

Medtronic Receives FDA Clearance for ZEVO(TM) Anterior Cervical Plate System

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DUBLIN - May 4, 2015 -Medtronic plc (NYSE: MDT) announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the ZEVO(TM) Anterior Cervical Plate System. This system is now commercially available for the treatment of cervical degenerative disc disease, trauma, tumors, deformity, pseudoarthrosis, and/or failed previous fusions.

The ZEVO System represents Medtronic's latest technology for anterior cervical discectomy with fusion (ACDF) procedures. It features shorter plating options coupled with hyper-screw angulations, allowing the physician to select the smallest possible plate for the patient's individual surgical needs while securing the plate as far as possible from the adjacent disc.^[1] Literature shows this technique may lower the incidence of Adjacent Level Ossification Development (ALOD) or bone growth next to the treated level^[1].

"Versatility is important in ACDF procedures, and the ZEVO(TM) Anterior Cervical Plate System was designed to give surgeons more options," said Doug King, president of the Spinal business and senior vice president of Medtronic. "This system represents Medtronic's commitment to responding to surgeon needs, and innovating in ways that improve patient treatment and care."

Additionally, the ZEVO System features lower-profile plates with minimal thickness (1.9mm and 2.1mm) while increasing the stability of the construct for the 4-5 level options.

"Improved, thinner plates are important in ACDF procedures," said Dr. Richard Hynes, spine surgeon at The B.A.C.K. Center in Melbourne, FL. "ZEVO embodies these characteristics, with the added benefits of hyper screw angulations, which can be directed away from the spinal cord."

About the ZEVO(TM) Anterior Cervical Plate System

The ZEVO(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.

Risks of the ZEVO(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, and/or tissue or nerve damage caused by improper positioning and placement of implants or instruments.



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

Multimedia Release

A multimedia version of this release, with downloadable graphics can be found at: <https://medtronicmediacap.gcs-web.com/medtronic-receives-fda-clearance-zevotm-anterior-cervical-plate-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 plc (www.medtronic.com), headquartered in Dublin, Ireland, 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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[\[1\]](#) Lee et al. Anterior cervical plating technique to prevent adjacent-level ossification development. The Spine Journal 13 (2013) 823-829.

Contacts:

Victor Rocha
Public Relations
+1-901-399-2401

Jeff Warren
Investor Relations
+1-763-505-2696

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