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Spinal USA Gets FDA Approval for Two New Spinal Treatment Products

Pearl, MS – October 28, 2011 - Spinal USA, LLC announced today that it will introduce two new additions to the company's portfolio of spinal treatment solutions at this year's meeting of the North American Spine Society (NASS) in Chicago, IL, November 1-5.

The company will feature its new VAULT[™] Stand Alone ALIF System and Sure LOK[™] *PC* Posterior Cervical System, both of which recently received U.S. Food and Drug Administration 510(K) clearance.

The VAULT[™] Stand Alone ALIF System, designed for use with autogenous bone graft, is indicated for intervertebral body fusion of the spine in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis. It is intended for use at either a single level or at two contiguous levels between L2 and S1 in the lumbar spine. The new VAULT[™] System is designed to require no supplementary fixation other than the screws provided. It is intended to provide immediate mechanical fixation to adjacent vertebral bodies while maintaining a zero profile, and features a large graft window designed to maximize the opportunity for successful fusion.

The Sure LOKTM *PC* Posterior Cervical System is intended to promote fusion of the cervical and thoracic spine in skeletally mature patients, and is indicated for use in the treatment of DDD, spondylolisthesis, spinal stenosis, fracture/dislocation, revision of previous cervical spine surgery and tumors. The new Sure LOKTM *PC* System is designed to provide meaningful intraoperative flexibility for the surgeon. Its components include polyaxial screws with up to 40° of angulation for placement in the upper thoracic spine (T1-T3), and an array of lateral offsets, hooks, dominoes, transition rods and crosslinks designed to provide stabilization to promote fusion in the cervical/upper thoracic spine (C1-T3).

"These two technologies represent very important product line additions for Spinal USA," said Rich Dickerson, Sr. VP Operations for Spinal USA. "The availability of the VAULTTM System and the Sure LOKTM *PC* System provides our customers with a wider array of surgical options designed to improve patient outcomes. By providing a single product indicated for cases previously requiring up to two separate products, the VAULTTM System has the potential to reduce surgical trauma and yield a net cost savings. The Sure LOKTM *PC* System is designed to offer surgeons a comprehensive fixation system with enhanced ease of use and greater intraoperative flexibility."

About Spinal Disorders

Degenerative disc disease is characterized by back pain caused by degeneration of the disc and confirmed by history and radiographic studies. Spondylolithesis is a condition in which a bone (vertebra) in the lower part of the spine slips out of the proper position relative to an adjacent bone. The grade of spondylolisthesis is described using the ratio of the amount of slippage to the vertebra width and is reported as a percentage.

Cervical and thoracic spine surgery may be indicated for a variety of cervical spine problems, including degenerative disorders, trauma or instability. These conditions can produce pressure on the spinal cord or on the nerves extending from the spine. The goals of cervical spine surgery are to restore nerve function, stop or prevent abnormal motion in the spine, and relieve pain, numbness, tingling and weakness.

About Spinal USA

Spinal USA, LLC (www.spinalusa.com), headquartered in Pearl, Mississippi, is a privately held company. Spinal USA's mission is to provide innovative quality spine products designed to help treat serious medical conditions in a cost-effective manner to help reduce medical costs to the hospital, patient community and overall health care system. For more information, visit www.spinalusa.com

Contact

Rich Dickerson Sr. Vice President Operations rich@spinalusa.com 973.455.7150 Tony Cicatiello CN Communications acicatiello@cn-com.com 908.568.3280

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