

THEKEN ANNOUNCES FDA APPROVAL OF THE CORAL™ SPINAL SYSTEM

Providing relief for chronic lower back pain suffers

AKRON, OH (September 29, 2004) Theken, a leader in spinal implant systems, today announced approval of the Coral Spinal System by the FDA. The Coral Spinal System is a fusion implant system used for the correction and stabilization of the lumbar or lower region of the spine. Lower back pain affects 80% of Americans at some point in their lives according to Millennium Research Group's *US Markets for Spinal Implants 2003 Report*. When back pain is severe, a fusion implant system such as the Coral Spinal System may be used to alleviate the chronic back pain and limited mobility caused by various spinal disorders including spinal tumors.

Components of the Coral Spinal System incorporate a number of features that make it unique enabling a lumbar surgery to require fewer implants and fewer surgical steps. Features include a custom Torque Limiting System that eliminates stripping during final locking. It's designed to reduce the potential for false locking and cross threading as well to increase the speed, ease and reliability of connection rods to screws.

The Coral Spinal System is currently in a product evaluation study with leading spinal surgeons.

According to Randy Theken, Owner and President of Theken Spine, the Coral Spinal System would not be possible without the continued support of the FDA, the collaboration of Theken's team of engineers and the leading surgeons. "We are looking forward to the results of the product evaluation study and product launch. The Coral Spinal System's Torque Limiting System helps eliminate the issue of screws stripping during final locking. Based on our research, this feature will be well received by the surgeons."

Company Profile

The Theken family of companies Theken Spine LLC, Theken Orthopaedic LLC and Theken Disc Inc. specializes in pioneering spinal implant technologies that improve the surgical technique benefiting the patient as well as the surgeon. Theken provides comprehensive product lines that offer surgeons peace of mind through steadfast product reliability and easy-to-use instrumentation. Products include cervical plates, pedicle screws, interbody systems and trauma devices. Theken also leads the market in next-generation artificial disc technology.

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