

## **Leveraging Materials Science and Engineering Innovation to Improve Implant Performance**

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**Advances in materials are always exciting and significantly contribute to innovations in medical device technology. In the orthopedic arena, one company has developed a technique with which to enhance the material properties of polyethylene for hip and knee replacements.**

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British orthopedic surgeon Sir John Charnley revolutionized total hip arthroplasty—and orthopedics in general—by pioneering the use of ultra-high molecular weight polyethylene (UHMWPE) in hip implants in the early 1960s. The medical device community has continually sought ways of further improving the material's ability to improve implant performance and patient comfort. An abundant amount of research and development to date has focused on the properties of UHMWPE and the means of improving the wear characteristics of this bearing material, which is widely used in total hip arthroplasty and total knee arthroplasty.



Most recently, research has honed in on processes for crosslinking polyethylene to improve the structural strength of the material while reducing the potential for wear. Among the techniques used to crosslink polyethylene are gamma-irradiation and passing the material through an accelerated electron beam. Both of these processes crosslink the polyethylene chains and enhance wear resistance. The drawback of this technique is that it produces residual free radicals, which can facilitate the breakdown of the polyethylene over time through oxidization.

While Stryker was the first orthopedic company to release a crosslinked polyethylene, it has not been the only company to explore crosslinking processes with the potential for improving wear resistance. The great majority of these companies utilized a post-irradiation remelting process aimed at eliminating free radicals.

As a result of extensive study and research, Stryker determined that while the remelting process is effective at reducing free radicals, it actually can compromise the structural strength and long-term performance of the polyethylene. More specifically, once the polyethylene is remelted and cools, the crystal structure of the polyethylene actually becomes weaker, exposing the polyethylene to easier structural breakdown. This weaker structure could result in premature polyethylene fracture and implant failure, causing a patient to undergo revision surgery.

For Stryker's polyethylene, the company determined that an annealing or heat treatment process was effective in stabilizing these residual free radicals while preserving the polyethylene's structural properties. To create its most recent and advanced polyethylene, called X3, Stryker puts the polyethylene through three cycles of irradiation, each followed by an annealing treatment. This process facilitates the migration of free radicals while building a higher crosslink density without altering the material's crystalline structure.

Stryker's X3 material is used in a variety of hip and knee replacement implants today including its Triathlon and Scorpio Knee Systems, as well as its Trident Hip System. Based on current sales rates, more than 250,000 U.S. patients have received X3 in their implants, with approximately 50,000 more each year. Stryker's X3 is currently a component in implants used around the world, including the U.S., Canada, Europe, and Australia.

Numerous independent studies indicate that Stryker's X3 is the most resilient polyethylene on the market, with higher structural fatigue strength, greater wear reduction, and higher oxidization resistance than conventional polyethylene. As a result of Stryker's patented sequential irradiation and annealing manufacturing process, one study suggests that when used in hip replacements, X3 has a 97% greater wear resistance rate than conventional polyethylenes.

The implant performance improvements offered by Stryker's X3 underscore how innovation in the material sciences, along with precision engineering, are driving the evolution of the medical device industry and helping surgeons better meet their patients' needs. All medical device companies should continue making investments in materials study, and design and engineering process improvements to ensure the device industry continues to support the advancement of medicine.

## Online

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