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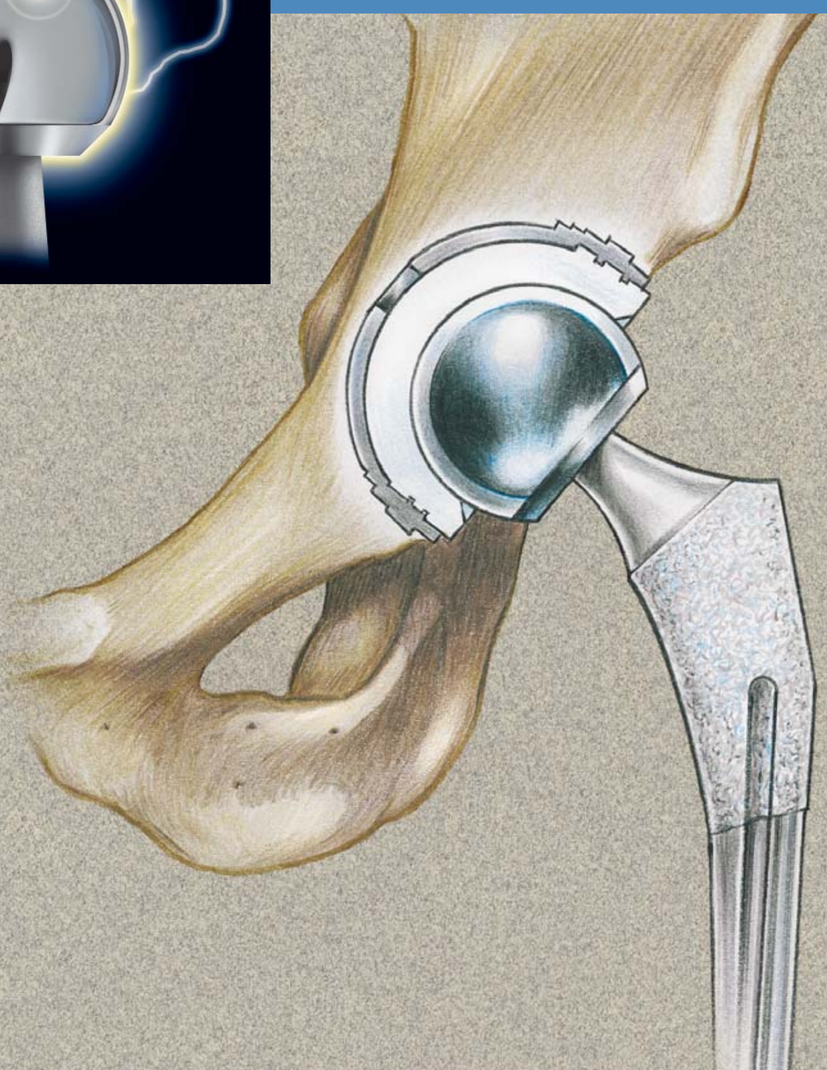
stryker®

Orthopaedics

LFIT™ Anatomic
CoCr Femoral Heads with X3® Liners

Frequently Asked Questions



X3® The Power of Technology

Preserving Strength | Reducing Wear | Resisting Oxidation

LFIT™ Anatomic CoCr Femoral Heads with X3® Liners

1. What is an LFIT™ Anatomic CoCr Femoral Head?

LFIT™ Anatomic CoCr Femoral Heads are Stryker®'s solution to surgeon's requests for large heads. Previously available in a 36mm diameter, 40mm and 44mm diameter options are now available in both C-Taper and V40™ taper dimensions. These Cobalt Chrome heads are manufactured using the same Low Friction Ion Treatment (LFIT™) process used by Stryker® for nearly 15 years.

2. What are the clinical advantages of LFIT™ Anatomic CoCr Femoral Heads?

LFIT™ Anatomic CoCr Femoral Heads, available in 36mm, 40mm, and 44mm diameters, offer surgeons the intra-operative flexibility to match patient anatomy and better restore natural biomechanics.

Larger femoral heads are designed to potentially:

- Restore stability in hips
- Prevent dislocation
- Increase ROM

The combination of a large femoral head and a corresponding liner and socket enhances capsular stability and better mimics the natural anatomy. Publications have demonstrated that the larger the femoral head, the greater the distance it must travel before the hip will dislocate.[1] Additionally, ROM increases as the ratio of the head diameter to the neck diameter increases.

3. What size diameters are LFIT™ Anatomic CoCr Femoral Heads available in?

LFIT™ Anatomic CoCr Femoral Heads are available in 36mm, 40mm, and 44mm diameters.

LFIT™ CoCr Heads are available in 22mm, 26mm, 28mm, and 32mm.

	LFIT™ Anatomic Head Offsets	
Head Size	C-Taper	V40™
36mm	-5, +0, +5, +10	-5, +0, +5, +10
40mm	-5, -2.5, +0, +2.5, +5, +7.5 +10	-4, +0, +4, +8, +12
44mm	-5, +0, +5	-4, +0, +4

4. What stem tapers are LFIT™ Anatomic CoCr Femoral Heads compatible with?

C-Taper and V40™

5. What Trident® cups and X3® liners are compatible with the 36mm, 40mm, and 44mm LFIT™ Anatomic CoCr Femoral Heads? What are the X3® insert thicknesses?

Head Size	Trident® Cup (PSL®/Hemispherical)	Insert Code	Insert Thickness (mm)
36mm	50/52	E	5.9
	54/56	F	7.9
	58/60	G	9.4
	62/64	H	11.2
	66/68	I	12.7
	70/72	J	14.7
40mm	54/56	F	5.8
	58/60	G	7.4
	62/64	H	9.1
	66/68	I	10.6
	70/72	J	12.6
44mm	62/64	H	7.1
	66/68	I	8.6
	70/72	J	10.6

6. Can LFIT™ Anatomic, 40mm and 44mm diameter, CoCr Femoral Heads be coupled with conventional polyethylene or Crossfire® polyethylene liners?

No, 40mm and 44mm heads can only be paired with X3® polyethylene liners.

It is important to note that the X3® technology is essential for the use of the 40mm and 44mm LFIT™ Anatomic CoCr Femoral Heads. Wear performance, combined with strength and functional fatigue characteristics of X3® polyethylene allows for a reduced thickness liner to accommodate the LFIT™ Anatomic CoCr Femoral Head.

7. What is the femoral head diameter in a non-diseased hip joint?

Multiple studies have been conducted to determine the anatomic range of the femoral geometry as a basis for designing new implants that better replicate natural anatomy. Dr. Phil Noble performed a femoral analysis that classified femoral canal shapes into a finite set of unique geometries called somatypes. These somatypes were the basis for the Partnership® stem design.[2]

This same analysis resulted in the finding that the average femoral head diameter (as measured in 200 non-diseased cadavers) ranges between 35mm and 58mm (average 46.1mm). LFIT™ Anatomic CoCr Femoral Heads, available in 36mm, 40mm, and 44mm diameters, provide surgeons with yet another option to help reproduce more natural anatomy.[2]

LFIT™ Technology

8. What does LFIT™ stand for and why is it important?

LFIT™ stands for "Low Friction Ion Treatment." LFIT™ is a manufacturing technology that enhances the material properties of CoCr to reduce frictional forces against UHMWPE surfaces, which results in the potential for reduced polyethylene wear. The LFIT™ process:

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

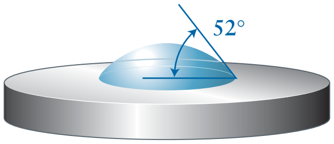


Figure 1
LFIT™ CoCr Wettability

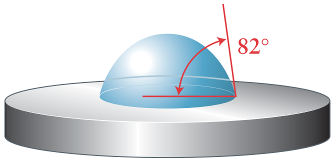


Figure 2
CoCr Wettability

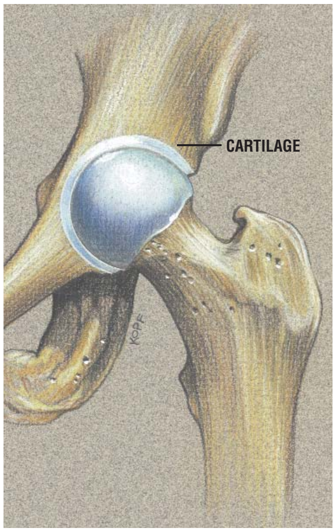


Figure 3
Anatomic Hip Naturally Lubricated

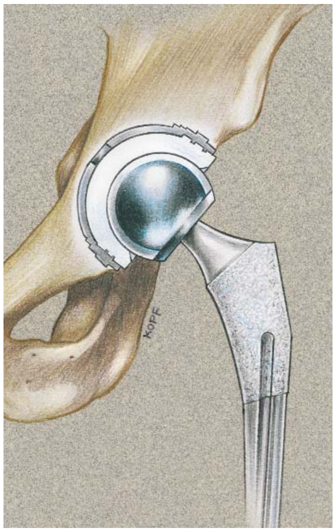


Figure 4
Hip Replacement Allowing Increased Lubrication

9. What clinical and laboratory data is available on the LFIT™ technology?

Clinical Data: Drs. D'Antonio, Capello, et al., published a study in *CORR* in 2004 that shows that LFIT™ heads demonstrated a 28% reduction in linear wear over CoCr heads in 110 patients at a minimum 3-year follow-up.[4]

Laboratory Data: A scientific report was published in *Surface Modification Technologies* that demonstrates that the LFIT™ process reduces the cup insert wear rate by 19% when compared to untreated CoCr within the first million cycles in bovine serum.[5]

LFIT™ Anatomic CoCr Femoral Heads with X3® Liners

X3® Technology – Wear and Strength Matters

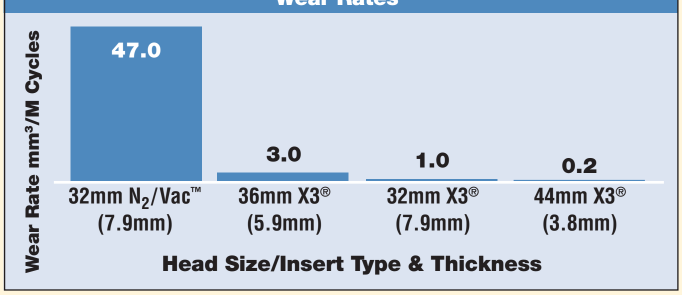
10. Why is the X3® Advanced Bearing Technology important for the use of LFIT™ Anatomic CoCr Femoral Heads?

The unique material characteristics of X3® allows the potential use of larger size femoral heads without affecting the bearing performance. Wear performance, combined with strength and functional fatigue characteristics of X3® polyethylene allows for the opportunity to implant a larger head in a smaller shell by reducing the insert thickness without compromising clinical outcomes.[6,7]

11. Is there a difference in wear rates between an LFIT™ Anatomic CoCr Femoral Head on X3® compared to conventional polyethylene?

Yes. Laboratory results show that the wear rates of an LFIT™ Anatomic CoCr Femoral Head on X3® are less than an LFIT™ Anatomic CoCr Femoral Heads on conventional polyethylene. See chart below.

Wear Rates[6]



Data Source: Test Reports: RD-04-029, RD-06-021 Rev. 2.

12. Do large diameter heads increase the potential for polyethylene wear as compared to smaller diameter heads?

Not when used with the X3® technology!

The physical reality is that larger heads and their increased contact area produce more wear than smaller heads with smaller contact areas.

Studies have shown that "the wear rate of conventional polyethylene liners increase with increasing femoral head size. In contrast, highly crosslinked polyethylene liners showed no detectable wear for femoral head sizes 46mm in diameter. Wear against highly crosslinked material was independent of head size over the range of head diameters from 22mm to 46mm."[8]

Highly Crosslinked Polyethylene Liners		
Inner/Outer Diameter/Liner Thickness (mm)	**Total Simulated Gait Cycles (millions)**	**Wear Rate of EtO Sterilized Highly Crosslinked Polyethylene (mm^3/M Cycles)**
22/39/5	27	-1.3 ± 0.1
28/41/3	27	-0.9 ± 0.5
38/51/3	11	-2.6 ± 1.2
46/59/3	11	-2.1 ± 1.5

Conventional Polyethylene Liners		
Inner/Outer Diameter/Liner Thickness (mm)	**Total Simulated Gait Cycles (millions)**	**Wear Rate of Gamma Sterilized Conventional Polyethylene (mm^3/M Cycles)**
22/39/5	27	13 ± 1.9
28/49/7	27	17 ± 1.2
46/59/3	11	48 ± 4.9

Data Source: Muratoglu, O., et al., "Larger Diameter Femoral Heads Used in Conjunction With a Highly Cross-linked Ultra-High Molecular Weight Polyethylene," *The Journal of Arthroplasty*, Vol. 16, No. 8, Suppl. 1, December 2001:24-30.

Note: The wear rates were calculated by the linear regression of the gravimetric measurements.

13. Some competitive highly crosslinked liners have been reported on the FDA web site for failure. Retrieval information appears to indicate that the rim of these liners create a higher propensity for failure under high loads. How do we anticipate X3® inserts to perform under similar rim-loading conditions?

During laboratory testing, X3® inserts did not break during aggressive rim loading conditions. The combination of a vertical cup and subluxation (the movement of the femoral head in and out of the acetabulum) can cause an insert to break. X3® inserts were tested with a shell at 67.5° (inclination angle), subluxation at 10%, and a compressive load of 375 lbs.[7]

These test parameters were based on a Crowninshield study, where competitive inserts fractured using the same test methodology.[9]

Jump Distance/Range of Motion

14. What is "jump distance" and its clinical relevance?

Jump distance is used to describe the distance a femoral head must travel to dislocate. 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

Due to the increased diameter of an LFIT™ Anatomic CoCr Femoral Head, the jump distance is increased and the risk of dislocation is reduced. With a smaller head, the jump distance is decreased and the risk of dislocation is potentially increased.

15. Why is ROM important? What happens when impingement occurs?

Range of motion is important because it allows the patient to obtain optimal movement and activity post-operatively. The combination of an LFIT™ Anatomic CoCr Femoral Head paired with one of Stryker®'s reduced neck geometry stems can potentially influence a patient's hip movement, as well as stability and dislocation resistance.

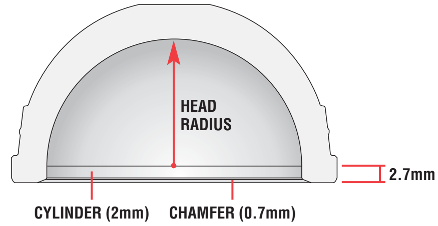
According to a Burroughs study, greater ROM was observed for larger heads (38mm and 44mm) compared with 28mm and 32mm. In laboratory testing, larger head sizes were shown to provide greater ROM before impingement. This is beneficial for joint stability considering that impingement is the precursor to dislocation. If impingement occurs, a greater amount of translation between the femoral head and acetabulum is required to achieve dislocation.[10]

There are three types of impingement:

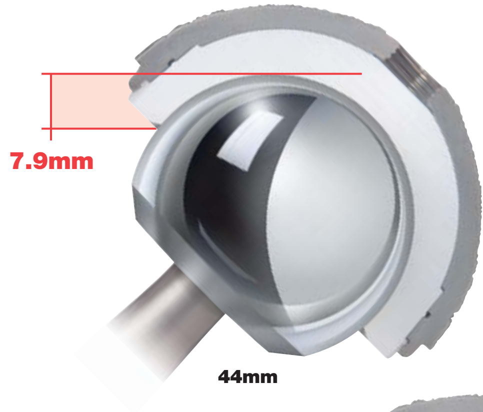
- Bone on bone/soft tissue
- Bone on component
- Component on component

16. What is the maximum ROM with the LFIT™ Anatomic CoCr Femoral Heads?

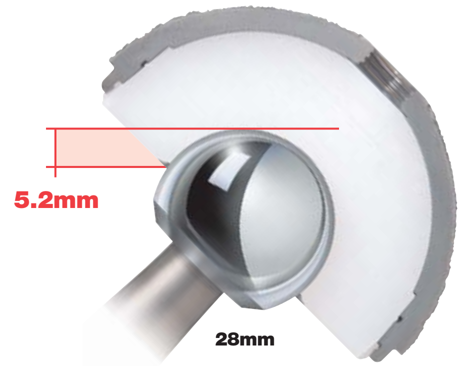
The maximum ROM (A/P sweep) for the LFIT™ Anatomic CoCr Femoral Heads is 148° when used with an Accolade® C (Size 7) hip stem, 44mm +8 offset head, and 44mm ID insert. Achievable ROM will vary with varying component size, implant position, and neck geometry.



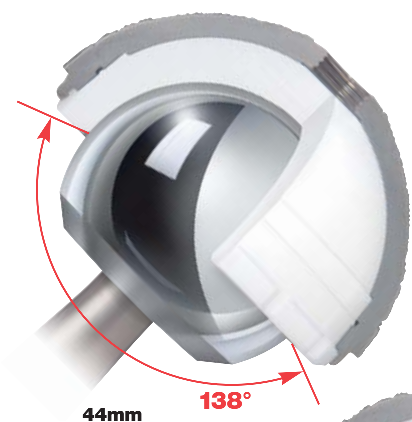
Jump Distance = Head Radius + 2.7mm Dislocation Safety Factor

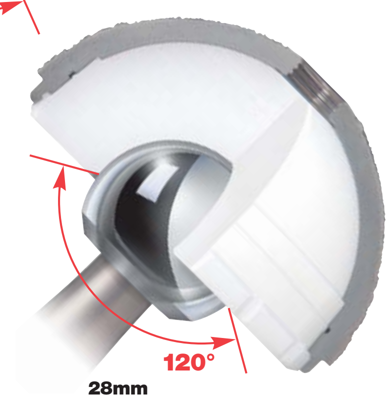


Jump distance is defined as the vertical distance the femoral head must travel to dislocate after impingement. Jump distance is only clinically relevant when it more closely mimics natural anatomy and is measured at 45°.



Increased Head Diameter = Increased ROM





LFIT™ Anatomic CoCr Femoral Heads with X3® Liners

Competition

17. What large head bearing systems are currently available on the market?

	Competitor			
	Zimmer®	Biomet®	Wright®	DePuy®
Head Sizes	38mm, 44mm	40-60mm Modular Heads	36-54mm	39-55mm
Brand	Durasul® VerSys®/Longevity® Metasul® LDH	M2a™ Magnum	Conserve® BFH®	ASR™ XL
Sleeves	no	yes	no	yes
Insert	highly x-linked polyethylene	metal-on-metal	metal-on-metal	metal-on-metal
ROM	140°	154-162°	up to 167°	—

*Only cleared for use with polyethylene inserts.

LFIT™ Anatomic/X3®/Trident® Acetabular System Positioning

18. How do I position LFIT™ Anatomic CoCr Femoral Heads with X3® liners with the other combinations of bearing surfaces available from Stryker®?

Stryker® offers a wide breadth of products to address the varying and changing requirements of a diverse patient population. Selection of hip replacement components is a clinical judgement best made by the physician for each individual patient.

Primary Issue	Bearing Surfaces
Wear	***Ceramic on Ceramic* still offers the best possible solution for wear as a hard-on-hard bearing, virtually eliminating wear and the potential for osteolysis**. It should be maintained as the premium bearing coupling. However, the alumina ceramic material limits the design options (i.e. hooded inserts, 40mm and 44mm Anatomic and skirted heads) that are readily available in other material constructs.
Dislocation	***LFIT™ Anatomic CoCr Femoral Heads with X3® liners* are an ideal solution for surgeons to address the short and long-term dislocation consequences sometimes associated with THA**. The X3® advanced bearing material addresses the three major factors influencing failure after THA including wear, strength, and oxidation. The X3® bearing, when coupled with LFIT™ Anatomic CoCr (36mm, 40mm, and 44mm) Femoral Heads provides surgeons the potential for enhanced hip stability, increased ROM, and decreased dislocation without compromising wear rates and material strength.
Strength	***X3® and Biolox®* delta *Ceramic Heads* provide a solution for surgeons that are concerned with the strength of a bearing coupling.** This combination provides you an advanced bearing couple that addresses the major factors influencing failure after THA while also offering a ceramic head with 50% greater strength than the alternative alumina ceramic. This also gives the surgeon the opportunity to mate Biolox® *delta* heads directly with a cobalt chrome stem; an advantage not available with alumina ceramic heads.

19. Does Stryker® have plans to manufacture a metal insert for the Trident® System?

No. Stryker® does not have plans to manufacture a metal insert for the Trident® Acetabular System. The portfolio of bearing options currently available are excellent designs that offer significant advantages over the competition, while addressing the major factors associated with failure of hip replacement surgery. The Trident® Alumina/Alumina ceramic bearing couple and the X3®/LFIT™ and X3®/Biolox® *delta* ceramic couple combinations offer surgeons a broad selection of products that address the clinical performance requirements of patients.

Pricing Analysis

20. What is the pricing strategy for the heads? Can the LFIT™ Anatomic CoCr Femoral Heads be discounted?

The LFIT™ Anatomic and X3® process and material technologies offer surgeons an alternative bearing couple designed to address the major factors influencing failure of Total Hip Surgery including wear, strength, and dislocation. These products have been priced within this alternate bearing category. For additional information on Hospital Pricing, please contact any member of the Primary Hip Marketing Team. Discounting questions and concerns should be discussed with your local/regional sales leaders.

Instrumentation

21. What instruments are available for LFIT™ Anatomic CoCr Femoral Heads and X3® Liners?

V40™ LFIT™ Anatomic Head Trials

Trial Cat. No.	Instrument Description
2402-1000	LFIT™ Anatomic V40™ Instrument Tray
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
2402-1010	LFIT™ Anatomic C-Taper Instrument Tray
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
2200-40F	Screw Liner Trials
2200-40G	Screw Liner Trials
2200-40H	Screw Liner Trials
2200-40I	Screw Liner Trials
2200-40J	Screw Liner Trials
2200-44H	Screw Liner Trials
2200-44I	Screw Liner Trials
2200-44J	Screw Liner Trials

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

** *X3® Liner Trials and Impactor Tips accommodate both the V40™ and C-Taper Instrument Trays.*

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

Supporting Literature

22. What supporting literature is available for the *New* LFIT™ Anatomic CoCr Femoral Heads?

Literature No.	Description
LRP186	Burroughs, Brian R. "Range of Motion and Stability in Total Hip Arthroplasty With 28, 32, 38 and 44mm Femoral Head Sizes," *JOA*, Vol. 20, No. 2005.
LRP188	Crowninshield, Roy D. "Biomechanics of Large Femoral Heads," *Clinical Orthopedics*, Number 429, pp. 102-107.
LRP189	Berry, Daniel J. "Effect of Femoral Head Diameter and Operative Approach on Risk of Dislocation After Primary Total Hip Arthroplasty," *JBJS*, November 4, 2005.
LRP43	Effect of Low Friction Ion Treated Femoral Heads on Polyethylene Wear Rates.
LLACX3-B	LFIT™ Anatomic CoCr Femoral Head Brochure.
LLACX3-SS	LFIT™ Anatomic CoCr Femoral Head Sell Sheet.
LFIT-B	LFIT™ Brochure.

For a complete list of supporting literature for the LFIT™ Anatomic Femoral Heads, go to MyStryker Sales, Literature List.

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Navigation

Endoscopy

Communications

Imaging

Patient Handling Equipment

EMS Equipment

References

1. Berry D., et al., "Effect of Femoral Head Diameter and Operative Approach on Risk of Dislocation After Primary Total Hip Arthroplasty," *The Journal of Bone and Joint Surgery*, Vol. 87-A, No. 11, November 2005, pp. 2456-2463
2. Nobel P., et al., "The Anatomic Basis of Femoral Component Design," *CORR* No. 235, October 1988, pg. 148-165
3. Stryker Orthopaedics Technical Report: RD910301.
4. 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.
5. Taylor S., "Reduction in Polyethylene Wear through Ion-Implantation in to CoCr Alloy," Surface Modification Technologies VI, The Minerals, Metals & Materials Society, 1993.
6. Stryker Orthopaedics Technical Report: RD-06-021 Rev. 1.
7. Stryker Orthopaedics Technical Report: RD-06-044.
8. Muratoglu O., et al., "Larger Diameter Femoral Heads Used in Conjunction With a Highly Cross-linked Ultra-High Molecular Weight Polyethylene," *The Journal of Arthroplasty*, Vol. 16, No. 8, Suppl. 1, December 2001:24-30.
9. Crowninshield R., et al., "Biomechanics of Large Femoral Heads", *Clinical Orthopaedics and Related Research*, No. 429, pp. 102-107.
10. Burroughs R., et al., "Range of Motion and Stability in Total Hip Arthroplasty with 28-, 32-, 38- and 44-mm Femoral Head Sizes," *The Journal of Arthroplasty*, Vol. 20, No. 1, January 2005: 11-19.

Claims

1. 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 N_2\Vac™ gamma sterilized UHMWPE, 620-00-32E. The insert tested was 7.5 mm thick with an inner diameter of 32mm. 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 mm^3/106 cycles for N_2\Vac™ gamma sterilized UHMWPE inserts and 1.35 ± 0.68 mm^3/106 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]

2. 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.

3. 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/m^3 before and after accelerated oxidative aging, respectively.

a. Wang A., et al., *Tribology International*, Vol. 31, No. 1-3:17-33, 1998.
b. Essner A., et al., 44th Annual Meeting, ORS, New Orleans, Mar. 16-19, 1998:774.
c. Essner A., et al., 47th Annual Meeting, ORS, San Francisco, Feb. 25-28, 2001:1007.

4. 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.

The information presented in this material is intended to demonstrate the breadth of Stryker product offerings. Always refer to the package insert, product label and/or user instructions before using any Stryker product. Surgeons must always rely on their own clinical judgment when deciding which treatments and procedures to use with patients. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Literature Number: **LLACFAQ**
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