Medtronic News

Late-Breaking Study Provides Evidence to Support Beneficial Seven-Year Clinical Outcomes and Patient Satisfaction for 2-Level Prestige LP(TM) Cervical Disc Patients

Study Represents Longest Patient Follow-Up Data for U.S. 2-Level Cervical Disc Patients

DUBLIN and CHICAGO - May 3, 2016 - Medtronic plc (NYSE: MDT) today announced results of seven-year follow-up data demonstrating favorable clinical outcomes and patient satisfaction for the 2-level Prestige LP(TM) Cervical Disc compared to 2-level anterior cervical discectomy and fusion (ACDF). The Prestige LP Disc - currently indicated for single-level cervical disc disease causing nerve or spinal cord compression from C3-C7 - is pending FDA PMA approval for 2-level use. The device is designed to preserve motion in the neck at the operated disc level, unlike a fusion surgery that does not allow for motion. The Prestige LP Disc is the third clinically-proven artificial cervical disc in Medtronic's portfolio. The Prestige LP Disc has a ball-and-trough design and moves in a range of motions, including bending, rotation and translation.

The data will be presented today during the late-breaking session at the 84th Annual Meeting of the American Association of Neurological Surgeons (AANS) in Chicago, IL by Todd Lanman, M.D., a neurosurgeon at the Cedar-Sinai Institute for Spinal Disorders in Los Angeles, CA.

"The seven-year results of this study show that the patients receiving 2-level cervical disc replacement exhibited beneficial clinical outcomes and maintained them over time," said Dr. Lanman. "At 84 months, the patients treated with the 2-level Prestige LP Disc demonstrated greater rates of overall success compared to the 2-level ACDF patients."

The randomized controlled investigational device exemption (IDE) trial included a total of 397 study subjects (209 investigational and 188 control) and compared results up to seven years. Key findings of the statistical analysis at seven years show that the 2-level Prestige LP Disc patients:

- Exhibited greater rates in overall success (78.6%) compared to the patients treated with 2-level ACDF (62.7%) (by using Bayesian statistics, probability of superiority = 99.8%).1
- Exhibited greater rates in neurological success (91.6%) compared to the patients treated with 2-level ACDF (82.1%) (probability of superiority= 99.0%).
- Exhibited greater success rates in patient-reported outcomes, including Neck Disability Index (87.0%), compared to the patients treated with 2-level ACDF (75.6%) (probability of superiority = 99.3%).
- Exhibited lower rates of second surgeries (4.2%) at the index levels compared to the patients treated with 2-level ACDF (14.7%).
- Adverse event profiles were similar between groups.

Risks of the Prestige LP Disc include, but are not limited to: bone formation (including heterotopic ossification) that may reduce spinal motion or result in a fusion, either at the treated or at adjacent levels.

"This is the longest follow-up data available on clinical study patients treated with 2-level cervical arthroplasty in the United States," said Tommy Carls, vice president of Research and Development for the Spine division, which is part of the Restorative Therapies Group at Medtronic. "We're committed to developing meaningful innovations - like the Prestige LP Disc - that fundamentally change patients' lives. That's why it's exciting to see that the patients treated with the Prestige LP Disc maintain their outcomes for seven years."

About Medtronic's Spinal Business

We shape spine surgery for the better - delivering smarter procedures and healing biologics. As a global leader, we partner with other healthcare stakeholders to accelerate innovations that create surgical efficiencies and improve outcomes for more patients. More information about spinal treatments can be found at our patient-education website, www.back.com.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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1 Overall Success is decided by combining the results from four different measurements of safety and effectiveness.

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