



## **DiFUSION Technologies Receives 510(k) Clearance of Xiphos™ Interbody Implants for Spinal Fusion**

*FDA Clearance of Posterior Interbody Implants Paves the Way Towards Commercialization*

**Austin, Texas - October 6, 2010** - DiFUSION Technologies Inc., a medical device company focused on the development and commercialization of its proprietary CleanFUZE™ anti-microbial technology for orthopedic implants, announced today the 510(k) clearance of its new Xiphos™ line of posterior interbody devices indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. The Xiphos™ System of implants is also indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The system is intended for the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation.

"This clearance marks a milestone in DiFUSION's commercial pathway. Not only does it provide us an early stage revenue source, the Xiphos line is also a platform on which we will continue to develop our CleanFUZE line of fusion devices," said John Kaelblein, President of DiFUSION Technologies.

Spinal fusion procedures are common orthopedic procedures used to treat disorders of the spine including degenerative conditions, deformities, spinal trauma and tumors. In fact, in 2009 over 500,000 spinal fusion procedures were performed in the US, a figure growing by over four percent annually. One of the implants often used in these procedures is the interbody fusion device, the market for which is now approaching \$1 billion. The Xiphos line of interbody devices is DiFUSION's entry into this segment.

"The Xiphos posterior interbody platform includes an array of implant shapes and sizes for varying patient anatomy and surgical preference allowing for posterior, posterior oblique and transforaminal approaches," remarked Dr. Jami Hafiz, PhD, VP of Development for DiFUSION Technologies. "We really focused on developing a best in class series of implants that could serve as a platform for future development."

### **About DiFUSION Technologies**

Founded in 2008 in Austin, Texas, DiFUSION Technologies, Inc. is a medical device company focused on reducing the rising incidence of surgical site infections in orthopedic and spine surgery through the development of a suite of patented antimicrobial orthobiologic polymeric implants. Initially focusing on the multi-billion dollar spinal implant market, the company has developed a technology with applicability

across a variety of orthopedic segments using well characterized implants with benefits for the patient, surgeon, hospital and payer. For more information about DiFUSION Technologies, visit [www.DiFUSIONtech.com](http://www.DiFUSIONtech.com).

CleanFUZE orthobiologic polymers have not been approved by the US FDA. CleanFUZE is not available for sale within the United States.

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