

• EXACTECH, INC 2320 NW 66th Court Gainesville, FL 32653

352.377.1140

## **a** 352.378.2617

## Exactech Announces FDA 510(k) Clearance Activit-E™ Knee Replacement Polyethylene

GAINESVILLE, Fla. (August 21, 2023) – Exactech, a developer and producer of innovative implants, instrumentation, and smart technologies for joint replacement surgery, announced 510(k) clearance from the U.S. Food and Drug Administration for its new, advanced Activit- $E^{TM}$  polyethylene for the Truliant® knee replacement system.

This new generation polyethylene is the latest, first-of-a-kind innovation by Orhun Muratoglu, Ph.D., Director of the Harris Orthopaedic Laboratory at Massachusetts General Hospital in Boston. Muratoglu invented the first crosslinked polyethylene, and the first of multiple generations of vitamin E, antioxidant polyethylene for leading orthopaedic companies.

"We replaced gamma radiation crosslinking with peroxide crosslinking and stabilized the poly with vitamin E to provide superior strength, superior flexibility, and toughness where it is needed most: total knee arthroplasty. This technology also addressed the looming shortage of gamma radiation for crosslinking, ensuring that patients will continue to benefit from the clinically proven advantages of highly crosslinked polyethylene in total joints," said Muratoglu.

Activit-E brings an optimized balance of material strength and toughness through chemically cross-linked polyethylene, while eliminating the need for gamma irradiation technology used in previous generations of polyethylene. It allows for active oxidative resistance and a long-term, high-performance poly bearing, ultimately providing for greater strength and active stabilization.

"After years of research and development in polyethylene, Activit-E represents a breakthrough achievement for Exactech," said Adam Hayden, CMO and SVP, Large Joints Business Unit at Exactech. "It is the next generation of highly cross-linked polyethylene with vitamin E anti-oxidant that furthers our primary goal of providing immense benefits to our patients."

The first products for Activit-E will launch in the beginning of Q3 2023 for select U.S. customers. Global expansion will begin in 2024.