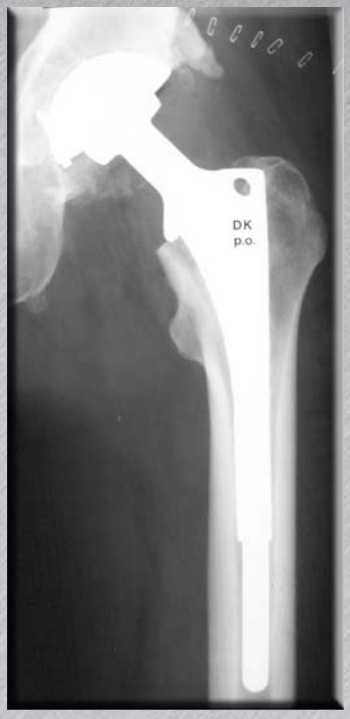
AML®

HIP SYSTEM

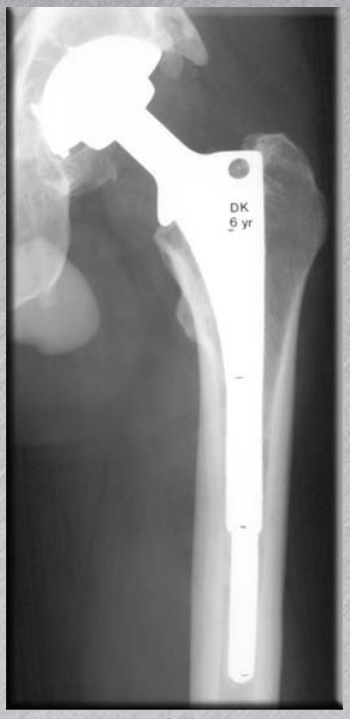
DESIGN RATIONALE

DePuy

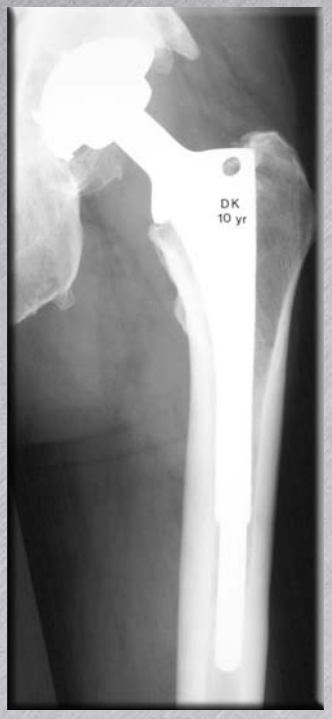
a Johnson & Johnson company



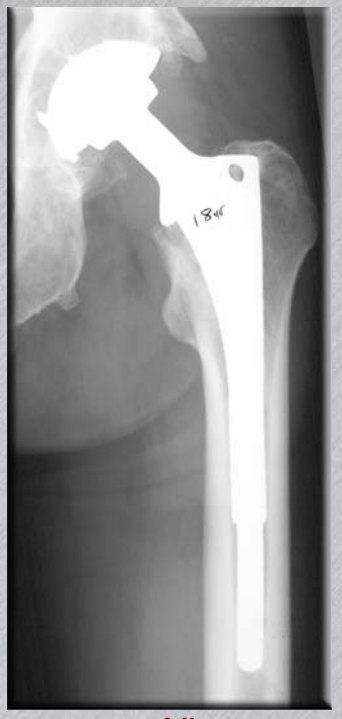
Post-op



6-year follow-up



10-year follow-up



18-year follow-up

Radiographic Series: 32 mm fixed head 5/8 coated AML stem

Published Results

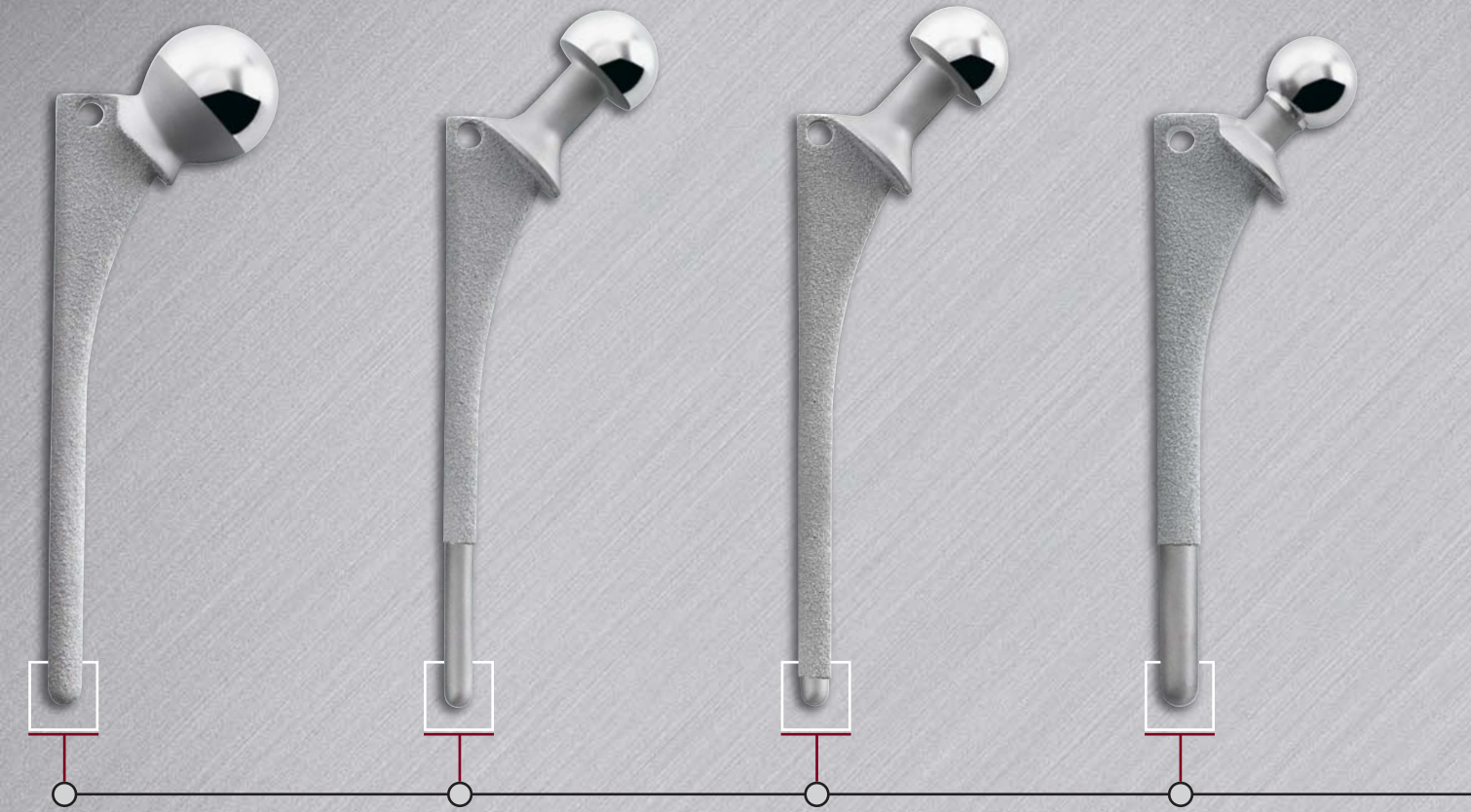
The durability of the extensively coated, parallel-sided family of implants has been well established through the documentation of clinical success in numerous published peer-reviewed studies.

Primary

- At a mean follow-up of 13.9 years, statistical analysis predicted the femoral component survivorship at 15 years to be 98.9 percent[1] *CORR 2001*
- The survivorship at 10 years for extensively coated stems was 99%[2] *AAOS 1996*
- The 9-year cumulative survivorship of variable-sized AML stems was 99.3%[3] *CORR 1994*

Revision

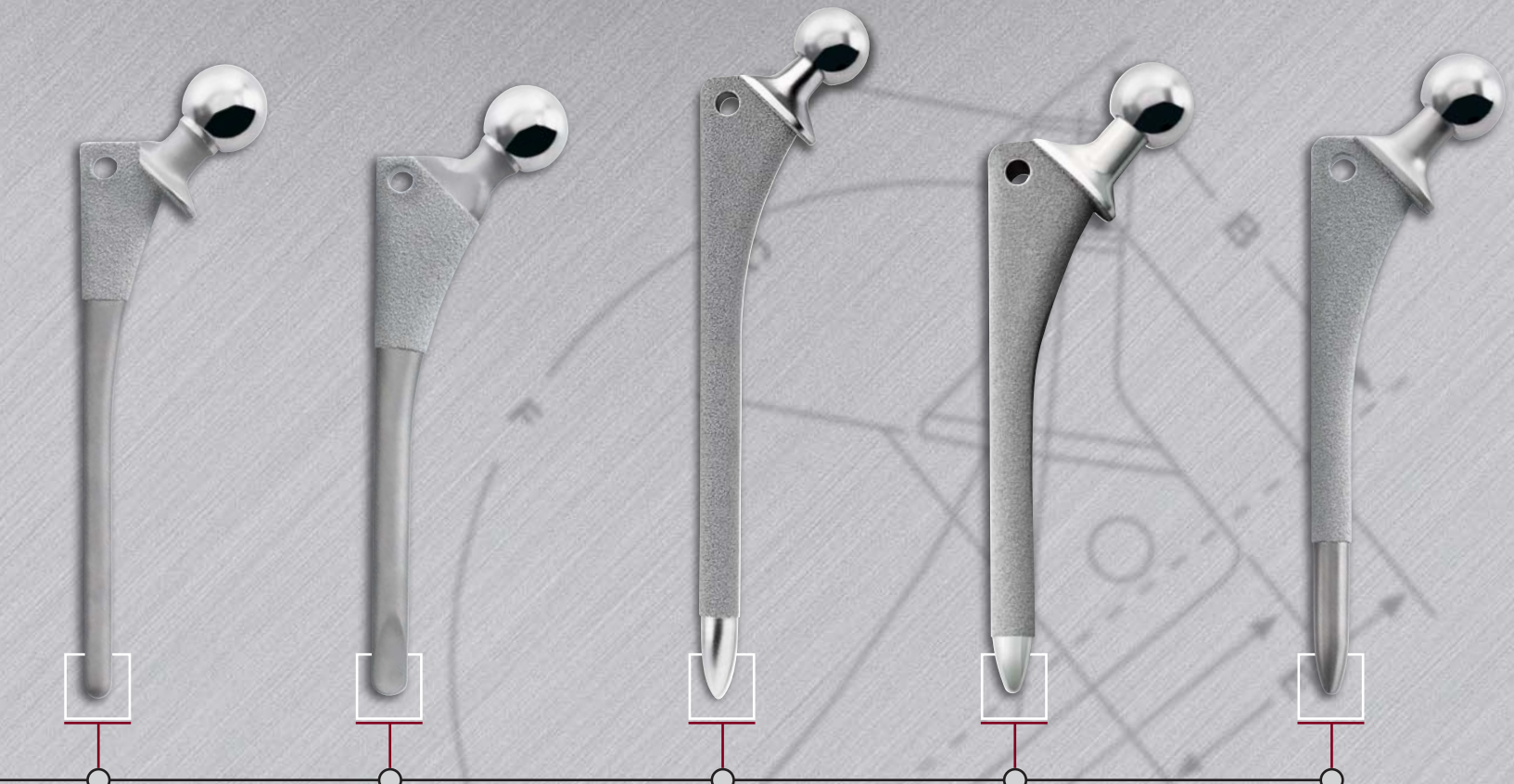
- At a mean follow-up of 4.4 years, statistical analysis showed femoral component survivorship to be 99 percent[4] *CORR 1998*
- At a mean follow-up of 8.2 years, statistical analysis showed femoral component survivorship to be 97.6 percent[5] *JOA 1997*
- At a mean follow-up of 14.2 years, stable biological fixation was achieved in greater than 95 percent of revision cases[6] *JOA* 2002



Evolution

Innovators strive to solve problems and pursue advanced solutions. As the leader in cementless total hip technology, DePuy Orthopaedics has continued to provide innovative solutions to advanced orthopaedic issues. Introduced in 1977 to solve the most pressing orthopaedic issue at the time — aseptic loosening of cemented total hip implants — the AML® was the original cementless total hip.

Since its introduction in 1977, evolutionary enhancements have enabled the AML hip and the philosophy of extensively coated, parallel-sided femoral components to become the standard in cementless total hip arthroplasty. The clinical success of the AML hip has been driven by the combination of Porocoat® Porous Coating and the reproducibility of diaphyseal fixation provided by the extensively coated, parallel-sided implant geometry. The clinical performance of the extensively coated, parallel-sided family of implants has been well documented, worldwide, in numerous peer-reviewed clinical journals.



– 1985 –
Proximally Coated AML stem

– 1986 –
Collarless AML stem

– 1989 –
Solution System® stem

– 1992 –
Fully Coated Prodigy® stem

– 1995 –
12/14 Taper AML stem

Surgeon Consultants

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Douglas Kilgus, MD
James McAuley, MD
John Moreland, MD
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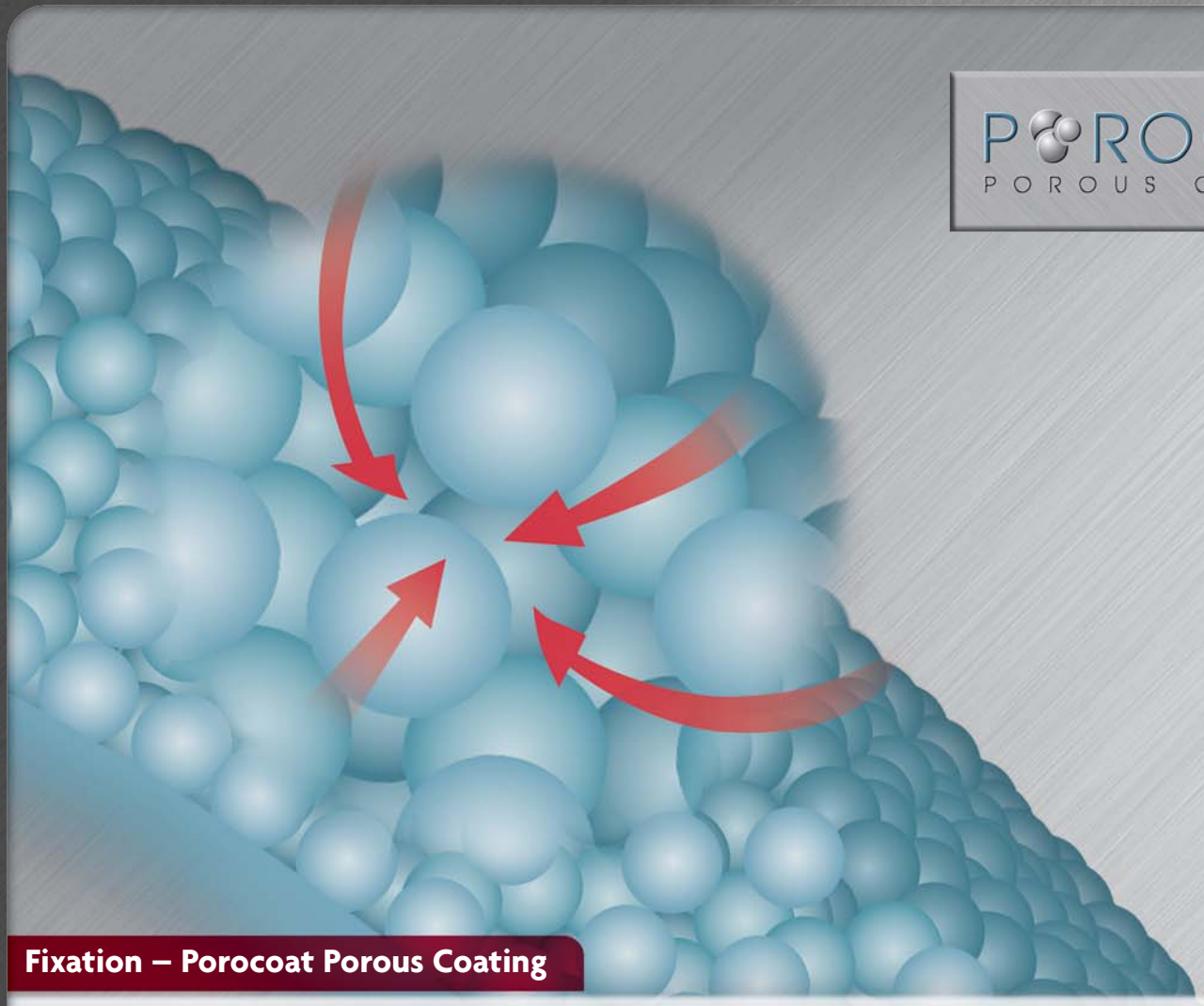
AML High
Offset Stem

Solution System®
8-in. Straight Stem

Solution System
9-in. Calcar Stem

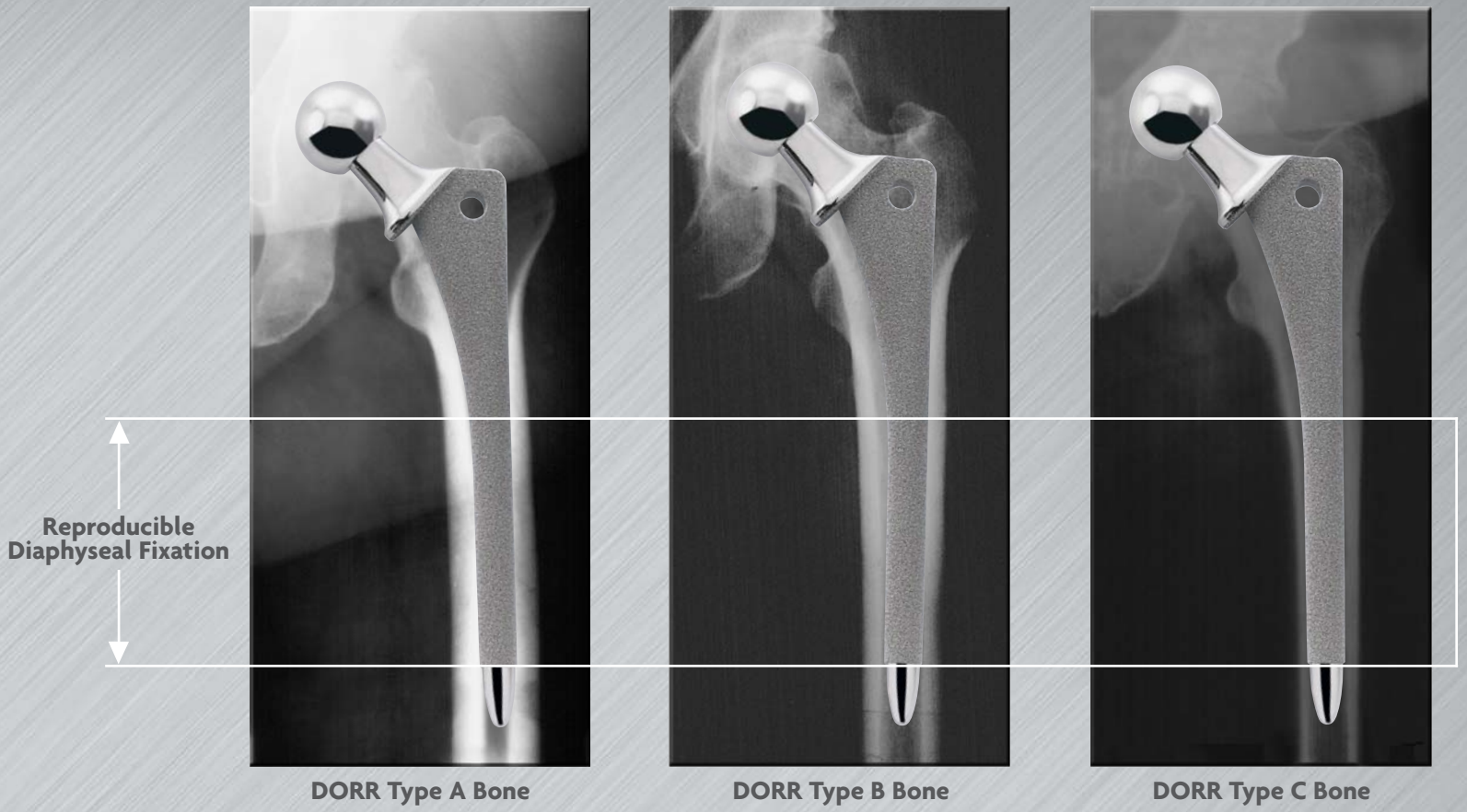
Innovation

- Additional Porocoat Porous Coating increases the potential for diaphyseal fixation
- Advanced offset options for improved biomechanics
- Reduced neck geometry increases range of motion
- Optimized Articul/eze® taper eliminates the “false” skirt
- Anatomic stem lengths and polished bullet tip aid in reducing cortical impingement



Fixation – Porocoat Porous Coating

- The foundation of successful joint reconstruction is built upon fixation. The proven initial and long-term fixation of Porocoat Porous Coating and the simple reproducibility of diaphyseal preparation work in tandem to provide this foundation.
- The clinical performance of Porocoat Porous Coating has been well documented. This performance is based on evidence that Porocoat Porous Coating successfully achieves initial stability and provides extensive long-term biological fixation.[7]
- The extensive, circumferential Porocoat Porous Coating maximizes the surface area available for tissue ingrowth.
- The sintered bead structure of Porocoat Porous Coating has remained unchanged for 25 years. The bead arrangement results in greater porosity at the bone-implant interface and a lower porosity at the implant substrate.
- The Porocoat Porous Coating porosity structure aids in optimizing the volume, density and quality of ingrowth. The pore size has been documented to be the optimum size for the penetration of bone.[8]
- Porocoat Porous Coating provides initial scratch-fit at the host bone implant interface, maximizing implant stability and the opportunity for extensive biological fixation.



DORR Type A Bone

DORR Type B Bone

DORR Type C Bone

Fixation – Reproducibility

- The clinical performance of the extensively coated hip is based on primary initial and long-term fixation in the femoral diaphysis, which has proven to be reproducible in all types and sizes of femora.[9]
- Exact fit of the femoral prosthesis within the femur is more readily achieved in the diaphysis. The easy marriage of the cylindrical, parallel-sided femoral diaphysis with the implant through the use of straight cylindrical reamers ensures excellent canal fill, allowing outstanding initial stability and long-term fixation.
- Extensive mechanical testing of bone ingrowth on autopsy retrievals has shown that the cortical bone of the femoral diaphysis has greater fixation strength than the cancellous bone of the metaphysis.[10]
- Anatomic stem lengths combined with a bullet-shaped stem tip aids in reducing anterior cortical impingement.

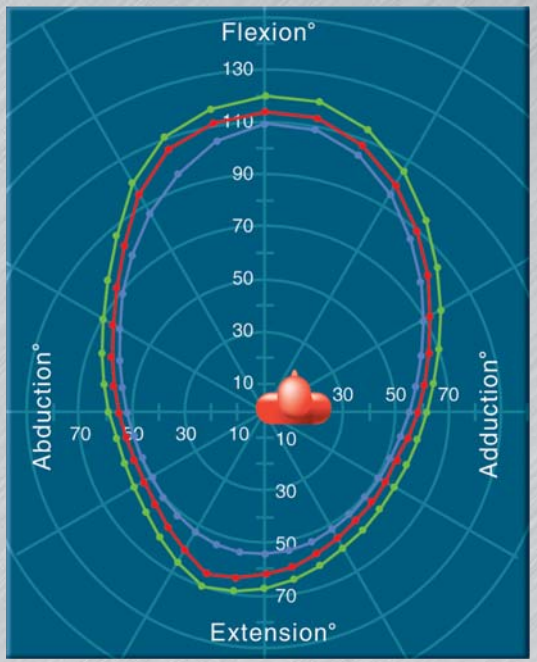
Small Stature
43 mm Offset

Large Stature
45 mm Offset

Large Stature
52 mm Offset

Advanced Biomechanics – Offset

- Optimizing biomechanical function is critical to the satisfactory outcome of hip arthroplasty and increases the longevity of the implant. To accomplish this, the surgeon must manage range of motion, offset and leg length while eliminating the potential for dislocation.
- Through the management of offset and leg length, joint reactive forces are reduced, thereby potentially minimizing loosening, wear debris generation and dislocation.
- To assist in the management of joint biomechanics, the cylindrical parallel-sided, extensively coated prosthesis can be positioned within the prepared femur to affect leg length without altering offset.
- Significantly higher dislocation rates have been found when offset has been decreased postoperatively when compared to preoperative offset. Therefore, it is important to have an offset range that enables the consistent recreation of femoral offset resulting in lower rates of dislocation.
- Biomechanical restoration is accomplished through the progressive offset architecture that provides an offset range from 40 mm to 64 mm. This offset range allows for the tensioning of soft tissue without altering leg length.
- The enhanced biomechanical architecture is based upon the design of the clinically established Prodigy stem, with the exception of anteversion. These biomechanics are based upon a radiographic analysis of over 360 patients.



Clinically established ROM (28 mm)

Reduced neck geometry ROM (28 mm)

Reduced neck geometry ROM (36 mm)

Multiple Head Diameter Options and Reduced Neck Geometry

Advanced Biomechanics – Range of Motion

- The new circulo-trapezoidal neck geometry optimization results in greater composite range of motion. This superior composite range of motion provides the surgeon with greater flexibility in component positioning and reduces the risk of mechanical impingement.
- The reduced neck geometry has been optimized to maintain strength while increasing range of motion. Enhancements include reduced geometry in the anterior-posterior neck and an optimization of the clinically proven Articul/eze taper.
- The combination of neck geometry reduction, optimized Articul/eze taper and increased head diameter options results in increased biomechanical options.
- Multiple head diameter options enable the management of both the head-neck ratio and the cup diameter to head diameter ratio, thus providing greater options for enhancing range of motion and reducing dislocation secondary to impingement.

Efficient Surgical Technique: Reproducible Results

IMPORTANT

This Essential Product Information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS

Total Hip Arthroplasty (THA) is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. **THA is indicated** for a severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis or congenital hip dysplasia; avascular necrosis of the femoral head; acute traumatic fracture of the femoral head or neck; failed previous hip surgery; and certain cases of ankylosis. **Hemi-hip arthroplasty is indicated in these conditions** where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral stem. Hemi-hip arthroplasty is indicated in the following conditions: Acute fracture of the femoral head or neck that cannot be reduced and treated with internal fixation; fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation; avascular necrosis of the femoral head; non-union of femoral neck fractures; certain high subcapital and femoral neck fractures in the elderly; degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement; and pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

CONTRAINDICATIONS

THA and hemi-hip arthroplasty are contraindicated in cases of: active local or systemic infection; loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb, rendering the procedure unjustifiable; poor bone quality; Charcot's or Paget's disease; for hemi-hip arthroplasty – pathological conditions of the acetabulum that preclude the use of the natural acetabulum as an appropriate articular surface. Ceramic heads are contraindicated in revision surgery when the femoral stem is not being replaced or for use with any other than a polyethylene or metal-backed polyethylene cup. In the USA, ceramic heads are not approved for use with metal cups.

WARNINGS AND PRECAUTIONS

Ceramic coated femoral stem prostheses are indicated for uncemented press fit fixation. **CAUTION: DO NOT USE BONE CEMENT FOR FIXATION OF A CERAMIC COATED PROSTHESIS.**

Components labeled for "Cemented Use Only" are to be implanted only with bone cement. The following conditions tend to adversely affect hip replacement implants: excessive patient weight, high levels of patient activity, likelihood of falls, poor bone stock, metabolic disorders, history of infections, severe deformities leading to impaired fixation or improper positioning, tumors of the supporting bone structures, allergic reactions to materials, tissue reactions, and disabilities of other joints.

ADVERSE EVENTS

The following are the most frequent adverse events after hip arthroplasty: change in position of the components, loosening of components, fracture of components, dislocation, infection, peripheral neuropathies, tissue reaction.

– Step 1 –
Canal Definition

– Step 2 –
Diaphyseal Reaming

– Step 3 –
Metaphyseal Broaching

– Step 4 –
Trialing

– Step 5 –
Component Insertion

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