Medtronic News

Medtronic Announces Second Bone Cement Solution Indicated for Treating Sacral Fractures

GLOBE NEWSWIRE via COMTEX) --Delivering Commitment to Find New Treatment Options for Patients

Suffering from Sacral Insufficiency Fractures

DUBLIN - June 20, 2018 - Medtronic plc (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance of Kyphon(TM) HV-R Bone Cement for fixation of pathological fractures of the sacral vertebral body (or ala) using sacral vertebroplasty or sacroplasty. This broadens Medtronic's commitment to treat fragility fractures beyond vertebral compression fractures caused by osteoporosis, cancer or benign lesions. With this expanded indication for Kyphon HV-R Bone, clinicians now have more options for treating patients with sacral insufficiency fractures.

"Patients who experience sacral insufficiency fractures often suffer a substantial degree of pain and disability," said Dr. Thomas Andreshak, orthopedic surgeon, Mercy St. Vincent Medical Center and St. Luke's Hospital, Maumee, Ohio. "This new indication for Kyphon HV-R cement, along with Kyphon(TM) Xpede Bone Cement will provide another excellent option to help these patients."

Sacral insufficiency fractures (SIFs) are a common cause of debilitating back pain. SIFs mimic the symptoms of lumbar spine pathology.1 Studies show more than two-thirds of patients diagnosed with SIFs aren't able to associate their pain with a traumatic event.2 As a result, physicians often prescribe conservative treatment, including physical therapy and prolonged bed rest. These patients report 20-45-day inpatient stays1 at the hospital, and prescription narcotic use associated with pain from untreated sacral insufficiency fractures, which are significant expenses to the healthcare system and result in lost productivity. Patients treated with bed rest are at increased risk of pulmonary embolism and DVT, as well as further muscle atrophy and bone loss.3

"In my practice, patients with sacral insufficiency fractures treated with sacroplasty experience immediate pain relief that allows them to resume daily activity and/or physical therapy without suffering from pain and physical limitations," said Dr. Labib F. Haddad, interventional radiologist, West County Radiological Group, St. Louis, Mo. "The procedure of sacroplasty with HV-R cement is a minimally-invasive procedure usually performed in an outpatient setting."

"Early intervention is an important consideration for both hospital costs and patient outcomes," said Jeff Cambra, vice president and general manager of the Interventional Pain Therapies business, which is part of the Restorative Therapies Group at Medtronic. "Combined with our 20 years of experience in vertebral compression fractures, this new indication for our bone cement solution allows us to continue to make an impact on vertebral compression fracture and sacral insufficiency diagnosis treatment in the U.S. by giving physicians options to deliver the best clinical solutions to their patients."

About Kyphon Bone Cement Solutions

Kyphon Xpede Bone Cement and Kyphon HV-R Bone Cement are indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e., kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathologic fracture may include a symptomatic microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Balloon kyphoplasty incorporates technology developed by Gary K. Michelson, M.D.

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 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused 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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1. Ortiz AO, et al. Sacroplasty. Tech Vasc Interv Radiol. 2009: 12(1); 51-63. doi: 10.1053.

2. Wagner D, Ossendorf C, Gruszka D, Hofmann A, Rommens PM. Fragility fractures of the sacrum: how to identify and when to treat surgicall? Eur J Trauma Emerg. Surg. 2015; 41(4): 349-362. doi: 10.1007/s00068-015-0530-z.

3. Dittmer et al. Complications of immobilization and bed rest. Part 1: Musculoskeletal and cardiovascular complications. Can Fam Physician. 1993 Jun; 39: 1428-32, 1435-7.

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Source: Medtronic plc via Globenewswire

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