Medtronic News

Medtronic Receives FDA Approval for Two-Level Prestige LP(TM) Cervical Disc Procedures

Two-Level Use of Prestige LP Cervical Disc Exhibited Statistical Superiority in Overall Success at 24 Months Compared to Patients Treated with Two-Level Fusion

DUBLIN - July 18, 2016 - Medtronic plc (NYSE: MDT) announced today the U.S. Food and Drug Administration's (FDA) approval of the Prestige LP(TM) Cervical Disc for the treatment of cervical disc disease causing nerve or spinal cord compression at two adjacent levels between the C3-C7 segments of the neck. The Prestige LP Disc is designed to allow motion in the neck at the operated levels, unlike a fusion surgery that does not preserve motion.

The Prestige LP Disc is Medtronic's third clinically-proven artificial cervical disc and its first to be determined safe and effective for both one- and two-level procedures. Additionally, it is the first artificial disc on the U.S. market to be proven statistically superior in overall success for both one- and two-level procedures.

"For my active patients with cervical disc disease at two adjacent levels, I want to preserve motion in their necks," said Dr. Jeff McConnell, a clinical trial investigator and orthopedic surgeon at Lehigh Valley Hospital in Allentown, Pa. "I choose to use the Prestige LP Disc at two levels because it provides superior clinical outcomes at 24 months and the titanium ceramic composite material allows post-op assessment and visualization by MRI."

Two pivotal clinical trials - a single-level and a two-level trial - were conducted to support the safety, effectiveness and FDA approval of the Prestige LP Disc. The two-level clinical trial included 397 patients (209 investigational and 188 control patients) at 30 sites around the U.S. At 24 months, the Prestige LP patient group demonstrated statistical superiority in overall success compared to patients treated with a two-level anterior cervical discectomy and fusion (ACDF). Overall success required a patient to meet all criteria for neurologic success, Neck Disability Index success, absence of serious, device-related adverse events, and absence of secondary surgeries at the treated levels. Overall success rates at 24 months were 81.4% in the investigational group and 69.4% in the control group. The posterior probability of superiority of the investigation group over the control group was 99.3%.

"Medtronic is committed to elevating spine care by combining innovative new technologies with clinical evidence," said Doug King, senior vice president and president of Medtronic's Spine division, which is part of the Restorative Therapies Group at Medtronic. "The Prestige LP Disc is a superior alternative to ACDF and an important motion-preserving option for physicians treating certain patients suffering from two-level cervical disc disease."

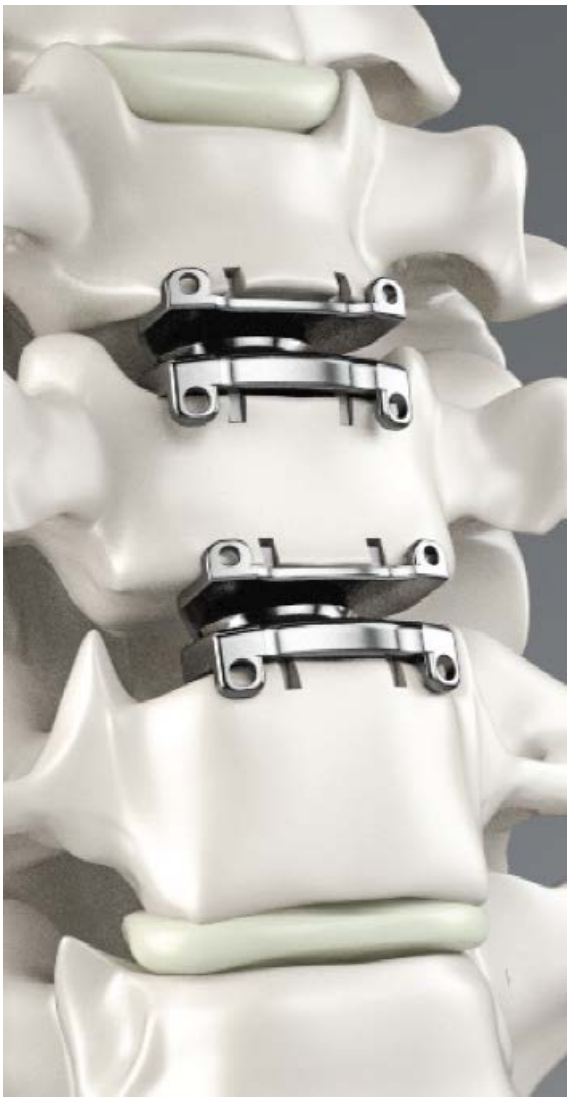
Risks of the Prestige LP Disc include, but are not limited to: development of new nerve or spinal cord compression or pain; allergic reaction to implanted material; or bone formation (including heterotopic ossification) that may reduce spinal motion or result in a fusion, either at the treated or at adjacent levels.

The low profile Prestige LP Disc has a ball-and-trough design and moves in a range of motions, including bending, rotation, and translation. The disc is made of titanium ceramic composite which provides improved wear resistance in combination with the mechanical, biocompatible, and imaging properties of the base titanium alloy. The device is MRI conditional at 1.5 and 3.0 Tesla and is now available in a smaller 5mm height.

About Prestige LP Cervical Disc

The Prestige LP Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following discectomy at one level or two contiguous levels for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to abnormality localized to the level of the disc space and at least one of the following conditions confirmed by imaging (CT, MRI, X-rays): herniated nucleus pulposus, spondylosis (defined by the presence of

osteophytes), and/or visible loss of disc height as compared to adjacent levels. The Prestige LP Disc is implanted using an anterior approach. Patients should have failed at least 6 weeks of non-operative treatment or have had the presence of progressive symptoms or signs of nerve root/spinal cord compression in the face of continued non-operative management prior to implantation of the Prestige LP Disc.



About Medtronic's Spine Division

We shape spine surgery for the better - delivering smart procedures and therapeutic biologics. As a global leader, we partner with other healthcare stakeholders to accelerate innovations that can improve surgical efficiencies and help create better outcomes for more patients.

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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