The information contained in this document is intended for healthcare professionals only.

Trident®
POLY ACETABULAR SYSTEM

Featuring:

CROSSFIRE®
Crosslinked Polyethylene

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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. More than 10,000 Trident® shells have been implanted globally and the success of the Trident® System continues to expand in the US. 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*
- Crossfire® polyethylene for improved wear performance
- The thickest polyethylene on the market
- Choice of shell geometries
- Arc-deposited roughened surface to help achieve immediate stability
- Purefix™ HA
- Eccentric and Constrained Inserts for revision options

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

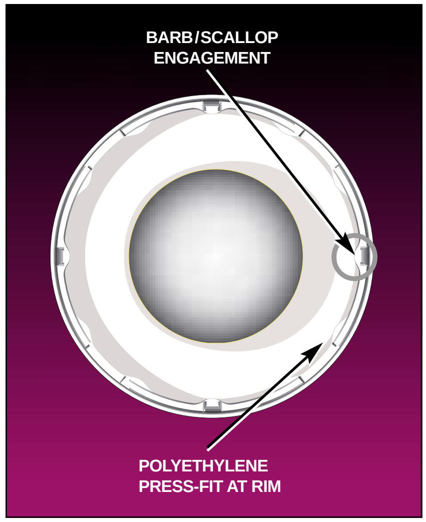
*Ceramic is not currently available in the US as of 7/15/2001.

Innerchange™ Locking Mechanism

The Innerchange™ Locking Mechanism allows for independent locking of polyethylene and ceramic inserts into the shell. This provides superior locking of both inserts without compromise.

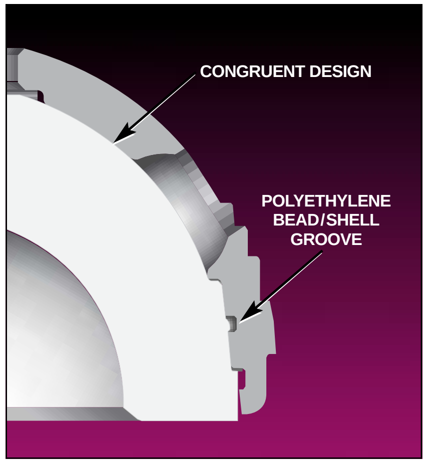
The Trident® polyethylene insert allows for proper rotational alignment using 12 indexable scallops. Polyethylene inserts lock into the shell in three ways:

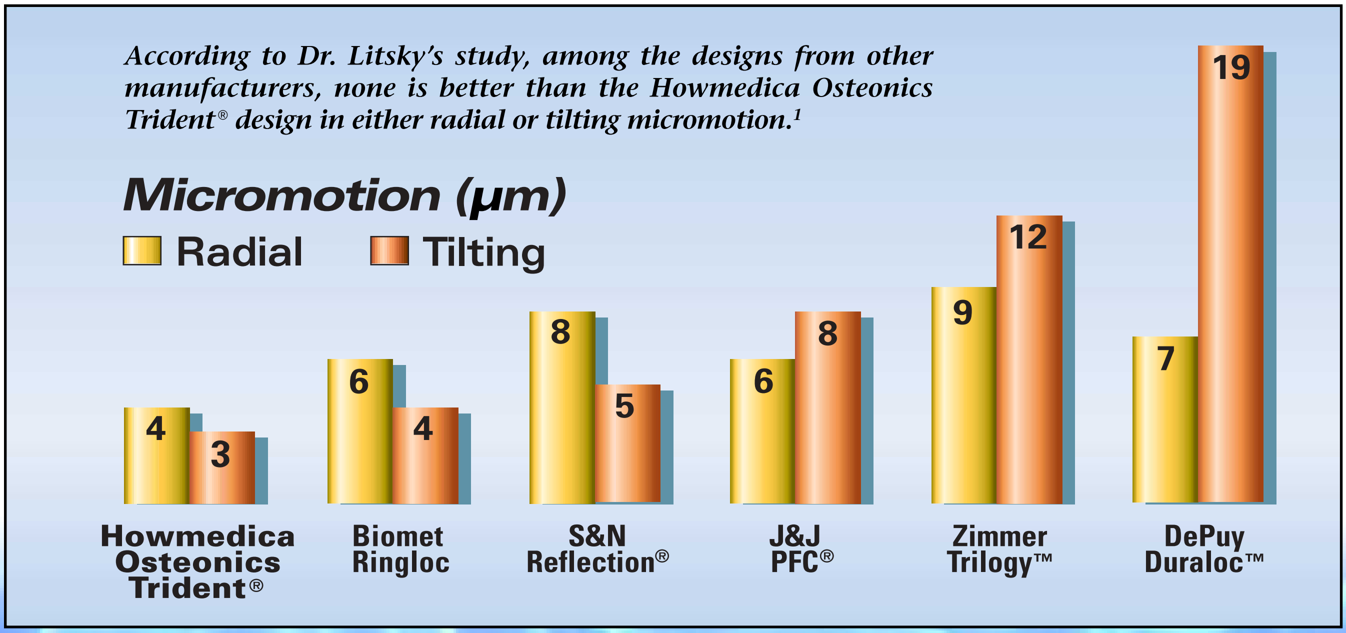
- Four alignment studs on the shell provide proper rotational and axial alignment
- Unique bead and groove mechanism
- Additional rim locking provides for exceptional insert stability



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 Crossfire® polyethylene has demonstrated improved wear performance[3]





Polyethylene

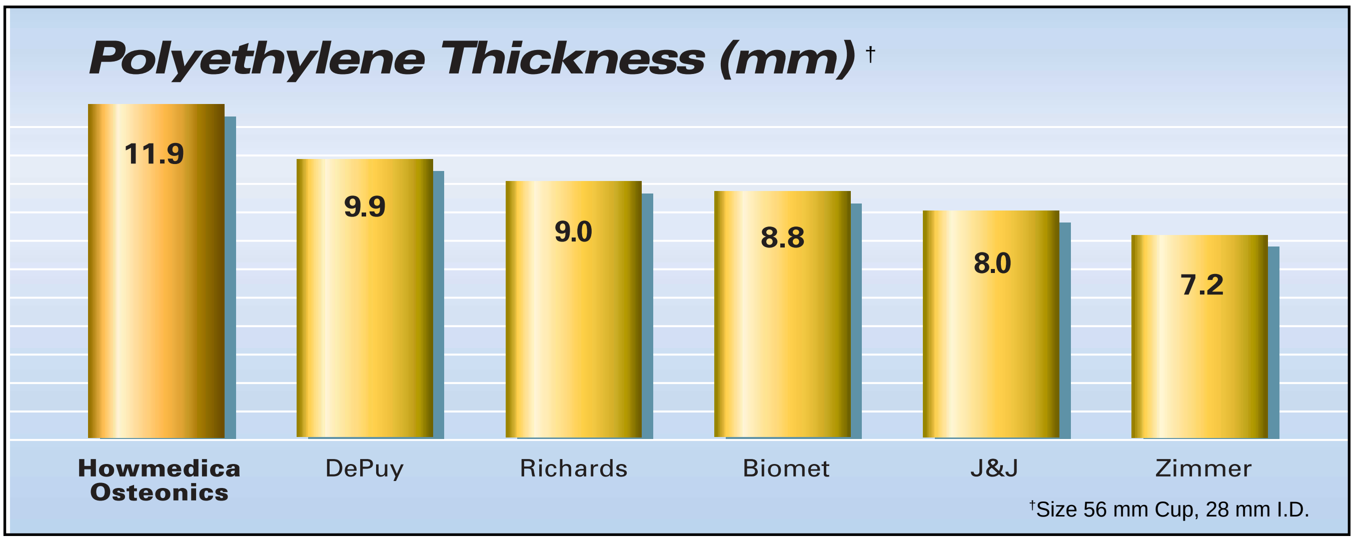
Trident® polyethylene inserts are:

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

Shell fully supports the Trident® insert

Polyethylene Thickness

Polyethylene thickness plays an important role in the wear performance.[4] Size for size, the Trident® polyethylene inserts are the thickest in the industry.



10 degree hooded inserts are available with the Trident® System (shown here)

Crossfire® Highly Crosslinked Polyethylene

Crossfire® Highly Crosslinked polyethylene has demonstrated significant wear reduction compared to standard polyethylene. Howmedica Osteonics' technology and conservative process have allowed increased crosslinking while maintaining the material properties of the polyethylene.

- ***90% reduction in wear[5]***
  Crossfire® polyethylene demonstrates 90% reduction in wear over nitrogen sterilized polyethylene in joint simulation testing, thereby reducing the potential for osteolysis.

- ***Material properties are retained***
  The material properties of Crossfire® polyethylene are similar to those of standard polyethylene, as shown in *Figure 1*.

- ***Preserves the polymer structure of UHMWPE***
  The crystalline and amorphous regions of Crossfire® are similar to standard polyethylene which suggests predictable clinical performance[6] (*Figure 2*).

- ***N_2/Vac™ packaging provides resistance to oxidation***
  Packaging polyethylene in an oxygen-free environment improves material toughness and strength on shelf-stored polyethylene up to 10 years.[7]

- ***Same particle size and shape as standard polyethylene***
  The biological response to Crossfire® particles is not expected to be different from standard polyethylene.

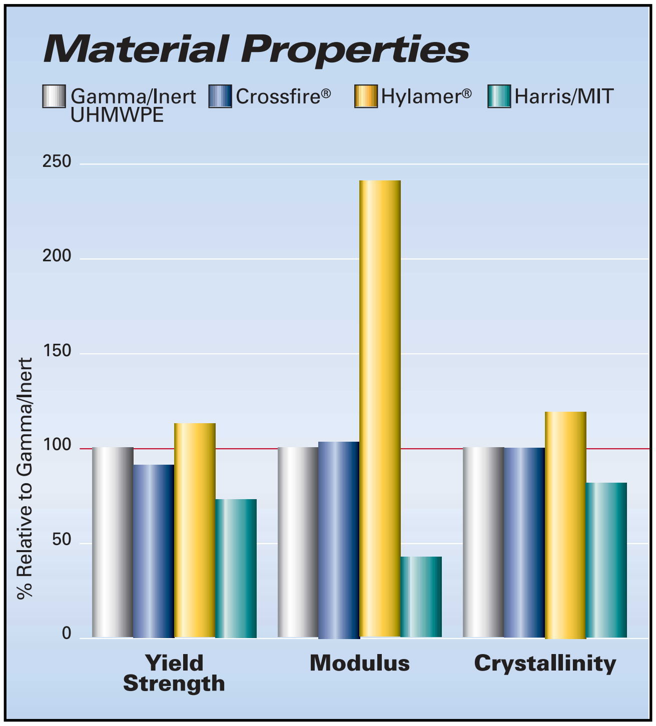


Figure 1 *Crossfire® polyethylene maintains similar yield strength, modulus and crystallinity as standard polyethylene. When these properties change significantly, the clinical wear performance cannot be predicted.*

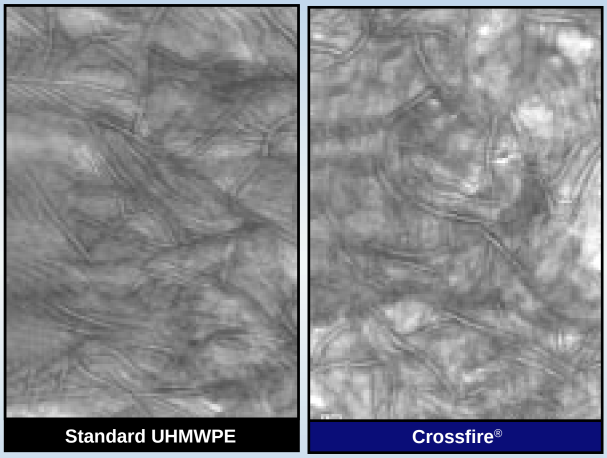


Figure 2 *Crossfire® exhibits a morphology that is very similar to that of standard UHMWPE*

LFIT™ Technology

Improved Wear Performance with LFIT™ Femoral Head Technology

Low Friction Ion Treatment (LFIT™) technology 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

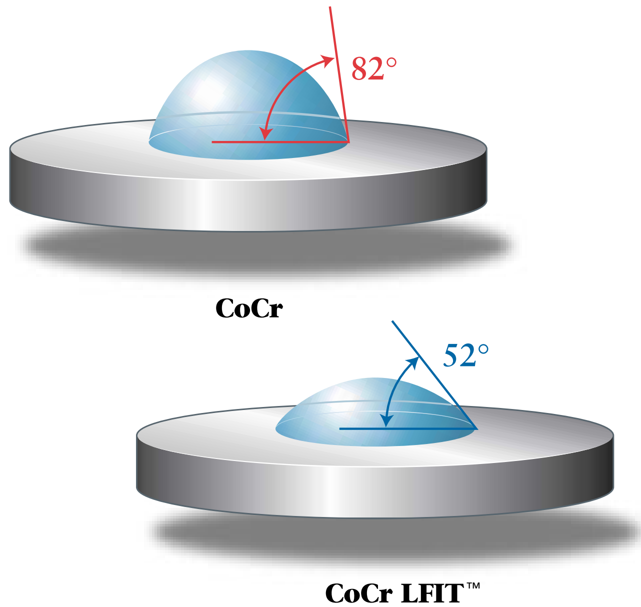
Wettable materials are important in total hip arthroplasty

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.[8]

"These results are encouraging...Nitrogen ion implanted femoral heads may be an effective way to decrease UHMWPE wear and increase implant longevity in THA."[9]



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 Crossfire® Highly Crosslinked Polyethylene for improved wear performance.[5] 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 high risk of hip dislocation. Constrained Inserts feature Howmedica Osteonics uniquely designed pre-assembled inserts with the UHR® bipolar ***(Figure 6)***.

Figure 4 *Trident® Hemispherical Multi-Hole Acetabular Shell*

Cross-section of Trident® Eccentric Insert

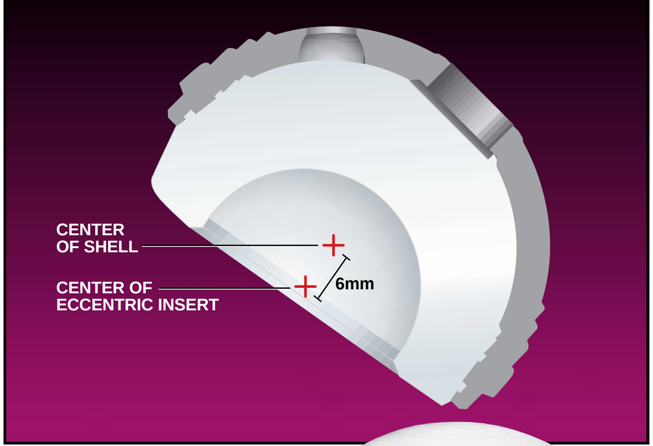


Figure 5

0° Eccentric Insert

10° Hooded Eccentric Insert

Cross-section of Trident® Constrained Insert

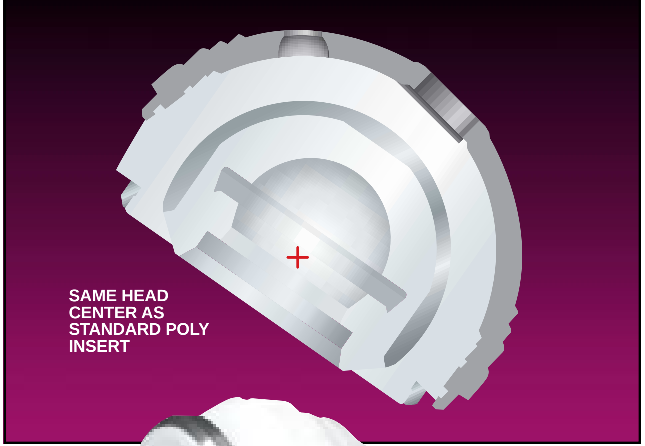


Figure 6

Constrained Insert

Revision Options

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)	Crossfire® 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	N/A
D	46, 48	48, 50	22, 26, 28	28
E	50, 52	52, 54	22, 26, 28, 32	28
F	54, 56	56, 58	22, 26, 28, 32	28
G	58, 60	60, 62	22, 26, 28, 32	28
H	62, 64	64, 66	22, 26, 28, 32	28
I	66, 68	68, 70	22, 26, 28, 32	28
J	70, 72	72, 74	22, 26, 28, 32	28

N/A=not available

References

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2 Data on file at Howmedica Osteonics.
3 Schmidig G, et al, "Trident® Polyethylene Acetabular Insert Performance Characteristics", Howmedica Osteonics Literature #LTAP/TM.
4 Jasty, M, et al, "Wear of Polyethylene Acetabular Components in Total Hip Arthroplasty," JBJS, 70A, March 1997.
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8 Taylor, S, "Reduction in Polyethylene Wear through Ion-Implantation into CoCr Alloy," Surface Modification Technologies VI, The Minerals, Metals & Materials Society, 1993.
9 Maruyama, M, et al, "Effect of Low Friction Ion Treated Femoral Heads on Polyethylene Wear Rates," CORR, Number 370, pp. 183-191.
10 Dong, et al, "Hip Joint Stability Determined by Acetabular Bearing Insert Design, An in-vitro Simulated Study," ORS, 1999.

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