Medtronic News

# Medtronic Receives FDA Approval for PRESTIGE® LP Cervical Disc System

*The PRESTIGE® LP Cervical Disc is Medtronic's Third Clinically-Proven Artificial Cervical Disc to Receive FDA Approval*

*MEMPHIS, TENN. - July 28, 2014 - Medtronic, Inc. (NYSE: MDT) announces that it has received approval from the U.S. Food and Drug Administration (FDA) to market the PRESTIGE® LP Cervical Disc System for the treatment of single-level cervical disc disease (radiculopathy and/or myelopathy).*

*The PRESTIGE® LP Cervical Disc is the third clinically proven artificial cervical disc in the Medtronic portfolio and builds upon the same design principles as the original PRESTIGE® Cervical Disc introduced in 2007. While incorporating the same ball-and-trough articulation, which is designed to allow the two components to move with respect to one another in a range of motions, including bending, rotation and translation, the PRESTIGE® LP Disc represents a departure from the original stainless steel PRESTIGE® in terms of materials and fixation mechanism. Instead of utilizing bone screws to attach to the vertebral bodies as in the original PRESTIGE® design, the LP design incorporates two rails positioned off midline that press-fit into two pre-drilled holes created during the surgical procedure.*

*In addition, the PRESTIGE® LP Disc is composed of a proprietary titanium-ceramic composite that has been shown to have a lower wear rate and produce less scatter on postoperative magnetic resonance imaging (MRI) than stainless steel (MR Conditional at 3 Tesla).*

*"Our goal was to maintain the same ball-and-trough articulation as in the original design, but to find a way to decrease the profile and use a material with improved postoperative MRI visualization," said Dr. Vincent Traynelis, director of Neurosurgery Spine Services and vice chairperson and professor of the Department of Neurosurgery at Rush University Medical Center in Chicago, IL. "To address these issues, the PRESTIGE® LP Disc incorporates a dual-rail fixation mechanism instead of bone screws and is made of a titanium-ceramic composite instead of stainless steel."*

*The PRESTIGE® LP Cervical Disc has been available outside the United States since 2004 and has been studied in a prospective, multicenter, historical-controlled U.S. IDE trial for a single-level indication.*

*"The introduction of PRESTIGE® LP Cervical Disc to the US market demonstrates Medtronic's commitment to cervical arthroplasty as a viable alternative to spinal fusion in appropriate patients and illustrates our vast experience with this technology," said Doug King, president of Medtronic's Spinal business. "Both physician and patients will benefit from having access to another clinically-proven option for treating single-level cervical disc disease."*

*Risks of the PRESTIGE® LP Cervical Disc include, but are not limited to: early or late loosening of any or all components and development of new radiculopathy, myelopathy or pain.*

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

*The PRESTIGE® LP Cervical Disc is indicated in skeletally mature patients for reconstruction of the disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to a single-level 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 Cervical 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 Cervical Disc.*

*The PRESTIGE® LP Cervical Disc should not be implanted in patients with an active systemic infection or localized infection at the surgical site; osteoporosis defined as a DEXA bone mineral density T-score equal to or worse than -3.5 or a T-score equal to or worse than -2.5 with vertebral compression fracture, or osteopenia defined as a DEXA bone mineral density T-score <= -1.0; allergy or sensitivity to titanium, aluminum or vanadium; marked cervical instability on neutral resting lateral or flexion/extension radiographs; translation >3.5mm and/or >11° rotational difference from that of either adjacent level; severe spondylosis at the level to be treated, characterized by bridging osteophytes, loss of disc height >50%, an absence of motion (<2°) as this may lead to a limited range of motion and may encourage bone formation (e.g. heterotopic ossification, fusion); severe facet joint arthropathy; significant cervical anatomical deformity or clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., by radiographic appearance of fracture callus, malunion or nonunion) or disease (e.g., ankylosing spondylitis, rheumatoid arthritis); significant kyphotic deformity or significant reversal of lordosis; or symptoms attributed to more than one cervical level.*

*The PRESTIGE® LP Cervical Disc should only be used by surgeons experienced in the surgical procedure who have undergone adequate hands-on training with this specific device, and are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with the PRESTIGE® LP Cervical Disc. 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: axial neck pain as solitary symptom; not skeletally mature; prior cervical spine surgery, including prior surgery at the index level; fused level adjacent to the level to be treated; facet joint pathology of involved vertebral bodies; spinal metastases; Paget's disease, osteopenia, osteomalacia, or other metabolic bone disease; overt or active bacterial infection, either local or systemic; 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; diabetes mellitus requiring daily insulin management; extreme obesity as defined by the NIH Clinical Guidelines Body Mass Index (i.e., BMI >= 40); and have not undergone at least six weeks of non-operative 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. Patients in the clinical study were instructed to use non-steroidal anti-inflammatory drugs (NSAIDs) for two weeks postoperatively. It has been reported in the literature that short-term postoperative use of NSAIDs may reduce the instance of heterotopic ossification (HO). To reduce the instance of HO, it is recommended that the PRESTIGE® LP device be implanted in subjects able to tolerate the use of NSAIDs for two weeks post-operatively.*

*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.*

*Multimedia Release*
*A multimedia version of this release, with links to graphics can be found at: https://medtronicmediacap.gcs-web.com/medtronic-receives-fda-approval-prestiger-lp-cervical-disc-system*

*About Medtronic's Spinal Business*
*Medtronic's 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. Medtronic's spinal business collaborates with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art therapies for spinal, neurological, orthopaedic and oral maxillofacial conditions. Medtronic is committed to developing affordable, minimally invasive procedures that provide lifestyle friendly surgical therapies. More information about spinal treatments can be found at its patient-education Web site, www.back.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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