

smith&nephew

REFLECTION®

XLPE Liners

Less wear for longer lasting hips





Less wear for longer lasting hips

Smith & Nephew technology continues to exceed expectations for the long-term success of total hip arthroplasty (THA).

Advanced material

REFLECTION XLPE Liners offer all the advantages of cross-linked polyethylene without susceptibility to the concerns of oxidation. The advanced bearing system of REFLECTION XLPE Liners paired with OXINIUM® Femoral Heads produces 98% less wear than conventional polyethylene without the concerns of head fracture or metal toxicity.

Mechanical stability

The combination of cross-linked polyethylene with the REFLECTION design provides a more structurally sound construct than competitive acetabular systems with traditional poly.

Unsurpassed versatility

Provided in multiple size and design options for increased stability and leg length variance, REFLECTION XLPE Liners have been optimized to provide a maximum range of motion (ROM).

Test results:

Finer filters improve accuracy of tests 5

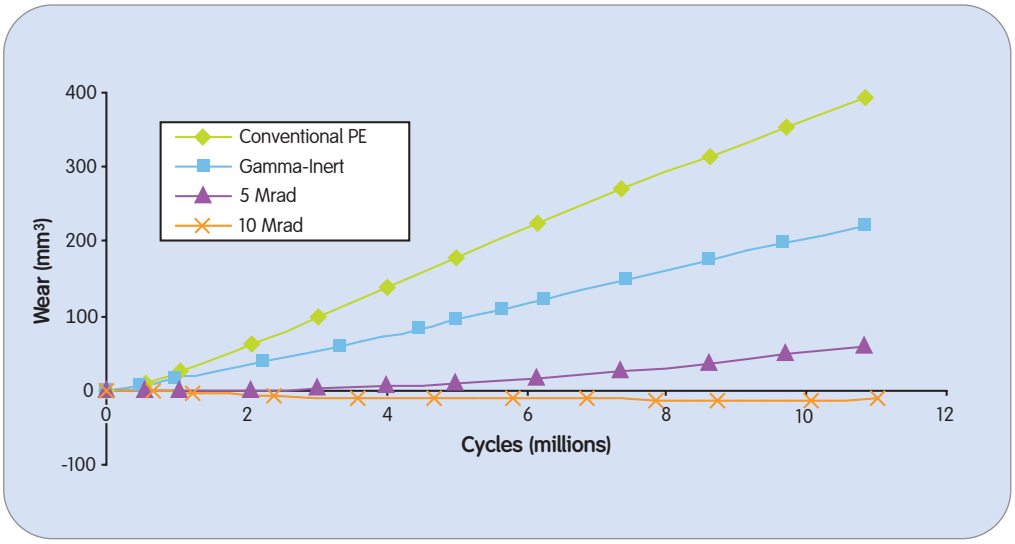
REFLECTION XLPE Liners minimize poly debris 6

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Less wear



The negative value for volumetric wear for REFLECTION XLPE Liners indicates that weight measurements are not appropriate for assessing wear of highly cross-linked polyethylene.

Wear rates for RELECTION XLPE Liners are so low that they cannot be determined using standard weight measurements.

Poly wear is usually measured by the volume of debris.* Unfortunately, lowering the volume does not guarantee fewer particles. In fact, with some materials a lower volume of wear produces a higher number of particles.

For that reason, assessing the effectiveness of bearings in reducing poly debris requires measuring both the volume of wear and the number of particles generated.

A standard wear test was conducted to evaluate the performance of 10 Mrad gamma-irradiated REFLECTION XLPE Liners compared to 5 Mrad gamma-irradiated cross-linked polyethylene, conventional EtO-sterilized polyethylene (CPE), and a commercially available gamma-inert sterilized compression molded polyethylene.

The test articulated 32 mm heads and liners in a hip simulator producing over 10 million cycles. The change in weight was measured at regular intervals, and the volume of wear was calculated based on the density of polyethylene.

With an expected level of wear for CPE, results showed a 40% decrease in volumetric wear for the gamma-inert poly and an 86% decrease for the 5 Mrad cross-linked poly.

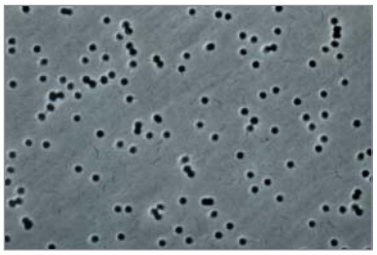
*The results of in vitro tests have not been shown to correlate with clinical wear mechanisms or performance.

Advanced tests

Finer filters

Since volumetric wear tests are not suitable for highly cross-linked polyethylene, more advanced tests measuring the number of particles generated by various bearings were utilized.

The serum from the wear test was filtered to isolate particles. For a more accurate assessment, the 0.2 µm (micron) filter membrane used in previous analyses was replaced with a 0.05 µm filter membrane. The finer filter can capture particles 98% smaller than those captured by the larger one. To measure the size of each particle, the filtered elements were analyzed in an SEM.

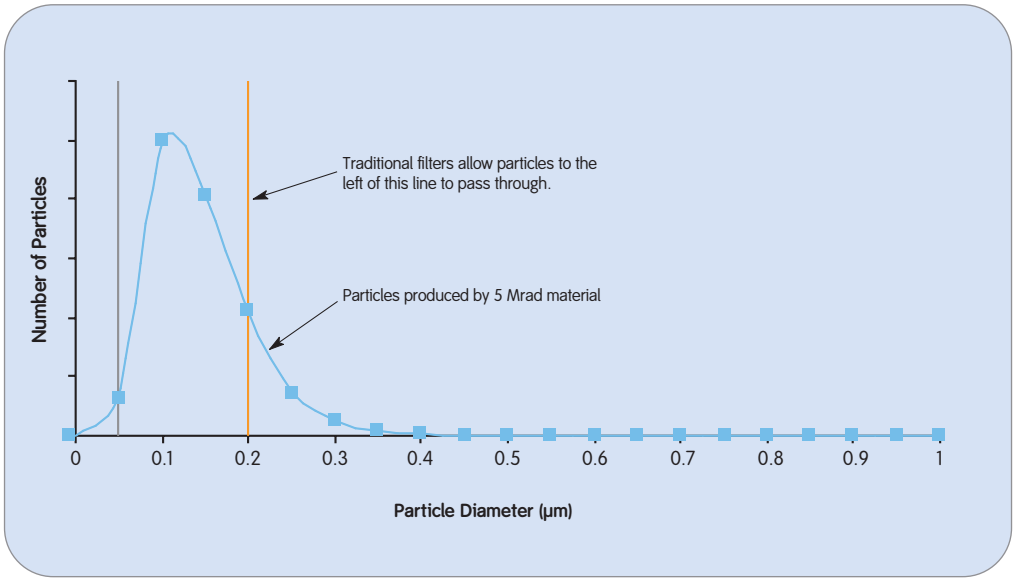


SEM of 0.2 µm filter membrane showing size of holes.



SEM of 0.05 µm filter membrane, which can capture particles 98% smaller than is possible with a 0.2 µm filter membrane.

Using the wrong filter size (0.2 µm) can lead to wear results that are unrealistic.

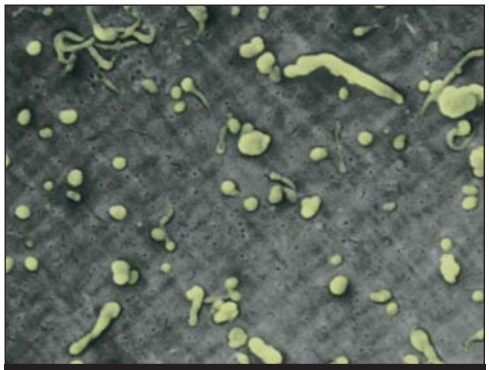


The finer 0.05 µm filter captures most of the particles generated.

Advanced material

Fewer particles

The charts below, displayed at a magnification level of 10,000 times, show the polyethylene debris particles captured when testing a variety of materials. The benefit of REFLECTION XLPE Liners is obvious.



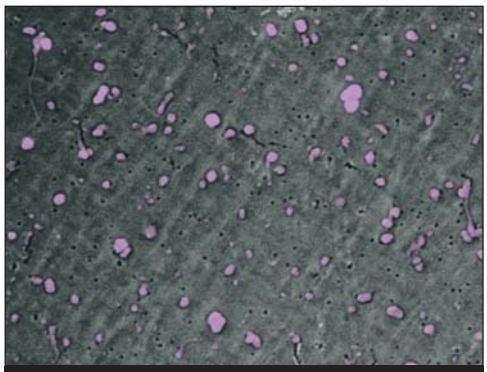
Conventional Polyethylene

The CPE shows a variety of debris, from small, rounded particles to large, elongated fibrils.



Gamma-Inert Poly

The Gamma-Inert sterilized polyethylene shows the same types of particles as CPE, but fewer large ones and many more small ones.



5 Mrad Cross-linked Poly

The 5 Mrad cross-linked polyethylene shows almost no large particles, but many small ones.

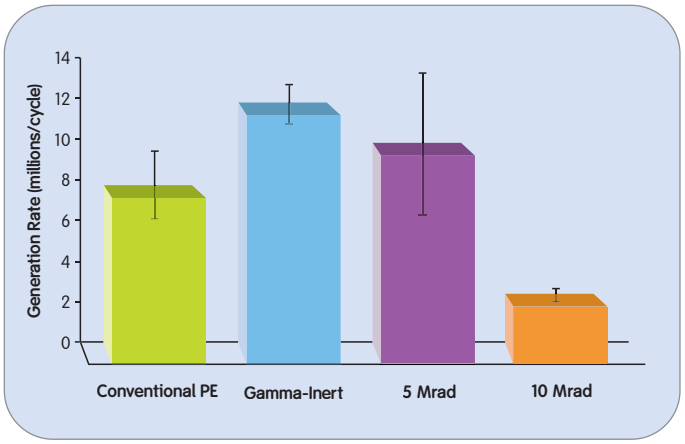


REFLECTION XLPE Liners (10 Mrad)

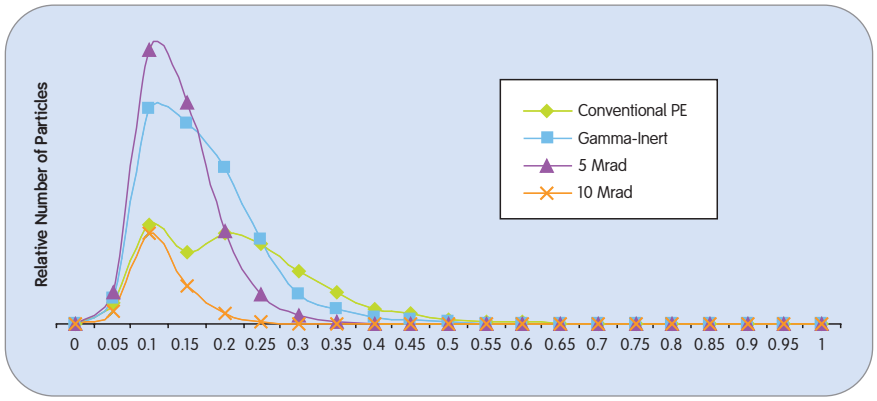
The 10 Mrad REFLECTION XLPE Liners show no large particles and very few small ones.

With REFLECTION XLPE Liners, the benefit is obvious.

REFLECTION XLPE 10 Mrad cross-linked polyethylene articulated against a CoCr head produces 72% fewer particles than conventional poly and generates the fewest particles at all size ranges.[1]

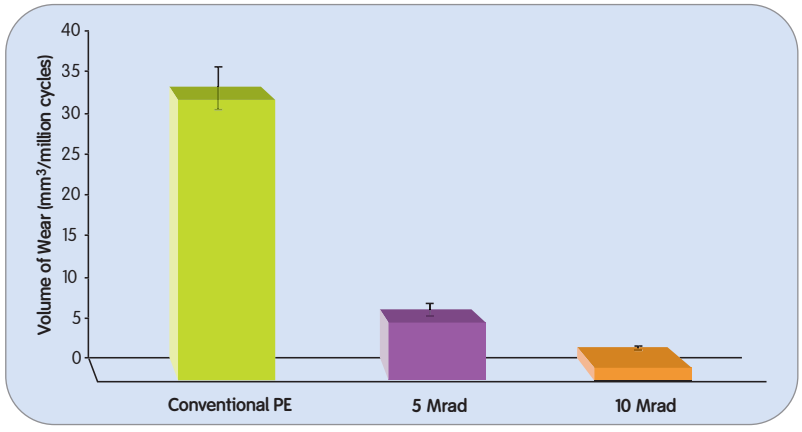


Particle generation rates. At 10 million cycles, CPE produces some 8 million particles per cycle. In comparison, Gamma-Inert Poly produces approximately 50% more particles, and 5 Mrad cross-linked poly approximately 25% more particles. REFLECTION XLPE Liners generate 72% fewer particles.



Particle size distribution. 5 Mrad cross-linked poly generates more small particles (<0.22 µm) than any other material. Gamma-Inert sterilized poly generates more small particles (<0.27 µm) than either CPE or 10 Mrad cross-linked poly. REFLECTION XLPE Liners generate the fewest particles at all size ranges.

The projected area of each particle was used to estimate its volume. Then the total wear volume was estimated from the sum of all the particles.



Volume of particles. The total wear volume was estimated from the sum of all the particles from the previous tests. As measured by particle analysis[2], the volumetric wear shows the same relationship between each type of material that was found using weight measurements.

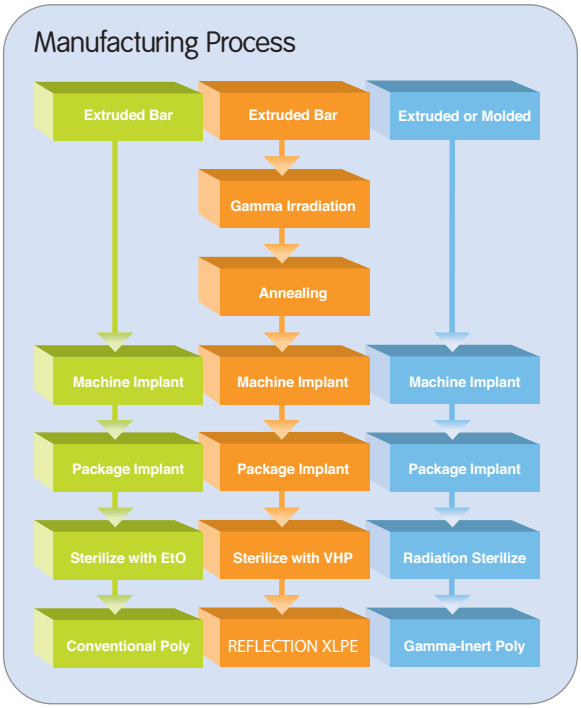
[1] Ries MD, Scott ML, and Jani S. Relationship Between Gravimetric Wear and Particle Generation in Hip Simulators: Conventional Compared with Cross-Linked Polyethylene. J. Bone Joint Surg. Am., Nov 2001; 83: S116-122.

[2] Scott M, Morrison M, et al. A method to quantify, etc.

Advanced material

Cross-linking without oxidation

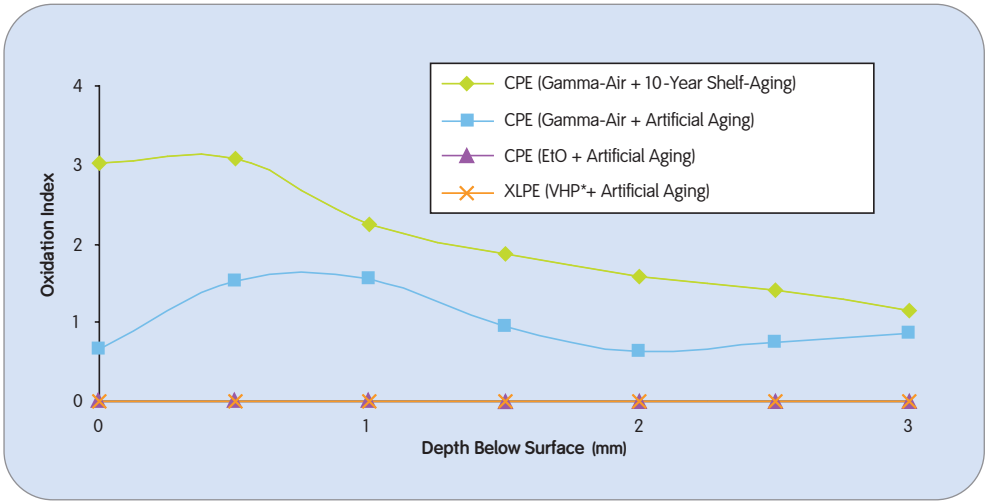
Smith & Nephew's cross-linking process completely anneals the polyethylene material and eliminates all measurable free radicals, making REFLECTION XLPE Liners resistant to oxidation. Oxidation index measurements cannot detect any oxidation occurring even after aggressive artificial aging as seen in the chart below.



REFLECTION XLPE (center column of Manufacturing Process chart at right) is cross-linked using 10 Mrad of gamma radiation while it is still in the bar form. To achieve full annealing and minimize any potential for oxidation, the material is heated to the melt temperature. Standard manufacturing processes are then followed, and vaporized hydrogen peroxide sterilization (VHP) is employed instead of radiation sterilization.

Conventional Poly (left column) also uses EtO sterilization but is not cross-linked.

The Gamma-Inert Poly (right column) is cross-linked through gamma sterilization. Unfortunately, that process leaves free radicals and as a result is susceptible to oxidation. Because the part is already formed, free radicals cannot be removed by fully annealing the material through high heat. For these reasons, Smith & Nephew avoids gamma sterilization.



*VHP is vaporized hydrogen peroxide.

REFLECTION XLPE Liners offer all the advantages of cross-linked polyethylene without the risks of oxidation.

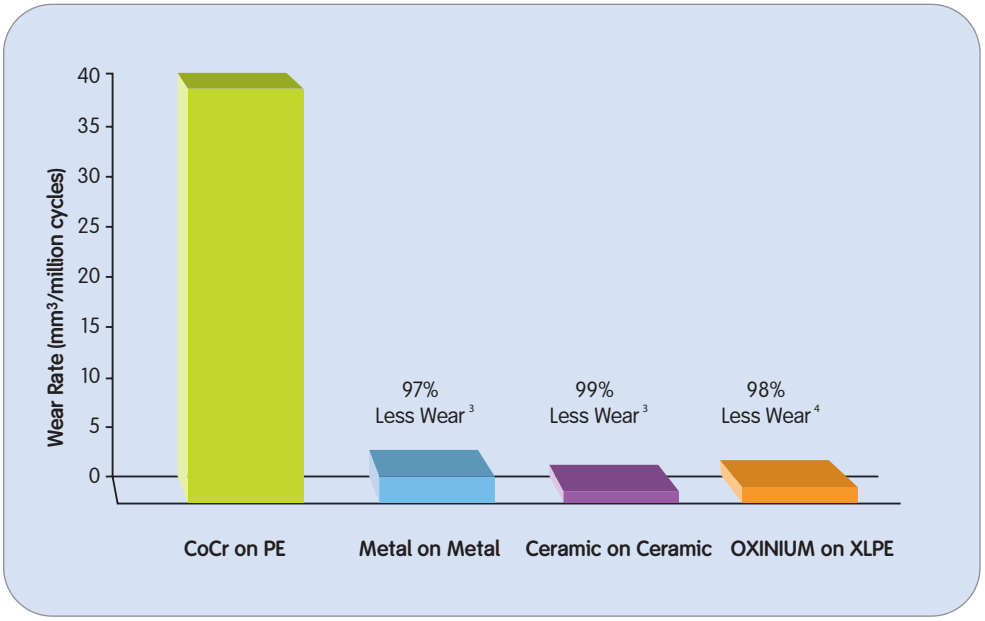


OXINIUM on XLPE



Advanced bearings

Through advanced technology, Smith & Nephew continues to help people regain their lives. The superior designs of advanced bearings manufactured by Smith & Nephew offer unique durability. OXINIUM Femoral Heads, made of the first new bearing material in orthopaedics in 20 years, offer long-lasting benefits to active patients. The Smith & Nephew combination of REFLECTION XLPE Liners paired with OXINIUM Femoral Heads offers more options and achieves significant wear reduction without the concern of head fracture.



The advanced bearing system of REFLECTION XLPE Liners paired with OXINIUM Femoral Heads dramatically reduced volumetric wear comparable to the level associated with ceramic on ceramic or metal on metal bearings. Only REFLECTION XLPE Liners are proven to reduce the number of polyethylene particles that are known to cause osteolysis.

[3] Clarke IC, Good P, Williams P, Schroeder D, Anissian L, Stark A, Oonishi H, Schuldies J, Gustafson G. Ultra-low Wear Rates for Rigid-on-rigid Bearings in Total Hip Replacements. Proc Inst Mech Eng [H]. 2000; 214(4); 331-47.

[4] Good V, Ries M, Barrack RL, Widding K, Hunter G, Heuer D. Reduced Wear with Oxidized Zirconium Femoral Heads, Presented at 2003 AAOS (New Orleans).

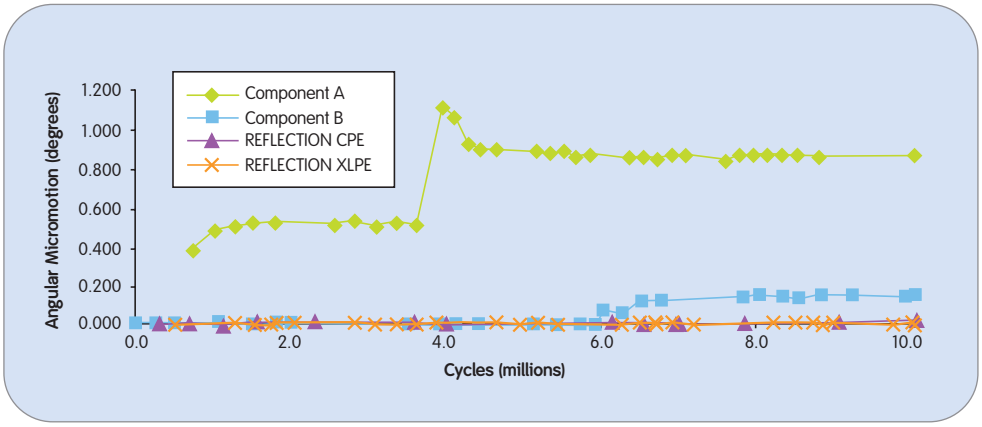
Mechanical stability

Fatigue testing

Fatigue testing demonstrates the superior performance of REFLECTION XLPE Liners in the MICROSTABLE® Liner Locking Mechanism.

When competitive acetabular systems with traditional poly were tested under the same conditions, steep changes in micromotion occurred, which is indicative of fatigue-related failure.

Combining cross-linked polyethylene with the REFLECTION design gives a structurally sound construct with a significant reduction in particle generation.



Liner Micromotion. In the micromotion assessments the REFLECTION component outperformed all other components tested, with 0.033° of liner excursion recorded. The greatest degree of liner micromotion measured at 1.749°.

Liner Abrasion. In general, the abrasion observed increased as the micromotion increased.

The combination of cross-linked polyethylene with the REFLECTION design provides a more structurally sound construct with a significant reduction in particle generation.

REFLECTION XLPE



Component A



Component B



Unsurpassed versatility

REFLECTION XLPE Liners provide unsurpassed options. More choices in design and size facilitate achievement of stability and leg length. The versatility of REFLECTION XLPE Liners combines with the highest liner/shell conformity[5] and greatest range of motion on the market[6] to make it the liner of choice.

Design options

REFLECTION XLPE Liners are offered in four different styles to address different needs. The various designs have all been optimized to provide maximum range of motion. In addition, the REFLECTION MICROSTABLE Liner Locking Mechanism allows the liner to be oriented in any one of 24 positions so the overhang can be oriented to best suit each patient.



Overhang liners provide 20° additional coverage to protect against minor instability.



Neutral liners provide maximum range of motion and are best used when the cup has sufficient anteversion and abduction.



Lateralized neutral liners have the face moved out 4 mm to accommodate when the cup is properly oriented but is too deep, or when there is not enough neck length on the femoral side.



Anteverted liners are lateralized liners (+4 mm) with the face changed 20°. These liners provide the coverage of an overhang liner but have material removed opposite the build-up to provide additional range of motion.

[5] BJ Rosner, PD Postak, AS Greenwald, Cup/Liner Conformity of Modular Acetabular Designs, Scientific Exhibit, 1995 AAOS, Orlando, FL.

[6] R Thornerry, C Lavernia, R Barrack, E Tozakoglou, The Effects of Neck Geometry and Acetabular Design on the Motion to Impingement in Total Hip Replacement, Scientific Exhibit, 1998 AAOS, New Orleans, LA.

Sizing options

REFLECTION design allows the use of a 36 mm head in shell sizes 54 mm and larger, which account for 57% of all cups sold. Liner thickness is maximized by avoiding cut-outs used in some locking mechanisms. The additional polyethylene can be gained by using one of the available lateralized liners.

Polyethylene thickness

Femoral Head Size	Acetabular Cup Size (mm)									
	40	42	44	46-48	50-52	54-56	58-60	62-64	66-68	70-76
22 mm	5	6	7	8	10	12	13	15	17	19
26 mm	-	-	5	6	8	10	11	13	15	17
28 mm	-	-	-	5	7	9	10	12	14	16
32 mm	-	-	-	-	5	7	8	10	12	14
36 mm	-	-	-	-	-	5	6	8	10	12

Range of motion

Liner Style	Head Diameter				
	22 mm	26 mm	28 mm	32 mm	36 mm
Neutral	133°	138°	142°	145°	148°
Overhang	112°	119°	122°	126°	128°
Anteverted	130°	133°	135°	138°	139°

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