Medtronic Receives Expanded Indications of the VERTEX® Reconstruction System

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Medtronic

Now FDA Cleared for Lateral Mass and Pedicle Screw Fixation in the Posterior Cervical Spine

DUBLIN - Feb. 16, 2015 - Medtronic plc (NYSE: MDT), today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) for expanded indications of the VERTEX® Reconstruction System. The new clearance for the VERTEX® family of products allows for lateral mass and pedicle screws to be used as a form of fixation to treat various pathologies occurring in the posterior cervical spine, making it one of the first FDA-cleared systems available in the United States for use of screws at C1-C7.

"Broadening the VERTEX® Reconstruction System's indication beyond current upper thoracic screw fixation displays Medtronic's commitment to provide surgeons with the most innovative and effective surgical treatment options with the goal of improved patient care," says Dr. Vincent Traynelis, neurosurgeon at RUSH University in Chicago, IL. "This clearance opens up new opportunities for collaboration with medical device companies such as Medtronic to create a sound foundation on which we can advance current techniques, create new solutions, and deliver the next level of care to our patients."

"Our commitment to spine surgery goes beyond procedural innovation. As an industry leader, Medtronic is also focused on improving patient care through areas like advocacy for access to needed therapies and world-class medical education," said Doug King, president of the Spinal business and senior vice president of Medtronic. "Medtronic led the way in the pursuit of posterior cervical screw clearance nearly a decade ago, when we applied for and received FDA cervical screw clearance for our AXIS® Fixation System, which became the predicate device for cervical multi-axial screw fixation that we have just obtained. Through perseverance and collaboration with the FDA, we are excited to have reached this milestone and see it become a reality for Medtronic, our physicians, patients and other industry partners. Medtronic can now partner with physicians and professional spine societies to provide the most productive educational experiences to further understand and enhance the various techniques for treating conditions in the posterior cervical spine. This achievement is an exciting time for the spinal industry, and we are thrilled to be a part of the advancement in procedural innovation and portfolio expansion."

About the VERTEX ® Reconstruction System

The VERTEX ® Reconstruction System consists of implants and instruments that can be used to surgically treat patients with a variety of conditions that can contribute to spinal instability, including degenerative disease, fracture, tumors, and/or deformity. To relieve the pain and other symptoms often associated with these conditions, surgeons can perform a procedure called spinal fusion, which involves placing bone graft material between the treated vertebrae so they will fuse, or join together, with the goal of restoring spinal stability. Surgeons will place titanium rods, screws, hooks, and/or other connecting components in the appropriate anatomical structures to provide internal stabilization to the posterior cervical spine while the fusion of vertebrae occurs. When paired with the VERTEX ® Occipitocervical Module, the VERTEX® System offers surgeons adjustability in their treatment options through multiple plate designs, rods, screws, and hooks, enabling them to tailor procedures to each patient's needs.

Product Indications and Risks

The VERTEX® Reconstruction System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic

studies, and degenerative disease of the facets with instability. The VERTEX® Reconstruction System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

Potential risks of the VERTEX® Reconstruction System include, but are not limited to: loosening, disassembly, bending, and/or breakage of components.

Multimedia Release
A multimedia version of this release, with a downloadable graphic can be found at: https://medtronicmediacap.gcs-web.com/medtronic-receives-expanded-indications-vertexr-reconstruction-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's therapies can be found at the business unit's patient-education website, 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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