DESIGN RATIONALE

DURALOC® Option

CERAMIC ACETABULAR CUP SYSTEM

COMBINING PROVEN FIXATION WITH EXCELLENT WEAR PERFORMANCE

BENEFITING MORE DEMANDING PATIENTS

DePuy
a Johnson & Johnson company

CERAMIC ACETABULAR CUP SYSTEM

INTRODUCTION

Alumina ceramics have been successfully utilized in orthopaedics since the 1970s, exhibiting excellent biocompatibility, good mechanical performance, and high hardness with significantly lower wear characteristics than conventional metal on polyethylene couples. Alumina ceramics are well suited for total hip arthroplasty (THA).

The foundation for long-term joint reconstruction success is built upon fixation. Incorporating low wear bearing couples, as part of a THA, is meaningless unless both the initial and long-term fixation issues are addressed. With over 25-years of successful clinical performance, DePuy's Porocoat® Porous Coating has been extensively documented and is well established in cementless fixation.

POROCOAT® POROUS COATING

Our DURALOC® Option Ceramic Acetabular System combines the proven fixation of our Porocoat Porous Coating, with contemporary ceramic bearing materials, creating a versatile system to address the unique challenges presented by today's more demanding patients.

DURALOC Option Ceramic Acetabular Cup System provides:

- Excellent Wear Characteristics
- Proven Fixation Technology

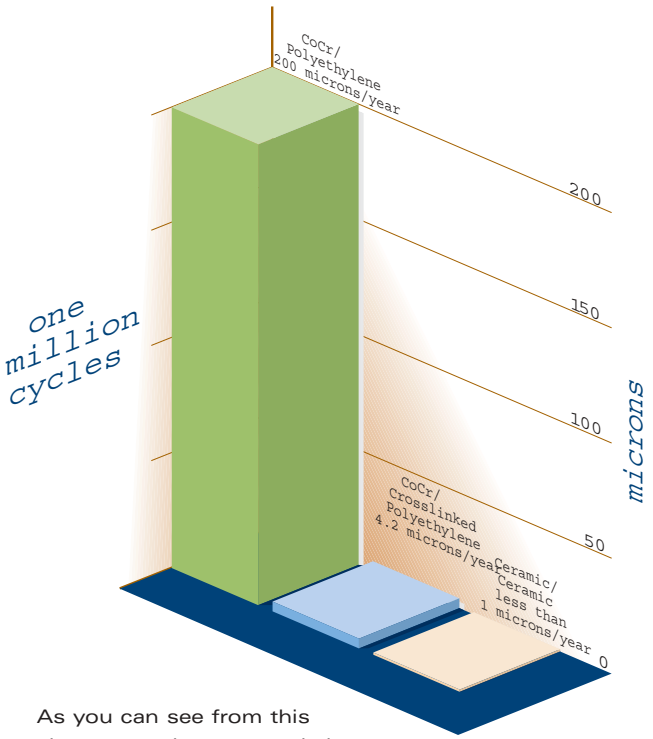
ALUMINA CERAMIC COMPONENTS:

Low Wear Properties for High-Quality Implant Performance

BIOLOX *forte* (Alumina) inserts and femoral heads are comprised of high-purity aluminum oxide ceramic to provide high hardness for extreme wear and scratch resistance. Ceramic on ceramic hip simulator studies have demonstrated wear rates of 0.09 mm^3 per million cycles compared to 40.8 mm^3 per million cycles for metal on standard polyethylene.[1]

LINEAR WEAR RATES

(microns/one million cycles)



As you can see from this chart, ceramic-on-ceramic has dramatically lower wear compared to that of standard polyethylene.

ALUMINA CERAMIC ADVANTAGES

Improved wear resistance

Long-term resistance to wear is a critical component of successful THA. Our DURALOC Option ceramic inserts are designed to minimize the generation of wear debris and have been shown to wear up to 2,000 times less than traditional bearing surfaces.[3]

High hardness

To reduce wear, it is essential to use components with a smooth surface finish. Due to its hardness, Alumina ceramic allows precise polishing to provide exceptionally smooth articulating surfaces for optimum wear resistance.

In addition, the hardness improves surface scratching resistance from third body particulate, which can lower the incidence of wear-related failure.

Biocompatibility

Alumina ceramic components offer excellent biocompatibility which make them well suited for THA.

HIGH COMPONENT RELIABILITY

All Alumina ceramic components are 100% proof tested. The proof test is only part of a comprehensive quality system that performs several specific and ongoing checks throughout the entire manufacturing process. Product characteristics such as chemical composition, microstructure (e.g., grain size or density), surface finish and dimensional compliance are inspected to ensure consistent design specifications. This standard of quality assures high product reliability.

POROCOAT® POROUS COATING:

A Proven Platform for Long-term Fixation

Immediate and long-term fixation of the acetabular shell to the host bone is the foundation for achieving the desired clinical results.

Our Porocoat Porous Coating, a proprietary porous surface comprised of biocompatible, sintered titanium beads, has shown successful clinical performance for more than 25 years. Ongoing studies continue to expand the definitive evidence that Porocoat Porous Coating successfully achieves initial stability and provides extensive long-term biological fixation.[4]

POROCOAT® POROUS COATING

POROCOAT POROUS COATING ADVANTAGES

Optimum Porosity
Pore size of 250 microns is documented in laboratory studies to be the optimum size for penetration of bone tissue. Pores below 50 microns may restrict blood vessel development and hinder uniform maturation of tissue. In larger pores, 400 microns and above, ingrowth may be slow, inconsistent and fibrous.[2]

Excellent Initial Stability
The high coefficient of friction exhibited by the bone contact surface enhances the “scratch-fit” and improves the immediate stability of the acetabular component.

Extensive Clinical Heritage
Available since 1977, the sintered bead structure of Porocoat Porous Coating has remained unchanged and has been used with clinical success on numerous implant designs.

DURALOC Option SECTOR™ ACETABULAR SHELL:

Advanced Design for Advanced Bearings

Our DURALOC Option shell system has been designed to accommodate the largest possible head within the smallest acetabular shell, without compromising strength.

- Ceramic inserts are offered in 28 and 32 mm IDs.
- Shells are offered in sizes 48-66 mm.

DURALOC Option SHELL SYSTEM ADVANTAGES

Sector Series Design
Two or three screw hole positions, depending on size, allow secure screw fixation. The screw hole pattern is positioned to access the ilium and posterior column for safe screw placement.

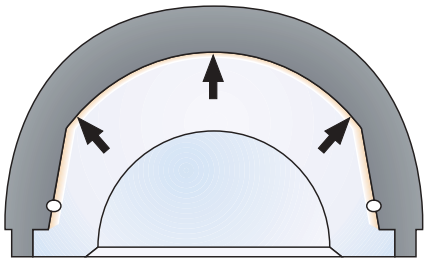
Full-profile Porous Coverage
180 degrees of Porocoat Porous Coating provides maximum contact with host bone.

Self-locating Insertion
The 18-degree taper of the DURALOC Option shell and Alumina ceramic insert provides a secure locking mechanism while providing a self-locating feature to ease insert placement.

Low-profile Rim
Our unique locking taper allows the surface of the ceramic insert to seat flush with the face of the DURALOC Option shell to reduce the risk of impingement and enhance range of motion.

Integral Apical Hole
Confirmation of complete shell seating is enhanced by an integral apical hole. After visual confirmation of proper seating, the hole can be occluded by inserting an apex hole eliminator.

Secure Insert Locking System
Our DURALOC Option shell design accommodates Enduron polyethylene liners and Alumina ceramic inserts. The standard Duraloc dynamic locking ring along with the taper of the inner shell and anti-rotational devices (ARDS) secure the DURALOC Option polyethylene liner in place. Ceramic inserts are securely locked into the shell via an 18-degree taper locking mechanism.

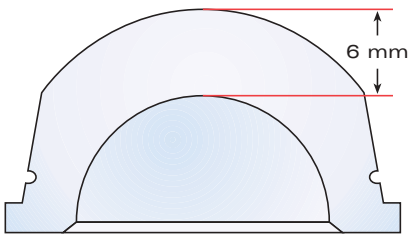


Lipped Liner

Even Polyethylene Loading
In keeping with the loading philosophy of the Duraloc system, DURALOC Option polyethylene liners are loaded against the shell in the dome region. Dome loading transfers stress to the liner evenly across the load-bearing area of the liner/shell interface, avoiding damaging peak stresses and loads at the rim of the shell/polyethylene liner, extending the cup life.

Standard Liner

Extended Durability
6 mm Polyethylene Thickness
Polyethylene liner thickness has been shown to affect the performance of the acetabular cup. Thin liners (below 4 mm) are reported to have contributed to failure and osteolysis.[5, 6, 7, 8, 9] DURALOC Option polyethylene liners have a minimum of 6 mm of polyethylene thickness in the maximum load-bearing regions.



Notes: The DURALOC Option cup allows the surgeon to select an Enduron polyethylene or BIOLOX® *forte* ceramic liner to match individual patient needs. The titanium shell accommodates ceramic inserts or polyethylene liners.

ENHANCED RANGE OF MOTION:

Reducing the Opportunity for Impingement

Subtle design refinements incorporated into the DURALOC Option shells eliminate the need for a protruding metal ring found in some competitive designs, thereby increasing the range of motion prior to mechanical impingement. Ceramic heads are available in several non-skirted neck lengths for maximum range of motion, accommodating individual patient requirements.

12/14 Articul/eze Taper for use with Summit Porocoat Tapered Hip Stem

Femoral Head Neck Length	A/P
28 mm +1.5	134°
28 mm +5	136°
32 mm +1	138°
32 mm +5	141°
32 mm +9	142°

Range of motion is measured with a 12/14 Articul/eze® Taper Summit Stem (size 6).

11/13 S-ROM Taper for use with S-ROM Modular Hip Stem

Femoral Head Neck Length	A/P
32 mm +0	132°
32 mm +6	139°

Range of motion is measured with a 11/13 S-ROM Taper Stem (size 36 STD).

Advanced neck geometry of the Summit stem allows for exceptional range of motion.

Note: The DURALOC Option Ceramic Acetabular System is approved for use with the Summit Porocoat Tapered Hip Stem and the S-ROM Modular Hip Stem.

The S-ROM stem allows for infinite placement of version to maximize range of motion and resulting hip stability.

Ceramic Acetabular Inserts – 28 mm and 32 mm

Shell Size (mm)	Femoral Head Size (mm)
48, 50	28
52	32
54, 56	32
58, 60	32
62, 64, 66	32

Ceramic femoral heads are available in 12/14 taper and 11/13 taper angles and a variety of neck lengths to accommodate individual patient requirements.

Ceramic Femoral Heads – 28 mm and 32 mm

Femoral Head Size (mm)	Taper	Lengths
28	12/14	+1.5, +5
32	12/14	+1, +5, +9
32	11/13	+0, +6

PRECISE INSTRUMENTATION:

Providing Reproducible Results

Simple, intuitive instrumentation is a key factor in the success of the DURALOC Option Acetabular System.

DURALOC Option Shell and Liner Trials

- Easy-to-use alignment guide provides accurate component positioning
- Trial liners securely attach to shell trials for accurate intra-operative evaluation

QUICKSET™ Acetabular Grater System

- Open back provides enhanced visualization
- Helical-cutting tooth pattern for precise acetabular preparation
- Low-profile handle minimizes soft tissue impingement

QUICKSET™ Acetabular Screw Set

- Rigid and flexible drill options provides surgical flexibility
- Multiple driver options accommodate surgeon preferences

ORDERING INFORMATION

DURALOC Option Sector Acetabular Shells

Cat. No.	Shell Size (mm)	Head Size
1599-01-048	48	28
1599-01-050	50	28
1599-01-052	52	32
1599-01-054	54	32
1599-01-056	56	32
1599-01-058	58	32
1599-01-060	60	32
1599-01-062	62	32
1599-01-064	64	32
1599-01-066	66	32

Apex hole eliminator Cat. No. 1246-03-000

BIOLOX *forte* Ceramic Femoral Heads

12/14 ARTICUL/EZE®
May only be used
with the Summit Porocoat Tapered Hip System

Cat. No.	Size (mm)
1365-73-000	28 +1.5
1365-74-000	28 +5
1365-76-000	32 +1
1365-77-000	32 +5
1365-78-000	32 +9

11/13 S-ROM®
May only be used
with the S-ROM Modular Hips System

Cat. No.	Size (mm)
52-8323	32 +0
52-8330	32 +6

DURALOC Option Alumina Ceramic Inserts

Cat. No.	Shell size (mm)	Size (mm)
1599-63-048	48 or 50	28
1599-64-052	52	32
1599-64-054	54 or 56	32
1599-64-058	58 or 60	32
1599-64-062	62, 64, or 66	32

Note: DURALOC Option ceramic inserts may only be used with BIOLOX *forte* ceramic heads.

DURALOC Option Polyethylene Liners

Standard Liners

Cat. No.	Liner Size (mm)	Size (mm)
1599-13-048	48 or 50	28
1599-13-052	52	28
1599-13-054	54 or 56	28
1599-13-058	58 or 60	28
1599-13-062	62, 64, or 66	28

LPW Liners

Cat. No.	Liner Size (mm)	Size (mm)
1599-23-048	48 or 50	28
1599-23-052	52	28
1599-23-054	54 or 56	28
1599-23-058	58 or 60	28
1599-23-062	62, 64, or 66	28

DURALOC Option polyethylene liners are only available in 28 mm IDs.

Duraloc 6.5 mm Cancellous Bone Screws

Cat. No.	Length (mm)
1172-15-000	15
1172-20-000	20
1172-25-000	25
1172-30-000	30
1172-35-000	35
1172-40-000	40

Cat. No.	Length (mm)
1172-45-000	45
1172-50-000	50
1172-55-000	55
1172-60-000	60
1172-65-000	65
1172-70-000	70

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Consult the package insert for complete labeling information.
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For more information about the DePuy products, visit our web site at **www.jnjgateway.com.**

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