Medtronic News

Medtronic Introduces the SOVEREIGN(TM) Spinal System for Lumbar Surgery

MEMPHIS, Tenn., Dec 18, 2009 (BUSINESS WIRE) -- Medtronic, Inc. (NYSE: MDT) today announced the U.S. launch of the SOVEREIGN(TM) Spinal System.

The SOVEREIGN Spinal System is an intervertebral body (interbody) fusion device used to treat patients who suffer from a degenerative condition that affects the lumbar spine. When a lumbar disc is diseased, it can lose height, compressing nerve roots and the spinal cord, causing pain in the legs and lower back. The SOVEREIGN Spinal System is designed to stabilize the spine and promote bony fusion, which involves the joining of two bones together, such as adjacent vertebrae. There are more than 200,000 lumbar fusion procedures performed each year to relieve leg and lower-back pain.

To restore a patient's disc height, surgeons have traditionally used bone grafts, stabilized and held in place by metal plates anchored to the spine with bone screws. The SOVEREIGN Spinal System incorporates a lens-shaped device with three holes for the placement of titanium screws, which protrude through the device and stabilize the adjacent vertebral bodies while preventing expulsion of the implant. The system also incorporates a cover plate that is designed to resist screw backout and that must be used in combination with the screws. Made of polyetheretherketone (PEEK), the SOVEREIGN device is radiolucent on x-rays, which allows the surgeon to view the spinal fusion during a follow-up visit.

The SOVEREIGN Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous vertebral levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. The implant may be implanted via a laparoscopic or an open anterior approach.

The SOVEREIGN intervertebral body fusion device may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the SOVEREIGN interbody device is intended to be used with the three titanium alloy screws and the accompanying cover plate. If the physician chooses to use less than three or none of the provided screws, then additional supplemental fixation which has been cleared by the U.S. Food and Drug Administration for use in the lumbar spine must be used to augment stability. The accompanying cover plate MUST be used anytime the device is used with any number of screws.

The SOVEREIGN(TM) Spinal System incorporates technology developed by Gary K. Michelson, MD.

About the Spinal and Biologics Business at Medtronic

The Spinal and Biologics business, based in Memphis, Tenn., is the global leader in today's spine market and is committed to advancing the treatment of spinal conditions. The Spinal business collaborates with world-renowned surgeons, researchers and innovative partners to offer state-of-the-art products and technologies for neurological, orthopaedic and spinal conditions. Medtronic is committed to developing affordable, minimally invasive procedures that provide lifestyle friendly surgical therapies. More information about the company and its spinal treatments can be found at http://cts.businesswire.com/ct/CT?

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id=smartlink&url=http%3A%2F%2Fwww.medtronic.com%2F&esheet=6123663&lan=en_US&anchor=www.medtronic.com&index=6&md5=06ba248f69b5e2e40a322b33b375dca1), 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 Annual Report on Form 10-K for the year ended April 24, 2009. Actual results may differ materially from anticipated results.

SOURCE: Medtronic, Inc.

Medtronic, Inc. Public Relations: Victor Rocha, 901-399-2401 or Investor Relations: Jeff Warren, 763-505-2696

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