X3™
Sequentially Annealed Irradiated Polyethylene

Hips
As a pioneer in wear performance technologies, Stryker® Orthopaedics has been dedicated to offering bearing surface improvements.

**Introduced in 1998, the clinical success of Crossfire™ Polyethylene has been highlighted in studies such as those presented by James D’Antonio, MD.**

- Mean 5-year follow-up.
- No structural failures.
- 72% reduction in total annual wear thus far.

**Robert Krushell, MD and Richard Fingeroth, MD also presented Crossfire data at the 2005 ORS.**

- ORS mean 4-year follow-up.
- 58% reduction of linear head penetration compared with standard polyethylene.
- No oxidation related failures in retrievals up to 5 years.

**Steve Kurtz, PhD, et al. presented a poster at the 2005 AAOS.**

- Implanted for period of time between 0 and 4.8 years, with none retrieved for wear or osteolysis.
- Minimal creep and wear was observed in retrievals.

**In 2005 Bo Nivbrant, MD and PhD, presented mean 4.5 years RSA data at the 51st annual ORS showing extremely low in vivo wear.**

- 90% wear reduction over the 0.05mm/annum suggested as a clinically safe level.

Traditional crosslinking consists of a two-step process involving both irradiation and a subsequent heat treatment step. Stryker’s patented highly crosslinked and annealing process provides wear reduction without compromising structural strength.

Building upon the clinical success of Crossfire™ Polyethylene, Stryker developed a third generation annealing process with three sequential irradiation/annealing steps to create X3™ Polyethylene.
X³™ Polyethylene is the first highly crosslinked polyethylene to offer simultaneously:

- Superior Structural Fatigue Strength\(^5,6\)
- Greater Wear Reduction than first generation highly crosslinked polyethylene\(^7\)
- Oxidation Resistance\(^6,8\)

Remelting following irradiation of polyethylene significantly alters the crystallinity and crystalline morphology, with up to a 35% drop in ultimate tensile strength and a 15% drop in yield stress. (Figure 1)\(^5\)

In contrast, annealing following irradiation has been shown to maintain those morphologies leading to preserved structural strength. (Figure 2)\(^5,6\)

Figure 1: The higher the irradiation dose, the more remelting compromises the strength of the polyethylene.

Figure 2: In laboratory studies of rim loaded thin acetabular liners made from different crosslinked polyethylene materials, highly crosslinked (10 MRads of irradiation) remelted liners fractured 100% of the time before 1 Million cycles, while 70% of the moderately crosslinked (5 MRads of irradiation) remelted polyethylene liners fractured.

Fractured 10 MRads e-beam remelted liner used for structural fatigue test.
Stryker Orthopaedics’ laboratory testing continues to be validated by clinical performance for first and second-generation crosslinked annealed polyethylene products.  

- In 2005, Grimm, et al. reported that Duration™ Polyethylene shows a clinical wear reduction of 30% over gamma-air conventional polyethylene.  

- Five-year data of Crossfire™ Polyethylene reported by D’Antonio, et al. shows better than 70% wear reduction than conventional polyethylene at the time of follow-up, while 4.5-year RSA data reported by Nivbrant, et al. revealed a 90% wear reduction over the suggested clinically safe level.  

97% Wear Reduction  

X3™ Polyethylene has 97% reduction in wear over conventional (gamma-inert sterilized) polyethylene, better than second-generation crosslinked annealed polyethylene.
X3™ Polyethylene demonstrates high oxidation resistance under extreme laboratory conditions (immersion in 5 atmospheres (ATM) of oxygen at 70°C for 14 days).8,9 (Figure 4)

X3™ Polyethylene maintains mechanical properties after accelerated oxidative age laboratory testing. No statistical difference was found for tensile-yield strength, ultimate tensile strength, and elongation.14 (Figure 5)8, 9

X3™...The Power of Technology

The first highly crosslinked polyethylene to offer simultaneously:

- Structural fatigue strength better than conventional polyethylene1,6
- 97% wear reduction; greater than first generation highly crosslinked polyethylene7
- Oxidation resistance similar to virgin polyethylene8,9
References

8. 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.
9. 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.
12. Stryker Orthopaedics Trident™ Acetabular Inserts made of X3™ UHMWPE, 721-00-32E, show a 97% reduction in volumetric wear rate versus the same insert fabricated from N2Vac™ gamma sterilized UHMWPE, 620-00-32E. The insert tested was 7.5mm 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.

Solely for use by Health Care professionals

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Literature Number: MTXLX3HB

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