# X3® The Power of Technology

Preserving Strength | Reducing Wear | Resisting Oxidation

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References:


1. Wang A, Manley M, Serekian P. "Wear and Structural Fatigue Simulation of Crosslinked Ultra-High Molecular Weight Polyethylene for Hip and Knee Bearing Applications." In: Kurtz SM, Gsell R, and Martell J, eds. Crosslinked and Thermally Treated Ultra-High Molecular Weight Polyethylene for Joint Replacements; ASTM STP1445. West Conshohocken, PA: ASTM International; 2003:151-168.

2. Essner A, et al. "Acetabular Liner Function Fatigue Performance of Crosslinked UHMWPE." 51st Annual ORS Paper no. 0245; Washington, DC, 2005.

3. Stryker® Orthopaedics Test Report: RD-03-082.

4. Stryker® Orthopaedics Triathlon® CR Tibial Inserts made from X3® UHMWPE, 5530-G-409 show a 68% reduction in volumetric wear rate versus the same insert fabricated from $N_2$\Vac™ gamma sterilized UHMWPE, 5530-P-409. The insert tested was Size 4, 9 mm thick. Testing was conducted under multiaxial knee simulator (multi-station MTS knee joint simulator[a]) for five million cycles using appropriate size CoCr counterfaces, a specific type of diluted calf serum lubricant and the motion and loading conditions, representing normal walking, outlined in ISO/DIS 14243-3. Volumetric wear rates were 17.7 ± 2.2 $mm^3/10^6$ cycles for standard polyethylene inserts and 5.7 ± 1.5 $mm^3/10^6$ cycles for test samples. Test inserts were exposed to a gas plasma sterilization process. In vitro knee wear simulator tests have not been shown to quantitatively predict clinical wear performance.

5. Stryker® Orthopaedics Triathlon® PS Tibial Inserts made of X3® UHMWPE, 5532-G-409 show a 64% reduction in volumetric wear rate versus the same insert fabricated from $N_2$\Vac™ gamma sterilized UHMWPE, 5532-P-409. The insert tested was Size 4, 9 mm thick. Testing was conducted under multiaxial knee simulator (multi-station MTS knee joint simulator[a]) for five million cycles using a size 7 CoCr counterfaces, a specific type of diluted calf serum lubricant and literature or fluoroscopy based motion and loading conditions representing stair climbing.[b, c] Volumetric wear rates were 3.6 ± 0.61 $mm^3/10^6$ cycles for standard polyethylene inserts and were 1.3 ± 0.44 $mm^3/10^6$ cycles for test samples. Test inserts were exposed to a gas plasma sterilization process. In vitro knee wear simulator tests have not been shown to quantitatively predict clinical wear performance.

6. Stryker® Orthopaedics Scorpio® CR Tibial Inserts made from X3® UHMWPE, 72-22-0708, show a 79% reduction in volumetric wear rate versus the same insert fabricated from $N_2$\Vac™ gamma sterilized UHMWPE, 72-2-0708. The insert tested was Size 7, 8 mm thick. Testing was conducted under multiaxial knee simulator (multi-station MTS knee joint simulator[a]) for five million cycles using appropriate size CoCr counterfaces, a specific type of diluted calf serum lubricant and the motion and loading conditions, representing normal walking, outlined in ISO/DIS 14243-3. Volumetric wear rates were 34.6 ± 1.5 $mm^3/10^6$ cycles for standard polyethylene inserts and 7.3 ± 0.7 $mm^3/10^6$ cycles for test samples. Test inserts were exposed to a gas plasma sterilization process. In vitro knee wear simulator tests have not been shown to quantitatively predict clinical wear performance.

7. Stryker® Orthopaedics Scorpio® PS Tibial Inserts made from X3® UHMWPE, 72-23-0708, show a 77% reduction in volumetric wear rate versus the same tibial insert fabricated from $N_2$\Vac™ gamma sterilized UHMWPE, 72-3-0708. The insert tested was Size 7, 8 mm thick. Testing was conducted under multiaxial knee simulator (multi-station MTS knee joint simulator[a]) for five million cycles using appropriate size CoCr counterfaces, a specific type of diluted calf serum lubricant and literature or fluoroscopy based motion and loading conditions representing stair climbing.[b, c] Volumetric wear rates were 35.8 ± 1.7 $mm^3/10^6$ cycles for standard polyethylene inserts and were 8.2 ± 0.7 m $m^3/10^6$ cycles for test samples. Test inserts were exposed to a gas plasma sterilization process. In vitro knee wear simulator tests have not been shown to quantitatively predict clinical wear performance.

8. 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 32 mm. Testing was conducted under multiaxial 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 m $m^3/10^6$ cycles for $N_2$\Vac™ gamma sterilized UHMWPE inserts and 1.35 ± 0.68 $mm^3/10^6$ 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.[d, e, f]

9. 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.

10. 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.

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12. D'Antonio J, Manley M, Capello W, Bierbaum B, et al. "Five-year Experience with Crossfire® Highly Cross-linked Polyethylene". CORR, No 441, 2005, pp. 143-150.

13. Essner A, Yau SS, Schmidig G, Wang A, Dumbleton J, Manley M, Serekian P. "Reducing Hip Wear Without Compromising Mechanical Strength: A Next Generation Crosslinked


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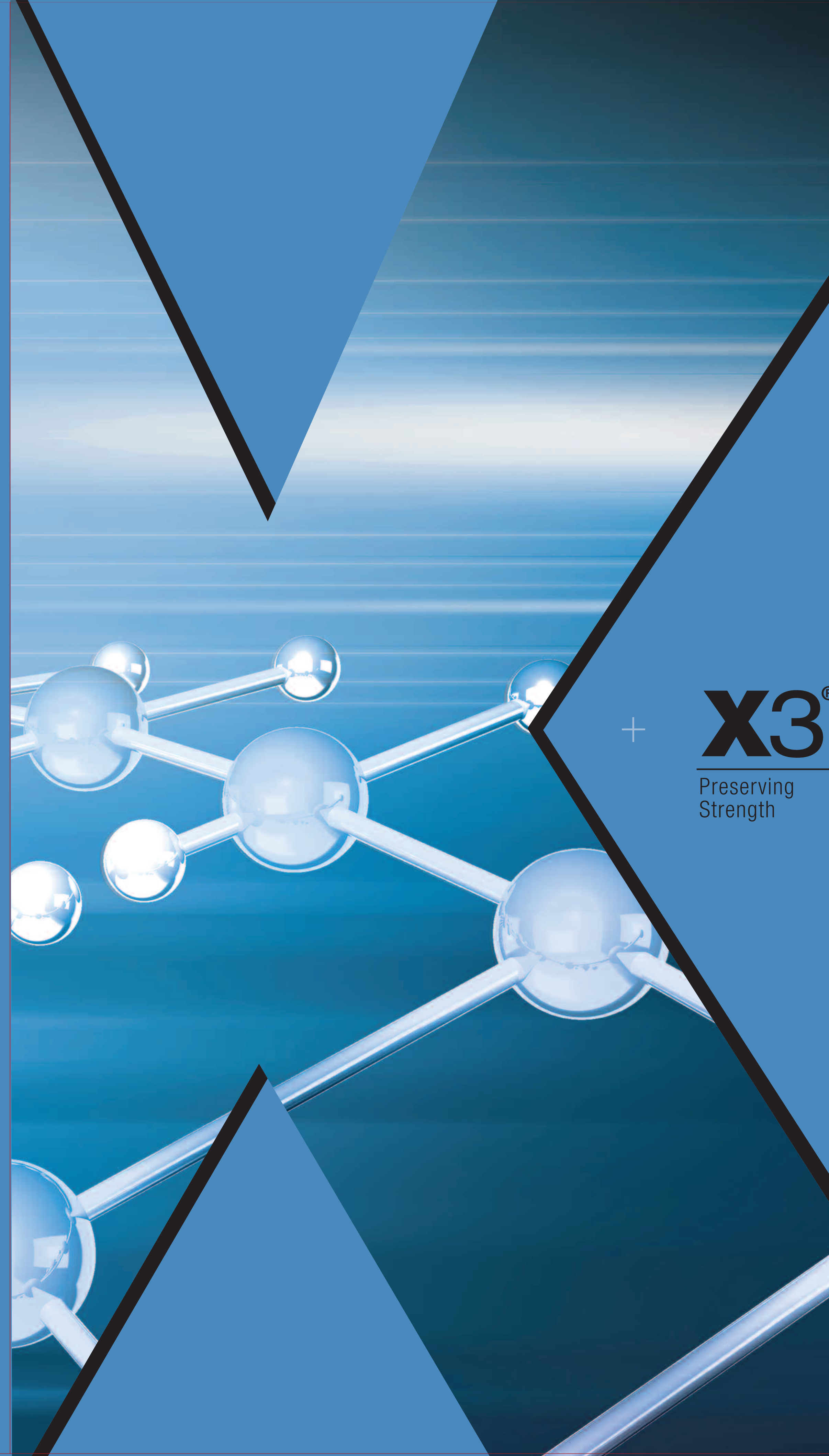

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**The information contained in this document is intended for healthcare professionals only.**

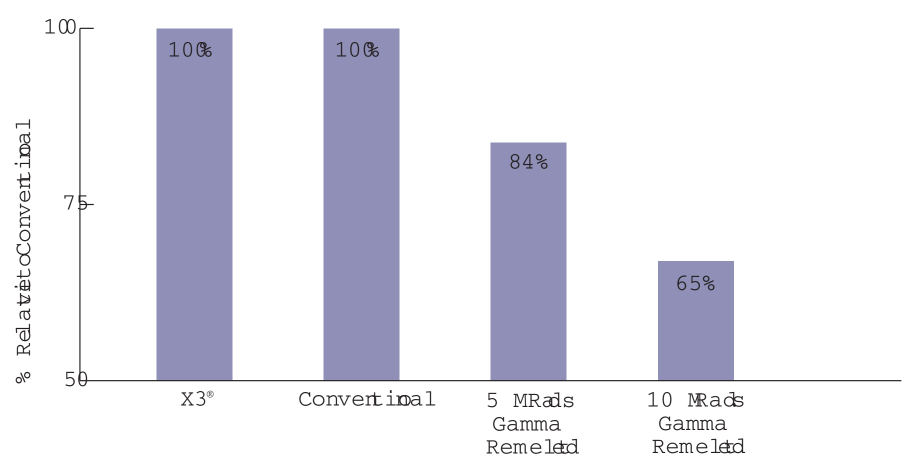
# Preserving strength matters for long-term performance of hip and knee replacements

The first generation of highly crosslinked polyethylene showed improved wear characteristics in hip liner applications compared to conventional polyethylene.[1,2] The process to achieve this improvement in wear characteristics may decrease the mechanical strength of the polyethylene, making it less than ideal for knee applications. Today, Stryker has developed an advanced polyethylene that improves wear characteristics while preserving mechanical strength, making it the ideal bearing for both hip and knee applications.

## Crystallinity Matters

Implants manufactured through commercial crosslinking methods are effective in reducing wear in applications such as hips, where a repetitive crossing pattern creates a high level of cross shear. When remelting heat treatment is used, reductions in crystallinity can cause a loss in strength.[1] The figure at right shows how X3® tensile strength stacks up against traditional polyethylene types.[1, 11, 13]

Tensile Strength




The higher the irradiation dose, the more remelting compromises the strength of the polyethylene.[1, 11, 13]

## X3®: Preserving Mechanical Strength

To promote crosslinking, irradiation is typically applied to virgin polyethylene. After irradiation, the material may be remelted in order to stabilize it. However, the process of irradiating and remelting polyethylene results in a loss of material strength including tensile yield and ultimate tensile strengths.[1] Applying an annealing heat treatment process below the melting temperature has been shown to stabilize polyethylene without compromising its mechanical strength.[11, 13, 14]

Stryker researchers have developed a method of sequential crosslinking and annealing that achieves wear reduction while preserving mechanical strength.[4-8, 11, 13, 14] X3® is sequentially crosslinked using three separate gamma radiation doses with an annealing step after each irradiation. Sequential irradiation and annealing provides more complete crosslinking with reduction

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# Reducing wear matters for long-term success of hip and knee replacements

Compared to conventional polyethylene, the first generation of highly crosslinked polyethylene has demonstrated improved wear characteristics in acetabular insert applications.[1,2] While the processing of this polyethylene significantly improves the wear characteristics, it may not achieve the functional strength of conventional polyethylene. The potentially reduced mechanical strength, combined with the biomechanical loading of the knee, limits the prudent application of this first generation highly crosslinked polyethylene in knee applications.

Stryker scientists have developed a breakthrough in bearing technology that results in a polyethylene bearing material that offers superior wear characteristics while preserving mechanical strength.[4-8, 11, 13, 14] The result is a bearing surface option with properties ideal for both hip and knee applications.

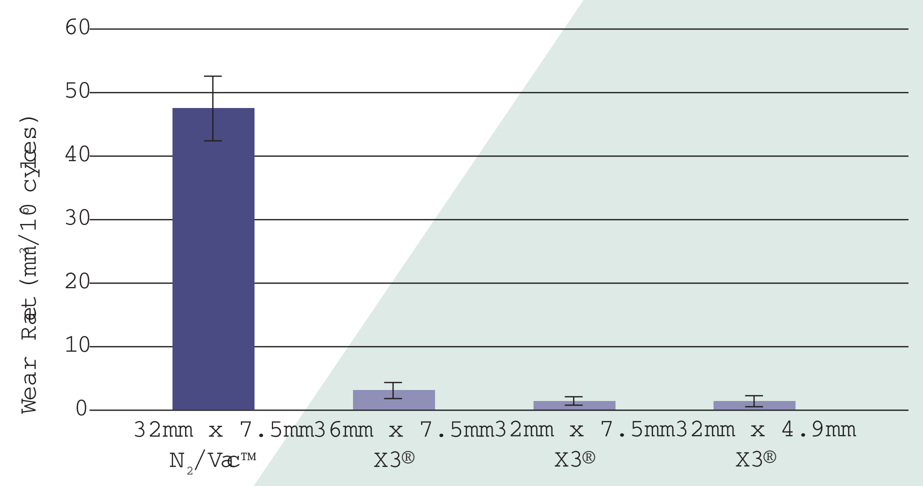
## Early Wear Solutions Caused Potential Compromises

Early efforts to improve wear resistance may not have achieved the same mechanical strength as conventional polyethylene. Radiation-induced crosslinking followed by remelting has shown to decrease tensile and yield strength of the polyethylene.[1]

## X3®: Improving Wear Without Compromise

Stryker scientists have developed a method of sequentially crosslinking polyethylene that achieves improved wear reduction over previous generations of polyethylene[4-8, 13, 16] while preserving mechanical strength similar to unaltered polyethylene.[11, 14] X3® is sequentially crosslinked using three separate gamma radiation doses with an annealing step following each irradiation. The sequential irradiation and annealing process provides a greater percentage of crosslinking with minimal free radicals.[11, 15, 17]

Wear Rate




Hip simulator testing comparing conventional and X3® polyethylene revealed that X3® wear rates did not vary significantly with head size or polyethylene thickness in the range shown.[8]

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# Resisting oxidation matters for confidence in long-term joint replacement outcomes

Delamination and pitting, sometimes reported in knee implant revisions, have been associated with evidence of oxidation and contact fatigue stress. While wear reduction in highly crosslinked polyethylene has provided long-term successes, today's patients are placing greater demands on both hip and knee replacements. Stryker scientists have developed a novel highly crosslinked polyethylene that provides oxidation resistance similar to virgin polyethylene without compromising strength.[9, 10, 11, 14]

## Expectations: TJA Patients

Demands on total joint replacements are continually increasing, fueled by patient expectations with respect to functional outcomes. When longer life expectancies are combined with these high expectations, lifestyle recovery objectives will result in new challenges for bearing surfaces. With these challenges, patients will demand technologies that provide improved material strength.

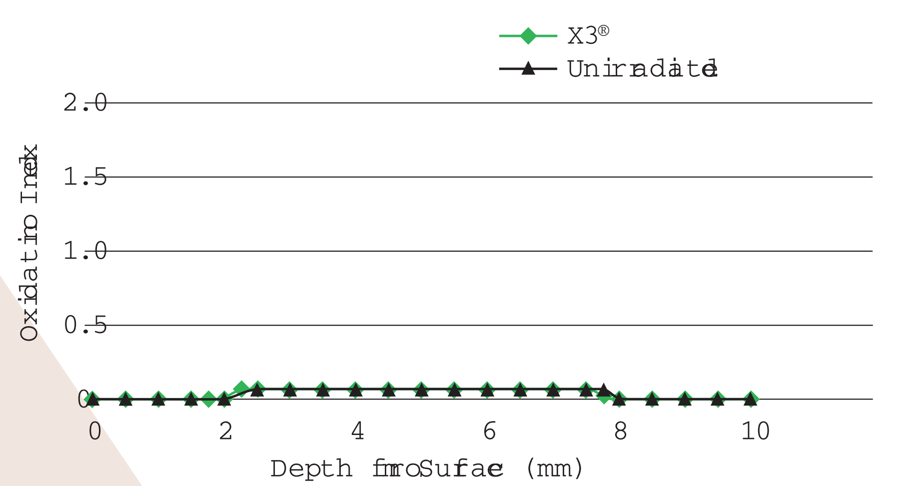
## Reassessing Remelting: Mechanical Strength Outcomes

Heat treatment has long been used after irradiation to encourage greater crosslinking while reducing free radical content. During this process, if the temperature is raised above the melting point, the crystalline structure and morphology of the polyethylene is altered. This remelting process affects the mechanical strength of the polyethylene. Specifically, it reduces the yield and ultimate tensile strengths.[1]

## X3®: A New Process to Resist Oxidation

Stryker researchers have found that annealing, in which polyethylene is heated below the melting temperatures, can reduce free radicals while preserving mechanical strength.[11,13-15] Further, a process of sequential crosslinking through a series of three irradiation doses and three annealing steps provides optimal strength and wear characteristics.[2, 4-8, 11, 13, 14, 16] This sequential crosslinking process

Oxidation Resistance

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## A Material Advancement in Hip and Knee Technology

X3® Polyethylene is the first highly crosslinked polyethylene to address three of the major causes of failure in hip and knee replacement surgery.

- Structural fatigue strength better than conventional polyethylene[1, 2]
- Improved wear reduction over conventional polyethylene and earlier crosslinked polyethylene[3-8]

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