Design Rationale

Not intended for use in the US
We would like to thank the following surgeons for their participation as part of the R3° Acetabular System design team:

**Robert Barrack, MD**  
St. Louis, Missouri

**Robert Bourne, MD**  
London Health Sciences Center  
London, Ontario, Canada

**Jonathan Garino, MD**  
University of Pennsylvania School of Medicine  
Philadelphia, Pennsylvania

**Wayne M. Goldstein, MD**  
Clinical Professor of Orthopaedics  
University of Illinois at Chicago  
Illinois Bone and Joint Institute  
Chicago, Illinois

**Richard Kyle, MD**  
Minneapolis, Minnesota

**Stephen J. McMahon MB BS, FRACS(Orth), FA(Orth)A**  
Senior Lecturer Monash University  
Malabar Orthopaedic Clinic  
Melbourne, Australia

**John L. Masonis, MD**  
OrthoCarolina  
Hip & Knee Center  
Charlotte, North Carolina

**Henrik Malchau, MD**  
Associate Professor Harvard Medical School  
Codirector The Harris Orthopaedic Biomechanics and Biomaterials Laboratory  
Massachusetts General Hospital  
Boston, Massachusetts

**Michael Ries, MD**  
University of California  
San Francisco, California

**Cecil Rorabeck, MD**  
Professor of Orthopaedic Surgery  
University of Western Ontario  
London, Ontario, Canada

**Van Paul Stamos, MD**  
Illinois Bone and Joint Institute  
Glenview, Illinois  
Clinical Instructor of Orthopaedic Surgery  
Northwestern University Medical School  
Chicago, Illinois

Not intended for use in the US
Contents

Introduction ............................................. 2
Advanced bearing options
   Ceramic-on-Ceramic .................................... 4
   OXINIUM® alloy on XLPE .............................. 8
Stability
   Larger head sizes ....................................... 10
   Locking mechanism .................................... 12
   STIKTITE® Porous Coating .............................. 14
Instrumentation .......................................... 16

Not intended for use in the US
We provide options. You build solutions.

The R3° Acetabular System combined with the Smith & Nephew portfolio of hip stems provides an advanced hip replacement system with:

- Wide range of advanced bearing options
- Excellent primary stability
- Flexible instrumentation

General features

- NO HOLE & THREE HOLE hemispherical shell offering
- Polished inner surface to minimize backside wear
- STIKTITE® Porous Coating for enhanced scratch-fit feel and enhanced initial fixation

Not intended for use in the US
R3° Liner options

Ceramic-on-Ceramic
offered in BIOLOX® Delta

BIOLOX® Delta liner not available in the US

XLPE
offered in 0 & 20 degree
and in 0 & 20 degree +4mm lateralized options

Not intended for use in the US
R3° Ceramic-on-Ceramic bearing couple

Ceramic-on-Ceramic bearing surfaces have been used worldwide in total hip replacement for more than 30 years. Renewed interest in ceramics as an alternate bearing surface has been driven by the following:

• New technology
• Manufacturing processes and standards
• New designs

This translates into improvements in the following:

• Mechanical and physical properties
• Wear characteristics
• Optimized biocompatibility
• Reliability expected by today’s more active patients

Due to the reduced grain size, ceramic components are harder than before. That has led to wear rates as low as 0.001mm/year.5,6

Impingement in ceramic bearing systems increases wear and decreases implant longevity. The improved design of R3 ceramic acetabular components:

• Reduces the effects of impingement
• Enhances wear and durability by utilizing liners that sit flush with the shell face

Advanced bearing surfaces: Ceramic-on-Ceramic

BIOLOX® Delta liner not available in the US

Not intended for use in the US
The R3™ system’s ceramic design is an assembled combination of:

- A ceramic component made from orthopaedic industry standard material.
  
  **BIOLOX® Delta**
  Not available in the US

- A precision-machined support ring made of a Titanium alloy (Ti-6Al-4V) that is commonly used in orthopaedic implants.

**BIOLOX® Delta**

Is composed of approximately 75% aluminum oxide, which provides the basic hardness and wear resistance, and approximately 25% zirconia, which together with other additives (mixed oxide platelets like chromium oxide) provide the improved mechanical properties. Compared with pure aluminum oxide, ceramic **BIOLOX® Delta** offers higher mechanical properties including higher fracture toughness.6
Titanium support ring for added strength

The unique feature about R3 ceramic liners is that they come with a titanium support ring around the periphery of the liner. The support ring and ceramic liner are precisely assembled utilizing a cold pressing process, which assures that the material properties of the ceramic and titanium are not altered.

The support ring offers greater protection against chipped edges and tensile forces for the ceramic insert that result in high fatigue and burst performance for insert assembly. Lab tests have shown that the burst strength of these liners is significantly higher than that of traditional ceramic liners with no band. Based on these test results, it can be hypothesized that these liners with titanium band would reduce the incidence of fracture of the ceramic liners.

**Note** BIOLOX® delta additionally exhibits extremely high fracture toughness. It has a higher capacity than BIOLOX forte ceramic to resist the onset of cracking and to arrest the propagation of cracks leading to a reduced risk of intra-operative and postoperative fractures and chipping.
BIOLOX® Delta liner not available in the US

Not intended for use in the US
Advanced bearing surfaces: OXINIUM° alloy on XLPE

R3° system with OXINIUM alloy is an advanced bearing option

OXINIUM is an Oxidized Zirconium alloy (97.5% Zirconium and 2.5% Niobium) with a transformed ceramic surface providing the wear performance of ceramics and the strength of metals. This provides all of the benefits of ceramic and metal bearing technology without some of the potential risks. OXINIUM material is especially useful for nickel-sensitive patients. OXINIUM material is an award winning, advanced bearing material that is designed for active patients.

OXINIUM alloy with 10 Mrad XLPE shows superior wear characteristics for bearing couples with polyethylene.8,10

OXINIUM material along with 10 Mrad XLPE provides the wear performance of hard bearings along with the intraoperative options of hard-on-soft bearing.

OXINIUM material has a clinical history of more than 10 years. Over 190,000 components have been implanted successfully to date. Impressive clinical wear performance of OXINIUM heads was supported by an RSA clinical study from Dr. Bo Nivbrant.8

Wear reduction of standard bearing vs. advanced bearings

Not intended for use in the US
Advanced bearing surfaces: OXINIUM™ alloy on XLPE

R3° system with OXINIUM alloy on XLPE

The Smith & Nephew 10 Mrad, fully annealed XLPE is the only crosslinked polyethylene proven to produce less volume of wear debris particles in all size ranges.\textsuperscript{11,12} Less wear debris provides a reduced chance for osteolysis.

All currently marketed crosslinked poly indicates a significant improvement in the volume of wear debris, which would lead one to assume all crosslinked poly is the same. However, Smith & Nephew investigated more closely and found that not all crosslinked poly minimizes the amount of particles generated. Because the wear particles of crosslinked poly can be smaller in size than with UHMWPE, it is possible to reduce the volume but actually increase the number of particles.\textsuperscript{11,12} Even though there are questions about some crosslinked poly increasing the number of particles, many surgeons are adopting the use of these materials in most of their more active patients.

The Smith & Nephew crosslinked polyethylene significantly reduces the number of particles generated. The gravimetric wear rate of R3 XLPE is not measurable in a hip simulator, but the number of particles generated is reduced by 80% compared to traditional CoCr on conventional poly bearing.\textsuperscript{13}
Stability: head/shell ratios

Optimized head/shell ratios

Use of larger diameter femoral heads has been clinically reported to decrease the probability of dislocation in patients.\(^{14,15,16,17}\)

- Large heads increase the ROM of the joint
- Large heads reduce the incidence of neck impingement with soft tissue or the edge of the shell
With the R3™ Acetabular System, surgeons have the option of using larger head sizes in smaller acetabular shells:

- R3 Ceramic-on-Ceramic acetabular system: 36mm ceramic head with a 52mm cup size
- R3 OXINIUM™ alloy on XLPE acetabular system: 36mm head in a 52mm cup size

R3 liner offering chart

<table>
<thead>
<tr>
<th>Cups</th>
<th>XLPE</th>
<th>Ceramic</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>28</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>32</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>36</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>40</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>42</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>44</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>46</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>48</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>50</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>52</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>54</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>56</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>58</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>60</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>62</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>64</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>66</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>68</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>70</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>72</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>74</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>76</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>78</td>
<td>🟩</td>
<td>🟩</td>
</tr>
<tr>
<td>80</td>
<td>🟩</td>
<td>🟩</td>
</tr>
</tbody>
</table>

Greater jump distance equals greater stability

Larger diameter heads increase the jump distance and reduce the dislocation risk.

Not intended for use in the US
R3° locking mechanism for secure liner stability

**R3 locking mechanism design features:**

- 12 large anti-rotational tabs on the poly liner that provide rotational stability
- Locking taper that supports metal and ceramic liners
- Double-channel lock design that provides axial stability for poly liners

Intraoperative adjustments to the liner position may be performed with true confidence. Independent researchers confirm that in some competitive locking designs, the liner can be significantly damaged by extraction, which prohibits liner repositioning. Laboratory tests of the R3 lock have shown it withstands consecutive insertions of the same liner without damaging its locking integrity.
Push-out and torque-to-failure tests of the R3™ locking mechanism demonstrate that it offers the benefit of a secure and stable liner. The R3 lock can withstand over 1112 N of push-out force in any of its liner options and over 40 N-m of torque.

Not intended for use in the US
Enhanced stability and fixation with STIKTITE Porous Coating

Utilizing STIKTITE coating on the R3° Acetabular Shells allows for a true scratch-fit feel during the shell seating and a clinically proven ingrowth surface for long-term implant success.20
STIKTITE Porous Coating demonstrated a higher coefficient of friction compared to porous tantalum when tested by the same method. The mean coefficient of friction for STIKTITE coating was higher than that of porous tantalum against both cancellous and cortical bone. These results indicate that STIKTITE coating should have superior friction, scratch-fit feel and initial fixation stability as compared to porous tantalum.

Frictional coefficients of bone ingrowth structures against cancellous and cortical bone (n=96 to 100)

STIKTITE coating is a sintered three-dimensional asymmetric titanium powder that has a porosity of about 60%. Increased porosity allows for potentially greater bone ingrowth, which can enhance long-term fixation and implant stability. STIKTITE coating provides enhanced initial mechanical stability, which is particularly important in damaged or less biologically active bone. The average pore size of STIKTITE coating (200 µm) is within the 100– to 500–µm range for optimal bone ingrowth.
Instrumentation

Streamlined instrumentation improves surgical efficiency

This seemingly simple technique is a very effective way of precisely placing the hard bearing liners inside the shell without the issue of improper seating due to misalignment as seen in other competitive systems.\textsuperscript{22,23} Cocking of a ceramic liner, in particular, during impaction can lead to a fracture of the liner.

Not intended for use in the US
References


Not intended for use in the US