



**Epsilon™
Durasul®
Constrained
Insert**



Stability without compromise

History of Dislocation and Constrained Acetabular Inserts

The Need for a Better Solution

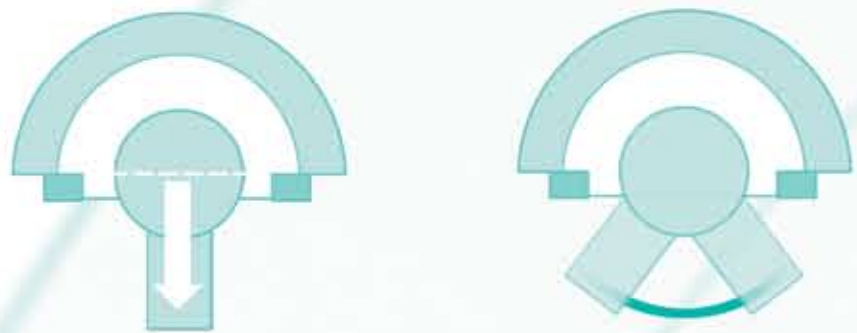
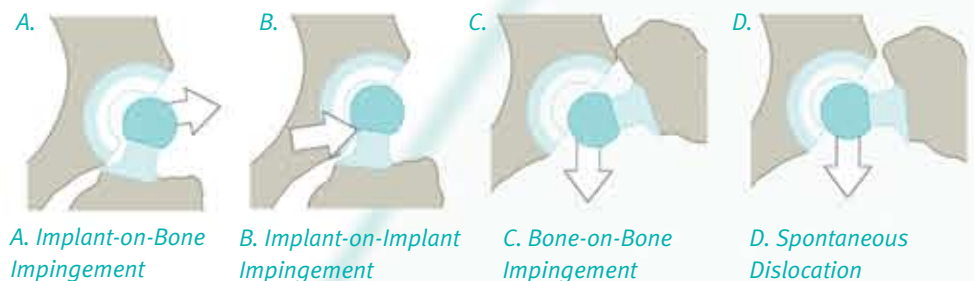
The Problem

Dislocation is the second most common complication in THA after loosening from wear-induced osteolysis. Reports in the literature state that dislocations occur in 2-10% of primary cases and in up to 20% of revision cases.^{1,2,3} Recurrent dislocation requires reoperation in 13-42% of cases.^{4,5} However, two studies have shown that 24-31% of patients who undergo revision because of recurrent dislocation experience further dislocation after reoperation.^{2,6}

The Traditional Solution

Traditional constrained inserts were designed to reduce the incidence of dislocation. They consist of a polyethylene component that surpasses the equator of the head, allowing the head to be snapped in. A metal ring is added to further resist the forces pulling the head from the insert.

However, traditional constrained inserts can severely restrict ROM, leading to impingement. This may lead to component failure,^{7,8} further dislocation,^{9,10} or implant loosening.⁷



Basic constrained insert: UHMWPE liner, CoCr ball head, and metal-alloy constraining ring.

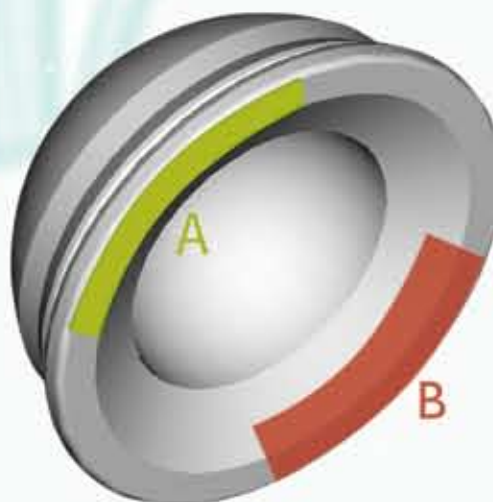
ROM Improved Where It's Needed Most

ROM Test Results

Where does impingement usually occur?

In a 2000 study by Yamaguchi et al., 111 retrieved polyethylene inserts were examined for evidence of neck impingement, as demonstrated by wear scars on the periphery of the insert.¹¹ 43 inserts with evidence of neck-insert impingement were identified, and the anatomical locations of the damage were noted. Two sites of concentrated impingement damage were identified at **(A) full flexion** and **flexion plus internal rotation** and **(B) extension with external rotation**.

The *Epsilon Durasul* Constrained Inserts are designed such that there is no constraint in these regions, and thus no reduction in ROM when compared to a circumferentially constrained insert.



Sawbones Set-up Used in ROM Testing



Neutral position. To optimize ROM, the small retaining finger is placed at the 1 o'clock position on a left hip, 11 o'clock on a right hip.



External rotation in extension.



Flexion plus internal rotation.



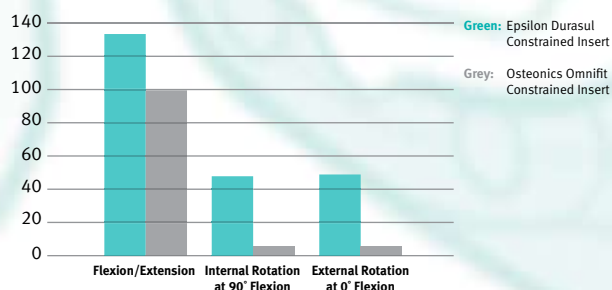
Full flexion.

ROM Increased over Traditional Constrained Insert

In testing using a saw-bones set-up and a three-dimensional goniometer, the *Epsilon Durasul* Constrained Insert demonstrated much-improved ROM when compared to a traditional constrained insert.¹⁴

ROM Testing

Range of motion (degree)



Constraining Functionality Maintained

Biomechanical Test Results

Lever-out Testing

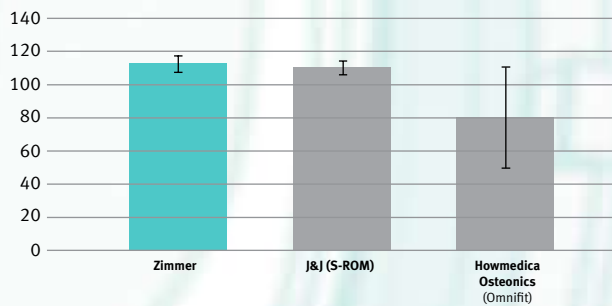
In lever-out testing, the *Epsilon Durasul* Constrained Insert performed as well as the two most commonly used constrained inserts.¹²

Lever-Out Test Fixture



Lever-out Testing

Lever-out of head from liner
(in - lbs)



Durasul Highly Crosslinked Polyethylene with Large Diameter Heads – Wear Independent of Head Size

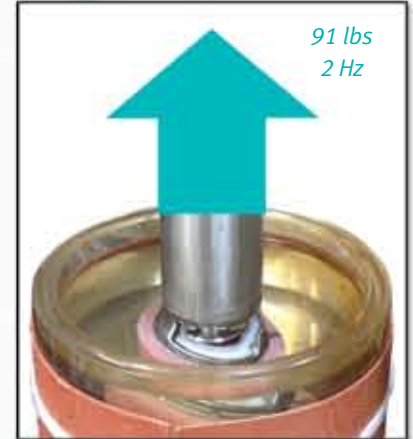
Durasul inserts were tested up to 27 million cycles by Massachusetts General Hospital on anatomical hip simulators. This testing models over 25 years of *in vivo* use.¹³ Wear rate was measured gravimetrically, that is, by change in weight. *Durasul* Highly Crosslinked Polyethylene inserts demonstrated no measurable wear.

Laboratory tests up to 11 million cycles have demonstrated that the wear rate of *Durasul* Highly Crosslinked Polyethylene is independent of the head diameter.¹³ That is, increasing the head diameter does not increase the wear rate of *Durasul* Highly Crosslinked Polyethylene. This makes the use of larger heads possible with the *Epsilon Durasul* Constrained Insert.

Fatigue Testing

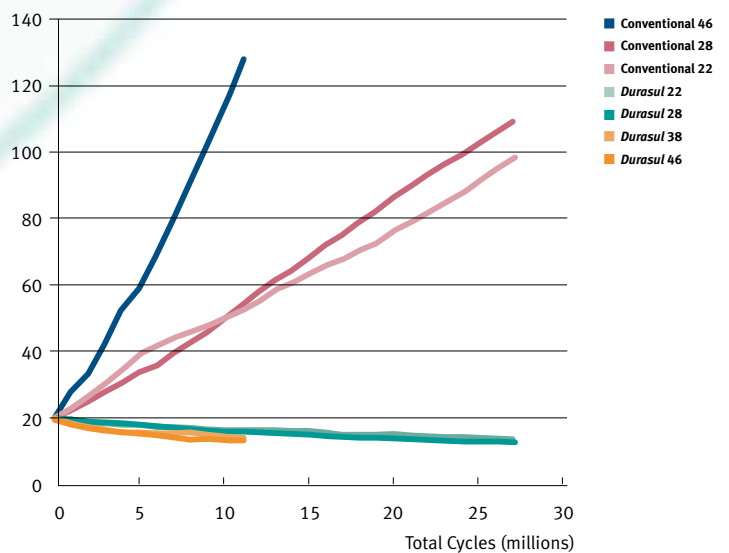
A fatigue test was conducted that pulled the head axially out of the insert and against the restraining fingers. Based on the possible lever arm from the head center to a possible bony impingement point and published dislocation torques, an anatomical pull-out force of 91 lbs was calculated. After 2 million cycles, the components were examined. In all cases, the head remained constrained, all components were structurally sound, and there was no evidence of fatigue damage.¹²

Pull-Out Fatigue Test Fixture



Hip Simulator Wear Results¹⁵

Average Total Weight Change (mg)



Today's Solution

Epsilon Durasul Constrained Insert

Features and Benefits

The *Epsilon Durasul* Constrained Insert addresses the primary shortcoming of traditional constrained inserts, limited ROM, while maintaining the constraining functionality.

In this design, ROM was increased by placing cut-outs in the rim of the constrained implant where impingement is most likely to occur. And because it is manufactured from *Durasul* Highly Crosslinked Polyethylene, larger heads can be used, further increasing the ROM.

Assembly similar to traditional constrained insert Like traditional constrained inserts, the *Epsilon Durasul* Constrained Insert consists of an insert and ring that are assembled at the time of surgery. After the insert is locked into the shell, the ring is placed around the femoral neck. The head is then reduced and the ring attached.



Manufactured from *Durasul* Highly Crosslinked Polyethylene, an advanced bearing surface that resists wear and aging.¹³

Head diameters up to 38 mm to increase ROM.¹³

Cut-outs increase ROM.

Compatible with Converge® CSTi™ Porous Acetabular System, built on 15 years of clinical success.¹⁵

Retaining fingers capture the head.



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