Novel surgical procedure offers new option for children with life-threatening curvature of spine

Amsterdam, The Netherlands—May 29, 2012 – Medtronic, Inc. (NYSE: MDT) announced today that a novel surgical procedure for children received CE (Conformité Européenne) Mark. The procedure, which can correct and maintain spinal deformities associated with severe, progressive, life-threatening curvature of the spine in young children (early-onset scoliosis) allows natural growth of their bodies. It is available for use across Europe. The product is not commercially available in the United States at this time.

The announcement was made at the Spine Week congress in Amsterdam (28th May – 1st June 2012).

The new surgical procedure, made possible by the SHILLA™ Growth Guidance System, is Medtronic’s first growth-guided instrumentation specifically designed for the growing child allowing natural growth and deformity correction of the spine, helping to minimise the number of spinal operations these children would have to undergo.

The treatment of children with progressive early onset scoliosis has proven to be difficult; initial methods of managing scoliosis include braces and casts worn externally to correct the curvature, although these are rarely effective in correcting scoliosis permanently. If these options do not work, surgery to fuse the spine in a straightened position is often performed. Although corrective, fusion inhibits spinal growth, which can damage the development of the trunk, potentially leading to problems with lung function. Other surgical treatments are distraction based systems which require patients to undergo repeated lengthening surgeries every 6 to 9 months. These repetitive surgical procedures may increase the risk of complications. In an attempt to solve these problems the SHILLA™ procedure is based on a growth guidance system that allows correction of the deformity while maintaining the correction over time and helping to minimise the number of spinal surgeries until skeletal maturity.

Professor Richard McCarthy, Orthopaedic Surgeon at the University of Arkansas for Medical Sciences and Arkansas Children’s Hospital, who invented the SHILLA™ system developed by Medtronic, comments: “Early onset scoliosis is extremely difficult to treat. The current gold standard technique to manage scoliosis long-term is to fuse the spine, but in children who are still growing this can have serious complications. Until now we were only able to offer operations which use implants to stabilise the curve in the spine, but these can mean twice yearly surgery as a child grows. SHILLA™ is the first time we can offer an effective management for the curvature of the spine which grows with these young patients.”

The SHILLA™ Growth Guidance system is a rod and screw based system which incorporates a unique flanged set screw designed to capture the rod, while allowing it to slide as the patient grows. As a result, the SHILLA™ System construct provides spinal stabilization and maintains curve correction while allowing for longitudinal spinal growth. SHILLA™ fixed head screws are placed at the apex levels in both pedicles, each level for correction and maintenance of correction. SHILLA™ Multi-axial screws are used for the growth guidance screws above and below the apical segments.

There are estimated to be 1-2 cases of early onset scoliosis for every 10,000 European children, and the condition affects more boys than girls. One in ten cases of early onset scoliosis currently progress to a severe and disabling condition. Early onset scoliosis has also been shown to increase the risk of death from respiratory failure compared to children diagnosed later (adolescent scoliosis).

Steve Swinson, Medtronic Vice-President Spinal & Biologics Western Europe and Canada, comments: “Medtronic is delighted to have worked closely with Professor McCarthy to make SHILLA™ available in Europe. It is a genuine advance, which means these severely ill children now have a new surgical option which can minimize the amount of secondary surgeries required which have the risk of pain, complications, and more anesthesia. Medtronic is committed to alleviating pain and restoring health for people all over the world.”

About SHILLA™ Growth Guidance System
The SHILLA™ Growth Guidance System, is indicated for correction and maintenance of the correction of multi-planar spinal deformities associated with patients with severe, progressive, life-threatening, early-onset scoliosis associated with thoracic insufficiency and spinal growth insufficiency that requires surgical treatment before 10 years of age. The SHILLA™ Growth Guidance System is intended to be removed after skeletal maturity. The product is not available for market in the United States at this time. Every spinal surgical procedure involves risks. Patients should consult with their physicians to discuss the potential risks associated with this procedure. Patients need to know that not all spinal surgeries are successful. Adverse events such as implant loosening or breakage may occur, which could result in the need for further surgery.

About early onset scoliosis

Early-onset scoliosis (EOS) is a significant curvature of the spine that can occur in the paediatric population before the age of five. Traditional treatment options for paediatric scoliosis have included observation, bracing, casting and fusion. Bracing is non-invasive and can preserve development growth and motion. It has been shown to be moderately successful at preventing curve progression in curves under 40°, however the incidence of surgery in braced-treated patients was reported to range from 1 to 43%, with an average of 23% of treated patients requiring surgical interventions. Instrumented spinal fusion is effective for preventing progression and correction of curves but fusion causes loss of motion and adversely impacts growth of spine height and development of the chest. In order to overcome some of the concerns associated with fusion in the growing child, fusionless technologies have been developed to provide growth-sparing surgical options that would allow growth development, maintain spine mobility and minimize surgical complications.

About the Spinal Business at Medtronic

The Spinal business, based in Memphis, Tenn., is the global leader in today’s spine market and is committed to advancing the treatment of spinal conditions. The Spinal business collaborates with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art products and technologies for 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.medtronic.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.

REFERENCES


Medtronic Media Contacts:
Jeff Warren, Investor Relations, 763-505-2696
Yvan Deurbroeck, Public Relations, (+41 21) 802-7574