Medtronic News

Medtronic Launches the Divergence(TM) Anterior Cervical Fusion System

System Offers New Approach to Single-Level ACDF Procedures

MEMPHIS, TENN. - October 21, 2014 - Medtronic, Inc. (NYSE: MDT) announced the U.S. launch of the DIVERGENCE(TM) Anterior Cervical Fusion System for the treatment of single-level cervical disc disease today at the 2014 Congress of Neurological Surgeons (CNS) Annual Meeting in Boston.

The DIVERGENCE(TM) System represents a new approach to one-level anterior cervical discectomy with fusion (ACDF) procedures, which traditionally use a four-hole plate and interbody fusion cage. With the DIVERGENCE(TM) System, the plate and interbody cage can be inserted simultaneously using a common set of instrumentation and one surgical technique. Traditional cervical fusion surgery requires a two-step insertion technique for the plate and interbody cage, and each implant requires its own set of instruments and its own surgical technique.

In addition, the DIVERGENCE(TM) System incorporates a laterally-divergent screw insertion technique, which requires less retraction compared to the traditional medially-convergent screw insertion techniques used with other anterior cervical plating systems.

In a 2013 edition of *The Spine Journal*, Dong-Ho Lee and colleagues published an article entitled "Anterior Cervical Plating Technique to Prevent Adjacent-Level Ossification Development." The study concluded that ACDF patients with plates placed less than 5mm from the adjacent level disc have statistically significant increases in the frequency and severity of adjacent-level ossification disease (ALOD), a condition in which osteophytes (bone spurs) develop at the adjacent level and may become symptomatic. The article also demonstrated that short plates allow for increased screw angulation, longer screw placement, reduced incision size, minimized dissection of the anterior longitudinal ligament (ALL) and limited encroachment by the plate on adjacent-level discs. The DIVERGENCE(TM) System plates are offered in relatively short lengths of 15.5mm to 20.5mm, and are designed for use with hyper-angulated screw insertion techniques.

"The introduction of the DIVERGENCE(TM) Anterior Cervical Fusion System demonstrates Medtronic's commitment to improving how spinal fusions are performed around the world," said Doug King, president of the Spinal business and senior vice president at Medtronic. "Physicians and patients will benefit from having access to these low-profile implants and an insertion technique that makes the ACDF procedure more efficient for the surgeon and less invasive for the patient."

Risks of the DIVERGENCE(TM) Anterior Cervical Fusion System include but are not limited to early or late loosening of any or all components and the development of new radiculopathy, myelopathy or pain.

About the DIVERGENCE(TM) Anterior Cervical Fusion System
The DIVERGENCE(TM) anterior cervical plate and bone screw components are intended for anterior interbody screw fixation from C2-T1. The indications and contraindications of spinal instrumentation systems should be well understood by the surgeon. The plate and bone screw components are indicated for use in the temporary stabilization of the anterior spine during the development of spinal fusions in patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) trauma (including fractures), 3) tumors, 4) deformity (defined as kyphosis, lordosis, or scoliosis), 5) pseudoarthrosis, and/or 6) failed previous fusions.

The DIVERGENCE(TM) Anterior Cervical Cage component is intended to be used for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on

posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This cage is to be used in patients who have had six weeks of nonoperative treatment. The DIVERGENCE(TM) Cage must be used with supplemental fixation. The DIVERGENCE(TM) Cage is also required to be used with autogenic bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

Multimedia Release

A multimedia version of this release, with links to graphics can be found at: https://medtronicmediacap.gcs-web.com/medtronic-launches-divergencetm-anterior-cervical-fusion-system

The DIVERGENCE(TM) Anterior Cervical Fusion System incorporates the technology of Gary K. Michelson, MD.



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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