Design Rationale

smith&nephew

R3◇

Acetabular System

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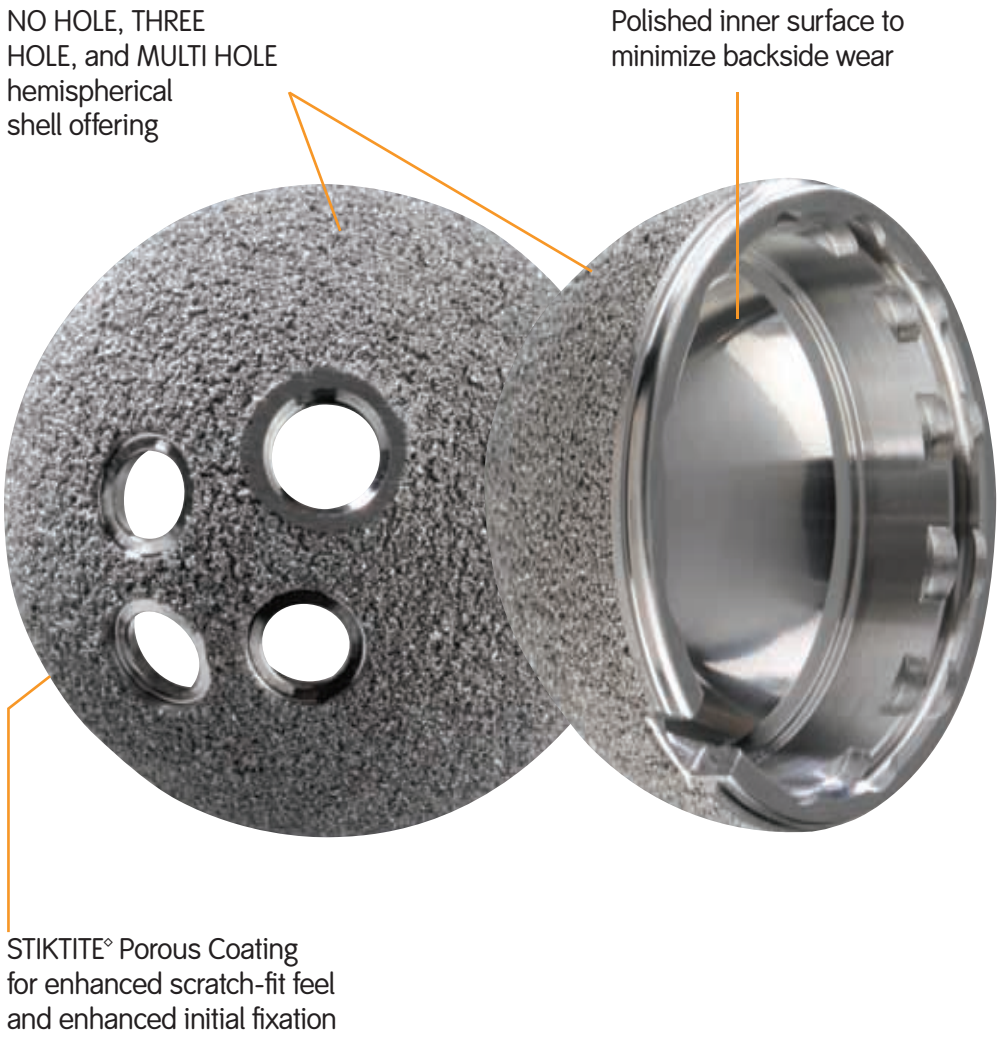
Contents

R3volution in motion

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



R3◇ Liner options

XLPE
Offered in 0 and 20 degree, 0 and 20 degree +4mm lateralized, and constrained options

Ceramic-on-ceramic
offered in BIOLOX® Forte

Advanced bearing surfaces: VERILAST◇ Technology Oxidized Zirconium with XLPE

R3◇ system with VERILAST Technology is an advanced bearing option

VERILAST◇ Technology for hips from Smith & Nephew uses the exclusive bearing combination of proprietary OXINIUM◇ and highly cross-linked polyethylene, which provides superior clinical survivorship and biocompatibility without sacrificing versatility or introducing the risk of ceramic-like fracture.[1]

Most importantly, VERILAST Technology provides low wear, corrosion avoidance and real-life results.OXINIUM material along with 10 Mrad XLPE provides the wear performance of hard bearings along with the intraoperative options of hard-on-soft bearings.

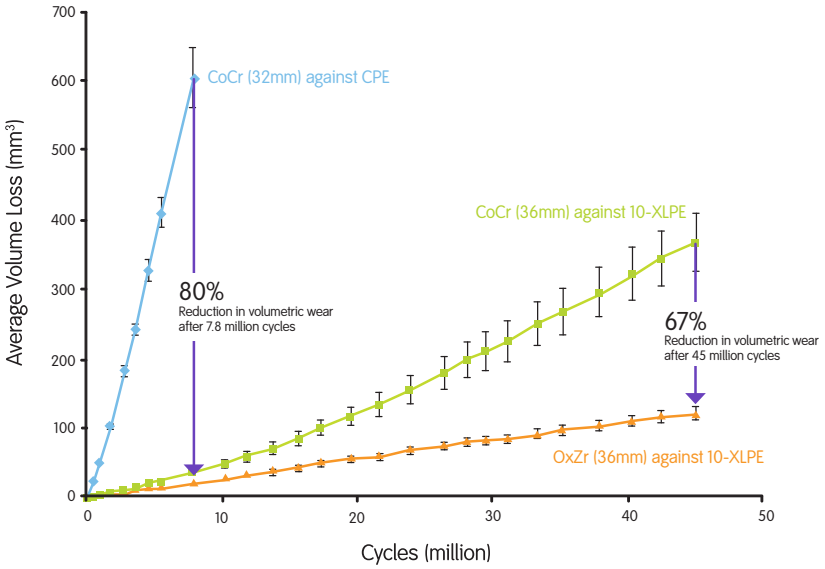
Real life results

Oxidized Zirconium 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 has been reported in global registry data. In the 2013 Australian Registry, the ceramicized metal/cross-linked polyethylene category, which includes the exclusive OXINIUM alloy from Smith & Nephew, had the highest survivorship of all bearing categories at five years: 98.0%.[1]

Wear performance

VERILAST Technology for total hip arthroplasty has been tested and shown to provide superior wear performance compared to CoCr on highly crosslinked polyethelene, for up to 45 million cycles.[2] With advanced materials designed to last, VERILAST Technology helps restore patients to their active lifestyles, allowing joint pain to be addressed earlier.

Cumulative volumetric wear comparison[2]



Biocompatibility
Protect against taper corrosion

There is a growing concern in the orthopaedic community about fretting and corrosion at the head neck taper junction.With its biocompatible properties, due to its use of Oxidized Zirconium, VERILAST Technology has shown to reduce taper corrosion in total hip arthroplasty, minimizing the concern of trunnionosis.

A study by Pawar et al. used an acidic fretting test to compare the potential corrosive and fretting responses of OXINIUM® (OxZr), cobalt chrome (CoCr) and stainless steel (StSt) femoral heads. As the study states, "The OxZr heads coupled with Ti-6Al-4V and SS trunnions showed the least chemical attack on either the head or the trunnion."[3]

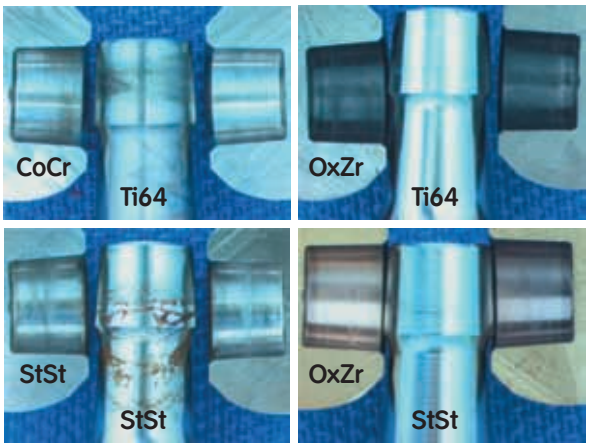


Image from Pawar et al., ASMI 2004.

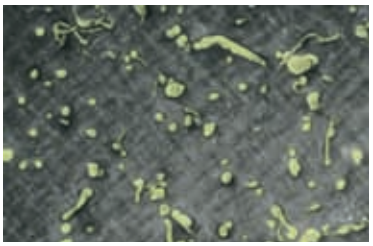
Not your average cross-linked poly

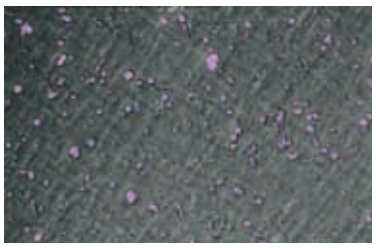
The Smith & Nephew 10 Mrad, fully annealed XLPE is the only crosslinked polyethylene proven to produce less volume of wear debris particles in all size ranges.[4,5] Less wear debris provides a reduced chance for osteolysis.

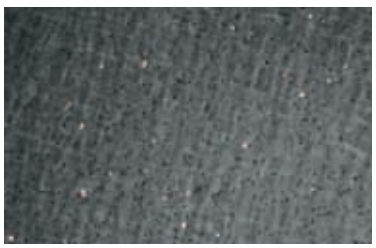
All currently marketed crosslinked poly indicates a significant improvement in the volume of wear debris, which would lead one to assume all crosslinked poly is the same. However, Smith & Nephew investigated more closely and found that not all crosslinked poly minimizes the amount of particles generated. 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.[4,5]

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.[6]

High magnification images of captured particles


Standard unirradiated polyethylene


5 Mrad irradiated crosslinked poly, showing an increase in the number of particles in conjunction with a decrease in average size


10 Mrad irradiated R3® XLPE showing a reduction in total number of particles

Advanced bearing surfaces: ceramic-on-ceramic

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
- Improved 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.[7,8]

Neck impingement
In ceramic bearing systems, increases wear and decreases implant longevity.[9]
The flush-seating liners of the R3 ceramic acetabular system in combination with Smith and Nephew femoral stem neck geometry:

- Increases the range of motion and consequently, may reduce the likelihood of impingement.[9]
- Mitigates the risks of metal transfer and increased friction imposed by designs with a raised rim.[10]

The R3 system's ceramic design is an assembled combination of:

- A ceramic component made from orthopaedic industry standard material, BIOLOX® Forte
- A precision-machined support ring made of a Titanium alloy (Ti-6Al-4V) that is commonly used in orthopaedic implants.

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.

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.[11-14]

- Large heads increase the ROM of the joint[11-13]
- Large heads reduce the incidence of neck impingement with soft tissue or the edge of the shell[14]

Stability: head/shell ratios *continued*

With the R3° Acetabular System, surgeons have the option of using larger head sizes in smaller acetabular shells:

R3 OXINIUM° alloy on XLPE acetabular system:
36mm head in a 52mm cup size

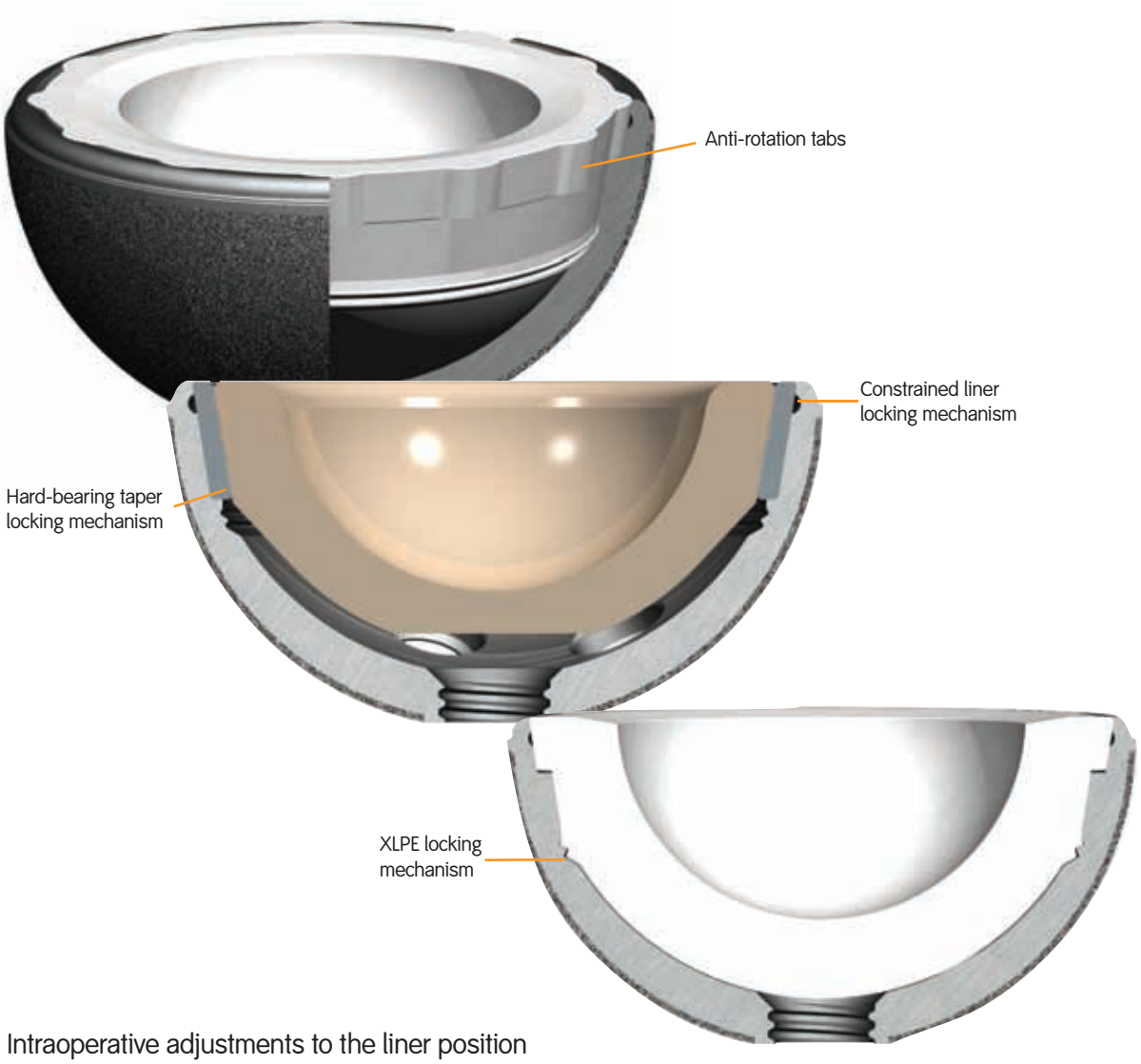
	XLPE						Ceramic		
Cups	22	28	32	36	40	44	28	32	36
40	●								
42	●								
44	●								
46		●							
48		●	●				●		
50		●	●				●		
52		●	●	●				●	
54		●	●	●				●	
56		●	●	●	●			●	
58		●	●	●	●				●
60		●	●	●	●	●			●
62			●	●	●	●			●
64				●	●	●			●
66				●	●	●			●
68				●	●	●			●
70				●	●	●			
72				●	●	●			
74				●	●	●			
76				●	●	●			
78				●	●	●			
80				●	●	●			

Stability: locking mechanism

R3◇ locking mechanism for secure liner stability

R3 locking mechanism design features:

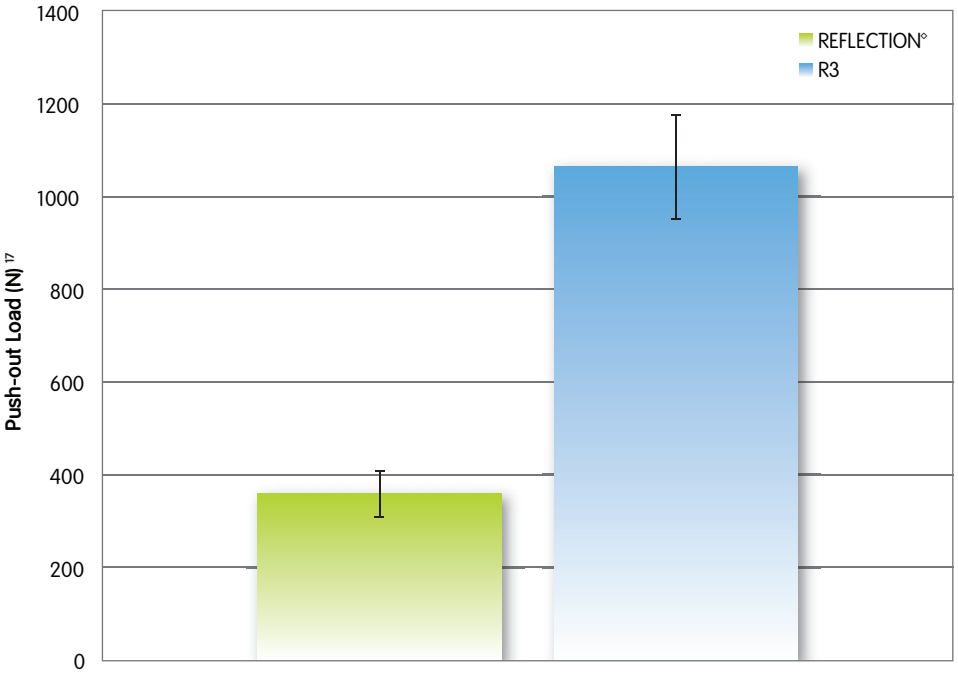
- Locking taper that supports ceramic liners
- Double-channel lock design that provides axial stability for poly liners
- 12 large anti-rotational tabs on the poly liner that provide rotational stability

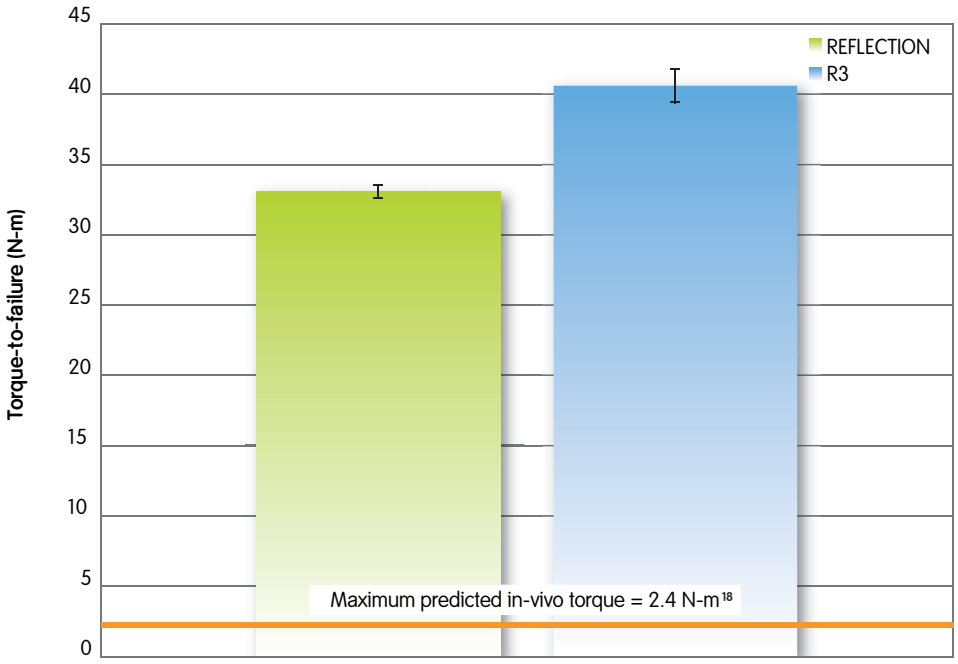


Intraoperative adjustments to the liner position may be performed with true confidence. Independent researchers confirm that in some competitive locking designs, the liner can be significantly damaged by extraction, which prohibits liner repositioning.[15] Laboratory tests of the R3 locking mechanism have shown it withstands consecutive insertions of the same liner without damaging its locking integrity.[16]

Stability: locking mechanism *continued*

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 1112N of push-out force in any of its liner options and over 40 N-m of torque.





Stability: STIKTITE◇ Porous Coating

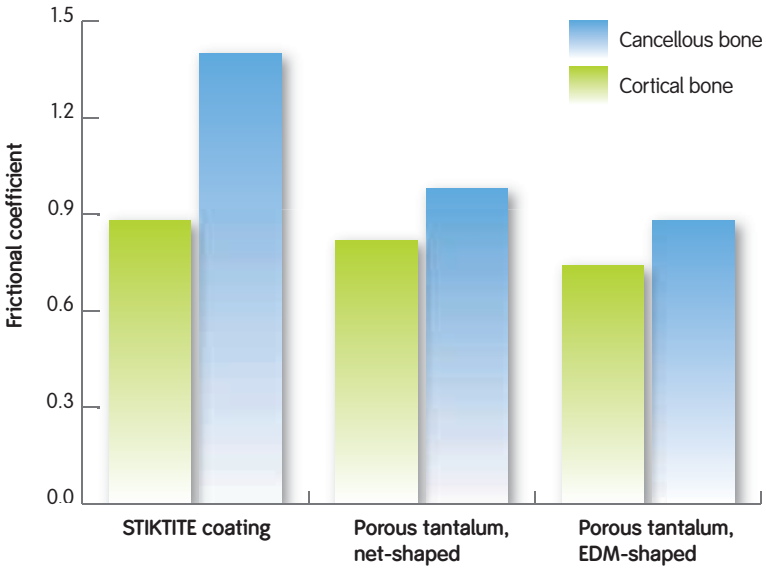
Enhanced stability and fixation with STIKTITE Porous Coating

Utilizing STIKTITE coating on the R3◇ Acetabular Shells allows for a true scratch-fit feel during the shell seating and a clinically proven in-growth surface for long-term implant success.[19]

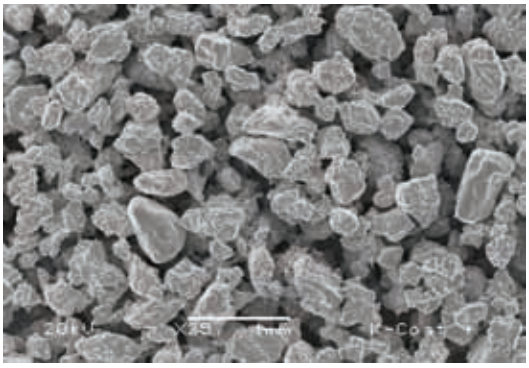
Stability: STIKTITE◇ Porous Coating *continued*

STIKTITE Porous Coating demonstrated a higher coefficient of friction compared to porous tantalum when tested by the same method.[20] 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)[20]



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.



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.[21-22] Cocking of a ceramic liner, in particular, during impaction can lead to a fracture of the liner.

Preassembled alignment ring on all hard bearing liners.

Alignment ring allows for easy placement of the hard bearing liner in the shell. The liner impactor can then be inserted through an opening in the alignment ring and the liner can be seated with an impaction force.

Upon impaction the ring will disengage and remain on the liner impactor for later disposal.

The hard bearing liner is now perfectly seated in the shell.

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