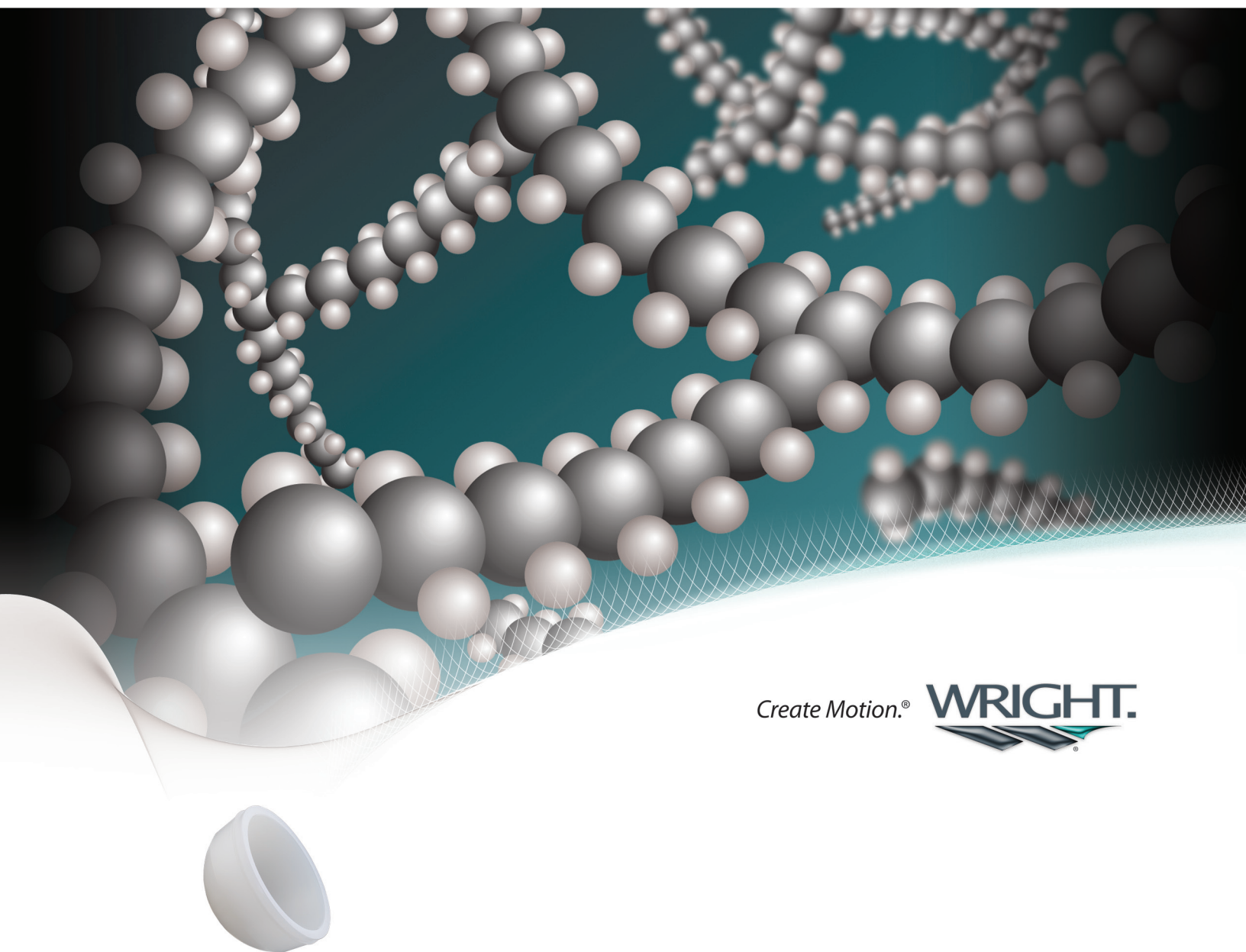


A-CLASS[®]

Highly Cross-Linked Polyethylene

Wear Less.



Create Motion.[®] **WRIGHT.**

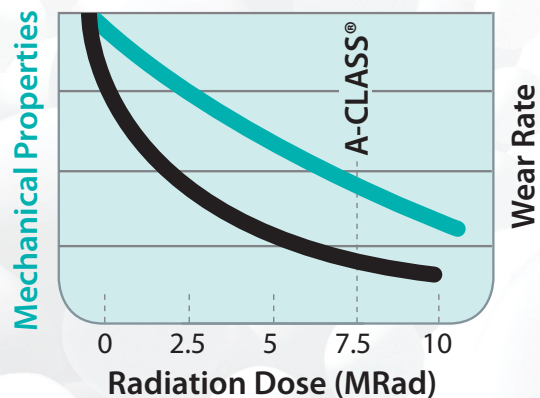
- 92% or Greater Reduction in Wear Compared to Conventional Poly
- Undetectable Free Radicals
- No Oxidation



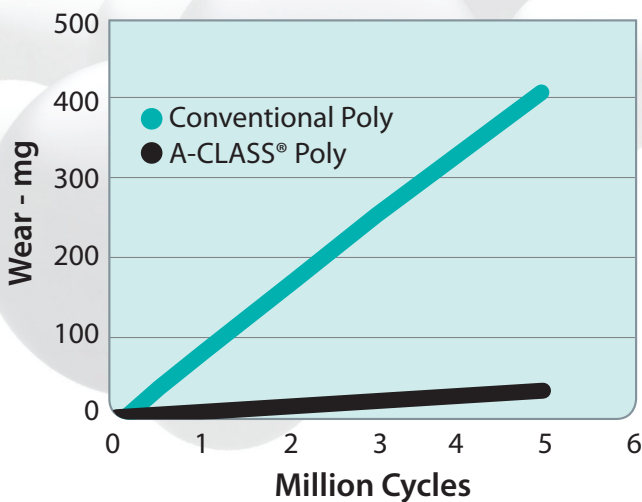
A-CLASS[®]

Highly Cross-Linked Polyethylene

- Highly cross-linked polyethylene refers to UHMWPE exposed to radiation doses in excess of 4 MRad¹ (A-CLASS[®] Poly = 7.5 MRad)
- Increasing cross-linking = increasing wear resistance + decreasing mechanical properties
- **Balanced processing of A-CLASS[®] polyethylene drastically reduces wear while maintaining good mechanical properties**



A-CLASS[®] Highly Cross-Linked Poly vs. Conventional Poly



- Wear induced osteolysis has been recognized as an important clinical issue with conventional poly²
- Highly cross-linked polyethylene was introduced in the mid 1990's to improve the bearing wear characteristics of THA and allow for larger heads
- **Wright testing shows a 92% or greater wear reduction for A-CLASS[®] polyethylene vs Wright conventional polyethylene³**

1 Poly Material Selection

- Wright uses compression molded GUR 1020 UHMWPE
- GUR 1020 has a **higher** impact strength, tensile strength, and yield strength than GUR 1050⁴

Product	Material ¹
A-CLASS® (Wright)	GUR 1020
Marathon® (DePuy)	GUR 1050
Longevity® (Zimmer)	GUR 1050
Crossfire® (Stryker)	GUR 1050
Durasul® (Zimmer)	GUR 1050
X3® (Stryker)	GUR 1020
E1® (Biomet)	GUR 1050

2 Cross-Linking Process

- Wright's A-CLASS® Poly is Irradiated with 7.5 MRads
- Higher radiation dose = more cross-linking, slightly better wear resistance, and weaker mechanical properties
- Wright has found an optimum balance of enhanced wear properties while maintaining important mechanical properties of the material

Product	X-Link Dose ¹
A-CLASS® (Wright)	7.5 MRad
Marathon® (DePuy)	5 MRad
Longevity® (Zimmer)	10 MRad
Crossfire® (Stryker)	10.5 MRad
Durasul® (Zimmer)	9.5 MRad
X3® (Stryker)	9 MRad
E1® (Biomet)	10 MRad

3 Heat Treatment

- Wright has developed a **proprietary** thermal remelting cycle that removes free radicals
- **Remelting has been shown to eliminate more free radicals than below-melt procedures⁵**
- **This process has been shown to improve the oxidative stability of the material⁶**
 - Validated in natural aging study: No detectable oxidation after wear testing to 5 Mc and aging in air for 3 years!
 - Validated in accelerated aging study: No detectable oxidation!
- **Wright remelting cycle eliminates need for anti-oxidant doping (i.e. Vitamin E)**

Product	Heat Treatment ¹
A-CLASS® (Wright)	Remelted
Marathon® (DePuy)	Remelted
Longevity® (Zimmer)	Remelted
Crossfire® (Stryker)	Below Melt
Durasul® (Zimmer)	Remelted
X3® (Stryker)	Below Melt
E1® (Biomet)	Below Melt*

*Heated during diffusion of Vitamin E.

4 Final Sterilization

- All polyethylene liners require post-processing sterilization
- Most common sterilization methods
 - Ethylene oxide (EtO)
 - Doesn't add free radicals⁷
 - Gas plasma
 - Doesn't add free radicals⁸
 - Gamma radiation
 - **Adds free radicals⁹**
- Sterilization without radiation enhances short and long-term oxidative resistance in simulator study¹⁰ and in shelf aging study¹¹

Product	Final Sterilization ¹
A-CLASS® (Wright)	ETO
Marathon® (DePuy)	Gas Plasma
Longevity® (Zimmer)	Gas Plasma
Crossfire® (Stryker)	3 MRad gamma-N2
Durasul® (Zimmer)	ETO
X3® (Stryker)	Gas Plasma
E1® (Biomet)	Gamma

References

1. Stephen Kurtz, PhD, UHMWPE Biomaterials Handbook, Second Edition: Ultra High Molecular Weight Polyethylene in Total Joint Replacement and Medical Devices (San Diego: Elsevier Academic Press, 2009), p55.
2. Bono JV, Sanford L, Toussaint JT. Severe polyethylene wear in total hip arthroplasty. Observations from retrieved AML PLUS hip implants with an ACS polyethylene liner. *J Arthroplasty*. Apr 1994;9(2):119-125.
3. Data on file at Wright.
4. "Standard Specification for Ultra-High-Molecular Weight Polyethylene Powder and Fabricated Form for Surgical Implants". ASTM International, 2007. F648-07.
5. Stephen Kurtz, PhD, The UHMWPE Handbook: Ultra-High Molecular Weight Polyethylene in Total Joint Replacement (San Diego: Elsevier Academic Press, 2004), p112.
6. Data on file at Wright.
7. Stephen Kurtz, PhD, The UHMWPE Handbook: Ultra-High Molecular Weight Polyethylene in Total Joint Replacement (San Diego: Elsevier Academic Press, 2004), p45.
8. Stephen Kurtz, PhD, The UHMWPE Handbook: Ultra-High Molecular Weight Polyethylene in Total Joint Replacement (San Diego: Elsevier Academic Press, 2004), p46.
9. Stephen Kurtz, PhD, The UHMWPE Handbook: Ultra-High Molecular Weight Polyethylene in Total Joint Replacement (San Diego: Elsevier Academic Press, 2004), p44.
10. McKellop H, Shen FW, Lu B, Campbell P, Salovey R. Effect of sterilization method and other modifications on the wear resistance of acetabular cups made of ultra-high molecular weight polyethylene. A hip-simulator study. *J Bone Joint Surg Am*. Dec 2000;82-A(12):1708-1725.
11. Willie BM, Ashrafi S, Alajbegovic S, Burnett T, Bloebaum RD. Quantifying the effect of resin type and sterilization method on the degradation of ultrahigh molecular weight polyethylene after 4 years of real-time shelf aging. *J Biomed Mater Res A*. Jun 1 2004;69(3):477-489.



Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN USA 38002
901.867.9971
800.238.7117
www.wmt.com

Wright Medical EMEA
Hoogoorddreef 5
1101 BA Amsterdam
The Netherlands
011.31.20.545.0100
www.wmt-emea.com

™Trademarks and ®Registered marks of Wright Medical Technology, Inc.
©2011 Wright Medical Technology, Inc. All Rights Reserved.

MH447-809 R411