SpineCraft

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FDA Clearance: ASTRA Spine System

SpineCraft Announces FDA Approval of ASTRA Spine System for Deformity Correction and Complex Spine Procedures

May 19, 2015 - SpineCraft, LLC, a privately-held US medical device company, recently announced that it has received regulatory clearance from the U.S. Food and Drug Administration (FDA) to market its ASTRA Spine System - a comprehensive posterior spinal fixation system.

The ASTRA Spine System is SpineCraft's next generation deformity correction technology, designed by industry leading spine professionals to treat a range of pathologies efficiently and effectively. The system is optimized for use with advanced instrumentation developed specifically for complex spine procedures. The ASTRA Spine System implants and instruments are functional and precise, providing surgeons with exemplary reliability. The implants are designed with proven technology that allows intraoperative flexibility to choose rod diameter and material types while maintaining a low profile and providing exceptional strength.

The ASTRA Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine; severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudo-arthrosis).

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