Medtronic News

Medtronic Receives First-Ever FDA Clearance for Cement-Augmented Pedicle Screws

Clearance Gives Spine Surgeons a New Treatment Option for Spinal Tumor Patients

DUBLIN - July 20, 2016 - Medtronic plc (NYSE: MDT) today announced U.S. Food and Drug Administration (FDA) 510(k) clearance of the CD Horizon® Fenestrated Screw Set, which can be used for patients diagnosed with advanced stage tumors involving the thoracic and lumbar spine. This marks the first U.S. clearance for cement-augmented pedicle screws. The CD Horizon® Fenestrated Screws are used with Medtronic's HV-R® Fenestrated Screw Cement, a polymethylmethacrylate (PMMA) cement, and are intended for use at spinal levels where the structural integrity of the spine is not severely compromised.

Metastatic bone disease has been reported to occur in 60-80% of cancer patients, most frequently among those with primary malignancies of the breast, prostate, liver, and lung.1The spine is the most common site of bone metastasis and can be impaired by metastatic bone tumors.2Cement-augmented screws are designed to restore spinal stability in patients whose life expectancy is insufficient to allow for fusion to occur.

"Current cancer treatments can weaken a patient's bones and primary malignancies often spread to the spine, which cause considerable pain and are complex to manage," said Francis H. Shen, M.D., orthopedic surgeon, Charlottesville, Va. "When placed into compromised bone, traditional screws run the risk of loosening over time. The ability to utilize cement augmentation directly through a fenestrated screw is a great advancement. It allows me to achieve immediate implant stability, which would not be possible with traditional non-augmented screws. More importantly this allows me to help to mobilize my patients more quickly."

Medtronic's CD Horizon Fenestrated Screw Set features cannulated pedicle screws designed with six holes (fenestrations) located near the end of the screw, allowing controlled cement injection into the targeted vertebral body after having placed all of the screws. This self-curing PMMA cement provides immediate screw fixation in the patient's spine and significantly increases the screw pull-out strength compared to standard screws*. The cement is injected through a continuous tract in the adapter and into the screw cannula. This continuous tract delivery system is designed to have a completely secure channel that can be visually verified outside the patient to help reduce the likelihood of cement leakage at the adapter/screw interface while being compatible for minimally invasive surgery (MIS) and open procedures.

"Palliative care is important for people with cancer, and Medtronic's cement-augmented screws are a meaningful innovation that are designed to restore the integrity of the spinal column in patients with debilitating spinal tumors," said Doug King, senior vice president and president of Medtronic's Spinal division, which is part of the Restorative Therapies Group at Medtronic. "The availability of our CD Horizon Fenestrated Screw Set represents an important advance for surgeons and provides them with another option for a complex procedure."

The CD Horizon Fenestrated Screw Set will be available this fall.

CD Horizon Fenestrated Screw Set incorporates the technology of Gary K. Michelson, MD.

About Medtronic's Spinal Division

We shape spine surgery for the better - delivering smart procedures and therapeutic biologics. As a global leader, we partner

with other healthcare stakeholders to accelerate innovations that can improve surgical efficiencies and help create better outcomes for more patients. More information about spinal treatments can be found at our patient education Web site, www.back.com.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services, and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 85,000 people worldwide, serving physicians, hospitals, and patients in approximately 160 countries. The company focuses on collaborating with stakeholders around the world to take healthcare Further, Together.

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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* Pull-out strength results are based upon direct comparisons of CD Horizon® Fenestrated Screws to non-cement augmented CD Horizon® Legacy MAS Screws performed in a cadaver study. Cadaver results are not necessarily indicative of clinical outcomes.

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1 Schulman et al. Economic burden of metastatic bone disease. American Cancer Society 2007:2334-2342.

2 Chow E, Finkelstein JA, Sahgal A, Coleman RE. Metastatic cancer to the bone. In: DeVita VT, Lawrence TS, Rosenberg SA, eds. DeVita, Hellman, and Rosenberg's Cancer: Principles & Practice of Oncology. 9th ed. Philadelphia, Pa: Lippincott Williams & Wilkins; 2011: 2192-2204.

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