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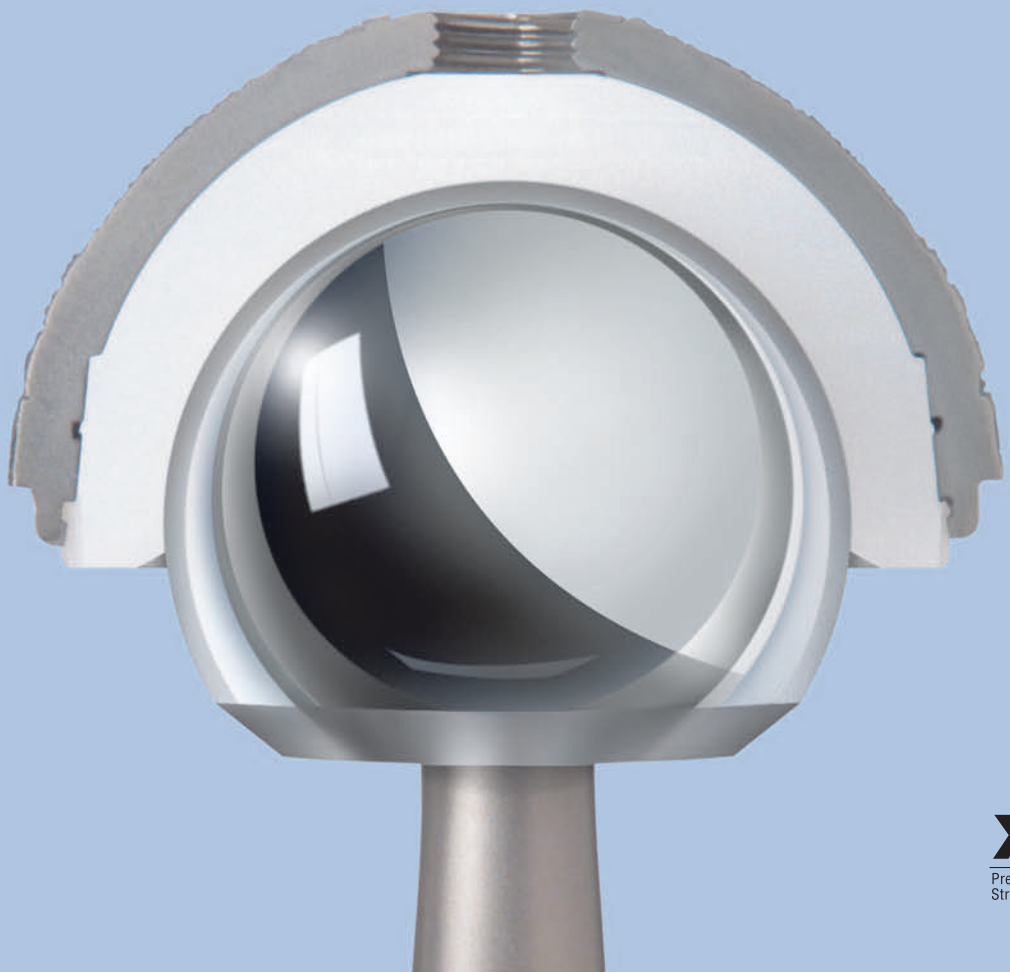
Orthopaedics

LFIT Anatomic
CoCr Femoral Heads with X3 Liners

Expanded X3 Liner Sizes Now Available

Anatomically Sized for Natural Hip Performance

- Minimizing Dislocation
- Maximizing ROM



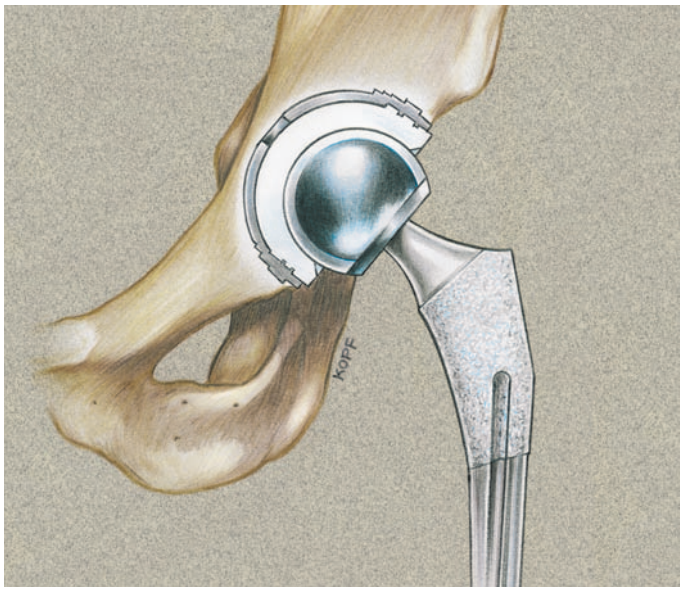
X3® The Power of Technology

Preserving Strength | Reducing Wear | Resisting Oxidation

LFIT Anatomic
CoCr Femoral Heads with X3 Liners

Anatomically Sized to Help Provide Natural Hip Performance

The combined technologies and designs of LFIT Anatomic CoCr Femoral Heads and X3 Advanced Bearing Technology can potentially provide substantial benefits to the surgeon, patient and hospital. LFIT Anatomic CoCr Femoral Heads with X3 Liners address three of the major clinical factors associated with failure in hip replacement surgery including dislocation, strength and wear. They also address the rising costs associated with hip dislocation after THA as it is designed to minimize the potential for recurring dislocation, thus minimizing the overall healthcare expense.



LFIT Anatomic Design Rationale

LFIT Anatomic CoCr Femoral Heads were designed to offer surgeons the intra-operative flexibility to better match patient anatomy and restore natural biomechanics. Studies have shown that the average femoral head diameter ranges between 35mm and 58mm, with an average of 46.1mm.[1]

LFIT Anatomic CoCr Femoral Heads were anatomically designed to:

- Enhance hip stability
- Minimize dislocation
- Maximize patient ROM

Minimizing Dislocation

Prevention of dislocation after total hip arthroplasty is critical in minimizing patient morbidity. Recommendations to decrease the prevalence of dislocations include, but are not limited to, implant design, component positioning and surgical approach. LFIT Anatomic CoCr Femoral Heads provide surgeons with a solution to help minimize dislocation.

Increase Jump Distance, Decreased Dislocation

Jump distance is the distance a femoral head must travel to dislocate. It is inversely proportional to the risk of dislocation. As jump distance increases, the risk of dislocation theoretically decreases. Typically, jump distance is measured by the radius of the femoral head. Stryker's unique Trident cup design incorporates an additional dislocation safety factor. The jump distance of an LFIT Anatomic CoCr Femoral Head in the Trident System is equal to the [head radius + 2mm cylinder + 0.7mm chamfer] for any given size.

Jump Distance = Head Radius + 2.7mm Dislocation Safety Factor (JD = r + DSF)

Increased ROM

Increased Head Diameter = Increased ROM

Range of motion is critical for the patient because it enhances optimal movement and activity post-operatively.

An LFIT Anatomic CoCr Femoral Head paired with a Stryker reduced neck geometry stem such as Accolade TMZF or Secur-Fit Max; can potentially maximize a patient's hip movement, as well as stability and dislocation resistance.

Clinical studies have shown that greater ROM was observed for larger heads (38mm and 44mm) compared with 28mm and 32mm versions.[2] In a computer simulation assessment, larger head sizes were shown to provide greater ROM prior to impingement.[3] Since impingement is the precursor to dislocation, large femoral heads can help provide optimum joint stability. In the case of impingement, a greater amount of translation between the femoral head and acetabulum is required to achieve dislocation with larger heads.

LFIT Technology

The **L**ow **F**riction **I**on **T**reatment technology enhances the material properties of CoCr to reduce frictional forces against UHMWPE surfaces, which potentially results in a reduction of polyethylene wear.

The LFIT manufacturing process embeds nitrogen ions under high energy into the metal surface without changing the dimensions of the implant. The ion distribution and penetration is in an integrated gradient throughout the subsurface. No separate layer is formed using this technique, thus preventing the delamination or chipping that can be common with surface treatments.

The LFIT process:

- Improves surface wettability[4] (**Figures 1 & 2**)
- Simulates the anatomic joint by allowing increased lubrication between components[4]
- Decreases the frictional forces against polyethylene, thus potentially reducing wear[4] (**Figures 3 & 4**)

Clinical studies have shown that LFIT CoCr heads demonstrate a 28% decrease in linear wear compared to standard CoCr heads.[5]

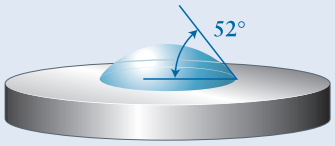


Figure 1
LFIT CoCr Wettability

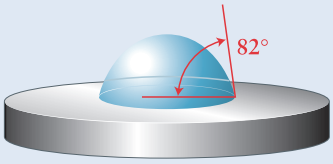


Figure 2
CoCr Wettability

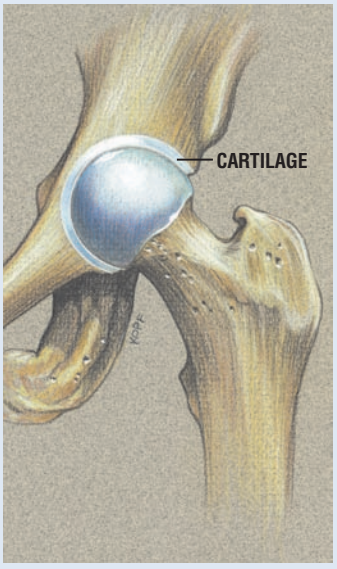


Figure 3
Anatomic Hip Naturally Lubricated

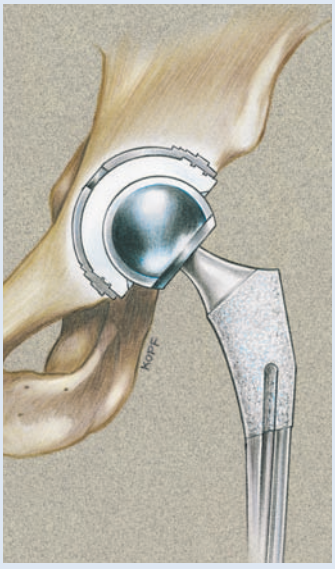


Figure 4
Hip Replacement Allowing Increased Lubrication

X3 Technology

X3 is an exciting advancement in bearing technology. Patented by Stryker's material scientists, X3 is the first polyethylene to address three of the major factors associated with failure of hip and knee replacement surgery:

- Strength[6,7]
- Wear[8,9]
- Oxidation Resistance[10-12]

The unique material characteristics of X3 allow the use of larger Anatomic femoral heads without potentially affecting the bearing performance.

The enhanced wear performance of X3, combined with exemplary strength and functional fatigue characteristics provide the ability to implant a larger head in a smaller shell without compromising clinical outcomes.

System Compatibility

LFIT Anatomic CoCr Femoral Heads with X3 Liners are the newest edition of the Trident Acetabular System. They are available in C-Taper and V40 taper dimensions and can be used with Trident PSL and Hemispherical shells. LFIT Anatomic CoCr Femoral Heads are compatible with Accolade TMZF, Secur-Fit Max, Citation TMZF, Hipstar, and most commercially available Stryker femoral hip stems.

C-Taper and V40 LFIT CoCr Femoral Heads

Catalog Information

C-Taper LFIT Anatomic Heads

Catalog No.	Diameter (mm)	Offset (mm)	Trial Catalog No.
06-3699	36	-5	1100-3699A
06-3600	36	+0	1100-3600A
06-3605	36	+5	1100-3605A
06-3610	36	+10	1100-3610A
06-4099	40	-5	1100-4099A
06-4097	40	-2.5	1100-4097A
06-4000	40	+0	1100-4000A
06-4025	40	+2.5	1100-4025A
06-4005	40	+5	1100-4005A
06-4075	40	+7.5	1100-4075A
06-4010	40	+10	1100-4010A
06-4499	44	-5	1100-4499A
06-4400	44	+0	1100-4400A
06-4405	44	+5	1100-4405A

V40 Taper LFIT Anatomic Heads

Catalog No.	Diameter (mm)	Offset (mm)	Trial Catalog No.
6260-9-036	36	-5	6264-8-036
6260-9-136	36	+0	6264-8-136
6260-9-236	36	+5	6264-8-236
6260-9-336	36	+10	6264-8-336
6260-9-040	40	-4	6264-8-040
6260-9-140	40	+0	6264-8-140
6260-9-240	40	+4	6264-8-240
6260-9-340	40	+8	6264-8-340
6260-9-440	40	+12	6264-8-440
6260-9-044	44	-4	6264-8-044
6260-9-144	44	+0	6264-8-144
6260-9-244	44	+4	6264-8-244

X3 Liners – Expanded X3 Liner Sizes Now Available

Catalog No.	Size	Description	Thickness (mm)
623-00-36D	36D	X3 Liner	3.9
623-00-40E	40E	X3 Liner	3.8
623-00-40F	40F	X3 Liner	5.8
623-00-40G	40G	X3 Liner	7.4
623-00-40H	40H	X3 Liner	9.1
623-00-40I	40I	X3 Liner	10.6
623-00-40J	40J	X3 Liner	12.6
623-00-44F	44F	X3 Liner	3.8
623-00-44G	44G	X3 Liner	5.4
623-00-44H	44H	X3 Liner	7.1
623-00-44I	44I	X3 Liner	8.6
623-00-44J	44J	X3 Liner	10.6

V40 LFIT Anatomic Head Trials

Trial Cat. No.	Instrument Description
6264-8-040	V40 40mm, -4 Offset Head Trial
6264-8-140	V40 40mm, +0 Offset Head Trial
6264-8-240	V40 40mm, +4 Offset Head Trial
6264-8-340	V40 40mm, +8 Offset Head Trial
6264-8-440	V40 40mm, +12 Offset Head Trial
6264-8-044	V40 44mm, -4 Offset Head Trial
6264-8-144	V40 44mm, +0 Offset Head Trial
6264-8-244	V40 44mm, +4 Offset Head Trial

C-Taper LFIT Anatomic Head Trials

Trial Cat. No.	Instrument Description
1100-4099A	C-Taper 40mm, -5 Offset Head Trial
1100-4097A	C-Taper 40mm, -2.5 Offset Head Trial
1100-4000A	C-Taper 40mm, +0 Offset Head Trial
1100-4025A	C-Taper 40mm, +2.5 Offset Head Trial
1100-4005A	C-Taper 40mm, +5 Offset Head Trial
1100-4075A	C-Taper 40mm, +7.5 Offset Head Trial
1100-4010A	C-Taper 40mm, +10 Offset Head Trial
1100-4499A	C-Taper 44mm, -5 Offset Head Trial
1100-4400A	C-Taper 44mm, +0 Offset Head Trial
1100-4405A	C-Taper 44mm, +5 Offset Head Trial

X3 Liner Trials

Trial Cat. No.	Instrument Description
2200-36D	Liner Trial
2200-40E	Liner Trial
2200-40F	Screw Liner Trial
2200-40G	Screw Liner Trial
2200-40H	Screw Liner Trial
2200-40I	Screw Liner Trial
2200-40J	Screw Liner Trial
2200-44F	Liner Trial
2200-44G	Liner Trial
2200-44H	Screw Liner Trial
2200-44I	Screw Liner Trial
2200-44J	Screw Liner Trial

Impactor Tips

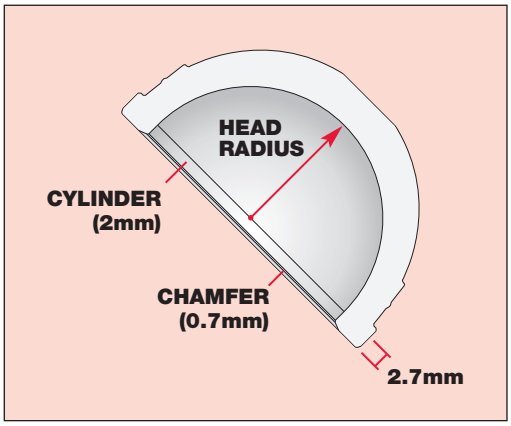
Catalog No.	Instrument Description
2111-3040	Plastic Impactor Tip
2111-3044	Plastic Impactor Tip
2111-0040	Silicone Impactor Tip
2111-0044	Silicone Impactor Tip

Cases & Trays

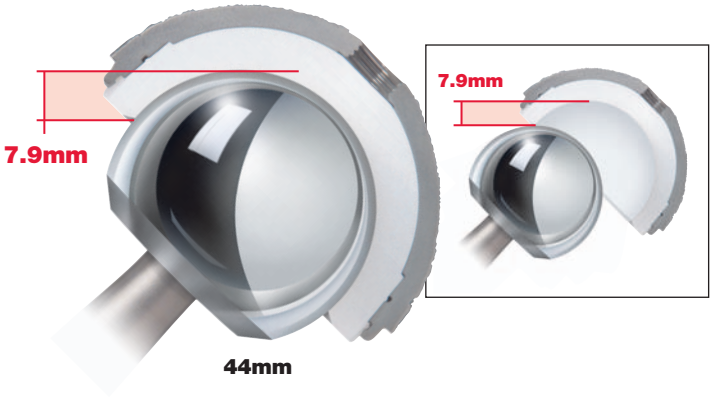
Catalog No.	Description
2402-1000	V40 Single Layer Sterilization Case
2402-1010	C-Taper Single Layer Sterilization Case
2402-1020	V40 Instrument Tray
2402-1030	C-Taper Instrument Tray
8000-0150	Sterilization Case Lid

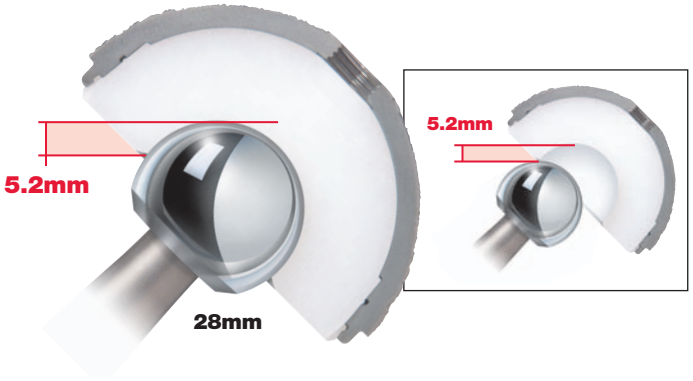
Jump Distance = Head Radius + 2.7mm Dislocation Safety Factor

Jump distance is defined as the vertical distance the femoral head must travel to dislocate after impingement. Jump distance is only clinically relevant when it more closely mimics natural anatomy and is measured at 45°.

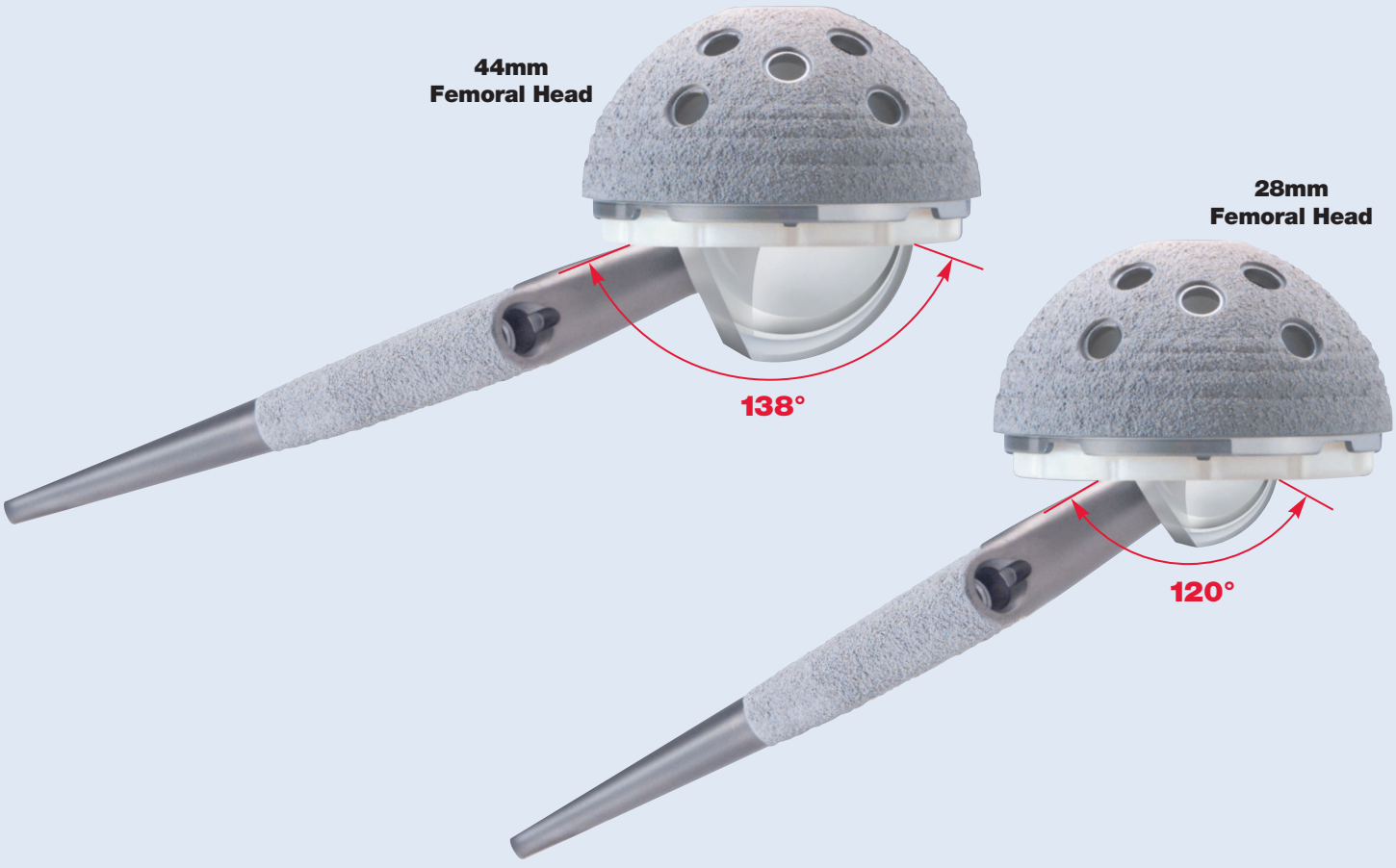


Jump Distance at 45°	
Head Diameter	**Jump Distance**
28mm	5.2mm
32mm	6.1mm
36mm	6.7mm
40mm	7.3mm
44mm	7.9mm





Increased Head Diameter = Increased ROM[3]



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3. ROM assessment was performed using the following components: Accolade TMZF hip stem, 127°, size 3; +0mm C-Taper femoral heads; and Trident 0° inserts.
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5. Maruyama M., Capello W., D'Antonio D., et al. "Effect of Low Friction Ion Treated Femoral Heads on Polyethylene Wear Rates," *CORR*, No. 370, pp. 183-191.
6. Wang A., Manley M., Serekian P., "Wear and Structural Fatigue Simulation of Crosslinked Ultra-High Molecular Weight Polyethylene for Hip and Knee Bearing Applications," Crosslinked and Thermally Treated Ultra-High Molecular Weight Polyethylene for Joint Replacements, ASTM STP1445, S.M. Kurtz, R. Gsell, and J. Martell, Eds., ASTM International,West Conshohocken, PA, 2003, pp. 151-168.
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8. Stryker Orthopaedics Test Report: RD-03-082
9. Stryker Orthopaedics Trident Acetabular Inserts made of X3 UHMWPE (unsterilized), 721-00-32E, show a 97% reduction in volumetric wear rate versus the same insert fabricated from N2\Vac 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 32 mm 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 N2\Vac gamma sterilized UHMWPE inserts and 1.35 ± 0.68 mm3/106 cycles for X3 UHMWPE (unsterilized) 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.[a, b, c]
10. X3 UHMWPE maintains mechanical properties after accelerated oxidative aging. No statistical difference was found for Tensile Yield Strength, Ultimate Tensile Strength and Elongation as measured per ASTM D638 before and after exposure to ASTM F2003 accelerated aging (5 Atmospheres (ATM) of oxygen at 70°C for 14 days). Tensile Yield Strength was 23.5 ± 0.3 MPa and 23.6 ± 0.2 MPa, Ultimate Tensile Strength was 56.7 ± 2.1 MPa and 56.3 ± 2.3 MPa, and Elongation was 267 ± 7% and 266 ± 9% before and after accelerated oxidative aging, respectively.
11. X3 UHMWPE resists the effects of oxidation. No statistical difference was found for Tensile Yield Strength, Ultimate Tensile Strength, Elongation, Crystallinity and Density as measured per ASTM D638, D3417 and D1505 before and after ASTM F2003 accelerated aging (5 ATM of oxygen at 70°C for 14 days). Tensile Yield Strength was 23.5 ± 0.3 MPa and 23.6 ± 0.2 MPa, Ultimate Tensile Strength was 56.7 ± 2.1 MPa and 56.3 ± 2.3 MPa, Elongation was 267 ± 7 % and 266 ± 9%, Crystallinity was 61.7 ± 0.6% and 61.0 ± 0.5%, and Density was 939.2 ± 0.1 kg/m3 before and after accelerated oxidative aging, respectively.
12. Yau S.S., Wang A., Essner A., Manley M., Dumbleton J., "Sequential Irradiation and Annealing of Highly Crosslinked Polyethylenes: Resist Oxidation without Sacrificing Physical/Mechanical Properties," Transactions of the 51st Annual Meeting of the Orthopaedic Research Society; Washington, DC, 2005: 1670.
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c. Essner A., et al., 47th Annual Meeting, ORS, San Francisco, Feb. 25-28, 2001:1007.

13. X3 UHMWPE maintains mechanical properties for Tensile Yield Strength and Ultimate Tensile Strength of N_2\Vac gamma sterilized UHMWPE as measured by ASTM D638. Tensile Yield Strength was 23.2 ± 0.4 MPa and 23.5 ± 0.3 MPa for N_2\Vac UHMWPE and X3 UHMWPE respectively. Ultimate Tensile Strength was 54.8 ± 2.5 and 56.7 ± 2.1 MPa for N_2\Vac UHMWPE and X3 UHMWPE respectively.

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