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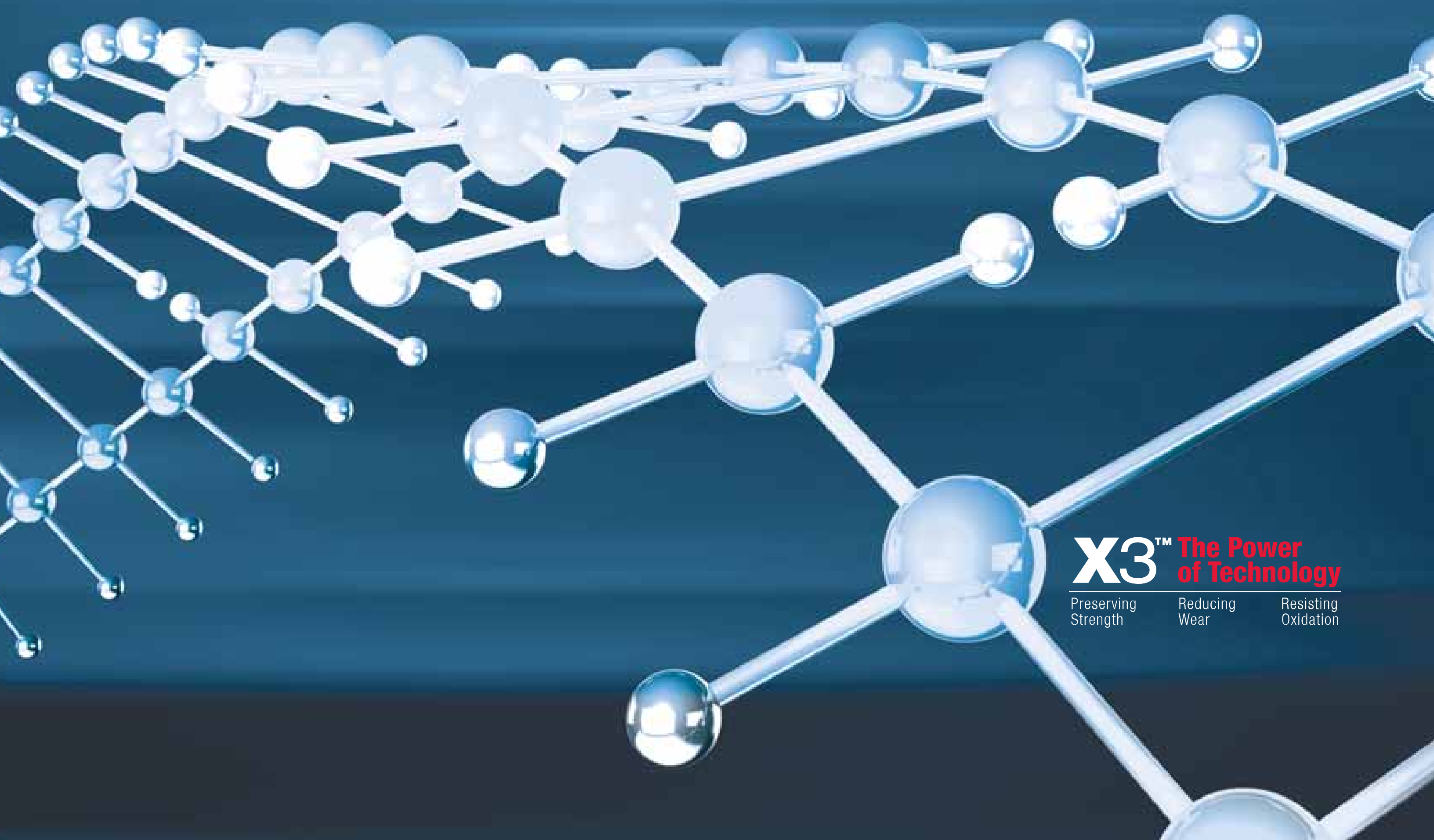
stryker®

Orthopaedics

X3™
Knee Technology

The Next Generation in Highly Crosslinked Knee Polyethylene



X3™ The Power of Technology

Preserving Strength | Reducing Wear | Resisting Oxidation

Innovation
Matters

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

Most recent bearing technologies have focused on hip application. While these technologies have helped to improve hip bearings, they have not been widely applied to knee bearings as wear patterns and modes vary between hips and knees.

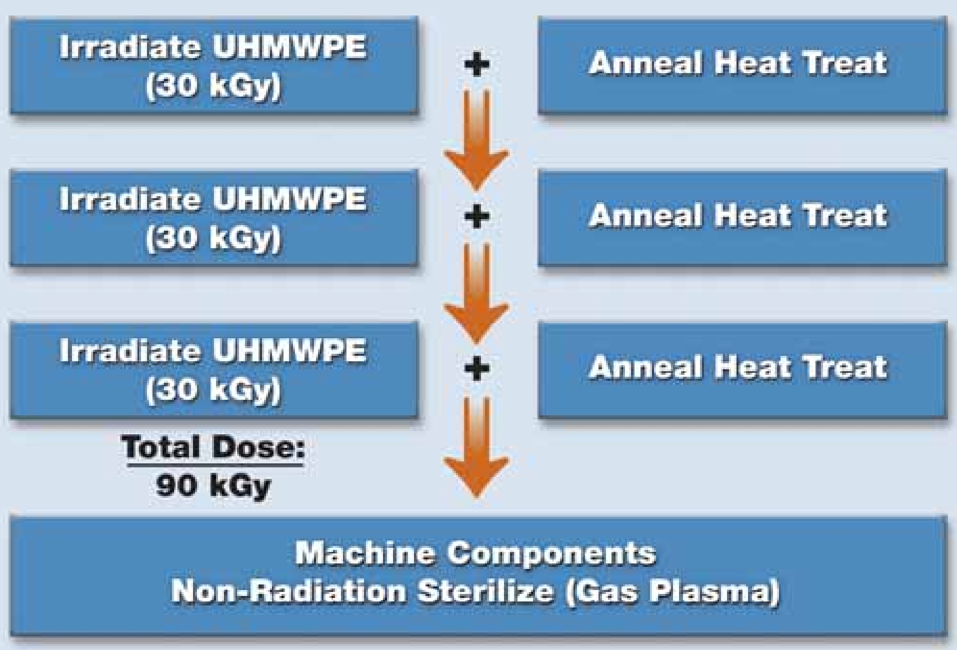
Most commercial crosslinking processes involve both irradiation and a subsequent remelting step, which decreases the strength of the polyethylene[1]. Stryker's patented annealing process provides wear reduction without compromising structural strength.[2, 3, 4, 5]

Wear performance technologies for knee applications cannot come at the expense of the structural strength of the polyethylene. Keeping this in mind, Stryker® developed a next generation process with three sequential irradiation/annealing steps to create X3™ polyethylene.

The results…

- Preserved Strength[2, 6]
- Reduced Wear[4, 5, 7]
- Oxidation Resistance[2, 8, 9]

The X3™ process:



Strength
Matters

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

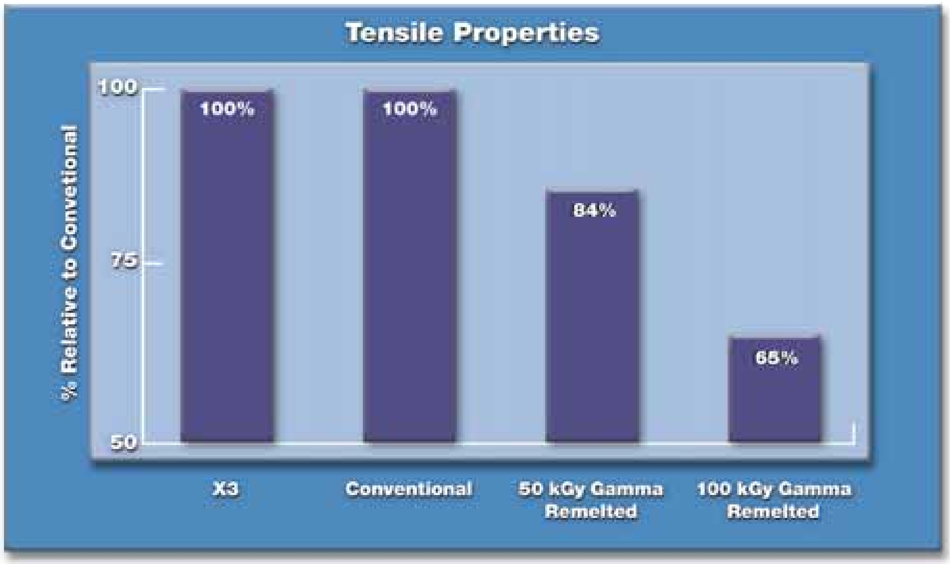


Figure 1: The higher the irradiation dose, the more remelting compromises the tensile strength of the polyethylene.

In contrast to remelting, annealing following irradiation has been shown to maintain those morphologies leading to preserved structural strength[2] **(Figure 2)**.

This structural strength allows X3™ technology to be applied to knee applications where abrasive, adhesive and fatigue wear may be present due to a more linear motion pattern.[10]

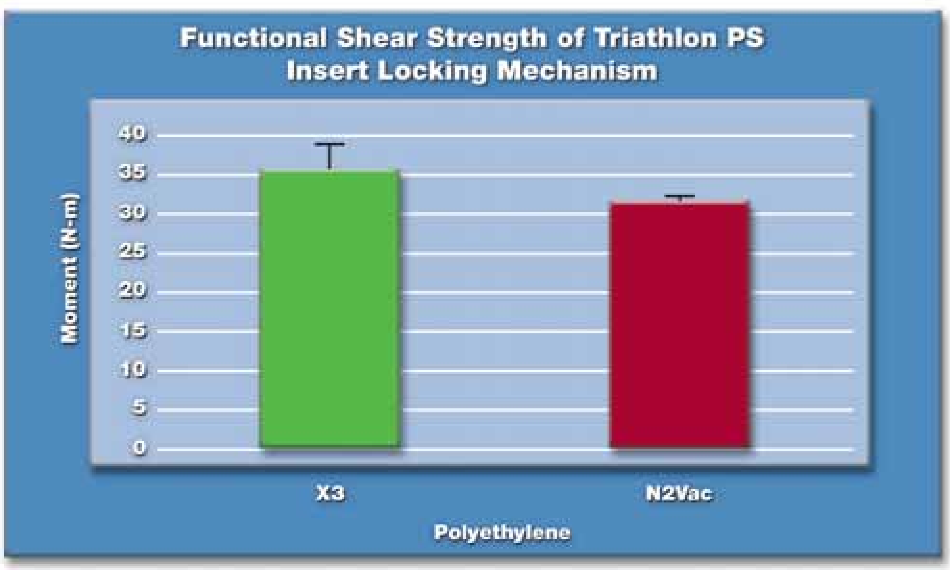


Figure 2: Maintenance of structural strength allows X3™ technology to be applied to tibial bearings that are subject to greater shear stresses such as posteriorly stabilized tibial inserts. These shear loads on the PS post create a moment arm to the locking mechanism, increasing the stress on the polyethylene in the posterior region of the mechanism.[11]

Wear
Matters

X3™ polyethylene has been shown to reduce the wear rate of tibial inserts by up to 79% compared to conventional polyethylene[4, 5, 7] **(Figure 3)**.

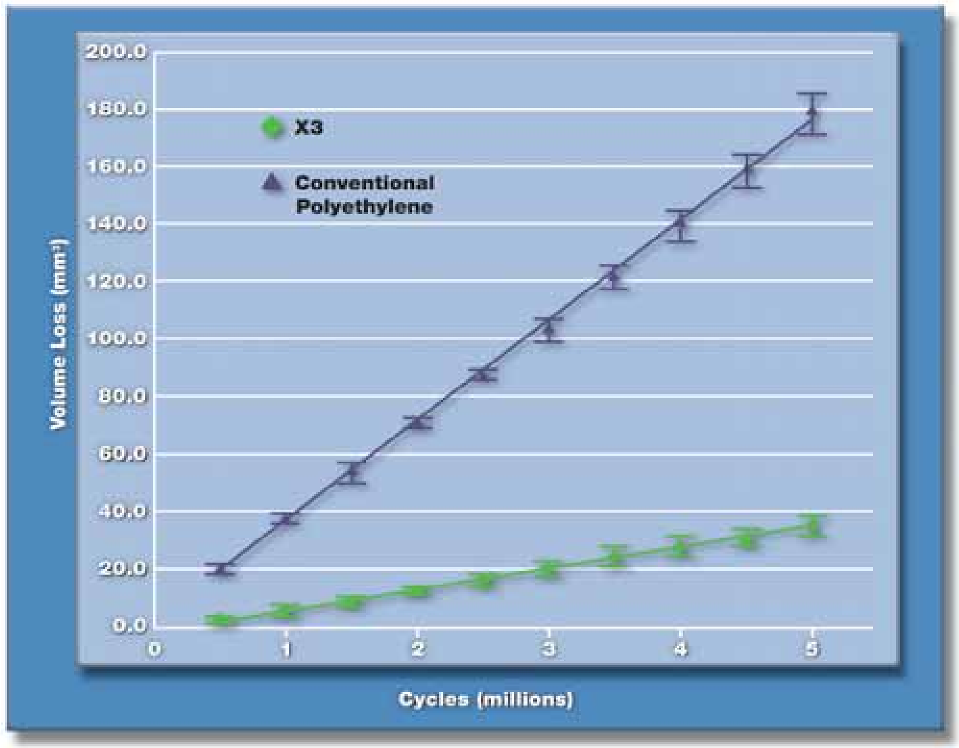


Figure 3: Knee simulator testing shows up to 79% wear reduction in Scorpio® CR tibial inserts compared to conventional polyethylene.

X3™ polyethylene shows a 41% reduction in wear compared to Prolong™ highly crosslinked polyethylene. This test compared wear rates of Scorpio X3™ tibial inserts vs. Scorpio inserts machined from packaged Zimmer Prolong™ NexGen® inserts[12] **(Figure 4)**.

Prolong material is prepared by electron beam irradiation of UHMWPE stock to 65 kGy followed by remelting.[13]

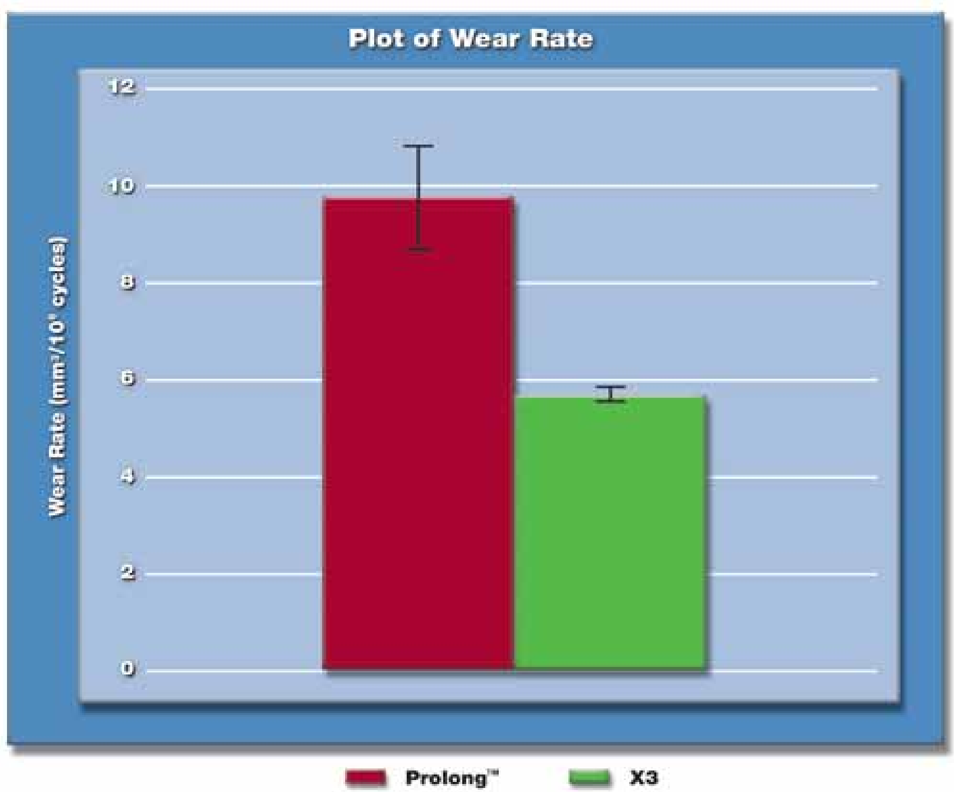


Figure 4: For this test, large sized packaged Prolong™ tibial inserts were machined into the shape of Scorpio® inserts. A head-to-head test was performed to compare the wear rates of the two materials.

Oxidation Resistance

X3™ polyethylene demonstrates high oxidation resistance under extreme laboratory conditions (immersion in 5 atmospheres of oxygen at 70 degrees Celsius for 14 days)[2] **(Figure 5)**.

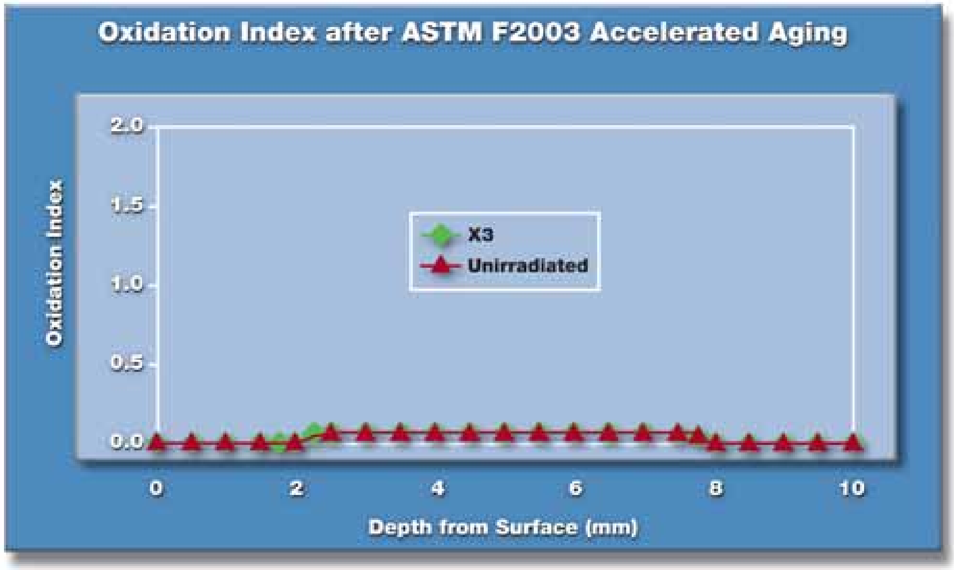


Figure 5: Oxidation resistance is shown to be similar to virgin, unirradiated polyethylene.

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[2, 8, 9] **(Figure 6)**.

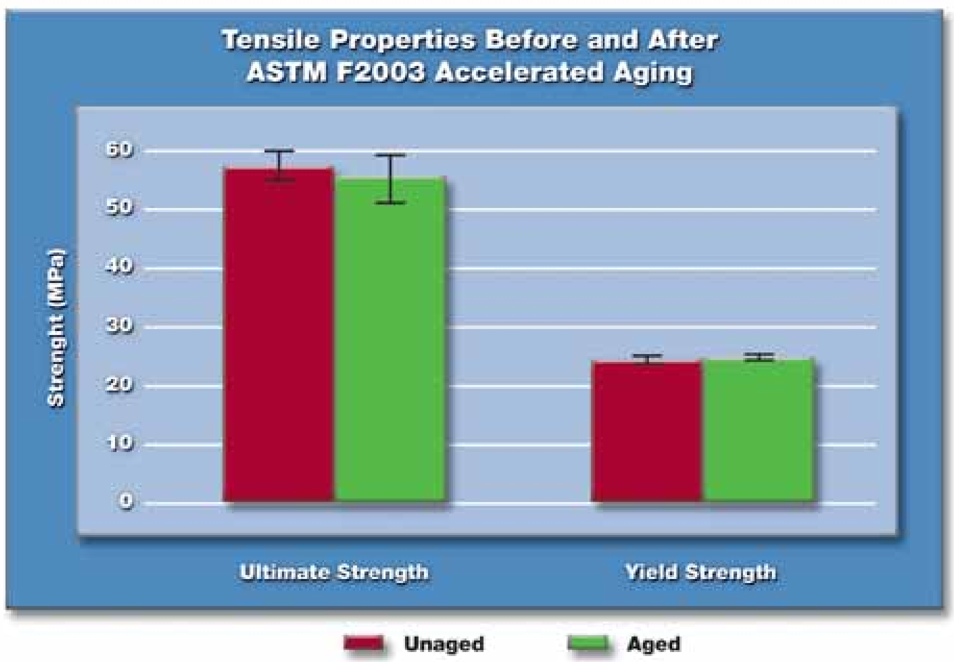


Figure 6: X3™ maintains mechanical strength after artificial accelerated aging.

X3™ The Power of Technology

Preserving Strength | Reducing Wear | Resisting Oxidation

References

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3. Essner, A., Yau, S.S., Schmidig, G., Wang, A., Dumbleton, J., Manley, M., Serekian, P., "Reducing Hip Wear Without Compromising Mechanical Strength: A Next Generation Crosslinked and Annealed Polyethylene." Transactions of the 5th Combined Meeting of the Orthopaedic Research Societies of Canada, USA, Japan and Europe, Calgary, Canada 2004: 80.
4. Essner, A., Herrera, L., Yau, S.S., Wang, A., Dumbleton, J.H., Manley, M.T., "Sequentially Crosslinked and Annealed UHMWPE CR Knee Wear," Transactions of the 51st Annual Meeting of the Orthopaedic Research Society, Washington, DC 2005: 312.
5. Essner, A., Zeng, H., Yau, S.S., Wang, A., Dumbleton, J.H., Manley, M.T., "Stair Climbing Knee Wear Simulation: Sequentially Crosslinked and Annealed UHMWPE," Transactions of the 30th Annual Meeting of the Society for Biomaterials, Memphis 2005: 199.
6. X3™ UHMWPE maintains mechanical properties for Tensile Yield Strength and Ultimate Tensile Strength of N_2Vac™ 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_2Vac™ UHMWPE and X3 UHMWPE, respectively. Ultimate Tensile Strength was 54.8 +/- 2.5 MPa and 56.7 +/- 2.1 MPa for N_2Vac™ UHMWPE and X3™ UHMWPE, respectively.
7. 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_2Vac™ gamma sterilized UHMWPE, 72-2-0708. The insert tested was size 7, 8mm thick. Testing was conducted under multi-axial knee simulator (multi-station MTS knee joint simulator [1]) 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 ± 1.5mm3/10^6 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.
   [1] Essner, A., Wang, A., Stark, C., and Dumbleton, J. H., "A Simulator for the Evaluation of Total Knee Replacement Wear," 5th World Biomaterials Congress, Toronto, Canada, May 1996, pg. 580.
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 70ºC 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, Elongation, Crystallinity and Density as measured per ASTM D638, D3417 and D1505 before and after ASTM F2003 accelerated aging (5 ATM of oxygen at 70ºC 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 +/- 0.1kg/m3 before and after accelerated oxidative aging, respectively.
10. Wang, A., Essner, A., Stark, C., Dumbleton, J.H., A Biaxial Line-Contact Wear Machine for the Evaluation of Implant Materials for Total Knee Joint Replacement. Wear 225-229. 1999 701-707.
11. Stryker Orthopaedics Test Report: RD-04-116.
12. Herrera, L., Essner, A., Wang, A., "Wear of Two Differently Crosslinked Tibial Bearing Materials Under Stair-Climbing Conditions." Report on file at Stryker Orthopaedics.
13. Zimmer Prolong™ product brochure.

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