Medtronic News

Medtronic Presents First-of-Its-Kind Data Showing Sustained Results with Cervical Disc Replacement After Seven Years

Thomson Reuters ONE via COMTEX) --Study Shows Prestige® Cervical Disc Replacement Maintained Clinical Improvements, Lower Rate of Additional Surgical Procedures Compared to ACDF

MEMPHIS, TENN. - Dec. 6, 2013 - Medtronic, Inc. (NYSE: MDT) presented 7-year clinical and radiographic outcomes of artificial disc replacement with PRESTIGE® Cervical Disc compared to anterior cervical discectomy and fusion (ACDF) yesterday at the Cervical Spine Research Society Annual Meeting held in Los Angeles, CA.

"In the past several years, the long-term implications of cervical disc replacement have been the subject of much debate," said Dr. Vincent Traynelis, director, Neurosurgery Spine Service, and vice chairperson and professor, Department of Neurosurgery, at Rush University Medical Center in Chicago, IL. "The 7-year results of this study show that patients receiving cervical disc replacement maintained their clinical improvements and had a significantly lower rate of additional surgical procedures compared to fusion."

Of the 541 patients enrolled, 395 patients (212 PRESTIGE® Disc and 183 fusion patients) completed seven years of clinical follow-up. Results indicate that significant improvements in pain and functional outcomes achieved by 1.5 months in both groups were sustained at seven years. Specific findings at seven years included:

- The rate of patient overall success - the primary study endpoint, comprising of important effectiveness and safety measures, was significantly higher ($p = 0.010$) in the PRESTIGE® Disc group (72.6%) as compared to fusion (60.0%).

- The rate of maintenance or improvement in neurological status was significantly higher ($p = 0.011$) compared to fusion (88.2% versus 79.7%).

- Neck pain was significantly lower ($p = 0.004$) compared to fusion (mean score of 13.1 versus 19.4 on a scale of 0-100).

- The rate of additional surgeries at the index level was significantly lower ($p < 0.001$, log-rank test from a Kaplan-Meier analysis) compared to fusion (4.8% versus 13.7%).

- At seven years, one incident of screw loosening in the investigational group classified as associated with implant/surgical procedure was observed.

PRESTIGE® Cervical Disc is a stainless steel device and articulates via a ball and trough mechanism. It was the first artificial cervical disc FDA-approved for the treatment of single-level cervical disc disease (radiculopathy and/or myelopathy). Risks of the PRESTIGE® Cervical Disc include, but are not limited to: development of new radiculopathy, myelopathy or pain.

"We are pleased to be the first company to offer 7-year level-one clinical evidence on cervical disc replacement," said Patrick Wilson, vice president, Global Cervical Spine Therapies of Medtronic's Spinal business, "both physicians and patients will benefit from access to this information when making decisions about the PRESTIGE® Disc."

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR THE PRESTIGE® CERVICAL DISC:

The PRESTIGE® Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from levels C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The PRESTIGE® device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation.

The PRESTIGE® Cervical Disc should not be implanted in patients with an active infection or with an allergy to stainless steel.

The PRESTIGE® Cervical Disc should only be used by surgeons who are experienced in the surgical procedure and have undergone adequate training with the device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, such as neurological complications.

The safety and effectiveness of this device has not been established in patients with the following conditions: more than one cervical level with DDD; not skeletally mature; clinically significant cervical instability; prior fusion at adjacent cervical level; severe facet joint pathology of involved vertebral bodies; prior surgery at treated level; osteopenia, osteomalacia, or osteoporosis as defined by bone mineral density T-score of -3.5, or -2.5 with vertebral crush fracture; spinal metastases; chronic or acute renal failure or history of renal disease; taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids); pregnant; cervical instability; severe insulin dependent diabetes; and were not refractory to at least six weeks of unsuccessful conservative treatment or had signs of progression or spinal cord/nerve root compression with continued non-operative care.

Implanted metal alloys release metallic ions into the body (especially those devices with metal-on-metal articulating surfaces). The long term effect of these ions on the body is not known.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

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 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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Contacts:

Victor Rocha

Public Relations

+1-901-399-2401

Jeff Warren

Investor Relations

+1-763-505-2696

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