Medtronic News

Medtronic Announces Global Launch of Titanium-Coated Peek Interbody Fusion Devices

MEMPHIS, TENN., - October 20, 2014 - Medtronic, Inc. (NYSE: MDT) introduced its Pure Titanium Coating (PTC) platform of interbody fusion devices for the spine today at the 2014 Congress of Neurological Surgeons (CNS) Annual Meeting in Boston. The PTC platform includes four products: the CAPSTONE PTC(TM) Spinal System, CLYDESDALE PTC(TM) Spinal System, ANATOMIC PEEK PTC Cervical Fusion System and CORNERSTONE-SR® Ti- Coated Anatomical Cervical Cage.

These devices are used to treat patients experiencing pain caused by compression of the spinal cord or nerve roots by helping to restore normal disc height. Disc height restoration may reduce the pressure on the nerve roots and the spinal cord and help alleviate much of the patient's pain.

Medtronic's PTC devices represent an evolution in interbody fusion technology because they are constructed of a combination of the two materials most commonly used in interbody fusion procedures: titanium and polyetheretherketone (PEEK). Both materials have a long clinical history of being used in orthopaedic and other medical implants. Surgeons have historically preferred interbody spacers made of titanium because of their strength and long clinical history. However, over the last 10 years PEEK has largely replaced titanium as the material of choice because it has a modulus of elasticity that is similar to human cortical bone1 and it does not show up on X-rays2. This radiolucency enables the surgeon to more easily assess the surgical site over time after surgery.

With the application of a thin layer of textured pure titanium about 1/10th of a millimeter thick to the top and bottom of each PEEK implant, the PTC devices possess attributes of both PEEK and titanium. Specifically, as demonstrated in mechanical testing compared to PEEK alone, the pure titanium coating has a greater coefficient of friction.3 Additionally, this textured coating increases the surface area of the implant, which means there is more area for bone to come into contact with the surface of the implant.4 Yet, the titanium layer is thin enough that it does not change the radiolucency or mechanical properties of the underlying PEEK implant.

"Our PTC platform of interbody spacers is the result of our relentless effort to add value to our products and respond to surgeon needs by offering the advantages of combined materials in a single implant," said Doug King, president of the Spine business and senior vice president at Medtronic. "We will continue to leverage our innovation to produce more advanced and differentiated products for surgeons to use to treat their patients."

<u>For Global Launch</u>

- The CAPSTONE PTC(TM) Spinal System and the CLYDESDALE PTC(TM) Spinal System received U.S. Food and Drug Administration (FDA) 510(k) clearance in March and launched in the U.S. in August. CE Mark (*Conformité Européenne*) was also received for both systems in July.
    - The CAPSTONE PTC(TM) Spinal System launched in Western Europe in September.
    - The CAPSTONE PTC(TM) Spinal System is expected to launch in Japan in November 2015 and CLYDESDALE PTC(TM) Spinal System is expected to launch in Japan in January 2016.

<u>For U.S. Launch Only</u>

- The ANATOMIC PEEK PTC Cervical Fusion System has received FDA 510(k) clearance and launched in the U.S. in September.

<u>For Launch Outside the U.S. Only</u>

- CORNERSTONE-SR® Ti- Coated Anatomical Cervical Cagehas received a CE Mark (*Conformité Européenne*) and launched in Western Europe in July. *This system is not for use in the United States or its territories.*

Indications for these devices are as follows:

- CAPSTONE PTC(TM) Spinal System and CLYDESDALE PTC(TM) Spinal System are indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1, for interbody fusions in the lower back or lumbar spine. These devices are intended to be used with supplemental fixation.
- CORNERSTONE-SR® Ti- Coated Cervical Fusion System is indicated for:
    - degenerative discopathy and instability
    - primary surgery for certain progressive degenerative discopathies or extensive anterior decompression
    - revision surgery for failed disc operation, stenosis, and/or post-operative instability
    - pseudarthrosis or failed arthrodesis
- The ANATOMIC PEEK PTC Cervical Fusion System is indicated for 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. The ANATOMIC PEEK PTC device is to be used with supplemental fixation and autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

Multimedia Release

A multimedia version of this release, with links to graphics can be found at: https://medtronicmediacap.gcs-web.com/medtronic-announces-global-launch-titanium-coated-peek-interbody-fusion-devices

The CAPSTONE PTC(TM) Spinal System, the CLYDESDALE PTC(TM) Spinal System, CORNERSTONE-SR® Ti-Coated Cervical Fusion System, and the ANATOMIC PEEK PTC Cervical Fusion System incorporate the technology of Gary K. Michelson, M.D.



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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1Mummaneni PV, Haid RW, Rodts GE. Lumbar interbody fusion: state-of-the-art technical advances. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. Journal of neurosurgery Spine 2004;1:24-30.

2Kurtz SM, Devine JN. PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomat 2007;28:4845-69.

3 Internal Medtronic Test Data

4 Medtronic Internal Test Data

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