

MARATHON™

CROSS-LINKED POLYETHYLENE

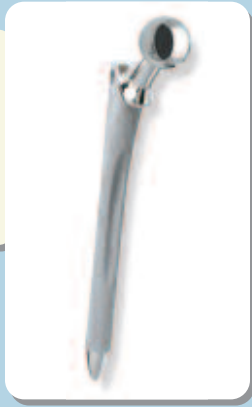


- ▶ FIXATION FIRST
- ▶ WEAR REDUCTION
- ▶ OXIDATIVE STABILITY
- ▶ MECHANICAL INTEGRITY
- ▶ PROVEN TECHNOLOGY

Fixation First

FIXATION FIRST

Prodigy Hip



- 1958 Charnley® Hip
Over 1,000,000 implanted¹
96.2 percent survivorship at 32 years²
- 1977 Porocoat® Porous Coating
Over 1,000,000 prostheses with
Porocoat Porous Coating implanted¹
- 1977 AML® Hip
Over 275,000 implanted¹
98.5 percent survivorship at 15 years³
- 1981 Tri-Lock® Hip
Over 5,000 implanted¹
98 percent survivorship at 13.5 years⁴
- 1985 S-ROM® Hip
Over 75,000 implanted¹
98 percent survivorship at 5.3 years⁵

S-ROM Hip



“Before discussing polyethylene performance, it is imperative to understand that proven fixation technology remains the single most important factor in ensuring successful clinical outcomes.”¹

C. A. ENGH, MD

C-Stem Hip



- 1986 Corail™ Hip
Over 85,000 implanted¹
97.7 percent survivorship at 10 years⁶
- 1986 HPS II™ Hip
- 1989 P.F.C.® Hip
- 1990 Solution System® Hip
Over 35,000 implanted¹
Over 95 percent survivorship at 13.2 years⁷
- 1991 Duraloc® Cup
Over 250,000 implanted¹
98 percent survivorship at 5 years⁸
- 1992 Prodigy® Hip
- 1993 Endurance® Hip
Over 40,000 implanted¹
98.8 percent survivorship at 3-5 years⁹
- 1994 C-Stem™ Hip
- 1997 Marathon™ Polyethylene
86 percent wear reduction in hip
simulator studies^{1, 10, 11}
- 1999 Pinnacle™ Acetabular Cup System
- 2001 Summit™ Tapered Hip System
- 2001 AML® Hip System
- 2001 Summit™ Cemented Hip System

Solution System Hip



Pinnacle Cup



Summit Hip



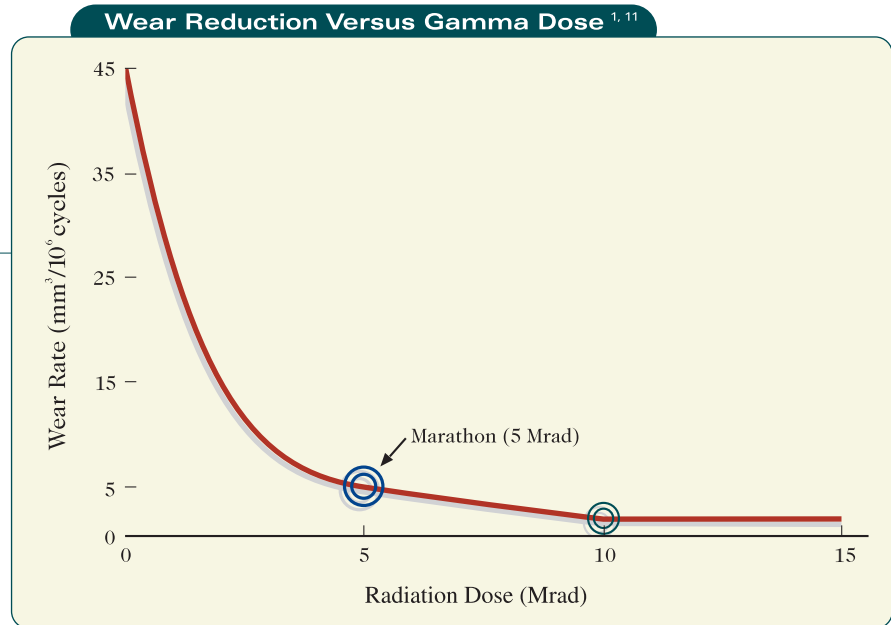
AML Hip



WEAR REDUCTION

“Decreasing wear utilizing optimally cross-linked polyethylene will make a good hip even better.”¹

T. SCHMALZRIED, MD



5 Mrad of cross-link inducing gamma-irradiation used in the Marathon process results in an 86 percent wear reduction in hip simulator studies.^{*1} This minimal increase in gamma irradiation above historical levels of 2.5 - 4.0 Mrad dramatically reduces wear rates when compared to non-cross-linked polyethylene.^{1, 10, 11}

Excessive wear and particulate generation can lead to osteolysis. The 25-year survivorship of arthroplasties with wear rates less than 15mm³/year exceeds 90 percent; in contrast, arthroplasty survivorship with wear greater than 56mm³/year is less than 30 percent at 20 years.¹²

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).^{10, 11}

Even when articulating against roughened femoral heads, Marathon Polyethylene continues to demonstrate significant reduction in wear rates in hip simulator studies.^{*11} Marathon wear reduction benefits both primary and revision patients through the potential reduction of osteolysis.

Marathon Polyethylene is the first FDA-cleared, third generation, cross-linked polyethylene.

Marathon Polyethylene **reduces wear by 86% in hip simulator studies**, resists oxidation and exceeds minimum ASTM mechanical standards.^{*1, 10, 11}

Marathon Polyethylene is an **optimally cross-linked patented polyethylene**.

Oxidative Stability

OXIDATIVE STABILITY

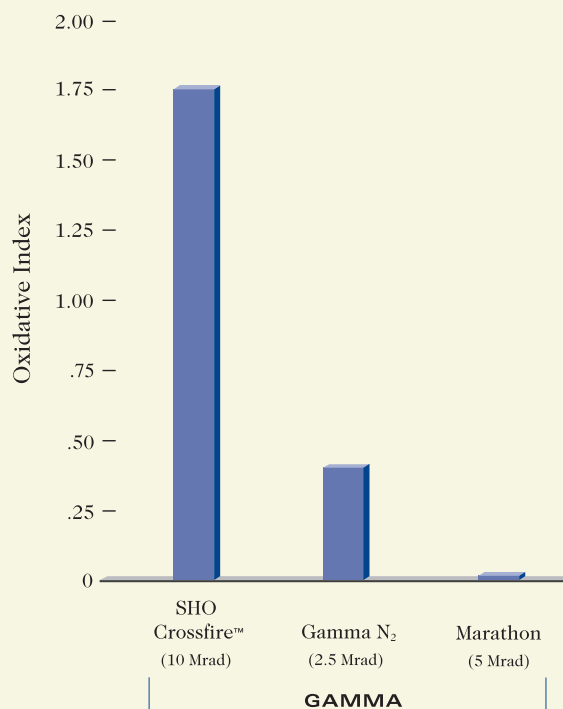


Shelf-aged, gamma in air-sterilized polyethylene demonstrating significant oxidation.

“Eliminating oxidation while maintaining mechanical properties is imperative



Surface Layer Oxidative Index Profiles¹³



Mechanical Integrity

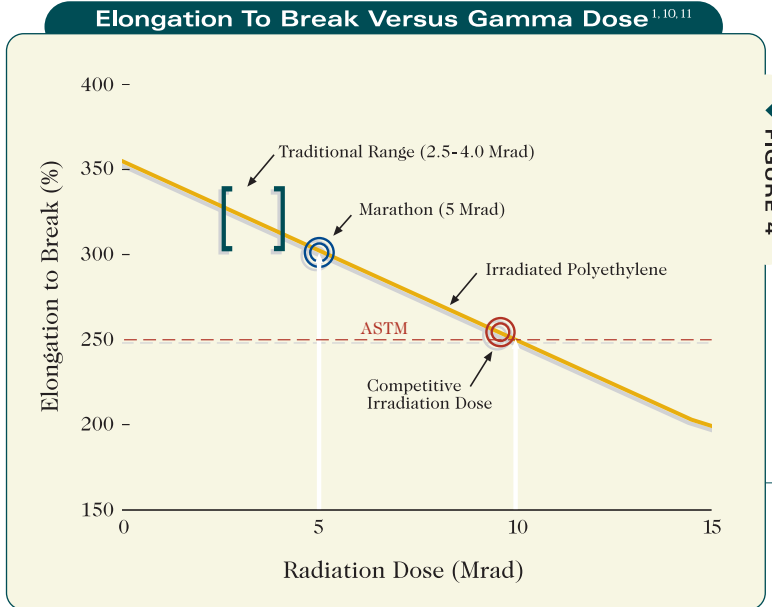


FIGURE 4

for clinical performance.”¹ J. COLLIER, DE

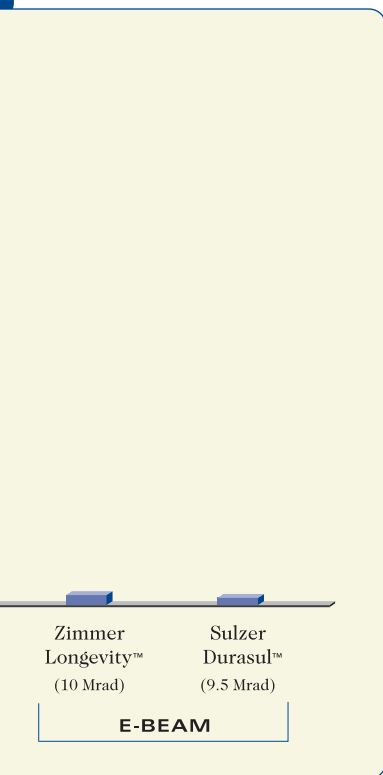


FIGURE 3

▶ Wear rates are comparable among third generation highly cross-linked polyethylene components; however, independent artificial aging tests have identified surface layer oxidation that may result in increased wear for some competitive materials (Figures 2 and 3).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.^{1, 10, 11} 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.^{1, 10, 11}

“Polyethylene that was cross-linked with gamma radiation has been the clinical gold standard for over 25 years.”¹

H. MCKELLOP, PHD

Cross-Link Inducing Gamma Radiation

- ▶ The clinical success of polyethylene cross-linked by gamma radiation is well documented and has been the orthopaedic “gold standard” for more than 25 years.¹⁴⁻¹⁷
- ▶ Gamma-irradiated polyethylene in the absence of oxidative degradation has been clinically successful. A process that combines the wear reduction benefits of gamma cross-linking and oxidative stability, such as the Marathon Polyethylene process, may benefit the patient.
- ▶ Alternative cross-link inducing radiation sources, such as electron beam, have no reported clinical documentation.

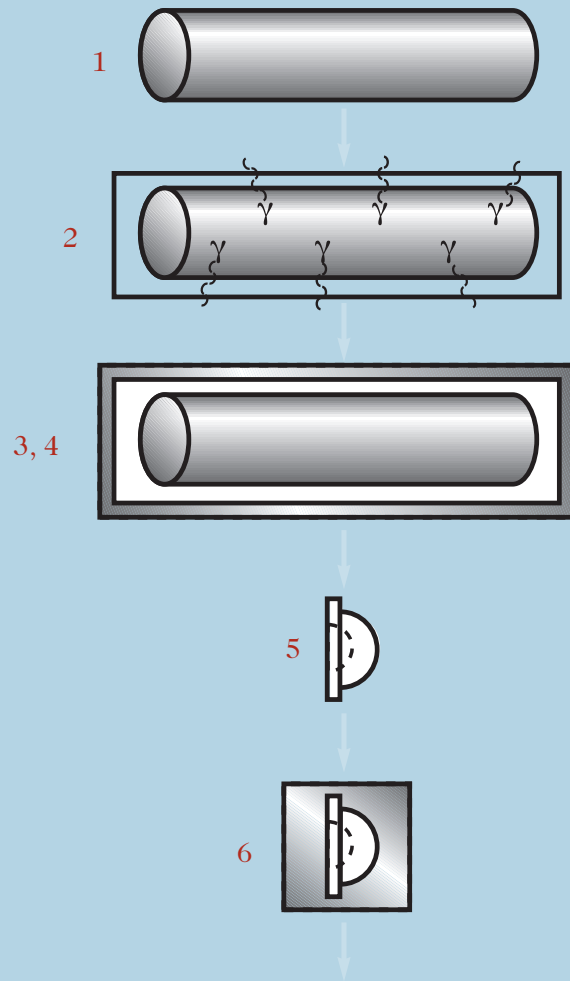
Gas Plasma Terminal Sterilization

- ▶ 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 reducing oxidative potential.



Proven Technology

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 thermally treated through a patented, proprietary process to force molecular recombination, extinguish free radicals, enhance material consolidation and reduce oxidative potential.

4 Quality Assurance

After thermal treatment, each Marathon Polyethylene bar is thoroughly tested using Electron Spin Resonance (ESR). This test confirms the elimination 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 in hip simulator studies, no free radicals and reduced oxidation.¹

Marathon Polyethylene is optimally cross-linked and processed for clinical success.

*In vitro wear results have not been correlated to clinical experience.

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US Patents 6,316,158; 6,281,264; 6,242,507; 6,228,900; 6,017,975.

For more information about DePuy products, visit our web site at www.jnjgateway.com/pinnacle.



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