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K2M Receives 510(k) Clearance for its CHESAPEAKE Anterior-Lumbar Stabilization System

LEESBURG, VA … September 7, 2010 – K2M, Inc., a spinal device company developing innovative solutions for the treatment of complex spinal pathologies, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its new CHESAPEAKE™ Anterior Lumbar Stabilization System, a unique interbody device designed for stabilization of the spine through an anterior approach. The system provides screw fixation through K2M's revolutionary tifix® Locking Technology, whereby each screw head forms an autogenic lock to the implant upon insertion.

CHESAPEAKE, an implant manufactured from biocompatible PEEK polymer, allows for anterior stabilization and fixation with a zero-profile design. Additionally, the system utilizes innovative instrumentation, such as the Anterior Insertion Ramp, which allows for parallel distraction and controlled threaded insertion while applying a zero-impact load on the interbody.

"CHESAPEAKE is the perfect offering for low-profile interbody instrumentation and, in my opinion, is the future of vertebral arthrodesis," stated Dr. Amiel Bethel, Division Head, Department of Surgery at Greater Baltimore Medical Center.

According to Dr. John I. Williams, Orthopedic Surgeon at Ortho NorthEast, "The screws utilize a unique tifix Locking Technology, which not only adds simplicity to the system, but gives an element of variability in terms of screw angulation into the vertebral body."

"FDA clearance for our CHESAPEAKE Anterior-Lumbar Stabilization System is an important expansion of our product offering for treating Degenerative Disc Disease (DDD), as well as more complex pathologies," stated Eric Major, K2M's President and CEO. "The zero-profile design and innovative locking technology facilitate and streamline anterior spinal stabilization and fixation procedures."

About K2M

K2M, Inc. is an innovative spinal device company committed to the research, development, and commercialization of simplified solutions for the treatment of complex spinal pathologies and procedures. The company is recognized as a worldwide leader in providing unique technologies for the treatment of deformity, degenerative, trauma, and tumor spinal patients. K2M's complete portfolio of next generation products includes: spinal stabilization systems, minimally invasive systems, and other advancing technologies such as motion preservation, annular repair, and nucleus replacement. Additional information is available online at www.K2M.com.

Media Contact

Elizabeth Venafro
Marketing Communications Manager
703.777.3155 ext.271
Email »