FDA Clears Innovative Spinal Fusion Device

The Associated Press

Surgeons treating patients with degenerative disc disease may now use a new stand-alone intervertebral body fusion device recently cleared by the Food and Drug Administration. Manufactured by Binder Biomedical Inc., the device presents a complete anterior lumbar fixation system with a simple, one-step locking mechanism.

Called LOGICT, the system is designed for use in a direct anterior surgical approach for accessing the intervertebral disc space of the patient's lumbar spine. The alpha release is expected in the first quarter of 2014. The nationwide launch is expected by the fourth quarter of 2014.

Binder Biomedical President Lawrence Binder said: "We are excited to bring such a streamlined device to market. Our design team has done a great job putting together such a comprehensive system, ensuring that it can be tailored to any surgeon's preferred surgical technique." Each implant is designed with a large central window for optimum autograft bone placement. Size offerings range from 10 to 20 mm in height, and all devices have an anatomically-shaped lordotic angle that matches the convex curvature of the vertebral endplates. The LOGICT devices are implanted into the intervertebral space and then three screws are placed through the device, into the vertebrae to provide stabilization and facilitate fusion.

The design team leader is Mark Testaiuti (MD, FAANS) a spine neurosurgeon at Coastal Spine, in Mt. Laurel, N.J. "Working with the Binder team on the LOGICT system," he said, "has been a rewarding and satisfying experience. Their responsiveness and attention to detail separates Binder from other companies I have worked with." The LOGICT system is manufactured using the PEEK-OPTIMA@ polymer from Invibio Biomaterial Solutions. Binder Biomedical has a long-term supply assurance agreement with Invibio, the leader in orthopedic biomaterials, to provide its proprietary PEEK-OPTIMA@ polymer for use in the manufacture of the LOGICT devices. All LOGICT devices are manufactured in FDA-registered facilities in the United States.

Team member Peter Whang (MD, FACS) is an associate professor in the Department of Orthopedics, Yale University School of Medicine.

"Rather than being content with the industry standard," he said, "we have created a truly innovative system that reflects our lengthy collective experience as surgeons and engineers. Together, we have created a world-class system that meets all of our needs while maintaining ease of use." The LOGICT device is indicated for stand-alone intervertebral body fusion in patients with degenerative disc disease, confirmed by radiographic studies, at one or two contiguous levels of the lumbosacral spine (L2-S1).

For a full list of the LOGICT system's Indications For Use or to discuss distribution opportunities, please contact: sales@bindermed.com By incorporating a unique approach to rapid product development, Binder Biomedical combines direct clinical feedback with vast industry experience to offer continuous streamlined product improvements to the spine market.