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stryker®

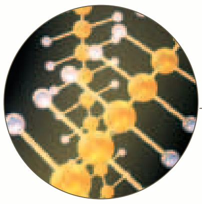
Orthopaedics

Trident®

Poly Acetabular System

Trident® PSL® HA Acetabular Shell with X3 Poly insert

Trident® Hemispherical Acetabular Shell



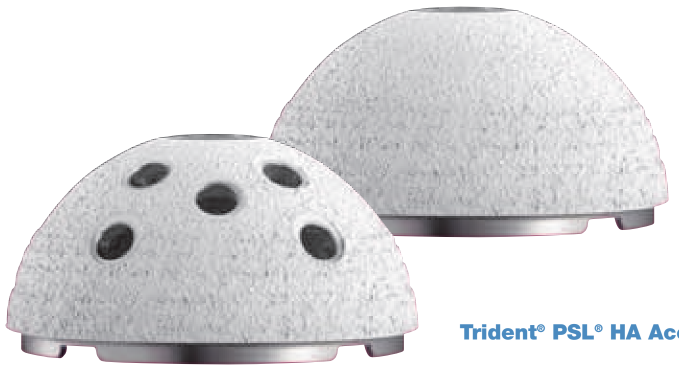
With New X3™ Polyethylene

Trident®
Poly Acetabular System

The Trident® Acetabular System has been implanted throughout the world since 1999 and, while commercially available, has also been included in a clinical evaluation through an IDE study in the United States. All Trident® Acetabular Shells feature the Innerchange™ Locking Mechanism, which provides independent locking of polyethylene or ceramic inserts into the shell.

The Trident® Acetabular System offers:

- Superior locking mechanisms for both polyethylene and ceramic inserts[(1)]
- X3™ polyethylene for improved wear performance[(A)]
- Choice of shell geometries
- Arc-deposited roughened surface to help achieve immediate stability
- Purefix™ HA
- Eccentric and Constrained Inserts for revision options



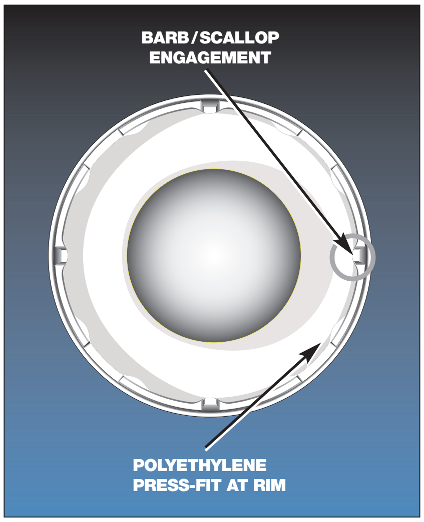
Trident® PSL® HA Acetabular Shell

The Trident® PSL® Acetabular Shells are designed to maximize fixation in the peripheral lunate region of the acetabulum. Purefix™ HA coating is featured on all Trident® PSL® shells.

Trident® Hemispherical Acetabular Shell

Trident® Hemispherical Acetabular Shells are a true hemispherical shape designed to achieve press-fit fixation by under-reaming the acetabulum.

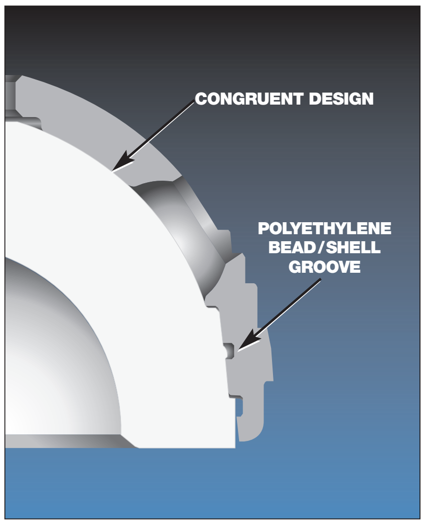
Innerchange™ Locking Mechanism



The Patented Innerchange™ Locking Mechanism allows for independent locking of polyethylene and ceramic inserts into the shell. This provides radial and tilting micromotion resistance.[(1)]

The Trident® polyethylene insert allows for proper rotational alignment using 12 indexable scallops. Polyethylene inserts lock into the shell in three ways:

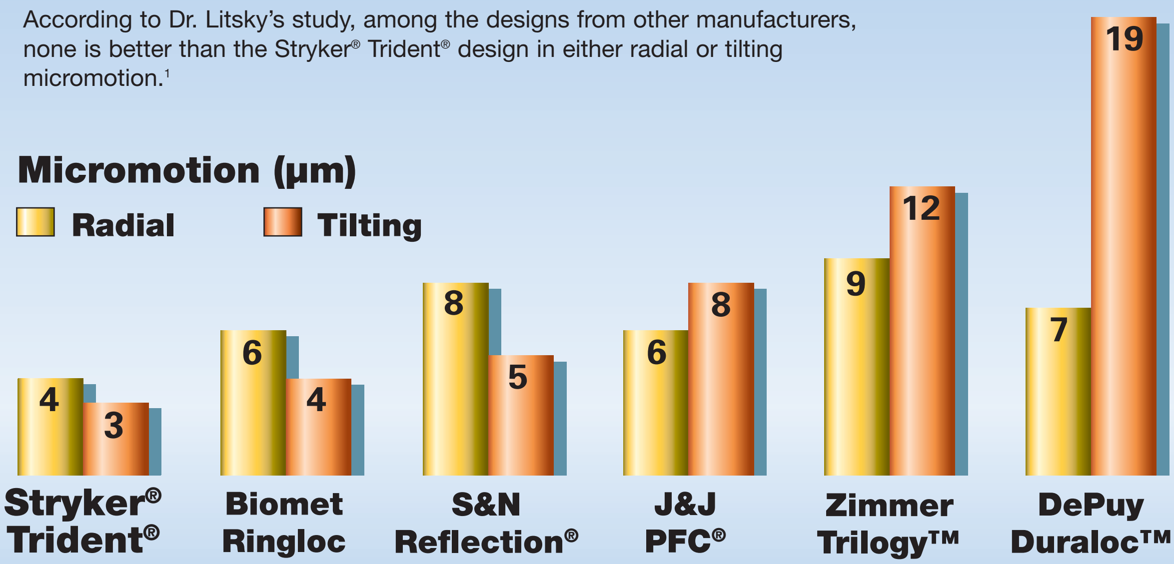
- Four alignment studs on the shell provide proper rotational and axial alignment
- Unique bead and groove mechanism
- Additional rim locking provides for exceptional insert stability



Extensively Tested Locking Mechanism

- Fully congruent design
- Independent testing by Alan Litsky, MD, PhD at Ohio State University[1]
- Robust push-out and lever-out resistance[2]
- Hip simulation testing with X3™ polyethylene has demonstrated improved wear performance[3, (A)]

According to Dr. Litsky's study, among the designs from other manufacturers, none is better than the Stryker® Trident® design in either radial or tilting micromotion.[1]



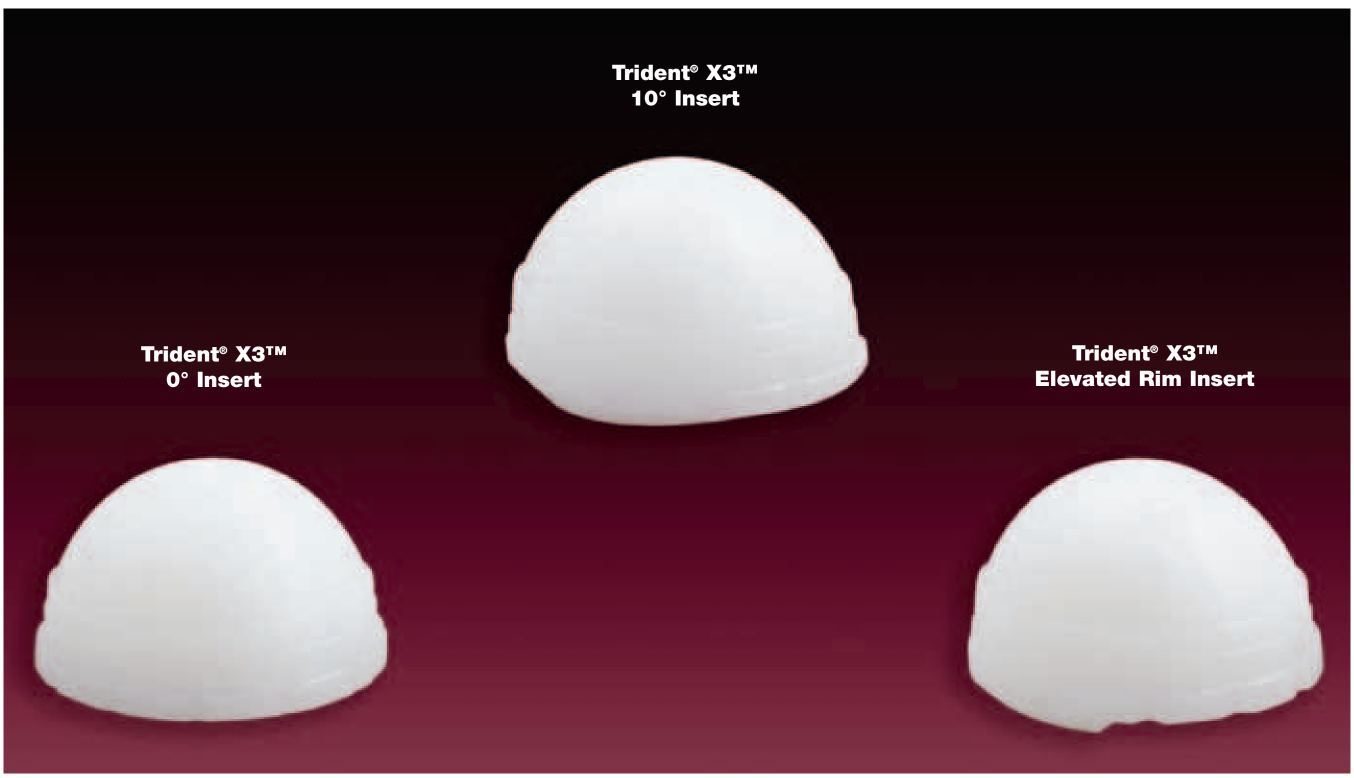
Polyethylene

Trident® polyethylene inserts are:

- Fully congruent to the shell
- Supported by extensive research on range of motion and head stability[8]
- Available in neutral, 10°, elevated rim, eccentric and constrained designs

Shell fully supports the Trident® insert

Neutral, 10° and Elevated Rim polyethylene options



X3™ Highly Crosslinked Polyethylene

X3™ Highly Crosslinked polyethylene has demonstrated significant wear reduction compared to standard polyethylene.[A] Stryker's technology and conservative process have allowed increased crosslinking while maintaining the material properties of the polyethylene.[B]

- **97% reduction in wear[3]**
  X3™ polyethylene demonstrates 97% reduction in wear over nitrogen sterilized polyethylene in joint simulation testing, thereby reducing the potential for osteolysis.[A]
- **Material properties are retained**
  The material properties of X3™ polyethylene are similar to those of standard polyethylene, as shown in ***Figure 1***.[B]
- **Preserves the polymer structure of UHMWPE**
  The crystalline and amorphous regions of X3™ are similar to standard polyethylene[C] (**Figure 2**).

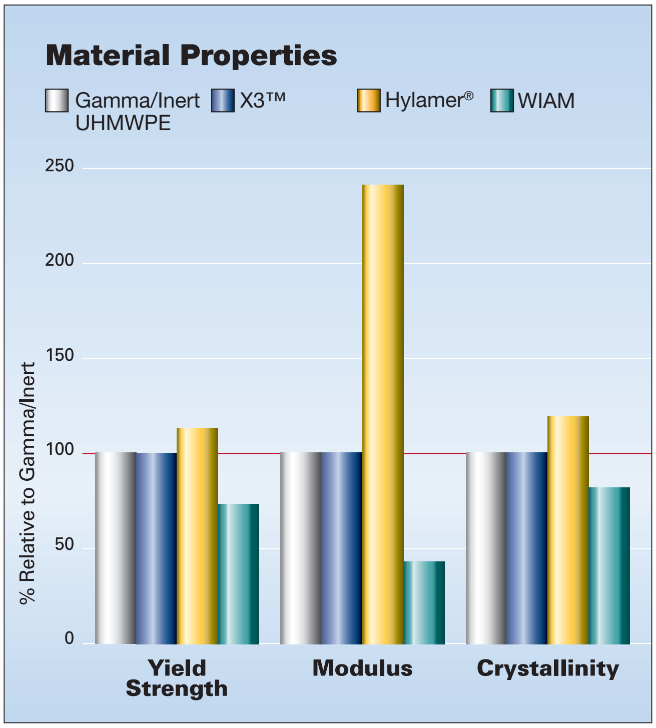


Figure 1 X3™ polyethylene maintains similar yield strength, modulus and crystallinity as standard polyethylene. When these properties change significantly, the clinical wear performance cannot be predicted.

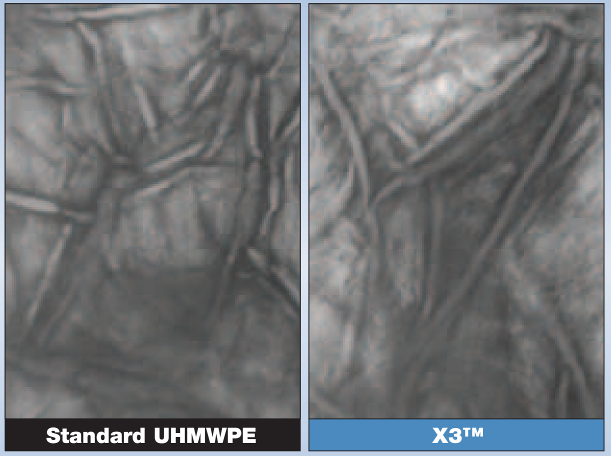


Figure 2 X3™ exhibits a morphology that is very similar to that of standard UHMWPE

LFIT™ Technology

Improved Wear Performance with LFIT™ Femoral Head Technology

Low Friction Ion Treatment (LFIT™) is a bombardment of nitrogen ions onto a CoCr surface, which enhances material properties of the metal, in turn reducing frictional forces against UHMWPE surfaces.

LFIT™:

- Improves wettability
- Reduces coefficient of friction[7]

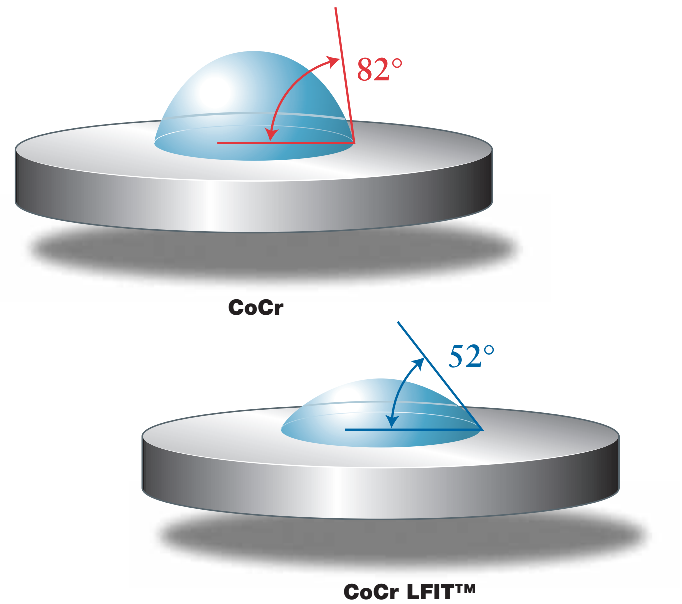
Wettable materials are important in total hip arthroplasty

In an anatomic hip joint, the femoral head is cushioned by cartilage, which seeps lubrication into the joint. When the joint is diseased or removed, the natural lubrication surface is also removed, and the femoral head and acetabular insert contact each other. LFIT™ femoral heads are designed to increase lubrication.

Clinical Experience with LFIT™

The LFIT™ heads demonstrated a 28% reduction in linear wear over CoCr heads in 110 patients at minimum 3-year follow up[9] (**Figure 3**). This data coincides with hip simulation testing.[6]

"These results are encouraging…Nitrogen ion implanted femoral heads may be an effective way to decrease UHMWPE wear and increase implant longevity in THA."[7]



Wettable materials have a lower boundary angle between a liquid and a solid.

UHMWPE Linear Wear

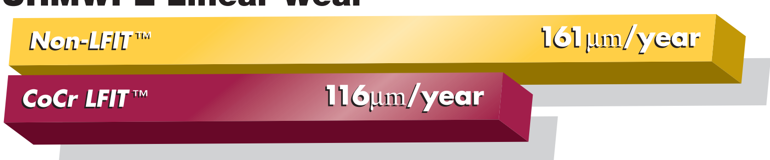


Figure 3 LFIT™ heads demonstrated a 28% reduction in linear wear over CoCr heads

Revision Options

- A Trident® Hemispherical Multi-Hole Acetabular Shell with Purefix™ HA is available providing increased screw hole options (**Figure 4**).
- Eccentric and Constrained Inserts augment the Trident® System with revision options to increase surgeon flexibility in complex primary or revision surgery.
- The Trident® Eccentric Inserts feature X3™ Highly Crosslinked Polyethylene for improved wear performance.[3, (A)] The head center is lateralized 6mm from the center of the acetabular shell allowing increased polyethylene thickness and joint stability (**Figure 5**).
- Trident® Constrained Inserts are available for total hip patients who exhibit a risk of hip dislocation. Constrained Inserts feature pre-assembled inserts with the unique Stryker® design UHR® bipolar (**Figure 6**).

Figure 4 Trident® Hemispherical Multi-Hole Acetabular Shell

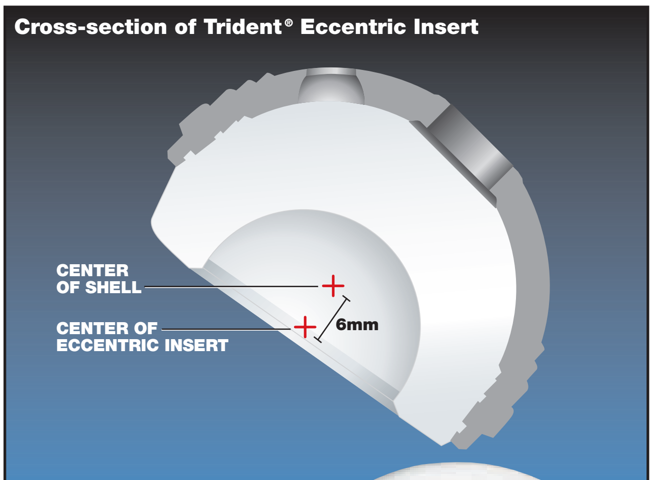


Figure 5

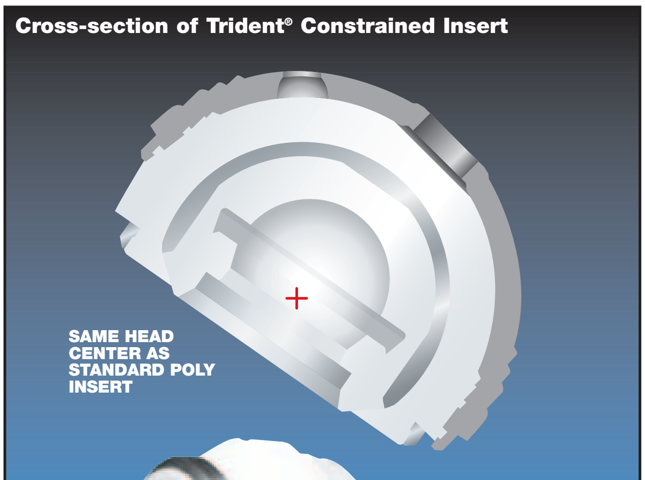


Figure 6

0° Eccentric Insert

10° Hooded Eccentric Insert

Constrained Insert

Trident®

Poly Acetabular System

Compatibility

Trident® polyethylene inserts may be used with V40™ or C-taper femoral heads.

The alphabetical letter at the end of all Trident® catalog numbers identifies compatibility among all Trident® acetabular components. Matching the shell and insert Alpha Codes will ensure proper compatibility.

Trident® Compatibility Chart

Alpha Code	Trident® PSL® HA Shell Size (mm)	Trident® Hemispherical Shell Size (mm)	X3™ 0° and 10° Inserts (mm)	N_2/Vac™ 0° and 10° Inserts (mm)
A	40	42	22	N/A
B	42	44	22	N/A
C	44	46	22, 26, 28	N/A
D	46, 48	48, 50	22, 26, 28, 32	28
E	50, 52	52, 54	22, 26, 28, 32, 36	28
F	54, 56	56, 58	22, 26, 28, 32, 36	28
G	58, 60	60, 62	22, 26, 28, 32, 36	28
H	62, 64	64, 66	22, 26, 28, 32, 36	28
I	66, 68	68, 70	22, 26, 28, 32, 36	28
J	70, 72	72, 74	22, 26, 28, 32, 36	28

N/A=not available

(A) Stryker Orthopaedics Trident Acetabular Inserts made of X3 UHMWPE, 721-00-32E, show a 97% reduction in volumetric wear rate versus the same insert fabricated from N2Vac gamma sterilized UHMWPE, 620-00-32E. The insert tested was 7.5 mm thick with an inner diameter of 32 mm. Testing was conducted under multi-axial hip joint simulation for 5 million cycles using a 32mm CoCr articulating counterface and calf serum lubricant. X3 UHMWPE Trident acetabular inserts showed a net weight gain due to fluid absorption phenomena but yielded a positive slope and wear rate in linear regression analysis. Volumetric wear rates were 46.39 ± 11.42 mm3/106 cycles for standard polyethylene inserts and 1.35 ± 0.68 mm3/106 cycles for test samples. Testing was performed on un-sterilized X3 UHMWPE Trident acetabular inserts. Although in-vitro hip wear simulation methods have not been shown to quantitatively predict clinical wear performance, the current model has been able to reproduce correct wear resistance rankings for some materials with documented clinical results.[1-3]

(B) X3 UHMWPE meets ASTM F648 for Density as measured per ASTM D1505. X3 UHMWPE exceeds ASTM F648 requirements for Tensile Yield Strength, Ultimate Tensile Strength, Elongation and Impact Strength for a Type 3 resin (Tensile strengths and elongation measured per ASTM D638, impact strength per F648, Annex A1).

(C) X3 UHMWPE has similar crystalline and lamellar structure as N2Vac gamma sterilized UHMWPE as measured by Small Angle X-ray Scattering (SAXS) and Differential Scanning Calorimetry (DSC) analysis. DSC determined crystallinity was 61.3 ± 0.8% and 61.7 ± 0.6% for N2Vac UHMWPE and X3 UHMWPE, respectively. Lamellar crystal thickness was 23.0 and 23.6 nanometers for N2Vac UHMWPE and X3 UHMWPE, respectively.

(D) Stryker Orthopaedics Trident Acetabular Inserts made of X3 UHMWPE shows similar wear particle shape and size as Stryker Orthopaedics Trident Acetabular Inserts made of N2Vac gamma sterilized UHMWPE. Un-sterilized Trident X3 UHMWPE acetabular insert wear debris showed a length of 0.471 ± 0.814 microns, a width of 0.247 ± 0.399 microns and an aspect ration of 1.99 ± 1.76, while N2Vac UHMWPE polyethylene Trident acetabular insert wear debris showed a length of 0.409 ± 0.553 microns, a width of 0.221 ± 0.356 microns and an aspect ratio of 2.34 ± 3.48. Wear debris was generated from multi-axial hip simulation testing and was isolated following published techniques.[4]

[1] Wang, A. et. al., Tribology International, Vol. 31, No. 1-3 : 17-33, 1998.
[2] Essner. A. et. al., 44th Annual Meeting, ORS, New Orleans, Mar. 16-19, 1998: 774.
[3] Essner, A. et. al., 47th Annual Meeting, ORS, San Francisco, Feb. 25-28, 2001: 1007.
[3] Essner. A. et. al., 47th Annual Meeting, ORS, San Francisco, Feb. 25-28, 2001: 1007.
[4] Scott, M. et. al., Transactions of the 6th World Biomaterials Congress (SFB), Minneapolis, 2000: 177.

References

1 Litsky, AS, et al, "Micromotion Between the cup and the Liner in Modular Acetabular Prostheses," 1999 Society for Biomaterials, 25th Annual Meeting Transactions.
2 RD-98-0101.
3 RD-03-082.
4 Jasty, M, et al, "Wear of Polyethylene Acetabular Components in Total Hip Arthroplasty," JBJS, 70A, March 1997.
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6 Taylor, S, "Reduction in Polyethylene Wear through Ion-Implantation into CoCr Alloy," Surface Modification Technologies VI, The Minerals, Metals & Materials Society, 1993.
7 Maruyama, M, et al, "Effect of Low Friction Ion Treated Femoral Heads on Polyethylene Wear Rates," CORR, Number 370, pp. 183-191.
8 Dong, et al, "Hip Joint Stability Determined by Acetabular Bearing Insert Design, An in-vitro Simulated Study," ORS, 1999.

US Patent 6,475,243

Literature Number: **LX3SB**
GC/GS 3.0m 04/05

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