Medtronic News

Medtronic Announces CD HORIZON(R) System 510k Pedicle Screw Clearance for Adolescent Idiopathic Scoliosis

New Indication Will Help Advance Spine Care and Research for Children

MEMPHIS, Tenn., Dec 02, 2010 (BUSINESS WIRE) --

Medtronic (NYSE: MDT) announced today it received clearance to treat adolescent idiopathic scoliosis (AIS). This marks the first such clearance by the FDA under the Agency's newly established category for pediatric AIS patients treated with posterior pedicle screw instrumentation.

AIS is the most common type of scoliosis seen in children and affects nearly one million children in the U.S. alone. Scoliosis is a side to side curvature of the spine. AIS is defined as scoliosis whose onset occurs after 10 years of age and whose cause is essentially unknown.

"This is a major milestone for surgeons and their pediatric patients," said Doug King, general manager of Medtronic's Spine business. "With this clearance we will now be able to provide training and education to surgeons to treat children diagnosed with AIS."

Pedicle screws are designed specifically for use in the thoracolumbar spine. They are frequently used in instrumentation procedures to affix rods to the spine to correct deformities.

"The opportunity to further research and study this patient population will allow us to move forward with our commitment and investment in pediatric innovation," said King. "Unlike adults, adolescent spines are still in a period of growth. Medtronic is committed to collaborating with the some of the world's best surgeons to develop and advance technologies to address the unique needs of children."

David L. Skaggs, MD, Professor and Chief of Orthopaedic Surgery at the Children's Hospital in Los Angeles says getting children back to their active lives and potentially reducing the need for additional surgeries are two key advantages of using pedicle screws.

"Using pedicle screws in the treatment of Adolescent Idiopathic Scoliosis gives my patients the best chance of correcting their spine and chest deformity, and preventing future surgeries," said Dr. Skaggs.

About Scoliosis Surgery

The goal of surgery is to halt the progression of the curve and reduce spinal deformity, to the extent possible, restoring proper spinal stability and alignment. Surgery, specifically spinal fusion, is recommended for severe curves and for curves that have not responded to non-surgical intervention. Spinal fusion involves placing bone grafting material between affected bones in the spine to encourage them to fuse or join together. Instrumentation, such as screws, rods and connectors, are implanted along the treated area. The instrumentation is key because it creates a bridge to fusion to help restore more natural alignment of the spine.

About CD HORIZON(R) Spinal System

The CD HORIZON(R) Spinal System is a broad platform of fixation technologies, including implants and instruments, designed to provide spinal stabilization and correction in degenerative, deformity, and trauma applications. More than 500,000 individuals worldwide have been treated using the system, including those patients who suffered from such debilitating conditions as spondylolisthesis and spinal fractures.

The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

About Medtronic's Spine Business

Medtronic's Spine business, based in Memphis, Tennessee, is the global leader in today's spine market and is committed to advancing the treatment of spinal conditions. Medtronic Spine collaborates with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art products and technologies for neurological, orthopaedic and spinal conditions. Medtronic is committed to developing affordable, minimally invasive procedures that provide lifestyle friendly surgical therapies. More information about the company and its spinal treatments can be found at www.medtronicspinal.com and its patient-education Web sites, www.back.com, www.iscoliosis.com, www.maturespine.com and www.necksurgery.com.

About Medtronic

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology-alleviating pain, restoring health, and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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