Medtronic News

Medtronic Announces 510(k) Clearance for the TSRH(R) Spinal System Pedicle Screw for the Treatment of Adolescent Idiopathic Scoliosis

AIS is the Most Common Type of Scoliosis Seen in Adolescents and Affects Nearly One Million Adolescents in the U.S. Alone

MEMPHIS, Tenn., Sep 15, 2011 (BUSINESS WIRE) --

Medtronic (NYSE: MDT) announced today it received a second clearance from the Food and Drug Administration (FDA) to treat adolescent idiopathic scoliosis (AIS) with pedicle screws. The TSRH(R) Spinal System is the second posterior fixation system by Medtronic to receive 510(k) clearance for this indication and Medtronic remains the only company with this clearance under the Agency's product category for pediatric AIS patients treated with posterior pedicle screw instrumentation.

Adolescent idiopathic scoliosis (AIS) is the most common pediatric spine condition, and its cause is unknown. Many patients with AIS have rotated and/or curved spines, which may resemble an "S" or "C" shape instead of a straight line seen with normal spines. Some of the bones in the spines of AIS patients can rotate, causing the shoulders or waist to appear uneven. If the curvature of the spine progresses as the patient grows, it could compress nerve roots and the spinal cord.

"This additional AIS clearance will further afford Medtronic the ability to provide training and education to spine surgeons treating patients diagnosed with AIS," said Doug King, vice-president and president of Medtronic Spinal. "This clearance also provides an opportunity to further research and study these patients allowing us to move forward with our commitment and investment in pediatric innovation."

TSRH(R) and CD HORIZON(R) pedicle screws are indicated for posterior use as an adjunct to fusion in the thoracolumbar spine when treating AIS. Pedicle Screws, in conjunction with autograft and/or allograft, are frequently used in surgical procedures to affix rods to the spine to correct deformities.

The use of pedicle screw fixation in the pediatric population presents risks, including pedicle screw malpositioning, neurological or vascular injury, reduced longitudinal spinal growth, or risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine. The safety and effectiveness of the TSRH & CD HORIZON(R) spinal systems have not been established for use as part of a growing rod construct. They are only intended to be used when definitive fusion is being performed at all instrumented levels.

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 autograft and/or allograft 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 TSRH(R) Spinal System

In 1987, Texas Scottish Rite Hospital (TSRH) collaborated with Medtronic- with hopes of developing a system to treat scoliosis- which led to the development of the TSRH(R) Spinal System. After more than 20 years of clinical use and the 2009 launch of TSRH(R) 3Dx(TM) Spinal System, the TSRH(R) Spinal System continues to drive innovation in spinal treatment. The instrumentation system offers several types of pedicle screws, implants and other instruments to correct and stabilize the spine when treating AIS.

About Medtronic's Spinal Business

Medtronic's Spinal 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 Spinal 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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