MARATHON Cross-Linked Polyethylene

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“Before discussing polyethylene performance, it is imperative to understand that proven fixation technology remains the single most important factor in ensuring successful clinical outcomes.”

C.A. ENGH, MD
5 Mrad of cross-link inducing gamma irradiation used in the Marathon process results in an 86 percent wear reduction. This minimal increase in gamma irradiation above historical levels of 2.5 - 4.0 Mrad dramatically improves wear rates when compared to noncross-linked polyethylene.\textsuperscript{1-3}

Excessive wear and particulate generation can lead to osteolysis. The 25-year survivorship of arthroplasties with wear rates less than 15mm\textsuperscript{3}/year exceeds 90 percent; in contrast, arthroplasty survivorship with wear greater than 56mm\textsuperscript{3}/year is less than 30 percent at 20 years.\textsuperscript{4}

Doubling the cross-link inducing radiation dose to 10 Mrad decreases wear only an additional four percent, but adversely impacts important material physical properties (Figures 1 and 4).\textsuperscript{2,3}

Even when articulating against roughened femoral heads, Marathon Polyethylene continues to demonstrate significant reduction in wear rates. Marathon wear reduction benefits both primary and revision patients through the potential reduction of osteolysis.

> Marathon\textsuperscript{TM} Polyethylene is the first FDA-cleared, third generation, cross-linked polyethylene.

> Marathon Polyethylene reduces wear by 86%, resists oxidation and exceeds minimum ASTM mechanical standards.\textsuperscript{1-3}

> Marathon Polyethylene is the optimally cross-linked patented\textsuperscript{*} polyethylene.

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\textsuperscript{*Patent \#6,017,975
Oxidative Stability

OXIDATIVE STABILITY

Gamma In Air Oxidation

FIGURE 2

Shelf-aged, gamma in air-sterilized polyethylene demonstrating significant oxidation.

Oxidative Index

2.00
1.75
1.50
1.25
1.00
0.75
0.50
0.25
0

Gamma N2 Marathon

SHO Crossfire* (10 Mrad) (5 Mrad)

Marathon Longevity* (10 Mrad)

Zimmer Durasul* (9.5 Mrad)

J. COLLIER, DE

Eliminating oxidation while maintaining mechanical properties is imperative for clinical performance.\textsuperscript{11}

Wear rates are comparable among third generation highly cross-linked polyethylene components; however, independent tests have identified surface layer oxidation that may result in increased wear for some competitive materials (Figures 2 and 3).\textsuperscript{13}

Physical and mechanical property measurements, such as elongation, predict material behavior. Maintaining these properties while reducing wear is critical to the successful clinical performance of cross-linked polyethylene.

Marathon Polyethylene exceeds minimum ASTM standards for elongation and other important properties.\textsuperscript{1-3} As the radiation dose increases to 10 Mrad, elongation properties approach minimum ASTM standards.

The results of mechanical property testing and wear simulations predict that Marathon Polyethylene will sustain the cyclic loads and motions required of a total hip arthroplasty.\textsuperscript{1-3}
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“Polyethylene cross-linked with gamma radiation has been the gold standard for over 20 years.”

H. MCKELLOP, PHD

Cross-Link Inducing Gamma Radiation

- The clinical success of gamma radiation to induce cross-linking in polyethylene is well documented and has been the orthopaedic “gold standard” for more than 20 years.14-17

- Gamma irradiated polyethylene has performed well clinically in the absence of oxidative degradation. A process that combines the wear reduction benefits of gamma cross-linking and oxidative stability, such as the Marathon Polyethylene process, will benefit the patient.

- Alternative, cross-link inducing radiation sources, such as electron beam, have no reported clinical documentation.

Gas Plasma Terminal Sterilization

- Marathon Polyethylene is terminally sterilized using gas plasma technology, which has been clinically proven through years of successful use with polyethylene.

- Gas plasma terminal sterilization introduces no radiation or free radicals into the polyethylene component, thus eliminating oxidative potential.
MARATHON PROCESS

1. Raw Material
   Quality controlled, calcium stearate-free polyethylene.

2. Radiation Cross-Linking
   Consolidated polyethylene is treated with 5 Mrad of gamma radiation to induce cross-linking. The creation of free radicals during this process is a by-product of this step.

3. Thermal Treatment
   Irradiated polyethylene bars are remelted through a patented, proprietary thermal treatment to force molecular recombination, extinguish free radicals, enhance material consolidation and eliminate oxidative potential.

4. Quality Assurance
   Each Marathon Polyethylene bar is thoroughly tested for the absence of free radicals, assuring oxidative resistance.

5. Manufacturing
   Cross-linked polyethylene bars are precision-manufactured into liners and packaged.

6. Terminal Sterilization
   Packaged liners are gas plasma sterilized. This technique does not alter the polyethylene’s molecular structure or introduce free radicals.

RESULTS
The Marathon process provides 86 percent wear reduction, no free radicals and no oxidation. Marathon Polyethylene is optimally cross-linked and processed for clinical success.
References

1. Data on file at DePuy Orthopaedics, Inc.


"Crossfire" is a trademark of Stryker Howmedica Osteonics Corp., "Longevity" is a trademark of Zimmer, Inc. and "Durasul" is a trademark of Sulzer Orthopedics, Inc.

Rx only.